Congresso Regionale CFC Lombardia
23 Ottobre 2015 -Como-

Atrial Fibrillation

Luigi R. Collarini

Ospedale Sacra Famiglia, Fatebenefratelli - Erba - (CO)

Direttore Unita' Operativa Complessa di Cardiologia

The Philosophy of Truth…

There is more than one way to evaluate the truth of a proposition.

- **CoHerence** → *It is true because it makes sense.*
  - It is logical
  - It conforms to our theory
- **CoRrespondence** → *It is true because it is empirically correct.*
  - It is supported by evidence

Until very recently, the management of AF was based on coherence

Rhythm control strategy:

- Restore normal sinus rhythm with electrical cardioversion and/or antiarrhymic medications.

Coherence rationale:

- Slow, regular rhythm optimizes pumping action.
- Contracting atria help fill ventricles.

Correspondence Approach to AF

- Observation that patients seem to tolerate slow AF with few or no symptoms
- Hypothesis that control of heart rate might be good enough treatment for AF
- Rate control strategy:
  - Slow the ventricular response by giving drugs that block conduction from the atria to the ventricles

AFFIRM Trial Results

Rhythm control no better than rate control

AFFIRM Investigators. NEJM 2002; 347(23)

Cardiologists cling to coherence

"Nature has equipped the human heart with a complex electrical system for the purpose of coordinated propulsion of blood under a variety of physiologic conditions. Considerable effort is expended by the heart to maintain sinus rhythm. Cardiac electrophysiologists…are frustrated by the conundrum that atrial fibrillation is associated with increased morbidity and mortality, yet attempts to prove that a strategy to maintain nature's rhythm has a favorable effect on patients have been met one setback after another."

Cain ME. *Rhythm control in atrial fibrillation—one setback after another*. New Engl J Med. 2008; 258-2725-7

Reaction to the AFFIRM Trial

- Accompanying editorial:
  - "An attempt to restore sinus rhythm is still appropriate, although it can no longer be deemed imperative."

- Skeptics cite "design flaws" in AFFIRM; many continue to favor rhythm control.

→ but…*five* subsequent correspondence trials also show detrimental effects of rhythm control.

AFFIRM Trial Results

The New England
Journal of Medicine

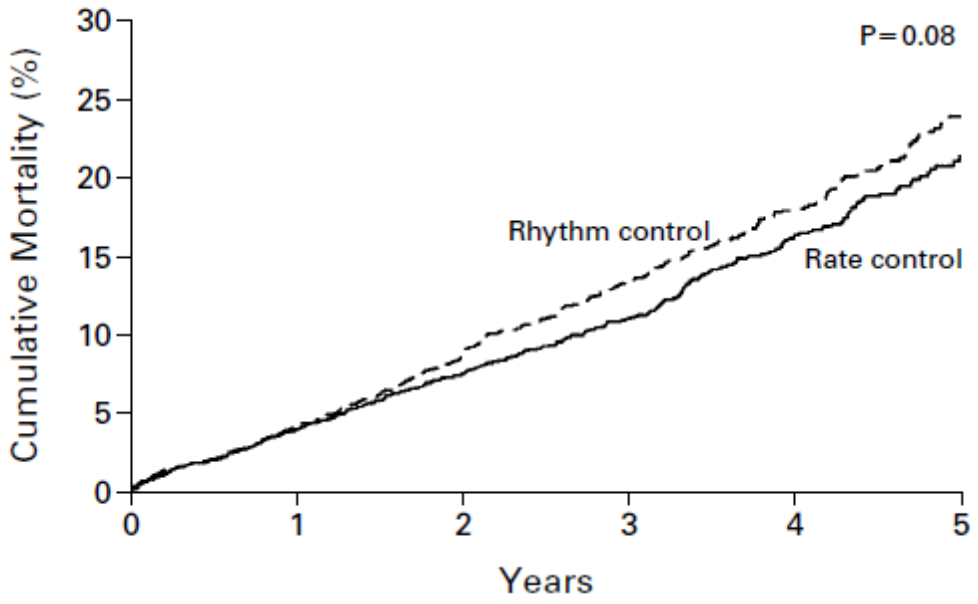
VOLUME 347 DECEMBER 5, 2002 NUMBER 23

A COMPARISON OF RATE CONTROL AND RHYTHM CONTROL IN PATIENTS WITH ATRIAL FIBRILLATION

THE ATRIAL FIBRILLATION FOLLOW-UP INVESTIGATION OF RHYTHM MANAGEMENT (AFFIRM) INVESTIGATORS*

AFFIRM Trial Results

RATE VERSUS RHYTHM CONTROL FOR ATRIAL FIBRILLATION



No. of Deaths		number (percent)				
Rhythm control	0	80 (4)	175 (9)	257 (13)	314 (18)	352 (24)
Rate control	0	78 (4)	148 (7)	210 (11)	275 (16)	306 (21)

Figure 1. Cumulative Mortality from Any Cause in the Rhythm-Control Group and the Rate-Control Group.

AFFIRM Investigators. NEJM 2002; 347(23)

AFFIRM Trial Results

None of the presumed benefits of rhythm control noted above were confirmed in this study. The implication is that rate control should be considered a primary approach to therapy and that rhythm control, if used, may be abandoned early if it is not fully satisfactory. Our data also suggest that continuous anticoagulation is warranted in all patients with atrial fibrillation and risk factors for stroke, even when sinus rhythm appears to be restored and maintained.

AFFIRM Investigators. NEJM 2002; 347(23)

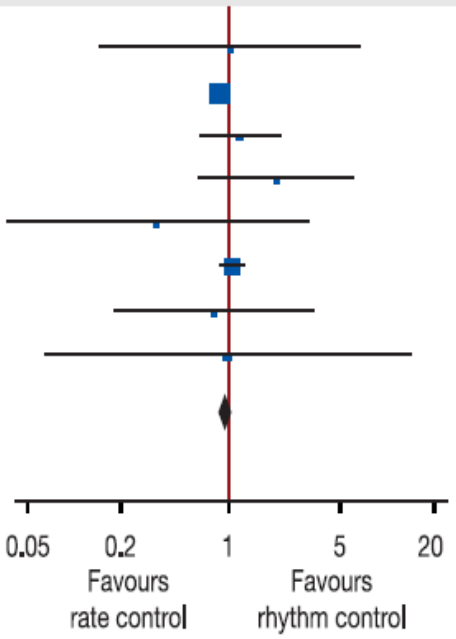
REVIEW

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

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 ($P = 0.32$)



