ovetats en revascularització coronaria : Stents farmacoatius (DES)

Dr. Antoni Serra
Hospital de Sant Pau
Barcelona

Sessió de la Societat Catalana de Cardiología, 13 de Gener 2014

Lancet 2013; 381: 629–38

Coronary artery bypass graft surgery versus percutaneous coronary intervention in patients with three-vessel disease and left main coronary disease: 5-year follow-up of the randomised, clinical SYNTAX trial

Friedrich W Mohr, Marie-Claude Morice, A Pieter Kappetein, Ted E Feldman, Elisabeth Ståhle, Antonio Colombo, Michael J Mack, David R Holmes Jr, Marie-angèle Morel, Nic Van Dyck, Vicki M Houle, Keith D Dawkins, Patrick W Serruys

Summary

Background We report the 5-year results of the SYNTAX trial, which compared coronary artery bypass graft surgery (CABG) with percutaneous coronary intervention (PCI) for the treatment of patients with left main coronary disease or three-vessel disease, to confirm findings at 1 and 3 years.

Interpretation CABG should remain the standard of care for patients with complex lesions (high or intermediate SYNTAX scores). For patients with less complex disease (low SYNTAX scores) or left main coronary disease (low or intermediate SYNTAX scores), PCI is an acceptable alternative. All patients with complex multivessel coronary artery disease should be reviewed and discussed by both a cardiac surgeon and interventional cardiologist to reach consensus on optimum treatment.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 20, 2012 VOL. 367 NO. 25

Strategies for Multivessel Revascularization in Patients with Diabetes

Michael E. Farkouh, M.D., Michael Domanski, M.D., Lynn A. Sleeper, Sc.D., Flora S. Siami, M.P.H., George Dangas, M.D., Ph.D., Michael Mack, M.D., May Yang, M.P.H., David J. Cohen, M.D., Yves Rosenberg, M.D., M.P.H., Scott D. Solomon, M.D., Akshay S. Desai, M.D., M.P.H., Bernard J. Gersh, M.B., Ch.B., D.Phil., Elizabeth A. Magnuson, Sc.D., Alexandra Lansky, M.D., Robin Boineau, M.D., Jesse Weinberger, M.D., Krishnan Ramanathan, M.B., Ch.B., J. Eduardo Sousa, M.D., Ph.D., Jamie Rankin, M.D., Balram Bhargava, M.D., John Buse, M.D., Whady Hueb, M.D., Ph.D., Craig R. Smith, M.D., Victoria Muratov, M.D., M.P.H., Sameer Bansilal, M.D., Spencer King III, M.D., Michel Bertrand, M.D., and Valentin Fuster, M.D., Ph.D., for the FREEDOM Trial Investigators*

European Heart Journal (2013) **34**, 2949–3003
doi:10.1093/eurheartj/eht296

ESC GUIDELINES

2013 ESC guidelines on the management of stable coronary artery disease

The Task Force on the management of stable coronary artery disease of the European Society of Cardiology

Task Force Members: Gilles Montalescot* (Chairperson) (France), Udo Sechtem* (Chairperson) (Germany), Stephan Achenbach (Germany), Felicita Andreotti (Italy), Chris Arden (UK), Andrzej Budaj (Poland), Raffaele Bugiardini (Italy), Filippo Crea (Italy), Thomas Cuisset (France), Carlo Di Mario (UK), J. Rafael Ferreira (Portugal), Bernard J. Gersh (USA), Anselm K. Gitt (Germany), Jean-Sebastien Hulot (France), Nikolaus Marx (Germany), Lionel H. Opie (South Africa), Matthias Pfisterer (Switzerland), Eva Prescott (Denmark), Frank Ruschitzka (Switzerland), Manel Sabaté (Spain), Roxy Senior (UK), David Paul Taggart (UK), Ernst E. van der Wall (Netherlands), Christiaan J.M. Vrints (Belgium).

European Heart Journal (2010) **31**, 2501–2555
doi:10.1093/eurheartj/ehq277

2010

ESC/EACTS GUIDELINES

Guidelines on myocardial revascularization

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)‡

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), David Taggart (UK)

- ✓ Guías conjuntas de las Sociedades Europeas de Cardiología (ESC) and Cirujanos cardiotorácicos (EACTS)
- ✓ 25 miembros de 13 paises europeos
  - ✓ 9 clinicos / no Intervencionistas
  - ✓ 8 Cardiologos Intervencionistas
  - ✓ 8 Cirujanos cardíacos

Refleja el “Heart Team”

HEART TEAM

Si no saps ni
cosirte els mitjons!!!
Millor li poso 4 stents.
Carnicer!!!

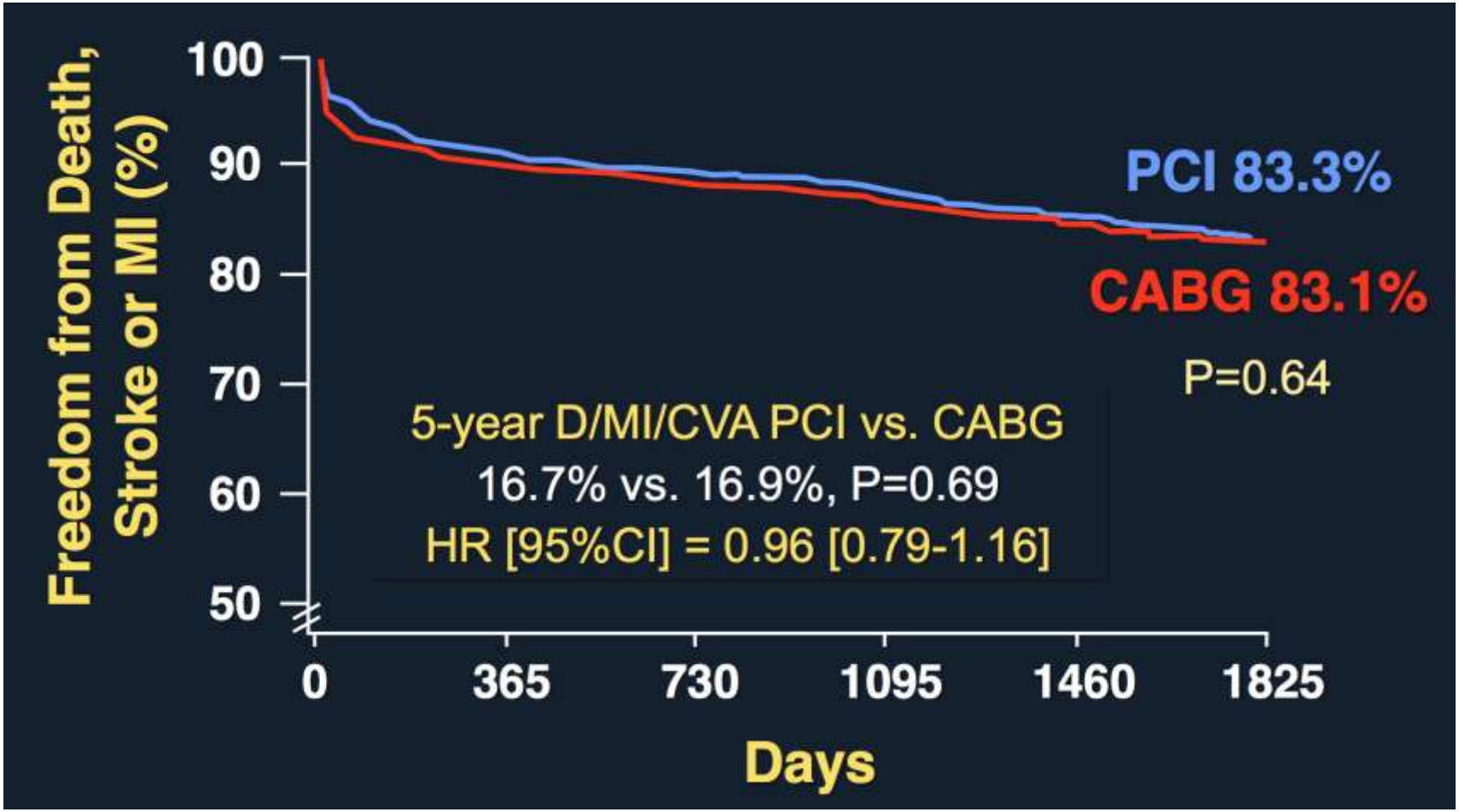
El pacient es meu.
Li posaré tres empelts!!!
Lampista!!!

NO!!!
Li afegiré Ivabradina

Evidencia científica per a decidir el tipus de revascularització miocàrdica

	RCT The Gold standard
Strengths	No Bias
Potential Weaknesses	Small numbers of patients Small % of eligible population Atypical patient populations Short duration of follow-up Large numbers of cross-overs

Bare Metal Stents vs. CABG
4RCTs (ARTS, ERACI-II, MASS-II, SoS)
3051 pts; 94% LIMA, 5 year follow-up



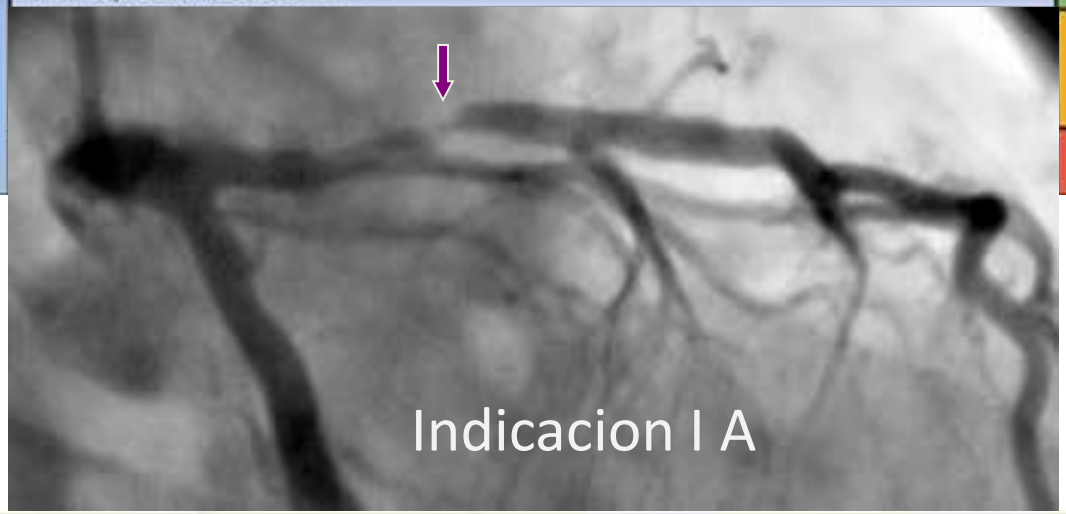
Daemon J. et al. Circulation 2006;118:1146-1154

Evidencia científica per a decidir el tipus de revascularització miocàrdica

	RCT The Gold standard	Registries (Propensity Matched)
Strengths	**No Bias**	Large Numbers of Patients Represent real clinical practice
Potential Weaknesses	Small numbers of patients Small % of eligible population Atypical patient populations Short duration of follow-up Large numbers of cross-overs	**Confounding/Bias**

2010 ESC/EACTS GUIDELINES on myocardial revascularization

	Subset of CAD by anatomy	Class	Level
For symptoms	Any stenosis > 50% with limiting angina or angina equivalent, unresponsive to OMT	I	A
		IIa	B
		III	C



Any stenosis > 50% with limiting angina or angina equivalent, unresponsive to OMT

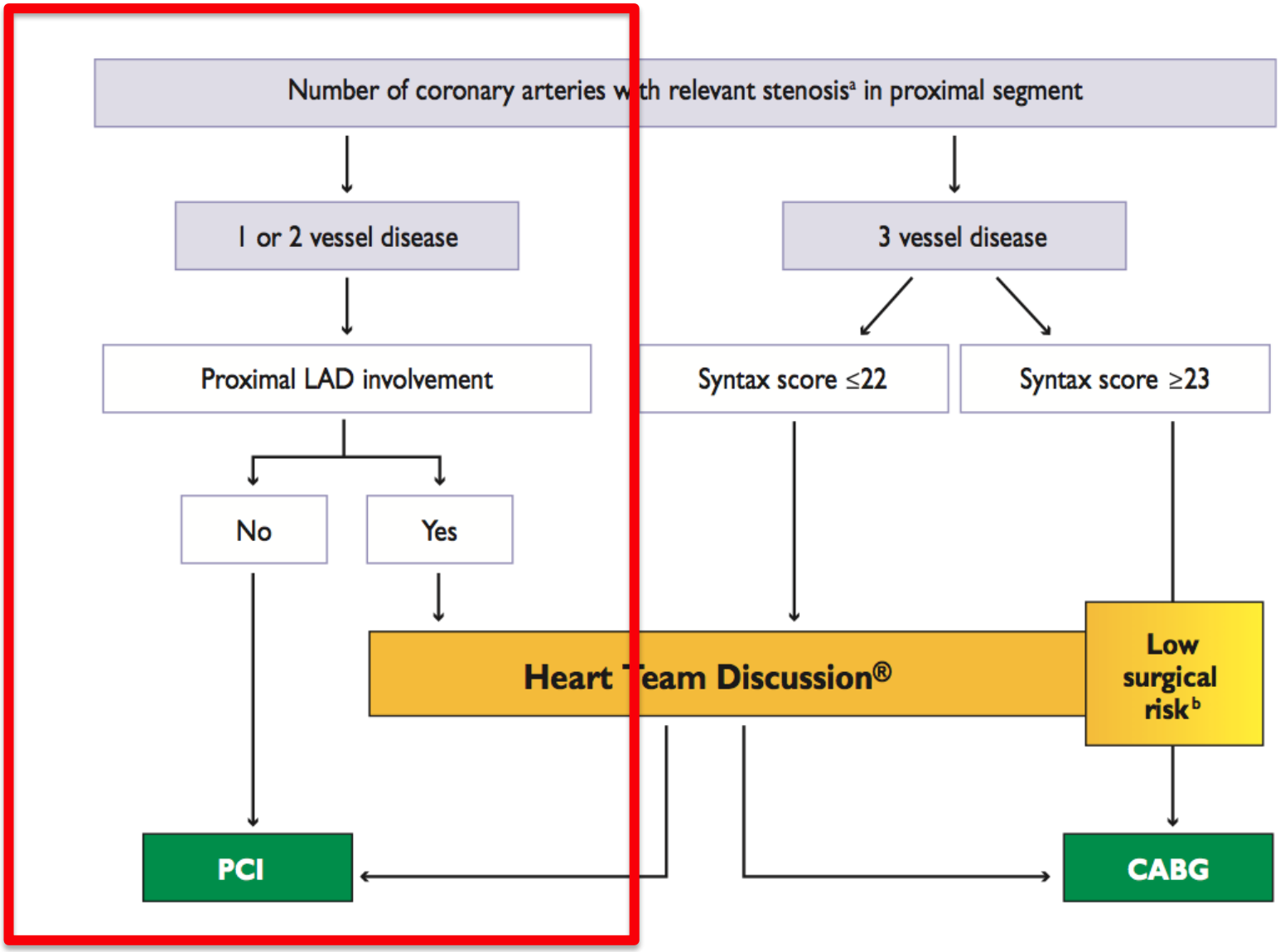
2010 ESC/EACTS GUIDELINES on myocardial revascularization

	Subset of CAD by anatomy	Class	Level
For symptoms	Any stenosis > 50% with limiting angina or angina equivalent, unresponsive to OMT	I	A
	Dyspnoea/CHF and > 10% LV ischaemia/viability supplied by > 50% stenotic artery	IIa	B
	No limiting symptoms with OMT	III	C

	Subset of CAD by anatomy	Class	Level
For prognosis	Left main > 50%*	I	A
	Any proximal LAD > 50%*	I	A
	2VD or 3VD with impaired LV function*	I	B
	Proven large area of ischaemia (> 10% LV)	I	B
	Single remaining patent vessel > 50% stenosis*	I	C
	1VD without proximal LAD and without > 10% ischaemia	III	A

* Con isquemia documentada o FFR (Reserva de flujo fraccional) < 0.80 para una estenosis angiográfica entre 50-90%

2013 ESC/EACTS GUIDELINES on the management of stable coronary artery disease



European Heart Journal 2013 34, 2949–3003

Comparison of Bare-Metal Stenting With Minimally Invasive Bypass Surgery for Stenosis of the Left Anterior Descending Coronary Artery

10-Year Follow-Up of a Randomized Trial

Conclusions At 10-year follow-up, PCI and MIDCAB in isolated proximal LAD lesions yielded similar long-term outcomes regarding the primary composite clinical endpoint. Target vessel revascularization was more frequent in the PCI group. (J Am Coll Cardiol Intv 2013;6:20–6) © 2013 by the American College of Cardiology Foundation

Table 1. MACE at Long-Term Follow-Up (10 Years)

	Stenting (n = 107)	MIDCAB (n = 105)	p Value	Relative Risk (95% CI)
Death	25 (23)	24 (23)	1.00	0.98 (0.51–1.35)
Cardiac death	9 (8)	10 (10)	0.81	1.07 (0.65–1.75)
Myocardial infarction	5 (5)	12 (11)	0.08	1.78 (0.84–3.76)
Target vessel revascularization	36 (34)	11 (11)	<0.001	0.56 (0.44–0.71)
Death or myocardial infarction	26 (24)	30 (29)	0.53	1.11 (0.83–1.54)
Any major adverse cardiac event	50 (47)	38 (36)	0.12	0.81 (0.62–1.05)

Blazek S. et al. JACC Intv 2013;6:20–26

Randomized Comparison of Minimally Invasive Direct Coronary Artery Bypass Surgery Versus Sirolimus-Eluting Stenting in Isolated Proximal Left Anterior Descending Coronary Artery Stenosis

Holger Thiele, MD,* Patrick Neumann-Schniedewind, MD,* Stephan Jacobs, MD,†
Enno Boudriot, MD,* Thomas Walther, MD,† Friedrich-Wilhelm Mohr, MD,†
Gerhard Schuler, MD,* Volkmar Falk, MD†

Leipzig, Germany

Objectives The purpose of this randomized study was to compare sirolimus-eluting stenting (SES) with minimally invasive direct coronary artery bypass (MIDCAB) surgery for patients with isolated proximal left anterior descending (LAD) coronary artery disease.

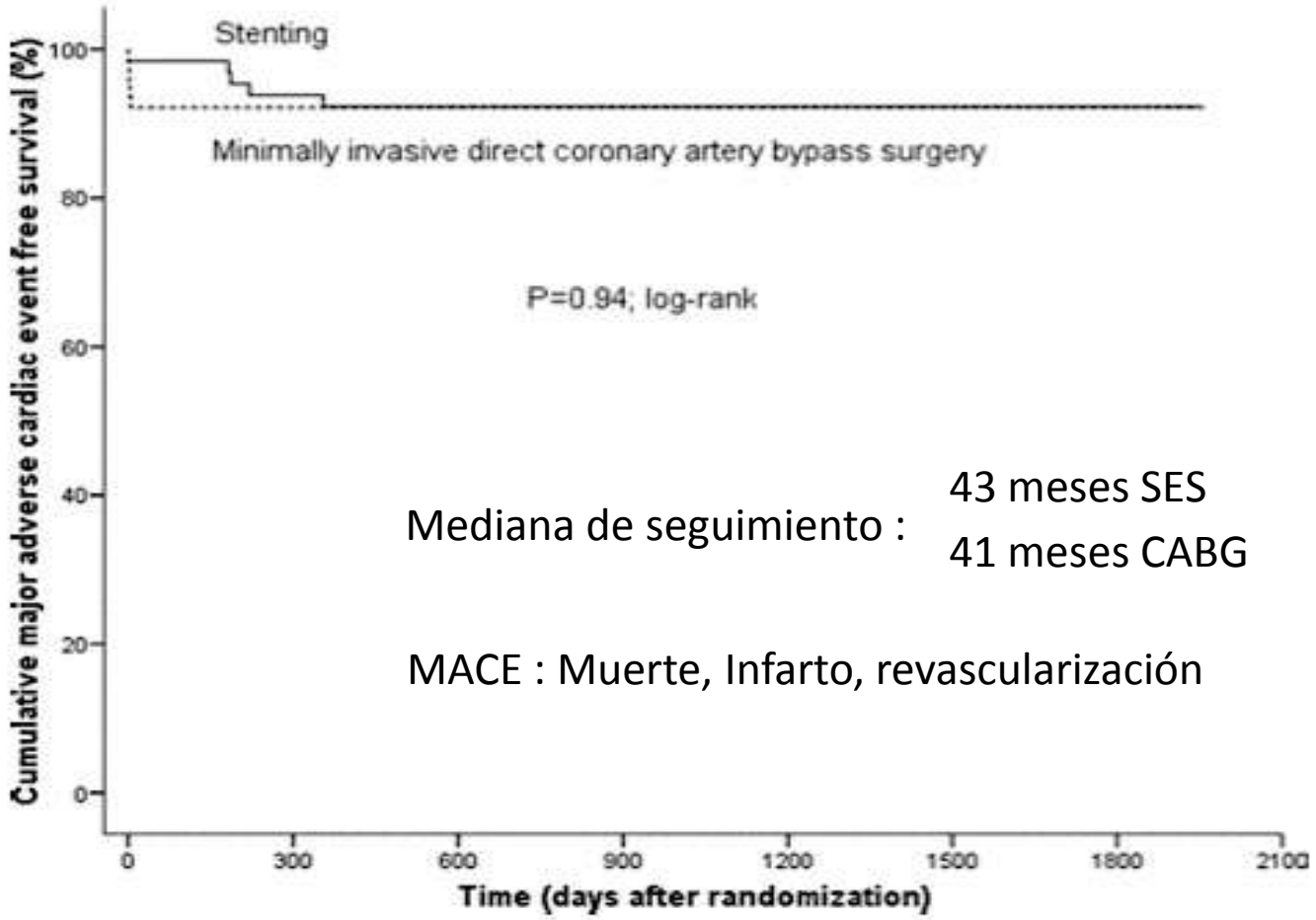
Background Bare-metal stenting is inferior to MIDCAB surgery in patients with isolated proximal LAD lesions due to a higher reintervention rate with similar results for mortality and reinfarction. SES are effective in restenosis reduction.

Methods A total of 130 patients with significant proximal LAD coronary artery disease were randomized to either SES ($n = 65$) or MIDCAB surgery ($n = 65$). The primary clinical end point was noninferiority in freedom from major adverse cardiac events (MACE), such as cardiac death, myocardial infarction, and the need for target vessel revascularization within 12 months.

Results Follow-up was completed for all patients. MACE occurred in 7.7% of patients after stenting, as compared with 7.7% after surgery ($p = 0.03$ for noninferiority). The individual components of the combined end point revealed mixed results. Although noninferiority was revealed for the difference in death and myocardial infarction (1.5% vs. 7.7%, noninferiority $p < 0.001$), noninferiority was not established for the difference in target vessel revascularization (6.2% vs. 0%, noninferiority $p = 0.21$). Clinical symptoms improved significantly in both treatment groups in comparison with baseline, and the percentage of patients free from angina after 12 months was 81% versus 74% ($p = 0.49$).

