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CARDIOVASCULAIRE  
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# Impact of 2-year SYNTAX LM Study

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## Major Advisory Guidelines Have Recommended CABG for the Treatment of LM Disease

### CABG

- ACC/AHA Guidelines for Coronary Artery Bypass Graft Surgery<sup>1</sup>
- Revised 2004

### PCI

- ACC/AHA Guidelines for Percutaneous Coronary Intervention<sup>2</sup>
- Revised 2006

<sup>1</sup> Eagle et al. ACC/AHA 2004 Guideline Update for Coronary Artery Bypass Graft Surgery. *Circulation* 2004;110:e340-e437.

<sup>2</sup> Smith SC Jr, Feldman TE, Hirshfeld JW Jr, Jacobs AK, Kern MJ, King SB III, Morrison DA, O'Neill WW, Schaff HV, Whitlow PL, Williams DO. ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention). American College of Cardiology Web Site. Available at: <http://www.acc.org/clinical/guidelines/percutaneous/updates/index.pdf>.

## Contemporary Trials of LM CABG vs PCI

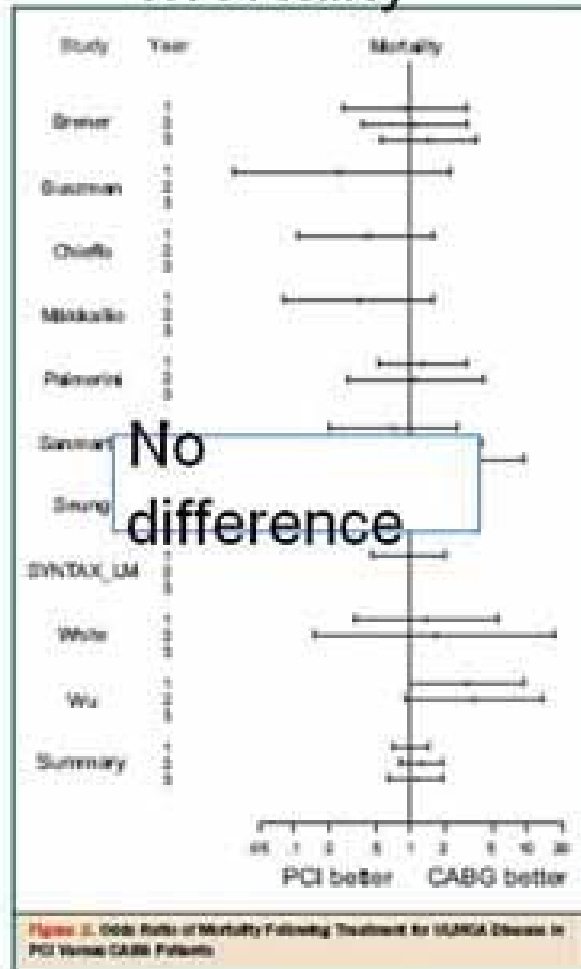
### Superior Treatment Modality for Outcomes

Trial*	N	Death	MI	Stroke	Revasc
Sanmartin 2007	341	ND	ND		CABG better
MAIN-COMPARE 2008	1102			n/a	
LEMANS 2008	105				
Palmerini 2006	311		PCI better	PCI better	ND
Chieffo 2006	249		ND		
Lee 2006	173		ND	ND	n/a
Makikallio 2008	287				
Brener 2008	287		n/a	n/a	CABG
White 2008	343				
Wu 2008 (DES)	112				

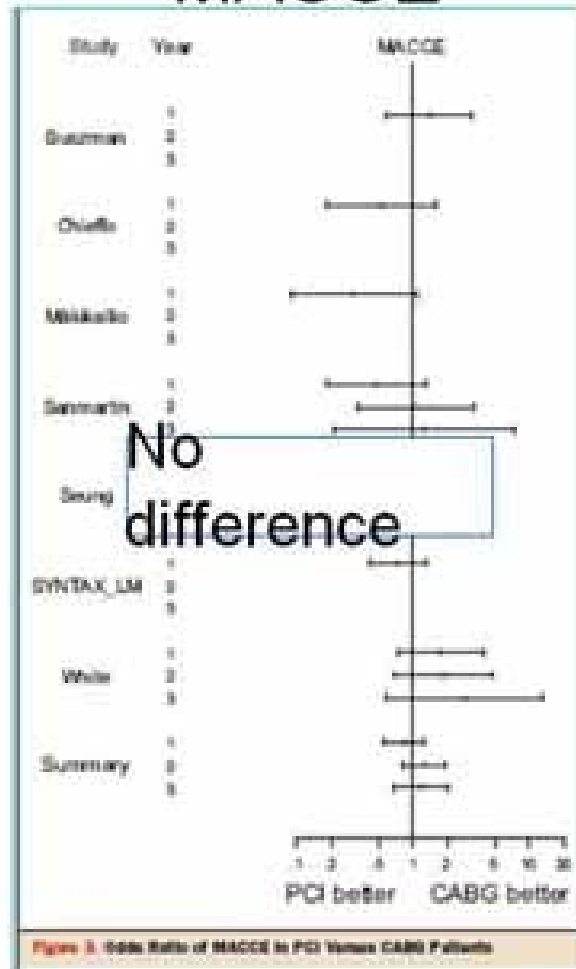
\*Studies with >50 patients per arm reported 2006-2008  
 ND=no difference; n/a=not available/not reported

