Venice, Italy October 16-18 2015

14th Edition

VENICE 2015 ARRHYTHMIAS

Heart failure and CRT: New topics and evidences in 2015

The role of remote monitoring system in CRT-D patient management: the IN-TIME study

Luca Santini, MD

Cardiology Division

Policlinico Tor Vergata - Rome

October 16 - 18
14th EDITION 2015

MY CONFLICTS OF INTEREST ARE

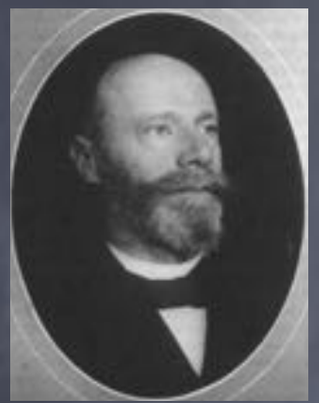
Received compensation from St. Jude Medical, Medtronic, Bayer, Boehringer and Boston Scientific for speaking

Received compensation from St. Jude Medical, Biotronik and
Boston Scientific for teaching and training courses

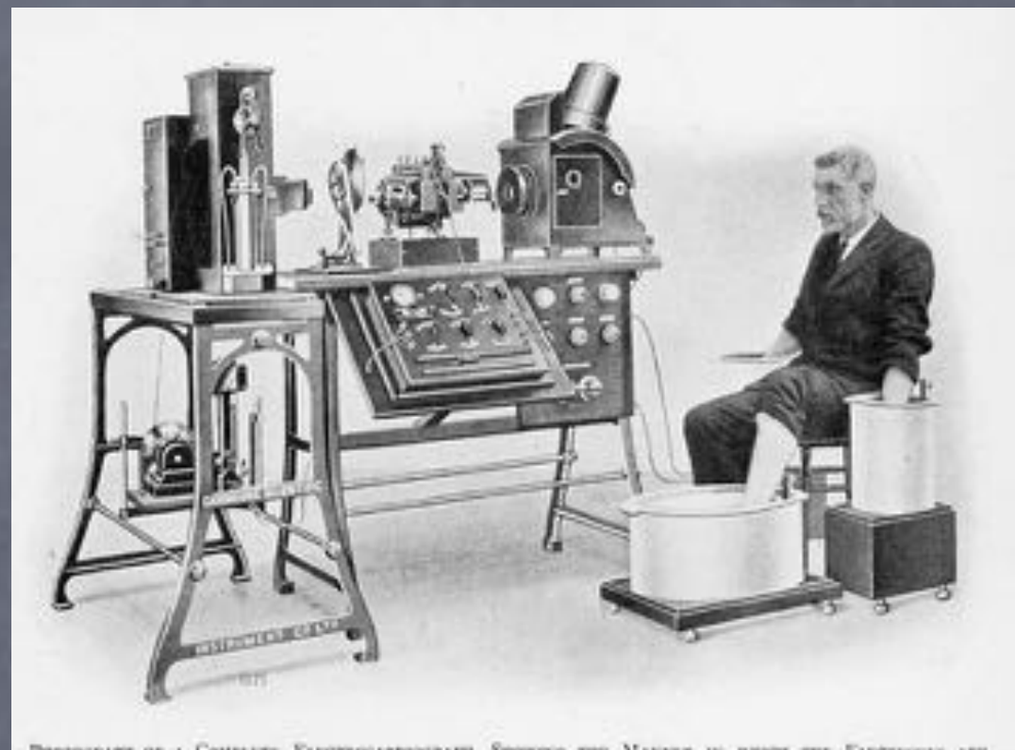
Received compensation for clinical research from Biotronik, Medtronic, St. Jude Medical and Boston Scientific

"Le telecardiogramme".
"Archives Internationales Physiologie" 4:132; 1906

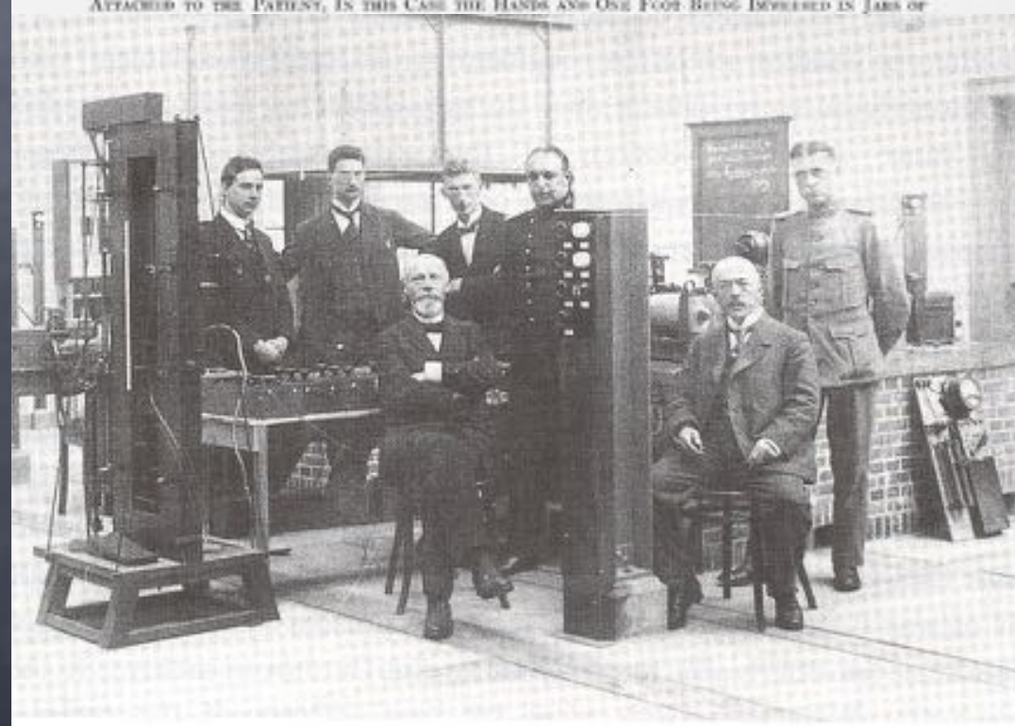
Wilhelm Einthoven



ECG transmission through the telephone line from the Hospital to the ECG lab (2 km)



PHOTOGRAPH OF A COMPLETE ELECTROCARDIOGRAPH, SHOWING THE MANNER IN WHICH THE ELECTRODES ARE ATTACHED TO THE PATIENT, IN THIS CASE THE HANDS AND ONE FOOT BEING IMMERSED IN JARS OF



REMOTE MONITORING

2001

2015

14 years of History

SAFE

EFFECTIVE

Early Detection

Safe follow-up reduction

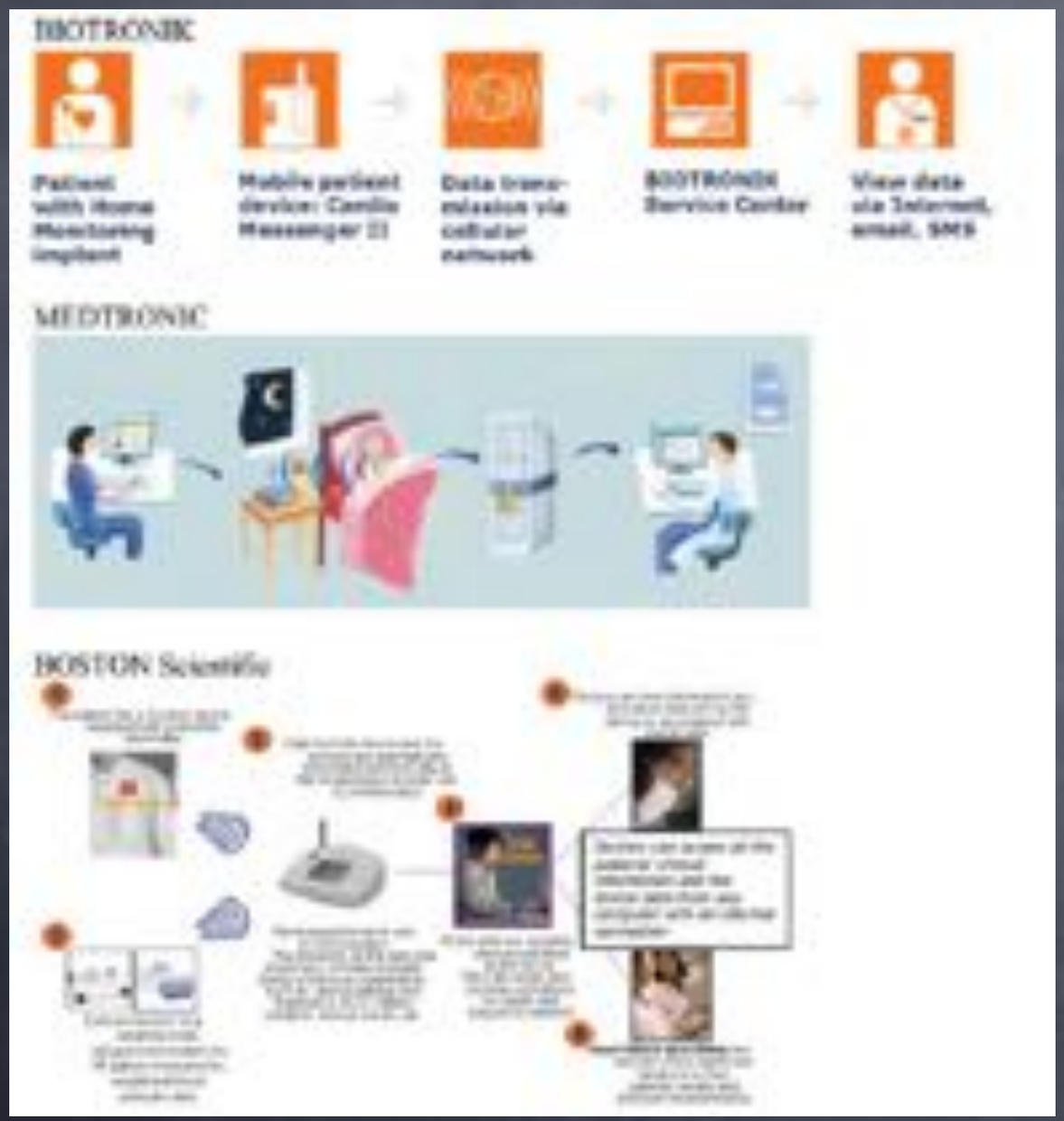
APPROVED

FDA CE 厚生労働省 Ministry of Health, Labour and Welfare

BIOTRONIK Home Monitoring®

REMOTE FOLLOW UP

All systems warrant Remote Follow Up



ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs). Europace (2012) 14, 278–293

Results and perspectives of remote control:which clinical and organizative Outcome may we expect?

ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs)

Sergio Dubner[1*], Angelo Auricchio[2], Jonathan S. Steinberg[3], Panos Vardas[4], Peter Stone[5], Josep Brugada[6], Ryszard Piotrowicz[7], David L. Hayes[8], Paulus Kirchhof[9,10], Günter Breithardt[10], Wojciech Zareba[11], Claudio Schuger[12], Mehmet K. Aktas[11], Michal Chudzik[13], Suneet Mittal[3], and Niraj Varma[14]

Document reviewers: Carsten Israel (Germany), Luigi Padeletti (Italy), and Michele Brignole (Italy)

- Systems for Remote control of CIEDs (PM, ICD, CRT, ILR) underwent through a terrific development in last decade.

Devices may be completely and automatically interrogated following events daily

- Numerous benefits have come by using these systems:
  - ✓ **Clinical advantages**
  - ✓ **Organizational advantages**

ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs)ESC 2013 - Europace (2012) 14, 278–293

REMOTE MONITORING

More than 150 published papers

Europace (2013) 15, i14–i16
doi:10.1093/europace/eut071

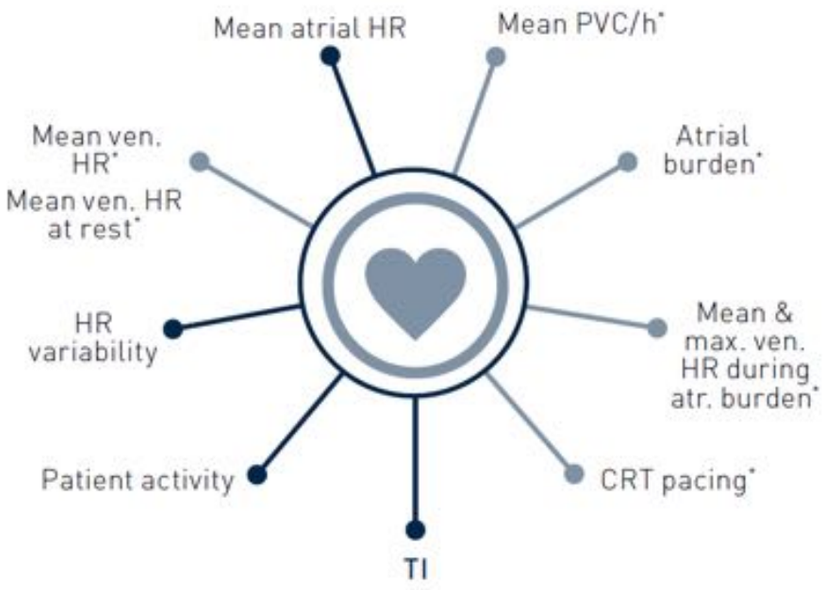
Remote follow-up and continuous remote monitoring, distinguished

Haran Burri*

Patient — Cardio-Messenger — GSM data transmission — BIOTRONIK Service Center — Data Review

System

- No interaction with patients



Clinical Benefits

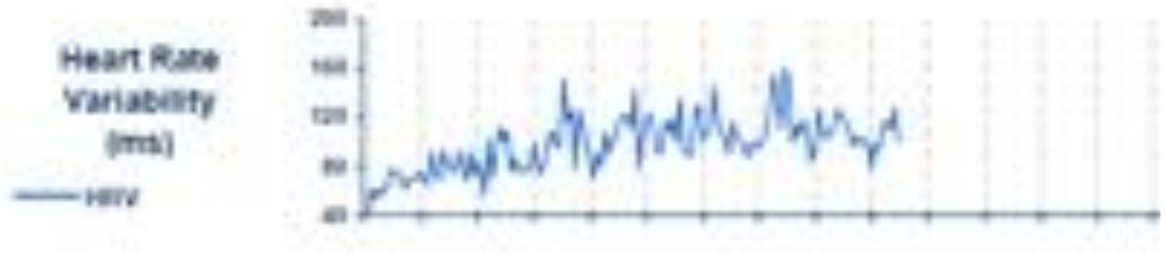
- **Proved early detection of significant clinical events (TRUST)**
- **Proved reduction of shocks(ECOST)**
- **Proved reduction of hospitalizations due to AF and of related strokes (COMPAS)**
- **Proved not significant reduction of mortality (TRUST)**

Efficiency Benefits

- **Reduction of follow up burden (TRUST, COMPAS, REFORM) compared to standard of care without RM**
- **High reliability of transmissions (TRUST)**
- **High patients‘ acceptance (Ricci. et al) & retention (TRUST) compared to standard of care without RM**

Diagnostic data

In addition to providing necessary therapies for cardiac arrhythmias and heart failure, the modern implantable devices also provide useful Patient Diagnostic information:



Heart Rate Variability

Device recorded HRV has recently been shown to be lower in patients at risk of mortality and hospitalization.

Adamson et al. Circulation. 2004;110:2389-94.

NHR

Abrupt changes in heart rate or in the differences between day and NHR may be another clinical sign of acutely worsening HF status

Adamson et al. Circulation. 2004;110:2389-94.

Patient Activity

The clinical utility of changes in the patient's daily activity level in terms of predicting worsening HF is just now being investigated

Page E. et al. Europace. 2007 May 3

Pacing Percentage

A high percentage of ventricular pacing is critical in order to obtain the maximal benefit of CRT therapy. However, atrial arrhythmias can lead to very high ventricular rates that result in inhibition of CRT pacing. .

Modern devices are requested to give not only a therapy but even to help for **clinical management** of the patients

From remote monitoring of the devices…
… to patients' disease management

Patient remote monitoring

Devices Remote Monitoring

Tempo

DETECTION of CLINICAL EVENTS

Retrospective analysis of 11.626 patients

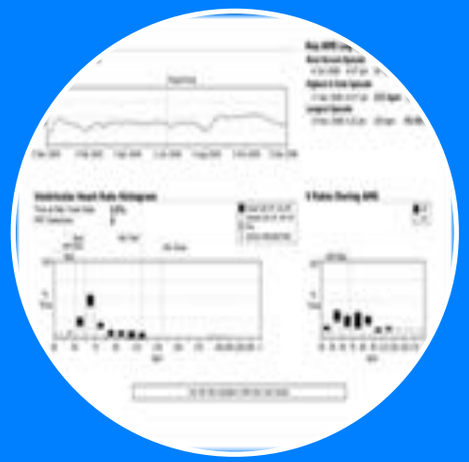
- 4.631 PM
- 6.548 ICD
- **445 CRT-D**

- Mean monitoring period from 1 to 49 months
- 3.004.763 trasmissions

86% of detected events are clinical events and not related to the device

A. Lazarus. Remote, Wireless, Ambulatory Monitoring of Implantable Pacemakers, Cardioverter Defibrillators, and Cardiac Resynchronization Therapy Systems: Analysis of a Worldwide Database; PACE 2007 (PACE 2007; 30:S2–S12)

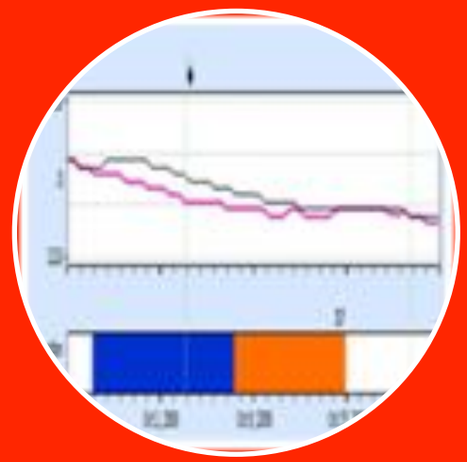
Remote Control…for every type of patien



Monitoring of arrhythmic episodes and therapies delivered

Management AT/AF

Monitoring % pacing, HR



Monitoring pulmonary congestion

Activity Trend / Exercise Trend / HR distribution

Monitoring % pacing, HR

Arrhythmic patient

HF patient

Clinical Impact on AF and HF

“The twin epidemies”

- Remote monitoring must be considered as “Gold Standard” for all CIEDs, above all for patients with AF and/or HF.

