

# XXXI Congreso Nacional de la Sociedad Española de Medicina Interna

## II Congreso Ibérico de Medicina Interna

# OVIEDO

17-20 Noviembre 2010

Auditorio-Palacio de Congresos  
"Príncipe Felipe"

VII Congreso de la Sociedad  
Asturiana de Medicina Interna

*Lo más importante de Cardiología en 2010*

**Dr. Vicente Bertomeu Martínez**  
**Servicio de Cardiología**  
**Hospital Universitario de San Juan. Alicante**

# ***Lo más importante de la cardiología en 2010***

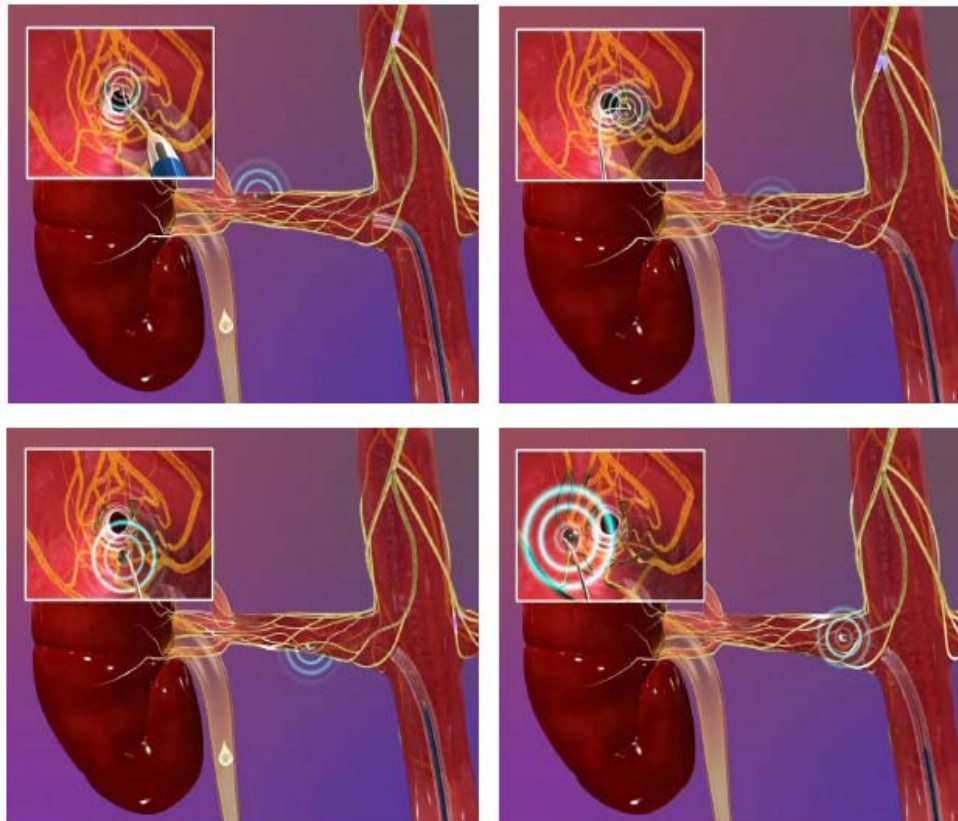
- Hipertensión Arterial
- Cardiopatía Isquémica
- Insuficiencia Cardíaca
- Arritmias
- Intervencionismo Percutáneo

# *Lo más importante de la cardiología en 2010*

- Hipertensión Arterial
- Cardiopatía Isquémica
- Insuficiencia Cardíaca
- Arritmias
- Intervencionismo Percutáneo

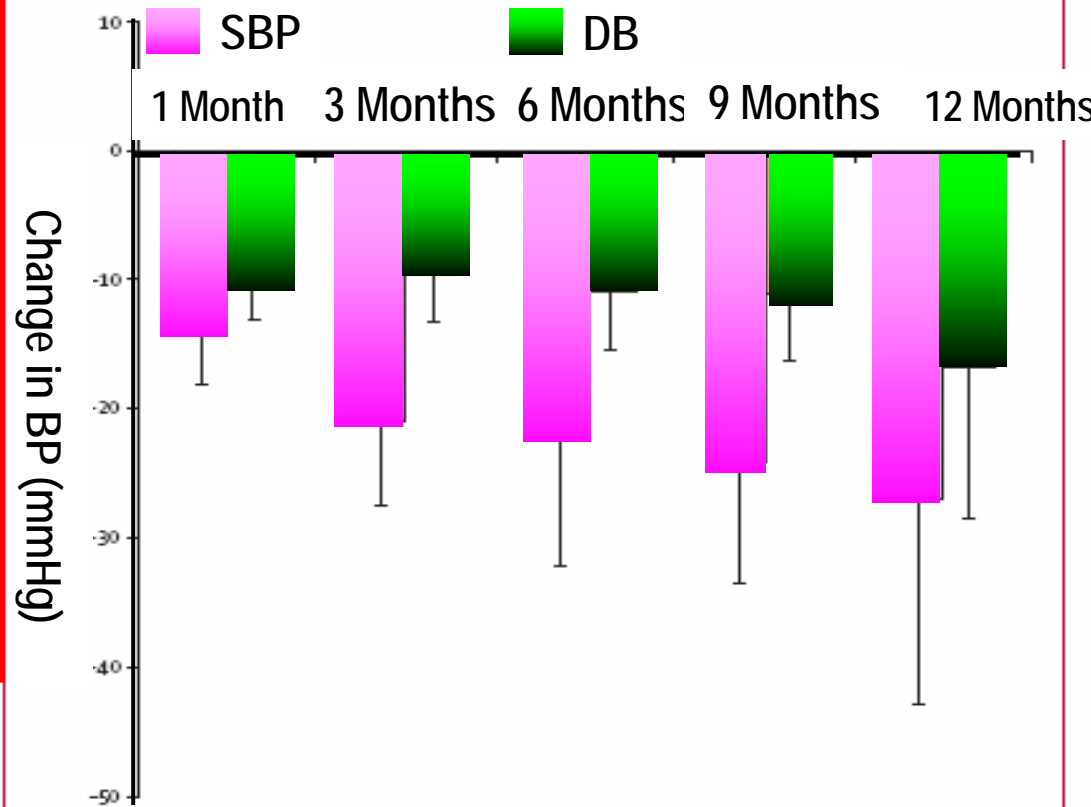
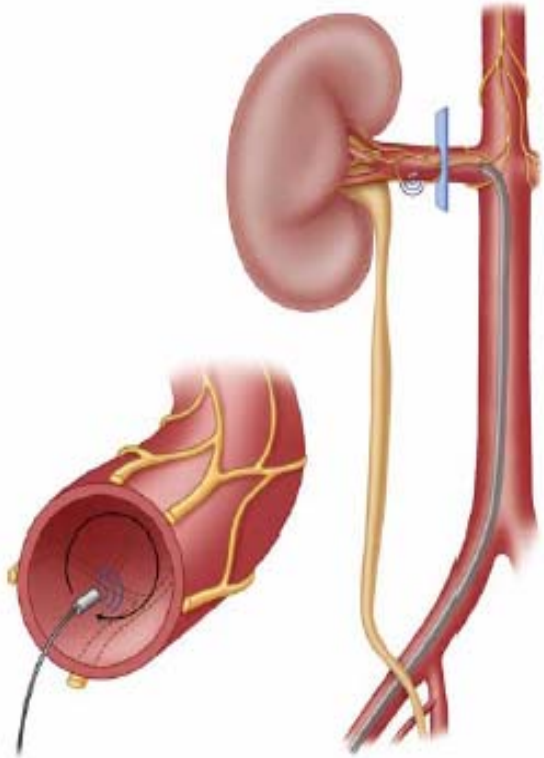
# Devices in Hypertension. BP changes with renal sympathetic denervation in patients with refractory HT

## Radio frequency ablation



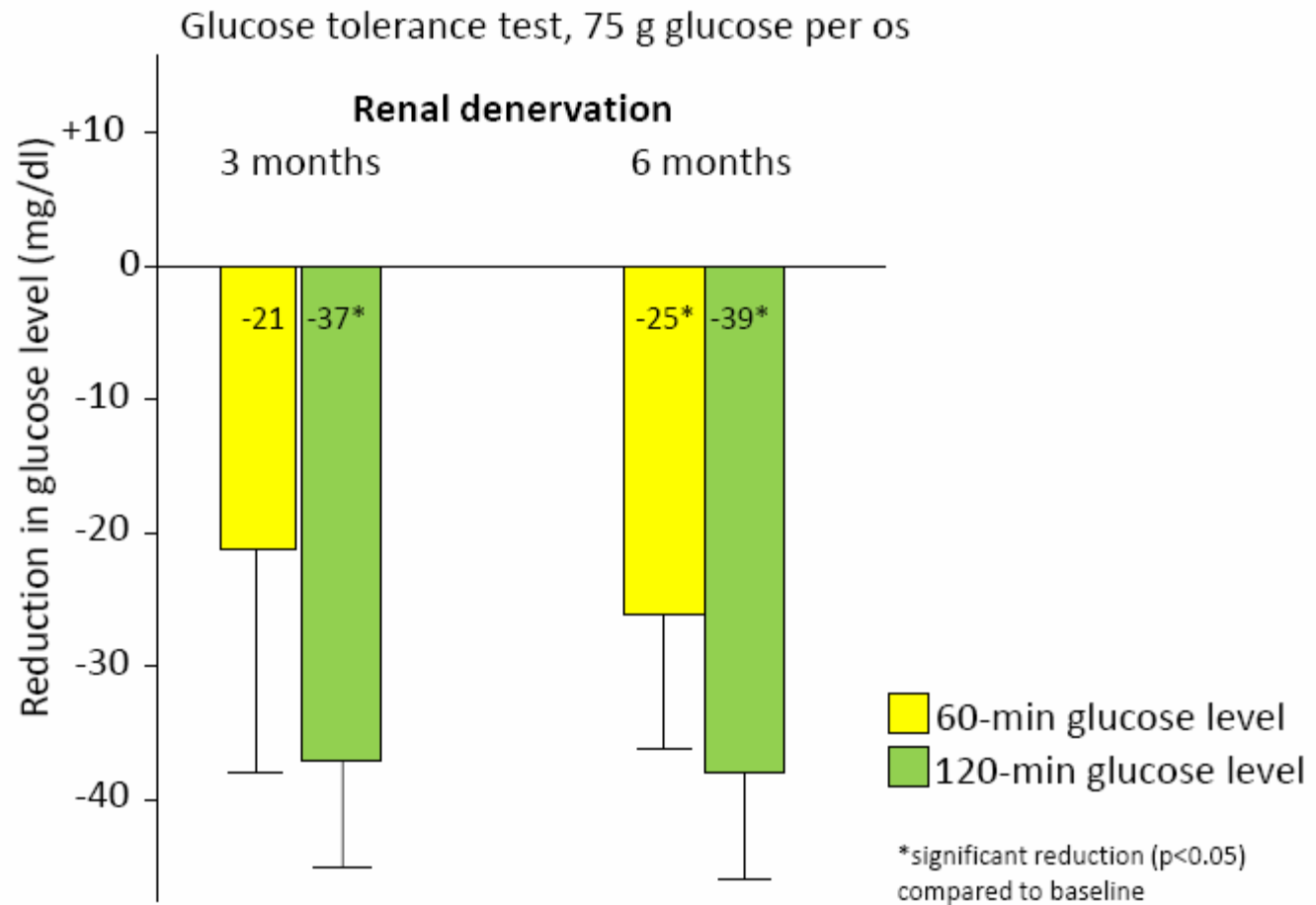
- Diameter >4 mm
- Length >20 mm
- 5 F LIMA or RDC guiding catheter

# Devices in Hypertension. BP changes with renal sympathetic denervation in patients with refractory HT



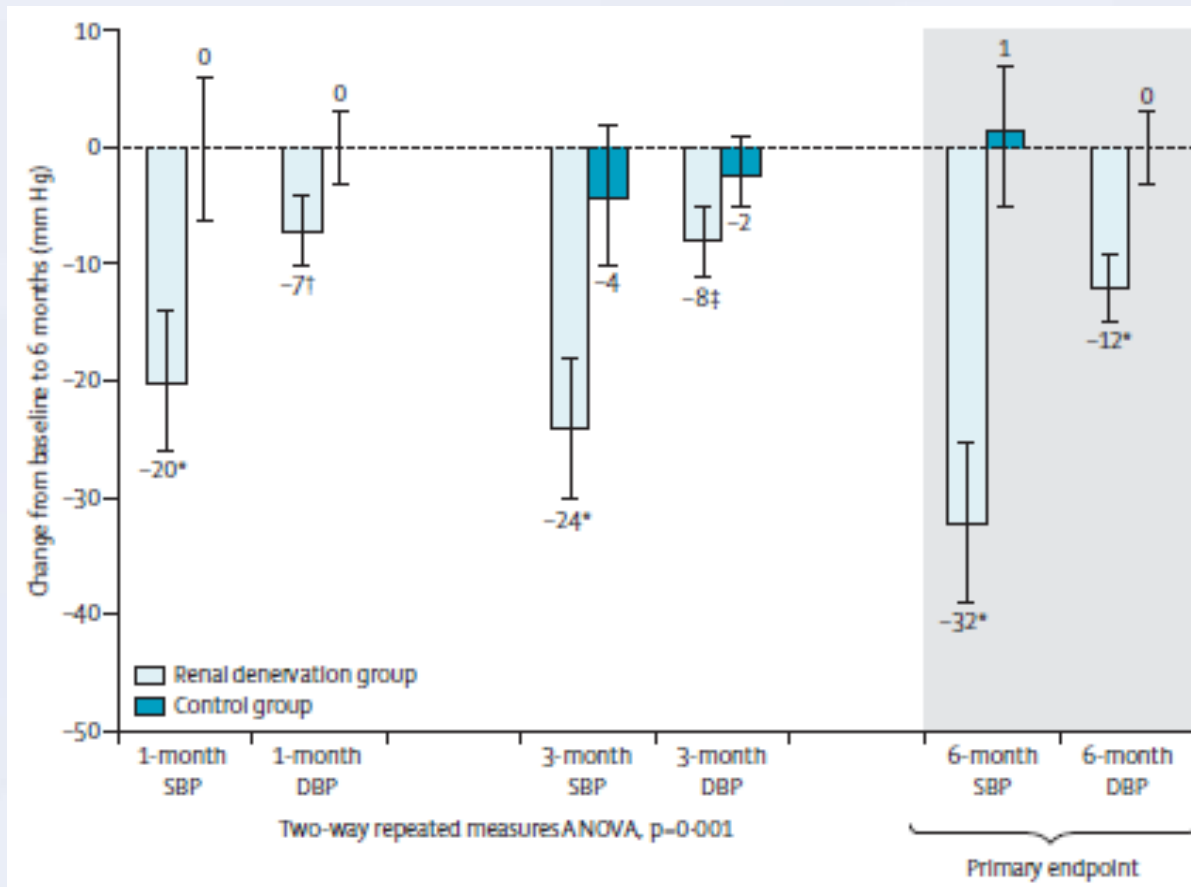
# Devices in Hypertension.