# Meta-Analysis of PCI vs CABG in 3,773 UPLM Patients (1)

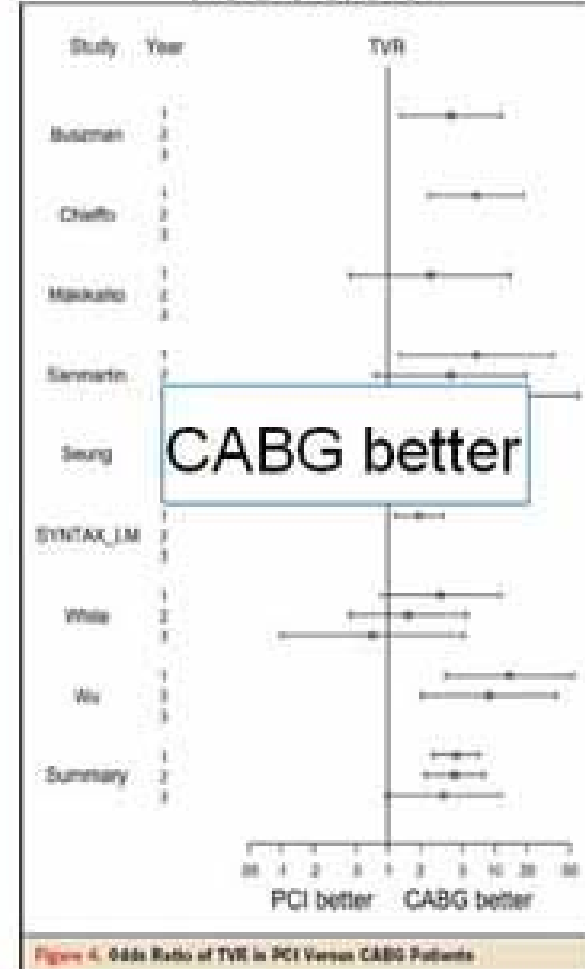
## Mortality



## MACCE



## Revasc



# 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%

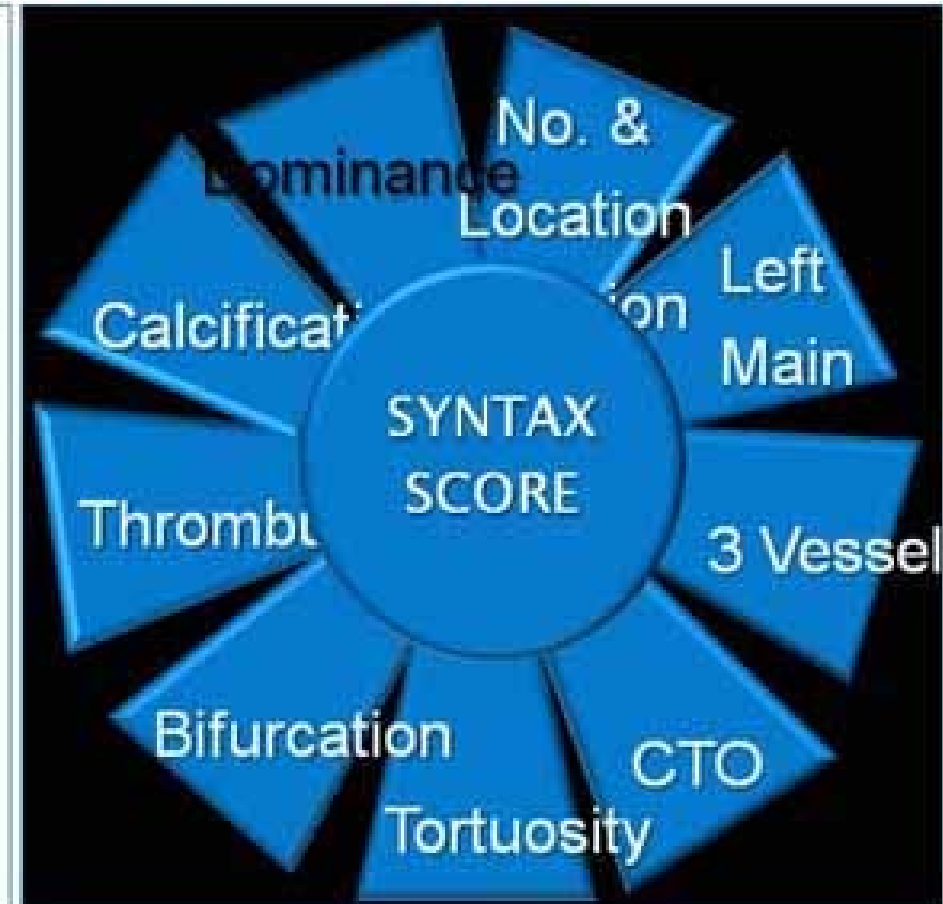
LM  
34.6%

\*TAXUS Express

# Patient evaluation

Each patient is evaluated by the surgeon and the interventional cardiologist according to the following criteria:

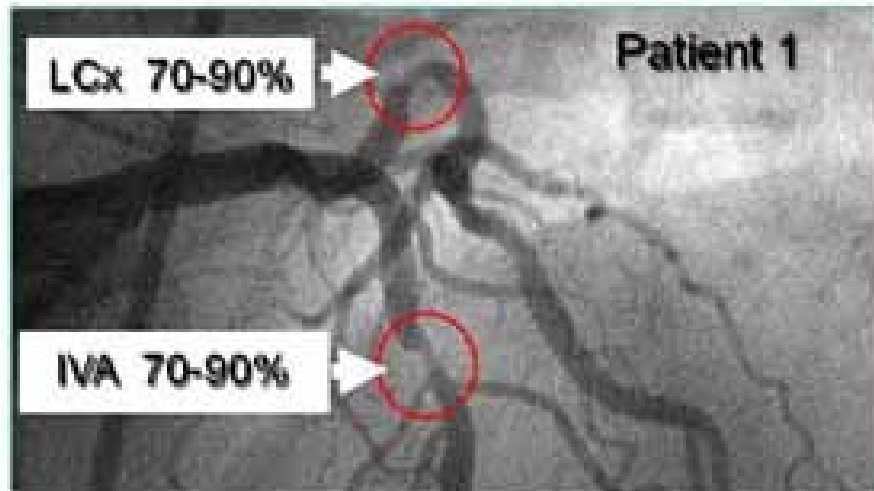
- Surgical risk (EuroSCORE & Parsonnet score)
- Complexity of the coronary lésions (new SYNTAXscore)
- Objective: SYNTAX score to help to determine the best revascularisation strategy for patients with high risk lesions



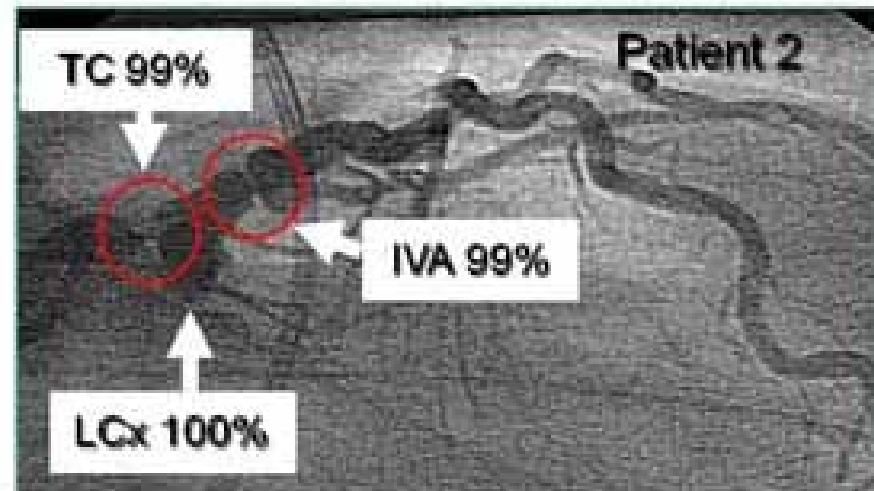
Sianos et al, EuroIntervention 2005;1:219-227  
Valgimigli et al, Am J Cardiol 2007;99:1072-1081  
Serruys et al, EuroIntervention 2007;3:450-459

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, JAm Coll Cardiol 1997;30:649-656

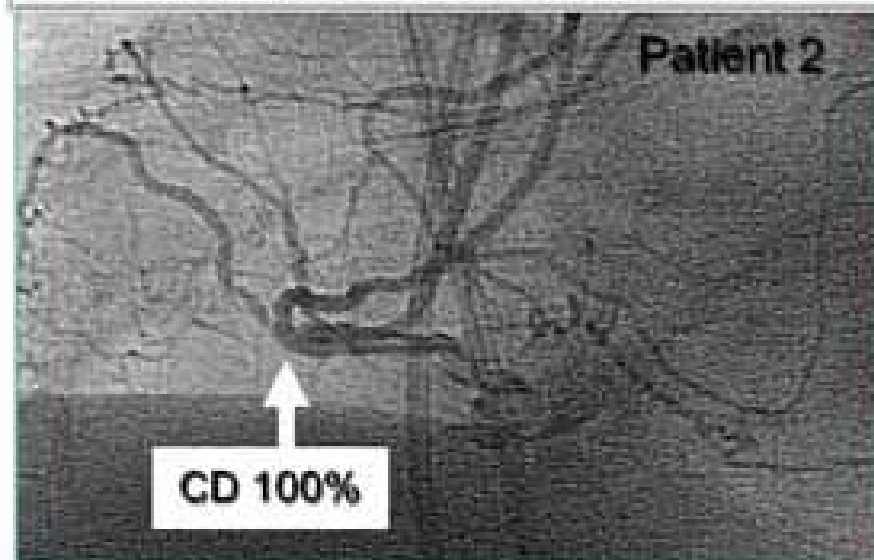
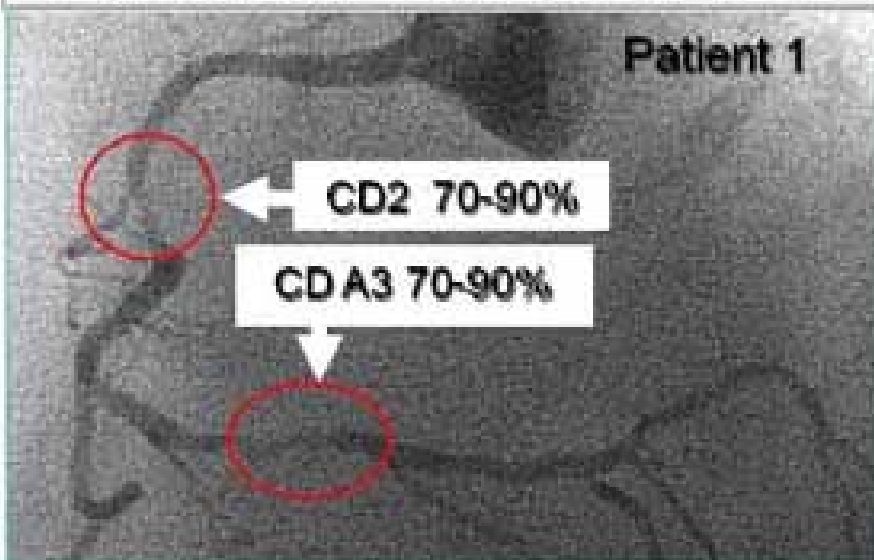
# 'complex 3VD and LM are not equal'



