

GRADE Approach

Clear separation of 2 issues:

1. **Four Categories of Quality of Evidence:**
 - High, Moderate, Low or Very Low
2. **Strength of Recommendations: 2 Grades**
 - Strong or Conditional (weak)
 - Quality of evidence only one factor

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GRADE: Rating Quality of Evidence

Quality	Comments
High	Future research unlikely to change confidence in estimate of effect; e.g. multiple well designed, well conducted clinical trials.
Moderate	Further research likely to have an important impact on confidence in estimate of effect and may change the estimate e.g. limited clinical trials, inconsistency of results or study limitations.
Low	Further research very likely to have a significant impact in the estimate of effect and is likely to change the estimate e.g. small number of clinical studies or cohort observations.
Very Low	The estimate of effect is very uncertain; e.g. case studies; consensus opinion.

Modified with permission from: Guyatt GH, et al. BMJ 2008;336:926

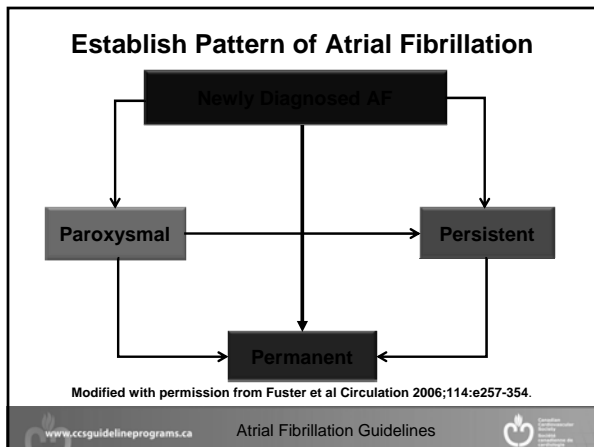
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Factors Determining the Strength of the Recommendation

Factor	Comment
Quality of Evidence	The higher the quality of evidence the greater the probability that a strong recommendation is indicated. e.g. strong recommendation that patients with AF at moderate to high risk of stroke be treated with oral anticoagulants.
Difference between desirable and undesirable effects	The greater the difference between desirable and undesirable effects the greater the probability that a strong recommendation is indicated e.g. strong recommendation that patients with AF ≥ 48 hr duration receive oral anticoagulation therapy for at least 3 weeks prior to planned cardioversion and 4 weeks following.
Values and Preferences	The greater the variation or uncertainty in values and preferences, the higher the probability that a conditional recommendation is indicated e.g. ASA may be a reasonable alternative to oral anticoagulant therapy in patients at low risk of stroke.
Cost	The higher the cost the lower the likelihood that a strong recommendation is indicated e.g. conditional recommendation for catheter ablation as first line therapy for AF.

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12-Lead Electrocardiogram

Document presence of AF
Assess for structural heart disease (myocardial infarction, ventricular hypertrophy, atrial enlargement, congenital heart disease) or electrical heart disease (ventricular pre-excitation, Brugada syndrome)
Identify risk factors for complications of therapy for AF (conduction disturbance, sinus node dysfunction or repolarization).
Document baseline PR, QT and QRS intervals.
Arrhythmia Monitoring Over Time (Holter or Event Recorder)
To document AF, assess efficacy of rate or rhythm control

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Practical Tips

- Aggressive treatment of hypertension may prevent or reduce recurrences
- Choice of antihypertensive therapy should favor rate controlling drugs e.g. β -blockers and Ca^{2+} channel blockers vs inhibitors of renin angiotensin system.
- Identify and treat obstructive sleep apnea



Recommendations Quality of Life

We recommend that the assessment of patient well-being, symptoms, and quality of life (QOL) be part of the evaluation of every patient with AF.

Strong Recommendation
Low Quality of Evidence

We suggest that QOL of the AF patient can be assessed in routine care using the CCS-SAF scale.

Conditional Recommendation
Low Quality of Evidence

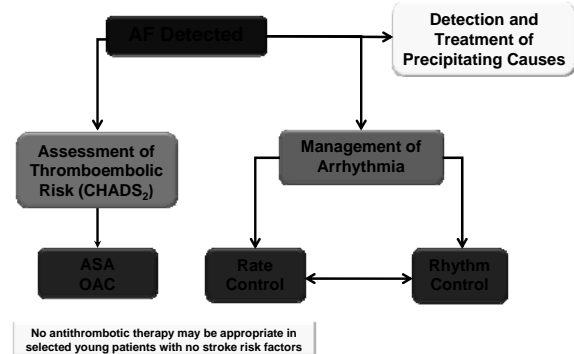
Values and Preferences: These recommendations recognize that improvement in QOL is a high priority for therapeutic decision making.



