Percutaneous coronary intervention in special subgroups of patients: Left main and multivessel coronary artery disease

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"Innovations in Interventional Cardiology & Electrophysiology IICE 2011"

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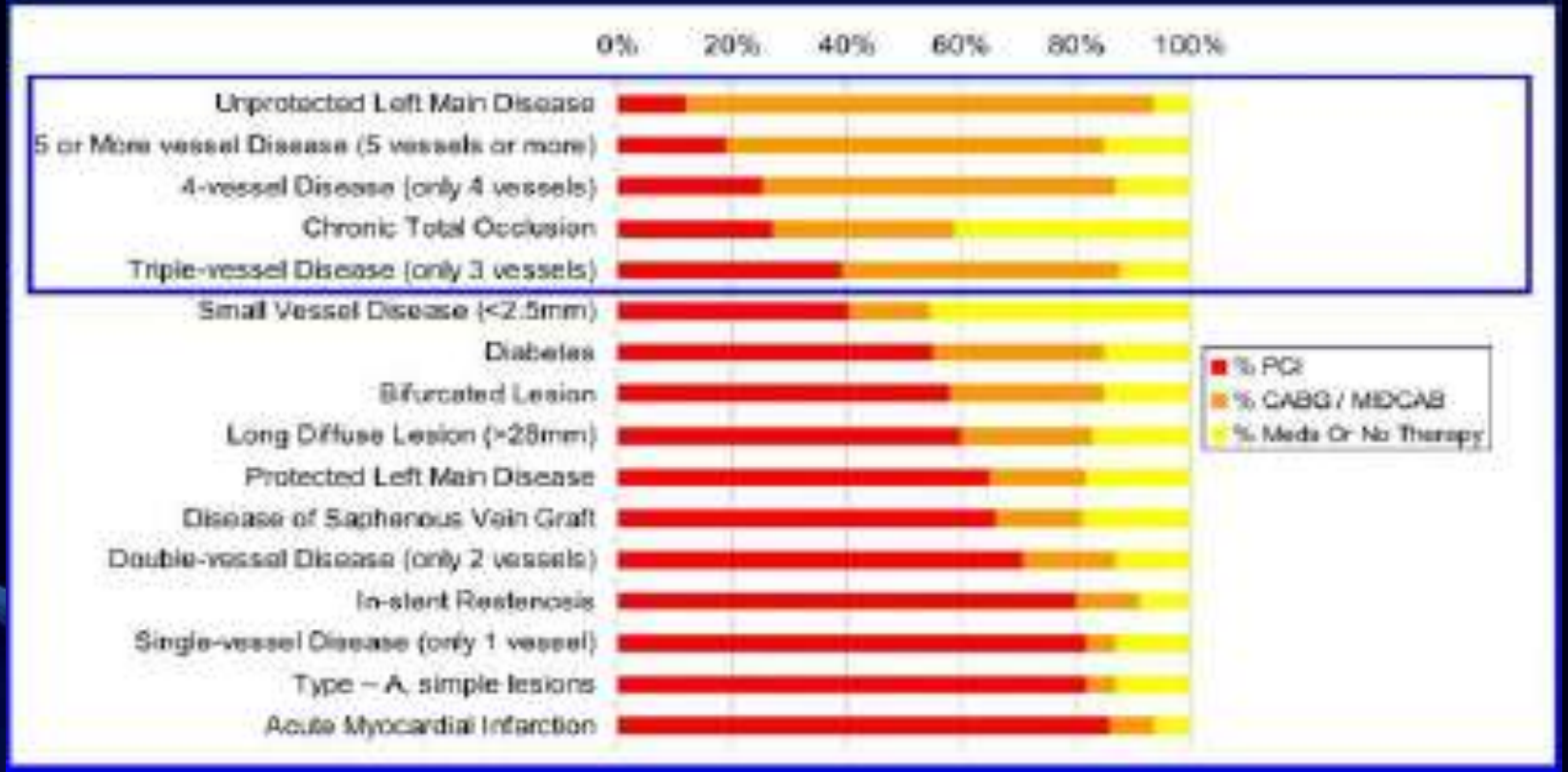
Treatment Modality Preference



Is revascularisation needed for this particular patient?

If so, which revascularisation technique seems to be the most appropriate for this particular patient?

LEFT MAIN PCI

Left Main Disease comes in many sizes and shapes

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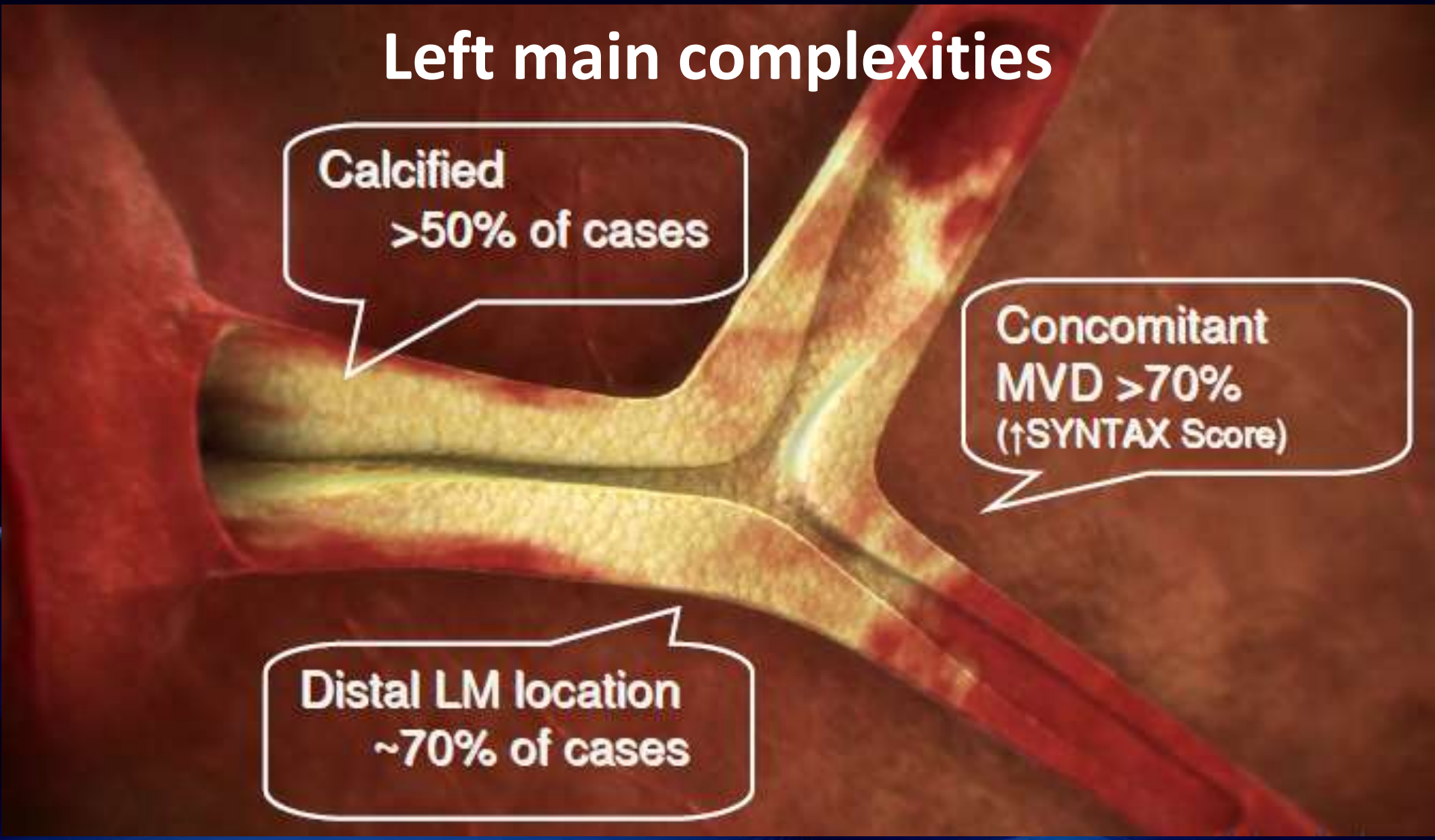
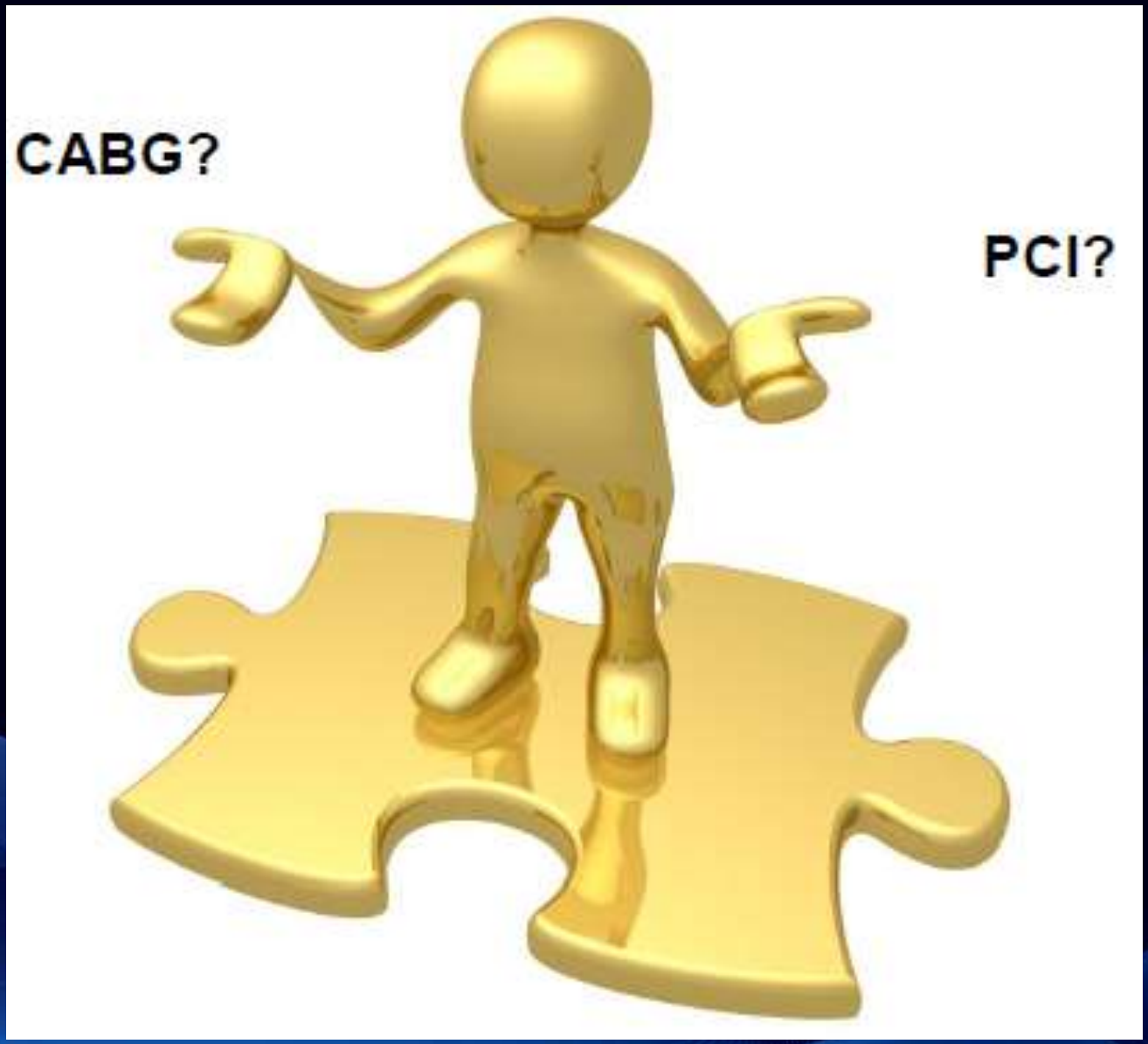
Left main complexities



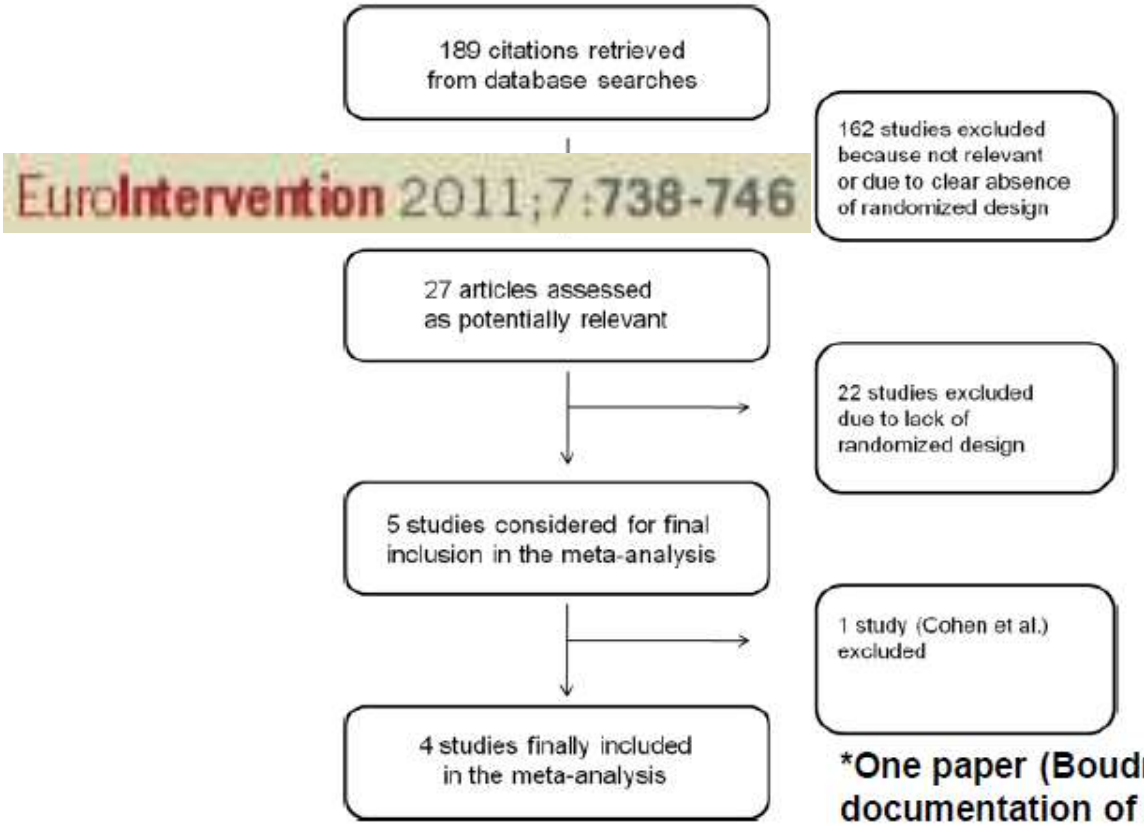

CABG?
PCI?


SEA OF
EVIDENCE
FOLEY

EuroIntervention The Official Journal of EuroPCR and the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

Percutaneous coronary intervention versus bypass surgery for left main coronary artery disease: a meta-analysis of randomised trials

Four randomised trials enrolling 1,611 patients



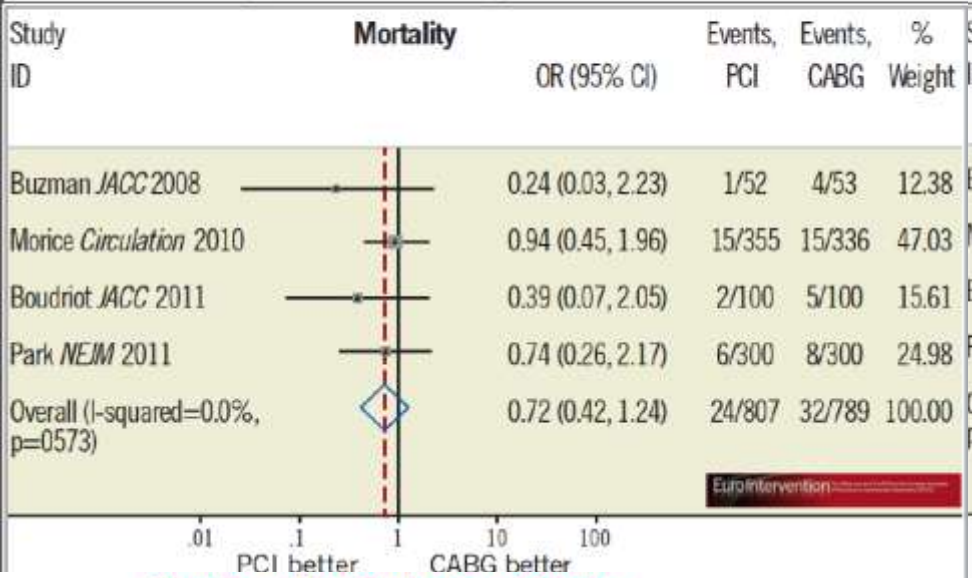
*One paper (Boudriot et al.) without documentation of stroke

Similar Risk of Mortality

(OR 0.72, 95% CI [0.42 to 1.24], p=0.23)

Ferrante et al.

Percutaneous Coronary Intervention versus Bypass Surgery for Left Main Coronary Artery Disease: a Meta-analysis of Randomized Trials

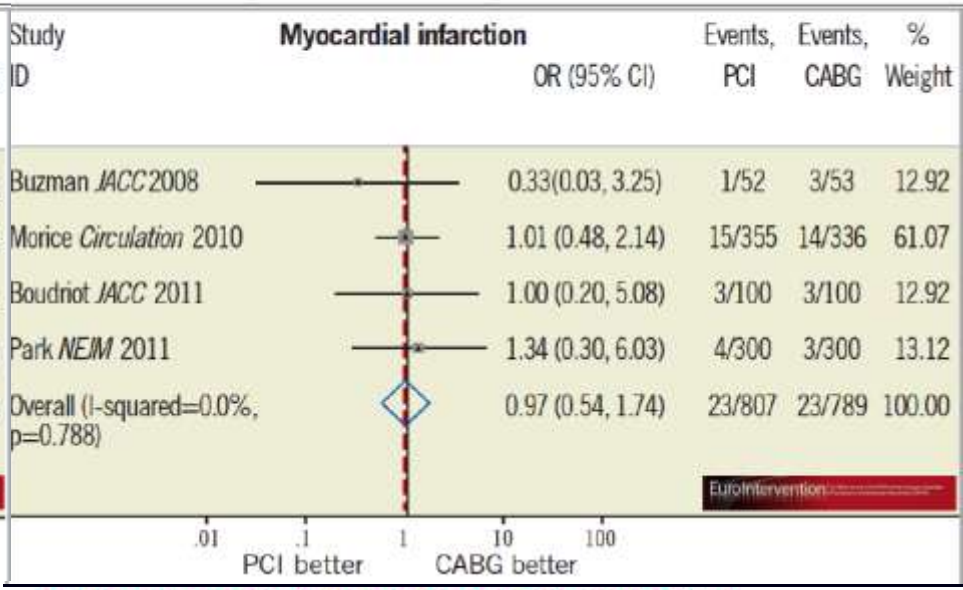


Similar Risk of Myocardial Infarction

OR 0.97, 95% CI [0.54 to 1.74], p=0.91)

Ferrante et al.

Percutaneous Coronary Intervention versus Bypass Surgery for Left Main Coronary Artery Disease: a Meta-analysis of Randomized Trials

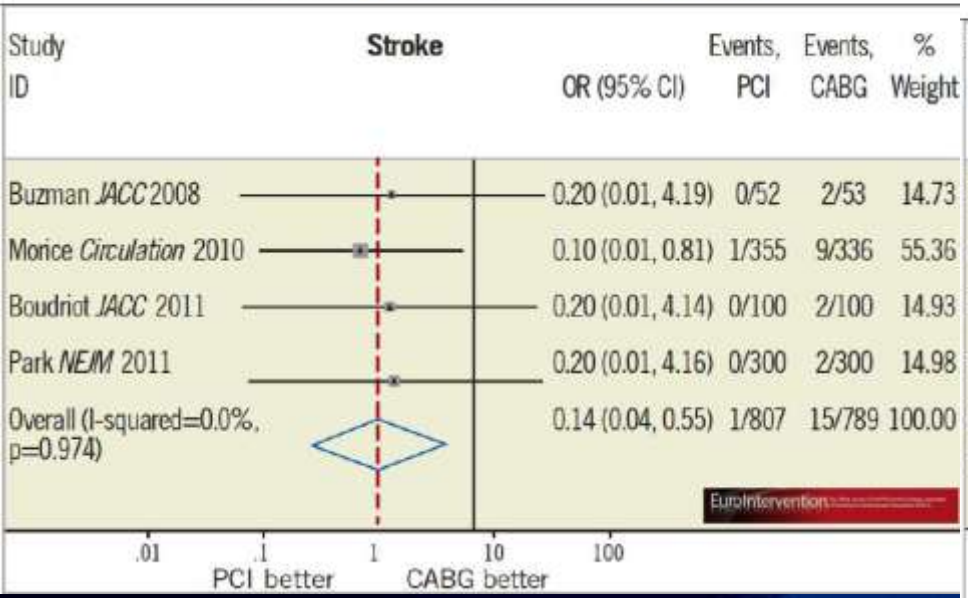


Significant Risk Reduction of Stroke

(0.12% vs. 1.90%, OR 0.14, 95% CI [0.04 to 0.55], p=0.004)

Ferrante et al.

Percutaneous Coronary Intervention versus Bypass Surgery for Left Main Coronary Artery Disease: a Meta-analysis of Randomized Trials

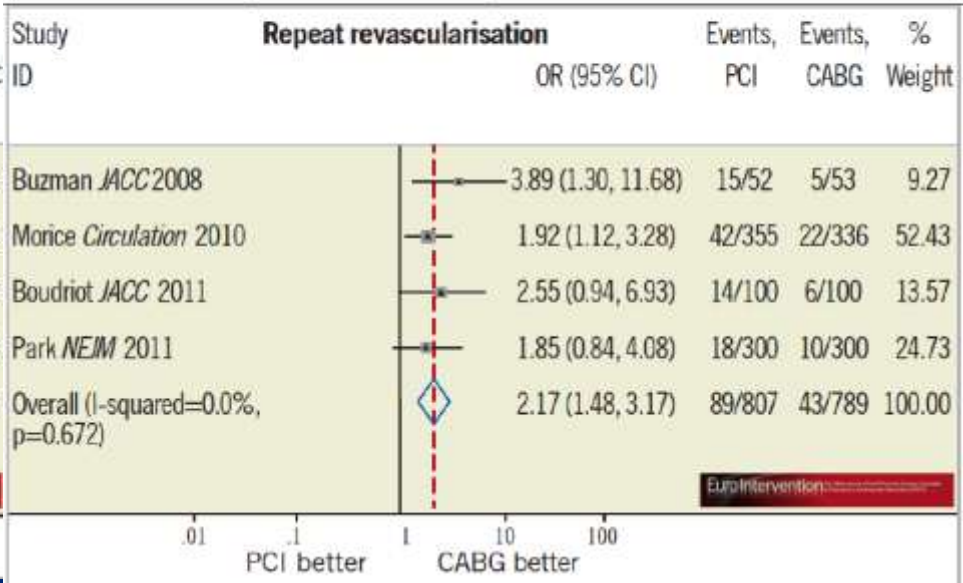


Significant Increased Risk of Repeat Revascularisation

(11.03% vs. 5.45%, OR 2.17, 95% CI [1.48 to 3.17], p <0.001)

Ferrante et al.

Percutaneous Coronary Intervention versus Bypass Surgery for Left Main Coronary Artery Disease: a Meta-analysis of Randomized Trials

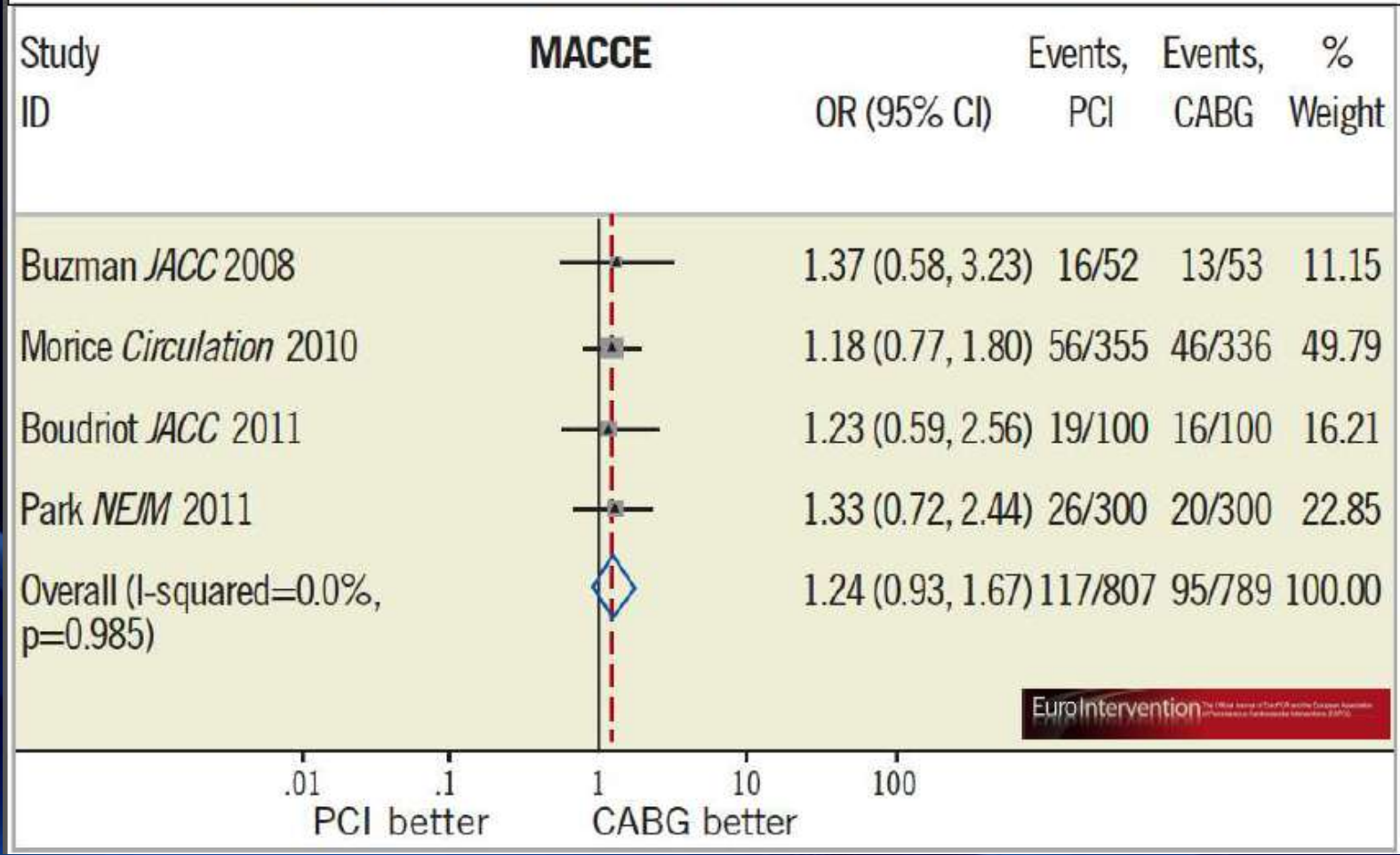


Similar Risk of MACCE

(14.49% vs. 12.04%, OR 1.24, 95% CI [0.93 to 1.67], p=0.15)

Ferrante et al.

