Asian Pacific TCT

Syntax – Data synthesis and Clinical Recommendations

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On behalf of the SYNTAX investigators

12:35–13:05, 2009
Symposium Arena, Level 3, Asian Pacific TCT

Background

- At the time of the trial design (in 2003-2004), a retrospective website survey of 104 medical centers over a period of 3 months, showed that 12,072 patients (1/3 LM, 2/3 3VD) were revascularized by surgery (2/3) or by PCI (1/3).
- The SYNTAX randomized trial is an attempt to provide an evidence-base to determine whether this approach, which is already currently practiced, is valid.

Kappetein et al, Eur J Cardiothorac Surg. 2006;29:486-491

SYNTAX: *Intended* All-Comers Design with Nested Registries

- Intended all-comers study design *instead of* a highly selected patient population
- Consensus physician agreement (surgeon & cardiologist) *instead of* inclusion & exclusion criteria
- And, nested registries for CABG only and PCI only to define patient characteristics and outcomes of these two unique treatment options

Patient Profiling

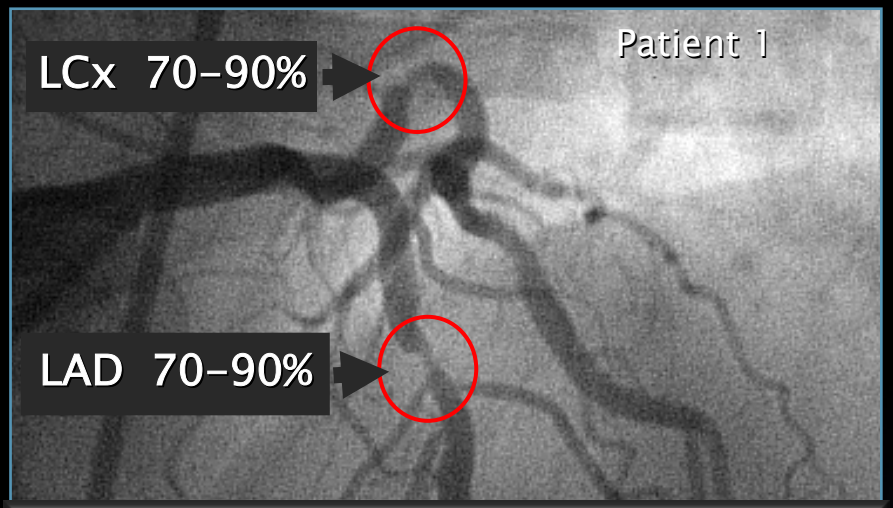
Local Heart team (surgeon & interventional cardiologist) assessed each patient in regards to:

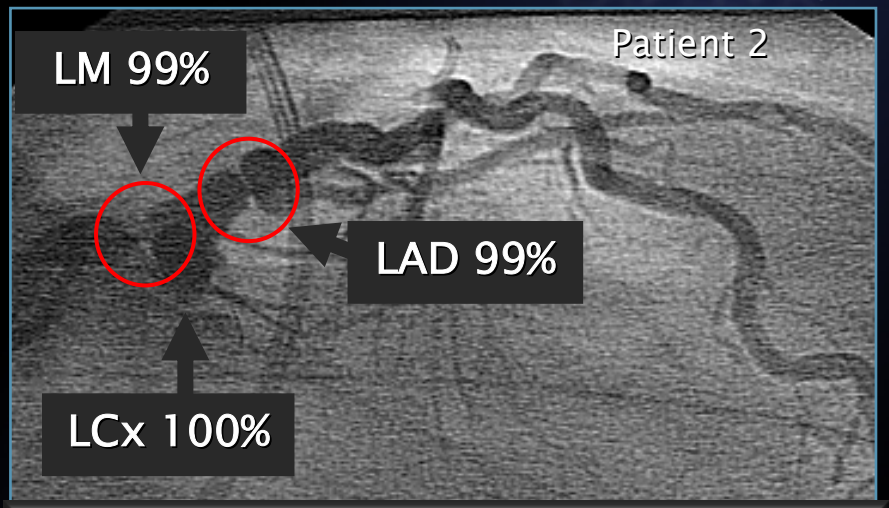
- Patient's operative risk (EuroSCORE & Parsonnet score)
- Coronary lesion complexity (newly developed SYNTAX score)
- Goal: SYNTAX score to provide guidance on optimal revascularization strategies for patients with high-risk lesions

Sianos et al, EuroIntervention 2005;1:219-227
Valgimigli et al, Am J Cardiol 2007;99:1072-1081
Serruys et al, EuroIntervention 2007;3:450-459

BARI classification of coronary segments
Leaman score, Circ 1981;63:285-299
Lesions classification ACC/AHA , Circ 2001;103:3019-3041
Bifurcation classification, CCI 2000;49:274-283
CTO classification, J Am Coll Cardiol 1997;30:649-656

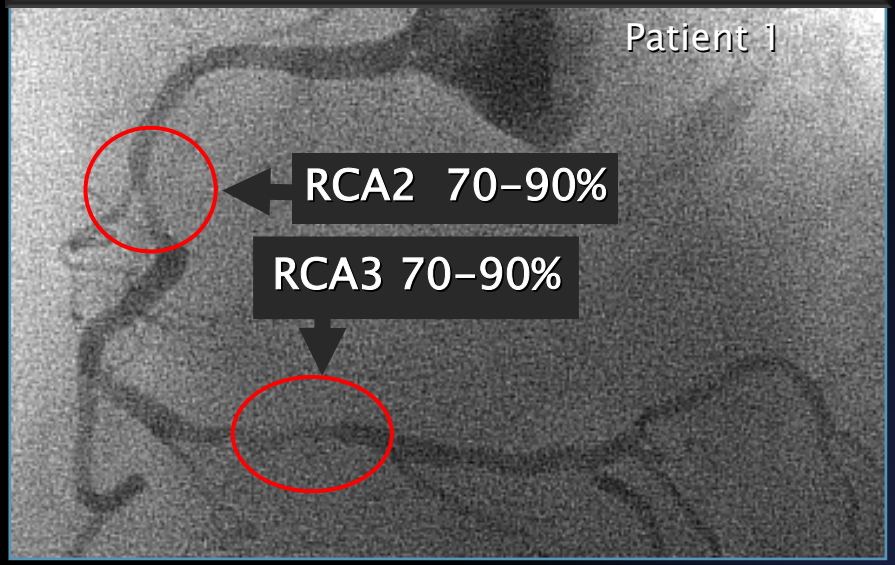
There is '3-vessel disease' and '3-vessel disease'

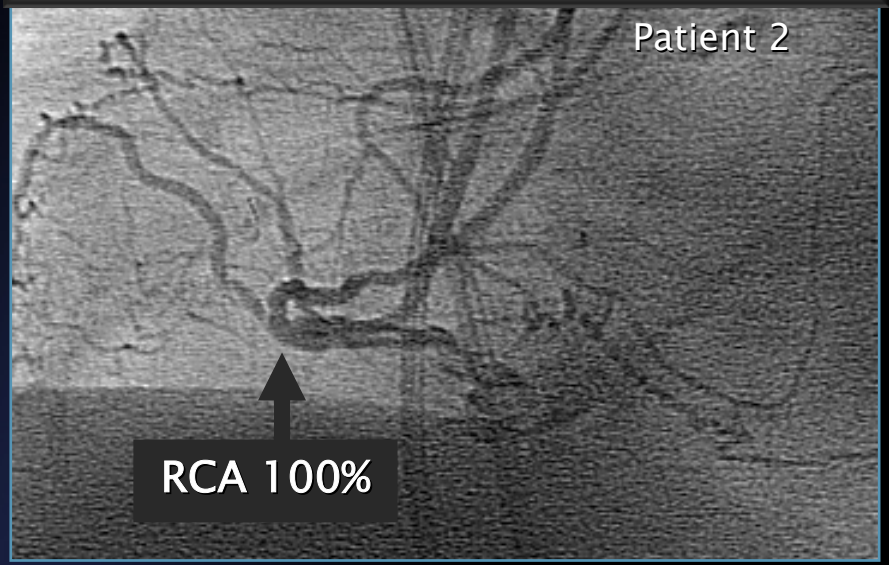




SYNTAX SCORE 21

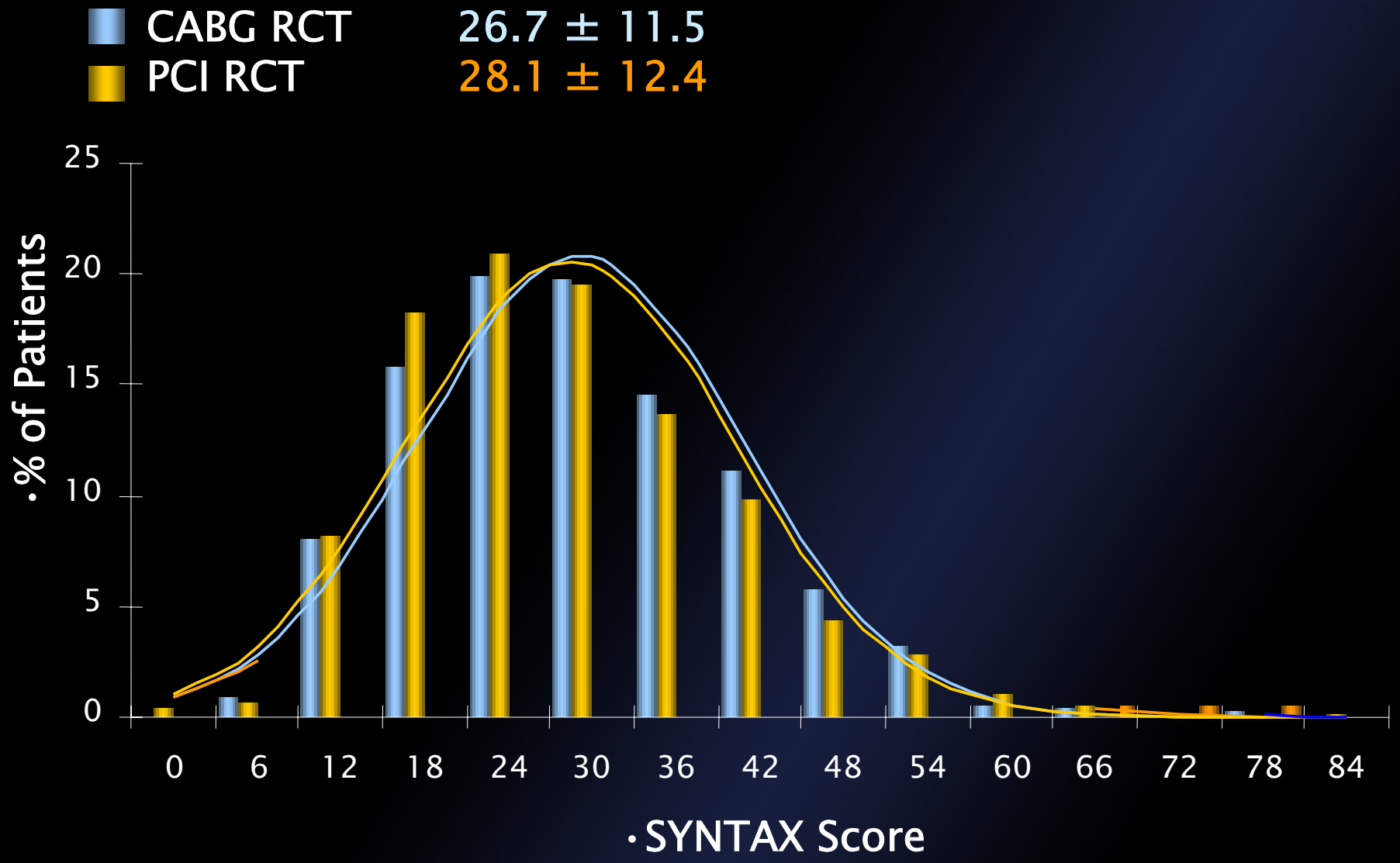
SYNTAX SCORE 55





SYNTAX Trial Patient Distribution

SYNTAX Score Distribution by Cohort and Treatment Group



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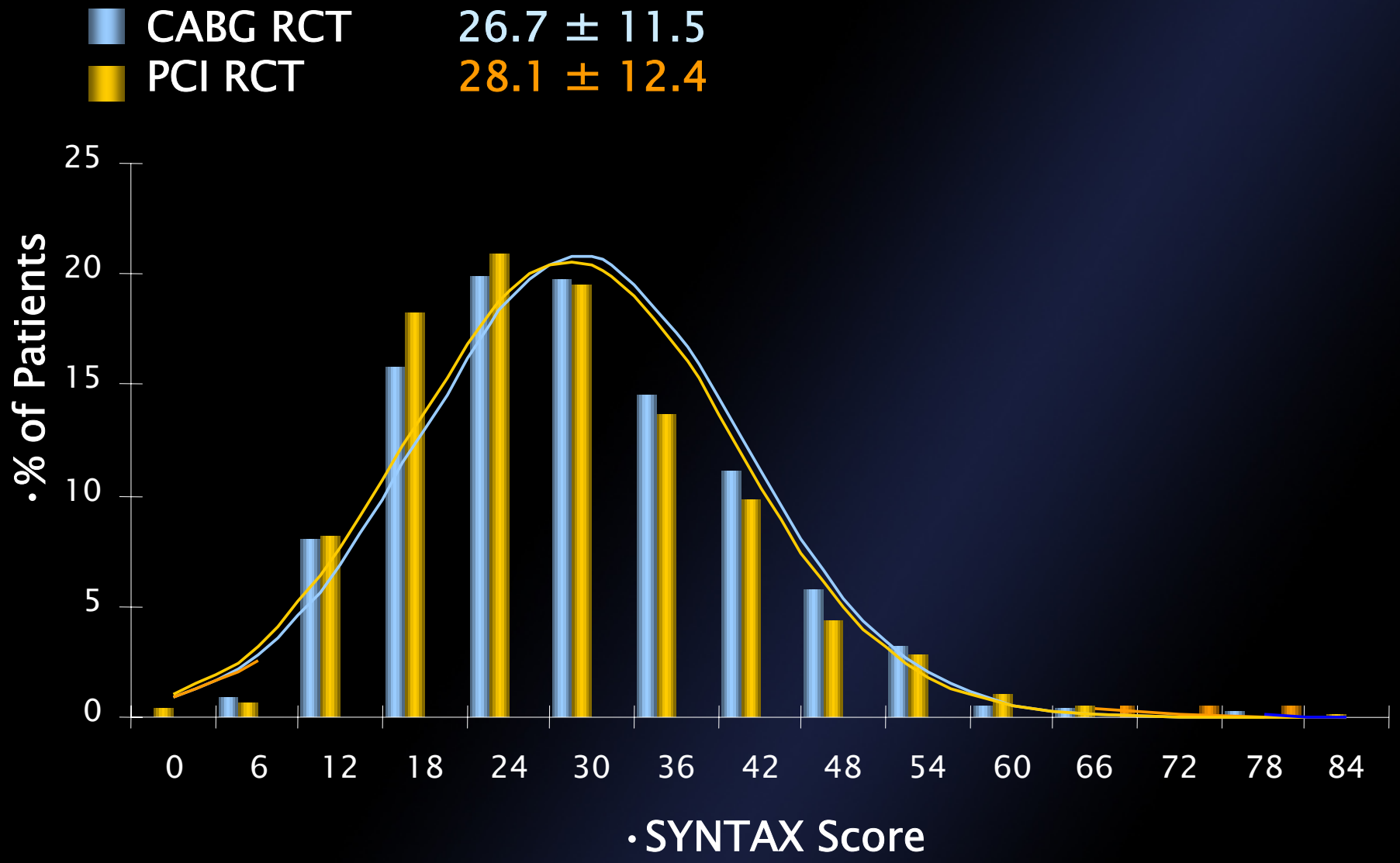

