New trial studies link between stroke and atrial fibrillation

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One evening last March, Larry Ambrose left his bed in the middle of the night to check the time. Much to the 71-year-old's surprise, he was only able to see three out of the four glowing numbers on the digital clock in his kitchen. Ambrose returned to bed, but within days was hospitalized for what was later diagnosed as a stroke. After extensive testing, his physicians told him they could not determine the cause.

Cryptogenic stroke, or stroke of undetermined cause, accounts for 25 percent of all strokes. In many of these cases, physicians believe atrial fibrillation may occur without the patient's knowledge, causing the stroke. To better understand the connection between atrial fibrillation and stroke, Northwestern Medicine physician researchers from cardiology and neurology have teamed up to monitor people diagnosed with a cryptogenic strokes for intermittent atrial fibrillation as part of a study called CRYSTAL AF (Study of Continuous Cardiac Monitoring to Assess Atrial Fibrillation after Cryptogenic Stroke).

During atrial fibrillation, the most common type of arrhythmia (abnormal heart beat), the heart's upper chambers, or atria, quiver rather than beat; this allows blood to stay in the chamber and potentially cause a clot. If the clot travels from the heart and reaches the brain, a stroke is imminent. "Patients with atrial fibrillation are at a greater risk for stroke than the general population," said Rod Passman, MD, medical director for the Center for Atrial Fibrillation at the Bluhm Cardiovascular Institute of Northwestern Memorial Hospital and associate professor of cardiology at Northwestern University's Feinberg School of Medicine. "Fifteen percent of all strokes are in patients with atrial fibrillation."

The CRYSTAL AF trial will enroll approximately 450 people who have been diagnosed with a cryptogenic stroke across 55 centers. Approximately half will be continuously monitored by an FDA-approved implanted cardiac monitor. The device will monitor for the first documented event of atrial fibrillation following enrollment in the trial. Co-investigators Passman and Richard Bernstein, MD, a neurologist at the Certified Primary Stroke Center at Northwestern Memorial and associate professor of neurology at Feinberg School of Medicine, are on the international steering committee for the CRYSTAL AF trial sponsored by Medtronic Cardiac Rhythm Disease Management.

"Screening for atrial fibrillation is routinely performed for a short period after a stroke as part of the evaluation for possible causes," said Bernstein. "The participants who are enrolled in CRYSTAL AF and implanted with the device will essentially have an electrocardiogram (ECG) in their chest 24/7. This device has the ability to determine if and when atrial fibrillation occurs; allowing physicians like Dr. Passman and me to better determine the optimal course of treatment and potentially prevent future strokes."

To date, Northwestern Medicine researchers have enrolled 11 subjects in the trial, with four being implanted with the cardiac monitor. The continuous monitoring device captures and automatically stores any abnormal ECG activity. Passman and his team then review and analyze remotely-transmitted data. They can look at individually stored ECG episodes or longer-term trended diagnostic data, including atrial fibrillation burden, activity levels and average day/night heart rates. After the participants have been implanted, they are followed at one month and every six months thereafter for three years. The control group receives standard of care optimal medical treatment and follows up at the same intervals.

"The device is placed just under the skin in the chest area during a short outpatient procedure," said Passman. "It's very small, about the size of a computer jump drive, and can provide up to three

years of continuous heart rhythm monitoring and the device is compatible for use in an MRI environment."

Ambrose, a Chicago resident, was identified by Bernstein as a cryptogenic stroke patient and ultimately became the first subject implanted by Passman with the cardiac monitoring device at Northwestern Memorial. Each day, he uses a handheld Patient Assist Device to monitor if the implanted monitor has recorded any abnormalities. "I hold it against the chest where the implant is; a beep goes off and it says 'okay,'" explained Ambrose. "If anything else comes up, then another instrument reports the results over the phone, or I can call the doctor."

While atrial fibrillation has not been detected since Ambrose was implanted, he finds comfort from the device. "Any kind of evidence to where the stroke was coming from was good to me," Ambrose said. "Every day it beeps okay, so it's a confirmation. It keeps me in the eyes of the doctors, and keeps them checking and investigating."

When atrial fibrillation is detected in a patient following stroke, anticoagulant therapy is recommended for secondary stroke prevention. While anticoagulant therapy can be successful in preventing future stroke, physicians do not use it proactively unless atrial fibrillation has been detected because of potential risk from the medication and complexity of the treatment.

"If we can monitor more cryptogenic stroke patients for atrial fibrillation beyond the standard timeframe, we may have the opportunity to uncover the cause of more strokes," said Bernstein. "This has the potential to expand proactive stroke prevention to more patients and avert secondary events."

Provided by Northwestern Memorial Hospital