Current Status of LM PCI Data and Guideline

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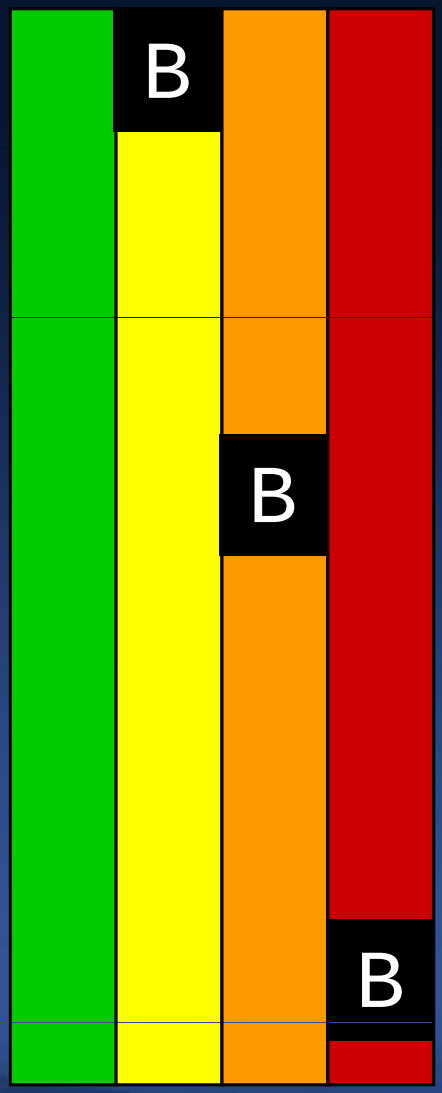
- **Recommendation**
  Updated guideline
- **Evidence**
  CABG vs. PCI for LM disease

ACC/AHA Guidelines 2011
Elective PCI for LM Stenosis

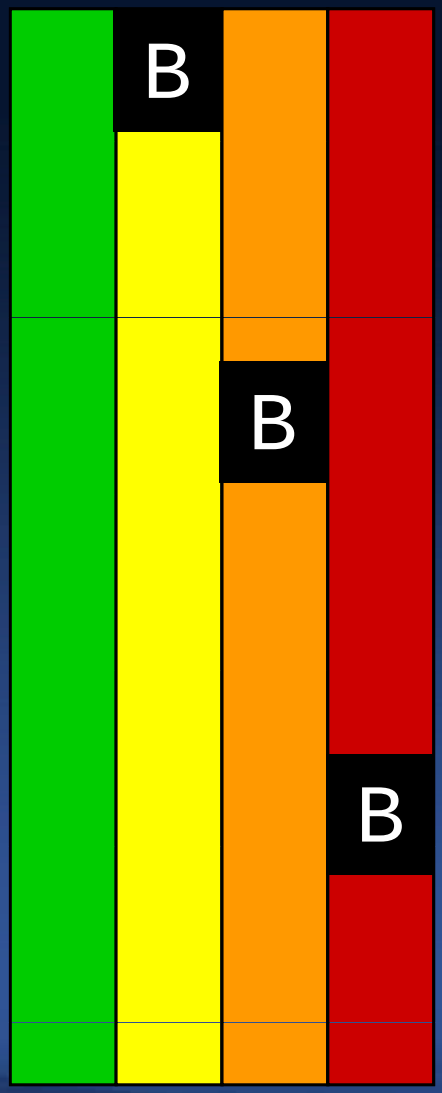


- Low risk PCI
  - SYNTAX score ≤ 22 OR
  - Ostial or shaft LM
- High risk CABG
  - STS risk ≥ 5%

- Intermediate-risk PCI
  - SYNTAX score < 33 OR
  - Bifurcation LM
- High risk CABG
  - STS risk ≥ 2% OR
  - COPD, disabled stroke, redo CABG

- Unfavorable anatomy for PCI, but good CABG candate

ESC Guidelines 2011
Elective PCI for LM Stenosis



- LM with
  - isolated or 1 VD & ostial or shaft LM
- LM with
  - isolated or 1 VD & bifurcation LM
  - 2 or 3 VD & SYNTAX score ≤ 32
- LM with
  - 2 or 3 VD & SYNTAX score ≥ 32

Randomized or Matched Patients PCI vs. CABG for LM Stenosis

	LEMAN		Matched Pt in MAIN-COMPARE		SYNTAX LM		Boudriot et al.		PRECOMBAT	
Design	RCT		Registry		RCT Substudy		RCT		RCT	
Treament	BMS, DES	CABG	BMS, DES	CABG	PES	CABG	DES	CABG	SES	CABG
No.	52	53	542	542	357	348	100	101	300	300

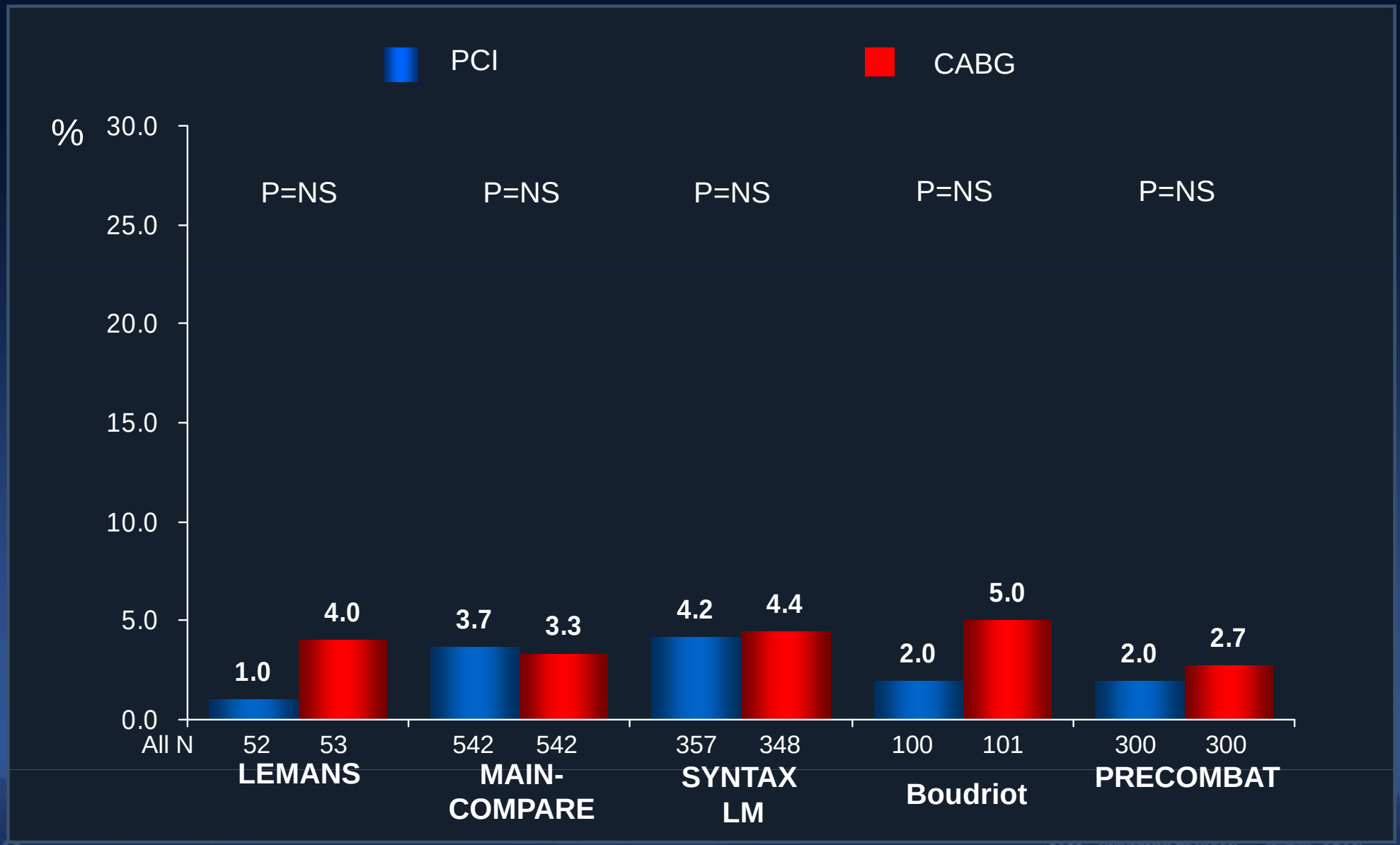
- Diabetics 17 ~ 40 %
- Distal LM involvement 52 ~ 74%
- 3 vessel disease 11 ~ 75 %
- EF 54 ~ 65 %
- EuroSCORE 2.4 ~ 3.9
- SYNTAX score 23 ~ 30

A representative of real world STENTABLE patients

4. J Am Coll Cardiol 2011;57:538 5. N Engl J Med. 2011;364:1718

General Outcomes
between PCI vs. CABG

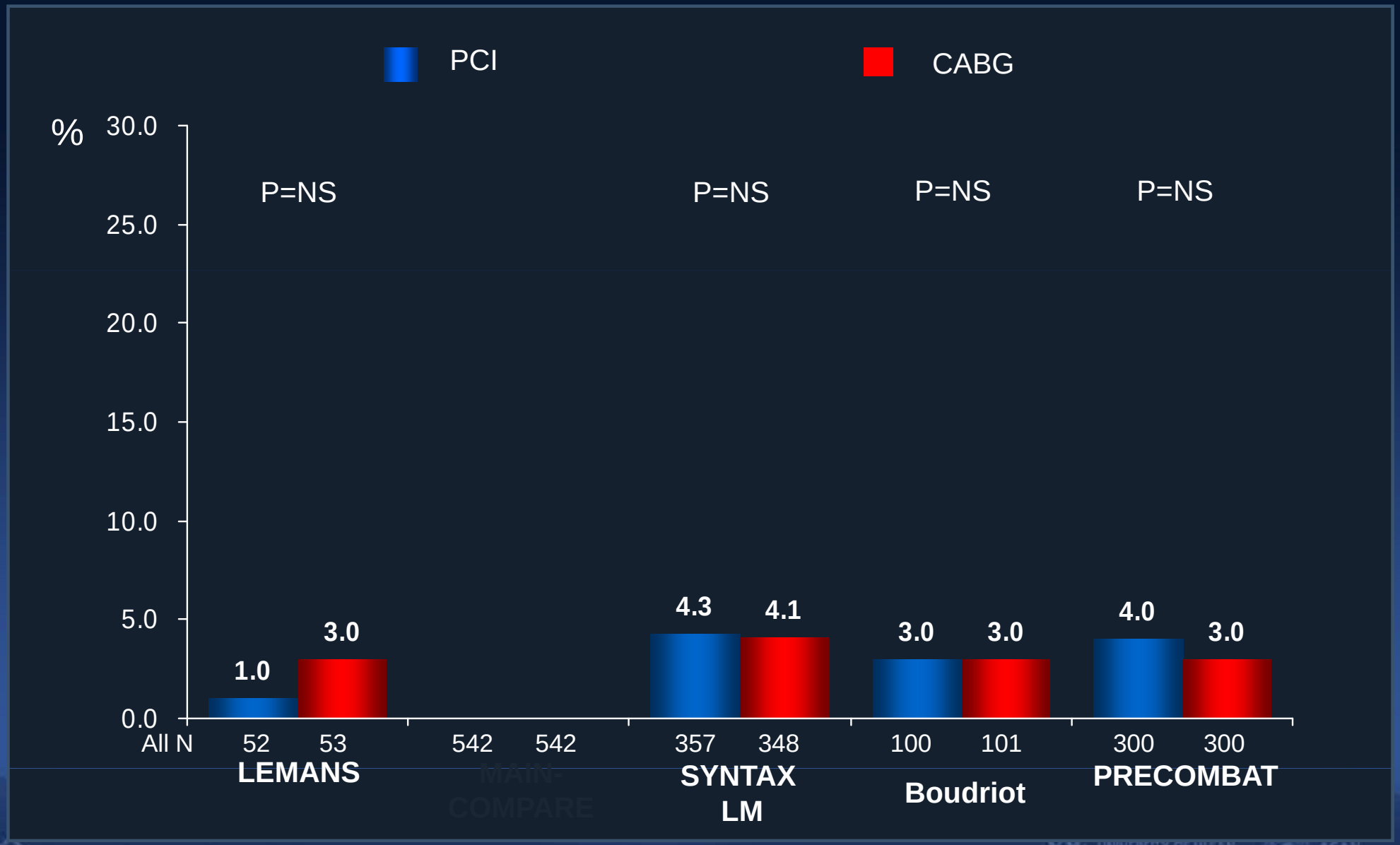
Matched or Randomized Patients
1-Year Mortality



