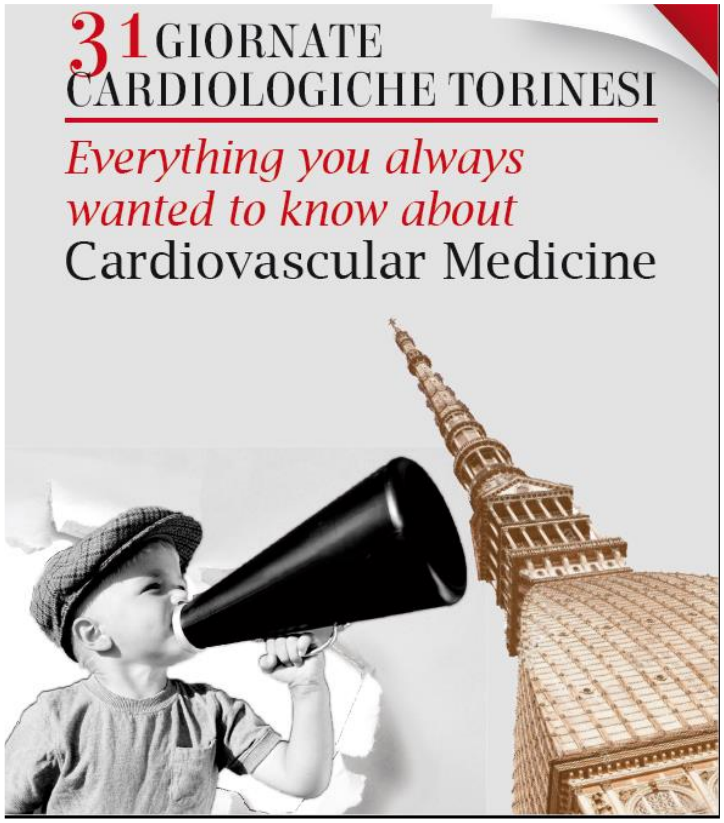


Remote Monitoring for Implantable cardiac device

Gabriele Zanotto, MD
"Mater Salutis" Hospital, Legnago (Verona), Italy

Disclosure of my Personal Conflicts of Interest

Consulting activity with Boston Scientific, Biotronik, Abbott.

Reports in sessions sponsored by Pfeizer, Boeringher, Novartis.

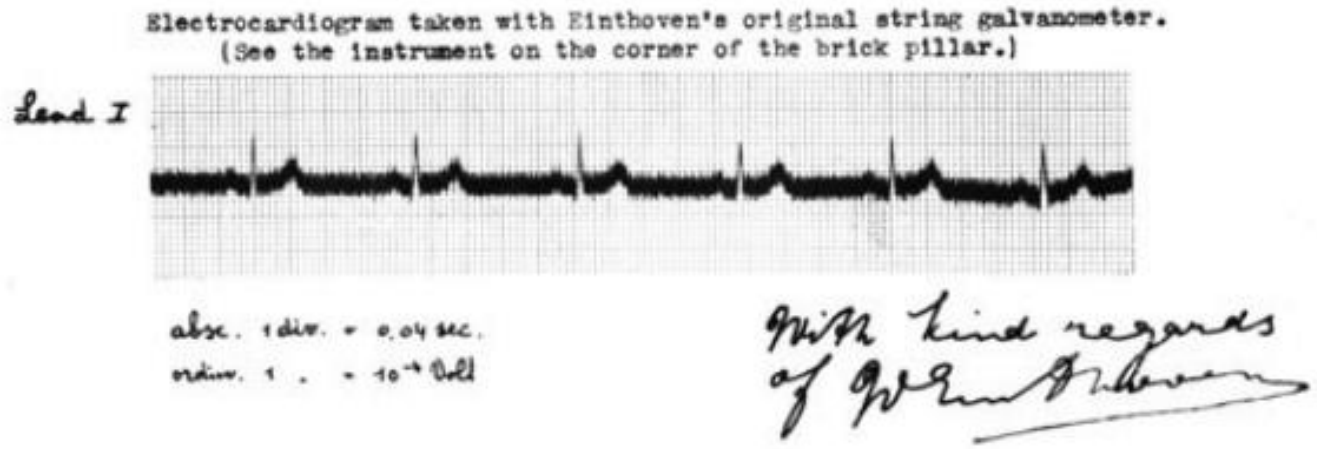
Summary

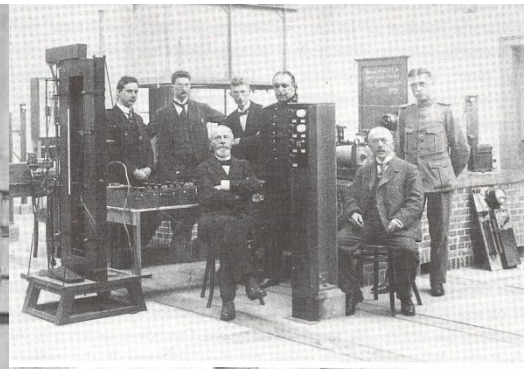
- History
- Remote Interrogation vs Remote Monitoring
- Device Surveillance, Shock Reduction, Optimization of Device Longevity
- Disease Management (Atrial Fibrillation, Heart Failure)
- Timing of IPE, RM and RI
- Organizational Model and Responsibilities of Patients, Physicians, Allied Professionals, Manufactorers
- Legal and Privacy Considerations
- Conclusion.

Summary

- **History**
- Remote Interrogation vs Remote Monitoring
- Device Surveillance, Shock Reduction, Optimization of Device Longevity
- Disease Management (Atrial Fibrillation, Heart Failure)
- Timing of IPE, RM and RI
- Organizational Model and Responsibilities of Patients, Physicians, Allied Professionals, Manufactorers
- Legal and Privacy Considerations
- Conclusion.

First Tele-ECG worldwide

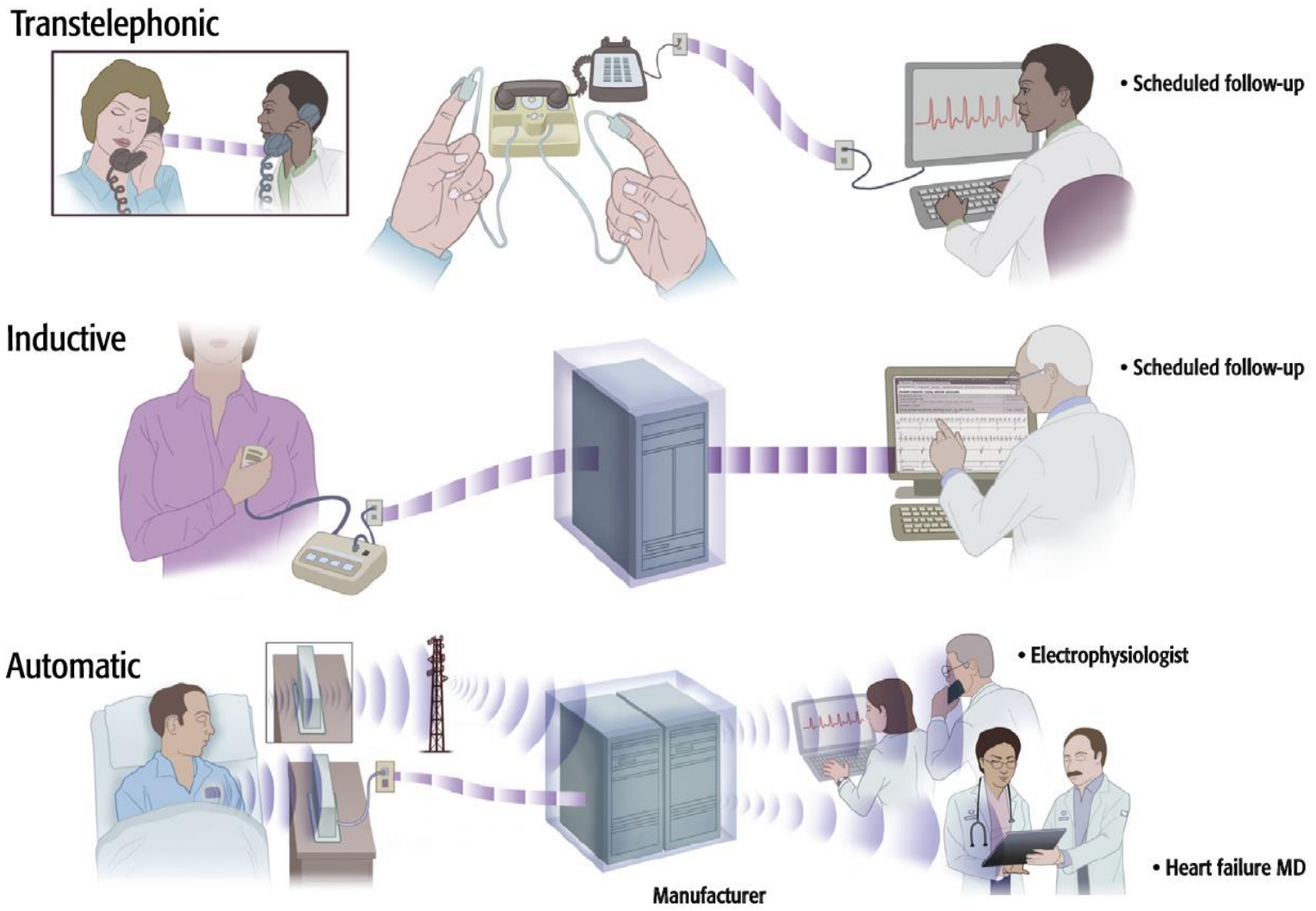




22 March 1905 : Wilhelm Einthoven fixed an electrocardiogram and phonocardiogram on a volunteer, his own assistant C.J.de Jongh (see photo). This data was transmitted via insulated cable between Academic Hospital in Leiden and Einthoven's Physiological laboratory (at distance 1500 meters). The Technical realization was performed by professor Johannes Bosscha (director of Polytechnic School in Delft)

Einthoven W. : Le Telecardiogramme // Archives Internationales Physiologie.-Vol. IV.-1906.-P.132-164.

Evolution of RM Technology



Europace (2008) 10, 707–725
doi:10.1093/europace/eun122

HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations

Developed in partnership with the Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA); and in collaboration with the American College of Cardiology (ACC), the American Heart Association (AHA), the European Society of Cardiology (ESC), the Heart Failure Association of ESC (HFA), and the Heart Failure Society of America (HFSA). Endorsed by the Heart Rhythm Society, the European Heart Rhythm Association (a registered branch of the ESC), the American College of Cardiology, the American Heart Association

Heart Rhythm, Vol 12, No 7, July 2015

HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices

David Slotwiner, MD, FHRS, FACC (Chair),[1,#] Niraj Varma, MD, PhD, FRCP (Co-chair),[2,#] Joseph G. Akar, MD, PhD,[3] George Annas, JD, MPH,[4] Marianne Beardsall, MN/NP, CCDS, FHRS,[5] Richard I. Fogel, MD, FHRS,[6] Nestor O. Galizio, MD,[7*] Taya V. Glotzer, MD, FHRS, FACC,[8] Robin A. Leahy, RN, BSN, CCDS, FHRS,[9] Charles J. Love, MD, CCDS, FHRS, FACC, FAHA,[10] Rhondalyn C. McLean, MD,[11†] Suneet Mittal, MD, FHRS,[12] Loredana Morichelli, RN, MSN,[13] Kristen K. Patton, MD,[14‡] Merritt H. Raitt, MD, FHRS,[15] Renato Pietro Ricci, MD,[13§] John Rickard, MD, MPH,[16] Mark H. Schoenfeld, MD, CCDS, FHRS, FACC, FAHA,[17] Gerald A. Serwer, MD, FHRS, FACC,[18‖] Julie Shea, MS, RNCS, FHRS, CCDS,[19] Paul Varosy, MD, FHRS, FACC, FAHA,[20] Atul Verma, MD, FHRS, FRCPC,[5] Cheuk-Man Yu, MD, FACC, FRCP, FRACP[21¶]

Summary

- History
- **Remote Interrogation vs Remote Monitoring**
- Device Surveillance, Shock Reduction, Optimization of Device Longevity
- Disease Management (Atrial Fibrillation, Heart Failure)
- Timing of IPE, RM and RI
- Organizational Model and Responsibilities of Patients, Physicians, Allied Professionals, Manufactorers
- Legal and Privacy Considerations
- Conclusion.

Remote Interrogation vs Remote Monitoring

RI refers to routine, scheduled, remote device interrogations structured to mirror in-office checkups.[4,5] Practically all information obtained during an in-office device checkup can now be obtained remotely. An important exception to this is the data for measuring the pacing capture threshold, which is available only for devices capable of automatically measuring the capture threshold.

RM refers to the automated transmission of data based on prespecified alerts related to device functionality and clinical events.[4] This provides the ability for rapid detection of abnormal device function and/or arrhythmia events.[6,7]

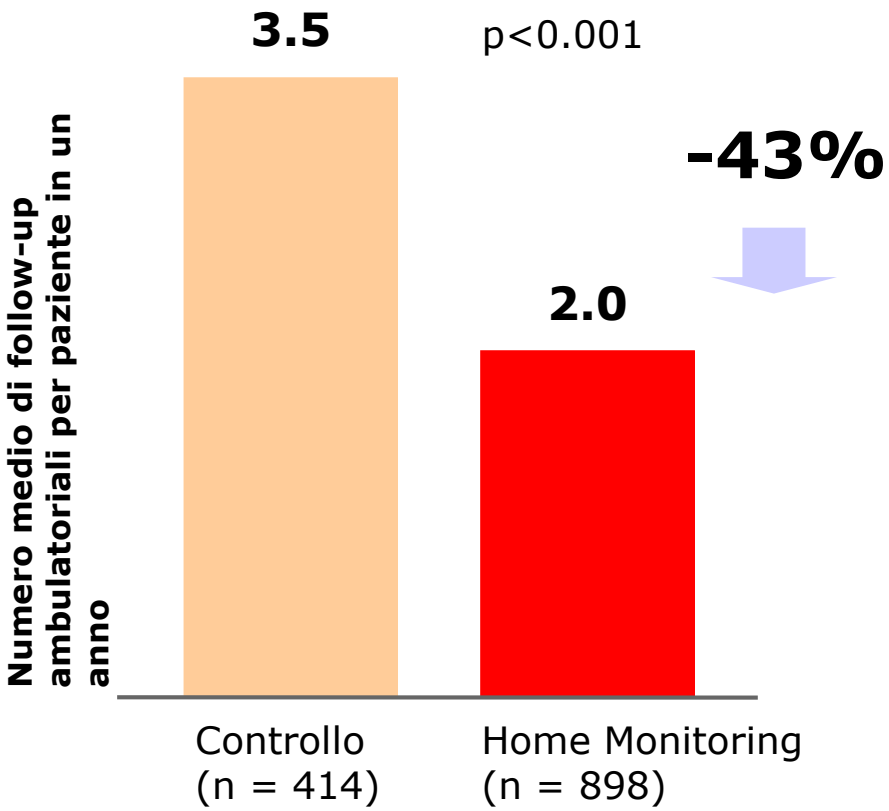
clinic workflow efficiency. The advent of automatic wireless RM has been critical to these results, a change in paradigm that forms the basis of new recommendations.

