

XVII Reunión
Insuficiencia Cardíaca
y Fibrilación Auricular



16-17 de Abril de 2015
Hotel Holiday Inn-Madrid

CONSIDERACIONES ESPECIALES DEL TRATAMIENTO DE LA DIABETES EN EL PACIENTE ANCIANO CON IC



Dr. Fco. Javier Carrasco
Complejo Hospitalario Universitario de Huelva

XVII Reunión Insuficiencia Cardíaca y Fibrilación Auricular

Conflicto de Intereses

Ponencias, trabajos científicos y panel de asesores para

Novo-Nordisk

Sanofi-Aventis

Novartis

Lilly

Boehringer-Ingelheim

Astra-Zeneca

Almirall

Jassen



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DIMENSIÓN DEL TEMA

ANCIANOS COMO POBLACIÓN ESPECIAL

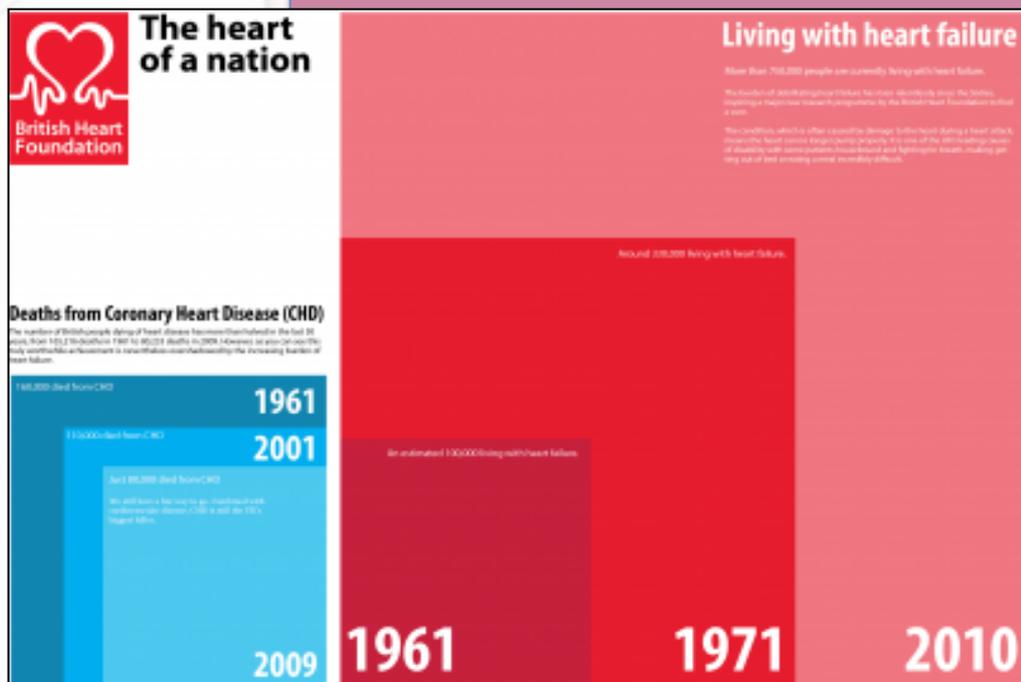
REVISIÓN FÁRMACOS

INCRETINAS: ICC

RECOMENDACIONES

XVII Reunión Insuficiencia Cardíaca y Fibrilación Auricular

Incidenca exponencial de la INSUFICIENCIA CARDIACA



ESTIMACIÓN PREVALENCIA DIABETES

World 2011 = 366 million
2030 = 552 million
Increase = 51%

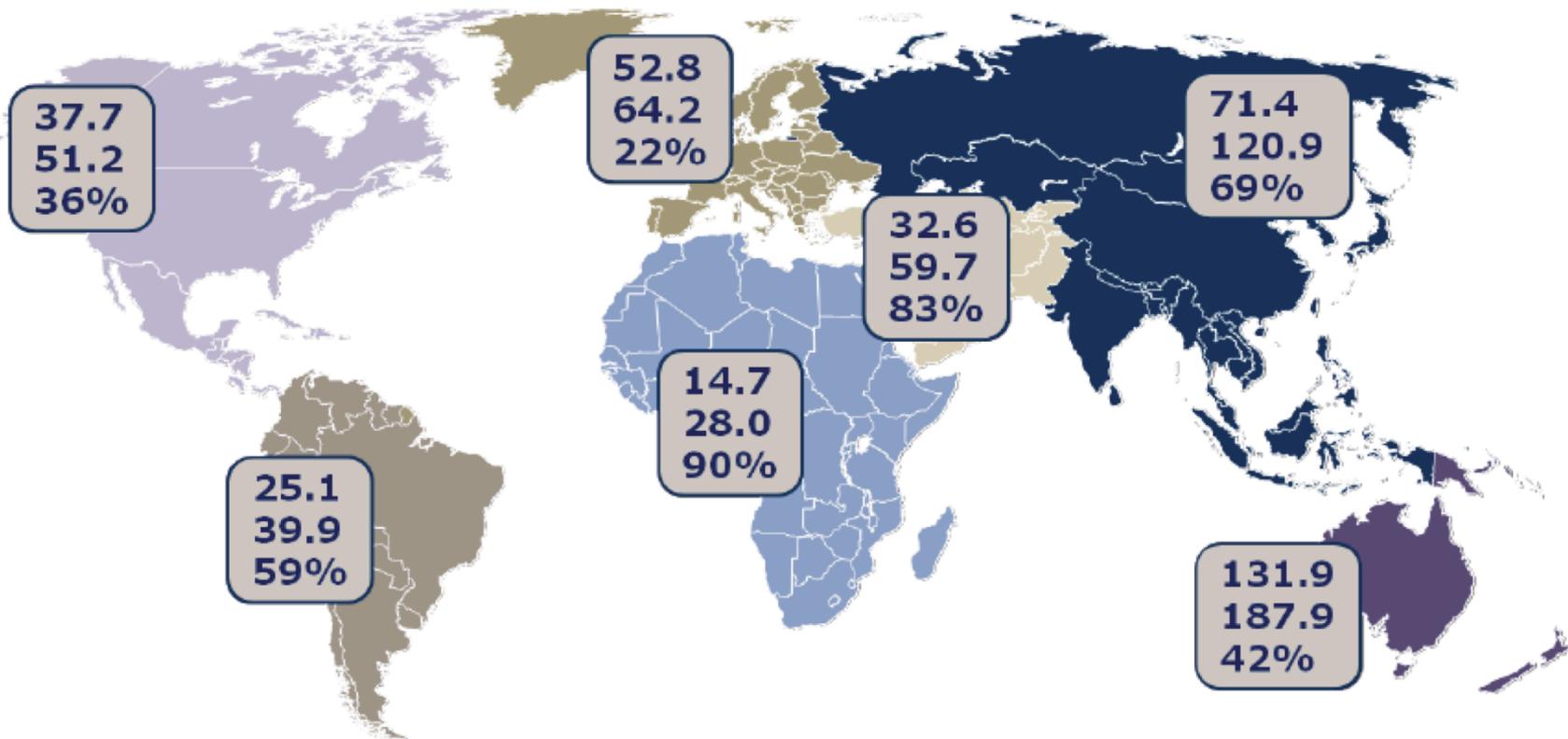
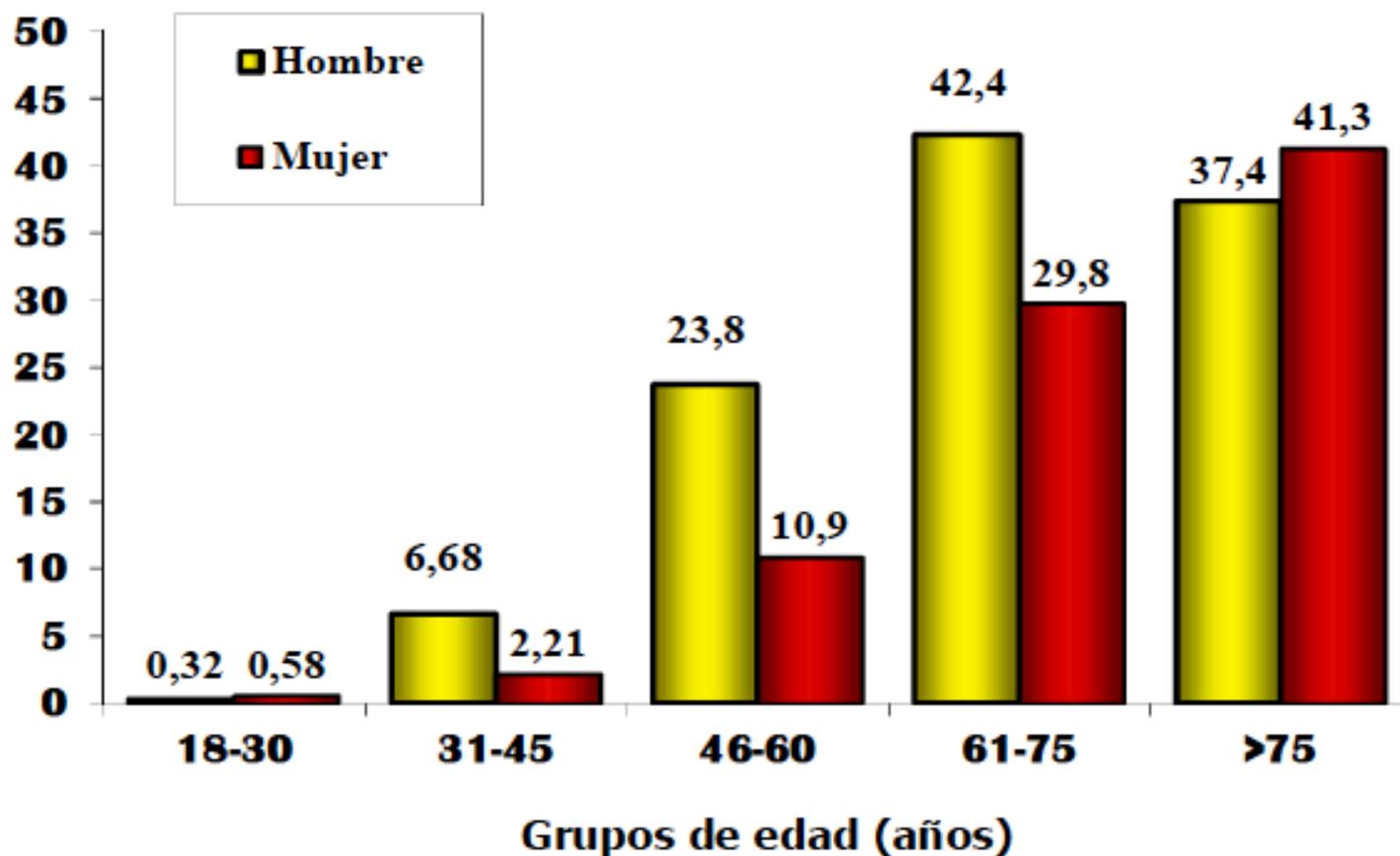