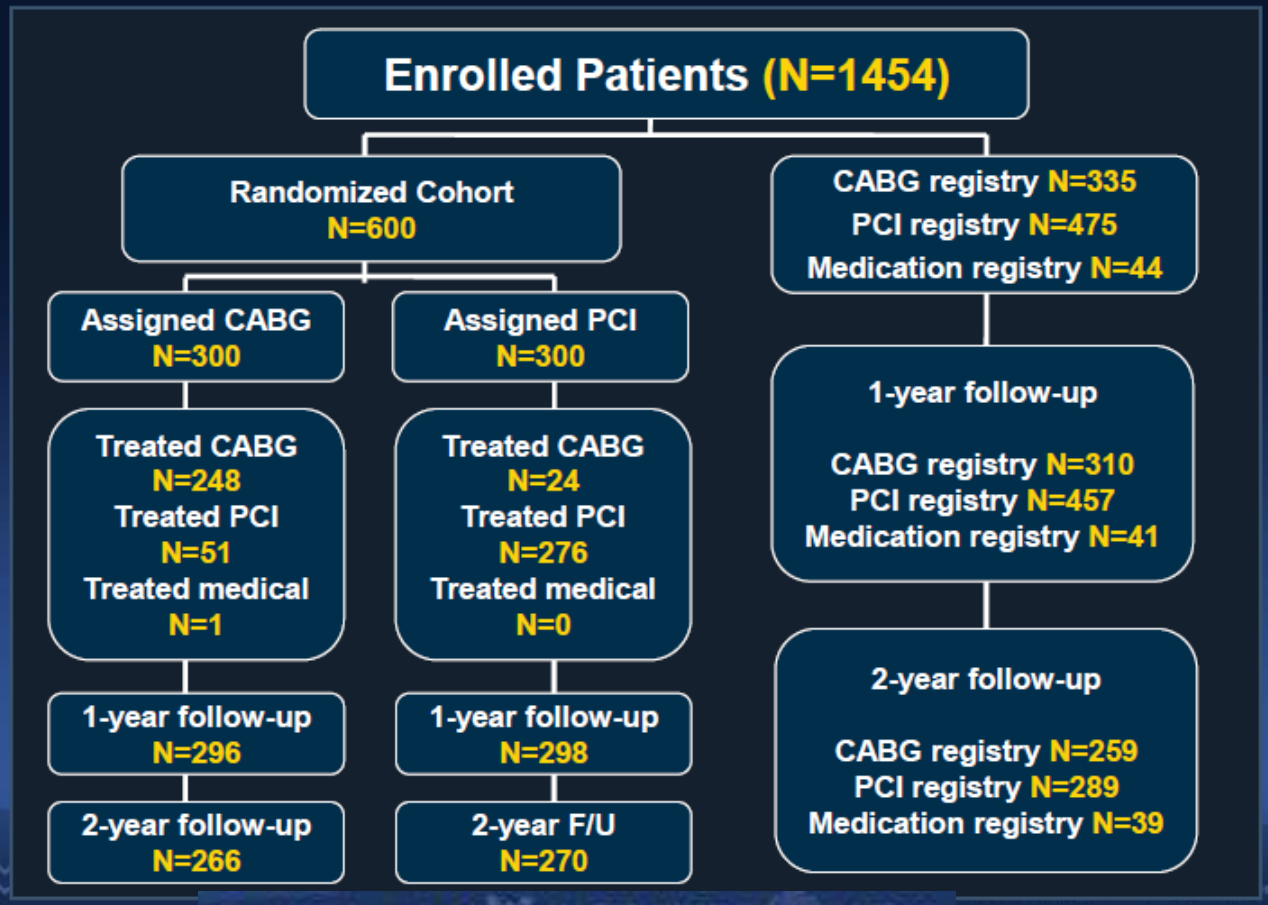
Percutaneous Coronary Intervention versus Bypass Surgery for Left Main Coronary Artery Disease: a Meta-analysis of Randomized Trials



Premier of Randomized Comparison of Bypass Surgery versus Angioplasty Using Sirolimus-Eluting Stent in Patients with Left Main Coronary Artery Disease

PRECOMBAT Trial

Patient Flow



Park SJ et al. N Engl J Med. 2011;364:1718

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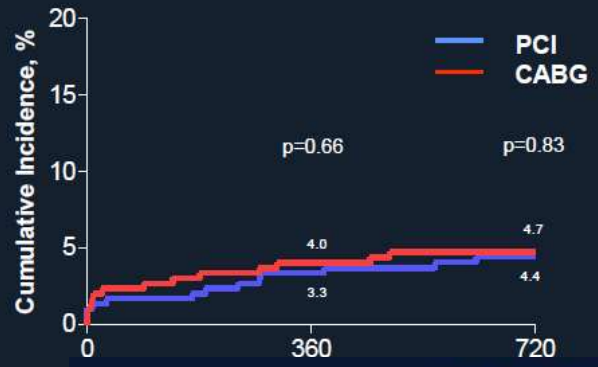
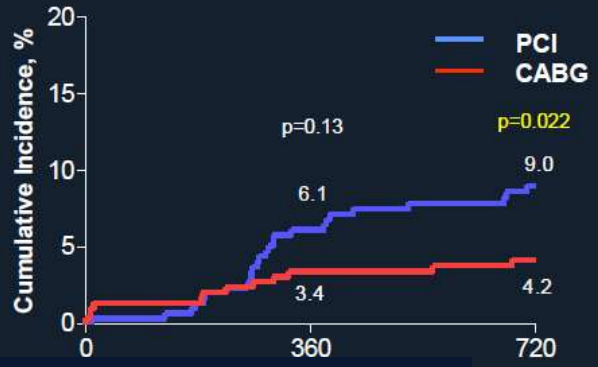
Death, MI or Stroke to 2 Years
PRECOMBAT



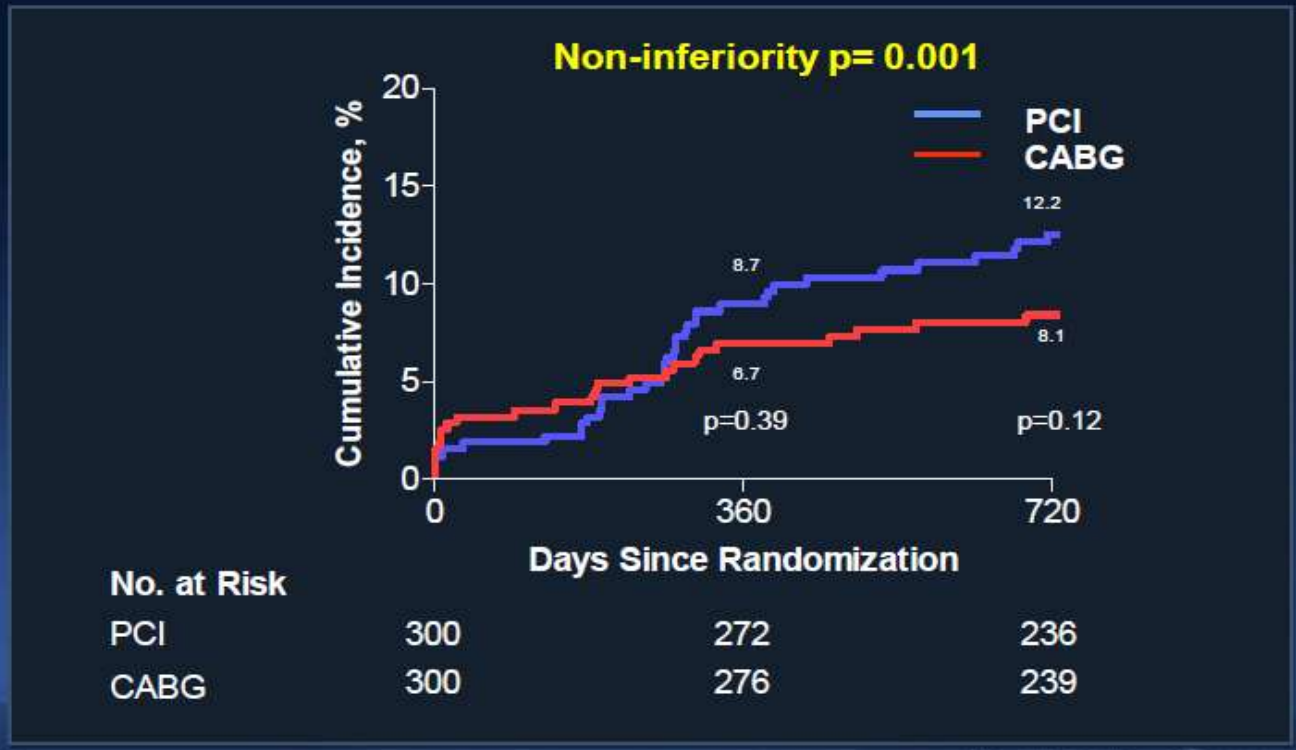
Ischemia-driven TVR to 2 Years
PRECOMBAT



No. at Risk
PCI
CABG

237
242

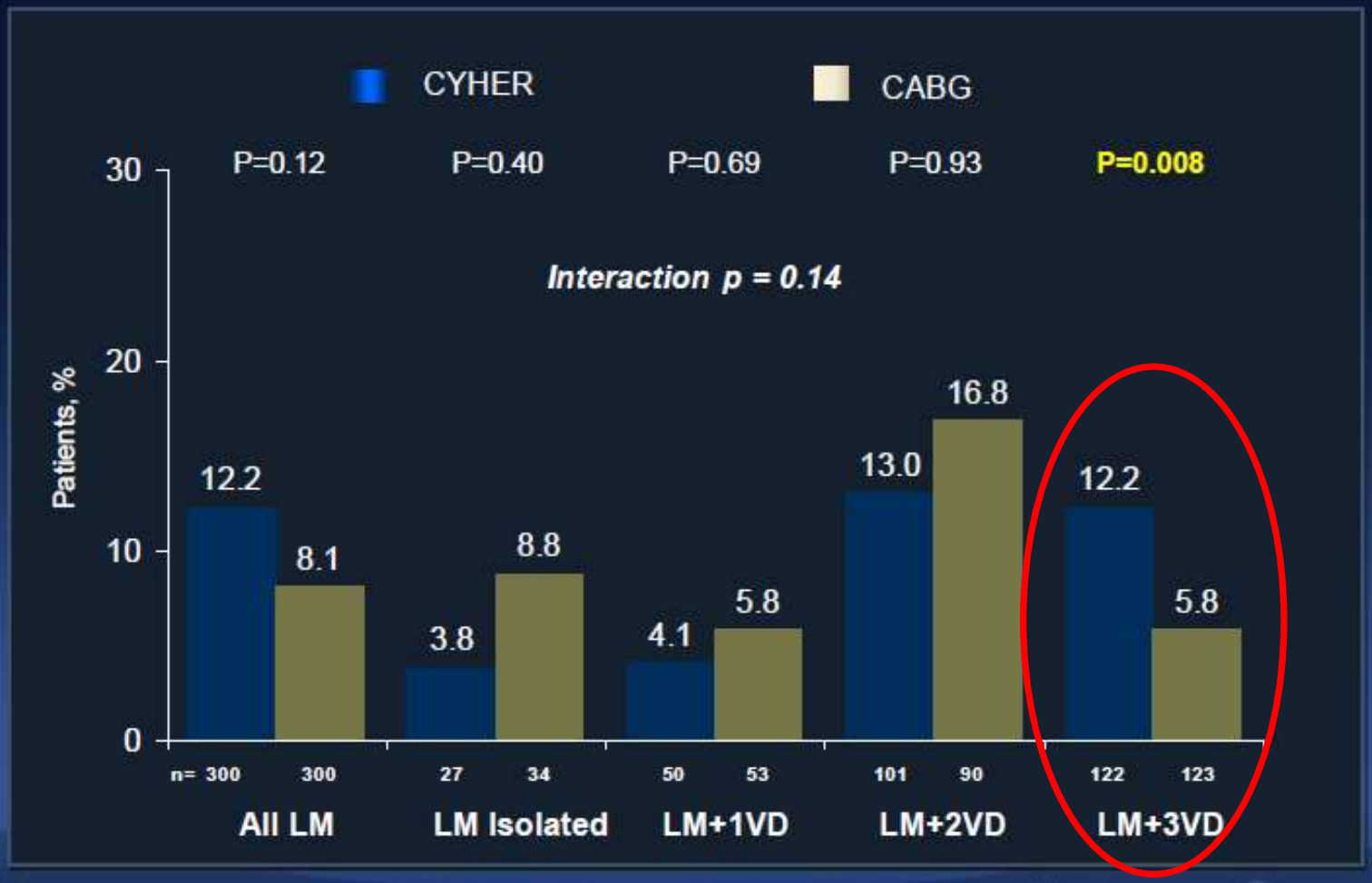
MACCE to 2 Years
PRECOMBAT



No. at Risk			
PCI	300	272	236
CABG	300	276	239

Park SJ et al. N Engl J Med. 2011;364:1718

MACCE to 2 Years in PRECOMBAT



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

Park SJ et al. N Engl J Med. 2011;364:1718

TCT2011

SYNTAX

The Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery: The SYNTAX Study

The 4-year Outcomes of the SYNTAX Trial in the Subset of Patients With Left Main Disease

Marie Claude Morice, MD, FESC, FACC
On behalf of the SYNTAX investigators

Monday, November 7th

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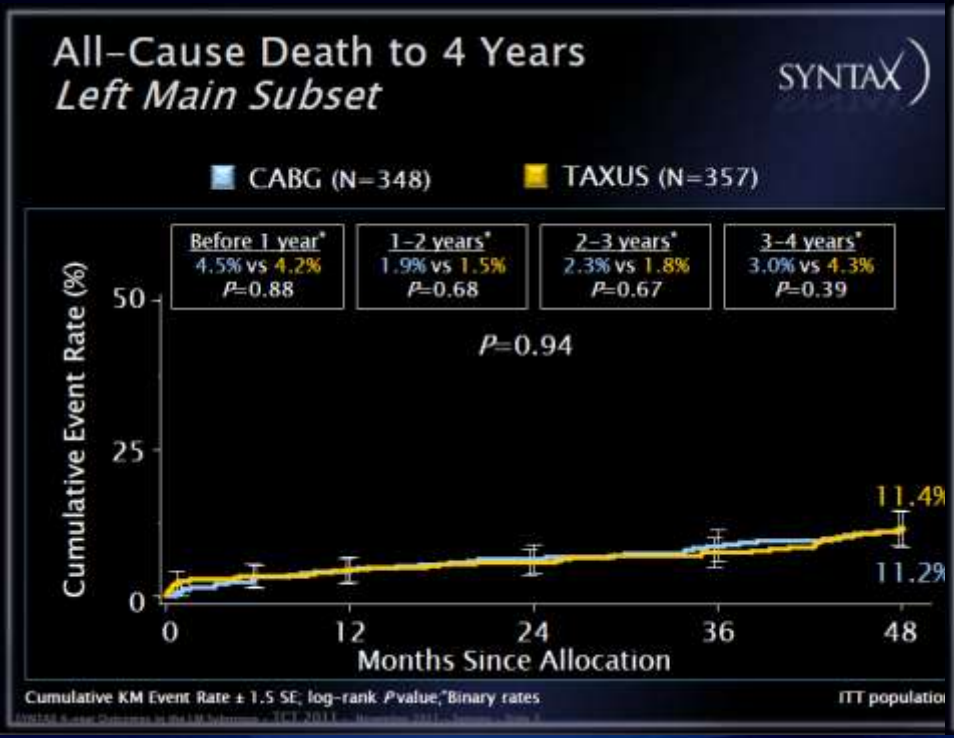

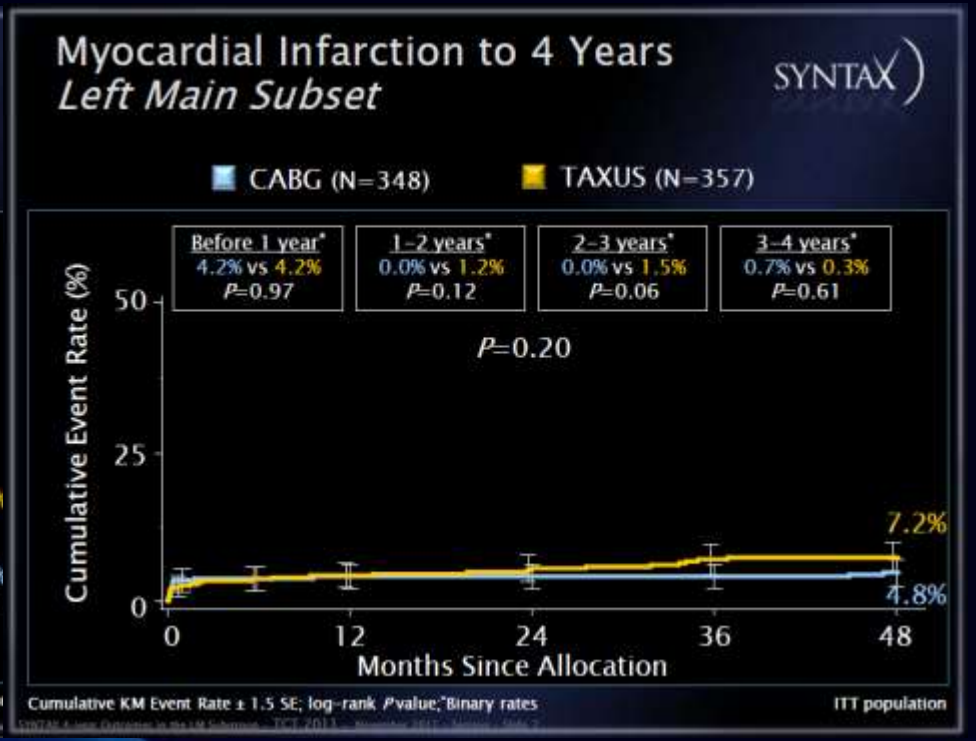

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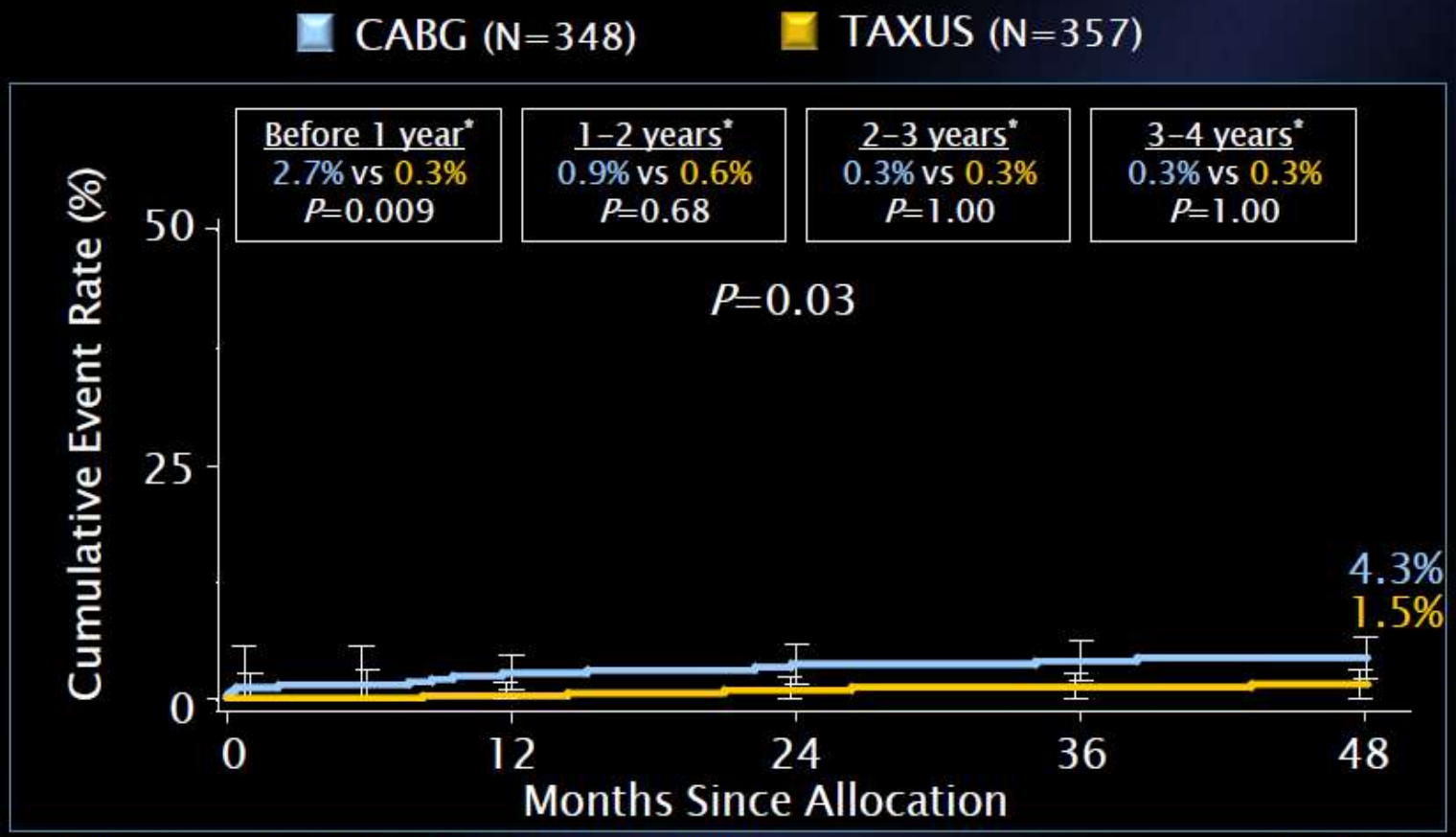
CVA to 4 Years
Left Main Subset

SYNTAX



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

ITT population

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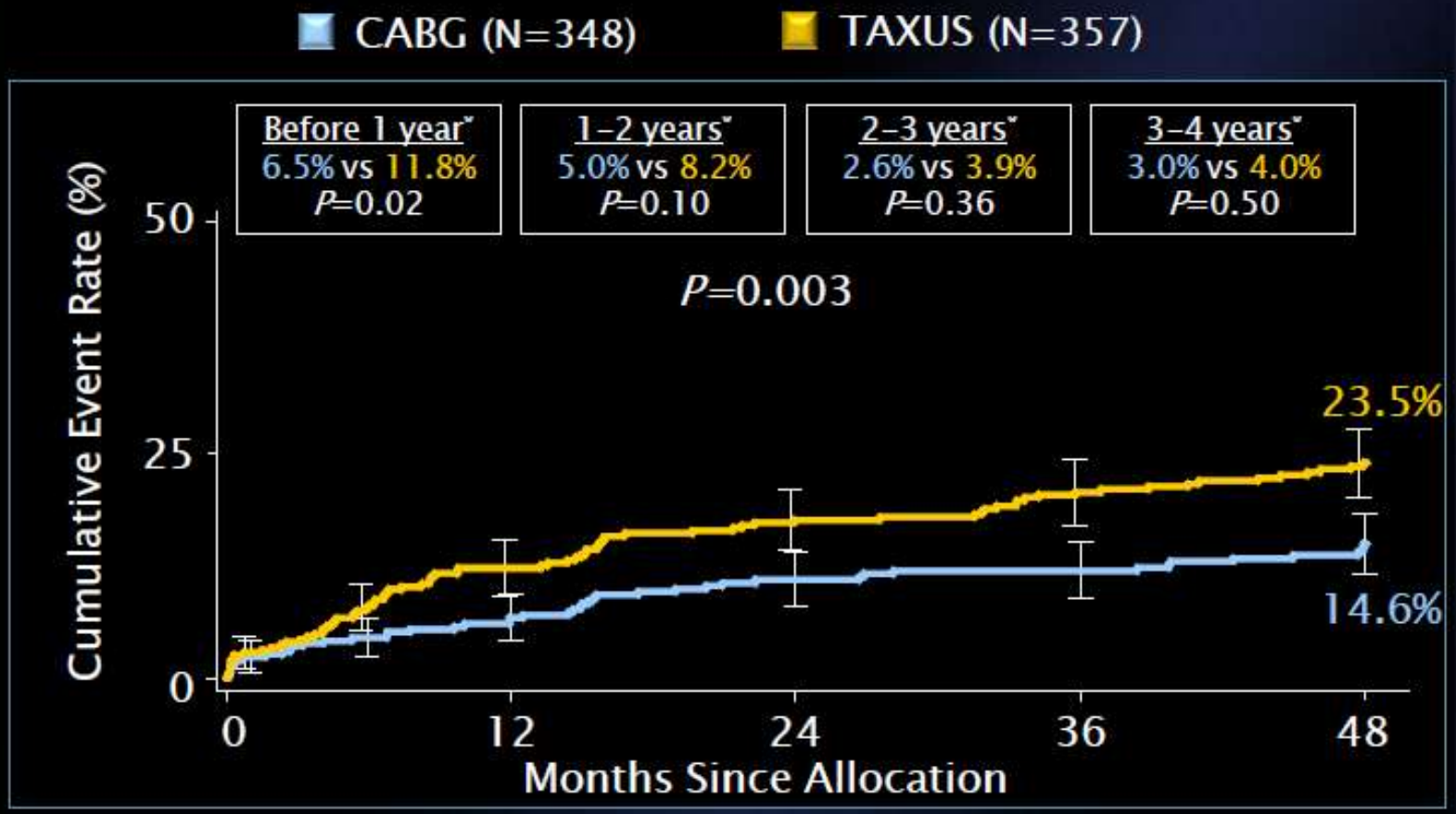
Repeat Revascularization to 4 Years
Left Main Subset