## Renal denervation improves glucose tolerance



# Renal sympathetic denervation in patients with treatment-resistant hypertension (The Symplicity HTN-2 Trial): a randomised controlled trial

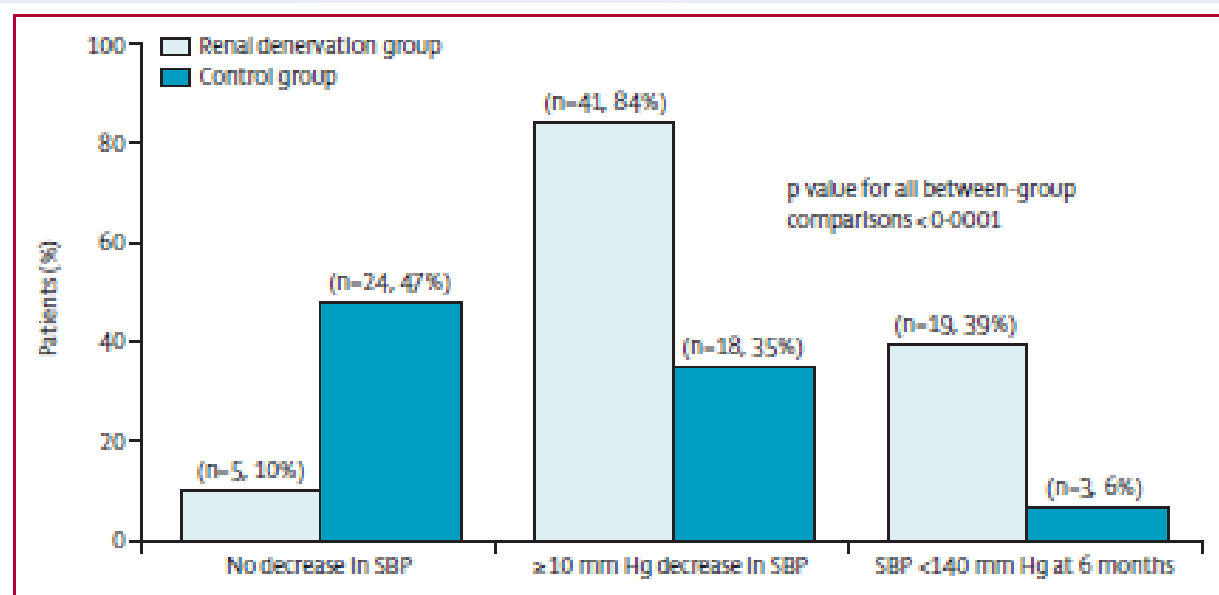
Symplicity HTN-2 Investigators\*



Late Trials AHA 2010  
Lancet on line 2010

# Renal sympathetic denervation in patients with treatment-resistant hypertension (The Symplicity HTN-2 Trial): a randomised controlled trial

Symplicity HTN-2 Investigators\*



Late Trials AHA 2010  
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# GUIAS DE REVASCULARIZACIÓN MIOCÁRDICA

## The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Developed with the special contribution of the European Association for Percutaneous Cardiovascular Interventions (EAPCI)<sup>†</sup>

**Authors/Task Force Members: William Wijns (Chairperson) (Belgium)\*, Philippe Kolh (Chairperson) (Belgium)\*, Nicolas Danchin (France), Carlo Di Mario (UK), Volkmar Falk (Switzerland), Thierry Folliguet (France), Scot Garg (The Netherlands), Kurt Huber (Austria), Stefan James (Sweden), Juhani Knuuti (Finland), Jose Lopez-Sendon (Spain), Jean Marco (France), Lorenzo Menicanti (Italy), Miodrag Ostojic (Serbia), Massimo F. Piepoli (Italy), Charles Pirlet (Belgium), Jose L. Pomar (Spain), Nicolaus Reifart (Germany), Flavio L. Ribichini (Italy), Martin J. Schalij (The Netherlands), Paul Sergeant (Belgium), Patrick W. Serruys (The Netherlands), Sigmund Silber (Germany), Miguel Sousa Uva (Portugal),**

Associations: Heart Failure Association (HFA), European Association for Cardiovascular Prevention and Rehabilitation (EACPR), European Heart Rhythm Association (EHRA), European Association of Echocardiography (EAE).

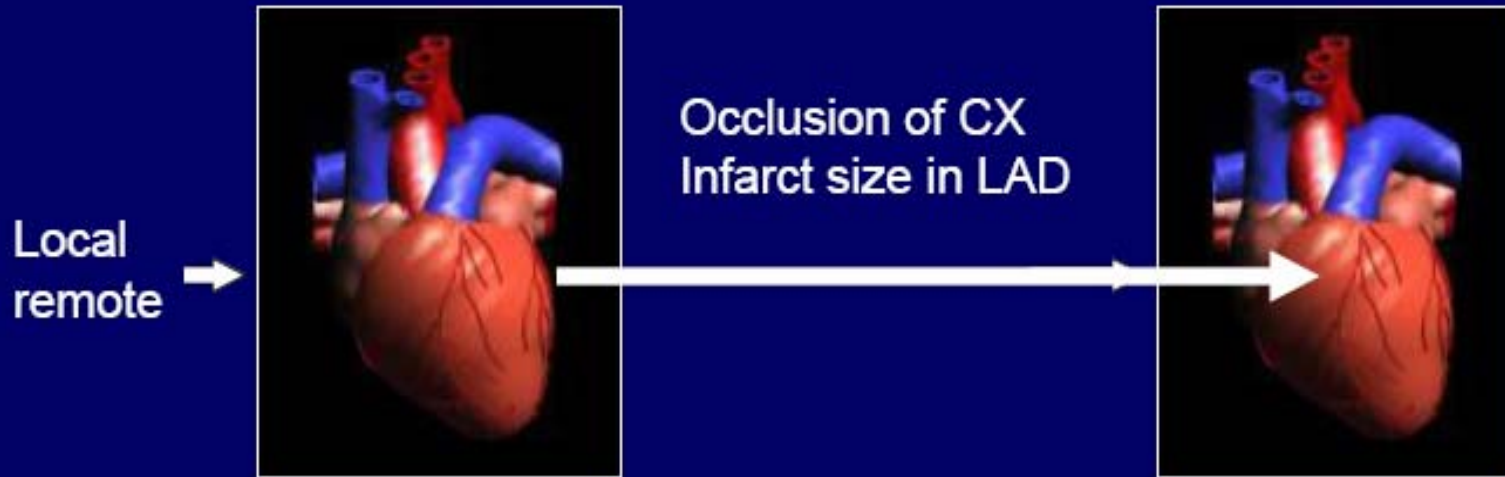
Working Groups: Acute Cardiac Care, Cardiovascular Surgery, Thrombosis, Cardiovascular Pharmacology and Drug Therapy.

Councils: Cardiovascular Imaging, Cardiology Practice.

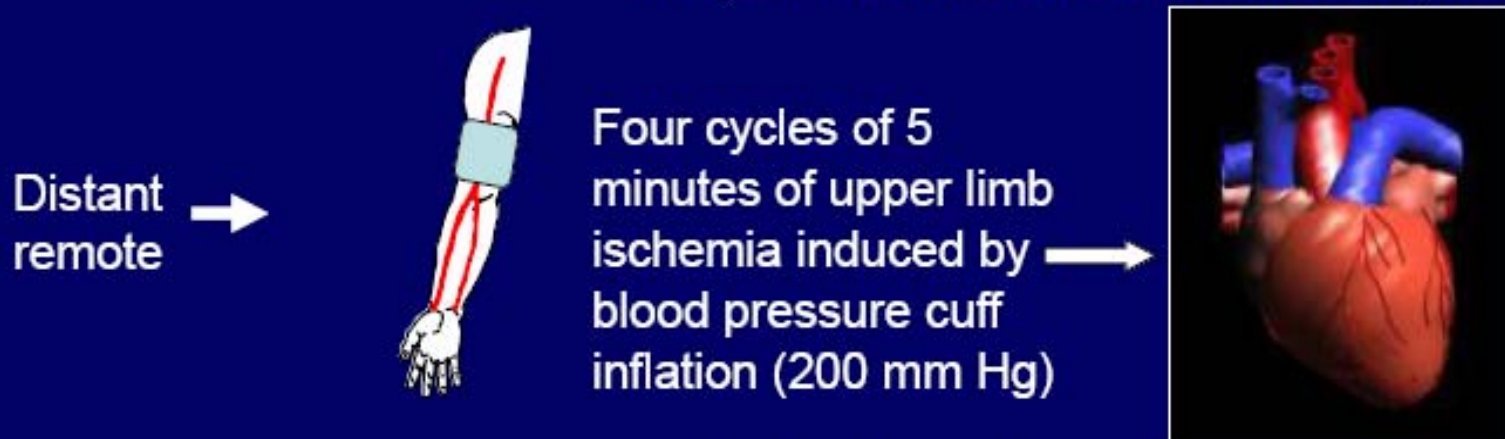
# Nuevas Guías de la SEC: Revascularización Miocárdica

- Aproximación a la mejor estrategia de tratamiento en un determinado contexto social y cultural
- Qué pacientes se benefician más
- Concepto del “**HEART TEAM**”
- Mayor discusión entre los médicos-cirujanos implicados
- Más tiempo entre el momento del diagnóstico y la intervención (PCI ó CABG)
- Mas transparencia, mejor información y mayor participación del paciente
- Individualiza las indicaciones en función de la presentación y la patología asociada

# CONCEPTO DE PRECONDICIONAMIENTO REMOTO



*Przyklenk K et al. Circulation 1993;87:893-9*



*Kharbanda R et al. Circulation 2002;106:2881-3*

# PRECONDICIONAMIENTO DURANTE EL TRASLADO PARA LA PCI



	PCI only (n=125)	rPerC (n=126)	P Value
Age, year (mean)	62±12	63±12	0.71
Male sex (%)	75	77	0.71
Diabetes Mellitus (%)	9	9	0.97
Current smoker (%)	57	56	0.67
Hypertension (%)	31	39	0.01
Statin Tx (%)	20	16	0.47
Symptom to balloon time, min (median [IQR])	185 [134; 309]	188 [132; 302]	0.98

ECG



Patient

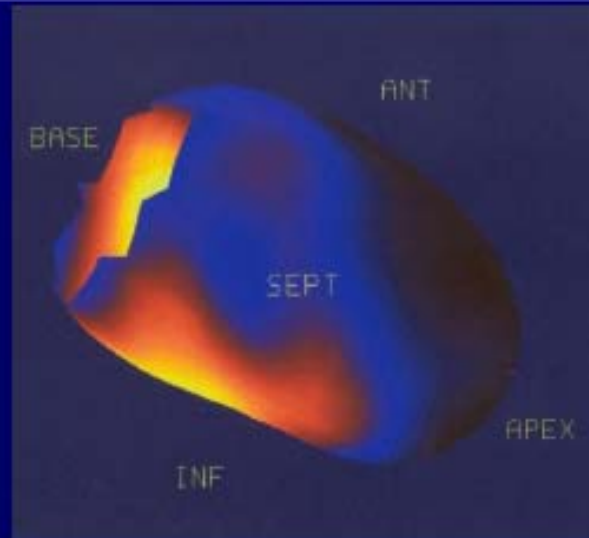
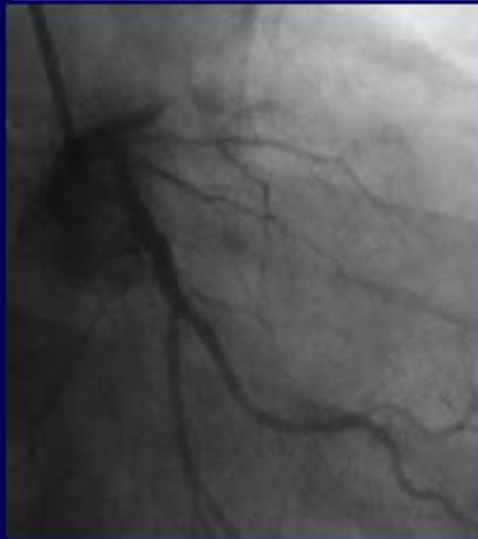
Randomization



