

Safety and efficiency of a common and simplified protocol for pacemaker and defibrillator surveillance based on remote monitoring only: a long-term randomized trial (RM-ALONE)

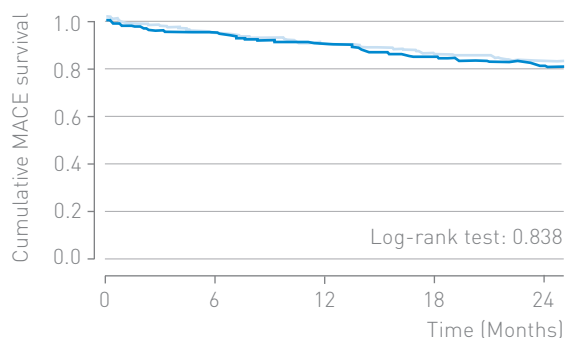
GARCIA FJ ET AL.,
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Study Design

- Prospective, randomized, multicenter clinical trial
- 445 pacemaker (PM) and ICD patients randomized 1:1 at 16 Spanish institutions
- Patient surveillance by Home Monitoring + remote device interrogations every 6 months (RM-ALONE protocol) vs. Home Monitoring + in-office evaluations every 6 months
- 24 months follow-up period*
- To demonstrate the possibility to safely and efficiently dispense with face-to-face follow-up visits by the RM-ALONE protocol for both pacemaker – and ICD-bearing patients

Main Result

The RM-ALONE protocol demonstrated non-inferiority in terms of safety in comparison to continuous remote monitoring associated with on-site visits every 6 months for the overall population of PM and ICD patients*.



Number of patients in risk

● HMo	220	203	186	170	142
● HM + IO	225	206	194	180	180

Simplified patient surveillance purely based on Home Monitoring (no scheduled in-office visits) was safe for real-world PM and ICD-patients*.

* Remote only follow-up for 24 months is not yet approved by the product labeling and at this point cannot be recommended by BIOTRONIK.

Cumulative major cardiac event survival in the overall study population (Primary safety endpoint).

HM + IO: home monitoring plus in-office evaluations; HMo: home monitoring only

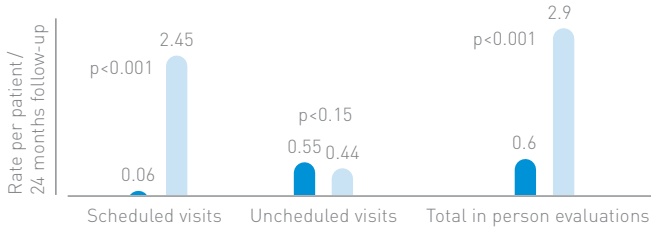
Clinical Relevance

- RM-ALONE is the first randomized trial surveilling PM and ICD patients with a simplified uniform follow-up pattern and using remote monitoring only as a gold standard in both groups.
- Before RM-ALONE, the main concern about extending the time between in-office follow-ups is that safety may be compromised. The RM-ALONE results indicate that surveillance of a real-world PM- and ICD- patient population exclusively based on remote monitoring is safe.
- CIED follow-up is the most frequent activity reported by cardiac electrophysiologists. By following the RM-alone follow-up protocol, the clinical workload resulting from follow-up activities can be significantly reduced for pacemaker and ICD patients.

Patient Surveillance Exclusively Based on Home Monitoring (RM-ALONE Protocol) Reduces Number of Follow-up Visits and Clinical Workload

Efficiency of RM-ALONE follow-up ● HMo ● HM+IO

(A) Total study population

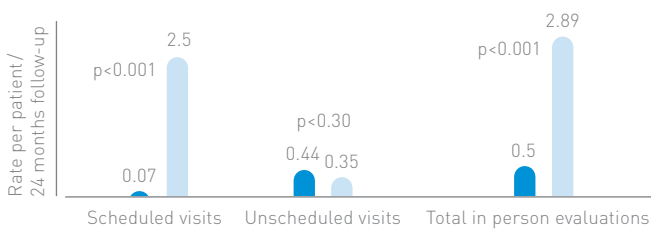


79%

79% Less Visits

Significant reduction of all face-to-face visits by >79% in the overall study population with a similar level of unscheduled visits compared to the control*

(B) Pacemaker patients

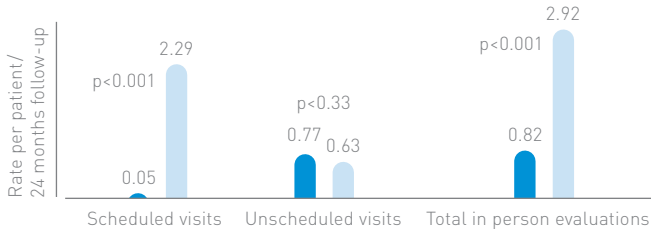


82%

82% Less Visits

Significant reduction of all face-to-face visits by >82% for pacemaker patients with a similar level of unscheduled visits compared to the control*

(C) ICD patients



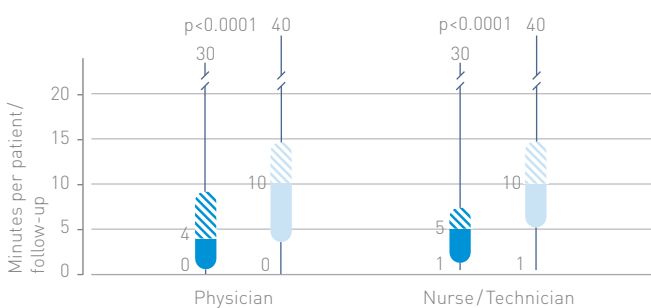
72%

72% Less Visits

Significant reduction of all face-to-face visits by >72% for ICD patients with a similar level of unscheduled visits compared to the control*

(A, B, C) Follow-up efficiency in the total study population (A), and in the PM-(B) and ICD-patient subgroup (C). Rate of follow-up visits per patient per 24 months for the RM-ALONE group (dark) and the control group (light). Scheduled visits (left hand side), unscheduled visits (middle) and total visits (scheduled and unscheduled (right hand side)).

Workload of staff



>40%

>40% Less Workload

Significant reduction of the average follow-up time per patient by 42% (physicians) and by 43% (nurses/technicians)*

Difference between the RM-Alone group (dark) and the control (light) in the rate of in-person evaluations per patient for the whole follow-up. Left hand side: physicians; right hand side: nurses/technicians

* Remote only follow-up for 24 months is not yet approved by the product labeling and at this point cannot be recommended by BIOTRONIK.

Source:

Garcia-Fernández FJ et al. Safety and efficiency of a common and simplified protocol for pacemaker and defibrillator surveillance based on remote monitoring only: a long-term randomized trial. European Heart Journal (2019) 0, 1–10; doi:10.1093/eurheartj/ehz067