

Cryptogenic Stroke and Underlying Atrial Fibrillation (CRYSTAL AF)

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.

In CS patients
AF was detected at a rate of

30%

in the ICM arm vs. 3% in the
standard follow up arm

84 days

median time to AF
detection in CS
patients

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 AF in patients with cryptogenic stroke at 6 months (primary endpoint) and 12 months follow-up (secondary endpoint)
- Determine actions taken after patients diagnosed with AF

Methods:

- 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

Patient Inclusion Criteria:

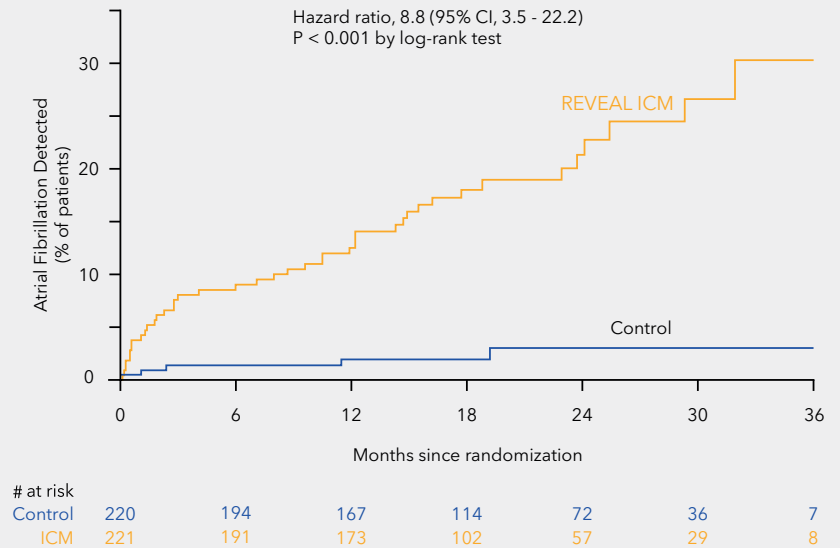
- ≥ 40 years of age
- Cryptogenic stroke (or clinical TIA), with infarct seen on MRI or CT, within the previous 90 days; and no mechanism (including AF) determined after:
 - 12-lead ECG
 - 24-hour ECG monitoring (e.g., Holter)
 - Transesophageal echocardiography (TEE)
 - CTA or MRA of head and neck to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

Patient Exclusion Criteria:

- History of AF or Atrial Flutter
- Permanent indication or contraindication for anticoagulation
- Indication for pacemaker or ICD

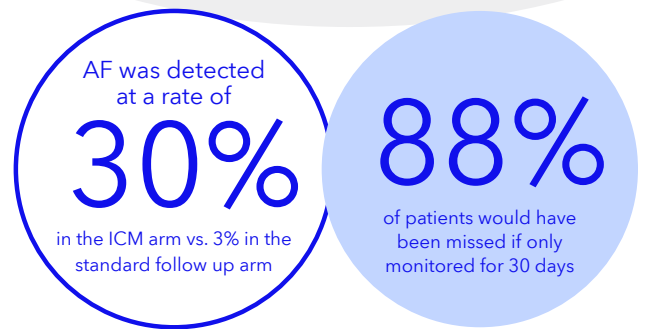


Atrial Fibrillation detection in Cryptogenic Stroke patients by 36 months



Results:

- Reveal® LINQ 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 vs. 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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Brief statement

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events..

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