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BENEFICI CLINICI ED ECONOMICI DEI DISPOSITIVI MEDICI IMPIANTABILI: REVISIONI LEGISLATIVE

UN PERCORSO POSSIBILE PER IL TRATTAMENTO DELLA FIBRILLAZIONE ATRIALE E DELL'*ICTUS* CARDIOEMBOLICO

Giovedì, 7 novembre 2013
ore 8.30 – 14.00

CAMERA DEI DEPUTATI
Palazzo Marini – Sala delle Colonne

Gianluca Botto, MD, FACC, FESC, FANMCO
UOS di Elettrofisiologia, Ospedale Sant' Anna, Como
Presidente Eletto Associazione Italiana Aritmologia e Cardiostimolazione (A.I.A.C.)

AF Confers a Prothrombotic and Hypercoagulable State by Fulfilling the Components of Virchow's Triad

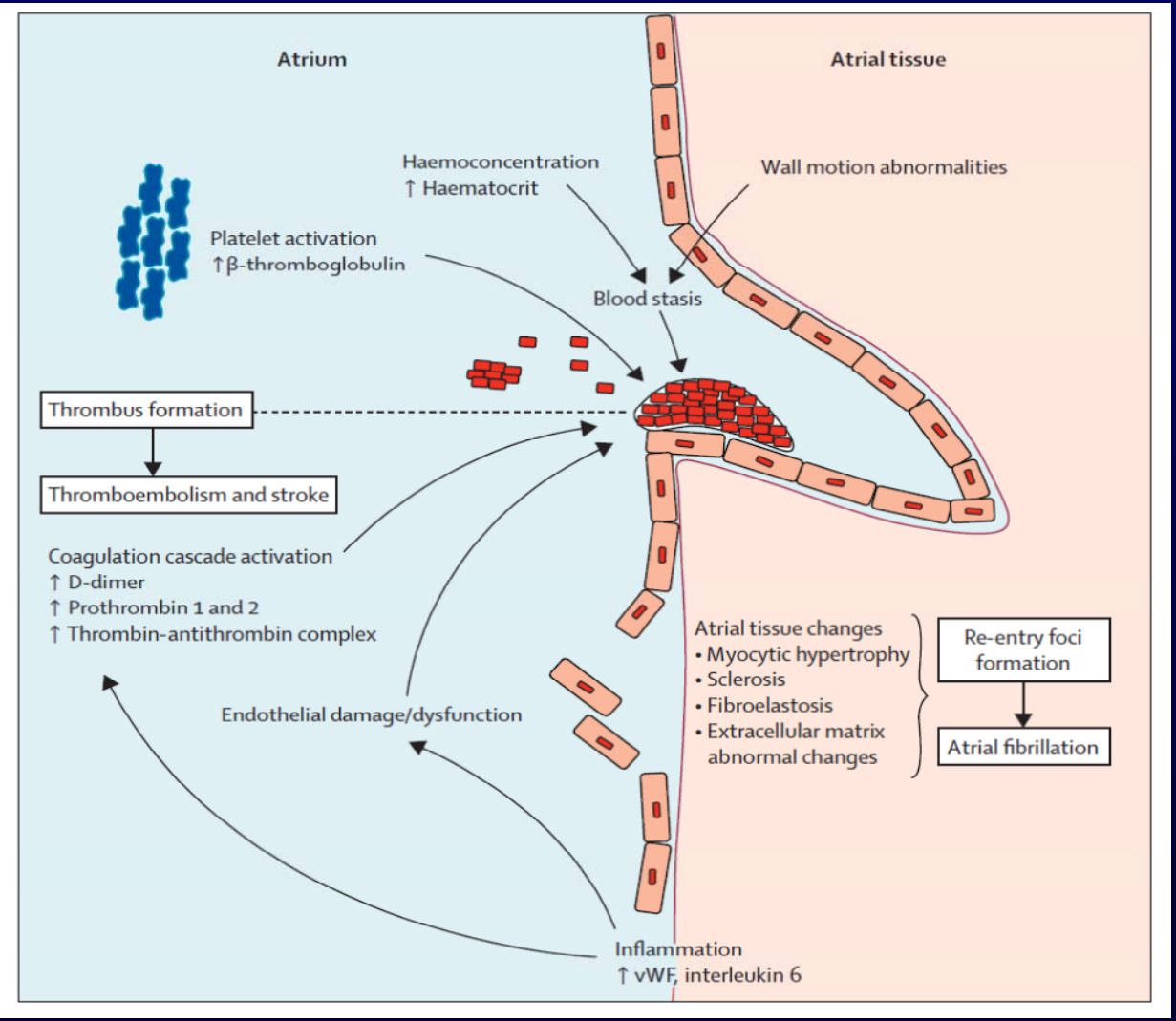
1855

Abnormal changes of:

- vessel wall
- blood flow
- blood constituents

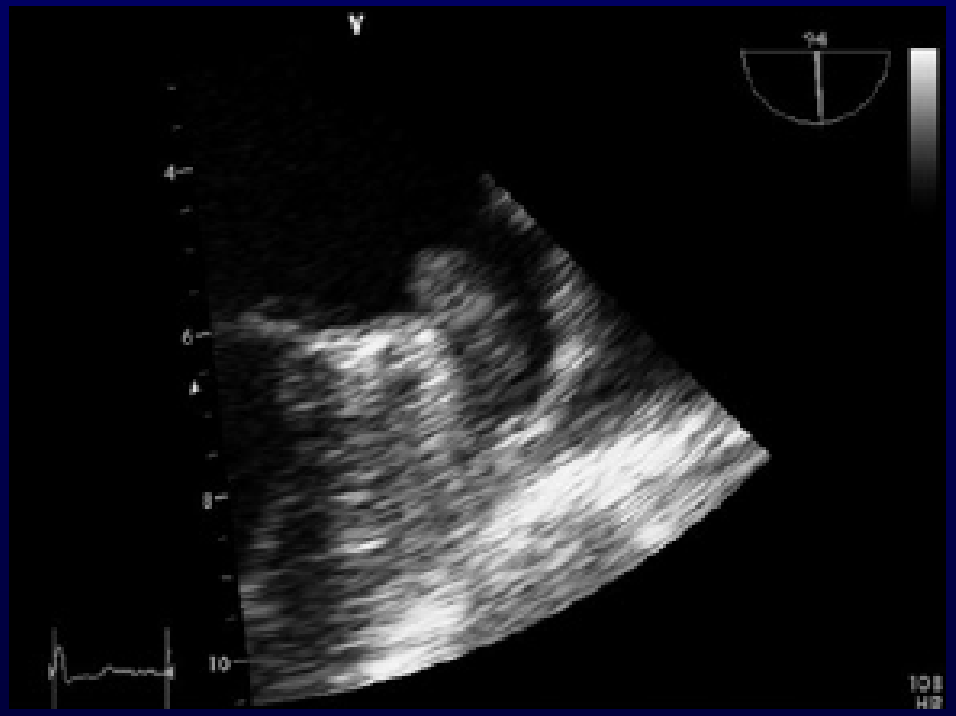
2009

- macro or microscopic changes in the LA wall
- abnormal stasis due to the loss of A function
- abnormal haemostasis, platelets and fibrinolysis