Ambulance

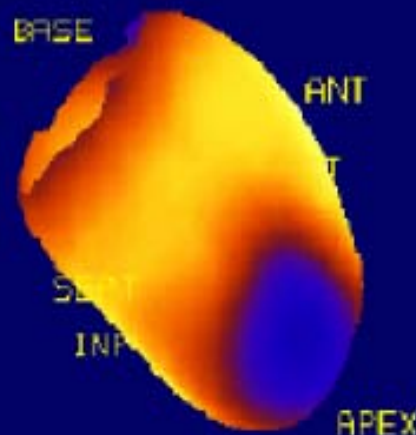


# **OBJETIVO PRIMARIO: INDICE DE MIOCARDIO SALVADO**



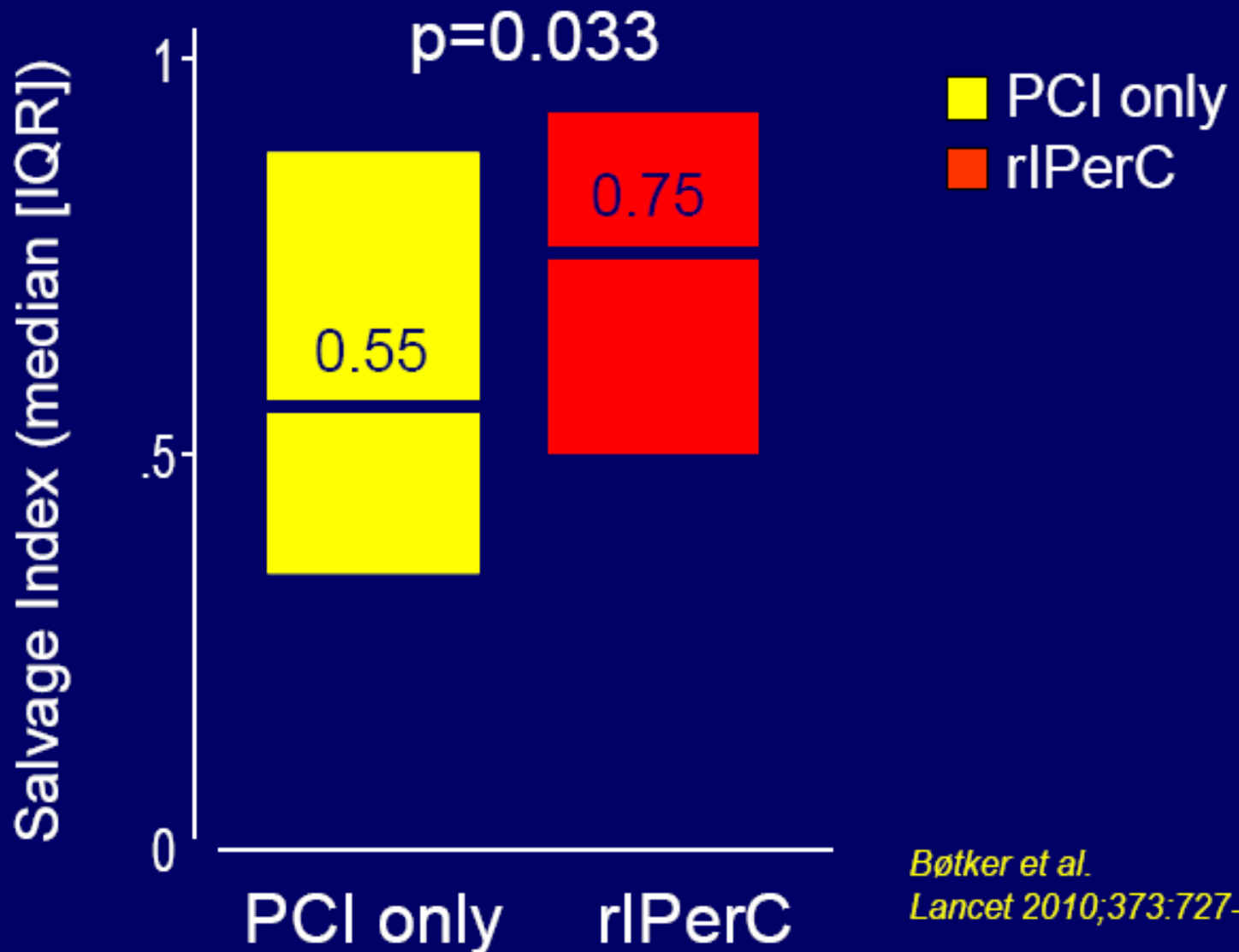
Acute scan:  
Area-at-risk  
(AAR)

$$\text{Salvage index} = \frac{\text{AAR-FIS}}{\text{AAR}}$$



One month scan:  
Final infarct size  
(FIS)

# OBJETIVO PRIMARIO: INDICE DE MIOCARDIO SALVADO



# Precondicionamiento Remoto en IAM

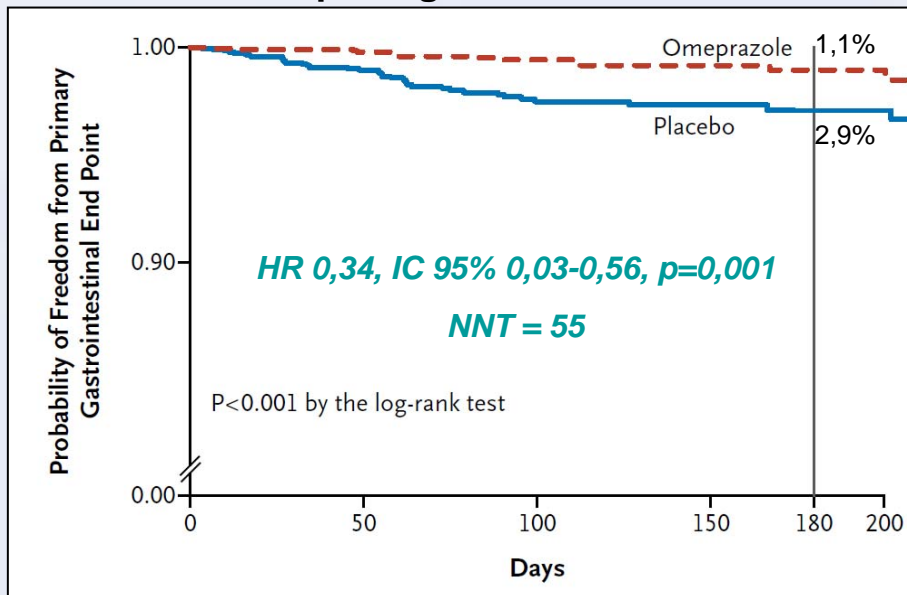
- El preconditionamiento isquémico remoto es factible
- Las evidencia acumuladas indican que el condicionamiento isquémico remoto reduce el daño letal de la reperfusión
- Es necesario conocer y entender los mecanismos que intervienen en la fisiopatología
- El uso generalizado de esta estrategia de tratamiento requiere mas evidencias a partir de ensayos clínicos a mayor escala que demuestren beneficio clínico



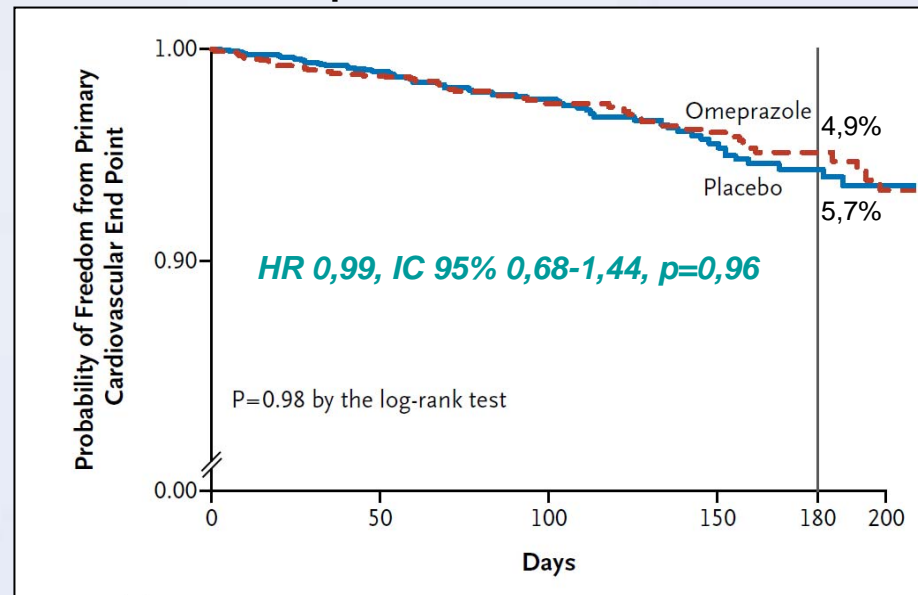
# COGENT

- Suspendido prematuramente por quiebra del espónsor
- 3761 pacientes con indicación de doble antiagregación  $\geq 12$  meses (SCA o stent).
- Clopidogrel (75 mg/d) + omeprazol (20 mg/d) vs clopidogrel solo.
- Endpoints primarios:
  - Gastrointestinal: sangrado GI, úlcera gastroduodenal, dolor persistente de origen G-I.
  - Cardiovascular: muerte cardiovascular, IAM, revascularización o ACV isquémico.

### Endpoint gastrointestinal



### Endpoint cardiovascular



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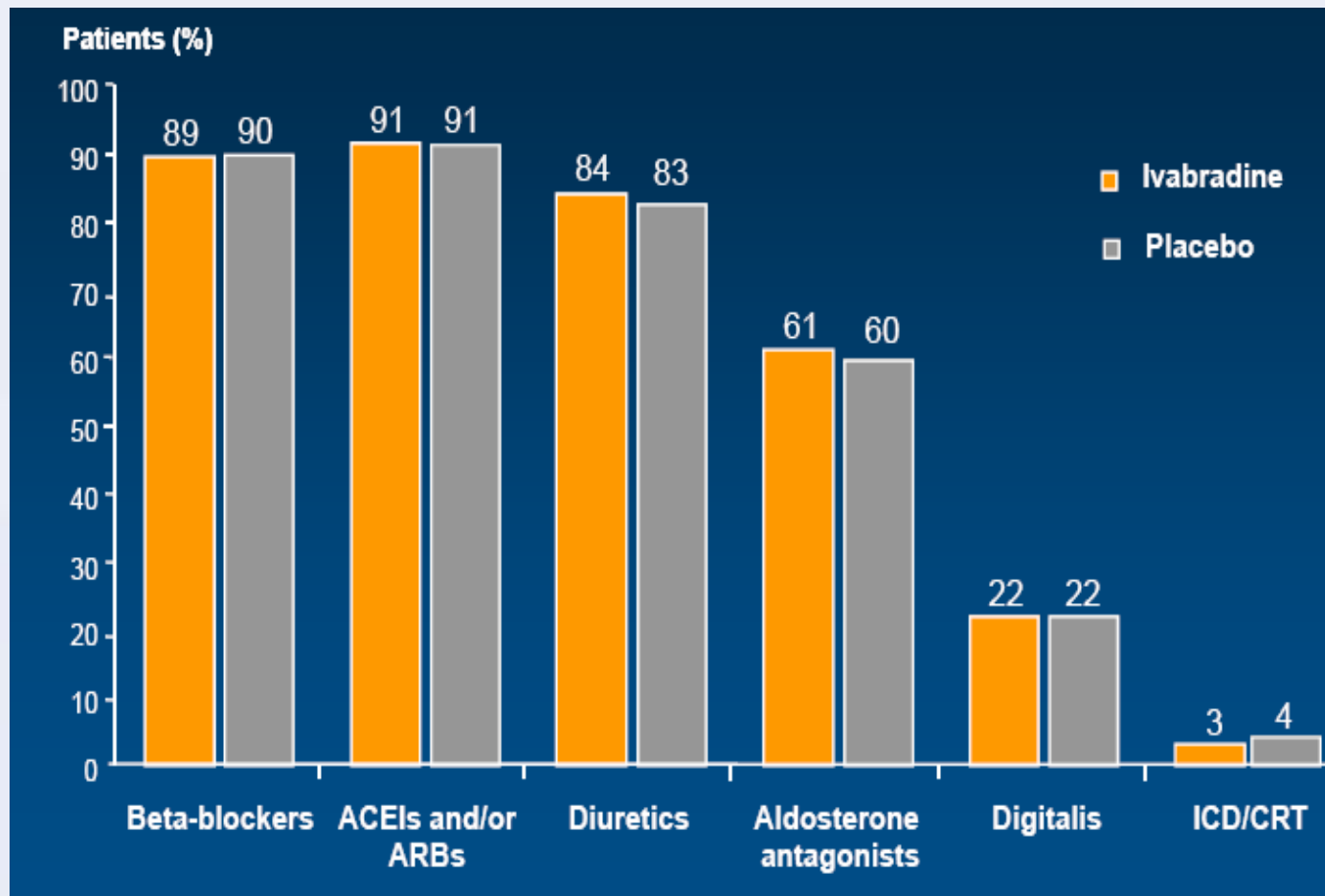
# Nuevas evidencias con Ivabradina en pacientes con IC

## SHIFT Study

## Criterios de inclusión

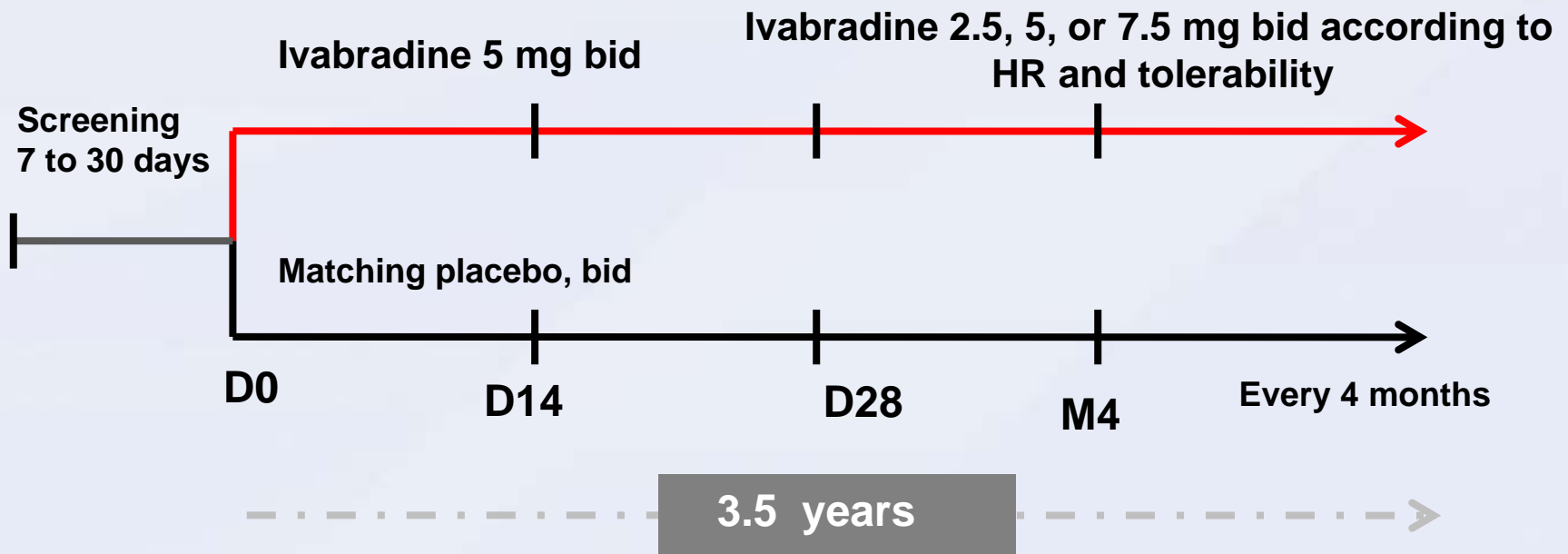
- ✓  $\geq 18$  years
- ✓ Class II to IV NYHA heart failure
- ✓ Ischaemic/non-ischaemic aetiology
- ✓ LV systolic dysfunction ( $EF \leq 35\%$ )
- ✓ Heart rate  $\geq 70$  bpm
- ✓ Sinus rhythm
- ✓ Documented hospital admission for worsening heart failure  $\leq 12$  months





