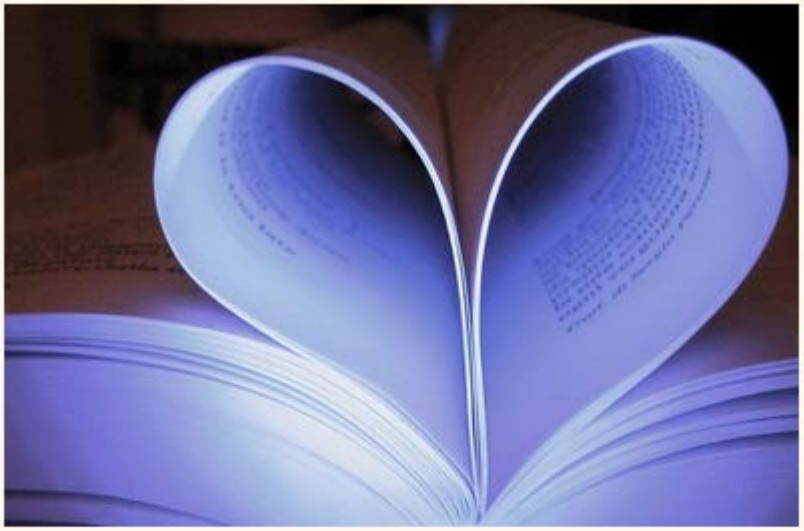

FIBRILLAZIONE ATRIALE E ICTUS CARDIOEMBOLICO:
MISURE LEGISLATIVE, STRATEGIE DI PREVENZIONE, ACCESSO ALLE CURE

Mercoledì, 15 maggio 2013 ore 8.30 – 14.00

Palazzo Marini – Sala delle Colonne
Roma

“RATE CONTROL” VS “RHYTHM CONTROL”: UNA CONTROVERSIA ANCORA IRRISOLTA

Dott. Nicola Binetti
PS ed emergenza territoriale
(Area Nord AUSL Bologna)

Rate control >< Rhythm control

CONTROVERSIA IR_RISOLTA ? !

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Several large randomized, controlled clinical trials have been performed to **compare the risks and benefits of rate versus pharmacological rhythm control** strategies in patients with AF

Atrial Fibrillation Follow-Up Investigation of Rhythm Management **(AFFIRM)**,
N Engl J Med. 2002 Dec 5;347(23):1825-33

RAte Control versus Electrical cardioversion for Persistent Atrial Fibrillation Study **(RACE)**
N Engl J Med. 2002 Dec 5;347(23):1834-40

Pharmacological Intervention in Atrial Fibrillation **(PIAF)**,
Lancet. 2000 Nov 25;356(9244):1789-94

Strategies of Treatment of Atrial Fibrillation **(STAF)**,
J Am Coll Cardiol. 2003;41:1690–1696

and How to Treat Chronic Atrial Fibrillation **(HOT CAFÉ)** trials,
Chest. 2004;126:476–486

and the Atrial Fibrillation and Congestive Heart Failure
Rhythm control versus rate control for atrial fibrillation and heart failure **(AF-CHF)**
N Engl J Med. 2008;358:2667–2677

Heist E K et al. Circulation 2011;124:2746-2755

Rate vs Rhythm Control Trials for AF

Trial	Year	n	Primary End Point	HR (Rate vs Rhythm Control)	*P*
PIAF[3]	2000	252	Improvement AF symptoms	1.10	0.31
AFFIRM[1]	2002	4060	Overall mortality	0.87	0.08
RACE[2]	2002	522	Composite	0.73	0.11
STAF[4]	2003	200	Composite	1.09	0.99
HOT CAF[5]	2004	205	Composite	1.98	>0.71
AF-CHF[6]	2008	1376	Cardiovascular mortality	0.94	0.59
PABA-CHF[15]	2008	81	Composite	Multiple (see below)	<0.001

these 6 studies, which in total randomly selected **6615 patients**
to rate versus (primarily) pharmacological **rhythm control strategies**, uniformly concluded that rate control **was not inferior to rhythm control** for the primary end points of the trials

Heist E K et al. Circulation 2011;124:2746-2755

Review

Interventions for the treatment of **atrial fibrillation**: A systematic literature review and meta-analysis.
Sullivan SD, Orme ME, Morais E, Mitchell SA.
Int J Cardiol. 2013 May 10;165(2):229-36.

REVIEW

Pharmacologic Rate versus Rhythm-Control Strategies in Atrial Fibrillation: An Updated Comprehensive Review and Meta-Analysis

PACE 2013; 36:122–133

Rate versus rhythm control in atrial fibrillation and clinical outcomes: Updated systematic review and meta-analysis of randomized controlled trials
Archives of Cardiovascular Diseases Volume 105, Issue 4; 2012 226 - 238

REVIEW

Rate versus rhythm control in atrial fibrillation and clinical outcomes: Updated systematic review and meta-analysis of randomized controlled trials

Daniel Caldeira[a], Cláudio David[a,*,b], Cristina Sampaio[a,c]

[a] *Laboratory of Clinical Pharmacology and Therapeutics, School of Medicine, University of Lisbon, Lisbon, Portugal*
[b] *Departement of Cardiology, Santa Maria University Hospital, Lisbon, Portugal*
[c] *Institute de Molecular Medicine, Lisbon, Portugal*

