

# Post ESC 2012

## «Lo mejor en Enfermedad Arterial Coronaria»

Xavier García-Moll Marimón  
Hospital de la Santa Creu i Sant Pau  
Barcelona



SOCIEDAD  
ESPAÑOLA DE  
CARDIOLOGÍA

# Estudios relevantes presentados en ESC2012 (orden alfabético)

- ATLAS 2 STEMI
- CARDIA
- CLARIFY
- CORE320
- DeFACTO
- Definición infarto
- FAME II
- FAST MI
- Guías STEMI
- IABP-SHOCK
- PROTECT
- TRA2P
- TRILOGY
- WOEST

# Estudios de imagen aplicados a cardiopatía isquémica

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- CORE320
- DeFACTO

# **Estudios relevantes a nivel epidemiológico**

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- FAST MI

# FAST MI. Características

- **Objetivo:**
  - Valorar los cambios en la mortalidad a 30 días en pacientes con IAMEST a lo largo de 4 cortes temporales separados por 5 años en Francia y las características en relación con cambios en las características de los pacientes y su manejo precoz
- **Pacientes:**
  - IAMSEST/IAMEST <48h de evolución en los 4 cortes. 6707 IAMEST.

# FAST MI. Resultados

## Cambios en las características basales 1995-2010

	1995	2000	2005	2010	P value
→ Age (years)	66.2±14.0	64.5±14.6	64.0±14.7	63.3±14.5	<0.001
Sex (% W)	28.1	27.1	28.4	24.7	0.06
Risk factors					
Hypertension	43.8	43.6	49.2	47.0	0.006
Hypercholesterolemia	34.8	39.0	43.4	39.3	0.001
Diabetes mellitus	15.8	19.7	18.7	16.5	0.92
Current smoking	32.0	35.3	37.2	40.9	<0.001
Obesity	14.3	16.3	20.8	20.1	<0.001
Cardiovascular history					
Previous MI	14.6	15.0	11.2	10.9	<0.001
Previous PCI	-	7.5	8.7	10.2	<0.001
Previous CABG	-	2.7	2.1	5.6	<0.001
Stroke or TIA	6.2	4.2	5.6	4.0	<0.001
Peripheral artery disease	9.7	7.9	5.3	4.8	<0.001
History of heart failure	6.4	4.6	3.5	2.4	<0.001
Co-morbidities					
Chronic kidney disease	-	3.6	3.1	2.4	0.05

# FAST MI. Resultados

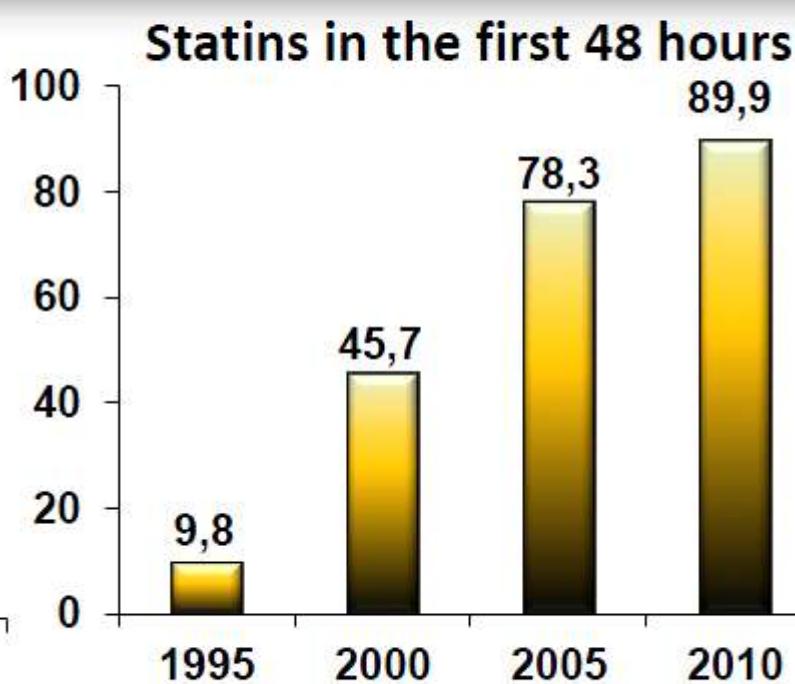
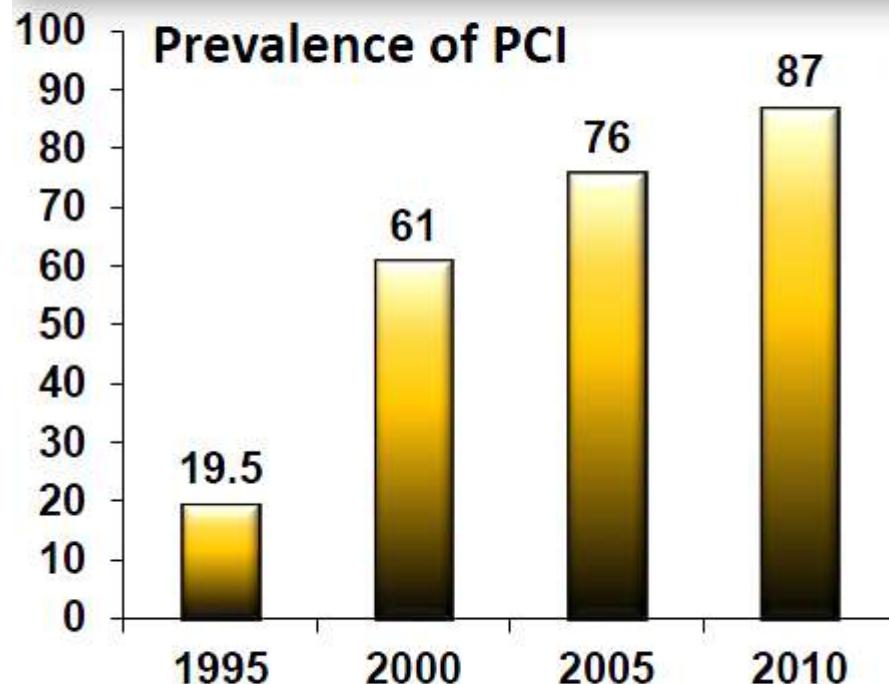
## IAMEST. Cambios en la presentación clínica

	1995	2000	2005	2010	P value
<b>Location of STEMI</b>					
• Anterior	636 (41)	746 (41)	647 (40)	657 (38)	0.07
<b>Initial Killip class</b>					
• I	-	79.7	81.9	84.6	
• II	-	13.1	11.5	9.9	0.001
• III	-	4.3	4.5	3.1	
• IV	-	2.8	2.1	2.3	
<b>Admission heart rate</b>	-	78 ± 19	78 ± 19	78 ± 21	0.90
<b>Admission SBP</b>	-	132 ± 27	135 ± 28	141 ± 28	<0.001
<b>EMMACE risk score</b>	-	0.188	0.176	0.156	<0.001
<b>2010 risk score</b>	0.053	0.048	0.048	0.045	<0.001

# FAST MI. Resultados

Disminución de la mortalidad independientemente de la estrategia inicial de reperfusión

	2000	2005	2010
Time to FMD (min)	120	90	74



PCI after lysis

15%

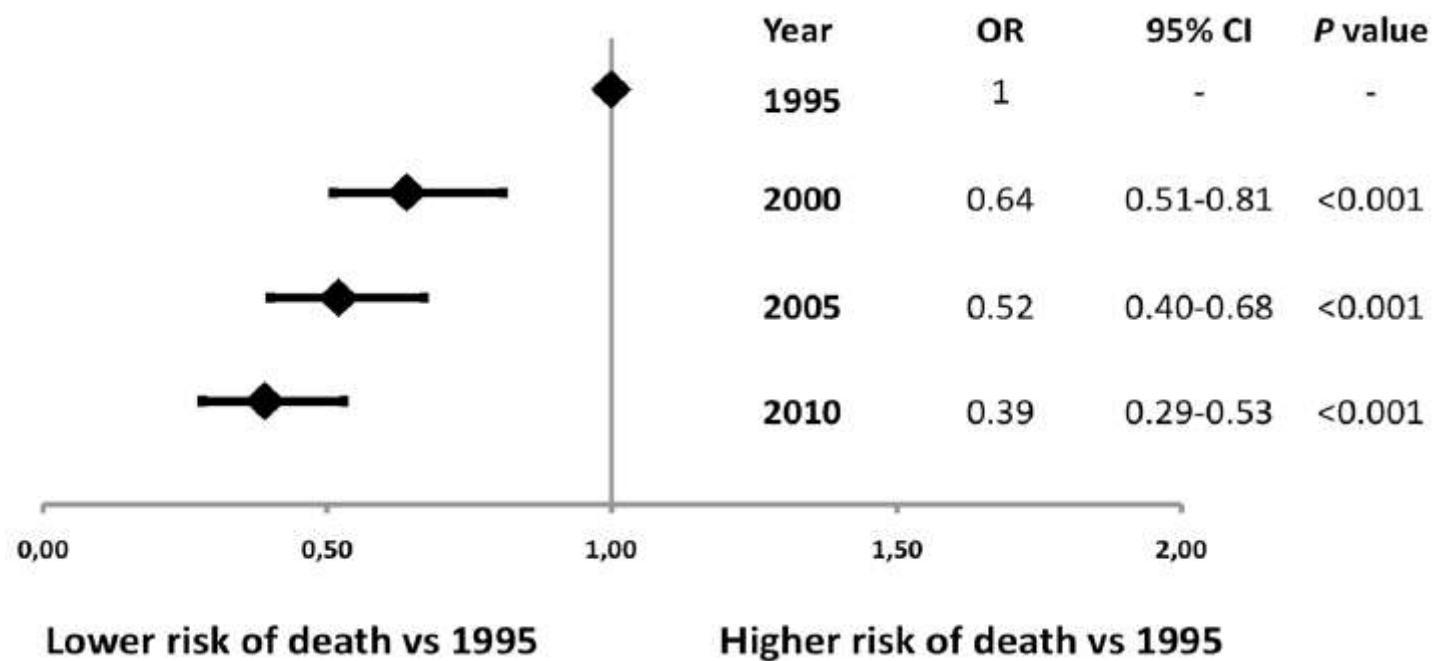
60%

84%

87%

# FAST MI. Resultados

## Mortalidad ajustada a 30 días



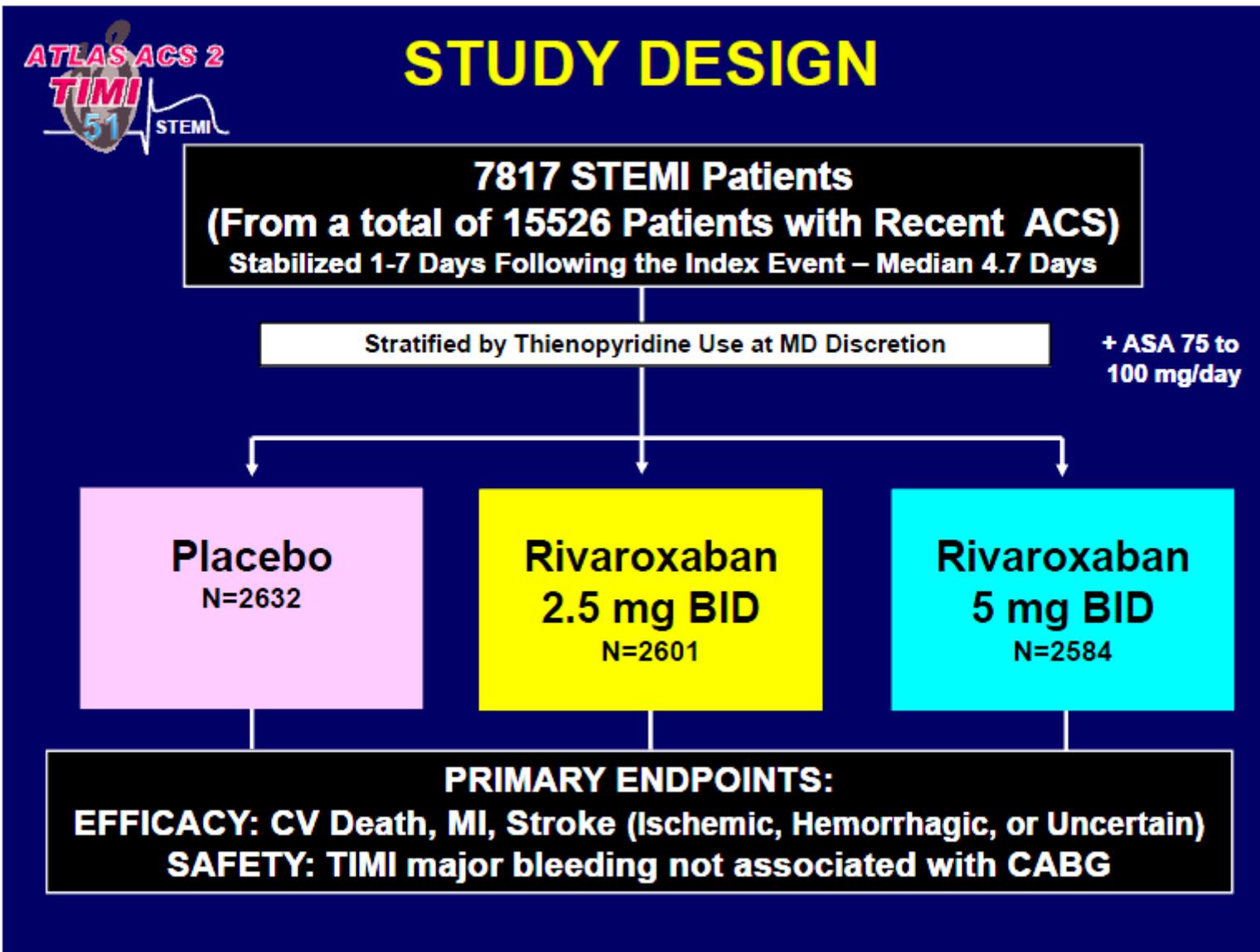
Ajustada por edad, sexo, IMC, factores de riesgo, antecedentes previos, uso y tipo de reperfusión.  
La reducción de mortalidad se consigue en todos los grupos de tratamiento (sin reperfusión, con fibrinolisis, con ICPP).

