

13<sup>th</sup> Annual

Angioplasty  
**Summit TCT Asia Pacific**

3<sup>rd</sup> APSIC Fellowship Convocation



## DES for Left Main Intervention

**Marco Valgimigli, MD, PhD**  
University of Ferrara, ITALY

# Current Recommendation for unprotected LMCA Stenosis



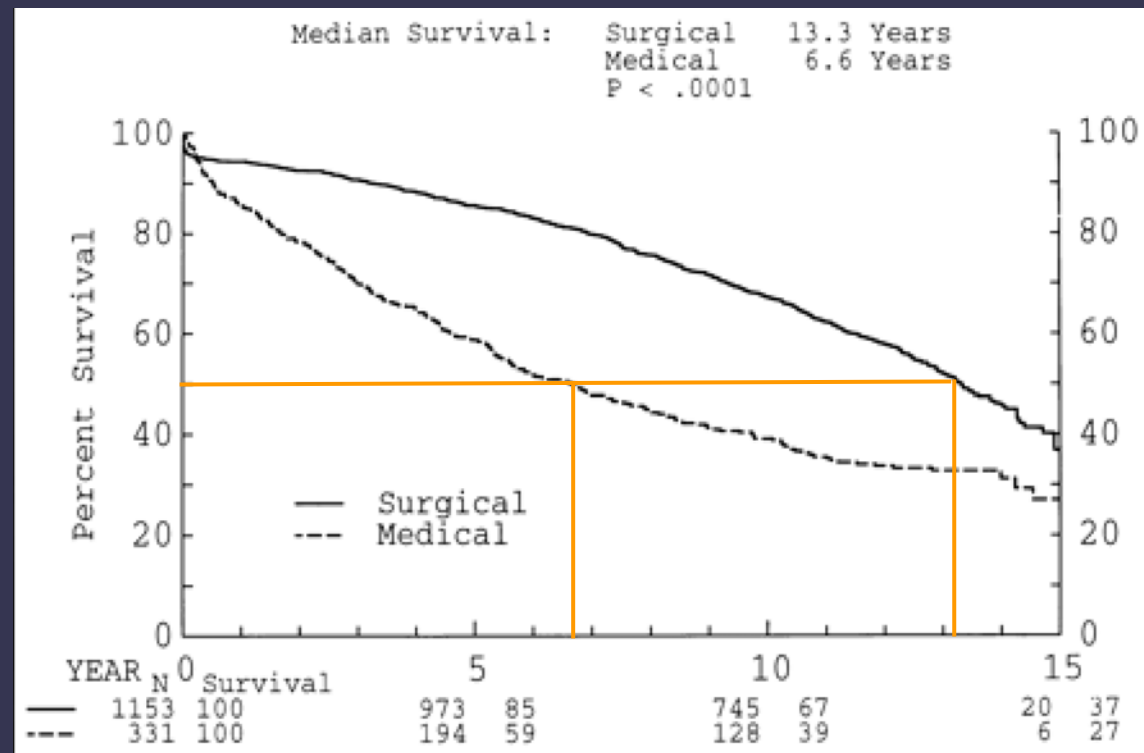
- Class **IIb C** in ESC guideline (2005) and Class **III** in ACC guideline (2006) in patients eligible for CABG
- Class III is the conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/ effective and in some cases may be harmful.

# Left Main Disease



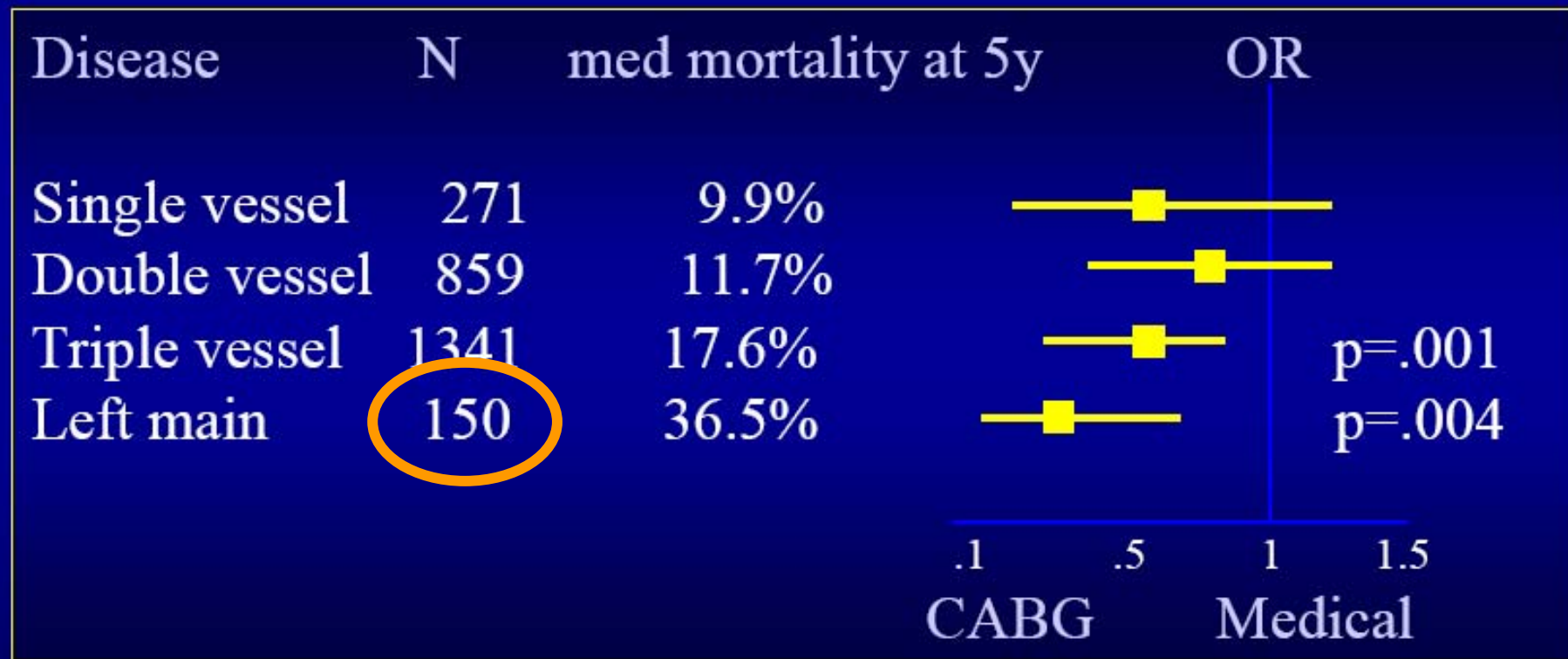
## Long-term CASS Experience

Cumulative survival estimates  
In 1484 CASS Registry patients  
with 50% LM coronary artery  
stenosis who were initially  
treated with CABG surgery or  
non surgical therapy.



# CABG versus Medical therapy

Coronary Artery Bypass Graft Surgery  
Trialists Collaboration (7 Randomized trials\*)



\*VA, ECS, CASS, Texas, Oregon, NZ, NZ

# Long-Term Clinical Outcomes After Unprotected Left Main Trunk Percutaneous Revascularization in 279 Patients

Walter A. Tan, MD, MS; Hideo Tamai, MD; Seung-Jung Park, MD, PhD;  
H.W. Thijis Plokker, MD, PhD; Masakiyo Nobuyoshi, MD; Takahiko Suzuki, MD;  
Antonio Colombo, MD; Carlos Macaya, MD; David R. Holmes, Jr, MD; David J. Cohen, MD;  
Patrick L. Whitlow, MD; Stephen G. Ellis, MD; for the ULTIMA Investigators\*

**Background**—Percutaneous coronary revascularization (PCI) has been increasingly applied to unprotected left main trunk (LMT) lesions, with varied long-term success. This study attempts to define the predictors of outcome in this population.

**Methods and Results**—Two hundred seventy-nine consecutive patients who had LMT PCI at 1 of 25 sites between 1993 and 1998 were studied. Forty-six percent of these patients were deemed inoperable or at high surgical risk. Thirty-eight patients (13.7%) died in hospital, and the rest were followed up for a mean of 19 months. The 1-year incidence was 24.2% for all-cause mortality, 20.2% for cardiac mortality, 9.8% for myocardial infarction, and 9.4% for CABG. Independent correlates of all-cause mortality were left ventricular ejection fraction  $\leq 30\%$ , mitral regurgitation grade 3 or 4, presentation with myocardial infarction and shock, creatinine  $\geq 2.0$  mg/dL, and severe lesion calcification. For the 32% of patients  $< 65$  years old with left ventricular ejection fraction  $> 30\%$  and without shock, the prevalence of these adverse risk factors was low. No periprocedural deaths were observed in this low-risk subset, and the 1-year mortality was only 3.4%.

**Conclusions**—Patients undergoing unprotected LMT PCI have frequent serious comorbidities and consequently have high event rates. PCI may be an alternative to CABG for a select proportion of elective patients and may also be appropriate for highly symptomatic inoperable patients. Meticulous follow-up of hospital survivors is required because of the rather high mortality during the first few months after treatment. (*Circulation*. 2001;104:1609-1614.)

