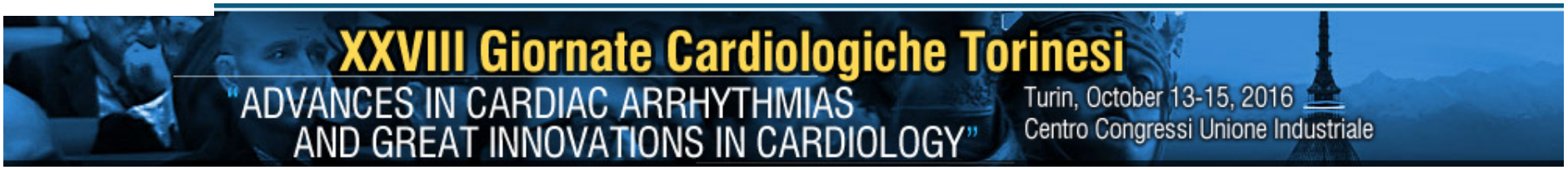


Remote monitoring in ICD patient within a therapeutic plan : a mere hope or reality?

Dr. Marcello Piacenti

Fondazione Toscana G. Monasterio

Fisiologia Clinica C.N.R., Pisa

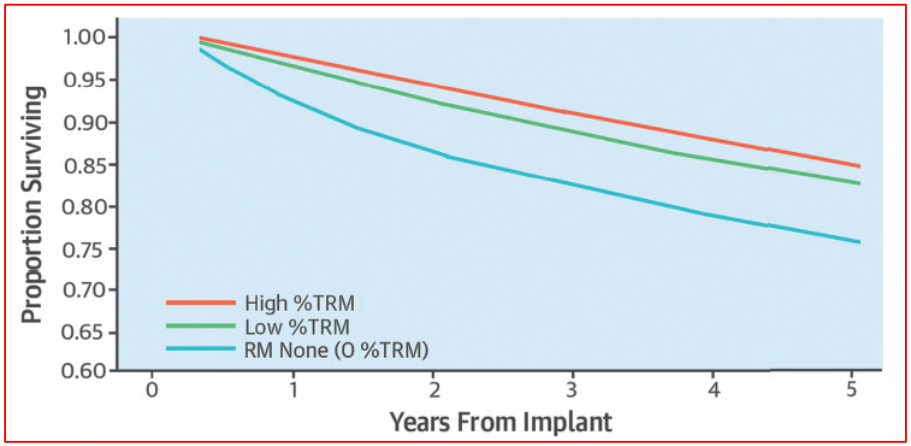
Remote Monitoring in ICD and CRT-D devices

- RM has been developed to increase detection of critical events and improve medical management of implanted patients
- Significant differences exist between device related RM provided by different manufacturers
- Several observational and randomized studies have been carried out to evaluate the advantages of RM

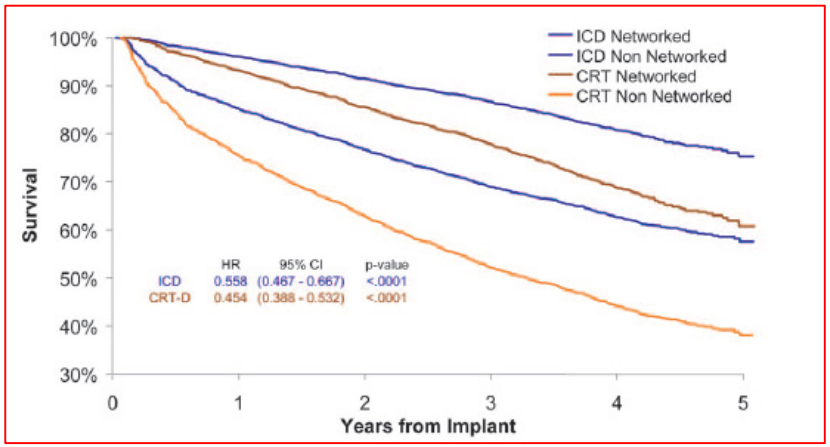
	Biotronik Home Monitorin	Medtrinic Carelink	Boston Scientific Latitude	Sorin Smart View	St Jude Merlin.net
Wireless communication with implanted device	Radiofrequency	Radiofrequency	Radiofrequency	Radiofrequency	Radiofrequency
Data transmission	GSM/GPRS network	Analogue phoneline and GSM network	Analogue phoneline and GSM network	Analogue phoneline and GSM network	Analogue phoneline and GSM network
Transmitter	Mobile or stationary (GSM)	Stationary	Stationary	Stationary	Stationary
Frequency of transmission	Schedules F-U; daily F-U; alert events	Schedules F-U; alert events, and alert on pts demand	Schedules F-U; alert events	Schedules F-U; alert events	Schedules F-U; alert events
Automatic Threshold	Automatic RA, RV and LV tresholds	Automatic RA, RV and LV tresholds	Automatic RA, RV and LV tresholds		Automatic RA, RV and LV tresholds
Heart failure monitoring	Comprehensive heart failure monitor, intrathoracic impedence measurement	Comprehensive heart failure monitor, intrathoracic impedence measurement,Optivol	Optional wireless weight scales and BP cuffs	Smart View HF featuring PhD clinical status	CorVue fluid status alert
Alerts	Configurable red and yellow alerts	Configurable red and yellow alerts	Configurable red and yellow alerts		Aletrs fully configurable online

Modified from Europace (2012) 14, 278–293

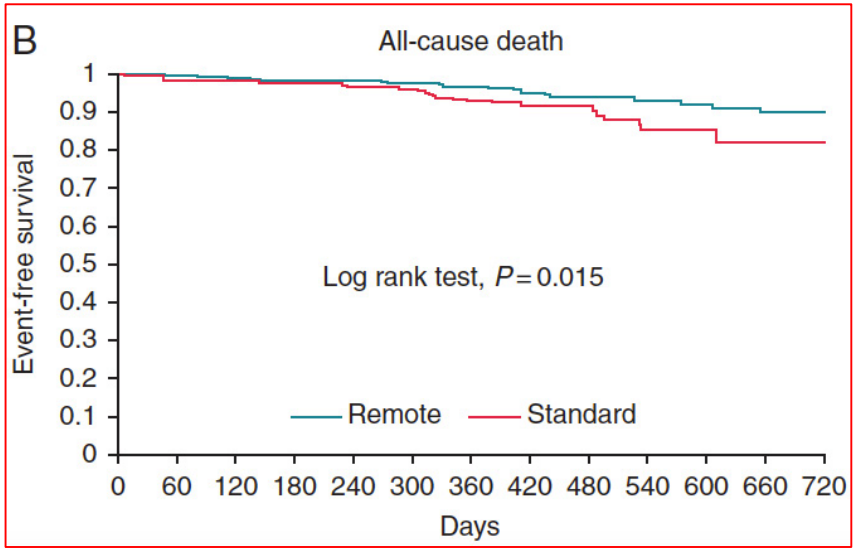
Observational studies



Varma et al J Am Coll Cardiol 2015;65:2601–10 (MERLIN)



Saxon et al Circulation . 2010;122:2359-2367 (ALTITUDE)



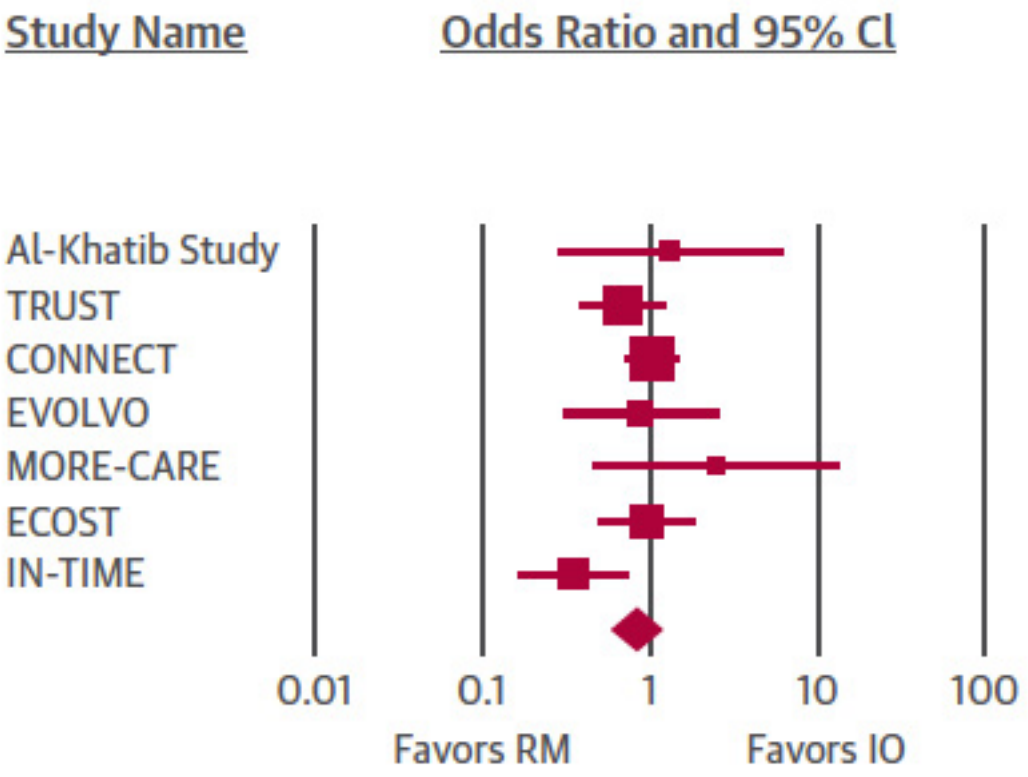
De Simone Europace (2015) 17, 1267–1275 (EFFECT)

Remote Monitoring of Implantable Cardioverter-Defibrillators

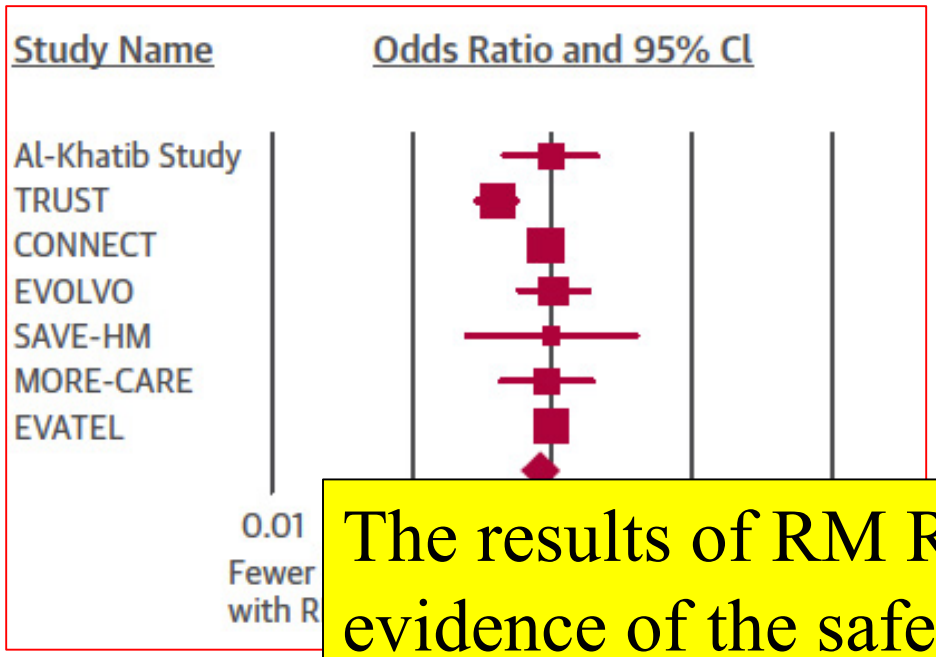
A Systematic Review and Meta-Analysis of Clinical Outcomes

