

Outcomes of 2nd Generation DES for LM

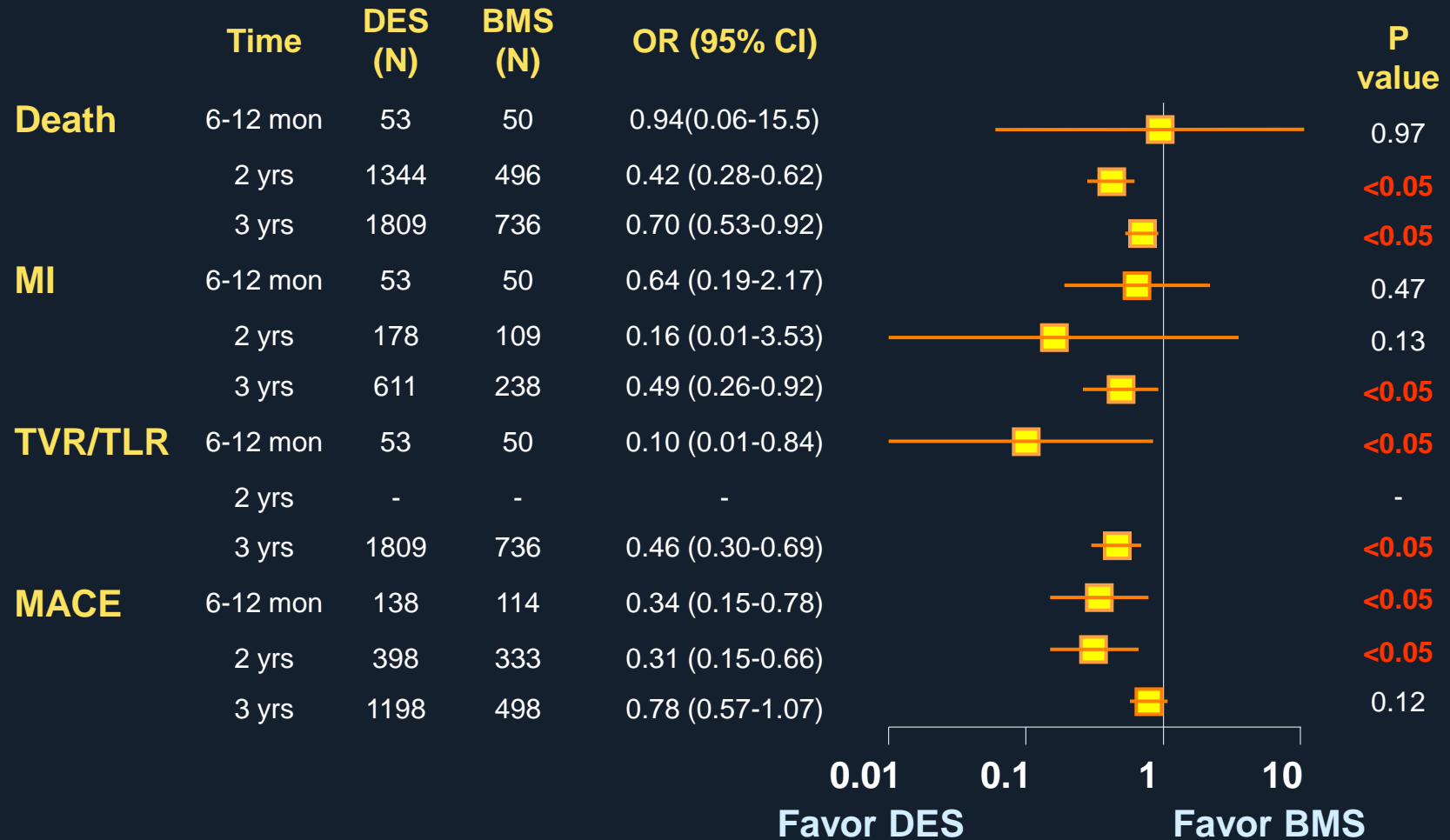
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BMS vs. 1st DES for LM

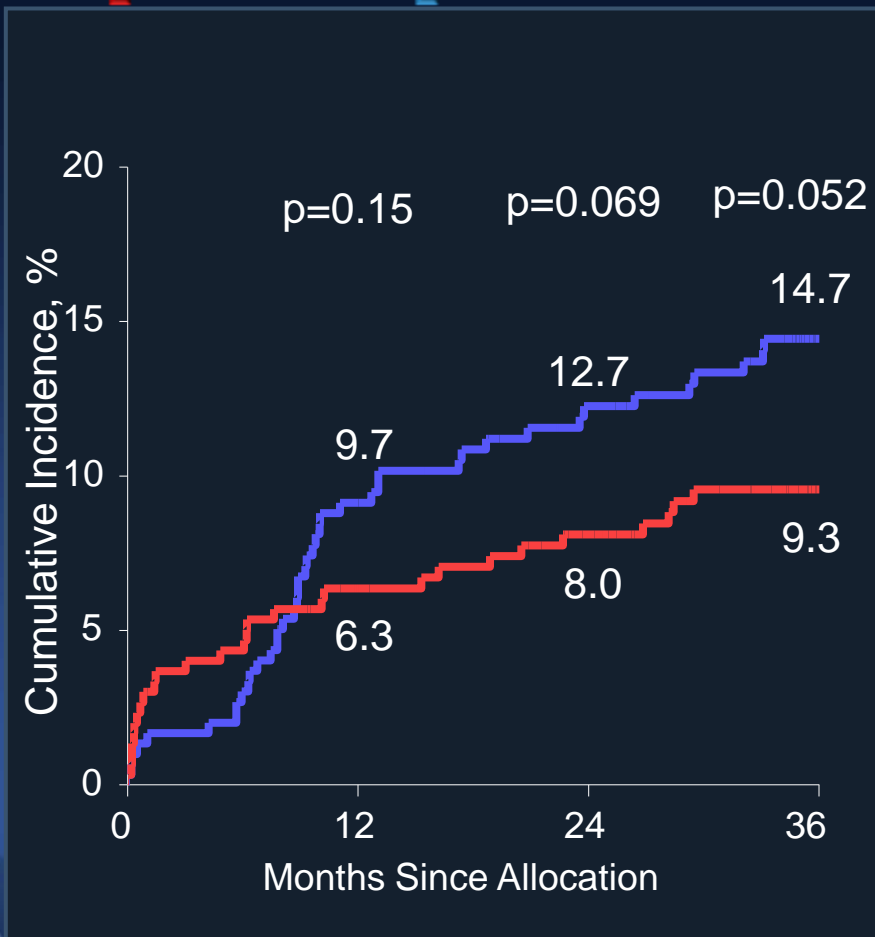
Meta-Analysis from 44 Studies and 10,342 Patients



1st DES vs. CABG MACCE Rate

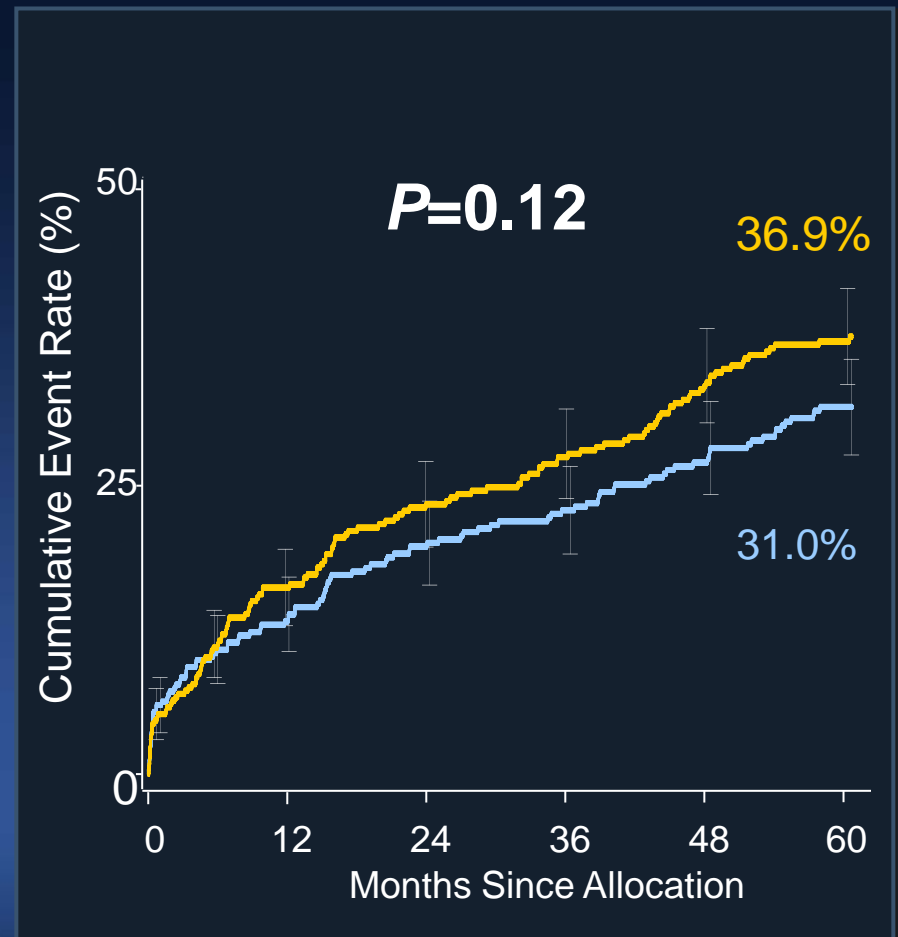
PRECOMBAT

CABG (N=300) CYPHER (N=300)



