
# Automated functions and remote monitoring in patients with a pacemaker: which are the advantages?

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**Torino 24 ottobre 2015**

# INTRODUCTION

Number of PM patients
Complexity of algorithms (requiring training)
Old leads

Economic resources
Time
Environmental resources

Device Automaticy: useful or needless?

# Pacemaker Automatic Functions

| Automatic functions purposes | Examples |
|---|---|
| Safety | Lead polarity switch<br>Autosensing<br>A&V capture control<br>…. |
| Battery longevity | A&V capture control<br>Spontaneous rhythm algorithms<br>… |
| Heart rate management | Dynamic adaptation of sensor rate<br>… |
| Arrhythmias management | Automatic switch mode<br>Afib prevention<br>… |
| Syncope management | CLS, SDR, RDR |
| Implant management easiness | Auto implant detection<br>Auto polarity configuration<br>… |
| Remote monitoring | |

# Pacemaker Automatic Functions


# Clinical use of automatic pacemaker algorithms: results of the AUTOMATICITY registry

Marco Alings[1*†], Elisa Vireca[2†], Dirk Bastian[3], Alexander Jacques Wardeh[4], Christopher Nimeth[5], Raymond Tukkie[6], Susanne Trinks[7], Walter Kainz[8], Colleen Delaney[9], and Gert Kaltofen[10] for the AUTOMATICITY Study Investigators

- Observational, prospective, multisite, non randomized study
- 915 patients with PM and at least one automaticity algorithm programmed to the automatic mode (817 had all available automaticity algorithms programmed ON/AUTO)
- 12 mesi fw
- Automaticity algorithms evaluated:
  - Automatic Capture
  - Ventricular and Atrial Autosense
  - Automatic rate response sensors

*Alings et al, Europace (2011) 13, 976-983*

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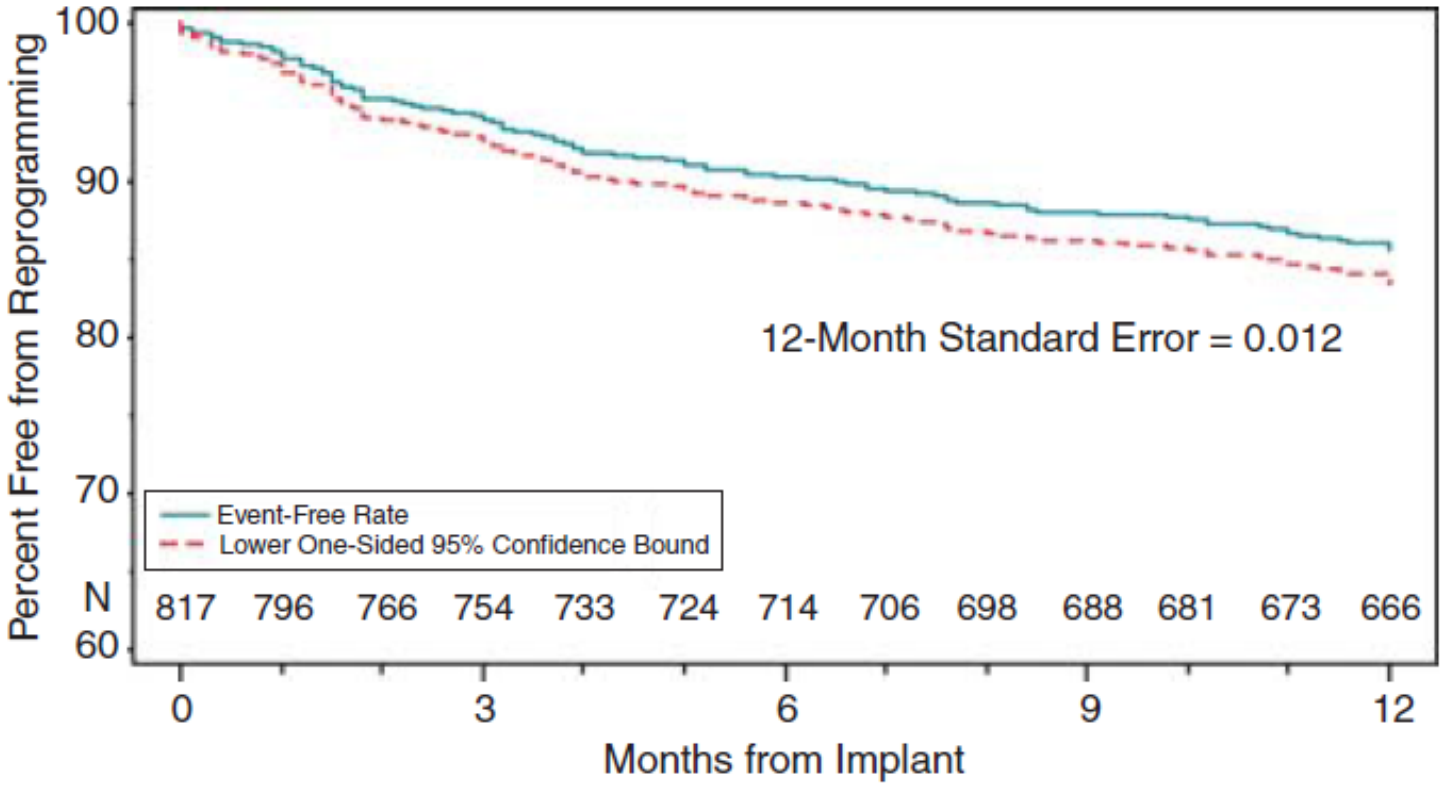


86.1% patients free from any algorithm reprogramming

*Alings et al, Europace (2011) 13, 976-983*

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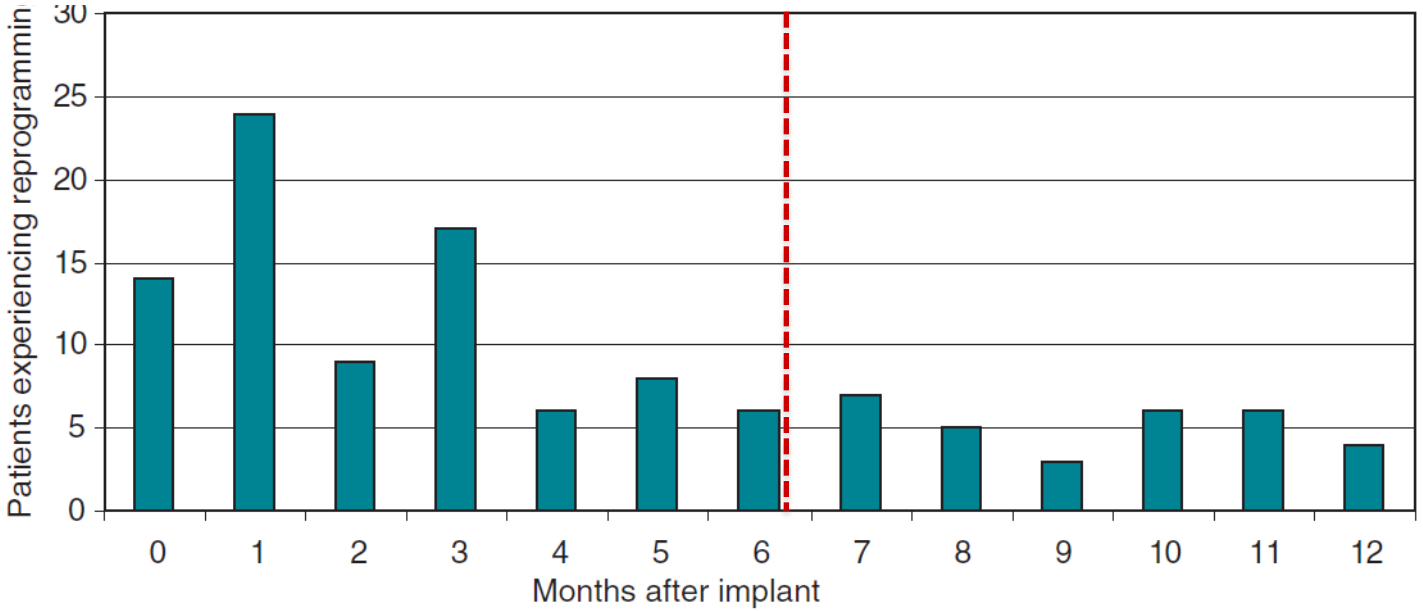


Of all reprogrammings, 67,8% occurred in the fist 6 months of follow-up.

