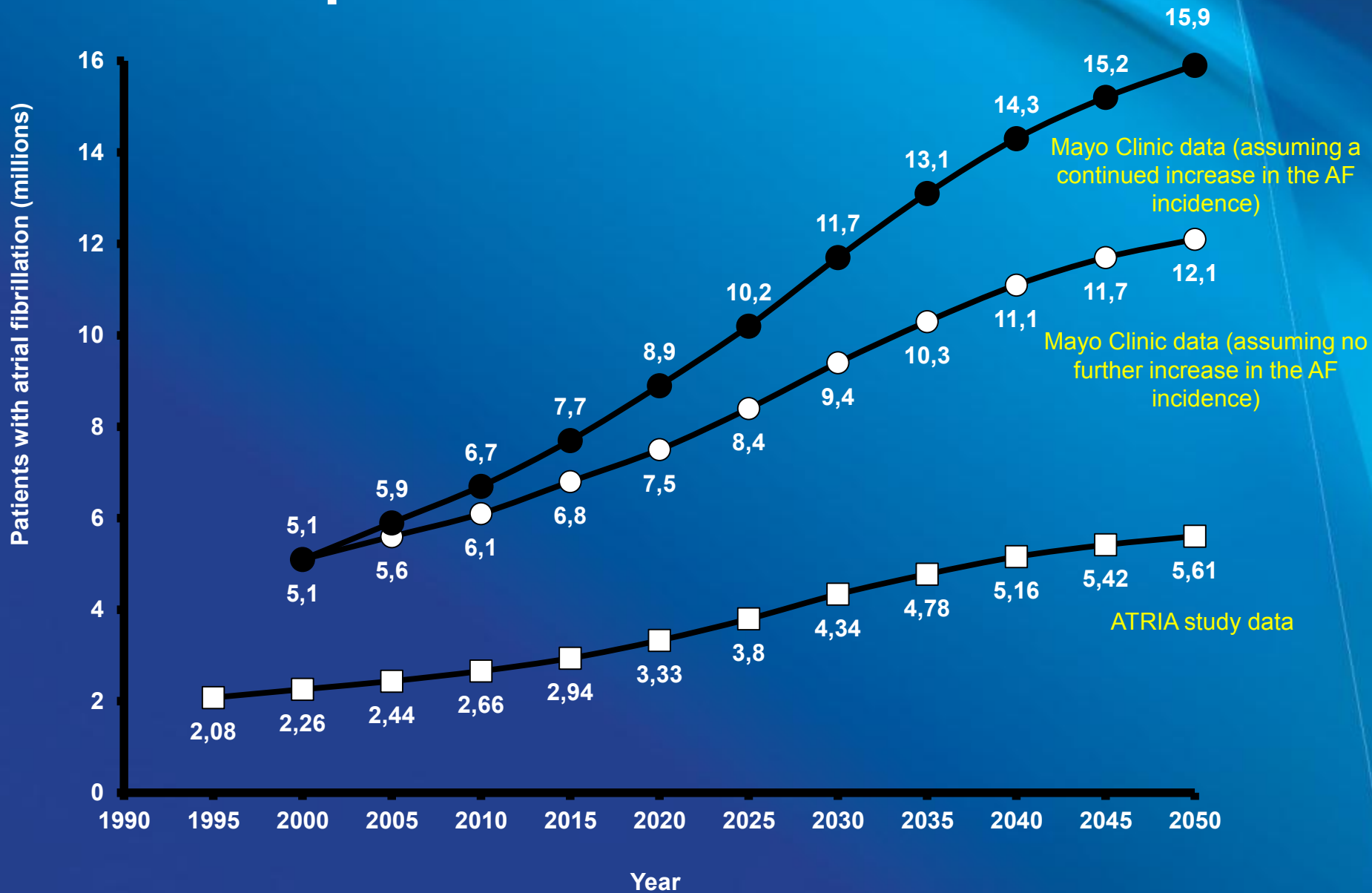


The role of AF monitoring in patients wearing a device can the risk of thromboembolic stroke be anticipated or reduced?



Dr. Giovanni Rovaris
Head of Interventional Electrophysiology
San Gerardo Hospital
ASST-Monza

The AF epidemic



Clinical Relevance of AF

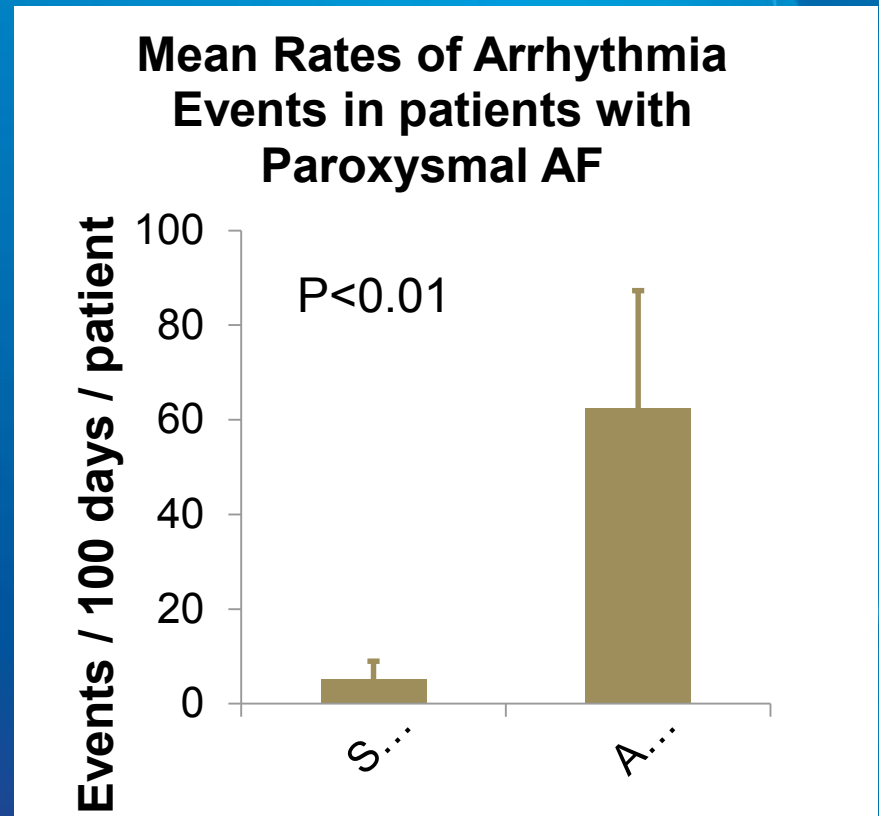
Reference	Main Message	Clinical Message
Camm AJ, EHJ 2010	AF increases a patients risk for stroke	Patient with AF are 5 times more likely to experience stroke
Page RL, Circ 1994	AF can be asymptomatic	Rates of asymptomatic AF are more frequent than symptomatic AF
Israel CW, JACC 2004	Asymptomatic AF is common	1/3 rd of AF episodes are asymptomatic
Healey JS, NEJM 2012	Asymptomatic AF is associated with stroke	Asymptomatic AF is associated with a 2.5 fold increase in risk of stroke and systemic embolism
Boriani G, CirCardQuaOutcomes 2012	Adherence to stroke prevention in AF guidelines is low	54% of patients were indicated but not taking OAC

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AF Can Be Symptomatic and Asymptomatic

- 22 patients with paroxysmal AF or supraventricular tachycardia were followed for 29 days
- A portable ECG monitor was used during symptoms & 24-hour ambulatory ECG monitor was used once per week
- Asymptomatic AF occurs far more frequently than symptomatic AF in PAF patients

