
# Implantable devices and remote monitoring: how frequently should diagnostic data be received?

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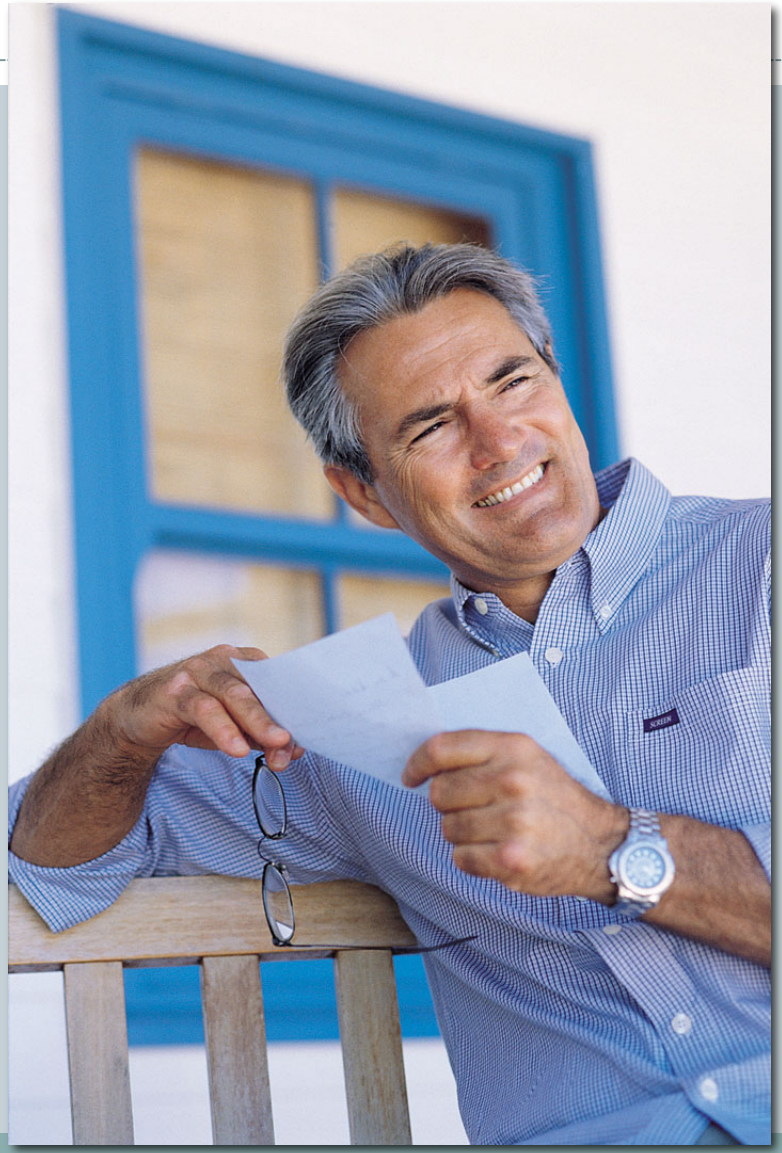
# What is remote device monitoring?

- “**Remote**" because you don't need to be at your doctor's office to have your device checked.
- "**Monitoring**" because the remote system can check your device for specific information for your doctor’s orders (for example, if the battery status and event information) and as scheduled by your doctor.
- How often your device is monitored is determined by your doctor.



Remote Device Monitoring

# Remote Device Monitoring Systems

- Systems commonly available:
  - Medtronic Carelink®
  - St. Jude Merlin™@Home and HouseCall Plus™
  - Biotronik CardioMessenger®
  - Boston Scientific LATITUDE® system

# Organizational Model

**Nurse**

**In case of critical events or uncertain interpretation**

**Phone Contact**

**(transmission interruptions, therapy compliance…)**

**Responsible Physician evaluation requested**

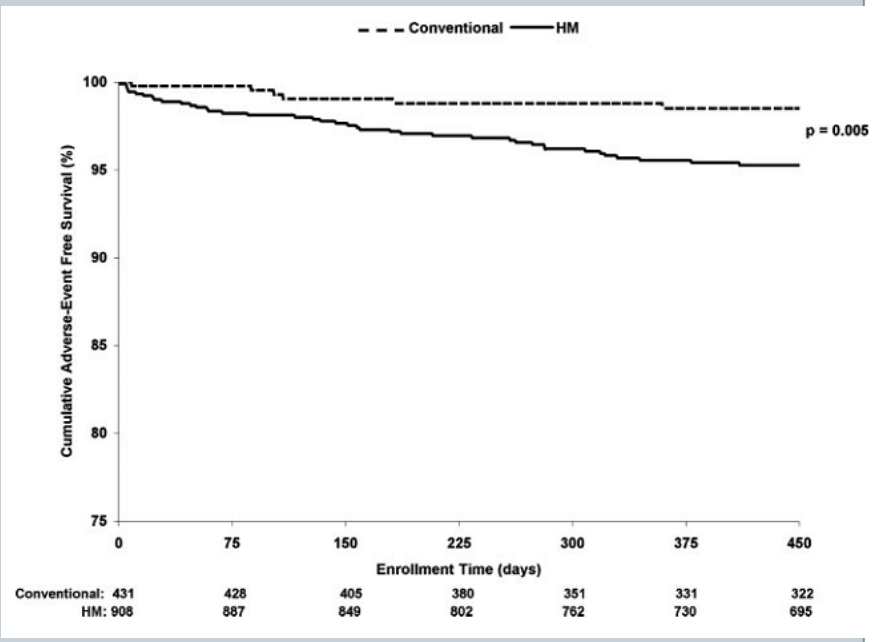
**No intervention required**

**Additional in-office visit**

- Topics
  - ✓ Technical issues management
  - ✓ HomeGuide Registry
  - ✓ Atrial Fibrillation management
  - ✓ Heart Failure management

# Early detection

- Sub-analisys from TRUST study
- 1339 pt. (908 HM and 431 no HM)
- The malfunctioning of catheters and ICD generator was infrequent and often asymptomatic. Only a minority of detected events has required surgery. The discovery of such events through automatic HM has allowed early detection and facilitated the management decisions.




**Varma et al., Automatic Remote Monitoring of Implantable Cardioverter-Defibrillator Lead and Generator Performance The Lumos-T Safely RedUceS RouTine Office Device Follow-Up (TRUST) Trial; Circ Arrhythm Electrophysiol. 2010;3:428-436**

# Early detection

- **ECOST Study (ICD)**
- Primary Endpiont: **SAFETY**
  - Safety is comparable in the two groups
- Secondary endpoint:
  - Reduction in appropriate and inappropriate shocks

