



## **Novità sulla cardioversione in PS: dallo studio X-vert all'esperienze sul campo**

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Napoli

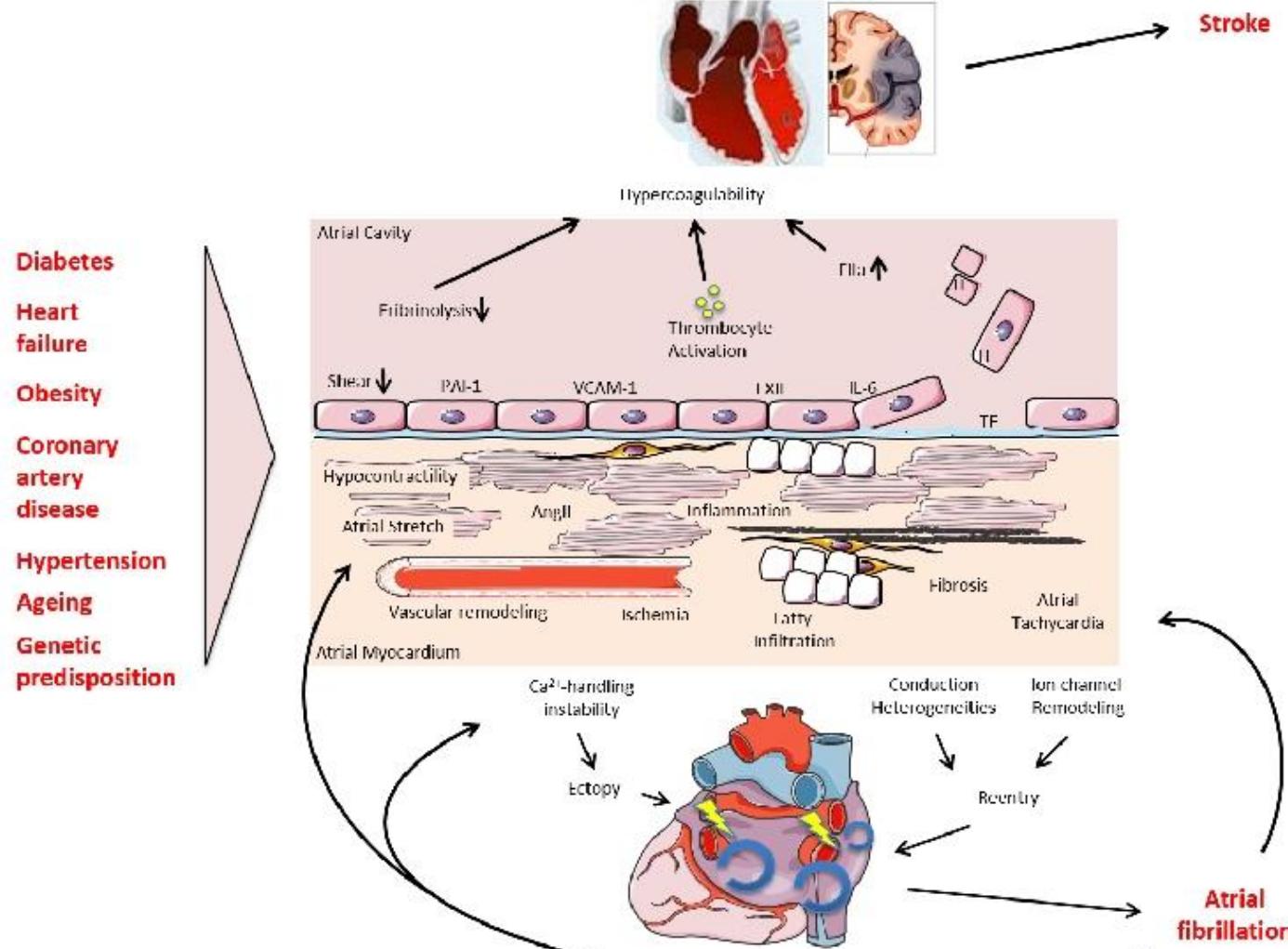
# Cardiovascular morbidity and mortality associated with atrial fibrillation

Event	Association with AF
Death	Increased mortality, especially cardiovascular mortality due to sudden death, heart failure or stroke.
Stroke	20–30% of all strokes are due to AF. A growing number of patients with stroke are diagnosed with 'silent', paroxysmal AF.
Hospitalizations	10–40% of AF patients are hospitalized every year.
Quality of life	Quality of life is impaired in AF patients independent of other cardiovascular conditions.
Left ventricular dysfunction and heart failure	Left ventricular dysfunction is found in 20–30% of all AF patients. AF causes or aggravates LV dysfunction in many AF patients, while others have completely preserved LV function despite long-standing AF.
Cognitive decline and vascular dementia	Cognitive decline and vascular dementia can develop even in anticoagulated AF patients. Brain white matter lesions are more common in AF patients than in patients without AF.

## Patterns of atrial fibrillation

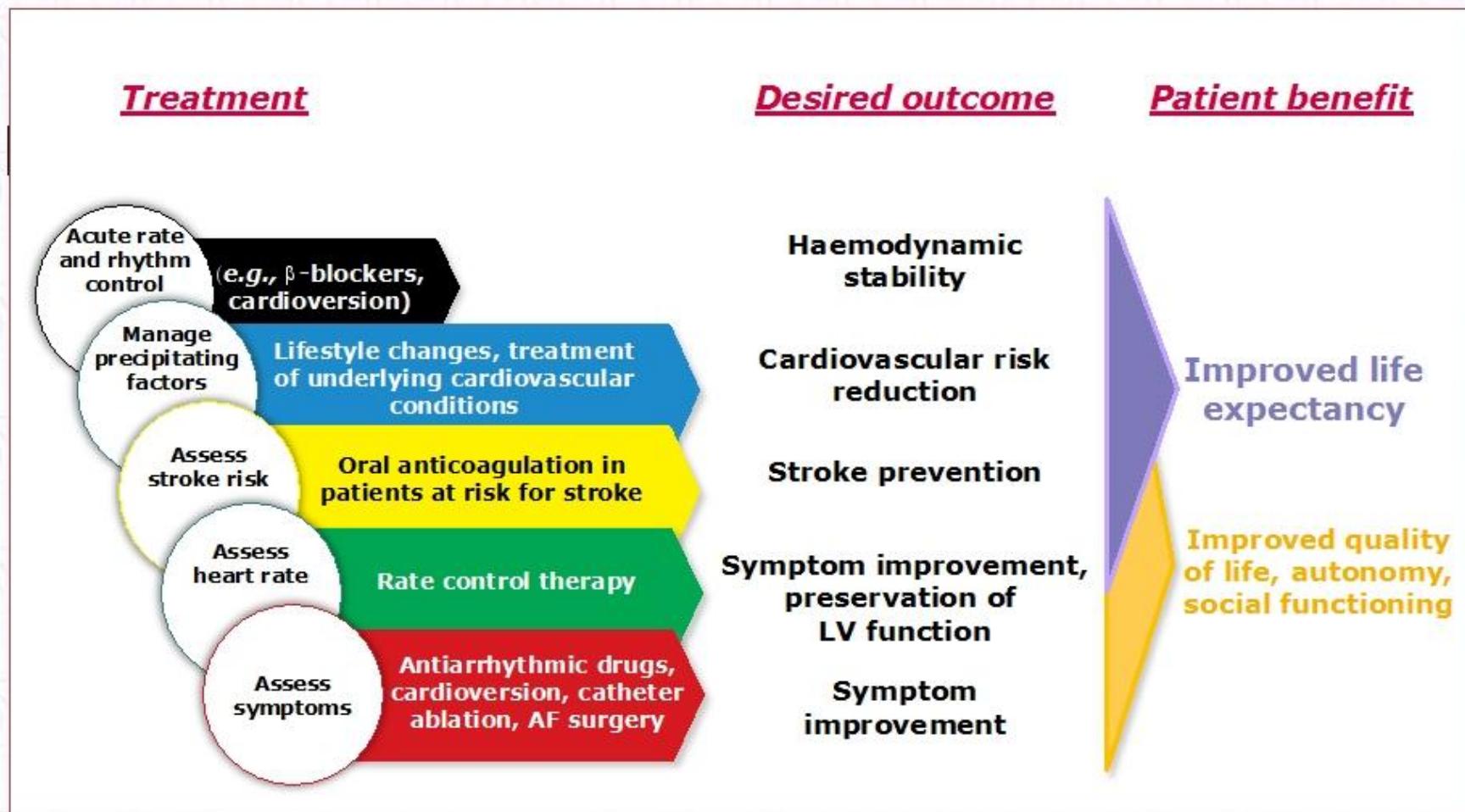
AF pattern	Definition
First diagnosed AF	AF that has not been diagnosed before, irrespective of the duration of the arrhythmia or the presence and severity of AF-related symptoms.
Paroxysmal AF	Self-terminating, in most cases within 48 hours. Some AF paroxysms may continue for up to 7 days. AF episodes that are cardioverted within 7 days should be considered paroxysmal.
Persistent AF	AF that lasts longer than 7 days, including episodes that are terminated by cardioversion, either with drugs or by direct current cardioversion, after 7 days or more.
Long-standing persistent AF	Continuous AF lasting for $\geq 1$ year when it is decided to adopt a rhythm control strategy.
Permanent AF	AF that is accepted by the patient (and physician). Hence, rhythm control interventions are, by definition, not pursued in patients with permanent AF. Should a rhythm control strategy be adopted, the arrhythmia would be re-classified as 'long-standing persistent AF'.