Figura 1: Prevalencia Diabetes en España: Distribución por sexo y grupos de edad en %





ELSEVIER

Contents available at ScienceDirect

Diabetes Research and Clinical Practice

journal homepage: www.elsevier.com/locate/diabres



International Diabetes Federation



Association between type-2 diabetes mellitus and post-discharge outcomes in heart failure patients: Findings from the RICA registry

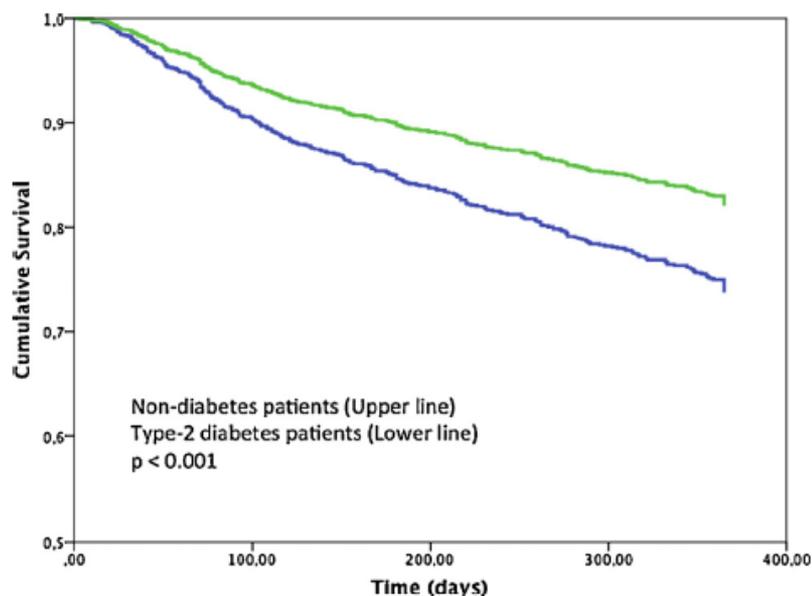


Fig. 1 – Adjusted impact on survival in heart failure patients with type-2 diabetes mellitus after discharge. Kaplan-

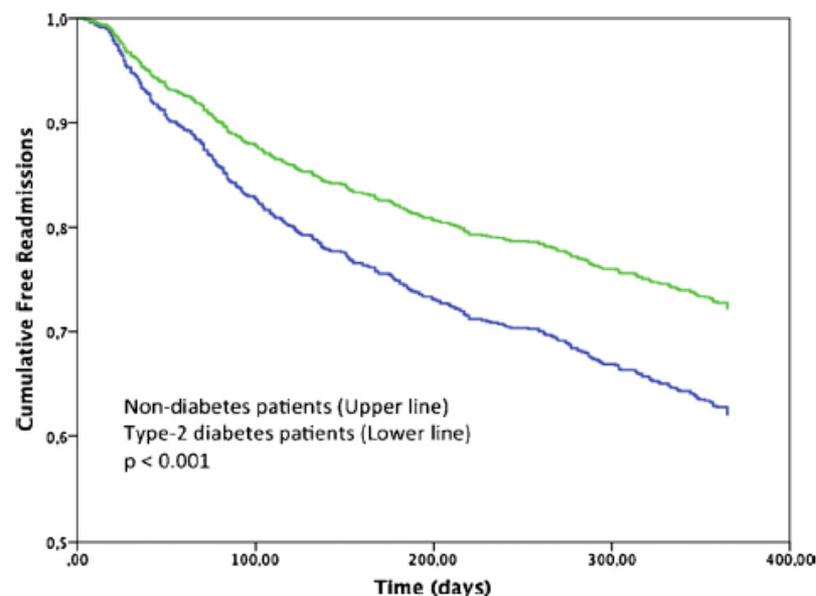


Fig. 2 – Adjusted impact on readmissions in heart failure patients with type-2 diabetes mellitus after discharge.

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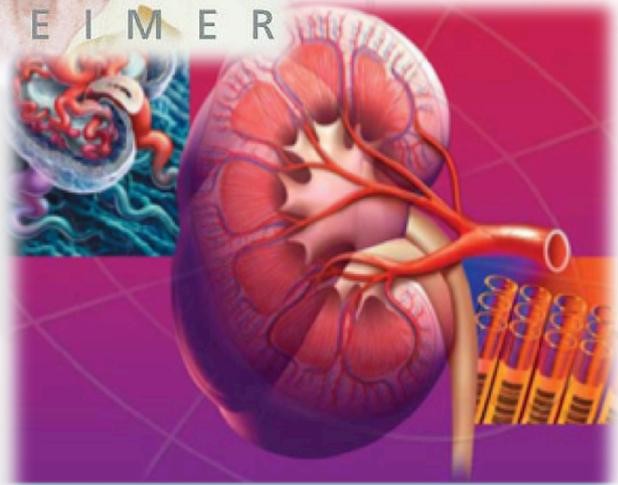
ANCIANOS

ICC

DM



A L Z H E I M E R



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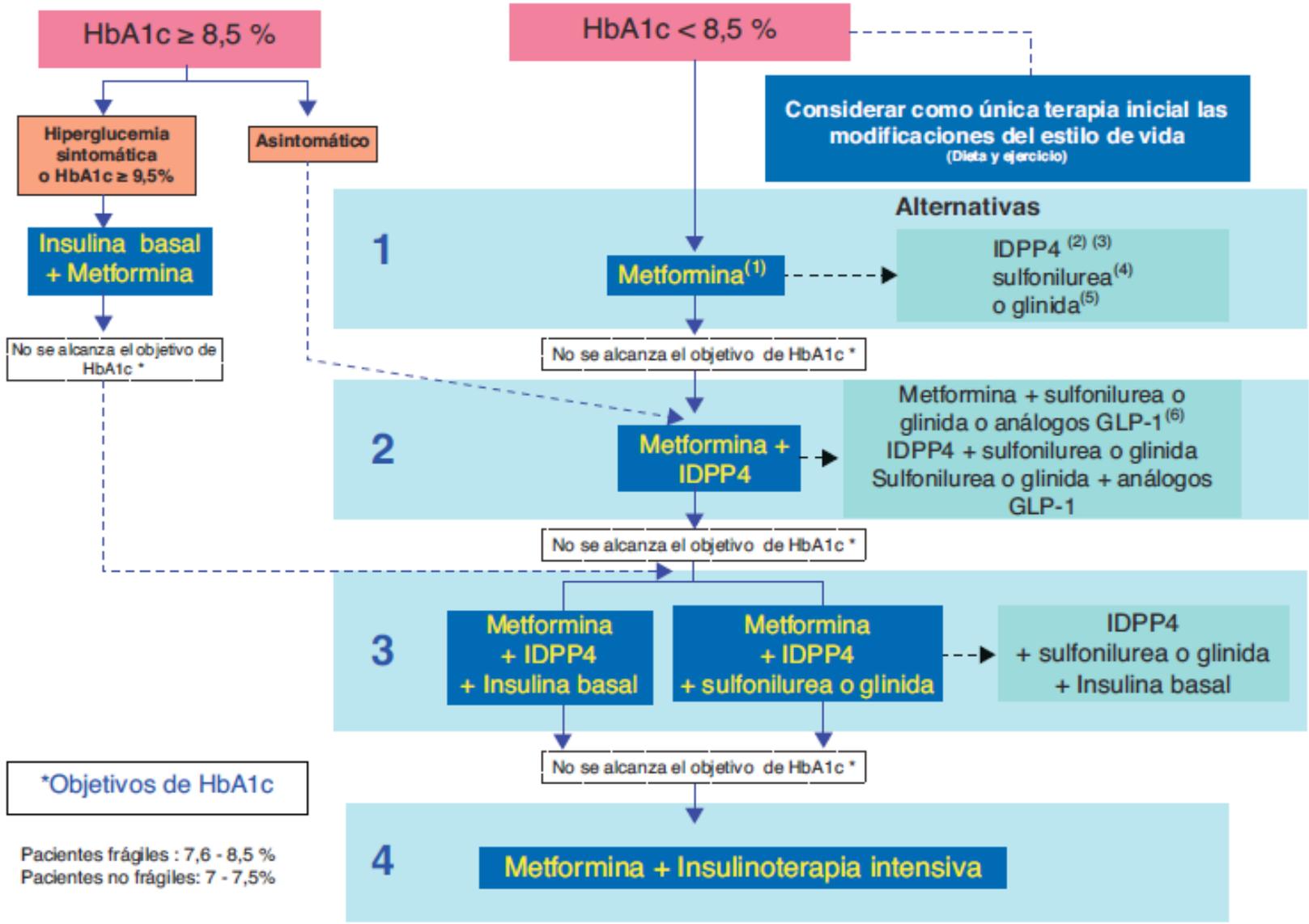


HIPOGLUCEMIA

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*Empezar Despacio
&
Continuar Despacio*



*Objetivos de HbA1c

Pacientes frágiles : 7,6 - 8,5 %
 Pacientes no frágiles: 7 - 7,5%

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Recommended glucose targets:
Fasting glucose range = 7.6-9.0 mmol/L
HbA_{1c} range = 7.6-8.5%

3-6 months dietary and lifestyle advice

Frailty criteria:
Care home residency
Significant cognitive decline
Major lower limb mobility disorder
History of disabling stroke

Not achieving agreed glucose targets

Metformin

Alternative treatments:
DPPIV inhibitors, or
Lower risk sulphonylureas (SU)
Glinides