Europace (2013) **15**, i47–i48
doi:10.1093/europace/eut120

Remote monitoring and the twin epidemics of atrial fibrillation and chronic heart failure

Massimo Santini*

Heart Failure

- Heart failure is a common disorder associated with significant morbidity and mortality

- Despite advances in treatment, patient with HF remains at high risk for frequent hospitalizations

Heart failure has emerged as a growing health problem likely to reach 'epidemic' proportions in developed countries [1–3]. This has been attributed to the combination of an ageing population and more effective treatment of its major precursor, myocardial infarction [3]. Not unexpectedly, heart failure-related hospitalisation rates have been steadily increasing in

prognostic outlook for those heart failur
who survive an acute hospitalisation remain
Unfortunately, heart failure continues t
'Cinderella' of cardiovascular disease stat
rarely identified as an important health is
public domain. This probably reflects, in
under-estimation of its prognostic significan
perception that it is almost exclusively c
older individuals who would derive little or
from more effective treatment.

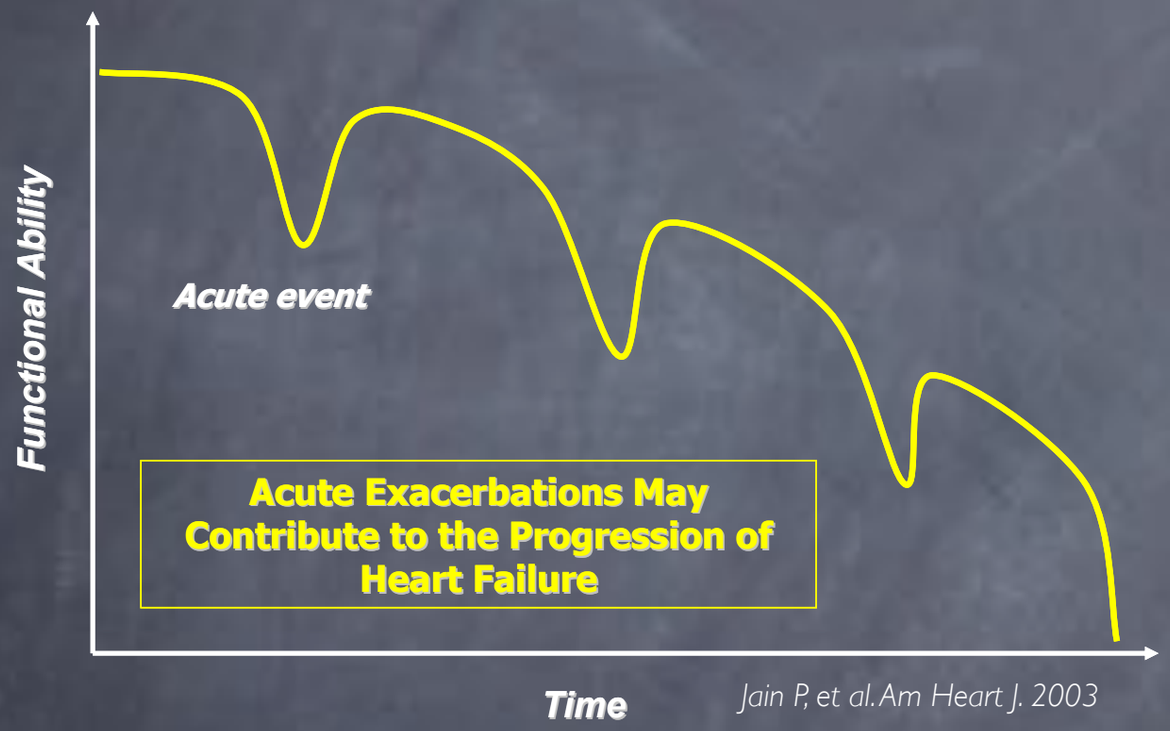
There are some data to suggest, however,

* Corresponding author. Tel.: +44-141-330-6588; fax: +44-141-330-6588.
E-mail address: jmcmurray@bio.gla.ac.uk (J.J. McMurray).

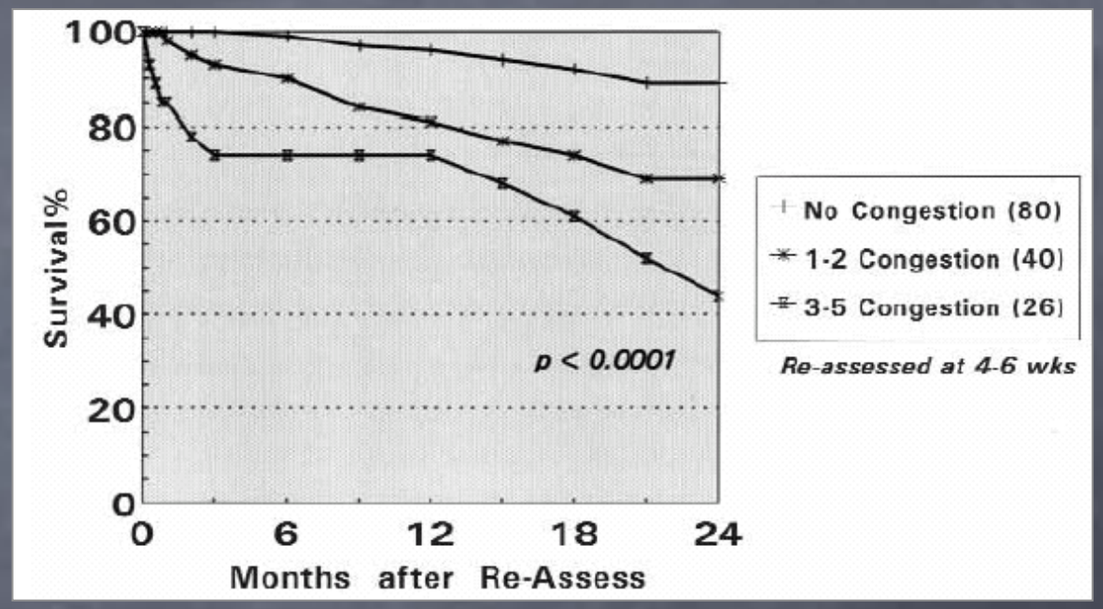
PII: S1388-9842(00)00141-0

Heart Failure Progression

Every acute event has a direct impact on disease progression



Jain P, et al. Am Heart J. 2003

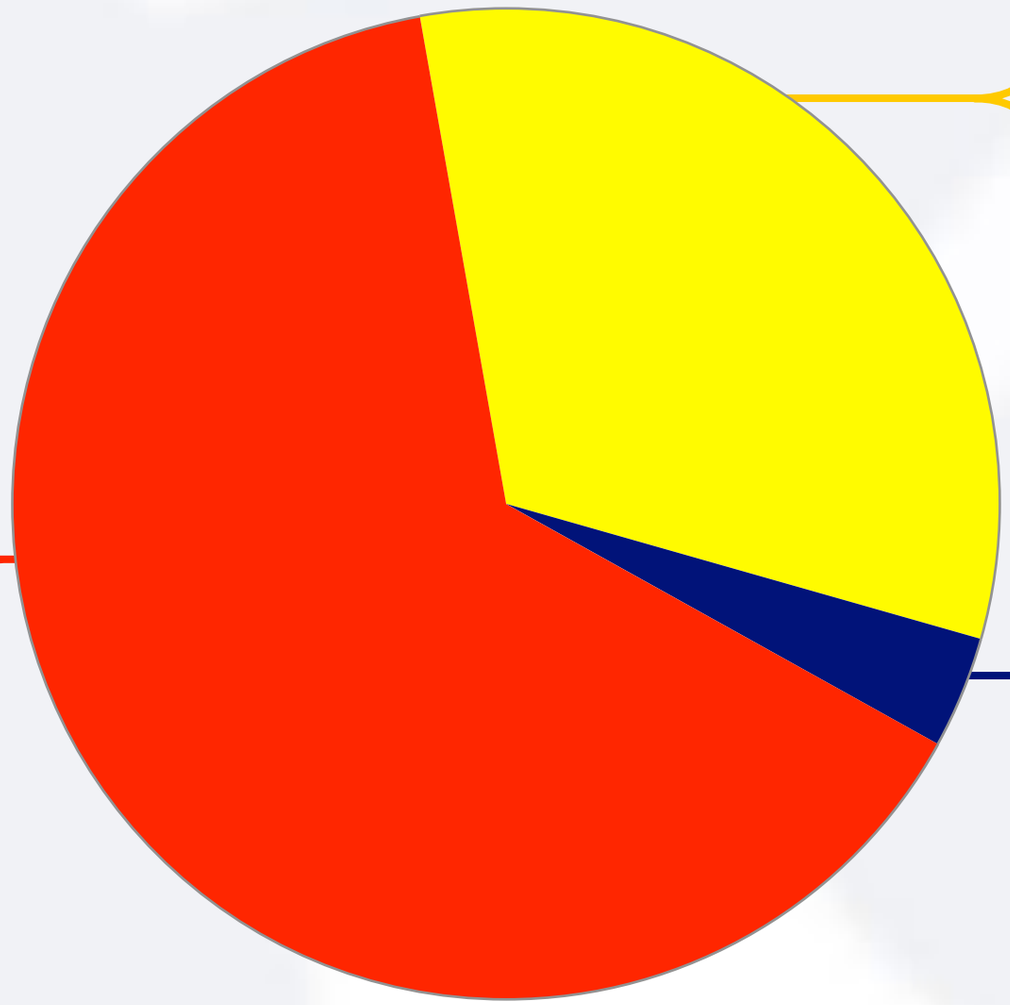


Jain P. Et al. Am Heart J. 2003; 145:S3-S17
Lucas et al., Am Heart J 2000; 140(6): 840-7

Avoiding acute episodes should be one of the main targets of CHF treatment

Decompensated Heart Failure: the Major Contributor to Cost of Care

Maintenance
- Medications
- Routine MD visits
- Nonmedical care



Episodes of decompensation
- Hospital care
- MD visits
- ED visits
- Dx testing

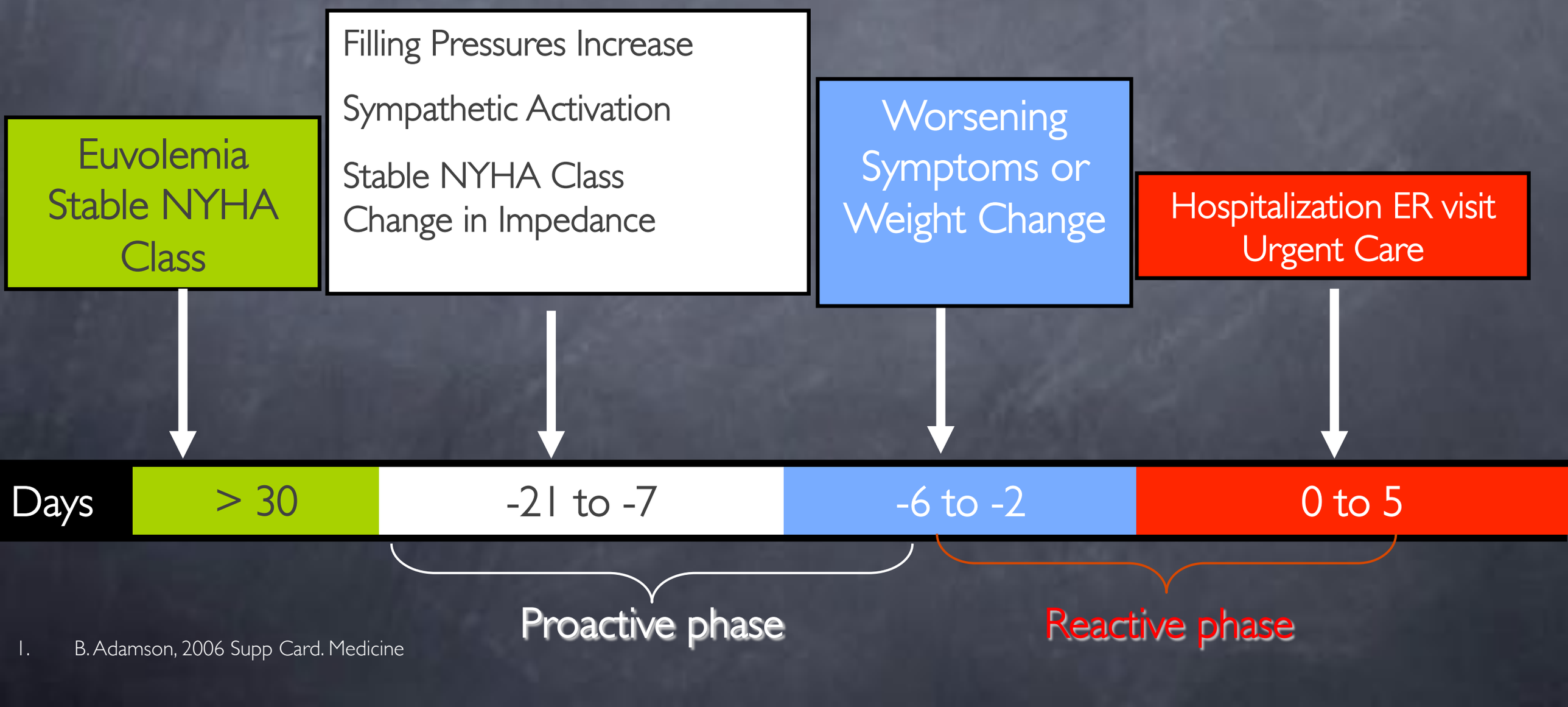
Surgical procedures to treat HF
- Heart transplantation
- Mechanical devices

USA

O'Connell JB. Clin Cardiol 2000;23:III-6

Background

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



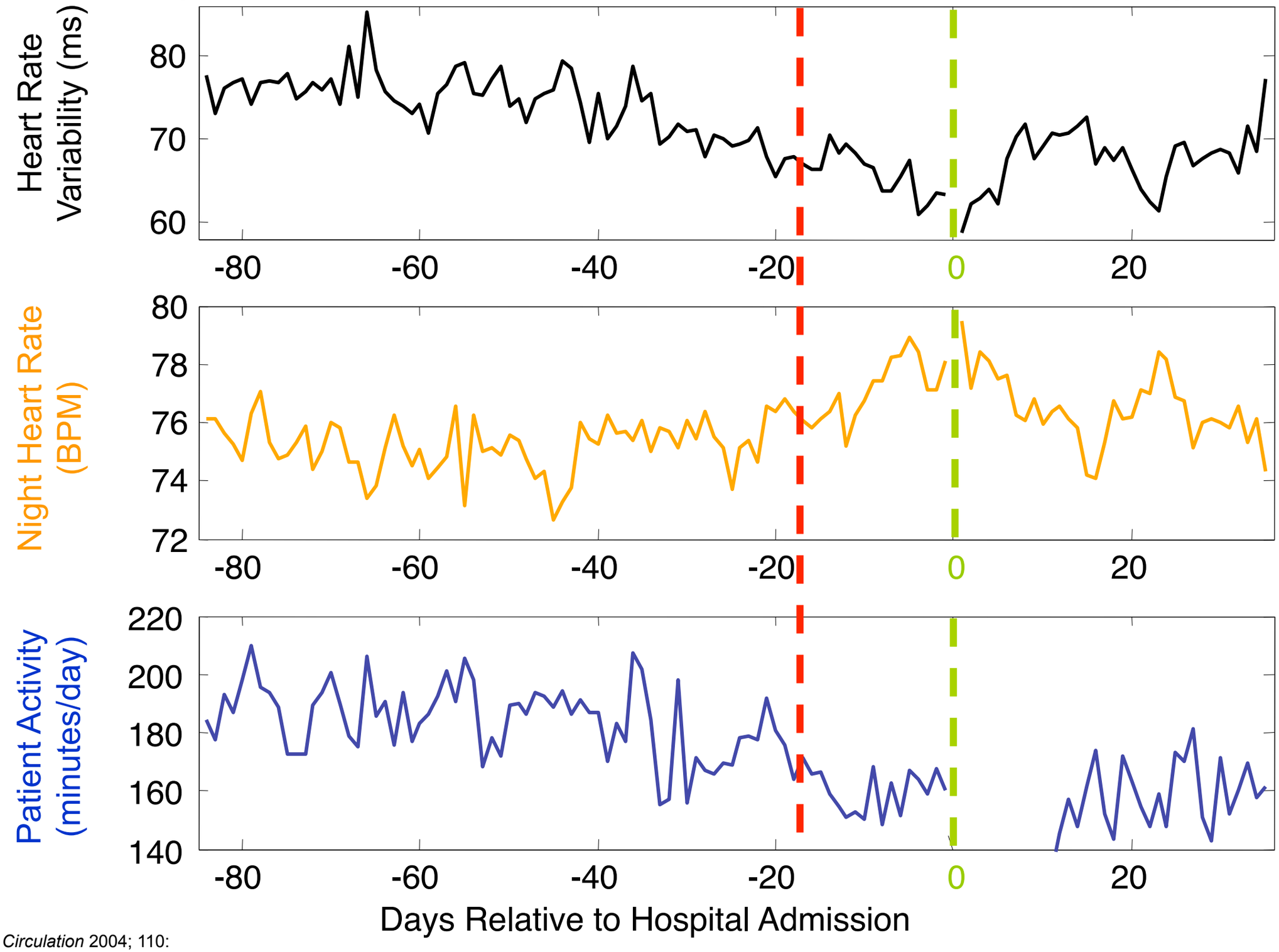
1. B. Adamson, 2006 Supp Card. Medicine

Background

Early detection of fluid overload and associated signs may:

- allow timely adjustment of therapy;
- improve patients care by avoiding hospitalization and associated costs.

Indicators for HF Decompensation (Continuous autonomic assessment)



Adamson PB. *Circulation* 2004; 110: 2389-2394

Continuous Autonomic Assessment in Patients With Symptomatic Heart Failure Prognostic Value of Heart Rate Variability Measured by an Implanted Cardiac Resynchronization Device
Philip B. Adamson, et al. *Circulation*. 2004;110:2389-2394.