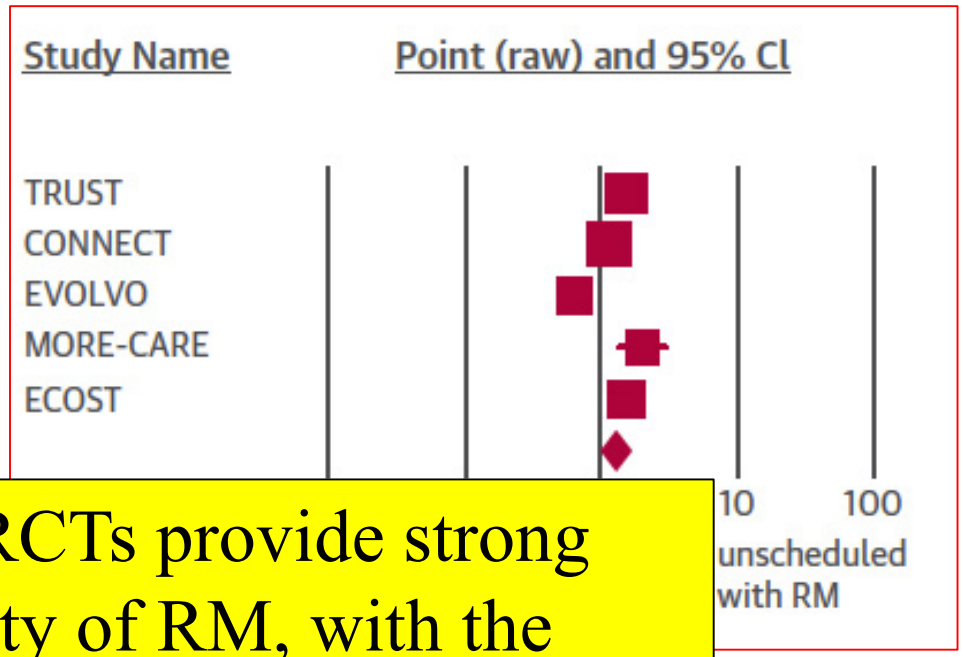
Nirmalatiban Parthiban,*† Adrian Esterman, PhD,‡ Rajiv Mahajan, MD, PhD,* Darragh J. Twomey, MBBS,* Rajeev K. Pathak, MBBS,* Dennis H. Lau, MBBS, PhD,* Kurt C. Roberts-Thomson, MBBS, PhD,* Glenn D. Young, MBBS,* Prashanthan Sanders, MBBS, PhD,* Anand N. Ganesan, MBBS PhD*

All cause mortality

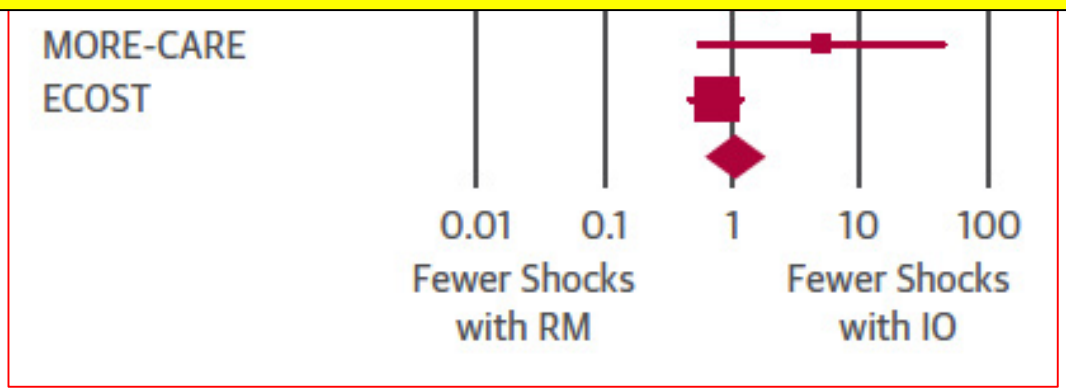


J Am Coll Cardiol 2015;65:2591–600





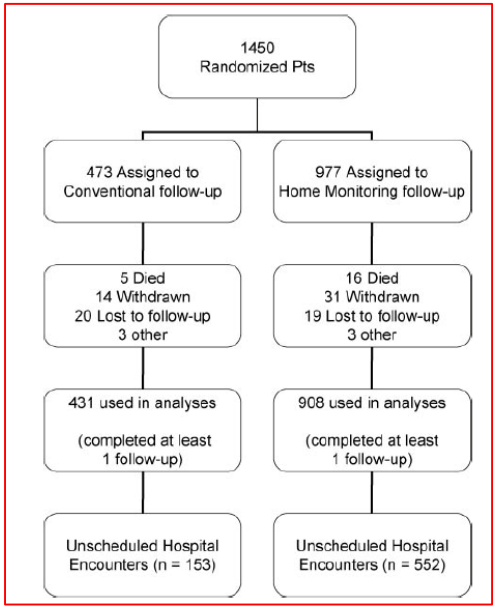
The results of RM RCTs provide strong evidence of the safety of RM, with the suggestion of a potential mortality benefit with technologies using daily transmission verification.



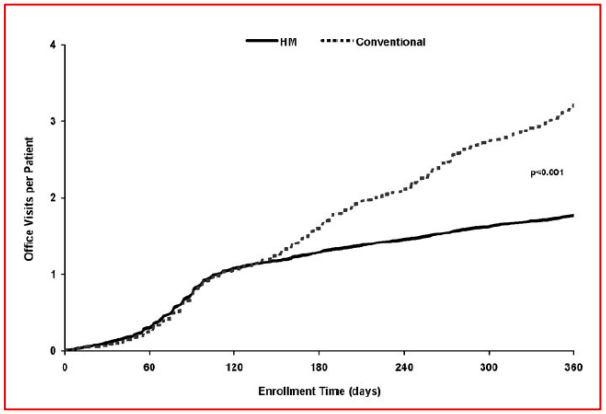
Efficacy and Safety of Automatic Remote Monitoring for Implantable Cardioverter-Defibrillator Follow-Up

The Lumos-T Safely Reduces Routine Office Device Follow-Up (TRUST) Trial

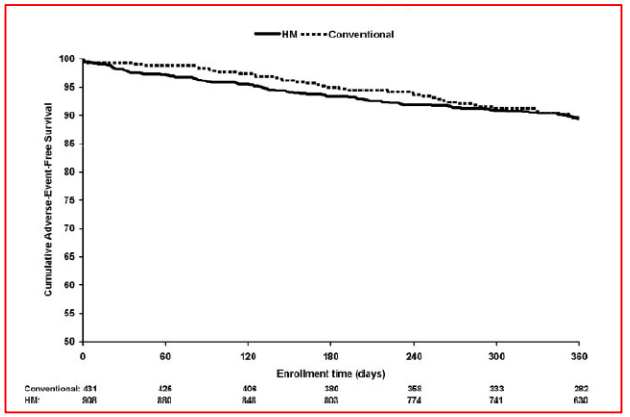
Niraj Varma, MA, DM, FRCP; Andrew E. Epstein, MD; Anand Irimpen, MD; Robert Schweikert, MD; Charles Love, MD; for the TRUST Investigators