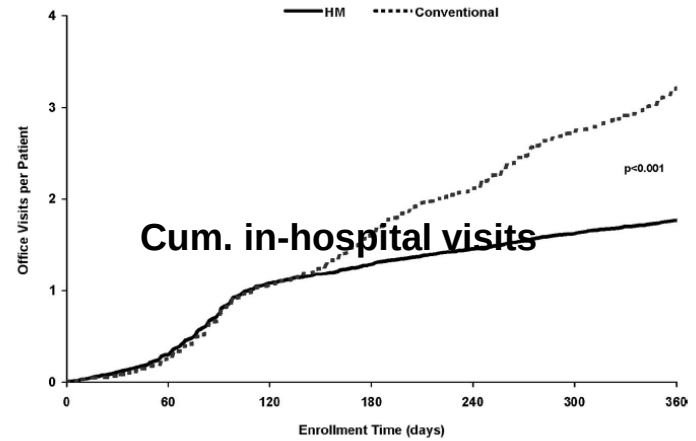
Summary

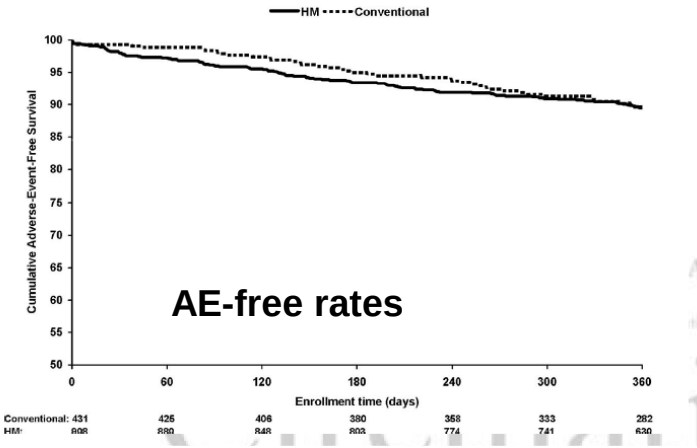
- History
- Remote Interrogation vs Remote Monitoring
- **Device Surveillance, Shock Reduction, Optimization of Device Longevity**
- Disease Management (Atrial Fibrillation, Heart Failure)
- Timing of IPE, RM and RI
- Organizational Model and Responsibilities of Patients, Physicians, Allied Professionals, Manufactorers
- Legal and Privacy Considerations
- Conclusion.

TRUST trial: In hospital follow-up reduction

Mean number of in-hospital follow-up per patient per year

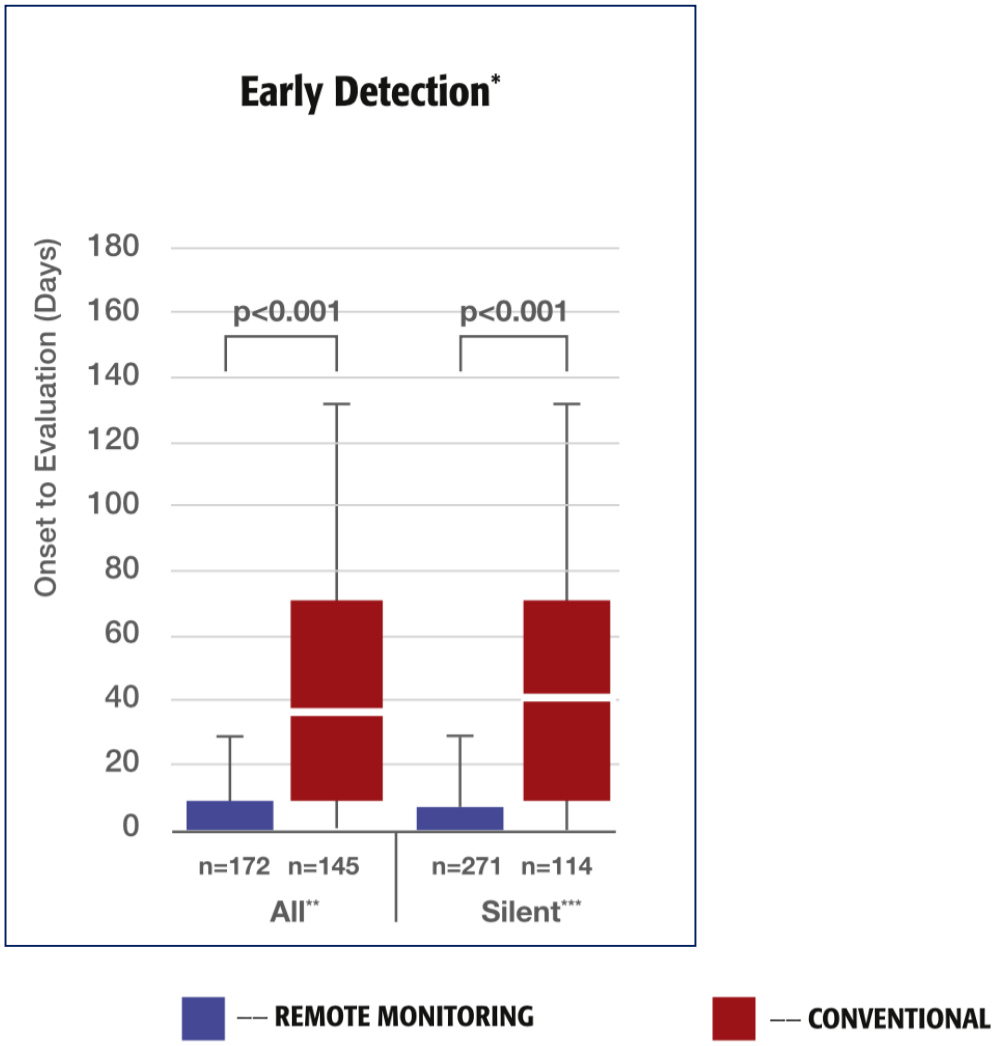






Varma N et al Circulation 2010, Jul 12

TRUST trial: event early detection



Varma N et. al. Efficacy and Safety of Automatic Remote Monitoring for Implantable Cardioverter-Defibrillator Follow-Up: The Lumos-T Safely Reduces Routine Office Device Follow-Up (TRUST) Trial. Circulation. 2010;122(4):325-32

Europace Advance Access published January 29, 2013

Europace
doi:10.1093/europace/eus440

CLINICAL RESEARCH

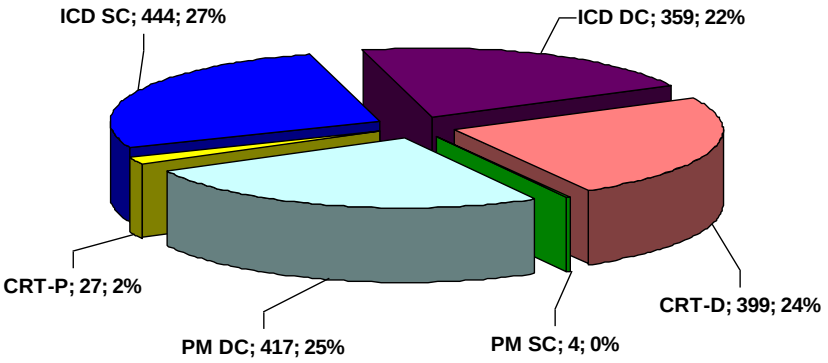
Effectiveness of remote monitoring of CIEDs in detection and treatment of clinical and device-related cardiovascular events in daily practice: the HomeGuide Registry

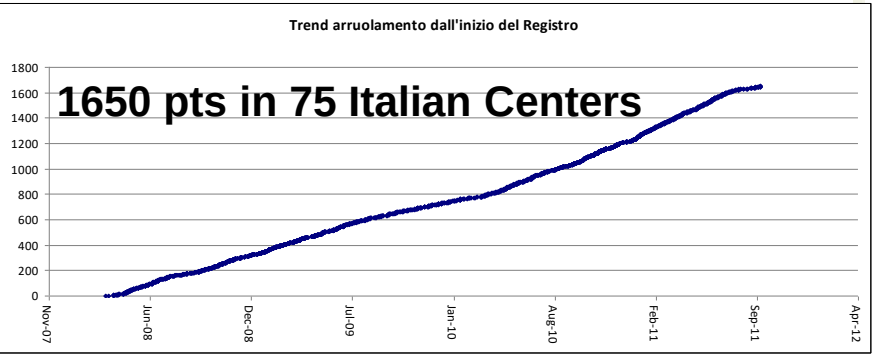
Renato Pietro Ricci[1]*, Loredana Morichelli[1], Antonio D'Onofrio[2], Leonardo Calò[3], Diego Vaccari[4], Gabriele Zanotto[5], Antonio Curnis[6], Gianfranco Buja[7], Nicola Rovai[8], and Alessio Gargaro[8]

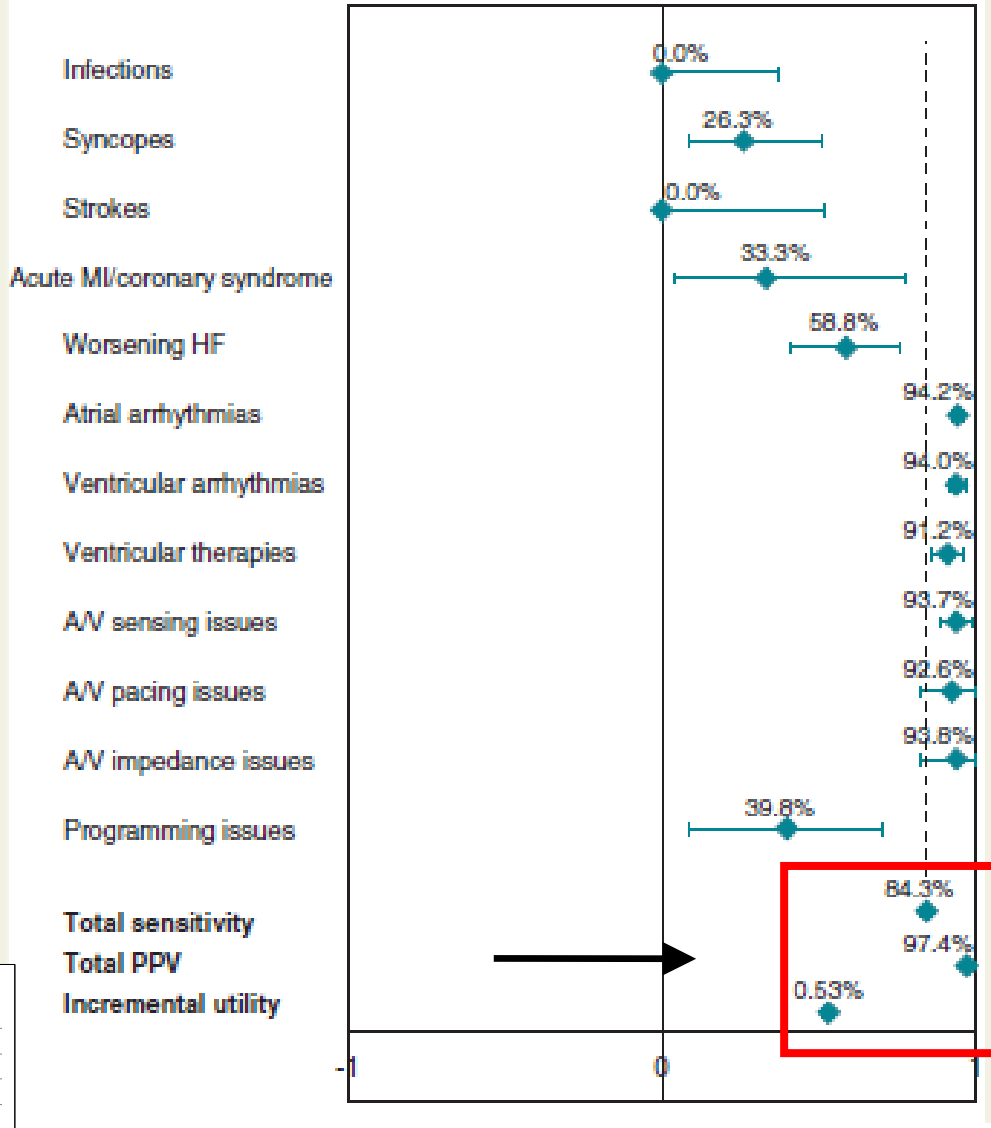
[1]Department of Cardiology, San Filippo Neri Hospital, via Martinotti 20, 00135 Rome, Italy; [2]UOSD Electrophysiology, Vincenzo Monaldi Hospital, Via L. Bianchi, 80131 Naples, Italy; [3]Department of Cardiology, Casilino Hospital, Via Casilina 1049, 00169 Rome, Italy; [4]Department of Cardiology, Civil Hospital, Via Togliatti 1, 31044 Montebelluna, Italy; [5]UOC Cardiology, Mater Salutis Hospital, Via Gianella 1, 37045 Legnago, Italy; [6]Electrophysiology, Spedali Civili, P.le Spedali Civili 1, 25123, Brescia, Italy; [7]Department of Cardiac Thoracic and Vascular Sciences, University of Padua, Via G. Nicolò 50, 35128 Padua, Italy; and [8]Clinical Office, Biotronik Italia S.p.a., V.le delle Industrie 11, 20900 Vimodrone (MI), Italy