Watson T, Shantsila E, Lip G. Lancet 2009: 373: 155-166

Stroke in the Territory of MCA as a First Devastating Sign of Atrial Fibrillation



AF increases of stroke risk 4-5 fold

Acute Stroke With AFIB

The Copenhagen Stroke Study

➔ 15% of all strokes attributable to AFIB

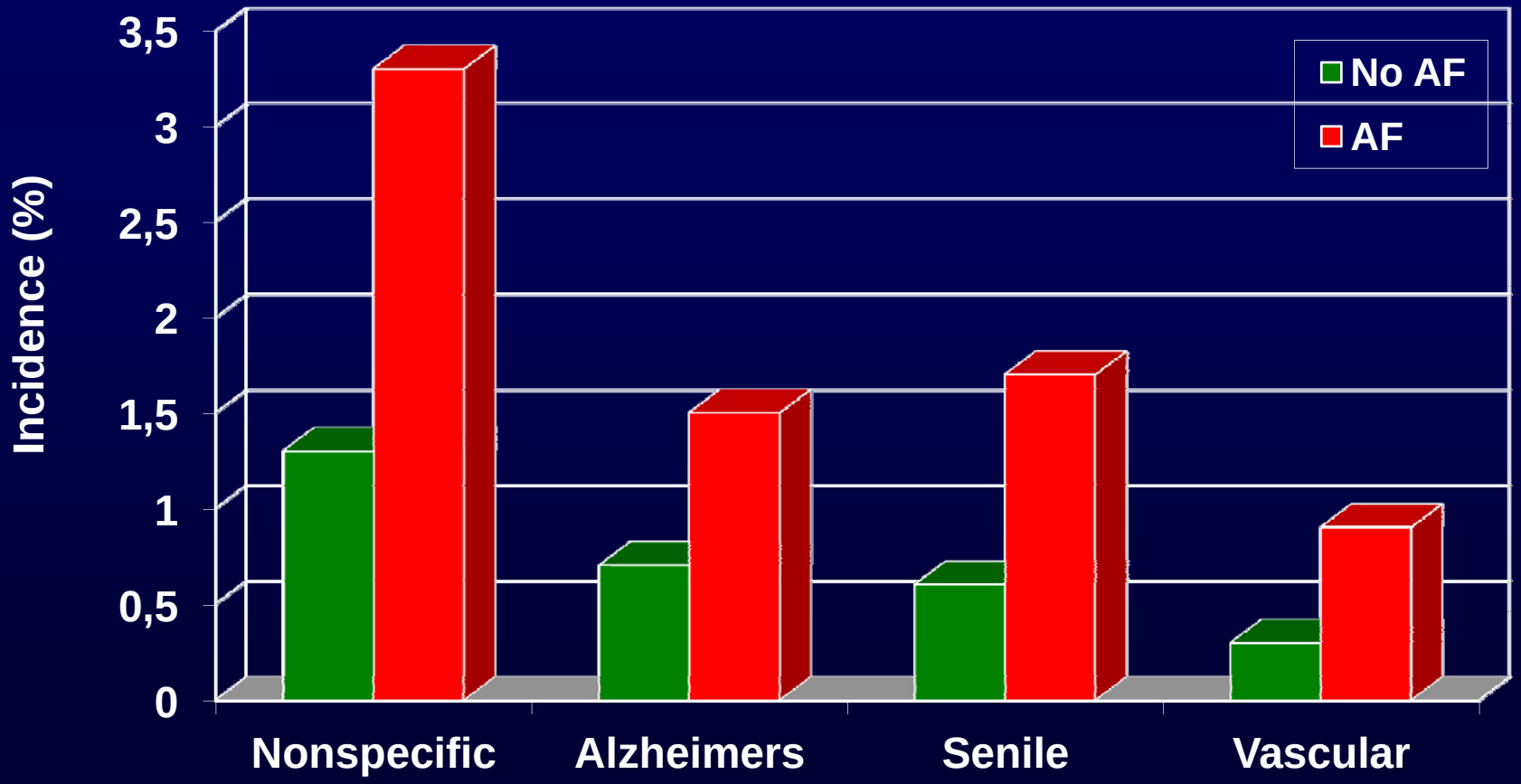
Stroke in pts with AFIB vs w/out-AFIB

- Higher mortality rate
  (OR 1.7; 95% CI 1.2-2.5)
- Longer hospital stay
  (50 vs 40 days; p<0.01)
- Lower discharge rate
  (OR 0.60; 95% CI 0.44-0.85)
- Poorer neurologic and functional outcome

➔ Explained by initially more severe strokes

Stroke 1996; 27: 1765-1769

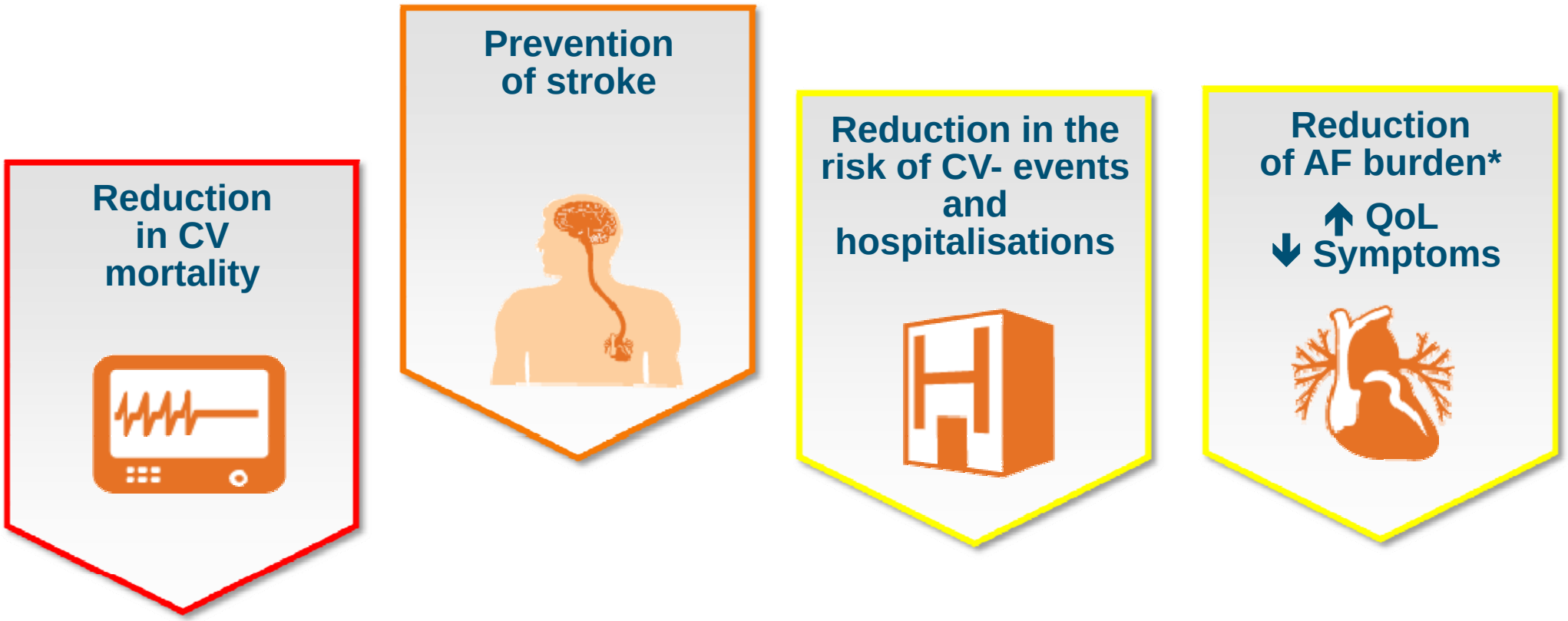
Higher Incidence of Various Type of Dementia in AF Patients



