Percutaneous Intervention for Unprotected Left Main Stenosis (LM PCI) in the Era of DES

Pre-COMBAT and COMBAT

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Asan Medical Center, *Seoul, Korea*

Issues …
in Unprotected LM PCI

- LM PCI in the era of BMS
- PCI vs CABG (BMS)
- LM PCI in the era of DES
- DES vs BMS
- Cypher vs TAXUS
- PCI vs CABG (DES)

Issues …
in Unprotected LM PCI

- **LM PCI in the era of BMS**

High Mortality in PCI ?

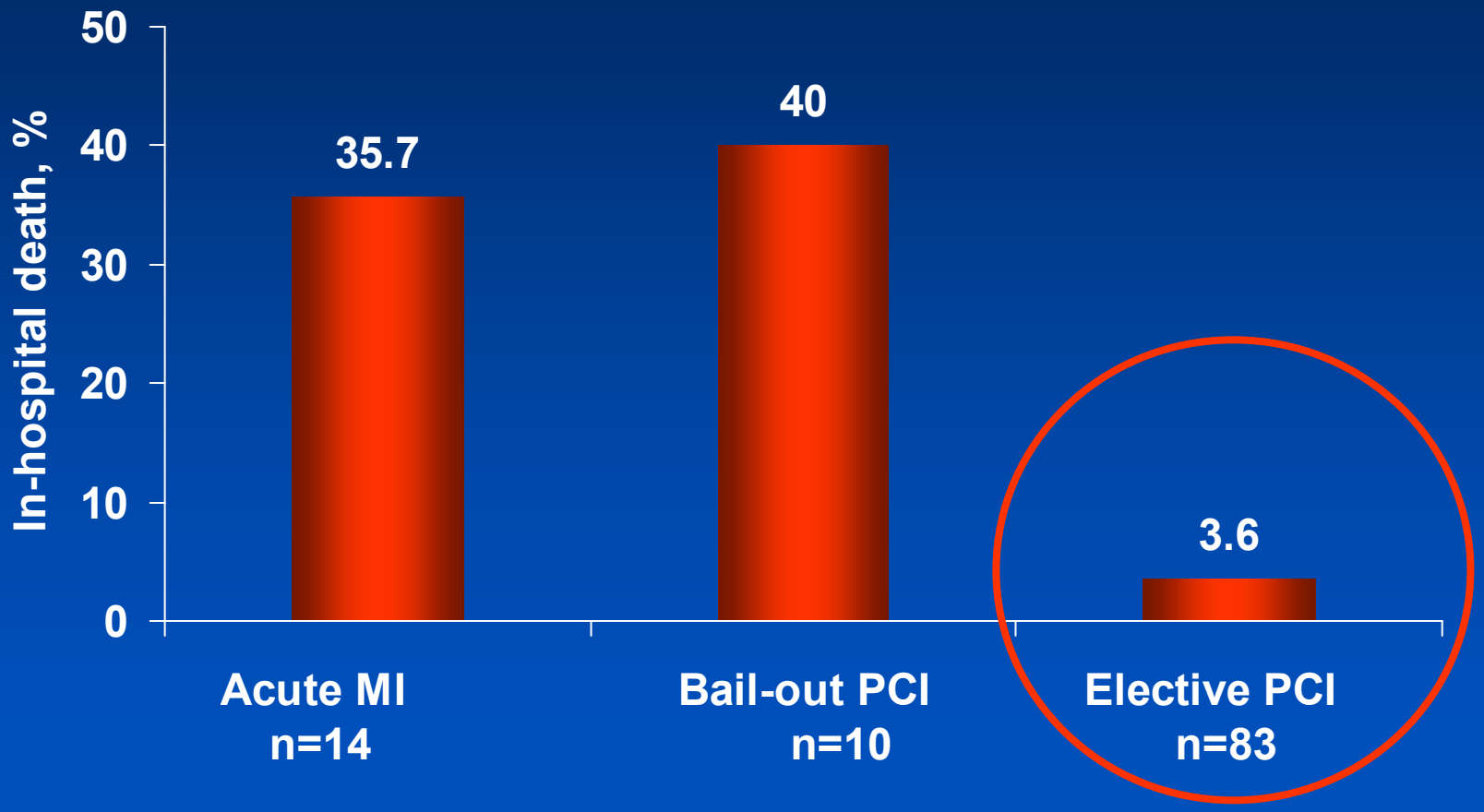
Procedural Success **(BMS)** in Left Main PCI Series

Study	Site(s)	Years	Pts #	Procedure success
Park et al, 1998	Asan Medical Center & WHC	1995-1997	42	100%
Silvestri et al	Marcielle, France	1993-1998	140	100%
Park et al				98.9%
Brueren et al	Nieuwegein, Netherlands	2001	71	94.4%
Takagi et al	Columbus Hospital and San Raffaele Hospital, Milan	1993-2001	67	91%
Ellis et al	16 hospitals (ULTIMA Registry)	1994-1996	107	98%

More than 1,300 patients were included

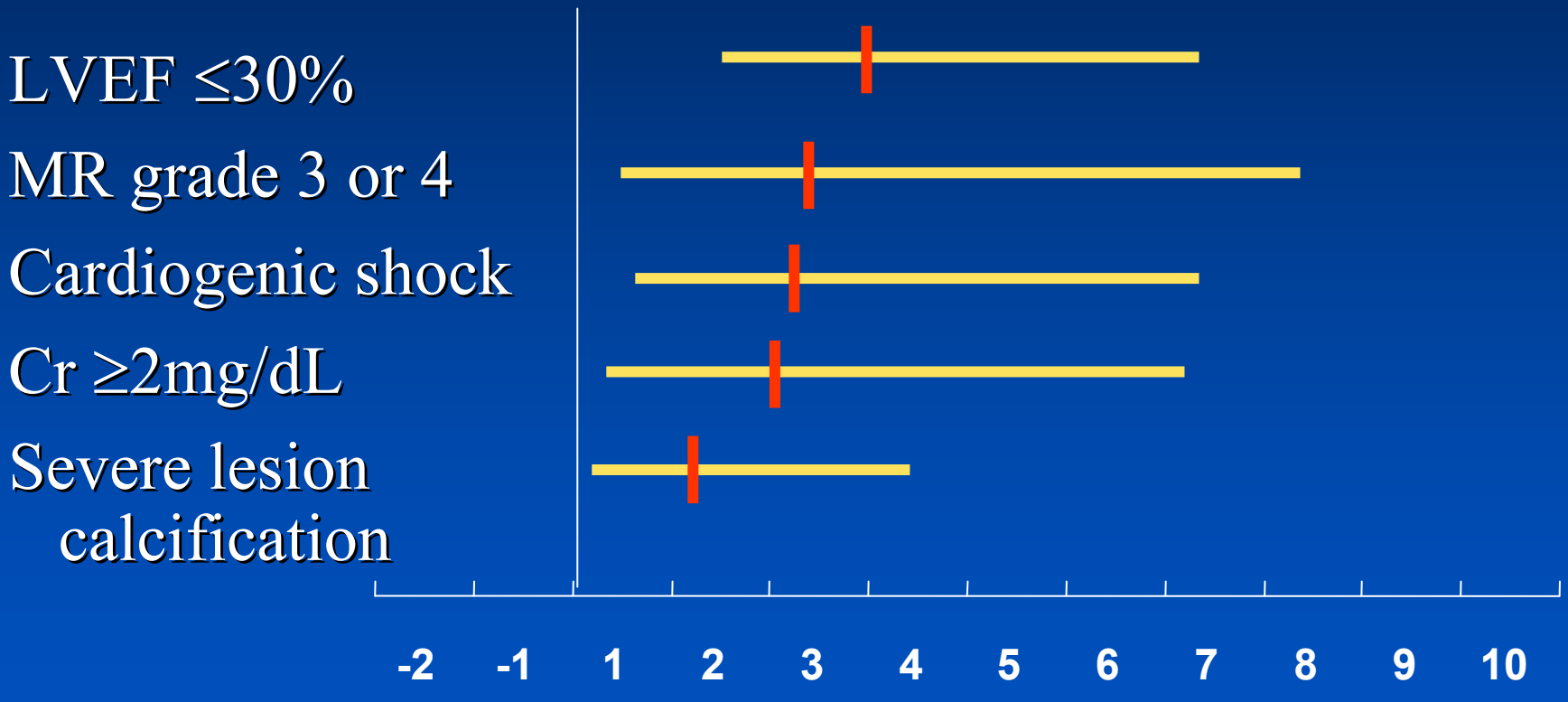
In-Hospital Mortality

In High-Risk vs. Low-Risk Patients



Kosuga et al, AJC, 1999

Multivariate Predictors of All-Cause Mortality: ULTIMA Registry



Tan et al, Circulation, 2001

Multivariate Predictors of All-Cause MI /Death : AMC data

324 patients who underwent elective coronary stenting for the treatment of unprotected LMCA

	Hazard ratio	95% CI	P value
High EuroSCORE (≥6)	3.362	1.181 – 9.574	0.023
No. of total used stents	1.792	1.021 – 3.146	0.042
Use of GP IIb/IIIa inhibitor	8.640	2.722 – 27.418	<0.001

Unpublished AMC data, 2006

Lessons from data of PCI on unprotected LM (BMS)

- In the reviewed series, outcomes of PCI are highly correlated with pre-procedure clinical risk profile of the patient (low mortality in low risk patients)
- Good candidate for surgery is good candidate for PCI

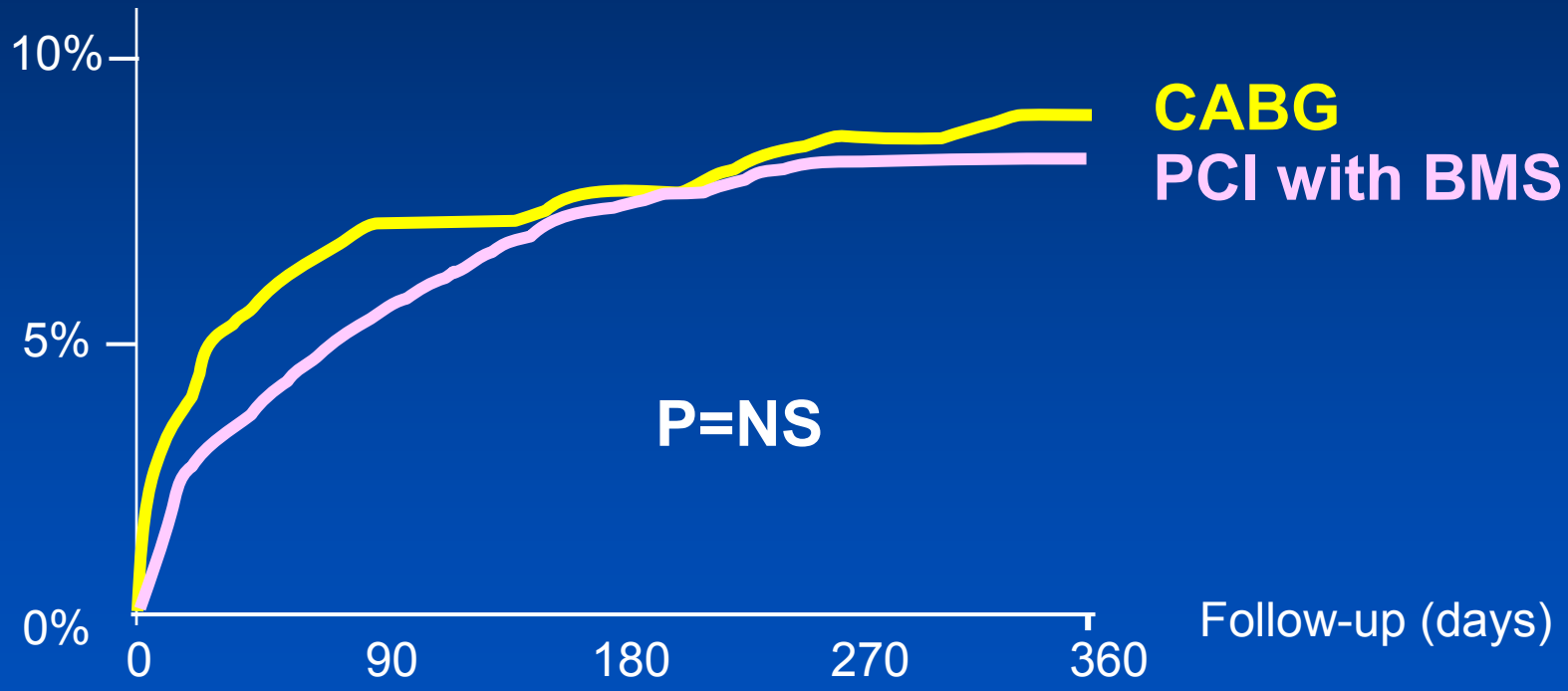
Issues …
in Unprotected LM PCI

- LM PCI in the era of BMS
- PCI vs CABG (BMS)

No data

Death, MI, Stroke in Multivessel Disease

Meta-analysis (ARTS, SoS, ERACI-2, MASS-2) between CABG vs. BMS

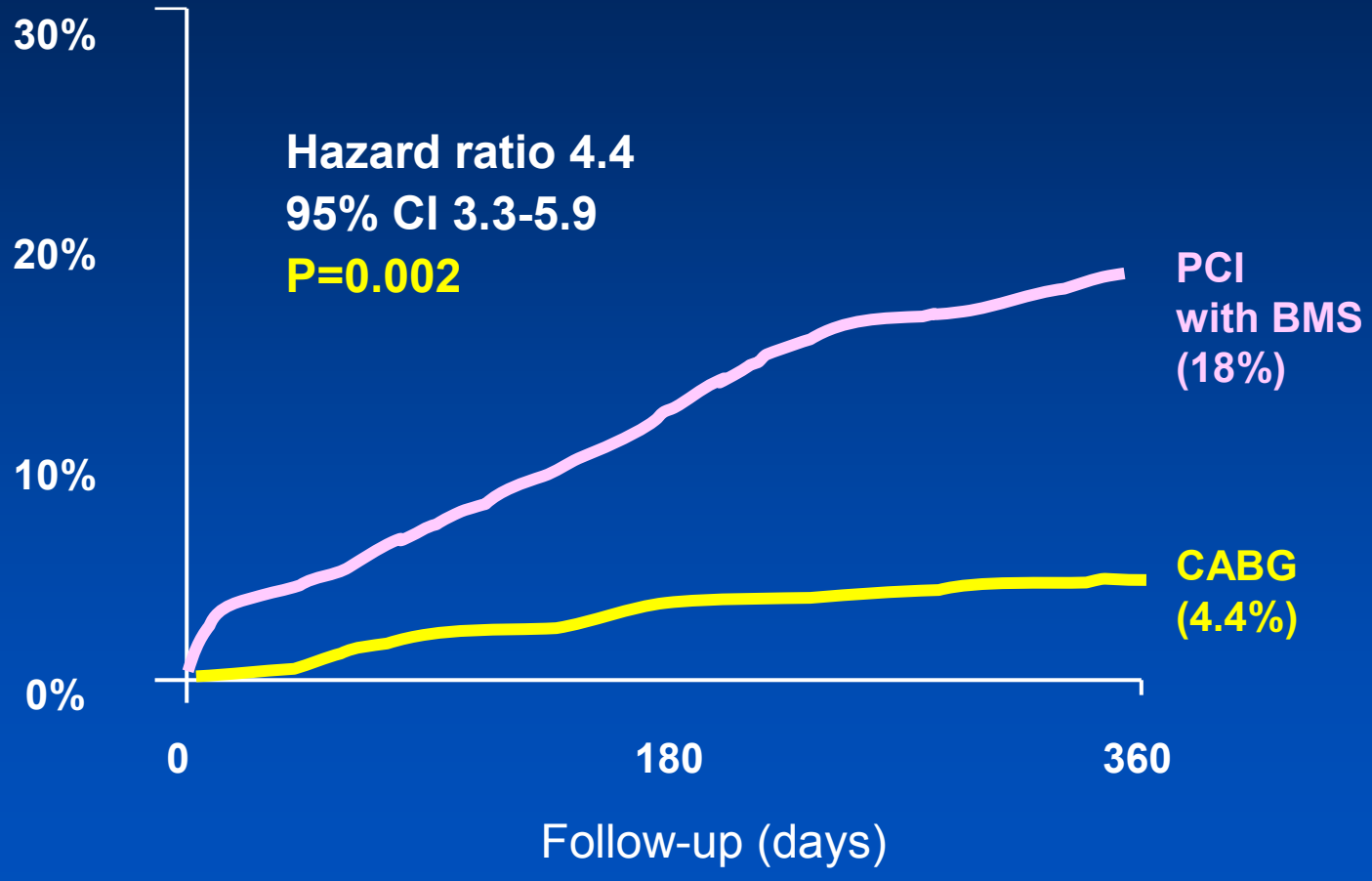


BMS=Bare metal stent

Mercado et al, J thoracic Cardiovasc Surg, 2005;130:512

Revascularization in Multivessel Disease

Meta-analysis of CABG vs. BMS



Mercado et al, J thoracic Cardiovasc Surg, 2005;130:512

Efficacy concerns of PCI (BMS) for LM disease
Compare to surgery

- PCI have comparable clinical outcomes at least one year follow-up period. There is no difference in rates of death, MI or stroke.
- Repeat revascularization is the only problem in PCI

Issues …
in Unprotected LM PCI

- LM PCI in the era of BMS
- PCI vs CABG (BMS)
- **LM PCI in the era of DES**

Limited data

In-Hospital Outcomes:
DES in Left Main PCI Series

Series	Procedure success	Death
Park et al	100%	0
Chieffo et al	100%	0
Valgimigli et al		1.0%
Gershlick et al		0
Lefevre et al*	96.9%	0.8%
Costa et al*	100%	0
Nakamura et al*	100%	0
Di Salvo et al*	98.7%	0

More than 1,000 patients were included

* Abstracts

Ostial and shaft LMCA PCI with DES
(Colombo, Serruys, Park)

	N= 144
Age, years	62.6 ±12.3
Gender, n (%)	53 (36.8)
Hypertension, n (%)	81 (56.2)
Hypercholesterolemia, n (%)	70 (48.6)
Smoking, n (%)	43 (29.8)
Diabetes Mellitus, n (%)	28 (19.4)
Unstable angina, n (%)	65 (45.1)
LVEF, %	55.2± 11.3
Euroscore>6, n (%)	57 (39.6)
Parsonnet>13 , n (%)	29 (20.1)
RCA disease, n (%)	52 (36.1)
RCA concomitant treatment, n	22

Unpublished Registry data

Ostial and shaft LMCA PCI with DES
(Colombo, Serruys, Park)

	N= 144
Ostial, n (%)	75 (52)
Shaft, n (%)	41 (29)
Ostial and shaft, n (%)	28 (19)
Number of vessel treated	1.33±0.9
Number of lesions treated	1.86±1.5
IABP, n (%)	5 (3.5)
GP IIb/IIIa inhibitors usage, n (%)	18 (12.5)
IVUS guidance, n (%)	73 (50.7)
Predilatation, n (%)	57 (39.6)
Cypher stent implantation, n (%)	105 (72.9)
Taxus stent implantation, n (%)	39 (27.1)
Stent length, mm	14.5±7.4
Max balloon diameter, mm	3.7±0.9
Max pressure inflation, atm	17.0± 4.9

Unpublished Registry data

Ostial and shaft LMCA PCI with DES

(Colombo, Serruys, Park)

	In Hospital	1 year F/U
Death, n (%)	0	1
MI, n (%)	0	0
TLR, n (%)	1 (0.7)	1 (0.7)
TVR, n (%)	1 (0.7)	2 (1.4)
MACE, n (%)	1 (0.7)	3 (2.0)

Unpublished Registry data

LM PCI with DES for Ostial and Shaft LMCA Stenosis ?

