Monitoraggio diagnostico: Loop Recorder impiantabili, esterni ... ed altro

EMOCLINIC SYMPOSIUM

Sulle sponde del Ticino

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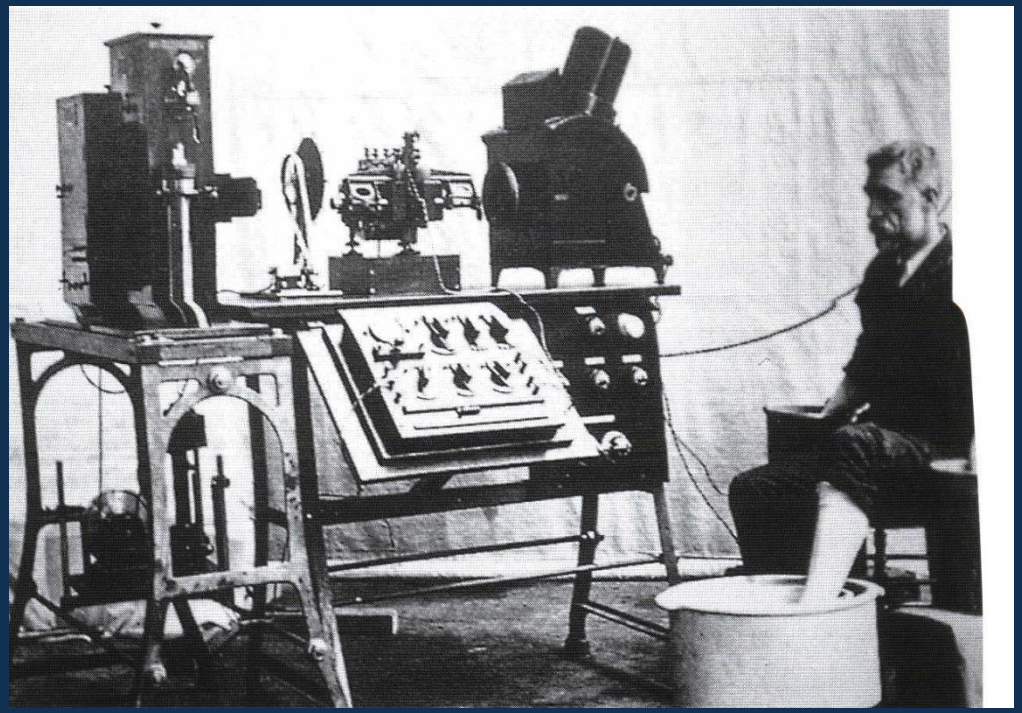
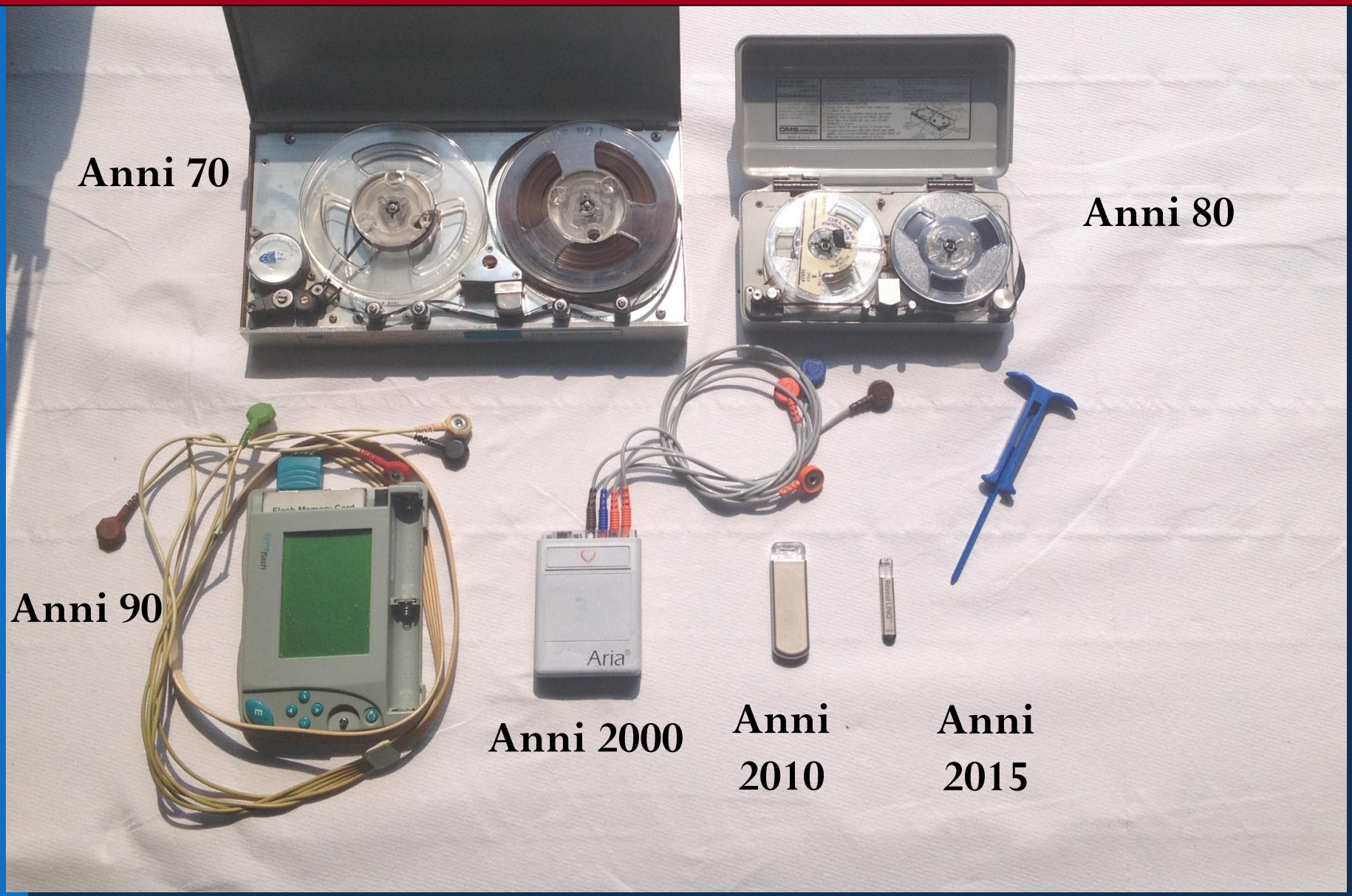
First continuous monitoring device



Einthoven W, Arch Int Physiol 1906

Dr Norman Jeff Holter, Montana 1940

ECG Monitoring tecnology evolution

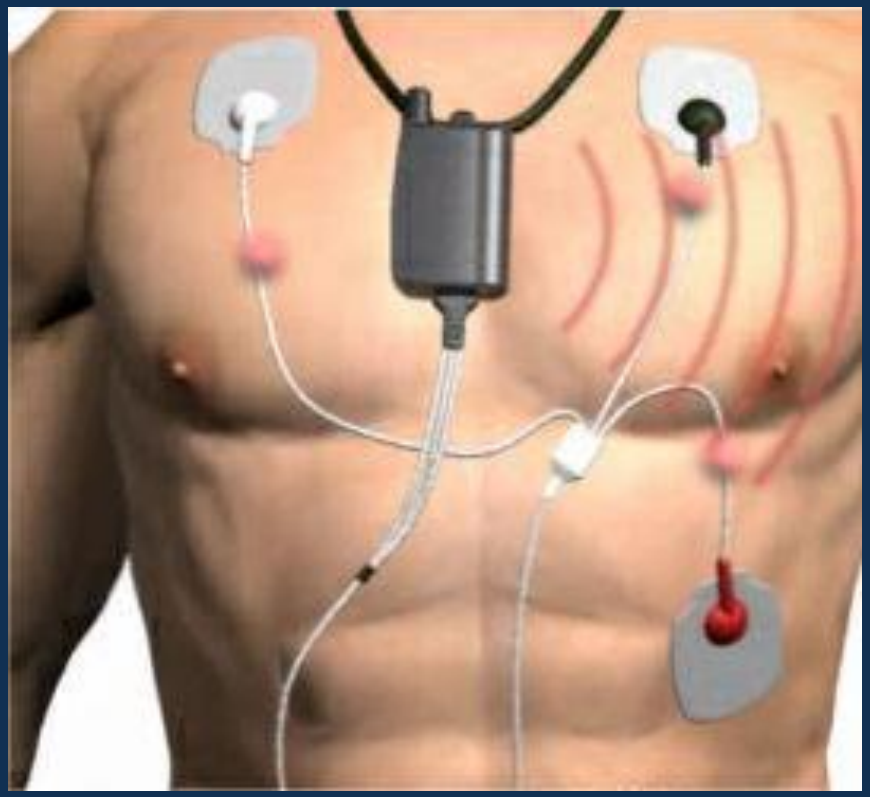


Eventi aritmici INFREQUENTI

REGISTRATORI DI EVENTI

LOOP RECORDER

Registratori di Eventi



-Dispositivi portatili
-Dimensioni ridotte
-facili da usare
-Quando sintomi → registrazione ECG (1 traccia)
- UTILITA': episodi intermittenti di cardiopalmo
- Durata ottimale monitoraggio: 3-4 settimane