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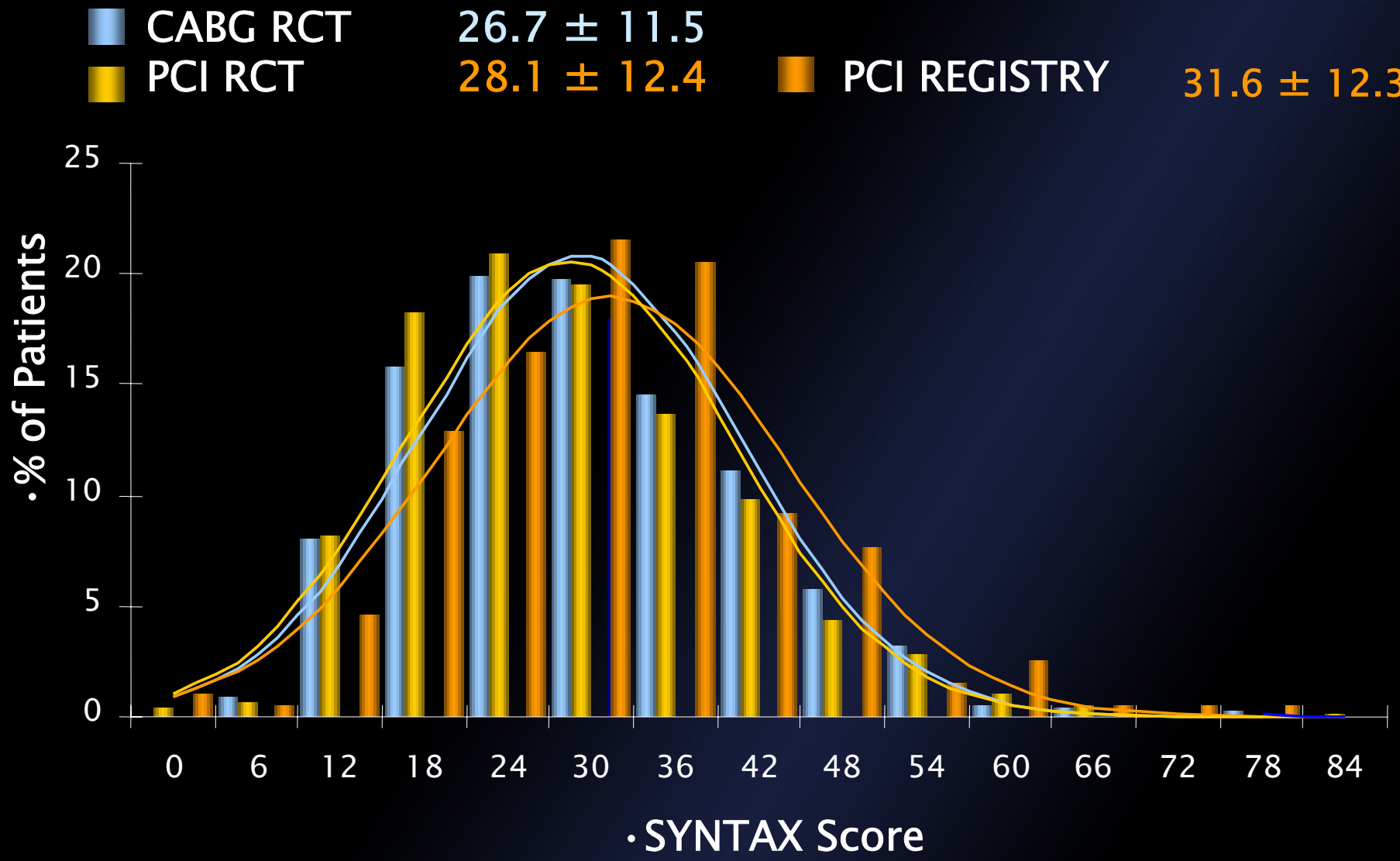

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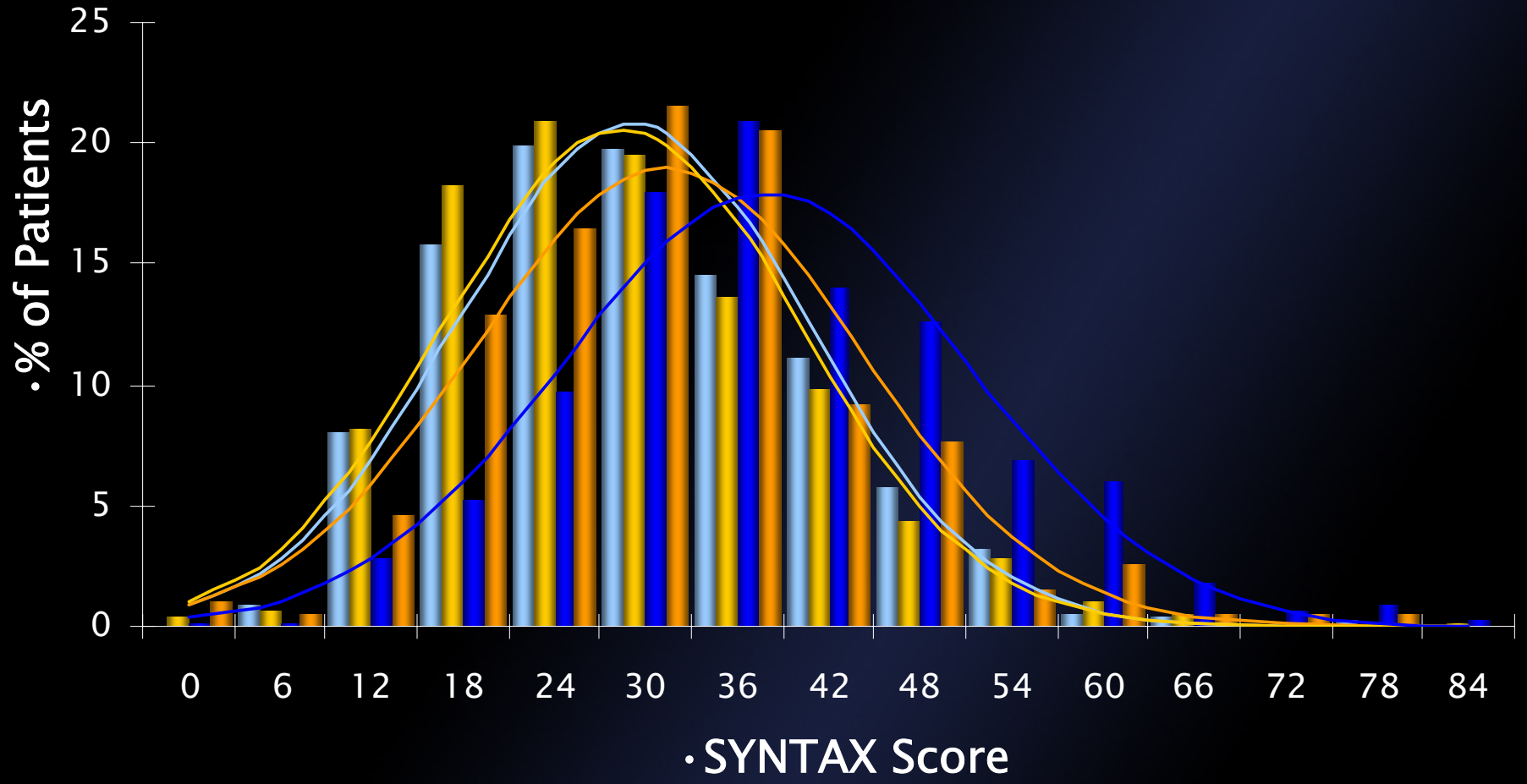
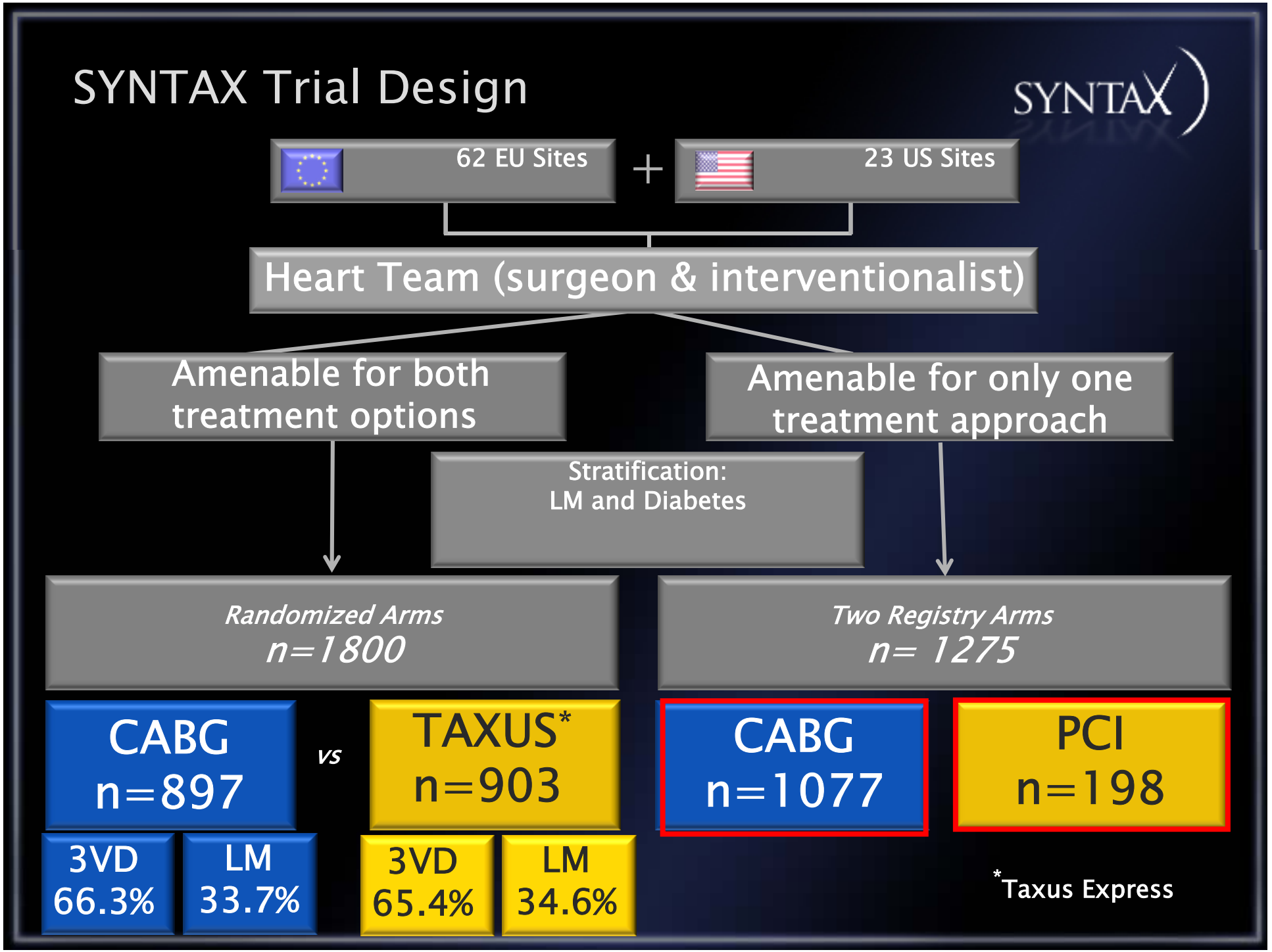