- 279 patients who underwent ULMCA PCI from 25 centres 1993-1998

- 15% acute MI (13% shock)

46% non eligible to CABG



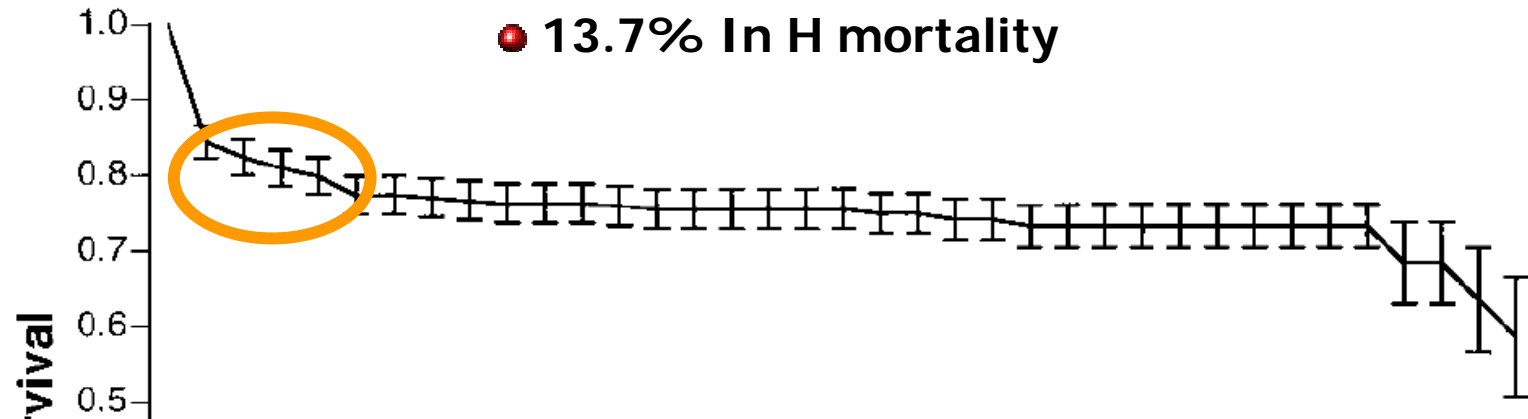
# ...Not really COURAGE-like Tx

TABLE 3. In-Hospital Treatment

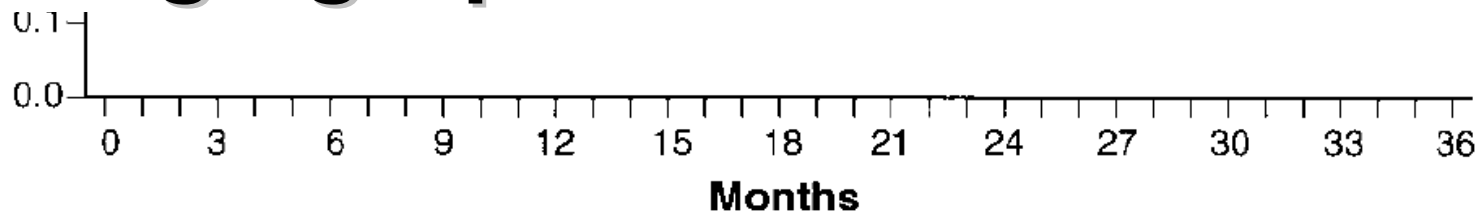
	All Patients (n=279), %	Low-Risk Subset (n=89), %
Aspirin	90.9	96.6
Ticlopidine	41.7	57.3
$\beta$ -Blockers	28.4	28.4
Abciximab	4.3	1.1
Balloon only	15.1	4.5
Stent	68.8	76.4
Rotablator as 1 <sup>o</sup> treatment	9.3	8.9
Directional coronary atherectomy	17.1	19.1
Ablation followed by stenting	11.2	11.2
Pulmonary artery catheter	16.8	3.9
Temporary pacer	31.6	20.5
Intra-aortic balloon counterpulsation	46.0	26.4
Prophylactic percutaneous cardiopulmonary support	5.9	0

# The ULTIMA registry

*Urgent and elective treatment*



- **RESTENOSIS is equal to DEATH**
- **Angiographic F-UP after LM PCI**

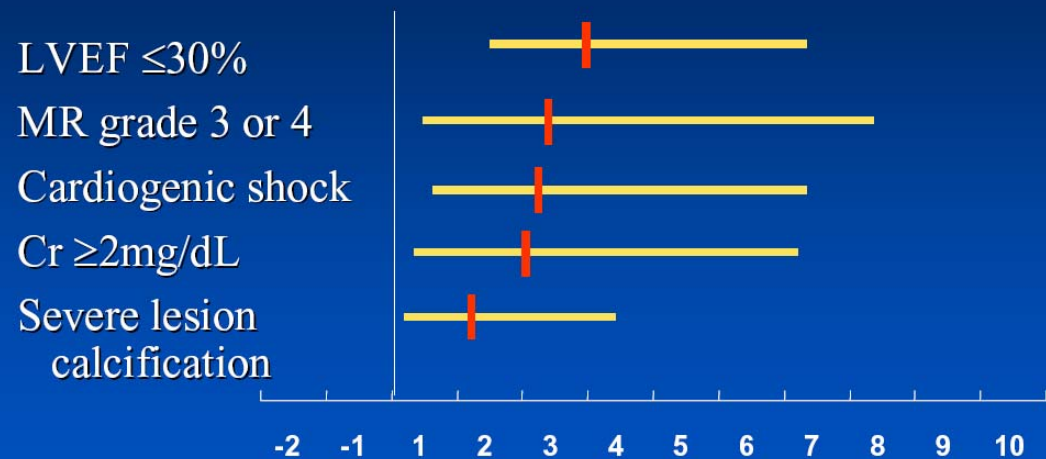


N = 278 226 214 204 200 191 191 93 81 81 81 14 12

# Restenosis = Death ?

- Excess of events confined  
To high surgical risk or  
those with Comorbidities

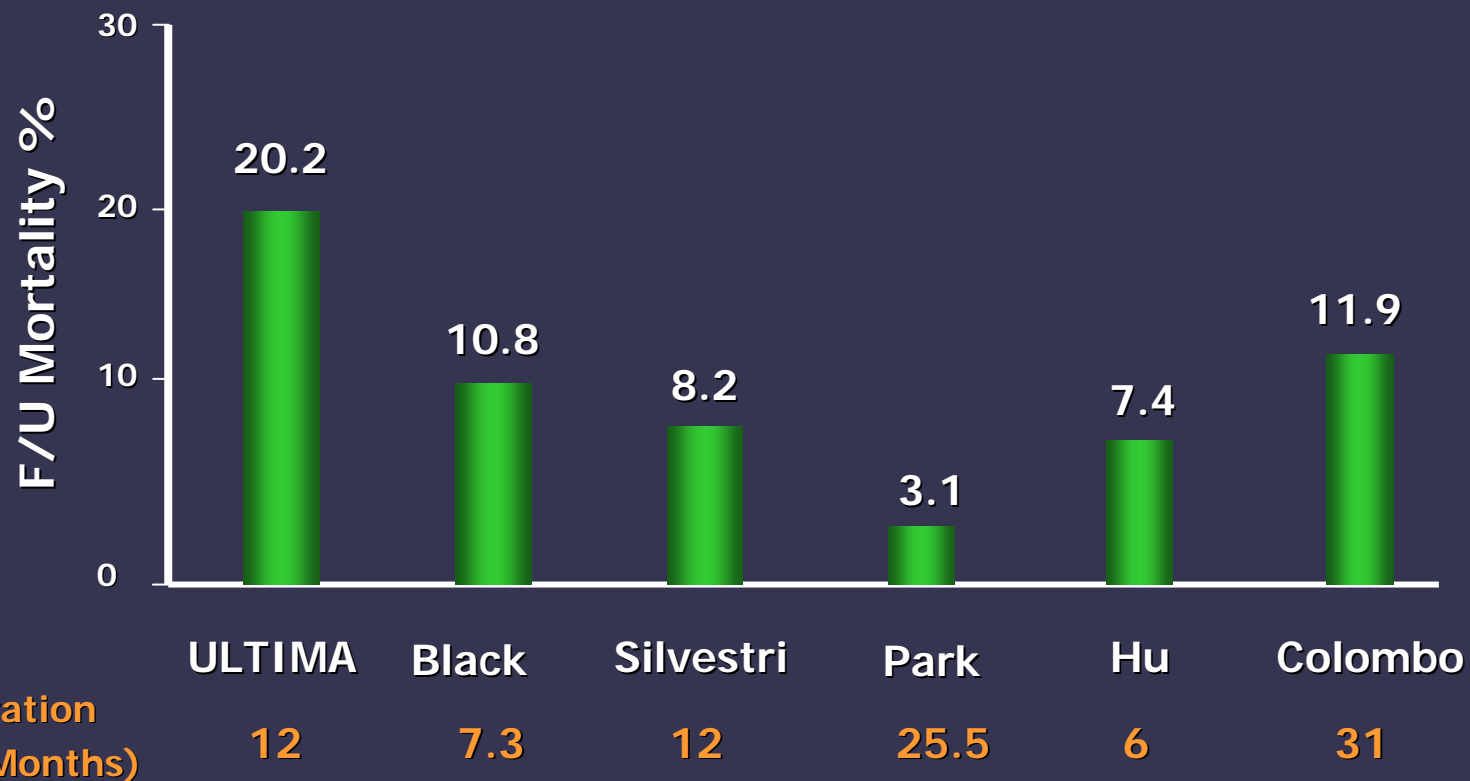
## Multivariate Predictors of All-Cause Mortality: ULTIMA Registry