SYNTAX-LM

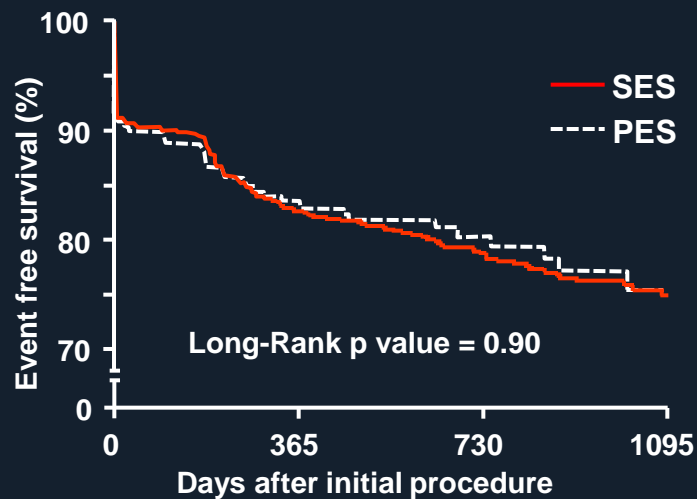
CABG (N=348) TAXUS (N=357)



Two 1st DES: SES vs. PES for LM

MAINCOMPARE

Death, MI, or TVR

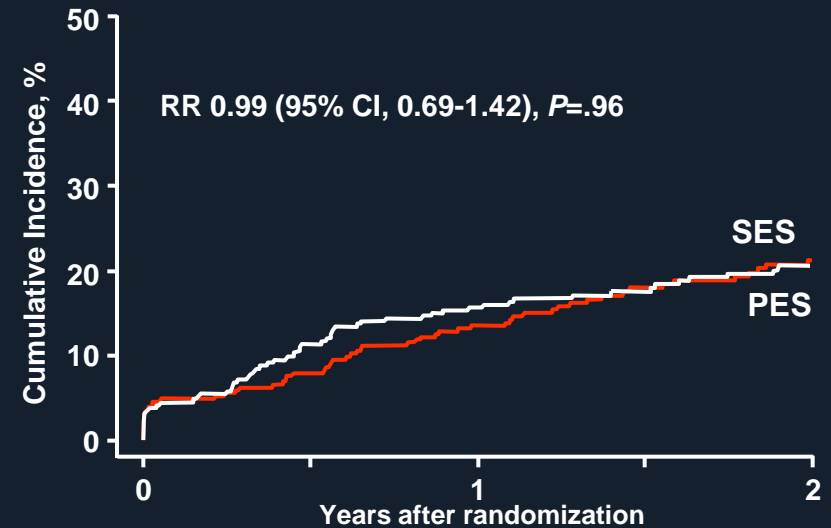


Number at risk

PES	189	153	94	31
SES	669	551	367	169

ISAR LM-1

Death, MI or TVR



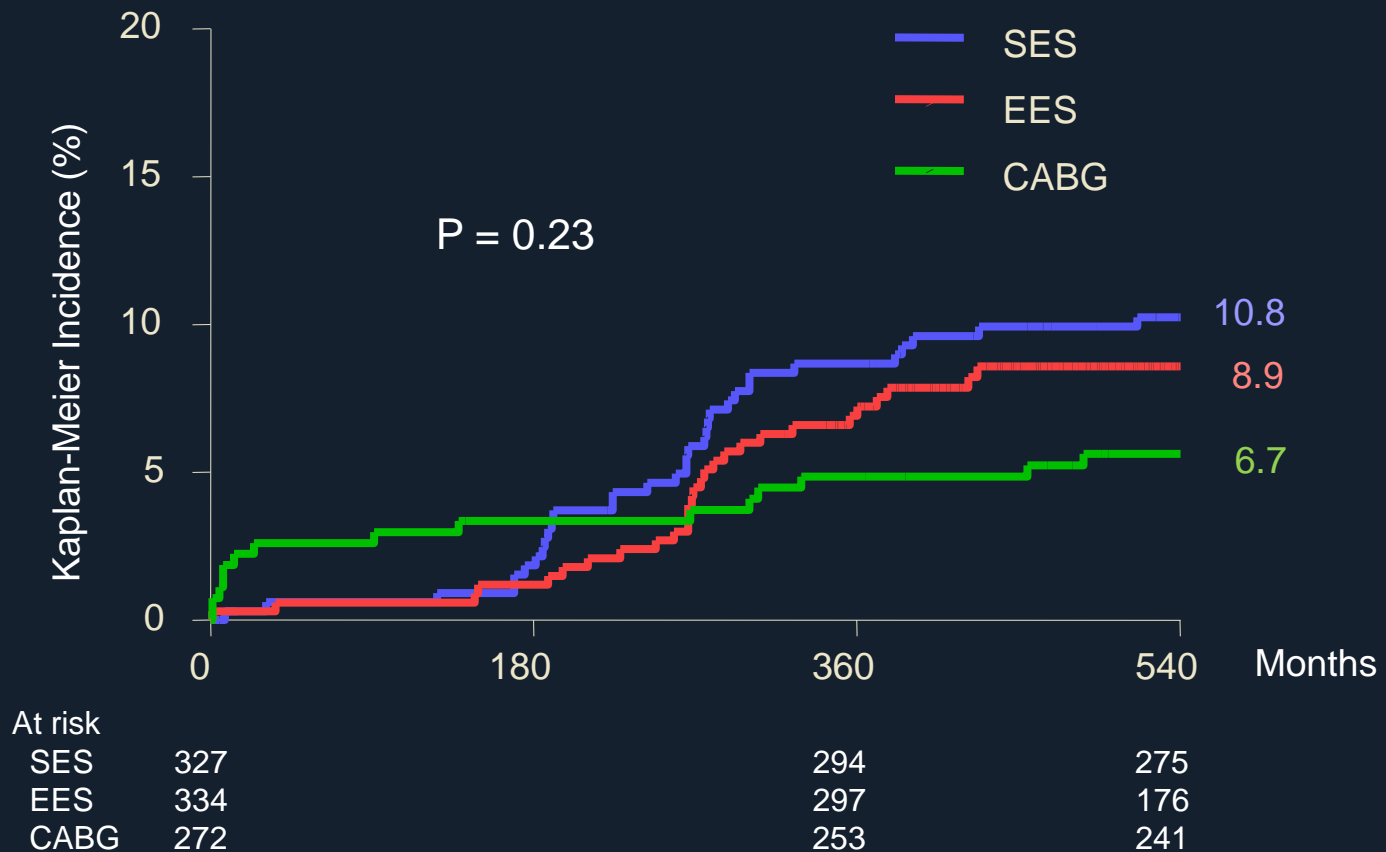
Patients at Risk

PES	302	278	250	189	160
SES	305	271	252	198	176

1st vs. 2nd DES for LM

PRECOMBAT-2 Study

MACCE



1st vs. 2nd DES for LM

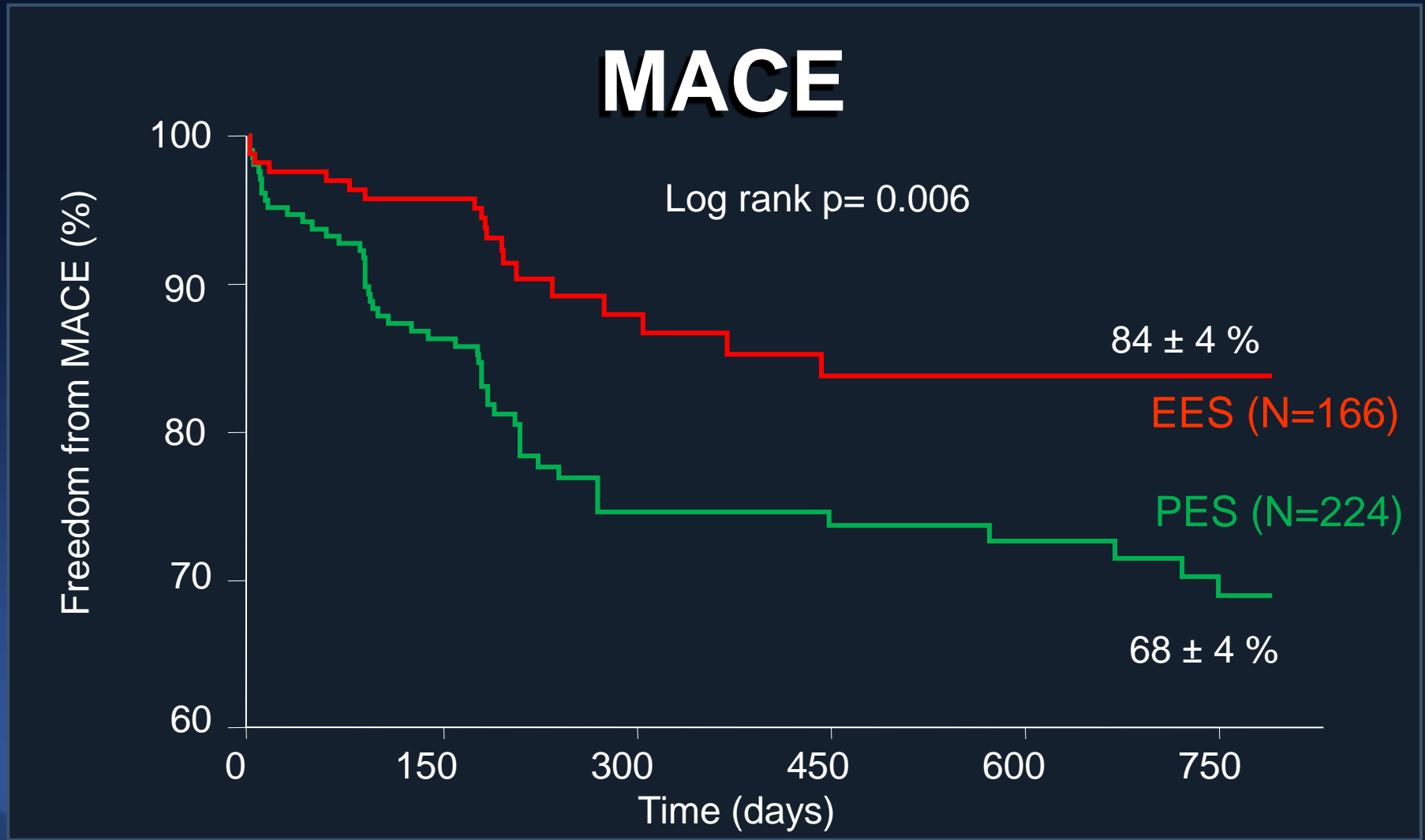
EXCELLENT registry

1 Year Outcome

	Events			Propensity Score Adjustment	
	EES (N=160)	SES (N=115)	P value	HR (95% CI)	P value
Death/MI/TVR	12 (7.5%)	16 (13.9%)	0.117	0.43 (0.20-0.95)	0.037
Death	7 (4.4%)	8 (7.0%)	0.383	0.52 (0.18-0.51)	0.23
Death/MI	8 (5.0%)	8 (7.0%)	0.529	0.60 (0.21-0.67)	0.323
TVR	4 (2.5%)	8 (7.0%)	0.096	0.28 (0.08-0.98)	0.046

