

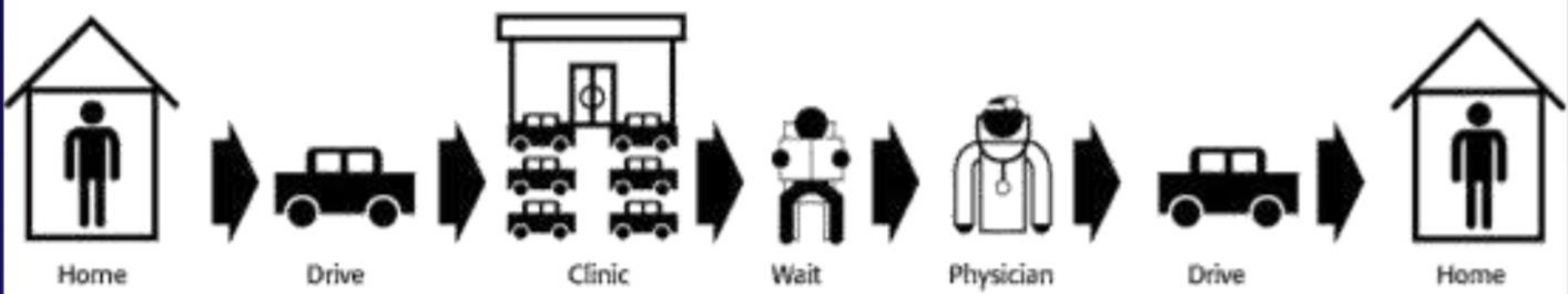
Last updates in telecardiology

Jérôme Taieb
CH Aix en Provence

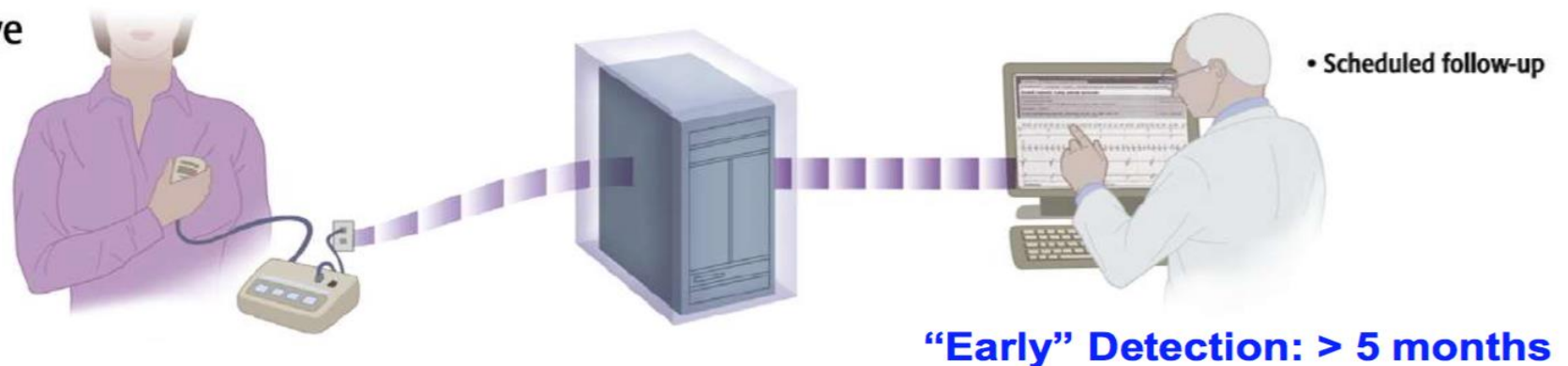
Disclosure

Research grant

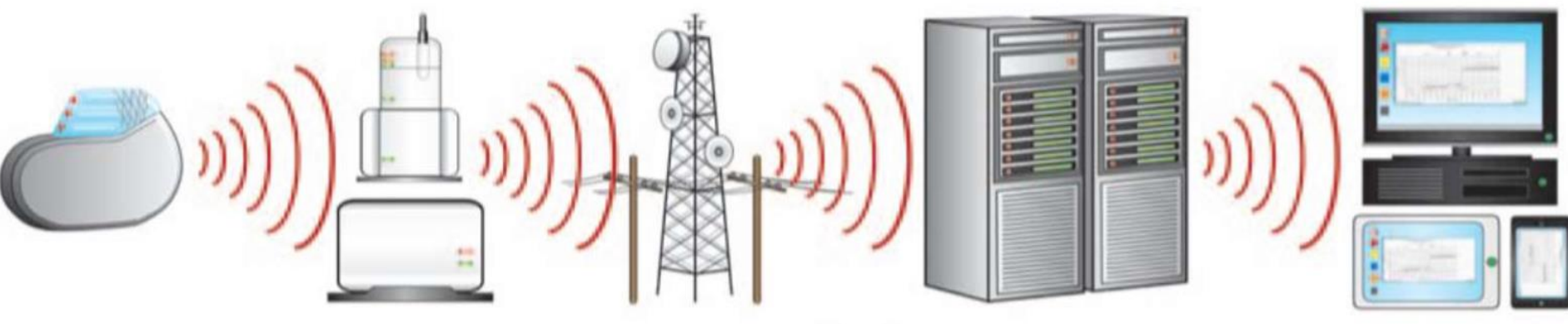
- Livanova
- Boston
- Biotronik
- Medtronic
- Abott



Inductive



Automatic remote monitoring



“Early” Detection: 5 minutes

Telemedicine technologies in Cardiology

1

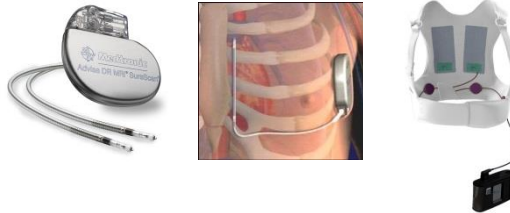
External Devices for **Self-measurement**

- Balance
- Blood pressure monitor
- Self measurement of BNP
- e-Questionnaires on symptoms

2

Implantable Cardiac Devices for **Therapeutic**

- Pacemaker
- Defibrillator
- LifeVest



3

Implantable Cardiac Devices for **Diagnosis**

- Pressure sensor
- Holter



Pacemaker and ICD

Technical parameters

- Battery
- Leads
- Device

Arrhythmias

- Ventricular
- Supraventricular

Heart failure parameters

- Heart rate
- Ventilation
- Activity
- Thoracic impedance
- HRV
- % CRT

Surveillance

2006

Recommendations

Industry: The Heart Rhythm Society recommends that cardiac rhythm management device manufacturers develop and utilize wireless and remote monitoring technologies