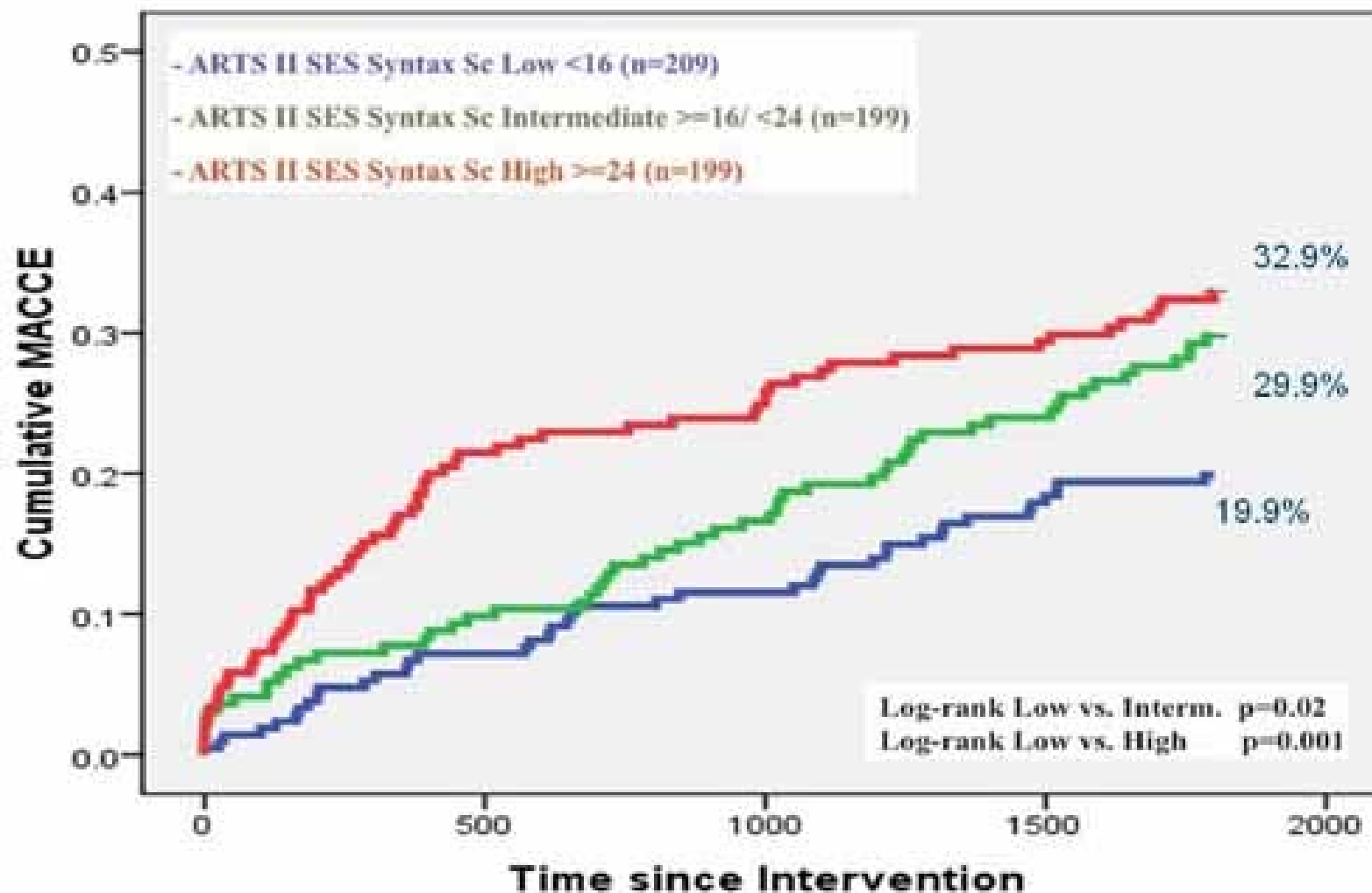
**SYNTAX SCORE 21**



**SYNTAX SCORE 52**



## ARTS II trial 607 pts with 2 et 3V disease



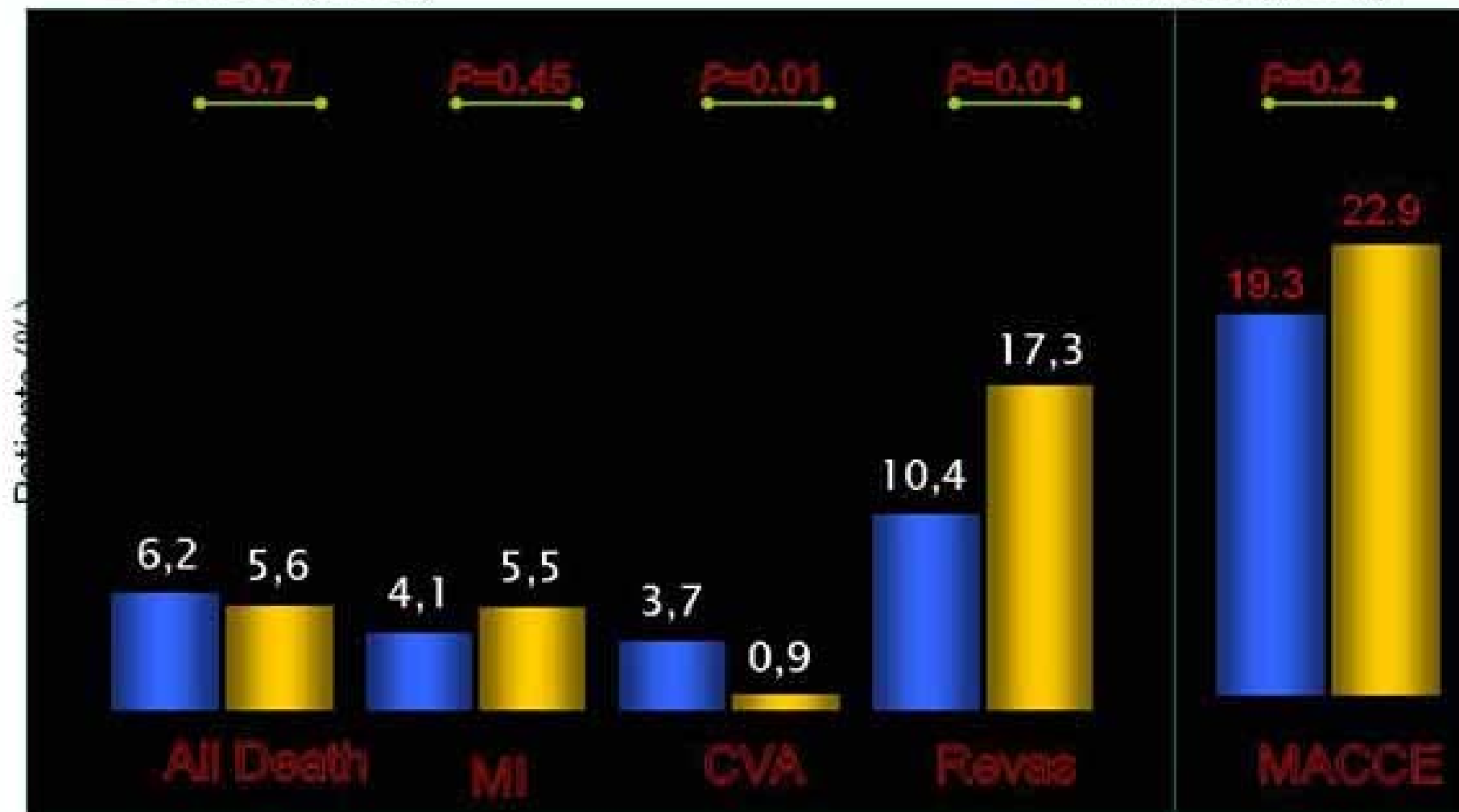


# MACCE to 2 Years

## Left Main Cohort

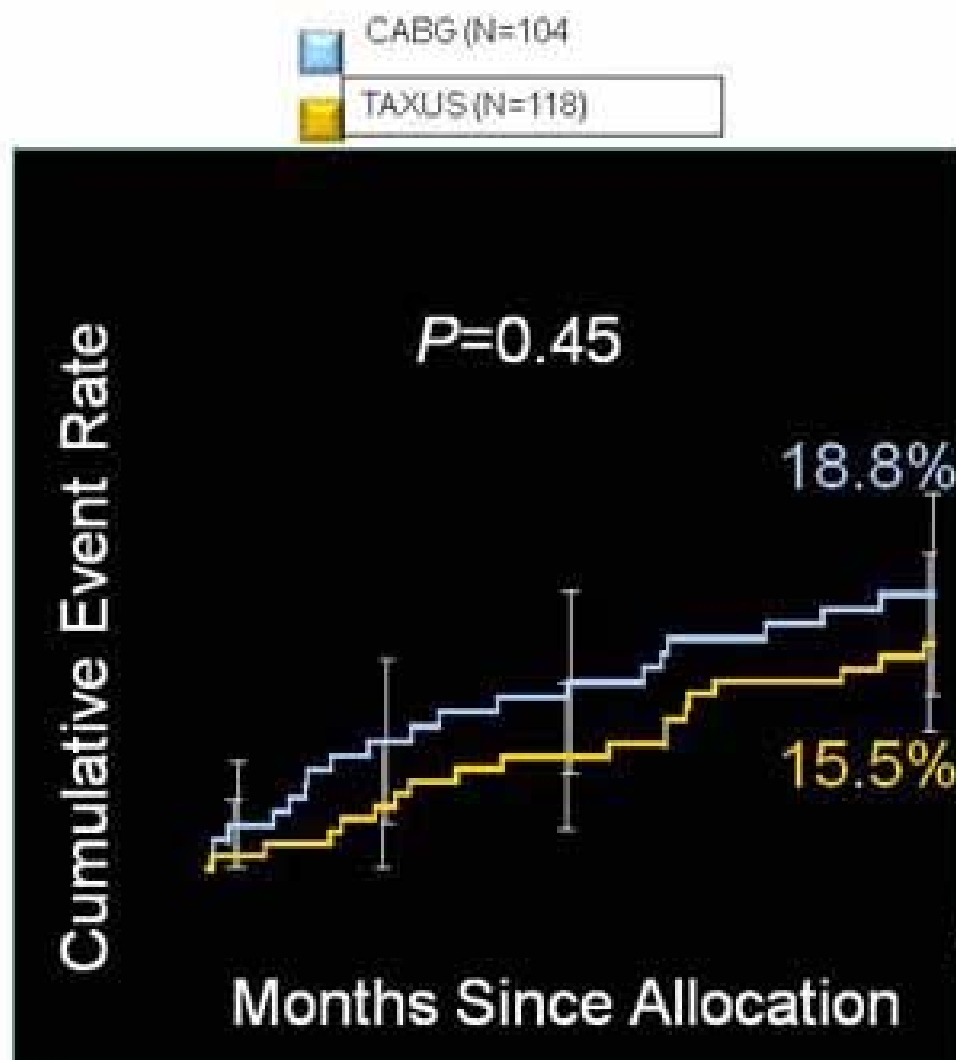
■ CABG (n=348)

■ TAXUS (n=357)



# MACCE to 2 Years by SYNTAX Score Tercile Low Scores (0-22) LM Subset†

	CABG		PCI
