



# Left Main Stem Intervention : What does the data currently indicate?

Interesting cases from Malaysia  
'Malaysia Live' – Interventional  
Cardiac Society of Malaysia

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FNHAM; FAsCC; FACC; FSCAI


23<sup>rd</sup>. April, 2013

# Disclosure

- Speaking & Faculty honorariums from Novartis, MSD, Roche, Solvay Pharma, Xepa-Soul Pattinson, Servier, Sanofi, Cordis J&J, Astra Zeneca, Lilly, Medtronic, Biosensor, Terumo
- No share ownership in any pharmaceutical companies
- No conflict of interest with reference to this lecture or meeting



# Sypnosis

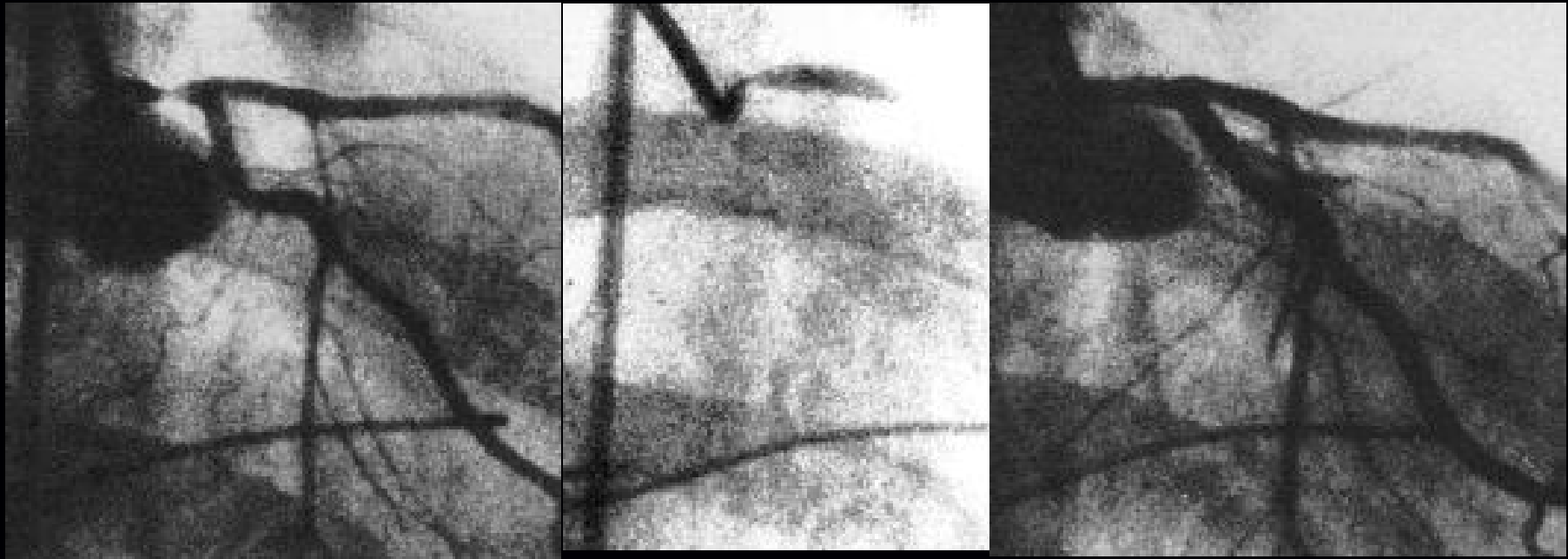
- Evidence for LMCA PCI vs CABG – Current Data RCT & Meta-analyses : Selection of patients for PCI
  - Technical Issues: BMS vs DES, New vs Old DES, Single vs 2-stent Techniques, Kissing Balloon Inflation
  - Optimisation of LM PCI Results : IVUS, FFR
  - Malaysia NCVD – PCI Registry : LM Intervention
  - Summary
- 





# Andreas Gruentzig's Log Book :

## 3<sup>rd</sup>. PCI case



“Third PCI patient ever treated. Forty-three year old man with severe angina pectoris since September, 1977. First angiogram (November 11) revealed severe stenosis of the main L.C.A. . . .”

Note: The patient expired suddenly about 4 months after this procedure.

Gruntzig A. Lancet 1978;1:263.

# Since 1994 :

1994

- Started BMS in Unprotected LM disease,

1998

- **J Am Coll Cardiol 1998;31:37-42 : Early experience,**
- Am J Cardiol 1998;82:670-3 : IVUS analysis
- J Am Coll Cardiol 2001;38:1054-60 : Role of debulking
- Circulation 2001;104:1609-1614 : ULTIMA registry
- Am J Cardiol 2002;90:374-8 : Bifurcation stenting
- Am J Cardiol 2003;91:12-6 : Long-term outcome
- Clin Cardiol 2004;27:393-5 : Bail-out stenting
- Int J Cardiol 2004;97:73-6 : Acute MI
- JACC 2005;45:351-6 : SES stenting.

2008

- Am J Cardiol 2006;98:1567-1570 : EuroSore evaluation
- Int J of Cardiology 2007. 208-213 : 5 year F/U data
- Catheter Cardio Interv 70:840-846, 2007: Kissing stent technique long-term

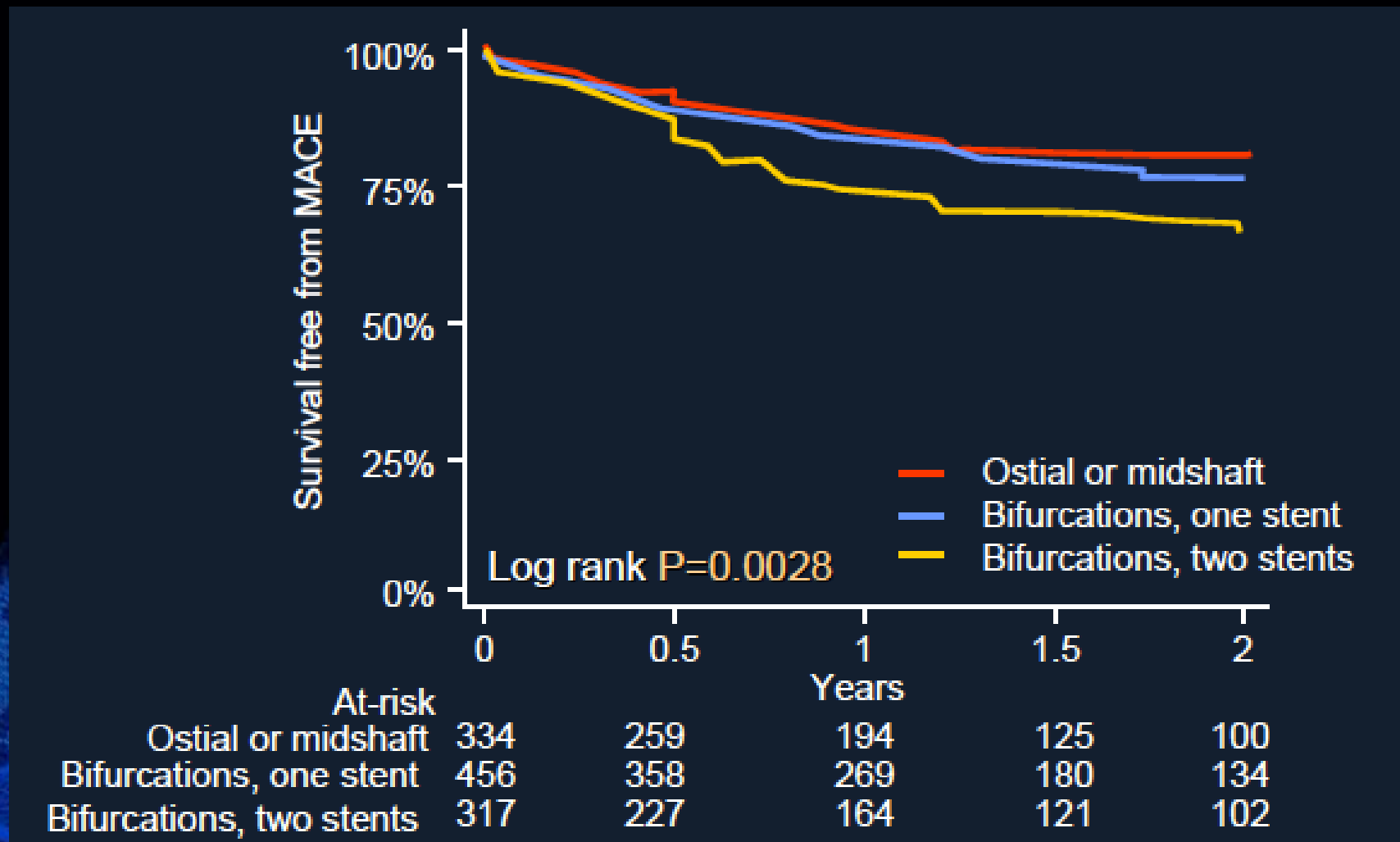
2011  
2012

- **NEJM. 2008 Apr 24;358(17):1781-92. MAIN COMPARE registry**
- JACC, ASAN-MAIN registry, MAIN-COMPARE 5-year results
- **NEJM, 2011 May 5;364(18):1718-27. PRECOMBAT, Randomized Study of PCI vs.CABG**
- Circulation. Cardiovascular Interventions. 2010 Apr;3(2):127-33, Major Predictor of Outcomes
- Journal of the American College of Cardiology. 2010 Oct 19;56(17):1366-75, 5-10 years Longterm
- JACC. Cardiovascular Interventions. 2011 Nov;4(11):1168-74, New IVUS MLA of LM, 4.8 mm<sup>2</sup>
- Circulation. Cardiovascular Interventions. 2011 Dec 1;4(6):562-9, Stent Optimization
- Catheterization and Cardiovascular Interventions. 2011 Jul 29, IVUS POC Concept
- Circulation. Cardiovascular Interventions. 2011 Aug 1;4(4):355-61, Geometric Changes after Single Stent Cross Over
- Circulation Journal. 2011 Apr;75(4):749-55. Review
- Journal of the American College of Cardiology. 2011 Mar 22;57(12):1349-58 , LM DES-ISR
- Catheterization and Cardiovascular Interventions. 2011 Apr;1:77:775-782, 1 vs. 2 stents in LM
- The American Journal of Cardiology. 2011 Feb 1;107(3):367-73 , MLA of POC influenced Severity of LM disease
- JACC. Cardiovascular Interventions. 2012 Jul;5(7):708-17, PRECOMBAT2,
- Catheterization and Cardiovascular Interventions. 2012 Aug 1;80(2):206-12. Os and Shaft lesion Long-term, MAIN COMPARE,
- Circulation. Cardiovascular Interventions. 2012 Aug 7, PCI vs.CABG in DM
- Current Treatment options in Cardiovascular Medicine. 2012 Feb;14(1):108-16. Review

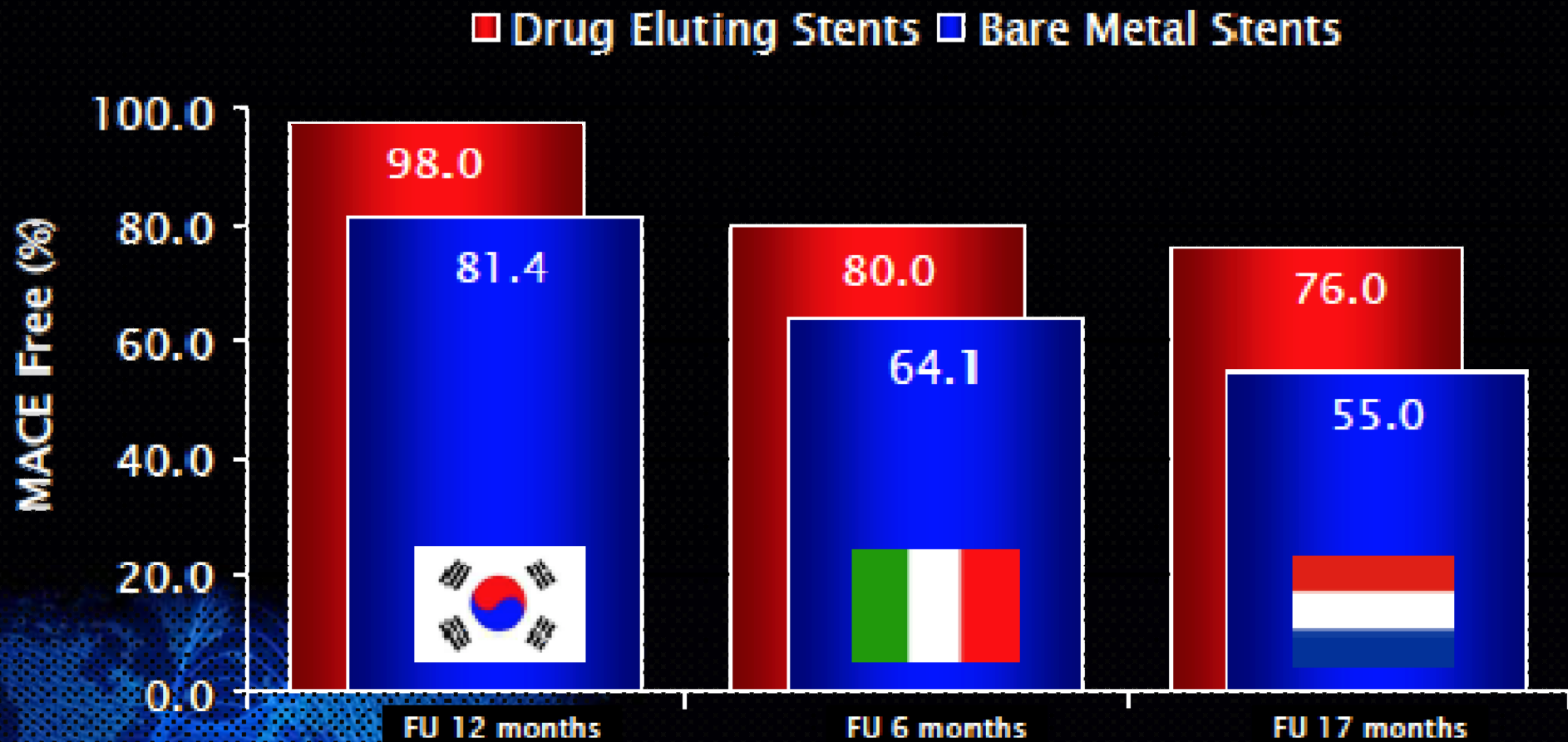
**>1200 Left Main PCI,  
42 Publications.**

# Ostial and Mid-shaft vs. Bifurcation in LMCA PCI: GISE-SICI

1111 patients treated with DES; 2 year follow-up



# BMS vs DES in LM PCI: MACE



DES better than  
BMS

Park S-J. J Am Coll Cardiol 2005;45:351-356

Valgimigli M. Circ 2005;111:1383-1389

Chieffo. Circ 2005;111:791-795



# MAIN-COMPARE Registry :

## DES PCI vs CABG for LM CAD

(N=2240, Stent 1102, CABG 1139, Propensity Matched Pair 542)

ORIGINAL ARTICLE

### Stents versus Coronary-Artery Bypass Grafting for Left Main Coronary Artery Disease

Ki Bae Seung, M.D., Duk-Woo Park, M.D., Young-Hak Kim, M.D., Seung-Whan Lee, M.D., Cheol Whan Lee, M.D., Myeong-Ki Hong, M.D., Seong-Wook Park, M.D., Sung-Cheol Yun, Ph.D., Hyeon-Cheol Gwon, M.D., Myung-Ho Jeong, M.D., Yangsoo Jang, M.D., Hyo-Soo Kim, M.D., Pum Joon Kim, M.D., In-Whan Seong, M.D., Hun Sik Park, M.D., Taehoon Ahn, M.D., In-Ho Chae, M.D., Seung-Jea Tahk, M.D., Wook-Sung Chung, M.D., and Seung-Jung Park, M.D.

NEJM 2008;358:1781-92

# MAIN-COMPARE Registry

## Stenting (BMS vs. DES) vs. CABG

January, 2000

### Phase I (Era of Bare-Metal Stents)

LMCA disease (N=775)

BMS (N=336)

CABG (N=439)

March, 2003

### Phase II (Era of Drug-Eluting Stents)

LMCA disease (N=1536)

DES (N=805)

CABG (N=731)

June, 2006

Total (N=2311)

PCI (N=1141)

CABG (N=1170)

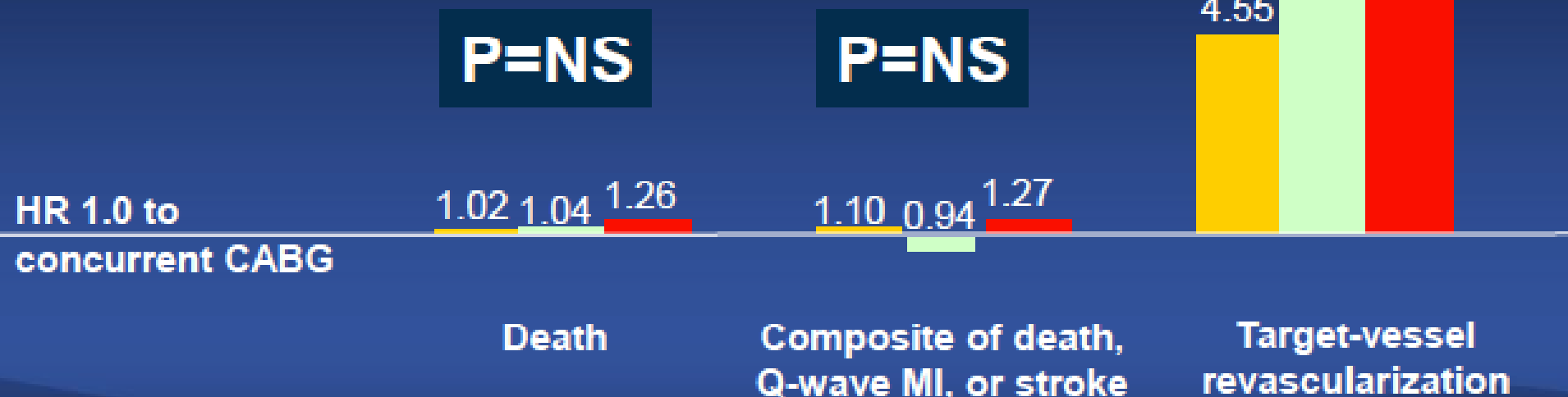


# Hazard Ratios for Clinical Outcomes

## Median 5-Year Outcomes

- All PCI patients (n=542 pairs)
- Bare-metal stents (n=207 pairs)
- Drug-eluting stents (n=542 pairs)

**P<0.001**



# PCI vs. CABG for Left Main Disease

## Meta-analysis of 4 RCTs.

N=1,611 pts

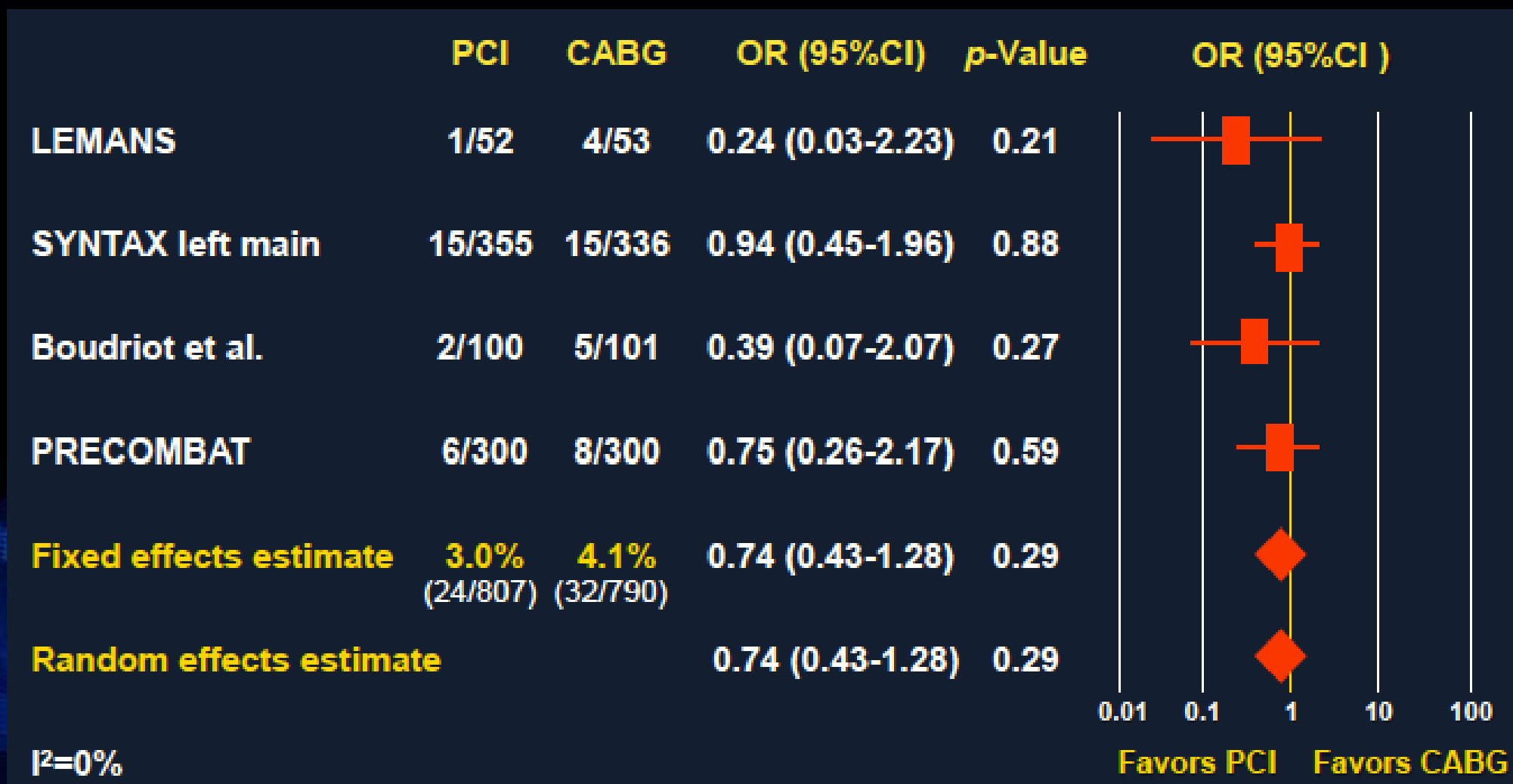
Trial	LEMANS	SYNTAX LM	Boudriot et al.	PRECOMBAT
Year	2008	2009	2010	2011
N total	105	705	201	600
Age, mean years	61	65	68	62
Male	67%	74%	75%	77%
Diabetes	18%	25%	36%	32%
Distal LM involved	58%	61%	71%	65%
+0/1/2/3 VD, %	0/9/23/68	13/20/31/36	29/31/27/14	10/17/32/41
Syntax Score, mean	25	30	24	25
Log Euroscore, mean	3.4	3.9	2.5	2.7
LIMA-LAD	81%	97%	99%	94%



