

New Data Show That Defibrillators Programmed to Wait Longer to Deliver Therapy Are Safe for Secondary Prevention ICD Patients with Medtronic SmartShock Technology

Late-breaking Clinical Trial Data Confirm Industry Leadership with 1 Percent Inappropriate Shocks Using Medtronic SmartShock Technology

MINNEAPOLIS and SAN FRANCISCO - May 10, 2014 - Medtronic, Inc. (NYSE: MDT) today announced the results from the first prospective randomized clinical trial to show that Medtronic implantable cardioverter defibrillators (ICDs) can safely extend detection times before triggering therapy in secondary prevention patients. The results of the PainFree SST sub-study, unveiled today as a late-breaking presentation at the Heart Rhythm Society's 35th Annual Scientific Sessions, demonstrate that physicians can choose to program ICDs with delayed detection interval settings without compromising safety for high-risk patients.

Previous studies of prolonged interval detection have focused on primary prevention patients, who have not experienced an episode of sudden cardiac arrest but are at risk. Secondary prevention patients are at higher risk for a deadly irregular heart rhythm, having already experienced an episode of sudden cardiac arrest.

"The results of this study are important for secondary prevention patients, who often are treated with more aggressive ICD programming to address arrhythmic events as quickly as possible," said Laurence D. Sterns, M.D. cardiologist at Royal Jubilee Hospital in Victoria, British Columbia, Canada. "Previous studies have demonstrated that devices programmed to wait longer to deliver therapy do not increase the risk of fainting episodes among primary prevention patients, and now we know the same strategy can be safely used in more patients, even patients at increased risk based on their disease progression."

Patients in the PainFree SST trial received Medtronic Protecta(TM) ICDs with SmartShock Technology, an exclusive shock reduction algorithm that enables the devices to better differentiate between dangerous and harmless heart rhythms. Secondary prevention participants were randomized into two groups: an extended interval detection group (30/40 intervals) and a standard interval detection group (18/24 intervals).

The study found that longer detection intervals did not significantly increase the risk of fainting episodes among secondary prevention patients after one-year of follow-up, establishing the safety of this programming strategy among higher-risk patients. The number of patients with syncope events within 24 hours of a device-detected arrhythmic event was similar between groups. Patients programmed to receive standard interval detection were 98 percent free of arrhythmic fainting episodes, compared to 96.9 percent of patients programmed to receive prolonged interval detection.

The study results also revealed that the portion of patients receiving inappropriate shocks, or unnecessary therapy delivered in response to benign arrhythmias or electrical noise sensed by the device, was low and not different between groups. After one year, only 1 percent of patients in the standard detection group and 1.3 percent of patients in the extended interval detection received inappropriate shocks. These results further demonstrate the efficacy of Medtronic ICDs with SmartShock Technology to deliver life-saving therapy only when appropriate.

"ICDs are extremely effective in treating dangerously fast ventricular arrhythmias that can lead to sudden cardiac arrest. Through scientific research and technological advances, Medtronic has successfully reduced the rate of inappropriate shock for ICD patients, helping to clear the way for more patients to benefit from this life-saving technology," said Marshall Stanton, M.D., vice president and general manager, Implantable Defibrillator Business, Cardiac Rhythm Disease Management at Medtronic.

[About the PainFree SST Clinical Trial](#)

The PainFree SST Clinical trial is a prospective, multicenter trial that enrolled 2,790 patients in 126 international centers. Of those patients, 786 had a secondary prevention indication and 705 consented to interval detection randomization. At baseline, 32 percent of the patients had atrial fibrillation (AF) and 33 percent had a history of syncope. The sub-study results were evaluated using a primary endpoint of one year of freedom from arrhythmic syncope, and secondary endpoints including time to first all-cause syncope, appropriate therapy and inappropriate shock.

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.

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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