SYNTAX



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

ITT population

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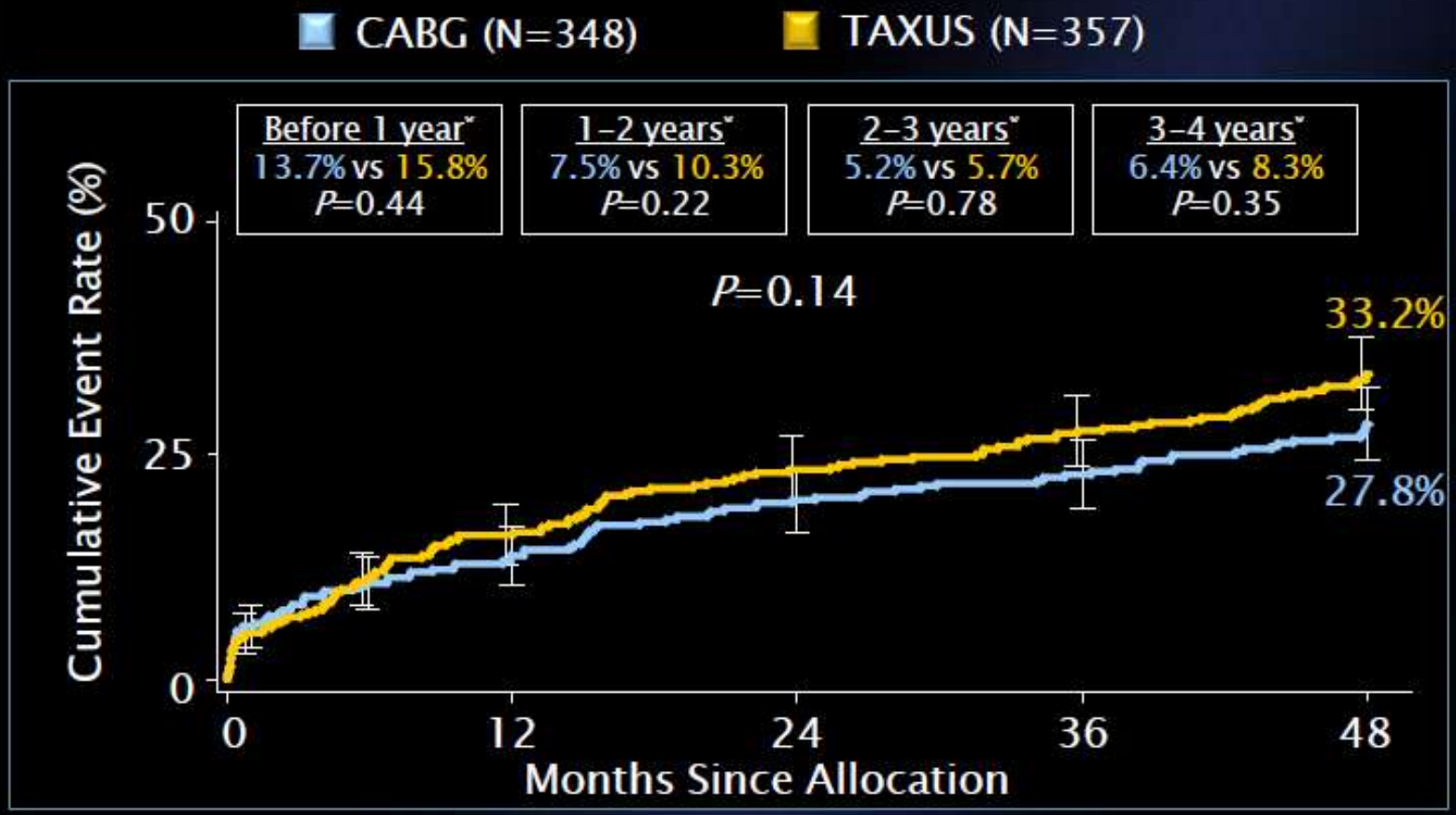
MACCE to 4 Years
Left Main Subset

SYNTAX



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

ITT population

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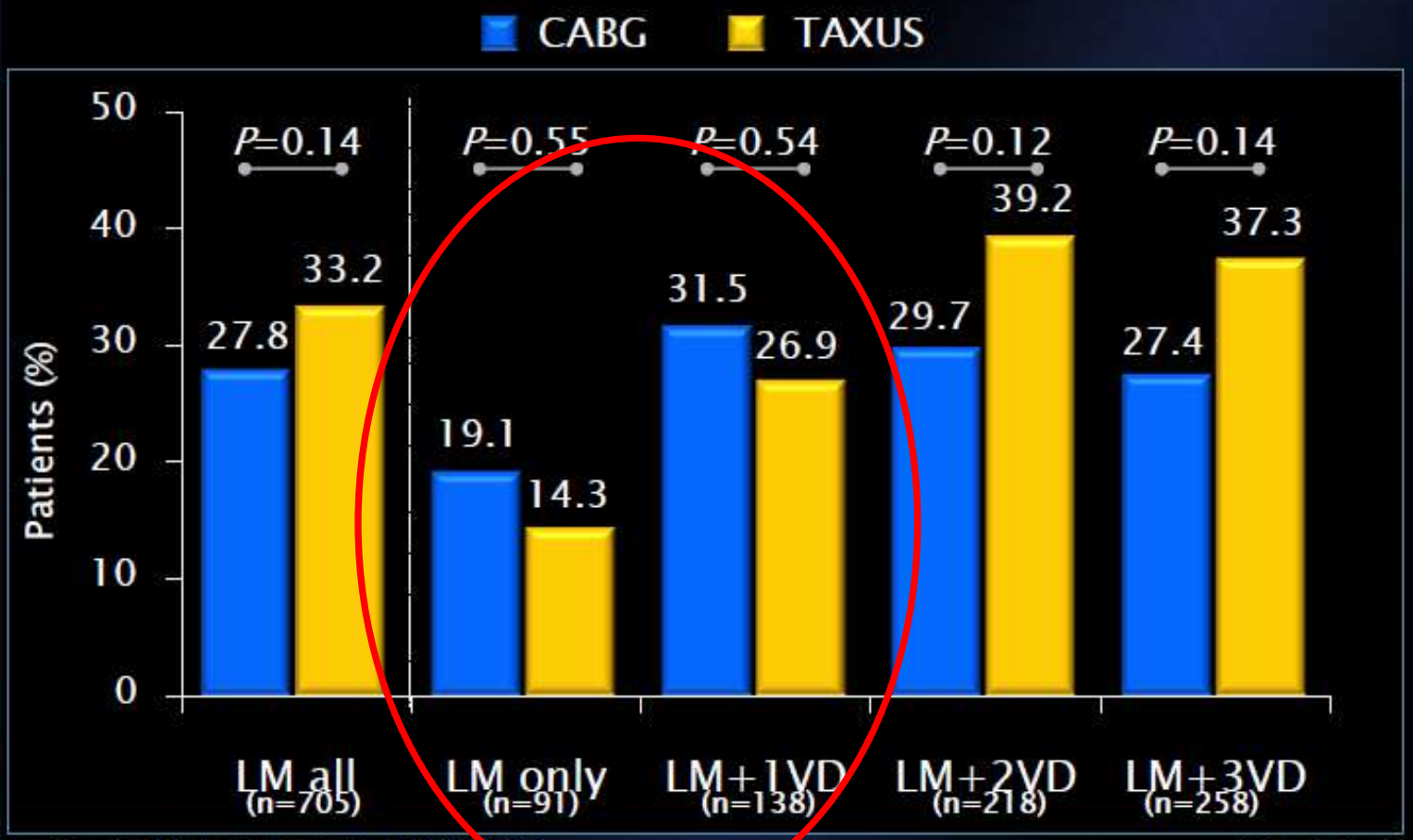
MACCE to 4 Years
Left Main Subsets

SYNTAX



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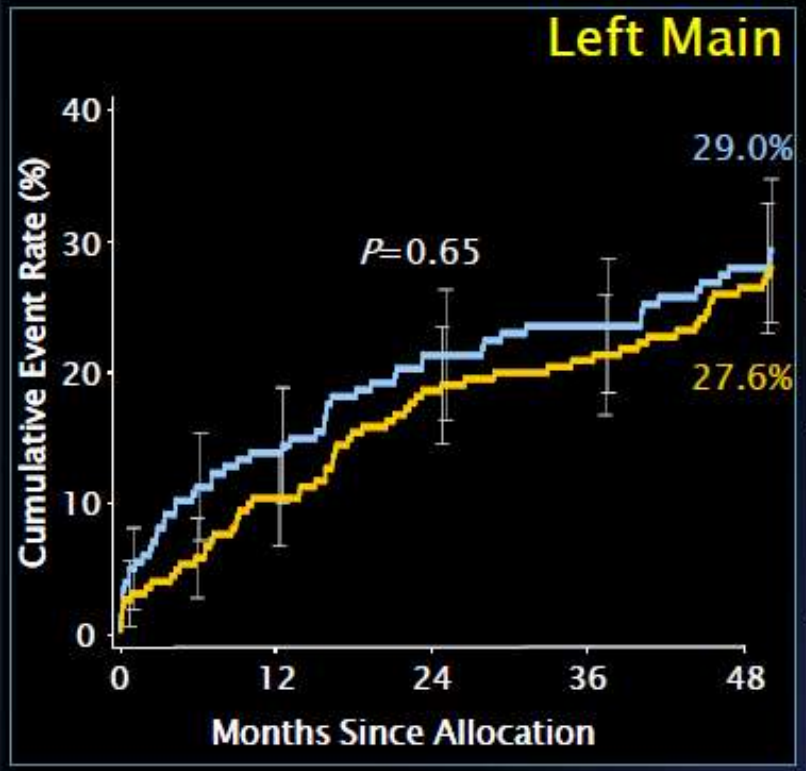
MACCE to 4 Years by SYNTAX Score Tercile *Low to Intermediate Scores (0–32)*

SYNTAX

CABG (N=196)
TAXUS (N=221)



	CABG	PCI	*P* value
Death	11.8%	> 7.5%	0.12
CVA	3.9%	> 1.4%	0.11
MI	3.8%	< 5.1%	0.55
Death, CVA or MI	17.1%	> 13.5%	0.25
Revasc.	16.9%	< 19.1%	0.57

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

Site-reported Data; ITT population

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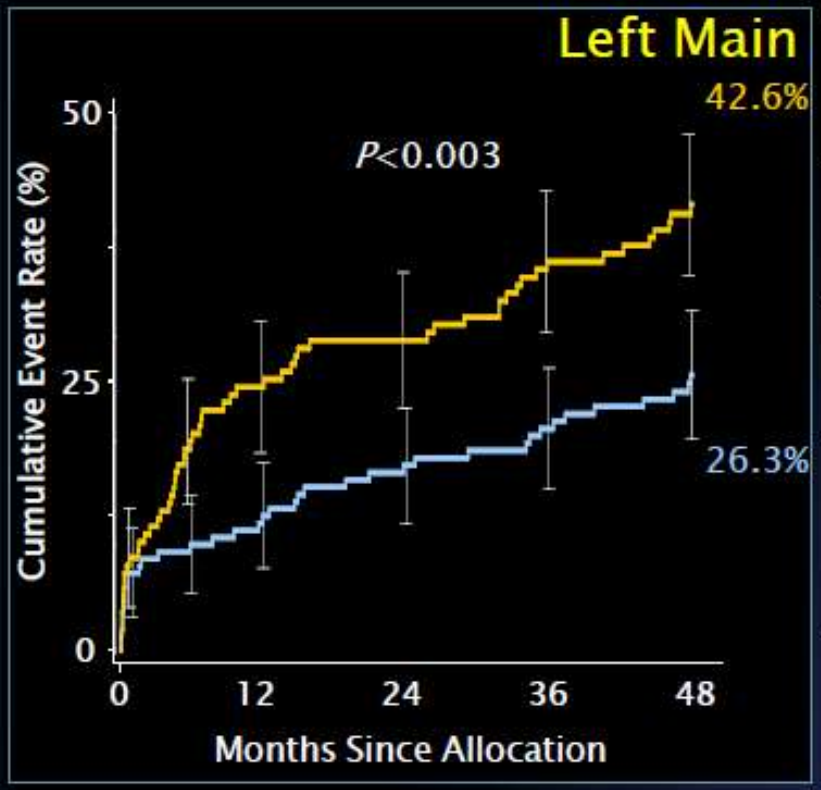
MACCE to 4 Years by SYNTAX Score Tercile *High Scores (≥33)*

SYNTAX

CABG (N=149)
TAXUS (N=135)



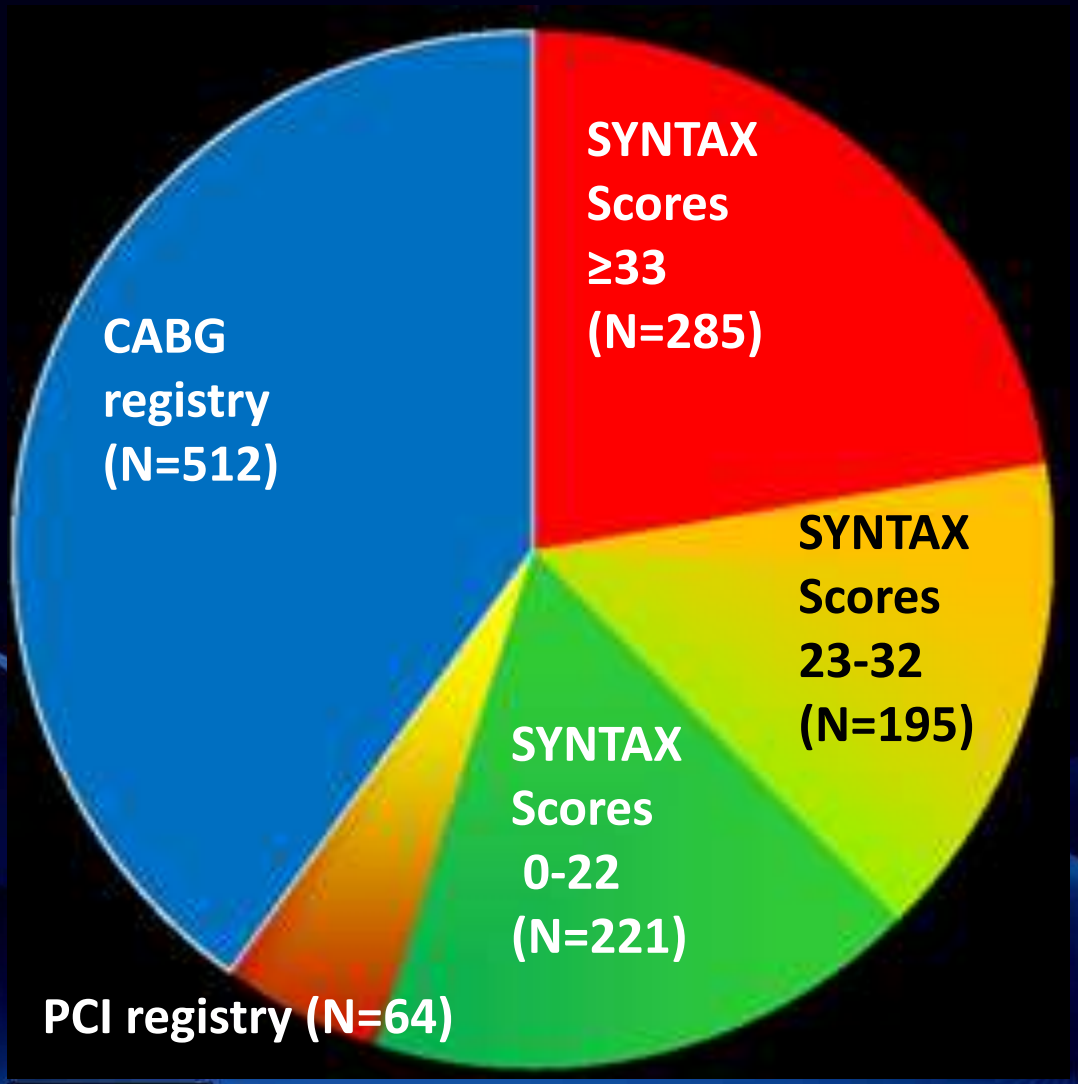
	CABG	PCI	*P* value
Death	10.5%	17.9%	0.06
CVA	4.9%	1.6%	0.14
MI	6.1%	10.9%	0.18
Death, CVA or MI	18.5%	23.1%	0.33
Revasc.	11.8%	31.3%	<0.001

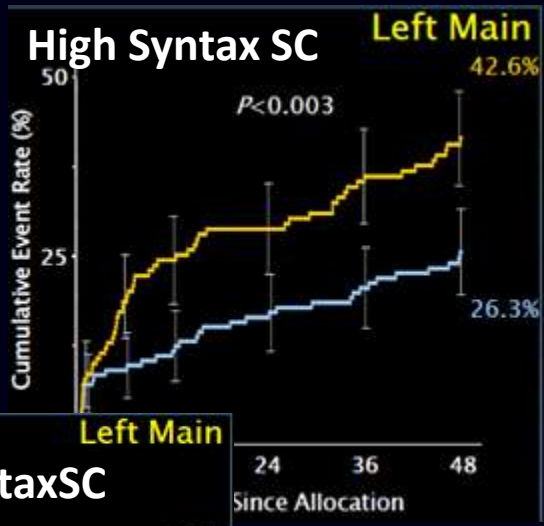
Cumulative KM Event Rate ± 1.5 SE; log-rank *P* value

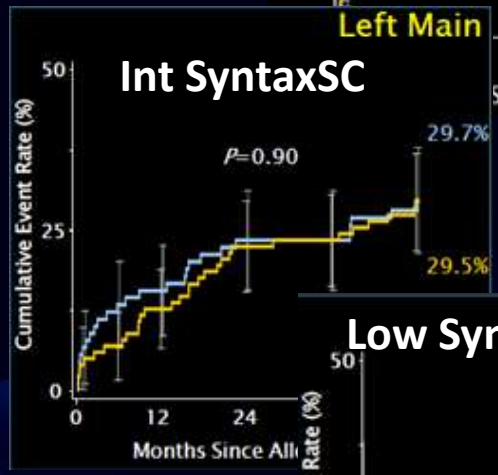
Site-reported Data; ITT population

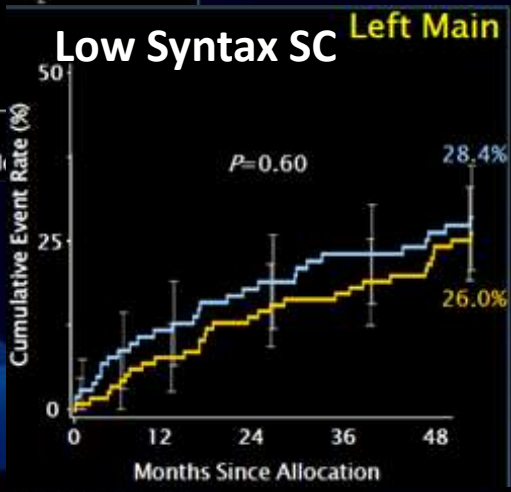
Do all patients with Left Main disease need CABG ?

SYNTAX Trial Patient Distribution









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SYNTAX Trial Patient Distribution

Results of the SYNTAX trial suggest that 34 % of all patients with Left Main Stem are best treated with PCI , an excellent alternative to surgery… up to four year

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)

2010

Subset of CAD by anatomy	Favours CABG	Favours PCI
Left main (isolated or 1VD, ostium/shaft)	I A	IIa B
Left main (isolated or 1VD, 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** **66%**	I A	III B

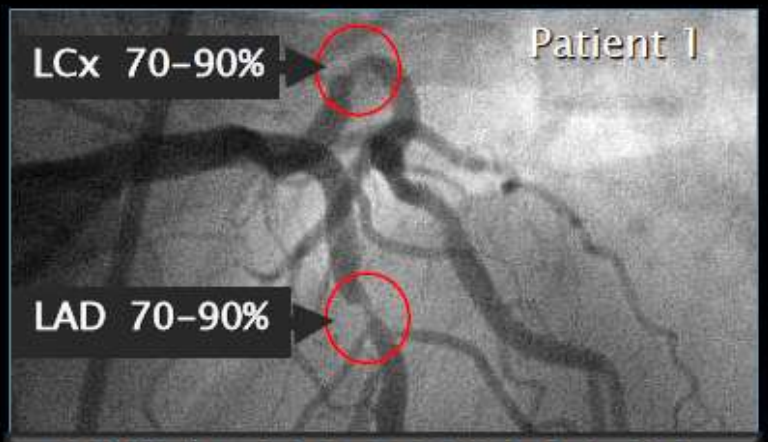
Classes of recommendations	Definition
Class IIa	*Weight of evidence/opinion is in favour of usefulness/efficacy.*
Class IIb	*Usefulness/efficacy is less well established by evidence/opinion.*
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.

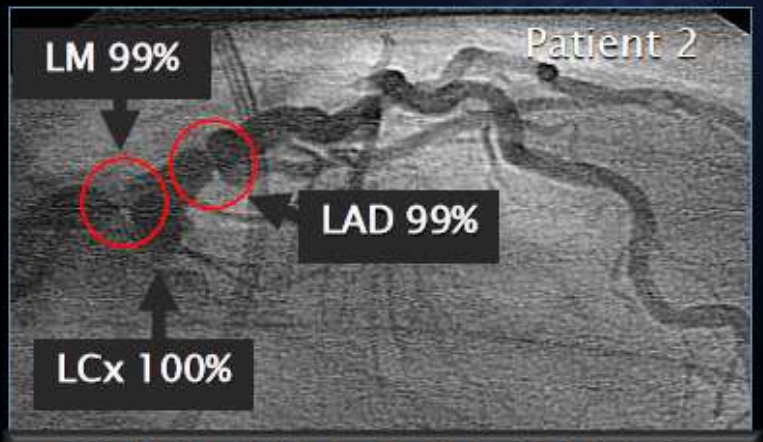
Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

“Optimal treatment of multivessel CAD is still a subject of debate.”

