Titolo Congresso
Torino, Ottobre 2012

Monitoraggio puntuale a distanza nel follow-up del paziente sottoposto ad ablazione di FA: il ruolo dei sistemi diagnostici impiantabili
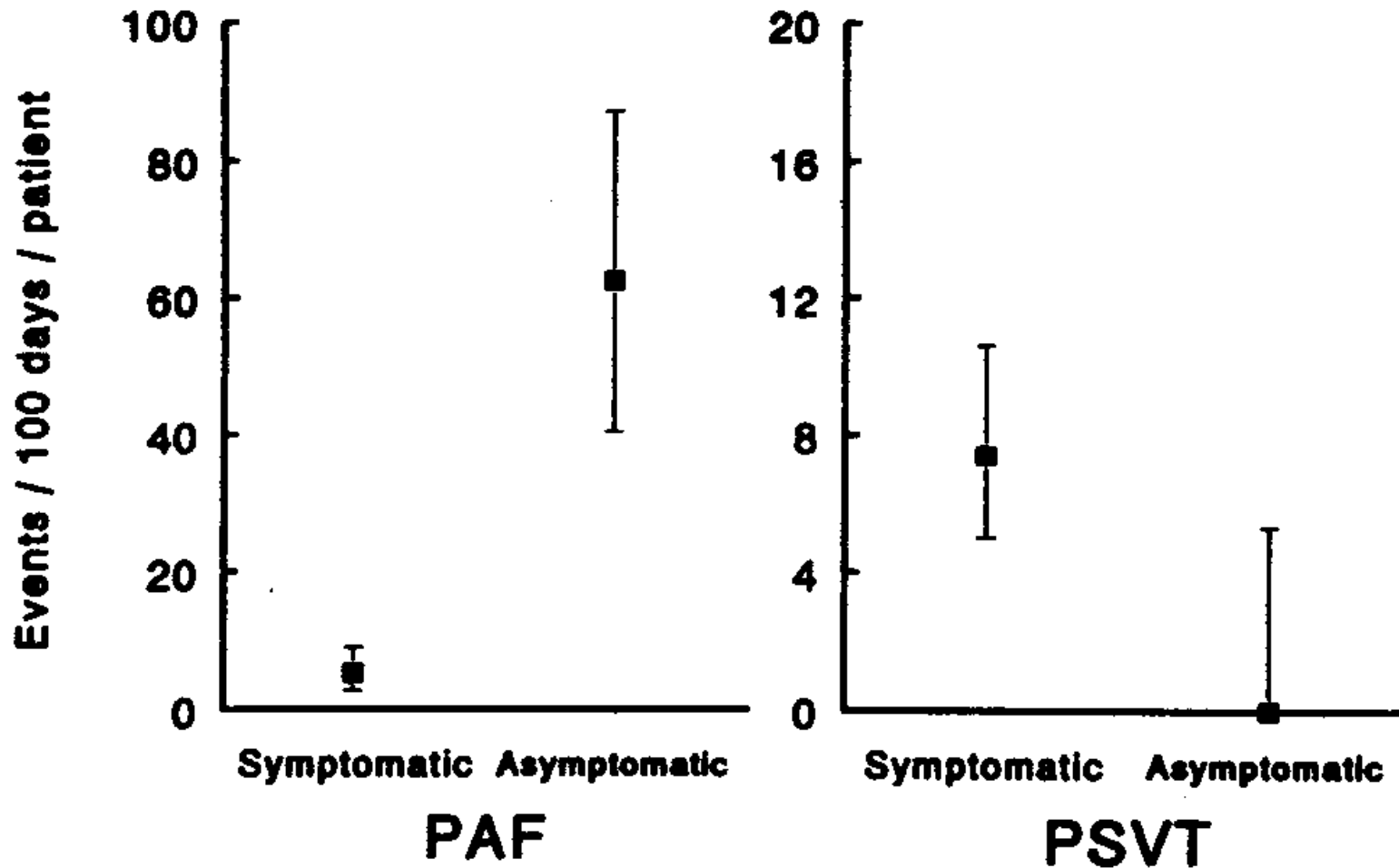
Ospedale Sant' Anna

Gianluca Botto, MD, FESC, FACC
U.O. Aritmologia Clinica ed Elettrofisiologia

Plots of Mean Rates of Arrhythmia Events
The Role of Asymptomatic Episodes

Page et al. Circulation 1994; 89: 224-227

Prevalence of Asymptomatic AF

- **Page (*Circulation* 1994)**
  - 12:1 ratio based on 5 days with 24-h Holter (i.e., 7.7% of AF symptomatic)
- **Israel (*JACC* 2004)**
  - 38% of pts with episodes of AF >48h were completely asymptomatic
  - Continuous monitoring with AT500 pacemaker
- **Strickberger (*Heart Rhythm* 2005)**
  - 6% of AF symptomatic; 17% of symptoms due to AF
  - Continuous monitoring with AT500 pacemaker
- **Hindricks (*Circulation* 2005)**
  - Before ablation, 5% of patients had only asymptomatic AF (7-day Holter)
  - After ablation, 37% of patients had only asymptomatic AF (7-day Holter)
- **Quirino (*PACE* 2009)**
  - 19% of AF symptomatic; 21% of symptoms due to AF
  - Continuous monitoring with Vitatron pacemaker

Rhythm Outcome and Perception of AF After PV Ablation
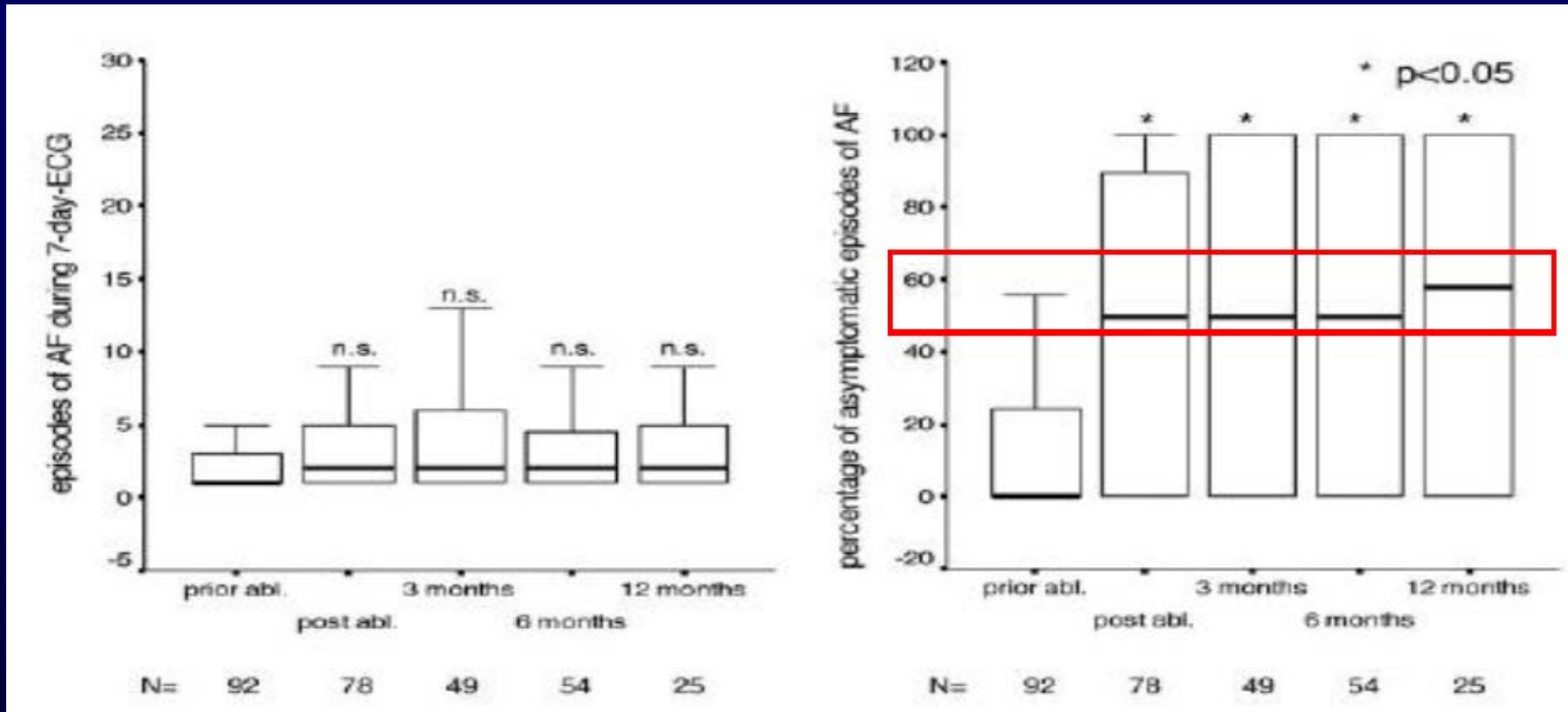
A symptom-only-based follow-up may substantially overstimate the success rate of the ablation procedure

Hindricks G. Circulation 2005; 112: 307-313

Conversion From Symptomatic to Silent AF During AAD Rx

52 patients with PAF with 24 hour Holter

AF duration at baseline (s)	AF duration on treatment (s)
2215 +/- 3843	16 +/- 10
HR at baseline (bpm)	**HR on treatment (bpm)**
126 +/- 27	82 +/- 8

No symptoms
Symptomatic

No PAF on Holter
PAF on Holter

Before

After

47%   53%

22%
78%

26%   74%

27%
73%

Wolk R. Int J: Cardiol 1996; 54: 207-211
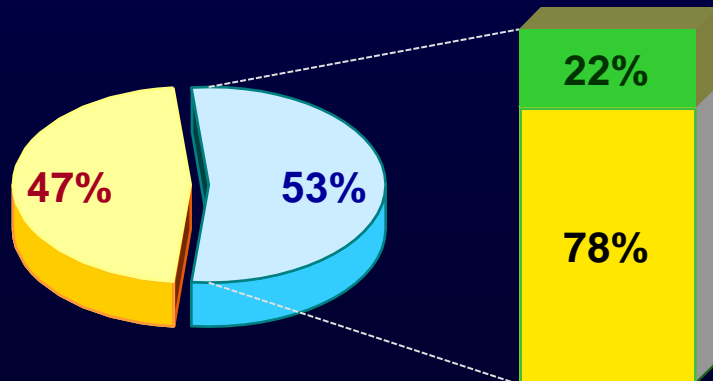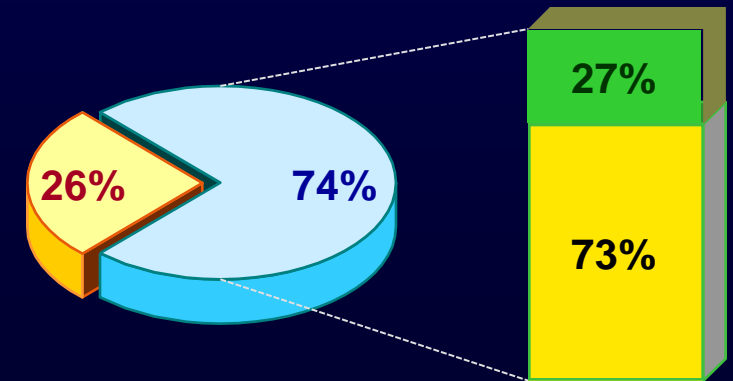
Relation B/ween Symptoms and ECG Transmission in AF

