CRYPTOGENIC STROKE AND UNDERLYING ATRIAL FIBRILLATION (CRYSTAL AF)[1]

Objectives:

- To assess whether a long-term cardiac monitoring strategy with an insertable cardiac monitor (ICM) is superior to standard monitoring for the detection of atrial fibrillation (AF) in patients with cryptogenic stroke at 6 months (primary end point) and 12 months follow-up (secondary end point).
- Determine actions taken after patient is diagnosed with AF.

Methods:

- 1:1 randomized trial comparing the yield of AF detection through continuous monitoring with an ICM versus standard medical care in cryptogenic stroke or transient ischemic attack (TIA) patients. 441 patients were enrolled.
- AF was defined in this study as an episode of irregular heart rhythm, without detectable P waves, of at least 30 seconds duration. AF episodes that qualified for analysis were adjudicated by an independent committee.

1 Patient Inclusion Criteria

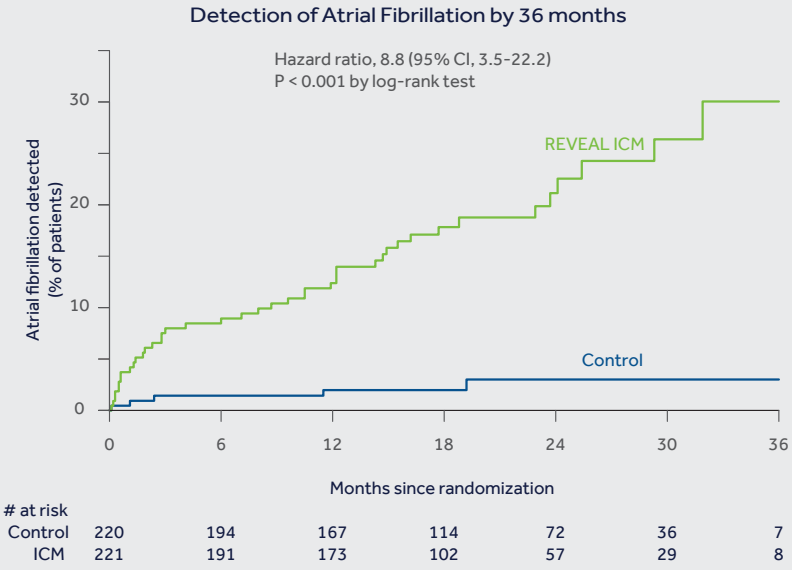
- ≥ 40 years of age
- Cryptogenic stroke (or clinical TIA), with infarct seen on MRI or CT, within the previous 90 days; and no mechanism (including AF) determined after:
  - 12-lead ECG
  - 24-hour ECG monitoring (e.g., Holter)
  - Transesophageal echocardiography (TEE)
  - CTA or MRA of head and neck to rule out arterial source
  - Screening for hypercoagulable states in patients < 55 years old

2 Patient Exclusion Criteria

- History of AF or atrial flutter
- Permanent indication or contraindication for anticoagulation
- Indication for pacemaker or ICD

Results:

- Reveal™ ICM is superior to standard medical care for the detection of AF in patients with a cryptogenic stroke
  - 6.4 times more patients found to have AF over 6 months using ICM
- At 3 years, AF was detected at a rate of 30% in the ICM arm versus 3% in the standard follow-up arm
- 30-day monitoring would not be sufficient in this patient population
  - Median time to AF detection was 84 days over 12 months of follow-up
- Patients had sustained periods of AF and physicians took action
  - 92% of patients in the ICM arm had a longest daily burden of AF of > 6 minutes
  - Vast majority of patients (97%) who had AF detected were prescribed OAC



Conclusion:

"In conclusion, our study showed that atrial fibrillation was more frequently detected with an ICM than with conventional follow-up in patients with a recent cryptogenic stroke. Atrial fibrillation after cryptogenic stroke was most often asymptomatic and paroxysmal and thus unlikely to be detected by strategies based on symptom-driven monitoring or intermittent short-term recordings."

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Reference

[1] Sanna T, Diener HC, Passman RS, et al. Cryptogenic Stroke and Underlying Atrial Fibrillation (CRYSTAL AF). *N Engl J Med*. June 26, 2014;370(26):2478-2486.

Reveal LINQ™ Insertable Cardiac Monitor and Patient Assistant

The Reveal LINQ insertable cardiac monitor 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. This device has not specifically been tested for pediatric use. **Patient Assistant:** The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates the data management feature in the Reveal™ insertable cardiac monitor to initiate recording of cardiac event data in the implanted device memory. **Contraindications:** There are no known contraindications for the implant of the Reveal LINQ insertable cardiac monitor. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated. **Warnings/Precautions: Reveal LINQ Insertable Cardiac Monitor:** Patients with the Reveal LINQ insertable cardiac monitor 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. **Patient Assistant:** Operation of the Patient Assistant near sources of electromagnetic interference, such as cellular phones, computer monitors, etc., may adversely affect the performance of this device. **Potential Complications:** Potential complications include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

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

See the device manual 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.

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