Home-CARE Trial

European Journal of Heart Failure (2011) 13, 1019–1027
doi:10.1093/eurjhf/hfr089

AIM

regard to their prospective value in predicting h

The opinions expressed in this article are not necessarily those of th

* Corresponding author. Tel: +31 50 3612355, Fax: +31 50 361439

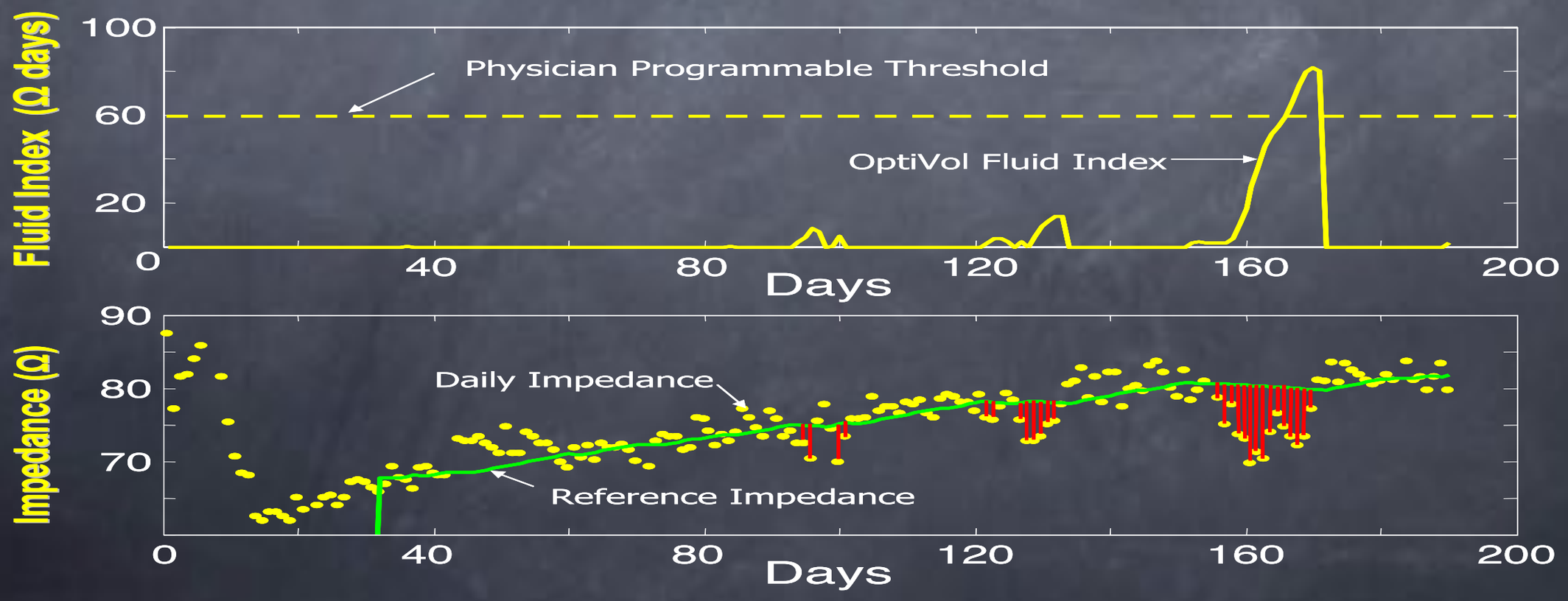
Figure 1 Sensitivity values for the basic five-parameter predictor (A) and for the enhanced seven-parameter predictor (B), to detect major cardiovascular events from Table 3. In (A), combinations of two, three, and four parameters were made by adding the next best individual parameter. (B) shows the sensitivities for two new parameters and for the combination of all seven parameters. The combination of the two new parameters from (B) without 'help' of parameters from (A) had still suboptimal sensitivity of 50% (not shown). All sensitivity values were calculated retrospectively for the target specificity of 99.5%.

This tool may increase patients' quality of life and reduce morbidity, mortality, and health economic burden, it now warrants prospective studies.

Monitoring of fluid status by implanted devices

Dryer lungs
Impedance increases

Wetter lungs
Impedance decreases

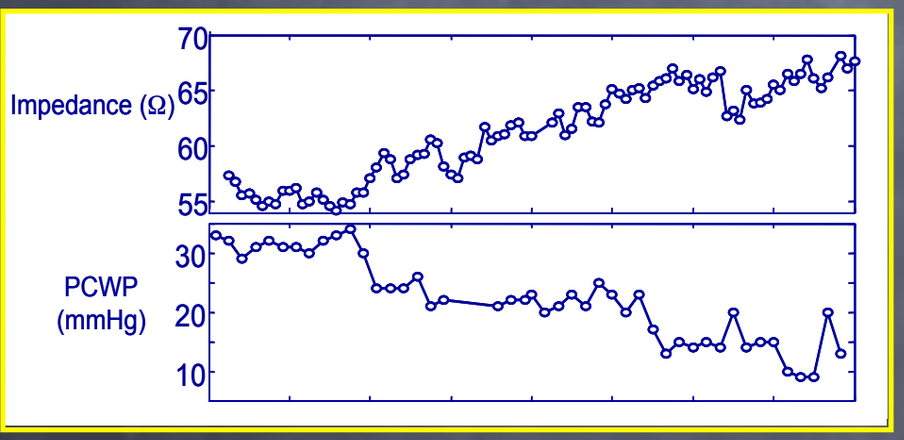


Clinical value of intrathoracic impedance monitoring

MID-HeFT trial

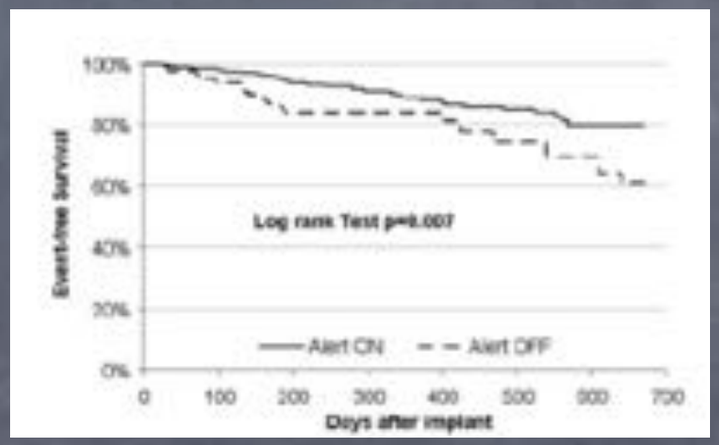
Changes in intra-thoracic impedance:
- may provide advanced warning of impending HF hospitalization
- are inversely related with PCWP and fluid status

(Yu et al,.Circulation. 2005;112:841-8.)



The alert capability reduces the number of HF hospitalizations by allowing timely detection and therapeutic intervention.

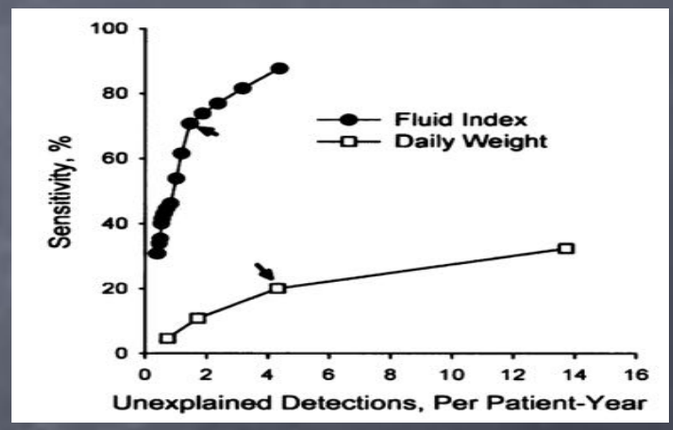
Catanzariti et al. PACE 2009; 32:363–370



Intrathoracic Impedance vs Daily Weight Monitoring FAST Study

Event Detection Performance

Abraham WT et al Congest Heart Fail 2011;17:51-55



Remote monitoring of patients with biventricular defibrillators through the CareLink system improves clinical management of arrhythmias and heart failure episodes

Santini M. *J Interv Card Electrophysiol.* 2009; 24: 53–61

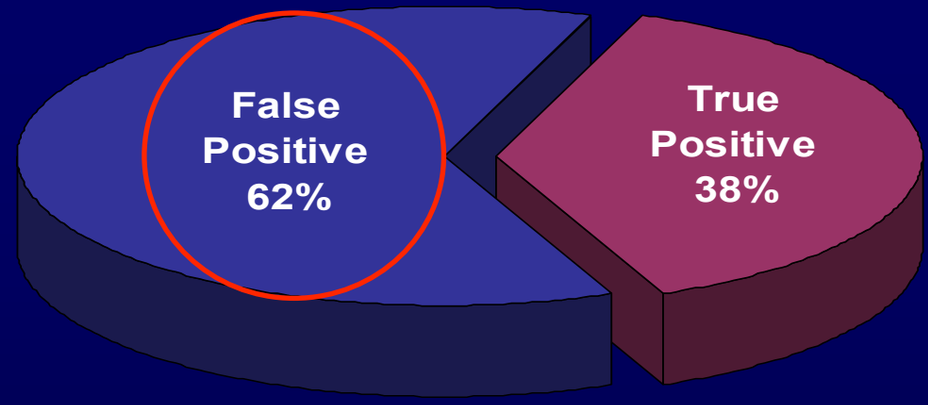
67 CRT-D pts. 28 OptiVol alerts:

- 20 were true positive (sensitivity 91%, PPV 71%)
- In 20 cases remote transmission, resulting in drug therapy adjustment (10), reassurance (4) and hospital visit (6)

Intra-thoracic impedance

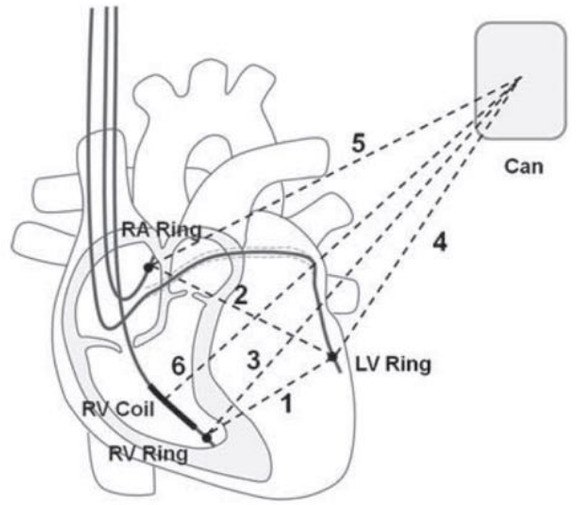
SENSE-HF was a prospective, multicenter study that investigated the performance of OptiVol Intrathoracic impedance fluid monitoring for prediction of HF hospitalisation in patients with HF newly implanted with an ICD or CRT-D device

SENSE-HF proved that only 38% of patients with a fluid index crossing show HF symptoms within 30 days



Conraads VM Eur H J 2011

CorVue™ Congestion Monitoring



J Interv Card Electrophysiol

Feasibility of using multivector impedance to monitor pulmonary congestion in heart failure patients

Philip F. Binkley · James G. Porterfield ·

- 75 patients enrolled in 23 US centers
- 8,2 ± 2,6 months of follow-up

	CRT-D	ICD	Single vector
Vector combination	LVr-Can and RVc-Can	RVr-Can and RVc-Can	RVc-Can
Detected clinical events	15 (14 cardiac)	13 (12 cardiac)	12 (11 cardiac)
Number of false positive algorithm-detected events	17	19	22
Total number of algorithm-detected events	32	32	34
FPR (false positives per patient-year)	0.56	0.63	0.74
Sensitivity (%)	71.4	61.9	57.1
Positive predictive value (%)	46.9	40.6	35.3

Published online: 12 June 2012

CorVue™ Congestion Monitoring

J Cardiovasc Med 2013, 14:726–732

Device monitoring of heart failure in cardiac resynchronization therapy device recipients: a single-center experience with a novel multivector impedance monitoring system

Giovanni B. Forleo[a], Germana Panattoni[a], Valentina Schirripa[a],

Table 2 Characteristics of congestion monitoring alerts

Patients with congestion monitoring alerts, *n* (%)	29 (36.3)
Congestion monitoring alerts, *n*	56
Congestion monitoring alerts/patient, median (range)	2 (1–3)
AT/AF alerts associated with congestion monitoring alerts, *n* (%)	5 (6.3)
FP congestion monitoring alerts, *n* (%)	32 (57.1)
TP congestion monitoring alerts, *n* (%)	24 (42.9)
Sensitivity for HF events, (%)[a]	61.5
Sensitivity for HF hospitalization, (%)	53.8
PPV for HF events, (%)[a]	42.9
PPV for HF hospitalization, (%)	17.9
FP detections per patient-year	0.60

[a] Defined as admissions in hospital for congestive heart failure or milder manifestations of heart failure deterioration.Values are mean ± SD unless otherwise specified. AT/AF, atrial tachycardia/atrial fibrillation; FP, false positive; HF, heart failure; PPV, positive predictive value; TP, true positive.

- 80 patients enrolled at Policlinico Tor Vergata
- 8,0 ± 4,4 months of follow-up

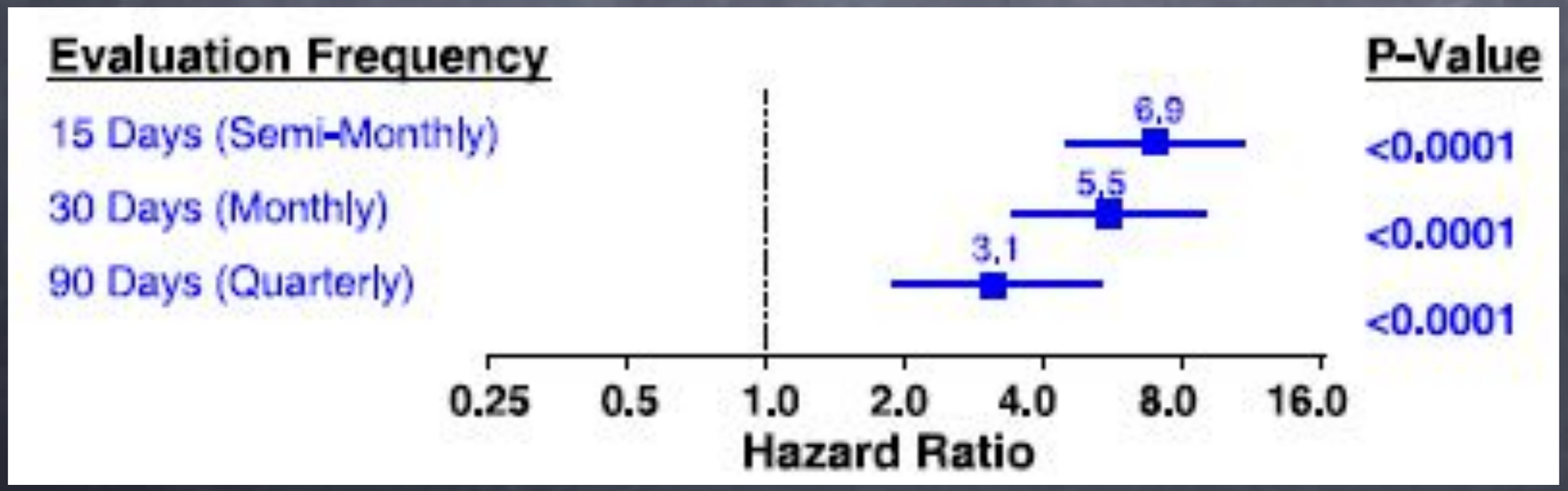
Advanced therapy monitoring

Clinical Evidence

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

Observing more diagnostic parameters, in a shortest time interval, allows to predict HF episodes more likely



PARTNERS HF Study
Combined Algorithm

Positive Combined Algorithm = any 2 criteria +

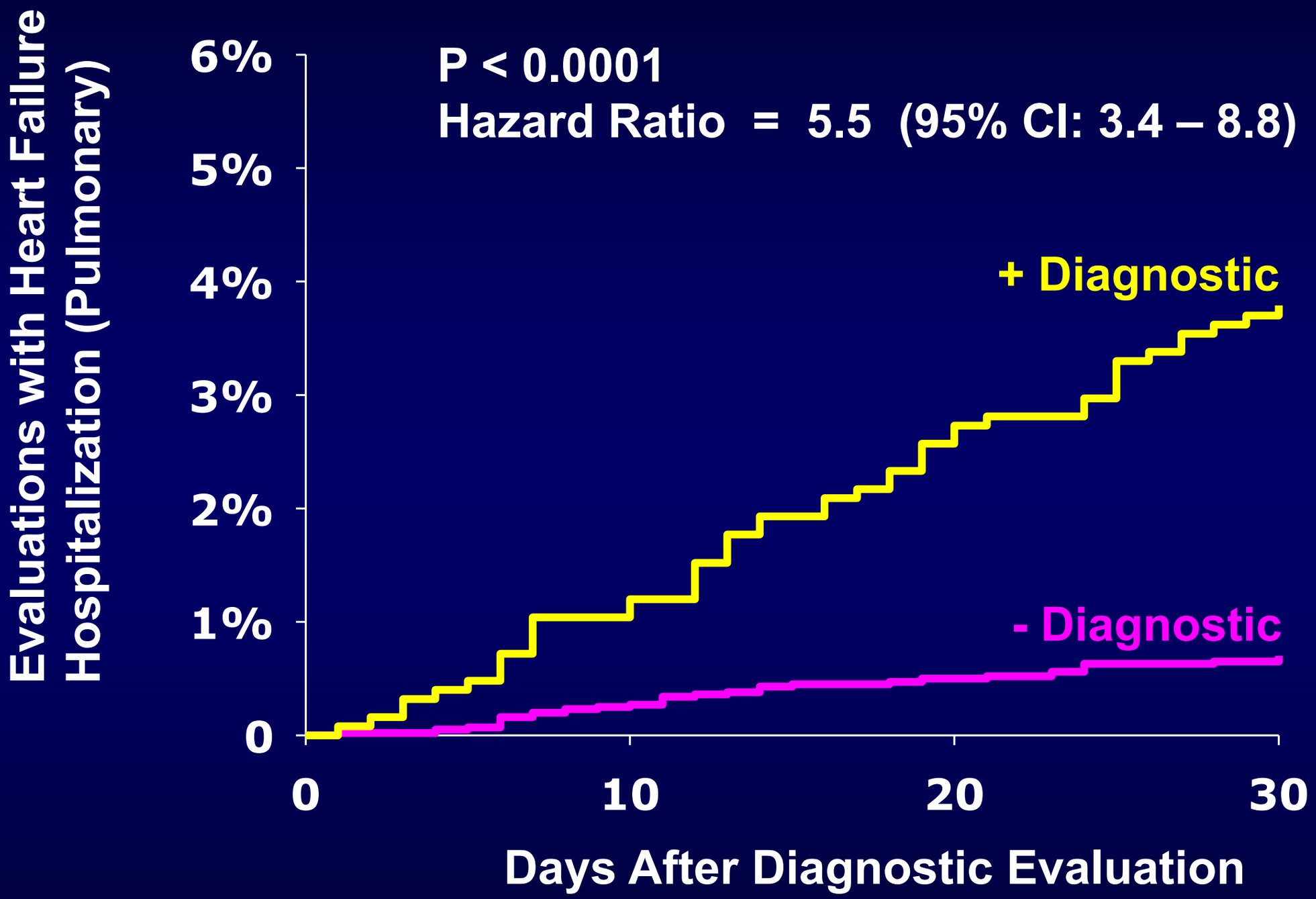
Parameter	Criterion
Fluid Index	≥60 ohm/days
AT/AF Duration	≥6 hours & not persistent AT/AF
V. rate during AT/AF	AT/AF ≥24 hrs & V. ≥ 90 bpm
Patient Activity	Avg. <1 hr over 1 week
Night Heart Rate	≥85 bpm for 7 consecutive days
HRV	<60 ms for 7 consecutive days
CRT % Pacing	< 90% for 5 of 7 days
Shock(s)	1 or more shocks

OR Fluid Index ≥100

Whellan et al. JACC Vol. 55, No. 17, April 27, 2010:1803–10

PARTNERS HF Study

Kaplan-Meier HF Hospitalization Curves



Risk of a HF hosp. for pts with + Diagnostic was 5.5 x risk of pts w/ - Diagnostic

Whellan et al. JACC Vol. 55, No. 17, April 27, 2010:1803–10

Other diagnostic data: what are their importance

J Interv Card Electrophysiol (2008) 23:235–242

Implantable CRT device diagnostics identify patients with increased risk for heart failure hospitalization

Giovanni B. Perego · Maurizio Landolina · Giuseppe Vergara · Maurizio Lunati · Gabriele Zanotto · Alessia Pappone · Gabriele Lonardi · Giancarlo Speca · Saverio Iacopino · Annamaria Varbaro · Shantanu Sarkar · Doug A. Hettrick · Alessandra Denaro · Optivol-CRT Clinical Service Observational Group

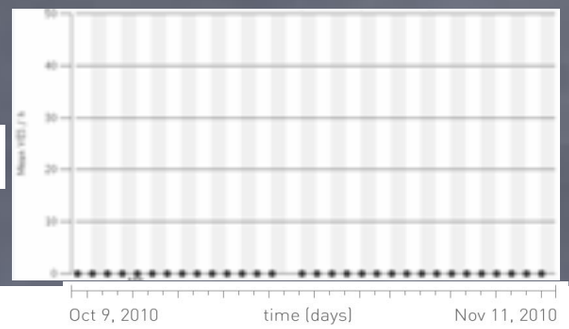
- Decreased intra-thoracic impedance detected by an implantable monitor, is associated with a 38% increased risk for HF hospitalization in a population of HF patients treated with CRT.