Forest plot for all-cause mortality

Caldeira D. Archives of Cardiovasc Dis 2012; 105: 226-238

Other Studies and Metanalysis

Table 4. Rate versus rhythm control meta-analyses summary

META-ANALYSIS	STUDIES INCLUDED	PATIENTS	KEY FINDINGS
Caldeira et al,[5] 2012	8 RCTs (PIAF,[9] RACE,[10] AFFIRM,[11] STAF,[12] HOT CAFE,[13] AF-CHF,[14] J-RHYTHM,[15] CAFE-II[16])	N = 7499 participants with AF, mean age 68 y, mostly men (63.4%-82%); HTN (42.8%-64.3%), valvular disease (4.9%-17%), CAD (7.4%-43.5%), HF (3.6%-70%); mean follow-up 2.9 y (range 1-3.5 y)	No significant difference between rate and rhythm control in all-cause mortality, CV mortality, arrhythmia or sudden death, ischemic stroke or embolic events, or serious bleeding; there were significantly fewer systemic embolic events in the rate-control group in trials where more than 50% of patients reported HF (RR = 0.43, 95% CI 0.21-0.89)
Cordina and Mead,[6] 2005	2 RCTs (PIAF,[9] AFFIRM[11])	N = 4312 participants > 18 y with acute, paroxysmal, or sustained AF or atrial flutter, of any duration and any cause (most patients were > 60 y with considerable CV risk factors)	No difference in mortality or quality of life between rate- or rhythm-control strategies; hospitalization ($P < .001$) and adverse events ($P < .05$) were significantly higher in the rhythm-control group
De Denus et al,[7] 2005	5 RCTs (PIAF,[9] RACE,[10] AFFIRM,[11] STAF,[12] HOT CAFE[13])	N = 5239 participants with first or recurrent AF, mean age 65.1 y, mostly men (65.3%); CAD (29.9%), HTN (52.7%); mean duration of follow-up 1.9 y	Rate control was significantly better for the combined end point of all-cause death and thromboembolic stroke (NNT = 50); however, for single end points of death and stroke individually, the difference between rate and rhythm strategies was non-significant; differences in serious bleeding (intracranial and extracranial) and systemic embolism were also not significant
Kumana et al,[8] 2005	5 RCTs (PIAF,[9] RACE,[10] AFFIRM,[11] STAF,[12] HOT CAFE[13])	N = 5239 participants with persistent or recurrent AF	Rate control was significantly better ($P < .01$) than rhythm control for preventing hospitalizations (NNH = 35 for rhythm control); differences in death, non-CNS bleeding, and ischemic stroke were non-significant

AF—atrial fibrillation, CAD—coronary artery disease, CNS—central nervous system, CV—cardiovascular, HF—heart failure, HTN—hypertension, NNH—number needed to harm, NNT—number needed to treat, RCT—randomized controlled trial, RR—relative risk.

Frankel G. Canadian Fam Phys 2013; 59

Differences in Clinical Outcomes with Rhythm and Rate Control Therapies for Atrial Fibrillation in the RecordAF Registry

- The results of AFFIRM, and other rate versus rhythm trials suggest that there is no advantage of rhythm control over rate control for the treatment of atrial fibrillation with respect to major cardiovascular outcomes
- However, randomized controlled trials often do not fully represent real life situations
- Registry data may be of value to complement information derived from randomized controlled trials
- The RecordAF Registry was established to trace the influence of the physician's choice of a rate versus rhythm control strategy for consecutive patients with first onset or recent recurrent atrial fibrillation

Differences in Clinical Outcomes with Rhythm and Rate Control Therapies for Atrial Fibrillation in the RecordAF Registry

Differences in Clinical Outcomes with Rhythm and Rate Control Therapies for Atrial Fibrillation in the RecordAF Registry

- Therapeutic success was achieved more frequently in patients treated by rhythm control, driven by 81% in SR in the rhythm control group and 74% at HR target of ≤ 80 bpm at 1 year in the rate control group
- The high occurrence of CV clinical events was dependent on co-morbidity rather than the choice of strategy
- In real life, the better success of AF management with rhythm control did not translate into better outcomes
- These results confirm and complement results from previous controlled randomized trials

Canadian CardioVascular Society – Atrial Fibrillation Guidelines 2010: rate and rhythm management

Table 3. Factors favouring rate versus rhythm control

FAVOURING RATE CONTROL	FAVOURING RHYTHM CONTROL
Persistent AF	Paroxysmal AF or newly detected AF
Less symptomatic	More symptomatic
Age ≥ 65 y	Age < 65 y
Hypertension	No hypertension
No history of HF	HF clearly exacerbated by AF
Previous failure of antiarrhythmic drug	No previous failure of antiarrhythmic drug
Patient preference	Patient preference

AF—atrial fibrillation, HF—heart failure.
Data from Gillis et al.[1]

Gillis AM. Can J Cardiol 2011; 27: 47-59

Linee guida AIAC 2010 per la gestione e il trattamento della FIBRILLAZIONE ATRIALE

- La strategia di controllo del ritmo è la strategia di prima scelta nei pazienti al primo episodio di FA (classe I, livello di evidenza C).
- La strategia di controllo del ritmo va mantenuta come prima scelta nei pazienti con FA ricorrente sintomatica in cui la probabilità di mantenere il RS sia elevata o in cui non sia possibile mantenere un adeguato controllo della risposta ventricolare media o nei quali la FA determini un deterioramento emodinamico (classe I, livello di evidenza C).

CLINICAL PRACTICE GUIDELINE

VOL. 64, NO. 21, 2014
ISSN 0735-1097/$36.00

2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: Executive Summary

2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: Executive Summary

5. RHYTHM CONTROL: RECOMMENDATIONS

CLASS IIa

1. A rhythm-control strategy with pharmacological therapy can be useful in patients with AF for the treatment of tachycardia-induced cardiomyopathy. *(Level of Evidence: C)*

CLASS IIb

1. It may be reasonable to continue current antiarrhythmic drug therapy in the setting of infrequent, well-tolerated recurrences of AF when the drug has reduced the frequency or symptoms of AF. *(Level of Evidence: C)*

2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: Executive Summary

3. The risks of the antiarrhythmic drug, including proarrhythmia, should be considered before initiating therapy with each drug. *(Level of Evidence: C)*

4. Because of its potential toxicities, amiodarone should only be used after consideration of risks and when other agents have failed or are contraindicated (129,137,142–145). *(Level of Evidence: C)*

Antiarrhythmics for maintaining sinus rhythm after cardioversion of atrial fibrillation (Review)

