Congreso SEC , Sábado 22 Octubre 2011

Cardiología Intervencionista

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Madrid

CARDIOACTUALIDAD 2011

Intervencionismo coronario

"Late Breaking Clinical Trials" (LBCT)

Congresos Anuales

122 LBCT **48**

2010 Junio — SHCI-Sitges

Julio

Agosto → ESC 2010 Stockholm

Septiembre → TCT 2010 Washington

Octubre

Noviembre → AHA 2010 Chicago

Diciembre

Enero

Febrero

Marzo → ACC 2011 N Orleans

Abril

Mayo → PCR 2011 Paris

2011 Junio — SHCI-Valencia

Estudios en Cardiología Intervencionista

Revisiones Anuales

Temas de actualidad en cardiología 2010

Actualización en cardiología intervencionista

José M. de la Torre Hernández[a,*], José F. Díaz Fernández[b], Manel Sabate Tenas[c] y Javier Goicolea Ruigómez[d]

Rev Esp Cardiol 2011;64(Supl 1):13-19.

Enero 2011 (91 Referencias)

YEAR IN CARDIOLOGY SERIES

The Year in Interventional Cardiology

Simon R. Dixon, MB, ChB, Cindy L. Grines, MD

Royal Oak, Michigan

Dixon SR, et al. J Am Coll Cardiol 2011;55:2207-20.

Mayo 2011 (143 Referencias)

Intervencionismo Coronario

PRECOMBAT

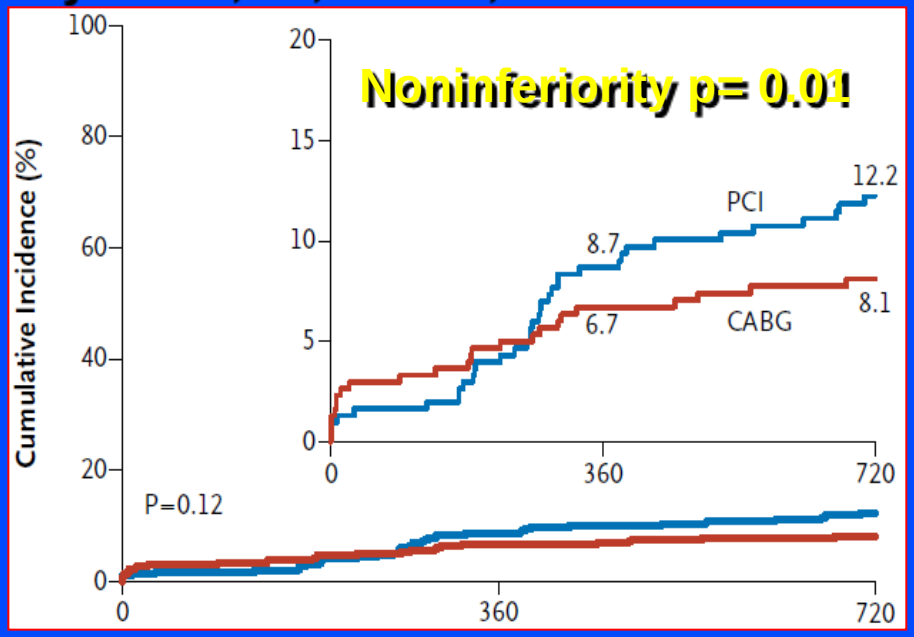
RCT Stents versus CABG for Left Main Coronary Artery Disease (13 Sites, Korea)
300 Pts SES vs 300 Pts CABG

ORIGINAL ARTICLE

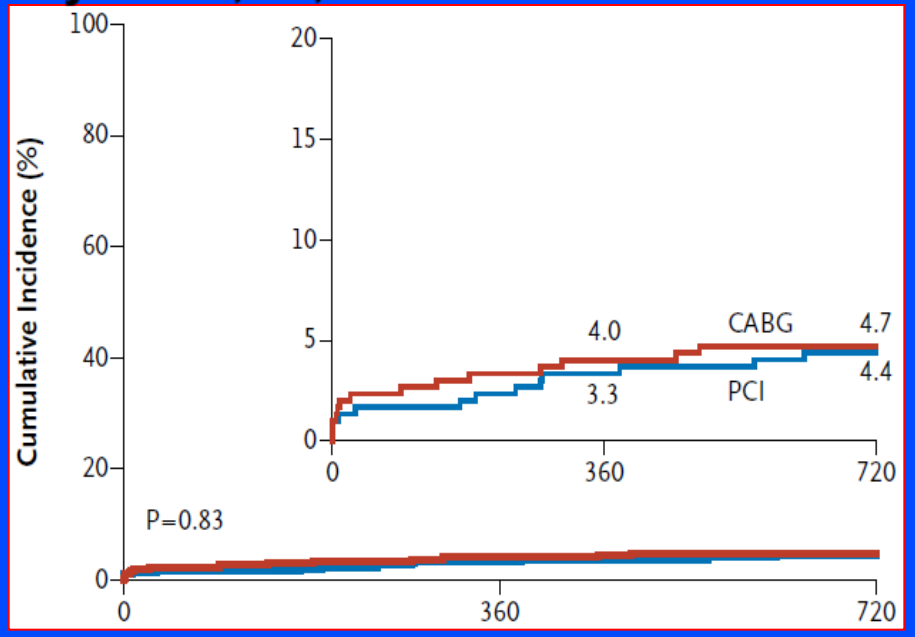
Randomized Trial of Stents versus Bypass Surgery for Left Main Coronary Artery Disease

Seung-Jung Park, M.D., Young-Hak Kim, M.D., Duk-Woo Park, M.D., Sung-Cheol Yun, Ph.D., Jung-Min Ahn, M.D., Hae Geun Song, M.D., Jong-Young Lee, M.D., Won-Jang Kim, M.D., Soo-Jin Kang, M.D., Seung-Whan Lee, M.D., Cheol Whan Lee, M.D., Seong-Wook Park, M.D., Cheol-Hyun Chung, M.D., Jae-Won Lee, M.D., Do-Sun Lim, M.D., Seung-Woon Rha, M.D., Sang-Gon Lee, M.D., Hyeon-Cheol Gwon, M.D., Hyo-Soo Kim, M.D., In-Ho Chae, M.D., Yangsoo Jang, M.D., Myung-Ho Jeong, M.D., Seung-Jea Tahk, M.D., and Ki Bae Seung, M.D.

1ry EP: D, MI, Stroke, I-TVR



2ry EP: D, MI, Stroke



Park SJ. N Engl J Med 2011;363:1718-1727.

PRECOMBAT

RCT Stents versus CABG for Left Main Coronary Artery Disease (13 Sites, Korea)
300 Pts SES vs 300 Pts CABG

I-TVR: 9.0% SES vs. 4.2% CABG (HR 2.18, 95%CI 1.1-4.32; p = 0.02).

Protocol: "… *Routine follow-up angiography was recommeded after SES but not recommended for CABG patients …* ".

Late FU angiography 75% SES vs 25%, p<0.001.

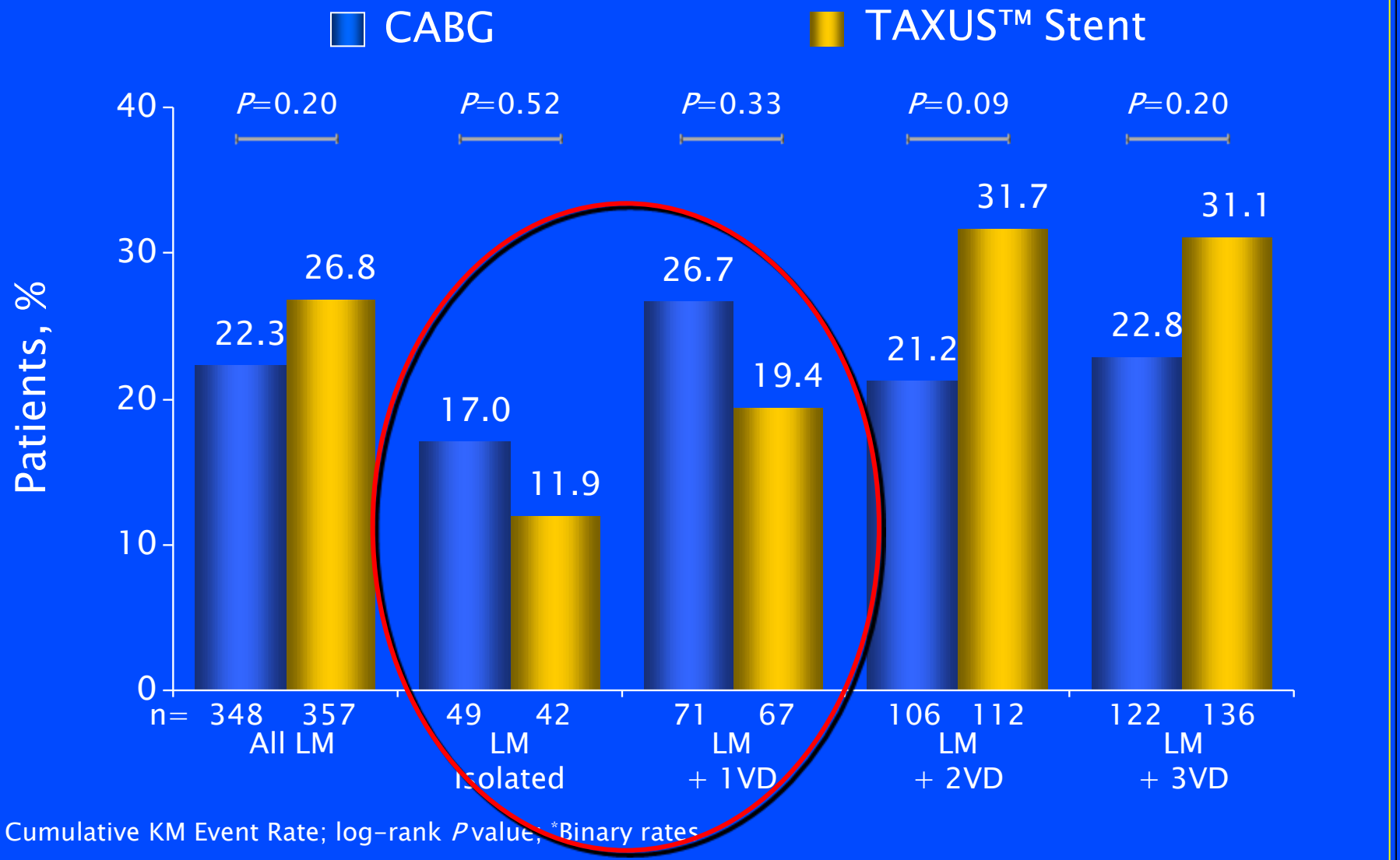
Subgroup	PCI	CABG	Hazard Ratio (95% CI)
	no./total no. (%)		
Coronary artery disease distribution			
Left main only	1/27 (3.8)	3/34 (8.8)	0.39 (0.04–3.72)
Left main with single-vessel disease	2/50 (4.1)	3/53 (5.8)	0.70 (0.11–4.16)
Left main with double-vessel disease	13/101 (13.0)	11/90 (12.2)	1.04 (0.47–2.32)
Left main with triple-vessel disease	20/122 (16.8)	7/123 (5.8)	3.05 (1.29–7.21)

The superb study results affected the prespecified noninferiority margin.
IVUS used in 91.2% Pts resulted favorable outcome …. Criteria ?

Park SJ. N Engl J Med 2011;363:1718-1727.

Left Main (All Subsets) MACCE at *3 Years*

Syntax



Cumulative KM Event Rate; log-rank *P* value; *Binary rates

DES: UPLM Meta-analysis RCT

Percutaneous Coronary Intervention Versus Coronary Artery Bypass Graft Surgery in Left Main Coronary Artery Disease

A Meta-Analysis of Randomized Clinical Data

Davide Capodanno, MD,* Gregg W. Stone, MD,† Marie C. Morice, MD,‡ Theodore A. Bass, MD,§ Corrado Tamburino, MD, PHD*

1,611 Pts, 1 Year:

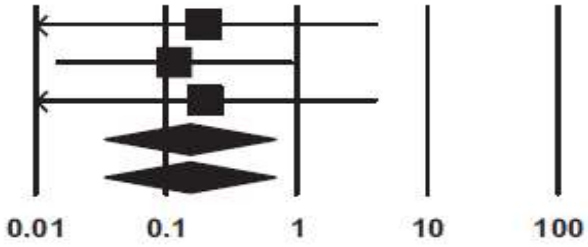
- LEMANS
- SYNTAX Left Main,
- Boudriot
- PRECOMBAT

Capodanno D, et al. J Am Coll Cardiol 2011;58:1426–32

DES: UPLM Meta-analysis RCT

Stroke

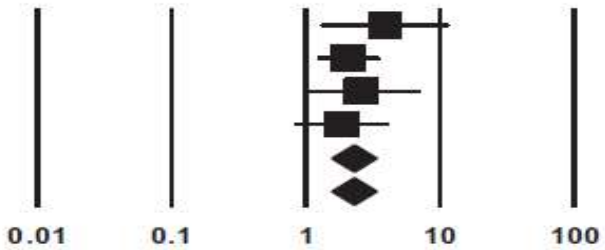
Model	Study name	Odds ratio	Lower limit	Upper limit	p-Value	Events / Total PCI	Events / Total CABG
	LEMANS	0.196	0.009	4.187	0.297	0 / 52	2 / 53
	SYNTAX left main	0.116	0.014	0.931	0.043	1 / 355	8 / 336
	PRECOMBAT	0.199	0.009	4.156	0.298	0 / 300	2 / 300
Fixed	Pooled estimate	0.150	0.033	0.671	0.013		
Random	Pooled estimate	0.150	0.033	0.671	0.013		
	$I^2 = 0\%$						



NNT 63

Repeat Revascularization

Model	Study name	Odds ratio	Lower limit	Upper limit	p-Value	Events / Total PCI	Events / Total CABG
	LEMANS	3.892	1.297	11.683	0.015	15 / 52	5 / 53
	SYNTAX left main	2.072	1.215	3.532	0.007	45 / 355	22 / 336
	Boudriot et al.	2.578	0.948	7.006	0.063	14 / 100	6 / 101
	PRECOMBAT	1.851	0.840	4.079	0.127	18 / 300	10 / 300
Fixed	Pooled estimate	2.246	1.537	3.282	0.000		
Random	Pooled estimate	2.246	1.537	3.282	0.000		
	$I^2 = 0\%$						



