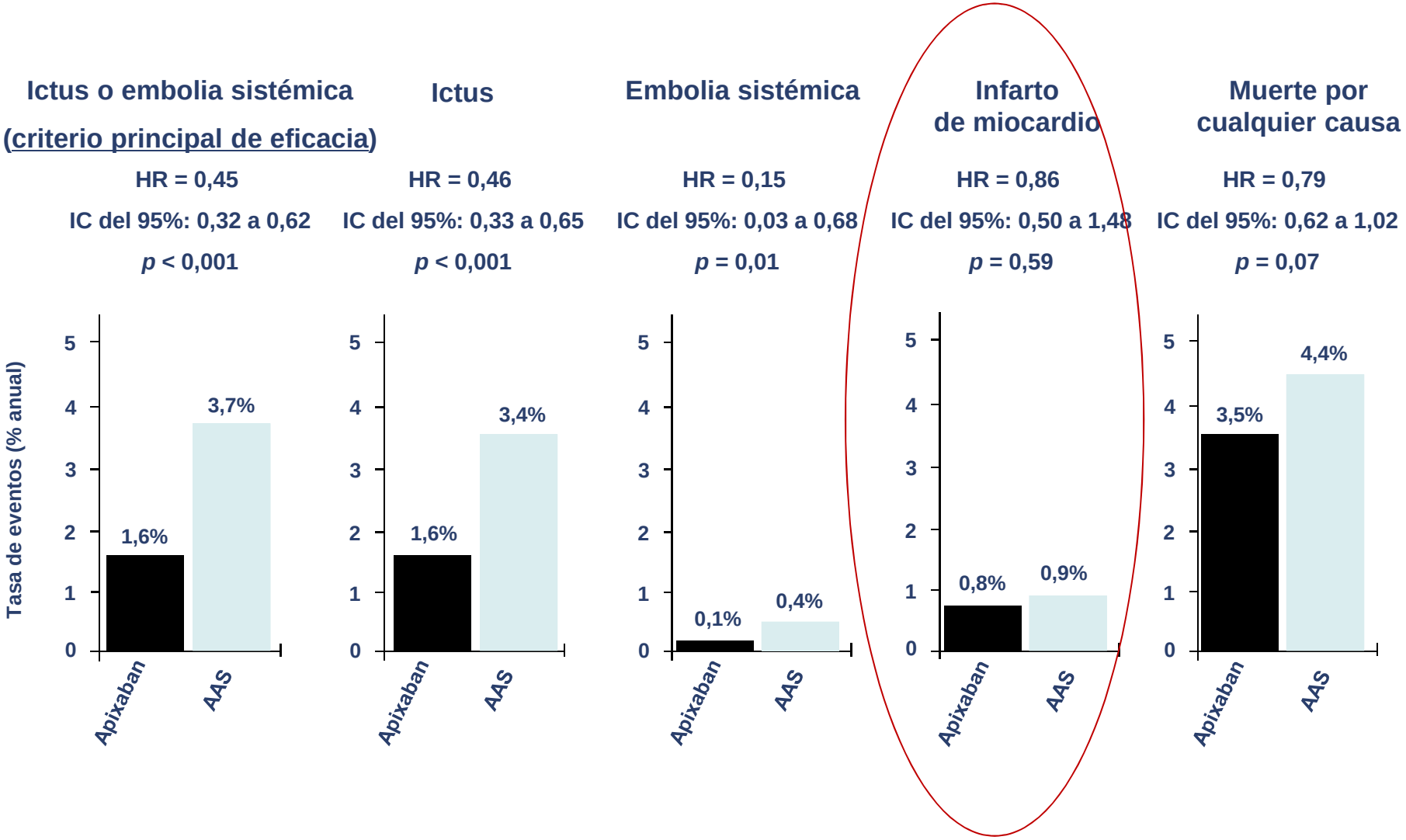
Seguridad Cardiovascular de NACOs y ADOs

Seguridad Cardiovascular de los NACOs

AVERROES:
resultados en el análisis de la eficacia



Figuras creadas a partir de datos de Connolly et al. N Engl J Med 2011;364:806-17.

ARISTOTLE: resultados en el análisis de la eficacia

Criterio de valoración	Apixaban (n = 9.120) Tasa de eventos (% anual)	Warfarina (n = 9.081) Tasa de eventos (% anual)	HR (IC del 95%)	Valor de *p*
Criterio principal de valoración de la eficacia: ictus o embolia sistémica	1,27	1,60	**0,79** (0,66 a 0,95)	**0,01**
Ictus	1,19	1,51	**0,79** (0,65 a 0,95)	**0,01**
Isquémico o no especificado	0,97	1,05	0,92 (0,74 a 1,13)	0,42
Hemorrágico	0,24	0,47	**0,51** (0,35 a 0,75)	**< 0,001**
Embolia sistémica	0,09	0,10	0,87 (0,44 a 1,75)	0,70
Infarto de miocardio	0,53	0,61	0,88 (0,66 a 1,17)	0,37
Muerte por cualquier causa	3,52	3,94	**0,89** (0,80 a 0,998)	**0,047**

N Engl J Med 2011;365:981-92.

Riesgo de Infarto de Miocardio

Estudio	Pacientes	Duración del tratamiento	Apixaban (Event-rate)	Comparador (Event-rate)	HR (95% CI)	Valor P
AVERROES	AF vs. ASA	1.1 años (media)	0.80%/año	0.90%/año	0.86 (0.50-1.48)	0.59
ARISTOTLE	AF vs. warfarina	1.8 años (mediana)	0.53%/año	0.61%/año	0.88 (0.66-1.17)	0.37

En los estudios ARISTOTLE Y AVERROES en pacientes con FANV apixaban no produjo un incremento de riesgo de IAM comparado con warfarina o ASA

Connolly et al. N Engl J Med 2011;364:806-17.
Granger et al. N Engl J Med 2011;365:981-92.