There is '3-vessel disease' and '3-vessel disease'

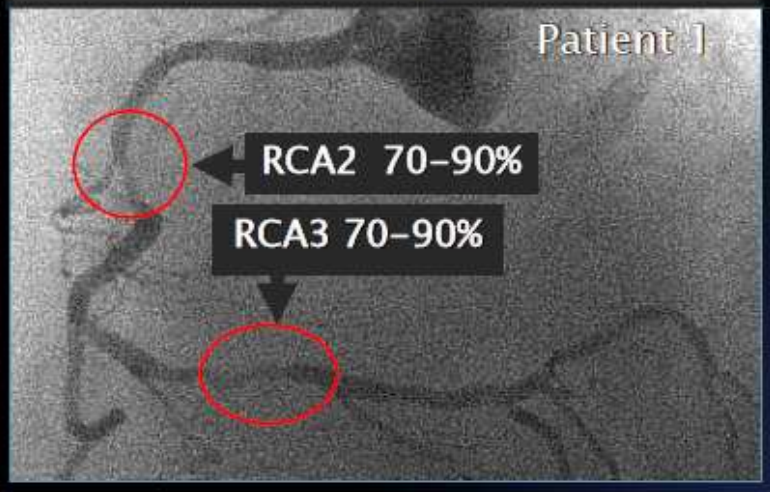
SYNTAX

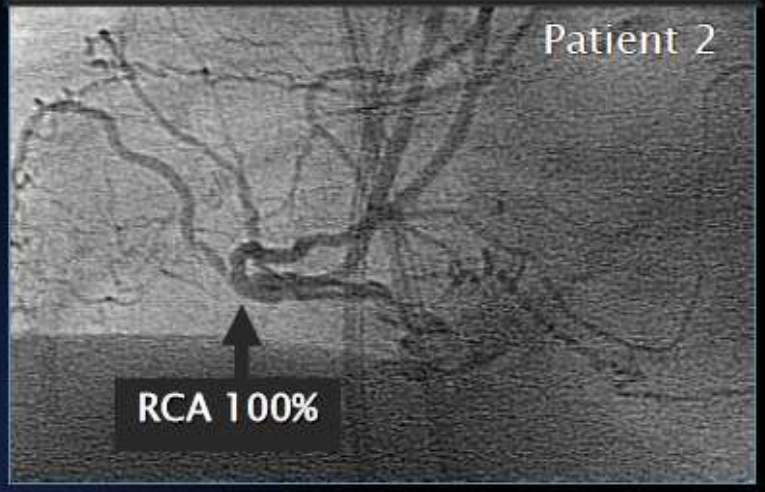




SYNTAX SCORE 21

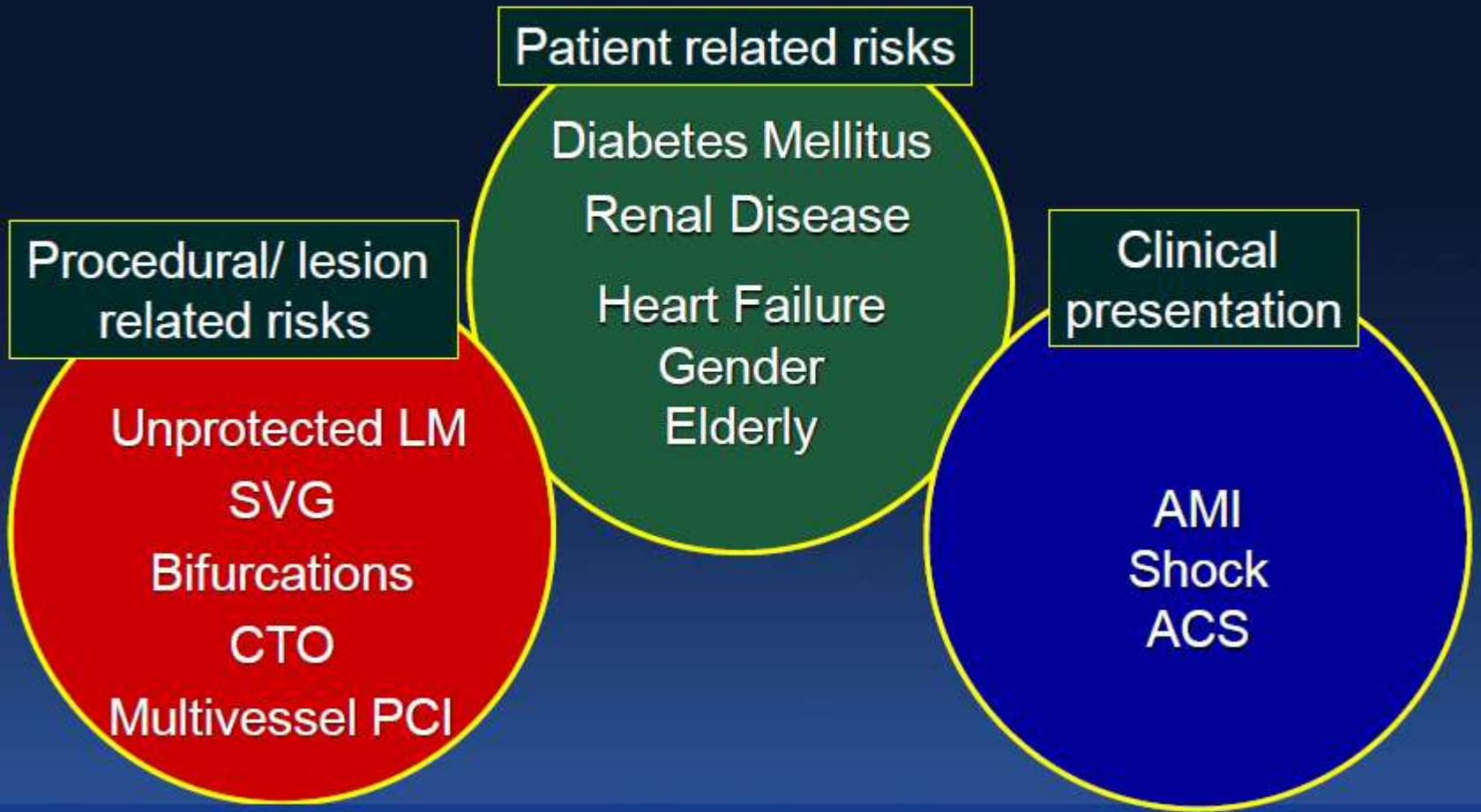
SYNTAX SCORE 52





Risk Assessment in the Patient with MVD

Complex Interplay of…



Do all patients with multivessel disease need CABG ?

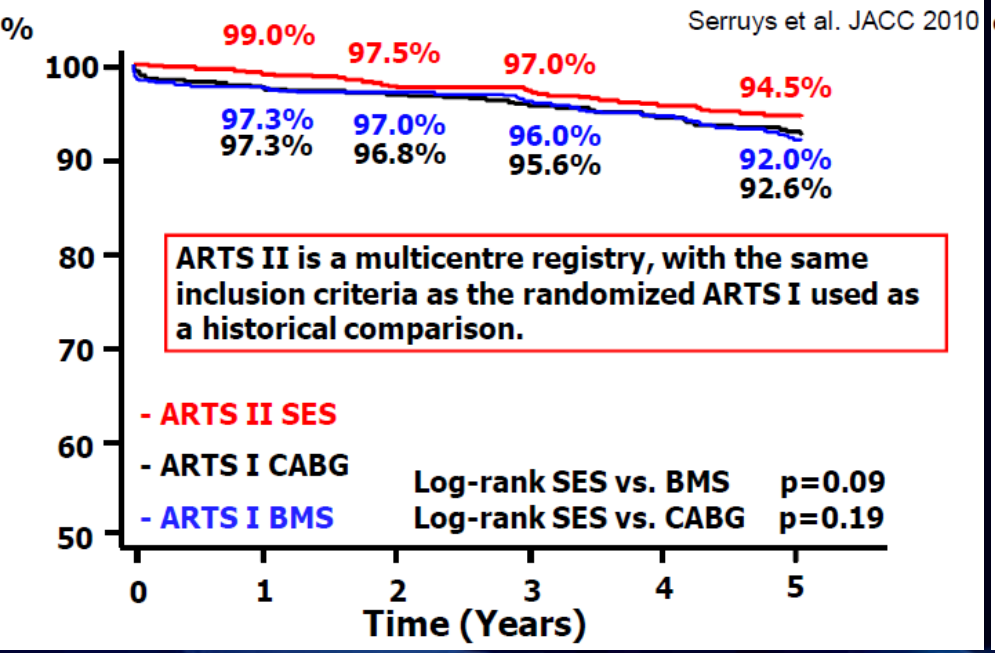
Multi-vessel Disease PCI

-Where We Are-

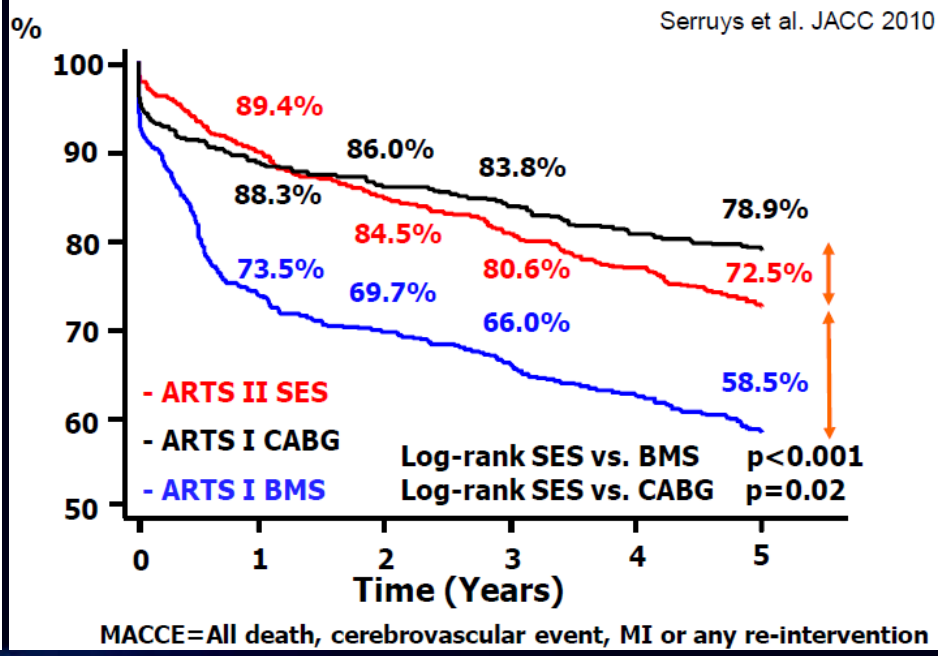
DES *vs.* CABG

From RCT to Registry

Freedom from Death up to 5 years



Freedom from MACCE up to 5 years

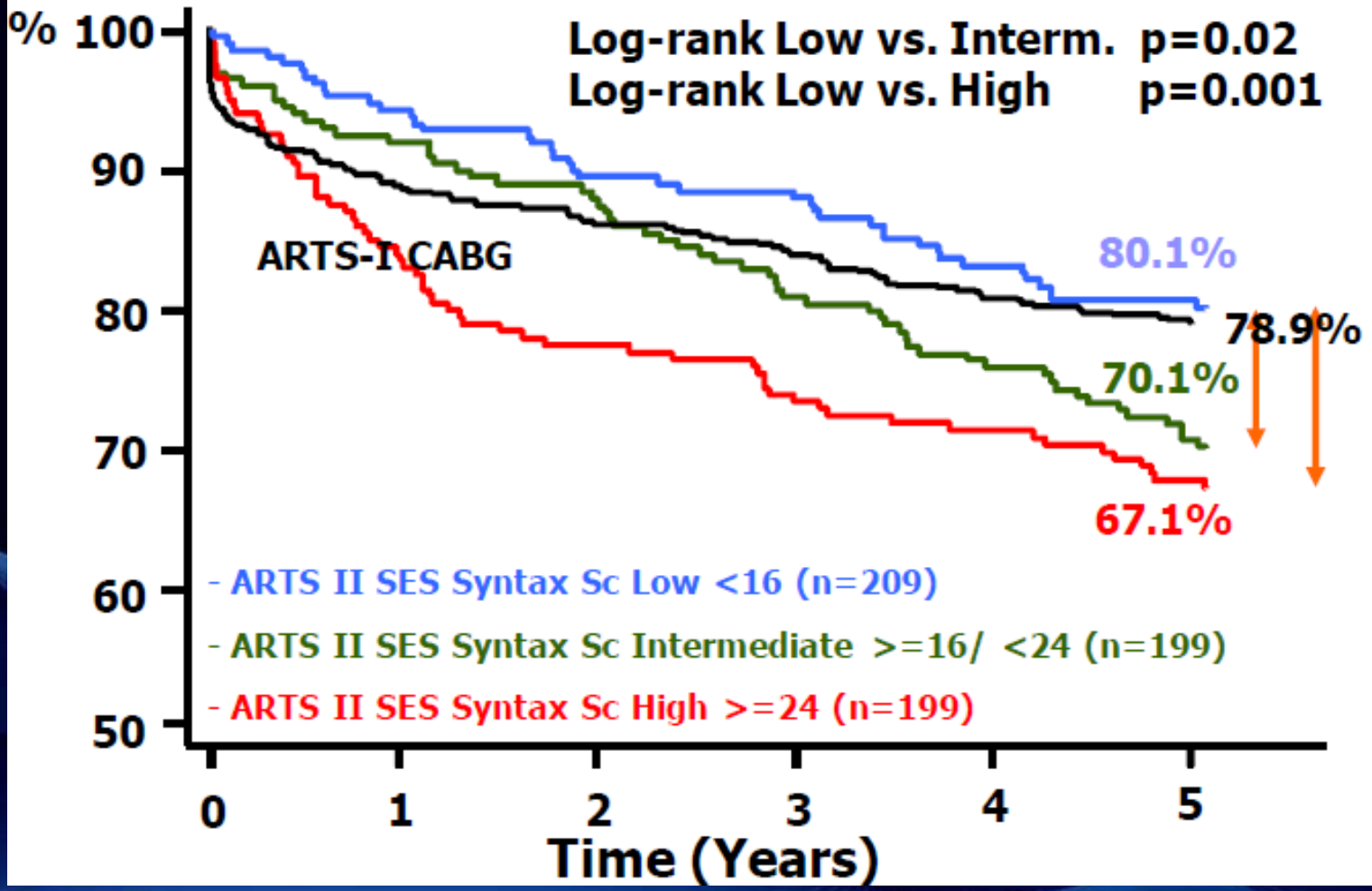


MACCE=All death, cerebrovascular event, MI or any re-intervention

ARTS-II SES

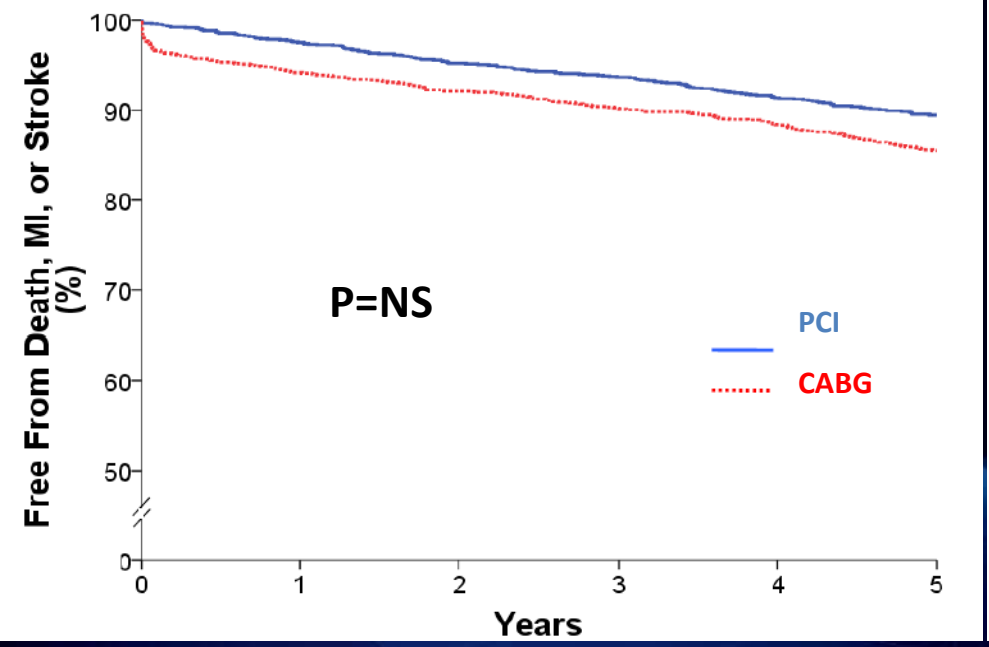
MACCE rate according to Syntax score tertiles

Serruys et al. JACC 2010

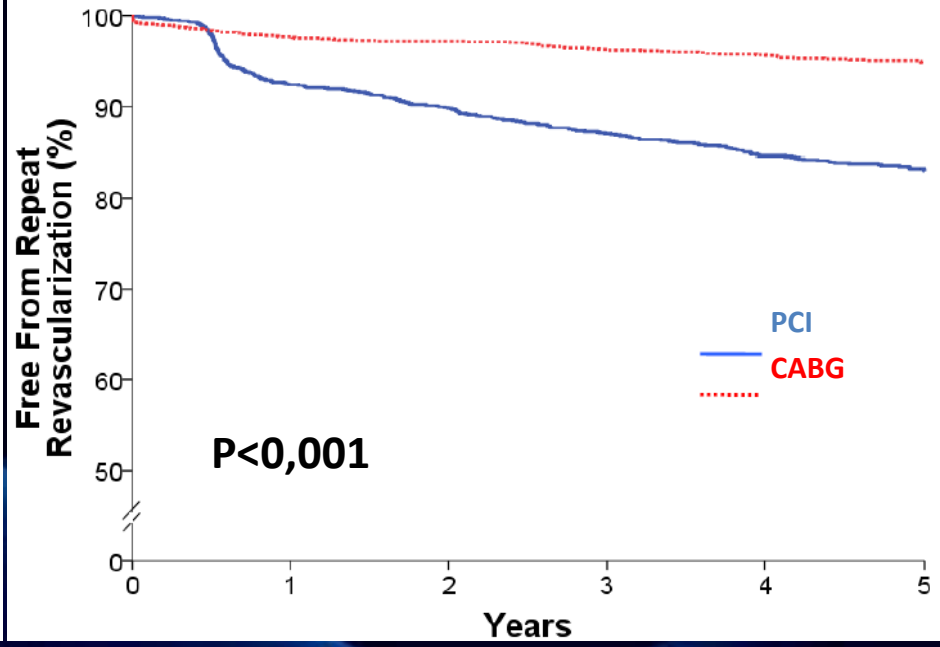


ASAN-Multivessel registry;
Analysis of 3042 “real-world” patients
(1495 CABG and 1547 DES) with multivessel CAD.

Unadjusted K-M Curves: Death, MI, Stroke



Unadjusted K-M Curves: Repeat Revas.



Percutaneous coronary intervention with drug-eluting stents versus coronary artery bypass surgery for multivessel coronary artery disease: a meta-analysis of data from the ARTS II, CARDia, ERACI III, and SYNTAX studies and systematic review of observational data

Summary of Randomized trials/ Registries with historical control

						Drug-eluting stent				Coronary artery bypass graft				
Study	Year	Total patients	DES patients	CABG patients	Stent type	Age	Male	DM	ACS	Age	Male	DM	ACS	Follow-up
ARTS II	2008*	1212	607	605	sirolimus	63±10	77%	26%	36%	61±9	76%	16%	37%	3 year
SYNTAX	2009	1800	903	897	paclitaxel	65±10	76%	26%	29%	65±10	79%	25%	28%	2 year
CARDia	2008	433	179	254	sirolimus	NA	NA	100%	NA	NA	NA	100%	NA	1 year
ERACI III	2007*	450	225	225	Both	65±11	81%	21%	74%	61±10	81%	17%	91%	3 year

DES: drug-eluting stent; CABG: coronary artery bypass graft; DM: diabetes mellitus; ACS: acute coronary syndrome; NA: not available

*The year corresponds to the publication date of the drug-eluting stent cohort. The cohort of patients undergoing CABG was originally published in 2001 for both the ARTS II and ERACI III trials.

Total 3895 pts (DES 1914pts , CABG 1981 pts)

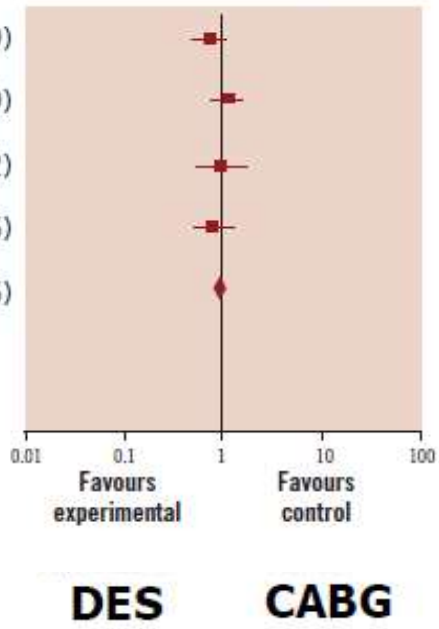
Eurointervention 2010: 6: 269-276

Percutaneous coronary intervention with drug-eluting stents versus coronary artery bypass surgery for multivessel coronary artery disease: a meta-analysis of data from the ARTS II, CARDia, ERACI III, and SYNTAX studies and systematic review of observational data

Risk of Death, MI or STROKE

Study or subgroup	DES Events	DES Total	CABG Events	CABG Total	Wt (%)	Risk ratio M-H, random (95% CI)
ARTS II	50	607	65	605	28.1	0.77 (0.54, 1.09)
SYNTAX	98	903	86	897	41.2	1.13 (0.86, 1.49)
CARDia	18	179	25	254	11.8	1.02 (0.57, 1.82)
ERACI III	30	225	37	225	18.8	0.81 (0.52, 1.26)
Total (95% CI)		1,914		1,981	100.0	0.94 (0.77, 1.16)
Total events	196		213			

Heterogeneity: $Tau^2=0.01$; Q-statistic=3.55, df=3 (P=0.31); $I^2=15\%$
Test for overall effect: Z=0.58 (P=0.56)



* Combined endpoint was not available; the values represent the addition of stroke patients to patients with published results of death or myocardial infarction.

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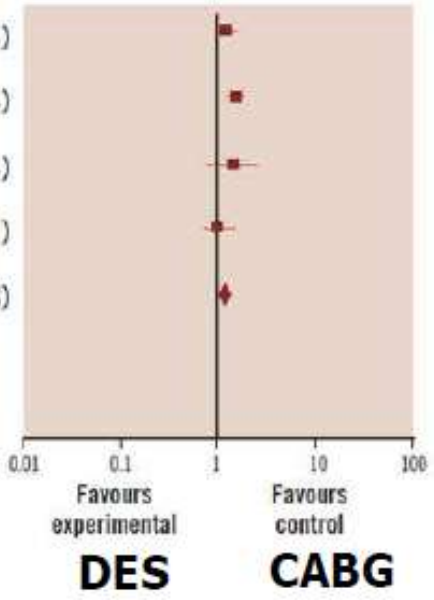
Risk of Major cardiac or cerebral vascular events

RANDOMIZED TRIALS

Study or subgroup	DES Events	DES Total	CABG Events	CABG Total	Wt (%)	Risk ratio M-H, random (95% CI)
ARTS II	117	607	97	605	30.2	1.20 (0.94, 1.54)
SYNTAX	211	903	146	897	43.1	1.44 (1.19, 1.74)
CARDia	27	179	28	254	9.1	1.37 (0.84, 2.24)
ERACI III	51	225	51	225	17.6	1.00 (0.71, 1.41)
Total (95% CI)		1,914		1,981	100.0	1.27 (1.09, 1.48)
Total events	406		322			

Heterogeneity: $Tau^2=0.01$; Q-statistic=3.73, df=3 (P=0.29); $I^2=20\%$
Test for overall effect: Z=3.04 (P=0.002)



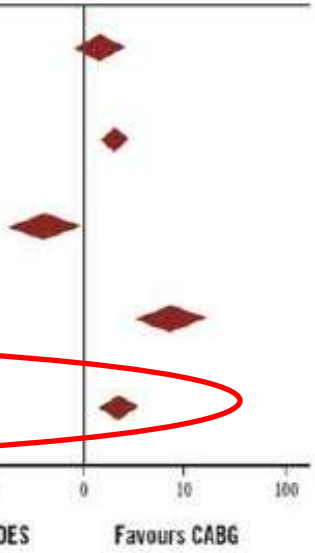
Eurointervention 2010: 6: 269-276

Percutaneous coronary intervention with drug-eluting stents versus coronary artery bypass surgery for multivessel coronary artery disease: a meta-analysis of data from the ARTS II, CARDia, ERACI III, and SYNTAX studies and systematic review of observational data

Pooled Analysis of outcomes from observational studies

11 OBSERVATIONAL STUDIES

Outcome	RR (95% CI)	P	DES No.	DES Total	CABG No.	CABG Total	I^2 (%)
Death	1.18 (0.80-1.75)	0.39	297	5,261	595	8,352	68.4
MI	1.56 (1.22-1.98)	<0.001	126	5,141	147	8,260	0.0
stroke	0.60 (0.33-1.07)	0.08	17	2,541	38	2,963	0.0
TVR	6.44 (3.59-1.07)	<0.001	544	4,614	84	5,126	74.2
MACCE	1.78 (1.24-2.55)	0.002	203	1,233	163	1.655	66.9



17333 pts (7095 DES,10238 CABG)

Eurointervention 2010: 6: 269-276

DES in complex multivessel disease: The Syntax Trial at 4 years: Overall results and breakdown of the 3VD cohort

Patrick W. Serruys, MD PhD
Erasmus Medical Center,
Rotterdam, The Netherlands
On behalf of the SYNTAX investigators

