Medtronic News

Medtronic-Sponsored Study Finds Pacemakers Reduce Fainting in Patients

ACC.12 Late-breaker Shows Promise of Pacemakers through Diminishing Fainting Recurrences in Patients Diagnosed with Syncope

MINNEAPOLIS & CHICAGO--(BUSINESS WIRE)--Mar. 26, 2012--Medtronic, Inc. (NYSE: MDT) today announced the results of a double-blind, randomized study, ISSUE-3, which found that patients who suffered from fainting due to neurocardiogenic syncope had fewer fainting occurrences when treated with a Medtronic pacemaker. The results, which found a statistically and clinically significant 57 percent relative reduction of fainting recurrence in patients at two years, were presented today in a late-breaking clinical trial session at the American College of Cardiology's (ACC's) 61st Annual Scientific Session in Chicago.

In the study, patients at high risk for syncope recurrence (known as asystolic neurally-mediated syncope or NMS) were identified through the use of Medtronic's Reveal® family of Insertable Cardiac Monitors (ICM), thereby allowing physicians to determine which patients could benefit from a pacemaker implant.

"This study adds to the strength of clinical evidence affirming the effectiveness of pacemakers in reducing the recurrence of asystolic syncope, allowing us to determine which patients may benefit best from pacing," said Michele Brignole, M.D., Ospedali del Tigullio in Lavagna, Italy and the principal investigator of ISSUE-3 (International Study on Syncope of Uncertain Etiology 3). "Based on these compelling results, the ISSUE investigators are hopeful that the clinical implications of this study will be taken into account when drafting updates to the current guidelines for these patients."

While a previous observational study, ISSUE-2 (International Study on Syncope of Uncertain Etiology-2), showed that the use of an ICM effectively diagnosed asystolic syncope, thereby leading to effective treatment outcomes, the ISSUE-3 study was needed to confirm these results through a more rigorous, randomized controlled trial.

The ISSUE-3 study was conducted in 51 centers in Western Europe and Canada in two phases: a screening phase, followed by a treatment phase. From September 2006 to November 2011, 511 patients met the inclusion criteria and received a Reveal device to assist with the diagnosis of each patient's syncope. Results of the ISSUE-3 include:

- Fainting reoccurred in 185 of the 511 study patients (36 percent).
- Fainting was documented by the ICM in 141 (76 percent) of these patients.
- The Reveal ICM diagnosed about half (51 percent) of patients with reoccurring fainting as an asystolic event, indicating them for a pacemaker and making them eligible for the treatment phase of the study. These patients received a dual-chamber Medtronic pacemaker and were randomized 1:1 (pacemaker on and pacemaker off).

The treatment phase of the study demonstrated significant reduction in recurrence of fainting in patients who received Medtronic pacemaker therapy. For patients receiving pacemaker implants, the fainting recurrence rate was 25 percent when the pacemaker was turned on and the fainting recurrence rate was 57 percent when the pacemaker was turned off (this condition is associated with a drop in blood pressure separate from the asystole).

"This study shows that a difficult-to-diagnose patient population can be identified early in the patient care pathway through the use of insertable cardiac monitors, and that treatment is available and effective for patients with asystolic syncope," said Elizabeth Hoff, vice president and general manager of Cardiac Connected Care at Medtronic.

Medtronic pacemakers are currently indicated for use in patients who have experienced one or more of the following conditions: symptomatic paroxysmal or permanent second- or third-degree AV block, symptomatic bilateral bundle branch block, symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders and bradycardia-tachycardia syndrome.

About Syncope

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 is difficult to diagnose as syncopal episodes are often too infrequent and unpredictable for detection with conventional monitoring techniques. As a result, approximately 1.5 million people worldwide suffer from unexplained syncope. Syncope accounts for one to six percent of hospital admissions1 and one percent of total ER visits2 per year. In almost 10 percent of patients, syncope has a cardiac cause; in 50 percent, a non-cardiac cause; and in 40 percent of patients the cause of syncope is unknown.3

Reveal In-Office Study Results

In addition to the late breaker, there will be an ACC poster presented on the safety and feasibility of implanting ICMs in the clinic in-office setting. Sixty-five patients at 9 centers were implanted with a Reveal® ICM and followed for an average 87 days. The study met the primary endpoint of a 3.4% 90-day event rate of patients with procedure-related complications requiring resolution by surgical intervention. It found that in-office ICM insertion can be accomplished in a more convenient setting, and with a high level of physician satisfaction, while expediting patient diagnoses.

In collaboration with leading clinicians, researchers and scientists, 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 worldwide.

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 Kapoor W. Evaluation and outcome of patients with syncope. Medicine (Baltimore). May 1990;69:160-175.

2 Brignole M, et al. Management of syncope referred urgently to general hospitals with and without syncope units. Europace. 2003;5:293-298.

3E.S. Soteriades et al. N Eng J Med. 2002; 347 (12):878-885

Source: Medtronic, Inc.

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