

**ADVANCES IN CARDIAC  
ARRHYTHMIAS  
and  
GREAT INNOVATIONS  
IN CARDIOLOGY**

**Directors**

Fiorenzo Gaita  
Sebastiano Marra

**Scientific Committee**

Malcolm Bell, *Usa*  
Martin Borggreffe, *Germany*  
Amir Lerman, *Usa*  
Jean Francois Leclercq, *France*  
Dipen Shah, *Suisse*

**Organization Committee**

Carlo Budano, *Italy*  
Davide Castagno, *Italy*  
Monica Andriani, *Italy*

**Turin**

**September 27-28, 2013**

*Centro Congressi  
Unione Industriale*



*Dipartimento  
Cardiovascolare  
Città della Salute e della  
Scienza di Torino*

**Daily automatic monitoring  
and the actionable model:  
from device control to the best  
management of the disease**

*Carlo Budano*



Università degli Studi di Torino





- The ability of a device to provide a wide spectrum of informations is not the only condition to be reached to achieve the best clinical management of the patient.
- Only a reliable and timely control system allows to optimize the use of informations and obtain an optimal clinical outcome

# Imagine the possibilities



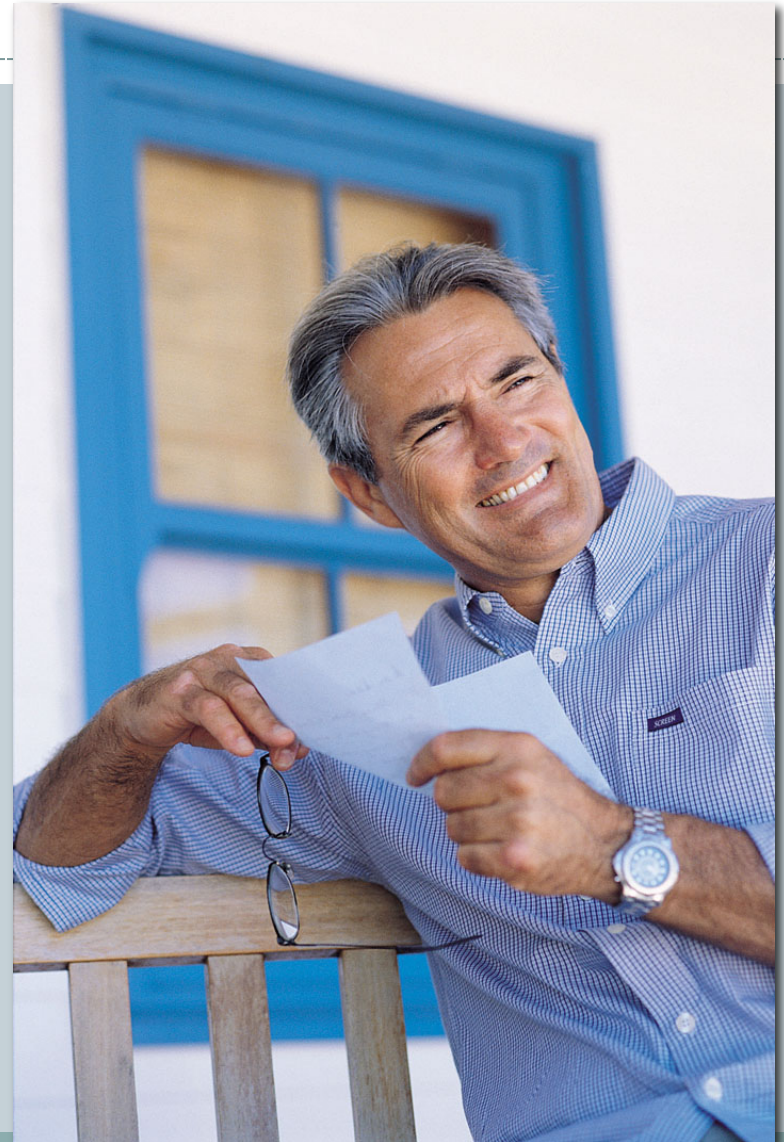
- Your doctor may be getting important information from your device while you are relaxing at home.





