

SEC 2011

Manejo óptimo de la glucemia y los factores de riesgo cardiovascular en el diabético

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¿Es el riesgo cardiovascular de los pacientes diabéticos equiparable al riesgo de los que han sufrido un infarto agudo de miocardio?

¿Cuáles son las cifras objetivo de HbA_{1c}?

¿Cuáles son las cifras de PA objetivo en el tratamiento del paciente diabético hipertenso?

¿Cuáles son las cifras de lípidos objetivo en el tratamiento del paciente diabético?

¿Deben tratarse con ácido acetil salicílico las personas diabéticas?

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Lotufo PA, Diabetes and all-cause and coronary heart disease mortality among US male physicians. *Arch Intern Med.* 2001;161(2):242-7.

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Cho E, The impact of diabetes mellitus and prior myocardial infarction on mortality from all causes and from coronary heart disease in men. *J Am Coll Cardiol.* 2002;40(5):954-60.

Becker A, et al. Cardiovascular events in type 2 diabetes: comparison with nondiabetic individuals without and with prior cardiovascular disease. 10-year follow-up of the Hoorn Study. *Eur Heart J.* 2003;24(15):1406-13.

Eberly LE, Impact of incident diabetes and incident nonfatal cardiovascular disease on 18-year mortality: the multiple risk factor intervention trial experience. *Diabetes Care.* 2003;26(3):848-54.

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Hackam DG, How does the prognosis of diabetes compare with that of established vascular disease? Insights from the Canadian Vascular Protection (VP) Registry. *Am Heart J.* 2004;148(6):1028-33.

Lee CD, Cardiovascular events in diabetic and nondiabetic adults with or without history of myocardial infarction. *Circulation.* 2004;109(7):855-60.

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Vaccaro O, Impact of diabetes and previous myocardial infarction on long-term survival: 25-year mortality follow-up of primary screenees of the Multiple Risk Factor Intervention Trial. *Arch Intern Med.* 2004;164(13):1438-43.

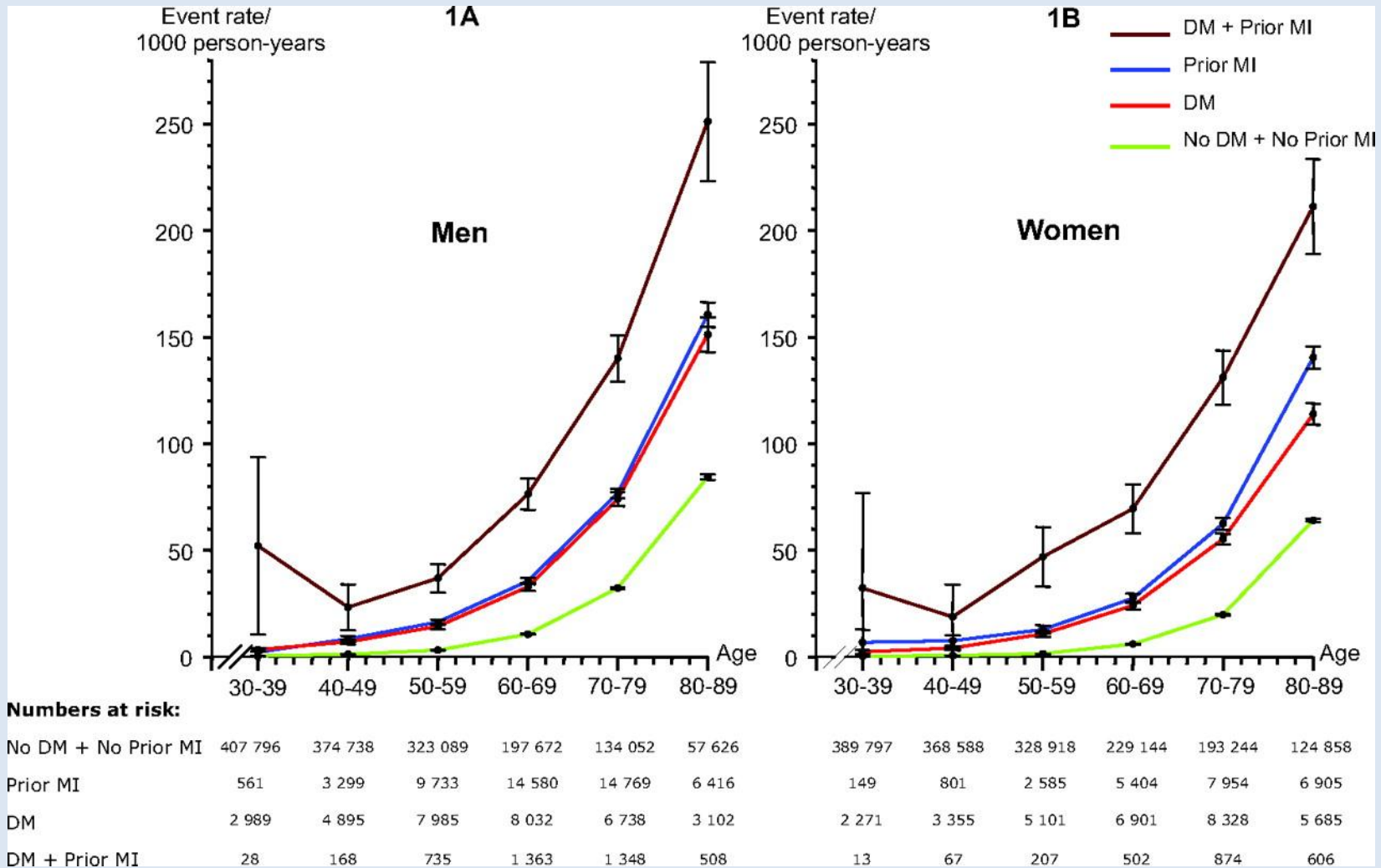
Hu G, The gender specific impact of diabetes and myocardial infarction at baseline and during follow-up on mortality from all causes and coronary heart disease. *J Am Coll Cardiol.* 2005;45(9):1413-8.

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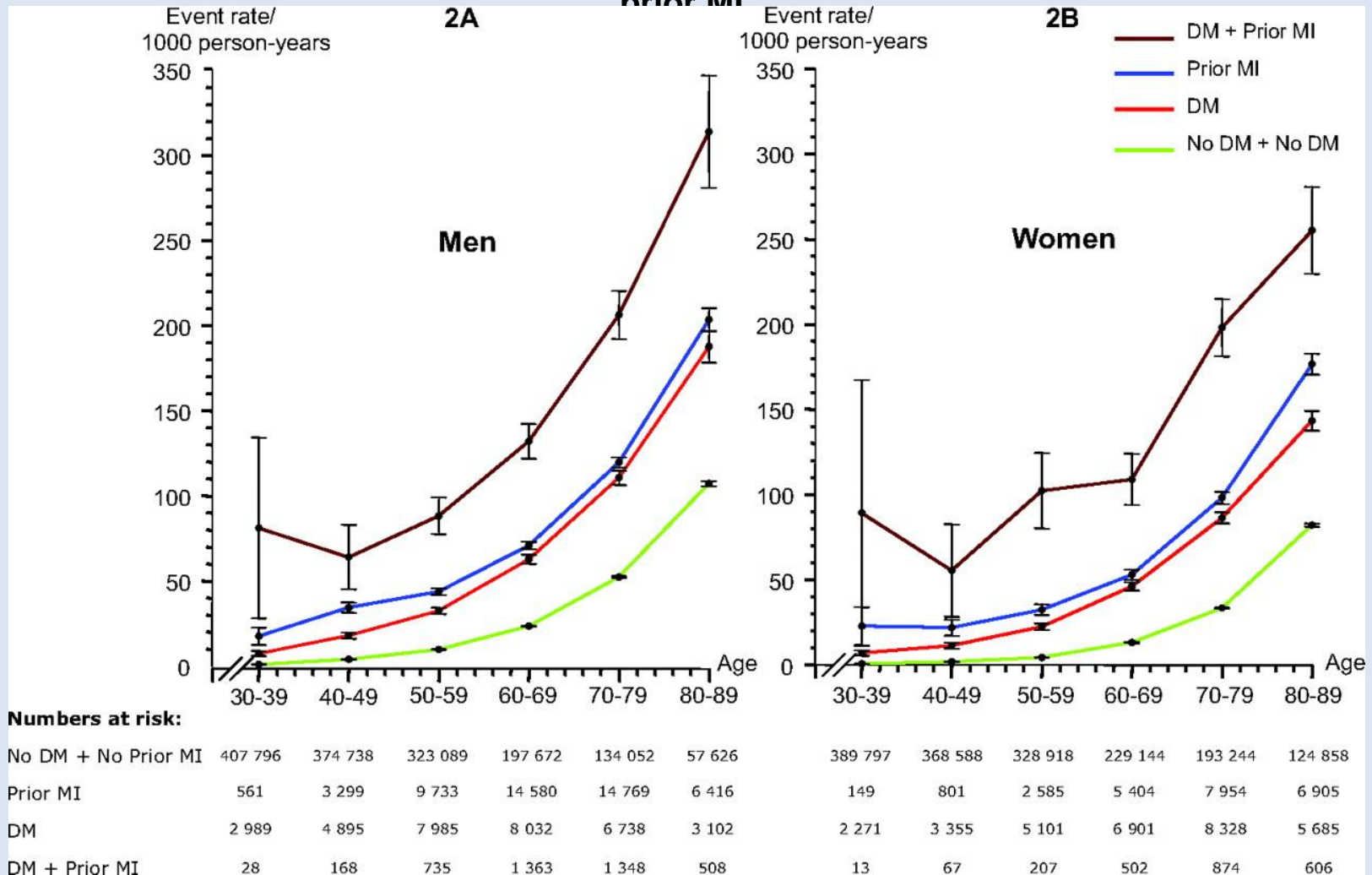
Cano F, Long-Term Cardiovascular Risk in Type 2 Diabetic Compared With Nondiabetic First Acute Myocardial Infarction Patients A population-based cohort study in southern Europe. *Diabetes Care* 2010; 33:2004-2009.

Event rates for cardiovascular mortality in men (A) and women (B) stratified by age and sex in relation to diabetes mellitus (DM) and a prior MI.



Schramm T K et al. Circulation 2008;117:1945-1954

Event rates for the composite end point of MI (nonfatal), stroke (nonfatal), and cardiovascular death in men (A) and women (B) stratified by age in relation to diabetes mellitus (DM) and a prior MI



Schramm T K et al. *Circulation* 2008;117:1945-1954

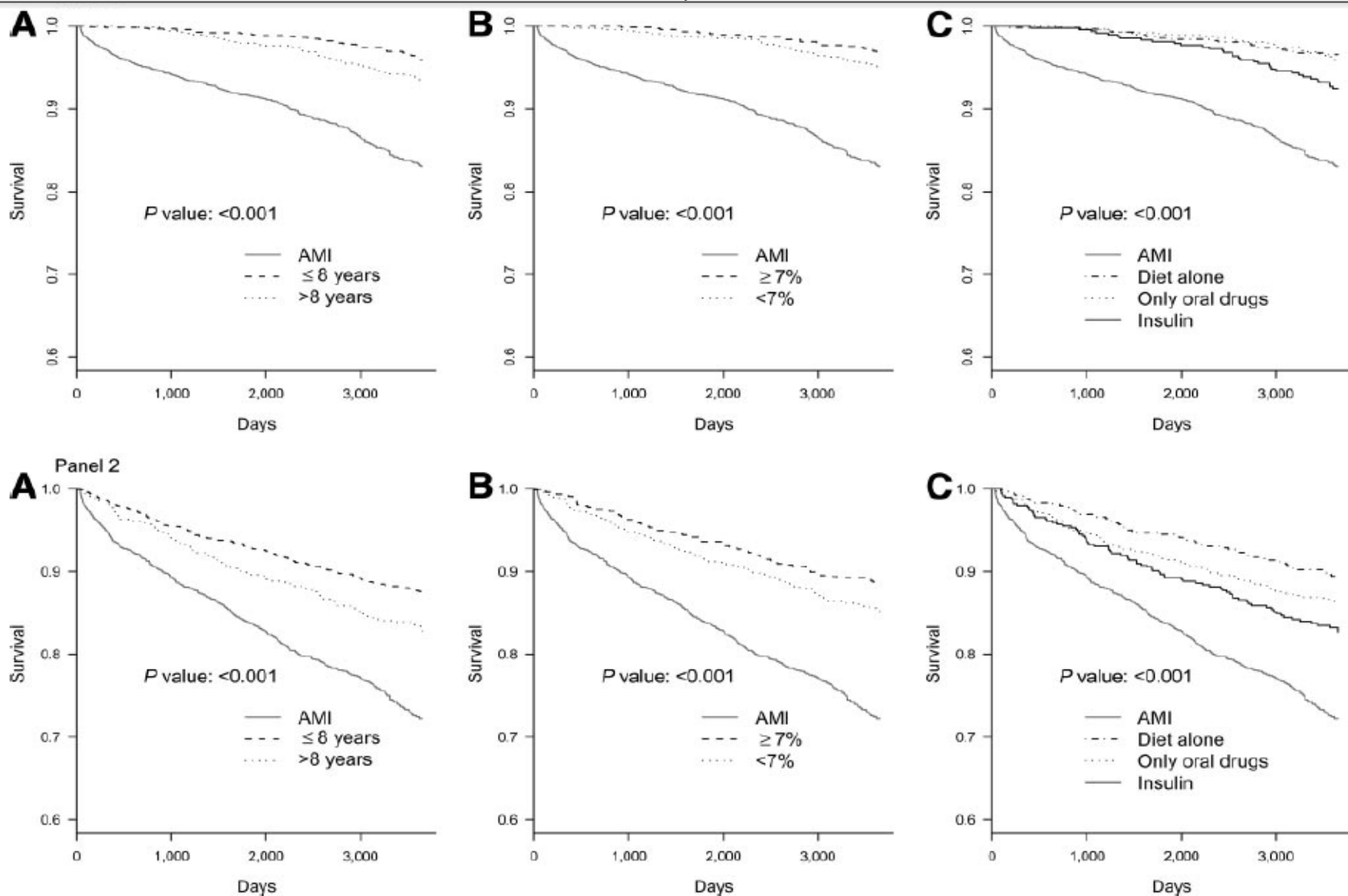


Figure 1—Free of cardiovascular mortality (panel 1) and free of coronary heart disease (panel 2) survival curves among initially non-coronary heart disease diabetic patients compared with nondiabetic first acute myocardial infarction (AMI) survivors. A: According to time of evolution of type 2 diabetes (cut point 8 years). B: According to A1C levels (cut point 7%). C: According to diabetes treatment (diet alone, only oral drugs, or insulin).