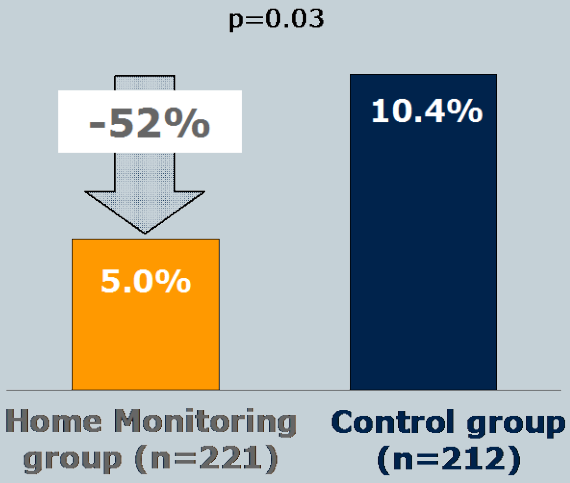



**Table 4** **All shocks, inappropriate shocks, and capacitor charges observed in the intention-to-treat population**

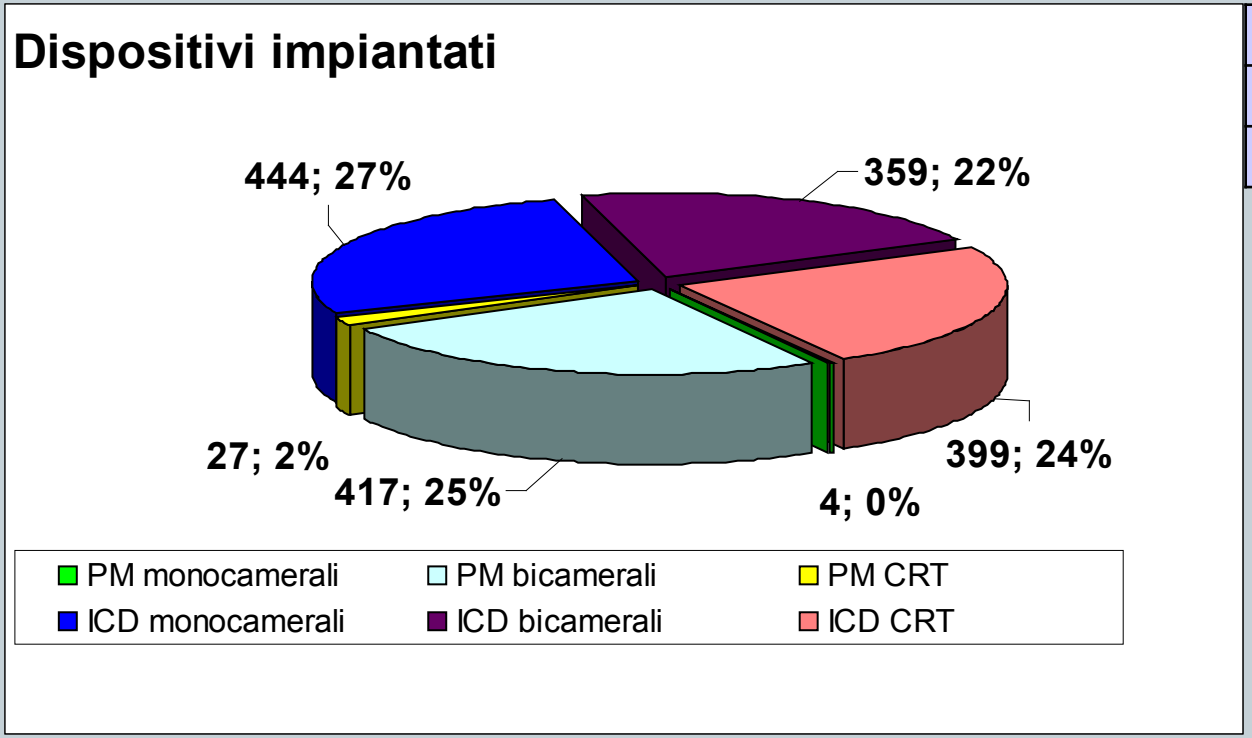
| | Study groups | | *P* |
|---|---|---|---|
| | Active ($n$ = 221) | Control ($n$ = 212) | |
| Appropriate and inappropriate shocks delivered | 193 [0–33] | 657 [0–116] | |
| Patients with ≥1 delivered shock | 47 (21.3) | 56 (26.4) | 0.21 |
| Mean per patient-month | 0.04 ± 0.27 | 0.20 ± 1.13 | 0.02 |
| Inappropriate shocks delivered | 28 [1–8] | 283 [1–82] | |
| Patients with ≥1 inappropriate shock | 11 (5.0) | 22 (10.4) | 0.03 |
| Mean per patient-month | 0.13 ± 0.15 | 0.83 ± 1.86 | 0.28 |
| Capacitor charges | 499 [0–58] | 2081 [0–760] | |
| Patients with ≥1 capacitor charge | 69 (31.2) | 72 (34.0) | 0.54 |
| Mean per patient-month | 0.11 ± 0.38 | 1.65 ± 18.81 | 0.11 |

Values are number of observations [ranges], numbers (%) of observations, or means ± SD.

Kacet S et al. A randomized study of remote follow-up of implantable defibrillators. Safety and Efficacy report of the ECOST trial. Eur Heart J, Dec. 2012

# HomeGuide Registry
## *Patients enrolled*

- **Last analisys on 1650 patients**
- **Mean Follow-up: 20 ± 13 months**

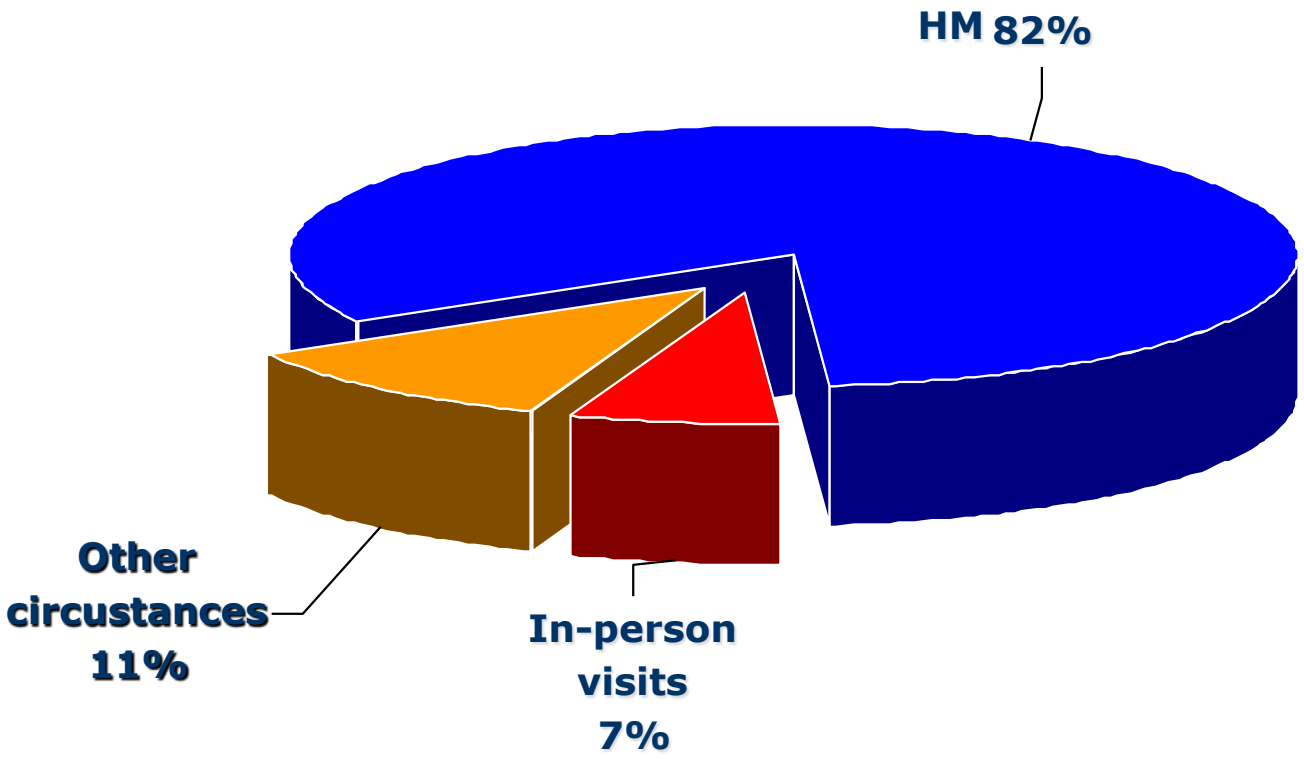



| | |
|---|---|
| PM | **448** |
| ICD | **803** |
| CRT-D | **399** |

# HomeGuide Registry

## *Major Cardiovascular Events (MCE) adjudication*

- 2471 adjudicated* MCEs in 838 patients (51%)