# Major mechanisms causing atrial fibrillation to consider when deciding on management



AngII = angiotensin II; TF = tissue factor; FXII = factor XII; IL-6 = interleukin 6; PAI-1 = plasminogen activator inhibitor 1; VCAM-1 = vascular cell adhesion molecule 1.

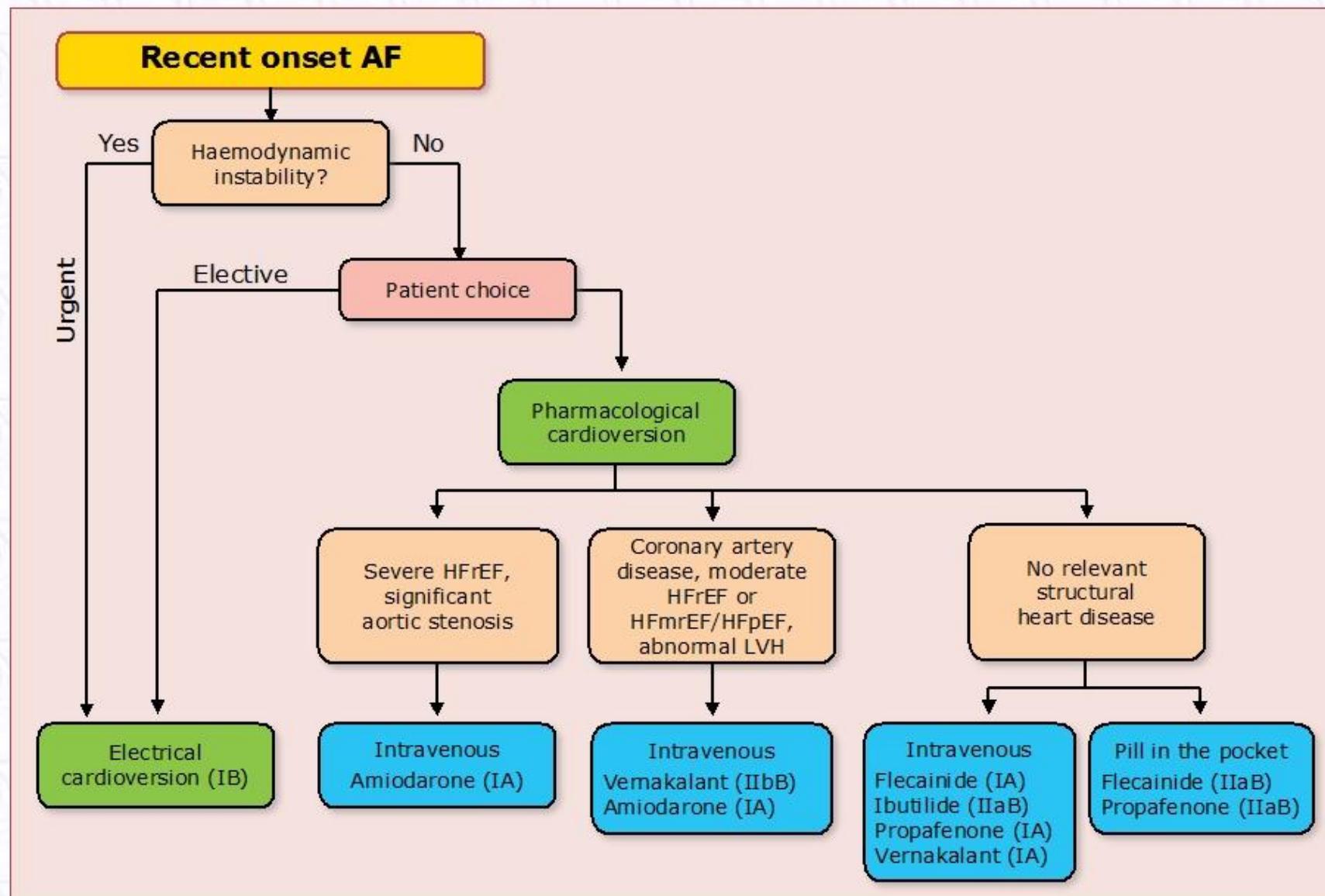
# The Five Domains of Integrated AF Management



# Rhythm control therapy (1) – Cardioversion of AF

Recommendations	Class	Level
<b>General recommendations</b>		
Rhythm control therapy is indicated for symptom improvement in patients with AF.	I	B
Management of cardiovascular risk factors and avoidance of AF triggers should be pursued in patients on rhythm control therapy to facilitate maintenance of sinus rhythm.	IIa	B
With the exception of AF associated with haemodynamic instability, the choice between electrical and pharmacological cardioversion should be guided by patient and physician preferences.	IIa	C
<b>Cardioversion of AF</b>		
Electrical cardioversion of AF is recommended in patients with acute haemodynamic instability to restore cardiac output.	I	B
Cardioversion of AF (either electrical or pharmacological) is recommended in symptomatic patients with persistent or long-standing persistent AF as part of rhythm control therapy.	I	B
Pre-treatment with amiodarone, flecainide, ibutilide, or propafenone should be considered to enhance success of electrical cardioversion and prevent recurrent AF.	IIa	B

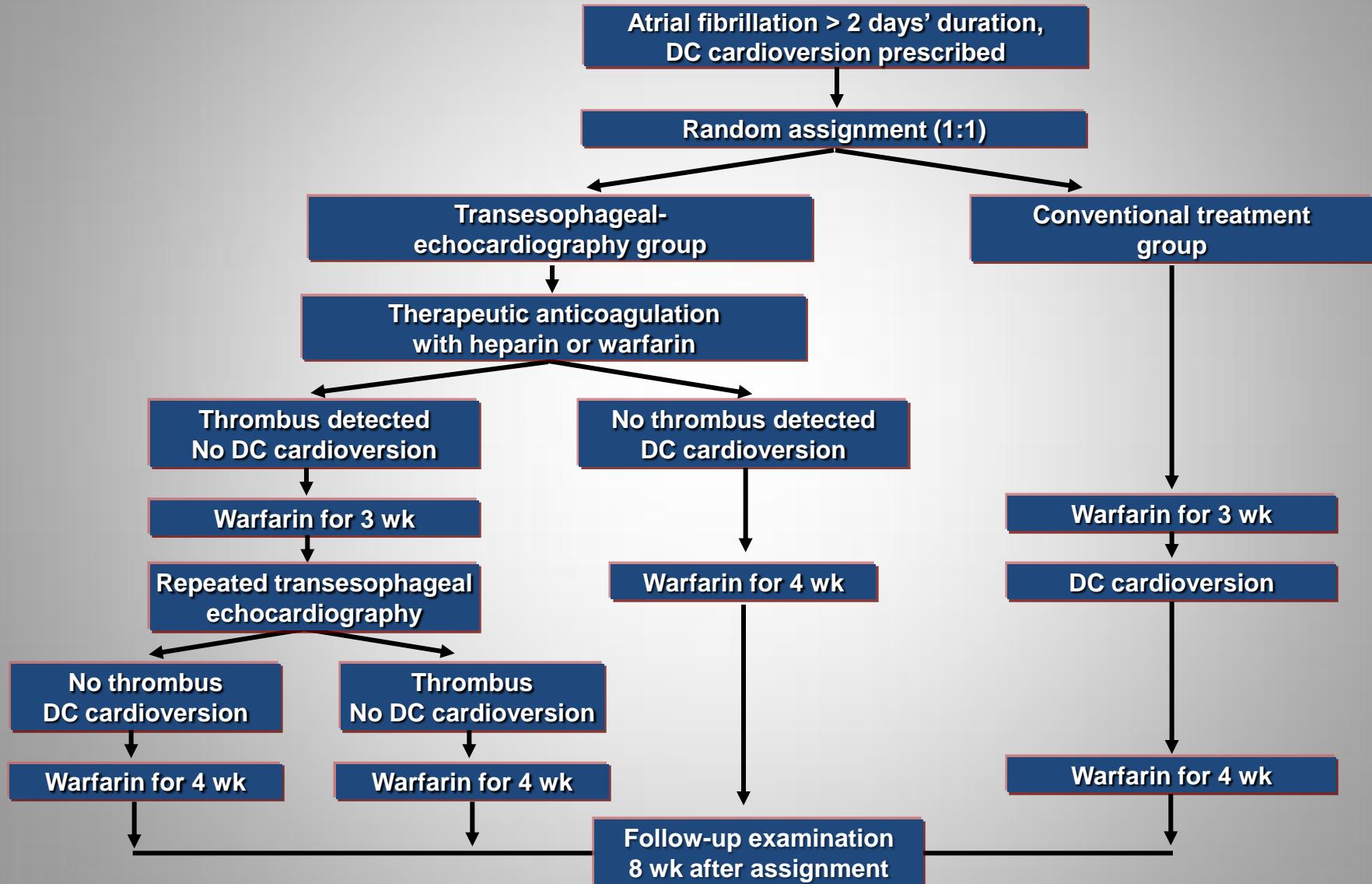
# Cardioversion of recent onset of atrial fibrillation