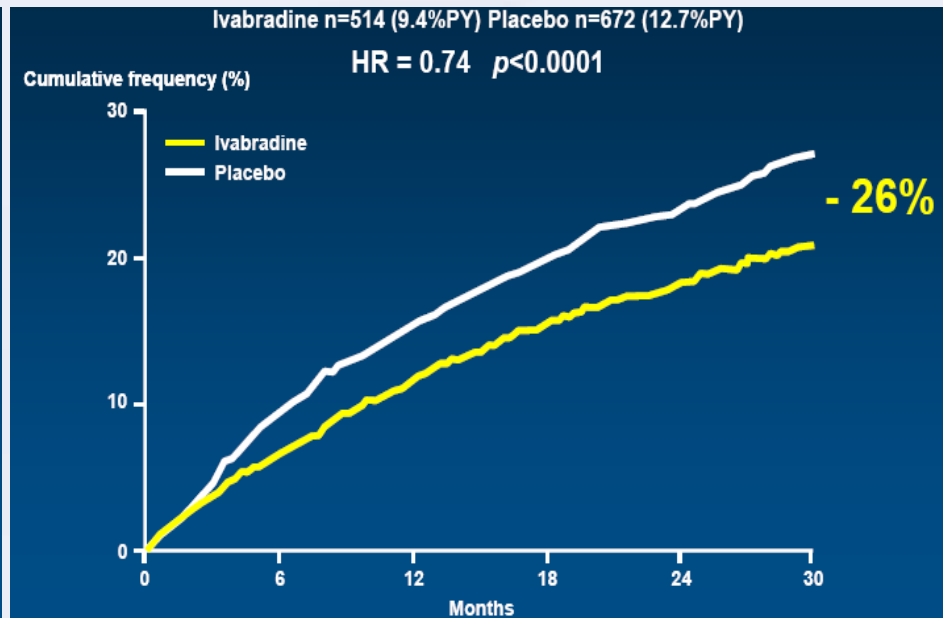
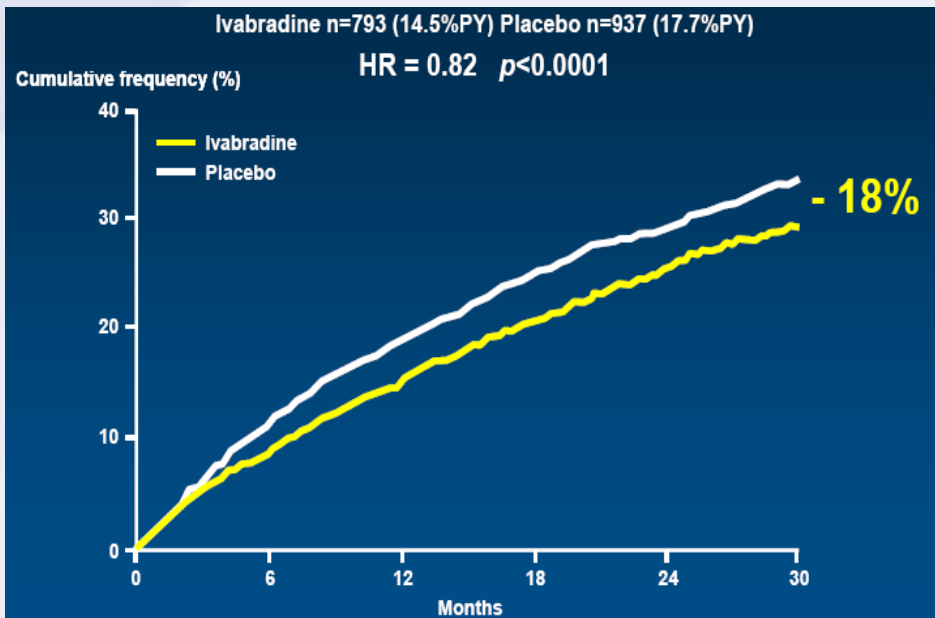
**PRIMARY COMPOSITE ENDPOINT:**

- Cardiovascular death
- Hospitalization for worsening heart failure



## Primary composite endpoint

## Hospitalization for heart failure



### Endpoints

### Hazard ratio

### 95% CI

### *p* value

CV death

0.91

[0.80;1.03]

$p=0.128$

All-cause death

0.90

[0.80;1.02]

$p=0.092$

Death from HF

0.74

[0.58;0.94]

$p=0.014$

Hospitalization for any cause

0.89

[0.82;0.96]

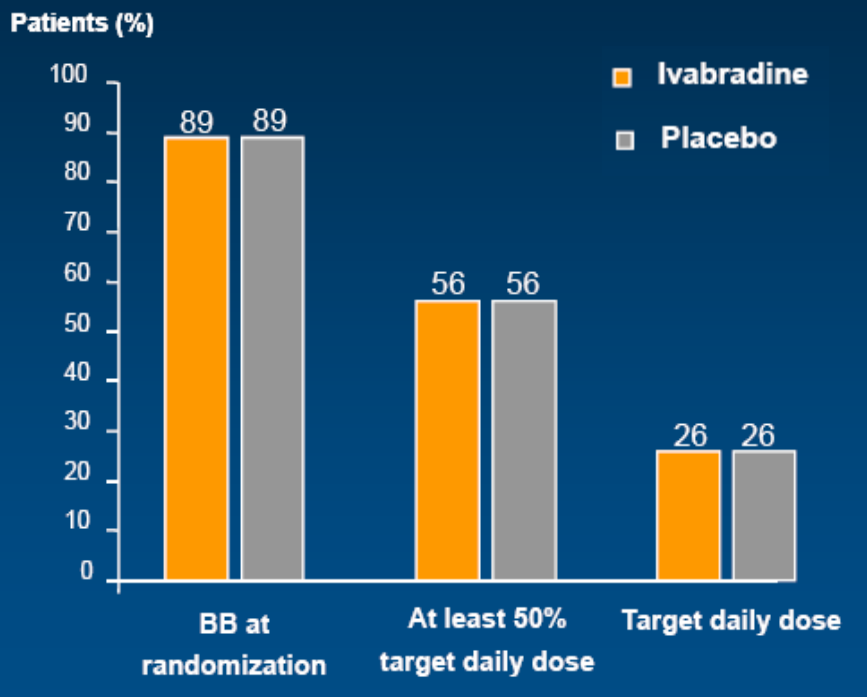
$p=0.003$

Hospitalization for CV reason

0.85

[0.78;0.92]

$p=0.0002$



## TARGET DOSE OF BETABLOCKERS IN HEART FAILURE TRIALS AND REGISTRIES

HF trials	% BB	HF registries	% BB
CIBIS	38	COHERE(USA,2004)	44
CIBIS II	43	VA NATIONAL (USA, 2009)	25
MERIT HF	64	EURO H. SURVEY (2005)	10
COPERNICUS	65	IMPACT RECO (FR,2009)	23
SENIORS	67	IMPROVE HF (USA,2010)	17
		ESC-HF Pilot (Europe,2010)	26

ORIGINAL ARTICLE

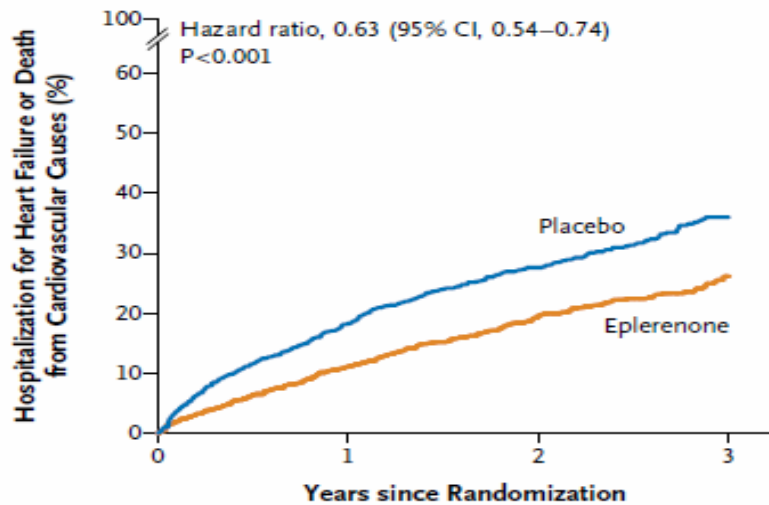
## Eplerenone in Patients with Systolic Heart Failure and Mild Symptoms

Faiez Zannad, M.D., Ph.D., John J.V. McMurray, M.D., Henry Krum, M.B., Ph.D., Dirk J. van Veldhuisen, M.D., Ph.D., Karl Swedberg, M.D., Ph.D., Harry Shi, M.S., John Vincent, M.B., Ph.D., Stuart J. Pocock, Ph.D., and Bertram Pitt, M.D.,  
for the EMPHASIS-HF Study Group\*

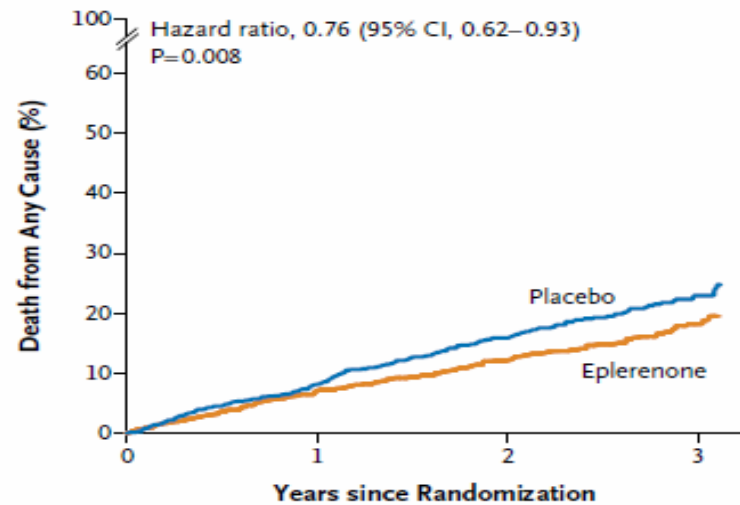
### **POBLACIÓN DEL ESTUDIO EMPHASIS:**

- Edad  $\geq 55$  años
- NYHA II
- FEVI no superior a 30% (si 30-35%, QRS  $> 130$  ms)
- Tratamiento a dosis recomendadas o toleradas máximas: IECA, ARA II (o ambos), BBLOQ

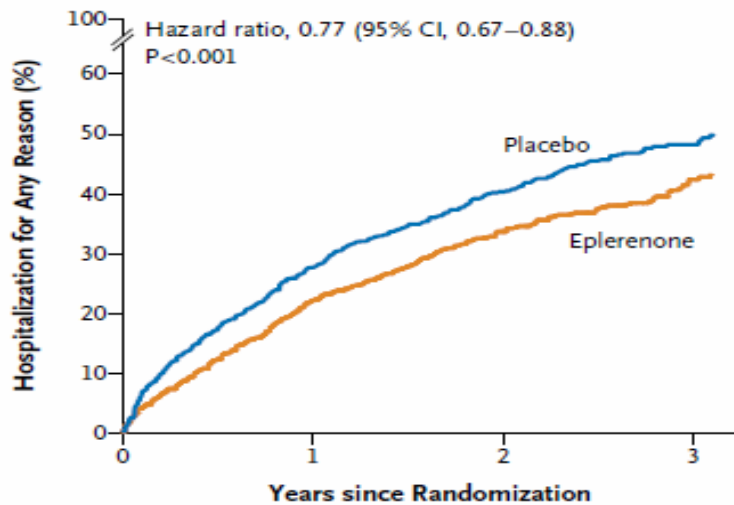


**A****No. at Risk**

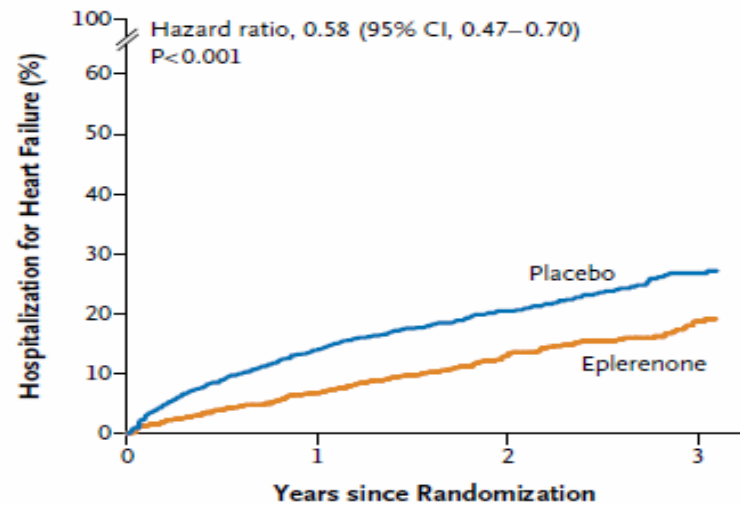
Placebo	1373	848	512	199
Eplerenone	1364	925	562	232

**B****No. at Risk**

Placebo	1373	947	587	242
Eplerenone	1364	972	625	269

**C****No. at Risk**

Placebo	1373	742	403	146
Eplerenone	1364	795	451	179

**D****No. at Risk**

Placebo	1373	848	512	199
Eplerenone	1364	925	562	232

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# RACE II

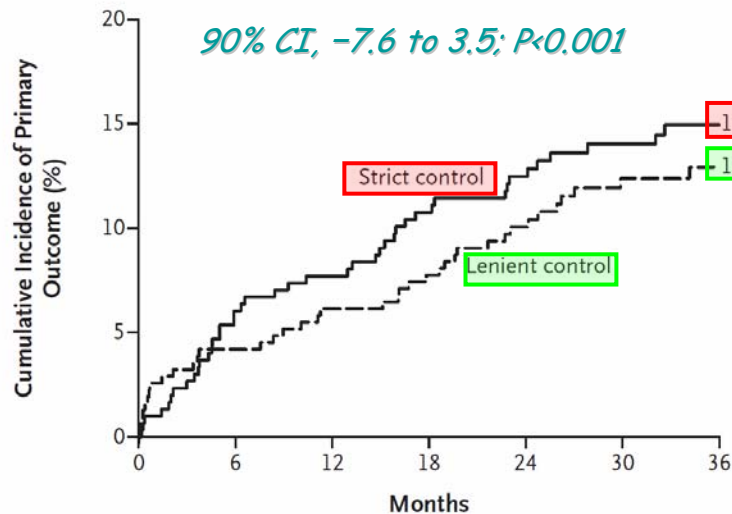
## Rate Control Efficacy in Permanent Atrial Fibrillation: comparison between Lenient versus Strict Rate Control II (RACE II)

614 p FA permanente

Randomizado (1:1): -Control estricto FC (FC basal < 80, FC ejercicio < 110)

-Control laxo FC (FC basal < 110)