# HomeGuide Registry

## *Major Cardiovascular Events (MCE) adjudication*

**Table 3 Classifications of 2411 true-positive MCEs**

| Event description | All | During HM sessions |
|---|---|---|
| Deaths | 134 | 0 |
| Strokes | 5 | 0 |
| Acute myocardial infarctions | 6 | 2 |
| Worsening heart failures | 137 | 74 |
| Syncope events | 19 | 5 |
| Atrial arrhythmias | 868 | 808 |
| Sustained ventricular arrhythmias | 434 | 394 |
| Unsustained ventricular arrhythmias | 178 | 170 |
| Effective/ineffective ventricular device therapies | 246 | 223 |
| Ineffective maximal energy shocks | 10 | 7 |
| Inappropriate device therapies | 62 | 57 |
| Sensing failures | 193 | 174 |
| Capture failures or threshold raises | 134 | 103 |
| Out-of-range impedances | 43 | 41 |
| Suboptimal device programming | 59 | 40 |
| Battery depletion or device error status | 4 | 4 |
| Pocket/device infections | 8 | 0 |
| Others | 351 | 276 |

# AF management

- The HM technology, reliable and automatic, it may be useful for the management of AF and its clinical decisions [1]
- The HM technology allows early diagnosis of atrial fibrillation and immediate intervention to optimize medical treatment, preventing the most serious complications especially in asymptomatic patients [2]

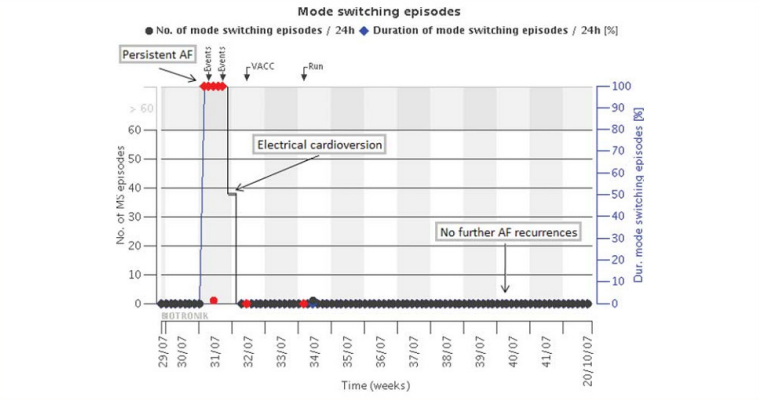



**Figure 4** Case report of a patient with asymptomatic persistent atrial fibrillation recurrence detected by the Home Monitoring™ analysis. The patient was called back to the hospital. An electrical cardioversion was performed and sinus rhythm was restored. The HM analysis allowed us to confirm long-term persistence of stable sinus rhythm.

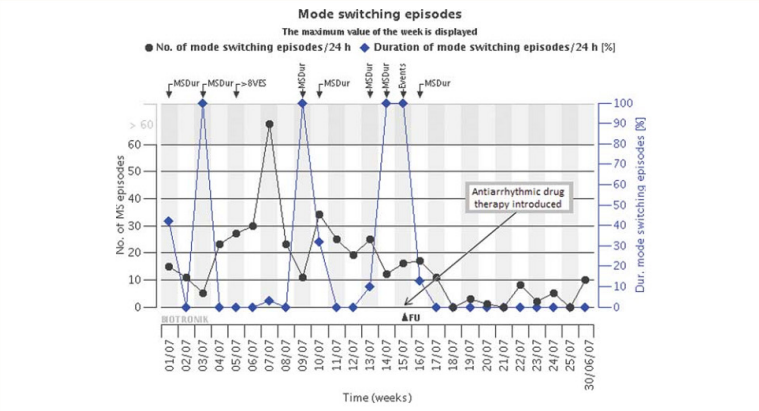
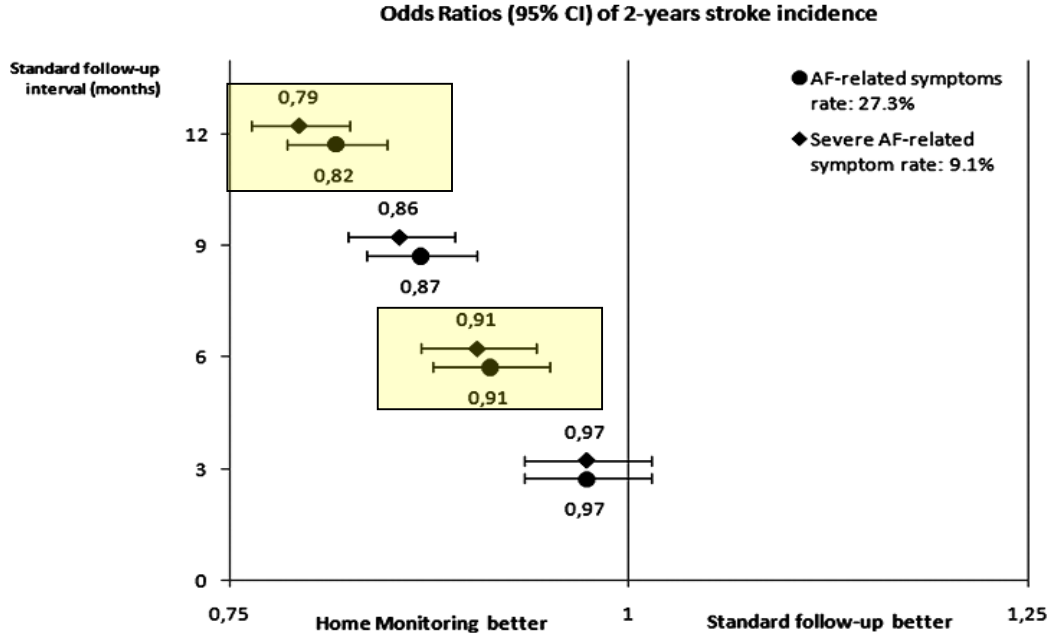



**Figure 5** Case report of a patient with recurrent paroxysmal atrial fibrillation. After an additional follow-up, antiarrhythmic drug therapy was introduced. Home Monitoring™ reports demonstrated a reduction in the number and duration of tachyarrhythmia episodes over time.


[1] Varma N. et al., Detection of atrial fibrillation by implanted devices with wireless data transmission capability. PACE 2005
[2] Ricci et al., Remote control of implanted devices through Home Monitoring technology improves detection and clinical management of atrial fibrillation. Europace 2008

# Home Monitoring & AF management

- **STROKE RISK REDUCTION**
  - HM technology could reduce the **stroke incidence if compared with standard FU**[3]
  - The risk reduction is about 10% if the FU are made every 6 months, and 18% if they are made every 12 months[3]




Estimate of the probability of stroke at 2 years in case of atrial fibrillation as simulated by the Monte Carlo model.

