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COMBINATION OF DRUG THERAPY AND PACEMAKER IS SUCCESSFUL FORMULA FOR PATIENTS WITH HEART FAILURE

European Counterpart of REVERSE Presents Two-Year Results

Orlando, FL – A 24-month European study measuring cardiac resynchronization therapy (CRT) showed that using a biventricular pacemaker combined with drug therapy on patients with mild heart failure and ventricular dyssynchrony showed the magnitude of worsening at measured time points was significantly lower than in the control group who received optimal medical therapy alone, 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.

Worsening is defined as either the occurrence of heart failure hospitalizations, death, the need to be programmed to the opposite randomization assignment, worse New York Heart Association (NYHA) functional class or worse wellbeing as judged by the patient.

This study is a multi-national European cohort of the REVERSE trial presented at ACC.08 which was a one-year multi-center trial that gauged whether CRT plus optimal medical therapy (CRT ON) can manage the progression of heart failure compared to optimal medical therapy alone (CRT OFF). The results from that earlier one-year study, which included both United States and European patients, failed to show that adding CRT to optimal medical therapy significantly influenced the primary end point, which was percent worsening. However, the data did show that device therapy most likely improved left ventricular function and prevented heart-failure hospitalizations – both secondary endpoints of the study.

“We wanted to assess if CRT in medically well-treated but mildly symptomatic patients or in asymptomatic patients with previous heart failure and with a wide QRS [when ventricles contract

during the cardiac cycle] could modify disease progression,” said Cecilia Linde, M.D., Ph.D, Karolinska University Hospital, Stockholm, Sweden.

The primary endpoint of comparing the worsening percentage in both CRT ON and CRT OFF increased over time, indicating disease progression did not stop. However, the magnitude of worsening at each time point was significantly lower in the CRT ON when compared to the CRT OFF group.

Improvement in left ventricular function was marked and progressed over 18 months with sustained benefit over the last six months of the study period. In contrast, the disease progression, being worsening ventricular function, in the CRT OFF group was seen towards the end of the observation period.

“We noticed that the 262 European patients improved by CRT, regarding the clinical composite response and in terms of sustained reverse remodeling,” Linde said. “This translates into a significant decrease in death and heart failure hospitalizations.”

As with the main REVERSE trial, there was no significant benefit in the NYHA functional classification, quality of life or exercise capacity, which is not surprising in mildly symptomatic or asymptomatic patients.

“Optimal heart failure medication, when properly introduced, means that patients who are admitted for heart failure for the first time may revert to an asymptomatic or mildly symptomatic stage,” Linde said.

Left ventricular function does not normalize or improve sufficiently by administering drugs in all patients. In these patients, disease progression that results in worsening symptoms or even the need for hospitalization due to heart failure over the following 12 to 24 months is expected.

“Our study demonstrated that CRT in a subset of such patients with wide QRS easily detected with an ordinary ECG and indicating delayed ventricular activation, is an important addition to treatment that achieves substantial reverse modeling, which postpones the time to the next heart failure progression,” Linde said. “Thus, we believe it impacts disease progression.”

Dr. Jean-Claude Daubert will present the study, “Cardiac Resynchronization Therapy Prevents Disease Progression in NYHA Class I-II Heart Failure Patients: 24 Months Results from the European Cohort of the REVERSE Trial” on Tuesday, March 31 at 11:04 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.