# PCI vs. CABG for Left Main Disease

## Meta-analysis of 4 RCTs.

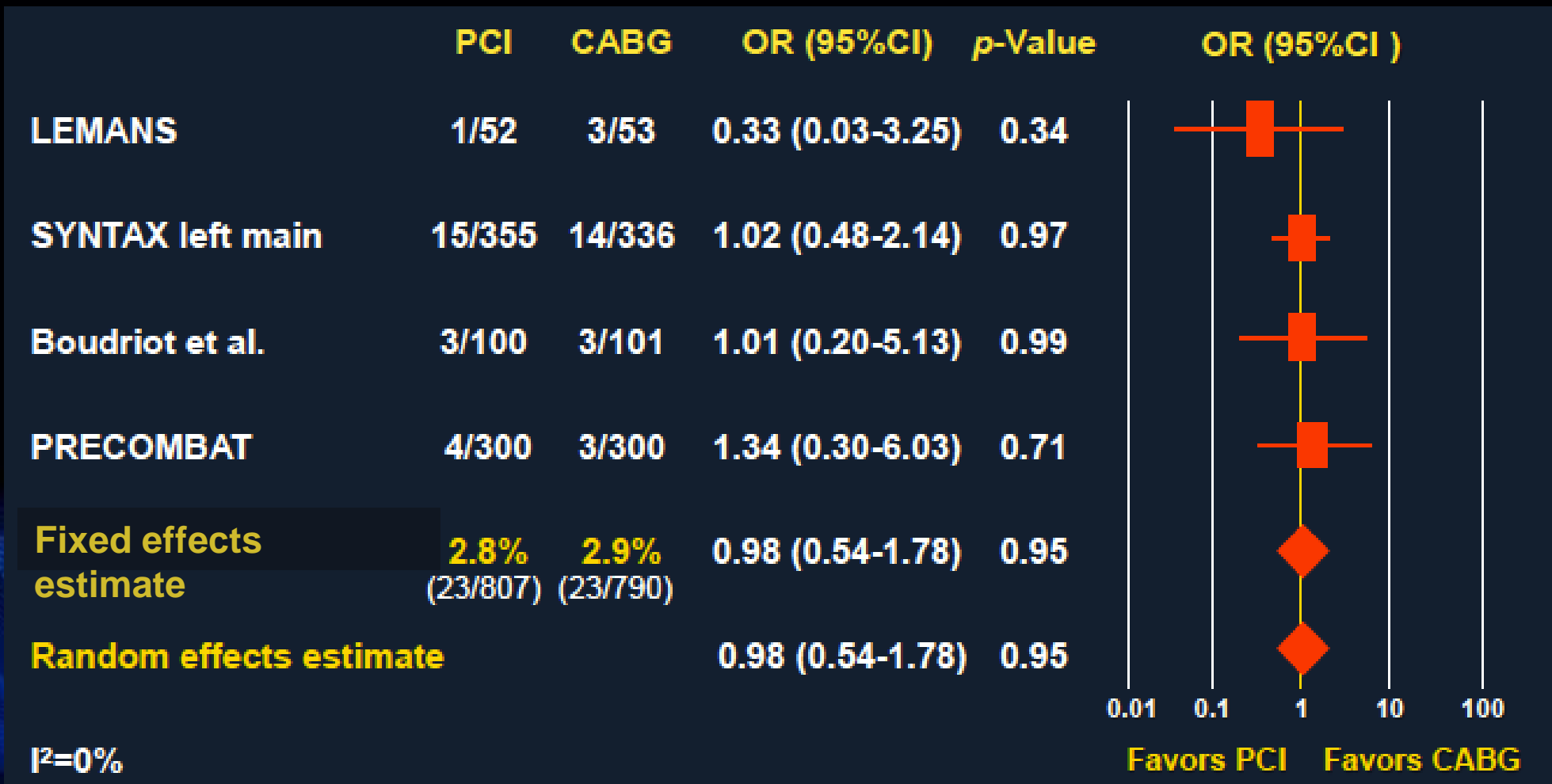
### 1 year mortality



# PCI vs. CABG for Left Main Disease

## Meta-analysis of 4 RCTs.

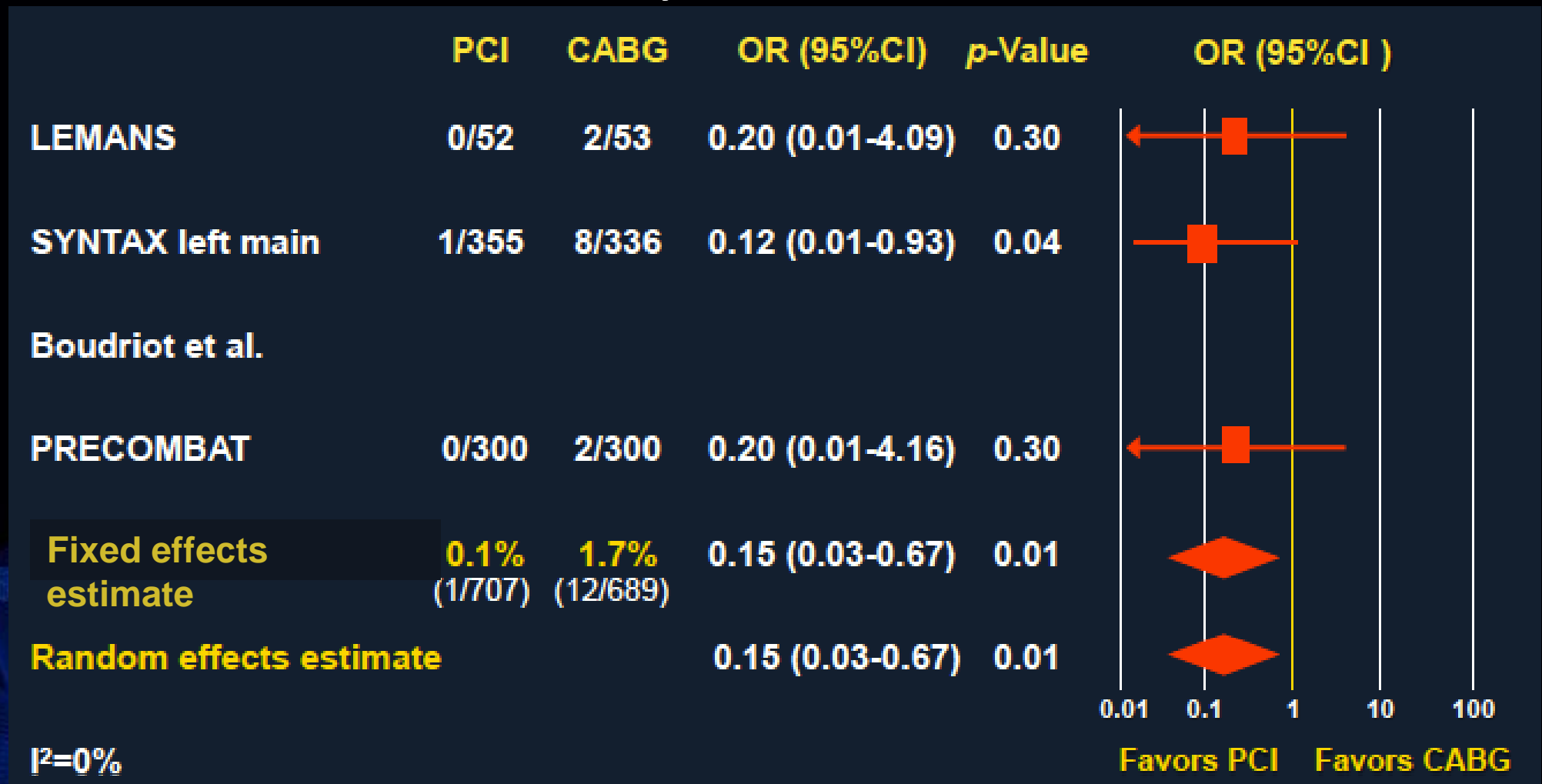
1 year MI



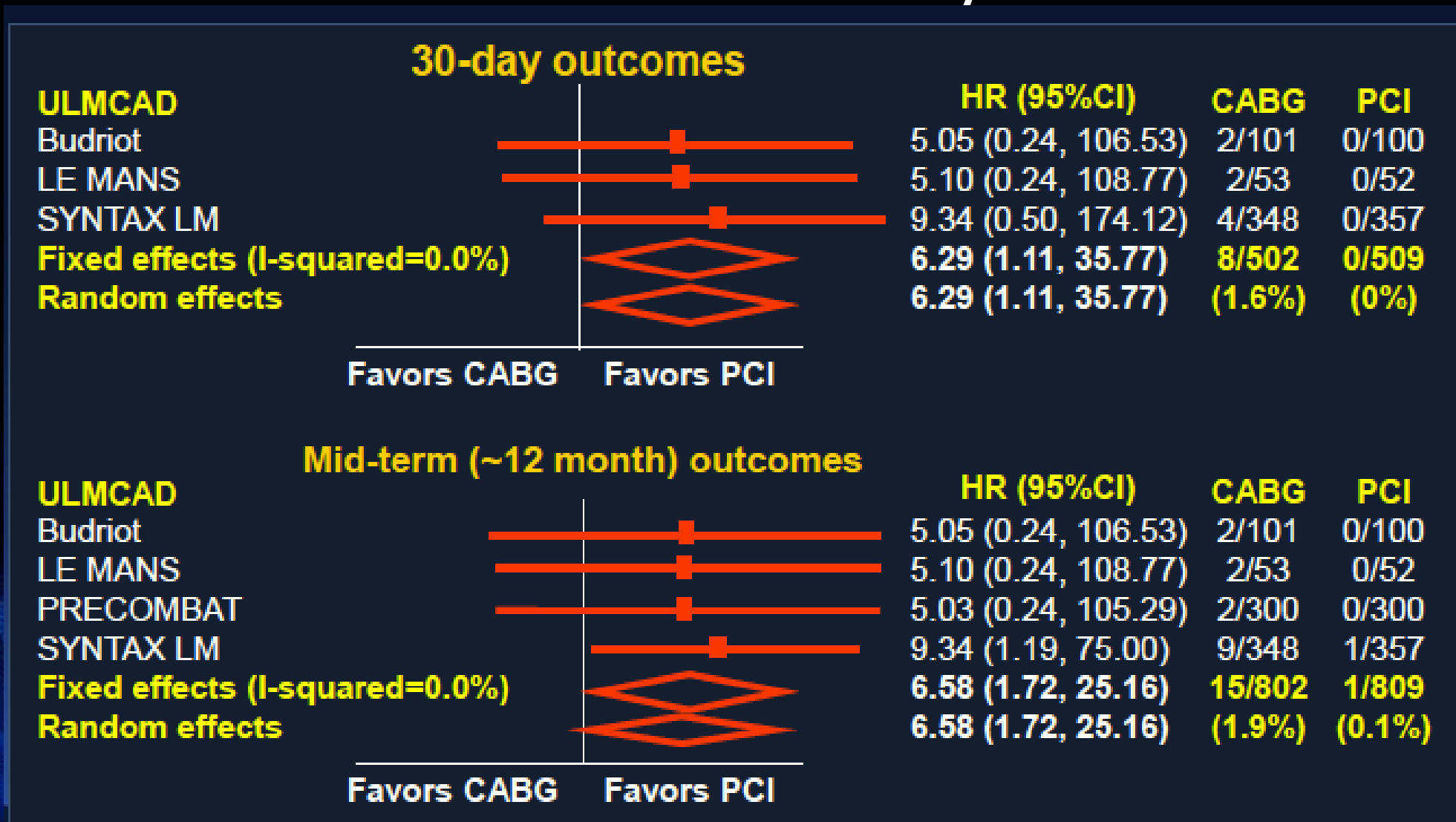
# PCI vs. CABG for Left Main Disease

## Meta-analysis of 4 RCTs.

### 1 year stroke



# PCI vs. CABG in LMCA disease: Stroke Meta-analysis

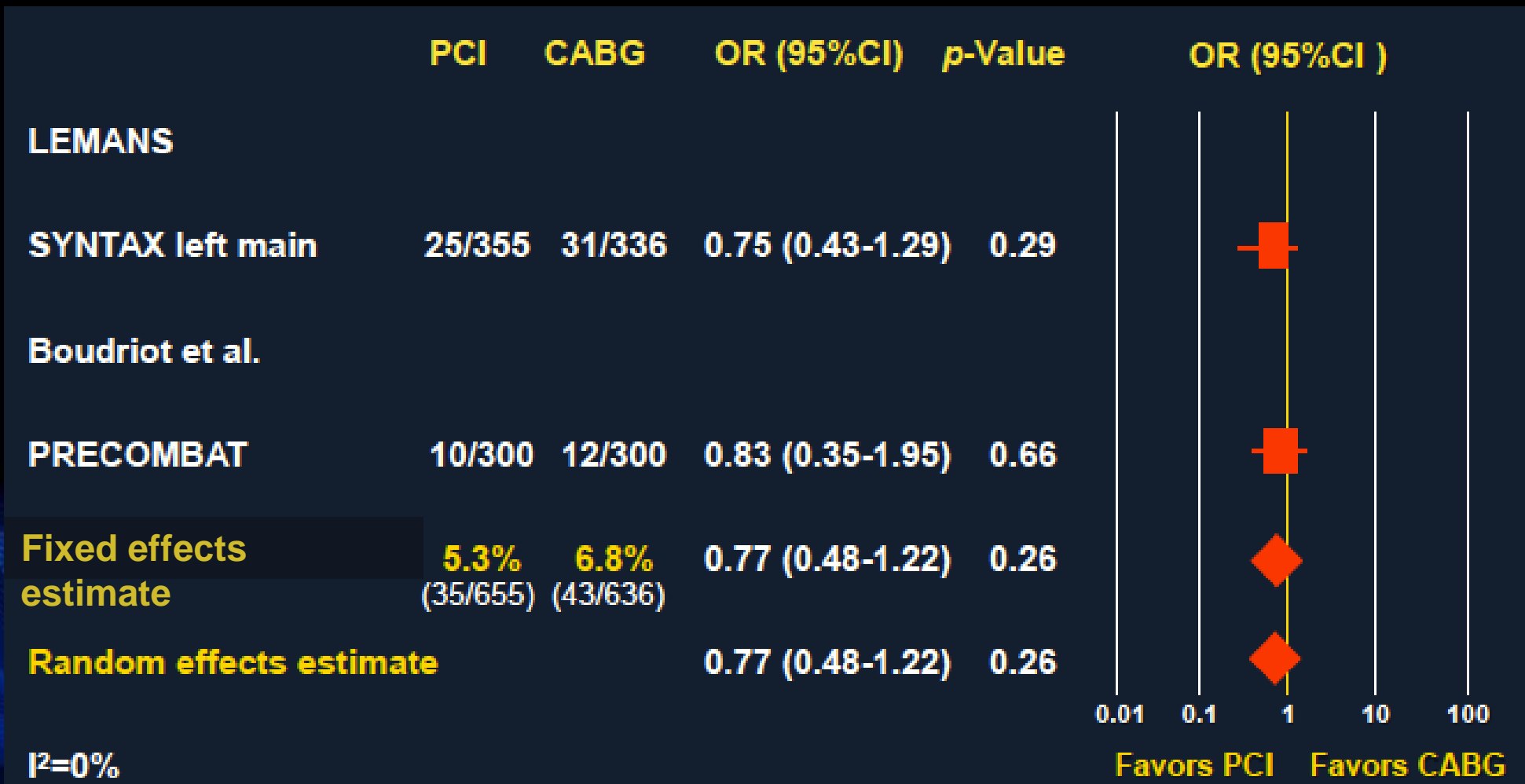




# PCI vs. CABG for Left Main Disease

## Meta-analysis of 4 RCTs.

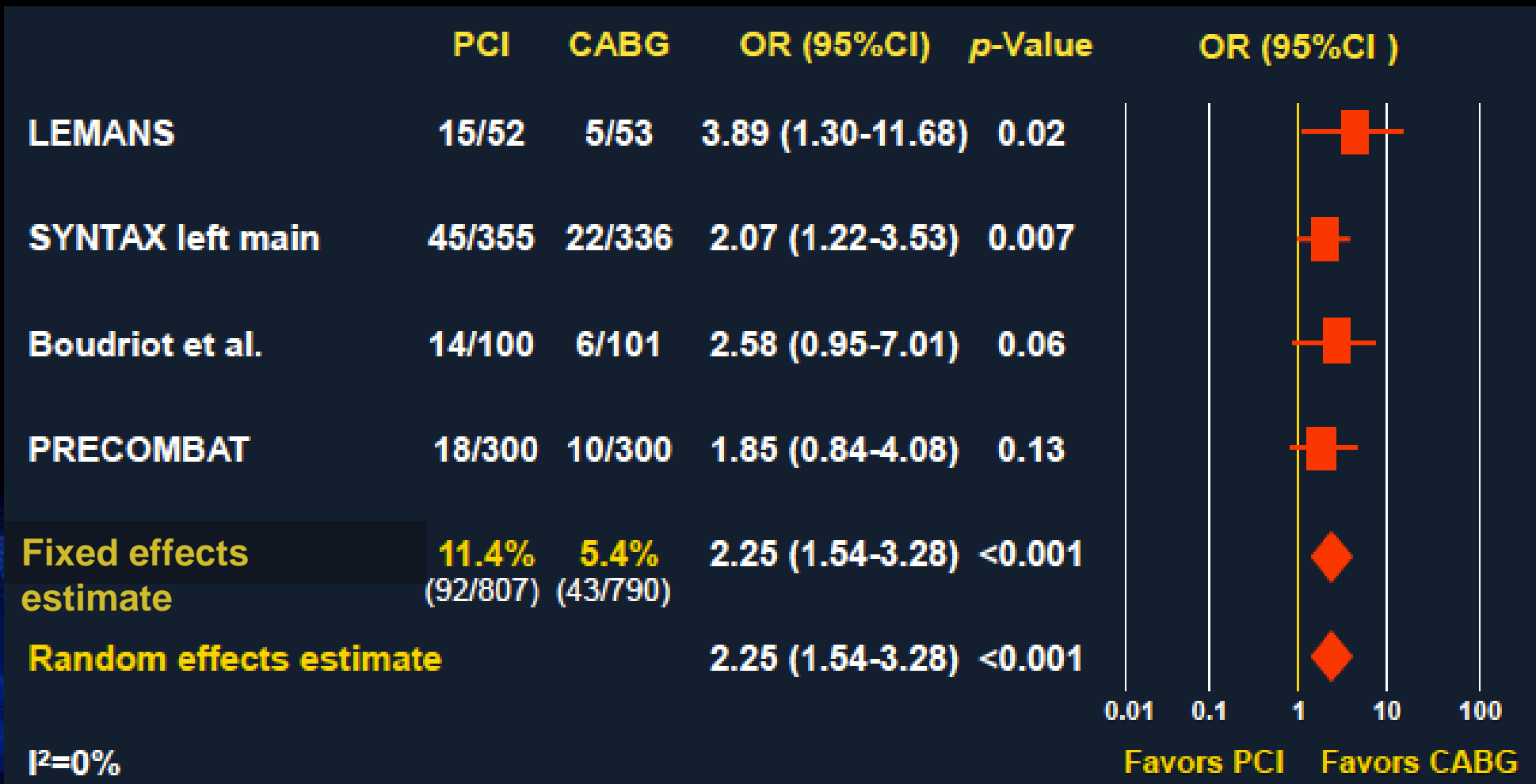
### 1 year Death/MI/Stroke



# PCI vs. CABG for Left Main Disease

## Meta-analysis of 4 RCTs.

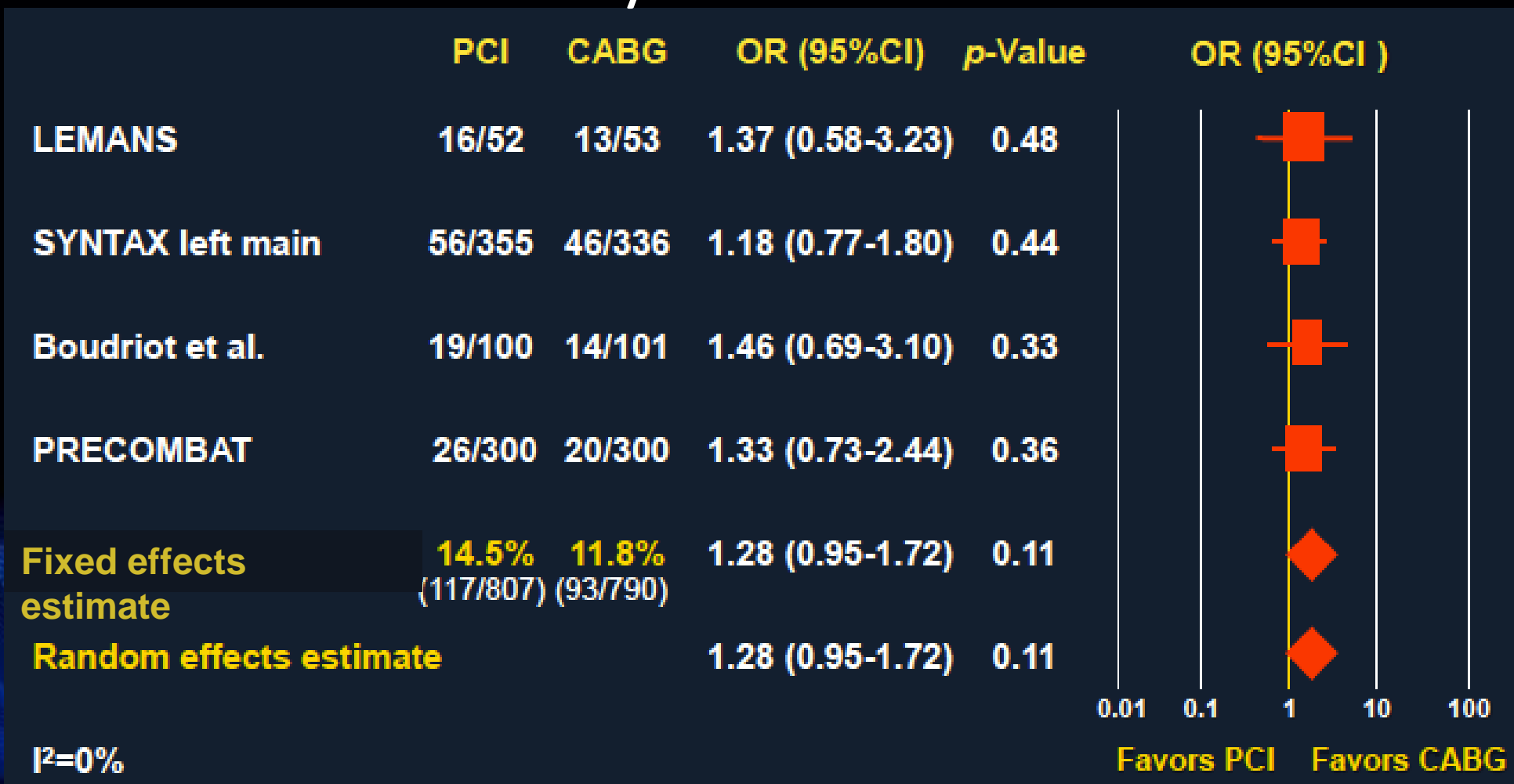
1 year TVR



# PCI vs. CABG for Left Main Disease

## Meta-analysis of 4 RCTs.

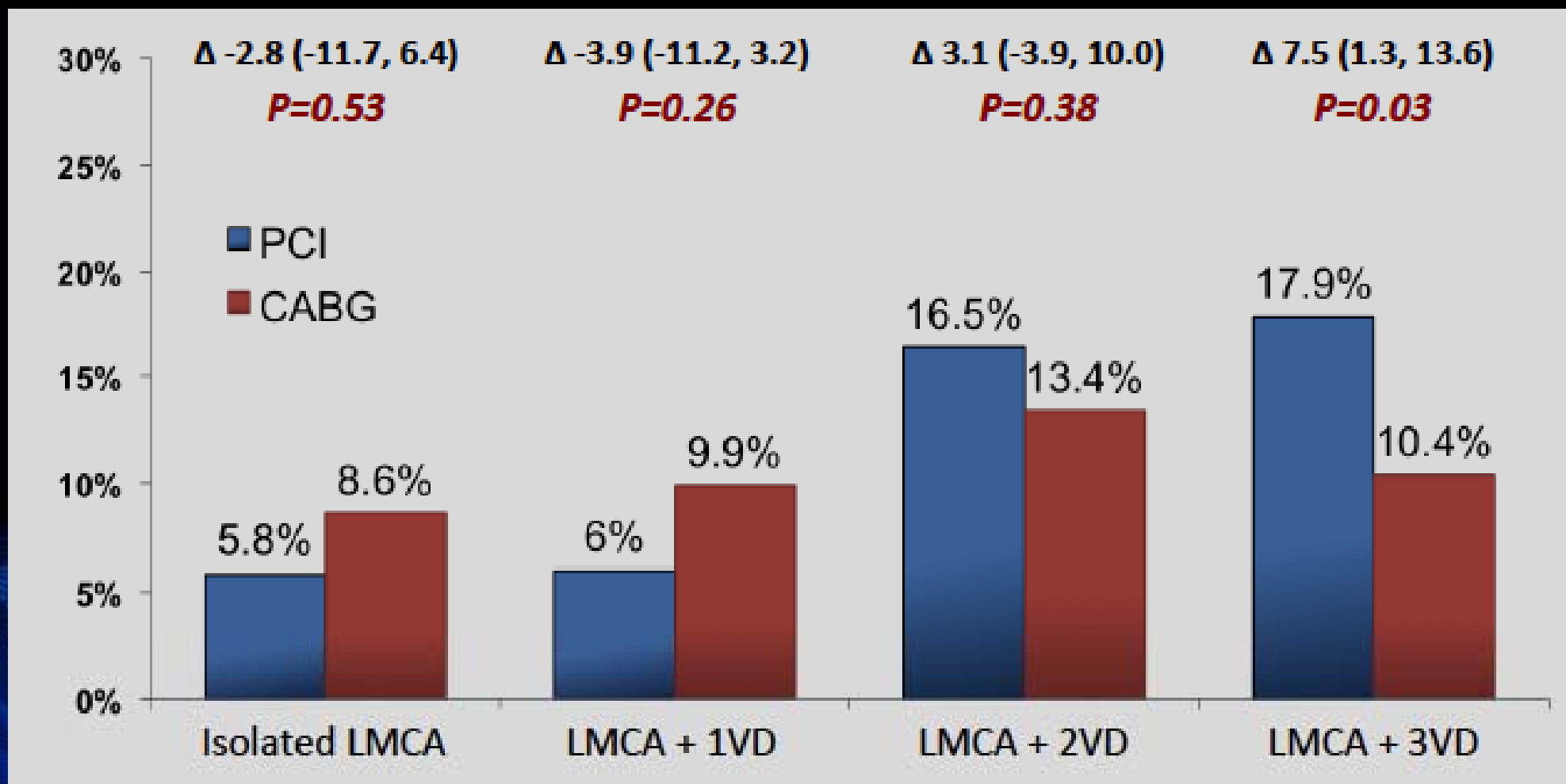
### 1 year MACCE



# PCI vs. CABG for Left Main Disease

## Meta-analysis of 4 RCTs, 1,611 Patients

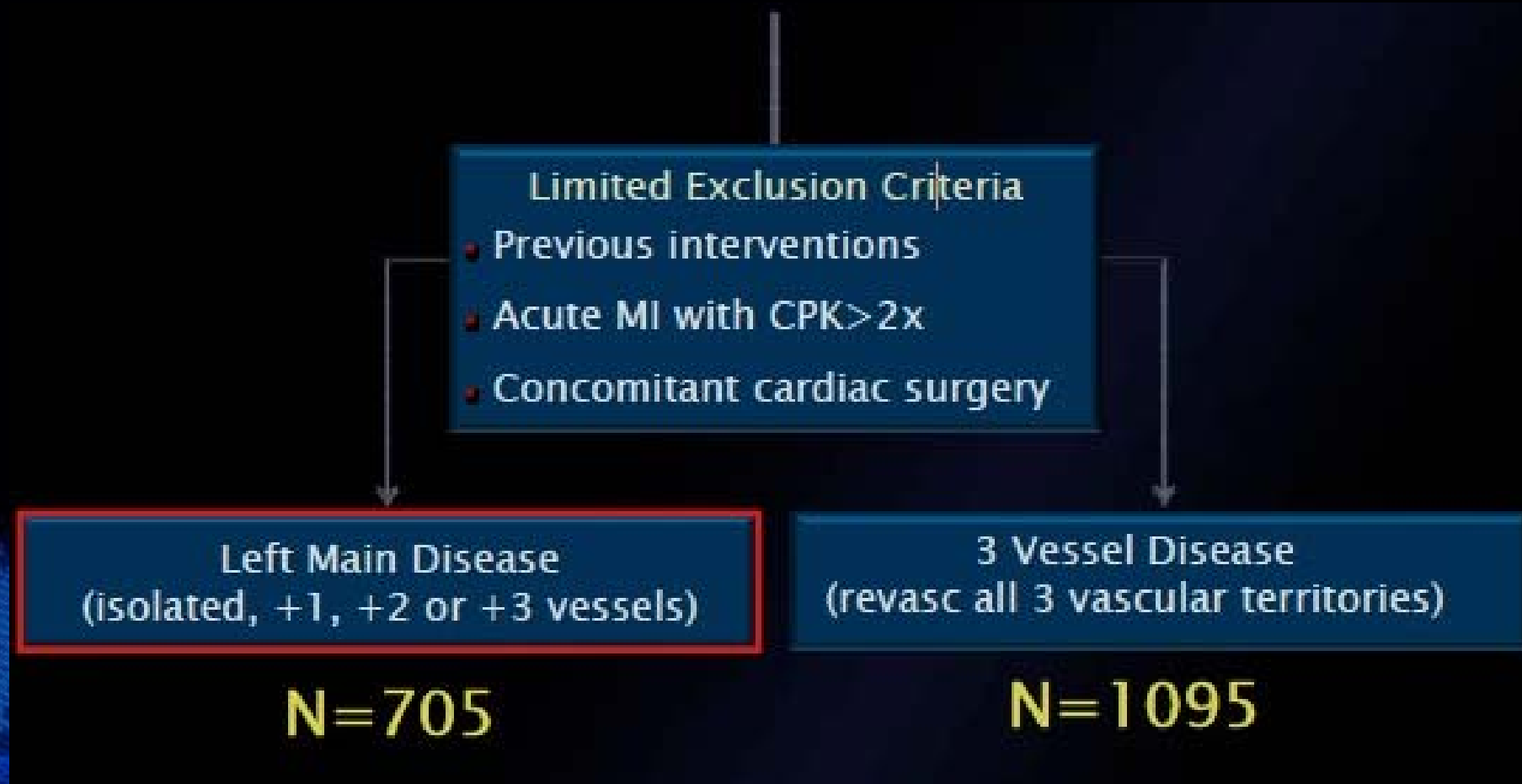
### 1 Year MACCE





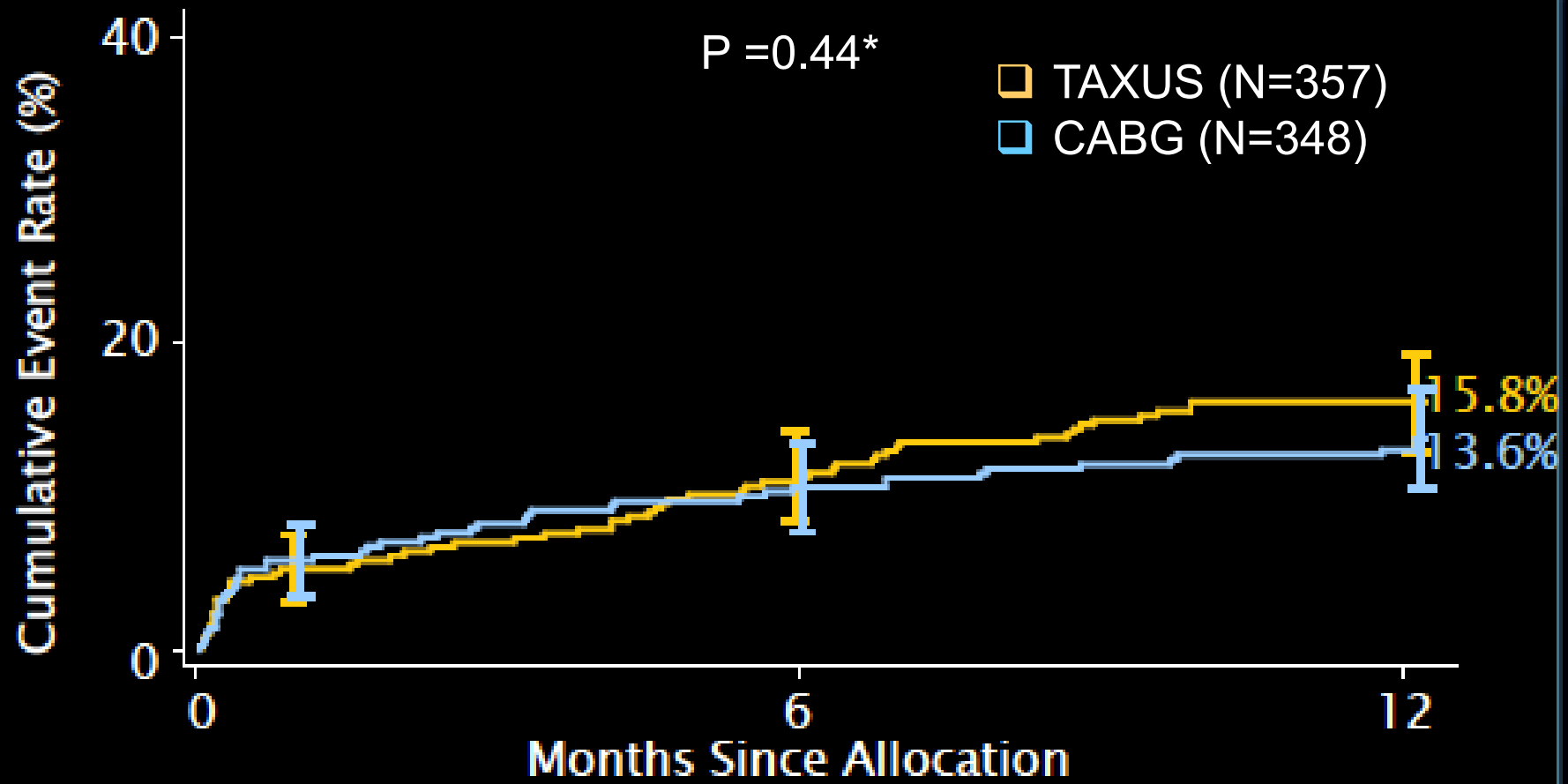
# SYNTAX: Left Main Subgroup

De novo disease (n=1800)



# SYNTAX - Left Main Subset :

## MACCE to 12 Months



Event rate  $\pm$  1.5 SE, \*Fisher exact test  
ITT population

Serruys PW. TCT 2008

