

Asian Pacific TCT



**Debate: Treatment Decision  
– Stenting vs. CABG for unprotected Left  
Main Disease  
Time to Move into stenting in All patients**



Patrick W. Serruys MD PhD  
Yoshinobu Onuma MD

10:00–10:12, 2009  
Main Arena, Asian Pacific TCT

Last year the debate went quite well...



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# This Year, in Asian-Pacific TCT 2009 ...

- I am no longer a debater in search of historical arguments... but I am a trialist relying on Evidence-based medicine.

# SYNTAX Trial Design



 62 EU Sites +  23 US Sites

Heart Team (surgeon & interventionalist)

Amenable for both treatment options

Amenable for only one treatment approach

Stratification:  
LM and Diabetes

*Randomized Arms*  
N=1800

*Two Registry Arms*  
N=1275

CABG  
n=897

vs

TAXUS\*  
n=903

CABG  
n=1077

PCI  
n=198

3VD  
66.3%

LM  
33.7%

3VD  
65.4%

LM  
34.6%

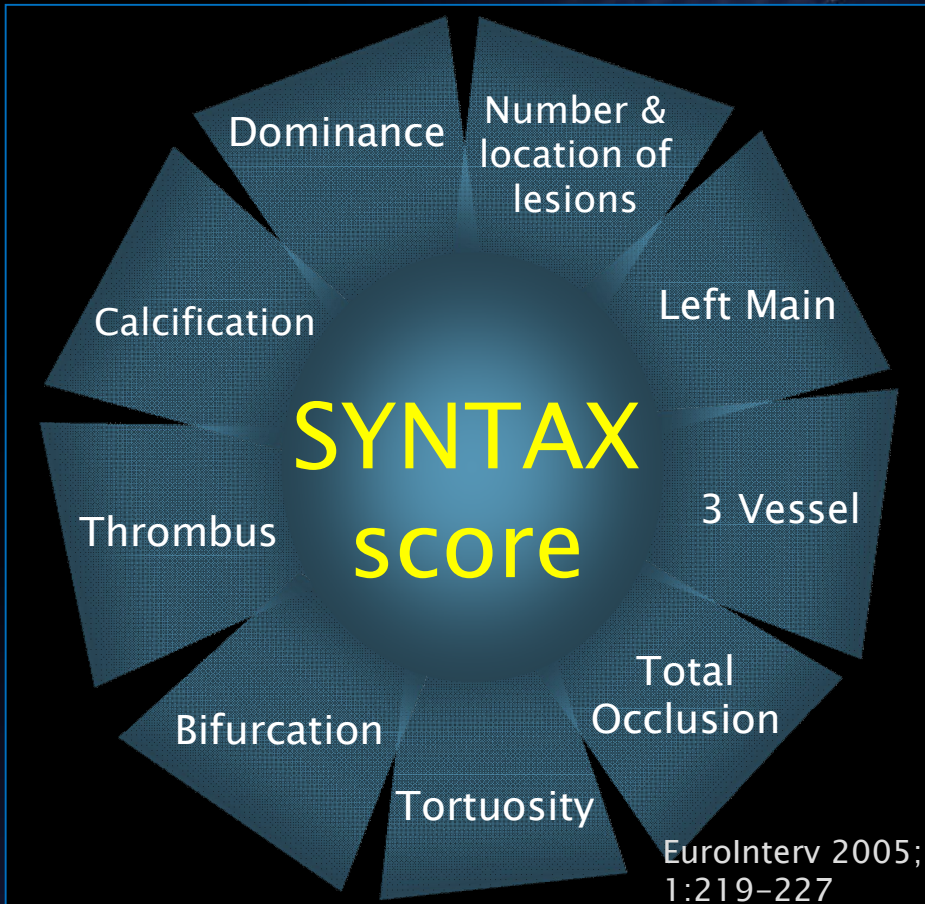
\*TAXUS Express

# Patient Profiling



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

- Patients' 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

LM > 50 %

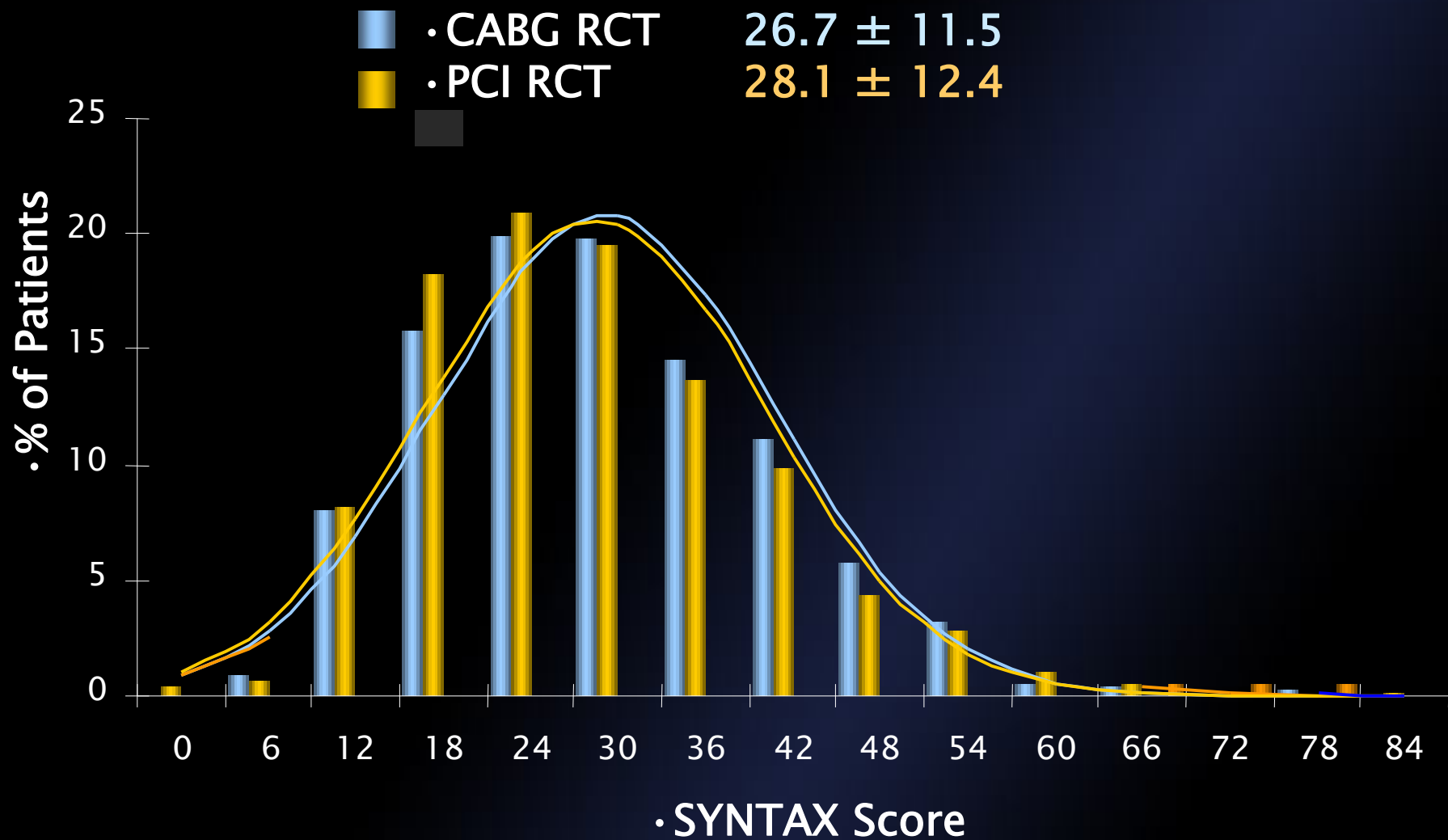
LAD > 50 %

LCx 100%

SYNTAX SCORE 52

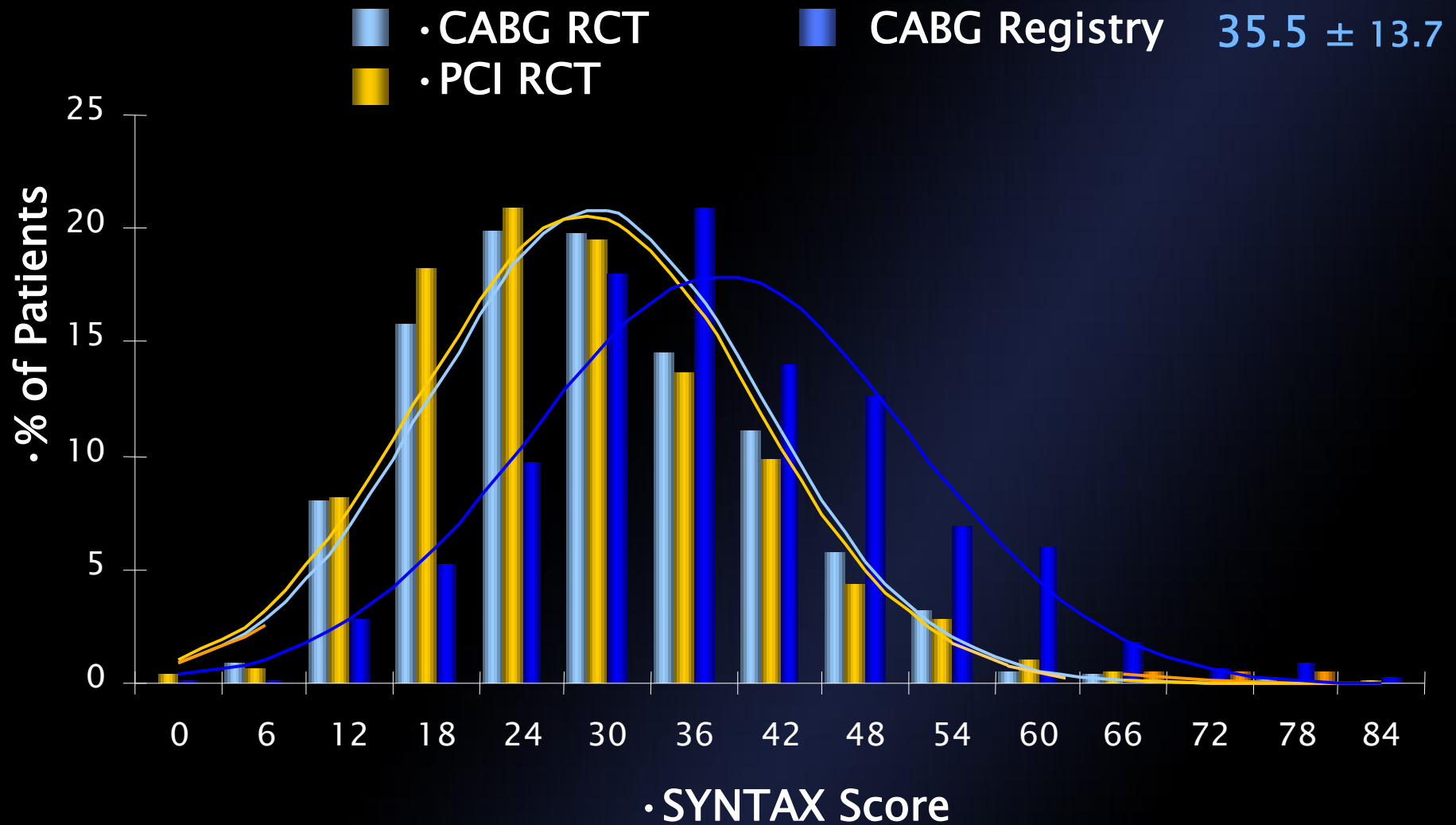
RCA 100%

# SYNTAX Score Distribution by Cohort and Treatment Group

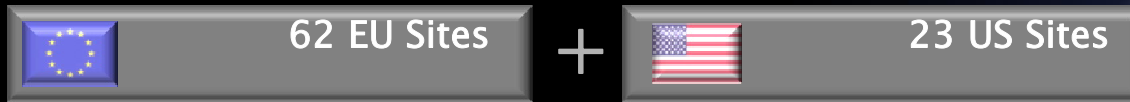




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# SYNTAX Trial Design