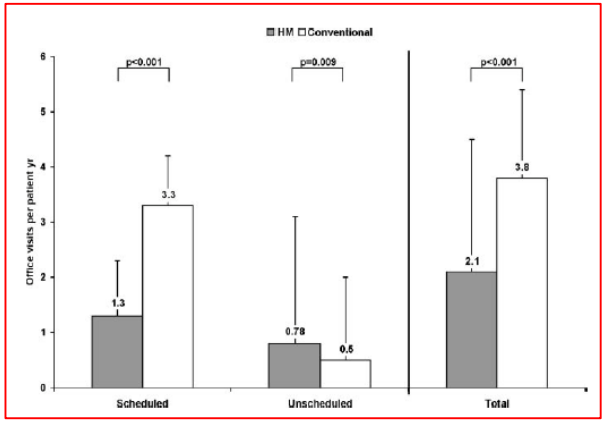
Office visits/patient



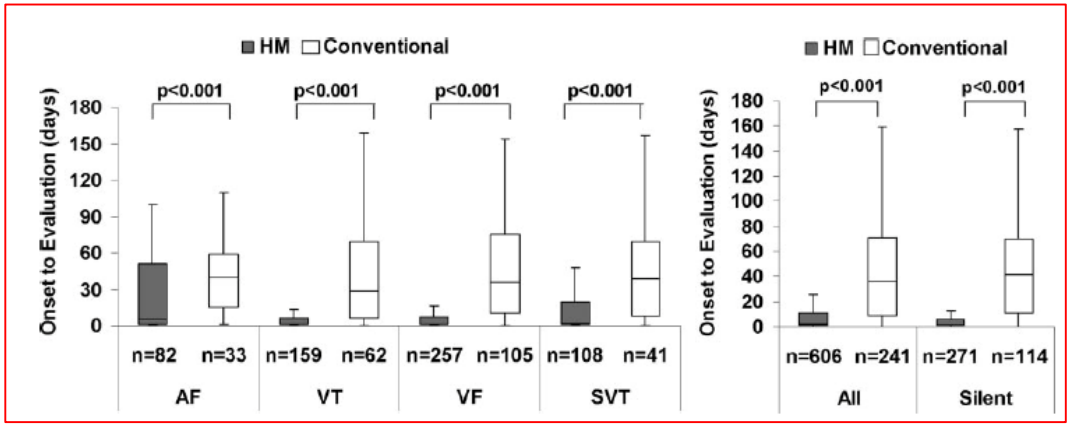
Cumulative adverse event free survival



Scheduled-unscheduled visits



Early arrhythmias dectection

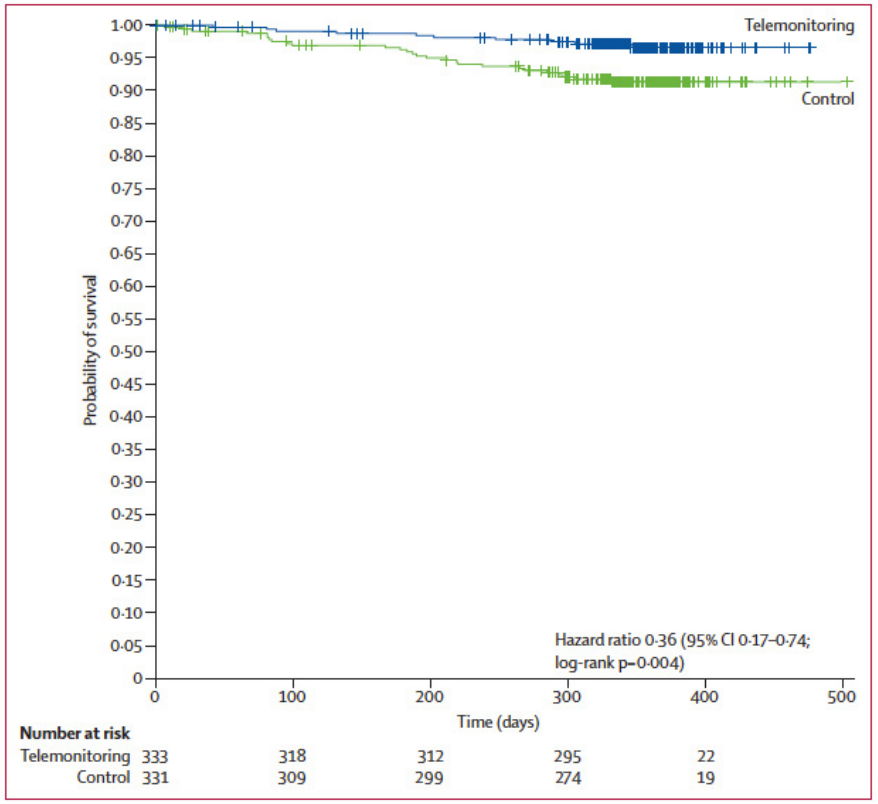


Circulation. 2010;122:325-332

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**

Kaplan-Meier curves of patient survival



Lancet 2014; 384: 583–90

A randomized study of remote follow-up of implantable cardioverter defibrillators: safety and efficacy report of the ECOST trial

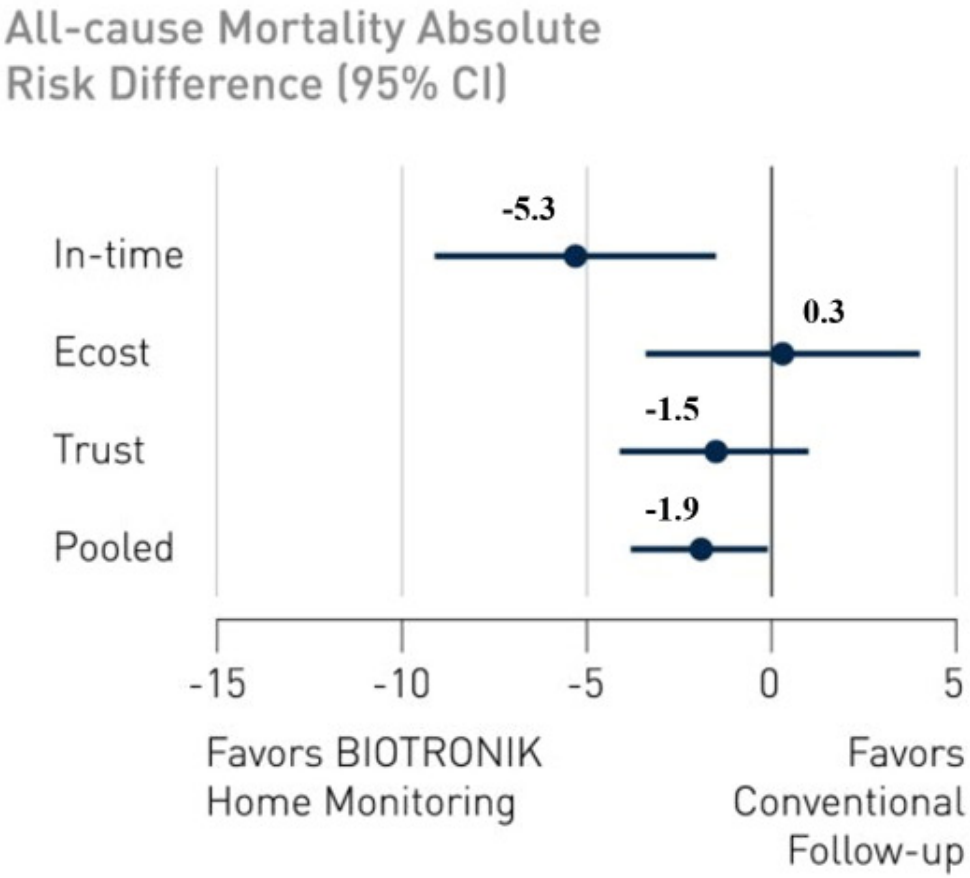
Laurence Guédon-Moreau[1]*, Dominique Lacroix[1], Nicolas Sadoul[2], Jacques Clémenty[3], Claude Kouakam[1], Jean-Sylvain Hermida[4], Etienne Aliot[2], Michel Boursier[5], Olivier Bizeau[6], and Salem Kacet[1], for the ECOST trial Investigators

All shocks, inapproriate shocks and capacitator 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

Europace 2012

Meta-analisi degli studi TRUST, ECOST e IN-TIME

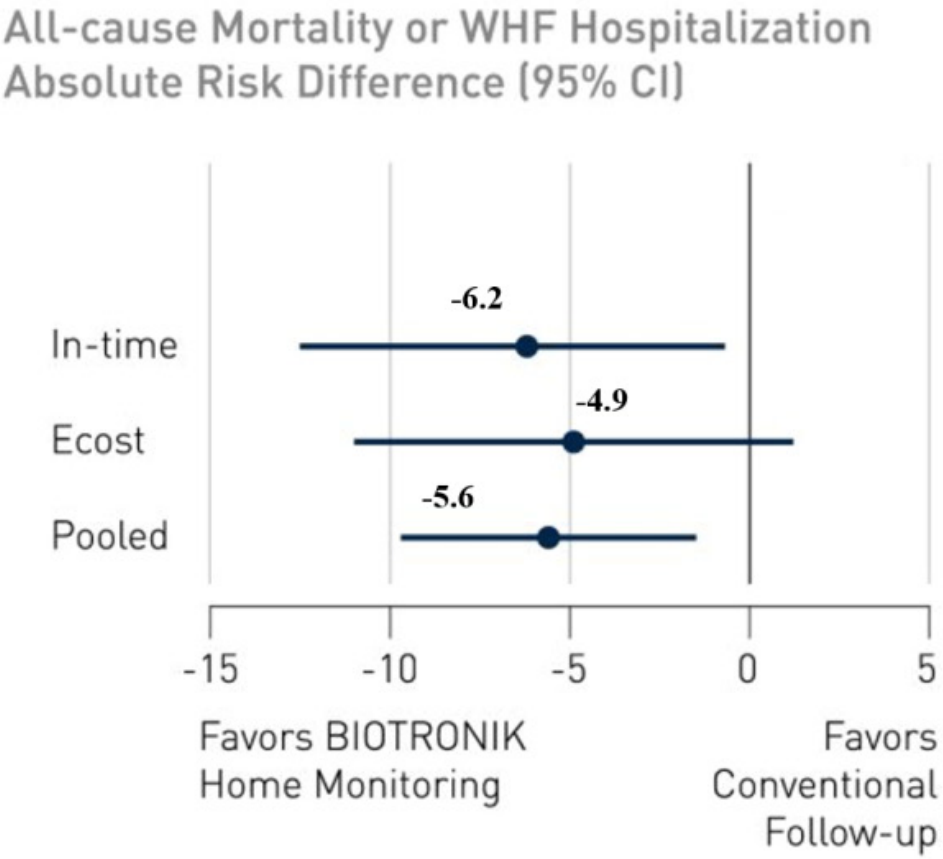


1.9%
absolute reduction
of
all-cause mortality
at 1 year

95% CI: -3.8% to -0.1%
p=0.037

Hindricks G et al: ESC 2016

Meta-analisi degli studi ECOST e IN-TIME

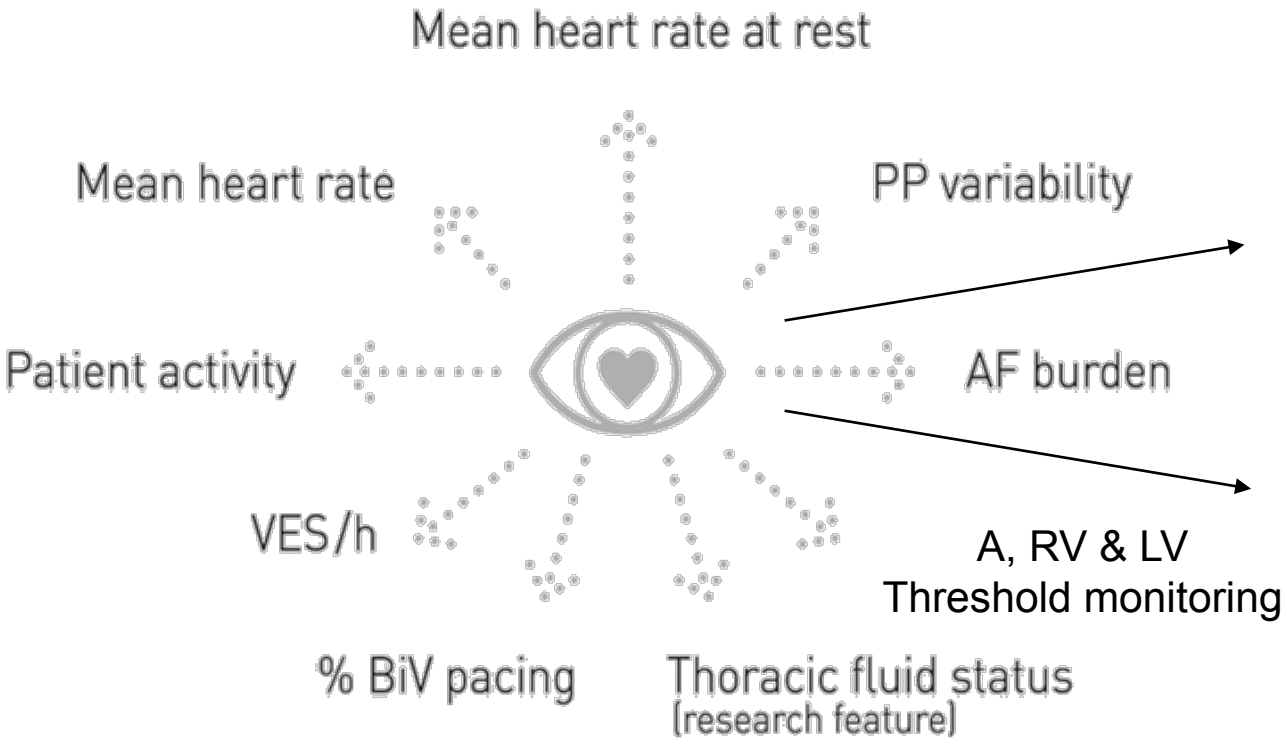


5.6%
absolute reduction
of
all-cause death or WHF hospitalization
at 1 year

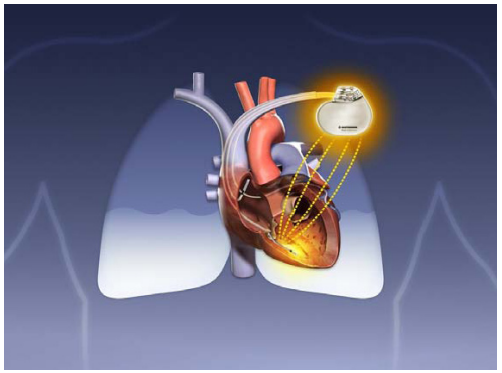
95% CI: -9.7% to -1.5%
p=0.007

Heart Failure Monitor (HF Monitor)

