

Unprotected Left Main Stenting: Patient Selection and Recent Experience

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AHA/ACC 2005 Guidelines Left Main CAD

Class IIa (Level B)

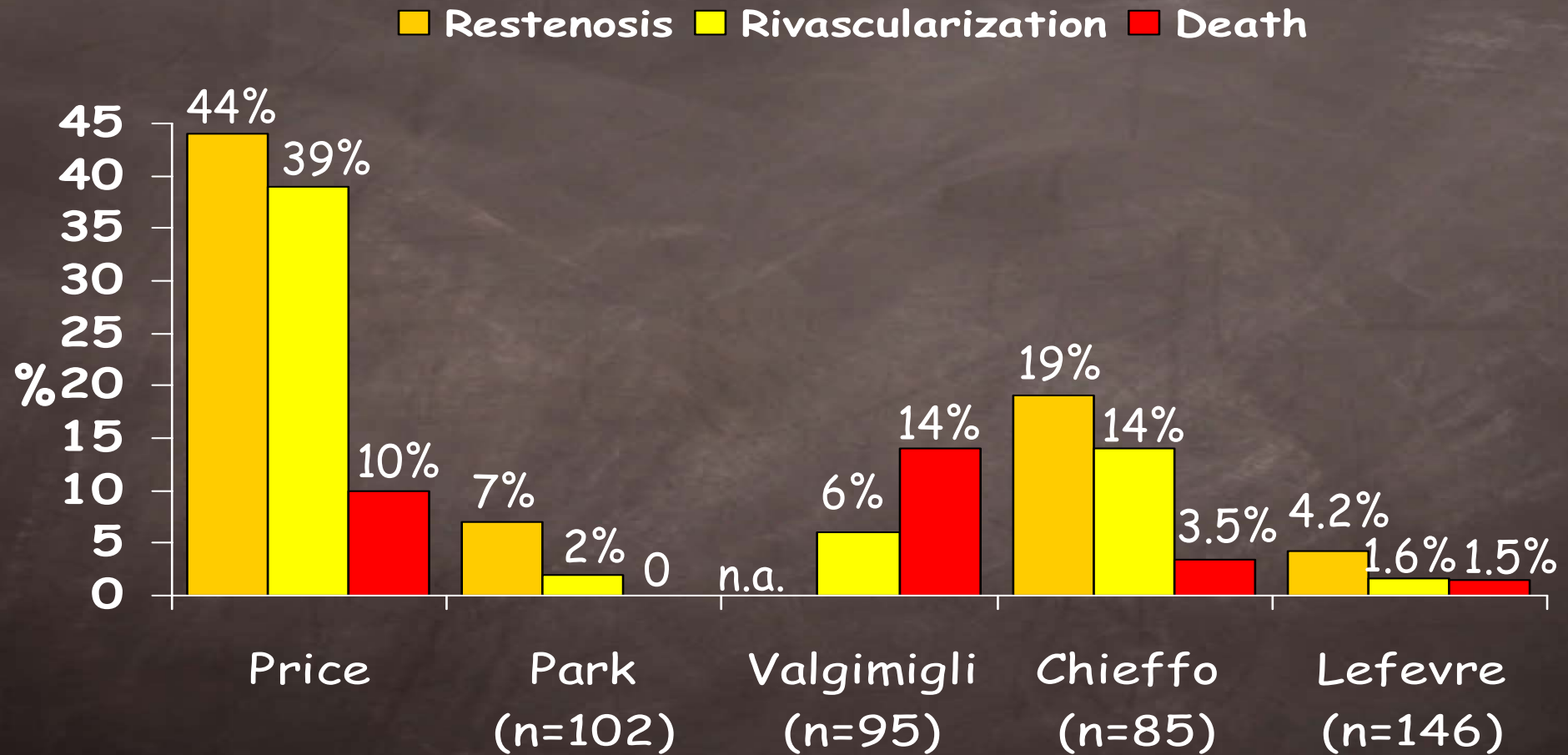
- The use of PCI for pts with significant unprotected LMCA stenosis is a reasonable revascularization in patients not eligible for CABG and in carefully selected pts.
- It is reasonable that patients undergoing PCI to unprotected left main coronary obstructions be followed up with coronaryangiography between 2 and 6 months after PCI (Level C).

Unprotected LMCA DES Registries



| Study | Site(s) | Years | Pts | Stent | Comment |
|------------------|--|---------------|-----|------------|--|
| Park et al | Asan Medical Center, Seoul, Korea | 2003- 2004 | 102 | SES | EF ≤ 40% excluded 71% bifurcation |
| Valgimigli et al | Erasmus Medical Center, Netherlands | 2001- 2003 | 95 | SES or PES | Acute MI 66% bifurcation |
| Chieffo et al | Columbus and San Raffaele Hospital, Milan | 2002- 2004 | 85 | SES or PES | 45% poor surgical candidates and 81% bifurcation |
| Price et al | Scripps Clinic | 2002- 2004 | 51 | SES | 24% had EF ≤ 40% and 92% bifurcation |
| Lefevre et al* | Institute Cardiovasculaire, France | 2003- 2004 | 130 | PES | 76% bifurcation |

Left Main Stenting with DES



886±308 days Clinical Follow-Up

| n = 147 | |
|---------------|----------|
| Death, n (%) | 5 (3.4) |
| Cardiac Death | 4 (2.7) |
| TLR, n (%) | 1 (0.7) |
| TVR, n (%) | 7 (4.7) |
| MI, n (%) | 0 |
| MACE, n (%) | 11 (7.4) |

Chieffo et al Circulation 2007;116(2):158-162.

6-Month Angiographic Follow-Up

Angiographic Fup was performed in 106
(73%) of the pts

| | n=106 |
|---------------|-------|
| Restenosis, % | 1 (1) |
| Late Loss, mm | -0.01 |

Chieffo et al Circulation 2007;116(2):158-162.

