Medtronic News

Medtronic Study Confirms Feasibility of New Extravascular Approach to ICD Therapy

Late-Breaking Presentation at Heart Rhythm 2018 Highlights Investigational Experience with ICD Lead Placed Under Sternum, Outside the Heart and Veins

DUBLIN and BOSTON - May 11, 2018 - Medtronic plc (NYSE:MDT) today announced results from a research study demonstrating the feasibility of a novel approach to delivering pacing and defibrillation therapy in which a lead is placed under the sternum (breastbone), outside of the heart and veins. Data from the Acute Extravascular Defibrillation, Pacing and Electrogram (ASD2) study were presented during a late-breaking session at Heart Rhythm 2018, the Heart Rhythm Society's 39th Annual Scientific Sessions.

The results of the international ASD2 feasibility study, an important step in the Medtronic extravascular (EV) ICD clinical development program, confirmed that an investigational extravascular ICD lead can sense, pace and defibrillate the heart, thus offering a potential future alternative to traditional transvenous ICD systems.

"Clinicians are highly interested in the potential for an extravascular ICD solution to provide both pacing and lifesaving defibrillation therapy without leads placed inside the heart or vasculature," said Lucas V.A. Boersma, M.D., Ph.D., cardiologist at St. Antonius Hospital, Department of Cardiology, Nieuwegein, the Netherlands and professor of cardiology, Academic Medical Center (AMC), University of Amsterdam, the Netherlands. "The ASD2 study offers very encouraging clinical insights, which bring us closer to implanting the first chronic investigational system in ambulatory patients."

The Medtronic EV-ICD System, which currently is in development and not available for use or sale, is a new approach to implantable defibrillation therapy that may offer the benefits of current transvenous defibrillators. In addition, the system may address current limitations of subcutaneous implantable defibrillators, including their inability to provide painless bradycardia pacing or antitachycardia pacing (ATP), and their larger size.

In ASD2, 79 patients who were already scheduled for elective cardiac surgery or a subcutaneous or transvenous ICD implant had an investigational EV-ICD lead inserted temporarily under the sternum and evaluated in conjunction with either a defibrillation patch or a defibrillator emulator. The ICD lead was designed to sense activity in the ventricles (lower chambers of the heart), provide pacing to the ventricles, and deliver a 30-joule defibrillation shock after ventricular fibrillation (VF) was induced.

Ventricular pacing was successful in 97 percent of patients, and shocks successfully terminated 83 percent of episodes, consistent with prior clinical studies of existing ICDs1.

Seven adverse events were reported in six of the 79 studied patients. As with any feasibility research evaluating a new procedure, the investigational procedure and lead implantation tools were refined during the study, with further technique training and education provided to all investigators in an effort reduce the adverse event rate in future patients.

"The ASD2 feasibility experience is an important step in our investigational extravascular defibrillation program, and the results give us confidence to continue with this research," said Mike Marinaro, vice president and general manager of the Cardiac Rhythm Management business, which is part of the Cardiac and Vascular Group at Medtronic. "We look forward to our next clinical evaluation - a first-in-human, chronic study to assess the safety and efficacy of the investigational Medtronic EV-ICD system in an ICD patient population."

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 84,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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 Blatt JA, Poole JE, Johnson GW, et al. No benefit from defibrillation threshold testing in the SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial). J Am Coll Cardiol. 2008 Aug 12;52(7):551-6.

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