¿Es el riesgo cardiovascular de los pacientes diabéticos equiparable al riesgo de los que han sufrido un infarto agudo de miocardio?

- NO puede afirmarse en base a la evidencia revisada
- La diabetes en mujeres supone un mayor riesgo relativo para enfermedad coronaria que en los hombres diabéticos y en algunos casos este riesgo es igual o incluso mayor al de las mujeres con antecedentes de cardiopatía isquémica.
- La duración de la DM es un factor de riesgo independiente y que, a partir de 10 años de evolución de la enfermedad, el riesgo coronario se iguala con los que tienen antecedentes de cardiopatía isquémica

REGICOR 2011

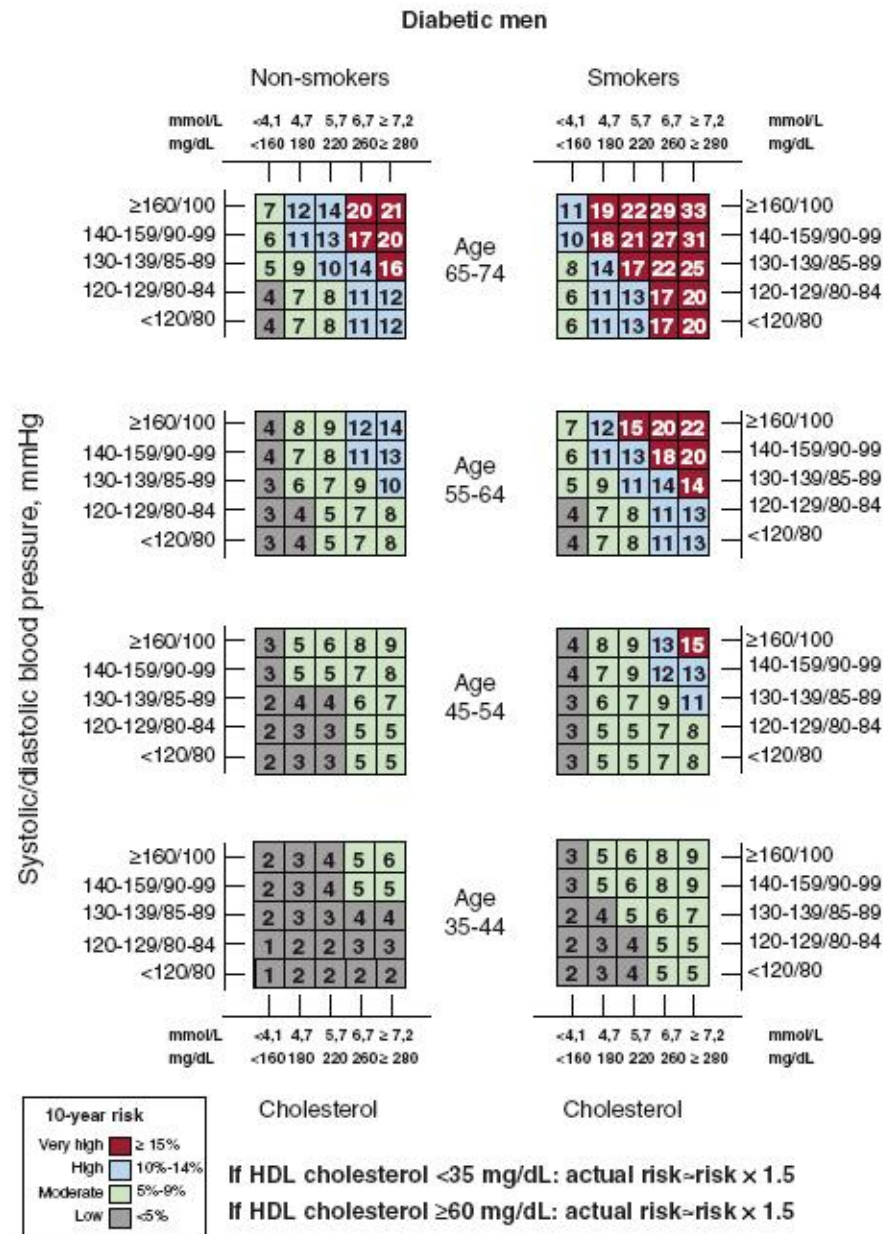


Figure 3. Framingham-based REGICOR risk function, simplified into 4 risk groups based on the risk cut-points at 10 years proposed by experts from several autonomous regions and in the concentration of events. HDL, high-density lipoproteins.

REGICOR 2011

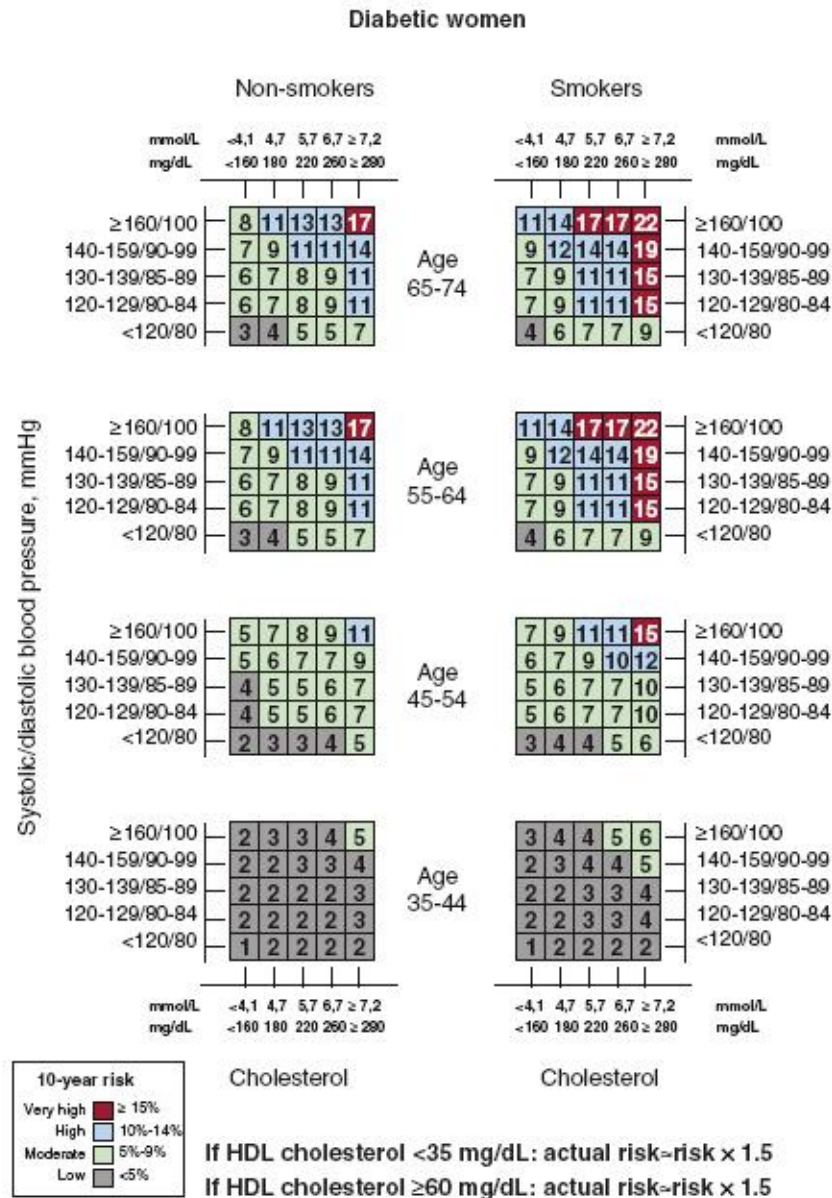
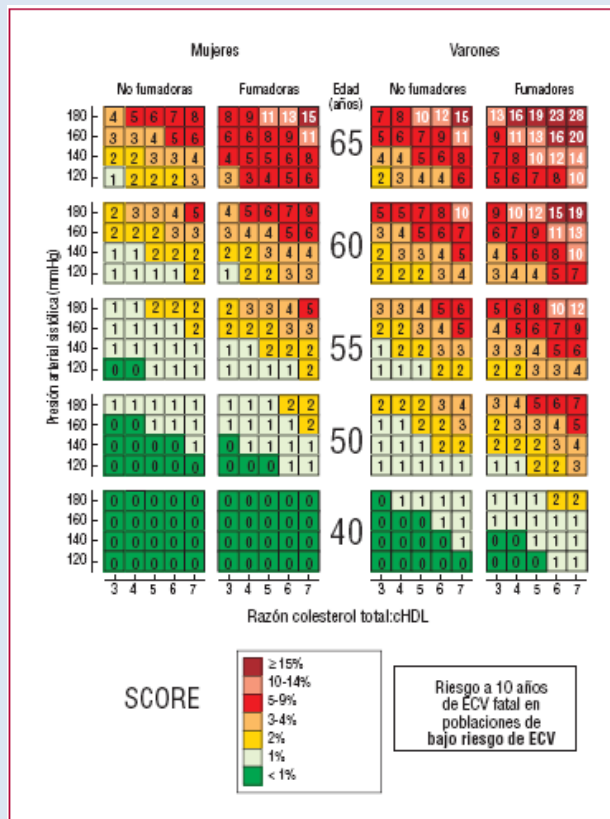


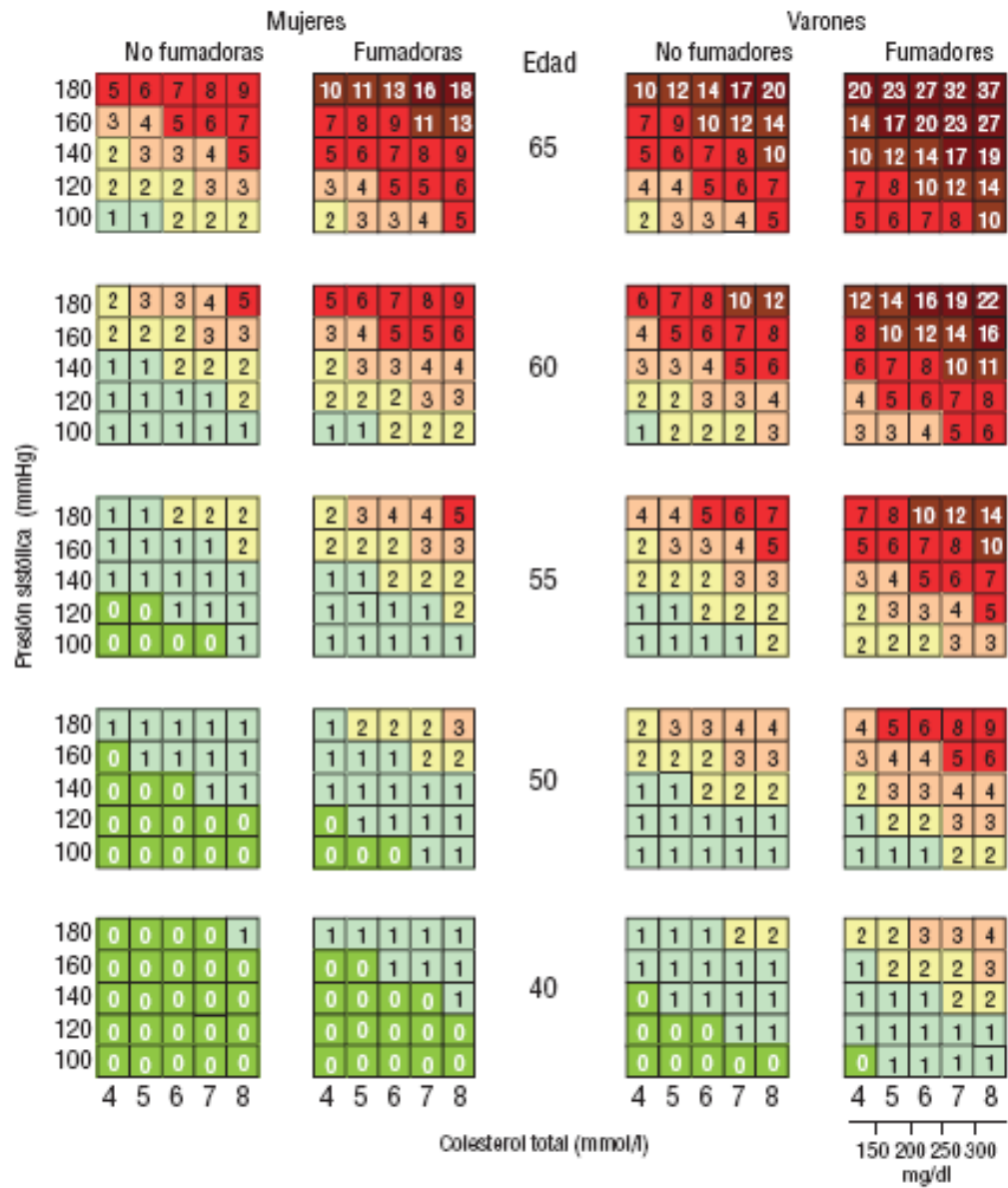
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Tablas SCORE

Riesgo de muerte cardiovascular para países europeos de baja mortalidad cardiovascular (basada en cociente CT/HDL)



Bélgica, Luxemburgo, Suiza, Italia, Grecia, Francia, Portugal, España



Sans S, Rev Esp Cardio 2007; 60(5):476-85

Multiplicar el riesgo
X 3 en hombres
X 5 en mujeres

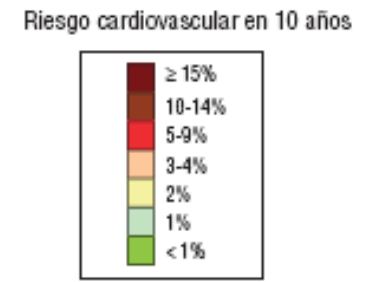


Fig. 2. Tabla SCORE calibrada para España del riesgo estimado de mortalidad cardiovascular aterosclerótica en 10 años, para valores específicos de presión arterial sistólica y colesterol total, según hábito tabáquico, sexo y edad.