Failure to achieve glucose targets

Metformin + DPPIV inhibitor

Alternative treatments:
Metformin + lower-risk SU
Metformin + GLP-1 agonist

Failure to achieve glucose targets

Metformin + insulin

Alternative treatments:
Low risk SU + insulin

Metformin contraindicated in renal/hepatic dysfunction, respiratory/heart failure, anorexia, gastrointestinal disease

Further weight loss with a GLP-1 agonist may have adverse consequences in a frail patient

Frailty associated with increased hypoglycaemia risk: caution when using insulin or sulphonylurea therapy



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www.em-consulte.com

Diabetes
& Metabolism

Diabetes & Metabolism 37 (2011) S27-S38

European Diabetes Working Party for Older People 2011
Clinical Guidelines for Type 2 Diabetes Mellitus. Executive Summary

A Report of the European Diabetes Working Party for Older People (EDWPOP) Revision Group
on Clinical Practice Guidelines for Type 2 Diabetes Mellitus

Fenformina



METFORMINA



**ACIDOSIS
LACTICA**

RESTRICCIÓN DE USO: I. RENAL – I. CARDIACA

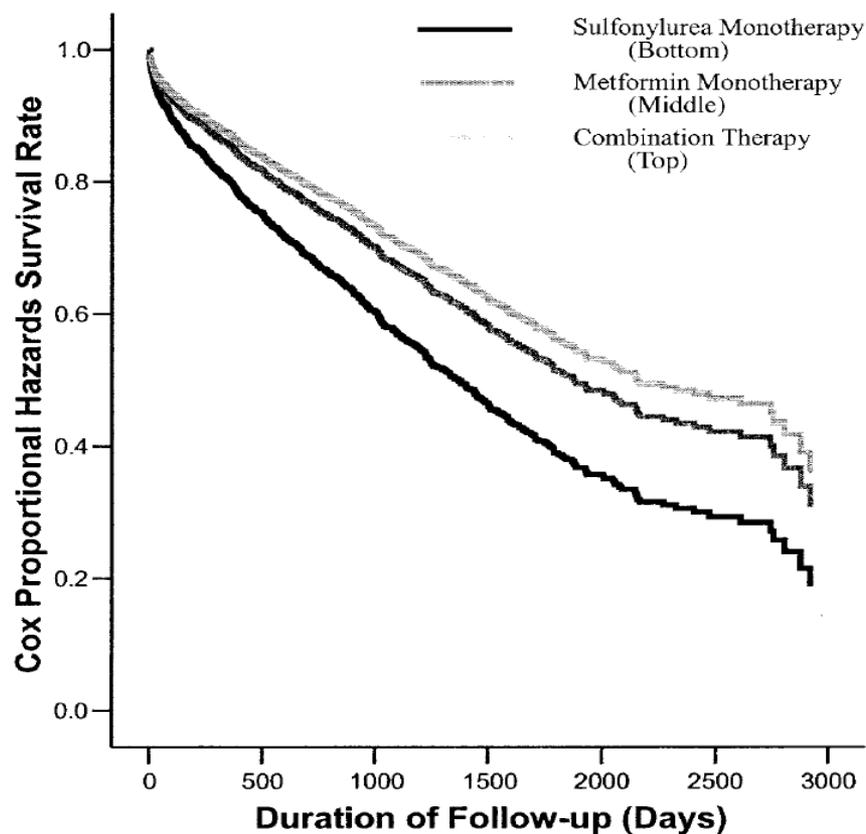
¿SEGURA Y EFECTIVA?

Improved Clinical Outcomes Associated With Metformin in Patients With Diabetes and Heart Failure

ROSS T. TSUYUKI, BSC(PHARM), PHARM.D.,
MSC^{1,2,4}
JEFFREY A. JOHNSON, PHD^{1,2}

Diabetes Care 2005; 28: 2345-51

All-Cause Mortality



Enfermedad renal crónica

Puede utilizarse en dosis plenas si $FG > 45$ ml/min

Reducir dosis si $FG < 45$ ml/min y suspender si $FG < 30$ ml/min

Contraindicada si $Cr \geq 1,5$ mg/dl en varones
o $\geq 1,4$ mg/dl en mujeres

**DISFUNCIÓN RENAL
EN LA
INSUFICIENCIA CARDIACA
AGUDA**

Comparative Safety and Effectiveness of Metformin in Patients With Diabetes Mellitus and Heart Failure

Systematic Review of Observational Studies Involving 34 000 Patients

Dean T. Eurich, PhD; Daniala L. Weir, BSc; Sumit R. Majumdar, MD, MPH;
Ross T. Tsuyuki, PharmD, MSc; Jeffrey A. Johnson, PhD; Lisa Tjosvold, MLIS;
Saskia E. Vanderloo, MSc; Finlay A. McAlister, MD, MSc

(*Circ Heart Fail.* 2013;6:395-402.)

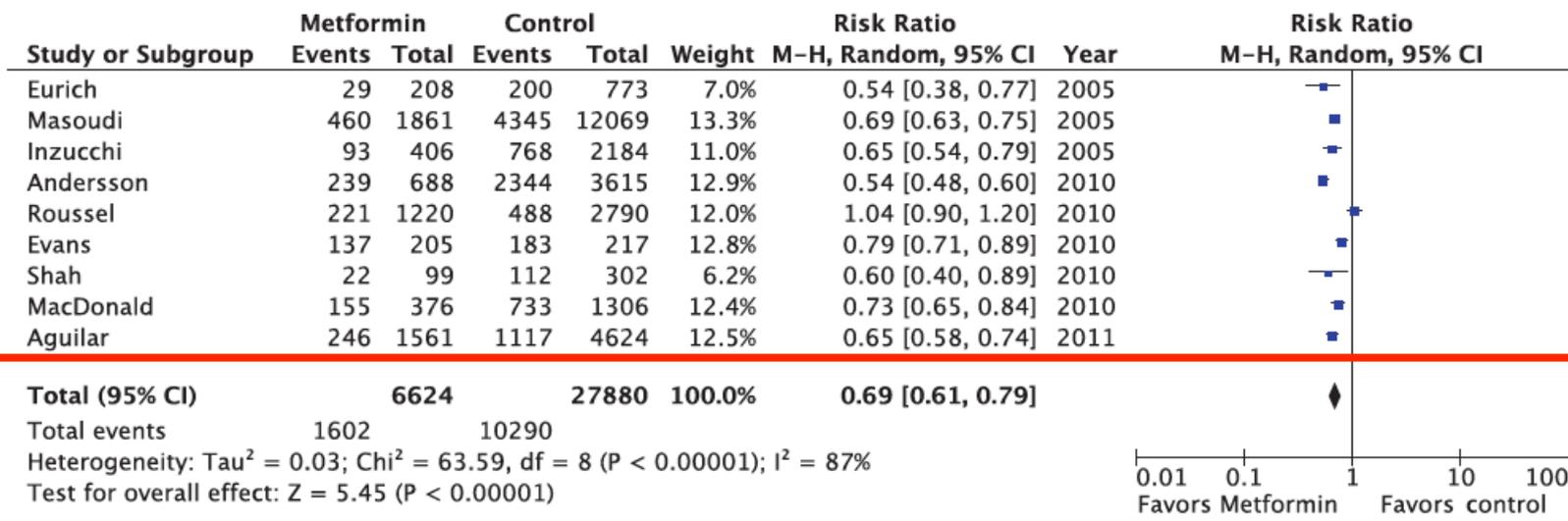


Figure 2. Pooled unadjusted risk ratios for metformin compared with other treatments for all-cause mortality. CI indicates confidence interval.

SULFONILUREAS

**HIPOGLUCEMIA
AGOTAMIENTO CÉLULA β
INSUFICIENCIA RENAL
SEGURIDAD EN IC ?**



10-Year Follow-up of Intensive Glucose Control in Type 2 Diabetes

Rury R. Holman, F.R.C.P., Sanjoy K. Paul, Ph.D., M. Angelyn Bethel, M.D.,
David R. Matthews, F.R.C.P., and H. Andrew W. Neil, F.R.C.P.

N Engl J Med 2008;359:1577-89.

**-Disminución
eventos CV en el
grupo de tto
intensivo incluido
los tratados con SU
-No datos de más
casos de IC**

The Prospective Pioglitazone Clinical Trial in Macrovascular Events (PROactive)

Can pioglitazone reduce cardiovascular events in diabetes? Study design and baseline characteristics of 5,238 patients

n	5,238
Demographic data	
Age (years)	61.8 ± 7.7
Male	3,463 (66.1)
Caucasian	5,162 (98.5)
Duration of type 2 diabetes (years)	9.5 ± 7.0