Conclusions In isolated proximal LAD disease, SES is noninferior to MIDCAB surgery at 12-month follow-up with respect to MACE at a similar relief in clinical symptoms. (MIDCAB Versus DES in Proximal LAD Lesions; NCT00299429) (J Am Coll Cardiol 2009;53:2324–31)

Randomized Comparison of Minimally Invasive Direct Coronary Artery Bypass Surgery Versus Sirolimus-Eluting Stenting in Isolated Proximal Left Anterior Descending Coronary Artery Stenosis



Mediana de seguimiento : 43 meses SES
41 meses CABG

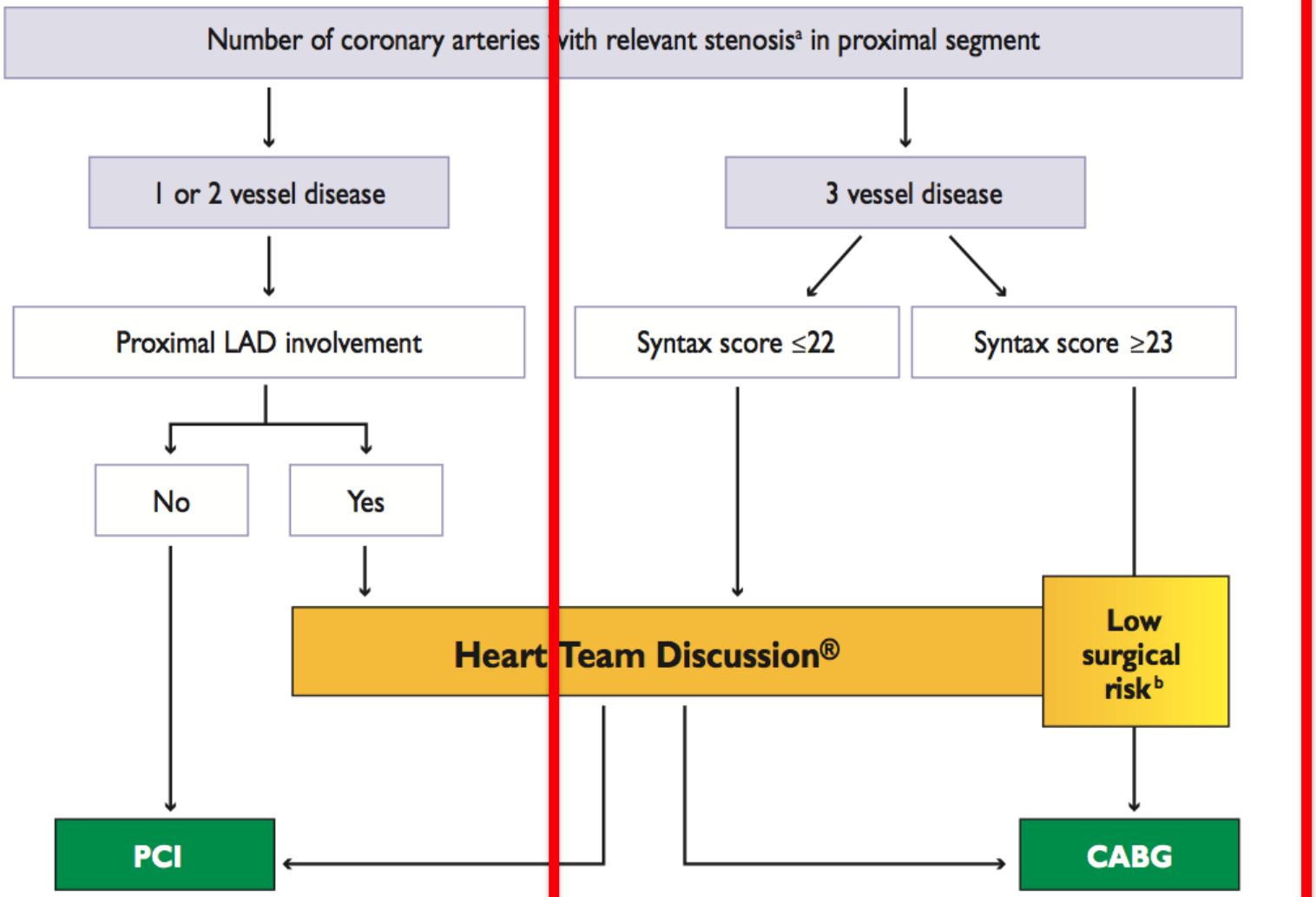
MACE : Muerte, Infarto, revascularización

Revascularització quirúrgica vs ICP

Subset of CAD by anatomy	Favours CABG	Favours PCI
1VD or 2VD - non-proximal LAD	IIb C	I C
1VD or 2VD - proximal LAD	I A	IIa B
3VD simple lesions, full functional revascularisation achievable with PCI, SYNTAX score ≤ 22	I A	IIa B
3VD complex lesions, incomplete revascularisation achievable with PCI, SYNTAX score > 22	I A	III A
Left main (isolated or 1VD, ostium/shaft)	I A	IIa B
Left main (isolated or 1VD, distal bifurcation)	I A	IIb B
Left main + 2VD or 3VD, SYNTAX score ≤ 32	I A	IIb B
Left main + 2VD or 3VD, SYNTAX score ≥ 33	I A	III B

European Heart Journal 2010;31:2501–2555

2013 ESC/EACTS GUIDELINES on the management of stable coronary artery disease



European Heart Journal 2013 34, 2949–3003

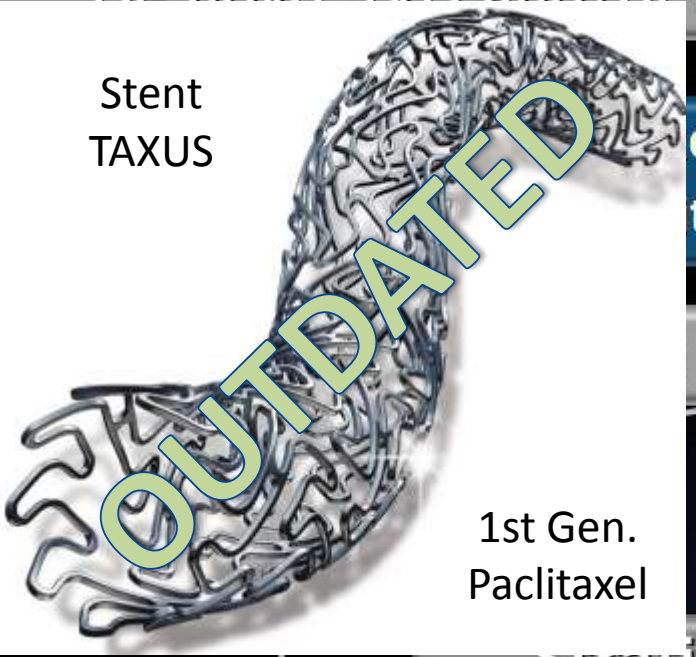
SYNTAX Trial Design

SYNTAX

62 EU Sites + 23 US Sites

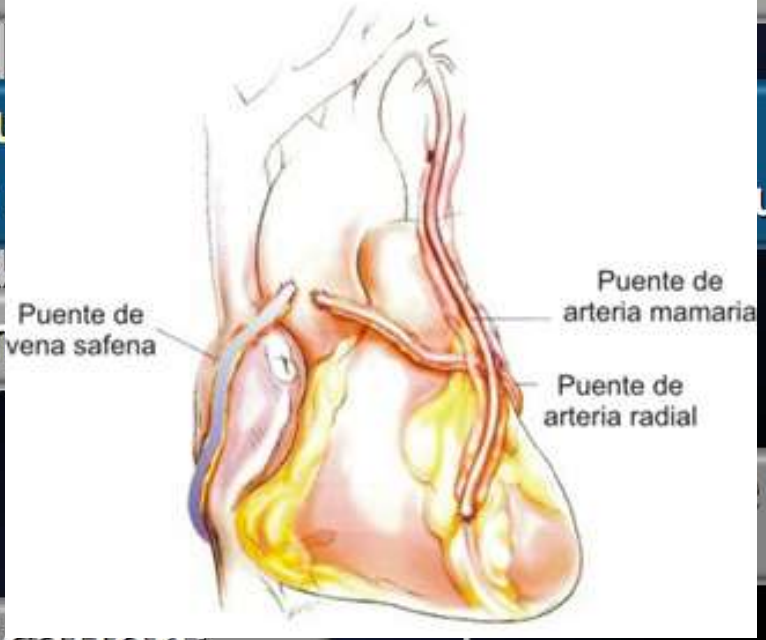
De novo 3VD and/or LM (isolated ±1, 2, 3 VD)

Stent
TAXUS



OUTDATED

1st Gen.
Paclitaxel



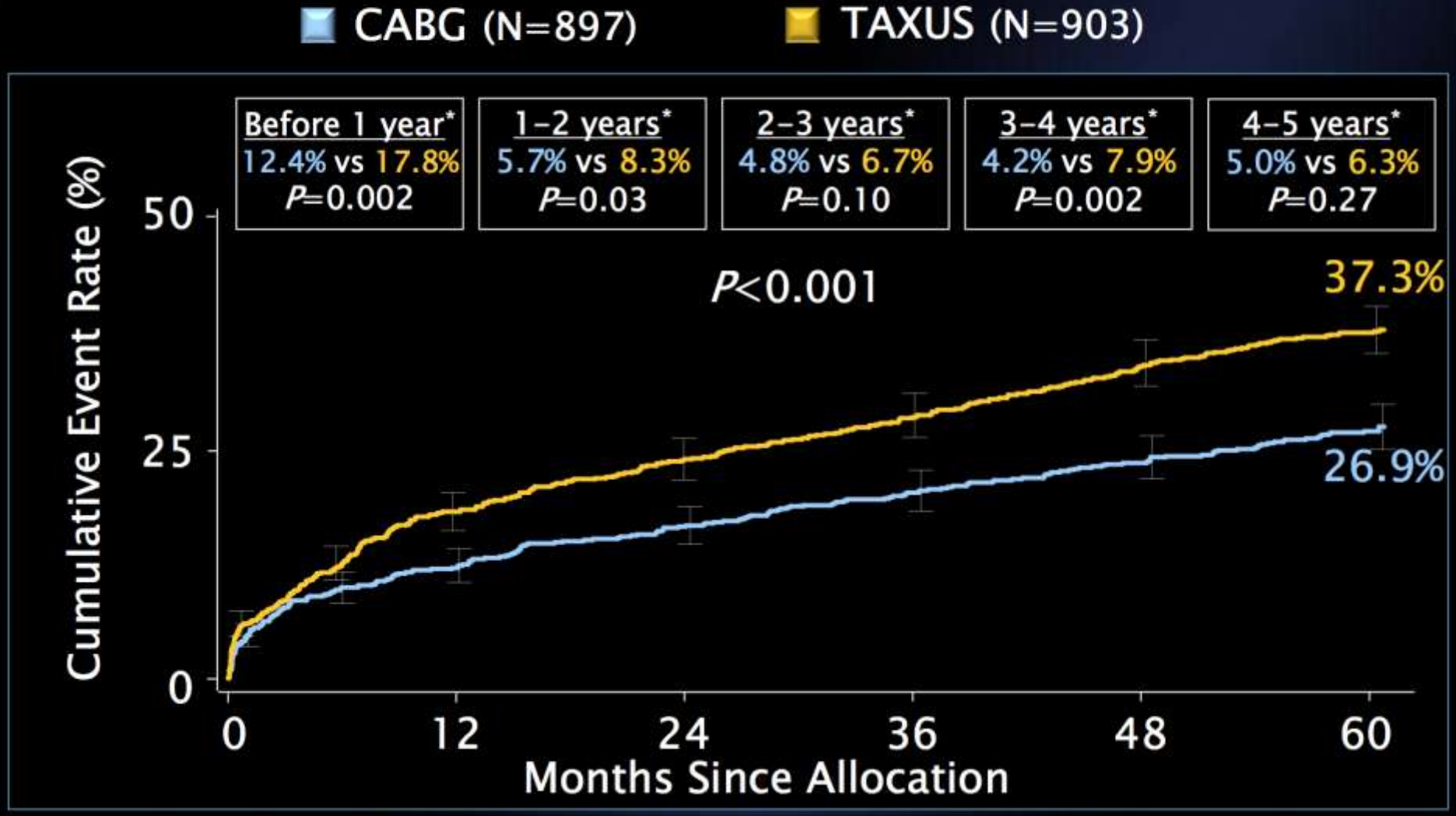
Stratification:
LM and Diabetes

Randomized Arms
N=1800

Two Registry Arms
N=1275

MACCE to 5 Years

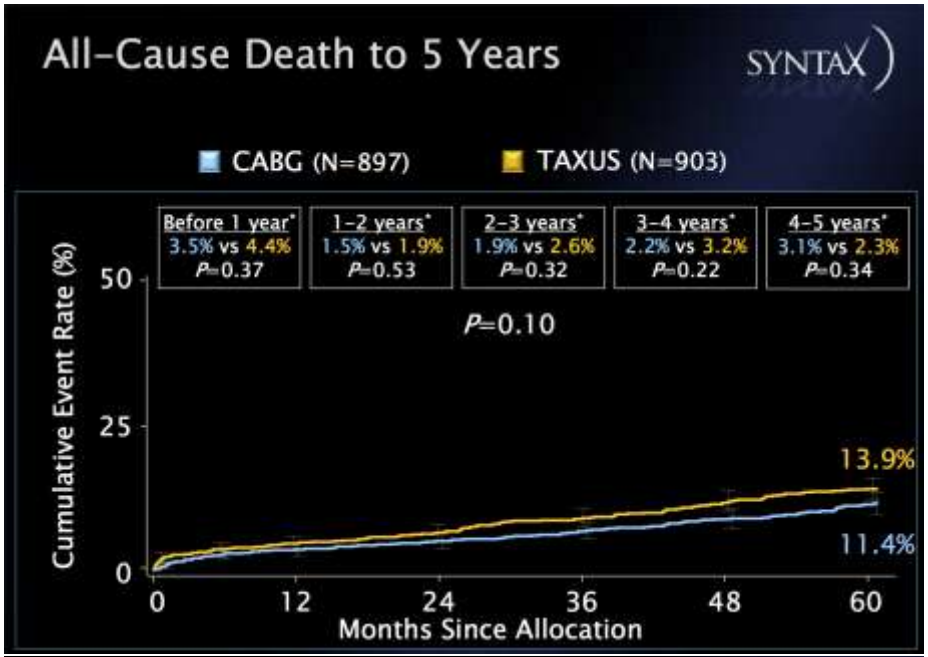
(All cause of death, MI, CVA, Target Lesion Revascularization)

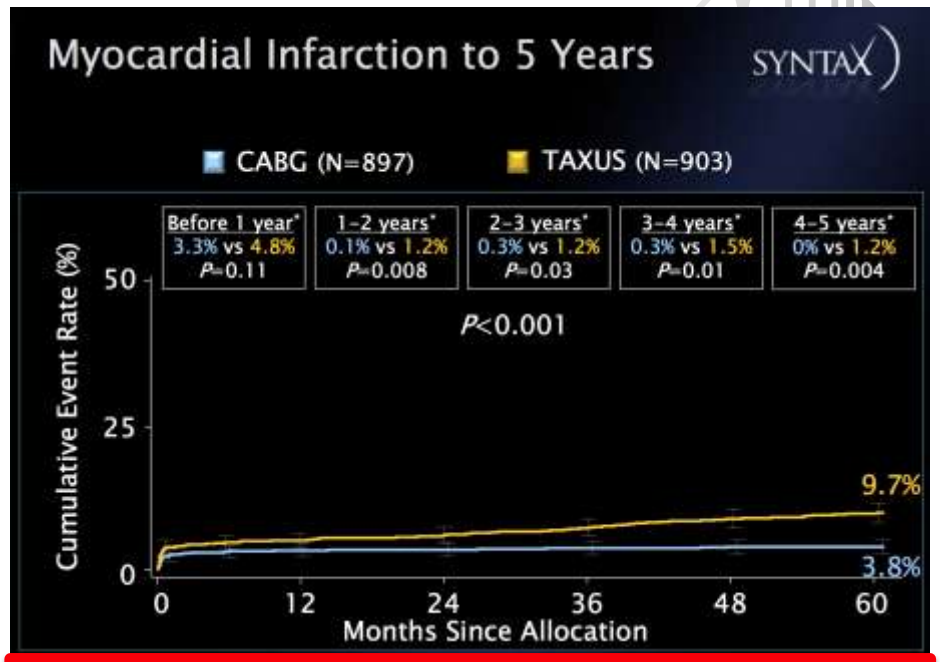


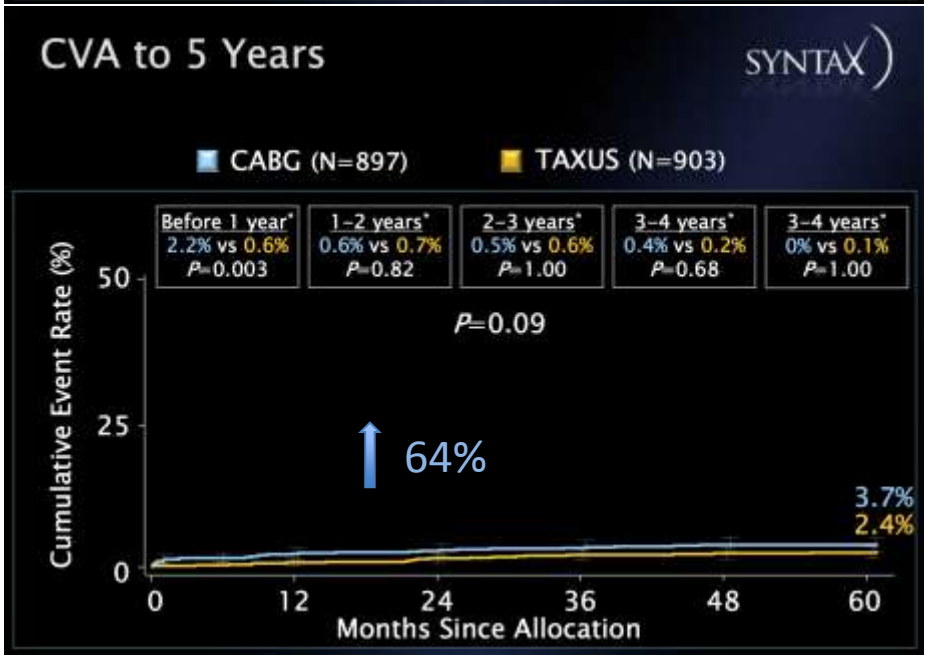
Cumulative KM Event Rate ± 1.5 SE; log-rank *P* value; *Binary rates

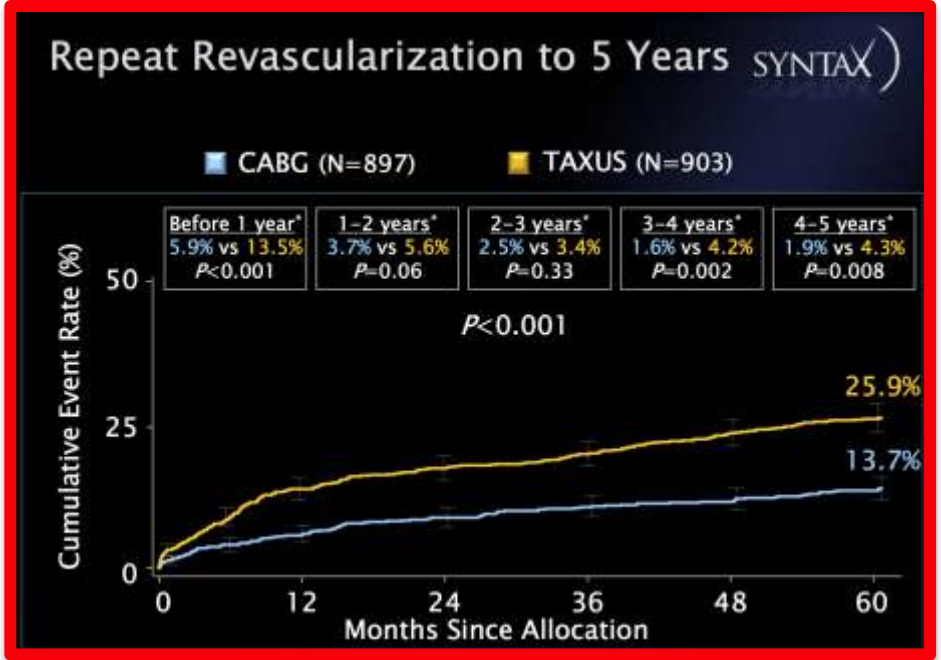
ITT population

Syntax 5 anys : Components del MACCE



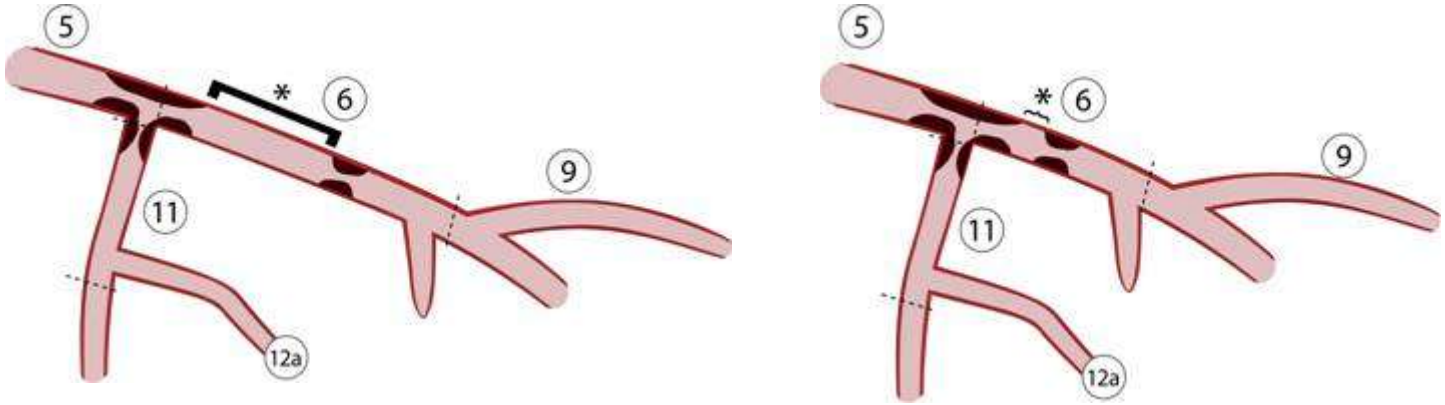






Syntax Score : Que evalúa

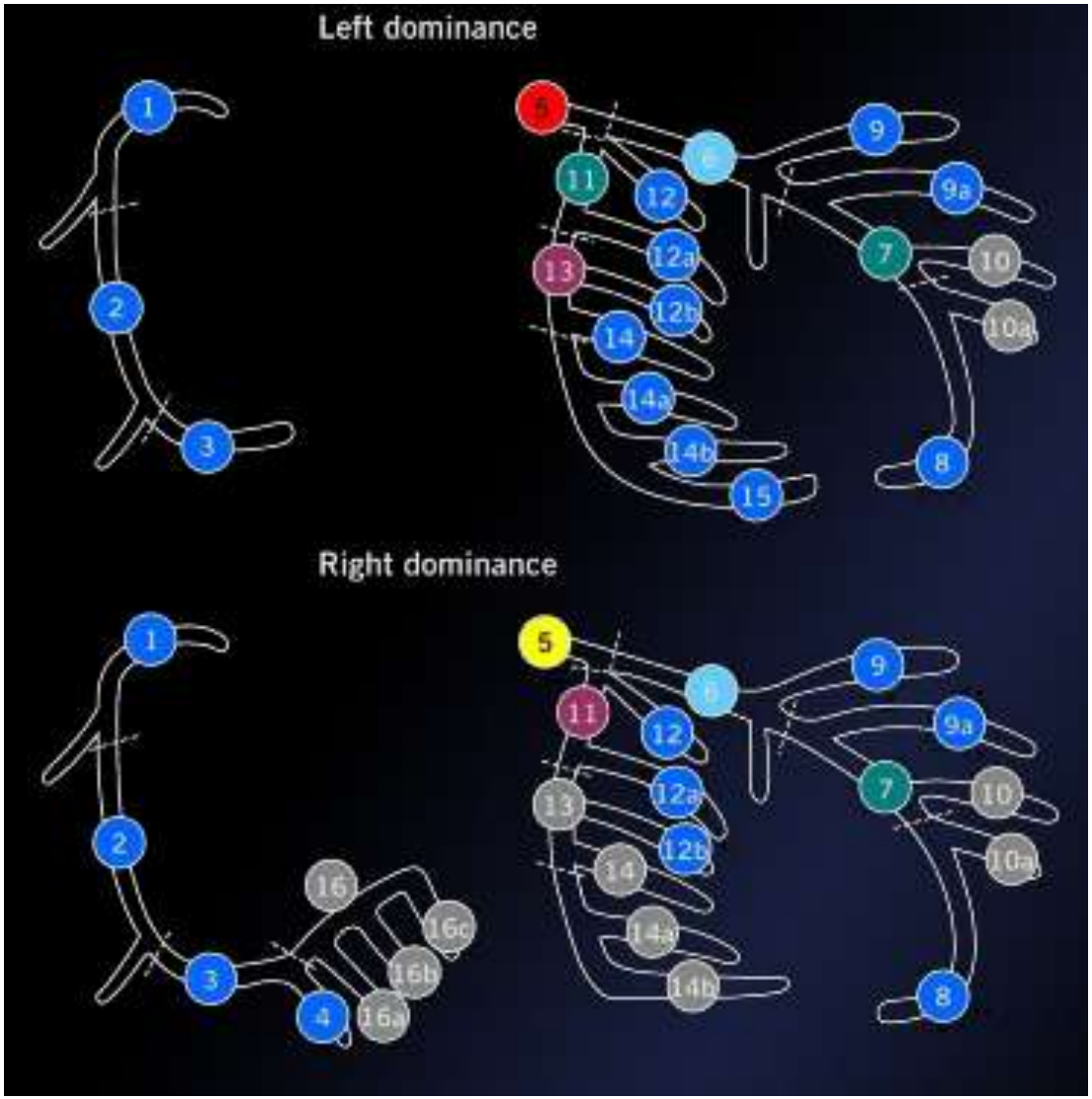
- ✓ Lesions coronàries amb estenosi ≥ 50%
- ✓ Només en artèries de >1.5 mm de diàmetre
- ✓ Cada lesió pot afectar a ≥1 segment malalt.