Tan et al, Circulation, 2001

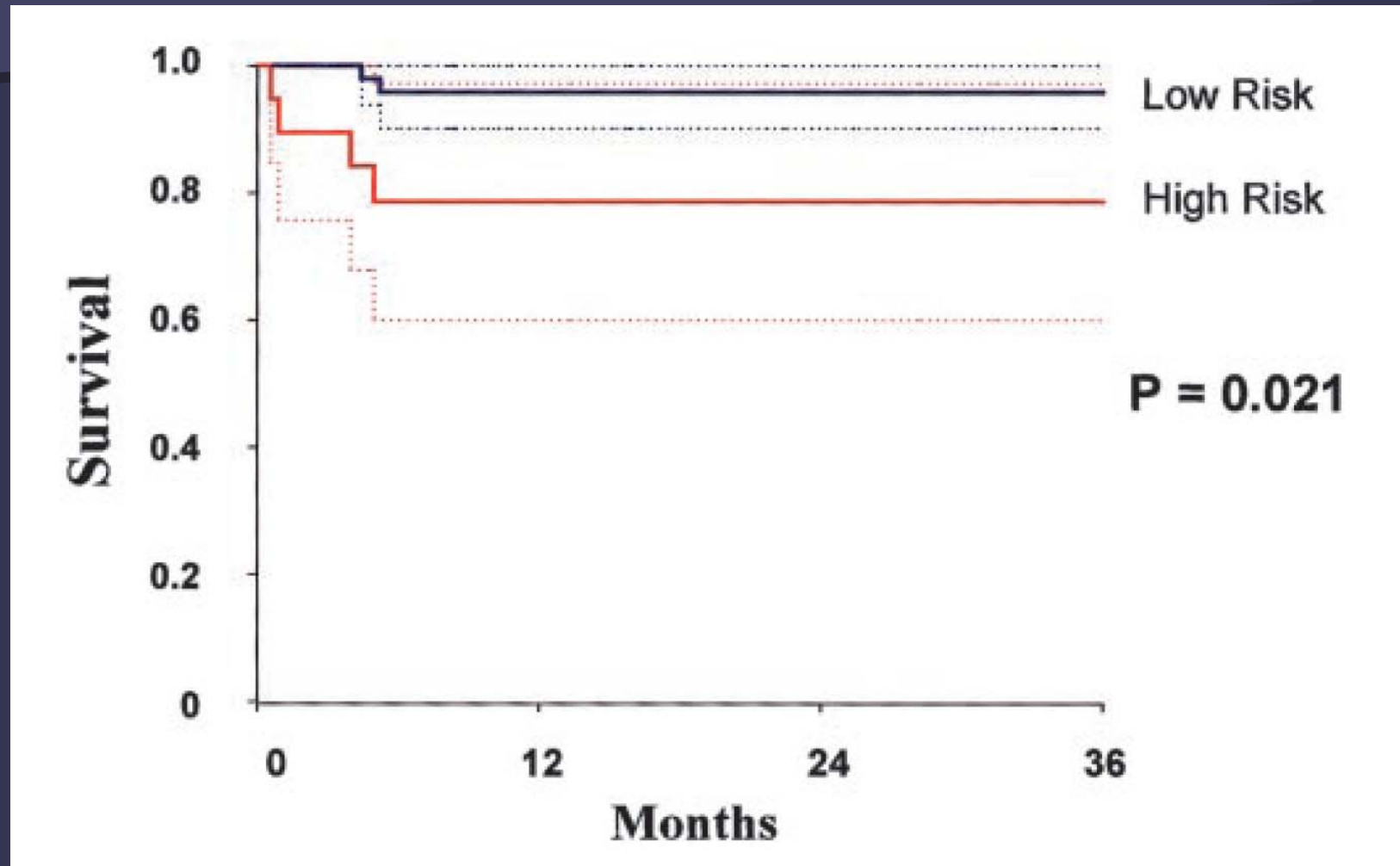


# Long-term Mortality Rate at F/UP In PCI series of unprotected LM



# Low Mortality for good surgical candidate

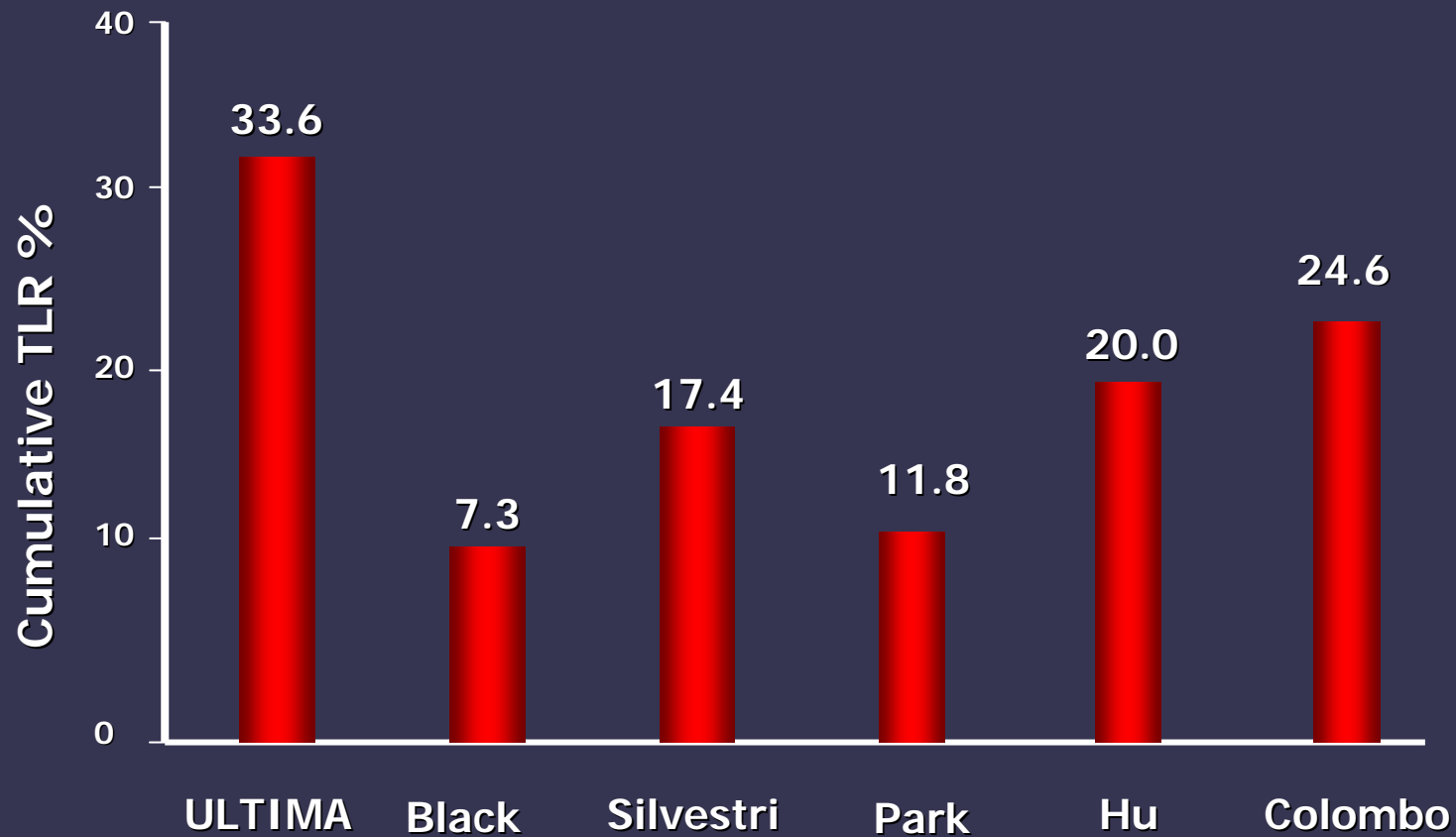
In-hospital death (%)



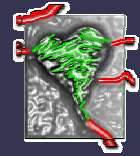
# Unprotected LMCA stenting in the BMS era

- PCI for unprotected LMCA stenosis is feasible
- Short and long-term mortality is extremely heterogeneous reflecting different patient selection
- Restenosis = death ?
- PCI should be reserved to very high surgical risk patients...i.e. PCI may just be better than medical TX

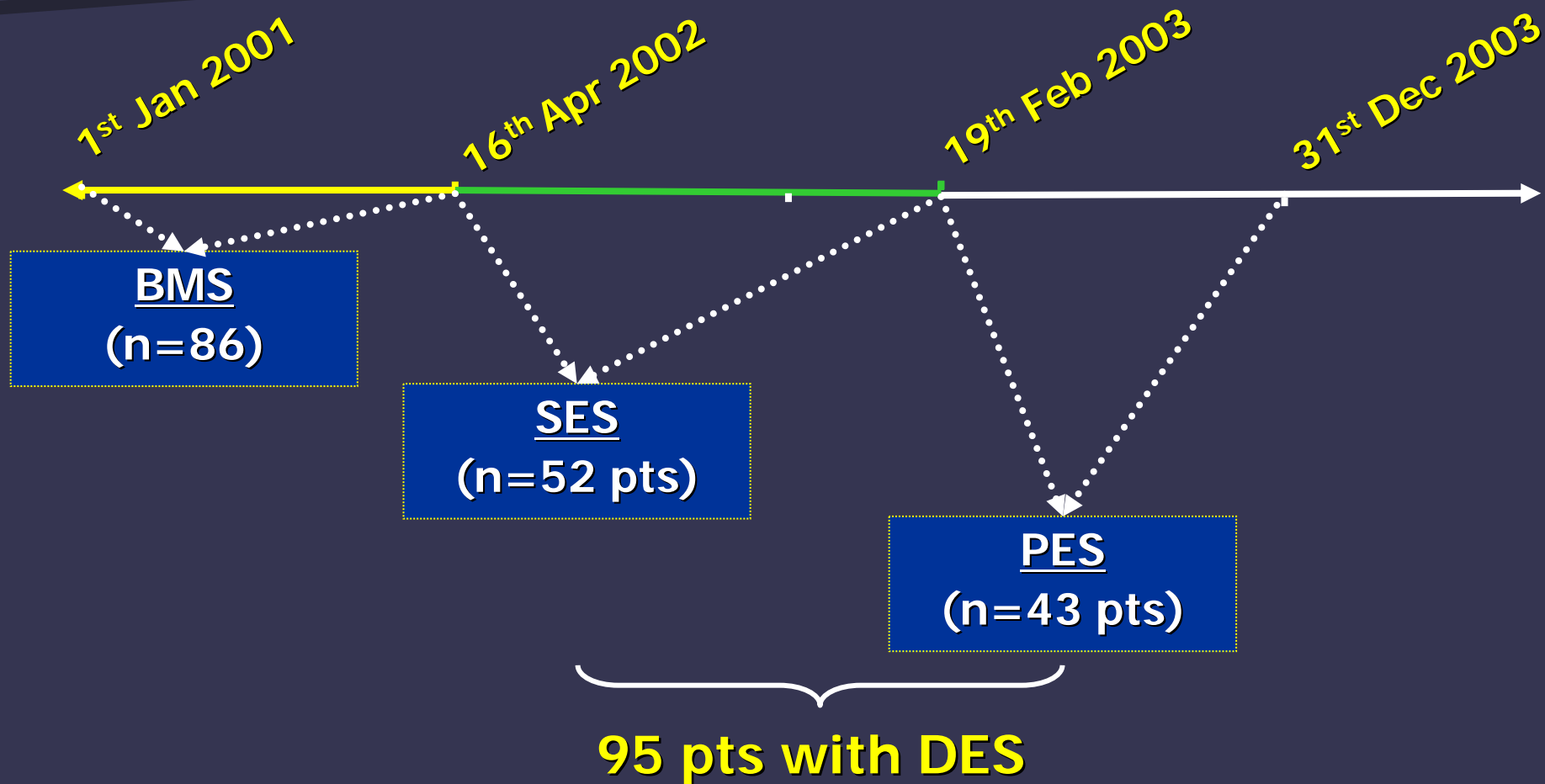
# Six month TLR In PCI series of unprotected LM



# Left Main Coronary Artery



# Left Main Substudy Population



## Left Main Coronary Artery



# Clinical Presentation (%)

Variables	BMS Group (N=86)	DES Group (N=95)	P-value
Stable Angina	50	48	0.8
Unstable Angina	33	33	1
Acute Myocardial Infarction*	17	20	0.70
Cardiogenic Shock at Entry*	9	12	0.66