The Moscone Centre 135
9:58–10:10, 7 Nov, 2011

Conflicts of Interest: None

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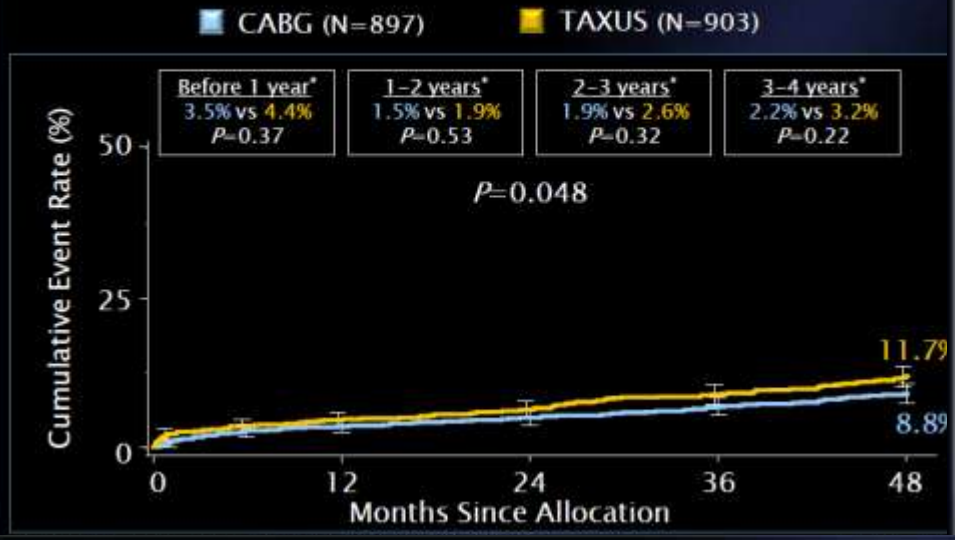
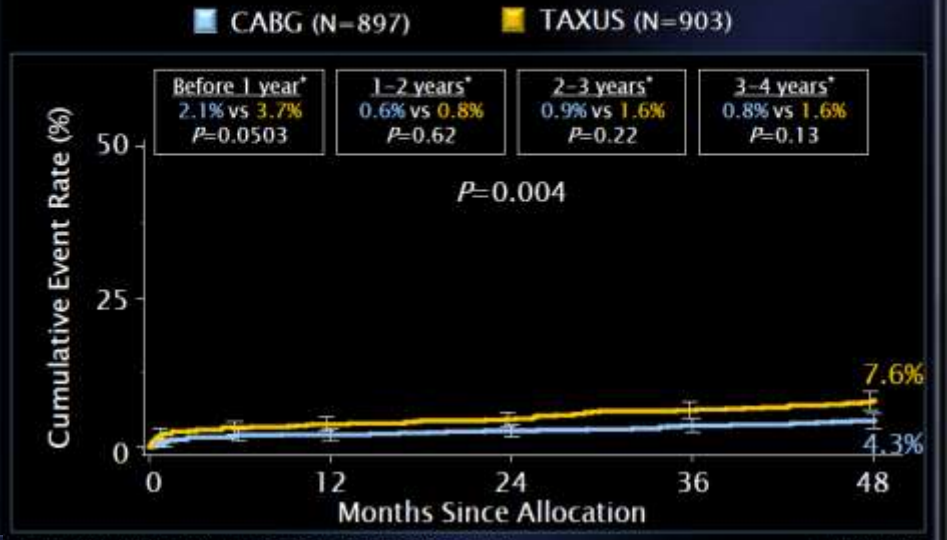
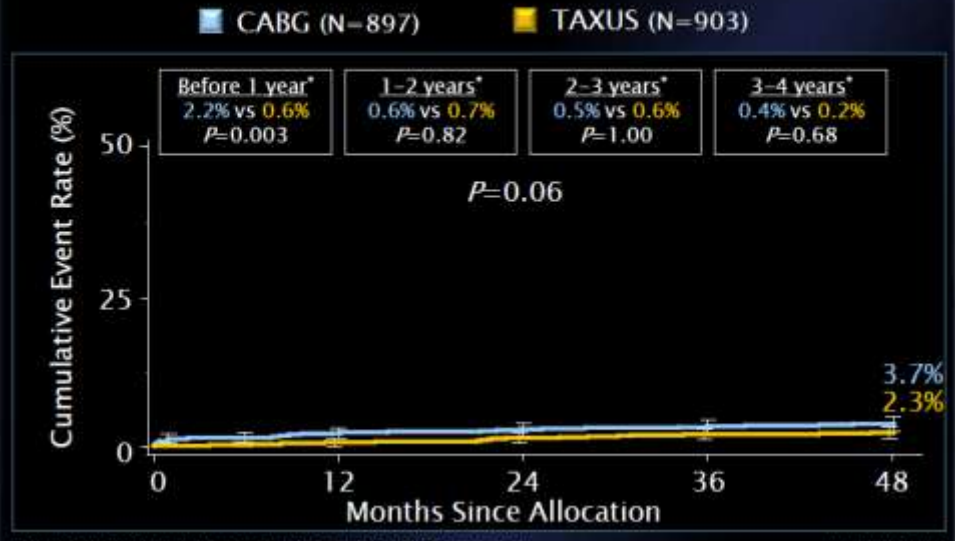
All-Cause Death to 4 Years



Cardiac Death to 4 Years



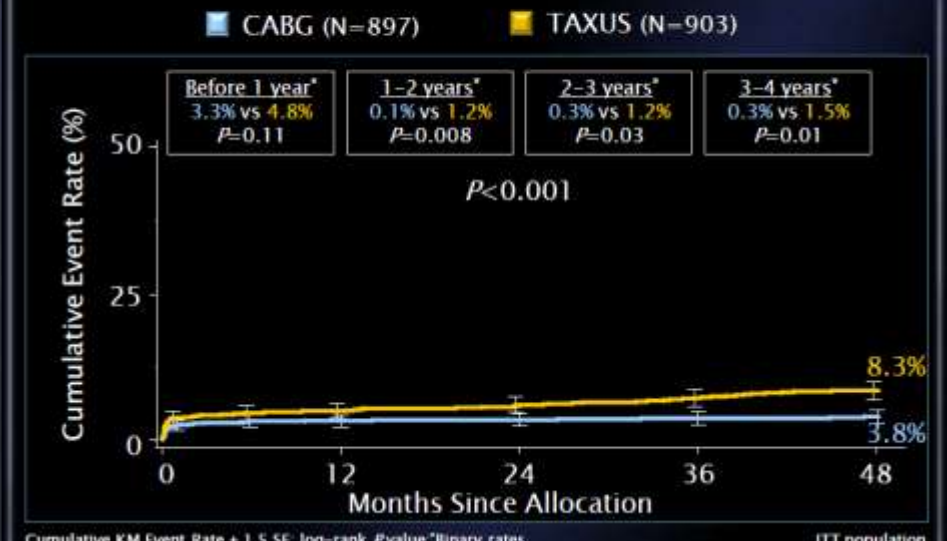
CVA to 4 Years



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

ITT population

Myocardial Infarction to 4 Years

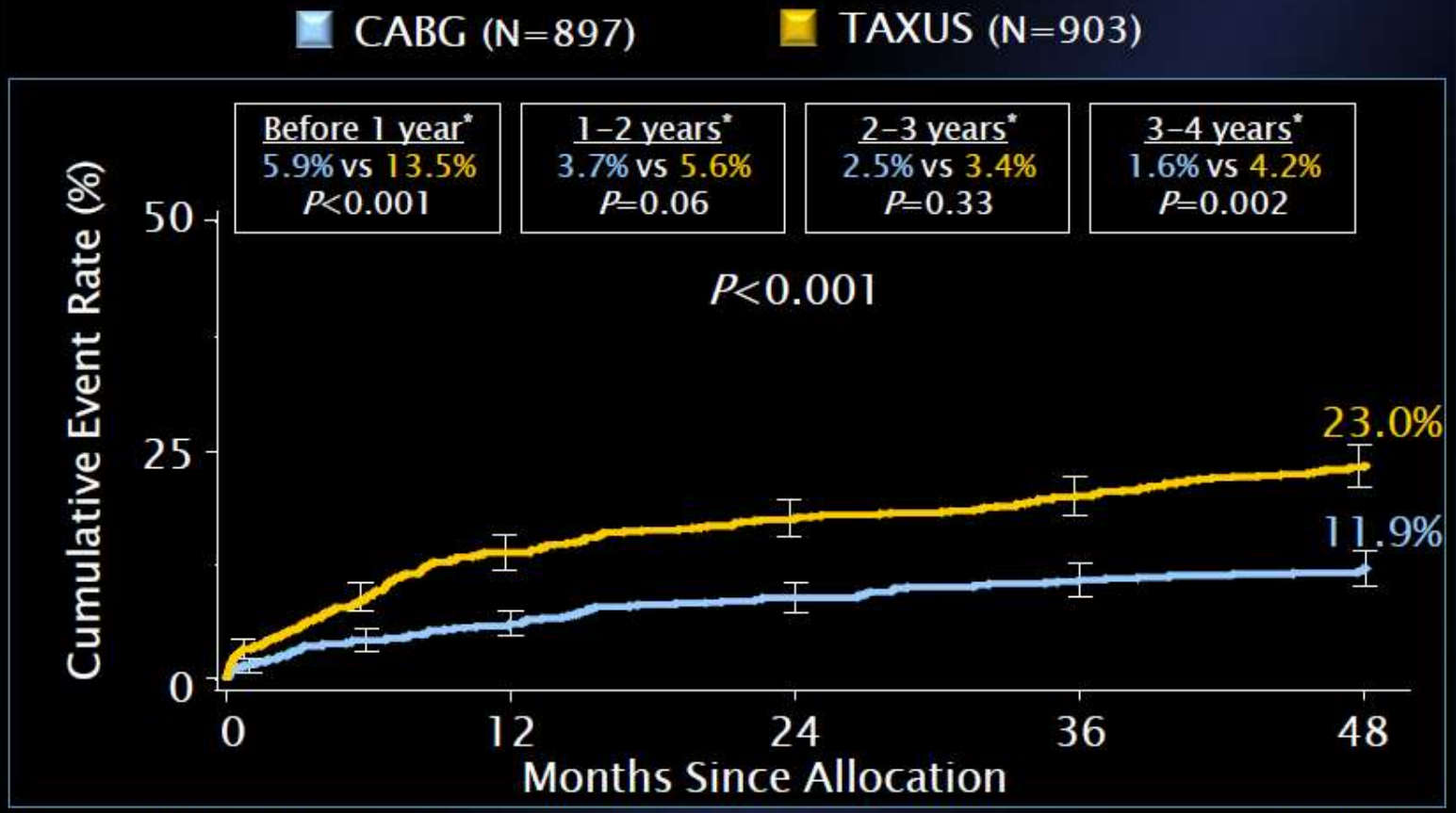


Cumulative KM Event Rate ± 1.5 SE; log-rank *P* value;*Binary rates

ITT population

Repeat Revascularization to 4 Years

SYNTAX



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

ITT population

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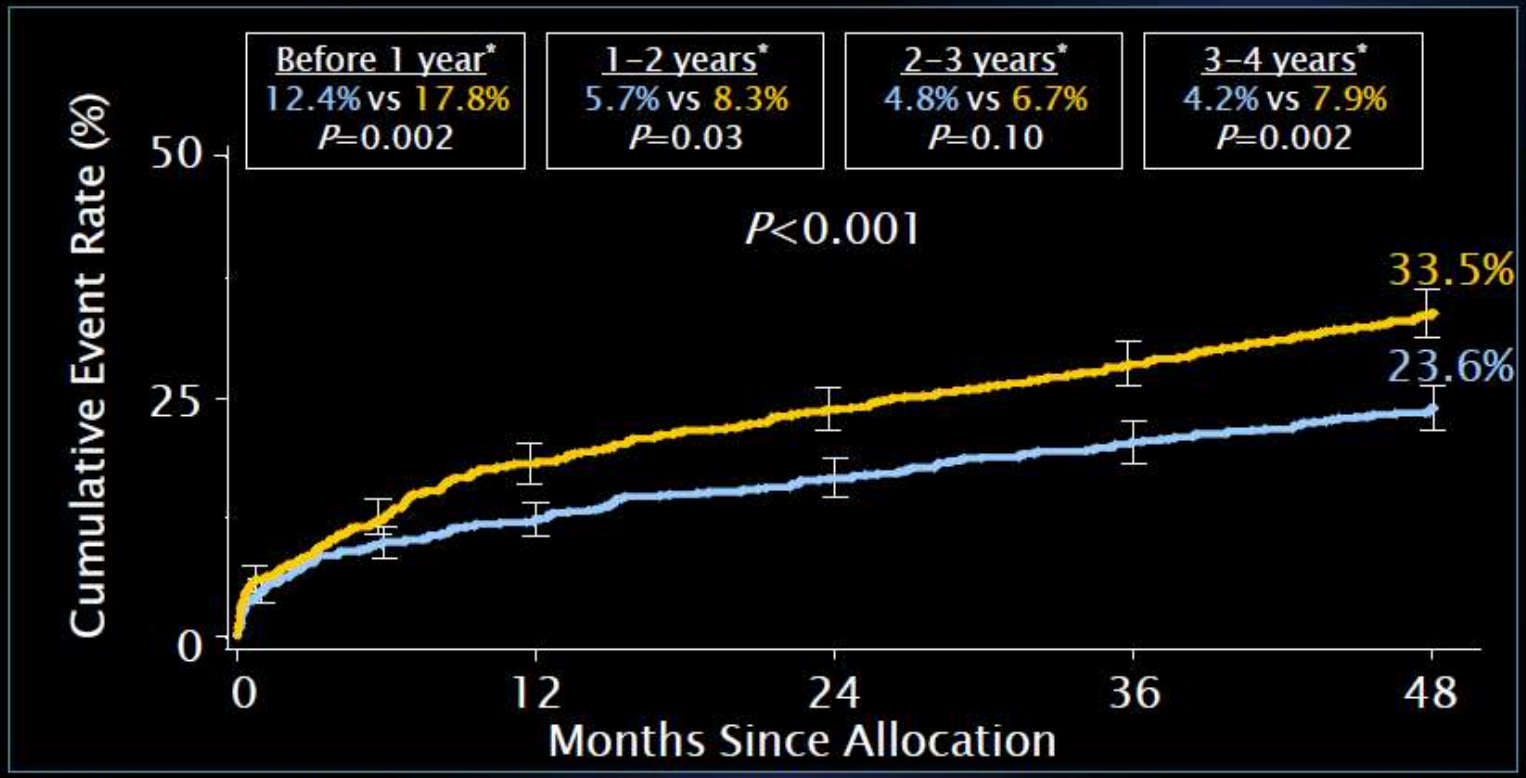
MACCE to 4 Years

SYNTAX

CABG (N=897) TAXUS (N=903)



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

ITT population

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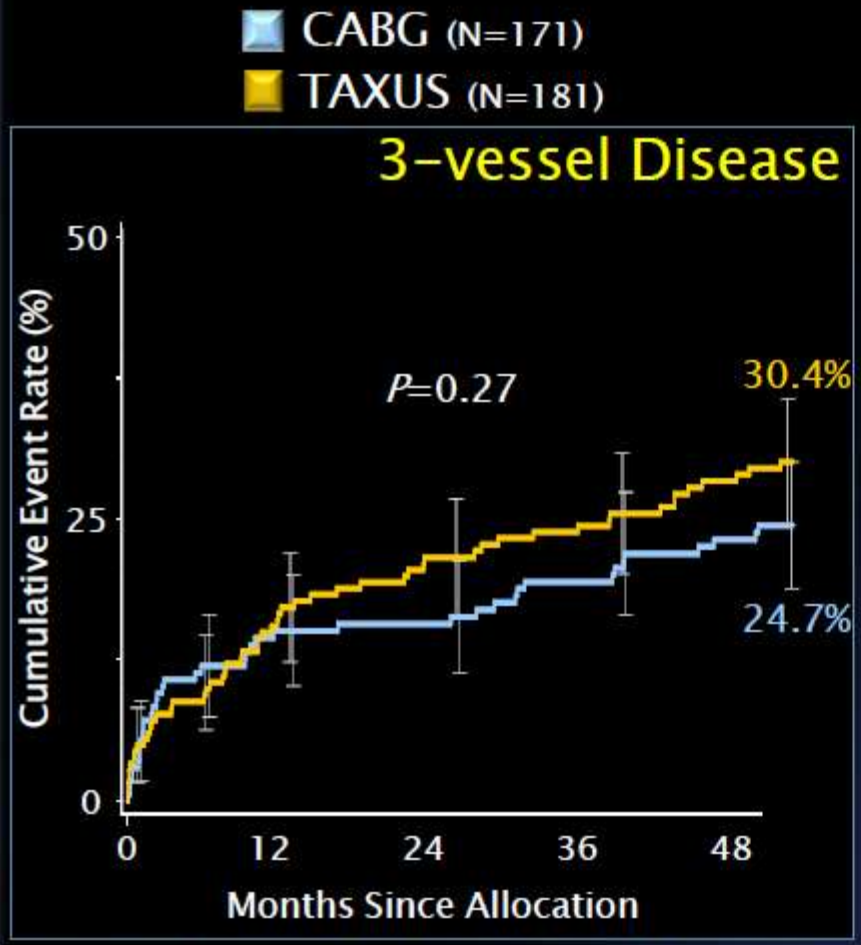
MACCE to 4 Years by SYNTAX Score Tercile *Low Scores (0–22)*



	CABG	PCI	*P* value
Death	8.7%	9.0%	0.92
CVA	3.9% >	1.2%	0.12
MI	4.9%	8.2%	0.27
Death, CVA or MI	14.8%	15.8%	0.84
Revasc.	11.6% <	21.2%	0.02

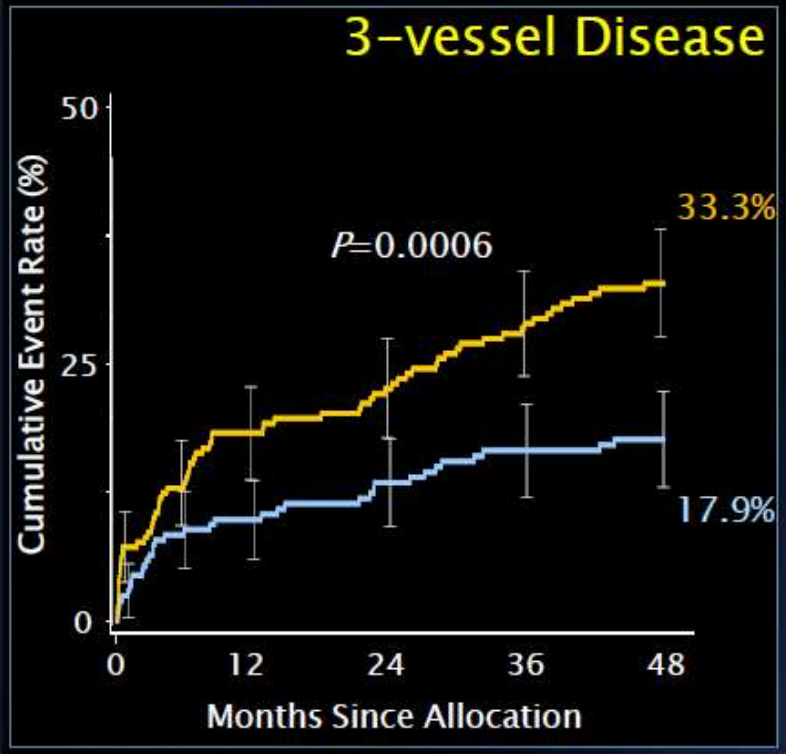
Cumulative KM Event Rate ± 1.5 SE; log-rank *P* value

Site-reported Data; ITT population

MACCE to 4 Years by SYNTAX Score Tercile *Intermediate Scores (23–32)*

SYNTAX

CABG (N=208)
TAXUS (N=207)



	CABG	PCI	*P* value
Death	12.4%	< 18.6%	0.048
CVA	3.6%	> 2.5%	0.53
MI	3.1%	< 10.5%	0.004
Death, CVA or MI	12.4%	< 18.6%	0.09
Revasc.	8.3%	< 21.0%	0.0005

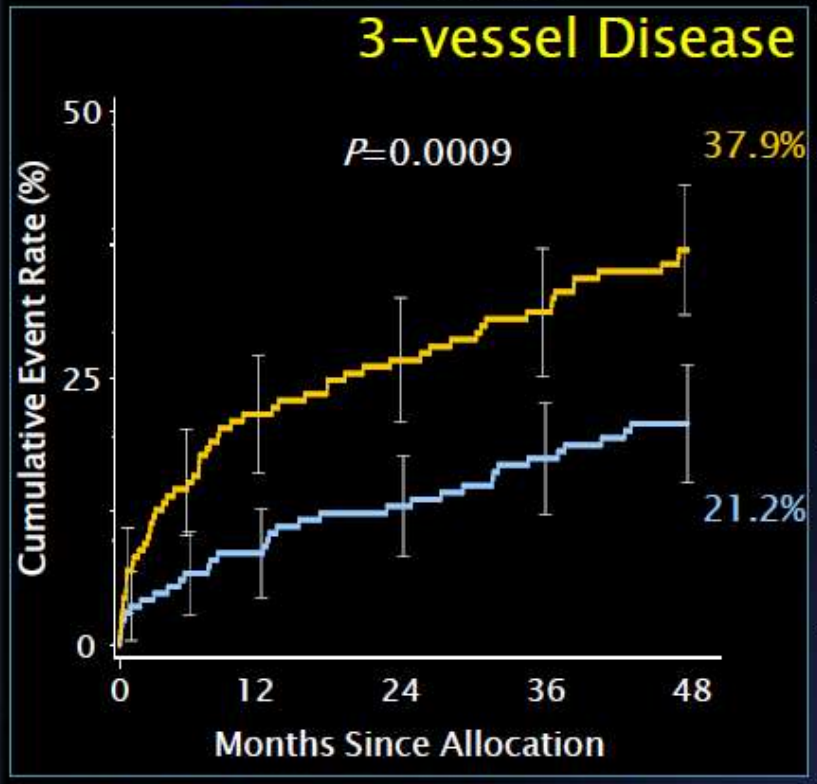
Cumulative KM Event Rate ± 1.5 SE; log-rank *P* value

Site-reported Data; ITT population

MACCE to 4 Years by SYNTAX Score Tercile *High Scores (≥33)*

SYNTAX

CABG (N=166)
TAXUS (N=155)



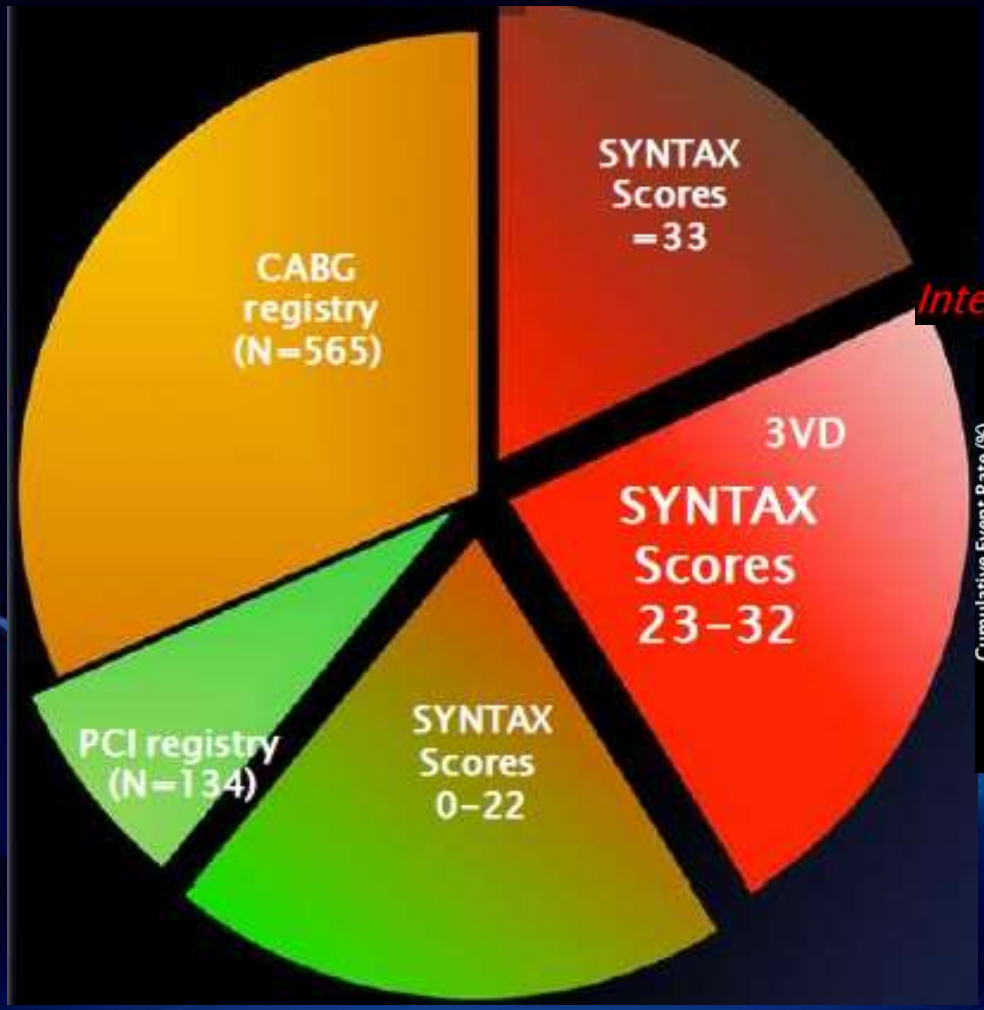
	CABG	PCI	*P* value
Death	6.5%	< 14.5%	0.02
CVA	2.6%	< 5.1%	0.31
MI	1.9%	< 7.9%	0.01
Death, CVA or MI	11.0%	< 22.3%	0.008
Revasc.	11.2%	< 26.7%	0.0005

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

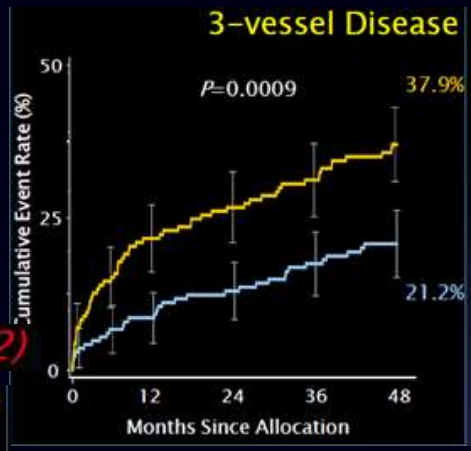
Site-reported Data; ITT population

The 4-year SYNTAX results suggest that CABG remains the standard of care for patients with complex disease (intermediate or high SYNTAX Scores); however, PCI may be an acceptable alternative revascularization method to CABG when treating patients with less complex (lower SYNTAX Score) disease including LM disease