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vs

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66.3%

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34.6%

\*Taxus Express

# Patient Characteristics (II)

## *Notable Differences CABG RCT + Registry*



### *Patient-based*

	CABG Reg (n=644)
Total SYNTAX Score	35.5 ± 13.7
Diffuse disease or small vessels, %	31.8
Number of lesions, mean ± SD	4.8 ± 1.9
3VD only, %	52.5
Left main, any, %	47.5
Left Main only	1.6
Left Main + 1 vessel	5.4
Left Main + 2 vessel	10.4
Left Main + 3 vessel	30.1
Total occlusion, %	59.3
Bifurcation, %	64.6
Trifurcation, %	13.0

# Patient Characteristics (II)

## *Left Main Subset: Randomized Cohort*



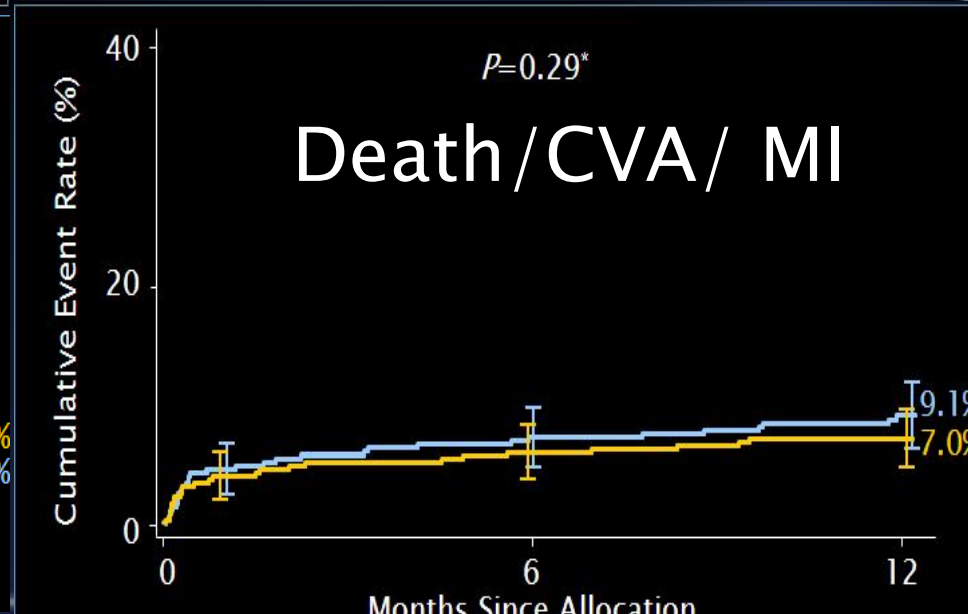
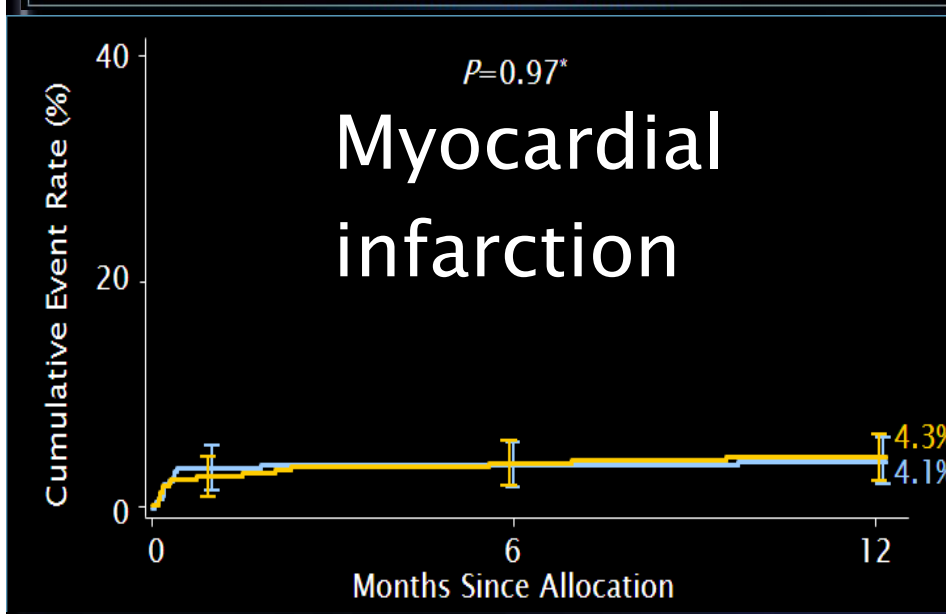
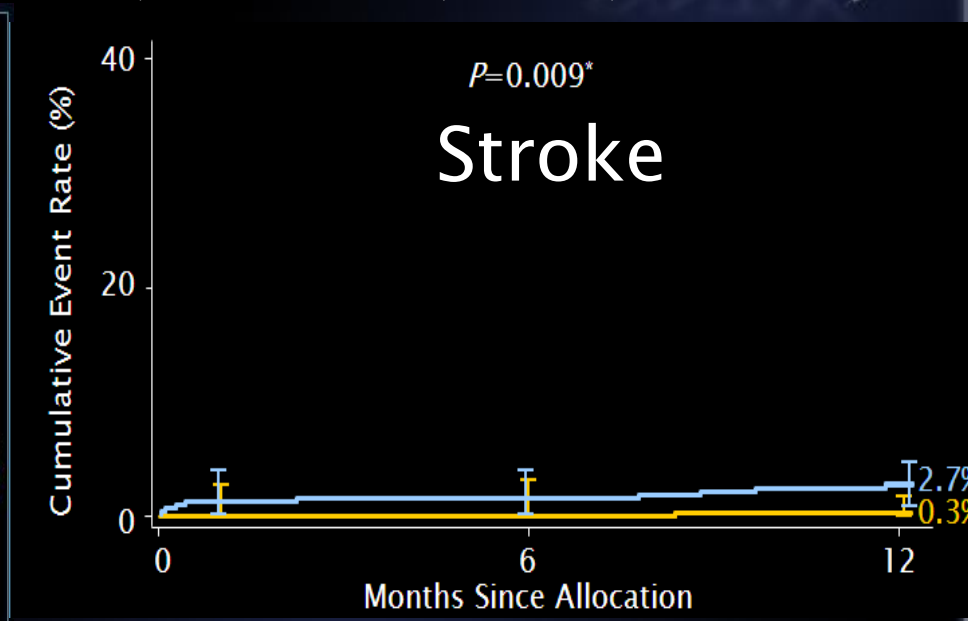
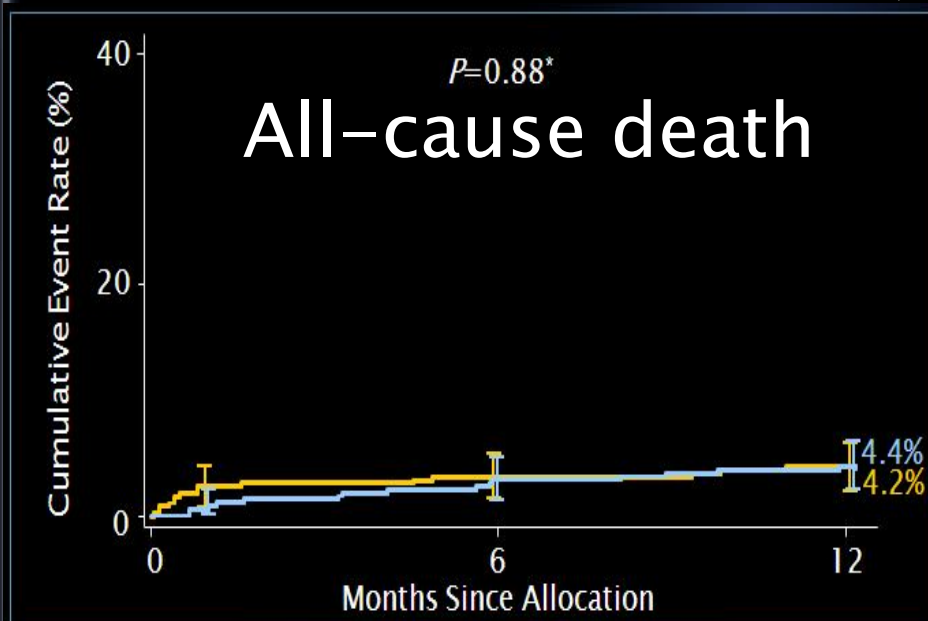
<i>Patient-based</i>	<b>CABG n=348</b>	<b>TAXUS n=357</b>	<i>P</i> value
<b>Total SYNTAX Score</b>	<b>26.7 ± 11.5</b>	<b>28.1 ± 12.4</b>	<b>0.13</b>
Diffuse disease or small vessels, %	12.9	11.8	0.64
No. lesions, mean ± SD	3.2 ± 1.9	3.3 ± 1.8	0.89
Left main disease type, %			
Left Main only	<b>14.1</b>	<b>11.8</b>	0.36
Left Main + 1 vessel	<b>20.4</b>	<b>18.8</b>	0.58
Left Main + 2 vessel	<b>30.5</b>	<b>31.4</b>	0.79
Left Main + 3 vessel	<b>35.1</b>	<b>38.1</b>	0.40
Total occlusion, %	14.7	17.9	0.24
Bifurcation, %	62.4	63.6	0.74
Trifurcation, %	12.6	13.2	0.84