CCS SAF Score	Impact	EHRA Class	Impact
CCS SAF 0	Asymptomatic	EHRA I	No symptoms
CCS SAF 1	Minimal effect on QOL	EHRA II	Mild symptoms
CCS SAF 2	Modest effect on QOL	EHRA III	Severe symptoms; daily activity affected
CCS SAF 3	Moderate effect on QOL	EHRA IV	Disabling symptoms; Normal daily activity discontinued
CCS SAF 4	Severe effect on QOL		



Overview of AF Management



Goals of AF Arrhythmia Management

- Identify and treat underlying structural heart disease and other predisposing conditions
- Relieve symptoms
- Improve functional capacity/quality of life
- Reduce morbidity/mortality associated with AF/AFL
 - Prevent tachycardia-induced cardiomyopathy
 - Reduce/prevent emergency room visits or hospitalizations secondary to AF/AFL
 - Prevent stroke or systemic thromboembolism



Factors Influencing Decision of Rate vs Rhythm Control

Favours Rate Control	Favours Rhythm Control
Persistent AF	Paroxysmal AF
	Newly Detected AF
Less Symptomatic	More Symptomatic
> 65 years of age	< 65 years of age
Hypertension	No Hypertension
No History of Congestive Heart Failure	Congestive Heart Failure clearly exacerbated by AF
Previous Antiarrhythmic Drug Failure	No Previous Antiarrhythmic Drug Failure



What is Optimal Target Heart Rate?

- RACE II suggested that strict rate control (< 80 bpm at rest, < 110 bpm with activity) was no different compared to lenient strategy (< 110 bpm at rest)
- However, actual HR in both groups were 75 and 86 bpm respectively
- Thus, the trial was not that lenient
- Few patients had HR > 100 bpm

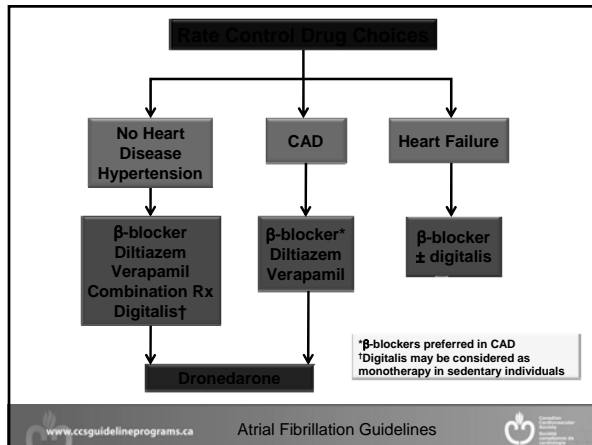


Ventricular Rate Control

We recommend that ventricular rate be assessed at rest in all patients with persistent and permanent AF/AFL.	Strong Recommendation Moderate Quality Evidence
We recommend that heart rate during exercise be assessed in patients with persistent or permanent AF/AFL and associated exertional symptoms.	Strong Recommendation Moderate Quality Evidence
We recommend that treatment for rate control of persistent/permanent AF/AFL should aim for a resting heart rate of less than 100 beats per minute.	Strong Recommendation High Quality Evidence

Values and Preferences

These recommendations place a high value on the randomized clinical trials and other clinical studies demonstrating that ventricular rate control of AF is an effective treatment approach for many patients with AF.



Ventricular Rate Control

We suggest that dronedarone may be added for additional rate control in patients with uncontrolled ventricular rates despite therapy with β-blockers, calcium channel blockers and/or digoxin.	Conditional Recommendation Moderate Quality Evidence
We suggest that amiodarone for rate control should be reserved for exceptional cases in which other means are not feasible or are insufficient.	Conditional Recommendation Low Quality Evidence

Values and Preferences

These recommendations recognize that selection of rate control therapy needs to be individualized based on the presence or absence of underlying structural disease, the activity level of the patient and other individual considerations.