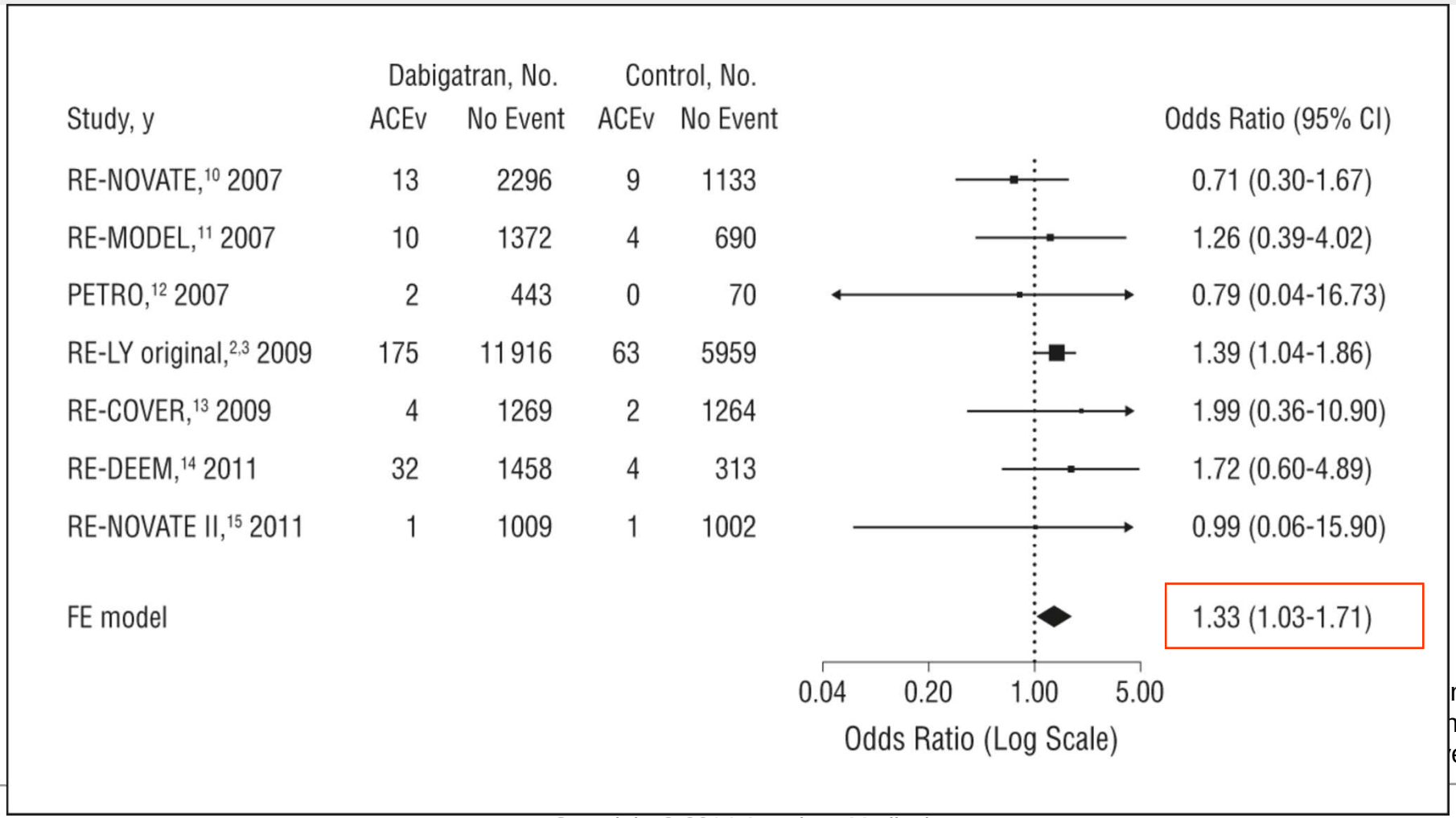
RE-LY

Table 4 Rates of MI and CV events in RE-LY,[1,2,12] randomized set

	Dabigatran 110 mg bid (n = 6,015)	Dabigatran 150 mg bid (n = 6,076)	Warfarin (n = 6,022)	Dabigatran 110 mg bid versus warfarin (n = 12,037)		Dabigatran 150 mg bid versus warfarin (n = 12,098)	
	n (%)	n (%)	n (%)	RR (95% CI)	*P*-value	HR (95% CI)	*P*-value
All stroke	171 (1.44)	122 (1.01)	186 (1.58)	0.91 (0.74–1.12)	0.38	0.64 (0.51–0.81)	<0.001
Total MI	98 (0.82)	97 (0.81)	75 (0.64)	1.29 (0.96–1.75)	0.09	1.27 (0.94–1.71)	0.12

From: **Dabigatran Association With Higher Risk of Acute Coronary Events: Meta-analysis of Noninferiority Randomized Controlled Trials**

Arch Intern Med. 2012;172(5):397-402. doi:10.1001/archinternmed.2011.1666



n of
n of
erall

Vascular Health and Risk Management

Dovepress

open access to scientific and medical research

Open Access Full Text Article

ORIGINAL RESEARCH

Cardiovascular outcomes during treatment with dabigatran: comprehensive analysis of individual subject data by treatment

Andreas Clemens[1]
Mandy Fraessdorf[2]
Jeffrey Friedman[3]

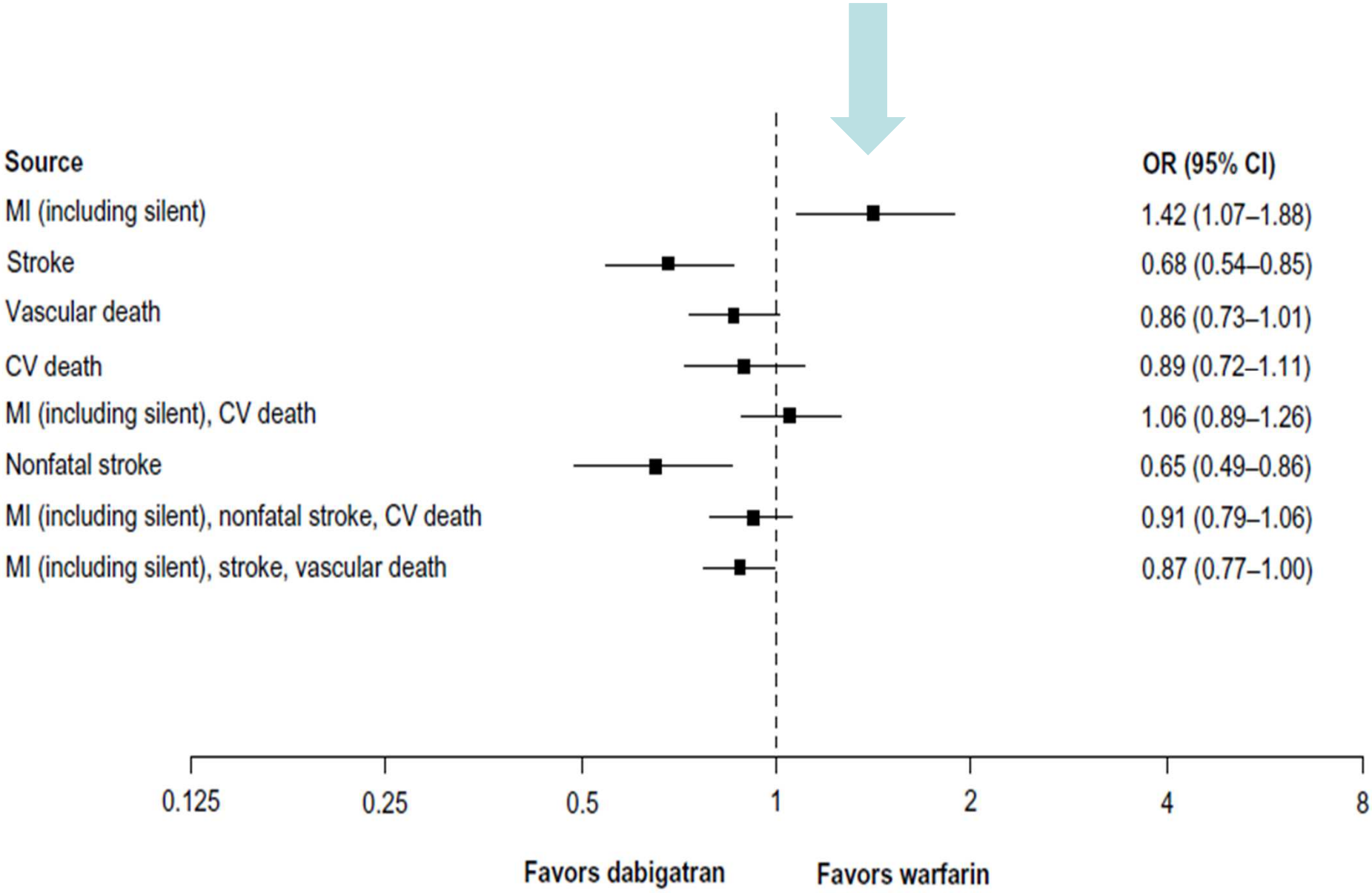
[1]Corporate Division Medicine, TA Cardiovascular, [2]Medical Data Services, Boehringer Ingelheim GmbH & Co KG, Ingelheim am Rhein, Germany; [3]Boehringer Ingelheim