Lafuente-Lafuente C, Valembois L, Bergmann JF, Belmin J

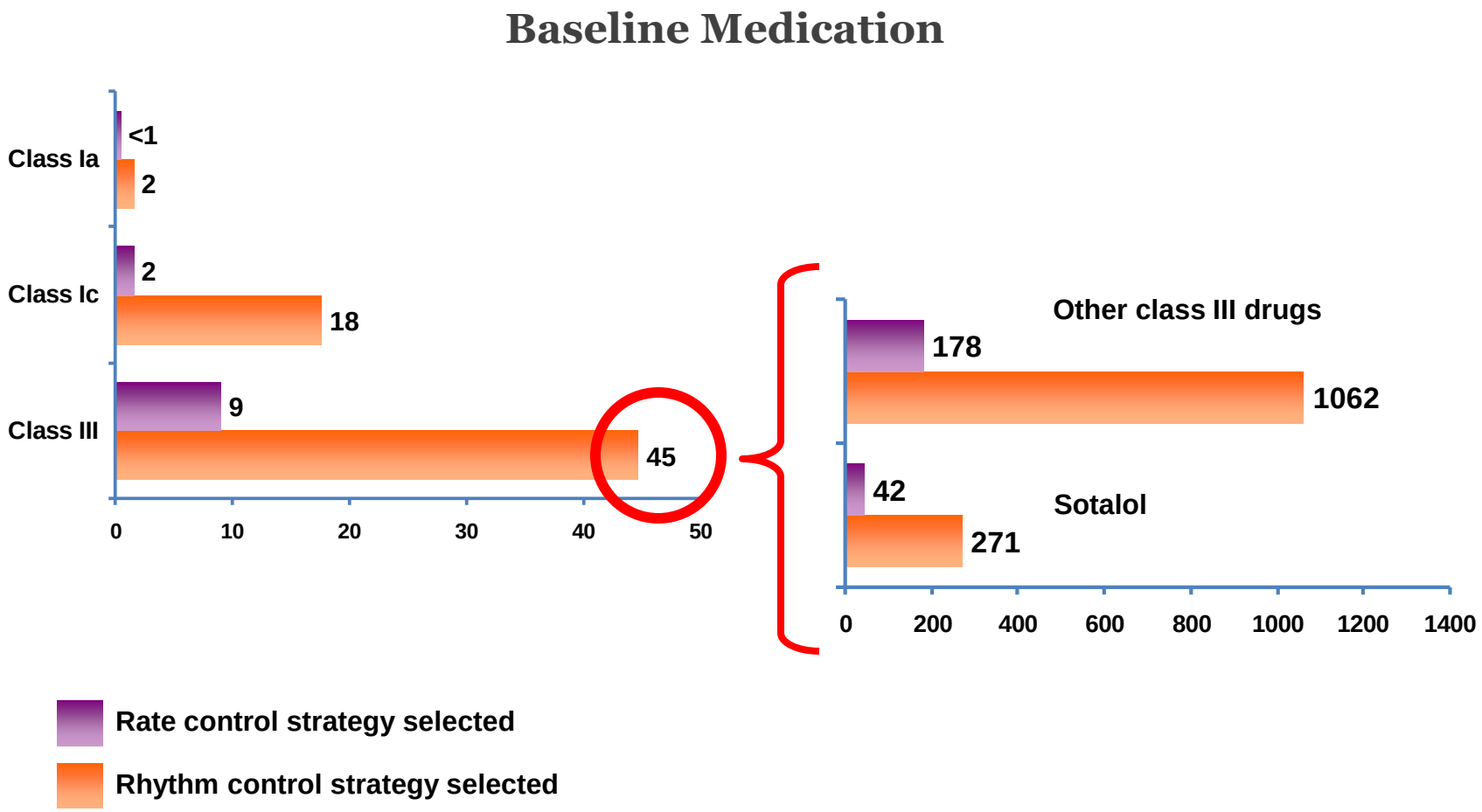
Several class IC (flecainide, propafenone) and III (amiodarone, dronedarone, sotalol) drugs significantly reduced recurrence of atrial fibrillation (OR 0.19 to 0.70, number needed to treat to beneft (NNTB) 3 to 16).

Betablockers (metoprolol) also significantly reduced atrial fibrillation recurrences (OR 0.62, 95% CI 0.44 to 0.88, NNTB 9).

Compared with controls, class IA drugs and sotalol were associated with increased all-cause mortality. Other antiarrhythmics did not seem to modify mortality.

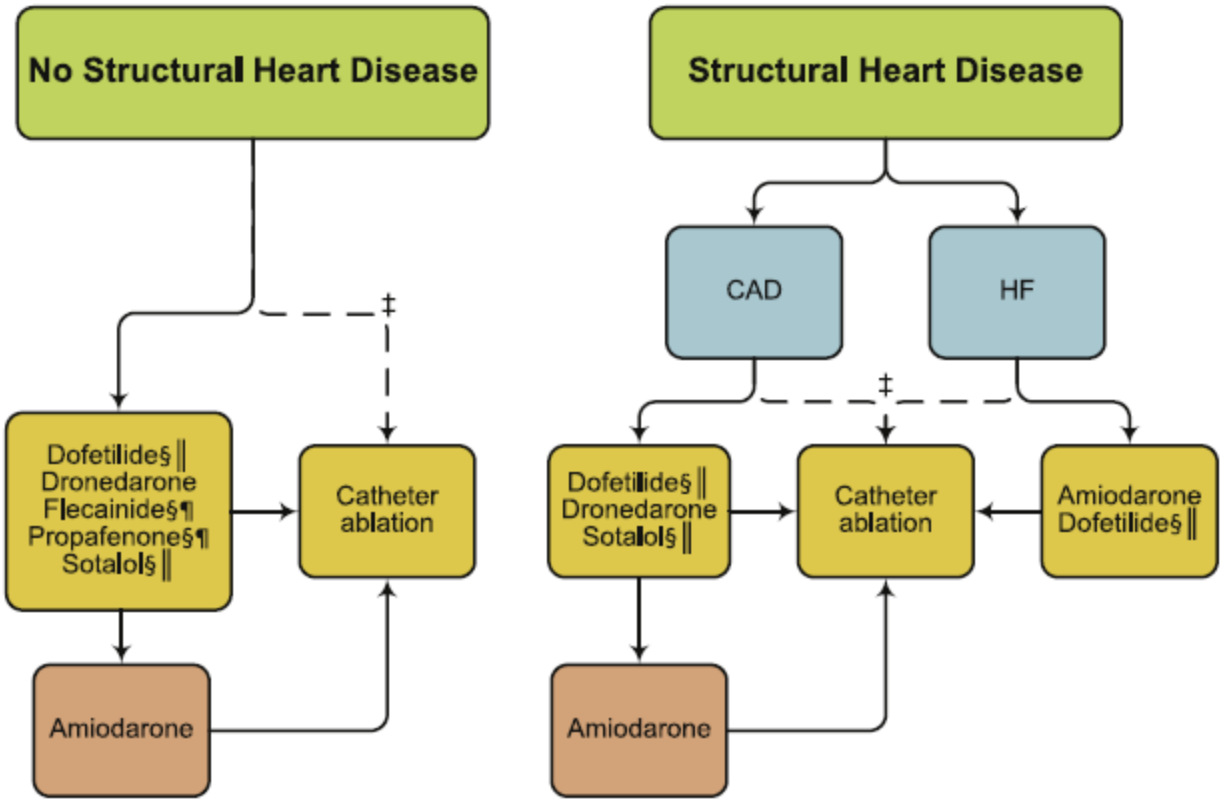
All analysed drugs increased withdrawals due to adverse affects and all but amiodarone, dronedarone and propafenone increased proarrhythmia.