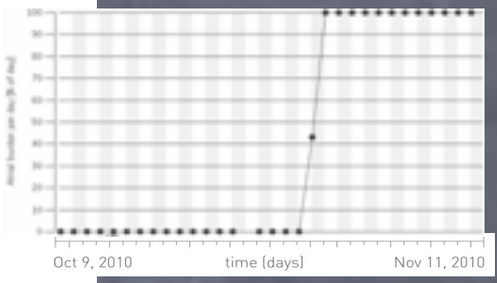
- Some device parameters including patient activity, VT episodes, NHR and HRV are weak prognostic predictors of Acute HF events, but can be associated with intrathoracic impedance indices to better evaluate the risk of Acute HF events.

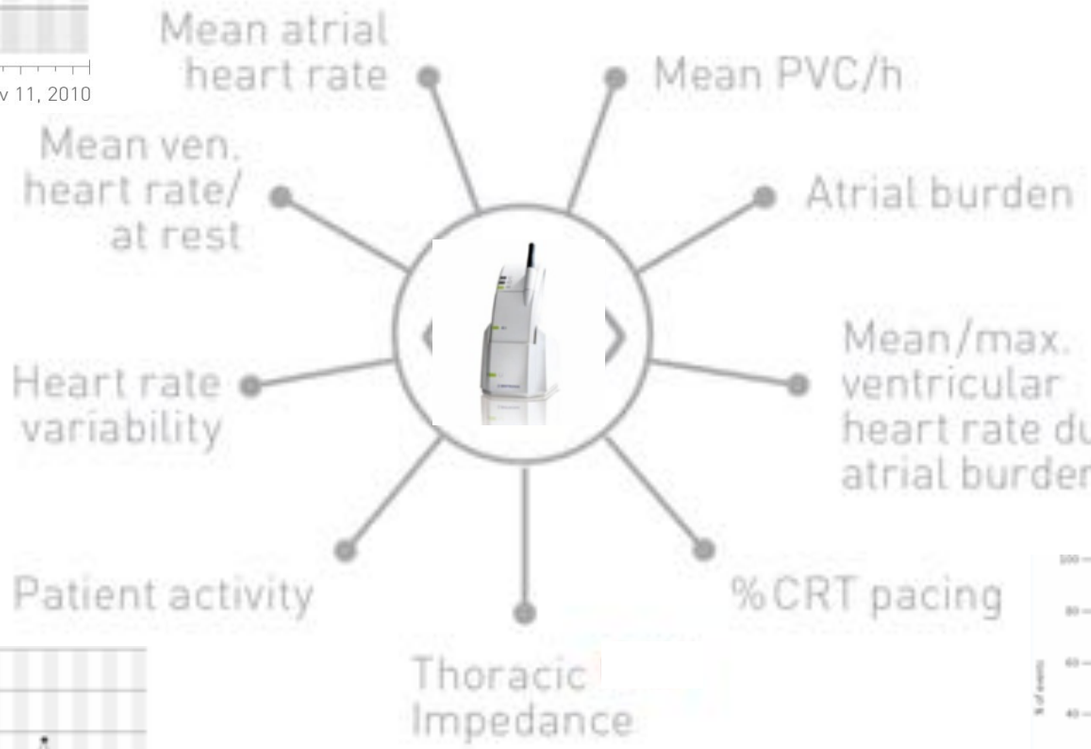
- **The combination of multiple device diagnostics may increase the clinical utility of alerts for monitoring HF status.**

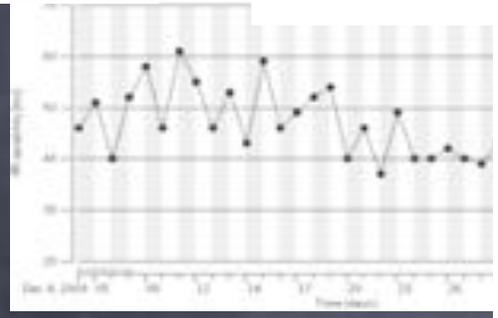
Heart Failure Remote Monitoring

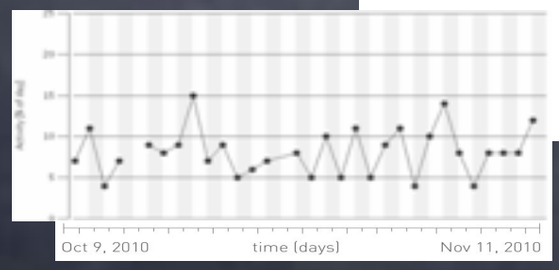
Observing more diagnostic parameters, in a shortest time interval, allows to predict HF episodes more likely.

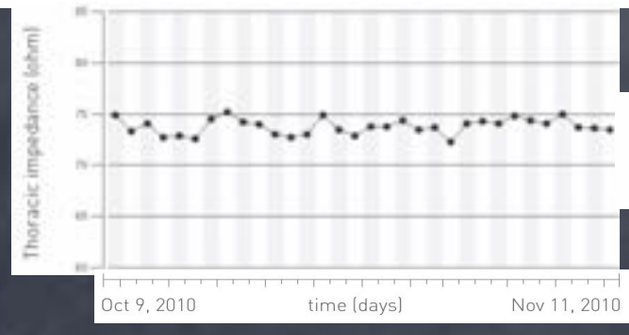


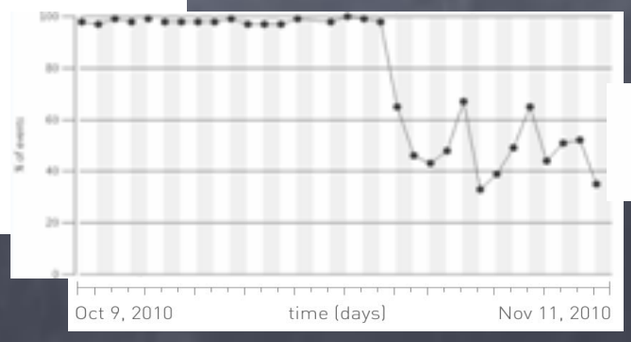






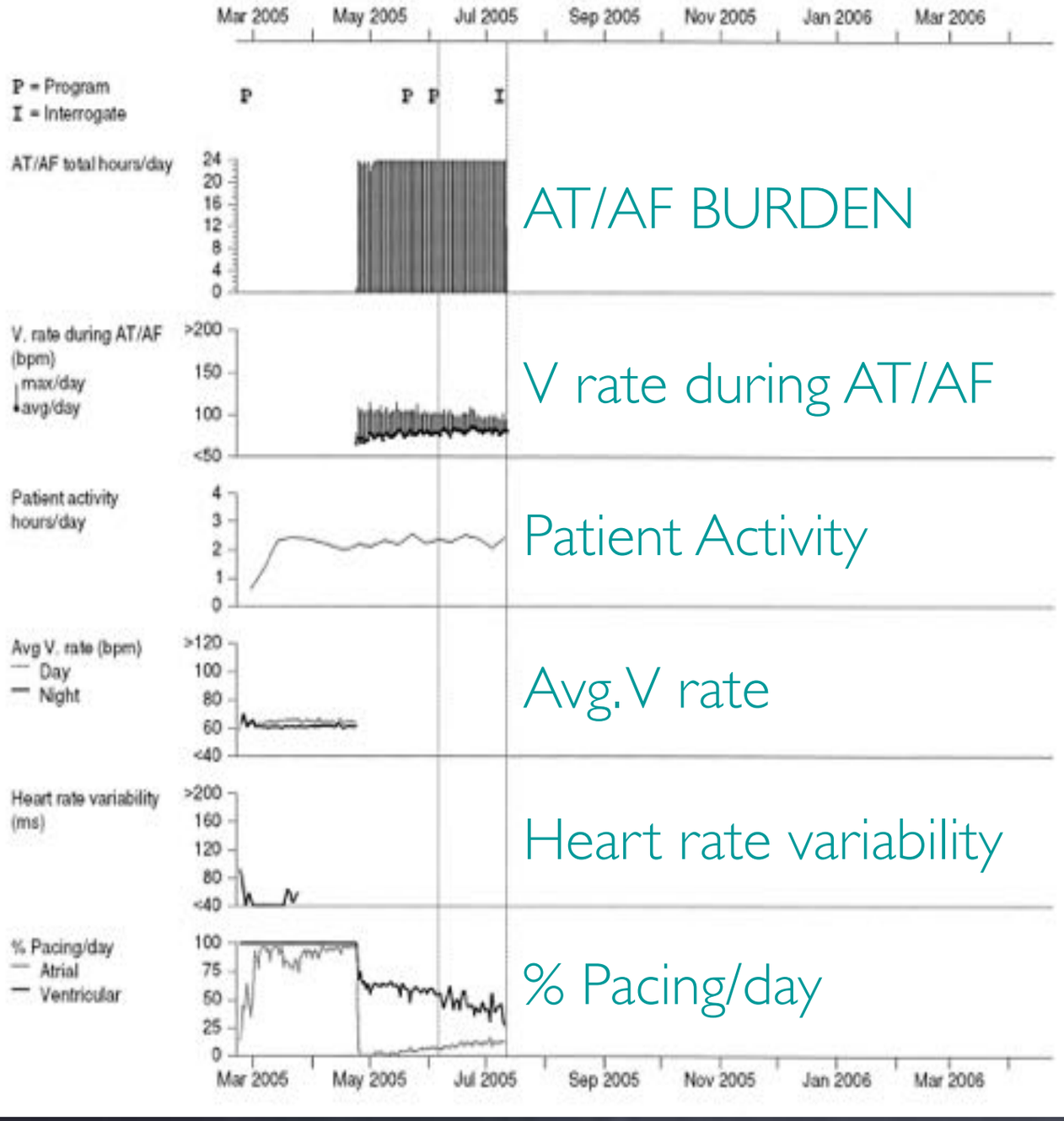






Heart Failure Management Report

ICD Model: InSync Sentry 7297 Serial Number: Date of Visit:



AT/AF BURDEN

V rate during AT/AF

Patient Activity

Avg.V rate

Heart rate variability

% Pacing/day

Heart Failure Management Report

ICD Model: InSync Sentry 7297 Serial Number: Date of Visit:

Date of Birth
History

EF, on
Implant

Hospital
Physician

Clinical Status (Jun 07, 2005 to Jul 12, 2005)

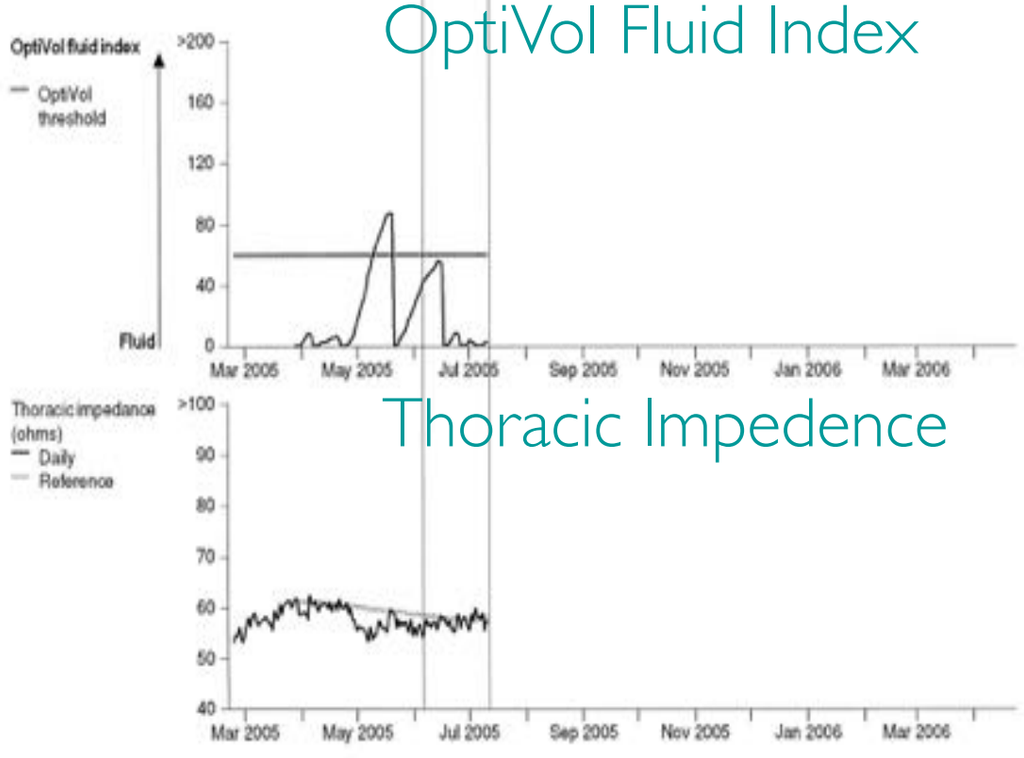
VT/VF	0 episodes	V. Pacing (V. beats)	44.5 %	Lower Rate	60 ppm
AT/AF	97 episodes	Atrial Pacing	11.4 %	Upper Rate	130 ppm
Time in AT/AF	24.0 hr/day (99.9 %)			Battery	OK

Observations (2) (Jun 07, 2005 to Jul 12, 2005)

- V. Pacing (V. beats) less than 90%.
- 35 days with more than 6 hours of AT/AF.

OptiVol Fluid Trends (Feb 2005 to Jul 2005)

OptiVol fluid index is an accumulation of the difference between the daily and reference impedance.



OptiVol Fluid Index

Thoracic Impedence

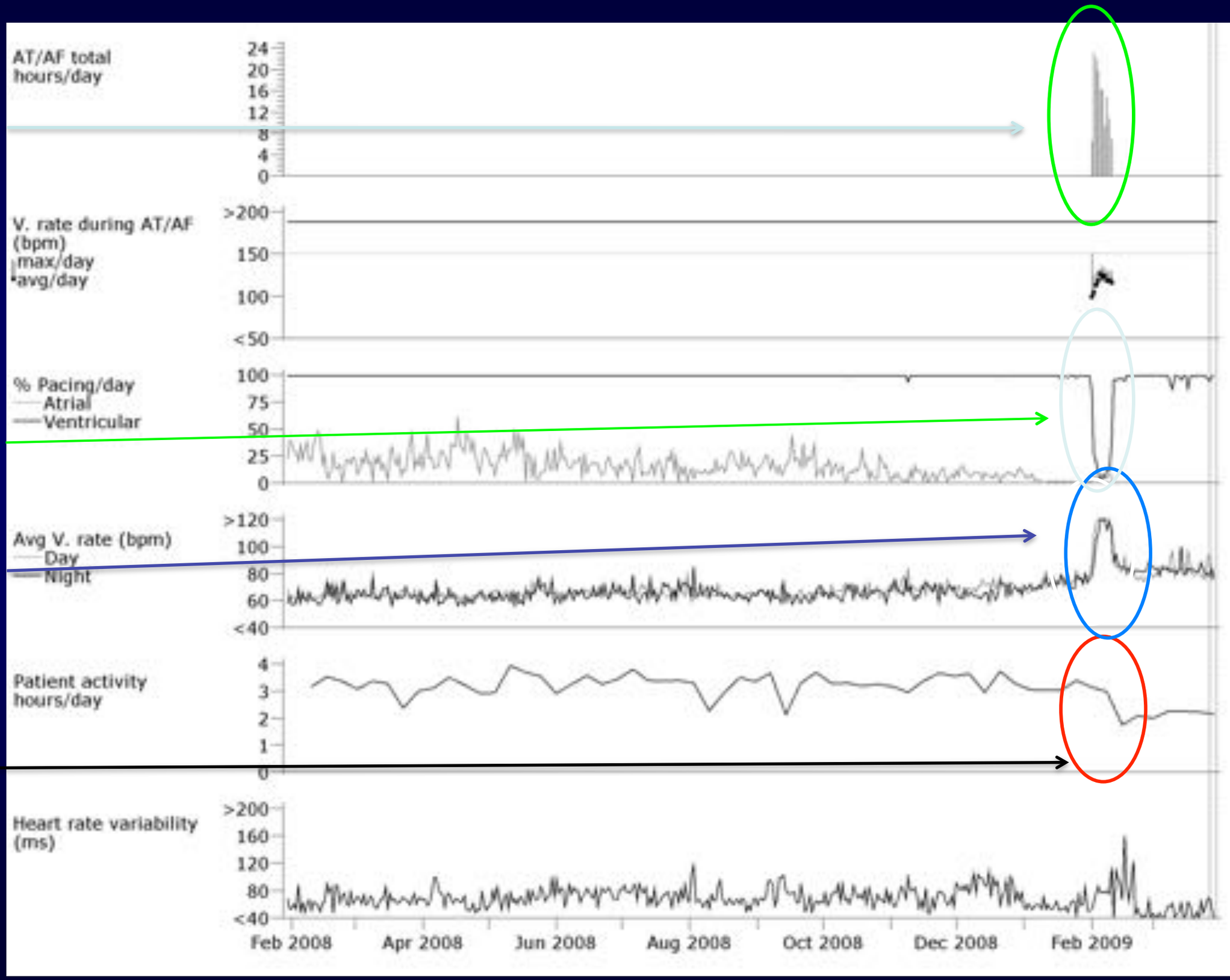
AF induced HF

AT/AF

↓ % CRT

Day and Night HR increase

↓ Patient Activity



Pulmonary fluid monitoring by the CorVue algorithm

T.G.