SYNTAX Trial Design



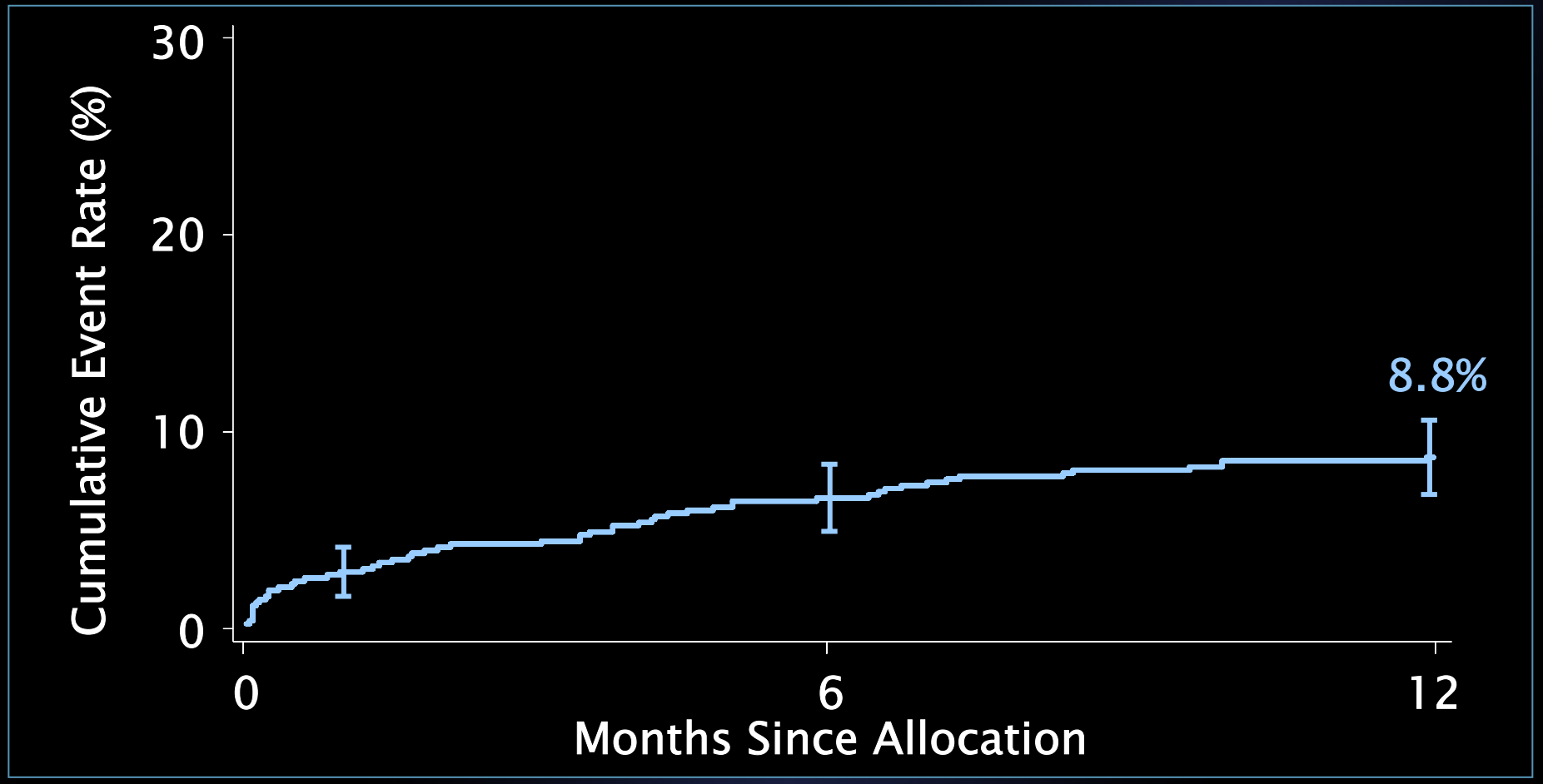
Patient Characteristics (II)

Notable Differences CABG RCT + Registry

Patient-based	CABG RCT* (n=897)	CABG Reg (n=644)
Total SYNTAX Score	24.8 ± 10.0	35.5 ± 13.7
Diffuse disease or small vessels, %	21.0	31.8
Number of lesions, mean ± SD	4.0 ± 1.7	4.8 ± 1.9
3VD only, %	61.2	52.5
Left main, any, %	38.8	47.5
Left Main only	5.5	1.6
Left Main + 1 vessel	7.9	5.4
Left Main + 2 vessel	11.8	10.4
Left Main + 3 vessel	13.6	30.1
Total occlusion, %	26.2	59.3
Bifurcation, %	64.5	64.6
Trifurcation, %	7.0	13.0

*For descriptive purposes only; no statistical comparisons done

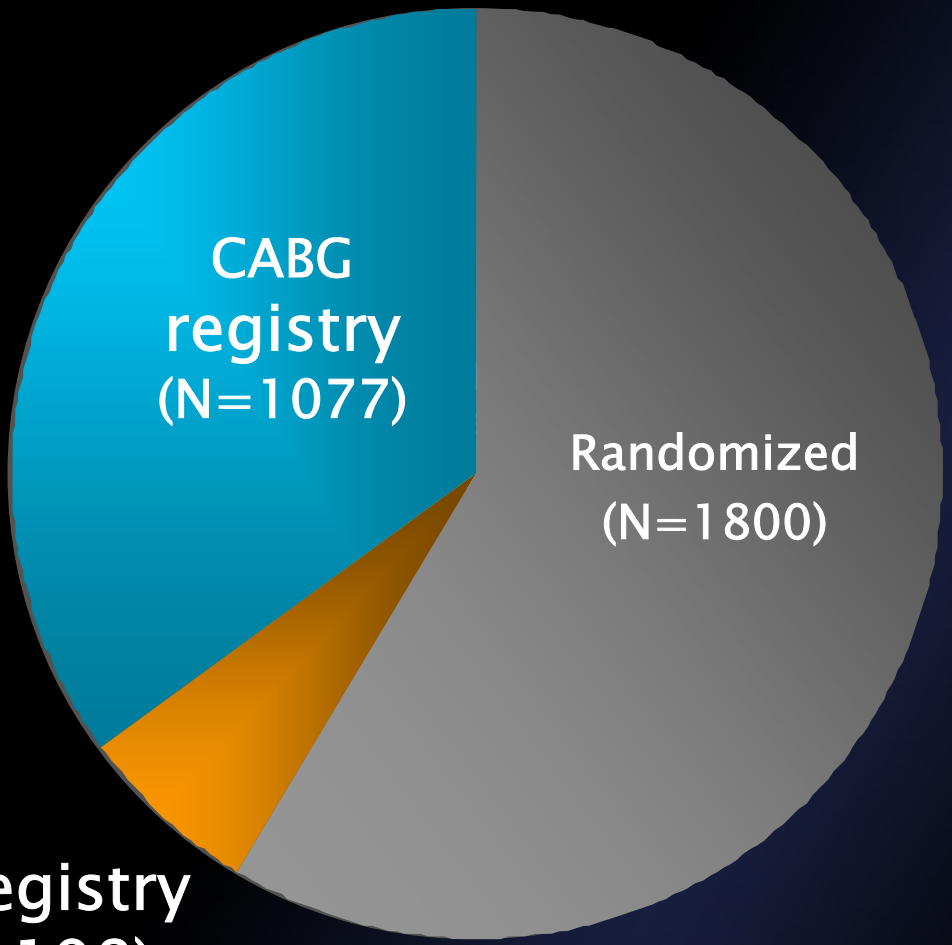
Overall MACCE to 12 Months
CABG Registry



Event Rate ± 1.5 SE

Per-protocol population

SYNTAX Trial Patient Distribution



Patient Characteristics

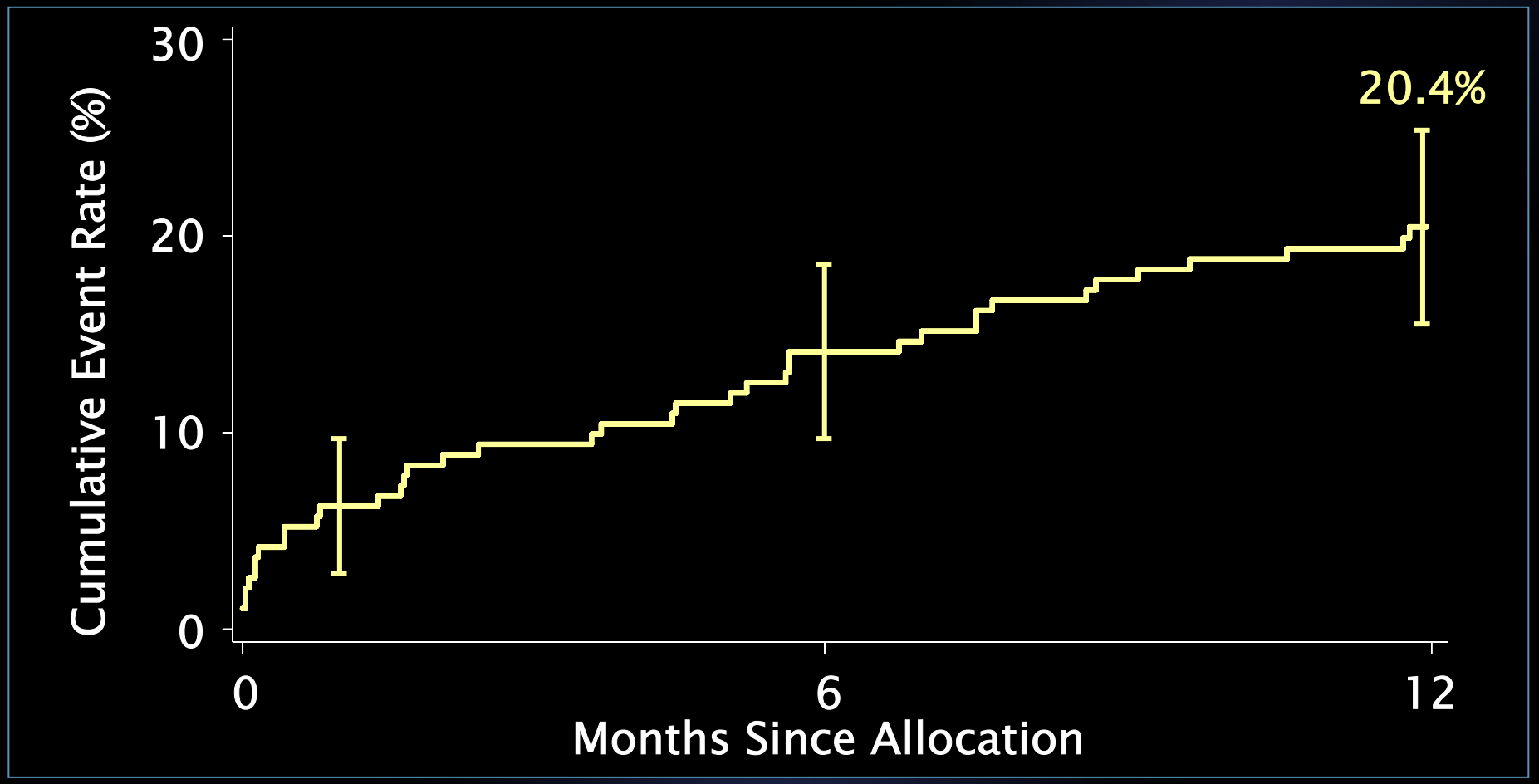
Notable Differences PCI RCT + Registry

	TAXUS RCT n=903	PCI Reg n=192
Age, mean±SD (y)	65.2 ± 9.7	71.2 ± 10
Male, %	76.4	70.3
SYNTAX score	28.4 ± 11.5	31.6 ± 12.3
Diabetes, %	28.2	35.4
Hyperlipidemia, %	78.7	67.5
Current smoker, %	18.5	11.2
Prior MI, %	31.9	40.4
Unstable angina, %	28.9	38.0
Add. EuroSCORE, mean±SD	3.8 ± 2.6	5.8 ± 3.1
Total Parsonnet score, mean±SD	8.5 ± 7.0	14.4 ± 9.5