# 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 per 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.



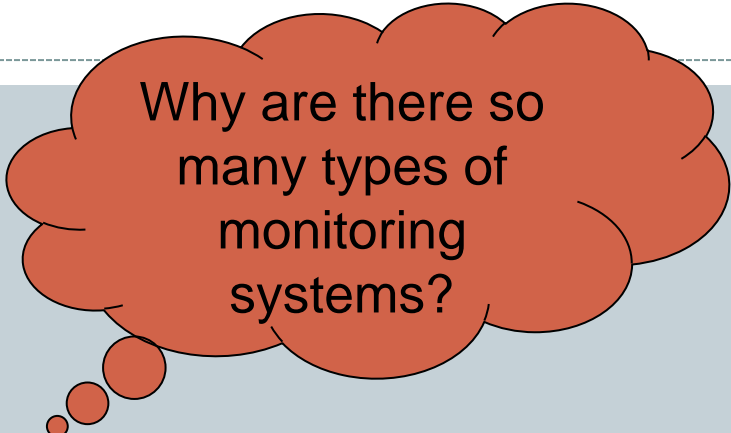
Remote Device Monitoring

# What is remote device monitoring?

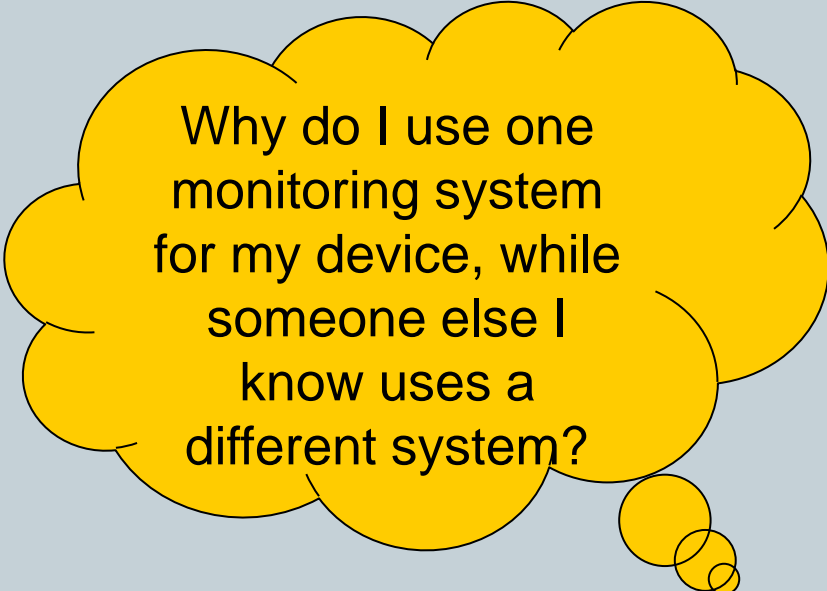
All patients should have regular monitoring of their device and health.

Three factors determine what type of monitoring system your doctor will prescribe for you:

1. The type of device you have.
2. The manufacturer of your device.
3. What you and your doctor decide is the best approach for you.



Why are there so many types of monitoring systems?



Why do I use one monitoring system for my device, while someone else I know uses a different system?

# Remote Device Monitoring Systems



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





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



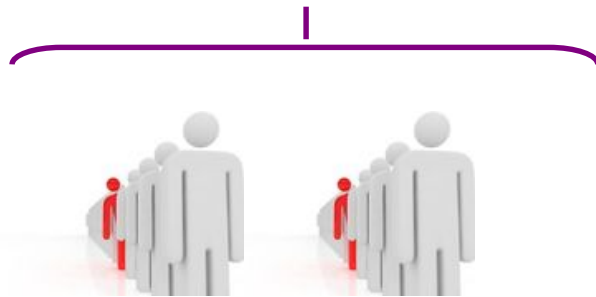
- **Topics**
  - ✓ **Home Guide Registry**
    - ✓ Atrial Fibrillation management
    - ✓ Heart Failure management
    - ✓ Technical issues management
- Conclusions



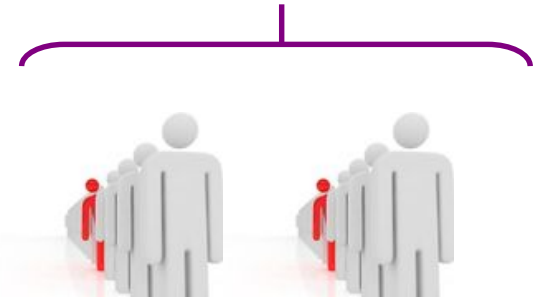
# Organizational Model



**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**



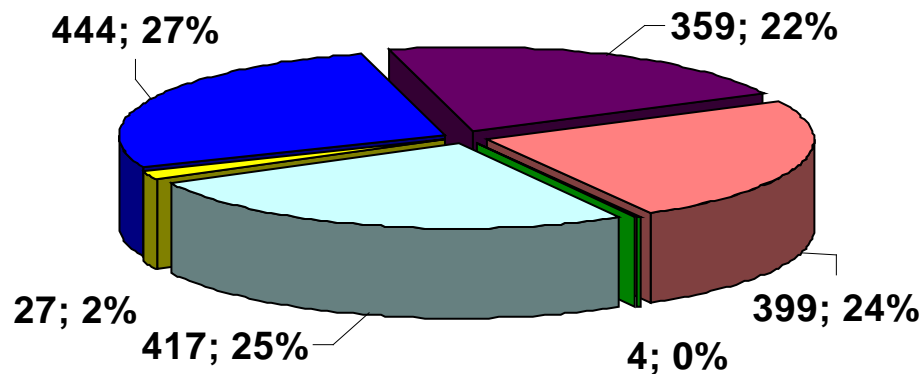
# HomeGuide Registry

## *Patients enrolled*



- Last analysis on 1650 patients
- Mean Follow-up:  $20 \pm 13$  months

### Dispositivi impiantati



■ PM monocalamerali	■ PM bicamerali	■ PM CRT
■ ICD monocalamerali	■ ICD bicamerali	■ ICD CRT

PM	448
ICD	803
CRT-D	399

# HomeGuide Registry

## *Patients enrolled*

**Table I** Population characteristics

	All patients (1650)	PM (448)	ICD (803)	CRT-D (399)
Mean age (years)	69.5 ± 11.4	73.7 ± 10.3	67.0 ± 12.2	69.9 ± 9.5
Male	1261 (76%)	282 (63%)	660 (82%)	319 (80%)
HD				
No HD	183 (11%)	168 (38%)	15 (2%)	0 (0%)
Cardiomyopathy	851 (53%)	30 (7%)	496 (62%)	325 (81%)
Ischaemic HD	689 (43%)	82 (18%)	421 (52%)	186 (47%)
Valvular HD	107 (7%)	20 (4%)	63 (8%)	24 (6%)
Channelopathies	27 (2%)	0 (0%)	27 (3%)	0 (0%)
Congenital HD	9 (1%)	3 (1%)	5 (1%)	1 (0%)
Others	5 (0%)	3 (1%)	2 (0%)	0 (0%)
NYHA class				
I	309 (19%)	189 (42%)	112 (14%)	8 (2%)
II	751 (46%)	181 (41%)	456 (57%)	114 (29%)
III	553 (33%)	73 (16%)	220 (27%)	260 (65%)
IV	37 (2%)	5 (1%)	15 (2%)	17 (4%)
QRS width (ms)	120 (100–142)	100 (87–120)	108 (98–120)	146 (125–160)
LVEF (%)	30.0 (25.0–42.0)	60.0 (50.0–60.0)	30.0 (26.0–38.0)	28.0 (25.0–30.0)
Ventricular tachyarrhythmias	447 (27%)	4 (1%)	355 (44%)	88 (22%)
Supraventricular tachyarrhythmias <sup>a</sup>	416 (25%)	135 (30%)	186 (23%)	95 (24%)
AT	93 (6%)	34 (7%)	37 (4%)	22 (6%)
AF	356 (22%)	118 (26%)	160 (20%)	78 (20%)
Paroxysmal	155 (44%)	72 (61%)	53 (33%)	30 (38%)
Persistent	71 (20%)	33 (28%)	27 (17%)	11 (14%)
Permanent	130 (37%)	13 (11%)	80 (50%)	37 (47%)
Bradyarrhythmias	538 (33%)	354 (79%)	92 (11%)	92 (23%)