Archives of Cardiovascular Disease (2012) 105, 226—238

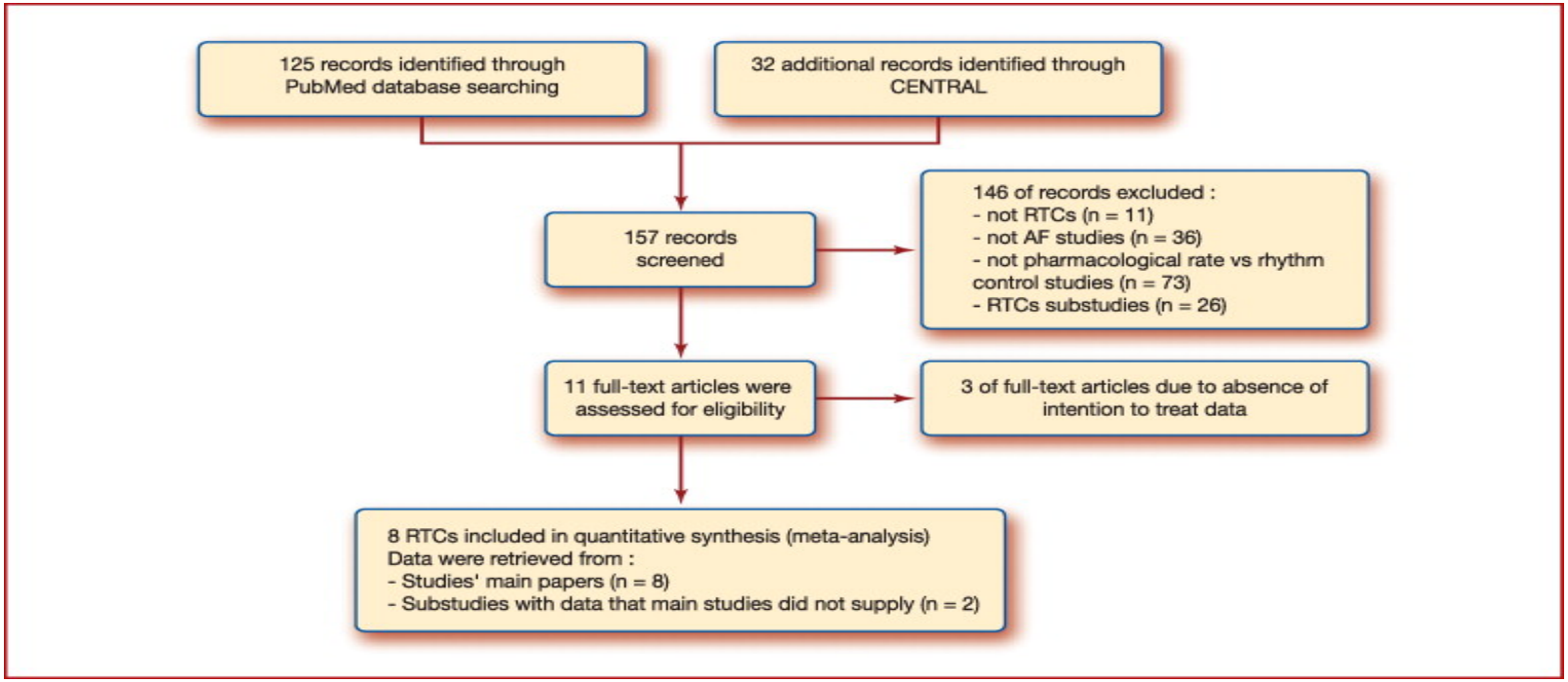
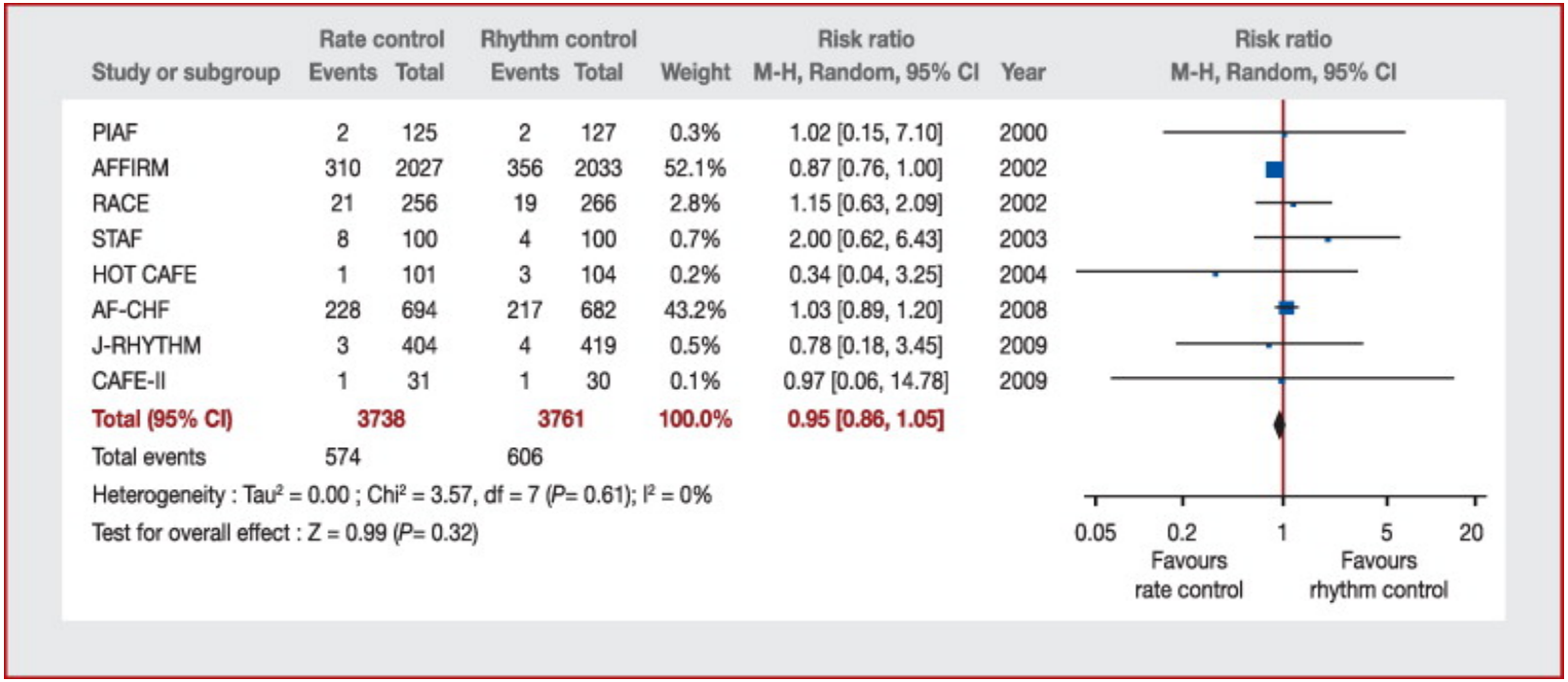


Figure 1 Flowchart of study selection for meta-analysis. AF: atrial fibrillation; CENTRAL: Cochrane Central Register of Controlled Trials; RCTs: randomized controlled trials.

Rate versus rhythm control in atrial fibrillation and clinical outcomes: Updated systematic review and meta-analysis of randomized controlled trials

Archives of Cardiovascular Disease (2012) 105, 226–238

All-cause mortality



Study or subgroup	Rate control Events	Total	Rhythm control Events	Total	Weight	Risk ratio M-H, Random, 95% CI	Year
PIAF	2	125	2	127	0.3%	1.02 [0.15, 7.10]	2000
AFFIRM	310	2027	356	2033	52.1%	0.87 [0.76, 1.00]	2002
RACE	21	256	19	266	2.8%	1.15 [0.63, 2.09]	2002
STAF	8	100	4	100	0.7%	2.00 [0.62, 6.43]	2003
HOT CAFE	1	101	3	104	0.2%	0.34 [0.04, 3.25]	2004
AF-CHF	228	694	217	682	43.2%	1.03 [0.89, 1.20]	2008
J-RHYTHM	3	404	4	419	0.5%	0.78 [0.18, 3.45]	2009
CAFE-II	1	31	1	30	0.1%	0.97 [0.06, 14.78]	2009
Total (95% CI)	**3738**		**3761**		**100.0%**	**0.95 [0.86, 1.05]**	
Total events	574		606				

Heterogeneity : $Tau^2 = 0.00$; $Chi^2 = 3.57$, df = 7 ($P = 0.61$); $I^2 = 0\%$

Test for overall effect : Z = 0.99 ($P = 0.32$)

Figure 2 Forest plot for all-cause mortality.

Archives of Cardiovascular Disease (2012) 105, 226–238

cardiovascular mortality

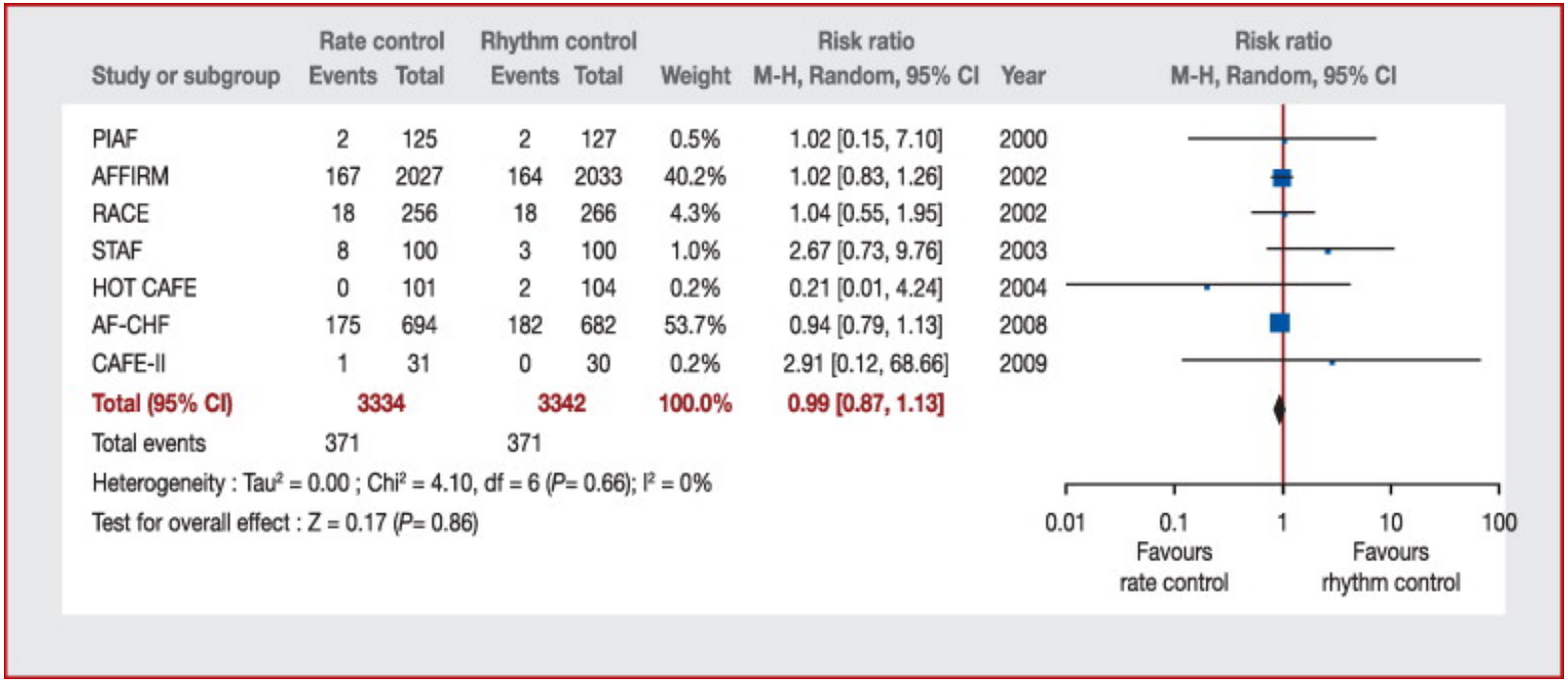


Figure 3 Forest plot for cardiovascular mortality.