\*: Parameters included in the Parsonnet classification

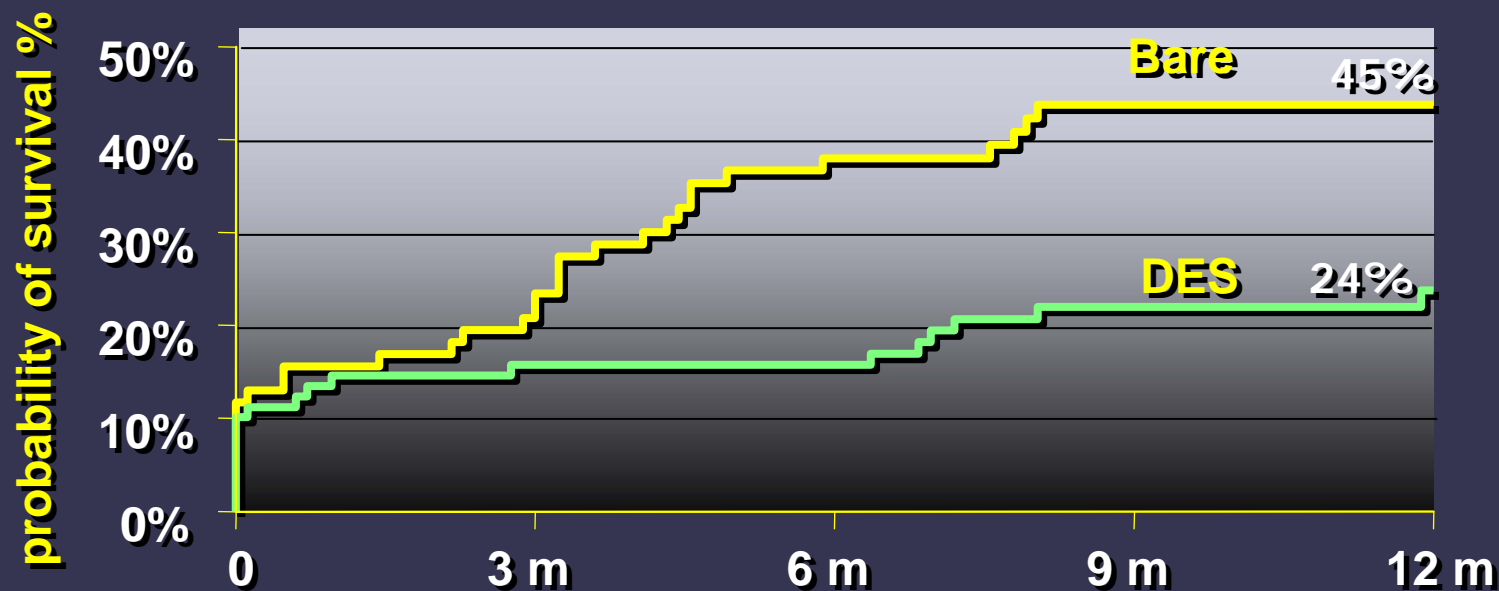


# Left Main Coronary Artery



## 1-year MACE Rate Whole Population

HR 0.54 [95% CI: 0.31-0.87]; p=0.01)



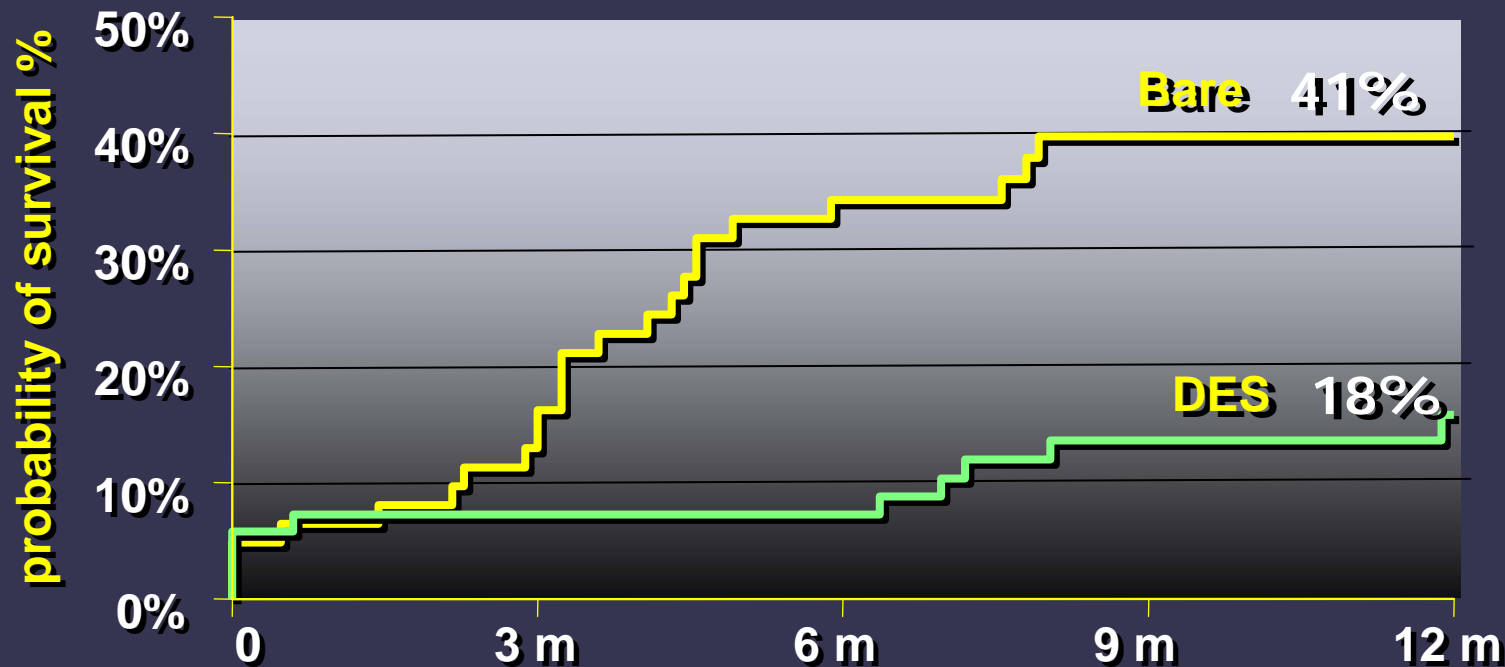
# Left Main Coronary Artery



## 1-year MACE Rate

Elective Population

HR 0.40 [95% CI: 0.21-0.78]; p=0.007)



Elective and unprotected (n=104) 38% vs. 15%  
(HR 0.37 [95% CI: 0.17-0.84]; p=0.01)