Very promising…

What about DES for Bifurcation LMCA Stenosis ?

More challenging issue

Different treatment strategy for LM bifurcation lesion

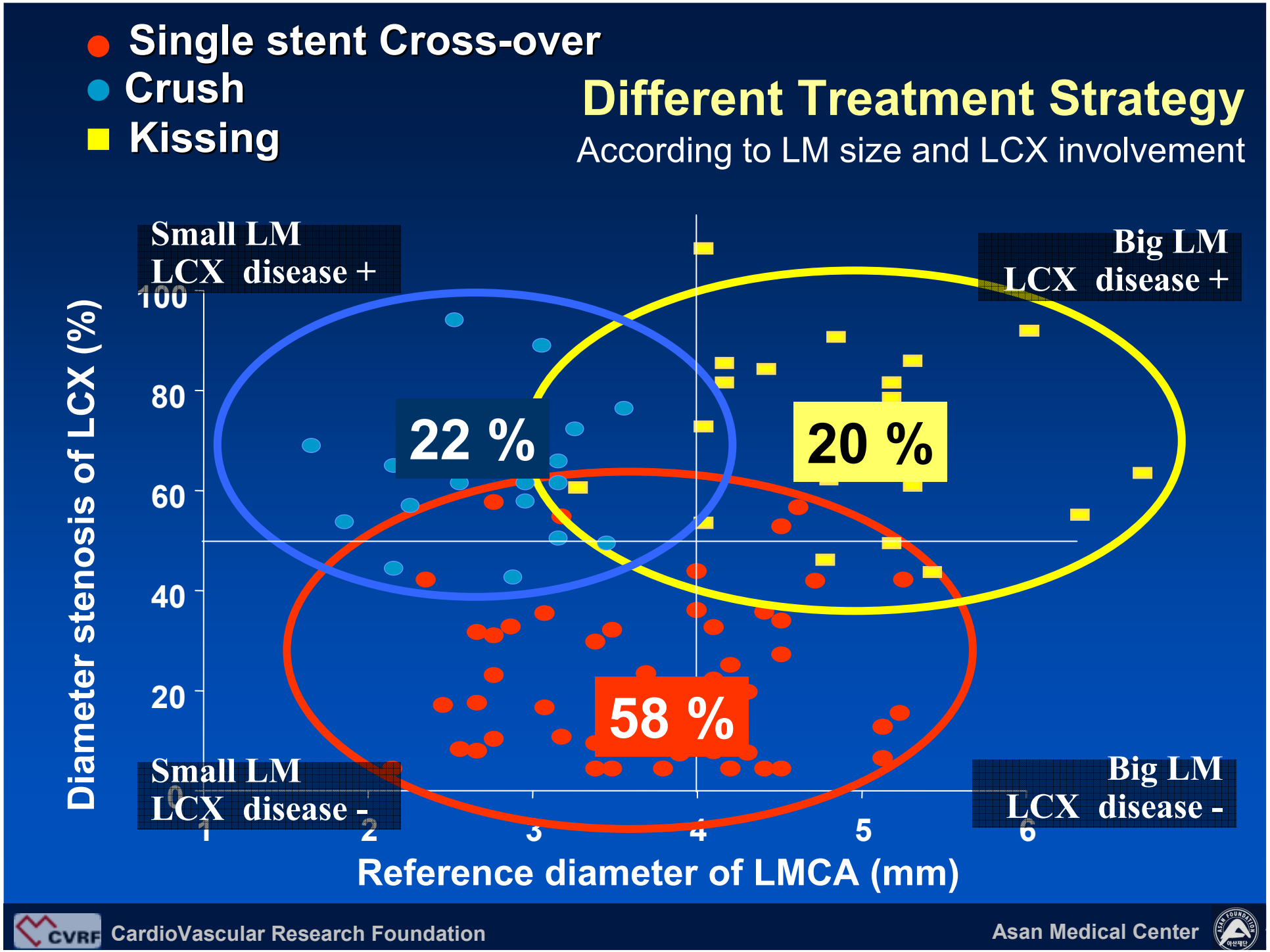
	Colombo A	Serruys PW	Park SJ
Distal location	69 (81.2%)	65%	72 (70.6%)
Bifurcation stenting	51 (74%)	40%	29 (41%)
Culotte	5 (10%)	36%	0
T technique	4 (8%)	44%	1 (3%)
Crush	30 (59%)	12%	11 (38%)
Kissing	12 (24%)	8%	17 (59%)
TLR	12 (14.1%)	6 (6%)	2 (2.0%)

Makes diverse TLR rates

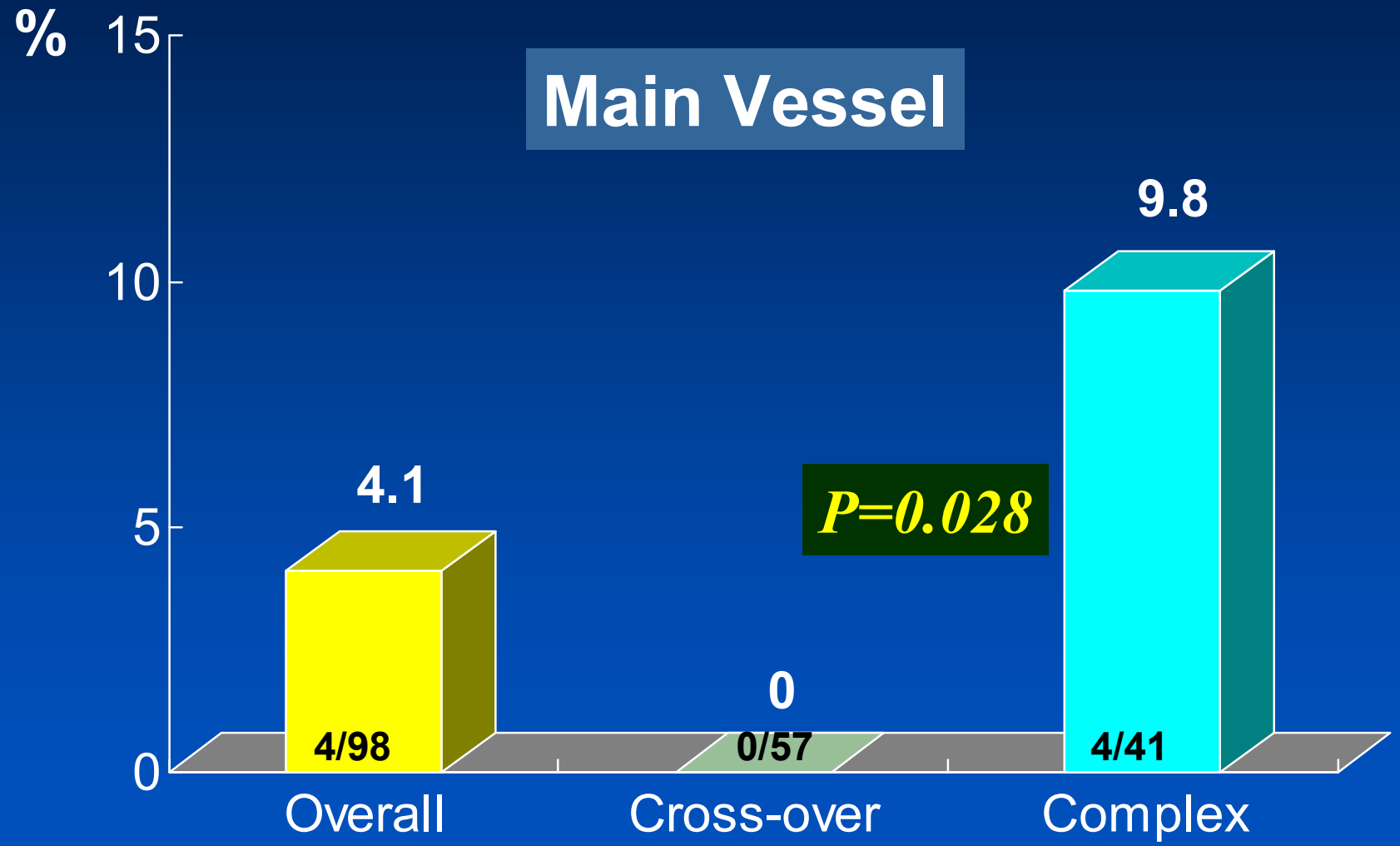
Recommended Treatment Strategy for LMCA bifurcation lesions

Stenting Cross-over
(provisional T stenting)

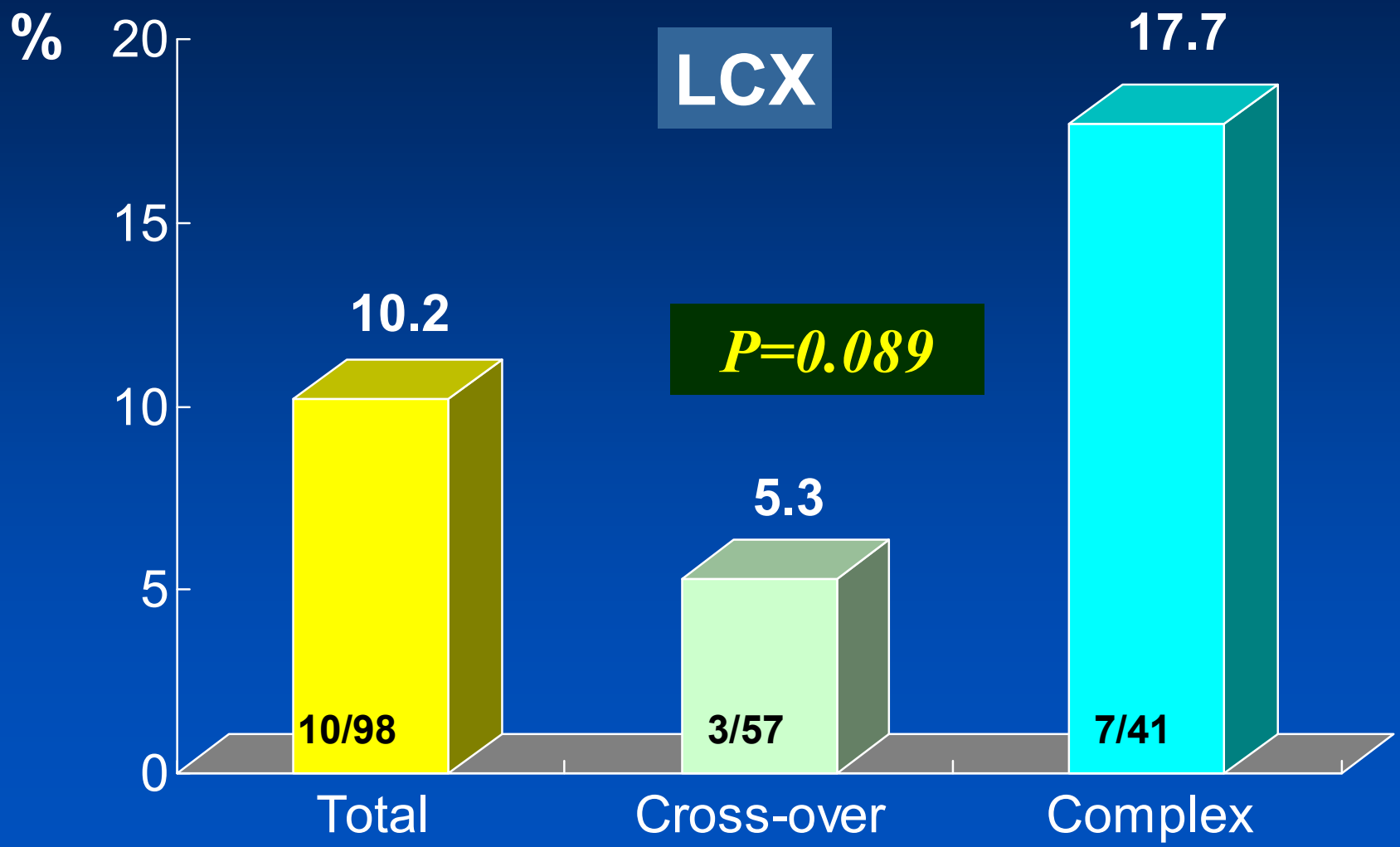
Kissing Stenting
Stent Crushing


Single stent Cross-over
Crush
Kissing
Different Treatment Strategy
According to LM size and LCX involvement
Small LM
LCX disease +
Big LM
LCX disease +
22 %
20 %
58 %
Small LM
LCX disease -
Big LM
LCX disease -
Diameter stenosis of LCX (%)
100
80
60
40
20
0
1
2
3
4
5
6
Reference diameter of LMCA (mm)

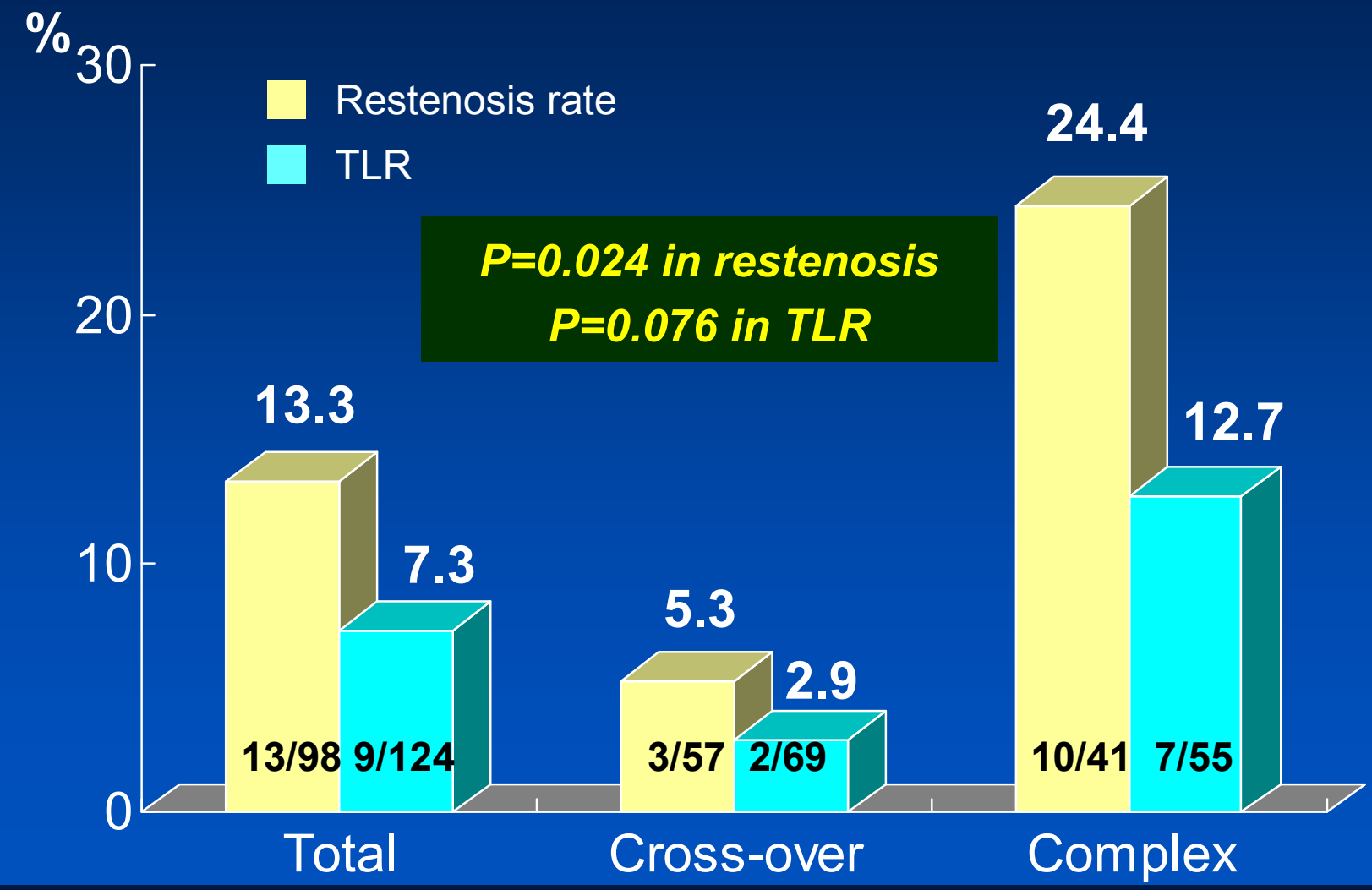
Restenosis Rate of 124 LM Bifurcation PCI



Restenosis Rate of 124 LM Bifurcation PCI



Restenosis Rates and TLR
Overall LM bifurcation PCI



Lessons from AMC data for LM Bifurcation PCI

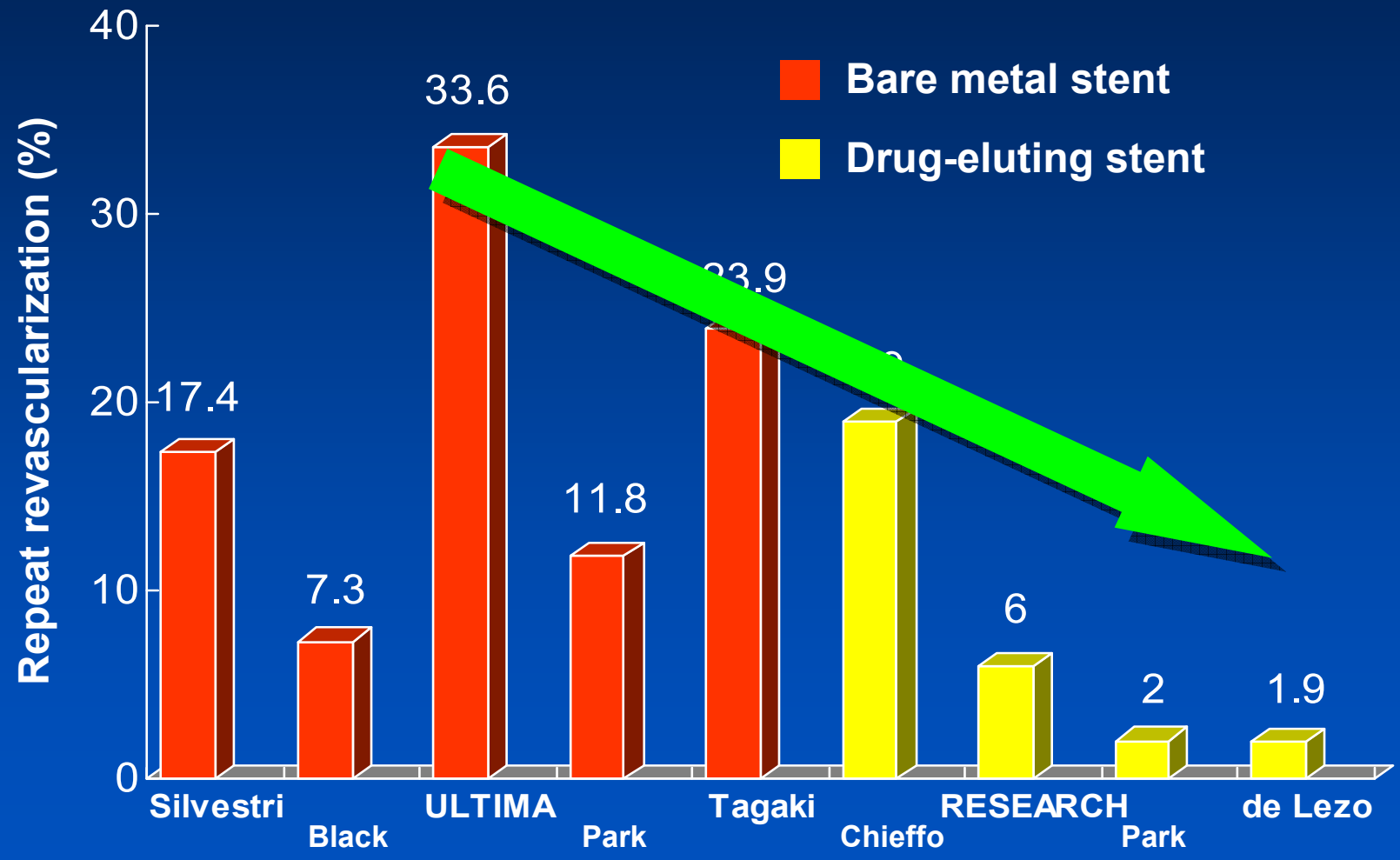
- Both the presence of ostial LCX disease (diameter stenosis ≥50%) and the LMCA size by angiographic and IVUS examinations were two important considerations in selecting the stenting strategy.

