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FIBRILLAZIONE ATRIALE ED ICTUS CARDIOEMBOLICO:

Misure legislative, strategie di prevenzione ed accesso alle cure nei 21 Sistemi Sanitari Regionali

Venerdì, 13 giugno 2014

ore 8.30 – 13.30

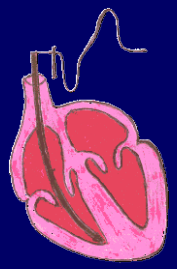
CAMERA DEI DEPUTATI

Palazzo Marini – Sala della Mercede
Via della Mercede, 55 – Roma

HTA del controllo remoto dei dispositivi impiantabili attivi

Renato P. Ricci

ACO S. Filippo Neri - Roma

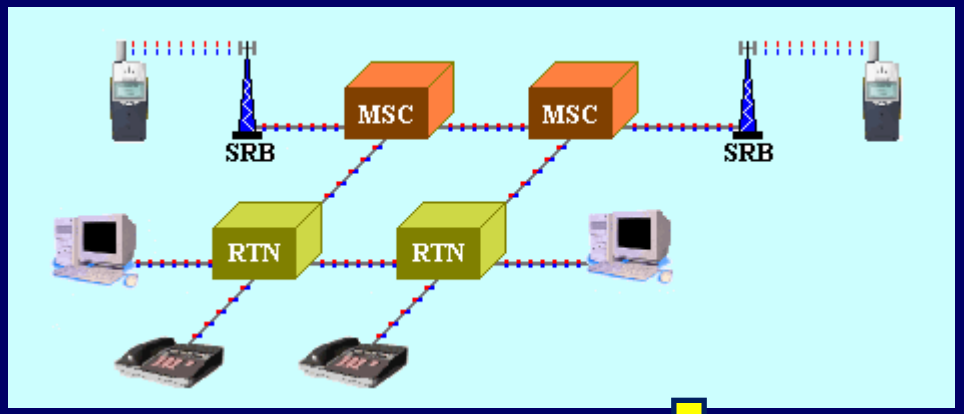


Health Technology Assessment (HTA)

HTA is a multidisciplinary process that summarises information about the *medical, social, economic and ethical issues* related to the use of a health technology in a systematic, transparent, unbiased, robust manner

Monitoraggio remoto flow-chart











European Heart Journal Advance Access published December 4, 2012



European Heart Journal
doi:10.1093/eurheartj/ehs388

CLINICAL REVIEW

Novel Devices

Telemedicine and cardiac implants: what is the benefit?

Niraj Varma[1]* and Renato Pietro Ricci[1,2]

[1]Cardiac Pacing and Electrophysiology, 9500 Euclid Avenue Desk J2-2, Cleveland Clinic, Cleveland, OH 44195, USA; and [2]San Filippo Neri Hospital, Rome, Italy

Received 30 April 2012; revised 15 October 2012; accepted 23 October 2012

Cardiac implantable electronic devices are increasing in prevalence. The post-implant follow-up is important for monitoring both device function and patient condition. However, practice is inconsistent. For example, ICD follow-up schedules vary from 3 monthly to yearly according to facility and physician preference and availability of resources. Recommended follow-up schedules impose significant burden. Importantly, no surveillance occurs between follow-up visits. In contrast, implantable devices with automatic remote monitoring capability provide a means for performing constant surveillance, with the ability to identify salient problems rapidly. Remote home monitoring reduces the volume of device clinic visits and provides early detection of patient and/or system problems.

Keywords Cardiac implantable electronic devices • ICD • Remote monitoring • Follow-up • Recall management • Early detection • Atrial fibrillation

Monitoraggio Remoto

Obiettivi principali

Ottimizzazione Follow-up

- Ridurre il carico di lavoro ambulatoriale
- Sorvegliare con efficacia e sicurezza le malfunzioni dei dispositivi
- Gestire la longevità dei dispositivi
- Ridurre i costi
- Migliorare la qualità di vita del paziente

Gestione clinica

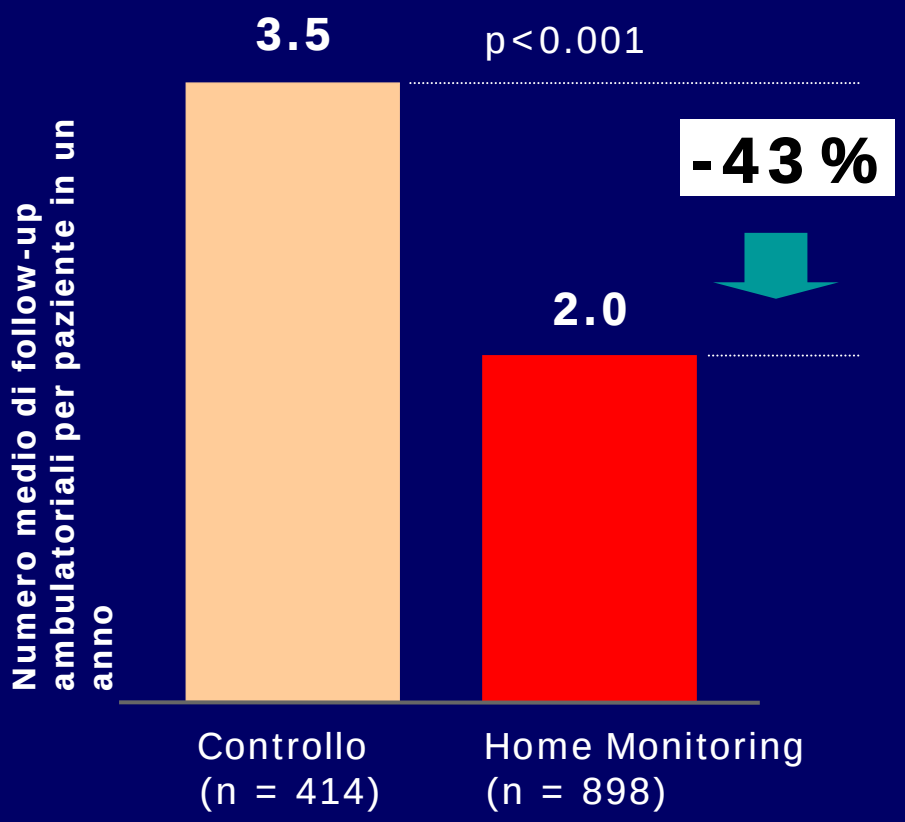
- Fibrillazione atriale
- Scompenso cardiaco
- Episodi VT – VF