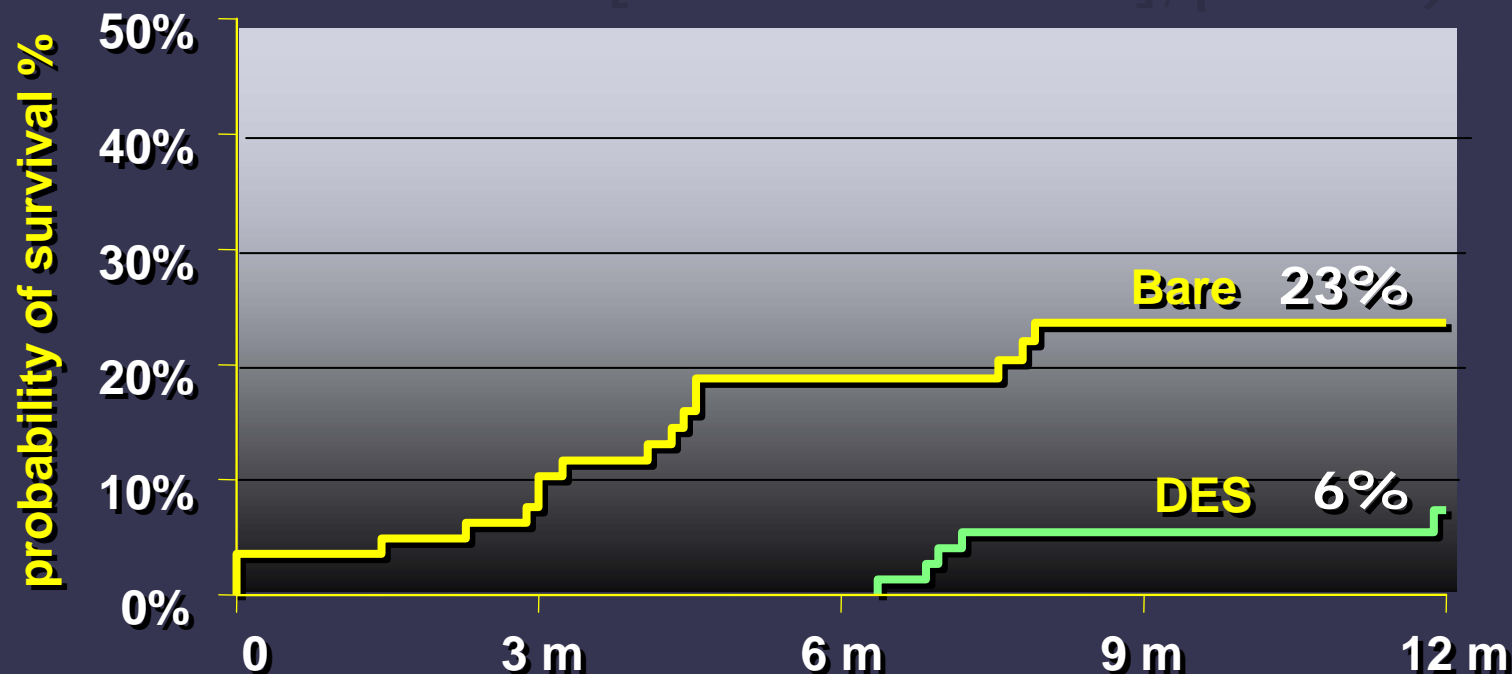
# Left Main Coronary Artery



## 1-year TVR

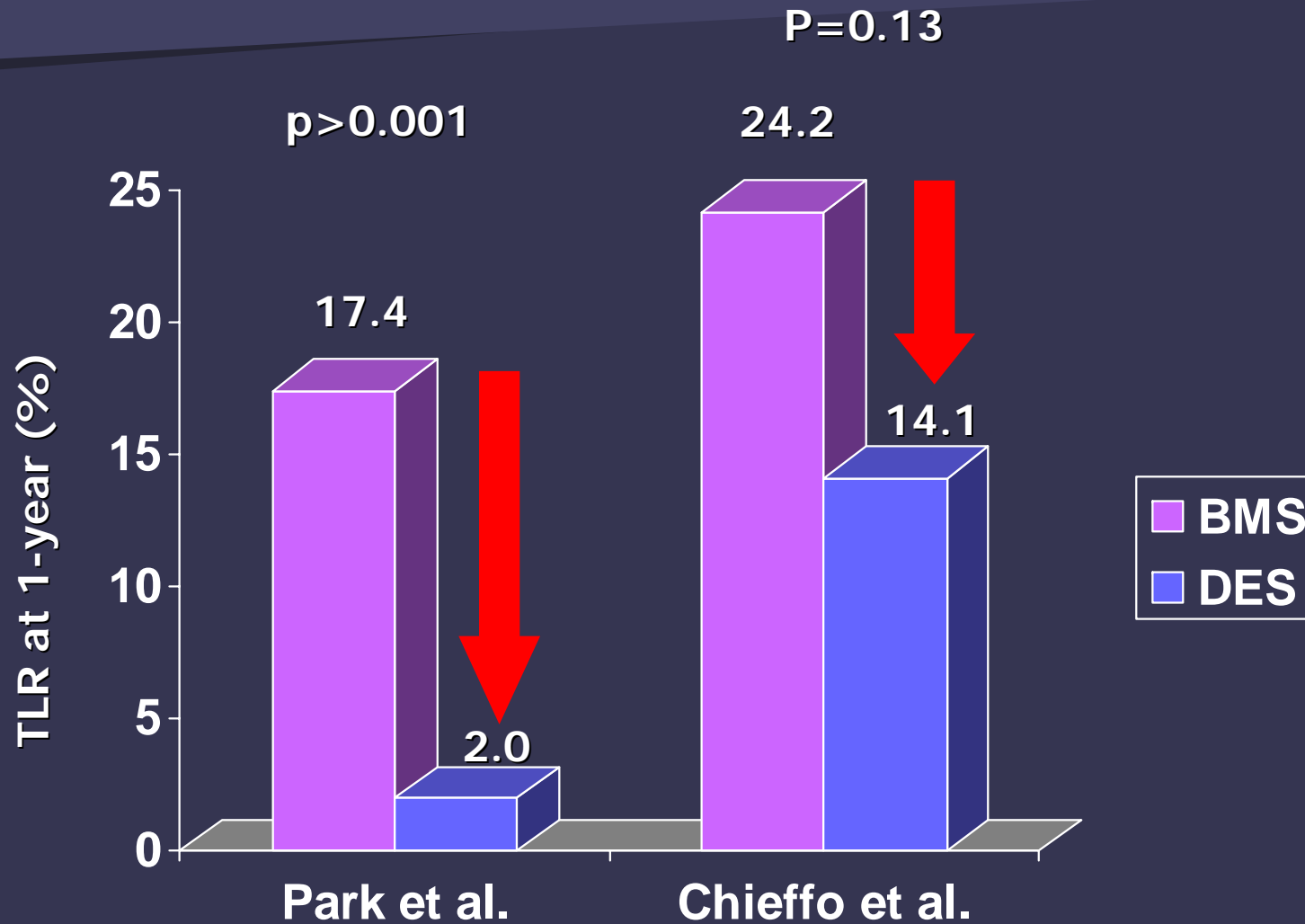
Whole Population

HR 0.26 [95% CI: 0.10-0.65]; p=0.004)



• Use of DES adjusted HR 0.33 [95% CI: 0.19-0.57];  
p=0.00009

# Re-Intervention Rates



# A COLLABORATIVE SYSTEMATIC REVIEW AND META-ANALYSIS ON 1,203 PATIENTS UNDERGOING PERCUTANEOUS DRUG- ELUTING STENTING FOR UNPROTECTED LMCA DISEASE

- At longest available F-up
  - MACE: 16.3% (11.4-21.2),
  - Death: 4.9% (2.8-7.0)
  - TVR: 6.5% (3.7-9.4)

**66%**

- DES versus BMS
  - HR for MACE 0.34 (0.16-0.71,  $p=0.004$ )

# LMCA DES Stenting...and so what?

- How to maximize DES performance?
  - Which DES?
  - IVUS guidance?
  - Single or systematic bifurcation stenting?
- What about Stent thrombosis?
- Should we start to DES LMCA BEFORE awaiting for RCT?



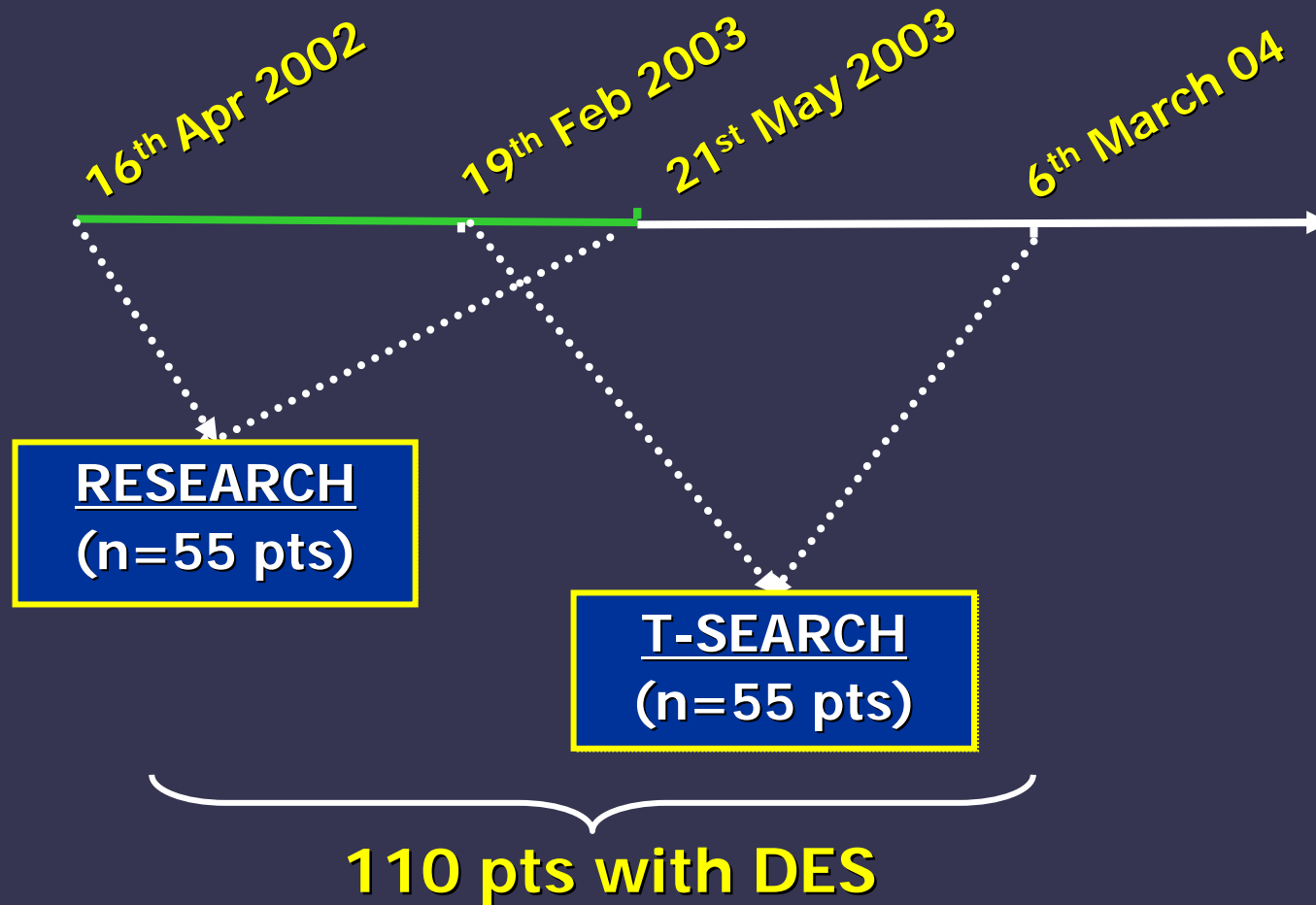
# LMCA DES Stenting...and so what?

- How to maximize DES performance?
  - Which DES?
  - IVUS guidance?
  - Single or systematic bifurcation stenting?
- What about Stent thrombosis?
- Should we start to DES LMCA BEFORE awaiting for RCT?