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

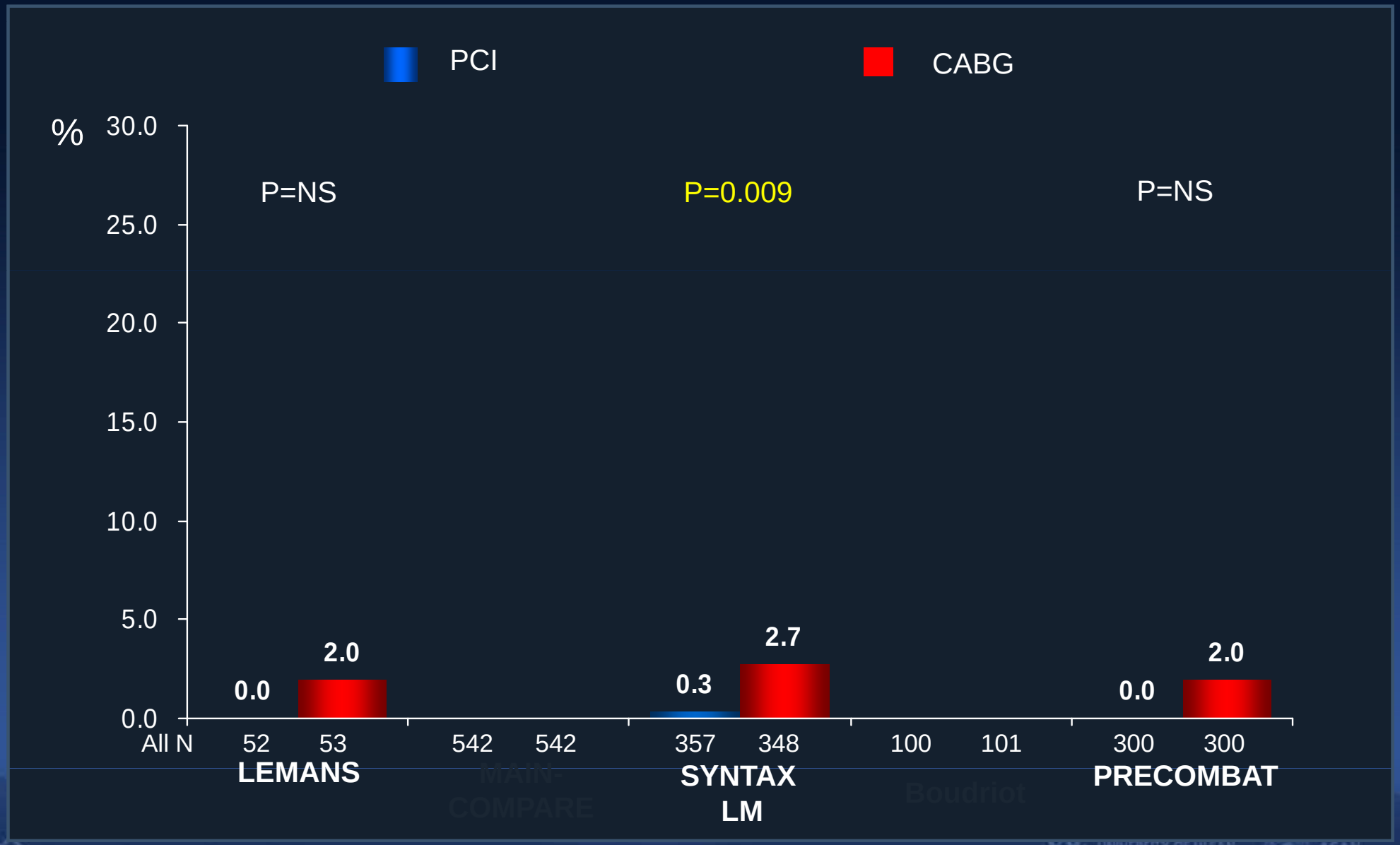
Matched or Randomized Patients

1-Year MI

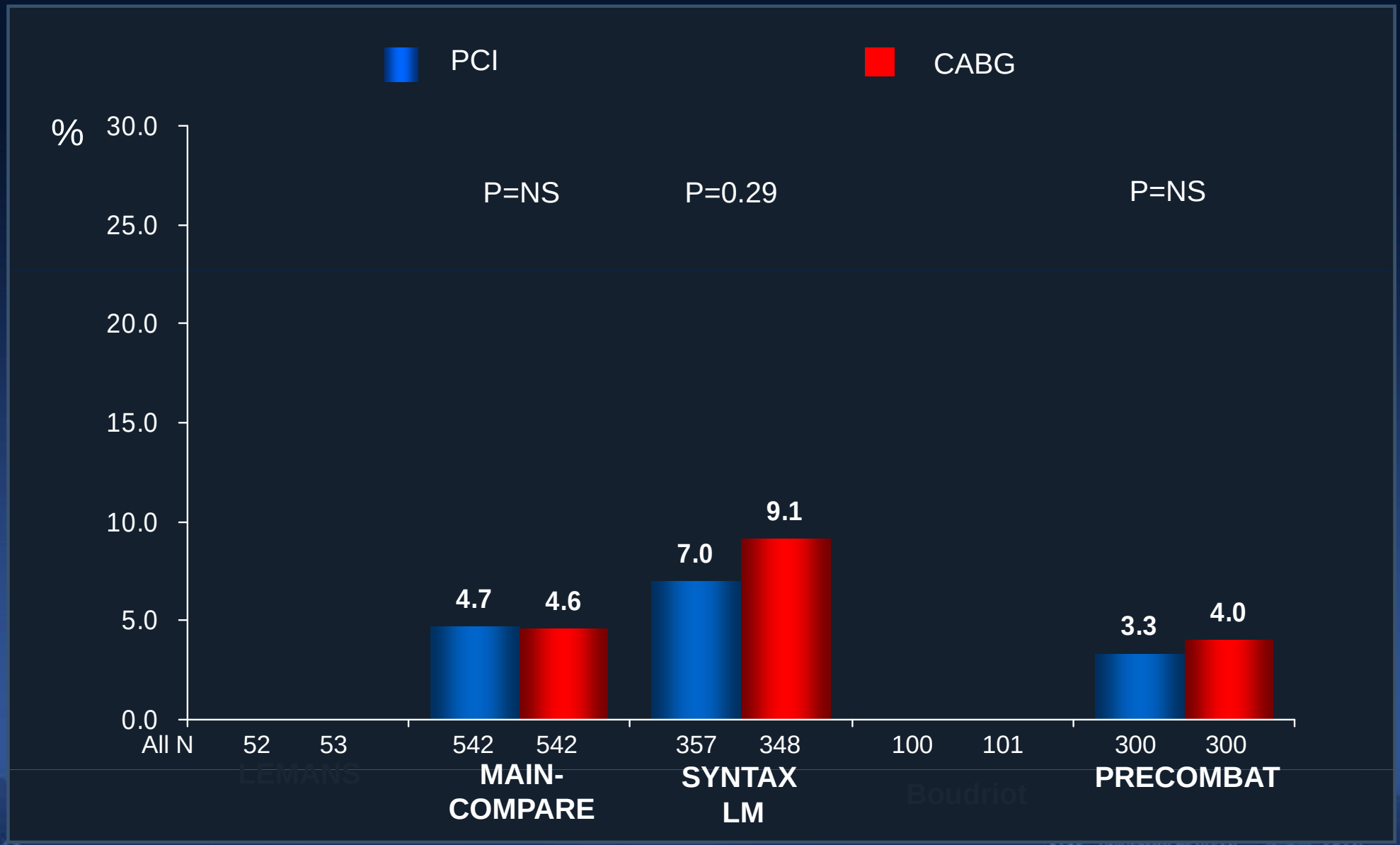


Matched or Randomized Patients

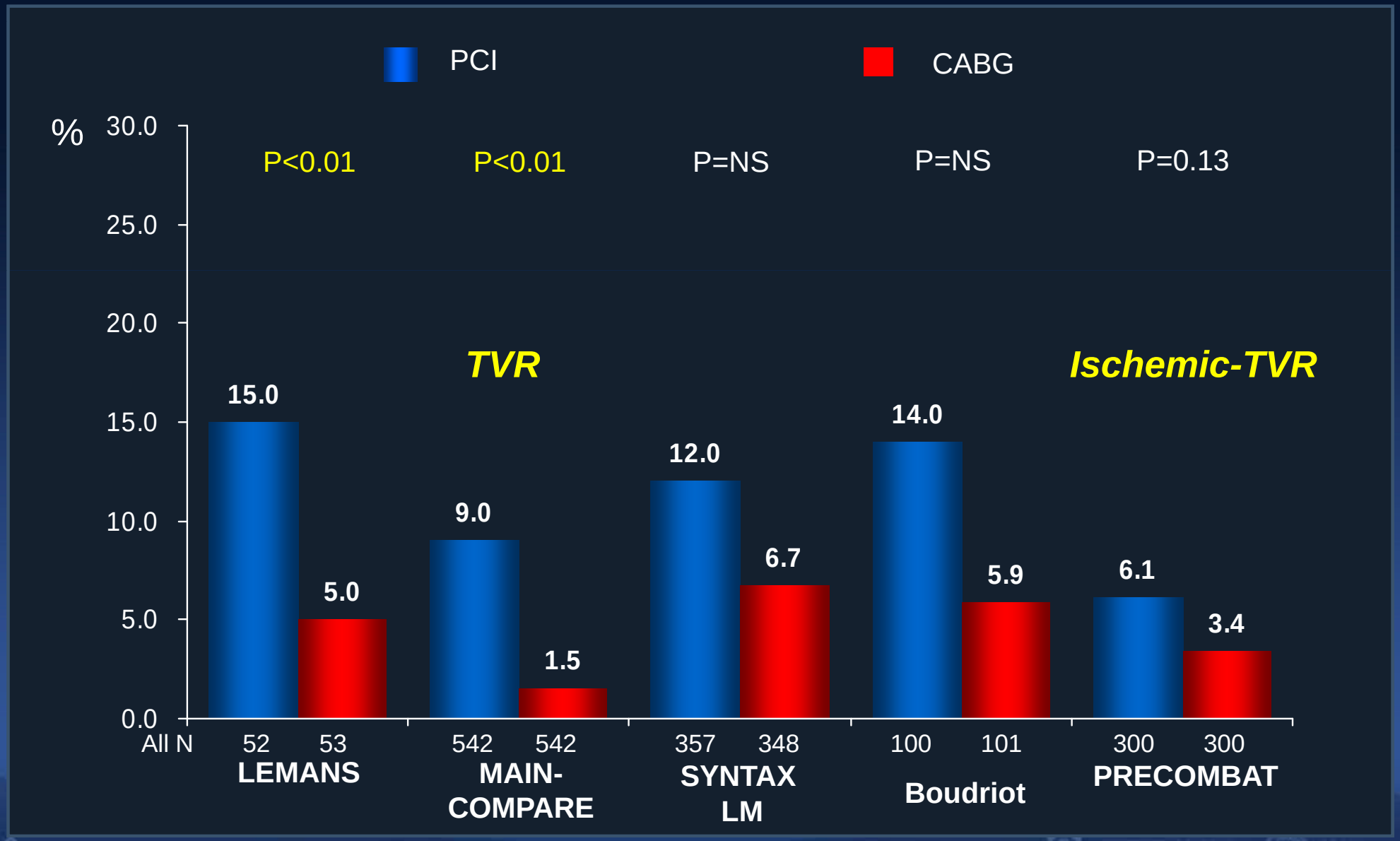
1-Year Stroke



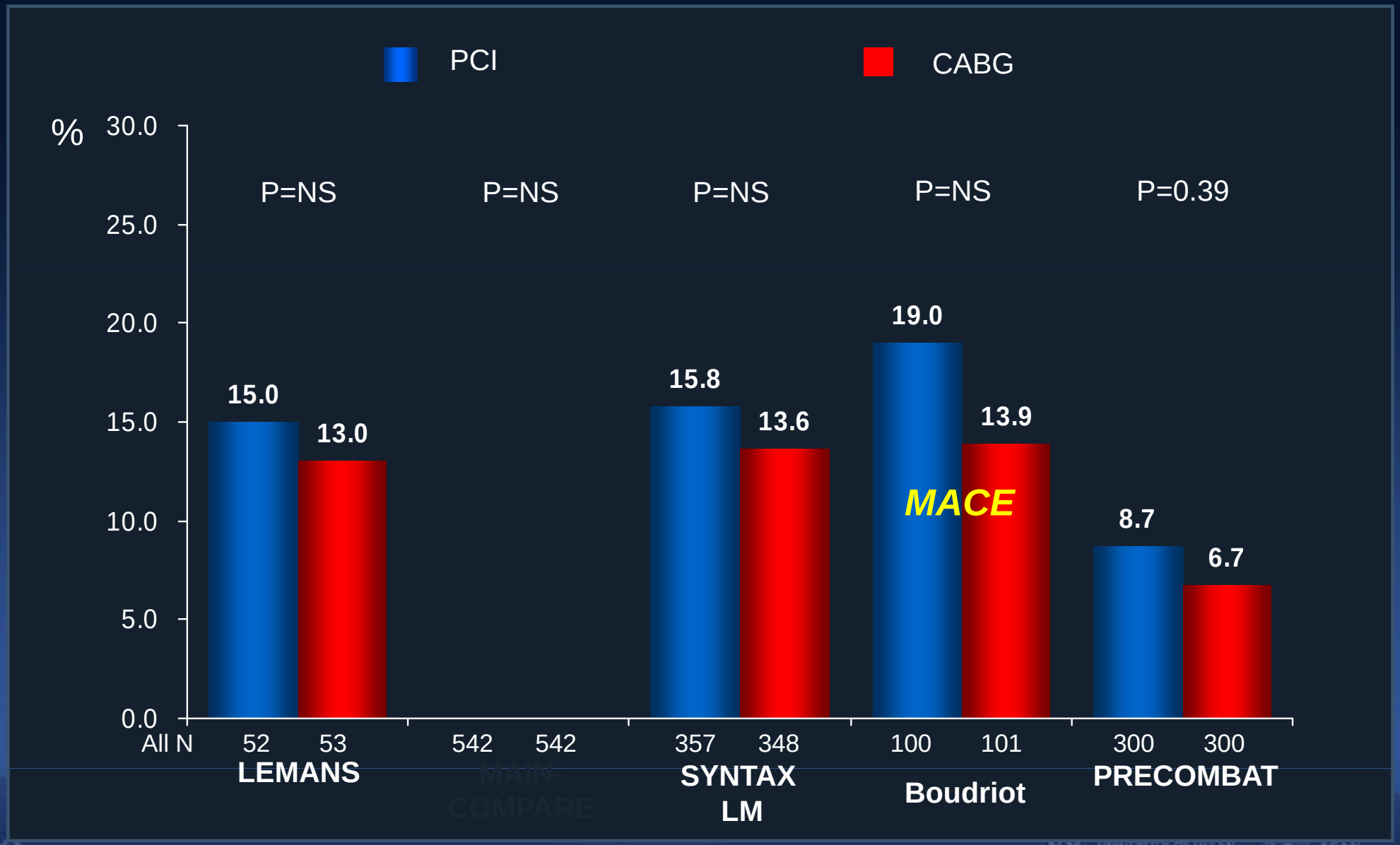
Matched or Randomized Patients
1-Year Death, MI or Stroke



Matched or Randomized Patients
1-Year Repeat Revascularization



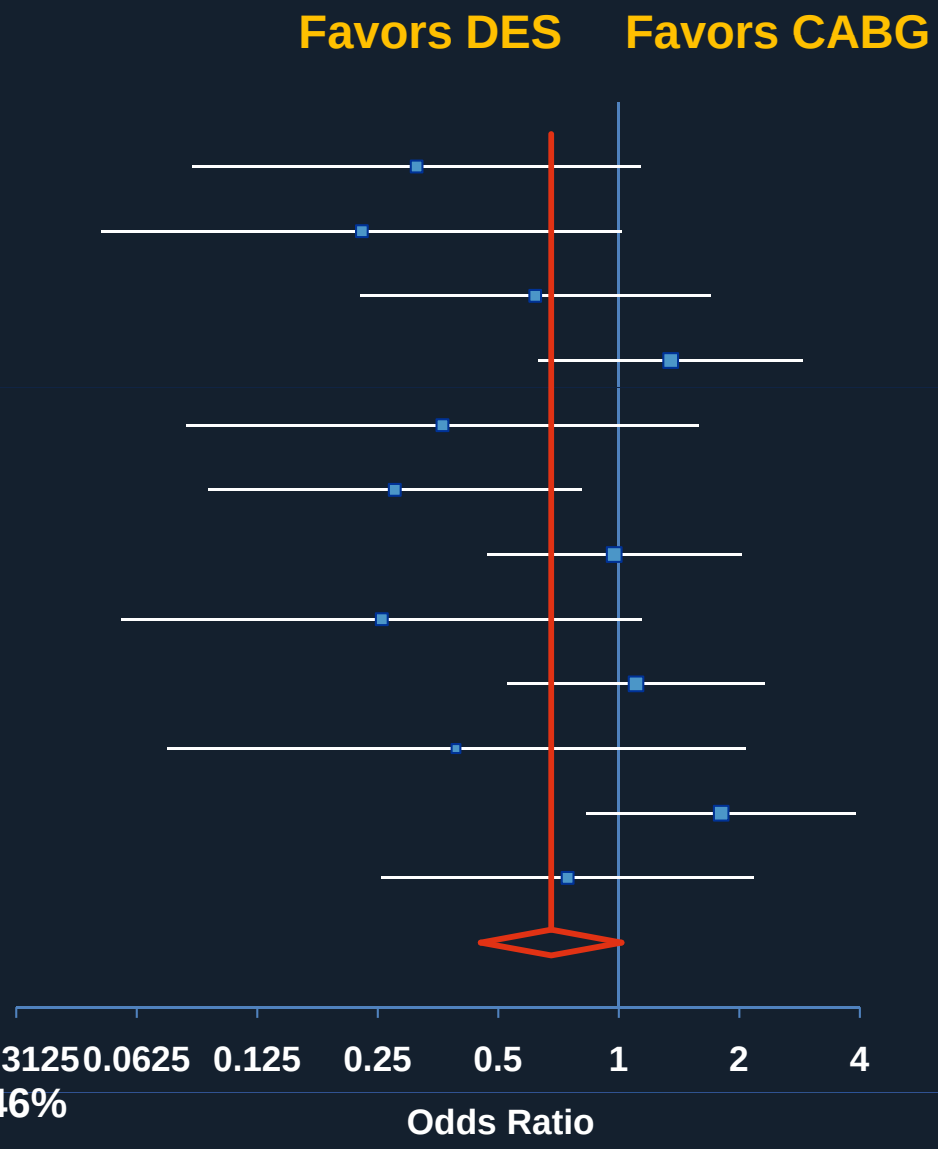
Matched or Randomized Patients
1-Year MACCE



Meta-analysis of RCT + Registry

Death

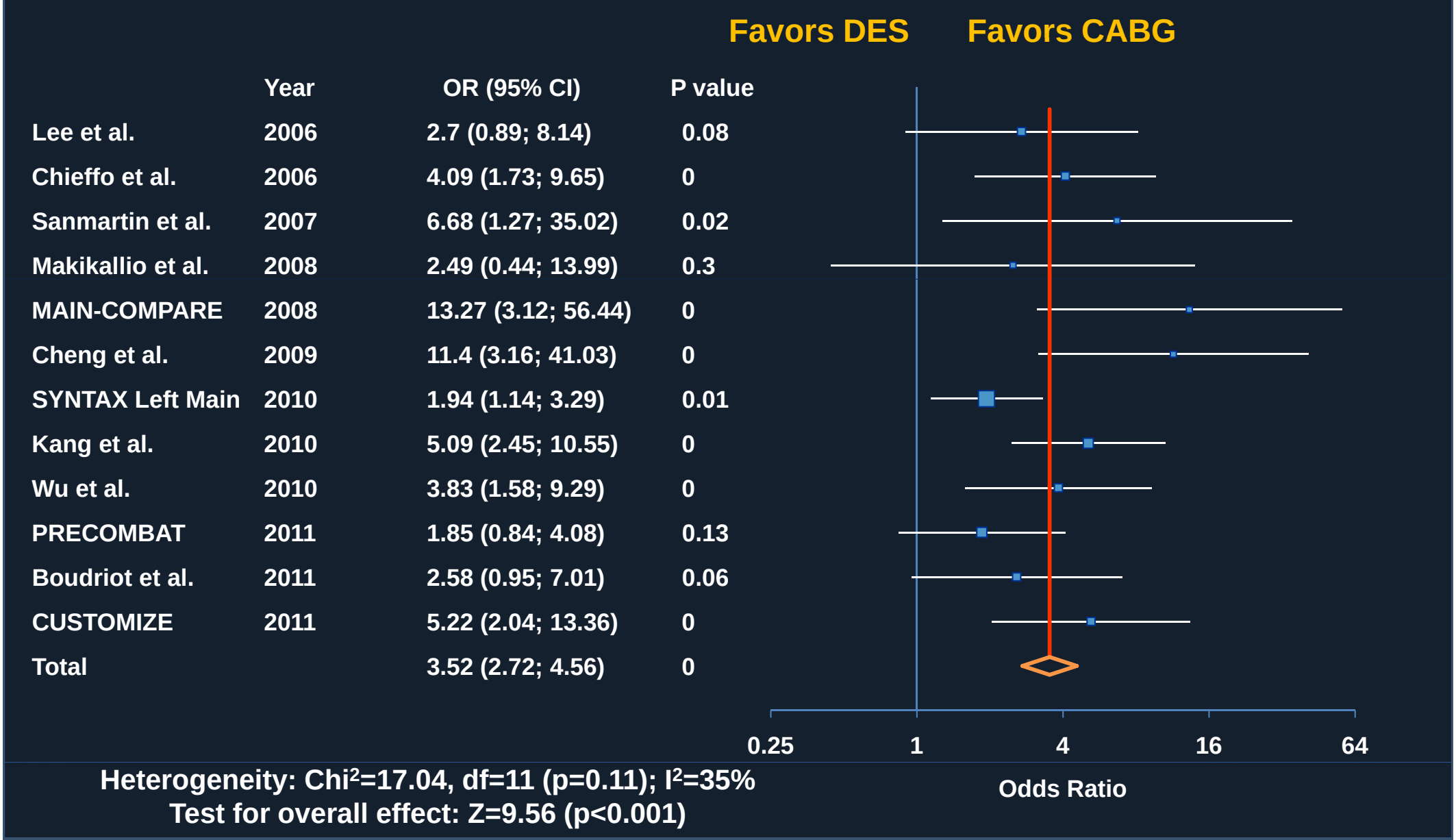
	Year	OR (95% CI)	P value
Chieffo et al.	2006	0.31 (0.09; 1.14)	0.08
Lee et al.	2006	0.23 (0.05; 1.02)	0.05
Sanmartin et al.	2007	0.62 (0.23; 1.7)	0.35
MAIN-COMPARE	2008	1.35 (0.63; 2.89)	0.44
Makikallio et al.	2008	0.36 (0.08; 1.58)	0.18
Cheng et al.	2009	0.28 (0.09; 0.81)	0.02
SYNTAX left main	2010	0.97 (0.47; 2.02)	0.94
Wu et al.	2010	0.26 (0.06; 1.14)	0.07
Kang et al.	2010	1.1 (0.53; 2.32)	0.79
Boudriot et al.	2011	0.39 (0.07; 2.07)	0.27
CUSTOMIZE	2011	1.8 (0.83; 3.91)	0.14
PRECOMBAT	2011	0.74 (0.26; 2.17)	0.59
Total		0.68 (0.45; 1.02)	0.06