Background: Dabigatran 150 mg twice daily was shown to be superior to warfarin in preventing stroke in subjects with nonvalvular atrial fibrillation (SPAF) in the RE-LY (Randomized Evaluation of Long-term anticoagulation therapY) trial. Numerically, more myocardial infarctions occurred in patients receiving dabigatran compared with well-controlled warfarin. This observation prompted a comprehensive analysis of cardiovascular outcomes, including myocardial infarction, in all completed Phase II and III trials of dabigatran etexilate.

Methods: The analysis included comparisons of dabigatran with warfarin, enoxaparin, and

Table 1 Summary of MI rates in studies of stroke prevention in AF

Study	Total treated (number on test treatment)	Test treatment	MI rate (% per year)	Comparator	MI rate (% per year)
ACTIVE-W[5]	6,706 (1,557)	Clopidogrel, ASA qd	0.86	Warfarin	0.55
ACTIVE-A[8]	7,554	ASA qd	0.9	N/A	
ACTIVE-A[8]	7,554	Clopidogrel/ASA	0.7	N/A	
AMADEUS[7]	4,576	Idraparinux	0.8	Warfarin	0.6
SPORTIF III[3]	3,407	Ximelagatran	1.1	Warfarin	0.6
SPORTIF V[4]	3,922	Ximelagatran	1.0	Warfarin	1.4
BAFTA[6]	973	ASA	1.2	Warfarin	1.1
RE-LY[1,2,a]	18,113	Dabigatran 110 mg bid	0.82	Warfarin	0.64
RE-LY[1,2,a]	18,113	Dabigatran 150 mg bid	0.81	Warfarin	0.64
AVERROES[9]	5,599	Apixaban 5 mg bid	0.8	ASA	0.9
ARISTOTLE[11,b]	18,201	Apixaban 5 mg bid	0.53	Warfarin	0.61
ROCKET[10,a]	14,236	Rivaroxaban 20 mg	0.91	Warfarin	1.12
RELY-ABLE[46]	5,851	Dabigatran 110 mg bid	0.72	N/A	N/A
RELY-ABLE[46]	5,851	Dabigatran 150 mg bid	0.69	N/A	N/A


Source
OR (95% CI)
MI (including silent)
1.42 (1.07–1.88)
Stroke
0.68 (0.54–0.85)
Vascular death
0.86 (0.73–1.01)
CV death
0.89 (0.72–1.11)
MI (including silent), CV death
1.06 (0.89–1.26)
Nonfatal stroke
0.65 (0.49–0.86)
MI (including silent), nonfatal stroke, CV death
0.91 (0.79–1.06)
MI (including silent), stroke, vascular death
0.87 (0.77–1.00)
0.125
0.25
0.5
1
2
4
8
Favors dabigatran
Favors warfarin

Journal of the American College of Cardiology
© 2013 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 61, No. 22, 2013
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2013.03.020

Efficacy and Safety of Dabigatran Etexilate and Warfarin in "Real-World" Patients With Atrial Fibrillation

A Prospective Nationwide Cohort Study

Torben Bjerregaard Larsen, MD, PhD,*† Lars Hvilsted Rasmussen, MD, PhD,†
Flemming Skjøth, MSc, PhD,* Karen Margrete Due, MSc,* Torbjörn Callréus, MD, PhD,‡
Mary Rosenzweig, MSc,‡ Gregory Y. H. Lip, MD†§