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¿Cuáles son las cifras de PA objetivo en el tratamiento del paciente diabético hipertenso?

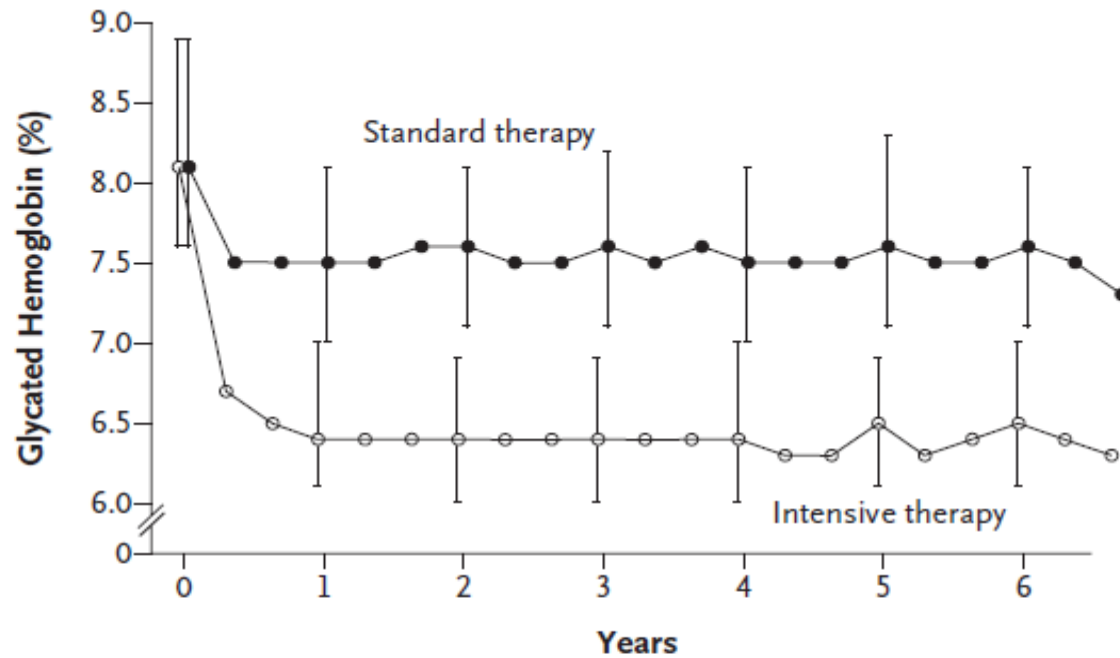
¿Cuáles son las cifras de lípidos objetivo en el tratamiento del paciente diabético?

¿Deben tratarse con ácido acetil salicílico las personas diabéticas?

Effects of Intensive Glucose Lowering in Type 2 Diabetes

The Action to Control Cardiovascular Risk in Diabetes Study Group

ACCORD. N Engl J Med 2008;358:2545-59.



No. at Risk	0	1	2	3	4	5	6
Standard therapy	5109	4774	4588	3186	1744	455	436
Intensive therapy	5119	4768	4585	3165	1706	476	471

OBJETIVOS

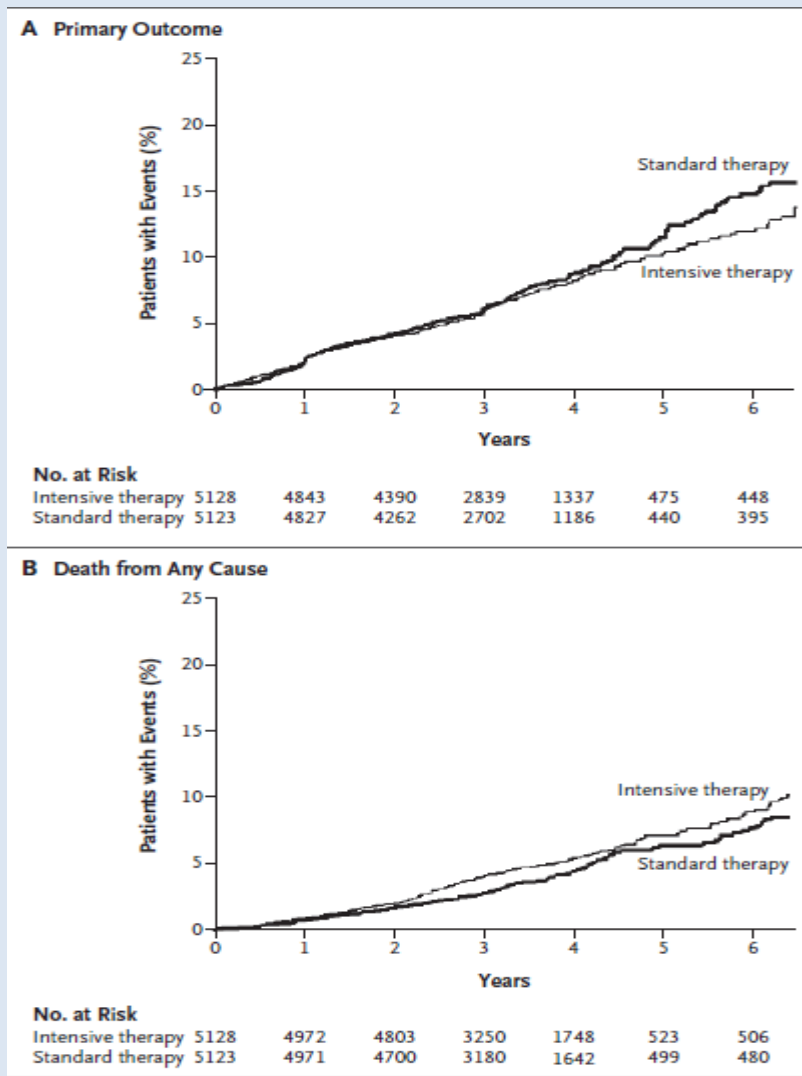
7-7,9%
<6%

Figure 1. Median Glycated Hemoglobin Levels at Each Study Visit.
I bars denote interquartile ranges.

Effects of Intensive Glucose Lowering in Type 2 Diabetes

The Action to Control Cardiovascular Risk in Diabetes Study Group

ACCORD. N Engl J Med 2008;358:2545-59.



IM no fatal, ictus
 no fatal, muerte por
 enfer. CV
 HR 0.90 IC 95% 0,78-
 0.14, p=0.16

Mortalidad total
 HR 1,22 IC 95% 1.01-1.46
 P = 0.04

Figure 2. Kaplan–Meier Curves for the Primary Outcome and Death from Any Cause.

Effects of Intensive Glucose Lowering in Type 2 Diabetes

The Action to Control Cardiovascular Risk in Diabetes Study Group

ACCORD. N Engl J Med 2008;358:2545-59.

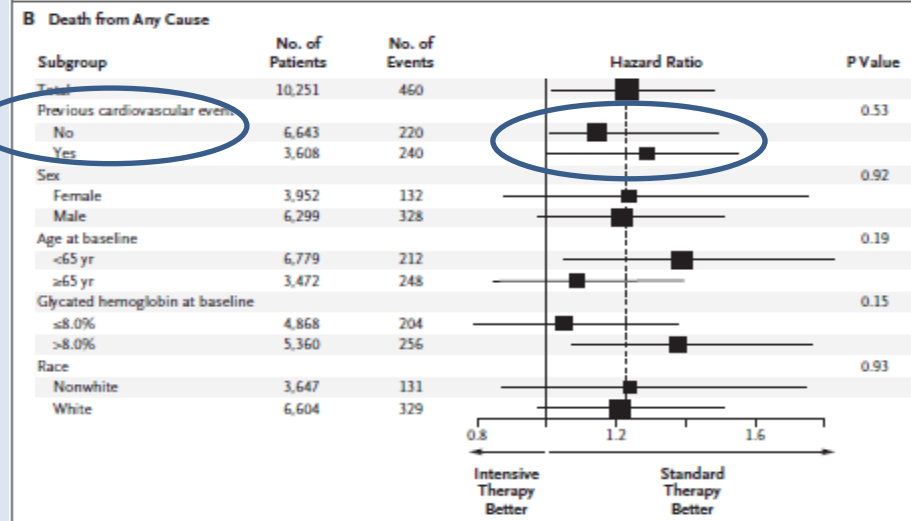
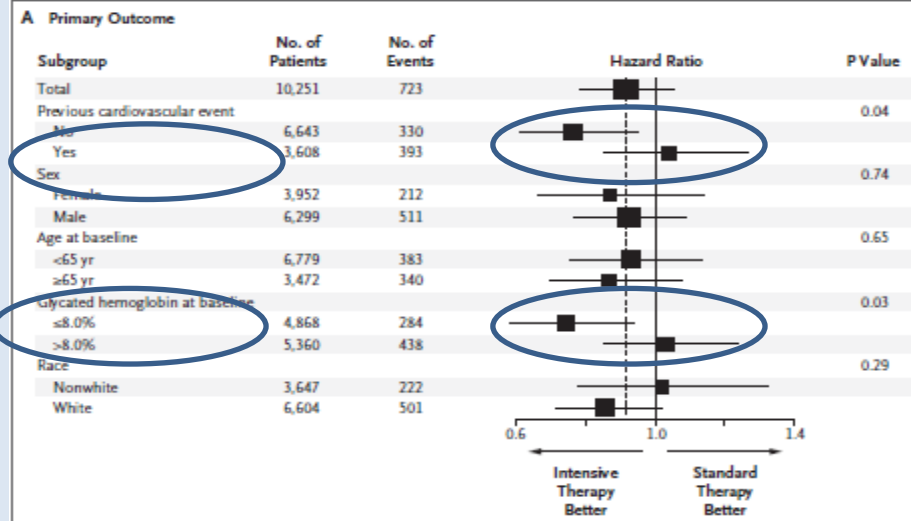


Figure 3. Hazard Ratios for the Primary Outcome and Death from Any Cause in Prespecified Subgroups. Data regarding glycated hemoglobin levels at baseline are presented for 10,288 patients because a baseline level was not available for 23 patients. Horizontal bars represent the 95% confidence interval, and vertical dashed lines indicate the overall hazard ratio. The size of each square is proportional to the number of patients.

Intensive Blood Glucose Control and Vascular Outcomes in Patients with Type 2 Diabetes

The ADVANCE Collaborative Group*

N Engl J Med 2008; 358:2560-72.

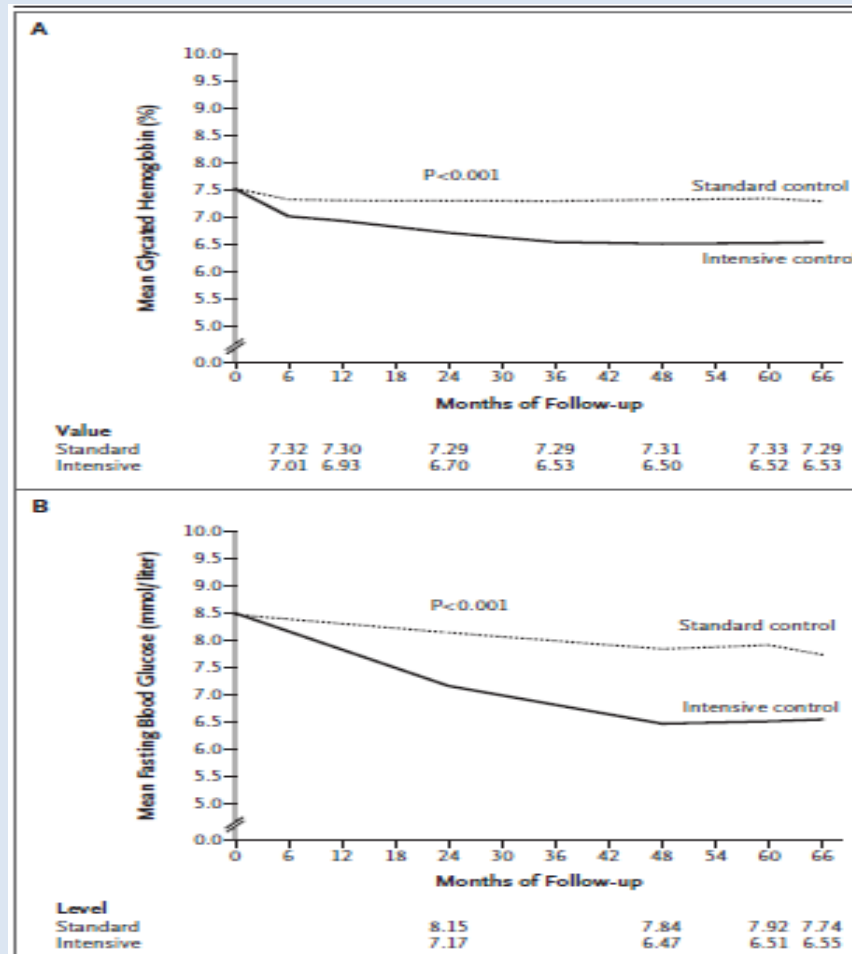


Figure 2. Glucose Control at Baseline and during Follow-up, According to Glucose-Control Strategy.