Bunch TJ. Heart Rhythm 2010; 7: 433-437

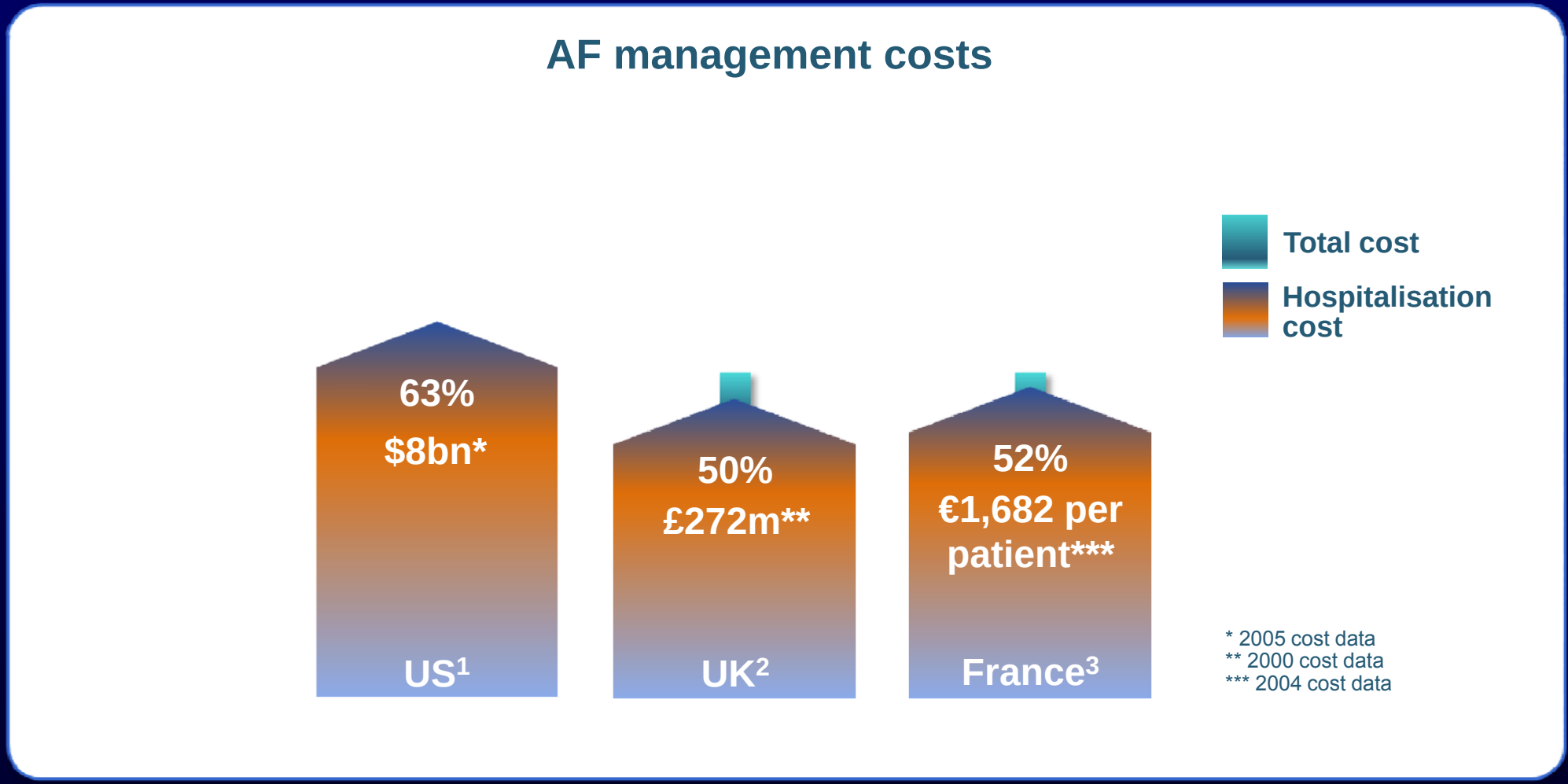
Comprehensive Management Of AF Should Address The Multiple Impacts Of The Condition

- In addition to stroke prevention and reduction of AF burden, successful management of AF should aim to reduce hospitalisations and CV morbidity and mortality