*Alings et al, Europace (2011) 13, 976-983*

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**Table 3** List of reasons for reprogramming and their occurrences

| Reasons for reprogramming | *n* | % |
|---|---|---|
| Unintentional or algorithm N/A | 49 | 1.8 |
| Others—not AE/algorithm related | 42 | 1.5 |
| Lead repositioning procedures | 7 | 0.3 |
| Other surgical procedures | 3 | 0.1 |
| **Ventricular oversensing** | **17** | **0.6** |
| **Unsatisfactory threshold test** | **12** | **0.4** |
| **Unsatisfactory rate response** | **10** | **0.4** |
| **Atrial oversensing** | **8** | **0.3** |
| **Atrial undersensing** | **8** | **0.3** |
| **Ventricular undersensing** | **0** | **0.0** |
| Overall | 156 | 5.7 |

**2 %**

Reprogrammings for the algorithm performance occurred in 2% of all active algorithms (55 of 2736)

*Alings et al, Europace (2011) 13, 976-983*

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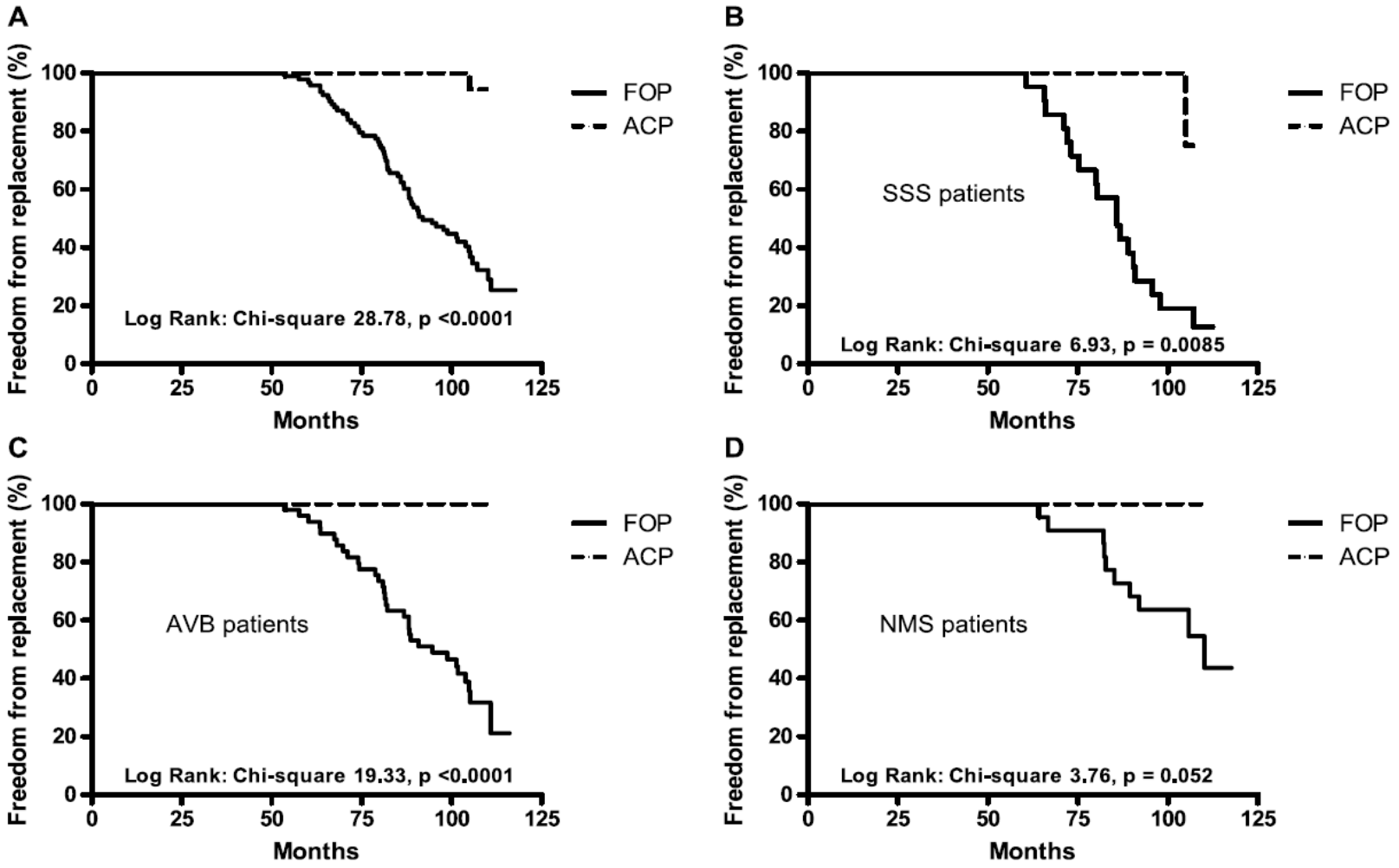
Out of the 55 reprogrammings related to the automatic algorithms only 10 were associated with serious adverse events

| | % free reprogramming | % reprogramming any reason | % issues algorithm | Adverse event related to algorithm |
|---|---|---|---|---|
| AUTOMATIC CAPTURE | 95.9% | 4.1% | 0.4% | 3 DIZZINESS<br>1 SYNCOPE |
| AUTOSENSE ATRIAL<br>AUTOSENSE VENTR | 94.3% | 6.7%<br>5.7% | 0.6%<br>0.6% | 1 PALPITATION<br>1 DIZZINESS |
| AUTOLIFESTYLE | 93.9% | 6.1% | 0.4% | 4 PALPITATION |

# Actual Pacemaker Longevity: The Benefit of Stimulation by Automatic Capture Verification

MAURO BIFFI, M.D., MATTEO BERTINI, M.D., PH.D., DAVIDE SAPORITO, M.D., MATTEO ZIACCHI, M.D., CRISTIAN MARTIGNANI, M.D., PH.D., IGOR DIEMBERGER, M.D., PH.D., and GIUSEPPE BORIANI, M.D., PH.D.
From the Institute of Cardiology, University of Bologna, Bologna, Italy




*Biffi et al, PACE (2010) 33, 873-881*

# Long-Term RV Threshold Behavior by Automated Measurements: Safety is the Standpoint of Pacemaker Longevity!

MAURO BIFFI, M.D., MATTEO BERTINI, M.D., PH.D., ANDREA MAZZOTTI, M.D., BEATRICE GARDINI, M.D., VALENTINA MANTOVANI, M.D., MATTEO ZIACCHI, M.D., CINZIA VALZANIA, M.D., PH.D., CHRISTIAN MARTIGNANI, M.D., PH.D., IGOR DIEMBERGER, M.D., PH.D., and GIUSEPPE BORIANI, M.D., PH.D.
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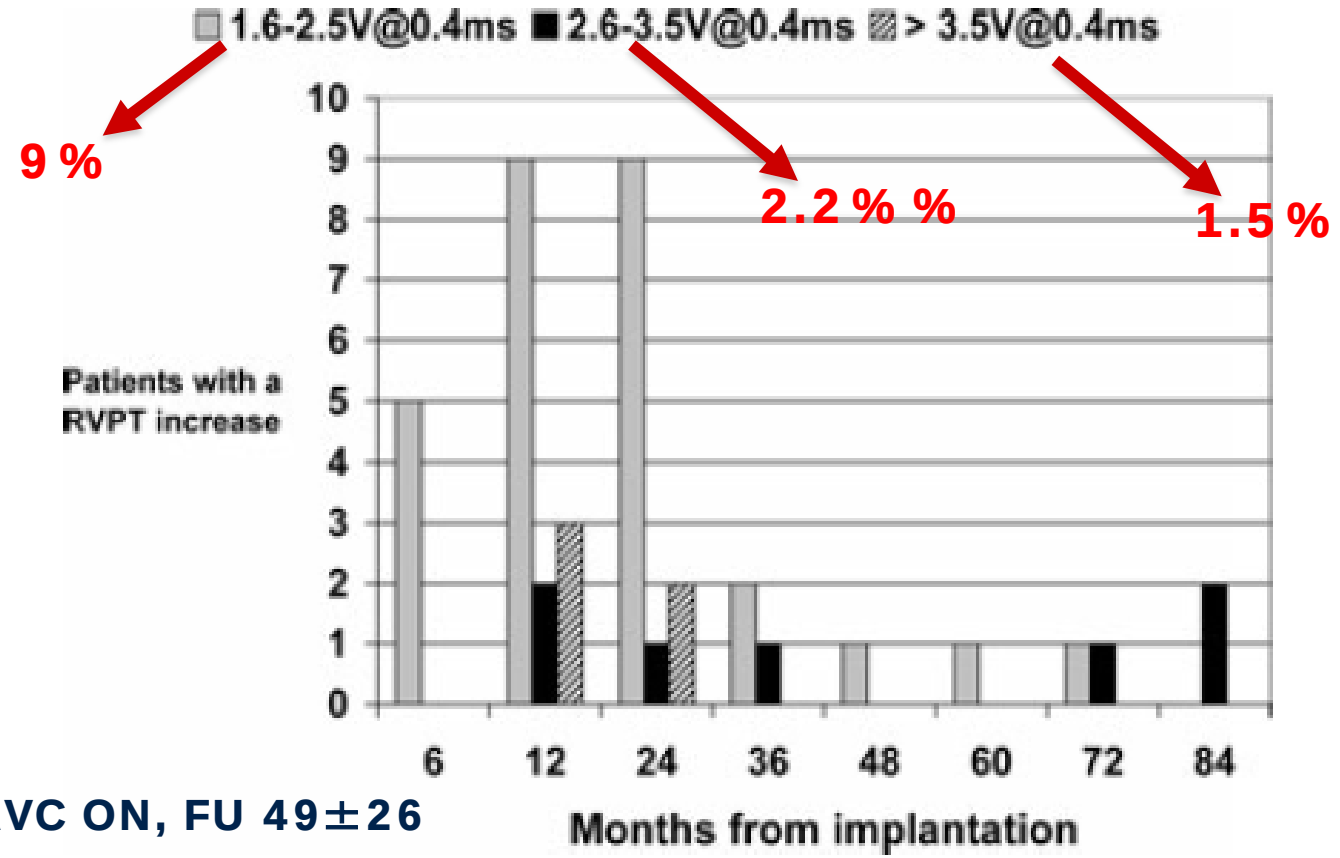