Heterogeneity: Tau^2=0.22; Chi^2=20.22, df=11 (p=0.04); I^2=46%
Test for overall effect: Z=1.88 (p=0.06)

Meta-analysis of RCT + Registry

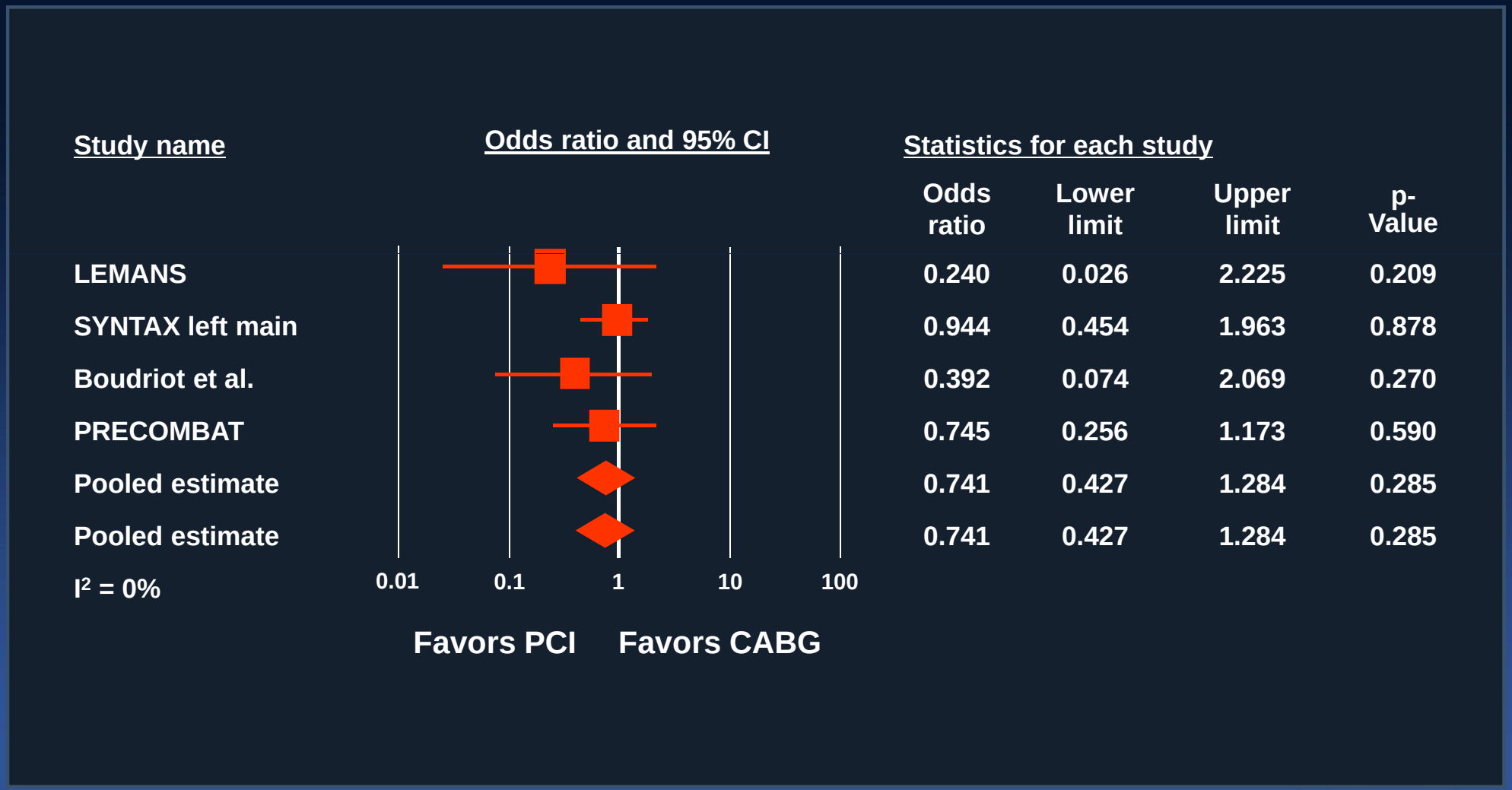
TVR



Heterogeneity: Chi²=17.04, df=11 (p=0.11); I²=35%
Test for overall effect: Z=9.56 (p<0.001)

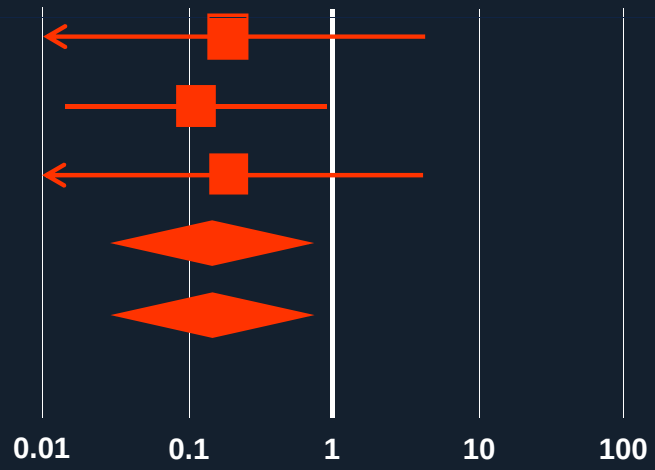
Meta-analysis of RCT

Death



Meta-analysis of RCT
Stroke

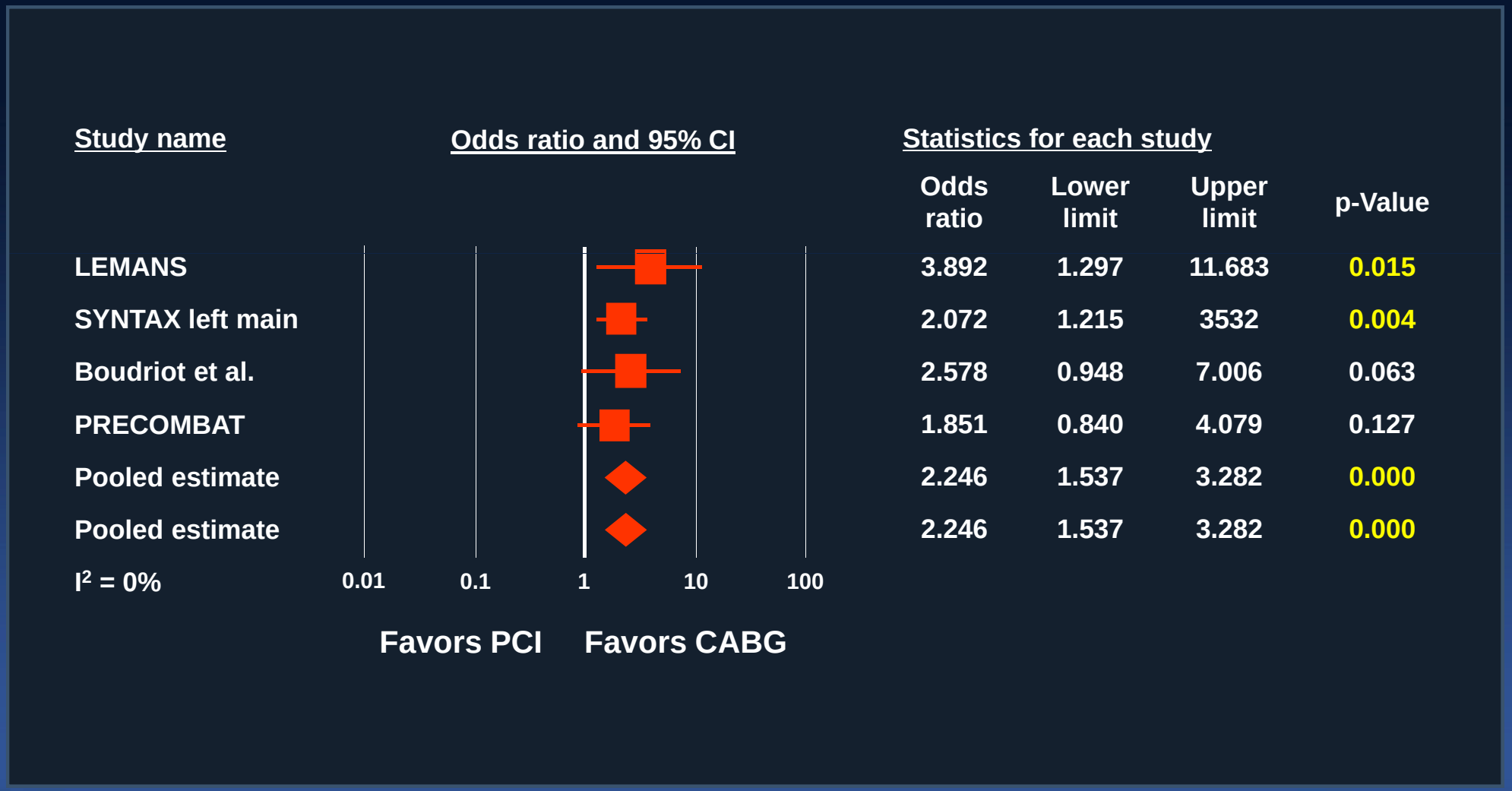
Study name	Odds ratio and 95% CI	Odds ratio	Lower limit	Upper limit	p-Value
LEMANS		0.196	0.009	4.187	0.297
SYNTAX left main		0.116	0.014	0.931	0.043
PRECOMBAT		0.199	0.009	4.156	0.298
Pooled estimate		0.150	0.033	0.671	0.013
Pooled estimate		0.150	0.033	0.671	0.013
I^2 = 0%					



Statistics for each study

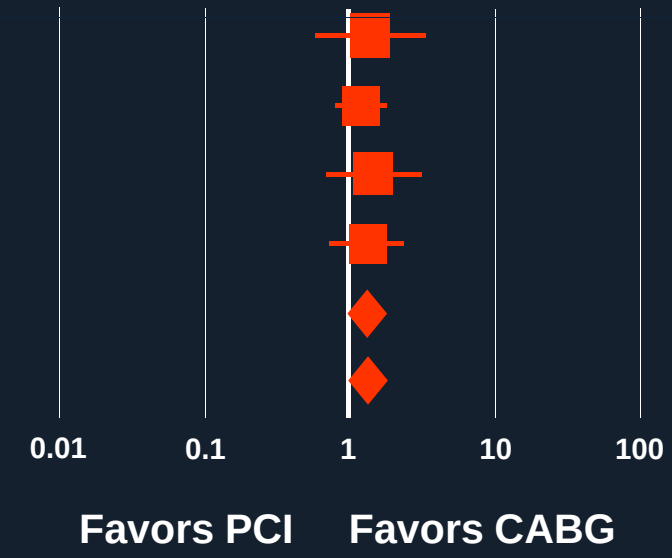
Meta-analysis of RCT

TVR



Meta-analysis of RCT

MACCE



Study name	Odds ratio	Lower limit	Upper limit	p-Value
LEMANS	1.368	0.579	3.229	0.475
SYNTAX left main	1.181	0.774	1.801	0.440
Boudriot et al.	1.458	0.686	3.098	0.327
PRECOMBAT	1.328	0.725	2.436	0.359
Pooled estimate	1.276	0.950	1.715	0.106
Pooled estimate	1.276	0.950	1.715	0.106