Ventricular Rate Control AV Junction Ablation

We recommend AV junction ablation and implantation of a permanent pacemaker in symptomatic patients with uncontrolled ventricular rates during AF despite maximally tolerated combination pharmacologic therapy	Strong Recommendation Moderate Quality Evidence
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Values and Preferences

This recommendation places a high value on the results of many small randomized trials and one systematic review reporting significant improvements in quality of life and functional capacity as well as a decrease in hospitalizations for AF following AV junction ablation in highly symptomatic patients.



Rhythm Control Recommendations

We recommend use of maintenance oral antiarrhythmic therapy as first-line therapy for patients with recurrent AF in whom long-term rhythm control is desired (see flow charts).	Strong Recommendation Moderate Quality Evidence
We recommend that oral antiarrhythmic drug therapy should be avoided in patients with AF/AFL and advanced sinus or AV nodal disease unless the patient has a pacemaker/implantable defibrillator	Strong Recommendation Low Quality Evidence
We recommend that an AV blocking agent should be used in patients with AF/AFL being treated with a class I antiarrhythmic drug (e.g. propafenone or flecainide) in the absence of advanced AV node disease.	Strong Recommendation Low Quality Evidence

Values and preferences

These recommendations place a high value on the decision of individual patients to balance relief of symptoms and improvement in QOL and other clinical outcomes with the potential greater adverse effects of Class I/III antiarrhythmic drugs compared to rate control therapy.



Rhythm Control Strategy

We recommend the optimal treatment of precipitating or reversible predisposing conditions of AF prior to attempts to restore/maintain sinus rhythm.	Strong Recommendation Low Quality Evidence
We recommend a rhythm control strategy for patients with AF/AFL who remain symptomatic with rate control therapy or in whom rate control therapy is unlikely to control symptoms.	Strong Recommendation Moderate Quality Evidence
We recommend that the goal of rhythm control therapy should be improvement in patient symptoms and clinical outcomes, and not necessarily the elimination of all AF.	Strong Recommendation Moderate Quality Evidence

Values and Preferences
These recommendations place a high value on the decision of individual patients to balance relief of symptoms and improvement in QOL and other clinical outcomes with the potential greater adverse effects of the addition of Class I/III antiarrhythmic drugs to rate control therapy.

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Antiarrhythmic Drug Choices Normal Ventricular Function

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Antiarrhythmic Drug Choices Abnormal Left Ventricular Function

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Pharmacologic Cardioversion

Drug	Dose	Efficacy	Risks
Class 1A Procainamide	15-17 mg/kg IV over 60 min	++	5% hypotension
Class IC* Propafenone Flecainide	450-600 mg PO 300-400 mg PO	+++ +++	Hypotension, 1:1 flutter, bradycardia Hypotension, 1:1 flutter, bradycardia
Class III Ibutilide	1-2 mg IV over 10-20 min Pre-treat with MgSO4 1-2 mg IV	++	2-3% Torsades de pointes

* Class IC drugs should be used in combination with AV nodal blocking agents (beta-blockers or calcium-channel inhibitors). Class IC agents should also be avoided in patients with structural heart disease.

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Wolff Parkinson White Syndrome

We recommend urgent electrical cardioversion if the patient is hemodynamically unstable	Strong Recommendation Low Quality Evidence
We recommend intravenous antiarrhythmic agents procainamide or ibutilide in stable patients	Strong Recommendation Low Quality Evidence
We recommend that AV nodal blocking agents (digoxin, calcium channel blockers, beta-blockers, adenosine) are contra-indicated.	Strong Recommendation Low Quality Evidence

Values and Preferences
These recommendations place a high value on avoidance of the degeneration of pre-excited AF to ventricular fibrillation. It is recognized that degeneration can occur spontaneously or it can be facilitated by the administration of specific agents that in the absence of ventricular pre-excitation would be the appropriate therapy for rate control of AF.