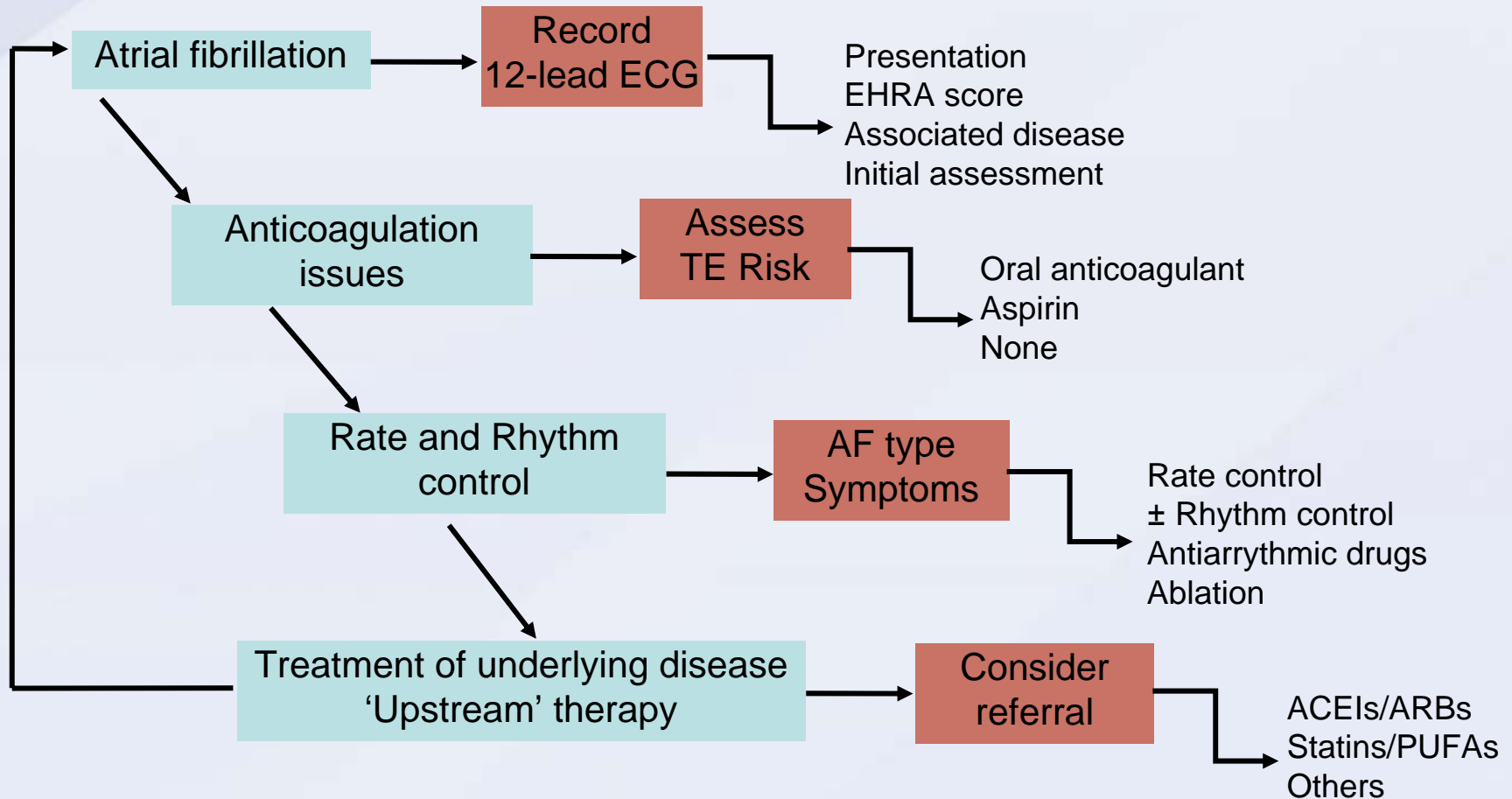
Seguimiento 2-3 años



No. at Risk	0	6	12	18	24	30	36
Strict control	303	282	273	262	246	212	131
Lenient control	311	298	290	285	255	218	138

Outcome	Lenient Rate Control (N=311) no. of patients (%)	Strict Rate Control (N=303) no. of patients (%)	Hazard Ratio (90% CI)
Composite primary outcome	38 (12.9)	43 (14.9)	0.84 (0.58–1.21)
Individual components			
Death from cardiovascular cause	9 (2.9)	11 (3.9)	0.79 (0.38–1.65)
From cardiac arrhythmia	3 (1.0)	4 (1.4)	
From cardiac cause other than arrhythmia	1 (0.3)	2 (0.8)	
From noncardiac vascular cause	5 (1.7)	5 (1.9)	
Heart failure	11 (3.8)	11 (4.1)	0.97 (0.48–1.96)
Stroke	4 (1.6)	11 (3.9)	0.35 (0.13–0.92)
Ischemic	3 (1.3)	8 (2.9)	
Hemorrhagic	1 (0.3)	4 (1.5)	
Systemic embolism	1 (0.3)	0	
Bleeding	15 (5.3)	13 (4.5)	1.12 (0.60–2.08)
Intracranial	0	3 (1.0)	
Extracranial	15 (5.3)	10 (3.5)	
Syncope	3 (1.0)	3 (1.0)	
Life-threatening adverse effect of rate-control drugs	3 (1.1)	2 (0.7)	
Sustained ventricular tachycardia or ventricular fibrillation	0	1 (0.3)	
Cardioverter–defibrillator implantation	0	1 (0.3)	
Pacemaker implantation	2 (0.8)	4 (1.4)	

# Fibrilación auricular. Guías ESC 2010



# Fibrilación auricular. ESC 2010

European Heart Journal  
doi:10.1093/eurheartj/ehq278

ESC GUIDELINES

**Guidelines for the management of atrial fibrillation**

The Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC)

Developed with the special contribution of the European Heart Rhythm Association (EHRA)<sup>1</sup>

Endorsed by the European Association for Cardio-Thoracic Surgery (EACTS)

## Highlights

1. Presentación clínica y diagnóstico
2. Refinamiento riesgo tromboembolismo y hemorragia
3. Nuevas recomendaciones de tratamiento
4. Ablación como método de tratamiento

CHA <sub>2</sub> DS <sub>2</sub> -VASc	Score
CHF	1
HTA	1
Age ≥ 75	2
Diabetes	1
Stroke/AIT/TE	2
Enfermedad Vasular	1
Age 65-75	1
Sexo (i.e. femenino) < 75	1

CHA <sub>2</sub> DS <sub>2</sub> -VASc	Tasa ACV (% año)
0 Nada/AAS	0
1 ACO/AAS	1.3
2 ACO	2.2
3	3.2
4	4.0
5	6.7
6	9.8
7	9.6
8	6.7
9	15.2

H	Hypertension	1
A	Abnormal renal/liver	1 ó 2
S	Stroke	1
B	Bleeding	1
L	Labile INR	1
E	Elderly (>75)	1
D	Drugs/Alcohol	1 ó 2

HAS-BLED ≤ 2: Dabigatran 150 mgs bid  
 HAS-BLED > 2: Dabigatran 110 mgs bid

Clase I nivel evidencia A

# ***Phase III trials comparing new anticoagulants in AF***

## **1. Versus Warfarin**

### **Direct Thrombin inhibition:**

Ximelagatran (Sportif III & V) - 2003, 2005

**Dabigatran (RELY) 2009**

### **Direct factor Xa inhibition:**

**Ribaroxaban (ROCKET) – Nov 2010**

Apixaban (ARISTOTELE) – Aug 2011

Edoxaban (ENGAGE AF – TIMI48) – 2012?

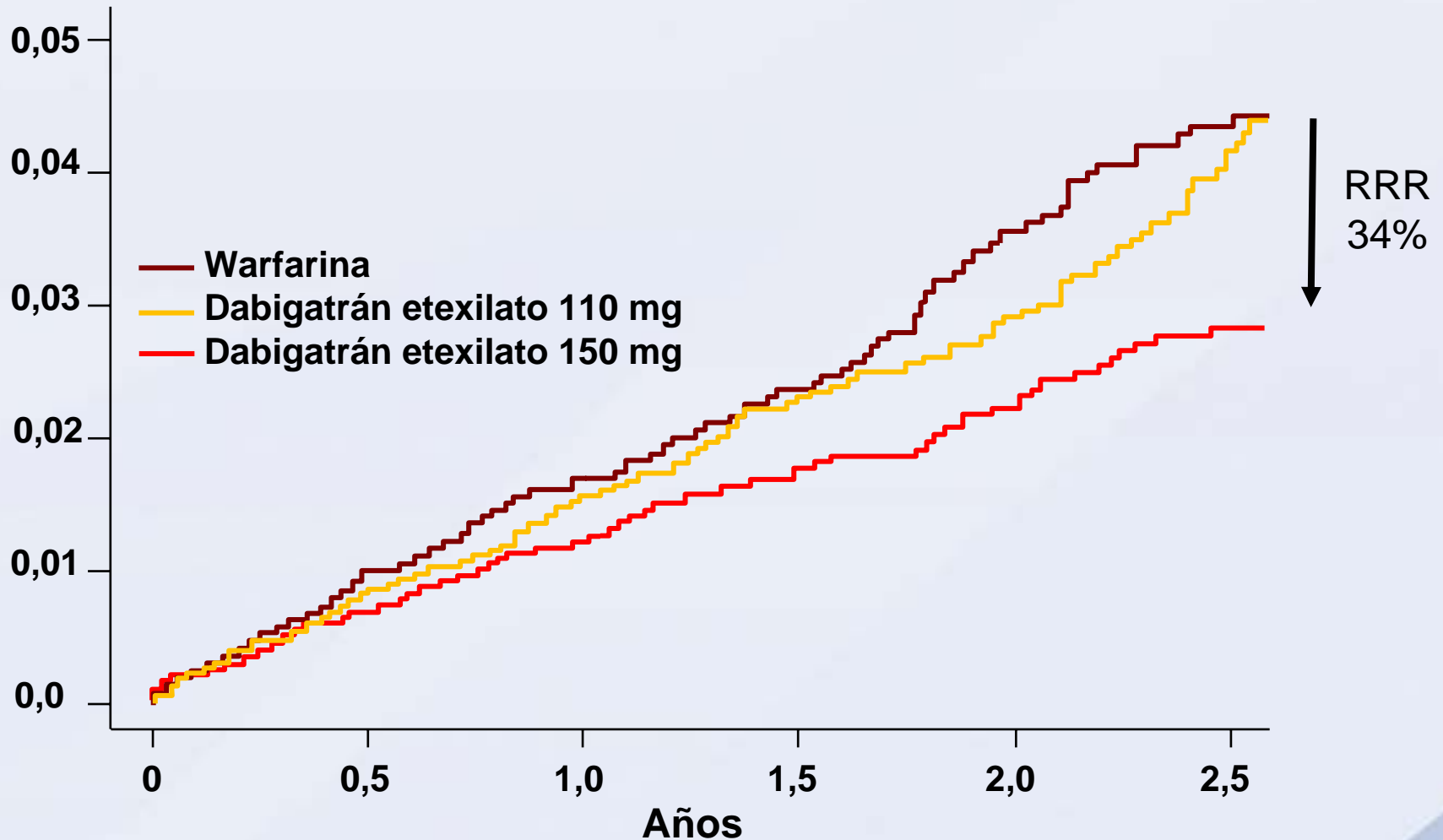
Betrixaban (start phase III 2011?) – 2014?

## **2. Versus Aspirin:**

**Apixaban (AVERROES) Aug 2010**

# E. RE-LY.

## FA. Tiempo hasta el primer ictus/ES

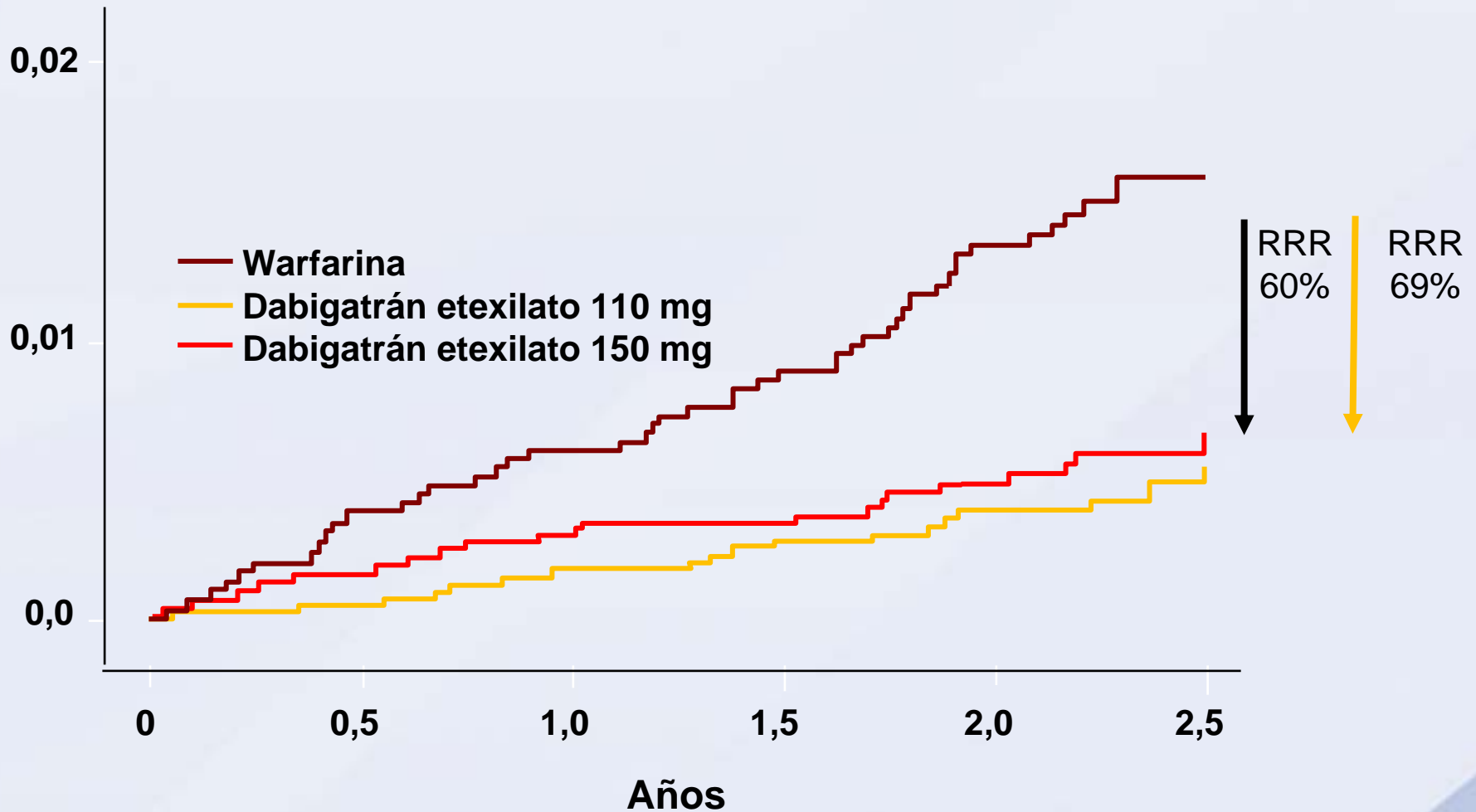


Connolly SJ., et al. NEJM publicado en línea el 30 de agosto de 2009.