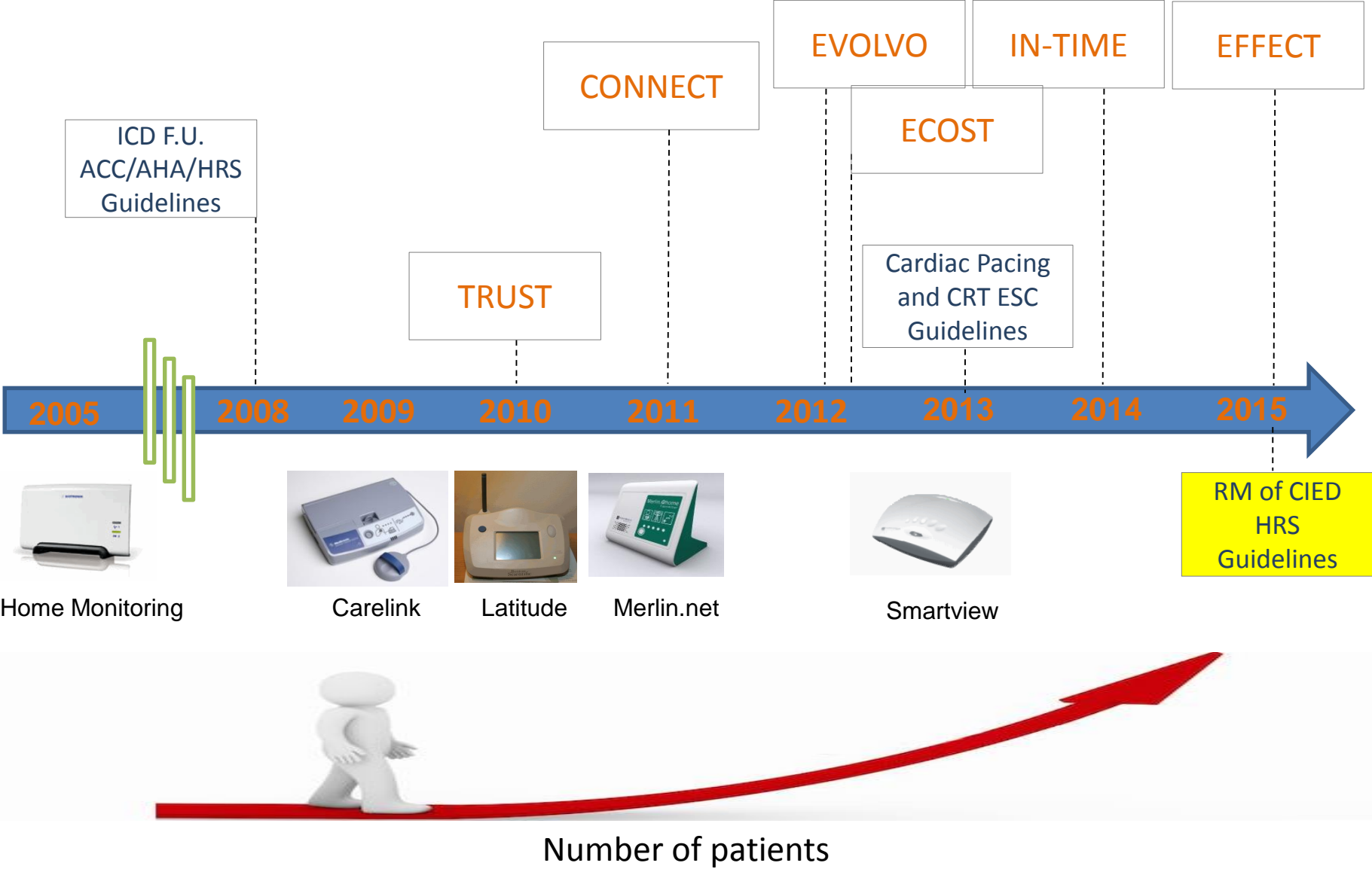


HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations 2008

The HRS Device Performance Task Force recognized that “physicians and patients need timely, accurate, and understandable information regarding device performance.”²⁴

2009

Remote monitoring of ICD : a pioneer application





Heart Rhythm SocietySM

May 2015

HRS Expert Consensus Statement on Remote Monitoring

Chairs

David Slotwiner, Niraj Varma

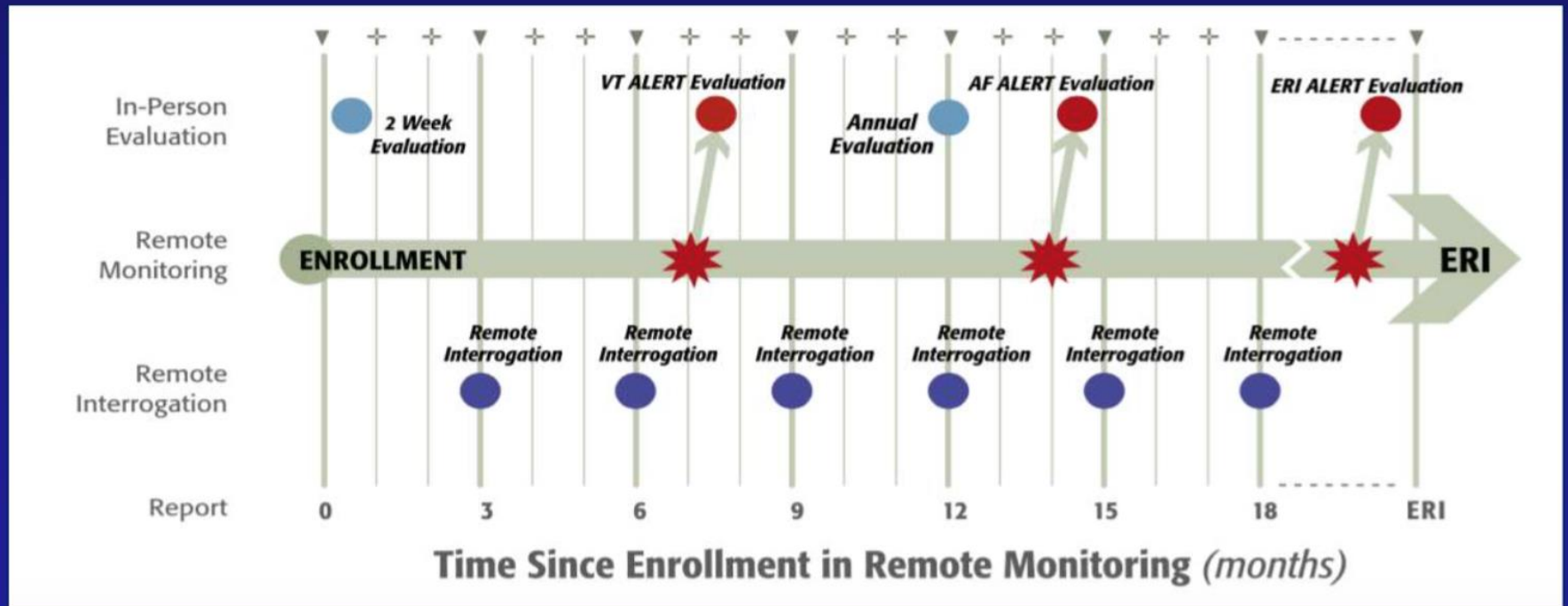
Writing Committee

Joseph G. Akar, Marianne Beardsall, CCDS, Richard I. Fogel, Nestor O. Galizio, Taya Glotzer, Robin A. Leahy, Charles J. Love, CM Yu, Rhondalyn C. McLean, Suneet Mittal, Loredana Morichelli, Kristen K. Patton, Merritt H. Raitt, Renato Pietro Ricci, John Rickard, Mark Schoenfeld, Gerald A. Serwer, Julie Shea, Paul Varosy, Atul Verma

| Device Monitoring | Class of Recommendation | Level of Evidence |
|---|-------------------------|-------------------|
| A strategy of <u>remote CIED monitoring</u> and interrogation, combined with at least annual IPE, is recommended <u>over a calendar-based schedule of in-person</u> CIED evaluation alone (when technically feasible) | I | A |

Cardiac Implantable Electronic Device

Standard of Care: Continuous monitoring with event-based follow-up



| Device Monitoring | Class of Recommendation | Level of Evidence |
|--|-------------------------|-------------------|
| <u>All patients</u> with CIEDs <u>should be offered RM</u> as part of the standard follow-up management strategy | I | A |