Received 22 October 2012; accepted after revision 24 December 2012

Dispositivi impiantati



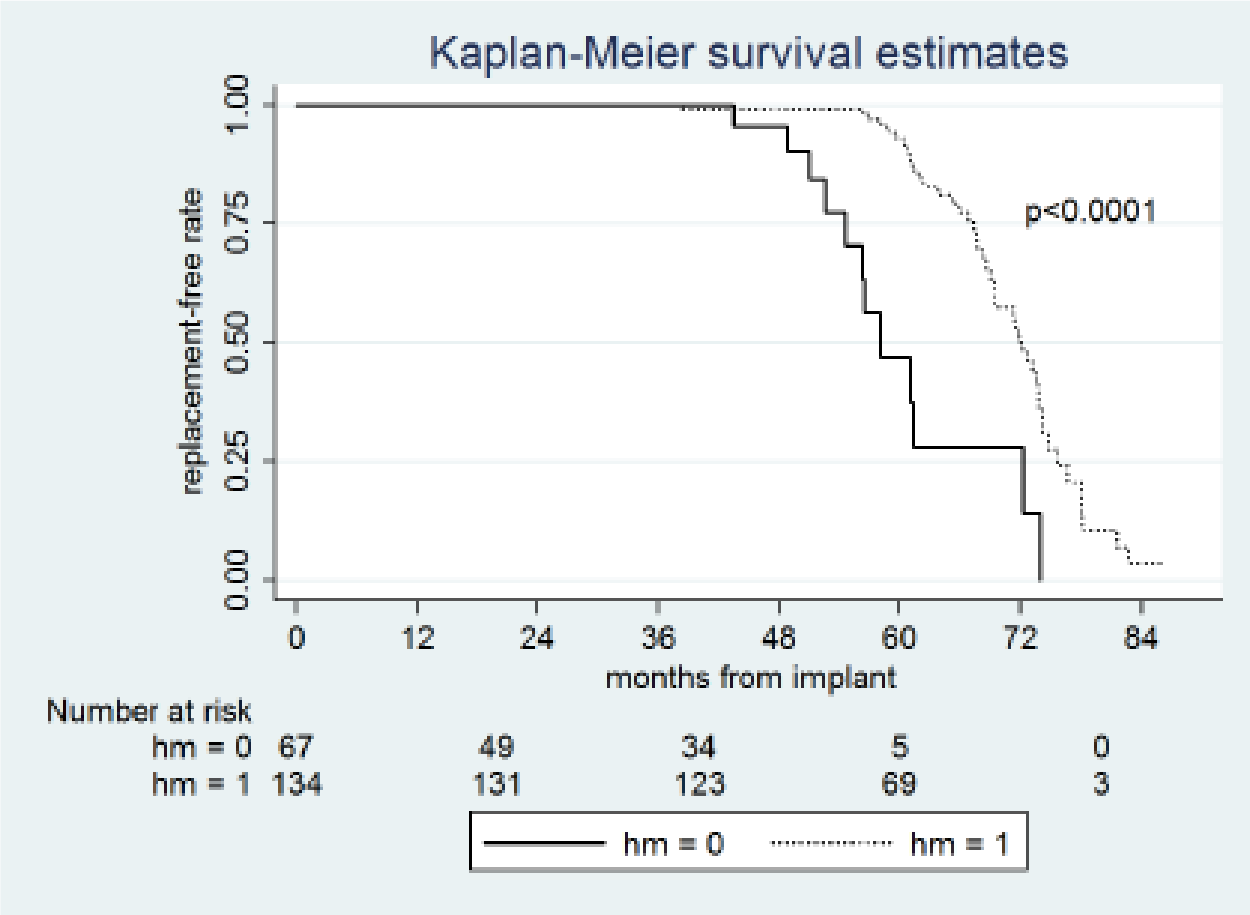




94% of asymptomatic events and 73% of actionable events detected by RM

Kaplan-Meier plots of time to device replacement due to battery depletion

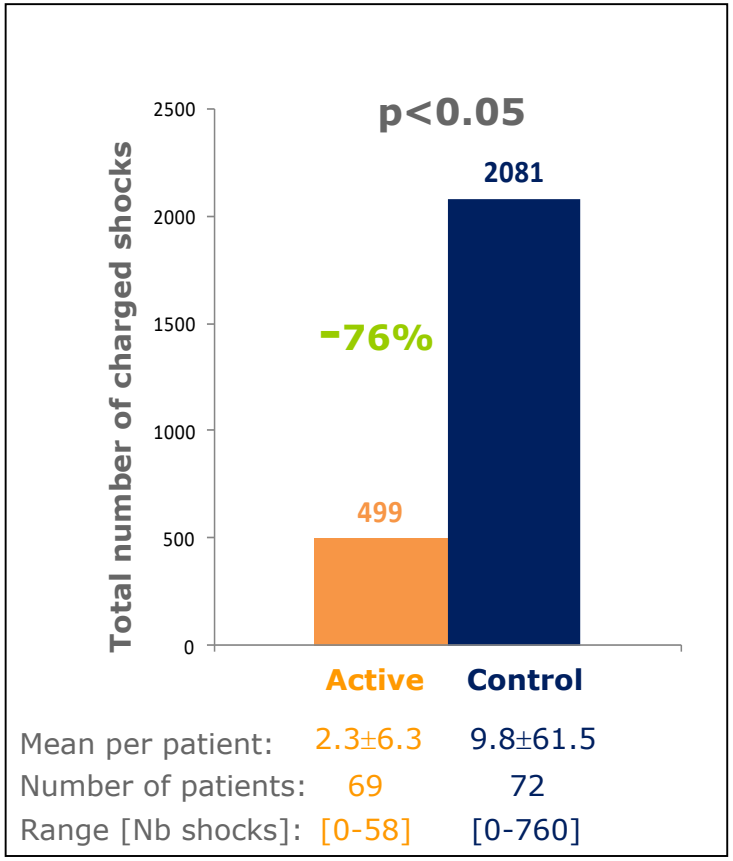
201 patients implanted with Cylos DR-T pacemaker

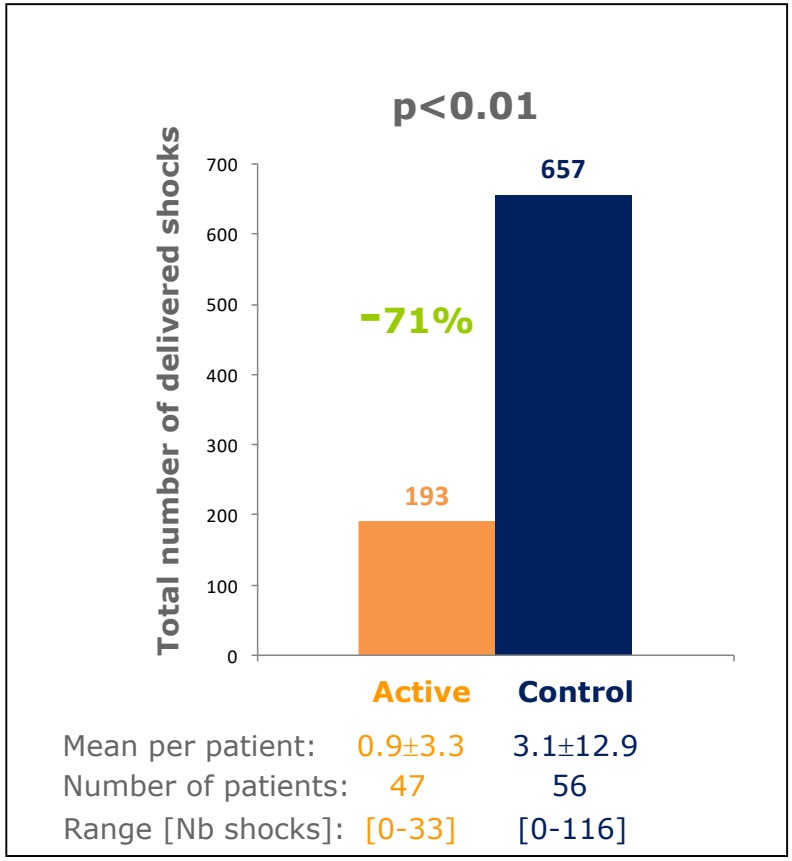


hm=0: Home Monitoring off; hm=1: Home Monitoring on.

Ricci RP et al Heart Rhythm 2015 Feb;12(2):330-7

ECOST trial: inappropriate shock reduction





52% reduction in inappropriate shocks

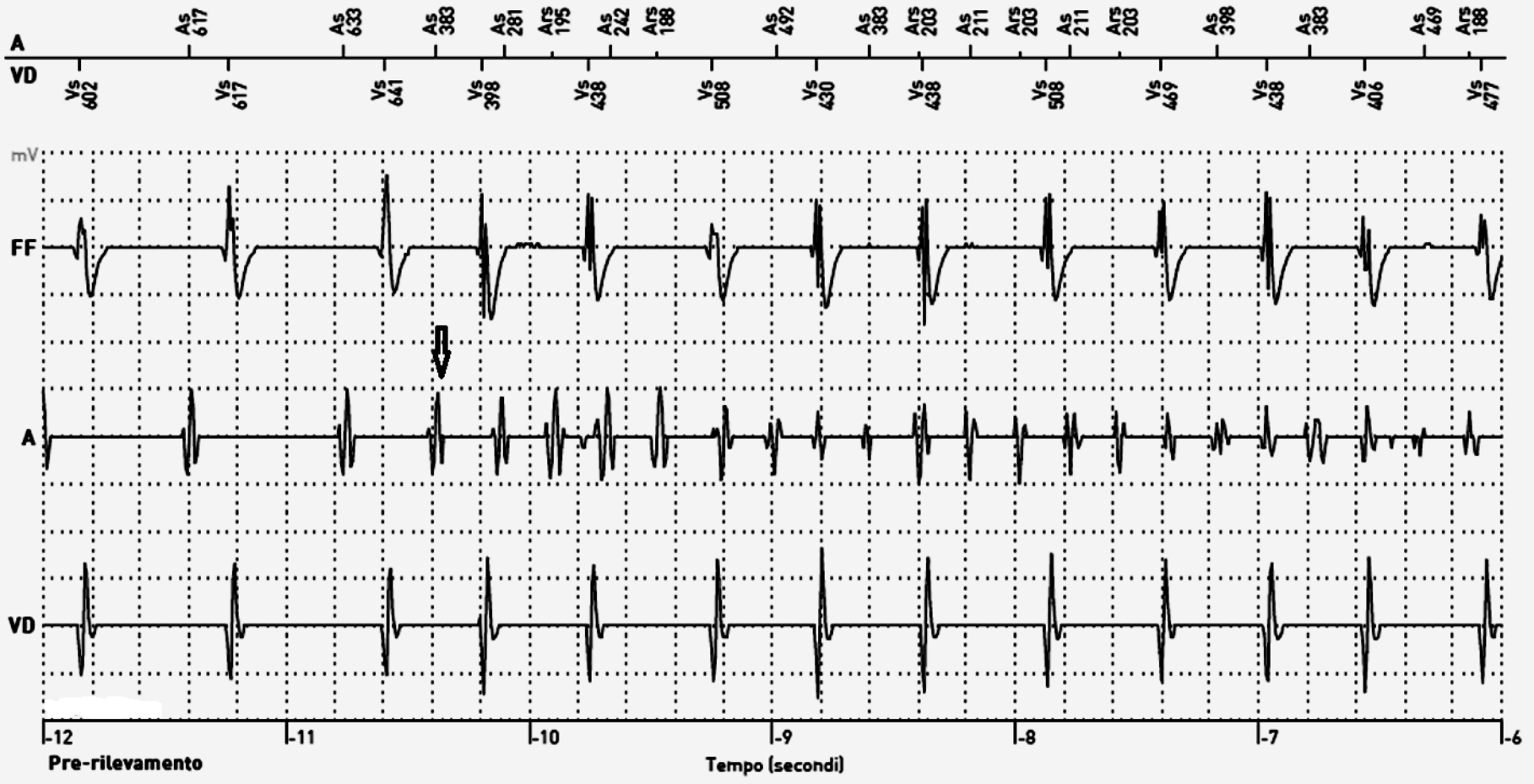
72% reduction of hospitalizations for inappropriate shocks

Guedon-Moreau L, et al. A randomized study of remote follow-up of implantable cardioverter defibrillators: safety and efficacy report of the ECOST trial. Eur Heart J. 2012;34(8):605-14.

Summary

- History
- Remote Interrogation vs Remote Monitoring
- Device Surveillance, Shock Reduction, Optimization of Device Longevity
- **Disease Management (Atrial Fibrillation, Heart Failure)**
- Timing of IPE, RM and RI
- Organizational Model and Responsibilities of Patients, Physicians, Allied Professionals, Manufactorers
- Legal and Privacy Considerations
- Conclusion.

