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IMPLANT DEVICE EFFECTIVELY MAINTAINS HEART FUNCTION FOR TRANSPLANT-LISTED PATIENTS

Additional Study Of Heart Failure Patients Shows Diuretic Drug Benefits

NEW ORLEANS, La. (March 27, 2007) — Whether a patient is awaiting a heart transplant or living with chronic heart failure, cardiologists are continuously looking for new therapies that address short-term and/or long-term needs of chronically impaired cardiac patients. Research presented today at the American College of Cardiology's 56th Annual Scientific Session reviewed new treatments and interventions, including LVAD implantation and diuretic therapies to support left ventricular function in severely compromised cardiovascular patients. ACC.07 is the premier cardiovascular medical meeting, bringing together cardiologists and cardiovascular specialists from around the world to further breakthroughs in cardiovascular medicine.

Multicenter Clinical Evaluation of the Heartmate II Continuous Flow Left Ventricular Assist System in Patients Awaiting Heart Transplantation (Presentation Number: 415-6)

Left ventricular assist device (LVAD) therapy is a life-saving technology for patients with heart failure. Mechanical circulatory support with an LVAD has become a standard therapy for patients with refractory heart failure as a bridge to heart transplantation. New devices are being examined for their safety and efficacy in this setting as well as in those who are deemed not eligible for heart transplantation.

One novel LVAD is called Heartmate II, which utilizes miniature continuous flow technology designed to provide mechanical circulatory support for years at a time. In a prospective, multi-center trial

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conducted at 26 sites in the US, 133 patients listed for heart transplantation and refractory to intravenous inotropic therapy, received a HeartMate II, which was then evaluated for safety and overall efficacy based on historical LVAD performance criteria.

Of the 133 patients, 75 percent achieved the primary endpoint, which was measured as survival to heart transplant or 180 days of device support. Actuarial survival rates were 77 percent after six months and 70 percent after one year post-implantation. In addition, the HeartMate II significantly improved functional status and quality of life, according to the study.

"New devices that can not only effectively support the circulation, but improve outcome as well as quality of life in patients with refractory heart failure, are important options for treating patients with advanced heart failure today" said Leslie W. Miller, M.D., of Washington Hospital Center and a lead author of the study. "Our goal for this study was to confirm the performance of this new continuous flow blood pump technology, of which the HeartMate II is the first to complete a US trial, and we are pleased it proved safe and effective. We now look forward to completing evaluation of this device in a larger sample of patients including those not eligible for heart transplant with the goal to prolong survival and quality of life in all of these patients with advanced heart failure."

Dr. Miller will present his study on Tuesday, March 27, at 11:30 a.m. in Hall H.

Randomized, Double Blind, Multicenter, Placebo-Controlled Study Evaluating the Effect of Eplerenone on Ventricular Remodeling in Patients with Left Ventricular Systolic Dysfunction and Mild to Moderate Heart Failure (Presentation Number: 415-7)

Heart failure is a condition in which the heart fails to pump adequate amounts of blood to the tissues to sustain normal bodily functions. While primarily caused by coronary artery disease, hypertension and cardiomyopathy, heart failure is triggered after a heart attack by left ventricular systolic dysfunction (LVSD), during which the left ventricle of the heart does not contract properly. Aldosterone antagonists, potassium-sparing diuretics that rid the body of excess salt and water, have been studied to treat patients with advanced heart failure and LVSD.

3 – 3 – 3 Ventricular Remodeling

In this study, researchers looked to determine the effect of the aldosterone antagonist eplerenone on patients with left ventricular (LV) dysfunction and mild to moderate heart failure, a group not previously well studied with this class of agents. The multi-center, randomized study was conducted among 226 heart failure patients, 117 of whom were administered eplerenone and 109 treated with placebo, and examined the effect of eplerenone on LV "remodeling", the unfavorable change in heart size and structure that takes place with progressive heart failure. Most patients (>90%) were already being treated angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers and beta-blockers.

The results demonstrate that eplerenone did not have an additional effect on LV remodeling over and above standard therapies in this very well treated group of patients.

"Our findings suggest eplerenone does not effect remodeling (a surrogate for heart failure progression) for patients with mild to moderate symptoms of heart failure and left ventricle dysfunction," said James E. Udelson, M.D., of Tufts New England Medical Center and lead author of the study. "We found though that there are some subsets of patients who may indeed benefit significantly, such as those with excessive fibrous tissue in the heart, and such patients can be the more focused target of future trials. We may also consider combining this therapy with other interventions to provide a greater benefit to patients suffering from heart failure."

Dr. Udelson will present his study on Tuesday, March 27, at 11:45 a.m. in Hall H.

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The American College of Cardiology (www.acc.org) represents the majority of board certified cardiovascular physicians in the United States. Its mission is to advocate for quality cardiovascular care through education, research, promotion, development and application of standards and guidelines- and to influence health care policy. ACC.07 and the i2 Summit 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.