HD, heart disease; LVEF, left ventricular ejection fraction; AT, atrial tachycardia/flutter; AF, atrial fibrillation.

<sup>a</sup>Individual patients could have multiple supraventricular arrhythmias.

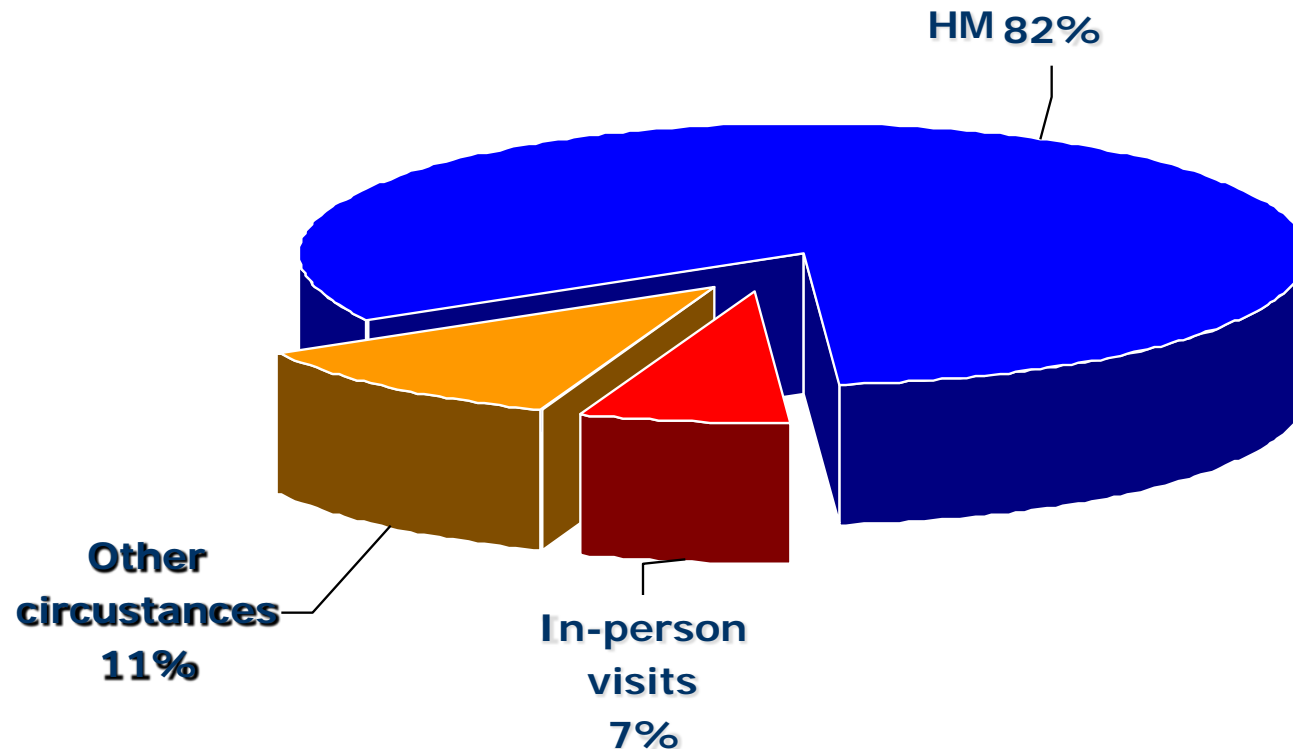
# HomeGuide Registry

## *Major Cardiovascular Events (MCE) adjudication*



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

\*Adjudicating Board: Brieda, Campana, Melissano, L.Santini, Toselli



# 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

# HomeGuide Registry

## *Major Cardiovascular Events (MCE) adjudication*



**Table 4** Clinical reactions to actionable events

Clinical reaction	All	During HM sessions number (%)
Pharmacological therapy optimization	381	297 (78%)
Therapy compliance recommendation	48	44 (92%)
Device reprogramming	315	244 (77%)
Device replacement	17	8 (47%)
Implantation surgical revision	73	47 (64%)
Device upgrading	12	5 (42%)
Pharmacological AF cardioversion	6	4 (67%)
Electrical AF cardioversion	35	26 (74%)
Radiofrequency ablation	21	15 (71%)
Further diagnostics exams	28	21 (75%)
Hospitalizations	151	69 (46%)
Others	69	58 (84%)

AF, atrial fibrillation.