Data are shown for mean glycated hemoglobin (Panel A) and mean fasting blood glucose (Panel B). The average difference between the intensive-control group and the standard-control group for the follow-up period was 0.67 percentage point (95% confidence interval [CI], 0.64 to 0.70) for glycated hemoglobin and 1.22 mmol per liter (21.9 mg per deciliter) (95% CI, 1.15 to 1.28 [20.8 to 23.0]) for fasting blood glucose.

Intensive Blood Glucose Control and Vascular Outcomes in Patients with Type 2 Diabetes

The ADVANCE Collaborative Group*

N Engl J Med 2008; 358:2560-72.

HR 0.90 IC 95%
0.82-0.98

HR 0.94 IC 95%
0.84-1.06

HR 0.86 IC 95%
0.77-0.97

Reducción
Relativa de
un 21% en
pacientes con
nefropatía

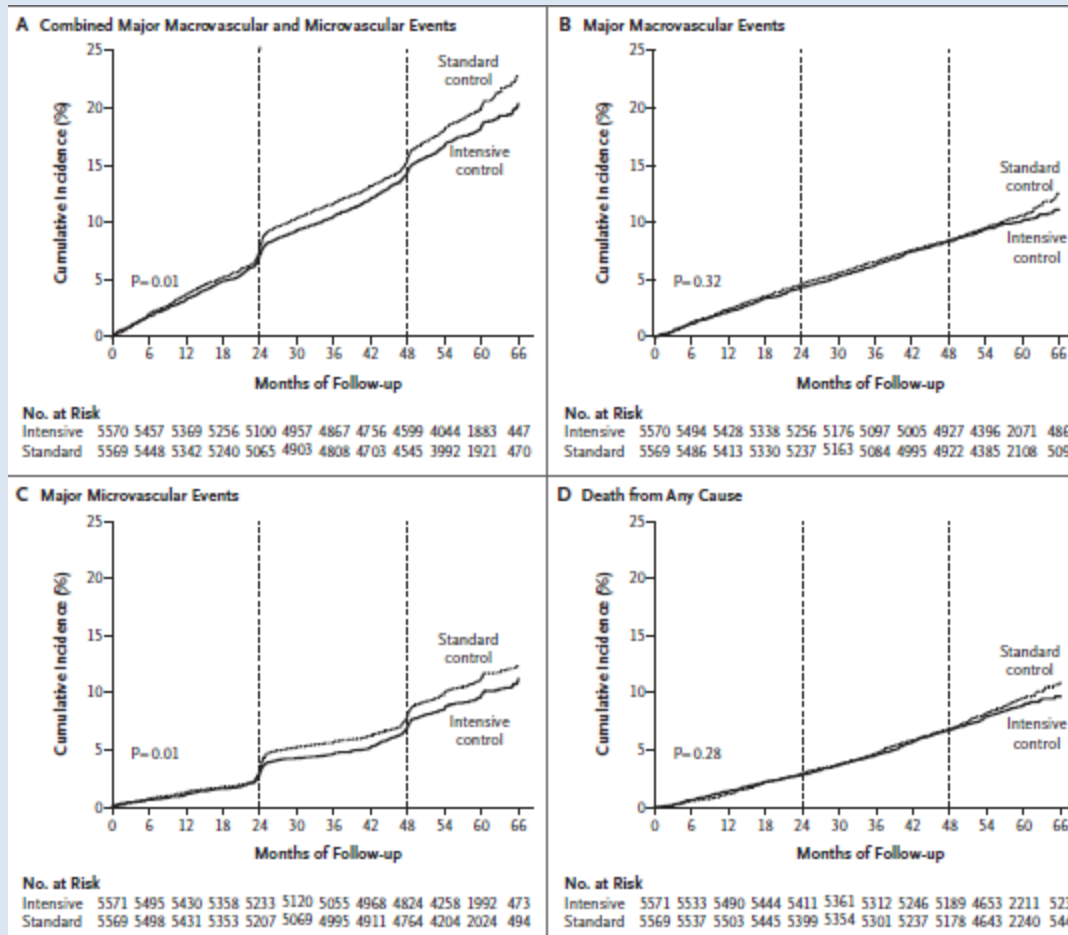
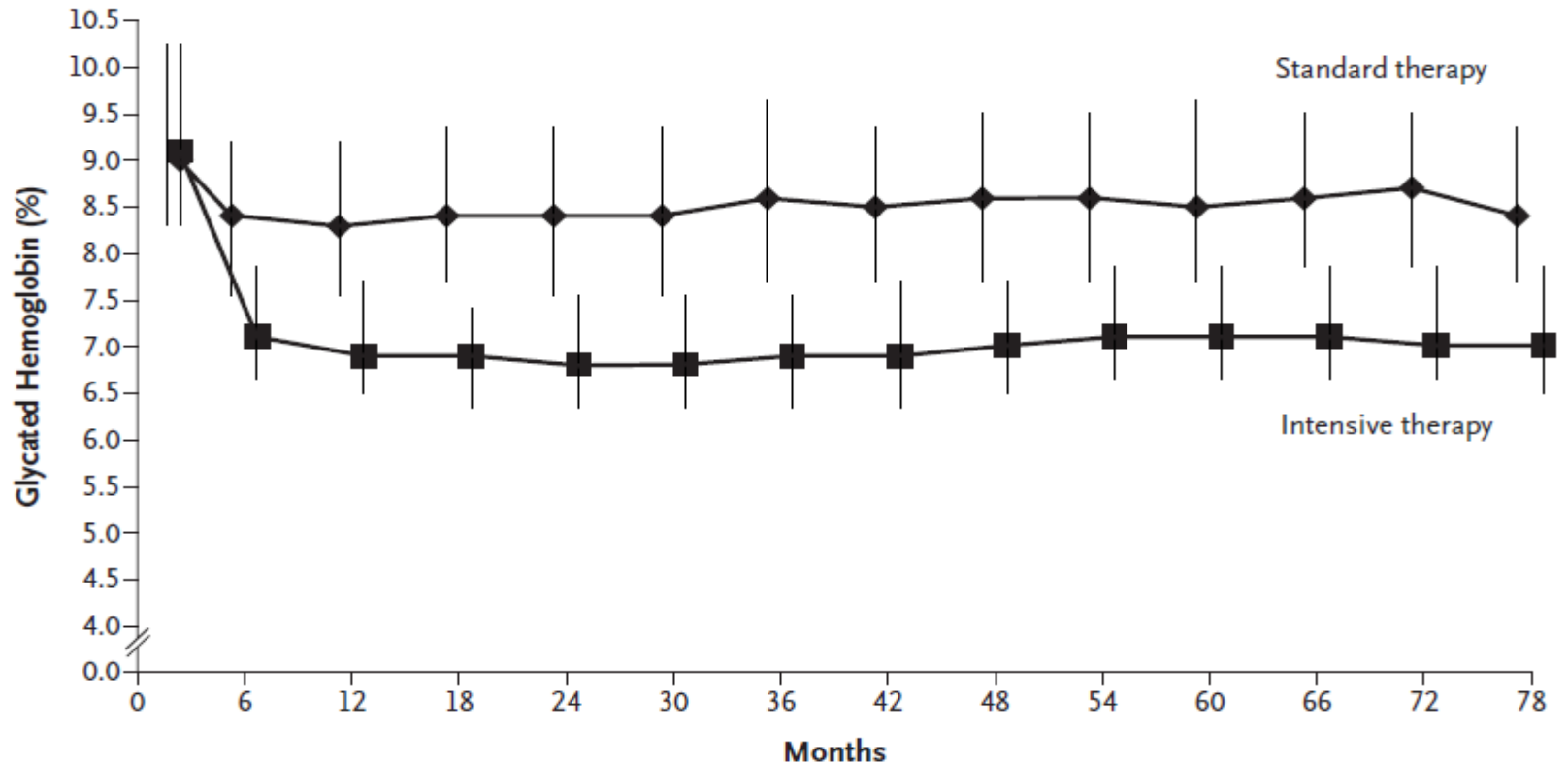


Figure 3. Cumulative Incidences of Events, According to Glucose-Control Strategy.

The hazard ratios for intensive glucose control as compared with standard glucose control were as follows: for combined major macrovascular or microvascular events, 0.90 (95% confidence interval [CI], 0.82 to 0.98) (Panel A); for major macrovascular events, 0.94 (95% CI, 0.84 to 1.06) (Panel B); for major microvascular events, 0.86 (95% CI, 0.77 to 0.97) (Panel C); and for death from any cause, 0.93 (95% CI, 0.83 to 1.06) (Panel D). The vertical dashed lines indicate the 24-month and 48-month study visits, at which additional data on microvascular events were collected, specifically the ratio of urinary albumin to creatinine and results of a retinal examination. For events relating to these data, the event time was recorded as the date of the visit. The curves were truncated at month 66, by which time 99% of the events had occurred. The effects of treatment (hazard ratios and P values) were estimated from unadjusted Cox proportional-hazard models that used all the available data.

Glucose Control and Vascular Complications in Veterans with Type 2 Diabetes

VADT. N Engl J Med 2009;360:129-39



No. at Risk

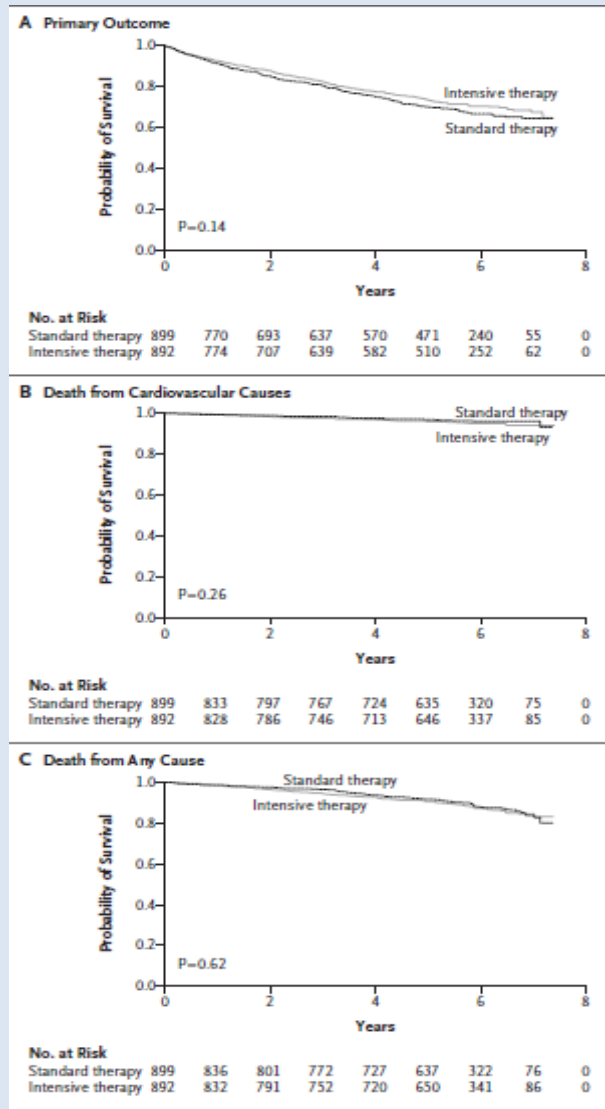
Standard therapy	899	811	812	759	760	727	727	707	688	667	644	472	329	225
Intensive therapy	892	801	805	763	754	729	706	692	668	661	639	489	340	223

Figure 2. Changes in Median Glycated Hemoglobin Levels from Baseline through 78 Months.

The vertical bars represent interquartile ranges.

Glucose Control and Vascular Complications in Veterans with Type 2 Diabetes

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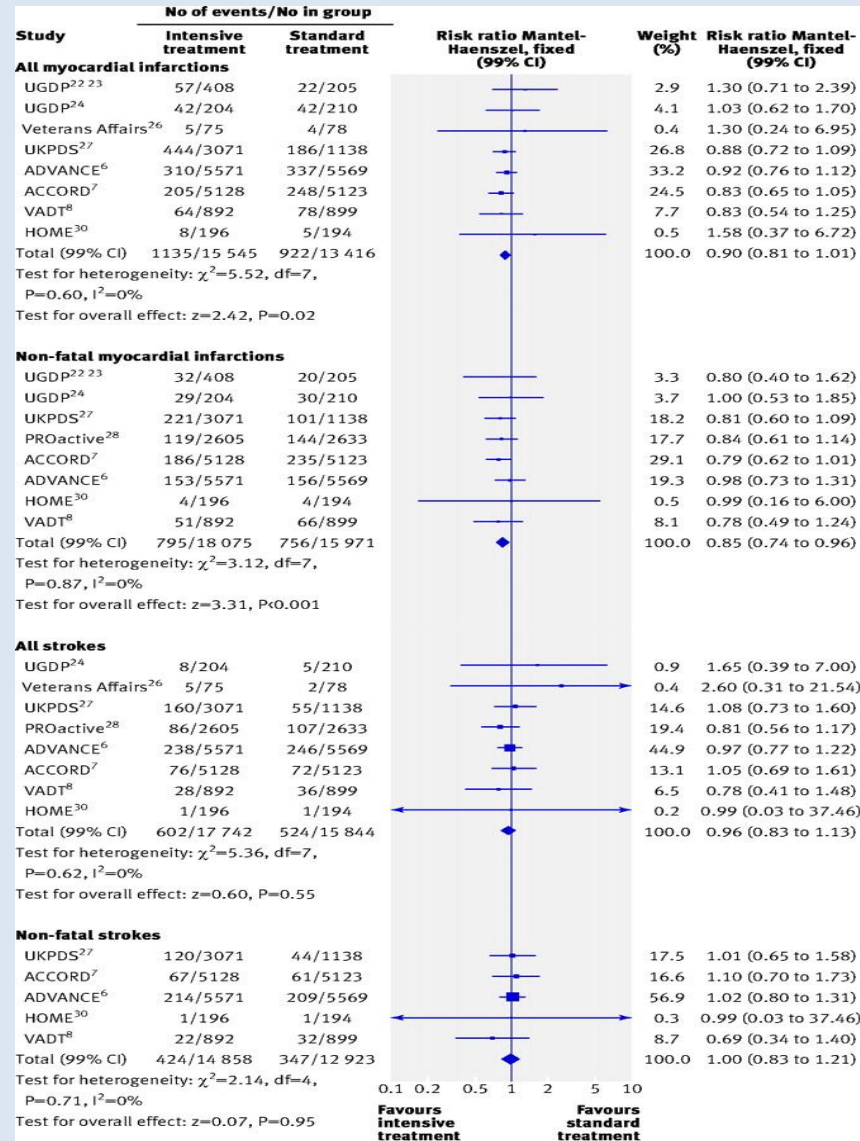