- *For descriptive purposes only; no statistical comparisons done

Overall MACCE to 12 Months

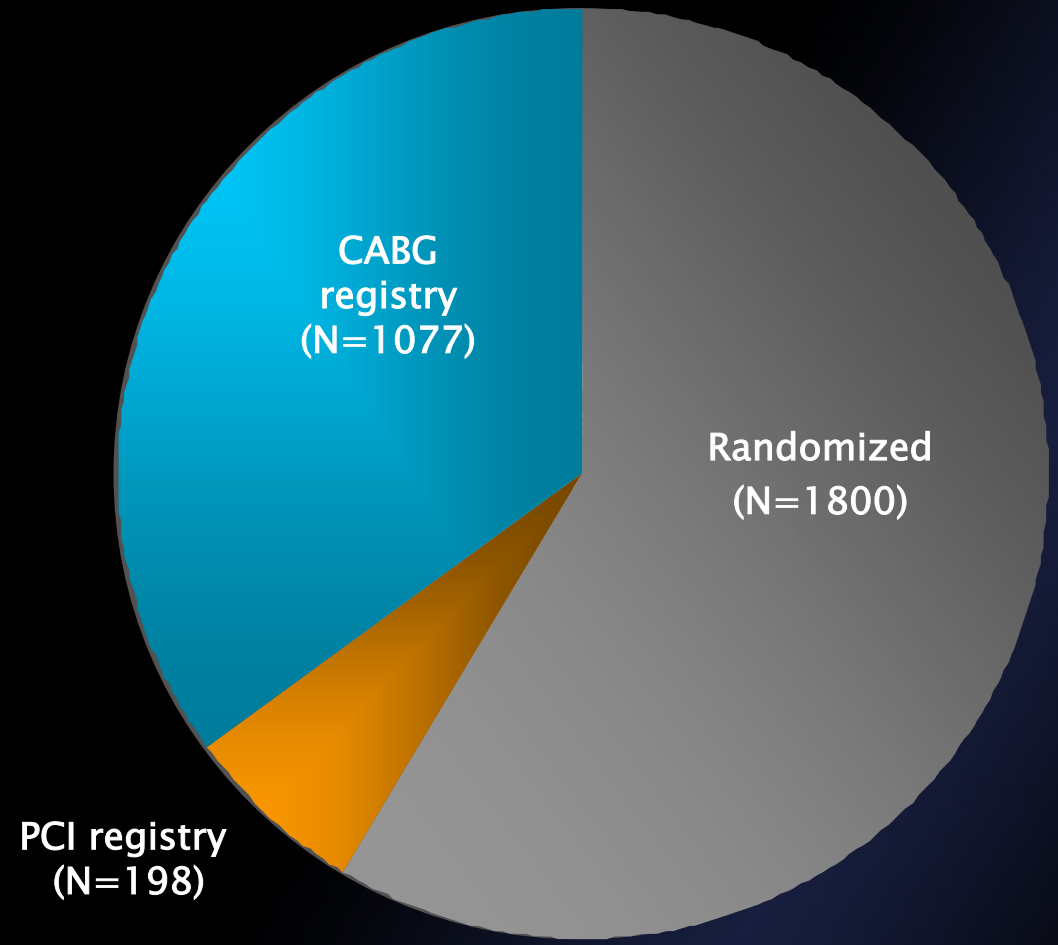
PCI Registry



Event Rate ± 1.5 SE

Per-protocol population

SYNTAX Trial Patient Distribution

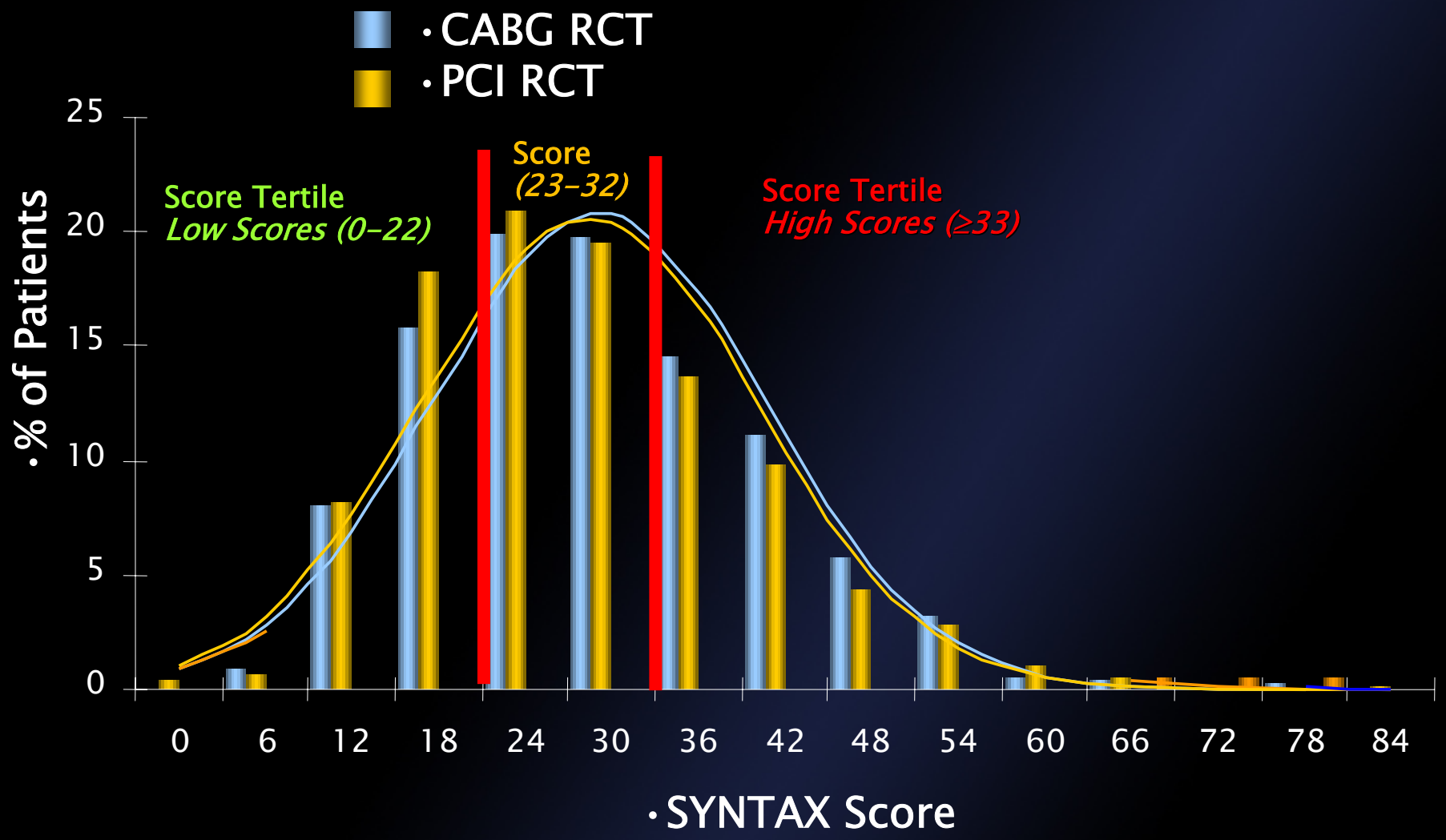


Patient Characteristics (II)

Randomized Cohort

Patient-based	CABG N=897	TAXUS N=903	*P* value
Total SYNTAX Score	29.1 ± 11.4	28.4 ± 11.5	0.19
Diffuse disease or small vessels, %	10.7	11.3	0.69
No. lesions, mean ± SD	4.4 ± 1.8	4.3 ± 1.8	0.44
3VD only, %	66.3	65.4	0.70
Left main, any, %	33.7	34.6	0.70
Left Main only	3.1	3.8	0.46
Left Main + 1 vessel	5.1	5.4	0.78
Left Main + 2 vessel	12.0	11.5	0.72
Left Main + 3 vessel	13.5	13.9	0.78
Total occlusion, %	22.2	24.2	0.33
Bifurcation, %	73.3	72.4	0.67
Trifurcation, %	10.6	10.7	0.92

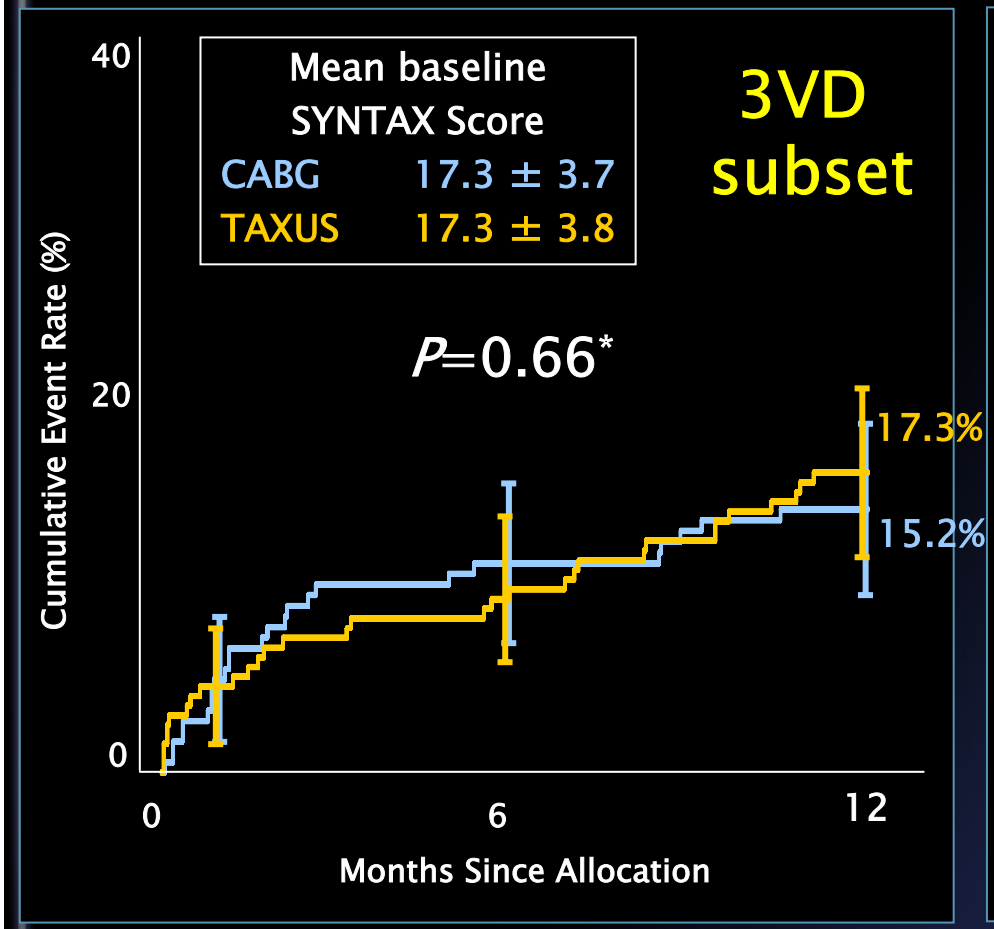
SYNTAX Score Distribution by Cohort and Treatment Group



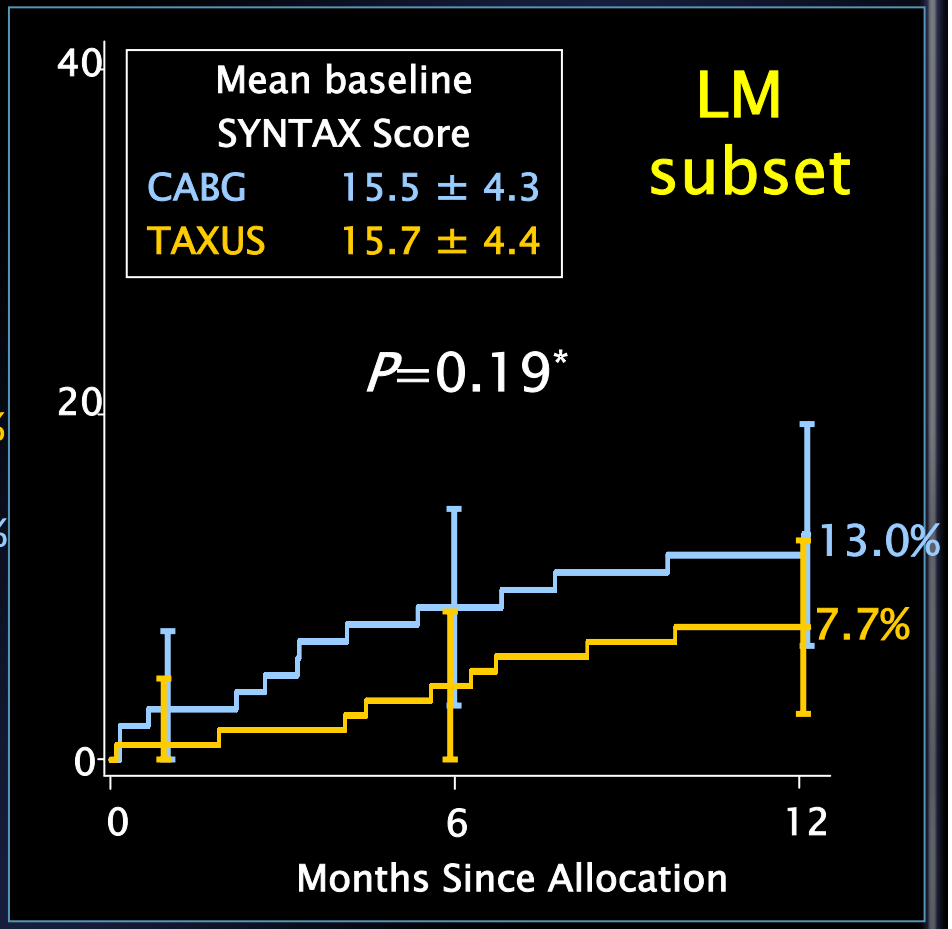
MACCE to 12 Months by SYNTAX Score Tertile *Low Scores (0–22)*

SYNTAX

CABG (N=171)
TAXUS (N=181)



CABG (N=103)
TAXUS (N=118)



Event rate ± 1.5 SE, *Fisher exact test

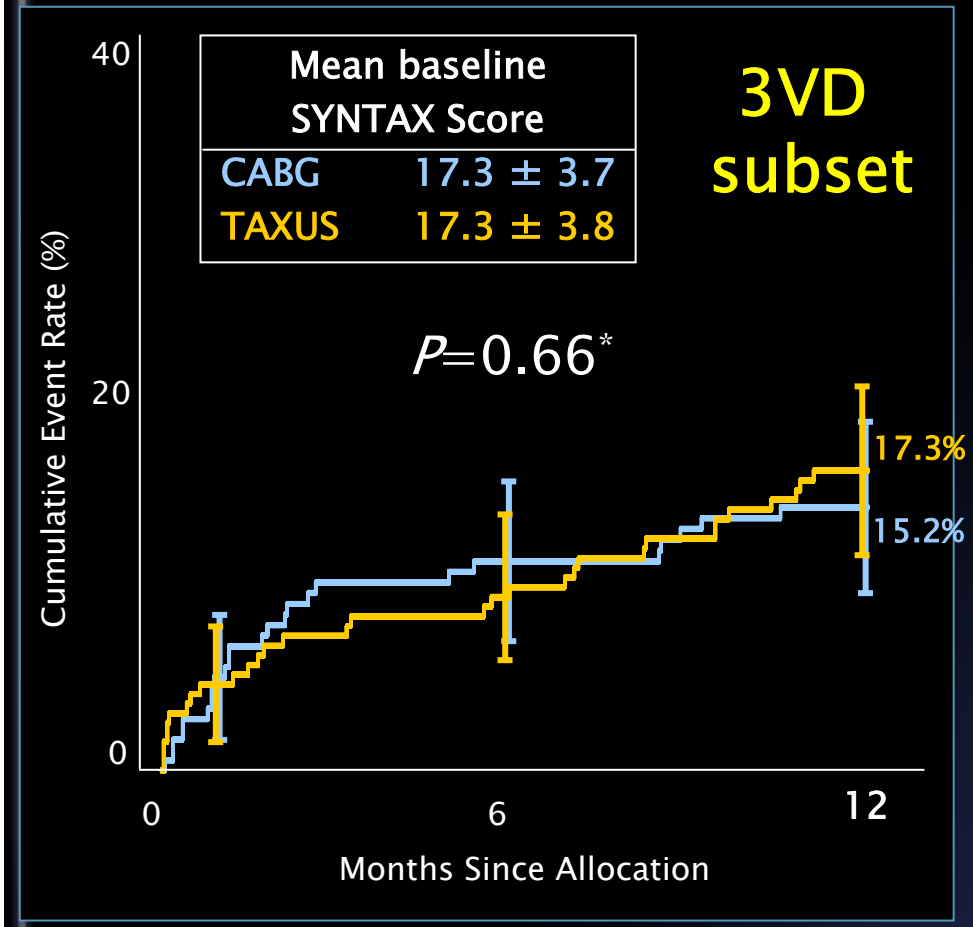
Calculated by core laboratory; ITT population