TABLE 1

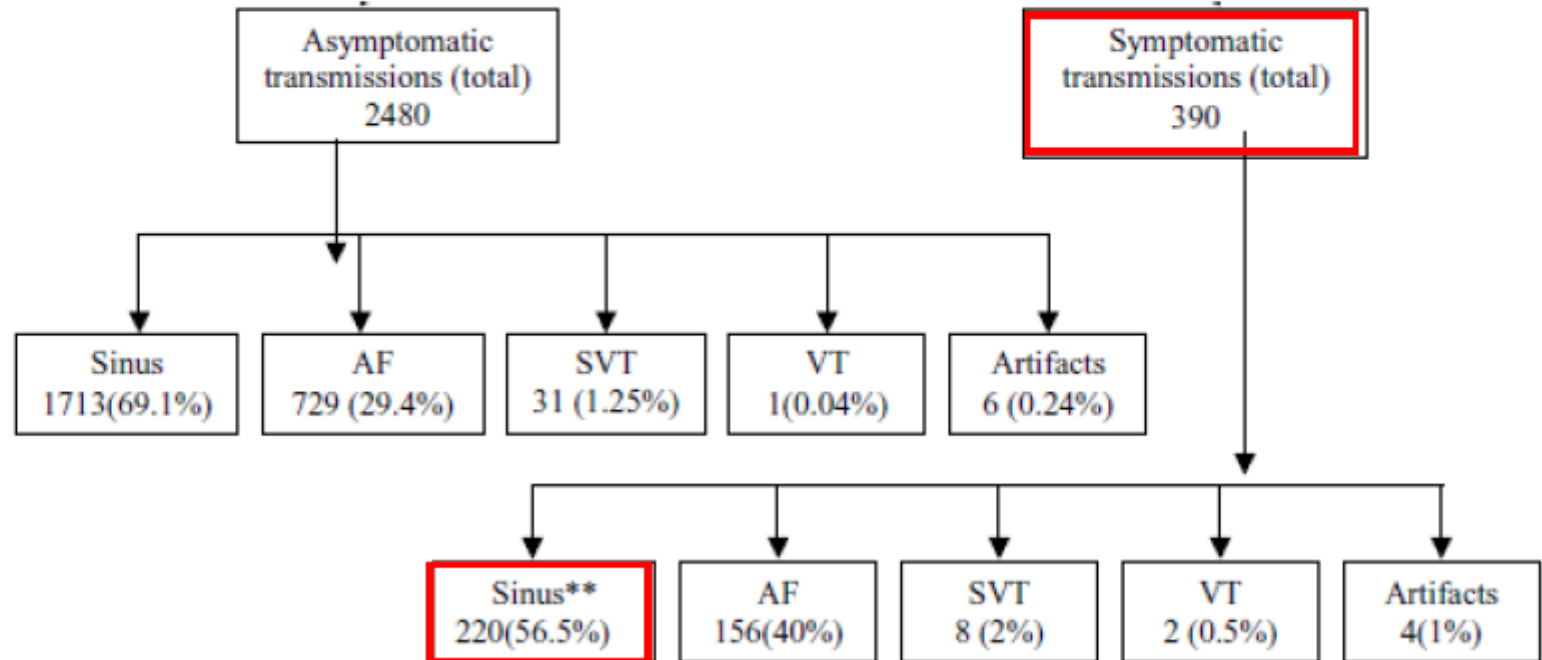Relation Between Individual Symptoms and AF Among All Symptomatic Transmissions (Total 390 Events)

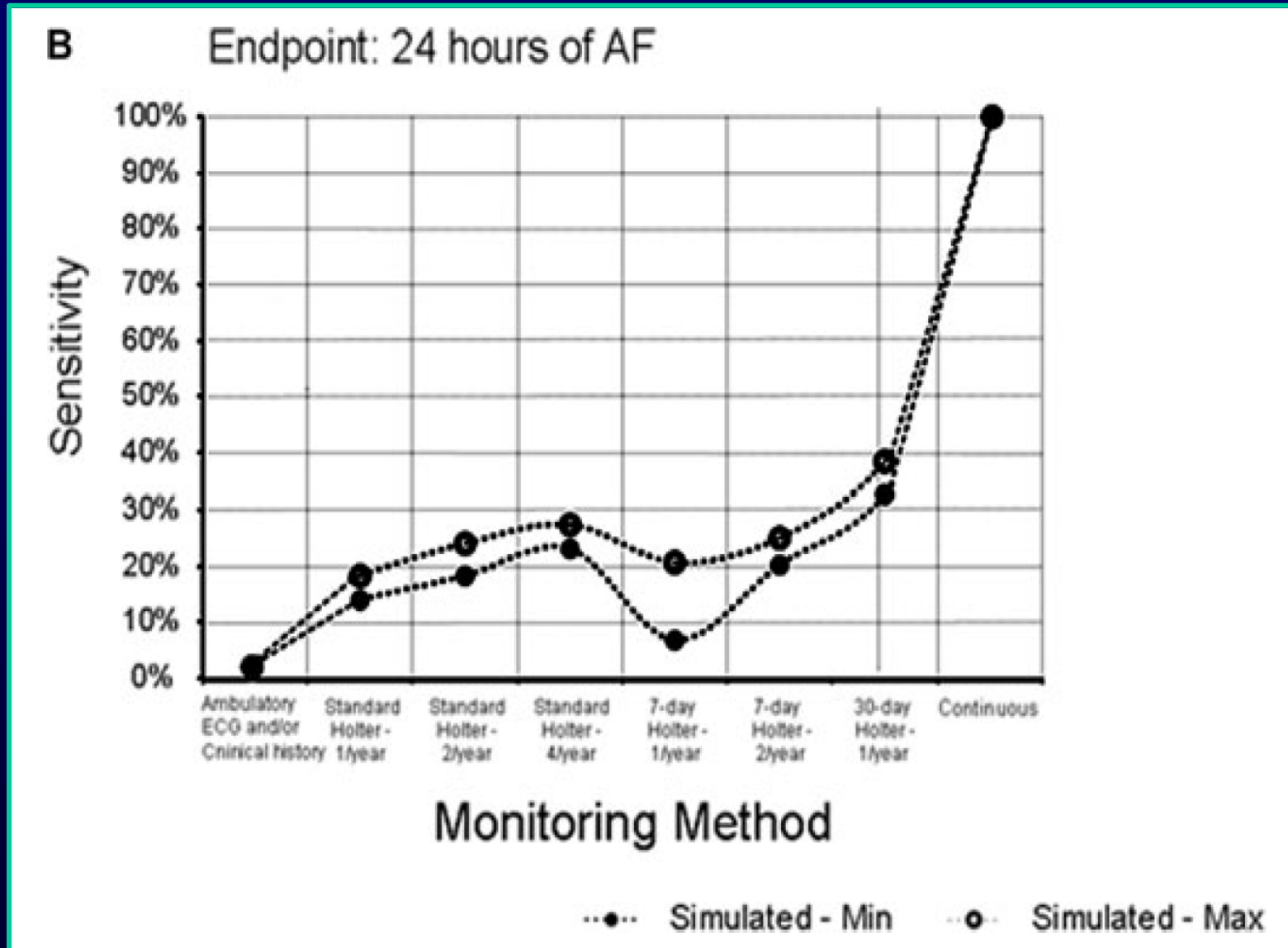| Symptom	Total (%)	AF	No AF	Odds (P Value) Ratio
Skipped beats	202 (52)	64	138	0.6 (ns)
Heart racing	132 (33)	68	64	2.4 (ns)
Fatigue	65 (17)	33	32	1.9 (ns)
Shortness of breath	51 (13)	36	15	5 (0.008)
Chest discomfort	42 (11)	30	12	5 (0.01)
Lightheadedness	39 (10)	11	28	0.6 (ns)
Fainting	0 (0)			

Perception of AF Before and After Ablation

Symptomatic and Asymptomatic Atrial Fibrillation in Patients Undergoing Radiofrequency Catheter Ablation

CHANDRASEKHAR R. VASAMREDDY, M.D.,* DARSHAN DALAL, M.D., M.P.H.,
JUN DONG, M.D., ALAN CHENG, M.D., DAVID SPRAGG, M.D., SAMEH Z. LAMIY, M.D.,
GLENN MEININGER, M.D., CHARLES A. HENRIKSON, M.D., JOSEPH E. MARINE, M.D.,
RONALD BERGER, M.D., PH.D., and HUGH CALKINS, M.D.

MCOT-System
Mobile Cardiac Outpatient Telemetry

Asymptomatic transmissions (total) 2480				
Sinus 1713 (69.1%)	AF 729 (29.4%)	SVT 31 (1.25%)	VT 1 (0.04%)	Artifacts 6 (0.24%)

Symptomatic transmissions (total) 390				
Sinus** 220 (56.5%)	AF 156 (40%)	SVT 8 (2%)	VT 2 (0.5%)	Artifacts 4 (1%)

Different Monitoring Methods to Detect AF

B Endpoint: 24 hours of AF

Monitoring Method

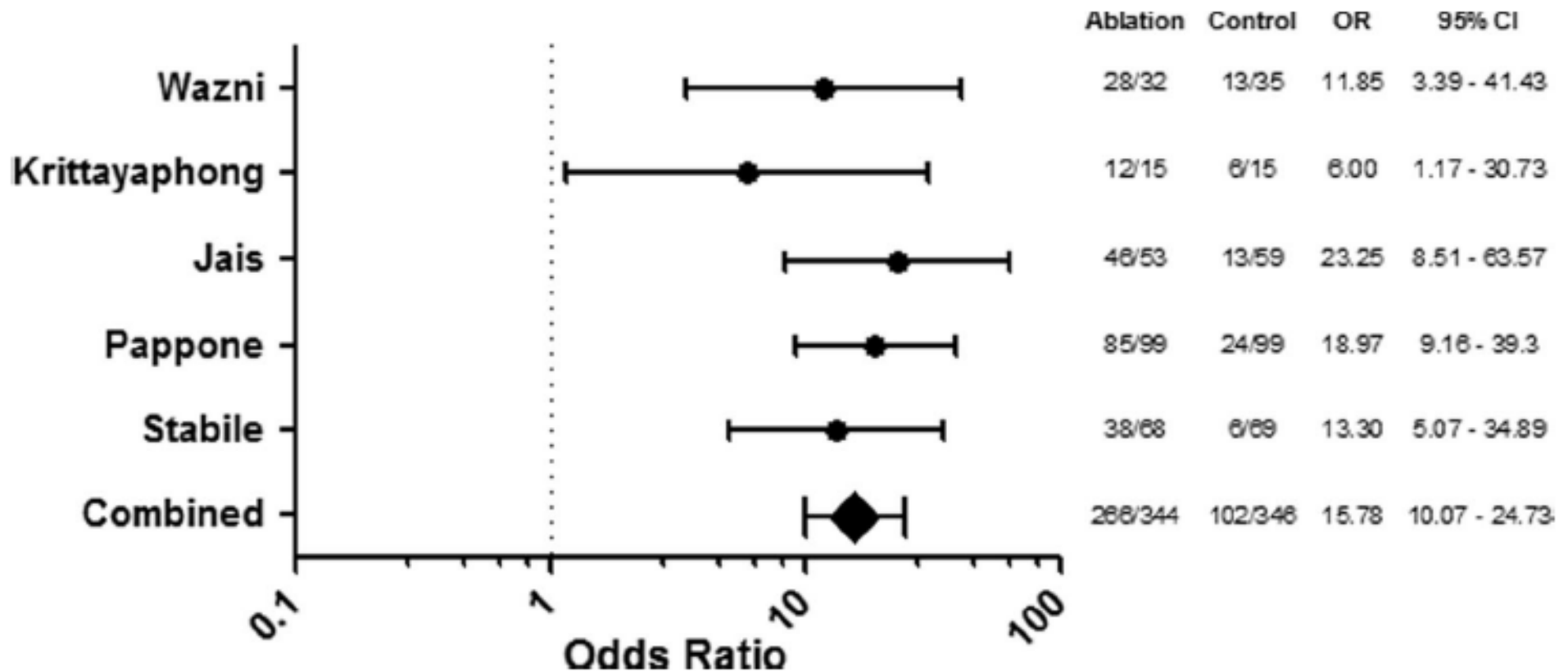···•··· Simulated - Min   ···o··· Simulated - Max