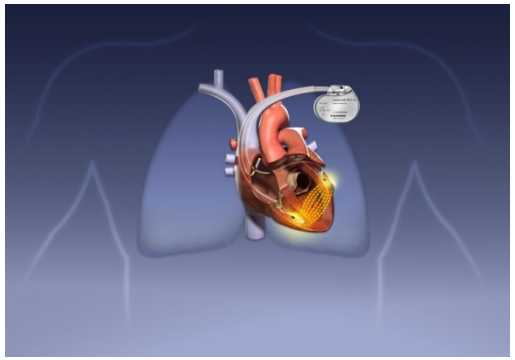
Daily Remote-transmitted Parameters



Intrathoracic Impedance

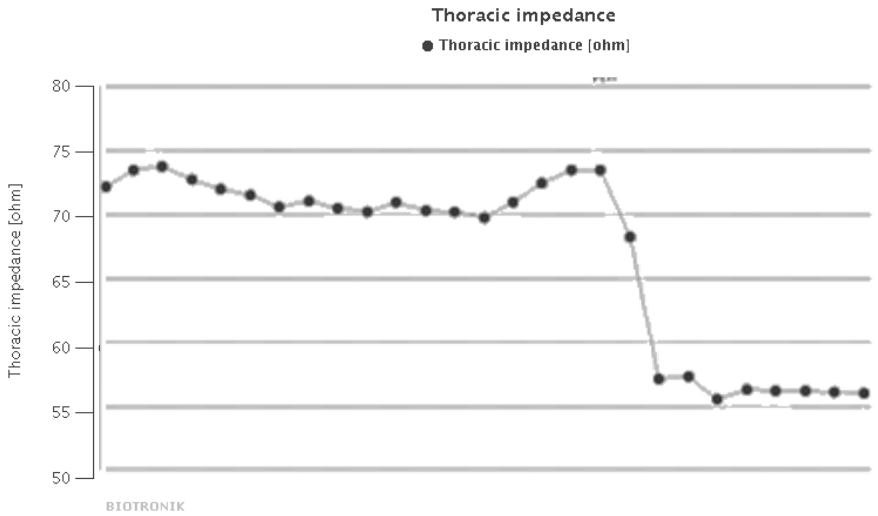


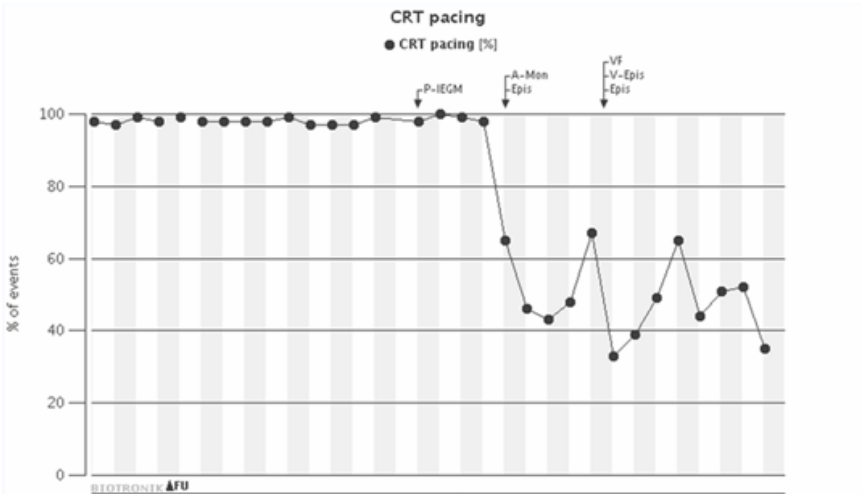
Intracardiac Impedance

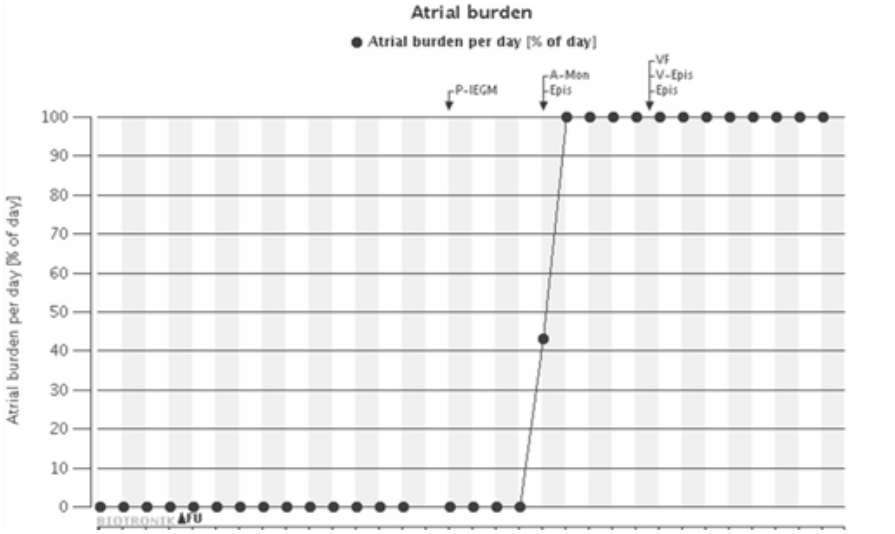


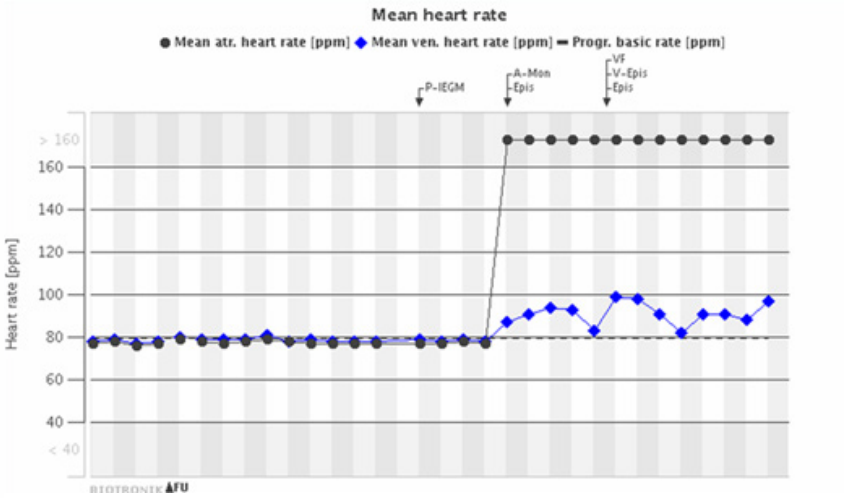
Multi-parameters HF Monitor

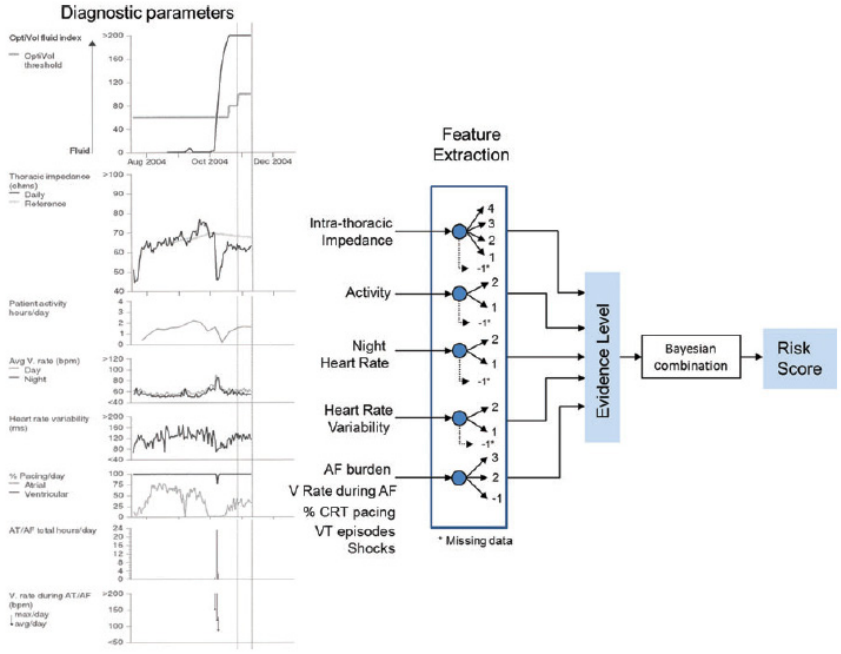
BIOTRONIK Home Monitoring Service Center