HM - AF detection

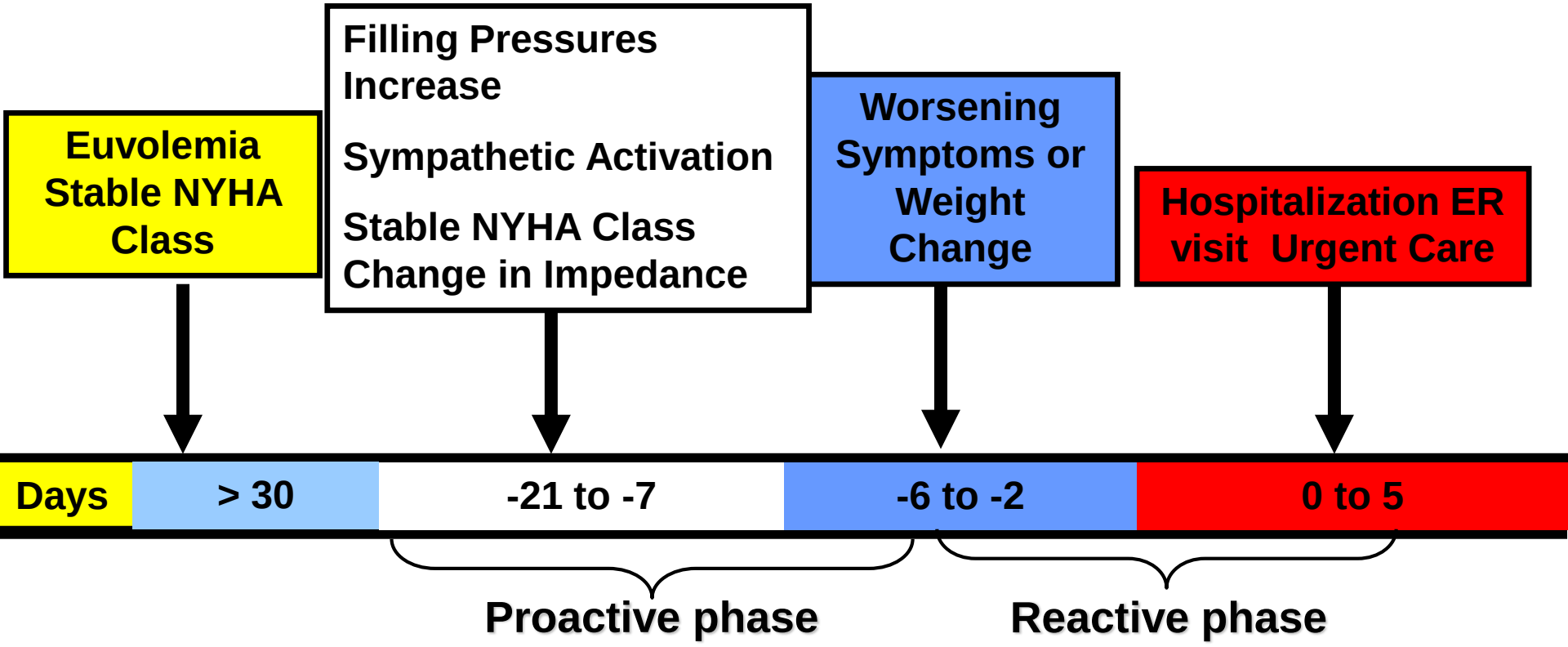


Benefits of AF early detection

- Early anticoagulation
- Antiarrhythmic drug treatment optimization
- Timely electrical cardioversion
- Rate control monitoring
- Ablation procedure scheduling (including AVN)
- Heart failure prevention
- Inappropriate shock prevention

Acute HF event prevention

Pulmonary congestion is difficult to recognize in its early stages of development because of the late appearance of symptoms before hospitalization.

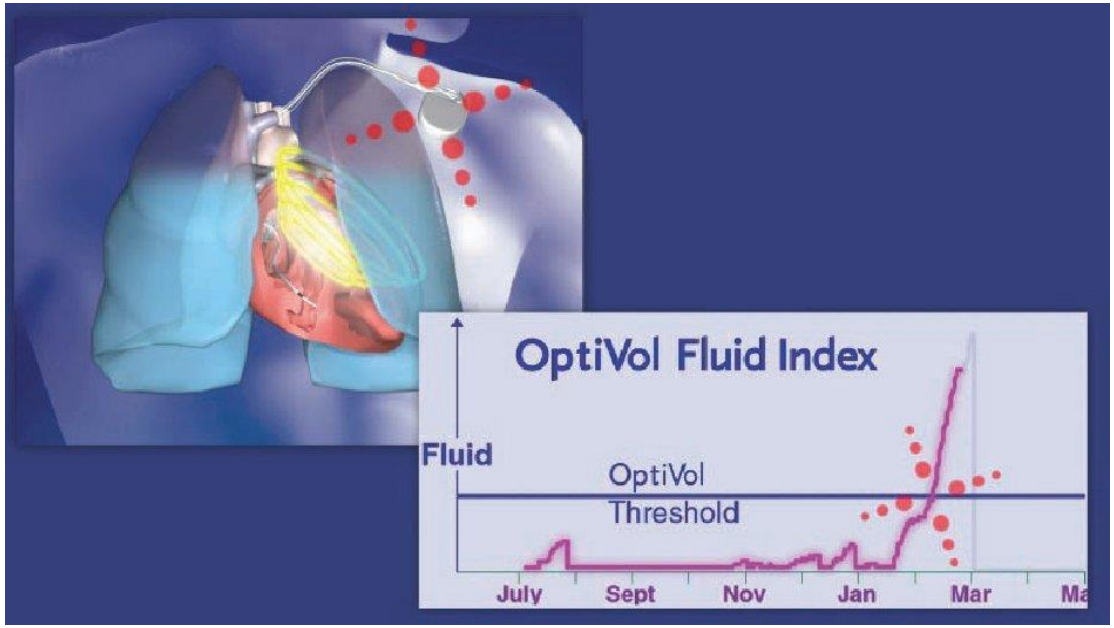


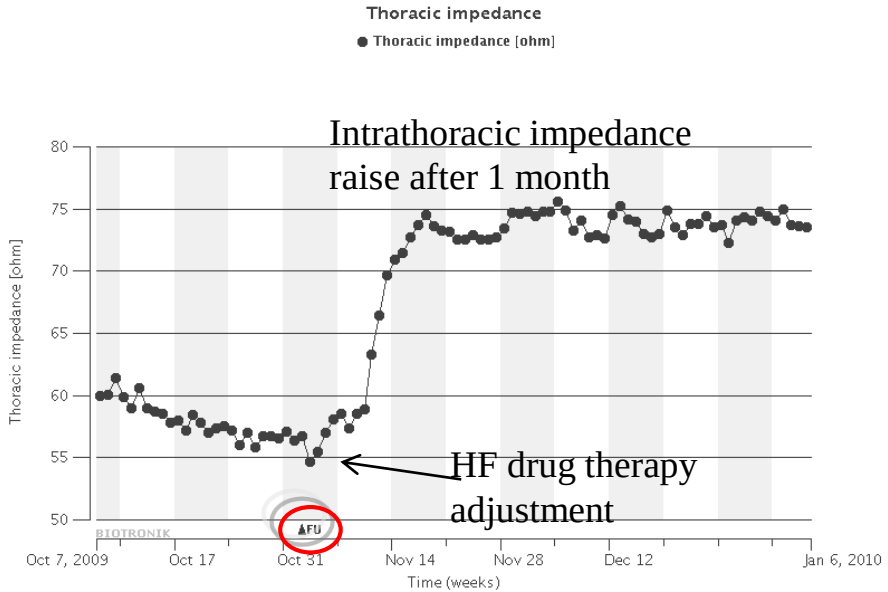
B. Adamson, 2006 Supp Card. Medicine

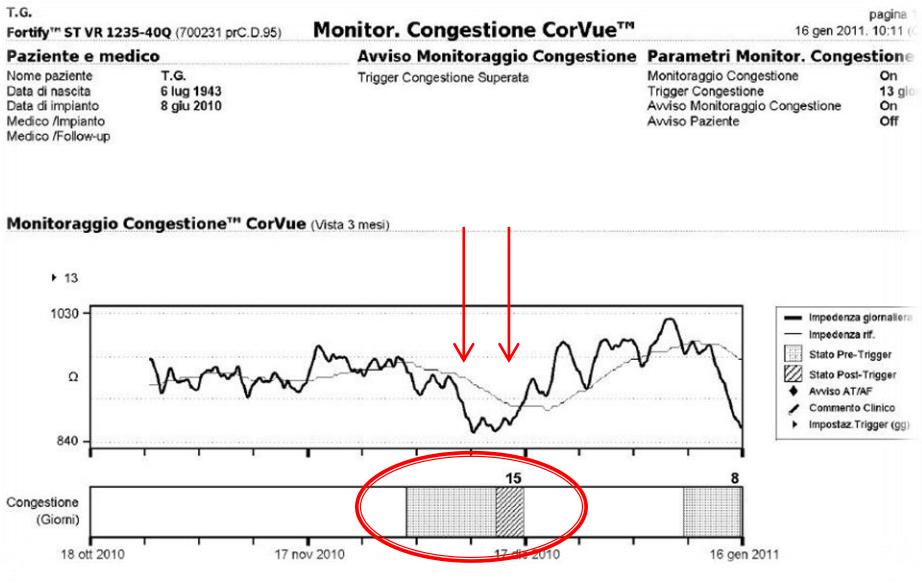
HF Longitudinal Indicators

Mean Heart Rate	⇨	**1.8% increased risk of wHF per 1 bpm increase of mean heart rate**
Atrial Arrhythmias	⇨	**Well assessed predictor of wHF**
PVC frequency	⇨	**Associated with 5.5-fold increased risk of cardiovascular death**
Exercise and daily activity	⇨	**Inability to maximal exercise for at least 4 minutes predicts death and wHF**
Heart Rate variability	⇨	**HRV reduction is associated with wHF**
Thoracic Impedance	⇨	**60% PPV (wHF)**
Ventricular Pacing Percentage	⇨	**As high as possible in CRT as low as possible in single / dual chamber ICD**

Intrathoracic Impedance







Disease Management
Heart Failure

JACC: HEART FAILURE
VOL. 5, NO. 3, 2017

ISSN 2213-1779
http://dx.doi.org/10.1016/j.jchf.2016.12.011

A Multisensor Algorithm Predicts Heart Failure Events in Patients With Implanted Devices

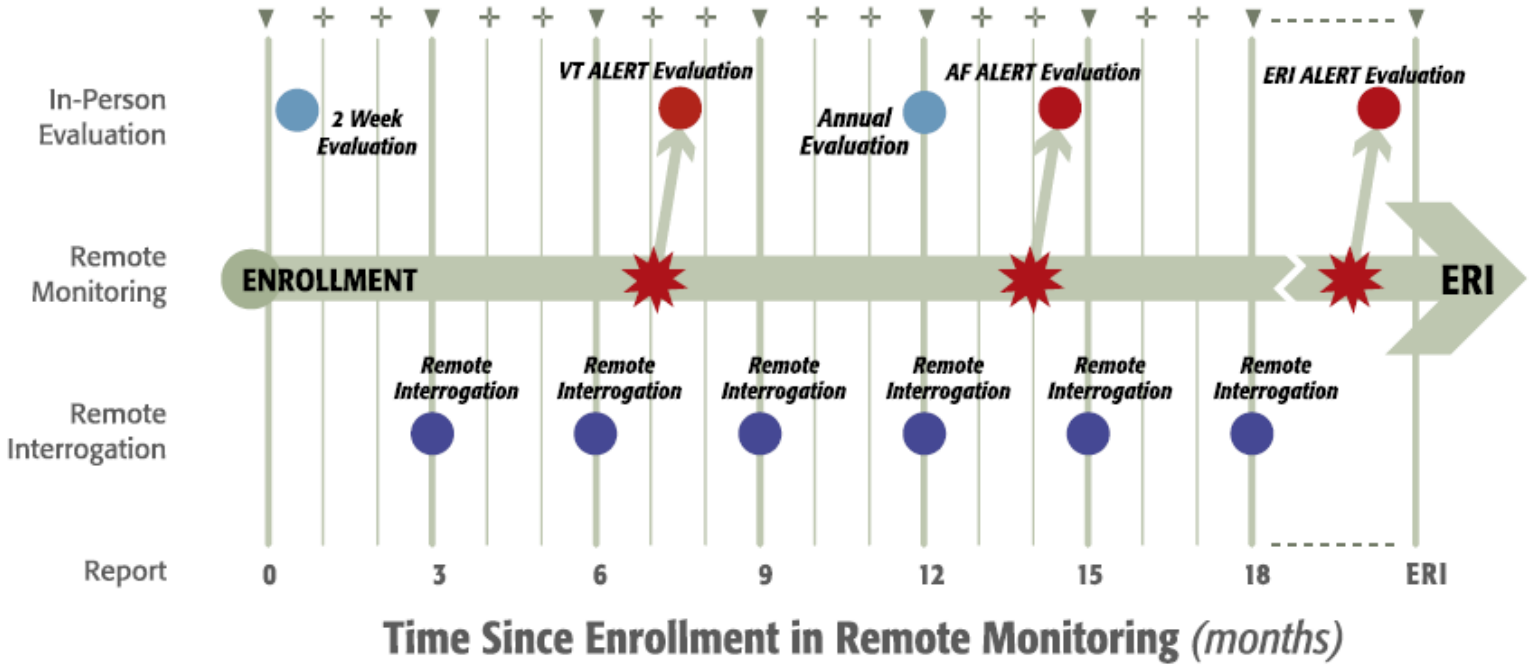
Results From the MultiSENSE Study

John P. Boehmer, MD,[a] Ramesh Hariharan, MD,[b] Fausto G. Devecchi, MD,[c] Andrew L. Smith, MD,[d] Giulio Molon, MD,[e] Alessandro Capucci, MD,[f] Qi An, PhD,[g] Viktoria Averina, PhD,[g] Craig M. Stolen, PhD,[g] Pramodsingh H. Thakur, PhD,[g] Julie A. Thompson, PhD,[g] Ramesh Wariar, PhD,[g] Yi Zhang, PhD,[g] Jagmeet P. Singh, MD, DPhil[h]

Summary

- History
- Remote Interrogation vs Remote Monitoring
- Device Surveillance, Shock Reduction, Optimization of Device Longevity
- Disease Management (Atrial Fibrillation, Heart Failure)
- **Timing of IPE, RM and RI**
- Organizational Model and Responsibilities of Patients, Physicians, Allied Professionals, Manufactorers
- Legal and Privacy Considerations
- Conclusion.

Timing of In-Person Evaluation, Remote Monitoring, Remote Interrogation



* Any wireless PM, ICD, CRT device with auto thresholds and auto-sensing algorithms
▼ Interim report generation & communication with other health care providers, including heart failure data
✛ Interim (monthly) remote monitoring heart failure report

ABBREVIATIONS: AF = atrial fibrillation; CHF = congestive heart failure; ERI = elective replacement indicator.

Figure 3 Event-based model of cardiac implantable electronic device follow-up.