# **Estudios relevantes a nivel de tratamiento en SCA**

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- ATLAS 2 STEMI
- TRA2P en pacientes con IAM previo
- IABP-SHOCK
- TRILOGY

# ATLAS 2 STEMI



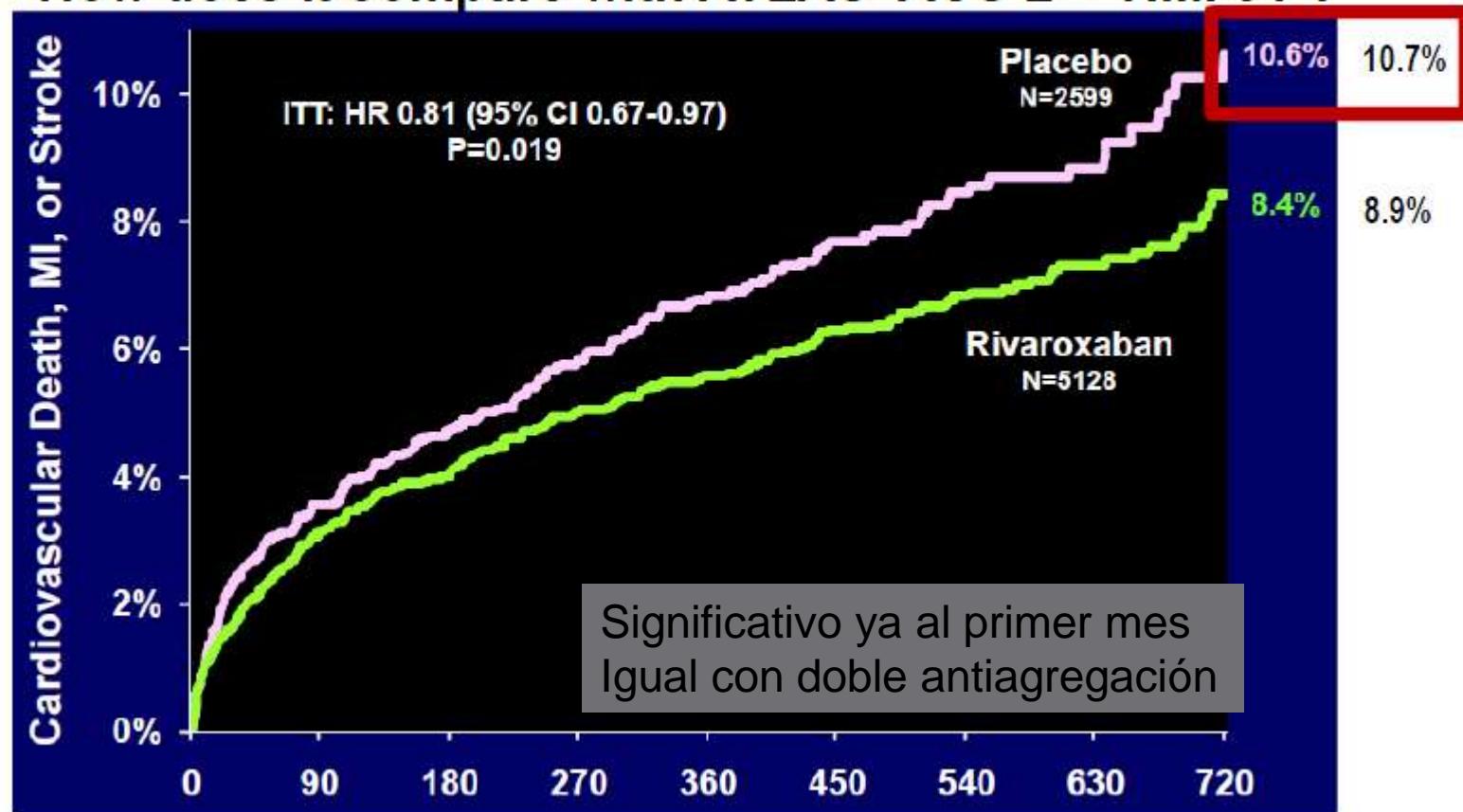
# ATLAS 2 STEMI. Resultados



## ATLAS ACS 2-TIMI 51: STEMI

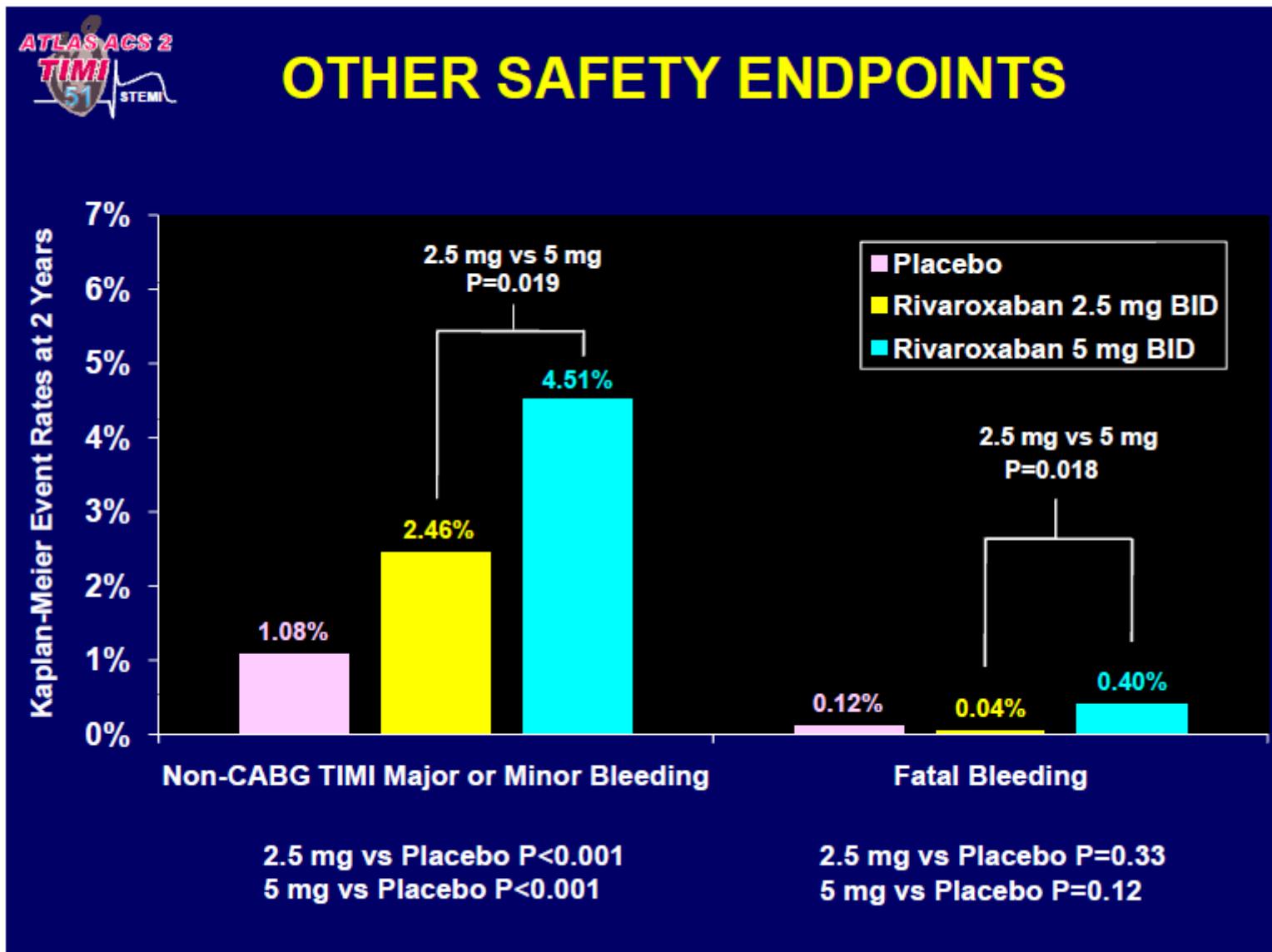


How does it compare with ATLAS ACS 2 – TIMI 51 ?



IAMEST/AI tienen el mismo riesgo que IAMCEST

# ATLAS 2 STEMI. Resultados





*Vorapaxar for Secondary Prevention in  
Patients with Prior Myocardial Infarction*

NCT00526474; Trial funded by Merck

**Benjamin M. Scirica, MD, MPH**

*On behalf of the TRA 2°P-TIMI 50 Steering Committee  
and Investigators*

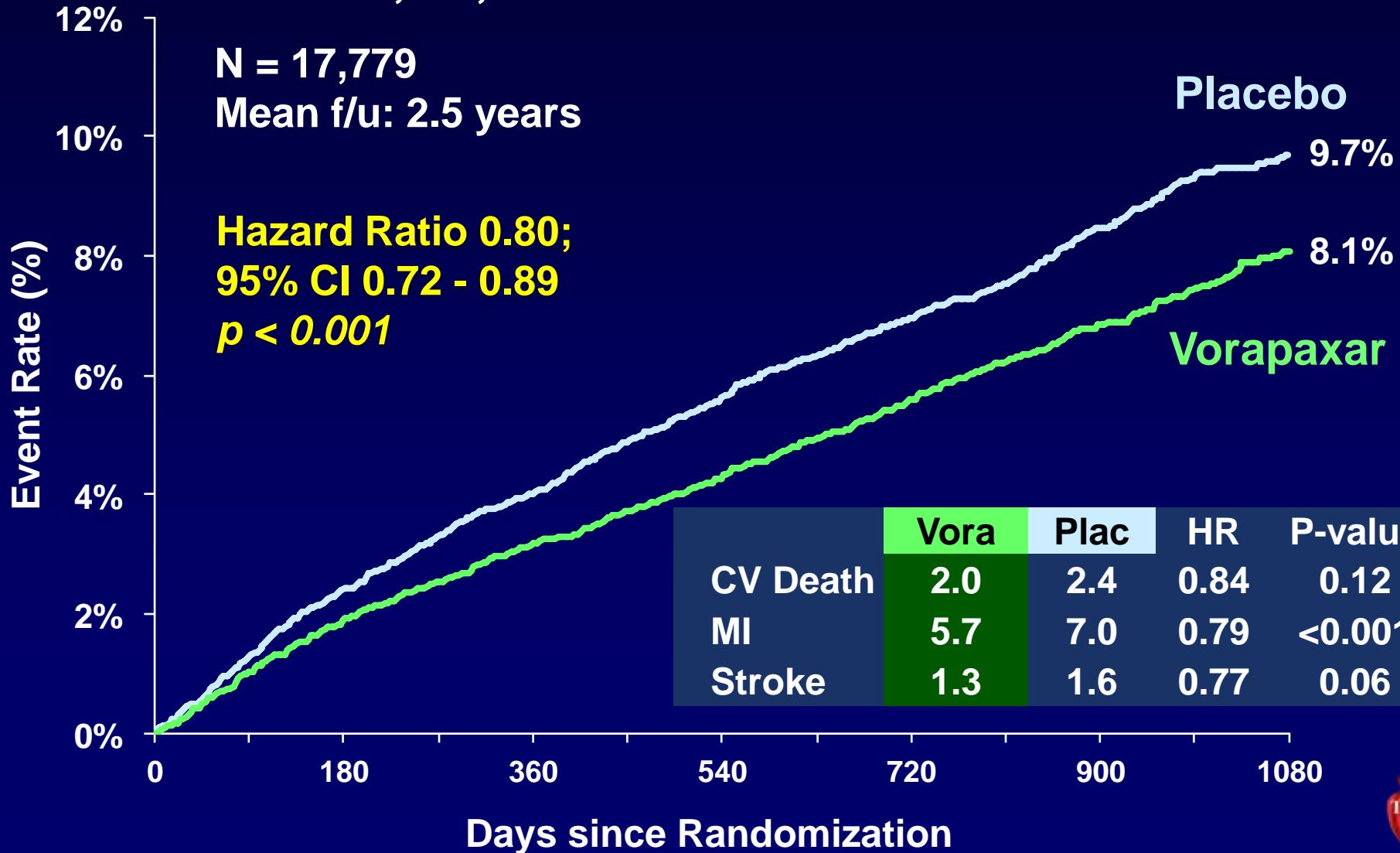
Clinical Trial Update  
European Society of Cardiology  
Munich, August 26, 2012



# Primary Efficacy Evaluation

Prior MI Cohort

## CV Death, MI, or Stroke



# Bleeding in Select Subgroups

Prior MI Cohort

GUSTO Mod/Severe  
Bleeding

■ Placebo

■ Vorapaxar

Age

Weight

Prior  
Stroke/TIA

Any High Risk  
Feature

<75 yr

≥75 yr

8

3,0

1,9

7,1

4,6

>60 kg

<60 kg

6

8

6

3,2

2,1

6,0

4

3,2

2,1

2

Yes

8,0

No

3,4

0

3-yr Kaplan-Meier rates (%)