Archives of Cardiovascular Disease (2012) 105, 226–238

arrhythmic/sudden death mortality

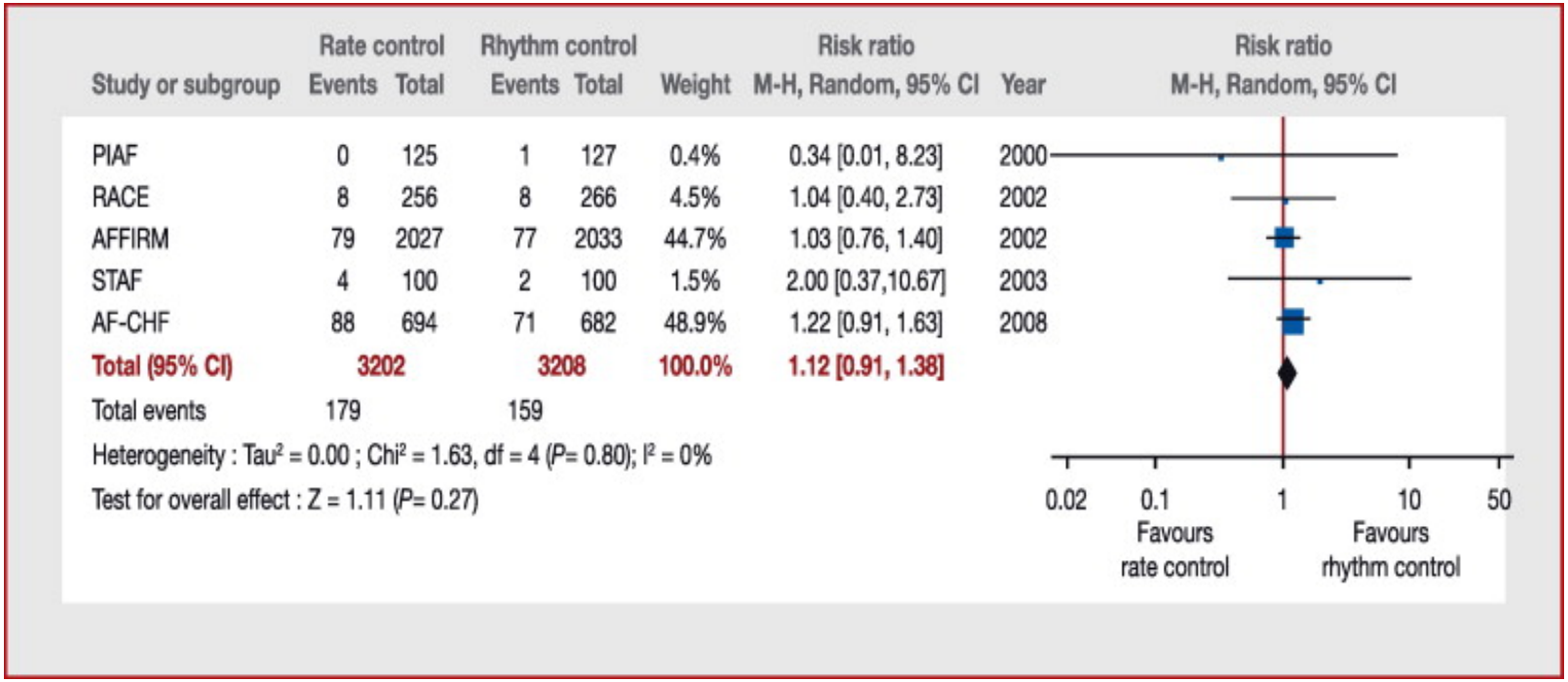


Figure 4 Forest plot for arrhythmic/sudden death mortality.

Archives of Cardiovascular Disease (2012) 105, 226–238

ischaemic stroke

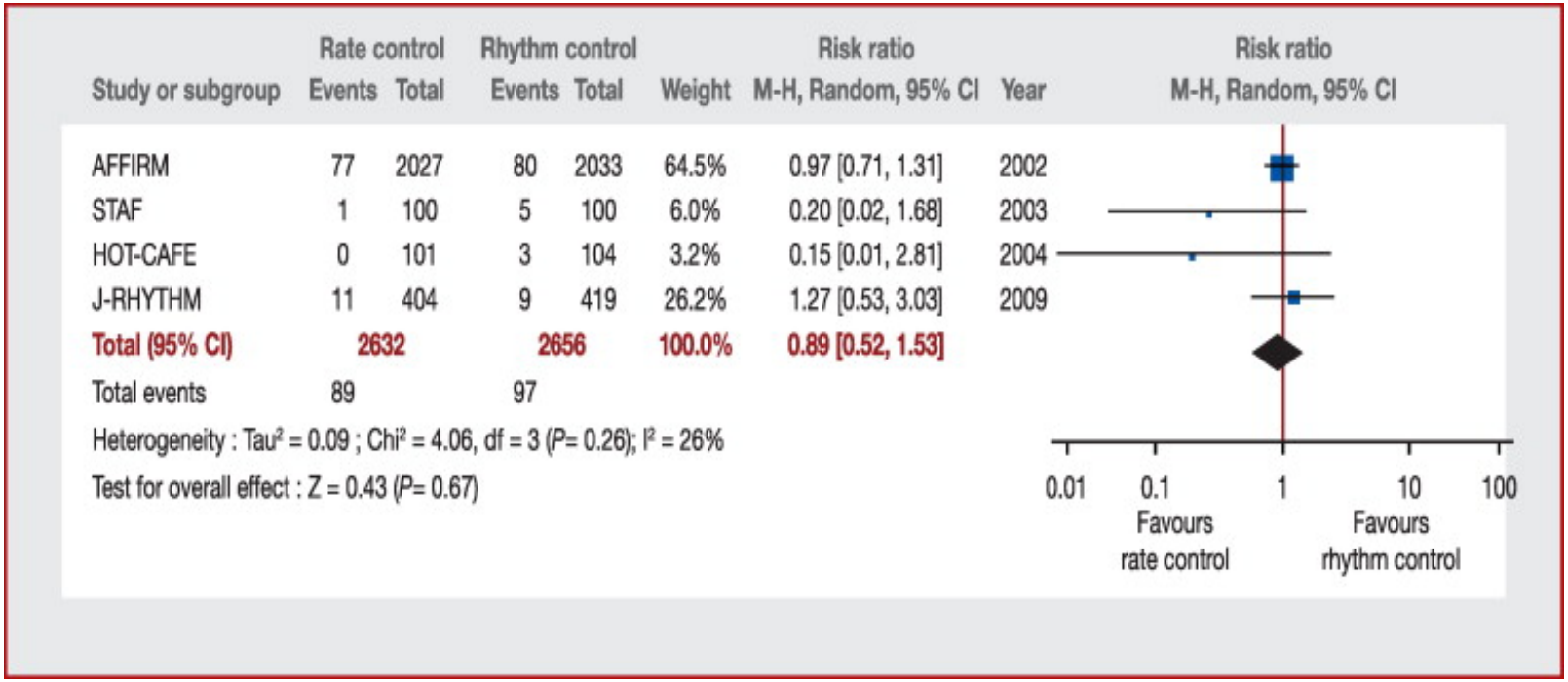


Figure 5 Forest plot for ischaemic stroke.