Differences in Clinical Outcomes with Rhythm and Rate Control Therapies for Atrial Fibrillation in the RecordAF Registry



Camm J. RECORD Registry

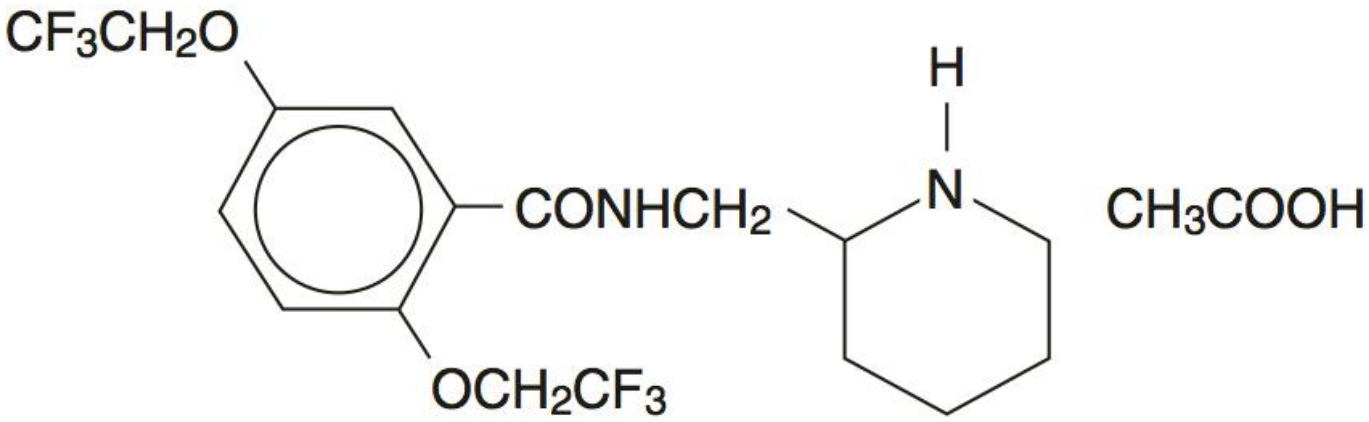
2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: Executive Summary



2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: Executive Summary

Vaughan Williams class IC			
Flecainide	• 50–200 mg once every 12 h	• Sinus or AV node dysfunction • HF • CAD • Atrial flutter • Infranodal conduction disease • Brugada syndrome • Renal or liver disease	• Metabolized by CYP2D6 (inhibitors include quinidine, fluoxetine, tricyclics; also genetically absent in 7%–10% of population) and renal excretion (dual impairment can ↑↑plasma concentration)
Propafenone	• Immediate release: 150–300 mg once every 8 h • Extended release: 225–425 mg once every 12 h	• Sinus or AV node dysfunction • HF • CAD • Atrial flutter • Infranodal conduction disease • Brugada syndrome • Liver disease • Asthma	• Metabolized by CYP2D6 (inhibitors include quinidine, fluoxetine, tricyclics; also genetically absent in 7%–10% of population)—poor metabolizers have ↑beta blockade • Inhibits P-glycoprotein: ↑digoxin concentration • Inhibits CYP2C9: ↑warfarin concentration (↑INR 25%)
Vaughan Williams class III			
Amiodarone	• Oral: 400–600 mg daily in divided doses for 2–4 wk; maintenance typically 100—200 mg QD • IV: 150 mg over 10 min; then 1 mg/min for 6 h; then 0.5 mg/min for 18 h or change to oral dosing; after 24 h, consider decreasing dose to 0.25 mg/min	• Sinus or AV node dysfunction • Infranodal conduction disease • Lung disease • Prolonged QT interval	• Inhibits most CYPs to cause drug interaction: ↑concentrations of warfarin (↑INR 0%–200%), statins, many other drugs • Inhibits P-glycoprotein: ↑digoxin concentration

Attuali “alternative” farmacologiche



Flecainide acetato

Eadem mutata resurgo

FLEIDERINA – flecainide a rilascio prolungato (monosomm.ne)

Meccanismo del rilascio prolungato

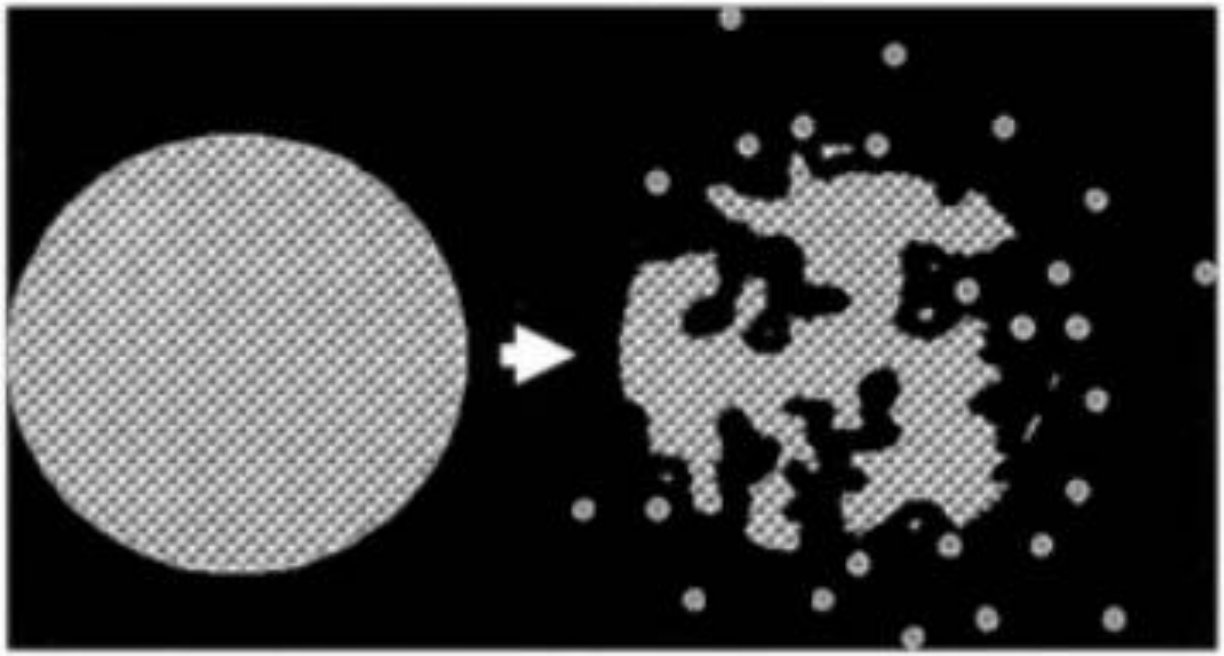
Le capsule rigide di Fleiderina R.P. contengono microgranuli rivestiti dal polimero a base di acido metacrilico-metil metacrilato (EUDRAGIT S-100).

E' grazie a questo polimero che avviene il rilascio prolungato del principio attivo.

Ogni singolo microgranulo agisce modulando il rilascio della flecainide acetato, e questo determina un prolungamento del tempo di assorbimento, senza modificare i parametri di eliminazione del farmaco.