Yes

6,9

3,9

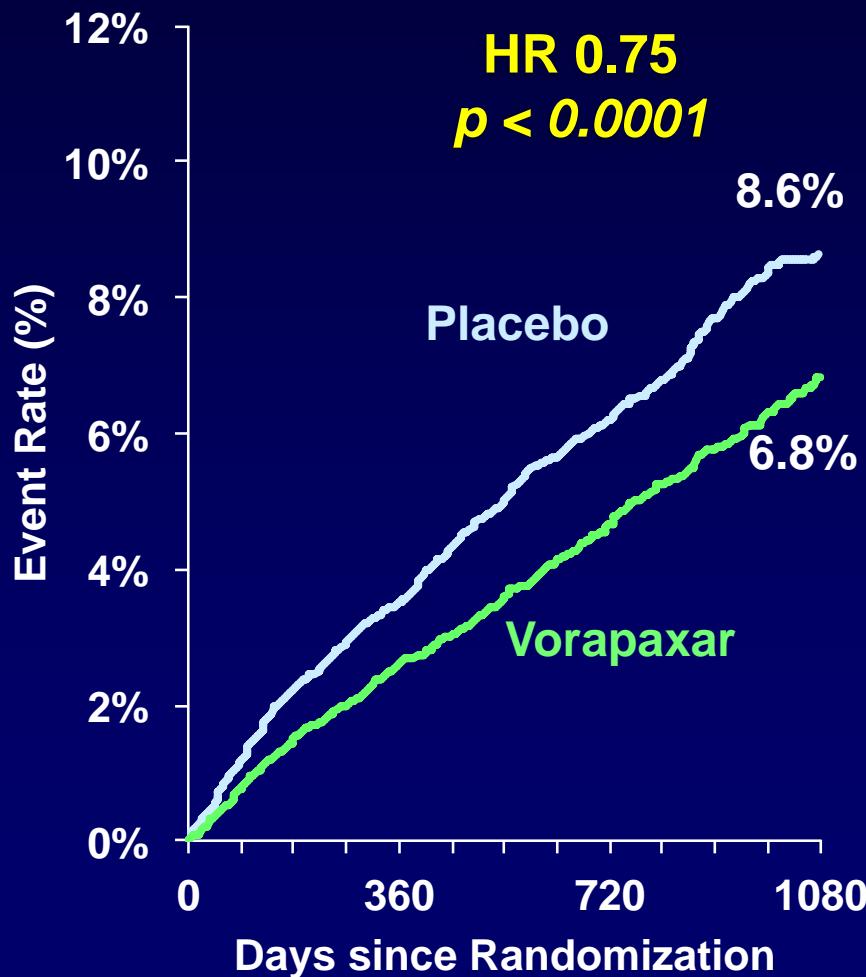
No

2,7

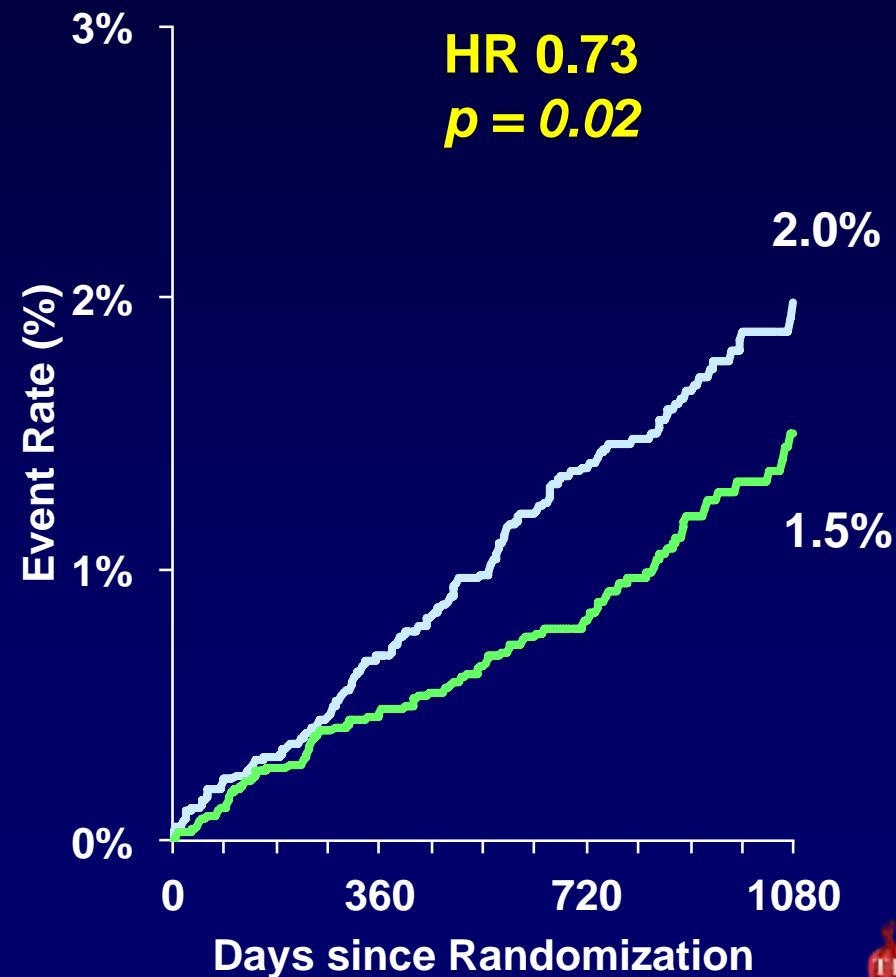
1,8



### CV Death, MI, or Stroke



### CV Death



## Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock



# Randomized comparison of intraaortic balloon counterpulsation versus

## optimal medical therapy in addition to early revascularization in acute myocardial infarction complicated by cardiogenic shock

Holger Thiele, MD

Uwe Zeymer, MD; Franz-Josef Neumann, MD; Miroslaw Ferenc, MD; Hans-Georg Olbrich, MD; Jörg Hausleiter, MD; Gert Richardt, MD; Marcus Hennersdorf, MD; Klaus Empen, MD; Georg Fuernau, MD; Steffen Desch, MD; Ingo Eitel, MD; Rainer Hambrecht, MD; Jörg Fuhrmann, MD; Michael Böhm, MD; Henning Ebelt, MD; Steffen Schneider, PhD; Gerhard Schuler, MD; and Karl Werdan, MD, for the IABP-SHOCK II Trial Investigators

on behalf of the **IABP-SHOCK II Trial** Investigators

University of Leipzig – Heart Center

# Patient Characteristics

	IABP (n=301)	Control (n=299)
Age (years); median (IQR)	70 (58-78)	69 (58-76)
Male sex; n (%)	202 (67.1)	211 (70.6)
Current Smoking; n/total (%)	96/295 (32.5)	108/299 (36.1)
Hypertension; n/total (%)	213/296 (72.0)	199/299 (66.6)
Hypercholesterolemia; n/total (%)	122/295 (41.4)	105/299 (35.1)
Diabetes mellitus; n/total (%)	105/297 (35.4)	90/299 (30.1)
Prior myocardial infarction; n/total n (%)	71/300 (23.7)	61/299 (20.4)
Fibrinolysis < 24 h before randomization; n/total (%)	28/301 (9.3)	20/299 (6.7)
STEMI/LBBB; n/total (%)	200/300 (66.7)	212/298 (71.1)
NSTEMI; n/total (%)	96/300 (32.0)	81/298 (27.2)
Resuscitation before randomization; n/total (%)	127/301 (42.2%)	143/299 (47.8)
Signs of impaired organ perfusion; n/total (%)		
Altered mental status	215/300 (71.7)	232/299 (77.6)
Cold, clammy skin and extremities	257/300 (85.7)	245/299 (81.9)
Oliguria	90/300 (30.0)	99/299 (33.1)
Serum lactate >2.0 mmol/l	226/300 (75.3)	218/298 (73.2)
Creatinine clearance (ml/min); median (IQR)	60.7 (43.4-86.6)	56.8 (39.7-78.1)
Infarct related artery; n/total (%)		
LAD	132/293 (45.1)	121/293 (41.3)
LCX	55/293 (18.8)	57/293 (19.5)
RCA	73/293 (24.9)	79/293 (27.0)
Left main	26/293 (8.9)	28/293 (9.6)
Bypass graft	7/293 (2.4)	8/293 (2.7)
Multivessel disease; n/total (%)	235/296 (79.4)	228/293 (77.9)
Left ventricular ejection fraction (%); median (IQR)	35 (25-45)	35 (25-45)

## Results

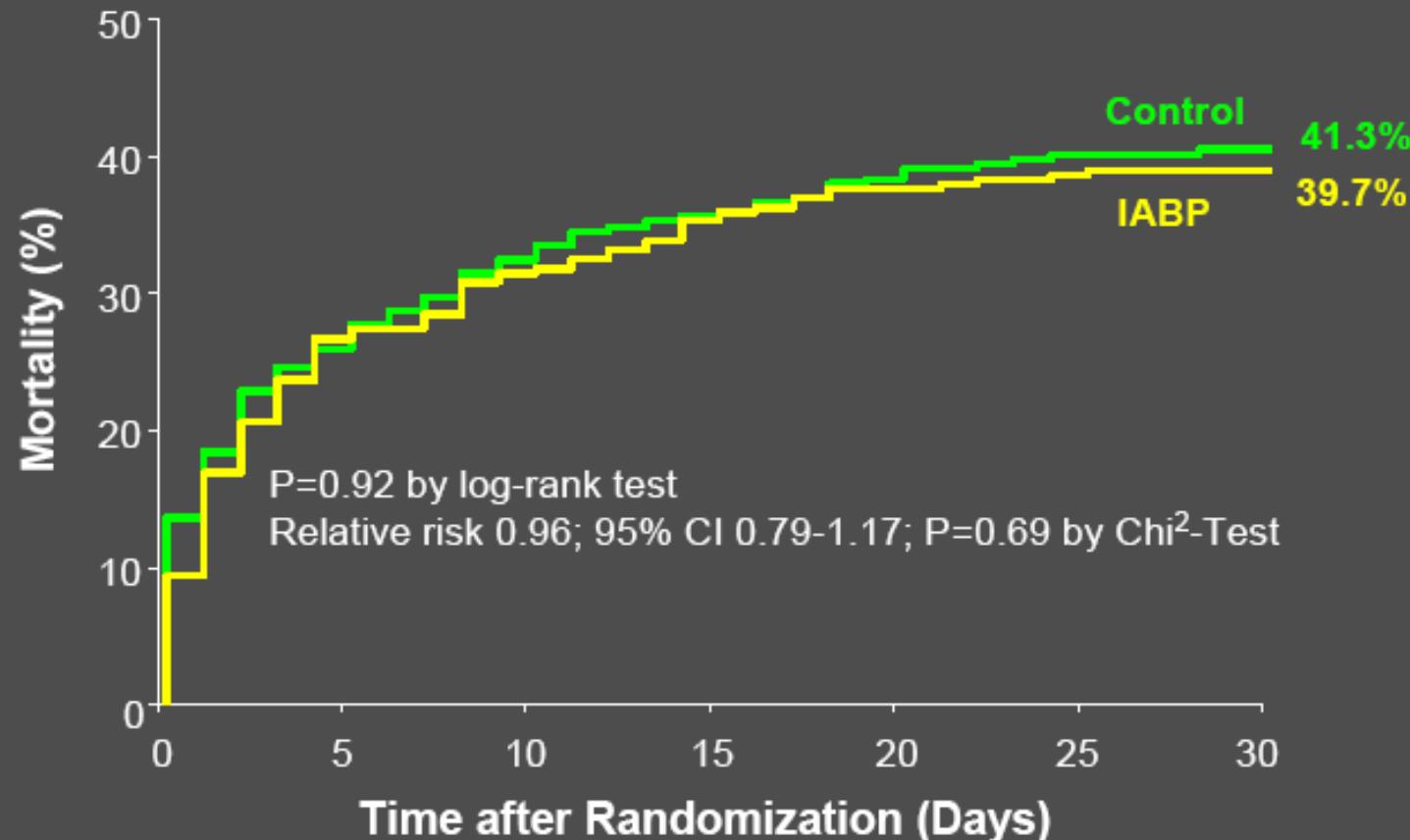
## Treatment + Process of Care Outcomes

Variable	IABP (n=301)	Control (n=299)	p
Primary PCI; n/total (%)	287/301 (95.3)	288/299 (96.3)	0.55
Stent implanted; n/total (%)	273/301 (90.7)	266/299 (89.0)	0.48
Drug-eluting stent; n/total (%)	126/301 (41.9)	123/299 (41.1)	0.86
Immediate PCI of non-culprit lesions; n/total (%)	90/301 (29.9)	81/299 (27.1)	0.45
Immediate bypass surgery; n/total (%)	8/301 (2.7)	10/299 (3.3)	0.62
Staged bypass surgery; n/total (%)	3/301 (1.0)	4/299 (1.3)	0.72
Active left ventricular assist device; n/total (%)	11/301 (3.7)	22/299 (7.4)	0.053
Mild hypothermia; n/total (%)	106/301 (35.2)	120/299 (40.1)	0.21
Mechanical ventilation; n/total (%)	240/301 (79.7)	252/299 (84.3)	0.15
Mechanical ventilation duration (days); median (IQR)	3.0 (1.0-8.0)	3.0 (1.0-8.0)	0.44
ICU treatment (days); median (IQR)	6.0 (3.0-12.0)	6.0 (3.0-13.0)	0.34
Renal replacement therapy; n/total (%)	62/301 (20.6)	47/299 (15.7)	0.12
Catecholamines ( $\mu\text{g/kg}$ per minute); median (IQR)			
Dopamine	4.1 (2.9-7.7)	4.2 (3.6-8.3)	0.76
Norepinephrine	0.3 (0.1-1.2)	0.4 (0.1-1.1)	0.73
Epinephrine	0.3 (0.1-1.3)	0.3 (0.2-1.4)	0.59
Dobutamine	10.2 (4.9-20.6)	9.0 (4.8-17.6)	0.25
Duration of catecholamines (days), median (IQR)	3.0 (1.0-5.0)	3.0 (1.0-6.0)	0.81
Time - hemodynamic stabilization (days); median (IQR)	3.0 (1.0-5.0)	3.0 (1.0-6.0)	0.50