En les lesions en tándem, si la distancia entre ambdues es :

- ✓ > 3 vegades el diàmetre de referencia : 2 lesions separades
- ✓ ≤ 3 vegades el dièmetre de referencia : 1 única lesió

Syntax Score : Asignación del segmento enfermo y puntuación



Clasificación AHA de segmentos coronarios modificada para el estudio ARTS

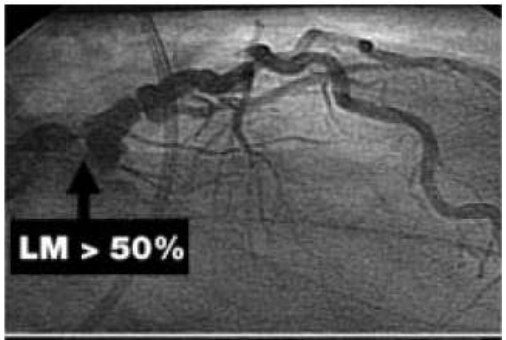
Leaman et al. Circulation 1981;63:285-292

Syntax Score : Descripció i finalitat

Eïna angiogràfica prospectiva per a avaluar la complexitat de la malaltía coronaria

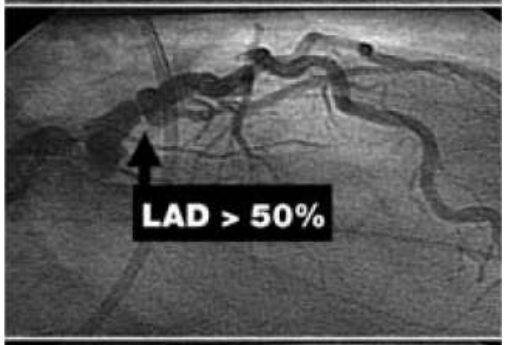
Obtenir guies basades en les evidències per seleccionar el tipus de revascularització (ICP o CABG)

Score : 0-22 (baix); 22-32 (intermig); ≥ 33 (alt)



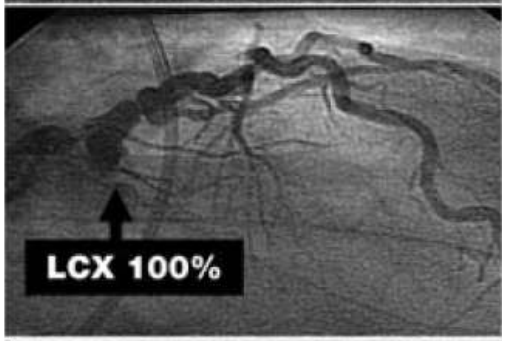
Lesion 1

Segment 5: 5x2	10
+ Bifurcation Type A	1
+ Heavy calcification	2
Lesion 1 score:	**13**



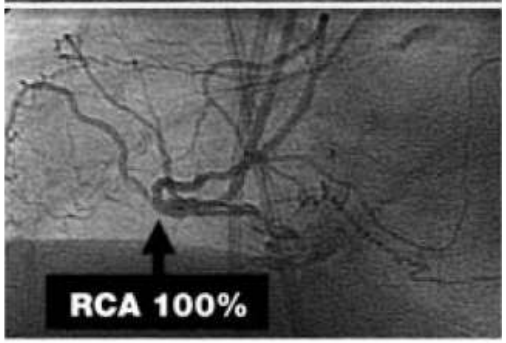
Lesion 2

Segment 6: 3,5x2	7
+ Bifurcation Type A	1
+ Angulation <70°	1
+ Heavy calcification	2
Lesion 2 score:	**11**



Lesion 3

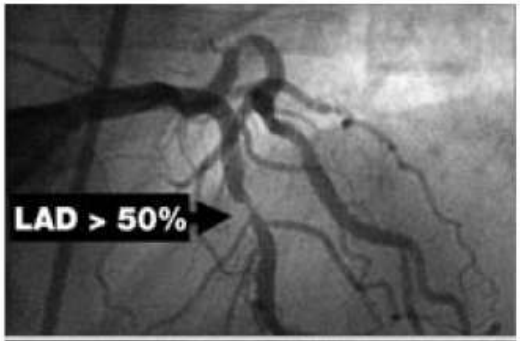
Segment 11: 1,5x5	7,5
Age T.O. is unknown	1
+ Blunt stump	1
+ side branch	1
First segment visualized by contrast : 13	1
+ Heavy calcification	2
+ Lenght	1
Lesion 3 score: 14,5	



Lesion 4

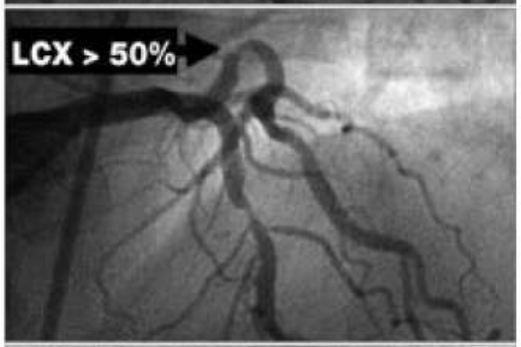
Segment 1: 1x5	5
Age T.O. is unknown	1
+ Blunt stump	1
+ side branch	1
first segment visualized by contrast: 4	3
+ Tortuosity	2
+ heavy calcification	2
+ Lenght	1
core:	**16**

SYNTAX SCORE 54.5



Lesion 1

Segment 6: 3,5x2	7
Lesion 1 score:	**7**

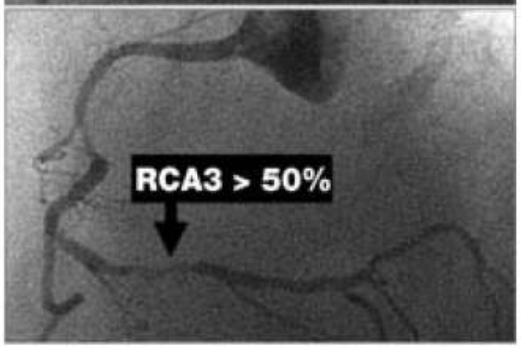


Lesion 2

Segment 11: 1,5x2	3
+ Tortuosity	2
Lesion 2 score:	**3**

Lesion 3

Segment 1 : 1x2	2
Lesion 3 score:	**2**

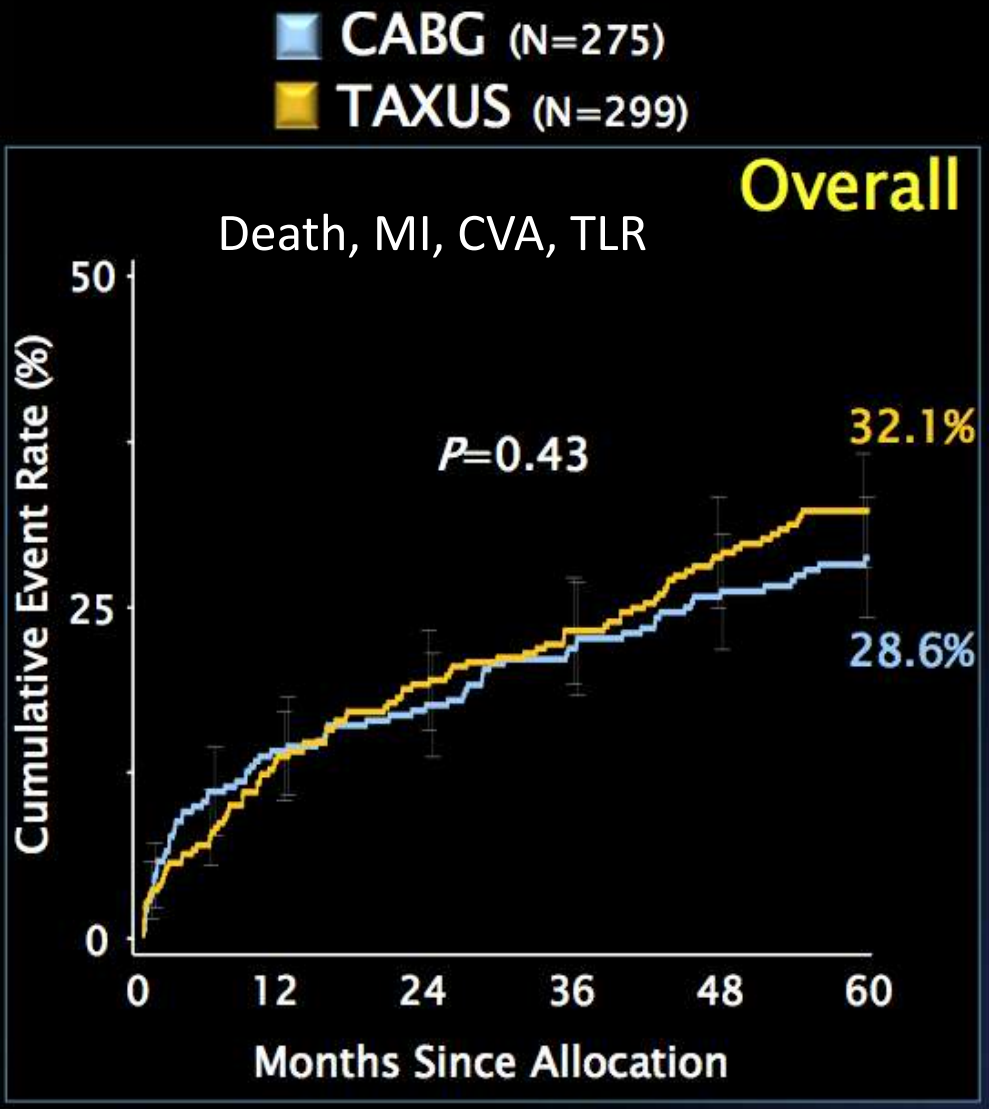


Lesion 4

Segment 1: 1x2	2
+ tortuosity	2
+ Lenght	1
lesion 4 score:	**5**

SYNTAX SCORE 17

MACCE to 5 Years by SYNTAX Score Tercile *Low Scores (0–22)*



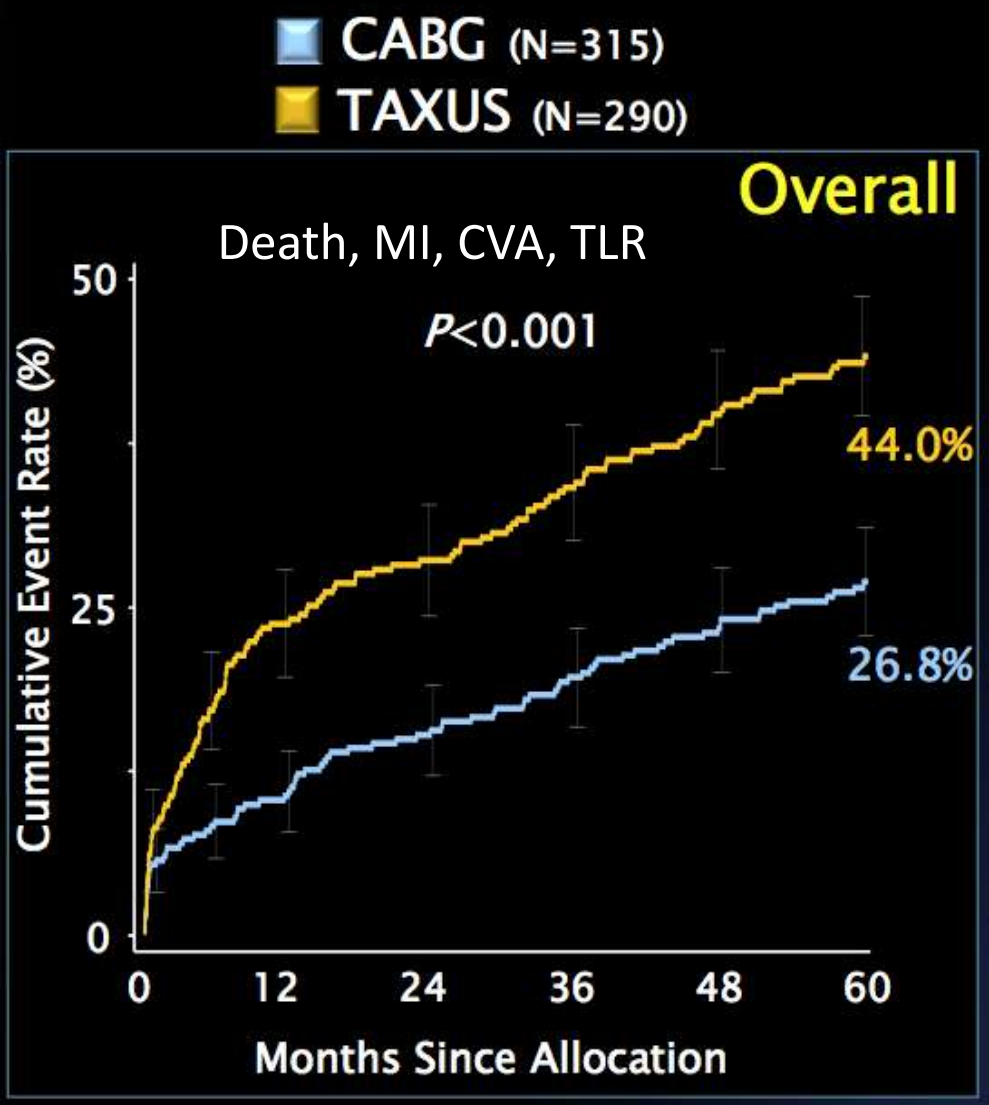
	CABG	PCI	*P* value
Death	10.1%	8.9%	0.64
CVA	4.0%	1.8%	0.11
MI	4.2%	7.8%	0.11
Death, CVA or MI	14.9%	16.1%	0.81
Revasc.	16.9%	23.0%	0.06

Cumulative KM Event Rate ± 1.5 SE; log-rank *P* value

Core lab-reported Data; ITT population

MACCE to 5 Years by SYNTAX Score Tercile *High Scores (≥33)*

SYNTAX

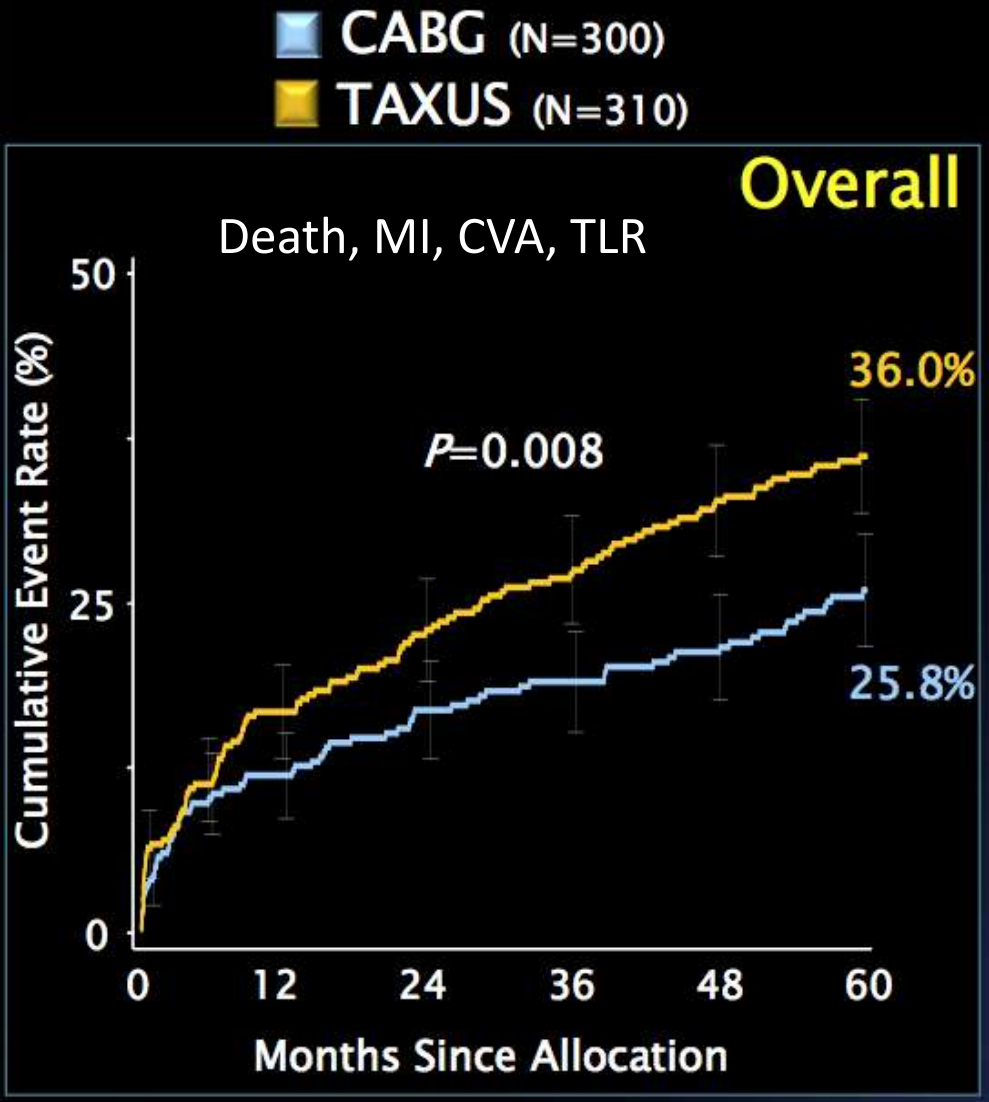


	CABG	PCI	*P* value
Death	11.4%	19.2%	0.005
CVA	3.7%	3.5%	0.80
MI	3.9%	10.1%	0.004
Death, CVA or MI	17.1%	26.1%	0.007
Revasc.	12.1%	30.9%	<0.001

Cumulative KM Event Rate ± 1.5 SE; log-rank *P* value

Core lab-reported Data; ITT population

MACCE to 5 Years by SYNTAX Score Tercile *Intermediate Scores (23–32)*



	CABG	PCI	*P* value
Death	12.7%	13.8%	0.68
CVA	3.6%	2.0%	0.25
MI	3.6%	11.2%	<0.001
Death, CVA or MI	18.0%	20.7%	0.42
Revasc.	12.7%	24.1%	<0.001

Cumulative KM Event Rate ± 1.5 SE; log-rank *P* value

Core lab-reported Data; ITT population

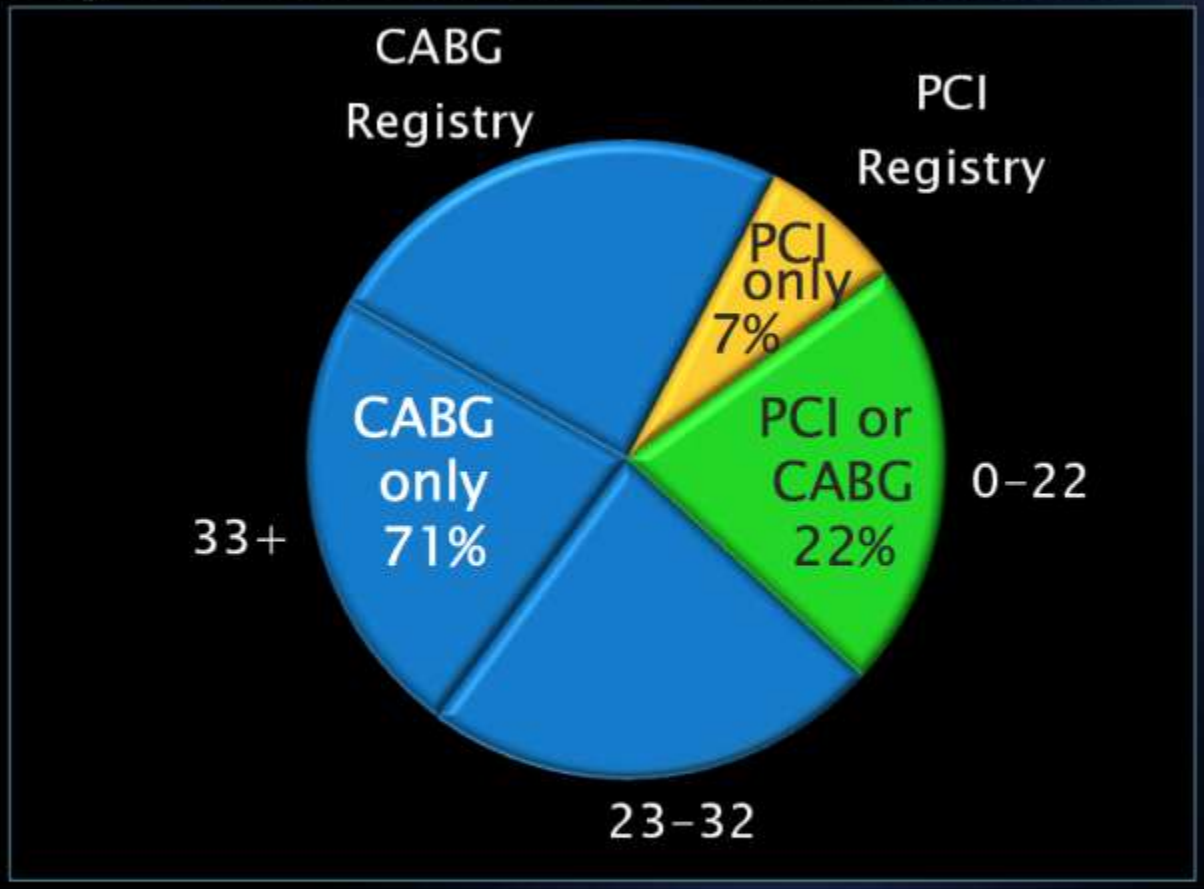
Revascularització quirúrgica vs ICP

Subset of CAD by anatomy	Favours CABG	Favours PCI
1VD or 2VD - non-proximal LAD	IIb C	I C
1VD or 2VD - proximal LAD	I A	IIa B
3VD simple lesions, full functional revascularisation achievable with PCI, SYNTAX score ≤ 22	I A	IIa B
3VD complex lesions, incomplete revascularisation achievable with PCI, SYNTAX score > 22	I A	III A
Left main (isolated or 1VD, ostium/shaft)	I A	IIa B
Left main (isolated or 1VD, distal bifurcation)	I A	IIb B
Left main + 2VD or 3VD, SYNTAX score ≤ 32	I A	IIb B
Left main + 2VD or 3VD, SYNTAX score ≥ 33	I A	III B

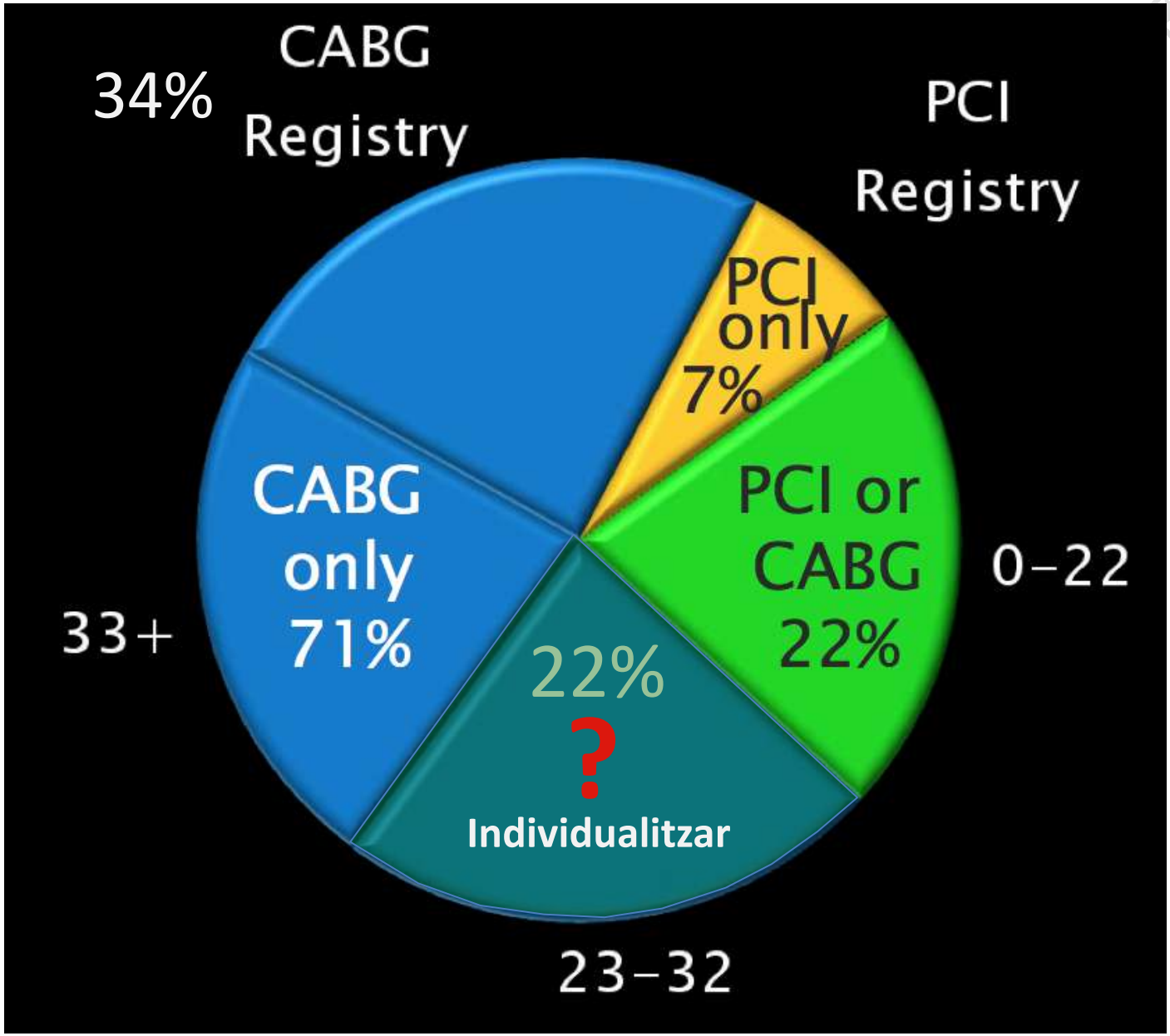
European Heart Journal 2010;31:2501–2555