Fortify™ ST VR 1235-40Q (700231 prC.D.95)

Monitor. Congestione CorVue™

pagina 1

16 gen 2011, 10.11 (C

Paziente e medico

Nome paziente	T.G.
Data di nascita	6 lug 1943
Data di impianto	8 giu 2010
Medico /Impianto	
Medico /Follow-up	

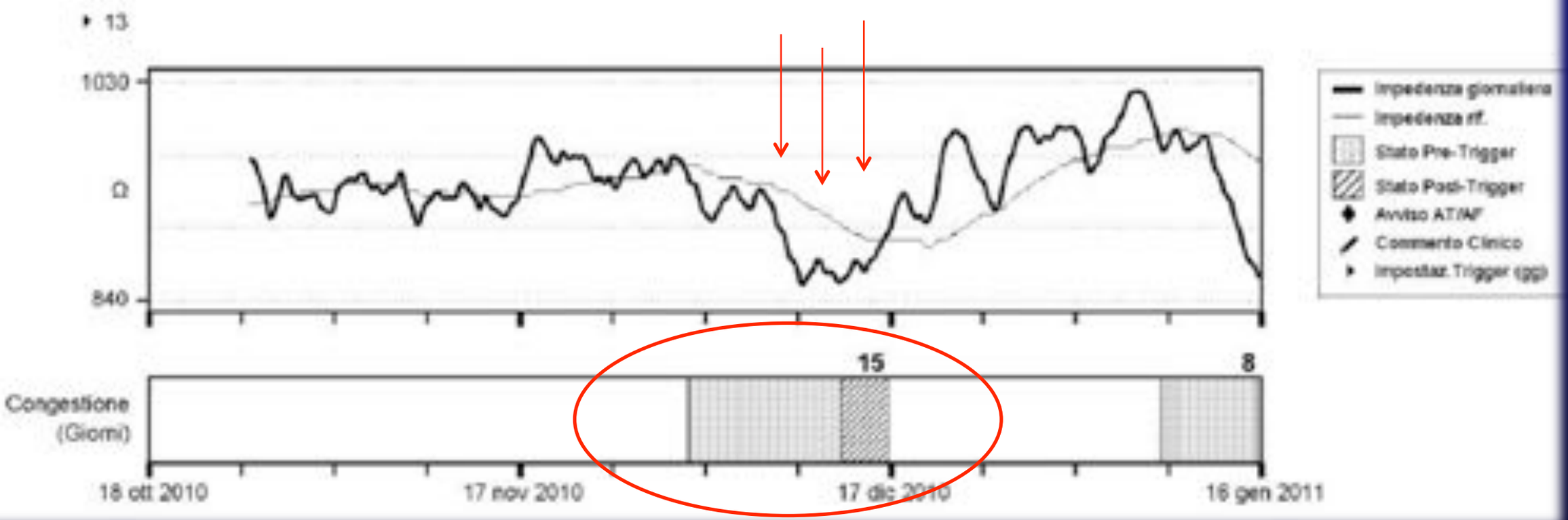
Avviso Monitoraggio Congestione

Trigger Congestione Superato

Parametri Monitor. Congestione

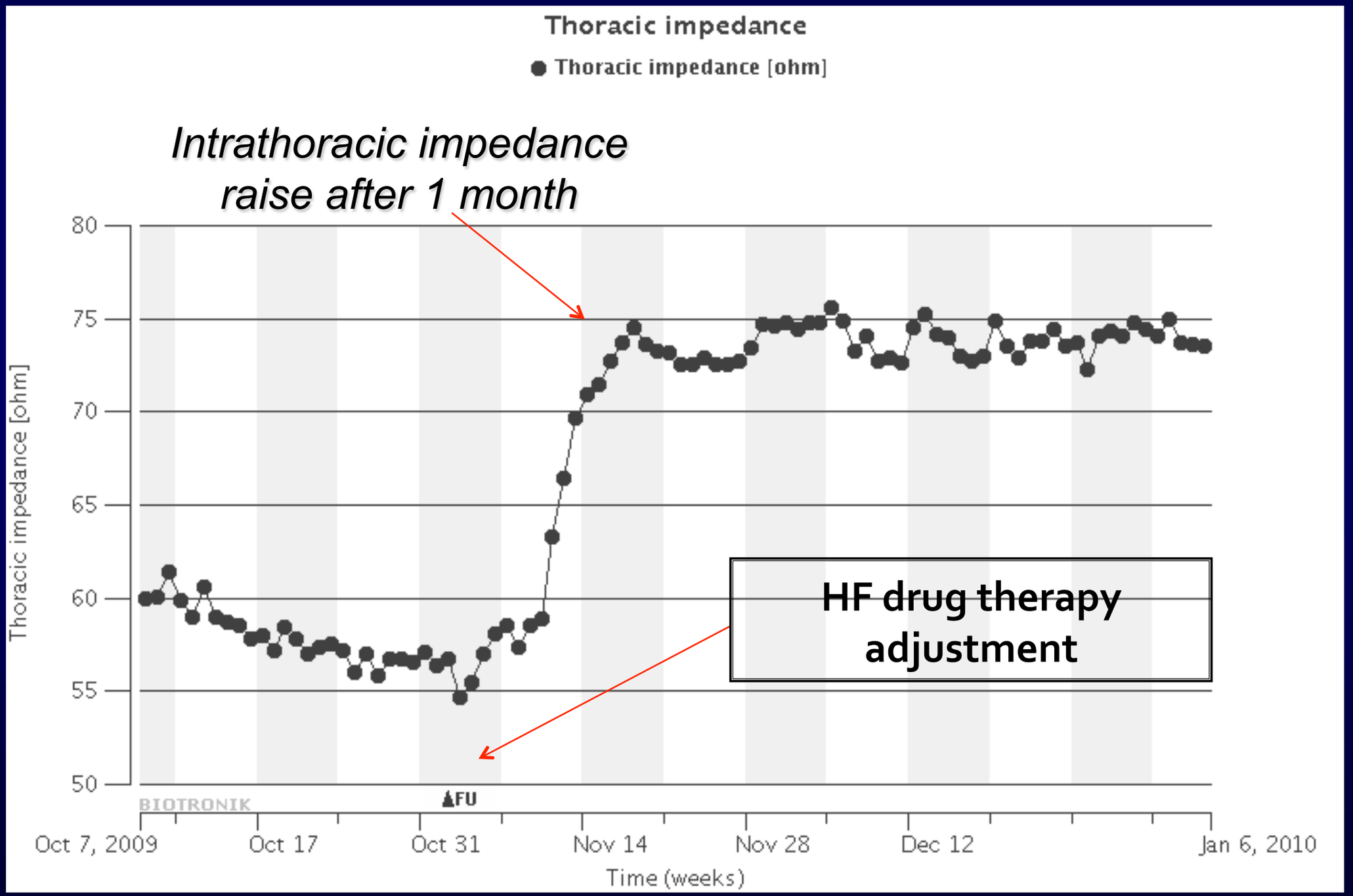
Monitoraggio Congestione	On
Trigger Congestione	13 gio
Avviso Monitoraggio Congestione	On
Avviso Paziente	Off

Monitoraggio Congestione™ CorVue (Vista 3 mesi)

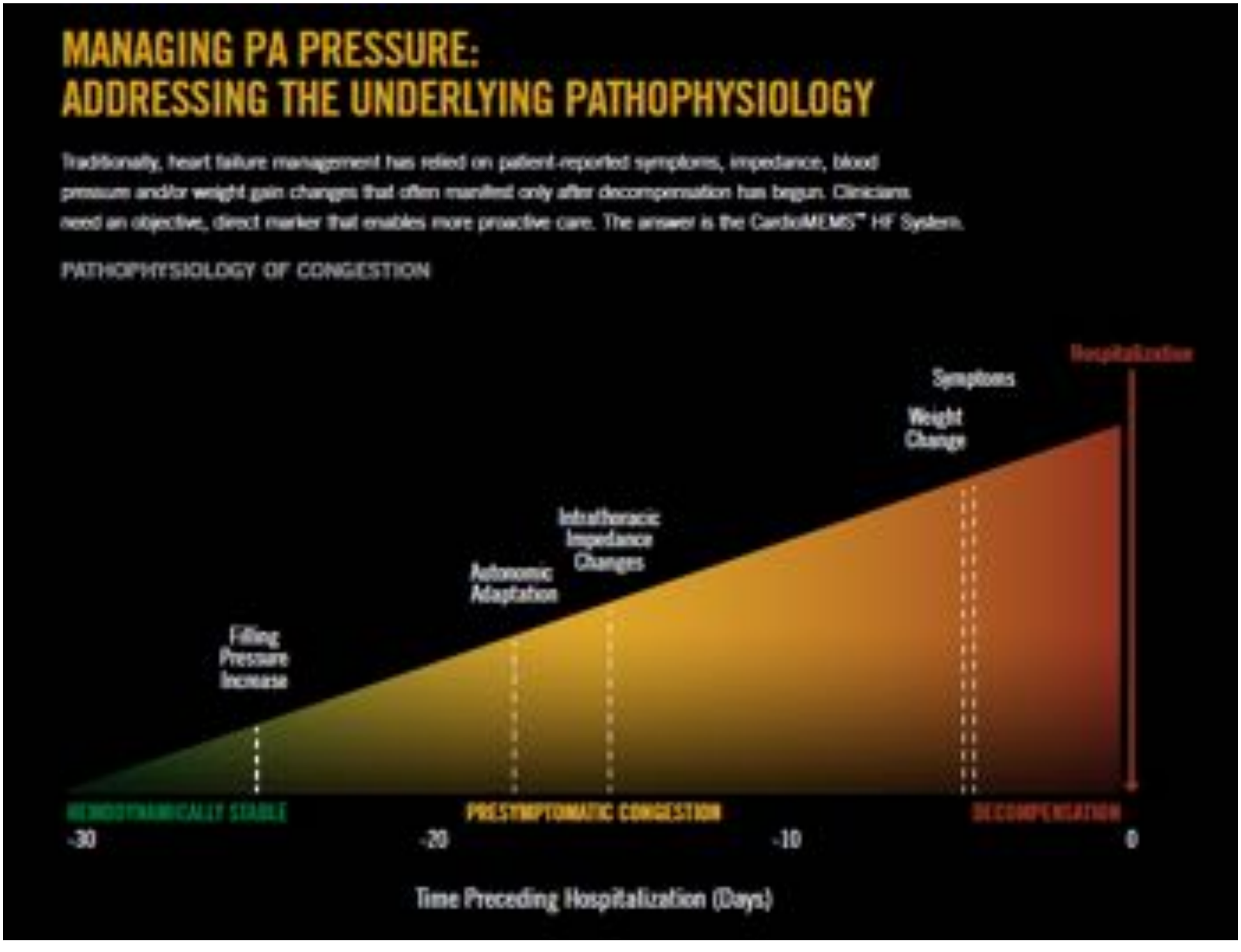


Intrathoracic Impedance Monitoring

Home Monitoring (Biotronik)



CARDIOMEMS™ HF SYSTEM



CARDIOMEMS™ HF SYSTEM

When used by clinicians to manage HF, the CardioMEMS™ HF System is the first and only FDA-approved HF monitor proven to significantly reduce HF hospital admissions and improve quality of life in NYHA class III patients.[14]

37%
REDUCTION IN HEART FAILURE HOSPITAL ADMISSIONS

0
SENSOR FAILURES

98.6%
COMPLICATION-FREE

FEWER DAYS IN HOSPITAL AT 6 MONTHS OF FOLLOW-UP AROSS OVER 1,167 PATIENT-YEARS OF EXPERIENCE

PA Sensor

Patient Electronics System

Data Retrieval

References
1. Abraham WT, Adamson PB, Bourge RC, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: A randomised controlled trial. *Lancet*. 2011;377(9766):658-66.
2. Adamson et al., Impact of Wireless Pulmonary Artery Pressure Monitoring on Heart Failure Hospitalizations and 30-Day Readmissions in Medicare-Eligible Patients with NYHA Class III Heart Failure: Results from the CHAMPION Trial AHA 2014, Chicago. Abstract 16744.

The CardioMEMS™ HF System

JUST RELEASED DATA FROM HRS 2015

ON CARDIOMEMS™ HF SYSTEM

Cost Effectiveness Assessment of Pulmonary Artery Pressure Monitoring for Heart Failure Management

Presenter: Philip Adamson, MD

Conclusions: The model suggests that PAP guided management of HF **using the CardioMEMS HF System is cost-effective**. This ICER of $30,167 was below the conventional US acceptability threshold of $50,000.

Pressure for Action: Implantable Pulmonary Artery Pressure Sensor Measurements Alone Beat Clinical Signs to Guide Prevention of Heart Failure Hospitalizations

Presenter: Lee Goldberg, MD, MPH

Conclusions: **Heart failure hospitalization rates were most effectively reduced by a management strategy based on pulmonary artery pressures** without reliance upon clinical changes. This supports the strategy of early intervention prior to clinical signs to avert clinical decompensation and heart failure readmissions.

Pulmonary Artery Pressure Management in Heart Failure Patients with Cardiac Resynchronization Therapy or Implantable Cardioverter Defibrillator Devices Significantly Reduces Hospitalizations and Mortality Above and Beyond Background Guideline-Directed Medical

Presenter: William Abraham, MD

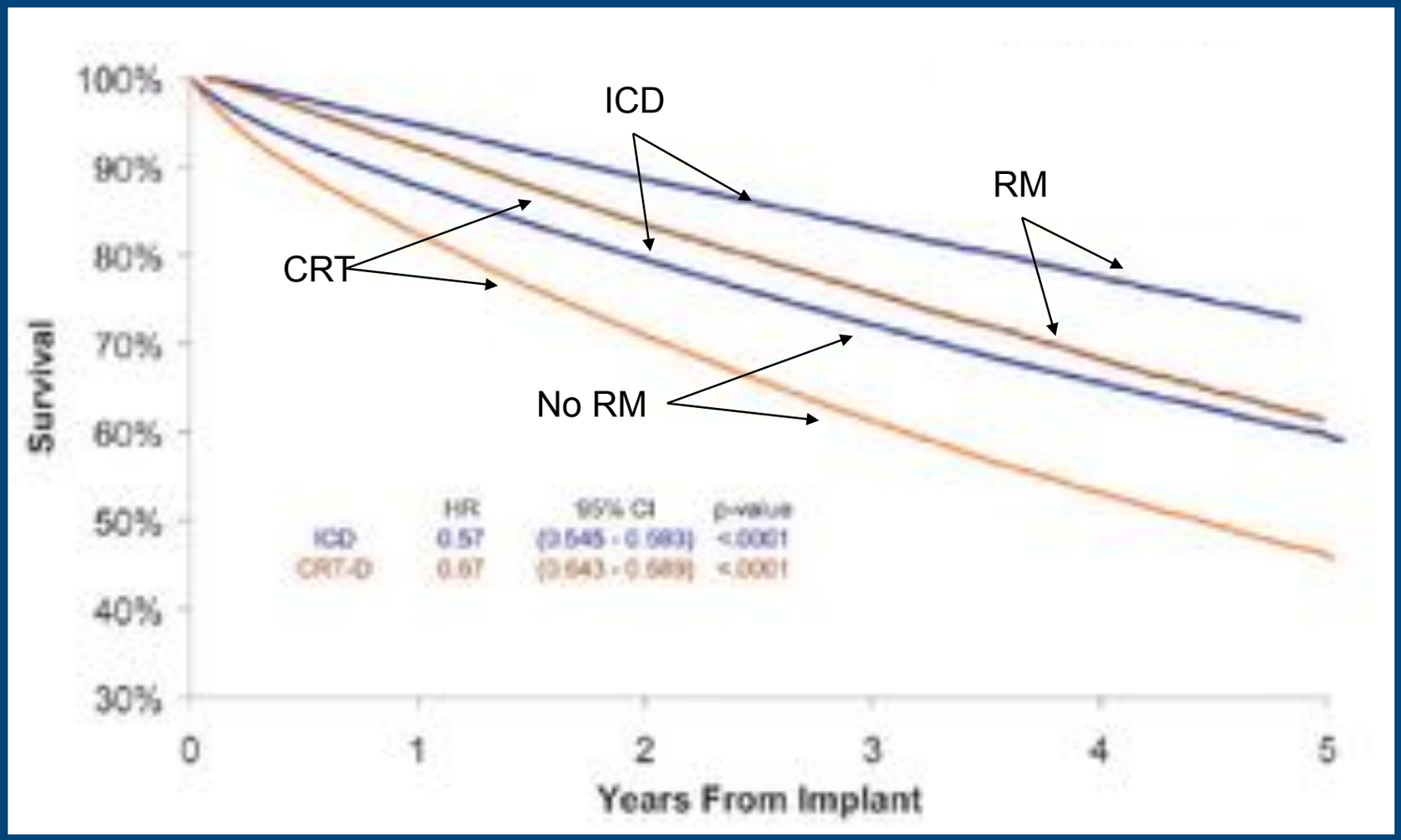
Conclusions: **On top of optimal medical therapy including CRT or ICD devices, PAP management still resulted in additional benefit to decrease all-cause hospitalizations and mortality**

Do HF patients benefit of Remote Monitoring?