Archives of Cardiovascular Disease (2012) 105, 226–238

systemic embolism

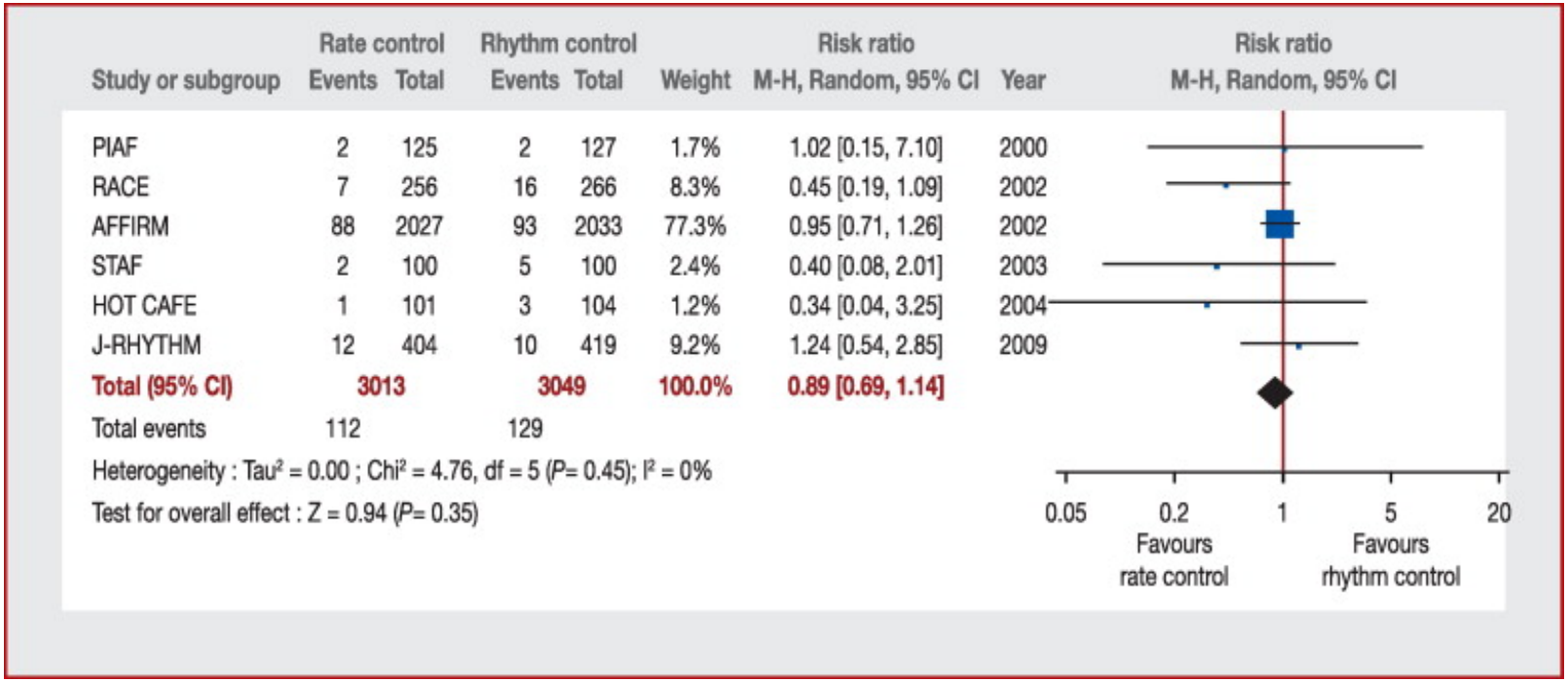


Figure 6 Forest plot for systemic embolism. AFFIRM: Atrial Fibrillation Follow-up Investigation of Rhythm Management study; AF-CHF: Atrial Fibrillation and Congestive Heart Failure study; CI: confidence interval; HOT CAF?: How to Treat Chronic Atrial Fibri...

Archives of Cardiovascular Disease (2012) 105, 226–238

In this review, **rate and rhythm control options did not differ in terms of** :

- **all-cause mortality,**
- **cardiovascular mortality,**
- **arrhythmic/sudden death,**
- **ischaemic stroke,**
- **systemic embolism and major bleeding.**

…… robustly reinforce the conclusions that:
rate and rhythm control are similar in terms of clinical outcomes.

This supports guidelines':
class I recommendations for rate and rhythm control strategies.

Archives of Cardiovascular Disease (2012) 105, 226—238

Arrhythmia/Electrophysiology

Rhythm Versus Rate Control Therapy and Subsequent Stroke or Transient Ischemic Attack in Patients With Atrial Fibrillation

Meytal Avgil Tsadok, PhD; Cynthia A. Jackevicius, PharmD, MSc; Vidal Essebag, MD, PhD; Mark J. Eisenberg, MD, MPH; Elham Rahme, PhD; Karin H. Humphries, DSc; Jack V. Tu, MD, PhD; Hassan Behlouli, PhD; Louise Pilote, MD, PhD

***Circulation*. 2012;126:2680-2687**

Studio osservazionale, condotto in Canada su una coorte di **57.518** pazienti
età ≥65 anni seguiti per un tempo medio di 2.8 anni (massimo 8.2 anni) >1999 _2007<.

Lo studio ha confrontato incidenza d'ictus e TIA in:
16.325 pazienti dimessi con una strategia Rhythm control
e
41.193 pazienti dimessi con una strategia Rate control.

Incidenza di ictus/TIA è stata significativamente minore nei pazienti in Rhythm control rispetto a quelli trattati in Rate control
(1.74 vs 2.49 per 100 persone_anni; p<0.001).

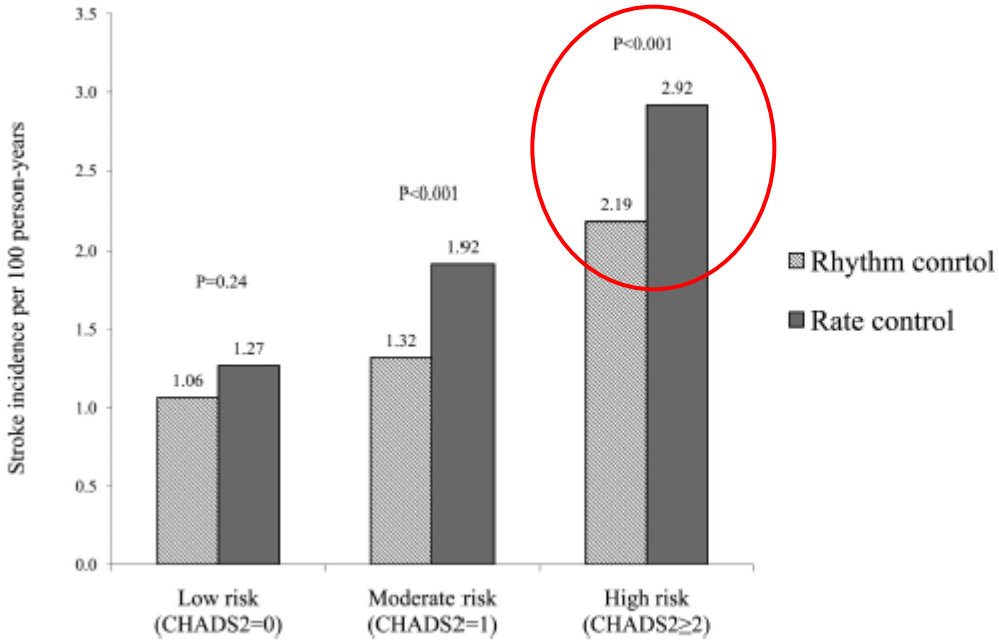


Figure 1. Crude incidence rates of stroke/TIA by $CHADS_2$ score. Stroke/TIA crude incidence per 100 person-years among AF patients with filled prescription for rhythm or rate control treatment, according to $CHADS_2$ score risk assessment for stroke. TIA indicates transient ischemic attack; $CHADS_2$, congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, and previous stroke or TIA; and AF, atrial fibrillation.