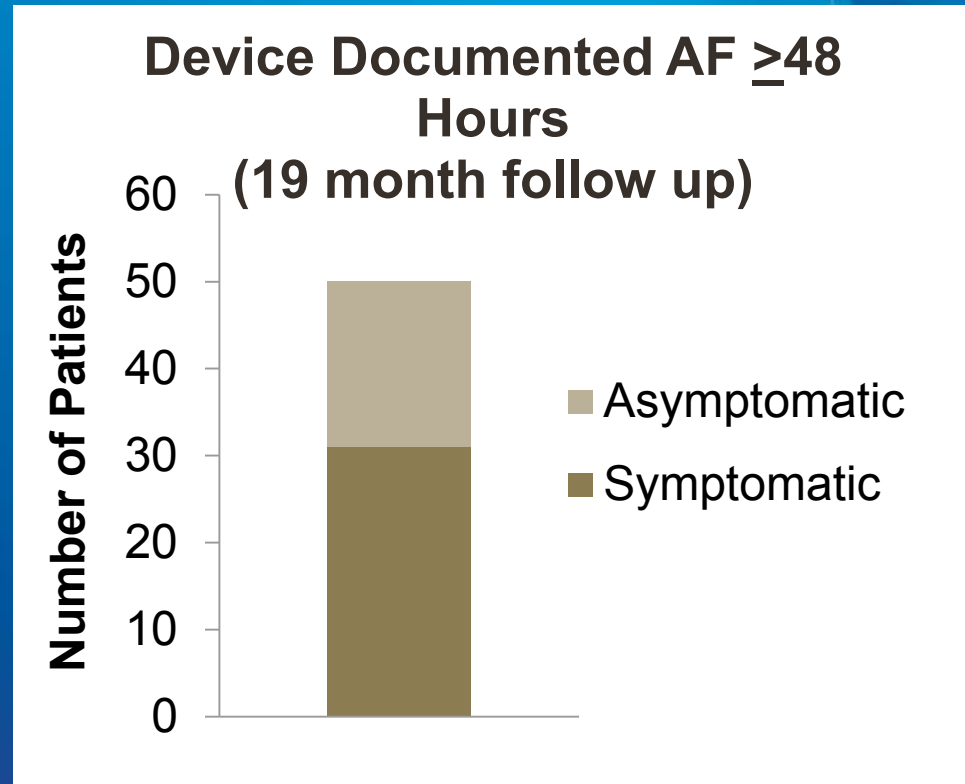


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Frequency of Asymptomatic AF

- 110 pacemaker patients with paroxysmal or persistent AF
- More than one-third (38%) of AF episodes were asymptomatic
- Difficult to know if patients are remaining in sinus rhythm



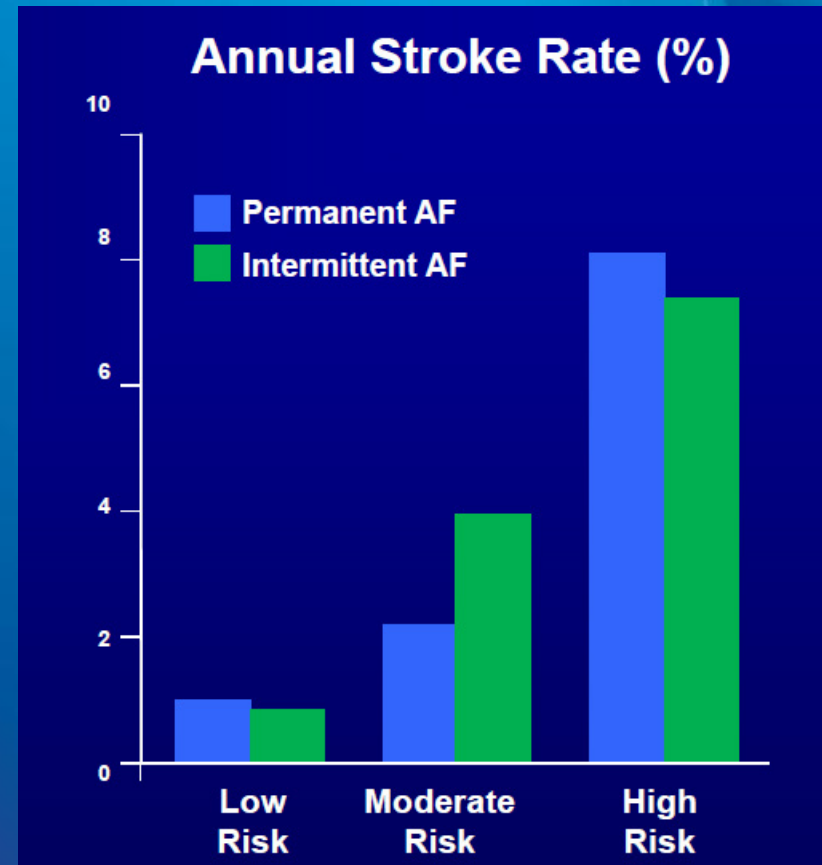
Israel MD, et al. JACC 2004; 47-52

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Stroke Risk Persists in Asymptomatic AF and Intermittent AF

- 460 patients with intermittent AF and 1552 patients with Permanent AF treated with aspirin.
- After a mean follow up of two years, the annualized rate was similar (Intermittent AF 3.2% and permanent AF 3.3%).



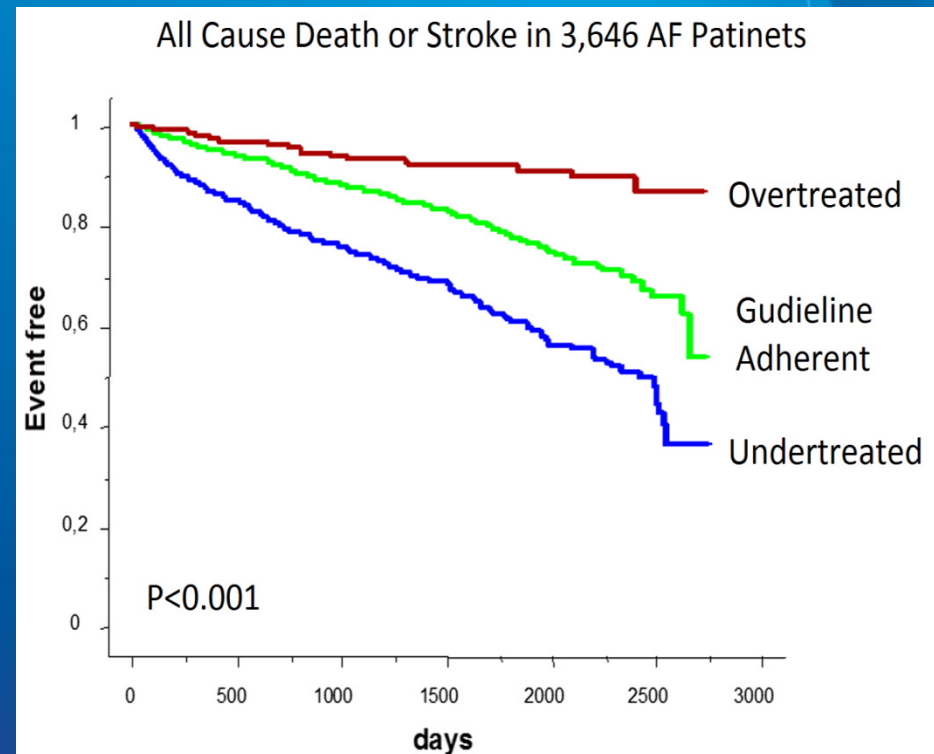
Hart RG, et al. JACC 2000; 35: 183-7
Camm AJ, et al. EHJ 2010; 31: 2369-2429

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Effective Stroke Prevention in AF