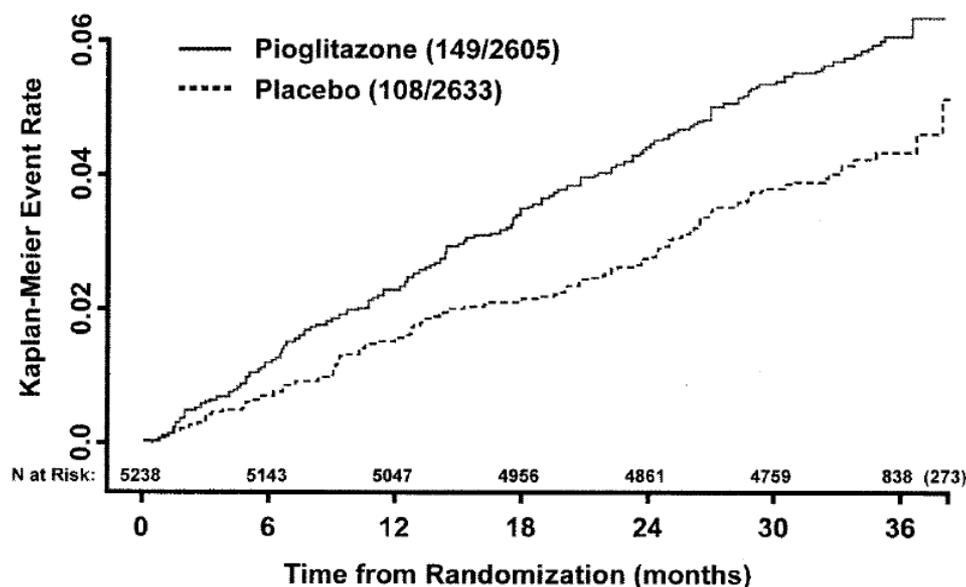
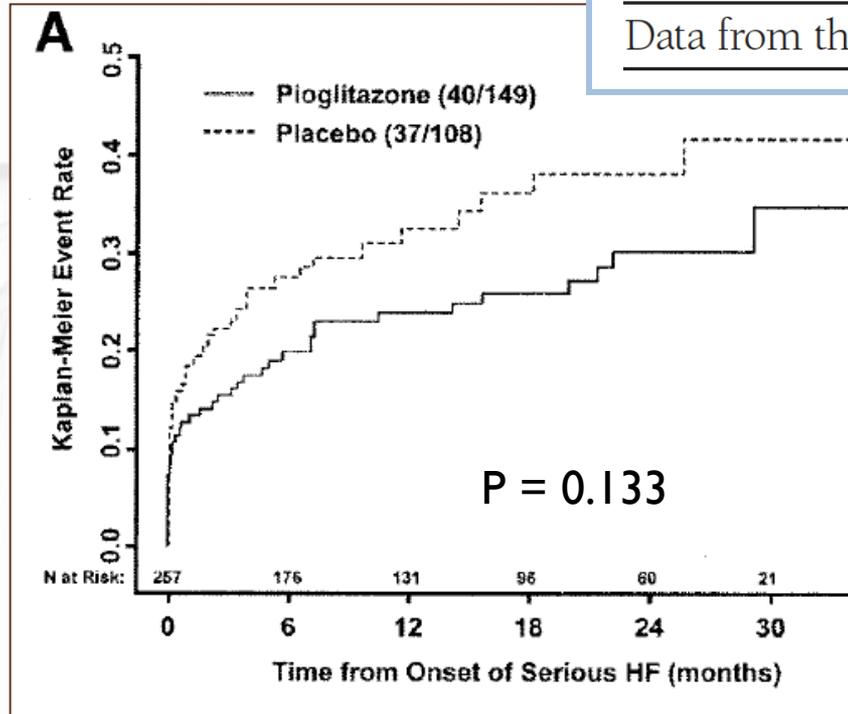


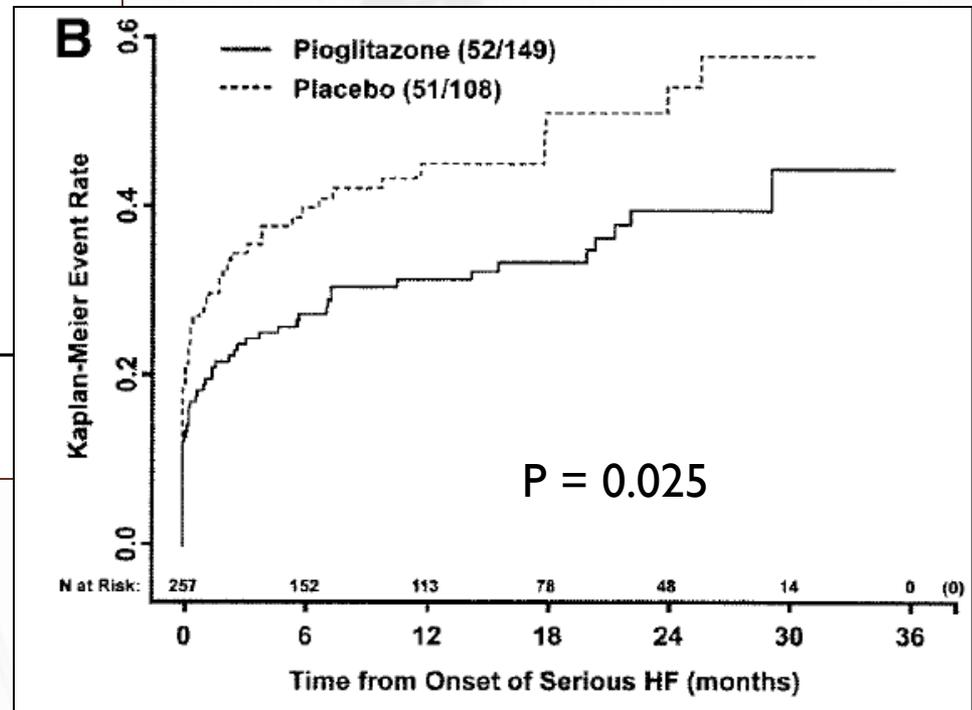
Figure 1—Kaplan-Meier estimates of time to serious heart failure.

Pioglitazone Use and Heart Failure in Patients With Type 2 Diabetes and Preexisting Cardiovascular Disease

Data from the PROactive Study (PROactive 08)



Mortalidad Total



Eventos Combinados

Clinical Trials

Pioglitazone and Heart Failure: Results From a Controlled Study in Patients With Type 2 Diabetes Mellitus and Systolic Dysfunction

Table 2. Incidence of Primary End Point and Contributing Events (ITT Analysis)

	Pioglitazone (n = 262)	Glyburide (n = 256)	P value
Composite event n (%)	35 (13.4)	21 (8.2)	.024
Death from CV cause	5 (1.9)	6 (2.3)	
Overnight hospitalization for worsening CHF	26 (9.9)	12 (4.7)	
ER visit for CHF	4 (1.5)	3 (1.2)	

Pioglitazone (n = 262)	Glyburide (n = 256)
64.2 (9.92)	63.4 (9.38)

Giles et al. J Cardiac Fail 2008; 14: 445-52

INHIBIDORES SGLT2

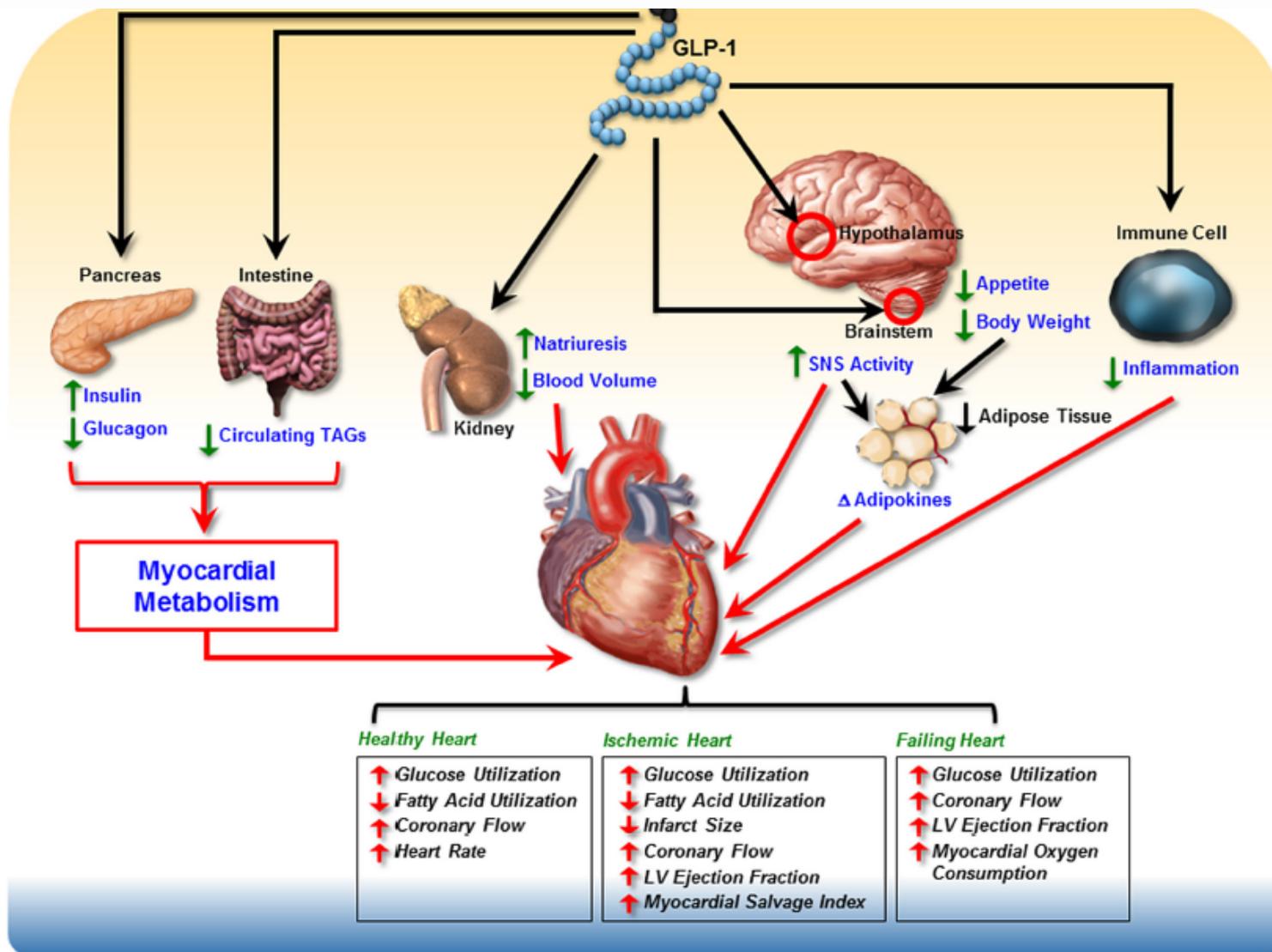
No disponemos de DATOS:

- > 65 AÑOS ; > 75 años
- DEPLECIÓN DE VOLUMEN
- NO USAR CON DIURETICOS DE ASA
- CONOCIMIENTO LIMITADO EN IC CLASE I-II
- DESCONOCIMIENTO EN CLASE III-IV



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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Saxagliptin and Cardiovascular Outcomes
in Patients with Type 2 Diabetes Mellitus

N Engl J Med 2013;369:1317-26.
DOI: 10.1056/NEJMoa1307684

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Alogliptin after Acute Coronary Syndrome
in Patients with Type 2 Diabetes

