Medtronic News

Real-World Study Shows 72 Percent of Atrial Fibrillation Would Have Gone Undiagnosed in Stroke Patients if Cardiac Monitoring Had Been Limited to 30 Days

Findings Demonstrate Detection of Atrial Fibrillation in Cryptogenic Stroke Patients with Medtronic Insertable Cardiac Monitor

DUBLIN and VANCOUVER - APRIL 20, 2016 - Medtronic plc (NSYE: MDT) today announced one-year results from a real-world study of patients who had a cryptogenic stroke, or stroke of unknown cause. The study found that the Reveal LINQ(TM) Insertable Cardiac Monitor (ICM) detected atrial fibrillation (AF) at a greater rate than previously reported in a randomized controlled clinical trial (the CRYSTAL AF Study, published in *The New England Journal of Medicine* in 2014). The results from the observational real-world study are being presented today at the 68th American Academy of Neurology Annual Meeting in Vancouver, Canada.

The study evaluated 1,247 patients across the U.S. to understand the incidence and duration of AF episodes in a large, real-world population of cryptogenic stroke patients with an ICM after one year of follow up and to compare the AF detection rates among these patients to those of the CRYSTAL AF Study. At 12 months, 1,737 AF episodes were detected in 192 patients, resulting in an AF detection rate of 16.3 percent. This represents a 32 percent relative increase compared to the rate observed in the CRYSTAL AF Study at the same time.

The current recommended guidelines for AF detection are 30-days of monitoring within six months of having a cryptogenic stroke. However, because AF may occur infrequently, it may not be detected by conventional monitoring techniques such as inhospital monitoring, electrocardiography or traditional ambulatory cardiac monitors such as a Holter. The real-world study found that 72 percent of patients diagnosed with AF would have been undiagnosed if their cardiac monitoring had been limited to 30 days.

"In clinical practice, we continue to see increased AF detection rates using the insertable cardiac monitor compared to the rigorously-controlled CRYSTAL AF study," said co-author John Rogers, M.D., cardiologist at Scripps Clinic in La Jolla, California. "What's most significant, however, is that the vast majority of patients had their first AF episode beyond the range of 30-day conventional monitoring, reinforcing the need to reevaluate the standard AF monitoring guidelines for cryptogenic stroke patients."

Each year, approximately 692,000 Americans experience ischemic strokes (the most common type of stroke); cryptogenic strokes account for approximately 20 - 40 percent of ischemic strokes in the majority of modern stroke registries and databases.1-7 Patients with AF - a common cardiac condition that occurs when the heart beats irregularly or rapidly - are five times more likely to have a stroke.8

The Reveal LINQ ICM System is the smallest insertable cardiac monitoring device available (~1 cc, or one-third the size of an AAA battery). Placed just beneath the skin through a small incision of less than 1 cm in the upper left side of the chest, the Reveal LINQ ICM is inserted using a minimally invasive procedure and its presence is often nearly undetectable to the naked eye once the incision has healed. The device communicates wirelessly with a patient bedside monitor that uploads device data to the Medtronic CareLink® network and is MR-Conditional, allowing patients to undergo magnetic resonance imaging (MRI), if needed. The Reveal LINQ ICM automatically and continuously detects and records abnormal heart rhythms for up to three years.

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.

About Medtronic

Medtronic plc (<u>www.medtronic.com</u>), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 85,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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 Sacco RL, Ellenberg JH, Mohr JP, et al. Infarcts of undetermined cause: the NINCDS Stroke Data Bank*Ann Neurol.* 1989:25:382-390.

- 2 Petty GW, Brown RD, Jr., Whisnant JP, Sicks JD, O'Fallon WM, et al. Ischemic stroke subtypes: a population-based study of incidence and risk factors. *Stroke*. 1999;30:2513-2516.
- 3 Kolominsky-Rabas PL, Weber M, Gefeller O, Neundoerfer B, Heuschmann PU. Epidemiology of ischemic stroke subtypes according to TOAST criteria: incidence, recurrence and long-term survival in ischemic stroke subtypes: a population-based study. *Stroke*. 2001;32:2735-2740.
- 4 Schulz UG, Rothwell PM. Differences in vascular risk factors between etiological subtypes of ischemic stroke: importance of population-based studies. *Stroke*. 2003;34:2050-2059.
- 5 Schneider AT, Kissela B, Woo D, et al. Ischemic stroke subtypes: a population-based study of incidence rates among blacks and whites. *Stroke*. 2004;35:1552-1556.
- 6 Lee BI, Nam HS, Heo JH, Kim DI. Yonsei Stroke Registry. Analysis of 1,000 patients with acute cerebral infarctions. *Cerebrovasc Dis.* 2001; 12:145-151.
- Heart Disease and Stroke Statistics 2015 Update *Circulation*. 2015; 131: e29-e322 Published online before print December 17, 2014, doi: 10.1161/CIR.00000000000152.
- 8 Wolf PA, et al. Stroke. 1991; 22: 983-988.

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