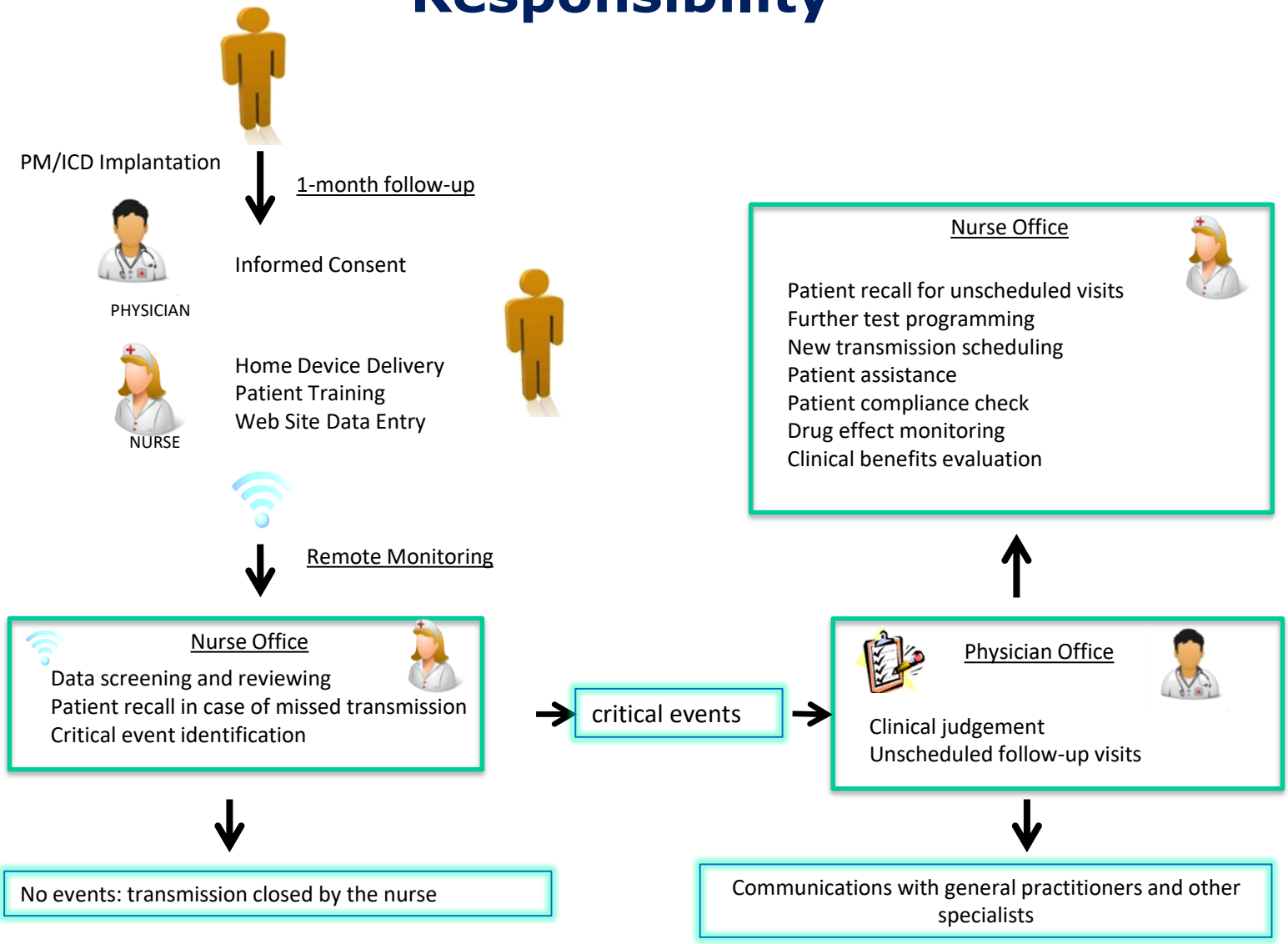
Summary

- History
- Remote Interrogation vs Remote Monitoring
- Device Surveillance, Shock Reduction, Optimization of Device Longevity
- Disease Management (Atrial Fibrillation, Heart Failure)
- Timing of IPE, RM and RI
- **Organizational Model and Responsibilities of Patients, Physicians, Allied Professionals, Manufactorers**
- Legal and Privacy Considerations
- Conclusion.

Patients Resposibilities

Patient enrollment represents a crucial point for the medical team to establish a clear and open strategy for communicating with patients and their caregivers and providing detailed information on the benefits and limitations of RM. A frequently misunderstood limitation of RM is its inability to act as an emergency response system. Patients and caregivers should be made aware that there is a delay between an episode or alert and the transmission of that alert to the CIED clinic. The CIED clinical organizational model should also not be constructed to immediately interpret and act on alerts, but rather it should do so within an acceptable time frame (such as the next business day).

Organizational Model and CIEDs Team Responsibility



Ricci et al.: Europace (2013)15;i49-i53

Organizational Model, the «Network» Model

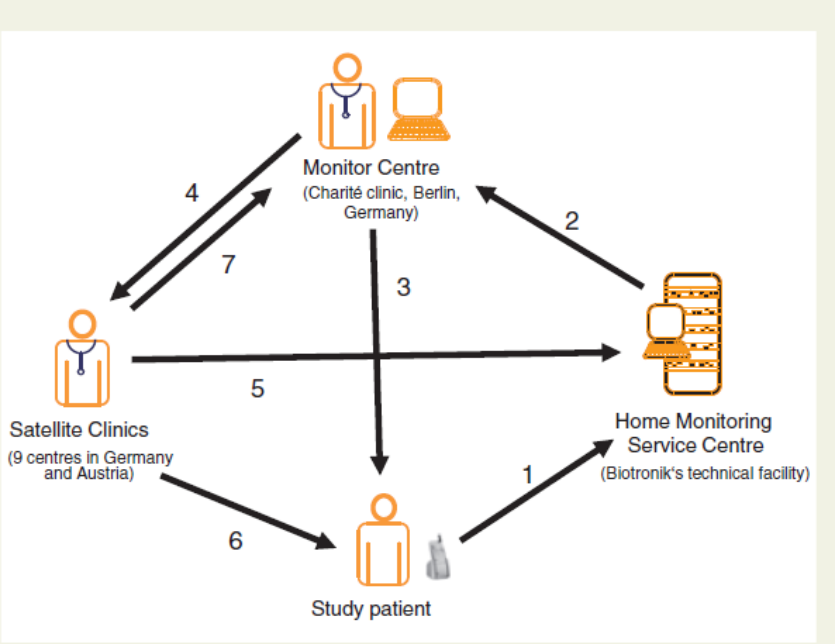
Europace Advance Access published November 9, 2012

Europace
doi:10.1093/europace/eus252

CLINICAL RESEARCH

Workload and usefulness of daily, centralized home monitoring for patients treated with CIEDs: results of the MoniC (Model Project Monitor Centre) prospective multicentre study

Thomas Vogtmann[1,8*], Sascha Stiller[2], Andrea Marek[1], Stefanie Kespohl[3], Michael Gomer[4], Volker Kühlkamp[5], Göran Zach[6], Steffen Löscher[7], and Gert Baumann[1]



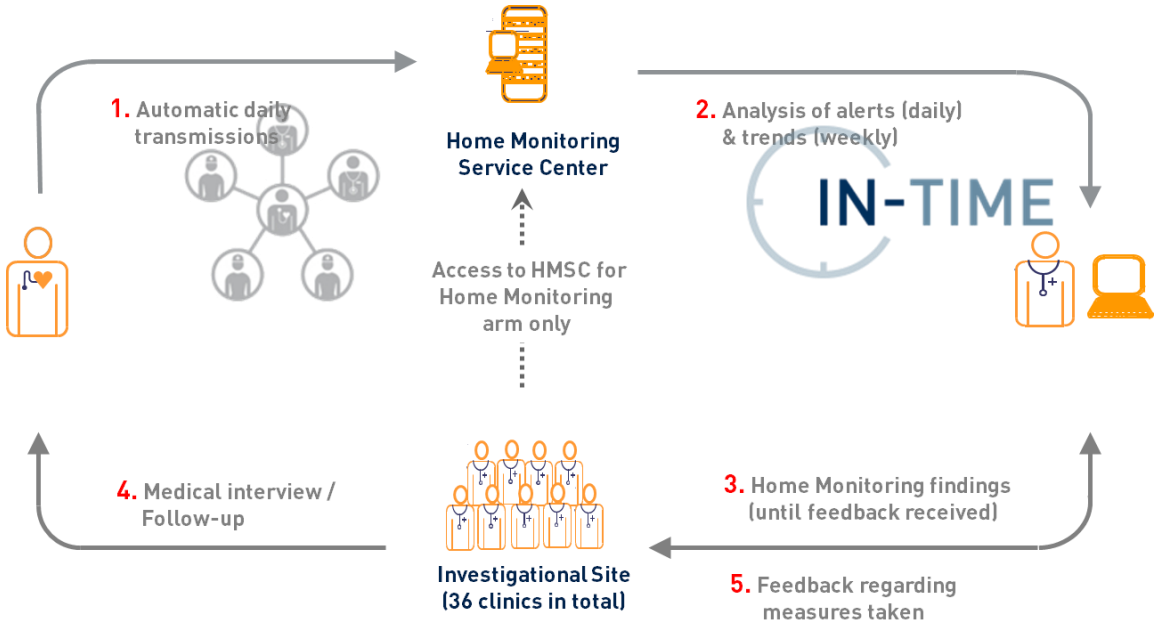
European Heart Journal (2016) 37, 2129–2200
doi:10.1093/eurheartj/ehw128

ESC GUIDELINES

2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)

Multiparameter monitoring based on ICD (IN-TIME approach) may be considered in symptomatic patients with HFrEF (LVEF ≤35%) in order to improve clinical outcomes.	IIb	B

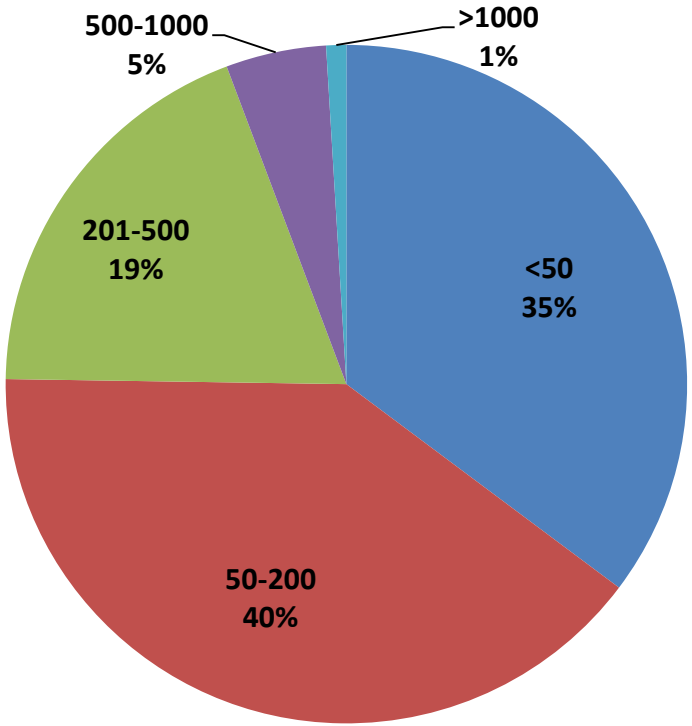


CIED Industry Responsibility

CIED manufacturers play a critical role in developing RI and RM technology and ensuring that adequate evidence is gathered to support the safety and effectiveness of the technology. The collected data includes proprietary industry

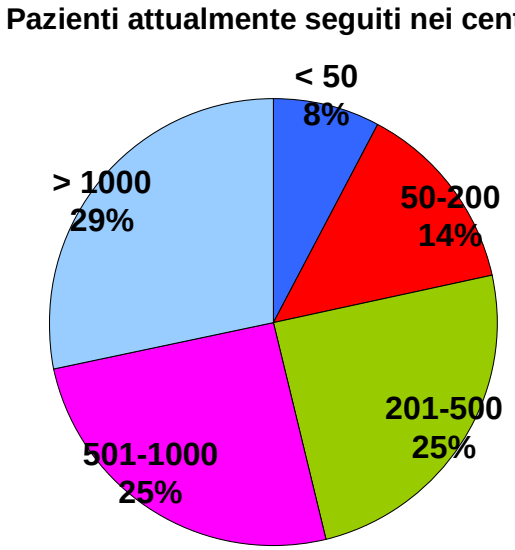
SURVEY AIAC 2012

Pazienti attualmente seguiti nei centri



> 200 = 25%
> 500 = 6%
> 1000 = 1%

SURVEY AIAC 2016



> 200 = 79%
> 500 = 54%
> 1000 = 29%

Summary

- History
- Remote Interrogation vs Remote Monitoring
- Device Surveillance, Shock Reduction, Optimization of Device Longevity
- Disease Management (Atrial Fibrillation, Heart Failure)
- Timing of IPE, RM and RI
- Organizational Model and Responsibilities of Patients, Physicians, Allied Professionals, Manufactorers
- **Legal and Privacy Considerations**
- Conclusion.

Legal and Privacy Considerations

Privacy remains a paramount concern.

An ongoing concern is the question as to who owns the data obtained through RM and to what extent manufacturers should be compelled to release data available in their registries when medically warranted. Another concern is how to protect patient privacy when such data are made available for other purposes, whether regulatory or research. The manufacturer of the RM data system has, by definition, custody of the RM data because it is collected on their servers. Patient medical records, by analogy, are in the custody of a practice or hospital.

Summary

- History
- Remote Interrogation vs Remote Monitoring
- Device Surveillance, Shock Reduction, Optimization of Device Longevity
- Disease Management (Atrial Fibrillation, Heart Failure)
- Timing of IPE, RM and RI
- Organizational Model and Responsibilities of Patients, Physicians, Allied Professionals, Manufactorers
- Legal and Privacy Considerations
- **Conclusion.**

Conclusion

Incorporation of RM into follow-up practice, integrating this technology with a modified frequency of the conventional IPE ensures greater patient retention and improves adherence to scheduled evaluations. These data form the basis of our recommendations that RM represents the new standard of care for patients with CIEDs, with alert-driven IPE replacing most routine office interrogations.

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

B-R = level of evidence B indicates a moderate level from randomized trials; CIED = cardiac implantable electronic device; ICD = implantable cardioverter-defibrillator; RM = remote monitoring.

REGIONE DEL VENETO

giunta regionale

Data 29 APR. 2019 | Protocollo N° 167762 Class. C.101 Prat. Fasc. | Allegati N° 1

Oggetto: Trasmissione della delibera n. 478 del 23.04.2019, avente ad oggetto *'Inserimento nel Nomenclatore Tariffario della specialistica ambulatoriale di una nuova prestazione della branca 8 Cardiologia ed estensione del numero di prestazioni della stessa branca erogabili in regime di esenzione alla compartecipazione della spesa sanitaria.'*.