- Compared to the complex stenting approach, the simple approach (stenting cross-over) was technically easier and appeared to be more effective in improving long-term outcomes for lesions with normal or diminutive LCX.

Issues …
in Unprotected LM PCI

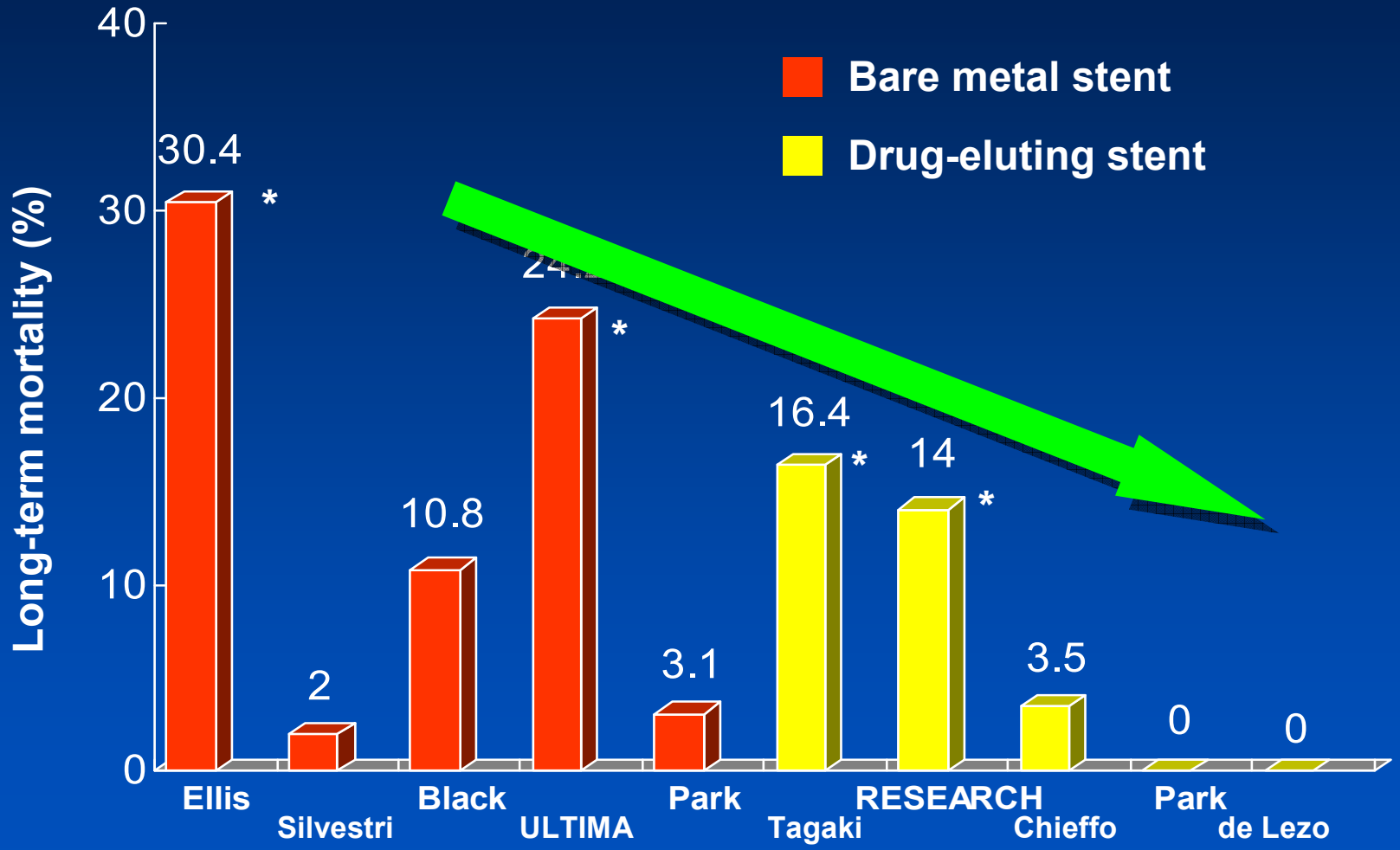
- LM PCI in the era of BMS
- PCI vs CABG (BMS)
- LM PCI in the era of DES
- **DES vs BMS**

Significant Reduction of TLR with DES
Unprotected Left main stenting



Long-term Mortality (after 6 Mo)

Acceptable in the patients at a low risk !



* High-risk surgical candidates

Current data suggested…

DES are safe in the treatment of LM stenosis, however, we have limited data about the long-term oucomes

Issues …
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- LM PCI in the era of DES
- DES vs BMS
- **Cypher vs TAXUS**

Cypher vs. TAXUS

for LMCA Stenosis

We do not have enough data to compare.
No randomized studies.

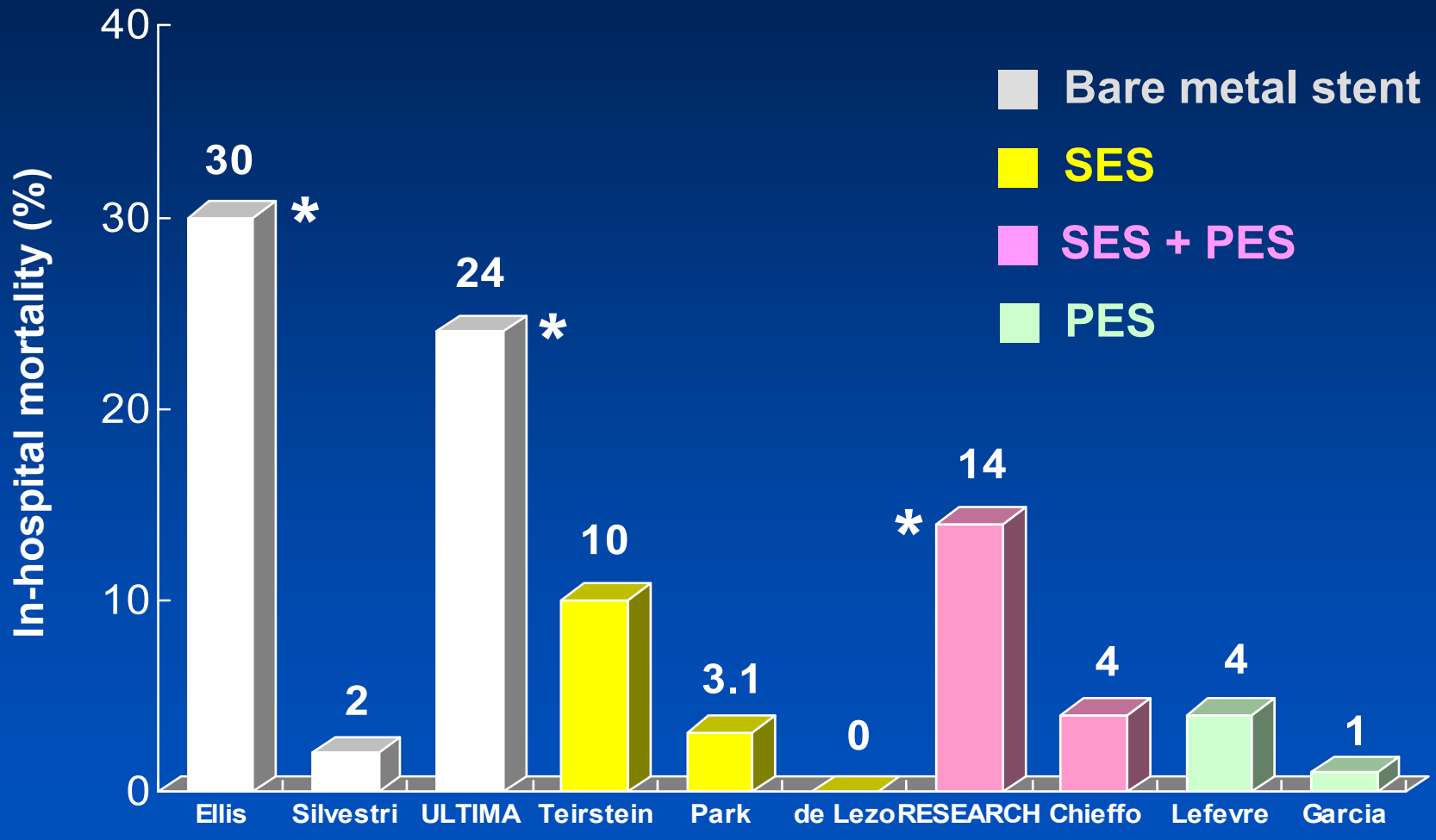
Cypher vs. TAXUS

for LMCA Stenosis

Safety concerns…

Long-term (6M-1Y) Mortality

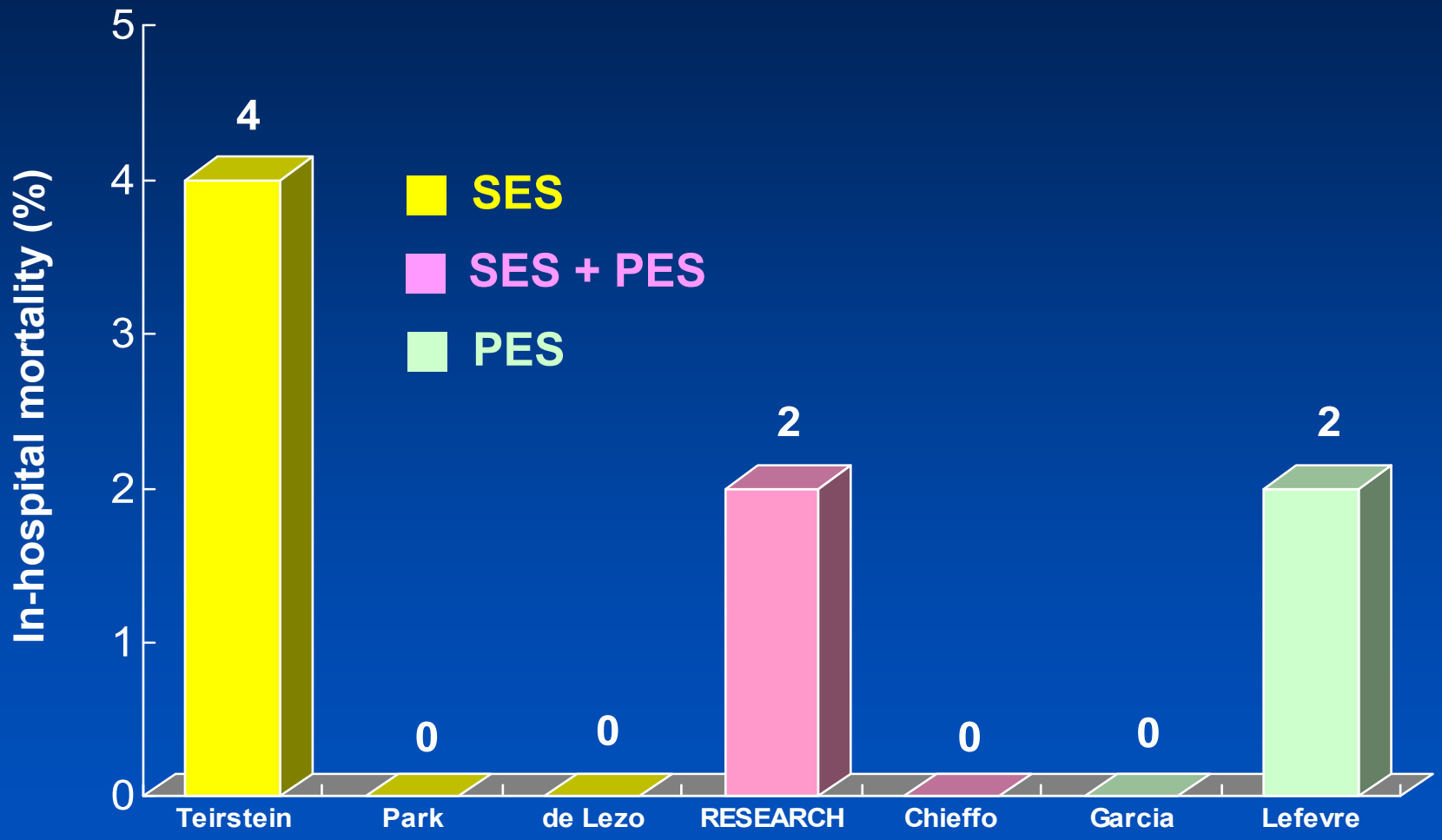
It is not associated with the stent type.