N Engl J Med 2013;369:1327-35.
DOI: 10.1056/NEJMoa1305889

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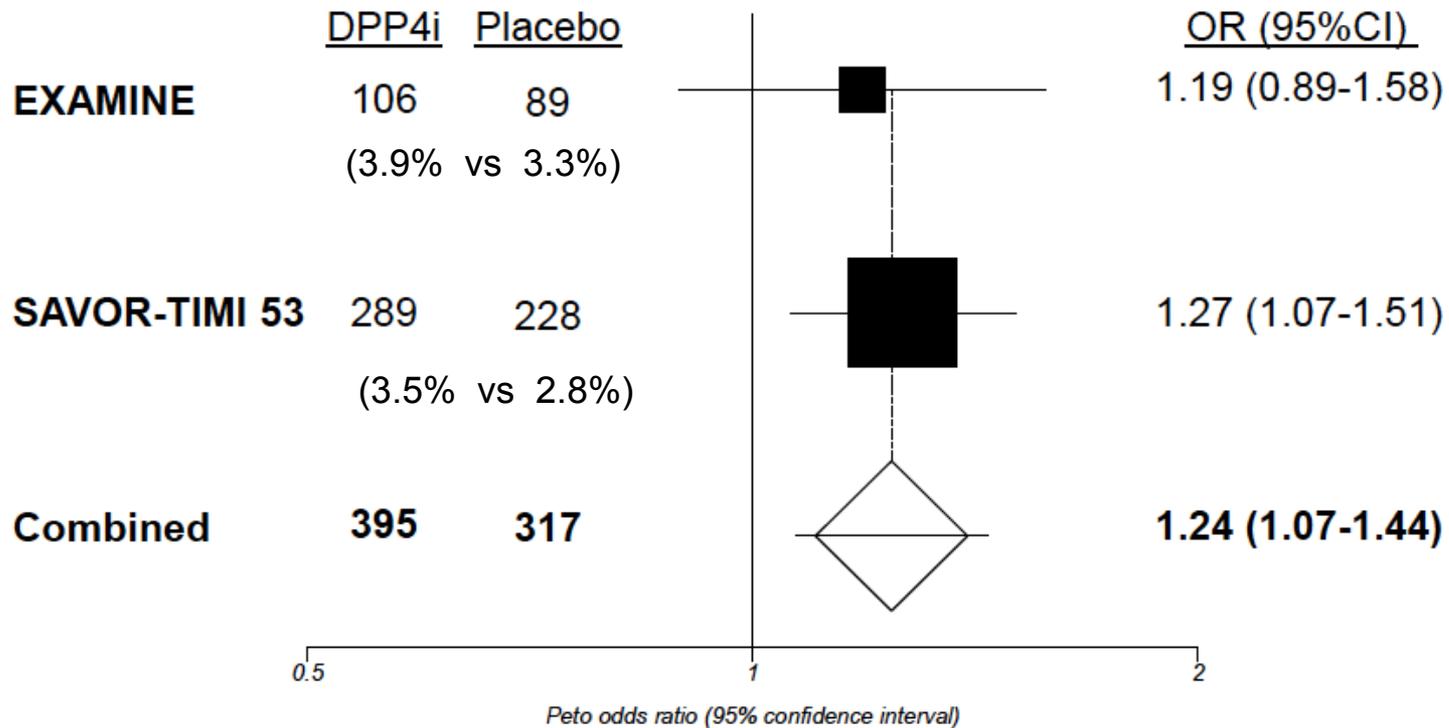
Table 2. Prespecified Clinical End Points.*

End Point	Saxagliptin (N= 8280)	Placebo (N= 8212)	Hazard Ratio (95% CI)	P Value
	<i>no. (%)</i>			
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

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Peto odds ratio plot



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Circulation 2014; 130:1579-1588



	N	Chi-Square	Adjusted Hazard Ratio	95% Confidence Intervals		P values
NT-proBNP > 332 pg/ml (Quartile 4)	2949	161.9	5.47	4.21	7.10	<0.01
Prior Heart Failure	1537	99.0	2.98	2.40	3.69	<0.01
Albumin/creatinine ratio > 33.9 mg/mmol	1211	38.1	2.35	1.79	3.08	<0.01
eGFR ≤60 ml/min	3237	14.5	1.43	1.12	1.83	<0.01
Non-Hispanic	3463	14.0	1.54	1.23	1.92	<0.01
Albumin/creatinine ratio 3.4 - ≤ 33.9 mg/mmol	9129	8.2	1.80	1.32	2.45	<0.01
Saxagliptin	5915	6.4	1.30	1.06	1.60	0.01
Prior MI	4562	4.8	1.28	1.03	1.60	0.03
Female	3949	4.3	0.78	0.62	0.99	0.04
Age ≥ 75 years	1630	2.7	1.23	0.96	1.57	0.10
Dyslipidemia	8403	1.7	1.18	0.92	1.51	0.19
Established CV disease	9210	0.7	1.17	0.82	1.68	0.39

Table 2. Multivariable Analysis Evaluating the Relationship between Baseline Clinical Characteristics and Risk for Hospitalization for Heart Failure in the overall SAVOR-TIMI 53 population.

	N	Chi-Square	Adjusted Hazard Ratio	95% Confidence Intervals		P values
Prior Heart Failure	1986	231.99	4.18	3.48	5.02	<0.01
Albumin/creatinine ratio > 33.9 mg/mmol	1,638	119.26	3.66	2.90	4.62	<0.01
Albumin/creatinine ratio 3.4 - ≤ 33.9 mg/mmol	4,426	35.77	1.89	1.54	2.34	<0.01
eGFR ≤60 ml/min	4602	49.86	2.00	1.65	2.42	<0.01
Age ≥ 75 years	2192	24.92	1.70	1.38	2.09	<0.01
Prior MI	5933	15.62	1.47	1.21	1.78	<0.01
Non-hispanic	12327	10.71	1.56	1.20	2.04	<0.01
Established CV disease	12344	8.81	1.64	1.18	2.28	<0.01
Saxagliptin	7916	7.77	1.29	1.08	1.54	0.01
Female	5205	6.93	0.76	0.62	0.93	0.01
Dyslipidemia	11213	4.63	1.27	1.02	1.59	0.03

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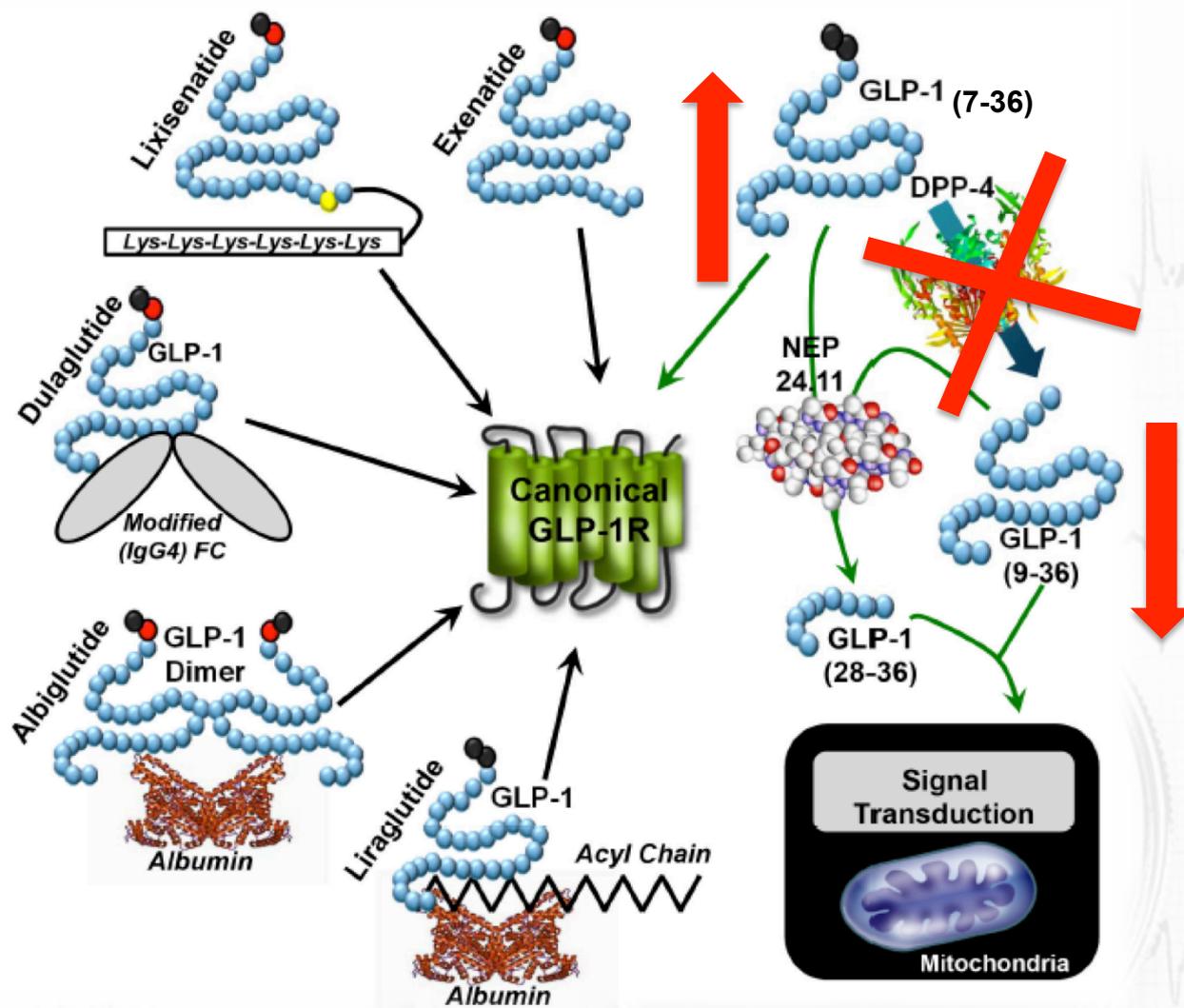


Table. Contrasting Actions of Native GLP-1, GLP-1R Agonists, DPP-4 Inhibitors, and GLP-1(9–36) on the Cardiovascular System and Cardiovascular Risk Factors

	GLP-1R Agonists	GLP-1	DPP-4 Inhibitors	GLP-1(9–36)
LV function	Increased	Increased	Increased	Increased
Heart rate	Increased	Increased	No effect	No effect
Coronary flow	No effect	Increased	No effect	Increased
Infarct size	Decreased	Decreased	Decreased	Decreased
Body weight	Decreased	Decreased	No effect	No effect
Blood pressure	Decreased	Decreased	No effect/decreased	ND

The table depicts the effects of native GLP-1, GLP-1R agonists, GLP-1(9–36), and DPP-4 inhibitors on the parameters important for the cardiovascular system as inferred from available preclinical and limited clinical studies. Scant data from head-to-head clinical trials using these agents limit extrapolation of the available data to human subjects. DPP-4 indicates dipeptidyl peptidase-4; GLP-1R, glucagon-like peptide-1 (GLP-1) receptor; LV, left ventricular; and ND, not determined.