**321 pts, AVC ON, FU 49±26**

**Threshold increase 12.8 % pts**

*Biffi et al, PACE (2011) 34: 89 - 95*

# Long-Term RV Threshold Behavior by Automated Measurements: Safety is the Standpoint of Pacemaker Longevity!

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From the S.Orsola-Malpighi Hospital, Institute of Cardiology, University of Bologna, Bologna, Italy

*…"According to the absolute value and to the timing of RVPT increase, we identified seven patients (2.1%) who would have experienced exit block in the event a fixed output stimulation as 2.5 V at 0.4 ms had been programmed at FU"…*

*Biffi et al, PACE (2011) 34: 89 - 95*

# Clinical evaluation of pacemaker automatic capture management and atrioventricular interval extension algorithm

**Ke-ping Chen[1], Geng Xu[2], Shulin Wu[3], Baopeng Tang[4], Li Wang[5], and Shu Zhang[1]*, for the China PANORAMA Study Investigators**

[1]Clinical EP Lab and Arrhythmic Center, Fuwai Hospital, Beijing, China; [2]Department of Cardiovascular Disease, Second Affiliated Hospital Zhejiang University College of Medicine, Hangzhou, China; [3]Guangdong Cardiovascular Institute, Guangdong Provincial People's Hospital, Guangzhou, China; [4]Department of Cardiovascular Disease, First Affiliated Hospital of Xinjiang Medical University, Urumuqi, China; and [5]Medtronic, Inc., Minneapolis, MN, USA

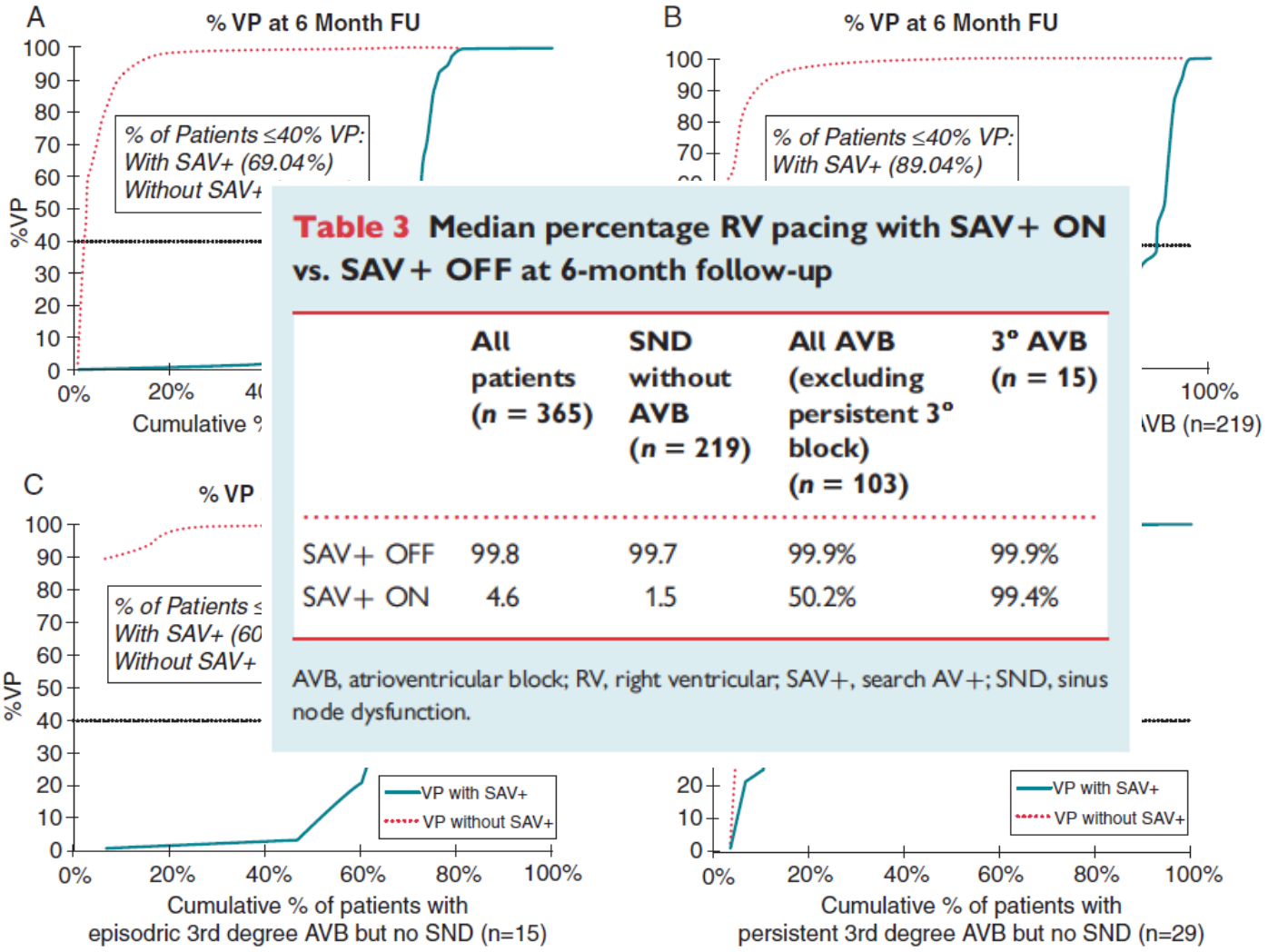


**Table 3** Median percentage RV pacing with SAV+ ON vs. SAV+ OFF at 6-month follow-up

| | All patients ($n$ = 365) | SND without AVB ($n$ = 219) | All AVB (excluding persistent 3° block) ($n$ = 103) | 3° AVB ($n$ = 15) |
|---|---|---|---|---|
| SAV+ OFF | 99.8 | 99.7 | 99.9% | 99.9% |
| SAV+ ON | 4.6 | 1.5 | 50.2% | 99.4% |

AVB, atrioventricular block; RV, right ventricular; SAV+, search AV+; SND, sinus node dysfunction.

*Chen et al, Europace (2013) 15, 395-401*

# Pacemaker Automatic Functions

SAFETY
LONGEVITY
RHYTHM PERFORMANCE
CARDIAC PERFORMANCE

EASIER FOLLOWUP
REDUCED COSTS

***COMPLEXITY OF ALGORITHMS***

# REMOTE MONITORING SYSTEMS

Patient

Cardio-Messenger

Data trasmission

Service Center

Data Review

# REMOTE MONITORING SYSTEMS

SORIN GROUP
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Boston Scientific
Advancing science for life™

ST. JUDE MEDICAL

BIOTRONIK

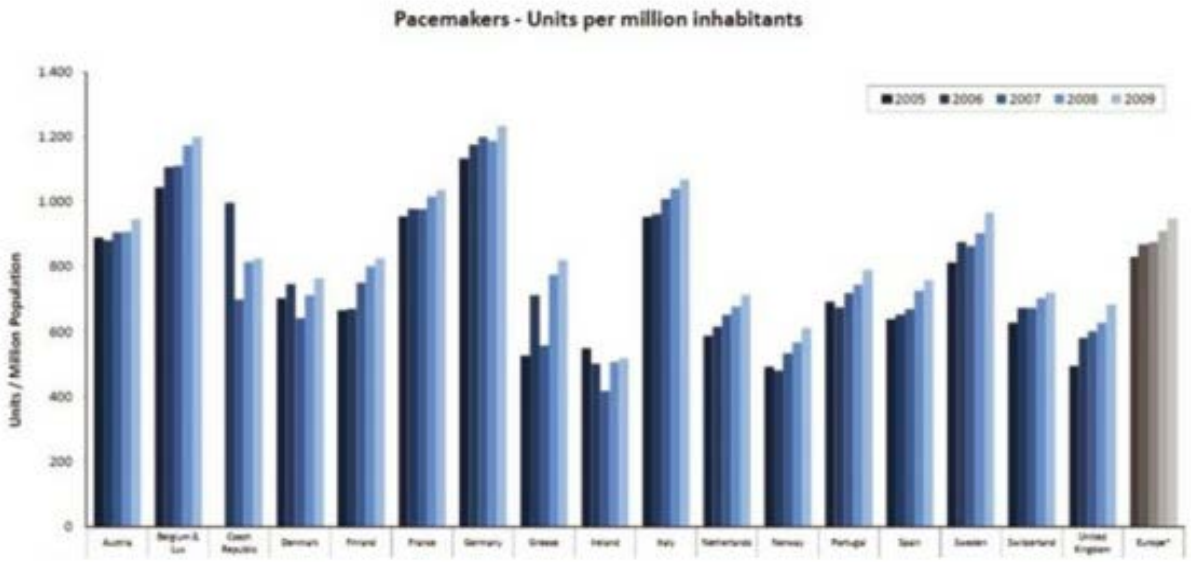
Medtronic

BIOTRONIK

# Office PACEMAKER Follow-up

- PATIENT CLINICAL STATUS
- CAN LOCAL TOLERANCE
- DEVICE PARAMETERS
  - THRESHOLDS
  - LEAD IMPEDANCE
  - BATTERY VOLTAGE
  - ….
- RHYTHM
  - ARRHYTMIC EVENTS
  - IEGM
  - % PACING
- DEVICE REPROGRAMMING
- DRUG TREATMENT OPTIMISATION

# Workload for PM follow-up



# OFFICE PM FOLLOW-UP LIMITATION

- LARGE COHORT OF PATIENTS REQUIRING SYSTEMATIC FOLLOW-UP
- IN THE MAJORITY OF SCHEDULED VISITS, THE DEVICE PROGRAMMING OR DRUG REGIMEN IS LEFT UNCHANGED
- NO CORRELATION BETWEEN SCHEDULED VISIT AND CLINICAL E/O TECHNICAL EVENT
- REAL BENEFIT OF IMPLANT CENTRE CONTROL?
  - DEVICE DYSFUNCTION ?
  - EVENT ANALYSIS ?
  - DEVICE REPROGRAMMING ?
  - PREDICTION UNEXPECTED EVENT ?