Death	4.9%	>	0.9%
CVA	4.1%	>	0.9%
MI	2.0%	<	3.6%
CVA or MI	9.9%	>	4.5%
Revasc.	10.1%	>	14.7%



# MACCE to 2 Years by SYNTAX Score Tercile

## Intermediate Scores (23-32)

	CABG		PCI
Death	11.3%	>	4.9%
CVA	2.3%	>	1.0%
MI	3.3%	<	4.0%
CVA or MI	14.5%	>	9.8%
Revas	12.8%	<	14.9%

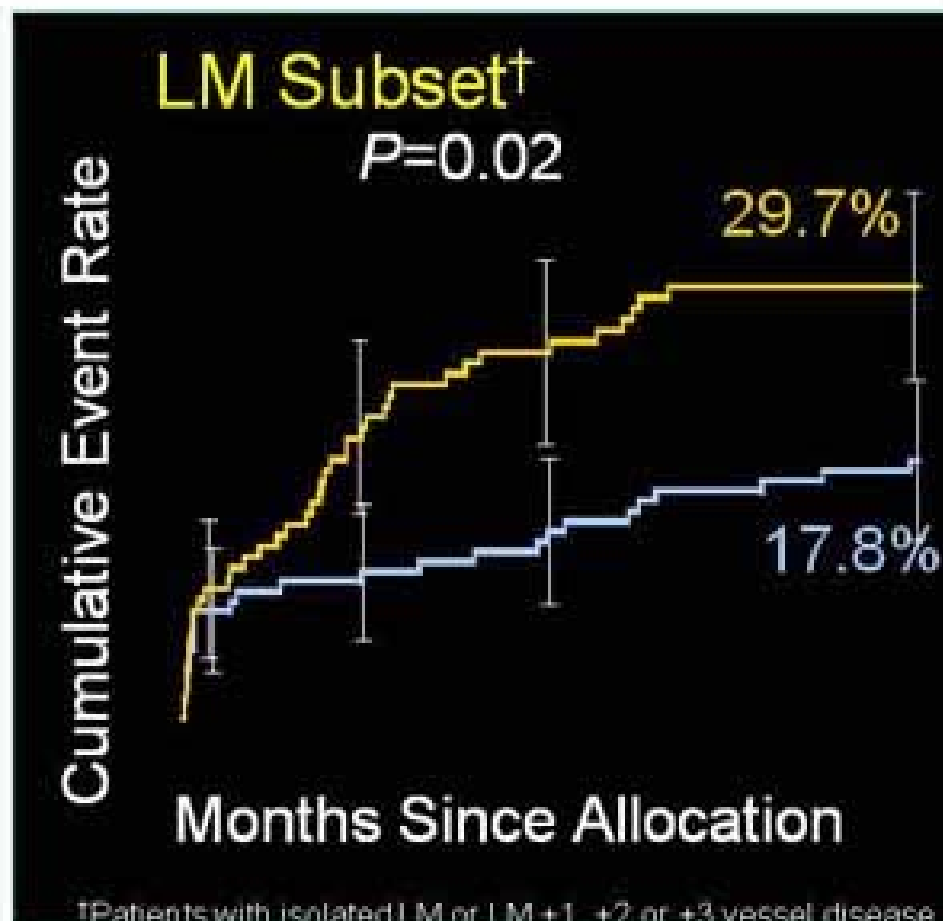
■ CABG (N=92)  
■ TAXUS (N=103)



