

TROMBOC@T Working Group

Els Anticoagulants d'acció directe (ACOD) en situacions especials

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Table 2. Approved Indications and Doses for the NOACs

	Dabigatran	Rivaroxaban	Apixaban	Edoxaban
Atrial fibrillation	150 mg BID; 110 mg BID (EU and Canada) in patients aged >80 y, CrCl=30–50 mL/min, or high risk for bleeding; 75 mg BID (US) when CrCl=15–30 mL/min	20 mg OD; 15 mg OD when CrCl=30–50 mL/min (EU and Canada) and 15–50 mL/min (US)	5 mg BID; 2.5 mg BID in patients with 2 of the following: age >80 y, weight <60 kg, or creatinine >1.5 mg/dL (133 μmol/L)	60 mg OD; 30 mg OD when CrCl=15–50 mL/min; edoxaban should not be used when CrCl >95 mL/min (US)
Venous thromboembolism treatment	150 mg BID (after at least 5 days of heparin)	15 mg BID for 21 days, then 20 mg OD	10 mg BID for 7 days, then 5 mg BID	60 mg OD (after 5–10 days of heparin); 30 mg OD if CrCl=15–50 mL/min, weight ≤60 kg or if taking potent P-gp inhibitors
Thromboprophylaxis after hip or knee arthroplasty	220 mg OD (EU and Canada); 150 mg OD in patients aged ≥75 y, CrCl=30–50 mL/min, concomitant verapamil, amiodarone, or quinidine	10 mg OD	2.5 mg BID	Not licensed in EU or North America

; EU, European Union; NOAC, non-vitamin K antagonist oral anticoagulant; OD, once daily; P-gp, P-glycoprotein;

1. PROPIEDADES FARMACOCINÉTICAS Y FARMACODINÁMICAS

CARACTERÍSTICAS	DABIGATRAN	RIVAROXABAN	APIXABAN	EDOXABAN
Mecanismo de acción	Inhibidor del FIIa (trombina)	Inhibidor directo del FXa	Inhibidor directo del FXa	Inhibidor directo del FXa
Dosis (mg)	150 110	20 15	5 2.5	15,30* 60**
Frecuencia	Cada 12 horas	Cada 24 horas	Cada 12 horas	Cada 24 horas
Biodisponibilidad %	6.5 (pH dependiente)	80 (100% con alimentos)	50	62
Eliminación renal %	80	33 (metabolito activo)	25	35-50



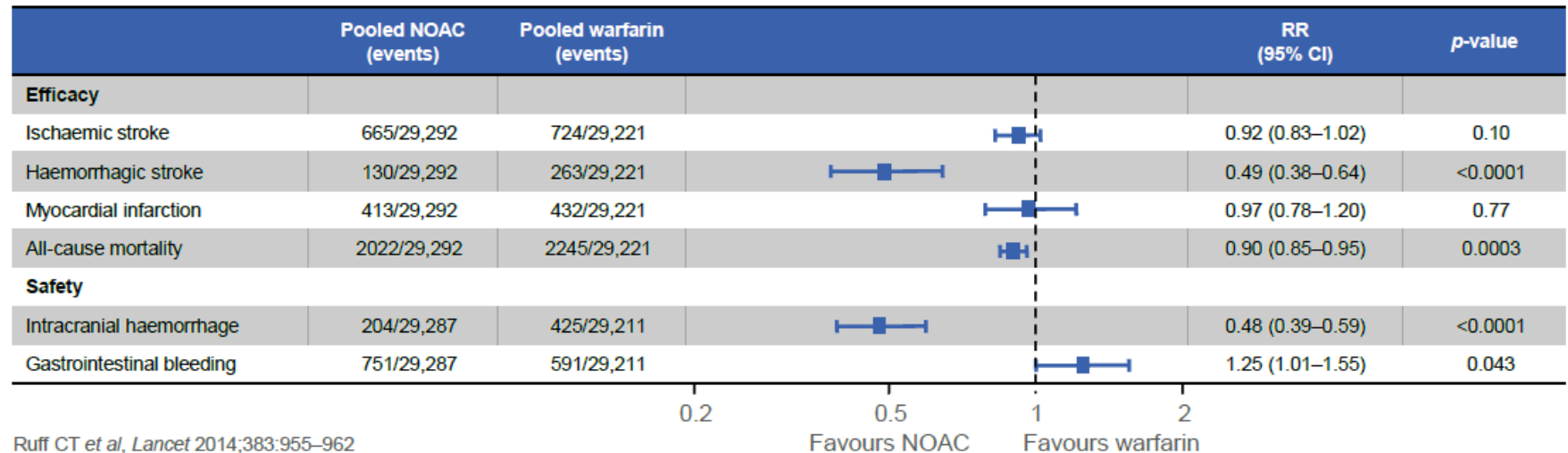
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All Licensed Anticoagulants Deliver Greater Benefit than Risk, NOACs More than VKAs

NOACs are associated with significant reductions in:

- ◆ Haemorrhagic stroke (with a strong trend towards lower rates of ischaemic stroke)
- ◆ All-cause mortality (with a trend towards lower rates of myocardial infarction)
- ◆ Intracranial haemorrhage

Whereas the risk of gastrointestinal bleeding is increased



ACODs en situacions especials

- Pacients d'edat avançada
- Insuficiència renal
- Càncer
- Hemorràgies
- Perioperatori



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Per què **TROMBOC@T**

Disparitat de protocols i formes de treball

No existeixen Guies clíniques comuns

Davant els dubtes ¿¿??

No hi ha un foro

Objectius **TROMBOC@T**

***El.laboració de protocols,
guies clíniques i bases de
dades comuns***

***Posar en marxa
diferents activitats en
formació i recerca***

***Foro per intercanviar
inquietuds i
experiències***

Objectius

- No existeixen estudis que comparin els diferents ACODs de forma directe
- Dades de trials, metaanàlisis i «Real Life»
- Intentar perfilar el tractament antitrombòtic segons les característiques clíniques del pacient

**PACIENTES TRATADOS
CON ANTICOAGULANTES
ORALES INHIBIDORES
DIRECTOS DE LA
COAGULACIÓN (DOACs)**

Guía de manejo y
seguimiento



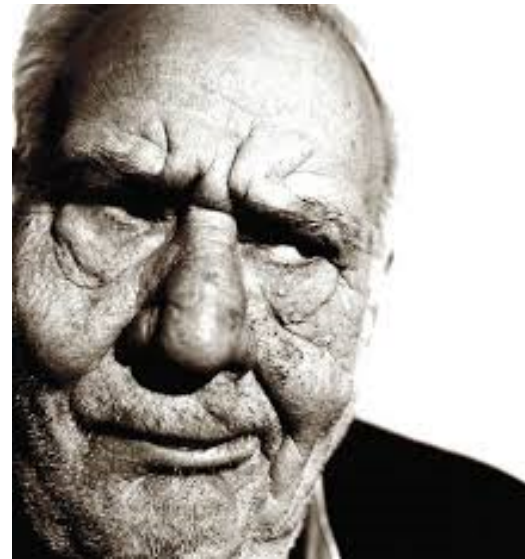
**SITUACIONES ESPECIALES
DE LOS INHIBIDORES
DIRECTOS DE LA
COAGULACIÓN (ACODs)**