1st vs. 2nd DES for LM

PCI Florence Registry



1st vs. 2nd DES for LM

ESTROFA-LM registry

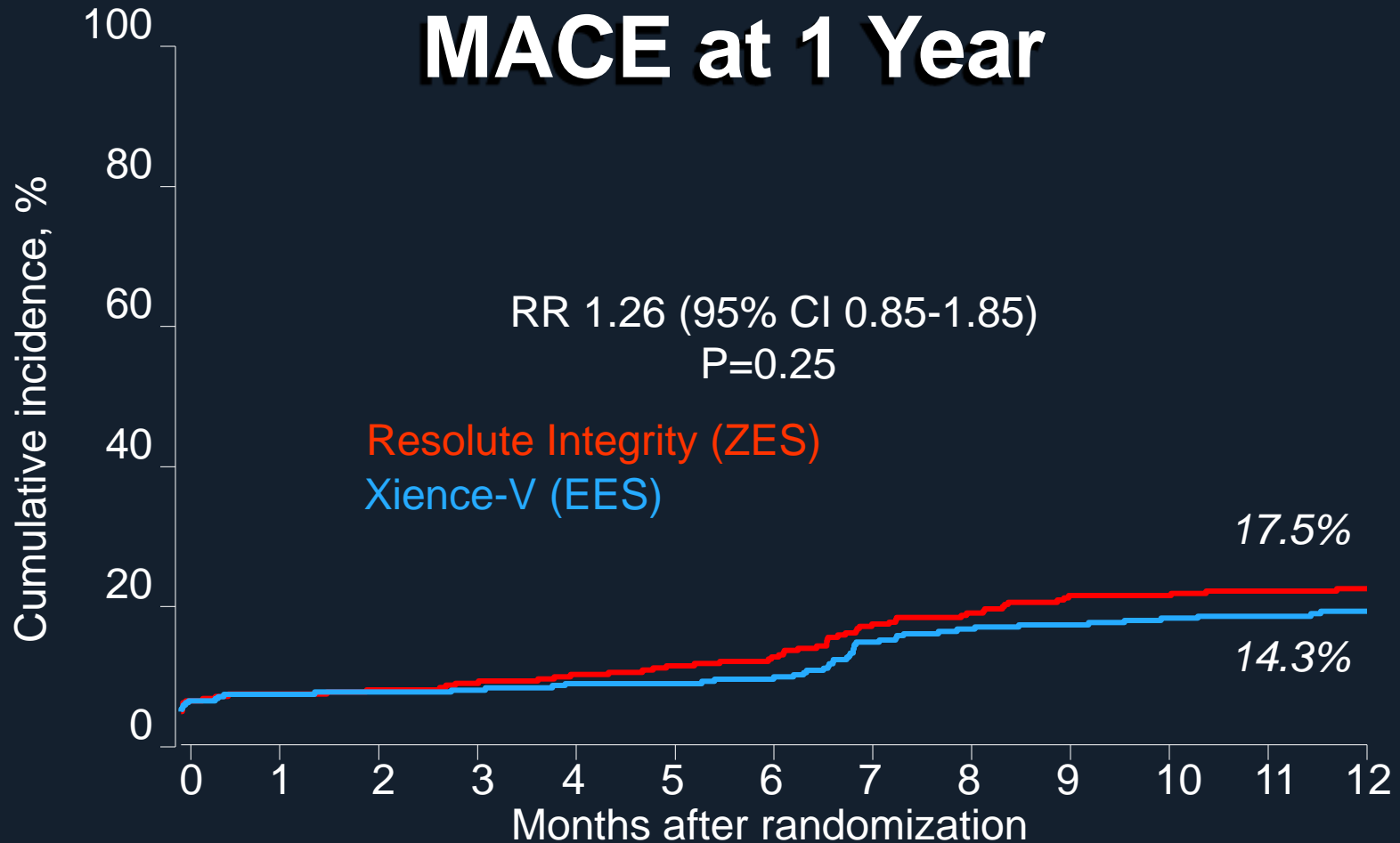
3 Year Event Free Survival

	Events		P value
	PES (N=415)	EES (N=355)	
Death and MI	86%	87%	0.50
Cardiac Death and MI	92%	91%	0.90
TLR	96%	94%	0.10
All revascularization	84%	86%	0.10
Death, MI, and TLR	84%	82%	0.60

2nd DES for LM

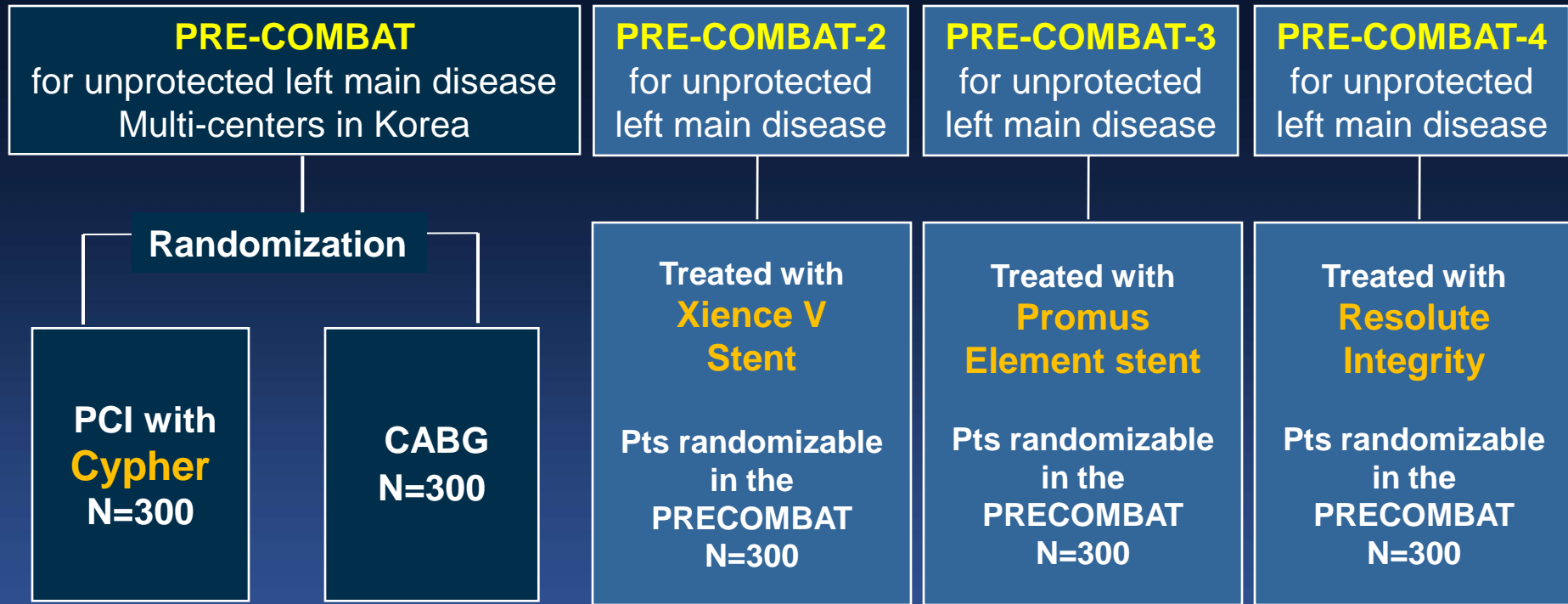
ISAR Left Main 2 RCT (n=650)

MACE at 1 Year



PRECOMBAT Series

New DES Evaluation !



Primary Endpoint (MACCE):
2-year death, MI, Stroke, and ischemic driven TVR

PRECOMBAT-3 Trial

Design

- **DESIGN:** a prospective, single arm, registry
- **OBJECTIVE:** To evaluate the outcomes of PCI with everolimus-eluting **PROMUS ELEMNT (PtCr-EES)** stents for patients with ULMCA stenosis, the results were compared with those of patients receiving SES, CoCr-EES and CABG in the PRECOMBAT trial
- **PRINCIPAL INVESTIGATOR**
Seung-Jung Park, MD, PhD, Asan Medical Center, Seoul, Korea

Purpose of PRECOMBAT-3

- To evaluate the safety and efficacy of PCI using platinum chromium everolimus-eluting Promus Element stent (Boston Scientific) for patients with ULMCA stenosis.
- The results were compared with those of historical controls of patients receiving PCI with Cypher, Xience V or CABG in the PRECOMBAT-1 and 2 study

Subjects

- Between August 2010 and July 2013, 300 patients who met the inclusion and exclusion criteria of PRECOMBAT randomized study were entered from 330 patients undergoing ULMCA stenting with PtCr-EES in 23 Korean cardiac centers.