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;

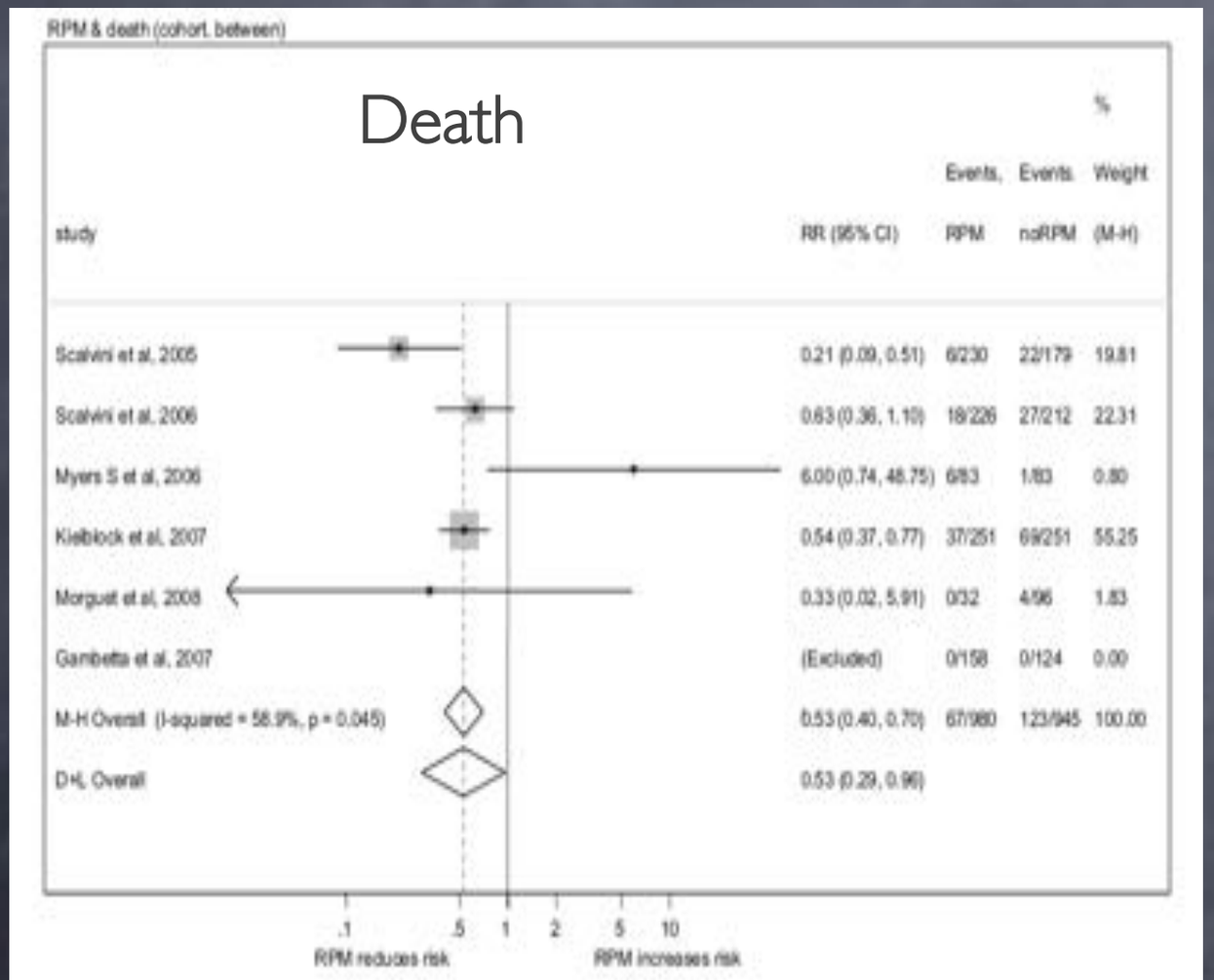
P<0.0001).

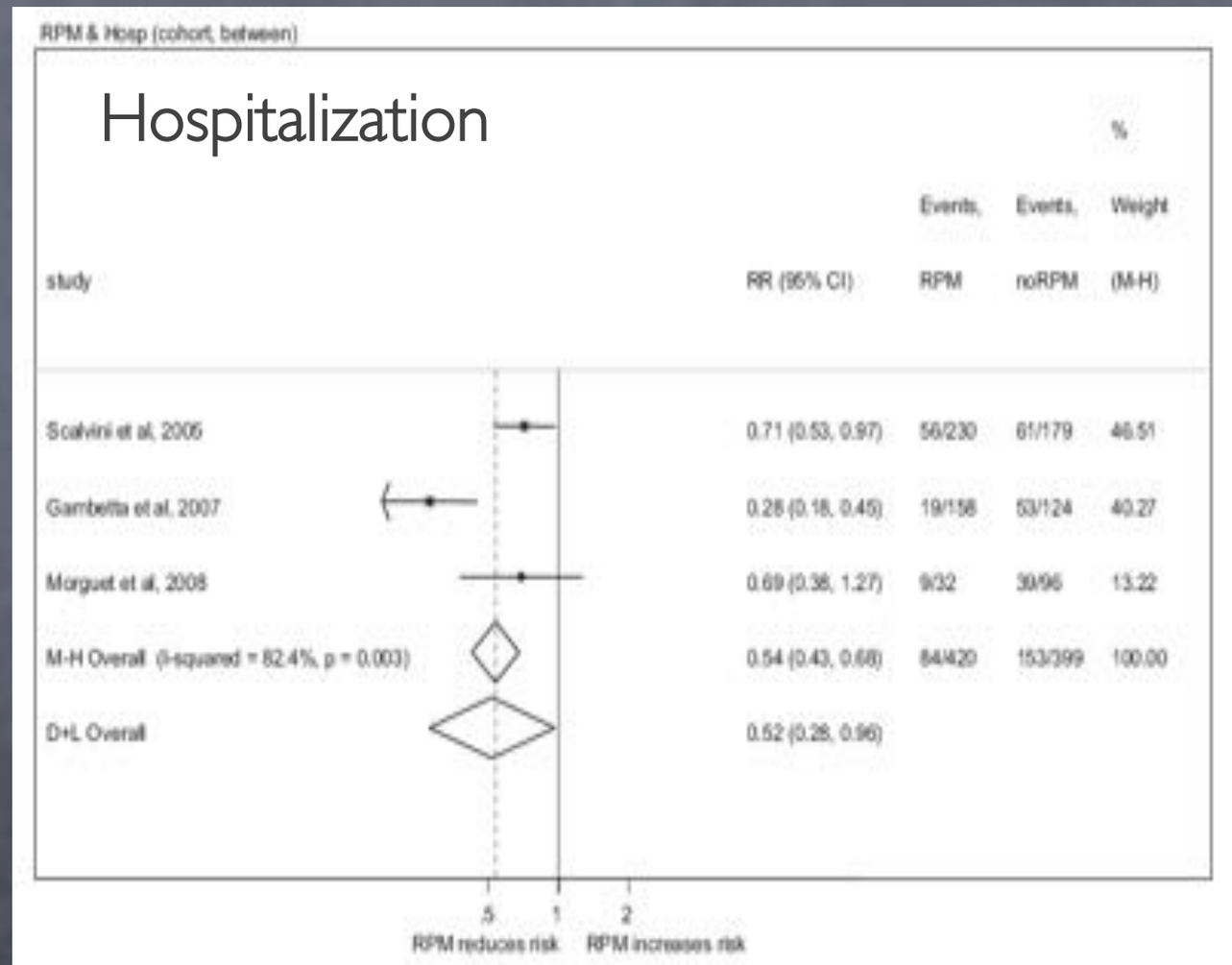
Saxon LA et al. Circulation 2010

A Meta-Analysis of Remote Monitoring of Heart Failure Patients

Catherine Klersy, MD, MSc,* Annalisa De Silvestri, MSc,* Gabriella Gabutti, MA,† François Regoli, MD,*‡ Angelo Auricchio, MD‡

Pavia, Italy; and Lugano, Switzerland





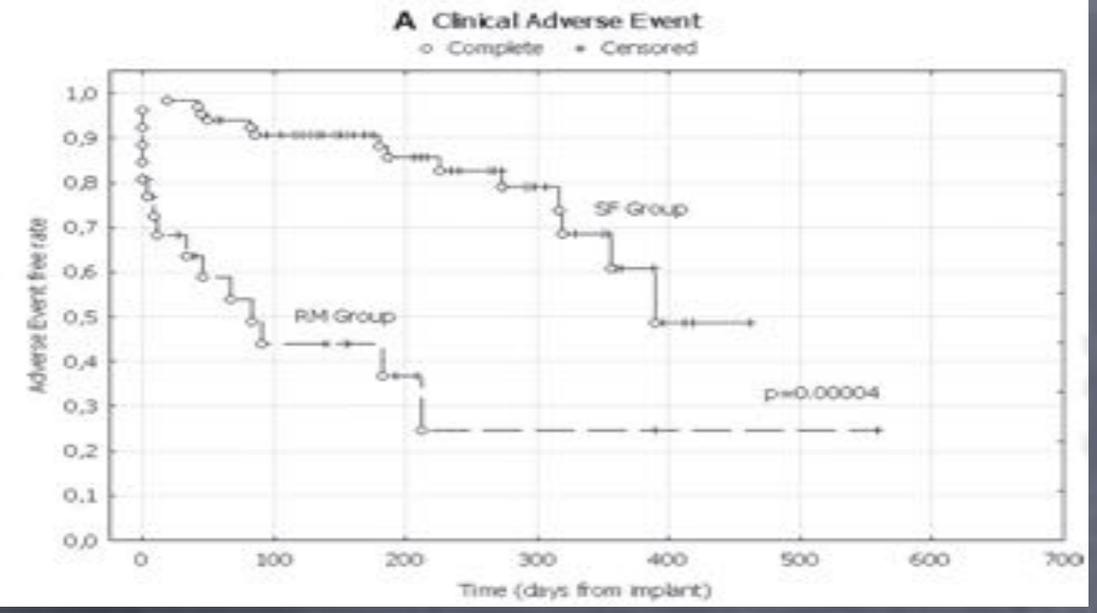
Conclusions

RPM confers a significant protective clinical effect in patients with chronic HF compared with usual care. (J Am Coll Cardiol 2009;54:1683–94) © 2009 by the American College of Cardiology Foundation

Home Monitoring and management of HF

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,



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.

CRT-D patients without HM had a 86% rate of clinical adverse events due to the late diagnosis of critical events, during a mean follow-up of 7 months.

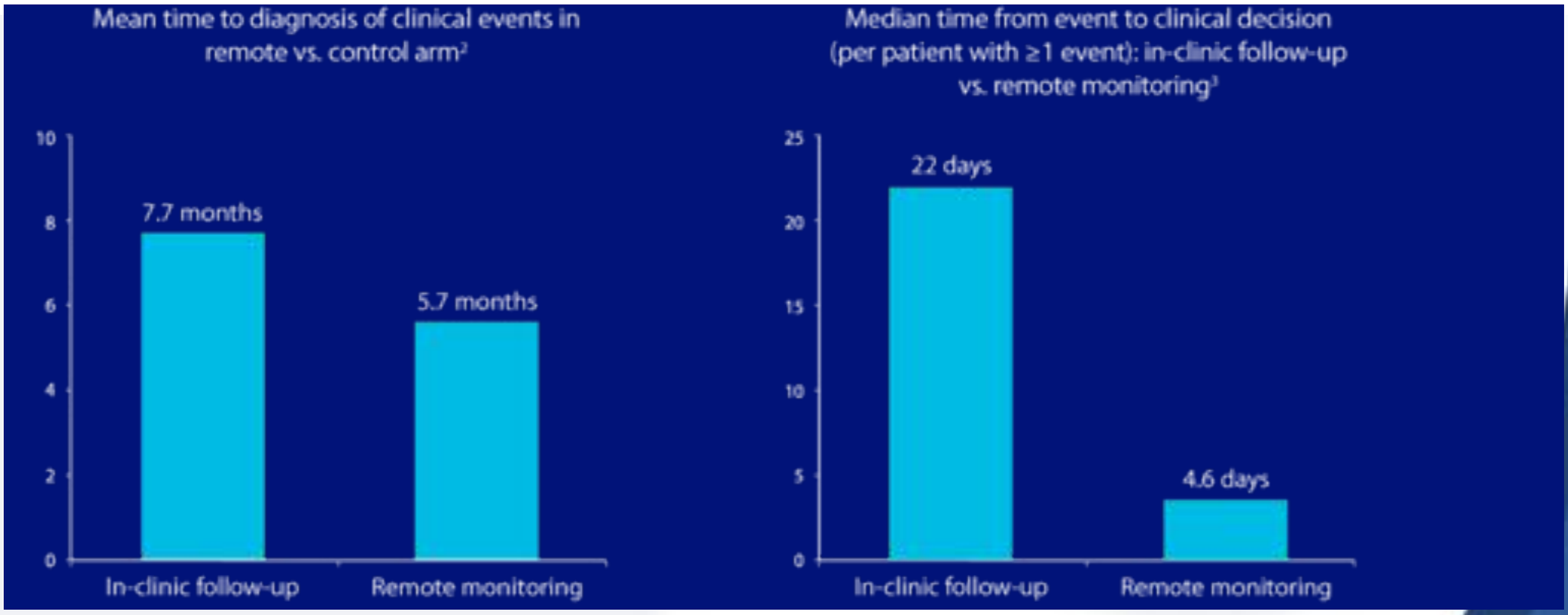
From Cox analysys it 's overt that the only two independent predictors of AEc within the 18 months of f.u. are **the method used to make f.u. and EF**

(De Ruvo, PACE 2010)

The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) trial: the value of wireless remote monitoring with automatic clinician alerts.

Crossley GH et al. CONNECT Investigators J Am Coll Cardiol.2011 Mar 8;57(10):1181-9

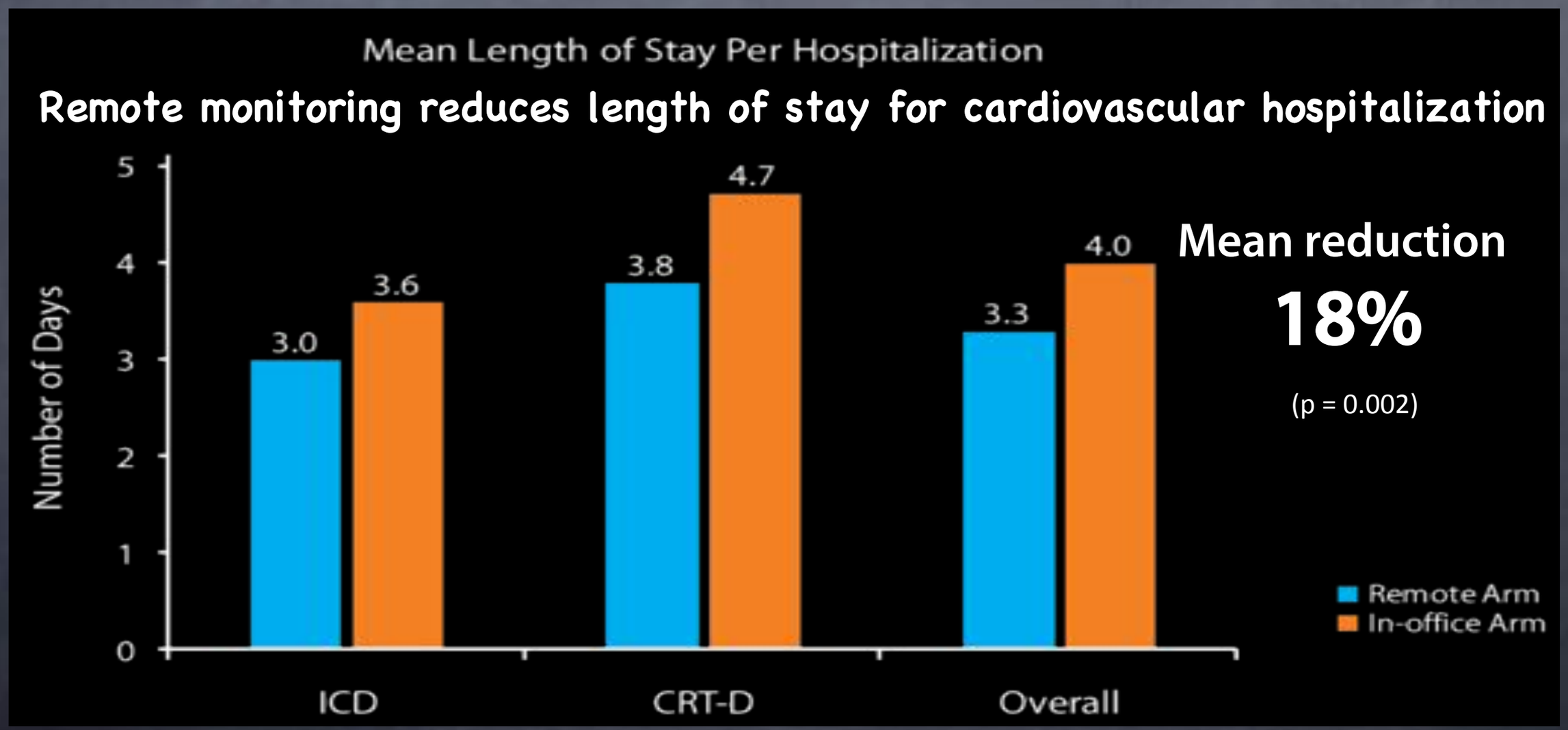
Multicenter, prospective, randomized study involving 1,997 patients underwent insertion of ICD and CRT-D ; Medtronic Carelink system. F.u.: 15 months



Crossley et al. (2011) showed that remote monitoring leads to earlier identification of device/disease-related problems, enabling timely, potentially life-saving intervention to improve clinical outcomes-

Overall time to the physician's clinical decision was 22 days for those monitored in-clinic, versus 4.6 days for patients in the RM group (p<0.001)

Secondary objective:
to compare the rates of CV health care utilization between patients the remote and in-office arms



* Estimated using the Medicare Limited Data Set - Standard Analytic Files from 2002-2007

Estimated savings per hospitalization $1,659*

Italy: EVOLVO STUDY

EVOLVO: Italian study powered by Medtronic and Region Lombardia

Remote control reduces HF visits, hospitalizations and costs

6-12 dicembre 2011 — Sanità — MEDICINÆ 27

Convegno Regione Lombardia-ministero della Salute sulla telemedicina per il cuore

Evolvo monitora lo scompenso

Il "controllo a distanza" abbatte visite, ricorso all'ospedale e costi

Il confronto con e senza dispositivo

Gli effetti sulla spesa (euro)

Costi paziente	Braccio standard	Braccio remoto
Costo medio per paziente (annuo)	300,89	325,02
Per visite schedulate in ambulatorio	179,45	96,67
Per visite non schedulate in ambulatorio	100,64	(-3,4)
In ambulatorio per visita in Ps	20,80	(-5,7)

Riduzione del 36% delle visite urgenti per cause cardiache o legate al defibrillatore, riduzione del 23% di tutti gli accessi ospedalieri per queste cause, riduzione del tempo tra un evento clinico (sintomi, condizioni di allarme del defibrillatore, shock erogati dal defibrillatore) e la valutazione da parte dell'operatore sanitario da circa 25 giorni a circa 1 giorno, miglioramento della qualità di vita dei pazienti (misurata con questionari validati). Sono questi i risultati del progetto «Evolvo» (Evoluzione tecnologica e valutazione organizzativa dei modelli di cura per la prevenzione delle ospedalizzazioni dello scompenso cardiaco in pazienti portatori di defibrillatori impiantabili), condotto nell'ambito del Programma Ricerca sanitaria 2006 del ministero della Salute per il quale la Lombardia è stata la Regione pilota. I primi risultati del progetto sono stati presentati la scorsa settimana in un incontro organizzato a Milano dalla Regione Lombardia e dal ministero della Salute in collaborazione con Il Sole 24 Ore Sanità e con il contributo non condizionante di Medtronic Italia e il patrocinio delle società scientifiche Anmc, Aiaroo, Sic.

