Medtronic Studies Show Cardiac Resynchronization Therapy Extends Life, Reduces Hospital Readmissions

November 16, 2014 9:30 AM CT

Data Demonstrate Clinical and Economic Value of Underutilized Treatment for Heart Failure Patients at American Heart Association's Scientific Sessions 2014

MINNEAPOLIS and CHICAGO - Nov. 16, 2014 - Medtronic, Inc. (NYSE: MDT) today announced new data supporting the clinical and economic value of its cardiac resynchronization therapy (CRT) devices for the treatment of heart failure, including a significant reduction in all-cause 30-day readmissions after heart failure hospitalizations. Additionally, heart failure patients who benefited early from CRT lived longer and consumed fewer hospital resources than patients who did not experience early benefit from the therapy. These new data were featured in separate presentations at the American Heart Association's Scientific Sessions 2014 in Chicago.

"The efficient management of heart failure is a growing priority for healthcare," said Linda Gillam, M.D., MPH, chair, Cardiovascular Medicine, Atlantic Health System. "These new economic data reinforce the important benefits of CRT and demonstrate its value, not only for patient health, but also the fiscal health of the hospitals and health systems that treat them."

One million people with heart failure are hospitalized each year, and 25 percent of them will be re-hospitalized within 30 days. [1] Additionally, heart failure consumes intensive resources during hospitalizations and continues to cause problems following hospital stays, with six-month readmission rates of 50 percent[2,3,4] and mortality rates of approximately 30 percent. [5]

Lower 30-Day Readmissions with Medtronic CRT Devices

In the meta-analysis titled, "Reduced 30-Day Hospital Readmissions in Systolic Heart Failure Patients with Cardiac Resynchronization Therapy: Evidence from Five Randomized Controlled Trials," researchers analyzed pooled data from five Medtronic-sponsored randomized controlled trials (CARE-HF, MIRACLE, MIRACLE-ICD, RAFT and REVERSE) involving 3,872 patients, to determine whether CRT reduces the rate of all-cause readmission within 30 days of a heart failure hospitalization. Among the 678 subjects with an index heart failure hospitalization, there was a 26 percent relative reduction of hospital readmissions in patients treated with CRT. For patients with more advanced heart failure, Class III/IV, the benefit was higher, at 31 percent, than Class II patients at 10 percent.

Clinical and Economic Value of CRT

In a separate presentation titled, "Clinical and Economic Value of Maximizing Response to Cardiac Resynchronization Therapy (CRT): Evidence from Five Randomized Controlled Trials," researchers found that patients who improved or remained unchanged six months after CRT were projected to live longer and consumed fewer hospital resources (i.e. fewer and/or shorter heart failure-related hospitalizations), than patients who worsened.

Results were measured using the Packer Clinical Composite Score (CCS), which analyzes a patient's condition as improved, unchanged or worsened using variables including death, heart failure hospitalization, a patient global assessment questionnaire, and change in symptoms as measured by New York Heart Association (NYHA) heart failure class.

The pooled analysis of five Medtronic-sponsored trials (MIRACLE, MIRACLE-ICD, InSync III Marquis, PROSPECT and Adaptive CRT) identified 1,603 total patients, 1,089 of which improved (68 percent), 235 remained unchanged (15 percent) and 279 worsened (17 percent). Patients who improved or remained unchanged at six months of receiving CRT were projected (using Markov modeling) to live approximately eight years compared to less than two years in the worsened group.

Additionally, heart failure hospitalization rates in the first year after the six-month clinical composite score assessment were 0.13 for those who improved, 0.27 for those who were unchanged and more than three times higher (0.90) for those who worsened ($p<0.0001$).

"Medtronic is committed to bringing forward sound innovation that improves patients' lives and provides economic value by reducing cost to the healthcare system," said David Steinhaus, M.D., vice president and general manager, Heart Failure, and medical director for the Cardiac Rhythm and Heart Failure Business at Medtronic. "Cardiac resynchronization therapy is an important tool in the management of heart failure and these data are a prime example of how innovations, including Medtronic's AdaptivCRT pacing algorithm, can enhance the clinical and economic value of an already proven therapy."

About Cardiac Resynchronization Therapy (CRT)
CRT is designed to help the heart pump more effectively in a coordinated rhythm. A stopwatch-sized device implanted in the upper chest sends small electrical impulses to stimulate the heart muscle. CRT has been proven to be a cost-effective and beneficial therapy for indicated patients, reducing the risk of death and offering improvements in quality of life, cardiac structure and function for heart failure patients.

In numerous randomized clinical trials, Medtronic CRT devices have been shown to reduce mortality and improve patient quality of life. These devices have been safely and effectively used for more than a decade to treat patients with mildly symptomatic, moderate or severe heart failure, and more recently for some patients with AV block and reduced ejection fraction, a measure of pumping function.

As part of its comprehensive approach to treating heart failure patients with CRT, Medtronic offers a variety of solutions across every stage of care, including the proprietary AdaptivCRT algorithm, which has been shown to increase patient response to the therapy[6] and reduce 30-day hospital readmissions by nearly half[7]. AdaptivCRT is available on Medtronic Viva® XT and Viva® Quad XT CRT-defibrillators and Viva® CRT-pacemakers.

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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[1] http://newsroom.heart.org/news/six-steps-could-cut-heart-failure-readmissions

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