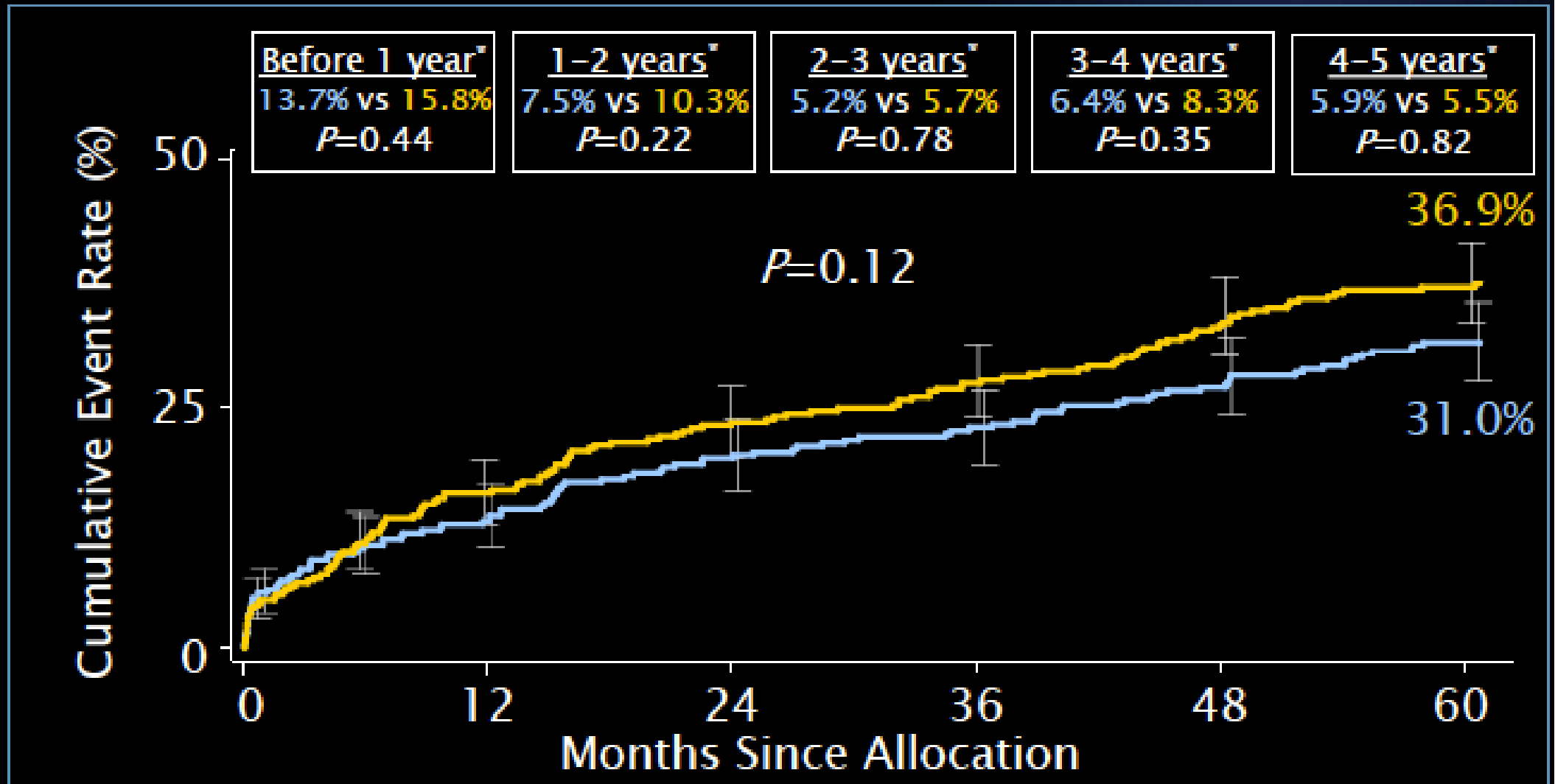
# SYNTAX: MACCE to 5 Years

## *Left Main Subset*



■ CABG (N=348)

■ TAXUS (N=357)

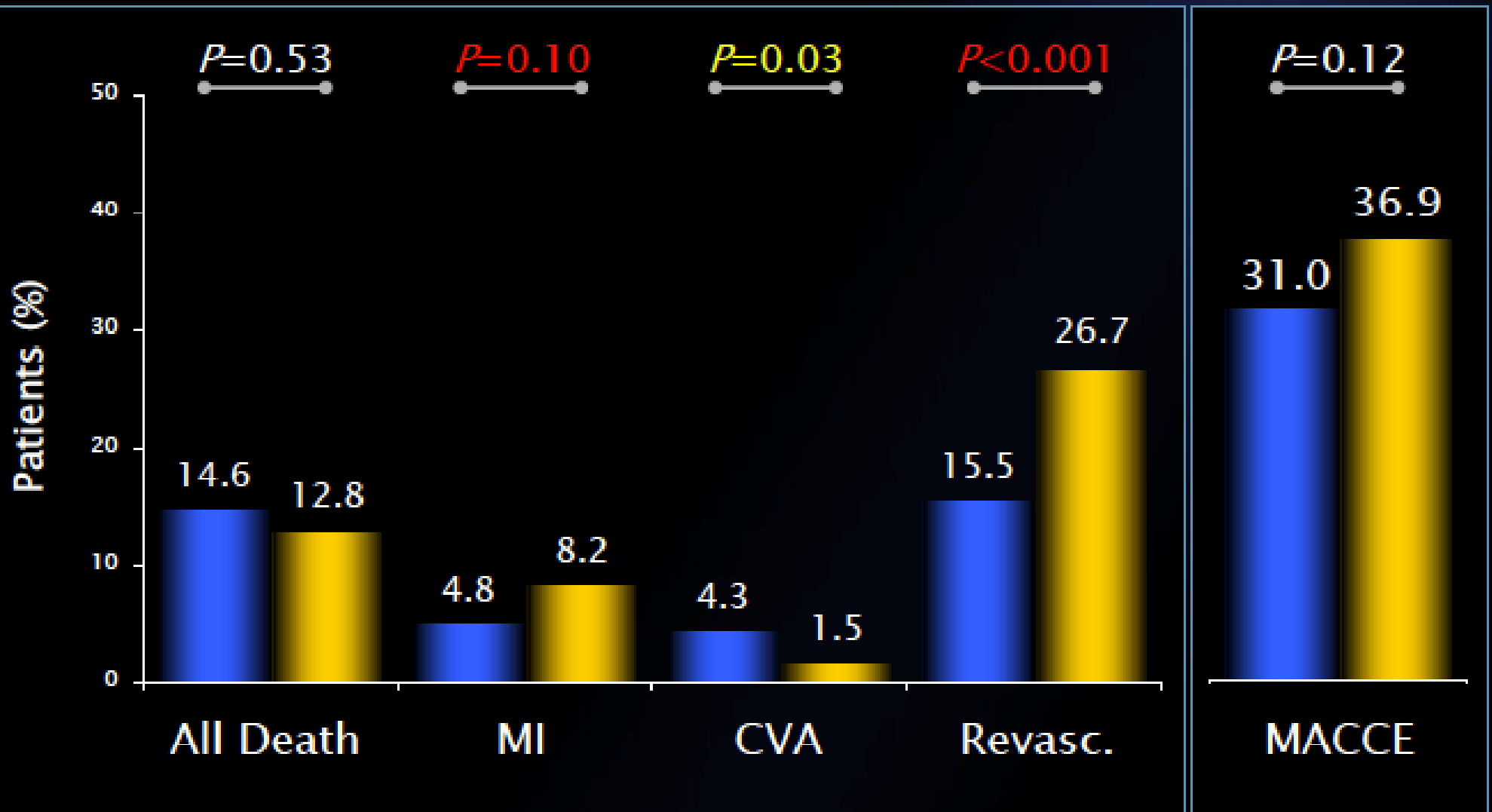


# SYNTAX : *Left Main Disease*

5 year Outcomes [n=705]

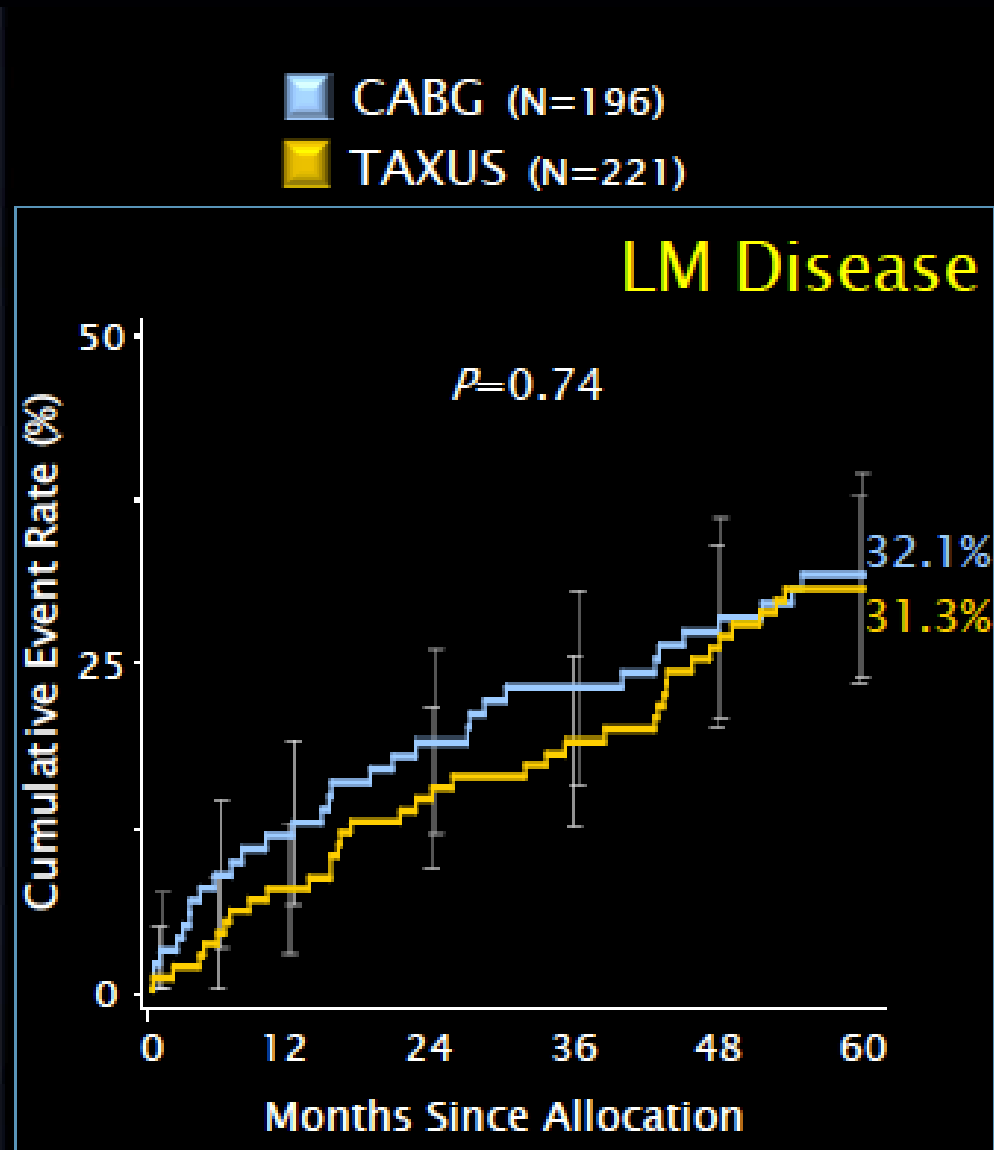
■ CABG (n=348)

■ TAXUS (n=357)



# MACCE to 5 Years by SYNTAX Score Tercile

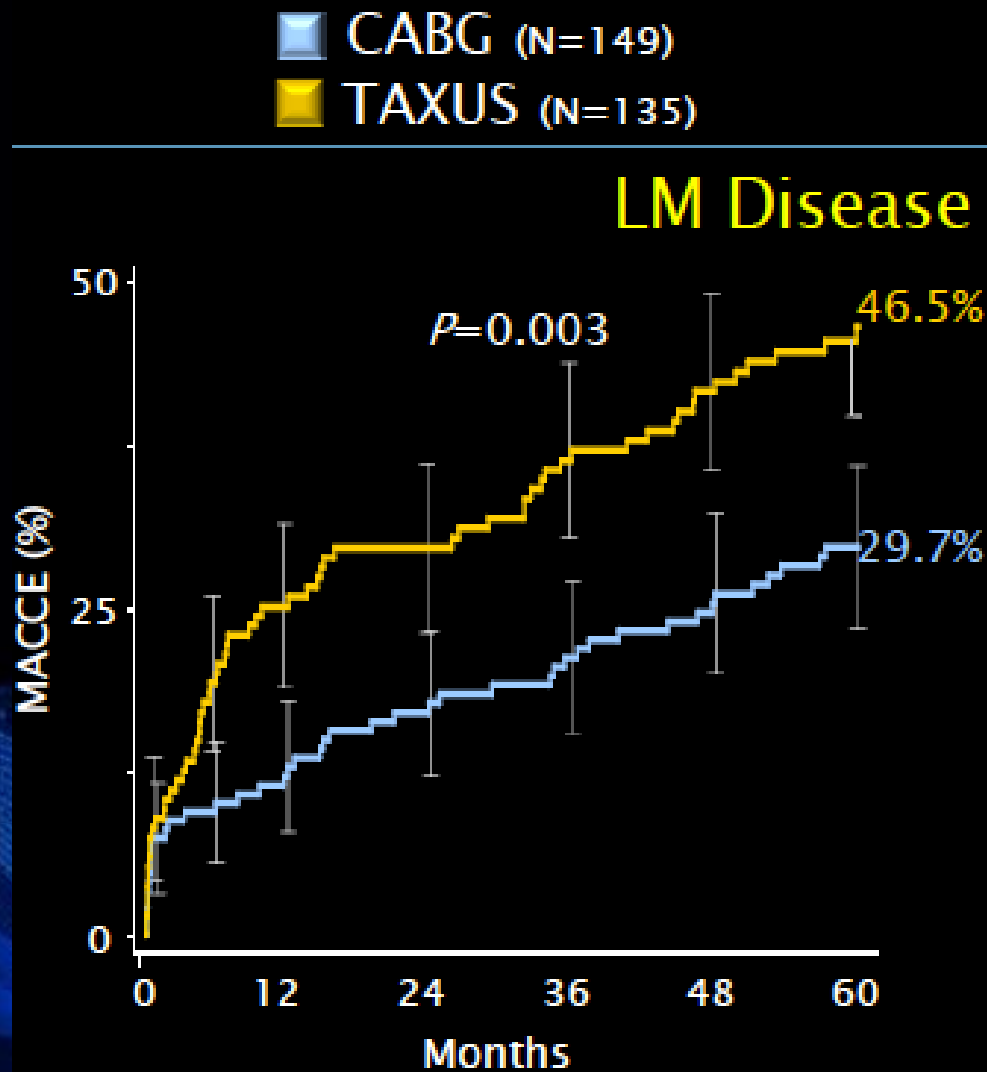
## Low to Intermediate Scores (0-32)



	CABG	PCI	Pvalue
Death	15.1%	7.9%	<b>0.02</b>
CVA	3.9%	1.4%	0.11
MI	3.8%	6.1%	0.33
Death, CVA or MI	19.8%	14.8%	0.16
Revasc.	18.6%	22.6%	0.36

# MACCE to 5 Years by SYNTAX Score Tercile

*High Scores  $\geq 33$*



	CABG	PCI	<i>P</i> value
Death	14.1%	20.9%	0.11
CVA	4.9%	1.6%	0.13
MI	6.1%	11.7%	0.13
Death, CVA or MI	22.1%	26.1%	0.40
Revasc.	11.6%	34.1%	<b>&lt;0.001</b>

LMCA PCI : 1 or 2-stents



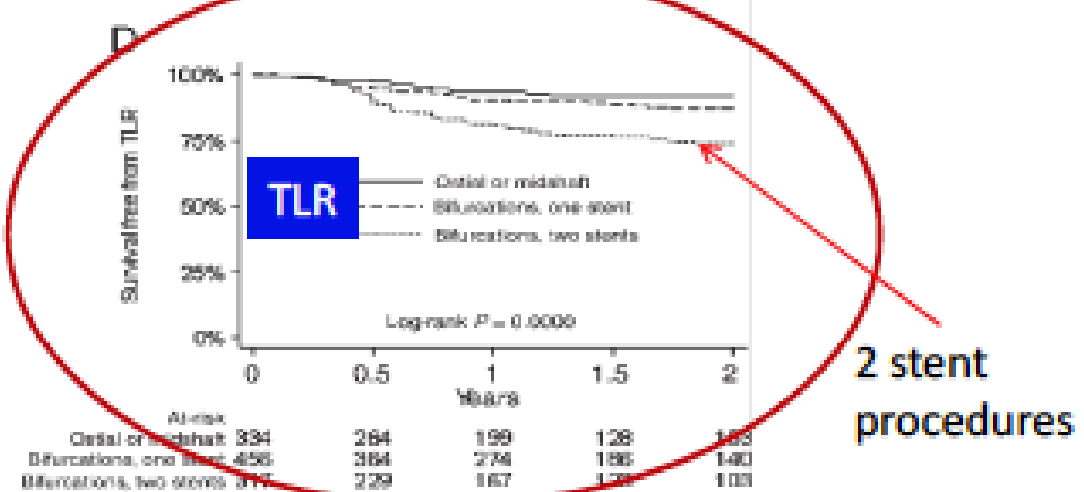
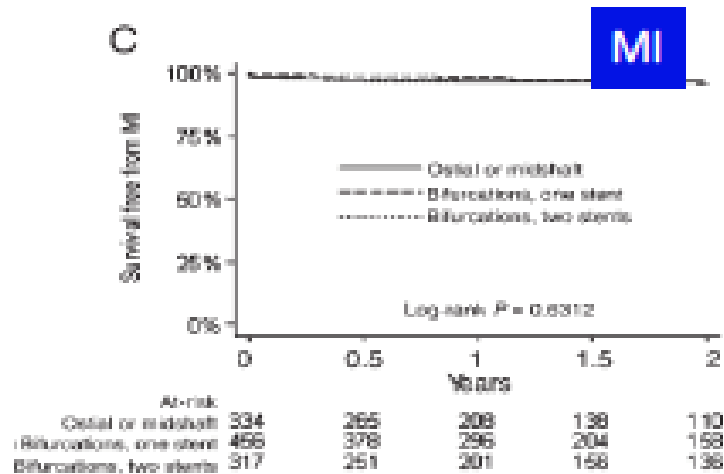
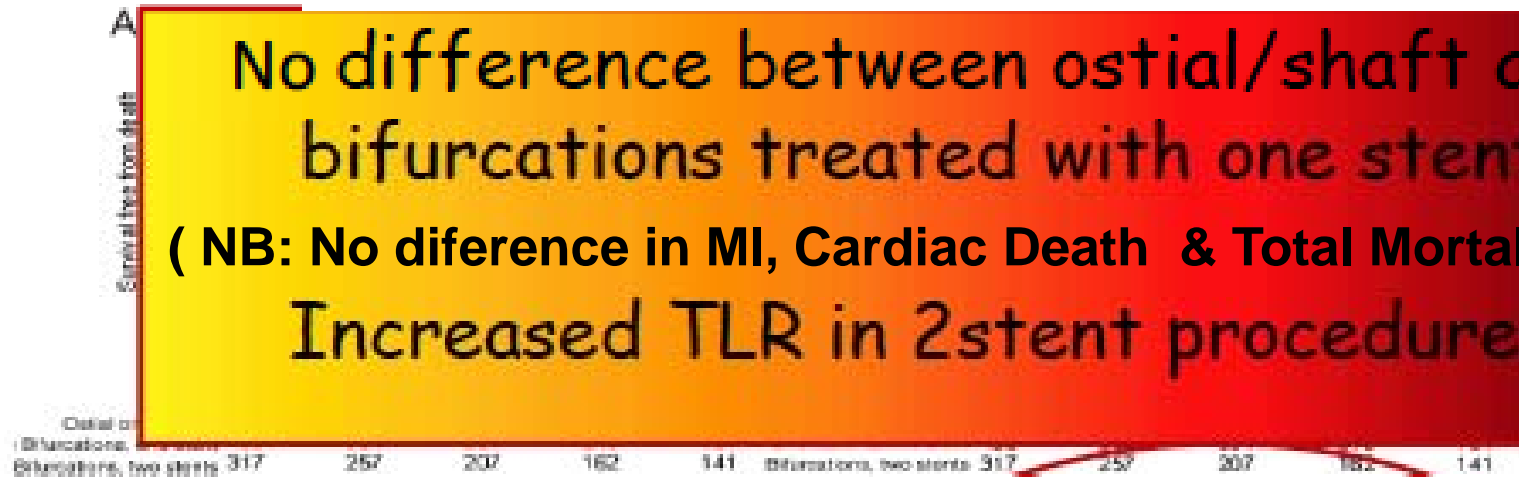


# Distal LMS and Stent Strategy

Italian Registry: N:1111

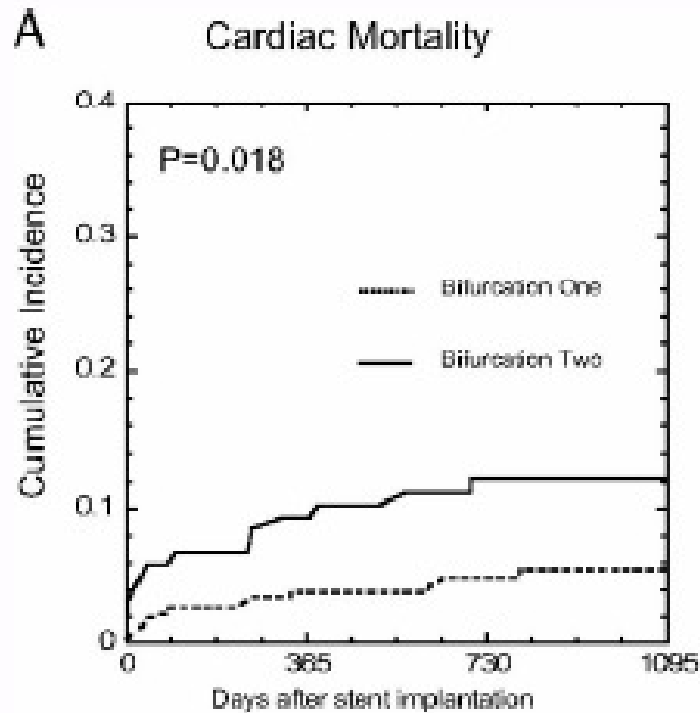
777 bifurcations/ 334 non-bifurcation

No difference between ostial/shaft and bifurcations treated with one stent (NB: No difference in MI, Cardiac Death & Total Mortality) Increased TLR in 2stent procedures