DOI 10.1056/NEJMoa0905561

# *E. RE-LY.*

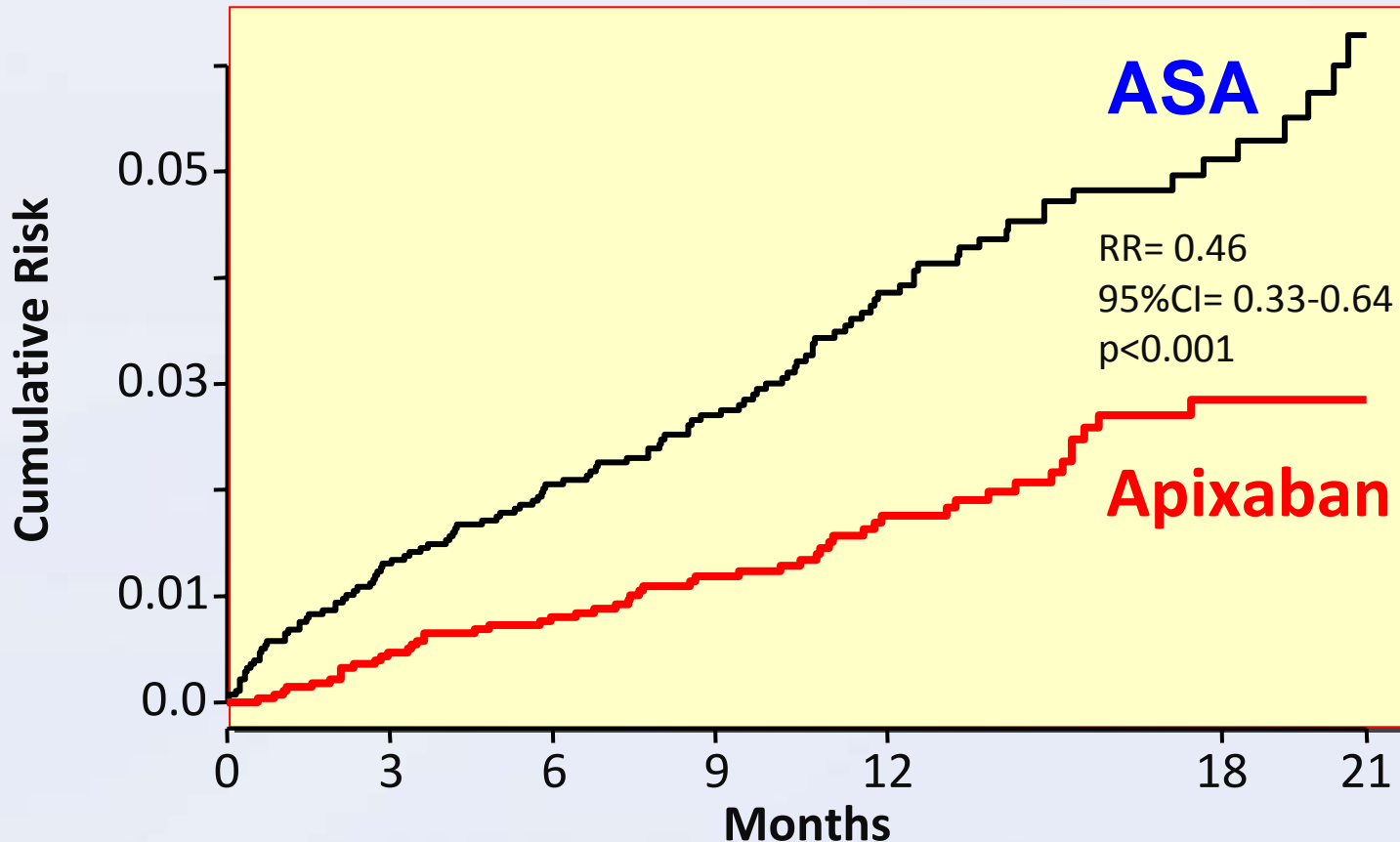
## *Tiempo hasta la primera hemorragia intracraneal*





# ***AVERROES***

## ***Stroke or Systemic Embolic Event***

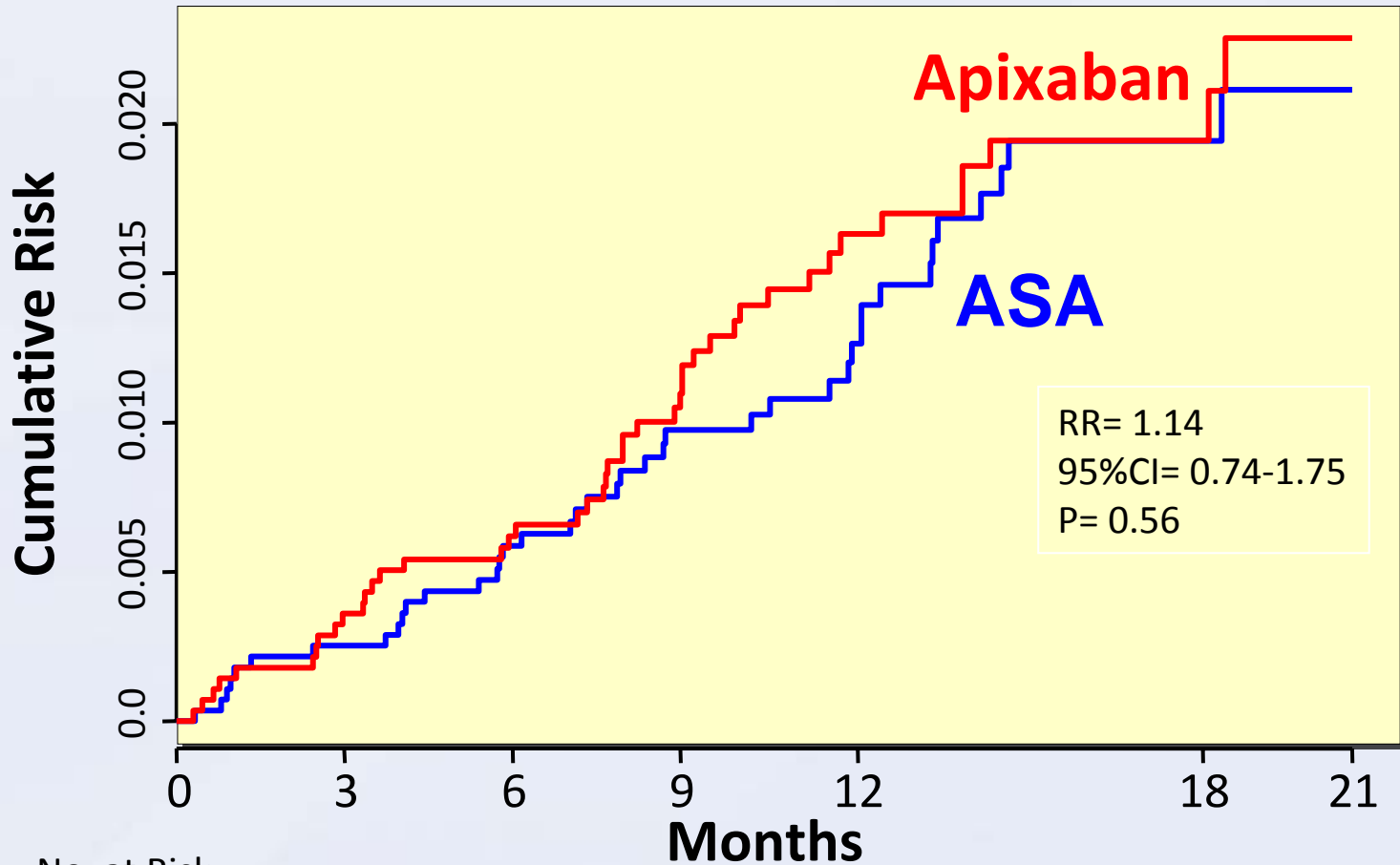


No. at Risk

ASA	2791	2720	2541	2124	1541	626	329
Apix	2809	2761	2567	2127	1523	617	353

# ***AVERROES***

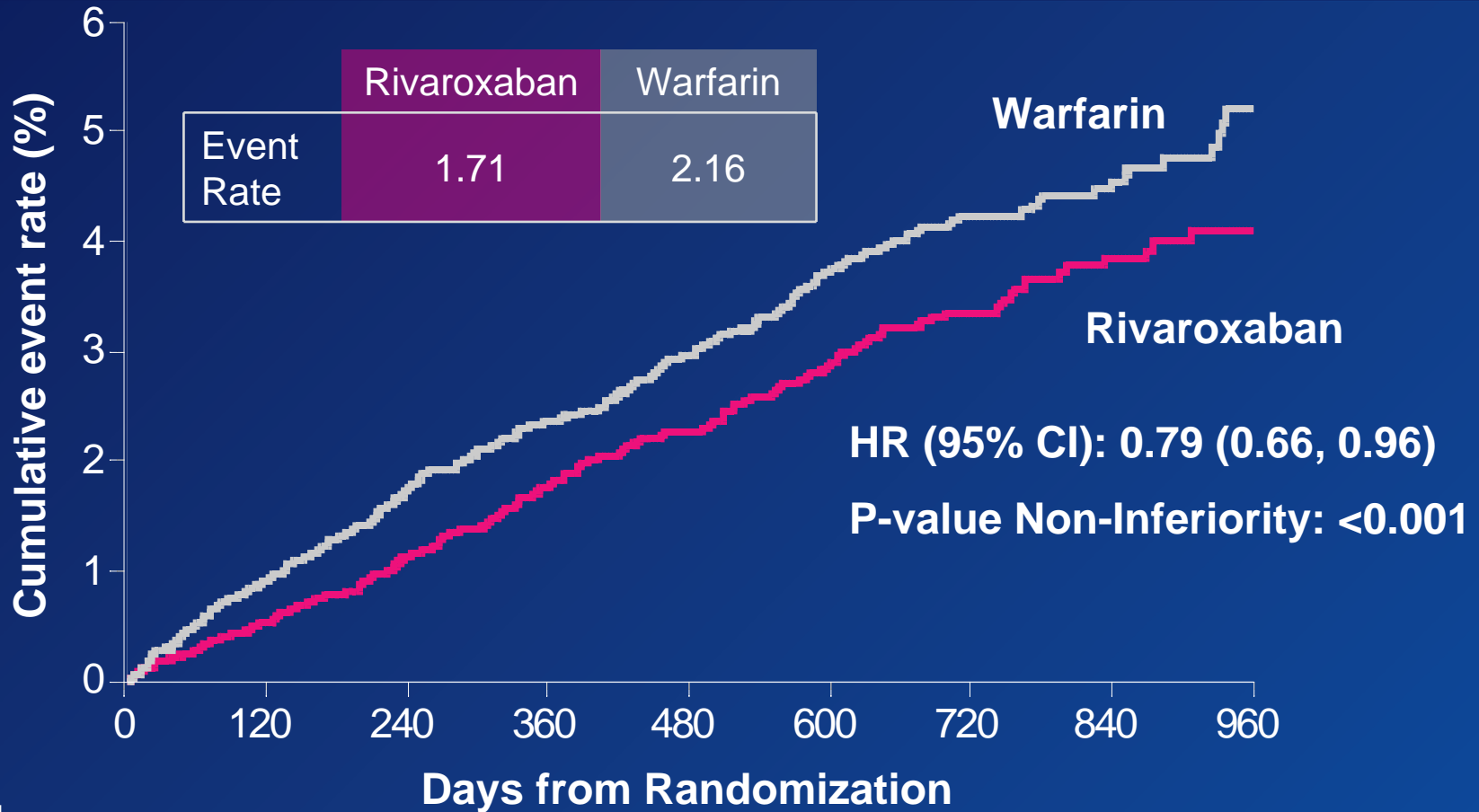
## ***Major Bleeding***



No. at Risk		0	3	6	9	12	18	21
ASA	2791	2744	2572	2152	1570		642	340
Apix	2809	2763	2567	2123	1521		622	357

# Primary Efficacy Outcome

## Stroke and non-CNS Embolism



No. at risk:

Rivaroxaban	6958	6211	5786	5468	4406	3407	2472	1496	634
Warfarin	7004	6327	5911	5542	4461	3478	2539	1538	655

Event Rates are per 100 patient-years  
 Based on Protocol Compliant on Treatment Population

# Primary Safety Outcomes

	Rivaroxaban	Warfarin		
	Event Rate or N (Rate)	Event Rate or N (Rate)	HR (95% CI)	P- value
Major	3.60	3.45	1.04 (0.90, 1.20)	0.576
≥2 g/dL Hgb drop	2.77	2.26	1.22 (1.03, 1.44)	0.019
Transfusion (> 2 units)	1.65	1.32	1.25 (1.01, 1.55)	0.044
Critical organ bleeding	0.82	1.18	0.69 (0.53, 0.91)	0.007
Bleeding causing death	0.24	0.48	0.50 (0.31, 0.79)	0.003
Intracranial Hemorrhage	55 (0.49)	84 (0.74)	0.67 (0.47, 0.94)	0.019
Intraparenchymal	37 (0.33)	56 (0.49)	0.67 (0.44, 1.02)	0.060
Intraventricular	2 (0.02)	4 (0.04)		
Subdural	14 (0.13)	27 (0.27)	0.53 (0.28, 1.00)	0.051
Subarachnoid	4 (0.04)	1 (0.01)		