# HomeGuide Registry

## *Sensitivity for class of MCE*



Infection		0.0%
Syncopes		26.3%
Strokes		0.0%
ACS		33.3%
Worsening HF		58.8%
Atrial Arrhythmias		94.2%
V. Arrhythmias		94.0%
V. Therapies		91.2%
AV sensing issues		93.7%
AV pacing issues		92.6%
AV impeded. issues		93.8%
Programming issues		39.8%
<b>Total Sensitivity</b>		<b>84.3%</b>

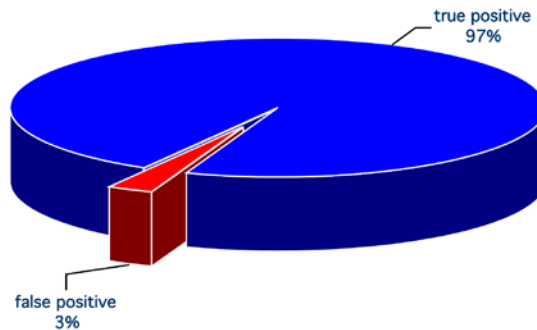
# HomeGuide Registry

## *Major Cardiovascular Events (MCE) adjudication*

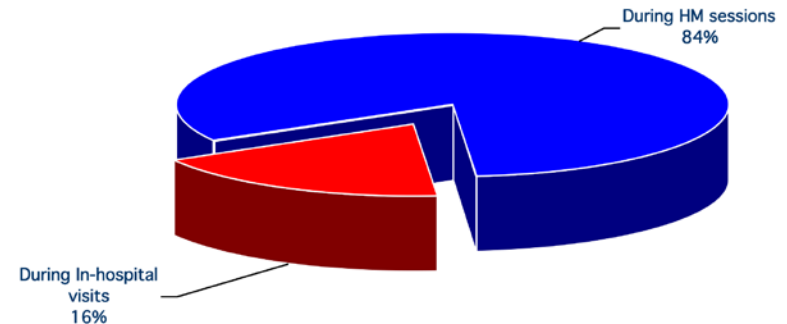


### HM Reliability

Observed MCEs



### HM Sensitivity



HM: { **Sensitivity:** 84% (95% CI, 82%-86%)  
**Positive Predictive Value:** 97% (95% CI, 96%-98%)

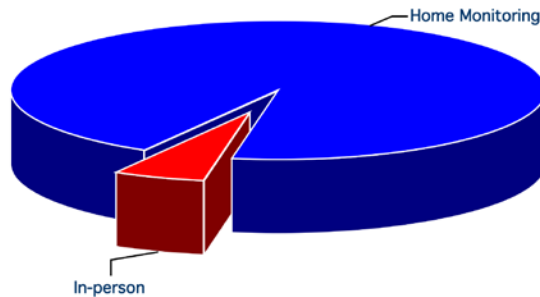
GEE-adjusted estimates

# HomeGuide Registry

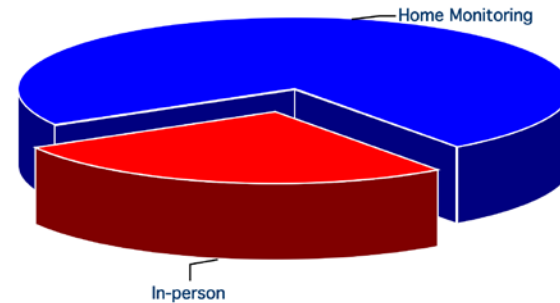
## *Major Cardiovascular Events (MCE) adjudication*



### Asymptomatic



### Actionable



**94% of asymptomatic MCEs were detected during HM sessions**

**73% of actionable MCEs were detected during HM sessions**

# HomeGuide Registry

## Health Care Resource Consumption (Manpower)

Europeace Advance Access published February 23, 2011



Europeace  
doi:10.1093/europeace/eur026

CLINICAL RESEARCH

### Healthcare personnel resource burden related to in-clinic follow-up of cardiovascular implantable electronic devices: a European Heart Rhythm Association and Eucomed joint survey

Giuseppe Boriani<sup>1\*</sup>, Angelo Auricchio<sup>2</sup>, Catherine Klersy<sup>3</sup>, Paulus Kirchhof<sup>4</sup>, Josep Brugada<sup>5</sup>

#### Aims

A pilot European survey was conducted to assess the cumulative time spent by healthcare personnel for in-office follow-up of cardiac implantable electrical devices (CIEDs), including cardiac pacemakers, implantable cardioverter-defibrillators, and cardiac resynchronization therapy (CRT) devices.

#### Methods and results

Resource use data were collected during a session of in-clinic follow-up. Among 407 visits, 93% were scheduled and 7% unscheduled. Visit duration (total cumulative time) lasted a mean of 27 min for scheduled visits, and was ~30% longer for unscheduled visits. Independent determinants of visit duration were: unscheduled visit (+7.6 min,  $P = 0.01$ ), the need for device reprogramming (+7.5 min,  $P < 0.001$ ), and the type of device checked, with CRT devices needing 9.1 and 6.6 more minutes than single- ( $P < 0.001$ ) and dual-chamber devices ( $P = 0.002$ ), respectively. Most visits involved two different types of healthcare personnel (239 of 407, 59%), simultaneously. The most frequent combination was the involvement of both a cardiologist and a nurse (216 of 407 visits with both of them only, and 65 additional visits with also an internal technician, an external technician, or both). Overall, an external technician was involved in 18% of visits.

#### Conclusions

In 'real-world' practice, the follow-up of CIEDs nowadays requires important resources in terms of time dedicated by specialized personnel, corresponding to cardiologists, nurses, internal technicians, and external, industry-employed technicians. These observations should be the basis for addressing clinical, organizational, financial, and policy initiatives targeted to optimize follow-up procedures in order to face the increase in the number of patients treated with CIEDs expected for the next years.