AF Discovery
Opportunity of Monitoring

- Symptoms are not a reliable indicator of AF

- External monitors (continous or event recorder) have a very low yeld due to poor compliance (skin irritation, interference with daily activities) and intermittent sampling

- Implantable systems (ILRs, IPGs, ICDs) have hight sensitivity and high PPV for detection of AF

PVI vs ADDs Meta-Analysis of RCTs

	Ablation	Control	OR	95% CI
Wazni	28/32	13/35	11.85	3.39 - 41.43
Krittayaphong	12/15	6/15	6.00	1.17 - 30.73
Jais	46/53	13/59	23.25	8.51 - 63.57
Pappone	85/99	24/99	18.97	9.16 - 39.3
Stabile	38/68	6/69	13.30	5.07 - 34.89
Combined	266/344	102/346	15.78	10.07 - 24.73

PVI vs ADDs Meta-Analysis of RCTs
ECG Monitoring and Follow-up

Trial	Blanking Period	12-Lead ECG	24-h Holter Recording	Event Monitor	Imaging
Krittayaphong et al[10]	3 mo	1, 3, 6, 12 mo	1, 3, 6, 12 mo	NR	NR
Wazni et al[14]	2 mo	NR	Discharge, 3, 6, and 12 mo	2 to 3 times daily for 1 mo during mos1 and 3; additional recording after 3 mo if symptomatic	CT at 3, 6, 12 mo (PVI arm only)
Stabile et al[13]	1 mo	1, 4, 7, 10, 13 mo and symptom directed	1, 4, 7, 10, 13 mo	Daily transmission for 30 s and with symptoms ×3 mo	Echo at 1, 4, 7, 10, 13 mo TEE at 4 mo (PVI arm only)
Oral et al[11]	3 mo	3, 6, 12 mo	NR	5 d per week for 3 min and with symptoms	Echo at 3, 6,12 mo
Pappone et al[12]	6 wk	3, 6, 12 mo	3, 6, 12 mo (48-h monitor)	1 to 3 times daily and with symptoms	Echo at 3, 6, 12 mo
Jais et al[15]	3 mo	3, 6, 12 mo	3, 6, 12 mo	NR	Echo after each ablation and at 12 mo

Single-Procedure Outcome of Drug-Refractory AF Ablation
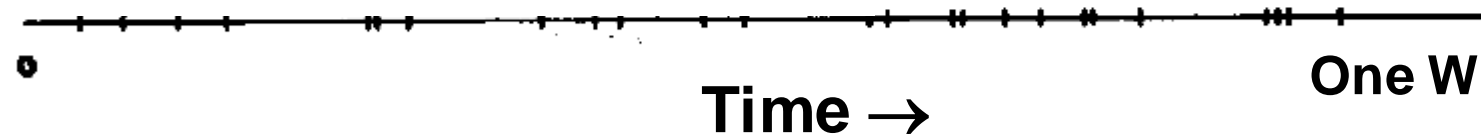## *A 6-Year Multicenter Experience*

Total Population

Paroxysmal vs Persistent AF

Bertaglia E. Europace 2010; 12: 181-187
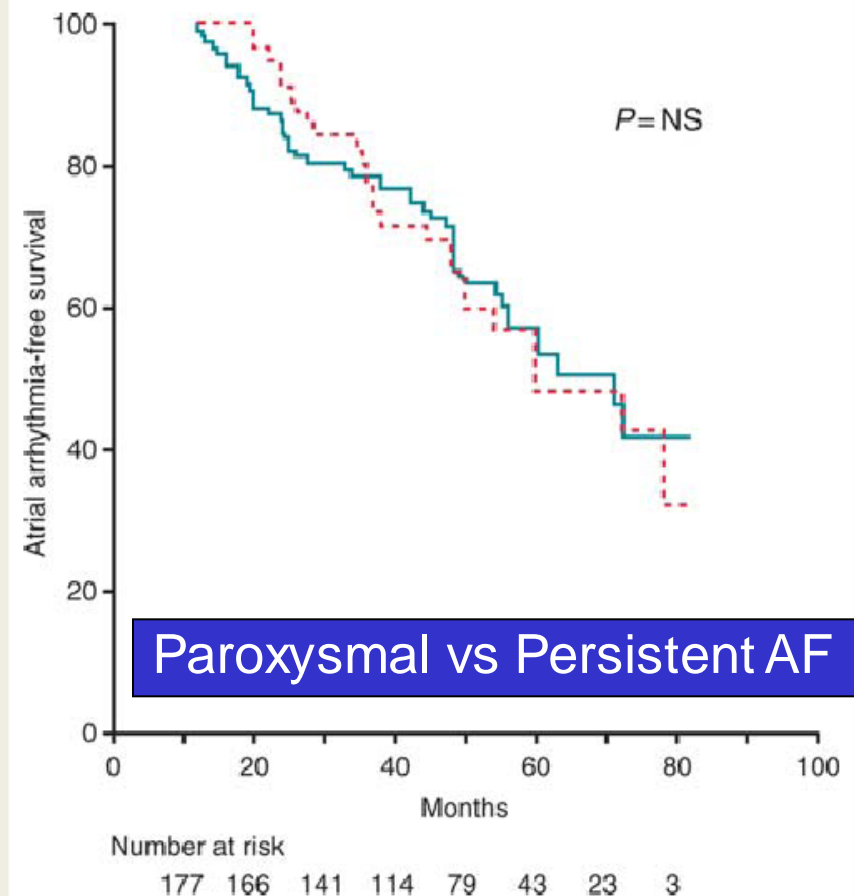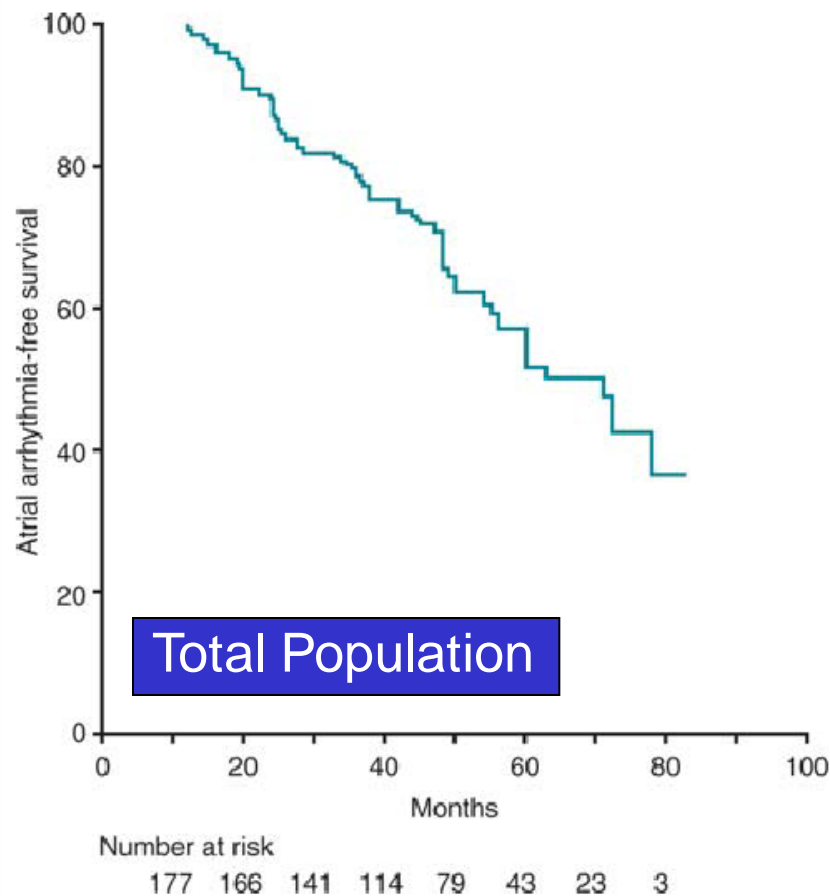
Long-term Outcome After AF-Ablation of Atrial Fibrillation
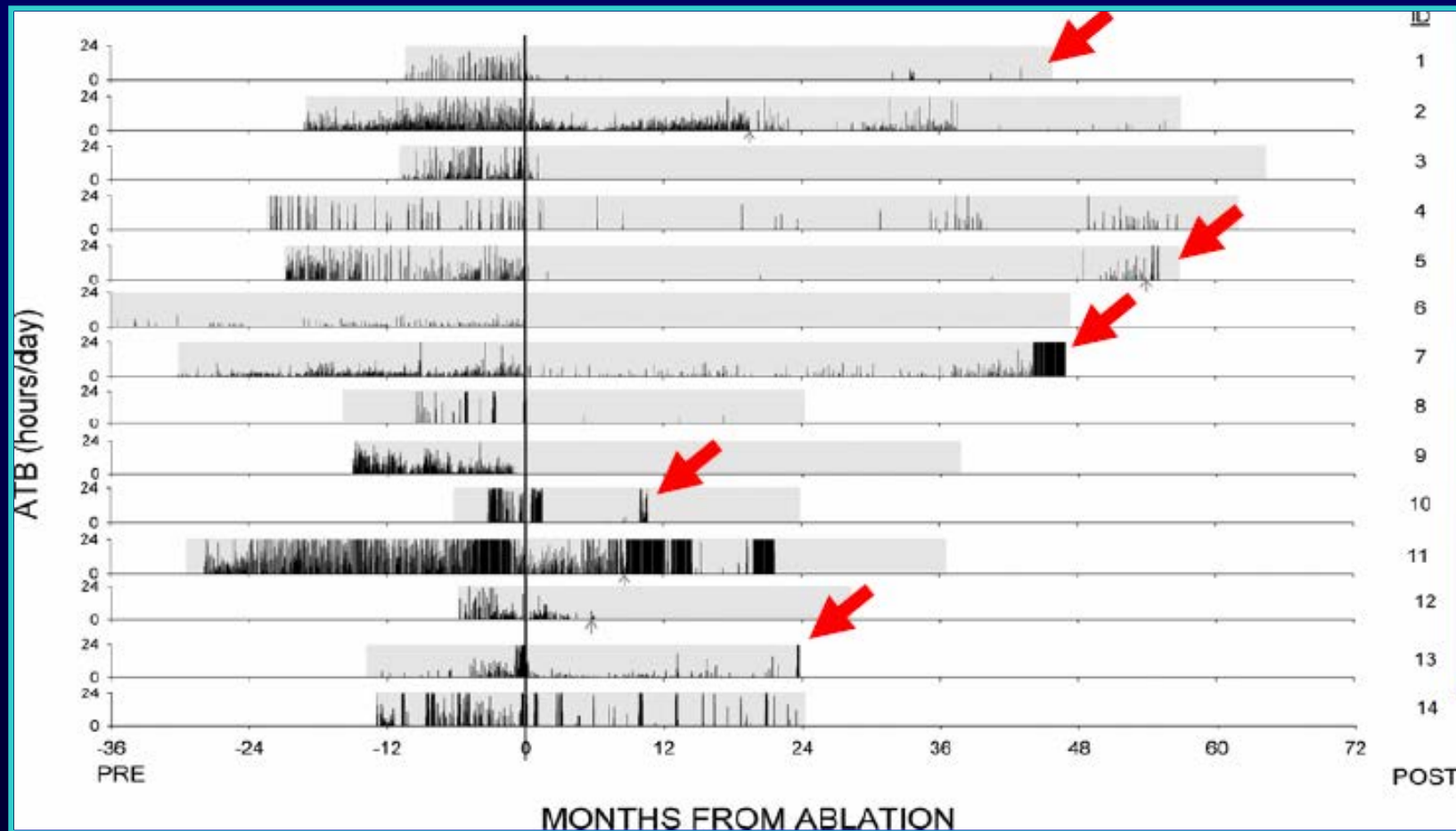
Data From Patients With Implantable Devices