Drug Eluting stent for LeFT main (DELFT) Registry

Study population

April 2002



April 2004

358

consecutive patients with
de novo ULMCA disease



SES or PES

Baseline Clinical Characteristics

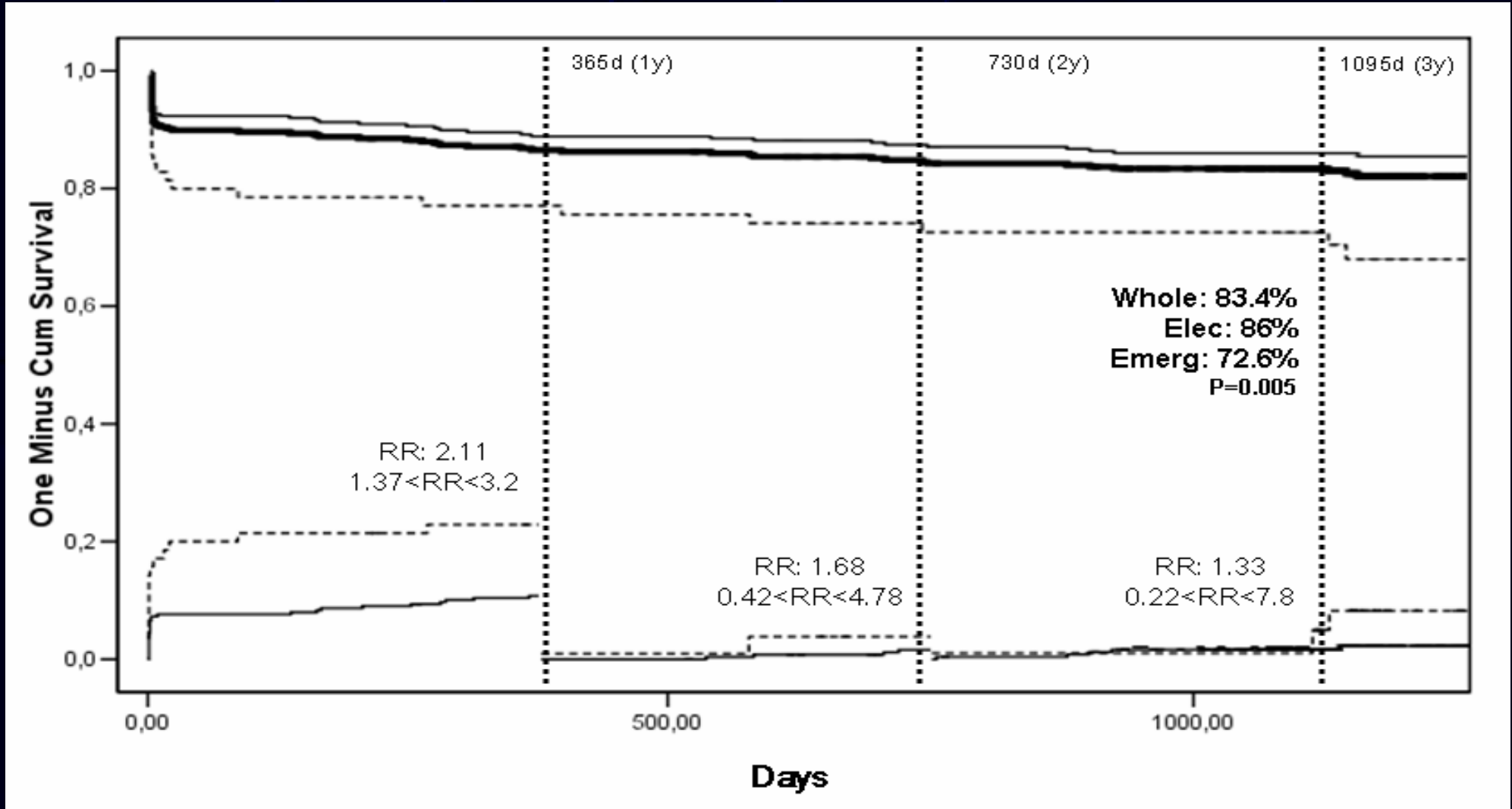
| | |
|------------------------|-----------|
| Diagnosis at admission | |
| Stable Angina | 44.1% |
| Unstable Angina | 41.9% |
| AMI | 8.4% |
| AMI+shock | 2.8% |
| Silent Ischemia | 2.8% |
| LVEF | 48.6±12.8 |
| EuroScore | 6.4±4.1 |
| >6 | 20.1% |
| >9 | 31.0% |
| Elective | 5.7±3.8 |
| Emergent | 9.9±3.5 |

19.6% Emergent PCI



DELFT

K-M survival analysis - Death + MI



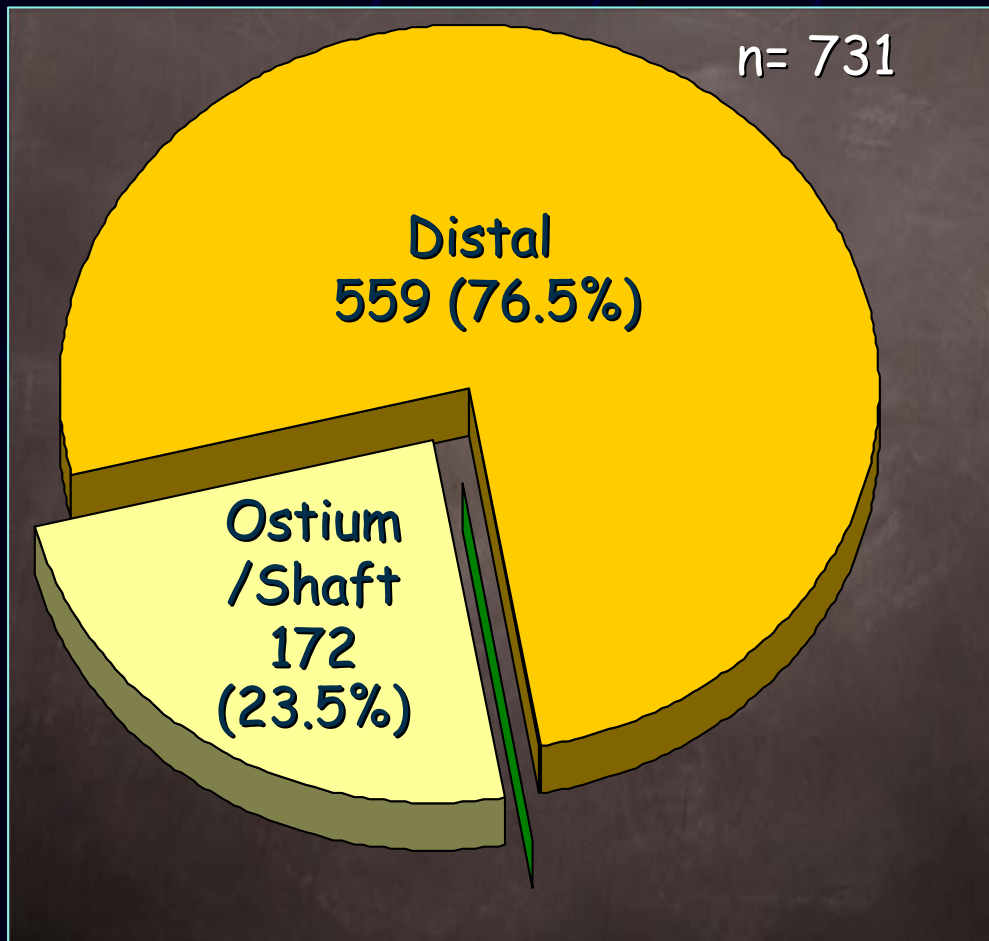
Baseline Clinical Characteristics I

| | DES (n = 731) |
|-----------------------|------------------|
| Age, years | 63.1±11.8 |
| Current or ex-smoker | 247 (33.8%) |
| Hypercholesterolemia | 368 (50.3%) |
| Systemic hypertension | 427 (58.4%) |
| Diabetes Mellitus | 176 (24.0%) |