NNT 17

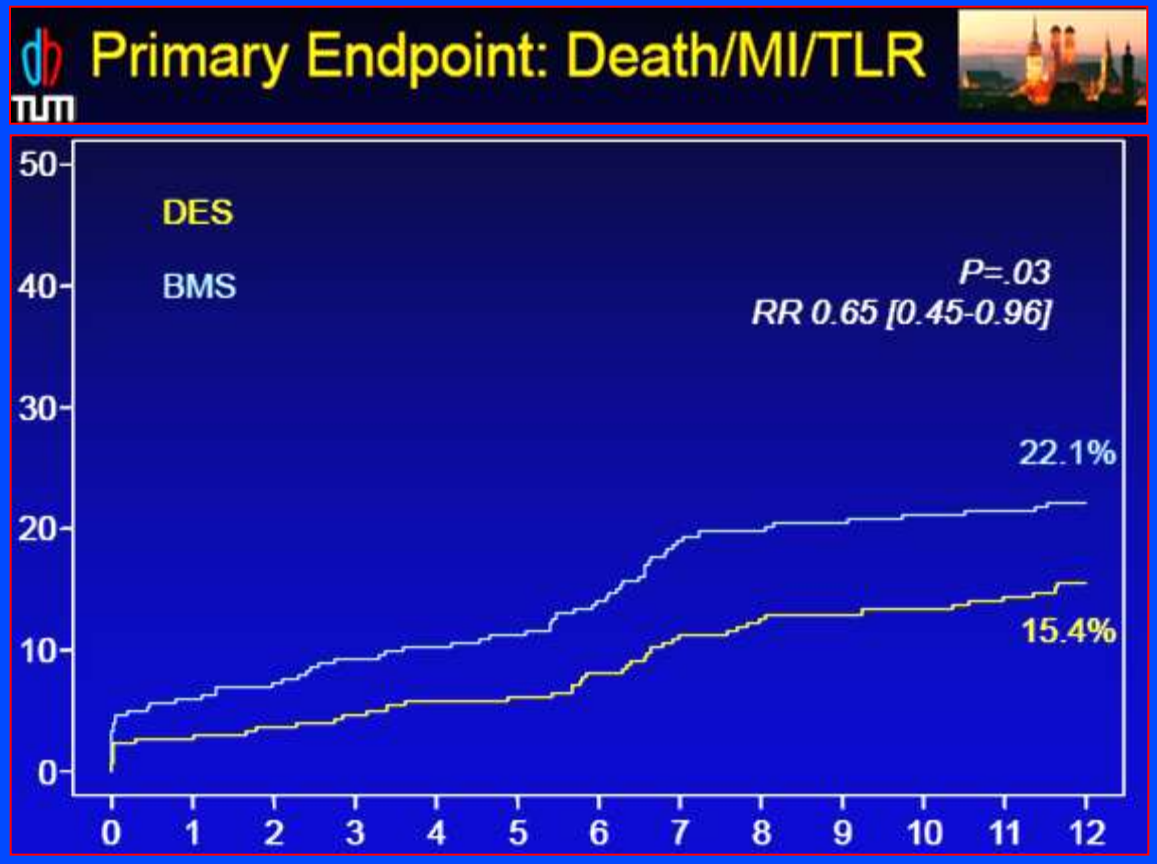
Capodanno D, et al. J Am Coll Cardiol 2011;58:1426–32

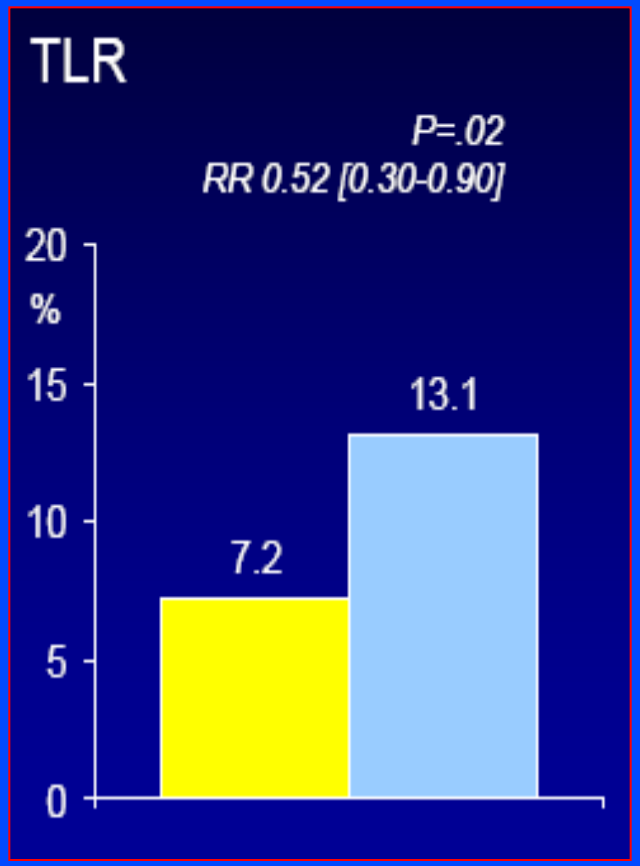
ISAR-CABG

*I*s Drug-Eluting *S*tenting *A*ssociated With Improved *R*esults in*C*oronary *A*rtery *B*ypass *G*rafts?

RCT, Superiority Trial of DES vs BMS in SVG de novo Lesions

610 PTs SVG: 303 Pts DES (SES/PES) vs 307 Pts BMS





Similar individual rates of Cardiac Death, MI, ST

Mehilli J. Munich

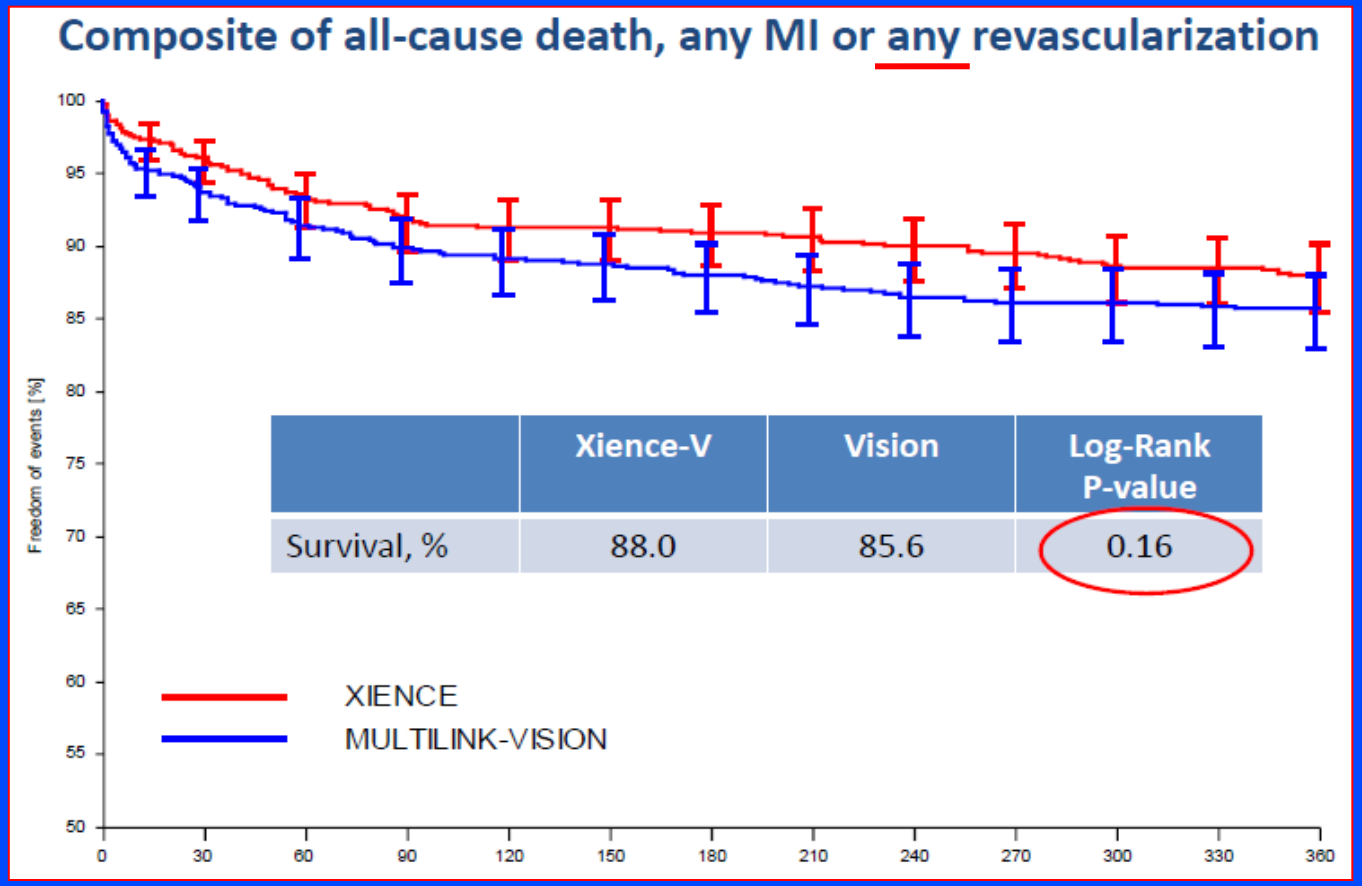
EXAMINATION

(clinical Evaluation of Xience-V stent in Acute Myocardial INfArcTION)

"All Comers" design. 13 Centres 3 Countries

1504 STEMI (751 Pts Xience V vs 747 Pts Multi-link Vision)

1ry EP



	Xience-V	Vision	Log-Rank P-value
Survival, %	88.0	85.6	0.16

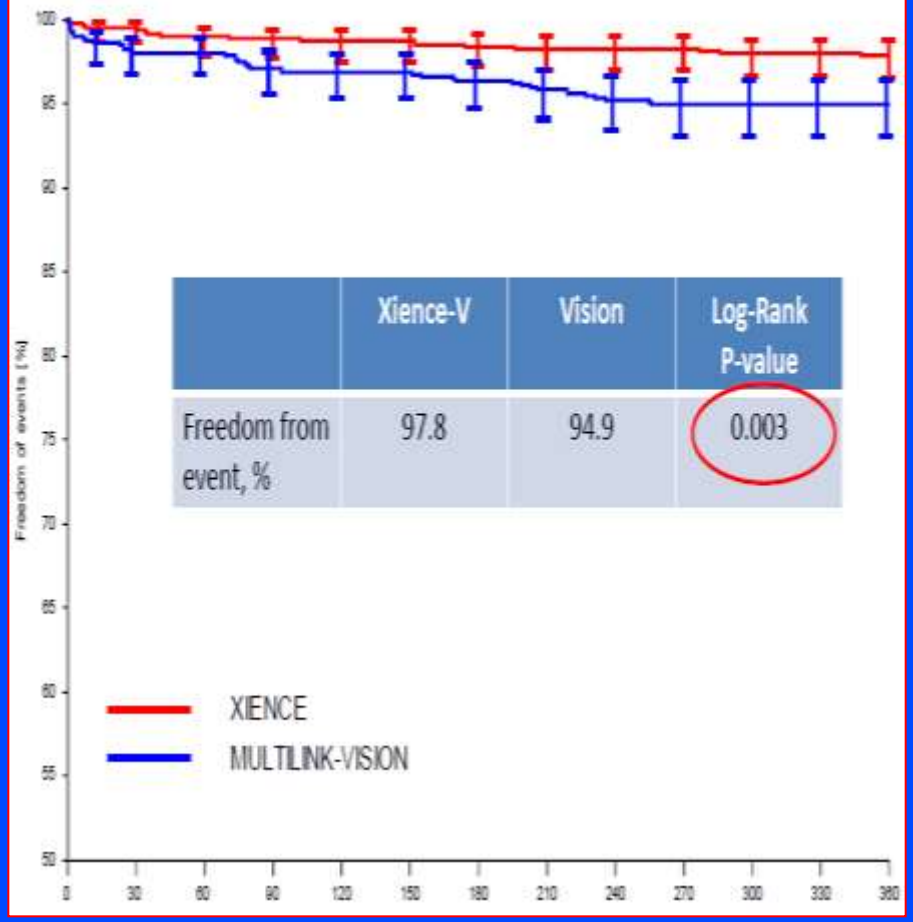
Sabate M, Barcelona, Spain

EXAMINATION

(clinical Evaluation of Xience-V stent in Acute Myocardial INfArcTION)

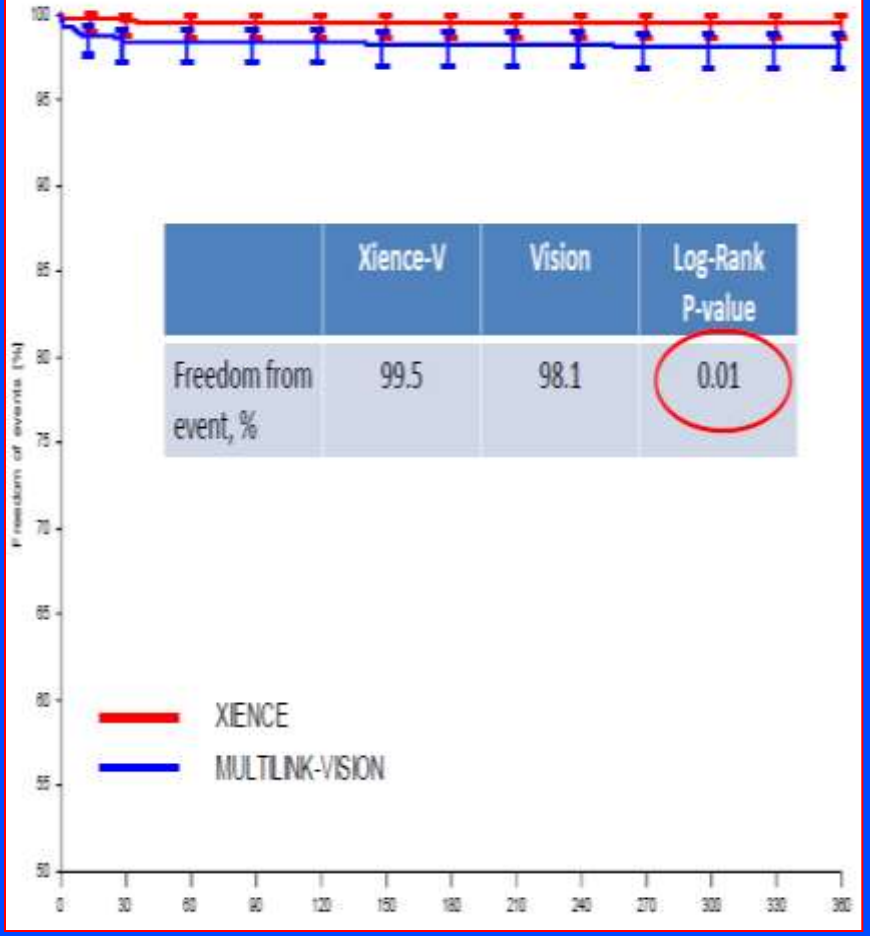
1504 STEMI (751 Pts Xience V vs 747 Pts Multi-link Vision)

Target Lesion Revascularization



	Xience-V	Vision	Log-Rank P-value
Freedom from event, %	97.8	94.9	0.003

Definite Stent Thrombosis



	Xience-V	Vision	Log-Rank P-value
Freedom from event, %	99.5	98.1	0.01

Sabate M, Barcelona, Spain

Second vs First Generation DES

2Y Meta-analysis (EES vs PES) 4 RCT (6,608 Pts)

SPIRIT II

A randomised comparison of an everolimus-eluting coronary stent with a paclitaxel-eluting coronary stent: the SPIRIT II trial

Serruys PW, et al. Eurointervention 2006:2:286-294.