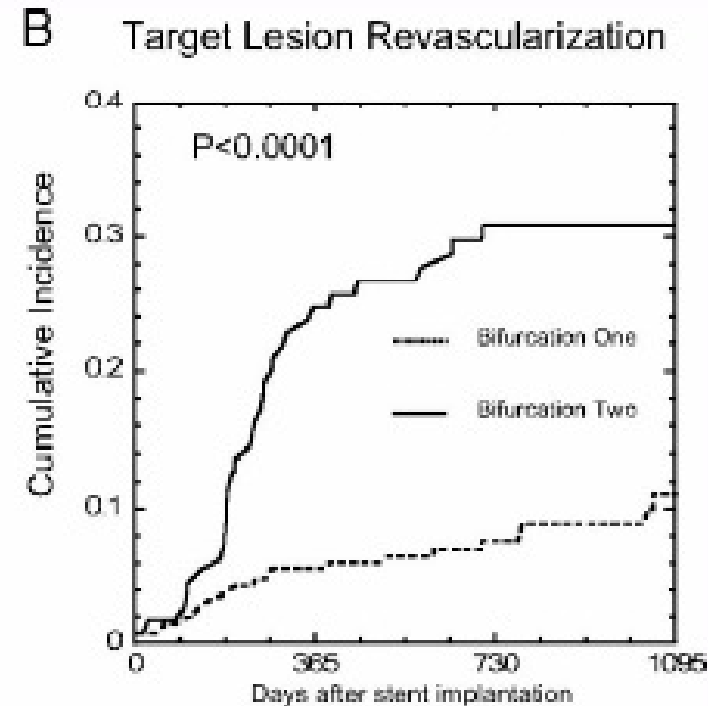


Palmerini et al. EHJ 2009;30:2087

# J-Cypher Registry : 3 yr outcomes after SES implantation for ULM CAD



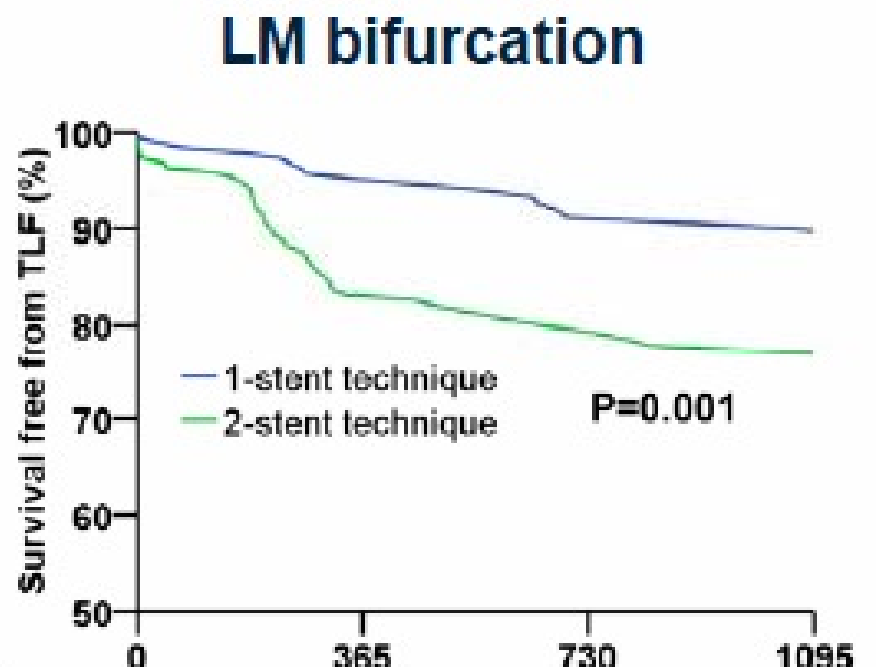
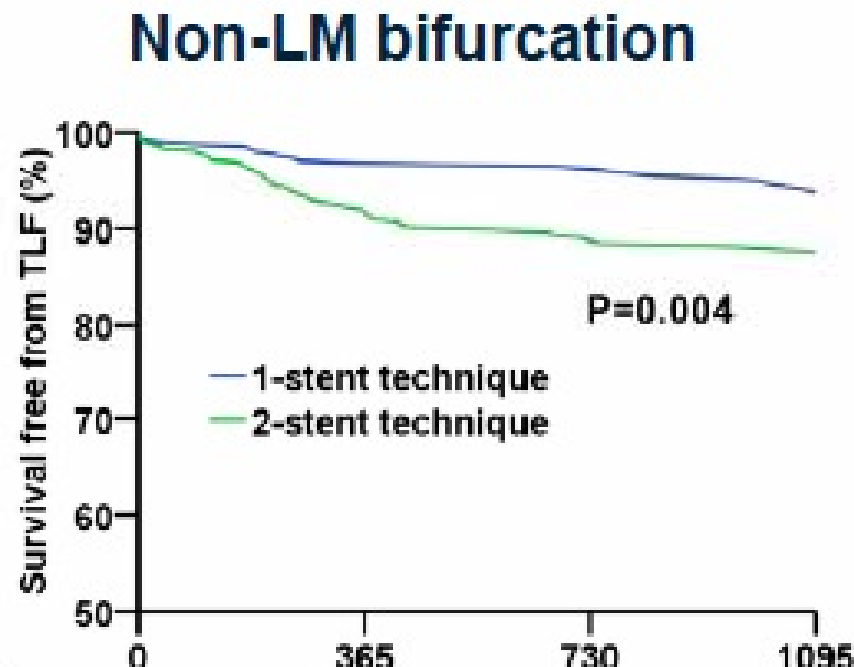
Day	0	365	730	1095
<b>Bifurcation One</b>				
Incidence (%)		3.6	4.9	5.5
No. at risk	261	242	180	86
<b>Bifurcation Two</b>				
Incidence (%)		9.4	12.2	12.2
No. at risk	119	105	88	52



Day	0	365	730	1095
<b>Bifurcation One</b>				
Incidence (%)		5.6	7.8	11.1
No. at risk	261	229	161	76
<b>Bifurcation Two</b>				
Incidence (%)		24.6	30.9	30.9
No. at risk	119	81	62	37

# COBIS Registry II 1-stent vs. 2-stent for LMCA bifurcation

## TLF in Propensity-Matched Cohort



No. at risk

1-stent  
2-stent

442  
442

366  
360

Days

294  
311

186  
217

No. at risk

1-stent  
2-stent

192  
192

164  
146

Days

128  
108

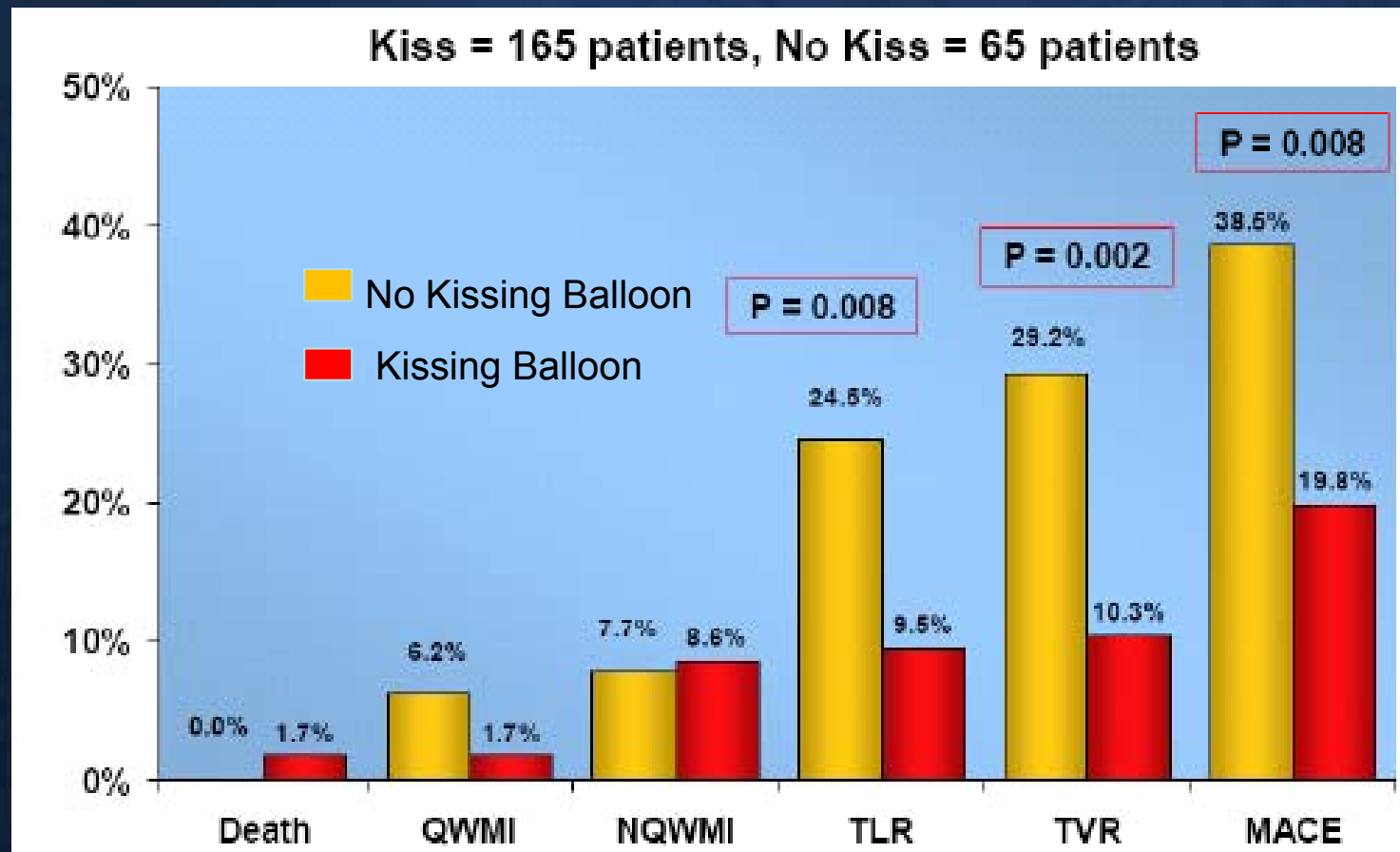
76  
64

# Kissing Balloon Inflation



# Importance of Kissing Balloon Inflation in Classical Crush Stenting

## Nine-month outcome after Crush Stenting

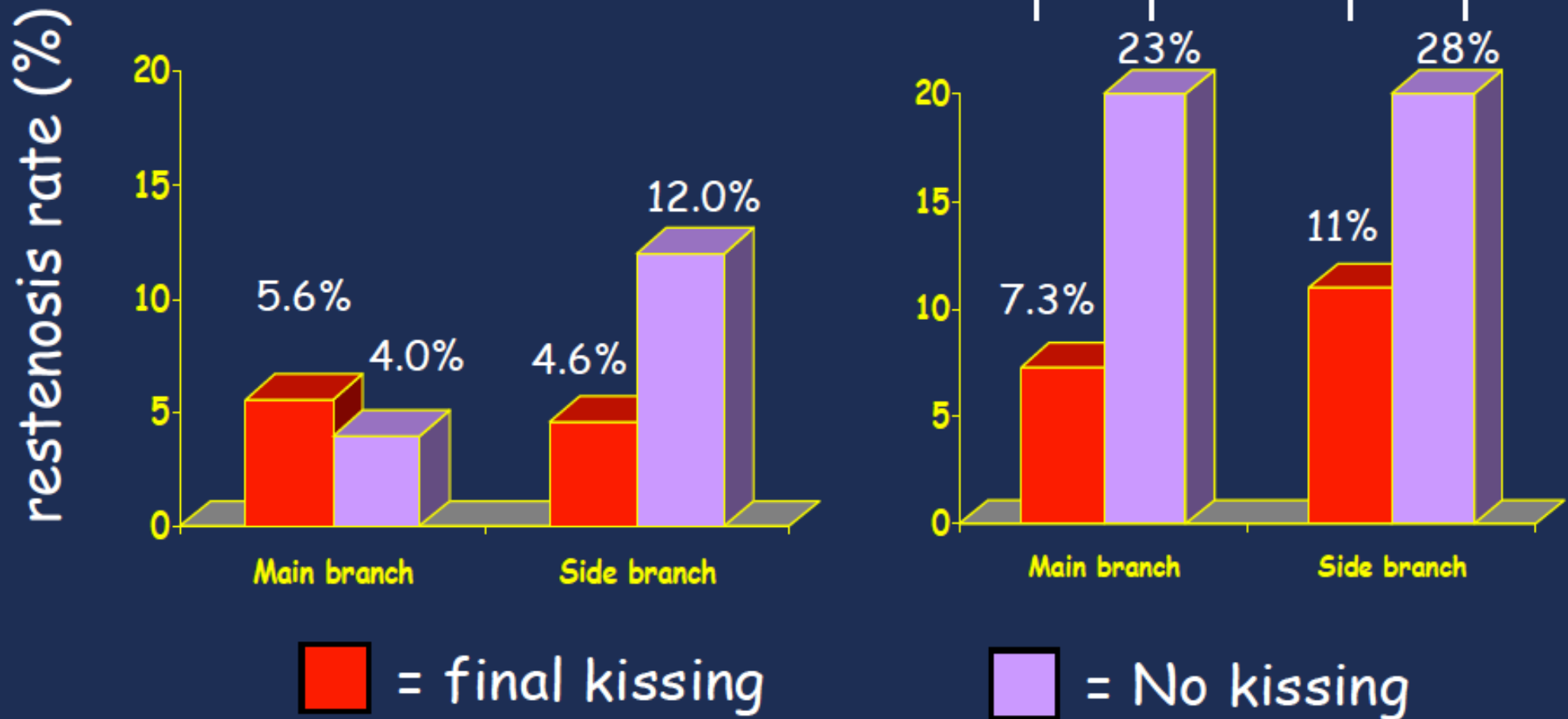


# DES in Bifurcation (Milan Experience: April 2002-March 2005)

Angiographic follow-up

One stent only 155 pts

Stents on both branches 119pts



Total no.= 274  
Out of 368

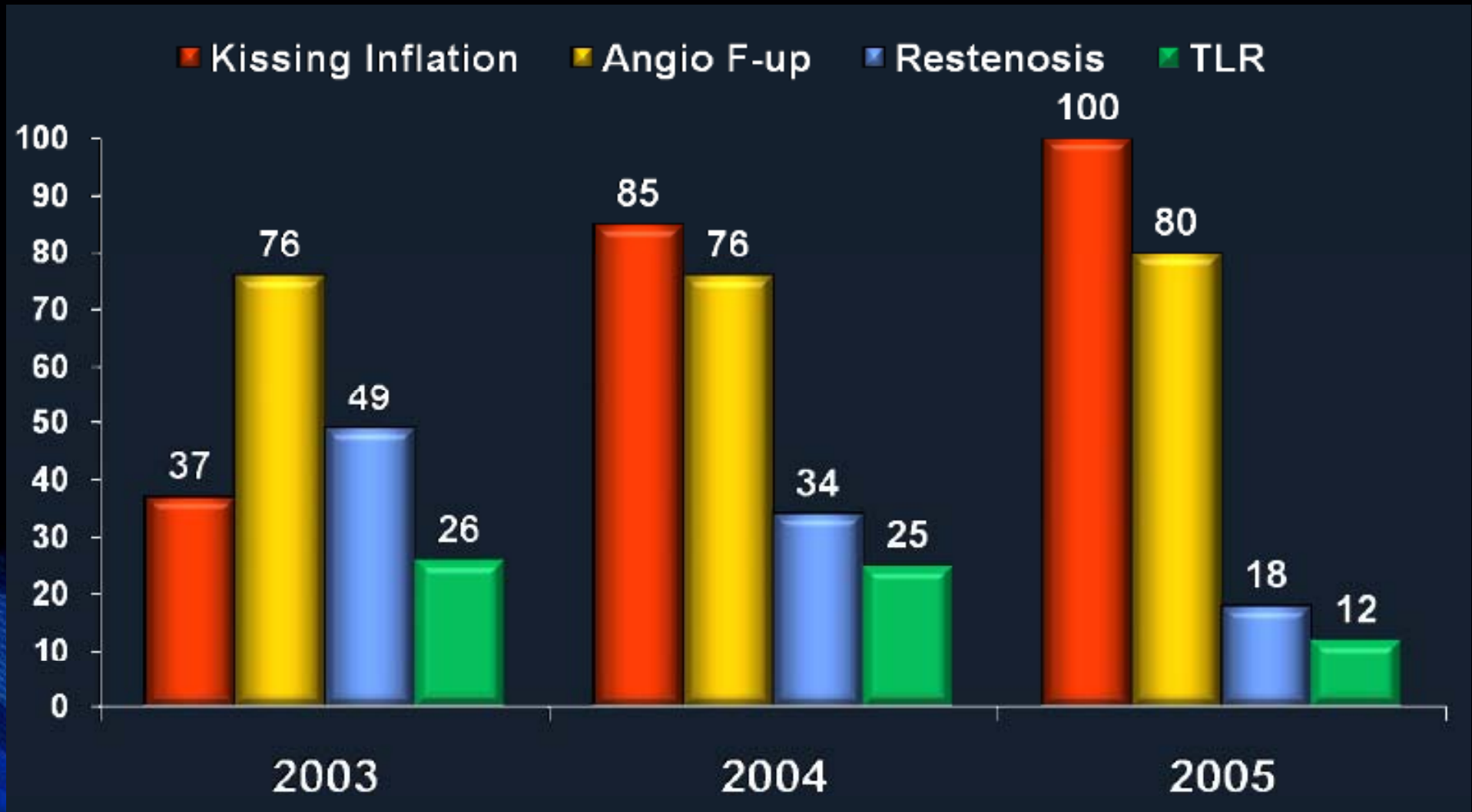
Antonio Colombo, ACC 2006

# Role of Kissing Balloon Inflation in Crush Technique : CACTUS Trial Insight

	YES Final Kissing 163 pts.	NO Final Kissing 14 pts.	P
Myocardial infarction	7.5%	29%	0.001
TLR	6.3%	12.9%	0.25
MB restenosis	4.7%	16%	0.03
SB restenosis	11.9%	36%	0.001
Stent thrombosis	0.9%	6.5%	0.06



# Optimal performance of 2 stent techniques important in reducing event rates



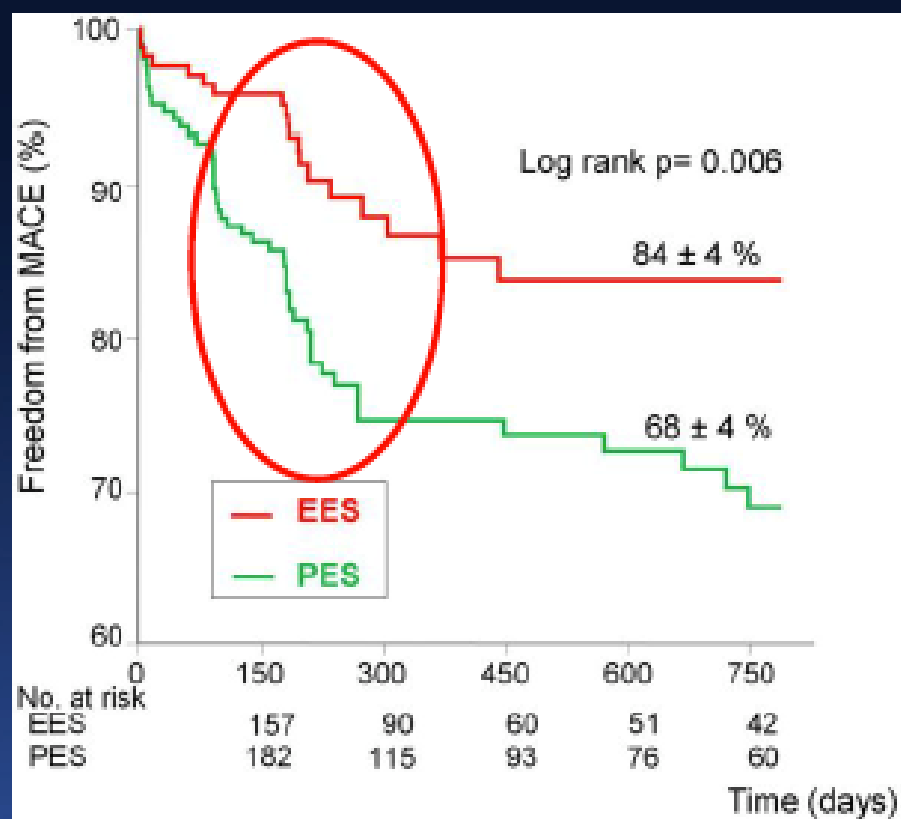
Impact of learning curve in Technique; TCT 2006

# DES : Old vs New



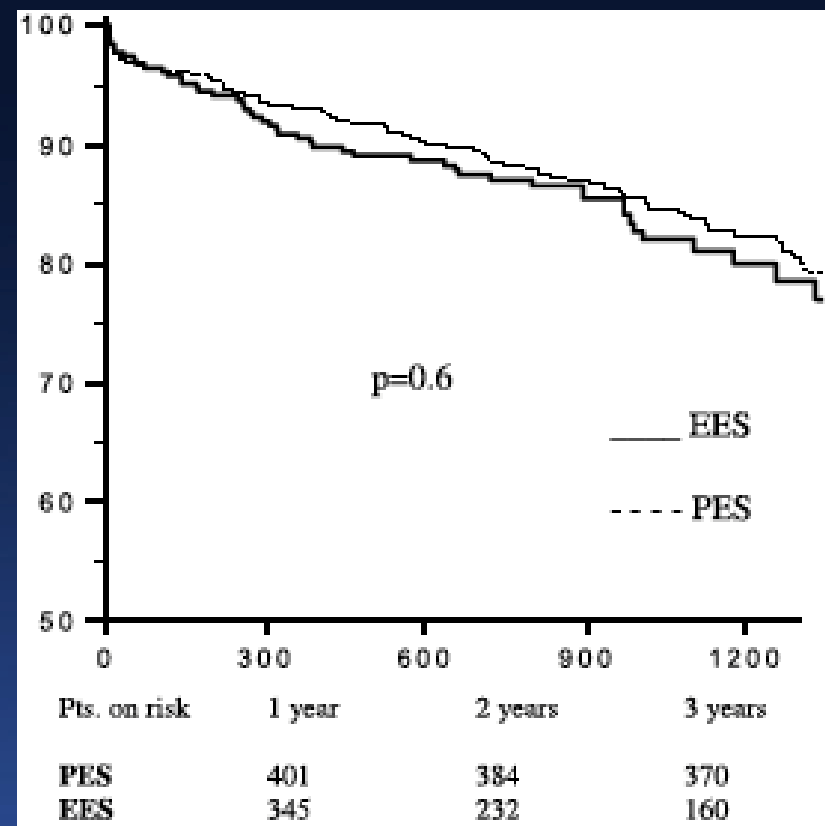
# New vs Old DES for ULMCA PCI : Discordant Results