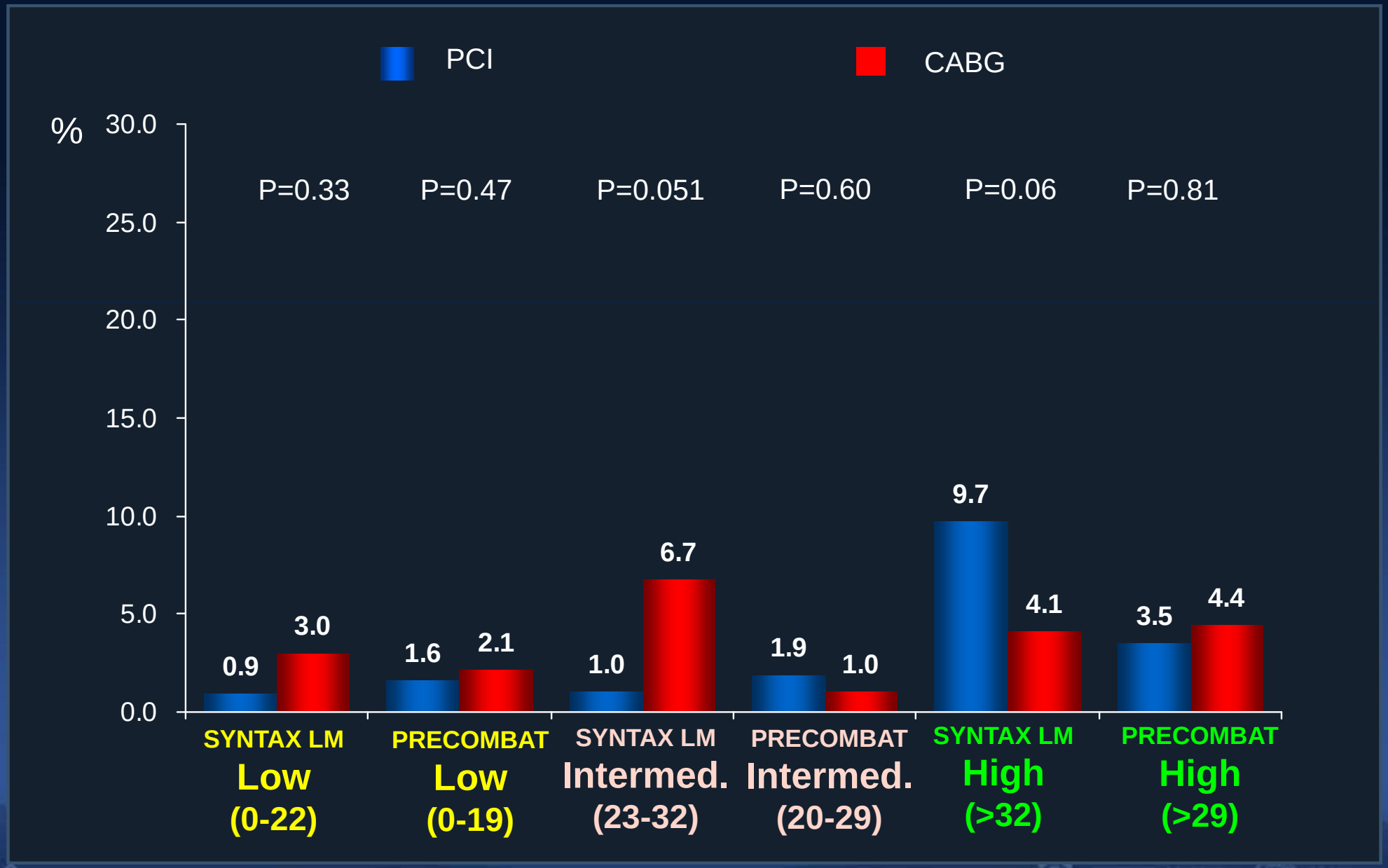
$I^2 = 0\%$

Outcomes in Subgroups

According to Disease Extent

Death at 1 Year

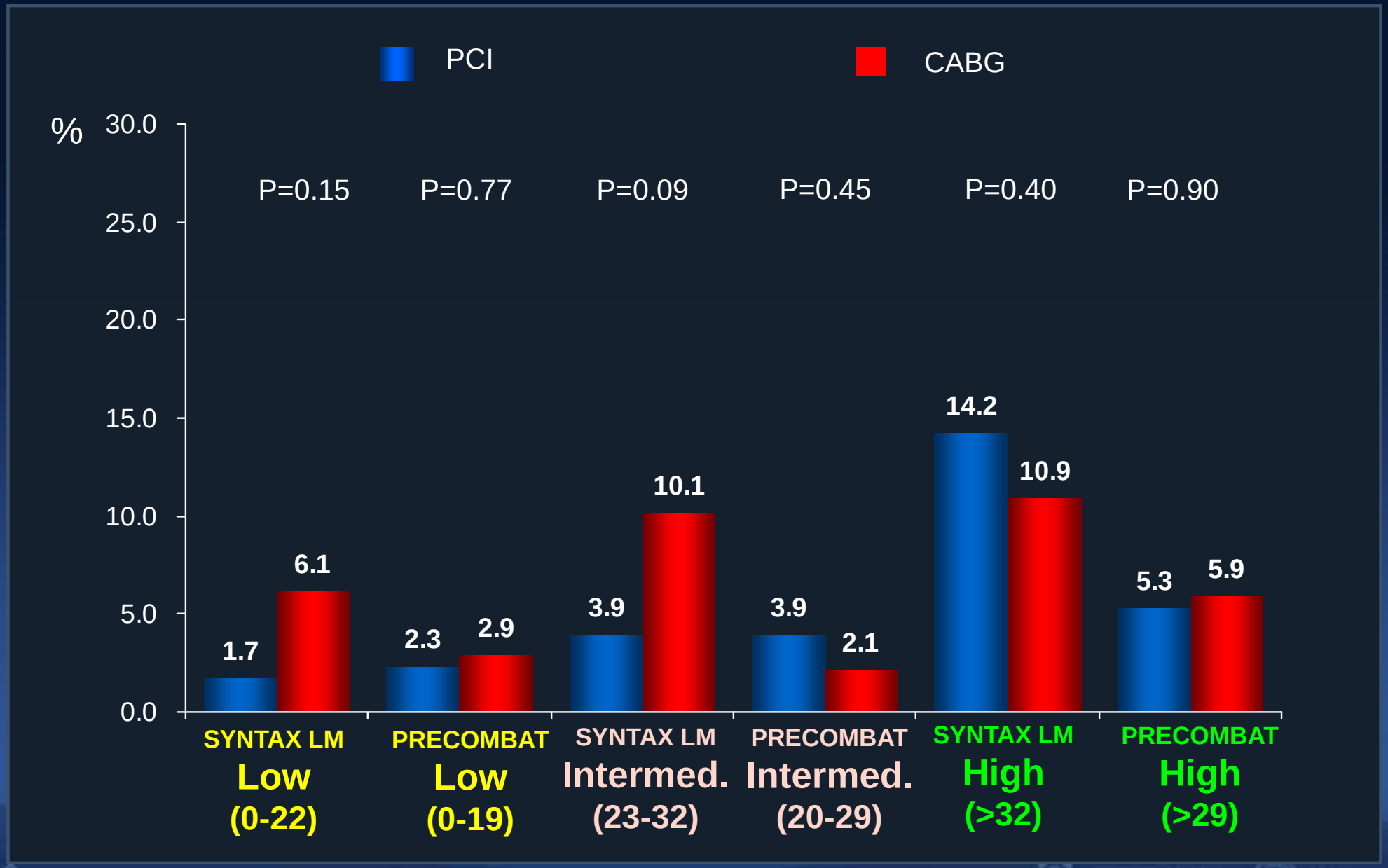
Classified by SYNTAX Tertiles



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

Death, MI, or Stroke at 1 Year

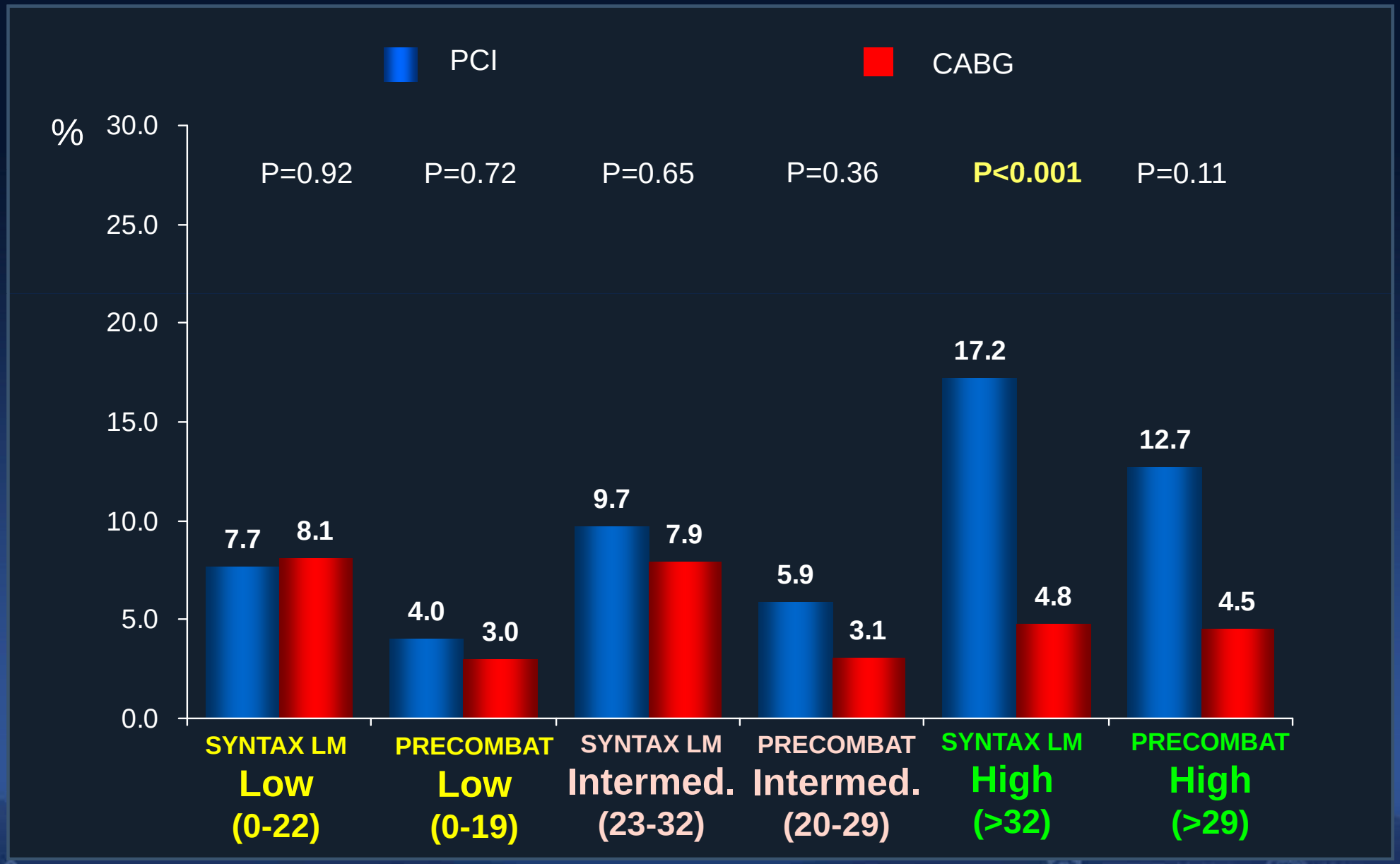
Classified by SYNTAX Tertiles



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

Repeat Revascularization at 1 Year

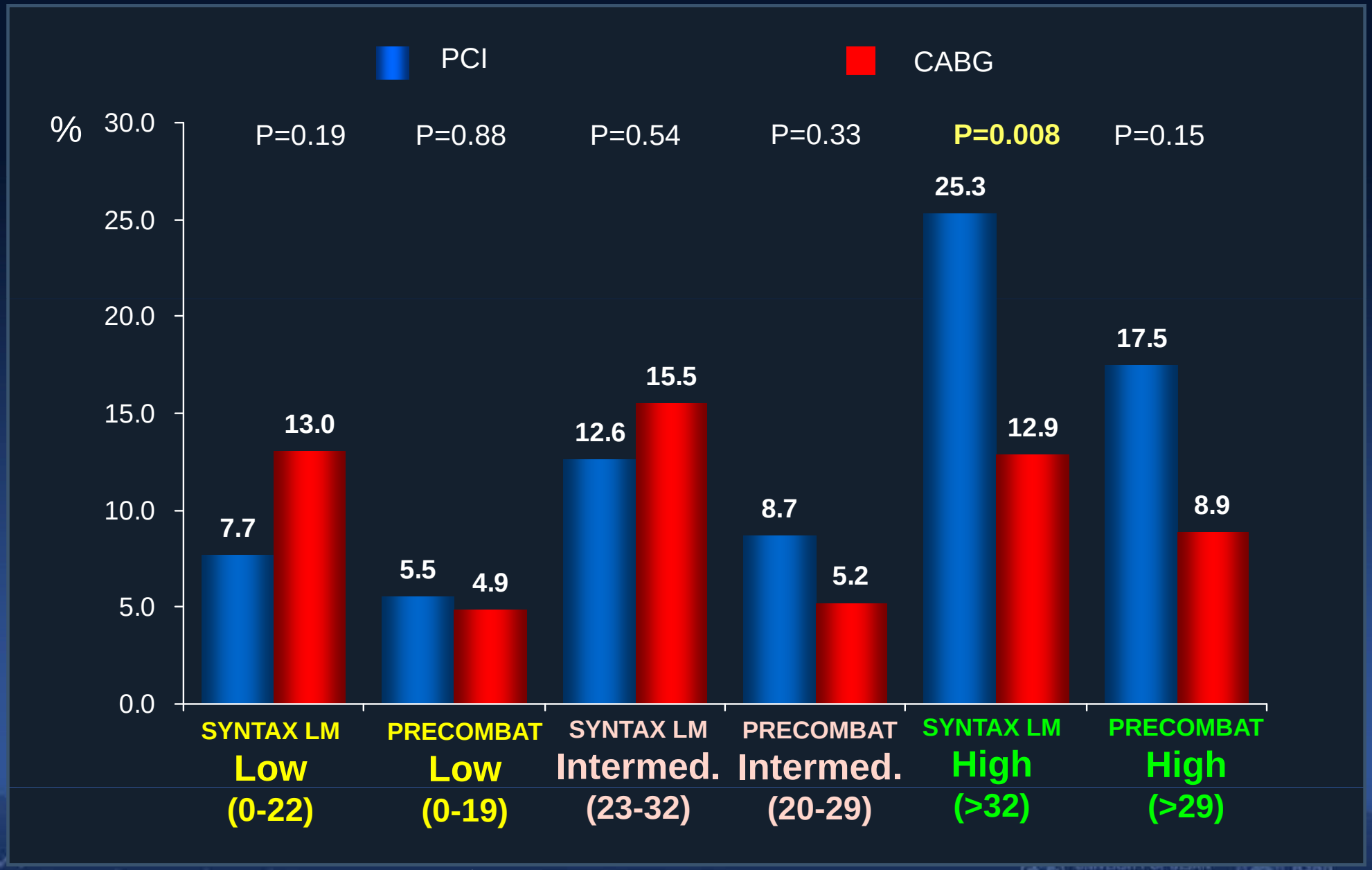
Classified by SYNTAX Tertiles



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

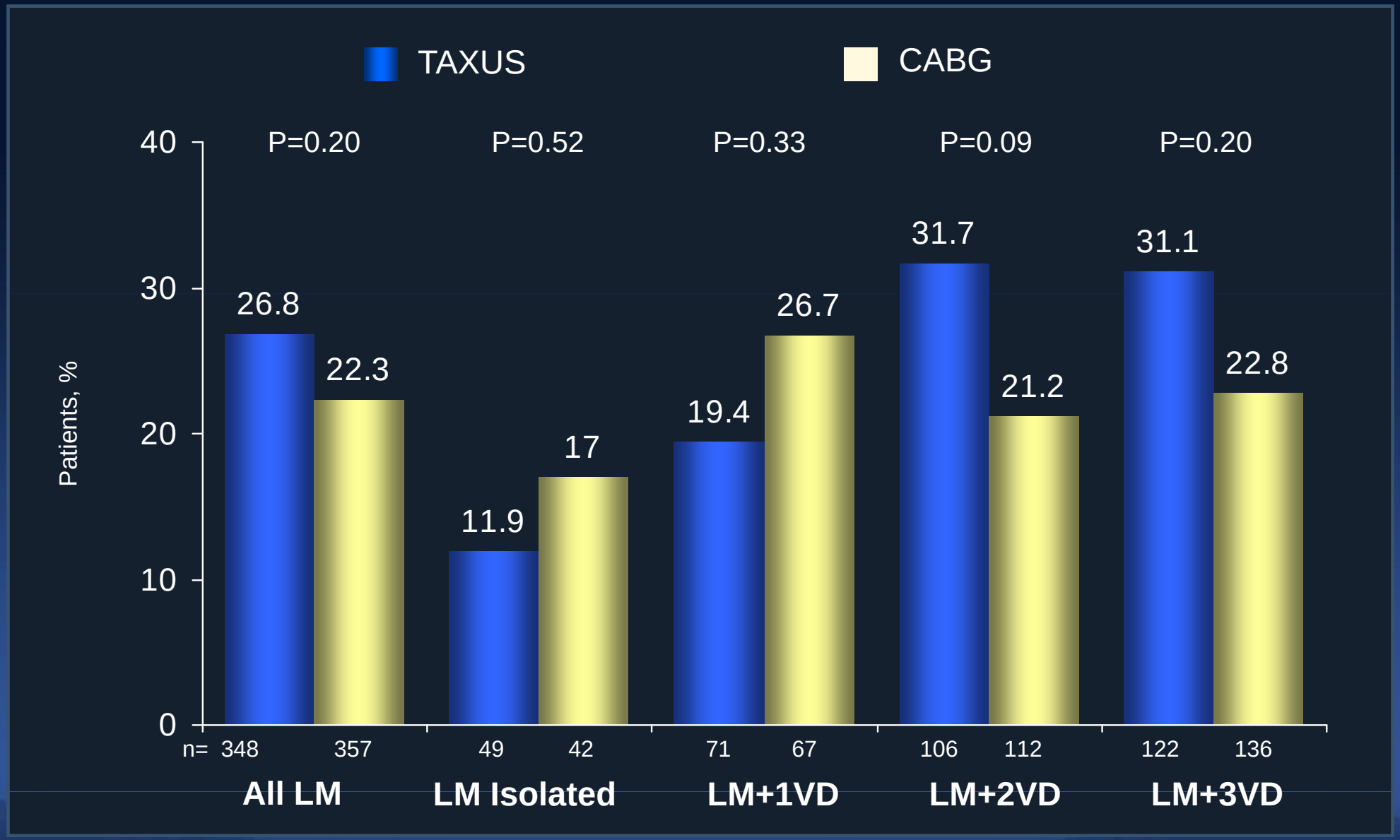
MACCE at 1 Year

Classified by SYNTAX Tertiles



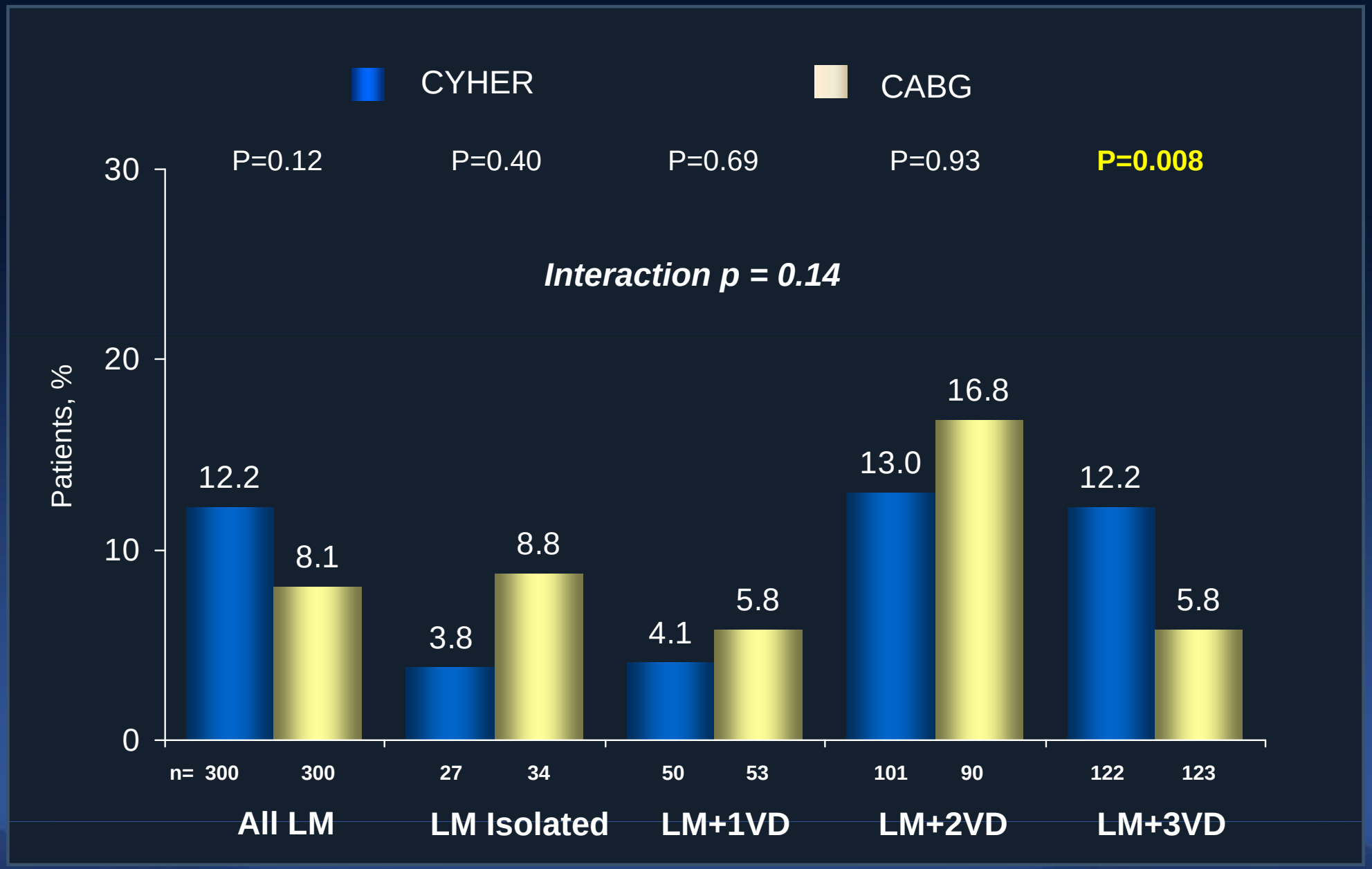
Cumulative KM Event Rate; log-rank P value; *Binary rates