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**RESULTADO GLOBAL
OR 1.19 (1.03-1.37)
p=0.015**



META-ANALYSIS

Dipeptidyl peptidase-4 inhibitors and heart failure: A meta-analysis of randomized clinical trials



M. Monami ^a, I. Dicembrini ^{b,c}, E. Mannucci ^{c,*}

Subgrupos

	N trials	Heart failure (n events)		Forest plot			MH-OR	LL	UL	p
		DPP4i	Comparator	0.10	1.00	100.00				
SAVOR+EXAMINE	2	395	317				1.24	1.07	1.45	0.004
Trials with non-CV end.	35	53	44				0.85	0.56	1.29	0.45
Excluding trials vs TZDs	33	52	41				0.83	0.54	1.28	0.41
Excluding trials vs TZDs/SUs	26	36	18				0.73	0.44	1.20	0.22
vs other comparators										
Sitagliptin	11	14	15				0.99	0.44	2.24	0.980
Vildagliptin	6	6	10				0.55	0.20	1.53	0.25
Saxagliptin	10	300	237				1.22	1.03	1.45	0.024
Linagliptin	5	16	8				1.56	0.66	3.65	0.310
Alogliptin	5	112	91				1.18	0.89	1.56	0.250

Sitagliptin Use in Patients With Diabetes and Heart Failure

A Population-Based Retrospective Cohort Study

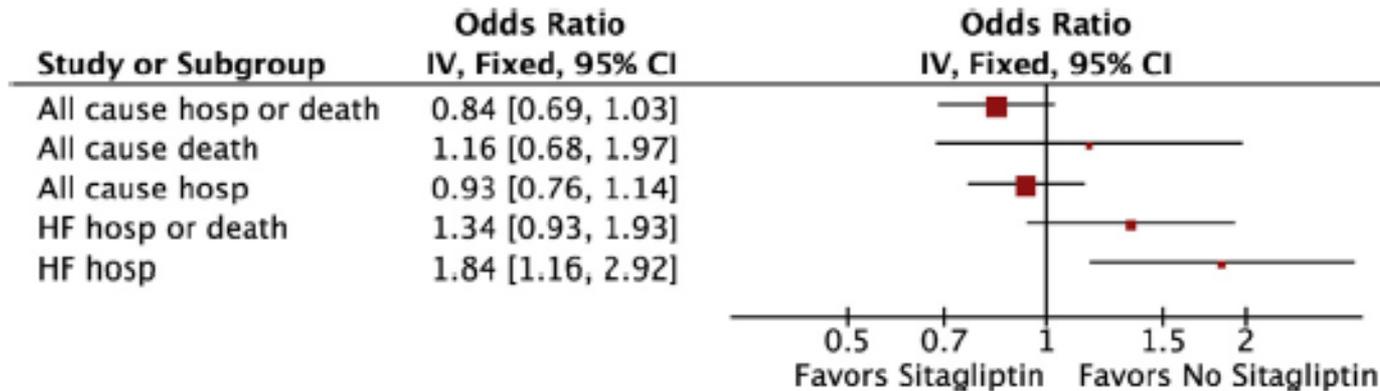


FIGURE 3 Forest Plot of Primary and Secondary Endpoints According to Sitagliptin Use

Primary and secondary endpoints after incident HF were evaluated according to sitagliptin use versus nonuse 90 days before each outcome. CI = confidence interval; HF = heart failure; hosp = hospitalization; IV = interval.

Control (n = 41,297)	Case (n = 4,137)	p Value*
54.6 ± 8.7	54.6 ± 8.7	0.97

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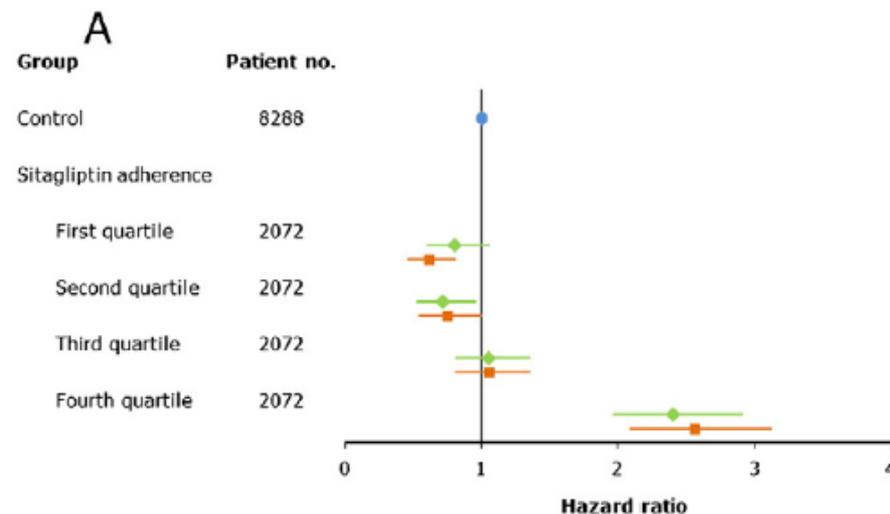
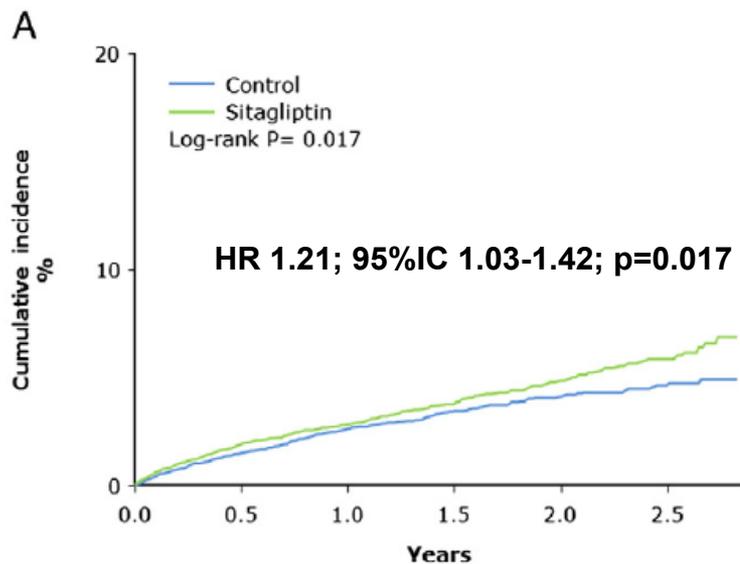
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International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Sitagliptin and the risk of hospitalization for heart failure: A population-based study[☆]

No asociación a la MORTALIDAD



Baseline characteristics of the patients.

Characteristic	Control (N = 8288)	Sitagliptin (N = 8288)	P value
Age, year	64.3 ± 9.9	64.4 ± 10.4	0.864

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Diabetes Care Volume 38, February 2015



Incretin-Based Drugs and the Risk of Congestive Heart Failure

Diabetes Care 2015;38:277–284 | DOI: 10.2337/dc14-1459

Table 3—Crude and adjusted ORs of hospitalization for CHF, comparing incretin-based drugs to combinations of oral antidiabetic drugs^a

Current exposure ^b	Case subjects (n = 1,118)	Control subjects (n = 17,626)	Crude OR (95% CI)	Adjusted OR ^c (95% CI)
≥2 oral antidiabetic drugs, n (%)	267 (23.9)	4,198 (23.8)	1.00 (Reference)	1.00 (Reference)
Incretin-based drugs, n (%)	64 (5.7)	923 (5.2)	0.98 (0.73–1.33)	0.85 (0.62–1.16)
DPP-4 inhibitors	54 (4.8)	808 (4.6)	0.96 (0.70–1.32)	0.88 (0.63–1.22)
GLP-1 analogs	10 (0.9)	115 (0.7)	1.18 (0.59–2.39)	0.67 (0.32–1.42)
Duration of incretin-based drug use, ^d n (%)				
1–83 days	25 (2.2)	310 (1.8)	1.18 (0.74–1.89)	1.01 (0.62–1.63)
84–265 days	18 (1.6)	299 (1.7)	0.86 (0.51–1.44)	0.79 (0.46–1.36)
>265 days	21 (1.9)	314 (1.8)	0.92 (0.56–1.50)	0.75 (0.45–1.25)
				P trend = 0.39

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Trial record 1 of 1 for: NCT01243424

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CAROLINA: Cardiovascular Outcome Study of Linagliptin Versus Glimepiride in Patients With Type 2 Diabetes

This study is ongoing, but not recruiting participants.

Sponsor:
Boehringer Ingelheim

Collaborator:
Eli Lilly and Company

Information provided by (Responsible Party):
Boehringer Ingelheim

ClinicalTrials.gov Identifier:
NCT01243424

First received: November 17, 2010
Last updated: March 17, 2015
Last verified: March 2015

ClinicalTrials.gov

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Trial record 1 of 1 for: NCT00790205

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Sitagliptin Cardiovascular Outcome Study (MK-0431-082) (TECOS)

This study is ongoing, but not recruiting participants.

Sponsor:
Merck Sharp & Dohme Corp.

Collaborator:
Duke Clinical Research Institute, Oxford Diabetes Trials Unit

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00790205

First received: November 11, 2008
Last updated: February 25, 2015
Last verified: February 2015
[History of Changes](#)

BMJ
open
accessible medical research

Effects of exenatide and liraglutide on heart rate, blood pressure and body weight: systematic review and meta-analysis

Louise E Robinson,¹ Tim A Holt,^{1,2} Karen Rees,¹ Harpal S Randeva,¹
John P O'Hare¹

Studies included in review
(n =32)

BMJ Open 2013;**3**:e001986. doi:10.1136/bmjopen-2012-001986

- Heart rate rises were more evident for liraglutide than exenatide, and for exenatide long-acting release than exenatide twice daily.