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Comparison of North American and European Guidelines

	CCS Guidelines		ESC Guidelines		ACCF/AHA/HRS	
	Strength	Level of Evidence	Class	Level of Evidence	Class	Level of Evidence
Paroxysmal*	Conditional	Moderate	IIa (Conditional)	A (High)	I (Strong)¶	A (High)
Persistent*	Conditional	Moderate	IIa (Conditional)	B (Moderate)	IIa (Conditional)	A (High)
Failed 1 drug	Conditional	Moderate	--	--	I (Strong)¶	A (High)
Failed ≥ 2 drugs	Strong	Moderate	--	--	--	--
1 st Line	Conditional	Low	IIb (Conditional)	B (Moderate)	--	--
PAF / sign. structural heart disease	--	--	--	--	IIb (Conditional)	A (High)

* Applies to patients with symptomatic AF and failed at least one anti-arrhythmic drug.
 ¶ Dictates ablation performed in experienced centre in patient with minimal heart disease
 -- Not directly addressed. Often this group is incorporated into other recommendations

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Pill in the Pocket For Rhythm Control

We recommend intermittent antiarrhythmic drug therapy ("pill in pocket") in symptomatic patients with infrequent, longer-lasting episodes of AF/AFL as an alternative to daily antiarrhythmic therapy.

**Strong Recommendation
Moderate Quality Evidence**

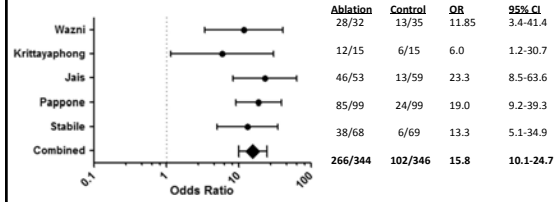
- Single dose flecainide (200-300 mg) or propafenone (450-600 mg) as an oral dose
- Often prescribed with a short-acting beta-blocker at the same time (metoprolol 50-100 mg)

Values and preferences

This recommendation places a high value on the results of clinical studies demonstrating the efficacy and safety of intermittent antiarrhythmic drug therapy in selected patients.



Systematic Review of RCTs Ablation vs Drug Rx



- 9 RCTs / 3 systematic reviews in 1274 patients who have failed ≥ 1 drug
- uniformly demonstrate large differences in recurrence of AF
- (OR 9.74 95% CI, 3.98 to 23.87) in favour of ablation vs AAD

Piccini JP et al. Circ Arrhythm 2009;2:626



Risk Stratification Stroke Prevention Bleeding Risk

We recommend that all patients with AF or AFL (paroxysmal, persistent or permanent), should be stratified using a predictive index for stroke (e.g. CHADS₂) and for the risk of bleeding (e.g. HAS-BLED), and that most patients should receive antithrombotic therapy.

**Strong Recommendation
High Quality Evidence**



Predictive Index for Stroke

CHADS₂

Risk Factor	Score	Patients (n = 1733)	Adjusted Stroke Rate (%/yr) 95% CI	CHADS ₂ Score
Congestive Heart Failure	1	120	1.9 (1.2 to 3.0)	0
Hypertension	1	463	2.8 (2.0 to 3.8)	1
Age ≥ 75	1	523	4.0 (3.1 to 5.1)	2
Diabetes Mellitus	1	337	5.9 (4.6 to 7.3)	3
Stroke/TIA/Thromboembolism	2	220	8.5 (6.3 to 11.1)	4
Maximum Score	6	65	12.5 (8.2 to 17.5)	5
		5	18.2 (10.5 to 27.4)	6



CHADS₂

CHA₂DS₂-VASc

Risk Factor	Score	Risk Factor	Score
Congestive Heart Failure	1	Congestive Heart Failure	1
Hypertension	1	Hypertension	1
Age ≥ 75	1	Age ≥ 75	2
Diabetes Mellitus	1	Diabetes Mellitus	1
Stroke/TIA/Thromboembolism	2	Stroke/TIA/Thromboembolism	2
		Vascular Disease	1
		Age 65-74	1
		Female	1
Maximum Score	6	Maximum Score	9



Patients (n = 7329)	Adjusted Stroke Rate (%/yr) 95% CI	TE Rate assuming no warfarin	CHA ₂ DS ₂ -VASc Score
1	0	0	0
422	0.46 (0.10 to 1.34)	1.3	1
1230	0.78 (0.44 to 1.29)	2.2	2
1730	1.16 (0.79 to 1.64)	3.2	3
1718	1.43 (1.01 to 1.95)	4.0	4
1159	2.42 (1.75 to 3.26)	6.7	5
679	3.54 (2.49 to 4.87)	9.8	6
294	3.44 (1.94 to 5.62)	9.6	7
82	2.41 (0.53 to 6.88)	6.7	8
14	5.47 (0.91 to 27.0)	15.2	9