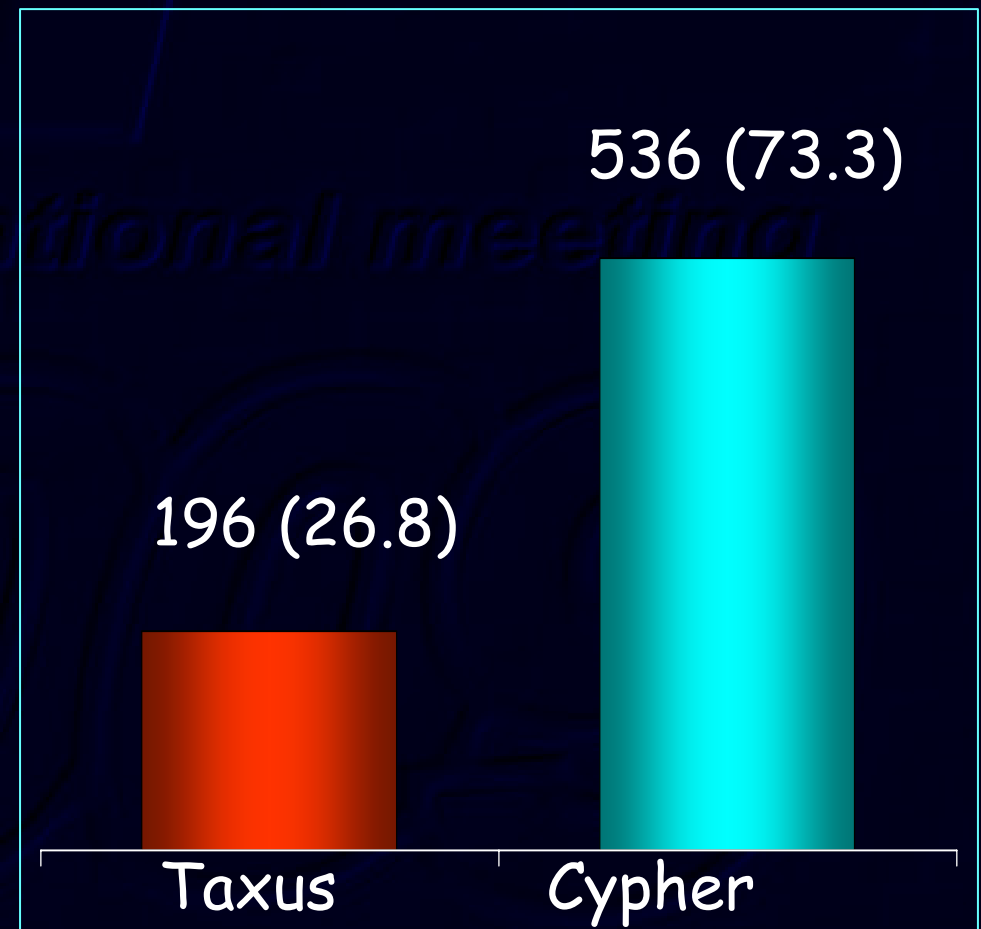


Lesion and Procedural Characteristics

Lesion Location

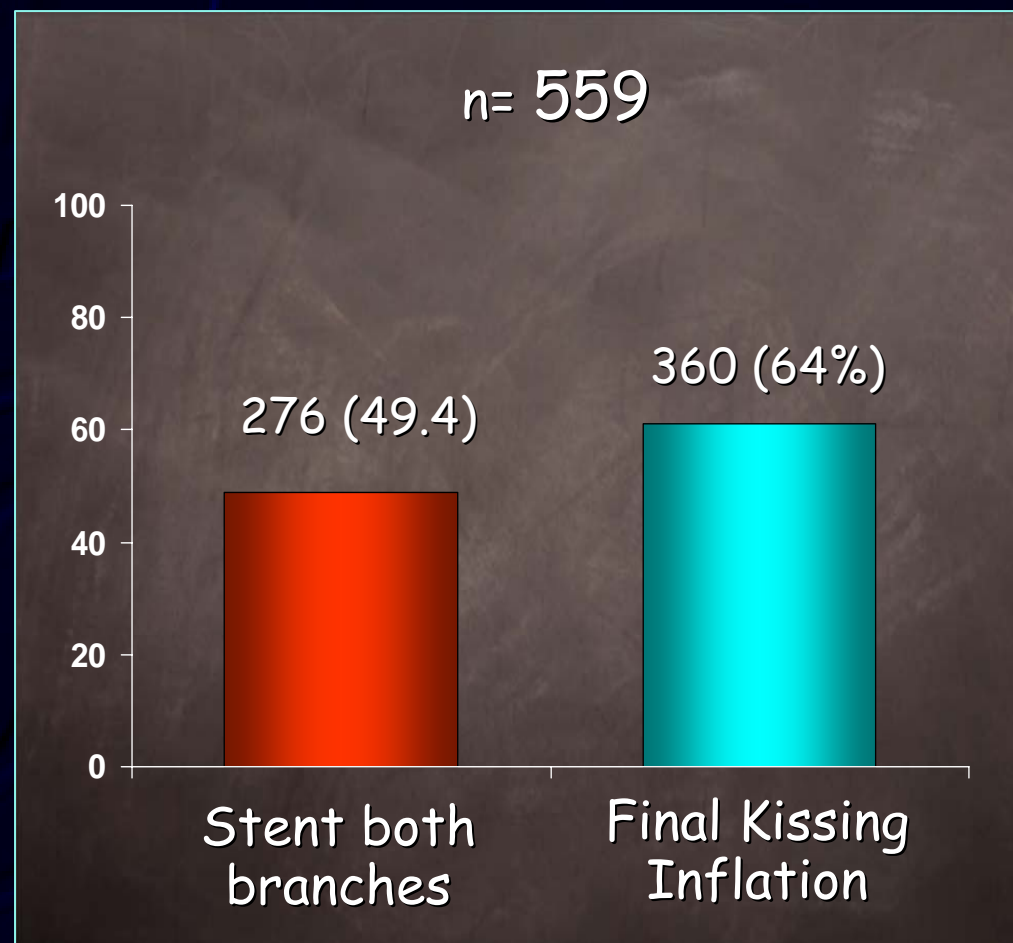
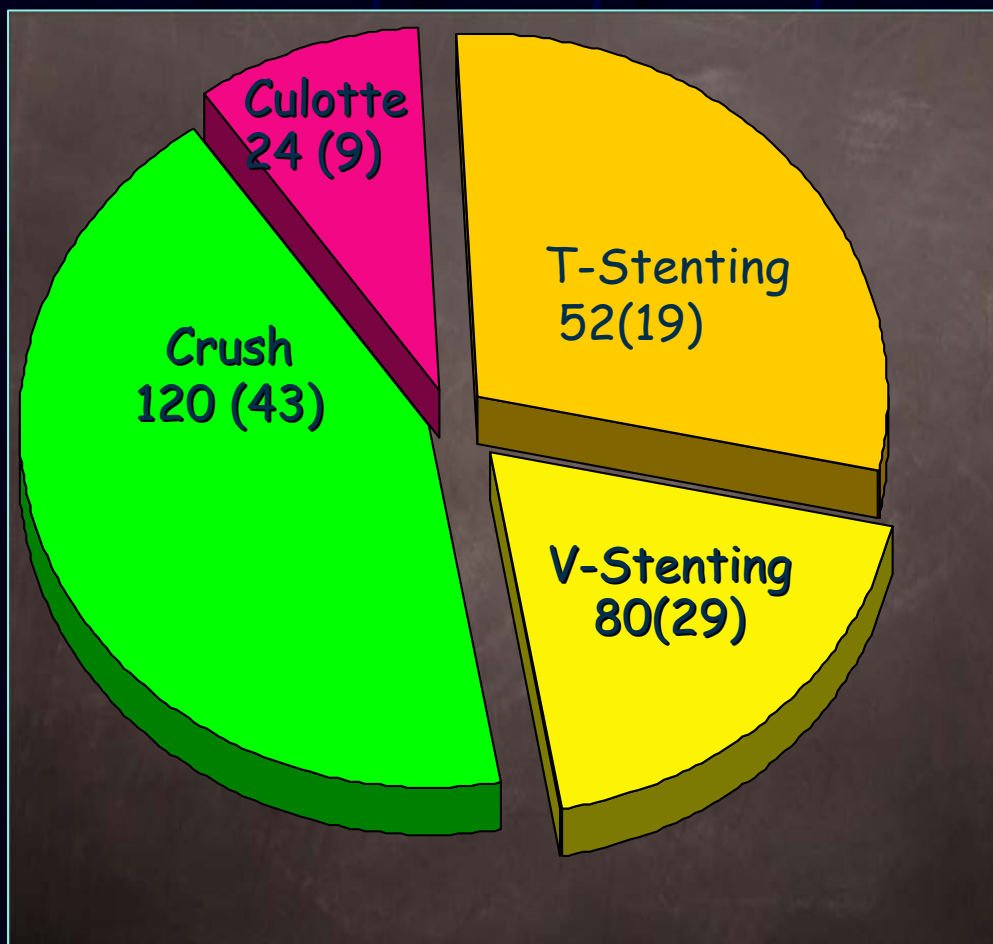