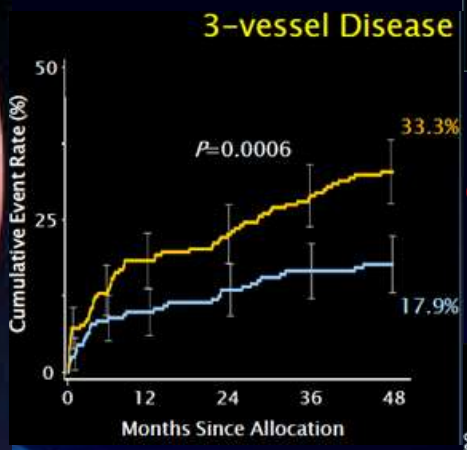
SYNTAX Trial 3VD Patient Distribution



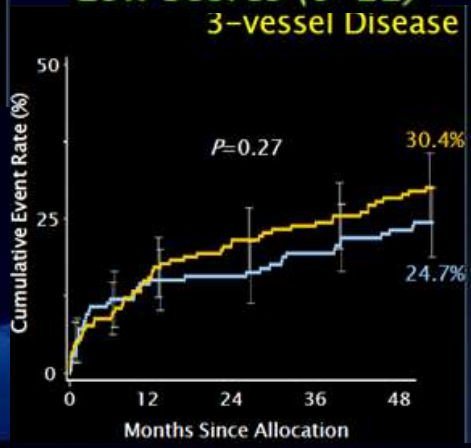
High Scores (≥33)



Intermediate Scores (23–32)



Low Scores (0–22)



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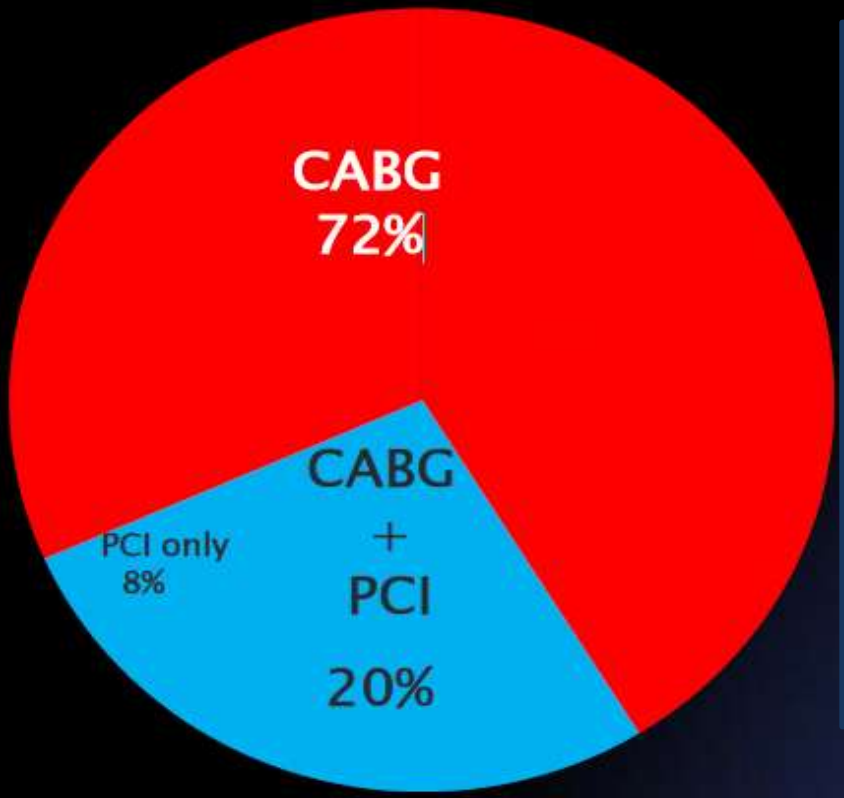
SYNTAX Trial Patient Distribution



Results of the SYNTAX trial suggest that 72% of 3VD patients are still best treated with CABG, however for the remaining patients, PCI is an alternative to surgery at to ….. 4 years

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)

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

Classes of recommendations	Definition
Class IIa	*Weight of evidence/opinion is in favour of usefulness/efficacy.*
Class IIb	*Usefulness/efficacy is less well established by evidence/opinion.*
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.

Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

Based on these data : I can conclude at this point my presentation
No discussion : CABG is preferred in patients with intemediate/high SYNTAX SCORE

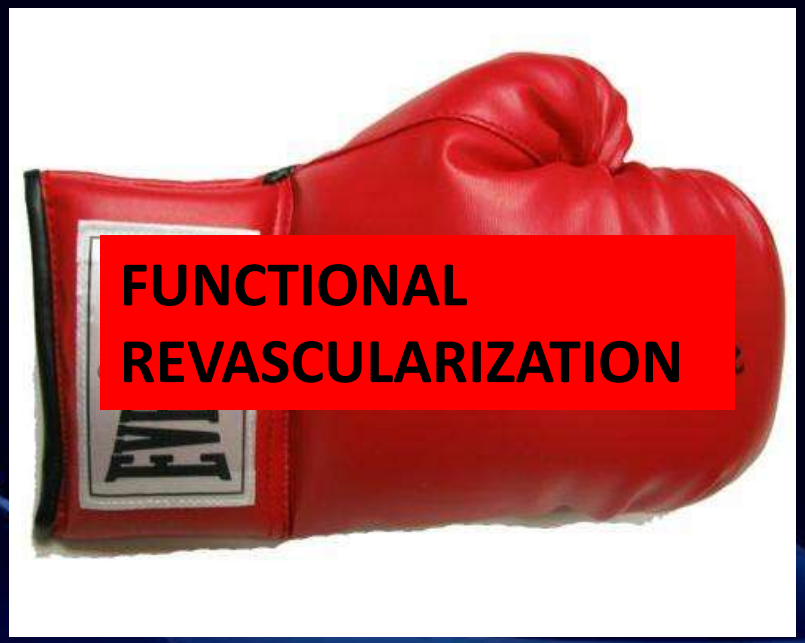
The Selection of Patients with Multi-vessel CAD can Improve Outcomes

Current Guidelines for MVD

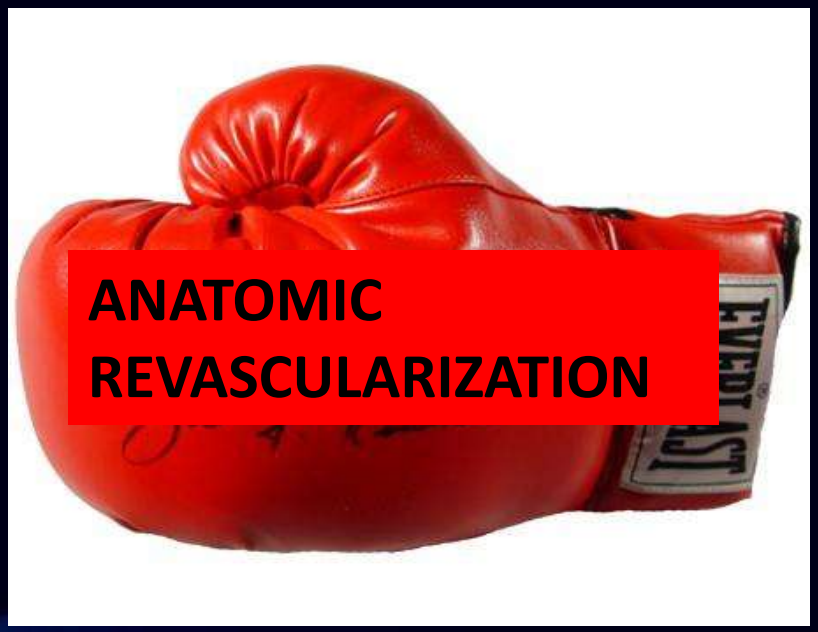
Subset of CAD by anatomy	Favours CABG	Favours PCI	Ref.
1VD or 2VD - non-proximal LAD	IIb C	I C	—
1VD or 2VD - proximal LAD	I A	IIa B	30, 31, 50, 51
3VD simple lesions, full functional revascularization achievable with PCI, SYNTAX score ≤22	I A	IIa B	4, 30–37, 53
3VD complex lesions, incomplete revascularization achievable with PCI, SYNTAX score >22	I A	III A	4, 30–37, 53
Left main (isolated or 1VD, ostium/shaft)	I A	IIa B	4, 54
Left main (isolated or 1VD, distal bifurcation)	I A	IIb B	4, 54
Left main + 2VD or 3VD, SYNTAX score ≤32	I A	IIb B	4, 54
Left main + 2VD or 3VD, SYNTAX score ≥33	I A	III B	4, 54

But, can YOU seriously believe CORONARY ANGIOGRAPHY ?

Wijns W, EHJ 2010;31:2501–2555.


FUNCTIONAL
REVASCULARIZATION

VS

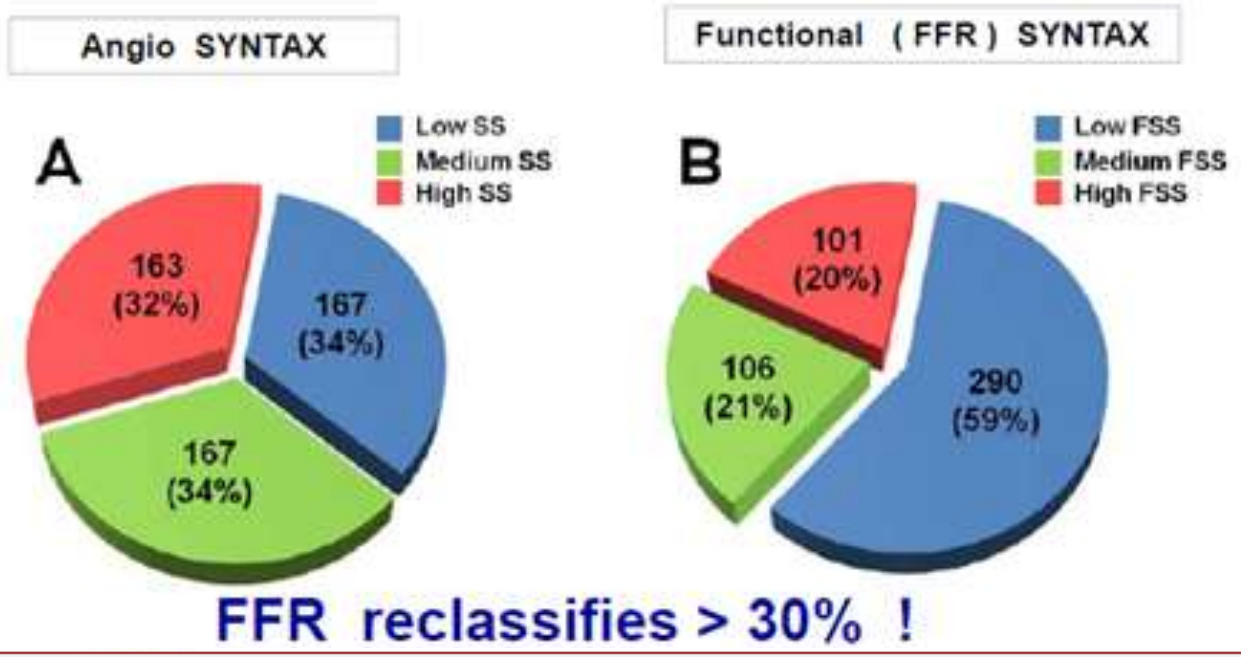

ANATOMIC
REVASCULARIZATION

FUNCTIONAL REVASCULARIZATION

This new approach shed some light on the strategy of PCI treatment in multivessel CAD patients by supporting the evolving paradigm of functionally complete revascularization (ie, stenting of ischemic lesions and medical treatment of nonischemic lesions).

Functional SYNTAX Score

- 497 patients , FFR-guided arm of FAME Study
- 2-3 vessel disease
- Angio Syntax Score : Conventional fashion
- Functional (FFR) Syntax Score : counting only the lesions with FFR < 0.80



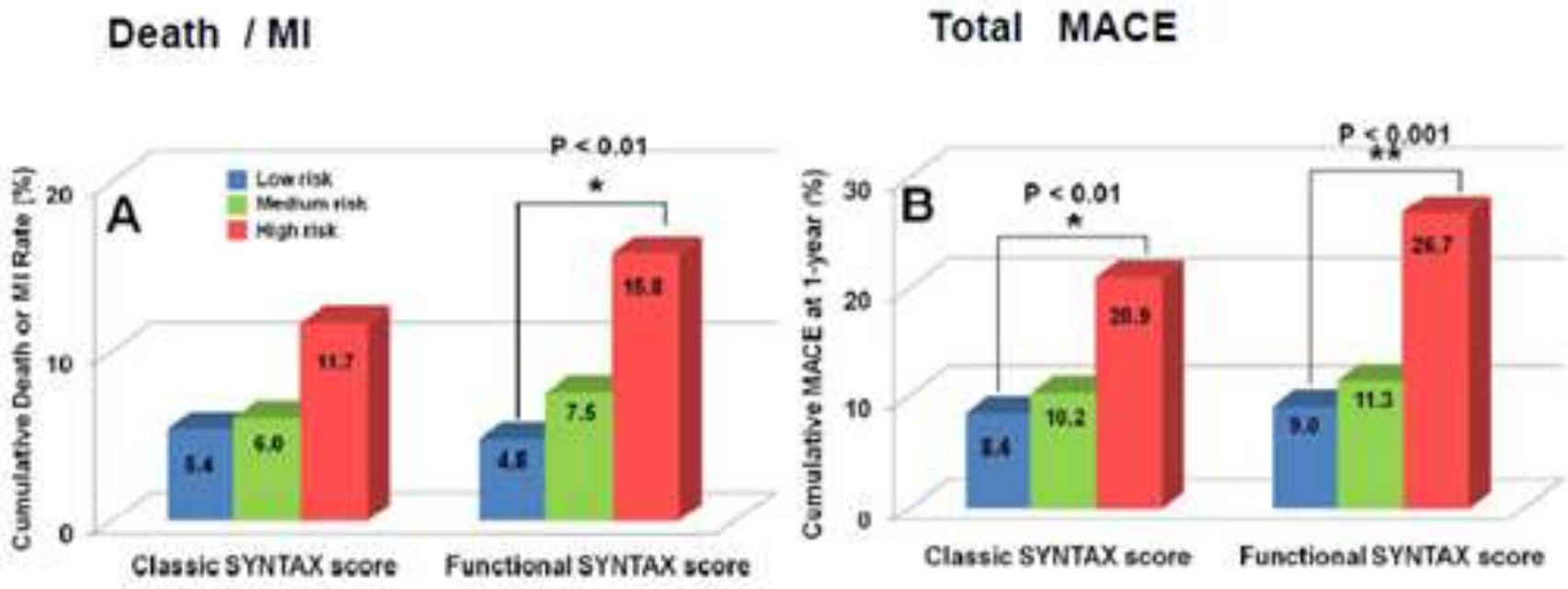
FFR reclassifies > 30% !

The mean FSS decreased by ~25% compared to the mean SS

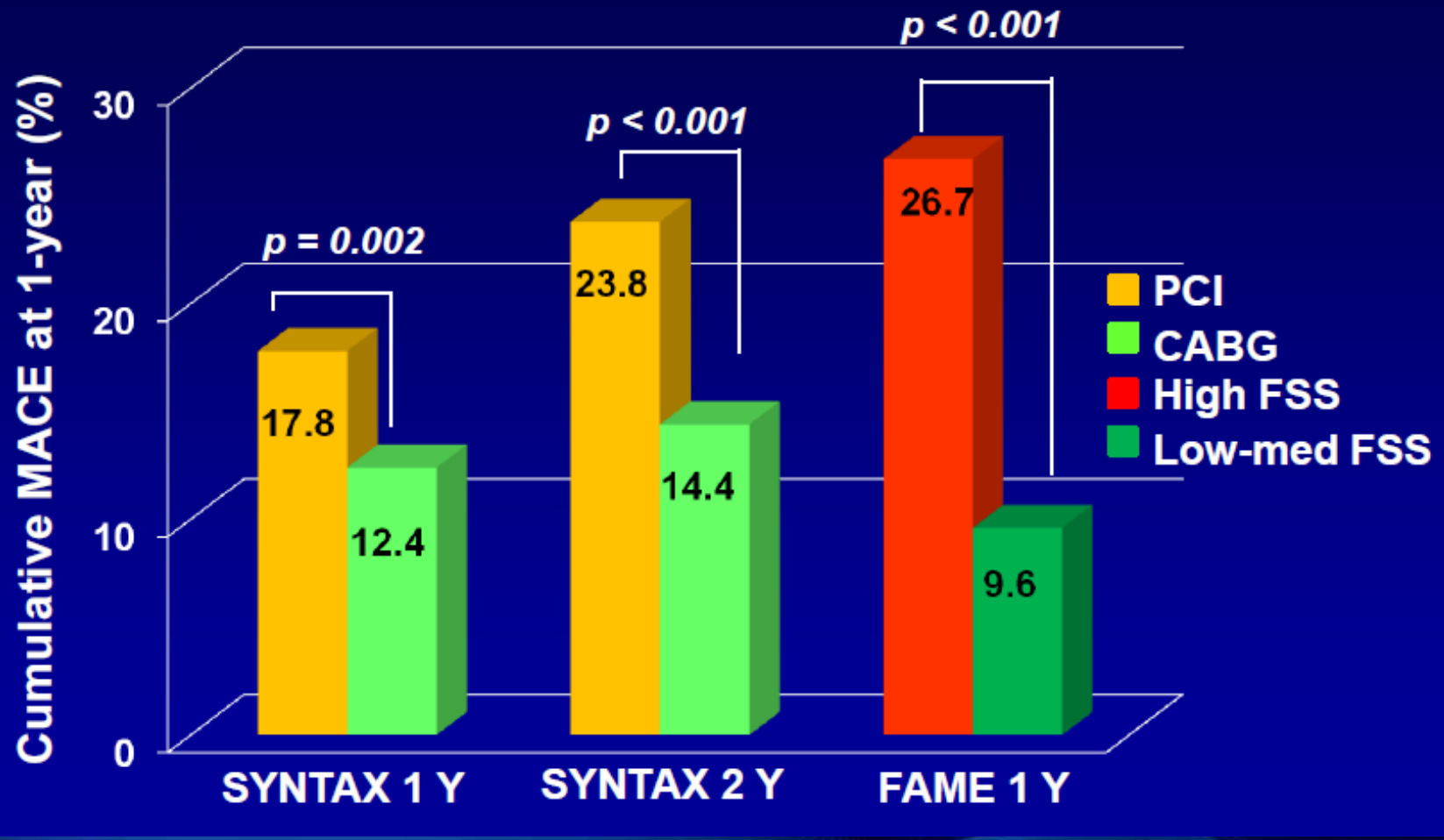
43% of patients with a SS > 22 moved to an FSS < 22

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

Funtctional SYNTAX Score desciminates Risk of Death/MI and Risk of Total MACE



Outcomes of SYNTAX and FAME

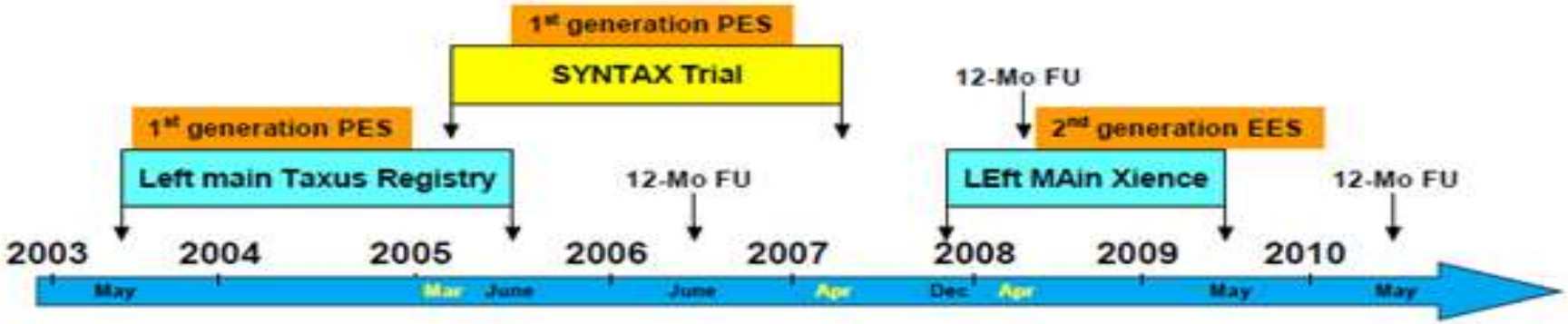


If FFR is applicable in the patients with multi-vessel CAD, the number of lower-risk patients who usually are recommended PCI can be dramatically increased.

The selection of target vessels, the method for revascularization, and the determination of prognosis in patients with multi-vessel CAD are improved by FFR-guided risk in daily practice.

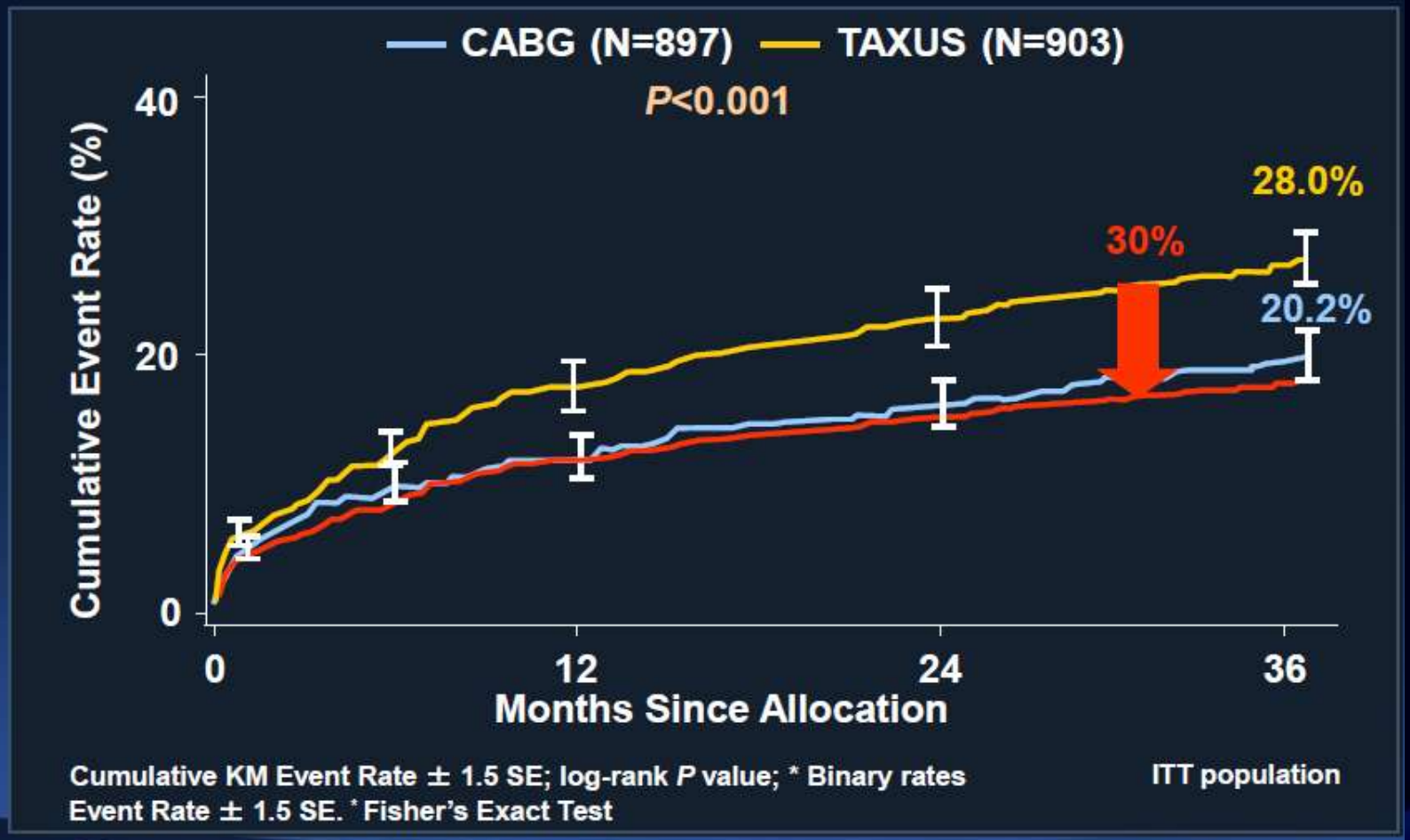
We may reasonably think that the rate of adverse events might have been in favor of PCI if patients had received newer-generation DES?