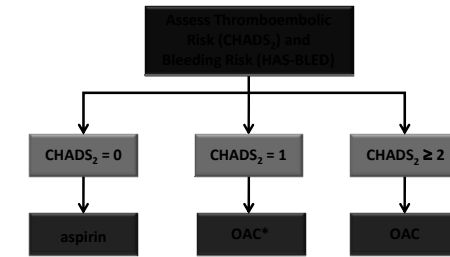
Bleeding Risk – HAS-BLED Score

Letter	Clinical Characteristic	Points
H	Hypertension	1
A	Abnormal Liver or Renal Function 1 point each	1 or 2
S	Stroke	1
B	Bleeding	1
L	Labile INRs	1
E	Elderly (age > 65 yr)	1
D	Drugs or Alcohol 1 point each	1 or 2
		Maximum 9 points

Pisters R et al. Chest. 2010 Nov;138:1093-100



Overview of Thromboembolic Management



No antithrombotic may be appropriate in selected young patients with no stroke risk factors

*Aspirin is a reasonable alternative in some as indicated by risk/benefit

Dabigatran is preferred OAC over warfarin in most patients.



ASA for Stroke Prevention

We recommend that patients at very low risk of stroke (CHADS ₂ = 0) should receive aspirin (75-325 mg/day).	Strong Recommendation High Quality Evidence
We suggest that some young persons with no standard risk factors for stroke may not require any antithrombotic therapy.	Conditional Recommendation Moderate Quality Evidence



Anticoagulant Therapy for Stroke Prevention

We recommend that patients at low risk of stroke (CHADS ₂ = 1) should receive OAC therapy (either warfarin [INR 2 – 3] or dabigatran).	Strong Recommendation High Quality Evidence
We suggest, based on individual risk/benefit considerations, that aspirin is a reasonable alternative for some.	Conditional Recommendation Moderate Quality Evidence
We recommend that patients at moderate risk of stroke (CHADS ₂ ≥ 2) should receive OAC therapy (either warfarin [INR 2 – 3] or dabigatran).	Strong Recommendation High Quality Evidence

Values and preferences: These recommendations place relatively greater weight on the absolute reduction of stroke risk with both warfarin and dabigatran compared to aspirin and less weight on the absolute increased risk for major hemorrhage with an oral anticoagulant compared to aspirin.



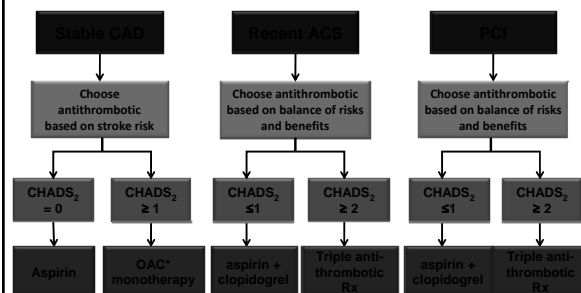
Dabigatran vs Warfarin

We suggest, that when OAC therapy is indicated, most patients should receive dabigatran in preference to warfarin. In general, the dose of dabigatran 150 mg po bid is preferable to a dose of 110 mg po bid.	Conditional Recommendation High Quality Evidence
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Values and preferences: This recommendation places a relatively high value on the greater efficacy of dabigatran over a relatively short time of follow-up, particularly among patients who have not previously received an oral anticoagulant, the lower incidence of intracranial hemorrhage and its ease of use, and less value on the long safety experience with warfarin.

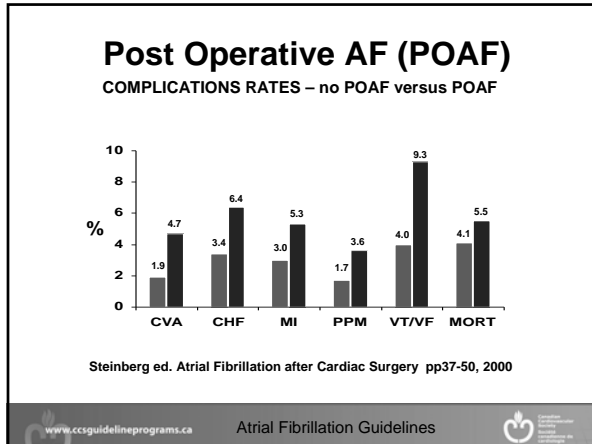


Antithrombotic Management of AF/AFL in CAD



* Warfarin is preferred over dabigatran for patients at high risk of coronary events