MACCE to 3 Years in SYNTAX LM



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

MACCE to 2 Years in PRECOMBAT

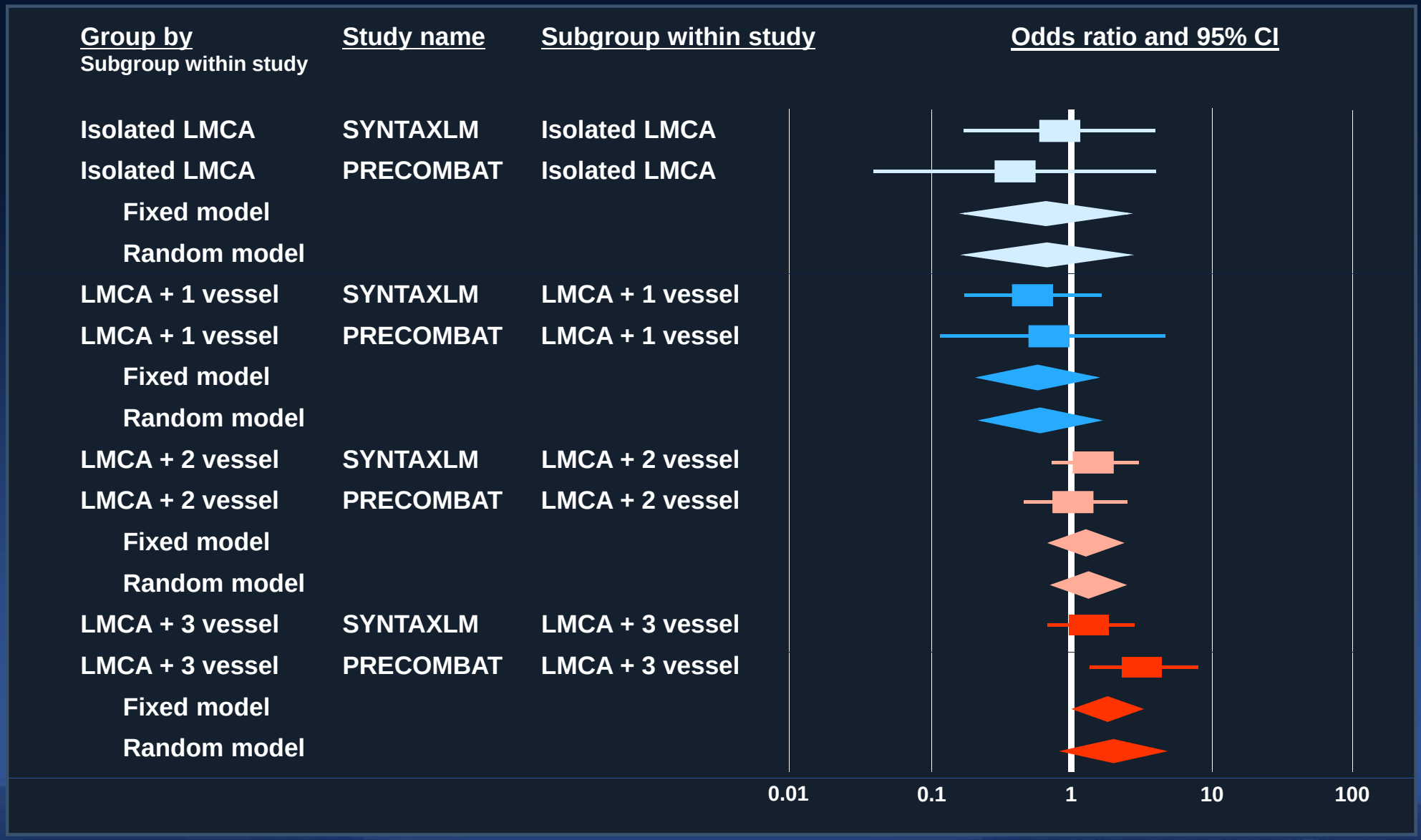


Cumulative KM Event Rate; log-rank P value; *Binary rates

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

Meta-analysis of RCT

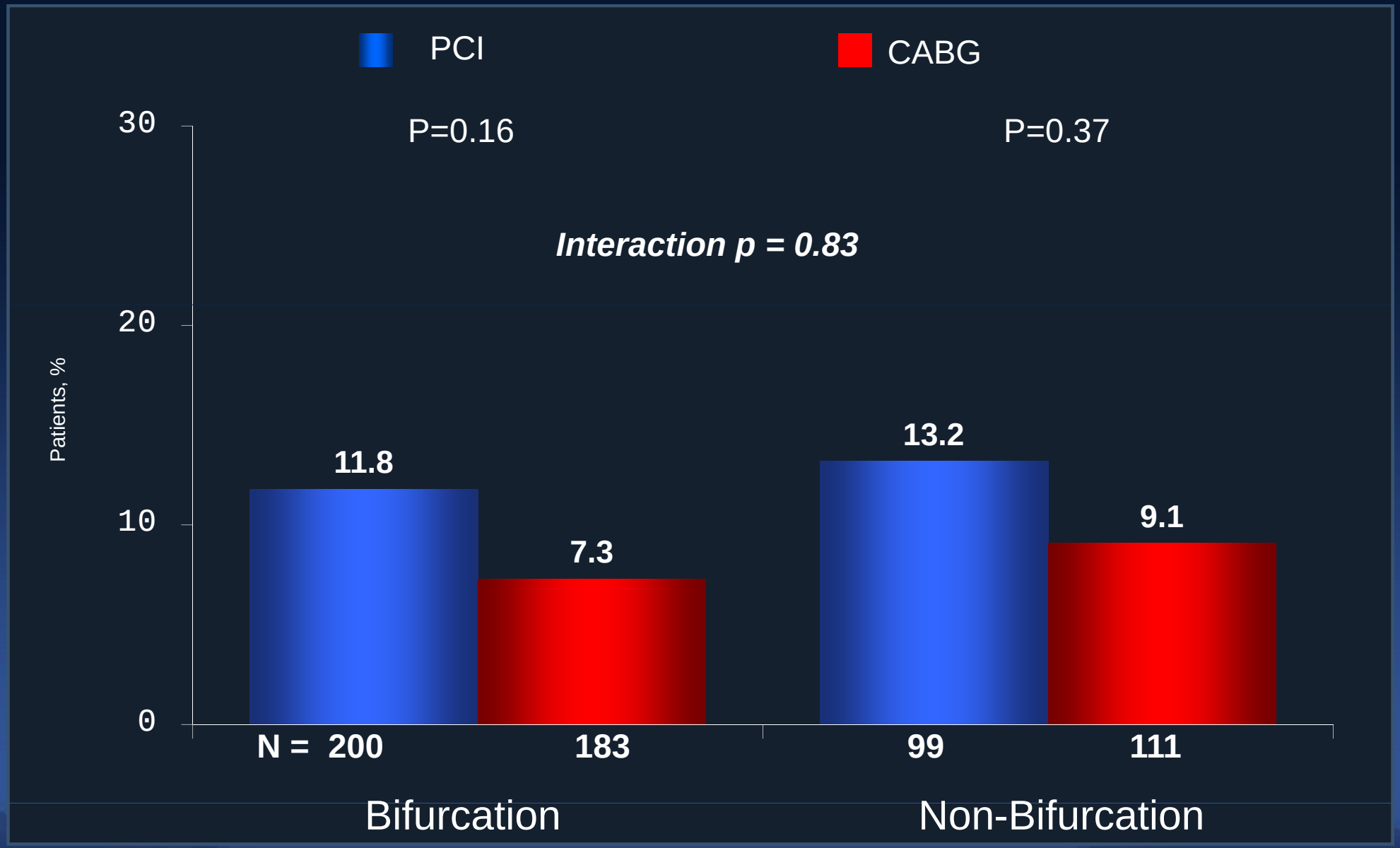
MACCE According to Vessel Involvement



Outcomes in Major Subgroups

MACCE to 2 Years in PRECOMBAT

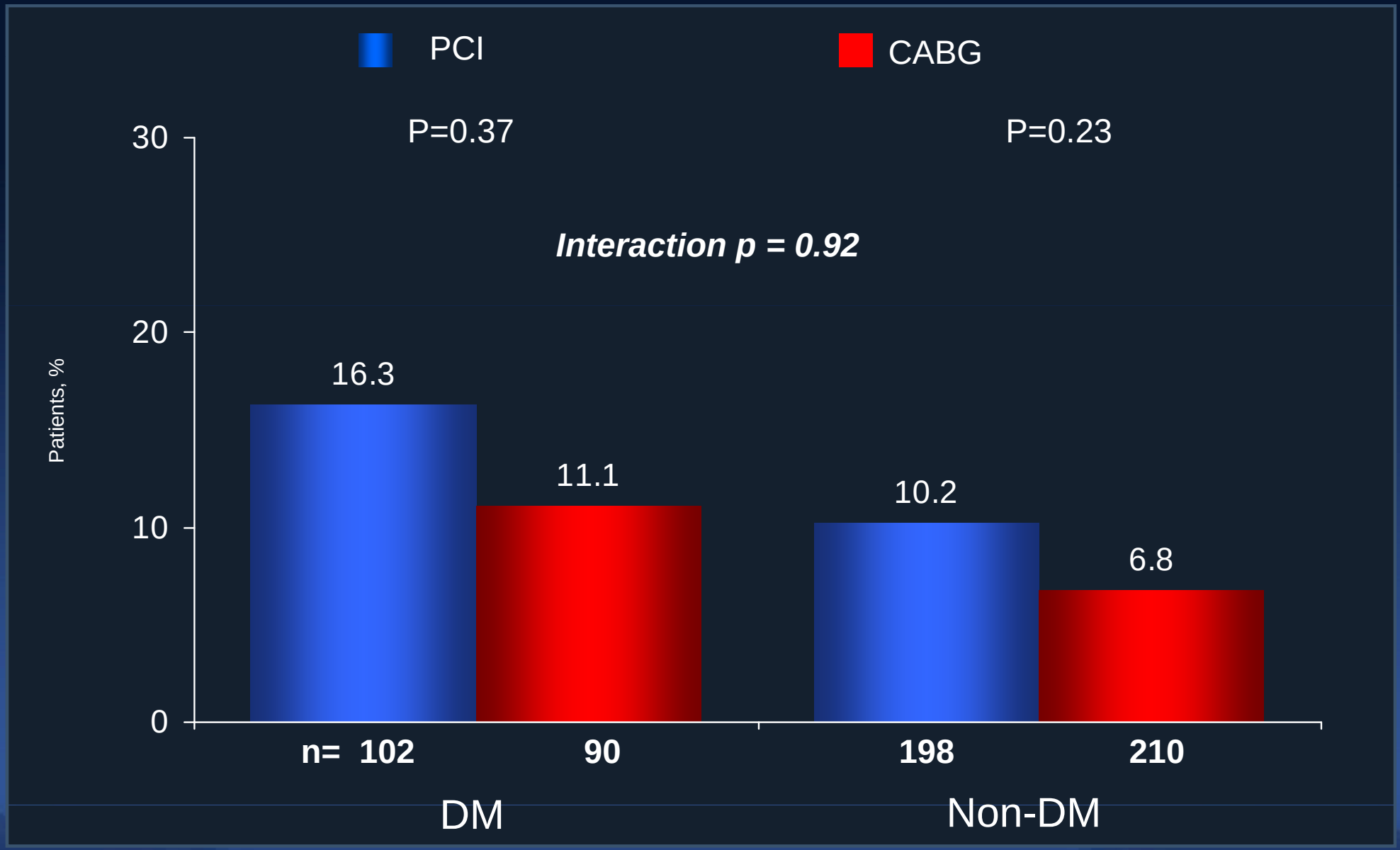
LM Bifurcation



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

MACCE to 2 Years in PRECOMBAT

DM

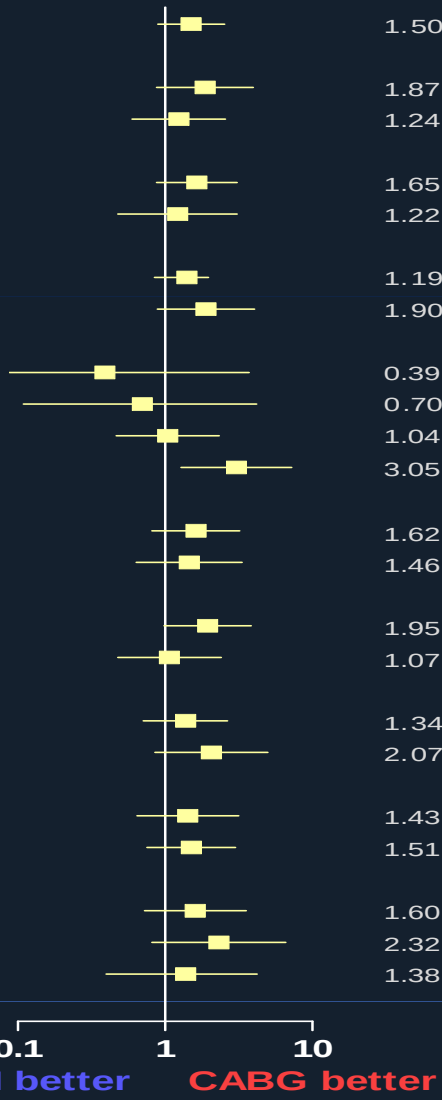


Cumulative KM Event Rate; log-rank P value; *Binary rates

Subgroup Analysis in PRECOMBAT

2-Year MACCE

Subgroup	MACCE		Hazard Ratio (95% CI)	P value	P value for Interaction
	PCI	CABG			
	Cumulative incidence, %				
Overall	12.2	8.1	1.50 (0.90, 2.52)	0.12	-
Age					0.44
≥65 yr	11.9	9.7	1.87 (0.88, 3.97)	0.10	
<65 yr	12.5	6.7	1.24 (0.60, 2.56)	0.57	
Sex					0.59
Male	11.7	7.0	1.65 (0.88, 3.07)	0.12	
Female	13.9	11.7	1.22 (0.48, 3.08)	0.68	
LM stenosis					0.63
>70 %	10.8	9.0	1.19 (0.57, 2.47)	0.64	
50-70 %	13.6	7.1	1.90 (0.89, 4.03)	0.10	
Vascular extent					0.14
LM only	3.8	8.8	0.39 (0.04, 3.72)	0.41	
LM with 1VD	4.1	5.8	0.70 (0.11, 4.16)	0.69	
LM with 2VD	13.0	12.2	1.04 (0.47, 2.32)	0.93	
LM with 3VD	16.8	5.8	3.05 (1.29, 7.21)	0.01	
Bifurcation involvement					0.83
Yes	11.8	7.3	1.62 (0.82, 3.20)	0.16	
No	13.2	9.1	1.46 (0.64, 3.32)	0.37	
RCA involvement					0.27
Yes	15.8	8.3	1.95 (0.99, 3.84)	0.05	
No	8.7	7.9	1.07 (0.48, 2.40)	0.86	
ACS					0.44
Yes	15.1	11.7	1.34 (0.70, 2.55)	0.38	
No	9.6	3.9	2.07 (0.85, 5.02)	0.11	
Diabetes					0.92
Yes	16.3	11.1	1.43 (0.65, 3.16)	0.37	
No	10.2	6.8	1.51 (0.76, 2.99)	0.24	
SYNTAX score					0.80
>29	15.9	11.1	1.60 (0.73, 3.54)	0.24	
>19 to ≤29	13.9	5.7	2.32 (0.82, 6.57)	0.11	
≤19	8.5	5.9	1.38 (0.40, 4.21)	0.57	



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

Predictors of 3-Year Mortality

MAIN-COMPARE Registry

	PCI		CABG	
	HR (95% CI)	**p**	**HR (95% CI)**	**p**
Age ≥ 75 y	-		1.94 (1.17, 3.21)	0.009
Heart failure	2.98 (1.41, 6.31)	0.004	-	
CRF	4.28 (2.10, 8.73)	<0.001	-	
Atrial fibrillation	-		3.08 (1.47, 6.45)	0.003
RCA disease	-		1.78 (1.09, 2.92)	0.02
LM bifurcation stenosis	-		1.49 (1.01, 2.18)	0.04
EuroSCORE ≥ 6	2.57 (1.44, 4.58)	0.001	2.31 (1.49, 3.56)	<0.001