Inclusion and Exclusion

- Identical to the PRECOMBAT randomized study
- In brief, patients with angiographic ULMCA stenosis (> 50% stenosis), who did not have ST-segment elevation MI, cardiogenic shock, other serious comorbidity or contraindication of DES, were included.

Procedures and Follow-up

- PtCr-EES (Promus Element) was the default stent for all lesions with LMCA in the study period
- IVUS and other devices were used at the operator's discretion.
- Annually clinical follow-up to 5 years

End Points

Identical to those used in the PRECOMBAT.

- **MACCE** : Primary end point, a composite of death, MI, stroke and ischemia-driven TVR.
- **Death** : cardiac and non-cardiac deaths.
- **MI** : Q-MI within 48 hours after procedure and spontaneous MI thereafter.
- **TVR** : ischemia-driven revascularization.

Statistics

- Analysis among as-treated groups
- ANOVA and t-test for continuous variables
- Chi-square and Fisher-exact for categorical variables
- Censoring at 2 years (720 days) or events
- Log-rank for survival analysis
- Multivariate Cox analysis to adjust different baseline characteristics

Baseline Characteristics

	SES (N=327)	CoCr-EES (N=334)	PtCr-EES (N=300)	CABG (N=272)	P value
Age, years	62.0±10.0	62.9±10.4	64.3±10.3	62.5±9.4	0.026
Male sex	249 (76.1)	236 (70.7)	231 (77.0)	209 (76.8)	0.19
Diabetes mellitus	109 (33.3)	116 (34.7)	94 (31.3)	82 (30.1)	0.63
Hypertension	176 (53.8)	189 (56.6)	191(63.7)	140 (51.5)	0.018
Hyperlipidemia	139 (42.5)	149 (44.6)	155 (51.7)	107 (39.3)	0.021
Current smoker	97 (29.7)	75 (22.5)	70 (23.3)	74 (27.2)	0.13
Previous PCI	42 (12.8)	27 (8.1)	51 (17.0)	34 (12.5)	0.009
Previous MI	16 (4.9)	13 (3.9)	15 (5.0)	17 (6.3)	0.62
Previous heart failure	0	4 (1.2)	11 (3.7)	2 (0.7)	0.001

Baseline Characteristics

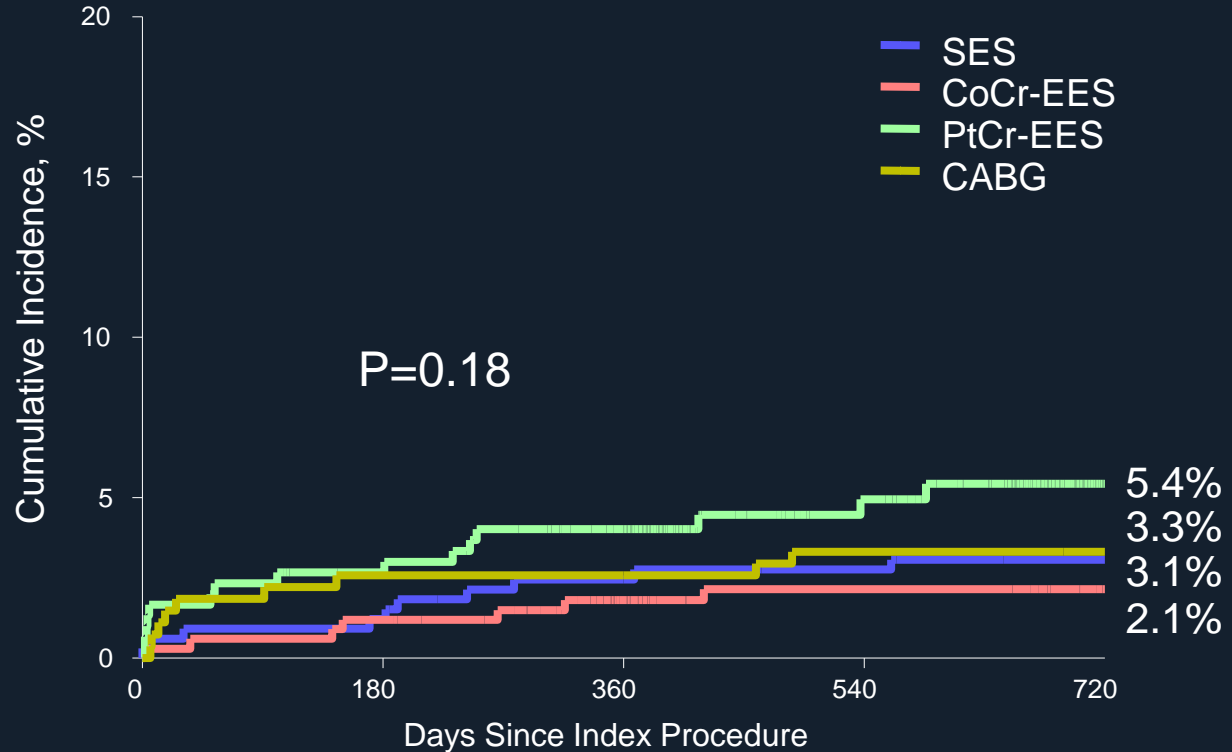
	SES (N=327)	CoCr-EES (N=334)	PtCr-EES (N=300)	CABG (N=272)	P value
Chronic renal failure	3 (0.9)	4 (1.2)	15 (5.0)	2 (0.7)	< 0.05
Peri. vascular disease	15 (4.6)	6 (1.8)	18 (6.0)	7 (2.6)	0.02
Chronic lung disease	8 (2.4)	4 (1.2)	9 (3.0)	7 (2.6)	0.46
ACS	155 (47.4)	151 (45.2)	151 (50.3)	147 (54.0)	0.16
Ejection fraction, %	61.5±8.4	61.1±8.2	59.0±9.9	60.8±8.4	< 0.05
EuroSCORE	2.8±1.9	2.9±2.0	3.4±2.4	2.9±2.0	< 0.05
Multivessel disease	231 (70.6)	191 (57.2)	198 (66.0)	205 (75.4)	< 0.05
LM bifurcation	219 (67.0)	240 (71.9)	207 (69.0)	163 (59.9)	< 0.05
SYNTAX Score	23.8±9.5	21.1±8.8	21.0±9.6	26.8±10.4	<0.05

Procedures

	SES (N=327)	CoCr-EES (N=334)	PtCr-EES (N=300)	CABG (N=272)	P value
Total stent N. in left main	1.6±0.8	1.8±0.9	1.7±0.8	–	< 0.05
Total stent N. per patient	2.6±1.4	2.3±1.3	2.3±1.2	–	< 0.05
IVUS	294 (89.9)	302 (90.4)	270 (90.0)	–	0.83
Two-stent technique	112 (34.3)	88 (26.3)	81 (27.0)	–	0.049
Angiographic follow-up	249 (76.1)	203 (60.8)	121 (40.3)	–	< 0.05
N. of conduits	–	–	–	2.7±0.9	
N. of arterial conduits	–	–	–	2.1±0.9	
Off-pump surgery	–	–	–	166 (61.0)	
Use of LIMA	–	–	–	254 (93.4)	