* High-risk surgical candidates

Stent Thrombosis

Acceptably Rare Incidence of Acute and Subacute Stent Thrombosis



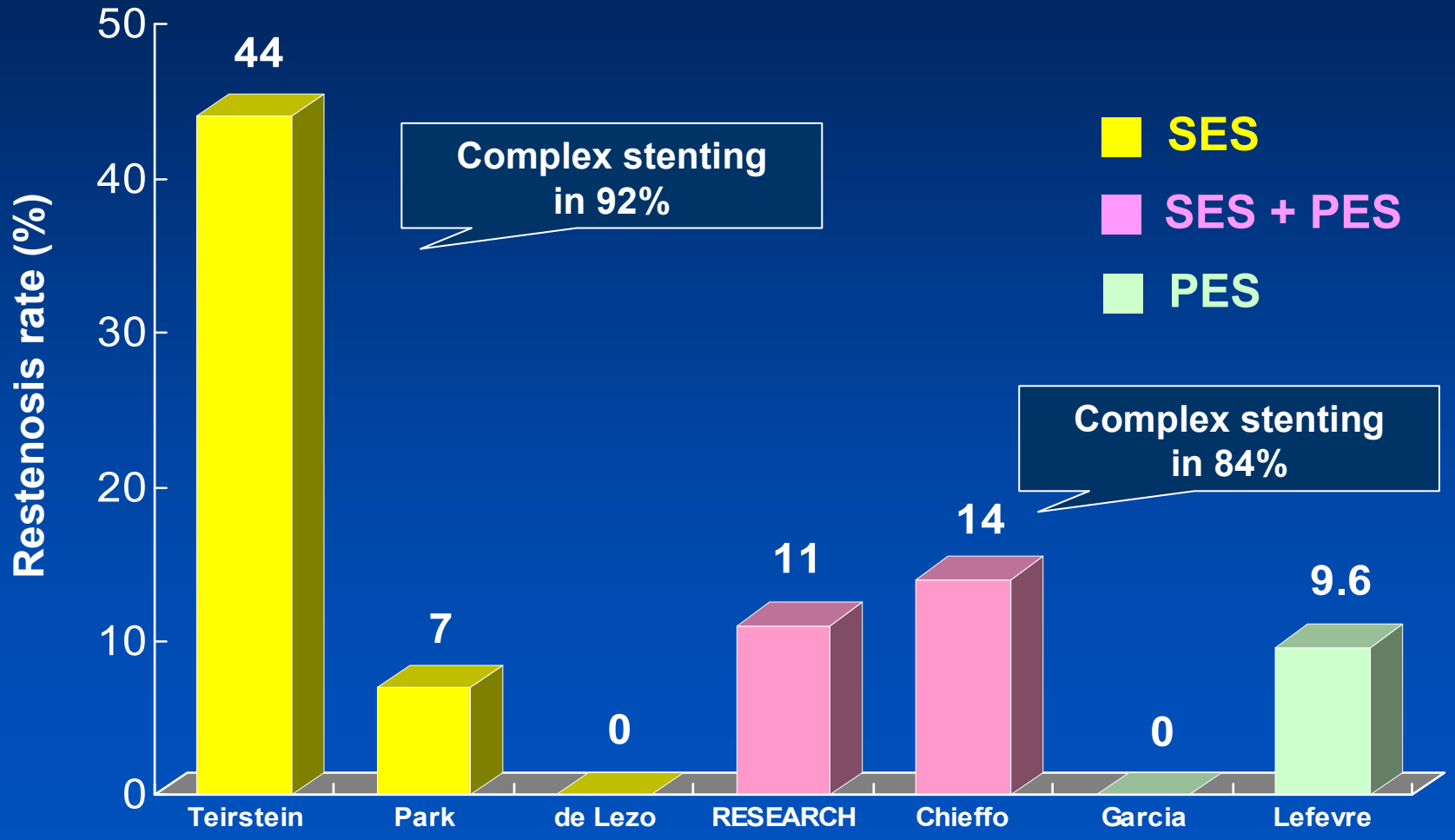
Cypher vs. TAXUS

for LMCA Stenosis

Efficacy concerns…

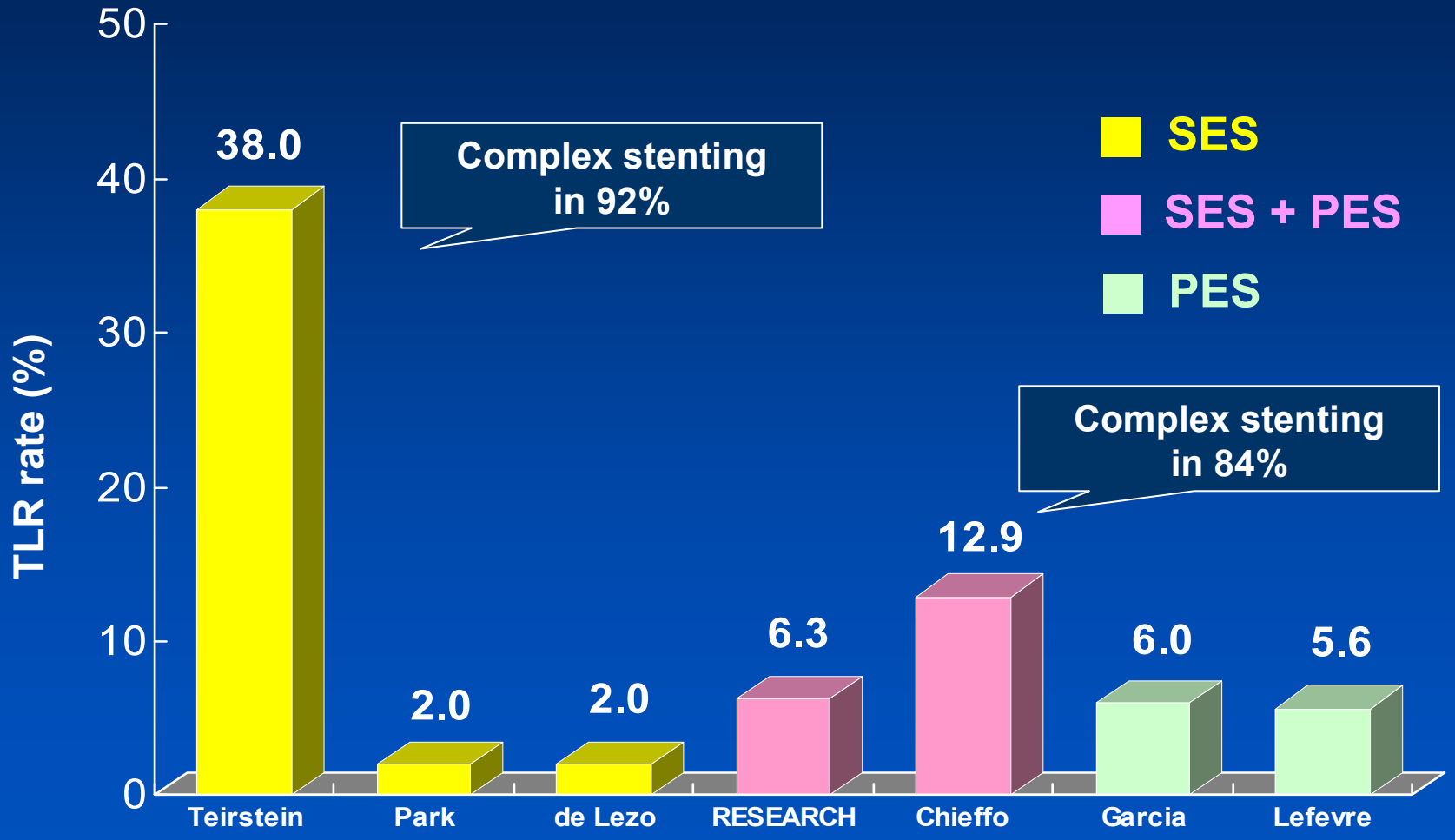
Restenosis Rate

Diverse lesion characteristics and stenting technique make it hard to compare.



TLR Rate

Proportion of bifurcation and stenting technique may be more strongly related with restenosis and TLR rate than the stent type.



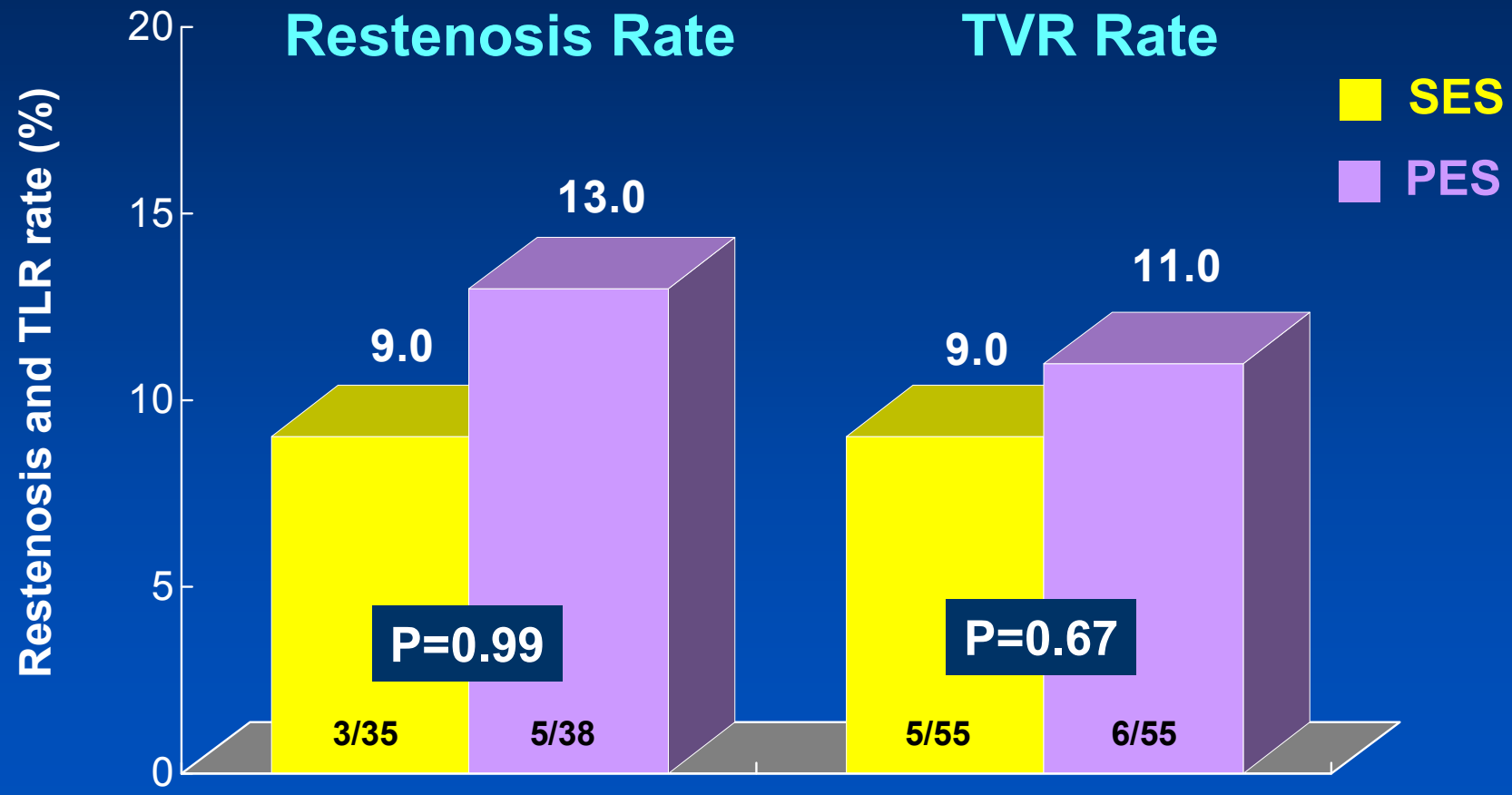
Angiographic Outcome
RESEARCH vs. T-SEARCH

	CYPHER (n=35)	TAXUS (n=38)	p
Reference (mm)	3.20 ± 0.57	3.20 ± 0.73	0.82
Lesion length (mm)	9.5 ± 3.3	10.0 ± 4.4	0.56
In-lesion MLD (mm)			
After procedure	2.47 ± 0.54	2.46 ± 0.58	0.61
At follow-up	2.44 ± 0.85	2.35 ± 0.60	0.60
In-stent late loss (mm)	0.32 ± 0.74	0.46 ± 0.57	0.36
In-segment late loss (mm)	0.22 ± 0.73	0.25 ± 0.46	0.86

Valgimigli M et al. J Am Coll Cardiol 2006;47:507

Restenosis and TVR Rates

RESEARCH vs. T-SEARCH



Valgimigli M et al. J Am Coll Cardiol 2006;47:507

Cypher vs. TAXUS
for LMCA Stenosis

Summary

- Although there was still diverse TLR rate, DES's (Cypher and Taxus) are safe and effective for the LM PCI.
- The efficacy of Cypher vs. Taxus seemed to be comparable.
- However, further large scaled randomized study should be done to clarify.

Issues …
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- PCI vs CABG (BMS)
- LM PCI in the era of DES
- DES vs BMS
- Cypher vs TAXUS
- **PCI vs CABG (DES)**

Compare to Surgery,

Efficacy concerns
of PCI with DES…

CABG vs. DES

Non-randomized comparison in USA

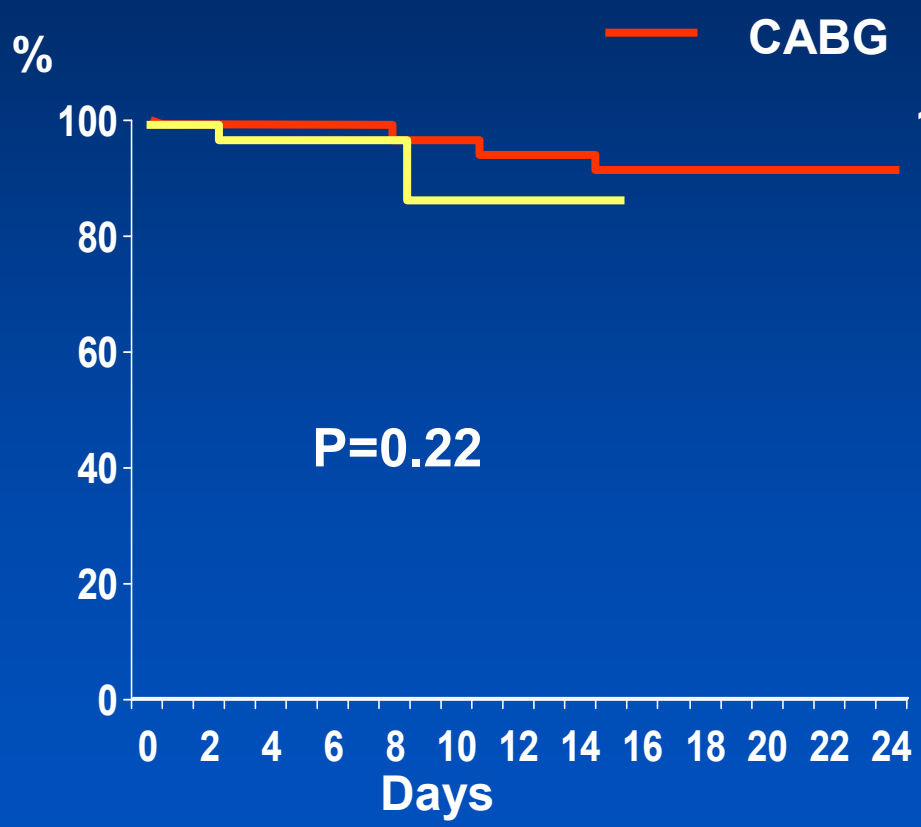
	CABG (n=123)	PCI (n=50)	P value
Age	70 ± 10	72 ± 15	0.33
Men (%)	76	50	<0.01
Hypercholesterolemia (%)	72	74	0.85
Previous stroke (%)	10	8	0.72
DM (%)	31	36	0.48
Cr ≥ 1.5mg/dL (%)	5	16	0.02
ACS (%)	45	66	0.02
Parsonnet score	13.7 ± 9.7	18.3 ± 10.9	<0.01
LV EF (%)	52 ± 10	51 ± 15	0.64