Linee guida AIAC per la gestione e il trattamento della fibrillazione atriale. Aggiornamento 2013

Antonio Raviele (Chairman)[1], Marcello Disertori[2] (Co-Chairman), Paolo Alboni[3], Emanuele Bertaglia[4], Gianluca Botto[5], Michele Brignole[6], Riccardo Cappato[7], Alessandro Capucci[8], Maurizio Del Greco[2], Roberto De Ponti[9], Matteo Di Biase[10], Giuseppe Di Pasquale[11], Michele Gulizia[12], Federico Lombardi[13], Sakis Themistoclakis[14], Massimo Tritto[15]

[1]*Alleanza per la Lotta alla Fibrillazione Atriale - ALFA, Mestre-Venezia*
[2]*Dipartimento di Cardiologia, Ospedale S. Chiara, Trento*
[3]*Sezione di Cardiologia, Ospedale Privato Accreditato Quisisana, Ferrara*
[4]*Clinica Cardiologica, Dipartimento di Scienze Cardiologiche, Toraciche e Vascolari, Università degli Studi, Padova*
[5]*U.O. di Cardiologia, Ospedale S. Anna, Como*
[6]*Dipartimento Cardiologico - Centro Aritmologico, Ospedale del Tigullio, Lavagna (GE)*
[7]*Centro Aritmologico ed Elettrofisiologico, IRCCS Policlinico San Donato, San Donato Milanese (MI)*
[8]*Clinica di Cardiologia, Università Politecnica delle Marche, Ancona*
[9]*Dipartimento Cardiocerebrovascolare, Ospedale di Circolo e Fondazione Macchi - Università dell'Insubria, Varese*
[10]*Dipartimento Cardiologico, Università degli Studi, Foggia*
[11]*U.O. di Cardiologia, Ospedale Maggiore, Bologna*
[12]*U.O. di Cardiologia, Ospedale di Garibaldi-Nesima, Catania*
[13]*U.O. di Cardiologia, Ospedale San Paolo, Dipartimento di Scienze della Salute, Università degli Studi, Milano*
[14]*Dipartimento Cardiovascolare, Centro Aritmologico e per la Fibrillazione Atriale, Ospedale dell'Angelo, Mestre-Venezia*
[15]*U.O. di Elettrofisiologia ed Elettrostimolazione, Istituto Clinico Humanitas Mater Domini, Castellanza (VA)*

G Ital Cardiol 2013;14(3):215-240

“Dato, però, il carattere osservazionale dello studio, i suoi risultati, per quanto basati su una casistica consistente, necessitano di essere confermati da futuri trial randomizzati e controllati condotti su un campione adeguato di pazienti.

Essi, pertanto, al momento non permettono di modificare l’opinione che le due strategie, controllo del ritmo e controllo della frequenza, sono sostanzialmente simili circa la capacità di prevenire i fenomeni tromboembolici cerebrali”

G Ital Cardiol 2013;14(3):215-240

“IMPLICATIONS OF THE RHYTHM-CONTROL VERSUS RATE-CONTROL STUDIES”

- I dati della letteratura supportano le LG internazionali
- L’opinione tra le LG è omogenea

European Heart Journal Advance Access published January 25, 2013

European Heart Journal
doi:10.1093/eurheartj/ehs446

CURRENT OPINION

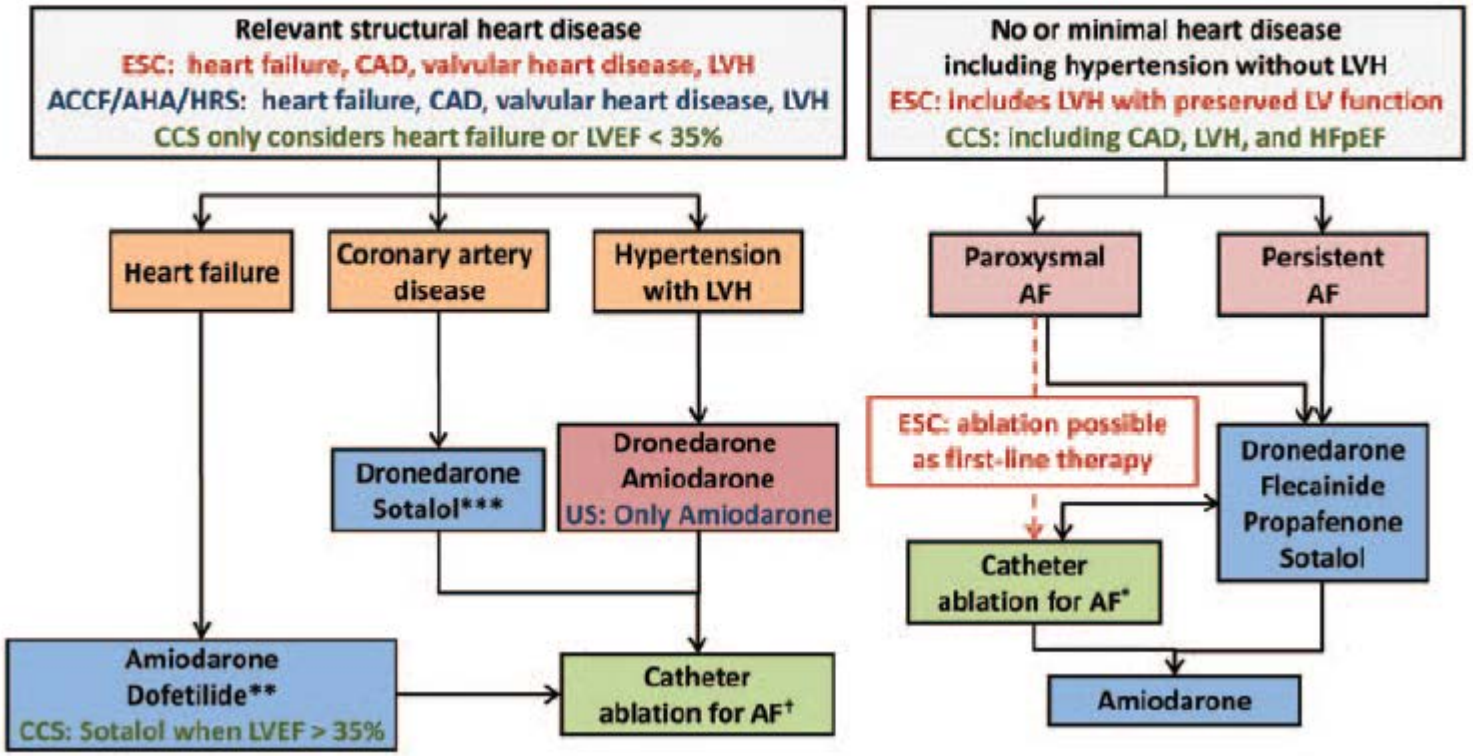
Atrial fibrillation guidelines across the Atlantic: a comparison of the current recommendations of the European Society of Cardiology/European Heart Rhythm Association/European Association of Cardiothoracic Surgeons, the American College of Cardiology Foundation/American Heart Association/Heart Rhythm Society, and the Canadian Cardiovascular Society

Paulus Kirchhof[1,2]*, Anne B. Curtis[3], Allan C. Skanes[4], Anne M. Gillis[5], L. Samuel Wann[6], and A. John Camm[7]

[1]University of Birmingham Centre for Cardiovascular Sciences, Institute for Biomedical Research, 1st Floor, Birmingham B15 2TT, UK; [2]Department of Cardiovascular Medicine, University of Münster, Münster, Germany; [3]Department of Medicine, University at Buffalo, Buffalo, NY, USA; [4]Arrhythmia Service, University Hospital, University of Western Ontario, London, ON, Canada; [5]Libin Cardiovascular Institute of Alberta, University of Calgary, Calgary, AB, Canada; [6]Wisconsin Heart Hospital, Medical College of Wisconsin, Milwaukee, WI, USA; and [7]St George's University of London, London, UK

Choosing rhythm control therapy in atrial fibrillation based on the ACCF/AHA/HRS 2011 update, the CCS 2012 update, and the ESC 2012 update of their atrial fibrillation guidelines.

The decision for rhythm control therapy based on AF-related symptoms.