# Management of atrial flutter

Recommendations	Class	Level
For patients with atrial flutter, antithrombotic therapy is recommended according to the same risk profile used for AF.	I	B
Overdrive atrial pacing of atrial flutter should be considered as an alternative to electrical cardioversion, depending on local availability and experience.	IIa	B
Management of typical atrial flutter with ablation of the cavotricuspid isthmus is recommended for patients failing antiarrhythmic drug therapy or as first-line treatment considering patient preference.	I	B
If atrial flutter has been documented before AF ablation, ablation of the cavotricuspid isthmus should be considered as part of the AF ablation procedure.	IIa	C

# Prospective Companion of TEE-guided vs. Conventional-treatment Cardioversion of A. Fib

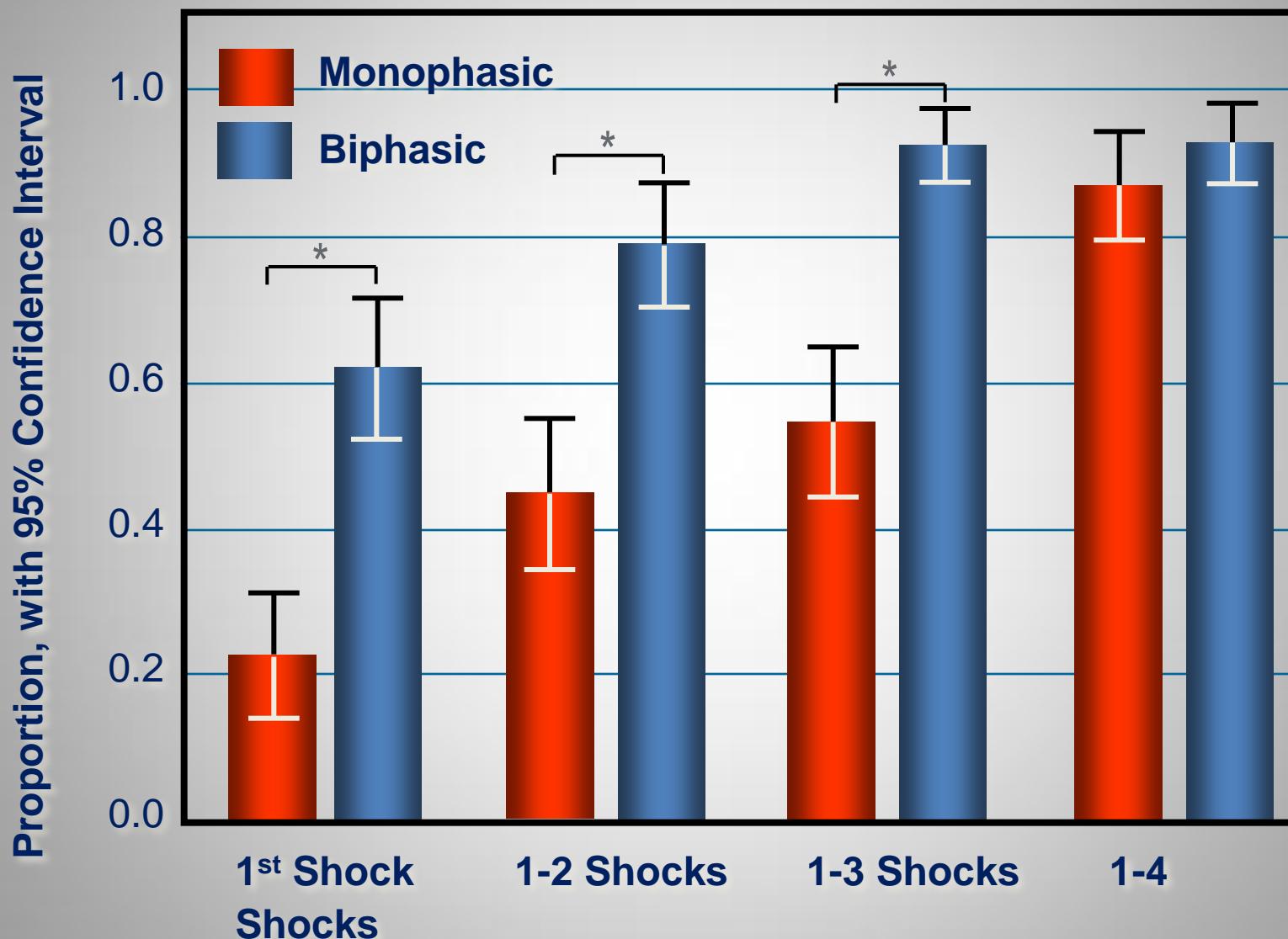


# Clinical Outcomes of TEE-guided vs. Conventional-treatment Cardioversion of A. Fib

Variable	TEE Guided (n= 619)	Conventional Treatment (n=603)
Successful Cardioversion (%)	80.3	79.9
<b>Time to Cardioversion (d)</b>	<b><math>3.0 \pm 5.6^*</math></b>	<b><math>30.6 \pm 10.6</math></b>
Embolic Events (%)	5 (0.8%)	3 (0.5%)
Hemorrhagic events (%)	18 (2.9%)*	33 (5.5%)
Death (%)	15 (2.4%)	6 (1.0%)
SR at 8 wks (%)	52.7	50.4

Klein AL, N Engl J Med 2001; 344: 1411-20

# Cumulative Success in Cardioversion of A. Fib: Biphasic vs. Monophasic Waveform



# Procedural Aspects of Direct-current Cardioversion of Atrial Fibrillation

- Ensure appropriate anticoagulation
- Use adequate general anesthesia in fasting state
- Electrodes positioned anterior-posterior or anterior-lateral
- Confirm R-wave synchronization
- Biphasic shock waveform preferable
- Determine the need for pretreatment with antiarrhythmic drugs