# Left Main Coronary Artery



## LMCA stenting at the Thoraxcenter

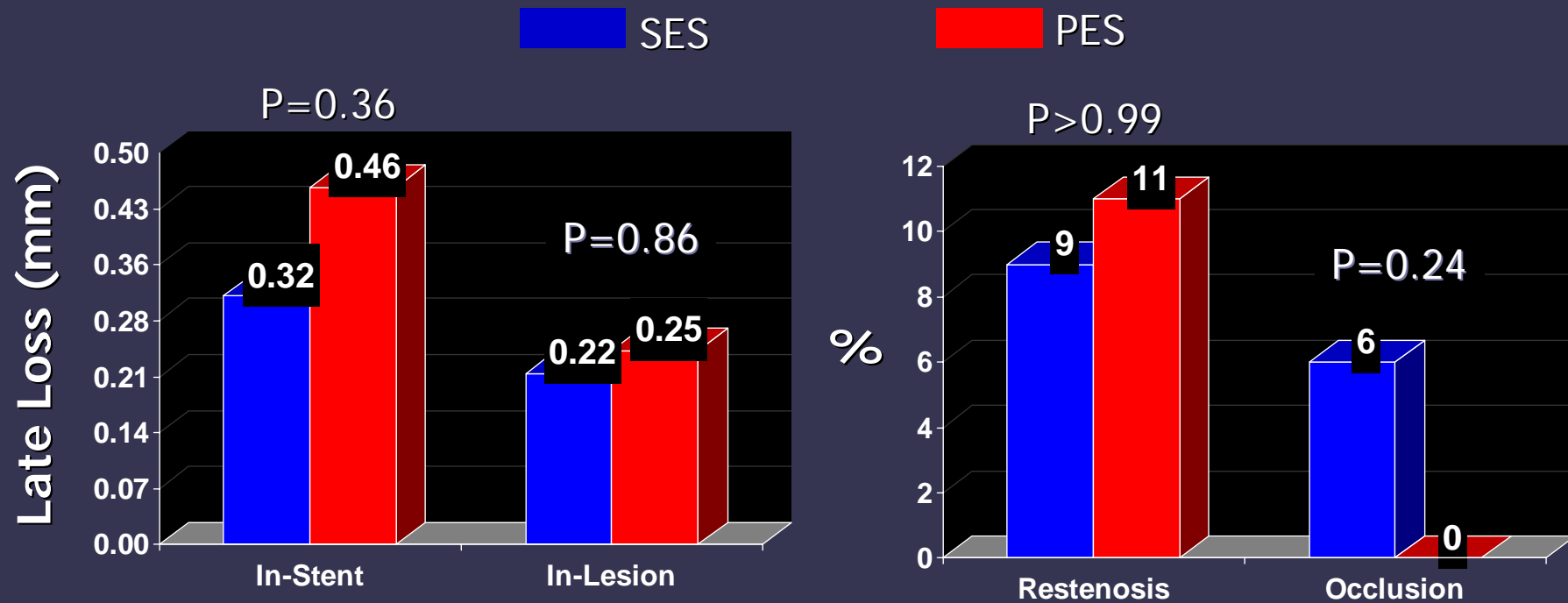


# Left Main Coronary Artery

## SES vs. PES

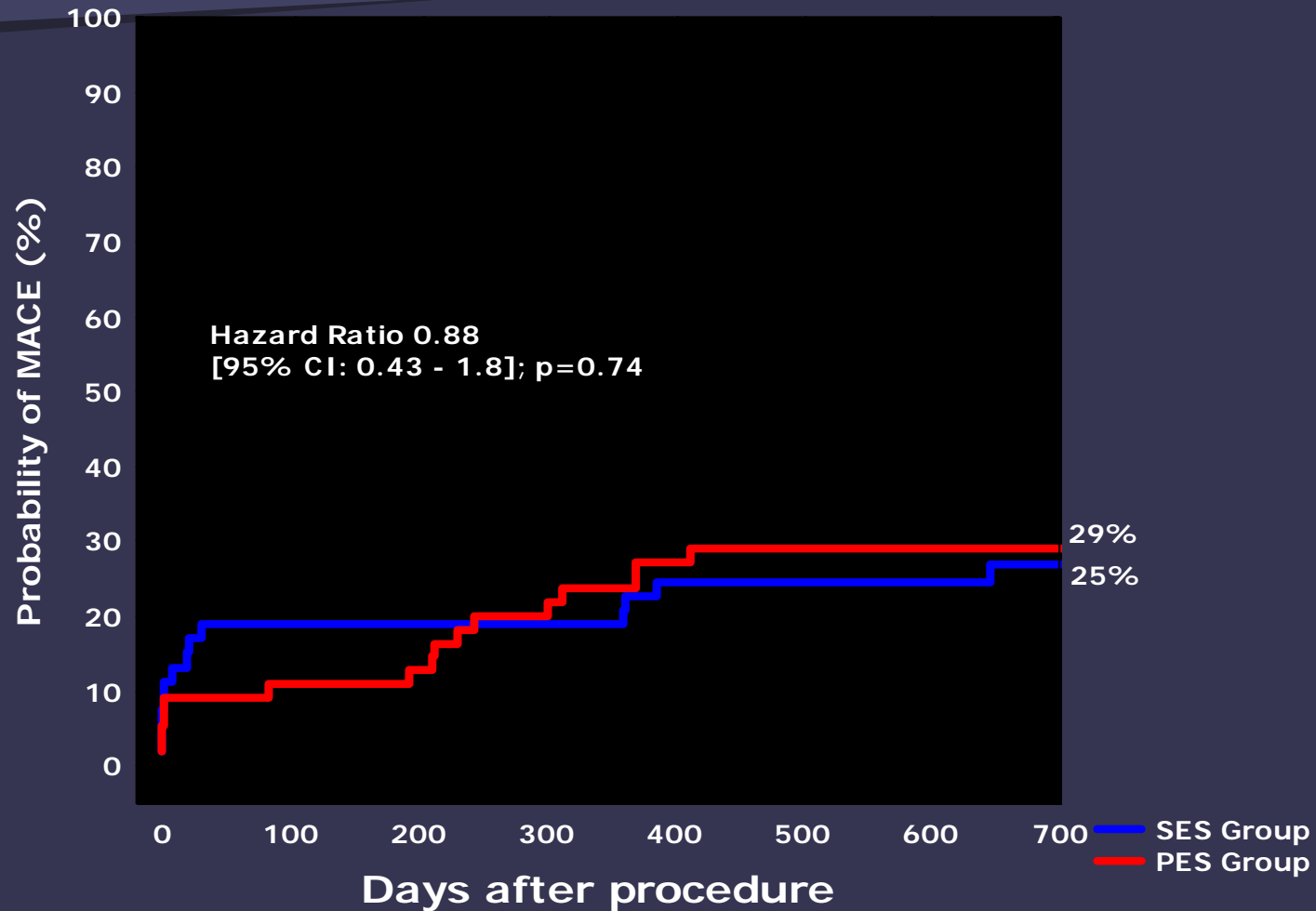


### Angiographic outcome



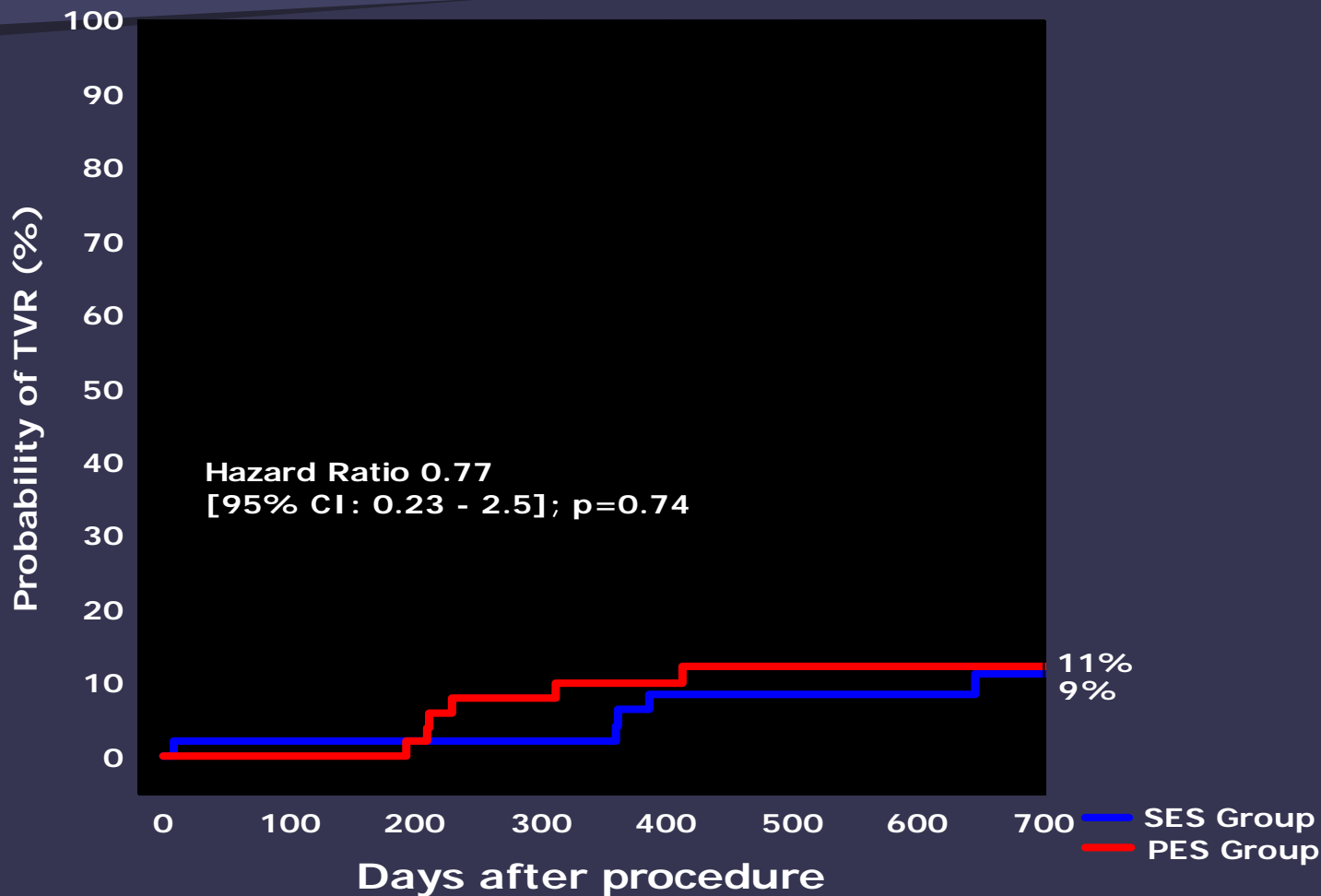
# Left Main Coronary Artery

## SES vs. PES



# Left Main Coronary Artery

## SES vs. PES

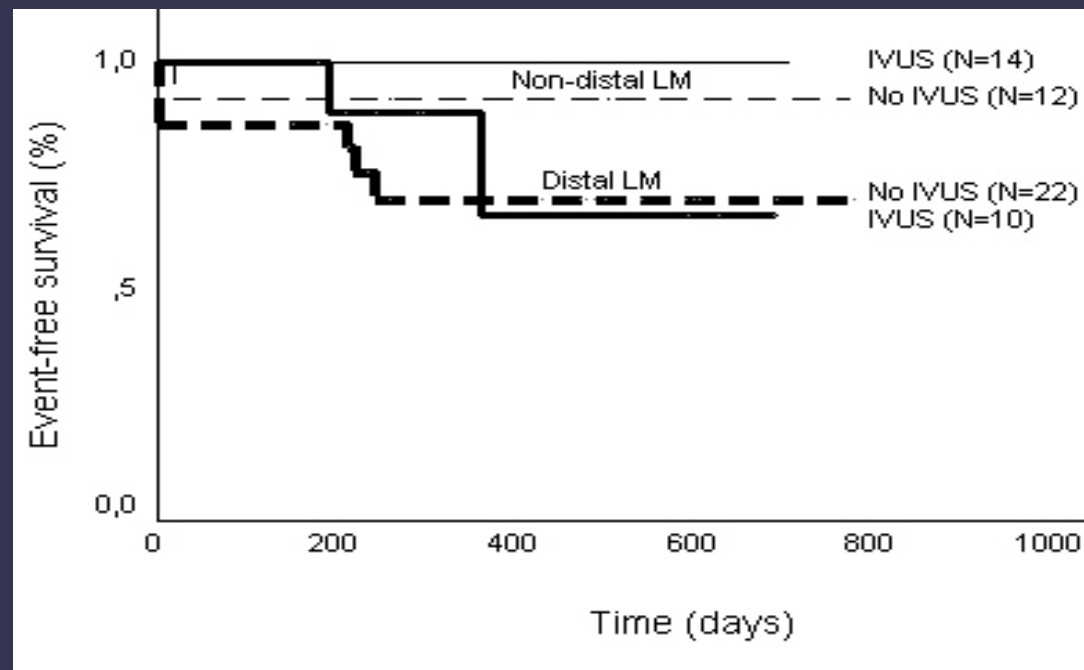


## Left Main Coronary Artery



# Role of IVUS

- 58 pts undergoing elective and unprotected intervention at LMCA
- 24 (41%) had Stent deployment under IVUS guidance