# REMOTE PACEMAKER FOLLOW UP EXPECTED ADVANTAGES

- **CARE IMPROVEMENT**
  - EASY DEVICE FOLLOW-UP
  - EOL MANAGEMENT
  - EARLY DETECTION OF CLINICAL AND DEVICE-RELATED ADVERSE EVENTS
  - REDUCTION OF HOSPITALISATIONS
- **COST REDUCTION**
  - REDUCED NUMBER OF AMBULATORY VISITS
  - REDUCTION OF HOSPITALISATION
  - REDUCED COSTS OF TRANSPORTATION

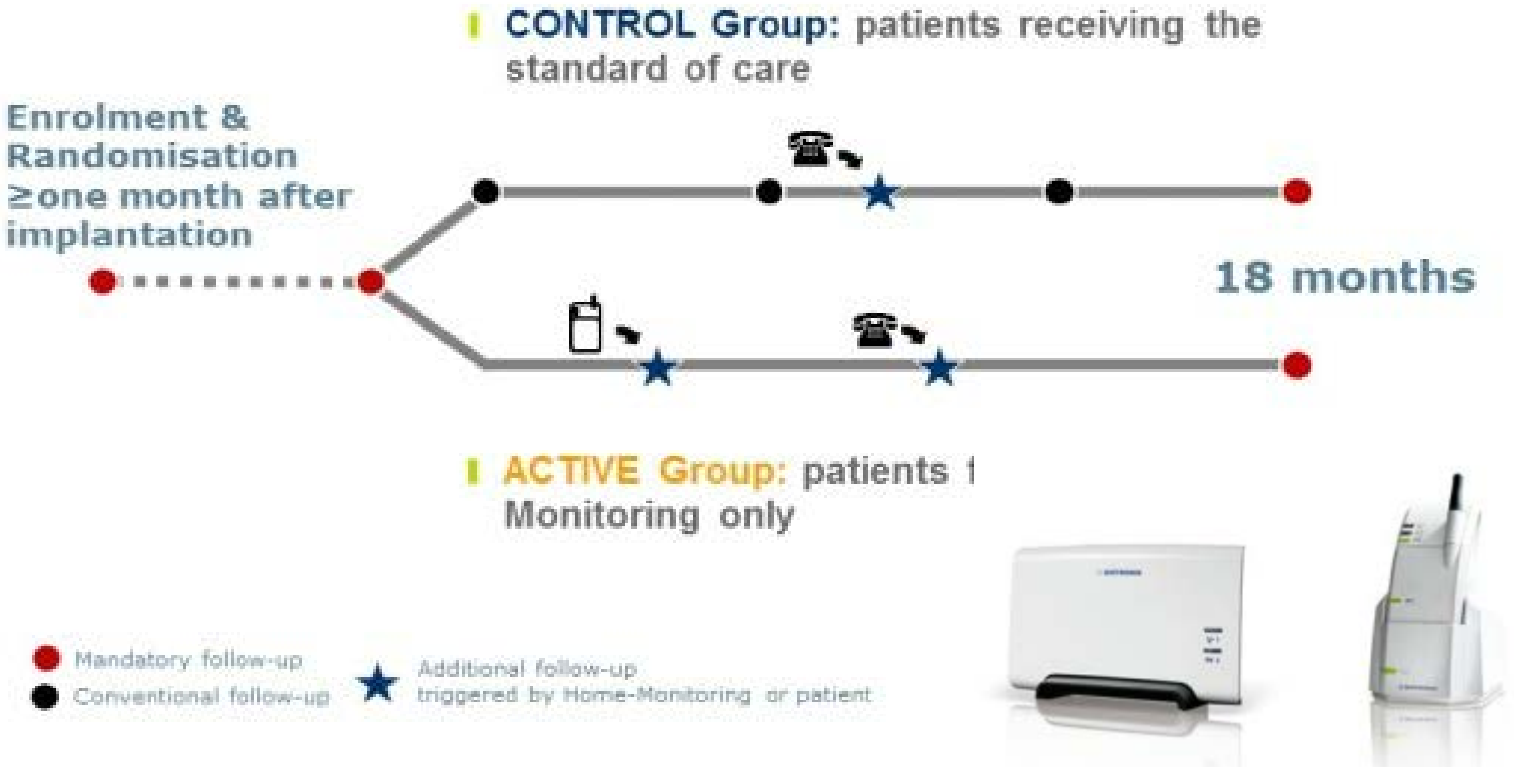
# REMOTE PM FOLLOW-UP

- PACEMAKER REMOTE FEATURES LIMITED TO SOME MANUFACTORS (MOST OLD DEVICES EXCLUDED)
- ONLY A FEW STUDIES OF PERMANENTLY PACED PATIENTS HAVE BEEN PUBLISHED
- PROSPECTIVE TRIAL IN PM PATIENTS

## COMPAS STUDY (Eur Heart J, 2012)

# Compas Study - Design

The study investigates whether Home-Monitoring follow-up of PM patients is as efficient as conventional method in terms of Significant Serious Adverse Event (SSAE).



# Compas Study – Primary endpoint

## SAFETY

The study investigates with a non-inferiority hypothesis whether remote monitoring has an impact on the incidence of Serious Adverse Events* (SAE) comprising:

- Death (all causes)
- Cardiovascular SAE
- Device related SAE

# COMPAS STUDY
## SECONDARY ENDPOINTS

- COMPARE THE INCIDENCE OF SAE IN BOTH GROUPS
- MEASURE THE DECRESASE IN THE NUMBER OF IN-OFFICE FOLLOW-UP
- RETROSPECTIVELY ANALYSE THE DELAY IN THE MANAGEMENT OF ADVERSE EVENT IN BOTH GROUPS
- EFFECT OF REMOTE MONITORING ON QUALITY OF LIFE

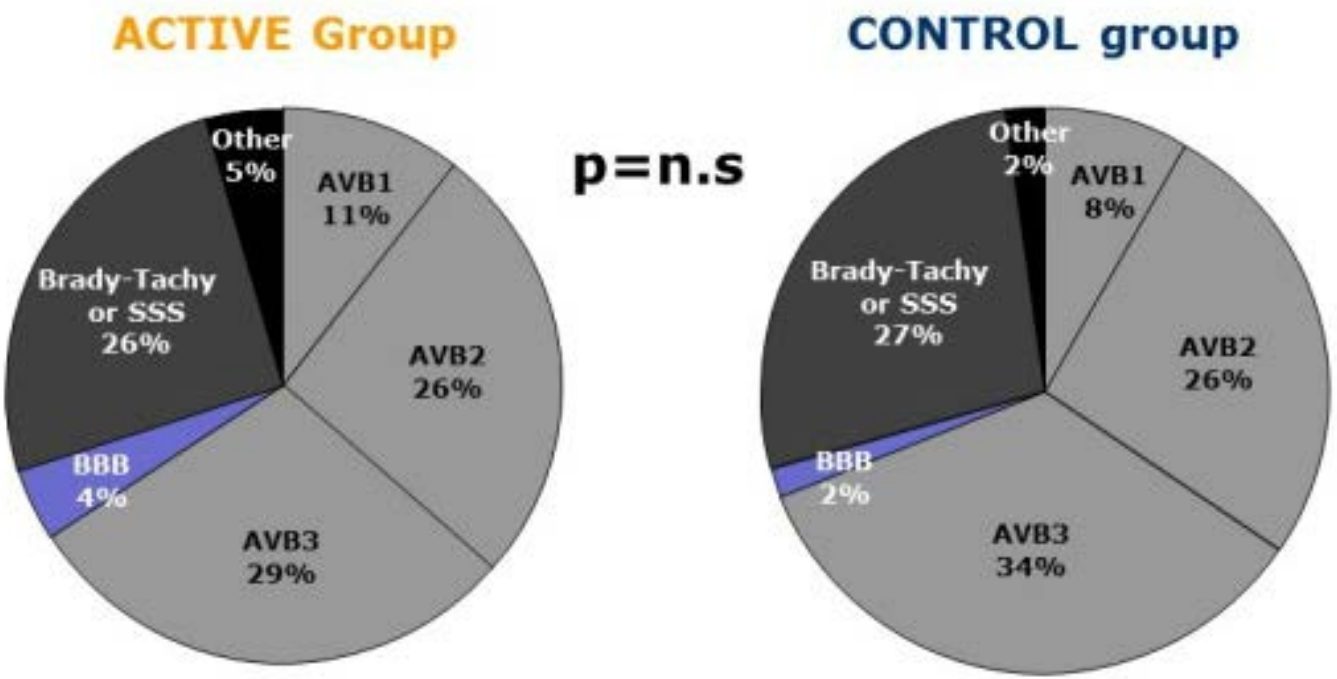
# Population

## Clinical characteristics similar in both study groups

| | ACTIVE | CONTROL |
|---|---|---|
| Number of patients | 269 | 269 |
| Age | 76±9 | 77±8 |
| Gender (male) | 180 (67%) | 170 (63%) |
| EF (%) | 59±13 | 56±12 |