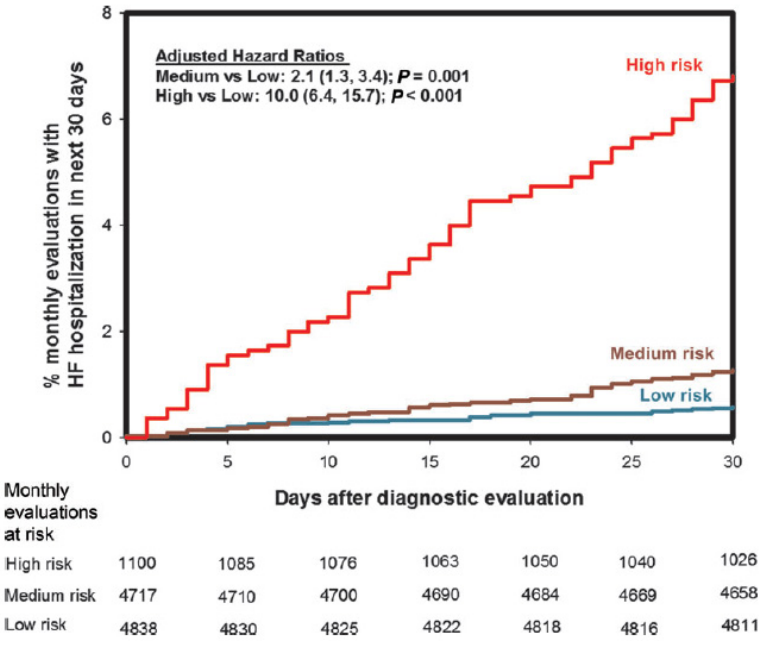
Diagnostic parameter	Diagnostic criteria	Evidence level
OptiVol	Fluid index ≥100	4
	60≤ Fluid index <100	3
	30≤ Fluid index <60	2
	0≤ Fluid index <30	1
	Data not available	−1
Night heart rate (NHR)	AvgNHR ≥85 b.p.m. OR AvgNHR ≤55 b.p.m.	2
	NHRtrendIndex*≥NHR trend threshold	2
	If condition for evidence level 2 not met	1
	Data not available	−1
Patient activity (ACT)	AvgACT ≤60 min	2
	ACTtrendIndex*≥ACT trend threshold	2
	If condition for evidence level 2 not met	1
	Data not available	−1
Heart rate variability (HRV)	AvgHRV ≤60 ms	2
	HRV trend index*≥HRV trend threshold	2
	If condition for evidence level 2 not met	1
	Data not available	−1
Arrhythmia/pacing combination	VTepisodes ≥5 OR Shock = 'True' OR AF burden ≥1 h/day OR MeanVRAF ≥90 b.p.m. AND AF ≥6 h/day OR %Ventricular pacing ≤90% AND CRT device	1
	Two or more of the above 5 arrhythmia conditions met	2
	No condition met OR data not available	−1

European Heart Journal (2013) 34, 2472–2480
doi:10.1093/eurheartj/eht083

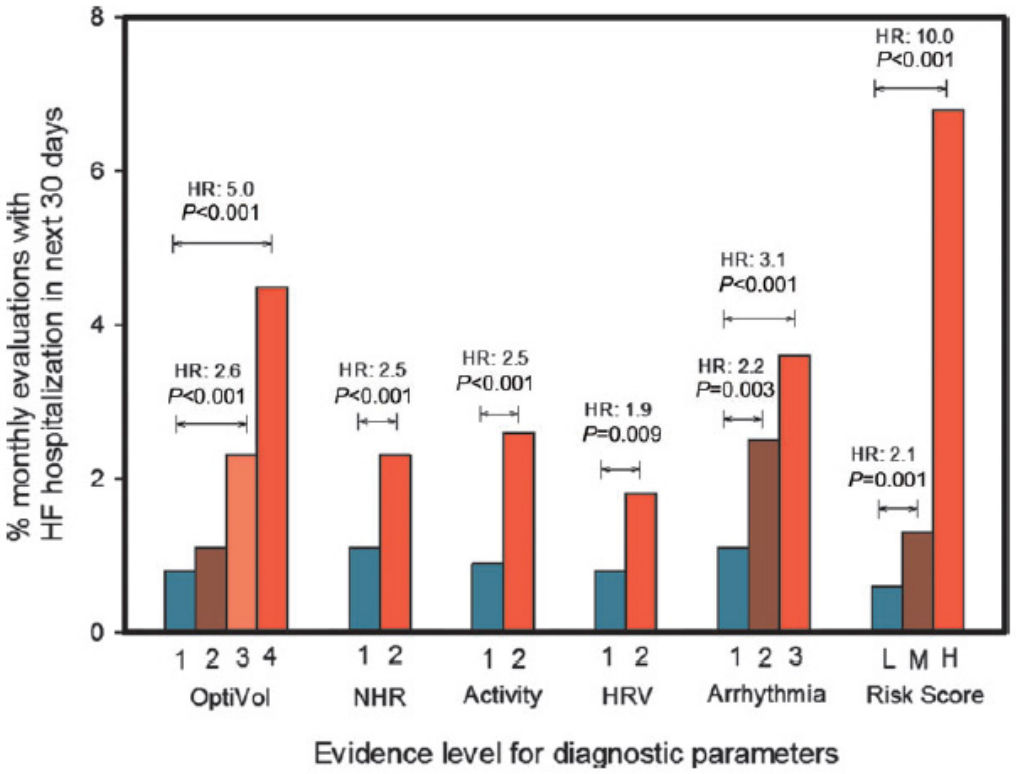
CLINICAL RESEARCH
Heart failure/cardiomyopathy

Development and validation of an integrated diagnostic algorithm derived from parameters monitored in implantable devices for identifying patients at risk for heart failure hospitalization in an ambulatory setting

Martin R. Cowie[1,2]*, Shantanu Sarkar[3], Jodi Koehler[3], David J. Whellan[4], George H. Crossley[5], Wai Hong Wilson Tang[6], William T. Abraham[7], Vinod Sharma[3], and Massimo Santini[8]



Monthly evaluations at risk							
High risk	1100	1085	1076	1063	1050	1040	1026
Medium risk	4717	4710	4700	4690	4684	4669	4658
Low risk	4838	4830	4825	4822	4818	4816	4811

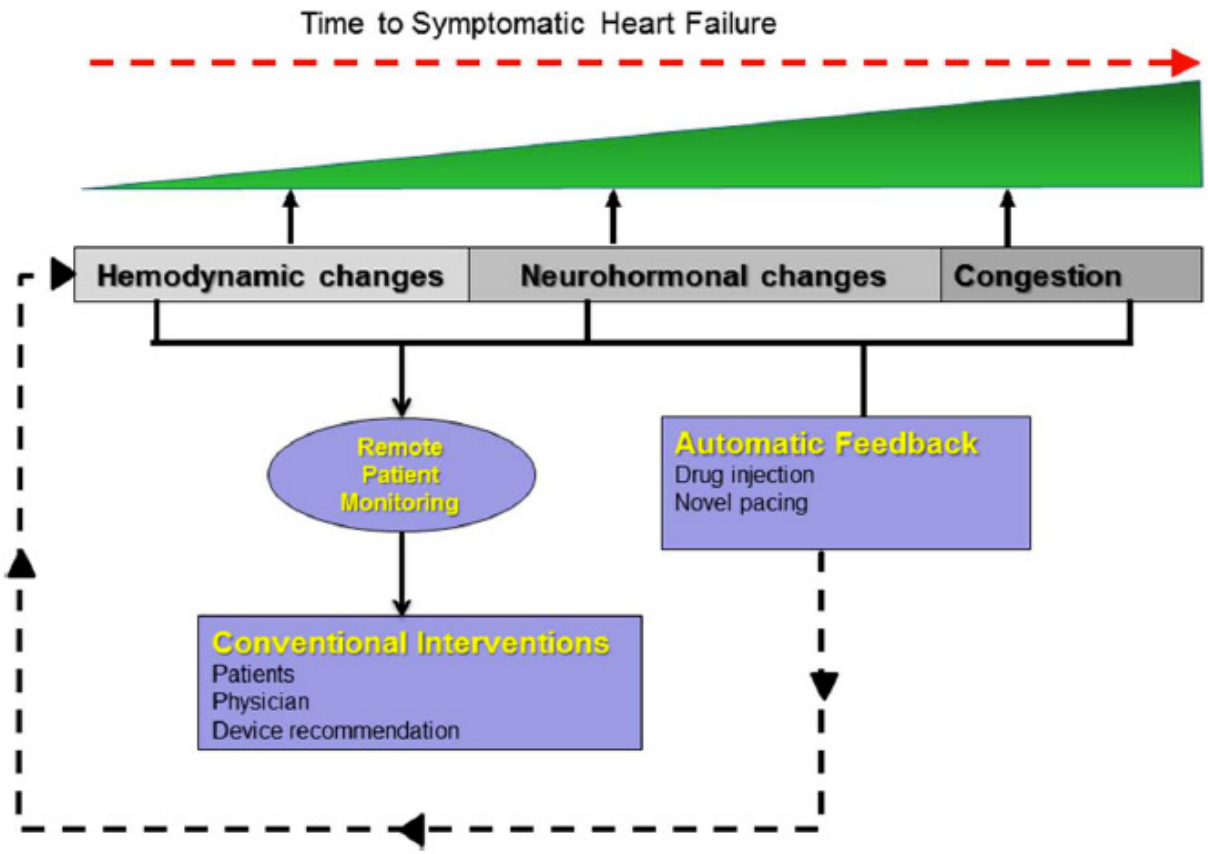


1. Long-term ambulatory monitoring using implantable devices featuring remote access and wireless alerting capabilities enables the dynamic assessment of the HF status, thus providing the opportunity to optimize treatment strategies for HF in a timely fashion.
2. Like any diagnostic (weight, temperature, ECG, etc.), diagnostic information must be coupled with appropriate clinical actions in order to improve outcomes in HF patients.

European Heart Journal (2013) 34, 2472–2480

Future of Implantable Devices for Cardiac Rhythm Management

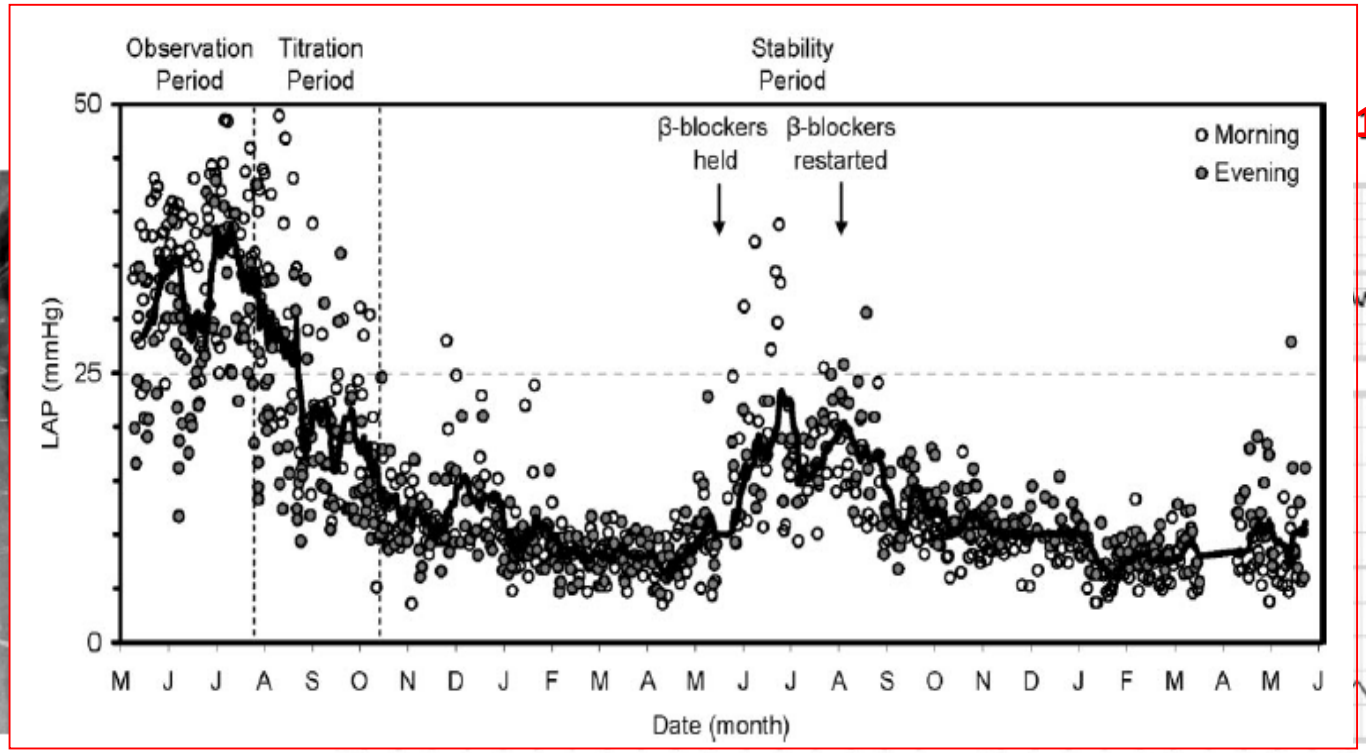
Chu-Pak Lau, MD; Chung-Wah Siu, MD; Hung-Fat Tse, MD, PhD