Lee et al, J Am Coll Cardiol, 2006

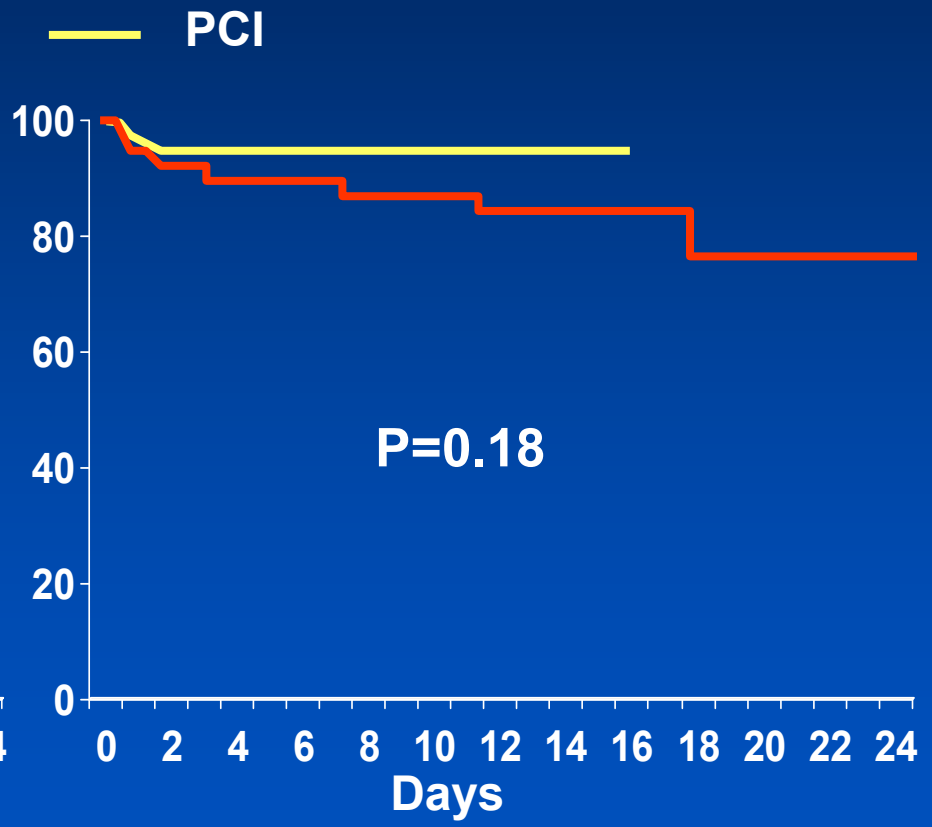
CABG vs. DES

Similar Intermediate-term Outcomes

Survival Curve



MI-free Survival Curve

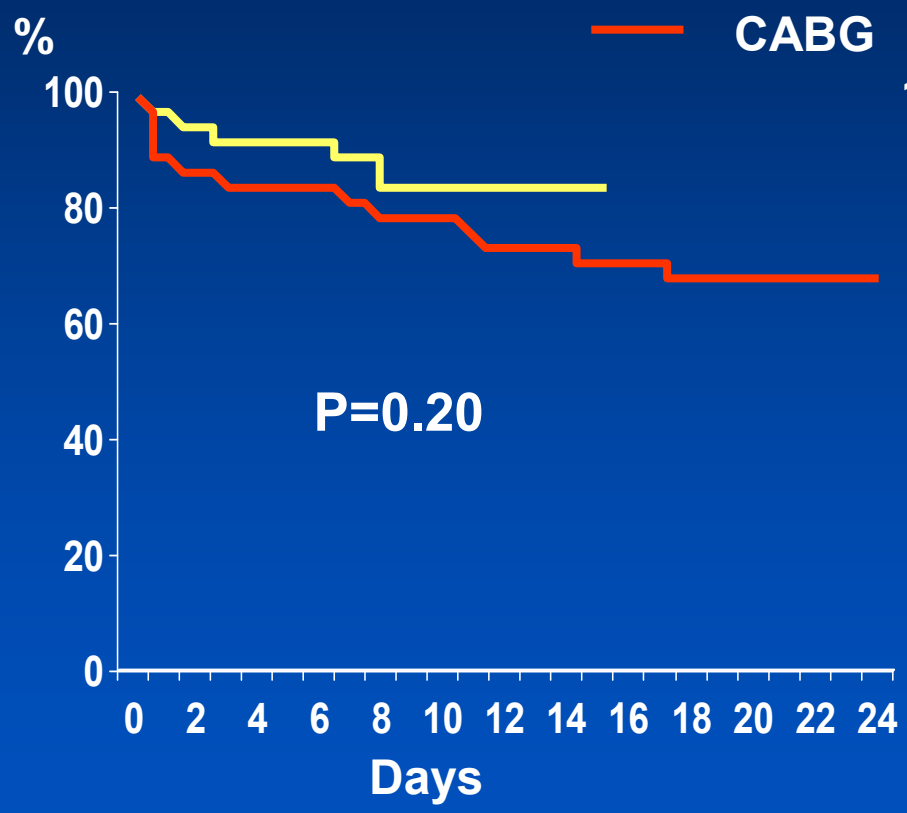


Lee et al, J Am Coll Cardiol, 2006

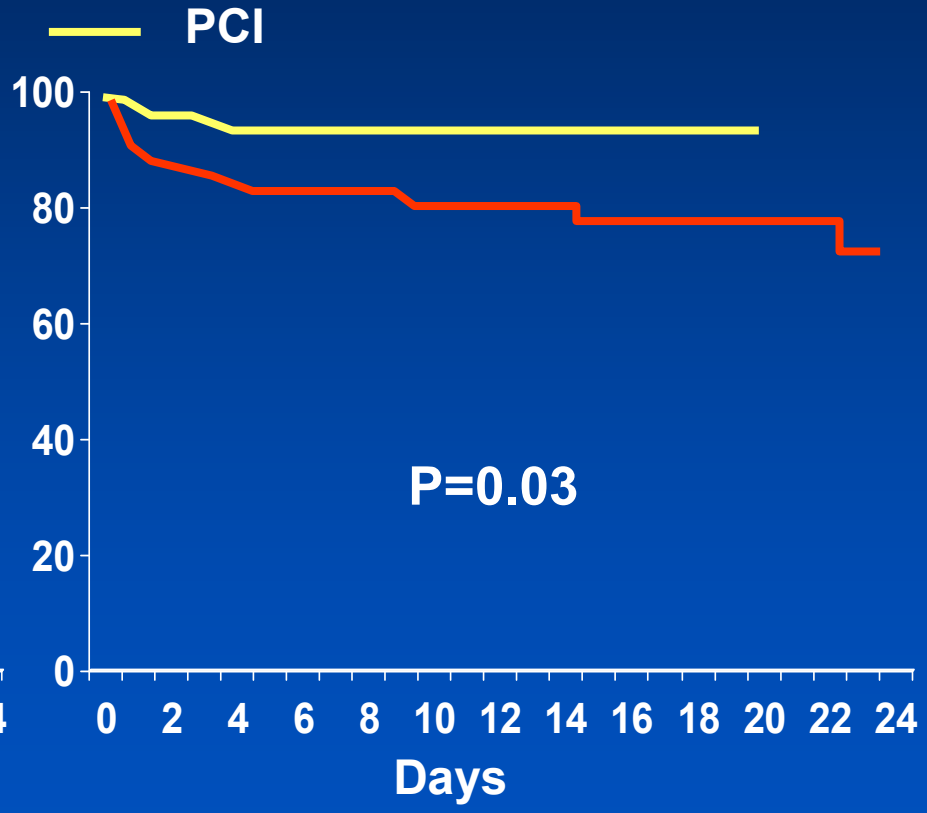
CABG vs. DES

Similar Intermediate-term Outcomes

TLR-Survival Curve



MACE-free Survival Curve



Lee et al, J Am Coll Cardiol, 2006

CABG vs. DES

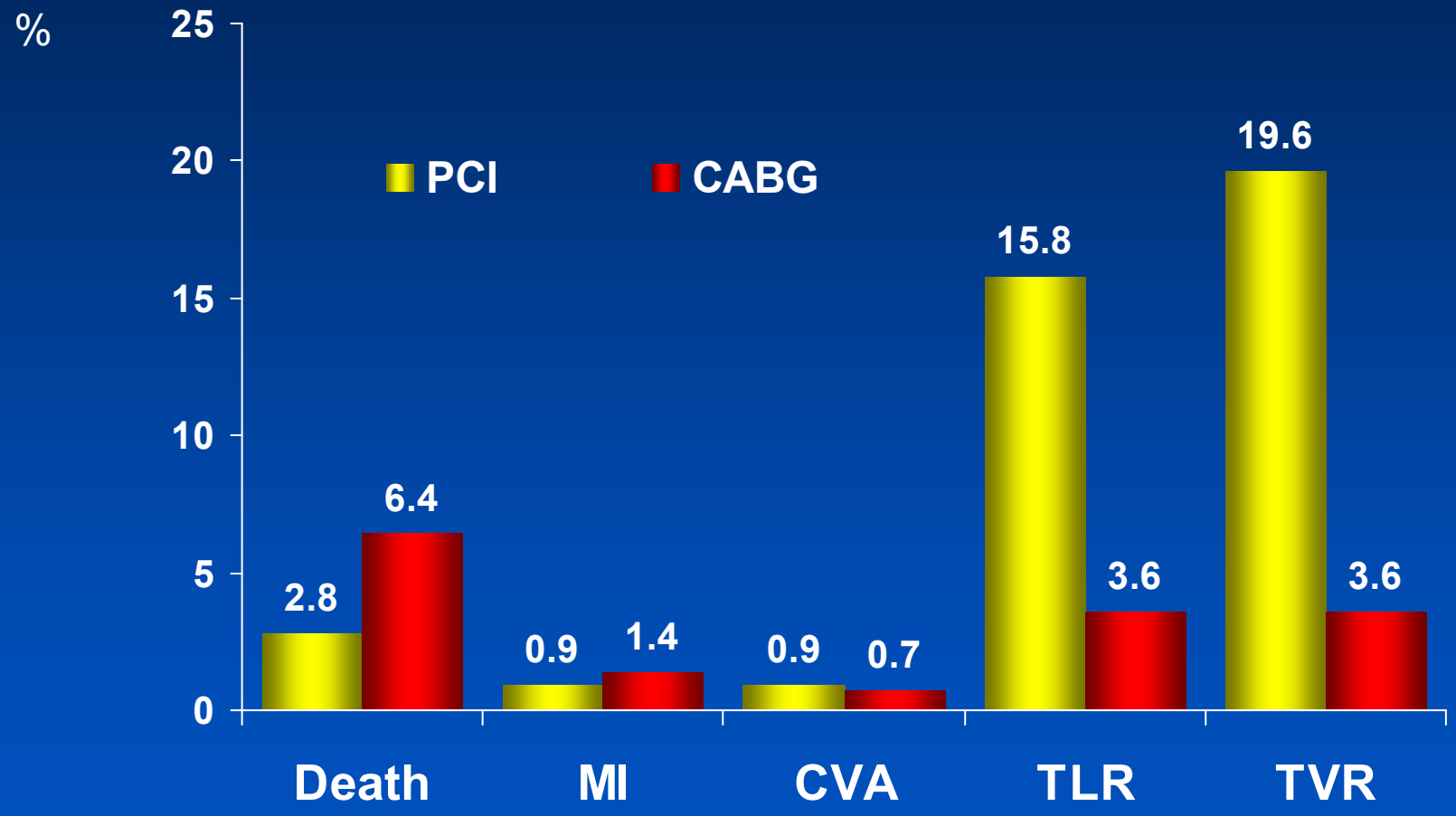
157 PCI (94 DES) and 154 CABG in Italy

	CABG (n=154)	PCI (n=157)	P value
Age (yrs)	69.3 ± 9.5	73.0 ± 10.9	0.002
Men (%)	76	70	0.296
Previous stroke (%)	10	8	0.72
DM (%)	25	26	0.976
Previous MI (%)	35	30	0.398
Stable angina (%)	28	27	0.917
Parsonnet score, median	12.5	16.5	0.004
EuroSCORE, median	5	6	0.032
LV EF ≤ 30% (%)	4	12	0.022
3 vessel disease (%)	46	25	<0.001

Palmerini et al, Am J Cardiol 2006

CABG vs. DES

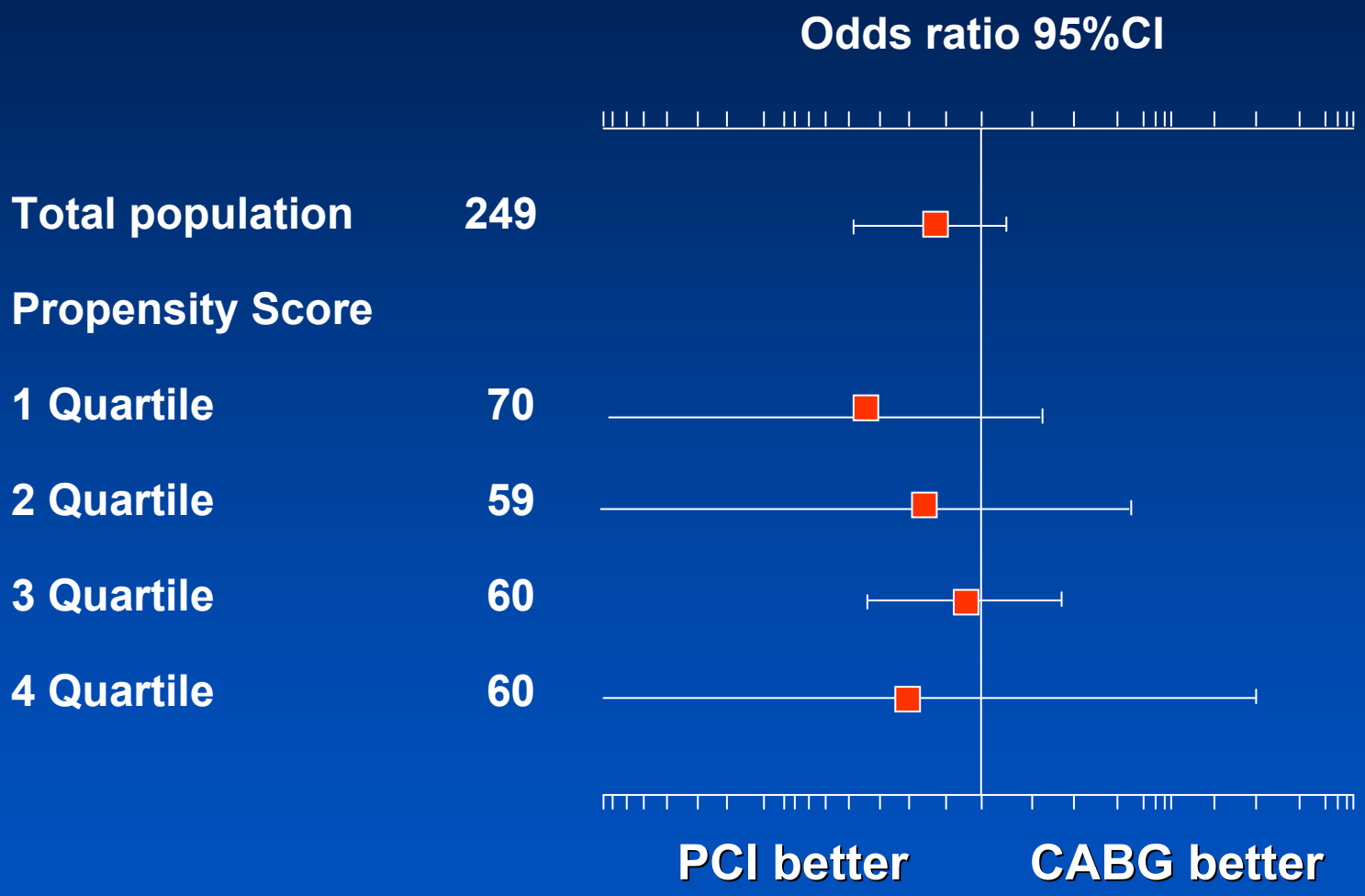
One-year Outcome for 107 DES and 142 CABG in Milan



