Medtronic News

Medtronic's Reveal(R) Insertable Cardiac Monitor Led to Effective Diagnosis and Specific Treatment for Patients with Unexplained Fainting

PICTURE Registry Results Published Online Today in EP-Europace

MINNEAPOLIS, Nov 19, 2010 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE:MDT) today announced the publication of data showing that use of its Reveal(R) family of Insertable Cardiac Monitors led to diagnosis and specific treatment for 78 percent (170 of 218) of patients who experienced a recurrent syncopal (fainting) event during the course of the study. Of those diagnosed patients, 75 percent were shown to have had a cardiac cause of their syncopal event. PICTURE (Place of Reveal In the Care Pathway And Treatment of patients with Unexplained Recurrent SyncopE), the largest international, multi-center clinical trial on Insertable Cardiac Monitors to date, was published online today in *EP-Europace*, the *European Journal of Pacing, Arrhythmias and Cardiac Electrophysiology*.

In the course of the study, it was found that patients were evaluated by an average of three different specialists for management of their syncope and underwent a median of 13 tests (range 9-20) without providing a conclusive diagnosis. Patients were followed up until the first recurrence of a syncopal event for at least one year. These findings support current guidelines suggesting that an Implantable Loop Recorder, also known as an Insertable Cardiac Monitor, be implanted earlier rather than later in the evaluation of unexplained syncope.

"Getting to the root of what causes a patient's symptoms can be costly and time-consuming, but is the first step in recommending an effective treatment," said Nils Edvardsson, M.D., Ph.D., the lead investigator of the PICTURE trial, with Sahlgrenska University Hospital in Göteborg, Sweden. "The results of the PICTURE trial suggest that insertable cardiac monitors may more quickly diagnose the patient's underlying cause of syncope and may provide physicians the information they need to effectively treat their patients."

Syncope, also known as fainting, is a sudden loss of consciousness that usually occurs when the blood pressure drops and not enough oxygen reaches the brain. Syncope accounts for one to six percent of hospital admissions1 and approximately one percent of visits to the emergency department per year2-3. While some causes of unexplained fainting are harmless, others may be life threatening. Heart-related causes, including abnormal heart rhythms, are among the most serious causes of syncope. In addition, fainting may lead to further injury, as 70 percent of patients in the PICTURE trial had been hospitalized at least once for syncope and more than one-third had experienced significant physical trauma in association with a syncopal episode.

"These findings provide important, real-world insights into the diagnosis of unexplained syncope and validate the current treatment guidelines set forth by the European Society of Cardiology," said Andrew Krahn, M.D., professor of medicine with University of Western Ontario in London, Ontario. "The results suggest that the large number of tests often performed prior to arriving at a definitive diagnosis may delay effective treatment and increase overall healthcare costs."

About the PICTURE Trial

The PICTURE study is the largest clinical trial to date to evaluate the use and effectiveness of a Reveal Insertable Cardiac Monitor in diagnosing patients with unexplained, recurrent syncope (and pre-syncope). Reveal-guided diagnoses led to pacemaker implants in 51 percent of diagnosed cases. Antiarrhythmic drug therapy (7 percent), other pharmacologic treatment (5 percent), implantable cardioverter defibrillators (6

percent) and ablation (5 percent) were also prescribed treatments.

A total of 650 patients presenting with unexplained, recurrent (pre-) syncope and scheduled for an implant with a Reveal Insertable Cardiac Monitor were originally enrolled in the PICTURE study from 2006 until 2008. Of these patients, follow-up visit data (with or without syncopal events) were available for 570 subjects who were included in the analyzed population. Patients received the implant based on clinical indications and were followed up until the first recurrence of a syncopal event leading to a diagnosis or for at least 12 months after implant. Seventy-one study sites in 11 countries (Austria, The Czech Republic, Denmark, Finland, France, Germany, Israel, The Netherlands, The Slovak Republic, Sweden and Switzerland) participated in the trial.

About the Reveal(R) DX and Reveal(R) XT Insertable Cardiac Monitors
In patients with unexplained and unpredictable symptoms such as syncope and palpitations, the RevealDX and RevealXT Insertable Cardiac Monitors can be used to rule in or rule out an abnormal heart rhythm as the cause.

Placed just under the skin of the chest area in an outpatient procedure, RevealDX and XT capture and store electrocardiogram (ECG) recordings in two ways: a patient-activated feature allows the patient to press a button and store an ECG recording during a symptomatic episode, and an auto-activation feature automatically detects and records predefined arrhythmic events. Later, a physician analyzes the stored information which can be transmitted remotely via the Medtronic CareLink(R) Network, or viewed during an in-office patient visit.

The latest generation product, Reveal XT, has added the capability to detect atrial fibrillation (AF) and provides longer-term trended diagnostic data via Reveal XT's ICM's Cardiac Compass(R) Report, including daily AF burden, patient activity, and average day and night heart rates.

Medtronic Reveal devices are labeled MR-Conditional for use in MRI machines, meaning patients with a device implanted may safely undergo MRI scans under certain conditions.

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.

1 Kappor W.N. *Am J Med.* 1991 : 90 ; 91-106
2 Brignole M, et al. *Europace.* 2003 ; 5 :293-298
3 Blanc J-J, et al. *Eur Heart J.* 2002 ; 23 :815-820

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