Stent Type



Procedural Characteristics

Stenting Technique



In-Hospital and Long Term Fup

| | In Hospital n=731 | Follow-up (29.5.±13.7 ms) n= 726 |
|----------------------|----------------------|--|
| Cardiac Death, n (%) | 5 (0.7) | 26 (3.6) |
| Total Death, n (%) | 5 (0.7) | 40 (5.5) |
| MI, n (%) | 69(9.4) | 11 (1.5%) |
| TLR, n (%) | 2 (0.3) | 76 (10.5) |
| TVR, n (%) | 2 (0.3) | 95 (13.0) |
| MACE, n (%) | 73 (9.9%) | 138 (19.0) |



Stent Thrombosis ARC Definitions

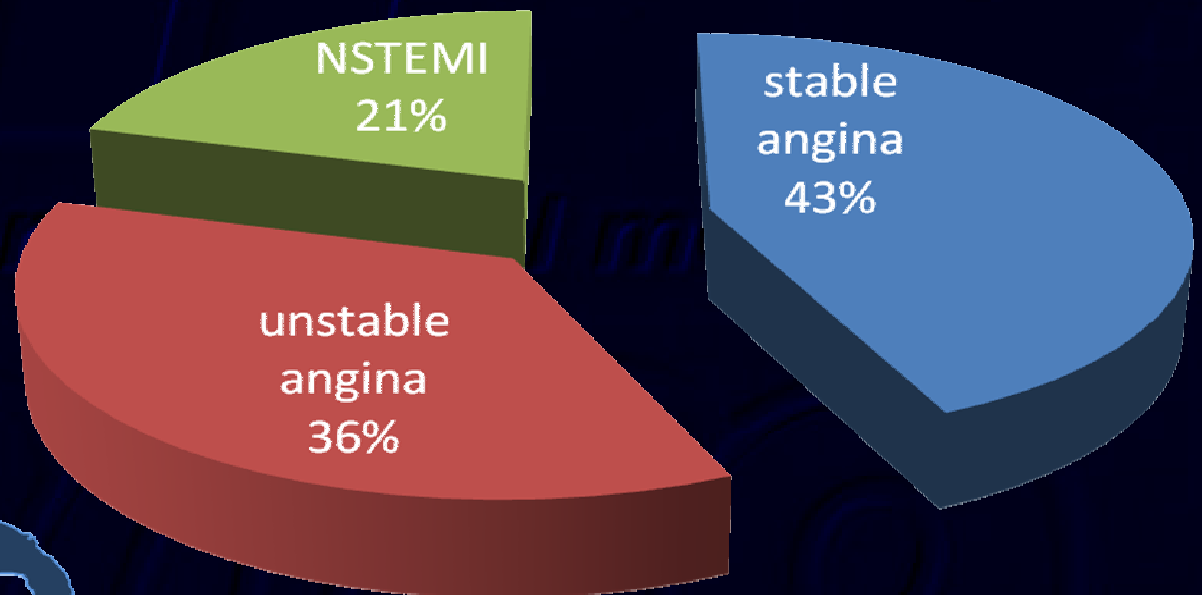
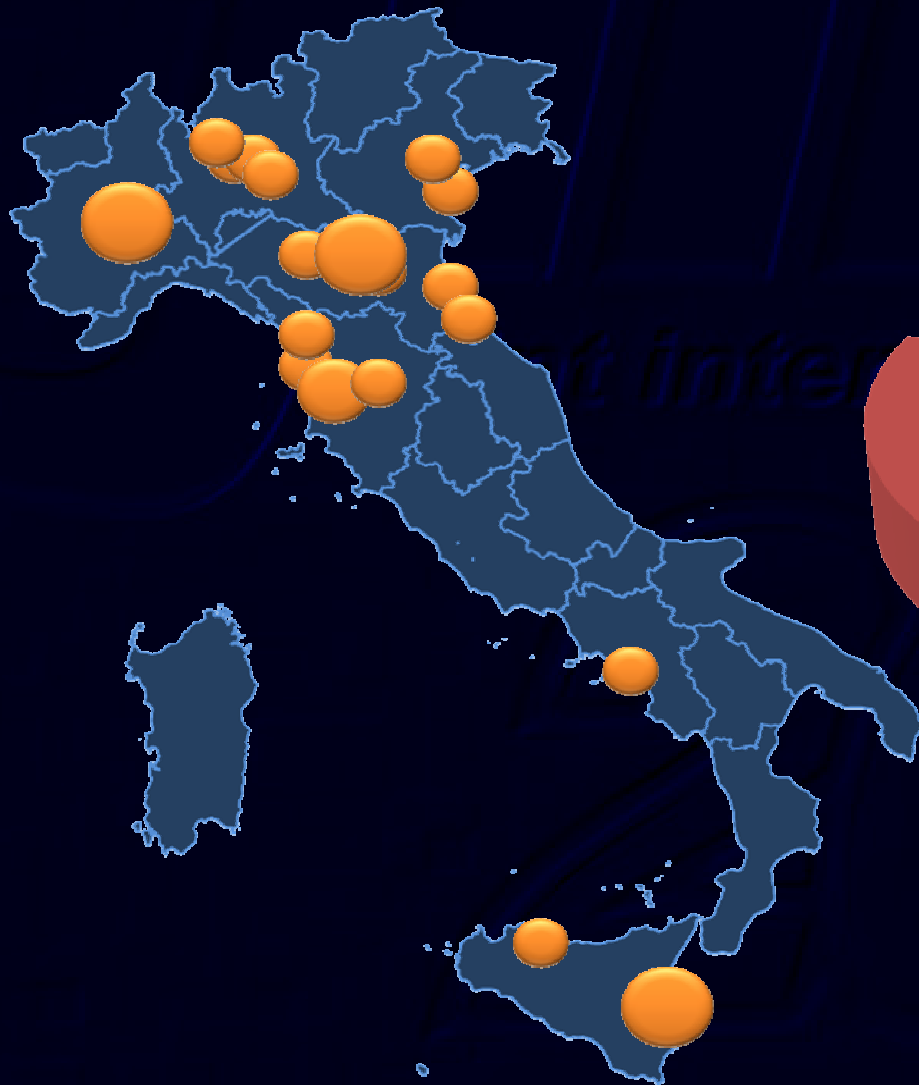
| n = 731 | |
|---------------------------|------------|
| Definite Stent Thrombosis | 4* (0.54%) |
| Probable Stent Thrombosis | 3 (0.4%) |
| Possible Stent thrombosis | 20 (2.7%) |