Aalborg and Copenhagen, Denmark; and Birmingham, United Kingdom

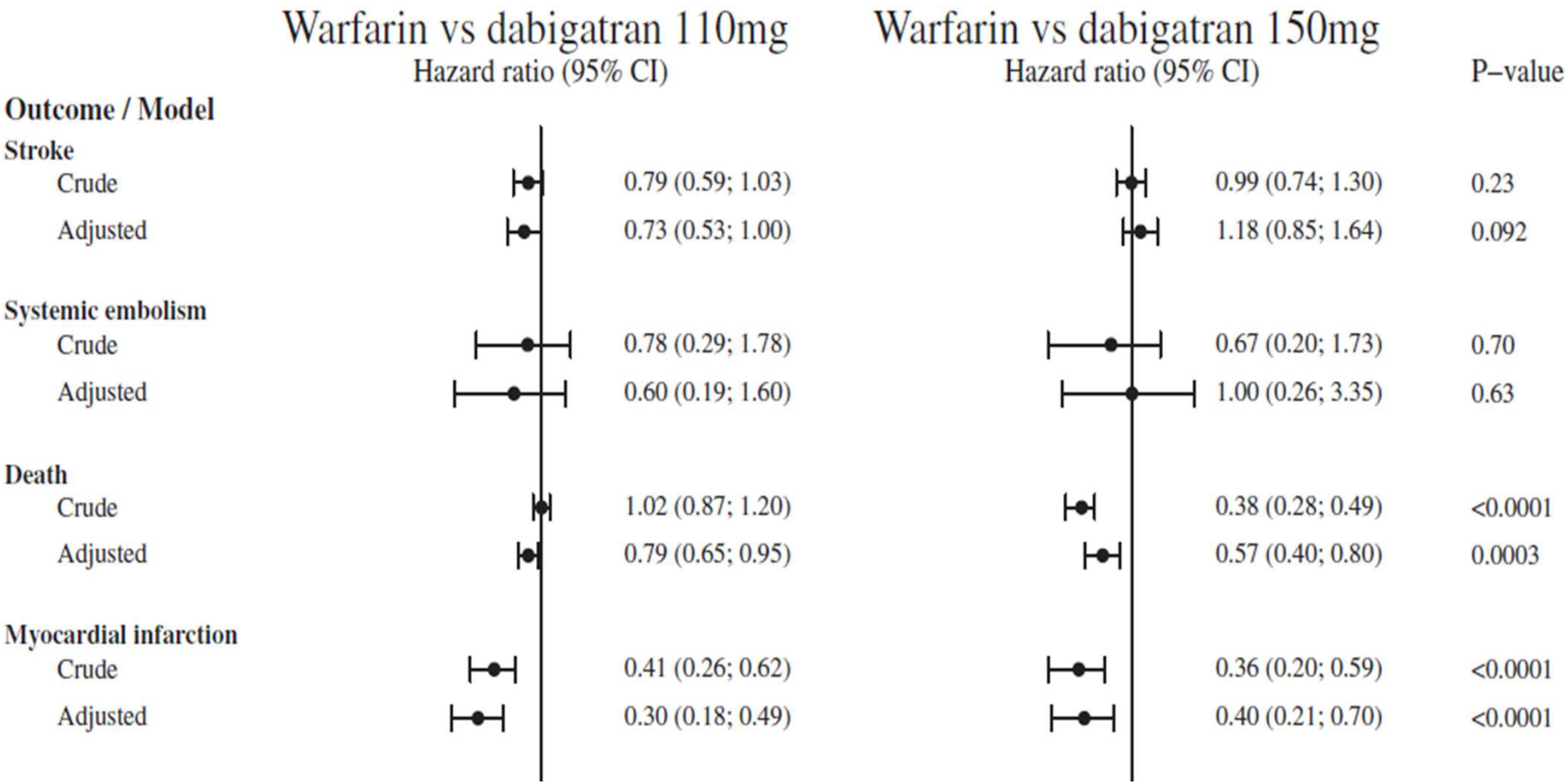

Warfarin vs dabigatran 110mg
Hazard ratio (95% CI)
Warfarin vs dabigatran 150mg
Hazard ratio (95% CI)
P–value
Outcome / Model
Stroke
Crude
0.79 (0.59; 1.03)
0.99 (0.74; 1.30)
0.23
Adjusted
0.73 (0.53; 1.00)
1.18 (0.85; 1.64)
0.092
Systemic embolism
Crude
0.78 (0.29; 1.78)
0.67 (0.20; 1.73)
0.70
Adjusted
0.60 (0.19; 1.60)
1.00 (0.26; 3.35)
0.63
Death
Crude
1.02 (0.87; 1.20)
0.38 (0.28; 0.49)
<0.0001
Adjusted
0.79 (0.65; 0.95)
0.57 (0.40; 0.80)
0.0003
Myocardial infarction
Crude
0.41 (0.26; 0.62)
0.36 (0.20; 0.59)
<0.0001
Adjusted
0.30 (0.18; 0.49)
0.40 (0.21; 0.70)
<0.0001

Table 1 Baseline Characteristics According to Treatment Group

	2009–2010*	2011–2012†				
	Warfarin (n = 8,936)	Warfarin and Dabigatran All (n = 14,267)	Dabigatran, 150 mg (n = 2,239)	Dabigatran, 110 mg (n = 2,739)	Warfarin (n = 9,289)	RE-LY Trial All (n = 18,113)
Age, yrs	69.7 ± 12.5	70.8 ± 12.1	67.4 ± 8.5	74.7 ± 11.8	70.4 ± 12.6	71.8 ± 8.7
≥65	70.0 (6,242)	73.8 (10,524)	68.6 (1,536)	80.5 (2,206)	73.0 (6,782)	N/A
≥75	37.0 (3,295)	38.6 (5,508)	18.3 (410)	52.8 (1,445)	39.3 (3,653)	N/A
≥80	20.1 (1,797)	23.0 (3,275)	2.4 (54)	40.9 (1,121)	22.6 (2,100)	N/A
≥85	7.6 (670)	10.1 (1,437)	0.8 (19)	19.7 (540)	9.5 (878)	N/A
Female	40.2 (3,595)	43.5 (6,203)	38.5 (861)	53.1 (1,455)	41.9 (3,887)	36.4 (6,599)
$CHADS_2$‡	1.17 ± 1.18	1.16 ± 1.18	0.96 ± 1.07	1.27 ± 1.27	1.18 ± 1.17	2.13 ± 1.13
$CHADS_2$ 3–6	14.2 (1,271)	14.3 (2,047)	9.5 (212)	18.9 (518)	14.2 (1,317)	32.5 (5,882)
Prior stroke, transient ischemic attack, or systemic embolism	17.3 (1,542)	16.1 (2,297)	17.1 (383)	17.5 (478)	15.5 (1,436)	20.0 (3,623)
Heart failure	8.5 (764)	8.3 (1,179)	5.2 (116)	6.9 (188)	9.4 (875)	32.0 (5,793)
Myocardial infarction	9.6 (861)	9.5 (1,362)	6.1 (136)	8.0 (218)	10.9 (1,008)	16.6 (3,005)
Diabetes mellitus	12.3 (1,099)	12.0 (1,713)	12.1 (270)	10.8 (295)	12.4 (1,148)	23.3 (4,221)
Hypertension	19.3 (1,721)	20.9 (2,977)	22.7 (509)	18.0 (493)	21.2 (1,975)	78.3 (14,183)

Comparative coronary risks of apixaban, rivaroxaban and dabigatran: a meta-analysis and adjusted indirect comparison.

Br J Clin Pharmacol. 2014 Mar 11. doi: 10.1111/bcp.12376. [Epub ahead of print]
Loke YK, Pradhan S, Yeong JK, Kwok CS

RESULTADOS DE 27 ENSAYOS

	OR	IC
DABIGATRAN	**1,45**	1,14-1,86
APIXABAN	**0,89**	0,73-1,06
RIVAROXABAN	**0,81**	0,72-0,93

¿Podemos concluir?

- Como resultado de análisis post-hoc,los pacientes en tratamiento con dabigatran por FA y con perfil semejante al incluido en los ensayos clínicos tienen mayor riesgo de IAM pero en términos absolutos escaso.

