

UMDNJ HEART TOPICS

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Study for Heart Failure Patients Uses Implant to Measure Left Atrial Pressure

by Marc Klapholz, MD



Patient Advisor Module counsels patients about medications based on left atrial pressure measurements.

A new clinical trial at UMDNJ–New Jersey Medical School (NJMS) empowers heart failure patients to take more control over their treatment, giving them the ability to adjust their medications on a daily basis according to measurements they receive directly from their heart. Called the LAPTOP-HF trial (Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy), this study is evaluating the usefulness of a small implantable pressure sensor that measures left atrial pressure and wirelessly transmits that information to a patient activated handheld device. I am a member of the national steering committee responsible for designing this pivotal randomized, controlled, prospective 700 patient trial and in bring-

ing the trial to UMDNJ–University Hospital in Newark, one of 75 medical centers in the country that will conduct the study.

Left atrial pressure provides critical information on the clinical status of the heart failure patient. A rise in left atrial pressure precedes the development of pulmonary edema (fluid in the lungs). It is the fluid in the lungs that accounts for much of the shortness of breath that heart failure patients experience and also that is responsible for causing more than 1 million hospitalizations every year in the United States for heart failure. Jim Maher, MD, assistant professor of medicine and site principal investigator for LAPTOP at University Hospital, [Continued on page 2](#)

The Primary Prevention of Cardiovascular Disease

by John B. Kostis, MD

Over the last three decades, age-adjusted mortality from heart attack, heart failure and stroke has decreased because of lifestyle changes, lower rates of smoking, and the use of medications. Nevertheless, cardiovascular disease still represents a major problem accounting for a large proportion of premature death and disability worldwide. Also, the low rates of control of hypertension, high cholesterol, and other risk factors to currently recommended targets are in part responsible for this epidemic.

Current guidelines for primary prevention base treatment recommendations on the estimated risk of developing a heart attack in the next 10 years. Such decisions, based on 10-year risk, result in under-treatment of younger individuals, especially women. For example, a commonly used guideline for the treatment of high cholesterol advises cholesterol lowering medication when the 10-year risk is 10% or higher, unless the cholesterol is very high. According to the



Framingham algorithm, or the newer Reynolds algorithm, most women in their late 40s have a 10-year risk lower than the 10% threshold used for cholesterol lowering treatment even in the presence of marked elevations of blood pressure or cholesterol and low HDL cholesterol (“good”

or protective cholesterol). In one report, 95% of women younger than 65 years of age who were admitted to a hospital with a heart attack did not qualify for therapy the day before the heart attack.

We have proposed to remove age from algorithms used to decide [Continued on page 3](#)

Clinical Trials

New Jersey Medical School/ University Hospital, Newark

Trial Name: LAPTOP-HF (Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy Study)

Purpose: First-in-man, randomized study evaluating the efficacy of direct, continuous and wirelessly transmitted left atrial pressures (LAP) in combination with dynamic treatment algorithms (see newsletter article)

Trial Name: TRACER (Thrombin Receptor Antagonist for Clinical Event Reduction in Acute Coronary Syndrome)

Purpose: To evaluate the safety and efficacy of SCH 530348, novel thrombin receptor antagonist, in subjects with acute coronary syndromes

Trial Name: CARDIOXYL (Study Evaluating the Hemodynamic Effects, Safety and Tolerability of CXL-1020 in Patients with Systolic Heart Failure)

Purpose: To assess the effects of this novel nitric oxide donor in treating acute decompensated heart failure

Trial Name: dal-OUTCOMES (Randomized, Double-blind Study Assessing the Effect of Dalcetrapib on Cardiovascular Mortality and Morbidity in Patients with Recent Acute Coronary Syndrome)

Purpose: To assess the effect of the CETP inhibitor, Dalcetrapib, on cardiovascular mortality and morbidity in patients with acute coronary syndrome

Trial Name: RED-HF (Double-blind, Randomized, Placebo-controlled Study to Assess the Efficacy and Safety of Darbepoetin alfa in Heart Failure Patients)

Purpose: To assess safety and efficacy of Darbepoetin alfa on morbidity and mortality in heart failure subjects with symptomatic systolic dysfunction and anemia.