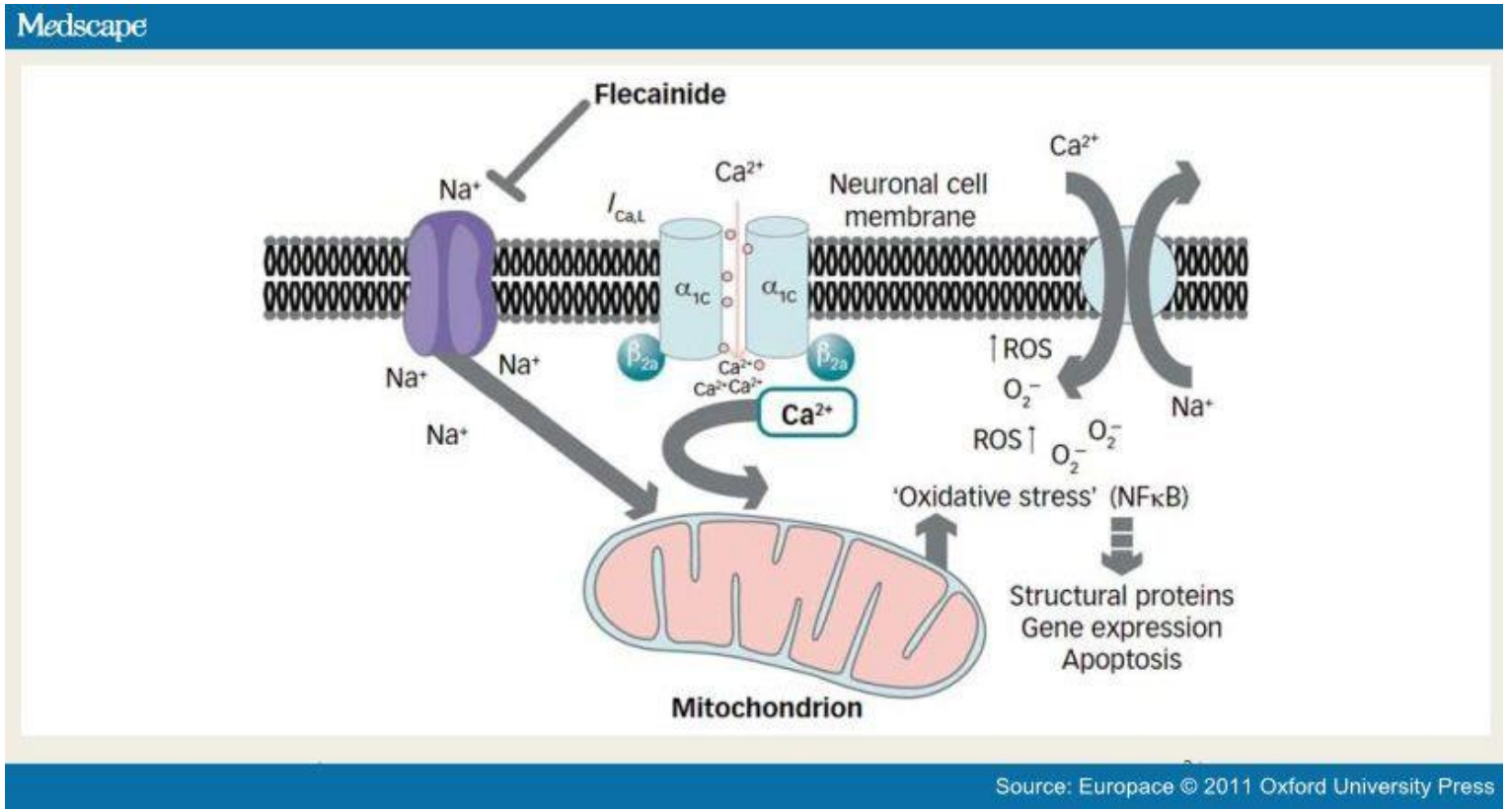
L'emivita di eliminazione (t ½) risulta essere di circa 12 -13 ore.

FLEIDERINA – flecainide a rilascio prolungato (monosomm.ne)



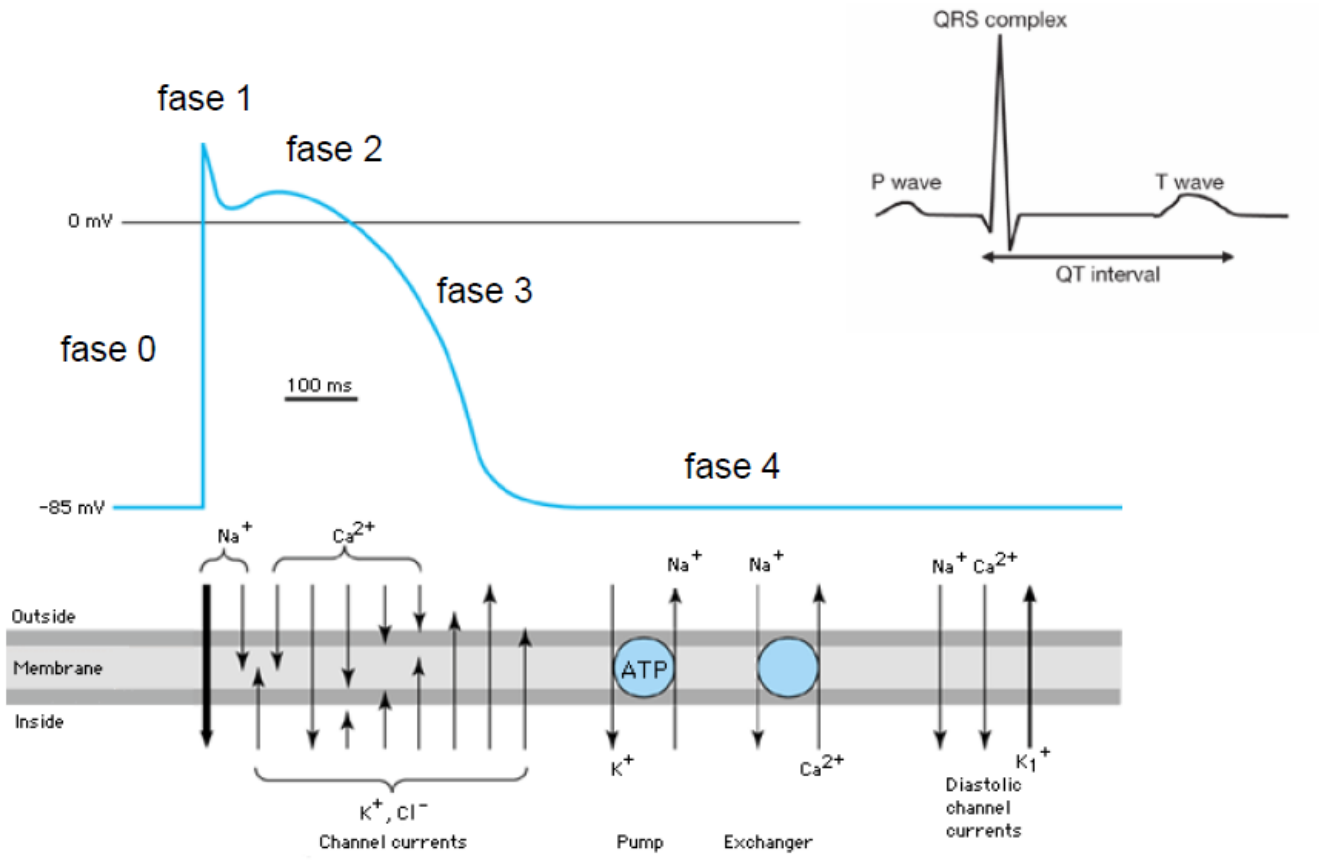
Il rilascio del principio attivo Flecainide avviene gradualmente per erosione e dissoluzione del rivestimento di polimero.