Camm AJ, Eur Heart J 2012;33:2719-2747

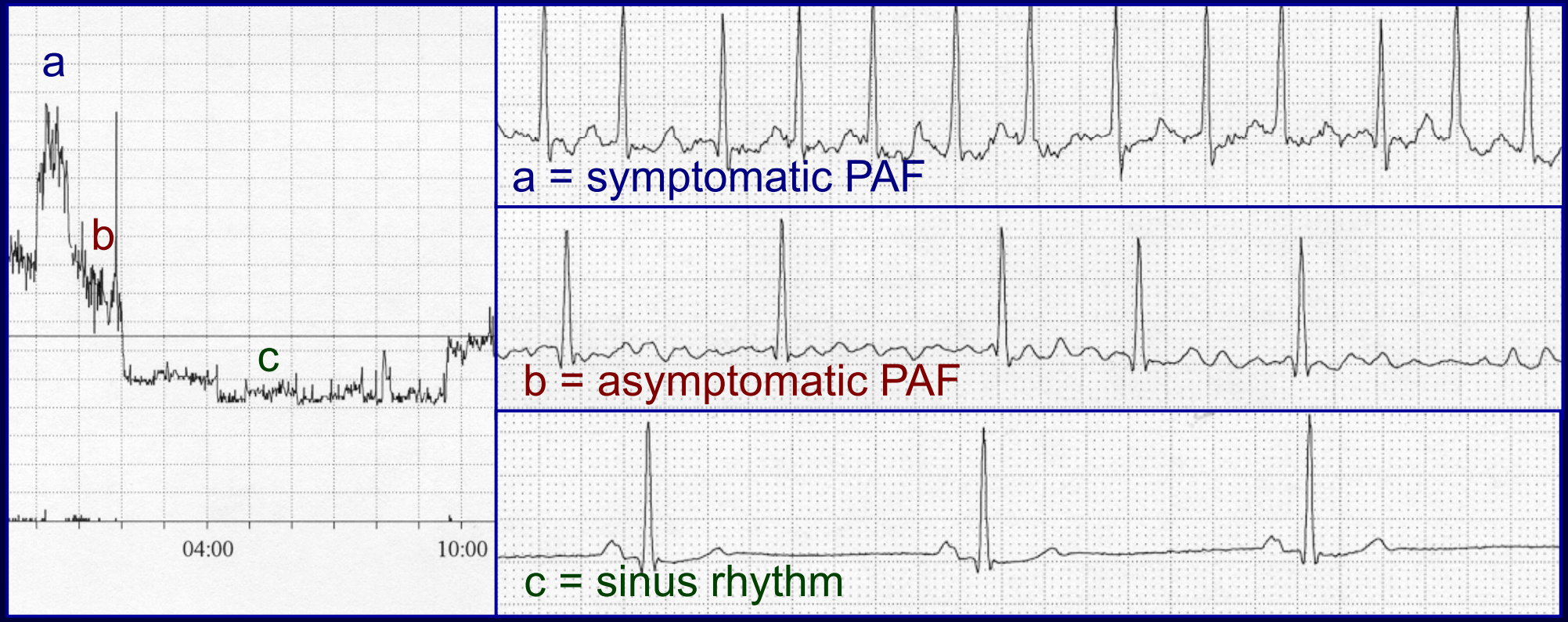
Hospitalisation Is The Biggest Contributor To The Cost Of Managing AF



1. Kim MH. Adv Ther 2009; 26: 847–57
2. Stewart S. Heart 2004; 90: 2086–292
3. Le Heuzey JY. Am Heart J 2004; 147: 121–6

Paroxysmal Atrial Fibrillation

Symptomatic vs Asymptomatic



AF can be silent

Conversion From Symptomatic to Silent AF During AAD Rx

52 patients with PAF with 24 hour Holter

No symptoms

Symptomatic

AF duration at baseline (s)
2215 +/- 3843

HR at baseline (bpm)
126 +/- 27

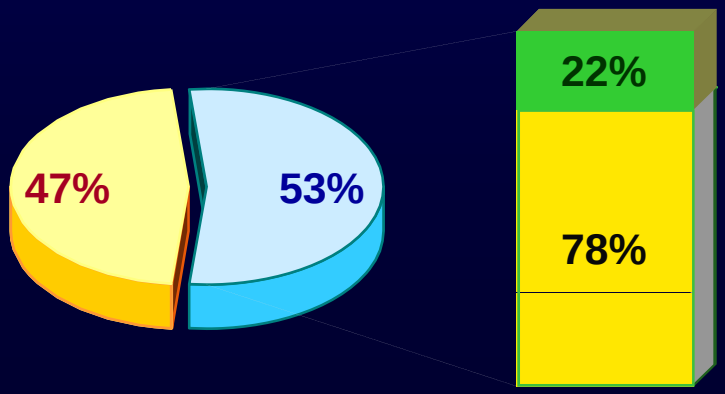
AF duration on treatment (s)
16 +/- 10

HR on treatment (bpm)
82 +/- 8

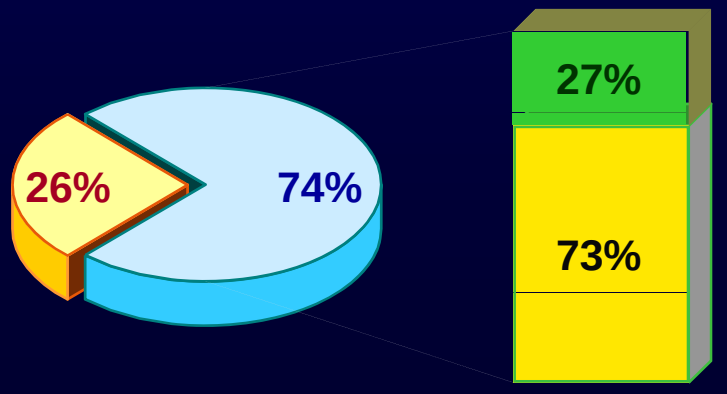
No PAF on Holter

PAF on Holter

Before



After



Wolk R. Int J: Cardiol 1996; 54: 207-211

The Clinical Relevance of Silent AF

Substudy of The AFFIRM Trial

- Ambulatory ECG & Questionnaire on Cardiac Symptoms
- N° 481asymptomatic pts
- Pts with asymptomatic AF have less serious heart disease but more cerebrovascular disease.
- Asymptomatic pts receive different therapies than symptomatic patients
- Absence of symptoms and the differences in treatment does not confer a more favorable prognosis when differences in baseline clinical parameters are considered.

Table I. Demographics and patient history prior to randomization

	Asymptomatic	Symptomatic	*P* value
N	481	3576	
Age (mean ± SD)	70.0 ± 8.3	69.7 ± 9.0	.502
Gender, men	370 (77)	2095 (59)	<.0001
Coronary artery disease	137 (28)	1413 (40)	<.0001
Congestive heart failure	64 (13)	873 (24)	<.0001
Hypertension	327 (68)	2547 (71)	.14
Cardiomyopathy	30 (6)	310 (9)	.07
Valvular heart disease	56 (12)	446 (12)	.6
Stroke or transient ischemic attack	84 (17)	457 (13)	.005