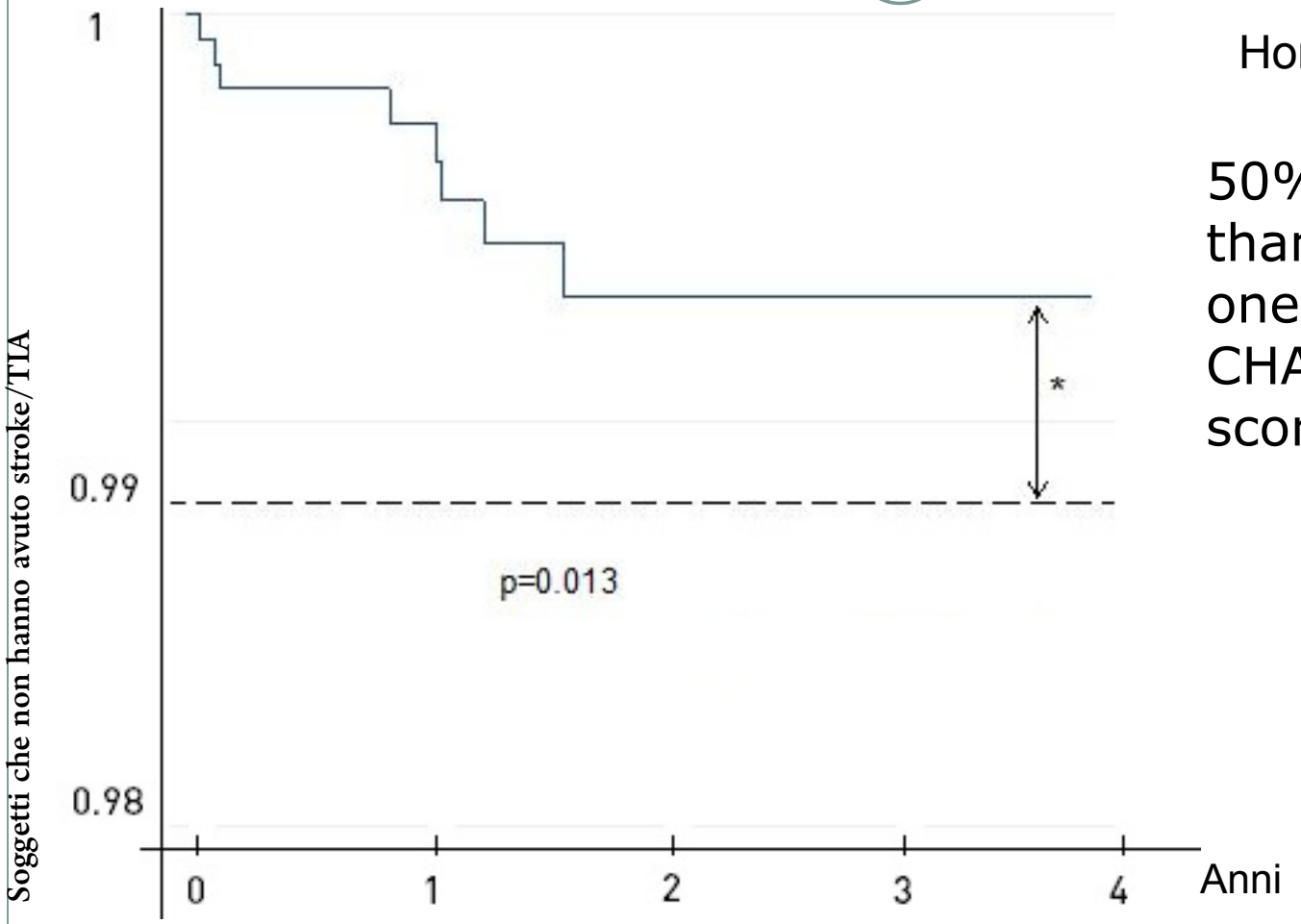
Probability and confidence interval are shown as a function of the interval between 2 consecutive outpatient follow-up.

The circular symbols refer to the probability resulting from considering 27.3% of symptoms related to FA, the square symbols refer to the probability obtained by considering only 9.1% of symptoms related to AF.

[3] Ricci et al., Home Monitoring in Patients with Implantable Cardiac Devices: Is There a Potential Reduction of Stroke Risk? Results from a Computer Model Tested Through Monte Carlo Simulations. JCE 2009

# Stroke Risk Reduction






HomeGuide subanalysis*

50% Stroke reduction than the expected one evaluating $CHA_2DS_2VASc$ risk score

* Ricci RP et al. Stroke incidence in patients with cardiac implantable electronic devices remotely controlled with automatic alerts of atrial fibrillation. A sub-analysis of the HomeGuide Study. Int J Cardiol 2016. doi:10.1016/j.ijcard.2016.06.016

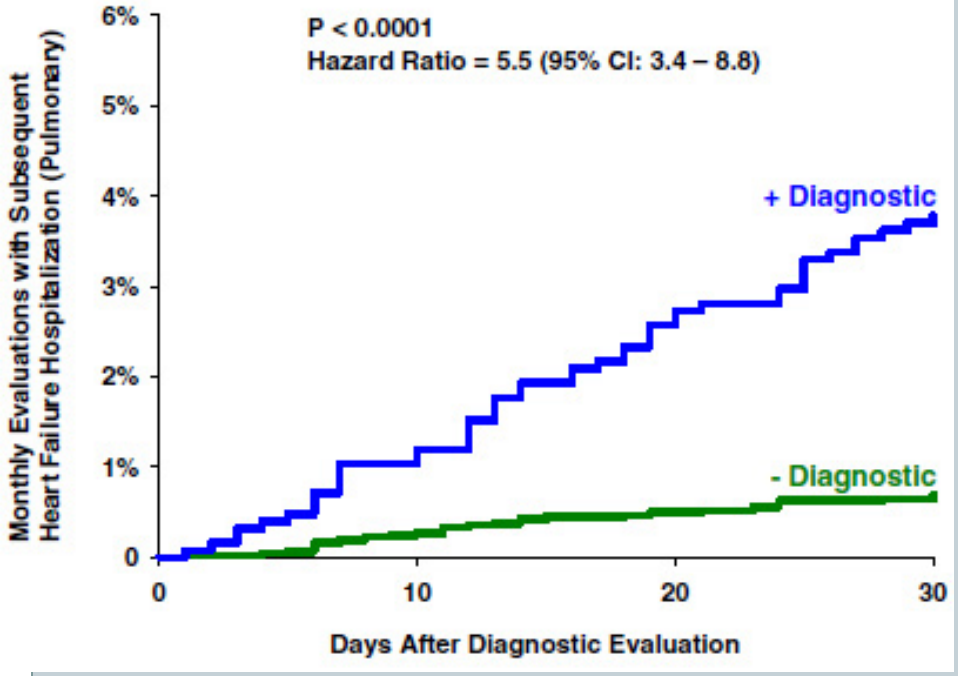
# HF Monitoring

- Daily transmission of 10 parameters for the possible prevention of failure events
  - ✓ Ventricular rate during AF
  - ✓ Mean ventricular rate
  - ✓ Ventricular rate at rest
  - ✓ Mean atrial rate
  - ✓ PVC
  - ✓ AF Burden
  - ✓ Activity
  - ✓ SDANN
  - ✓ CRT %
  - ✓ Transtoracic impedance