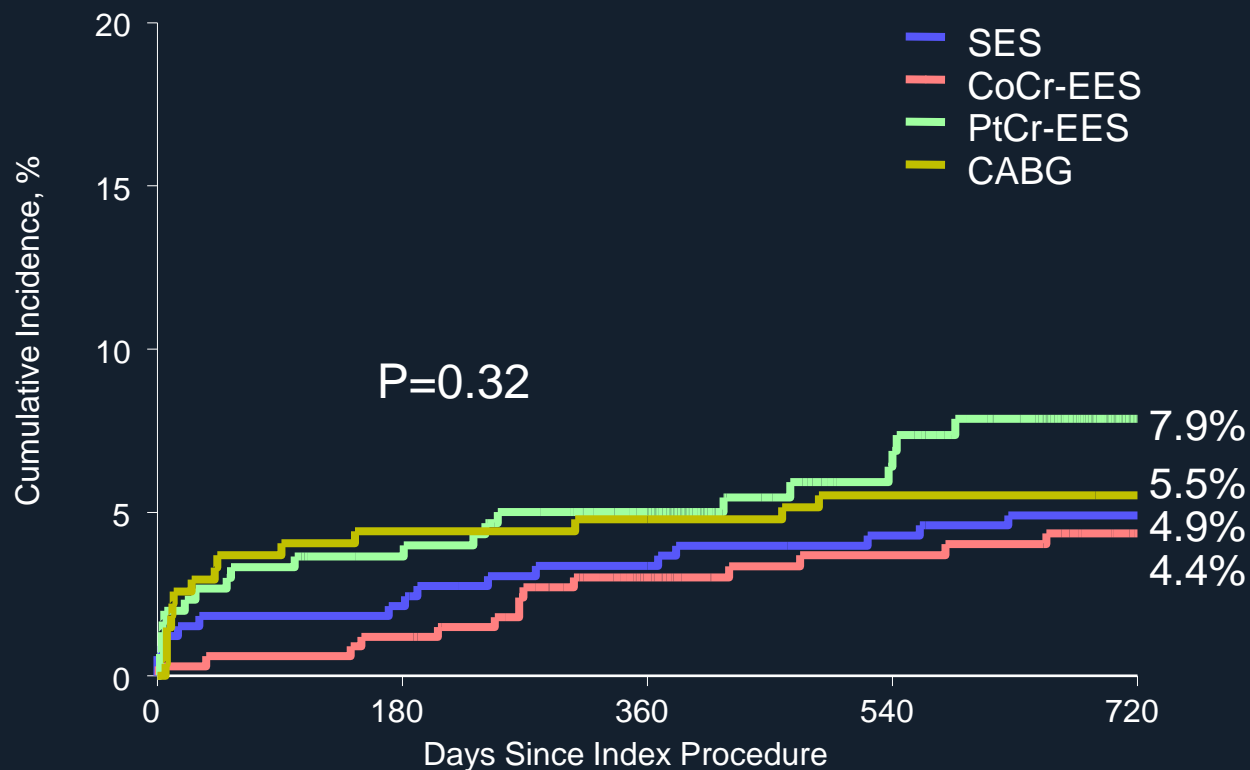
Clinical Outcomes

Death



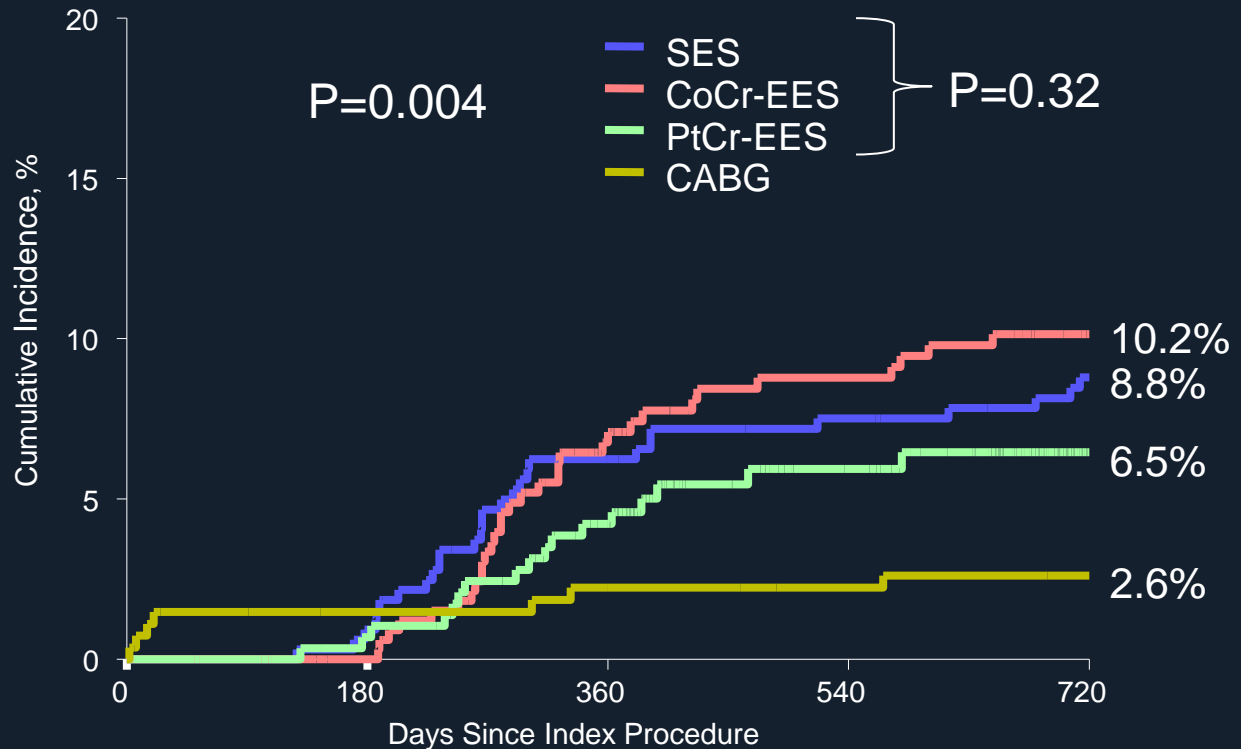
N. at risk					
SES	327	324	317	315	311
CoCrEES	334	331	308	292	282
PtCrEES	300	289	273	200	119
CABG	272	265	264	262	260

Death, MI, or Stroke



N. at risk	0	180	360	540	720
SES	327	321	314	310	306
CoCrEES	334	331	304	287	275
PtCrEES	300	286	270	194	116
CABG	272	260	258	256	254

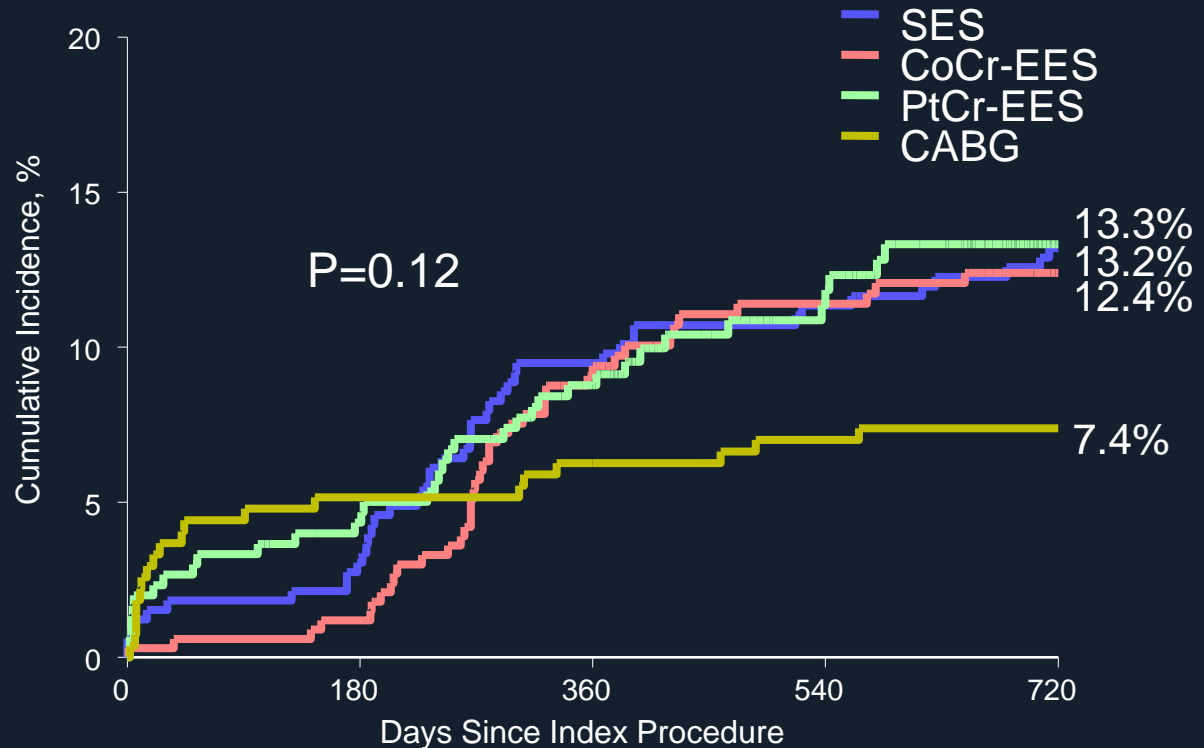
TVR



N. at risk

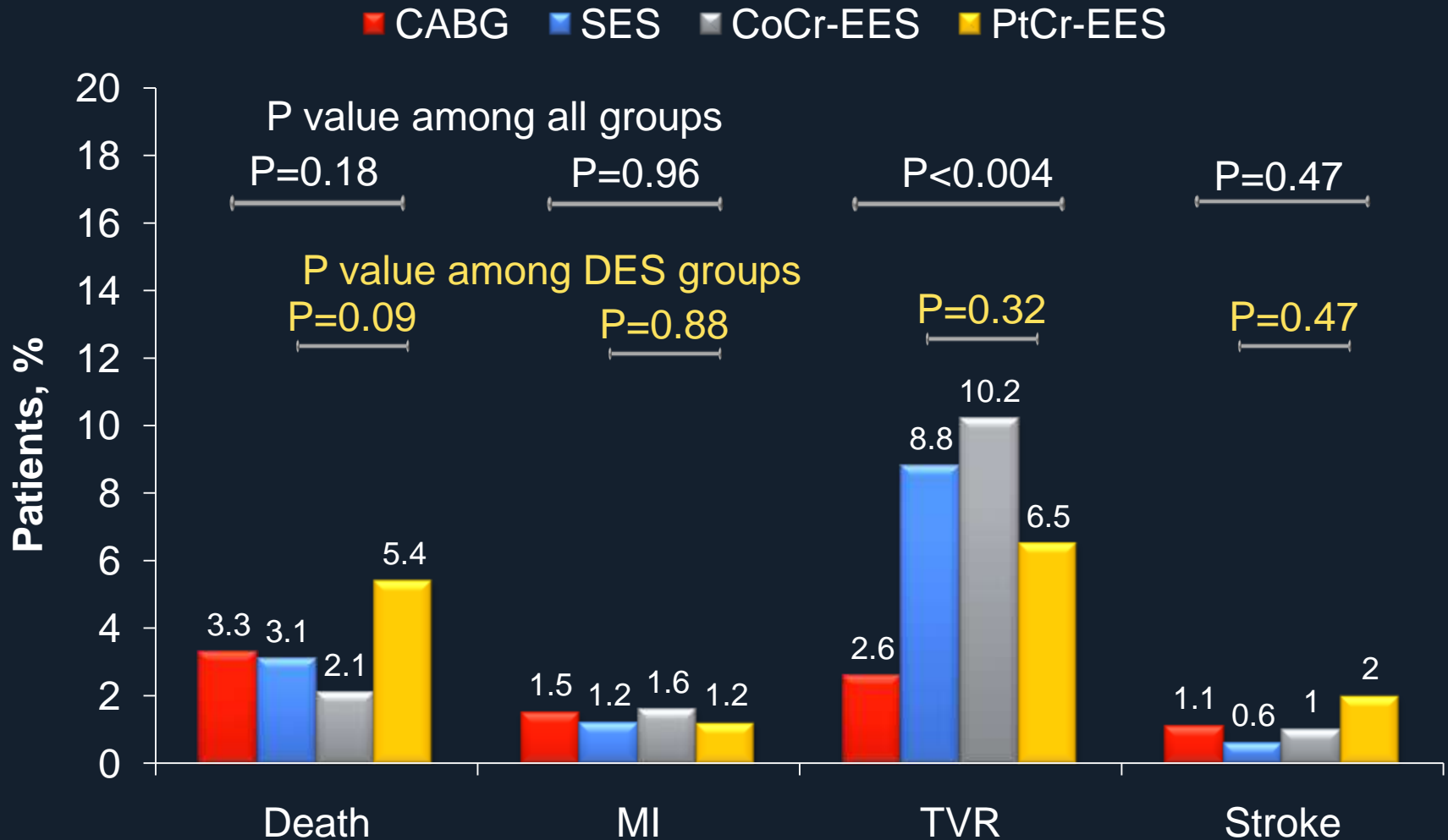
SES	327	321	298	292	284
CoCrEES	334	331	289	269	255
PtCrEES	300	287	263	188	114
CABG	272	263	260	258	255