Trial Name: CRISP-AMI (Counterpulsation to Reduce Infarct Size Pre-PCI for Acute Myocardial Infarction)

Purpose: To evaluate the effect on infarct size of intra-aortic balloon counterpulsation during primary PCI of acute anterior wall myocardial infarction

Trial Name: PATENT-1 (Randomized, Double-blind, Study to Evaluate the Efficacy of BAY 63-12521 in Patients with Symptomatic Pulmonary Arterial Hypertension-PAH)

Purpose: To study the intermediate-term effects of this direct stimulator of guanylate cyclase, which mediates vasorelaxation and inhibition of platelet aggregation in patients with PAH

Trial Name: RELAX AHF (Randomized, Double-blind Study to Evaluate the Efficacy and Safety of Relaxin in Patients with Acute Heart Failure)

Purpose: To assess the safety, hemodynamic and symptomatic effect of IV Relaxin, a potent vasodilator hormone released during pregnancy in patients with acute decompensated heart failure

Trial Name: EXAMINE (Examination of Cardiovascular Outcomes with Alogliptin in Patients with Type 2 Diabetes Mellitus and Acute Coronary Syndrome)

Purpose: To examine the effects of Alogliptin (selective dipeptidyl peptidase inhibitor) on morbidity in patients with type 2 diabetes mellitus and recent acute coronary syndrome

Trial Name: CKL X2401 (Randomized, Double-blind Study to Evaluate the Effects of Lixivaptan in Patients with Congestive Heart Failure)

Purpose: To evaluate the effects of this specific vasopressin receptor 2 antagonist for treating acute decompensated heart failure

Trial Name: ASCEND (Randomized, Double-blind Acute Study of Clinical Effectiveness of Nesiritide in Subjects With Decompensated Heart Failure)

Purpose: To evaluate the short- and intermediate-term effects of nesiritide (Natrecor) in treating patients with acute decompensated heart failure (ADHF)

Trial Name: RESPECT (Randomized Evaluation of Recurrent Stroke Comparing PFO Closure to Established Current Standard of Care Treatment)

Purpose: To evaluate the efficacy of the AMPLATZER percutaneous closure device vs. medical therapy in patients with PFO to prevent recurrent stroke

For information about participating in these studies, call 973-972-4708.

STAT MI Cuts Heart Attack Damage, Eliminates Gender Bias

Heart attacks demand swift medical action. The NJMS/UH cardiology team's inspired application of cell phone technology to reducing delays in getting patients into the cardiac catheterization laboratory has had an enormous impact since its launch (noted just over two years ago in *Time* magazine's review of the year's top medical triumphs). The team uses new wireless technologies and software linked in a network to transmit high resolution electrocardiograms (ECGs) from the ambulance directly to cardiologists via their smart phones.

The time from administering the initial ECG in the field to availability for view by the physician on the smart phone is approx-

imately 90 seconds. If the cardiologist verifies that the patient is having a heart attack, the patient skips the ER and is transported directly into the hospital's cardiac catheterization lab for primary angioplasty.

Now, this same group has taken another giant step in heart care, demonstrating the value of the STAT MI program way beyond their own wildest imaginations. They've proven that heart attack size is smaller, length of hospital stay is shorter and mortality is reduced for patients treated through this early identification wireless network system. "The size of the heart attack is the biggest predictor of long-term outcome," says Marc Klapholz, MD, professor of medicine and director of | *Continued on page 4*

Study for Heart Failure

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noted that the purpose of the trial is to demonstrate that daily direct left atrial pressure measurements will lead to fewer hospitalizations for heart failure because it will allow patients to adjust their medications on a daily basis in response to the pressure measurements. Patients may also live longer and have a better quality of life.

The device, the size of a small pacemaker, is implanted under the skin and is attached to a thin wire with a miniaturized pressure sensor at its tip that goes into the left atrium. The patient receives a small handheld device called the Patient Advisor Module (PAM) that wirelessly retrieves the left atrial pressure measurements from the implanted pressure sensor twice daily. Based on the pressure measurements, the PAM tells the patient what medication to take and at what dose based on a predefined prescription plan developed by the patient's physician, who tailors it to the individual patient's needs. The

physician also receives the patient's information via computer download and can make changes to the prescription plan according to the patient clinical response and status. This program of physician-directed patient self-management, based on daily objective measures of a patient's heart failure status, can allow physicians to optimize and personalize HF therapy. In many ways this is similar to diabetes management where a patient, based on prior recommendations from their physician, self-administers insulin according to their blood glucose levels.

This technology has the possibility of being a real game changer, as it is the first time that direct left atrial pressure can be directly monitored on a daily basis outside the hospital and where real time, dynamic, patient specific therapy can be given to try and improve the outcomes of heart failure.

A small sensor implanted in the heart provides patients and physicians with a wealth of information.



Marc Klapholz, MD, is director of the Division of Cardiology and professor of medicine at NJMS. For an appointment call 973-972-2573.

For information on participating in this study, contact Ryann Mattessich, APN, clinical coordinator, Heart Failure Program, NJMS and University Hospital, 973-972-6794. For treatment of heart failure, contact Marc Klapholz, MD, at 973-972-2573.

Sleep Apnea's Link to Heart Disease

Sleep apnea, a frequent stoppage of breathing during sleep, can be life-threatening. It has been characterized as a potentially “deadly phantom” with an often unrecognized link to heart disease. Sleep apnea patients have faster heart rates than non-apnea patients, but have less variability in their heart rates. This combination is an indicator of potential cardiovascular problems.