*While prespecified, these subgroup analyses are*

*intended to be observational and hypothesis-generating.*

# Clinical outcomes to 12 Months

Left Main Subset ■ CABG (N=348) ■ TAXUS (N=357)



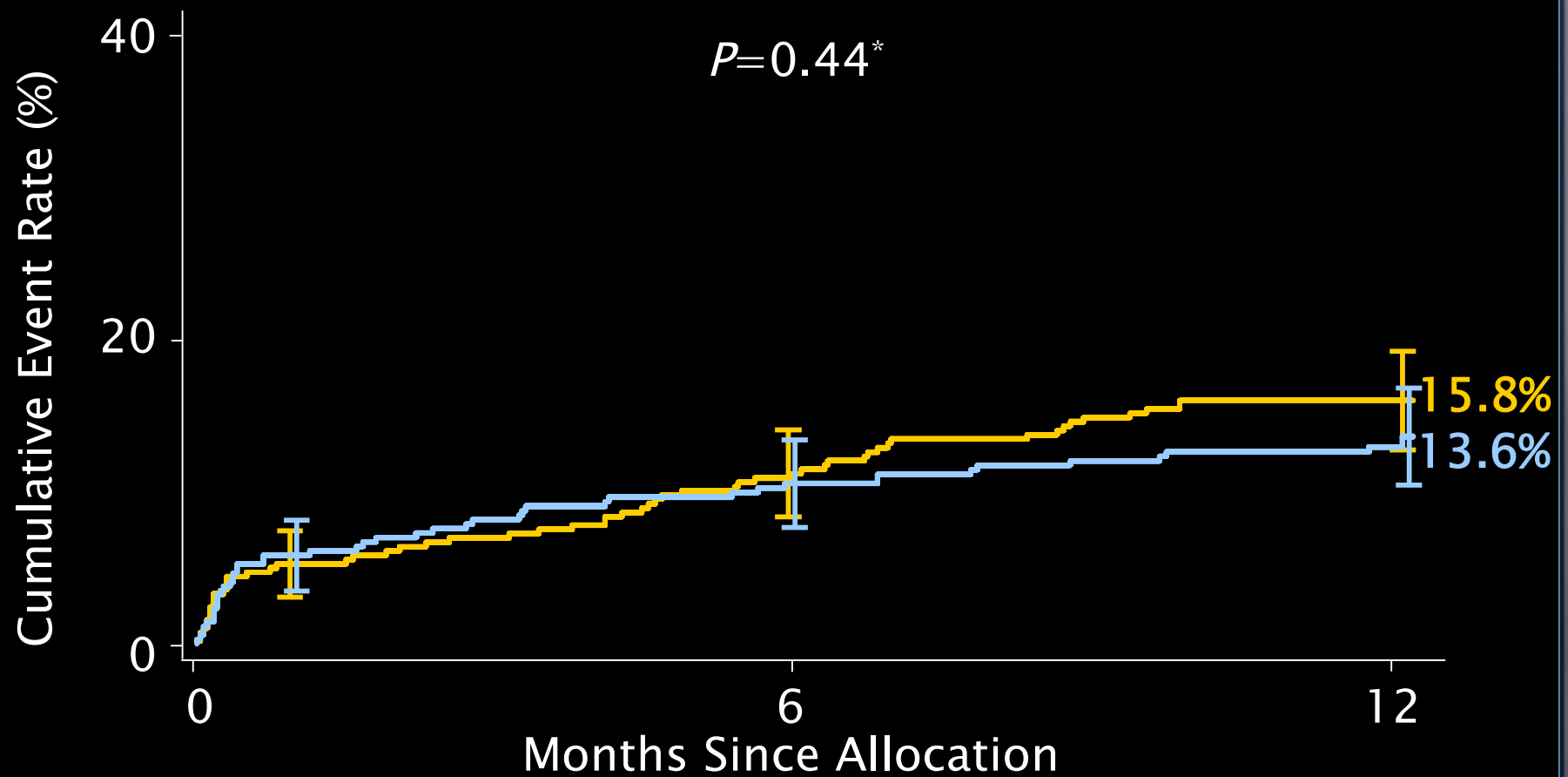
# MACCE to 12 Months

*Left Main Subset*



■ CABG (N=348)

■ TAXUS (N=357)



