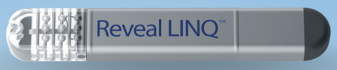


STROKE AF

Atrial Fibrillation in Non-Cardioembolic Stroke of Presumed Known Origin[1]

As published in *JAMA*, June 2021

PRIMARY OBJECTIVE

To determine whether long-term cardiac monitoring is superior to usual care for AF detection in patients with stroke attributed to large or small vessel disease through 12 months of follow-up.

STUDY OVERVIEW

- Prospective, multisite, randomized, clinical trial enrolling 496 patients at 33 centers in the United States
- Randomization 1:1 to continuous monitoring arm with Reveal LINQ ICM or control arm following site-specific usual care for detection of cardiac arrhythmias
- Follow-up: minimum 12 months, maximum 36 months

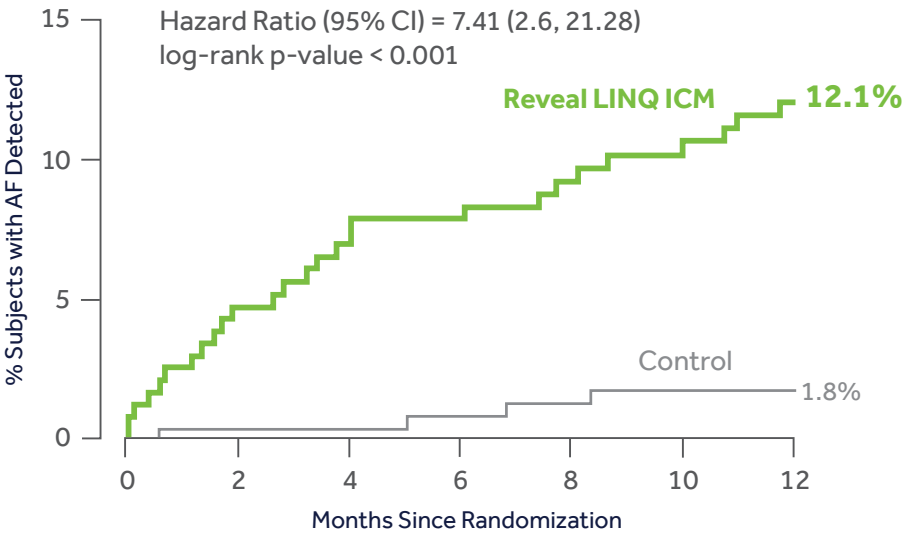
See back side for definitions, and inclusion and exclusion criteria.

RESULTS

Reveal LINQ™ insertable cardiac monitor (ICM) is superior to usual care for AF detection in large and small vessel stroke patients.

- 12.1% (n = 27) in the Reveal LINQ ICM arm versus 1.8% (n = 4) in the control group
- Among ICM patients, there was no significant difference in AF detection in subjects with large versus small vessel stroke (11.7%, n = 15, versus 12.6%, n = 12)

Detection of AF at 12 Months



Large and small vessel stroke patients are at high risk of having asymptomatic AF.

- At 12 months, 96.3% (n = 27) of first AF episodes were asymptomatic in the ICM arm
- The majority of patients (55.5%, n = 27) with AF detected in the ICM arm had an episode lasting greater than one hour

30 days of cardiac monitoring is insufficient to capture the vast majority of AF.

- Median time to detection of AF was 99 days in the ICM arm
- At 12 months, 78% (n = 27) of patients would have been missed if only monitored for 30 days

CONCLUSION

Among patients with stroke attributed to large or small vessel disease, monitoring with an ICM compared with usual care detected significantly more AF over 12 months.

Medtronic

Definitions:

AF: episode of irregular heart rhythm, without detectable P waves, lasting more than 30 seconds, adjudicated by a Clinical Events Committee (CEC); ICM only capable of detecting episodes lasting at least two minutes in duration

Recurrent stroke: any ischemic event with rapid onset of a focal or global neurological deficit or other neurological signs/symptoms consistent with stroke; all strokes were determined by the stroke centers and confirmed by the CEC

Usual care: 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.

Inclusion Criteria

- Patients with an ischemic stroke attributed by the local investigator using standard diagnostic workup to small vessel occlusion, or large artery (cervical or intracranial) atherosclerosis within the past 10 days
- Age ≥ 60 years, or 50–59 years with at least one additional risk factor for stroke: congestive heart failure, hypertension, diabetes, prior stroke (within 90 days of index stroke), or vascular disease (prior MI, peripheral artery disease, or aortic plaque)

Exclusion Criteria

- Previous cryptogenic or cardioembolic stroke
- Prior history of AF or atrial flutter
- Permanent indication or contraindication for OAC therapy
- Pacemaker, ICD, CRT, or implantable hemodynamic monitor

Reference

[1] Bernstein RA, Kamel H, Granger CB, et al; for the STROKE AF Investigators. Effect of Long-term Continuous Cardiac Monitoring vs Usual Care on Detection of Atrial Fibrillation in Patients With Stroke Attributed to Large- or Small-Vessel Disease. JAMA. Published online June 1, 2021. doi:10.1001/jama.2021.6470

Brief Statement
Reveal LINQ™ Insertable Cardiac Monitor

Indications: The Reveal LINQ Insertable Cardiac Monitor (ICM) is an implantable patient-activated and automatically activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia

The device has not been tested specifically for pediatric use.

Contraindications: There are no known contraindications for the implant of the Reveal LINQ ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

Warnings/Precautions: Patients with the Reveal LINQ ICM should avoid sources of diathermy, high sources of radiation, electrosurgical cautery, external defibrillation, lithotripsy, therapeutic ultrasound, and radiofrequency ablation to avoid electrical reset of the device and/or inappropriate sensing as described in the medical procedure and EMI precautions manual. MRI scans should be performed only in a specified MR environment under specified conditions as described in the Reveal LINQ MRI Technical Manual.

Potential Complications: Potential complications of the Reveal LINQ device include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

See the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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