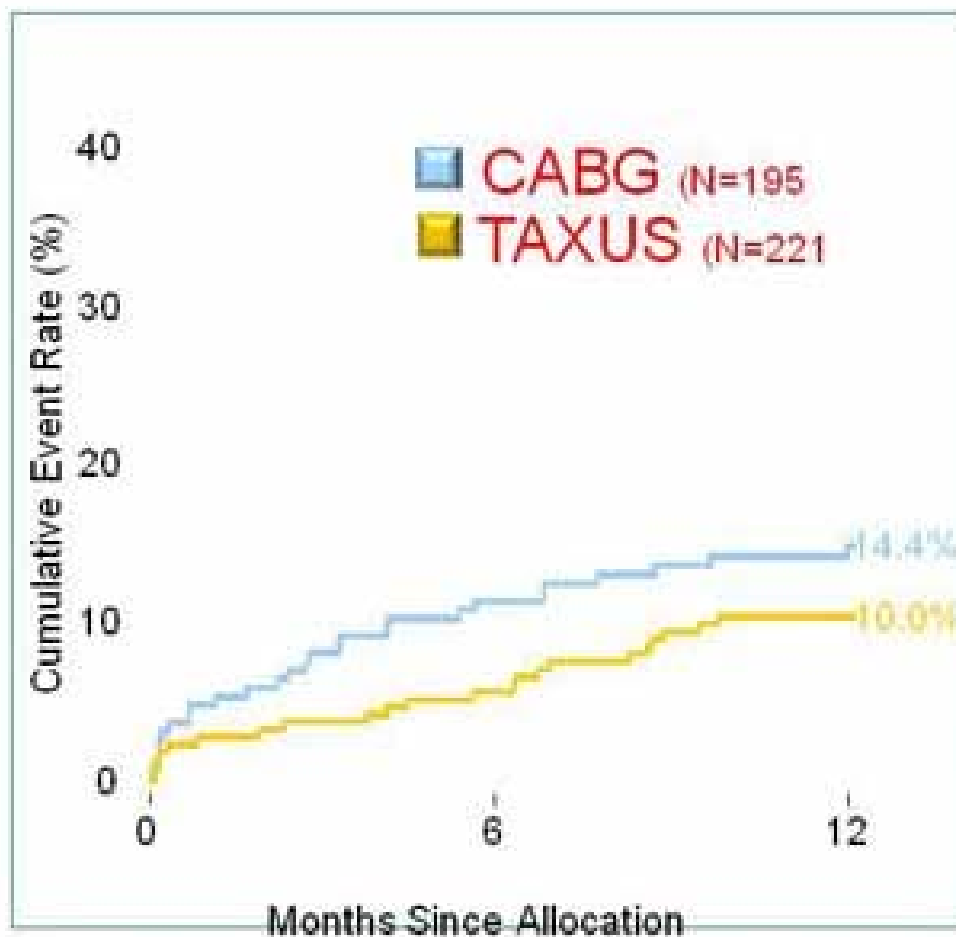
## MACCE to 2 Years by SYNTAX Score Tercile High Scores (33+)

	CABG		PCI
Death	4.1%	<	10.4%
CVA	4.2%	>	0.8%
MI	6.1%	<	8.4%
CVA	11.5%	<	15.6%
Revasc.	9.2%	<	21.8%

■ CABG (N=150)  
■ TAXUS (N=135)



## Left Main scores below 33

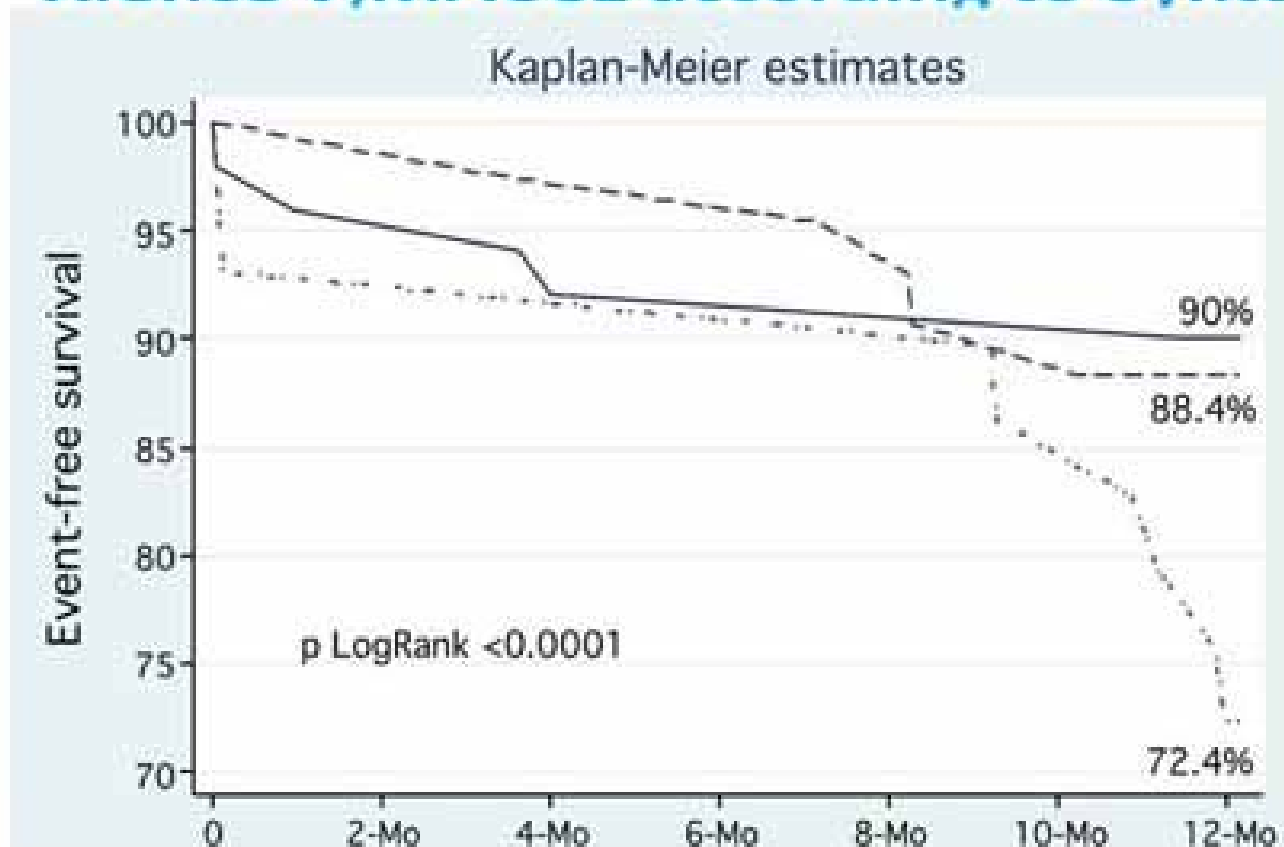


Cumulative KMEvent Rate  $\pm$  1.5 SE; log-rank P value  
[www.icps.com.fr](http://www.icps.com.fr)

	CABG	PCI	P
Death	4.8%	0.9%	0.02
CVA	2.1%	0%	0.04
MI	2.7%	2.3%	1.00
Death, CVA or MI	8.0%	2.7%	0.02
Revasc	8.0%	8.6%	0.81