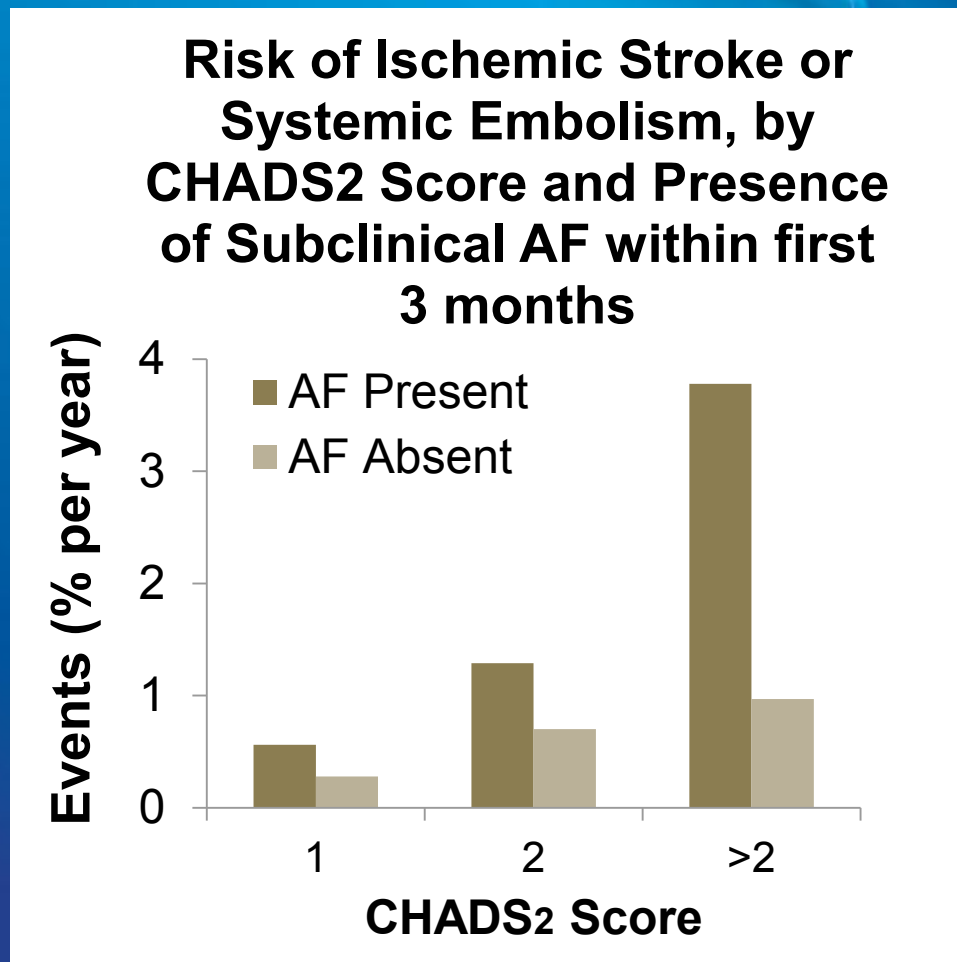
- 3646 patients with AF were followed for 2.5 years
- 31% were considered OAC undertreated, 53% treated according to guidelines and 16% overtreated.
- Guideline compliant patients experienced a 53% relative risk reduction in all cause death or stroke compared to those who were undertreated ($P < 0.001$).



Gorin L, et al. CHEST 2011; 140(4): 911-917

Ischemic Stroke in ASSERT

- 2580 pacemaker and ICD patients with hypertension and no history of AF
- 10% experienced asymptomatic AF within 3 months.
- Asymptomatic AF was associated with a 2.5-fold increase in the risk for ischemic stroke and systemic embolism (P=0.007).



Healey JS, et al. NEJM 2012; 366: 120-9

Clinical Application & Benefit of Monitoring for AF

Reference	Main Message	Clinical Message
Singer DE, CHEST 2008	Primary Prevention of Stroke Timely diagnosing of AF and initiation of OAC reduces AF related strokes	
Miller DJ, J Neuro Sciences 2013	Secondary Prevention of Stroke Undetected AF could be the cause of cryptogenic stroke but is difficult to diagnose	17% of cryptogenic stroke patients followed with monitoring were found to have paroxysmal AF
Botto GI, J Card Ele 2009	Accurate AF Detection Continuous monitoring is required for truly accurate AF detection	1/3 rd of AF episodes would not be seen if 1 month holter monitoring is used, compared with continuous monitoring

Atrial Fibrillation Burden and Short-Term Risk of Stroke

Case-Crossover Analysis of Continuously Recorded Heart Rhythm From Cardiac Electronic Implanted Devices

Mintu P. Turakhia, MD, MAS; Paul D. Ziegler, MS; Susan K. Schmitt, PhD; Yuchiao Chang, PhD; Jun Fan, MS; Claire T. Than, MPH; Edmund K. Keung, MD; Daniel E. Singer, MD

we found that AF burden of ≥ 5.5 hours in a given day raised the short-term risk of stroke 4- to 5-fold. This risk was highest in the initial 5 to 10 days after the episode of AF and rapidly declined after longer periods.

Clinical Application & Benefit of Monitoring for AF

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Atrial Fibrillation Studies – CRYSTAL AF

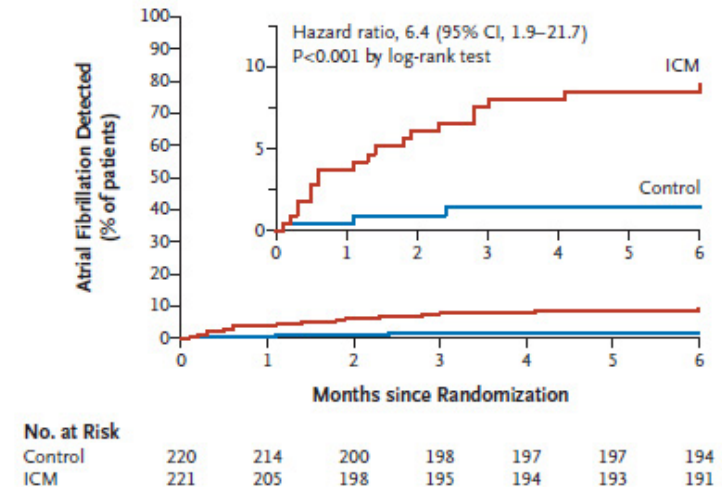
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

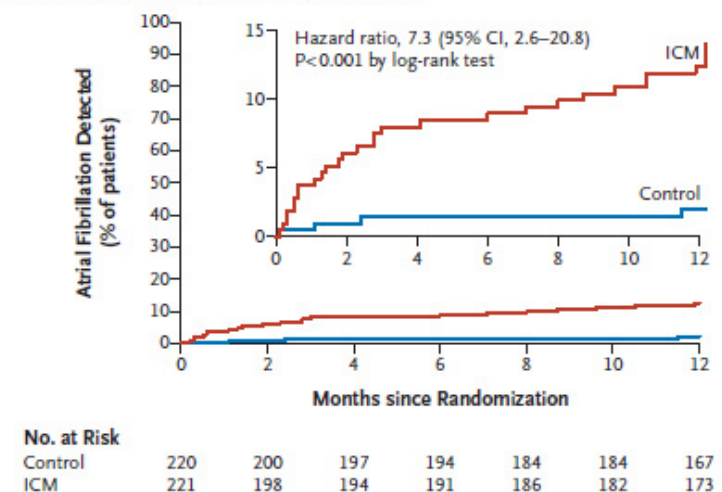
Cryptogenic Stroke and Underlying Atrial Fibrillation