Registratori di Eventi

NON indicazione nella diagnosi di SINCOPE (NON MEMORIA RETROSPETTIVA)

Monitoraggio continuo: LOOP RECORDER

Eventi Aritmici INFREQUENTI

LOOP RECORDER

-Attivazione MANUALE se sintomi ←(paziente) (durante o subito dopo)

-Attivazione AUTOMATICA se EVENTI anche asintomatici (in base alla programmazione)

Eventi Aritmici INFREQUENTI

LOOP RECORDER

ECG non solo al momento del sintomo/evento, ma anche PRIMA e DOPO→

MEMORIA RETROSPETTIVA

External Loop Recorder

- Monitor up to 40 days
- 1 st day continuous ECG
- Pre-event and post-event:
- All RR intervals recorded
- ECG holter quality:
- 1 alkaline or lithium AAA battery
- Communication: Audio modulation
- ECG patient cable: 1 or 2 channels
- Recording stored on a Sorin SD card
- Weight: 50 g w/o battery
- Dimensions: 75 X 50 X 19.5 mm

External Loop Recorder

Pazienti motivati

PALPITAZIONI DI BREVE DURATA
e con sintomi recidivanti ogni 4-6 settimane

40 giorni: intervallo massimo tollerato dal paziente

Loop Recorder Esterno

CAUSE NON RAGGIUNGIMENTO DIAGNOSI:

- no cardiopalmo
- artefatti
- no attivazione da parte del pz

Sensibilità tra il 66% ed il 75%

Implantable Loop Recorder

62 x 19 x 8 mm
Vol 9 ml peso 15 gr

44,8 x 7,2 x 4 mm
Vol 1,2 ml peso 2,5 gr

56 x 18 x 8 mm
Vol 6,5 ml peso 12 gr

Vol 1.4 ml peso 3 gr

88 x 15 x 6 mm
Vol 5 ml peso 10 gr

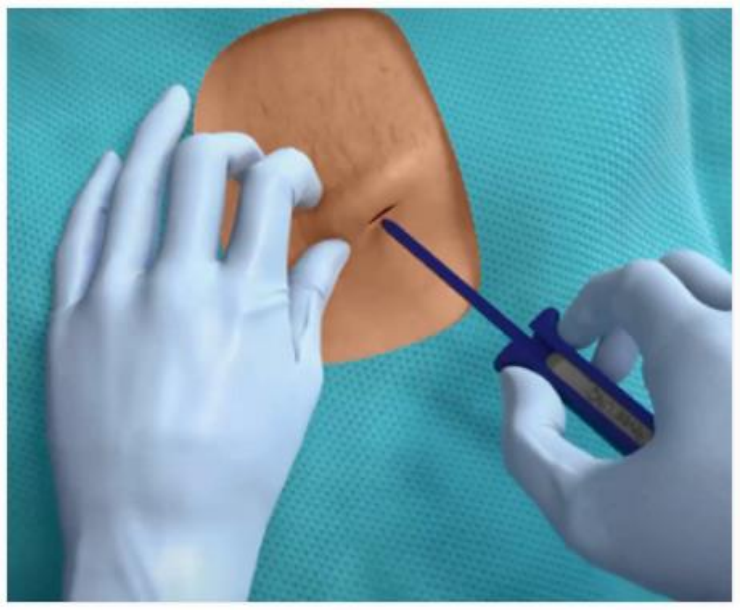
LRI

Durata batteria:
REVEAL XT circa 36 mesi (3 anni)
LINQ circa 24 mesi (2 anni)
BioMonitor2 circa 4 anni
SJM CONFIRM circa 3 anni
SJM Confirm Rx: circa 2.5 anni

ottimale per un monitoraggio
A LUNGO TERMINE

Implantable Loop Recorder positioning

Subcutaneous Injection



Surgical incision with creation of a subcutaneous pocket

Implantable Loop Recorder

- Riconoscimento episodi aritmici rilevando in modo continuo l'ECG sottocutaneo ed analizzando gli intervalli RR degli eventi ventricolari

- Il LinQ possiede un algoritmo per il riconoscimento anche delle onde P

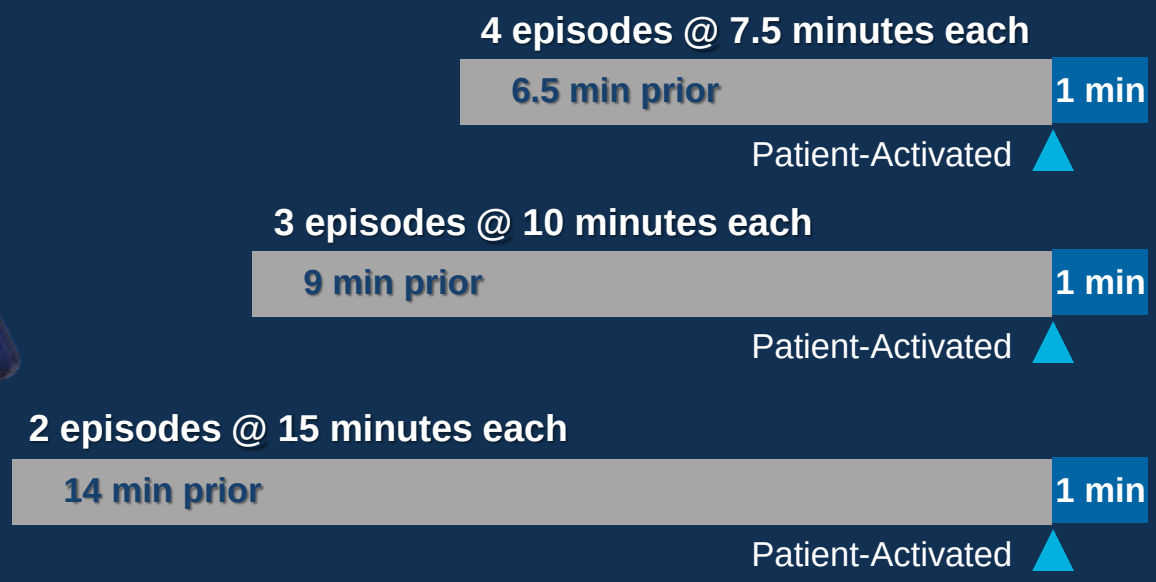
Aritmie ipocinetiche:
BRADICARDIE, PAUSE, ASISTOLIE