# **Cardioversion: Data derived from NOACs trials**

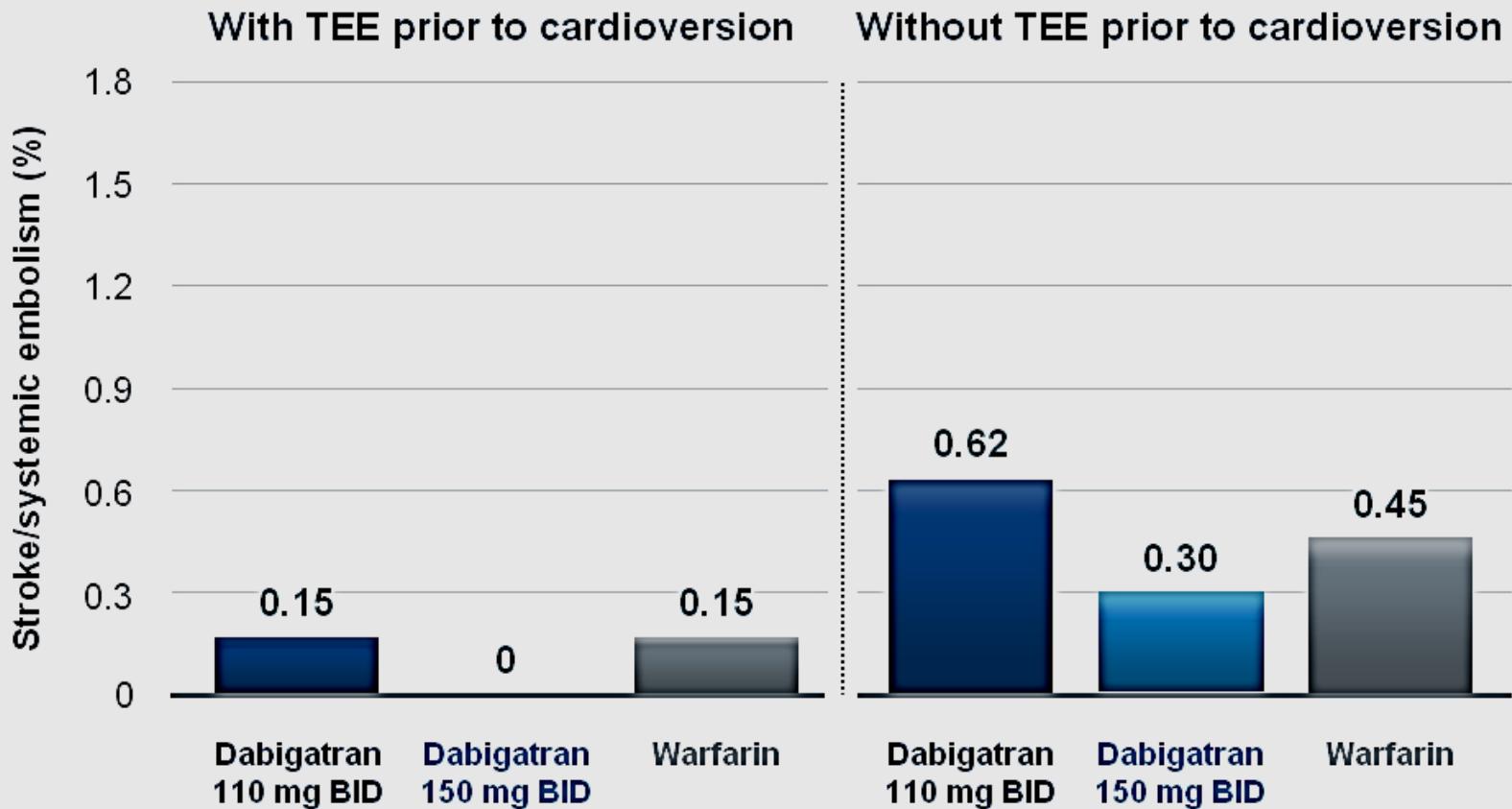
# Arrhythmia/Electrophysiology

## Dabigatran Versus Warfarin in Patients With Atrial Fibrillation An Analysis of Patients Undergoing Cardioversion

Rangadham Nagarakanti, MD; Michael D. Ezekowitz, MBChB, DPhil, FRCP, FACC;  
Jonas Oldgren, MD, PhD; Sean Yang, MSc; Michael Chernick, PhD; Timothy H. Aikens, BA;  
Greg Flaker, MD; Josep Brugada, MD; Gabriel Kamenský, MD, PhD, FESC; Amit Parekh, MD;  
Paul A. Reilly, PhD; Salim Yusuf, FRCPC, DPhil; Stuart J. Connolly, MD

- **1.983 CV during RE-LY trial**
- **TEE performed pre-CV in 25% of pts**

# CV subgroup analysis: Stroke or SE with or without TEE



## Outcomes After Cardioversion and Atrial Fibrillation Ablation in Patients Treated With Rivaroxaban and Warfarin in the ROCKET AF Trial

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Manesh R. Patel, MD,\* Jonathan L. Halperin, MD,† Daniel E. Singer, MD,‡  
Graeme J. Hankey, MD,§ Werner Hacke, MD, PhD,|| Richard C. Becker, MD,\*  
Christopher C. Nessel, MD,¶ Kenneth W. Mahaffey, MD,\* Keith A. A. Fox, MB, CHB,#  
Robert M. Califf, MD,\*\* Günter Breithardt, MD†† for the ROCKET AF Steering Committee  
& Investigators

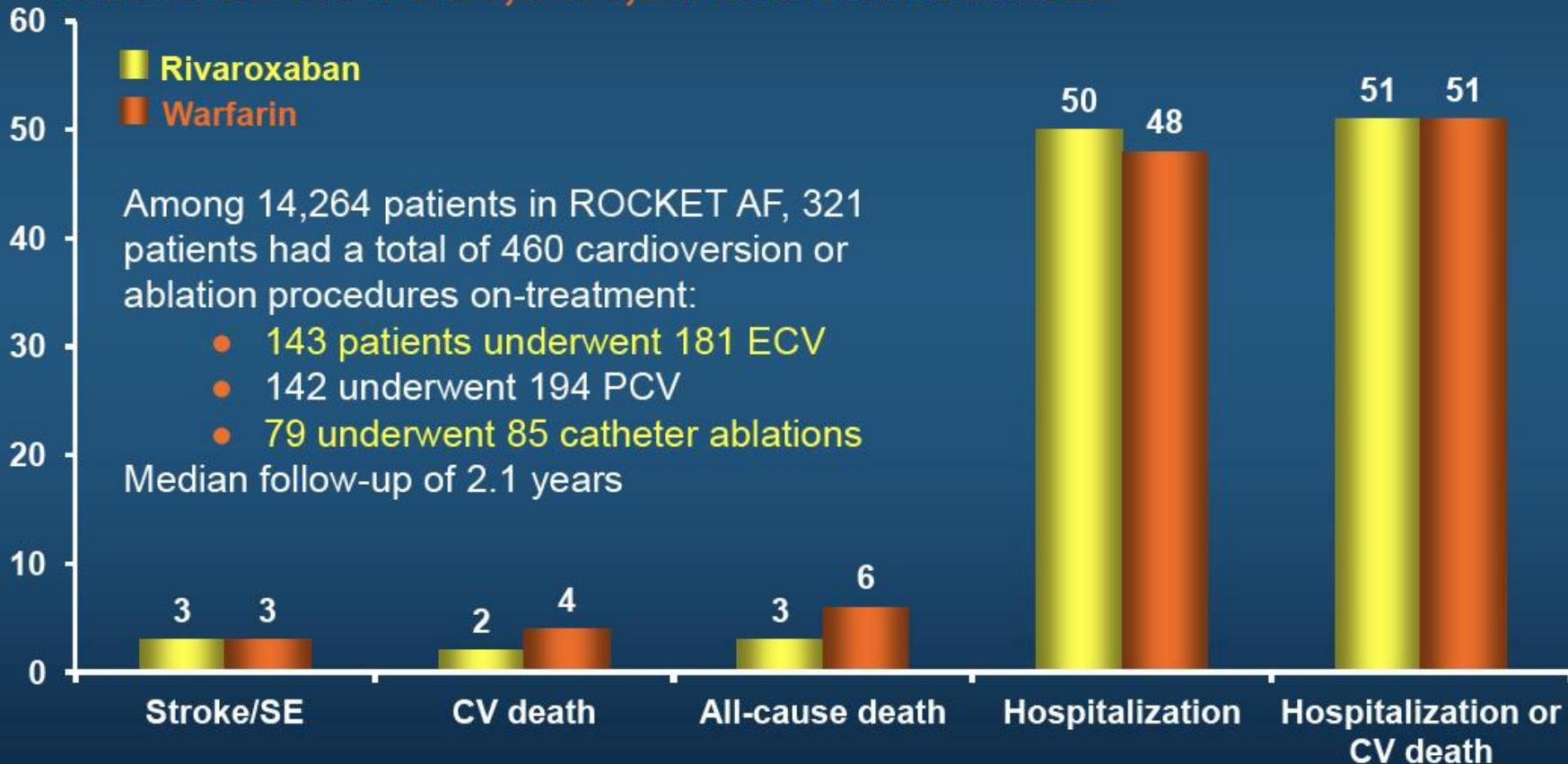
- 142 pts underwent electrical CV
- 142 pts underwent pharmacological CV
- 79 pts underwent AF ablation

No significant differences in baseline characteristics in subgroups

# ROCKET AF

## Subanalysis Cardioversion/ablation

### Outcomes after ECV, PCV, or catheter ablation





# Efficacy and Safety of Apixaban in Patients After Cardioversion for Atrial Fibrillation

Insights From the ARISTOTLE Trial  
(Apixaban for Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation)