Guía de manejo y
recomendaciones



ACODs en situacions especials

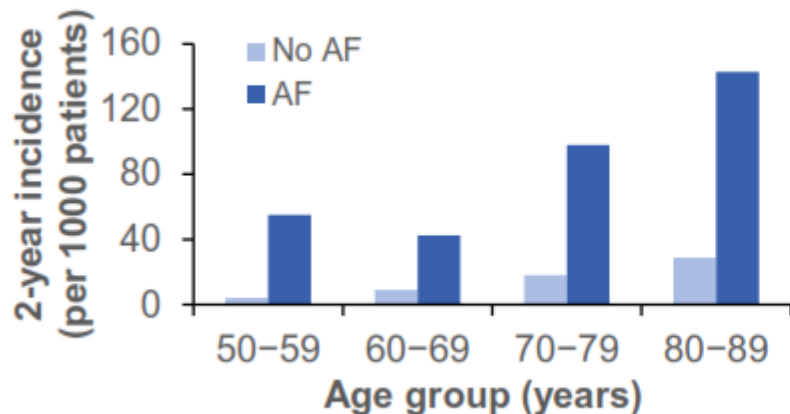
- **Pacients d'edat avançada**
- Insuficiència renal



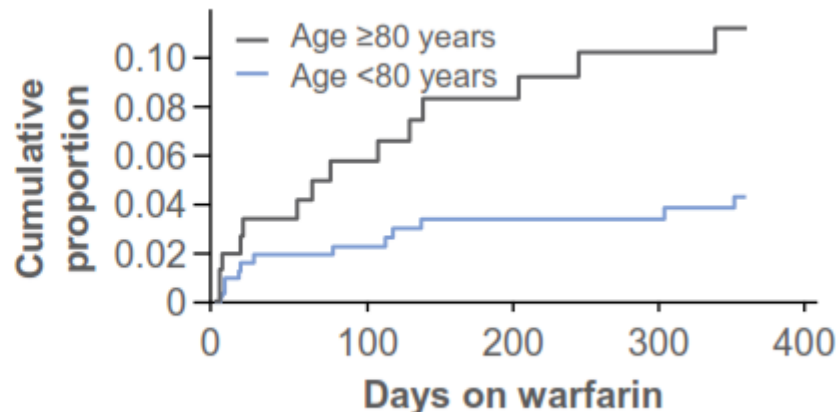
ACODs i pacients d'edat avançada

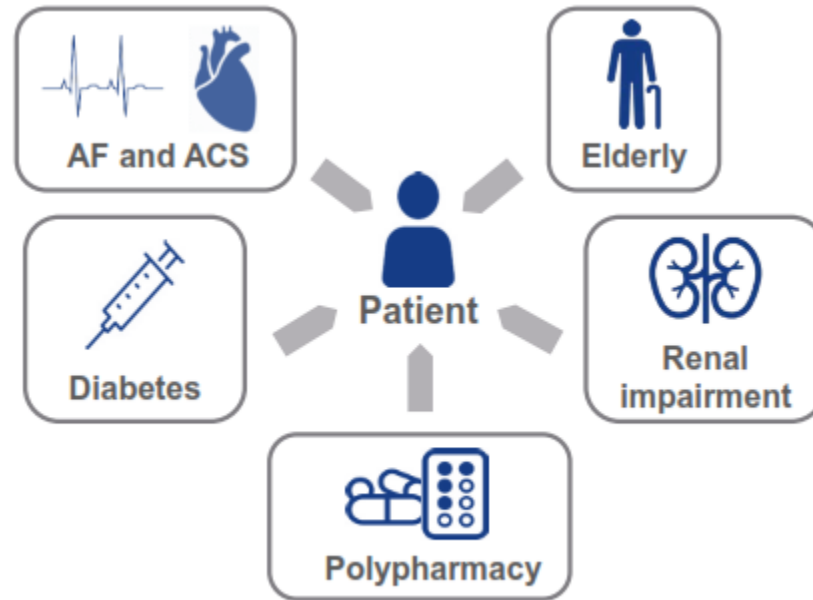
- El 10% del pacients >85^a tenen FA
- Augment incidència 4% anual d'ictus i de MTEV
- Augment del risc hemorràgic amb AVK un 40% per cada 10 anys de edat
- Només porten AVK un 35% del pacients >85^a amb FA

Stroke¹



Major bleeding⁵





- Mobilitat reduïda
- Comorbiditats
- Polimedicats
- Funció renal
- Major risc de caigudes

ACODs i pacients d'edat avançada

Estudis de subgrups

Table I Summary of risk of stroke/thromboembolism and major bleeding comparing direct oral anticoagulants and warfarin in patients aged >75 years and <75 years

	Stroke/systemic thromboembolism (%/year)		Major bleeding (%/year)	
	Age <75 years*	Age >75 years	Age <75 years*	Age >75 years
RE-LY				
Dabigatran 150 mg	0.9	1.4	2.1	5.1
Warfarin	1.4	2.1	3	4.4
ROCKET-AF				
Rivaroxaban	2	2.3	2.7	4.9
Warfarin	2.1	2.9	2.8	4.4
ARISTOTLE				
Apixaban	1.2	1.6	2	3.3
Warfarin	1.7	2.2	2.8	5.2
ENGAGE-TIMI 48				
Edoxaban – high intensity	1.7	1.9	2.5	4
Edoxaban – low intensity	2.6	2.6	1.6	2.3
Warfarin	1.8	2.3	3.3	4.8

Note: *Age <75 years: includes patients between 65 and 74 years.

Abbreviations: RE-LY, Randomized Evaluation of Long-Term Anticoagulation Therapy; ROCKET-AF, Rivaroxaban Once Daily Oral Direct Factor Xa Inhibition Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism Trial in Atrial Fibrillation; ARISTOTLE, Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation trial; ENGAGE-TIMI 48, Effective Anticoagulation with Factor Xa Next Generation in Atrial Fibrillation-Thrombolysis in Myocardial Infarction 48 trial.

