Medtronic News

New Data Shows Clinical Benefit of Cardiac Resynchronization Therapy (CRT) in Atrial Fibrillation (AF)

Results Provide Evidence Supporting Potential Expansion of Indications for CRT in Symptomatic, Permanent Atrial Fibrillation Patient Population

MINNEAPOLIS & SAN FRANCISCO, May 05, 2011 (BUSINESS WIRE) --

Data presented as a Late Breaking Clinical Trial at Heart Rhythm 2011, the Heart Rhythm Society's 32nd Annual Scientific Sessions, shows the clinical benefit of cardiac resynchronization therapy (CRT) versus conventional right-ventricle (RV) pacing in improving heart failure (HF) in patients undergoing atrioventricular (AV) junction ablation for permanent atrial fibrillation (AF). In the clinical trial, patients receiving CRT had a 26 percent reduction in the primary composite endpoint of death from HF, hospitalization from HF, or worsening HF when compared to patients undergoing RV pacing (11 percent).

The APAF (Assessment of Cardiac Resynchronization Therapy in Patients with Permanent Atrial Fibrillation) clinical trial was supported by Medtronic. The use of Medtronic CRT devices in permanent AF patients with depressed LV function undergoing AV nodal ablation is investigational and not an approved use in the United States.

"These findings suggest CRT should be considered as the preferred treatment approach for patients that require the 'ablate and pace' procedure," said Michele Brignole, M.D., lead investigator and electrophysiologist, Ospedali del Tigullio, Lavagna, Italy. "While these results provide evidence supporting the potential expansion of indications regarding the use of CRT as a first-line treatment for all permanent AF patients who must undergo AV junction ablation, we look forward to conducting additional studies to provide further confirmation that will ultimately result in the modification of treatment guidelines."

Often referred to as "ablate and pace" therapy, AV junction ablation, which produces complete AV block to assure heart rate control and rhythm regulation, followed by implantation of a cardiac pacing device, is a routine, clinically validated treatment for patients with symptomatic, drug-refractory permanent AF. Additionally, CRT is a well-established treatment for heart failure that uses a specialized cardiac pacing device to improve the pumping efficiency of the heart. While heart failure and AF are increasingly common, life-threatening diseases that often predispose one another, CRT has not been extensively studied in the treatment of AF. Based on current U.S. and European treatment guidelines, CRT is not currently recommended as a treatment for all patients with permanent AF and refractory heart failure.

Approximately 25 percent of patients in the APAF trial met the current CRT indication criteria set forth in the treatment guidelines, while 75 percent did not. The findings showed that the relative clinical benefit of CRT over RV pacing was significant and independent of whether the patients were indicated for CRT in the guidelines.

"This Medtronic-supported research builds upon the growing body of evidence suggesting guideline changes for the use of CRT therapy in patients with permanent AF," said Pat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic. "We are committed to offering physicians advanced medical solutions that provide the best level of care to patients with AF and other cardiac rhythm diseases, and we are focused on ensuring patients who could significantly benefit from our innovative therapies are able to receive them."

About the APAF Study

The prospective, multicenter study included 186 patients who had successfully undergone AV junction ablation and CRT, and who were randomized to receive echo-guided CRT (97 patients) or RV apical pacing (89 patients). During a median follow-up of 20 months, the CRT group had fewer worsening HF symptoms and HF hospitalizations; total mortality was similar in both groups. Additionally, only the CRT mode remained an independent predictor of absence of clinical failure (defined as death due to HF, hospitalization due to HF or worsening HF) during the follow-up.

About Atrial Fibrillation

Atrial fibrillation is the most common and one of the most undertreated heart rhythm disorders, affecting more than 7 million people worldwide. It is estimated that half of all diagnosed AF patients fail drug therapy, and if left untreated, patients have up to a five times higher risk of stroke and an increased chance of developing heart failure. Additionally, since AF is often age-related, the need for more effective treatment options is escalating as the global population grows older.

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