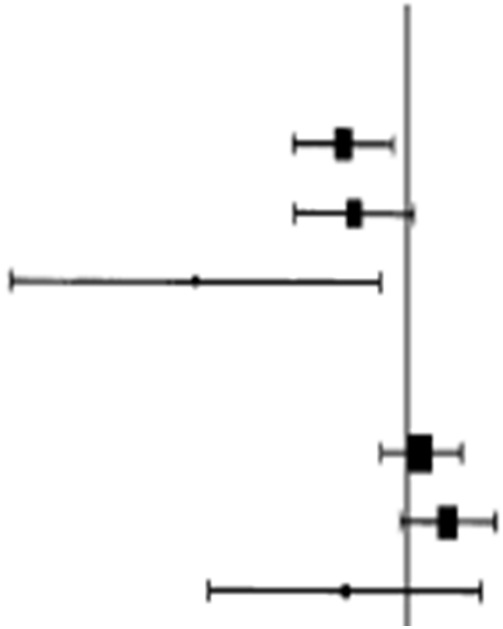
Seguridad Cardiovascular de los ADOs

Diabetologia (2011) 54:1308–1317

DIGAMI 2 Study

Prognostic implications of glucose-lowering treatment in patients with acute myocardial infarction and diabetes: experiences from an extended follow-up of the Diabetes Mellitus Insulin–Glucose Infusion in Acute Myocardial Infarction

	Hazard ratio (95 % CI)	*p*-value
Metformin (185/888)[a]		
Death (47/271)[b]	0.65 (0.47–0.90)	0.0094
CV death (31/176)[b]	0.72 (0.49–1.06)	0.0995
Cancer death (6/31)[b]	0.25 (0.08–0.83)	0.0235
Sulfonylurea (250/823)[a]		
Death (79/239)[b]	1.09 (0.84–1.42)	0.5251
CV death (57/152)[b]	1.29 (0.94–1.76)	0.1145
Cancer death (11/26)[b]	0.67 (0.28–1.61)	0.3686



American Diabetes Association. Diabetes Care

Effects of Metformin Versus Glipizide on Cardiovascular Outcomes in Patients With Type 2 Diabetes and Coronary Artery Disease

Compara 3 años 30 mg Glipizida *vs* 1500 mg Metformina

- **Doble ciego**
- **Seguimiento 5 años**
- **Muerte o evento CV**

- **304 DM tipo 2 con enfermedad coronaria**

Resultados

- **103 eventos en 5 años**

- **HR 0,54 (0,3-0,9) para metformina frente a glipizida**

Conclusión

CONCLUSIONS Treatment with metformin for 3 years substantially reduced major cardiovascular events in a median follow-up of 5.0 years compared with glipizide. Our results indicated a potential benefit of metformin therapy on cardiovascular outcomes in high-risk patients.

La seguridad cardiovascular tiene un punto de inflexión ….

ROSIGLITAZONA

Tabla 1 Criterios de la *Food and Drugs Administration* para determinar seguridad cardiovascular en el desarrollo clínico de antidiabéticos

Hazard ratio	IC 95%	
Superioridad	LS < 1	Autorizado: hipótesis de superioridad demostrada
No inferioridad	LS < 1,3	Autorizado: hipótesis de no inferioridad demostrada
No inferioridad	LS > 1,3 y LS < 1,8	Hipótesis de no inferioridad no demostrada Para la autorización se requiere un estudio poscomercialización adicional
Inferior	LS > 1,8 (LI > 0)	No autorización
Potencia insuficiente	LS > 1,8 (LI < 0)	No autorización

IC: intervalo de confianza; LI: límite inferior; LS: límite superior.

Table 3 | Cardiovascular outcomes in pooled phase II–III trials of DPP-4 inhibitors

DPP-4 inhibitor	Meta-analysis	Number of trials and patients	Events with gliptin vs control (per 100 patient years)	RR (95% CI) of cardiovascular events
Alogliptin	White *et al.* (2010)[112]	Eight trials, *n*=3,489	0.28 vs 0.50 cardiovascular deaths, MI, or stroke	0.63 (0.21–1.91)
Linagliptin	Johansen *et al.* (2011)[113]	Eight trials, *n*=5,239	0.53 vs 1.68 MACE*	0.34 (0.16–0.70)
Saxagliptin	Frederich *et al.* (2010)[110] Cobble *et al.* (2012)[111]	Eight trials, *n*=4,607	0.7 vs 1.4 cardiovascular deaths, MI, or stroke	0.43 (0.23–0.80)
Sitagliptin	Williams-Herman *et al.* (2010)[108]	19 trials, *n*=10,246	0.6 vs 0.9 MACE	0.68 (0.41–1.12)
Vildagliptin	Schweizer *et al.* (2010)[109]	25 trials, *n*=10,988	1.32 vs 1.64 MACE*	0.84 (0.62–1.14)‡

Table 4 | Ongoing, prospective clinical trials of DPP-4 inhibitors with cardiovascular outcomes

DPP-4 inhibitor	Trial name	Trial design	Patient characteristics	Primary end point
Alogliptin	EXamination of cArdiovascular outcoMes: alogliptIN vs standard of carE in patients with type 2 diabetes mellitus and acute coronary syndrome (EXAMINE)[117]	*n* = 5,400 6.25 mg, 12.5 mg, or 25.0 mg vs placebo Superiority trial	HbA1c 6.5–11.0% Acute coronary syndrome 15–90 days before randomization	Time from randomization to the first occurrence of a primary major adverse cardiac event (nonfatal MI, nonfatal stroke, or cardiovascular death)
Linagliptin	CARdiOvascular outcome study of LINAagliptin versus glimepiride in patients with type 2 diabetes (CAROLINA)[118]	*n* = 6,000 5 mg vs glimepiride 1–4 mg Noninferiority and superiority trial	HbA1c 6.5–8.5% High cardiovascular risk	Time to the first occurrence of nonfatal MI, nonfatal stroke, hospitalization for unstable angina, or cardiovascular death
Saxagliptin	Saxagliptin Assessment of Vascular Outcomes Recorded in patients with diabetes mellitus (SAVOR-TIMI 53) trial[116]	*n* = 16,500 2.5 mg or 5.0 mg vs placebo Noninferiority and superiority trial	HbA1c ≥6.5% High cardiovascular risk	Time to first confirmed cardiovascular event (nonfatal MI, nonfatal ischaemic stroke, or cardiovascular death)
Sitagliptin	Trial Evaluating Cardiovascular Outcomes with Sitagliptin (TECOS)[119]	*n* = 14,000 50 mg or 100 mg vs placebo Noninferiority trial	HbA1c 6.5–8.0% History of cardiovascular disease	Time to first confirmed cardiovascular event (nonfatal MI, nonfatal stroke, or hospitalization for unstable angina)

Anuncio de seguridad

25.11.13
Comunicado de la FDA sobre la seguridad de los medicamentos:

FDA requiere que se eliminen ciertas restricciones al recetar y dispensar medicamentos para la diabetes que contienen rosiglitazona