Tommaso Sanna, M.D., Hans-Christoph Diener, M.D., Ph.D.,

A Detection of Atrial Fibrillation by 6 Months



B Detection of Atrial Fibrillation by 12 Months



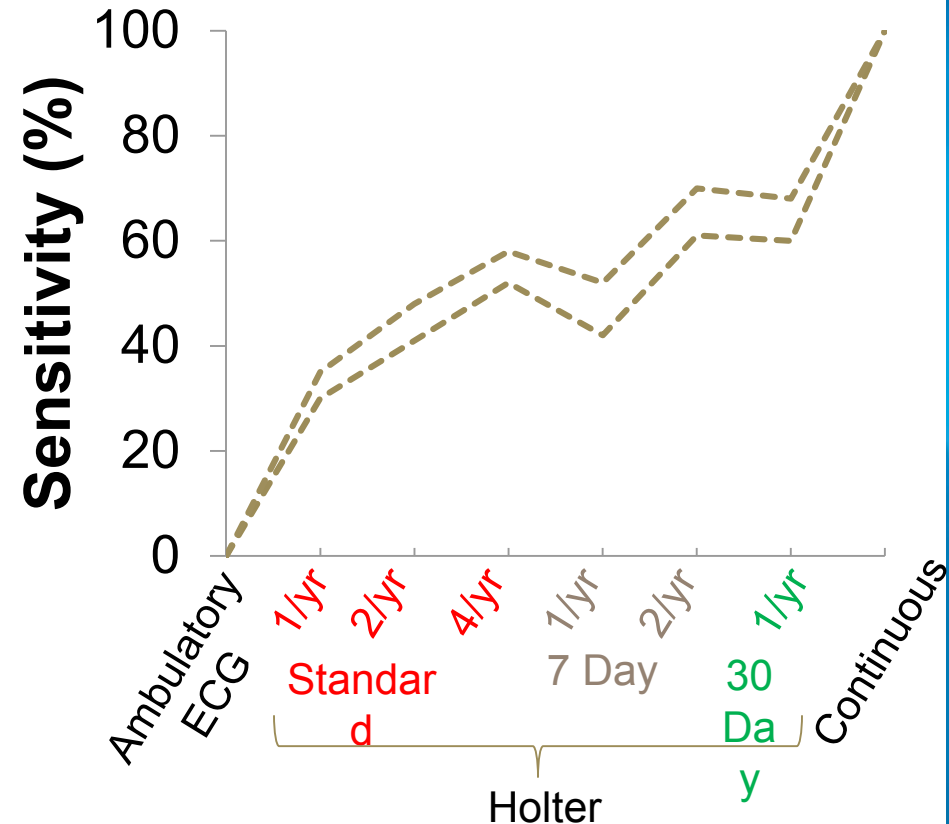
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Continuous Monitoring for Accurate AF Detection

- 568 pacemaker patients with continuous monitoring data available for 1 year were retrospectively analyzed.
- From a 365-day period of continuous monitoring period random 24h, 1 week and 30 day samples were taken.
- Continuous monitoring is more sensitive than intermittent strategies

Minimum and Maximum Sensitivity levels for different Monitoring Strategies

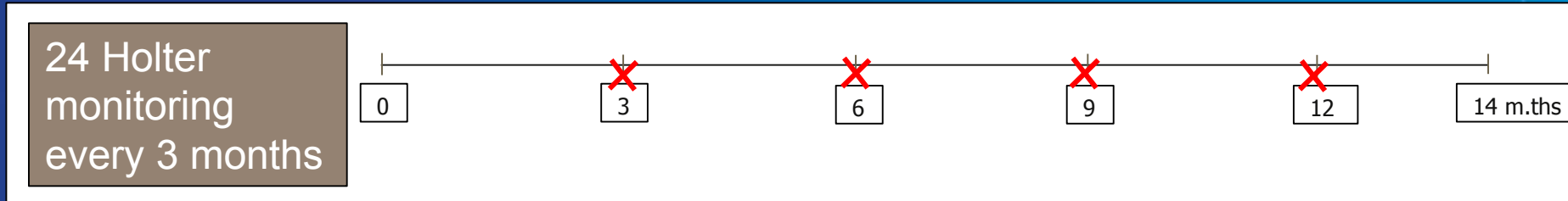
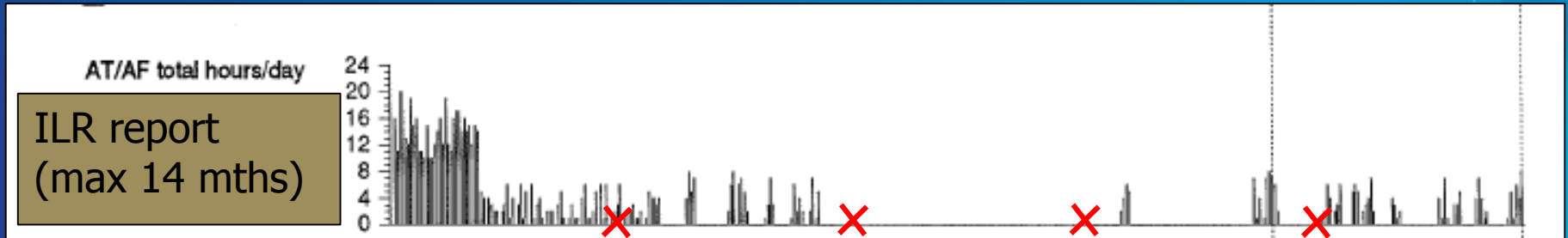


Botto GL, et al. J Cardiovasc Electrophysiol 2009; 20: 241-8

AMBULATORY ECG RECORDING VS IMPLANTABLE LOOP RECORDER IN DETECTION OF ATRIAL FIBRILLATION RECURRENCES AFTER PULMONARY VEINS ISOLATION

G. Rovaris et al.

ITALY; *progress in clinical pacing* 2012.



The Relationship Between Daily Atrial Tachyarrhythmia Burden From Implantable Device Diagnostics and Stroke Risk

The TRENDS Study

Taya V. Glotzer, MD; Emile G. Daoud, MD; D. George Wyse, MD, PhD; Daniel E. Singer, MD; Michael D. Ezekowitz, MD, PhD; Christopher Hilker, MS; Clayton Miller, BS; Dongfeng Qi, PhD; Paul D. Ziegler, MS

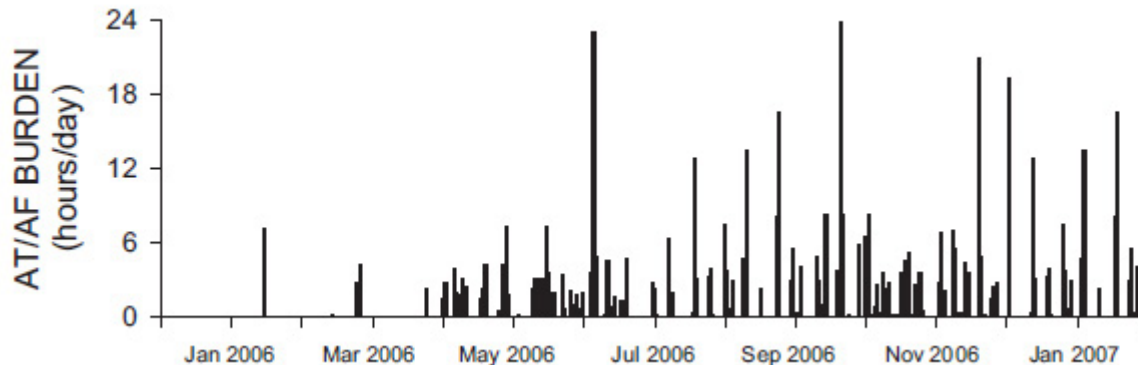


Figure 1. Example of long-term continuous recording of AT/AF burden data from an implantable device. Each black vertical line represents the total hours of AT/AF on each day.