Event Rates are per 100 patient-years  
Based on Safety on Treatment Population

# Fibrilación auricular. ESC 2010

European Heart Journal  
doi:10.1093/eurheartj/ehq278

ESC GUIDELINES

**Guidelines for the management of atrial fibrillation**

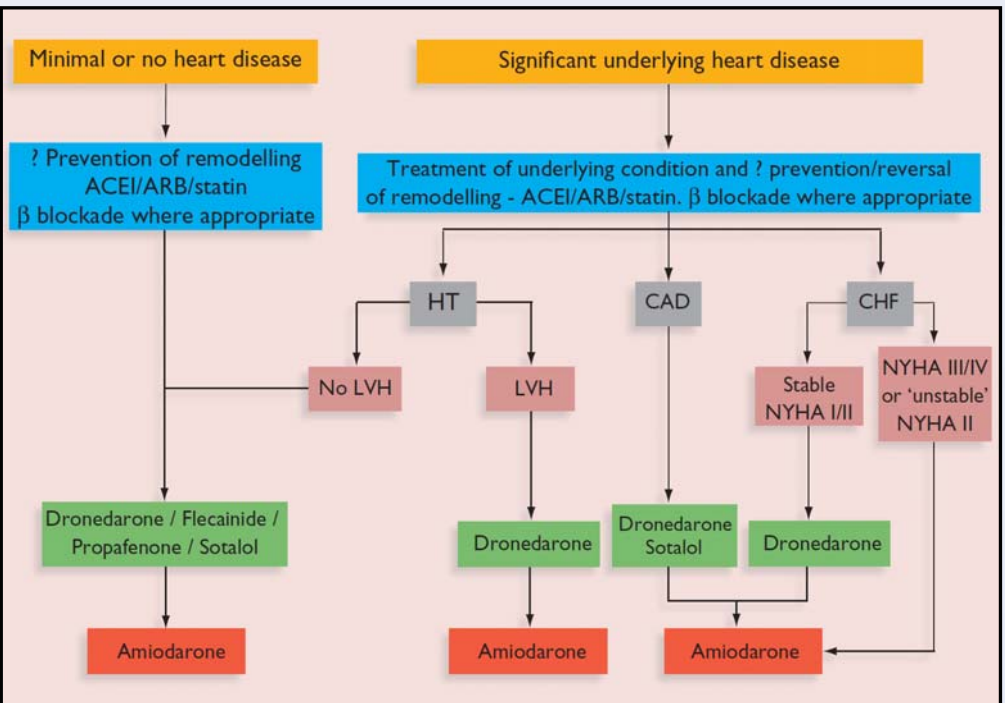
The Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC)

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3. **Nuevas recomendaciones de tratamiento**
4. Ablación como método de tratamiento



Recommendations	Class <sup>a</sup>	Level <sup>b</sup>
The following antiarrhythmic drugs are recommended for rhythm control in patients with AF, depending on underlying heart disease:		
• amiodarone	I	A
• dronedarone	I	A
• flecainide	I	A
• propafenone	I	A
• d,l-sotalol	I	A
Amiodarone is more effective in maintaining sinus rhythm than sotalol, propafenone, flecainide (by analogy), or dronedarone (LoE A), but because of its toxicity profile should generally be used when other agents have failed or are contraindicated (LoE C).	I	A C

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4. **Ablación como método de tratamiento**

Recommendations	Class <sup>a</sup>	Level <sup>b</sup>
Ablation of common atrial flutter is recommended as part of an AF ablation procedure if documented prior to the ablation procedure or occurring during the AF ablation.	I	B
Catheter ablation for paroxysmal AF should be considered in symptomatic patients who have previously failed a trial of antiarrhythmic medication.	IIa	A
Ablation of persistent symptomatic AF that is refractory to antiarrhythmic therapy should be considered a treatment option.	IIa	B

Catheter ablation of AF in patients with heart failure may be considered when antiarrhythmic medication, including amiodarone, fails to control symptoms.	IIb	B
Catheter ablation of AF may be considered prior to antiarrhythmic drug therapy in symptomatic patients despite adequate rate control with paroxysmal symptomatic AF and no significant underlying heart disease.	IIb	B

"(...) considering the potential of AF catheter ablation to achieve rhythm control in symptomatic patients with paroxysmal AF and minimal or no heart disease, and the relative safety of the technique when performed by experienced operators, ablation may be considered as an initial therapy in selected patients."



# El tema del año

## Guidelines for the management of atrial fibrillation

The Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology

Developed with the special contribution of the Heart Failure Association (EHRA)<sup>†</sup>

Endorsed by the European Association of Cardiovascular Imaging (EACVI)

Authors/Task Force Members

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ESC Committee for Practice Guidelines (Switzerland), Jeroen Janssens (Belgium), Christian Vassilios (Greece), Christian Vassilios (Greece), Bogdan A. Popescu (Romania), Zeljko Reiner (Croatia), Udo Sechtem (Germany), Per Anton Sirnes (Norway), Michael...

Document Reviewers (France), Toshio Balci (The Netherlands), (Belgium), Dietrich... (Turkey), John McMurtry (Spain), Martin J. Stegeman (Poland), Janina Stepinska (Poland)

The disclosure forms of the authors and reviewers are available on the ESC website [www.escardio.org/guidelines](http://www.escardio.org/guidelines)

Recommendations	Class <sup>a</sup>	Level <sup>b</sup>
Ablation of common atrial flutter is recommended as part of an AF ablation procedure if documented prior to the ablation procedure or occurring during the AF ablation.	I	B
Catheter ablation for paroxysmal AF should be considered in symptomatic patients who have previously failed a trial of antiarrhythmic medication.	IIa	A
Ablation of persistent symptomatic AF that is refractory to antiarrhythmic therapy should be considered a treatment option.	IIa	B
The following antiarrhythmic drugs are recommended for rhythm control in patients with AF, depending on underlying heart disease:		
• amiodarone	I	A
• dronedarone	I	A
• flecainide	I	A

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(Italy), Harry Crijns

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(Portugal),

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ng/guidelines

## 2010 Focused Update of ESC guidelines on device therapy in heart failure

An update of the 2008 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure and the 2007 ESC guidelines for cardiac and resynchronization therapy

Developed with the special contribution of the Heart Failure Association and the European Heart Rhythm Association

Authors/Task Force Members, Kenneth Dickstein (Chairperson) (Norway)\*, Panos E. Vardas (Chairperson) (Greece)\*, Angelo Auricchio (Switzerland), Jean-Christophe Dehaert (France), Cecilia Lindqvist (Sweden), John McMurtry (UK)

Recommendation	Patient population	Class <sup>a</sup>	Level <sup>b</sup>
CRT preferentially by CRT-D is recommended to reduce morbidity or to prevent disease progression <sup>d</sup>	NYHA function class II LVEF ≤35%, QRS ≥150 ms, SR Optimal medical therapy	I	A

The disclosure forms of the authors and reviewers are available on the ESC website [www.escardio.org/guidelines](http://www.escardio.org/guidelines)

**Keywords:** Guidelines • Heart failure • Devices • Cardiac resynchronization therapy • Biventricular pacing • Implantable cardioverter defibrillator • Left ventricular assist device • CRT • CRT-P • CRT-D • ICD • LVAD

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† Other ESC entities having participated in the development of this document: Associations: European Association of Echocardiography (EAE), European Association for Cardiovascular Prevention & Rehabilitation (EACPR), Heart Failure Association (HFA), Working Groups: Cardiovascular Surgery, Developmental Anatomy and Pathology, Cardiovascular Pharmacology and Drug Therapy, Thrombosis, Acute Cardiac Care, Valvular Heart Disease, Councils: Cardiovascular Imaging, Cardiology Practice, Cardiovascular Primary Care

**Disclaimer.** The ESC Guidelines represent the views of the ESC and were arrived at after careful consideration of the available evidence at the time they were written. Health professionals are encouraged to take them fully into account when exercising their clinical judgement. The guidelines do not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patients, in consultation with that patient, and where appropriate and necessary the patient's guardian or carer. It is also the health professional's responsibility to verify the rules and regulations applicable to drugs and devices at the time of prescription. © The European Society of Cardiology 2010. All rights reserved. For permissions please email: [journals.permissions@oxfordjournals.org](mailto:journals.permissions@oxfordjournals.org)

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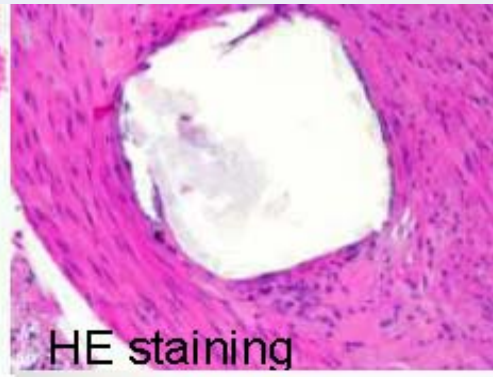
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# ***Lo más importante de la cardiología en 2010***

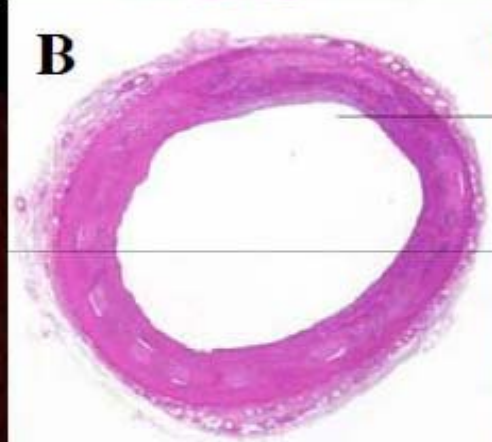
- Hipertensión Arterial
- Cardiopatía Isquémica
- Insuficiencia Cardíaca
- Arritmias
- Intervencionismo Percutáneo



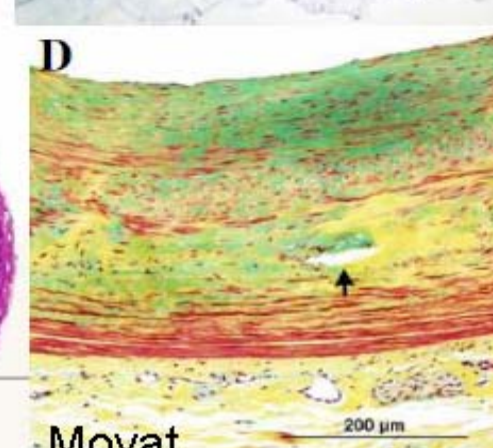
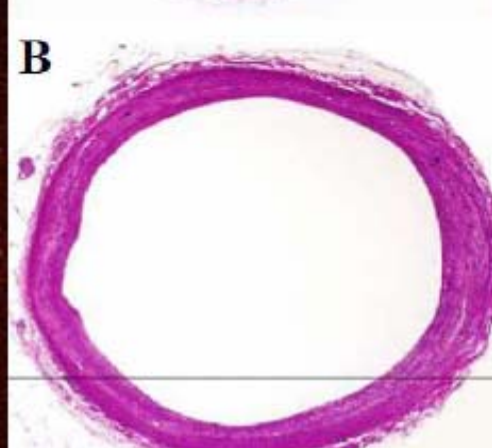
# Stent Bioabsorbible



By chromatography, polymeric struts were no longer detectable



Strut voids were filled with young proteoglycan and coalesced with vessel wall.



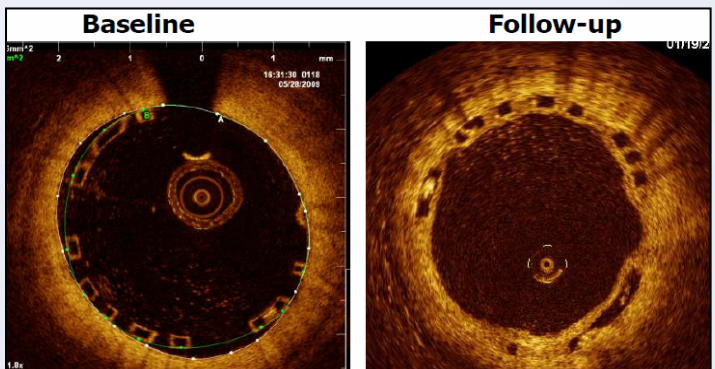
**collagen = yellow**  
**proteoglycans/muco polysaccharides = blue/green**  
**SMCs = red**

density of smooth muscle cells at the presumed site of polymeric struts

# ABSORB “Cohort B” Trial

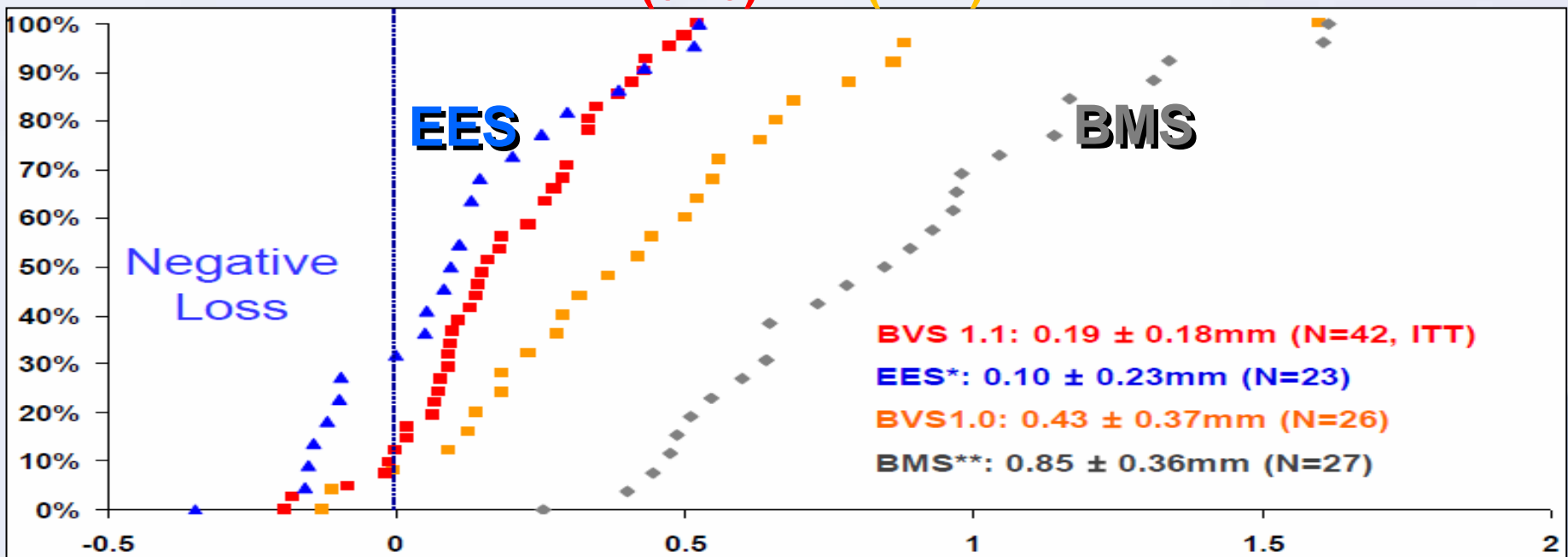
Bioresorbable Everolimus-Eluting Vascular Scaffold (BVS)

45 Patients



**ABSORB B (0.19)**    **ABSORB A (0.43)**

Late Loss (mm)