# Simplified Acute Physiology Score-II



# Primary Study Endpoint (30-Day Mortality)



# Prasugrel versus Clopidogrel for Acute Coronary Syndromes without Revascularization

Matthew T. Roe, M.D., M.H.S., Paul W. Armstrong, M.D.,  
Keith A.A. Fox, M.B., Ch.B., Harvey D. White, M.B., Ch.B., D.Sc.,  
Dorairaj Prabhakaran, M.D., D.M., M.Sc., Shaun G. Goodman, M.D., M.Sc.,  
Jan H. Cornel, M.D., Ph.D., Deepak L. Bhatt, M.D., M.P.H.,  
Peter Clemmensen, M.D., D.M.Sc., Felipe Martinez, M.D., Diego Ardissono, M.D.,  
Jose C. Nicolau, M.D., Ph.D., William E. Boden, M.D., Paul A. Gurbel, M.D.,  
Witold Ruzyllo, M.D., Anthony J. Dalby, M.D., Darren K. McGuire, M.D., M.H.Sc.,  
Jose L. Leiva-Pons, M.D., Alexander Parkhomenko, M.D., Ph.D.,  
Shmuel Gottlieb, M.D., Gracita O. Topacio, M.D., Christian Hamm, M.D.,  
Gregory Pavlides, M.D., Assen R. Goudev, M.D., Ali Oto, M.D.,  
Chuen-Den Tseng, M.D., Ph.D., Bela Merkely, M.D., Ph.D., D.Sc.,  
Vladimir Gasparovic, M.D., Ph.D., Ramon Corbalan, M.D., Mircea Cînteză, M.D., Ph.D.,  
R. Craig McLendon, R.N., Kenneth J. Winters, M.D., Eileen B. Brown, Ph.D.,  
Yuliya Lokhnygina, Ph.D., Philip E. Aylward, B.M., B.Ch., Ph.D., Kurt Huber, M.D.,  
Judith S. Hochman, M.D., and E. Magnus Ohman, M.B., Ch.B.,  
for the TRILOGY ACS Investigators\* [www.nejm.org](http://www.nejm.org) - 8.26.12

# TRILOGY ACS Study Design

## Medically Managed UA/NSTEMI Patients



**Randomization Stratified by:**  
**Age, Country, Prior Clopidogrel Treatment**  
(Primary analysis cohort — Age < 75 years)

Median Time to  
Enrollment = 4.5 Days

**Medical Management Decision ≤ 72 hrs**  
(No prior clopidogrel given) — 4% of total

Clopidogrel<sup>1</sup>  
300 mg LD  
+  
75 mg MD

Prasugrel<sup>1</sup>  
30 mg LD  
+  
5 or 10 mg MD

**Medical Management Decision ≤ 10 days**  
(Clopidogrel started ≤ 72 hrs in-hospital OR  
on chronic clopidogrel) — 96% of total

Clopidogrel<sup>1</sup>  
75 mg MD

Prasugrel<sup>1</sup>  
5 or 10 mg MD

Minimum Rx Duration: 6 months; Maximum Rx Duration: 30 months

**Primary Efficacy Endpoint: CV Death, MI, Stroke**

1. All patients were on aspirin and low-dose aspirin (< 100 mg) was strongly recommended. For patients <60 kg or ≥75 years, 5 mg MD of prasugrel was given. Adapted from Chin CT et al. *Am Heart J* 2010;160:16-22.e1.

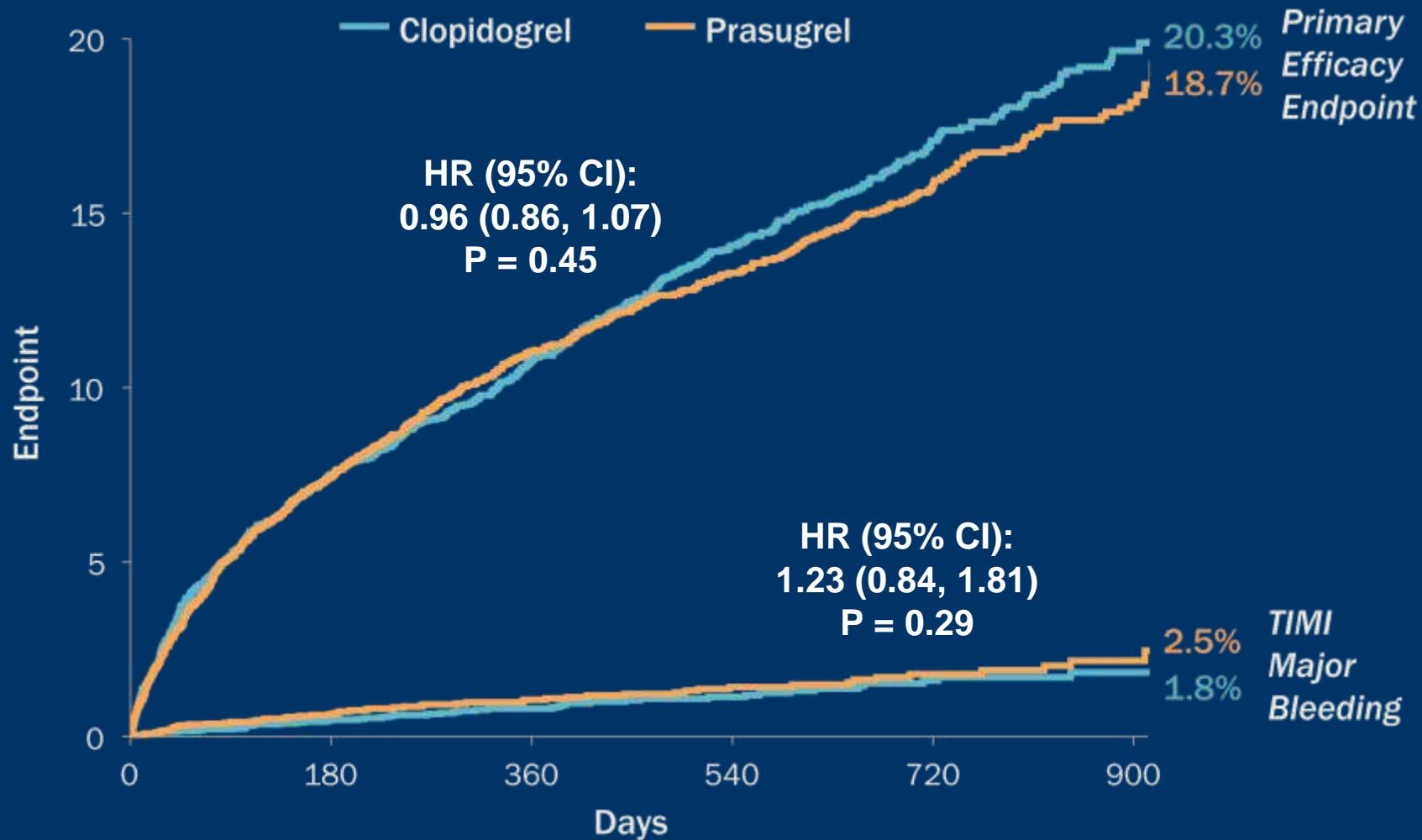
# Baseline Characteristics

	Age < 75 Years (N = 7243)		Overall Population (N = 9326)	
	Prasugrel (N = 3620)	Clopidogrel (N = 3623)	Prasugrel (N = 4663)	Clopidogrel (N = 4663)
<b>Age—yr</b>	62 (56–68)	62 (56–68)	66 (58–74)	66 (59–73)
<b>Female sex—%</b>	36.2	35.6	39.2	39.1
<b>Body weight &lt; 60 kg—%</b>	13.1	12.8	15.2	14.9
<b>Disease classification—%</b>				
NSTEMI	67.8	67.2	70.4	69.4
Unstable angina	32.2	32.8	29.6	30.6
<b>Medical History—%</b>				
Diabetes mellitus	38.5	39.3	37.7	38.3
Current/recent smoking	23.3	23.6	19.7	20.2
Prior myocardial infarction	43.3	44.8	42.9	43.3
Prior PCI	27.0	29.1	25.6	26.7
Prior CABG	14.6	16.3	15.2	16.1
<b>Baseline risk assessment</b>				
GRACE risk score	114 (101–128)	115 (102–128)	122 (105–140)	121 (106–138)
Creatinine clearance—mL/min	81 (63–104)	81 (63–102)	73 (54–97)	73 (54–96)
<b>Angiography performed pre-randomization—%</b>	42.1	43.1	41.2	41.4

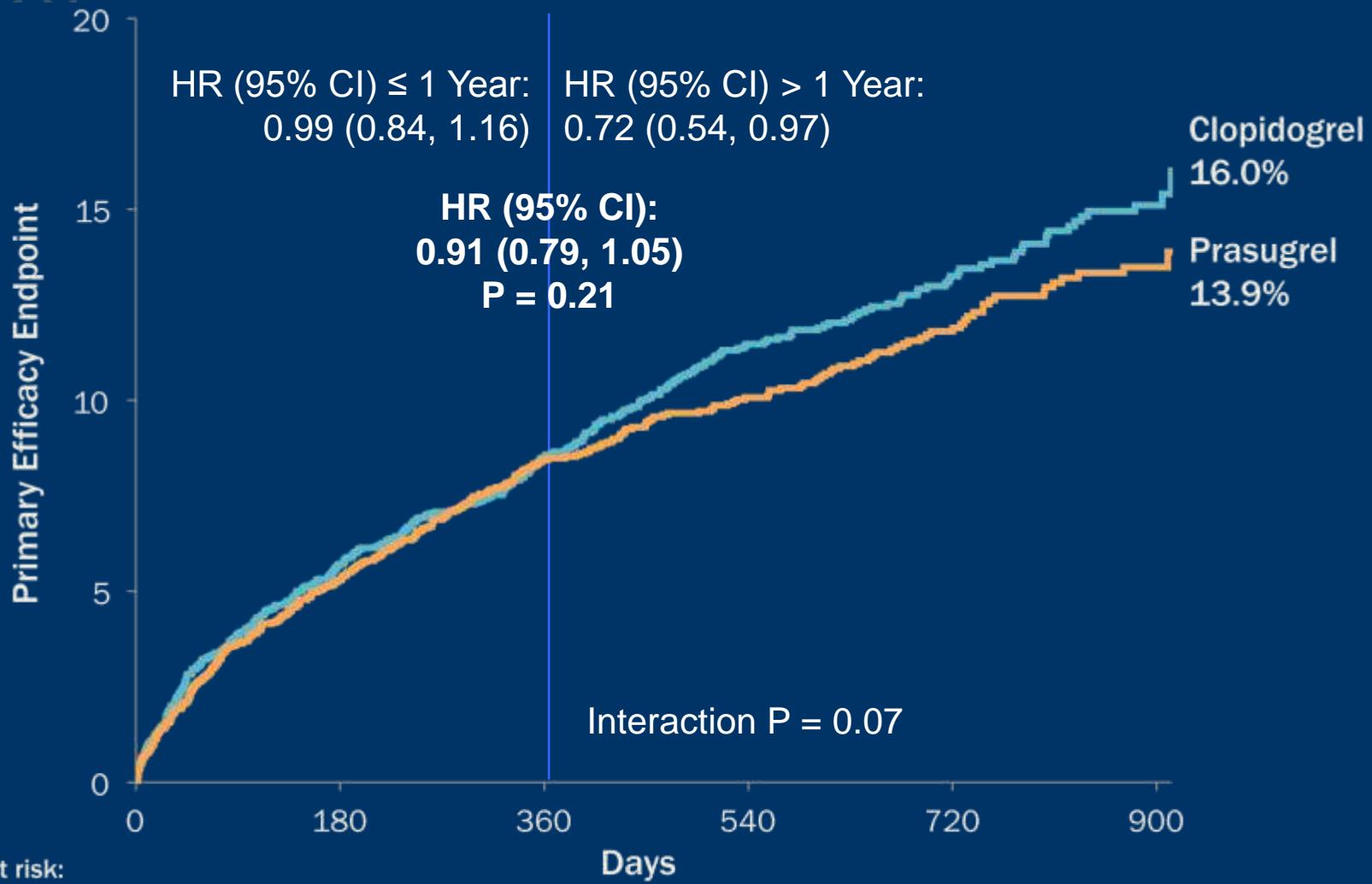
Post-randomization revascularization performed in 7.5% of patients

Search Institute

# Primary Efficacy Endpoint and TIMI Major Bleeding Through 30 Months (Overall population)



# Primary Efficacy Endpoint to 30 Months (Age < 75 years)



# Evaluation of All Ischemic Events Over Time\*

(Age < 75 years)

- Lower risk multiple recurrent ischemic events suggested with prasugrel using the pre-specified Andersen-Gill model (HR = 0.85, 95% CI: 0.72–1.00, P=0.04)
- Significant interaction with treatment and time (HR for > 12 mos = 0.64, 95% CI: 0.48–0.86, Interaction P=0.02)

	Prasugrel	Clopidogrel
<b>≥ 1 event</b>	364	397
<b>≥ 2 events</b>	77	109
<b>3–7 events</b>	18	24

\* Pre-specified evaluation of all CV death, MI, or stroke events by treatment

# Estudios relevantes en cardiopatía isquémica crónica

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- CLARIFY
- CARDIA
- FAME 2
- WOEST

# Clarify



European Heart Journal  
doi:10.1093/eurheartj/ehs289

FASTTRACK

CLINICAL TRIAL & REGISTRY UPDATE

## Women and men with stable coronary artery disease have similar clinical outcomes: insights from the international prospective CLARIFY registry