A Comparison of 12-Months Follow-up After Unprotected Left Main Lesions Stenting Using the Paclitaxel (Taxus) and the Everolimus (Xience)-eluting Stents



Composite endpoints				
Target Lesion Failure	*CD+TVMI+CDTLR*	8 (4.6%)	27 (9.3%)	0.033
MACE	*All D+ All MI+CDTLR+CABG*	12 (6.9%)	36 (12.4%)	0.031

Potential SYNTAX MACCE with 2nd Gen DES



Cumulative KM Event Rate ± 1.5 SE; log-rank *P* value; * Binary rates Event Rate ± 1.5 SE. * Fisher's Exact Test

ITT population

Columbia University Medical Center
NewYork-Presbyterian

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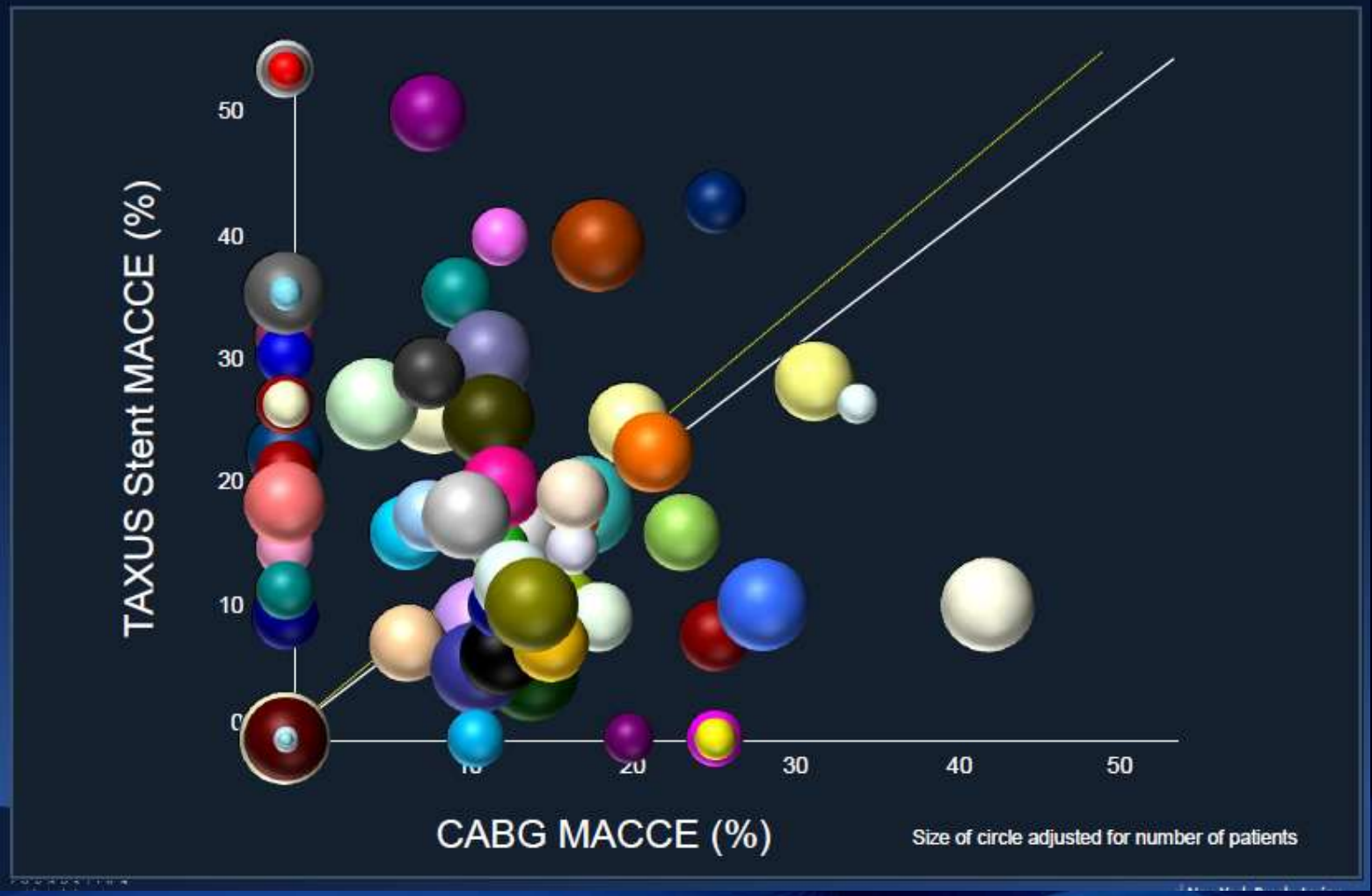
Role of Experience

Operator or device dependent ?

SYNTAX: One-year MACCE Rates by Site

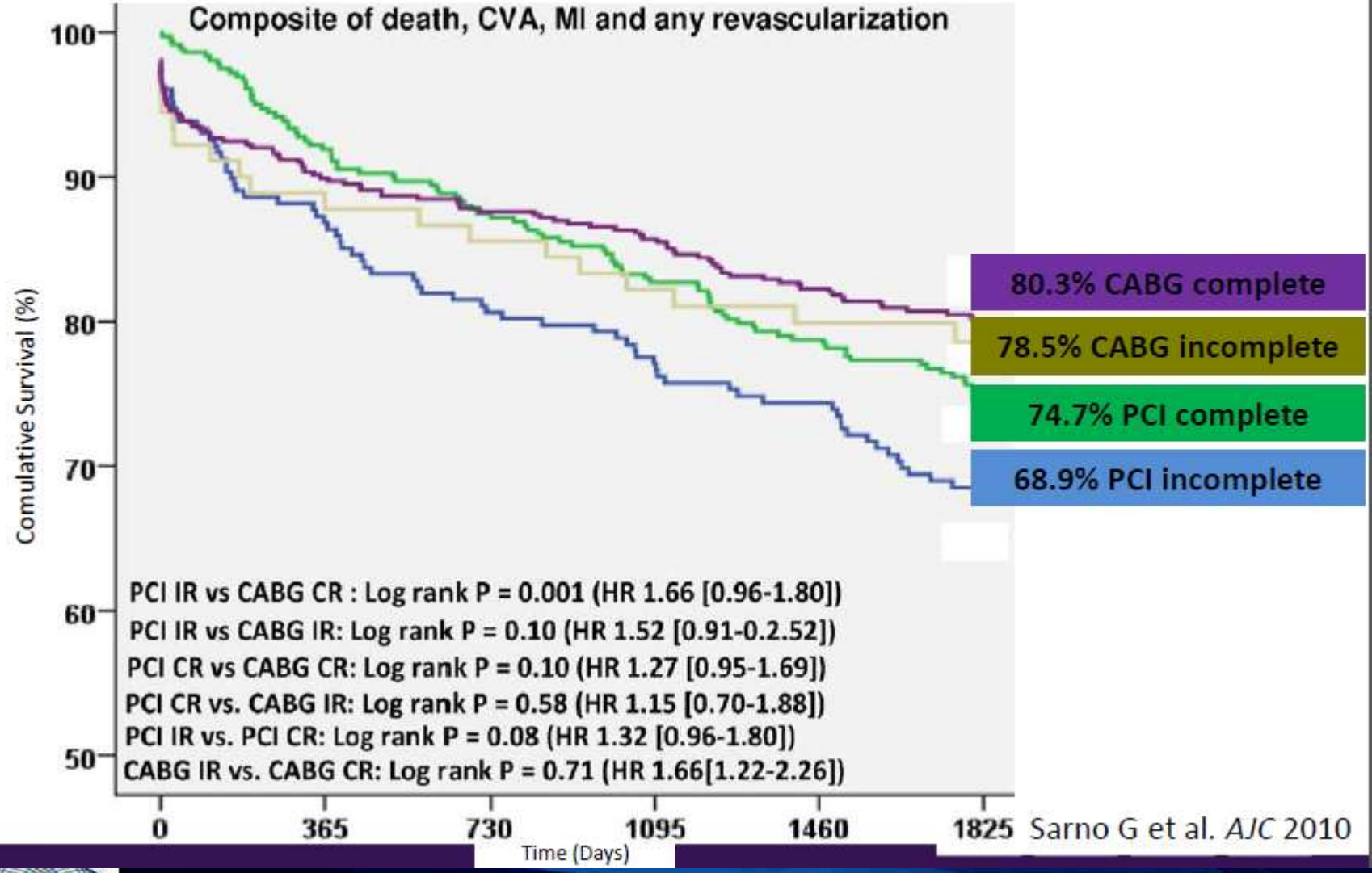


Definitions of Complete Revascularization

Ong AT, Serruys PW. *Circulation* 2006

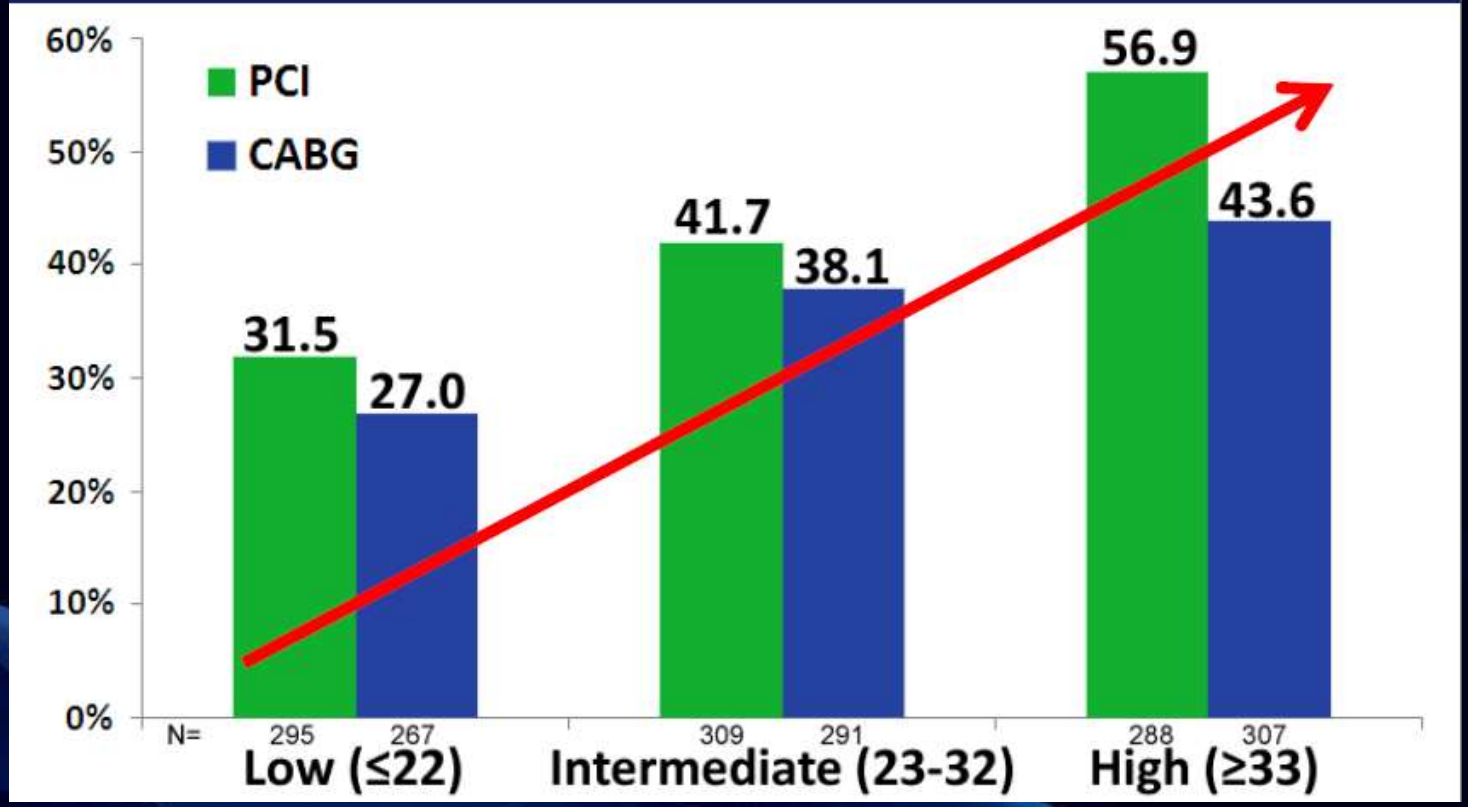
REVASCULARIZATION	DEFINITION
Complete anatomic revascularization	
Unconditional	All stenotic vessels are revascularized, irrespective of size and territory supplied
Conditional	All stenotic vessels greater than a defined diameter are revascularized OR All stenotic main-branch vessels are revascularized
Complete functional revascularization	All ischemic myocardial territories are reperfused; areas of old infarction with no viable myocardium are not required to be reperfused
Complete numeric revascularization	The number of stenotic vessels must equal the number of distal anastomoses
Complete revascularization by a predetermined scoring cutoff value	Scoring of stenoses in different vessels at different locations. The overall extent of disease is a continous variable, the treatment is another variable, and the post-treatment score determines completeness of revascularization
Anatomic	Irrespective of viable myocardium
Functional	Jeopardy score: The post-revascularization score is calculated on the basis of the amount of remaining myocardium at risk

Impact of Completeness of Revascularization on the 5-Year Outcome in PCI and CABG (from the ARTS-II Study)



Sarno G et al. *AJC* 2010

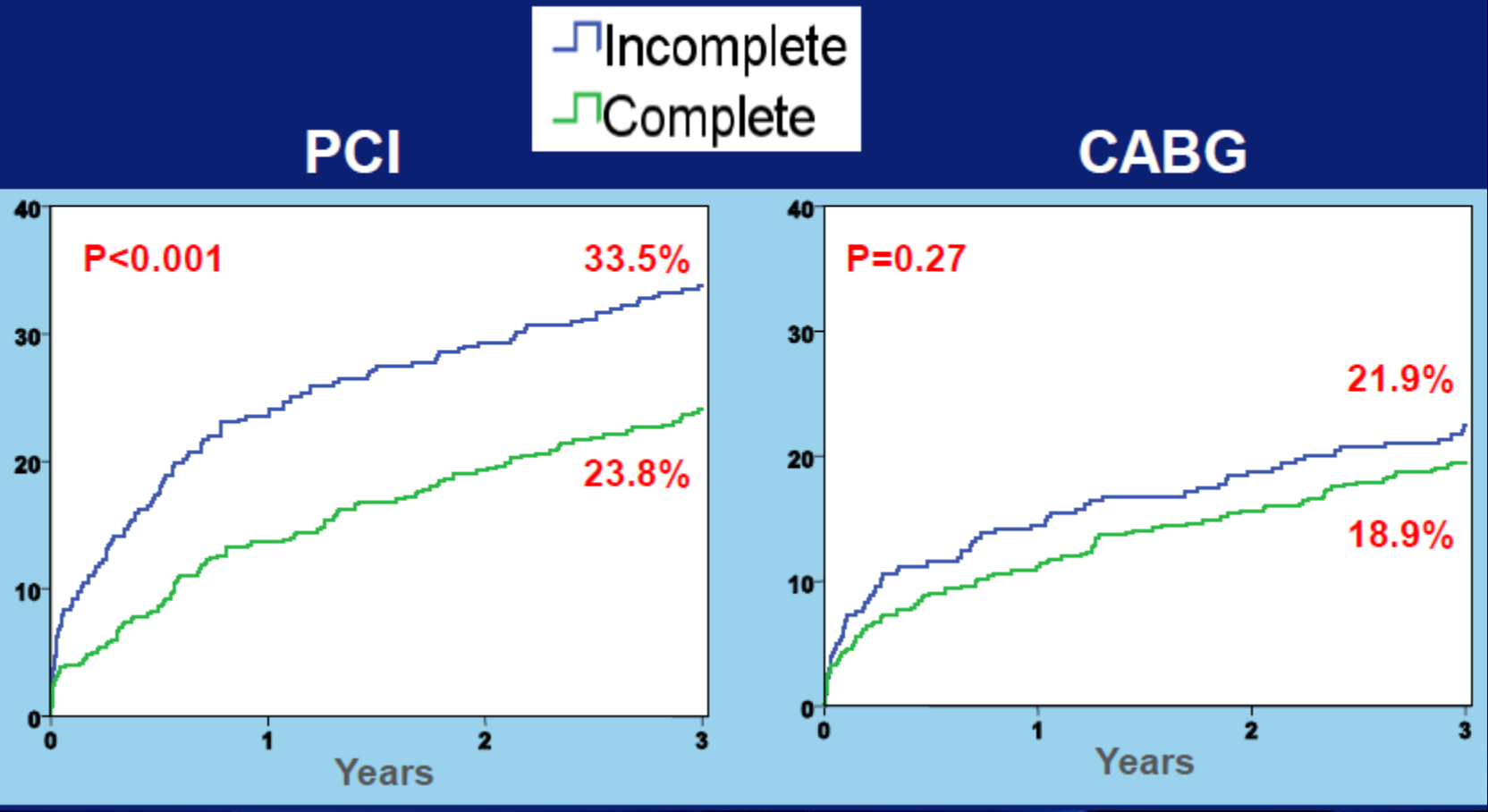
Incomplete revascularization according to SYNTAX score



PCI → 43% (388/896)

CABG → 37% (320/870)

3-year MACCE


Incomplete
Complete
PCI
CABG
P<0.001
33.5%
23.8%
P=0.27
21.9%
18.9%
40
30
20
10
0
0
1
2
3
Years

Unmeasured Confounders

Frailty Assessment Not Captured

Patient A

vs.

Patient B

Same age and predicted risk
One passes the "eyeball test" – one does not

Fundamental Question

WHY DOES CABG HAVE SUCH A SURVIVAL BENEFIT OVER PCI ?

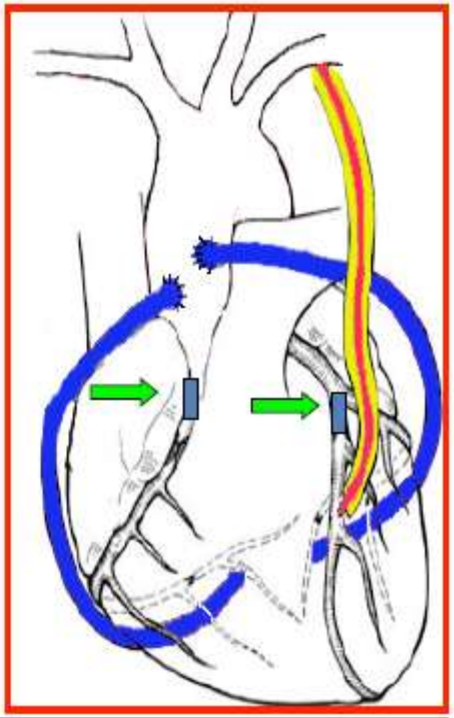
Anatomically, atheroma is mainly located in the proximal coronary arteries

During CABG placing bypass grafts to the **MID CORONARY VESSEL** has **TWO** effects

(i) treats the '**CULPRIT**' lesion (of ANY complexity)

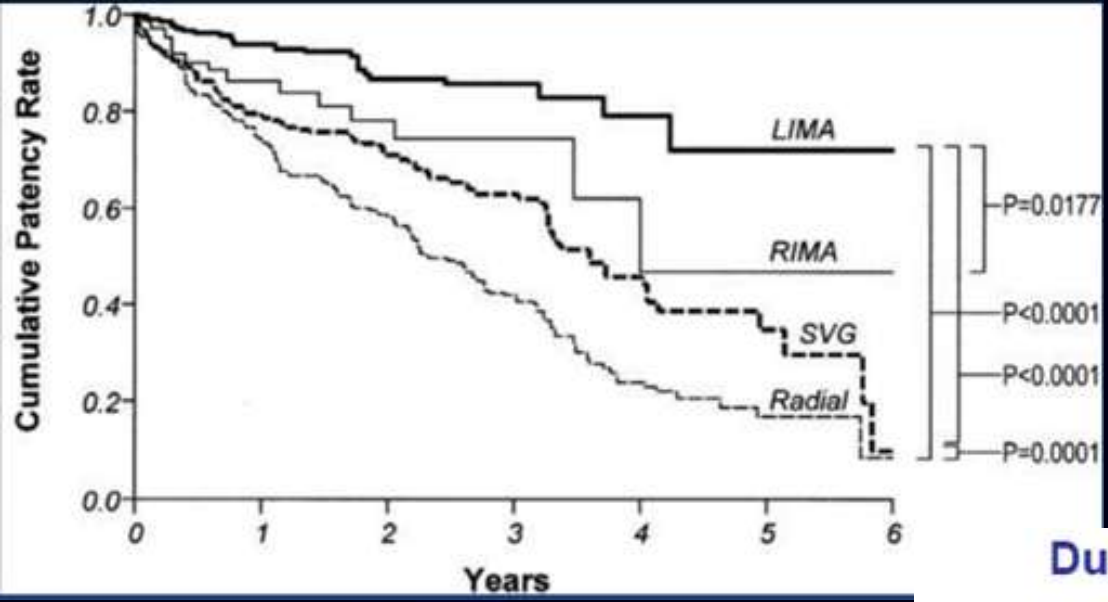
(ii) over the long term, CABG offers prophylaxis against **FUTURE** 'culprit' lesions by protecting whole zones of vulnerable proximal myocardium in diffusely unstable coronary endothelium

- In contrast, PCI with stents ( ) only treats '**SUITABLE**' localised proximal 'culprit' lesions but has **NO PROPHYLACTIC BENEFIT** against new disease (proximal to, within or distal to the stent) which nullifies the benefit of the stent

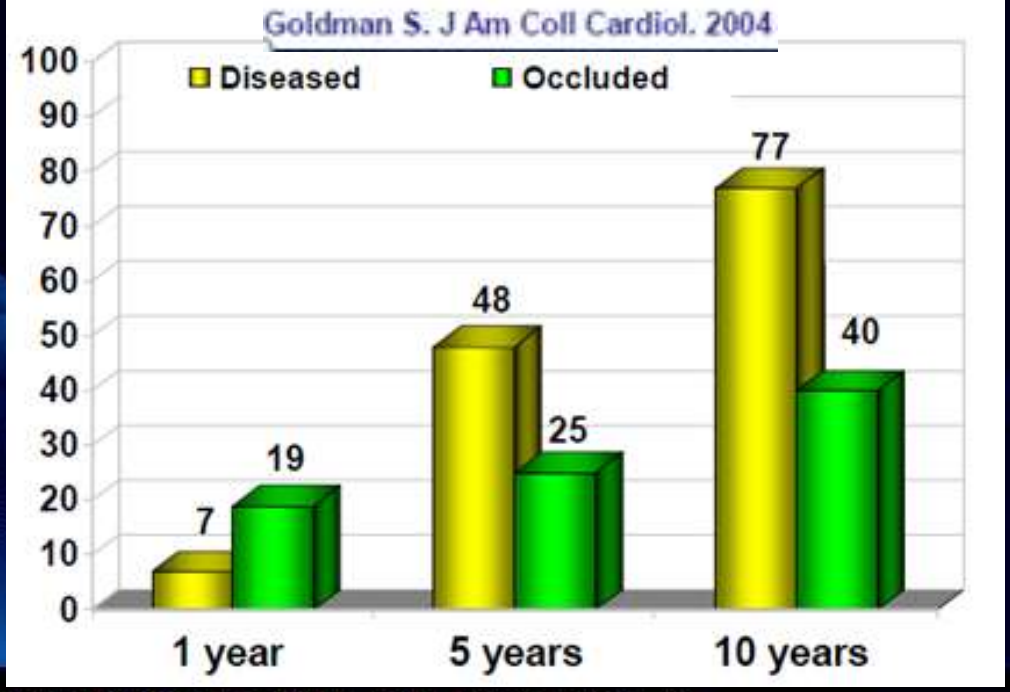


2. PCI means incomplete revascularization (Hannan Circ 2006)
- Of 22,000 PCI 69% had incomplete revascularization
- >2 vessels (+/- CTO) HR for mortality 1.4 (95% CI = 1.1-1.7)

PCI will 'never' match the results of CABG for LM/MVD (POBA;BMS;DES)



Durability of Saphenous Vein Grafts



PREVENT IV Trial

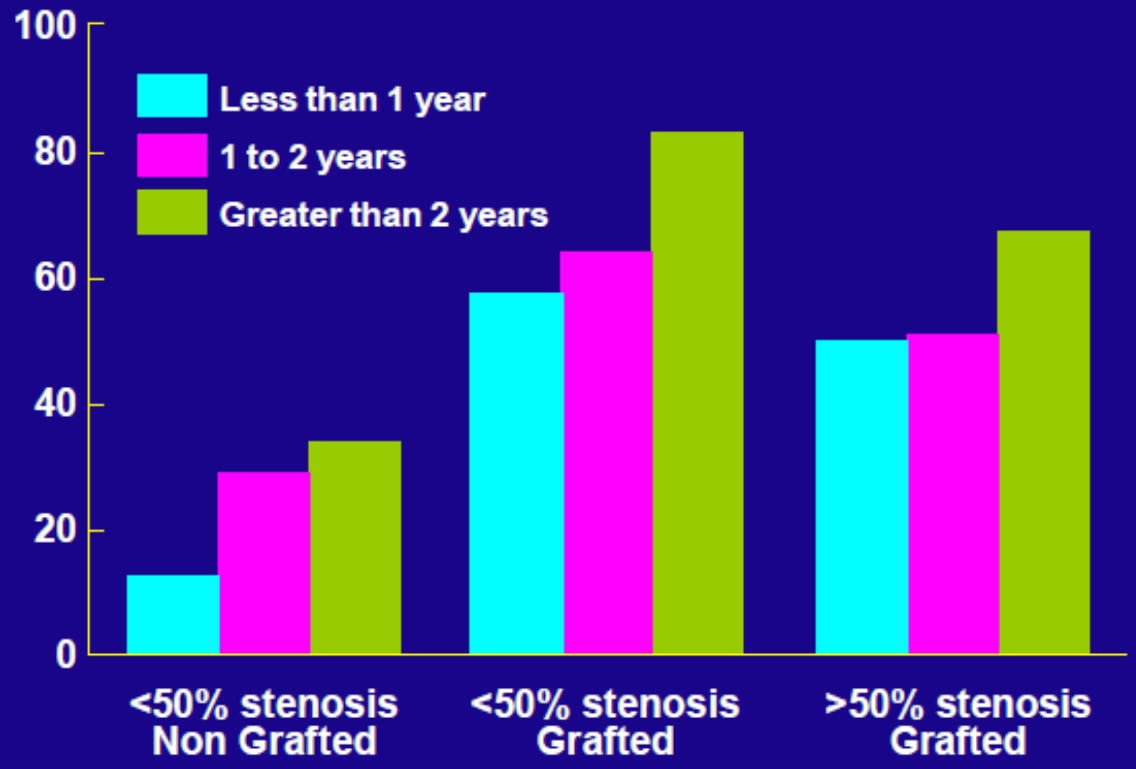
Event	No./Total (%) Edifoligide	Placebo	OR (95% CI)	*P* Value
Per patient				
Vein graft failure	436/965 (45.2)	442/955 (46.3)	0.96 (0.80-1.14)	.66
Vein graft occlusion	403/964 (41.8)	397/951 (41.7)	1.00 (0.84-1.20)	.97
Per vein graft				
Vein graft failure	650/2303 (28.5)	671/2254 (29.7)	0.94 (0.80-1.10)	.44
Vein graft occlusion	601/2295 (26.1)	597/2242 (26.5)	0.98 (0.83-1.15)	.83
Internal thoracic artery graft failure	69/809 (8.5)	60/784 (7.6)	1.12 (0.78-1.61)	.53

Abbreviations: CI, confidence interval; OR, odds ratio.
*Data were available for 1920 of the 2400 angiographic cohort patients. Per vein graft percentages are adjusted for intrapatient correlation.