IN-TIME Study

➤ 50 % reduction in 1 year mortality

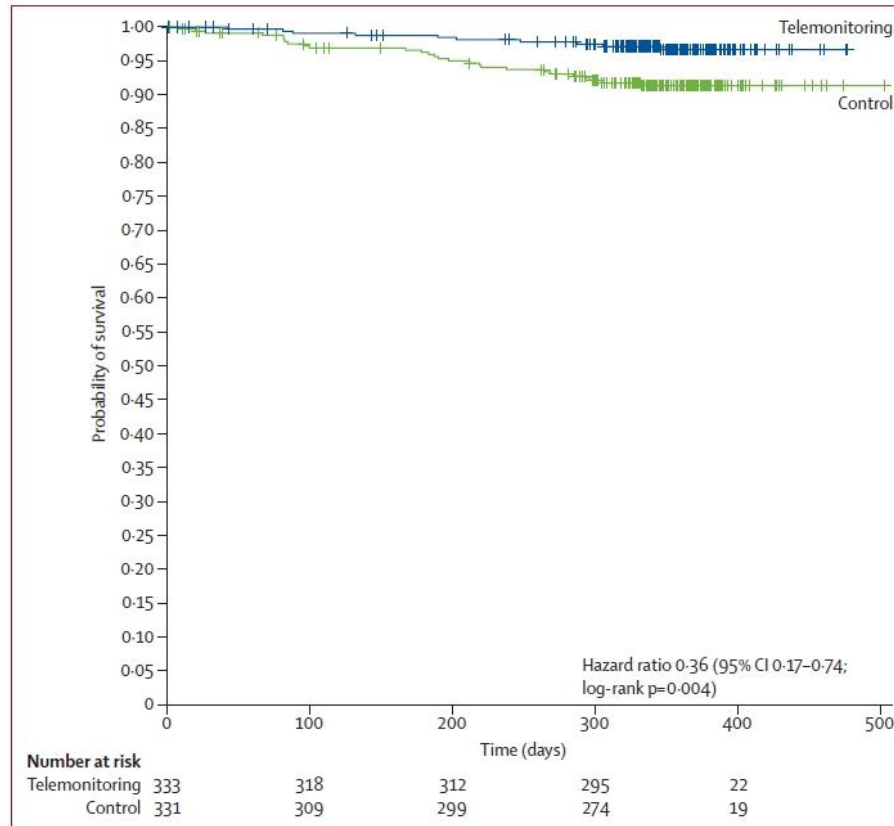


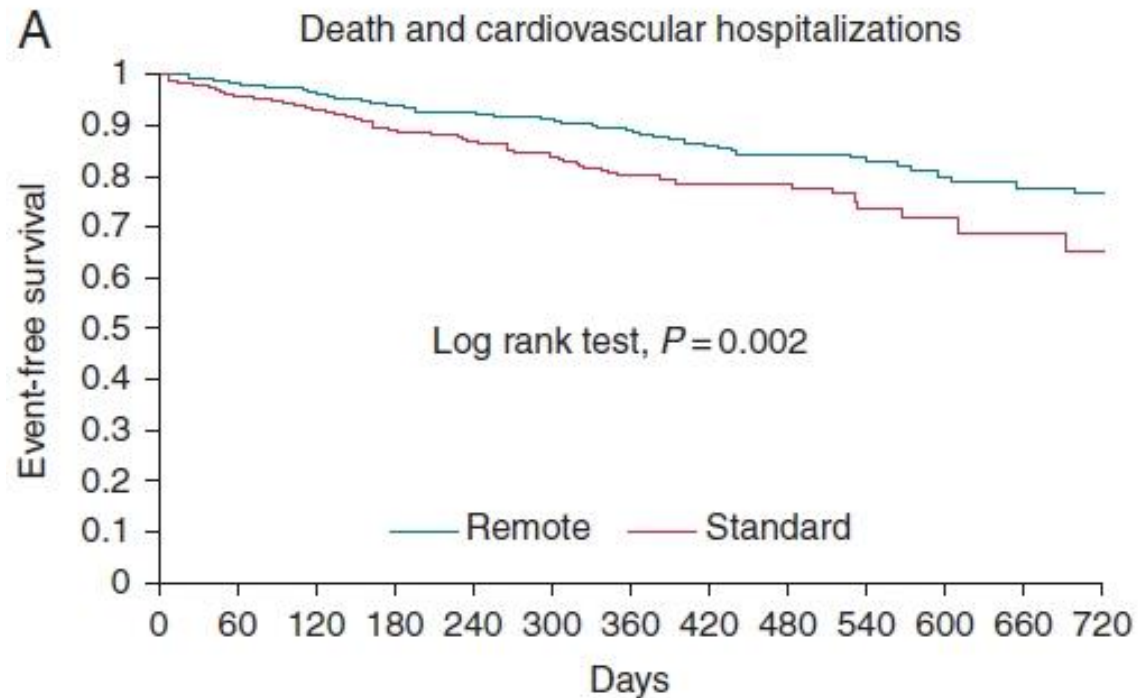
Figure 2: Kaplan-Meier curves of patient survival

Prospective randomized study
333 patients (remote group) vs 331 (control group)

Hindricks Lancet 2014

EFFECT Study

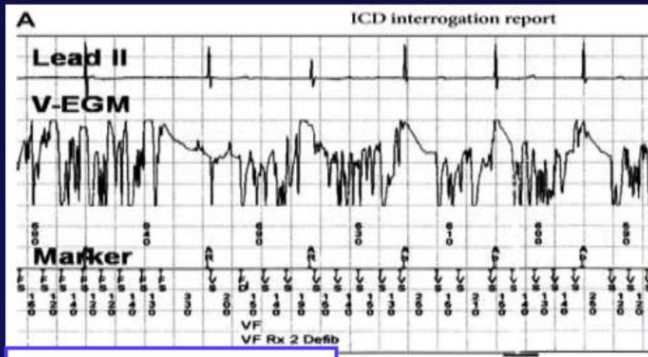
56% decrease of deaths and cardiovascular hospitalizations with RM



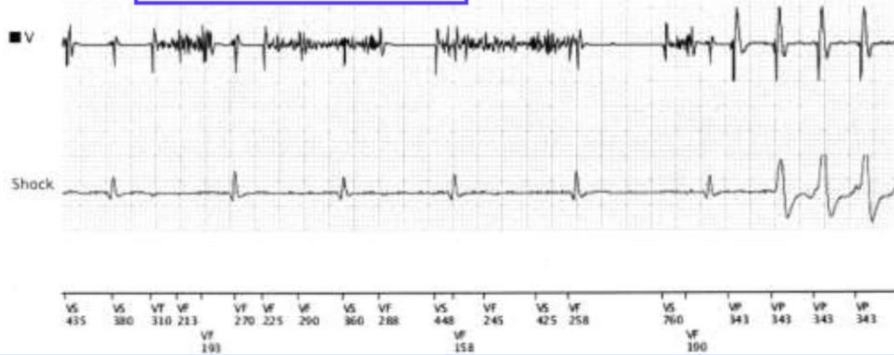
Prospective non-randomized study
499 patients (**remote** group) vs 488 (**control** group)
Primary endpoint: Death + cardiovascular hospitalization

| Device & Disease Management | Class of Recommendation | Level of Evidence |
|---|-------------------------|-------------------|
| RM should be performed for <u>surveillance of lead function and battery conservation</u> | I | A |
| Patients with a CIED component that <u>has been recalled or is on advisory</u> should be enrolled in RM to enable early detection of <u>actionable events</u> | I | E |
| RM is useful to <u>reduce</u> the incidence of <u>inappropriate ICD shocks</u> | I | B-R |