Min SY et al. Circ Cardiovasc Interv. 2010;3:127

Predictors of 1-Year MACCE

SYNTAX LM Study

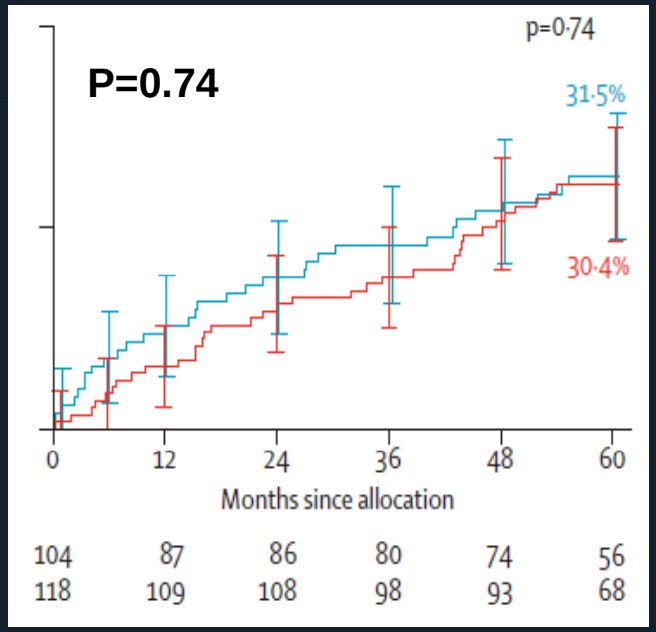
	PCI		CABG	
	OR (95% CI)	**p**	**OR (95% CI)**	**p**
Prior TIA	3.19 (1.03, 9.86)	0.04	-	
SYNTAX score	1.03 (1.01, 1.05)	0.01	-	
CRF	6.17 (0.92, 41.54)	0.06	-	
EuroSCORE	1.12 (1.00, 1.25)	0.045	1.19 (1.04, 1.35)	0.009
Emergent revascularization	-		6.27 (1.62, 24.22)	0.008
COPD	-		2.52 (0.94, 6.73)	0.07
DM	-		2.05 (0.91, 4.62)	0.08

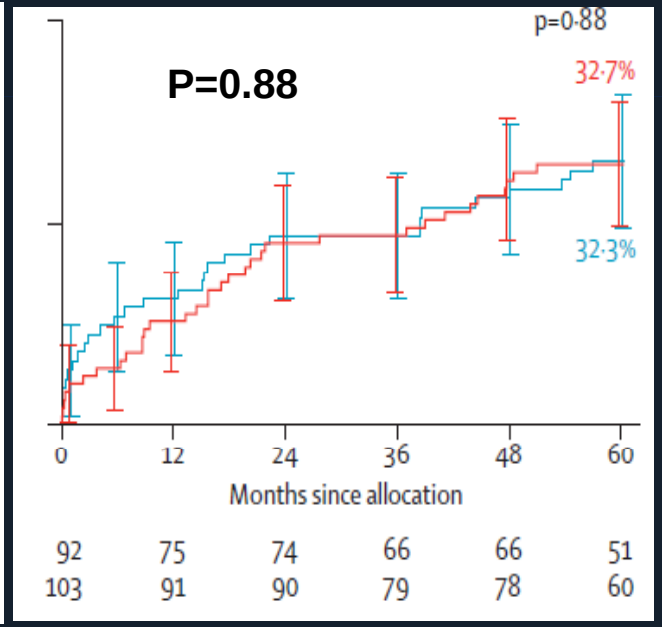
Min SY et al. Circ Cardiovasc Interv. 2010;3:127