Flaker (the AFFIRM Investigators). Am Heart J 2005; 149: 657-63

Relation B/ween Symptoms and ECG Transmission in AF

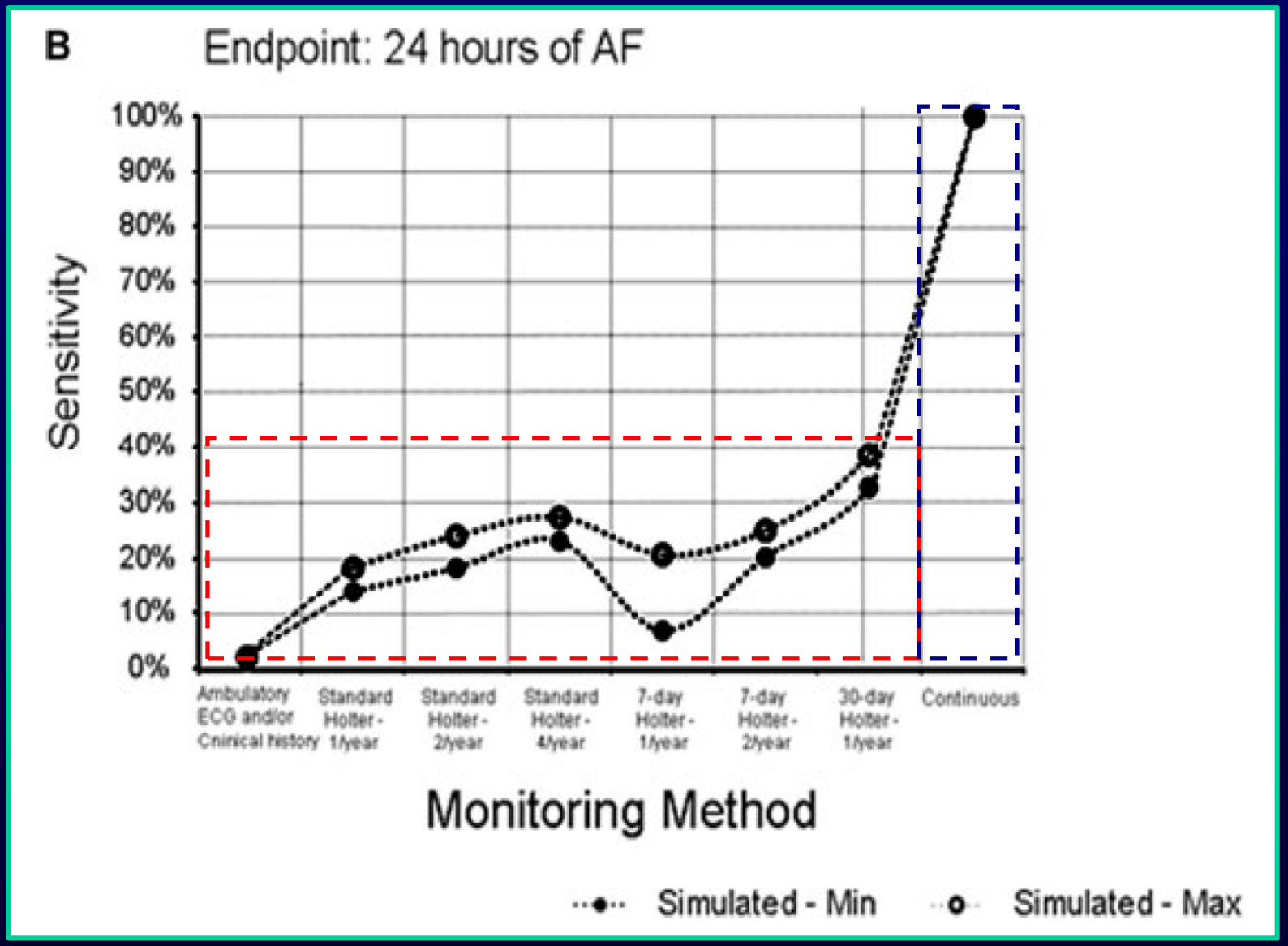
TABLE 1

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)			

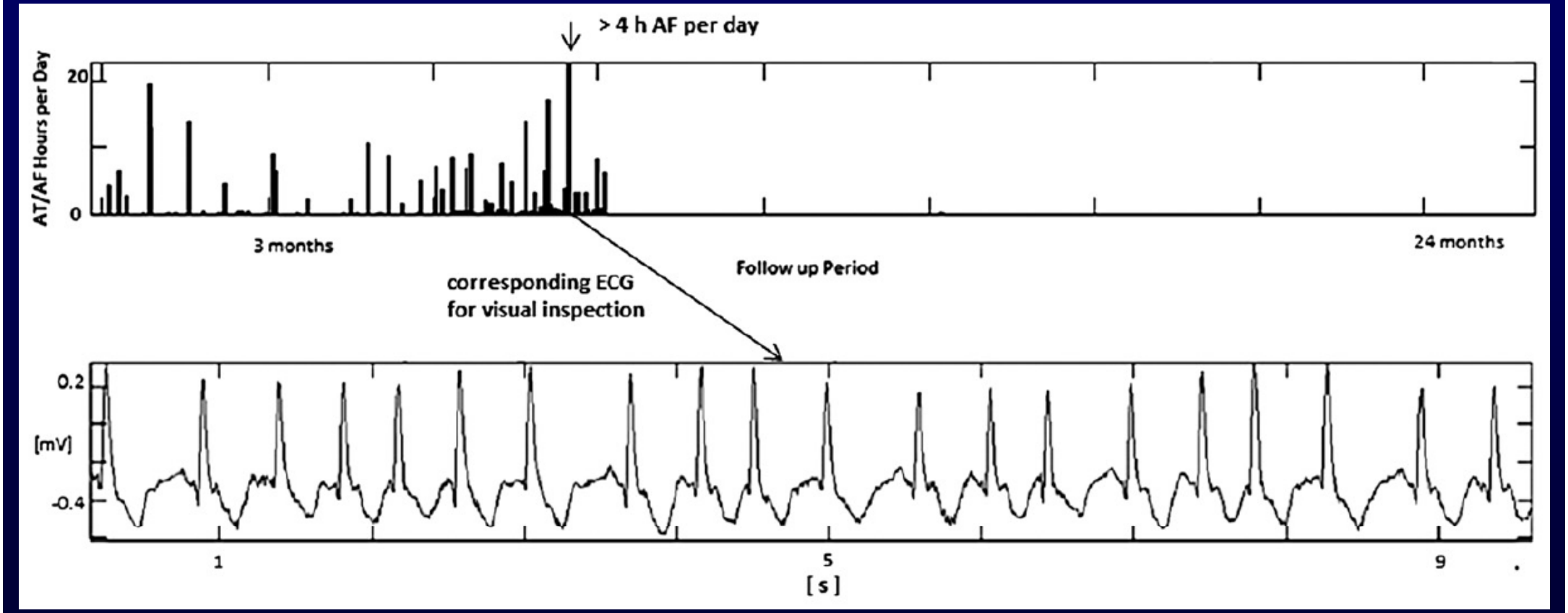
Vesamreddy et al. J Cardiovasc Electrophysiol 2006; 17: 134-139

Different Monitoring Methods to Detect AF



Botto GL. JCE. 2009;20:241-248

Example of Cardiac Compass
(Medtronic Inc. ®)