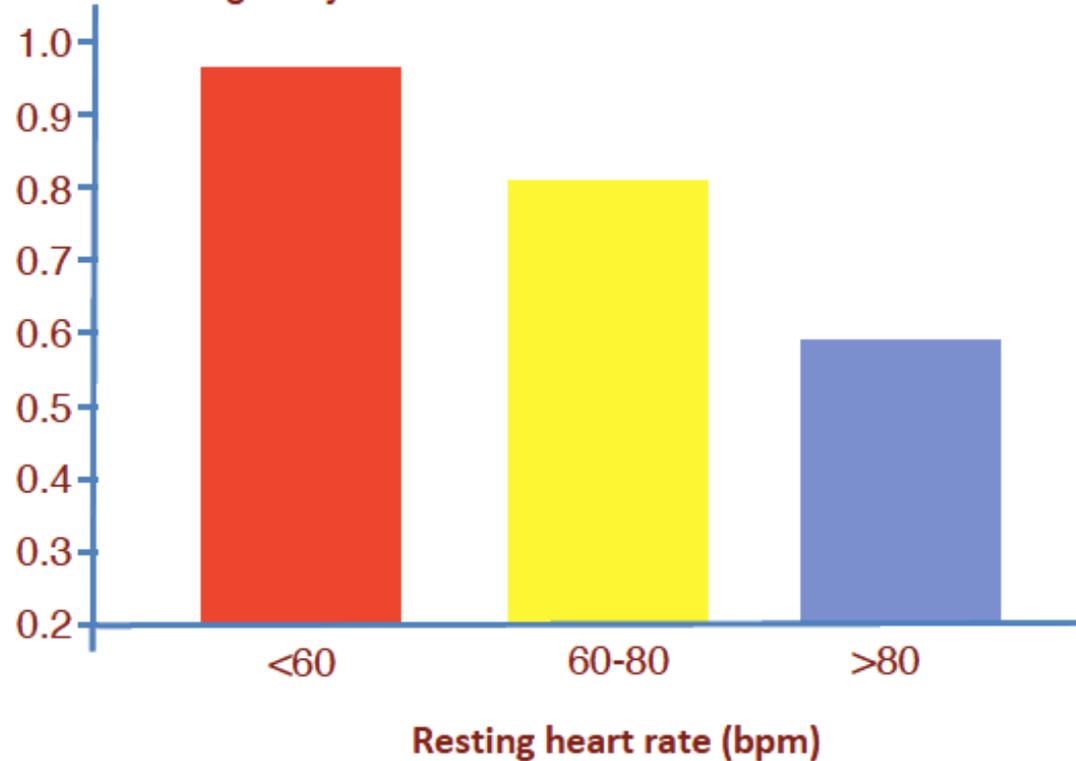
- La **frecuencia cardíaca** se midió en decúbito supino a las 24h tras la última administración del estudio (día 29)
 - Con lixisenatida disminuyó 3,6 lpm frente a un aumento de 5,3 lpm con liraglutida, con una **diferencia neta de 8,9 lpm que fue estadísticamente significativa.**

	Lixisenatide (n = 77)	Liraglutide (n = 71)
<i>Vital sign measurements</i>		
Δ heart rate, bpm [mean (95% CI)]†	-3.6 (-5.8, -1.3)	5.3 (2.9, 7.7)
Treatment difference, mmHg (95% CI)	-8.9 (-12.2, -5.6)	
Δ ECG heart rate, bpm [mean (95% CI)]†	-3.4 (-5.6, -1.2)	5.9 (3.6, 8.2)
Treatment difference, mmHg (95% CI)	-9.3 (-12.5, -6.1)	
Δ SBP, mmHg [mean (95% CI)]†	-2.0 (-4.9, 0.8)	-2.8 (-5.9, 0.2)
Treatment difference, mmHg (95% CI)	0.8 (-3.3, 5.0)	
Δ DBP, mmHg [mean (95% CI)]†	-0.6 (-2.2, 1.1)	1.1 (-0.7, 2.8)
Treatment difference, mmHg (95% CI)	-1.7 (-4.1, 0.7)	

Frecuencia Cardíaca en reposo predice supervivencia en > 65 años

The Cohort study (n=1407)

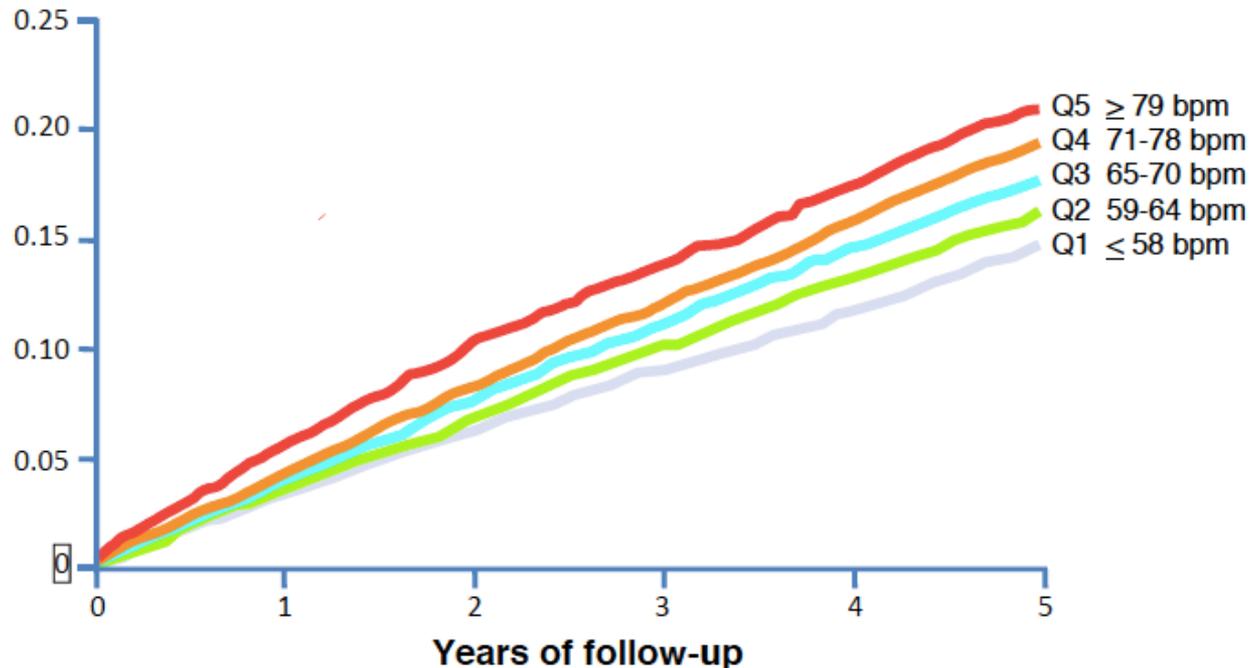
Risk of ratio of survival to age 85 years



La FC se asocia con un aumento del riesgo de eventos CV en diabéticos con Enf. Coronaria Estable

The ONTARGET/TRANSCEND trial (n=31531)

Cumulative incidence rates

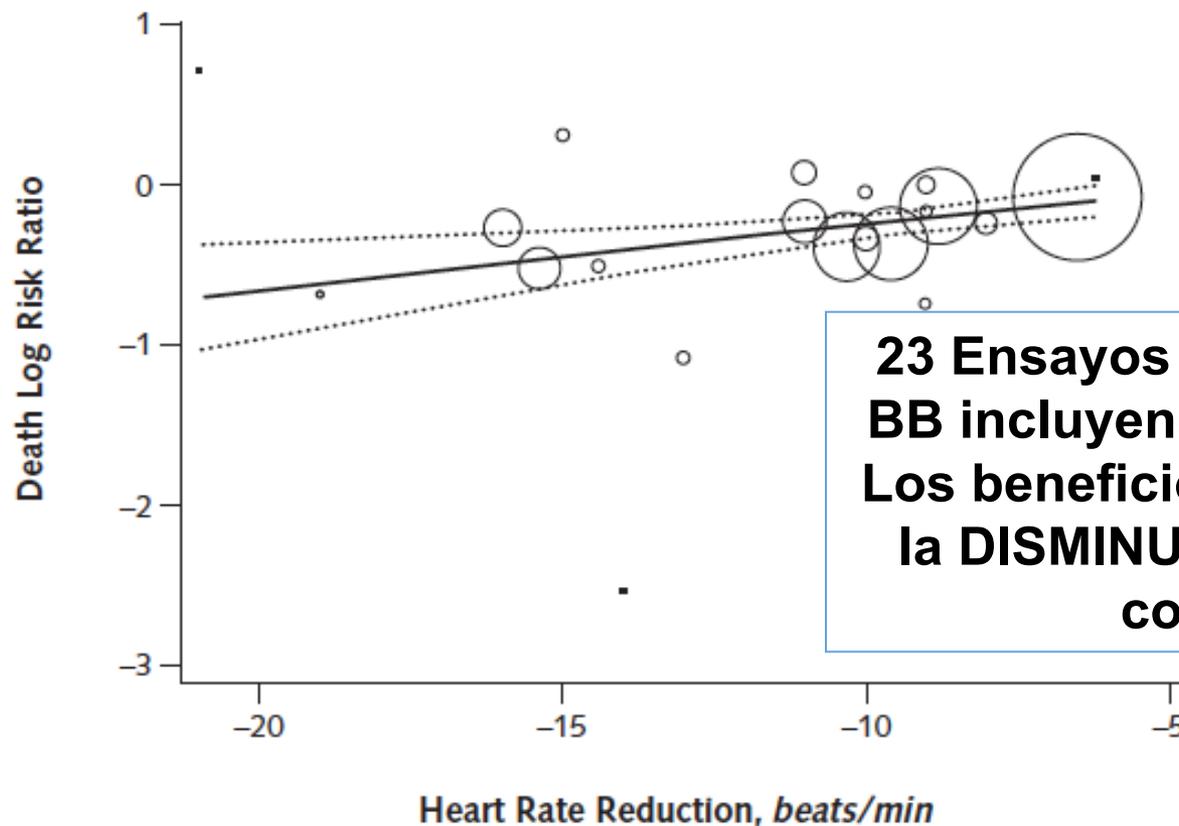


REVIEW

Annals of Internal Medicine

Meta-analysis: β -Blocker Dose, Heart Rate Reduction, and Death in Patients With Heart Failure

Ann Intern Med. 2009;150:784-794.



23 Ensayos Clínicos en ICC con BB incluyendo 19.209 pacientes. Los beneficios se relacionan con la DISMINUCIÓN de la FC y no con la dosis.