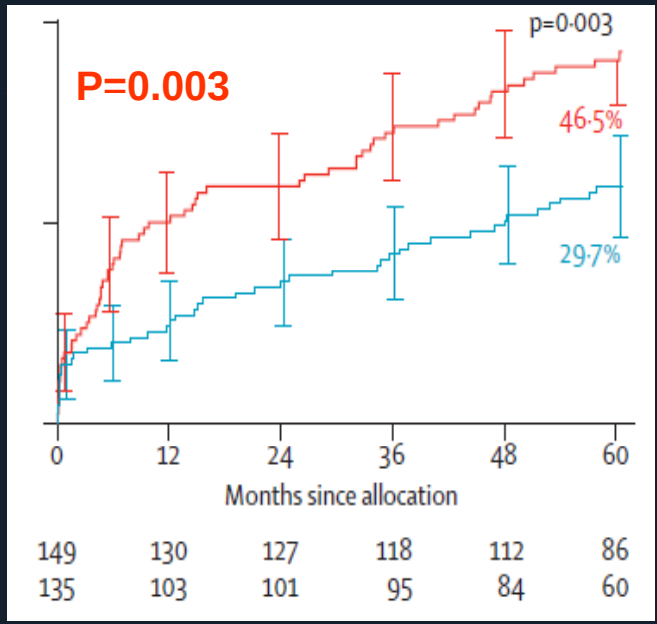
Durable Safety and Efficacy

MACCE to 5 Years
SYNTAX LM

SYNTAX score 0-22	SYNTAX score 23-32	SYNTAX score ≥ 33





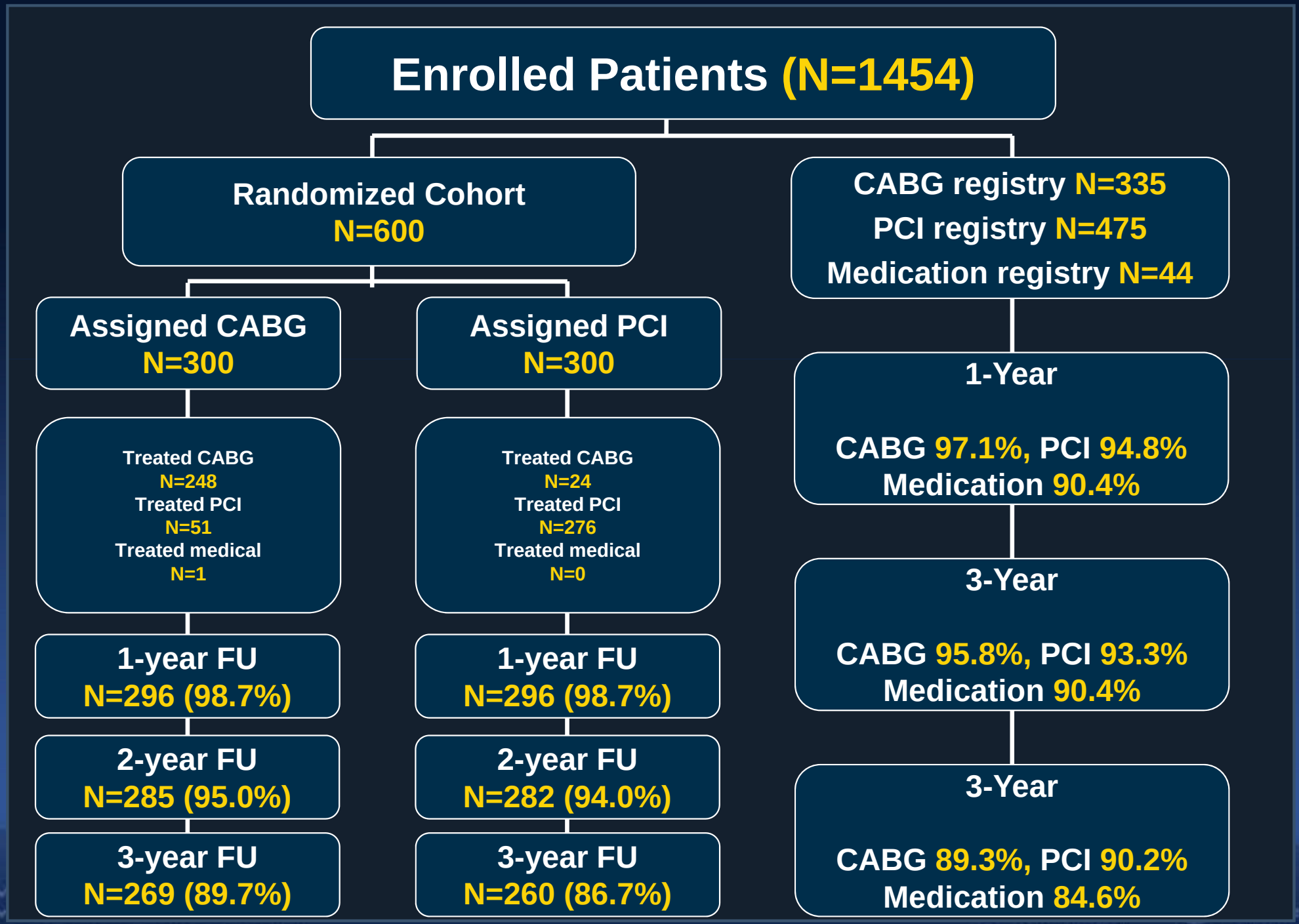


PCI CABGI

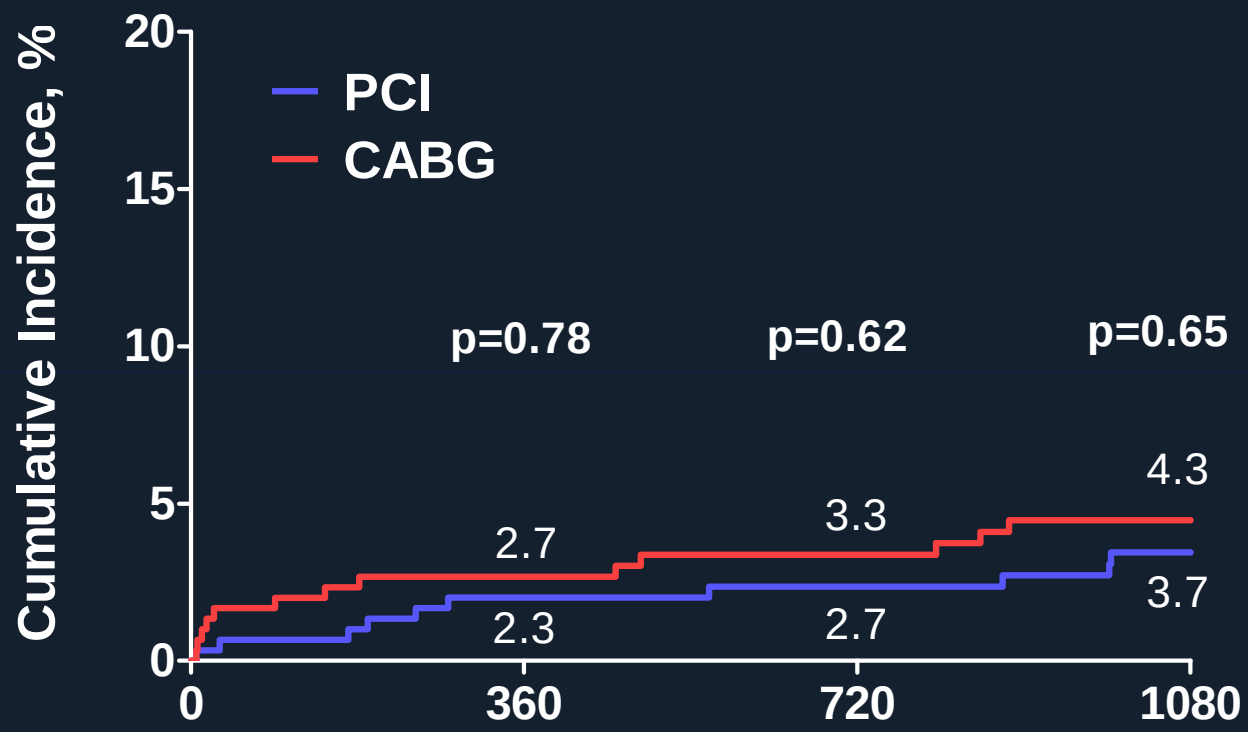
Mohr FW et al. Lancet 2013;381:629

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

3-Tear Follow-up of PRECOMBAT

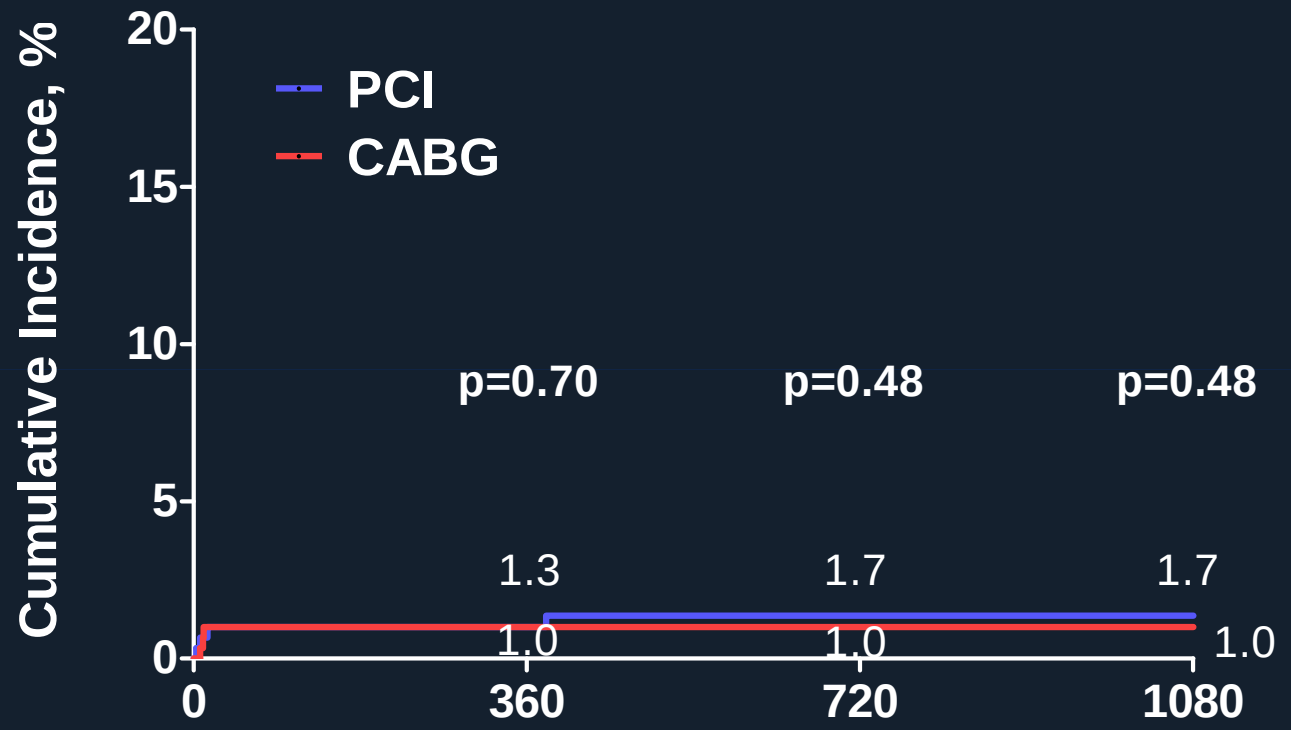


Death



No. at Risk				
PCI	300	288	277	250
CABG	300	283	272	239

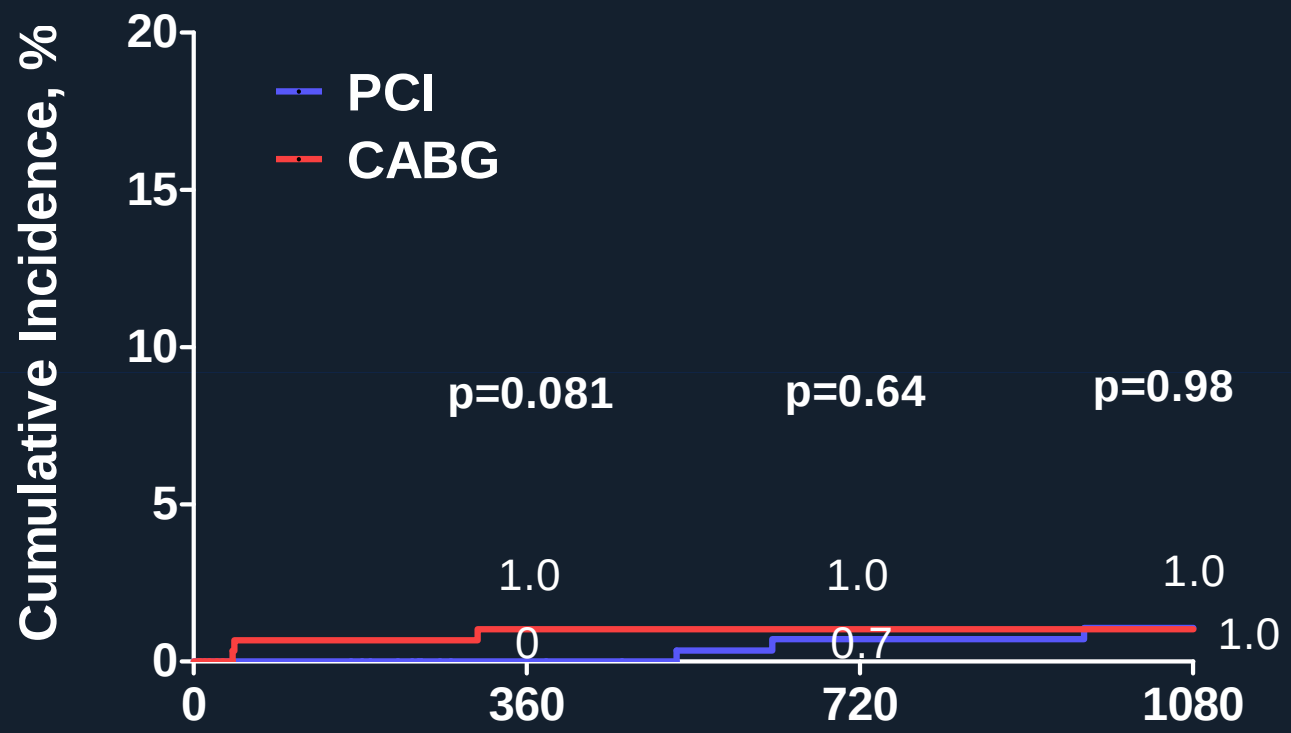
Myocardial Infarction



No. at Risk

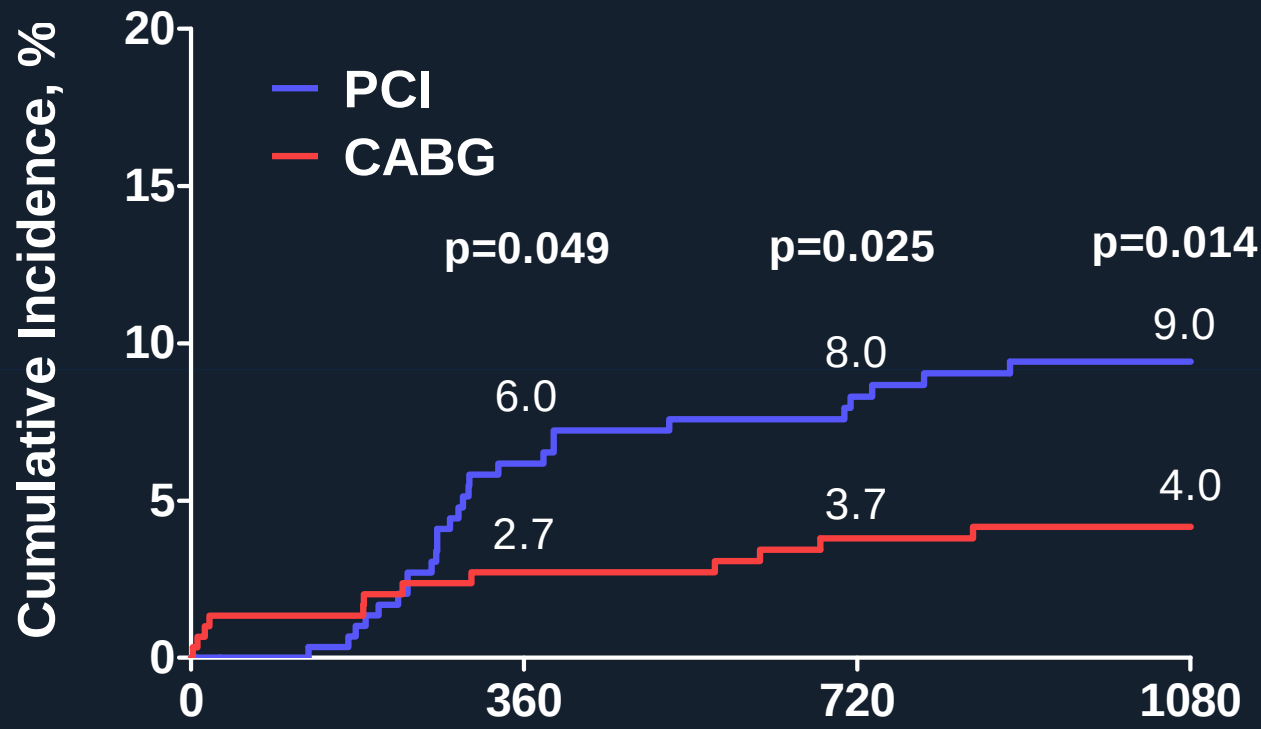
PCI	300	284	272	245
CABG	300	281	270	238

Stroke



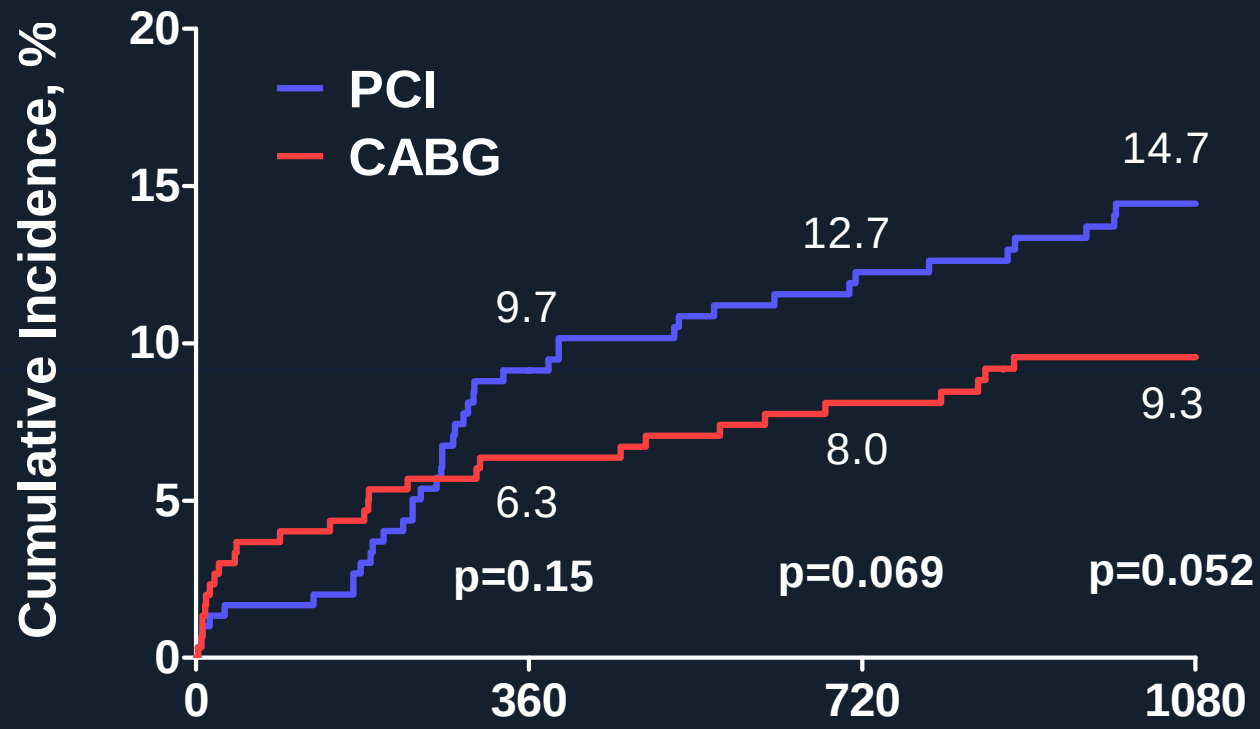
No. at Risk				
PCI	300	288	276	248
CABG	300	281	270	237

Ischemia-Driven TVR



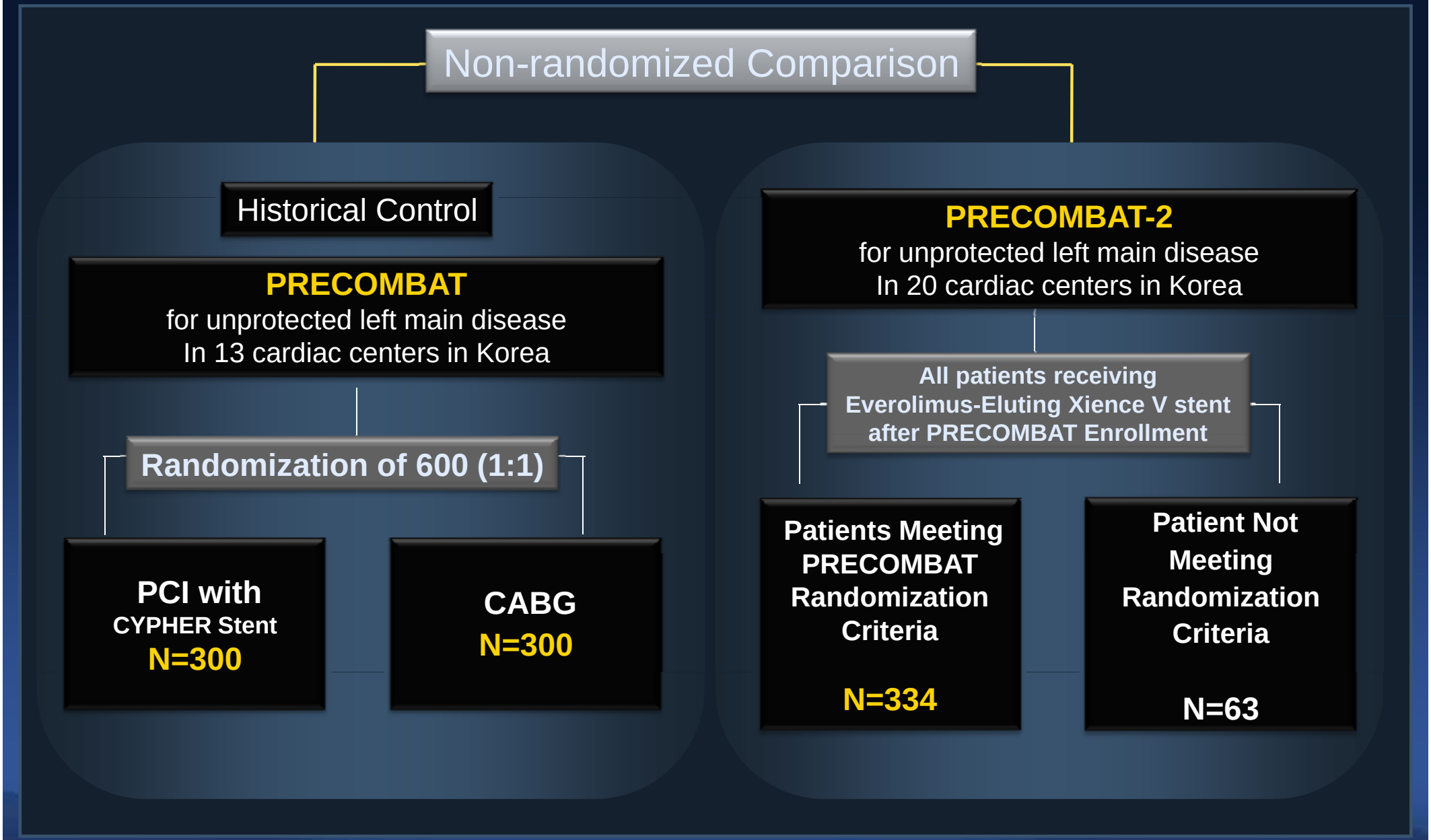
No. at Risk				
PCI	300	270	253	223
CABG	300	278	264	230

Primary End Point of MACCE



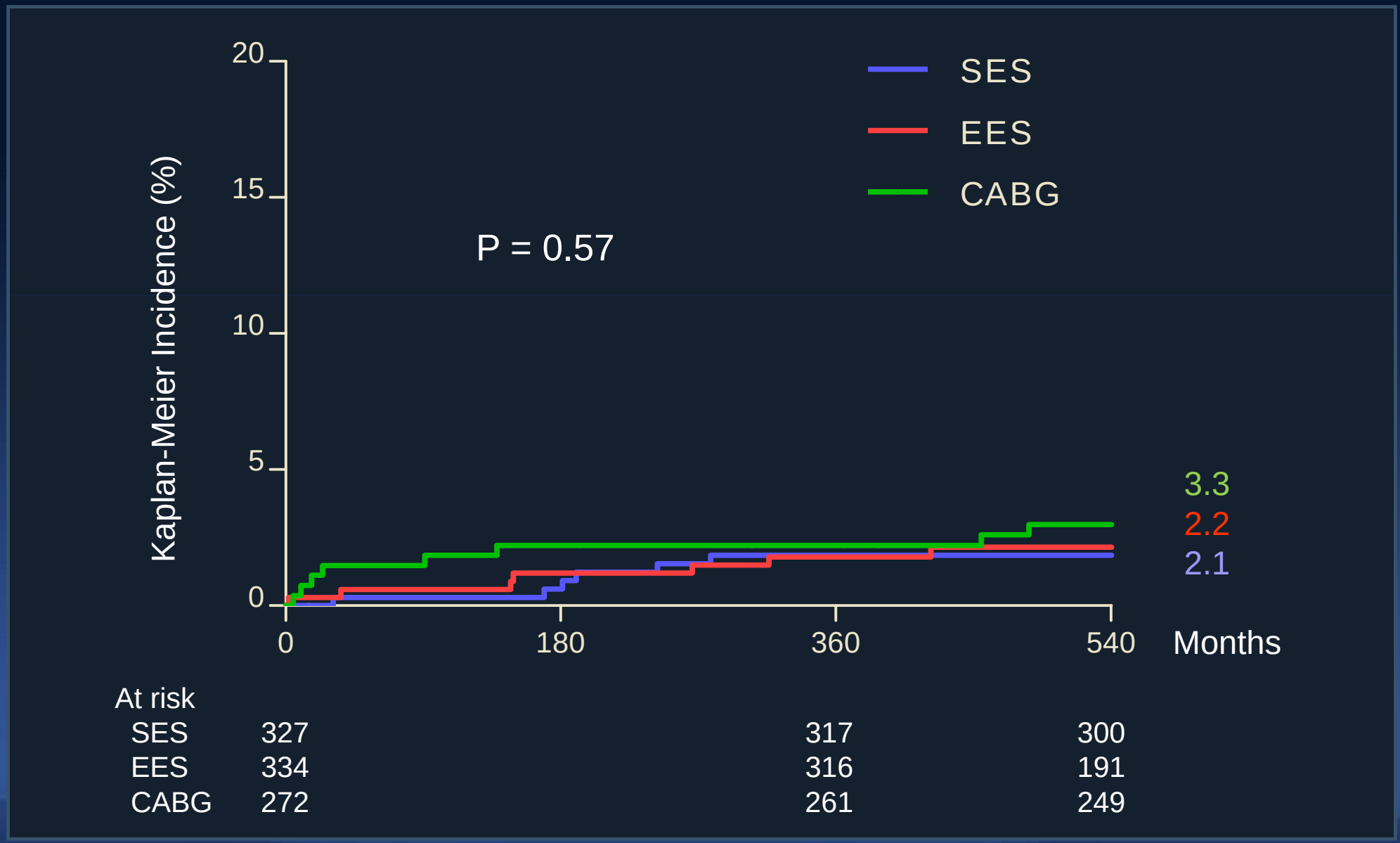
No. at Risk				
PCI	300	266	248	218
CABG	300	274	260	227

New-generation DES : PRECOMBAT-2



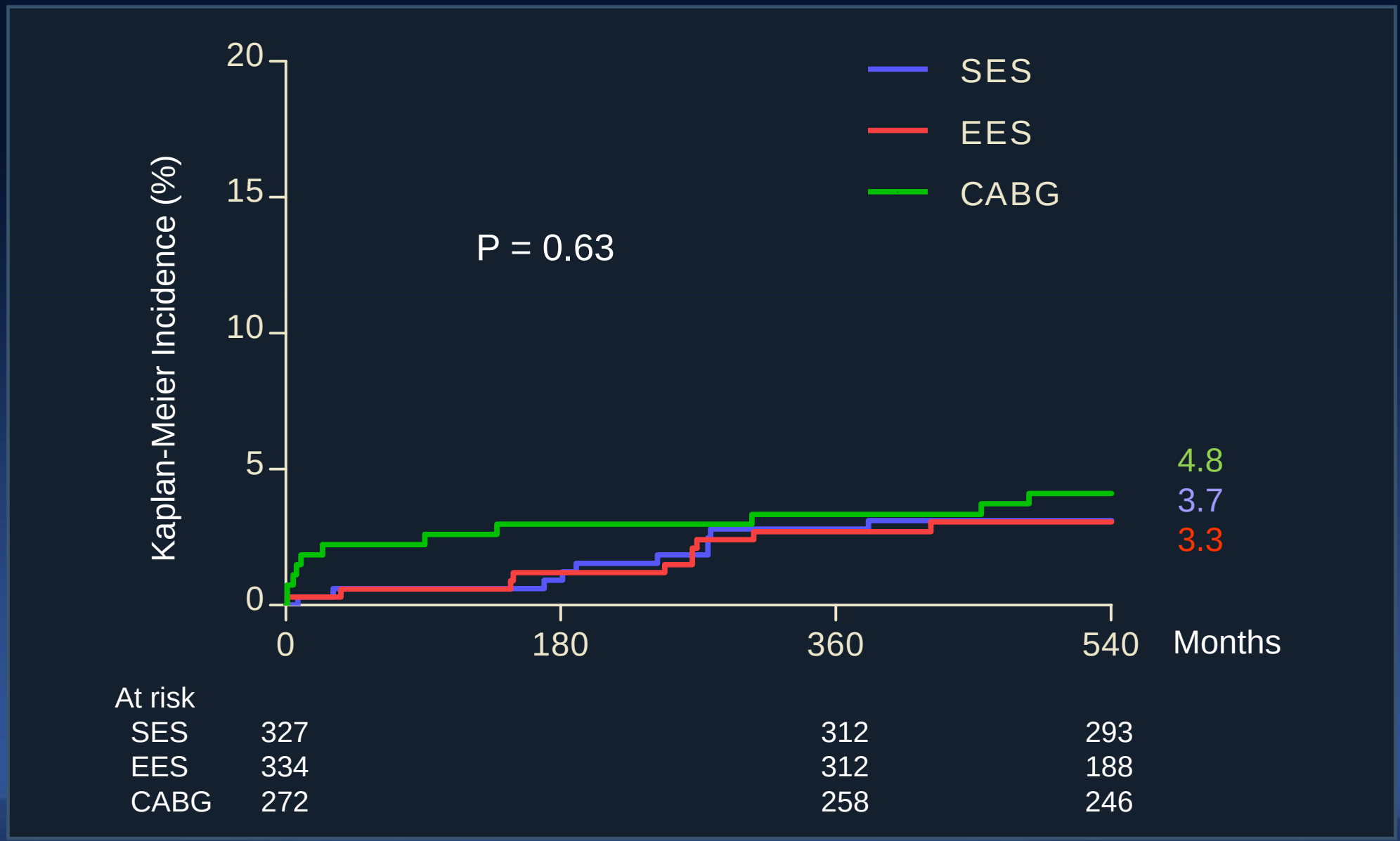
Kim YH et al. J Am Coll Cardiol Intv 2012;5:708