ROSIGLITAZONA

- **El análisis de datos tras una revaluación integral realizada por expertos externos del Duke Clinical Research Institute (DCRI).**
- **NO HAY un riesgo mayor de ataque al corazón en comparación con los medicamentos estándar metformina y sulfonilurea para la diabetes de tipo 2.**
- **Como resultado, estamos requiriendo que se eliminen las restricciones que se pusieron en vigor en el 2010 para recetar y dispensar medicamentos con rosiglitazona.**

The design and rationale of the Saxagliptin Assessment of Vascular Outcomes Recorded in patients with diabetes mellitus–Thrombolysis in Myocardial Infarction (SAVOR-TIMI) 53 Study

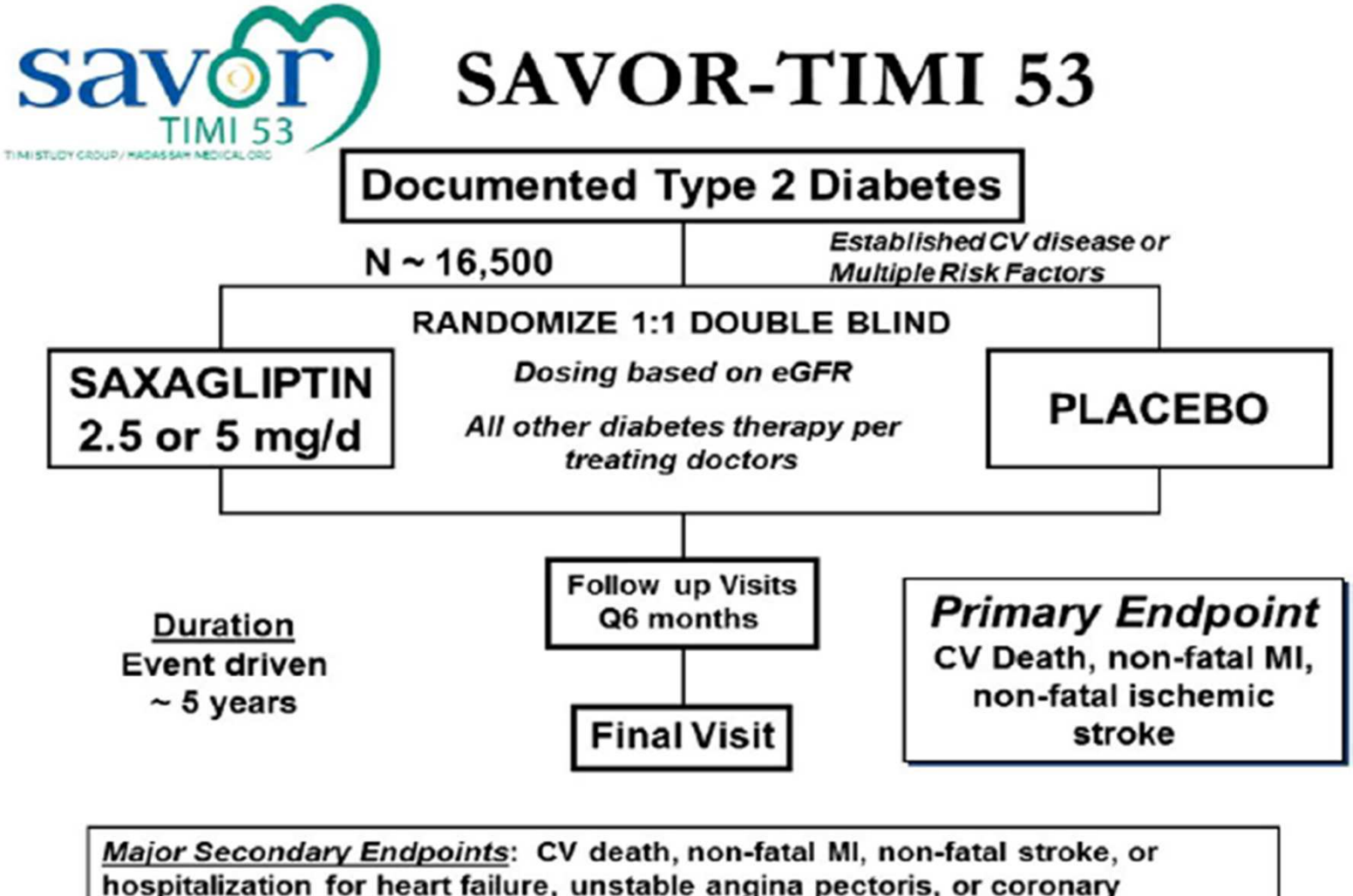
Original Article

Saxagliptin and Cardiovascular Outcomes in Patients with Type 2 Diabetes Mellitus

Benjamin M. Scirica, M.D., M.P.H., Deepak L. Bhatt, M.D., M.P.H., Eugene Braunwald, M.D., P. Gabriel Steg, M.D., Jaime Davidson, M.D., Boaz Hirshberg, M.D., Peter Ohman, M.D., Robert Frederich, M.D., Ph.D., Stephen D. Wiviott, M.D., Elaine B. Hoffman, Ph.D., Matthew A. Cavender, M.D., M.P.H., Jacob A. Udell, M.D., M.P.H., Nihar R. Desai, M.D., M.P.H., Ofri Mosenzon, M.D., Darren K. McGuire, M.D., Kausik K. Ray, M.D., Lawrence A. Leiter, M.D., Itamar Raz, M.D., for the SAVOR-TIMI 53 Steering Committee and Investigators

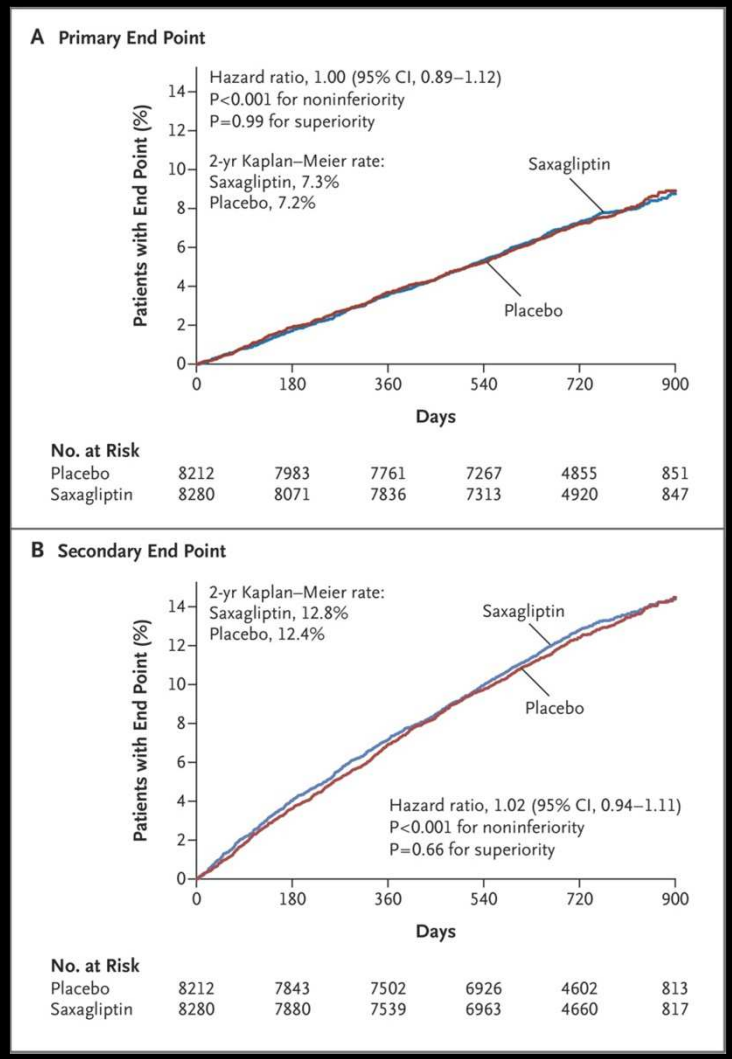
N Engl J Med
Volume 369(14):1317-1326
October 3, 2013