Table 2. TE Rates for the Overall Study Group (Unadjusted)

AT/AF Burden Subset	Annualized TE Rate (95% CI), %	Annualized TE Rate Excluding TIAs (95% CI), %
Zero AT/AF burden	1.1 (0.8–1.6)	0.5 (0.3–0.9)
Low AT/AF burden (<5.5 h)	1.1 (0.4–2.8)	1.1 (0.4–2.8)
High AT/AF burden (≥5.5 h)	2.4 (1.2–4.5)	1.8 (0.9–3.8)

Atrial Fibrillation Studies – SOS AF

European Heart Journal Advance Access published December 11, 2013



EUROPEAN
SOCIETY OF
CARDIOLOGY®

European Heart Journal
doi:10.1093/eurheartj/ehs491

CLINICAL RESEARCH

Atrial fibrillation

Device-detected atrial fibrillation and risk for stroke: an analysis of >10 000 patients from the SOS AF project (Stroke preventiOn Strategies based on Atrial Fibrillation information from implanted devices)

Giuseppe Boriani^{1*}, Taya V. Glotzer², Massimo Santini³, Teena M. West⁴, Mirko De Melis⁴, Milan Sepsi⁵, Maurizio Gasparini⁶, Thorsten Lewalter⁷, John A. Camm⁸, and Daniel E. Singer⁹

Atrial Fibrillation Studies – SOS AF

- 24% of AF >5 min at 3months and 43% of AF >5 min at 24months

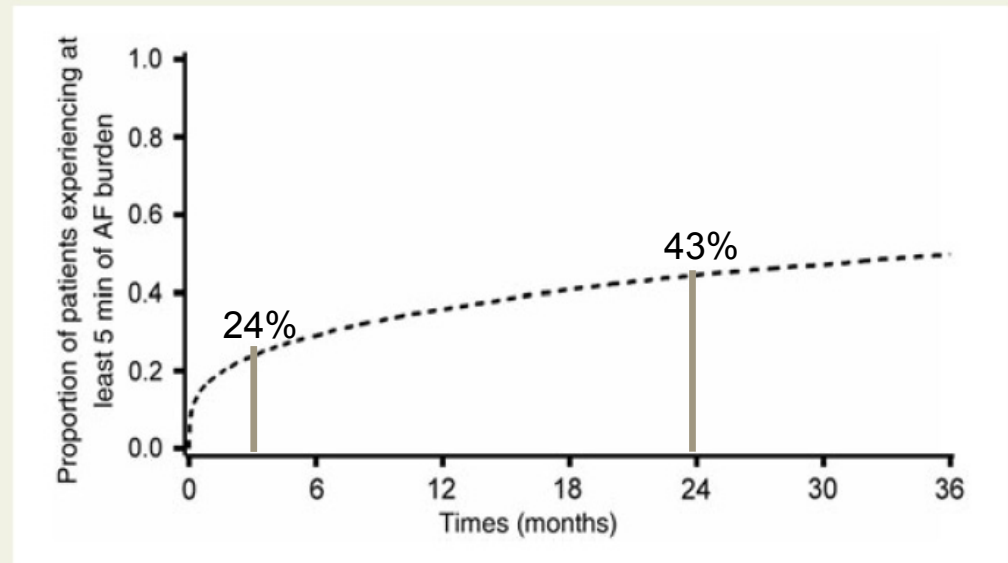
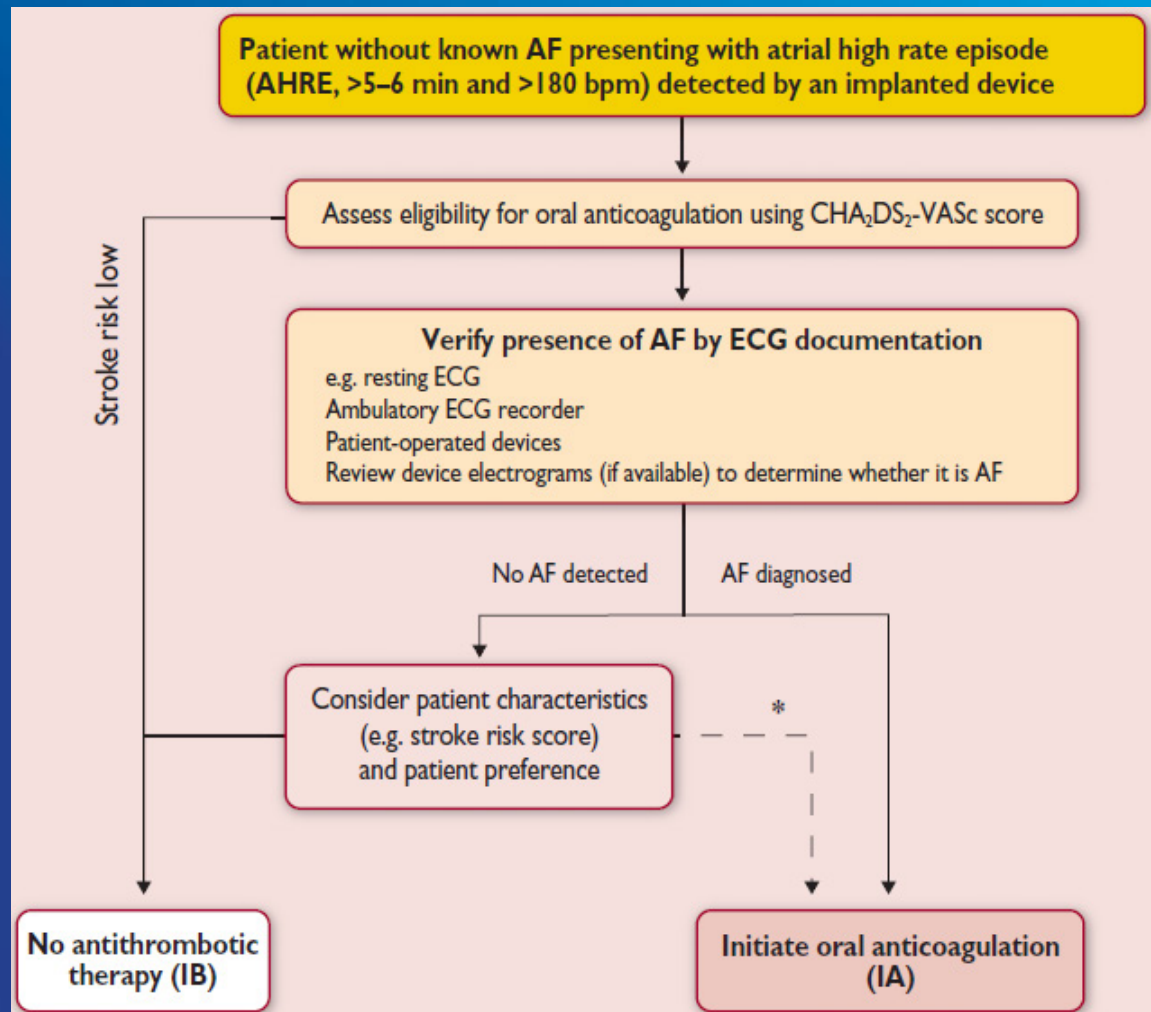


Figure 1 Atrial fibrillation burden along with time during the follow-up. Kaplan–Meier curve of patients experiencing a first day with at least 5 min of atrial fibrillation burden, among all subjects ($n = 10\,016$).