Circulation. 2014;129:811-822

Physician-Directed Patient Self-Management of Left Atrial Pressure in Advanced Chronic Heart Failure

Jay Ritzema, MRCP; Richard Troughton, FRACP, PhD; Iain Melton, FRACP; Ian Crozier, FRACP, MD; Robert Doughty, FRACP, MD; Henry Krum, FRACP, PhD; Anthony Walton, FRACP; Philip Adamson, MD; Saibal Kar, MD; Prediman K. Shah, MD; Mark Richards, FRACP, DSc; Neal L. Eigler, MD; James S. Whiting, PhD; Garrie J. Haas, MD; J. Thomas Heywood, MD; Christopher M. Frampton, PhD; William T. Abraham, MD; on Behalf of the Hemodynamically Guided Home Self-Therapy in Severe Heart Failure Patients (HOMEOSTASIS) Study Group



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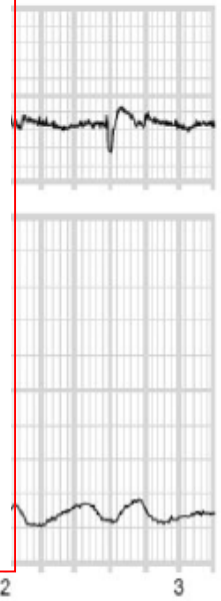
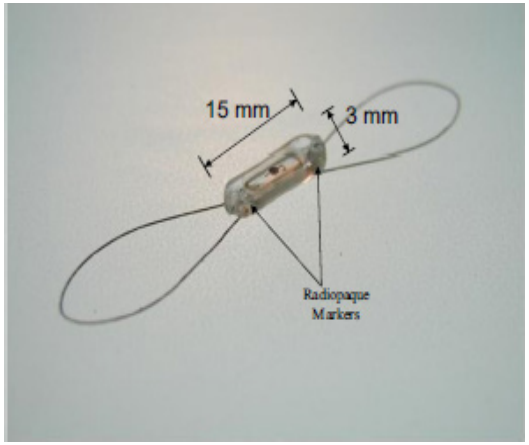


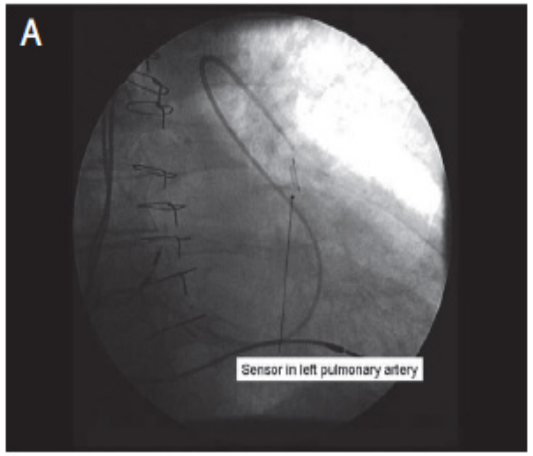
Circulation. 2010;121:1086-1095

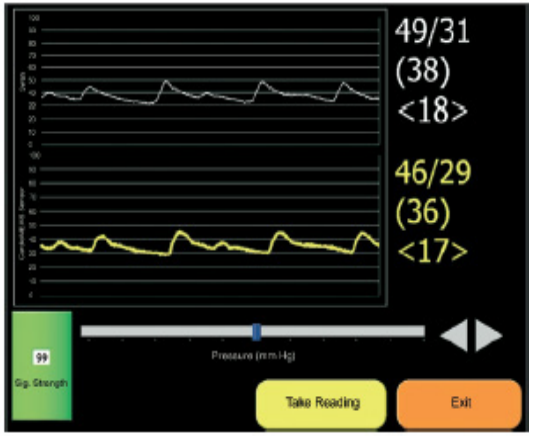
Comparison of a Radiofrequency-Based Wireless Pressure Sensor to Swan-Ganz Catheter and Echocardiography for Ambulatory Assessment of Pulmonary Artery Pressure in Heart Failure

Hugo E. Verdejo, MD,* Pablo F. Castro, MD,* Roberto Concepción, MD,† Marcela A. Ferrada, RN,* Mario A. Alfaro, MD,† Milton E. Alcaíno, MD,† Carlos C. Deck, MD, FASCI,† Robert C. Bourge, MD‡

Santiago, Chile; and Birmingham, Alabama

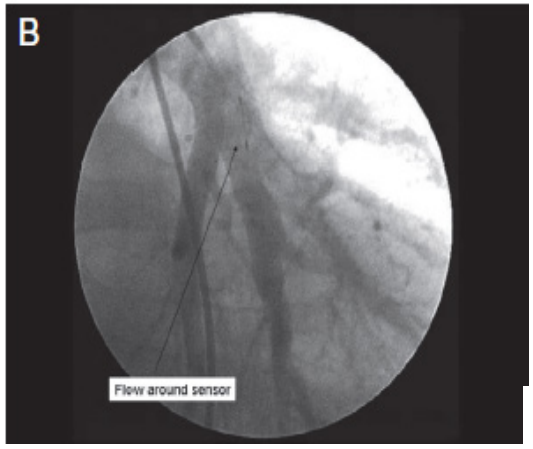






S-G meas

CardioMEMS

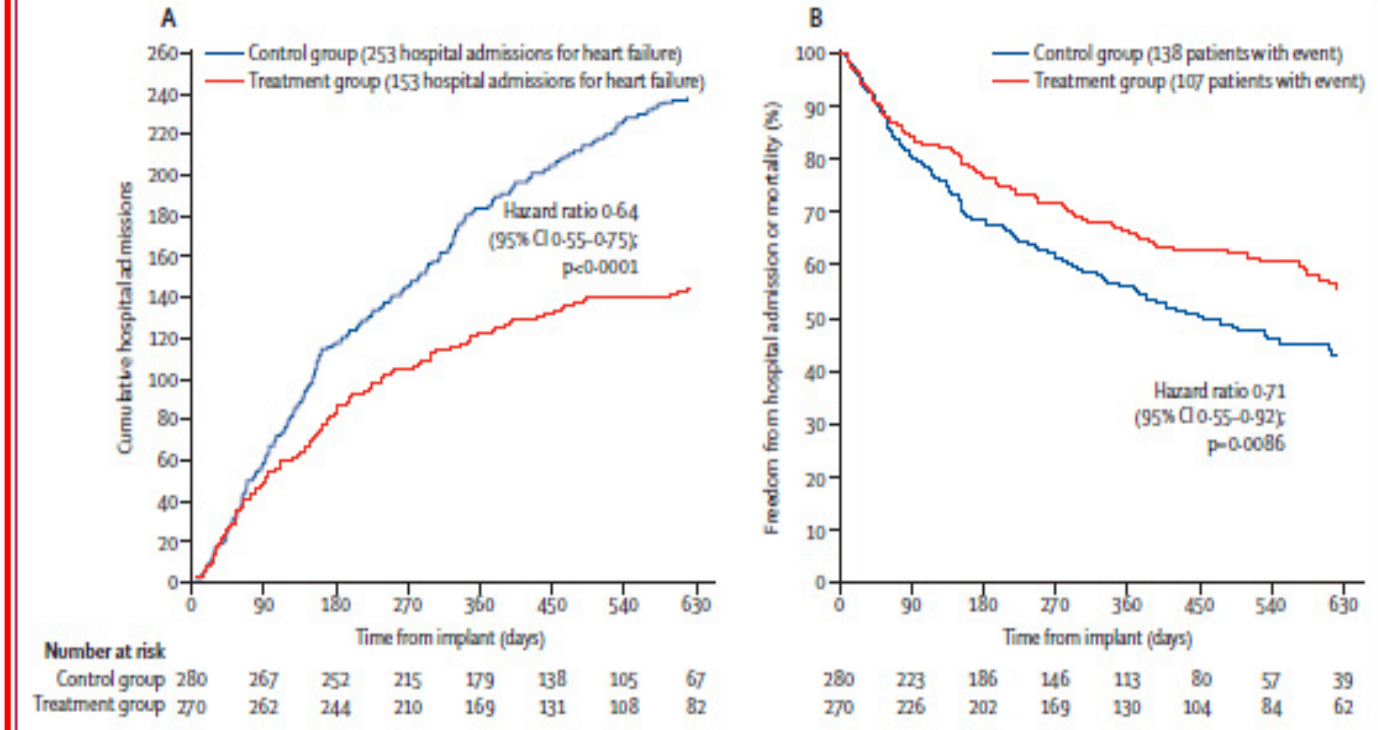


JACC Vol. 50, No. 25, 2007
December 18/25, 2007:2375–82

Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial

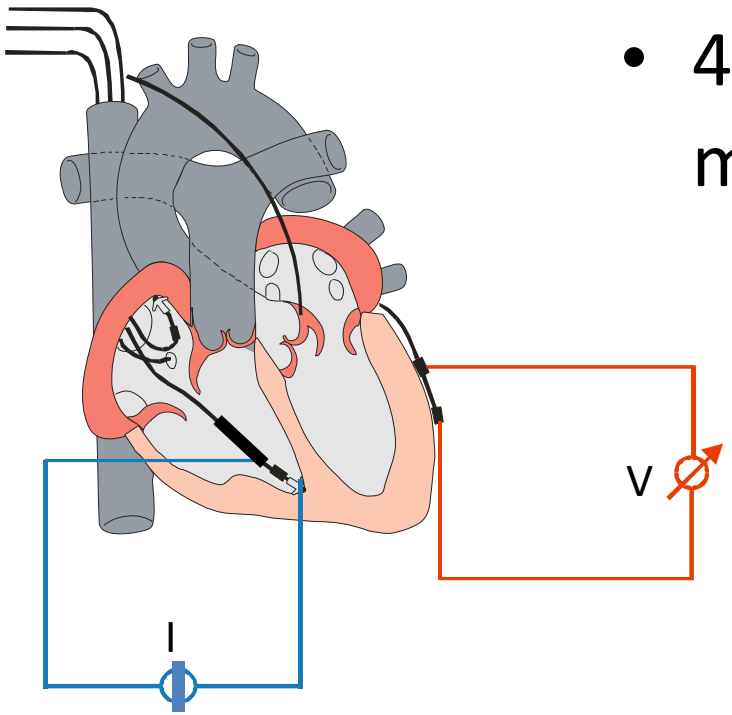
William T Abraham, Philip B Adamson, Robert C Bourge, Mark F Aaron, Maria Rosa Costanzo, Lynne W Stevenson, Warren Strickland, Suresh Neelagaru, Nirav Raval, Steven Krueger, Stanislav Weiner, David Shavelle, Bradley Jeffries, Jay S Yadav, for the CHAMPION Trial Study Group*

Lancet 2011; 377: 658–66



Interpretation Our results are consistent with, and extend, previous findings by definitively showing a significant and large reduction in hospitalisation for patients with NYHA class III heart failure who were managed with a wireless implantable haemodynamic monitoring system. The addition of information about pulmonary artery pressure to clinical signs and symptoms allows for improved heart failure management.