PK/PD of 5 Novel Oral Agents

	Dabigatran	Apixaban	Rivaroxaban
Target	IIa (thrombin)	Xa	Xa
Hrs to Cmax	2	1-3	2-4
CYP Metabolism	None	15%	32%
Half-Life	12-14h	8-15h	9-13h
Renal Elimination	80%	40%	33%

Ruff CR and Giugliano RP. Hot Topics in Cardiology 2010;4:7-14
 Erickson BI et al. Clin Pharmacokinet 2009; 48: 1-22
 Ruff CR et al. Am Heart J 2010; 160:635-41

CYP = cytochrome P450; NR = not reported

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Phase III AF Trials

	Re-LY	ROCKET-AF	ARISTO TLE
Drug	Dabigatran	Rivaroxaban	Apixaban
Dose (mg)	150, 110	20 (15*)	5 (2.5*)
Freq	BID	QD	BID
N	18,113	14,266	18,206
Design	PROBE	2x blind	2x blind
AF criteria	AF x 1 < 6 mths	AF x 2 (>1 in <30d)	AF or AFI x 2 <12 mths
% VKA naive	50%	38%	43%

*Dose adjusted in patients with ↓ drug clearance. PROBE = prospective, randomized, open-label, blinded end point evaluation

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RELY	Dabigatran 110 mg	Dabigatran 150 mg	Warfarin
CHADS ₂ Mean	2.1	2.2	2.1
0-1 (%)	32.6	32.2	30.9
2 (%)	34.7	35.2	37.0
3+ (%)	32.7	32.6	32.1

ROCKET AF	Rivaroxaban	Warfarin
CHADS ₂ Mean	3.5	3.5
2 (%)	13	13
3 (%)	43	44
4 (%)	29	28
5 (%)	13	12
6 (%)	2	2

ARISTOTLE	Rivaroxaban	Warfarin
CHADS ₂ Mean	2.1	2.1
0-1 (%)	34	34
2 (%)	35.8	35.8
3+ (%)	30.2	30.2

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Comparison of Trial Metrics

	RE-LY	ROCKET AF	ARISTOTLE
Time in Therapeutic Range (TTR)	64% 67% warfarin-experienced 61% warfarin-naïve	Mean 55% Median 58%	Mean 62% Median 66%

Patel MR et al. NEJM 2011; Connolly SJ, et al. N Engl J Med. 2009;361:1139-1151; Granger C et al. N Engl J Med 2011

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Primary Endpoint of Stroke or Systemic Embolism: Non-inferiority Analysis

	RE-LY	ROCKET AF	ARISTOTLE
Dabigatran 110 mg	1.53% per year	Rivaroxaban 20mg Warfarin 1.7% per year 2.2% per year	Apixaban 5 mg Warfarin 1.27% per year 1.60% per year
Dabigatran 150 mg	1.11% per year		
Warfarin	1.69% per year		
	HR = 0.91 p<0.001	HR = 0.79 p<0.001	HR = 0.79 p<0.001

No ITT analysis is available for non-inferiority in Rocket AF. An on treatment or per-protocol analysis is generally performed in the assessment of non-inferiority. If numerous patients come off of study drug, this biases the trial towards a non-inferior result in an ITT analysis. This is the basis for performing a per-protocol analysis in a non-inferiority assessment.

Patel MR et al. NEJM 2011; Connolly SJ, et al. N Engl J Med. 2009;361:1139-1151; Granger C et al. N Engl J Med 2011

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Hemorrhagic Stroke

RELY		HR	ITT P-value
Dabigatran 110 mg	0.12% / yr	0.31	<0.001
Dabigatran 150 mg	0.10% / yr	0.26	<0.001
Warfarin	0.38% / yr		

ROCKET		HR	ITT P-value
Rivaroxaban 20 mg	0.26% / yr	0.59	0.012*
Warfarin	0.44% / yr		

ARISTOTLE		HR	ITT P-value
Apixaban 5 mg	0.24% / yr	0.51	<0.001
Warfarin	0.47% / yr		

*In an on treatment analysis in Rocket AF Hemorrhagic Stroke rates were 0.26% / yr for rivaroxaban and 0.44% / yr for warfarin, p=0.024. No on treatment analysis is available from RE-LY.