Courtesy of John Camm

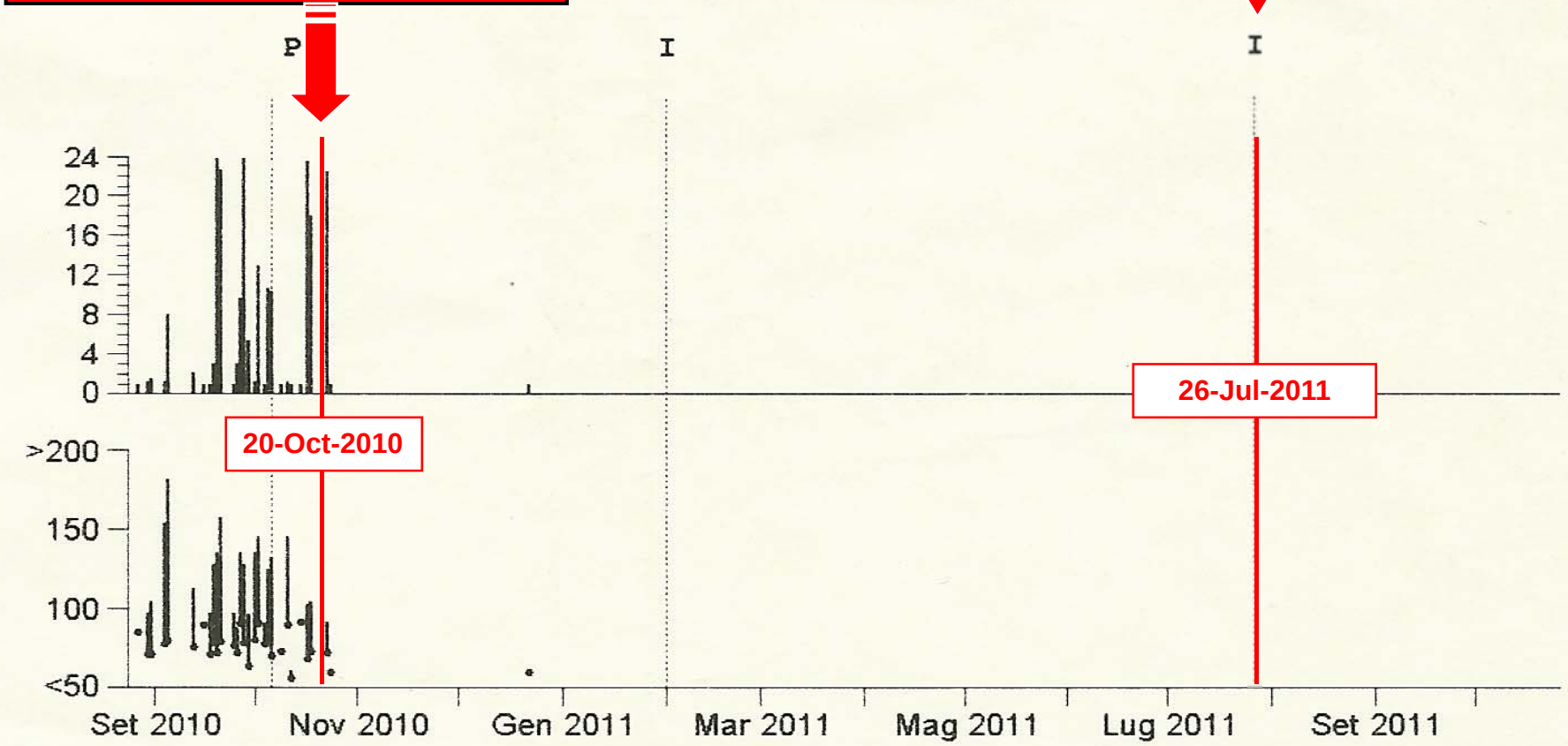
Dispositivo: **Advisa DR MRI A3DR01**
Num. di serie: **PZK604569S**

Data della visita: **26-Lug-2011 18:41:39**
9987 Version software 7.2

Rapporto del Cardiac Compass

P = Programm.
I = Interrog.
_ = Remote View

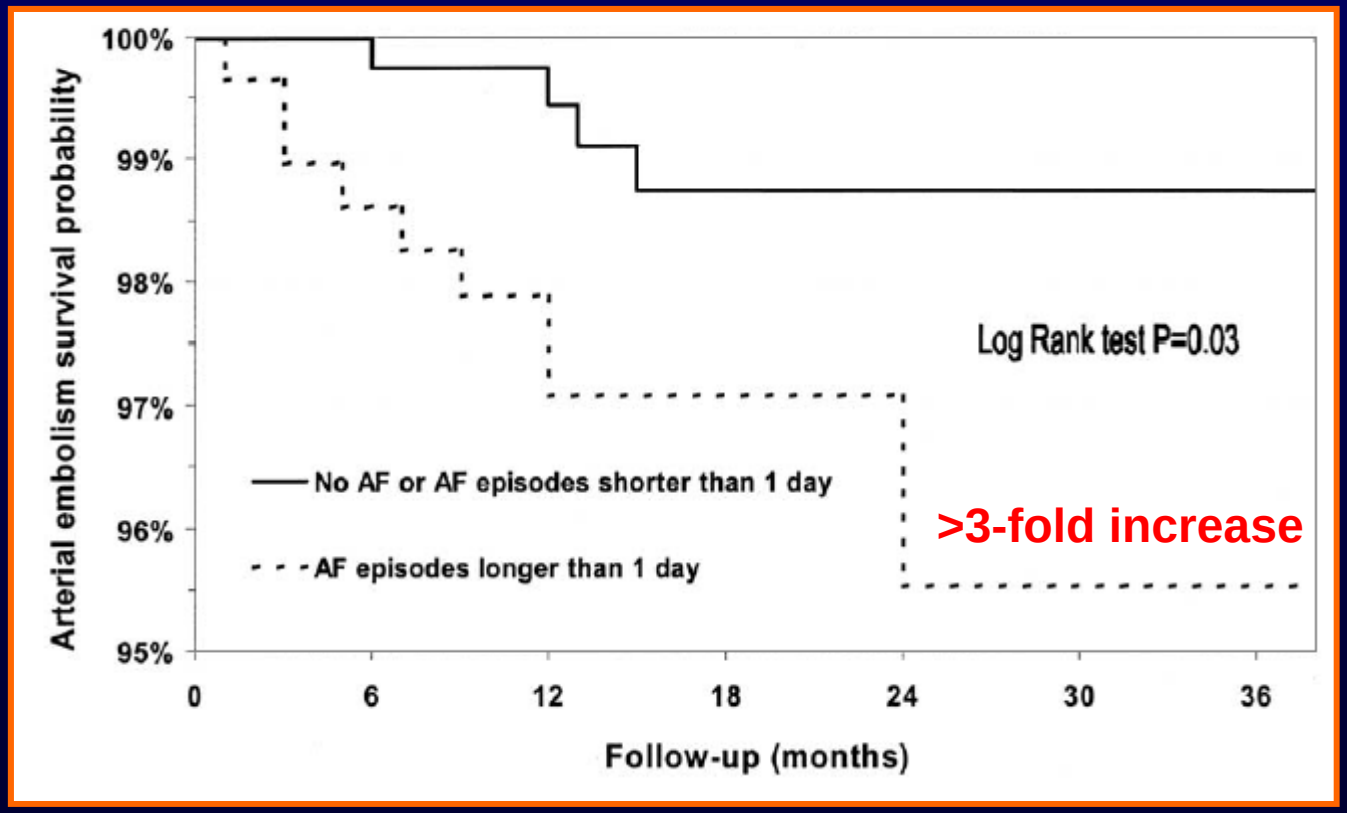
DRONEDARONE STARTED HERE



AF Monitoring by Pacemaker

The Issue of Anticoagulant Rx

725 pts with brady-tachy syndrome, implanted with a MDT AT-500 ® followed for 2-ys