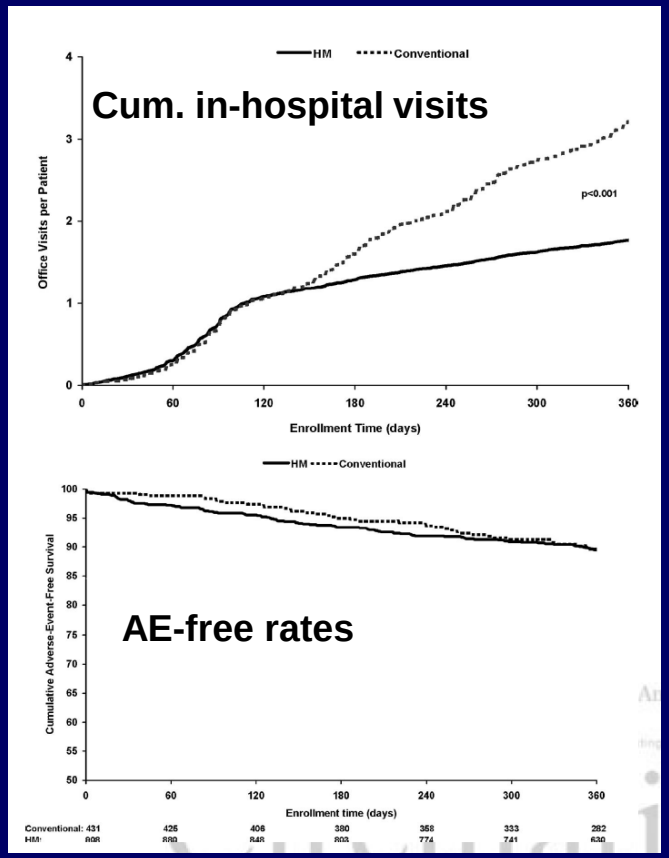
→ Diagnosi preclinica di eventi avversi

→ Riduzione di ospedalizzazioni, morbidità e mortalità

TRUST study
In hospital follow-up reduction

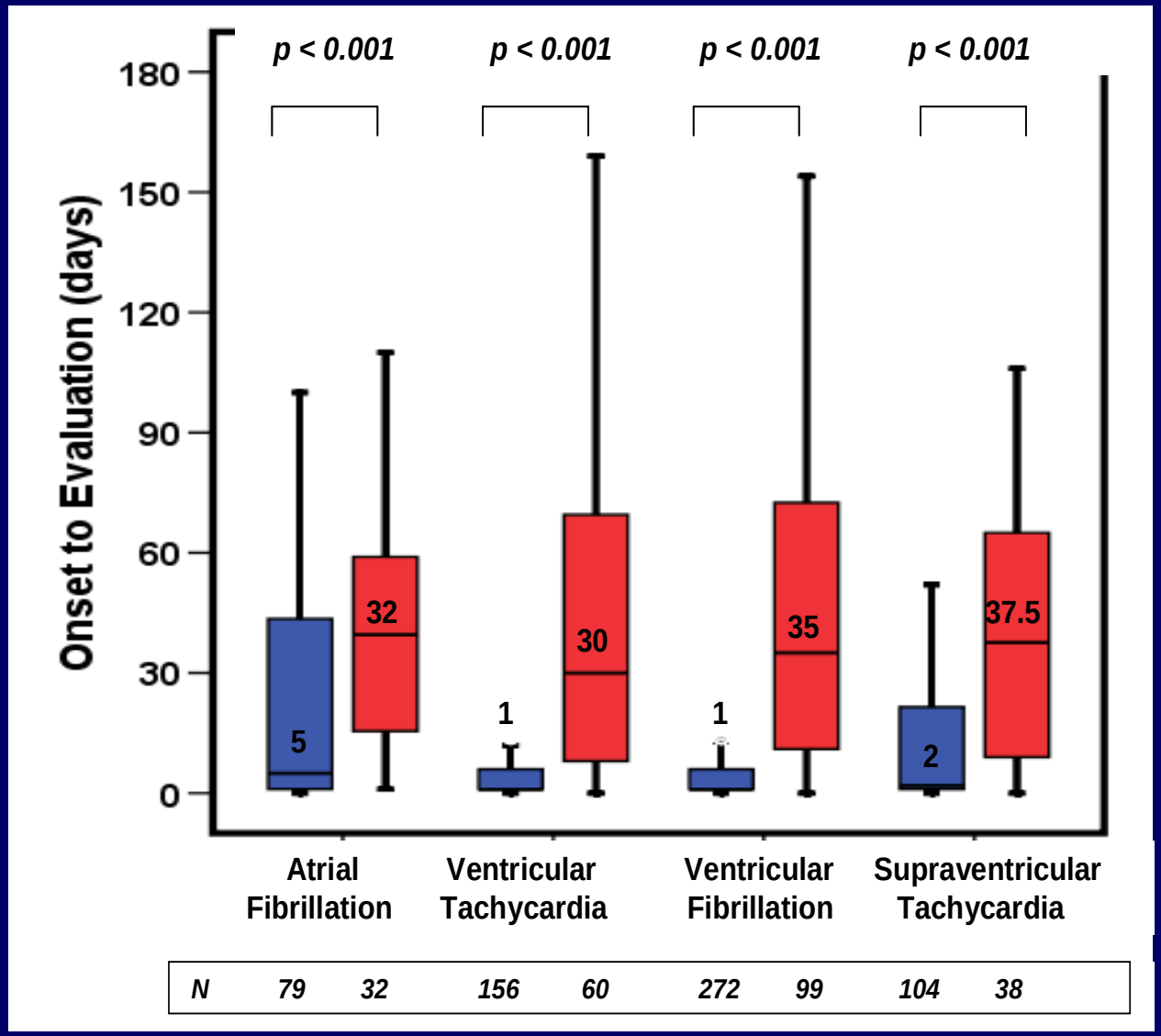
Mean number of in-hospital follow-up per patient per year





Varma N et al Circulation 2010, Jul 12

TRUST: Early Event Detection



Conventional

Remote Monitoring

Varma N 2010

RM reduced time from arrhythmia onset to evaluation

Europace Advance Access published January 29, 2013

Europace
doi:10.1093/europace/eus440

CLINICAL RESEARCH

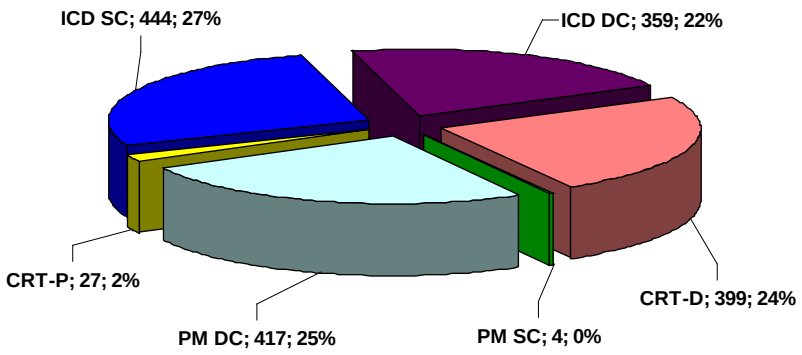
Effectiveness of remote monitoring of CIEDs in detection and treatment of clinical and device-related cardiovascular events in daily practice: the HomeGuide Registry