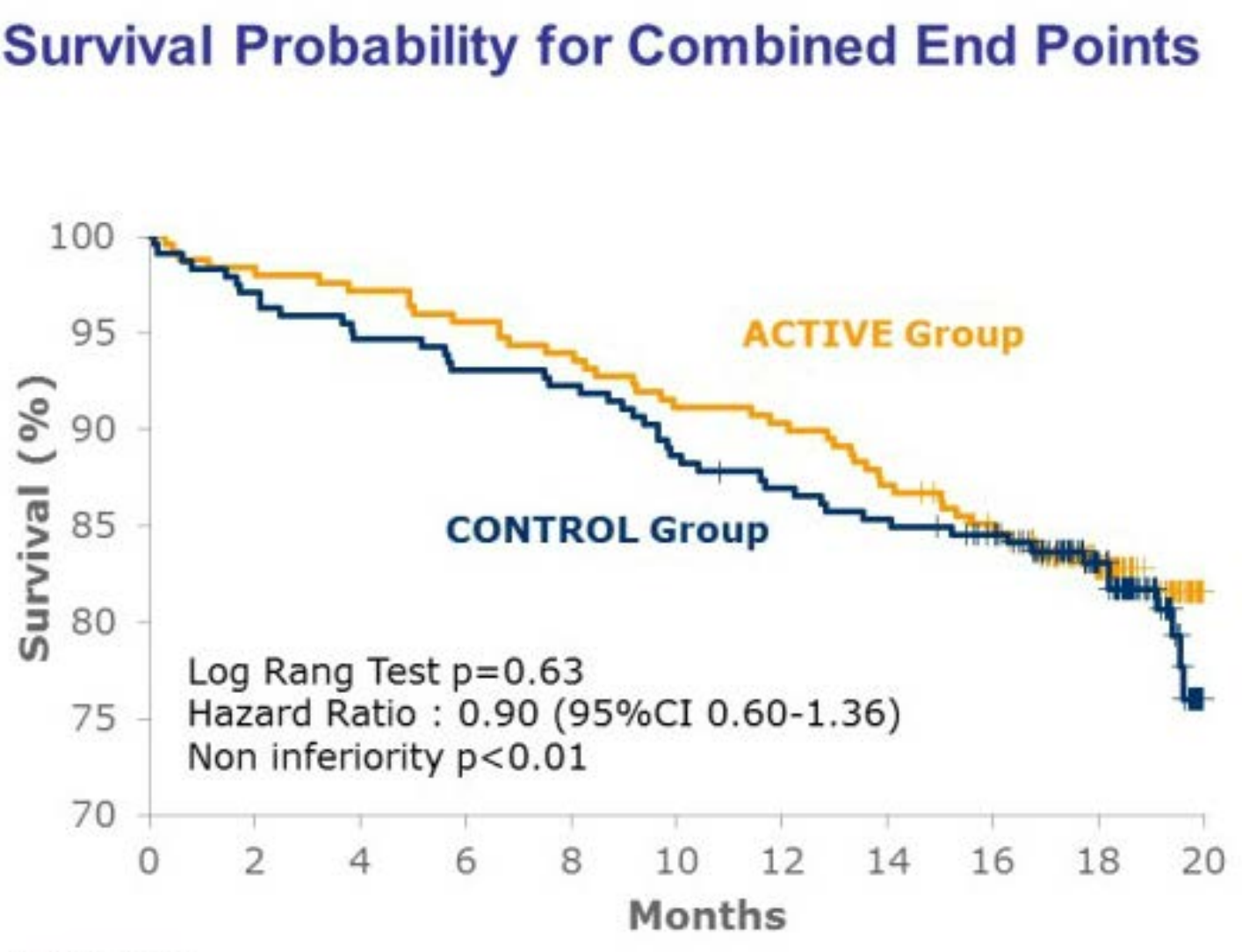
p=n.s

# Primary PM indications




*BBB=Bundle Branch Block

# COMPAS STUDY
## PRIMAR ENDPOINT



# COMPAS trial

## Deaths

| | ACTIVE (n=248) | CONTROL (n=246) |
|---|---|---|
| Stroke | 0 | 4 |
| Heart failure | 3 | 0 |
| Cancer | 6 | 3 |
| Non cardiac cause | 6 | 4 |
| Unknown cause | 3 | 2 |
| TOTAL | 18 (7,3%) | 13 (5,3%) |

p=ns

# COMPAS trial

## Device related SAE

| | ACTIVE (n=248) | CONTROL (n=246) |
|---|---|---|
| Infection / Extrusion | 0 | 4 |
| Lead dislodgement | 0 | 2 |
| Venous Thrombosis / lead | 2 | 1 |
| High Ventricular Threshold | 0 | 1 |
| TOTAL | 2 SAE (1 pt: 0,4%) | 8 SAE (7 pts: 2,8%) |

**P=0.03**

# COMPAS trial

| Cardiovascular SAE | ACTIVE (n=248) | | CONTROL (n=246) | |
|---|---|---|---|---|
| | Events | Patients | Events | Patients |
| Ventricular arrhythmia | 1 | 1 | 1 | 1 |
| Atrial arrhythmia | 4 | 4 | 10 | 10 |
| Stroke | 2 | 2 | 8 | 7* |
| Heart failure | 18 | 13 ** | 6 | 6 |
| Acute Coronary Event | 6 | 5 | 6 | 6 |
| Valvular heart disease | 2 | 2 | 1 | 1 |
| Pericardial disease | 2 | 2 | 0 | 0 |
| Other | 2 | 2 | 1 | 1 |
| TOTAL | 37 SAE (29 pts: 11,7%) | | 33 SAE (32 pts: 13,0%) | |

* Including 4 deaths

** Including 3 deaths

p=ns

# COMPAS trial

| Cardiovascular SAE | ACTIVE (n=248) | | CONTROL (n=246) | |
|---|---|---|---|---|
| | Events | Patients | Events | Patients |
| Ventricular arrhythmia | 1 | 1 | 1 | 1 |
| Atrial arrhythmia & related stroke | 6 Patients | | 17 Patients | |
| Heart failure | 18 | 13 ** | 6 | 6 |
| | | 5 | 6 | 6 |
| Valvular heart disease | 2 | 2 | 1 | 1 |
| Pericardial disease | 2 | 2 | 0 | 0 |
| Other | 2 | 2 | 1 | 1 |
| TOTAL | 37 SAE (29 pts: 11,7%) | | 33 SAE (32 pts: 13,0%) | |

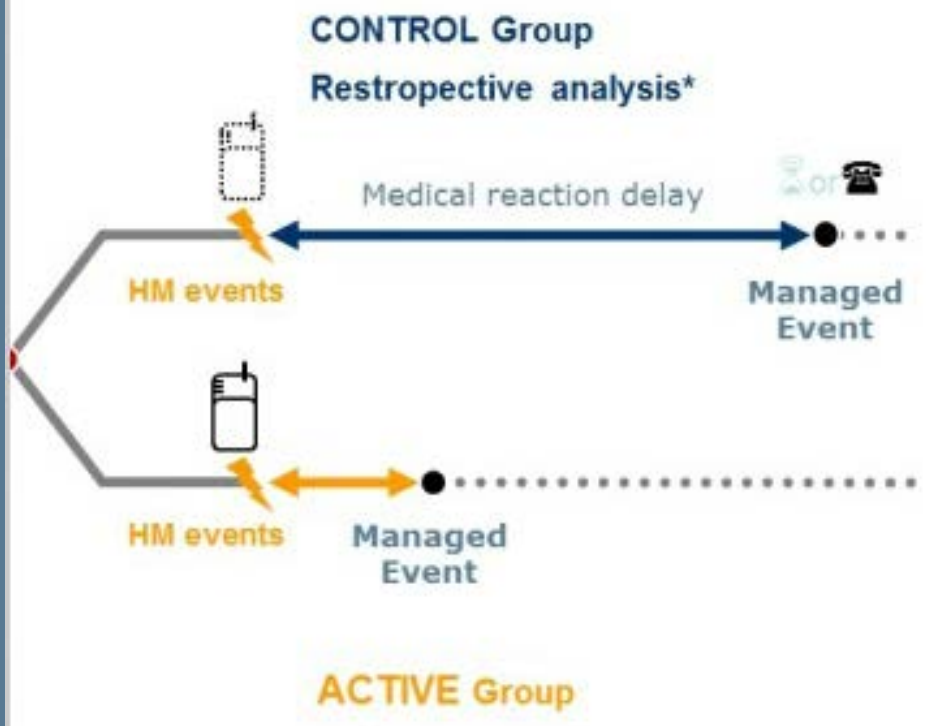
**p<0.01**
OR:0.33 (95%IC 0.13-0.86)