MACCE to 12 Months by SYNTAX Score Tertile *Low Scores (0–22)*

CABG (N=171)
TAXUS (N=181)

Mean baseline SYNTAX Score	
CABG	17.3 ± 3.7
TAXUS	17.3 ± 3.8

3VD subset



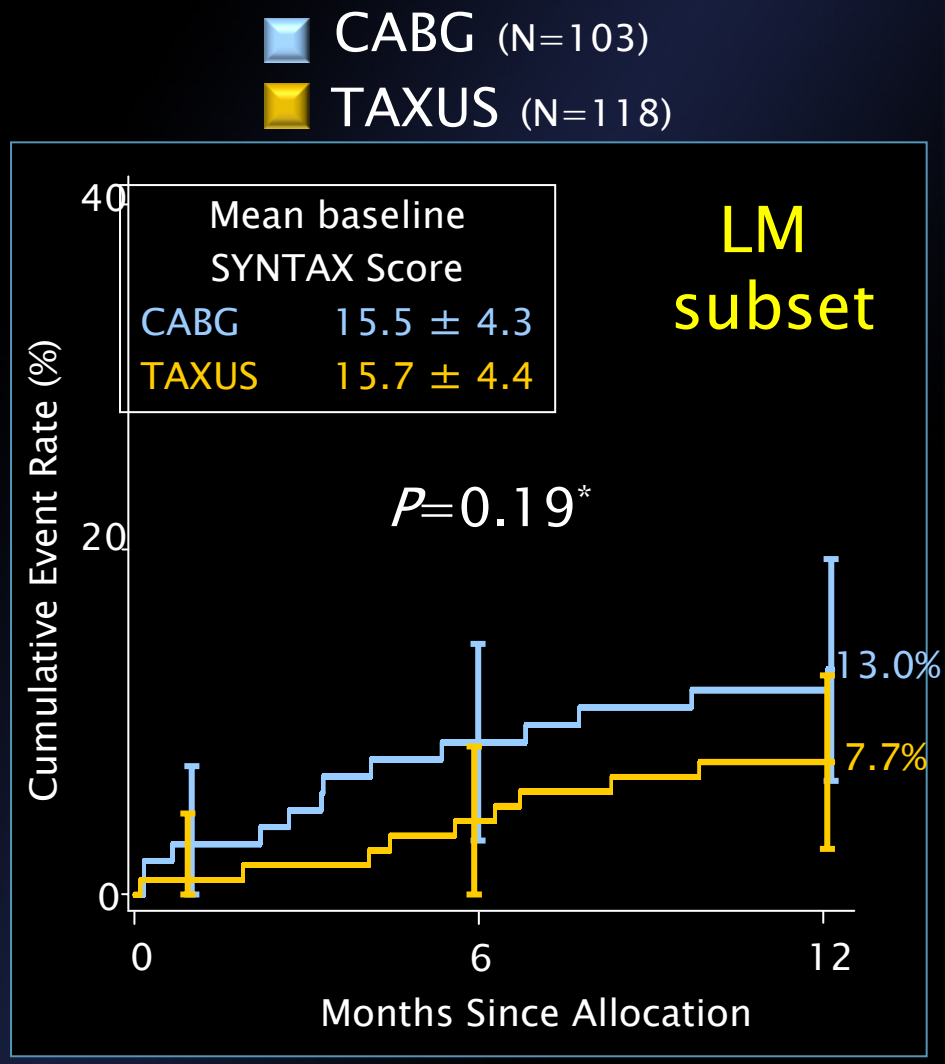
	CABG	PCI	P-value
Death	4.3%	2.8%	0.44
CVA	1.9%	0.6%	0.35
MI	4.2%	3.3%	0.63
Death, CVA or MI	8.5%	5.6%	0.26
Revasc.	6.9%	14.1%	0.03

Event rate ± 1.5 SE, *Fisher exact test

Calculated by core laboratory; ITT population

MACCE to 12 Months by SYNTAX Score Tertile *Low Scores (0–22)*

	CABG	PCI	P-value
Death	3.0	0.9	0.15
CVA	2.0	0.0	0.21
MI	2.0	1.7	1.0
Death, CVA or MI	6.1	1.7	0.15
Revasc.	8.1	7.7	0.22



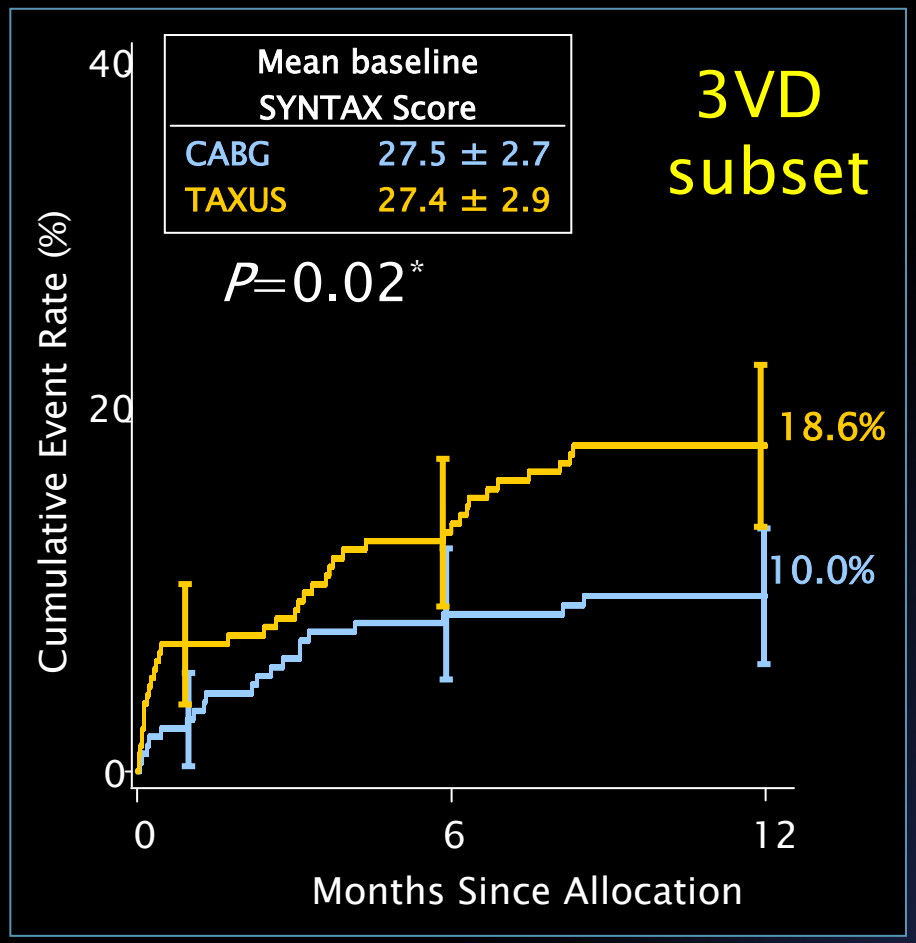
Event rate ± 1.5 SE, *Fisher exact test

Calculated by core laboratory; ITT population

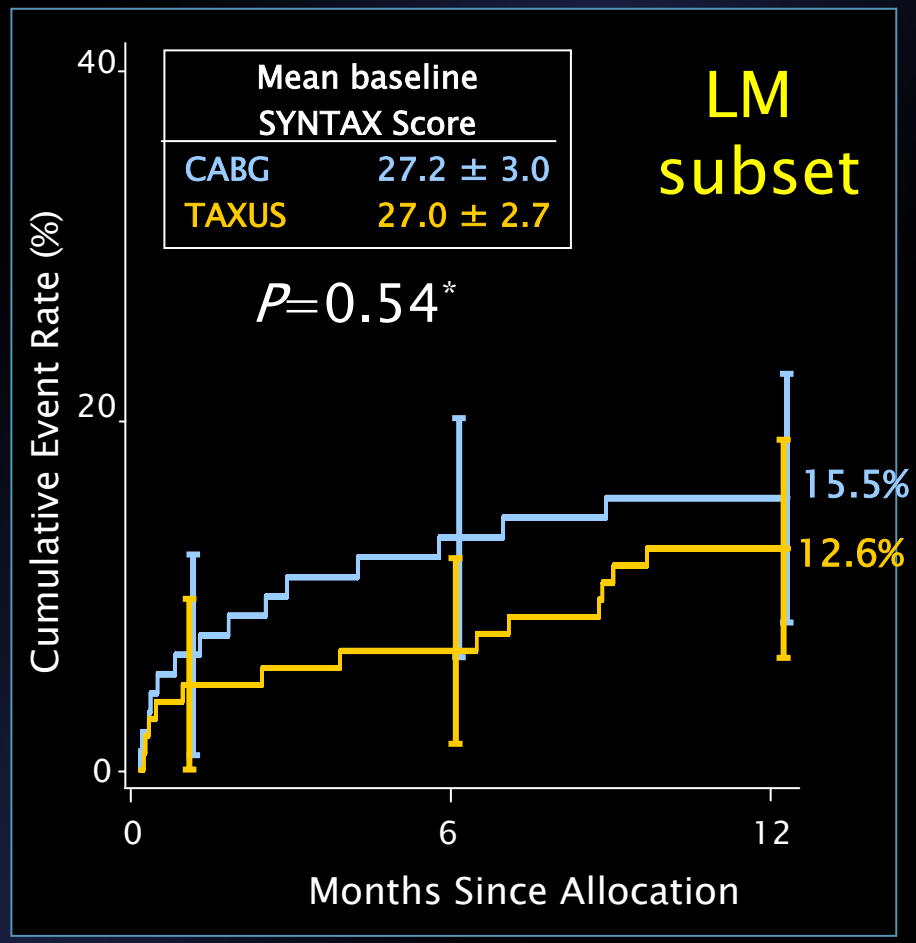
MACCE to 12 Months by SYNTAX Score Tertile

Intermediate Scores (23–32)

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



CABG (N=92)
TAXUS (N=195)



Event Rate ± 1.5 SE, *Fisher exact test

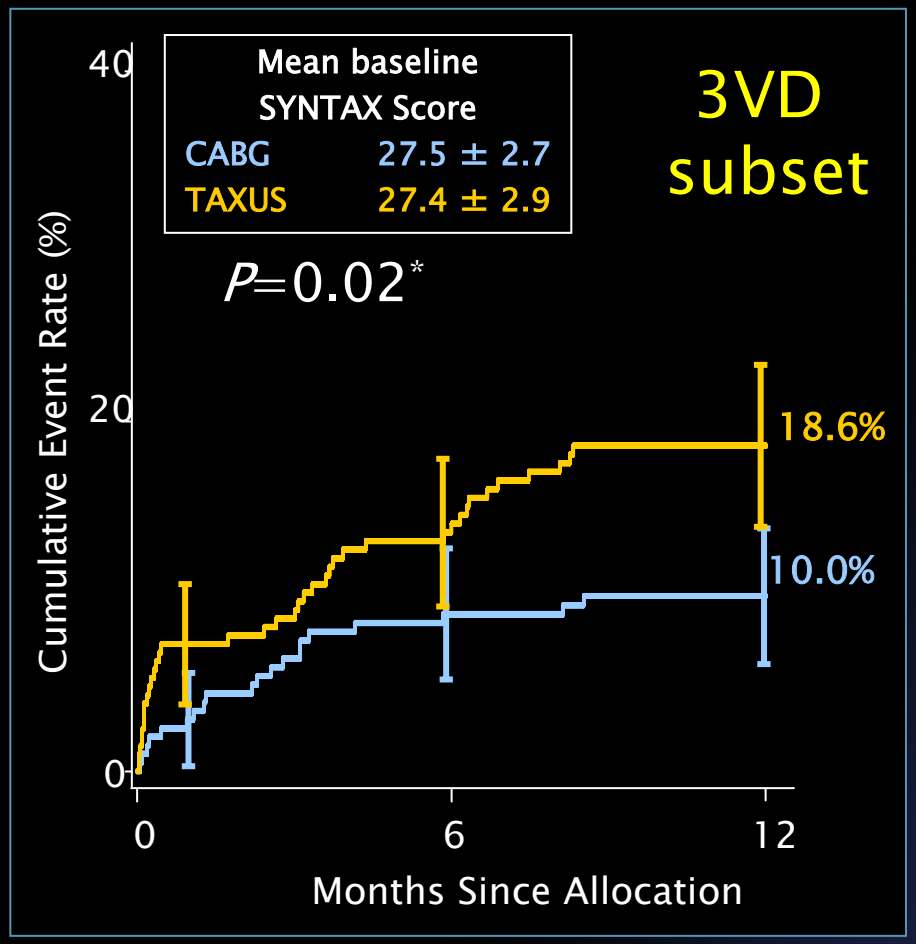
Calculated by core laboratory; ITT population

MACCE to 12 Months by SYNTAX Score Tertile

Intermediate Scores (23–32)

CABG (N=208)

TAXUS (N=207)



	CABG	PCI	P-value
Death	3.0%	4.4%	0.48
CVA	2.5%	1.5%	0.50
MI	2.0%	5.8%	0.05
Death, CVA or MI	6.5%	8.7%	0.41
Revasc.	4.6%	13.5%	0.003