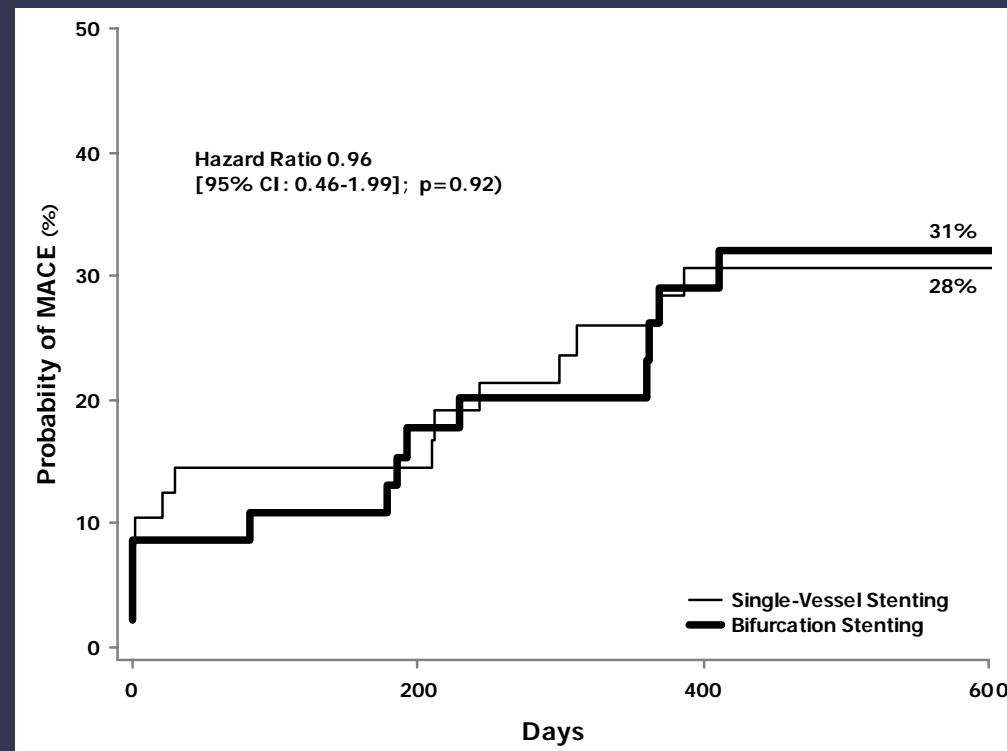


## Left Main Coronary Artery



# Role of Stenting technique

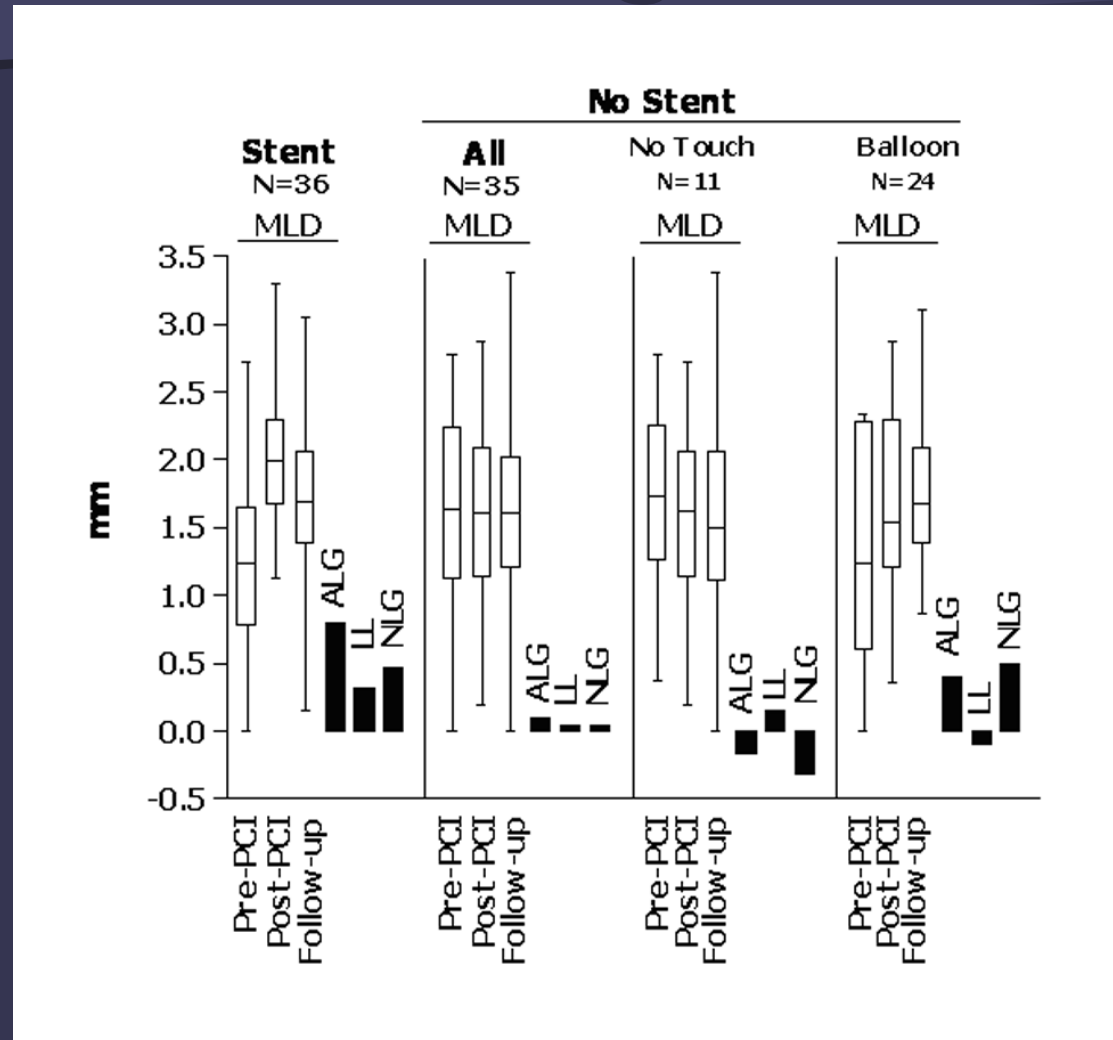
- 94 pts undergoing treatment for distal LMCA stenosis
- 48 (51%) pts received single vessel; 46 pts bifurcation stenting



# Left Main Coronary Artery



## Role of Stenting technique



# LMCA DES Stenting...and so what?

- How to maximize DES performance?
  - Which DES? **SES or PES**
  - IVUS guidance? **No data to recommend systematic IVUS**
  - Single or systematic bifurcation stenting?  
**The easiest the better**
- What about Stent thrombosis?
- Should we start to DES LMCA *BEFORE* awaiting for RCT?

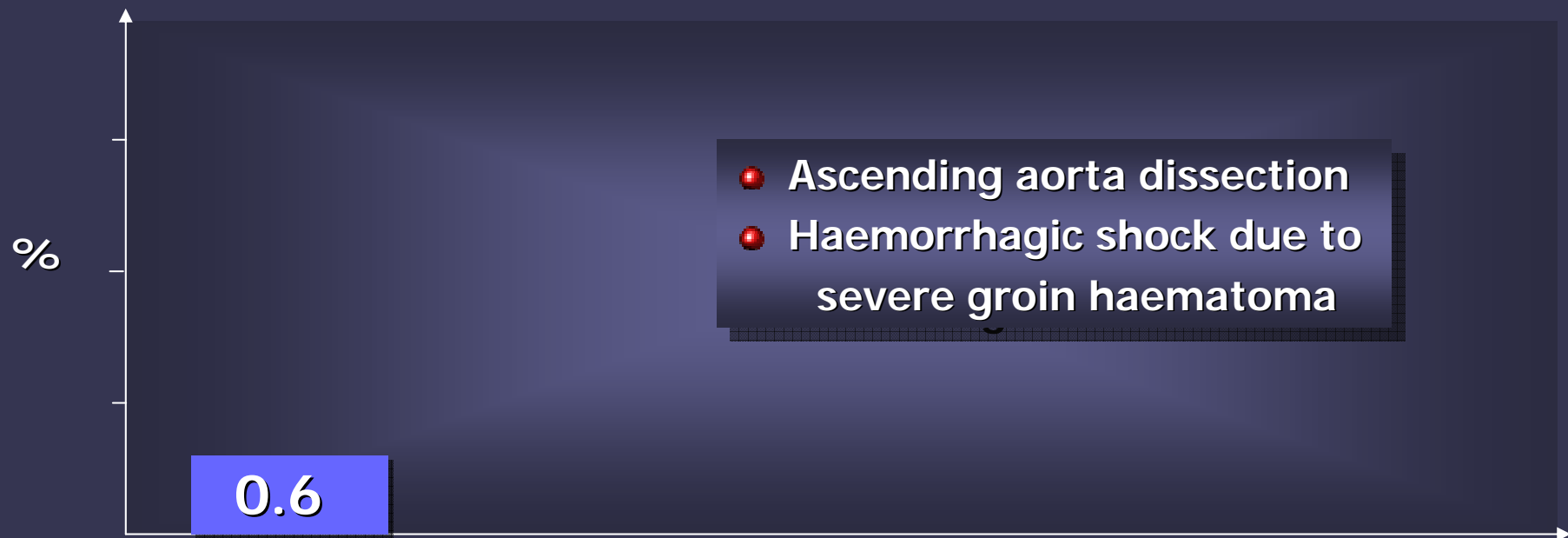
# LMCA DES Stenting...and so what?