HR 0.88 IC 95%
0.74-1.05

Reducción significativa
de la progresión
de la albuminuria

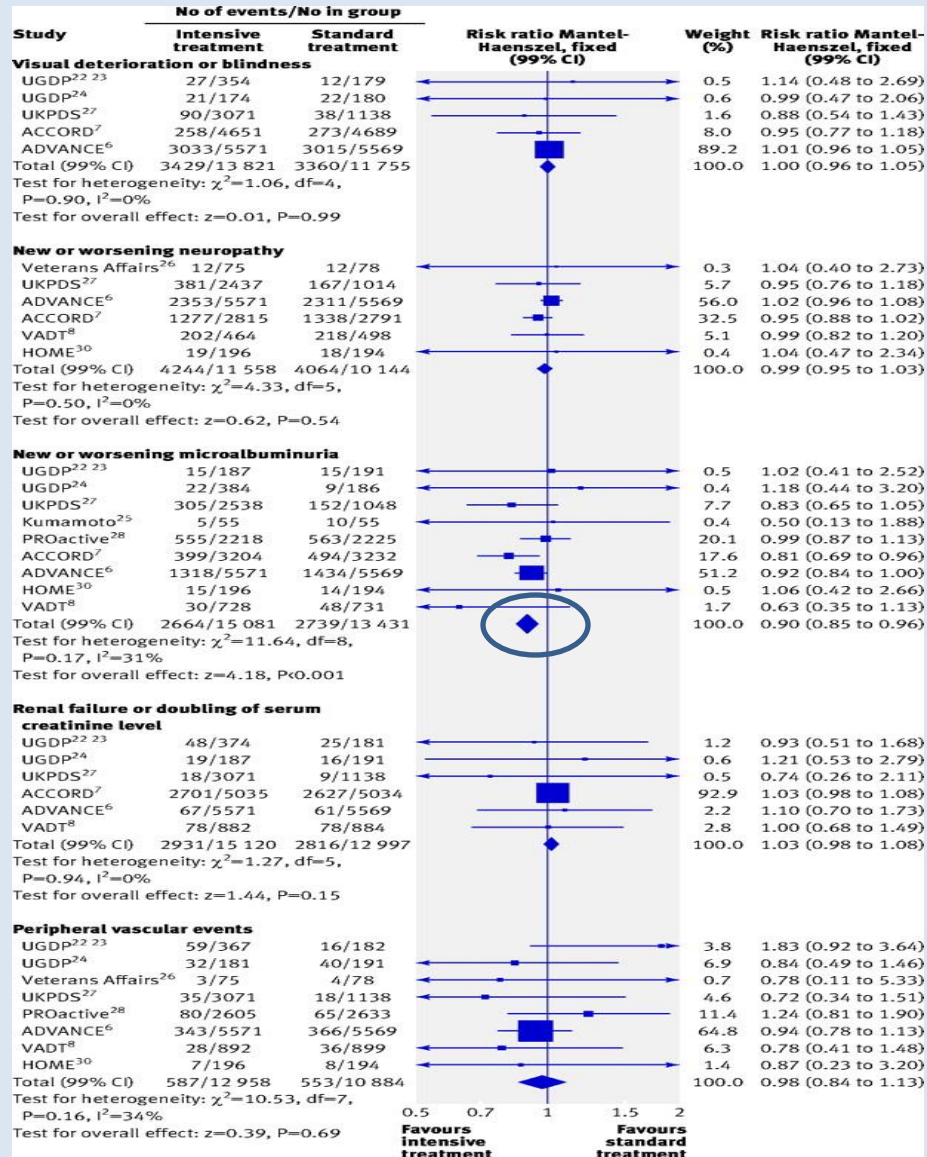
META-ANALYSIS

Forest plot for macrovascular events: myocardial infarction (fatal and non-fatal) and stroke (fatal and non-fatal).



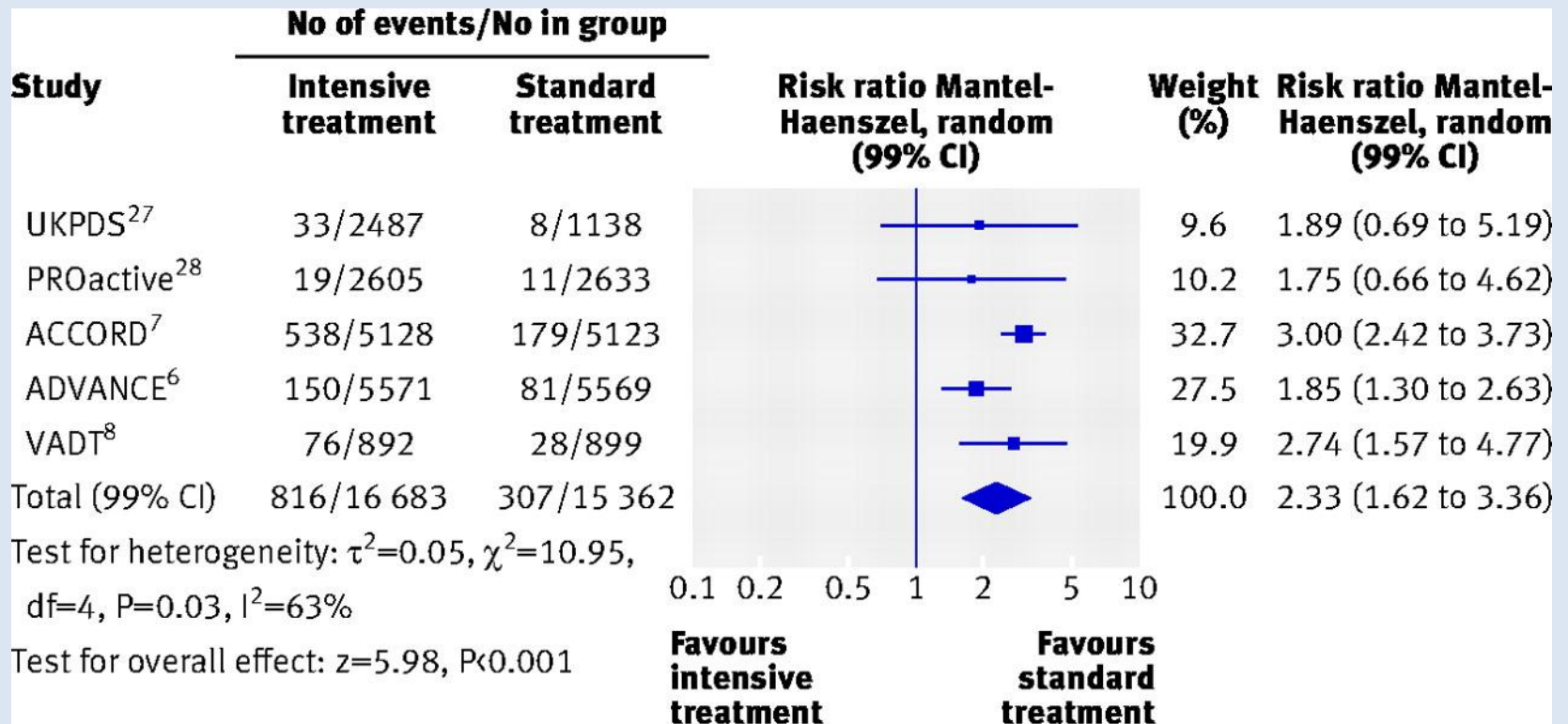
META-ANALYSIS

Forest plot for microvascular events: visual deterioration, neuropathy, microalbuminuria, renal failure or doubling of serum creatinine level, and peripheral vascular events



META-ANALYSIS

Forest plot for severe hypoglycaemia.



Boussageon R et al. BMJ 2011;343:bmj.d4169

¿Cuáles son las cifras objetivo de HbA_{1c}?

- Objetivo de control HbA_{1c} < 7%
- En pacientes con enfermedad cardiovascular valores de HbA_{1c} entre 7-8% pueden ser aceptables y más seguros
- Los pacientes que se pueden beneficiar más de un tratamiento intensivo son los pacientes con nefropatía

¿Es el riesgo cardiovascular de los pacientes diabéticos equiparable al riesgo de los que han sufrido un infarto agudo de miocardio?

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¿Cuáles son las cifras de PA objetivo en el tratamiento del paciente diabético hipertenso?

¿Cuáles son las cifras de lípidos objetivo en el tratamiento del paciente diabético?

¿Deben tratarse con ácido acetil salicílico las personas diabéticas?

Effects of a fixed combination of perindopril and indapamide (or placebo) on macrovascular and microvascular outcomes in patients with type 2 diabetes mellitus (the ADVANCE trial)

Lancet 2007; 370:829 - 840

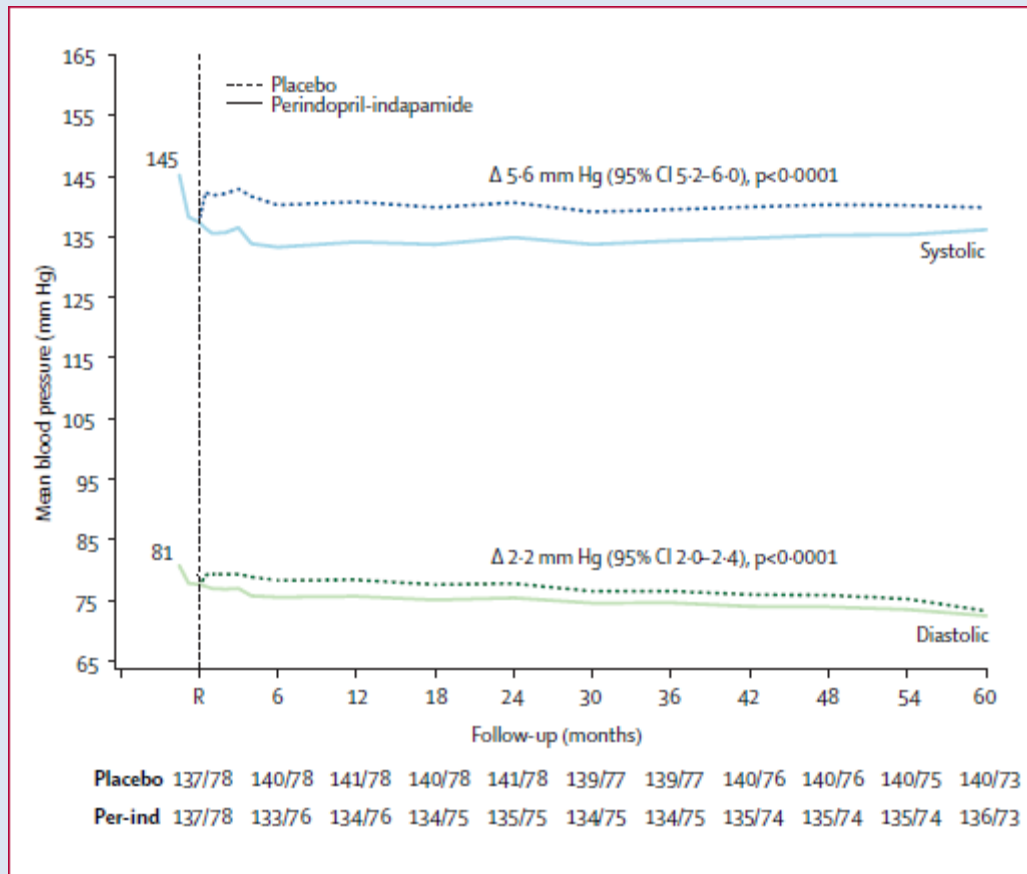


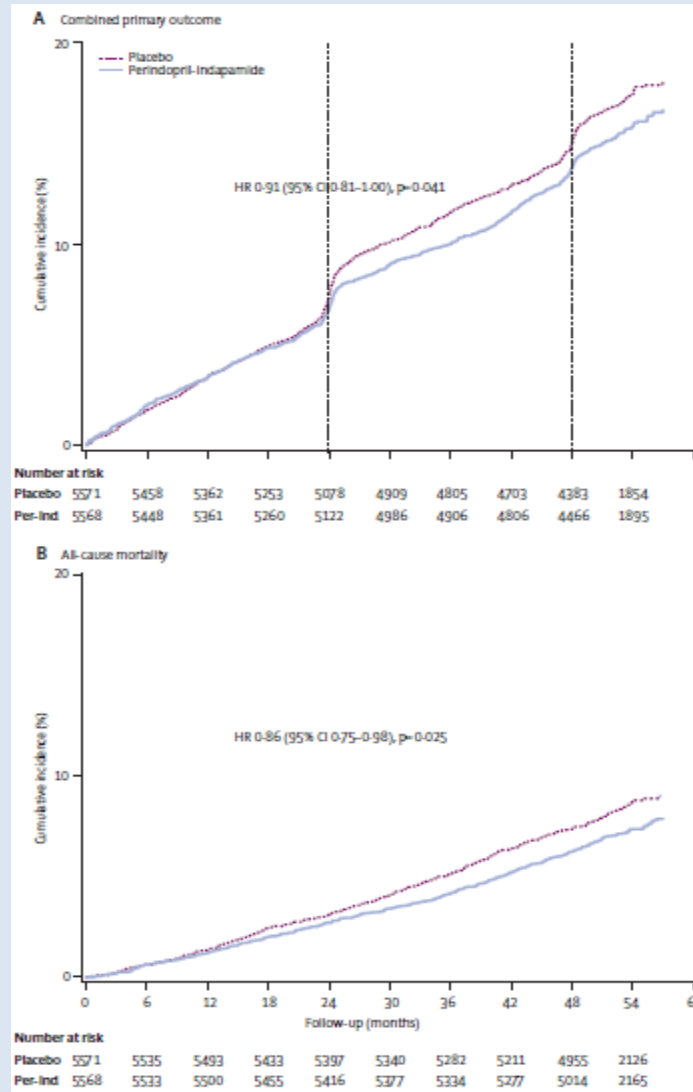
Figure 2: Mean systolic and diastolic blood pressure during run-in on active treatment and after randomisation to active treatment or placebo

Δ=average difference between randomised groups during follow-up. R=randomisation.