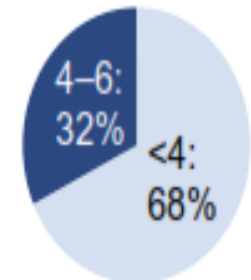
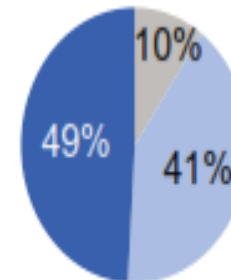
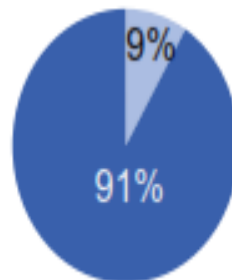
Differences in Characteristics of Elderly Patients in ROCKET AF and ARISTOTLE

Patients aged ≥ 75 years

	ROCKET AF ¹	ARISTOTLE ²	ENGAGE AF ³
n	6229	5678	8474
Mean CHADS ₂ score	3.7	2.7	3.2
CHF, %	65.5	24.3	45
Hypertension, %	88.8	83.0	93
Diabetes mellitus, %	44.7	21.1	28
Prior stroke/TIA/SE, %	65.0	21.8	25

CHADS₂ score

- ≤ 1
- 2
- 3–6



1. Halperin JL et al, *Circulation* 2014;130:138–146; 2. Halvorsen S et al, *Eur Heart J* 2014;35:1864–1872; 3. Kato ET et al, *J Am Heart Assoc* 2016;5:doi/10.1161/JAHA.116.003432

ACODs i pacients d'edat avançada

Estudis de subgrups

Table I Summary of risk of stroke/thromboembolism and major bleeding comparing direct oral anticoagulants and warfarin in patients aged >75 years and <75 years

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	Age <75 years*	Age >75 years	Age <75 years*	Age >75 years
→ RE-LY				
Dabigatran 150 mg	0.9	1.4	2.1	5.1
Warfarin	1.4	2.1	3	4.4
ROCKET-AF				
Rivaroxaban	2	2.3	2.7	4.9
Warfarin	2.1	2.9	2.8	4.4
ARISTOTLE				
Apixaban	1.2	1.6	2	3.3
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Note: *Age <75 years: includes patients between 65 and 74 years.

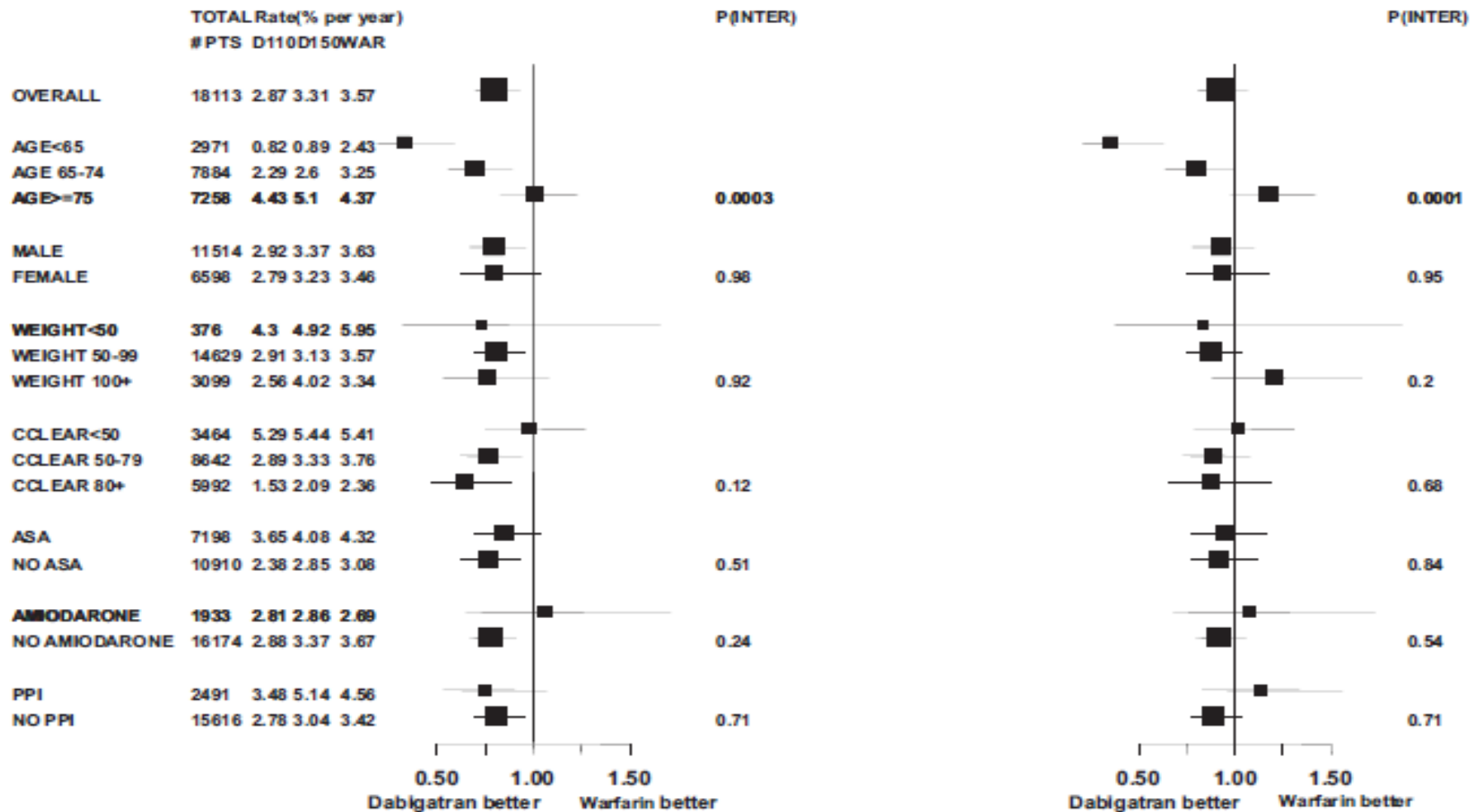
Abbreviations: RE-LY, Randomized Evaluation of Long-Term Anticoagulation Therapy; ROCKET-AF, Rivaroxaban Once Daily Oral Direct Factor Xa Inhibition Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism Trial in Atrial Fibrillation; ARISTOTLE, Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation trial; ENGAGE-TIMI 48, Effective Anticoagulation with Factor Xa Next Generation in Atrial Fibrillation-Thrombolysis in Myocardial Infarction 48 trial.