## LEMAX Trial

(French registry of LM Pts treated with Xience V, MACCE according to Syntax

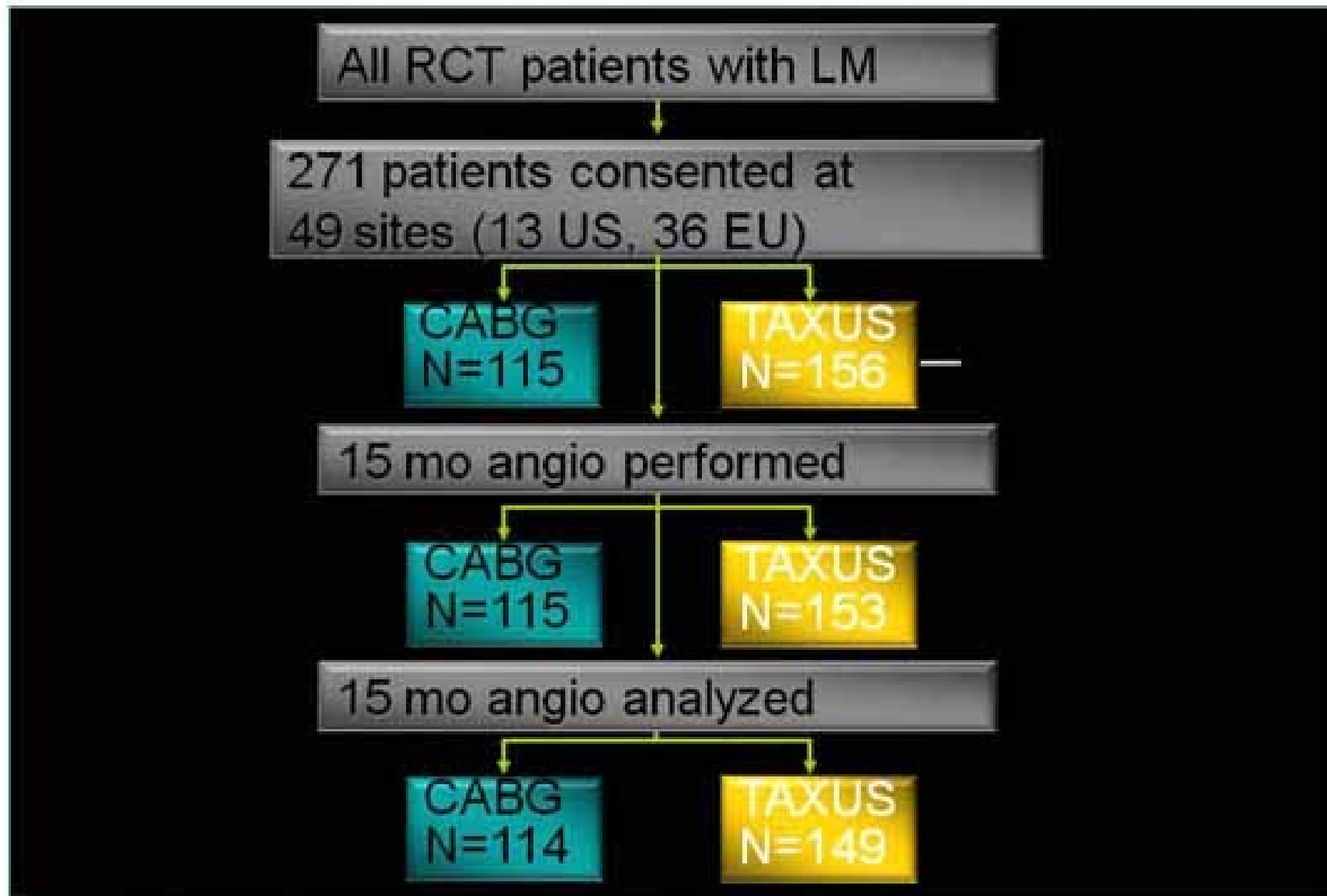


**Low Score 10%**

**Intermediate  
Score 11.6%**

**High Score  
27.4%**

# SYNTAX-LE MANS Trial Design



# MACCE to 2 Years

## LM PCI Subset: Distal vs Non-distal Lesions

■ Distal (n=229)    ■ Non-distal (n=128)





# MACCE to 2 Years

## LM Distal PCI: T-stenting vs Non T-stenting

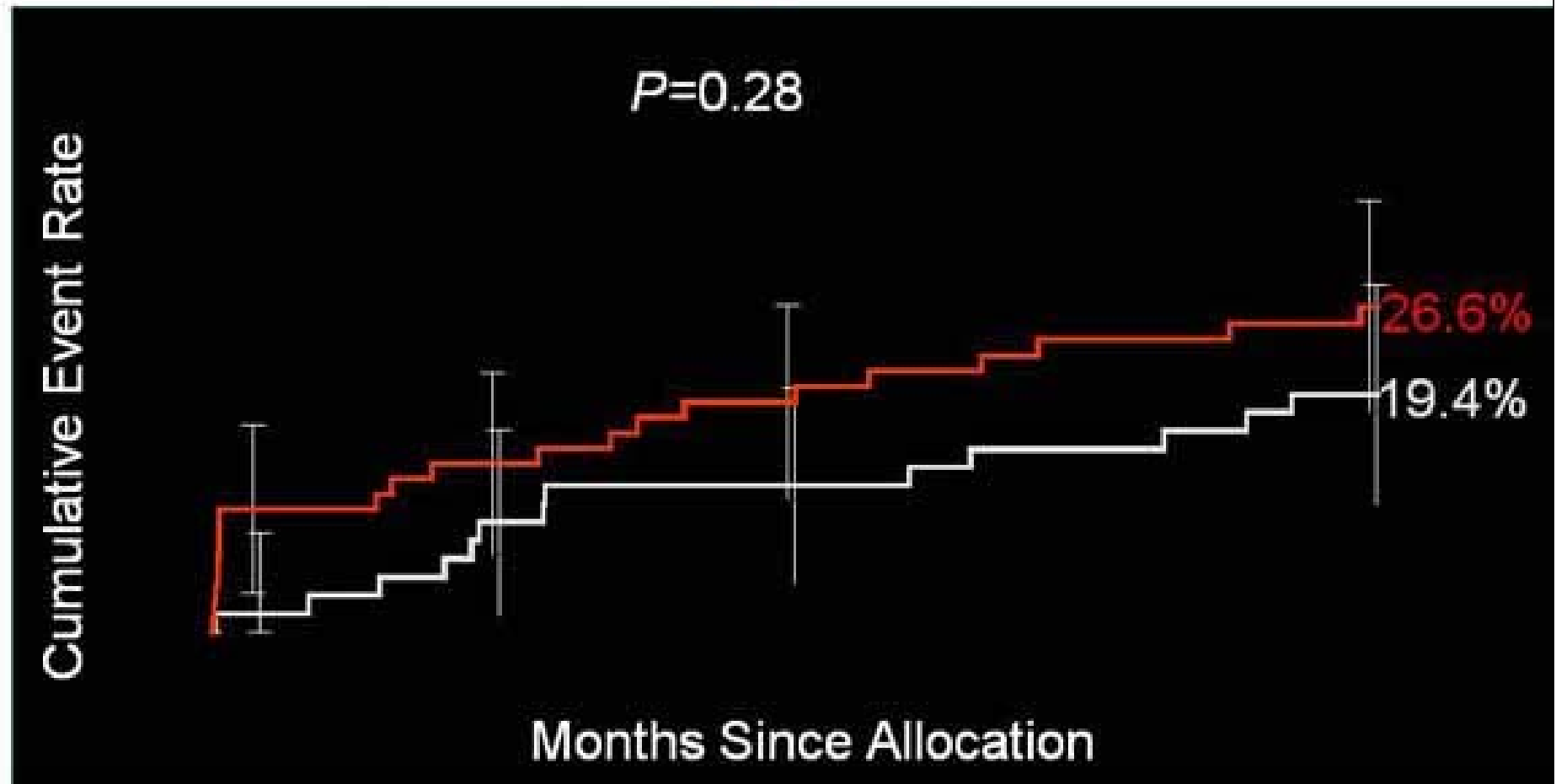
■ T-stenting (n=135) ■ Non T-stenting n=49)



# MACCE to 12 Months

LM Distal PCI Bifurcations:† 1 vs ≥2 stents

■ 1 stent (n=67) ■ 2 stents (n=80)