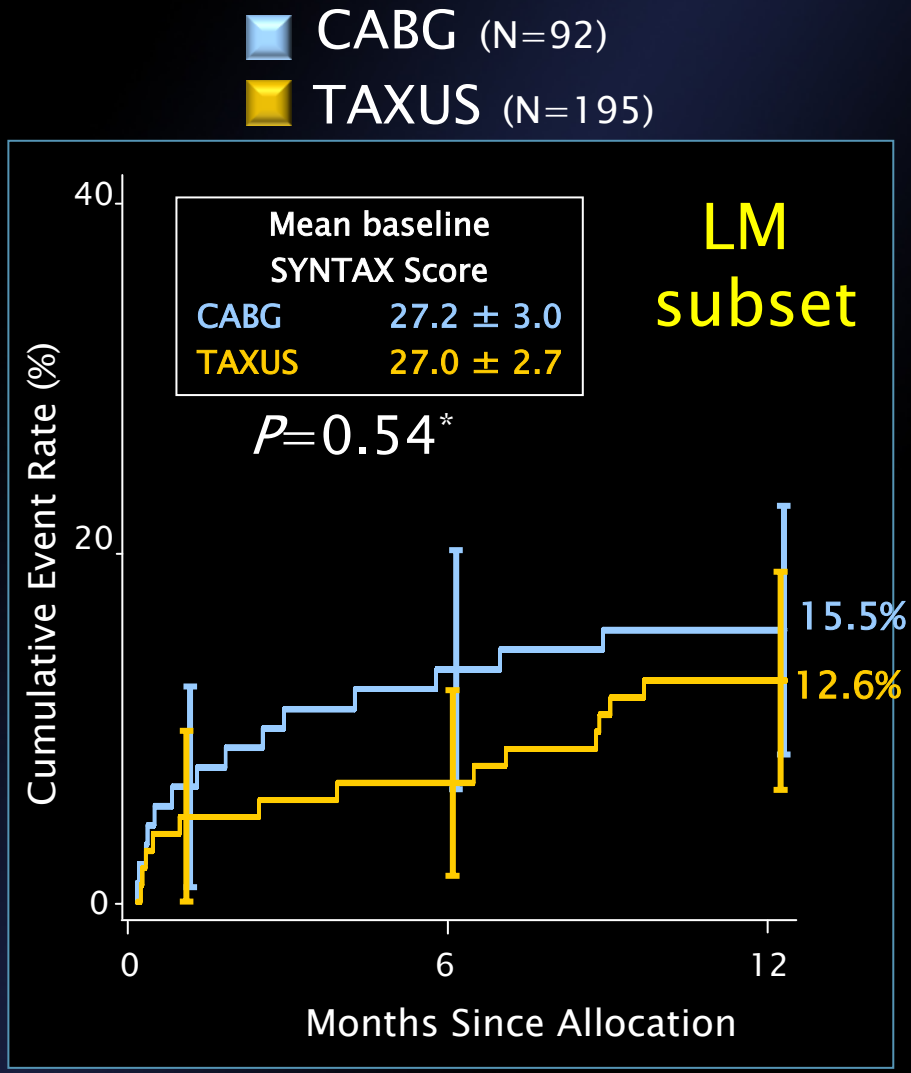
Event Rate ± 1.5 SE, *Fisher exact test

Calculated by core laboratory; ITT population

MACCE to 12 Months by SYNTAX Score Tertile

Intermediate Scores (23–32)

	CABG	PCI	P-value
Death	6.7	1.0	0.051
CVA	2.2	0.0	0.21
MI	3.4	2.9	1.0
Death, CVA or MI	10.1	3.9	0.09
Revasc.	7.9	9.7	0.65

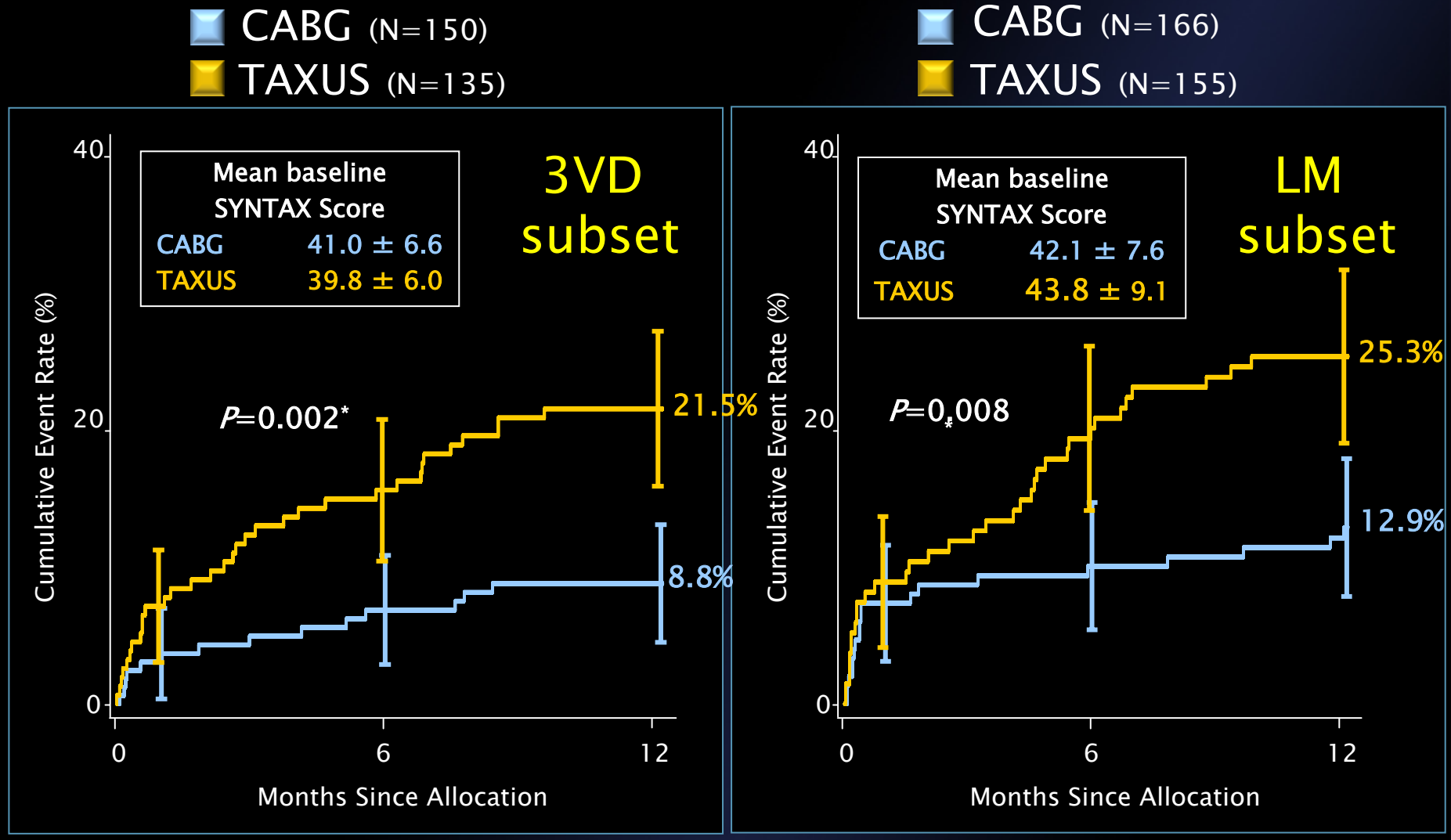


Event Rate ± 1.5 SE, *Fisher exact test

Calculated by core laboratory; ITT population

MACCE to 12 Months by SYNTAX Score Tertile

High Scores (≥33)



Event Rate ± 1.5 SE, *Fisher exact test

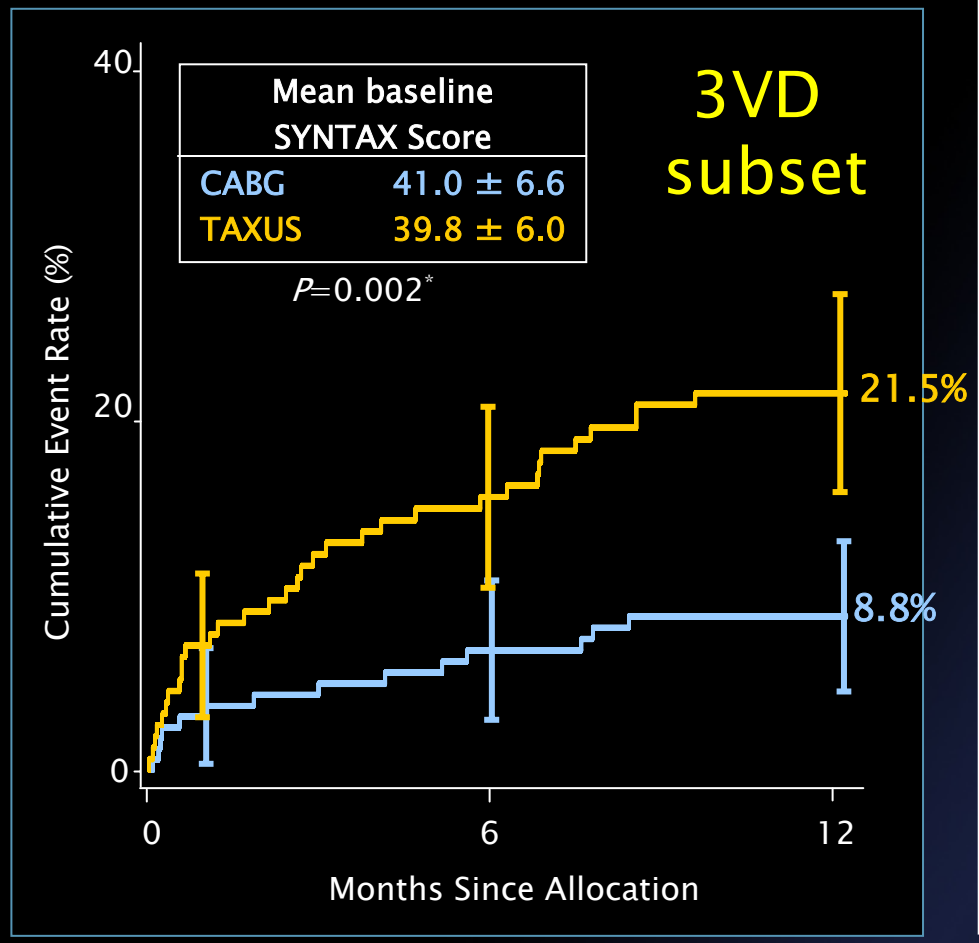
Calculated by core laboratory; ITT population

MACCE to 12 Months by SYNTAX Score Tertile

High Scores (≥33)

CABG (N=150)

TAXUS (N=135)



	CABG	PCI	P-value
Death	1.2%	6.5%	0.02
CVA	1.2%	0.0%	0.50
MI	1.9%	6.5%	0.04
Death, CVA or MI	4.3%	9.7%	0.07
Revasc.	5.1%	16.6%	0.001

Event Rate ± 1.5 SE, *Fisher exact test

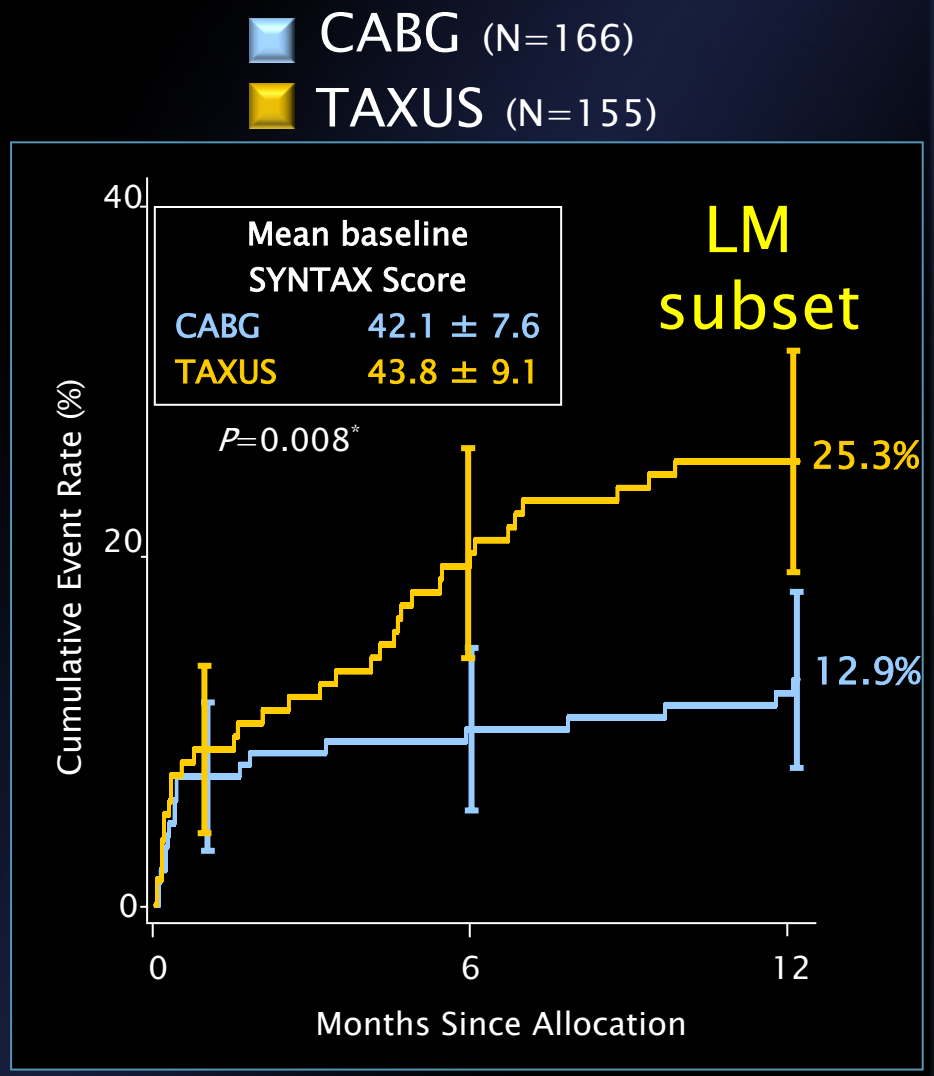
Calculated by core laboratory; ITT population

MACCE to 12 Months by SYNTAX Score Tertile

High Scores (≥33)

	CABG	PCI	P-value
Death	4.1	9.7	0.06
CVA	3.4	0.7	0.69
MI	6.1	7.5	0.65
Death, CVA or MI	10.9	14.2	0.41
Revasc.	4.8	17.2	<0.01