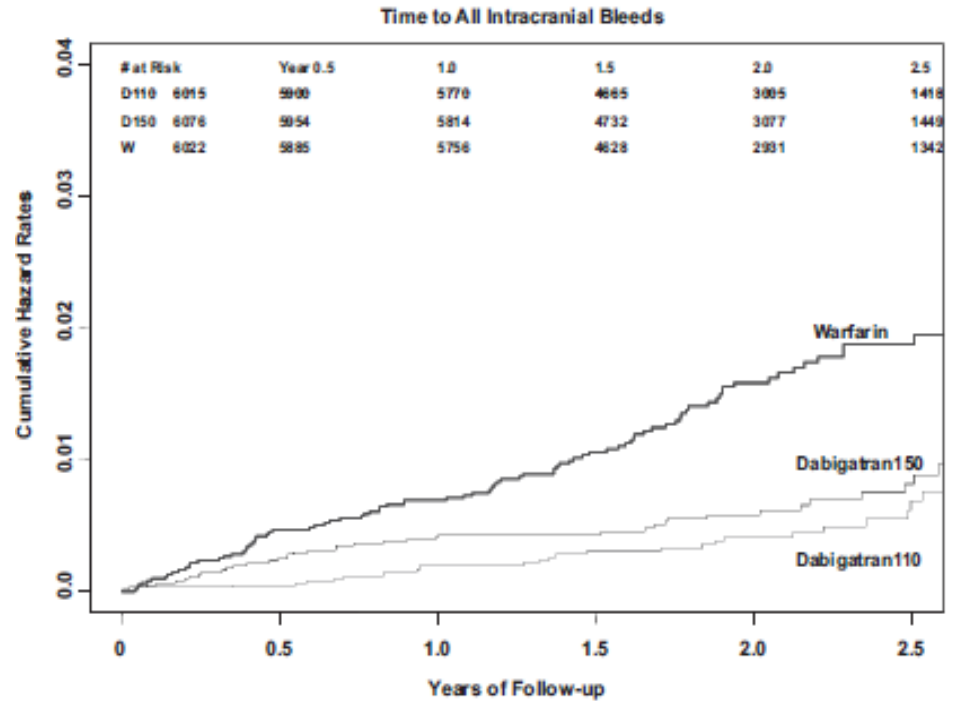
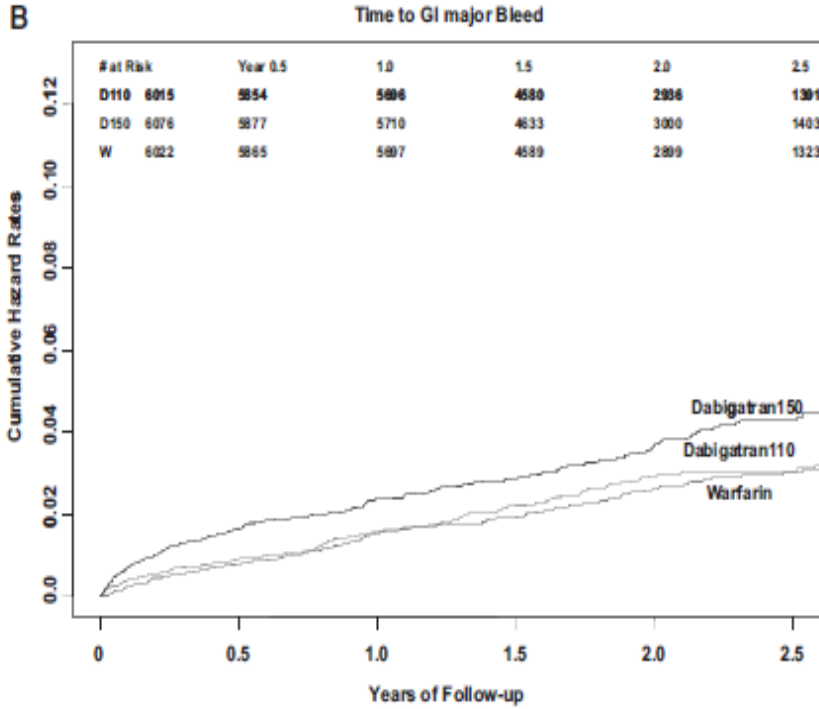
Dabigatran: Risc d'hemorragia major

A

Dabigatran110 vs. WARFARIN

Dabigatran150 vs. WARFARIN





ACODs i pacients d'edat avançada

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Rivaroxaban

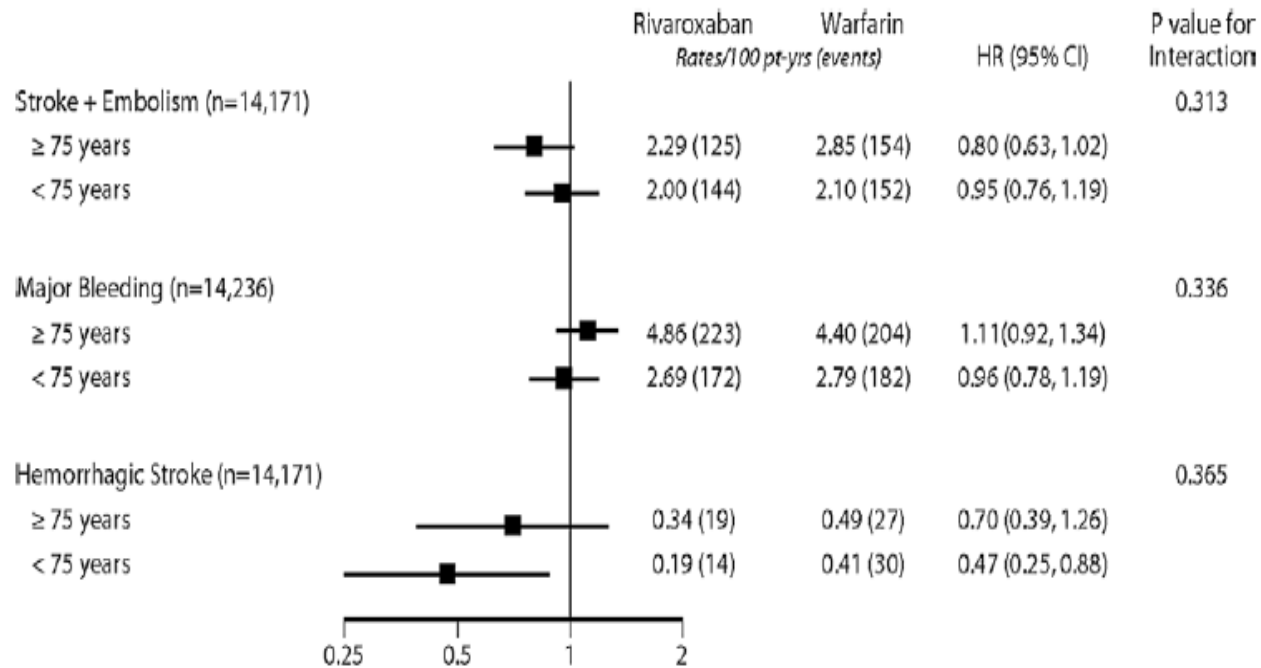


Figure 3. Relative risks of major clinical outcome events with rivaroxaban vs warfarin in older and younger patients. CI indicates confidence interval; and HR, hazard ratio.

(*Circulation*. 2014;130:138-146.)