# Home Monitoring & HF Management

**Combined Heart Failure Device Diagnostics Identify Patients at Higher Risk of Subsequent Heart Failure Hospitalizations**

Results From PARTNERS HF (Program to Access and Review Trending Information and Evaluate Correlation to Symptoms in Patients With Heart Failure) Study

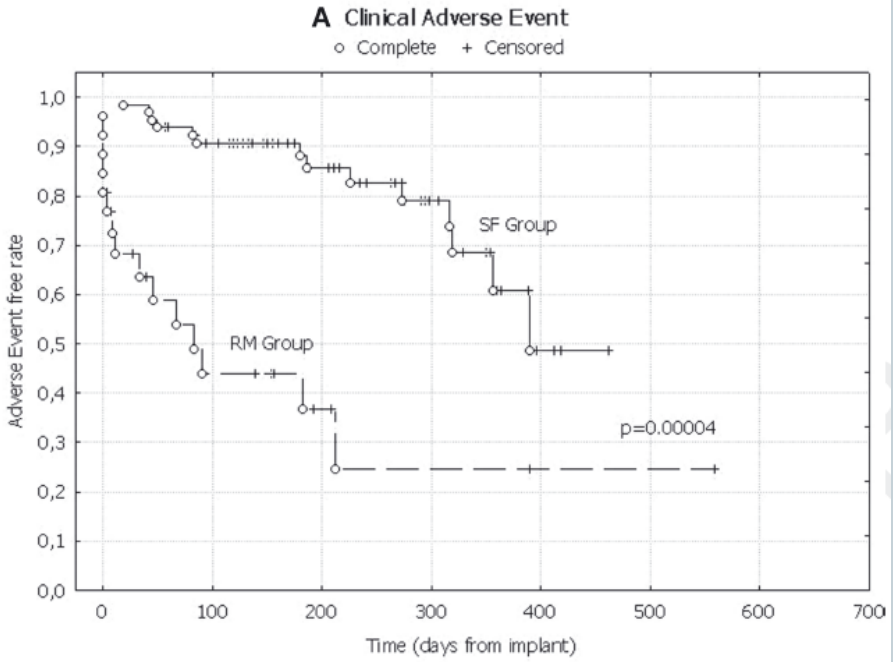



The possibility of having more diagnostic criteria combined, provide a greater ability to recognize patients who may present heart failure events.

# Home Monitoring & HF Management

**Early Detection of Adverse Events with Daily Remote Monitoring versus Quarterly Standard Follow-Up Program in Patients with CRT-D**

ERMENEGILDO DE RUVO, M.D.,* ALESSIO GARGARO, PH.D., M.D.,† LUIGI SCIARRA,




The CRT-D patients followed up with standard visits, without daily remote monitoring, went to meet a **86% increase in the risk of adverse clinical events** due to late detection posed by the monitoring method used during a mean follow-up of 7 months. No difference about device-related adverse events.

*(De Ruvo, PACE 2010)*

# Remote Monitoring of implantable cardiac devices

Remote monitoring of CIEDs exists for more than a decade and have been advanced over time. Some significant differences exists among available technologies about:

- Patient interaction (required for transmitter set up and for data transmission or not)
- Number and variety of alarms
- **Frequency of data transmission (daily, weekly, monthly, quarterly)**

# Does the frequency of transmissions play a role in terms of events detection?

**A prospective comparison of remote monitoring systems in implantable cardiac defibrillators: potential effects of frequency of transmissions**

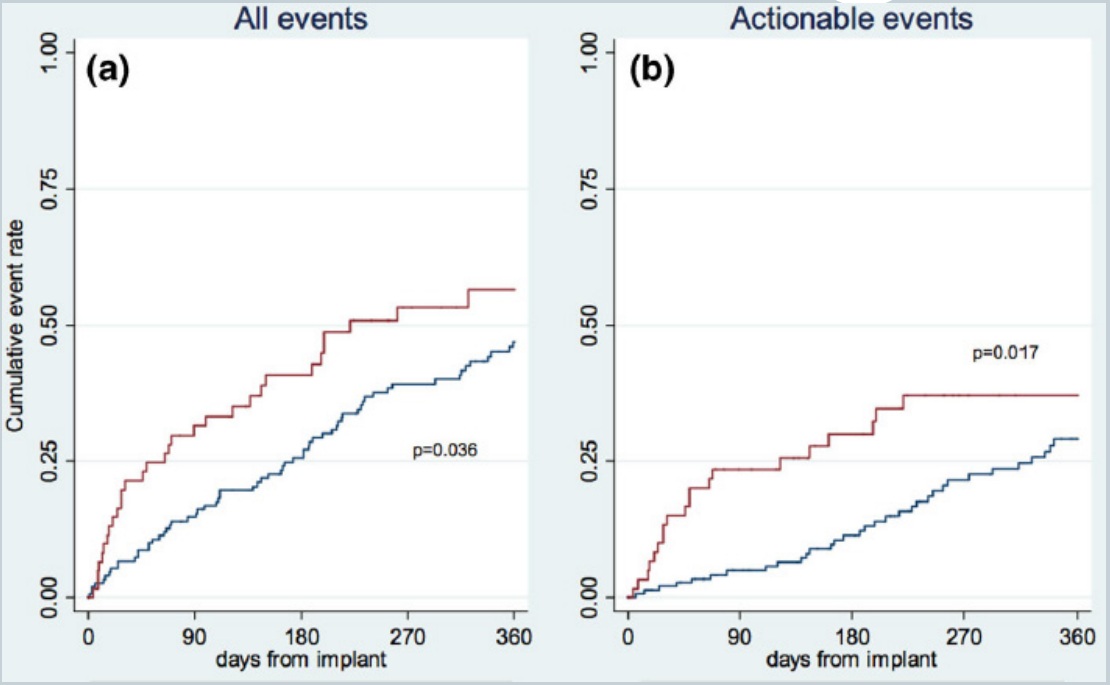
Ermenegildo de Ruvo[1] · Luigi Sciarra[1] · Anna Maria Martino[1] · Marco Rebecchi[1] · Renzo Venanzio Iulianella[1] · Francesco Sebastiani[1] · Alessandro Fagagnini[1] · Alessio Borrelli[1] · Antonio Scarà[1] · Domenico Grieco[1] · Claudia Tota[1] · Federica Stirpe[1] · Leonardo Calò[1]

- This study was independently designed to prospectively collect RM data from patients from January 2009 to January 2011
- All four RM technologies available on the market in those years were used, assigned to patients prior to implant, and activated at discharge.

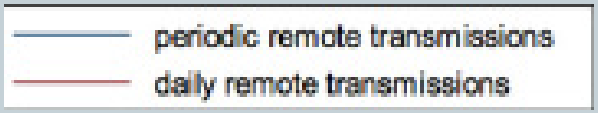
# End points

- Primary end point: time to investigator's first evaluation of a true-positive clinical or device-related event during the first year whichever was first observed during a remote follow-up (whether or not it was triggered by an automatic alert) or during an in-person visit.
- The number of RM transmissions, alerts, and the mean intervals between consecutive RM transmissions were also registered and compared.
- Frequency of transmissions was taken into consideration as this is the major aspect differentiating current RM systems.