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

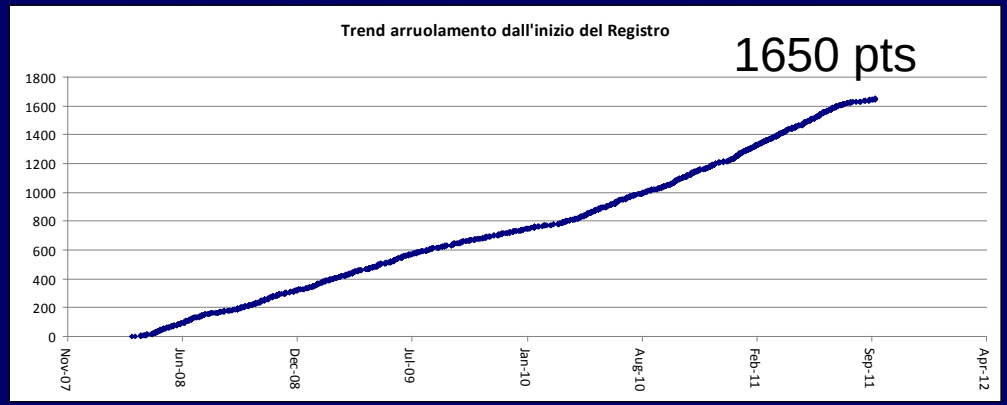
Received 22 October 2012; accepted after revision 24 December 2012