ACODs i pacients d'edat avançada

Estudis de subgrups

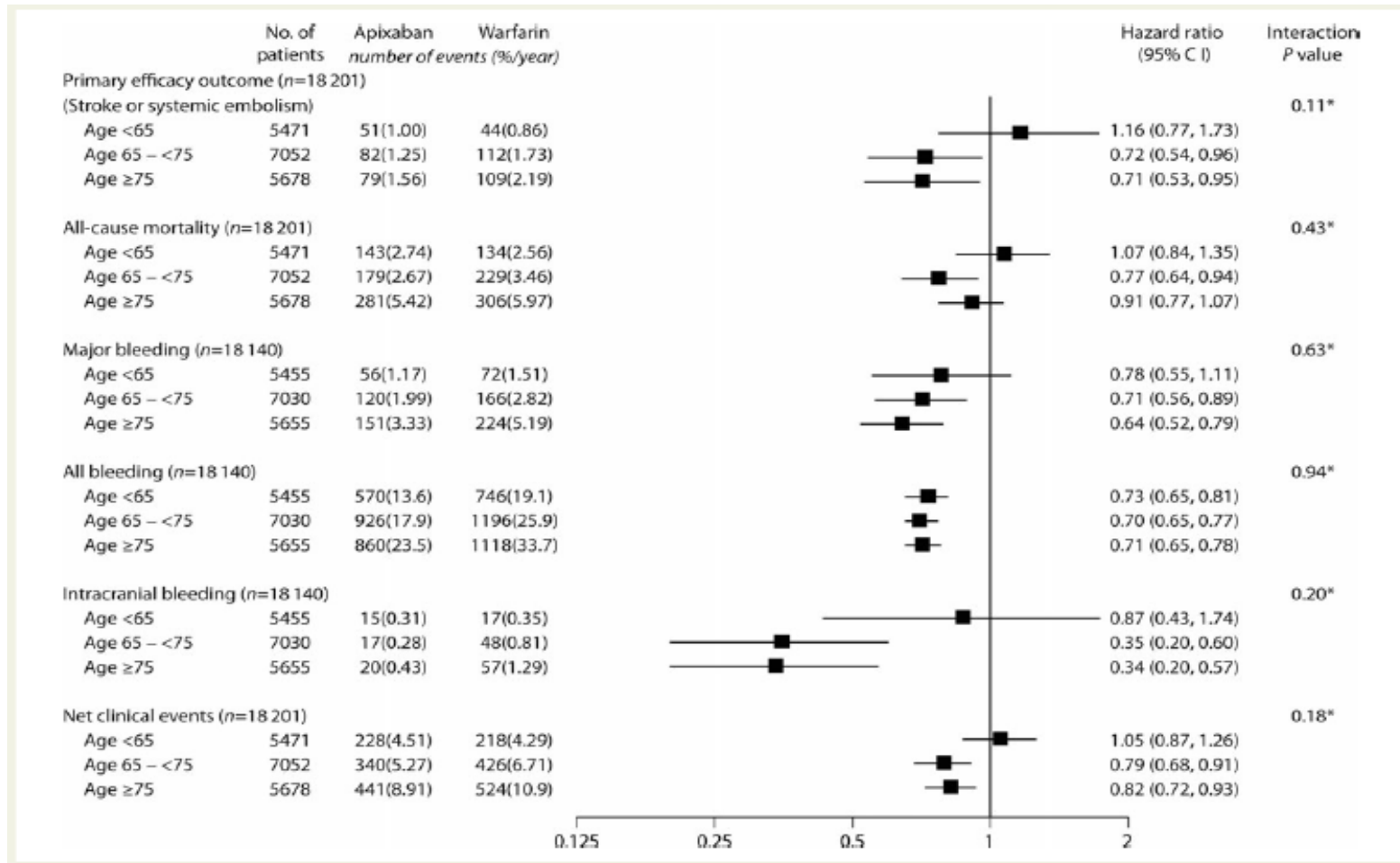
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ROCKET-AF				
Rivaroxaban	2	2.3	2.7	4.9
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→ ARISTOTLE				
Apixaban	1.2	1.6	2	3.3
Warfarin	1.7	2.2	2.8	5.2
ENGAGE-TIMI 48				
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Apixaban



ACODs i pacients d'edat avançada

Estudis de subgrups

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Warfarin	1.4	2.1	3	4.4
ROCKET-AF				
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ACODs i pacients d'edat avançada

Considerar ≥ 75 anys

- Els ACODs tenen un bon perfil risc-benefici vs warfarina
- No hi han estudis comparatius entre ACODs en pacient gran ($>80^a$) que valorin eficàcia i seguretat
- Valorar risc hemorràgic i necessitat d'altres tractaments antiagregants
- Optimitzar adherència o facilitar posologia
- En patologia gastrointestinal (hernia de hiatus, reflux, gastritis, esofagitis, ulcus): No es recomana Dabigatran 150 mg/12h donat el major risc de hemorràgia major .
- Vigilar patologies concomitants: trombopènia, insuf. Renal, anèmia, demència...



ACODs en situacions especials

- Pacients d'edat avançada
- **Insuficiència renal**



ACODs i insuficiència renal

- Frequent coexistència de IRC i FA
- La IRC augmenta el risc de ictus, MTEV i hemorràgia
- Els ACODs tenen eliminació renal en diferent grau
- En els trials es van excloure la IRC severa (30-25%)
- La eficàcia i seguretat dels ACODs en IRC s'ha valorat en subanàlisis

1. PROPIEDADES FARMACOCINÈTICAS Y FARMACODINÀMICAS

CARACTERÍSTICAS	DABIGATRAN	RIVAROXABAN	APIXABAN	EDOXABAN
Mecanismo de acción	Inhibidor del FIIa (trombina)	Inhibidor directo del FXa	Inhibidor directo del FXa	Inhibidor directo del FXa
Dosis (mg)	150 110	20 15	5 2.5	15,30* 60**
Frecuencia	Cada 12 horas	Cada 24 horas	Cada 12 horas	Cada 24 horas
Biodisponibilidad %	6.5 (pH dependiente)	80 (100% con alimentos)	50	62
Eliminación renal %	80	33 (metabolito activo)	25	35-50



ACODs i insuficiència renal

Estudi de subgrups

Table 2 Summary of risk of stroke/thromboembolism and major bleeding comparing direct oral anticoagulants and warfarin in patients with a CrCl <50 mL/min and >50 mL/min

	Stroke/systemic thromboembolism (%/year)		Major bleeding (%/year)	
	CrCl 30–49 mL/min	CrCl ≥50–80 mL/min	CrCl 30–49 mL/min	CrCl ≥50–80 mL/min
RE-LY				
Dabigatran 150 mg	1.5	1.2	5.4	3.3
Warfarin	2.8	1.8	5.5	3.8
ROCKET-AF				
Rivaroxaban	1.7	1.6	4.5	3.2
Warfarin	2.1	2	4.7	3.4
ARISTOTLE				
Apixaban	2.1*	1.2	3.2*	2.4
Warfarin	2.7*	1.7	6.4*	3.2
ENGAGE-TIMI 48				
Edoxaban	2.3	1.5	3.8	3.1
Warfarin	2.7	2.1	5.1	3.5

Note: *CrCl 25–50 mL/min.

Abbreviations: CrCl, creatinine clearance; RE-LY, Randomized Evaluation of Long-Term Anticoagulation Therapy; ROCKET-AF, Rivaroxaban Once Daily Oral Direct Factor Xa Inhibition Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism Trial in Atrial Fibrillation; ARISTOTLE, Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation trial; ENGAGE-TIMI 48, Effective Anticoagulation with Factor Xa Next Generation in Atrial Fibrillation-Thrombolysis in Myocardial Infarction 48 trial.