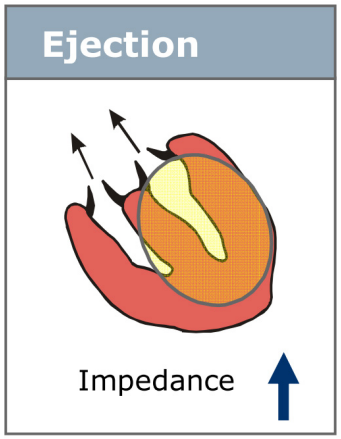
Intracardiac Impedance (ICI)



- 4-terminal impedance measurement is used:
  - Current is **injected via RV-lead** coil and tip
  - Current is conducted by surrounding blood and myocardial tissue
  - Voltage is **sampled via** tip and ring of **LV lead**

I… Current (injected)
V… Voltage (measured)

ICI & Hemodynamics



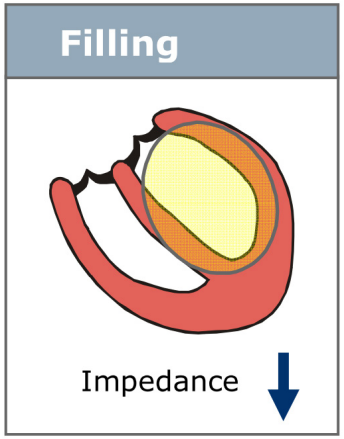
Ventricular contraction:

- smaller fraction of blood between RV and LV lead
- smaller distance between RV and LV lead

➔ measurement of large voltage

➔ **larger impedance Z**

$$Z = \frac{V}{I}$$



Ventricular relaxation:

- bigger fraction of blood between RV and LV lead
- bigger distance between RV and LV lead

➔ measurement of small voltage

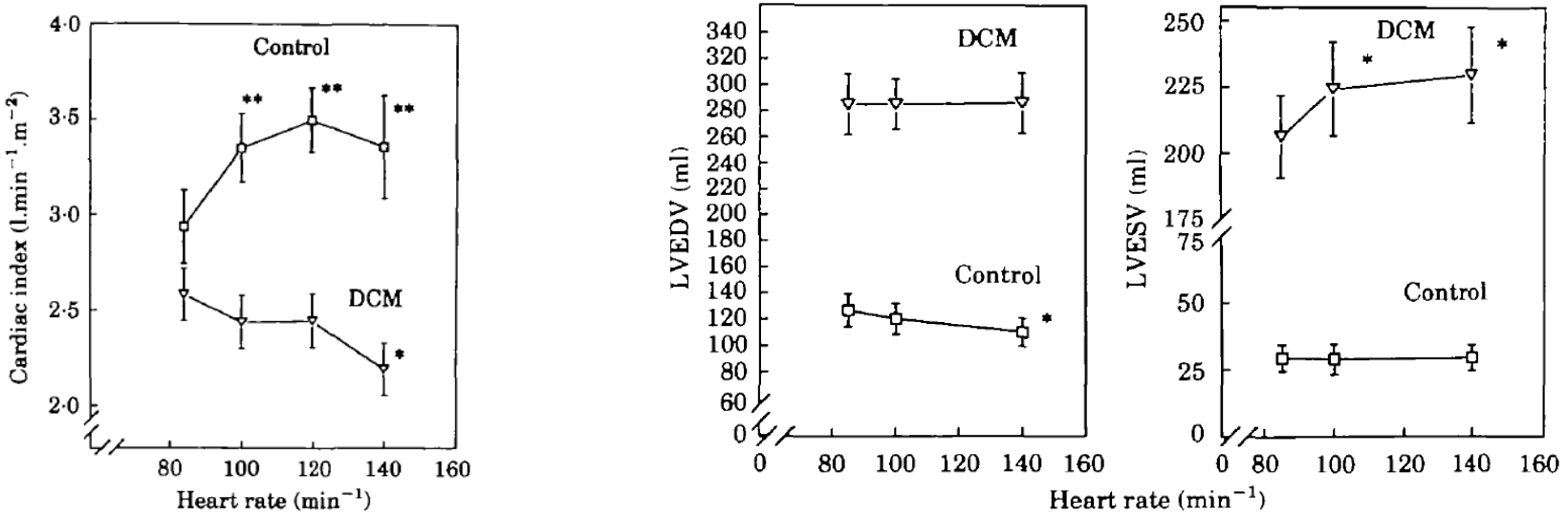
➔ **lower impedance Z**

European Heart Journal (1994) **15**, 164–170

Influence of the force–frequency relationship on haemodynamics and left ventricular function in patients with non-failing hearts and in patients with dilated cardiomyopathy

G. Hasenfuss, C. Holubarsch, H.-P. Hermann, K. Astheimer, B. Pieske and H. Just

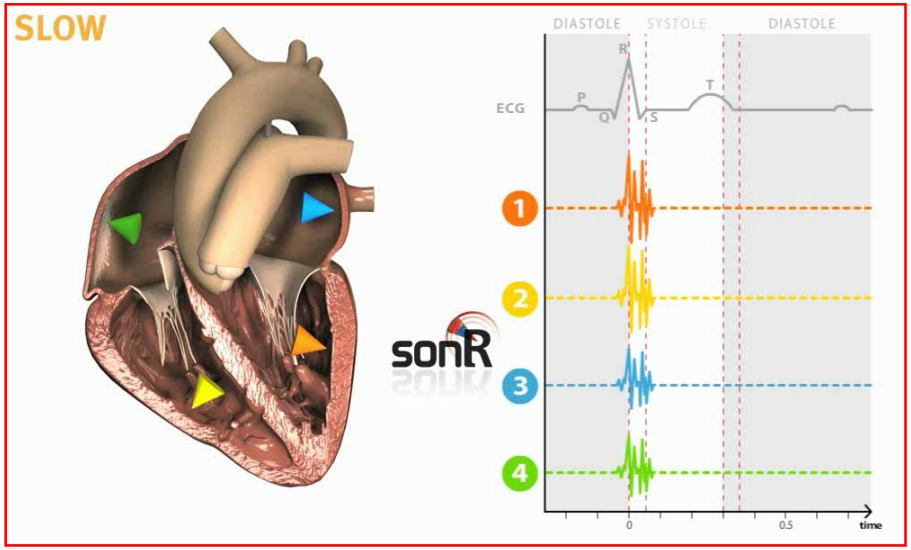
Medizinische Klinik III, Universität Freiburg, Germany

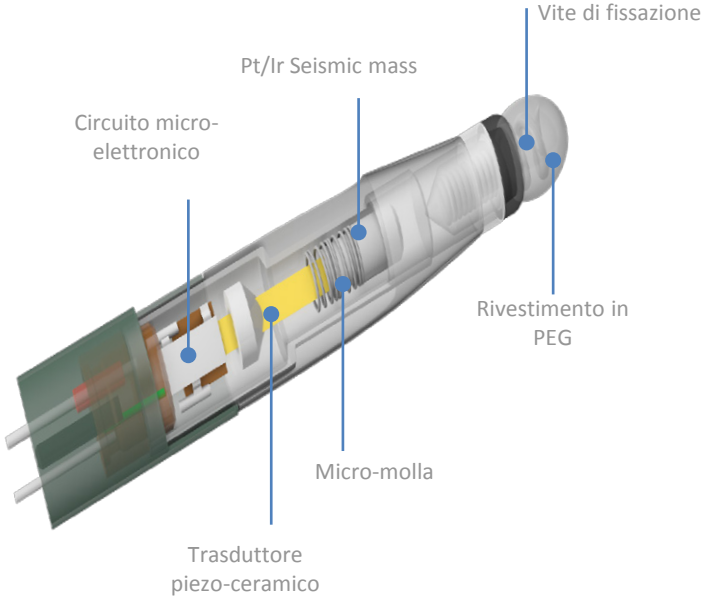


Normal heart: increasing HR ➔ CI increases; ESV does not change with reduced EDV
Dilated hearts: increasing HR ➔ CI decreases; ESV increases with unchanged EDV

SonR

- SonR utilizza un esclusivo sensore emodinamico integrato nella punta dell'elettrocatetere di stimolazione/detezione atriale SonRtip™
- Il sensore rileva le vibrazioni del muscolo cardiaco che rispecchiano il primo tono cardiaco e sono correlate alla contrattilità ventricolare sinistra
- Esiste una notevole correlazione tra SonR e il primo tono cardiaco ($p < 0,0001$)
- L'ampiezza del tono cardiaco rispecchia le variazioni del valore di LV dP/dt_{max}





Contributions of a Hemodynamic Sensor Embedded in an Atrial Lead in a Porcine Model

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SYLVAIN PLOUX, M.D.,*,† LOUIS LABROUSSE, M.D.,*,† CYRIL CASSET,§
MICHEL HAISSAGUERRE, M.D.,*,† and PIERRE DOS SANTOS, M.D., PH.D.*,†

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Journal of Cardiovascular Electrophysiology *Vol. 22, No. 5, May 2011*