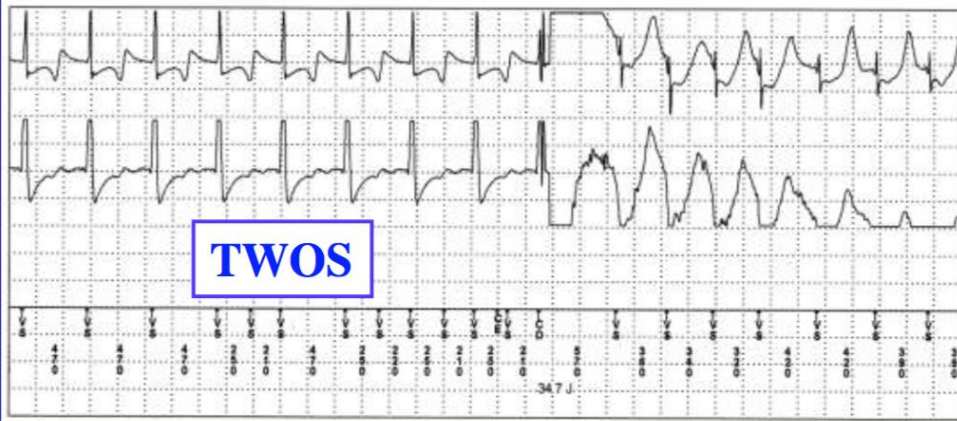
CHOCK



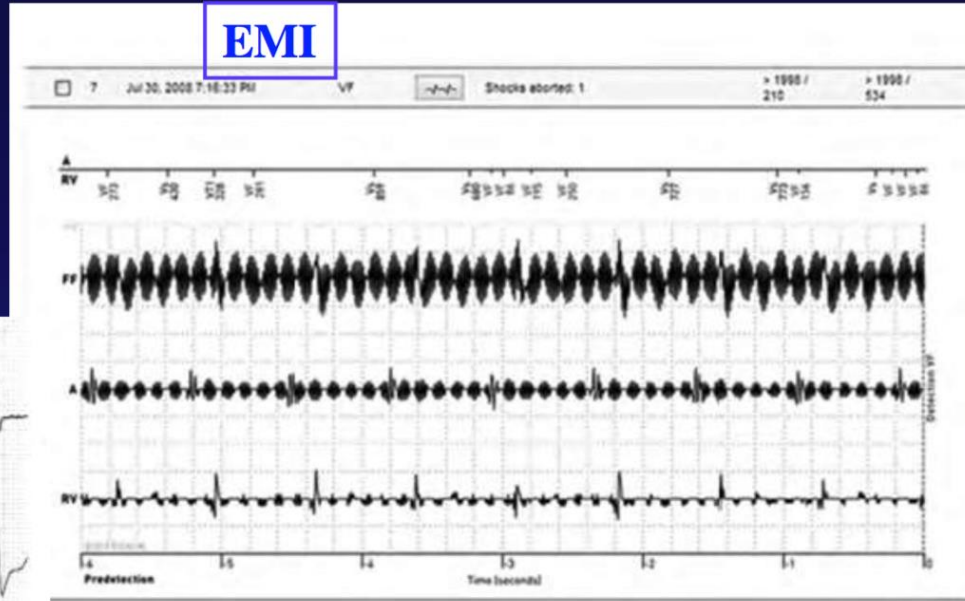
Lead Fracture



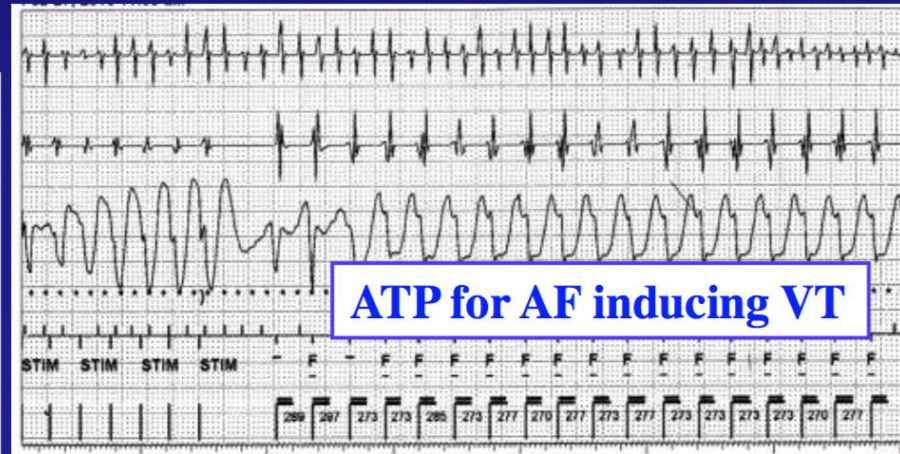
TWOS



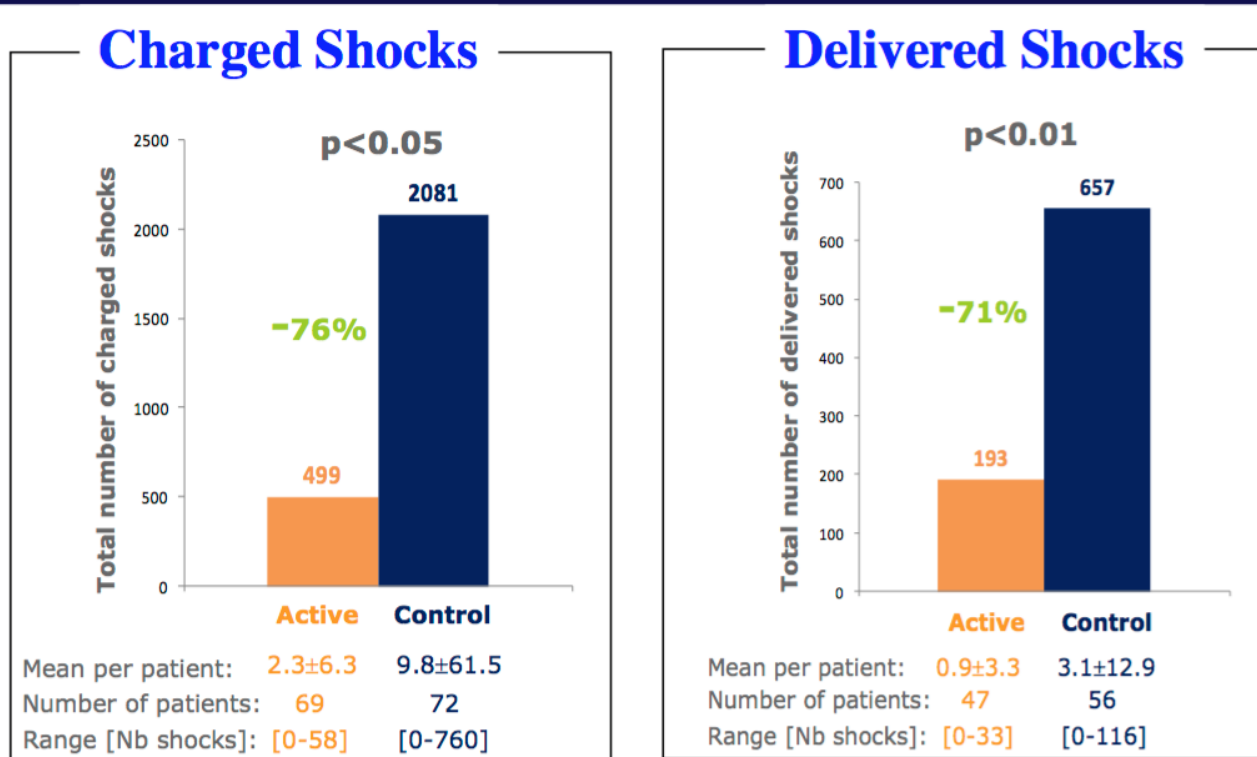
EMI



ATP for AF inducing VT



Device Management: ICD Shocks



52% reduction in inappropriate shocks

72% reduction of hospitalizations for inappropriate shocks

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

RM is useful to reduce the incidence of inappropriate ICD shocks

|

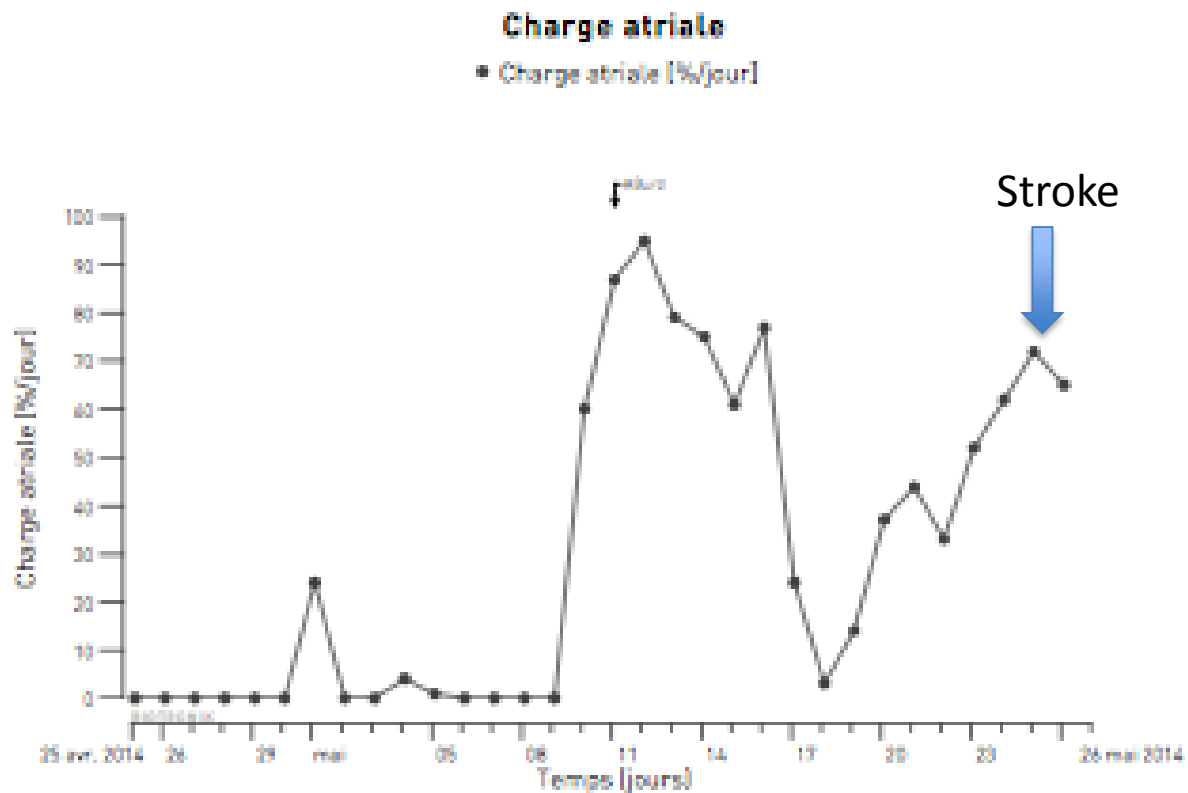
B-R

Atrial fibrillation

RM is useful for the early detection and quantification of atrial fibrillation.

I

A



Remote Monitoring & early detection of AF

| Author | | RM system | Device | Nb of Patients | Endpoint |
|----------|------|---|-------------|----------------|--|
| Varma | 2005 | Home Monitoring | PM | 276 | Home Monitoring detected AF in 29 patients (3 unknown AF) |
| Lazarus | 2007 | Home Monitoring | PM + ICD | 11 624 | >60% of PM patients' alerts were related to AF detection |
| Crossley | 2009 | CareLink 3-month Remote Interrogations | PM | 980 | Almost twice AT/AF events detected in the remote arm |
| Ricci | 2009 | Home Monitoring | 73% PM | 166 | 20% of patients had alerts for AF. 88% of unscheduled follow-up for AF were actionable Reduction of reaction time: 148 days |
| Varma | 2010 | Home Monitoring | ICD | 1339 | Reduction of detection time: 5.5 days for HM vs 40 days for ambulatory follow-up |
| Crossley | 2011 | CareLink | ICD + CRT-D | 1997 | Reduction of the time of AF detection to clinical decision: 3 days in RM vs 24 in in-office groups |
| Amara | 2014 | Home Monitoring | PM | 595 | Reduction of detection time: 114 days in the RM vs 224 in in-office groups |

AF detected with RM and strokes