MACCE to 5 Years

Interpreting Results Based on SYNTAX Score

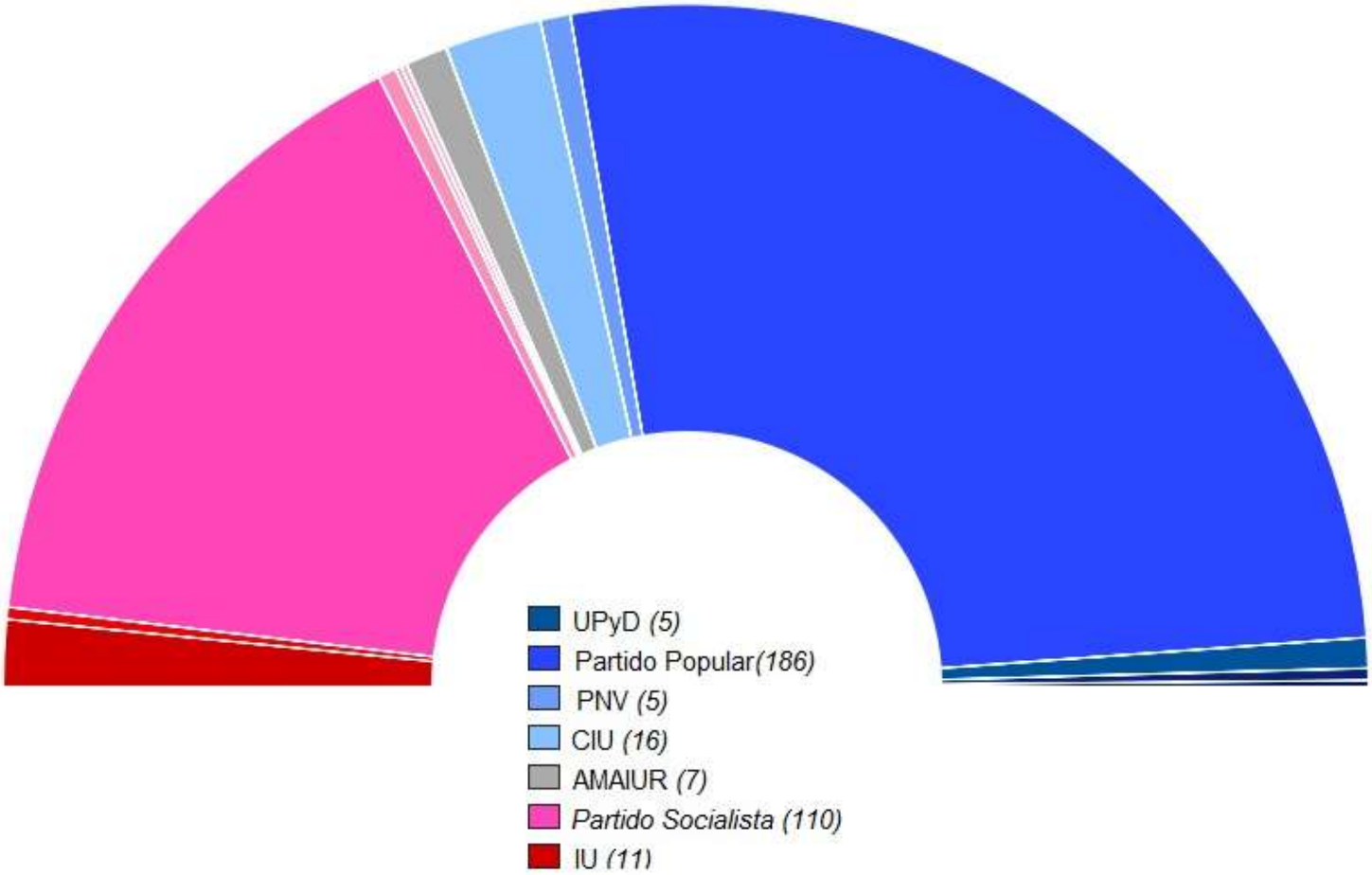


Five-year results of the SYNTAX trial suggest that 71% of all patients are still best treated with CABG; however, for the remaining patients PCI is an alternative to surgery


34%
CABG
Registry
PCI
Registry
PCI
only
7%
CABG
only
71%
PCI or
CABG
22%
0–22
33+
22%
?
Individualitzar
23–32

CONGRÈS DELS DIPUTATS – MADRID

Eleccions Legislatives 2011



Que hem après del Syntax?

- ✓ La Cirurgia coronaria es el tractament d'elecció en la malaltia multivas complexa (Syntax Score $\geq$ 33).
- ✓ En pacients amb anatomies menys complexes (Syntax Score $\leq$ 22) la ICP ofereix els mateixos resultats que la cirurgia (amb menys AVC).
- ✓ En els pacients amb Scores intermitjos (23-32), s'ha d'individualitzar el tipus de tractament.
- ✓ S'han de tenir en compte les preferencies dels pacients, després del anàlisis de risc-benefici particularitzat i la discussió entre el Heart Team.

SYNTAX TRIAL : Ho podem fer millor?

- ✓ Seleccionant el millor DES possible
- ✓ Revascularitzant amb criteris fisiològics i no només anatòmics (FFR)
- ✓ Trobant un score que inclogui variables clíniques a més de les anatomiques i sigui més discriminatiu.

Son iguals tots els DES ?

Primera generació

Segona generació

TAXUS® LIB.

Strut Thick…

Stai…

Poly… Thickness:

17.8 µm

PACLITAXEL

CYPHER®

OUTDATED

Strut Thickness:

140 µm

Stainless steel

Polymer Thickness:

13.7 µm

SIROLIMUS

XIENCE V® / PROMUS

Strut Thickness:

81 µm

Cobalt Chr.

Polymer Thickness:

7.8 µm

EVEROLIMUS

ENDEAVOR®

Strut Thickness:

91 µm

Cobalt Chr.

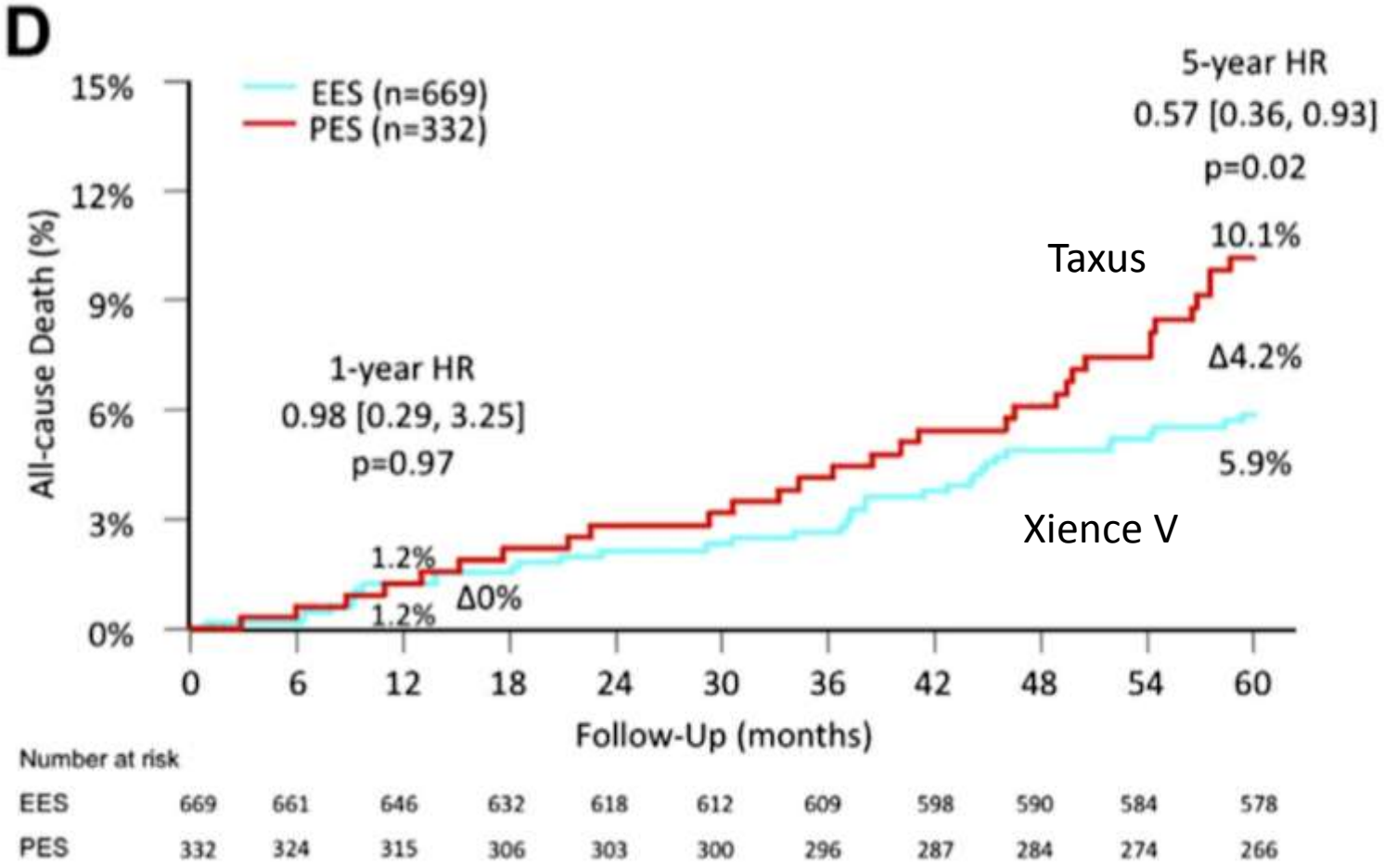
Polymer Thickness:

4.8 µm

ZOTAROLIMUS

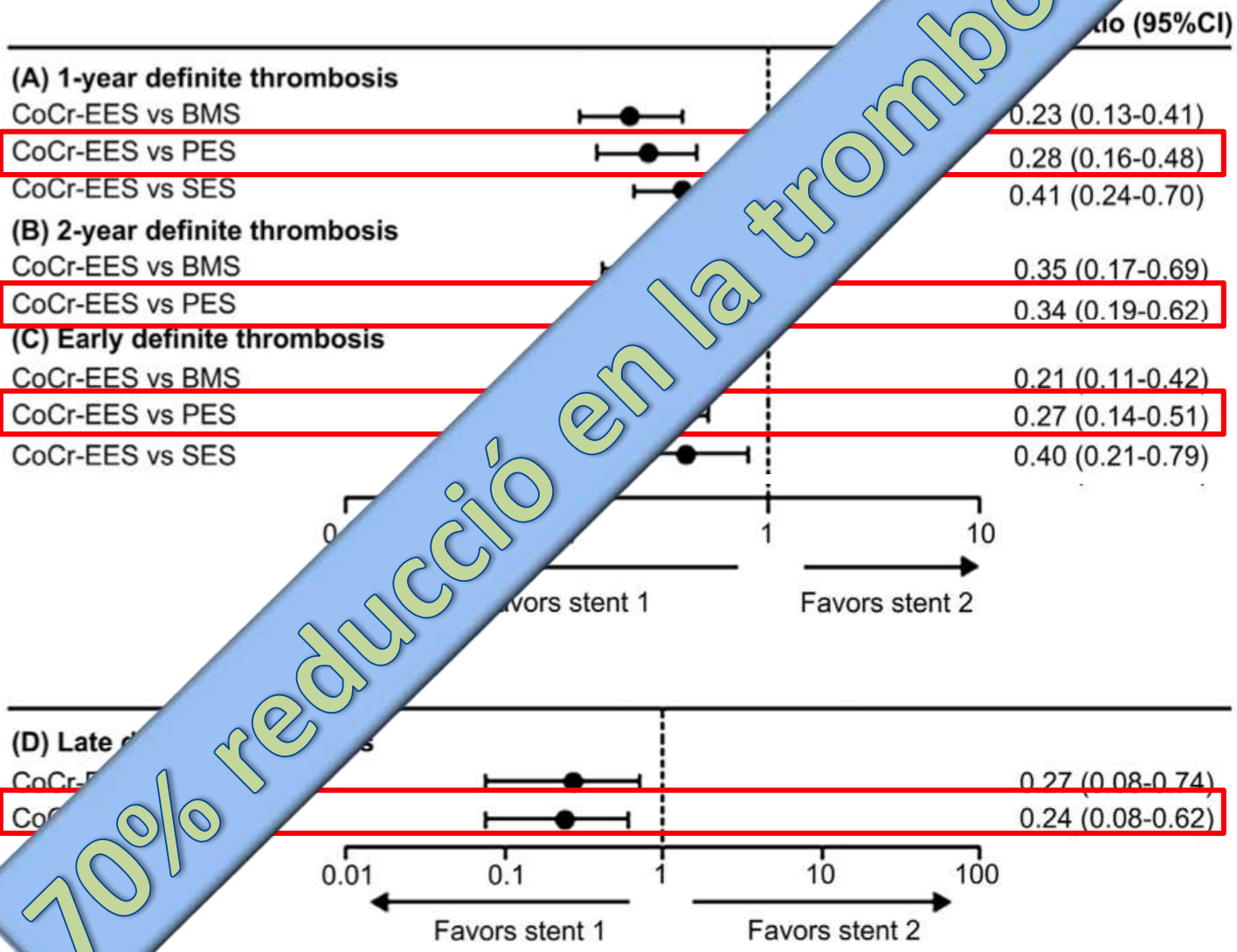
3.0 mm diameter stents, 500x magnification

Seguiment a cinc anys del Assaig Aleatorizat Comparatiu entre els stents XIENCE V (Everolimus) y TAXUS (Paclitaxel). SPIRIT III Trial



Hada H et al. JACC Intv 2013;6:1263–1266

Risc de Tromboss Definitiva del Stent en di nts periodes de temps: Metanàlisi en

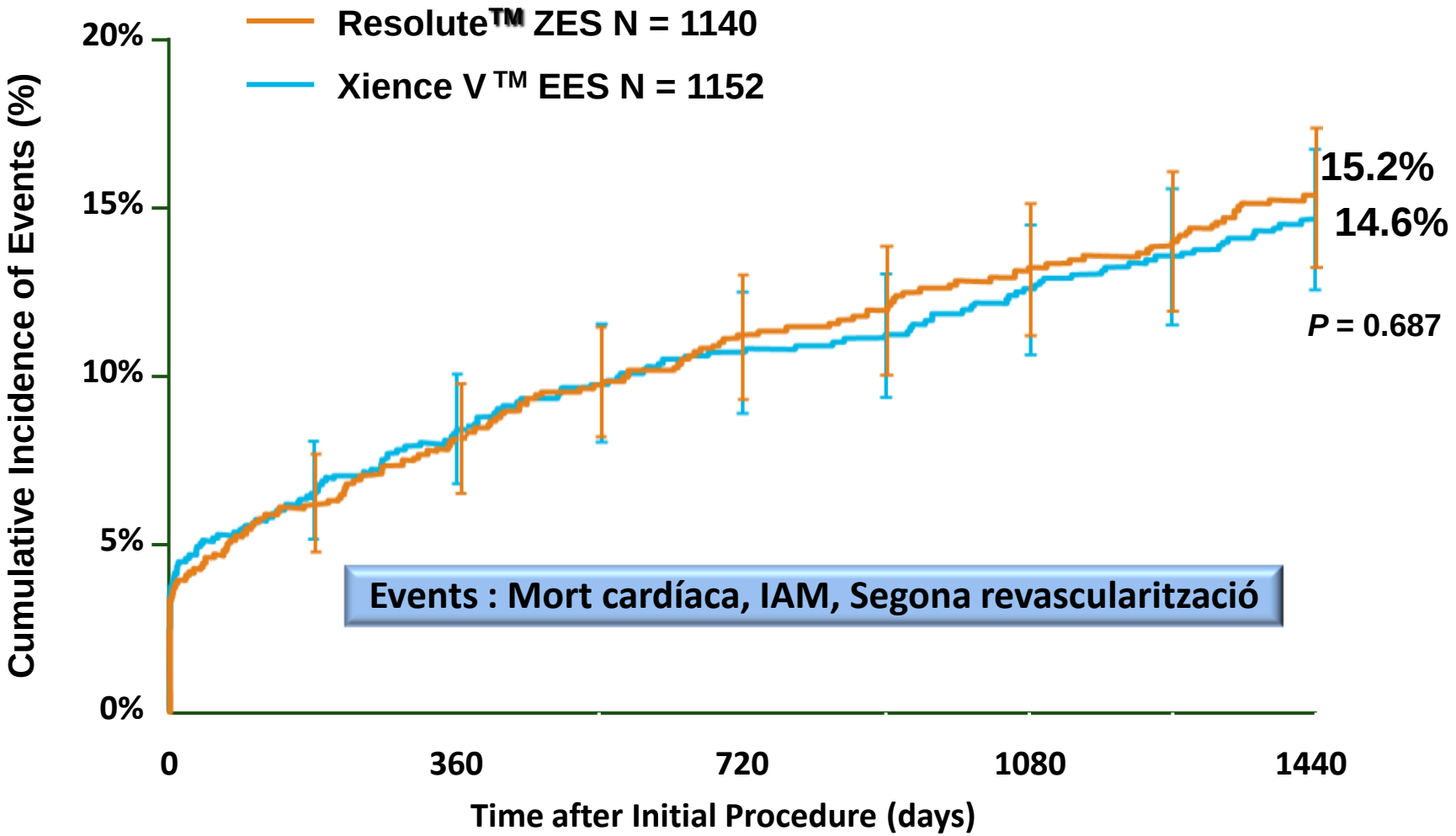


70% reducció en la trombosi

Palmerini T et al. JACC 2013;62:1915-1921

RESOLUTE All Comers

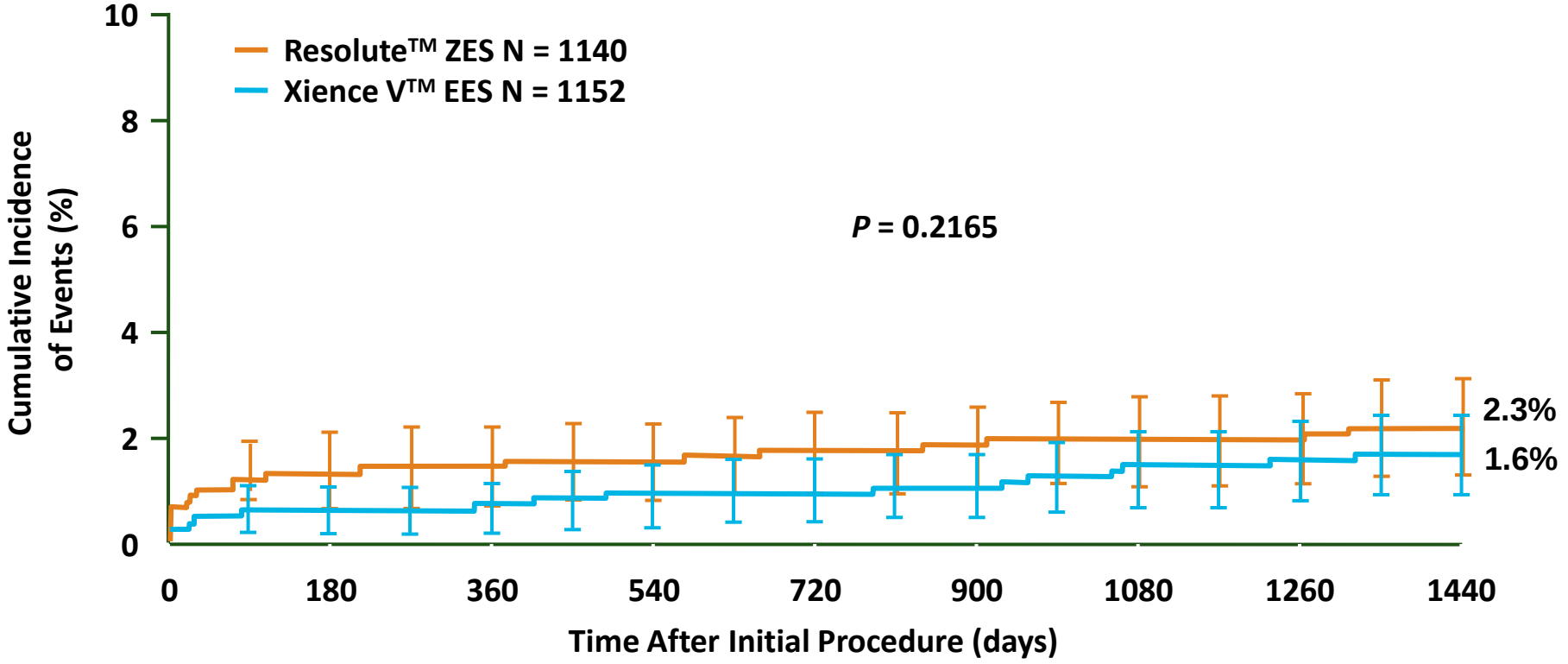
Target Lesion Failure to 4 Years



TLF (Target Lesion Failure) is defined as cardiac death, TVMI, or clinically driven TLR.

RESOLUTE All Comers

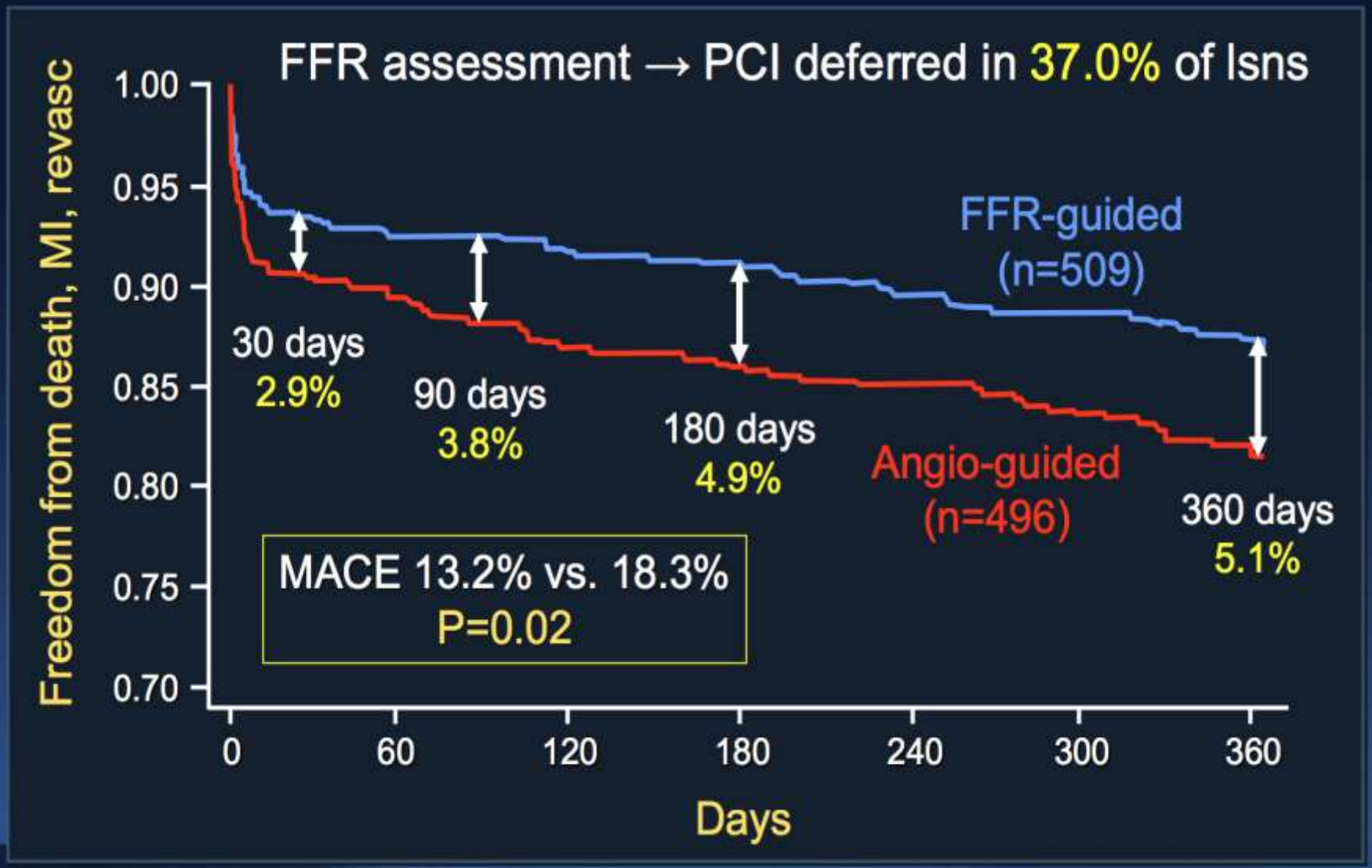
Stent Thrombosis (Definite / Probable) to 4 years



