REAL-WORLD EVIDENCE

FEATURED STUDY: INSERTABLE CARDIAC MONITORING RESULTS IN HIGHER RATES OF ATRIAL FIBRILLATION DIAGNOSIS AND ORAL ANTICOAGULATION PRESCRIPTION AFTER ISCHAEMIC STROKE

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Our featured real-world evidence data comes from a nationwide study of U.S. Medicare beneficiaries with cryptogenic stroke who received an insertable cardiac monitor (ICM) or external cardiac monitor (ECM) after ischaemic stroke.

The results demonstrate long-term cardiac monitoring through an ICM device yielded more frequent and timely AF detection rates and oral anticoagulant (OAC) prescriptions compared to short-term ECM devices. Patients with ICMs were almost 3 times more likely to be diagnosed with AF and to be prescribed an OAC compared to patients who only received an ECM.

CLINICAL IMPACT

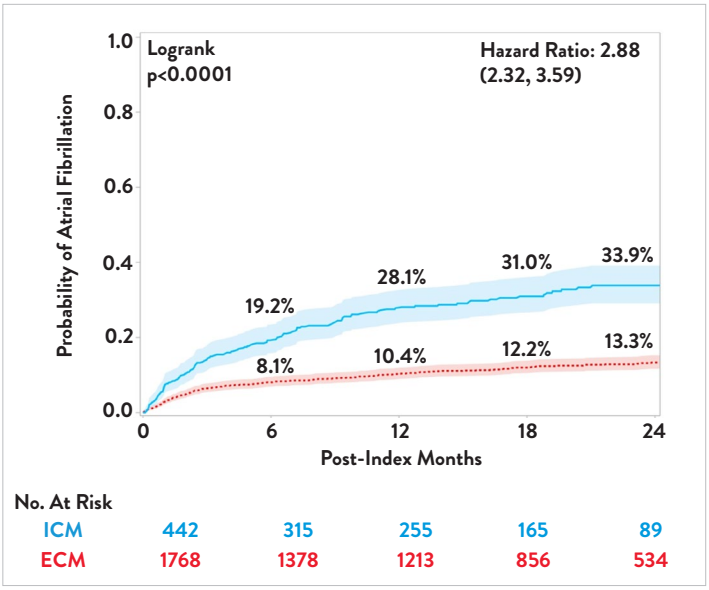
Oral Anticoagulant Use by Cardiac Monitoring Method

FOLLOW-UP (MONTHS)	ICM% (95% CI)	ECM% (95% CI)
6	13.6 (10.5-17.5)	11.2 (9.7-12.9)
12	30.9 (25.7-36.8)	14.7 (12.9-16.8)
18	35.9 (30.1-42.4)	16.8 (14.7-19.2)

- ICM patients had significantly higher probability of OAC initiation (HR 2.91, 95% CI [2.28, 3.72]) compared to ECM alone.
- **~3X more** ICM patients were **protected** with an OAC at 1.5 years compared to ECM patients.

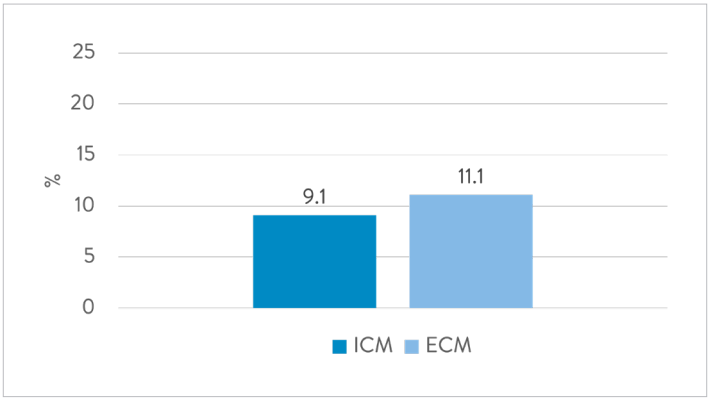
MAIN RESULT

New AF Diagnosis in ICM vs ECM Patients



2-year AF incident rates estimated using the Kaplan Meier method. Hazard ratios (HR) estimated by cox proportional hazard models are also shown.

MORTALITY AT 2 YEARS†



ICM patients demonstrated less mortality compared to ECM patients at 2 years, indicating potential survival benefit of the ICM through more frequent and timely AF diagnosis and OAC adoption. There were 197 (11.1%) ECM patients and 40 (9.1%) ICM patients who died during study follow-up.

STUDY BACKGROUND

The impact of monitoring strategies for AF detection in cryptogenic stroke patients has mostly been evaluated in randomized control trials (RCTs), with important differences compared to real-world populations and practice. This RWE study confirms the findings of a few prior RWE studies and adds evidence for the AF detection capabilities of ICMs in an older, sicker patient population with cryptogenic stroke.

PATIENT CHARACTERISTICS

The matched cohort consisted of 2,210 Medicare beneficiaries (ICM, n=442; ECM, n=1,768):

- 53% female
- Mean age 75±9 years
- CHA_2DS_2-VASc score 4.6±1.6
- Stroke hospitalization length of stay 3.5±3.0 days

PATIENT INCLUSION CRITERIA

- Received an ECM (Holter monitor, outpatient cardiac telemetry, memory loop event monitor) or Confirm Rx ICM during November 15, 2017-December 31, 2019.
- Hospitalized with an ischemic stroke in prior 3 months.
- Minimum 1-year Medicare enrollment.
- No history of atrial tachyarrhythmias, cardiac implantable devices, or OAC prescriptions.

STUDY DESIGN

- Retrospective observational study using Medicare and Abbott Laboratories device registration data.
- Compared AF detection and OAC rates between ICM (Confirm Rx™ ICM) and ECM in a real-world population with cryptogenic stroke.

END POINTS

- Primary: AF detection defined by at least one inpatient or two hospital outpatient visits or physician claims with AF diagnosis codes in the first or second positions on the claim.
- Secondary: OAC prescription fill.

STATISTICAL ANALYSIS

- Propensity score matched ICM and ECM 1:4 on baseline characteristics.
- AF evaluated at 2 years and OAC at 1.5 years using the Kaplan Meier (KM) method.
- Multivariable Cox regression, clustered by stroke hospitalization.

KEY FINDINGS

- **Significant ~3X higher rate** of AF detection with ICM compared to ECM.
- ICM patients are **diagnosed faster** with AF compared to ECM patients.

READ THE ABSTRACT ON EP EUROPACE HERE.

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Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: An Abbott ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias. It is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation. Abbott ICMs have not been specifically tested for pediatric use.

Intended Use: Abbott ICMs are intended to help physicians monitor, diagnose and document the rhythm in patients who are susceptible to cardiac arrhythmias and unexplained symptoms, as indicated.

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

Adverse Events: Possible adverse events (in alphabetical order) associated with the device, include the following: Allergic reaction, Bleeding, Chronic nerve damage, Erosion, Excessive fibrotic tissue growth, Extrusion, Formation of hematomas or cysts, Infection, Keloid formation and Migration. Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

An Abbott mobile transmitter is available for patients without their own compatible mobile device.

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