| Author | System | Device | Nb of Patients | Follow-up | Endpoint |
|-------------------|--------------------|--------------------|----------------|-----------|---|
| Capucci 2005 | Medtronic | PM | 725 | 22 months | The risk of embolism is 3 times increased in patients with device-detected AF episodes > 1 day |
| Glotzer 2009 | Medtronic | PM ICD CRT-D | 2 486 | 1.4 year | AT/AF burden \geq 5.5 hours on any prior days doubles thromboembolic risk |
| Daoud 2011 | Medtronic | PM ICD CRT-D | 40 | 1.4 year | AT/AF was detected prior to cerebrovascular events/systemic emboli in only 50% of the patients |
| Shanmugam 2012 | Home Monitoring | CRT-D | 560 | 370 days | Patients with AHRE > 3.8 h over a day were 9 times more likely to develop thromboembolic complications |
| Brambatti 2014 | St Jude Medical | PM ICD | 2 580 | 2.5 years | SCAF \geq 6 min is associated with a 2.5-fold increased risk of stroke and systemic embolism Only 8% patients had SCAF within 30 days before TE |
| Boriani 2014 | Medtronic | PM ICD CRT-D | 10 016 | 24 months | 43% of the patients experienced at least 1 day with an atrial burden of at least 5 min For every additional hour increase in the daily maximum of AF burden the relative risk for stroke increased by about 3% |

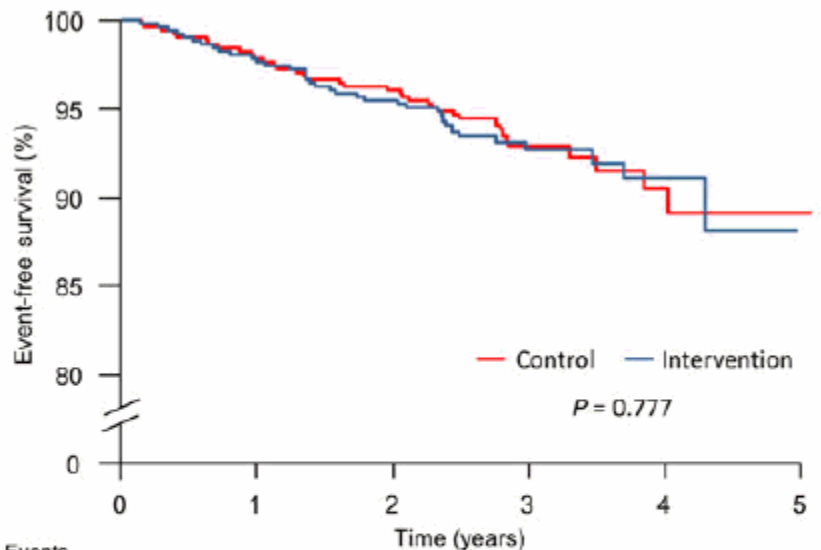
No temporal relationship between AHRE and strokes

IMPACT study

**Start & stop anticoagulation based on atrial burden detected by Remote Monitoring
VS
Anticoagulation determined by the standard clinical criteria**

Prospective randomized multicenter study
2 718 patients with dual chamber or CRT ICD

Follow-up: 701 days



The incidence of the composite endpoint of stroke, systemic embolism & major bleeding did not differ between groups