0.9%

*Late thrombosis in a Taxus stent in LAD at 3 ms

GISE-SICI survey on Left Main Stenting

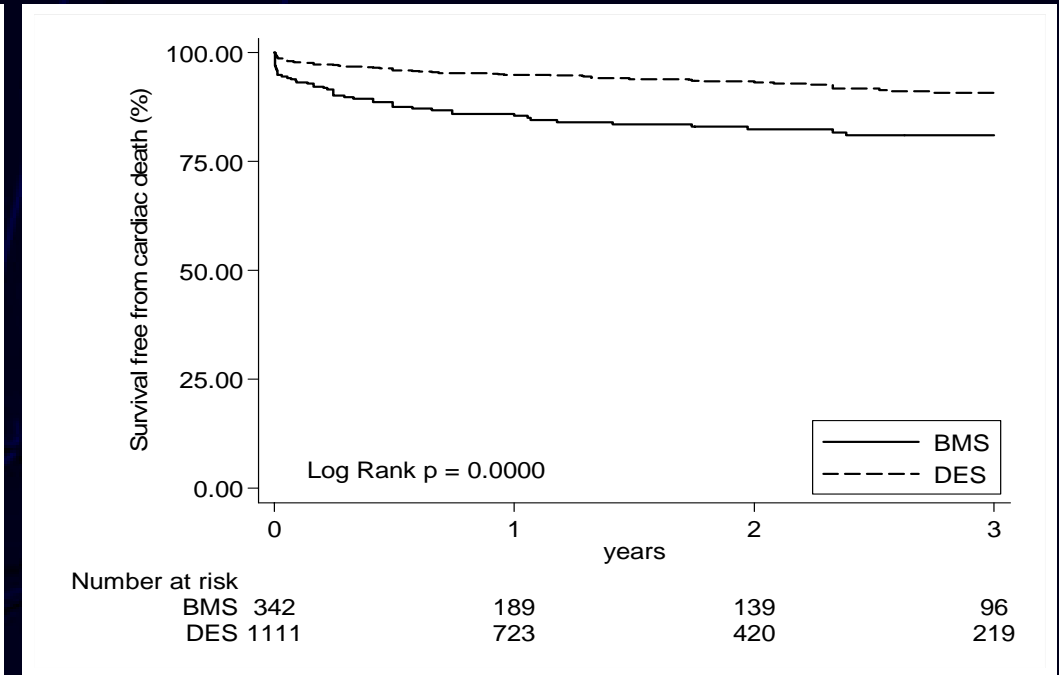
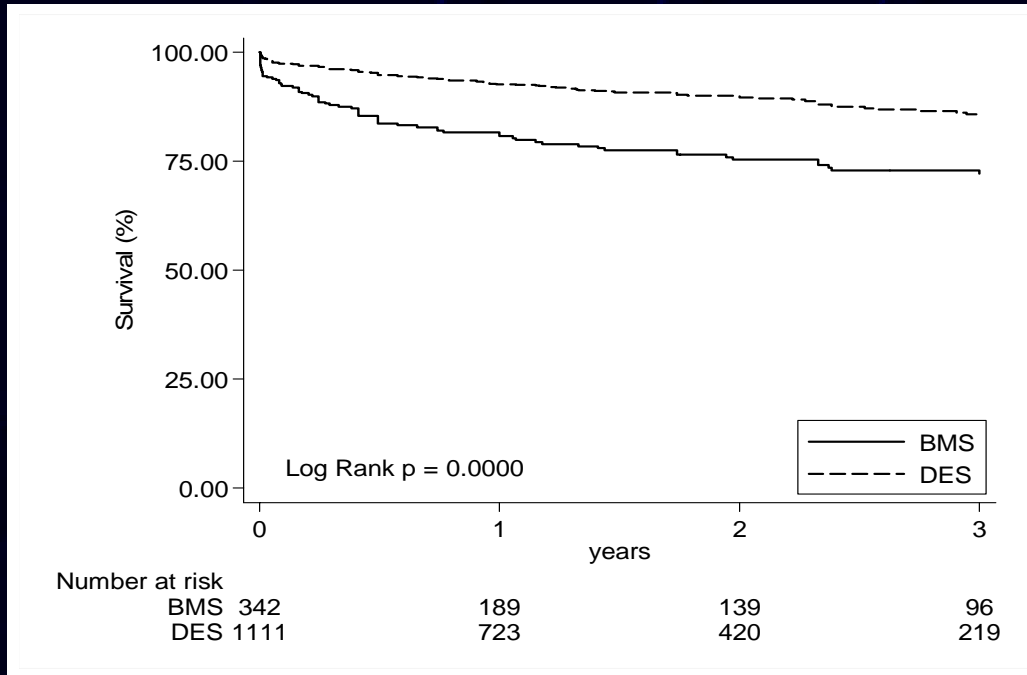
n = 1,453 patients, 19 Italian Centers



