Medtronic News

Medtronic's Reveal(R) XT Insertable Cardiac Monitor Helps Determine AF Burden in Symptomatic and Asymptomatic Patients Following RF Ablation

MINNEAPOLIS & SAN FRANCISCO, May 05, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today announced findings from the DISCERN AF trial, which utilized Medtronic's Reveal(R) XT insertable cardiac monitor to conduct long-term monitoring to assess the incidence of symptomatic versus asymptomatic atrial fibrillation (AF) episodes in patients before and after undergoing radiofrequency (RF) ablation as compared to the AF status reported prior to the procedure. The clinical trial showed an 86 percent reduction in total AF burden (total amount of time spent in atrial fibrillation) from 2.0±0.5 hours per day per patient pre-ablation to 0.3±0.2 hours per day per patient post- ablation (p=0.005), with 56 percent of the total burden being asymptomatic.

The investigator-initiated study, which was supported by Medtronic and presented today as a late-breaking clinical trial at Heart Rhythm 2011, the Heart Rhythm Society's 32nd Annual Scientific Sessions, also showed the ratio of asymptomatic to symptomatic AF increased post-RF ablation. When analyzing symptoms alone, 58 percent of patients were free of AF according to Reveal XT monitoring. This finding suggests that symptoms clearly underestimate overall disease burden post-ablation, since 12 percent of patients in the trial had only asymptomatic AF recurrence as documented by Reveal XT.

"These study findings are promising and fulfill a significant unmet need in the cardiac clinical community when it comes to determining asymptomatic AF in patients who are defined as 'cured' based on symptoms," said Atul Verma, M.D., principal investigator and electrophysiologist, Southlake Regional Health Centre, Newmarket, Ontario, Canada. "Given the incidence of asymptomatic AF before and after RF ablation, a better understanding of the true AF burden may help physicians in their long-term management of this patient population."

RF ablation is considered an effective treatment method for atrial fibrillation. Patients currently indicated for this procedure have highly symptomatic AF that is resistant to drug therapy. However, the overall incidence of asymptomatic AF episodes post-ablation is unclear. Determining the occurrence of asymptomatic AF episodes may be important to ensure patient safety, as the disease can lead to a significantly higher risk of stroke and an increased risk of heart failure. The Reveal family of devices offers varying capabilities and information to physicians seeking to diagnose patients with suspected arrhythmias, and to monitor patients with AF to help make disease management decisions.

"This study underscores the value of Reveal in providing solid clinical insight into the progression of AF and the effect of ablation treatment, which can help guide AF patient care," said Pat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic. "Medtronic is committed to developing leading medical technologies to treat and manage cardiac rhythm diseases such as AF, and new research such as DISCERN AF is a cornerstone to guide our development strategies."

About the DISCERN AF Study

The prospective, multicenter study included 50 patients with symptomatic atrial fibrillation. All patients underwent an implant of Reveal XT with an automated AF detection algorithm at least 3 months prior to ablation and were continuously monitored for 18 months following the procedure. Patients kept a diary to note the exact onset and offset of arrhythmia symptoms. Reveal data were downloaded every three months and all episodes were correlated with the symptom diary.

About the Reveal(R) DX and Reveal(R) XT Insertable Cardiac Monitors

Placed just under the skin of the chest area in an outpatient procedure, RevealDX and XT capture and store 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 additional capability to detect atrial fibrillation (AF) and provides longer-term trended diagnostic data via Reveal XT's Cardiac Compass(R) Report, including daily AF burden, patient activity, and average day and night heart rates.

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. The Reveal family of devices is categorized as a "Class 1" recommendation in the current syncope treatment guidelines set forth by the European Society of Cardiology in collaboration with the U.S. Heart Rhythm Society, meaning there is evidence and/or general agreement that a given diagnostic procedure/treatment is beneficial, useful and effective.1

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 Atrial Fibrillation

Atrial fibrillation is the most common and one of the most undertreated heart rhythm disorders in America. Approximately 3 million Americans are estimated to have the disease, and about 40 percent don't exhibit symptoms and may be under-diagnosed. Half of all diagnosed atrial fibrillation patients fail drug therapy2, and if left untreated patients have up to a five times higher risk of stroke3 and an increased chance of developing heart failure. Additionally, since atrial fibrillation is often age-related, as the U.S. population continues to grow older, the need for more effective treatment options is escalating.

Clinical data show the Reveal XT reliably identifies patients with AF and correctly confirms the absence of AF in patients, which may allow physicians to regulate treatment such as anticoagulation to prevent stroke and more optimal heart rate and rhythm control in a timelier manner as appropriate4. It is widely known that AF is an independent risk factor for stroke, increasing risk approximately five-fold5. Several recent studies have indicated that the correlation between AF episodes and symptoms is poor, meaning that patients may be symptom-free during AF, or experience AF-like symptoms not related to AF6,7. Therefore, detection and continuous monitoring of AF can provide important clinical information to guide treatment decisions.

Current methods for detecting AF, such as Holter monitors and 24-hour event monitors, have limited effectiveness, even if performed repeatedly, given the transitory nature of the monitoring8,9.

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.

Abstract #LB-02

1http://www.escardio.org/guidelines-surveys/esc-guidelines/Pages/syncope.aspx

2 JAMA 2001; 285:2370-5.

3 Fuster et al. *Journal of the American College of Cardiology* 2006; 48:854-906.

4 XPECT Performance Trial

5 Stroke: 1991; 22:983-988

6 M. Patten. Event-recorder monitoring in the diagnosis of atrial fibrillation in symptomatic patients: subanalysis of the SOPAT trial. JCE 2006: 17; 1216-1220

7 G. Senatore. Role of transtelephonic electrocardiographic monitoring in detecting short-term arrhythmia recurrences after radiofrequency ablation in patients with atrial fibrillation. JACC 2005; 45: 873-876

8 P. Ziegler. Comparison of continuous versus intermittent monitoring of atrial arrhythmias. Heart Rhythm 2006; 3: 1445-1452

9 H. Kottkamp. Time courses and quantitative analysis of atrial fibrillation episode number and duration after circular plus linear left atrial lesions. JACC 2004: 44; 869-877

SOURCE: Medtronic, Inc.

Medtronic, Inc.
Wendy Dougherty
Public Relations
763-526-2853
or
Jeff Warren
Investor Relations
763-505-2696

---

https://news.medtronic.com/2011-05-05-Medtronics-Reveal-R-XT-Insertable-Cardiac-Monitor-Helps-Determine-AF-Burden-in-Symptomatic-and-Asymptomatic-Patients-Following-RF-Ablation