Dispositivi impiantati



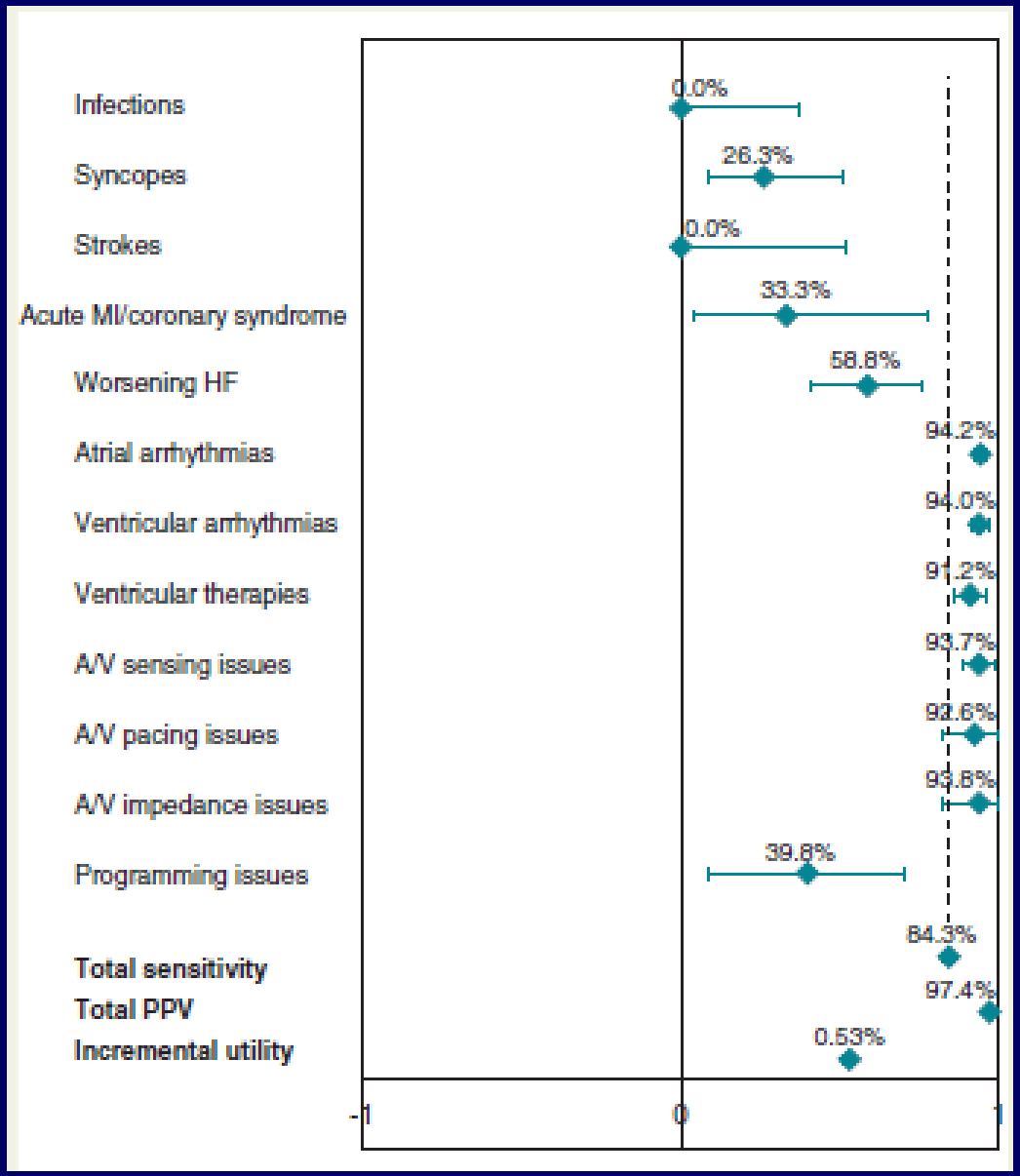
Mean follow-up: 20.4 ± 12.6 months

HOMEGUIDE : Enrolment Trend



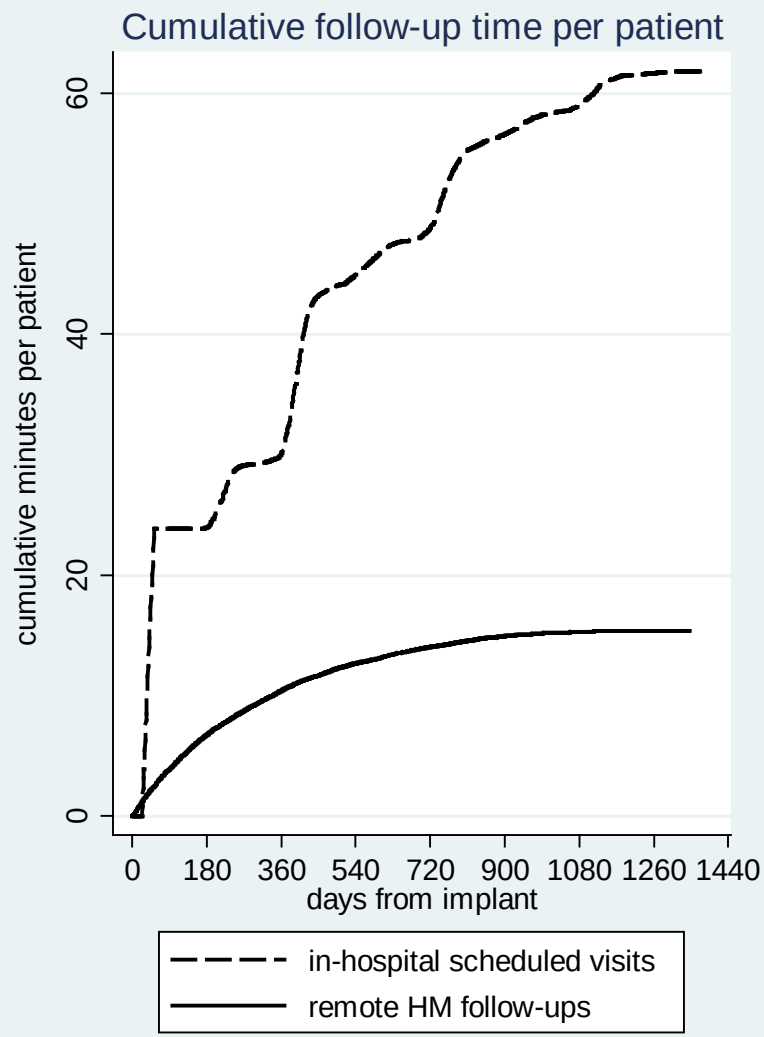
in 75 Italian Centers

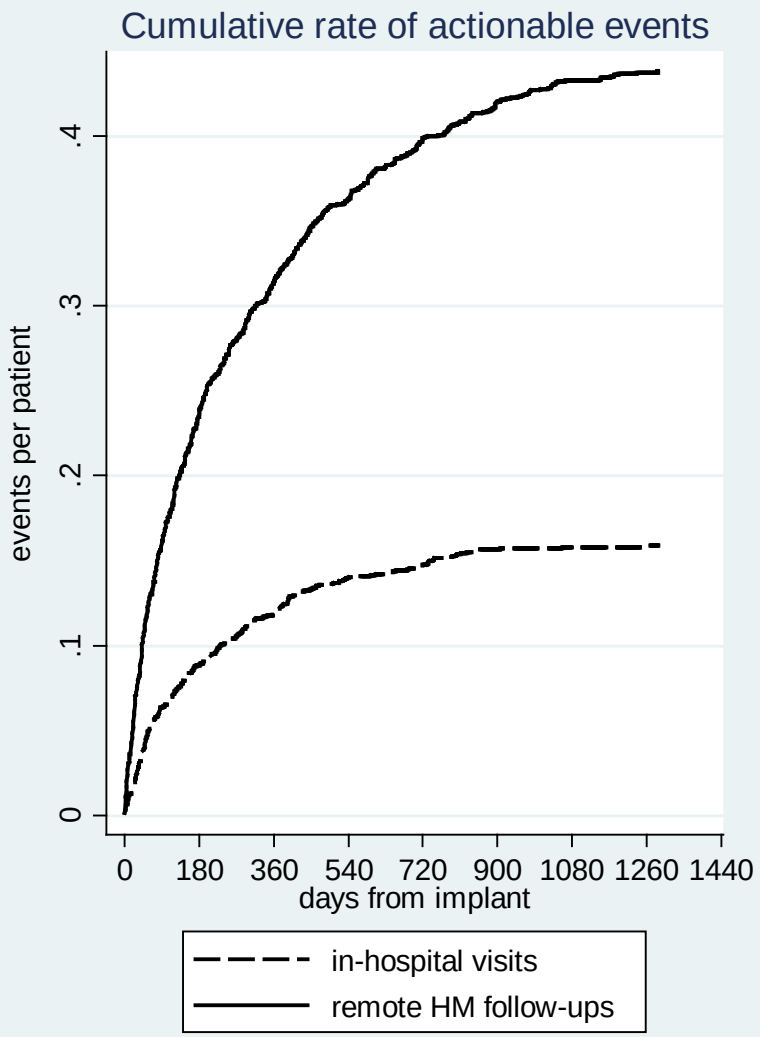
HM Sensitivity for class of MCEs



Ricci RP et al, Europace 2013;15(7): 970-977

Relationship between time consumption and actionable event detection





Ricci RP et al, J Cardiovasc Electrophysiol 2014, in press

Manpower (per month)

Total time spent by all clinical staff per patient per month

55 (22-107) minutes x health personnel / month every 100 pts

p<0.0000

Nurse

43 (4-95) min x RN / month per 100 patients

Physician

10 (1-31) min x RP / month per 100 patients

Ricci RP et al, Europace 2013;15(7): 970-977

In-clinic follow-up burden in Europe

Table I Predictors of visit duration (in terms of total cumulative time)

Predictor	Category	Mean (SD)	Difference in minutes (95% CI)[a]	*P* value
Unscheduled visit	No	26.7 (16.8)	–	
	Yes	34.8 (20.0)	7.6 (1.8–13.4)	0.010
Defibrillation capability (ICD and CRT-D)	No	24.8 (16.2)	–	
	Yes	29.5 (12.6)	1.8 (−1.4–5.1)	0.27
Type of device				<0.001
	Single	25.5 (17.9)	–	
	Dual	24.6 (16.3)	2.5 (−0.8 to 5.9)[b]	
	CRT	34.3 (15.9)	9.1 (4.8–13.3)[b]	
Reprogramming	No	26.0 (15.5)	–	
	Yes	30.6 (20.2)	7.5 (4.3–10.6)	<0.001
Time since device implantation	≤5 years	27.9 (16.3)	–	
	>5 years	24.8 (19.8)	0.0 (−3.6–3.5)	0.99

Multivariable random effects mixed model (random effect for centre): Wald chi-square = 56.13, *P*-value <0.001.

[a]Regression coefficient from the multivariable random effect model.

[b]*Post hoc* comparisons for device: dual vs. single: $P = 0.18$; CRT vs. single: $P < 0.001$ (significant after Bonferroni correction); CRT vs. dual: difference = 6.6 min, 95% CI 2.4–10.8, $P = 0.002$ (significant after Bonferroni correction).

Healthcare personnel resource burden related to in-clinic follow-up of cardiovascular implantable electronic devices: a European Heart Rhythm Association and Eucomed joint survey. Boriani G et al Europace 2011