* Including 4 deaths

** Including 3 deaths

# COMPAS STUDY

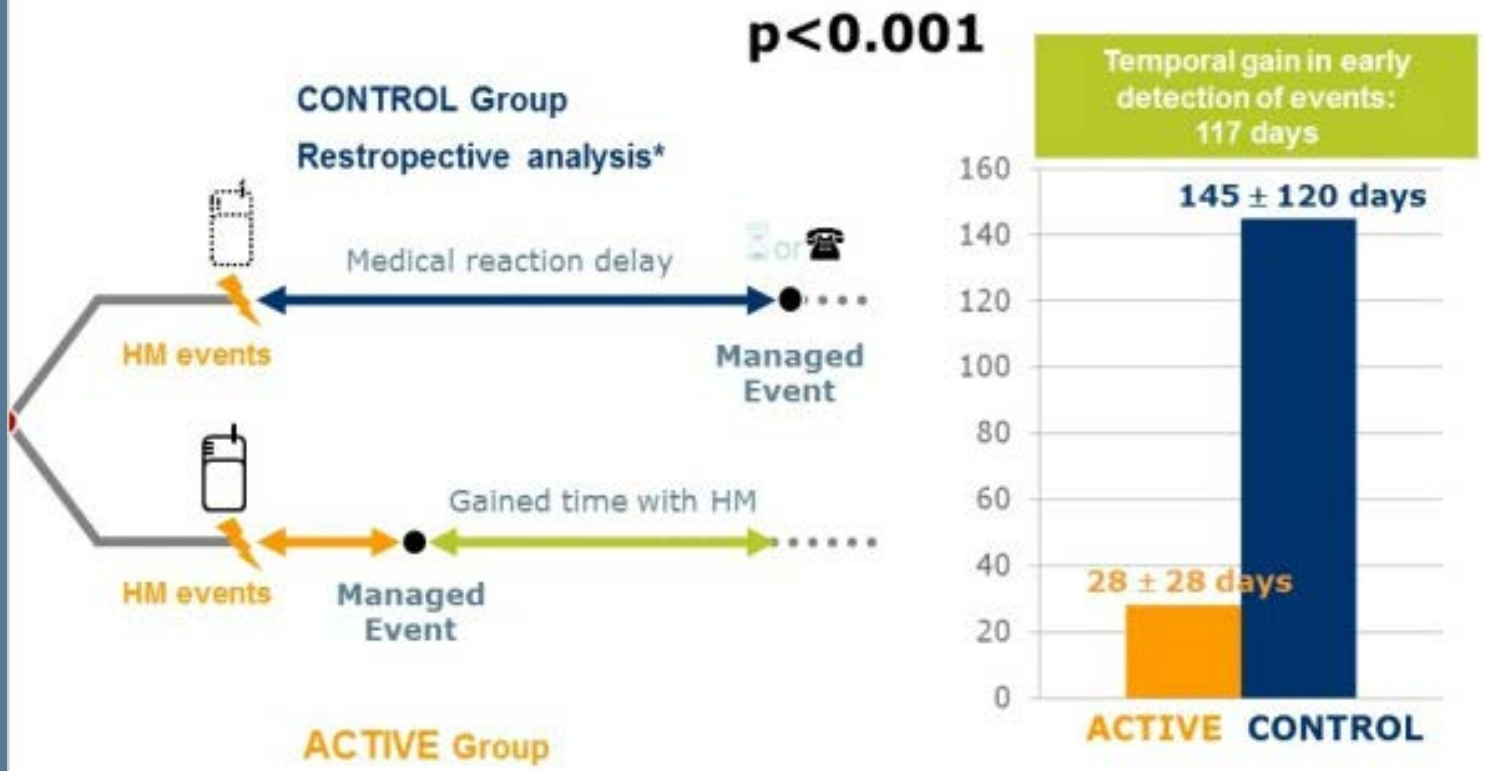
## Medical Reaction Delay




* To allow a retrospective analysis, the control group patients were equipped with Blinded Remote Monitoring.

# COMPAS STUDY

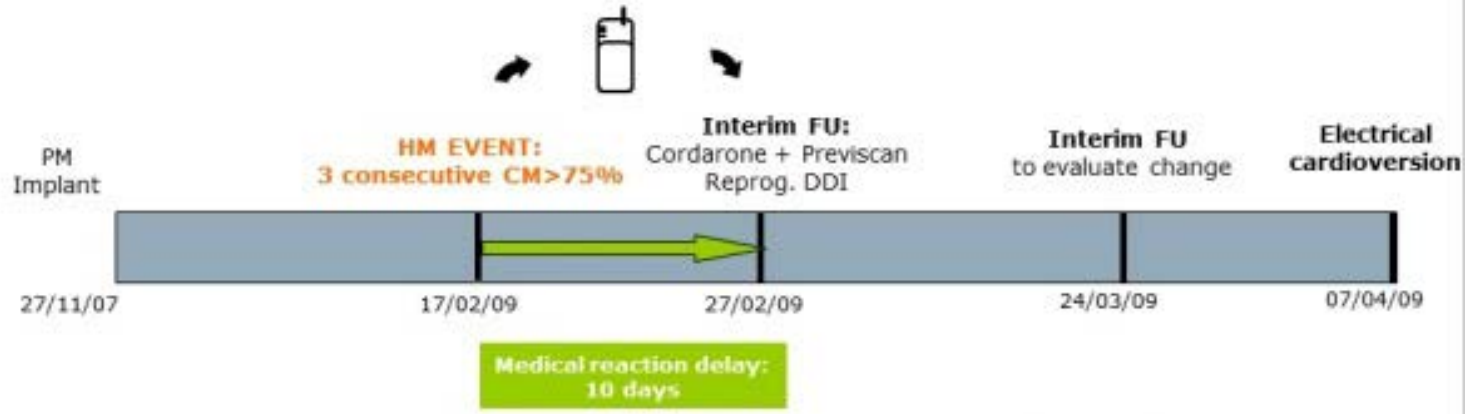
## Medical Reaction Delay

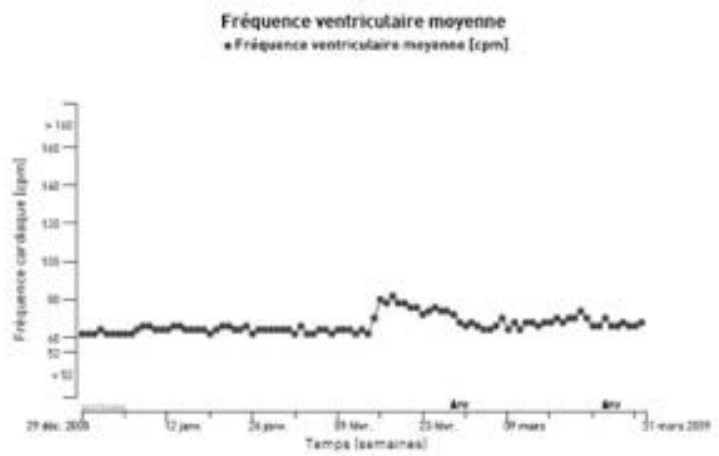



* To allow a retrospective analysis, the control group patients were equipped with Blinded Remote Monitoring.

# COMPAS STUDY

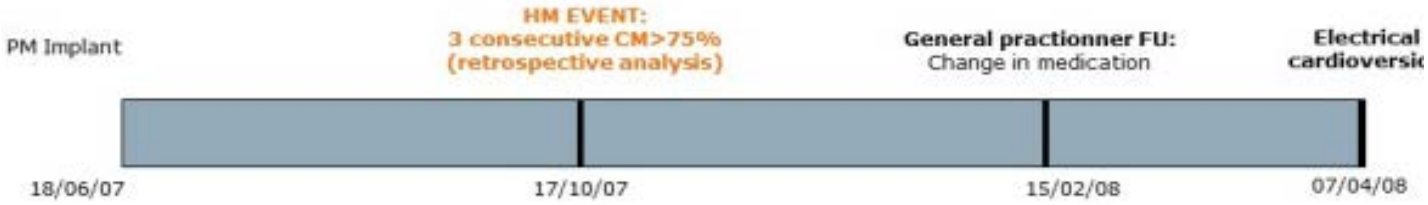
## CLINICAL CASE (Active group)

