URMC First in Nation to Implant Heart Failure Device That Offers Glimpse of Personalized Medicine

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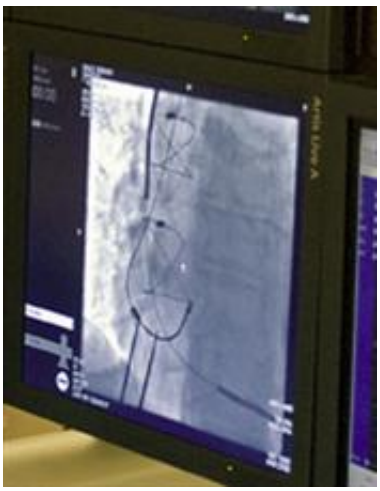

(PhysOrg.com) -- Cardiologists at the University of Rochester Medical Center are the first to enroll in a clinical trial for an investigational management system for congestive heart failure patients. The technology will help patients and their doctors more closely monitor heart health status on a daily basis and potentially could impact the progression of heart failure.

The LAPTOP-HF trial (Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy), sponsored by St. Jude Medical, is a pivotal,

randomized, controlled, prospective, multi-center clinical investigation to evaluate the safety and effectiveness of the company's implantable left atrial pressure (LAP) heart failure management system. The system is being studied under an investigational device exemption from the U.S. Food and Drug Administration. Currently, there is no other means of obtaining left atrial pressure measurements outside the clinic or hospital setting.

The technology aims to direct therapy in a more timely manner and prevent episodes of worsening heart failure, potentially improving symptoms and reducing the need for repeat hospitalization.The system includes:

• A small, pacemaker-size, stand-alone, implantable LAP monitoring device, or a cardiac rhythm management (CRT/ICD) device with an integrated LAP monitoring device;

• A lead, or thin wire from the device to the heart, with an LAP sensor, called the HeartPOD

• Patient Advisor Module (PAM), a portable, wireless, hand-held device used by the patient to check LAP status and, through the DynamicRx feature, directs the patient to take specific medicines or make lifestyle adjustments based on the LAP measurement.

Cardiac electrophysiologist Spencer Z. Rosero, M.D., associate professor of Medicine at URMC and director of the of the Hereditary Arrhythmia Clinic, and transplant cardiologist Leway Chen, M.D., M.P.H., associate professor of Medicine and director of the Program in Heart Failure and Transplantation, are leading the study in Rochester.

The pivotal trial is expected to enroll about 700 patients at up to 75 centers across the United States. URMC was the first center in the nation

to implant the technology, in September, as part of a feasibility trial and is also the first center to participate in this current phase of the study.

Study volunteers will consist of New York Heart Association (NYHA) Class III patients with a history of ischemic or non-ischemic cardiomyopathy for at least six months and at least one heart failure hospitalization within the past 12 months. They are randomized to a treatment group that receives the implantable sensor along with the hand-held device that wirelessly collects data from the LAP sensor and provides that information as well as medication recommendations from their physician directly to the patient, or to a control group that receives standard heart failure therapy.

Currently, physicians' care decisions are guided primarily by patient-reported symptoms such as breathlessness, reduced exercise capacity, swelling of the ankles, fatigue and weakness. Using these red flags, a diagnosis can be made regarding worsening heart failure and can, for instance, prompt a change in medication dosage. Often, though, by the time symptoms become obvious, the patient needs to be hospitalized.

The investigational St. Jude Medical technology could allow patients and physicians to become aware earlier of subtle changes in the body and spur treatment changes before symptoms begin or become more serious

"This technology, if it proves to be effective in clinical trials, could eventually improve patients' quality of life by potentially keeping them healthier and out of the hospital," Rosero said. "This approach is clearly proactive and is an important step toward personalized health monitoring that focuses on providing patients themselves with real-time information and control over their care."

Physician-directed, patient self-management, which has become standard in diabetes management, is a new approach for heart failure

management. It is intended to provide physicians with the ability to better personalize and optimize heart failure management using daily, objective measures of a patient's status. By providing patients with daily feedback on their left atrial pressure status and associated prescription instructions, it may also encourage self-management and treatment adherence.

"Being able to monitor a patient's health on a daily basis, in real time, can help us catch subtle physiological changes and adjust treatment to address them, before long-term effects impact heart failure," Chen said. "And for patients, this truly empowers them, giving them more control over their health."

Provided by University of Rochester Medical Center