FLEIDERINA – flecainide a rilascio prolungato (monosomm.ne)

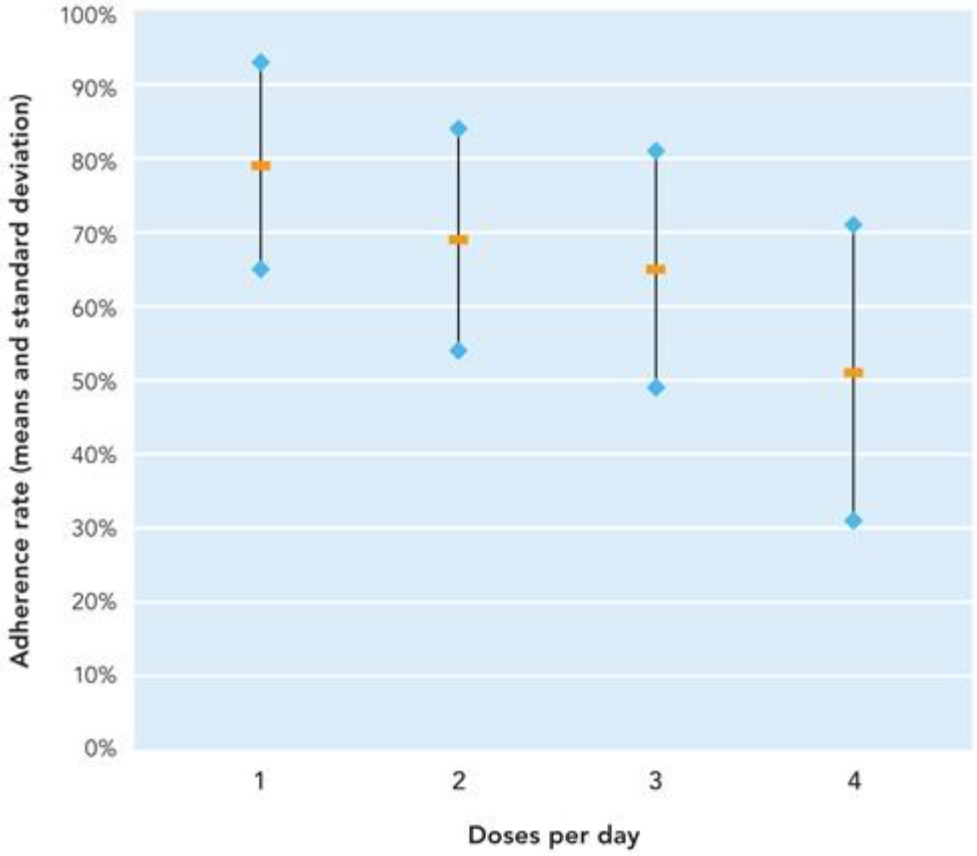


Inhibition of Na+ channels by flecainide during rapid atrial activation attenuates excess cellular Ca2+ accumulation and reduces oxidative stress. I Ca,L, L-type calcium current; ROS, reactive oxygen species; NFκB, nuclear factor-κB.

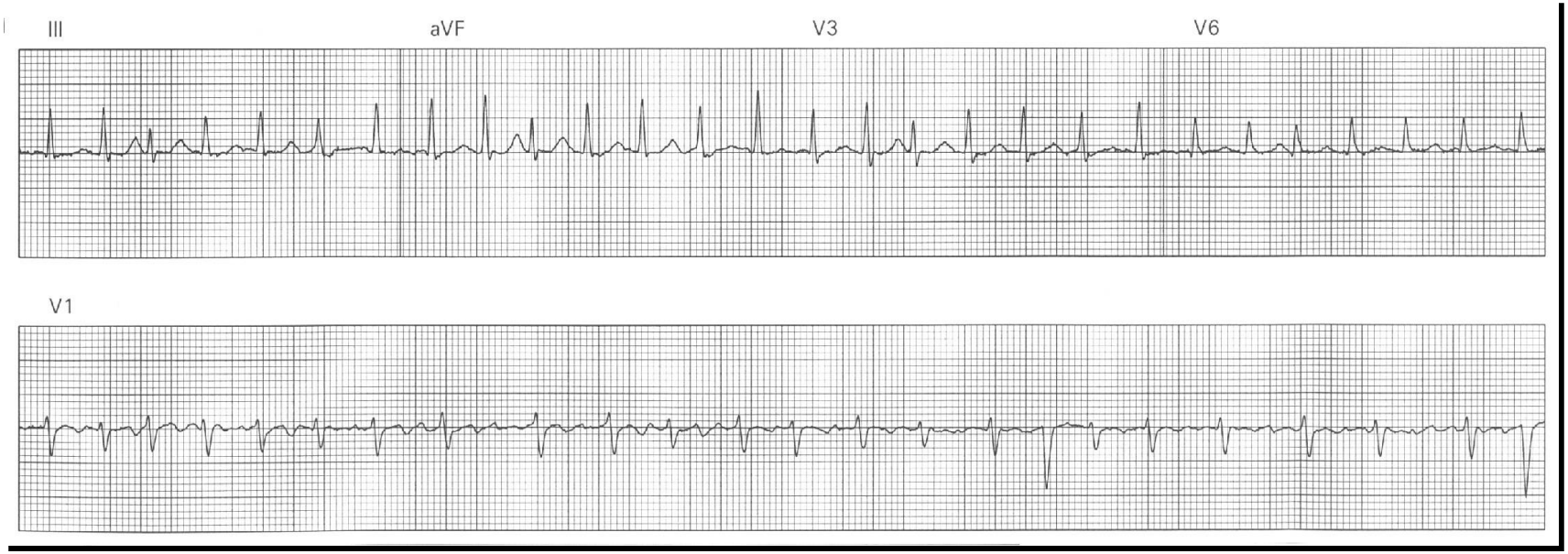
Potenziale d'azione cardiaco



Compliance to therapy



FLEIDERINA – studi clinici



Philippe Coumel, MD, *Pierre Maison-Blanche, MD, †Eliane Tarral, MD, ‡Antoine Périer, MPhil, *Paul Milliez, MD, and *Antoine Leenhardt, MD

Equivalenza Farmacodinamica di due formulazioni a base di flecainide acetato in pazienti con fibrillazione atriale parossistica mediante analisi del tratto QRS dell'elettrocardiogramma ambulatoriale.

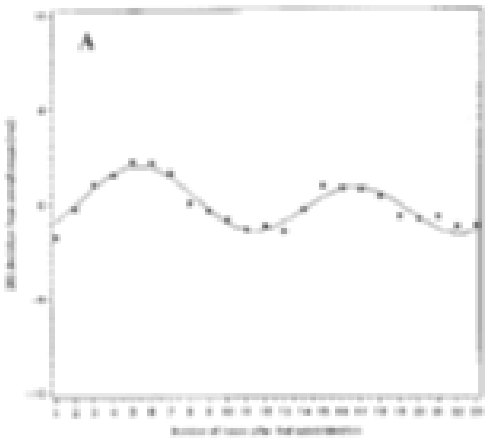
J Cardiovasc Pharmacol™ 2003

Obiettivo Dello Studio:

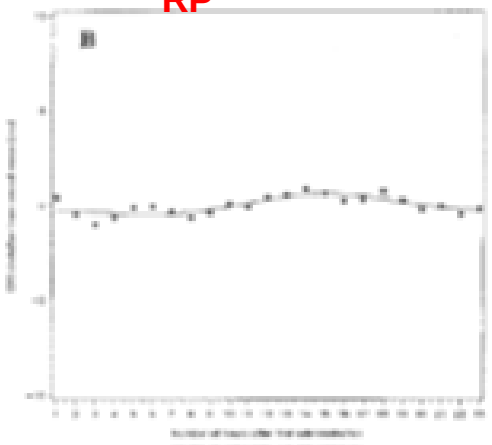
L'equivalenza farmacodinamica tra due formulazioni di flecainide acetato a rilascio immediato (IR) ed a rilascio prolungato (RP) è stata valutata in funzione della durata del QRS in pazienti già in trattamento con una formulazione di flecainide a IR .