All'incontro sono intervenuti **Massimo Cacciello**, direttore generale della ricerca scientifica e tecnologica del ministero della Salute, **Antonio Cirrito** dell'Università degli Studi di Brescia e della Sic, **Maurizio Landolina** dell'Ircss Policlinico San Matteo di Pavia e dell'Aiaroo, **Massimo Tritto** dell'Humanitas Mater Domini di Castellanza e dell'Anmc, **Maurizio Marzegalli** (Ao San Carlo Borromeo, Milano), **Antonio Vincenti** (Ao San Gerardo di Monza), **Gian Battista Perego** (Ircss Istituto auxologico italiano, Milano), **Cristina Mazella** (Politecnico di Milano), **Maurizio Lunati** (Ao Niguarda Ca' Granda, Milano), **Gianfranco Parati** (Università Milano Bicocca, Ircss Istituto auxologico italiano, Milano), **Luciano Frattini** (presidente e amministratore delegato di Medtronic Italia).

Il progetto si basa sul sistema di monitoraggio remoto CareLink Medtronic e ha come obiettivi la valutazione del beneficio associato ai dispositivi di gestione in remoto, in termini di riduzione delle visite ospedaliere urgenti e non pianificate per cause cardiache o relative al dispositivo. Lo studio è stato condotto nei 6 centri della Regione Lombardia. Il numero totale dei pazienti arruolati è 200. La durata dell'osservazione per ogni paziente è stata di 16 mesi. I pazienti arruolati sono stati assegnati a due gruppi paralleli: il primo (braccio remoto) in cui i pazienti erano monitorati anche da remoto, il secondo (braccio standard) dove il controllo dei dati veniva effettuato solo attraverso visite periodiche programmate. Nel braccio remoto i pazienti sono stati dotati di ricevitore cure link per la trasmissione automatica da casa dei dati raccolti dal dispositivo, accessibili al medico tramite interfaccia web.

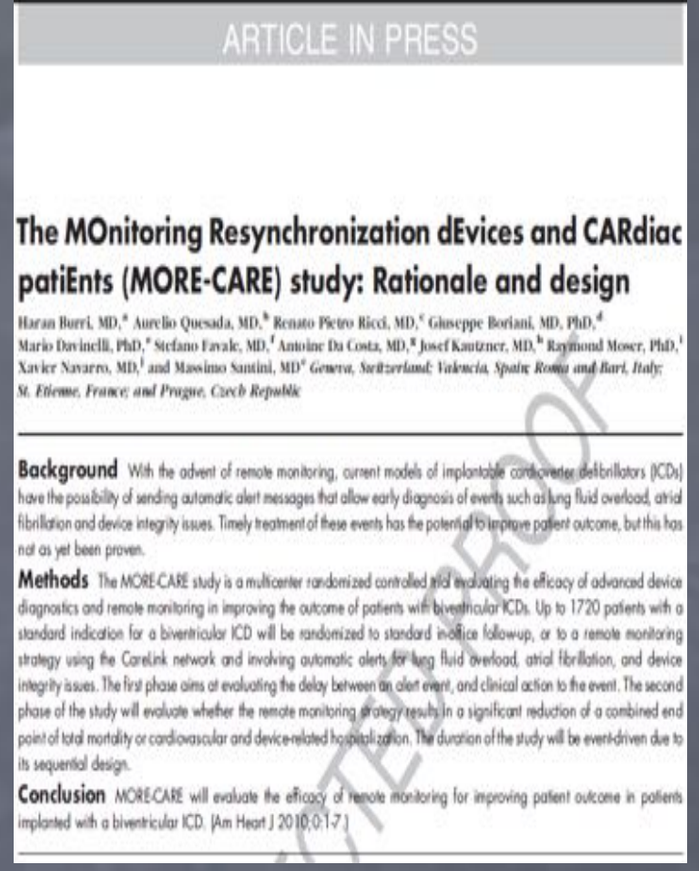
Dall'incontro di Milano è emerso che rispetto alla gestione tradizionale, il sistema di telemonitoraggio consente di ottimizzare l'efficacia delle strutture ospedaliere e di migliorare la qualità della cura fornita ai pazienti. Dal punto di vista economico, i dati mostrano un risparmio annuo per il paziente del 25 per cento. I costi considerati sono stati, tra gli altri, il trasporto presso la struttura ospedaliera dove effettuare il controllo, la mancata produttività a causa dell'assenza da lavoro e i costi sostenuti dal caregiver.

Rispetto alle risorse spese dal Ssn, i risultati mostrano che, anche quantificando che le visite in remoto siano economicamente quelle ambulatoriali, i pazienti seguiti mediante telemedicina sono più monitorati e presentano benefici sia per quanto riguarda l'emergenza e urgenza, sia per il numero generale di accessi in ospedale correlati alla parte cardiovascolare/device, senza ulteriori risorse spese, ma a parità di costi rispetto ai pazienti seguiti solo in ambulatorio.

In Lombardia, il sistema di monitoraggio da remoto per i pazienti con dispositivi cardiaci impiantabili è presente in 46 ospedali, per un totale di quasi 5.000 pazienti seguiti. In tutta Italia i pazienti portatori di dispositivo seguiti e controllati con questa modalità sono oltre 15mila. Al termine dell'incontro, infatti, **Luca Merlino**, vice-direttore della Direzione generale Sanità della Regione Lombardia, ha annunciato la volontà di prendere in considerazione la sperimentazione per una futura tariffazione e ha auspicato che i prossimi sviluppi delle reti per la cronicità in Regione possano utilizzare la telemedicina per facilitare la continuità di cura dei pazienti.

Red. San.

MORE-CARE



ARTICLE IN PRESS

The MOnitoring Resynchronization dEvices and CARdiac patiEnts (MORE-CARE) study: Rationale and design

Haran Burri, MD,[a] Aurelio Quesada, MD,[b] Renato Pietro Ricci, MD,[c] Giuseppe Boriani, MD, PhD,[d] Mario Davinelli, PhD,[e] Stefano Favale, MD,[f] Antoine Da Costa, MD,[g] Josef Kautzner, MD,[h] Raymond Moser, PhD,[i] Xavier Navarro, MD,[j] and Massimo Santini, MD[e] *Geneva, Switzerland; Valencia, Spain; Roma and Bari, Italy; St. Etienne, France; and Prague, Czech Republic*

Background With the advent of remote monitoring, current models of implantable cardioverter defibrillators (ICDs) have the possibility of sending automatic alert messages that allow early diagnosis of events such as lung fluid overload, atrial fibrillation and device integrity issues. Timely treatment of these events has the potential to improve patient outcome, but this has not as yet been proven.

Methods The MORE-CARE study is a multicenter randomized controlled trial evaluating the efficacy of advanced device diagnostics and remote monitoring in improving the outcome of patients with biventricular ICDs. Up to 1720 patients with a standard indication for a biventricular ICD will be randomized to standard in-office follow-up, or to a remote monitoring strategy using the CareLink network and involving automatic alerts for lung fluid overload, atrial fibrillation, and device integrity issues. The first phase aims at evaluating the delay between an alert event, and clinical action to the event. The second phase of the study will evaluate whether the remote monitoring strategy results in a significant reduction of a combined end point of total mortality or cardiovascular and device-related hospitalization. The duration of the study will be event-driven due to its sequential design.

Conclusion MORE-CARE will evaluate the efficacy of remote monitoring for improving patient outcome in patients implanted with a biventricular ICD. (Am Heart J 2010;0:1-7.)

Comparison between remote patient management (CareLink) and regular follow-up

Enrollment
n=1,000
80 EU centers

Randomisation

Follow-up

- CRT-D indication according to current guidelines

Remote FU CareLink

Control – in office

Follow up visits every 4 months

Primary end point:
1. Time between event onset and clinical decision
2. Death from any cause, CV and device-related hospitalization

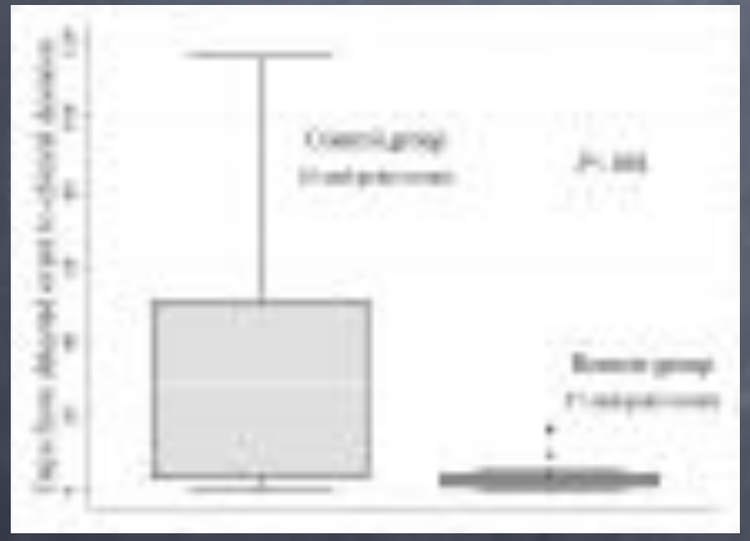
Analysys ongoing

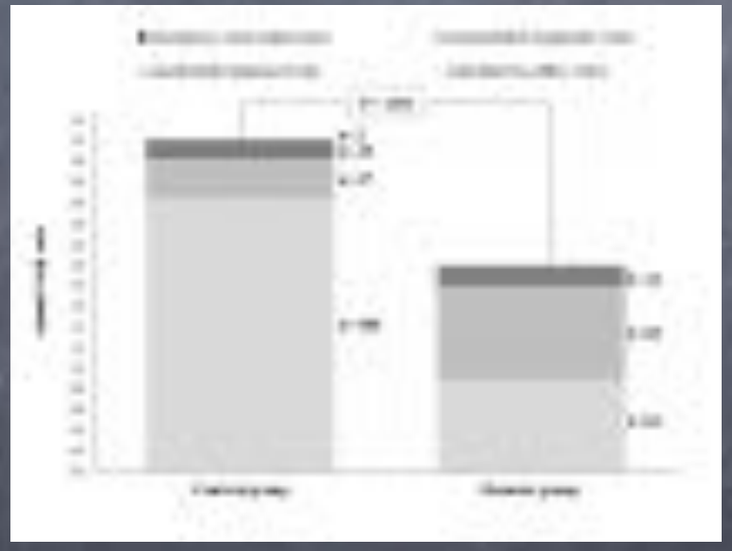
Journal of Medical Internet Research
ISSN 1438-8871
The leading peer-reviewed journal for health and healthcare in the Internet age
About Search Review Archive Current Issue Submit Membership Editorial Board

The MOnitoring Resynchronization dEvices and CARdiac patiEnts (MORE-CARE) Randomized Controlled Trial: Phase 1 Results on Dynamics of Early Intervention With Remote Monitoring

Giuseppe Boriani, MD, PhD, Antoine Da Costa, MD, [...], and On Behalf Of The MORE-CARE Investigators

The primary endpoint of Phase 1 was the delay between an alert event and clinical decisions related to the event in the first 154 enrolled patients followed for 1 year.





Overall, taking into account both scheduled and unscheduled visits (in a referral clinic) plus emergency department visits (with or without subsequent hospitalization) a 37.5% reduced burden was observed in the Remote group

Conclusion

The Phase 1 results of the MORE-CARE randomized study indicate that RM allows a significant reduction in delay from event onset to clinical decisions. The impact of RM on clinical aspects of disease management in heart failure patients needs to be assessed in the second phase of the trial

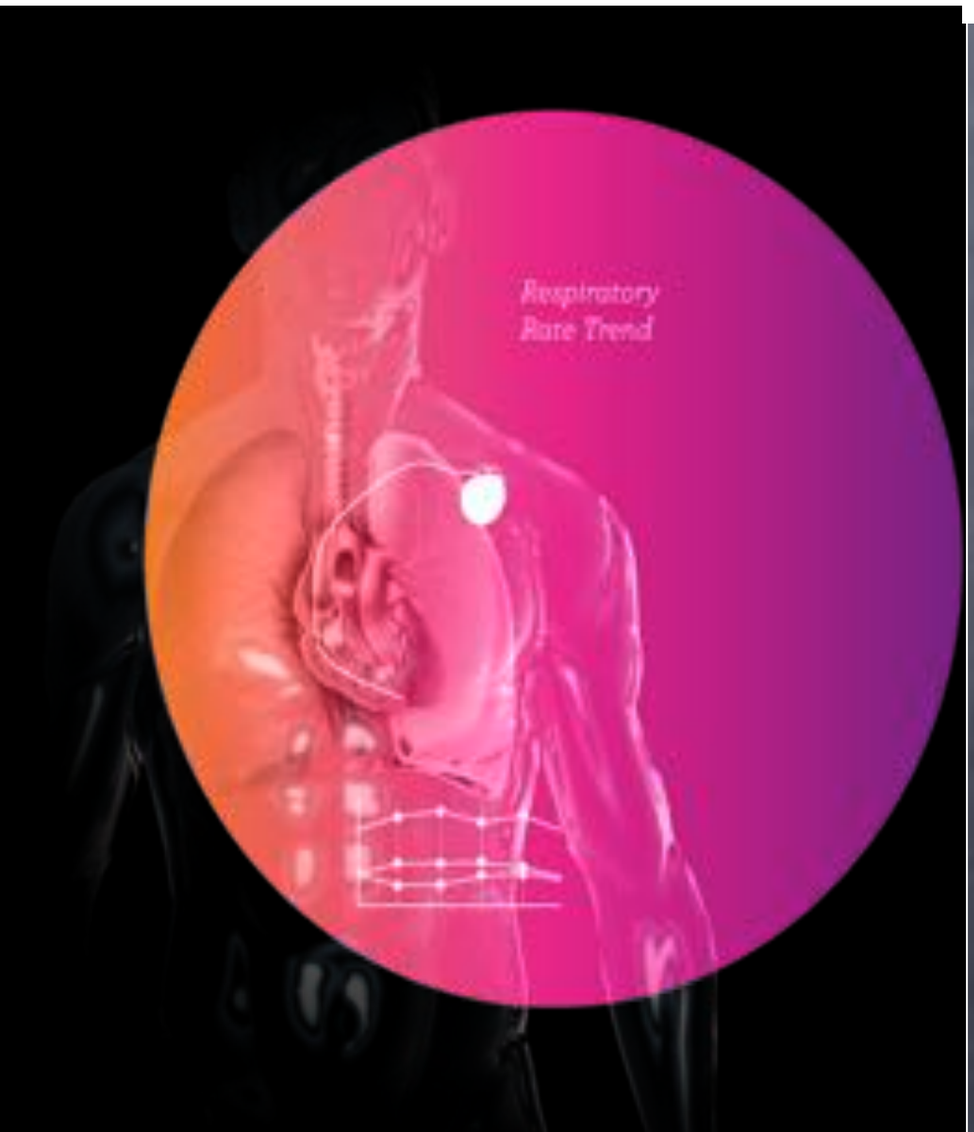
MULTITUDE-HF

MULTIparameTric evalUation of Heart Failure in DEvice-implanted patients

J Interv Card Electrophysiol
DOI 10.1007/s10840-015-0007-3

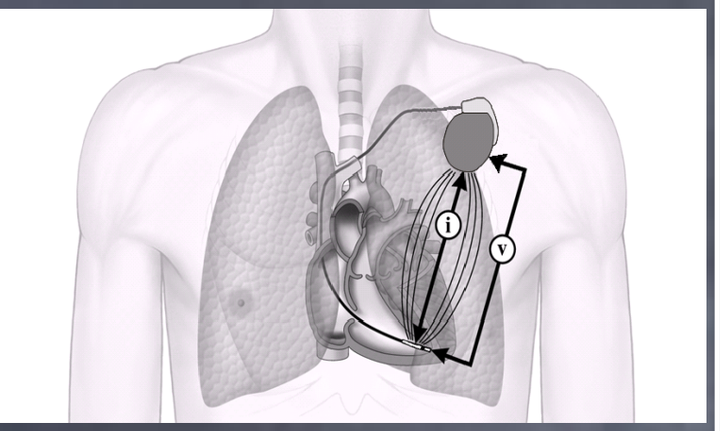
Long-term monitoring of respiratory rate in patients with heart failure: the Multiparametric Heart Failure Evaluation in Implantable Cardioverter-Defibrillator Patients (MULTITUDE-HF) study

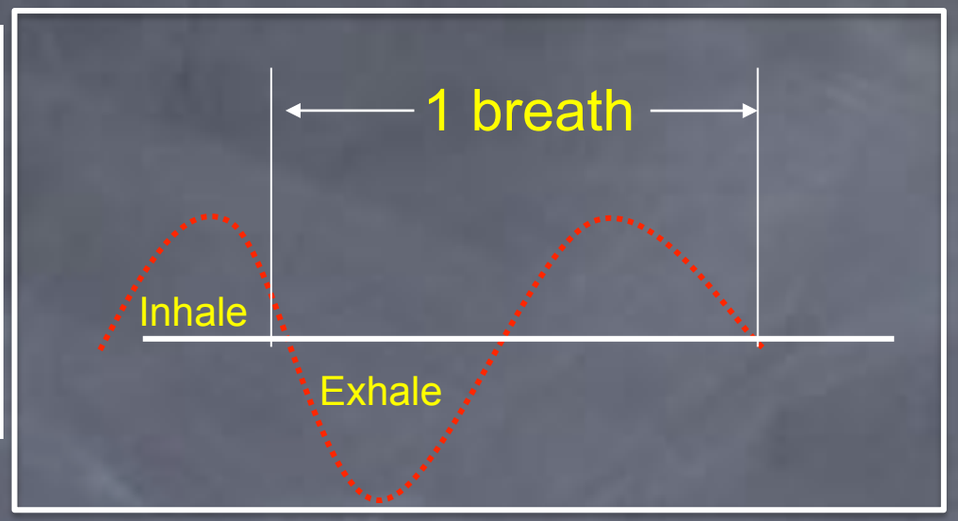
Giovanni B. Forleo[1] · Luca Santini[1] · Massimiliano Campoli[2] · Mario Malavasi[2] · Alberto Scaccia[3] · Maurizio Menichelli[4] · Umberto Riva[5] · Filippo Lamberti[6] · Giovanni Carreras[7] · Serafino Orazi[8] · Valentina Ribatti[1] · Luigi Di Biase[9,10,11] · Mariolina Lovecchio[5] · Andrea Natale[11] · Sergio Valsecchi[5] · Francesco Romeo[1]

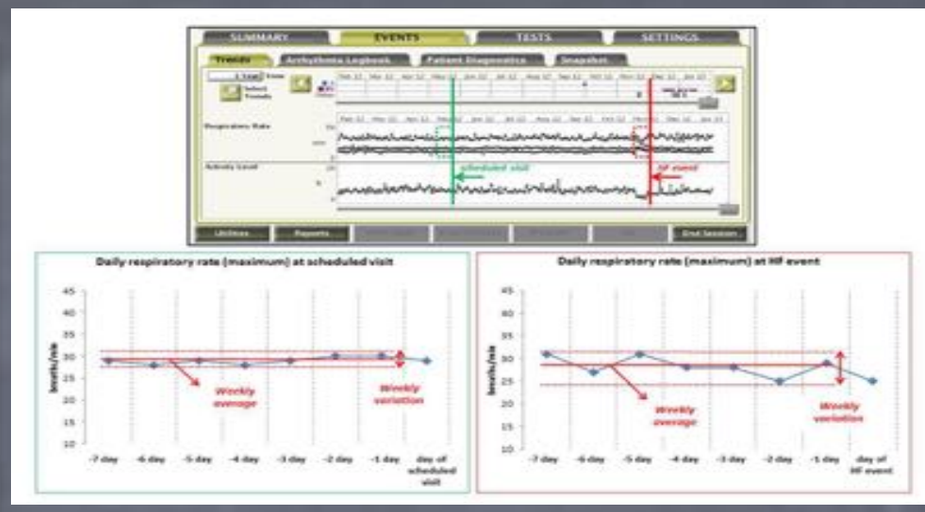


AIM of the study

The MULTIparameTric EvalUation of Heart Failure in DEvice-implanted patients (**MULTITUDE-HF**) trial has been designed **to assess the respiratory trends correlation with clinically relevant heart failure events.**







Endpoint: Evaluation of predictive value of RRT for HF events (hospitalizations and/or accesses to ED for HF and change of drug therapy)

Methods : 124 patients with a history of HF and implanted with ICD endowed with the RR Trend diagnostic feature (Boston Scientific Inc., Natick, MA, USA) were prospectively enrolled. Patients were followed-up for 12 months

Results:

- the weekly variation of RR was significantly higher prior hospitalization (33 events) ($p<0.05$).
- A weekly variation >3breaths/min of maximum RR predicted an impending event of hospital admission for HF with sensitivity of 73% and specificity of 57%.