Greg Flaker, MD,\* Renato D. Lopes, MD, PhD,† Sana M. Al-Khatib, MD, MHS,†  
Antonio G. Hermosillo, MD,‡ Stefan H. Hohnloser, MD,§ Brian Tinga, MS,† Jun Zhu, MD,||  
Puneet Mohan, MD, PhD,¶ David Garcia, MD,# Jozef Bartunek, MD, PhD,\*\*  
Dragos Vinereanu, MD, PhD,†† Steen Husted, MD, DMSc,†† Veli Pekka Harjola, MD, PhD,§§  
Marten Rosenqvist, MD,||| John H. Alexander, MD, MHS,† Christopher B. Granger, MD,†  
for the ARISTOTLE Committees and Investigators

- 740 CV were performed in 540 pts
- TEE was performed in 27% of pts before CVE
- Mean time from study entry to CV: 243 ± 231 days

# Clinical Outcomes After Any CV Within 30 Days in Pts Assigned to Either Warfarin or Apixaban

Outcomes	Warfarin (n = 412)	Apixaban (n = 331)	Total (n = 743)
Stroke or systemic embolism	0	0	0
Myocardial infarction	1 (0.2)	1 (0.3)	2 (0.2)
Major bleeding	1 (0.2)	1 (0.3)	2 (0.2)
Death	2 (0.5)	2 (0.6)	4 (0.5)

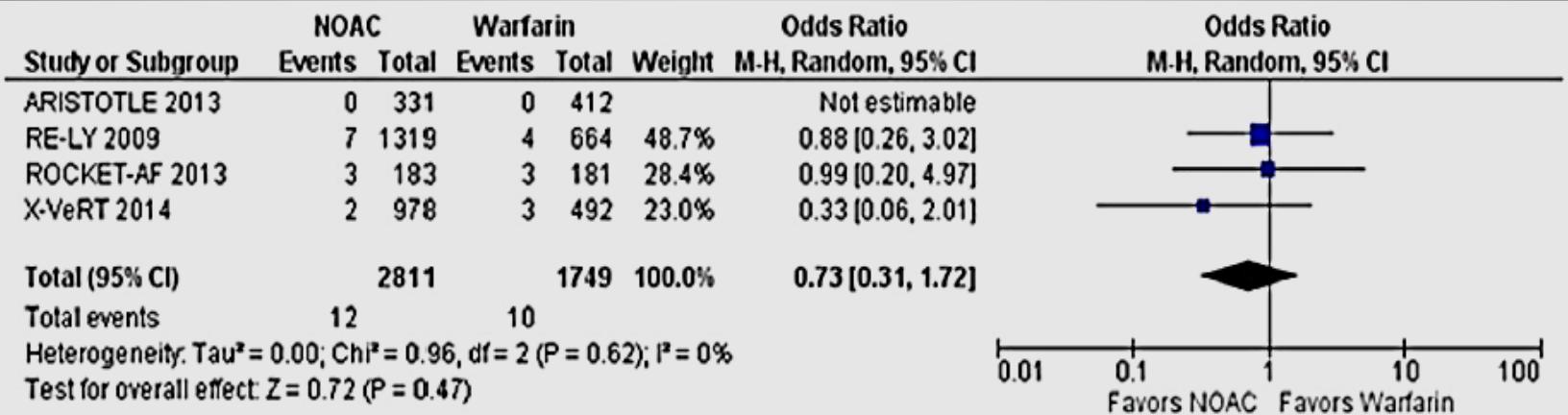
Values are n (%).

## Outcomes After Cardioversion in Atrial Fibrillation Patients Treated with Non-Vitamin K Antagonist Oral Anticoagulants (NOACs): Insights from a Meta-Analysis

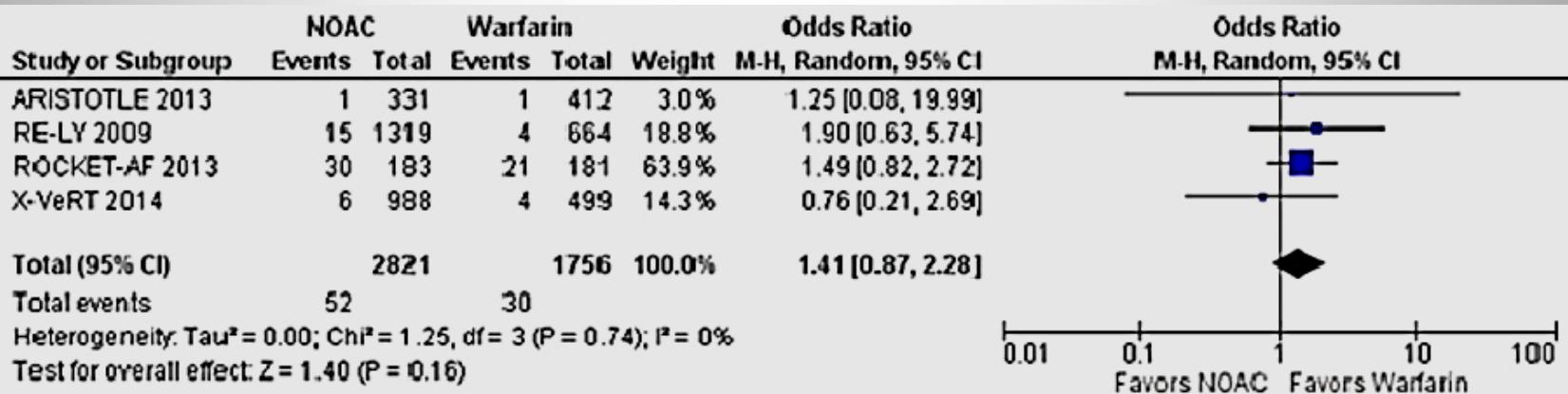
Prijat Sen<sup>1</sup>  · Amartya Kundu<sup>2</sup> · Partha Sardar<sup>3</sup> · Saurav Chatterjee<sup>4</sup> · Ramez Nairooz<sup>5</sup> · Hossam Amin<sup>6</sup> · Wilbert S. Aronow<sup>7</sup>

Study characteristics	Trial			
	RE-LY	ROCKET-AF	ARISTOTLE	X-VeRT
Total number of patients included in subgroup analysis (% of total study population)	1270 (7.01)	321 (2.25)	540 (2.96)	1504 (100)
Total number of cardioversions or ablations (n)	1983	364	743	1167
Total population in the study	18,113	14,264	18,201	1504
Follow-up period		2.1 years (IQR 1.6–2.4)		
Study design	Prospective, randomized, open-label, blinded-endpoint (PROBE)	Multicenter, randomized, double-blind, double-dummy	Randomized control, double-blind, parallel-arm	Prospective, multinational, randomized, open-label, parallel-group

## Stroke and systemic embolism



## Major bleeding



Data from patients enrolled in RCTs, showed that NOACs are effective and safe for AF patients undergoing cardioversion



# X-vert

EXplore the efficacy and safety of once-daily oral  
riVaroxaban for the prevention of caRdiovascular  
events in subjects with non-valvular aTrial  
fibrillation scheduled for cardioversion

# Rivaroxaban vs. vitamin K antagonists for cardioversion in atrial fibrillation

Riccardo Cappato<sup>1†</sup>, Michael D. Ezekowitz<sup>2†\*</sup>, Allan L. Klein<sup>3</sup>, A. John Camm<sup>4</sup>, Chang-Sheng Ma<sup>5</sup>, Jean-Yves Le Heuzey<sup>6</sup>, Mario Talajic<sup>7</sup>, Maurício Scanavacca<sup>8</sup>, Panos E. Vardas<sup>9</sup>, Paulus Kirchhof<sup>10,11,12</sup>, Melanie Hemmrich<sup>13</sup>, Vivian Lanius<sup>14</sup>, Isabelle Ling Meng<sup>13</sup>, Peter Wildgoose<sup>15</sup>, Martin van Eickels<sup>13</sup>, and Stefan H. Hohnloser<sup>16</sup>, on behalf of the X-VeRT Investigators

- First prospective randomized trial of a NOAC in pts with AF undergoing elective CV
- 1504 patients assigned to Rivaroxaban vs VKA in 2:1 ratio
- Two cardioversion strategy:
  - early (target period of 1–5 days after randomization)
  - delayed (3–8 weeks)