A. Poisson distribution

Time →

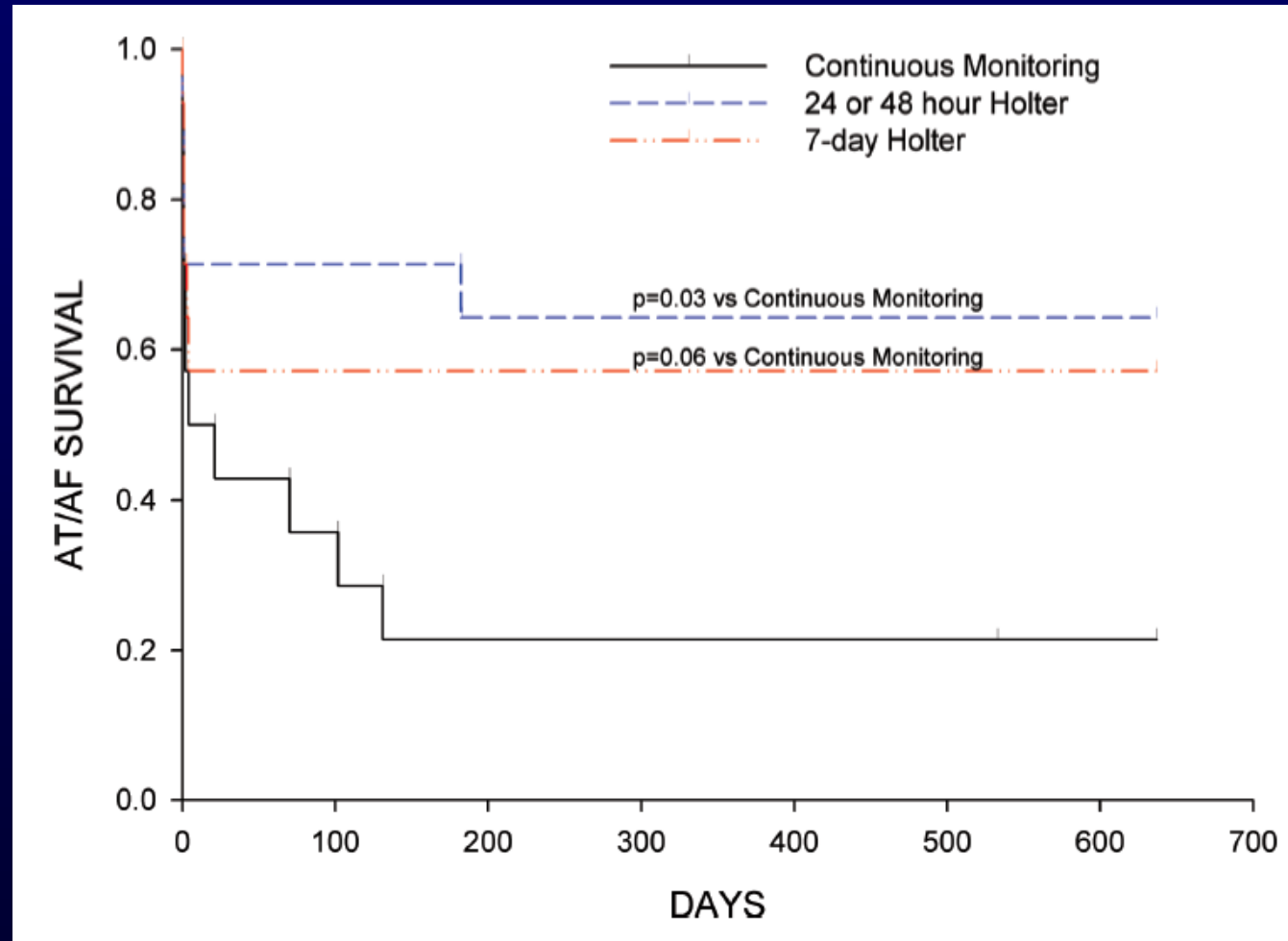One W

**B. Weibull distribution**

Time →

One W

➔ Recurrences are NOT RANDOM and
ARE DEPENDENT of a preceding event

➔ PAF episodes trend to cluster in time

Time to First Recurrence of AF in Days After 3-Month Blanking Period

Martinek M. *J Cardiovasc Electrophysiol 2007; 18: 818-823*

Stroke as a First Devastating Sign of Atrial Fibrillation

- 75 yr-old male patient with acute hemi-paresis
- Preceding dyspnea NYHA for 7 days
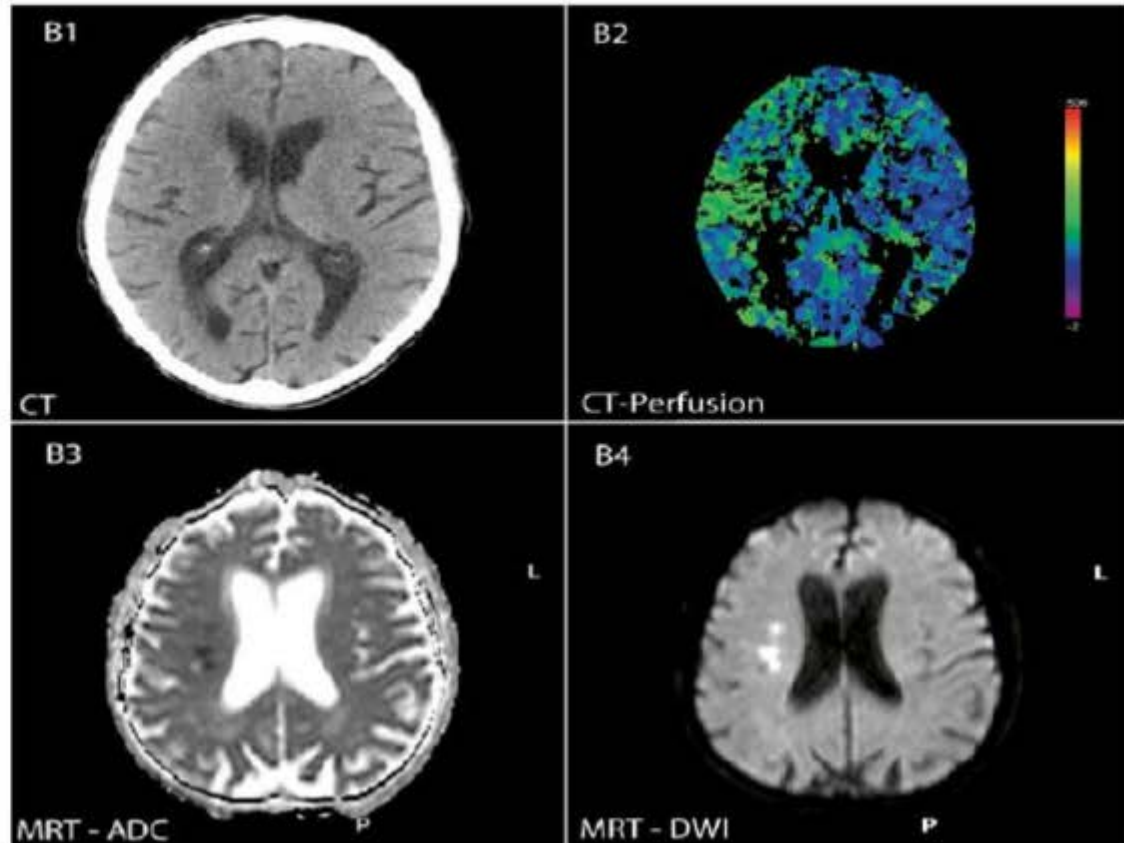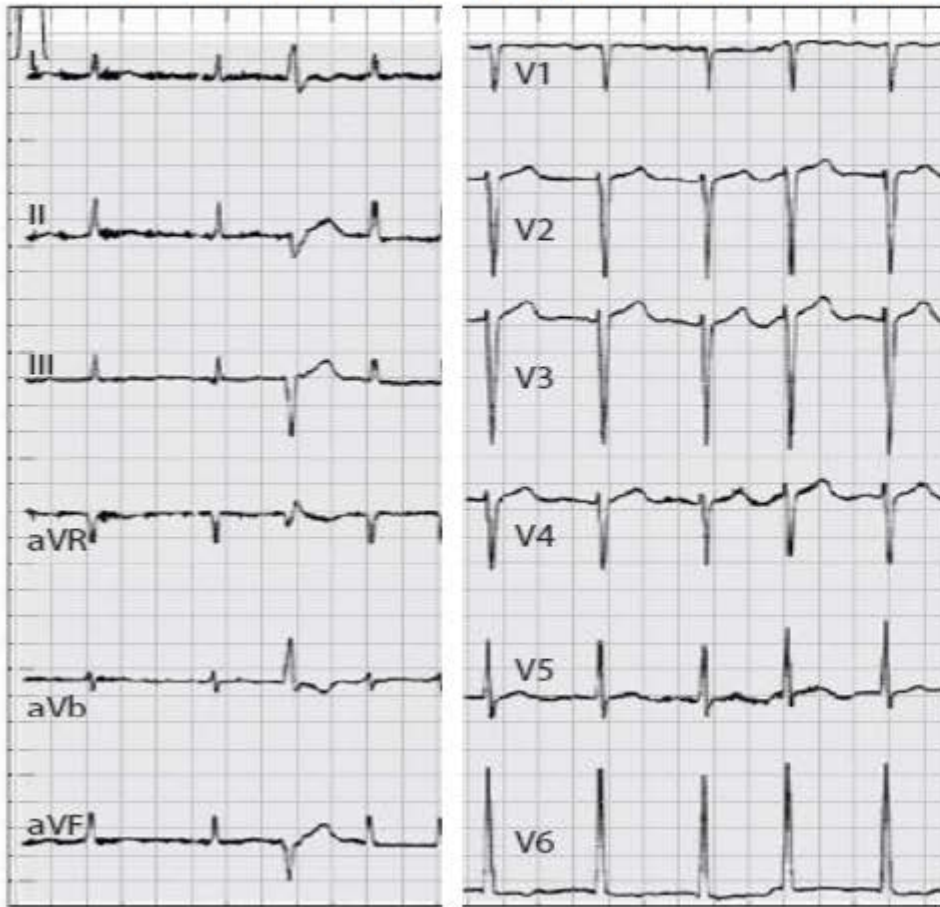
How Much
Atrial Fibrillation
Is Needed to Cause
Thromboembolism ?