<sup>1</sup>Institute of Cardiology, Univ  
Ticino, Lugano, Switzerland; <sup>2</sup>  
and Angiology, University Ho  
Offices, Southampton, UK; an

# HomeGuide Registry

## *Health Care Resource Consumption (Manpower)*



- **Home Monitoring**

- ✓ Minutes x health personnel /  
month every 100 pts:

**~~55.5~~ (22.0-107.0)**

- **Standard in-office follow-up**

- ✓ Minutes x health personnel to  
manage 100 scheduled /  
unscheduled follow-up:

**~~2100~~ (1500-3500)**

**Net saving of 34 labor hours per 100 follow-up**

**80% of the visits are carried out with doctor and nurse (Eucomed Survey)  
Gross Salary €0.79 per minute for a doctor, €0.63 for a nurse (ISTAT 2010)**

**Cost-saving €2.322 per 100 follow-up**

# HomeGuide Registry

## *Conclusions*



Europace  
doi:10.1093/europace/eu440

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**

Renato Pietro Ricci<sup>1\*</sup>, Loredana Morichelli<sup>1</sup>, Antonio D'Onofrio<sup>2</sup>, Leonardo Calò<sup>3</sup>, Diego Vaccari<sup>4</sup>, Gabriele Zanotto<sup>5</sup>, Antonio Curnis<sup>6</sup>, Gianfranco Buja<sup>7</sup>, Nicola Rovai<sup>8</sup>, and Alessio Gargaro<sup>9</sup>

## **Home Monitoring as implemented through HomeGuide organizational model is:**

- ✓ **Highly sensitive (84%) and predictive (97%), especially for asymptomatic events that require corrective action (actionable)**
- ✓ **Highly effective for resources optimization (55 minutes / month per 100 patients)**





- **Topics**

- ✓ HomeGuide Registry

- ✓ **Atrial Fibrillation management**

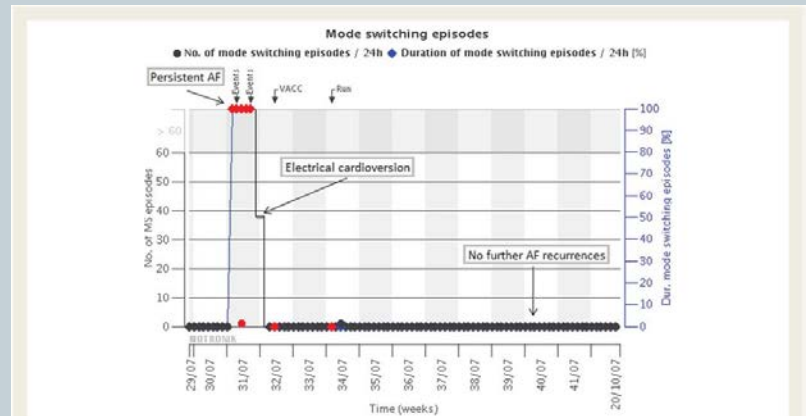
- ✓ Heart Failure management

- ✓ Technical issues management

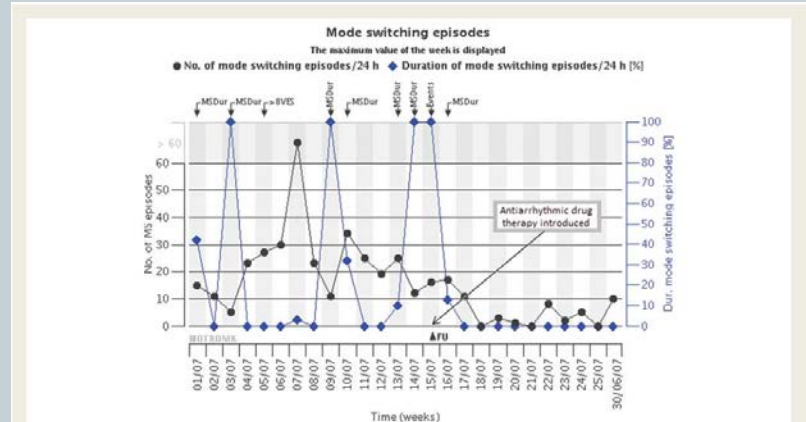
- **Conclusions**

# 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

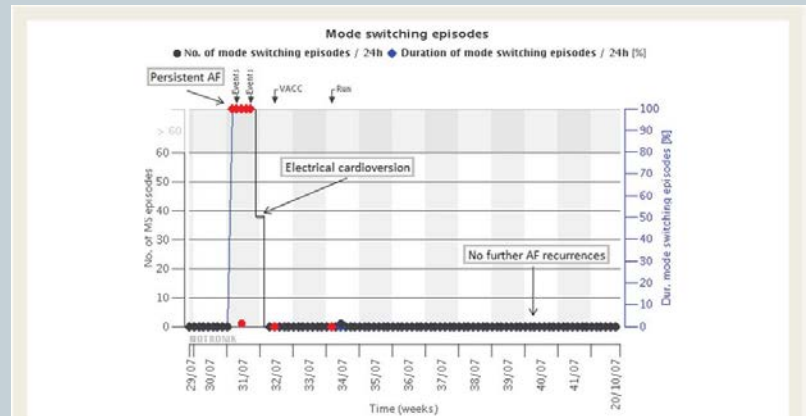
# Home Monitoring & AF management

## • HM & FA

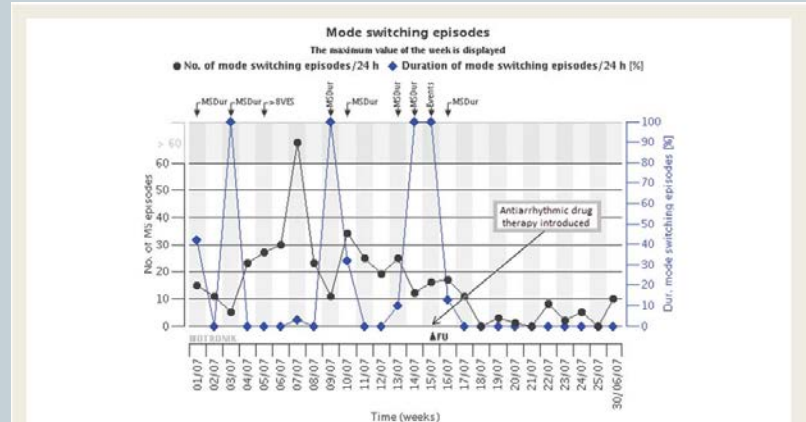
- 166 patients (121 PM, 22 ICD, 23 CRT-D)
- Mean FU  $488 \pm 203$  gg
- 42 (26%) pt. with AF ALERT
- 33/42 (78%) pt. with unscheduled FU
  - ✦ 22/33 (67%) no AF history
  - ✦ 24/33 (73%) Asymptomatic
  - ✦ 16/33 (48%) started antiarrhythmic
  - ✦ 17/33 (51%) started anticoagulant

