Medtronic News

Medtronic's Insertable Cardiac Monitor Documented Arrhythmias in Post-Heart Attack Patients

Reveal(R) Plus Study Results Published Today in Circulation

MINNEAPOLIS, Sep 28, 2010 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE:MDT) today announced the publication of results from a multicenter, prospective study that demonstrated that the company's Reveal(R) Plus implantable cardiac monitor recorded arrhythmias in 46 percent of patients with ejection fractions1 less than or equal to 40 percent and who had previously suffered an acute myocardial infarction (AMI). Approximately 86 percent of the arrhythmias detected were asymptomatic.

The CARISMA (Cardiac Arrhythmias and Risk Stratification after Myocardial Infarction) trial, published today in*Circulation*, is the first study to investigate the incidence and prognostic significance of arrhythmias documented by an insertable cardiac monitor among this patient population.

"For the first time there are data showing that continuous long-term monitoring allows detailed insight into post-AMI arrhythmias," said the principal investigator, Dr. Poul Erik Bloch Thomsen, Gentofte University Hospital, Copenhagen, Denmark. "Additional information about post-AMI patients can help physicians determine appropriate medical intervention, such as an implantable cardioverter-defibrillator, pacemaker, or modified drug therapy."

Pinpointing the frequency of arrhythmias in post-AMI patients has been limited due to a lack of clinically-validated measurement tools, resulting in a significant need for continuous long-term monitoring devices with the ability to provide insight into patients' arrhythmic profiles.2, 3

Of the patients diagnosed with cardiac arrhythmias in the CARISMA study, 27 percent experienced new onset atrial fibrillation, 9.8 percent had high-degree atrioventricular (AV) block, 6.7 percent had sinus bradycardia, and 13 percent had non-sustained ventricular tachycardia. Additionally, 56 patients received an implantable cardioverter-defibrillator (11 for secondary indications; 45 for primary indications) and 15 patients received a pacemaker. Cox regression analysis revealed that high-degree AV block was the most powerful predictor of cardiac death (hazard ratio, 6.75; 95 percent confidence interval, 2.55 to 17.84; $P<0.001$).

"Our Reveal family of devices can provide special monitoring information for physicians managing patients at risk for arrhythmias, providing more information to help determine the most appropriate treatment option," said Pat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic. "Medtronic is committed to investing in next-generation medical technologies that advance the treatment of cardiovascular disease and we look forward to furthering our offerings in this space."

About the CARISMA Study

The CARISMA trial, co-sponsored by Medtronic and Cambridge Heart, was designed to document the incidence and assess the prognostic significance of cardiac arrhythmias obtained from patients with AMI and reduced left ventricular ejection fraction, and to analyze the predictive value of insertable cardiac monitors, electrophysiological testing and non-invasive screening tests for life-threatening tachyarrhythmias in patients surviving an AMI. The clinical trial published today in *Circulation* reports on information obtained from the use of an insertable cardiac monitor. The CARISMA data focused on the predictive value of electrophysiological testing and noninvasive screening tests performed in this study were reported in the *European Heart Journal* in 2009.4

In the CARISMA trial, a total of 1393 of 5869 patients (24 percent) screened in the acute phase (3 to 21 days) of an AMI had left ventricular ejection fraction less than or equal to 40 percent. After exclusions, 297 patients (21 percent) (mean±SD age,

64.0±11.0 years; left ventricular ejection fraction, 31± 7 percent) received a Reveal Plus insertable cardiac monitor within 11±5 days of the AMI and were followed up every 3 months for an average of 1.9±0.5 years. The end points used in the analysis were cardiac death and all-cause mortality.

About the Reveal(R) Family of Insertable Cardiac Monitors
Reveal Plus is an earlier iteration of Medtronic's current generation insertable cardiac monitors Reveal(R) DX and Reveal(R) XT. Placed just under the skin of the chest area in a short outpatient procedure, these monitors capture and store ECG recordings in two ways: an external 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 Cardiac Compass(R) Report, including daily AF burden, patient activity, and average day and night heart rates.

Medtronic Reveal devices are labeled 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 Ejection fraction is a measure of the heart's pumping ability.

2 Yeh, Robert, et al. Population Trends in the Incidence and Outcomes of Acute Myocardial Infarction. *NEJM*. Vol. 362:No. 23. June 10, 2010.

3 Buxton, A. Implantable Loop Recorder in Survivors of Acute Myocardial Infarction: A Glimpse of Reality? *Circulation*. September 28, 2010.

4 Huikuri HV, Raatikainen MJ, Moerch-Joergensen R, Hartikainen J, Virtanen V, Boland J, Anttonen O, Hoest N, Boersma LV, Platou ES, Messier MD, Bloch-Thomsen PE. Prediction of fatal or near-fatal cardiac arrhythmia events in patients with depressed left ventricular function after an acute myocardial infarction. *Eur Heart J*. 2009;30:689-698.

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