Aritmie ipercinetiche:
TACHICARDIE SOPRAVENTRICOLARI E VENTRICOLARI

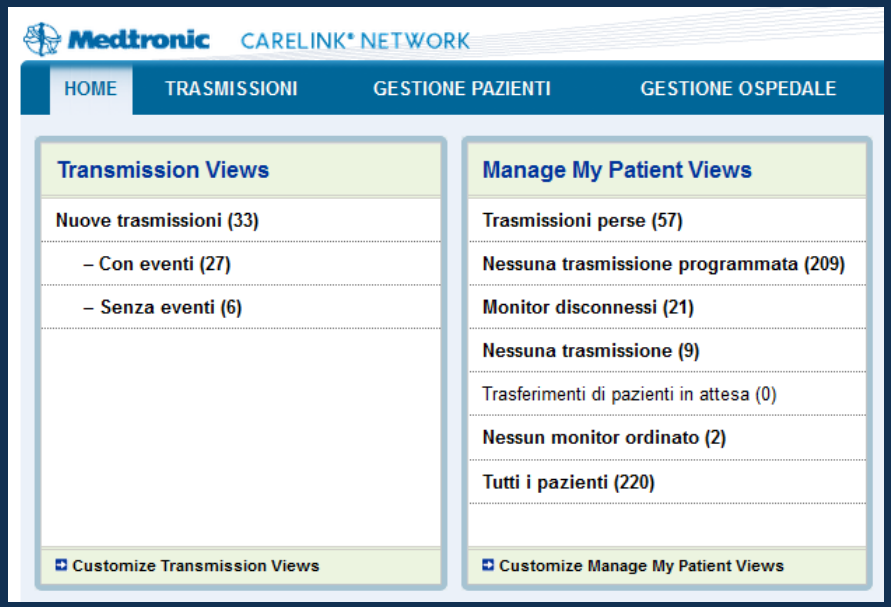
Arrhythmia detection

Symptom triggered detection: 27,5 min

Reveal® Patient Assistant



Data transmission



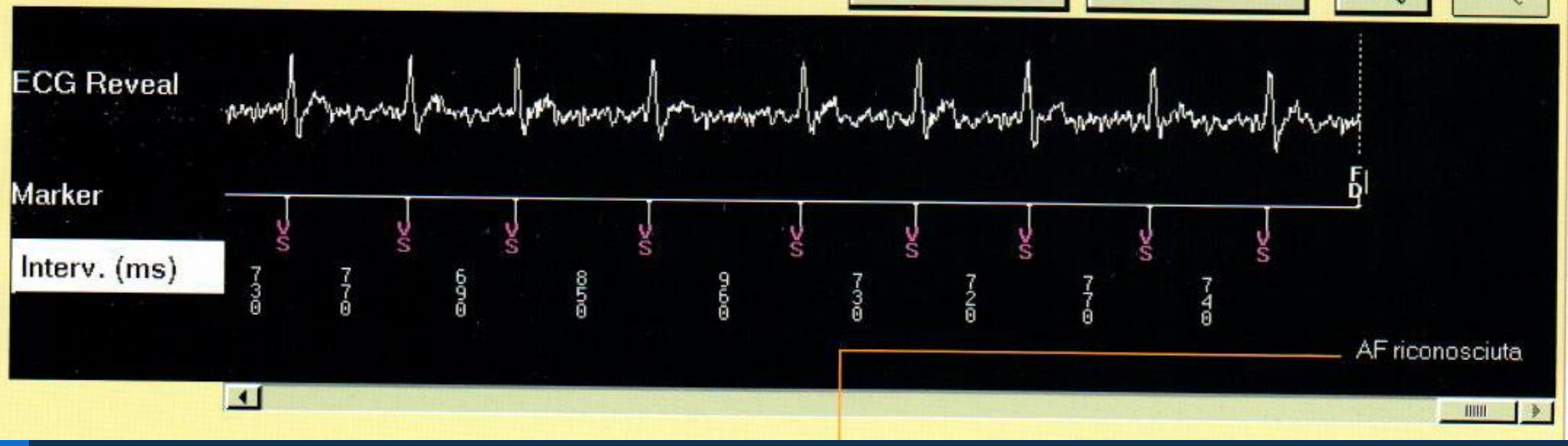
Short Term Report

Episodi aritmia

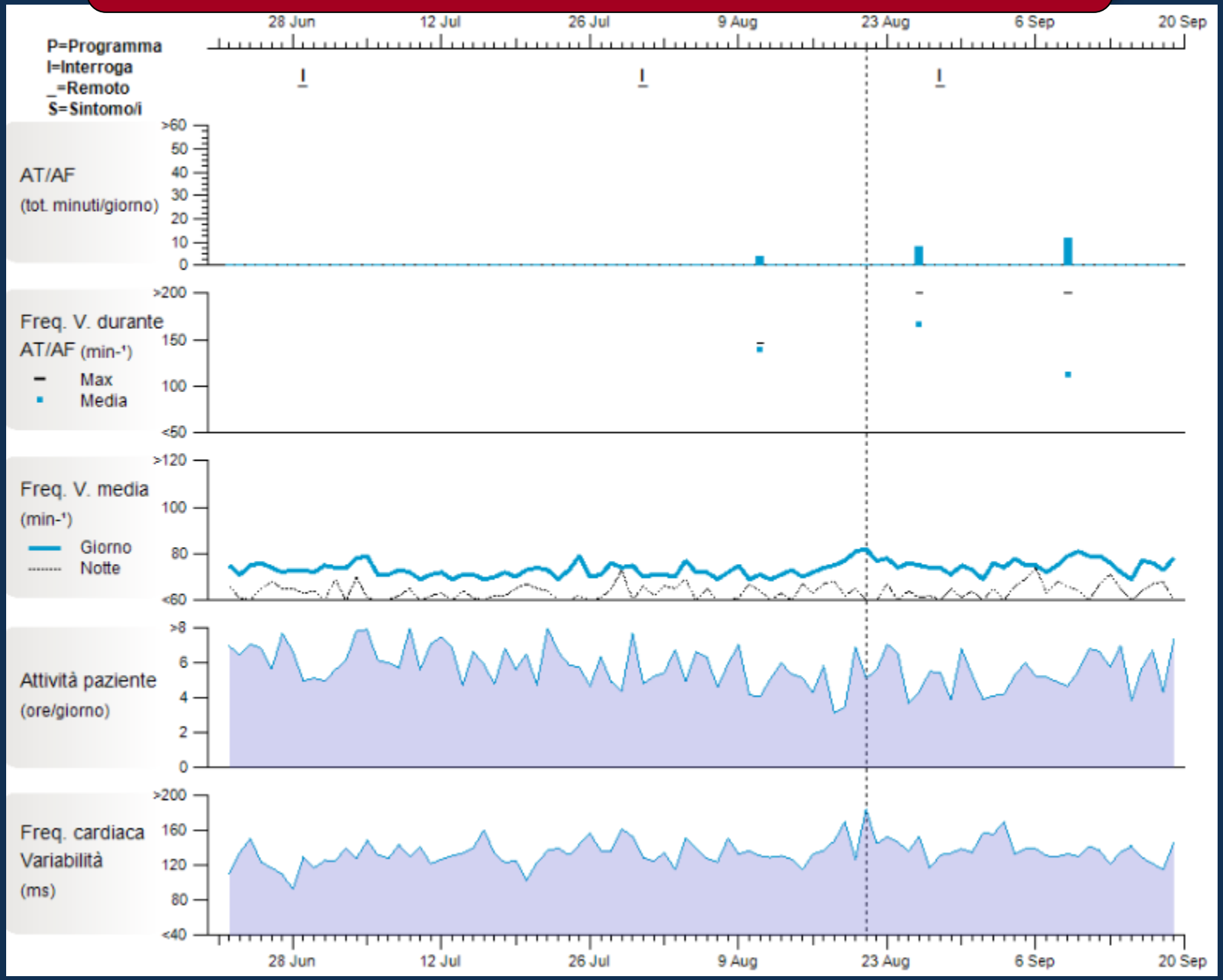
☑ SINTOMO ☑ FVT ☑ VT ☑ Asistolia ☑ Brady ☐ AT ☑ AF Ordinati per Data/Ora

#	Tipo	Data	Ora hh:mm	Durata hh:mm:ss	Frequenza V max.	Frequenza V mediana	Dettagli
138	AF	05-Mar-2007	09:47	01:18:00	87 min-¹ (690 ms)	80 min-¹ (750 ms)	ECG
137	AF	04-Mar-2007	15:16	:56:00	86 min-¹ (700 ms)	81 min-¹ (740 ms)	ECG
136	AF	03-Mar-2007	16:12	02:00:00	83 min-¹ (720 ms)	78 min-¹ (770 ms)	ECG
135	AF	02-Mar-2007	15:07	01:26:00	85 min-¹ (710 ms)	76 min-¹ (790 ms)	ECG
134	AF	01-Mar-2007	09:01	02:36:00	85 min-¹ (710 ms)	80 min-¹ (750 ms)	ECG