Rate and rhythm control of AF

Recommendations	Class[a]	Level[b]
Rate control should be the initial approach in elderly patients with AF and minor symptoms (EHRA score 1).	I	A
Rhythm control is recommended in patients with symptomatic (EHRA score ≥ 2) AF despite adequate rate control.	I	B
Rate control should be continued throught a rhythm control approach to ensure adequate control of the ventricular rate during recurrences of AF.	I	A
Rhythm control as an initial approach should be considered in young symptomatic patients in whom catheter ablation treatment has not been ruled out.	IIa	C
Rhythm control should be considered in patients with AF secondary to a trigger or substrate that has been corrected (e.g. ischaemia, hyper-thyroidism).	IIa	C
Rhythm control in patients with AF and AF-related heart failure should be considered for improvement of symptoms.	IIa	B

[a]Class of recommendation. [b]Level of evidence.

AF = atrial fibrillation; EHRA = European Heart Rhythm Association.

www.escardio.org/guidelines

European Heart Journal (2010) 31, 2369-2429

EUROPEAN SOCIETY OF CARDIOLOGY®

EHRA SCORE OF AF-RELATED SYMPTOMS

EHRA class	Explanation
EHRA I	**‘No symptoms’**
EHRA II	**‘Mild symptoms’; normal daily activity not affected**
EHRA III	**‘Severe symptoms’; normal daily activity affected**
EHRA IV	**‘Disabling symptoms’; normal daily activity Discontinued**

Guidelines for the management of atrial fibrillation, ESC 2010

Fuster et al. **JACC Vol. 57, No. 11, 2011**
ACC/AHA/ESC Practice Guidelines March 15, 2011:e101–98

“IMPLICATIONS OF THE RHYTHM-CONTROL VERSUS RATE-CONTROL STUDIES”

Rhythm Control teoricamente vantaggioso.
RACE e AFFIRM: qualche dubbio!
AFFIRM > mortalità in Rhythm control.
Ma RACE e AFFIRM non consideravano pz + giovani, sintomatici.

In conclusione:
RATE CONTROL in paz anziani paucisintomatici per FA.
Rhythm Control nei paz + giovani e sintomatici
(Valutazione calata sul paz)

Pazienti per i quali non è consigliata la cardioversione:
• presenza di malattia cardiaca strutturale
(es ingrandimento atriale > 5,5 cm, stenosi mitralica) che preclude il mantenimento a lungo termine del RS;
• storia di molteplici tentativi falliti di CV e/o recidive, anche in assenza di trattamento antiaritmico in cronico;
• presenza di una possibile causa di FA in fase attiva ma reversibile (es tireotossicosi).

Rhythm Control: Classe I, livello C

- **Primo episodio di FA**

- **FA ricorrente sintomatica in cui:**

1. *probabilità di mantenere il RS elevata*
2. *o in cui non sia possibile mantenere un adeguato controllo della FCM*
3. *o nei quali la FA determini un deterioramento emodinamico*

LG AIAC: giac marzo 2013

RATE Control: Classe I, livello C

- Pz refrattari alla tp antiaritmica con numerose recidive ai tentativi di cardioversione e che non hanno indicazione all'ablazione
- Pz di età avanzata in cui non è possibile seguire la strategia Rhytm Control
- Pz con una cardiopatia sottostante in cui non è possibile seguire la strategia Rhytm Control
- Pz anziani a/pauci_sintomatici con FA persistente e buon compenso emodinamico
- Pz anziani con FA ricorrente, scompenso cardiaco e bassa frazione di eiezione

LG AIAC: giac marzo 2013

RealiseAF

Real life global survey evaluating patients with Atrial Fibrillation

The RealiseAF registry:

An International, observational, cross-sectional survey evaluating atrial fibrillation management and the cardiovascular risk profile of AF patients

initial results

Enrollment from October 30th, 2009 to May 3rd, 2010

www.realiseaf.org

RealiseAF

Upcoming data: HRC, Birmingham, Oct 4, 2010

- Use of medications
- Compliance with guidelines
- Detailed symptoms description according to strategy
- Health-related QoL data

Pre-specified Aims

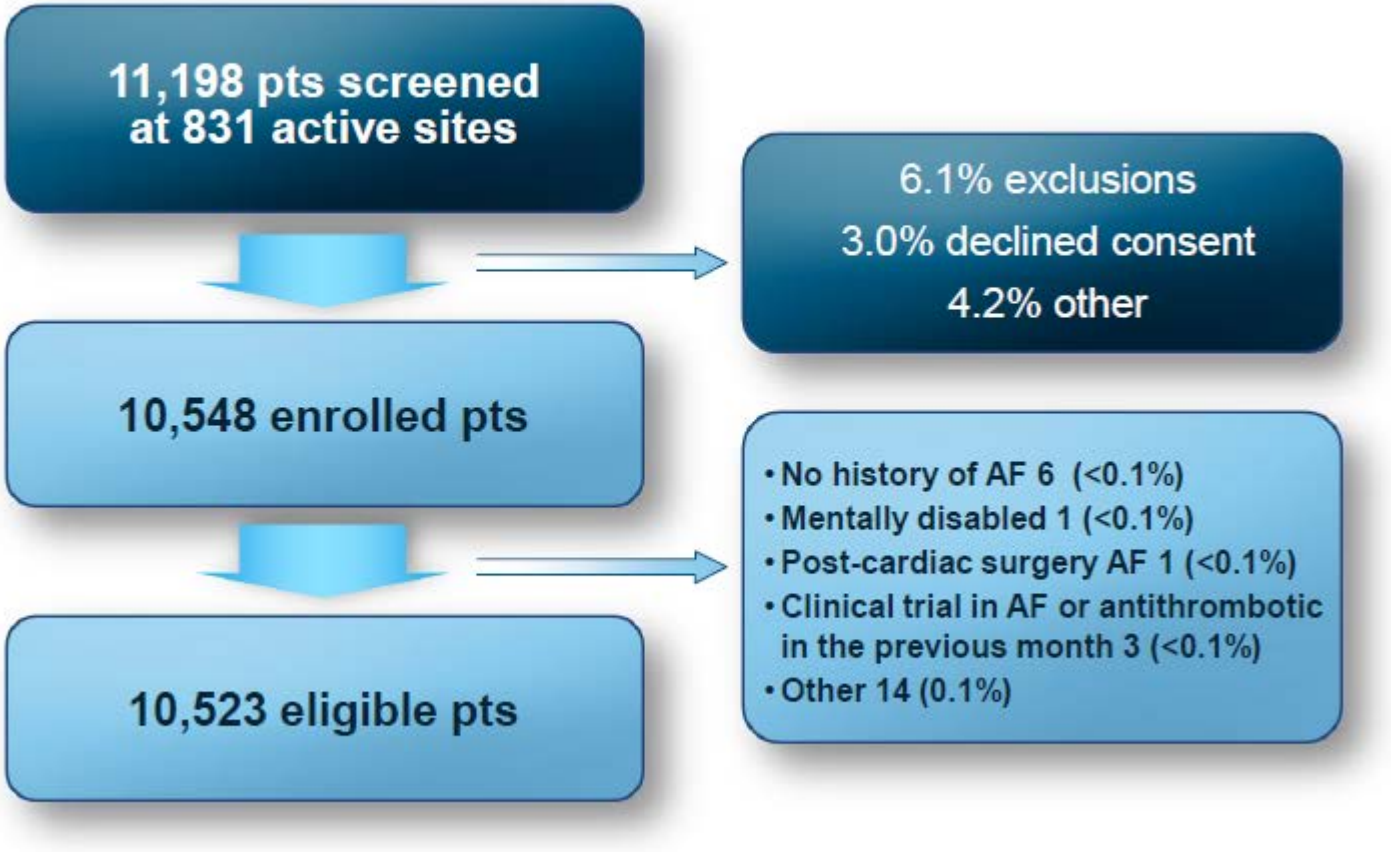
- **Primary:**
  - Assess "control" of AF (either SR or AF with HR ≤ 80 bpm) at the time of the visit
  - Investigate the CV risk profile of AF pts
- **Secondary:**
  - Describe AF characteristics
  - Describe AF management strategies
    - Rate vs rhythm control
    - Rhythm and/or rate control agents
  - Assess whether practice is consistent with evidence based guidelines
    - Use of antithrombotics as a function of $CHADS_2$ score
    - Appropriate therapies consistent with ACC/AHA/ESC 2006 guidelines
  - The frequency of patients with pre-specified symptoms and the scoring of symptoms according to EHRA AF cardiac symptoms classification
  - Assess Health-related QOL associated with AF

Heart. 2012 Feb;98(3):195-201.