2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS

The Task Force for the management of atrial fibrillation of the European Society of Cardiology (ESC)



Recommendations for screening for atrial fibrillation

Recommendations	Class ^a	Level ^b	Ref ^c
Opportunistic screening for AF is recommended by pulse taking or ECG rhythm strip in patients >65 years of age.	I	B	130, 134, 155
In patients with TIA or ischaemic stroke, screening for AF is recommended by short-term ECG recording followed by continuous ECG monitoring for at least 72 hours.	I	B	27, 127
It is recommended to interrogate pacemakers and ICDs on a regular basis for atrial high rate episodes (AHRE). Patients with AHRE should undergo further ECG monitoring to document AF before initiating AF therapy.	I	B	141, 156
In stroke patients, additional ECG monitoring by long-term non-invasive ECG monitors or implanted loop recorders should be considered to document silent atrial fibrillation.	IIa	B	18, 128
Systematic ECG screening may be considered to detect AF in patients aged >75 years, or those at high stroke risk.	IIb	B	130, 135, 157

Recommendations for prediction of stroke and bleeding risk

Recommendations	Class ^a	Level ^b	Ref ^c
The CHA ₂ DS ₂ -VASc score is recommended for stroke risk prediction in patients with AF.	I	A	368, 371, 386
Bleeding risk scores should be considered in AF patients on oral anticoagulation to identify modifiable risk factors for major bleeding.	IIa	B	384, 386, 387, 389–392
Biomarkers such as high-sensitivity troponin and natriuretic peptide may be considered to further refine stroke and bleeding risk in AF patients.	IIb	B	380–382, 387, 393

Performance of Atrial Fibrillation Detection in a Single Lead ICD

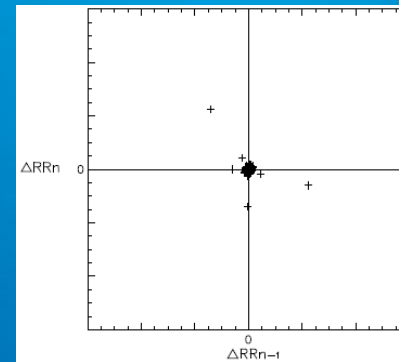
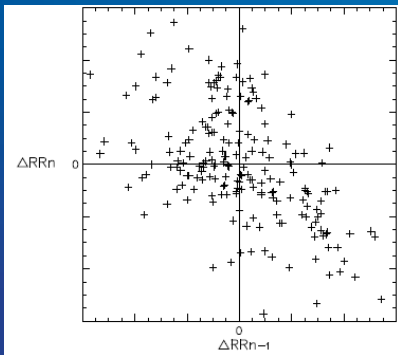
Dr. G Rovaris¹, Brian Schousek², Mark Brown², Dr. Paul Friedman³

¹S.Gerardo H. Italy, ²Medtronic plc, Dublin, Ireland, ³Mayo Clinic

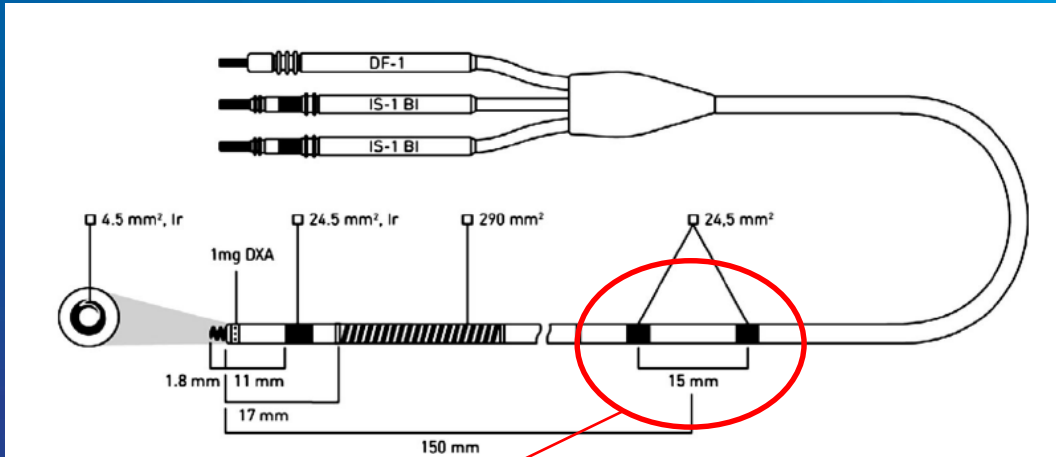
Detection Threshold	Mean Pt Duration Sensitivity	Mean Pt Duration Specificity	No. Pts.	Gross Sensitivity	Gross Specificity	No. Records
6 minutes	93.3%	97.0%	70	93.2%	99.8%	84
10 minutes	90.8%	96.9%	66	91.7%	99.8%	80
20 minutes	89.8%	96.8%	64	89.9%	99.8%	73
30 minutes	73.1%	96.6%	61	88.1%	99.8%	70

The AF detection algorithm adapted for use in single chamber ICDs provides excellent duration sensitivity and specificity. This may permit early AF detection with better outcomes for patients. The ability to allow AF detection using standard, approved, reliable single chamber leads may add clinical benefit.

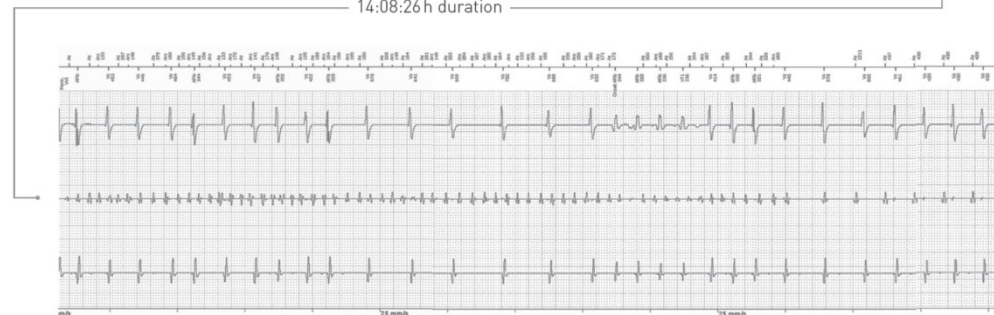
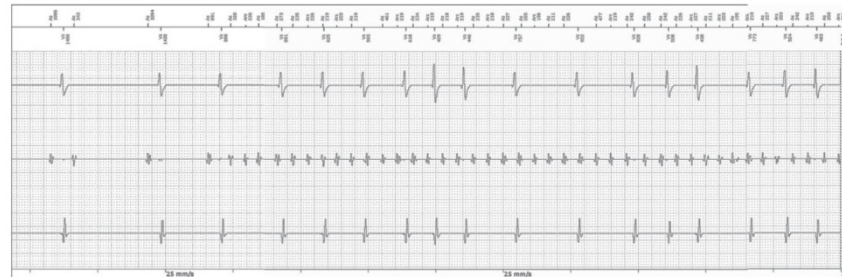
SINGLE CHAMBER ICD: VISIA AF



SINGLE CHAMBER DX



**Dipolo flottante atriale
montato 150/170mm
dalla punta**



Implant and Long-Term Evaluation of Atrial Signal Amplification in a Single-Lead ICD

FILIPPO STAZI, M.D.,*,† MASSIMO MAMPIERI, M.D.,* MARIO CARDINALE, M.D.,*
M. TERESA LAUDADIO, Ph.D.,‡ ALESSIO GARGARO, Ph.D.,§
and GIOVANNI BATTISTA DEL GIUDICE, M.D.*

From the *Department of Cardiology, San Giovanni Addolorata Hospital, Rome, Italy; †Centro per la Lotta contro l'Infarto (CLI) Foundation, Rome, Italy; ‡Gelmec s.r.l., Rome, Italy; and §Biotronik Italia, Rome, Italy