ACODs i insuficiència renal

Table 3 Dosing of direct oral anticoagulants in atrial fibrillation based on creatinine clearance

	Dabigatran	Rivaroxaban	Apixaban	Edoxaban
Normal renal function (CrCl >80 mL/min)	150 mg twice daily	20 mg daily	5 mg twice daily or 2.5 mg twice daily*	60 mg daily Avoid if CrCl ≥95 mL/min
Mild renal impairment (CrCl 50–80 mL/min)	150 mg twice daily	20 mg daily	5 mg twice daily or 2.5 mg twice daily*	60 mg daily
Moderate renal impairment (CrCl 30–50 mL/min)	150 mg twice daily	20 mg daily** 15 mg daily	5 mg twice daily or 2.5 mg twice daily*	60 mg daily** or 30 mg daily [†]
Severe renal impairment [†] (CrCl <30 mL/min)	75 mg twice daily	15 mg daily	Avoid	30 mg daily [†]
Severe renal impairment on hemodialysis [†]	Avoid	Avoid	5 mg twice daily or 2.5 mg twice daily*	Avoid

Notes: *Apixaban 2.5 mg daily if two patient characteristics including serum creatinine ≥ 1.5 mg/dL, ≥80 years, ≤60 kg are present; [†]CrCl 15–50 mL/min; **in CrCl > 50 mL/min;

[†]no evidence from RCTs in CrCl <30 mL/min and hemodialysis with dabigatran, rivaroxaban and edoxaban and <25 mL/min with apixaban.

Abbreviations: CrCl, creatinine clearance; RCTs, randomized controlled trials.



ELSEVIER



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Canadian Journal of Cardiology 30 (2014) 888–897

Systematic Review/Meta-analysis

Novel Oral Anticoagulants in Patients With Renal Insufficiency: A Meta-analysis of Randomized Trials

Partha Sardar, MD,^a Saurav Chatterjee, MD,^b Eyal Herzog, MD,^b Ramez Nairooz, MD,^c
Debabrata Mukherjee, MD, MS,^a and Jonathan L. Halperin, MD^d

^a Department of Cardiology, Texas Tech University Health Sciences Center, El Paso, Texas, USA

^b Department of Cardiovascular Diseases, St Luke's-Roosevelt Hospital of the Mount Sinai Health System, New York, New York, USA

^c Department of Cardiology, University of Arkansas for Medical Sciences, Little Rock, Arkansas, USA

^d Department of Cardiovascular Diseases, The Cardiovascular Institute, Mount Sinai Medical Center, New York, New York, USA

See editorial by Witt and Healey, pages 853-854 of this issue.