Event rate  $\pm$  1.5 SE, \*Fisher exact test

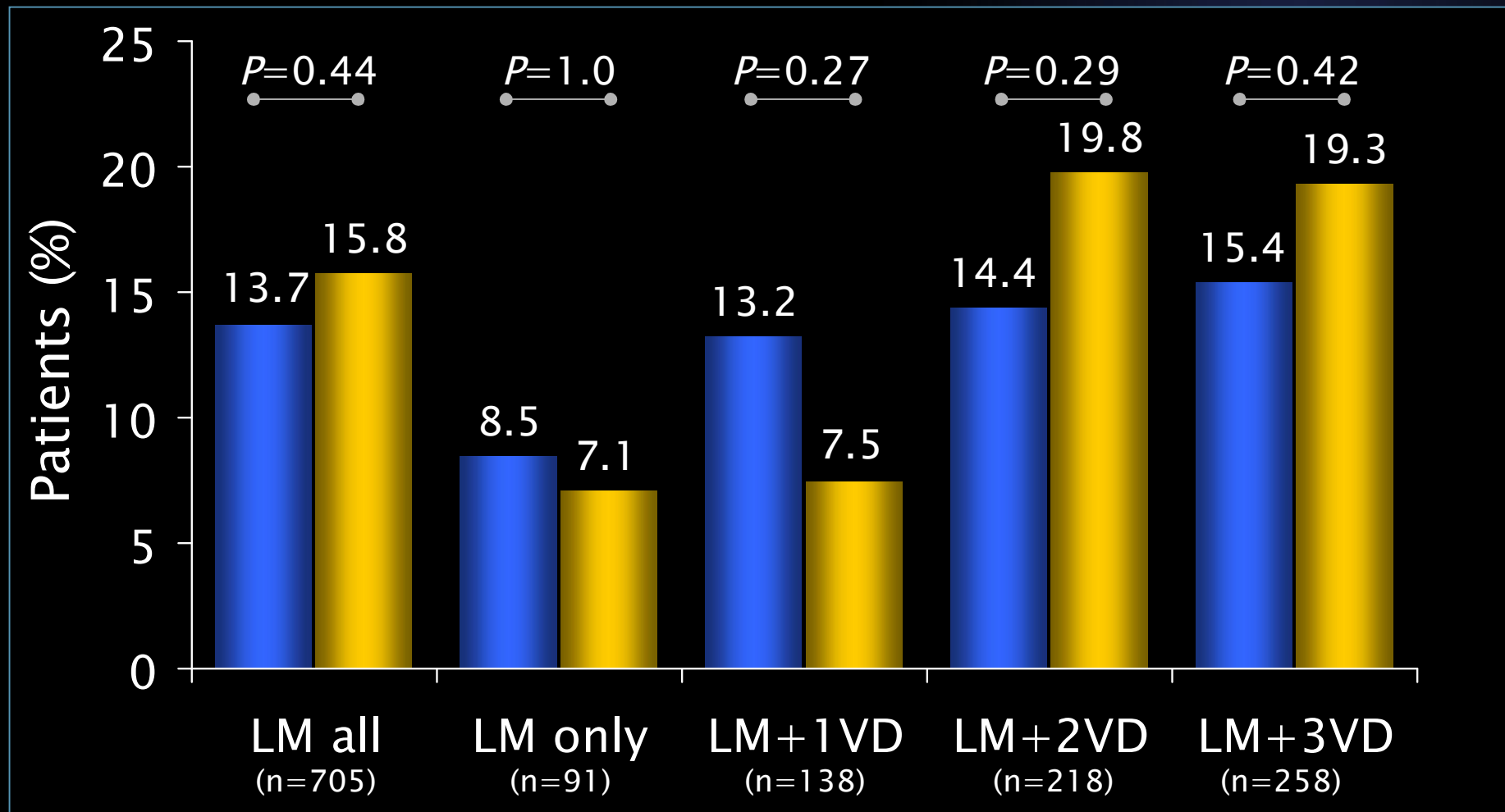
ITT population

# Overall MACCE at 12 Months

## Left Main Subset



■ CABG    ■ TAXUS

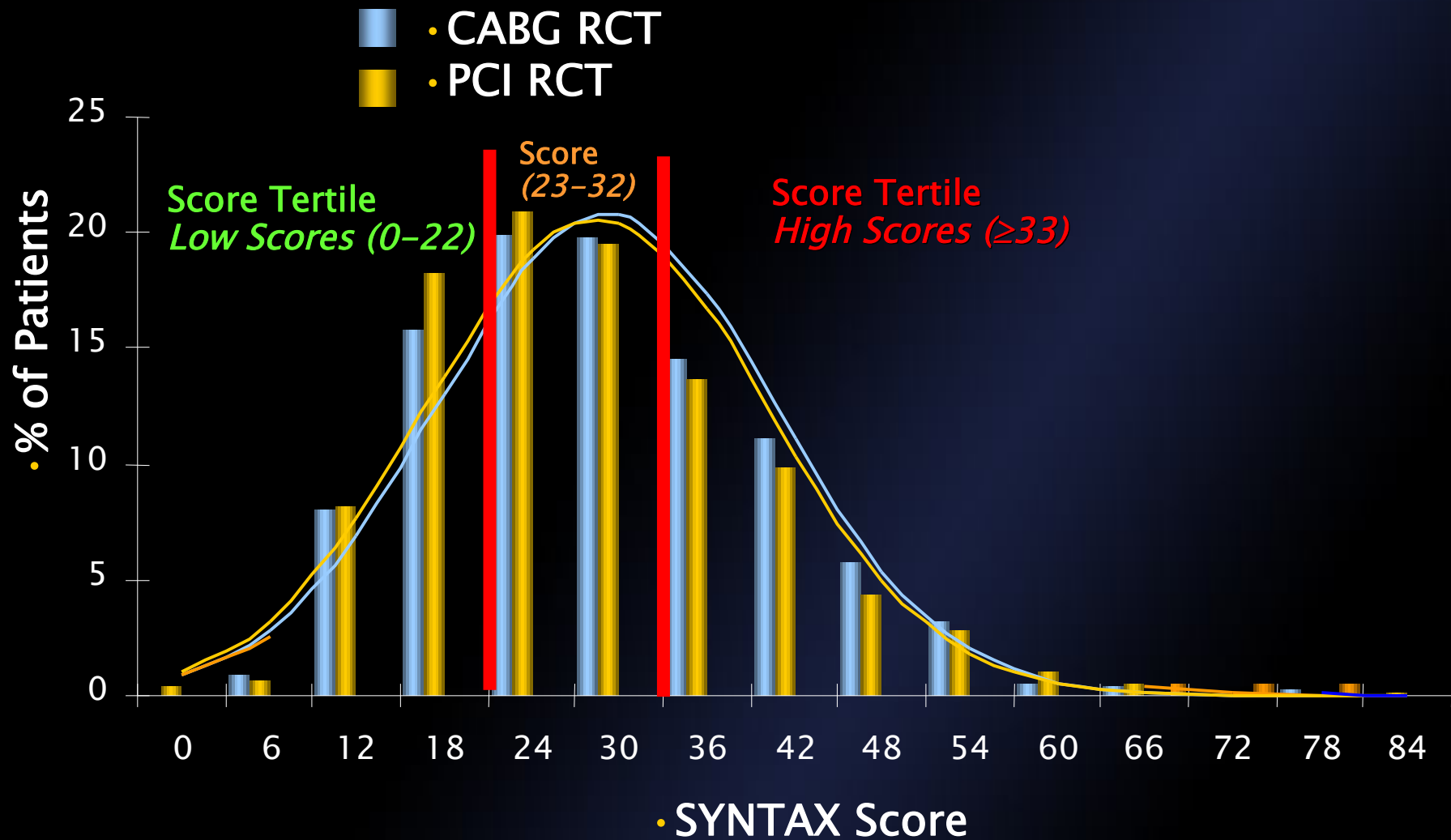


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ITT population

# SYNTAX Score Distribution by Cohort and Treatment Group



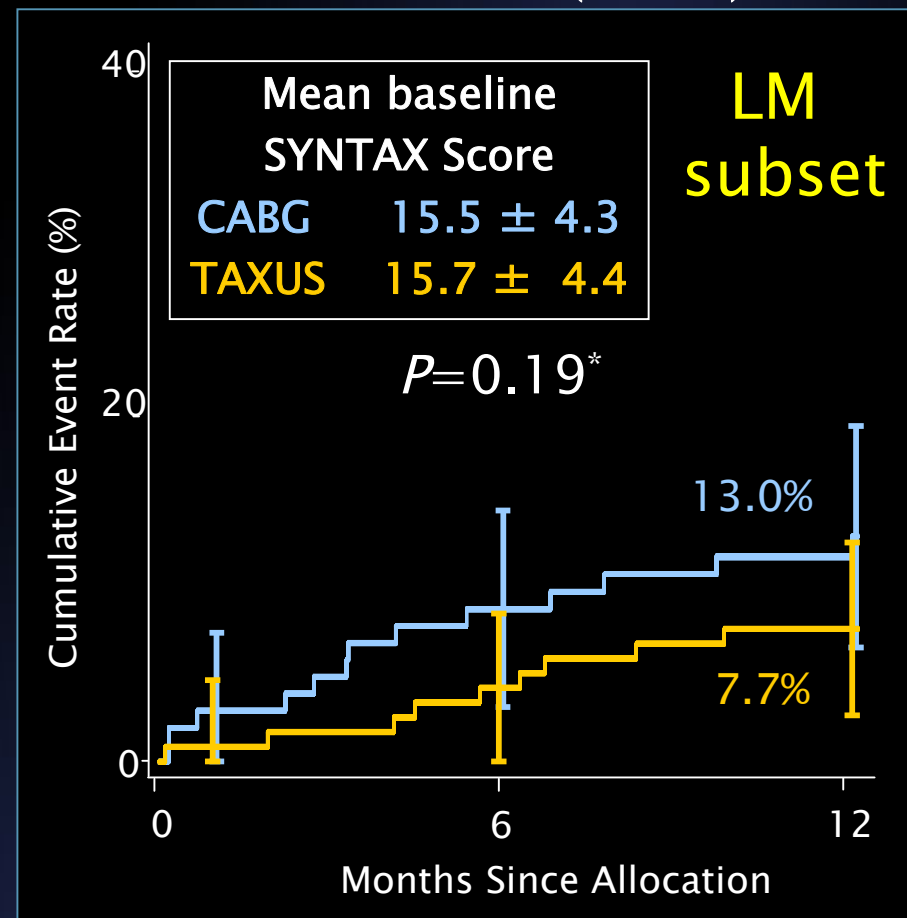


# MACCE to 12 Months by SYNTAX Score Tertile *Low Scores (0-22)*



	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

■ CABG (N=103)  
■ TAXUS (N=118)