The NEW ENGLAND JOURNAL of MEDICINE



Trial schema of the SAVOR-TIMI 53 Trial.

Kaplan–Meier Rates of the Primary and Secondary End Points.



Scirica BM et al. N Engl J Med 2013;369:1317-1326

The NEW ENGLAND JOURNAL of MEDICINE

Prespecified Clinical End Points.

Table 2. Prespecified Clinical End Points.*

End Point	Saxagliptin (N=8280)	Placebo (N=8212)	Hazard Ratio (95% CI)	P Value
	no. (%)			
Cardiovascular death, myocardial infarction, or stroke: primary efficacy end point	613 (7.3)	609 (7.2)	1.00 (0.89–1.12)	0.99
Cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina, heart failure, or coronary revascularization: secondary efficacy end point	1059 (12.8)	1034 (12.4)	1.02 (0.94–1.11)	0.66
Death from any cause	420 (4.9)	378 (4.2)	1.11 (0.96–1.27)	0.15
Death from cardiovascular causes	269 (3.2)	260 (2.9)	1.03 (0.87–1.22)	0.72
Myocardial infarction	265 (3.2)	278 (3.4)	0.95 (0.80–1.12)	0.52
Ischemic stroke	157 (1.9)	141 (1.7)	1.11 (0.88–1.39)	0.38
Hospitalization for unstable angina	97 (1.2)	81 (1.0)	1.19 (0.89–1.60)	0.24
Hospitalization for heart failure	289 (3.5)	228 (2.8)	1.27 (1.07–1.51)	0.007
Hospitalization for coronary revascularization	423 (5.2)	459 (5.6)	0.91 (0.80–1.04)	0.18
Doubling of creatinine level, initiation of dialysis, renal transplantation, or creatinine >6.0 mg/dl (530 μmol/liter)	194 (2.2)	178 (2.0)	1.08 (0.88–1.32)	0.46
Hospitalization for hypoglycemia	53 (0.6)	43 (0.5)	1.22 (0.82–1.83)	0.33

* Event rates and percentages are 2-year Kaplan–Meier estimates.

Scirica BM et al. N Engl J Med 2013;369:1317-1326

The NEW ENGLAND JOURNAL of MEDICINE

AstraZeneca and Bristol-Myers Squibb Announce Top Line Results for SAVOR-TIMI-53 Cardiovascular Outcomes Trial of saxagliptin

- **No se ha demostrado la superioridad de saxagliptina sobre placebo en la reducción de una variable final combinada** de muerte cardiovascular, IM no mortal o ictus isquémico no fatal cuando se añade al tratamiento habitual en los pacientes con diabetes tipo 2, con historia de enfermedad cardiovascular establecida o con múltiples factores de riesgo de ECV.

- Saxagliptina cumplió con el objetivo primario de **seguridad de no inferioridad**, y no cumplió con el objetivo primario de **eficacia de superioridad**, en la variable principal combinada.

Original Article

Alogliptin after Acute Coronary Syndrome in Patients with Type 2 Diabetes

William B. White, M.D., Christopher P. Cannon, M.D., Simon R. Heller, M.D., Steven E. Nissen, M.D., Richard M. Bergenstal, M.D., George L. Bakris, M.D., Alfonso T. Perez, M.D., Penny R. Fleck, M.B.A., Cyrus R. Mehta, Ph.D., Stuart Kupfer, M.D., Craig Wilson, Ph.D., William C. Cushman, M.D., Faiez Zannad, M.D., Ph.D., for the EXAMINE Investigators

N Engl J Med
Volume 369(14):1327-1335
October 3, 2013

The NEW ENGLAND JOURNAL of MEDICINE

Study Overview

- Alogliptin, a new antihyperglycemic agent of the DPP-4 class, was shown to have no significant effect on cardiovascular risk over a median treatment period of 18 months.
- Although alogliptin did not increase cardiovascular risk, the drug also did not significantly reduce it.

The NEW ENGLAND JOURNAL of MEDICINE

Major Safety End Points.

Table 3. Major Safety End Points.

End Point	Placebo (N = 2679)	Alogliptin (N = 2701)	Hazard Ratio for Alogliptin Group (95% CI)	P Value*
	no. (%)			
Primary end point†	316 (11.8)	305 (11.3)	0.96 (≤1.16)‡	0.32
Components of primary end point				
Death from cardiovascular causes	111 (4.1)	89 (3.3)	0.79 (0.60–1.04)	0.10
Nonfatal myocardial infarction	173 (6.5)	187 (6.9)	1.08 (0.88–1.33)	0.47
Nonfatal stroke	32 (1.2)	29 (1.1)	0.91 (0.55–1.50)	0.71
Principal secondary end point§	359 (13.4)	344 (12.7)	0.95 (≤1.14)‡	0.26
Other end points				
Death from any cause	173 (6.5)	153 (5.7)	0.88 (0.71–1.09)	0.23
Death from cardiovascular causes¶	130 (4.9)	112 (4.1)	0.85 (0.66–1.10)	0.21

* P values for testing the superiority of alogliptin to placebo were calculated with the use of a Cox regression analysis.
† The primary end point was a composite of death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke.
‡ The parenthetical value is the upper boundary of the one-sided repeated CI, at an alpha level of 0.01.
§ The secondary end point was a composite of death from cardiovascular causes, nonfatal myocardial infarction, nonfatal stroke, or urgent revascularization due to unstable angina within 24 hours after hospital admission.
¶ Included are deaths that occurred as primary end-point events and deaths that occurred after a nonfatal primary end-point event.