Chieffo et al, Circulation, 2006

CABG vs. DES for MACCE

Propensity Analysis for 107 DES and 142 CABG in Milan

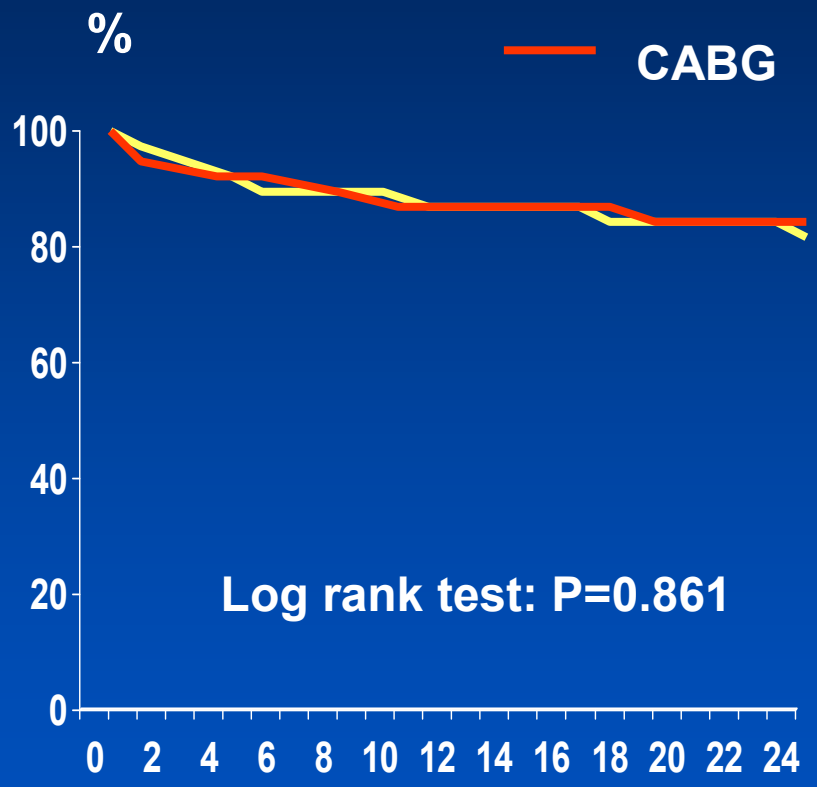


Chieffo et al, Circulation, 2006

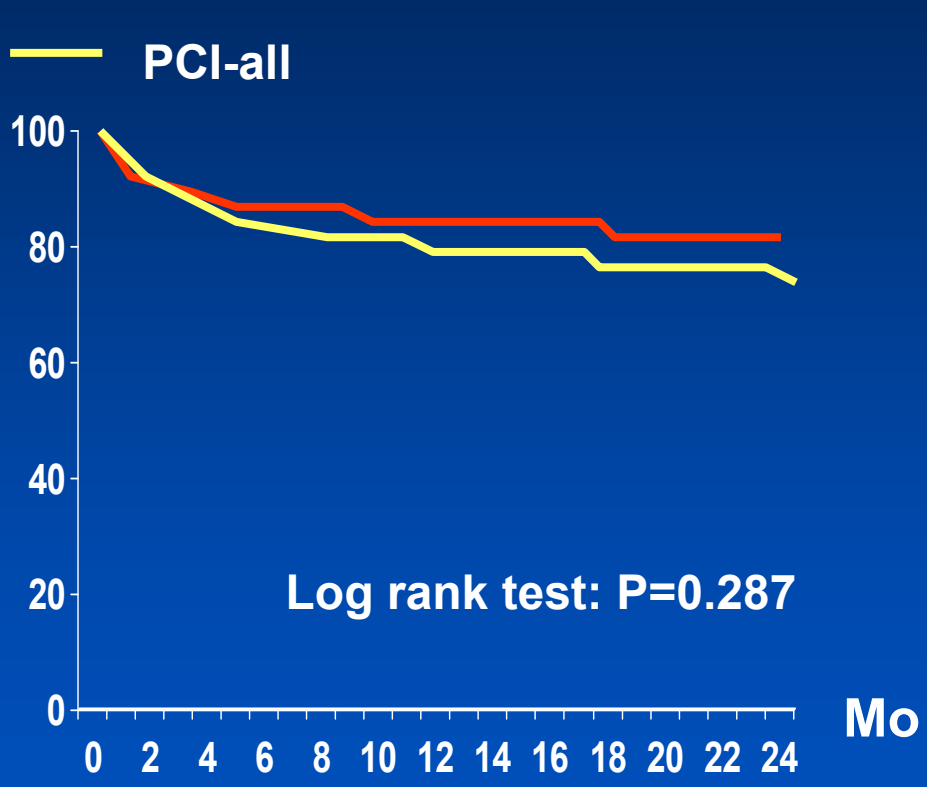
CABG vs. DES

157 PCI (94 DES) and 154 CABG in Italy

Survival



MI-free survival

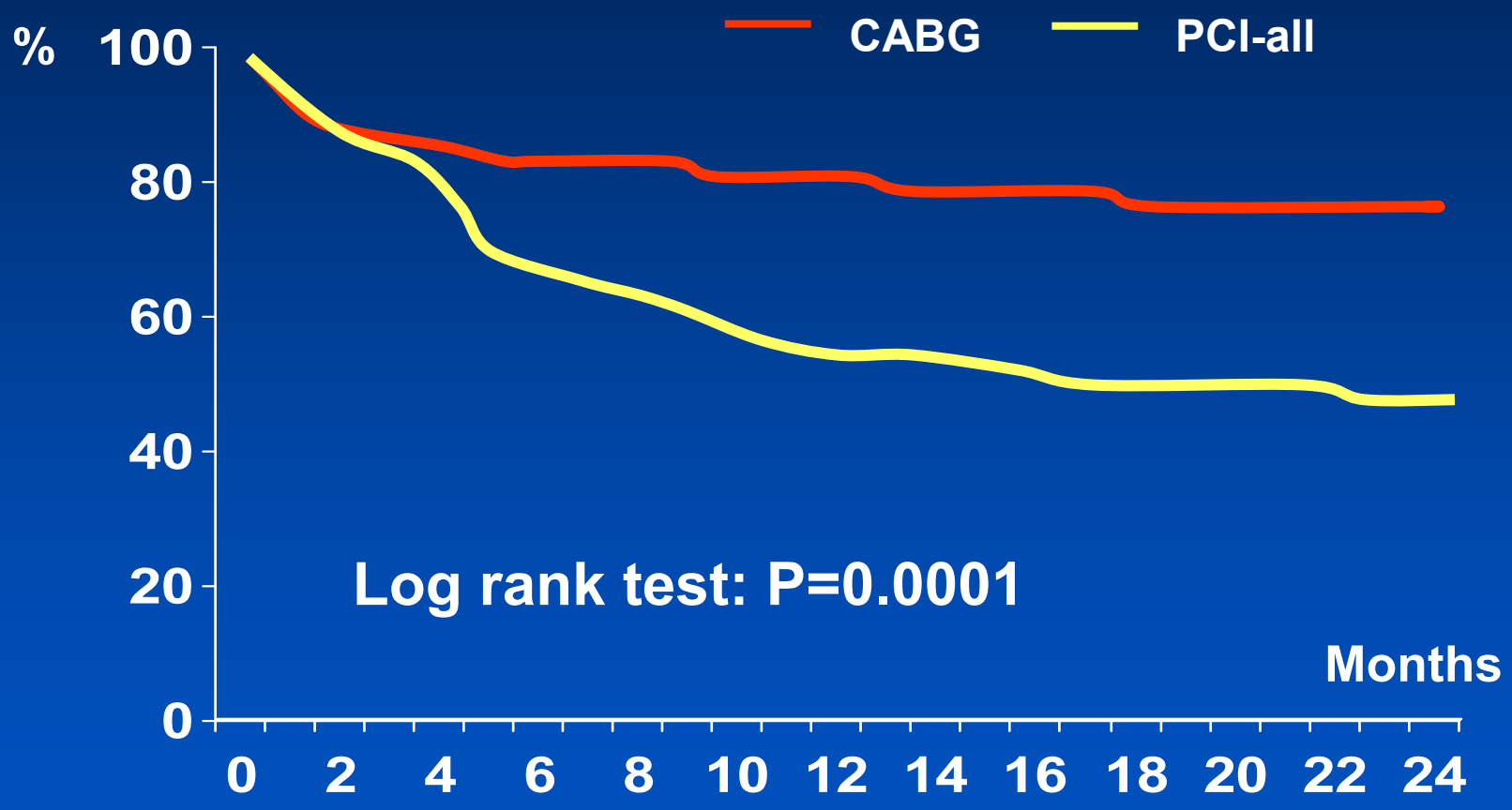


Palmerini et al, Am J Cardiol 2006

CABG vs. DES

157 PCI (94 DES) and 154 CABG in Italy

MACE-free Survival for All PCI

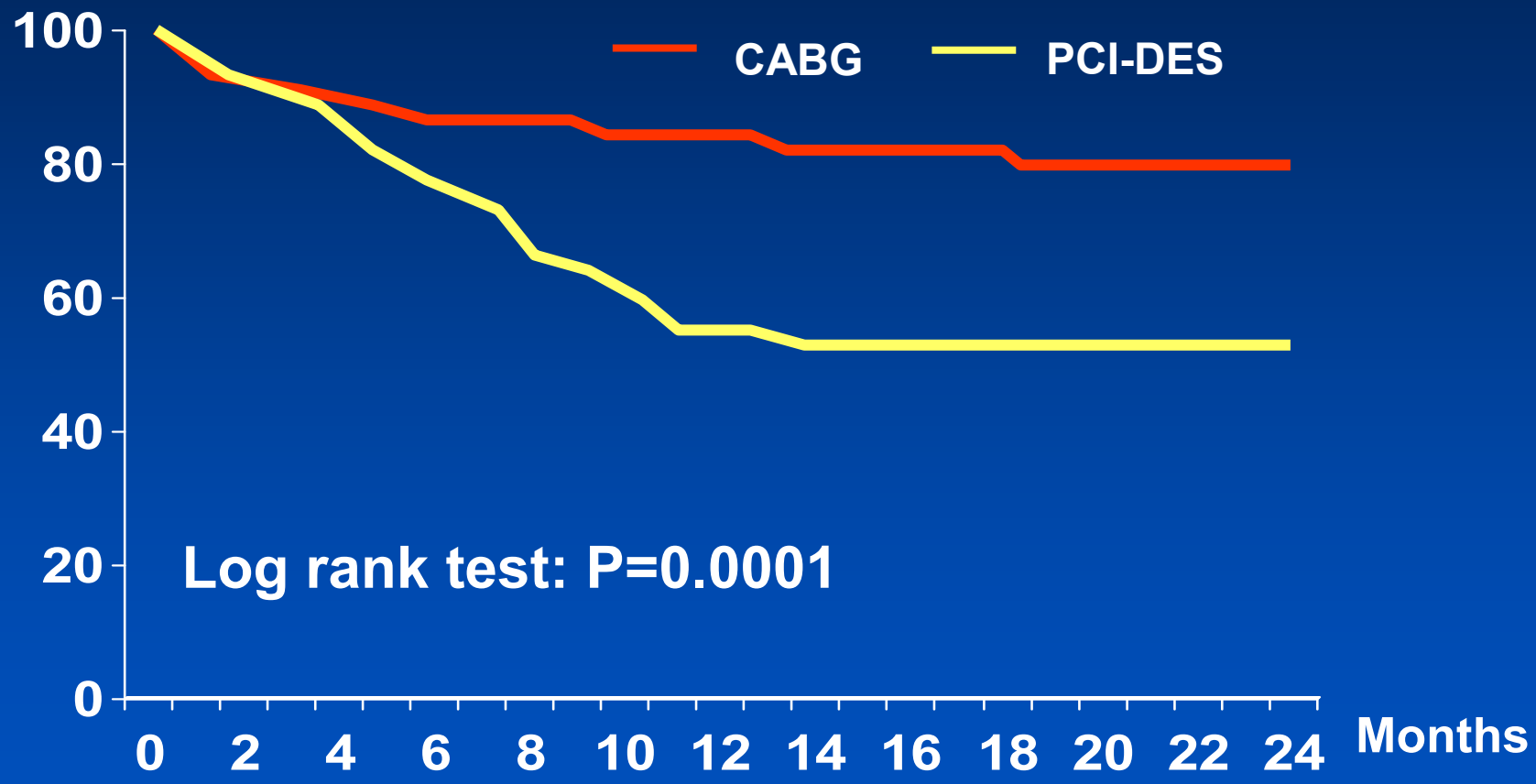


Palmerini et al, Am J Cardiol 2006

CABG vs. DES

157 PCI (94 DES) and 154 CABG in Italy

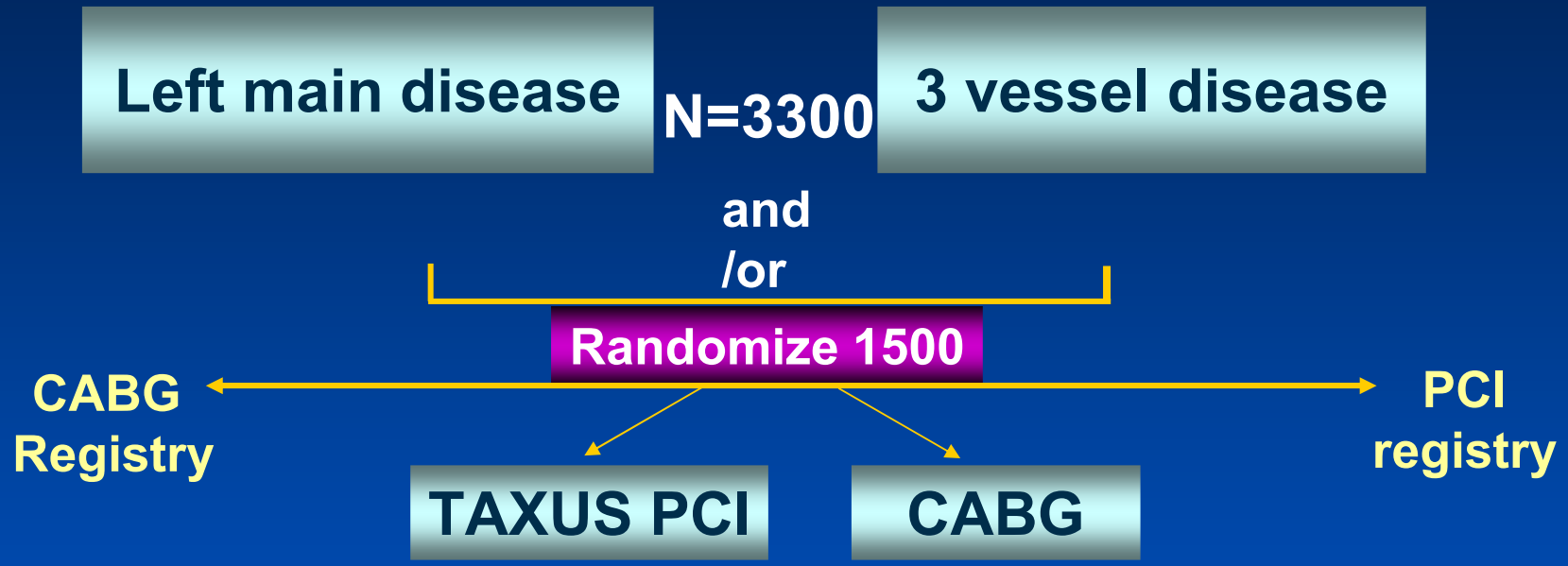
MACE-free Survival for PCI with DES



Palmerini et al, Am J Cardiol 2006

SYNTAX Randomized Trial

De novo disease acceptable for revascularization



Primary NI endpiont – 1 year MACCE
All cause death, MI, cerebrovascular
Event, repeat revascularization

Led by Patrick Serruys
And Frederick Mohr

PREmiere of COMparison of Bypass surgery and Angioplasty using sirolimus-eluting stent in patients with unprotected left main coronary artery disease

PRE-COMBAT

-Preliminary data-

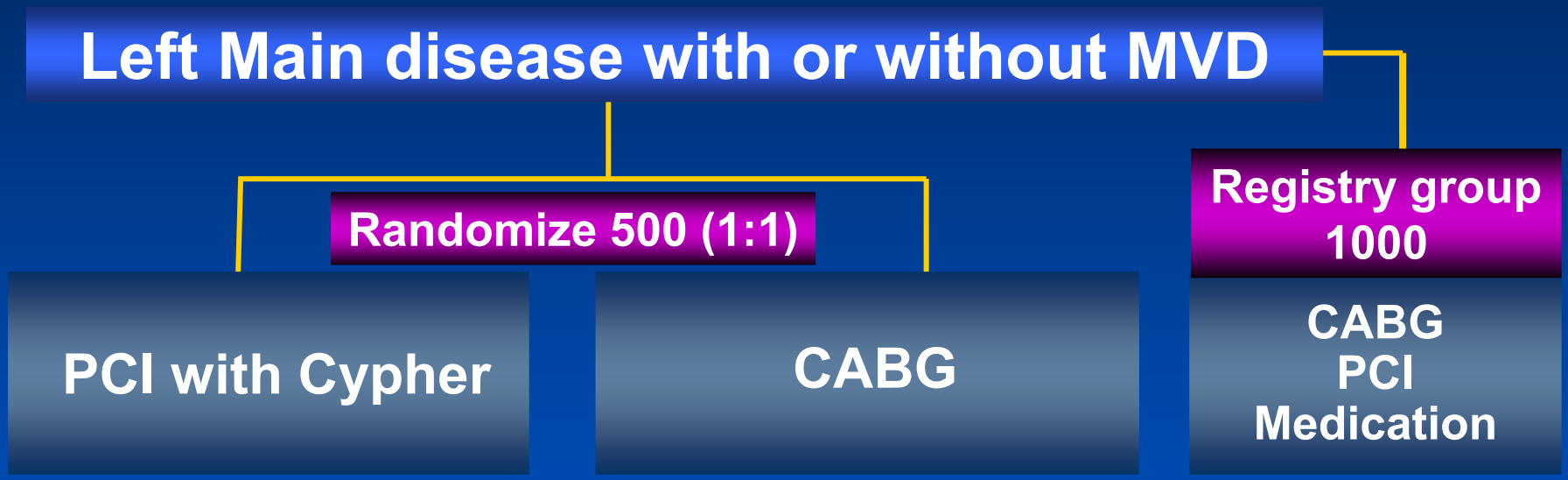
Seung-Jung Park, MD, PhD,

for the investigators of PRE-COMBAT trial

Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea

PRE-COMBAT Trial

*PRE*miere of *COM*parison of *B*ypass surgery and *A*ngioplas*T*y Using Sirolimus Electing Stent in Patients with Left Main Coronary Disease



PRIMARY Endpoint: 1-year death, MI, stroke and TVR

PI: Seung-Jung Park
8 major centers in Korea

Methodology

Prospective

Open label

Multicenter

Dual arm

Randomized

Objectives
Primary end point

- One-year (mean) MACCE including
  - Death
  - Cerebrovascular events
  - Non-fatal myocardial infarction
  - Target vessel revascularization either percutaneous or surgical

Objectives
Secondary end point

- MACCE at 6 months, 2 year, 3 years, and 5 years
- Re-admission with a cardiac cause
- Reocclusion or restenosis rate at 6 months and 2 years
- Cost-effectiveness of the two treatment at 2 years

Study Administration

Principal investigator :

- Seung-Jung Park, MD, PhD, Asan Medical Center

Data monitoring :

- CardioVascular Research Foundation (CVRF), Seoul, Korea
- IRBs

Data analysis :

- CVRF
- Clinical Research Center in Asan Medical Center

Angiographic Core Lab :

- CVRF

Independent event committee :

- CVRF

Grants :

- Korean Ministry of Health & Welfare as part of the Korea Health 21 R&D Project

Investigating Centers

8 Centers in Korea

Asan Medical Center, University of Ulsan	SJ Park, MD
Ajou University Hospital	SJ Tahk, MD
Catholic University Hospital	KB Seung, MD
Chonnam Nat'l University Hospital	MH Jeong, MD
Samsung Medical Center	HC Gwon, MD
Seoul Nat'l University Hospital	HS Kim, MD
Seoul National University Hospital	IH Chae, MD
Yonsei University Hospital	YS Jang, MD

Inclusion Criteria

- Patients with stable or unstable angina pectoris considered for coronary revascularization (angioplasty or bypass surgery).
- Patients with atypical chest pain or asymptomatic are eligible provided they have documented myocardial ischemia
- Significant left main stenosis (>50% by angiographic analysis)
- Left main lesion and lesions outside LMCA (if present) potentially treatable with coronary stenting and CABG
- Written informed consent

Key Exclusion Criteria

- LVEF < 30%
- Cardiogenic shock
- Prior CABG or valve surgery
- Creatinine $\geq$ 2.5 mg/dL
- Hepatic dysfunction
- Acute MI within 7 days
- Any previous PCI of LM, ostial LAD or ostial LCx
- Previous PCI of any other vessels in last 12 months
- Intention to treat 2 or more CTOs

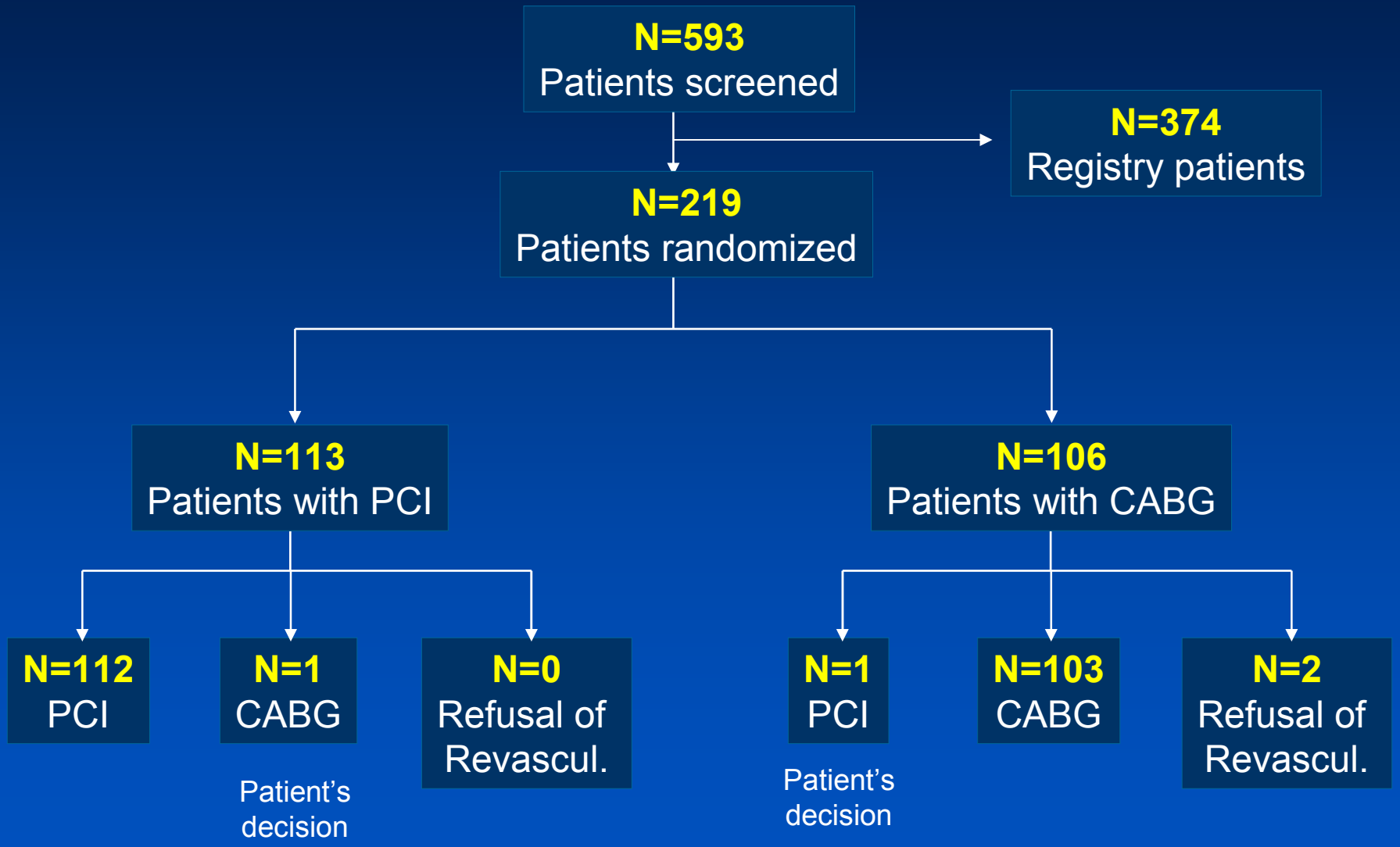
Sample Size

- Non-inferiority design
- A total of 500 patients in each of the two groups was required for the study to be able to reject the null hypothesis that the difference in MACCE in favor of CABG at one year will not exceed 8%.
- The sample size justification was done by the reference of historical controls of the CASS surgery patients and the patient with SES conducted in Asan Medial Center.
- With the actual sample size, the study achieved a power of 90 percent with the assumption of a one-sided type I error rate of 0.05.

Registry

- Patients with unprotected LMCA disease ≥50% were not enrolled due to patient or physician preference, were included in a prospective registry.

Disposition of Randomized Patients



Preliminary Analysis Intention-to-treat

Randomization Group

Baseline Characteristics

	PCI (N=113)	CABG (N=106)	p
Age (years)	60.1 ± 10.8	61.0 ± 9.8	0.533
Men	76.1 %	72.6 %	0.557
Smoker	33.9 %	32.4 %	0.970
Cholesterol > 220mg/dL	29.5 %	34.6 %	0.417
Diabetes mellitus	29.2 %	32.4 %	0.611
Hypertension	54.0 %	60.3 %	0.370
Family history of CAD	9.8 %	10.5 %	0.873
Previous MI	5.3 %	8.6 %	0.342
LV ejection fraction (%)	63.2 ± 8.8	61.5 ± 9.6	0.187

Baseline Characteristics

	PCI (N=113)	CABG (N=106)	p
Previous CVA	8.0 %	3.8 %	0.196
Previous PCI	11.5 %	12.4 %	0.842
H/O Kidney disease	8.8 %	5.7 %	0.375
H/O lung disease	4.4 %	1.9 %	0.292
Previous CEA	0	0	NA
H/O Peripheral Vs disease	4.4 %	7.6 %	0.320
Clinical manifestation			0.343
Stable angina	39.3 %	34.3 %	
Acute coronary syndrome	60.7 %	65.7 %	

Angiographic Findings

	PCI (N=113)	CABG (N=106)	p
Angiographic diagnosis			0.872
LM + 1 vessel	35.4 %	33.0 %	
LM + 2 vessel	21.2 %	25.5 %	
LM + 3 vessel	23.9 %	24.5 %	
LM only	19.5 %	17.0 %	
RCA involvement	42.3 %	40.6 %	0.796
LM site			0.807
Ostium	20.4 %	17.0 %	
Shaft	13.3 %	13.2 %	
Bifurcation	66.4 %	69.8 %	

Procedural Characteristics

	PCI (N=113)	CABG (N=106)	p
GP IIb/IIIa inhibitor	11.5 %	0.9 %	0.001
Use of IABP	3.6 %	10.5 %	0.061
Total number of stents	2.5 ± 1.3		
Use of IVUS	92.0 %		
Direct stenting	25.0 %		
Bifurcation PCI technique			
Simple (provisional T)	54.8 %		
Kissing	20.6 %		
Crush	19.2 %		
Others	6.9 %		
No of total conduit		2.7 ± 1.0	
No of arterial conduit		2.2 ± 0.9	
Off-pump CABG		58.4 %	