# Daily transmissions and events detection



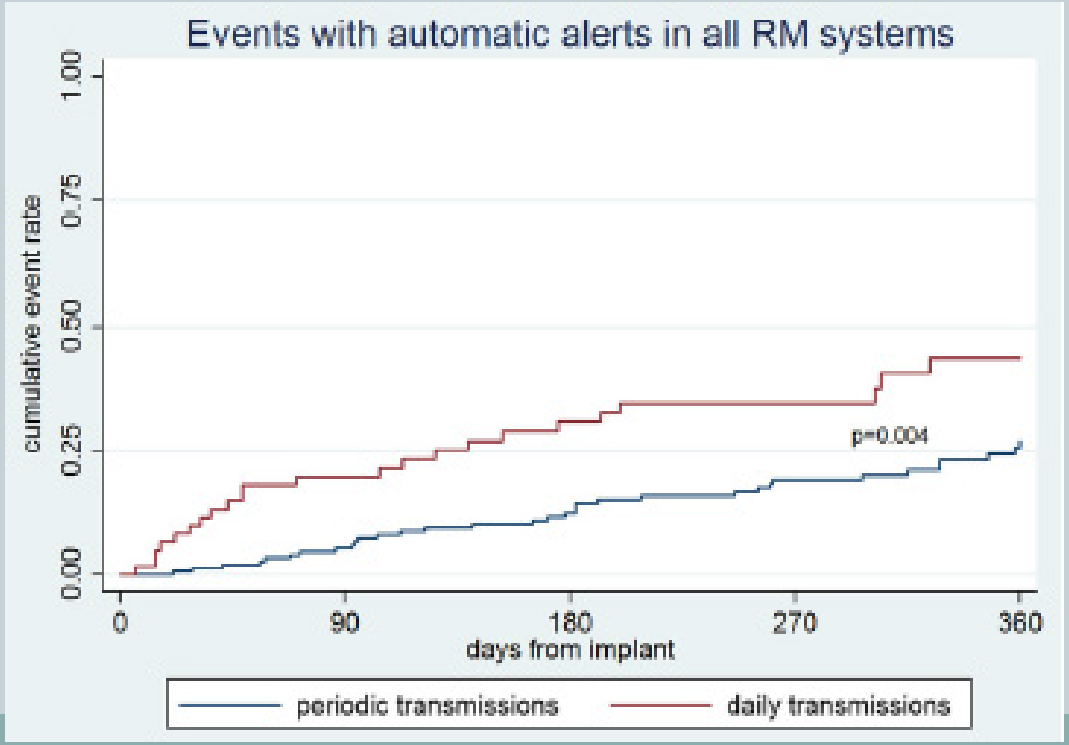

Daily transmissions were associated to a significantly higher cumulative event rate




The difference in evaluation timing considering periodic and daily remote transmission is about 56 days.

# Daily transmissions and events detection

in order to better investigate how frequency of transmissions affects detection timing, we repeated the analysis including only the events for which automatic alerts were available in all the RM systems. In turn, we excluded deaths and capture threshold



EUROPEAN SOCIETY OF CARDIOLOGY®
Europace
doi:10.1093/europace/eus440

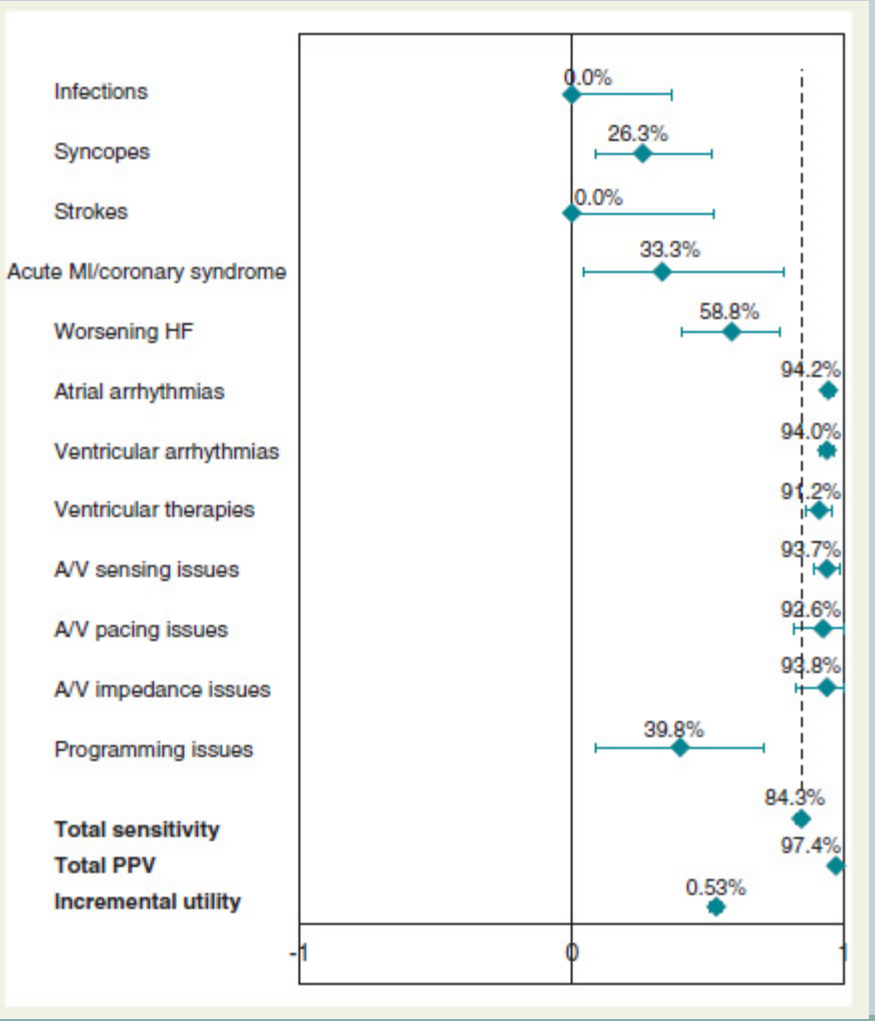
CLINICAL RESEARCH

# Effectiveness of remote monitoring of CIEDs in detection and treatment of clinical and device-related cardiovascular events in daily practice: the HomeGuide Registry

The HomeGuide study demonstrate that high frequency of remote transmissions is not related to a parallel increase of workload for caregivers.

Seventy-five Italian sites enrolled 1650 patients to estimate effectiveness of daily remote monitoring in major cardiovascular event detection and management to measure healthcare source consumption.

# Daily data transmissions and workload




Home Monitoring sensitivity and PPV were very high.

The large majority of the events were detected during HM sessions and were asymptomatic and actionable.

Impact on outpatient clinic workload and resource consumption was remarkably low

Monthly manpower of 55.5 (IQR, 22.0–107.0) min × health personnel/100 patients

# Remote Monitoring and clinical outcome

## Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial

*Gerhard Hindricks, Milos Taborsky, Michael Glikson, Ullus Heinrich, Burghard Schumacher, Amos Katz, Johannes Brachmann, Thorsten Lewalter, Andreas Goette, Michael Block, Josef Kautzner, Stefan Sack, Daniela Husser, Christopher Piorkowski, Peter Søgaard, for the IN-TIME study group**

At the end of the study, patients in the control group had worsen composite clinical score than telemonitoring group.

This difference was mainly driven by the lower mortality in the telemonitoring group than in the control group.

The Kaplan-Meier estimate of 1-year all-cause mortality in the telemonitoring group was 3,4% versus 8,7% in the control group with a probability of survival of more than 60% in the telemonitoring group.