SPIRIT III

Comparison of an Everolimus-Eluting Stent and a Paclitaxel-Eluting Stent in Patients With Coronary Artery Disease
A Randomized Trial

Stone G, et al. JAMA 2008;299:1903-13.

SPIRIT IV

Everolimus-Eluting versus Paclitaxel-Eluting Stents in Coronary Artery Disease

Stone G, et al. N Engl J Med 2010;362:1663-74.

COMPARE

Second-generation everolimus-eluting and paclitaxel-eluting stents in real-life practice (COMPARE): a randomised trial

Kedhi E, et al. Lancet 2010;375:201-09.

Alfonso F, Fernandez C. J Am Coll Cardiol 2011; 58:26-29

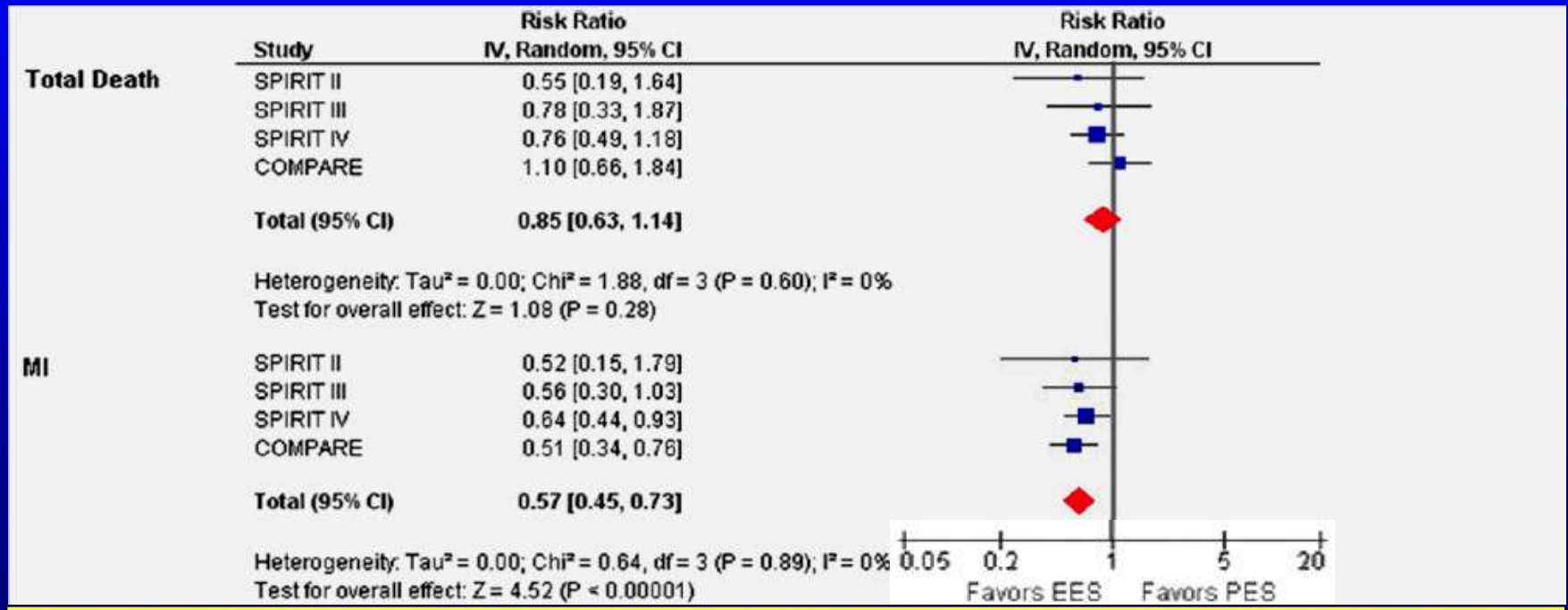
Second vs First Generation DES

EDITORIAL COMMENT

Second-Generation Drug-Eluting Stents

Moving the Field Forward*

EES vs PES
2Y Meta-analysis
4 RCT (6,608 Pts)



Random-Effects Meta-Analysis of the 2-Year Results of the 4 Randomized Clinical Trials Comparing EES With PES

Alfonso F, Fernandez C. J Am Coll Cardiol 2011; 58:26-29

Second vs First Generation DES

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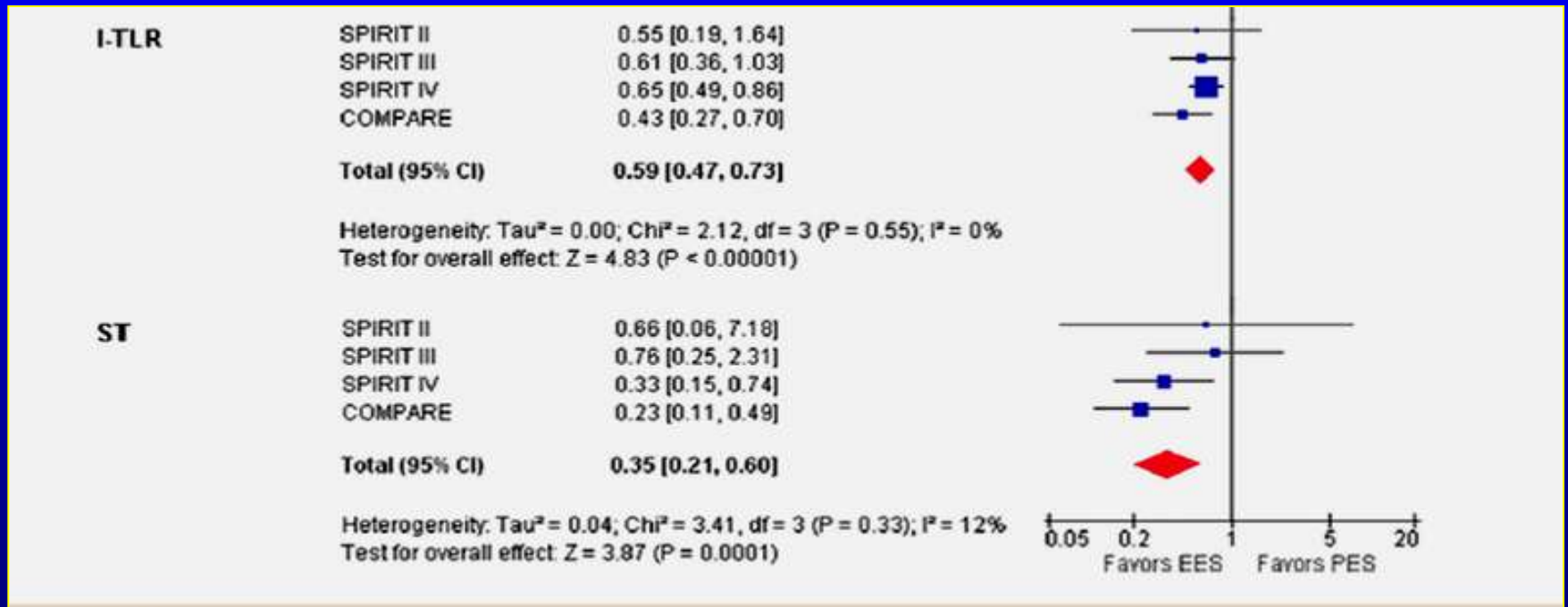


Random-Effects Meta-Analysis of the 2-Year Results of the 4 Randomized Clinical Trials Comparing EES With PES

Alfonso F, Fernandez C. J Am Coll Cardiol 2011; 58:26-29

Second vs First Generation DES

1Y Meta-analysis EES vs SES: 8 RCT (11,351 Pts)

- BASKET-PROVE
- EXCELLENT
- SEA-SIDE
- ISAR-TEST-4
- SORT-OUT-4
- ESSENCE-DIABETES
- X-AMI
- RESET

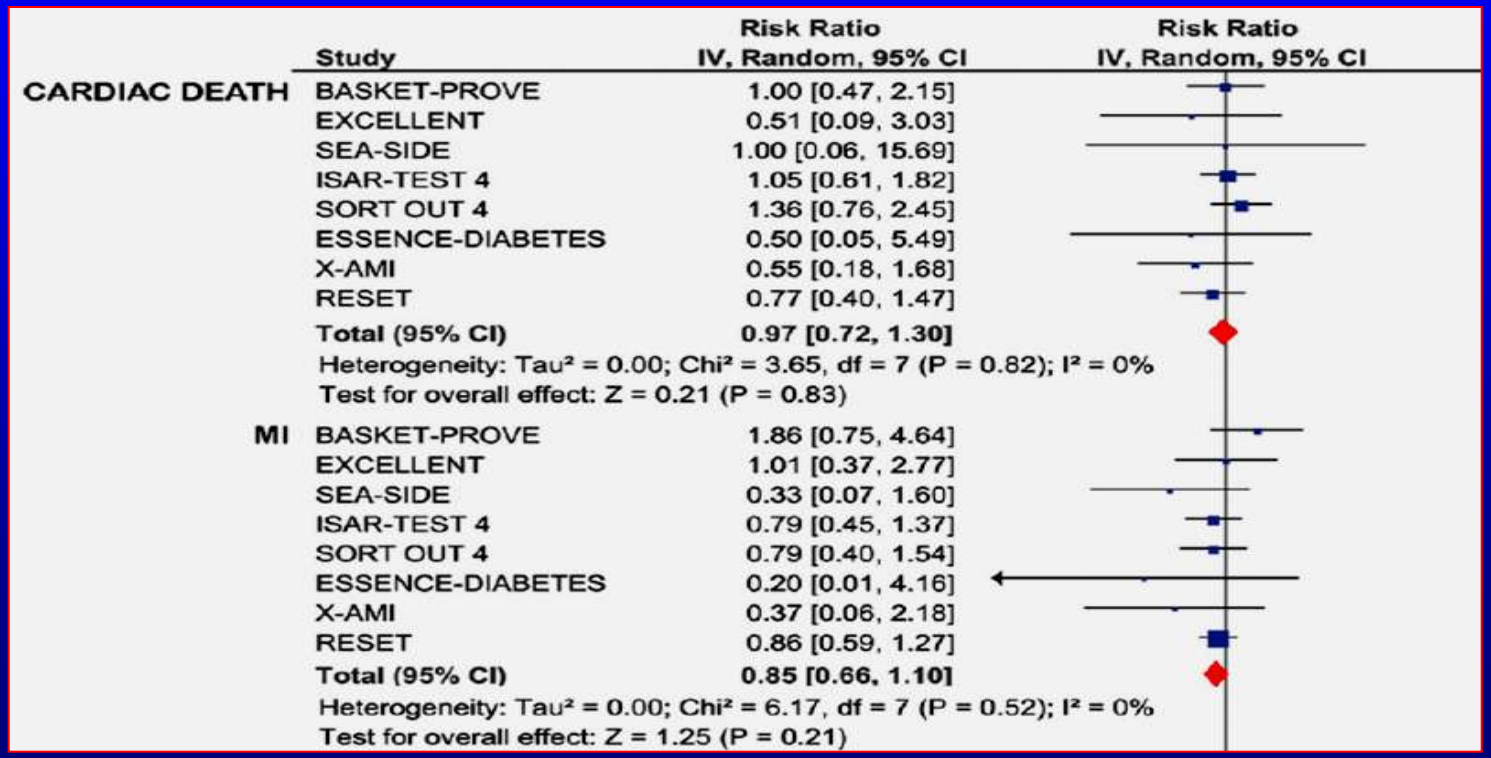
Alfonso F, Fernandez C. J Am Coll Cardiol 2011;58:1855-8.

Second vs First Generation DES

Head-to-Head Randomized Comparisons of Limus-Eluting Coronary Stents

Pursuing Excellence or Flying Too High?*

EES vs SES
1Y Meta-analysis
8 RCT (11,351 Pts)



Alfonso F, Fernandez C. J Am Coll Cardiol 2011;58:1855-8.

Second vs First Generation DES

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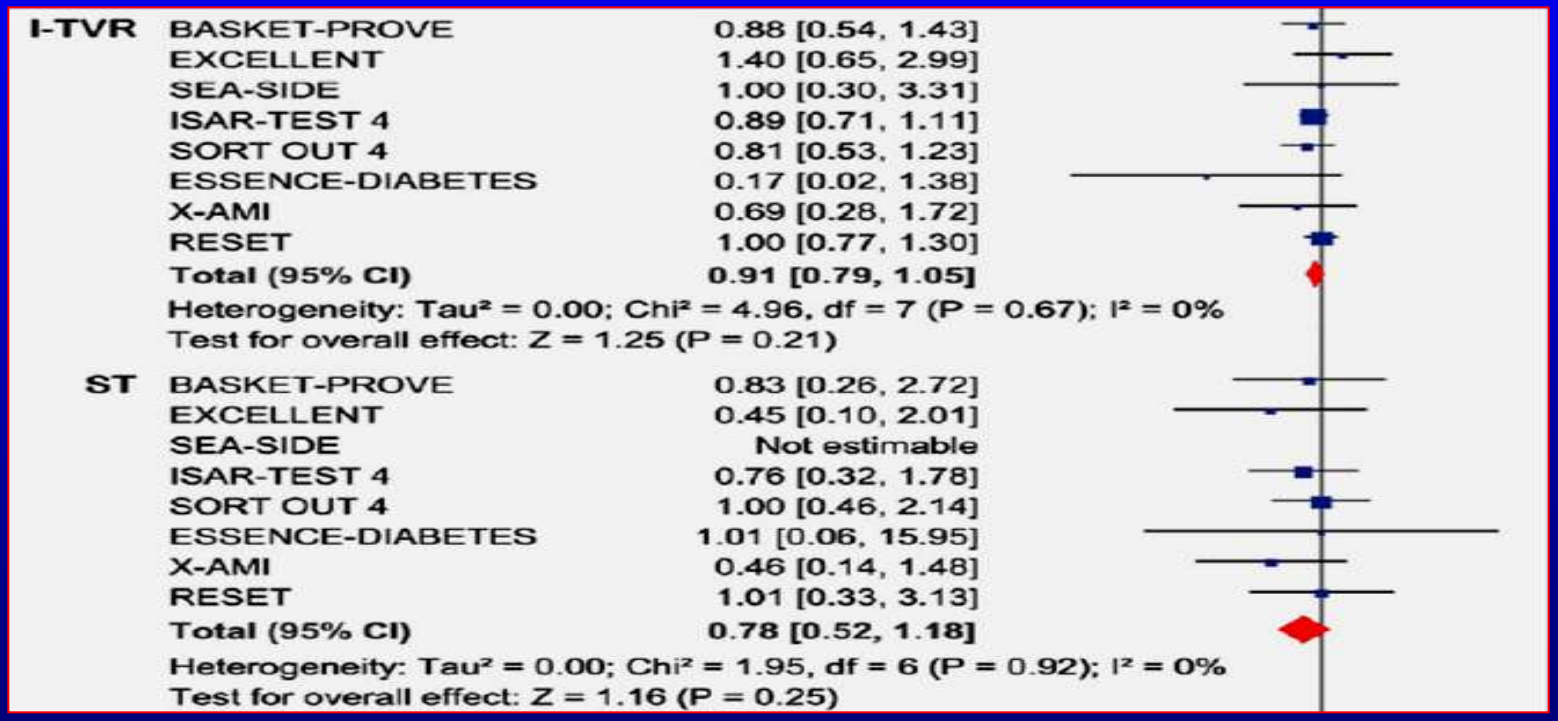


Alfonso F, Fernandez C. J Am Coll Cardiol 2011;58:1855-8.