ULMD Florence Registry



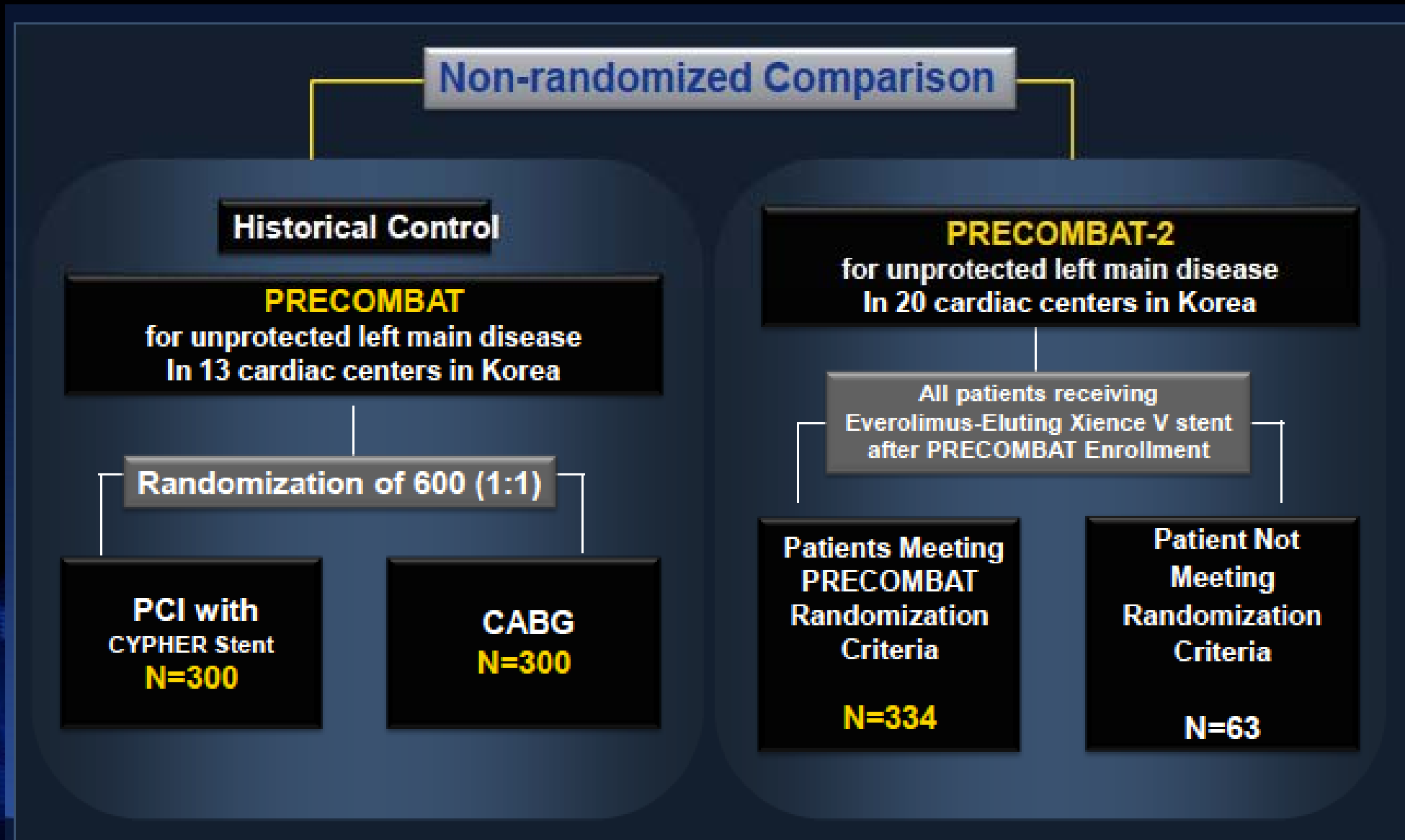
Valenti et al, JACC 2012

ESTROFA-LM

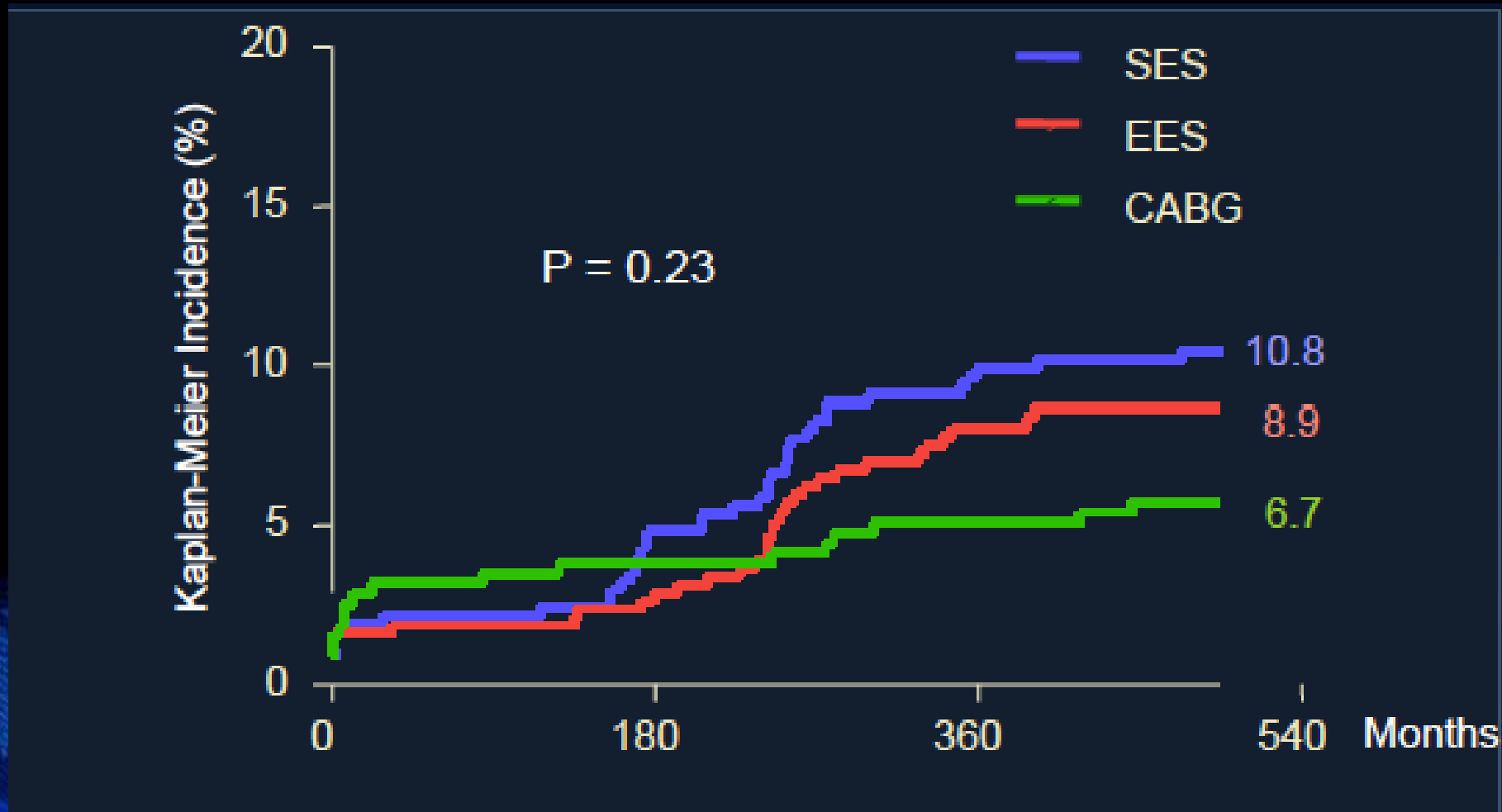


De La Torre Hernandez et al, AJC 2013

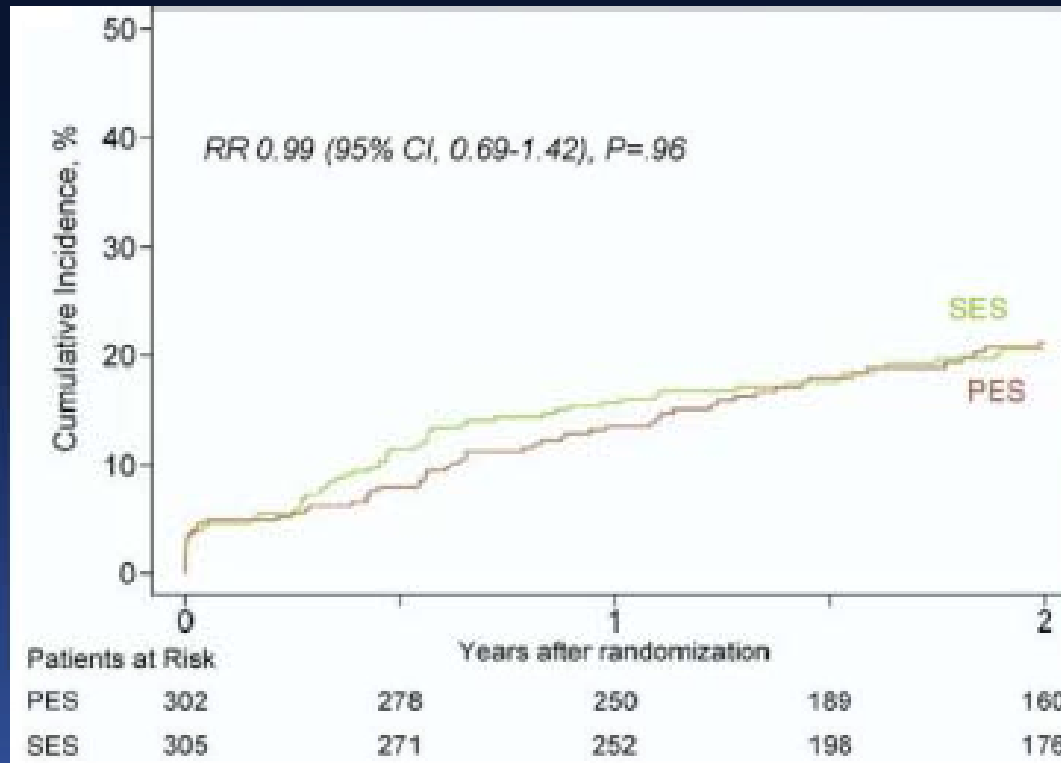
# PRE-COMBAT – 2 Design



# MACCE Death, MI, Stroke or Ischemic TVR



# MACCE : *Death, MI, or TLR* (SES vs. PES vs. EES vs. ZES)



## ISAR-LM SES vs. PES

RR 1.26 (95% CI 0.85-1.85)  
P= .25

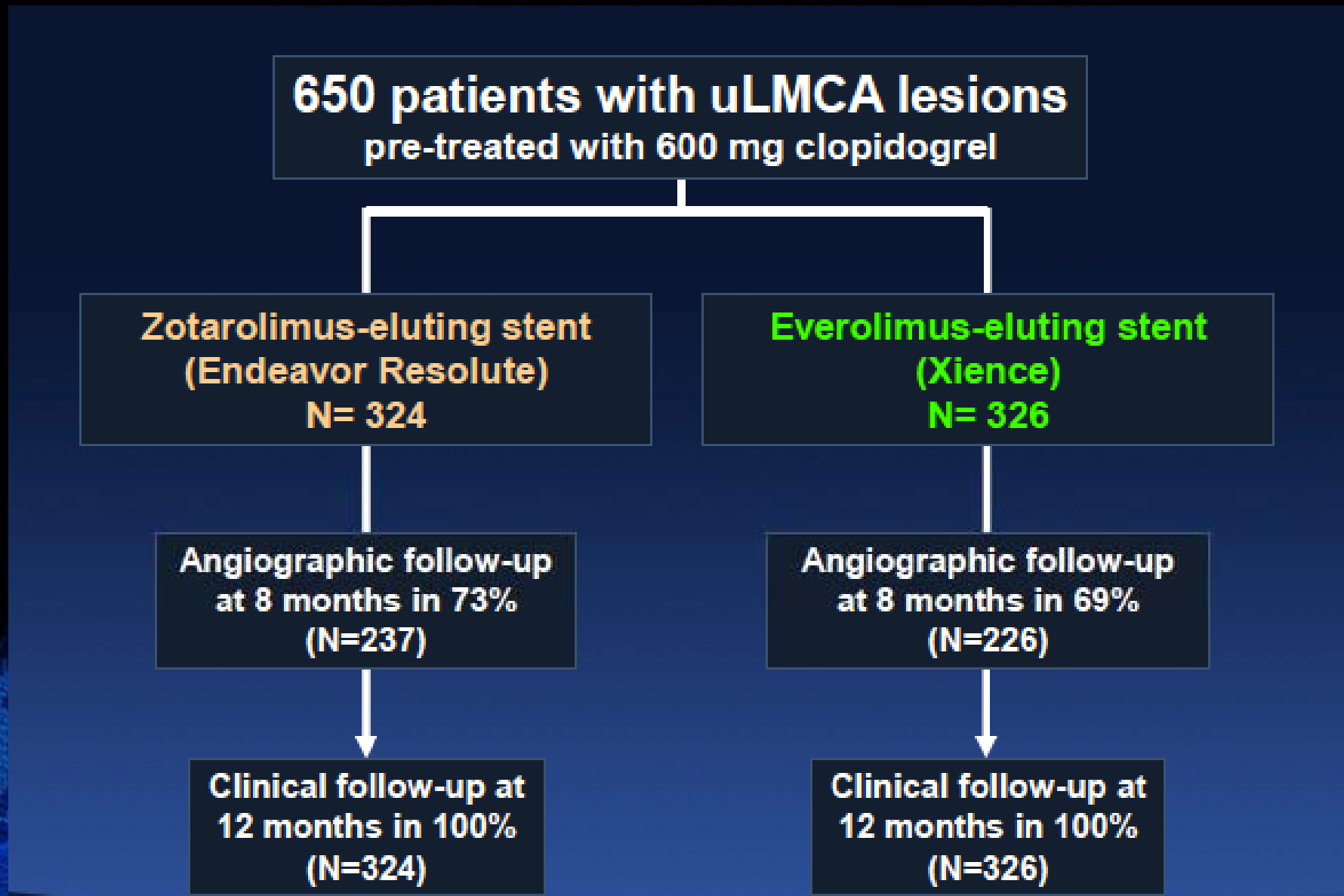
Resolute  
Xience

## ISAR-LM2 EES vs. ZES



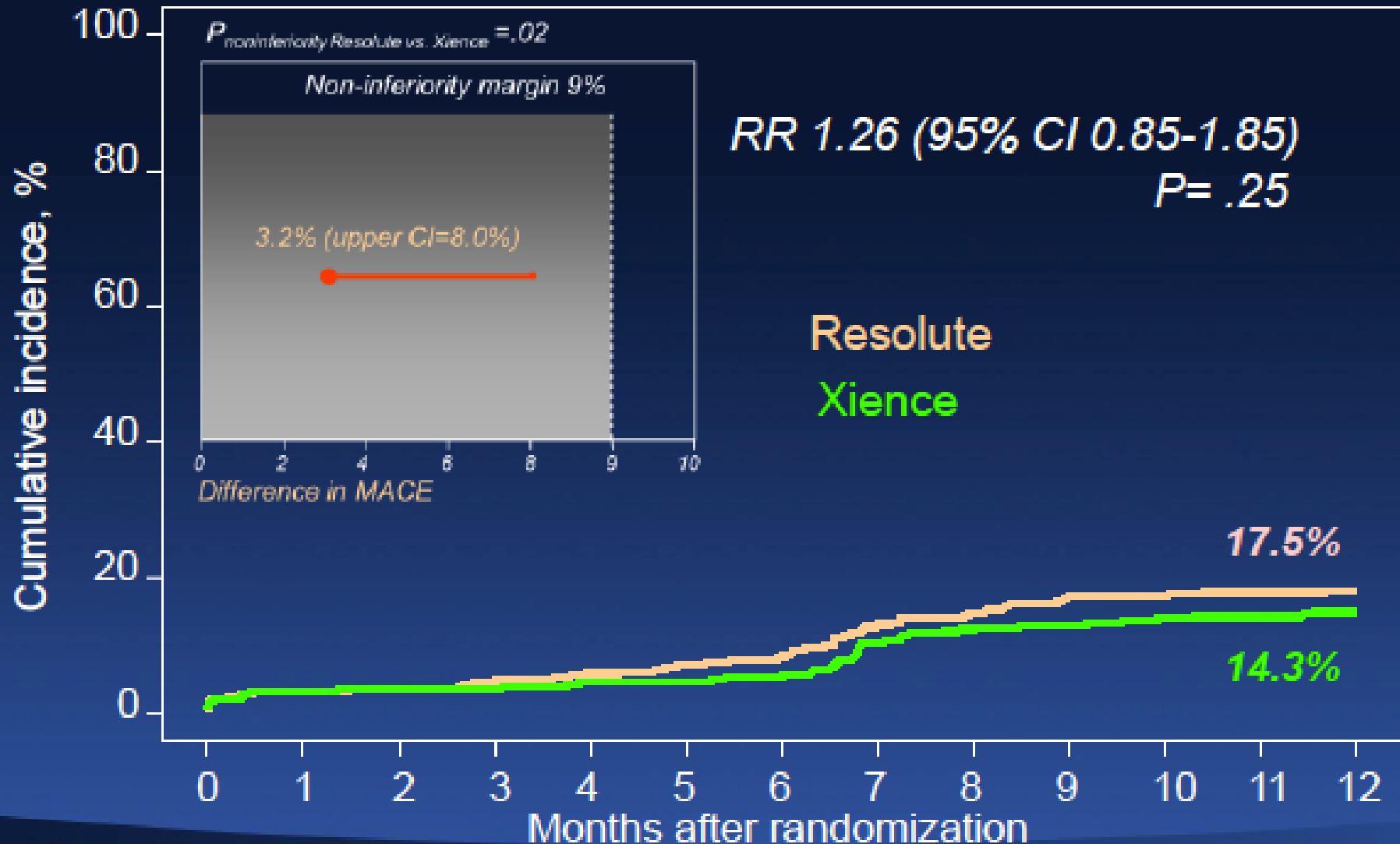
Mehilli et al., J Am Coll Cardiol 2009,  
Mehilli et al., TCT 2012

# ISAR LEFT MAIN 2 Trial

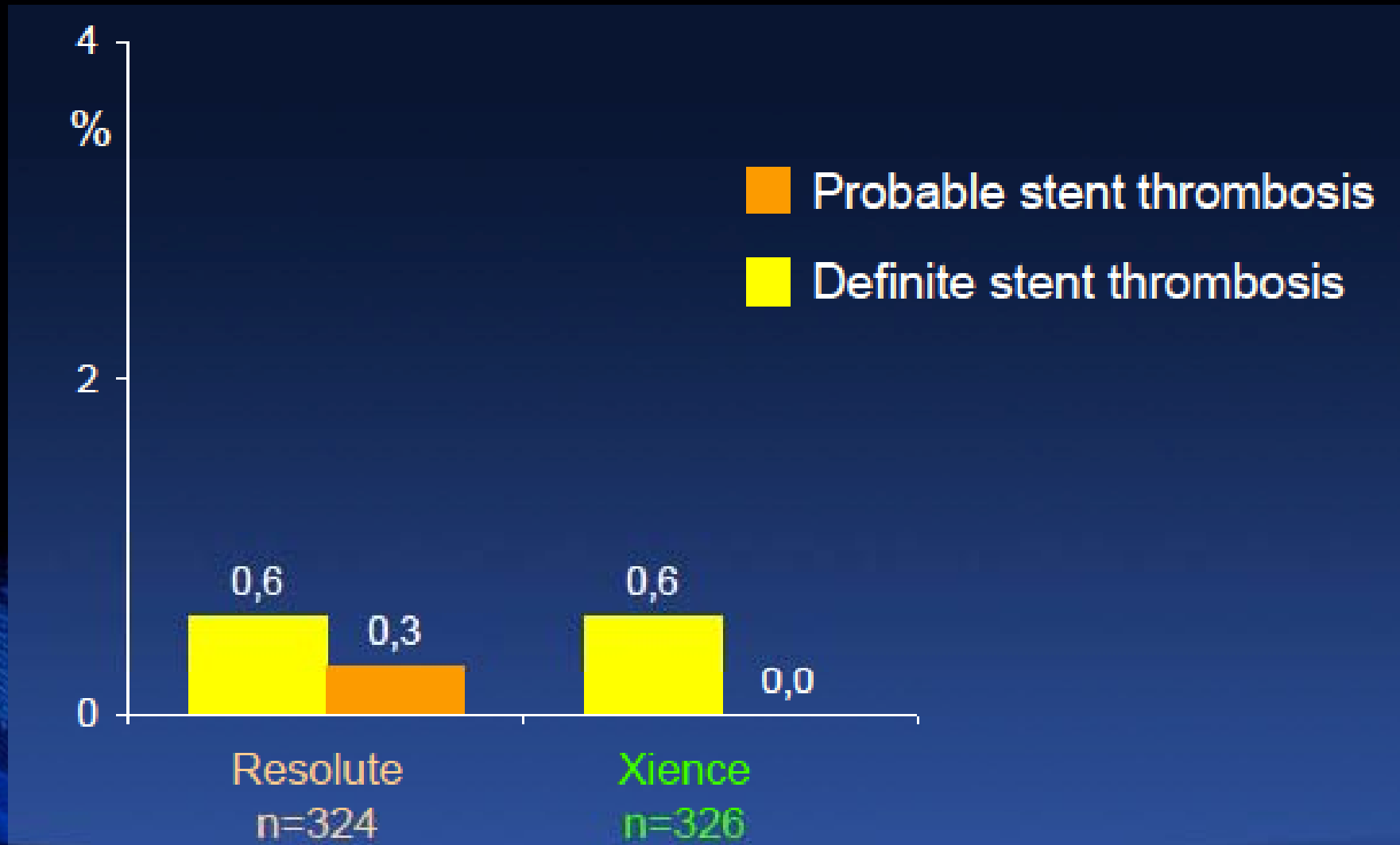




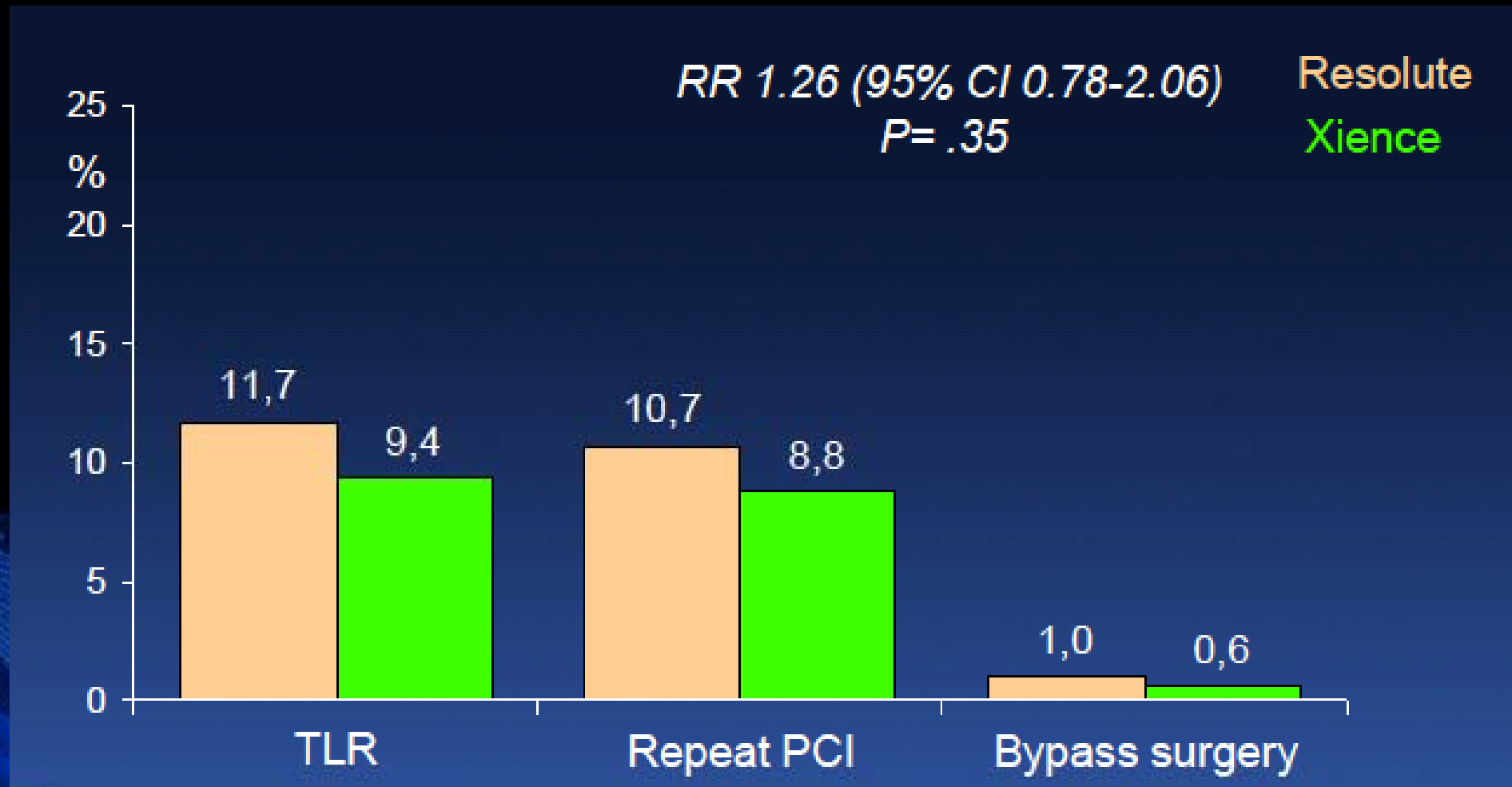
# ISAR Left Main 2 : MACE



## ISAR Left Main 2: Incidence of Stent Thrombosis - *secondary endpoint* -



# ISAR Left Main 2 : Target Lesion Revascularisation



# ACC / AHA Guidelines :

## *Left main PCI for Stable CAD*

**IIa**

- Both must be present:

- Anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g., a low SYNTAX score of  $\leq 22$ , ostial or trunk left main CAD)

**B**

- Clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g. STS-predicted risk of operative mortality  $\geq 5\%$ )

# ACC / AHA Guidelines :

## *Left main PCI for Stable CAD*

IIb

B

### Both must be present

- Anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (e.g., low-intermediate SYNTAX score of <33, bifurcation left main CAD)
- Clinical characteristics that predict an increased risk of adverse surgical outcomes (e.g., moderate-severe COPD, disability from prior stroke, or prior cardiac surgery; STS-predicted risk of operative mortality >2%)

# ACC / AHA Guidelines :

## *Left main PCI for Stable CAD*

III

**B**

### HARM

- In patients with unfavorable anatomy for PCI (e.g. Syntax score  $\geq 33$ ) and who are good candidates for CABG (vs. performing CABG)

# 2012 SIHD Guidelines: Heart Team Approaches to Revascularization Decisions



A Heart Team approach to revascularization is recommended in patients with unprotected left main or complex CAD.



Calculation of the STS and SYNTAX scores is reasonable in patients with unprotected left main and complex CAD.