Event rate ± 1.5 SE, \*Fisher exact test

Calculated by core laboratory; ITT population

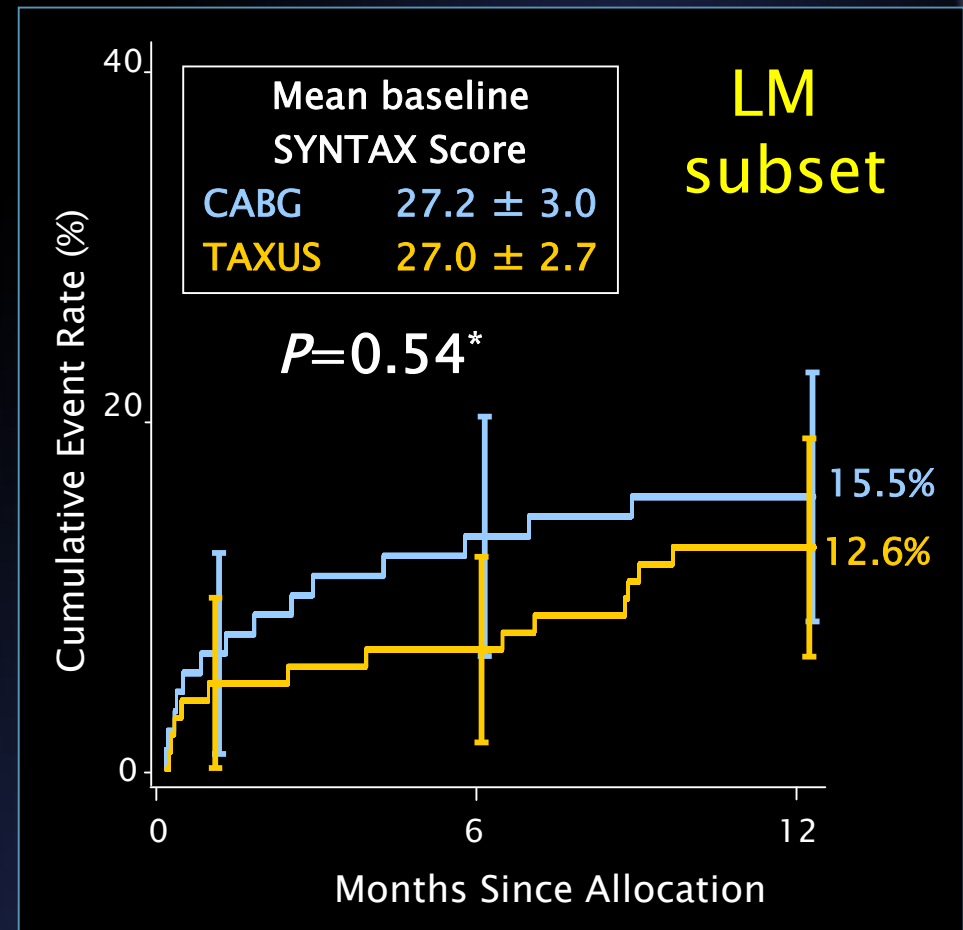
# MACCE to 12 Months by SYNTAX Score Tertile

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

■ CABG (N=92)  
 ■ TAXUS (N=195)



Event Rate ± 1.5 SE, \*Fisher exact test

Calculated by core laboratory; ITT population

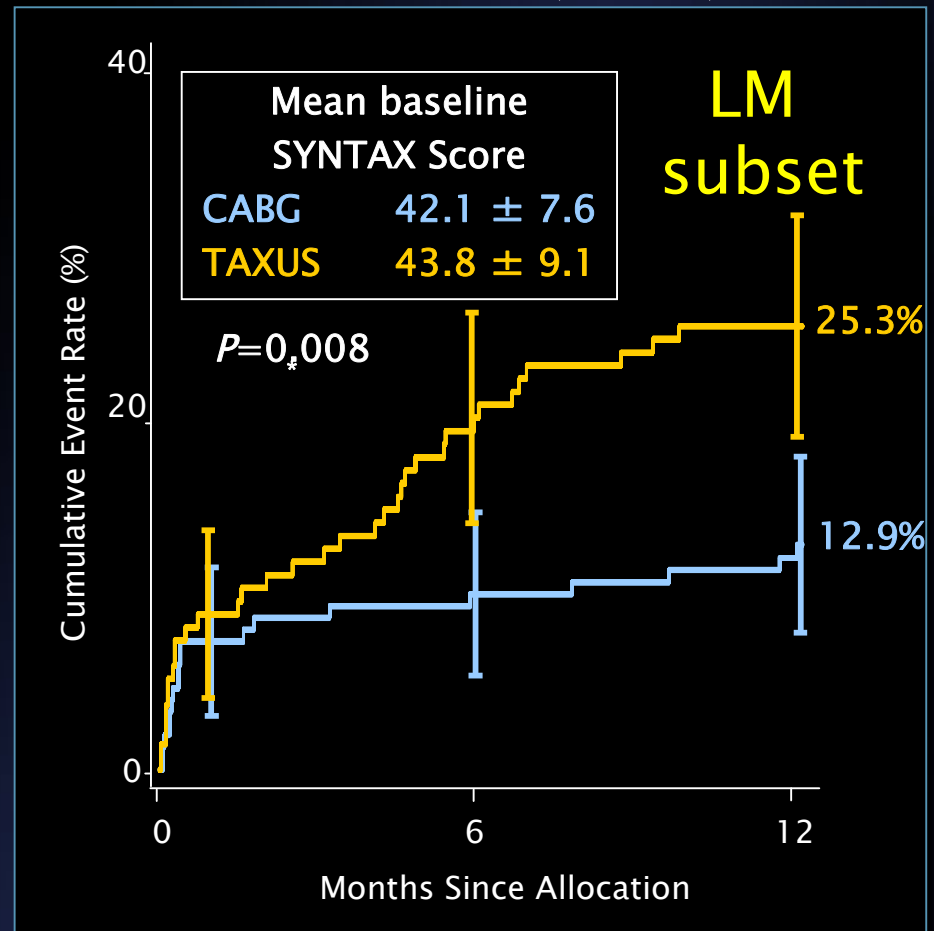
# MACCE to 12 Months by SYNTAX Score Tertile

High Scores ( $\geq 33$ )



	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

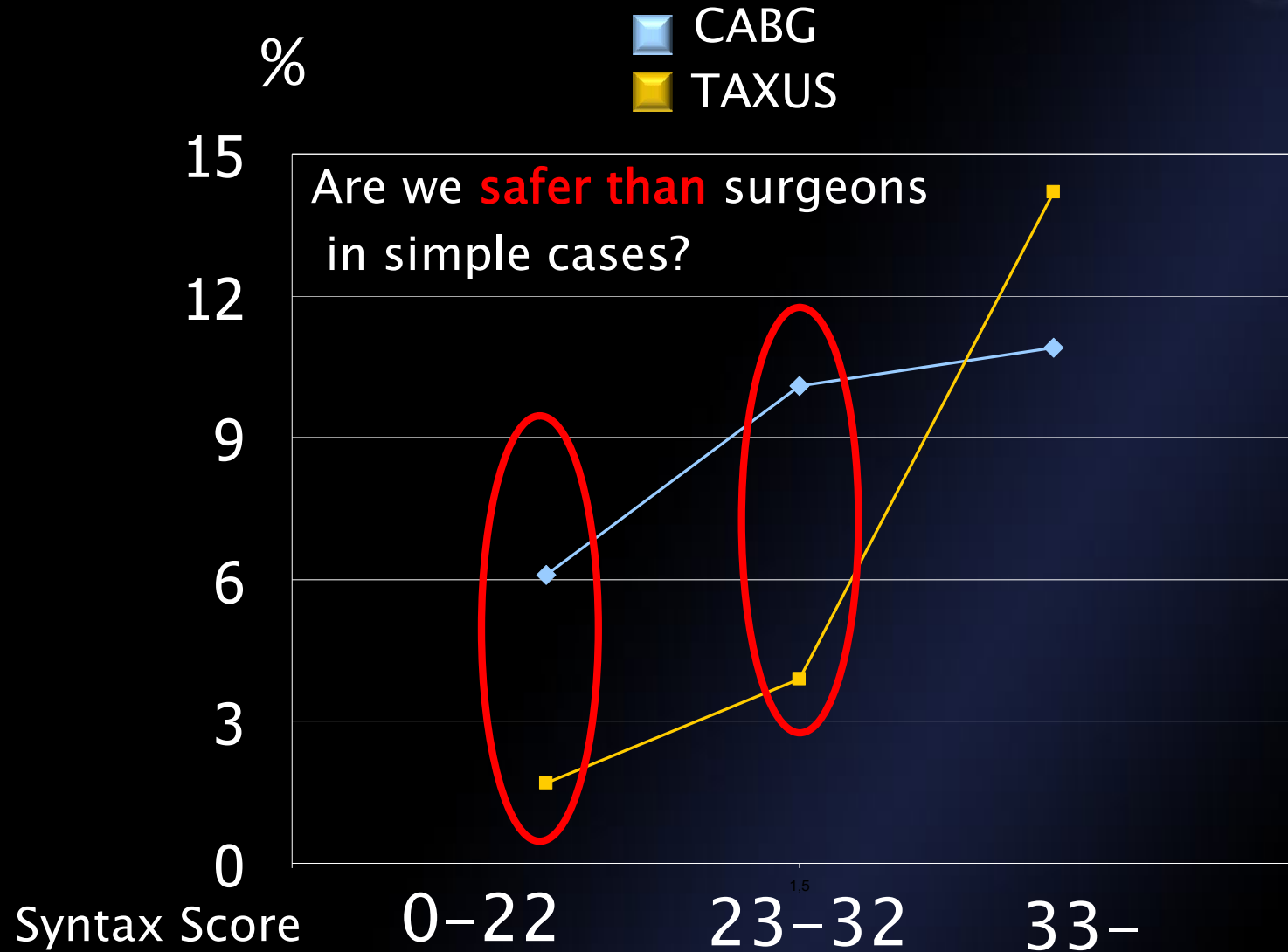
■ CABG (N=166)  
 ■ TAXUS (N=155)