Event Rate ± 1.5 SE, *Fisher exact test



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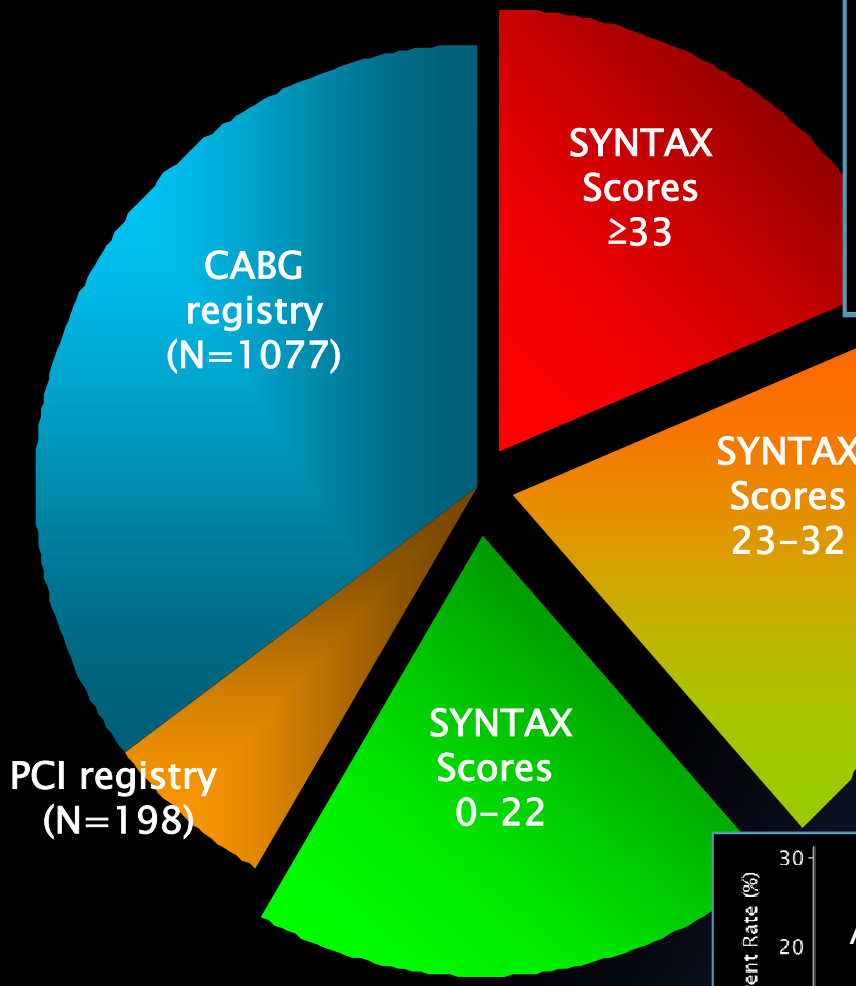
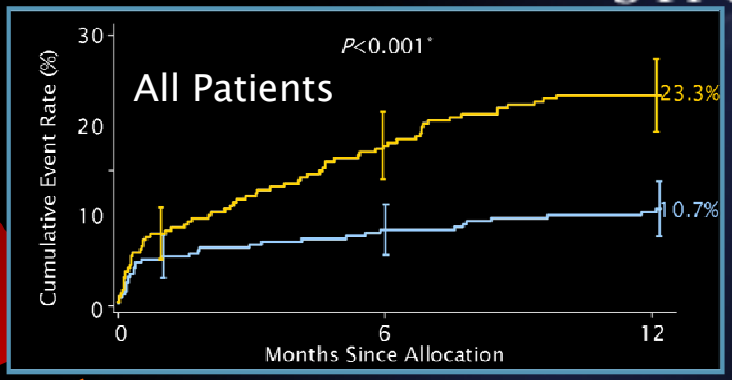
SYNTAX Trial Patient Distribution





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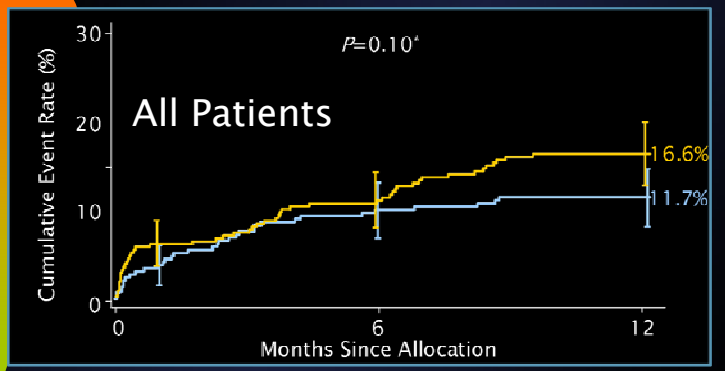

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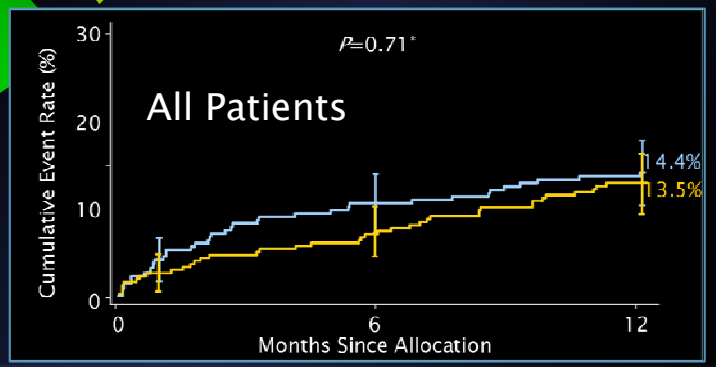

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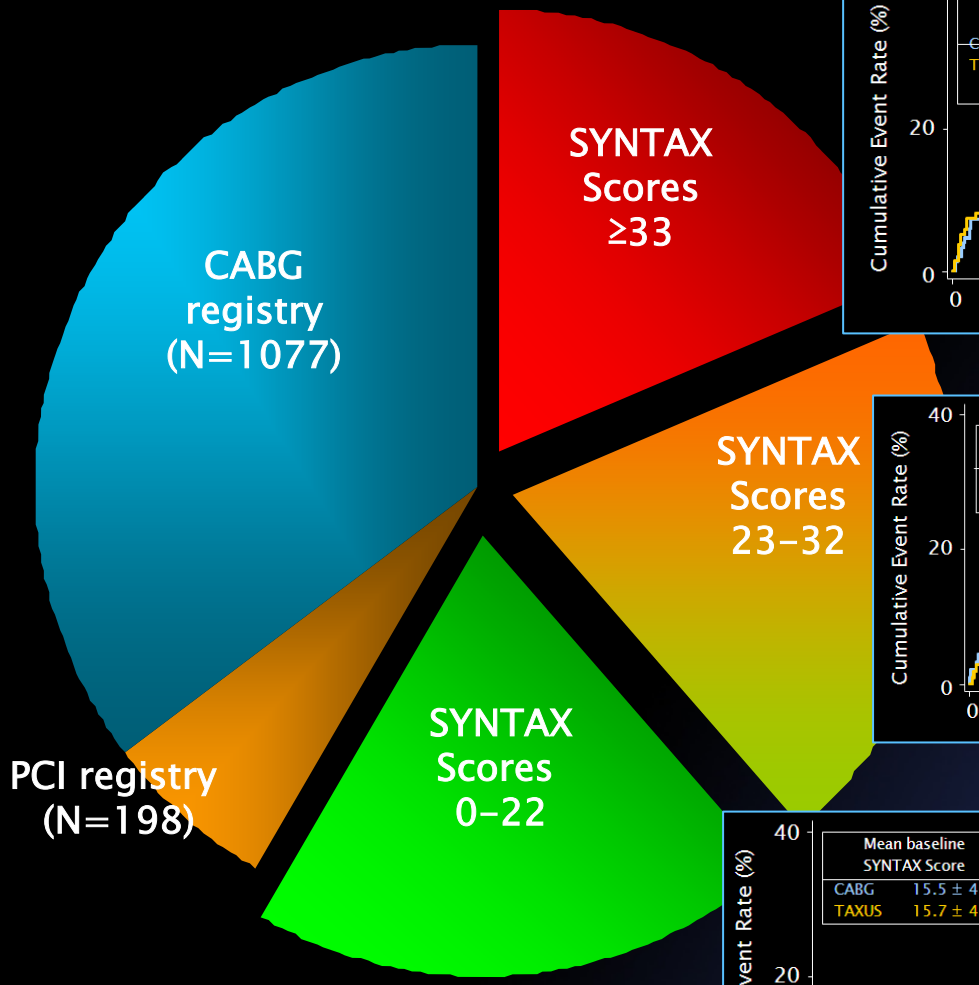