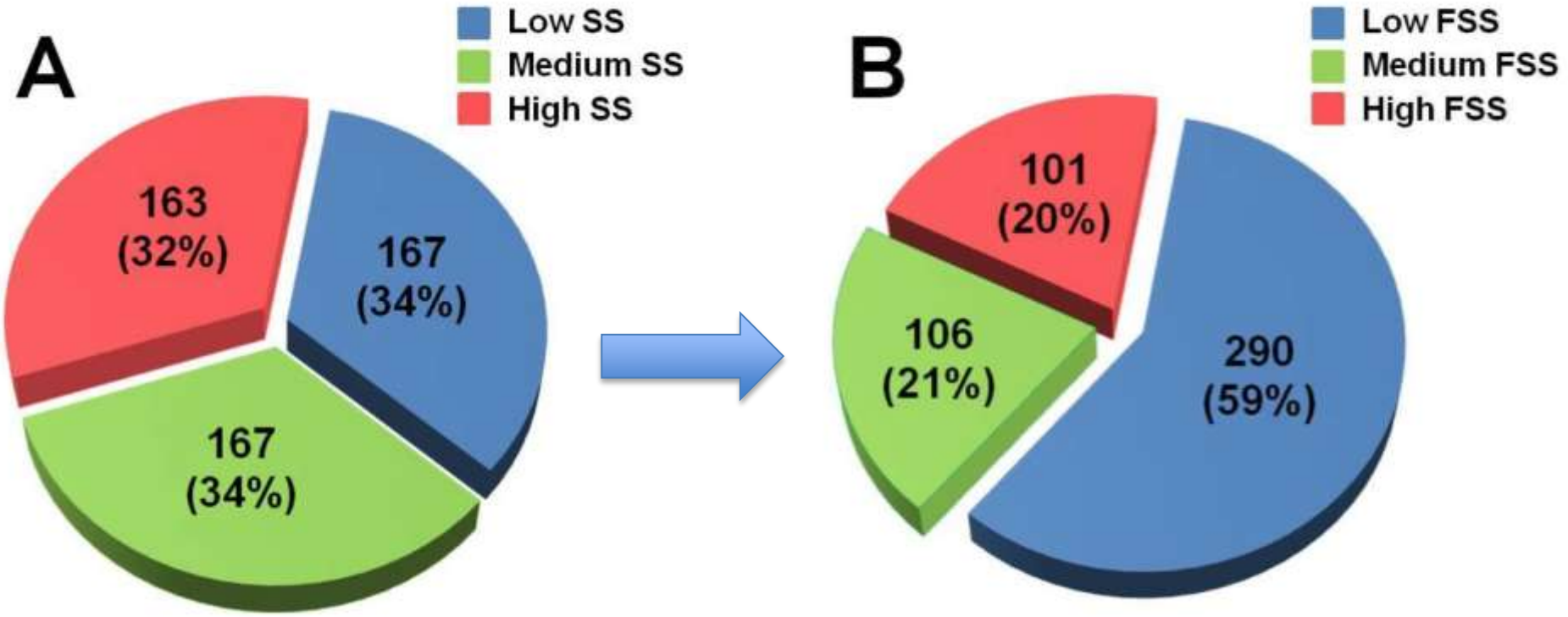
Resolute ZES									
No. at risk	1140	1134	1107	1097	1082	1070	1058	1041	1025
% CI	0.4	1.5	1.6	1.7	1.9	2.0	2.1	2.1	2.3
Xience V EES									
No. at risk	1152	1150	1124	1103	1085	1080	1063	1043	1024
% CI	0.0	0.6	0.7	0.9	1.0	1.1	1.4	1.5	1.6

FAME: Primary Endpoint

1005 pts with MVD undergoing PCI with DES were randomized to FFR-guided vs. angio-guided intervention



FFR reclassifica > 30% dels casos



Abans de FFR

Després de FFR

Nam CW, et al. J Am Coll Cardiol 2011;58:1211-8

Global Risk Classification

EuroScore	SyntaxScore		
	≤22	23-32	≥33
0-2	LOW	LOW	MED
3-5	LOW	LOW	MED
≥6	MED	MED	HIGH

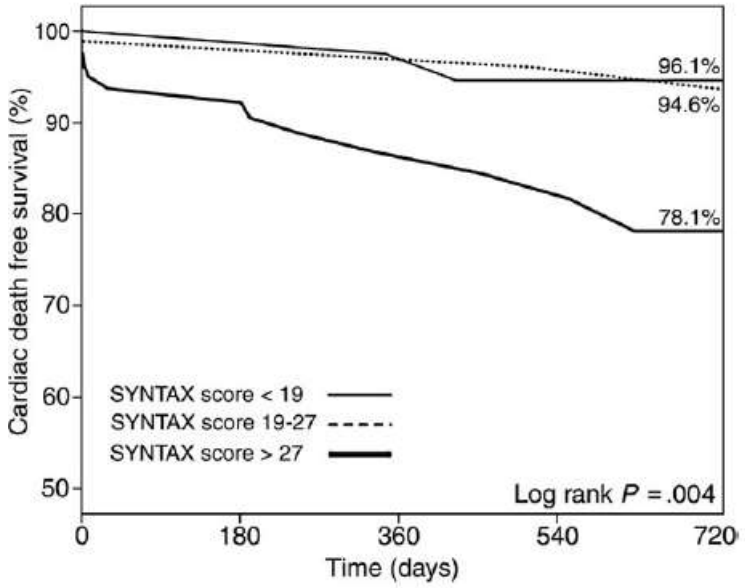
LOW: SyntaxSc <33 & EuroScore <6

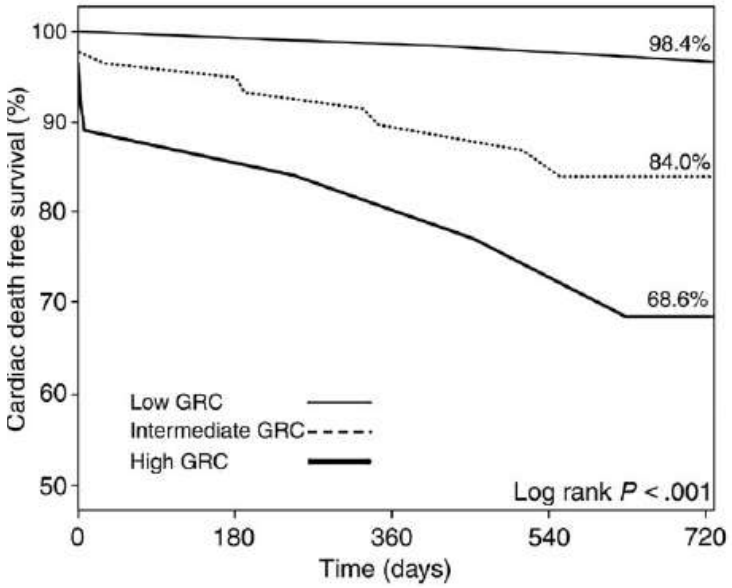
MED: Either SyntaxSc<33 & EuroScore ≥6 or EuroScore <6 & SyntaxScore≥33

HIGH: SyntaxSc≥33 and EuroSc ≥6

EuroSCORE	SYNTAX score <19	SYNTAX score 19-27	SYNTAX score >27
0-2	L	L	I
3-6	L	L	I
> 6	I	I	H

GRS : Global Risk Score





Napodano D. et al. Am Heart J 2010;159:103-9

History #3

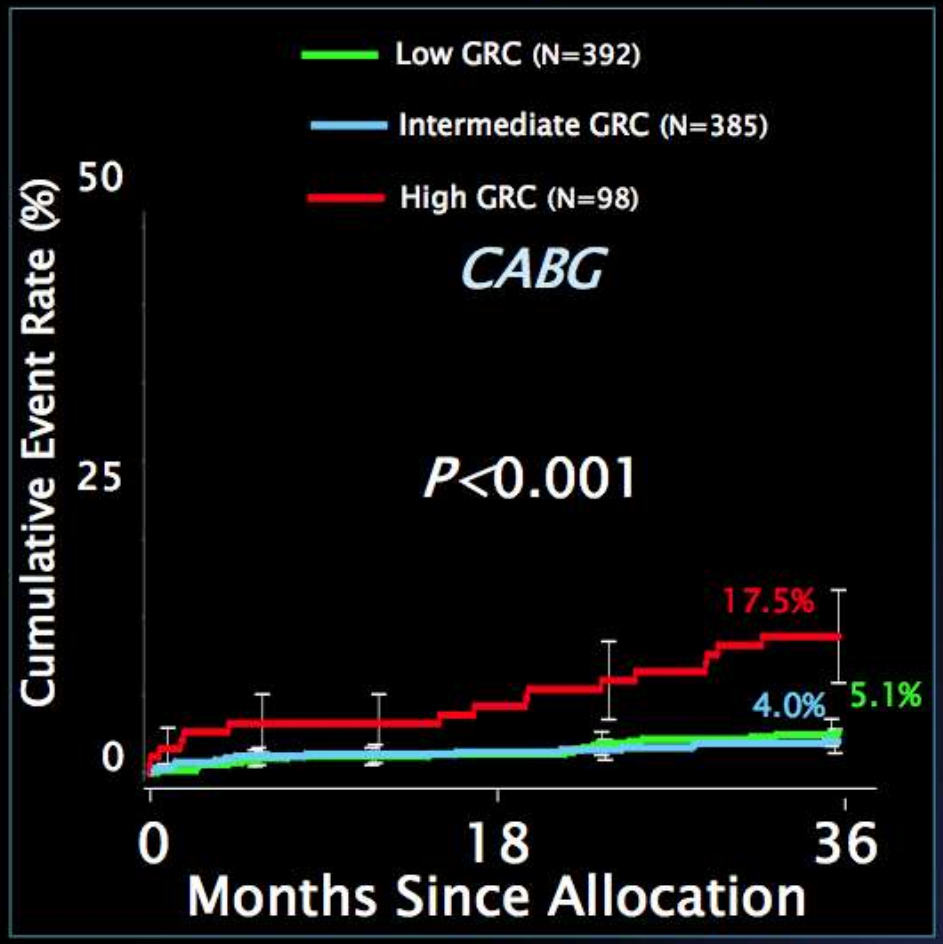
All-cause mortality to 3 years

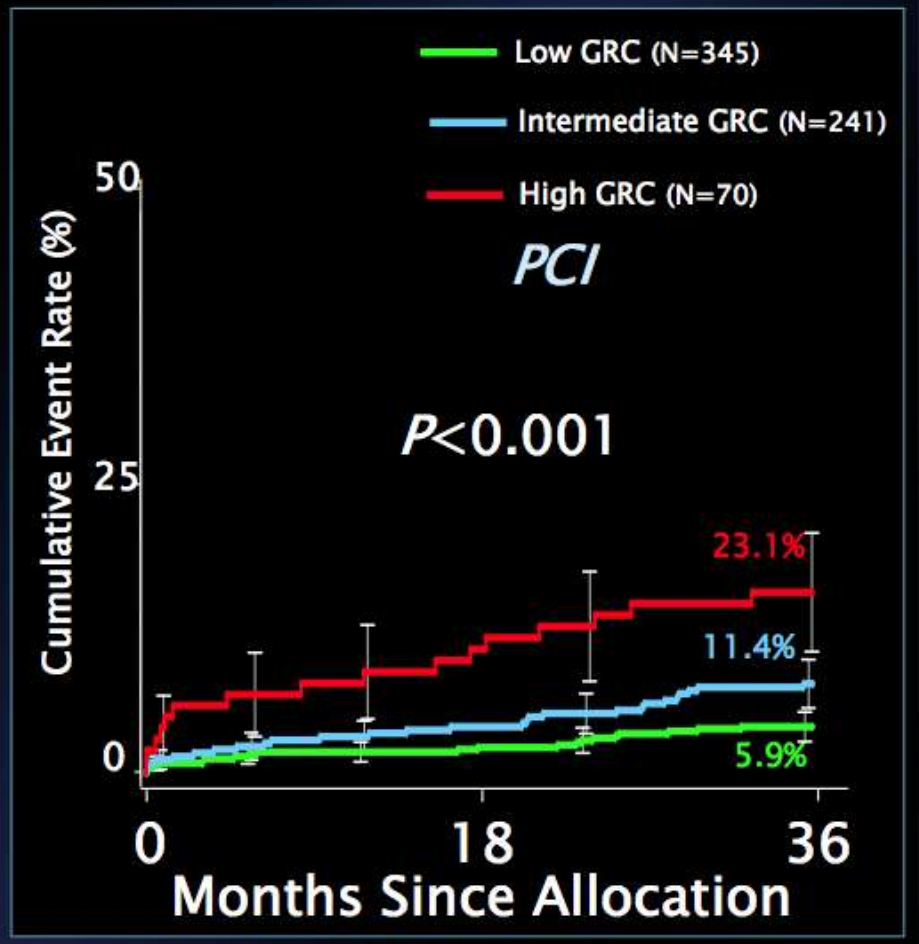
3VD Patients (randomized + registry)

Total N=1531

Euro SCORE	SX Score <22	23-32	>33
0-2	low	low	mid
3-5	low	low	mid
>6	mid	mid	high

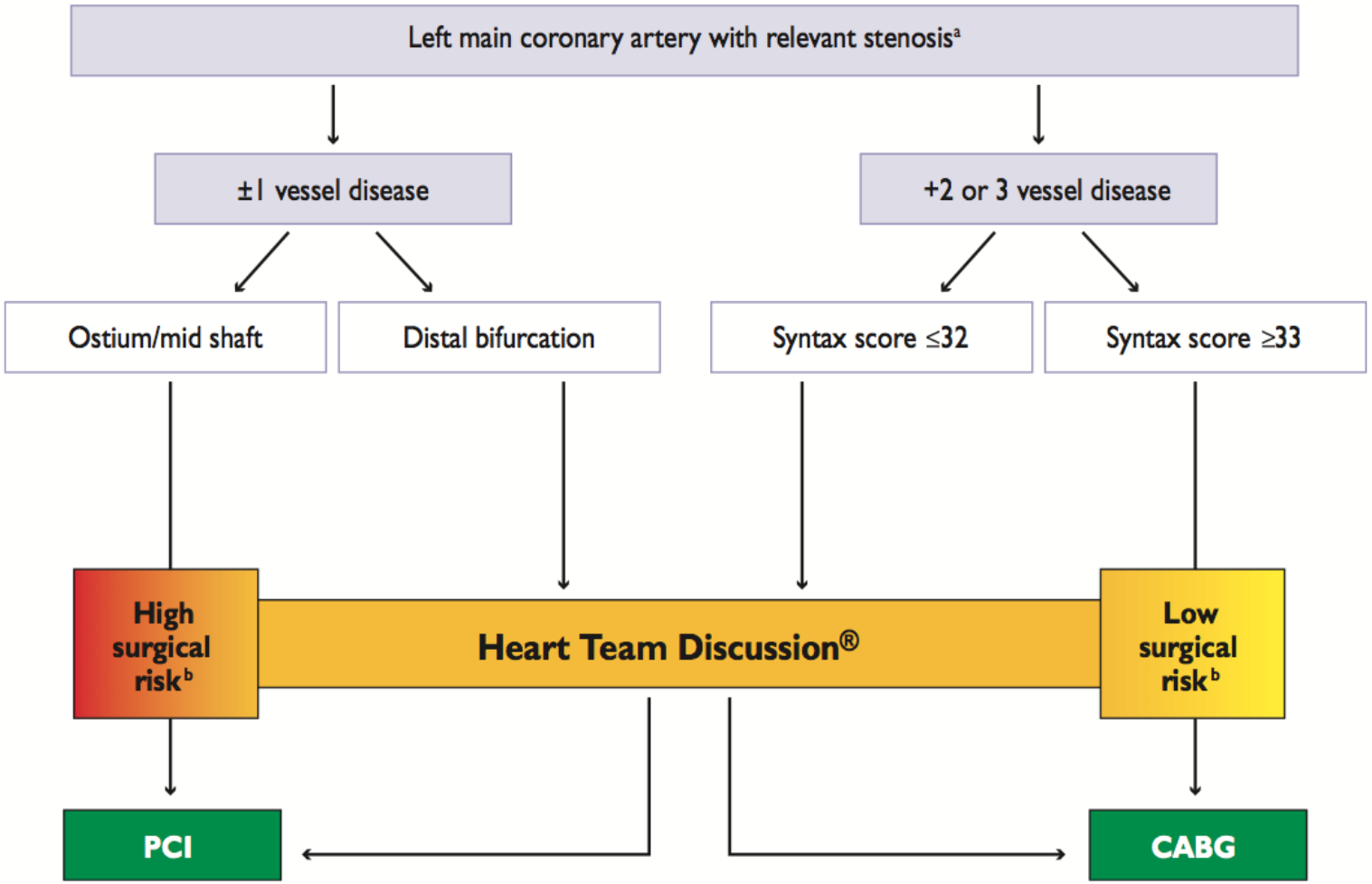
50% (N=737) can be treated with PCI





Cumulative KM Event Rate ± 1.5 SE; log-rank *P* value

2013 ESC/EACTS GUIDELINES on the management of stable coronary artery disease



European Heart Journal 2013 34, 2949–3003

SYNTAX Eligible Patients

De novo disease (n=1800)

Limited Exclusion Criteria

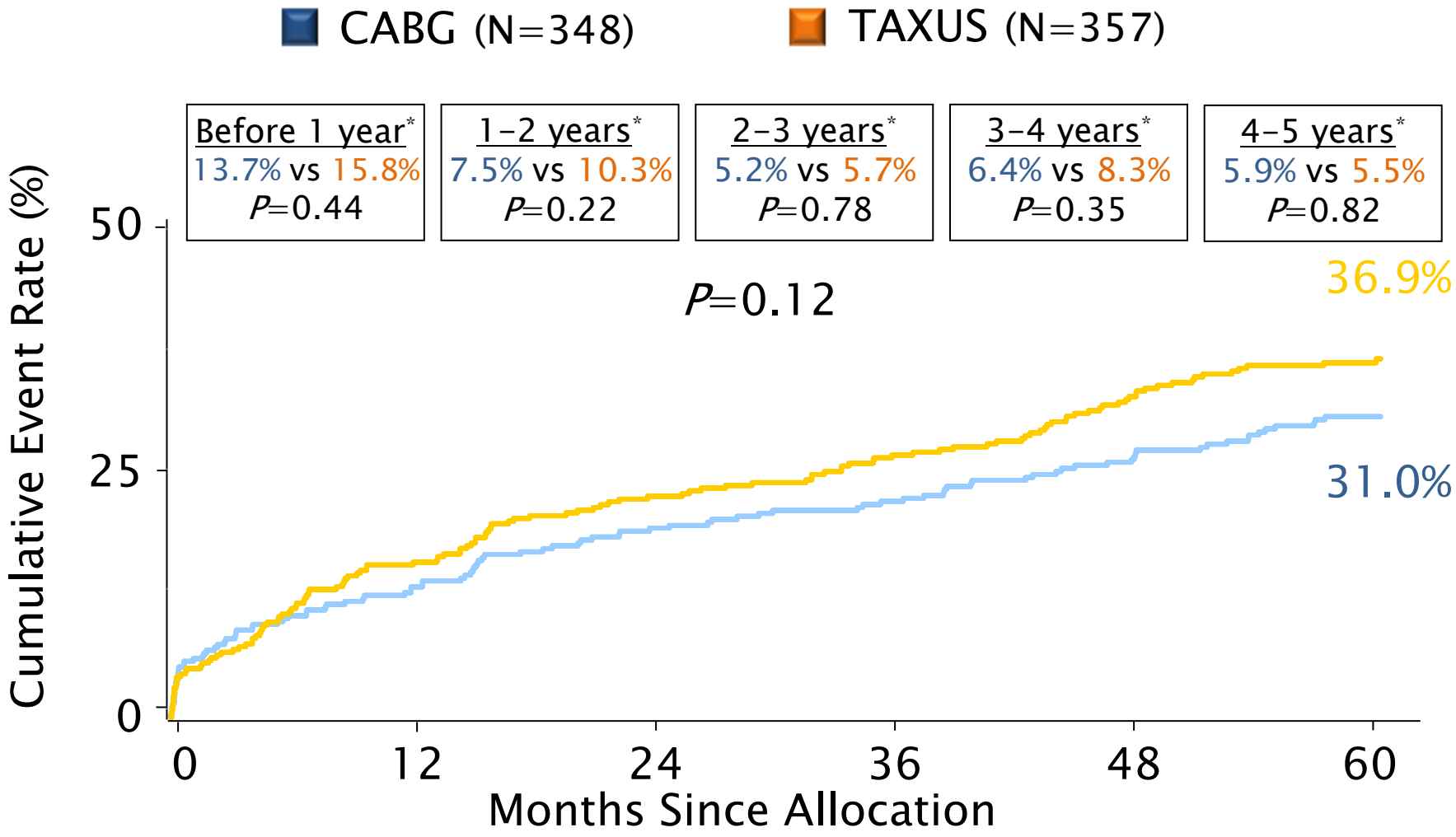
- Previous interventions
- Acute MI with CPK>2x
- Concomitant cardiac surgery

