

Study Shows CRT-D Devices with Medtronic AdaptivCRT(TM) Associated with Reduction of Costs of Atrial Fibrillation

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Study Supplements Earlier Data Showing Reduction in Hospital Readmissions for Heart Failure Patients with AdaptivCRT Technology

MINNEAPOLIS, USA and NICE, FRANCE - June 18, 2014 - New data from the Medtronic, Inc. (NYSE: MDT) Adaptive CRT trial show a 61 percent ($p=0.01$) lower risk of atrial fibrillation (AF)-related problems in patients who receive a cardiac resynchronization therapy-defibrillator (CRT-D) with the Medtronic-exclusive AdaptivCRT(TM) algorithm compared to conventional biventricular pacing therapy. Presented today at CARDIOSTIM / EHRA EUROPACE 2014, World Congress in Electrophysiology and Cardiac Techniques, the data also indicate a 55 percent relative reduction in healthcare utilizations (HCUs, including hospitalizations, emergency department or clinic visits) when patients have devices with AdaptivCRT.

Patients with heart failure, which is a progressive disease, are more likely than the general population to develop AF. AF is associated with worsening heart failure symptoms and higher mortality, along with patients' increased use of healthcare resources. Previous data from this trial showed patients with heart failure who received the AdaptivCRT technology were at a 46 percent lower risk of spending 48 consecutive hours or more in AF compared to conventional CRT patients¹.

According to the analysis of 476 patients, potential use of healthcare resources because of AF are reduced with the AdaptivCRT technology; specific data was presented for the healthcare systems in the United States and Germany, which showed AF-related provider cost savings of \$630 USD per patient and €130 over 24 months, respectively. Nearly all of these cost savings (92 percent in the U.S., 93 percent in Germany) were from a reduction in hospitalizations.

"The study results are clear in showing that CRT devices with adaptive algorithms reduce the risk of atrial fibrillation adverse events and related costs," said Prof. Dr. Med. Bernd Lemke, head of the Department of Cardiology at Lüdenscheid Hospital, Germany. "On an individual level, the algorithm's personalized therapy helps keep more patients out of the hospital. On a system-level, this results in savings and less use of healthcare resources."

Recent data presented at Heart Rhythm 2014 from the Adaptive CRT trial also showed that the AdaptivCRT feature reduced 30-day readmissions for heart failure by nearly half², and 30-day readmissions for all-cause hospitalizations by more than 40 percent², which are both noteworthy since readmissions within 30 days of discharge may result in reduced or no payment under many payment settings. Heart failure leads to more than 1 million hospitalizations in the United States yearly³, and U.S. patients are readmitted on average 1.23 times the first year after initial heart failure diagnosis⁴. As a consequence, heart failure is currently the fourth-leading cause of 30-day hospital readmissions⁵ and the leading cause of readmission of Medicare patients⁶. More than 60 percent of patients indicated for any type of CRT therapy do not receive it⁷.

Because of the favorable evidence showing reduction in AF incidence and all-cause hospitalizations among patients with the AdaptivCRT technology, Medtronic plans to conduct a global study of 3,000 patients to evaluate the superiority of CRT with AdaptivCRT therapy in reducing heart failure events and mortality, compared to conventional bi-ventricular pacing.

The AdaptivCRT feature, found on market-released Medtronic Viva® CRT-D and Viva® CRT-P devices, works by preserving normal heart rhythms and automatically adjusting to the patient's needs every minute, creating a customized therapy for each patient⁸. The research presented today builds on previous findings from the Adaptive CRT trial that showed the benefits of the AdaptivCRT algorithm, including:

- AdaptivCRT increases CRT response rate by 12 percent⁹;
- Patients with AdaptivCRT have demonstrated a 21 percent reduction in Heart Failure hospitalization¹⁰ and a reduced risk of death⁹;
- Patients with the AdaptivCRT technology have a 46 percent reduced risk of AF¹.

"As today's healthcare environment evolves and more focus is placed on curbing readmission rates, hospital administrators and payers must increasingly focus on both the health benefits and quality of life of individual patients and the long-term cost savings of effective treatments," said Sheri Dodd, vice president of Clinical Research, Healthcare Economics and Policy for the Cardiac Rhythm Disease Management business at Medtronic. "Hospital administrators must increasingly look to new solutions for tackling heart failure and associated costs, and this is made easier with this data showing the benefit of implanting devices that have the adaptive algorithm."

About the Adaptive CRT Trial

The global Adaptive CRT trial is a prospective, multicenter, randomized, double-blind study designed to evaluate the clinical benefit of synchronized left ventricular pacing (sLVP) provided by the AdaptivCRT algorithm. The trial enrolled 522 patients who received a CRT device and were randomized to either receive the AdaptivCRT algorithm (treatment arm) or conventional CRT with echocardiographic optimization of the pacing parameters (control arm) in a 2:1 ratio. All patients were followed at six and 12 months and subsequently every six months until study closure. Overall, the Adaptive CRT trial demonstrated non-inferiority of the AdaptivCRT algorithm to echocardiographically optimized CRT.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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⁸ Abraham WT, Fisher WG, Smith AL, et al. Cardiac resynchronization in chronic heart failure. *N Engl J Med*. June 13, 2002;346(24): 1845-1853.

⁹ Birnie D, Lemke B, Aonuma K, et al. Clinical outcomes with synchronized left ventricular pacing: Analysis of the adaptive CRT trial. *Heart Rhythm*. September 2013;10(9):1368-1374.

¹⁰ Tarab AD, Dougher CE, Rogers TB, et al. Budget impact of selecting cardiac resynchronization therapy (CRT) devices with adaptive ("aCRT") programming algorithms under the United States Medicare Payment Setting. *Value in Health*. November 2012;15(7):A349.

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