Medtronic News

Medtronic Insertable Cardiac Monitor Detects Significantly Higher Rates of Atrial Fibrillation in Large and Small Vessel Stroke Patients Compared to Standard of Care

Publication in JAMA Shows Reveal LINQ™ ICM Demonstrated a Seven-Fold Increase in Detecting AF vs. Standard of Care

DUBLIN, June 7, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced clinical trial results from the STROKE AF trial demonstrating the superiority of the Reveal LINQ™ Insertable Cardiac Monitor (ICM) to detect abnormal heartbeats, otherwise known as atrial fibrillation (AF), in both large and small vessel stroke patients compared to standard of care. The findings were published in the June 1, 2021 issue of the *Journal of the American Medical Association* (JAMA).

Stroke impacts more than 795,000 people every year. More than 87% of strokes are ischemic strokes, which occur when vessels that allow blood to flow to the brain are blocked.[1] AF is a major risk factor for ischemic stroke. In fact, there is a five-fold increase in ischemic stroke risk for AF patients.

The STROKE AF study evaluated 496 patients[2], including 284 large vessel and 208 small vessel stroke patients. The findings demonstrated Reveal LINQ ICM was superior to the standard of care for AF detection:

- At 12 months, AF was detected in 12.1% (or one in eight) patients in the ICM arm compared to 1.8% in the standard of care arm (HR=7.41; p<0.001). This equates to a greater than seven-fold increase in detecting AF in the ICM arm.
- 78% of patients who had AF would have been missed if only monitored for 30 days.[3]
- Median time to detection of AF was 99 days.
- Rates of AF detection in the ICM arm were similar between patients with index strokes due to small vessel versus large vessel disease (12.6% compared to 11.7% respectively; p=0.74).
- At 12 months, 96.3% of first AF episodes were asymptomatic in ICM arm.
- The majority (55.5%) of patients with AF detected had an episode lasting more than one hour.

"STROKE AF showed that many patients with large vessel or small vessel stroke actually have AF, which is challenging to find using standard cardiac monitoring," said Richard Bernstein, M.D., Ph.D., Northwestern Medicine Distinguished Physician in Vascular Neurology, Medical Director of Telehealth, and professor of Neurology, Northwestern University Feinberg School of Medicine. "Our job as neurologists includes identifying potential causes of future strokes to adequately protect our patients. AF is a risk that we can't afford to miss, and without long-term monitoring, we are missing it."

"The Stroke AF trial shows that long-term monitoring with an ICM resulted in significantly higher rates of AF detection compared to routine follow-up at both six months and one year after the patient's index stroke," said Lee H. Schwamm, M.D., vice president of Virtual Care and Digital Health, Mass General Brigham and C. Miller Fisher chair in Vascular Neurology, Massachusetts General Hospital. "Preventing recurrent stroke is challenging. I believe the findings from the STROKE AF study strongly suggest the need to re-examine the role of ICMs in secondary prevention, go beyond just the cryptogenic stroke patient, and embrace a broader conceptual framework that shifts the emphasis away from the cause of the index stroke and onto future stroke prevention."

STROKE AF is a 1:1, randomized clinical trial, taking place at 33 clinical sites across the U.S. Individuals 60 years and older with ischemic stroke believed to be due to small vessel disease, large vessel cervical or intracranial atherosclerosis within the past 10 days, as well as individuals 50 to 59 years older with stroke risk factors, were enrolled in the trial. Patients randomized to the ICM arm were given a Medtronic Reveal LINQ Insertable Cardiac Monitor. Patients in the control group received site-specific usual care, consisting of external cardiac monitoring such as 12-lead ECGs, Holter monitoring, telemetry, or event recorders. Incidence rates of AF and recurrent stroke will be compared over a three-year study duration. The study is led by co-principal investigators, Dr. Bernstein and Dr. Schwamm.

"Medtronic has been an innovative leader in ICM technology for 20 years and has made significant contributions to understanding the clinical utility of using ICMs in the cryptogenic stroke population, including publication of the CRYSTAL-AF Study in 2014. Now with the STROKE AF study, we are able to deepen our understanding in this additional patient population," said Rob Kowal, M.D., Ph.D., chief medical officer of the Cardiovascular Diagnostics and Services business, which is part of the Cardiovascular Portfolio at Medtronic. "We believe that prolonged cardiac monitoring with the Reveal LINQ ICM can assist clinicians as they seek to prevent secondary strokes among their patients who have suffered an initial ischemic stroke. Findings from the STROKE AF study clearly validate the benefits of long-term monitoring for this high-risk population and have the potential to be practice-changing."

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 of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

About Medtronic

Medtronic plc (www.medtronic.com), 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 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 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.

[1] Virani SS, Alonso A, Benjamin EJ, Bittencourt MS,Callaway CW, Carson AP, et al. Heart disease and stroke statistics—2020 update: a report from the American Heart Associationexternal icon. *Circulation.* 2020;141(9):e139–e596.

[2] A total of 496 patients were enrolled in the study and 492 were randomized

[3] Based on data through 12 months

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