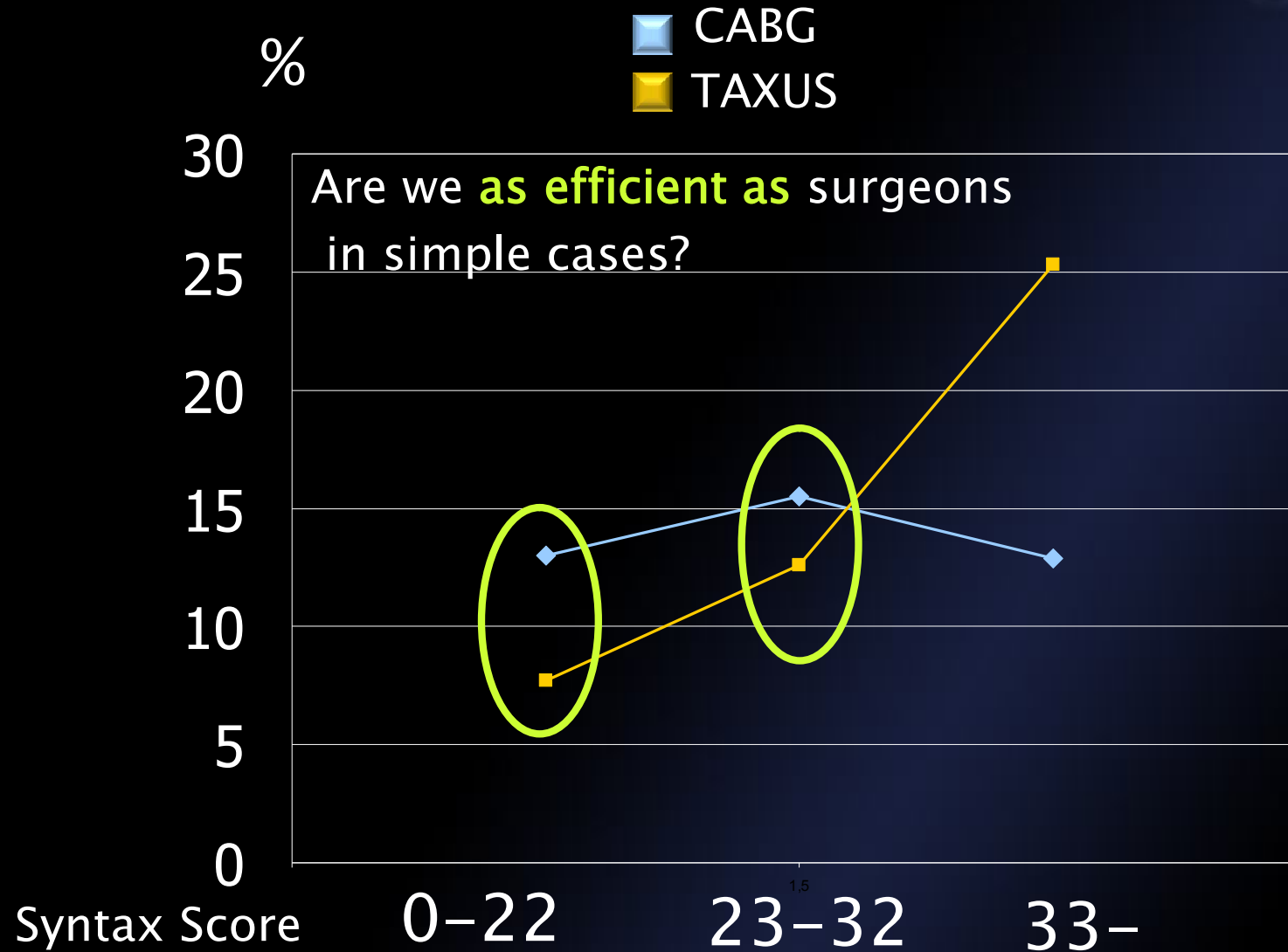
Event Rate  $\pm$  1.5 SE, \*Fisher exact test

Calculated by core laboratory; ITT population

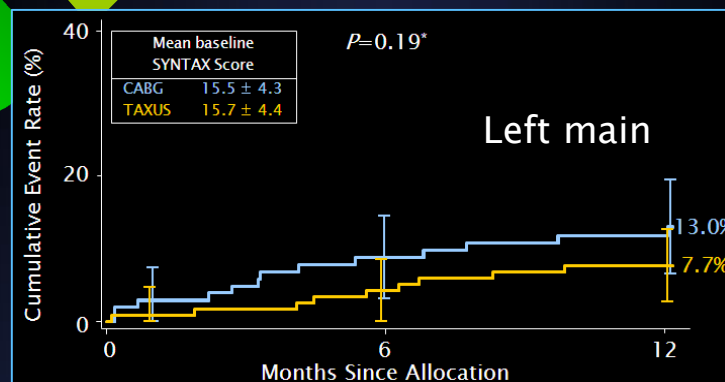
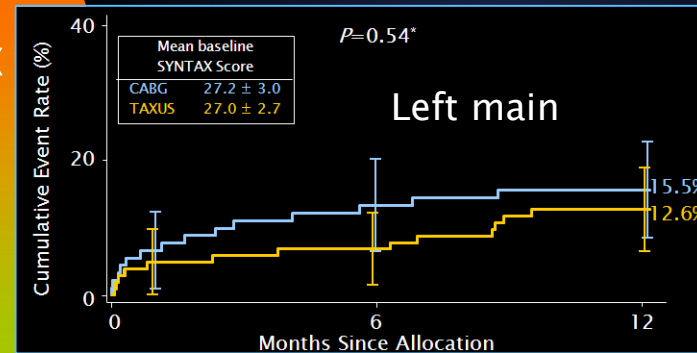
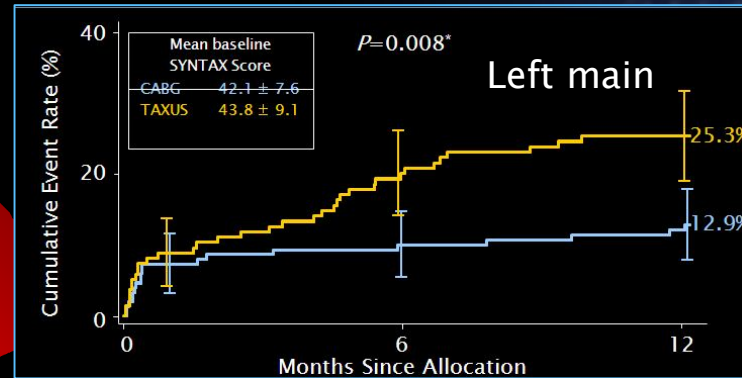
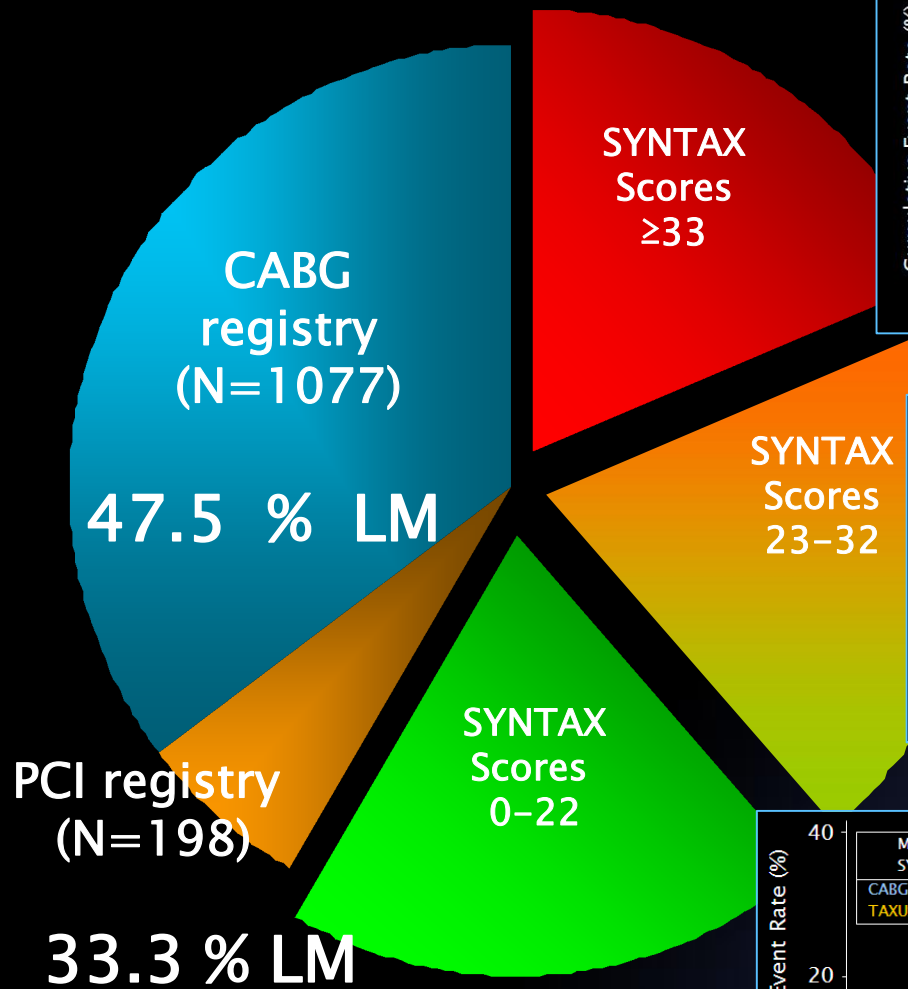
# Death/ MI/ CVA in LM Disease