CHADS2 Score, AF Duration and Stroke Risk
568 Pts with MDT AT500 IPG Continuously Monitored for 1 Year

CHADS$_2$ score

	0	1	2	≥3
No AF at FU (AT/AF < 5 min in 1 day)	1.7%	0%	0%	25%
5 min < AT/AF Episodes < 24 h	1.8%	1.3%	2.4%	0%
AT/AF Episodes > 24 h	0%	4.4%	4.4%	33%

(3 out of 351 Pts) **0.8 %**   vs   **5 %** (11 out of 217 Pts)   **P = 0.035**

Botto GL, Padeletti L. Santini M. J Cardiovasc Electrophys 2009; 20: 241-248

ASSERT Trial: *Primary Outcome*

- 2582 pts with SSS
- HT and no prior AF
- 76±7 years
  42% female
  mean CHADS$_2$ score
  2.41
- AF > 6 min, > 190
  bpm in 36% of pts

Event	Device-Detected Atrial Tachyarrhythmia				Device-Detected Atrial Tachyarrhythmia Present vs. absent		
	Absent N=2319		Present N= 261				
	events	%/year	events	%/ year	RR	95% CI	p
Ischemic Stroke or Systemic Embolism	40	0.69	11	1.69	2.49	1.28 – 4.85	0.007
Vascular Death	153	2.62	19	2.92	1.11	0.69 – 1.79	0.67
Stroke / MI / Vascular Death	206	3.53	29	4.45	1.25	0.85 – 1.84	0.27
Clinical Atrial Fibrillation or Flutter	71	1.22	41	6.29	5.56	3.78 – 8.17	<0.001

This risk correlated strongly with baseline stroke risk factors and
- was 2.14% per year in patients with a CHADS$_2$ score ≥2, AT/AF+
- and only 0.19% per year for those with a CHADS$_2$ score=1 AT/AF-

Healey JS. AHA Meeting Chicago 2010

Temporal relationship of atrial tachyarrhythmias, cerebrovascular events, and systemic emboli based on stored device data: A subgroup analysis of TRENDS

Emile G. Daoud, MD,* Taya V. Glotzer, MD,† D. George Wyse, MD, PhD, FHRS,‡ Michael D. Ezekowitz, MD, PhD,¶ Christopher Hilker, MS,§ Jodi Koehler, MS,§ Paul D. Ziegler, MS§; TRENDS Investigators

- 2486 pts enrolled in TRENDS
  - at least 1 TE risk factor
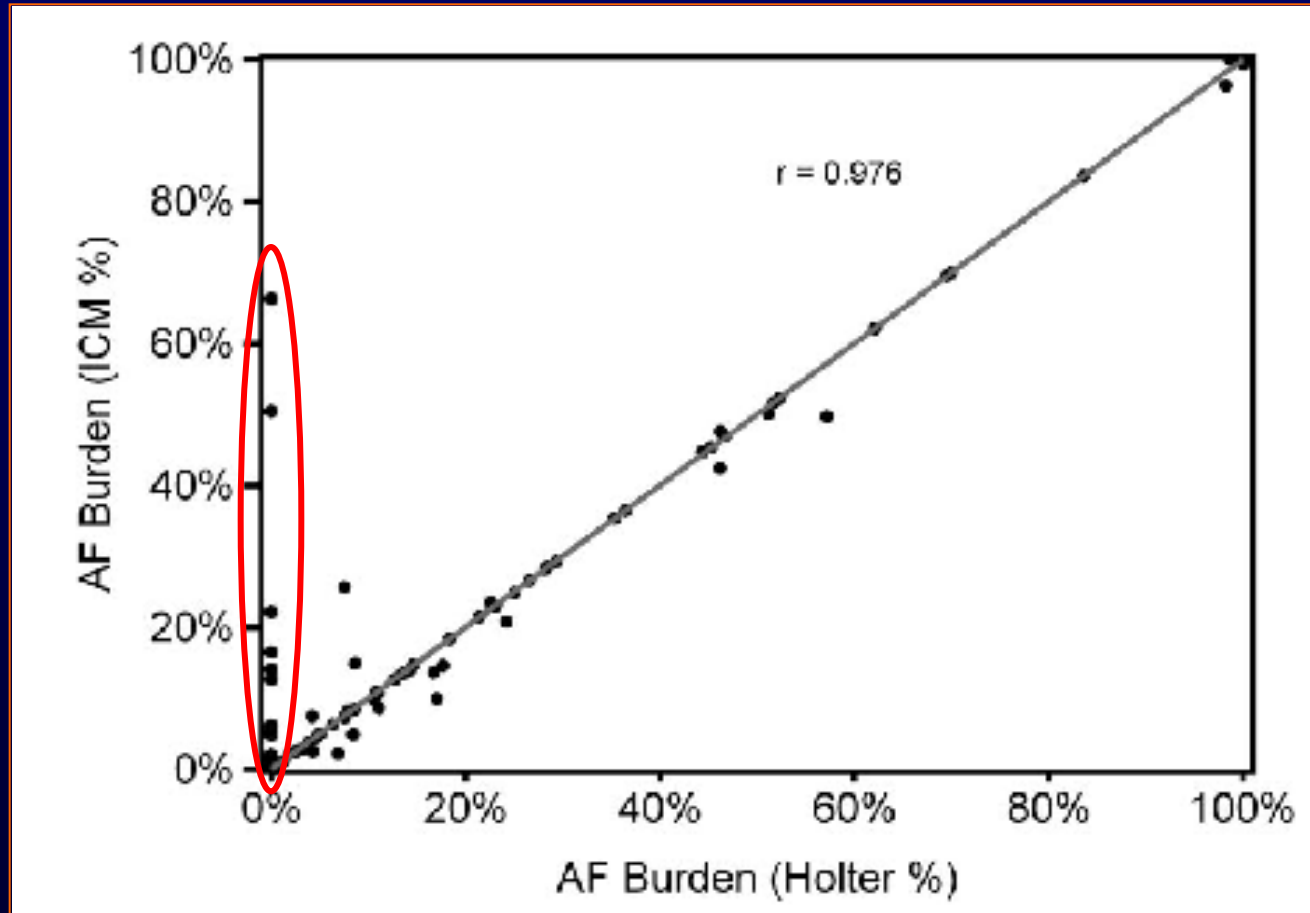- 40 (1,6%) pts with CVE/SE
- AT/AF detected in 20 (50%)
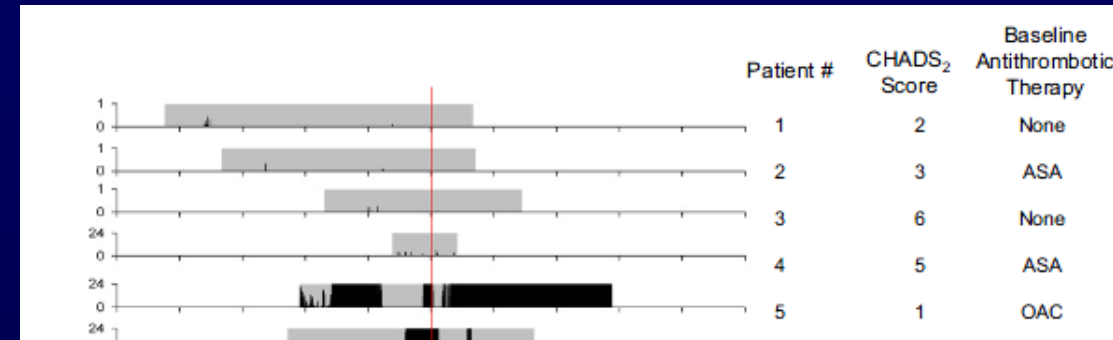
The mechanisms of CVE/SE in pts with implantable devices may importantly involve mechanisms other than cardioembolism due to atrial tachyarrhythmias
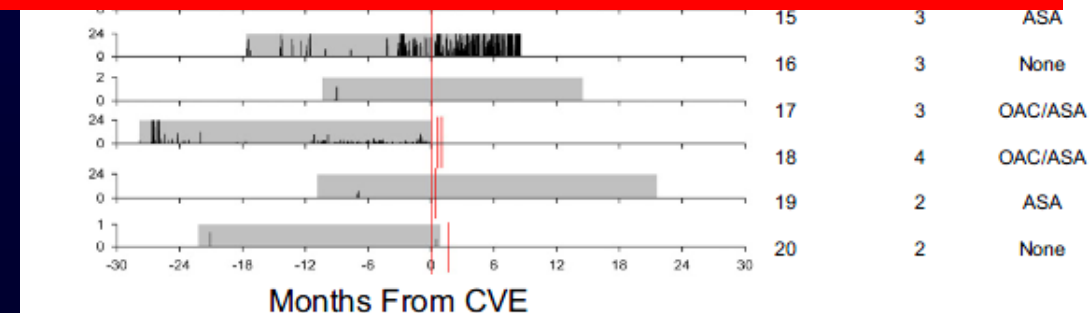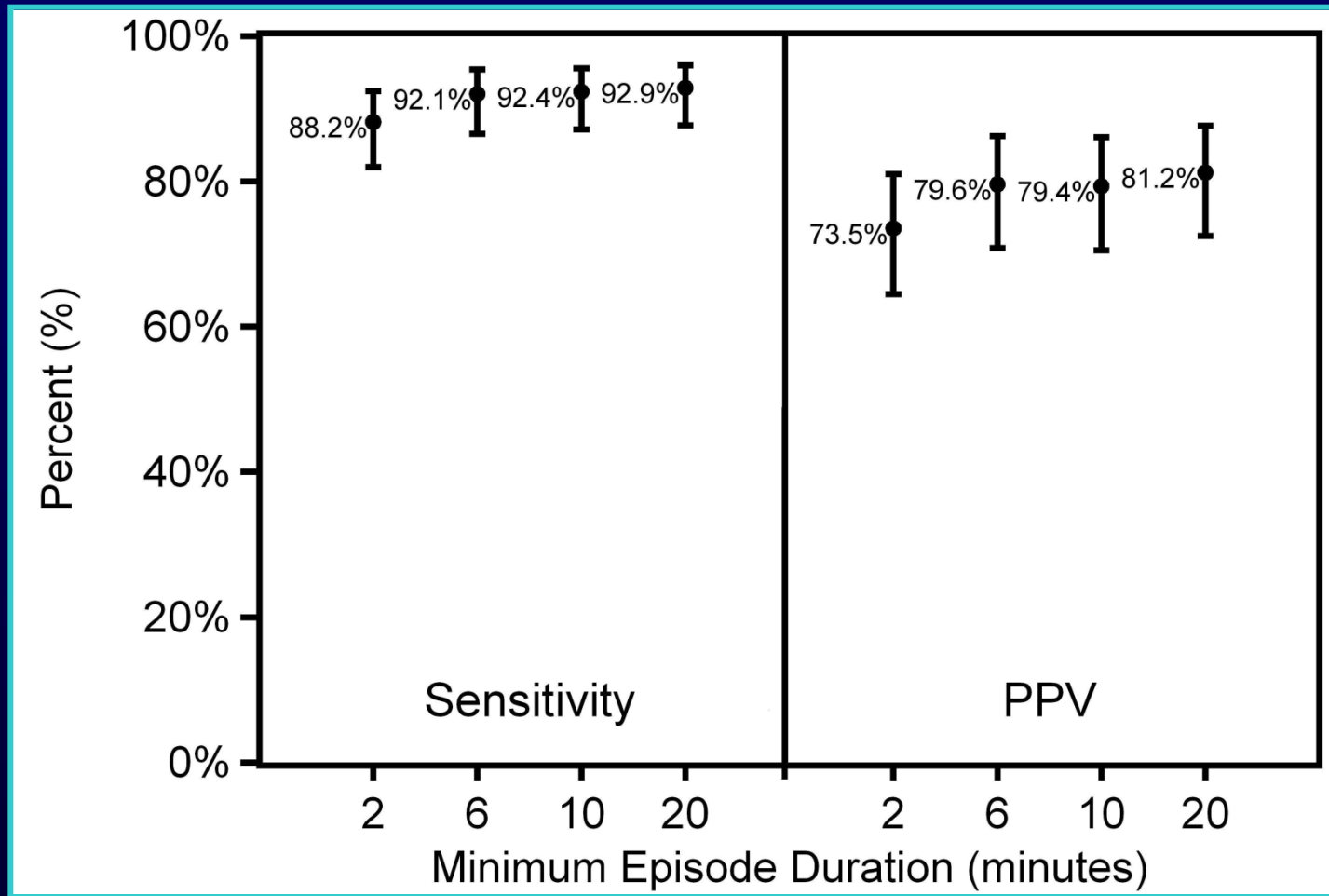
AF Burden Measured by ICM vs Holter Recording
Result of The XPECT Trial