*Helping Cardiovascular Professionals  
Learn. Advance. Heal.*

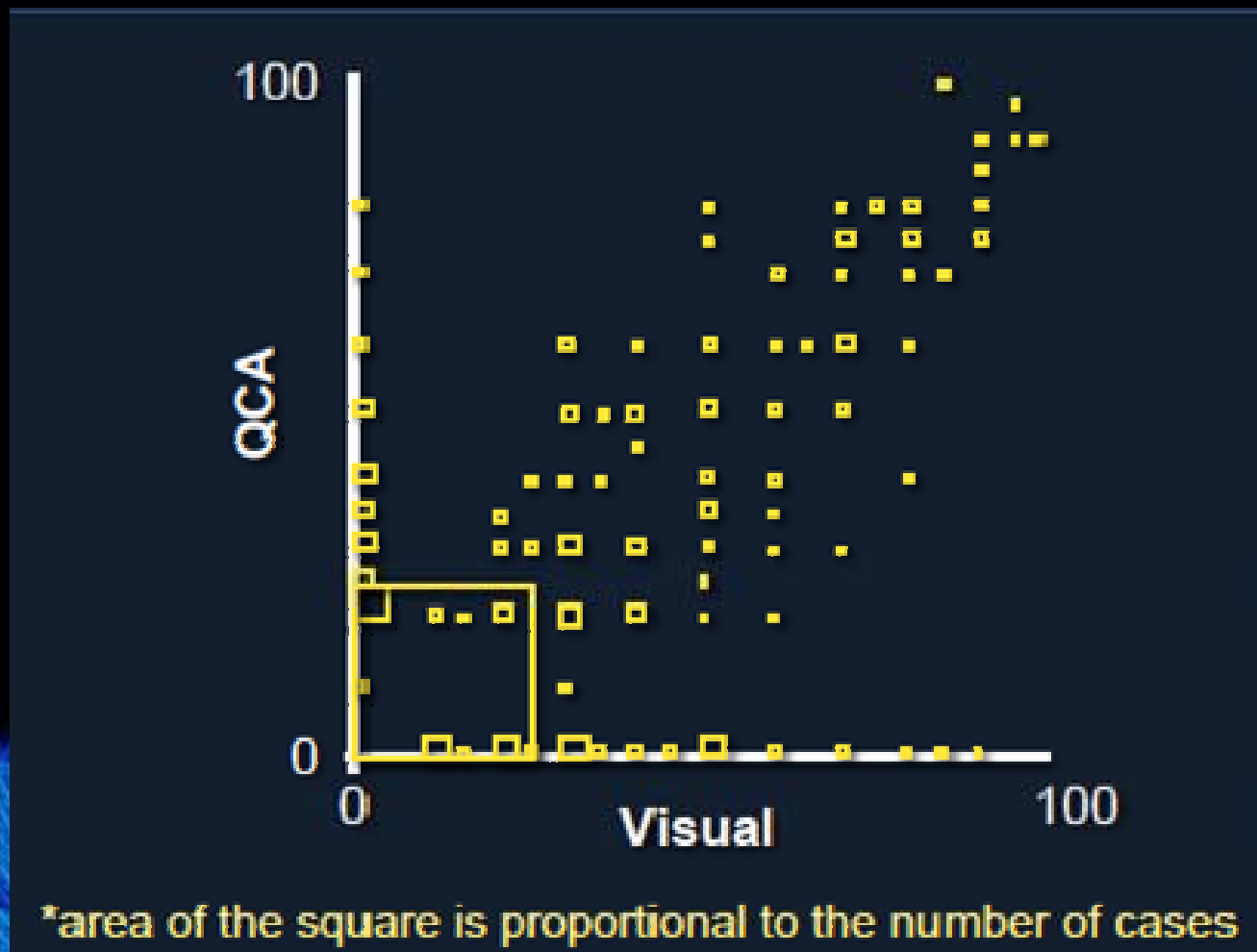




# Optimisation of LMS Intervention: Tools & Techniques



# Angiographic Variability in visual vs QCA assessment of LMCA DS%



LMCA has the greatest angiographic variability

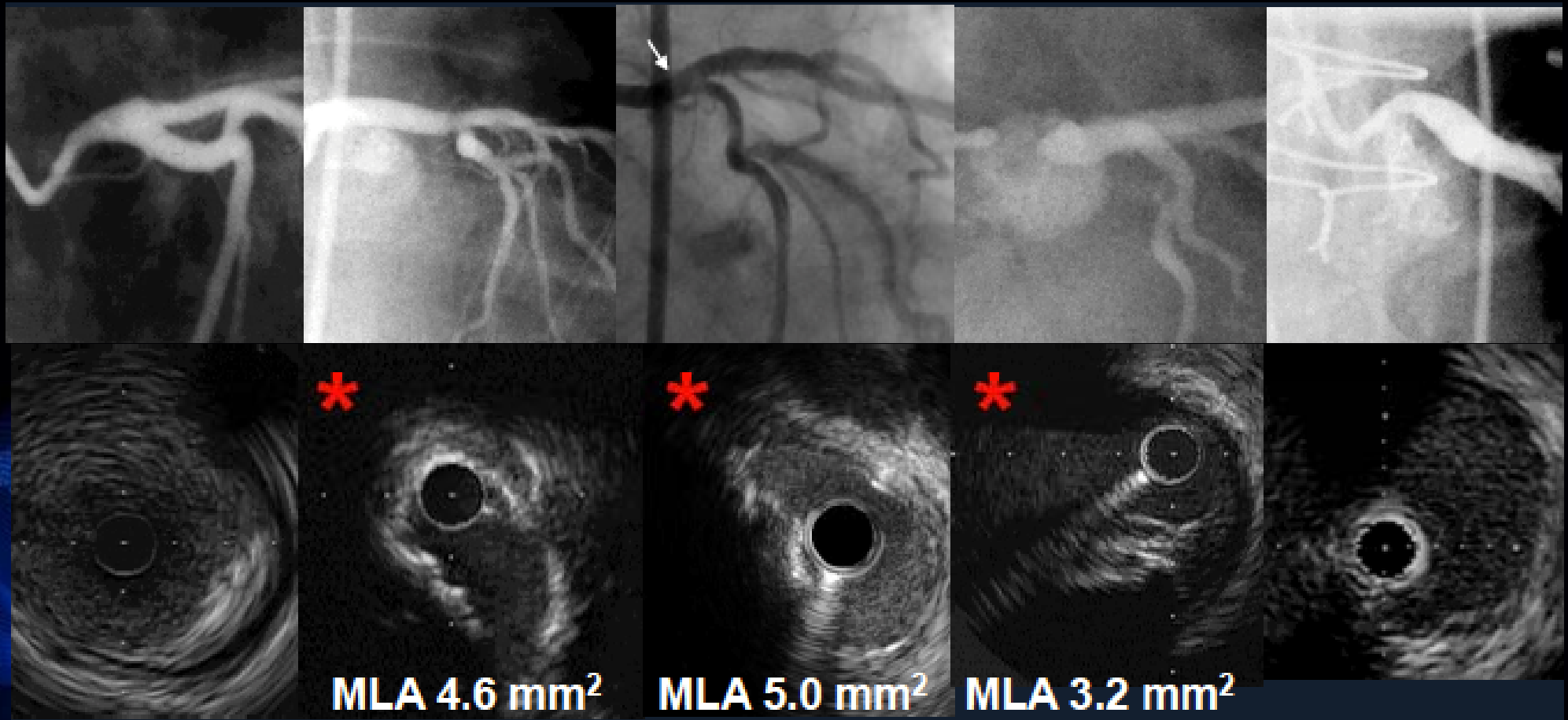
# Left Main Disease:

Which is Significant Angiographically



# Left Main Disease:

Which is Significant Angiographically –  
Versus IVUS Assessment



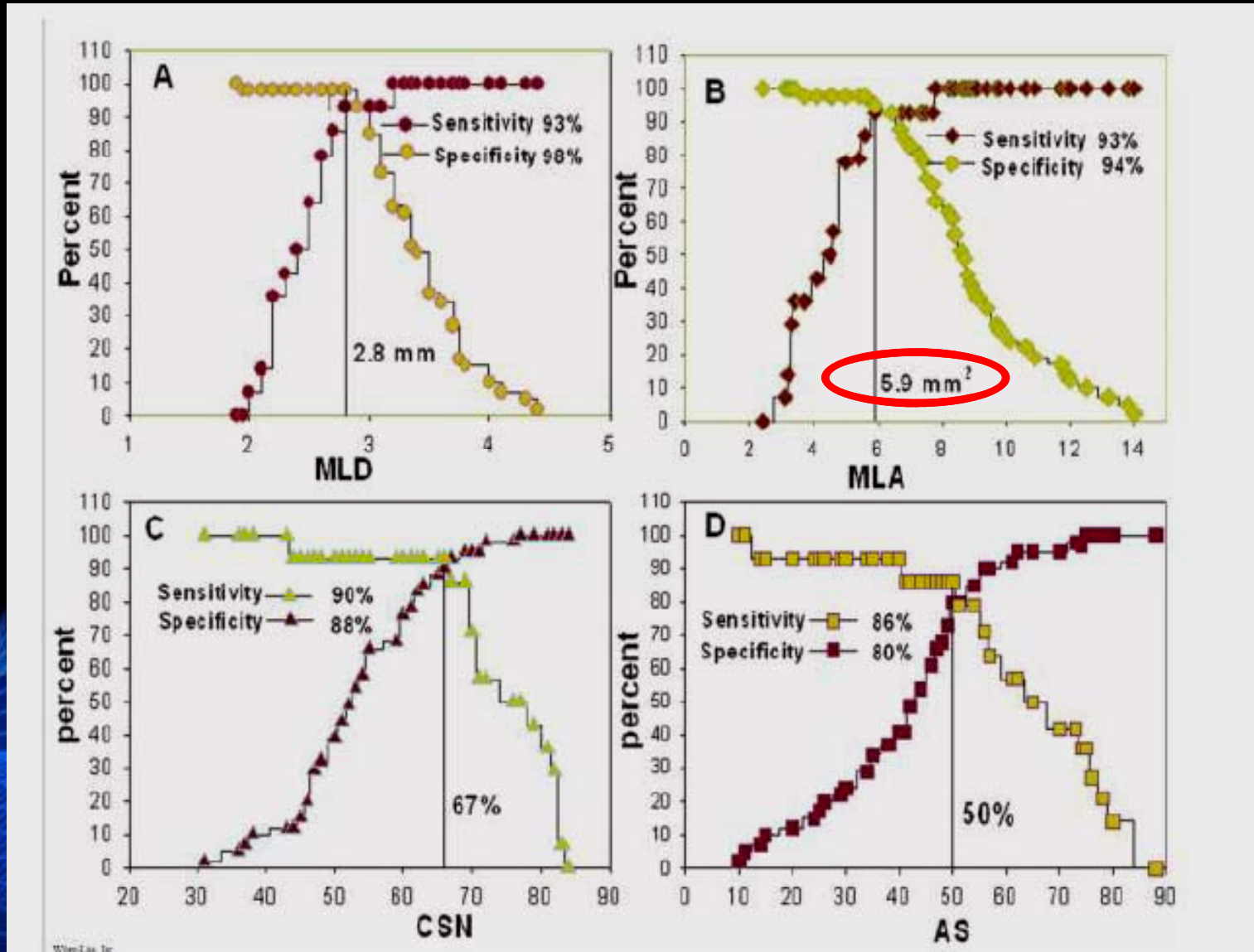
# IVUS Assessment of Ischaemia – based on MLA ( $\text{mm}^2$ )

- Proximal epicardial vessels:  $< 4.0 \text{ mm}^2$
- Left main stem :  $< 6.0 \text{ mm}^2$



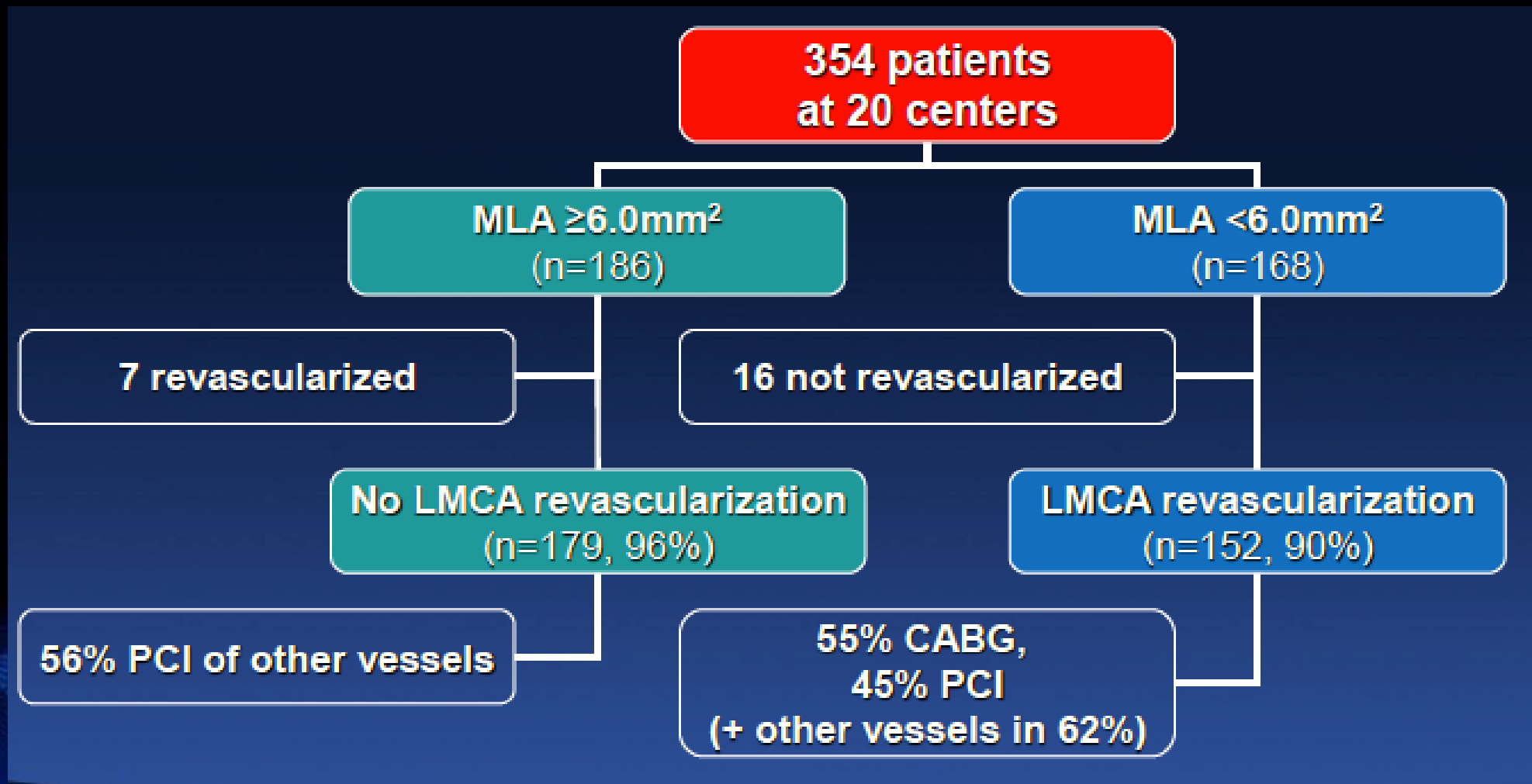
# IVUS determinants of LMCA FFR < 0.75

55 patients with ambiguous LMCA stenoses



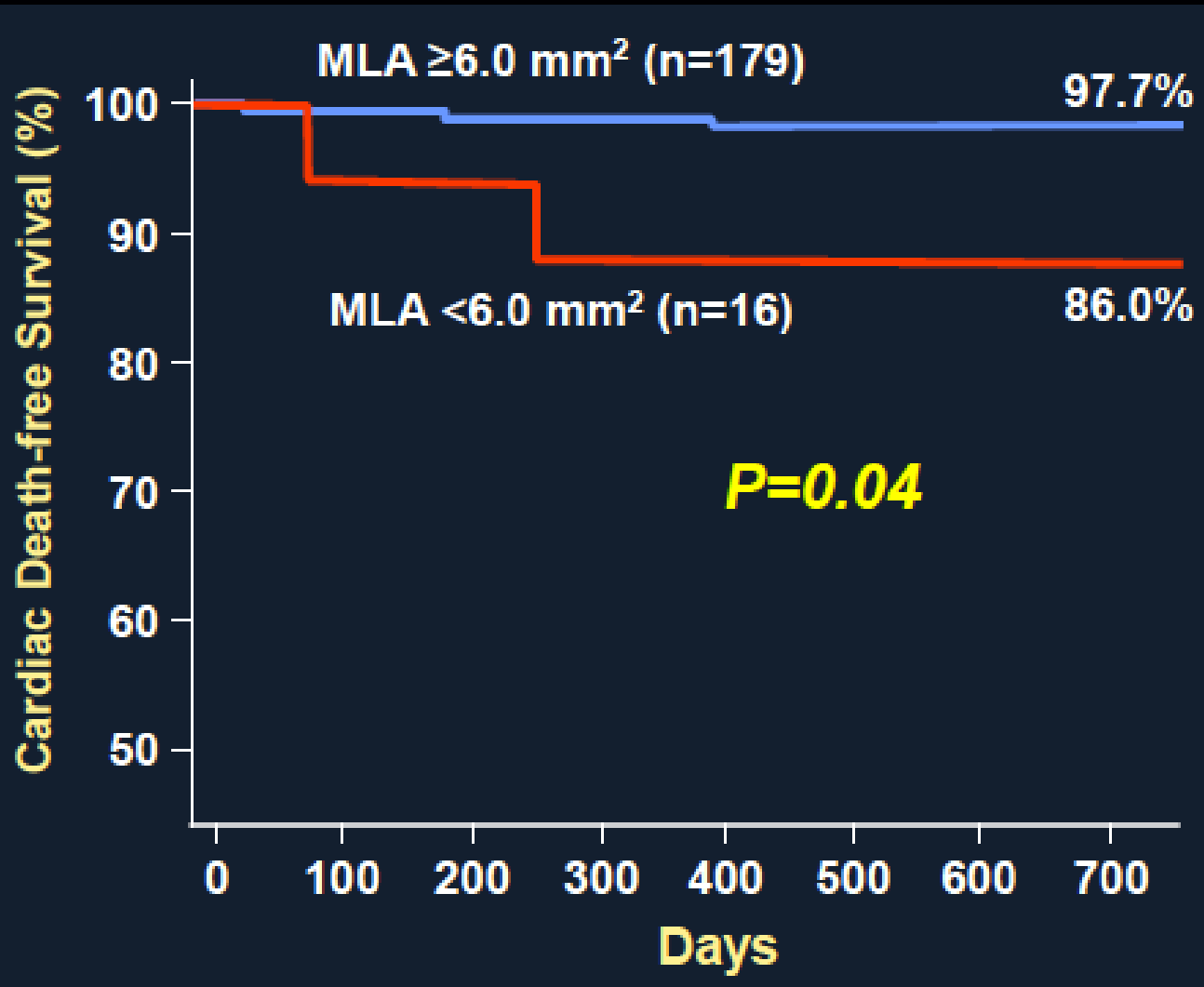


# The LITRO Study



Prospective application of predefined IVUS criteria for revascularization of intermediate LM lesions:

# LITRO: 2-year FU in Pts Without LM Revascularization According to MLA



Survival free from cardiac death, MI, or revascularization (MACE) was 62.5% in the in the group with MLA <6.0 mm<sup>2</sup> vs. 87.3% in the group with MLA ≥6.0 mm<sup>2</sup> ( $p=0.02$ )



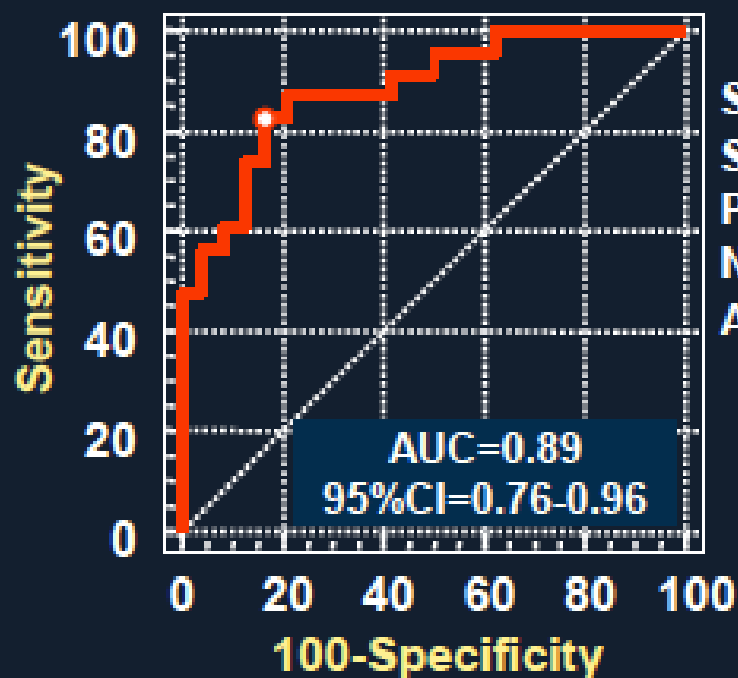
# IVUS Determinants of LM FFR (n=47)

Independent predictors of FFR (continuous variable)

MLA ( $p < 0.001$ ) and plaque burden ( $p = 0.036$ )

MLA predicting FFR < 0.80

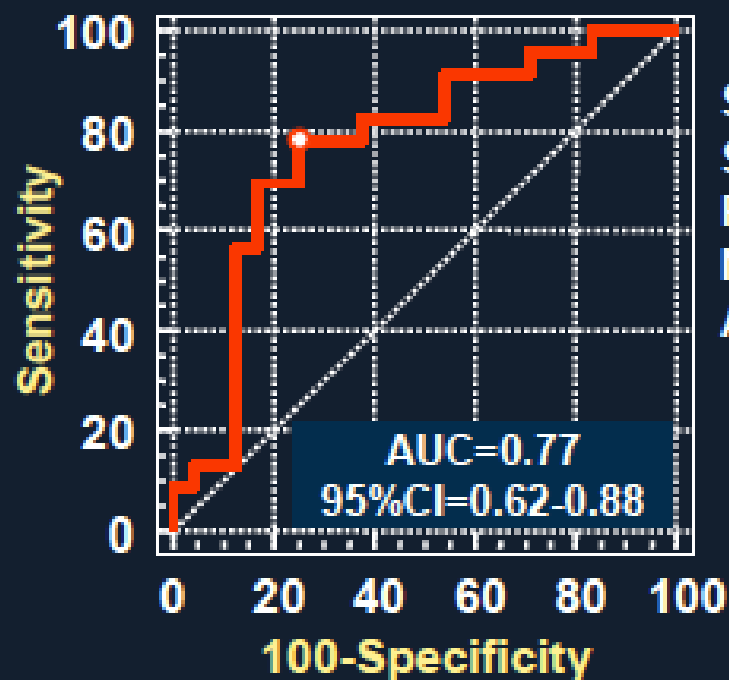
Cut-off = 4.8 mm<sup>2</sup>



Sensitivity 83%  
Specificity 83%  
PPV 83%  
NPV 83%  
Accuracy 83%

PB predicting FFR < 0.80

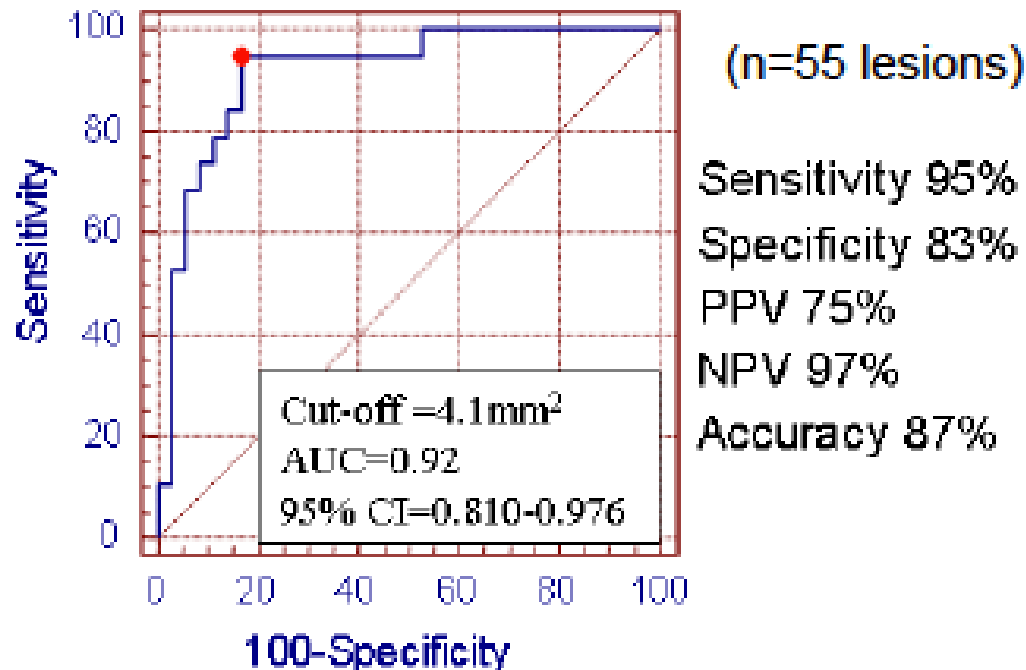
Cut-off = 72%



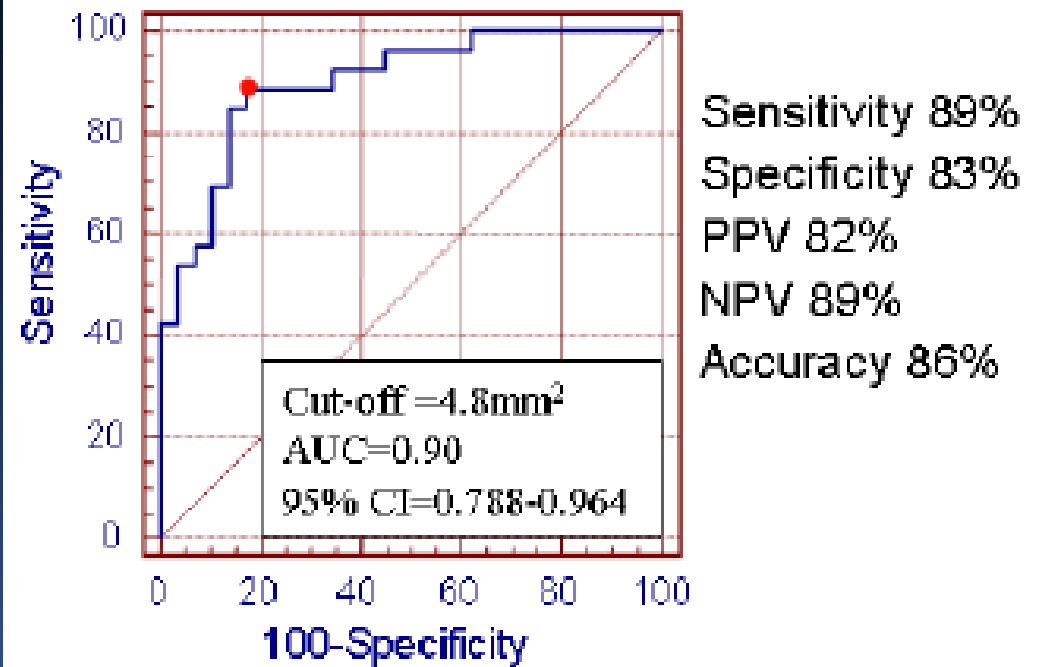
Sensitivity 78%  
Specificity 75%  
PPV 75%  
NPV 78%  
Accuracy 77%

