Medtronic News

Study Finds Medtronic Insertable Cardiac Monitors Detect Atrial Fibrillation In Stroke Patients Better Than Standard Care

(Thomson Reuters ONE via COMTEX) --MINNEAPOLIS - February 14, 2014 - Medtronic, Inc. (NYSE: MDT), today announced results from the CRYSTAL AF (CRYptogenic STroke And underLying Atrial Fibrillation) Clinical Trial, which found that continuous cardiac monitoring with the Reveal® XT Insertable Cardiac Monitor (ICM) was superior to standard care at detecting atrial fibrillation (AF) in patients who have had strokes of undetermined causes (cryptogenic stroke). Presented at a late-breaking science session at the American Stroke Association's International Stroke Conference, the randomized, global study met its primary endpoint by demonstrating that continuous monitoring with the Reveal ICM discovered AF in 6.4 times more patients than standard care at six months ($p=0.0006$).

In addition, the Trial found that compared to standard care (including electrocardiograms, Holter monitors and other short-term diagnostic tests prescribed over the follow-up period), the Reveal ICM detected AF in 7.3 times more patients at 12 months ($p<0.0001$), and 8.8 times more patients at 36 months ($p<0.0001$). When followed for 36 months, 30 percent of the patients in the ICM arm had AF detected.

"These study results should make us reconsider how we approach cryptogenic stroke patients. Compared to standard care, continuous monitoring is superior when attempting to diagnose AF in this at-risk patient population, and ICMs offer these patients new hope," said Richard A. Bernstein, M.D., professor of neurology in the Davee Department of Neurology at Northwestern University and director of the Stroke Program at Northwestern Memorial Hospital in Chicago, and member of the CRYSTAL AF steering committee. "We know patients with cryptogenic stroke are at an increased risk for a subsequent stroke, and finding AF allows us to put patients on medication that should be more effective at preventing these second strokes."

One of the reasons that AF can be difficult to detect is that often it is not associated with symptoms. In the study, 79 percent of the first AF episodes detected had no symptoms. This means AF likely would have gone undetected by standard care due to patients' inability to notice warning signs of this dangerous arrhythmia.

Stroke occurs when a blood vessel in the brain ruptures or is suddenly blocked, which results in damage to the brain tissue. If the cause of a stroke cannot be determined, the stroke is called "cryptogenic," or a stroke of unknown cause. Each year in the United States, 795,000 people suffer a stroke, and it is estimated that 25 to 40 percent of those strokes are cryptogenic in nature.[1] Patients with AF (upper chambers of the heart beat very fast and irregularly), which can be asymptomatic, are five times more likely to have a stroke.[2]

"As AF is often intermittent and asymptomatic, we can't rely on symptoms to decide who has AF or who needs monitoring. Continuous monitoring allows us to find the AF that short-term monitoring misses because significant amounts of time can pass between episodes," said Bernstein.

CRYSTAL AF is the largest global randomized clinical trial comparing continuous monitoring to standard care for the detection of AF in patients with recent cryptogenic strokes. It is a prospective, controlled trial that enrolled 441 patients at 55 centers in Europe, Canada and the U.S. from June 2009 to April 2012. The continuous monitoring arm used the Reveal ICM, which has an algorithm to automatically detect AF as well as other cardiac arrhythmias. The primary endpoint was time to AF detection at 6 months of follow-up.

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. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers

around the world.

Multimedia Release

A multimedia version of this release, with a link to additional background information can be found at: http://bit.ly/LEnI1p

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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[1] Adams HP Jr. Stroke. Jan 1993; 24; 35-41.

[2] Wolf PA, et al. Stroke. 1991; 22: 983-988.

Contacts:

Joey Lomicky

Public Relations

+1-763-526-2494

Jeff Warren

Investor Relations

+1-763-505-2696

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