Philippe Gabriel Steg<sup>1,2,3\*</sup>, Nicola Greenlaw<sup>4</sup>, Jean-Claude Tardif<sup>5</sup>, Michal Tendera<sup>6</sup>, Ian Ford<sup>4</sup>, Stefan Kääb<sup>7</sup>, Hélène Abergel<sup>1,2,3</sup>, Kim M. Fox<sup>8</sup>, and Roberto Ferrari<sup>9</sup>, on behalf of the CLARIFY Registry Investigators

<sup>1</sup>INSERM U698, Paris, France; <sup>2</sup>Université Paris Diderot, Paris, France; <sup>3</sup>Hôpital Bichat, 46 rue Henri Huchard, 75877 Paris Cedex 18, France; <sup>4</sup>University of Glasgow, Glasgow, UK; <sup>5</sup>Montreal Heart Institute, Université de Montréal, Montreal, Canada; <sup>6</sup>Medical University of Silesia, Katowice, Poland; <sup>7</sup>Department of Medicine I, Klinikum Großhadern, Ludwig-Maximilians University, Munich Heart Alliance, Munich, Germany; <sup>8</sup>NHIL Imperial College ICMS, Royal Brompton Hospital, London, UK; and <sup>9</sup>Department of Cardiology and LTTA Centre, University of Ferrara and Salvatore Maugeri Foundation, IRCCS, Lumezzane, Italy

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# Clarify. Criterios de entrada

- Pacientes elegibles tenían enfermedad arterial coronaria estable definida como al menos uno de los siguientes:
  - IM documentado >3 meses antes del estudio
  - Prueba angiográfica de estenosis coronaria >50%
  - Dolor torácico con evidencias de isquemia miocárdica (prueba de esfuerzo ECG)
  - CRC o ICP >3 meses antes del estudio
  - Estos criterios no eran mutuamente excluyentes
- Criterios de exclusión:
  - Ingreso hospitalario de causa CV (incluyendo revascularización) en los últimos 3 meses
  - Revascularización planeada
  - Problemas que impidieran su participación o seguimiento de 5 años (cooperación limitada, capacidad legal limitada, patologías no CV graves o patologías que disminuyan la calidad de vida (cáncer, drogadicción) u otras patologías CV graves(ICC avanzada, valvulopatía grave, antecedentes de substitución o reparación valvular)

# Clarify. Objetivos del análisis

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- Explorar las diferencias a 1 año entre hombres y mujeres con cardiopatía isquémica estable
- Explorar la consistencia de los resultados por subgrupos de pacientes post-IAM o post-revascularización

# Clarify. Características basales

	<b>Men (N= 23 975)</b>	<b>Women (N=7 002)</b>	<b>P value</b>
Age, years	63.4 (10.5)	66.5 (9.9)	<0.0001
BMI, kg/m <sup>2</sup>	27.3 [24.9, 30.1]	27.3 [24.2, 31.1]	0.87
Ethnicity			<0.0001
Caucasian	66.0	66.2	
Black/African	8.1	7.4	
Chinese	8.3	8.8	
Hispanic	3.2	3.8	
Japanese/Korean	4.1	5.1	
South Asian	0.9	1.3	
Unknown	9.4	7.4	

# Clarify. Factores de riesgo

	<b>Men (N= 23 975)</b>	<b>Women (N=7 002)</b>	<b>P value</b>
Family history of premature CAD, %	28	31	<0.0001
Treated hypertension, %	69	78	<0.0001
Diabetes, %	28	33	<0.0001
Dyslipidemia, %	75	75	0.98
Current smoking, %	14	7	<0.0001
Physical activity, %			<0.0001
None	14	23	
Light physical activity most weeks	51	56	
≥ 20 minutes vigorous physical activity 1–2 times/week	18	12	
≥ 20 minutes vigorous physical activity ≥3 times/week	17	10	

# Clarify. Antecedentes

	<b>Men (N= 23 975)</b>	<b>Women (N=7 002)</b>	<b>P value</b>
Time since diagnosis of CAD, years	5 [2, 10]	4 [2, 8]	<0.0001
Myocardial infarction, %	62	51	<0.0001
Coronary angiography performed, n (%)	20 747 (86)	5573 (80)	<0.0001
Non-invasive test for myocardial ischaemia, n (%)	15 003 (63)	4063 (58)	<0.0001
Evidence for myocardial ischaemia, n (%)	3851 (16)	1231 (18)	0.0025
PCI, %	59	55	<0.0001
CABG, %	25	17	<0.0001
Peripheral arterial disease, %	10	8	<0.0001
Asthma/COPD, %	7	9	<0.0001
Hospital admission for heart failure, %	4	5	0.014
Stroke, %	4	4	0.24
Transient ischaemic attack, %	3	4	0.0033

# Clarify. Síntomas CV

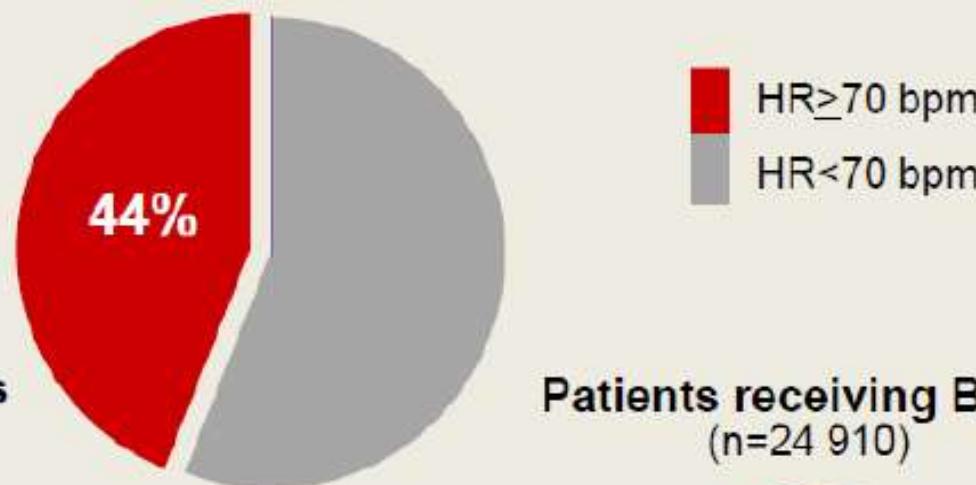
	<b>Men (N= 23 975)</b>	<b>Women (N=7 002)</b>	<b>P value</b>
Any angina %	21	29	<0.0001
CCS class, if angina (N= 7003)			
Angina CCS Class I	30	25	0.0018
Angina CCS Class II	53	54	
Angina CCS Class III	17	19	
Angina CCS Class IV	1	1	
CHF symptoms, %			<0.0001
No CHF	85	82	
CHF NYHA Class II	12	15	
CHF NYHA Class III	2	3	



## Proportion of patients with HR $\geq 70$ bpm

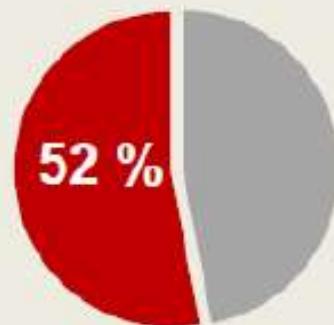
Total population

(n=33 177)



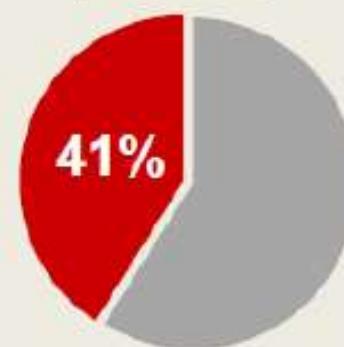
Patients not receiving BBs

(n=8 251)



Patients receiving BBs

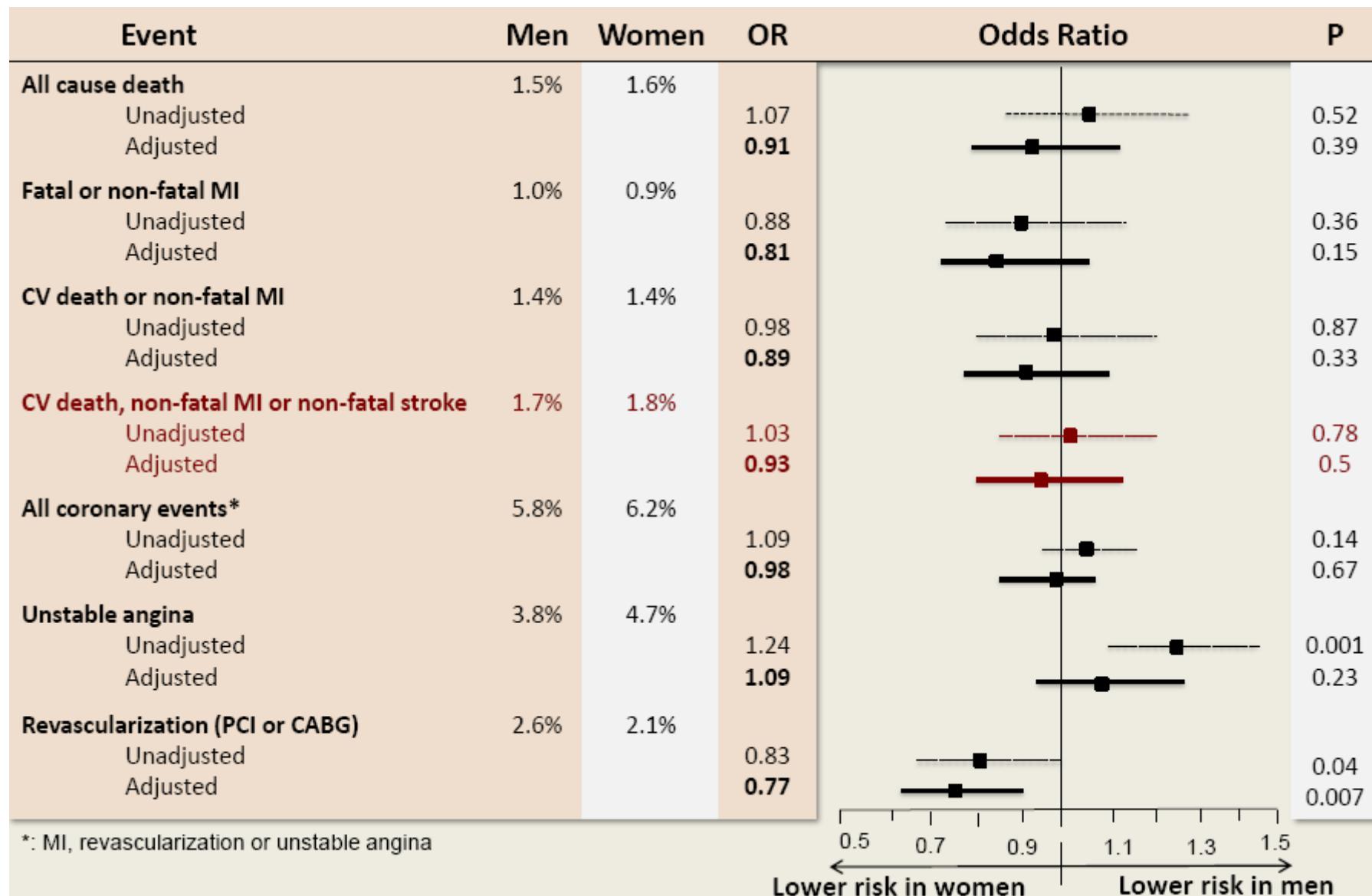
(n=24 910)



# Clarify. Parámetros cardiacos y hallazgos angiográficos

	<b>Men (N= 23 975)</b>	<b>Women (N=7 002)</b>	<b>P value</b>
Heart rate, palpation, bpm	67.9 (10.6)	69.6 (10.5)	<0.0001
ECG heart rate, bpm	66.7 (11.4)	69.0 (11.5)	<0.0001
ECG sinus rhythm, %	95	96	0.10
Atrial fibrillation/flutter	3	3	
SBP, mm Hg	130.4	133.3	<0.0001
DBP, mm Hg	77.3	77.0	0.0042
LV ejection fraction, % (N=21 283)	55.6	58.0	<0.0001
Angiographic findings, % (N= 26 282)			<0.0001
No diseased vessel	2.9	6.4	
One-vessel disease	39.8	46.4	
Two or more vessel disease	57.3	47.3	

# Clarify. Evolución a 1 año



# Clarify. Conclusiones

- Existen **importantes diferencias** en las características basales y en el riesgo entre hombres y mujeres; menos mujeres se sometieron a revascularización
- Sin embargo, las **tasas de mortalidad** a un año crudas y ajustadas de mortalidad y de sucesos cardiovasculares fueron **similares** entre sexos con AE
- El **seguimiento** más prolongado de esta población aportará más conocimiento sobre las diferencias entre sexos en pacientes con AE
- Se requiere **más investigación** para diseñar estrategias para minimizar el sesgo en el manejo y tratamiento de las mujeres

ESC Clinical trial and Registry update  
Munich 27<sup>th</sup> August 2012

# Coronary Artery Revascularisation in Diabetes Trial

**Presented by Roger Hall**  
On behalf of the CARDia Investigators

5 year follow up data

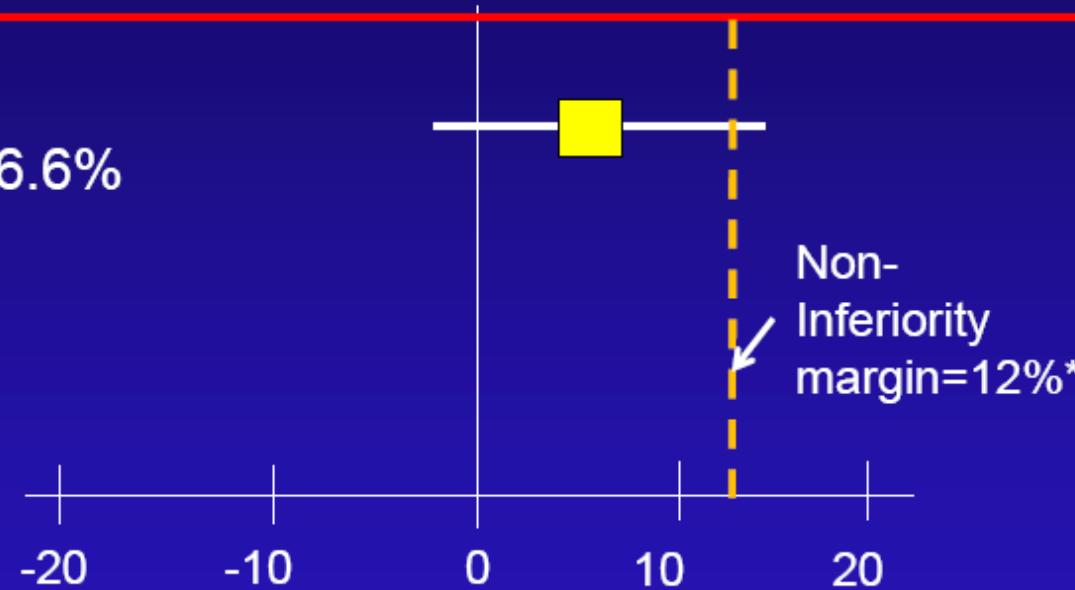


# Primary analysis for non inferiority



Percent difference	PCI better	CABG better
--------------------	---------------	----------------

Death, MI, Stroke  
CABG 20.5% vs PCI 26.6%  
+5.9% (-2 to +13%)



\*Non inferiority method based on PARTNER Trial NEJM 2011;364:2187-98.