Per-ind=perindopril-indapamide.

Effects of a fixed combination of perindopril and indapamide on macrovascular and microvascular outcomes in patients with type 2 diabetes mellitus (the ADVANCE trial)

Lancet 2007; 370:829 - 840



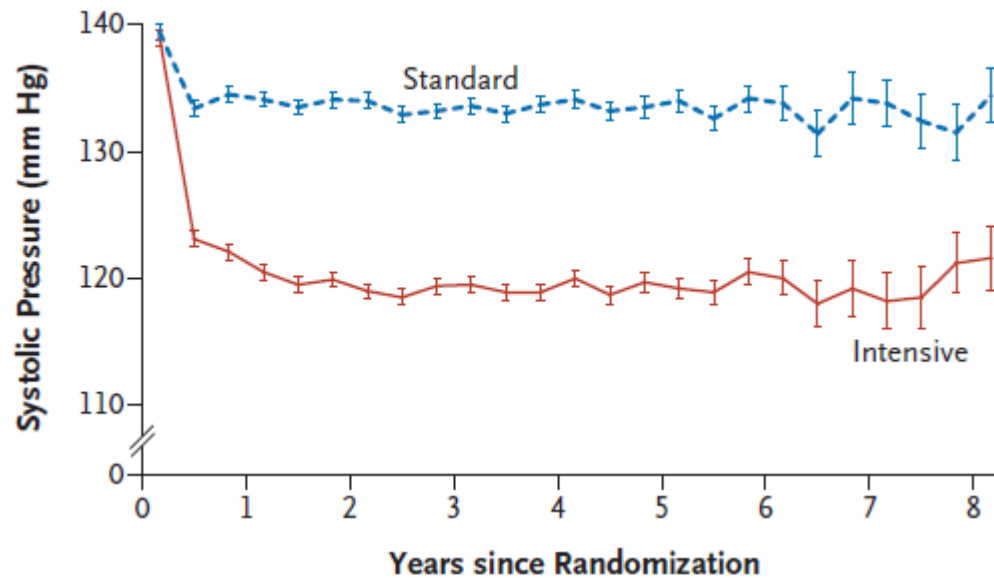
Reducción modesta de un 9% en el endpoint de enf. macro y microvasculares

No reducción de los eventos cardiovasculares

No se especificaron objetivos de PA: la media de PAS en el grupo I fue de 135 mmHg

Effects of Intensive Blood-Pressure Control in Type 2 Diabetes Mellitus The ACCORD Study Group*

N Engl J Med 2010;362:1575-85.



Mean No. of Medications Prescribed

Intensive	3.2	3.4	3.4	3.5	3.5	3.5	3.4	3.4
Standard	1.9	2.1	2.1	2.2	2.2	2.3	2.3	2.3

No. of Patients

Intensive	2174	2071	1973	1792	1150	445	156	156
Standard	2208	2136	2077	1860	1241	504	203	201

OBJETIVOS

PAS < 140

PAS < 120

Figure 1. Mean Systolic Blood-Pressure Levels at Each Study Visit.

I bars indicate 95% confidence intervals.

Effects of Intensive Blood-Pressure Control in Type 2 Diabetes Mellitus The ACCORD Study Group* N Engl J Med 2010;362:1575-85.

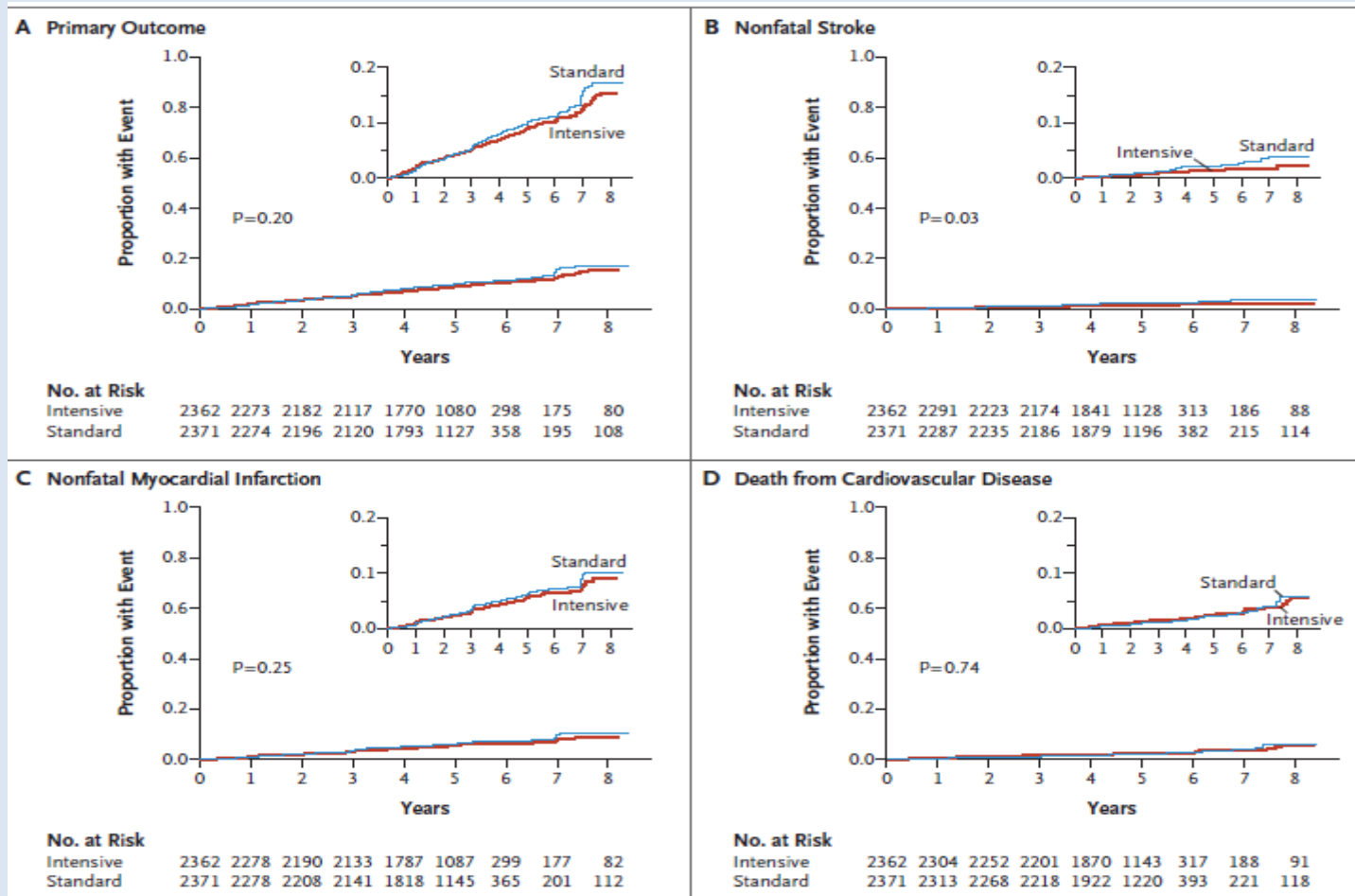


Figure 2. Kaplan–Meier Analyses of Selected Outcomes.

Shown are the proportions of patients with events for the primary composite outcome (Panel A) and for the individual components of the primary outcome (Panels B, C, and D). The insets show close-up versions of the graphs in each panel.

Effects of Intensive Blood-Pressure Control
in Type 2 Diabetes Mellitus
The ACCORD Study Group*
N Engl J Med 2010;362:1575-85.

- Reducción significativa del %
de pacientes con aumento creatinina
- Reducción significativa del %
de pacientes con $FG < 30 \text{ ml/min/1.73 m}^2$
- Reducción significativa del %
de pacientes con macroalbuminuria

¿Cuáles son las cifras de PA objetivo en el tratamiento del paciente diabético hipertenso?

- El objetivo de control de PA tradicionalmente recomendado de $< 130/80$ mmHg no se puede sostener por la evidencia actual (excepto en pacientes con nefropatía)
- El objetivo de control de la PA es de $<140/90$ mmHg

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Evidencia de ECs en prevención primaria y en prevención secundaria

Reduction in 10-year risk of major CVD endpoints (CHD death/non-fa in major statin trials, or substudies of major trials, in diabetic subject 16,032)					
Study (ref.)	CVD	Statin dose and comparator	Risk reduction (%)	Relative risk reduction (%)	Absolute risk reduction (%)
4S-DM (215)	2°	Simvastatin 20-40 mg vs. placebo	85.7 to 43.2	50	42.5
ASPEN 2° (220)	2°	Atorvastatin 10 mg vs. placebo	39.5 to 24.5	34	15
HPS-DM (216)	2°	Simvastatin 40 mg vs. placebo	43.8 to 36.3	17	7.5
CARE-DM (217)	2°	Pravastatin 40 mg vs. placebo	40.8 to 35.4	13	5.4
TNT-DM (218)	2°	Atorvastatin 80 mg vs. 10 mg	26.3 to 21.6	18	4.7
HPS-DM (216)	1°	Simvastatin 40 mg vs. placebo	17.5 to 11.5	34	6.0
CARDS (221)	1°	Atorvastatin 10 mg vs. placebo	11.5 to 7.5	35	4
ASPEN 1° (220)	1°	Atorvastatin 10 mg vs. placebo	9.8 to 7.9	19	1.9
ASCOT-DM (219)	1°	Atorvastatin 10 mg vs. placebo	11.1 to 10.2	8	0.9

Effects of Combination Lipid Therapy in Type 2 Diabetes Mellitus

The ACCORD Study Group* N Engl J Med 2010;362:1563-74.

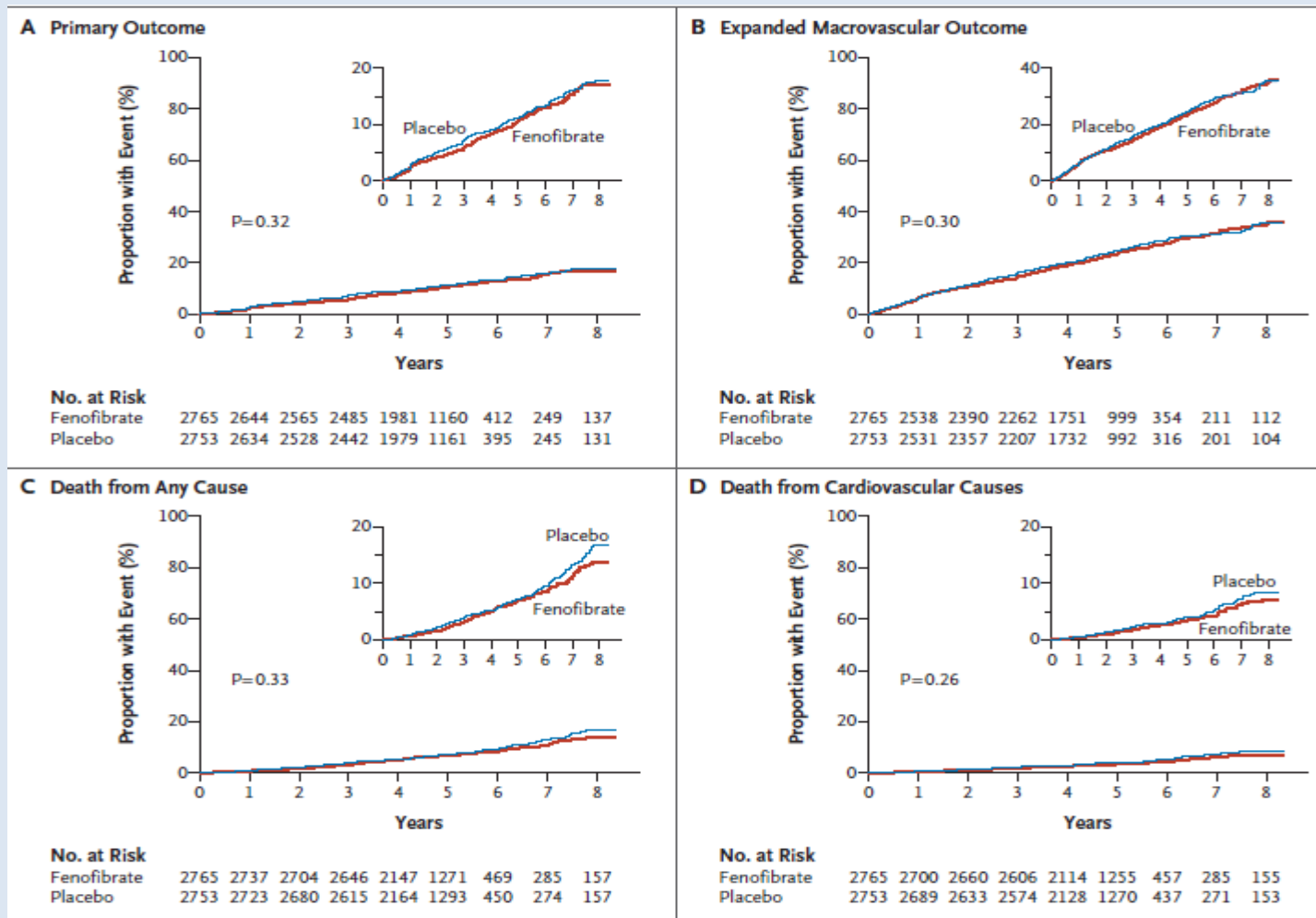


Figure 2. Kaplan–Meier Analyses of the Primary Outcome, Expanded Macrovascular Outcome, and Death.