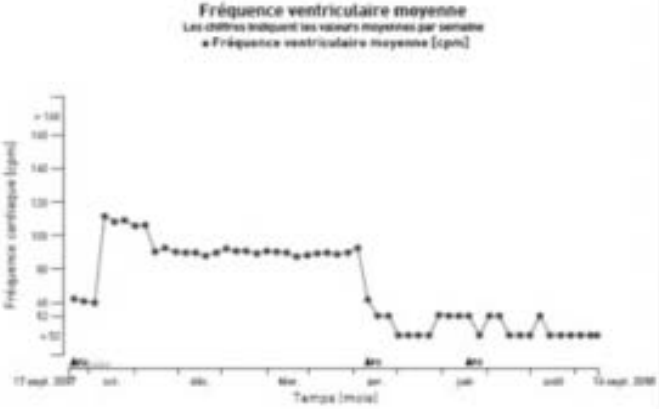


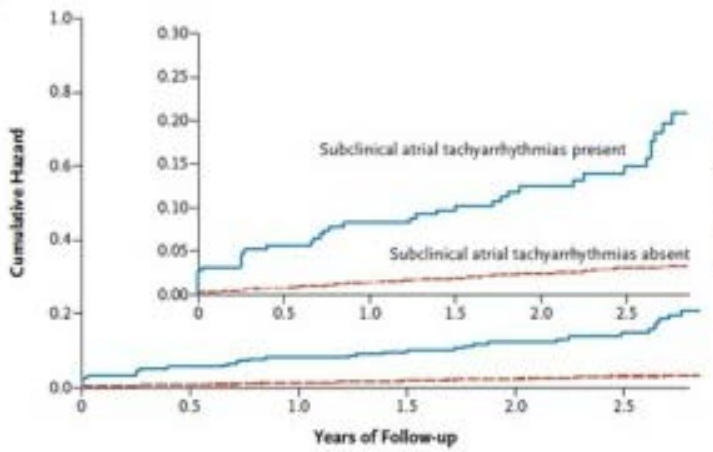

# COMPAS STUDY

## CLINICAL CASE (Control group)

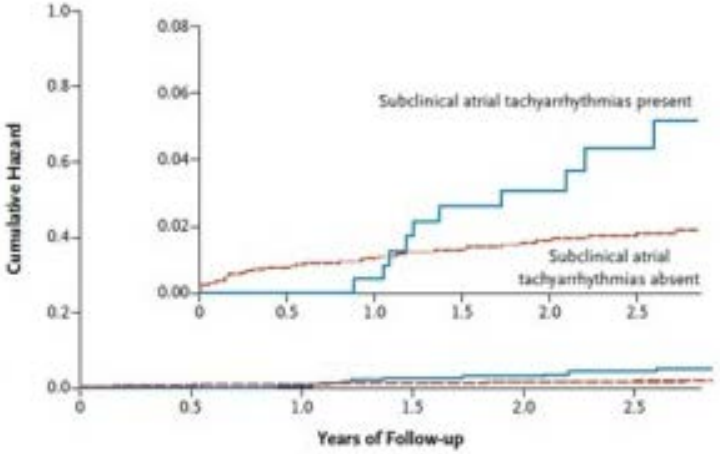



# PM detected atrial tachyarrhythmia and prognosis




Risk of clinical atrial tachyarrhythmia




Risk of ischemic stroke or systemic embolism

**ASSERT Trial**

*Healey JS, NEJM 2012; 366: 120-9*

# Reduction of atrial fibrillation in remotely monitored pacemaker patients: results from a Chinese multicentre registry

CHEN Ke-ping, DAI Yan, HUA Wei, YANG Jie-fu, LI Kang, LIANG Zhao-guang, SHEN Fa-rong, CHEN Si-lin, SU Yan-gang, DING Yan-sheng and ZHANG Shu

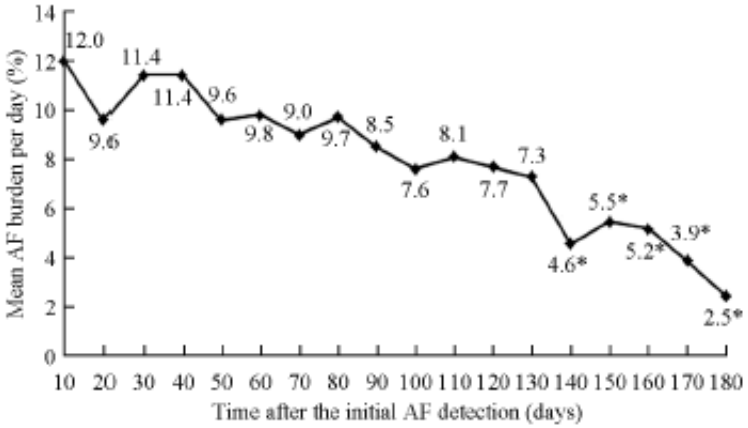



**Figure 1.** Atrial fibrillation (AF) burden trend for 141 patients developing AF after dual-chamber pacemaker implantation. Each data point designates a mean value for a 10-day period. Day 0 is the day of initial AF detection by Home Monitoring. Screening by Home Monitoring lasted for 180 days after day 0. *$P$ <0.05 compared with the 12.0% value for days 1–10.

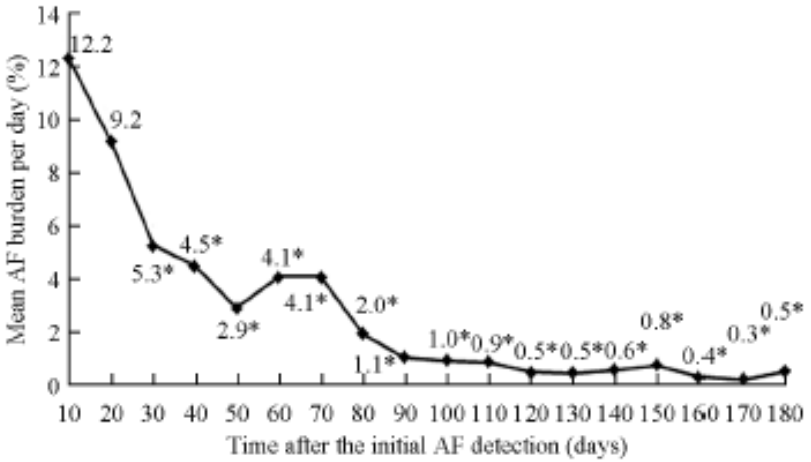
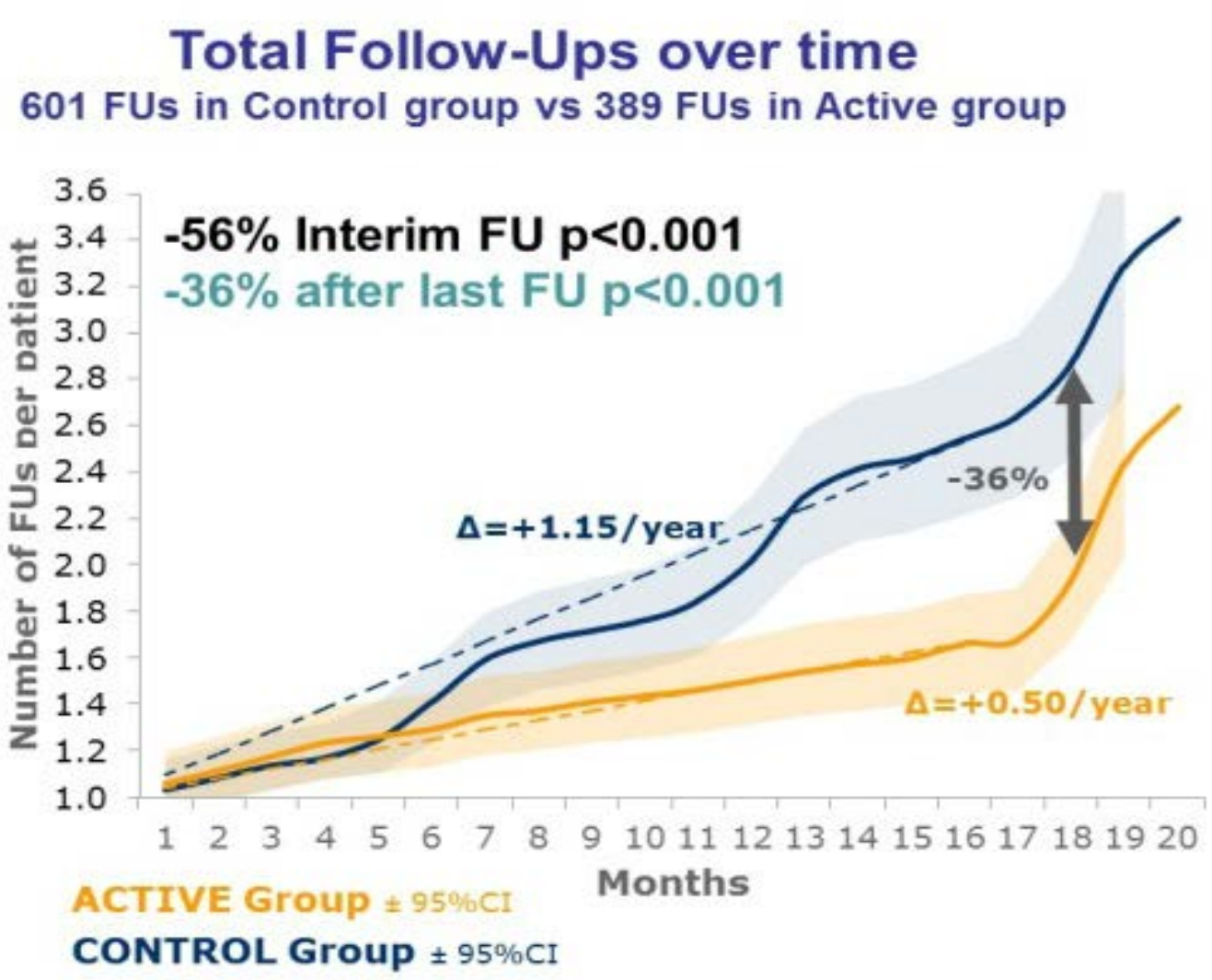



**Figure 3.** Atrial fibrillation (AF) burden trend for 21 patients developing AF after biventricular pacemaker implantation. Further explanations as in Figure 1. *$P$ <0.05 compared with the 12.2% value for days 1–10.

