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ELECTRICAL IMPULSES TO HEART BOOST OUTLOOK FOR HEART FAILURE PATIENTS

*Novel Device Helps Heart to Pump more Forcefully; Improves
Exercise Capability, Quality of Life*

Orlando, FL – An investigational device that delivers electrical impulses to the heart, thereby strengthening the force of each contraction, is showing promise in patients with heart failure, helping them to exercise more vigorously and promoting a greater sense of well-being, according to research presented today at the American College of Cardiology’s 58th annual scientific session. ACC.09 is the premier cardiovascular medical meeting, connecting cardiologists and cardiovascular specialists to the latest and most innovative findings in cardiovascular science.

The FIX-HF-5 study found that cardiac contractility modulation (CCM) significantly improved peak ventilatory oxygen uptake (pVO₂) and quality of life in patients with moderate-to-severe heart failure, when compared to the best available medical care. In patients with only moderate heart failure, CCM also improved anaerobic threshold, a new marker being tested as a gauge of treatment effectiveness.

“Cardiac contractility modulation shows great promise for the treatment of heart failure,” said William T. Abraham, M.D., a professor of medicine, physiology, and cell biology and director of cardiovascular medicine at The Ohio State University in Columbus. “It has the potential to be a real breakthrough.”

Approximately 5.2 million Americans have heart failure. About 40 percent of them fit into New York Heart Association (NYHA) class III or IV, meaning they experience moderate-to-severe disability despite the best medical therapy. The CCM device – known as the Optimizer (Impulse Dynamics, Orangeburg, NY) – g looks much like a pacemaker and, like that device, is implanted under the skin in the chest with wires threaded into the right side of the heart. Unlike a pacemaker, which controls the heart rate and rhythm, CCM delivers its electrical impulses precisely when the heart is recharging between beats and will not respond by contracting.

Instead, the heart converts the electrical energy into a more forceful contraction the next time it beats.

For the study, researchers recruited 428 patients with NYHA class III or IV heart failure, an ejection fraction of ≤ 35 percent, and narrow QRS tracings on the electrocardiogram (which would rule out the use of another, increasingly popular form of device therapy, cardiac resynchronization).

Patients were randomly assigned to optimal medical therapy alone (213 patients) or CCM plus optimal medical therapy (215 patients). At baseline and six months after device implantation, researchers tested the effectiveness of CCM by having all patients exercise on a treadmill while wearing a mask that measures the air that is breathed in and out. The investigators evaluated both peak VO_2 , an indicator of maximum exercise capacity, and a new indicator, anaerobic threshold, which shows how vigorously a patient can exercise before running out of ready energy reserves and switching to a less efficient form of metabolism. Researchers also measured quality of life using the Minnesota Living with Heart Failure Questionnaire. With this questionnaire, a lower score indicates a better quality of life.

At six months, safety was equally good in both groups, while Peak VO_2 and quality of life were significantly better among patients treated with CCM, as compared to optimal medical therapy alone. Peak VO_2 was better by 0.65 mL/kg/min, $p = 0.024$; and the quality of life score was 9.7 points lower, $p < 0.0001$. There was no significant difference in anaerobic threshold.

However, when researchers analyzed data only for the 185 patients with moderate heart failure (NYHA class III) and an ejection fraction ≥ 25 percent, all three indicators improved significantly more in the CCM group (anaerobic threshold was better by 0.64 mL/kg/min, $p = 0.03$; pVO_2 was better by 1.31 mL/kg/min, $p = 0.001$; and the quality of life score was lower by 10.8 points, $p = 0.003$).

“It may be that some people are too sick, or their heart is too damaged, to respond to CCM,” Abraham said. “This study has provided us with important insight into the ‘sweet spot,’ where this therapy is most effective.”

Dr. Abraham will present the study “Multicenter Randomized Controlled Trial of Cardiac Contractility Modulation in Patients with Advanced Heart Failure” on Sunday, March 29 at 10:47 a.m. in Hall A2.

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The American College of Cardiology (www.acc.org) works to influence health care policy and represents the majority of board certified cardiovascular care specialists through education, research, promotion, and the development and application of standards and guidelines. ACC.09 is the largest cardiovascular meeting, bringing together cardiologists and cardiovascular specialists to share the newest discoveries in treatment and prevention, while helping the ACC achieve its mission to address and improve issues in cardiovascular medicine.