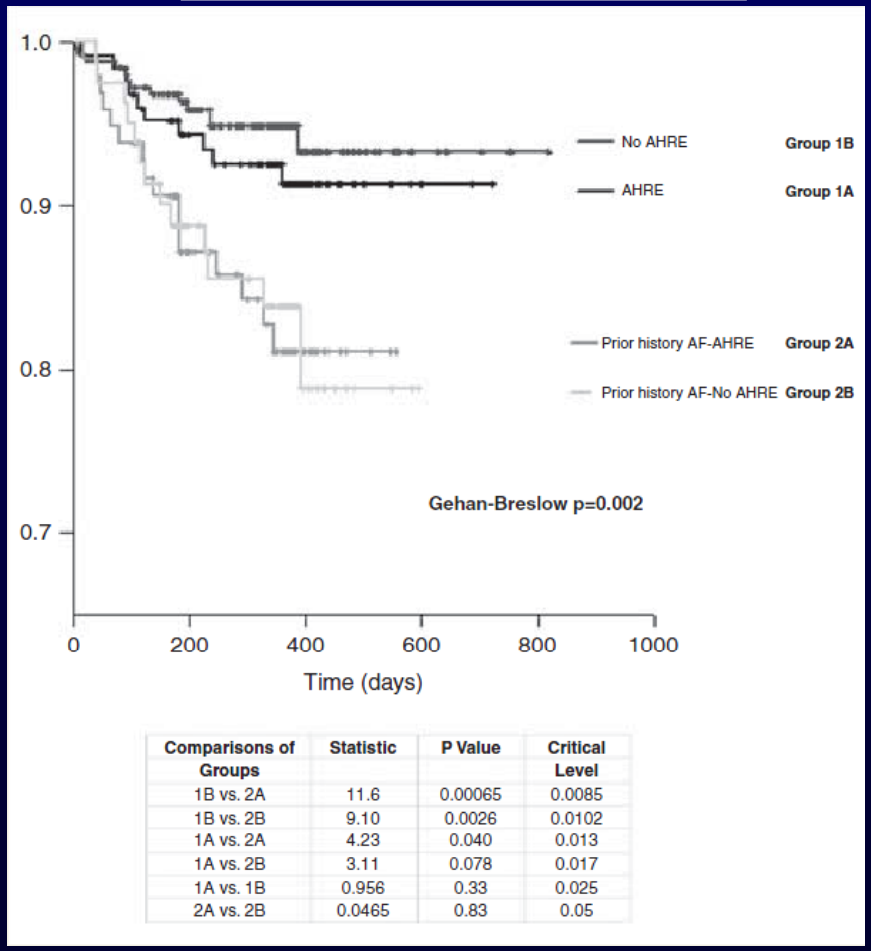


Capucci A, Botto GL, Padeletti L. JACC, 2005; 46: 1913-1920.

Detection Of AHRE (>180 bpm) By Continuous Home

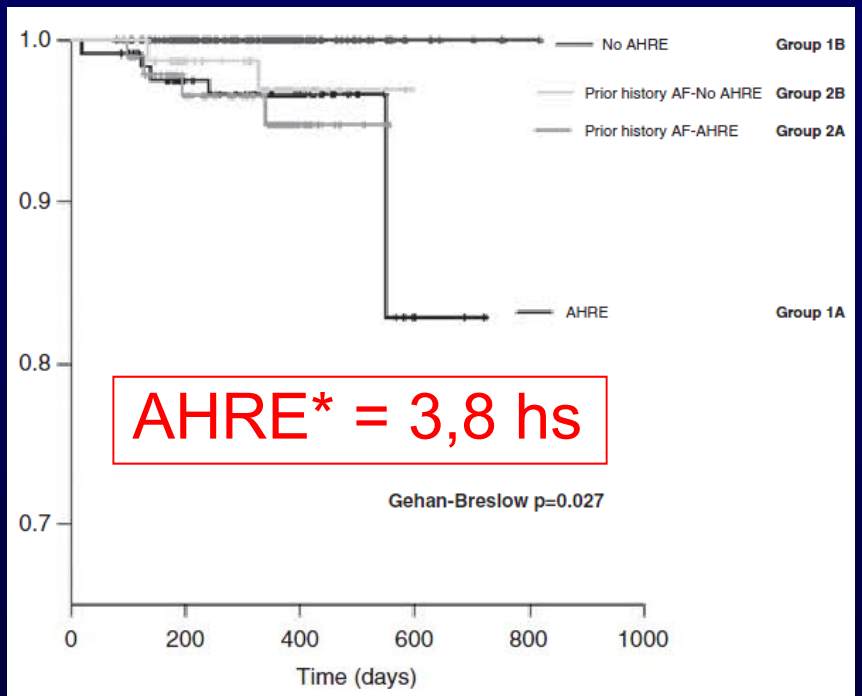
Monitoring Clinical Significance In The CRT Population

HF Hospitalization



Comparisons of Groups	Statistic	P Value	Critical Level
1B vs. 2A	11.6	0.00065	0.0085
1B vs. 2B	9.10	0.0026	0.0102
1A vs. 2A	4.23	0.040	0.013
1A vs. 2B	3.11	0.078	0.017
1A vs. 1B	0.956	0.33	0.025
2A vs. 2B	0.0465	0.83	0.05

Thromboembolic Events



Comparisons of Groups	Statistic	P Value	Critical Level
1B vs. 2A	10.6	0.0011	0.0085
1A vs. 1B	8.11	0.0044	0.0102
1B vs. 2B	5.83	0.016	0.013
2A vs. 2B	0.54	0.46	0.017
1A vs. 2B	0.153	0.70	0.025
1A vs. 2A	0.125	0.73	0.05

Shanmugam N. Europace 2012; 14, 230–237

Atrial Fibrillation

CHA_2DS_2VASc Score And Stroke Rate

Risk factor-based approach expressed as a point based scoring system, with the acronym CHA_2DS_2-VASc
(Note: maximum score is 9 since age may contribute 0, 1, or 2 points)