*Chin Med J 2013;126 (22): 4216-4221*

# COMPAS STUDY



# PM Remote FU - Potential Advantage

- Early detection of atrial arrhythmias
  - need for anticoagulation ?
  - need for antiarrhythmic treatment ?
  - limits: false-positive
    - → need for a prospective interventional study
- Lead integrity
- Battery status: closed to EOL
  - → delayed can replacement
- Dicrease in « face to face » visits

# 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*

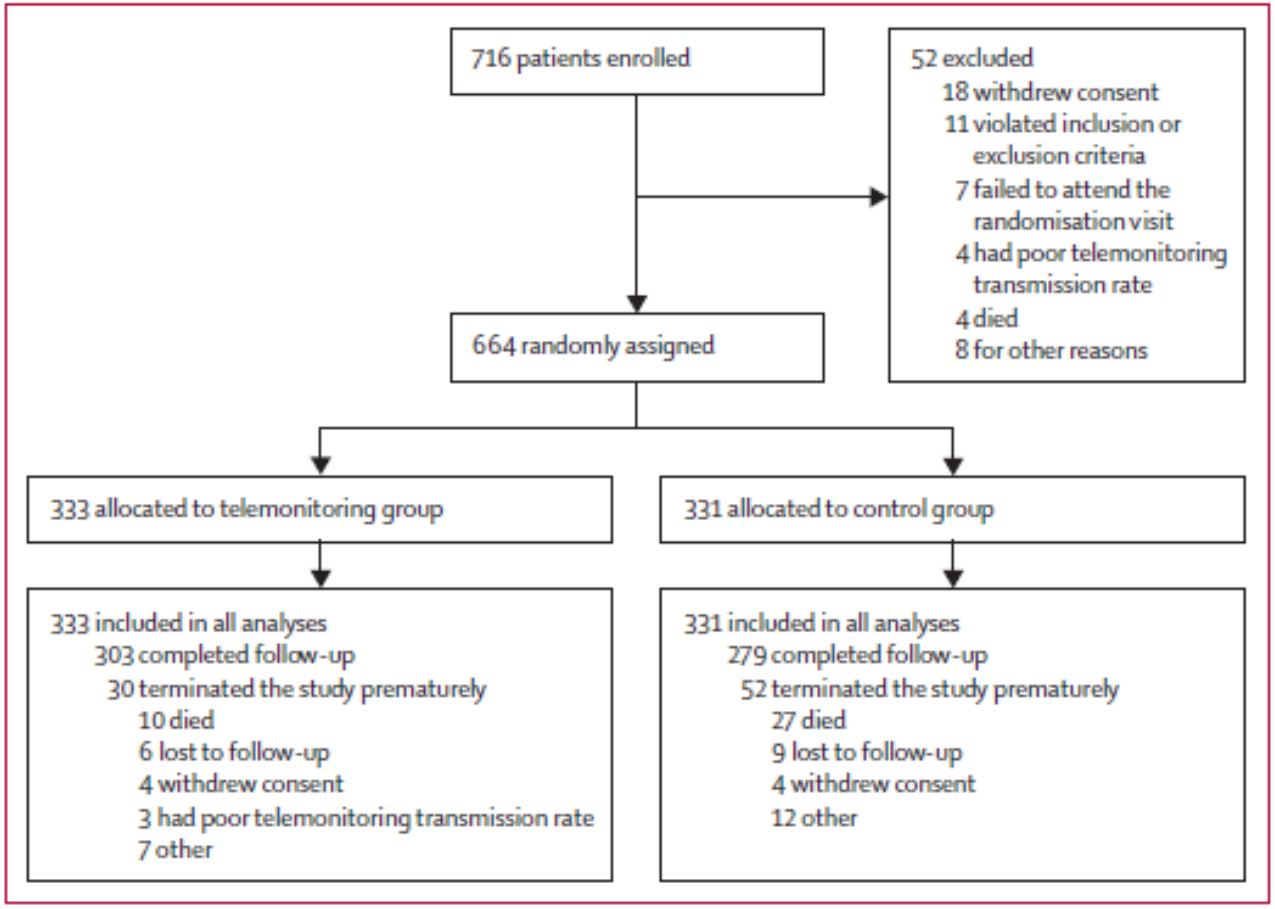



***Figure 1:*** **Trial profile**

Patients were randomly assigned (1:1) to receive telemonitoring in addition to standard care or to standard care without telemonitoring for 12 months.

***Lancet*** **2014; 384: 583–90**

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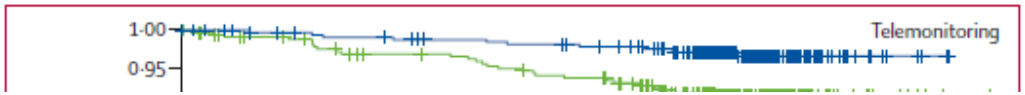
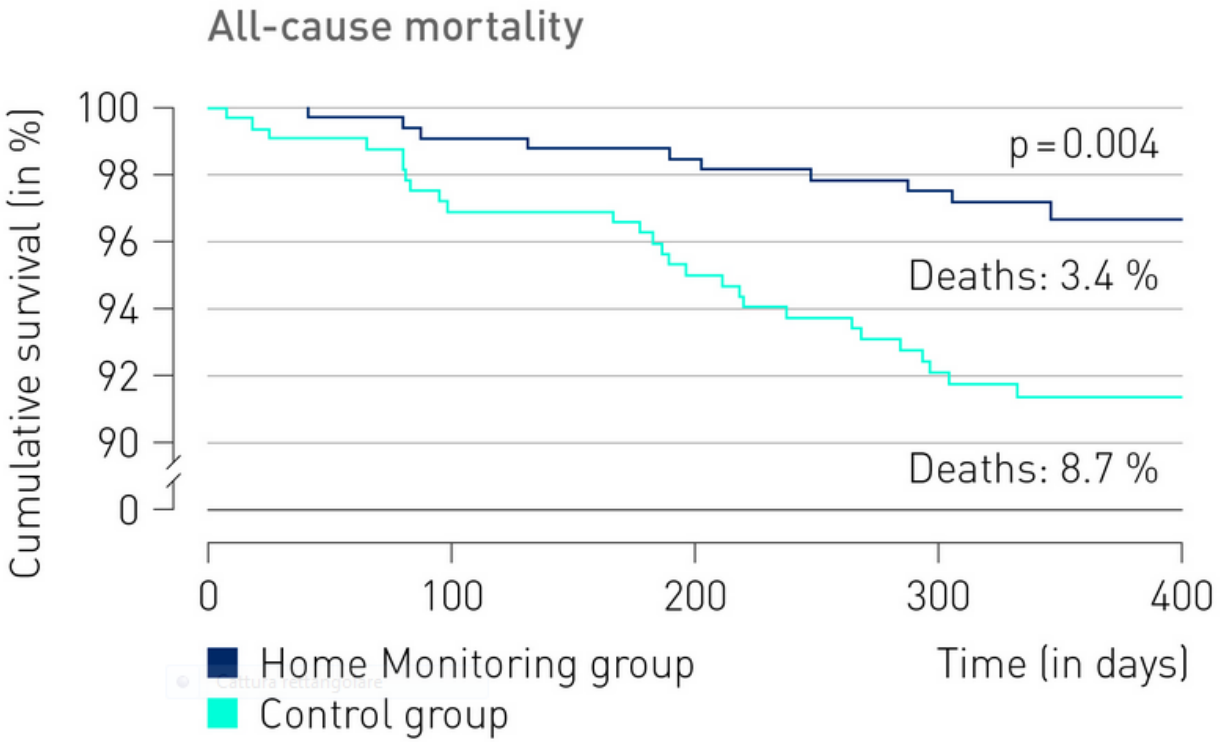



## > 50% reduction in all-cause mortality




Primary outcome: worsening of a composite clinical score at 12 months (death or hospital admission for heart failure, NYHA functional classification, global self-assessment)

*Lancet* 2014; 384: 583–90

# Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial

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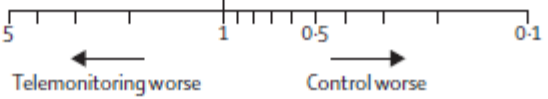
| | Number of patients | | Number of events | | Odds ratio (95% CI) | P value | $P_{interaction}$ |
|---|---|---|---|---|---|---|---|
| | Tele-monitoring group | Control group | Tele-monitoring group | Control group | | | |
| Age (years) | | | | | | | 0·71 |
| ≤67 years | 182 | 170 | 29 | 37 | 0·68 (0·40–1·17)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

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# CONCLUSIONS

- PM Automated Functions and Remote Monitoring have demonstrated a positive impact in terms of safety, battery longevity, reduction of costs and hospitalization, reduction of serious adverse events
- The great number of automated functions makes advisable a continuous training of the operators
- Remote monitoring requires a clear shared procedure for the clinical and administrative management of patients data