MACCE: Death, MI, Stroke, or TVR

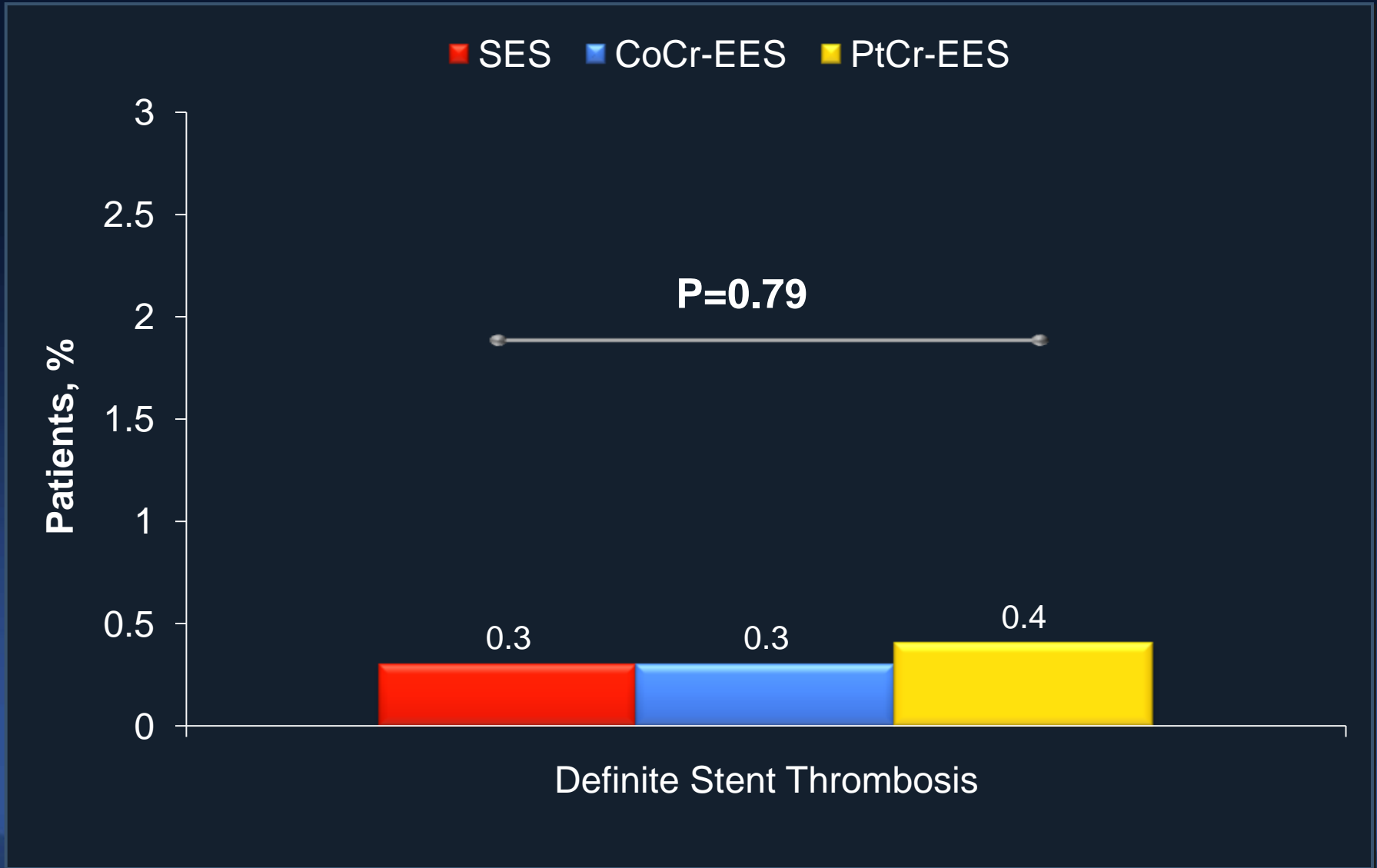


N. at risk	0	180	360	540	720
SES	327	318	295	288	280
CoCrEES	334	331	286	266	253
PtCrEES	300	284	259	183	112
CABG	272	258	254	252	249