Conclusion: In our study, elevated values of ICD-monitored RR allowed to identify patients with worse functional status and lower systolic function. The weekly variation of RR increased before events of HF decompensation

IN-TIME

Impact of BIOTRONIK Home Monitoring® on the clinical status of Heart Failure patients

Results of the IN-TIME Study

Inclusion and Exclusion Criteria

716 HF patients, 36 investigational sites

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

Hindricks G et al. The Lancet. 2014, 384(9943).

Clinical Trial Design

Prospective, randomized, multi-center design

716 Enrolled

Run-in Phase (1 month)

52 excluded before randomization

- 18 consent withdrawal
- 11 inclusion criteria violated
- 7 missing 1-month FU
- 4 death
- 12 other reasons

664
Randomized
analysis population

R

Home Monitoring
333

Conventional
331

143 ICD

131 ICD

(total = 274 ICD; 41%)

200 CRT-D

(total = 390 CRT-D; 59%)

Hindricks G et al. The Influence of Implant-Based Home Monitoring on the Clinical Status of Heart Failure Patients with an Impaired Left Ventricular Function ESC 2013

1
9

Endpoints

Primary endpoint: modified Packer score

At study end, a patient is classified „worsened“ in case of

- death
- overnight hospitalization for worsening heart failure
- worsening in NYHA class
- deterioration in the patient’s global self-assessment

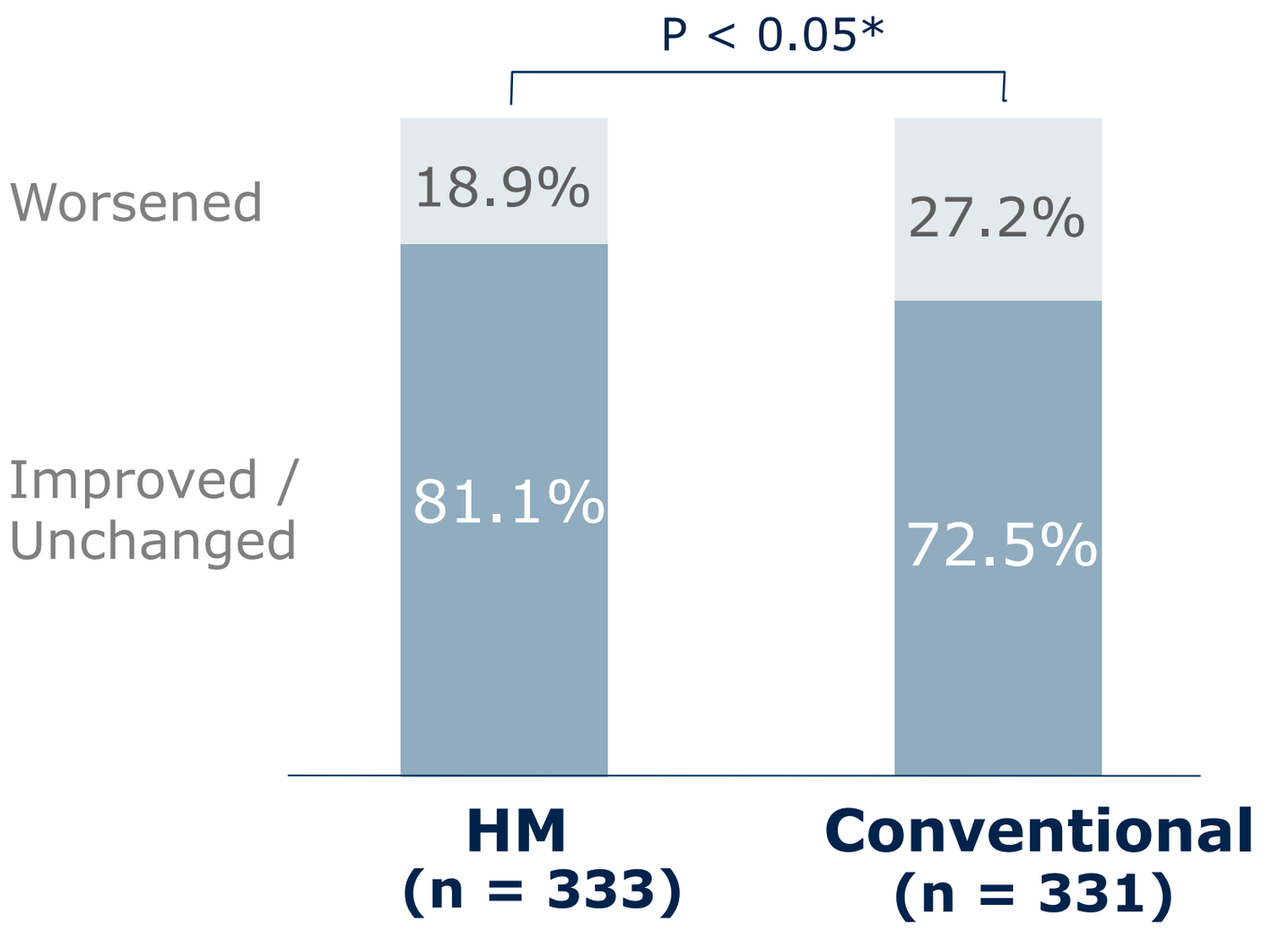
Major secondary endpoint: all-cause mortality, number of hospitalizations due to HF and lenght of hospital stay

Hindricks G et al. The Lancet. 2014, 384(9943).

Primary Endpoint
Reduction of worsening of clinical status

IN-TIME

Impact on Modified Packer Score of heart failure patients with ICD and CRT-D devices



* χ^2 test

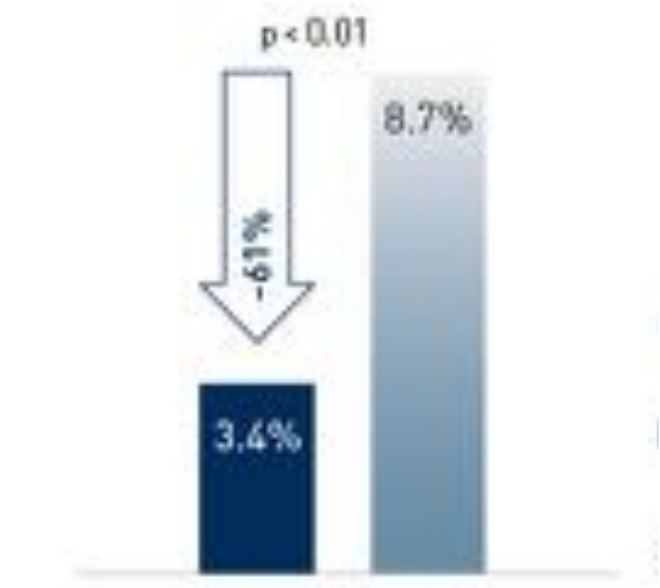
Hindricks G et al. The Lancet. 2014, 384(9943).

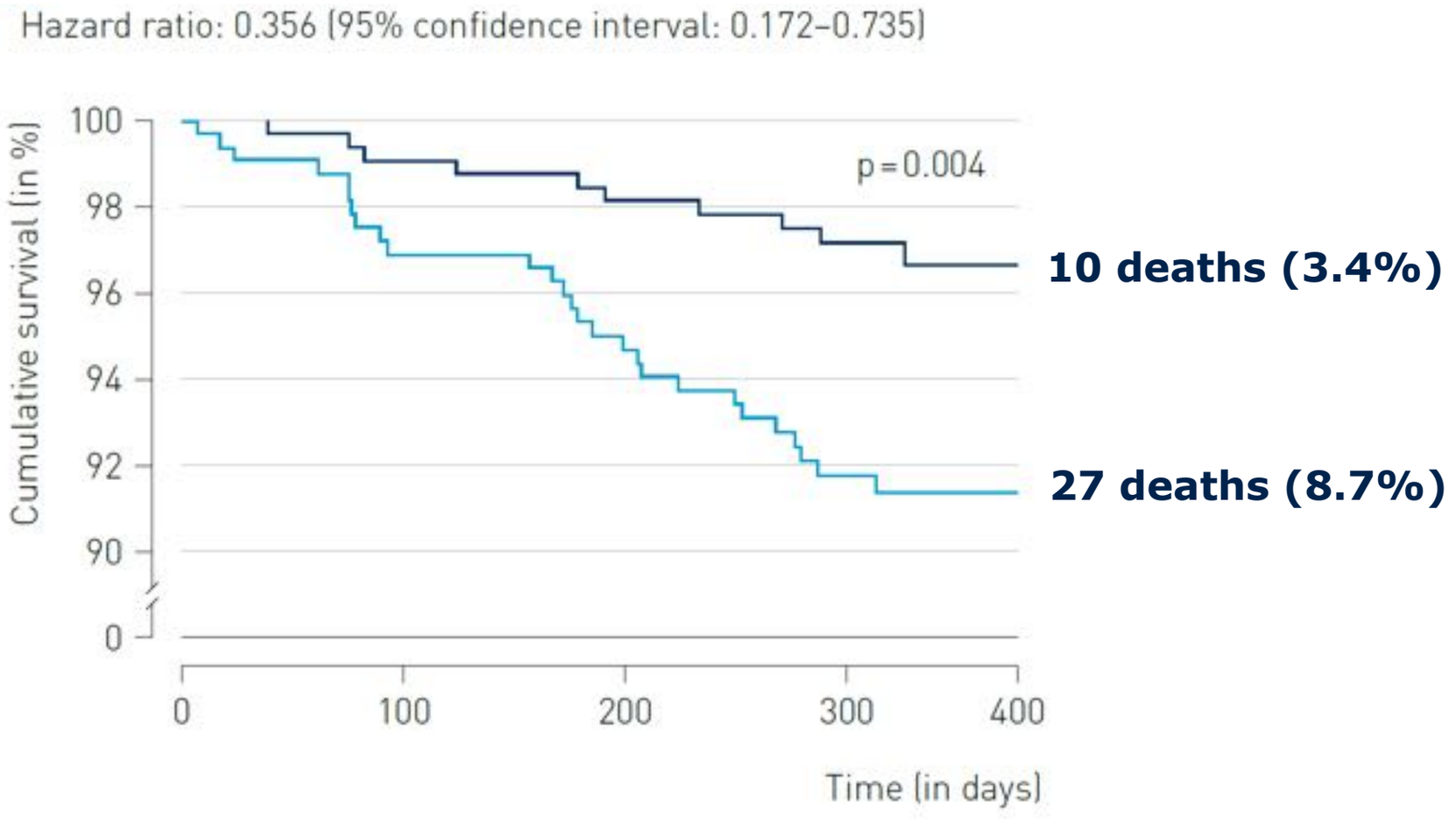
CRT-D / ICD

Secondary Endpoint
> 50% reduction in all-cause mortality

IN-TIME

Impact on all-cause mortality of heart failure patients with ICD and CRT-D devices





CRT-D / ICD

Hindricks G et al. The Lancet. 2014, 384(9943).

IN-TIME Conclusion

- IN-TIME is the first randomized clinical trial to show a mortality benefit for heart failure patients with device-based remote monitoring.

- Early detection of arrythmias & suboptimal therapy, and closer patient monitoring lead to **>50% reduction in all-cause mortality**.

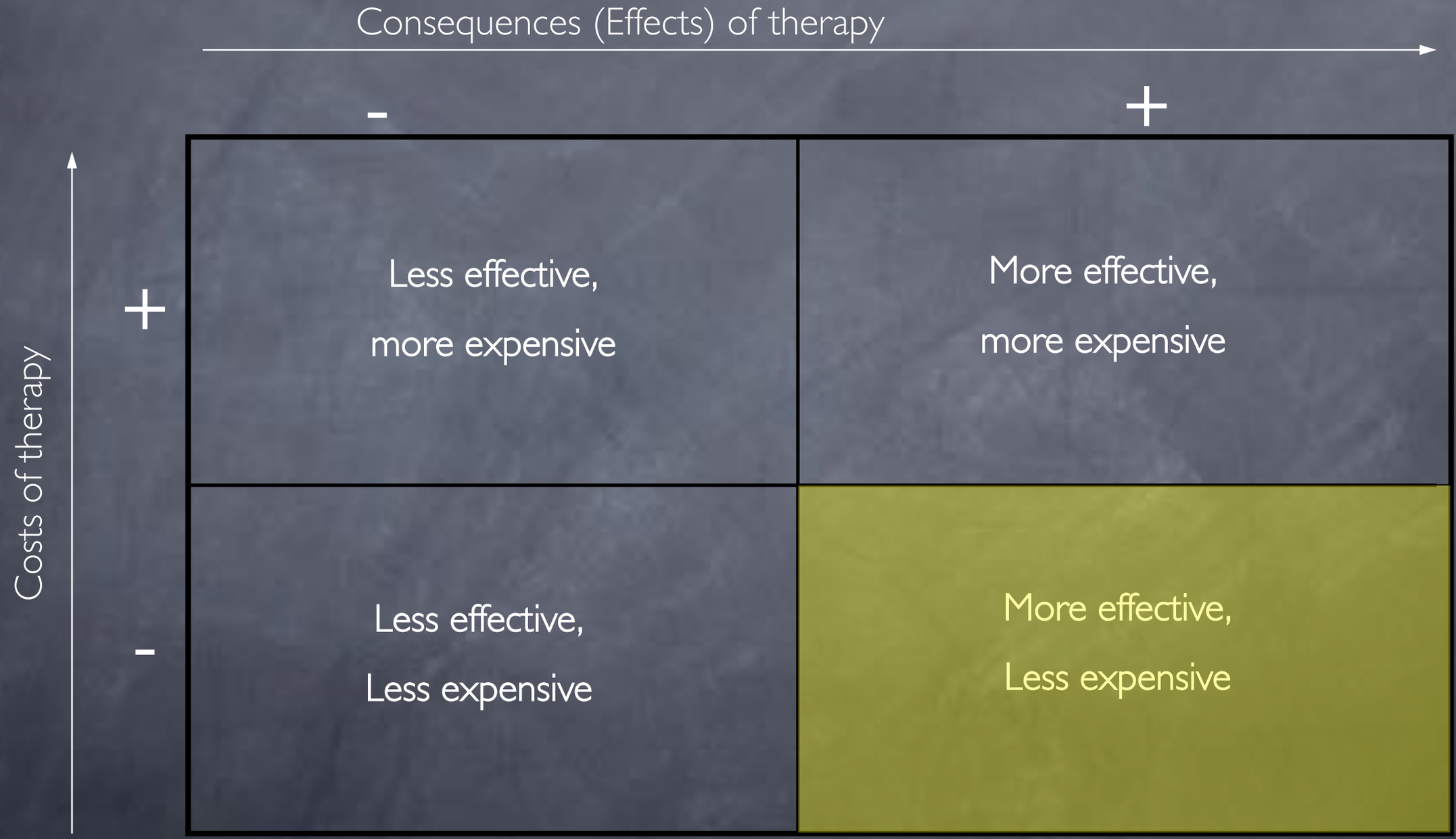
- Monitoring IN-TIME requires a clinically relevant set of parameters, a highly reliable technical platform, and a workflow that supports a quick response.

Summarizing:

The value of continuous remote monitoring in providing better care

- Reduces the burden of in-clinic follow-up on healthcare systems, physicians and patients
- Reduces overall cost of follow-up
- Allowing any device problems to be detected immediately
- Anticipating clinical actionable events and reducing time from event to clinical decisions
- Diagnosing asymptomatic conditions
- Allowing individual tailoring of patient treatment and continuous updating of therapeutical strategy
- Reducing length of stay for cardiovascular hospitalization

What is cost-effectiveness?



Summarizing:

The value of continuous remote monitoring in providing better care

Reduces the burden of in-clinic follow-up on healthcare systems, physicians and patients

Reduces overall cost of follow-up

Allowing any device problems to be detected immediately

Anticipating clinical actionable events and reducing time from event to clinical decisions

Diagnosing asymptomatic conditions

Allowing individual tailoring of patient treatment and continuous updating of therapeutical strategy

Reducing length of stay for cardiovascular hospitalization

Cost-effectiveness

Conclusions

- Remote monitoring is a efficient method to manage HF patients with CIEDs

- Several indexes may be used to identify early changes in hemodynamic status to prevent acute events and hospitalizations

- Hemodynamic sensors may increase diagnostic sensitivity and specificity

- To integrate all available diagnostics into an algorithm capable of predicting impending heart failure with a low rate of false alerts represents the challenge for the near future.

CONCLUSIONI

"The future in cardiology is remote monitoring, potentially of all types of cardiac patients, which will come to be regarded as so important as to be on a level with, for example, dual-chamber pacing, lithium batteries, active can defibrillation, and cardiac resynchronization therapy in the evolution of the technology of implantable devices."

(Richard Sutton)

Sutton R. Remote monitoring as a key innovation in the management of cardiac patients including those with implantable electronic devices. Europace (2013) 15, i3–i5

Thank you for your attention