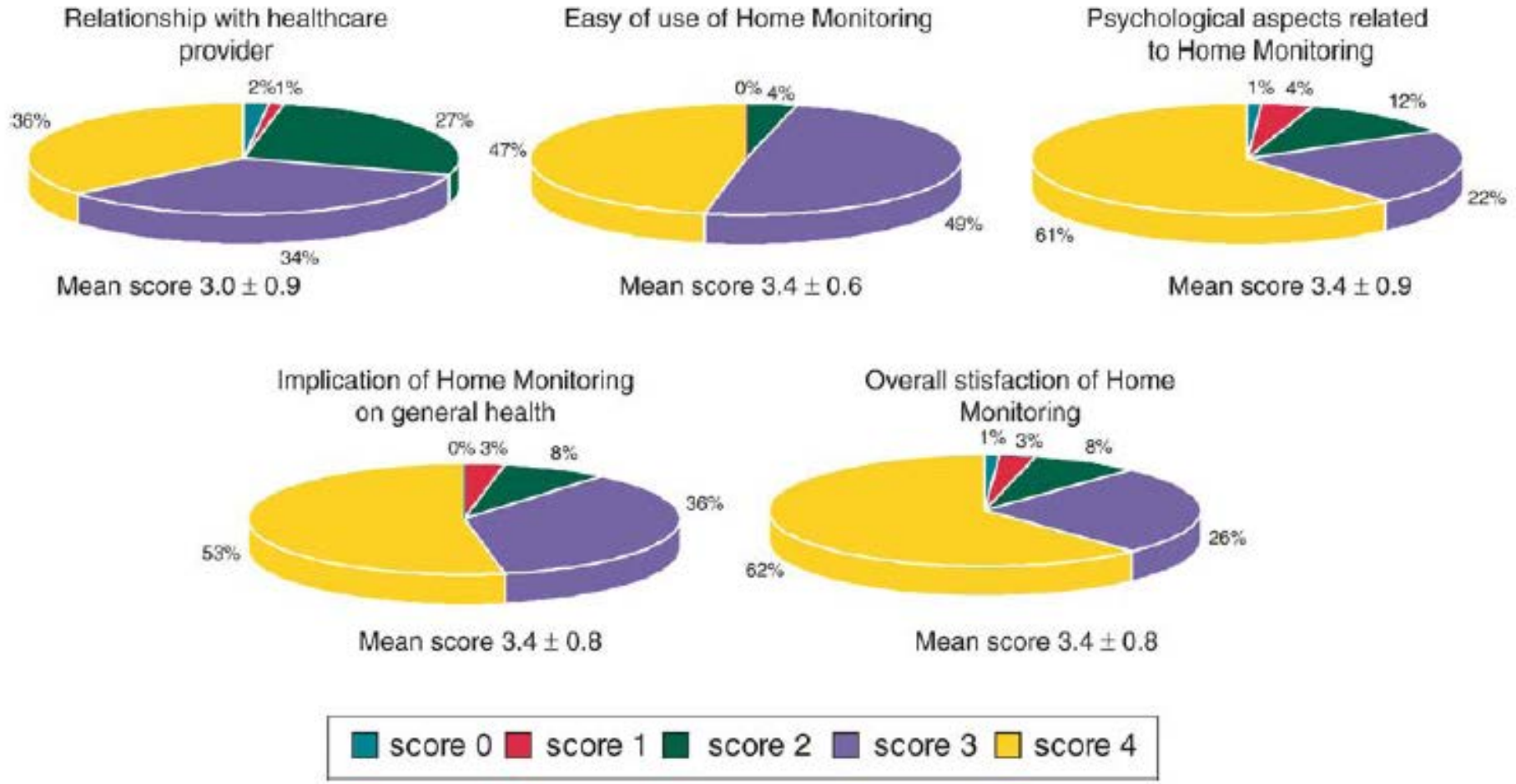
Europace (2010) 12, 674–679
doi:10.1093/europace/euq046

Long-term patient acceptance of and satisfaction with implanted device remote monitoring

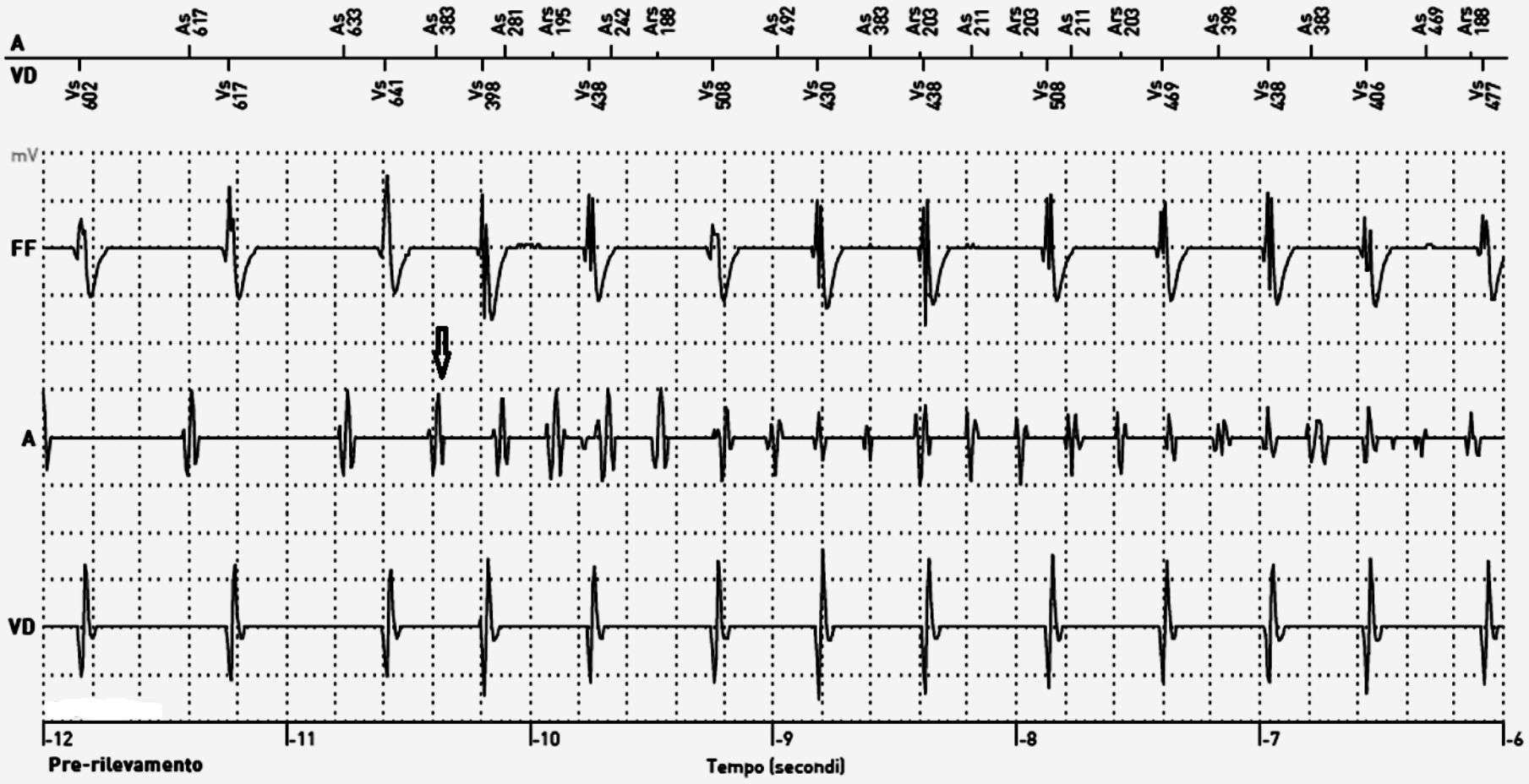
Renato Pietro Ricci [1]*, Loredana Morichelli [1], Laura Quarta [1], Anna Sassi [1], Antonio Porfili [1], Maria Teresa Laudadio [2], Alessio Gargaro [2], and Massimo Santini [1]

[1]Department of Cardiovascular Diseases, San Filippo Neri Hospital, Via Martinotti, 20, Rome 00135, Italy; and [2]Biotronik Italia S.p.A, Rome, Italy

Received 10 December 2009; accepted after revision 25 January 2010; online publish-ahead-of-print 2 March 2010