White WB et al. N Engl J Med 2013;369:1327-1335

The NEW ENGLAND JOURNAL of MEDICINE

Outcome Reduction with Initial Glargine INtervention

¿ Proporcionar insulina basal glargina para conseguir normoglucemia en ayunas de manera segura reduce la incidencia de eventos CV en personas con elevación moderada de la glucemia y alto riesgo CV más que el tratamiento estándar ?

ORIGIN cuestiones a investigar

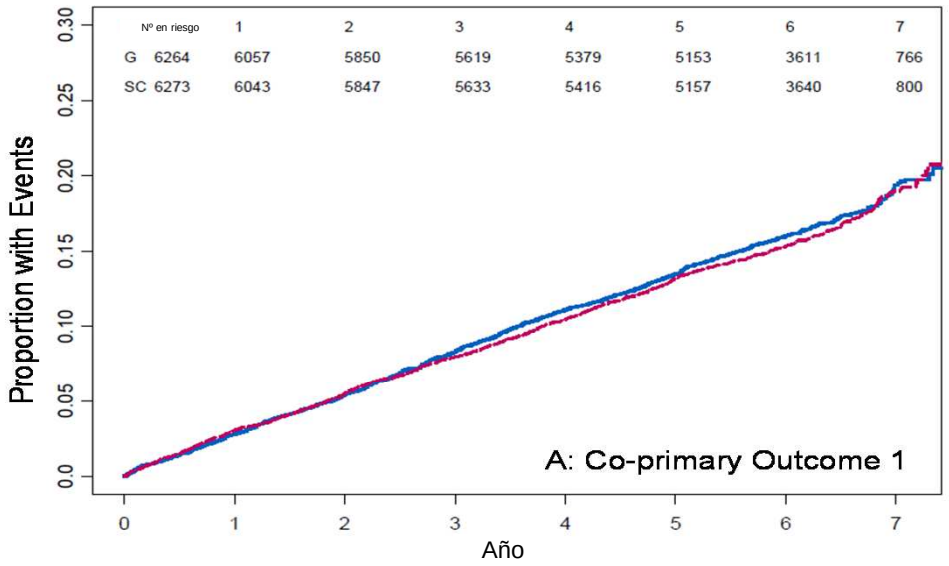
en pacientes de alto riesgo, con alteraciones de la glucemia o diabetes reciente,

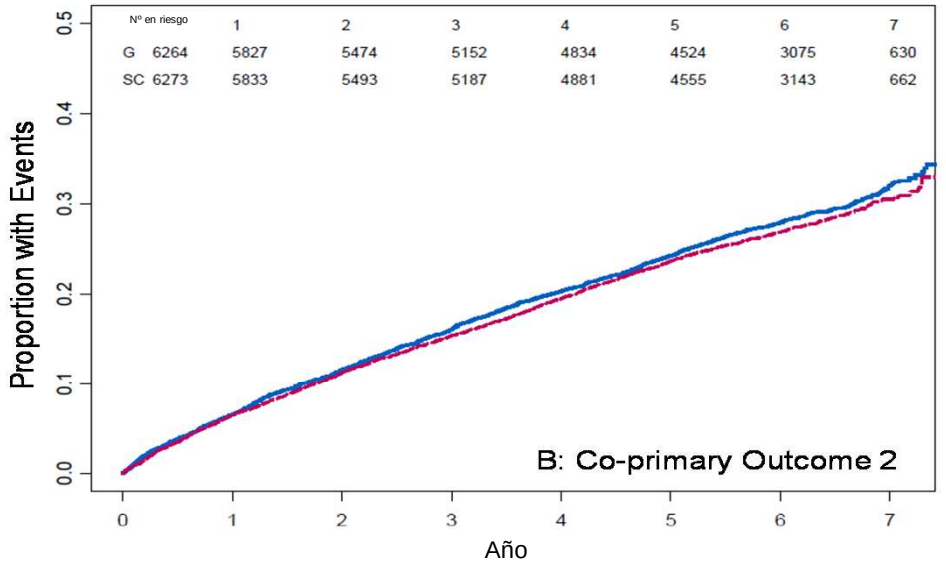
El tratamiento con insulina glargina para glucemia en ayunas (≤ 95 mg/dl)

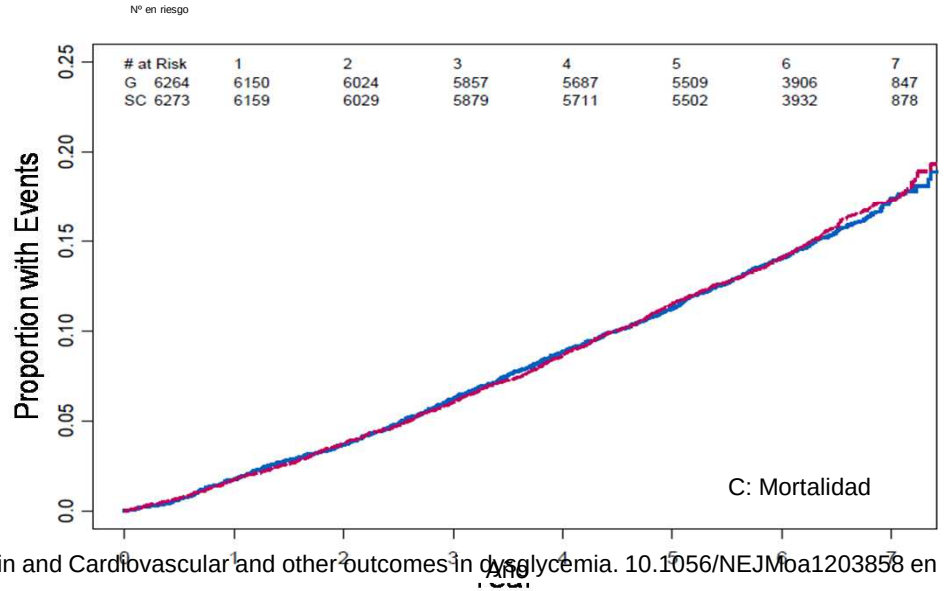
¿reduce los eventos CV frente al tratamiento convencional?

Criterios principales de valoración y mortalidad

Cuando se usa glargina para conseguir niveles normales de GA durante más de 6 años tiene un efecto neutro en las variables cardiovasculares







The ORIGIN trial Investigators. Basal insulin and Cardiovascular and other outcomes in dysglycemia. 10.1056/NEJMoa1203858 en NEJM.org

Qué podemos concluir.....

- 1º Que las sulfonilureas se deben utilizar con precaución o evitar tras un SCA
- 2º Que no hay evidencia para contraindicar rosiglitazona por mayor riesgo de infartos
- 3º Que para los nuevos fármacos antidiabéticos aun teniendo un perfil cardiovascular favorable, habrá que esperar al resultado de los estudios de seguridad cardiovascular para confirmarlo