**Detection 148 gg (5 months)**  
**Before than scheduled Follow-Up\***

\* (every 6 month for ICD and 12 month for PM)



**Figure 4** Case report of a patient with asymptomatic persistent atrial fibrillation recurrence detected by the Home Monitoring<sup>TM</sup> 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.

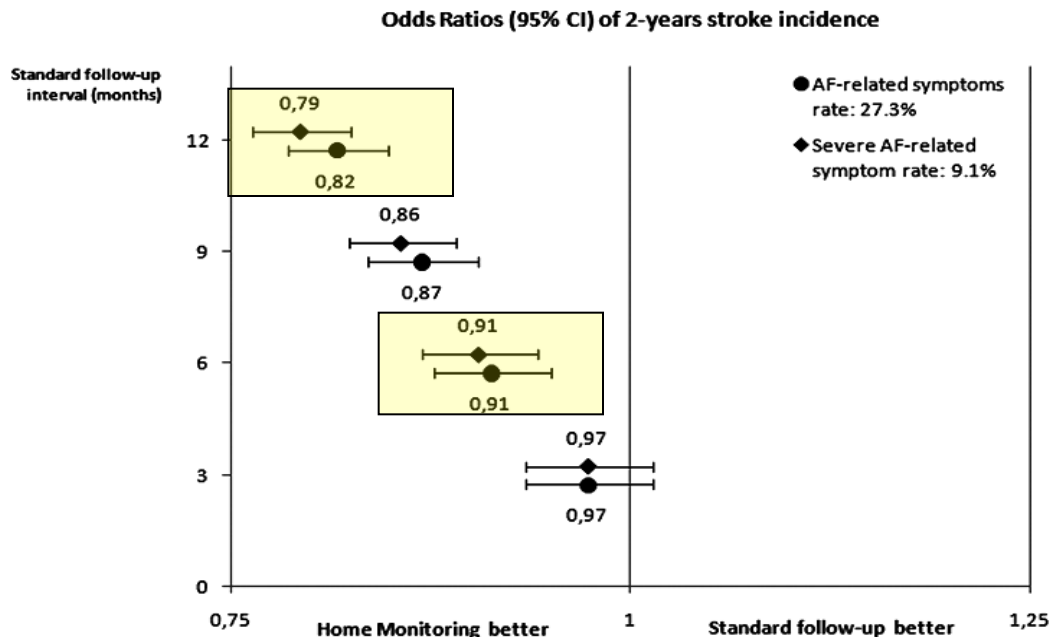


**Figure 5** Case report of a patient with recurrent paroxysmal atrial fibrillation. After an additional follow-up, antiarrhythmic drug therapy was introduced. Home Monitoring<sup>TM</sup> reports demonstrated a reduction in the number and duration of tachyarrhythmia episodes over time.

# Home Monitoring & AF management

## • STROKE RISK REDUCTION

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



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.

# Home Monitoring & AF management



- **STROKE RISK REDUCTION**

- The Home Monitoring technology provides a unique opportunity to assess the number and frequency of episodes of AF
- Mean Follow-up 370 gg
- The primary endpoint of the study was the incidence of thromboembolic events
- Registered AHRE in 40% of patients, of whom 11 (2%) developed thromboembolic complications



- **Topics**

- ✓ HomeGuide Registry
- ✓ Atrial Fibrillation management
- ✓ **Heart failure management**
- ✓ Technical issues management

- **Conclusions**



# HF Monitor<sup>®</sup>

- Daily transmission of 10 parameters for the possible prevention of failure events

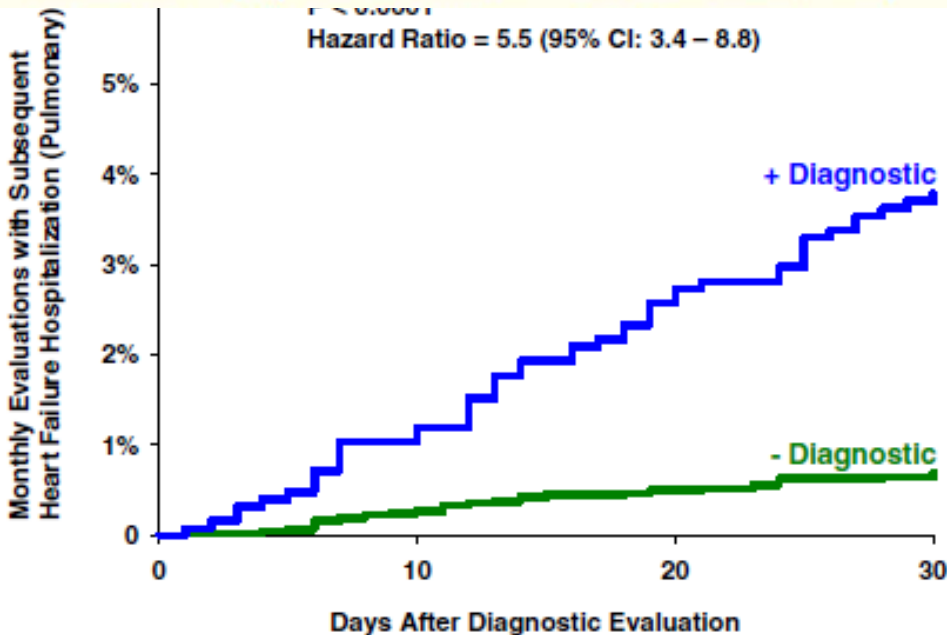
- ✓ Ventricular rate during AF
- ✓ Mean ventricular rate
- ✓ Ventricular rate at rest
- ✓ Mean atrial rate
- ✓ PVC
- ✓ AF Burden
- ✓ Activity
- ✓ SDANN
- ✓ CRT %
- ✓ Transtoracic impedance