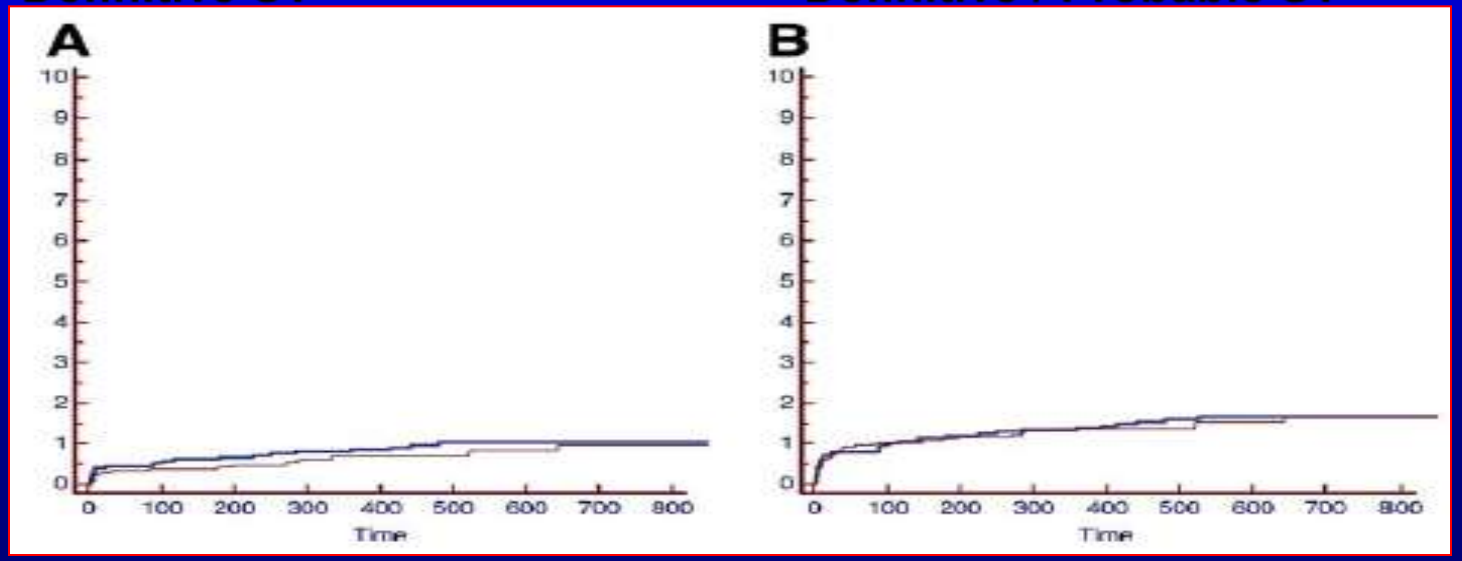
Second vs First Generation DES

Thrombosis of Second-Generation Drug-Eluting Stents in Real Practice

Results From the Multicenter Spanish Registry ESTROFA-2 (Estudio Español Sobre Trombosis de Stents Farmacoactivos de Segunda Generacion-2)

From 2005 to 2008, 4,768 patients were included in 34 centers:
2,549 treated with ZES, and 2,219 with EES.
The cumulative incidence of definite/probable ST for ZES was 1.3% at 1 year and 1.7% at 2 years and for EES 1.4% at 1 year and 1.7% at 2 years.
The increment of definite ST between the first and second year was 0.2% and 0.25%, respectively.

Definitive ST | **Definitive / Probable ST**



De la Torre JM, et al, Am Coll Cardiol Intv 2010;3:911–9

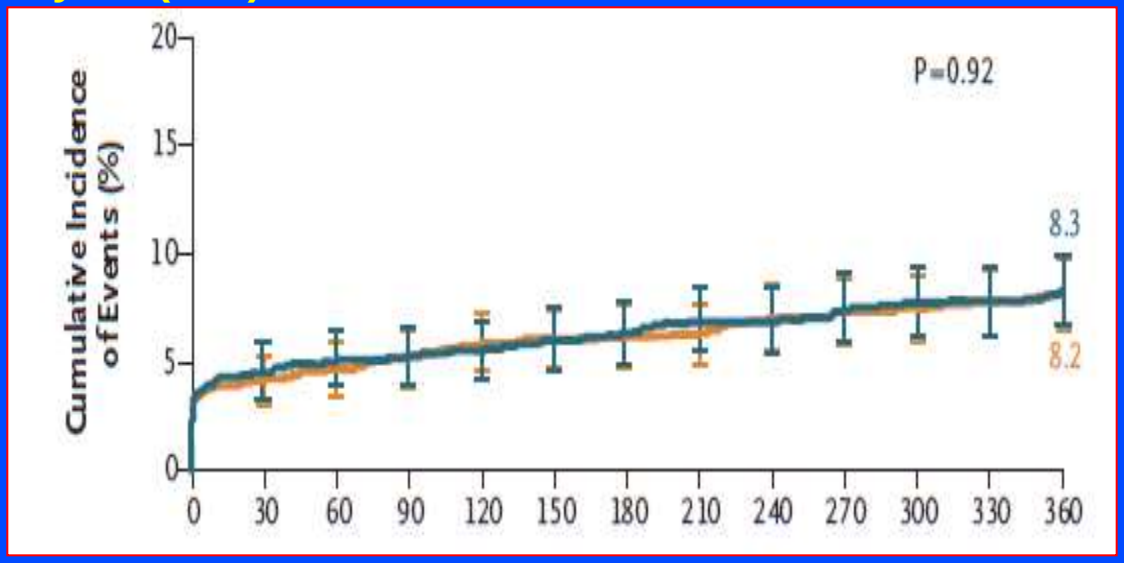
RESOLUTE "All Comers"

Comparison of Zotarolimus-Eluting and Everolimus-Eluting Coronary Stents

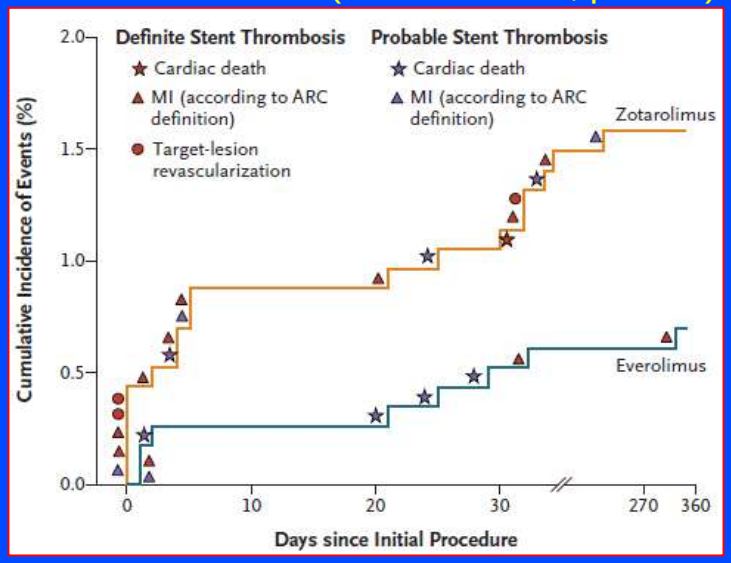
2292 Pts. Noninferiority

1ry EP was target-lesion failure (TLF) (cardiac death, MI, ITL at 1Y)

1ry EP (TLF)



ST (2.3% vs 1.5%, p=0.17)



In-stent late lumen loss was 0.27±04 mm ZES vs 0.19±0.4 mm EES, p=0.08)

Serruys PW, et al. N Engl J Med 2010;363:136-46.

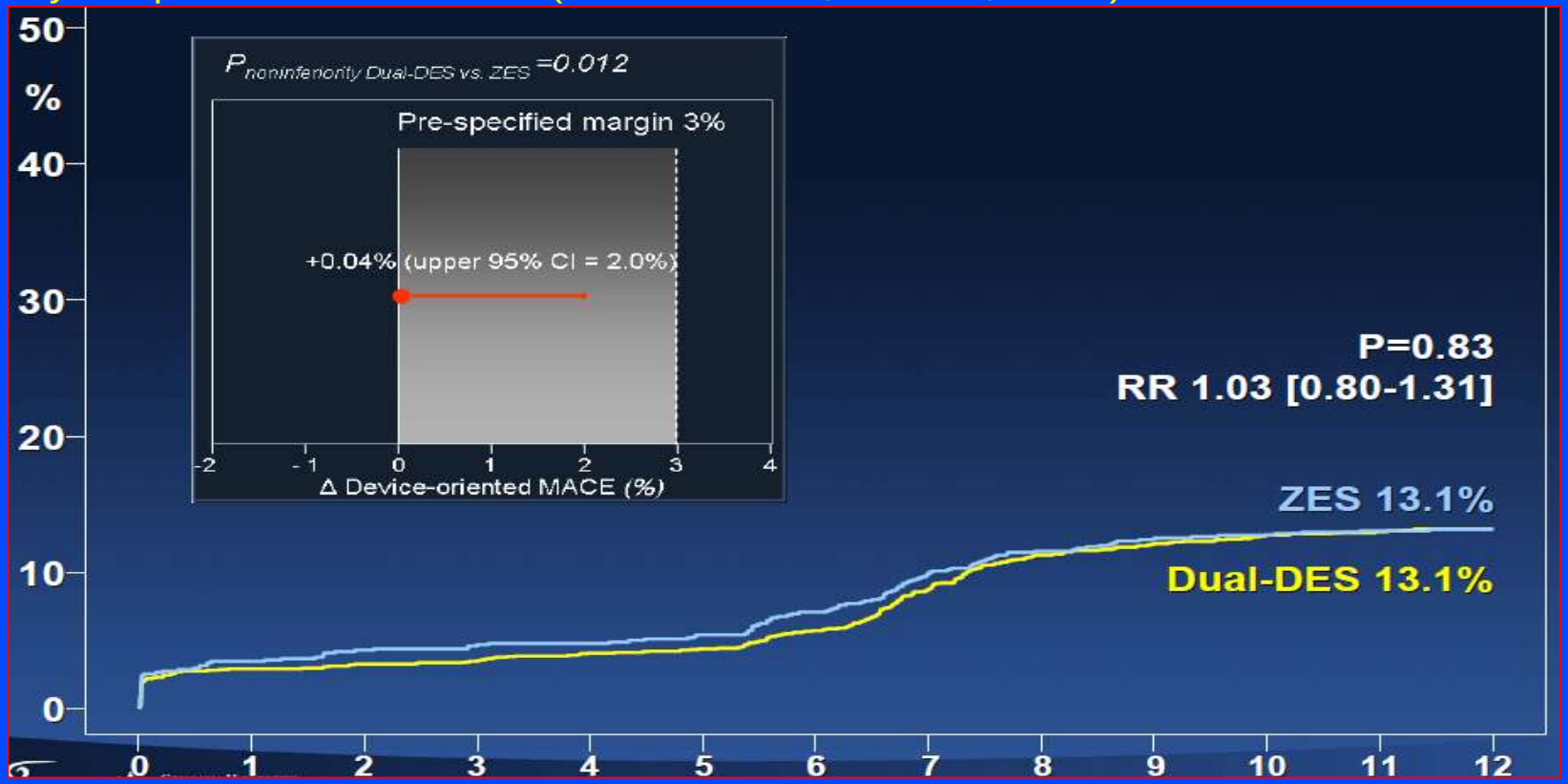
ISAR TEST 5

Intracoronary Stenting and Angiographic Results: Test Efficacy of Rapamycis/Probucol- and Zotarolimus-Eluting STents - 5

Dual-DES:Rapamycin / Probucol / Natural Resin
No polymer
N = 2002

(ZES):*(Endeavor Resolute)*
BioLinx polymer
N = 1000

1ry Endpoint Device-oriented (Cardiac Death, TVR-MI, I-TLR)