#137: ○ Diagram. ● ECG ○ Testo Precedente Successivo



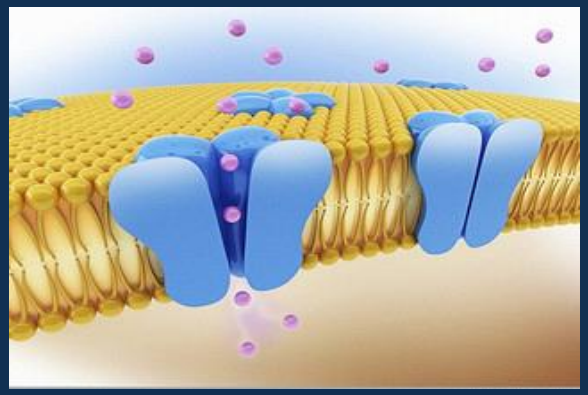
Long term Report



Indications

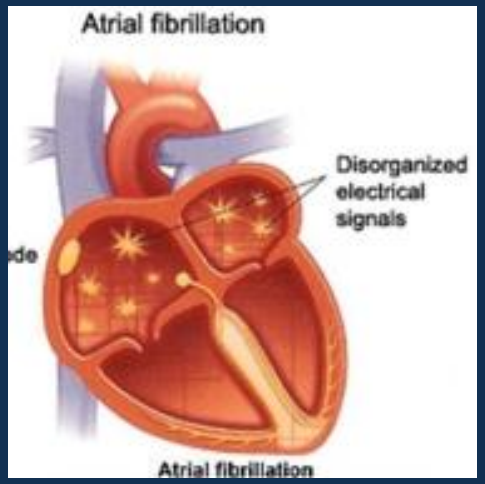
Syncope Diagnosis

Channellopathies



Criptogenic stroke

Atrial Fibrillation



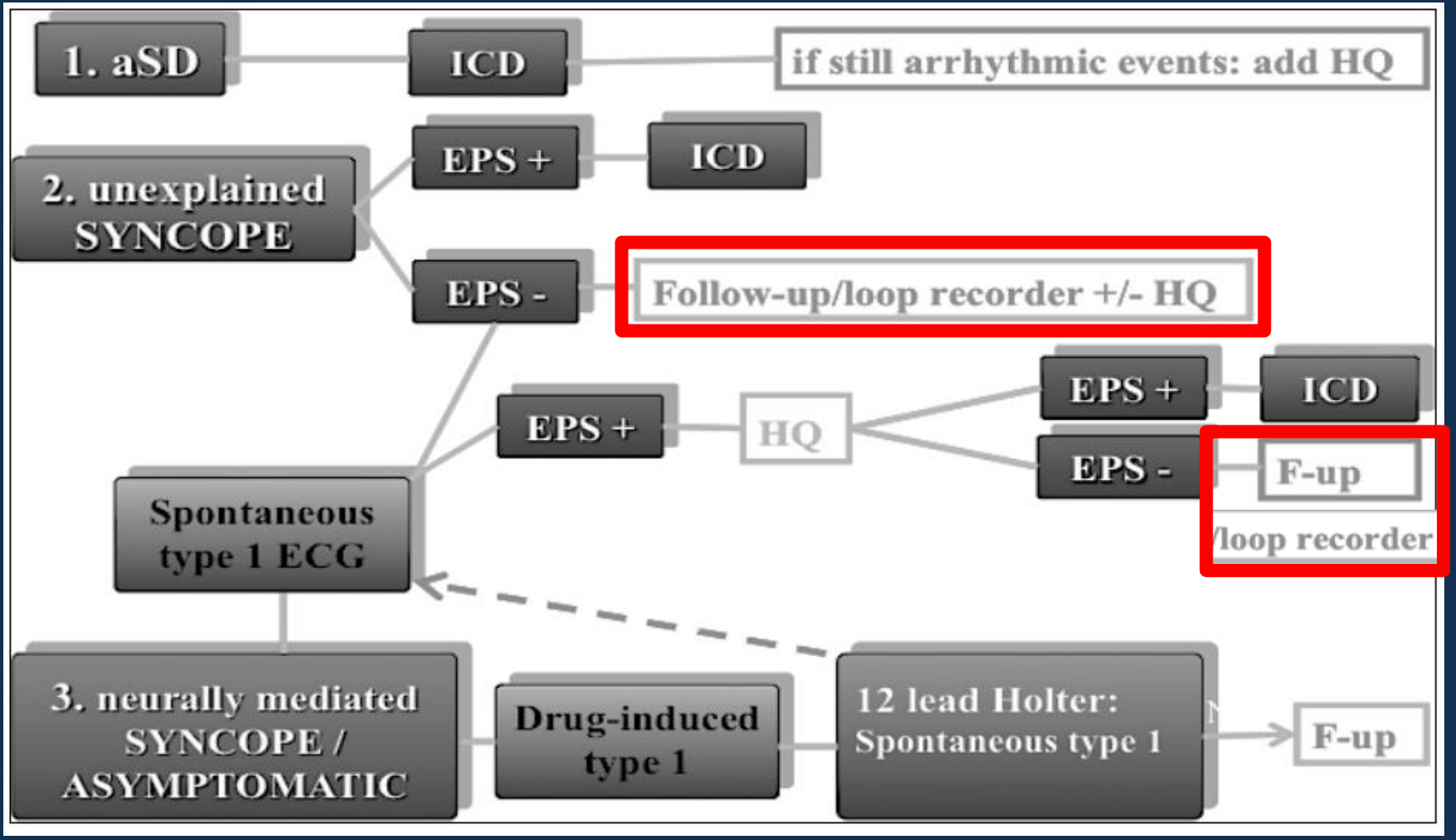
ESC Guidelines on Syncope

Electrocardiographic monitoring

Recommendations	Class[a]	Level[b]
Indications		
Immediate in-hospital monitoring (in bed or by telemetry) is indicated in high-risk patients (defined in *Table 6*).	I	C
Holter monitoring should be considered in patients who have frequent syncope or presyncope (≥1 episode per week).[161]	IIa	B
External loop recorders should be considered, early after the index event, in patients who have an inter-symptom interval ≤4 weeks.[162,166,168,201]	IIa	B
ILR is indicated in an early phase of evaluation in patients with recurrent syncope of uncertain origin, absence of high-risk criteria (listed in *Table 6*), and a high likelihood of recurrence within the battery life of the device.[175,176,181–184,202], *Supplementary Data Table 5*	I	A
ILR is indicated in patients with high-risk criteria (listed in *Table 6*) in whom a comprehensive evaluation did not demonstrate a cause of syncope or lead to a specific treatment, and who do not have conventional indications for primary prevention ICD or pacemaker indication.[174,180,187,188,195], *Supplementary Data Tables 5 and 6*	I	A
ILR should be considered in patients with suspected or certain reflex syncope presenting with frequent or severe syncopal episodes.[184–186]	IIa	B
ILR may be considered in patients in whom epilepsy was suspected but the treatment has proven ineffective.[137,189–191], *Supplementary Data Table 7*	IIb	B
ILR may be considered in patients with unexplained falls.[191–194], *Supplementary Data Table 8*	IIb	B

ESC 2018 Guidelines

Valutazione nelle channelopatie: Sindrome di Brugada



Evaluation in AF: diagnostic value

Silent AF detection following cryptogenic stroke

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

ESC 2016 Guidelines

AHRE: ATRIAL HIGH RATE EVENT

Atrial high rate event (AHRE): atrial high-rate episodes are defined as atrial tachyarrhythmia episodes with rate >190 beats/min detected by cardiac implantable electronic devices.

> 190 beats/min detected by cardiac implantable electronic <u>devices</u>

ESC European Society of Cardiology

Europace (2017) **19**, 1556–1578
doi:10.1093/europace/eux163

EHRA CONSENSUS DOCUMENT

2017

SUBCLINICAL ATRIAL FIBRILATION (SCAF)

Subclinical atrial fibrillaton (AF): atrial high-rate episodes (>6 minutes and <24-hours) with lack of correlated symptoms in patients with cardiac implantable electronic devices, detected with continuous ECG monitoring (intracardiac) and without prior diagnosis (ECG or Holter monitoring) of AF.

> 6 minutes e < 24 hours with lack of symptoms in patients with cardiac implantable electronic devices

ESC European Society of Cardiology
Europace (2017) 19, 1556–1578
doi:10.1093/europace/eux163

EHRA CONSENSUS DOCUMENT
2017

SILENT (asymptomatic) AF

Silent (asymptomatic) AF: documented AF in the absence of any symptoms or prior diagnosis often presenting with a complication related to AF e.g. stroke, heart failure, etc.

<u>DOCUMENTED AF</u> in the absense of any symptoms or prior diagnosis, often presenting with a complication related to AF (stroke, heart failure..).