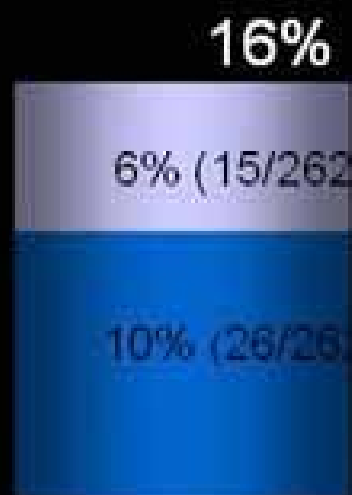


# Principal Results

## CABG Cohort

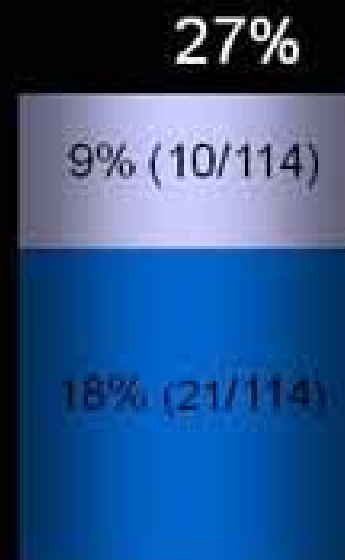
Primary Endpoint (Per graft):

- $\geq 50\%$  to  $<100\%$
- $=100\%$



Per patient:

- $\geq 50\%$  to  $<100\%$
- $100\%$



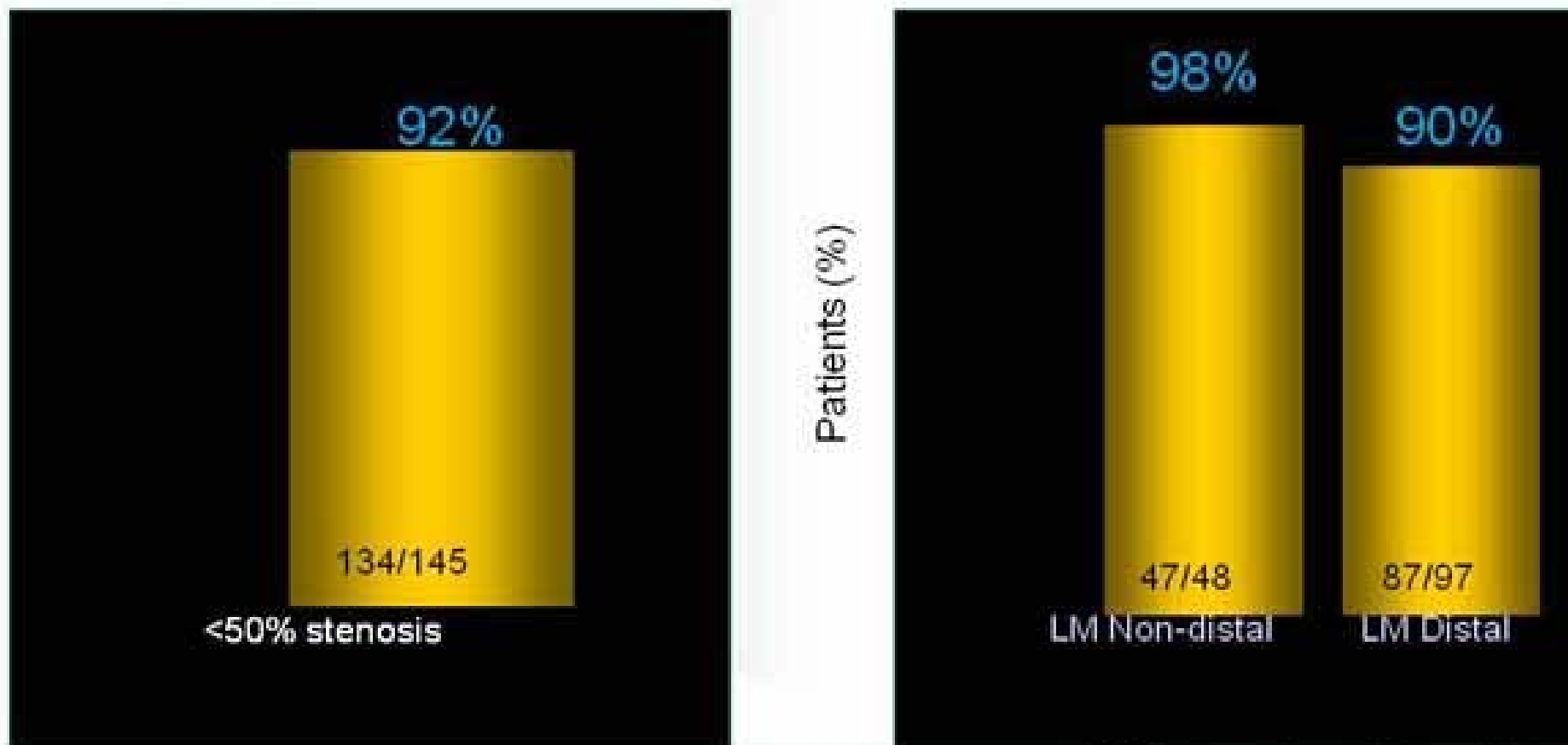
Occlusion Ratio: ratio of  $\geq 50\%$  obstructed or 100% occluded grafts/anastomoses (visual estimate) to the number of grafts/anastomoses placed

\*Proportion of patients with at least 1 obstructed/occluded graft

# Principal Results

## TAXUS Cohort

### Primary Endpoint:

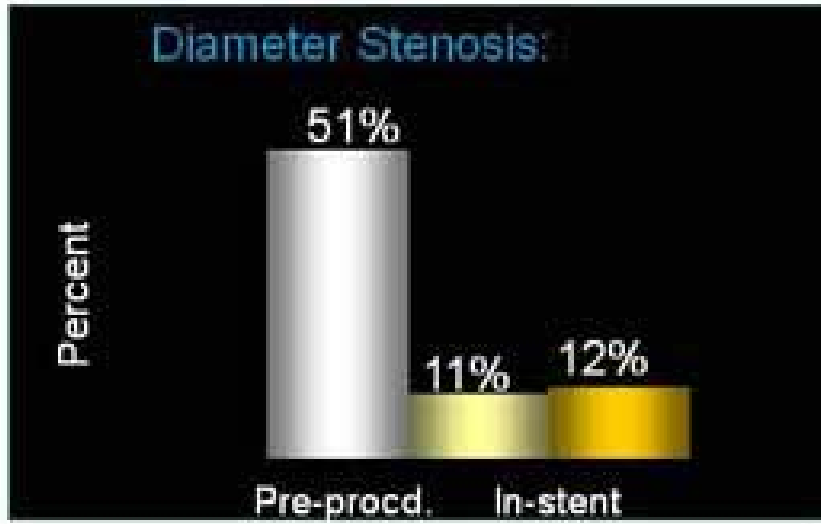
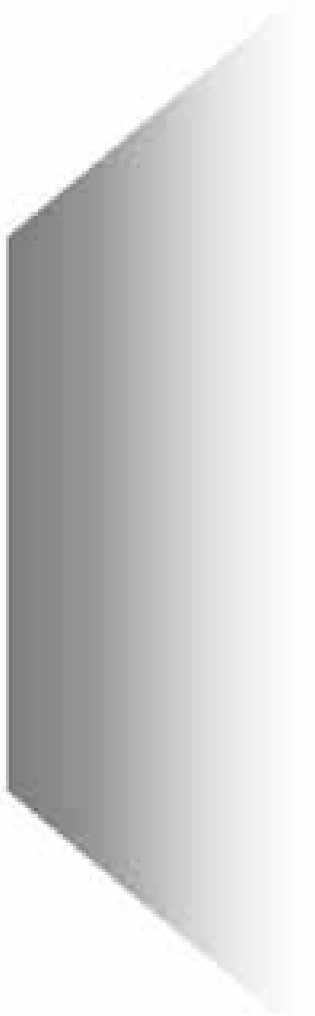