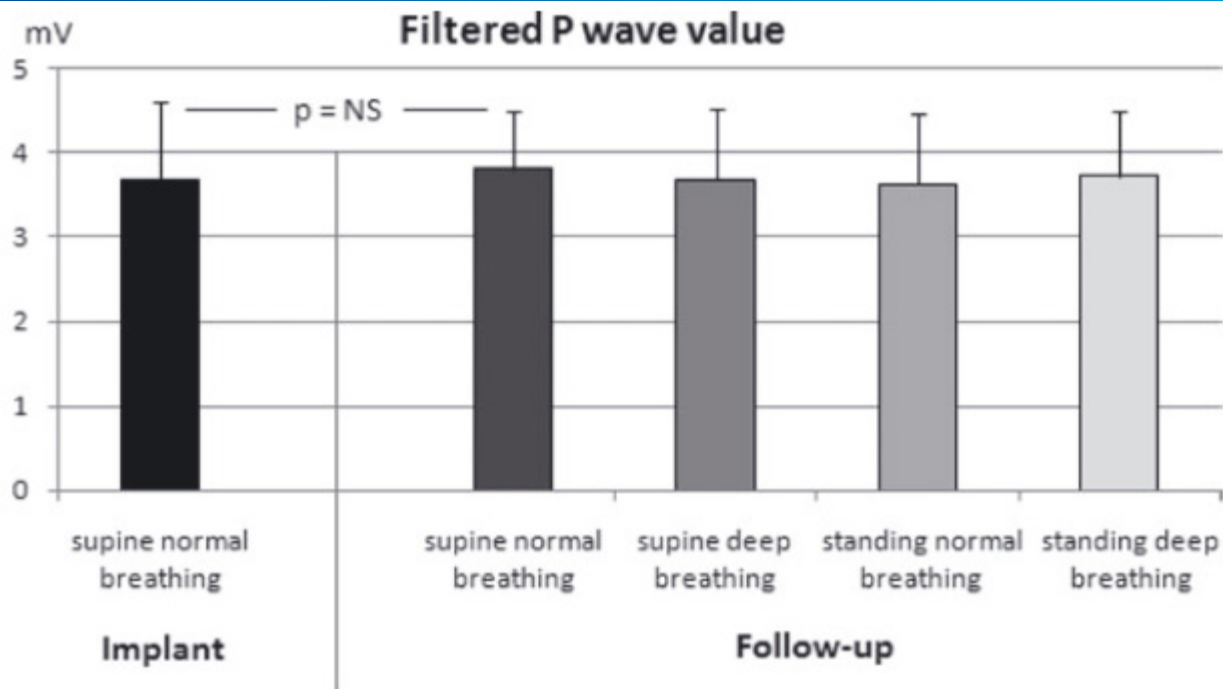
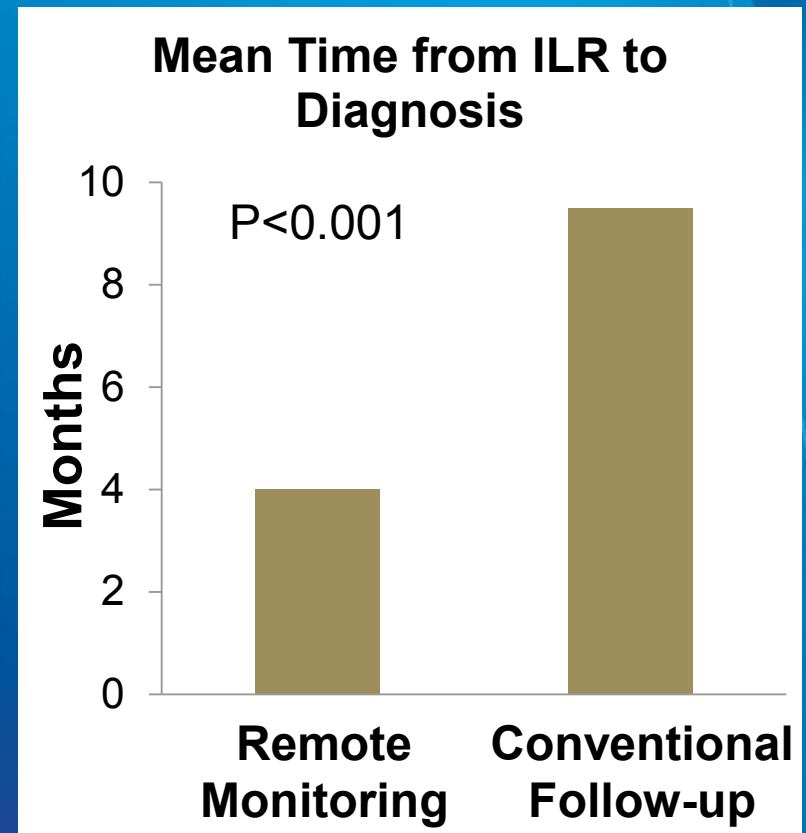


Figure 4. P-wave values detected by ICD at implant and at follow-up in different conditions: normal or deep breath, supine position or standing. Statistically significant differences were not found.

Earlier Diagnosis with Remote Monitoring

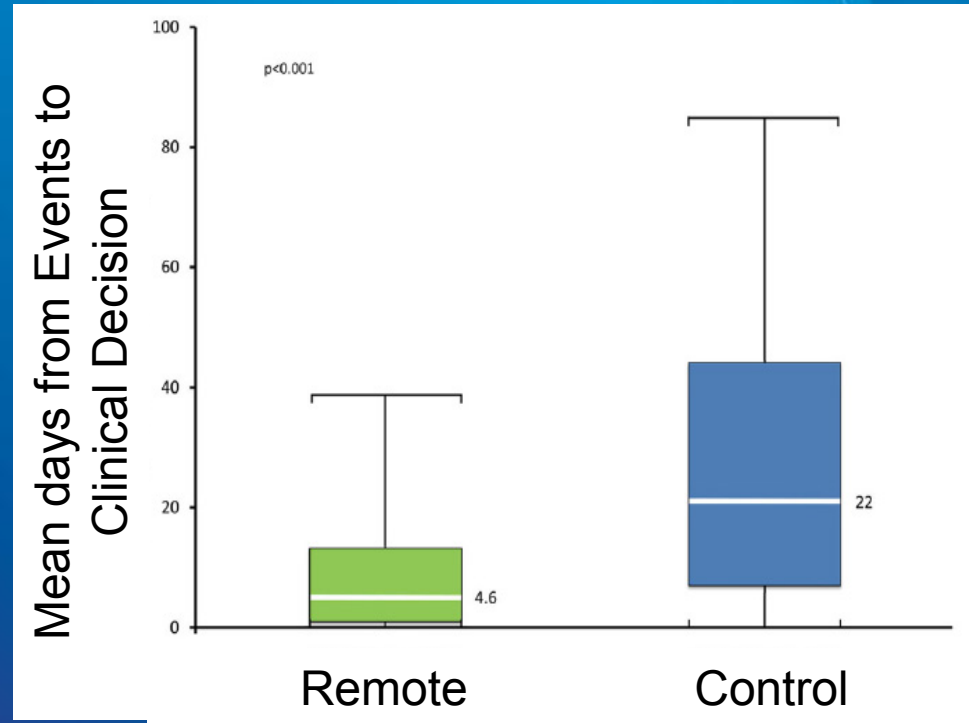
- 92 patients implanted with an ILR for unexplained syncope were retrospectively reviewed.
- 57 monitored by Carelink® remote monitoring and 35 by conventional in-hospital follow-up.
- 47% reduction in mean time from ILR to diagnosis in the remote monitored group.