ESC European Society of Cardiology

Europace (2017) **19**, 1556–1578
doi:10.1093/europace/eux163

EHRA CONSENSUS DOCUMENT

2017

SCAF

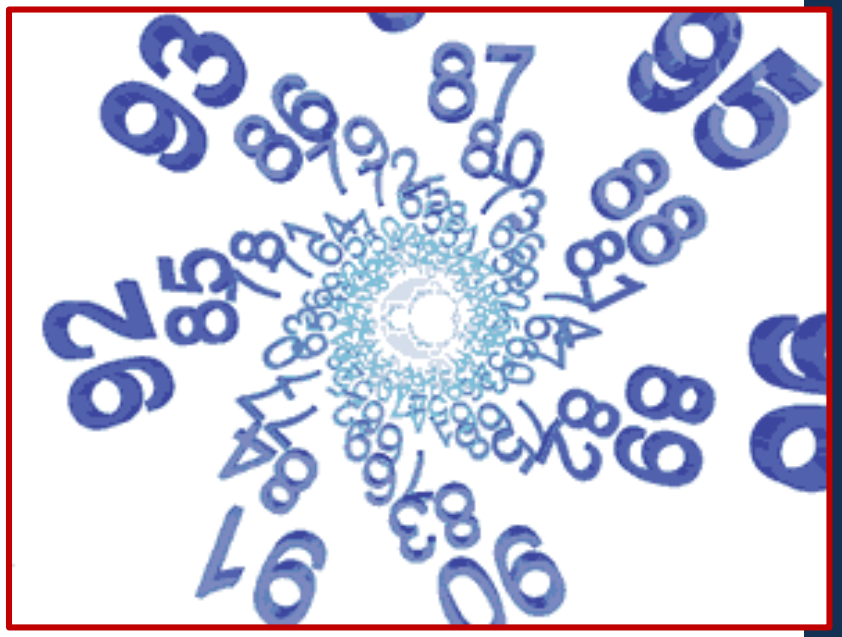
AHRE

INCIDENZA?

Varia in base alla popolazione in esame

How Much Atrial Fibrillation Is Too Much Atrial Fibrillation?

Gervasio Lamas, M.D.



INCIDENZA DI AHRE-SCAF

Year	Study	Device Indication	Clinical Profile of Patients	Follow-up	Incidence of AF
2002	Gillis *et al.*[16]	PPMs for sinus node disease	All	718±383 days	157/231 (68%)
2003	MOST[5]	PPMs for sinus node disease	All	median 27 months	156/312 (50%)
2006	BEATS[21]	PPMs for all indications	All	Prospective, 12 months	137/254 (54%)
2010	TRENDS[17]	PPMs and ICDs All indications	History of prior stroke No history of AF No OAC use ≥1 stroke risk factor	Mean 1.4 years	45/163 (28%)
2012	TRENDS[6]	PPMs and ICDs All indications	No history of prior stroke No history of AF No OAC use ≥1 stroke risk factor	1.1±0.7 years	416/1368 (30%)
2012	ASSERT[7]	PPMs and ICDs All indications	History of hypertension No history of AF No OAC use	2.5 years	895/2580 (34.7%)
2013	Healey *et al.*[4]	PPMs All indications	All	Single center retrospective	246/445 (55.3%)

INCIDENZA DI AHRE-SCAF

Atrial High Rate Episodes Detected by Pacemaker Diagnostics Predict Death and Stroke

Report of the Atrial Diagnostics Ancillary Study of the MOde Selection Trial (MOST)

MOST TRIAL 2003: 312 pazienti, sottogruppo del MOST (MOde Selection Trial), uno studio randomizzato di 6 anni sul confronto tra DDDR versus VVIR in pazienti sottoposti ad **impianto di PM per SSS.**

Almeno 1 AHRE >5 minuti. Follow-up di 27 mesi.

Incidenza del 50%

INCIDENZA DI AHRE-SCAF

Incidence of Atrial Tachyarrhythmias in Pacemaker Patients: Results from the Balanced Evaluation of Atrial Tachyarrhythmias in Stimulated Patients (BEATS) Study

CARSTEN W. ISRAEL,* HORST NEUBAUER,† HANS-GEORG OLBRICH,‡ WOLFGANG HARTUNG,§ SVEN TREUSCH,¶ and STEFAN H. HOHNLOSER* on Behalf of the BEATS Study Investigators

<u>BEATS STUDY 2006</u>: 254 pazienti sottoposti ad impianto di PM DDD*(R) per indicazioni di classe I* – Registrazioni di attività atriale con FC > 170 bpm di almeno 8 cicli.

Incidenza del 54%

INCIDENZA DI AHRE-SCAF – Popolazione selezionata– TRENDS STUDY - 2006

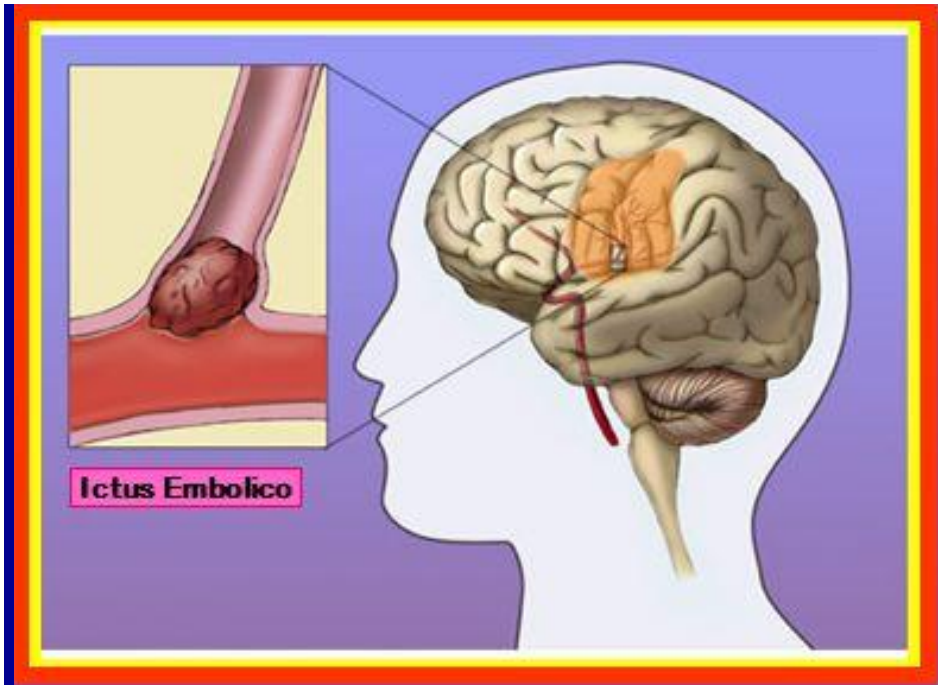
Detection of Previously Undiagnosed Atrial Fibrillation in Patients With Stroke Risk Factors and Usefulness of Continuous Monitoring in Primary Stroke Prevention

Paul D. Ziegler, MS[a,*], Taya V. Glotzer, MD[b], Emile G. Daoud, MD[c], Daniel E. Singer, MD[d], Michael D. Ezekowitz, MD, PhD[e], Robert H. Hoyt, MD[f], Jodi L. Koehler, MS[a], James Coles, Jr., PhD[a], and D. George Wyse, MD, PhD[g]

1368 PM-ICD-CRTD. Nuovo riscontro di AT/AF di almeno 5 minuti, in pts con ≥ 1 Fdr CV; senza precedente stroke o storia di AT/AF. Incidenza del 30%

The detection of undiagnosed atrial tachycardia/atrial fibrillation (AT/AF) among patients with stroke risk factors could be useful for primary stroke prevention. We analyzed newly detected AT/AF (NDAF) using continuous monitoring in patients with stroke risk factors but without previous stroke or evidence of AT/AF. NDAF (AT/AF >5 minutes on any day) was determined in patients with implantable cardiac rhythm devices and ≥1 stroke risk factors (congestive heart failure, hypertension, age ≥75 years, or diabetes). All devices were capable of continu-

AHRE-SCAF e RISCHIO DI TROMBOEMBOLISMO



SCAF

AHRE

INCIDENZA DI AHRE-SCAF –Popolazione selezionata–

ASSERT STUDY - NEJM

Subclinical Atrial Fibrillation and the Risk of Stroke

Jeff S. Healey, M.D., Stuart J. Connolly, M.D., Michael R. Gold, M.D., Carsten W. Israel, M.D., Isabelle C. Van Gelder, M.D., Alessandro Capucci, M.D., C.P. Lau, M.D., Eric Fain, M.D., Sean Yang, M.Sc., Christophe Bailleul, M.D., Carlos A. Morillo, M.D., Mark Carlson, M.D., Ellison Themeles, M.Sc., Elizabeth S. Kaufman, M.D., and Stefan H. Hohnloser, M.D., for the ASSERT Investigators*

The ASSERT study[27] prospectively evaluated 2580 patients without prior history of AF and found a 10.1% incidence of SCAF (atrial rate ≥190/min lasting >6 min) at 3 months. The presence of SCAF increases the risk of clinical AF by 5.6 times.

2580 PM/ICD, ≥ 65 aa, ipertesi, senza storia di FA.

Follow-up di *3 mesi*. AHRE > 190 bpm e > 6 min.