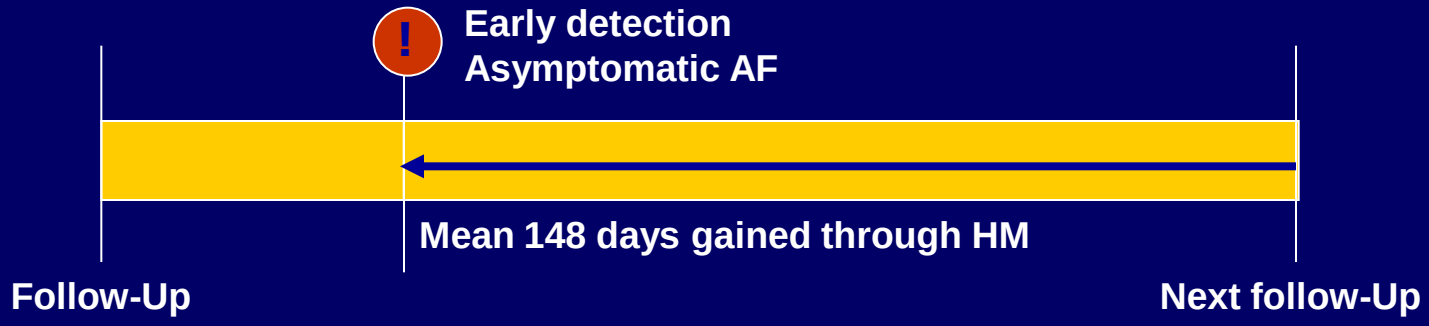
HM - AF detection



Reaction time to the first AF alert

(in 33/166 pts)

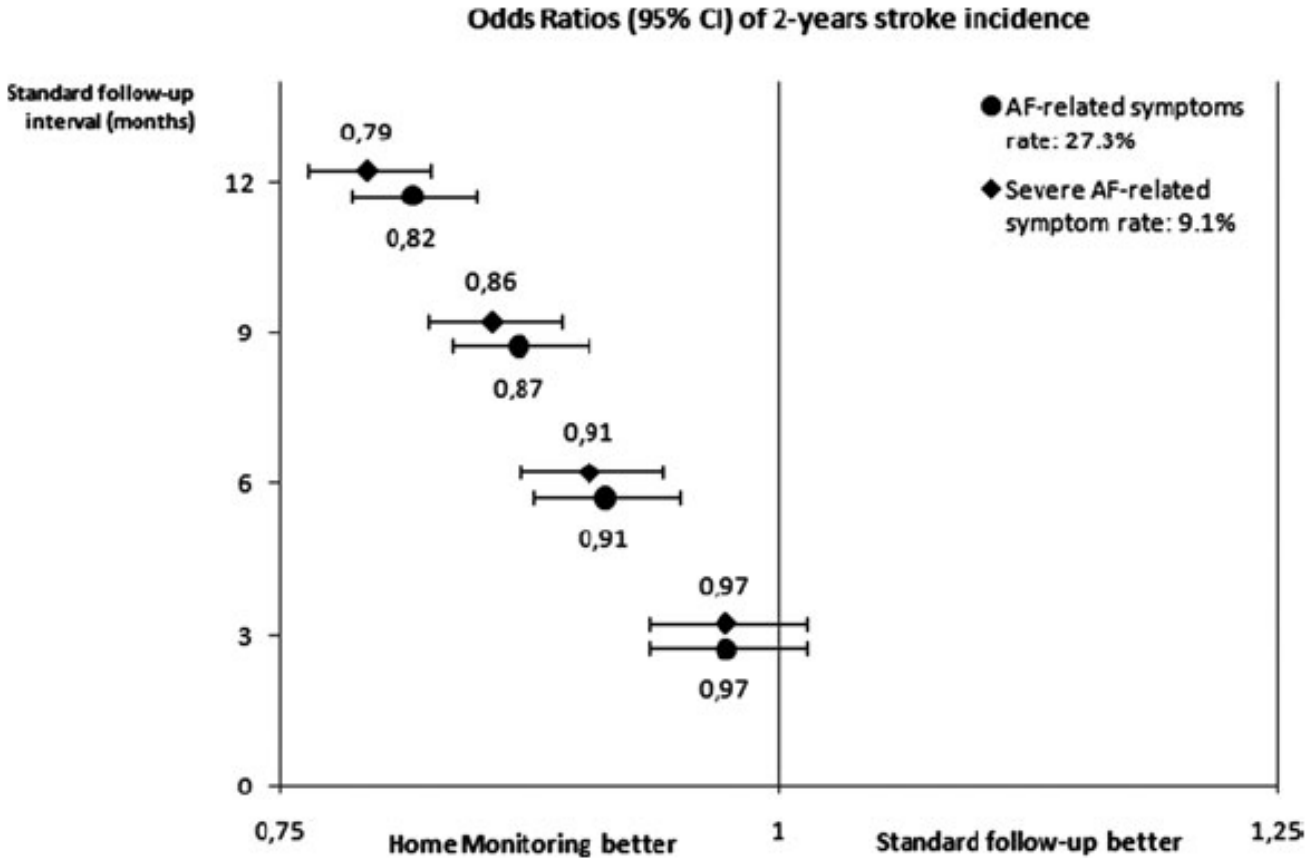
	Median (days)	Interquartile interval (days)	
Median time from the last in-hospital follow-up visit to the detection and the first intervention for AF	50	10	244
Median value of reaction time to AF in advance to the scheduled follow-up	**148**	75	170



Ricci R, et al… Europace 2009;11:54-61.

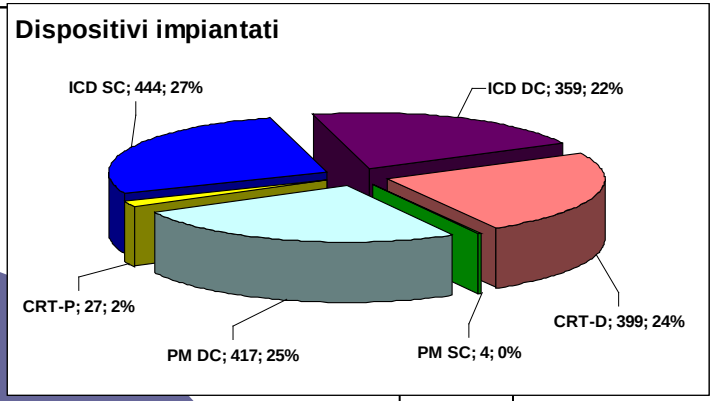
Home Monitoring in Patients with Implantable Cardiac Devices: Is There a Potential Reduction of Stroke Risk? Results from a Computer Model Tested Through Monte Carlo Simulations

RENATO P. RICCI, M.D.,* LOREDANA MORICHELLI, M.S.N.,* ALESSIO GARGARO, PH.D.†
MARIA T. LAUDADIO, PH.D.,† and MASSIMO SANTINI, M.D., F.A.C.C., F.E.S.C.*



(J Cardiovasc Electrophysiol, Vol. 20, pp. 1244-1251, November 2009)

HomeGuide



Enrolled Patients
1650

Mean follow-up: 20±13 mo.