Methods: W
catheter tip mi
Myocardial co
We searched,
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to measure dP/dt$_{max}$.
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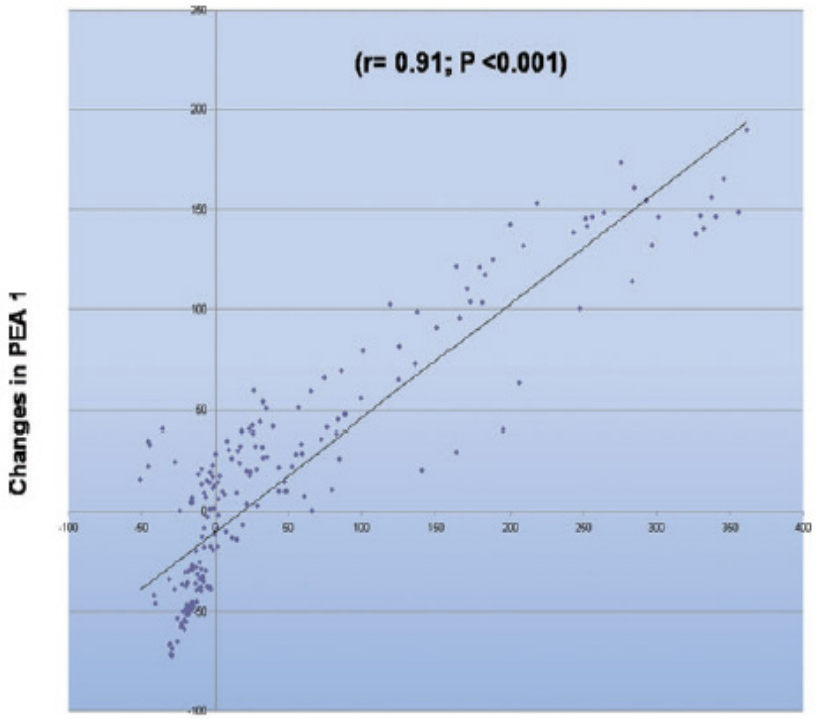
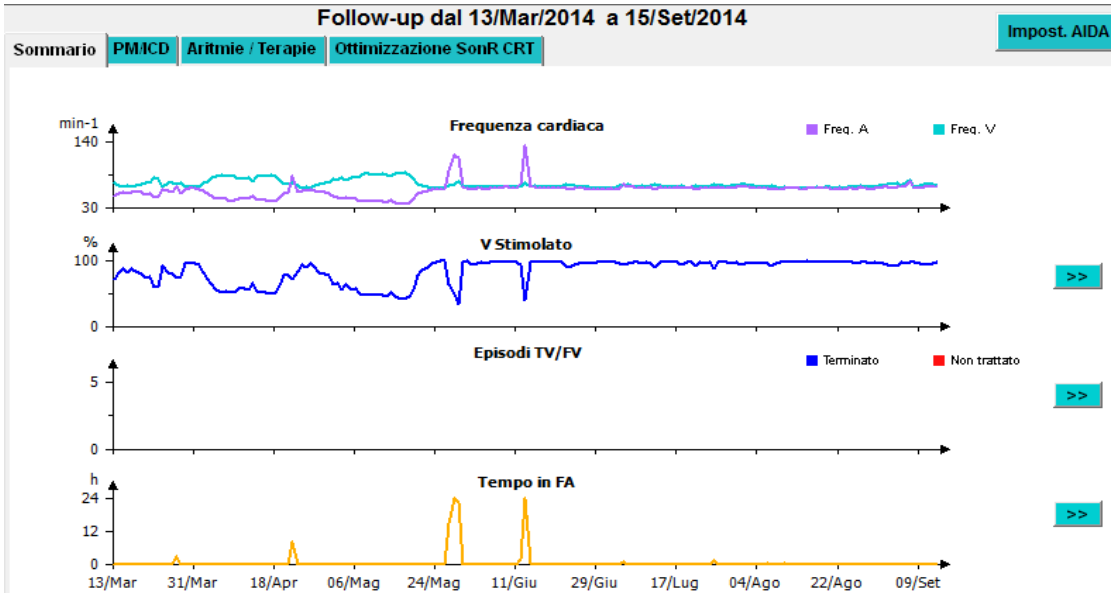
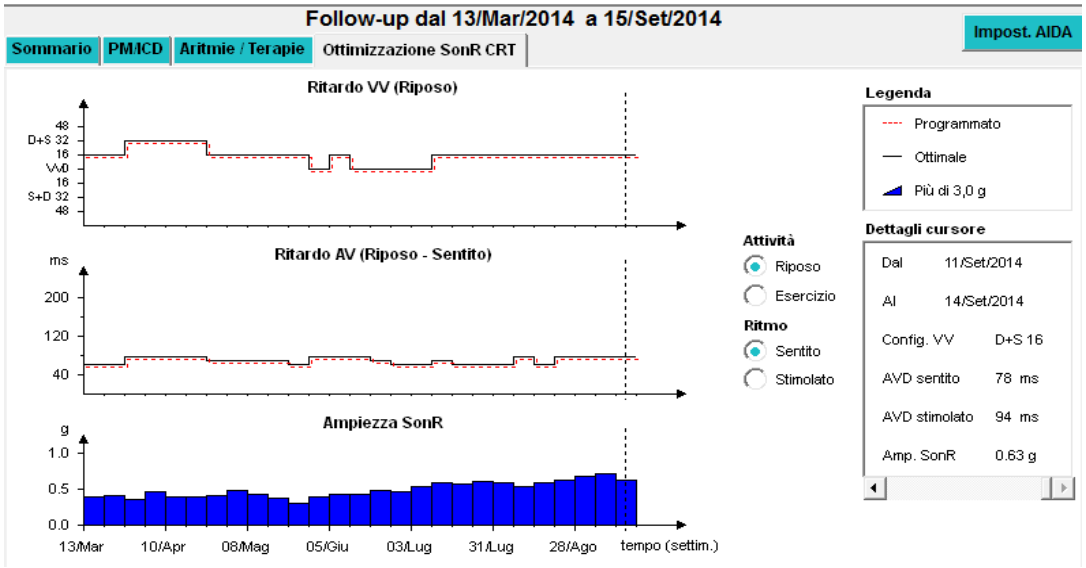
on.




Follow-up dal 13/Mar/2014 a 15/Set/2014
Impost. AIDA
Sommario
PM/ICD
Aritmie / Terapie
Ottimizzazione SonR CRT
Frequenza cardiaca
min-1
140
30
Freq. A
Freq. V
V Stimolato
%
100
0
>>
Episodi TV/FV
Terminato
Non trattato
5
0
>>
Tempo in FA
h
24
12
0
>>
13/Mar
31/Mar
18/Apr
06/Mag
24/Mag
11/Giu
29/Giu
17/Lug
04/Ago
22/Ago
09/Set


Follow-up dal 13/Mar/2014 a 15/Set/2014
Impost. AIDA
Sommario
PM/ICD
Aritmie / Terapie
Ottimizzazione SonR CRT
Ritardo VV (Riposo)
48
D+S 32
16
VVD
16
S+D 32
48
Ritardo AV (Riposo - Sentito)
ms
200
120
40
Ampiezza SonR
g
1.0
0.5
0.0
13/Mar
10/Apr
08/Mag
05/Giu
03/Lug
31/Lug
28/Ago
tempo (settim.)
Attività
Riposo
Esercizio
Ritmo
Sentito
Stimolato
Legenda
Programmato
Ottimale
Più di 3,0 g
Dettagli cursore
Dal 11/Set/2014
Al 14/Set/2014
Config. VV D+S 16
AVD sentito 78 ms
AVD stimolato 94 ms
Amp. SonR 0.63 g

Impact of remote monitoring on clinical events and associated health care utilization: A nationwide assessment

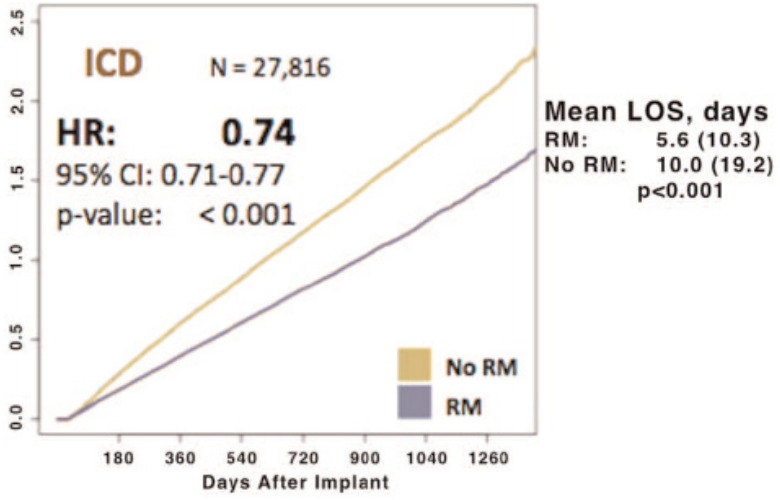
Jonathan P. Piccini, MD, MHSc,[*] Suneet Mittal, MD,[†] Jeff Snell, AB,[‡] Julie B. Prillinger, PhD,[§] Nirav Dalal, MS, MBA,[§] Niraj Varma, MD, PhD[‖]

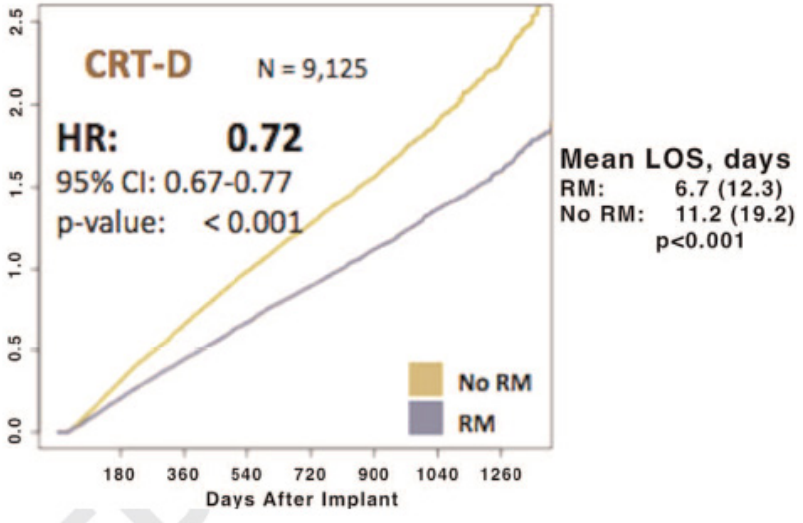
Objective: determine whether RM was associated with reduced hospitalization and costs in clinical practice

Overall 92.566 patients with PM, CRT-P, ICD, CRT-D were evaluated with a mean F-U of 19 ± 12 months:

1. Only 37% (34.259) of patients used RM
2. While 63% (58.307) were followed with in-person visits only

All-cause hospitalization according to Remote Monitoring use





Heart Rhythm2016;0:-1–8

Conclusions:

- Remote monitoring is likely going to play an important role in disease management of ICD and CRT-D patients

- RCT have shown that RM can reduce all-cause mortality and WHF hospitalizations, when optimal work flow and multiparametric approach are carried out

- Haemodymanic sensors will further increase our capability to follow HF patients.