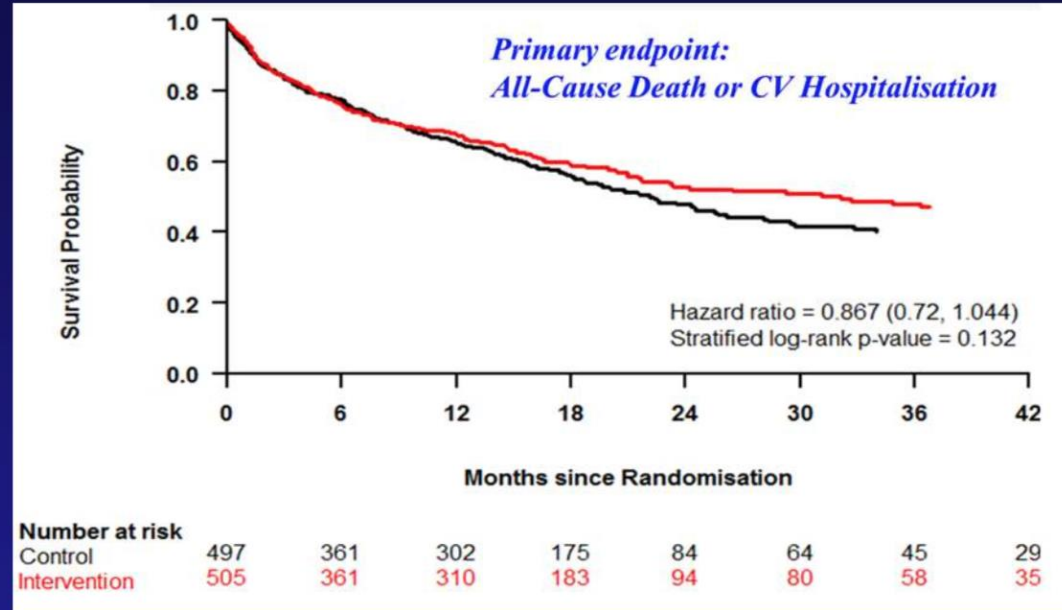
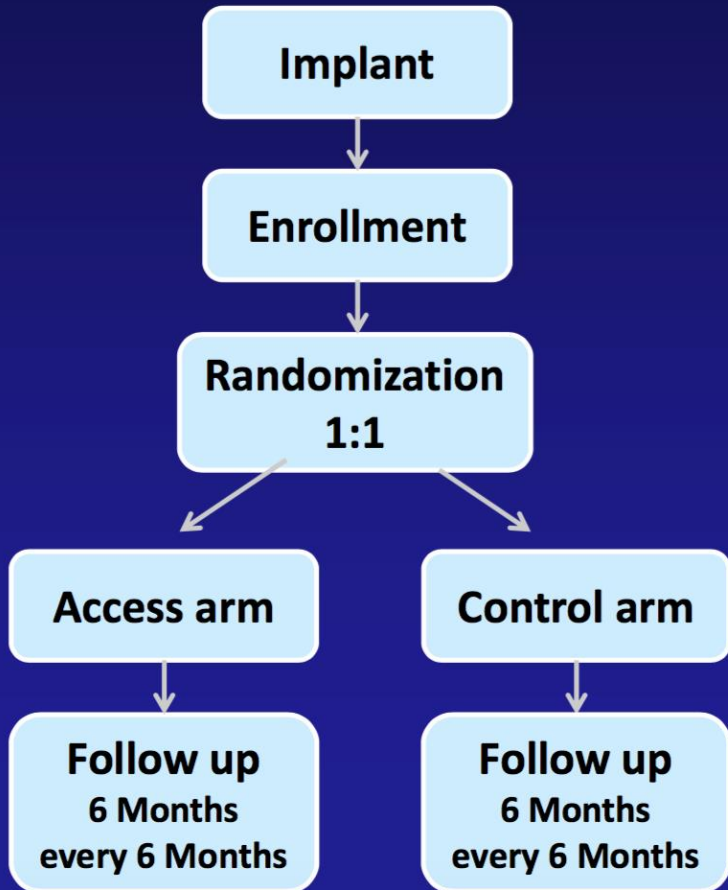
Figure 3 Primary events (first stroke, systemic embolism, or major bleeding event) in the two treatment groups (intention-to-treat analysis).

The management of anticoagulation therapy guided by Remote Monitoring of atrial vulnerability requires further studies

- A population with a high risk of stroke
- A rational programming of the parameters for the automatic diagnosis of AF & for AF related alerts
- A confirmation with the EGMs of automatically detected AF, before starting anticoagulation
- No withdrawal of anticoagulation whatever the evolution of atrial burden
- Use of direct oral anticoagulants
- Long follow-up

Heart failure

Effect of implanted device-based impedance monitoring with telemedicine alerts on mortality and morbidity in heart failure



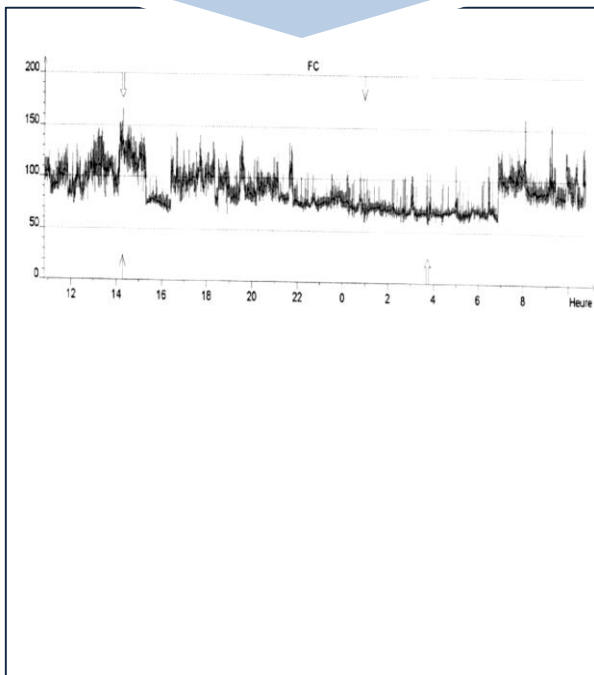
| Device & Disease Management | Class of Recommendation | Level of Evidence |
|--|-------------------------|-------------------|
| The effectiveness of RM for thoracic impedance alone or combined with other diagnostics to <u>manage congestive heart failure is currently uncertain</u> | IIb | C |