RealiseAF

Real life global survey evaluating patients with Atrial Fibrillation

Patient flow



768 / 831 active sites completed the screening log

Patients and AF characteristics

	Total N=10,523
Age ≥ 60 years (%)	73.9
Age mean (SD)	66.6 (12.2)
Males (%)	56.4
Ethnicity(%)	
Caucasian	84.2
Black	0.1
Asian	10.1
Hispanic	3.5
Other	2.1
BMI (kg/m²) mean (SD)	28.3 (5.2)
SBP (mm Hg) mean (SD)	132.8 (19.4)
DBP (mm Hg) mean (SD)	79.8 (11.4)

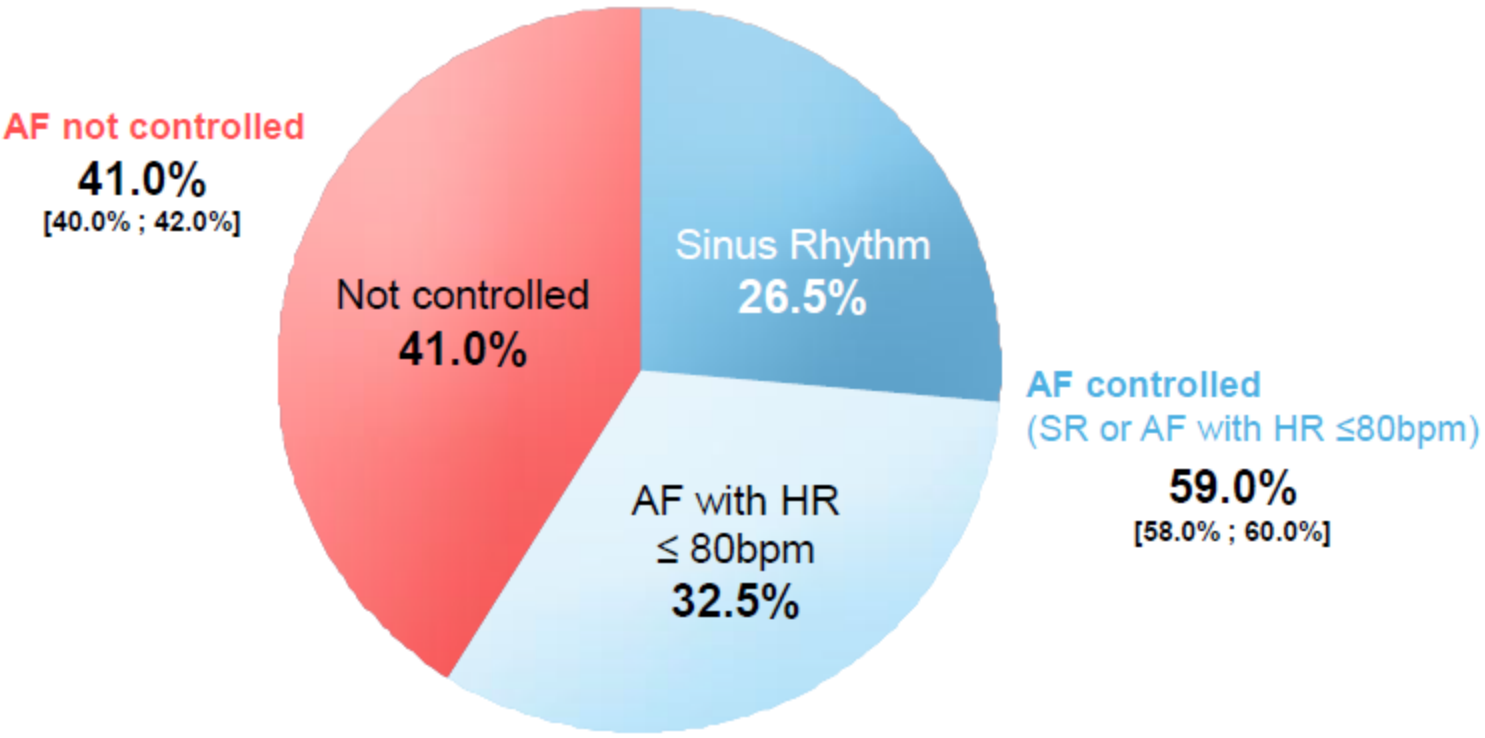
	Total (%)
Lone AF*	5.1
Time since AF diagnosis	
< 3 months	20.6
3 to 6 months	6.3
6 to 12 months	10.2
> 12 months	62.9
Type of AF	
Paroxysmal	24.8
Persistent	22.3
Permanent	46.4
Unable to assign (first episode)	6.4
Paroxysmal+Persistent	<0.1

RealiseAF
Real life global survey evaluating patients with Atrial Fibrillation

Primary outcome: control of AF

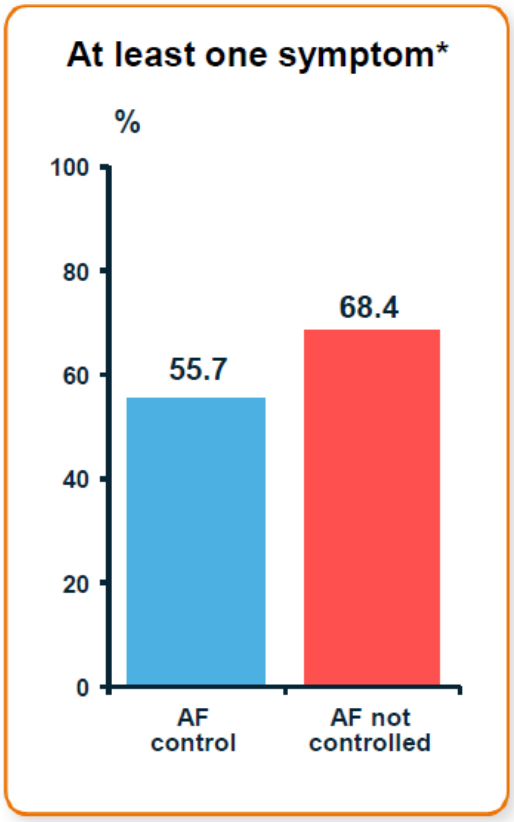
Sinus rhythm or AF with HR ≤ 80 bpm, on the ECG the day of the visit

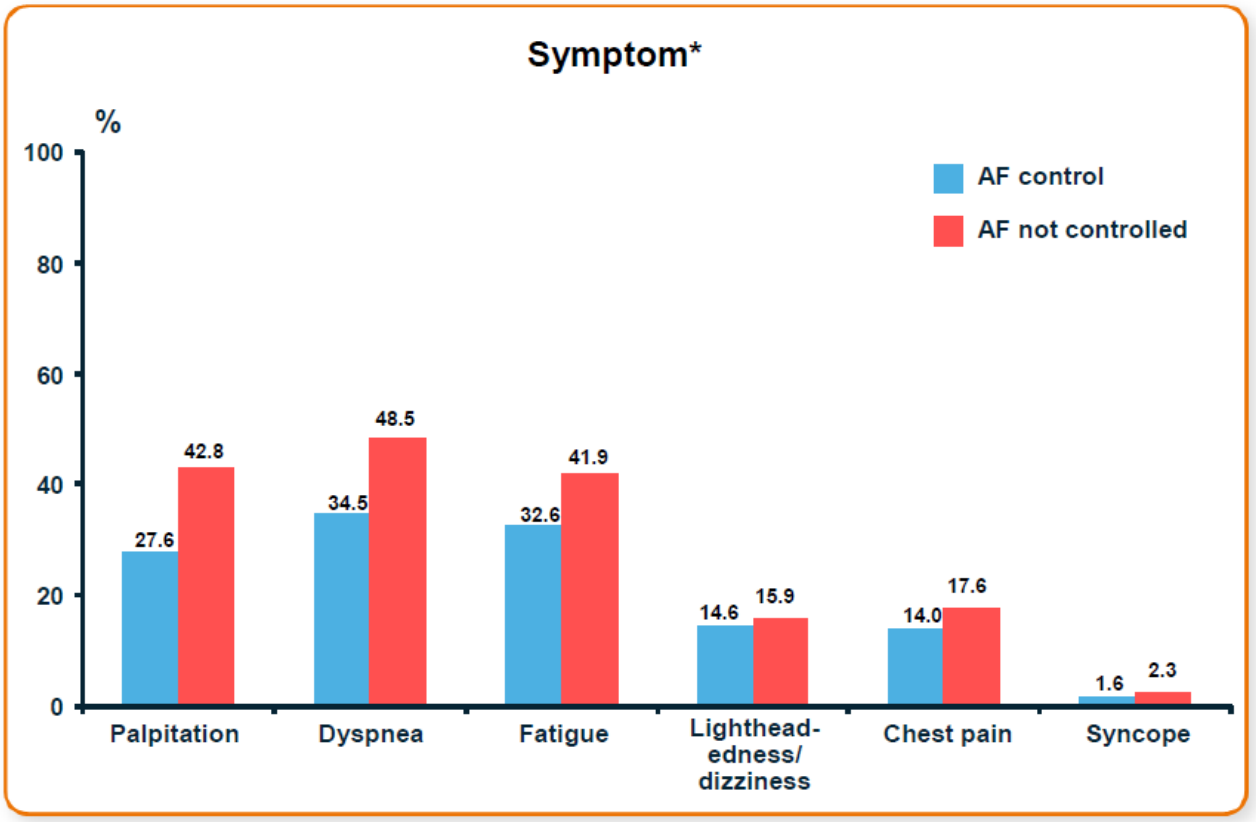
Patients evaluable for primary criterion (n=9,665)