By 12 months ¼ of SVG's are occluded; 40% of patients had at least one occluded SVG

Percent of Native Arteries with Progression

----- Cosgrove et al. Cleveland Clinic; J Thorac and Cardiovasc Surg 82:520-530, 1981



Progression (> 20% decrease in MLD) of atherosclerosis in native vessels was accelerated by vein grafts and occurred in over 50% of native vessels within 2 years of surgery

You Can Call Me Now…

…Or You Can Call Me Later

Vein graft failure profoundly increased death, MI and revascularization

Table 5. Clinical Event in Patients by Vein Graft Failure Status

Type of Event	No./Total (%) of Patients	
	Vein Graft Failure (n = 878)	No Vein Graft Failure (n = 1042)
Perioperative MI in CABG surgery	118 (13.4)	71 (6.8)
Death or MI*	122 (13.9)	9 (0.9)
Death, MI,* or revascularization	228 (26.0)	19 (1.8)

Abbreviations: CABG, coronary artery bypass graft; MI, myocardial infarction.
*Not including perioperative MI in CABG surgery.

Saphenous vein graft failure

+ Native disease acceleration

= A very difficult day for the Interventional cardiologist!

HELLENIC INSTITUTE OF CARDIOVASCULAR DISEASES

Joint ESC/EACTS Guidelines for Myocardial Revascularization 2010

4.1 Patient Information

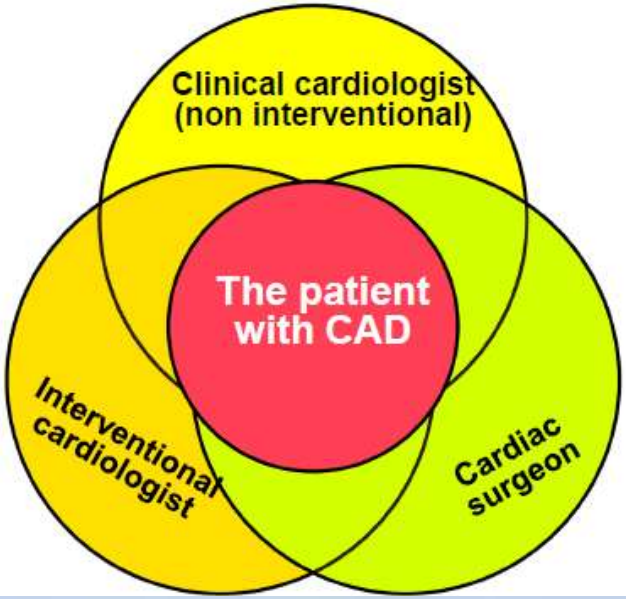
Patient information needs to be objective and unbiased, patient orientated, evidence based, up-to-date, reliable, understandable, accessible, relevant and consistent with legal requirements. Informed consent requires transparency, especially if there is controversy about the indication for a particular intervention. Specialty bias and self referral should not interfere with the process.

4.2 Multidisciplinary decision making (Heart Team)

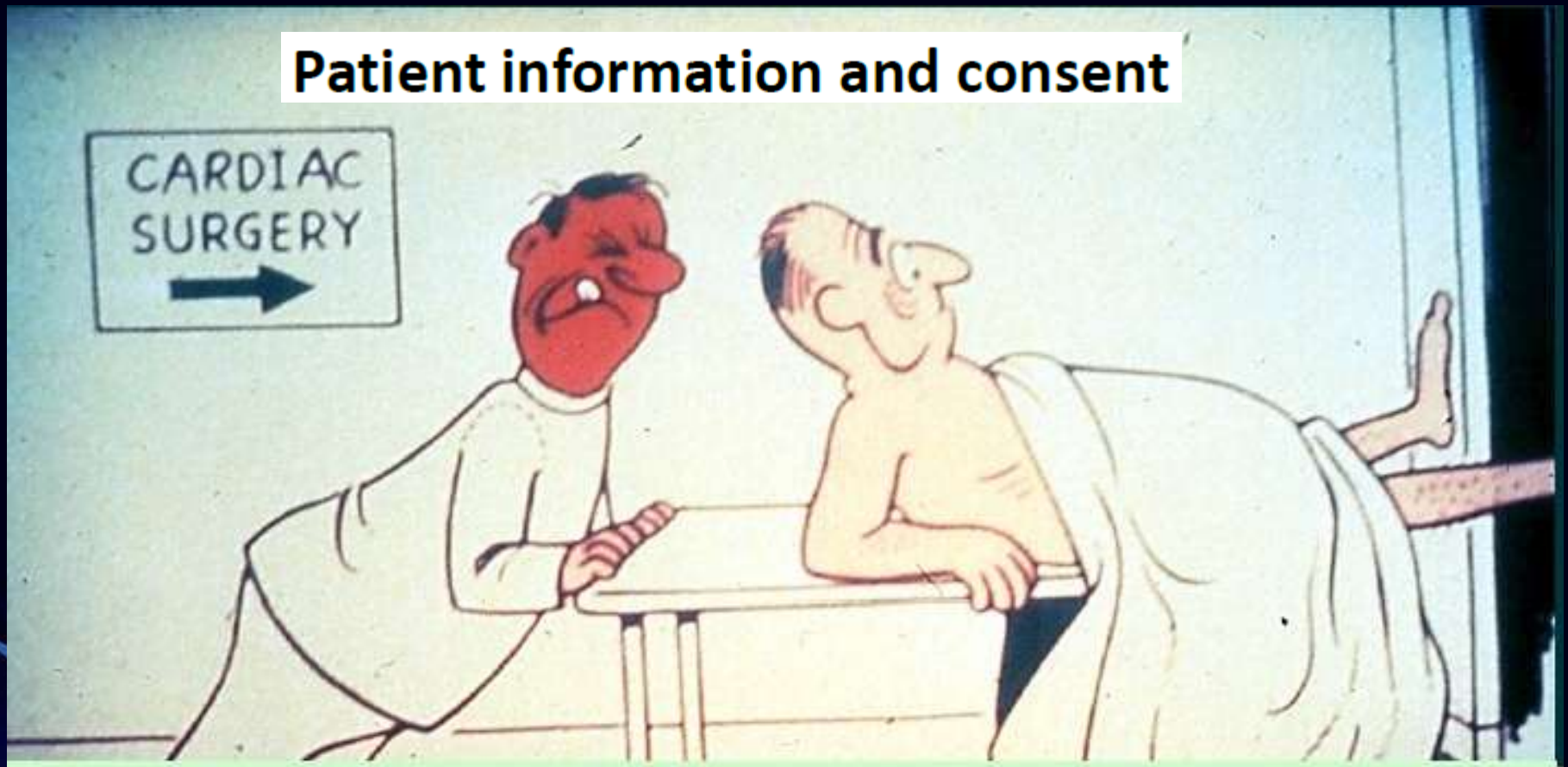
The creation of a Heart Team serves the purpose of a balanced multidisciplinary decision process. Standard protocols compatible with the current Guidelines may be used to avoid the systematic need for case-by-case review of all diagnostic angiograms.

	Class	Level
It is recommended that patients be adequately informed about the potential benefits and short- and long-term risks of a revascularisation procedure. Enough time should be spared for informed decision making.	I	C
The appropriate revascularisation strategy in patients with MVD should be discussed by the Heart Team.	I	C

The Heart Team



Patient information and consent



When asked, most patients will prefer the less invasive PCI over surgery

Risk/benefit tradeoff

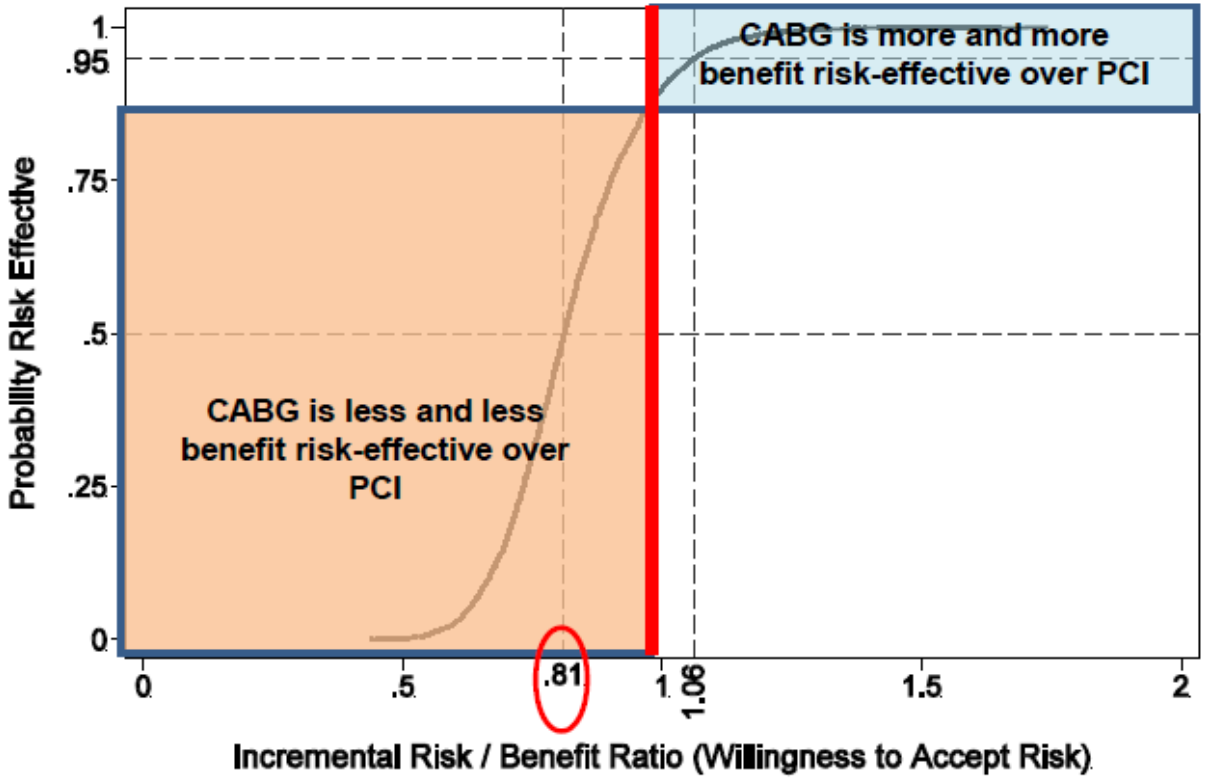
Quantification of a level of risk that a patient would be willing to accept to maintain his present functional state.

Risk/benefit tradeoff

For some, exchanging the increased risk of repeat PCI or CABG to obtain short-term pain relief and a rapid return to full mobility will be acceptable, whereas others may prefer to endure short-term pain to obtain a higher probability of avoiding a subsequent revascularization.

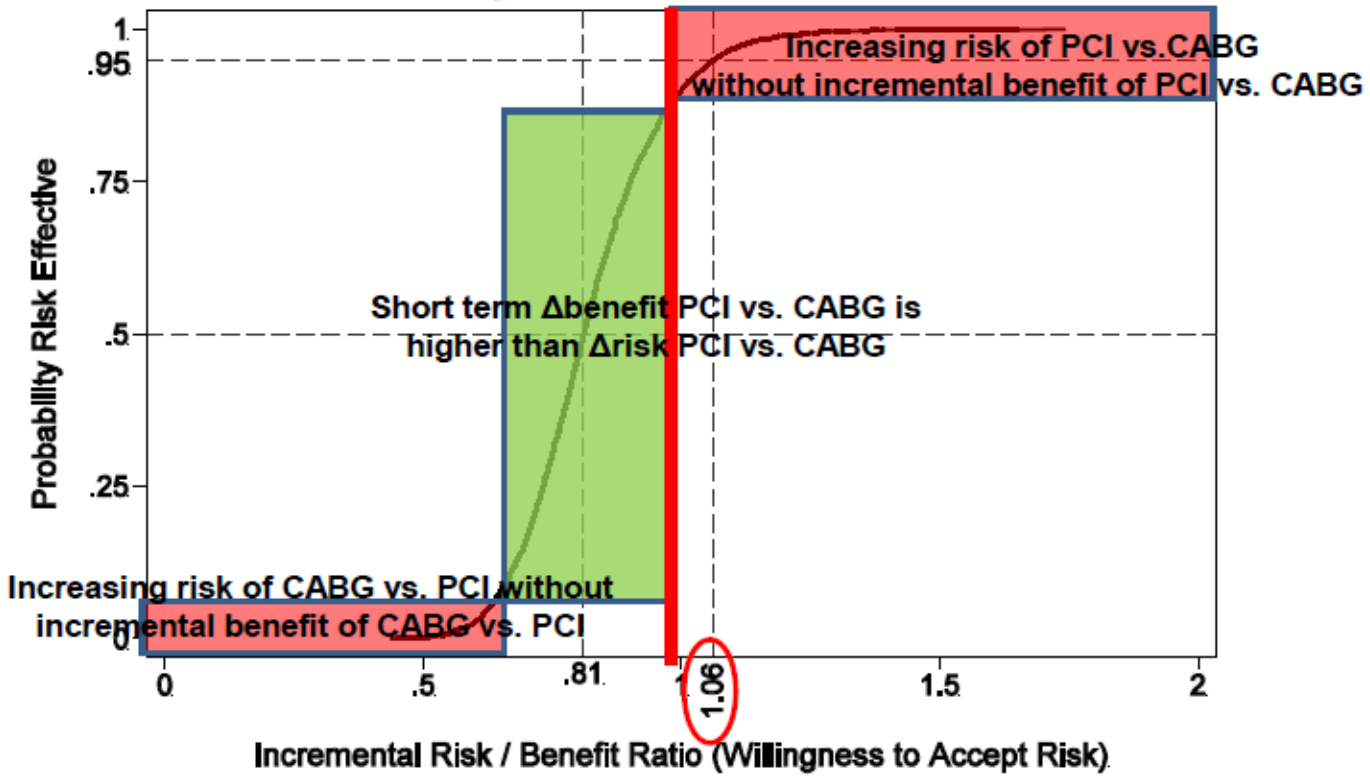
Consequently, from the patient's perspective, the balance between these conflicting considerations appears to play a crucial role in the identification of the preferred revascularization strategy.

Risk benefit acceptability curve for incremental risk of additional revascularization within 3 years vs. freedom from pain at 1 month



In ARTS I, PCI patient or his/her physician faced a risk of 0.81 additional revascularization events over 3 years in exchange for being pain-free at one month

Risk benefit acceptability curve for incremental risk of additional revascularization within 3 years vs. freedom from pain at 1 month



A patient or his/her physician would need to be willing to tolerate a risk of 1.06 additional revascularization at 3 ys PCI over CABG in order to be 95% confident that choosing PCI over CABG is risk-effective


PCI versus CABG
its not over yet

Draft design

EXCEL: Study Design

4000 pts with left main disease

↓

SYNTAX score ≤32

Consensus agreement by heart team

↓ Yes (N=2500) → R

→ No (N=1500) → PCI and CABG registries (limited in-hosp data)

- **PCI (Xience Prime)** (N=1250)
- **CABG** (N=1250)

Clinical follow-up: 30 days, 6 months, yearly through 5 years

FAME II

Stable patients scheduled for one-, two- or three vessel DES stenting

↓

FFR in all indicated stenoses

- **There is at least one Stenosis With FFR ≤ 0.80** → 1:1 Randomization
  - PCI+OMT → **Cohort A**
  - OMT → **Cohort A**
- **There is no Stenosis with an FFR ≤ 0.80** → OMT → **Cohort B**

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

ASCERT Study

ACCF-STS Collaboration on the Comparative Effectiveness of Revascularization sTrategies

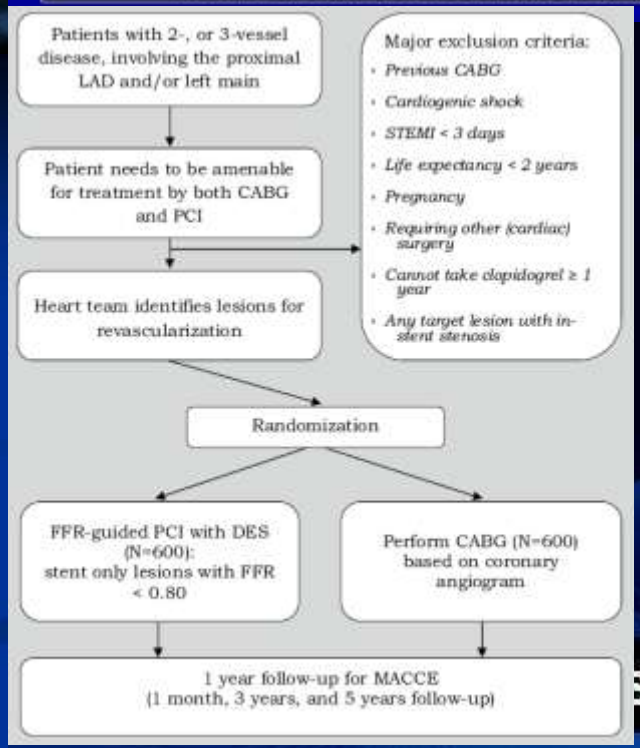
NHLBI, NIH funded STS Database & NCDR linkage [15M pts]; CMS 100% denominator file data

- 3-5 yr results of PCI, CABG
  - Death rates
  - Repeat revascularization
  - Rehospitalizations
  - Presentation of new cardiac disease conditions
  - Medication requirements at various time points

PI's: William Weintraub (NCDR), Fred H. Edwards (STS Database)

FAME III

CABG vs FFR-guided PCI



Guidelines on myocardial revascularization

ACCF/SCAI/STS/AATS/AHA/ASNC

The Future…?

Subset of CAD by anatomy	Favours CABG	Favours PCI
LOW GLOBAL RISK	I A	I B
INTERMEDIATE GLOBAL RISK	I A	III B
HIGH GLOBAL RISK	I A	III B

Classes of recommendations	Definition
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.
Class IIa	*Weight of evidence/opinion is in favour of usefulness/efficacy.*
Class IIb	*Usefulness/efficacy is less well established by evidence/opinion.*
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.

Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

In Making the decision, consider

- What is the Syntax score?
- Can we achieve complete revascularization?
  - Is revascularization of an occluded RCA important?
- Are the vessels heavily calcified?
- Is the patient a diabetic?
- Do co-morbid considerations make the patient a poor candidate for CABG?
- Will/can patient take antiplatelet therapy?
- Patient´s willingness

Our experience in patients with 3-vessel disease

114 consecutive patients

Mean age 63 years (range: 37 to 83 years).

Average stented length per patient was 86.6±28.9mm

Clinical follow-up was available from 109 patients and during a period of 31.3±19.3 months (range: 4 to 68 months) there were:

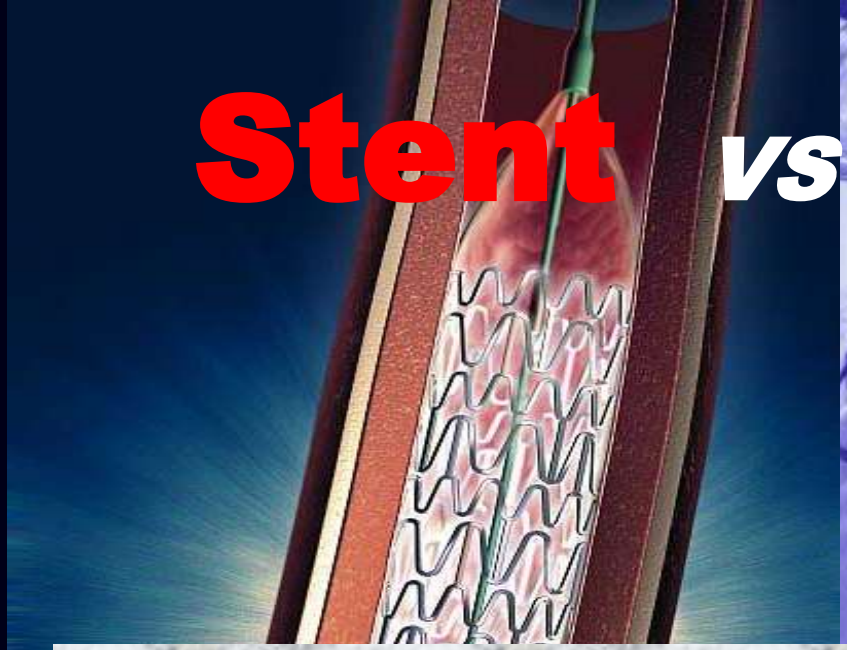
- 3 (2.6%) non-cardiac deaths
- 1(0.9%) patient died ten days after the index PCI, due to probable stent thrombosis
- 4 (3.5%) patients underwent repeat percutaneous revascularisation
- 1 (0.9%) patient underwent CABG

TOTAL MACCE: 8,25%

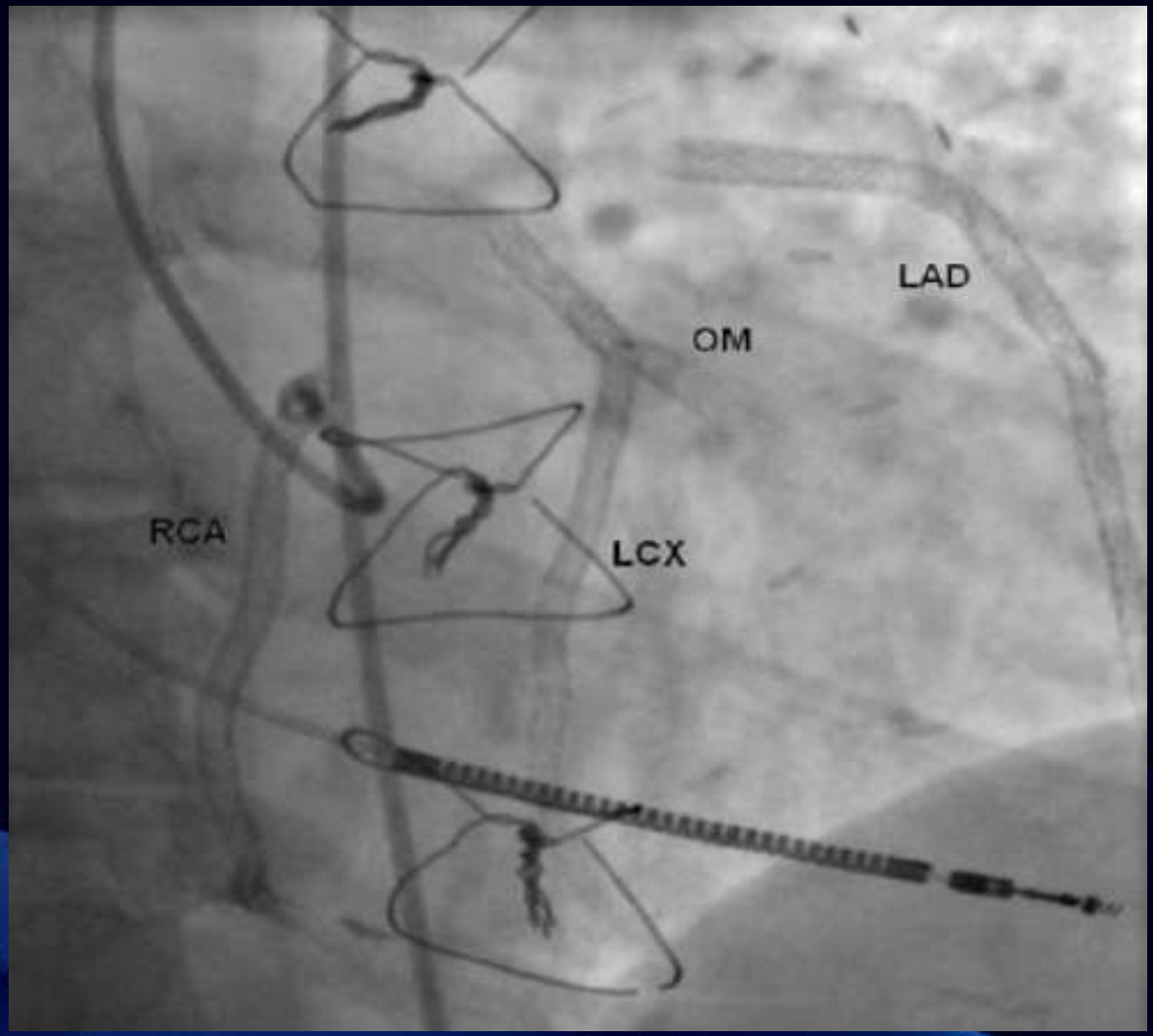
Presented at ICE 2010

HELLENIC INSTITUTE OF CARDIOVASCULAR DISEASES

Stent vs CABG



No one claim that PCI can replace CABG in all patients with LM/multi-vessel disease.
I believe that we will find a selected group of patients who will do absolutely fine or even better with PCI and a subset of patients who will do better with bypass surgery.



Thank you for your attention