Medtronic News

Continuous Rhythm Monitoring Reveals Strong Short-Term Risk Association Between Atrial Fibrilation Episodes and Ischemic Stroke

Study Published in JAMA Cardiology Demonstrates a Three-Fold Increased Risk of Ischemic Stroke Within 30 Days of a Multi-Hour AF Event

DUBLIN, Oct. 4, 2021 /PRNewswire/ -- Medtronic plc (NYSE: MDT), the global leader in medical technology, today announced the publication of a study demonstrating, through the use of a Medtronic continuous rhythm monitoring device, that atrial fibrillation (AF) is directly and transiently associated with ischemic stroke. The findings were published online on September 29 in *JAMA Cardiology*.

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, increasing risk of stroke 5-fold compared with those patients who do not have AF.[2]

This retrospective case-crossover study leveraged data from 466,635 patients included in both the Optum deidentified electronic health record (EHR) and the Medtronic CareLink™ network databases. Of those, a total of 891 patients with Medtronic cardiovascular implantable electronic devices (CIEDs) capable of continuous rhythm monitoring sustained both an ischemic stroke and received 120 days of continuous monitoring prior to their stroke. A threshold of AF exposure was defined as AF lasting 5.5 hours or more on any given day. Patients were evaluated during a case period that included days 1 to 30 prior to the index stroke and a control period that included days 91 to 120 prior to the event. It was found that 76.5% (682/891) subjects had no AF meeting the threshold in either 30-day period, 16% (143/891) had at least one day with 5.5 hours or more of AF in both periods, and 7.4% (66/891) had informative, discordant rhythm patterns (defined as those that had AF exceeding 5.5 hours in only one period). Key findings were as follows:

- Among patients with CIEDs with informative, discordant rhythm patterns, having AF of 5.5 hours or more raised the 30-day risk of ischemic stroke more than three-fold.
- Stroke risk was highest within five days of a 5.5 hour or more episode of AF and diminished rapidly thereafter.
- A temporal association between AF and stroke was not seen in patients who had been prescribed oral anticoagulants (OACs).

"Overall, these findings significantly underscore traditional thinking that AF is likely a causal risk factor for ischemic stroke as opposed to just a risk marker," said Daniel Singer, M.D., professor of medicine atHarvard Medical School, professor in the Department of Epidemiology at the Harvard T.H. Chan School of Public Health, and Division of General Internal Medicine at Massachusetts General Hospital. "The results indicate that prolonged episodes of AF increase stroke risk, but this risk decreases rapidly following the end of the episode. These findings raise the possibility that time-limited anticoagulation for infrequent episodes of AF may be an effective stroke prevention strategy."

In this study, subjects evaluated had Medtronic CIEDs capable of continuous heart rhythm monitoring via the Medtronic CareLink™ network, including 114 patients with Medtronic insertable cardiac monitors (ICMs) and 777 with various Medtronic transvenous devices with atrial leads, including implantable cardioverter defibrillators (ICDs), cardiac resynchronization therapy (CRT) devices, and pacemakers.

"As of late, there has been significant discussion surrounding the temporal relationship of AF episodes to stroke, as well as the use of continuous cardiac monitoring, specifically with ICMs, to detect clinically meaningful AF episodes that may lead to a stroke," 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. "This evidence highlights that patients are at highest risk for a stroke within five days of an AF episode that lasts five and a half hours or more. In addition to supporting the use of OACs in this patient

population, this study also suggests the value of long-term cardiac monitoring to accurately detect these critical AF episodes."

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.

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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 Wolf PA, Abbott RD, Kannel WB. Atrial fibrillation as an independent risk factor for stroke: the Framingham Study. Stroke. 1991;22:983-988.

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