Definitions

Diameter stenosis was assessed by QCA

<50% stenosis 15 months

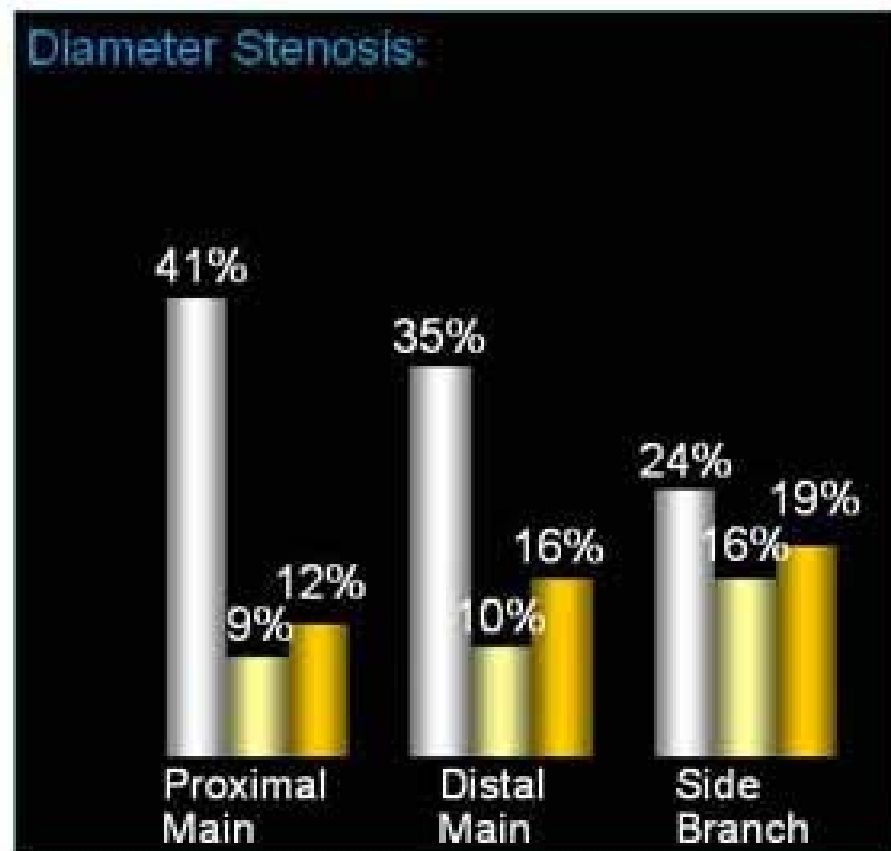
# LM Non-distal Angio Endpoints (QCA)



- Pre-procedure
- Post-procedure
- 15 Months

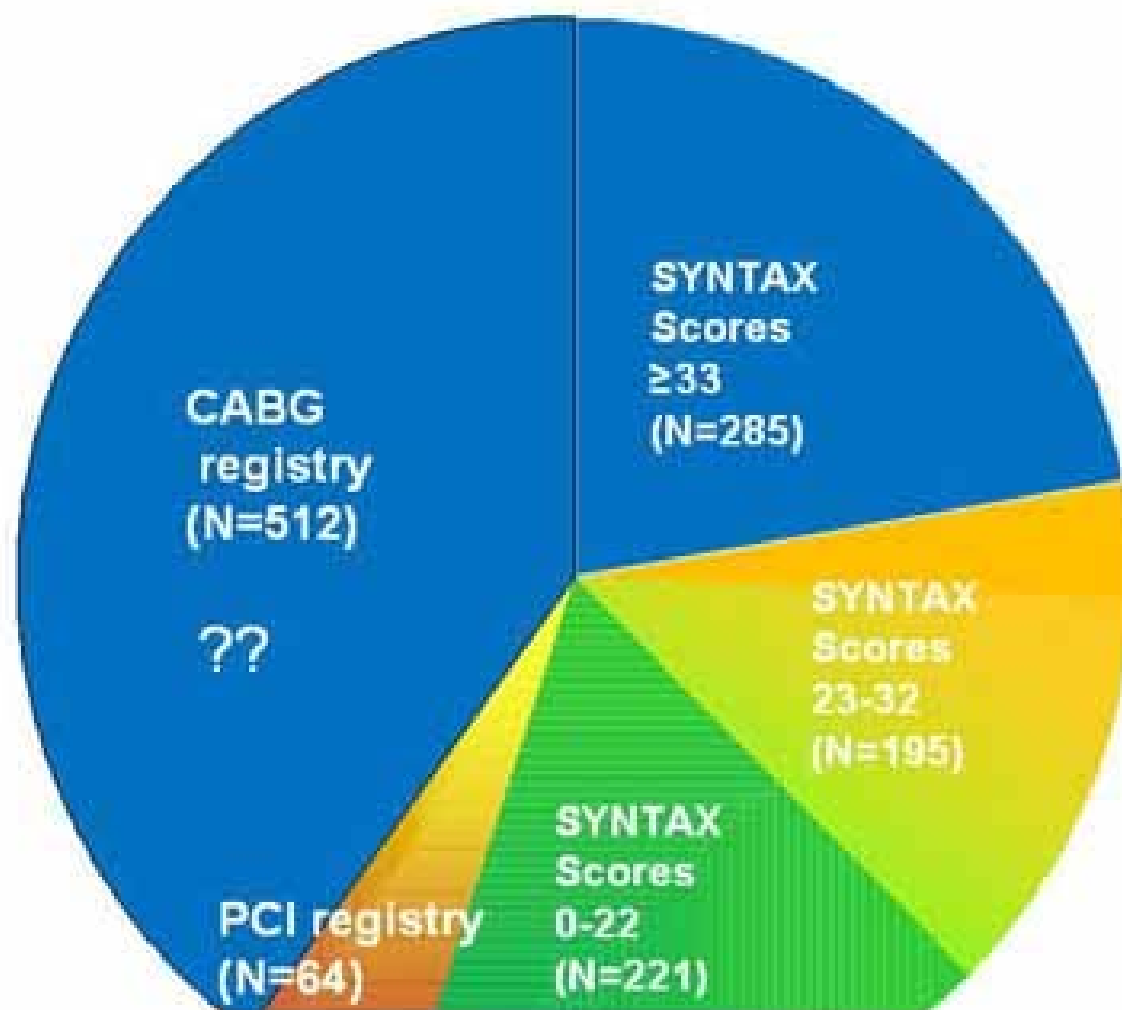
# LM Distal Angio Endpoints

Diameter Stenosis:



- Pre-procedure
- Post-procedure
- 15 Months

## SYNTAX Trial Patient Distribution



## Summary and Conclusions

- As the SYNTAX primary endpoint was not met, the results of the LM cohort are only exploratory (but the cohort was prespecified and adequately powered for significance)
- Results strongly suggest that PCI is a safe alternative to CABG, at least when SYNTAX Score is below 33 (two-thirds of LM randomised patients)
  - **Price to pay is an increased rate of reintervention (+7% at 2 years)**
  - **But counterpart is ¼ of stroke with PCI compared with CABG**



## Summary and Conclusions

- From the 15-month angio subgroup:
  - 27% grafts per patient occluded (few MACCE)
  - 92% patency with PCI (98% for non distal)
  - Distal Left Main Lesions does not have a poor outcome if properly treated, even if there is still room for technical improvement.

**The Noble and EXCEL trial will give definitive answers on which patients can (must?) be treated by PCI**

# Major Advisory Guidelines

## Have Recommended CABG for the Treatment of LM Disease

### CABG

- ACC/AHA Coronary Artery Bypass Graft Surgery
- Revised 2004

### PCI

Guidelines for Percutaneous Coronary Intervention

Time to revise the guidelines for LM disease?  
Yes already done ( IIB) but will change again...

1 Eagle et al. ACC/AHA 2004 Guideline Update for Coronary Artery Bypass Graft Surgery. Circulation 2004;110:e340-e437.

2 Smith SC Jr, Feldman TE, Hirshfeld JW Jr, Jacobs AK, Kern MJ, King SB III, Morrison DA, O'Neill WW, Schaff HV, Whitlow PL, Williams DO. ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention). American College of Cardiology Web Site. Available at: <http://www.acc.org/clinical/guidelines/percutaneous/update/index.pdf>.



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