Left Main Disease
(isolated, +1, +2 or +3 vessels)
N=705

3 Vessel Disease
(revasc all 3 vascular territories)
N=1095

Serruys PW et al. NEJM 2009;360:961-72

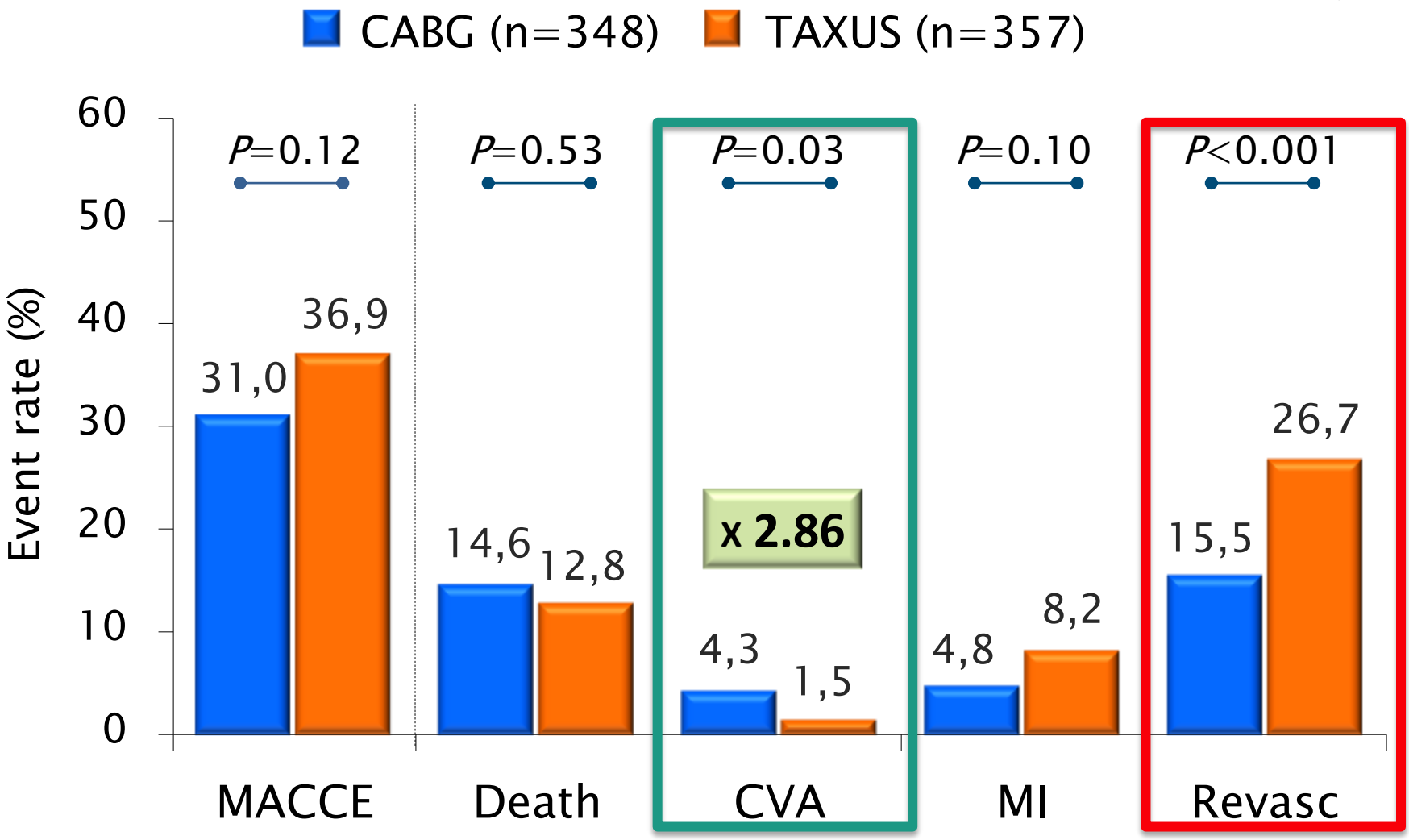
MACCE to 5 years. LM Subset



Cumulative KM Event Rate ± 1.5 SE
log-rank *P* value;*Binary rates

Serruys PW et al. Lancet 2013;381:629–38

MACCE to 5 years. LM Subset

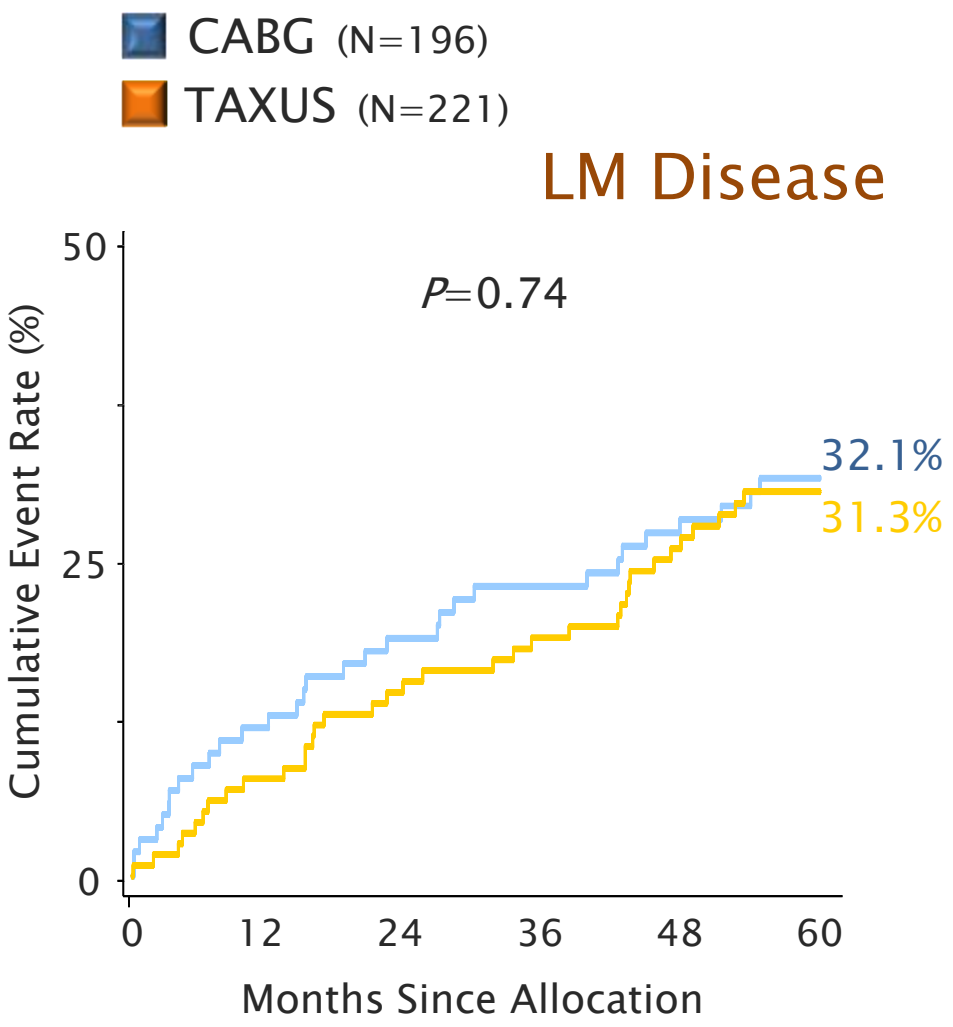


Cumulative KM Event Rate
Log-rank *P* value

Serruys PW et al. Lancet 2013;381:629-38

MACCE to 5 years by SYNTAX Score Tercile

Low to Intermediate Scores : 0-32

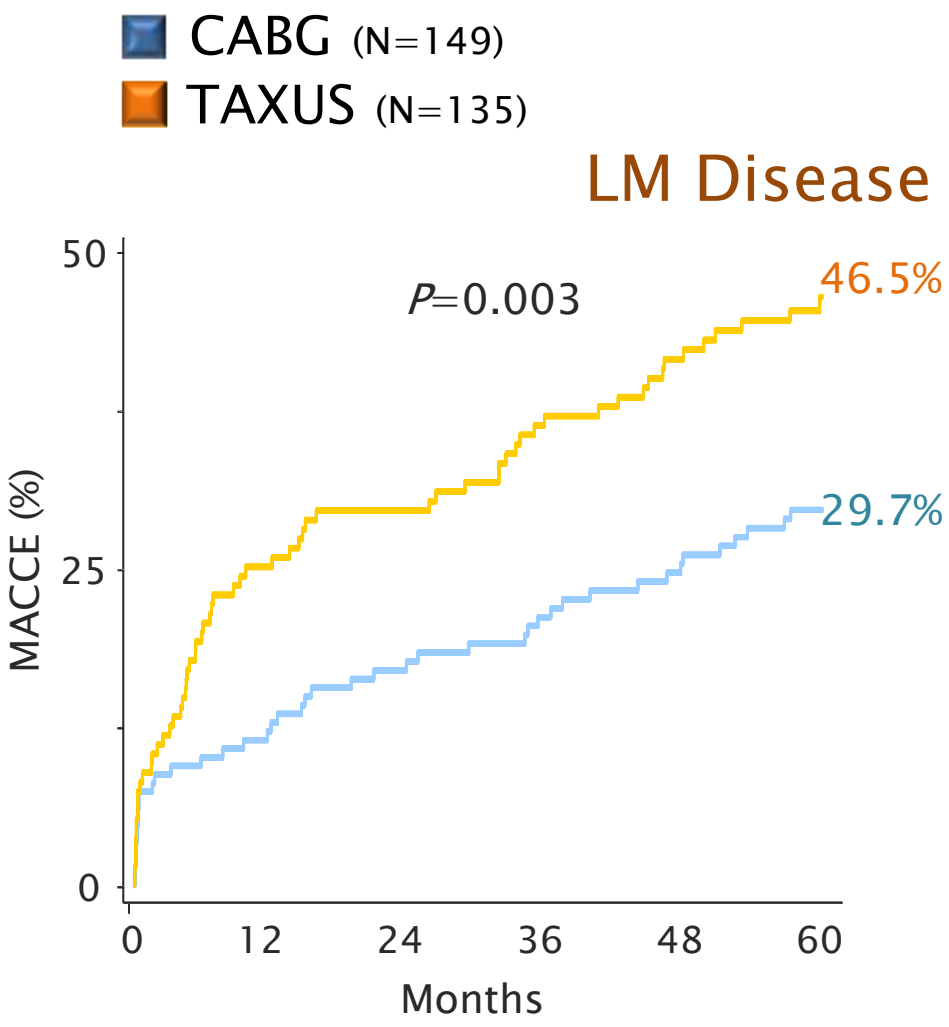


	CABG		PCI	*P* value
Death	15.1%	>	7.9%	**0.02**
CVA	3.9%	>	1.4%	0.11
MI	3.8%		6.1%	0.33
Death, CVA or MI	19.8%	>	14.8%	0.16
Revasc.	18.6%	<	22.6%	0.36

Serruys PW et al. Lancet 2013;381:629–38

MACCE to 5 years by SYNTAX Score Tercile

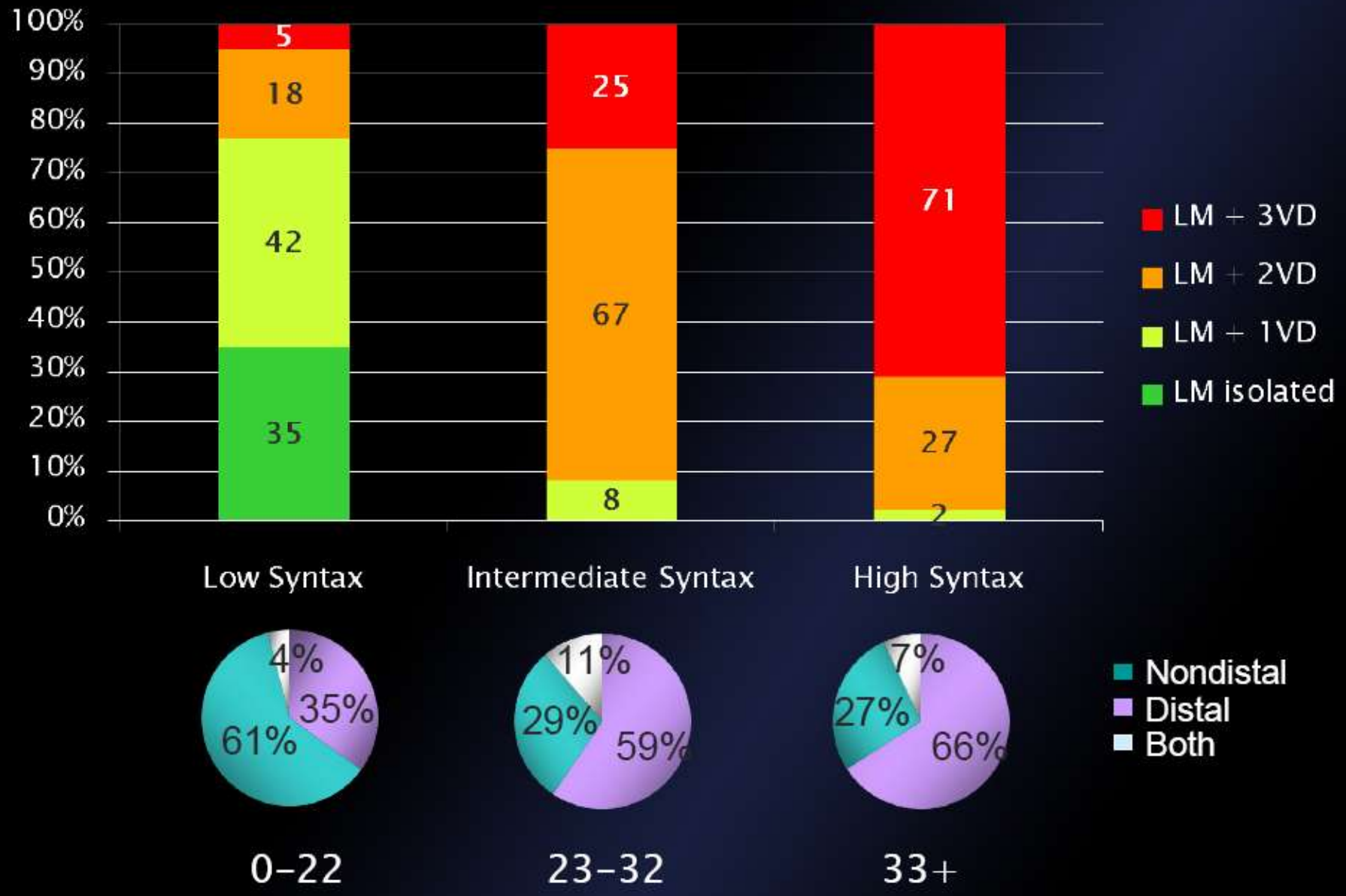
High Scores ≥ 33



	CABG	PCI	*P* value
Death	14.1%	20.9%	0.11
CVA	4.9%	1.6%	0.13
MI	6.1%	11.7%	0.13
Death, CVA or MI	22.1%	26.1%	0.40
Revasc.	11.6%	34.1%	<0.001

Serruys PW et al. Lancet 2013;381:629–38

Vessel Distribution in LM Population According to Syntax Score Terciles



ICP (1st gen) DES vs CABG en nefermedad TC
Meta-analisis de 4 RCTs, 1.611 pts

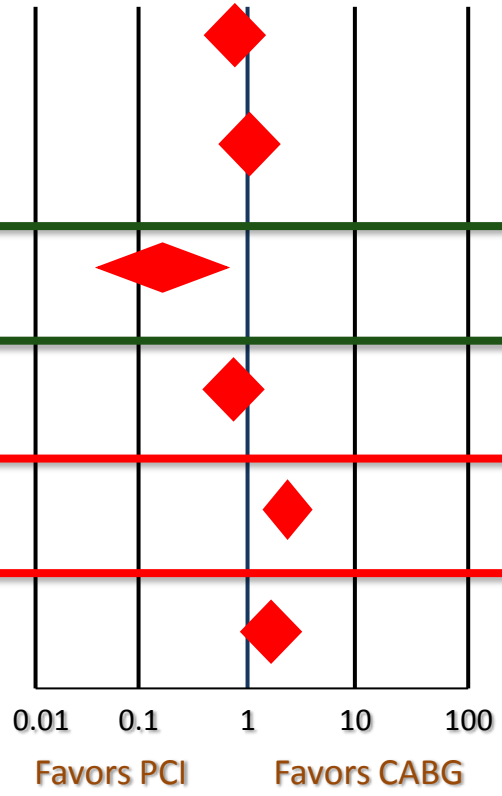
Estudio	LEMANS	SYNTAX LM	Boudriot et al.	PRECOMBAT
Año	2008	2009	2010	2011
N total	105	705	201	600
Edad, media años	61	65	68	62
Hombres	67%	74%	75%	77%
Diabetes	18%	25%	36%	32%
Agectación TCdistal	58%	61%	71%	65%
+0/1/2/3 V, %	0/9/23/68	13/20/31/36	29/31/27/14	10/17/32/41
Syntax Score, media	25	30	24	25
Log Euroscore, media	3.4	3.9	2.5	2.7
LIMA-LAD	81%	97%	99%	94%

Capodanno D et al. JACC 2011;58:1426-32

PCI (1st gen) DES vs CABG en enfermedad TC
Meta-analisis de 4 RCTs, 1.611 pts

Resultados a 12 meses

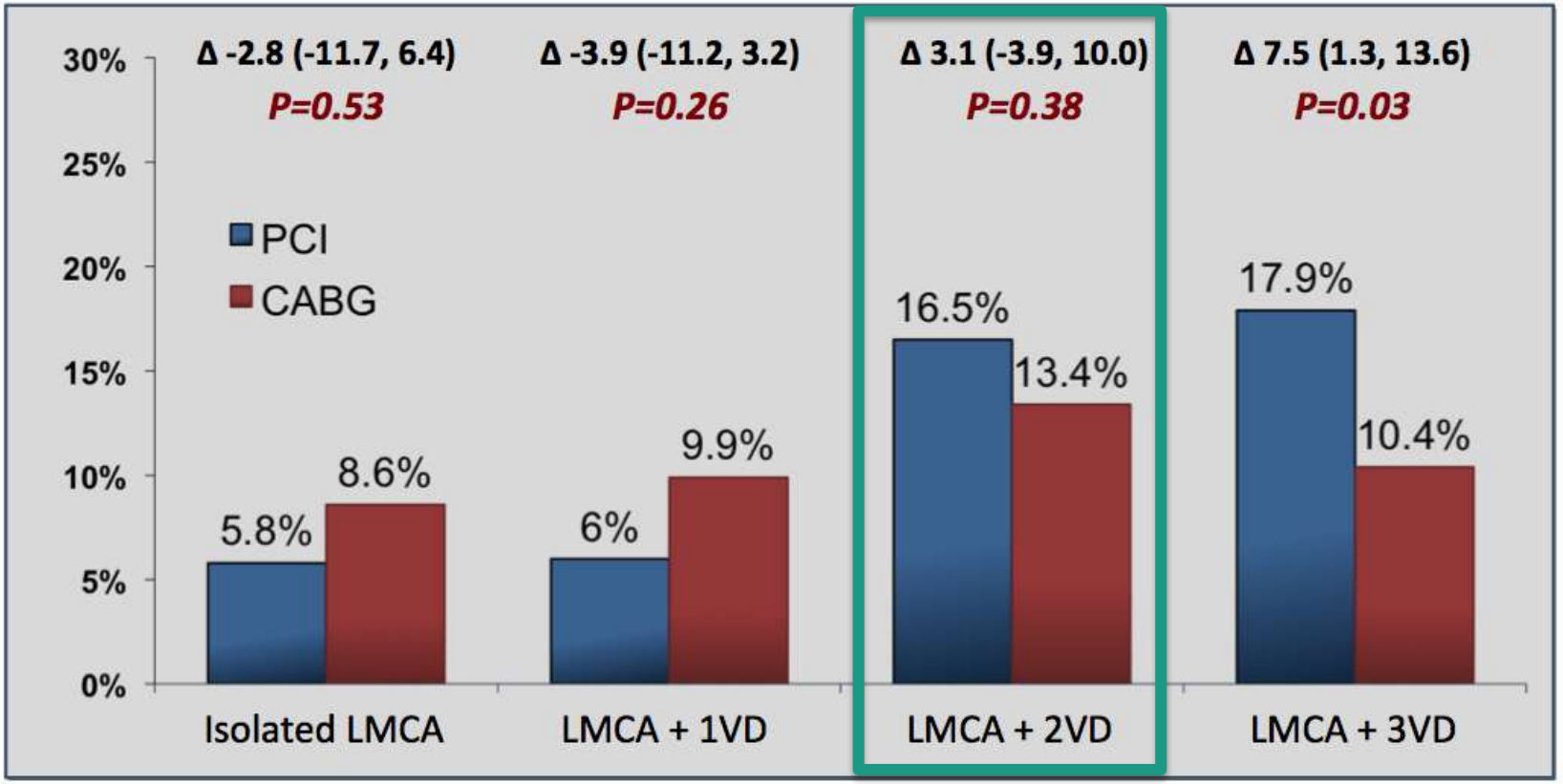
	PCI	CABG	OR (95%CI)	p-Value
Muerte	3.0% (24/807)	4.1% (32/790)	0.74 (0.43-1.28)	0.29
Infarto	2.8% (23/807)	2.9% (23/790)	0.98 (0.54-1.78)	0.95
AVC	0.1% (1/707)	1.7% (12/689)	0.15 (0.03-0.67)	0.01
Muerte, IAM, AVC	5.3% (35/655)	6.8% (43/636)	0.77 (0.48-1.22)	0.26
2ª Revascularización	11.4% (92/807)	5.4% (43/790)	2.25 (1.54-3.28)	<0.001
MACE	14.5% (117/807)	11.8% (93/790)	1.28 (0.95-1.72)	0.11



Capodanno D et al. JACC 2011;58:1426-32

ICP (1st gen) DES vs CABG en enfermedad TC
Meta-analisis de 4 RCTs, 1.611 pts

Resultados a 12 meses



Capodanno D et al. JACC 2011;58:1426-32

Revascularització quirúrgica vs ICP

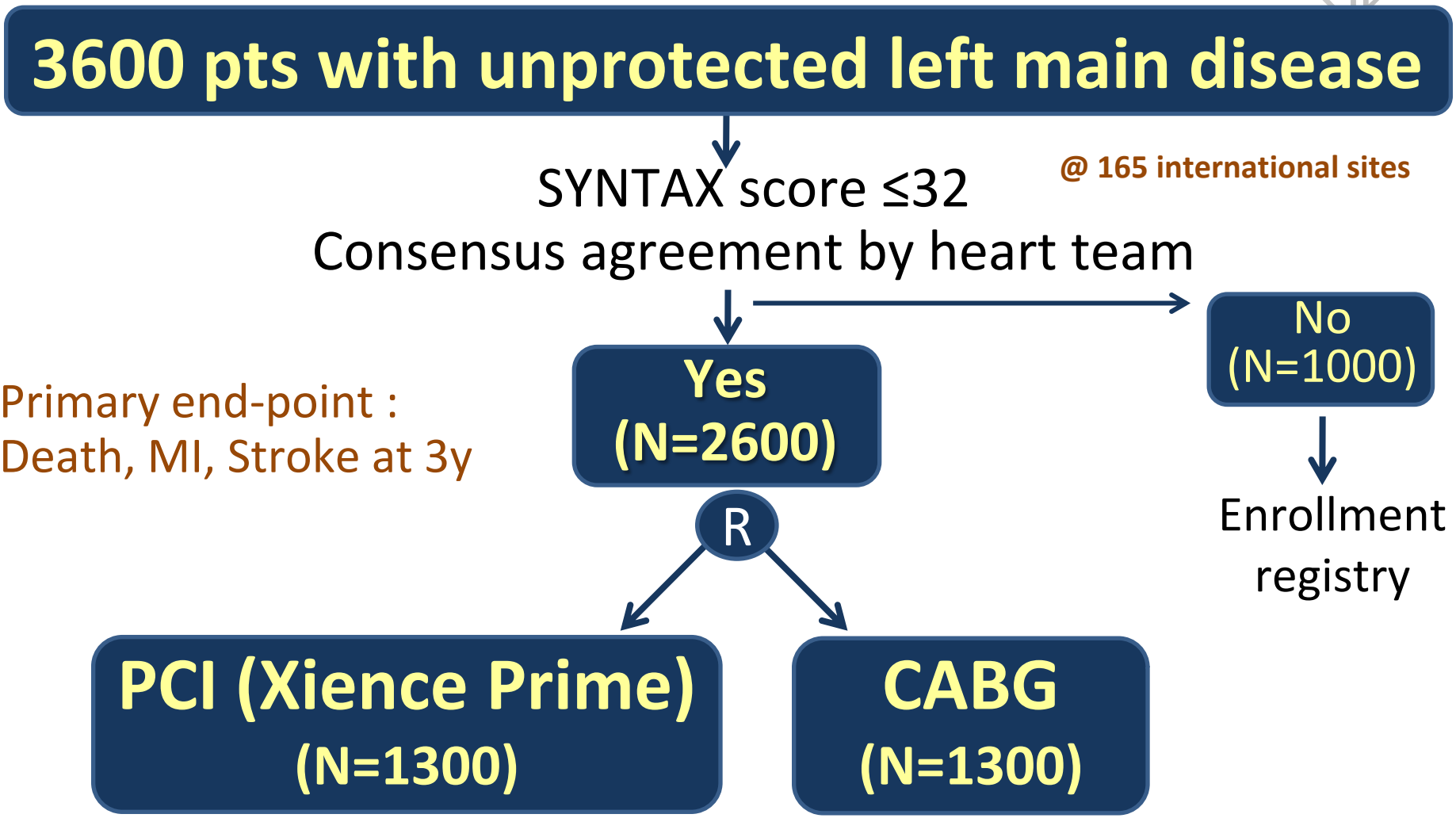
Subset of CAD by anatomy	Favours CABG	Favours PCI
1VD or 2VD - non-proximal LAD	IIb C	I C
1VD or 2VD - proximal LAD	I A	IIa B
3VD simple lesions, full functional revascularisation achievable with PCI, SYNTAX score ≤ 22	I A	IIa B
3VD complex lesions, incomplete revascularisation achievable with PCI, SYNTAX score > 22	I A	III A
Left main (isolated or 1VD, ostium/shaft)	I A	IIa B
Left main (isolated or 1VD, distal bifurcation)	I A	IIb B
Left main + 2VD or 3VD, SYNTAX score ≤ 32	I A	IIb B
Left main + 2VD or 3VD, SYNTAX score ≥ 33	I A	III B

European Heart Journal 2010;31:2501–2555

Que hem après del Syntax Left Main ?

- ✓ La ICP en la lesió del TC no protegit té un perfil d'eficàcia i seguretat comparable a la cirurgia.
- ✓ Per tant, la ICP es una alternativa raonable a la cirurgia quan el SYNTAX Score es baix ($\leq$ 22) o intermig (23-32).
- ✓ Els resultats de la ICP son excel.lents en relació a la cirurgia en la malaltia aïllada del TC o TC + 1V. Els pacients amb SYNTAX Scores $\geq$ 33, o TC + 3V tenen millors resultats amb la cirurgia.