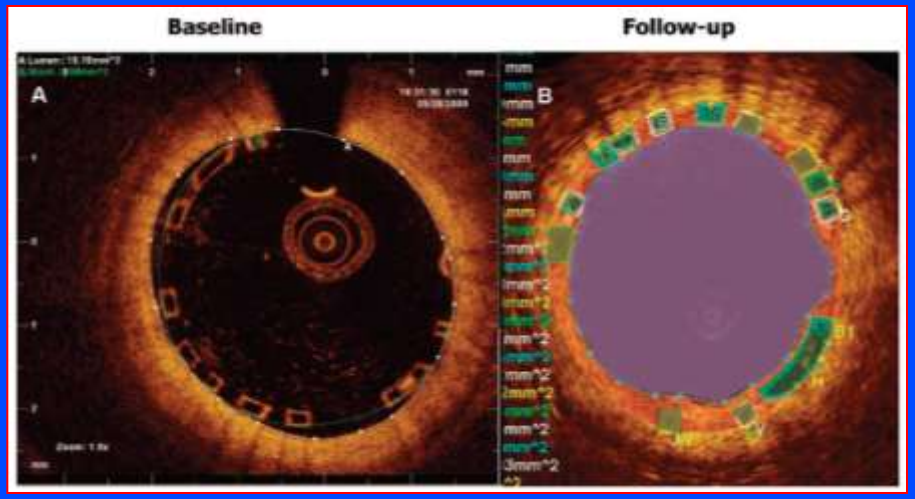
Mehilli J, Munich

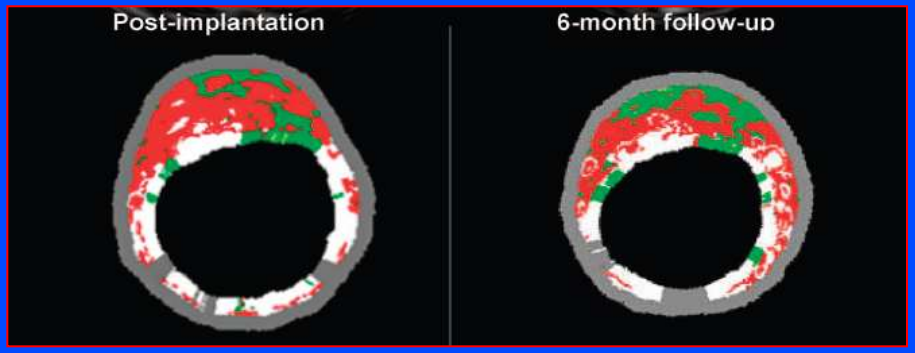
All Individual end-points at 1Y SIMILAR

ABSORB-B

45 Pts

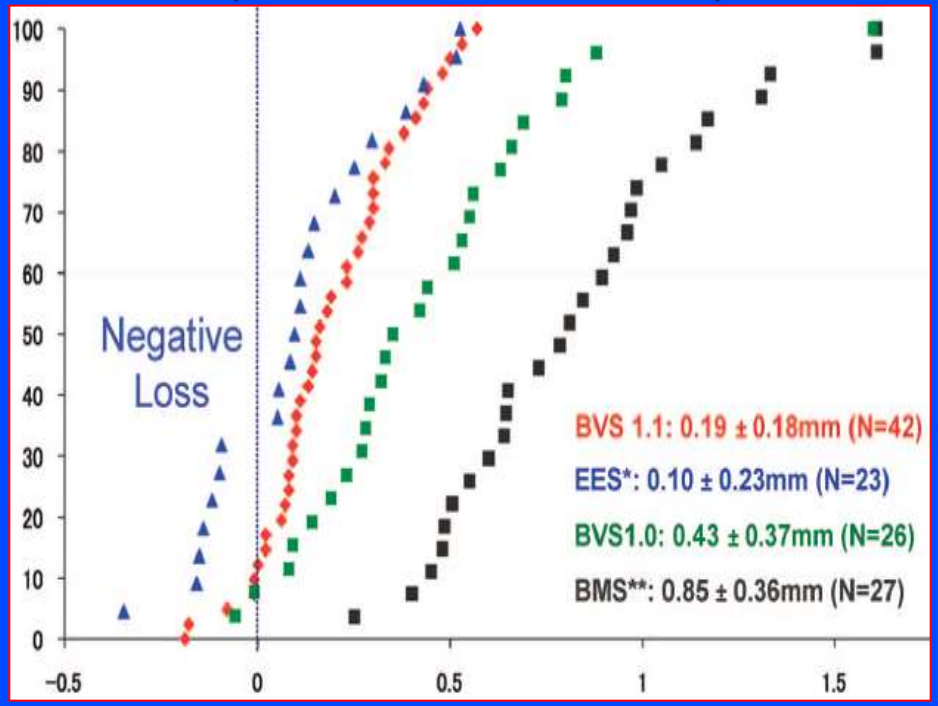
The strut design and the manufacturing process were modified lower hydrolysis (in vivo degradation) rate of the polymer.





The backscattering of the polymeric struts did not decrease over time

Late loss (Absorb-B vs Absorb-A)

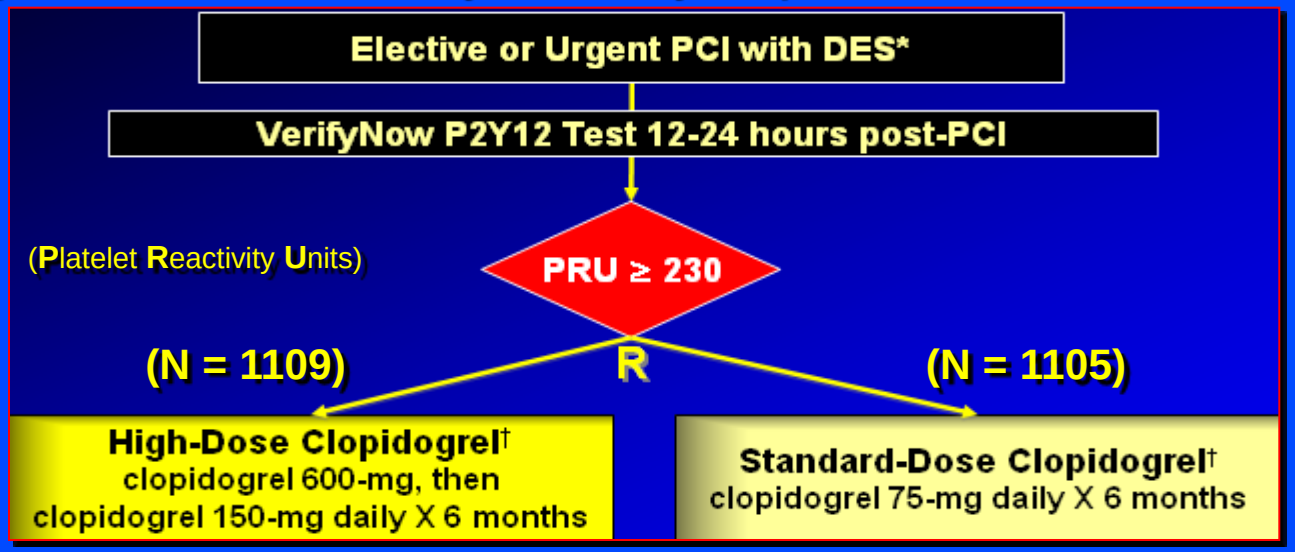


Serruys PW, et al. Circulation. 2010;122:2301-2312

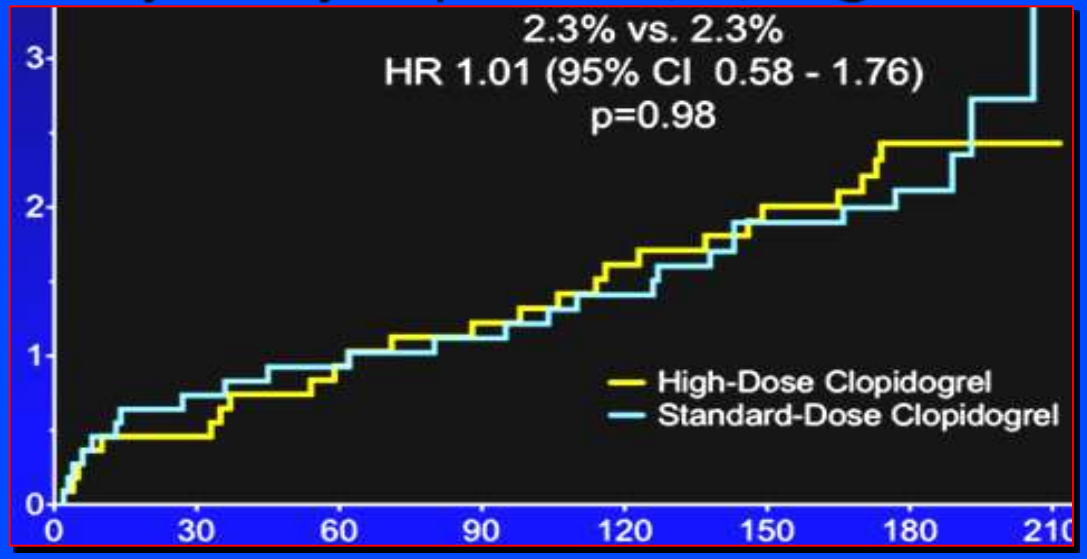
Tratamiento Farmacológico

GRAVITAS

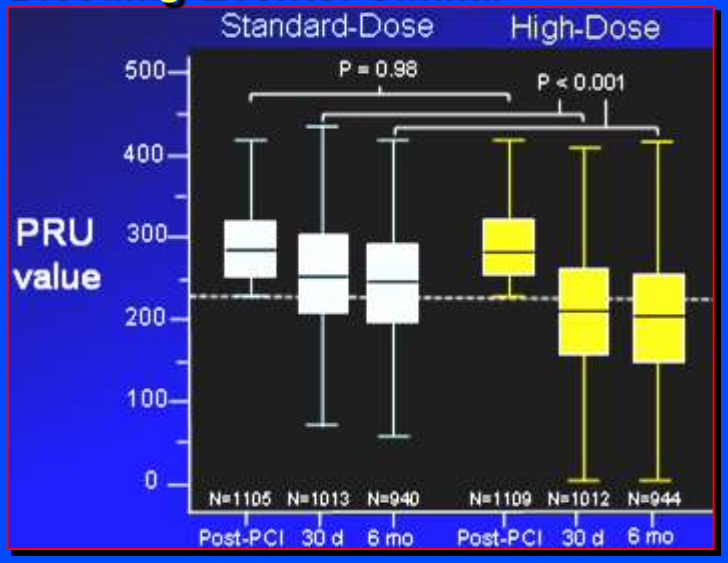
Gauging Responsiveness with A VerifyNow Assay - Impact on Thrombosis And Safety Trial



Primary Efficacy Endpoint: CV D, MI, ST @ 6 Mo



Bleeding Events: Similar



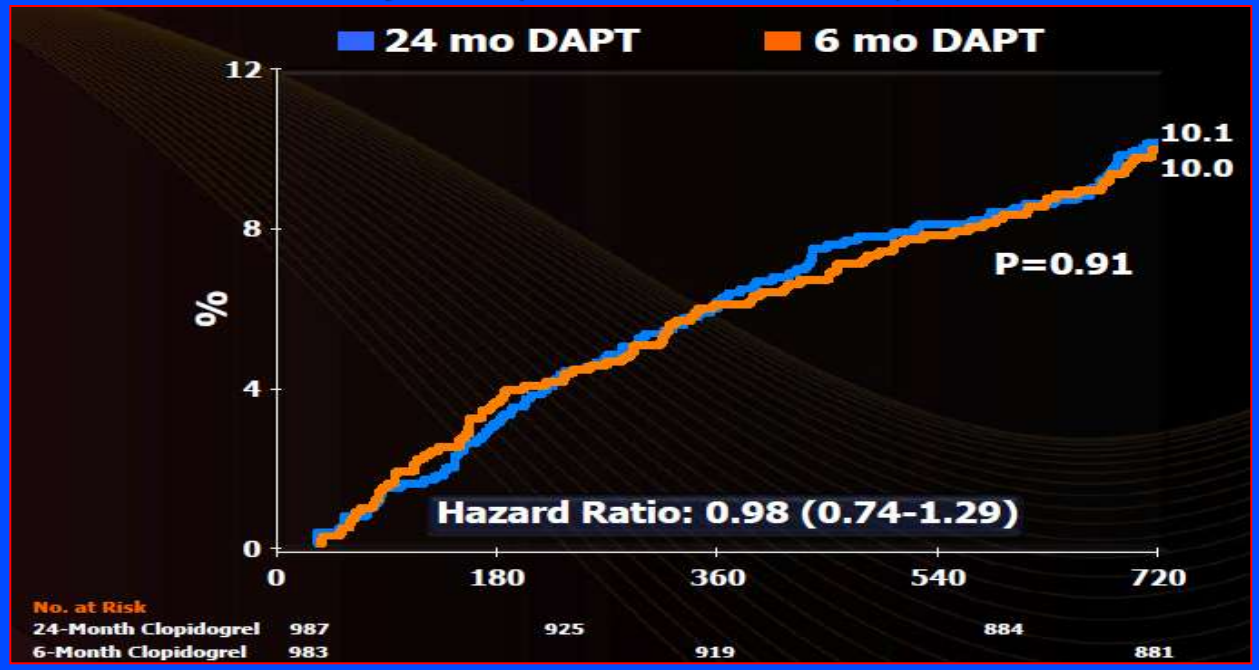
Price MJ et al. JAMA. 2011;305(11):1097-1105

PRODIGY

PROlonging Dual antiplatelet treatment after Grading stent-induced Intimal hyperplasia studY

1,970 Patients DES: DAT 6m vs 2Y.

1ry EP (Death, MI, CVA)



24 mo DAT increased rate of bleeding

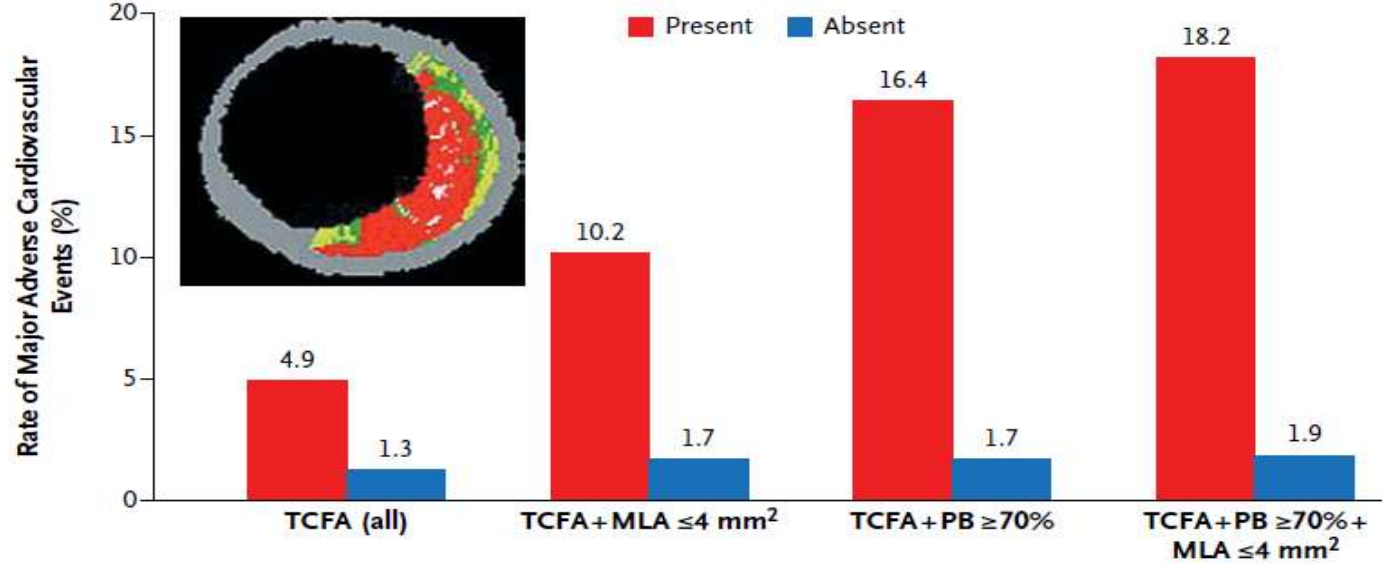
Valgimi gli M. Ferrara Italy

Técnicas Diagnóstico Intracoronario

PROSPECT

A Prospective Natural-History Study of Coronary Atherosclerosis

697 ACS Pts 3V IVUS VH after PCI. Follow-up 3.4 years
1ry EP (Cardiac D, cardiac arrest, MI, hospitalization: UA or progressive angina)
"Non-culprit lesion" Events: 12% of patients after PCI



Lesion hazard ratio (95% CI)	3.90 (2.25–6.76)	6.55 (3.43–12.51)	10.83 (5.55–21.10)	11.05 (4.39–27.82)
P value	<0.001	<0.001	<0.001	<0.001
Prevalence (%)	46.7	15.9	10.1	4.2

Figure 2. Event Rates for Lesions That Were and Those That Were Not Thin-Cap Fibroatheromas, at a Median Follow-up of 3.4 Years.