# 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

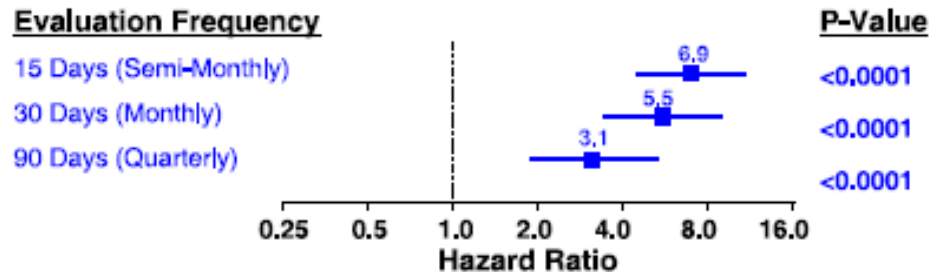


The possibility of having more diagnostic criteria combined, provide a greater ability to recognize patients who may present heart failure events.

# Home Monitoring & HF Management

## 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 observing the diagnostic parameters faster results in a greater capacity to recognize heart failure events.



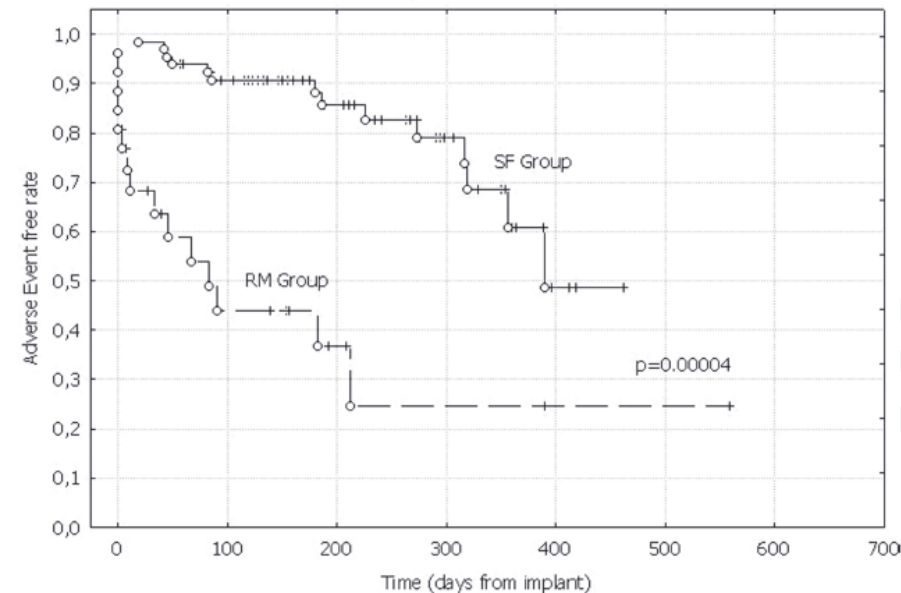
# Home Monitoring & HF Management

## 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,

### A Clinical Adverse Event

○ Complete + Censored



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)

# 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, LUCIA DE LUCA, M.D.,\* LORENZO MARIA ZUCCARO, M.D.,\* FEDERICA STIRPE, C.G. MARCO REBECCHI, M.D.,\* ANTONELLA SETTE, M.D.,\* ERNESTO LIOY, M.D.,\* and LEONARDO CALÒ, M.D.\*

Model significance: P = 0.0001 Baseline predictor	Model regression coefficient (Standard Error)	Exponential Coefficient	P
Follow-up method (RM/standard in-person visits)	1.73 (0.40)	5.67	0.00001
LVEF	-0.08 (0.02)	0.93	0.02
Gender (male/female)	-0.62 (0.55)	0.53	0.25
Age	0.01 (0.02)	1.01	0.73
Cardiomyopathy (ischemic/nonischemic)	0.19 (0.22)	1.21	0.38
NYHA class (III/IV)	0.56 (0.67)	1.74	0.41

LVEF = left ventricle ejection fraction.

The Cox proportional hazards model showed that the only two independent predictors of AEC in the 18 months of observation are the method of FU and Ejection Fraction.