HM sensitivity for
Atrial Arrhythmias Events Detection
94.2% [92.2-96.1%]

868
Atrial Arrhythmias Events

269 patients [16,3%]

9.8/100 patient-years

808
AA Events Witnessed by HM

Median reaction time: 3 days

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, 21044 Montebellunа, Italy; [5]UOC Cardiology, Peter Salute Hospital, Via Gianella 1, 37045 Legnago, Italy; [6]Electrophysiology, Spedali Civili, Pie 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., Vie delle Industrie 11, 20900 Vimodrone (MI), Italy

Received 22 October 2012; accepted after revision 24 December 2012



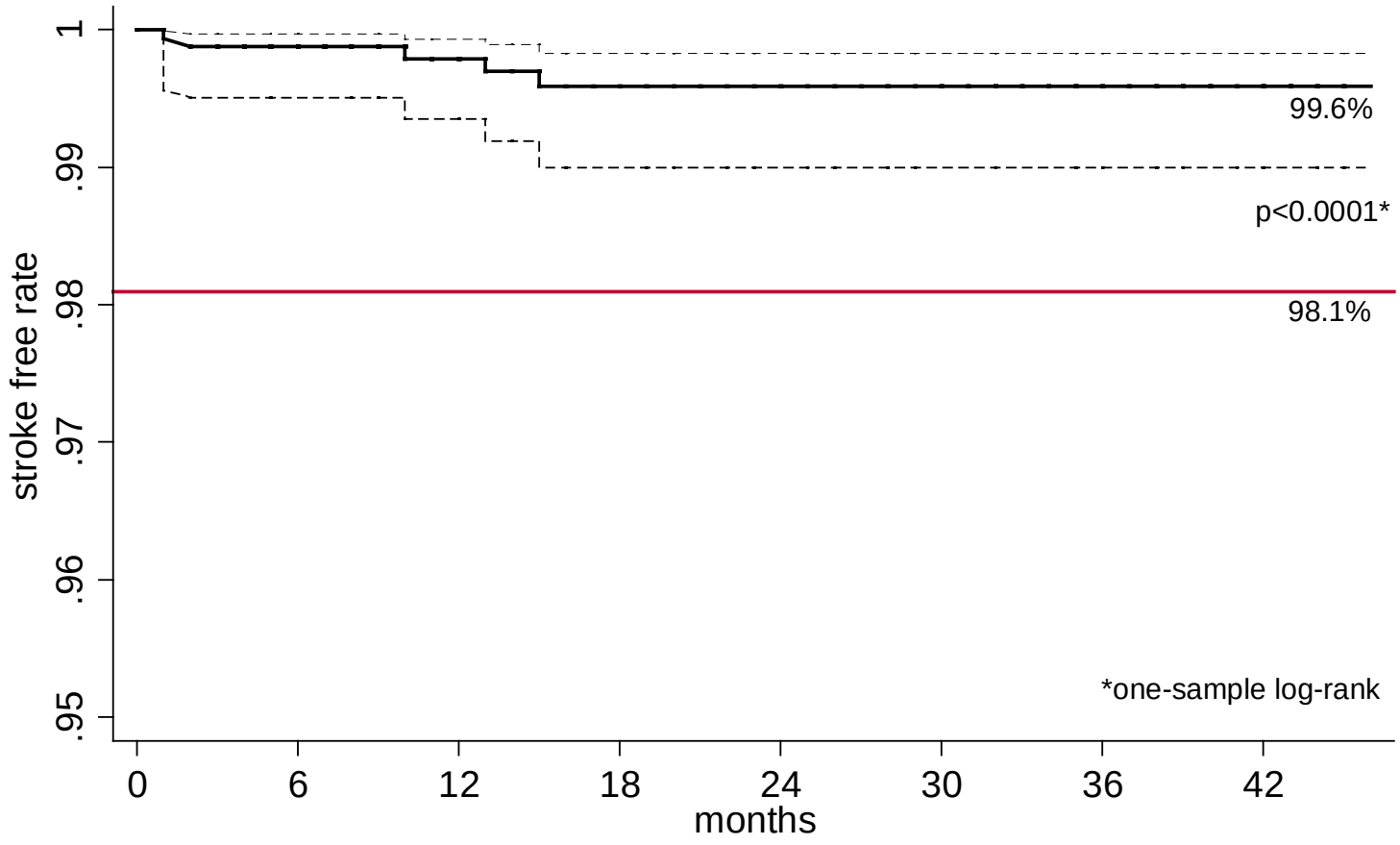
Home Guide Stroke Analysis

- Enrolled patients: 1650
- Fu period: 20.4 ± 12.6 months
- # TIA/Stroke events: 5; incidence rate 0.18/100 patient-years,

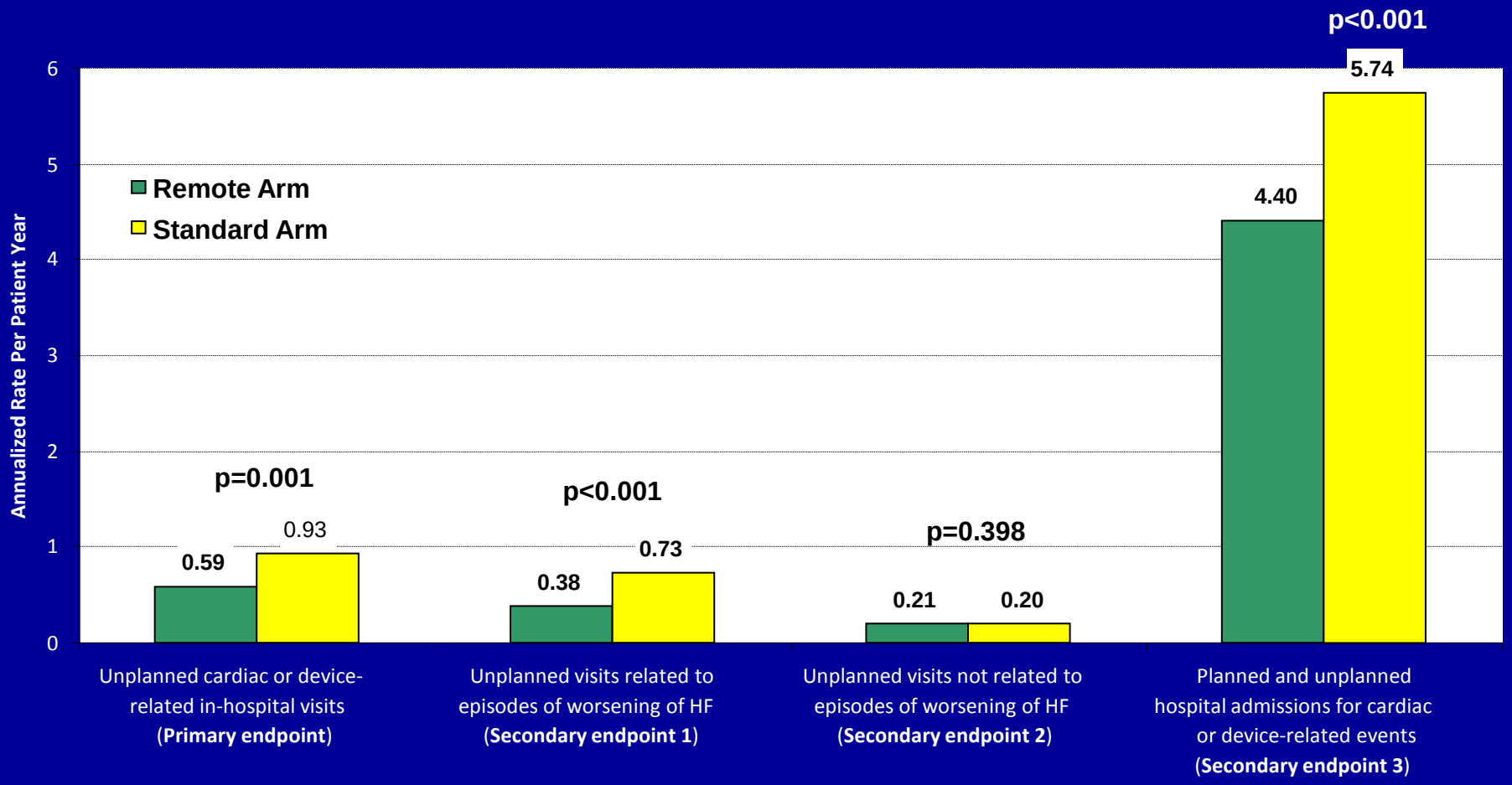
- Through a Monte Carlo Simulation, we calculated the expected number of strokes in a population without remote monitoring, with the same stroke risk distribution of the real population, based on AF and CHA2DS2-VASc score [1,2]