- How to maximize DES performance?
  - Which DES?
  - IVUS guidance?
  - Single or systematic bifurcation stenting?
- What about Stent thrombosis?
- Should we start to DES LMCA BEFORE awaiting for RCT?

**A pooled analysis on 340 patients  
treated at three European referral  
centers (Milan\_Massy\_Rotterdam)**

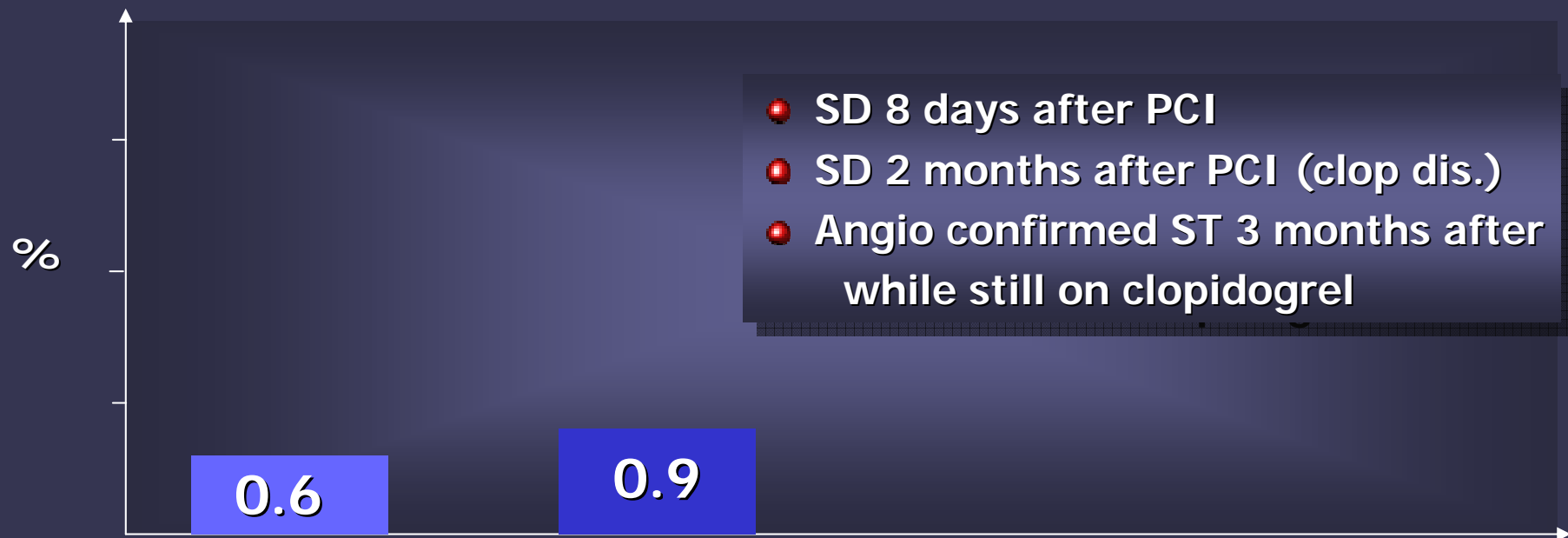
**A pooled analysis on 340 patients treated at three European referral centers (Milan\_Massy\_Rotterdam)**

## **In-hospital mortality**



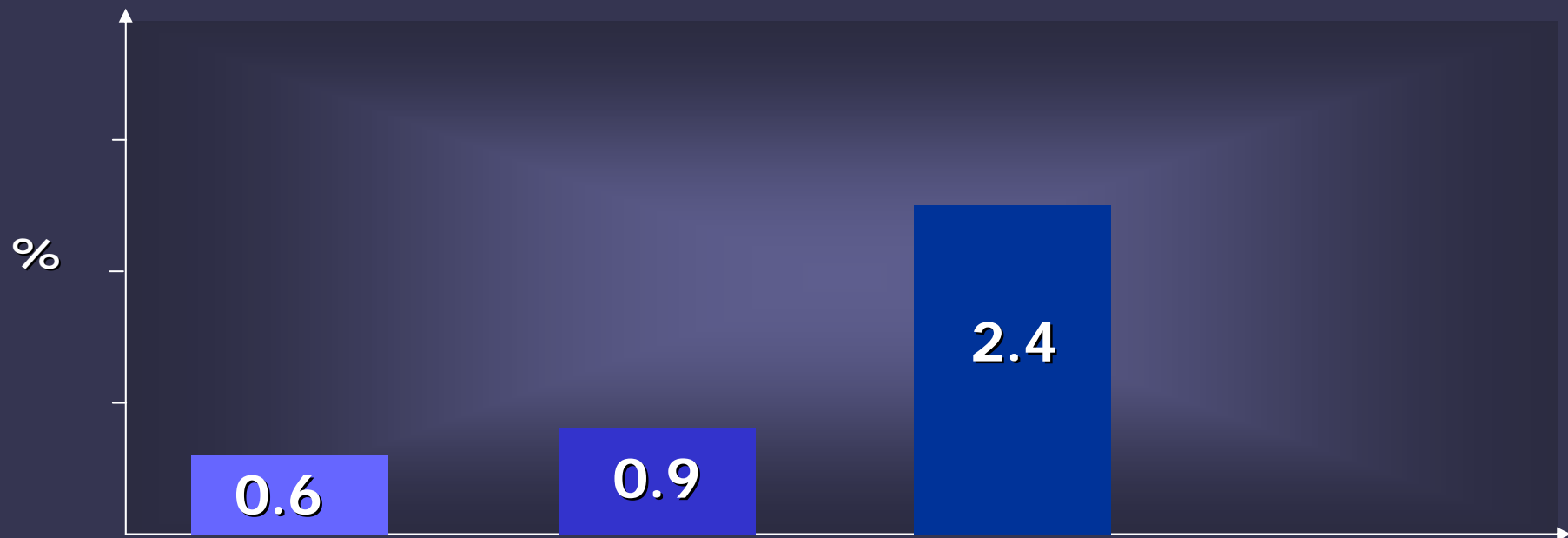
**A pooled analysis on 340 patients treated at three European referral centers (Milan\_Massy\_Rotterdam)**

## Stent thrombosis (ARC)



# A pooled analysis on 340 patients treated at three European referral centers (Milan\_Massy\_Rotterdam)

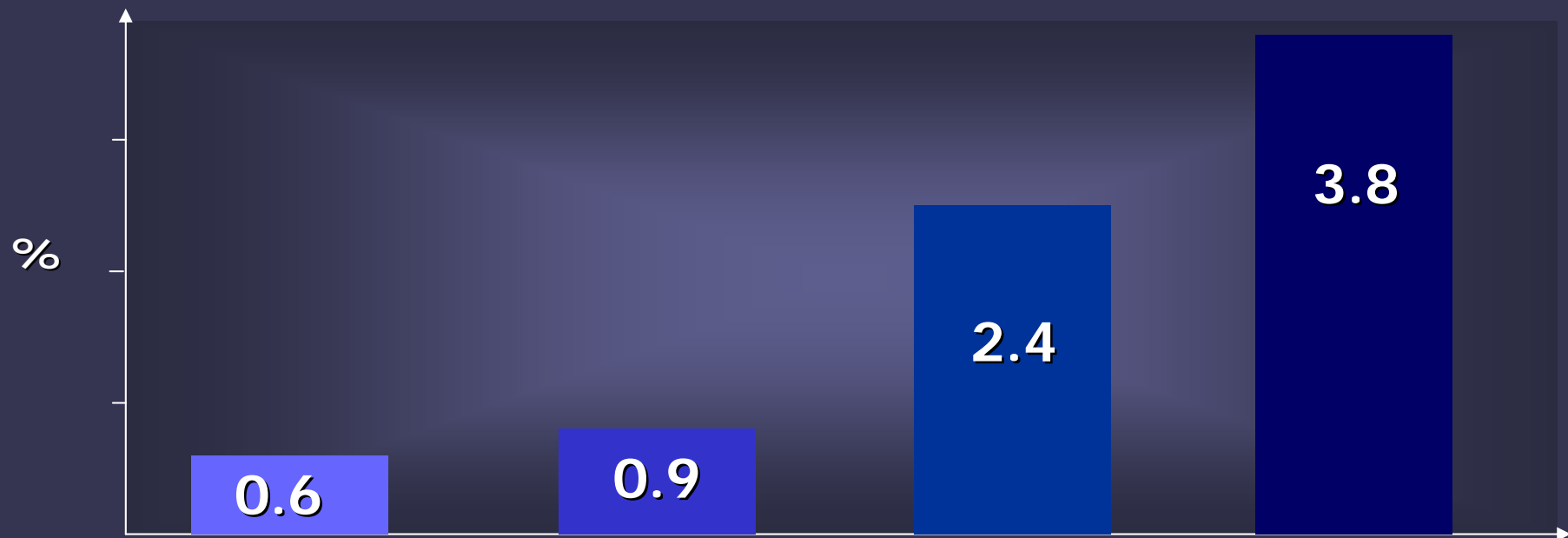
## out of hospital cardiac death-MI at 1-year





# A pooled analysis on 340 patients treated at three European referral centers (Milan\_Massy\_Rotterdam)

## Overall mortality rate at 1-year



# LMCA DES Stenting...and so what?

- How to maximize DES performance?

- Which DES?

- IVUS guidance?

- Single or systematic bifurcation stenting?

- What about Stent thrombosis?

Reassuring data...at 1-year!!

- Should we start to DES LMCA BEFORE awaiting for RCT?

# LMCA DES Stenting...and so what?

- How to maximize DES performance?
  - Which DES?
  - IVUS guidance?
  - Single or systematic bifurcation stenting?
- What about Stent thrombosis?
- Should we start to DES LMCA BEFORE awaiting for RCT?

**CABG is the**

**Because it reduces long term mortality  
compared to medical therapy**

**Gold Standard**

100% Guaranteed Customer Satisfaction