Shown are the cumulative incidence of the primary outcome (nonfatal myocardial infarction, nonfatal stroke, or death from cardiovascular causes) (Panel A), the expanded macrovascular outcome (a combination of the primary outcome plus revascularization or hospitalization for congestive heart failure) (Panel B), and death from any cause (Panel C) or from cardiovascular causes (Panel D) during follow-up. The insets show close-up versions of the graphs in each panel.

¿Cuáles son las cifras de lípidos objetivo en el tratamiento del paciente diabético?

- El objetivo de control del cLDL es < 100 mg/dl
- En pacientes con enf.CV es recomendable un objetivo < 70 mg/dl (diabéticos de alto riesgo ?)
- Si no se llegan a estos objetivos con el tratamiento con estatinas a las dosis máximas toleradas una reducción del cLDL en un 30-40% del valor inicial es un objetivo alternativo.
- Se recomienda un nivel de TG < 150 mg/dl, cHDL en hombres > 40 y en mujeres > 50

¿Es el riesgo cardiovascular de los pacientes diabéticos equiparable al riesgo de los que han sufrido un infarto agudo de miocardio?

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¿Cuáles son las cifras de PA objetivo en el tratamiento del paciente diabético hipertenso?

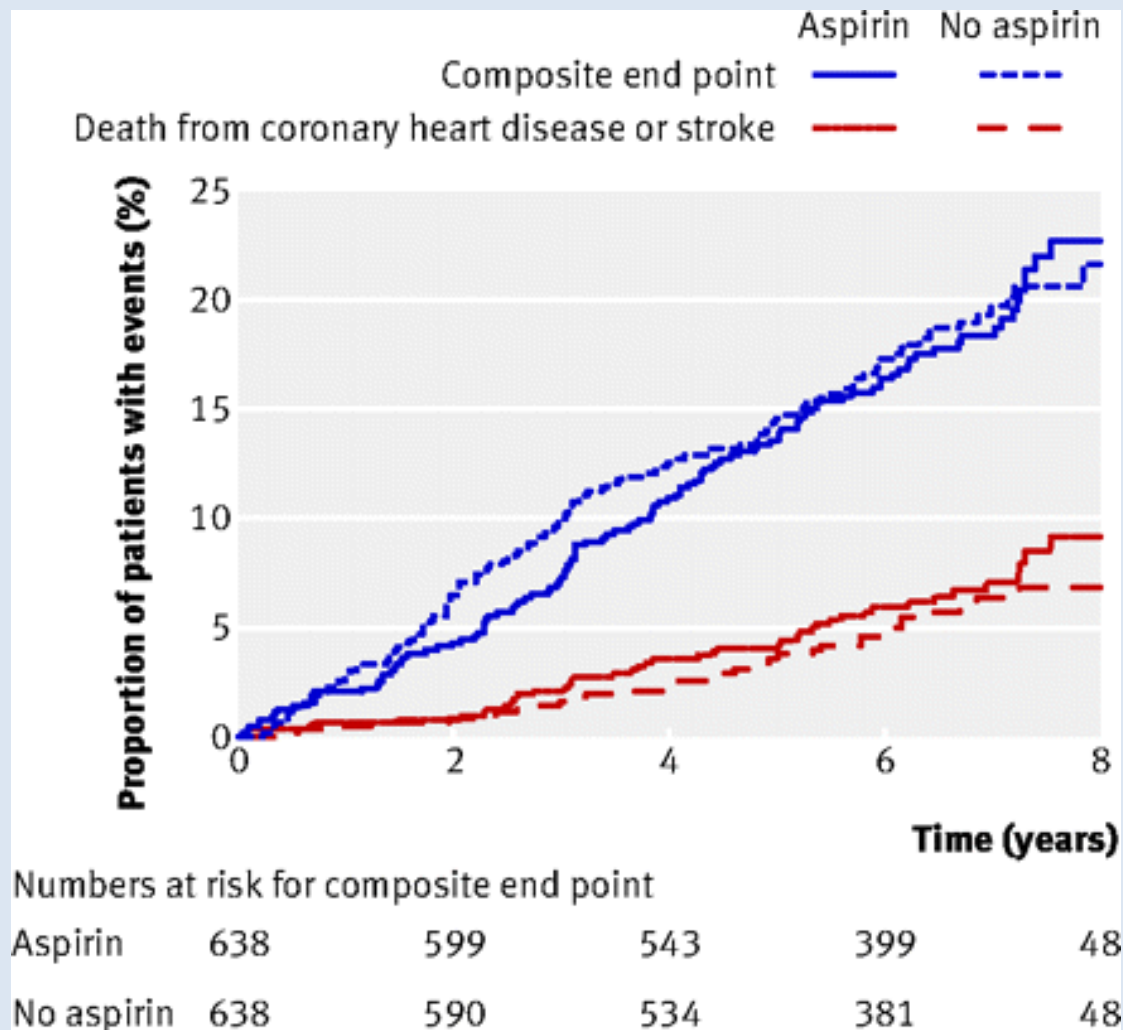
¿Cuáles son las cifras de lípidos objetivo en el tratamiento del paciente diabético?

¿Deben tratarse con ácido acetil salicílico las personas diabéticas?

Estudio POPADAD

The prevention of progression of arterial disease and diabetes (POPADAD) trial: factorial randomised placebo controlled trial of aspirin and antioxidants in patients with diabetes and asymptomatic peripheral arterial disease

Kaplan-Meier estimates in aspirin and no aspirin groups of proportion of patients who experienced the composite end point of death from coronary heart disease or stroke, non-fatal myocardial infarction or stroke, or above ankle amputation for critical limb ischaemia; and death from coronary heart disease or stroke



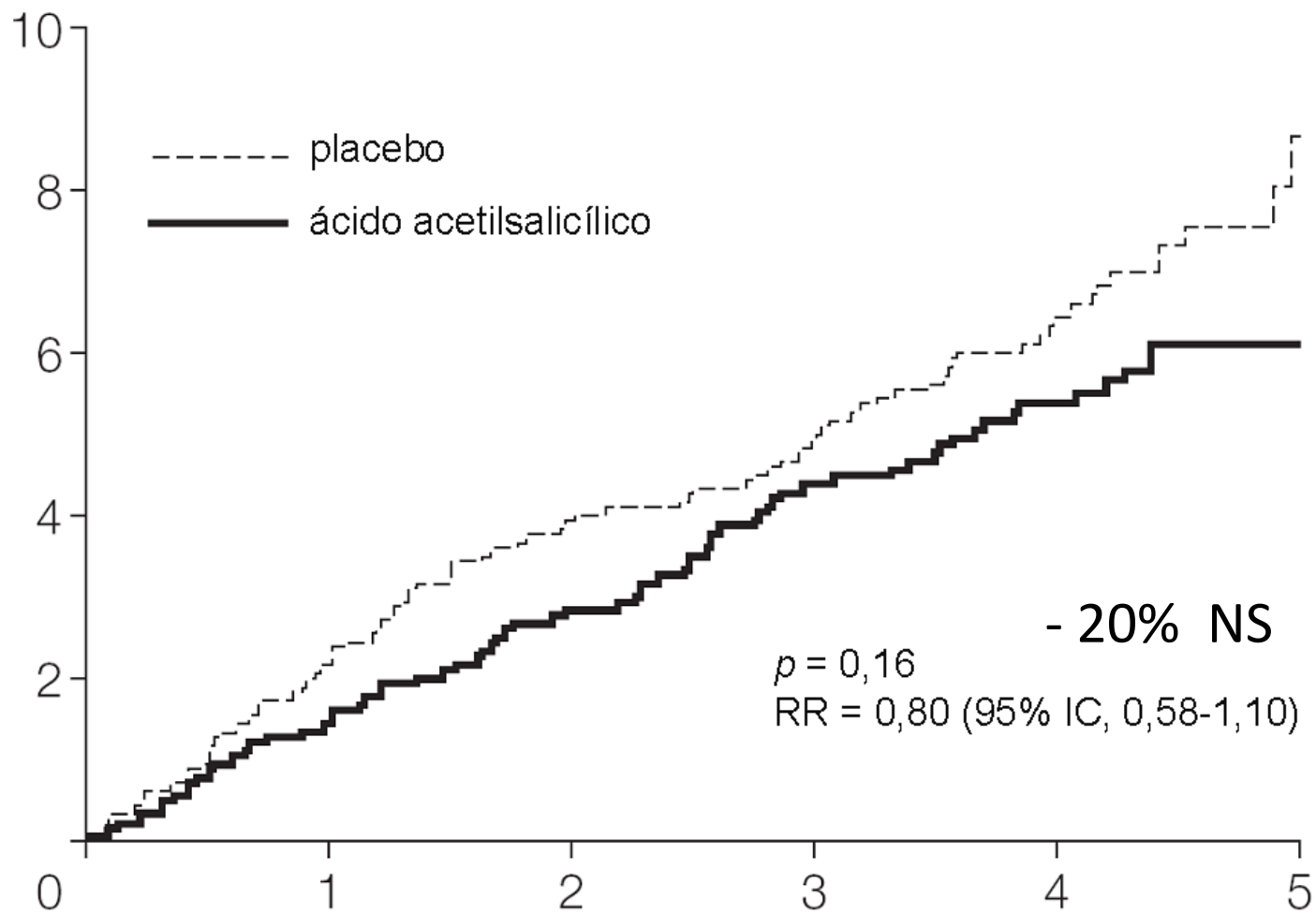
Belch, J. et al. *BMJ* 2008;337:a1840

Estudio JPAD

Low-dose aspirin for primary prevention of atherosclerotic events in patients with type 2 diabetes: a randomized controlled trial.

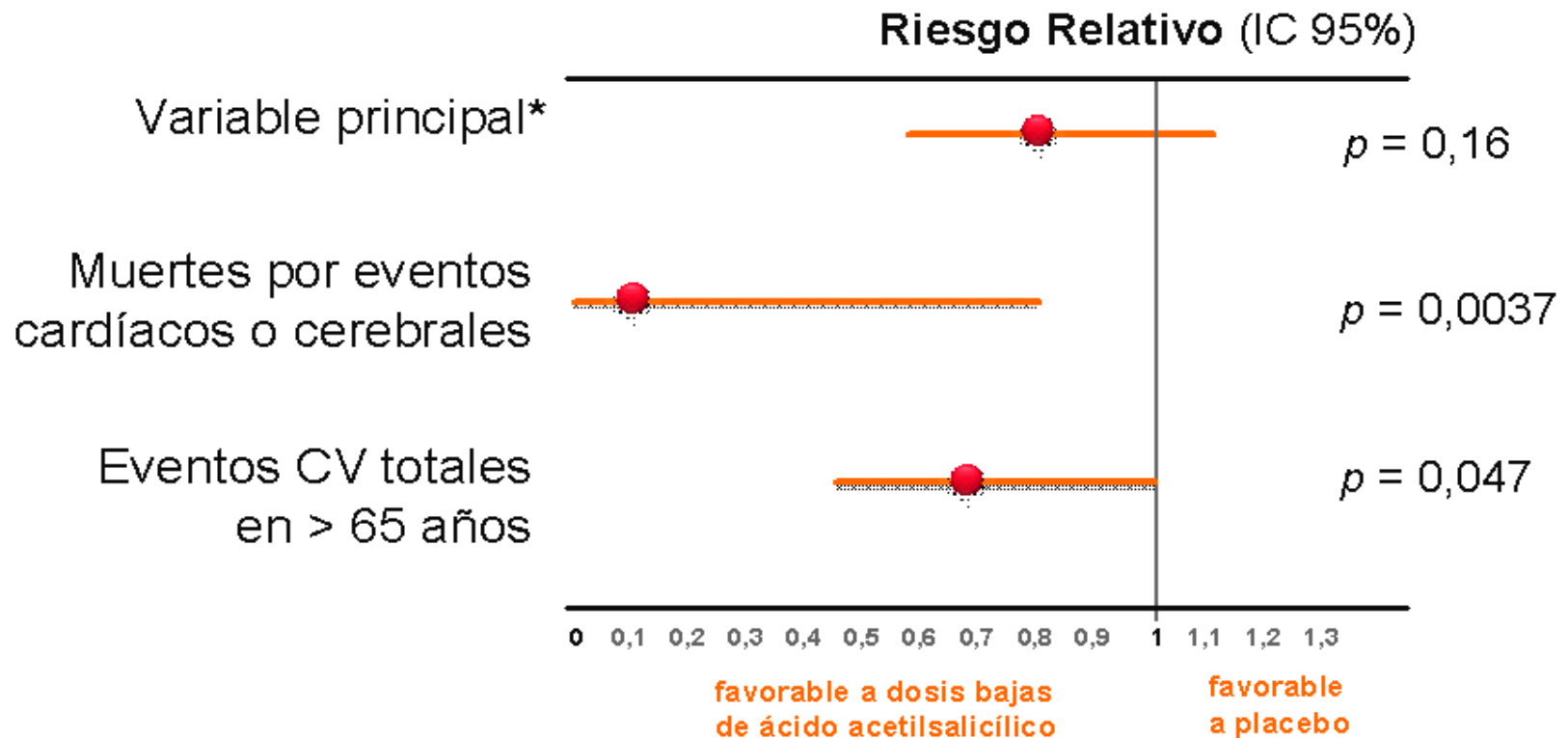
n = 2539 patients with type 2 DM

% Total de eventos ateroscleróticos según el grupo de tratamiento



RR = riesgo relativo ; IC = intervalo de confianza

Riesgo relativo para los objetivos primarios y secundarios en el análisis por grupos de edad



* Compuesta por la incidencia de muerte súbita; muerte por causa coronaria, cerebrovascular, o aórtica; IM no fatal, angina inestable, angor de esfuerzo de nueva aparición; ictus isquémico o hemorrágico no fatal; TIA; o enfermedad vascular o aórtica no fatal

Effect of aspirin therapy on primary prevention of major cardiovascular events, myocardial infarction, stroke, death from cardiovascular causes, and all cause mortality in participants with diabetes (6 ENSAYOS CLÍNICOS).