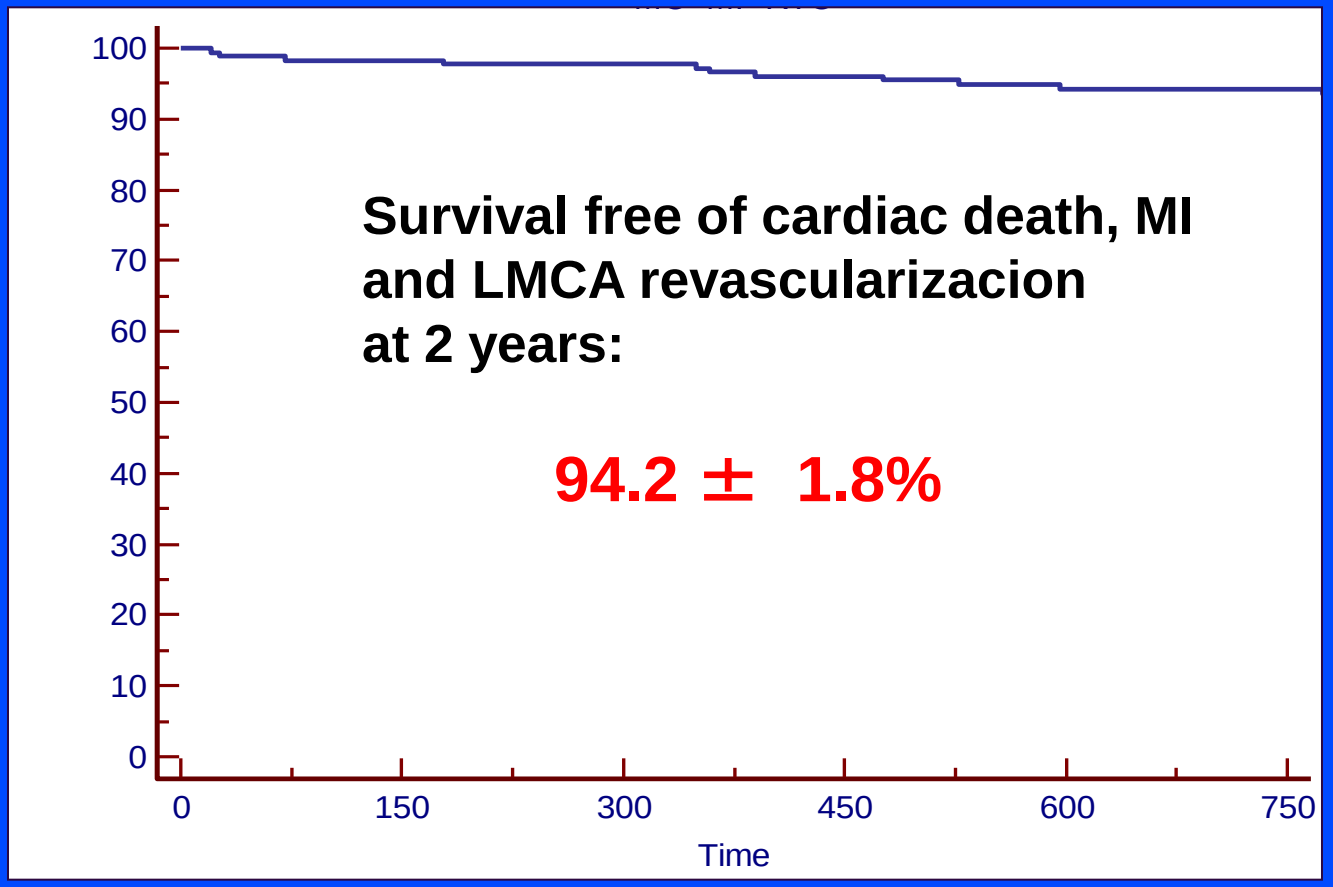
Sotne G, et al. N Engl J Med 2011;364:226-35.

LITRO

Prospective Application of Predefined Intravascular Ultrasound Criteria for Revascularization of Intermediate Left Main Coronary Artery Lesions

354 Pts in 22 centers. LMCA revascularization 91% (152 of 168) of Pts with an MLA <6 mm_2) and deferred in 96% (179 of 186) of Pts with MLA of ≥6 mm_2

Pts with deferred revascularization (MLA ≥6 mm^2)



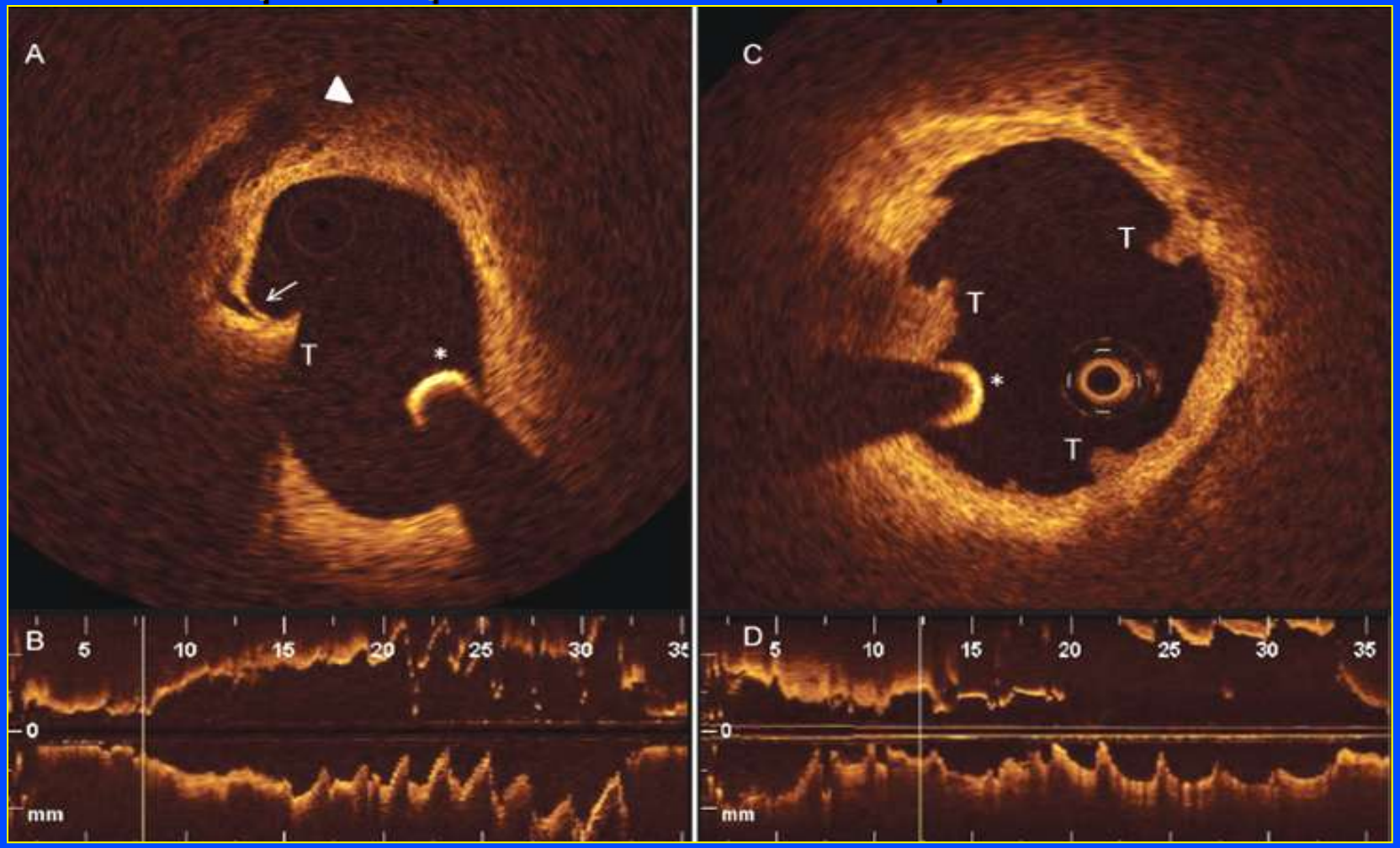
De la Torre JM et al. J Am Coll Cardiol 2011 Jul 19;58(4):351-8.