The Lancet, Volume 384, Issue 9943, 16–22 August 2014, Pages 583–590

European Journal of Heart Failure (2016)
doi:10.1002/ejhf.626

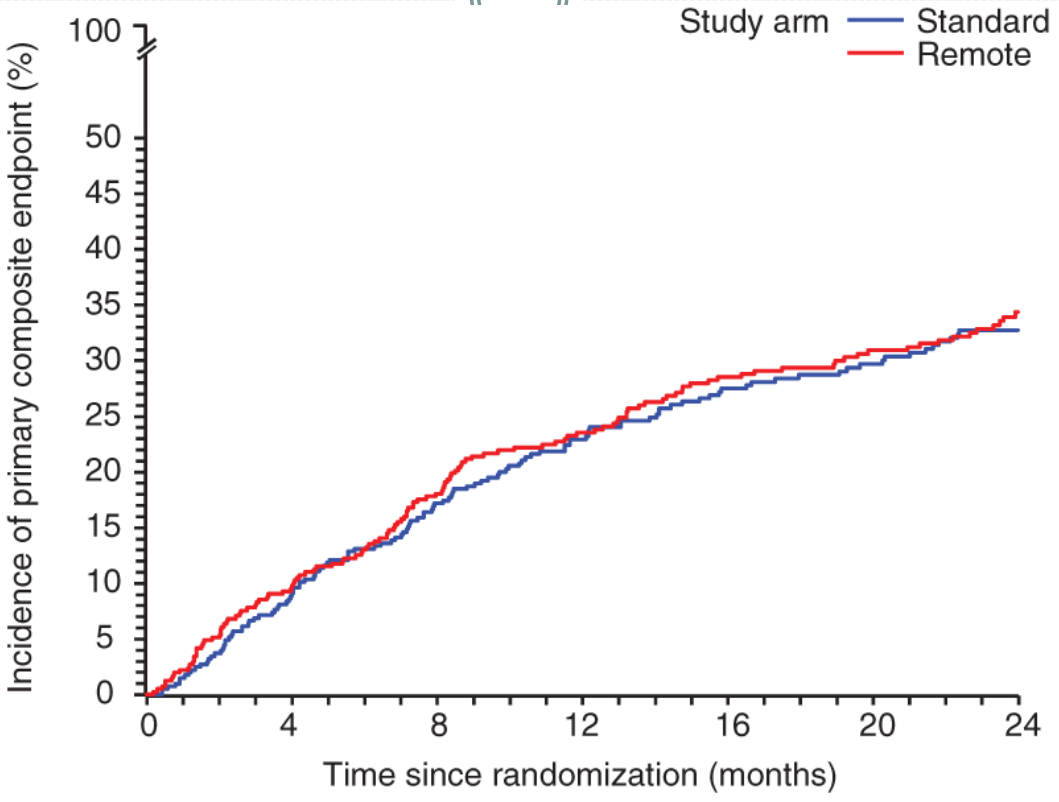
# Effects of remote monitoring on clinical outcomes and use of healthcare resources in heart failure patients with biventricular defibrillators: results of the MORE-CARE multicentre randomized controlled trial

**Giuseppe Boriani[1,2]*, Antoine Da Costa[3], Aurelio Quesada[4], Renato Pietro Ricci[5], Stefano Favale[6], Gabriele Boscolo[7], Nicolas Clementy[8], Valentina Amori[9], Lorenza Mangoni di S. Stefano[9], Haran Burri[10], on behalf of the MORE-CARE Study Investigators**

[1]University of Modena and Reggio Emilia, Policlinico di Modena, Modena, Italy; [2]University of Bologna, S. Orsola-Malpighi University Hospital, Bologna, Italy; [3]University Hospital, St. Etienne, France; [4]University General Hospital, Valencia, Spain; [5]San Filippo Neri Hospital, Rome, Italy; [6]University Hospital, Bari, Italy; [7]Chioggia ULSS 14, Chioggia, Italy; [8]Tours University Hospital, Tours, France; [9]Medtronic EMEA Regional Clinical Center, Rome, Italy; and [10]University Hospital of Geneva, Geneva, Switzerland

Received 5 July 2016; revised 27 July 2016; accepted 27 July 2016

# Effects of remote monitoring on clinical outcomes and use of healthcare resources in heart failure patients with biventricular defibrillators: results of the MORE-CARE multicentre randomized controlled trial



# Does the frequency of transmission may have an effect on clinical outcome?

## Remote Monitoring of Implantable Cardioverter-Defibrillators

### A Systematic Review and Meta-Analysis of Clinical Outcomes

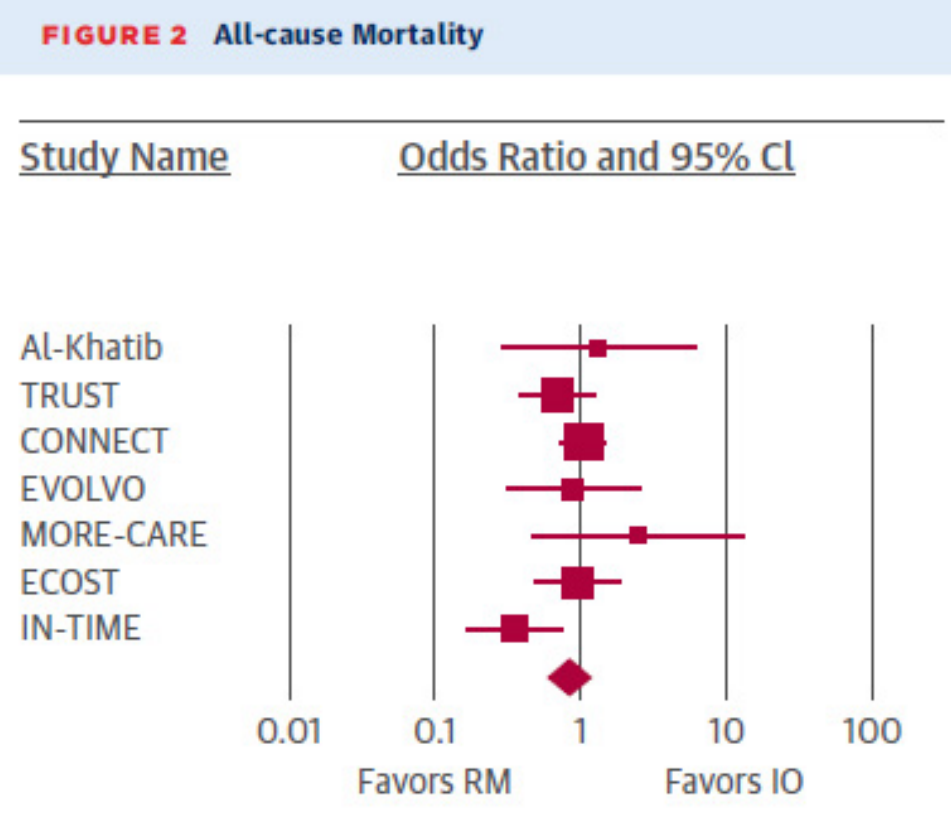
Nirmalatiban Parthiban,*† Adrian Esterman, PhD,‡ Rajiv Mahajan, MD, PhD,* Darragh J. Twomey, MBBS,* Rajeev K. Pathak, MBBS,* Dennis H. Lau, MBBS, PhD,* Kurt C. Roberts-Thomson, MBBS, PhD,* Glenn D. Young, MBBS,* Prashanthan Sanders, MBBS, PhD,* Anand N. Ganesan, MBBS PhD*

**CONCLUSIONS** Meta-analysis of RCTs demonstrates that RM and IO follow-up showed comparable overall outcomes related to patient safety and survival, with a potential survival benefit in RCTs using daily transmission verification.