**ORIGINAL ARTICLE**

# Fractional Flow Reserve–Guided PCI versus Medical Therapy in Stable Coronary Disease

Bernard De Bruyne, M.D., Ph.D., Nico H.J. Pijls, M.D., Ph.D.,  
Bindu Kalesan, M.P.H., Emanuele Barbato, M.D., Ph.D.,  
Pim A.L. Tonino, M.D., Ph.D., Zsolt Piroth, M.D., Nikola Jagic, M.D.,  
Sven Mobius-Winckler, M.D., Gilles Rioufol, M.D., Ph.D., Nils Witt, M.D., Ph.D.,  
Petr Kala, M.D., Philip MacCarthy, M.D., Thomas Engström, M.D.,  
Keith G. Oldroyd, M.D., Kreton Mavromatis, M.D., Ganesh Manoharan, M.D.,  
Peter Verlee, M.D., Ole Frobert, M.D., Nick Curzen, B.M., Ph.D.,  
Jane B. Johnson, R.N., M.Sc., Peter Jüni, M.D., and William F. Fearon, M.D.,  
for the FAME 2 Trial Investigators\*

# Objetivo

Comparar objetivos clínicos entre ICP guiado por FFR junto con tratamiento médico óptimo (TMO) respecto TMO en pacientes con enfermedad coronaria estable.

## Criterios de inclusión

Referidos a ICP por

- Angina estable (CCS 1, 2, 3)
- Angina estabilizada CCS 4
- Dolor atípico o no dolor con isquemia documentada

Y

Lesiones angiográficas de 1, 2, o 3 vasos

## Criterios de exclusión

- Cirugía coronaria previa
- FEVI <30%
- Enfermedad de tronco común

# Flow Chart

**Stable CAD patients scheduled for 1, 2 or 3 vessel DES-PCI  
N = 1220**

**Randomized Trial**

**FFR in all target lesions**

**Registry**

**At least 1 stenosis  
with FFR  $\leq 0.80$  (n=888)**

**Randomization 1:1**

**PCI + MT**

**MT**

**73%**

**When all FFR  $> 0.80$   
(n=332)**

**MT**

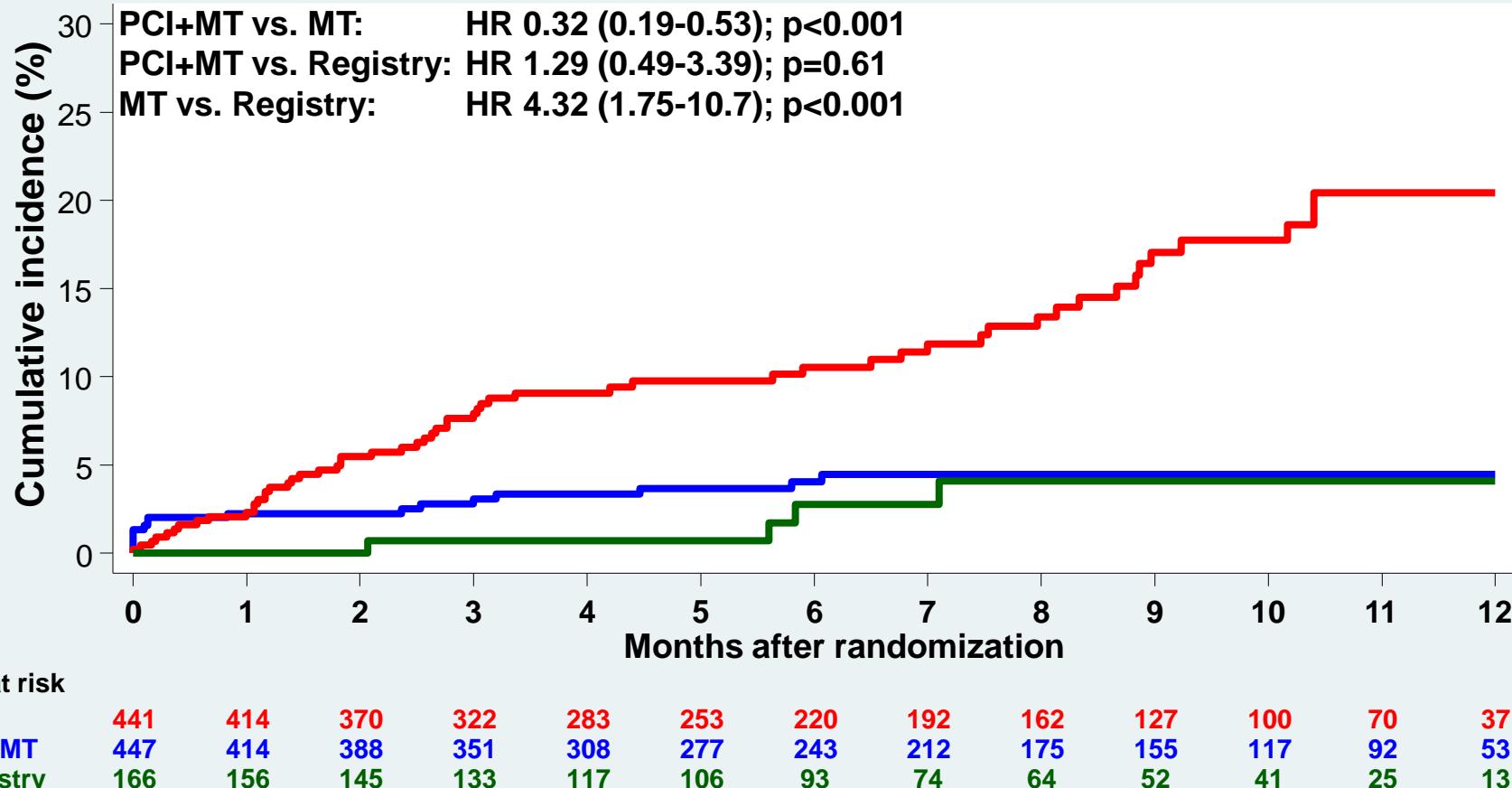
**27%**

**50% randomly  
assigned to FU**

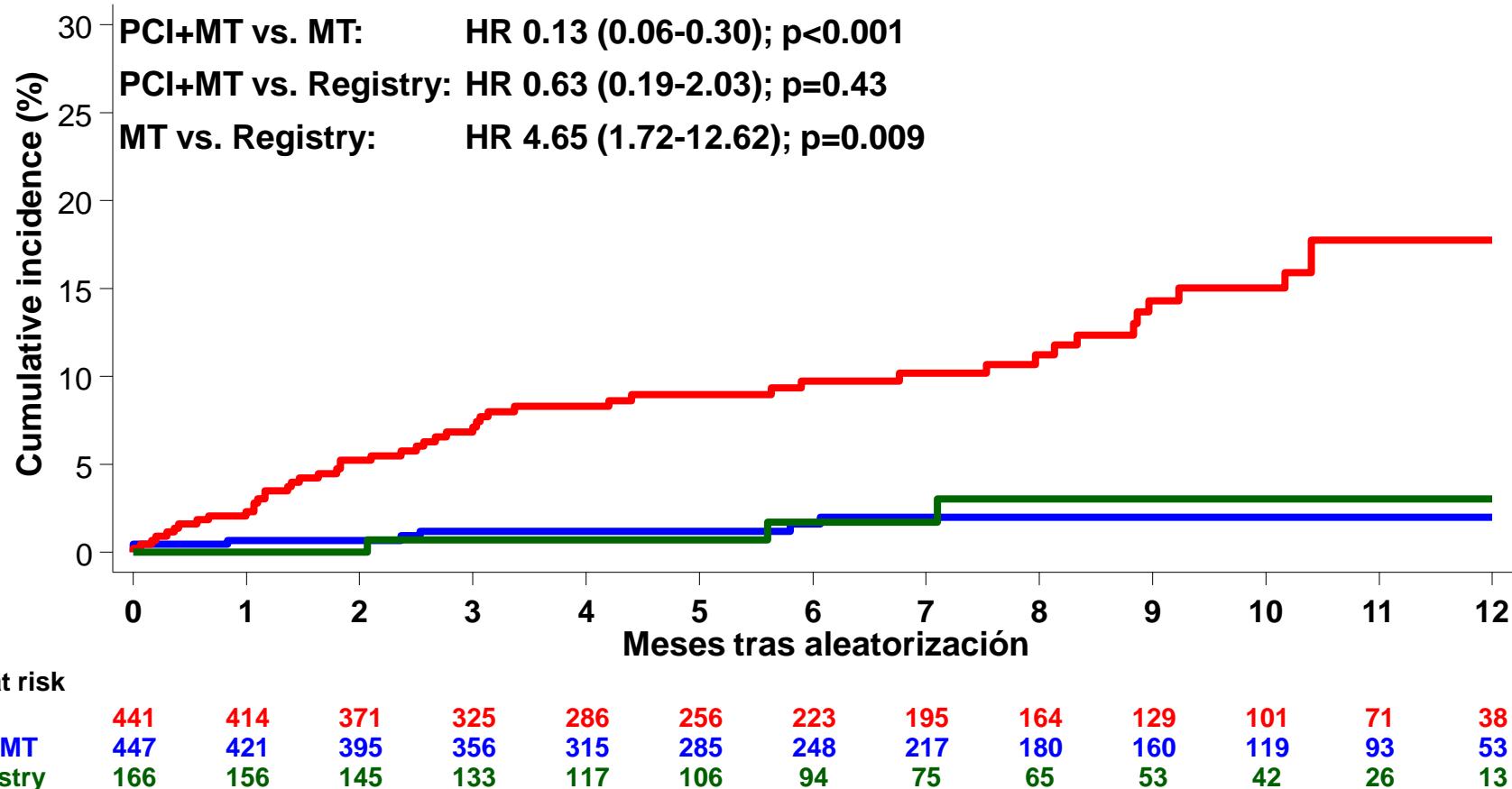
**Follow-up after 1, 6 months, 1, 2, 3, 4, and 5 years**

## Variable principal

(mortalidad global, infarto de miocardio, ingreso no previsto por revascularización urgente)