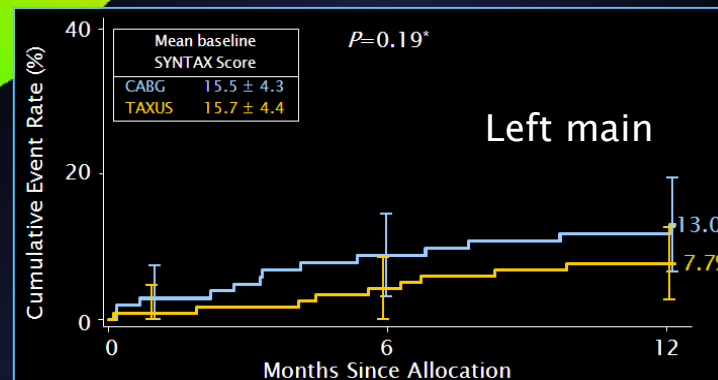
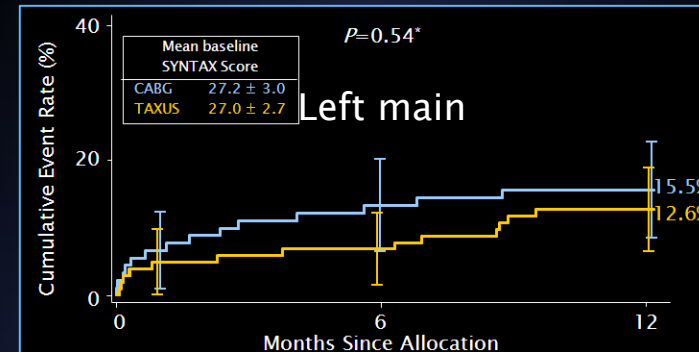
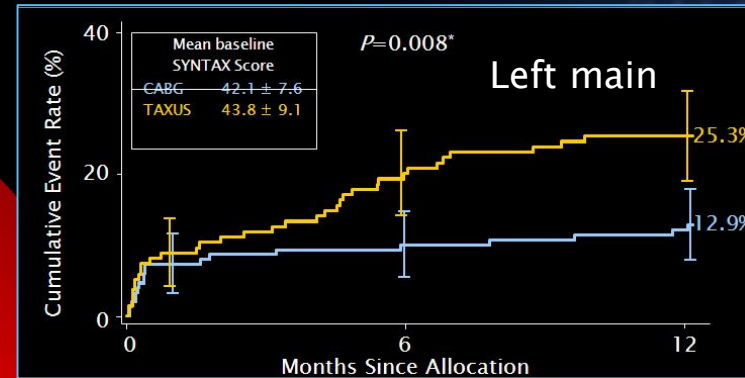
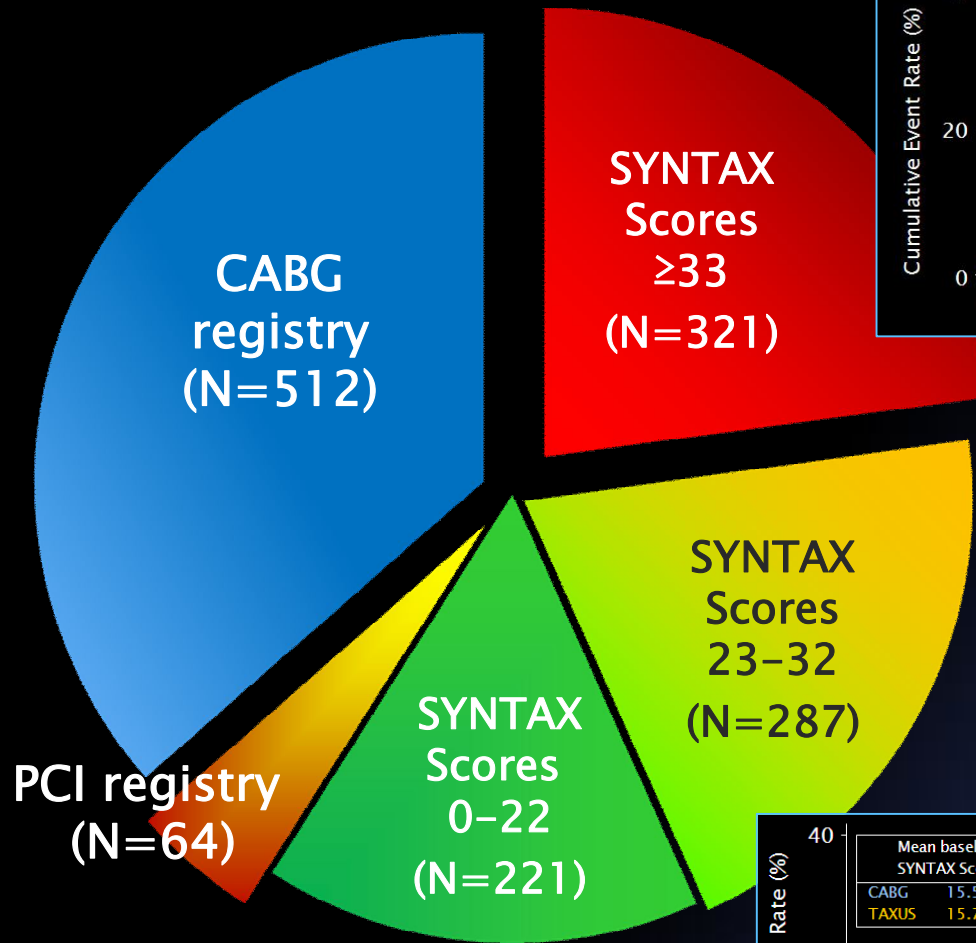
# MACCE in LM Disease



