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VAGUS NERVE STIMULATION A PROMISING NEW TREATMENT FOR CONGESTIVE HEART FAILURE

Chronically Stimulating the Vagus Nerve Improves LV Function in Humans

Orlando, FL – Data from a first-in-man study showed chronic vagus nerve stimulation resulted in improvements in ejection fraction, New York Heart Association (NYHA) functional class, six-minute walk test, and quality of life in patients with severe congestive heart failure (CHF), 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.

This study sought to determine the feasibility and safety of chronic vagus stimulation in patients with heart failure. It tested the hypothesis that direct stimulation of the vagus nerve would simultaneously reduce sympathetic hyperactivity and increase vagal activity to correct autonomic imbalance and thereby obtain beneficial results similar to those obtained in animals.

“Current treatments include using drugs such as beta blockers, diuretics and ACE inhibitors to correct hyperactivation of the sympathetic nervous system, which we know to be deleterious. Biventricular pacing is also beneficial in patients with CHF, but still, about one-third of patients do not respond to this therapy,” said Gaetano M. De Ferrari, M.D., head of the Cardiac Intensive Care Unit, Policlinico San Matteo, Pavia, Italy. “We first performed vagal stimulation in conscious animals 20 years ago with Dr. Peter J. Schwartz, chairman of cardiology at the University of Pavia in Italy, resulting in a striking decrease in sudden death after myocardial infarction. More recently, K. Sunagawa in Japan and A. Sabbah in the USA showed that chronic vagal stimulation in animals with heart failure markedly improves left ventricular function and survival.”

The multicenter European study (Principle Investigator, P.J. Schwartz) included 32 patients with New York Heart Association (NYHA) functional class II - IV heart failure, in sinus rhythm and

stable clinical condition. Patients had a mean left ventricular ejection fraction of 22.5 percent at study entry. The patients were implanted with the CardioFit™ (BioControl, Yehud, Israel) vagus nerve stimulation system.

The device delivers heart rate synchronized electrical pulses to the right cervical vagus nerve via a cuff electrode to enhance efferent parasympathetic activity.

After a three-week recovery period, the patients entered the up-titration phase of the study, where the electrical current was progressively increased to the maximal level tolerable by the patient. The study end points were feasibility and safety at six months. Left ventricular ejection fraction, NYHA functional class, exercise capacity as measured by six-minute walk test (how many meters the patient could walk in six minutes), and quality of life were also examined.

After six months, the mean ejection fraction increased slightly, but significantly, from 22.5 percent to 26.6 percent. Half of the patients had a decrease of at least one NYHA class, and the six-minute walk significantly increased from 410 meters to 471 meters. Quality of life, which was rated by the patients themselves on the Minnesota Living with Heart Failure (MLWHF®) questionnaire, also significantly improved, going from 48 to 32.

“Part of the benefit might be due to a placebo effect, but these benefits persisted for six months. Usually the placebo effect lasts only for one or two months,” De Ferrari said. “Still, we showed that chronic vagal stimulation in patients with advanced CHF is feasible, well-tolerated and safe. Further control studies are needed to confirm these initial, first-in-man results.”

Dr. De Ferrari will present the study “Chronic Vagus Nerve Stimulation: A New Treatment Modality for Congestive Heart Failure” on Monday, March 30 at 8:45 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.

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