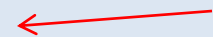
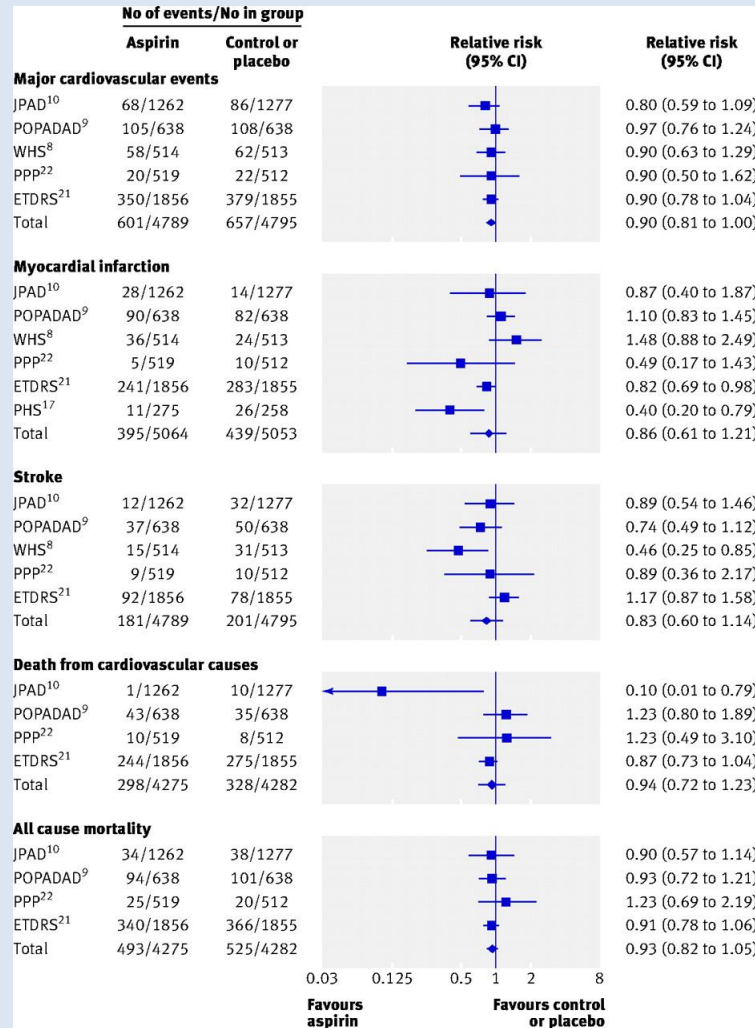
Eventos CV

IM

Ictus

Muertes CV

Mortalidad total

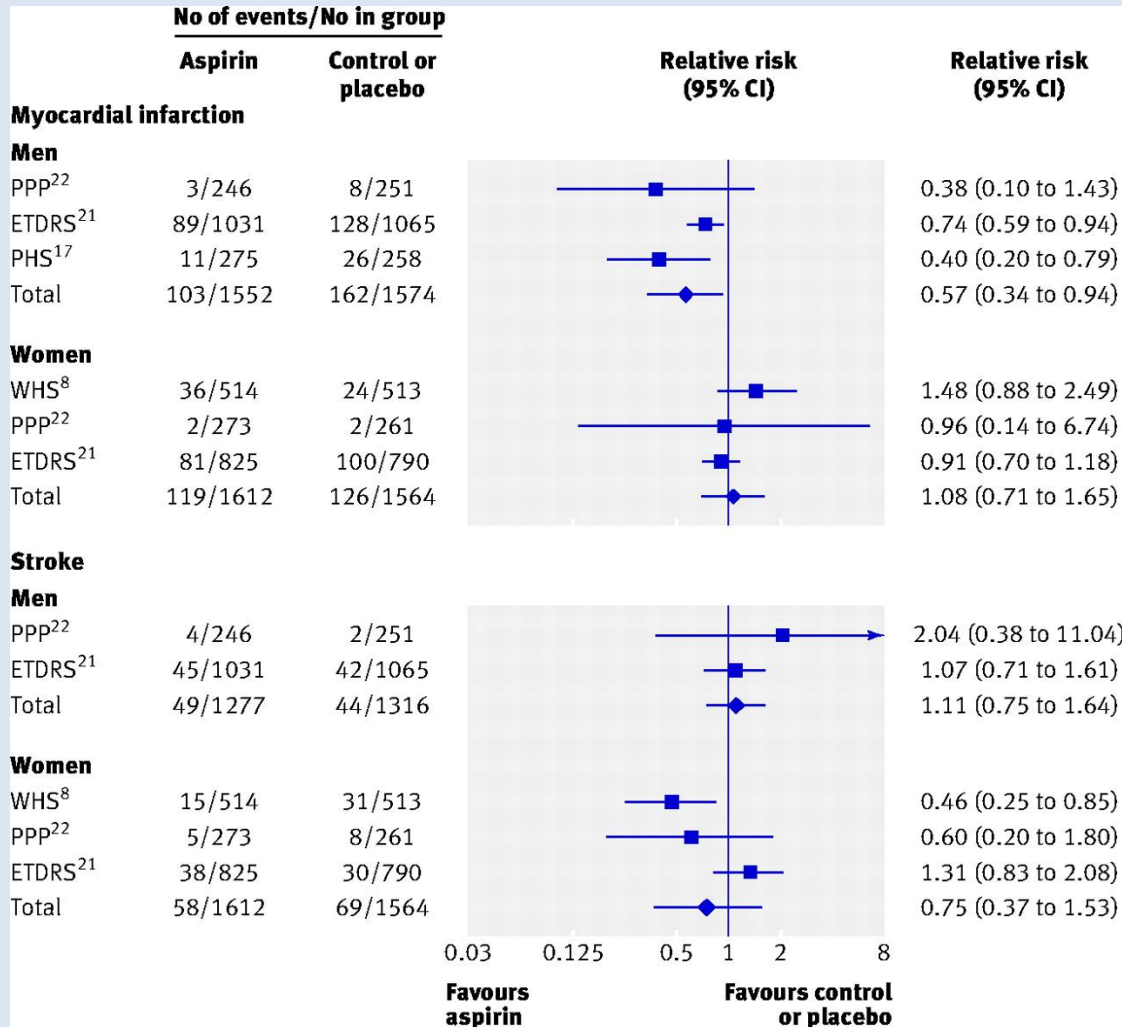


RRR 10%
RAR 1.2%
NNT < 100

De Berardis, G. et al. BMJ 2009;339:b4531



Effect of aspirin therapy on primary prevention of myocardial infarction and stroke among men and women with diabetes.



← RRR 43%
RAR 3.5%
NNT < 30

De Berardis, G. et al. BMJ 2009;339:b4531



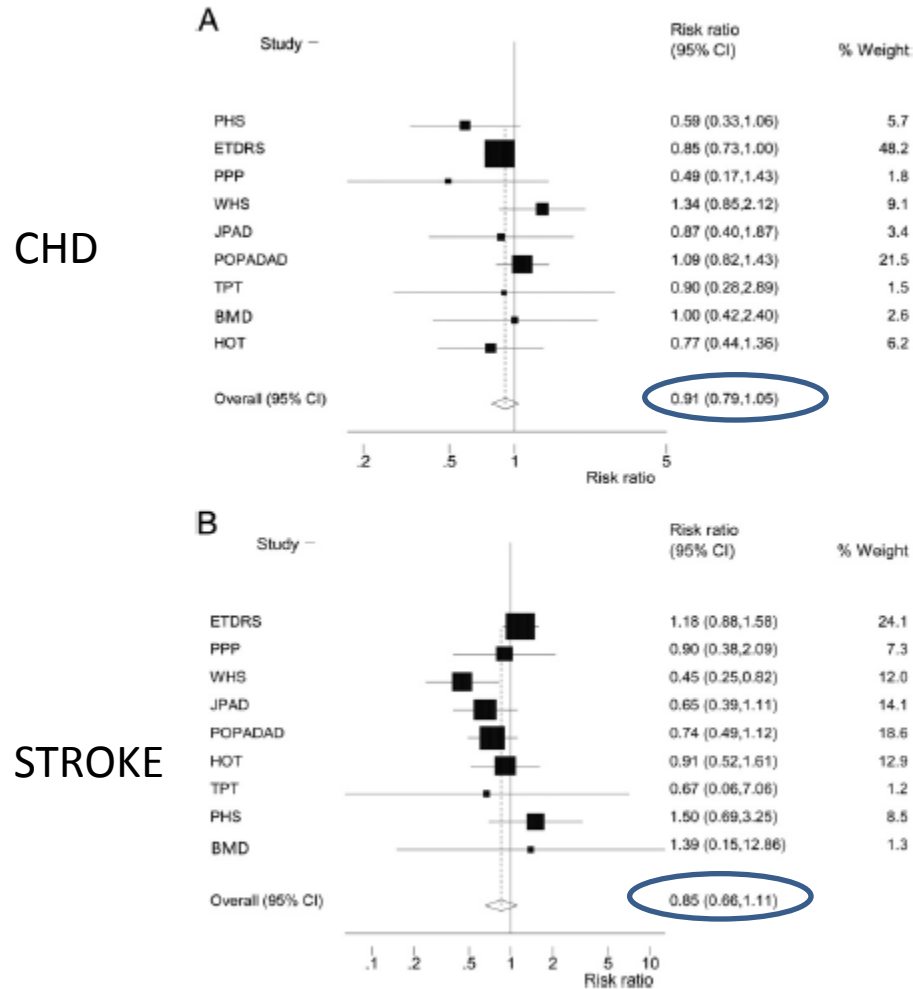


Figure 1. Meta-Analysis of Trials Examining the Effects of Aspirin on Risk of Cardiovascular Disease Events in Patients With Diabetes

A: Effect of aspirin on coronary heart disease events. Tests for heterogeneity: $\chi^2=8.71$, $P=0.367$, $I^2=8.2\%$. B: Effect of aspirin on risk of stroke in patients with diabetes. Tests for heterogeneity: $\chi^2=12.48$, $P=0.131$, $I^2=35.9\%$. BMD indicates British Medical Doctors (11); CI, confidence interval; ETDRS, Early Treatment of Diabetic Retinopathy Study (18); HOT, Hypertension Optimal Treatment (14); JPAD, Japanese Primary Prevention of Atherosclerosis with aspirin for Diabetes (9); PHS, Physicians' Health Study (12); POPADAD, Prevention of Progression of Arterial Disease and Diabetes (10); PPP, Primary Prevention Project (15); TPT, Thrombolysis Prevention Trial (13); and WHS, Women's Health Study (17).

FUTUROS ENSAYOS CLÍNICOS

ACCEPT-D (Aspirin and Simvastatin Combination for CV events Prevention Trial in Diabetes)

Ensayo en prevención primaria (ITALIA)

Diabéticos sin enfermedad vascular

Tratados con Simvastatina

Grupos: AAS+SIMVA / SIMVA sola

Tiempo de seguimiento: 5 años

Pacientes a reclutar: 4700

Endpoints: total eventos CV

FUTUROS ENSAYOS CLÍNICOS

ASCEND

(A study of CV events in Diabetes)

Ensayo en prevención primaria

Diabéticos sin enfermedad vascular

Grupos: AAS+AG-OMEGA3/AAS sola

Tiempo de seguimiento: 5 años

Pacientes a reclutar: 10,000

Endpoints: total eventos CV

Aspirin for Primary Prevention of Cardiovascular Events in People With Diabetes

New Joint Position Statement of the ACC/ADA/AHA

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association
Learn and Live...

Aspirin for Primary Prevention of Cardiovascular Events in People With Diabetes. A Position Statement of the American Diabetes Association, a Scientific Statement of the American Heart Association, and an Expert Consensus Document of the American College of Cardiology Foundation
Michael Pignone, MD, MPH, FACP*, John A. Colwell, MD, PhD, MACP, Mary Cushman, MD, MSc, Silvio E. Inzucchi, Debabrata Mukherjee, Robert S. Rosenson, Craig D. Williams, Peter W. Wilson and M. Sue Kirkman

Circulation published online May 27, 2010;
DOI: 10.1161/CIR.0b013e3181e3b133
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75214
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Reviews/Commentaries/ADA Statements

Aspirin for Primary Prevention of Cardiovascular Events in People With Diabetes

A position statement of the American Diabetes Association, a scientific statement of the American Heart Association, and an expert consensus document of the American College of Cardiology Foundation

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history of CVD, hypertension, smoking, dyslipidemia, or albuminuria (8). These recommendations were derived from several older trials that included relatively small numbers of patients with diabetes. Results of two recent randomized controlled

EXPERT CONSENSUS DOCUMENT

Aspirin for Primary Prevention of Cardiovascular Events in People With Diabetes

A Position Statement of the American Diabetes Association, a Scientific Statement of the American Heart Association, and an Expert Consensus Document of the American College of Cardiology Foundation

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- Aspirin (75–162 mg/day) para adultos con diabetes en prevención primaria que tengan un riesgo de enfermedad coronaria >10% a los 10 años y que no tengan riesgo de hemorragia.

¿Es el riesgo cardiovascular de los pacientes diabéticos equiparable al riesgo de los que han sufrido un infarto agudo de miocardio?

NO

SI, si 10 años evolución

¿Cuáles son las cifras objetivo de HbA_{1c}?

< 7%

7-8% (en pacientes con enf CV)

¿Cuáles son las cifras de PA objetivo en el tratamiento del paciente diabético hipertenso?

<140/90 mmHg

¿Cuáles son las cifras de lípidos objetivo en el tratamiento del paciente diabético?

LDL < 100 mg/dl

< 70 mg/dl (en prevención secundaria)

¿Deben tratarse con ácido acetil salicílico las personas diabéticas?

NO todos. SI, si riesgo > 10%