CODICE	PRESTAZIONE	TARIFFA
89.50.2	CONTROLLO IN REMOTO DI PAZIENTI PORTATORI DI PACEMAKER, DEFIBRILLATORE E LOOP RECORDER (ciclo di 4 controlli). Massimo 4 controlli/anno	€ 25,55

« … In the long history of the human race (and also of the animal genus …) those who have learned to collaborate and to improvise more effectively, have prevailed …»

(Charles Darwin)

Thanks

La necessità di un modello organizzativo dedicato al controllo/monitoraggio remoto dei dispositivi impiantabili

E’ arrivato il tempo di pensare a nuove modalità di gestire i pazienti portatori di dispositivi, sia in relazione al controllo periodico dei parametri elettrici che per quanto riguarda le diagnostiche cliniche

2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

The Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA).

Recommendations	Class [a]	Level [b]	Ref. [c]
Device-based remote			174–176

HRS Exp
and mon
devices

A strategy of rem
recommended o
technically feasi

All patients with
strategy.

Device and Di

RM should be

Incorporation of RM into follow-up practice, integrating this technology with a modified frequency of the conventional IPE ensures greater patient retention and improves adherence to scheduled evaluations. These data form the basis of our recommendations that RM represents the new standard of care for patients with CIEDs, with alert-driven IPE replacing most routine office interrogations.

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
RM is useful to reduce the incidence of inappropriate ICD shocks.	I
RM is useful for the early detection and quantification of atrial fibrillation.	I

Introduction

Recommendations for exercise, multidisciplinary management and monitoring of patients with heart failure

2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)

Multiparameter monitoring based on ICD (IN-TIME approach) may be considered in symptomatic patients with HFrEF (LVEF ≤35%) in order to improve clinical outcomes.	IIb	B	630

Introduction

- What is the IN-TIME approach?
- Which are the major findings?

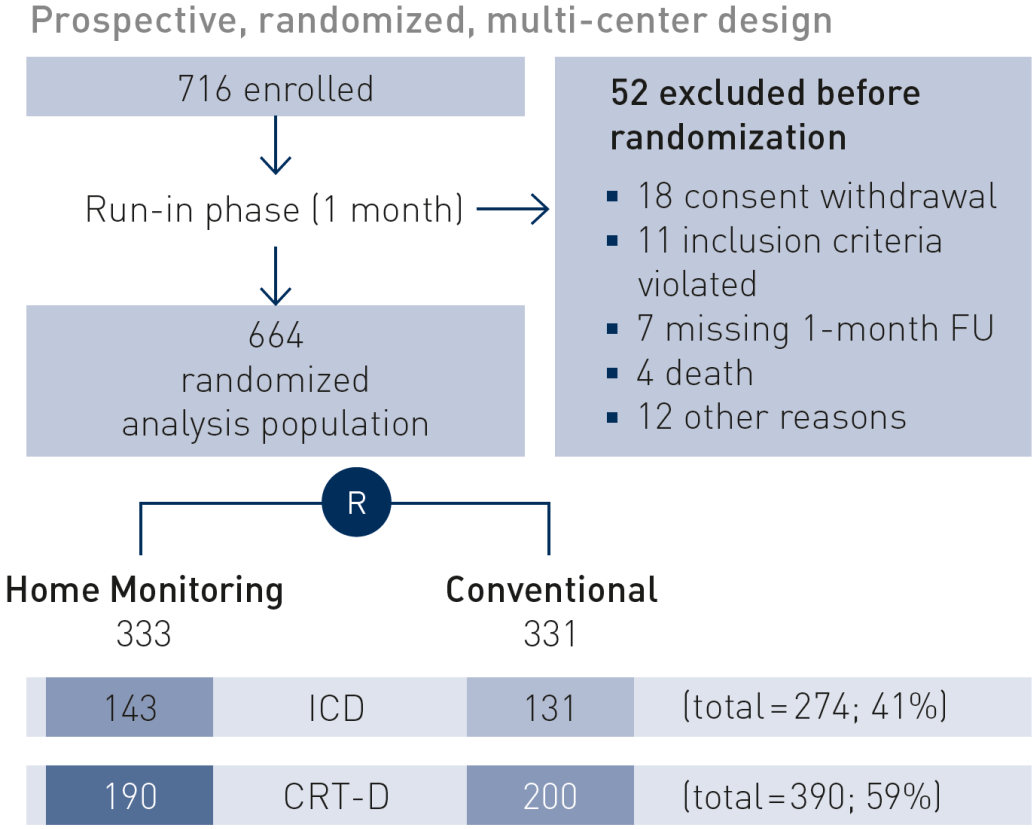
IN-TIME

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**

IN-TIME study

Study design and inclusion criteria



Major inclusion criteria

- Dual-chamber ICD or CRT-D indication
- Chronic heart failure with NYHA Class II or III
- LVEF ≤ 35% within 3 months prior to screening
- Indication for therapy with diuretics

Before randomization:

- Stable optimal drug therapy
- Transmission performance of Home Monitoring ≥ 80%

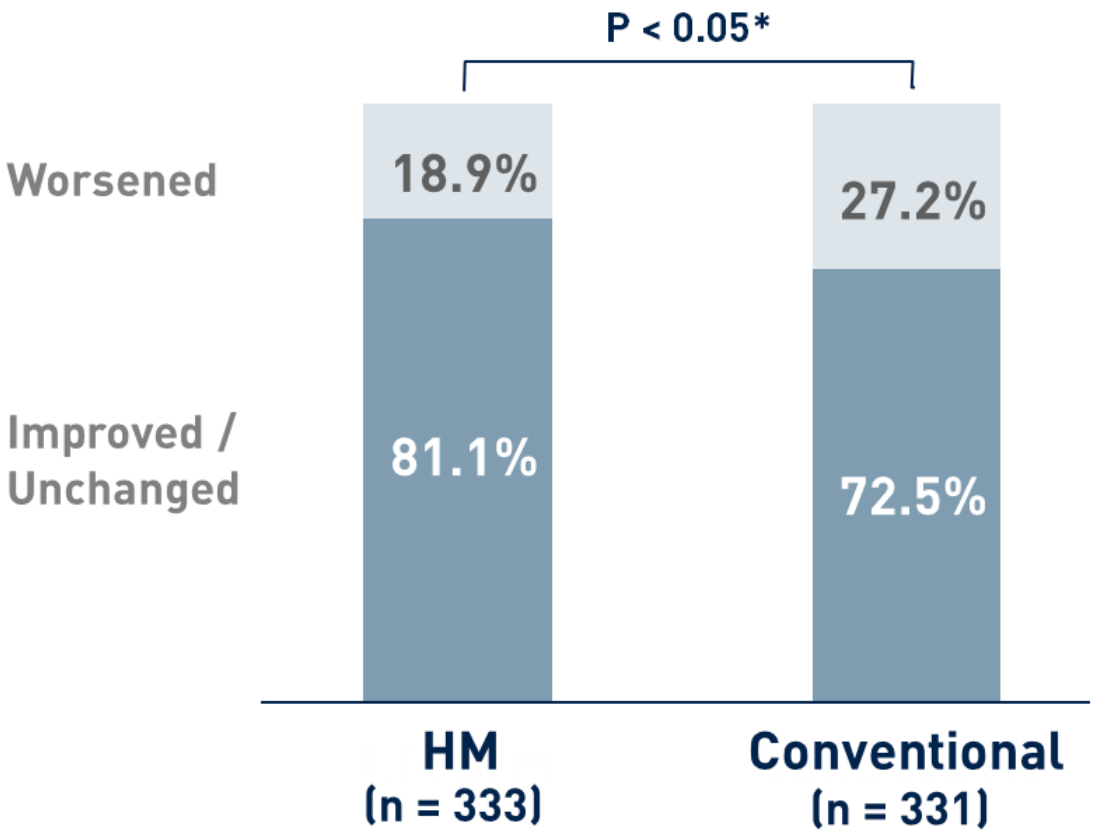
Major exclusion criteria

- Permanent atrial fibrillation

IN-TIME study

Results Primary composite endpoint

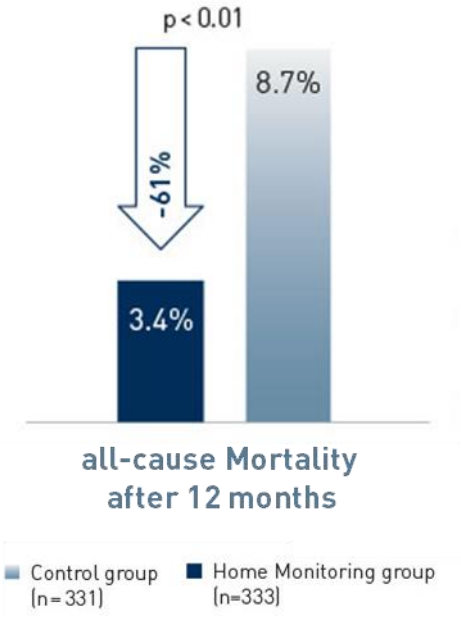
Reduction of worsening of clinical status in HM group.

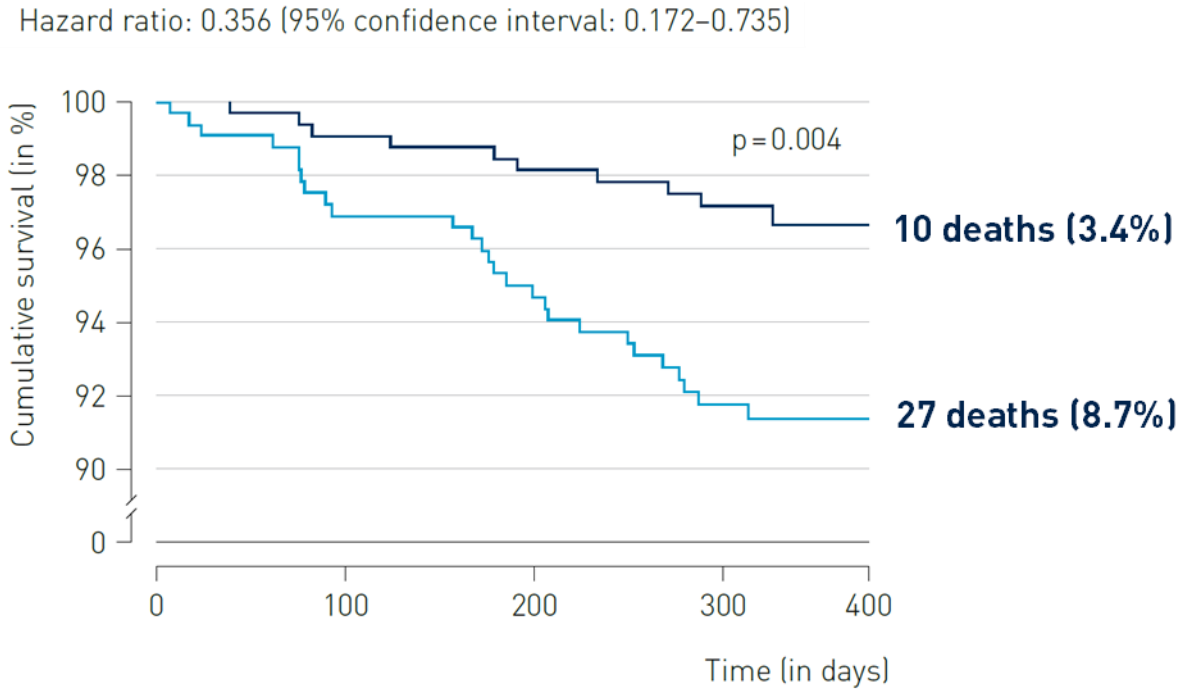


IN-TIME study

Results

- This difference was mainly driven by the lower mortality in the HM group.
- All-cause mortality reduction 61%(3.4% vs. 8.7%, HR 0.36, 95% CI 0.17–0.74, P=0.004), this means 51 lives saved every 1000 patients in 1 year follow-up.
- The result was similar considering only cardiovascular deaths.

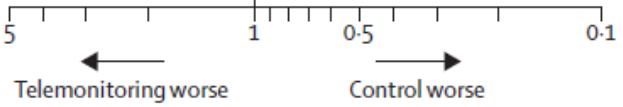




IN-TIME study

Subgroups analysis

	Number of patients		Number of events		Odds ratio (95% CI)	p value	$p_{interaction}$
	Tele-monitoring group	Control group	Tele-monitoring group	Control group			
Age (years)							0·71
≤67 years	182	170	29	37	0·68 (0·40–1·17)	0·16	
>67 years	151	161	34	53	0·59 (0·36–0·98)	0·042	
LVEF within 3 months of enrolment*							0·58
≤25%	168	166	36	46	0·71 (0·43–1·18)	0·18	
>25%	150	151	25	39	0·57 (0·33–1·01)	0·054	
Sex							0·71
Men	274	262	53	71	0·65 (0·43–0·97)	0·034	
Women	59	69	10	19	0·54 (0·23–1·27)	0·16	
NYHA at enrolment*							0·16
II	150	135	16	29	0·44 (0·23–0·85)	0·014	
III	182	196	47	61	0·77 (0·49–1·21)	0·26	
NYHA at 1 month*							0·53
I–II	233	223	42	54	0·69 (0·44–1·08)	0·11	
III–IV	99	108	21	36	0·54 (0·29–1·01)	0·053	
History of atrial fibrillation*							0·044
No	257	238	50	55	0·80 (0·52–1·24)	0·32	
Yes	76	92	13	35	0·34 (0·16–0·70)	0·003	
Device type							0·58
ICD	143	131	20	30	0·55 (0·29–1·02)	0·058	
CRT-D	190	200	43	60	0·68 (0·43–1·08)	0·10	
ACE/ARB use at enrolment							0·31
No	26	45	9	15	1·06 (0·38–2·93)	0·91	
Yes	307	286	54	75	0·60 (0·41–0·89)	0·011	
All	**333**	**331**	**63**	**90**	**0·63 (0·43–0·90)**	**0·012**	



IN-TIME study

Discussion

”Three mechanisms contributed in parallel to the improved clinical outcome, but their contributions are unclear”

- Early detection of ventricular and atrial tachyarrhythmias;
- Suboptimal device function;
- Patient interviews raised patients’ awareness and encouraged them to take more responsability for their own health.