# New LM IVUS MLA Criteria for Intervention Matched with FFR <0.80

### C. MLA predicting FFR<0.75



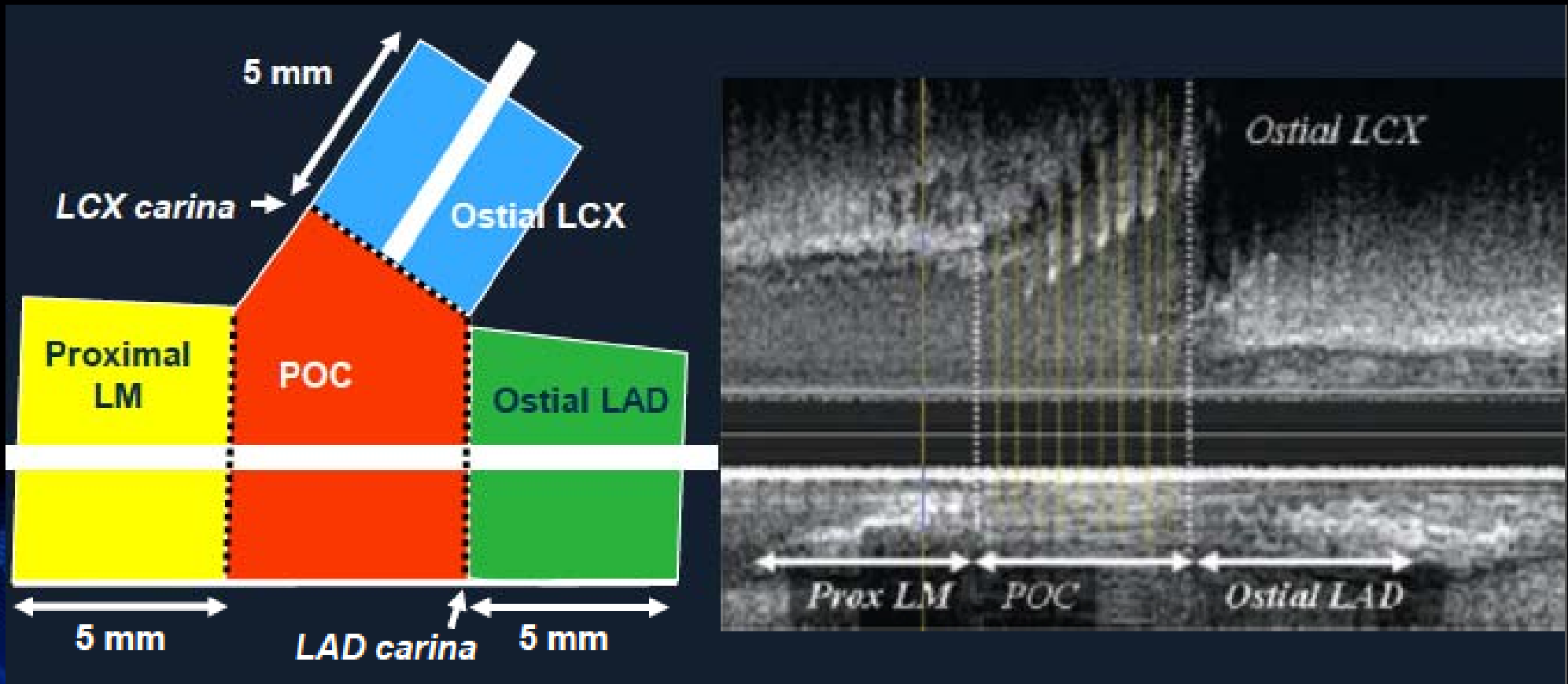
### A. MLA predicting FFR<0.80



4.1 mm<sup>2</sup>

4.8 mm<sup>2</sup>

# Post-Stenting IVUS Evaluation : Criteria for Stent Underexpansion at the Distal LM Bifurcation Complex (n=403 with Routine 9-month Angio FU): IVUS Segmentation

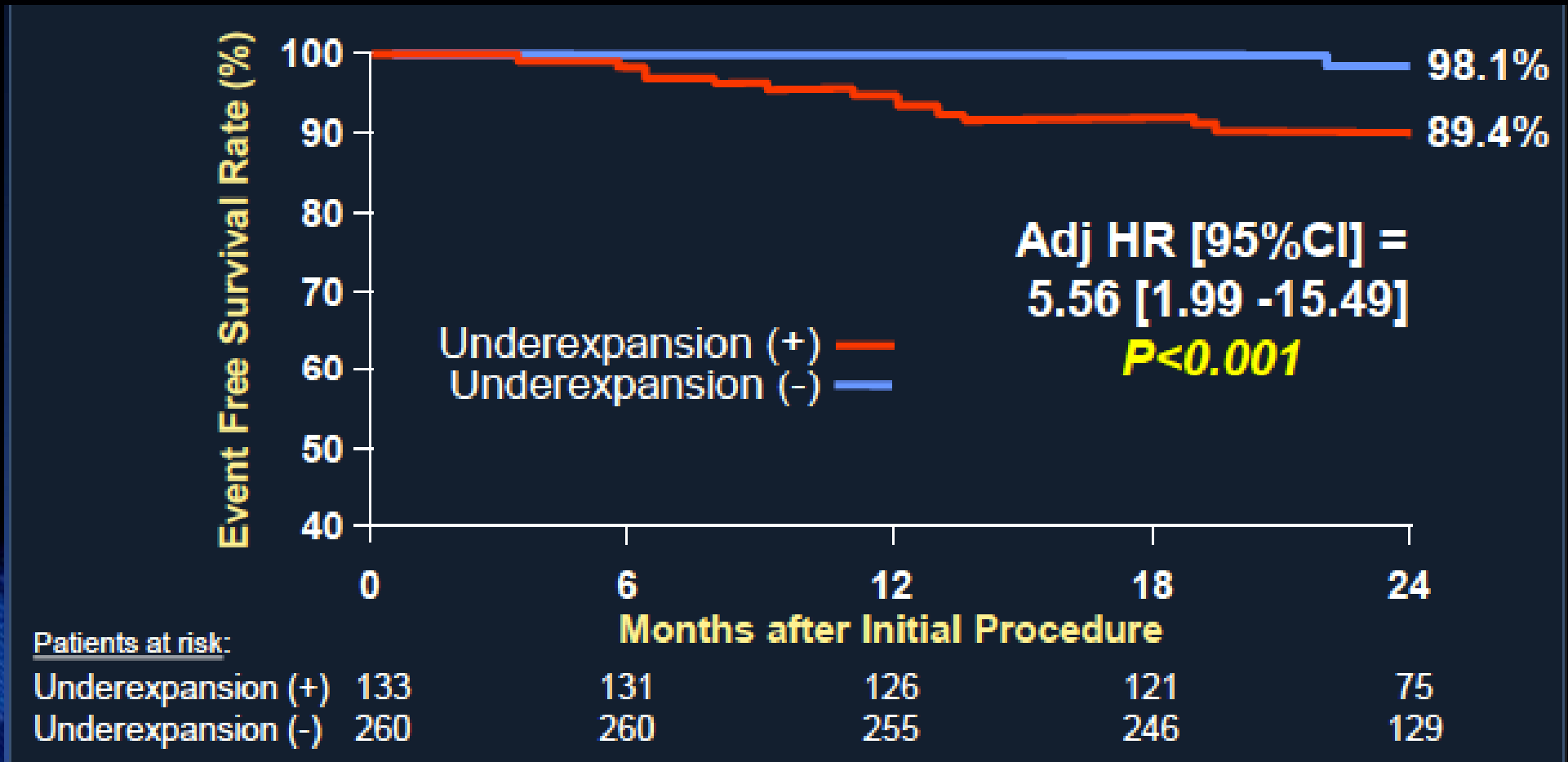


**POC = polygon of confluence**

# Stent Underexpansion Predicts MACE

133 pts (33.8%) had  $\geq 1$  segment underexpansion(UE)

N=403; Routine 9-mth Angio F/up



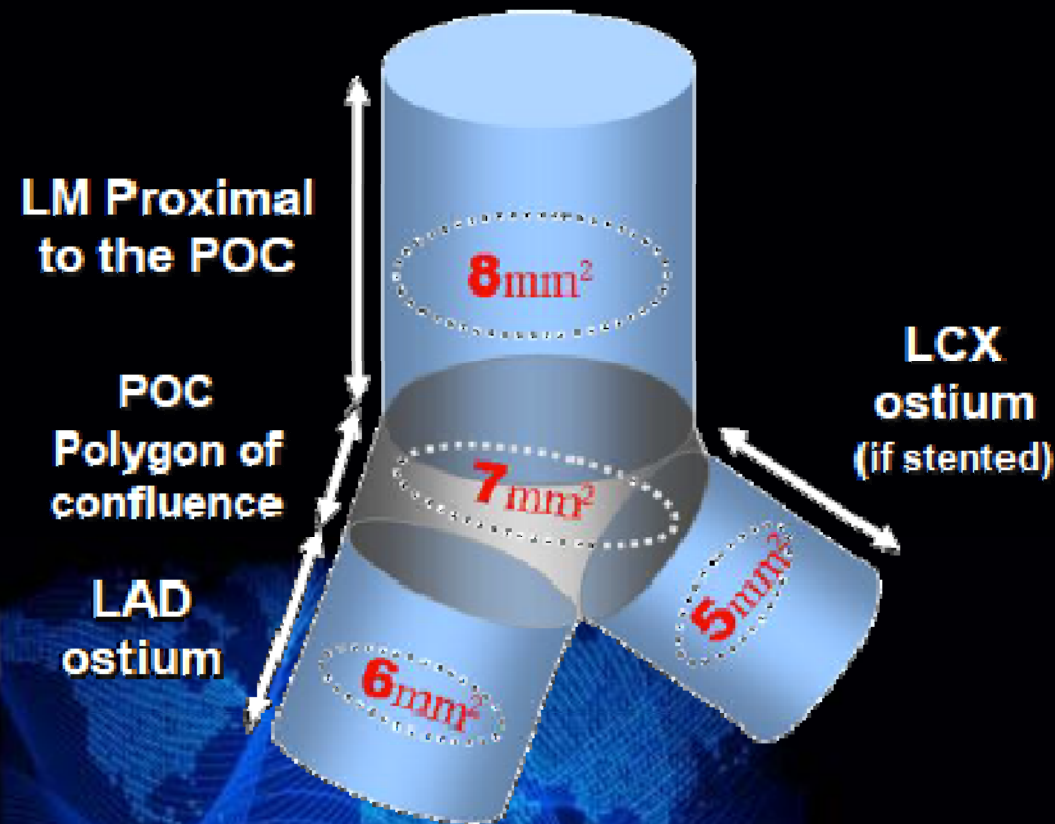
LCX not imaged in 10 2-stent pts

# Stent Underexpansion Predicts MACE & TLR

133 pts (33.8%) had  $\geq 1$  segment underexpansion(UE)

N=403; Routine 9-mth Angio F/up

## Optimal expansion criteria (post hoc)

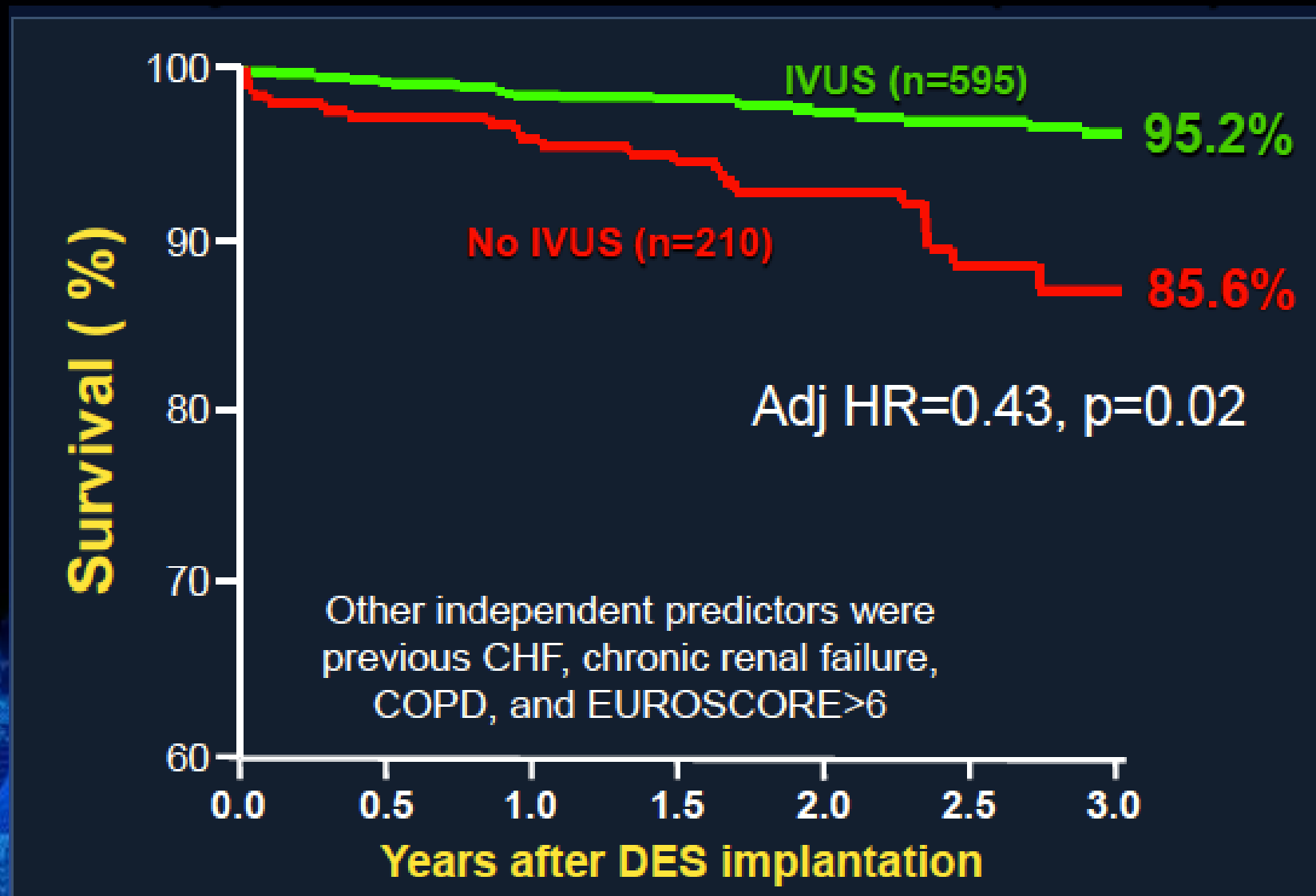


LCX not imaged  
in 10 2-stent pts

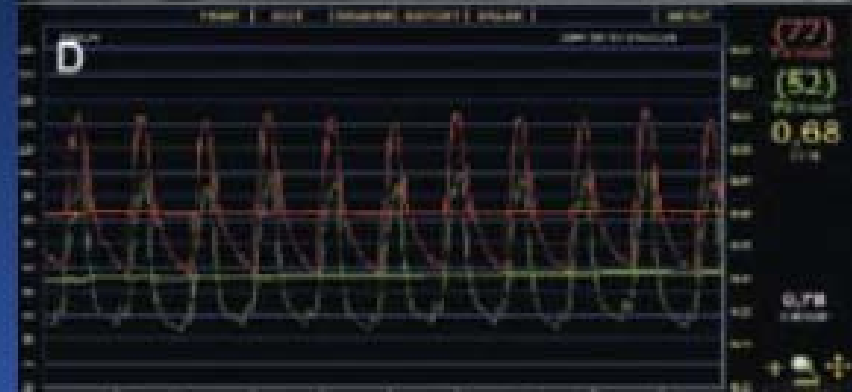
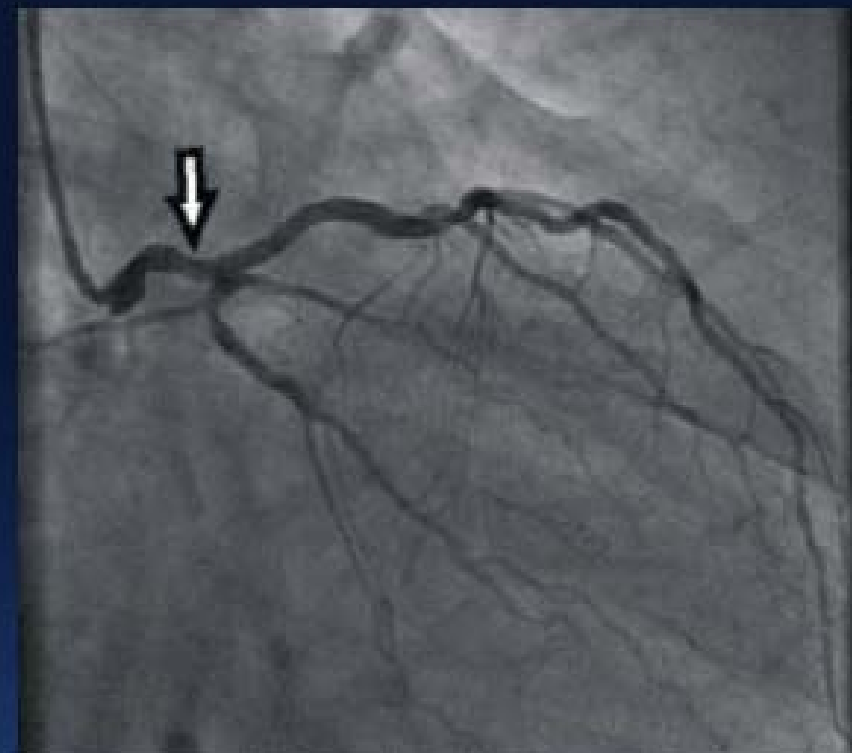
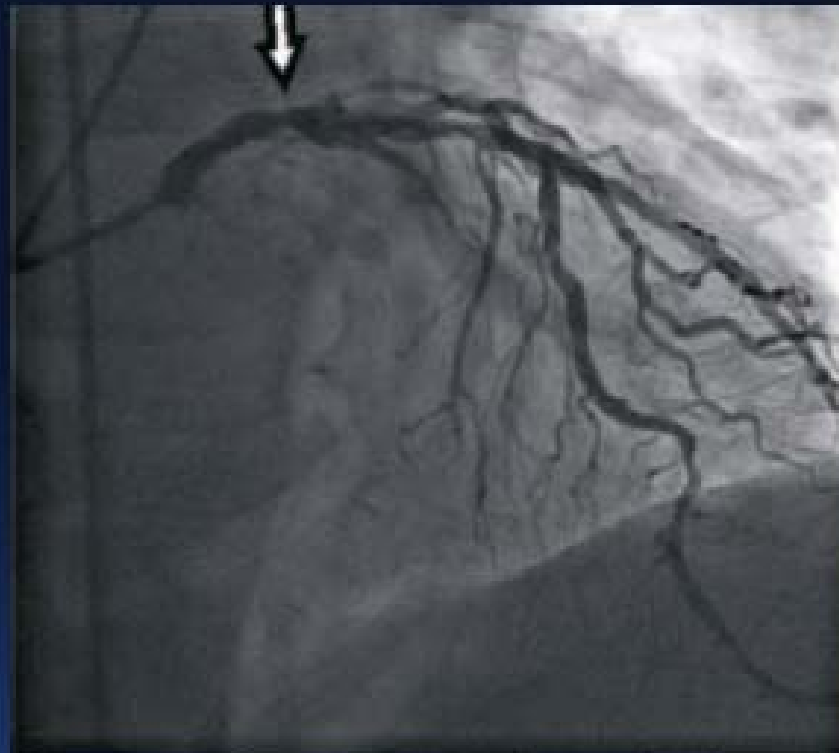
**2-year MACE-free survival** was lower in pts with vs. without underexpansion (89.4% vs. 98.1%; adj HR 5.56 [1.99 -15.49]; P<0.001)

**2-year TLR-free survival** was lower in pts with vs. without underexpansion (90.9% vs 98.5%; adj HR 6.08 [1.94 - 19.02]; P=0.002); 12/16 TLRs (80%) occurred in cases with underexpansion

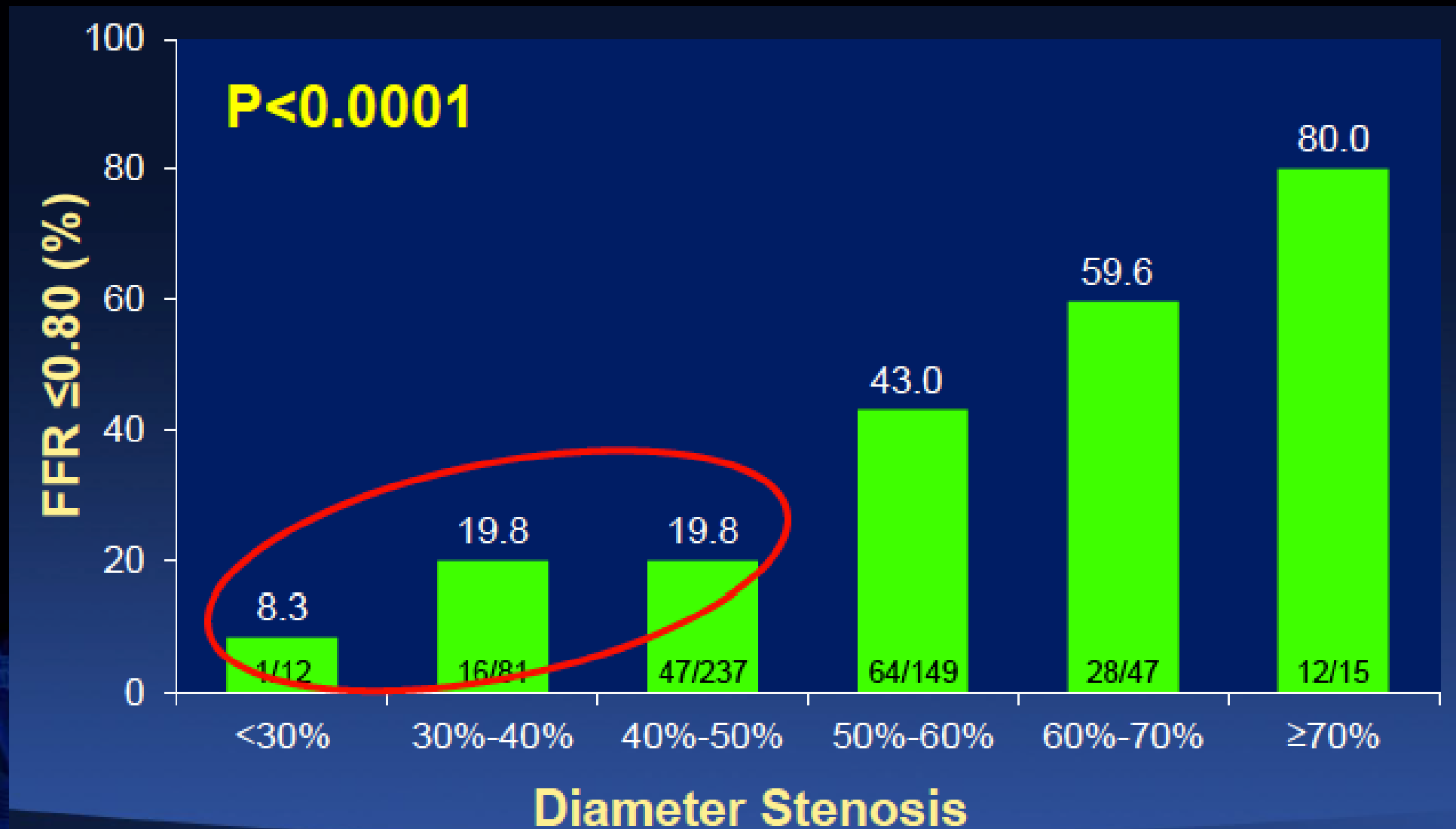
# MAIN-COMPARE: Impact of IVUS guidance on mortality after LMCA-DES Implantation



# Visual assessment vs. LM FFR



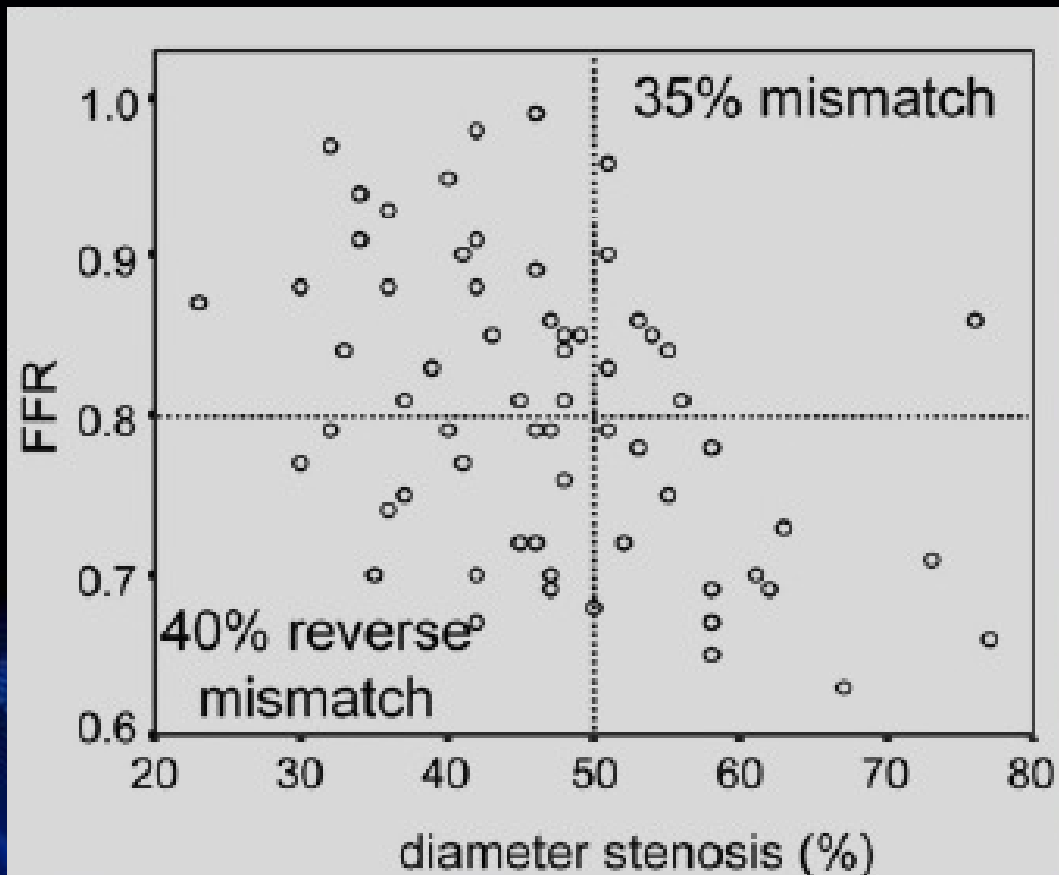
# QCA DS% and FFR Correlation



VERDICT & F1RST studies. Stone GW. TCT2012; submitted

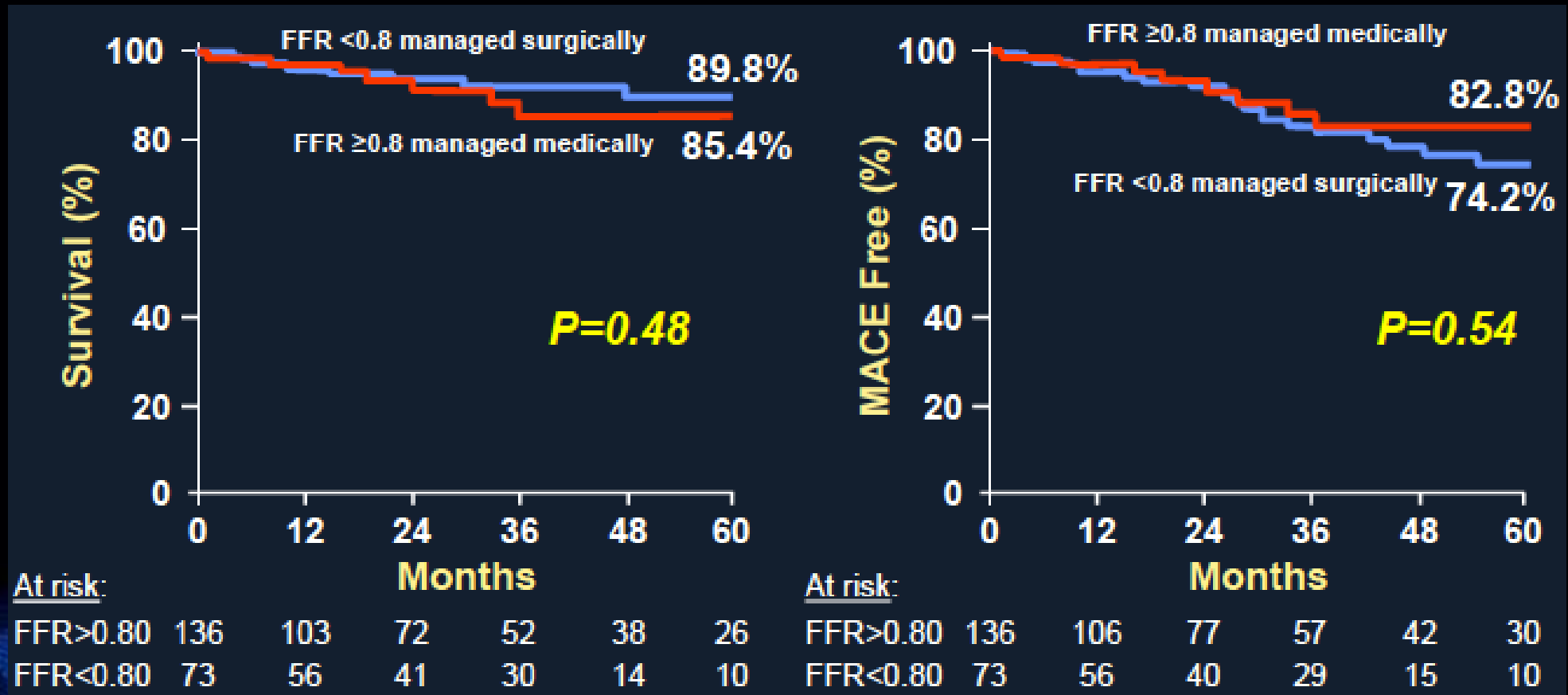


# Visual-Functional Mismatch in LMCA Lesions: FFR vs. QCA 63 LMCA lesions included in overall analyses



- LMCA lesions had a greater frequency of reverse mismatch (**underestimation**), but lower mismatch (**overestimation**)
- The presence of plaque rupture influenced the assessment of mismatches