Courtesy of Prof Tamburino

GISE Registry DES vs BMS

Overall and Cardiac Mortality



Overall mortality: DES 85.8% vs 72.2%

Cardiac mortality: DES 90.8% vs 81.0%

Adjusted HR 0.40 (95% CI 0.25-0.63)

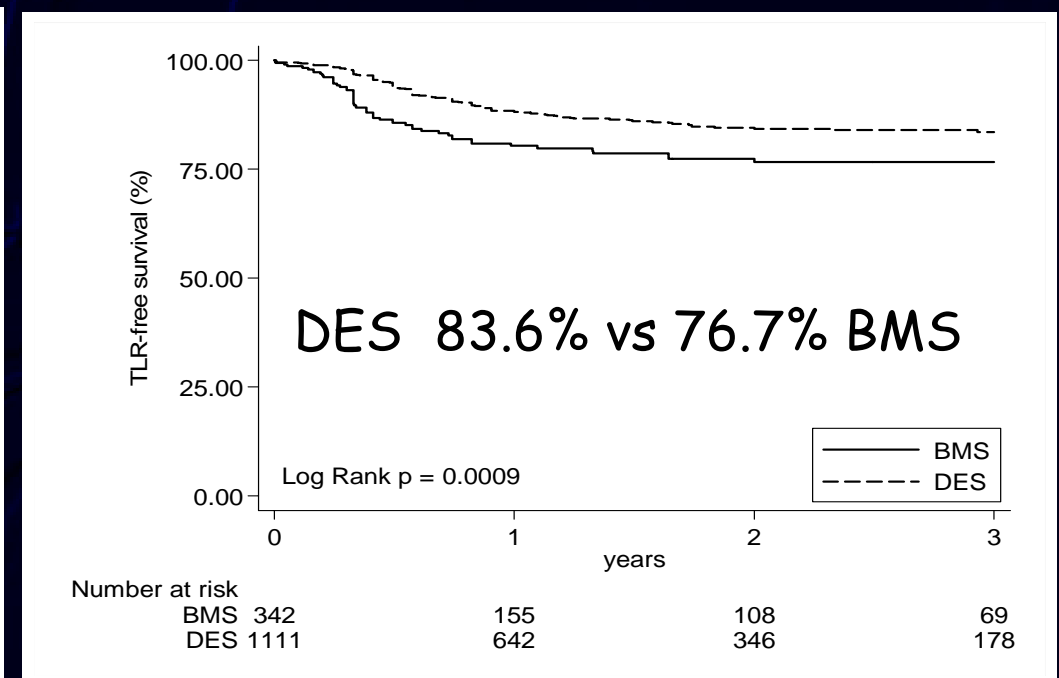
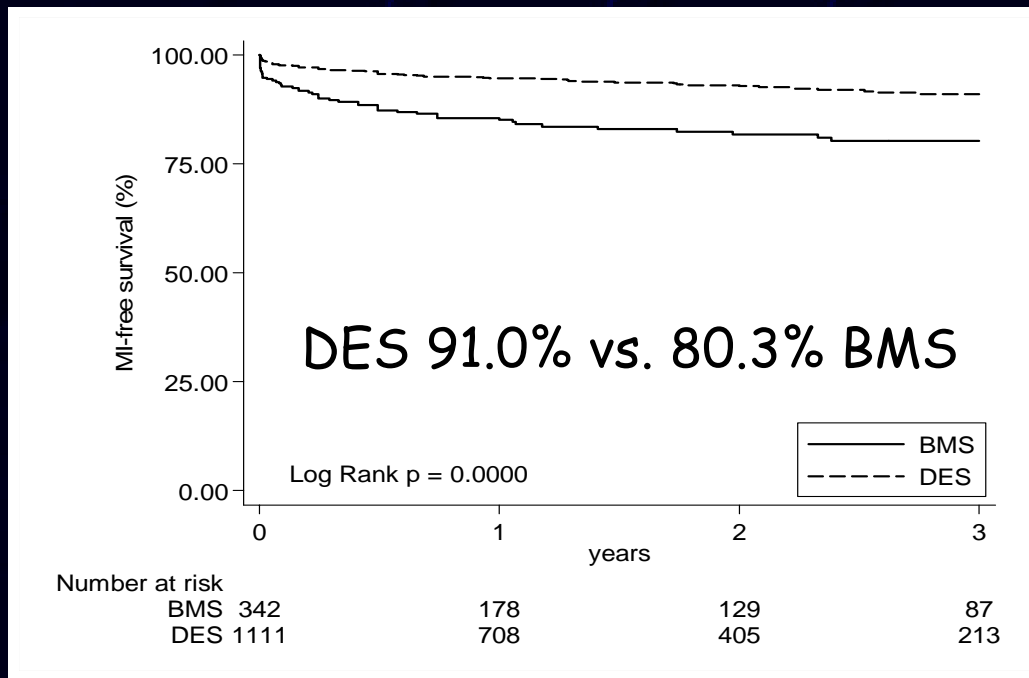
Adjusted HR 0.32 (95% CI 0.19-0.55)