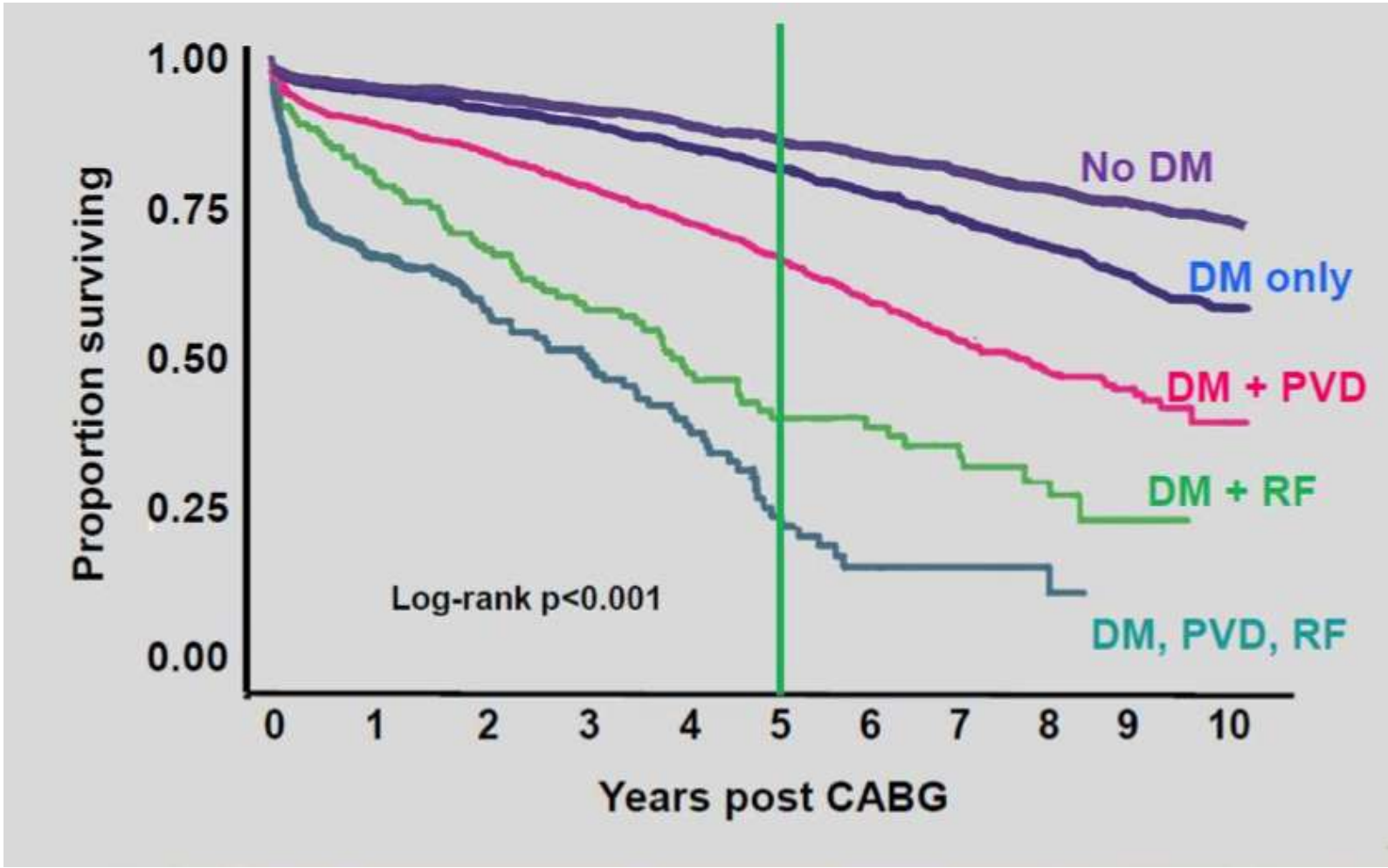
EXCEL trial : Study design




DIABETES

Impacto de Diabetes, Insuficiencia renal y Enfermedad Vascular Periférica en la supervivencia post CABG

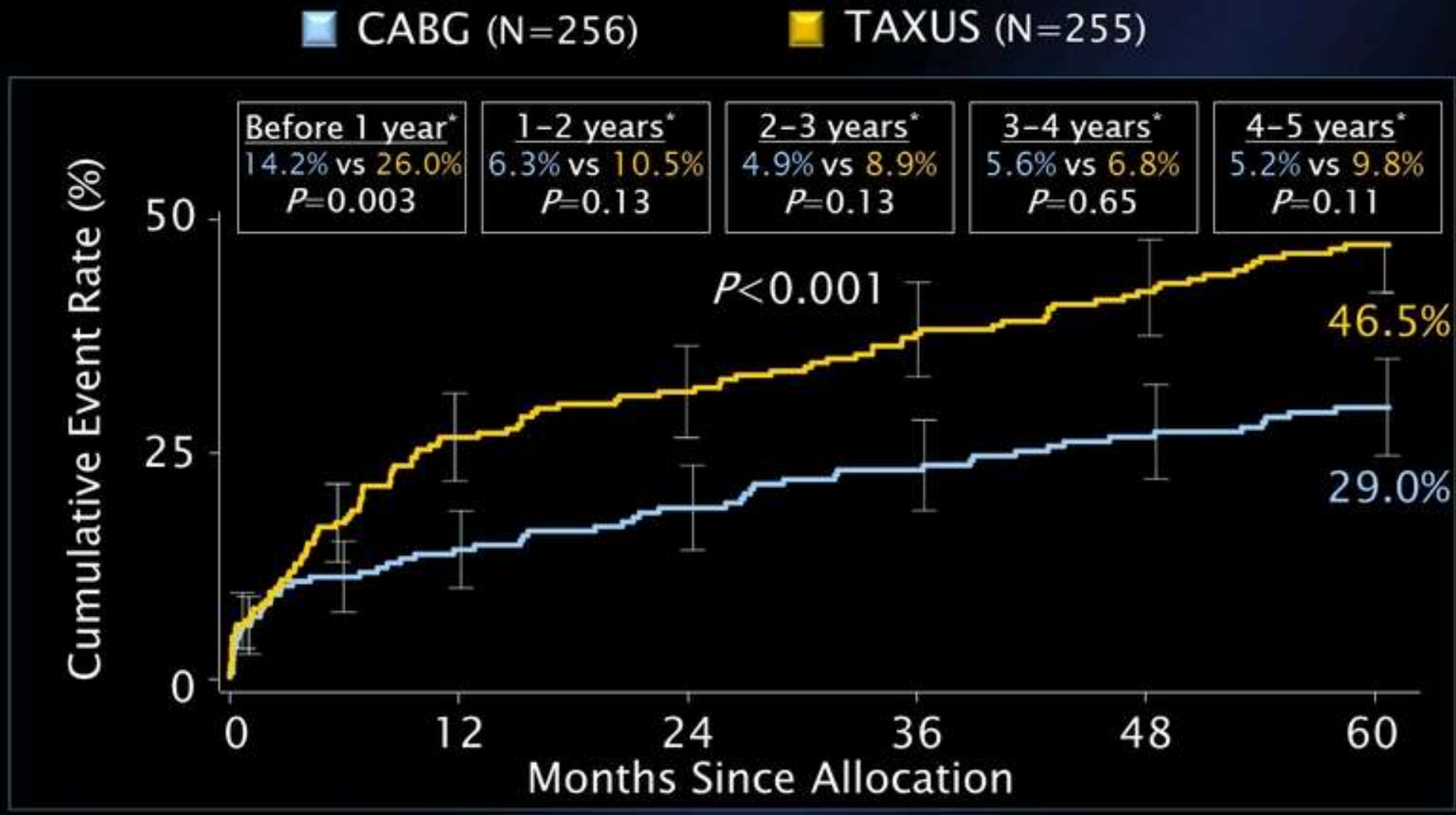
36.641 pacientes consecutivos (CABG) en el norte de Nueva Inglaterra de 1992-2001



Leavitt BJ et al. Circulation 2004;110:II-41-II-44

MACCE to 5 Years
Medically-treated Diabetic Subset

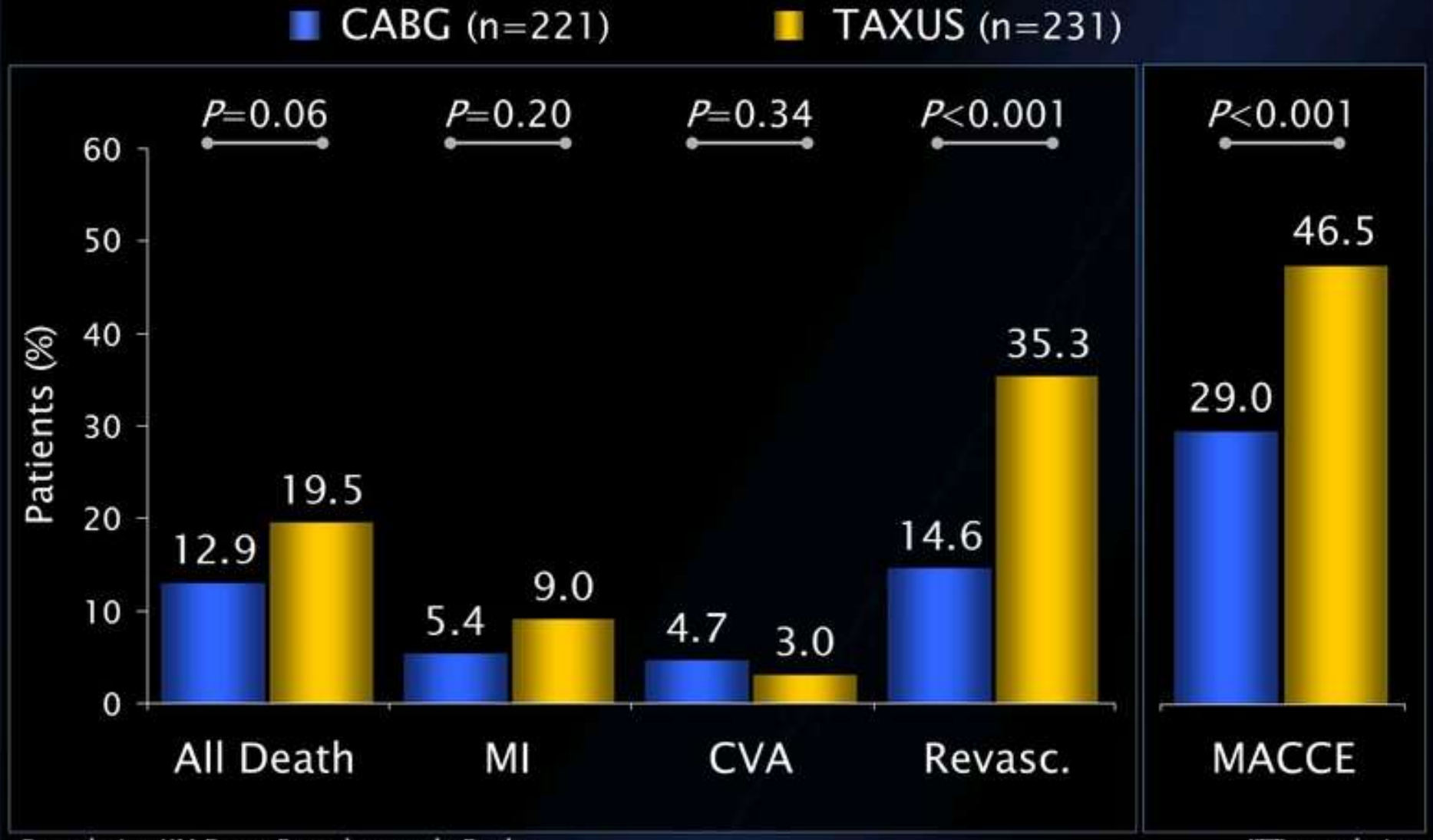
SYNTAX



Cumulative KM Event Rate ± 1.5 SE; log-rank *P* value; *Binary rates

ITT population

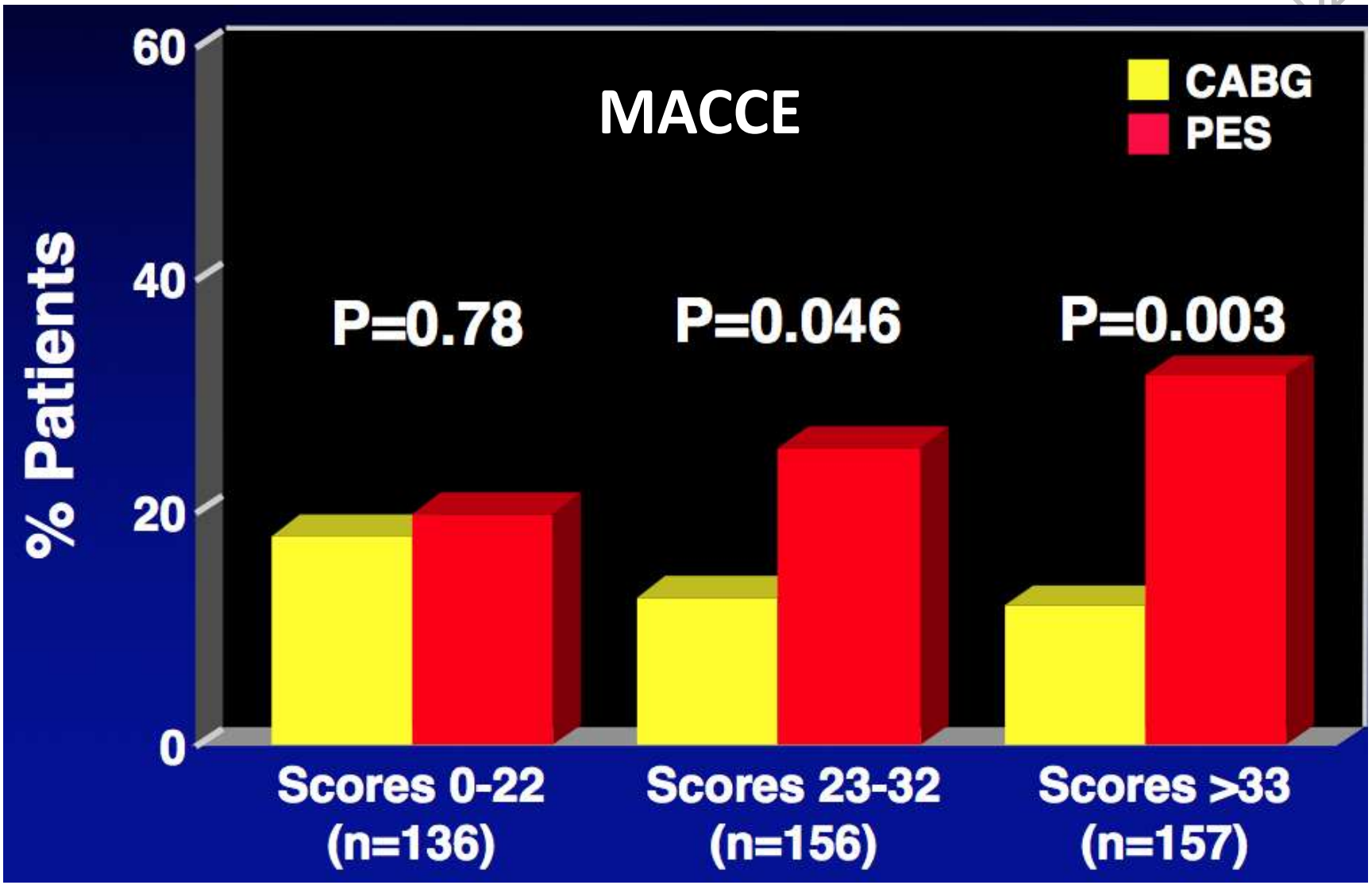
Medically-treated Diabetic Patients
5-year Outcomes (N=452)



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

ITT population

SYNTAX DIABETICS (n=452)



Banning AP et al. JACC 2010;55:1067-1075

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 20, 2012 VOL. 367 NO. 25

Strategies for Multivessel Revascularization in Patients with Diabetes

and Valentin Fuster, M.D., Ph.D., for the FREEDOM Trial Investigators*

RESULTS

From 2005 through 2010, we enrolled 1900 patients at 140 international centers. The patients' mean age was 63.1±9.1 years, 29% were women, and 83% had three-vessel disease. The primary outcome occurred more frequently in the PCI group (P=0.005), with 5-year rates of 26.6% in the PCI group and 18.7% in the CABG group. The benefit of CABG was driven by differences in rates of both myocardial infarction (P<0.001) and death from any cause (P=0.049). Stroke was more frequent in the CABG group, with 5-year rates of 2.4% in the PCI group and 5.2% in the CABG group (P=0.03).

CONCLUSIONS

For patients with diabetes and advanced coronary artery disease, CABG was superior to PCI in that it significantly reduced rates of death and myocardial infarction, with a higher rate of stroke. (Funded by the National Heart, Lung, and Blood Institute and others; FREEDOM ClinicalTrials.gov number, NCT00086450.)

TRIAL SCREENING & ENROLLMENT

32,966 Patients were screened for eligibility

3,309 were eligible (10%)

1,409 did not consent

1,900 consented (57%)

953 Randomized to PCI/DES*

5 underwent CABG
3 withdrew prior to procedure
3 died prior to procedure
3 underwent neither PCI/DES or CABG

16 withdrew post-procedure
43 were lost to follow-up

947 Randomized to CABG

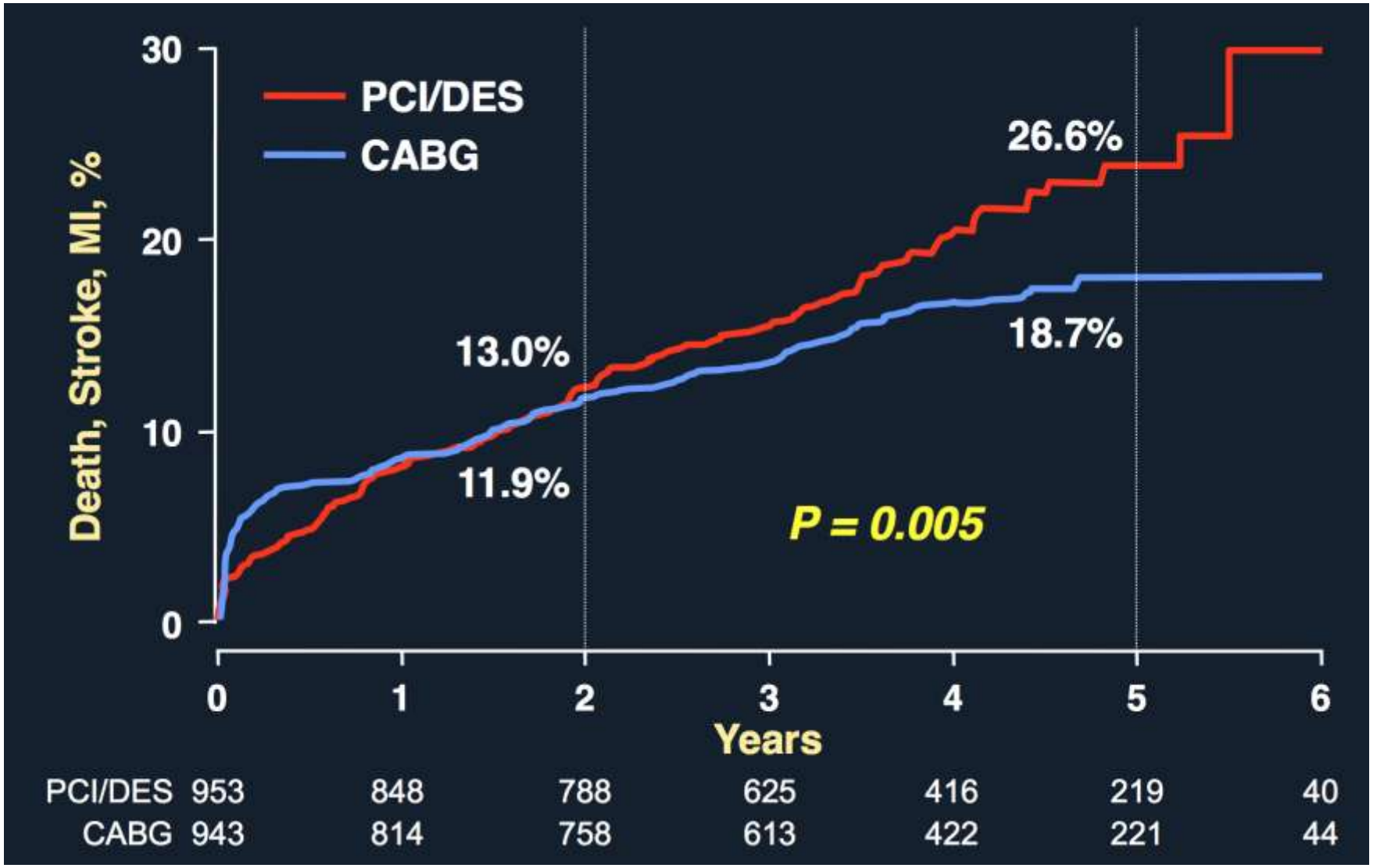
18 underwent PCI/DES
26 withdrew prior to procedure
3 died prior to procedure
7 underwent neither PCI/DES or CABG

36 withdrew post-procedure
51 were lost to follow-up

*953 and 947 included ITT analysis using all available follow-up time post-randomization

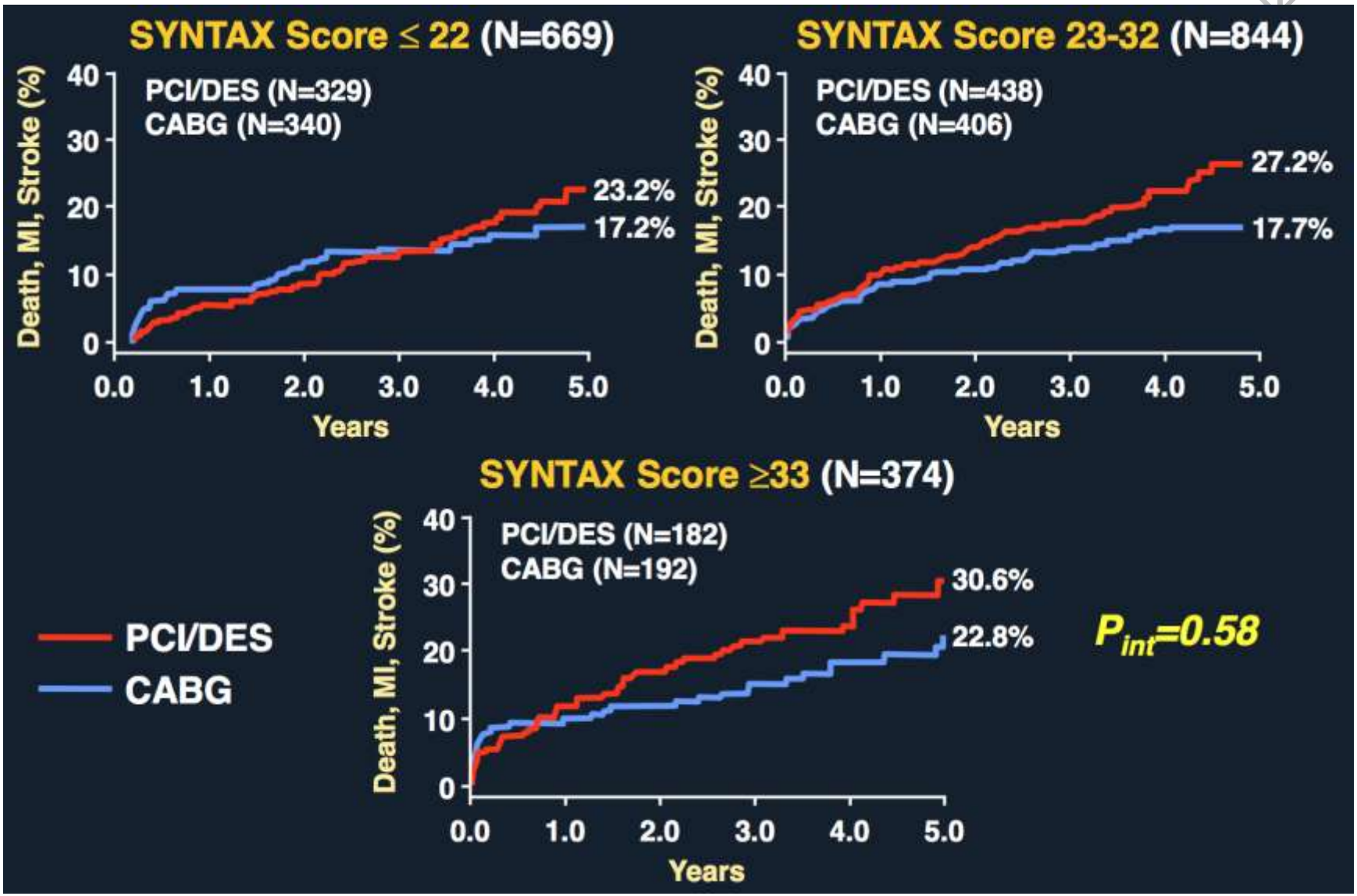
FREEDOM: 1900 pts with diabetes +MVD randomized to SES/PES vs. CABG