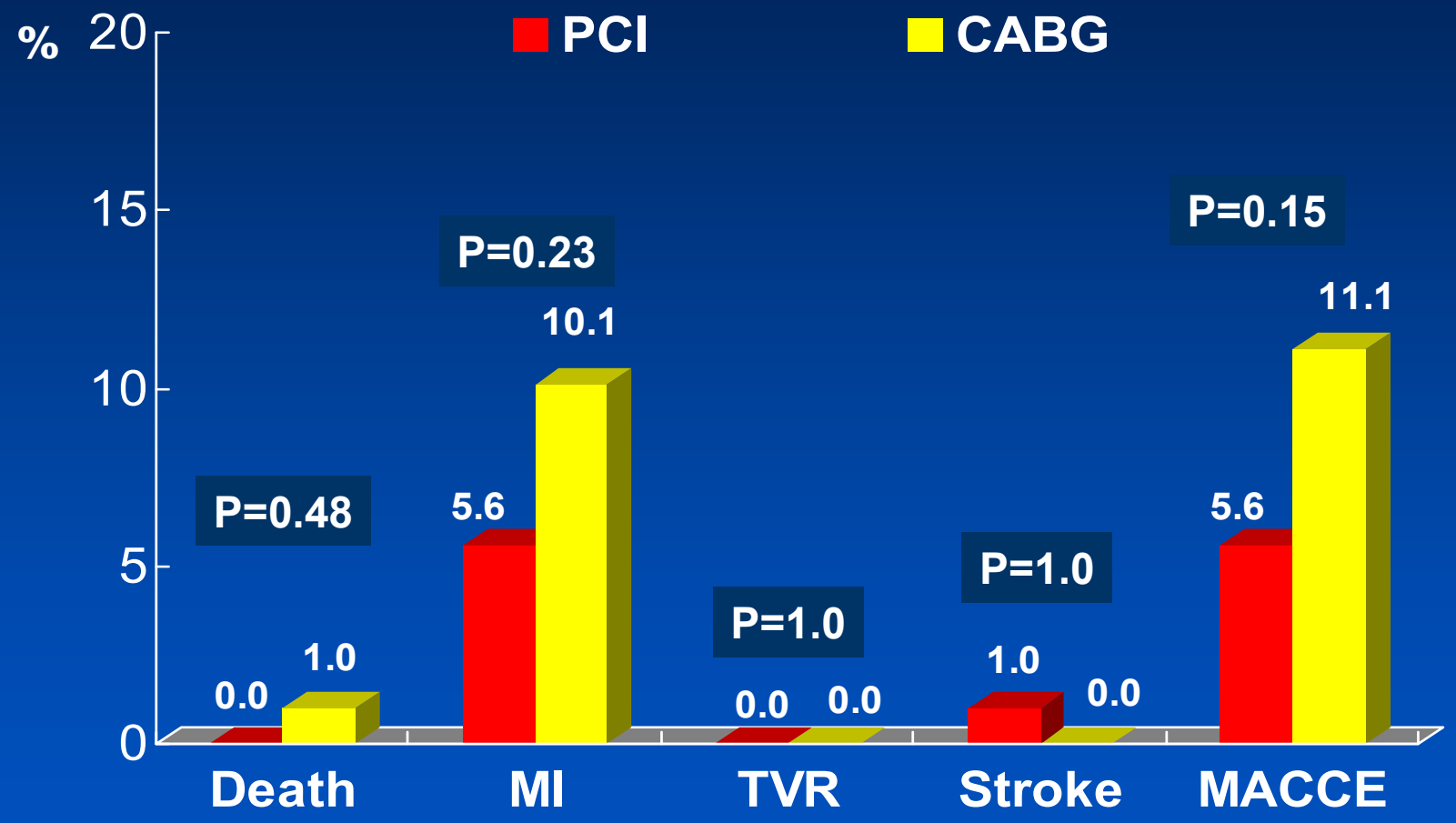
In-Hospital Outcome

	SES N=113	CABG N=104	p
Death	0	1 (1.0%)	0.479
Cardiac	0	0	
Non-cardiac	0	1 (1.0%)	0.479
Myocardial infarction	6 (5.3%)	10 (9.6%)	0.225
Q MI	0	4 (3.8%)	0.051
Non-Q MI (CK-MB X3 in PCI, X10 in CABG)	6 (5.3%)	6 (5.8%)	0.558
Major stroke	1 (0.9%)	0	1.000
Repeat revascularization	0	0	
CABG	0	0	
PCI	0	0	
MACCE	6 (5.3%)	11 (10.6%)	0.149

30-Day Outcome

	SES N=107	CABG N=109	p
Death	0	1 (1.0%)	0.481
Cardiac	0	0	
Non-cardiac	0	1 (1.0%)	0.481
Myocardial infarction	6 (5.6%)	10 (10.1%)	0.229
Q MI	0	4 (4.0%)	0.052
Non-Q MI	6 (5.6%)	6 (6.1%)	0.890
Major stroke	1 (1.0%)	0	1.000
Repeat revascularization	0	0	1.000
CABG	0	0	
PCI	0	0	
MACCE	6 (5.6%)	11 (11.1%)	0.151

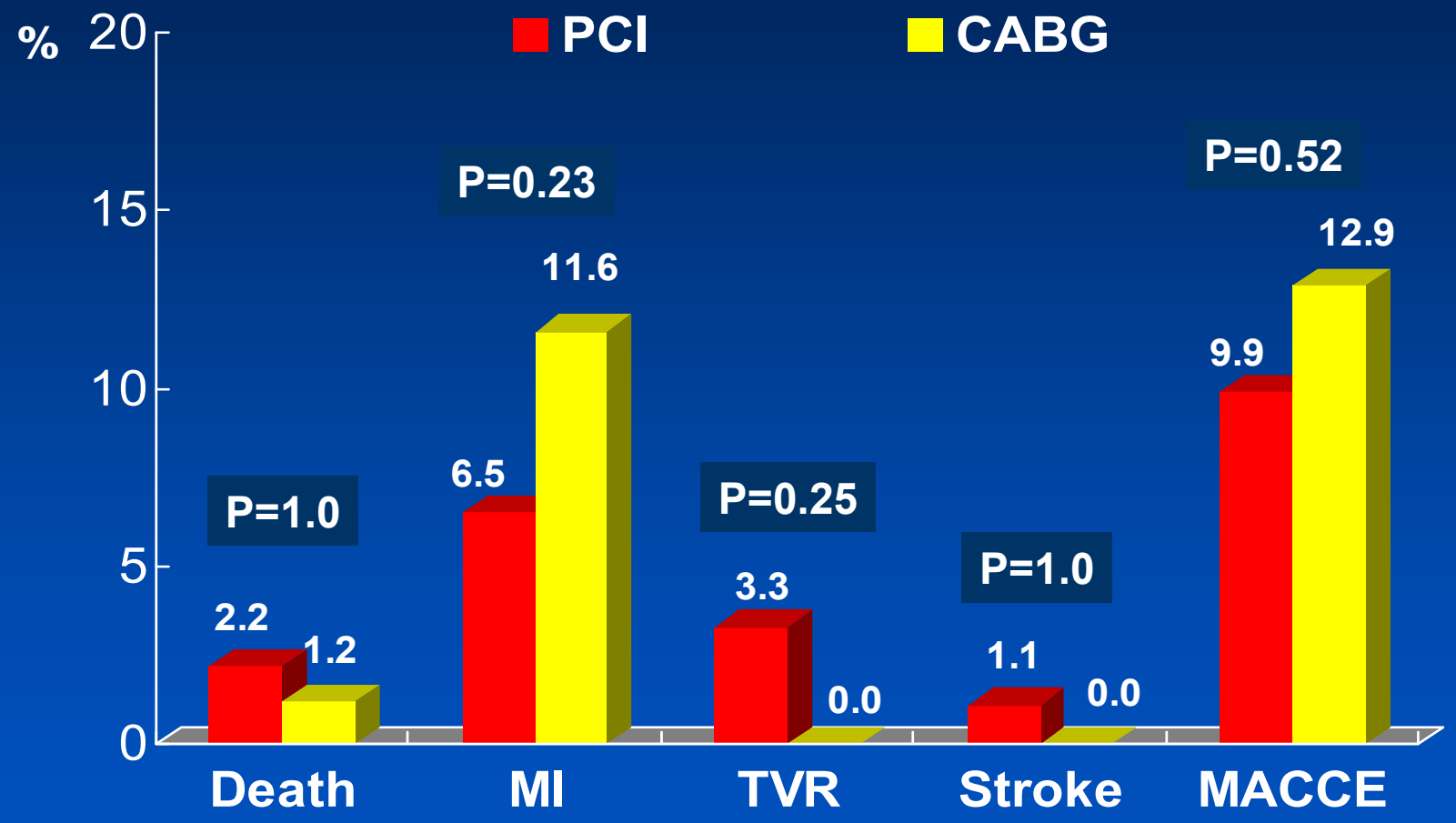
30-Day Outcome



6-Months Outcome

	SES N=91	CABG N=85	p
Death	2 (2.2%)	1 (1.2%)	1.000
Cardiac	1 (1.1%)	0	1.000
Non-cardiac	1 (1.1%)	1 (1.0%)	1.000
Myocardial infarction	6 (6.5%)	10 (11.6%)	0.225
Q MI	0	4 (4.7%)	0.035
Non-Q MI	6 (6.5%)	6 (7.0%)	0.888
Major stroke	1 (1.1%)	0	1.000
Repeat revascularization	3 (3.3%)	0	0.247
CABG	3 (3.3%)	0	0.247
PCI	0	0	
MACCE	9 (9.9%)	11 (12.9%)	0.524

6-Month Outcome



Preliminary Analysis Intention-to-treat

Registry Group

Primary reasons of exclusion from randomization

	PCI group N=150	CABG group N=207
Patient's or doctor's preference	67 %	14 %
Complex lesion, not suitable for stenting	0	57 %
Chronic total occlusion	4 %	19 %
Previous PCI within 1 year	9 %	1 %
Acute STEMI	6 %	1 %
Renal failure	5 %	1 %
Age more than 80 years	4 %	0
Disabled CVA	1 %	1 %
Emergent CABG	0	3 %
Bail-out PCI	1 %	0
Patients who need major surgery	4 %	1 %

Baseline Characteristics

	PCI (N=150)	CABG (N=207)	p
Age (years)	62.8 ± 11.1	64.3 ± 8.3	0.149
Men	72.0 %	78.7 %	0.141
Smoker	26.0%	33.3 %	0.308
Cholesterol > 220mg/dL	25.3 %	32.5 %	0.142
Diabetes mellitus	35.3 %	44.0 %	0.101
Hypertension	54.7 %	60.9 %	0.241
Family history of CAD	8.1 %	12.1 %	0.220
Previous MI	8.7 %	15.5 %	0.059
LV ejection fraction (%)	59.8 ± 9.8	54.2 ± 12.1	<0.001

Baseline Characteristics

	PCI (N=150)	CABG (N=207)	p
Previous CVA	9.3 %	13.5 %	0.225
Previous PCI	22.7 %	12.6 %	0.012
H/O Kidney disease	12.7 %	18.8 %	0.119
H/O lung disease	6.7 %	7.7 %	0.703
Previous CEA	0	0.5 %	1.000
H/O Peripheral Vs disease	7.3 %	2.9 %	0.075
Clinical manifestation			0.085
Stable angina	33.3 %	25.8 %	
Acute coronary syndrome	66.7 %	74.2 %	

Angiographic Findings

	PCI (N=150)	CABG (N=207)	p
Angiographic diagnosis			<0.001
LM + 1 vessel	25.5 %	4.3 %	
LM + 2 vessel	26.2 %	10.0 %	
LM + 3 vessel	24.2 %	85.2 %	
LM only	24.2 %	0.5 %	
RCA involvement	32.2 %	89.1 %	<0.001
LM site			0.015
Ostium	28.2 %	16.4 %	
Shaft	12.8 %	10.6 %	
Bifurcation	59.1 %	72.9 %	

Procedural Characteristics

	PCI (N=150)	CABG (N=207)	p
GP IIb/IIIa inhibitor	8.0 %	3.3 %	0.052
Use of IABP	6.7 %	10.7 %	0.260
Total number of stents	2.2 ± 1.2		
Use of IVUS	85.2 %		
Direct stenting	33.3 %		
Bifurcation PCI technique			
Simple (provisional T)	54.1 %		
Kissing	14.1 %		
Crush	28.2 %		
Others	3.5 %		
No of total conduit		3.2 ± 1.0	
No of arterial conduit		2.5 ± 0.9	
Off-pump CABG		48.2 %	

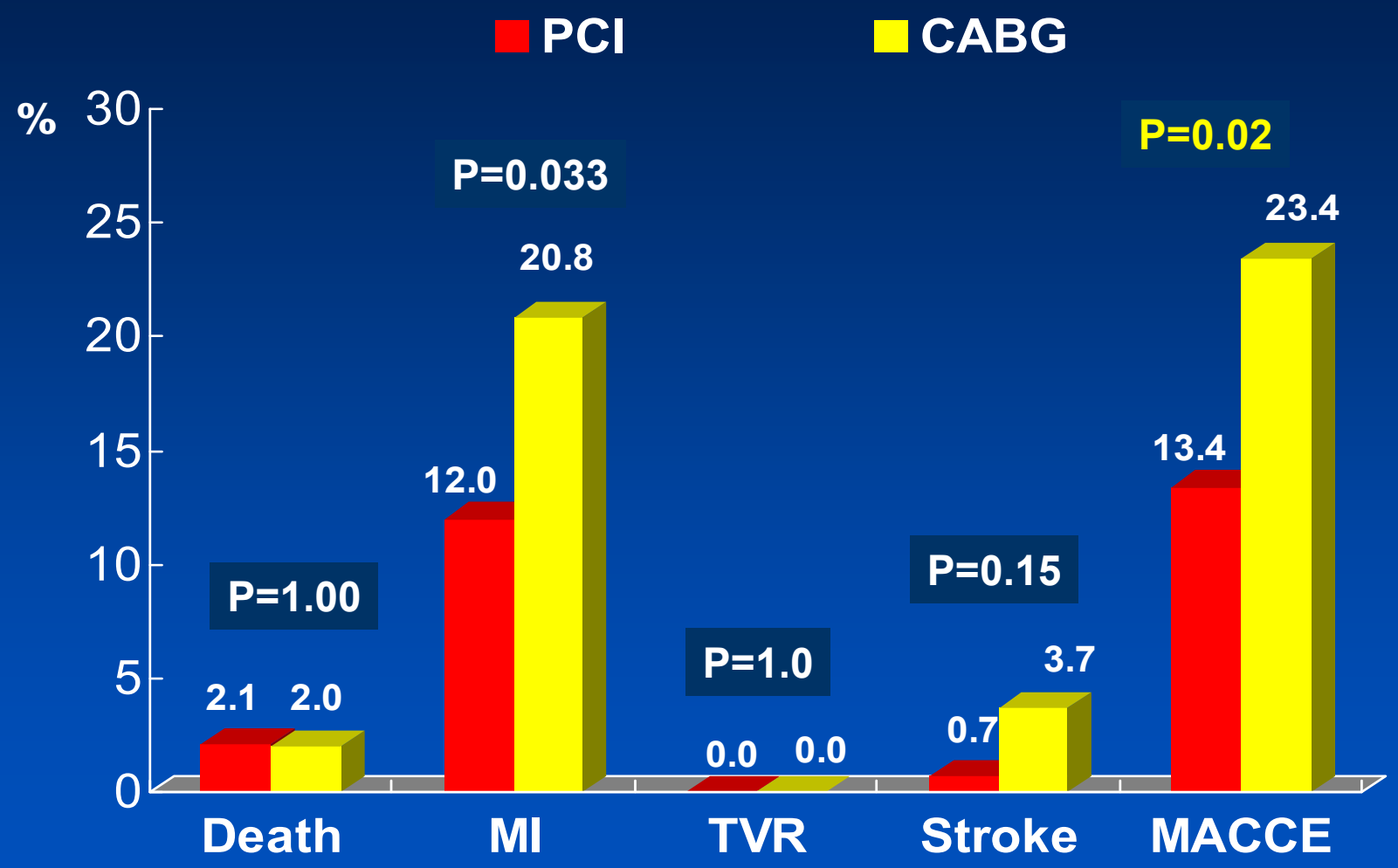
In-Hospital Outcome

	SES N=150	CABG N=204	p
Death	3 (2.0%)	4 (2.0%)	1.000
Cardiac	3 (2.0%)	4 (2.0%)	1.000
Non-cardiac	0	0	0.479
Myocardial infarction	16 (10.7%)	41 (20.1%)	0.017
Q MI	1 (0.7%)	9 (4.4%)	0.049
Non-Q MI	15 (10.0%)	32 (15.7%)	0.119
Major stroke	1 (0.7%)	5 (2.6%)	0.240
Repeat revascularization	0	0	
CABG	0	0	
PCI	0	0	
MACCE	17 (11.3%)	45 (22.1%)	0.009

30-Day Outcome

	SES N=142	CABG N=197	p
Death	3 (2.1%)	4 (2.0%)	1.000
Cardiac	3 (2.1%)	4 (2.0%)	1.000
Non-cardiac	0	0	0.479
Myocardial infarction	17 (12.0%)	41 (20.8%)	0.033
Q MI	2 (1.4%)	9 (4.6%)	0.129
Non-Q MI	15 (10.6%)	32 (16.2%)	0.135
Major stroke	1 (0.7%)	7 (3.7%)	0.145
Repeat revascularization	0	0	1.000
CABG	0	0	
PCI	0	0	
MACCE	19 (13.4%)	46 (23.4%)	0.021

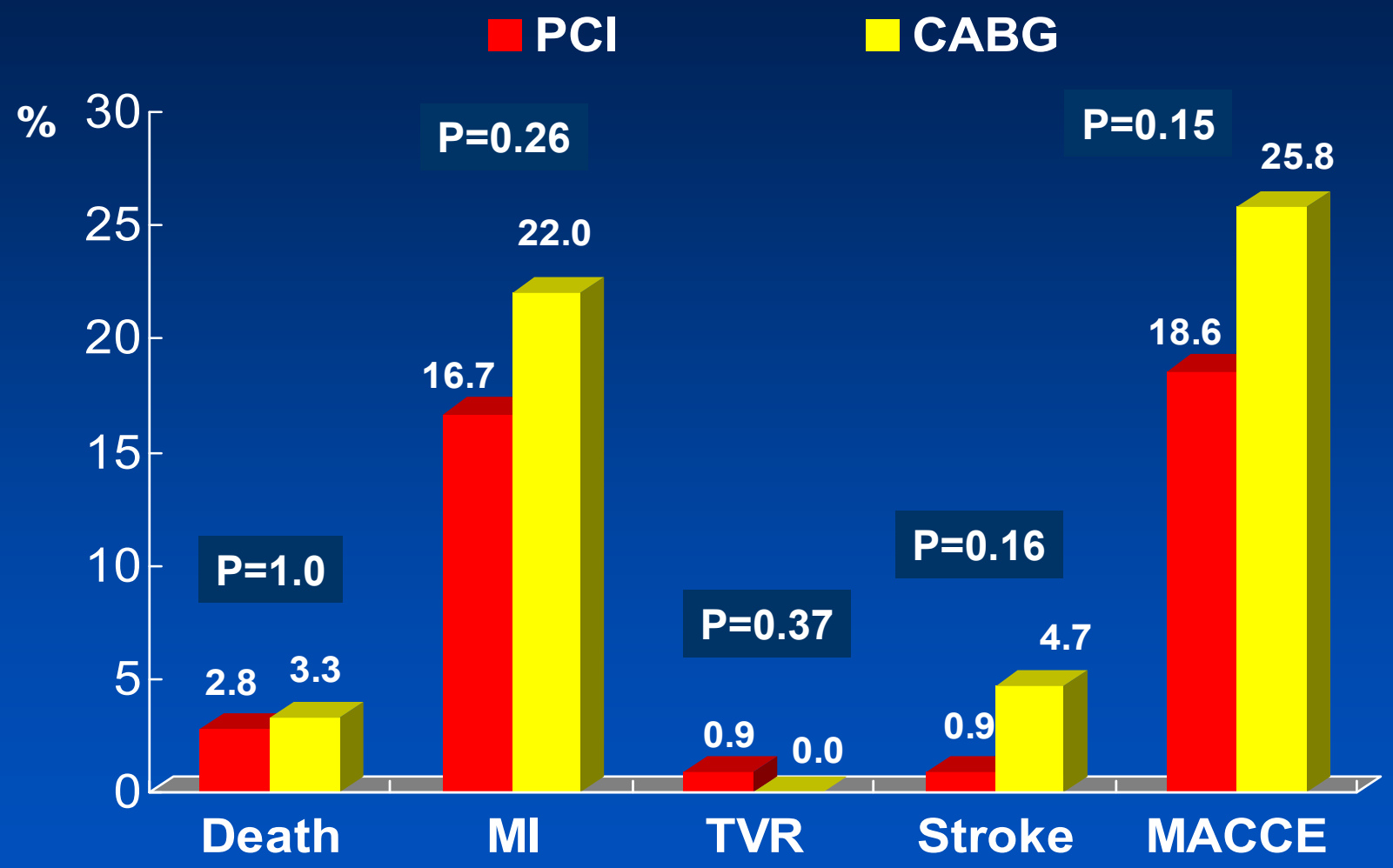
30-Day Outcome



6-Month Outcome

	SES N=108	CABG N=184	p
Death	3 (2.8%)	6 (3.3%)	1.000
Cardiac	3 (2.8%)	5 (2.7%)	1.000
Non-cardiac	0	1 (0.5%)	1.000
Myocardial infarction	18 (16.7%)	41 (22.0%)	0.258
Q MI	2 (1.4%)	9 (4.8%)	0.222
Non-Q MI	16 (14.0%)	32 (17.2%)	0.467
Major stroke	1 (0.9%)	8 (4.7%)	0.160
Repeat revascularization	1 (0.9%)	0	0.374
CABG	1 (0.9%)	0	0.374
PCI	0	0	
MACCE	21 (18.6%)	48 (25.8%)	0.151