Por CADA 5 LATIDOS DISMINUYE LA MORTALIDAD 18%

Sanofi Announces Top-Line Results for Cardiovascular Outcomes Study of Lyxumia® (lixisenatide)

- Results support resubmission of U.S. New Drug Application in Q3 2015 -

Paris, France – March 19, 2015 - [Sanofi](#) announced today top-line results of the Phase IIIb ELIXA cardiovascular outcomes study, which compared lixisenatide to placebo in a high-risk population of adults with type 2 diabetes evaluating cardiovascular safety. The study showed that lixisenatide was non-inferior, although not superior, to placebo for cardiovascular safety.

Liraglutide Effect and Action in Diabetes: Evaluation of Cardiovascular Outcome Results - A Long Term Evaluation (LEADER®)

This study is ongoing, but not recruiting participants.

Sponsor:
Novo Nordisk A/S

Information provided by (Responsible Party):
Novo Nordisk A/S

ClinicalTrials.gov Identifier:
NCT01179048

First received: August 6, 2010
Last updated: January 7, 2015
Last verified: January 2015
History of Changes

Recruiting Exenatide Study of Cardiovascular Event Lowering Trial (EXSCEL): A Trial To Evaluate Cardiovascular Outcomes After Treatment With Exenatide Once Weekly in Patients With Type 2 Diabetes Mellitus

Condition: Type 2 Diabetes Mellitus

Interventions: Drug: Exenatide Once Weekly; Drug: Placebo

Active, not recruiting

Researching Cardiovascular Events With a Weekly Incretin in Diabetes (REWIND)

Conditions: Cardiovascular Disease; Diabetes Mellitus, Type 2

Interventions: Drug: Dulaglutide; Drug: Placebo

Insulina Basal

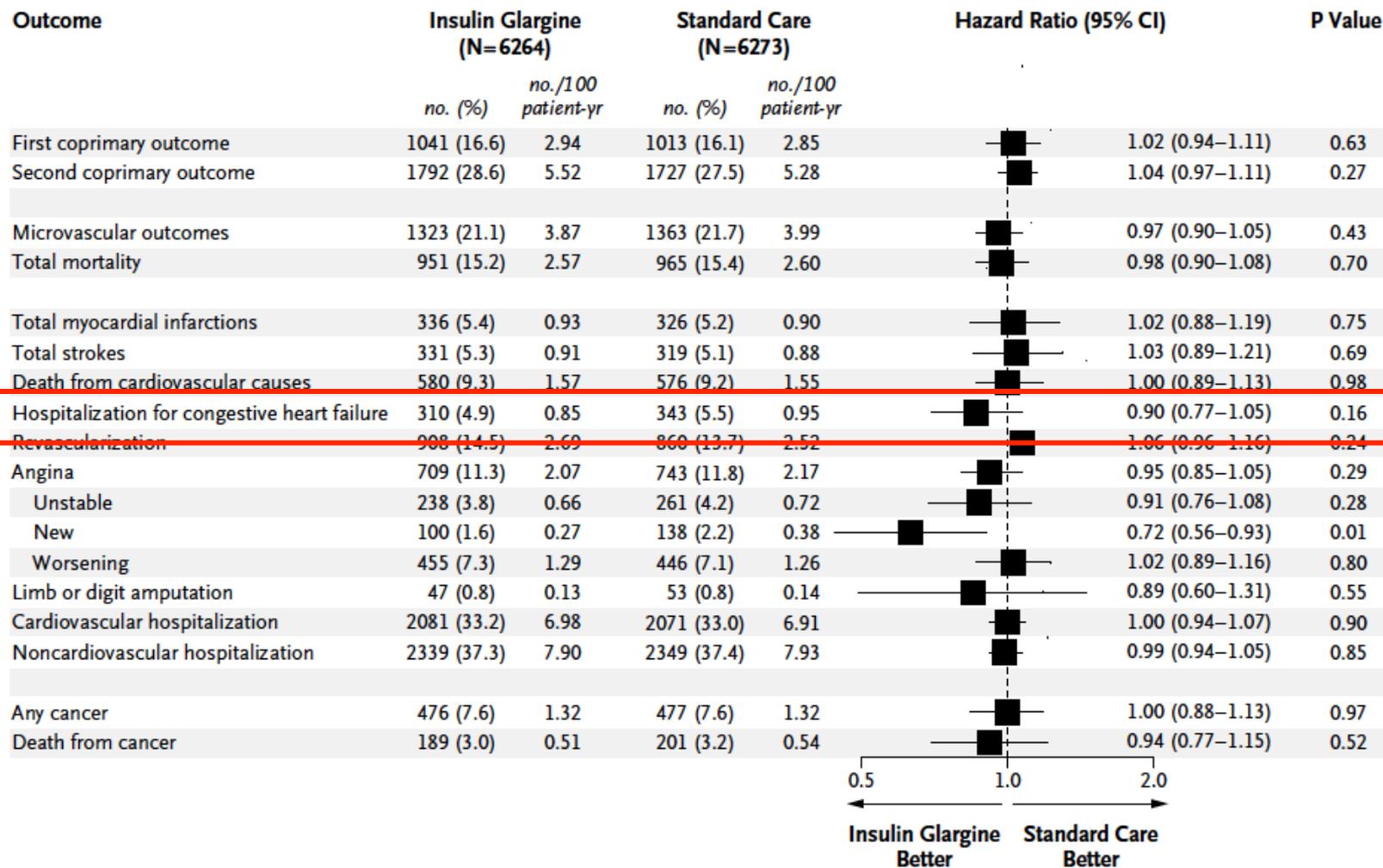


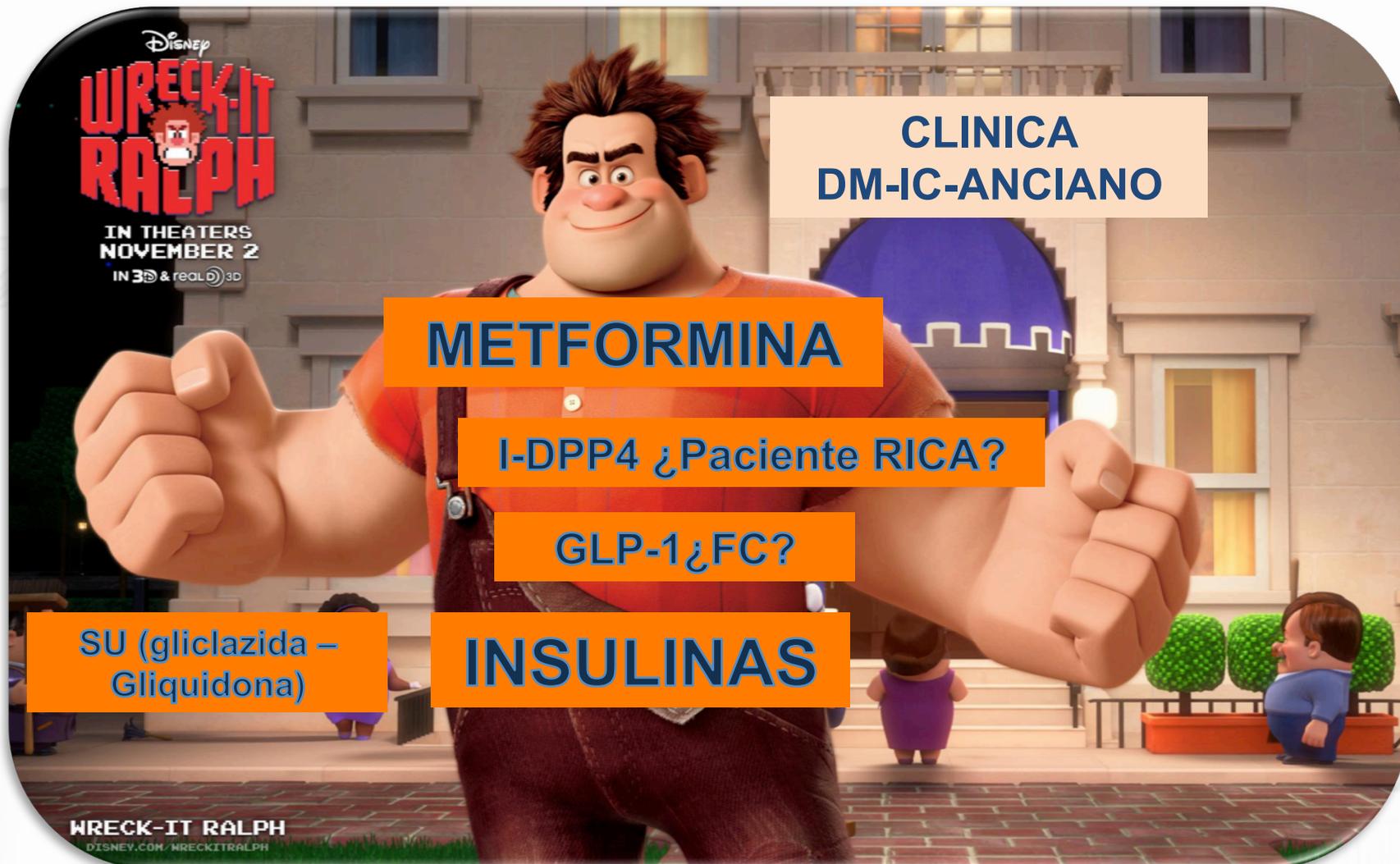
Figure 1. Hazard Ratios for the Coprimary and Other Outcomes.

MENSAJES BÁSICOS

- ARTE MÉDICO del INTERNISTA
- INDIVIDUALIZAR con MAYÚSCULAS
 - Plantear OBJETIVOS de control
 - Disminuir Riesgo de Hipoglucemia
- Evaluar SIEMPRE la Función Renal
- Elección muy SABIA:
 - METFORMINA mejor perfil
 - SU limitadas por hipoglucemia e I. Renal
 - No se recomienda la Pioglitazona
 - iDPP-4 ¿Cuidado en el Paciente RICA?
 - GLP-1 Vigilar la frecuencia cardiaca
 - Insulina Muy buen perfil de seguridad controlando la hipoglucemia



XVII Reunión Insuficiencia Cardíaca y Fibrilación Auricular



**CLINICA
DM-IC-ANCIANO**

METFORMINA

I-DPP4 ¿Paciente RICA?

GLP-1¿FC?

**SU (gliclazida –
Gliquidona)**

INSULINAS

WRECK-IT RALPH
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