Hindricks G. Circul Arrhytm Electrophysiol 2010; 3: 141-147

Performance of Reveal XT in Deyecting AF
The XPECT Trial

Hindricks G. Circ Arrhythm Electrophysiol 2010; 3: 141-147

Symptomatic vs Asymptomatic AF

- DISCERN AF:
  - Comparison of the incidence of symptomatic and asymptomatic AF before and after AF ablation
- 86% reduction in AF burden post ablation
- 56% of AF burden was asymptomatic
- AF was more asymptomatic post ablation

n=50

	Asymptomatic Pre-ablation	Ratio Asymptomatic: Symptomatic Pre-ablation	Asymptomatic Post-ablation	Ratio Asymptomatic: Symptomatic Post-ablation	p value
AF/AFL episodes	51.9%	1.1	78.7%	3.7	0.002
AF/AFL burden	35.8%	0.6	67.6%	2.1	0.0008

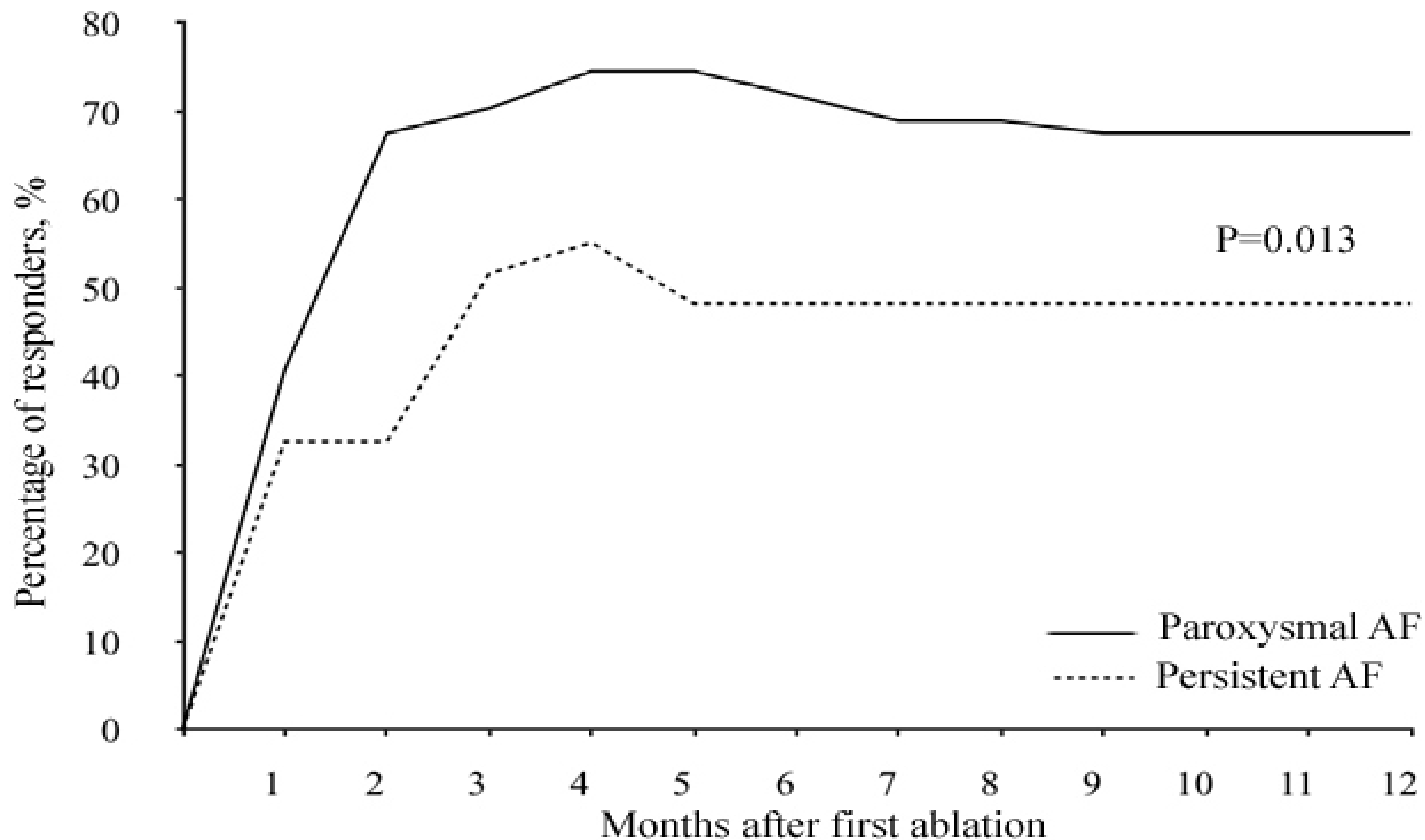Verma A. Presented at the Late Breaking Clinical Trial session during HRS 2011

Definition of Responders

- Patients with an AF%<0.5% were considered AF-free (Responders).

- This cut-off of 0.5% corresponds to a maximum cumulative time in AF of 3.6h in 1 month and to more than 99.5% of the time spent in sinus rhythm during the overall follow-up period (1 month).

- Patients with AF%>0.5% were classified as non-Responders: AF was visually verified by investigators through the analysis of the stored ECGs.
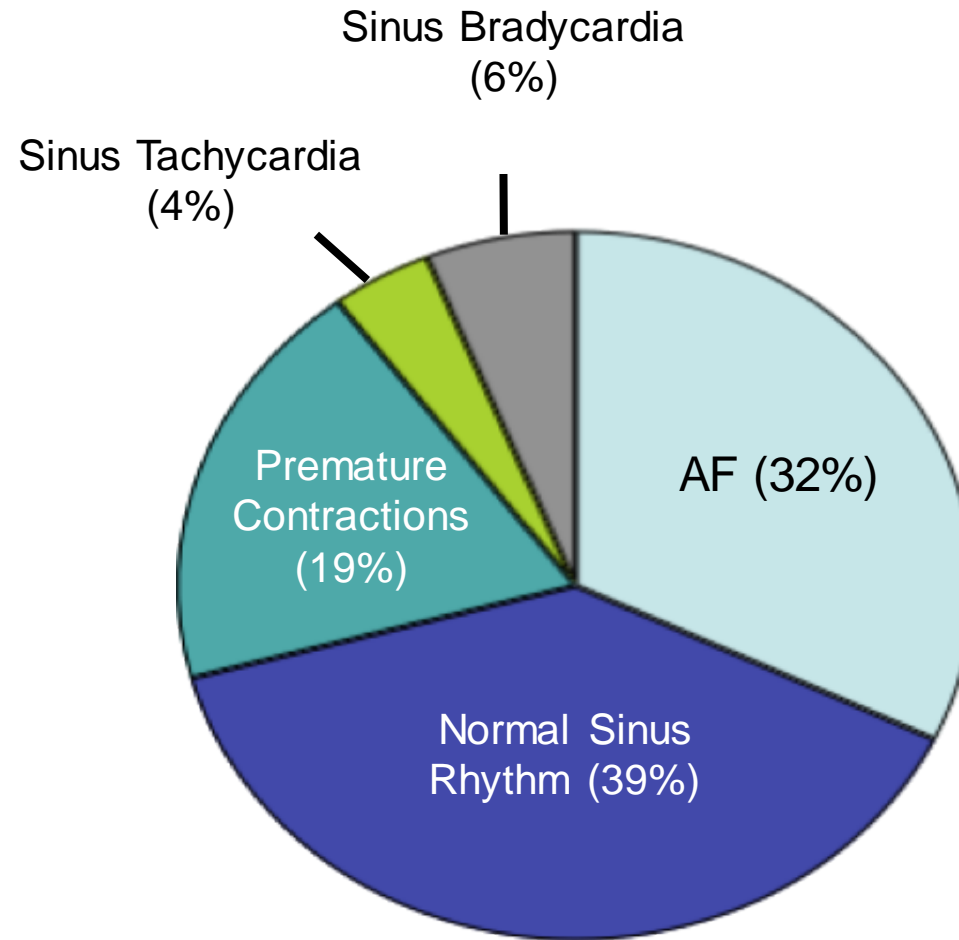
Examples of Responders & Non-Responders After PVI