	Observation sent to investigational site	Patient contact by investigational site	Further action by investigational site*
Ventricular tachyarrhythmia or shock†	42 (56)	24 (38)	15 (22)
Atrial tachyarrhythmia‡	65 (109)	53 (70)	18 (24)
CRT <80% over 48 h§	35 (91)	28 (63)	15 (26)
Ventricular extrasystole frequency >110 per hour or increasing trend over 7 days	46 (54)	34 (39)	7 (7)
Decreasing trend of patient activity over 7 days	1 (1)	1 (1)	0 (0)
Abnormal IEGM or sensing safety notification¶	34 (51)	20 (25)	14 (15)
Pacing or impedance safety notification‖	26 (43)	13 (14)	5 (5)
Gap in data transmission of >3 days	241 (818)	174 (401)	4 (4)
Total	280 (1225)	238 (641)	63 (99)
Mean per patient-year	4·0	2·1	0·3
Median per patient-year (IQR)	3·0 (1·1–5·7)	1·1 (0·0–3·0)	0·0 (0·0–0·0)

IN-TIME approach

What does it consist?

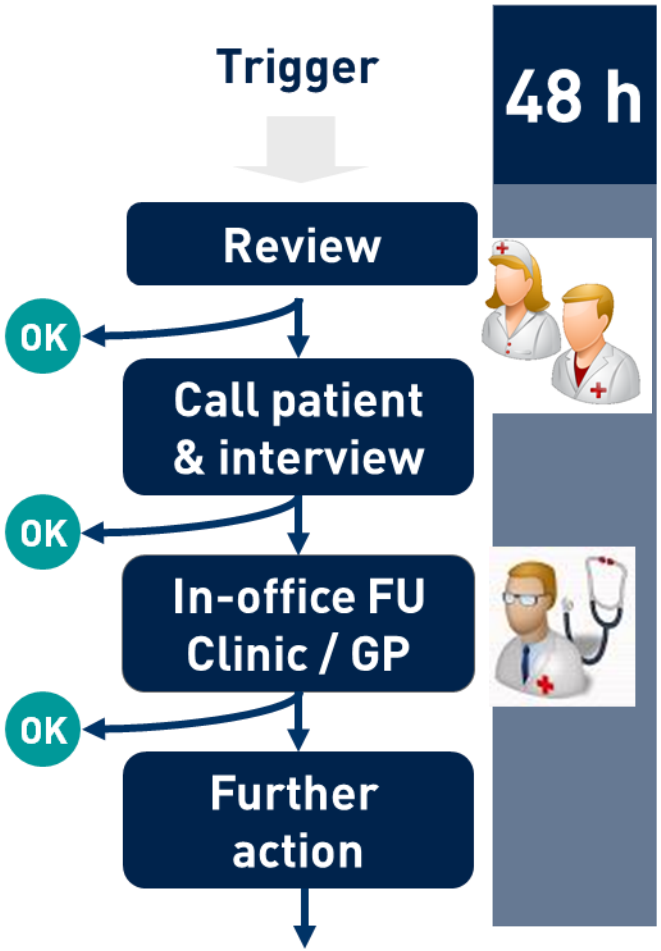
Multiparameter monitoring based on ICD (IN-TIME approach) may be considered in symptomatic patients with HFrEF (LVEF ≤35%) in order to improve clinical outcomes.	IIb	B	630

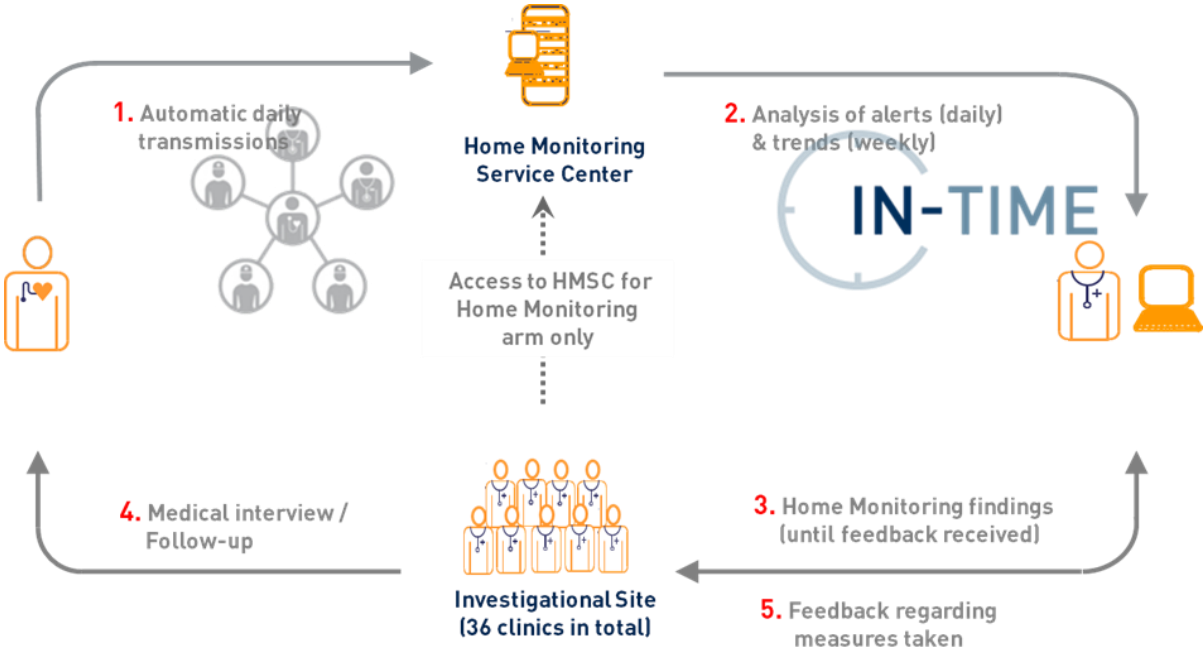
IN-TIME approach

Workflow for detection of critical events and medical management of events

1

Workflow model



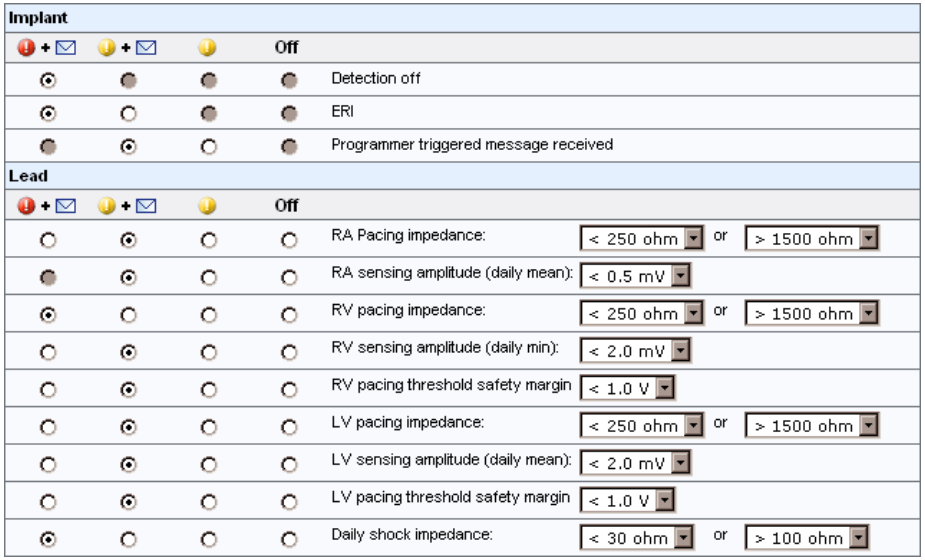


IN-TIME approach
Multiparameter monitoring

2 IN-TIME

Multiparameter

- Several typologies of alerts that can be personalized to the subject



Implant						
			Off			
◉	○	○	○	Detection off		
◉	○	○	○	ERI		
○	◉	○	○	Programmer triggered message received		
Lead						
			Off			
○	◉	○	○	RA Pacing impedance:	< 250 ohm or	> 1500 ohm
○	◉	○	○	RA sensing amplitude (daily mean):	< 0.5 mV	
◉	○	○	○	RV pacing impedance:	< 250 ohm or	> 1500 ohm
○	◉	○	○	RV sensing amplitude (daily min):	< 2.0 mV	
○	◉	○	○	RV pacing threshold safety margin	< 1.0 V	
○	◉	○	○	LV pacing impedance:	< 250 ohm or	> 1500 ohm
○	◉	○	○	LV sensing amplitude (daily mean):	< 2.0 mV	
○	◉	○	○	LV pacing threshold safety margin	< 1.0 V	
◉	○	○	○	Daily shock impedance:	< 30 ohm or	> 100 ohm

Atrial Arrythmia:

- First AF Episode >30s
- Long AF Duration
- High AF burden

Ventricular Arrythmia:

- Ventricular Storm
- First Shock
- First slow VT

Technical Parameters:

- Low CRT Stimulation
- Technical Parameter
- Missing HM message

Trends / Other:

- Decreasing patient activity
- Increasing VES
- Suspicious IEGMs

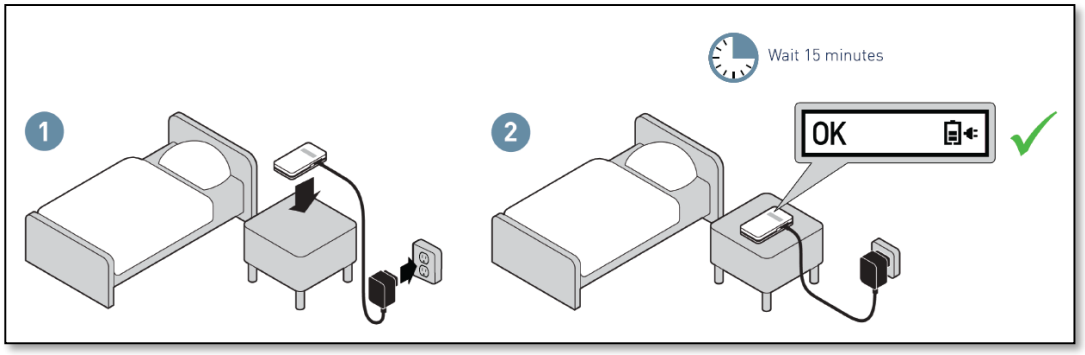
IN-TIME approach

Daily, automatic and reliable transmissions

3

Transmissions

- Daily fully automatic system;
- Alert for lack of transmissions (after 3 days of missing messages);
- TRUST (Home Monitoring): 87% of days with successful transmission;
- IN-TIME (Home Monitoring): 85% of days with successful transmission;
- With other system percentage of successful transmission with alert ranges from 55 to 83%.



Our logistic model in Legnago Cardiology

1 dedicated cardiology technician

daily review of all RM transmissions
training and education to the patients
solve gap of transmissions issues
filtering known problems
comunication of critical events to responsible physician
close collaboration with HF ambulatory

Time to reaction of RM alerts

RED alerts: immediate comunication to the physician

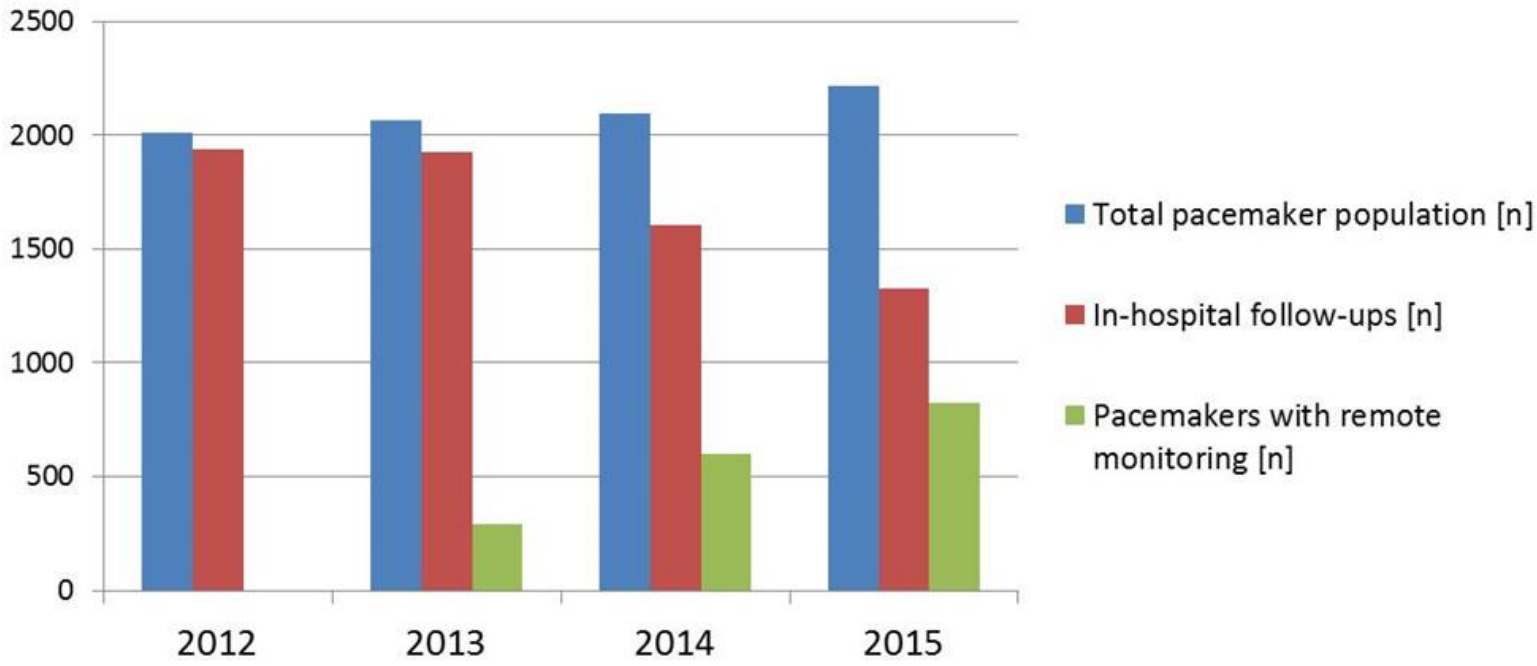
YELLOW alerts: comunication to the physician by the end of the day

Monitored patients at our centre

	ICD	PM	Loop rec
Medtronic	261	303	51
Biotronik	281	560	2
Boston	98	315	
St Jude	13	22	
Monitored patients Tot. patients	653 653	961 2685	49 53
Monitored patients: 1894 Tot patients: 3391			