# Novedades en Intervencionismo Percutáneo

## *The* NEW ENGLAND JOURNAL *of* MEDICINE

### Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D.,  
Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D.,  
Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D.,  
Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela C. Douglas, M.D.,  
John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D.,  
and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators\*

# PARTNER Study Design



## Symptomatic Severe Aortic Stenosis

ASSESSMENT: High Risk AVR Candidate  
3105 Total Patients Screened

Total = 1058 patients

2 Parallel Trials:  
Individually Powered

n= 700

High Risk

ASSESSMENT:  
Transfemoral Access

High Risk TF

High Risk TA

1:1 Randomization

1:1 Randomization

TAVI  
Trans  
femoral

VS

Surgical  
AVR

TAVI  
Trans  
femoral

VS

Surgical  
AVR

Primary Endpoint: All Cause Mortality (1 yr)  
(Non-inferiority)

Inoperable

n=358

ASSESSMENT:  
Transfemoral Access

1:1 Randomization

Not In Study

TAVI  
Trans  
femoral

VS

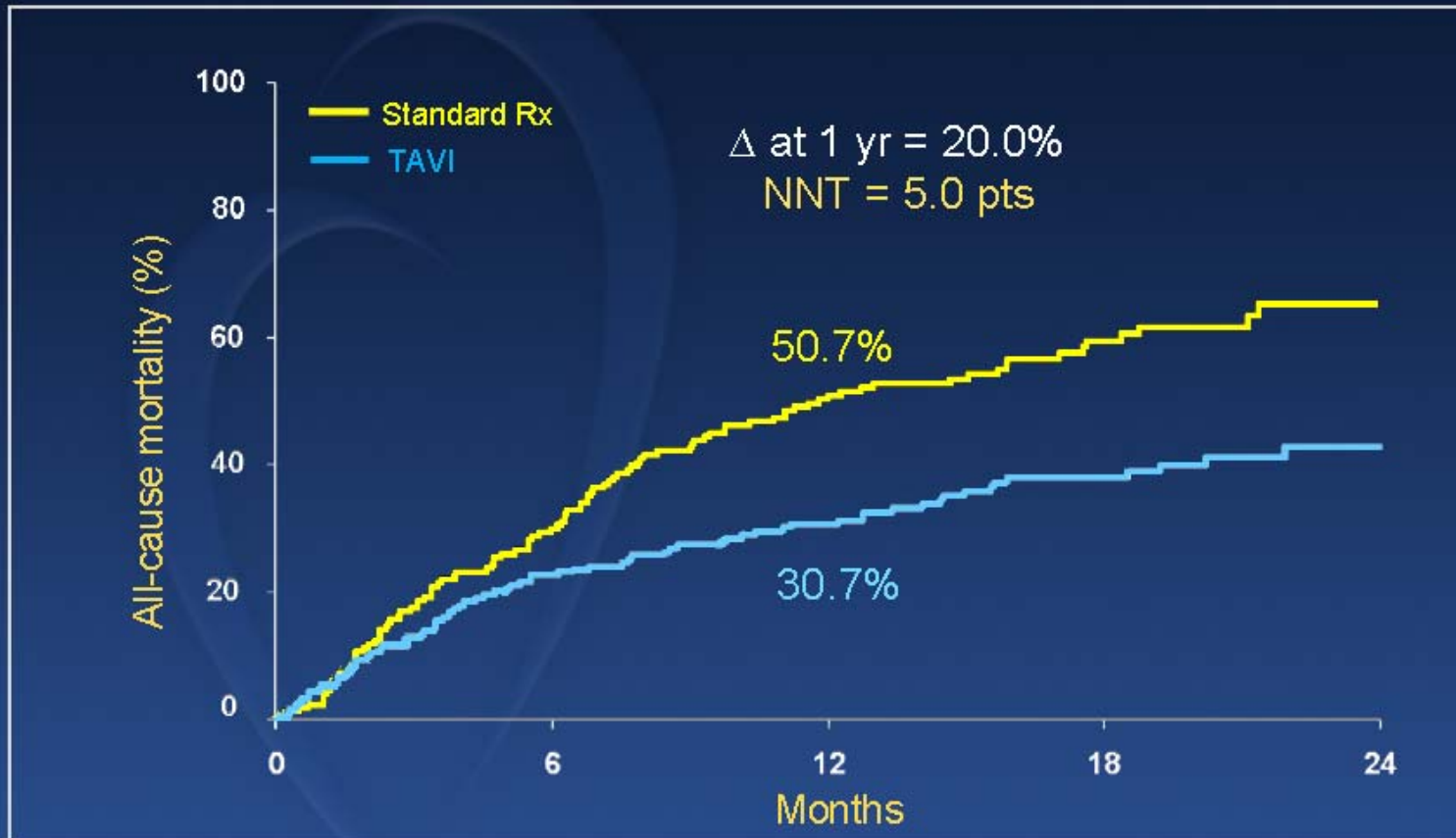
Standard  
Therapy  
(usually BAV)

Primary Endpoint: All Cause Mortality over  
length of trial (Superiority)

# Partner Trial



## All Cause Mortality

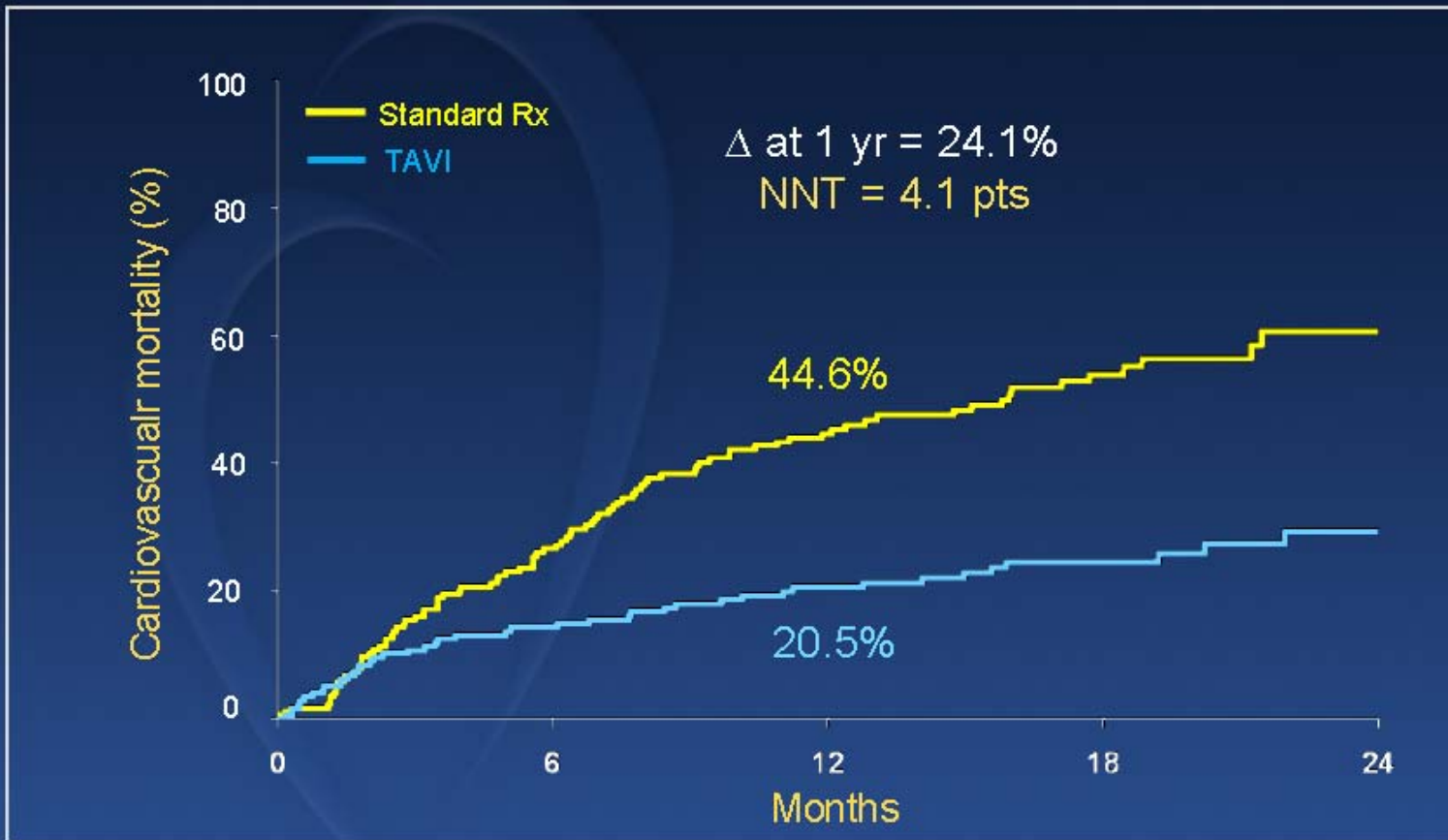


Numbers at Risk

TAVI	179	138	122	67	28
Standard Rx	179	121	83	41	12

# Partner Trial

## Cardiovascular Mortality



Numbers at Risk

	0	6	12	18	24
TAVI	179	138	122	87	28
Standard Rx	179	121	83	41	12

# EVEREST II

Endovascular Valve Edge-to-Edge REpair Study (EVEREST II)  
Randomized Clinical Trial: Primary Safety and Efficacy Endpoints



Catheter-Based Mitral Valve Repair (MitraClip® System)



# EVEREST II

ACC/i2 2010

## Study Design

279 Patients enrolled at 37 sites

**Significant MR (3+-4+)**  
**Specific Anatomical Criteria**

↓  
Randomized 2:1

↙ ↘  
**Device Group**  
MitraClip System  
N=184

↙ ↘  
**Control Group**  
Surgical Repair or Replacement  
N=95

↓ ↓  
**Echocardiography Core Lab and Clinical Follow-Up:**  
Baseline, 30 days, 6 months, 1 year, 18 months, and  
annually through 5 years



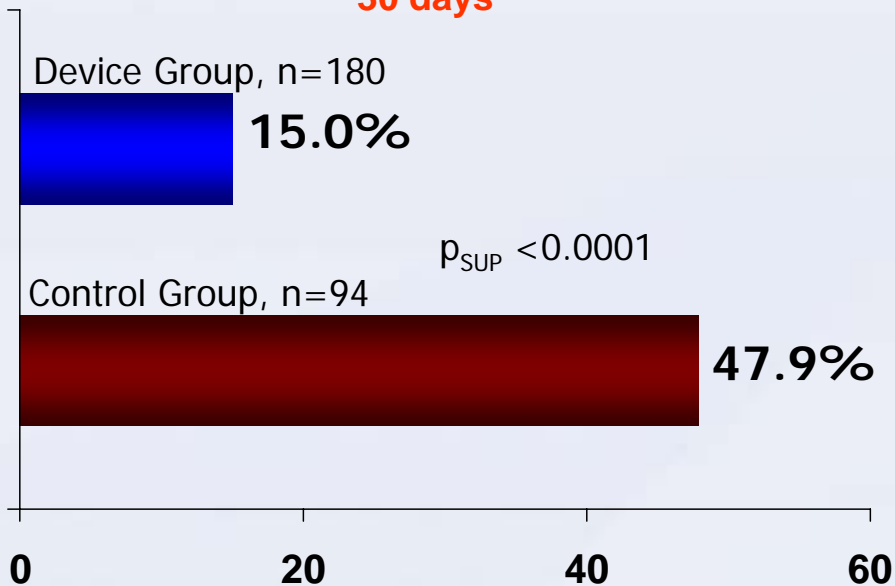
# EVEREST II



## Intention to Treat Cohort

### Safety

Major Adverse Events  
30 days

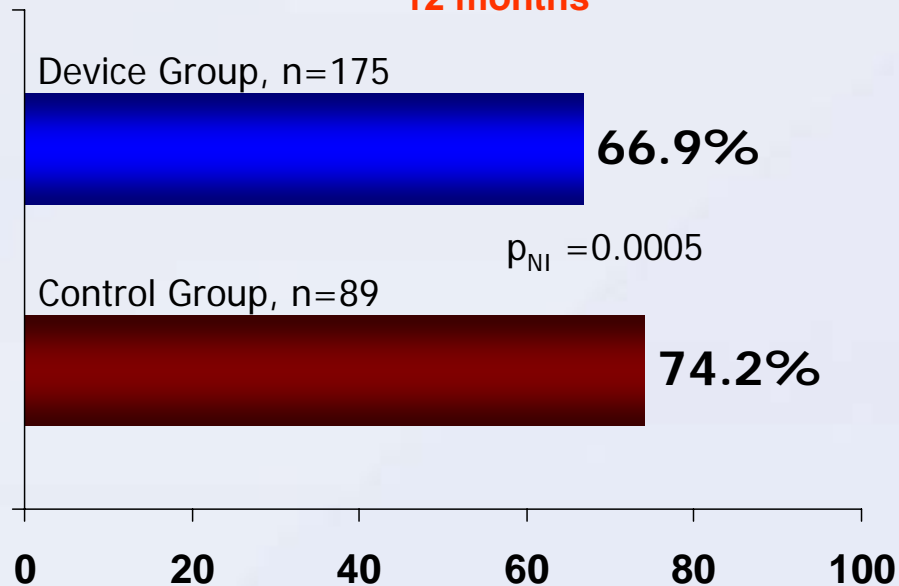


### Met superiority hypothesis

- Pre-specified margin = 2%
- Observed difference = **32.9%**
- 97.5% LCB = 20.7%

### Effectiveness

Clinical Success Rate\*  
12 months



### Met non-inferiority hypothesis

- Pre-specified margin = 25%
- Observed difference = **7.3%**
- 95% UCB = 17.8%

# *Conclusiones*

- Nuevas opciones terapéuticas en HTA
- Manejo de la C. Isquémica mas adaptado al medio.
- “Nuevos” fármacos en IC
- Menos estrictos en el control de la frecuencia cardiaca en FA permanente
- Nueva etapa de la anticoagulación.
- Mayor peso de procedimientos intervencionistas:
  - Ablación de la FA
  - Implante de Prótesis Aortica Percutanea
  - Clip Mitral



***ROADMAP. Lowest SBP and/or highest SBP reduction quartile are associated with increased CV mortality in CHD patients. The “J” curve effect again***

Last SBP before event

2.5

1.0



SBP reduction

1.6

1.0



mmHg <122.3 122.3-126.4 126.4-132.2 >132.2 mmHg <17.3 17.3-8.1 8.0-<0.2 >0.2

Cohort of patients with pre-existing CHD (1104)

# *CV Event Incidence in Relation to Mean FU Systolic BP (up to 1st event) in VALUE*