1° Endpoint: Death, Stroke, or MI



Farkhou ME. et al. NEJM 2012 (December 20);367:2375-84

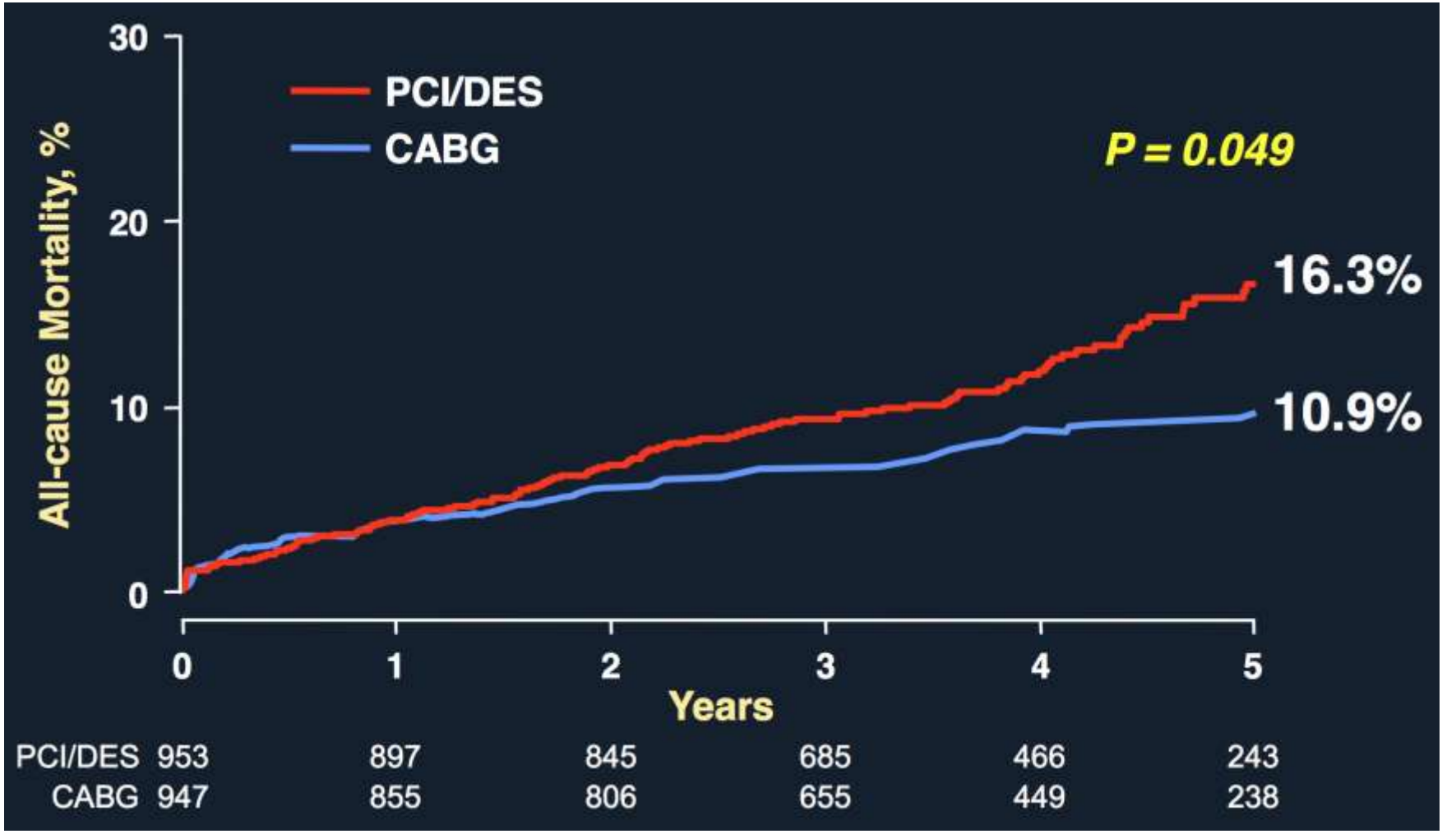
Death, Stroke, MI by Syntax Score



Farkhou ME. et al. NEJM 2012 (December 20);367:2375-84

FREEDOM: 1900 pts with diabetes +MVD randomized to SES/PES vs. CABG

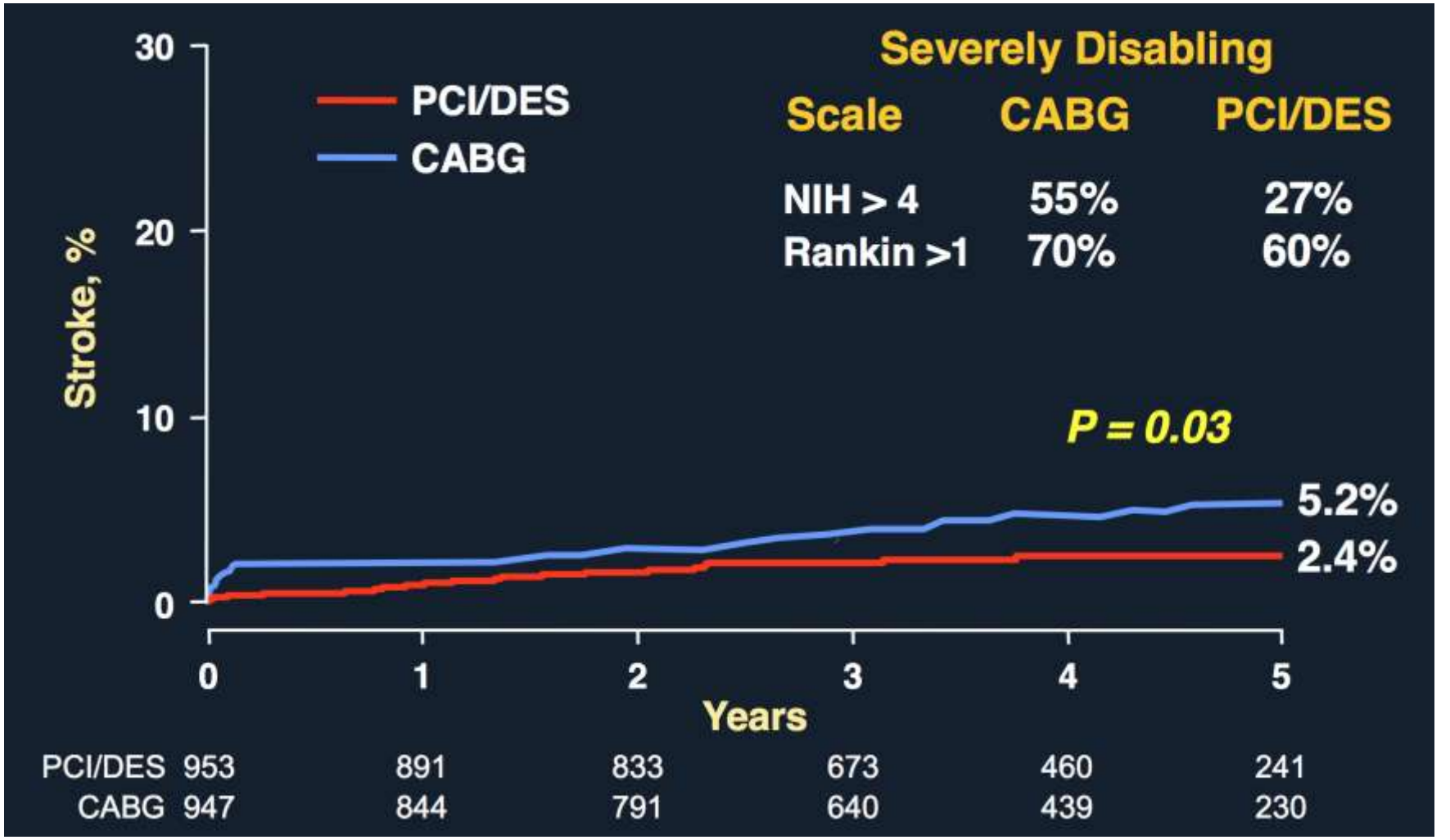
All-cause Mortality



Farkhou ME. et al. NEJM 2012 (December 20);367:2375-84

FREEDOM: 1900 pts with diabetes +MVD randomized to SES/PES vs. CABG

Stroke



Farkhou ME. et al. NEJM 2012 (December 20);367:2375-84

CABG vs ICP con stent en pacientes diabéticos

Meta-análisis de 8 RCT con 7468 pts (3612 con diabetes); 4 estudios con DES y 4 con BMS

CABG vs. PCI: 5-Year Follow-up	RR (95% CI)	*P* Value
All-Cause Mortality	0.67 (0.52-0.86)	0.002
Repeat Revascularization	0.41 (0.29-0.59)	< 0.0001
Nonfatal Stroke	1.72 (1.18-2.53)	0.005

Verma S et al. Lancet Diabetes Endocrinol. 2013: Epub ahead of print

Late Stroke: Comparison of PCI vs. CABG in Patients with Multivessel and Unprotected LM Disease

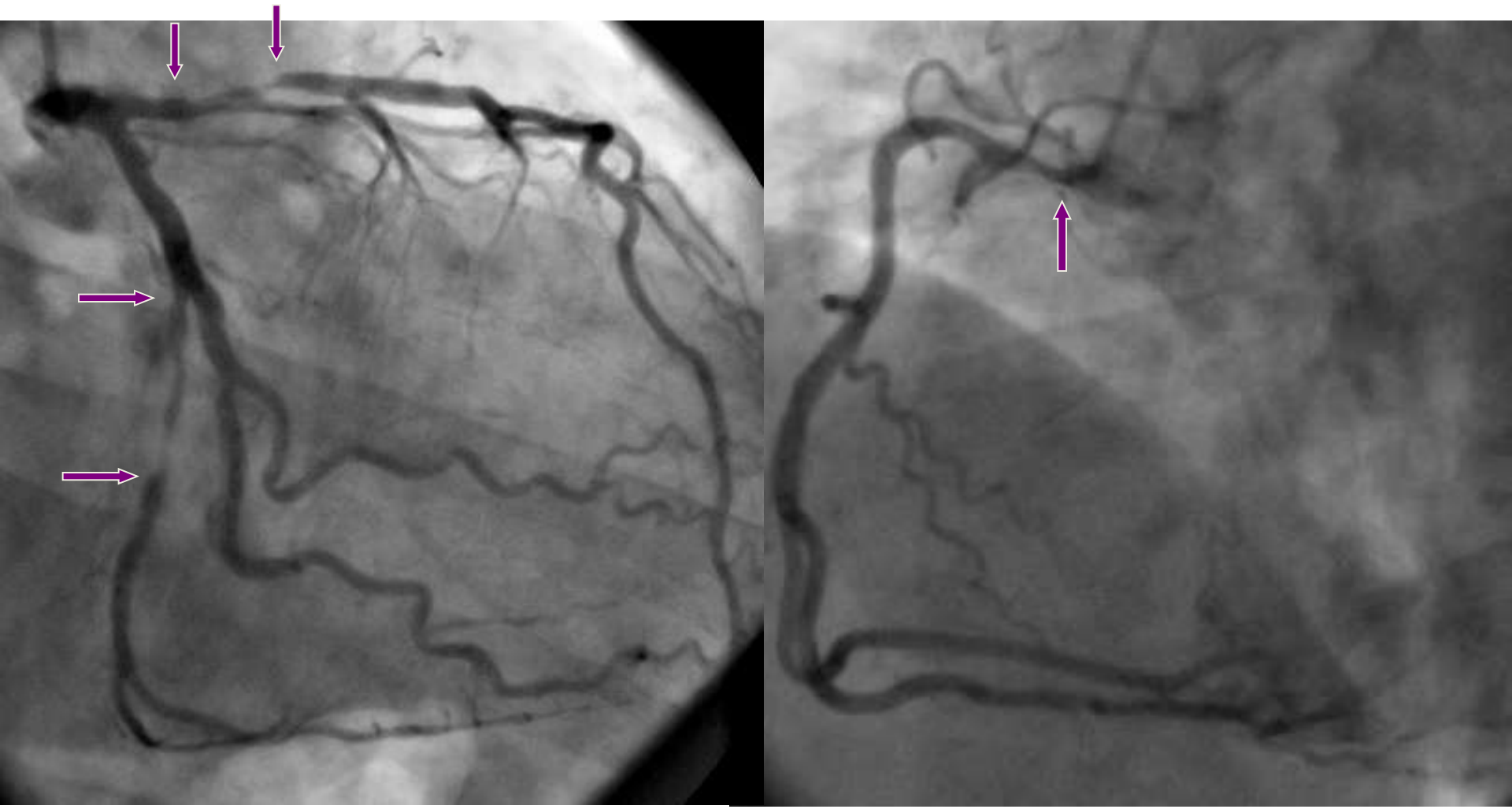
Meta-analysis: 80,314 patients enrolled in 57 studies (9 randomized, 48 non-randomized) underwent PCI with stenting (51.8%) or CABG (48.2%).

- **Compared with CABG, PCI was linked with a lower cumulative incidence of stroke out to 5 years**
- **Subgroup analyses of patients with multivessel disease, unprotected LM stenosis, diabetes confirmed these results**
- **Stroke within 30 days (early and delayed stroke) occurred less often after PCI than CABG (OR 0.26; 95% CI 0.20-0.35) with a similar incidence of late stroke in the 2 groups**

Implications: **PCI is associated with lower risk of stroke within 30 days and cumulative stroke out to 5 years compared with CABG, especially in patients with multivessel disease, unprotected LM stenosis, and diabetes.**

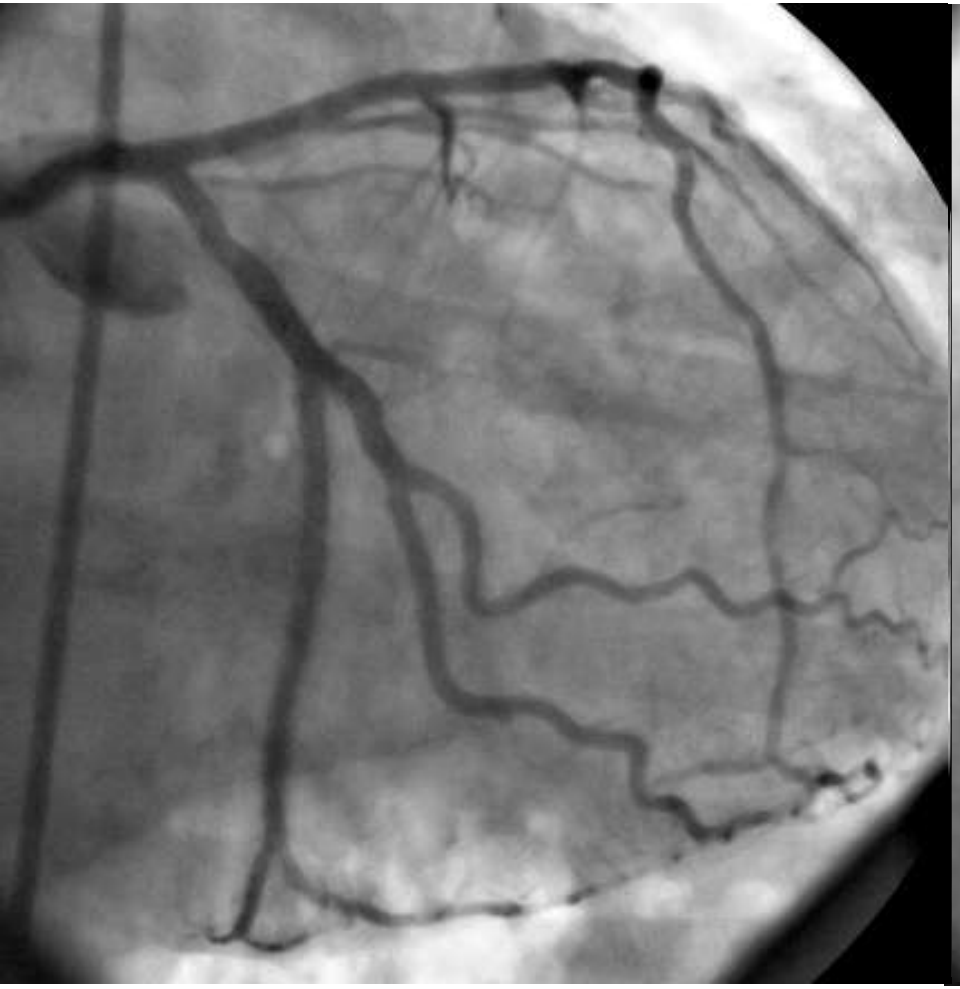
Athappan G, et al. *Stroke.*

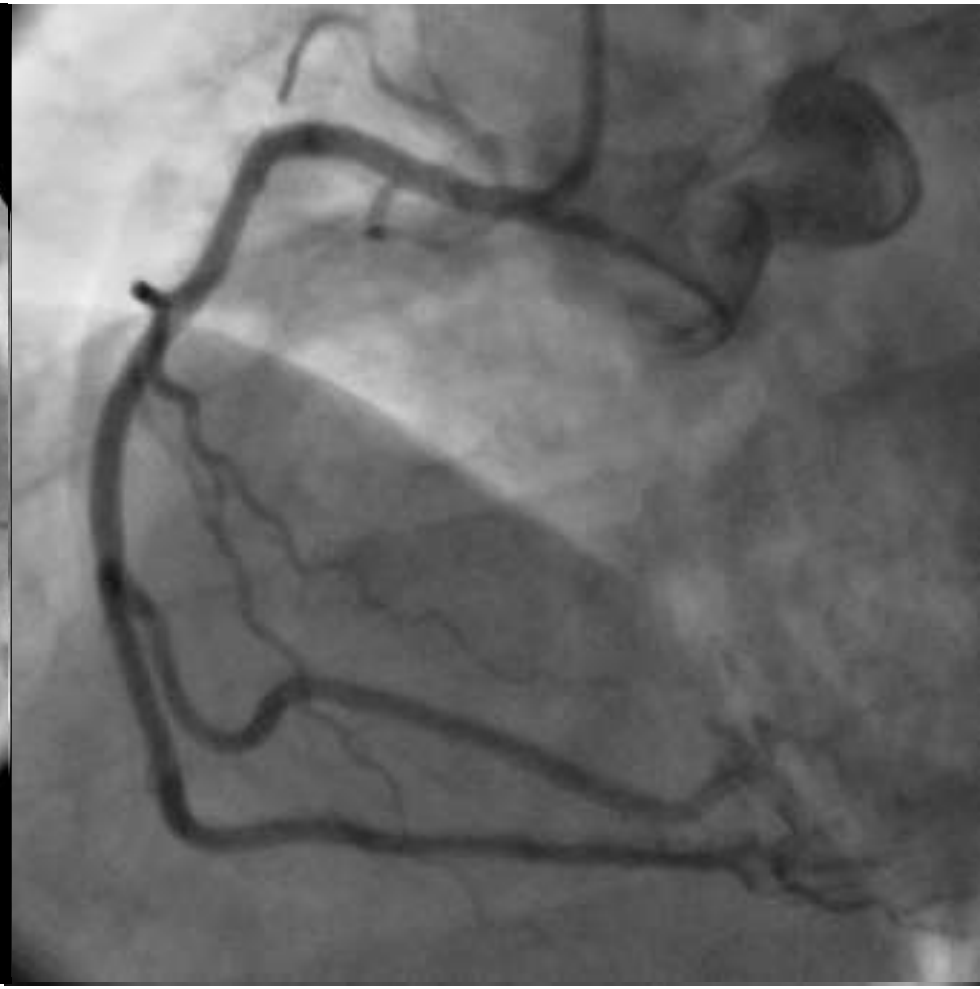
Diabetes y Enfermedad Multivaso



DMNID, Syntax Score 18, Euroscore 2

Diabetes y Enfermedad Multivaso





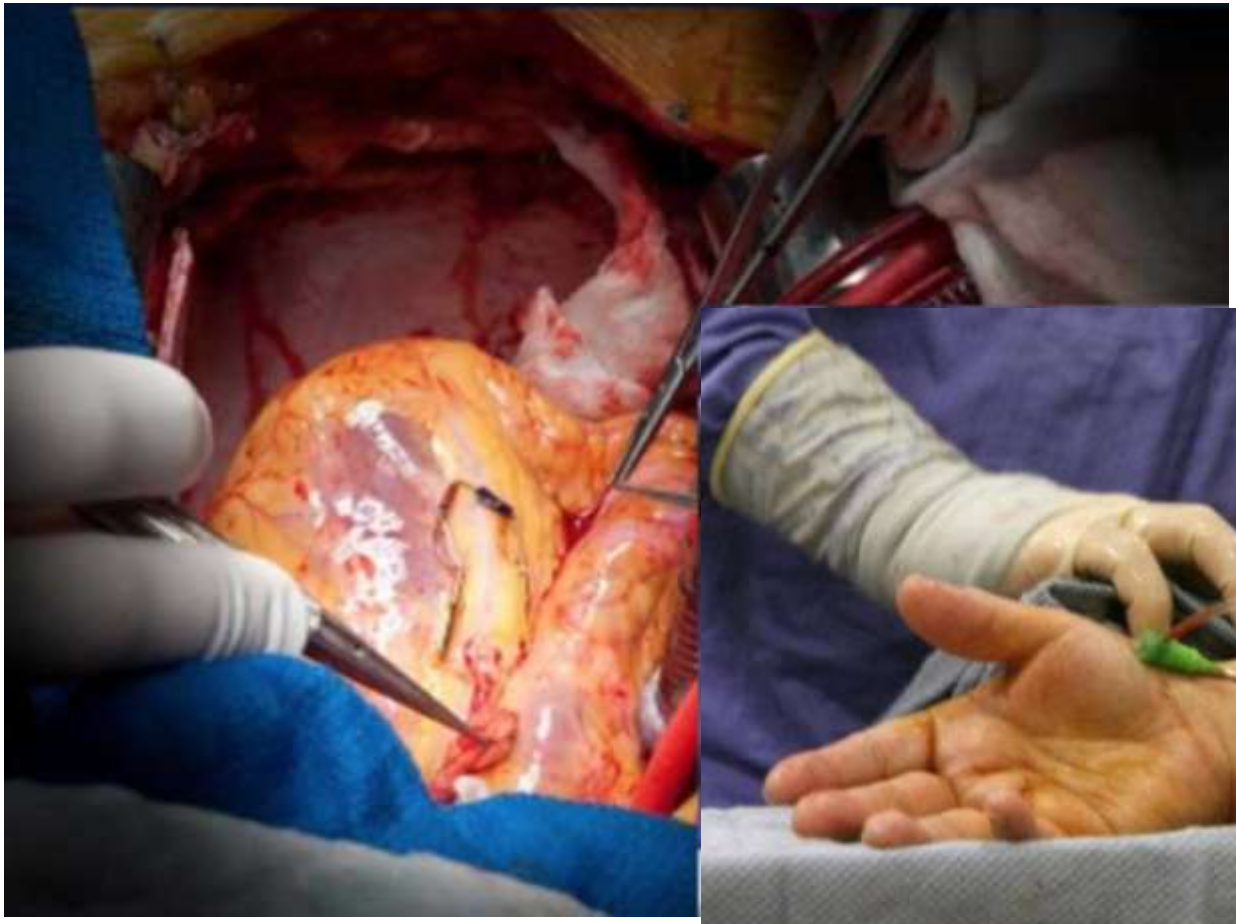
DMNID, Syntax Score 18, Euroscore 2

Take Home Message

- ✓ la revascularització miocàrdica (ICP o CABG)
- ✓ Les mesures de prevenció secundaria, i
- ✓ El tractament antiisquèmic óptim

son els 3 pilars bàsics per el tractament de l'isquemia miocárdica i, ademés, no son formes de tractament excluyents, sinó COMPLEMENTARIAS.

ICP versus CABG



ICP versus CABG

Cardiologia Intervencionista

DES 2004

Stents 1ª generació
Stents 2ª generació
Stents Bioabsorbibles

Cirurgia Cardiaca

1968

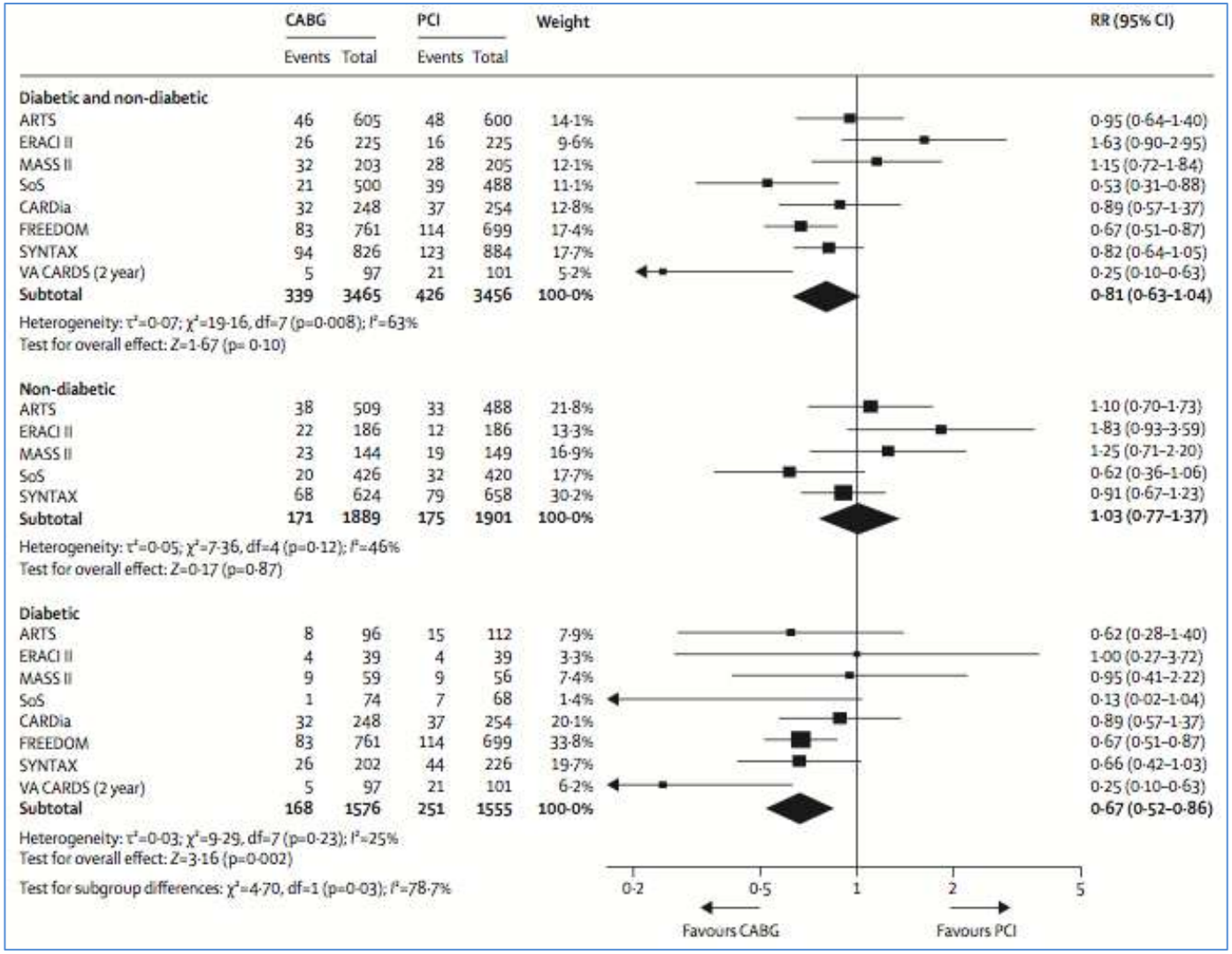
Vena Safena
Arteria mamaria

Com ha de ser el HEART TEAM ?


Moltes Gràcies

CABG vs ICP con stent en pacientes diabéticos

Meta-análisis de 8 RCT con 7468 pts (3612 con diabetes); 4 estudios con DES y 4 con BMS



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