# Revascularización urgente

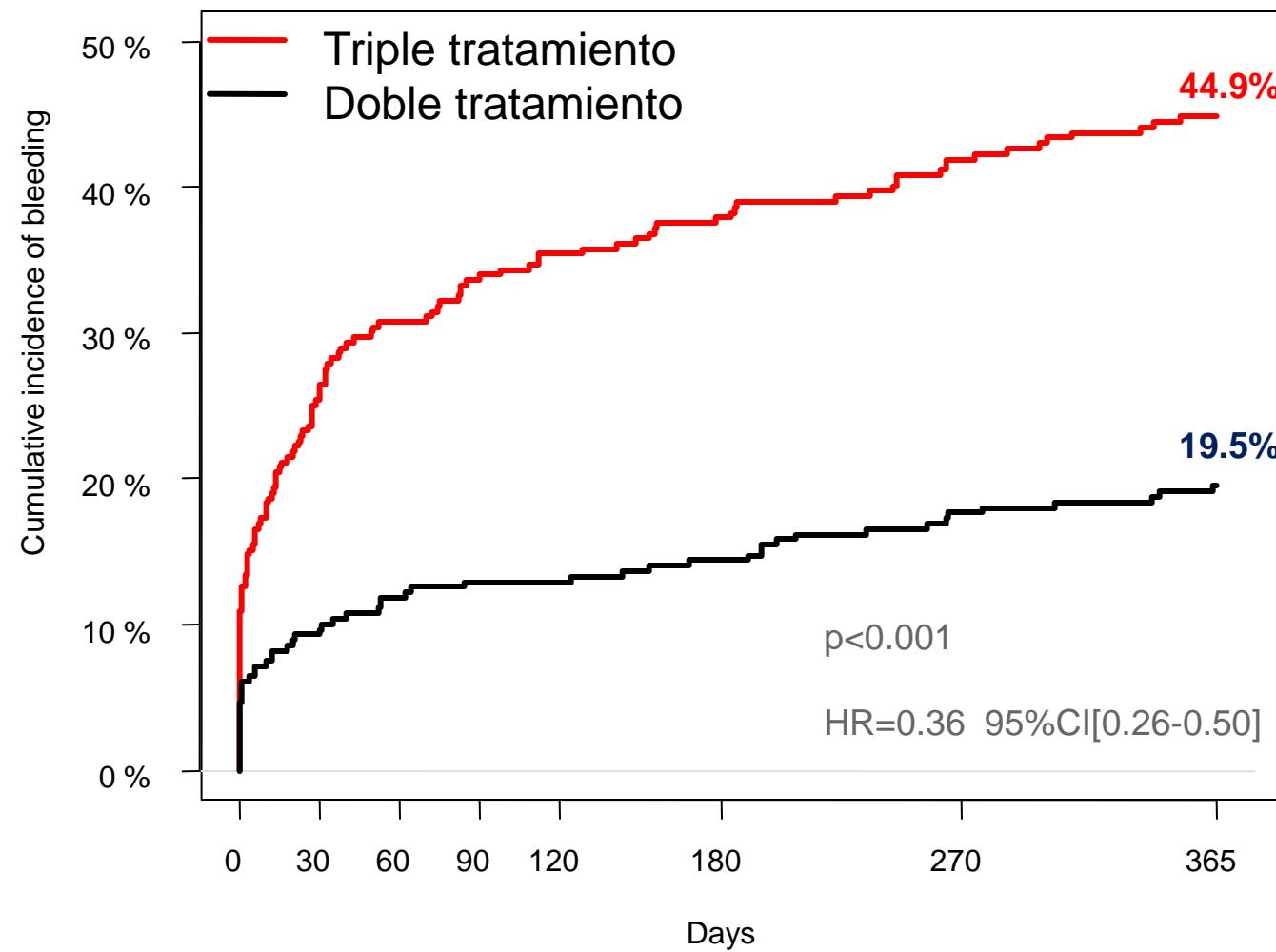


# **The WOEST Trial: First randomised trial comparing two regimens with and without aspirin in patients on oral anticoagulant therapy undergoing coronary stenting**

Willem Dewilde, Tom Oirbans, Freek Verheugt, Johannes Kelder, Bart De Smet, Jean-Paul Herrman, Tom Adriaenssens, Mathias Vrolix, Antonius Heestermans, Marije Vis, Saman Rasoul, Kaioum Sheikjoesoef, Tom Vandendriessche, Carlos Van Mieghem, Kristoff Cornelis, Jeroen Vos, Guus Brueren, Nicolien Breet and Jurriën ten Berg

The WOEST Trial= What is the Optimal antiplatElet and anticoagulant therapy in patients with oral anticoagulation and coronary StenTing ([clinicaltrials.gov](http://clinicaltrials.gov) NCT00769938)

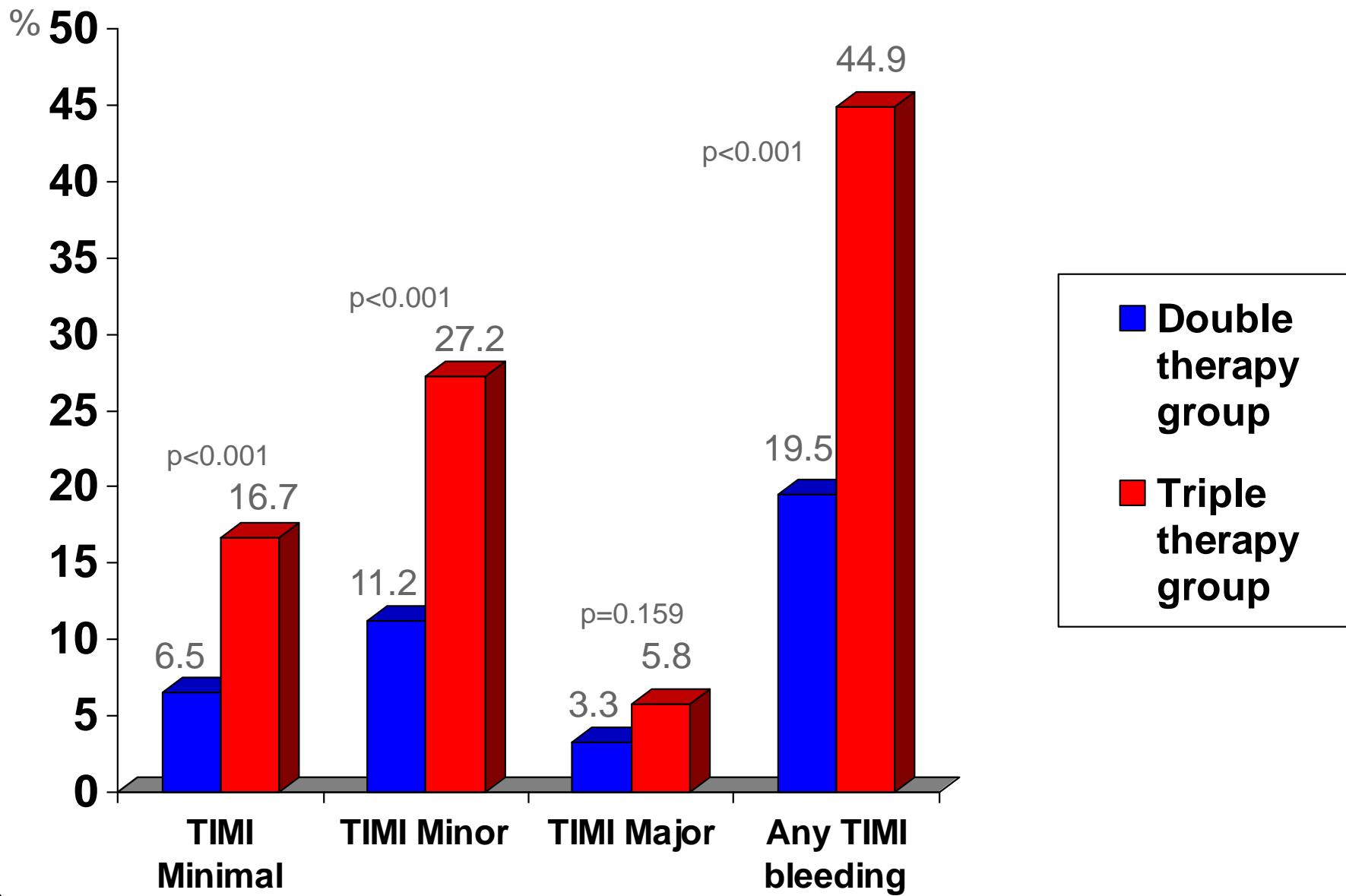
## Objetivo principal: Número total de hemorragias TIMI



n at risk:

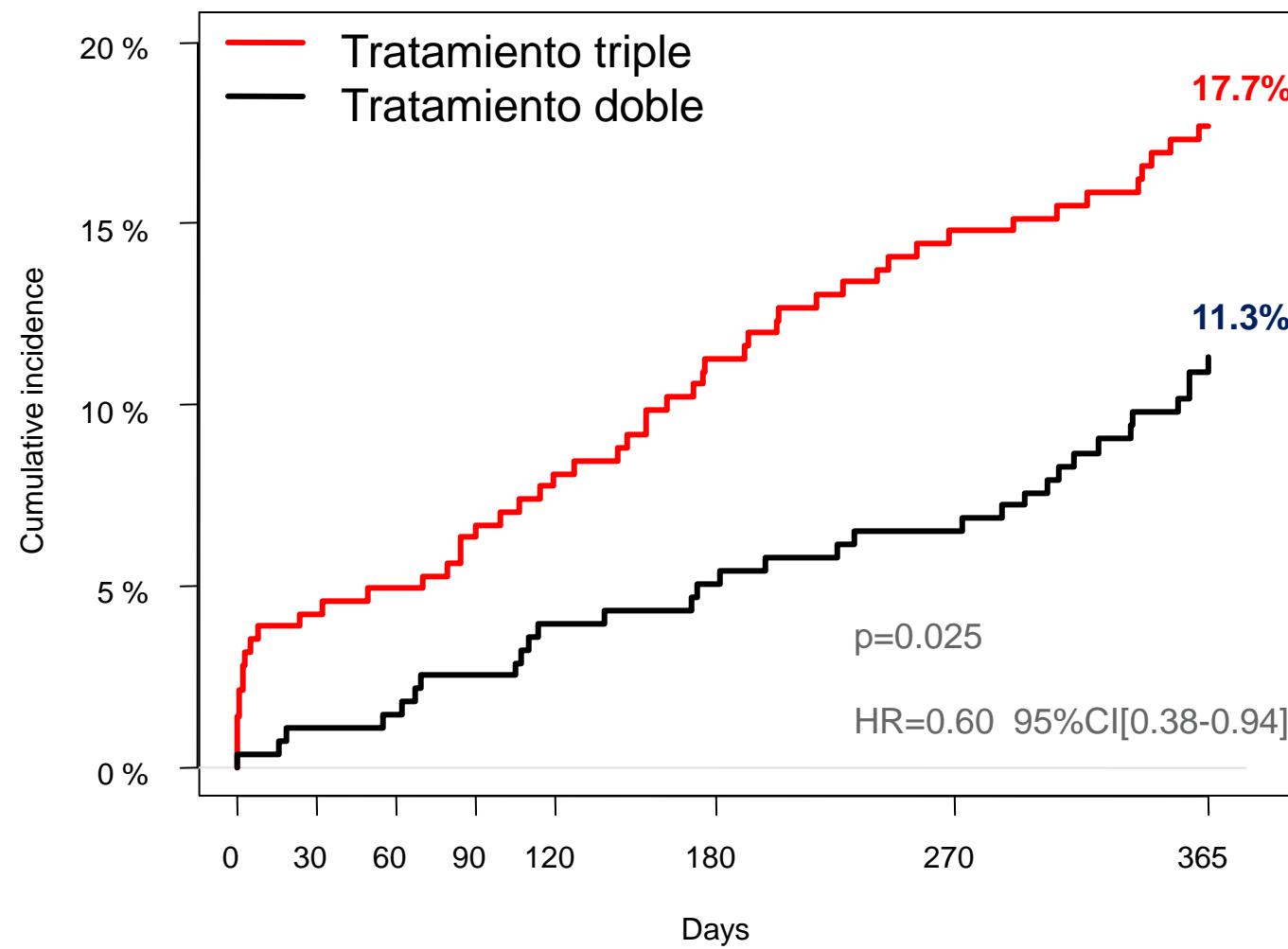
284	210	194	186	181	173	159	140
279	253	244	241	241	236	226	208

## Objetivo principal: Clasificación de hemorragias TIMI



WOEST

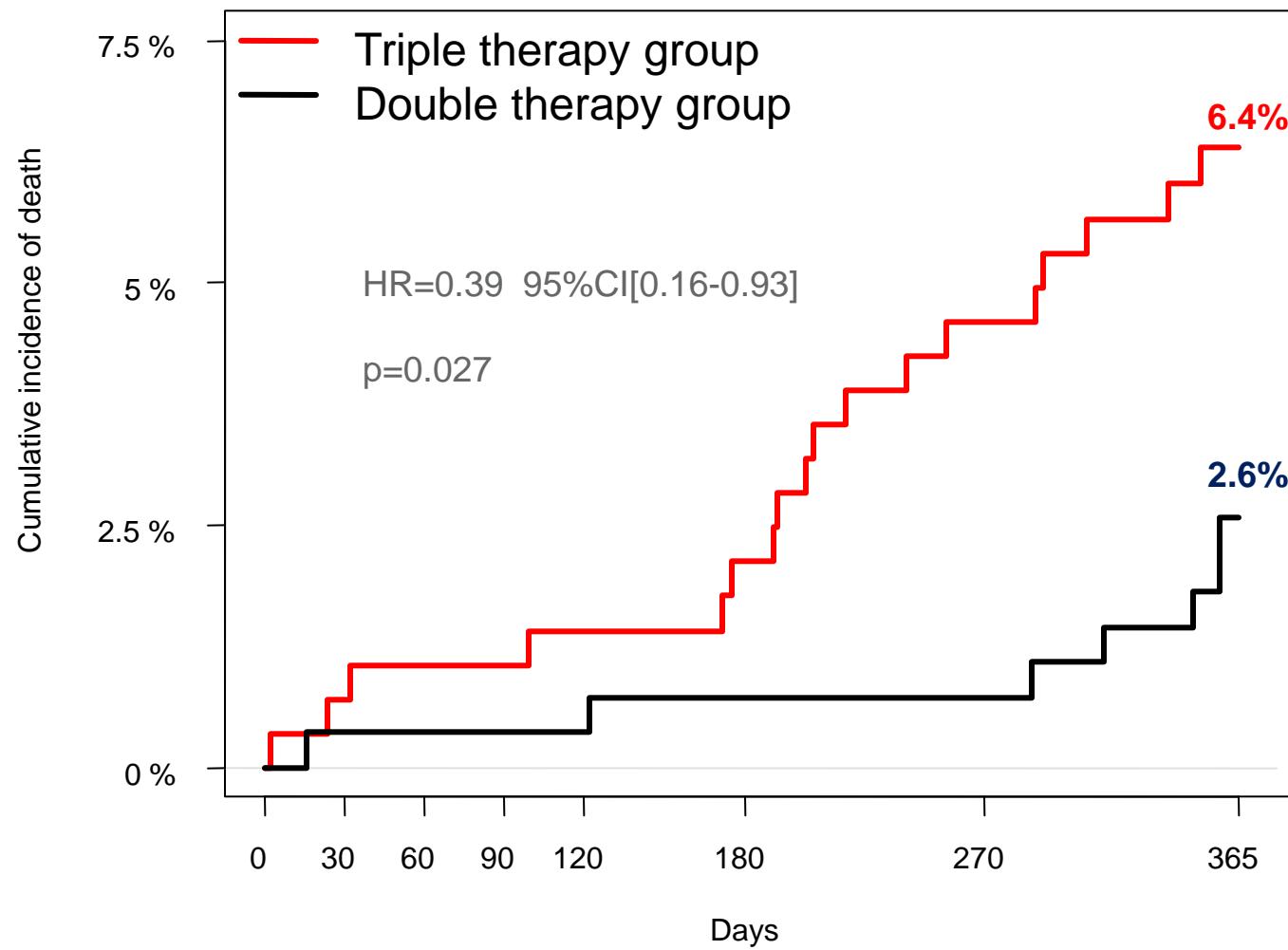
## Objetivo secundario (muerte, IM, TVR, AVC, Tromb stent)



n at risk:

284	272	270	266	261	252	242	223
279	276	273	270	266	263	258	234

## Mortalidad de cualquier causa



n at risk: 284 281 280 280 279 277 270 252  
279 278 276 276 276 275 274 256

# Nuevos documentos oficiales de la ESC

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- Definición infarto
- Guía STEMI

# Tercera definición de IAM

## Puntos principales:

1. La necrosis miocárdica puede ser el resultado de mecanismos no isquémicos (ICC, etc). No se debe clasificar como infarto, sino como lesión miocárdica
2. Los biomarcadores preferidos para la detección de IAM son las troponinas. Se define como troponina incrementada aquella por encima del percentil 99 de la población normal de referencia
3. Se establecen 5 tipos de infarto en función de su fisiopatología
4. TAVI puede causar lesión miocárdica. En razonable aplicar los criterios de IM tipo 5
5. cRMN con realce tardío puede diferenciar cardiopatía isquémica y otras alteraciones miocárdicas

**Table 2** Universal classification of myocardial infarction**Type 1: Spontaneous myocardial infarction**

Spontaneous myocardial infarction related to atherosclerotic plaque rupture, ulceration, fissuring, erosion, or dissection with resulting intraluminal thrombus in one or more of the coronary arteries leading to decreased myocardial blood flow or distal platelet emboli with ensuing myocyte necrosis. The patient may have underlying severe CAD but on occasion non-obstructive or no CAD.

**Type 2: Myocardial infarction secondary to an ischaemic imbalance**

In instances of myocardial injury with necrosis where a condition other than CAD contributes to an imbalance between myocardial oxygen supply and/or demand, e.g. coronary endothelial dysfunction, coronary artery spasm, coronary embolism, tachy-/brady-arrhythmias, anaemia, respiratory failure, hypotension, and hypertension with or without LVH.

**Type 3: Myocardial infarction resulting in death when biomarker values are unavailable**

Cardiac death with symptoms suggestive of myocardial ischaemia and presumed new ischaemic ECG changes or new LBBB, but death occurring before blood samples could be obtained, before cardiac biomarker could rise, or in rare cases cardiac biomarkers were not collected.

**Type 4a: Myocardial infarction related to percutaneous coronary intervention (PCI)**

Myocardial infarction associated with PCI is arbitrarily defined by elevation of cTn values  $>5 \times 99^{\text{th}}$  percentile URL in patients with normal baseline values ( $\leq 99^{\text{th}}$  percentile URL) or a rise of cTn values  $>20\%$  if the baseline values are elevated and are stable or falling. In addition, either (i) symptoms suggestive of myocardial ischaemia, or (ii) new ischaemic ECG changes or new LBBB, or (iii) angiographic loss of patency of a major coronary artery or a side branch or persistent slow- or no-flow or embolization, or (iv) imaging demonstration of new loss of viable myocardium or new regional wall motion abnormality are required.

**Type 4b: Myocardial infarction related to stent thrombosis**

Myocardial infarction associated with stent thrombosis is detected by coronary angiography or autopsy in the setting of myocardial ischaemia and with a rise and/or fall of cardiac biomarkers values with at least one value above the  $99^{\text{th}}$  percentile URL.

**Type 5: Myocardial infarction related to coronary artery bypass grafting (CABG)**

Myocardial infarction associated with CABG is arbitrarily defined by elevation of cardiac biomarker values  $>10 \times 99^{\text{th}}$  percentile URL in patients with normal baseline cTn values ( $\leq 99^{\text{th}}$  percentile URL). In addition, either (i) new pathological Q waves or new LBBB, or (ii) angiographic documented new graft or new native coronary artery occlusion, or (iii) imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.

# Guía IAMCEST

- Énfasis en la necesidad de disponer de redes geográficas con protocolos consensuados.
- La mejor organización y coordinación del cuidado del IAMEST debería reducir los retrasos en su tratamiento. Las nuevas guías son más exigentes en cuestiones de tiempos que las previas del 2008. El tiempo contacto médico – ECG: 10 minutos. Dos horas el límite de tiempo aceptable para el traslado desde un centro sin ICPP a un centro ICPP, pero se debería procurar 90 minutos. Si se cree que no es posible la ICPP en menos de dos horas desde el inicio de dolor se debería administrar fibrinolisis en menos de 30 minutos.
- Se recomienda monitorizar y publicar los resultados, incluyendo los tiempos puerta-balón y cualquier otra fuente de retraso. Europa no dispone de un registro paneuropeo de IAMEST, pero algunos países tienen registros nacionales.

# Guía IAMCEST

- Si la fibrinólisis tiene éxito, se puede realizar coronariografía de cara a eventual ICP en las siguientes 3 a 24h. Si la fibrinólisis no tiene éxito, se debería considerar ICP inmediato
- Se recomienda implantar stents farmacoliberadores en los pacientes en los que no esté contraindicado la doble antiagregación y tengan una buena cumplimentación. Se recomienda prasugrel o ticagrelor sobre clopidogrel
- Se apoya el uso de la vía radial en lugar de la femoral, pero sólo en manos de hemodinamistas experimentados
- Se identifican varias áreas sobre las que investigar: tratamiento pre-hospitalario, manejo a largo plazo, doble antiagregación en pacientes anticoagulados, etc.

# Recomendaciones de tratamiento post-IAMCEST

Table 22 Routine therapies in STEMI

Recommendations		I	A
Active smokers with STEMI must receive smoking cessation support.	Antiplatelet therapy with low dose aspirin (75–100 mg) is indicated indefinitely after STEMI.	I	A
Each hospital participating in the care of patients with STEMI must have a smoking cessation programme.	In patients who are intolerant to aspirin, clopidogrel is indicated as an alternative to aspirin.	I	B
Exercise-based rehabilitation is recommended.	DAPT with a combination of aspirin and prasugrel or aspirin and ticagrelor is recommended (over aspirin and clopidogrel) in patients treated with PCI.	I	A
Antiplatelet therapy with low dose aspirin is recommended.	DAPT with aspirin and an oral ADP receptor antagonist must be continued for up to 12 months after STEMI, with a strict minimum of:	I	C
In patients who are intolerant to aspirin:	<ul style="list-style-type: none"> <li>• 1 month for patients receiving BMS</li> <li>• 6 months for patients receiving DES</li> </ul>	I	C
In patients with left ventricular thrombus:	In patients with left ventricular thrombus, anticoagulation should be instituted for a minimum of 3 months.	IIa	B
If patients require triple antithrombotic therapy (e.g. due to an obligatory indication for OAC, the duration of DAPT should be increased to 1 year).	In patients with a clear indication for oral anticoagulation (e.g. atrial fibrillation with CHA <sub>2</sub> DS <sub>2</sub> -VASc Score ≥2 or mechanical valve prosthesis), oral anticoagulation must be implemented in addition to antiplatelet therapy.	I	C
Gastric protection with a proton pump inhibitor should be considered in patients at high risk of bleeding.	If patients require triple antithrombotic therapy, combining DAPT and OAC, e.g. because of stent placement and an obligatory indication for OAC, the duration of dual antiplatelet therapy should be minimized to reduce bleeding risk.	I	C
Oral treatment with beta-blockers is recommended in all patients without contraindications.	In selected patients who receive aspirin and clopidogrel, low-dose rivaroxaban (2.5 mg twice daily) may be considered if the patient is at low bleeding risk.	IIb	B
Continuous beta-blockers must be avoided in patients with heart failure.	DAPT should be used up to 1 year in patients with STEMI who did not receive a stent.	IIa	C
Intermittent beta-blockers should be avoided in patients with high blood pressure, tachycardia and hypotension.	Gastric protection with a proton pump inhibitor should be considered for the duration of DAPT therapy in patients at high risk of bleeding.	IIa	C
A fasting lipid profile must be obtained.			
It is recommended to initiate or continue statins in patients without contraindications or history of ischaemic stroke.			
Reassessment of LDL-cholesterol after 6 months, if the target level (70 mg/dL) has been reached.			
Vasopressin may be considered for sepsis in patients without heart failure.			
ACE inhibitors are indicated starting from systolic dysfunction, diabetes or anemia.	Oral treatment with beta-blockers should be considered during hospital stay and continued thereafter in all STEMI patients without contraindications.	IIa	B
An ARB, preferably valsartan, is an alternative to ACE inhibitors in particular those who are intolerant.	Oral treatment with beta-blockers is indicated in patients with heart failure or LV dysfunction.	I	A
ACE inhibitors should be considered in patients with heart failure.	Intravenous beta-blockers must be avoided in patients with hypotension or heart failure.	III	B
Alpha-1 adrenergic antagonists, e.g. apreelin, should be avoided in patients with heart failure and diabetes, provided no renal failure or hypotension.	Intravenous beta-blockers should be considered at the time of presentation in patients without contraindications, with high blood pressure, tachycardia and no signs of heart failure.	IIa	B

ACE = angiotensin-converting enzyme; ACS = acute coronary syndrome;

DES = drug-eluting stent; LDL = low-density lipoprotein cholesterol.

\*Class of recommendation.

†Level of evidence.

‡References.

# Recomendaciones de tratamiento de insuficiencia cardiaca post-IAMCEST

**Table 23** Treatment of heart failure and left ventricular dysfunction

Recommendations	Class <sup>a</sup>	Level <sup>b</sup>	Ref <sup>c</sup>
<b>Treatment of mild heart failure (Killip class II)</b>			
Oxygen is indicated to maintain a saturation >95%	I	C	-
Loop diuretics, e.g. furosemide 20–40 mg i.v., are recommended and should be repeated at 1–4 h intervals if necessary	I	C	-
Isosorbide or isosorbide nitroprusside should be considered in patients with elevated systolic blood pressure.	IIa	C	-
An ACE inhibitor is indicated in all patients with signs or symptoms of heart failure and/or evidence of LV dysfunction in the absence of hypotension, hypocalcaemia, or renal failure.	I	A	309–312
An ARB (losartan) is an alternative to ACE inhibitors particularly if ACE inhibitors are not tolerated.	I	B	281
An adenosine antagonist (telmisartan) is recommended in all patients with signs or symptoms of heart failure and/or evidence of LV dysfunction provided no renal failure or hyperkalaemia.	I	B	282
Hydralazine and isosorbide dinitrate should be considered if the patient is intolerant to both ACE inhibitors and ARBs.	IIa	C	313
<b>Treatment of moderate heart failure (Killip class III)</b>			
Oxygen is indicated.	I	C	-
Ventilatory support should be instituted according to blood gases.	I	C	-
Loop diuretics, e.g. furosemide 20–40 mg i.v., are recommended and should be repeated at 1–4 h intervals if necessary.	I	C	-
Morphine is recommended. Respiration should be monitored. Nausea is common and an antiemetic may be required. Frequent low-dose therapy is advisable.	I	C	-
Nitrates are recommended if there is no hypotension.	I	C	-
Inotropic agents:			
• Dopamine	IIa	C	-
• Dobutamine (inotropic)	IIa	C	-
• Levosimendan (inotropic/vasodilator)	IIb	C	-
An adenosine antagonist such as sotalol/oxatolam or epoprostenol must be used if LVEF ≤40%.	I	B	282,314
Ultrafiltration should be considered.	IIa	B	315
Early revascularization must be considered if the patient has not been previously revascularized.	I	C	-
<b>Treatment of cardiogenic shock (Killip class IV)</b>			
Oxygen/mechanical respiratory support is indicated according to blood gases.	I	C	-
Urgent echocardiography/Doppler must be performed to detect mechanical complications, assess systolic function and leading conditions.	I	C	-
High-risk patients must be transferred early to tertiary centres.	I	C	-
Emergency revascularization with either PCI or CABG in suitable patients must be considered.	I	B	100
Fibrinolysis should be considered if revascularization is unavailable.	IIa	C	-
Trans-aortic balloon pumping may be considered.	IIb	B	1,38,305
DN assist devices may be considered for circulatory support in refractory shock.	IIb	C	-
Haemodynamic assessment with balloon flotation catheter may be considered.	IIb	B	316
Inotropic/Vasopressor agents should be considered:			
• Dopamine	IIa	C	-
• Dobutamine	IIa	C	-
• Nitroglycerin (preferred over dopamine when blood pressure is low).	IIb	B	300,317

ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker; CABG = coronary artery bypass graft; i.v. = intravenous; LV = left ventricular ejection fraction; PCI = percutaneous coronary intervention.

<sup>a</sup>Class of recommendation.

<sup>b</sup>Level of evidence.

<sup>c</sup>References.

# «Lo mejor en Enfermedad Arterial Coronaria»

Xavier García-Moll Marimón  
Hospital de la Santa Creu i Sant Pau  
Barcelona



SOCIEDAD  
ESPAÑOLA DE  
CARDIOLOGÍA