Death

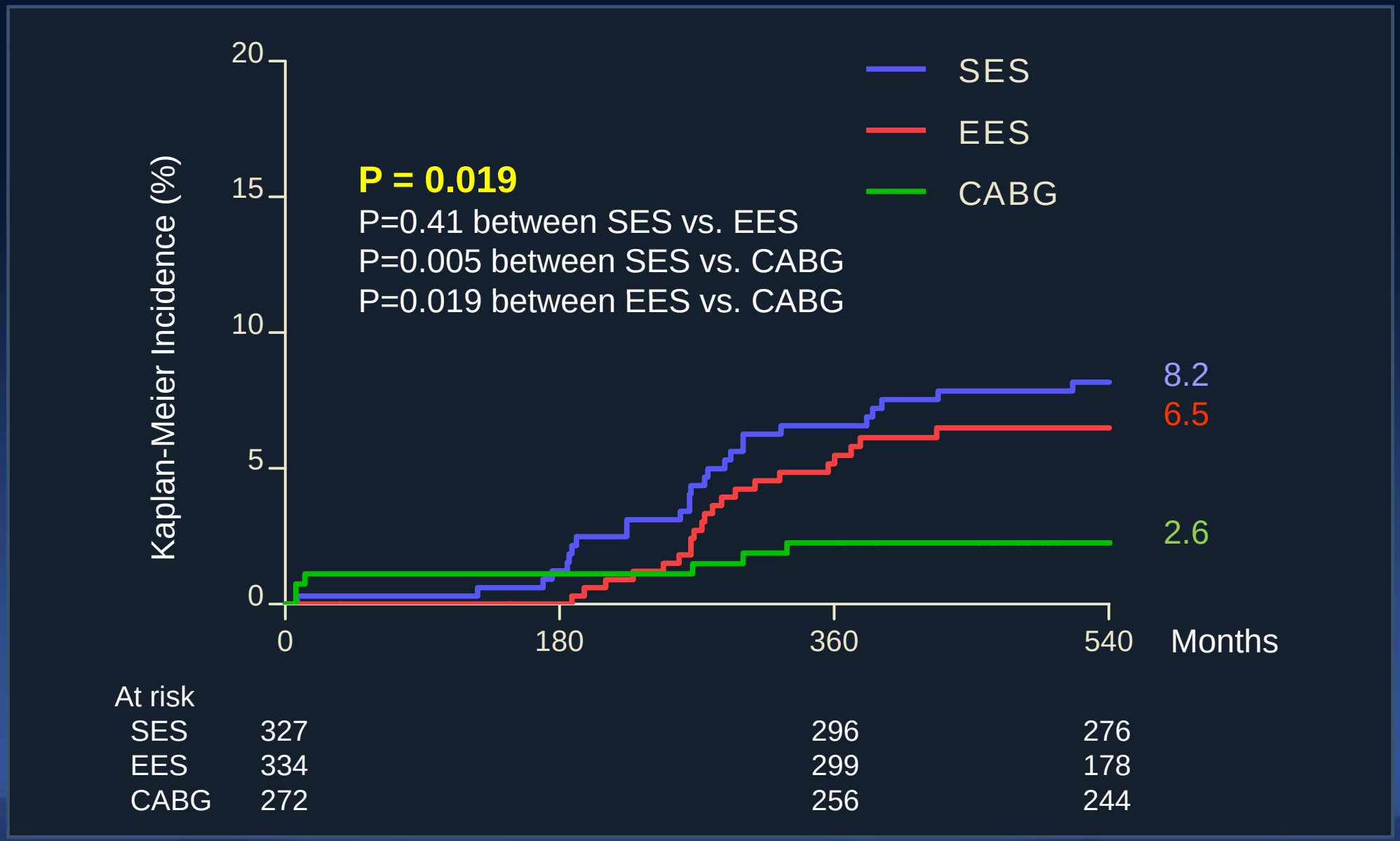


Kim YH et al. J Am Coll Cardiol Intv 2012;5:708

Death, MI, or Stroke

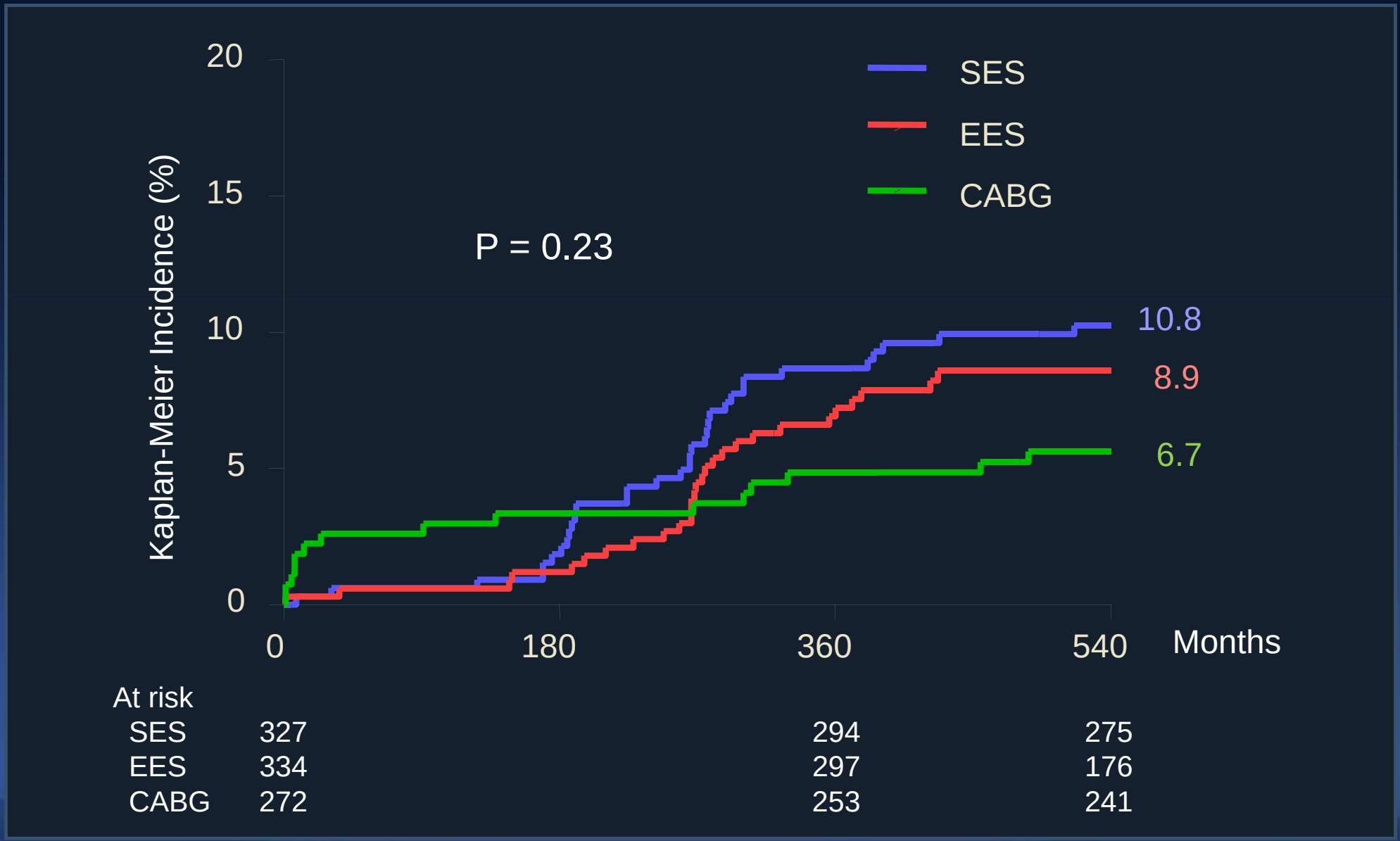


Ischemia-driven TVR



MACCE

Death, MI, Stroke or Ischemic TVR



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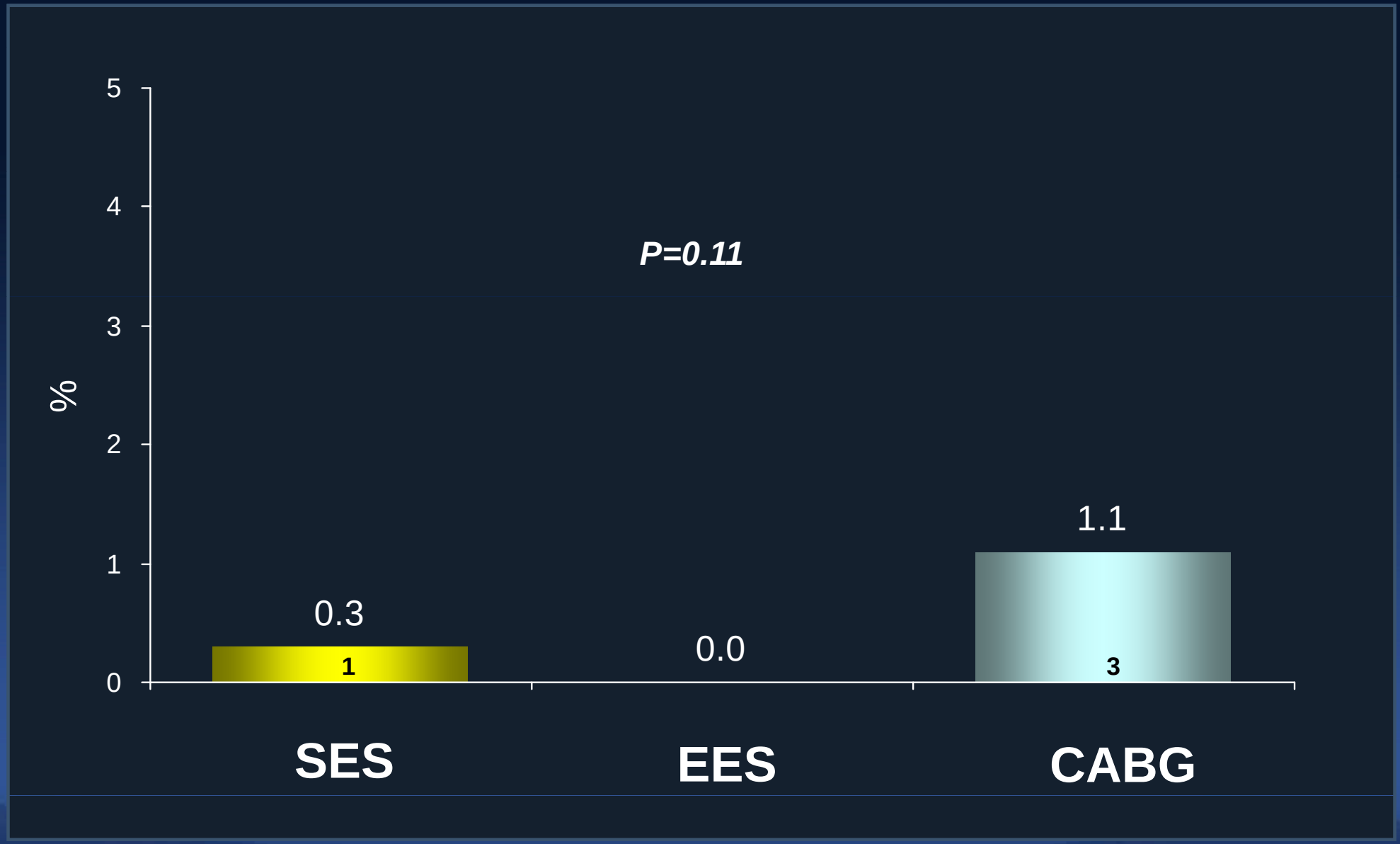
Symptomatic Graft Occlusion & Stent Thrombosis to 18 Months



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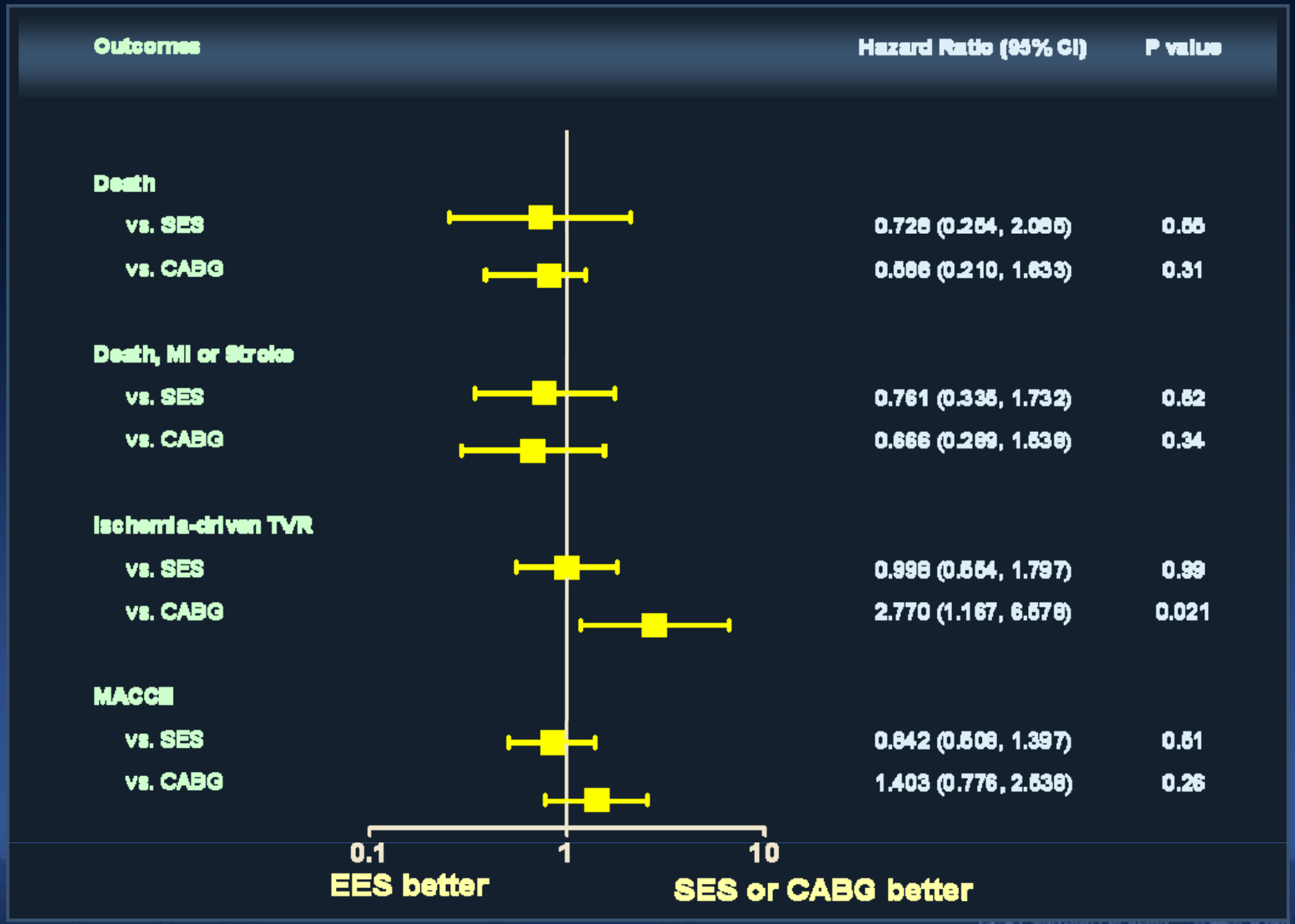
Hazard Ratios of EES after Adjustment



Conclusions

- PCI yielded comparable long-term safety and efficacy as CABG in patients with ULMCA stenosis with respect to composite of MACCE.
  - Similar rates of death or MI.
  - A tendency of higher risk of CVA after CABG.
  - Higher repeat revascularization after PCI even with DES.
- CBAG may be preferred in patients with extensive CAD.
- PCI had durable safety and efficacy to 5 years.
- The new generation DES had similar or better outcomes compared with the first-generation DES.
- A larger study of EXCEL trial will clarity a difference in the treatment effect between PCI and CABG.