Inflammation & Pathological Substrate

25 ACS Pts

Plaque Rupture

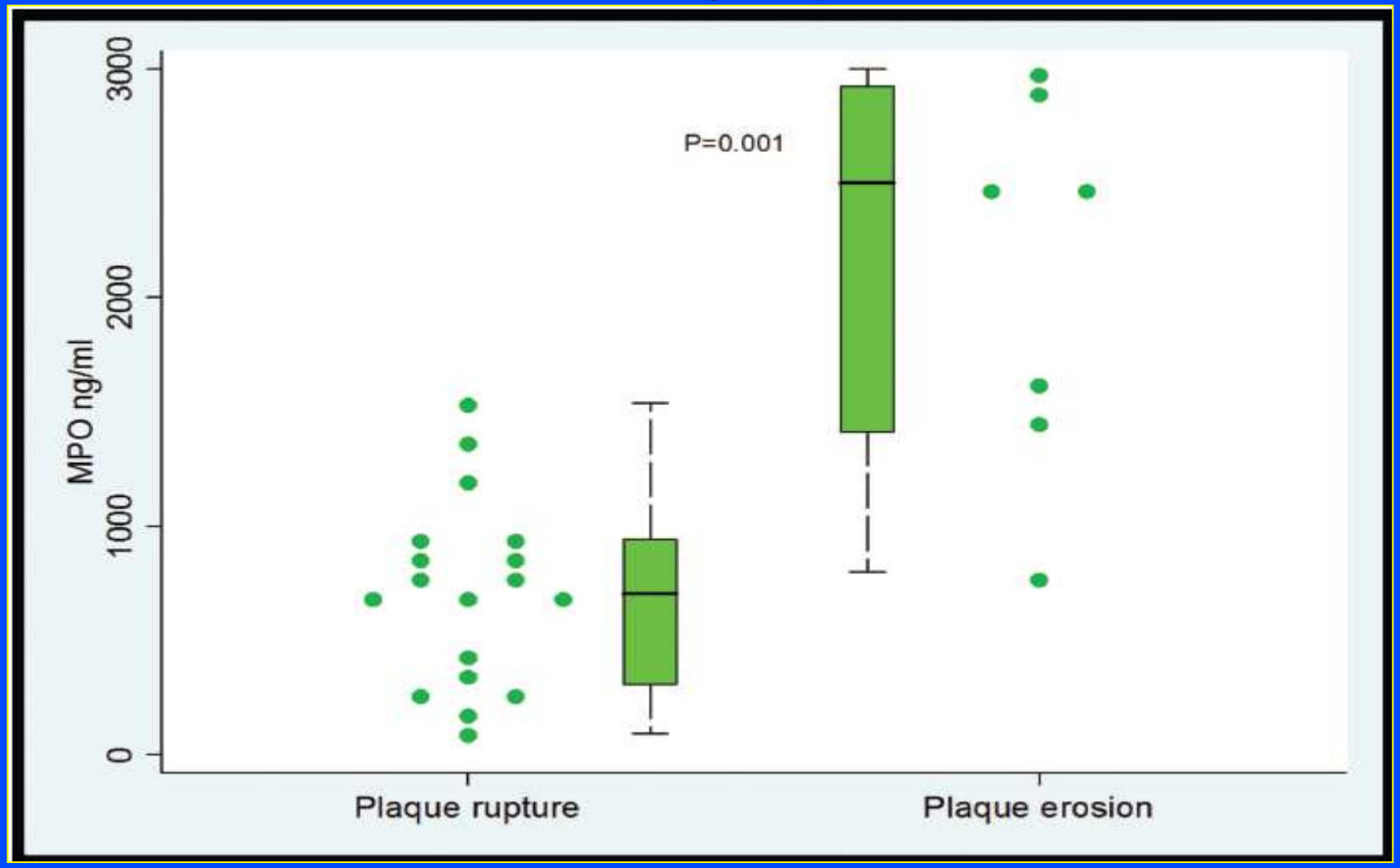
Plaque Erosion



Ferrante G. Circulation 2011;122;2505-2513

Inflammation & Pathological Substrate

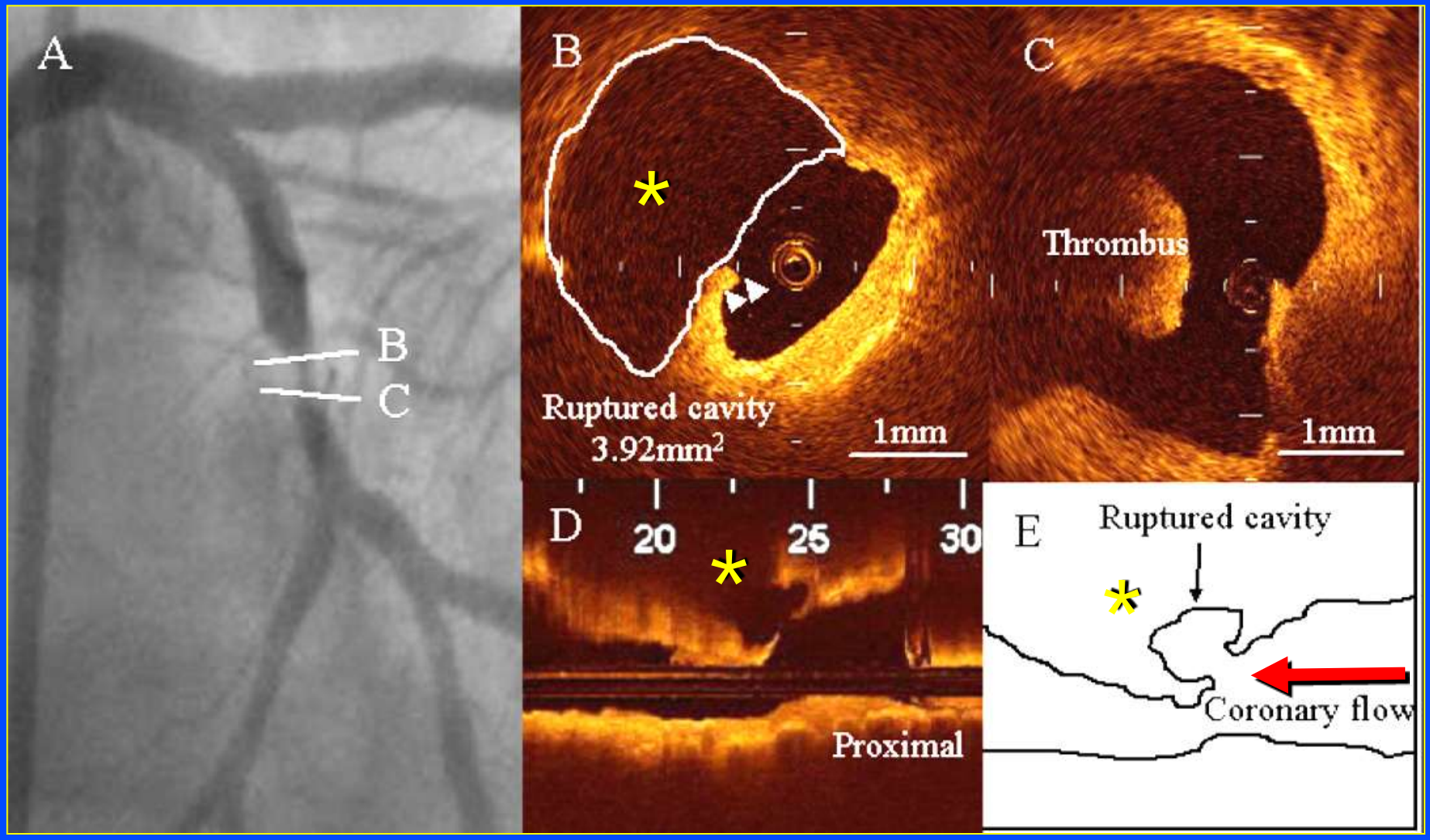
Serum Levels Myeloperoxidase



Ferrante G. Circulation 2011;122;2505-2513

Underlying Pathological Substrate: STEMI vs NSTEMI

STEMI



Ino Y, et al. JACC Cardiovasc Interv. 2011;4:76-832.

Otras Alternativas Terapeúticas

RIVAL

RadIal Vs femorAL access for coronary interventions in ACS

Canadian Institutes of Health Research

Primary and Secondary Outcomes

	Radial (n=3507) %	Femoral (n=3514) %	HR	95% CI	P
Primary Outcome					
Death, MI, Stroke, Non-CABG Major Bleed	3.7	4.0	0.92	0.72-1.17	0.50
Secondary Outcomes					
Death, MI, Stroke	3.2	3.2	0.98	0.77-1.28	0.90
Non-CABG Major Bleeding	0.7	0.9	0.73	0.43-1.23	0.23

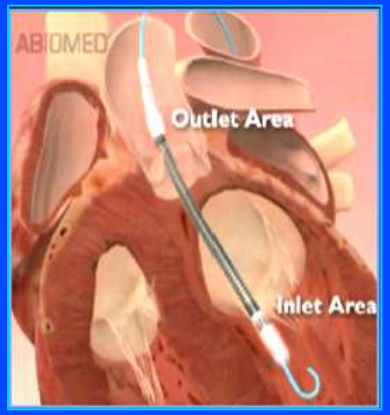
Radial : > Cross-over and Fluoroscopy times. Better in STEMI

Major Vascular Access Site Complications *(Large hematoma, PSA, Fistula, Vascular surgery)*	1.4	3.7	0.37	0.27-0.52	<0.0001

Jolly SS, Canada

PROTECT II

RCT Comparing Prophylactic Impella to IABP in High-Risk PCI



Patients Requiring Prophylactic Hemodynamic Support
During Non-Emergent High Risk PCI on
Unprotected LM/Last Patent Conduit and LVEF≤35% OR
3 Vessel Disease and LVEF≤30%

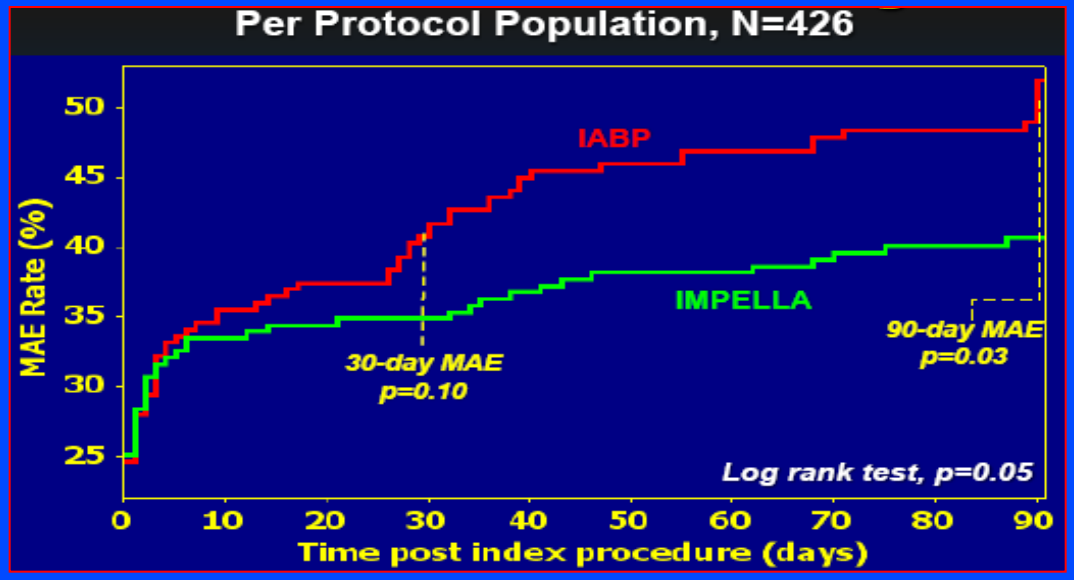
R
1:1
447 Pts

IABP + PCI
223 Pts

IMPELLA 2.5 + PCI
224 Pts

Primary Endpoint = 30-day Composite MAE* rate

1ry EP: MI, Any Revascularization, Angio failue, Renal dysf, Severe hypotension …)



O´Neill W, Different Procedural Characteristics (Medication & Devices)

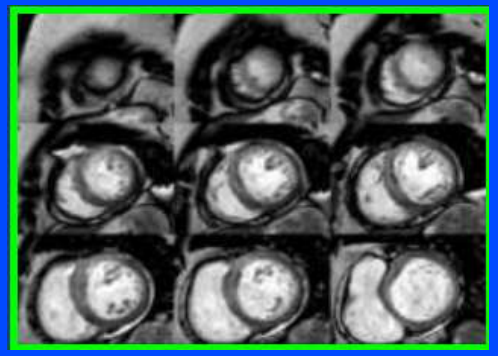
CRISP-AMI

ONLINE FIRST

Intra-aortic Balloon Counterpulsation and Infarct Size in Patients With Acute Anterior Myocardial Infarction Without Shock

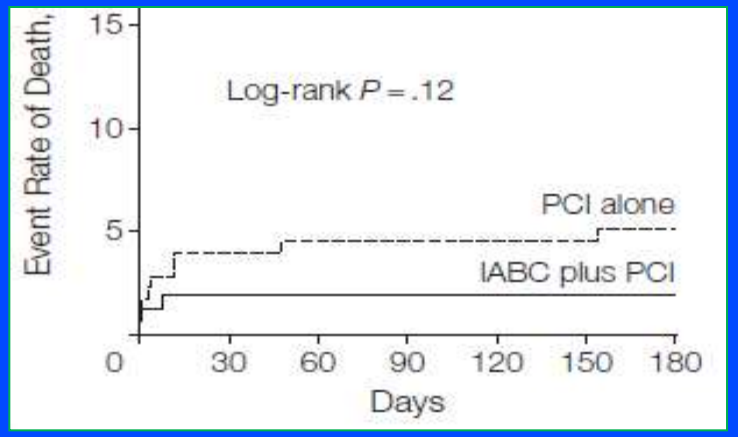
The CRISP AMI Randomized Trial

CRISP am — counterpulsation reduces infarct size pre pci in acute myocardial infarction



1ry EP (NMR) Infarct size similar in both groups: IABC+PCI: 42.1% vs 37.5% ICP alone *P=.06.*

Time to coronary device was 77 minutes for IABC+PCI group vs 68 minutes for the PCI alone group (*P=.04).*



Patel MR, et al. JAMA. 2011;306(12):1329-1337

Intervencionismo Estructural

PARTNER

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 21, 2010 VOL. 363 NO. 17

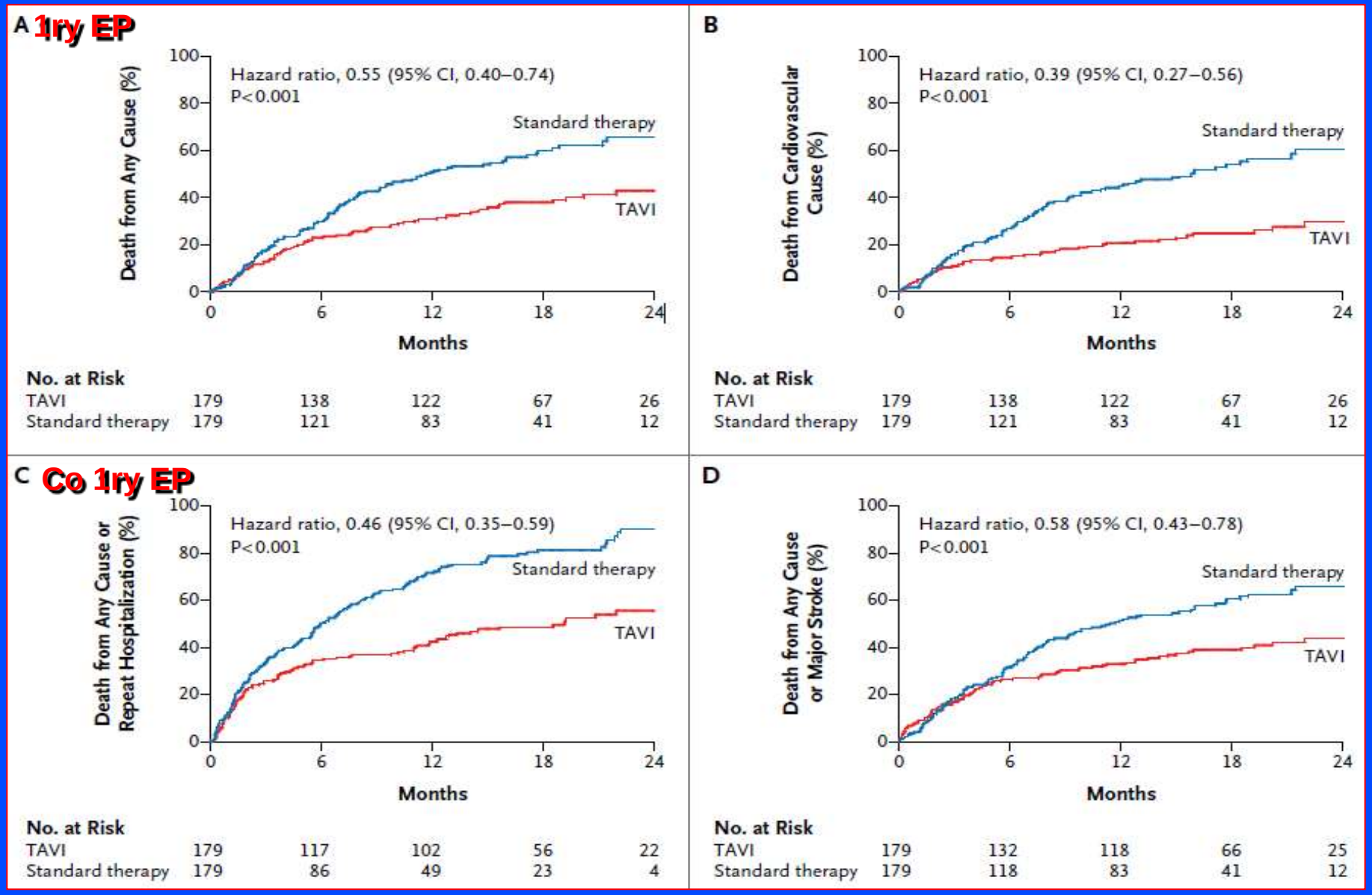
Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

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 S. 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*

328 Pts SAS (21 Centers) TAVI vs Medical Management (including BAV)

Leon MB. N Engl J Med 2010;363:1597-1607.