GISE Registry DES vs BMS

MI and TLR

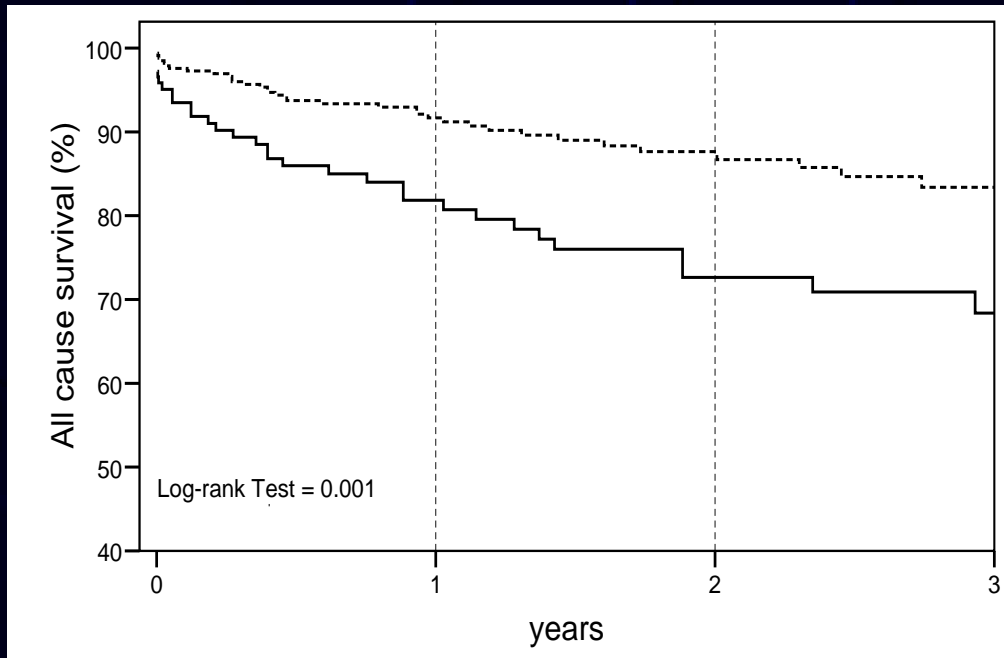
MI

TLR



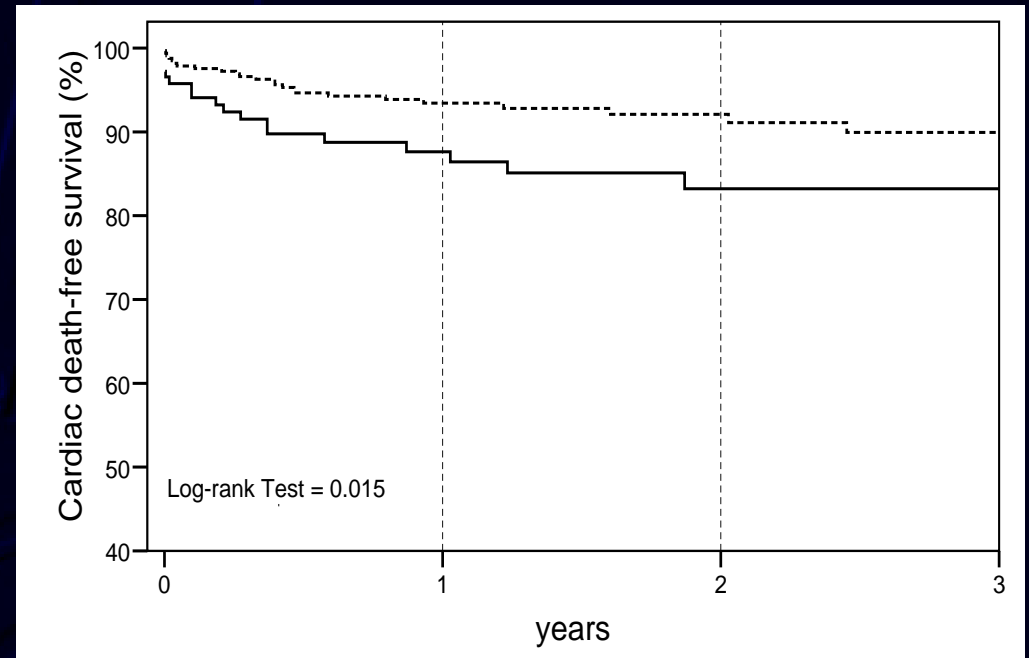
GISE Registry DES vs BMS

Ostium and shaft subanalysis - 3 years outcome



Overall mortality - unadjusted

$P < 0.001$

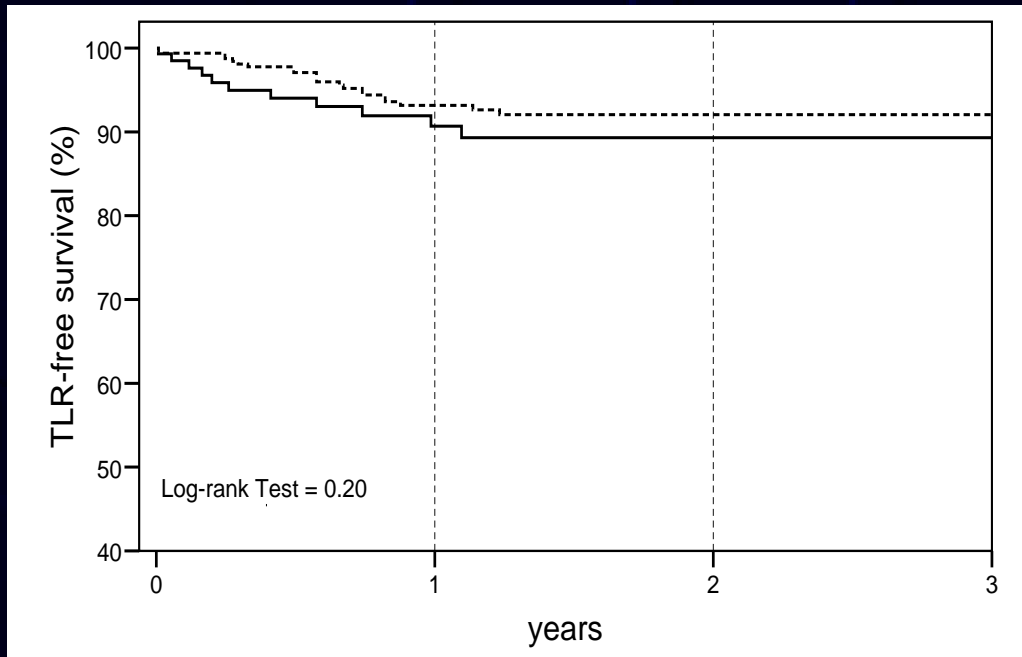


Cardiac mortality - unadjusted

$P = 0.015$

