Medtronic

PER DIEM study

Effect of implantable versus prolonged external electrocardiographic monitoring on atrial fibrillation detection in patients with ischemic stroke[1]

Study objective

To determine, in patients with a recent ischemic stroke, whether 12 months of insertable cardiac monitoring detects more occurrences of atrial fibrillation (AF) compared with conventional external loop recorder monitoring for 30 days

Study overview

- Prospective, randomized controlled trial (RCT) at three centers in Alberta, Canada
- 300 patients
- 1:1 randomization to ICM (Reveal LINQ ICM) or an external loop recorder (SpiderFlash-T)
- Follow-up visits at 30 days, 6 months, and 12 months
- Patients rated device satisfaction at 12 months

Participant characteristics

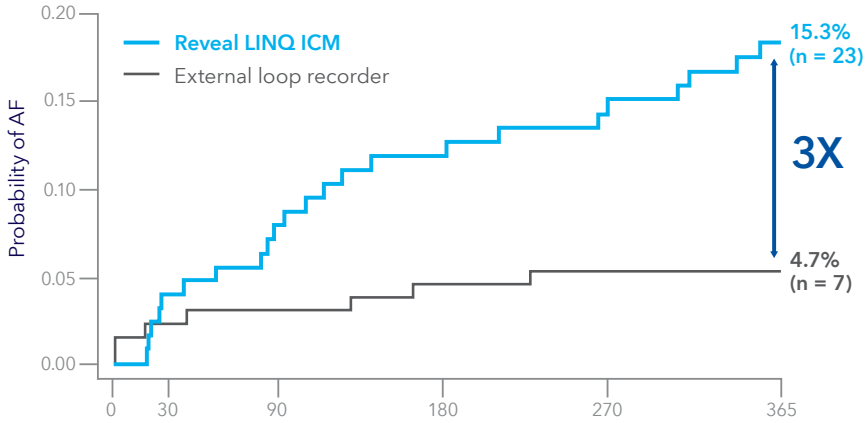
- Median patient age was 64.1 years (interquartile range, 56.1–73.7 years)
- Median CHA_2DS_2-VASC score was 4 (interquartile range, 3–5)
- Diagnosis of an acute ischemic stroke or TIA and no prior evidence of AF

See back for key inclusion and exclusion criteria

Conclusion

Among patients with ischemic stroke and no prior evidence of AF, insertable cardiac monitoring, compared with external monitoring for 30 days, resulted in a significantly greater proportion of patients with AF detected over 12 months.

New AF or flutter lasting two minutes or longer



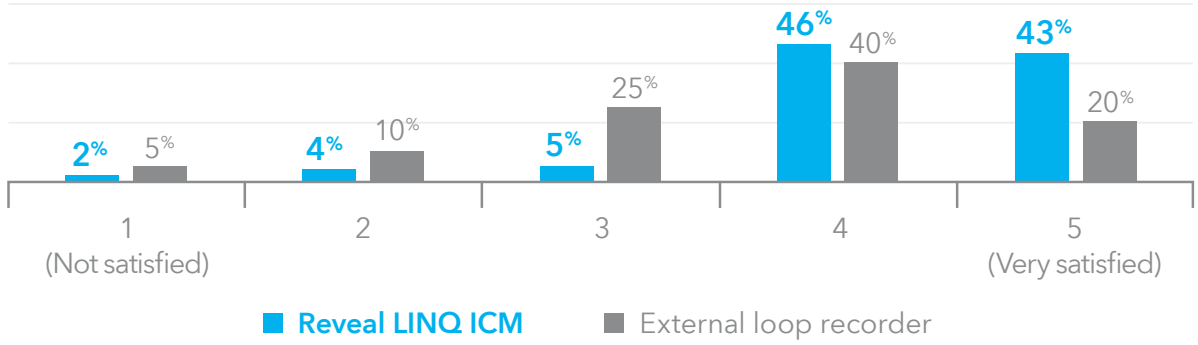
3X **Reveal LINQ ICM finds 3x more AF**
15.3% AF detected in ICM arm (n = 23) versus 4.7% in 30-day external loop recorder arm (n = 7)

70% **30 days of monitoring is not enough**
70% of patients with AF in the ICM arm (16/23) were detected beyond 30 days

100% **Find AF, treat AF, and reduce stroke**
All study patients with a "definite AF/high probability" diagnosis were started on oral anticoagulant; numerically fewer recurrent strokes in the ICM arm (although this was not statistically significant; 3.3% [n = 5] versus 5.3% [n = 8])

Patients are more satisfied with Reveal LINQ ICM than 30-day external loop recorder

More than twice as many patients reported being very satisfied with Reveal LINQ™ ICM versus the 30-day external loop recorder (43%, n = 54 in ICM arm versus 20%, n = 26 in external loop recorder arm)



Key inclusion criteria:

- Age > 18 years
- Diagnosis of an acute ischemic stroke or TIA
- All mechanisms (except AF)
- Within 180 days from index event

Exclusion criteria:

- Any previously documented AF
- Any pre-existing condition with indication for anticoagulation, pacemaker, or ICD
- Carotid disease with planned CEA/stenting (post-procedure allowed)

PER DIEM was supported by Alberta Innovates Health Solutions Collaborative Research and Innovations Opportunities and by a grant from the Partnership for Research and Innovation in the Health System, government of Alberta. Unrestricted in-kind support (insertable cardiac monitor devices and the electrocardiographic core laboratory) was provided by Medtronic Canada.

Reference

[1] Buck BH, Hill MD, Quinn FR, et al. Effect of Implantable vs Prolonged External Electrocardiographic Monitoring on Atrial Fibrillation Detection in Patients With Ischemic Stroke: The PER DIEM Randomized Clinical Trial. *JAMA*. June 1, 2021;325(21):2160–2168.

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.

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000

medtronic.com

UC202205442a EN ©2022 Medtronic.
Minneapolis, MN. All Rights Reserved.
Printed in USA. 03/2022

Medtronic