Incidenza del 10%

AHRE-AF e RISCHIO DI TROMBOEMBOLISMO

Year	Trial	Number of patients	Duration of follow-up	Atrial rate cut-off	AF burden threshold	Hazard ratio for TE event	TE event rate (below vs. above AF burden threshold)
2003	Ancillary MOST[5]	312	27 months (median)	>220 bpm	5 min	6.7 (P=0.020)	3.2% overall (1.3% vs. 5%)
2005	Italian AT500 Registry[18]	725	22 months (median)	>174 bpm	24 h	3.1 (P=0.044)	1.2% annual rate
2009	Botto *et al.*[19]	568	1 year (mean)	>174 bpm	$CHADS_2$+AF burden	n/a	2.5% overall (0.8% vs. 5%)
2009	TRENDS[20]	2486	1.4 years (mean)	>175 bpm	5.5 h	2.2 (P=0.060)	1.2% overall (1.1% vs. 2.4%)
2012	Home Monitor CRT[22]	560	370 days (median)	>180 bpm	3.8 h	9.4 (P=0.006)	2.0% overall
2012	ASSERT[7]	2580	2.5 years (mean)	>190 bpm	6 min	2.5 (P=0.007)	(0.69% vs. 1.69%)
2014	SOS AF[23]	10016	2 years (median)	>175 bpm	1 h	2.11 (P=0.008)	0.39% per year Overall

Rischio tromboembolico nel tempo…..

AHRE-AF e RISCHIO DI TROMBOEMBOLISMO

	n	Mean age (years)	FU (months)	Prior AF (%)	Atrial activation	Duration	Clinical AF (RR)	P
MOST[20]	312	74	27	60	AHRE ≥ 220/min	>5 min	5.9	0.0001
Capucci[22]	725	71	22	100	AT/AF	>1 day	–	–
Botto[21]	568	70	12	100	AT/AF	>1 day	–	–
TRENDS[26]	2486	71	17	20	AT/AF burden	≥5.5 h/day	–	–
ASSERT[27]	2580	76	34	0	AT ≥ 190/min	>6 min	5.6	<0.001

	n	Prior TE (%)	Prior OAC (%)	$CHADS_2$	Number of pts with TE	TE (RR)	P	TE (%/year)	SCAF (+) Annual TE%	SCAF (−) Annual TE%
MOST[20]	312	20	24	–	?10	2.8	0	1.60	2.20	0.60
Capucci[22]	725	1.80	32	1.8	14	3.1	0.04	1.20	–	–
Botto[21]	568	1.40	25.20	~1.0	14	5.3	–	2.50	3.60	0.60
TRENDS[26]	2486	13.40	20.80	2.2	40	2.2	0.06	1.20	2.40	1.10
ASSERT[27]	2580	12.10	18	~1.2	51	2.5	0.01	0.89	1.78	0.69

AHRE-AF e RISCHIO DI TROMBOEMBOLISMO – MOST

Atrial High Rate Episodes Detected by Pacemaker Diagnostics Predict Death and Stroke

Report of the Atrial Diagnostics Ancillary Study of the MOde Selection Trial (MOST)

AHRE > 5 min (FC > 220 bpm)
è predittore indipendente di

- Mortalità totale (HR: 2,48),
- Mortalità o stroke non fatale (HR: 2,79)
- Fibrillazione atriale clinica (HR 5.93)

Evaluation in AF: AF burden

How Much Atrial Fibrillation Is Too Much Atrial Fibrillation?

Gervasio Lamas, M.D.

Burden a confronto ...

AHRE-AF e RISCHIO DI TROMBOEMBOLISMO – Italian Registry – Capucci

Monitored Atrial Fibrillation Duration Predicts Arterial Embolic Events in Patients Suffering From Bradycardia and Atrial Fibrillation Implanted With Antitachycardia Pacemakers

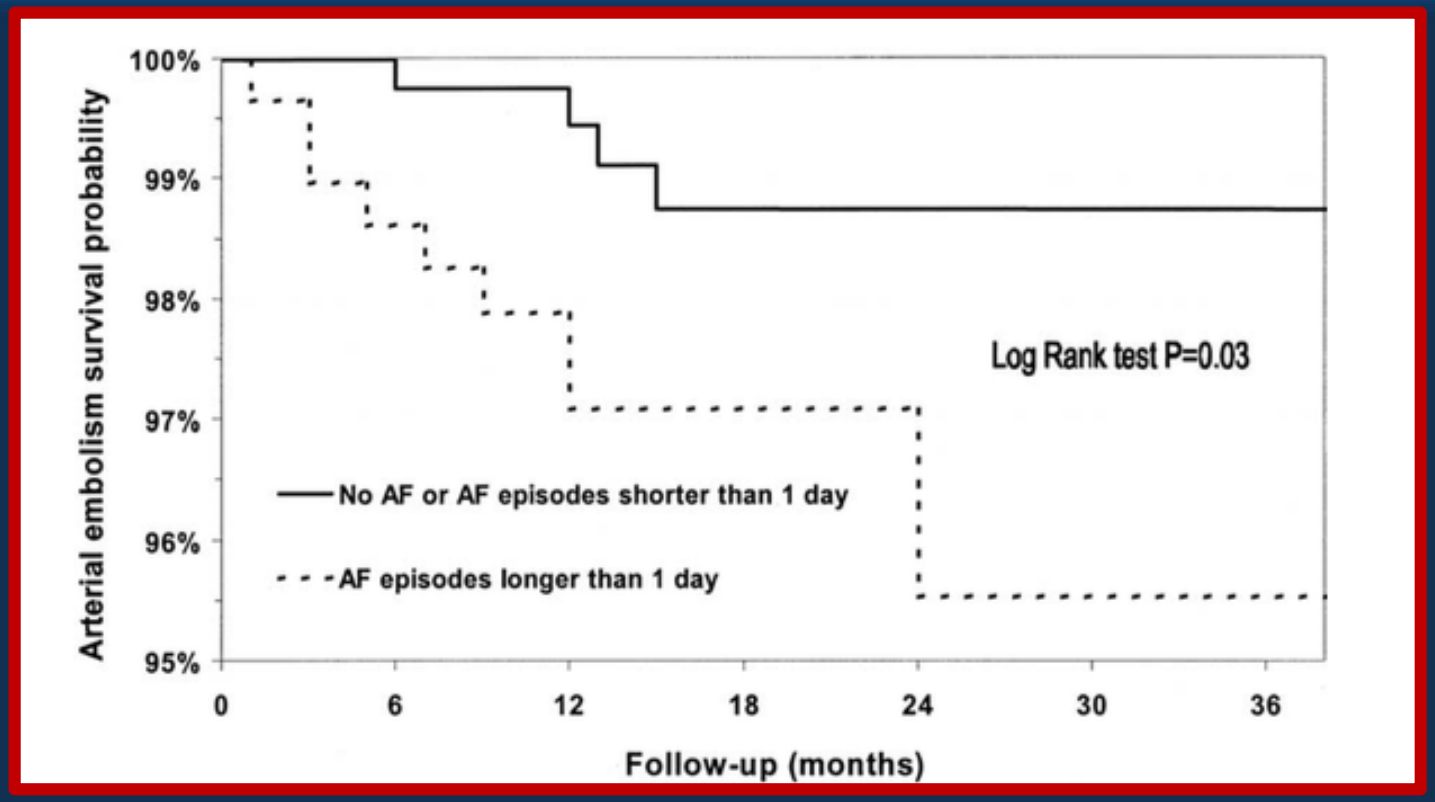
Alessandro Capucci, MD,* Massimo Santini, MD,† Luigi Padeletti, MD,‡ Michele Gulizia, MD,§ GianLuca Botto, MD,‖ Giuseppe Boriani, MD,¶ Renato Ricci, MD,† Stefano Favale, MD,# Francesco Zolezzi, MD,** Natale Di Belardino, MD,†† Giulio Molon, MD,‡‡ Fabrizio Drago, MD,§§ Giovanni Q. Villani, MD,* Elena Mazzini, MS,‖‖ Marco Vimercati, MS,‖‖ Andrea Grammatico, PHD,‖‖ on behalf of the Italian AT500 Registry Investigators

Piacenza, Rome, Florence, Catania, Como, Bologna, Bari, Vigevano, Velletri, Negrar, and Milan, Italy

725 pazienti, portatori di PM in Classe I-II

Confronto CUTOFF AHRE
$\geq$ 5 min vs $\geq$ 24 h

RISCHIO DI TROMBOEMBOLISMO – Italian Registry – Capucci



AHRE > 24 h aumenta il rischio TE
(vs NO AHRE or AHRE tra 5 min e 24h)
[aumento di 3.1 volte; IC 95% 1-10.5, p 0.044]