Clinical Outcomes at 2 Years

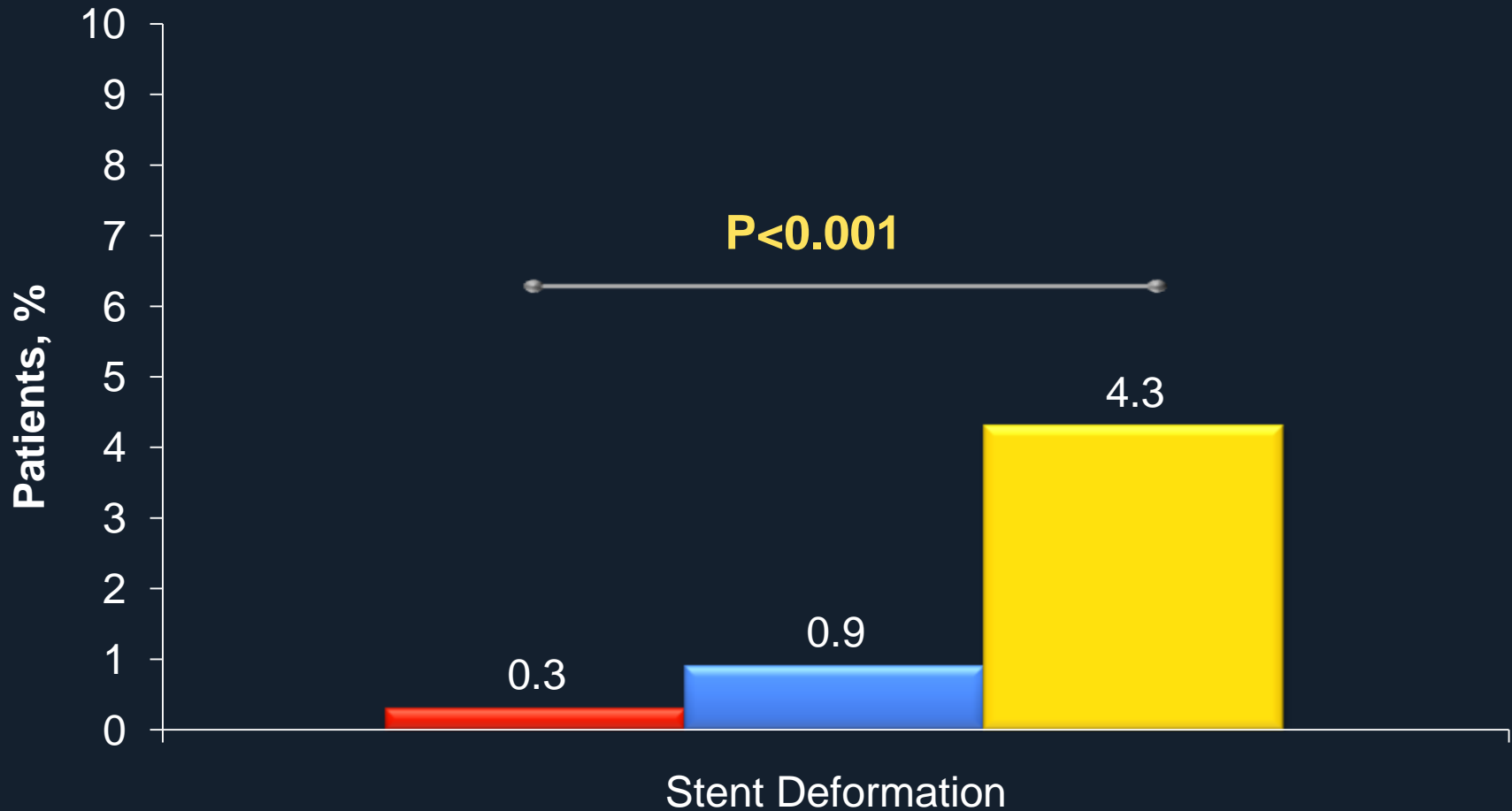


Definite Stent Thrombosis at 2 Years

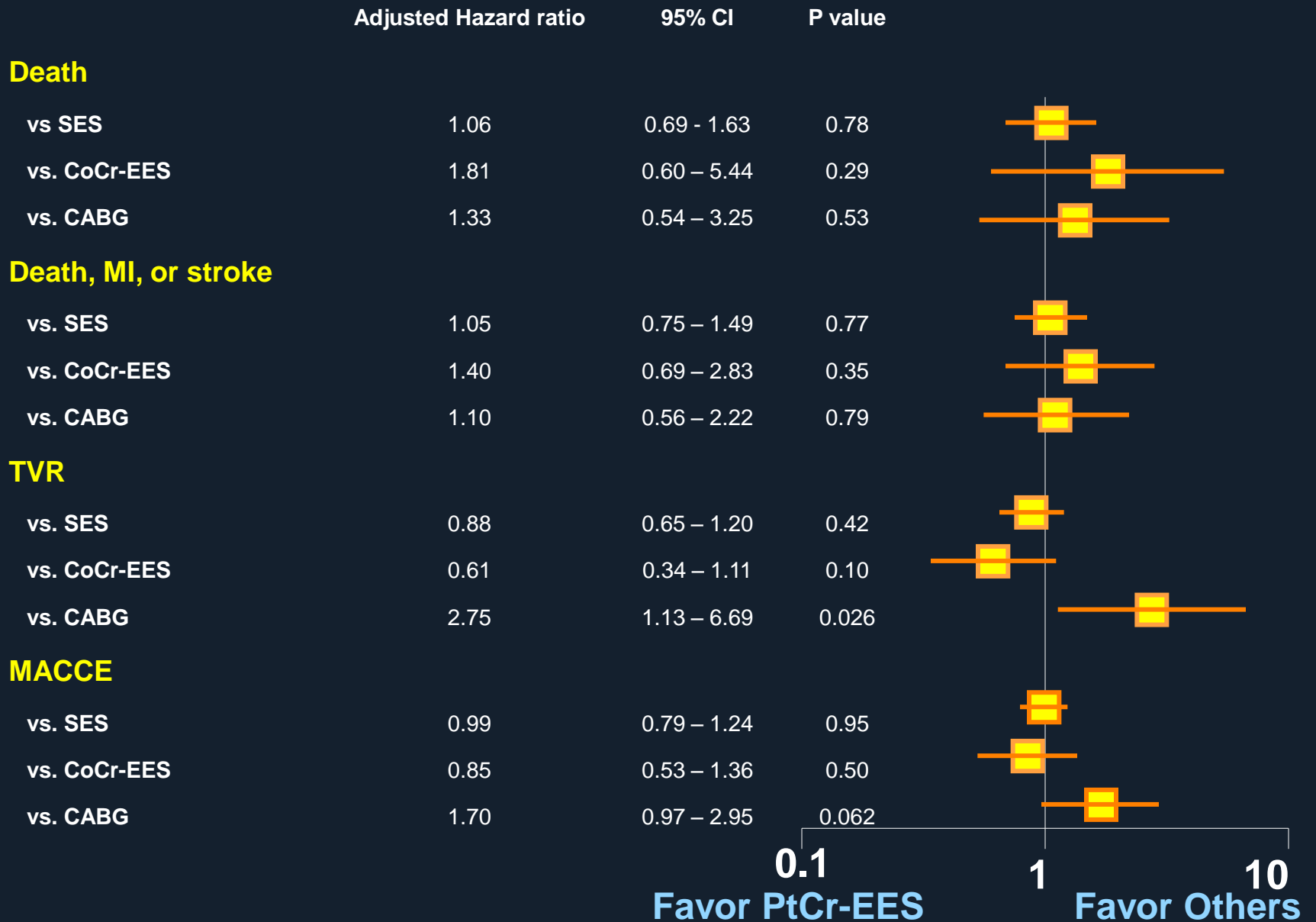


Stent Deformation

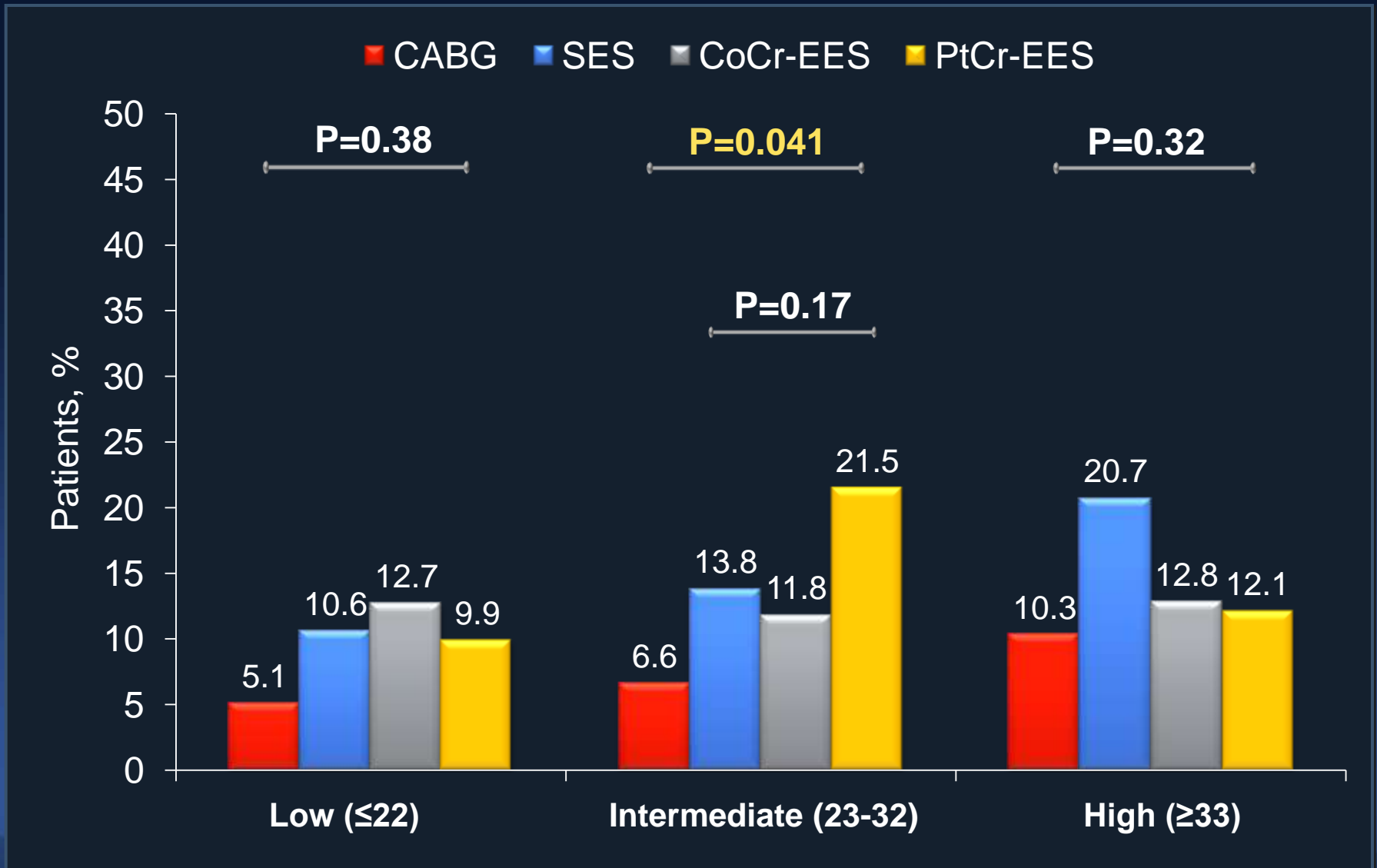
■ SES ■ CoCr-EES ■ PtCr-EES



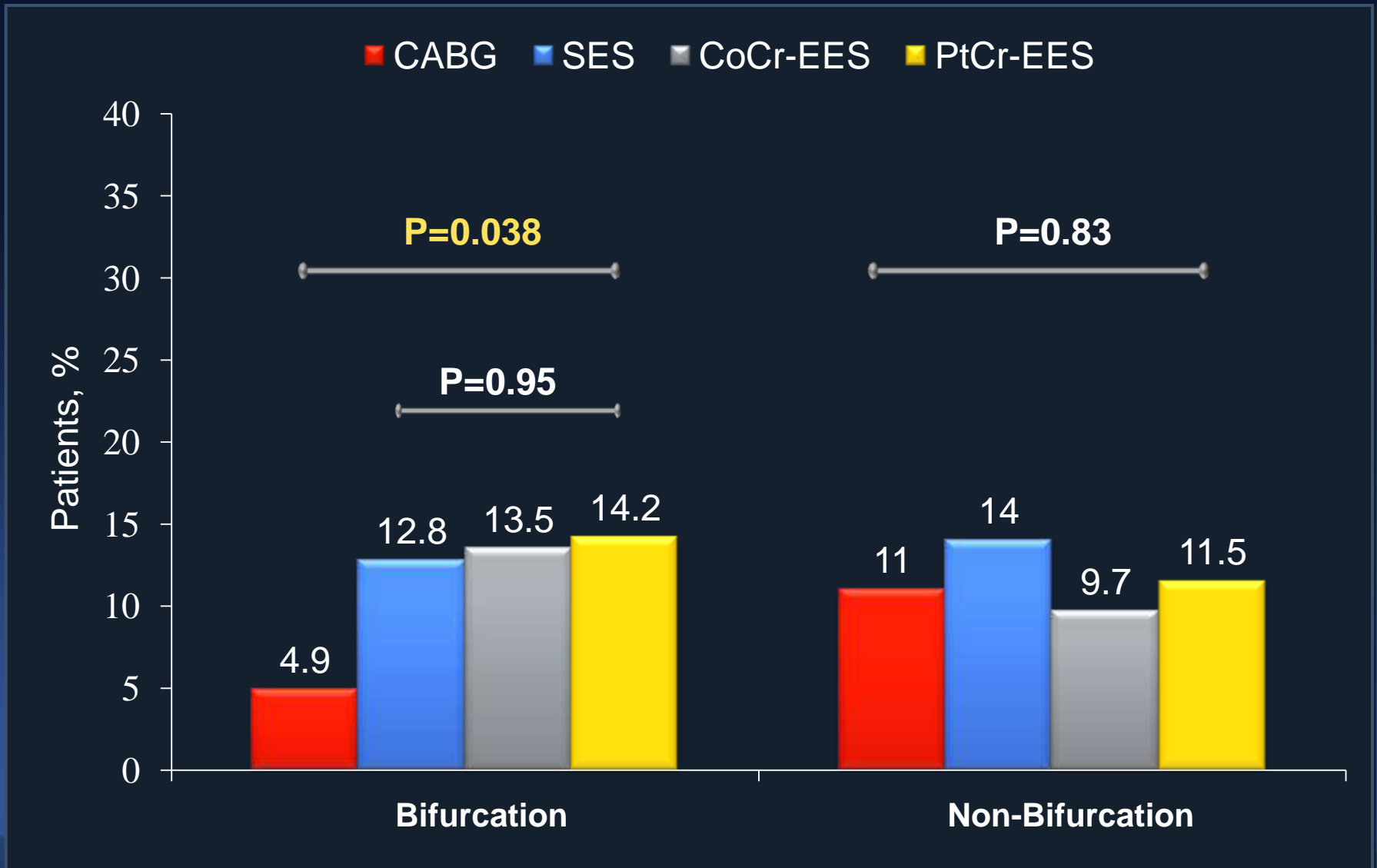
Adjusted HR for PtCr-EES



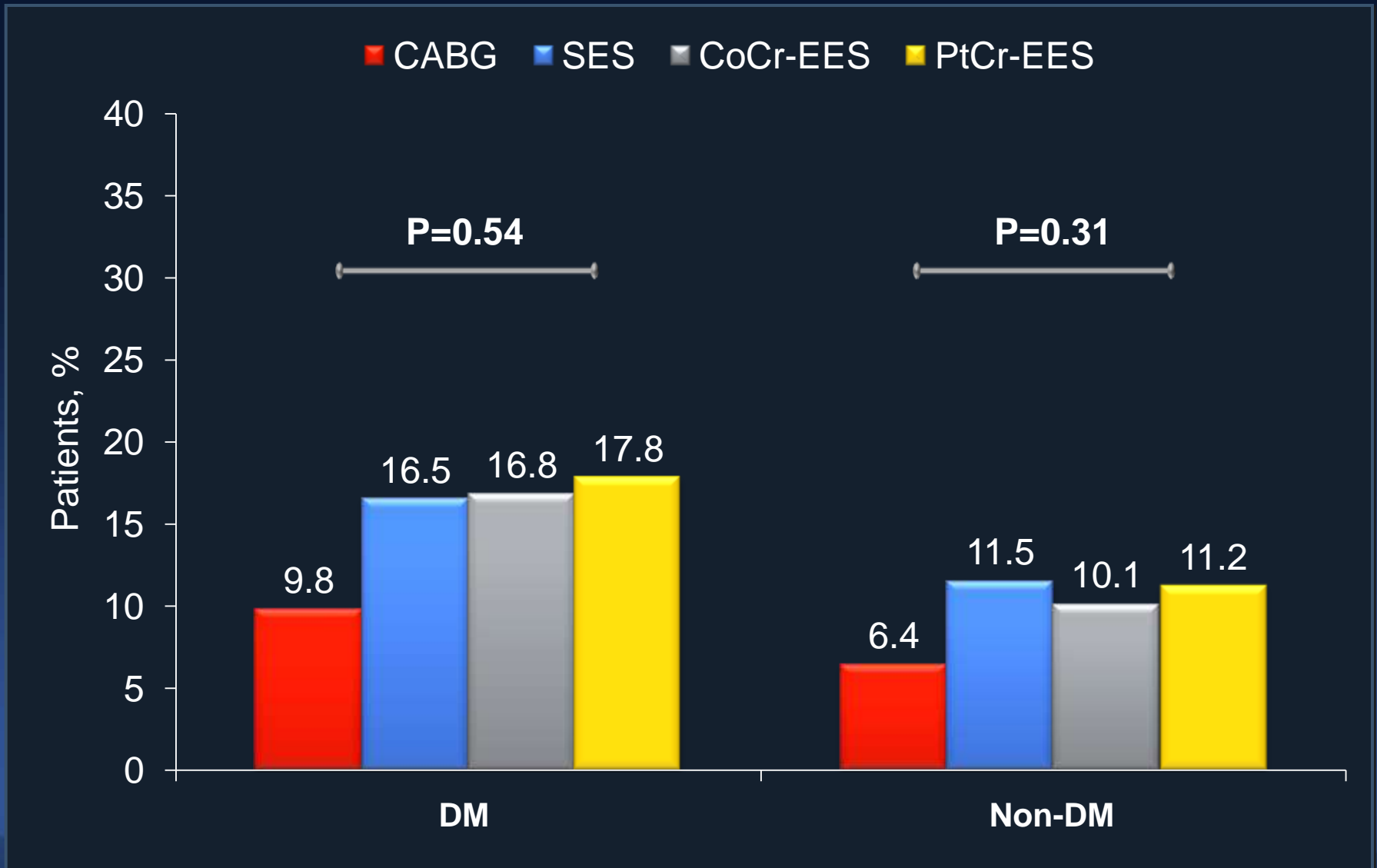
2-Y MACCE in SYNTAX Subgroup



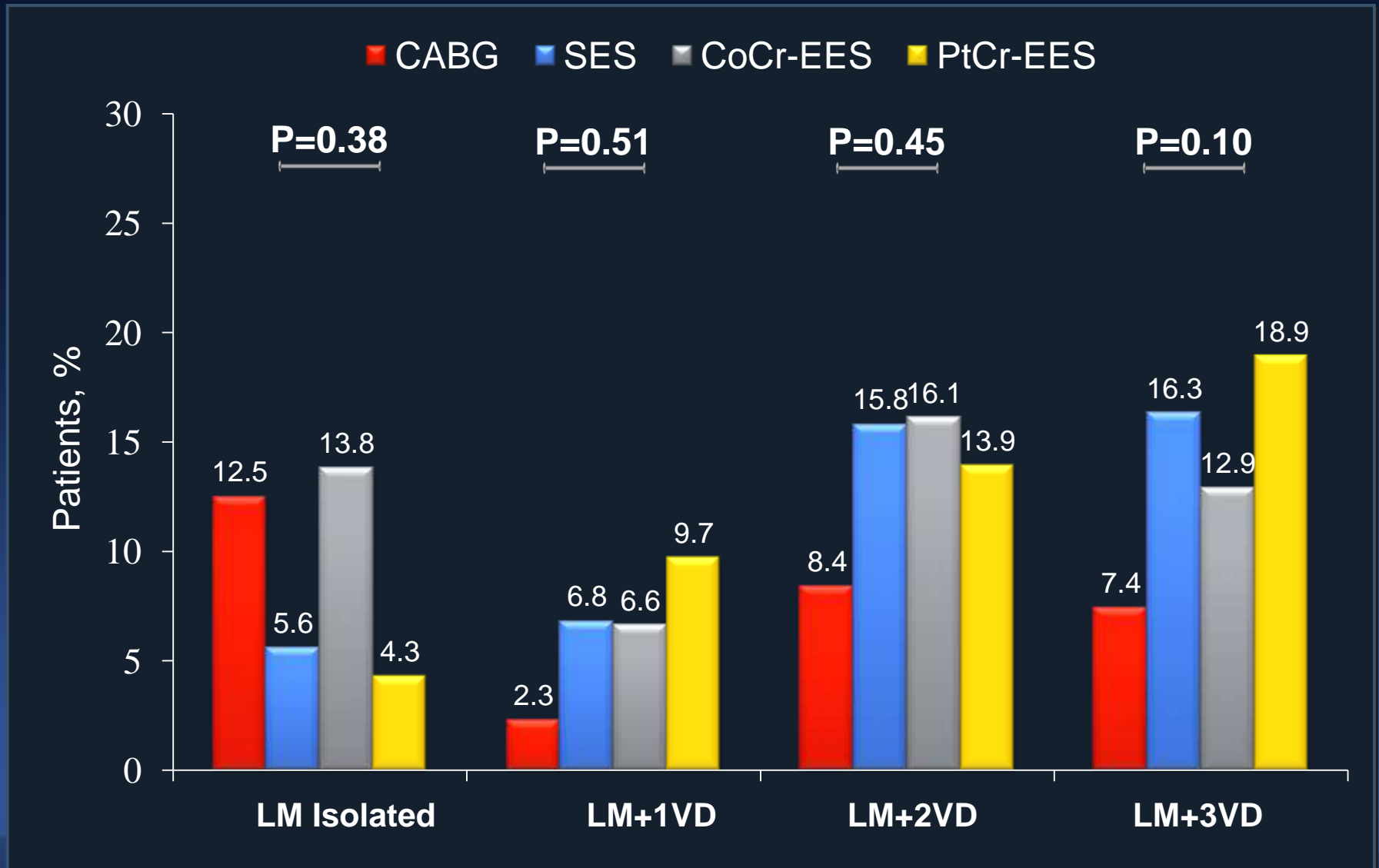
2-Y MACCE in Bifurcation



2-Y MACCE in DM



2-Y MACCE in LM Subgroups



Conclusions

- The PRECOMBAT-3 trial demonstrated PCI for ULMCA stenosis using PtCr-EES was safe and effective compared with previous version of DES including SES or CoCr-EES.
- However, the adoption of more flexible stent design was associated with the higher rate of stent deformation.
- In addition, compared with the historical control of CABG group in PRECOMBAT-1 trial, PtCr-EES stenting was associated with the similar rate of the death, MI, or stroke but the higher rate of the repeated revascularization at 2 year follow-up.