Böhm M, et al EuHJ, 2016

HF Remote monitoring

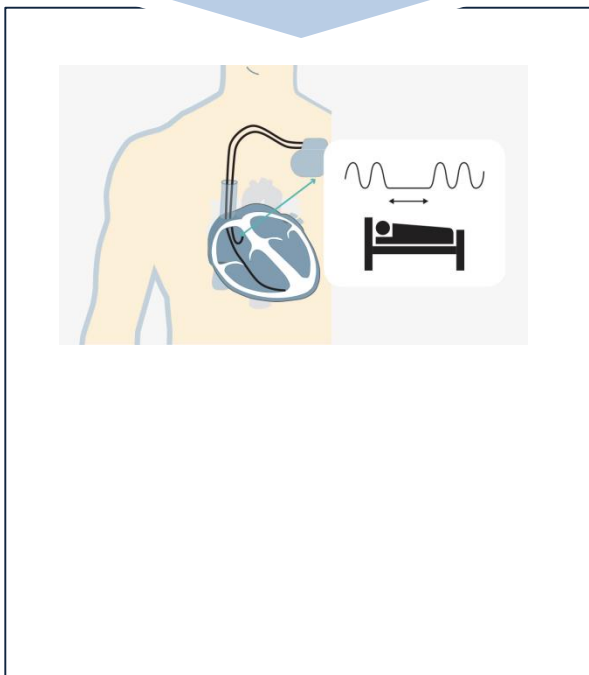
1

Heart rate



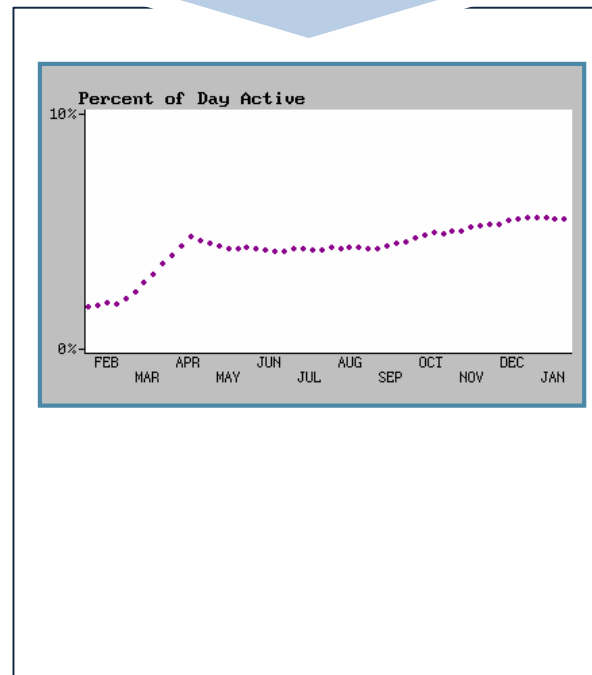
2

Ventilation



3

Activity

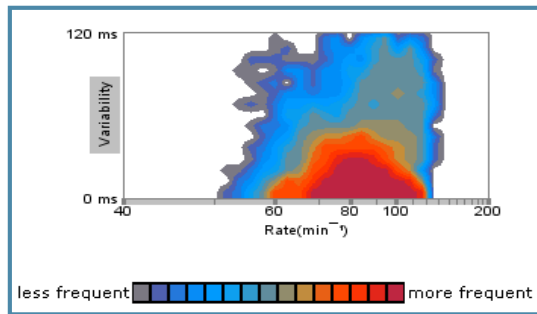
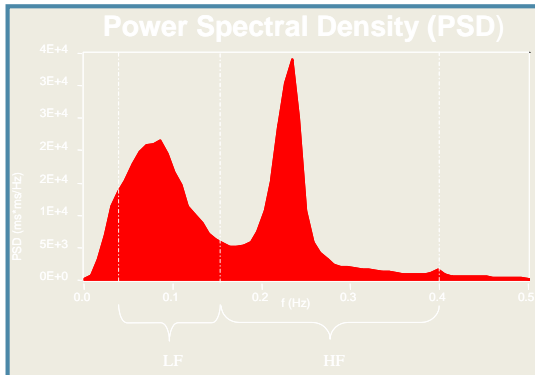


HF Remote monitoring

3

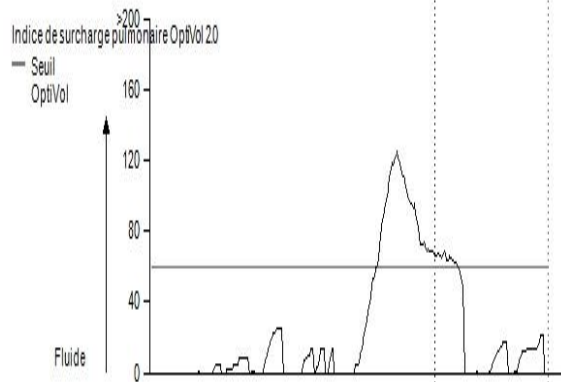
Autonomic tone

- SDNN 140 ± 40 ms
- SDANN 127 ± 35 ms
- Footprint 40 - 60 %
- LF / HF 1.5 - 2



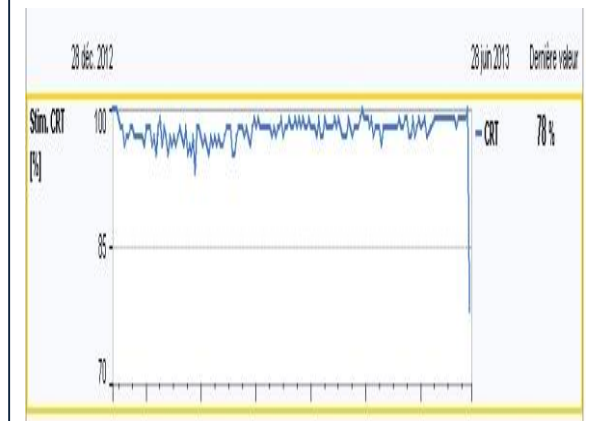
4

Thoracic impedance



5

CRT %



%CRT

Heart rate

HRV

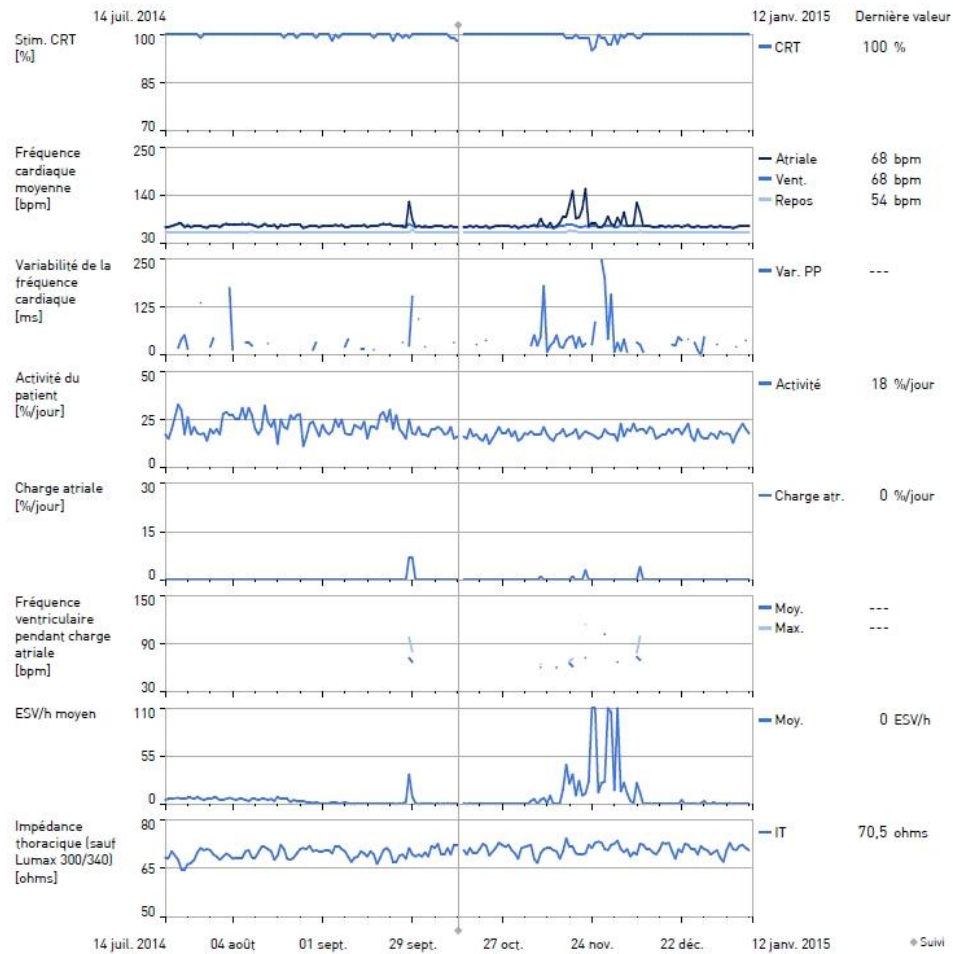
Activity

Atrial burden

HR during AF

ESV

Thoracic impedance



ECOST-CRT

The Efficacy, safety and **Cost** of comprehensive versus standard remote monitoring of patients with Cardiac Resynchronization Therapy study



Objective: to assess the impact of the remote monitoring with a new operating system on heart failure patients implanted with a CRT device (CRT-D or CRT-P).