# Methods

- Electronic databases and reference lists were searched for Randomized Controlled Studies (RCTs) reporting clinical outcomes in ICD patients who did or did not undergo RM. Data were extracted from RCTs, including 6,469 patients, 3,496 of whom were randomized to RM and 2,973 to IO follow-up.

# Results




It was not possible to identify a significant overall all-cause mortality benefit in meta-analysis of the 7 RCTs reporting mortality.

A highly significant mortality benefit was seen in the subset of trials using **daily transmission system** (OR: 0.65; 95% CI: 0.45 to 0.94; p = 0.021).

Authors suggested that a possible mechanism to explain this advantage could include daily verification of RM transmission.

*ESC Congress 2016, Rome*

Daily remote monitoring of implantable cardioverter-defibrillators: Pooled individual patient data from IN-TIME, ECOST, and TRUST trials suggest a mechanism of clinical benefit

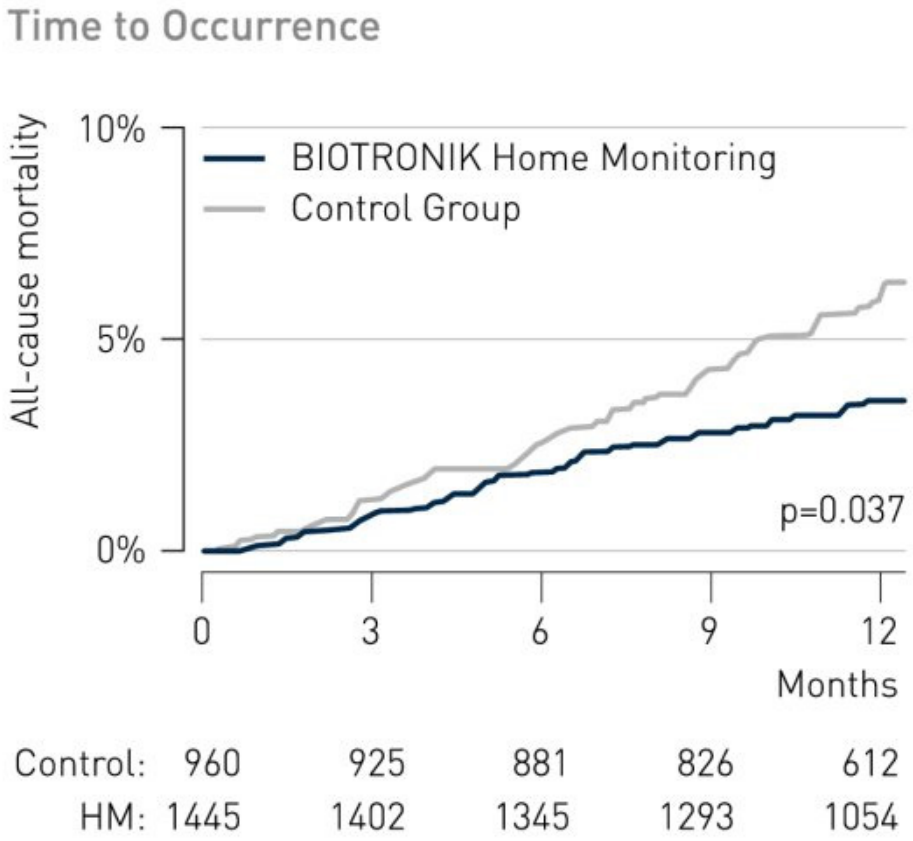
Preliminary result discussed:

All-cause mortality reduction: 38% (absolute risk reduction 1.9%) $p<0.05$

All-cause mortality or worsening HF hospitalization: 36% (absolute risk reduction 5.6%) $p<0.01$

# Mortality Reduction






**38%**

relative reduction one year all cause mortality

Relative risk = 0.62
95% CI: 0.40 to 0.95

Hindricks G, J. Proff, N. Varma, S. Kacet, T. Lewalter, P. Sogaard, L. Guedon-Moreau, TA. Gerds, SD. Anker
Daily remote monitoring of implantable cardioverter-defibrillators: Pooled individual patient data from IN-TIME, ECOST, and TRUST trials suggest a mechanism of clinical benefit, ESC Congress 2016, Rome

# HRS Remote Monitoring Consensus Statement Recommendations

| Device Follow-Up Paradigm | Recommendation | Evidence |
|---|---|---|
| A strategy of remote CIED monitoring and interrogation, combined with at least annual IPE, is recommended over a calendar-based schedule of in-person CIED evaluation alone (when technically feasible). | I | A |
| All patients with CIEDs should be offered RM as part of the standard follow-up management strategy. | I | A |
| Before implementing RM, it is recommended that each patient be educated about the nature of RM, their responsibilities and expectations, potential benefits, and limitations. The occurrence of this discussion should be documented in the medical record. | I | E |

| Device and Disease Management | Class of Recommendation | Level of Evidence |
|---|---|---|
| RM should be performed for surveillance of lead function and battery conservation. | I | A |
| Patients with a CIED component that has been recalled or is on advisory should be enrolled in RM to enable early detection of actionable events. | I | E |
| RM is useful to reduce the incidence of inappropriate ICD shocks. | I | B-R |
| RM is useful for the early detection and quantification of atrial fibrillation. | I | A |
| The effectiveness of RM for thoracic impedance alone or combined with other diagnostics to manage congestive heart failure is currently uncertain. | IIb | C |

HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices, Heart Rhythm, Vol 12, No 7, July 2015

# In an emergency…

- Remote monitoring does **not** replace physician contact!
- **Always** call 118 in an emergency.
- **Always** call your doctor if your health changes suddenly or dramatically.

**Un traguardo importante per la Telecardiologia trentina**

Pubblicato il 27 settembre 2016

Cari Colleghi,

ho il piacere di comunicarvi che, dopo molti sforzi e grazie alla perseveranza nell'inseguire l'obiettivo, con delibera della Giunta Provinciale di Trento del 13 giugno 2016 (allegata) in Trentino è stata inserita nel Nomenclatore delle prestazioni di assistenza specialistica ambulatoriale la voce "Controllo remoto di pazienti portatori di pacemaker, defibrillatori e loop recorder" (massimo 4 controlli/anno – codice 89.48.2 – tariffa 25,55 euro).

Questo è sicuramente un passo molto importante nel cammino della Telecardiologia perché ufficializza un percorso già intrapreso da molti di noi ma a cui finora non era stato dato riscontro dalle Amministrazioni.

L'ottenimento della Codifica è stato ottenuto grazie alla volontà del dott. Maurizio Del Greco che ha presentato domanda in Azienda Sanitaria, al Servizio Governance Clinica. Qui l'iter burocratico ha incontrato la grande disponibilità della dott.ssa Michelina Monterosso, che si è attivata per presentare la richiesta alla Giunta Provinciale di Trento. La Giunta ha approvato la codifica di questa nuova prestazione, assieme ad altre prestazioni in ambito diabetologico, con delibera del 13/06/2016 (PDF: 190 Kb), a dimostrazione di una certa attenzione e sensibilità verso l'innovazione in Medicina. L'APSS di Trento ha recepito tale delibera e ci ha informati con lettera del 28/06/2016 (PDF: 240 Kb).