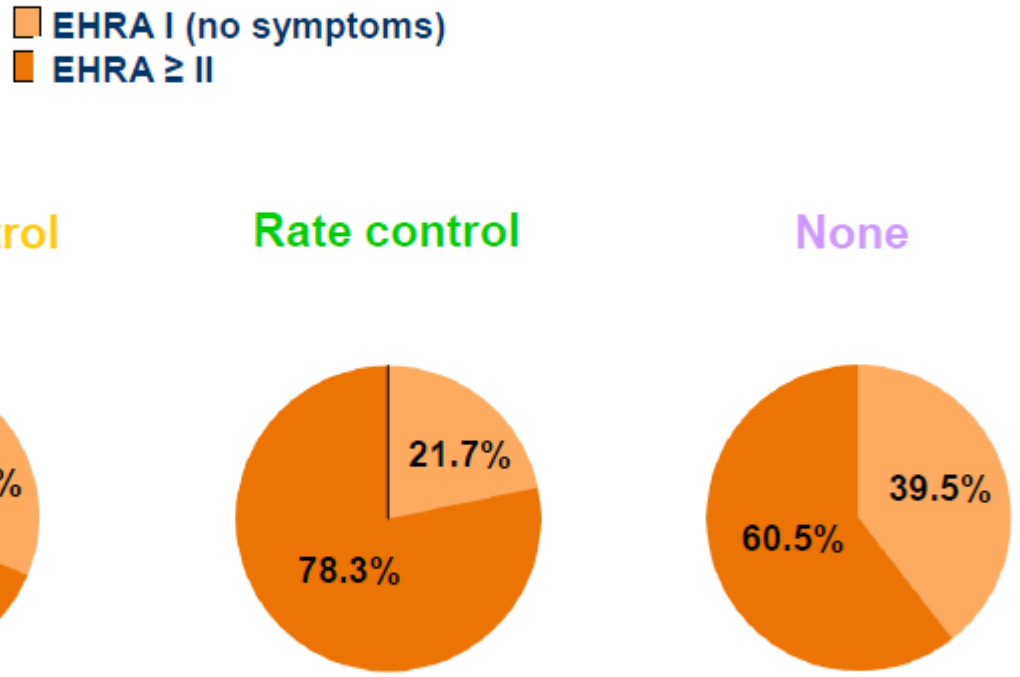
RealiseAF
Real life global survey evaluating patients with Atrial Fibrillation

AF control was not indicative of symptom control





Symptoms (EHRA ≥II) in Each Type of Management Strategy at the End of the Visit



EHRA, European Heart Rhythm Association.

$p < 0.001$

Heart. 2012 Feb;98(3):195-201.

Sguardo d'insieme al paziente

- Rhythm control
- Rate control

Dominant Strategy

Happy Face

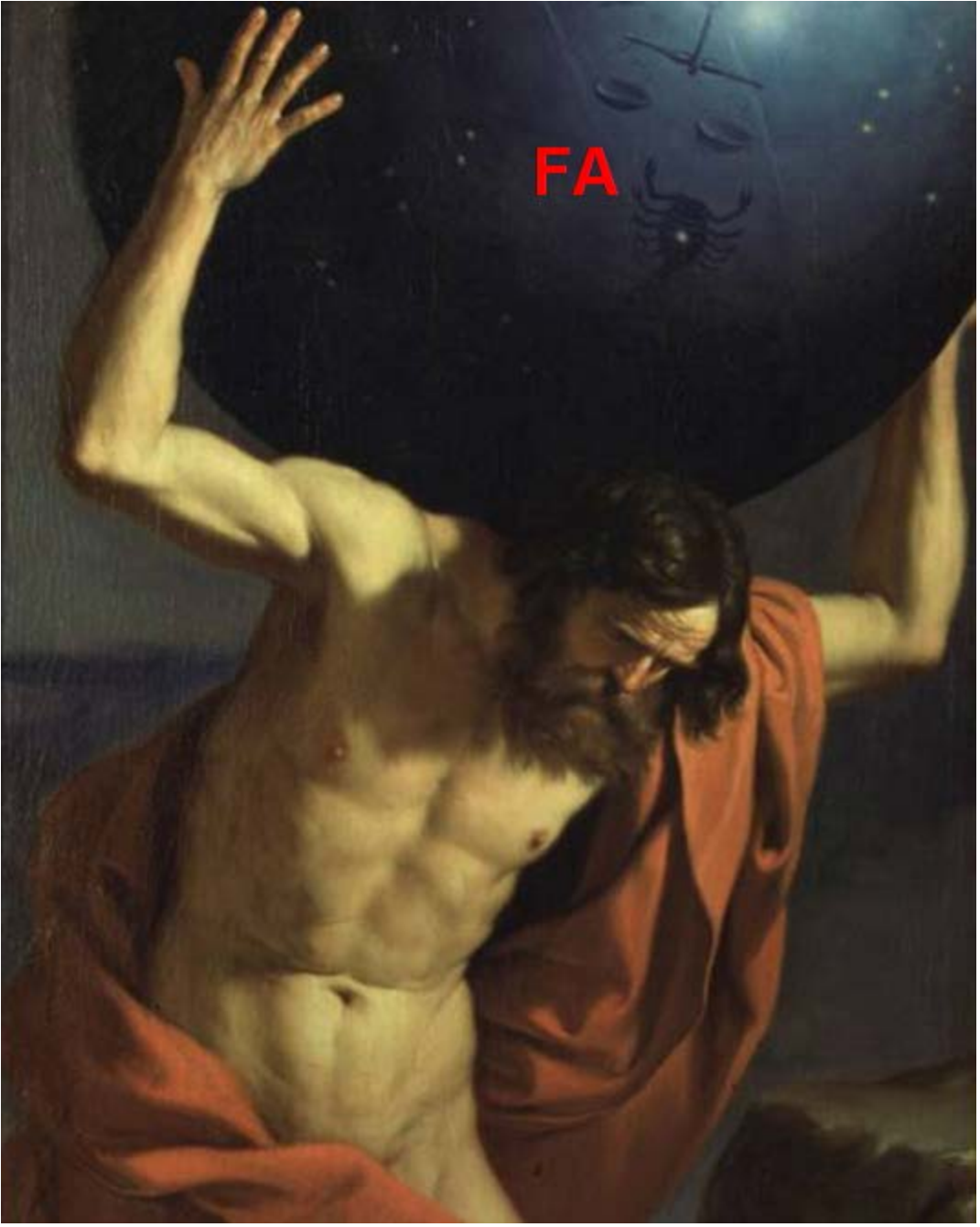
- Asymptomatic
- Marginaly symptomatic
- Older
- Relatively sedentary
- Risk of proarrhythmia

→ **Rate**

Sad /Angry Face

- When rate control inefficient
- Moderate – severe symptoms
- Younger
- Active
- First episode
- Reversible cause

→ **Rhythm**



emergentista
cardiologo
internista

Linguaggio comune e condiviso
(adesione alle LG)

Centralità del paziente