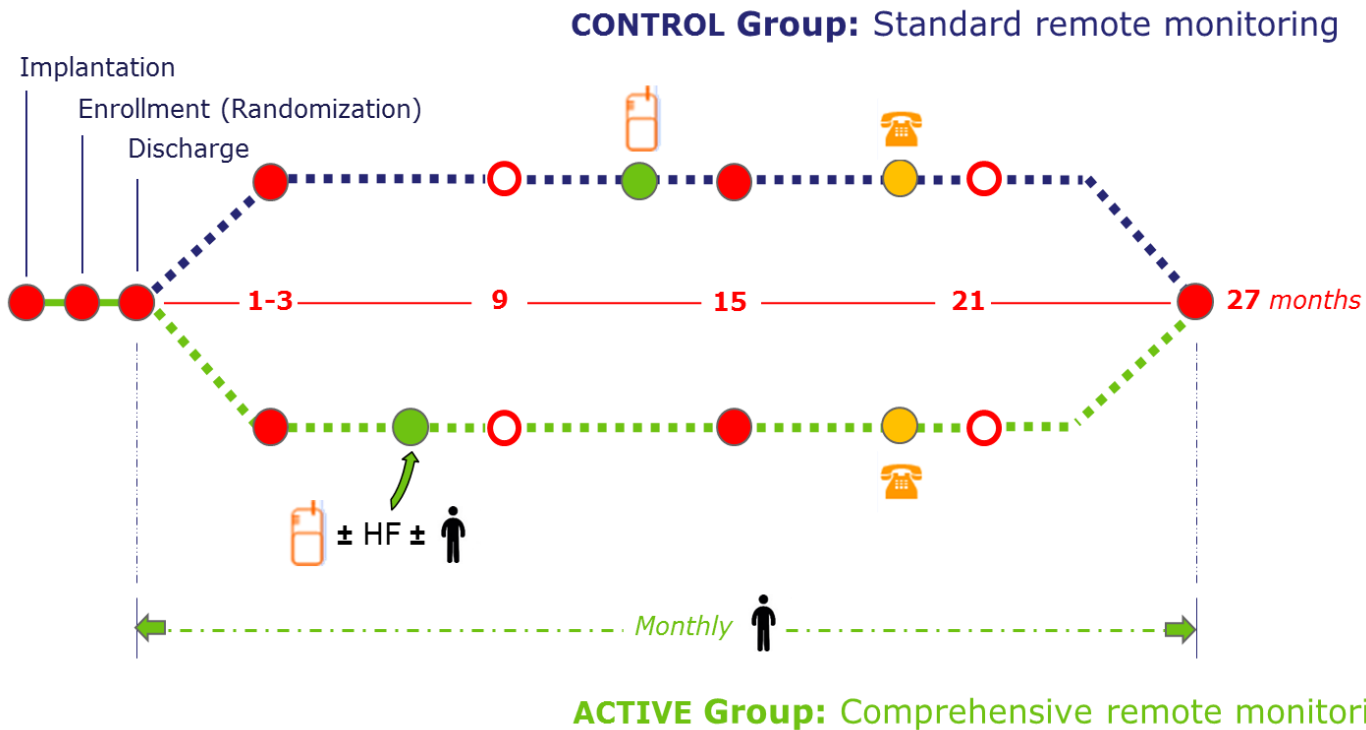
Primary endpoint: A clinical composite outcome based on all-cause mortality and hospitalizations for worsening heart failure.

Methodology

- Prospective (652 patients / Enrollment period, 24 months)
- Interventional
- Open randomized clinical trial in 1:1
- National (50 French centers)
- Biotronik CRT-P / CRT-D devices
- Remote Monitoring activated

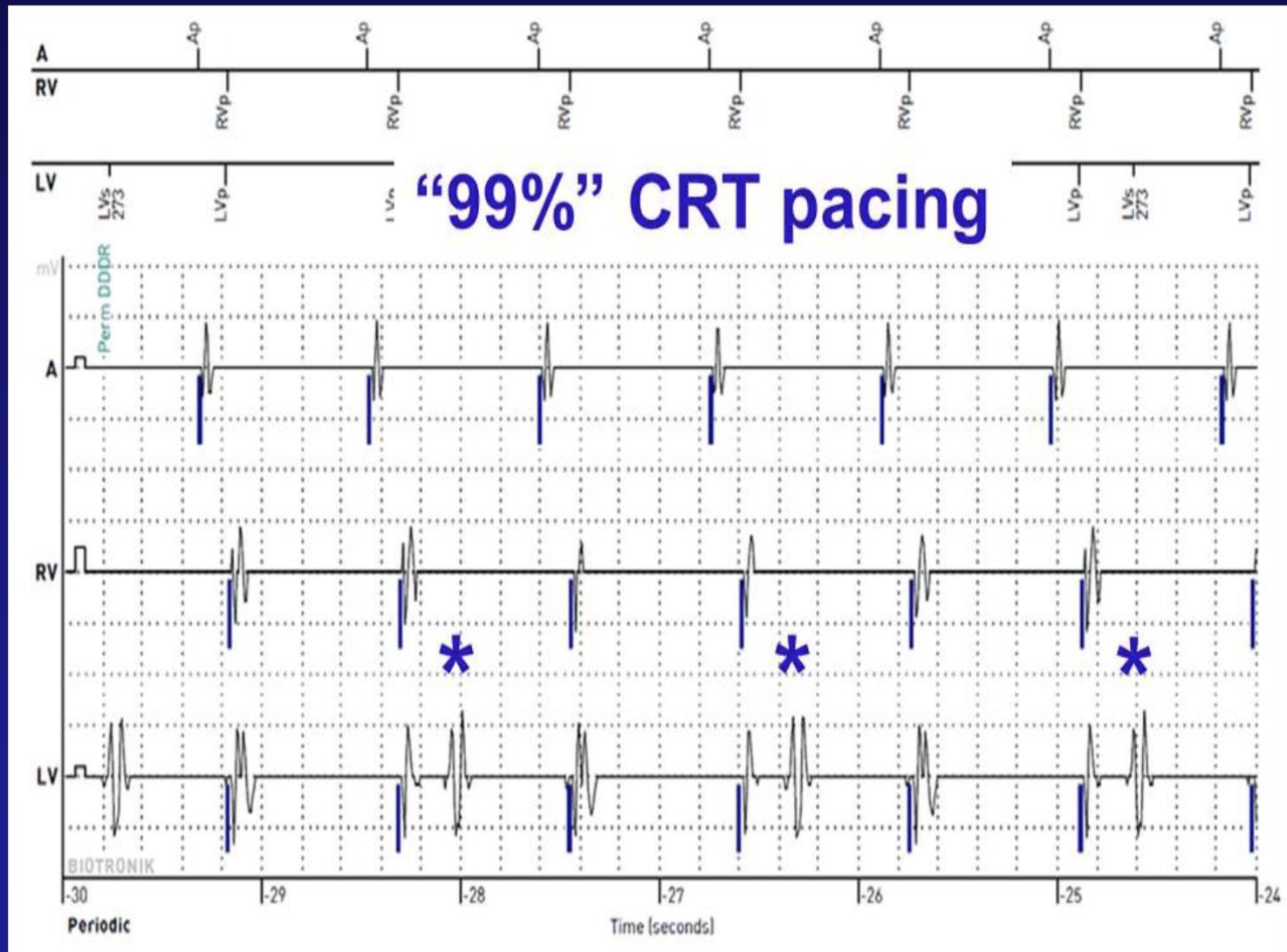


**Centre Hospitalier Régional
Universitaire de Lille**



Active group: In addition to notifications related to technical events and ventricular arrhythmias, the physician will receive notifications related to HF parameters, atrial arrhythmias, and patient's symptoms and signs

Device Management: The Random Electrogram



Ploux S, Eschalier R, Varma N, Ritter P, Klotz N, Haïssaguerre M, Bordachar P.

Enhanced cardiac device management utilizing the random EGM: A neglected feature of remote monitoring. *Heart Rhythm*. 2016

Conclusion

The implantable cardiac electronic devices remote monitoring has become the gold standard for the follow-up of patients .

Studies are expected to optimise remote management of AF and HF