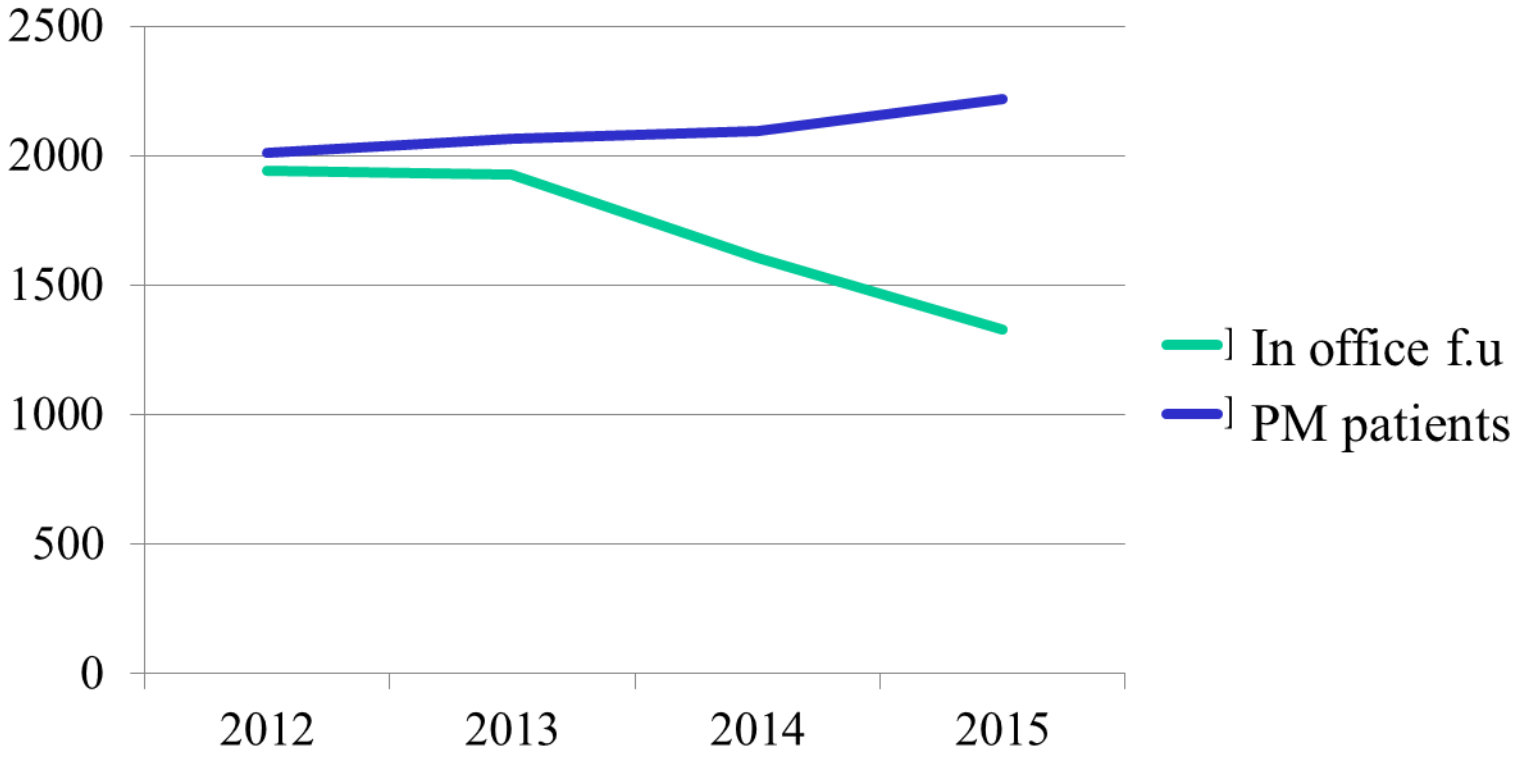
Data updated to September 2017

Results of 3 years of PM RM in Legnago



A stable yearly reduction of around 17% of the in-hospital visits was found since the second year from the RM introduction.

Results of 3 years of PM RM in Legnago



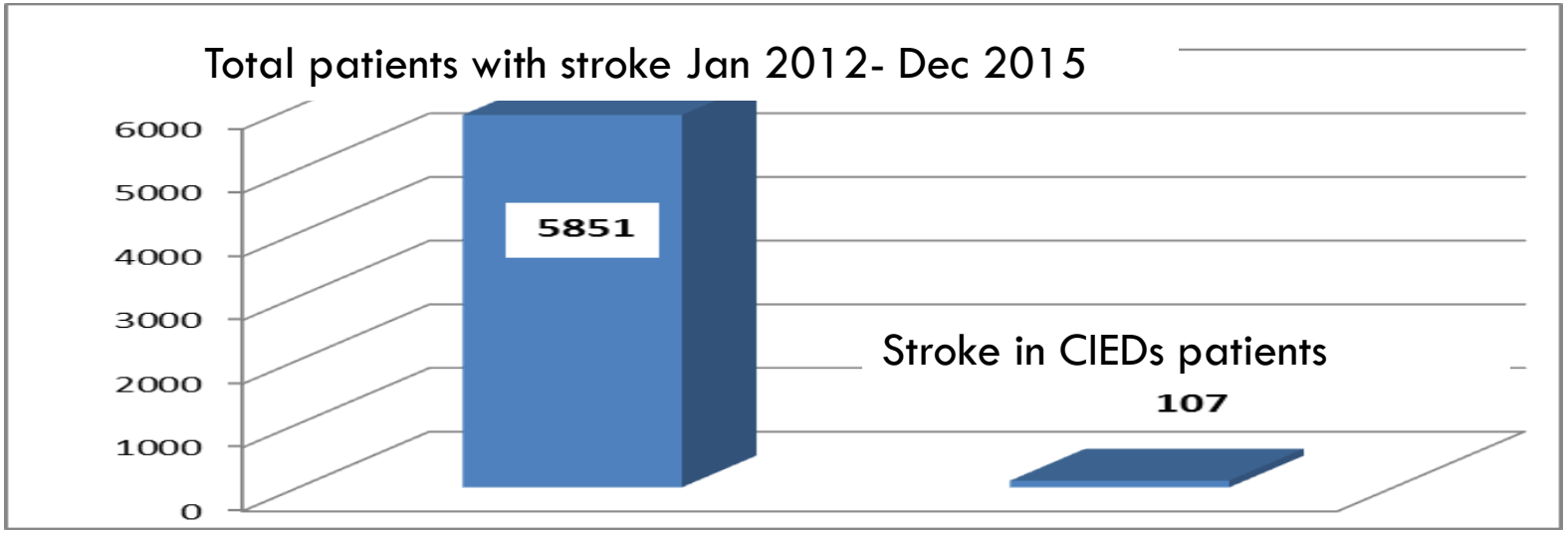
Despite the increase of CIEDs patients, the implementation of this RM model allows the 32% reduction of in office follow up visits in 3 years

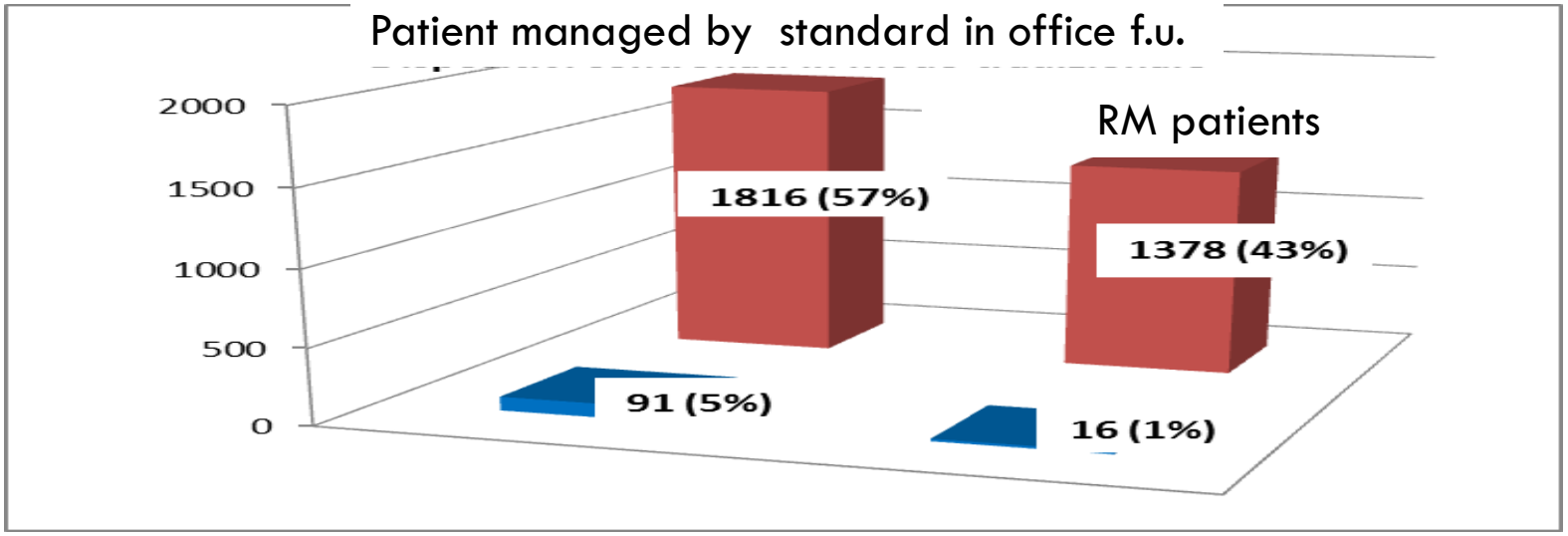
Tipologia di allarmi

Unscheduled in-hospital follow up triggered by RM alerts [n(%)]	2013	2014	2015
Autocapture deactivation	12 (21)	19 (20)	29 (26)
Pacing mode reprogramming	12 (21)	18 (19)	10 (9)
Pacing mode reprogramming for AT/AF	8 (14)	12 (12)	19 (17)
Threshold increase	6 (11)	9 (9)	13 (12)
Sensing decrease	2 (3)	5 (5)	6 (5)
Pacing impedance out of range	0 (0)	1 (1)	3 (3)
Transmission problems	13 (23)	22 (23)	20 (18)
Pharmacological therapy optimization	4 (7)	10 (10)	10 (9)
Total	57 (100)	96 (100)	110 (100)

La percentuale di fup ambulatoriali non programmati è del 14% nei pazienti in controllo remoto e del 3,5% nel gruppo convenzionale

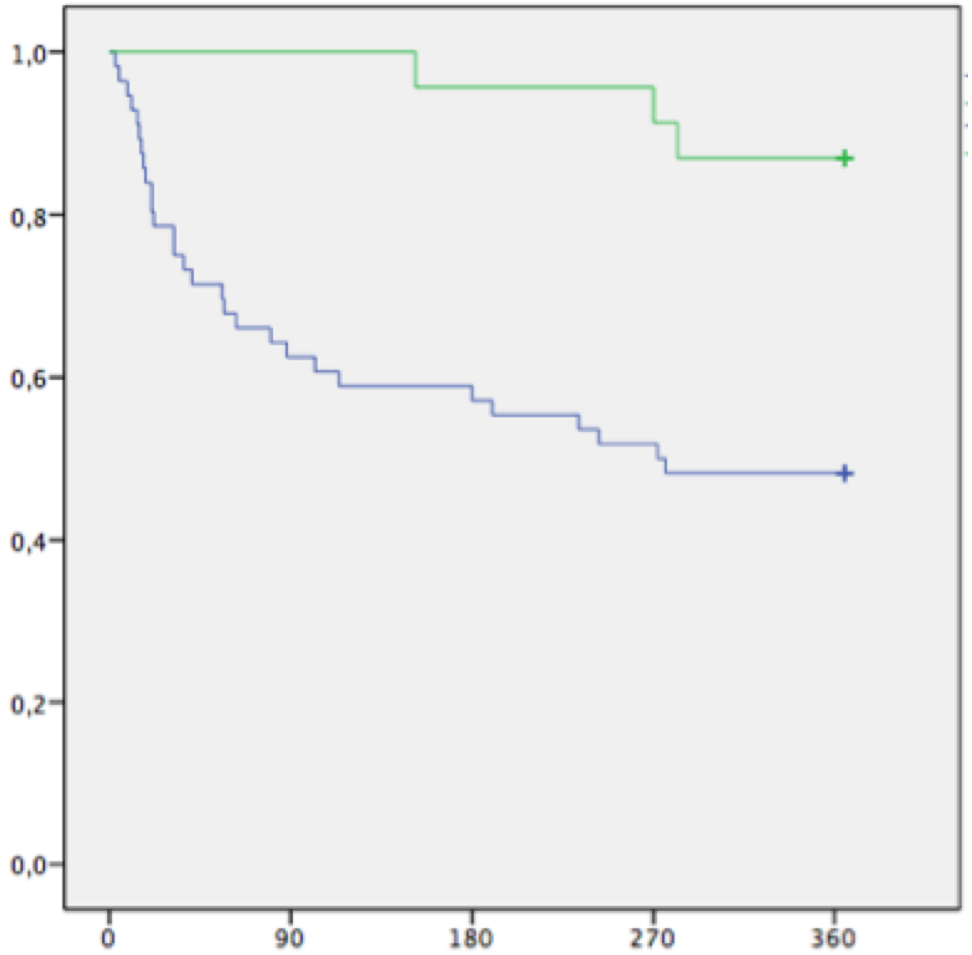
Thromboembolic stroke in CIEDs patients





Thromboembolic stroke in CIEDs patients

Cumulative survival



87% Monitored Group

48,2% not Monitored Group

Conclusions and further perspectives

- The use of clinical diagnostic of devices is a possible important tool to improve the management fo HF patients
- The IN TIME approach is a potential model
- In our daily clinical practice, we need a model with nurses or clinicians dedicated to remote monitoring of ICD and CRT-D patients
- We need a real collaboration between the remote monitoring service and the HF ambulatory
- This logistic model should be further investigated in ordinary practice to assess its feasibility and efficacy

Thanks

Final thoughts

- Remote monitoring technologies will play a key role in disease management of patients with CIEDs
- Technology and work flow matters; not all remote technology platforms are the same.
- Remote monitoring parameters (single parameter vs. multi parameter) and work flow for detection of critical events and medical management of events play a significant role.
- Pre-defined treatment pathways and central monitoring seems critical.
- There is evidence that multiparameter monitoring and optimal work flow reduce mortality in CIEDs patients.