Flecainide RP
e migliore stabilità a livello cardiaco
rispetto alla flecainide IR

Flecainide IR



Flecainide RP



La somministrazione della Flecainide RP riduce
le variazioni circadiane della durata del QRS rispetto alla flecainide IR.

La flecainide RP neutralizzando gli aumenti delle variazioni del QRS dimostrati durante l'attività diurna dei pazienti, può ridurre potenziali problemi di tolleranza

Conclusioni:

Le variazioni orarie circadiani della durata del QRS, come rilevato mediante analisi armonica, hanno mostrato la comparsa di un ampliamento del picco QRS in seguito all'assunzione di una formulazione a IR, mentre tale aspetto non è stato osservato con la formulazione RP.

Questi ultimi risultati sono coerenti con una maggiore presenza nell'arco delle 24 h di variazioni della frequenza - QRS dipendenti in seguito all'assunzione di una formulazione IR rispetto alla formulazione RP .

Aliot E , De Roy L , Capucci A, Hernández J , Denjoy io , Lupoglazoff JM , Coumel P.

La sicurezza di una formulazione flecainide acetato rilascio prolungato nella prevenzione della fibrillazione atriale parossistica in pazienti ambulatoriali .

Ann Cardiol Angeiol (Paris). 2003

Obiettivo Dello Studio :

La sicurezza a livello cardiaco di una formulazione in monosomministrazione da 200 mg a rilascio prolungato di flecainide acetato nella prevenzione della fibrillazione atriale parossistica (PAF) è stata valutata in pazienti non ospedalizzati.

.

Metodi :

Il farmaco è stato somministrato per 24 settimane a 227 pazienti con diagnosi di episodi ricorrenti di PAF (dopo aver interrotto precedenti trattamenti antiaritmici*).

La sicurezza cardiaca è stata valutata principalmente in funzione della massima variazione rispetto al basale della durata del QRS .

Cambiamenti nella funzione ventricolare sinistra in ecocardiografia , l'incidenza di effetti proaritmici determinati da ECG e Holter registrazioni e gli eventi cardiovascolari avversi sono stati inoltre presi in considerazione per valutare la sicurezza cardiaca .

L'efficacia è stata documentata mediante analisi statistica basata su metodi attuariali.

*Wash-out: da 10 giorni fino a 3,5 mesi per l'amiodarone

Risultati:

L’aumento massimo significativo del QRS rispetto ai valori basali è stato dell’11,4% (n = 181) ;
l’aumento del QRS è < 15% nel 71,8 % dei pazienti e > o = 25% nel 18,8% .

Solo 4 pazienti hanno avuto il massimo valore del QRS > 100 ms durante il trattamento .

La frazione di eiezione ventricolare sinistra è rimasta entro + / - 20 % dei valori basali nel 90 % dei pazienti , un aumento superiore al 20 % per l’ 8,6% e una riduzione al di sotto del 30% per il 1,4 % (n = 139) .

Risultati:

Gli effetti proaritmici identificati più frequenti sono stati bradicardia (13,2 %, n = 129) e extrasistoli ventricolari (10,6 %, n = 104).

Blocco atrio-ventricolare (4,0 %) , tachicardia sopra- ventricolare (2,2 %), blocco di branca (1,8 %) e la fibrillazione atriale (1,3 %) sono stati gli eventi avversi cardiaci più frequenti correlati al farmaco.

La % di efficacia al trattamento è stato del 74 % (95 % IC: [68 %, 80%]) e l'incidenza di episodi PAF ridotti da un valore basale del 28,6% al 11,0 % ($p < 0,0001$) .

Conclusioni:

Lo studio ha fornito la prova di un buon profilo di sicurezza a livello cardiaco della formulazione a rilascio prolungato di flecainide acetato e confermando l'efficacia del farmaco nella prevenzione delle recidive PAF .

Guédon - Moreau L , Capucci A, Denjoy io , Morgan CC , Périer A, Leplège A, Kacet S.

Impatto del controllo della fibrillazione atriale parossistica sintomatica sulla qualità della vita connessa alla salute.

Europace. 2010

Obiettivi:

I pazienti con fibrillazione atriale (AF) considerano i sintomi correlati dirompenti per la loro qualità di vita (QoL) .

Questo studio mira a valutare l'impatto del controllo di FA parossistica sintomatica (PAF) sulla QoL .

Metodi E Risultati

I pazienti sintomatici con PAF sono stati trattati per 48 settimane in aperto con flecainide acetato a rilascio prolungato (Flec RP) sia 100 mg che 200 mg in monosomministrazione.

La qualità della vita è stata valutata tramite punteggio mediante SF-36 e l'Atrial Fibrillation Severity Scale al basale , alla settimana 12 (W12) , W24 e W48 .

Dei 229 pazienti trattati con Flec RP , 217 sono stati analizzati per la QoL (123 con PAF controllata e 94 con PAF incontrollata sintomatica) .

I pazienti erano già trattati con altri farmaci antiaritmici.

Il gruppo con PAF controllata aveva una qualità di vita simile o migliore (SF-36) al basale rispetto ad una popolazione di riferimento (significativamente migliore per: funzionalità fisica , dolore fisico , e attività fisica) .

Il gruppo con PAF incontrollata aveva una qualità di vita inferiore (significativamente peggiori per: ruolo fisico , salute generale , vitalità , ruolo emozionale , funzionamento sociale , salute mentale , e componente mentale) .

Metodi E Risultati

Quando trattati con Flec RP , i punteggi di QoL del primo gruppo sono stati mantenuti rispetto al basale mentre i punteggi del gruppo con PAF incontrollata sono risultati migliorati ad un livello paragonabile al punteggio del gruppo con PAF controllata.

I risultati relativi alla sicurezza riflettono il noto profilo di sicurezza clinica di flecainide acetato .