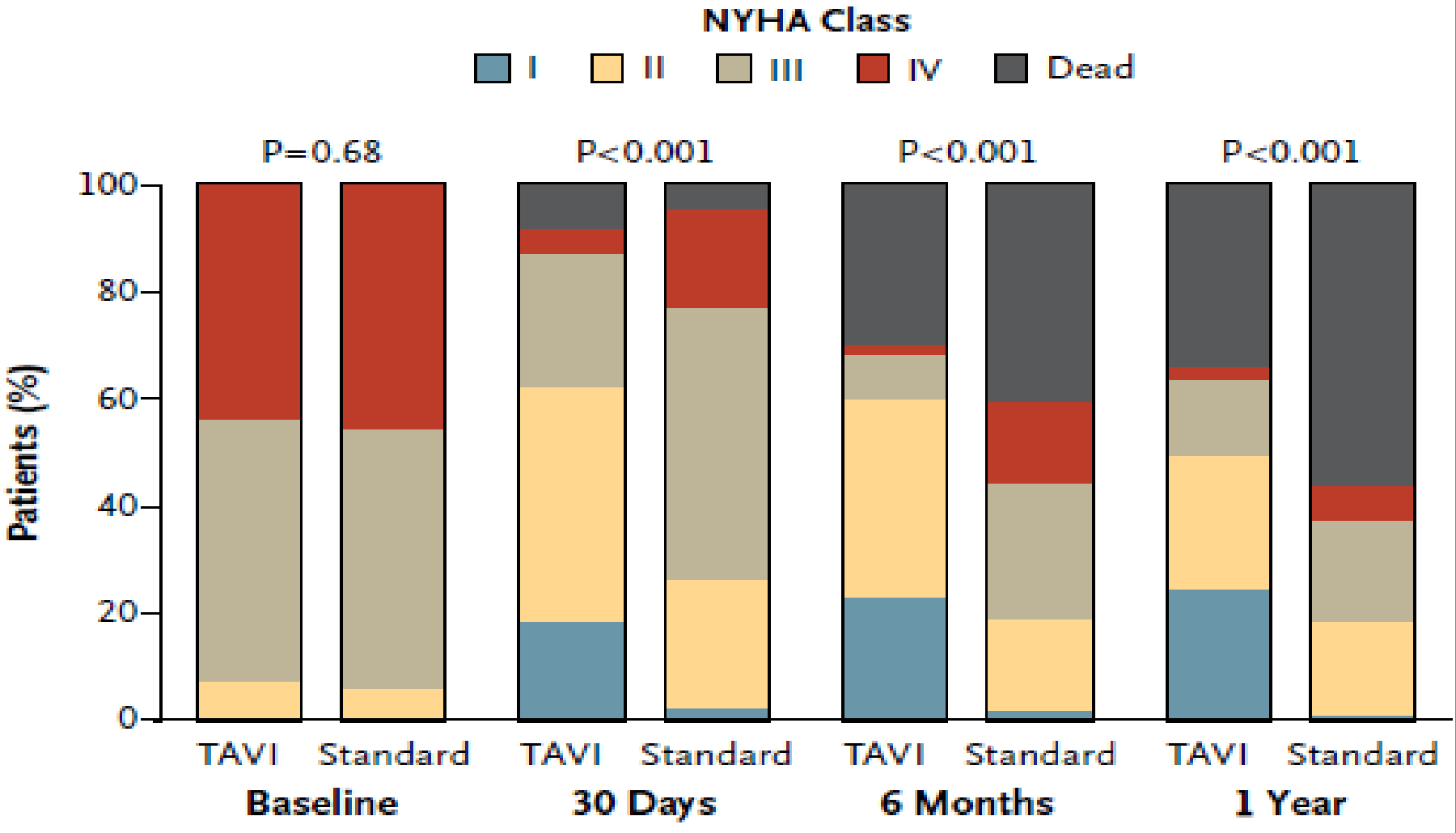
PARTNER



Leon MB. N Engl J Med 2010;363:1597-1607.

PARTNER

At 30 days, TAVI, as compared with standard therapy, was associated with a higher incidence of major strokes (5.0% vs. 1.1%, P = 0.06) and major vascular complications (16.2% vs. 1.1%, P<0.001)



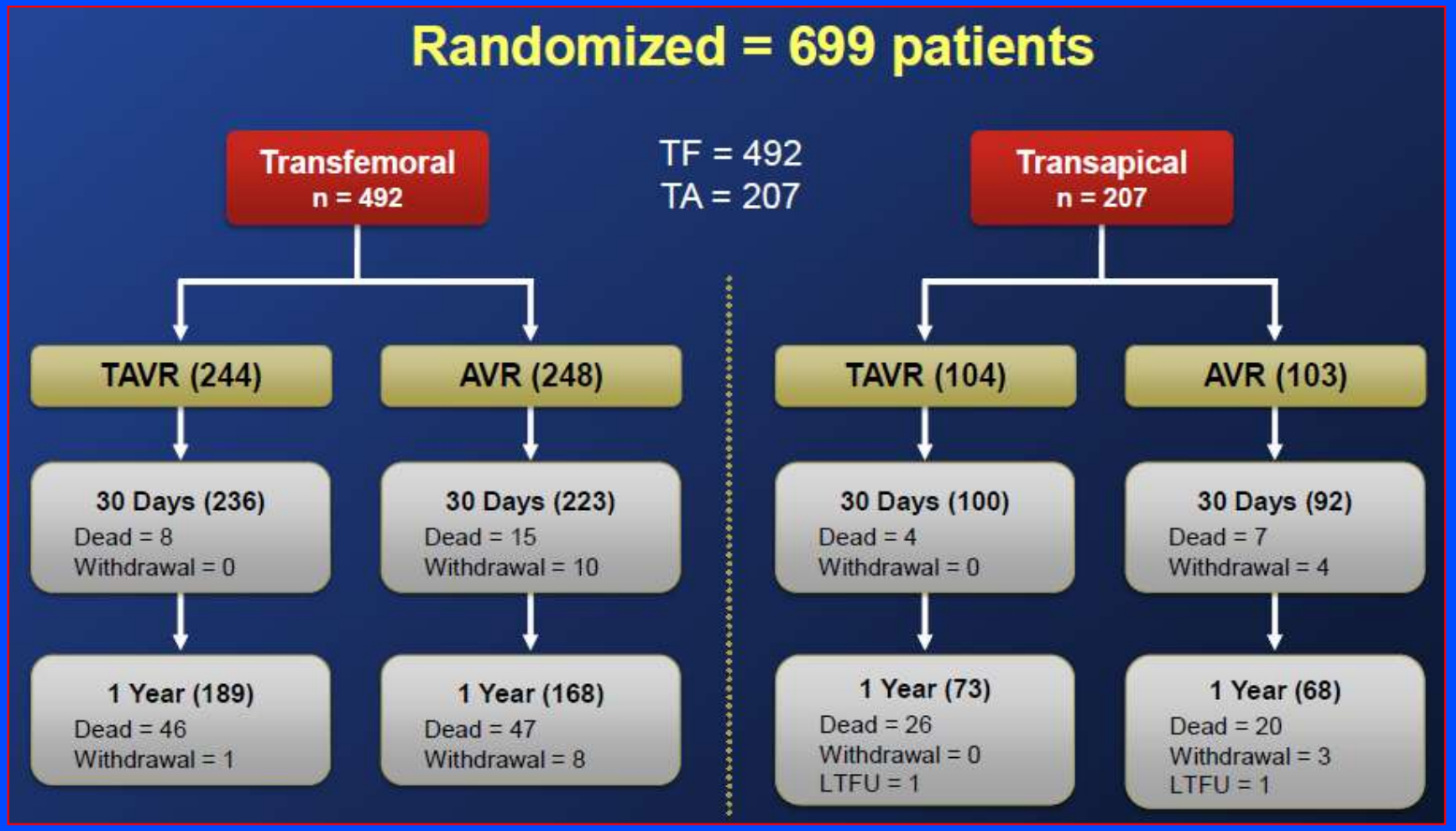
Leon MB. N Engl J Med 2010;363:1597-1607.

PARTNER

"High-Risk" SAS

Operative Mortality >15%
STS score >10

Assessment Transfemoral Access



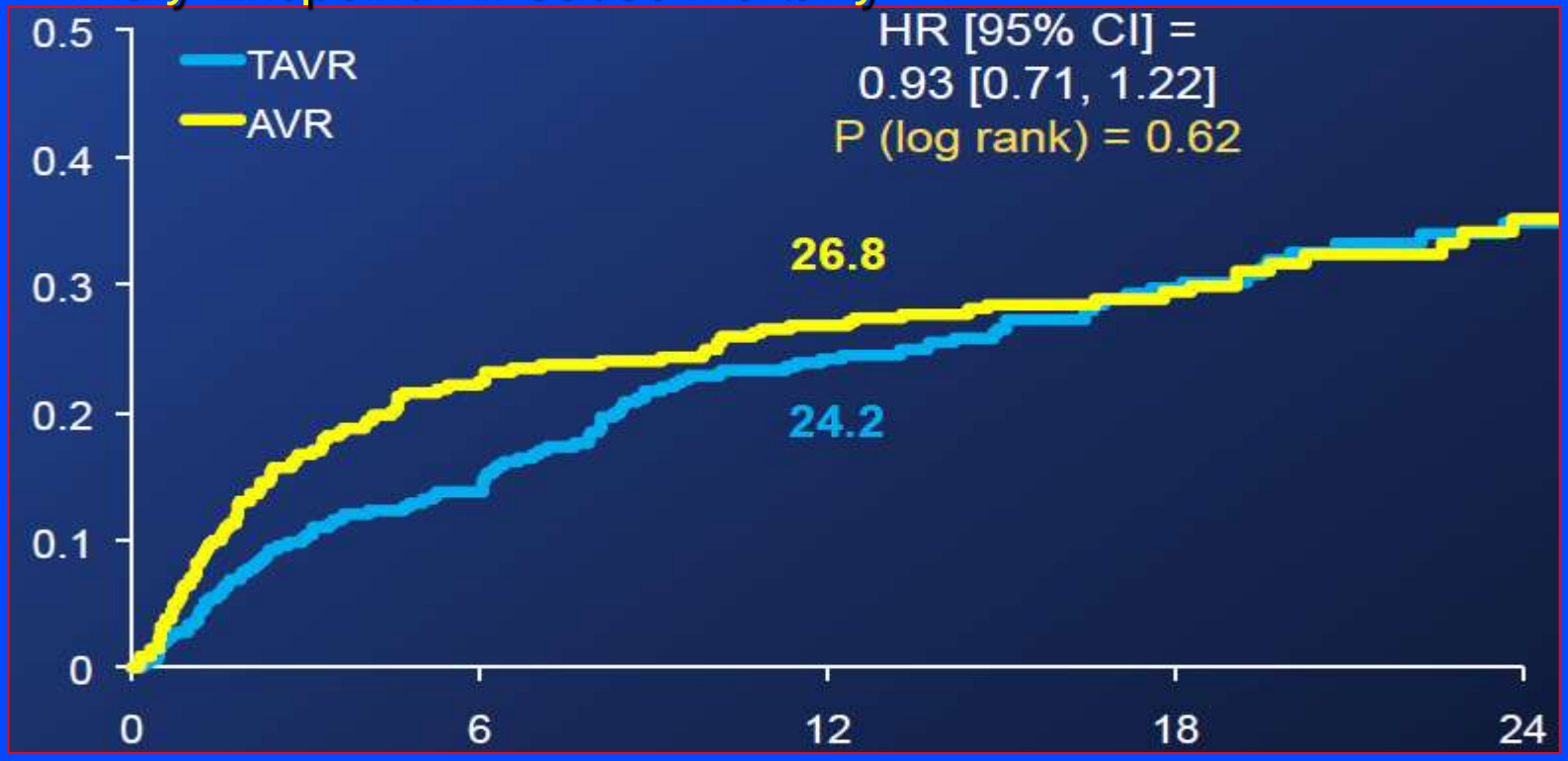
Early Devices. Most sites no previous TAVR experience

Smith CR,

PARTNER

"High-Risk" SAS

Primary Endpoint: All Cause Mortality 1Y



Pre-specified Noninferiority Margin 7.5%

Smith CR, et al. N Engl J Med 2011;364:2187-98.

CLOSURE I

CLOSURE I
Investigating the PFO Stroke Connection

STARTFlex

1ry EP Composite
Stroke/TIA 2Y
<30d Death
>30d Neuro Death

Pts ≤60 y, cryptogenic stroke or TIA and PFO documented with TEE

(Presumed paradoxical embolism through a Patent Foramen Ovale)

N=447
STARFlex®
Closure (within 30 Days)
6 Months Aspirin and Clopidigrel
followed by 18 Months Aspirin

N = 447

N=462
Best Medical Therapy
24 Months Aspirin Or Warfarin
Or Combination

N = 462

2 Year Primary Endpoint ITT

	STARFlex n = 447	Medical n = 462	Adjusted P value*
Composite	5.9% (n=25)	7.7% (n=30)	0.30
Stroke	3.1% (n=12)	3.4% (n=13)	0.77
TIA	3.3% (n=13)	4.6% (n=17)	0.39

Major vascular complications*	3.2% (n =13)	0.0%	<0.001
Atrial fibrillation	5.7% (n= 14/23 periprocedural)	0.7% (n=3)	<0.001
Major bleeding	2.6% (n=10)	1.1% (n=4)	0.11

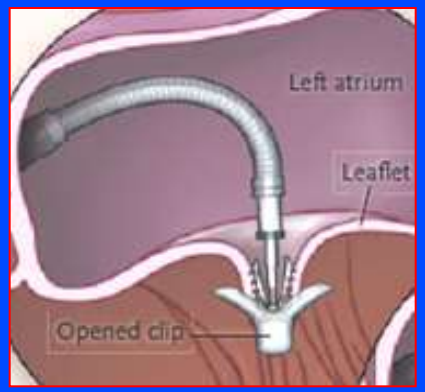
Furlan AJ, Cleveland

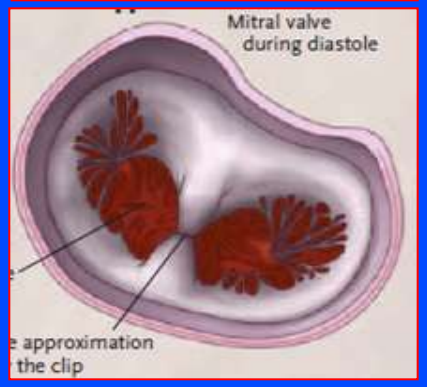
EVEREST II

Percutaneous Repair or Surgery for Mitral Regurgitation

Ted Feldman, M.D., Elyse Foster, M.D., Donald D. Glower, M.D., Saibal Kar, M.D., Michael J. Rinaldi, M.D., Peter S. Fail, M.D., Richard W. Smalling, M.D., Ph.D., Robert Siegel, M.D., Geoffrey A. Rose, M.D., Eric Engeron, M.D., Catalin Loghin, M.D., Alfredo Trento, M.D., Eric R. Skipper, M.D., Tommy Fudge, M.D., George V. Letsou, M.D., Joseph M. Massaro, Ph.D., and Laura Mauri, M.D., for the EVEREST II Investigators*

279 Pts 3+/4+ MR randomized (2:1) to undergo percutaneous repair or conventional surgery for repair/replacement





1ry EP (12 Months) for efficacy was freedom from death, surgery for mitral-valve dysfunction and 3+/4+ MR
55% percutaneous vs 77% surgical (p=0.007)

Major adverse events (1 Month):
15% percutaneous vs 48% surgical (p<0.001).

At 12 months, both groups improved:
- left ventricular size
- NYHA
- QOL

Feldman T, et al. N Engl J Med 2011;364:1395-406.

Seguimos Mejorando