Medtronic

STROKE AF study

Atrial fibrillation in non-cardioembolic stroke of presumed known origin[1,2]

Primary objective

Compare incidence rates of atrial fibrillation (AF) through 12 months

Secondary objective

Compare incidence rates of AF through 36 months

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 AF in patients with prior ischemic stroke attributed to large-artery atherosclerotic disease (LAD) or small-vessel occlusive disease (SVD)
- Follow-up: minimum 12 months, maximum 36 months

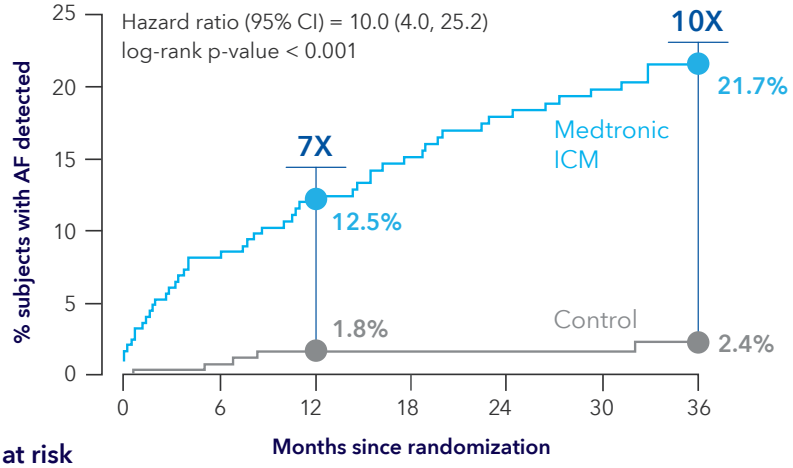
See back side for definitions, and inclusion and exclusion criteria

Results

Reveal LINQ ICM is superior to usual care for AF detection in large- and small-vessel stroke patients.

- Over a seven-fold increase with ICM at 12 months (12.5% in the ICM arm versus 1.8%)
- Ten-fold increase with ICM at 36 months (21.7% in the ICM arm versus 2.4%)

Detection of AF at 36 months



 # at risk

Control	250	225	203	186	170	163	82
ICM	242	204	186	171	160	149	91

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

- At three years, 88% of AF episodes were asymptomatic in the ICM arm.
- The majority of patients (67.4%, n = 31) with AF detected in the ICM arm had an episode lasting greater than one hour.
- Most of the patients who had at least six minutes of AF burden (66%, n = 28), had AF burden progression. The median (IQR) increase in AF burden from first to longest instance was 9.8 (4.0–15.3) hours.
- Body mass index, congestive heart failure, left-atrial enlargement, and QRS duration were independently associated with an increased likelihood of AF detection during three years of monitoring.

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

- Median time to detection of AF in the ICM arm was 99 days at 12 months and 284 days at 36 months.
- At three years, 87% (n = 40) of patients with AF would have been missed if only monitored for 30 days.

Conclusion

Patients with ischemic stroke attributed to LAD or SVD face an increasing risk of AF over time, and most of the AF occurrences are not reliably detected by standard medical monitoring methods.

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 ten 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

References

[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*. June 1, 2021;325(21):2169-2177.

[2] Bernstein RA et al. Atrial Fibrillation In Patients With Stroke Attributed to Large- or Small-Vessel Disease: 3-Year Results From the STROKE AF Randomized Clinical Trial. *JAMA Neurol*. October 30, 2023:e233931.

Brief statement
Important Safety Information for LINQ Family of Insertable Cardiac Monitors (ICMs) Systems and Accessories

The Reveal LINQ™ ICM is an insertable automatically-activated and patient-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

This device has not been tested specifically for pediatric use.

The LINQ II™ ICM is an insertable automatically-activated and patient-activated monitoring system that records subcutaneous ECG and is indicated in adult patients, and in pediatric patients who are at least 2 years old, 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

Contraindications
There are no known contraindications for the insertion of a LINQ Family ICM or their accessories. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically inserted device can be tolerated.

Warnings and Precautions
Patients with a LINQ Family 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 Warnings, Precautions and Guidance Manual. MRI scans should be performed only in a specified MR environment under specified conditions as described in the Reveal LINQ ICM or LINQ II ICM MRI Technical Manual.

Accessories available for use with the LINQ Family of ICMs may experience connectivity or performance issues. See product manuals for details and troubleshooting instructions.

Potential Adverse Events or Potential Complications
Potential adverse events from the LINQ Family of ICMs include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

There are no known adverse events associated with the use of any LINQ Family of ICMs accessories.

See the device manuals for detailed information regarding the implant procedure, indications / intended use, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at (800) 328-2518 (Technical Services), (800) 551-5544 (Patient Services), and/or consult Medtronic's website at www.medtronic.com.

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

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