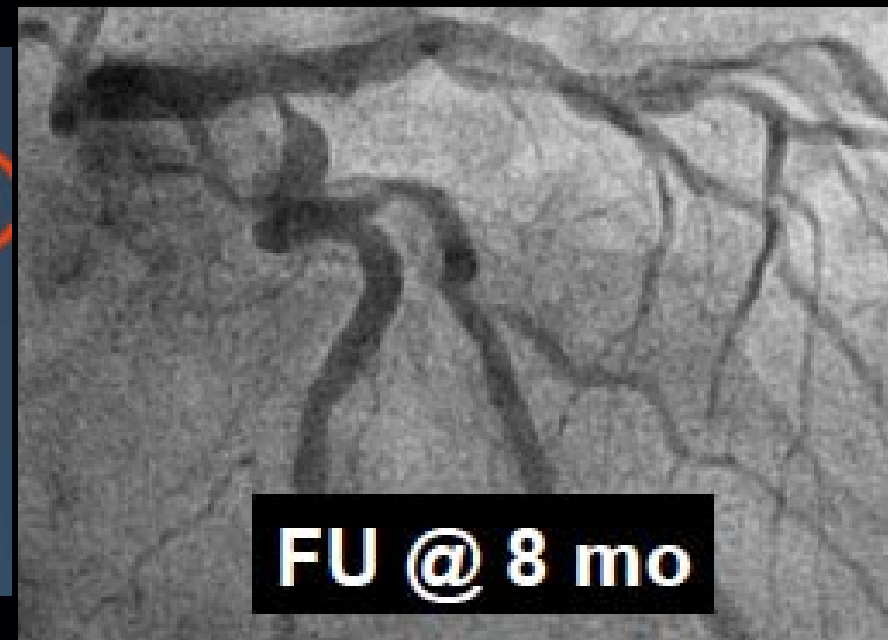
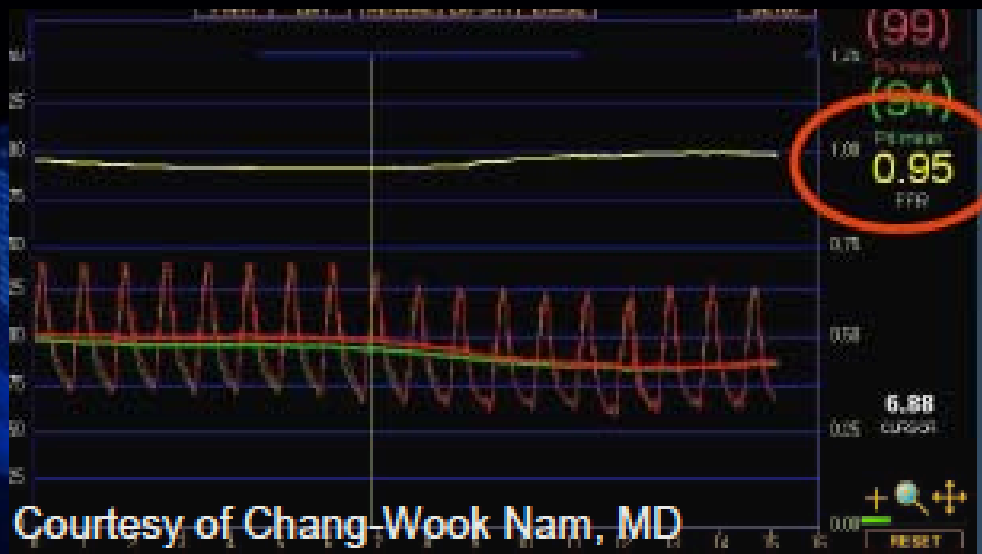
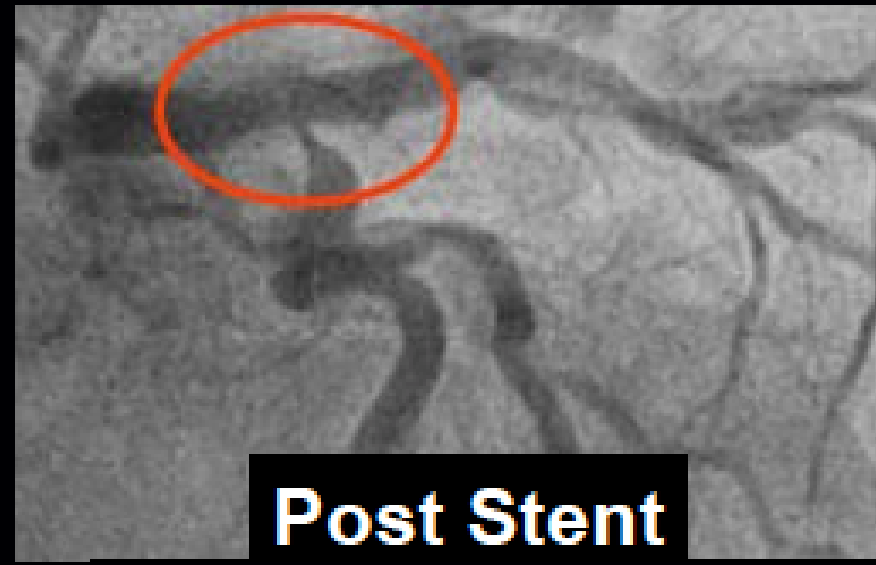
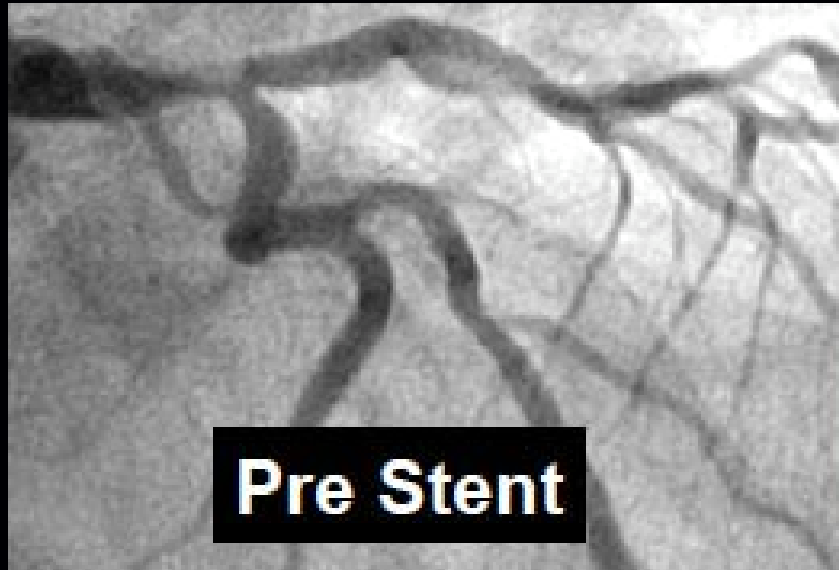
# 136 LM pts with FFR $\geq 0.8$ managed medically vs. 73 LM pts with FFR $< 0.8$ managed surgically: 5-year follow-up



Isolated LM ds: 5-yr survival: 100%  
Med vs 75% Surg ( $P=0.32$ )

Isolated LM ds: 5-yr MACE-free survival:  
70% Med vs 66% Surg ( $P=0.54$ )

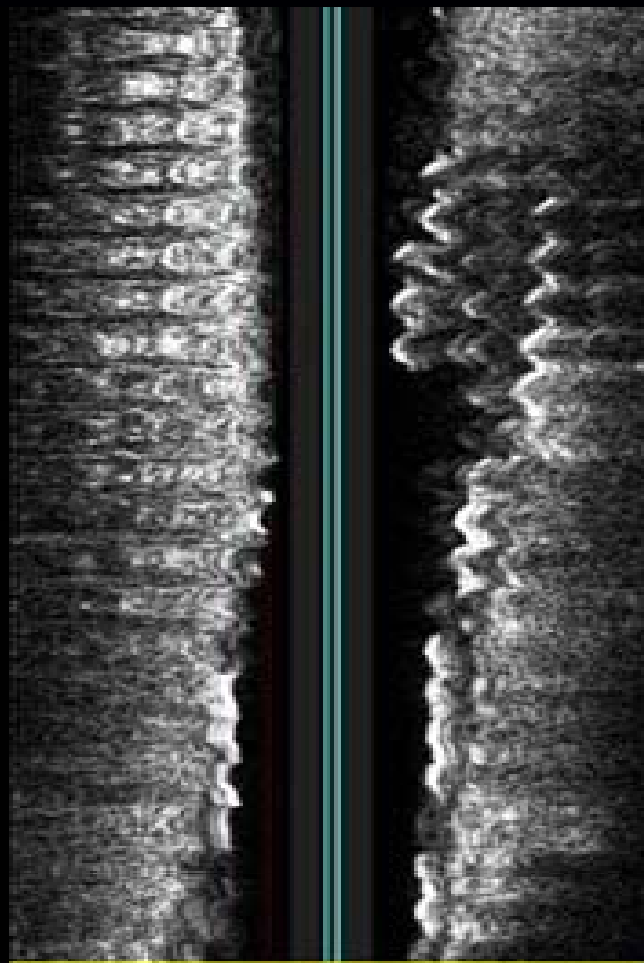
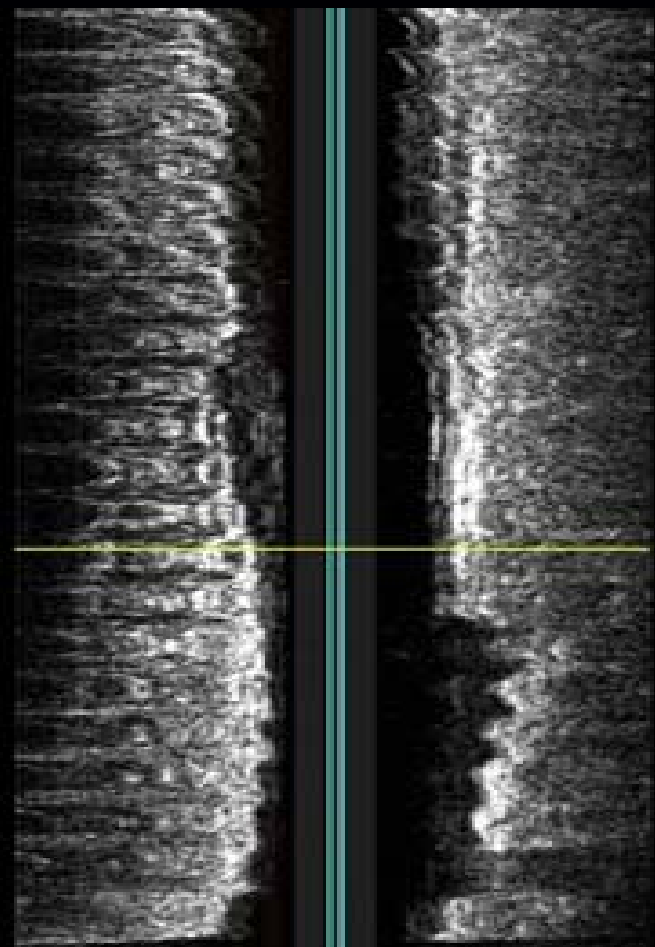
# Jailed LCx ostium: Should you do something about it?



# Carina Shift : Post-LM Crossover Single Stent Placement

LCX – Pre LAD Stent  
(Longitudinal View)

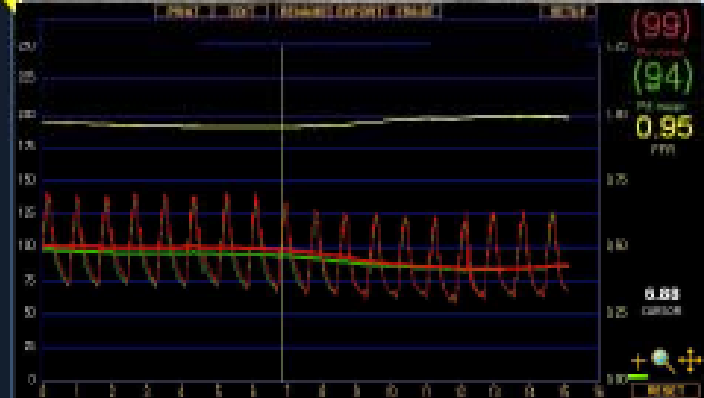
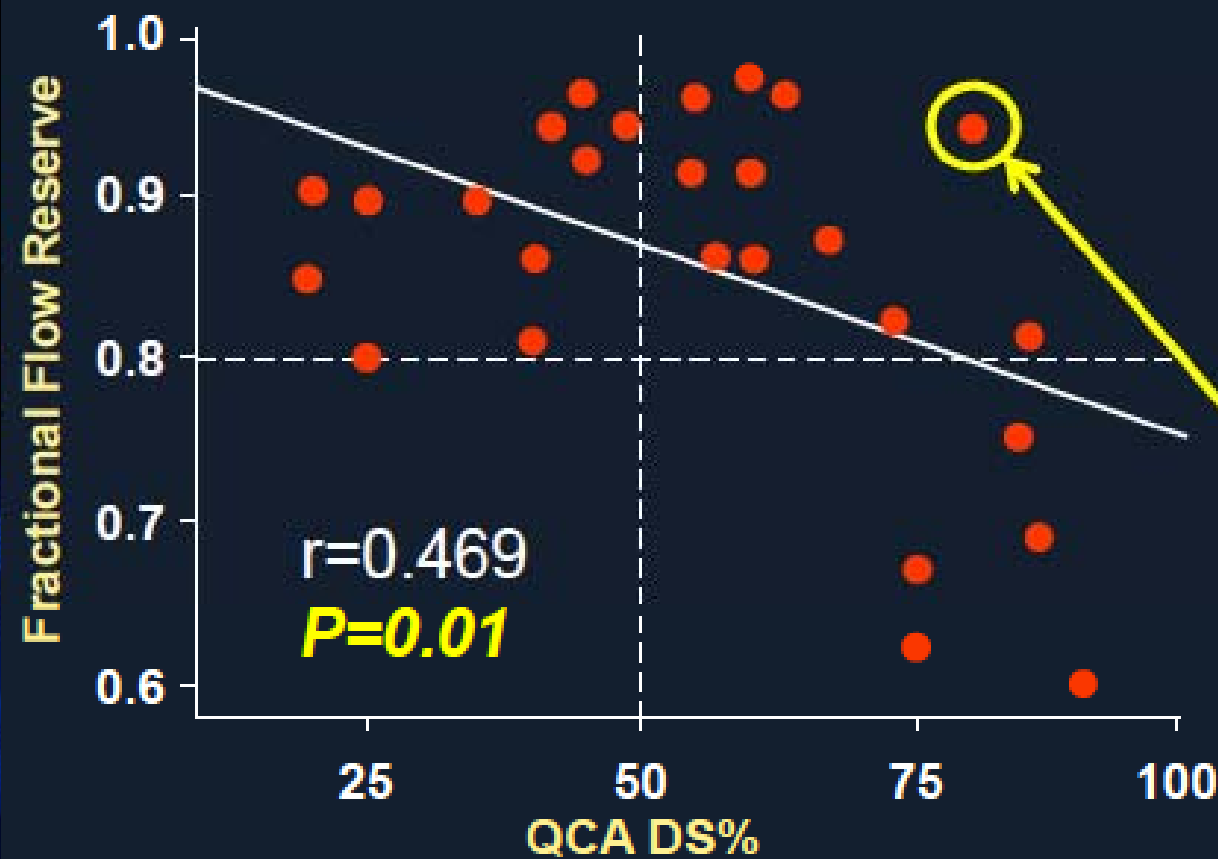
LCX – Post LAD Stent  
(Longitudinal View)



Pullback from LCx artery

# FFR of "Jailed" LCX After Stent from LM to LAD in 29 Pts

By QCA ostial LCX DS increased from  $30 \pm 15\%$  pre to  $56 \pm 21\%$  post ( $>50\%$  in 17 (59%) cases).  $FFR \leq 0.80$  in 5 (17%).



# Malaysia NCVD PCI registry – LMCA PCI



# NCVD PCI Registry - Malaysia

- 2007-2009 Report:
- Total patients = 10602
- Total reported procedures = 11,498
- Number of intervened lesions : 15,538
- LMS : 1.8% of lesions

## ANNUAL REPORT OF THE NCVD - PCI REGISTRY *year 2007-2009*





# NCVD PCI Registry – LM Subgroup

- This Analysis 2007-2010:
- Total patients = 13223
- Total reported procedure = 20774
- LMS procedure
  - Total patients = 352 (2.7% of patients)
  - Total procedure = 369



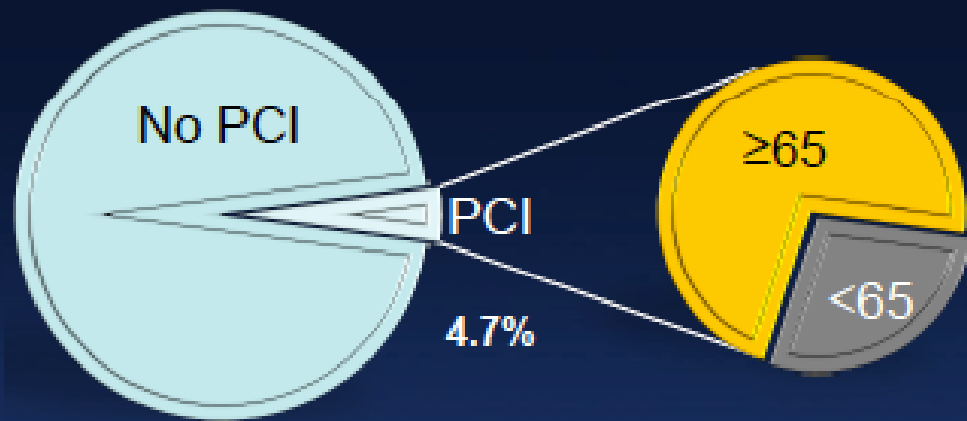


# Demographic

	All patients	Patients undergone LMS intervention	Significance
Number of patients	13223	352	
Mean age in years (SD)	57.2 (10.2)	61.6 (11.1)	p < 0.001
Body mass index (kg/m <sup>2</sup> )	26.7 (5.0)	26.2 (2.0)	
Gender (Male:Female)	81%:19%	76%:24%	
Hyperlipidemia	76.0%	80.0%	
Hypertension	73.9%	73.7%	
Diabetes Mellitus	47.1%	50.1%	
Previous myocardial infarct	44.0%	36.4%	p = 0.009
Heart failure	4.3%	7.7%	
Cerebro-vascular disease	1.4%	3.7%	
Renal impairment	6.8%	11.9%	p=0.004
Previous bypass surgery	4.2%	13.9%	P < 0.001
Presentation as acute coronary syndrome	43.3%	35.0%	
Smoking status			
Never smoked	44.7%	52.4%	
Former smoker	32.9%	30.8%	
Current smoker	22.4%	16.8%	

# Unprotected LM PCI in the USA NCDR CathPCI, 2004 - 2008

## Unprotected Left Main Disease



ULMCA PCI  
Cases/year

<6

6-15

>15

Centers (n)

660

25

8

	PCI (5,627)	No PCI (125,377)
Age	72 yrs	62yrs
Female	41%	24%
Prior MI	33%	36.4%
CHF	81%	7.7%
Stroke	21%	3.7%
COPD	27%	-NA-
CKD	13%	11.9%
STEMI	13%	ACS : 35%
Shock	16%	4%

# LMS intervention

- Majority of the left main stem intervention was done on unprotected LMS.
- Only 49 of 352 (13.9%) patients had previous CABG



# Clinical Presentation of LMS disease

Clinical Presentation	Number	Percentage of total LMS-PCI procedure (%)
Elective PCI	239	65.3
ST elevation Myocardial Infarct	56	15.2
NSTEMI/Unstable Angina	72	19.5

# LMS Lesion types

	Number	Percentage
De Novo	371	90.9
In Stent restenosis		8.3
• Previous DES	23	
• Previous BMS	6	
Acute stent thrombosis	1	0.3
Missing data	7	0.5

# Types of stents used

Type of stents	Numbers	Percentage
Drug Eluting Stent (DES)	381	86 %
Bare Metal Stent (BMS)	55	12 %
Antibody stent	6	1 %
Missing	1	0 %



# Devices used

Device	Number	% of all LMS intervention
IVUS	122	33.1
Intraaortic balloon pump	52	14.1
Rotablator	19	5.2
Cutting balloon	18	4.9
Drug eluting balloon	23	6.2

# LMS PCI Procedural Complications:

<b>Complications</b>	<b>Number</b>
<b>Dissection</b>	29
<b>Perforation</b>	4
<b>Transient no reflow</b>	3
<b>Persistent no reflow</b>	2



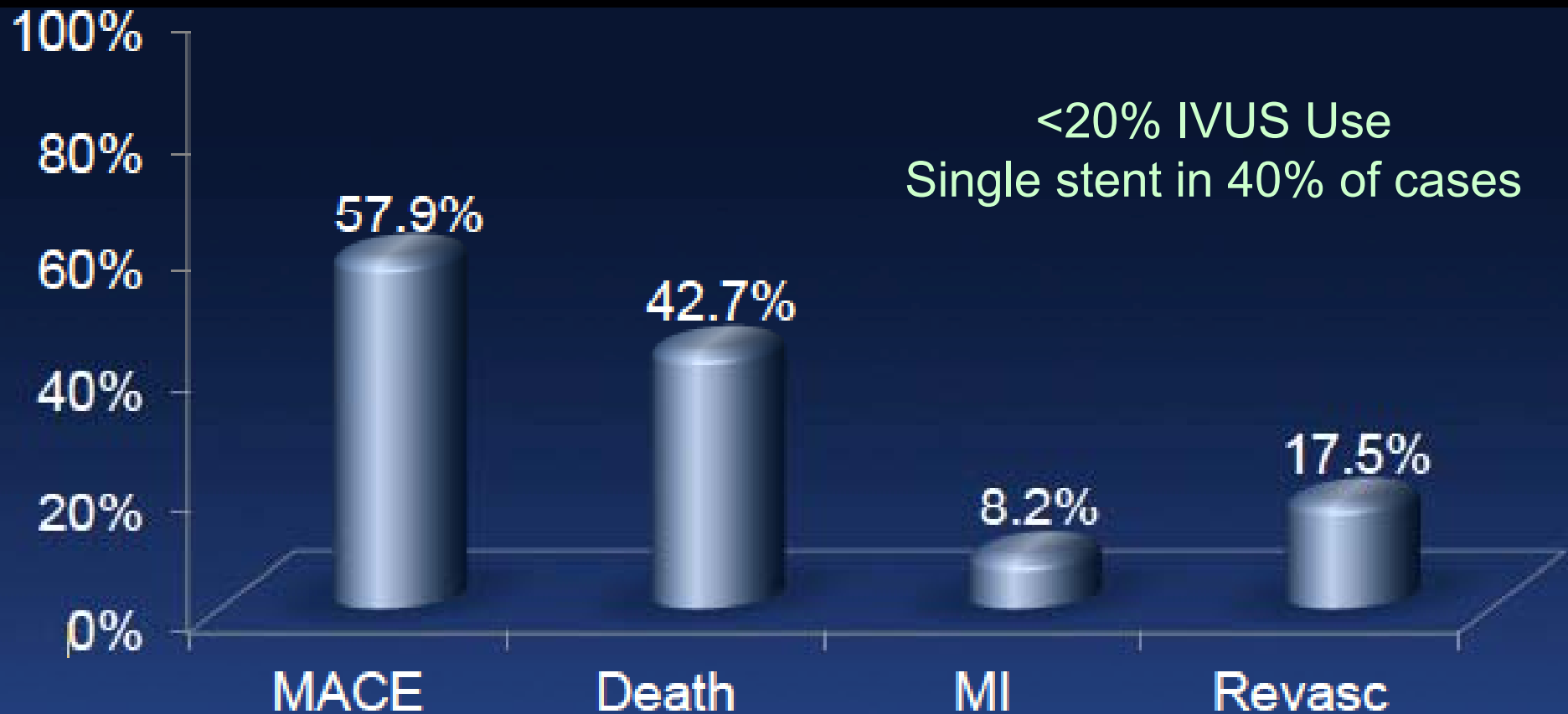
# In hospital mortality

	All PCI	LMS-PCI
ACS	8%	8%
Elective	0.4%	1.6%



# Unprotected LM PCI:

NCDR CathPCI 30-month Outcomes in 2765 pts  
with linked f/up data



# LM PCI in 2012 & Malaysia

- Unprotected LMCA PCI no longer 'restricted' indication
- Ostial/Body LMCA and LMCA Bifurcation PCI – safe and effective with proper patient selection and strategies
- Technical aspects : DES use, Single Provisional stent strategy or 2-stent techniques if necessary, IVUS and FFR guidance ('Functional PCI')
- Heart Team; Experienced operators and expanding evidence – improved LM PCI outcomes