Velu S, et al. Presented at Heart Rhythm Congress, 2012

Earlier Decision Making with Remote Monitoring

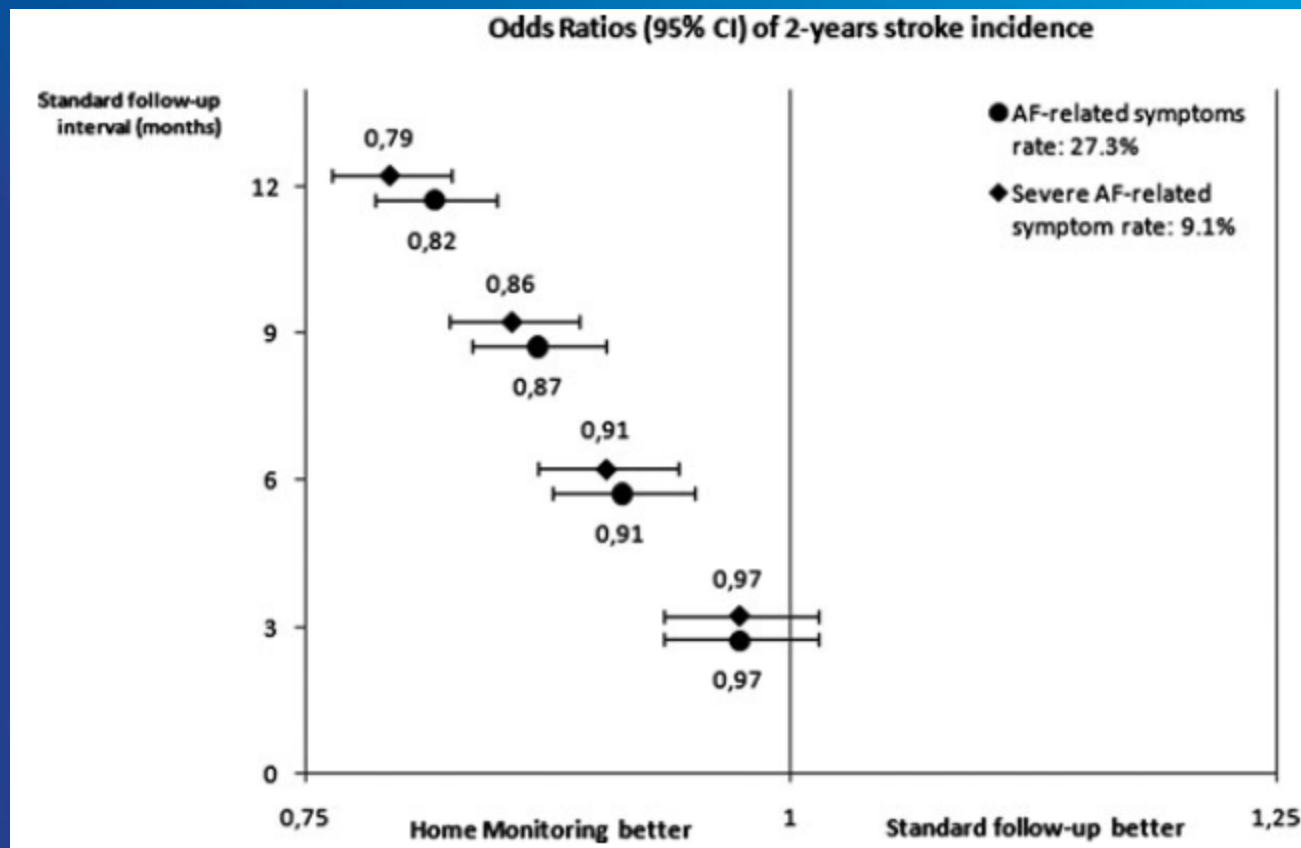
- The CONNECT Study
- 1997 ICD or CRT-D patients randomized
- The time from clinical event to clinical decision was compared in patients followed using wireless remote monitoring and standard in-office care
- Median time from clinical event to decision was reduced from 22 days to 4.6 days with remote monitoring.



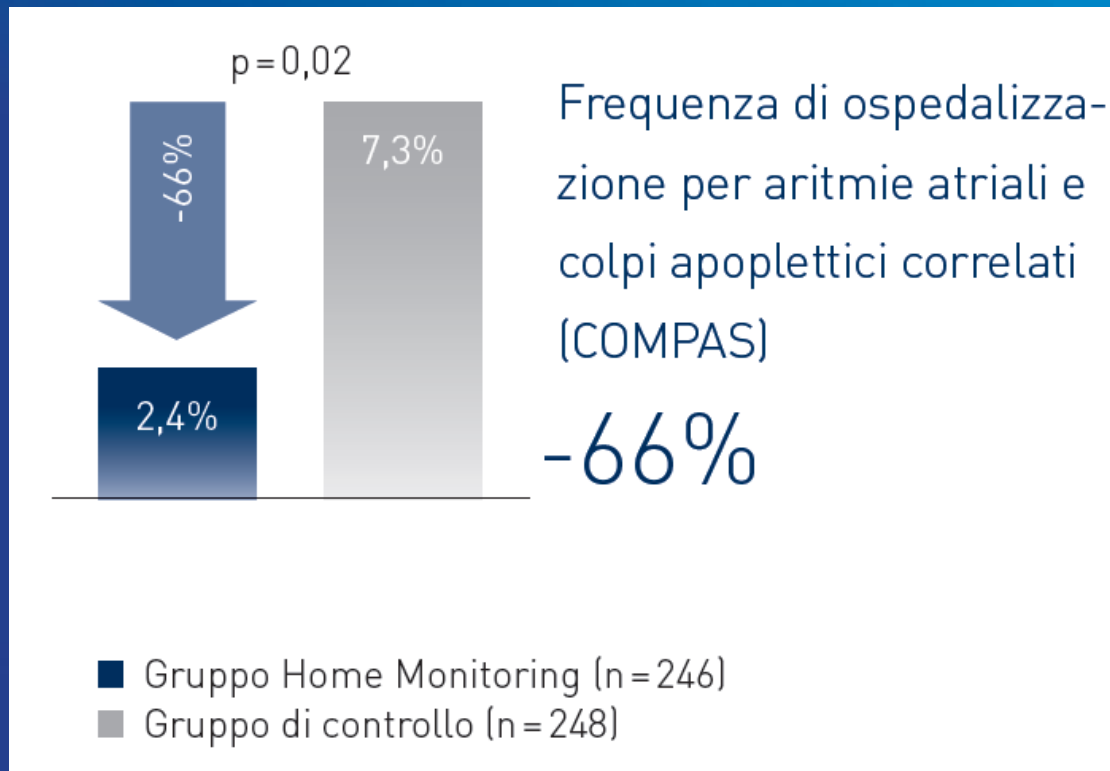
Crossley GH, et al. JACC 2011; 10: 1181-9

Home Monitoring in Patients with Implantable Cardiac Devices: Is There a Potential Reduction of Stroke Risk? Results from a Computer Model Tested Through Monte Carlo Simulations

RENATO P. RICCI, M.D.,* LOREDANA MORICHELLI, M.S.N.,* ALESSIO GARGARO, PH.D.†
MARIA T. LAUDADIO, PH.D.,† and MASSIMO SANTINI, M.D., F.A.C.C., F.E.S.C.*



Home monitoring decrease hospitalizations secondary to atrial tachycardias



CONCLUSIONS

SYMPTOMATIC AND ASYMPTOMATIC AF INCREASES PATIENTS RISK FOR STROKE

IT IS CRUCIAL TO DO A TIMELY DIAGNOSIS OF AF EVEN ASYMPTOMATIC

CONTINUOUS CARDIAC MONITORING AND REMOTE CONTROL REDUCES TIME TO DIAGNOSIS AND TREATMENT.

CONTINUOUS CARDIAC MONITORING AND REMOTE CONTROL DECREASE PATIENTS RISK FOR STROKE.

SINGLE-CHAMBER DEVICES WITH SPECIFIC ALGORITHMS FOR AF OR FLOATING BIPOLE IN RIGHT ATRIUM COULD BE ABLE TO REDUCE PATIENTS RISK FOR STROKE