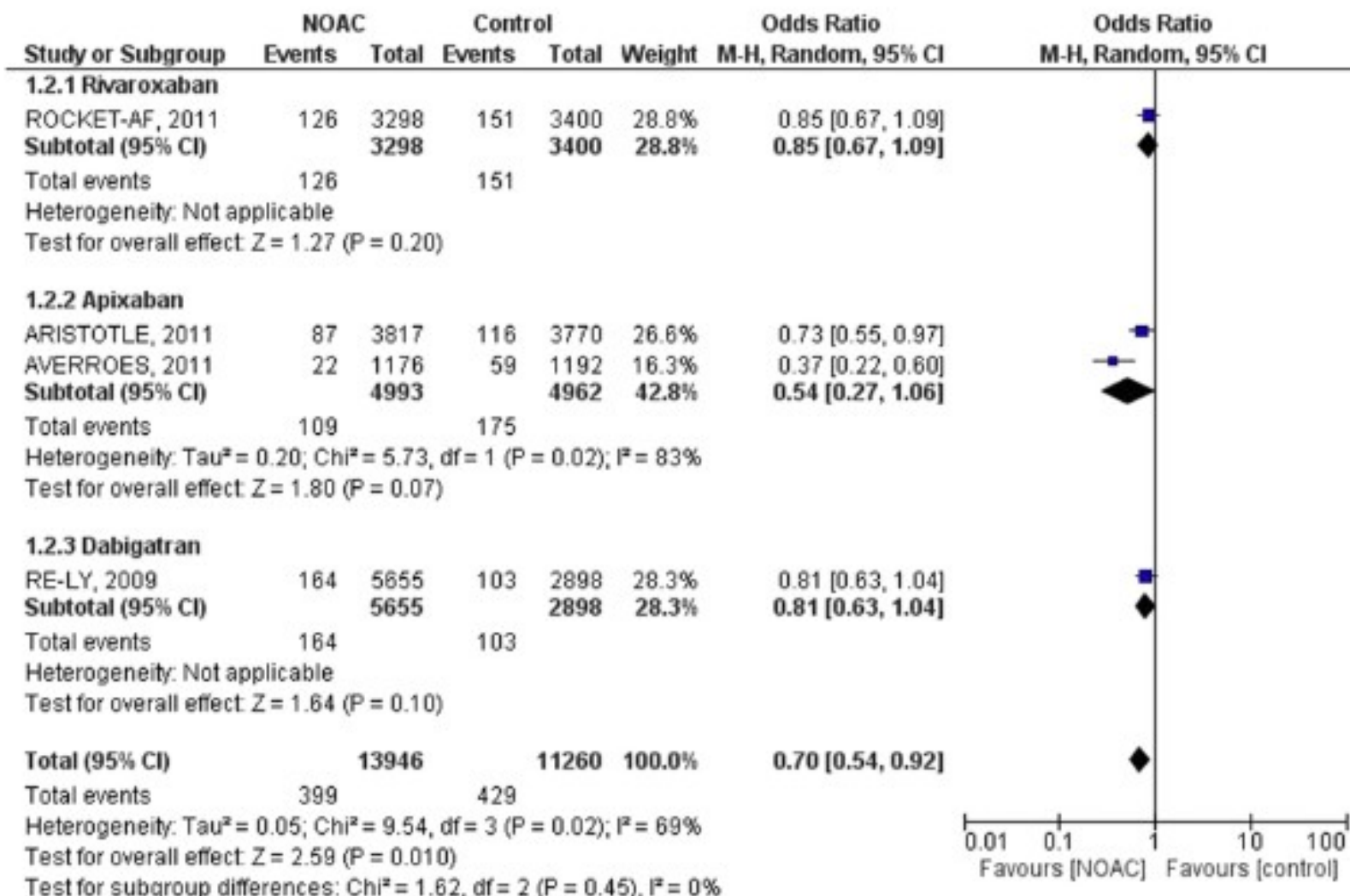


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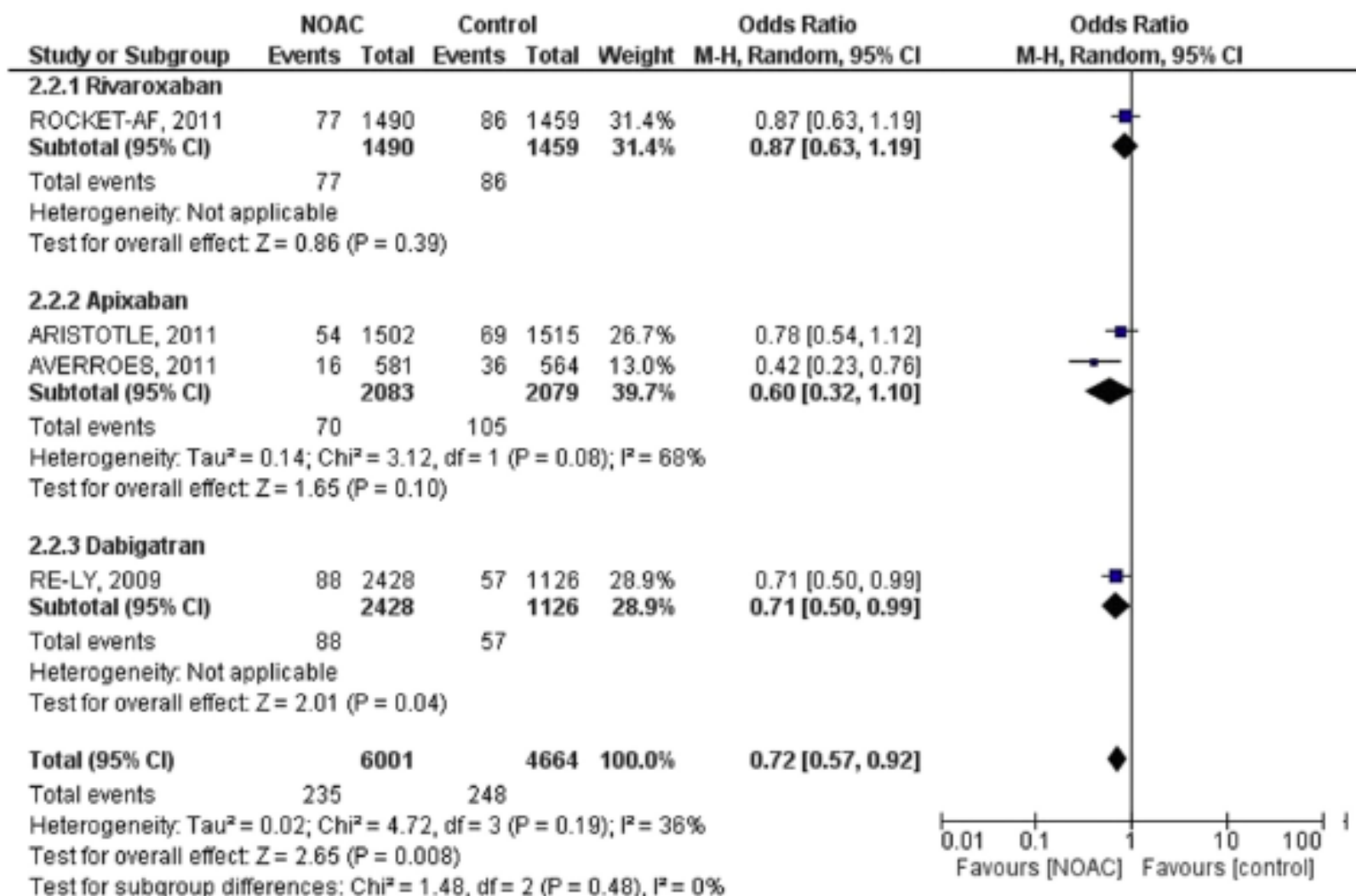
Patients with mild renal insufficiency

A Stroke or systemic embolism



Patients with moderate renal insufficiency

A Stroke or systemic embolism





SCIENCE VOLUNTEER

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ORIGINAL RESEARCH ARTICLE

On-Treatment Outcomes in Patients With Worsening Renal Function With Rivaroxaban Compared With Warfarin

Insights From ROCKET AF

Christopher B. Fordyce, Anne S. Hellkamp, Yuliya Lokhnygina, Samuel M. Lindner, Jonathan P. Piccini, Richard C. Becker, Scott D. Berkowitz, Günter Breithardt, Keith A. A. Fox, Kenneth W. Mahaffey, Christopher C. Nessel, Daniel E. Singer and Manesh R. Patel and On behalf of the ROCKET AF Steering Committee and Investigators

DOI <http://dx.doi.org/10.1161/CIRCULATIONAHA.116.021890>

Published: July 5, 2016

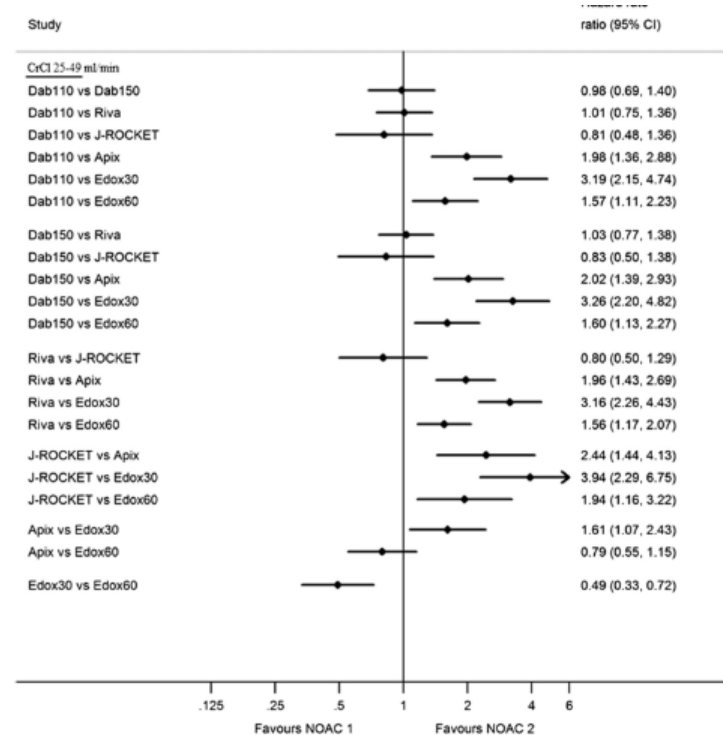


ORIGINAL PAPER

Renal function and non-vitamin K oral anticoagulants in comparison with warfarin on safety and efficacy outcomes in atrial fibrillation patients: a systemic review and meta-regression analysis

Peter Brønnum Nielsen · Deirdre A. Lane ·
Lars Hvilsted Rasmussen · Gregory Y. H. Lip ·
Torben Bjerregaard Larsen

- Estudi indirecte comparatiu
- IR (FG 50-79mL/min) : Apixaban i dabigatran 110mg es van relacionar amb menor tasa de sagnat major
- IR (FG 25-49ml/min): apixaban millor perfil de seguretat vs dabigatran 110mg



The screenshot shows a web browser window with the URL circ.ahajournals.org/content/134/1/24. The page is the Circulation journal website. At the top, there is a navigation bar with a search box, a 'DONATE' button, and user options: 'Hello, Guest!', 'MY ALERTS', 'SIGN IN', and 'JOIN'. The journal title 'Circulation' is prominently displayed in red. Below it is a horizontal menu with categories: HOME, ABOUT THIS JOURNAL, ALL ISSUES, SUBJECTS, BROWSE FEATURES, RESOURCES, and AHA JOURNALS. The main content area features the article title 'Impact of Renal Function on Outcomes With Edoxaban in the ENGAGE AF-TIMI 48 Trial' under the heading 'ORIGINAL RESEARCH ARTICLE'. The authors listed are Erin A. Bohula, Robert P. Giugliano, Christian T. Ruff, Julia F. Kuder, Sabina A. Murphy, Elliott M. Antman, and Eugene Braunwald. The DOI is <http://dx.doi.org/10.1161/CIRCULATIONAHA.116.022361> and the publication date is July 5, 2016. A CrossMark logo is also present. At the bottom of the article area, there are tabs for 'Article', 'Figures & Tables', 'Supplemental Materials', and 'Info & Metrics'. The browser's taskbar at the bottom shows various application icons and the system clock indicating 0:30 on 12/10/2016.