Sleep apnea occurs when the muscles relax enough to completely block the opening to the airway. The oxygen level in the blood drops, putting a strain on the heart. The right side of the heart may suffer damage because it has to pump harder to support the extra effort of the lungs trying to overcome the obstruction of the airway. As the upper airway becomes obstructed, the brain sends signals to the muscles around the airway causing the muscles to tense. Normal breathing is restored, allowing the body to fall back to sleep.

Repeated episodes can starve the heart of oxygen. People with coronary artery disease whose blood oxygen is lowered by sleep-disordered breathing may be at risk of ventricular arrhythmias.

A diagnosis of sleep apnea can be frightening, but it is a treatable condition.

Lifestyle changes can help: Lose weight; quit smoking; avoid alcohol, sleeping pills

Warning signs and symptoms of sleep apnea include:

- Frequent silences during sleep due to breaks in breathing (apnea)
- Choking or gasping during sleep to get air into the lungs
- Loud snoring
- Sudden awakenings to restart breathing or waking up in a sweat
- Daytime sleepiness and/or fatigue; feeling unrefreshed by a night's sleep, including falling asleep at inappropriate times



and sedatives; avoid caffeine and heavy meals before going to bed; maintain regular sleep hours. For sleep apnea that does not respond to these strategies, referral to a sleep specialist who can evaluate symptoms and find an effective treatment is imperative. Continuous Positive Airflow Pressure, or CPAP for short, is the gold standard treatment for moderate to severe obstructive sleep apnea. This technology is constantly being updated and improved. In fact, treatment has come a long way in recent times, with many new options.

For treatment of sleep apnea, contact Thomas Morley, MD, or Amita Vasoya, DO, at 856-566-6859 (School of Osteopathic Medicine) or Anays Sotolongo, MD, at 732-235-6511 (RWJMS).

Primary Prevention

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when to use drugs to prevent heart attack and to use instead an estimation of lifetime global risk to treat individuals according to the degree of their modifiable risk factors rather than age and gender. Rather than use 10-year risk, we propose to use lifetime risk in making decisions about treatment. Only 18% of US adults are at high short-term predicted risk (>10%) for cardiovascular disease. The majority (56%, or 87 million individuals) are at low short-term risk but high lifetime risk. Initiation of a healthy lifestyle and antihypertensive and lipid lowering therapy at younger ages will help in achieving “primordial prevention.”

We should aim to prevent the disease

(atherosclerosis) itself that causes heart attacks rather than allowing the disease to develop and then focusing on the prevention of complications. Heart attacks do not come out of the blue. Cardiovascular events occur among persons who already have sub-clinical disease for decades and do not know it. Focusing our efforts on younger men and women will result in saving more quality-adjusted life years. The emerging emphasis on personalized medicine may become a reality in the future. Until personalized medicine becomes a reality for cardiovascular disease, and until basic science advances make atherosclerosis a disease of the past, we should intervene on cardiovascular risk factors at an early age.

John B. Kostis, MD, is professor and chair of medicine, Robert Wood Johnson Medical School. For an appointment, call 732-235-7685.

Clinical Trials

Robert Wood Johnson Medical School Cardiovascular Institute, New Brunswick

Trial name: AIM-HIGH

Purpose: To compare the effectiveness and safety of statin therapy alone (simvastatin) and statin combination therapy (simvastatin plus niacin extended release) in reducing morbidity and mortality

Trial Name: COMPASS-HF, extension phase

Purpose: For continued surveillance of the Chronicle (implanted pulmonary artery pressure monitor) system and to allow continued access to the pressure data in subjects with heart failure

Trial Name: FREEDOM

Purpose: To study patients with diabetes and multi-vessel coronary artery disease randomized to either bypass surgery or angioplasty and long-term follow-up

Trial Name: PARADIGM-HF

Purpose: To evaluate the efficacy and safety of LCZ696 compared to enalapril relating to morbidity and mortality in patients with chronic heart failure and reduced ejection fractions

Trial Name: Cardiovascular Outcomes Study of Alogliptin in Subjects with Type 2 Diabetes and Acute Coronary Syndrome (EXAMINE)

Purpose: Patients with Type 2 diabetes, hospitalized within the last 60 days with a heart attack, are randomized to receive either Alogliptin or a placebo, in addition to usual medications, to determine if Alogliptin reduces the number of future heart attacks and strokes. This is a new class of diabetes medications designed to improve the body's ability to control blood glucose and blood insulin levels.