AHRE-AF e RISCHIO DI TROMBOEMBOLISMO
–Botto et al–

Presence and Duration of Atrial Fibrillation Detected by Continuous Monitoring: Crucial Implications for the Risk of Thromboembolic Events

3 gruppi AF: < 5 min / 5 min-24h / > 24h

AF classification	Pts (%)	Thromboembolic events	Stroke	TIA
No AF	166 (29)	2	2	0
AF >5 minutes	179 (31)	3	0	2
AF >24 hours	223 (39)	9	6	2

AHRE-AF e RISCHIO DI TROMBOEMBOLISMO –SOS AF Project– burden

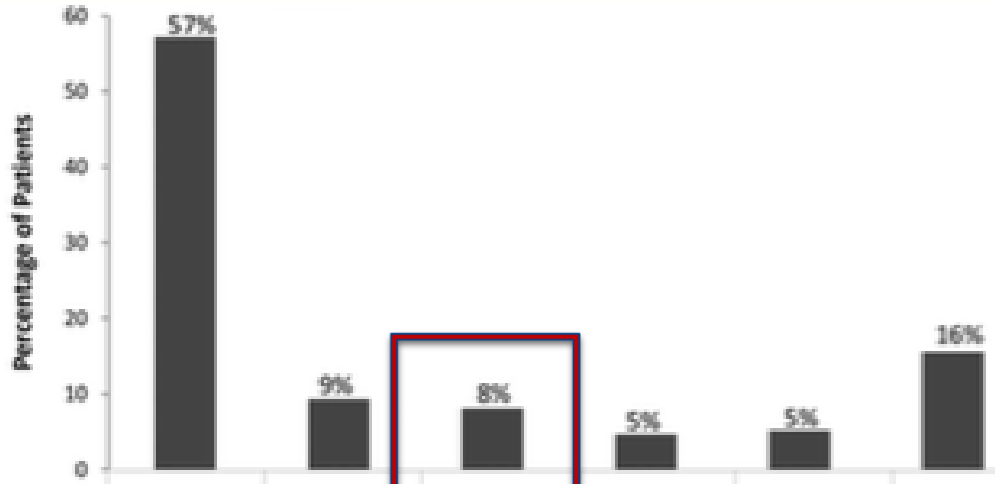
Device-detected atrial fibrillation and risk for stroke: an analysis of >10 000 patients from the SOS AF project (Stroke preventiOn Strategies based on Atrial Fibrillation information from implanted devices)

Giuseppe Boriani[1*], Taya V. Glotzer[2], Massimo Santini[3], Teena M. West[4], Mirko De Melis[4], Milan Sepsi[5], Maurizio Gasparini[6], Thorsten Lewalter[7], John A. Camm[8], and Daniel E. Singer[9]

5 studi prospettici per un totale di 10016 pazienti portatori di CIED con almeno 3 mesi di follow-up.

Burden di FA di 5 minuti, 1 h, 6 h, 12 h e 23 h era correlato ad un aumentato rischio di stroke ischemico. Correlazione indipendente rispetto al CHADSVASC score e alla terapia anticoagulante di base.

AHRE-AF e RISCHIO DI TROMBOEMBOLISMO –SOS AF Project– burden



	0 to <5 minutes of AF burden	≥5 minutes to <1 hour AF burden	≥1 hour to <6 hours AF burden	≥6 hours to <12 hours AF burden	≥12 hours to <23 hours AF burden	≥23 hours AF burden
Median Follow Up, months	21	27	26	26	27	28
Person years	12966	2491	2077	1171	1375	4314
Stroke events, n(%)	31 (0.54%)	2 (0.21%)	7 (0.86%)	3 (0.65%)	4 (0.77%)	10 (0.64%)
Stroke rate, % per year	0.24%	0.08%	0.34%	0.26%	0.30%	0.23%
Stroke or TIA events, n(%)	41 (0.72%)	8 (0.86%)	14 (1.72%)	5 (1.08%)	6 (1.15%)	25 (1.61%)
Stroke or TIA rate, % per year	0.32%	0.32%	0.67%	0.43%	0.44%	0.49%

AHRE-AF e RISCHIO DI TROMBOEMBOLISMO –SOS AF Project– burden

Table 3 Cox regression analysis performed on 8122 patients without oral anticoagulation at baseline, adjusted for the $CHADS_2$ score

	Total	Events	HR for AF burden ≥1 h vs. <1 h (95% CI)	*P*-value
Stroke	8122	44	2.09 (1.10, 3.96)	0.0239
Stroke + TIA	8122	69	2.05 (1.24, 3.39)	0.0051
Adjusting for $CHADS_2$ score				
Stroke	8122	44	1.90 (1.00, 3.61)	0.0487
Stroke + TIA	8122	69	1.89 (1.14, 3.12)	0.0135

Burden di 1 ora è stato associato ad un hazard ratio più alto per stroke ischemico.
(HR: 2.11 (95% CI: 1.22 – 3.64, p < 0.008).