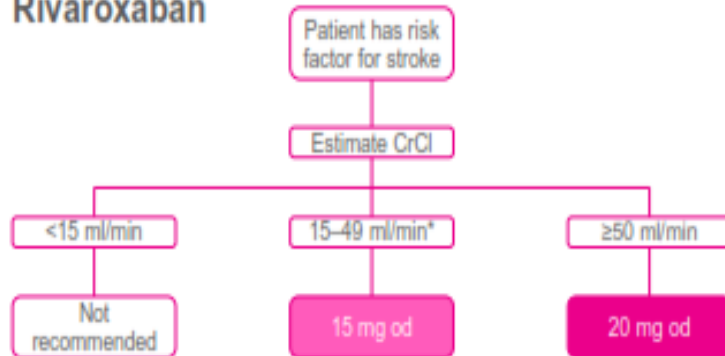
En FG 30-50mL/min endoxaban no va ser inferior a la warfarina amb prevencio del inctus amb reducció significativa del sagnat major

ACODs i insuficiència renal

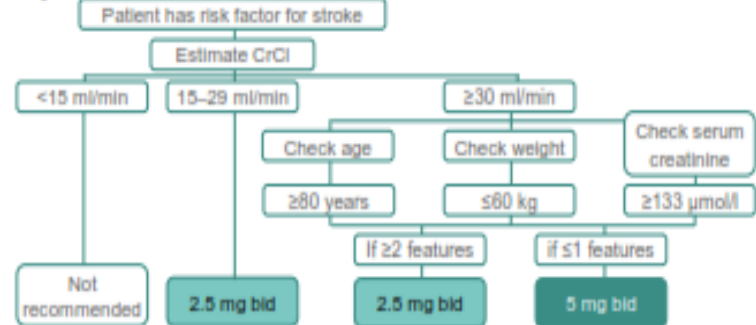
recomenacions ACC/AHA/HRS

Dose Adjustments in Non-valvular AF

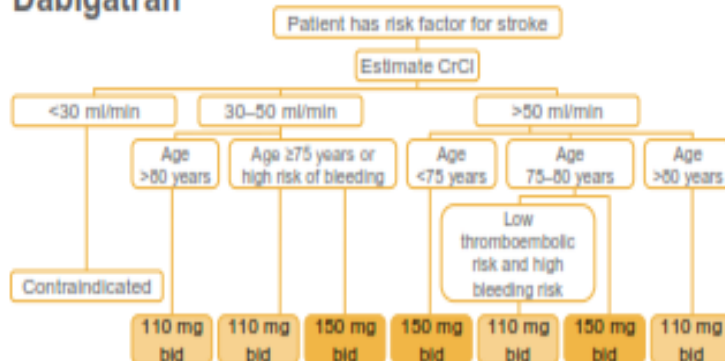
Rivaroxaban



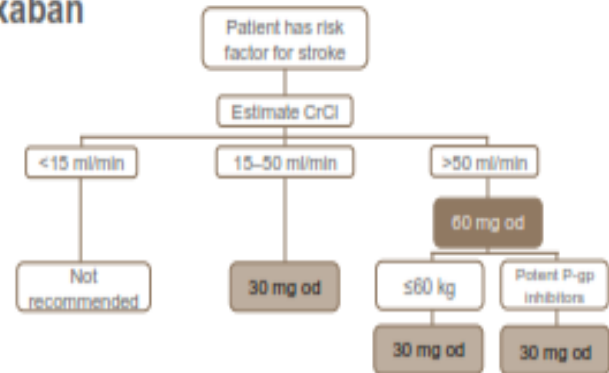
Apixaban



Dabigatran*



Edoxaban



*Patients receiving concomitant dabigatran and verapamil should reduce their dabigatran dose to 110 mg bid

1. Rivaroxaban SmPC; 2. Apixaban SmPC; 3. Dabigatran SmPC; 4. Edoxaban SmPC

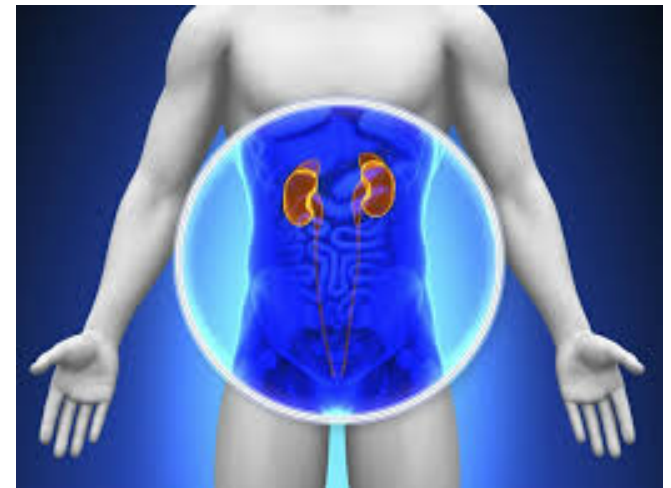
Recomenacions: ACODs i insuficiència renal

	DABIGATRAN	RIVAROXABAN	APIXABAN	EDOXABAN
FG >80mL/min	SI	SI	SI	PRECAUCIÓ ≥95mL/min NO
FG 50-79mL/min	SI 150 o 110mg/12h <ul style="list-style-type: none"> ◆ Age ≥80 years ◆ Concomitant verapamil use ◆ Age 75–80 years* ◆ Moderate renal impairment* ◆ Gastritis, oesophagitis or GI reflux* ◆ Increased risk of bleeding* 	SI	SI 5 o 2.5mg/12h <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 5px auto;"> <p>At least 2 of:</p> <ul style="list-style-type: none"> ◆ Age ≥80 years ◆ Body weight ≤60 kg ◆ Serum creatinine ≥1.5 mg/dl </div>	SI 60 o 30mg/dia <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 5px auto;"> <ul style="list-style-type: none"> ◆ CrCl 15–50 ml/min ◆ Body weight ≤60 kg ◆ Concomitant cyclosporine, dronedarone, erythromycin or ketoconazole use </div>
FG 31-49mL/min	PRECAUCIÓ 150mg/dia o 110mg/12h	SI 15mg/dia	SI 5 o 2.5mg/12h	SI 30mg/dia
FG 15-30mL/min	NO	PRECAUCIÓ 15mg/dia	PRECAUCIÓ 2.5mg/12h	PRECAUCIÓ 30mg/dia
FG <15mL/min dialisi	NO	NO	NO	NO

ACODs i insuficiència renal

Consideracions

- Els ACODs son segurs en la IRC moderada
- Al inici valorar funció renal i ajustar dosi
- Control de la funció renal



Moltes gràcies!



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