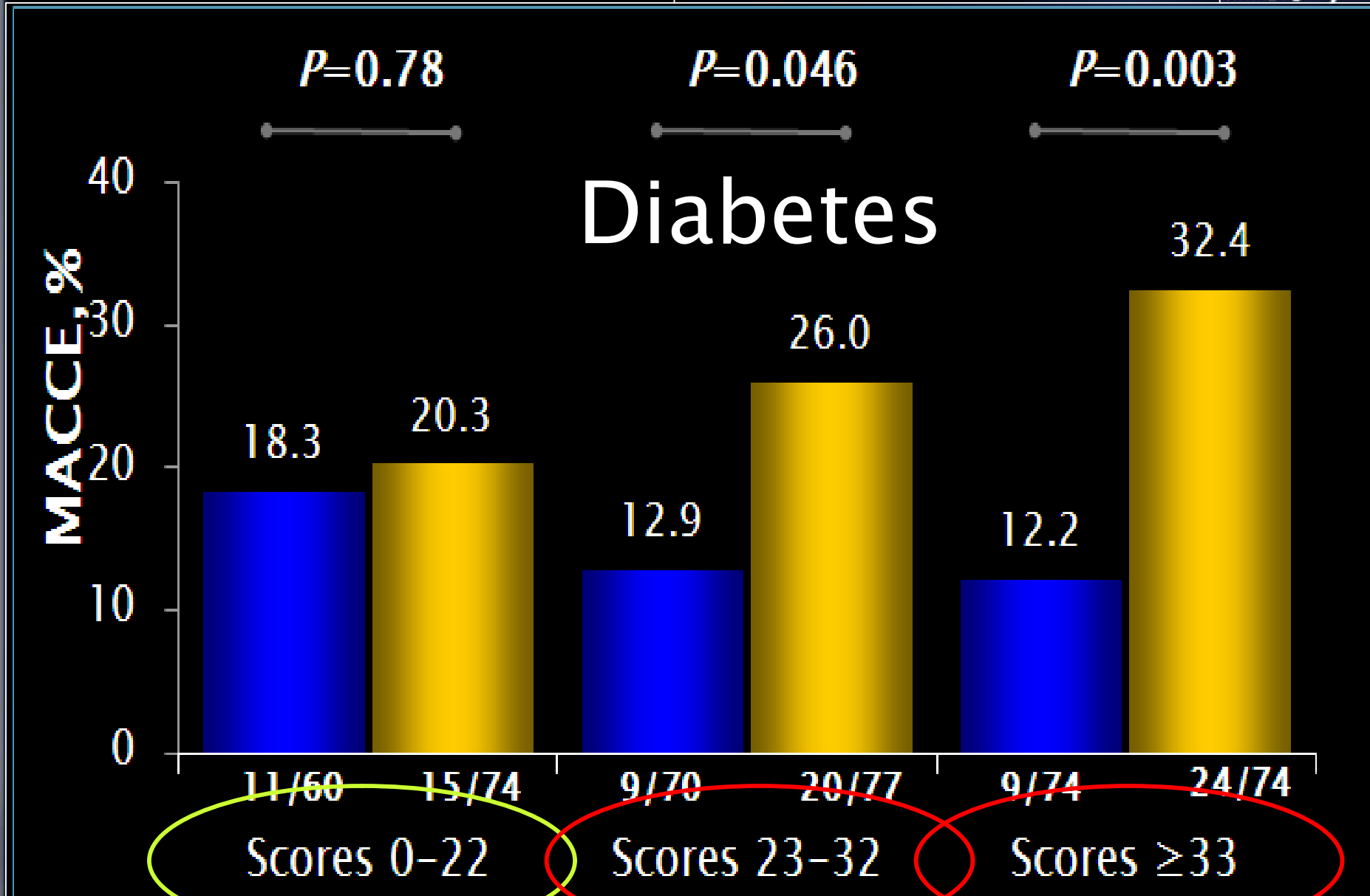
# SYNTAX Trial Patient Distribution



# Left Main Patient Distribution

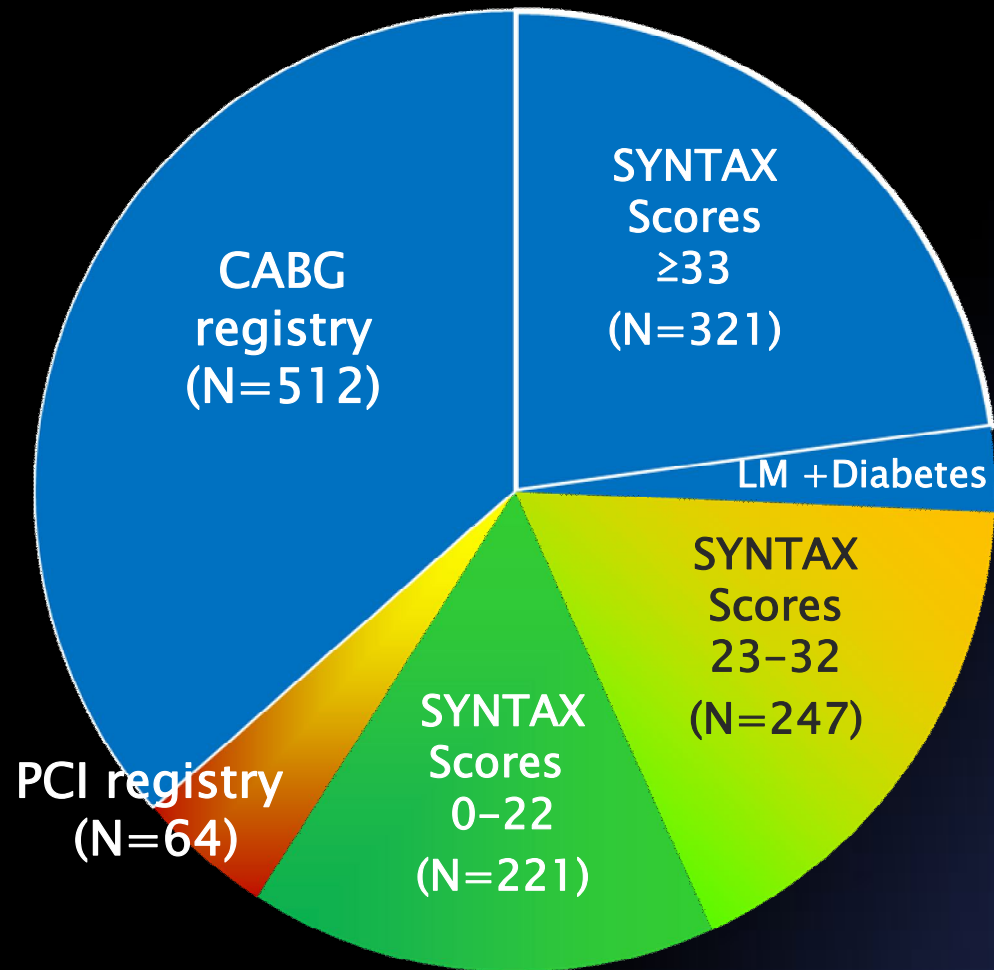


# SYNTAX Trial Patient Distribution

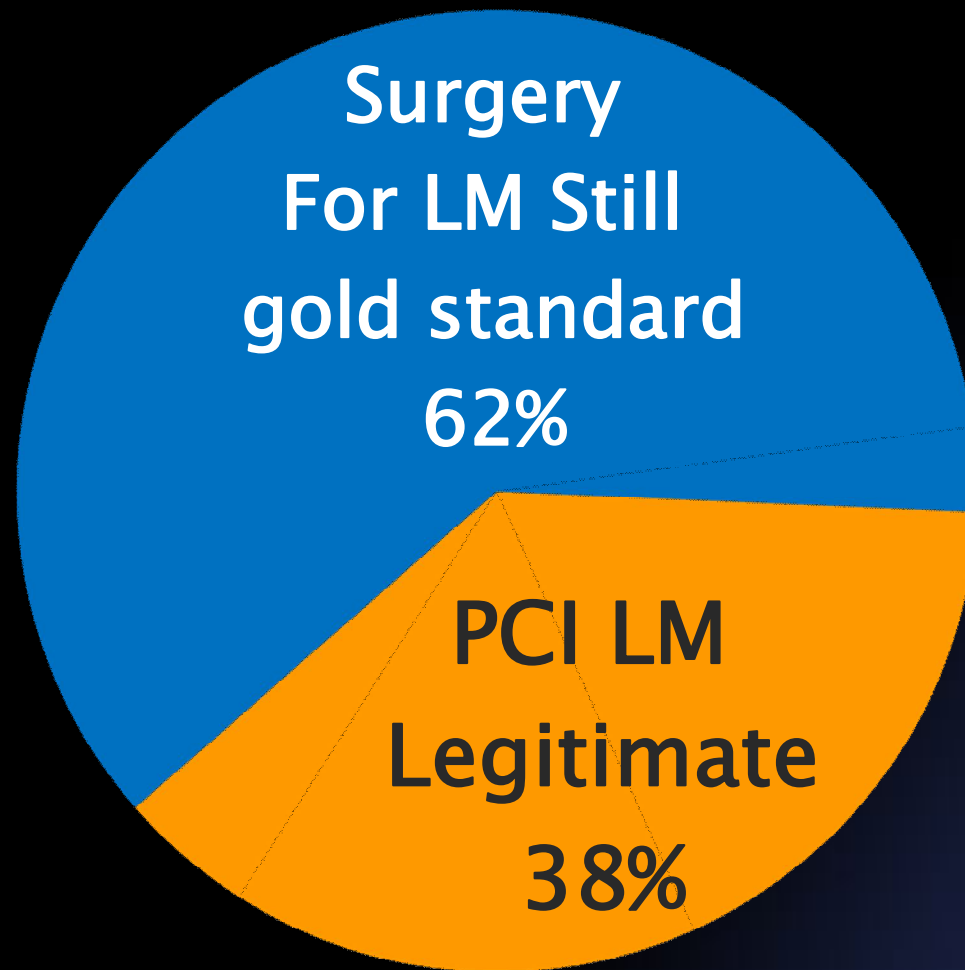




# SYNTAX Trial Patient Distribution



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Results of the SYNTAX trial suggest that 38 % of all patients with Left Main Stem are best treated with PCI , an excellent alternative to surgery... at least up to one year

This Year,  
in Asian-Pacific TCT 2009 ...

- I am no longer a debater in search of historical arguments... but I am a trialist relying on Evidence-based medicine.
- Let us speak now the surgical debater !

Thank you.