# X-VeRT: baseline demographics

	Rivaroxaban (n=1002)	VKA (n=502)	Total (N=1504)
<b>Region, % n</b>			
Europe	72.7	728	72.6
America	22.1	221	22.1
Asia Pacific	5.3	53	5.3
<b>Age, mean SD, years</b>	<b>64.9</b>	<b>10.6</b>	<b>64.9</b>
Male, % n	72.6	727	72.7
BMI, mean SD, kg/m <sup>2</sup>	30.1	5.8	5.9
Prior OAC use for ≥6 weeks, % n	42.3	424	42.8

ITT population

Cappato R et al. Eur Heart J 2014; doi: 10.1093/eurheartj/ehu367;  
Cappato R. ESC Congress 2014. Oral presentation 4945

# X-VeRT: stroke risk factors and other clinical characteristics

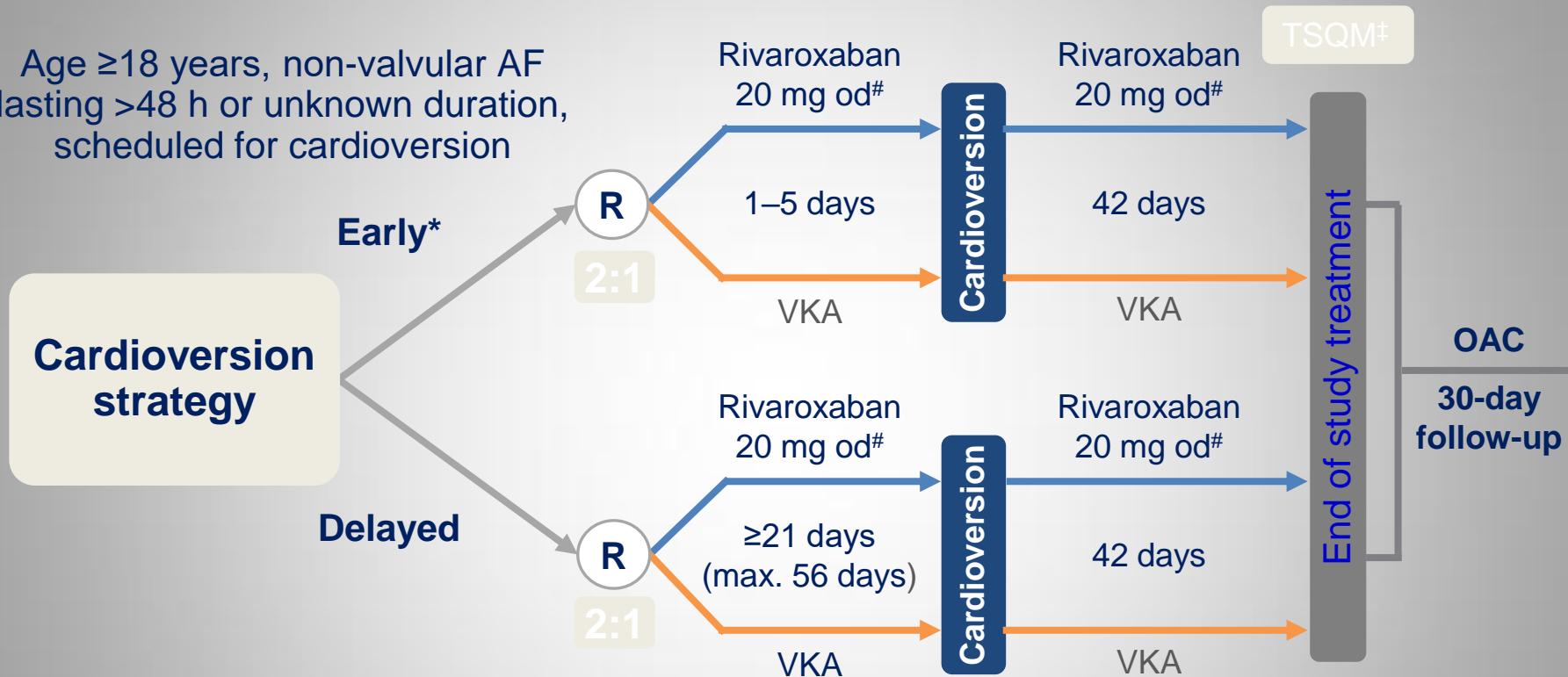
Characteristic	Rivaroxaban (n=1002)	VKA (n=502)	Total (N=1504)
CHADS <sub>2</sub> score, mean SD	1.3	1.1	1.4
CHA <sub>2</sub> DS <sub>2</sub> -VASc score, mean SD	2.3	1.6	2.3
Previous stroke/TIA or SE, % n	6.7	67	9.8
Congestive heart failure, % n	19.7	197	14.9
Hypertension, % n	65.0	651	68.7
Diabetes mellitus, % n	20.3	203	20.5
Previous vascular disease, % n	13.4	134	11.2
Renal function/CrCl, % n			
≥80 ml/min	61.5	616	57.6
50≤80 ml/min	30.9	310	35.1
30≤50 ml/min	6.8	68	6.0
<30 ml/min	0		0.2
Missing	0.8	8	1.2

ITT population

# Design: Randomized, Open-Label, Parallel-Group, Active-Controlled Multicentre Study

## Inclusion criteria:

Age  $\geq 18$  years, non-valvular AF lasting  $>48$  h or unknown duration, scheduled for cardioversion



### In X-VeRT:

- Rivaroxaban appears to be an effective and safe alternative to VKA
- Rivaroxaban provided important practical advantages over VKAs, with significantly more patients able to undergo cardioversion as planned and after a significantly shorter duration of pre-cardioversion anticoagulation

\*Protocol recommended only if adequate anticoagulation or immediate TEE; <sup>#</sup>15 mg if CrCl 30–49 ml/min; VKA with INR 2.0–3.0;  
‡TSQM questionnaire was completed at the end of study treatment

# X-VeRT: primary endpoints

Primary efficacy endpoints<sup>1</sup>

Primary safety endpoint<sup>1</sup>

A composite of:

- Stroke and TIA
- Non-CNS systemic embolism
- Myocardial infarction
- Cardiovascular death
- Major bleeding (ISTH definition)<sup>2</sup>

All endpoints adjudicated by treatment assignment-blinded Clinical Endpoint Committee

1. Cappato R et al. *Eur Heart J* 2014; doi: 10.1093/eurheartj/ehu367;

2. Schulman S et al. *J Thromb Haemost* 2005;3:692–694

# X-VeRT: primary efficacy endpoints

	Rivaroxaban (N=978)		VKA (N=492)		Risk ratio (95% CI)
	%	n*	%	n*	
<b>Primary efficacy endpoint</b>	<b>0.51</b>	<b>5</b>	<b>1.02</b>	<b>5</b>	<b>0.50 (0.15–1.73)</b>
Stroke	0.20	2	0.41	2	
Haemorrhagic stroke	0.20	2		0	
Ischaemic stroke		0	0.41	2	
TIA		0		0	
Non-CNS SE		0	0.20	1	
MI	0.10	1	0.20	1	
Cardiovascular death	0.41	4	0.41	2	

\*Number of patients with events; patients may have experienced more than one primary efficacy event  
MITT population