6-Month Outcome



Preliminary Analysis

Random vs. Registry Groups

Baseline Characteristics

	Random (N=219)	Regist (N=374)	p
Age (years)	60.6 ± 10.2	63.7 ± 9.6	<0.001
Men	74.4%	75.9 %	0.689
Smoker	33.2%	30.3%	0.253
Cholesterol > 220mg/dL	31.9%	29.5%	0.574
Diabetes mellitus	30.7%	40.3%	0.020
Hypertension	56.9%	58.3%	0.745
Family history of CAD	10.1%	10.4%	0.922
Previous MI	6.9%	12.6%	0.029
LV ejection fraction (%)	62.4 ± 9.2	56.5 ± 11.6	<0.001

Baseline Characteristics

	Random (N=219)	Regist (N=374)	p
Previous CVA	6.0%	11.8%	0.028
Previous PCI	11.9%	16.8%	0.111
H/O Kidney disease	7.3%	16.2%	0.002
H/O lung disease	3.2%	7.3%	0.042
Previous CEA	0	0.3%	1.000
H/O Peripheral Vs disease	6.0%	4.8%	0.530
Clinical manifestation			0.059
Stable angina	36.9%	28.9%	
Acute coronary syndrome	63.1%	71.1%	

Angiographic Findings

	Random (N=219)	Regist (N=374)	p
Angiographic diagnosis			<0.001
LM + 1 vessel	34.2%	13.2%	
LM + 2 vessel	23.3%	16.6%	
LM + 3 vessel	24.2%	59.8%	
LM only	18.3%	10.4%	
RCA involvement	41.5%	65.0%	<0.001
LM site			0.696
Ostium	18.7%	21.2%	
Shaft	13.2%	11.6%	
Bifurcation	68.0%	67.2%	

Procedural Characteristics

	Random (N=219)	Regist (N=374)	p
GP IIb/IIIa inhibitor	6.4 %	5.3 %	0.591
Use of IABP	3.6 %	10.5 %	0.061
Total number of stents	2.5 ± 1.3	2.2 ± 1.2	0.074
Use of IVUS	92.9 %	85.2 %	0.056
Bifurcation PCI technique			0.401
Simple (provisional T)	55.5 %	54.1%	
Kissing	20.3%	10.6%	
Crush	18.9%	28.2%	
Others	5.3%	7.1%	
No of vein conduit	0.5 ± 0.7	0.7 ± 0.7	0.045
No of arterial conduit	2.1 ± 0.9	2.5 ± 0.9	<0.001
Off-pump CABG	57.8%	48.2 %	0.114

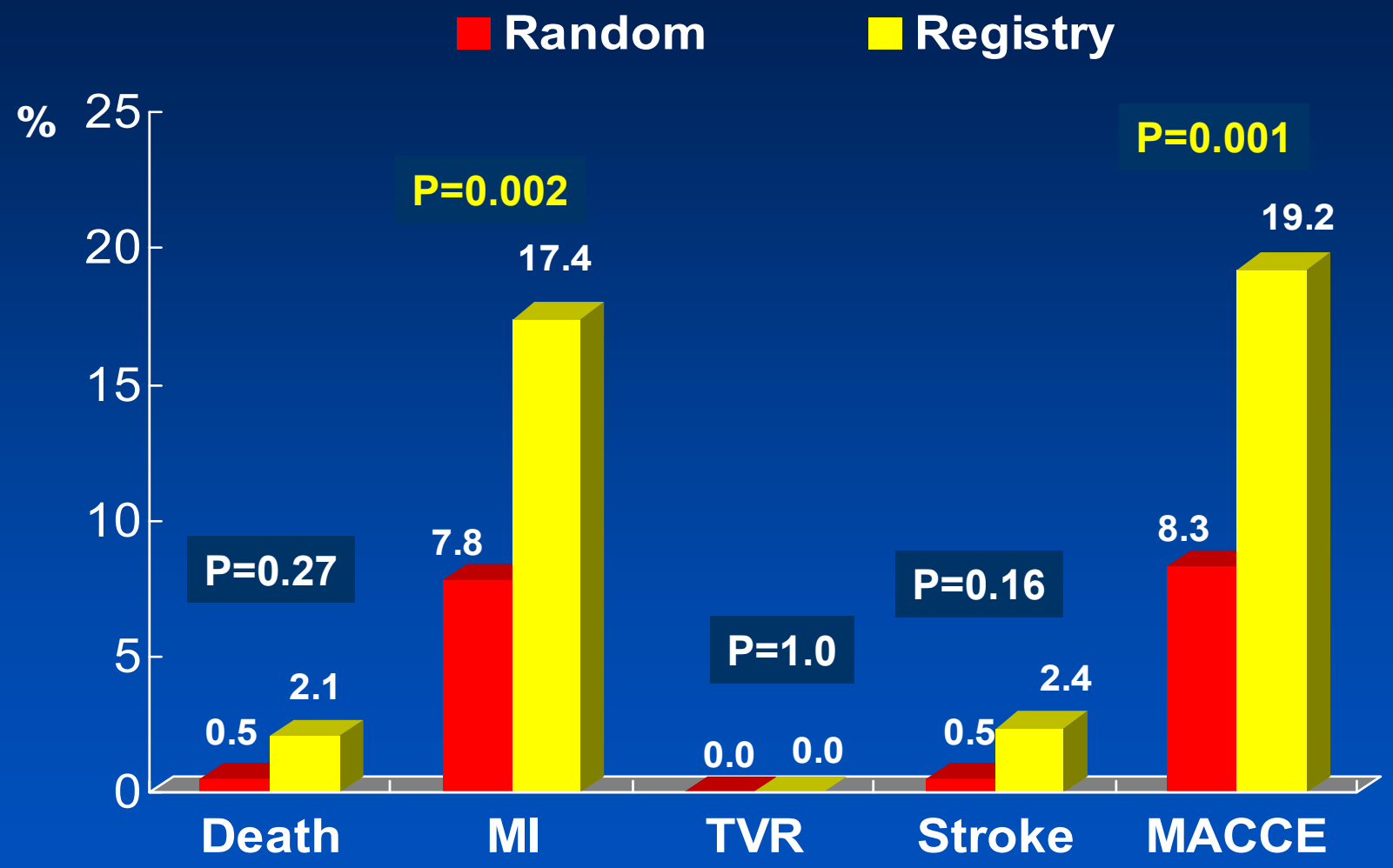
In-Hospital Outcome

	Random (N=217)	Regist (N=354)	p
Death	1 (0.5%)	7 (2.0%)	0.270
Cardiac	0	7 (2.0%)	0.048
Non-cardiac	1 (0.5%)	0	0.380
Myocardial infarction	16 (7.4%)	59 (16.7%)	0.001
Q MI	4 (1.8%)	12 (3.4%)	0.277
Non-Q MI (CK-MB X3 in PCI, X10 in CABG)	12 (5.5%)	47 (13.3%)	0.003
Major stroke	1 (0.5%)	6 (1.8%)	0.185
Repeat revascularization	0	0	NA
CABG	0	0	
PCI	0	0	
MACCE	17 (7.8%)	64 (18.1%)	0.001

30-Day Outcome

	Random (N=206)	Regist (N=339)	p
Death	1 (0.5%)	7 (2.1%)	0.137
Cardiac	0	7 (2.1%)	0.048
Non-cardiac	1 (0.5%)	0	0.378
Myocardial infarction	16 (7.8%)	59 (17.4%)	0.002
Q MI	4 (1.9%)	13 (3.8%)	0.310
Non-Q MI	12 (5.8%)	47 (13.9%)	0.003
Major stroke	1 (0.5%)	8 (2.4%)	0.163
Repeat revascularization	0	0	NA
CABG	0	0	
PCI	0	0	
MACCE	17 (8.3%)	65 (19.2%)	0.001

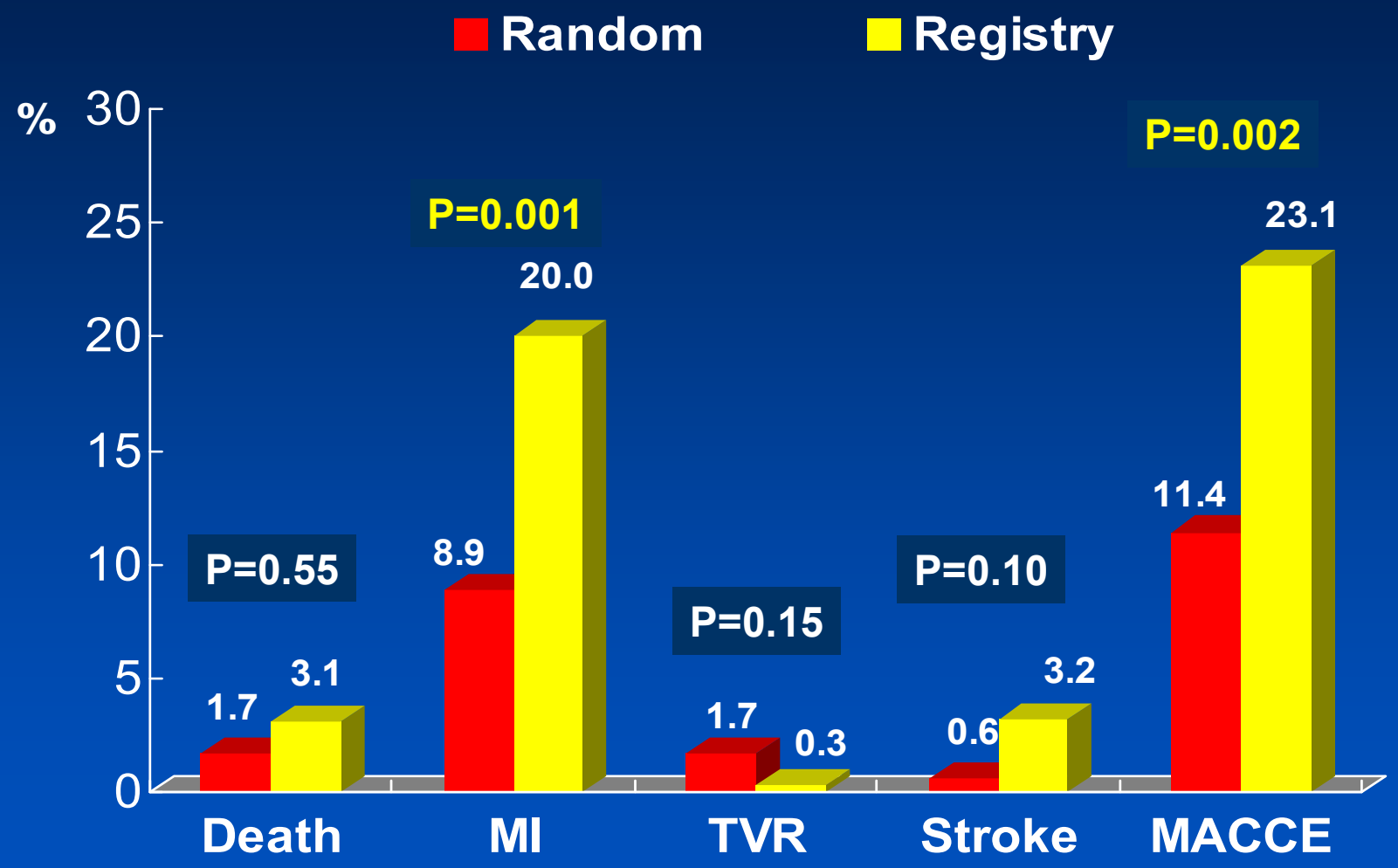
30-Day Outcome



6-Months Outcome

	Random (N=176)	Regist (N=292)	p
Death	3 (1.7%)	9 (3.1%)	0.548
Cardiac	1 (0.6%)	8 (2.7%)	0.163
Non-cardiac	2 (1.1%)	1 (0.3%)	0.559
Myocardial infarction	16 (8.9%)	60 (20.0%)	0.001
Q MI	4 (2.2%)	13 (4.3%)	0.310
Non-Q MI	12 (6.7%)	48 (16.0%)	0.003
Major stroke	1 (0.6%)	9 (3.2%)	0.097
Repeat revascularization	3 (1.7%)	1 (0.3%)	0.154
CABG	3 (1.7%)	1 (0.3%)	0.154
PCI	0	0	
MACCE	20 (11.4%)	69 (23.1%)	0.002

6-Month Outcome



Summary of PRE-COMBAT Randomization vs. Registry

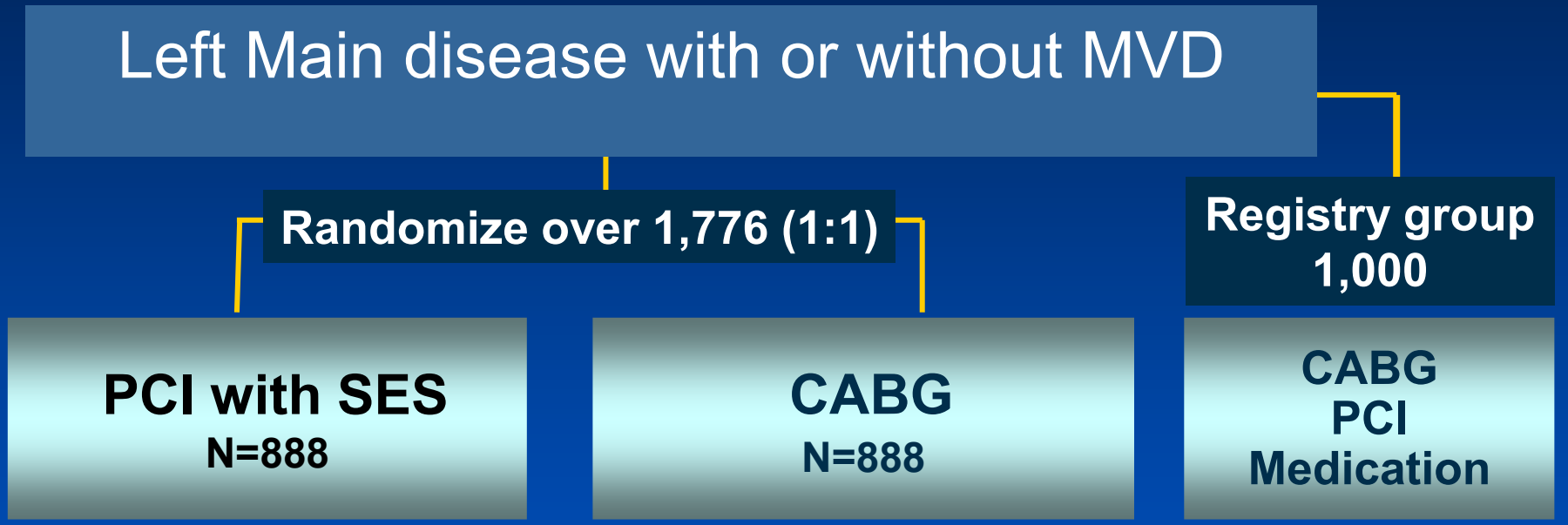
- As common as 2/5 of all LMCA patients has been randomized.
- Patient's and doctor's preference based on the patient complexity was the main cause of exclusion from randomization.
- Registry group involved more complex patients at a higher risk of poor prognosis than the randomization group.
- Treatment strategy was similar between the two groups.
- Initial outcomes of elective revascularization for unprotected LMCA stenosis were acceptably favorable in terms of less than 5% of mortality in both randomization and registry groups.
- Unfavorable initial and mid-term outcomes in the registry group imply that the prognosis of revascularization treatment is dependent on a patient procedural risk, which is in line with the previous registry reports.

Summary of PRE-COMBAT PCI vs. CABG

- Bifurcation location was identified in 2/3 of all LMCA disease.
- Simples stenting strategy acrossing circumflex artery was used in a half of patients with bifurcation LMCA stenosis.
- Arterial grafts were used in 2/3 of all grafts (LIMA in 98%).
- Initial outcomes of both treatments were similarly favorable in terms of low mortality and morbidity.
- There was a non-significant tendency of high periprocedural MI rate in CABG compared to PCI.
- Mid-term outcomes were comparable between the two groups.
- More complete follow-up of this cohort will be more powered to show the difference of two treatments.

COMBAT Randomized Trial

*COM*parison of *B*ypass surgery and *A*ngioplas*T*y using sirolimus electing stent in patients with left main coronary disease



Primary Endpoint: 2-year death, MI, and stroke
Key Secondary Endpoints: MACCE including primary end point and ischemia-driven TLR

PI: Seung-Jung Park, Martin B. Leon

Issues …
in Unprotected LM PCI

- **LM PCI in the era of BMS**
- **PCI vs CABG (BMS)**
- **LM PCI in the era of DES**
- **DES vs BMS**
- **Cypher vs TAXUS**
- **PCI vs CABG (DES)**

Unprotected left main PCI would be an effective alternative to surgery in selected patients in real world practice. We are waiting more solid data from large scaled randomized trials


Thank You !!
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