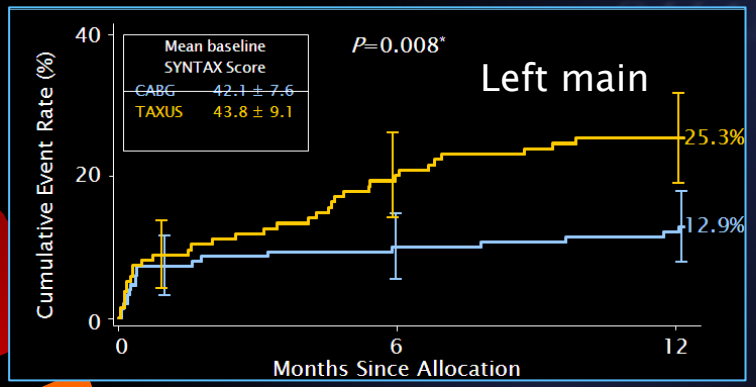

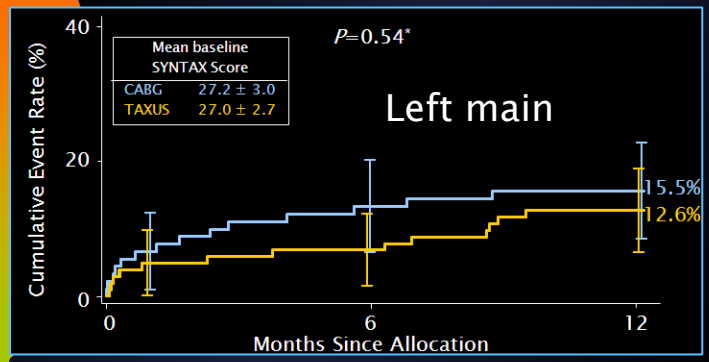

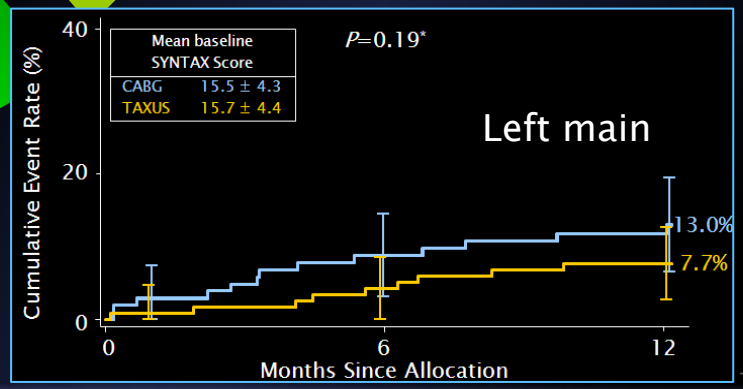

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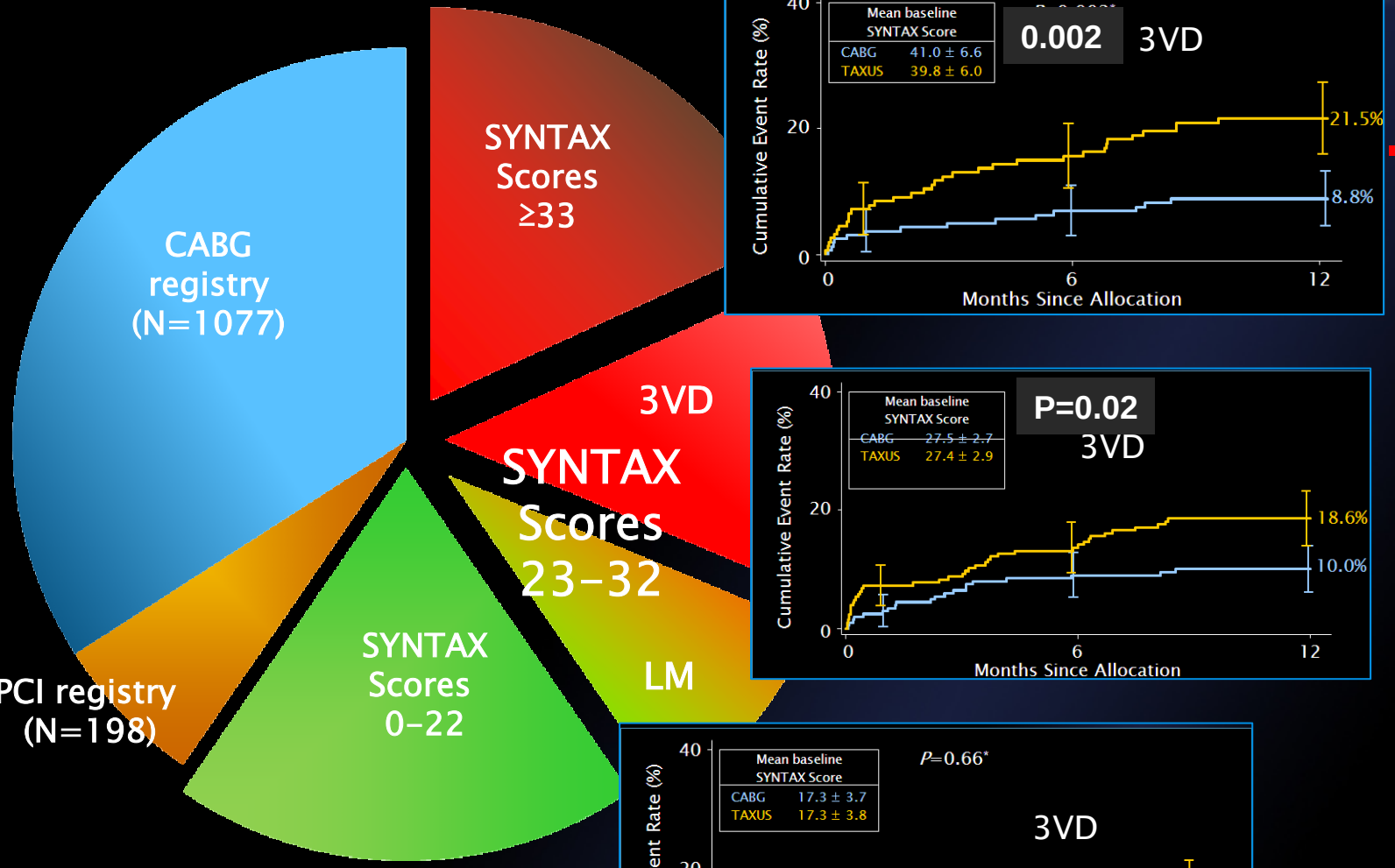
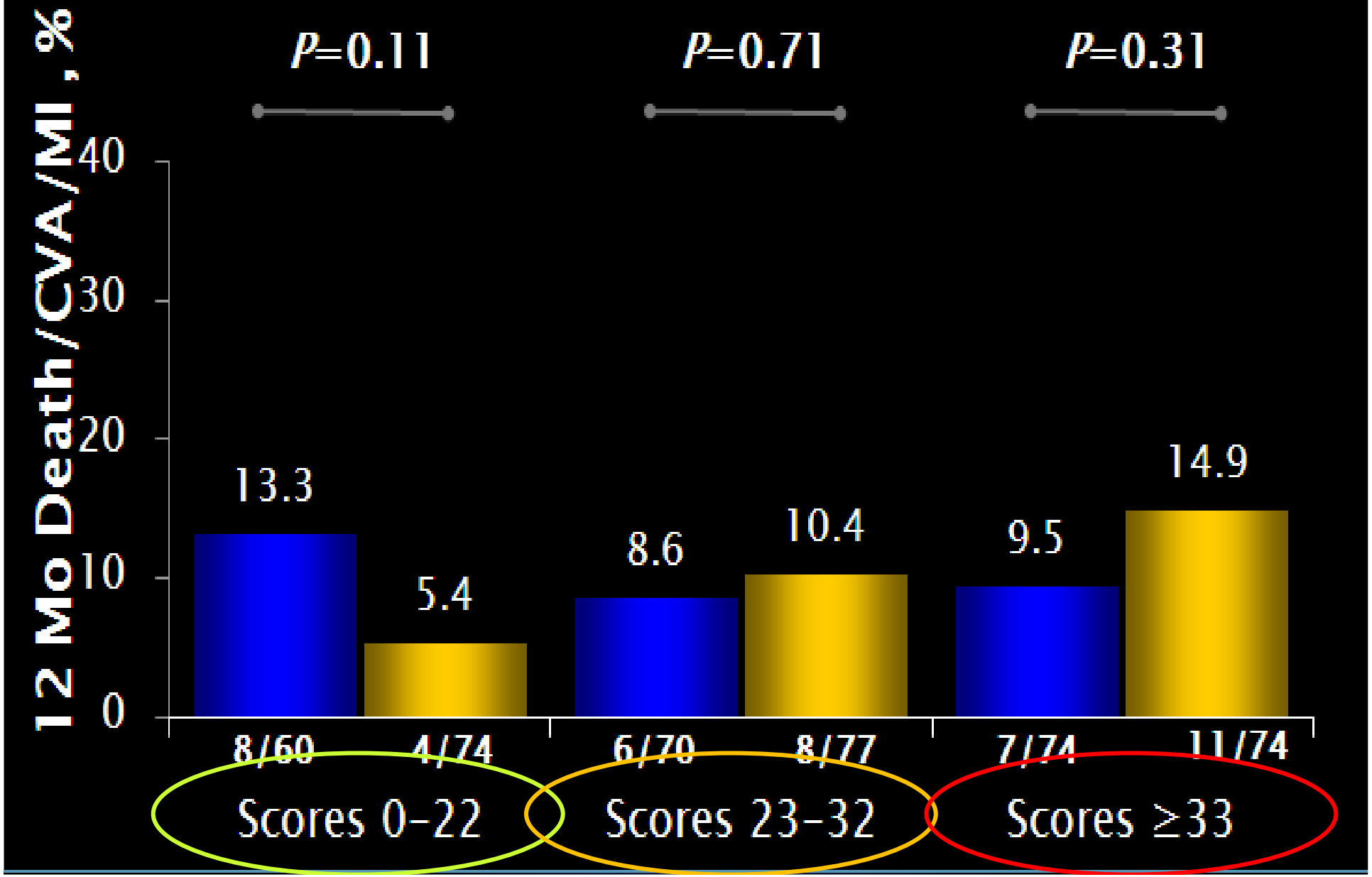


SYNTAX Trial Patient Distribution



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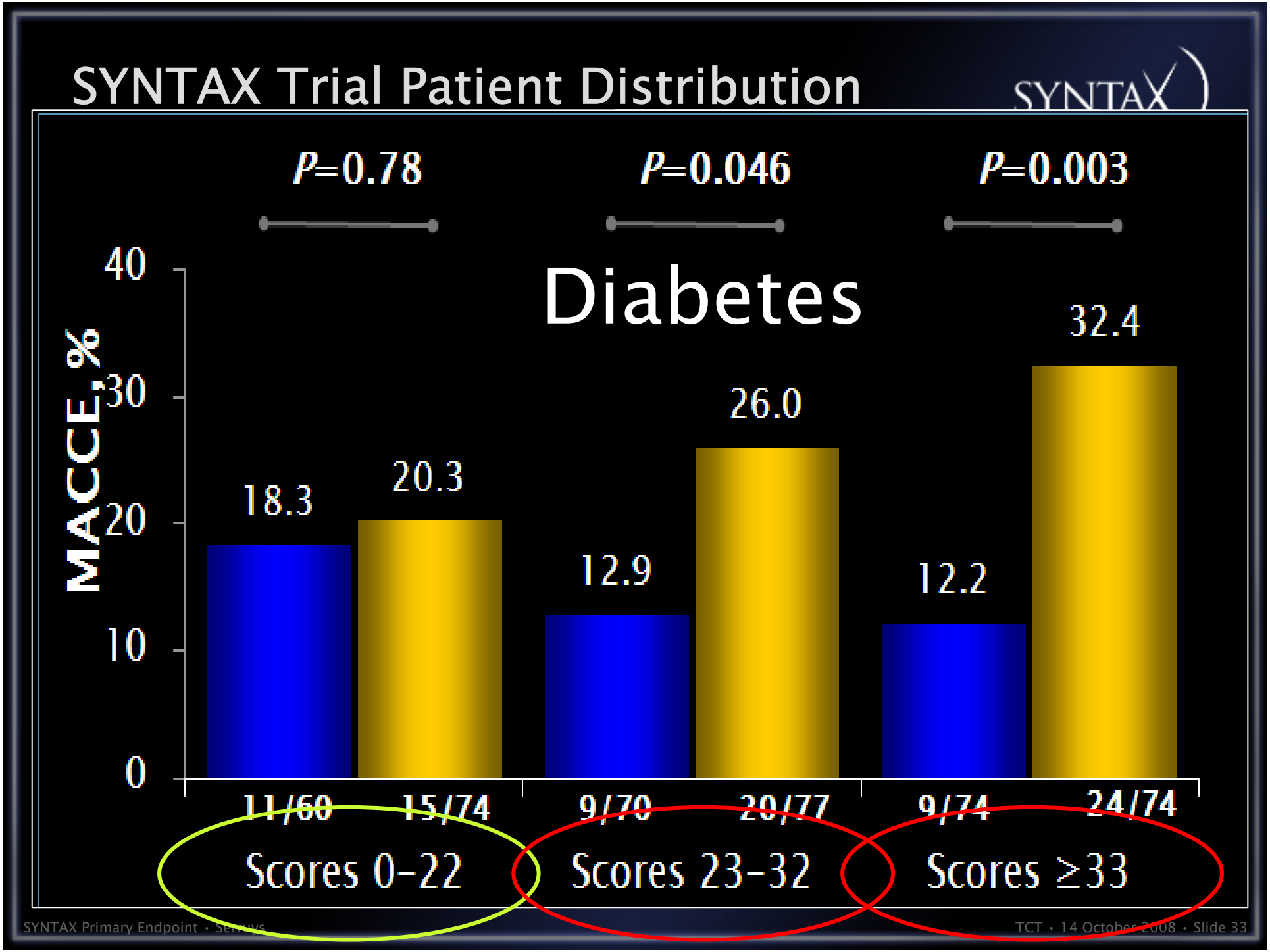
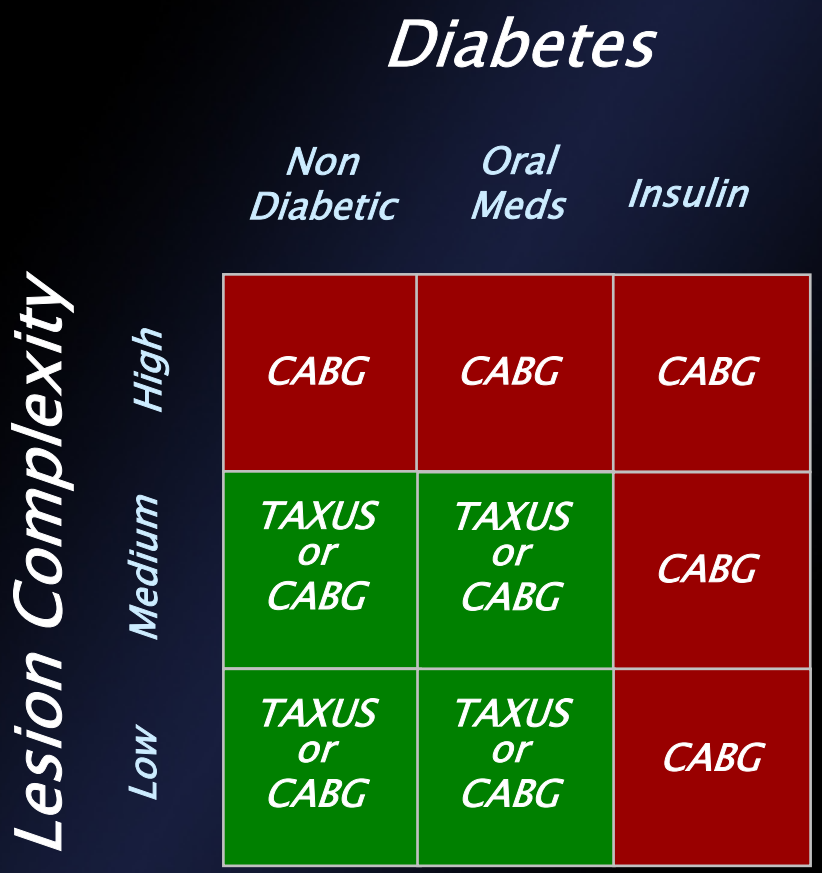


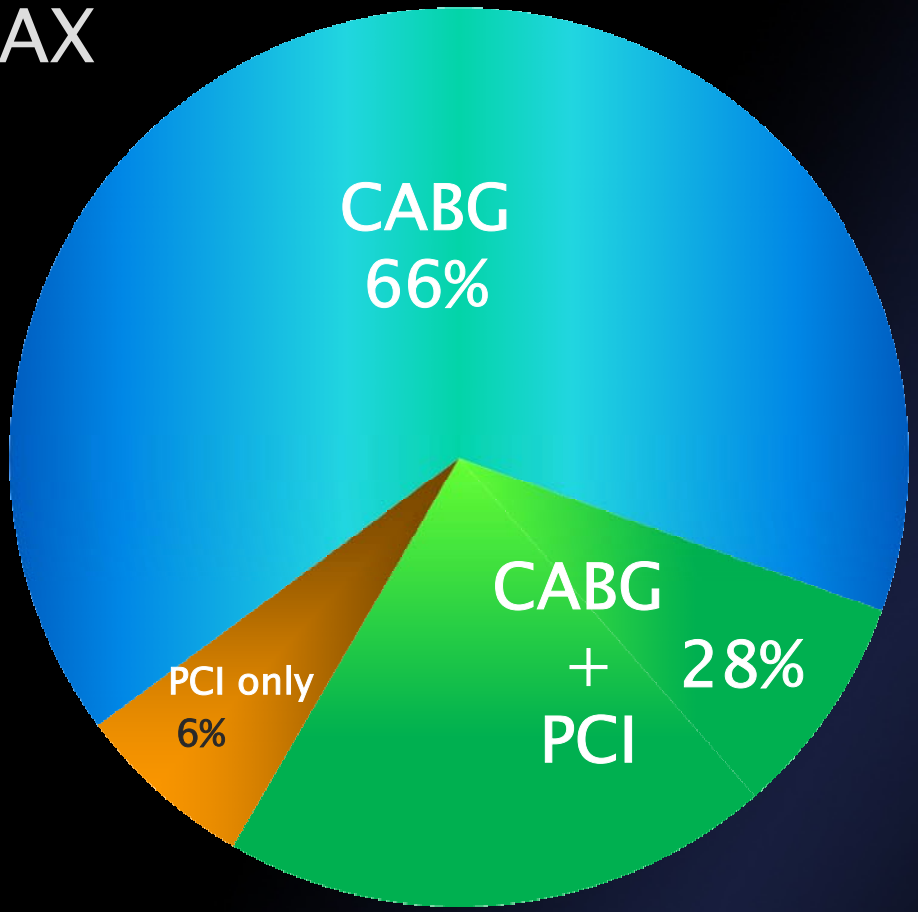
Conclusion

Patients with 3-vessel and/or left main disease

Both diabetic status and lesion complexity impact the relative safety between CABG and TAXUS Express stents and should be considered when evaluating treatment options in patients with left main and/or 3-vessel disease



Post SYNTAX



Results of the SYNTAX trial suggest that 66 % of all patients are still best treated with CABG, however, for the remaining patients PCI is an excellent alternative to surgery at least for one year

Conclusions

- Using as criteria, a non-significant difference in MACCE, we may state:
- Results of the SYNTAX trial suggest that 66% of all patients are still best treated with CABG, however, for the remaining patients PCI (Syntax Score 0-22) is an excellent alternative to surgery in multivessel disease, in left main disease and in diabetic patients...at least for a period of one year F/up
- Left main disease, non-diabetic with score of 23-32 could also be treated by PCI.