

META-ANALYSIS SUMMARY PROLONGED CARDIAC RHYTHM MONITORING AND SECONDARY STROKE PREVENTION

In Patients with Cryptogenic
Cerebral Ischemia¹



As published in *Stroke*, June 2019¹

OBJECTIVE:

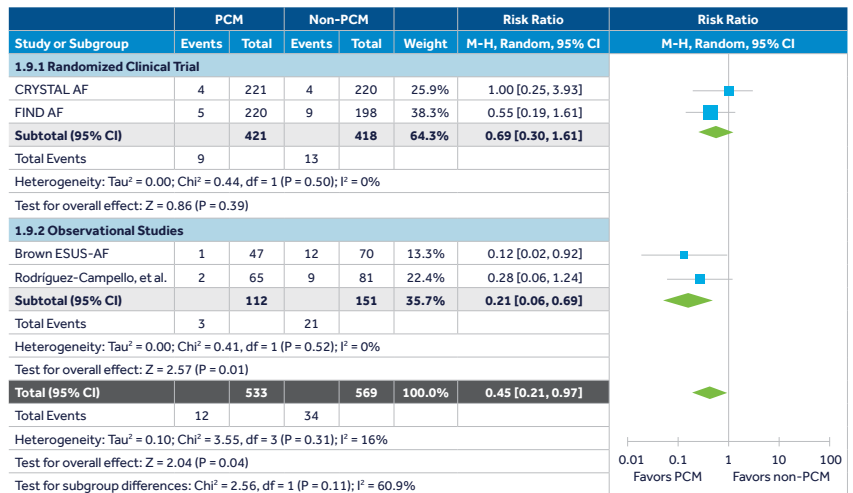
Evaluate the impact of prolonged cardiac rhythm monitoring (PCM) on secondary stroke prevention using data from available to date randomized clinical trials (RCTs) and observational studies.

RESULTS:

Patients who underwent PCM compared to conventional cardiac monitoring show:

- **2.5x increased incidence of AF detection**
(n = 1,102, RR = 2.46, 95% CI: 1.61-3.76, and P < 0.0001)
- **2.1x increased incidence of anticoagulant initiation**
(n = 956, RR = 2.07, 95% CI: 1.36-3.17, and P = 0.0008)
- **55% decreased risk of recurrent stroke**
(n = 1,102, RR = 0.45, 95% CI: 0.21-0.97, and P = 0.04)

Forest plot presenting the differences between prolonged and conventional (non-prolonged) cardiac rhythm monitoring in the risk of recurrent stroke, stratified by the study type.



CONCLUSION:

The use of prolonged cardiac monitoring has a potential impact on secondary stroke prevention, as patients with cryptogenic IS (ischemic stroke)/TIA undergoing PCM had higher rates of AF detection, anticoagulant initiation, and lower stroke recurrence.

Stroke Definition

The definition of the index events in available studies included cryptogenic stroke (CS) defined according to Trial of Org 10172 in Acute Stroke Treatment (TOAST) criteria in two studies,^{2,3} embolic strokes of undetermined source (ESUS) in one study⁴ and select IS patients (with no history of AF and no significant extracranial or intracranial arterial stenosis) in one study.⁵

Method

A comprehensive literature search of MEDLINE, SCOPUS, CENTRAL, and conference proceedings was conducted to identify studies reporting stroke recurrence rates in patients with a history of cryptogenic stroke or TIA receiving PCM as compared to patients receiving conventional (non-PCM) cardiac monitoring. Literature search was performed on October 14, 2018.

Identified Records: 885

Studies reporting stroke recurrence rates in patients with history of cryptogenic IS or transient ischemic attack (TIA) receiving PCM compared to patients receiving conventional (non-PCM). This includes:

- Randomized clinical trials (RCTs)
- Prospective/retrospective cohort studies
- Case-control studies

Records Excluded: 881

- Duplicates, case reports, and case series
- Studies not reporting stroke recurrence rates during follow-up or not providing data for the reference group receiving non-PCM
- Studies providing data on AF detection rates and/or change in management (anticoagulant initiation) according to PCM results without providing data on stroke recurrence
- Studies not including IS/TIA population, control group, or report on IS/TIA recurrence

Records Included: 4

The meta-analysis included 2 RCTs and 2 observational studies, for a total of 1,102 patients (mean age: 68 years, 41% women).²⁻⁵

- Brown ESUS-AF⁴
- CRYSTAL AF²
- FIND-AF⁵
- Rodriguez-Campello, et al.³

Study Limitations

- This analysis provides preliminary evidence for a potential impact of PCM on secondary stroke prevention.
- The data used is based on two RCTs and two observational studies.
- Prolonged cardiac monitoring consisted of insertable cardiac monitors (ICMs) in three of the studies (n = 704) and repeated Holter monitoring (n = 398) in one study (three periods of 10 days). As such, the results don't exclusively pertain to ICMs, although patients with ICMs made up the majority of the cohort.

References

- ¹ Tsigvoulis G, Katsanos AH, Grory BM, et al. Prolonged Cardiac Rhythm Monitoring and Secondary Stroke Prevention in Patients With Cryptogenic Cerebral Ischemia. *Stroke*. Published online June 20, 2019.
- ² Sanna T, Diener HC, Passman RS, et al. Cryptogenic stroke and underlying atrial fibrillation. *N Engl J Med*. June 26, 2014;370(26):2478-2486.
- ³ Rodríguez-Campello A, et al. *Eur Stroke J*. 2018;3:459. Available at: <https://www.morressier.com/article/atrial-fibrillation-detection-stroke-recurrence-patients-early-insertable-cardiac-monitor-casecontrol-study/5ab8f55cd462b8029238c875>. Accessed June 11, 2019.
- ⁴ Ricci B, Chang AD, Hemendinger M, et al. A Simple Score That Predicts Paroxysmal Atrial Fibrillation on Outpatient Cardiac Monitoring after Embolic Stroke of Unknown Source. *J Stroke Cerebrovasc Dis*. June 2018;27(6):1692-1696.
- ⁵ Wachter R, Gröschel K, Gelbrich G, et al. Holter-electrogram-monitoring in patients with acute ischaemic stroke (Find-AFRANDOMISED): an open-label randomised controlled trial. *Lancet Neurol*. April 2017;16(4):282-290.

Brief Statement

Indications

Reveal LINQ™ LNQ11 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 LNQ11 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.

Medtronic MyCareLink™ Patient Monitor, Medtronic CareLink™ Network, and CareLink™ Mobile Application

Intended Use

The Medtronic MyCareLink patient monitor and CareLink network are indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices based on physician instructions and as described in the product manual. The CareLink mobile application is intended to provide current CareLink network customers access to CareLink network data via a mobile device for their convenience. The CareLink mobile application is not replacing the full workstation, but can be used to review patient data when a physician does not have access to a workstation. These products are not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician. CareLink network availability and mobile device accessibility may be unavailable at times due to maintenance or updates, or due to coverage being unavailable in your area. Mobile device access to the Internet is required and subject to coverage availability. Standard text message rates apply.

Contraindications

There are no known contraindications.

Warnings and Precautions

The MyCareLink patient monitor must only be used for interrogating compatible Medtronic implantable devices.

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.

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

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