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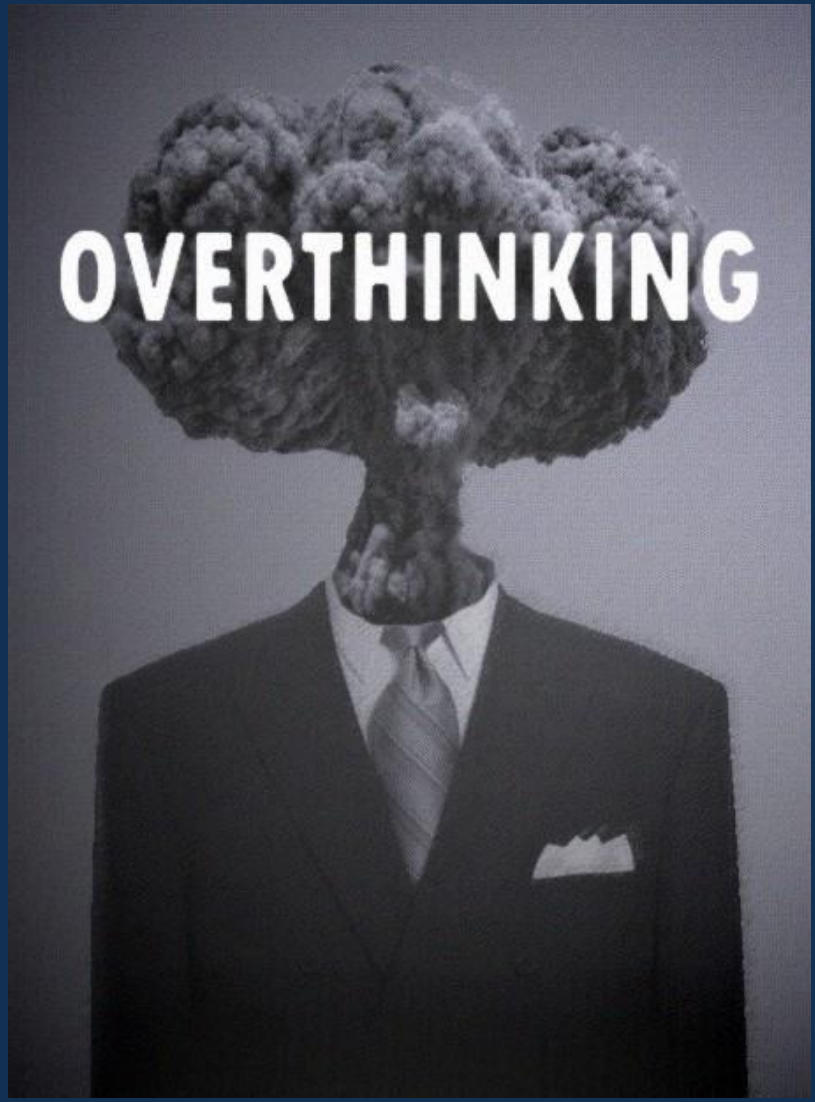
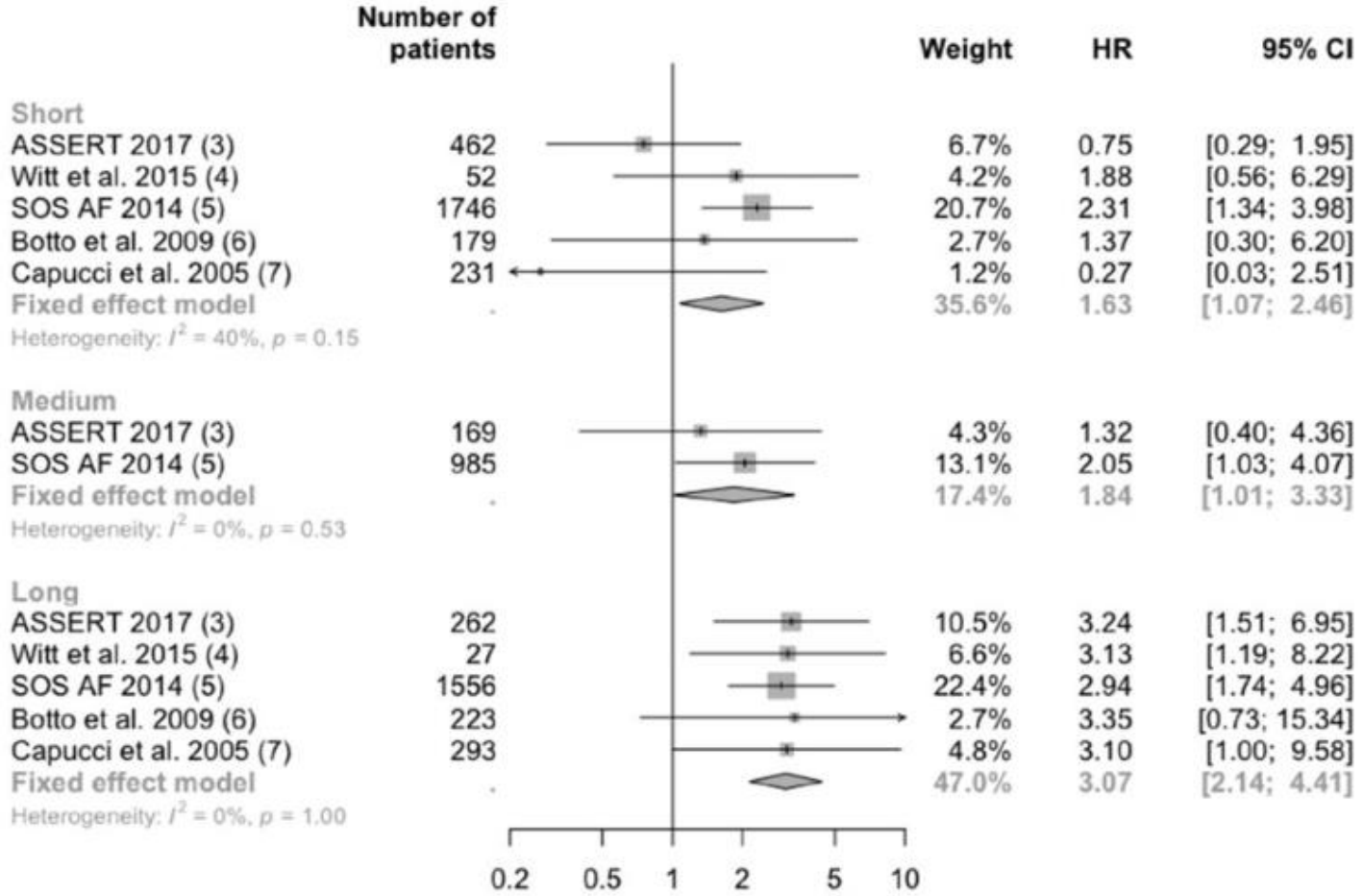
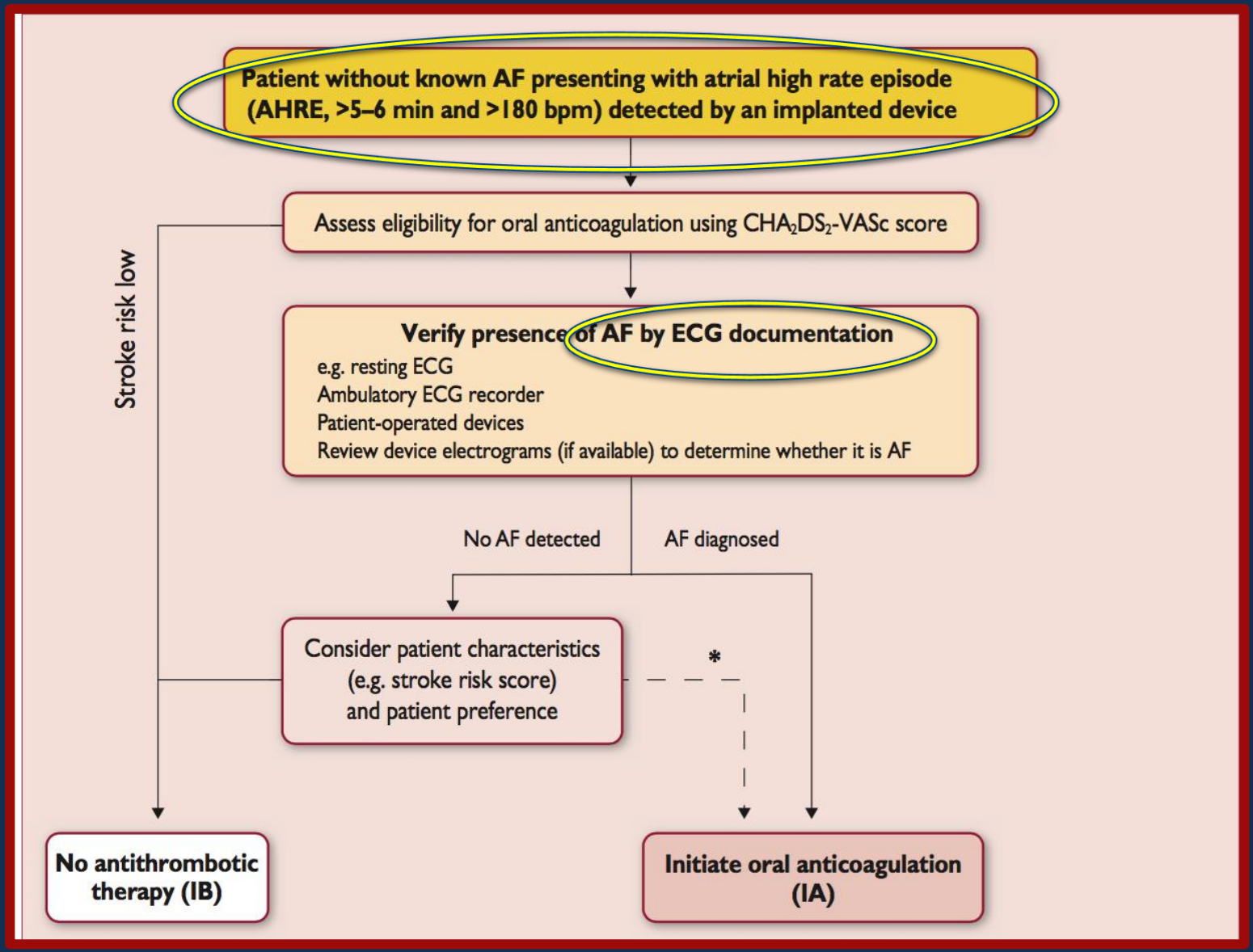

OVERTHINKING

Subclinical atrial fibrillation in need of more assertive evidence

Kazem Rahimi*



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



ESC European Society of Cardiology
Europace (2017) 19, 1556–1578
doi:10.1093/europace/eux163
EHRA CONSENSUS DOCUMENT

2017

Device-detected subclinical atrial tachyarrhythmias: definition, implications and management—an European Heart Rhythm Association (EHRA) consensus document, endorsed by Heart Rhythm Society (HRS), Asia Pacific Heart Rhythm Society (APHRS) and Sociedad Latinoamericana de Estimulación Cardíaca y Electrofisiología (SOLEACE)

Table 10 Recommendations for treatment of subclinical atrial fibrillation with oral anticoagulation

CHA_2DS_2-VASc score	Duration of AHRE	Recommendation
≥2	>5.5 h (lower duration if multiple stroke risk factors are present)*	
1 (male) or 2 (female)	>5.5 h*	

*Data suggests risk is similarly increased by a mere 5 min.
AHRE, atrial high rate episode.

CONCLUSIONI

ILR

SINCOPE: eventi ricorrenti di origine incerta

ICTUS CRIPTOGENETICO

RISCHIO TROMBOEMBOLICO

SINDROME DI BRUGADA: SEF negativo

FA SUBCLINICA

AHRE

BURDEN di FA – Studi in corso

SELEZIONE DEL PAZIENTE

GRAZIE PER L’ATTENZIONE