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Ischemic Stroke

RELY		HR	ITT P-value
Dabigatran 110 mg	1.34% / yr	1.20	0.35
Dabigatran 150 mg	0.92% / yr	0.76	0.03
Warfarin	1.20% / yr		

ROCKET		HR	ITT P-value
Rivaroxaban 20 mg	1.62% / yr	0.99	0.92*
Warfarin	1.64% / yr		

ARISTOTLE		HR	ITT P-value
Aoixaban 5 mg	0.97% / yr	0.92	0.42
Warfarin	1.05% / yr		

*In an on treatment analysis in Rocket AF Ischemic Stroke rates were 1.34% / yr for rivaroxaban and 1.42% / yr for warfarin, p=0.58. No on treatment analysis is available from RE-LY.

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Major Bleeding

RE-LY		HR	ITT P-value
Dabigatran 110 mg	2.71% / yr	0.8	0.003
Dabigatran 150 mg	3.11% / yr	0.93	0.31
Warfarin	3.36		

150 mg Dabigatran vs 110 mg Dabigatran = HR of 1.16 (1.00-1.34) p = 0.052

ROCKET		HR	On Treatment P-value
Rivaroxaban 20 mg	3.60% / yr	0.92	0.58*
Warfarin	3.45% / yr	2 g drop	

*There is no ITT analysis of safety in Rocket AF. There is no on treatment analysis of safety from RE-LY.

ARISTOTLE		HR	P-value
Apixaban 5 mg	2.13% / yr	0.69	<0.001
Warfarin	3.09% / yr	2 g drop in 24 hours	

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All Cause Mortality

RELY		HR	ITT p-value
Dabigatran 110 mg	3.75% / yr	0.91	0.35
Dabigatran 150 mg	3.64% / yr	0.88	0.051
Warfarin	4.13% / yr		

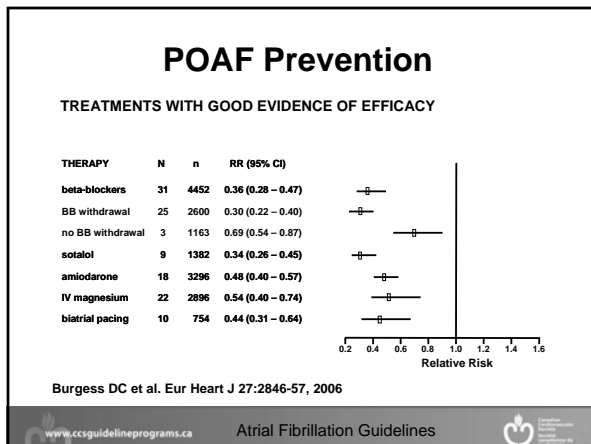
ROCKET		HR	ITT P-value
Rivaroxaban 20 mg	4.52% / yr	0.92	0.152*
Warfarin	4.91% / yr		

ARISTOTLE		HR	ITT P-value
Apixaban 5 mg	3.52% / yr	0.89	0.01
Warfarin	3.94% / yr		

95% CI 0.89 (0.80, 0.998)
N=448 events planned, 480 in trial

*In an on treatment analysis in Rocket AF mortality rates were 1.87% / yr for rivaroxaban and 2.21% / yr for warfarin, p=0.073. No on treatment analysis is available from RE-LY.

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Comparison - Prevention

	CCS Guidelines		ESC Guidelines	
	Strength	LOE	Class	LOE
BB continued if on	Strong	High	I	A
BB started if not on	Cond	Low	I	A
Amio if BB contraindicated	Strong	High	IIa	A
Sotalol may be considered	Cond	Mod	IIb	A
Bi-A Pace may be considered	Cond	Low	IIb	A
IV Mag may be considered	Cond	Low	--	--
Corticosteroids considered	--	--	IIb	B

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Comparison - Treatment

	CCS Guidelines		ESC Guidelines	
	Strength	LOE	Class	LOE
epicardial V-Pace wires at OR	Strong	Low	--	--
Rate control with BB, CA, dig	Strong	High	I	B
Rate control in that order	Strong	High	agree in text	
AF control AAD considered	Cond	Low	IIa	C
anticoag considered at 72hr	Cond	Low	IIa (48hr)	A (48 hr)
consider DC Rx at 6-12 weeks	Strong	Mod	--	--