Trial Name: Prochymal® Stem Cell

Purpose: To evaluate the safety and efficacy of PROCHYMAL® (ex vivo cultured adult human mesenchymal stem cells) intravenous infusion following acute myocardial infarction and left ventricular end systolic volume at 3 months

Trial Name: PROMISE (PROspective Multicenter Imaging Study for Evaluation of Chest Pain)

Purpose: Patients with cardiopulmonary symptoms but unproven coronary artery disease (CAD) are randomly assigned a noninvasive cardiovascular diagnostic test for CAD, either an exercise stress test or coronary CT angiography (CTA). The study's primary aim is to determine if information obtained from CTA will improve clinical outcomes compared to conventional functional testing.

Trial Name: Risk Stratification in MADIT II (Second Multicenter Automated Defibrillator Implantation Trial)

Purpose: To determine which clinical and ECG factors can identify patients at risk for cardiac events after heart attack and impaired heart

Trial Name: SATURN

Purpose: To compare the effect of treatment with rosuvastatin 40 mg or atorvastatin 80 mg on atherosclerotic disease as measured by intravascular ultrasound in patients with coronary artery disease

Trial Name: TRANSLATE-ACS (Translate-ACS: Treatment with ADP receptor iNhibitorS: Longitudinal Assessment of Treatment Patterns and Events after Acute Coronary Syndrome)

Purpose: To examine long-term effectiveness and safety of antiplatelet therapies, post-discharge care patterns and treatment adherence, and associated health care costs in a contemporary patient population with acute myocardial infarction

Trial Name: Women's Health Initiative Extension Study

Purpose: This extension follows women and their changes in health status over the course of 15 years. A five-year follow-up will be added (2015).

For information about participating in these studies, call 732-235-6546.

Can a Therapy Dog Help Heal Hearts?



Sami Abati, RN, gets heart failure patients up and moving with the help of Gypsy, her greyhound.

Sami Abate, RN, is the assistant nurse manager in the Cardiac Intensive Care Unit (ICU) as well as Cardiac Step-Down at South Jersey Regional Medical Center, and a master's student in UMDNJ-School of Health Related Professions (SHRP)'s Integrative Health and Wellness program. Working with heart failure patients—who often refuse to walk “based on how they feel, how important they judge walking to be and a misunderstanding of the need to walk”—pushed Abate into taking a creative look at her dog. Could Gypsy, she

wondered, a rescued greyhound she had trained as a therapy dog, get patients up and moving?

“She raced for four and a half years, but never won,” Abate explains, describing her pet. In the hospital, however, Abate has seen what a difference her dog can make. (Being a loser, by the way, is “incredibly amusing” to patients. “Walkers and oxygen tanks are more her pace.”)

At the hospital, Abate saw Gypsy truly making a difference. Hospitalized patients with congestive heart failure (CHF) are encouraged to walk daily with a restorative aide (a specially trained health-care-giver) but many refuse.

In a study being conducted by Abate, 69 patients increased their overall walking distance by 96 percent when Gypsy was alongside. The refusal rate decreased by 74 percent and 94 percent said they enjoyed their walks and that Gypsy influenced their decision to get moving. Abate hopes to see other patient populations given the chance to walk with a trained dog. “We know these unconventional therapies can be safe and effective. My ultimate goal would be to offer Animal Assisted Therapy (AAT) to more hospitalized patients who need to walk.” For more information, email: samiabate@aol.com.

improved pump function.”

And it doesn't stop there. Edo Kaluski, MD, director of interventional cardiology, explains that there is a “halo effect,” which means that even heart attack patients who walked into the emergency room, so were not part of the STAT MI group, benefited since medical response time for all patients was reduced. “STAT MI had a good effect for everybody. And refinements leading to improvements have continued over time—meaning further reductions in response time and greater improvements for all STAT MI and other heart attack patients,” he says.

STAT MI

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cardiology at UMDNJ-New Jersey Medical School and University Hospital, who heads up the project.

In addition, gender bias, which puts women at a serious disadvantage in heart attack treatment, is virtually eliminated. Klapholz explains: “The STAT MI program certainly benefits men—their time into treatment is cut by 63 minutes. But women benefit even more—their time is cut by 131 minutes, which translates into greatly reduced heart attack size and vastly



University Hospital Garners Honors for Cardiac Care

Look at 108 of the academic medical centers in the U.S. as well as their 233 affiliated hospitals—that's about 90 percent of the nation's non-profit healthcare hubs, by the way—for the quality of their heart failure care. Where is one of the very best places for a cardiac patient to go? The answer: Newark's UMDNJ-University Hospital (UH), which ranked fourth out of all those 108 academic medical centers in the U.S. when it comes to treating patients in heart failure with the recommended care, according to the University HealthSystem Consortium.

Their study results, published earlier this year, measured areas of discharge instructions, appropriate prescriptions of heart failure medications at discharge, evaluation of left heart function, and adult smoking cessation advice and counseling.

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