Medtronic News

Study Shows Promising Results with Novel Approach to Medtronic Cardiac Resynchronization Therapy

Late-Breaking Clinical Trial Data Show Implant Success with Pacing Inside the Left Ventricle in Heart Failure Patients

MINNEAPOLIS and SAN FRANCISCO - May 9, 2014 - Medtronic, Inc. (NYSE: MDT) today released study findings that show heart failure patients who have limited options for implanted device therapy may benefit from a novel implant technique for cardiac resynchronization therapy (CRT) devices. Data from the ALSYNC (Alternate Site Cardiac Resynchronization) study show that pacing from inside the heart's left ventricle - an alternate site compared to traditional implants - was successful in 89 percent of implant attempts. The data were presented during a Late-Breaking Clinical Trials Session at Heart Rhythm 2014, the Heart Rhythm Society's 35th Annual Scientific Sessions, by Prof. John Morgan, M.D., Southampton University Hospitals Trust, Southampton, U.K. The system evaluated in the ALSYNC study is not available for investigational or commercial use in the United States.

Some heart failure patients are not suitable for, or do not respond to, traditional CRT because of limitations associated with implanting a lead, or thin wire, in veins on the outside of the left ventricle; these limitations may include unique patient anatomy or suboptimal lead placement. As a potential alternative for these patients, the system evaluated in the study implants a lead placed inside the left ventricle by crossing the atrial septum, the wall that divides the two top chambers of the heart.

"There is a significant need for a new way to pace the left ventricle in patients unable to receive the clinical benefits of standard CRT therapy, and this study suggests left ventricular endocardial pacing is a feasible option," said Prof. Morgan, lead investigator of the ALSYNC study. "These findings will elevate this new approach from something that is investigational to one that is closer to the mainstream."

The ALSYNC study, the first of its kind to evaluate the safety and performance of a new delivery system and left ventricular endocardial (LVE) pacing lead for CRT implantation, included 138 patients at 18 centers in Europe and Canada, all of whom were indicated for CRT but were unable to receive a conventional system or did not respond to the therapy at least six months post-implant. LVE pacing was successful in 118 out of 133 (89 percent) implant attempts.

The ALSYNC study assessed the safety and performance of the system and implant procedure. The primary objective was to demonstrate that the complication rates were less than 30 percent at six months in patients with an implant attempt. The objective was met with an observed rate of 17.7 percent (upper confidence bound 24.2 percent), which is comparable to the complication rates of conventional CRT implants1.

"As the leader in CRT, we are committed to continued innovations in heart failure treatment and bringing renewed hope to the many patients who have previously had limited options," said David Steinhaus, M.D., vice president and general manager, heart failure, and medical director for the Cardiac Rhythm Disease Management business at Medtronic.

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 Van Rees JB, et al. Implantation-related complications of implantable cardioverter-defibrillators and cardiac resynchronization therapy devices. Journal of the American College of Cardiology, 58(10): 995-1000.

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