[1] Lip GY, Frison L, Halperin JL, Lane DA. Identifying patients at high risk for stroke despite anticoagulation: a comparison of contemporary stroke risk stratification schemes in an anticoagulated atrial fibrillation cohort. Stroke. 2010 Dec;41(12):2731-8. doi: 10.1161/STROKEAHA.110.590257. Epub 2010 Oct 21.
[2] Lip GYH, Hart RG, Conway DSG: Antithrombotic therapy for atrial fibrillation. BMJ 2002;325:1022-1025.

HomeGuide Stroke Analysis: Results



RM in Heart Failure



Landolina M and Evolvo Trial Investigators

ECOST Trial

Remote monitoring and ICD shocks

Laurence Guedon-Moreau et al, Eur Heart J 2012

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

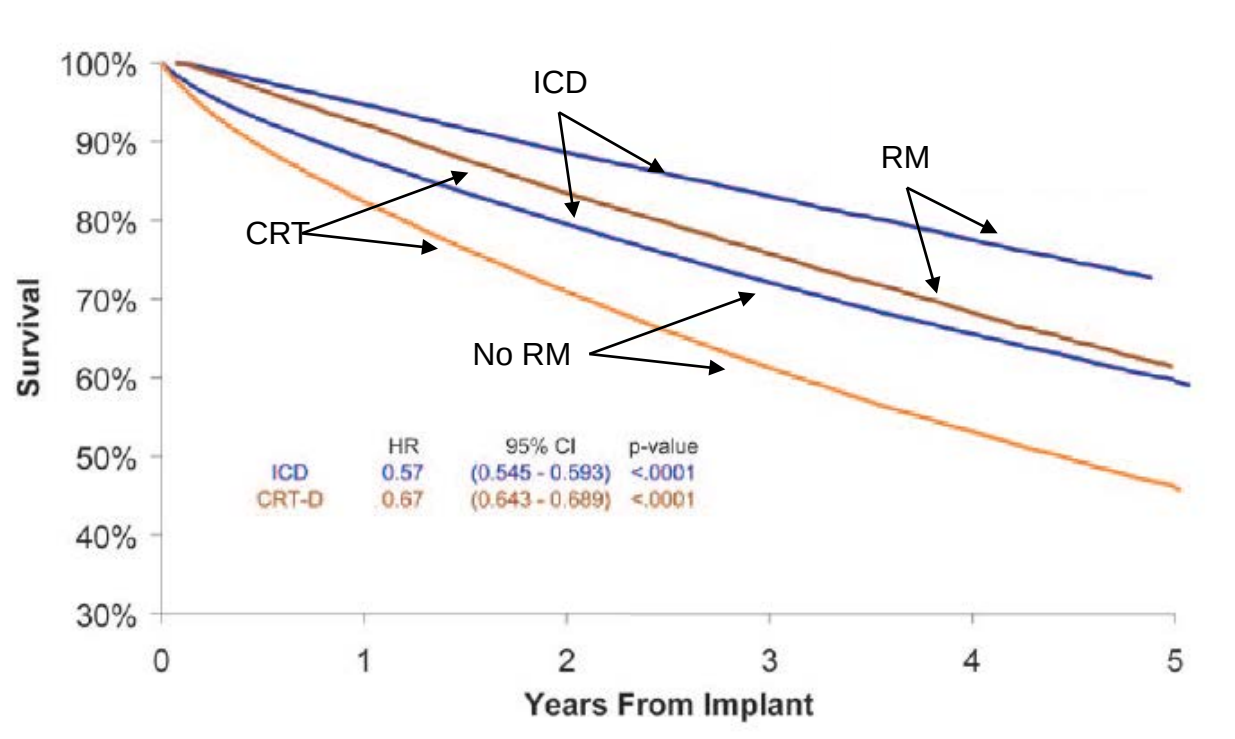
	Study groups		P
	Active ($n = 221$)	Control ($n = 212$)	
Appropriate and inappropriate shocks delivered	193 [0–33]	657 [0–116]	
Patients with ≥1 delivered shock	47 (21.3)	56 (26.4)	0.21
Mean per patient-month	0.04 ± 0.27	0.20 ± 1.13	0.02
Inappropriate shocks delivered	28 [1–8]	283 [1–82]	
Patients with ≥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.

Results from ALTITUDE database*

Large US database with 185.778 patients (ICD and CRT-D)

First analysis investigating the impact of RM on **mortality** in ICD/CRT-D



RM associated with a 50% relative reduction in the risk of death

Hazard ratios

ICD = 0.56;

CRT-D = 0.45;

P<0.0001).

*Saxon LA et al. Circulation 2010



AIAC

Associazione Italiana Aritmologia e Cardiostimolazione

11 dicembre 2013

Controllo remoto dei dispositivi impiantabili: Health Technology Assessment.

AIAC. Area di Telecardiologia.

Renato Pietro Ricci, Emanuela T. Locati, Andrea Campana, Ciro Cavallaro, Massimo Giammaria, Maurizio Landolina, Maurizio Marzegalli, Donato Melissano

European Heart Journal (2013) **34**, 2281–2329
doi:10.1093/eurheartj/eht150

2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

Recommendations	Class [a]	Level [b]	Ref. [c]
Device-based remote monitoring should be considered in order to provide earlier detection of clinical problems (e.g. ventricular tachyarrhythmias, atrial fibrillation) and technical issues (e.g. lead fracture, insulation defect).	IIa	A	174–176

HRS Expert Consensus Statement on Remote Monitoring.

Chairpersons: David Slotwiner and Niraj Varma

EHRA Representative	Renato P. Ricci
SOLAECE Representative	Nestor O. Galizio
APHRS Representative	Cheuk-Man Yu

Writing Committee Members

Joseph G. Akar, Marianne Beardsall, Richard Fogel, Taya Glotzer, Robin Leahy, Charles J. Love, Suneet Mittal, Loredana Morichelli, John Rickard, Mark Schoenfeld, Gerald A. Serwer, Julie Shea, Paul Varosy, Atul Verma

*It will be published online coincident with the Heart Rhythm Society Scientific Sessions in **May 2015** and in HeartRhythm journal in late summer 2015.*

Tutto bene …. Manca un dettaglio!!



Il rimborso da parte del S.S.N.