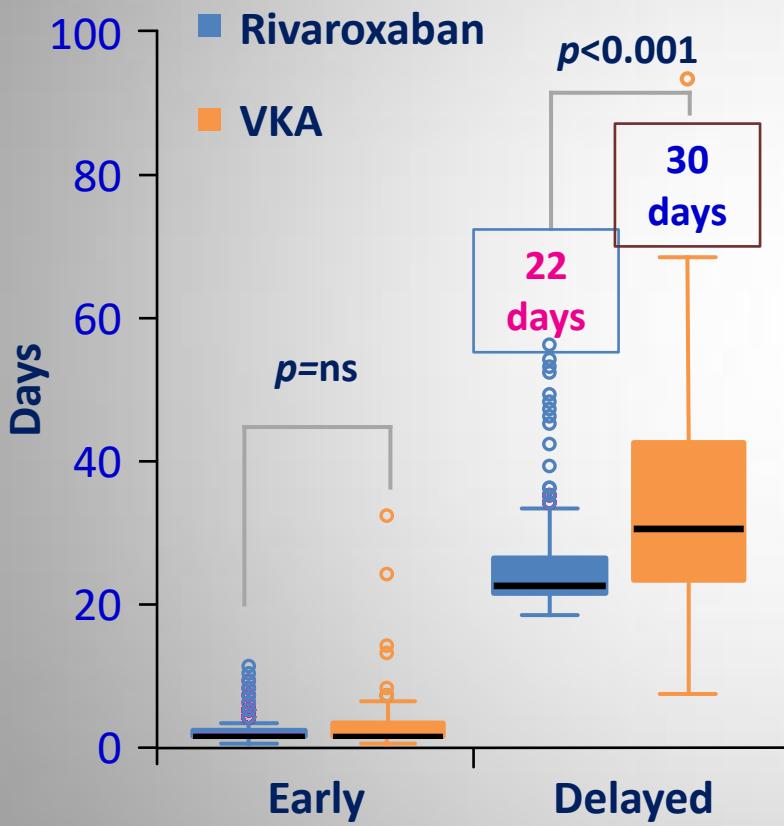
# X-VeRT: primary safety endpoints

	Rivaroxaban (N=988)		VKA (N=499)		Risk ratio (95% CI)
	%	n*	%	n*	
<b>Major bleeding</b>	<b>0.61</b>	<b>6</b>	<b>0.80</b>	<b>4</b>	<b>0.76 (0.21–2.67)</b>
Fatal	0.1	1	0.4	2	
Critical-site bleeding	0.2	2	0.6	3	
Intracranial haemorrhage	0.2	2	0.2	1	
Hb decrease ≥2 g/dl	0.4	4	0.2	1	
Transfusion of ≥2 units of packed RBCs or whole blood	0.3	3	0.2	1	

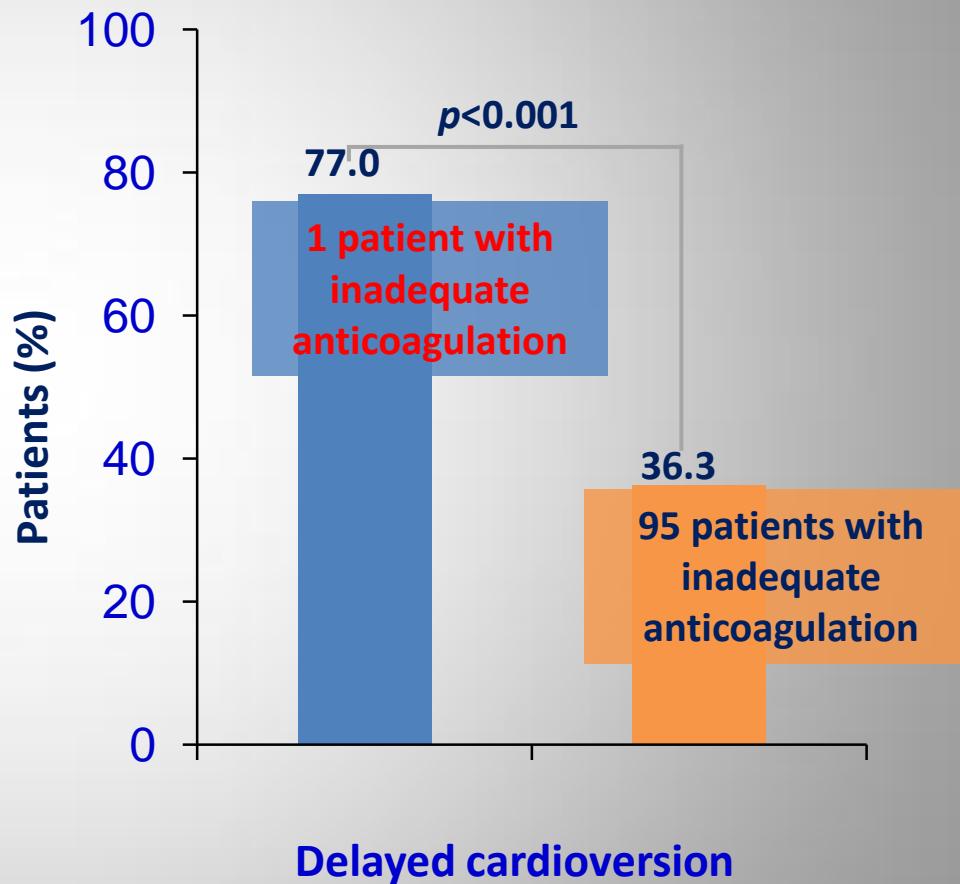
\*Number of patients with events; patients may have experienced more than one primary safety event  
Safety population

# Time to Cardioversion by Cardioversion Strategy

Median time to cardioversion



Patients cardioverted as scheduled\*



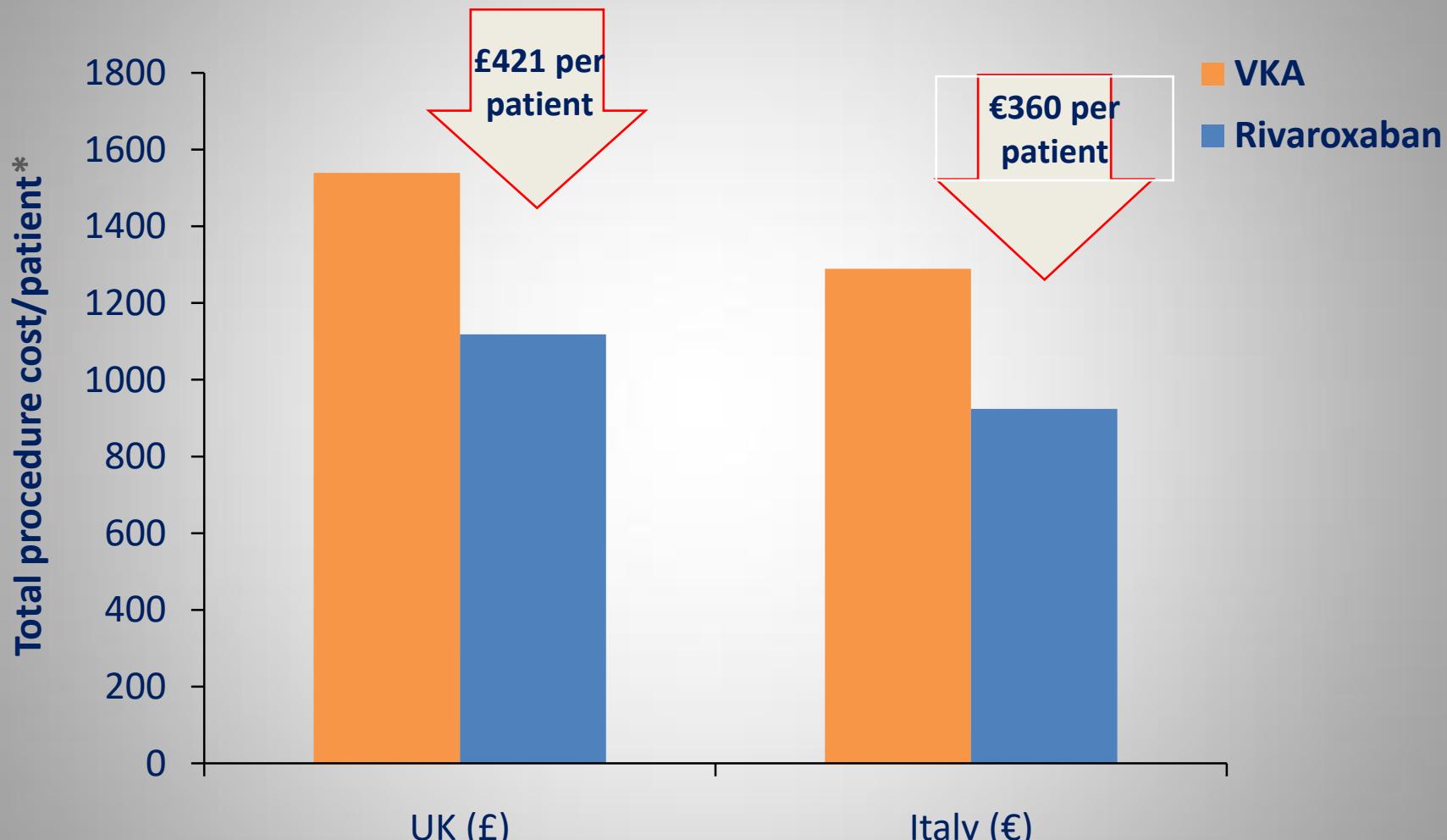
\*Reason for not performing cardioversion as first scheduled from 21–25 days primarily due to inadequate anticoagulation (indicated by drug compliance <80% for rivaroxaban or weekly INRs outside the range of 2.0–3.0 for 3 consecutive weeks before cardioversion for VKA)

