Ventricular Functional Response to Spinal Cord Stimulation for Advanced Heart Failure: Primary Results of the Randomized Defeat-HF Trial

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Background
Heart failure is a syndrome associated with symptoms caused by impaired ventricular function and abnormal neuro - hormonal activation that is responsible for further progression of disease. For the last decade, the primary treatment for heart failure has been through pharmacologic blockade of the abnormal neuro - hormonal activation through the use of beta-blockers and ACE inhibitors. Additionally, less than 25% of heart failure patients are indicated for cardiac resynchronization therapy (CRT), leaving many patients in need of new HF therapies that improve morbidity and mortality.

The purpose of the Defeat-HF clinical study is to evaluate whether spinal cord stimulation (SCS) improves heart failure (HF) metrics, including cardiac structure (e.g., heart size and muscle wall thickness), functional capacity (e.g., peak VO2 assessment), and symptoms. SCS may provide another method to slow down or reverse the progression of heart failure by modulating abnormal neuro -hormonal activation.

Design
The Defeat-HF study is a prospective, multicenter (25 sites in Canada, Europe, South Africa, and the United States), randomized (3:2), parallel single-blind controlled study to investigate whether SCS is a feasible therapy for the treatment of systolic heart failure. The inclusion criteria are (1) NYHA Class III heart failure, (2) LVEF < 35%, (3) QRS duration < 120ms and LVEDD >55mm. The primary objective of the Defeat-HF study is to evaluate the reduction in left- ventricular end systolic volume index (LVESVi) after 6 months of SCS therapy in the Treatment arm compared to the Control arm.

Demographics
In total, 82 patients were enrolled with 66 successfully randomized and implanted with the SCS device system. Seventy-six (76) % (50 of 66) had an ICD at the baseline visit, and among randomized subjects, the mean age was 61 years; 79% were male; mean LVEF was 27% and mean QRS duration was 105ms. Results
Currently, 66 randomized subjects have completed 6 months of follow-up and are expected to complete 12 month study follow-up visits in July 2014. Analyses of endpoints at 6 and 12 months will be performed and reviewed by the Data Monitoring Committee in September 2014 and available for the AHA presentation.

Disclosure

D.P. Zipes: Consultant/Advisory Board; Modest; Medtronic. P. Neuzil: Consultant/Advisory Board; Modest; EV3, EndoSense, CryoCath Technologies, Boston Scientific, CardioFocus. H. Theres: Consultant/Advisory Board; Significant; Medtronic. D. Caraway: Research Grant; Modest; Vertos Medical. Speakers Bureau; Modest; Medtronic, Vertos Medical. Consultant/Advisory Board; Modest; Medtronic, Vertos Medical. D.L. Mann: Consultant/Advisory Board; Modest; Medtronic, BioControl. C. Mannheimer: Research Grant; Modest; Medtronic. P. Van Buren: Consultant/Advisory Board; Modest; Medtronic. C. Linde: Research Grant; Modest; Medtronic. Other Research Support; Modest; Medtronic. Honoraria; Modest; Biotronik, St. Jude Medical. Consultant/Advisory Board; Modest; Cardio3 BioSciences, St. Jude Medical. B. Linderoth: Consultant/Advisory Board; Modest; Medtronic, St. Jude Medical, Boston Scientific. F. Kueffer: Employment; Significant; Medtronic. S.A. Sarazin: Employment; Significant; Medtronic. M.J. DeJongste: Speakers Bureau; Modest; Medtronic, St. Jude Medical.