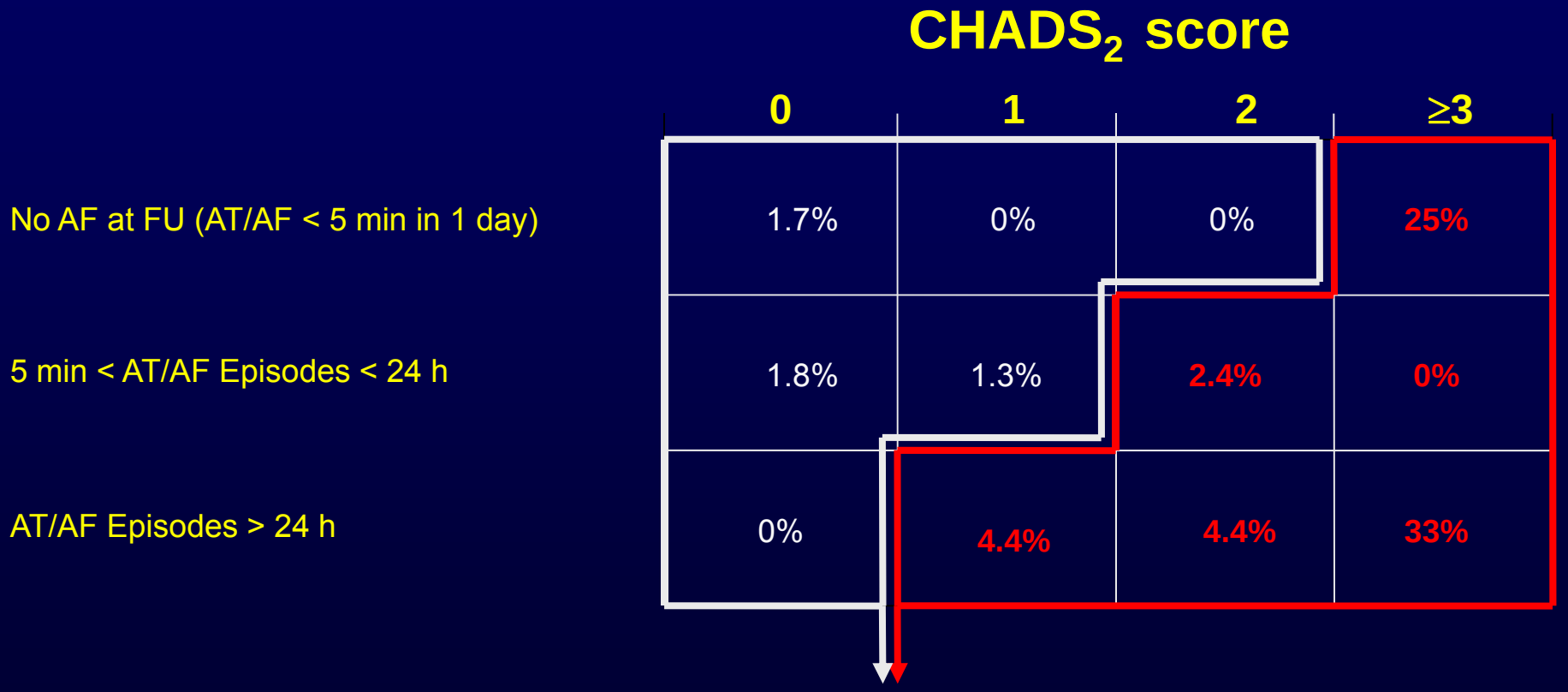
Risk factor	Score
Congestive heart failure/LV dysfunction	1
Hypertension	1
Age ≥75	2
Diabetes mellitus	1
Stroke/TIA/thrombo-embolism	2
Vascular disease[a]	1
Age 65–74	1
Sex category (i.e. female sex)	1
Maximum score	**9**

Adjusted stroke rate according to CHA_2DS_2-VASc score

CHA_2DS_2-VASc score	Patients (n=7329)	Adjusted stroke rate (%/year)[b]
0	1	0%
1	422	1.3%
2	1230	2.2%
3	1730	3.2%
4	1718	4.0%
5	1159	6.7%
6	679	9.8%
7	294	9.6%
8	82	6.7%
9	14	15.2%

CHADS2 Score, AF Duration and Stroke Risk

568 Pts with MDT AT500 IPG Continuously Monitored for 1 Year

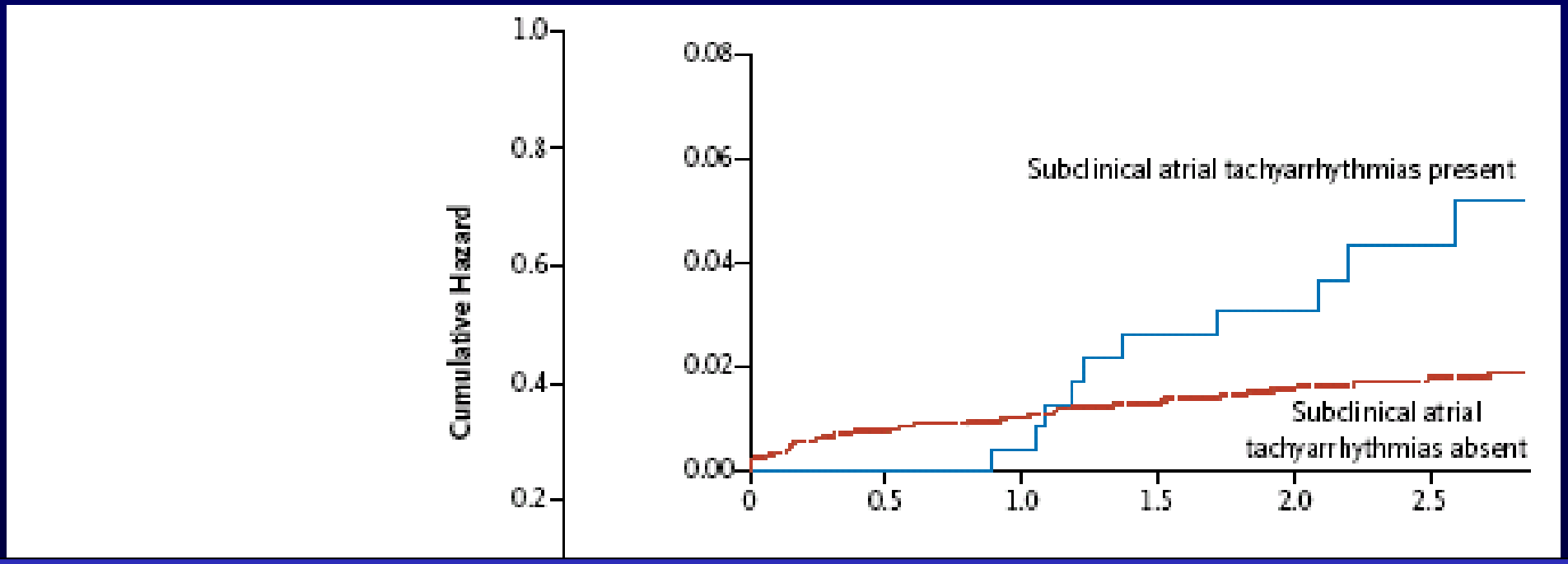


(3 out of 351 Pts) **0.8 %** vs **5 %** (11 out of 217 Pts) **P = 0.035**

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

ASSERT Trial

Risk of Ischemic Stroke or Systemic Embolism



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+
- only 0.19% per year for those with a $CHADS_2$ score=1 AT/AF-

Healey JS, New Engl J Med 2012: 366: 120-9

AF Discovery

Opportunity of Monitoring

- AF increases stroke risk 4-5 fold
- Stroke is more severe in pts with AF vs w/out-AF
- Hospitalisation is the biggest contributor to the cost of managing AF
- Symptoms are not a reliable indicator of AF
- Implantable systems (ILRs, IPGs, ICDs) have hight sensitivity for detection of AF
- New techs an investment more than a cost