Pokushalow E. *J Cardiovasc Electrophysiol.* 2011; 22: 369-75
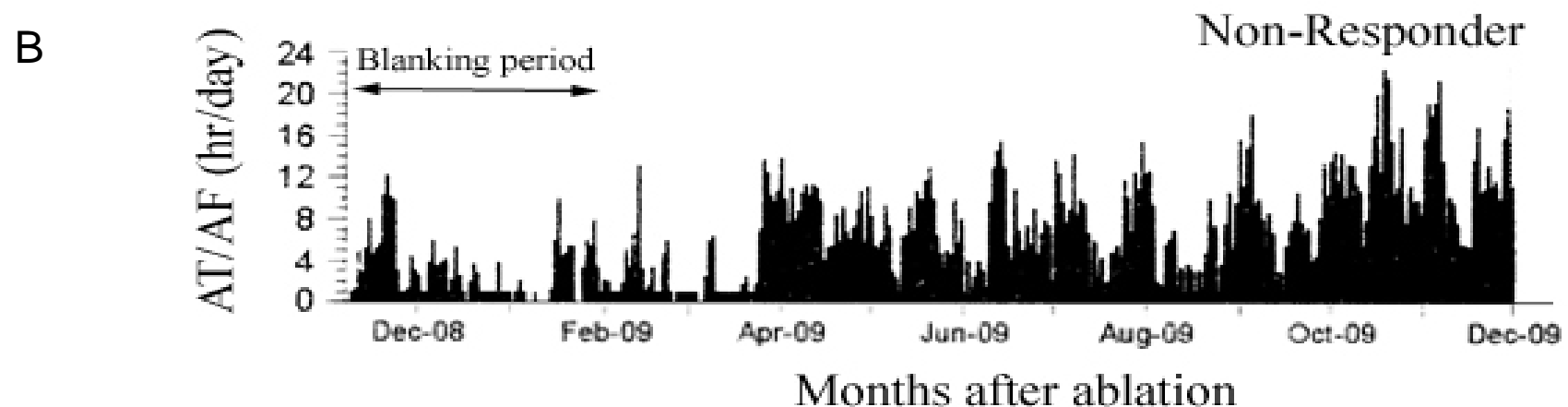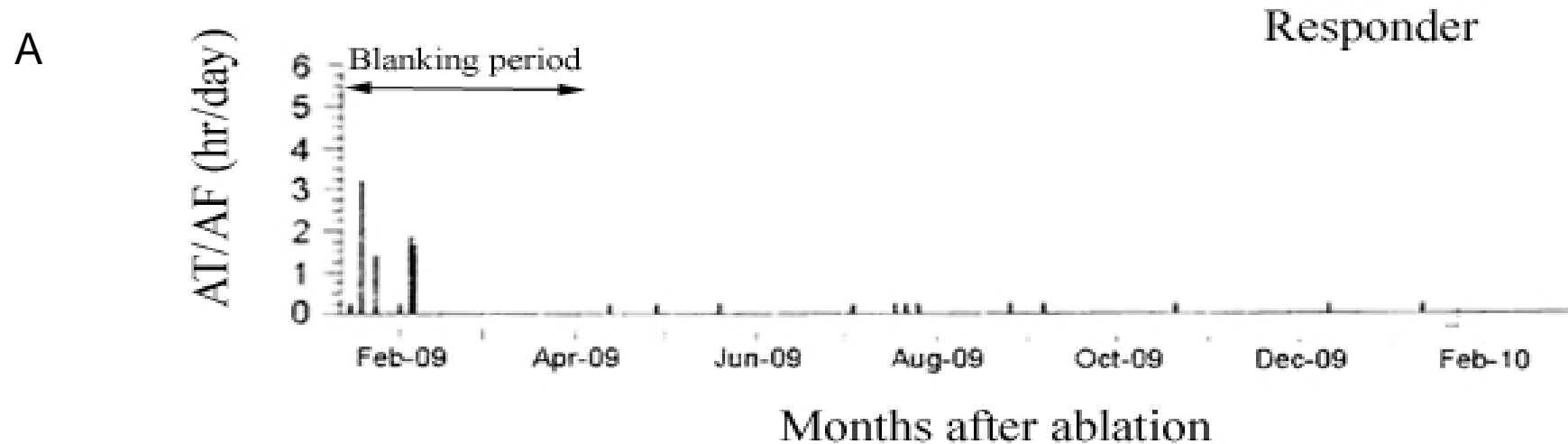
Post-Ablation Monitoring after First Procedure

Correlation Between Symptoms and AF

Sinus Bradycardia (6%)

Sinus Tachycardia (4%)

Premature Contractions (19%)

AF (32%)

Normal Sinus Rhythm (39%)

Pokushalow E. *J Cardiovasc Electrophysiol.* 2011; 22: 369-75

Validation of success following atrial fibrillation ablation: a European survey

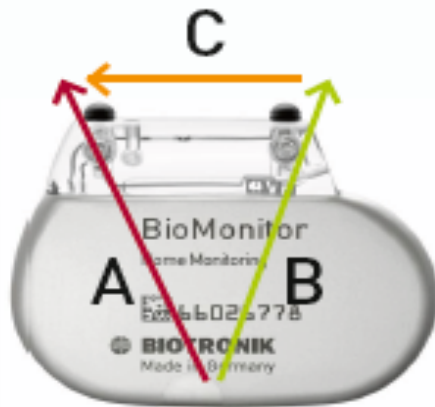**Franck Halimi[1]* and Lieselot Van Erven[2], on behalf of the EHRA Scientific Initiatives Committee (SIC)**
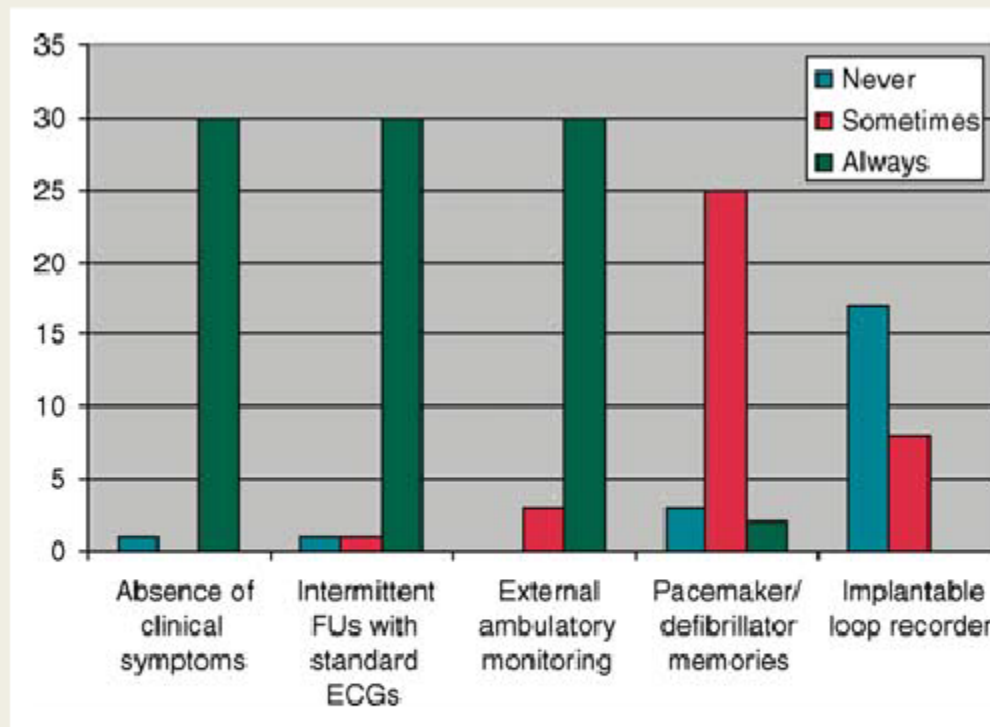
Figure 1 How do you confirm the absence of recurrence during the first year of follow-up after atrial fibrillation ablation? (Answers from 33 European centres.)

Thanks

New three-vector design

BioMonitor with its unique three-vector design
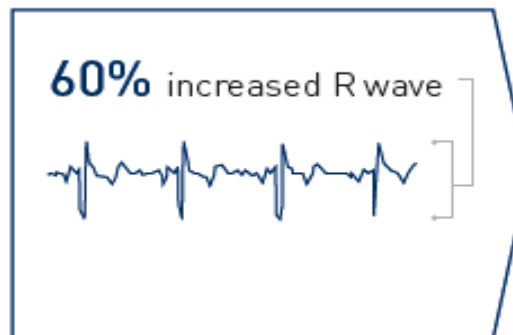
New three-vector design

- ✓ **Faster implant**: you don't have to map the device orientation, but the implant is like a normal pacemaker

- ✓ The final signal is the better combination of the three vectors: **higher R-wave amplitude (60%)**

- ✓ **Optimized signal/noise ratio** means better specificity for detection
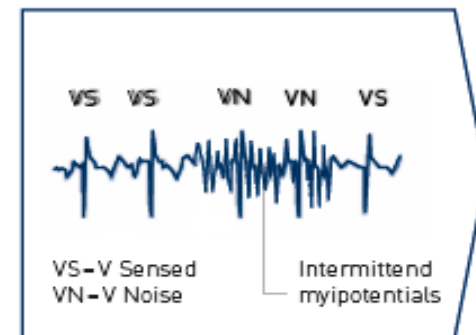

Three input signals

Channel A
Channel B
Channel C
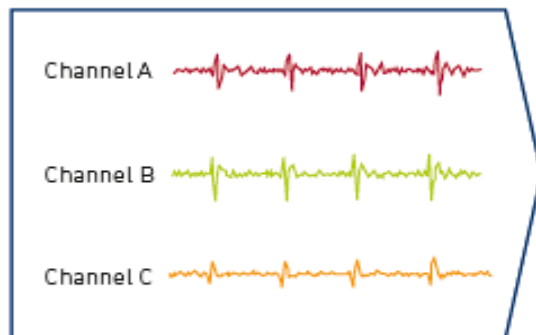
Three input signals are detected and analysed

Combined signal

60% increased R wave

One high quality signal is composed with optimized signal to noise ratio

Signal analysis

VS   VS   VN   VN   VS

VS – V Sensed
VN – V Noise

Intermittend myipotentials

Beat-to-beat R-wave analysis for correct signal evaluation

New three-vector design

ECG during shoulder's movement:

▌ Artefacts and fluctuation of baseline drift in channel A,B e C

▌ Channel C with lowest QRS amplitude

Result:

▌ The combination of three signals doubles QRS amplitude

▌ The baseline fluctuation is cancelled and the artefacts are reduced

▌ Bad signal on single channel is not important on final combined signal

Single channels

Combined 3 vector channel

Signal to noise ratio

Combined Channel   A   B   C
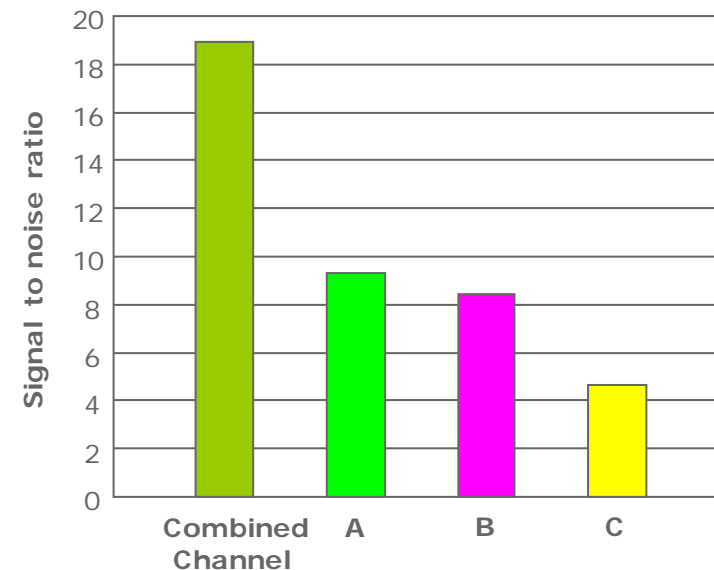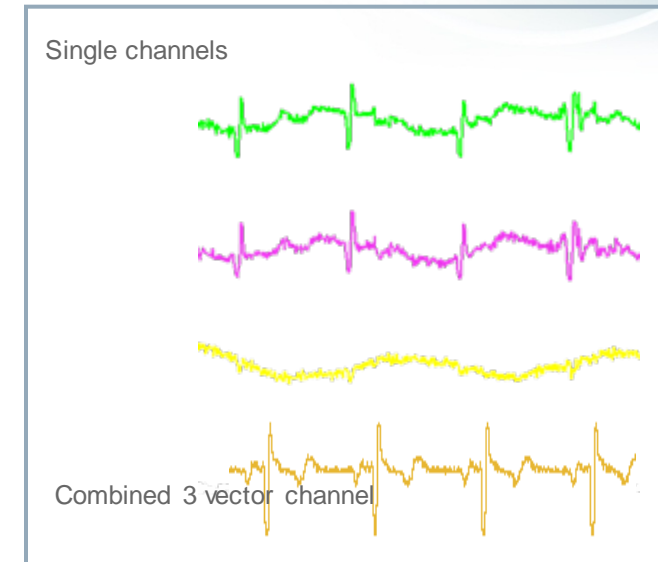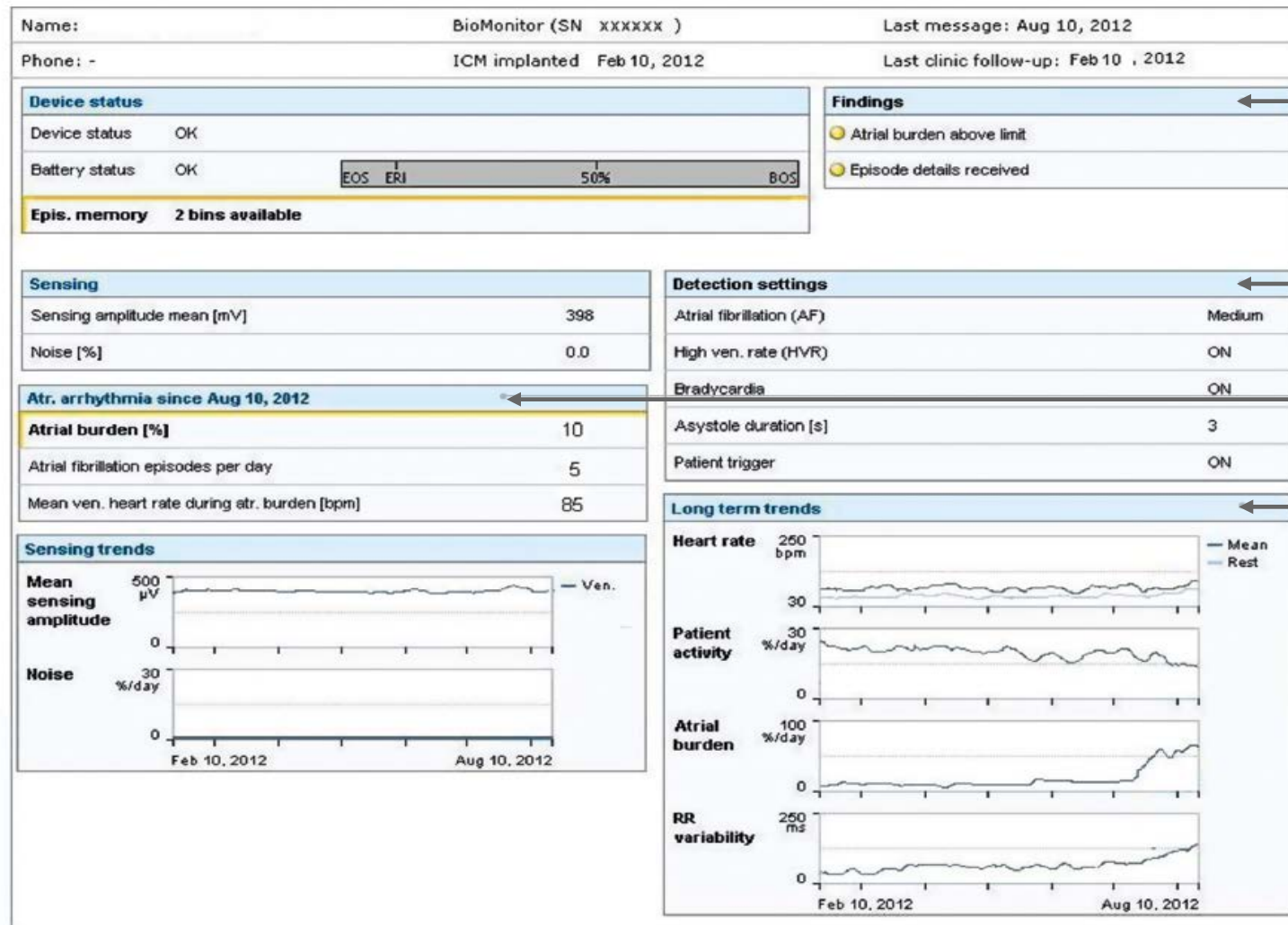
Biomonitor with Home Monitoring BIOTRONIK

CardioMessenger II-S

- ✓ First implantable cardiac monitor with daily alerts related to events through Home monitoring

- ✓ **Night Wireless comunication** with CardioMessenger II-S

- ✓ All data are avalible on Home Monitoring web site and they are updated to day before

- ✓ **High patient compliance**: no necessary interaction

- ✓ Automatic trasmission of basic ECG

- ✓ **Virtual endless Memory**: recorded event is sent to HomeMonitoring the same night

Biomonitor with Home Monitoring BIOTRONIK

Necessary information is always avalible

Detected arrhythmic events

Detection settings

Arrhythmic events details

Long-term trends

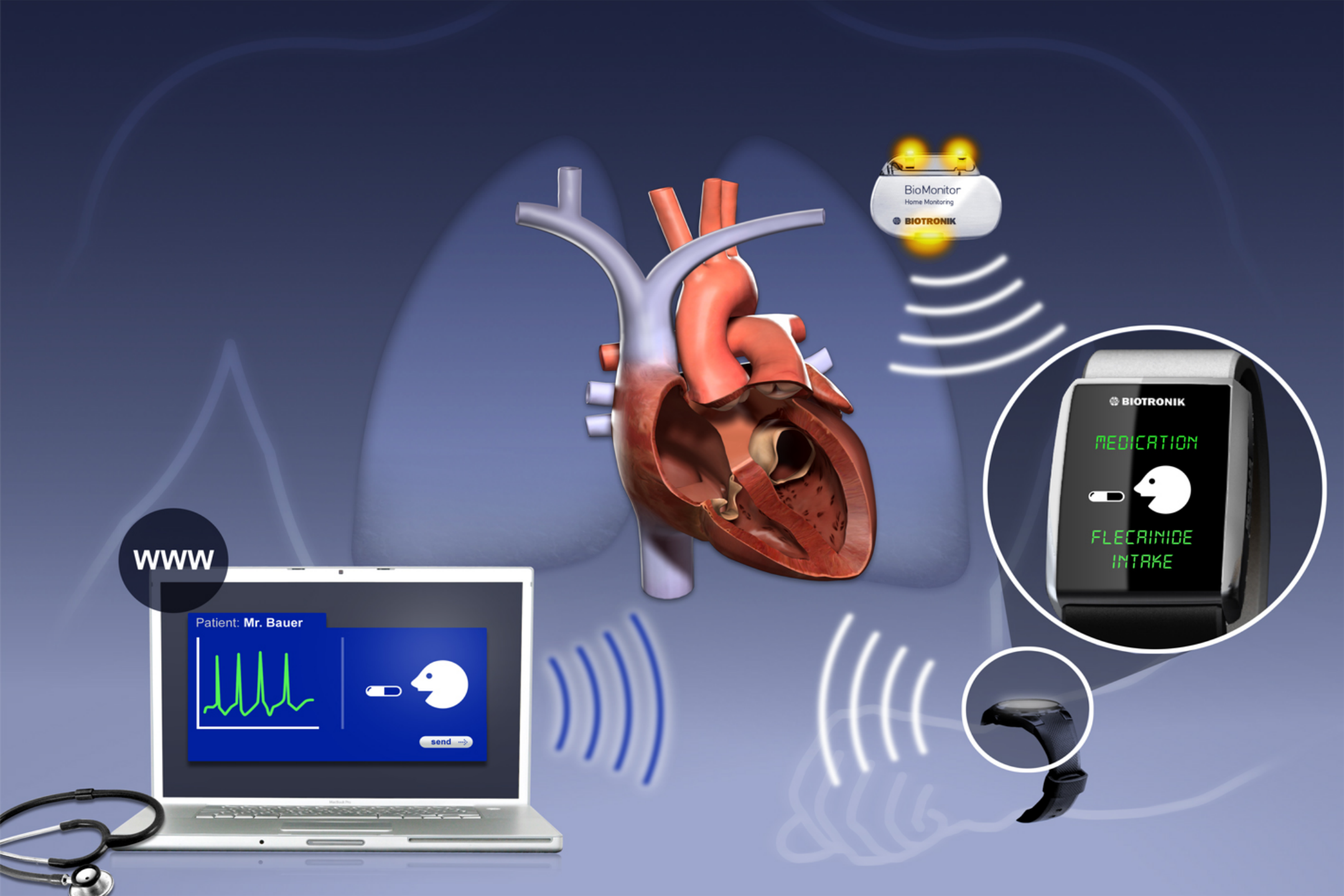# Biomonitor with Home Monitoring BIOTRONIK

SECG in Home Monitoring

- ✓ Total holter memory of 38,5 min
  - ✓ 22,5 min patient triggered events
  - ✓ 13,5 min automatic episodes
- ✓ Automatic episodes of 40 sec:
  - ✓ 30 sec pre trigger
  - ✓ 10 sec post trigger
- ✓ Patient triggered events of 7,5 min:
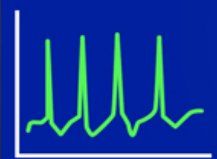 - ✓ 7 min pre trigger
  - ✓ 0,5 min post trigger

Extended Longevity

✓Extended longevity up to **6,4 anni*** with:

    ✓Daily complete diagnostic trasmission

    ✓Weekly trasmission of a SECG related to event

    ✓Automatic trasmission of basic SECG

Summary of Key Point

1. **"Silent AF" – Poor correlation between symptoms and AF episodes.**

   a) AF episodes may be asymptomatic

   b) Symptoms may not be related to AF episodes

2. **Intermittent monitoring leads to underdetection of AF.**

   a) Wrong decisions concerning AAD therapy, ablation and anticoagulation

   b) Wrong evaluation of therapy success   "The need for more accurate and extended diagnostic periods ..."

3. **AF duration and AF Burden impacts on stroke risk (AHRE?) .**

4. **Continuous monitoring is an indispensable tool resulting in accurate and more objective information about the AF status and the efficacy of treatment methods.**

5. **New implantable devices are capable of identifying AF with a good sensitivity and negative predictive value.**