Flecainide RP e miglioramento della qualità di vita anche nei pazienti con Fibrillazione atriale parossistica sintomatica incontrollata*

Table 3 Summary of controlled and uncontrolled subgroup scores for baseline, W12, W24, and W48 in SF-36 scores (QoL post-baseline data set)

Variable	Baseline											
	Day 0			Week 12			Week 24			Week 48		
	Controlled LS mean	Uncontrolled LS mean	*P*-value	Controlled LS mean	Uncontrolled LS mean	*P*-value	Controlled LS mean	Uncontrolled LS mean	*P*-value	Controlled LS mean	Uncontrolled LS mean	*P*-value
Physical Functioning	79.4	75.1	0.13	0.1	2.3	0.29	−1.3	3.4	0.08	0.2	4.9	0.08
Role Physical	71.3	61.4	0.06	3.2	8.4	0.26	1.3	15.5	0.02*	2.0	10.4	0.23
Bodily Pain	72.0	68.2	0.23	−0.1	3.2	0.49	−2.6	0.5	0.49	−0.4	2.9	0.49
General Health	64.1	57.6	0.01*	−0.5	4.0	0.03*	−1.5	5.8	0.002*	−1.7	5.2	0.003*
Vitality	58.8	50.8	0.001*	0.0	3.7	0.08	−1.1	5.5	0.004*	−0.1	4.5	0.07
Social Functioning	78.7	73.3	0.08	3.3	3.6	0.90	1.5	5.2	0.34	2.1	6.0	0.33
Role Emotional	73.6	66.5	0.16	2.6	9.4	0.14	−0.5	12.5	0.02*	−0.5	10.2	0.09
Mental Health	65.6	61.7	0.08	1.1	3.5	0.22	1.5	5.1	0.10	1.1	3.5	0.19
Mental Component scale	48.9	46.0	0.029*	0.8	2.3	0.16	0.7	3.3	0.04*	0.3	2.8	0.09
Physical Component scale	47.7	45.6	0.10	0.1	1.4	0.22	−1.1	1.8	0.03*	−0.1	2.0	0.10

Results are expressed in least square means (*P*-value) adjusted for age, country, and language in country. Missing post-baseline data were extrapolated using the LOCF method. *P*-values for post-baseline differences are adjusted for multiplicity using a step-down permutation procedure taking into account correlations among hypothesis tests.
*Statistically significant at the 0.05 level.

(punteggio massimo ottenuto alla 24 sett. e mantenimento dei risultati alla 48 sett.)
P significativo < 0,05

La QoL dei pazienti con
PAF sintomatica incontrollata
dopo trattamento con
Flecainide RP 100-200 mg
migliora ad un livello paragonabile
a quella del gruppo con
PAF sintomatica controllata
anche secondo la
Atrial Fibrillation Severity Scale

EOS: end of study

Table 4 Evolution of total AFSS [Part C (1–7)] (QoL baseline data set)

	Controlled	Uncontrolled
Score at Day 0		
n	121	95
Mean (SD)	11.8 (4.1)	16.1 (5.7)
Median	11.0	15.0
Min–max	6.0–26.0	7.0–30.0
Score at Week 12		
n	107	79
Mean (SD)	11.7 (4.8)	12.5 (4.0)
Median	11.0	12.0
Min–max	4.0–33.0	7.0–22.0
Score at Week 24		
n	96	72
Mean (SD)	11.5 (4.3)	10.8 (3.5)
Median	11.0	10.0
Min–max	7.0–28.0	6.0–21.0
Score at Week 48		
n	98	68
Mean (SD)	11.2 (4.2)	11.0 (4.2)
Median	10.0	10.0
Min–max	6.0–23.0	7.0–26.0
Score at EOS		
n	108	76
Mean (SD)	11.8 (4.7)	11.8 (5.2)
Median	10.0	10.0
Min–max	6.0–27.0	7.0–32.0

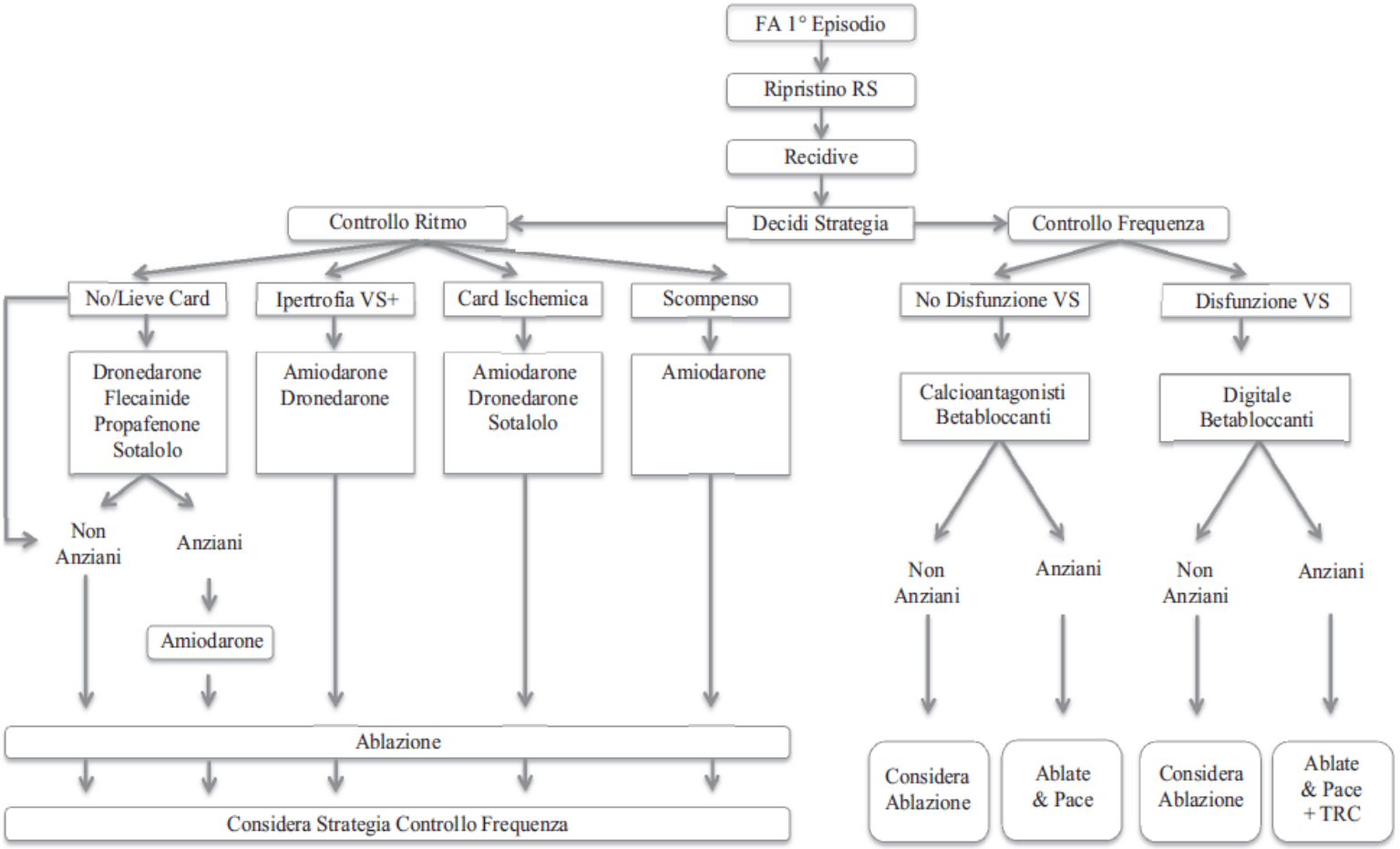
Conclusione :

In questo studio , i pazienti con PAF incontrollata sintomatica al basale avevano un QoL inferiore a quelli con PAF sintomatica controllata.

A seguito di trattamento con flecainide acetato a rilascio prolungato, la loro qualità di vita è migliorata ad un livello paragonabile ai pazienti con PAF controllata .

Flow-chart - trattamento della fibrillazione atriale

AIAC Guidelines 2013



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