*(De Ruvo, PACE 2010)*

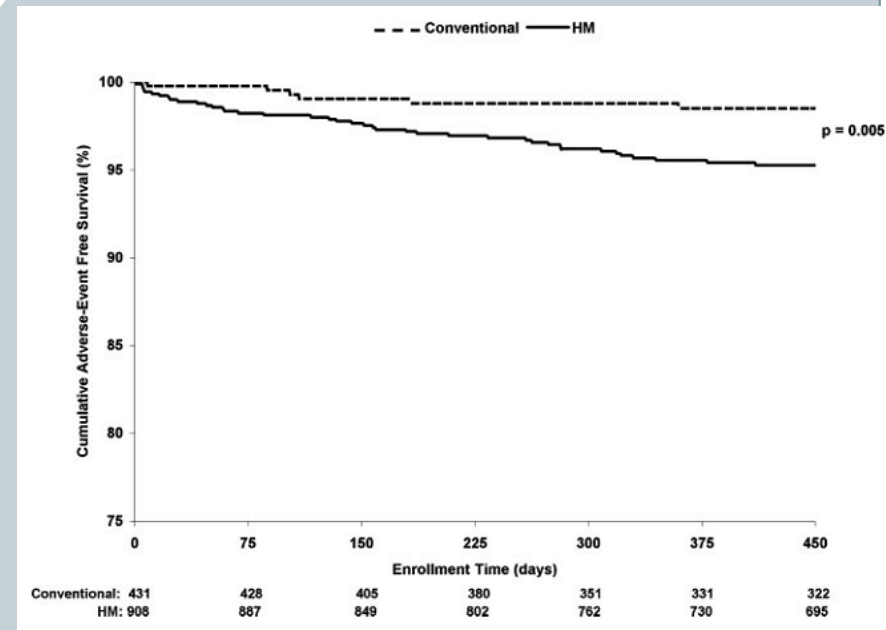


- **Topics**
  - ✓ HomeGuide Registry
  - ✓ Atrial Fibrillation management
  - ✓ Heart Failure management
  - ✓ **Technical issues management**
- Conclusions



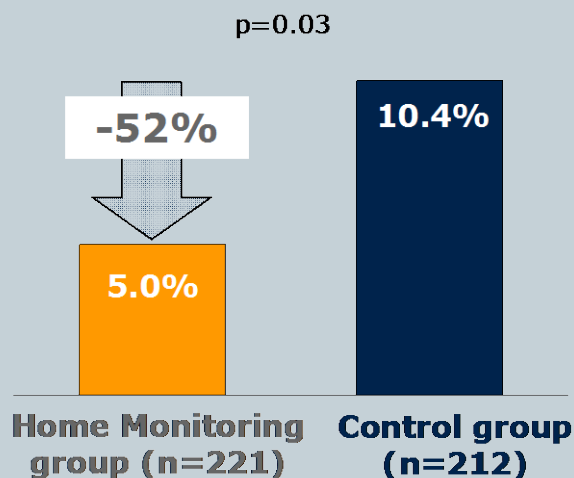
# Early detection

- Sub-analysys 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.



# Early detection

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



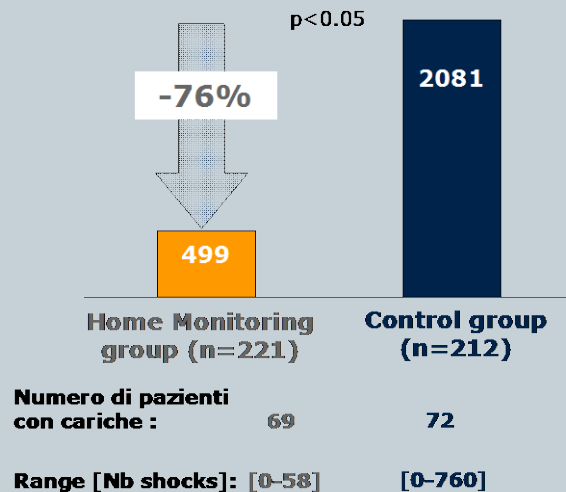
**Table 4** All shocks, inappropriate shocks, and capacitor charges observed in the intention-to-treat population

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

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

# Early detection

- **ECOST Study (ICD)**
- **Endpoint : SAFETY**
  - ✦ Safety is comparable in the two groups
- **Secondary endpoint:**
  - ✦ Reduction in appropriate and inappropriate shocks
  - ✦ Reduction in ICD capacitors charge



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

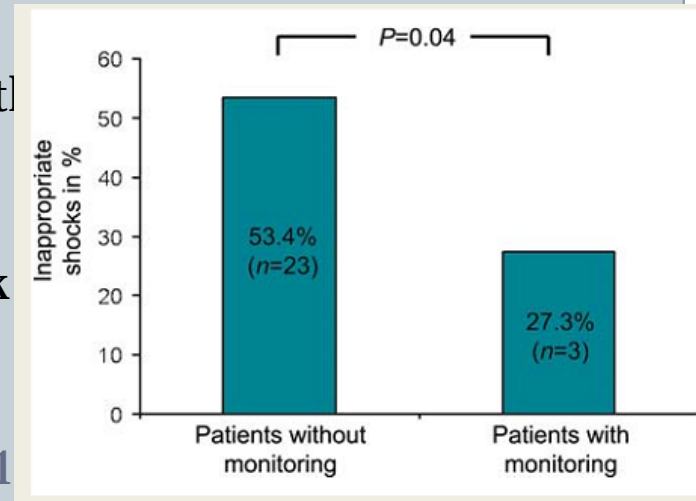
	Study groups		P
	Active (n = 221)	Control (n = 212)	
Appropriate and inappropriate shocks delivered	193 [0–33]	657 [0–116]	
Patients with $\geq 1$ delivered shock	47 (21.3)	56 (26.4)	0.21
Mean per patient-month	$0.04 \pm 0.27$	$0.20 \pm 1.13$	0.02
Inappropriate shocks delivered	28 [1–8]	283 [1–82]	
Patients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

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

# Early detection



- 54 ICD patients underwent to revision surgery due to the malfunctioning of the ventricular catheter (43 HM OFF vs 11 HM ON)
- The authors analyzed the data received from Biotronik HM system:
  - The diagnosis of complications associated with transvenous defibrillation was possible in 10/11 (91 cases thanks to an alert system HM \*
  - The automatic monitoring system of HM allows early detection of problems related to catheters and react quickly to avoid inappropriate therapy





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

# Conclusions



- Daily reporting of all parameters, with dedicated programmable alarms, highlights a unique ability to early detection of clinical and technical events (arrhythmias and heart).
- The easy use of the system leads to a reduction in workload without compromising patient safety.

# 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.