# **Patient-Reported Treatment Satisfaction and Budget Impact with Rivaroxaban versus Standard Therapy in Elective Cardioversion of Atrial Fibrillation**

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***A Post Hoc Analysis of the X-VeRT Trial***

# Total Procedure Cost Savings per Patient Following the Delayed Cardioversion Strategy, Based on an Economic Model



\*Components considered for this budget impact analysis include costs of: drug therapy (including extended treatment duration due to postponement); INR monitoring (based on X-VeRT data, INR of warfarin-treated patients was monitored approximately six times pre-cardioversion [i.e. 5.7 visits] and five times post-cardioversion [i.e. 4.7 visits]; cardioversion procedure; and rescheduling

Hohnloser S et al, *Europace* 2015;doi:10.1093/europace/euv294

# Summary

- Rivaroxaban was associated with significantly higher treatment satisfaction, compared with VKA in patients with non-valvular AF scheduled to undergo cardioversion
- The use of rivaroxaban in place of warfarin in the delayed cardioversion group could result in a saving of £421 per patient in the UK setting and €360 per patient in Italy
  - The estimated cost-savings may equate to over **£260,000 in the UK and €228,000 in Italy** – equivalent to the cost of ~318 and ~340 cardioversion procedures, respectively

# Efficacy and safety of dabigatran in a “real-life” population at high thromboembolic and hemorrhagic risk: data from MonaldiCare registry

V. RUSSO, V. BIANCHI<sup>1</sup>, C. CAVALLARO<sup>1</sup>, F. VECCHIONE<sup>1</sup>, S. DE VIVO<sup>1</sup>,  
L. SANTANGELO, B. SARUBBI, P. CALABRÒ, G. NIGRO, A. D'ONOFRIO<sup>1</sup>

Department of Cardio-Thoracic and Respiratory Sciences, Second University of Naples, Monaldi Hospital, Naples, Italy

<sup>1</sup>Department of Cardiology, Monaldi Hospital, AORN Ospedali dei Colli, Naples, Italy

	n	%	n	%
CVE performed	23	19	97	81
TEE	23	100	31	31,9

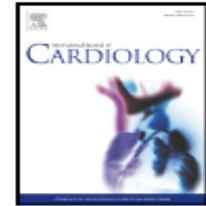
Tutti i pazienti hanno assunto DAB per almeno 3 settimane prima della CVE

Il 34% dei pazienti ha effettuato TEE: **NESSUN TROMBO RILEVATO**

MonaldiCare: 120 CVE effettuate

TEE = transoesophageal echocardiography





## Correspondence

A new integrated strategy for direct current cardioversion in non-valvular atrial fibrillation patients using short term rivaroxaban administration: The MonaldiVert real life experience



Vincenzo Russo <sup>a,\*</sup>, Lucia Di Napoli <sup>b</sup>, Valter Bianchi <sup>b</sup>, Vincenzo Tavoletta <sup>b</sup>, Stefano De Vivo <sup>b</sup>, Ciro Cavallaro <sup>b</sup>, Filipo Vecchione <sup>b</sup>, Anna Rago <sup>a</sup>, Berardo Sarubbi <sup>a</sup>, Paolo Calabro <sup>a</sup>, Gerardo Nigro <sup>a</sup>, Antonio D'Onofrio <sup>b</sup>

<sup>a</sup> Chair of Cardiology, Second University of Naples - Monaldi Hospital, Italy

<sup>b</sup> Departmental Unit of Electrophysiology, Evaluation and Treatment of Arrhythmias, Monaldi Hospital, Italy

Clinical and echocardiographic characteristics of study population (n: 78).

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Population characteristics

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Age (years), mean ± SD	59 ± 11
Female (%)	40
BMI (kg/m <sup>2</sup> ), mean ± SD	29 ± 5
Hypertension (%)	76.9
Coronary artery disease (%)	33.3
Diabetes (%)	38.5
Dilated cardiomyopathy (%)	6.4
Previous stroke or TIA (%)	2.6
CHA2DS2-VASc score, mean ± SD	4 ± 1
Creatinine clearance (mL/min), mean ± SD	62 ± 23
Left atrial diameter (mm), mean ± SD	48 ± 4
Left atrial volume (mL), mean ± SD	80 ± 26

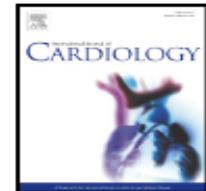




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A new integrated strategy for direct current cardioversion in non-valvular atrial fibrillation patients using short term rivaroxaban administration: The MonaldiVert real life experience



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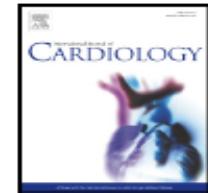
The aim was to evaluate the efficacy and safety of short term Rivaroxaban administration for direct current cardioversion in non-valvular AF patients, who have not achieved adequate preprocedural anticoagulation with VKA showing the last INR value not in the therapeutic range (INR:  $1.7 \pm 0.3$ ). All patients received treatment with rivaroxaban once daily, 20 mg (89.7%) or 15 mg (10.3%) according to the renal function, for  $3 \pm 1$  days and were scheduled for transesophageal echocardiography guided DCC.



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### A new integrated strategy for direct current cardioversion in non-valvular atrial fibrillation patients using short term rivaroxaban administration: The MonaldiVert real life experience



Vincenzo Russo <sup>a,\*</sup>, Lucia Di Napoli <sup>b</sup>, Valter Bianchi <sup>b</sup>, Vincenzo Tavolella <sup>b</sup>, Stefano De Vivo <sup>b</sup>, Ciro Cavallaro <sup>b</sup>, Filipo Vecchione <sup>b</sup>, Anna Rago <sup>a</sup>, Berardo Sarubbi <sup>a</sup>, Paolo Calabro <sup>a</sup>, Gerardo Nigro <sup>a</sup>, Antonio D'Onofrio <sup>b</sup>

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Our data show that the **29.4% of AF patients referred** to our hospital for direct current cardioversion and on warfarin therapy at least three weeks were rescheduled to perform the procedure, owing to INR levels outside the therapeutic range.

In our experience, the incidence of atrial thrombus at transesophageal echocardiography in patients assuming rivaroxaban for a short time before electrical cardioversion is low and similar to the incidence observed with long-term VKA and NOAC treatment.

# Transesophageal echocardiography in patients with persistent atrial fibrillation undergoing electrical cardioversion on new oral anticoagulants: A multi center registry<sup>☆</sup>

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Clinical characteristics of study population (n = 219 patients).

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Variable	Mean ± SD or %
Mean age (years)	67 ± 9.9
Sex (male/female)	156/63
Heart disease (%)	86
Hypertension (%)	83
Coronary artery disease (%)	26
Valvulopathy	13
Dilated cardiomyopathy	4
Diabetes (%)	17
Previous stroke (%)	4
Mean CHA <sub>2</sub> DS <sub>2</sub> -VASc score	2.37 ± 1.44

**The incidence of atrial thrombus in patients assuming NOACs before electrical cardioversion is reasonably low (1.3%) and similar to the incidence observed with VKA treatment (0.8–1.8%).**



86 pazienti dabigatran (39%)  
73 pazienti apixaban (33%)  
61 pazienti rivaroxaban (28%)

# CARDIOVERSIONE: CONCLUSIONI

**Indipendentemente dal rischio CHA<sub>2</sub>DS<sub>2</sub>VASC tutti i pazienti sottoposti a cardioversione devono essere anticoagulati.**

**I pazienti già in terapia anticoagulante orale da più di tre settimane possono essere cardiovertiti con o senza EcoTE.**

**In caso di VKA è necessario verificare i valori di INR-PT precedenti.**

**In caso di NOAC è necessario verificare l'aderenza alla terapia nelle tre settimane precedenti.**

# CARDIOVERSIONE: CONCLUSIONI

Pazienti non anticoagulati ed FA da più di 48 ore:

Protocollo rapido: NOAC seguito, dopo almeno 4 ore, da Eco TE e cardioversione (X-VeRT trial)

Protocollo classico: anticoagulazione efficace per 3 settimane. I dati della letteratura non evidenziano differenze tra VKA e NOACs in termini di sicurezza ed efficacia. Vantaggi di tipo organizzativo con i NOACs

Pazienti non anticoagulati ed FA da meno di 48 ore:

Dati insufficienti dalla letteratura. Anticoagulare e cardiovertire se si è certi della recente insorgenza. Eparina sodica permette una cardioversione immediata. Eparine a basso peso molecolare e NOACs attendere 4 ore.





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*edbucel et al. Europace, August 31, 2015*