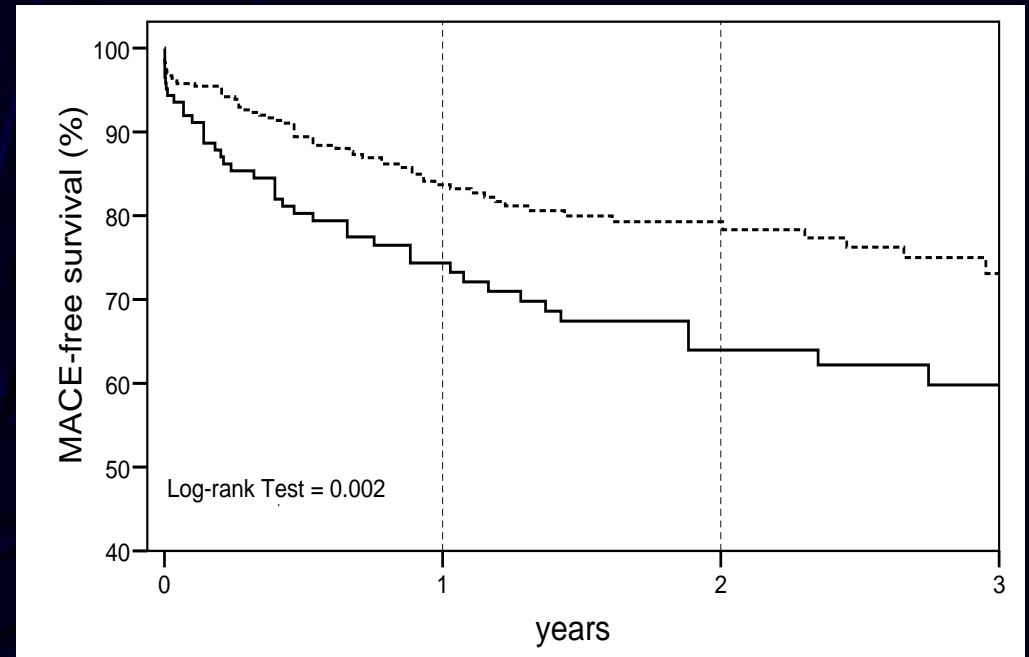
GISE Registry DES vs BMS

Ostium and shaft subanalysis - 3 years outcome



TLR - unadjusted

P = 0.20



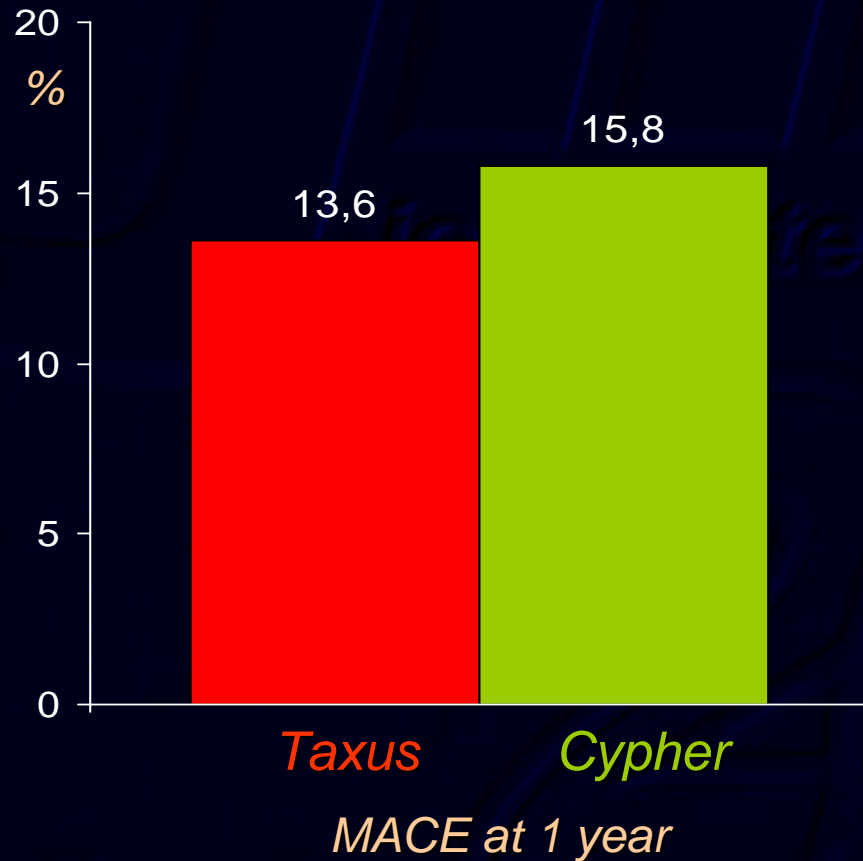
MACE-unadjusted

P = 0.002

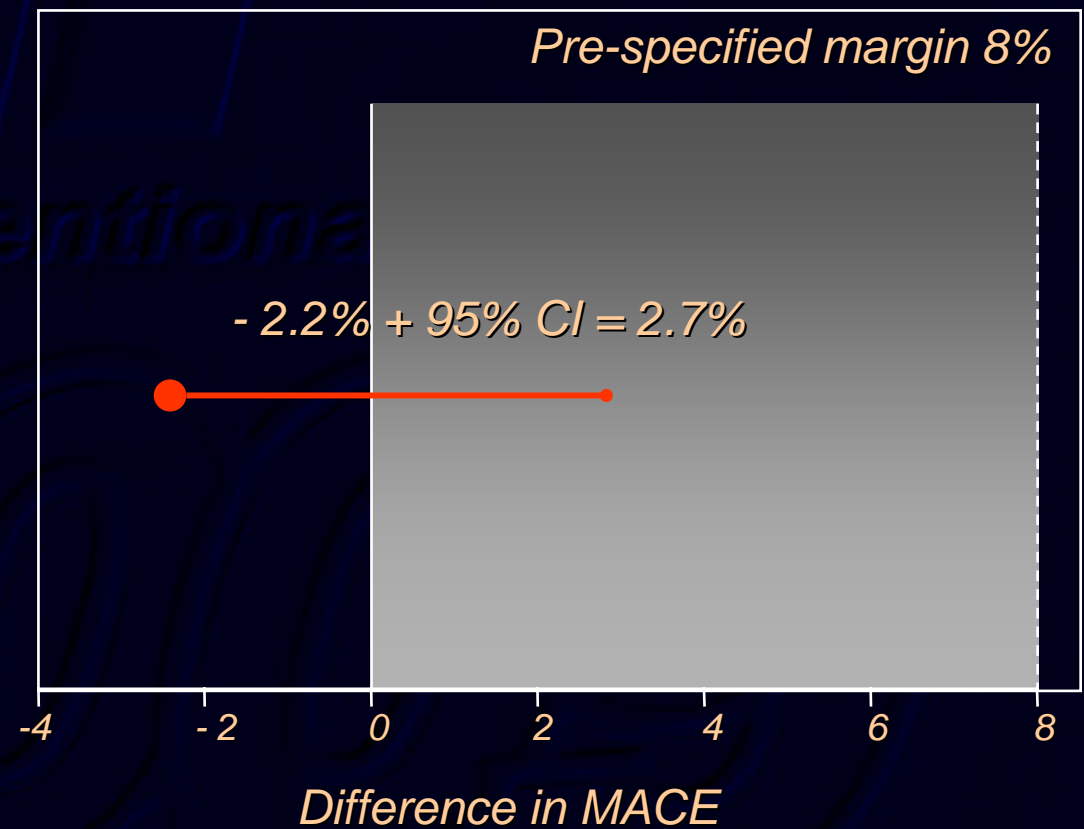
ISAR Left Main

Primary Endpoint: 1-Year MACE

RR 0.85; 95% CI 0.56 to 1.29



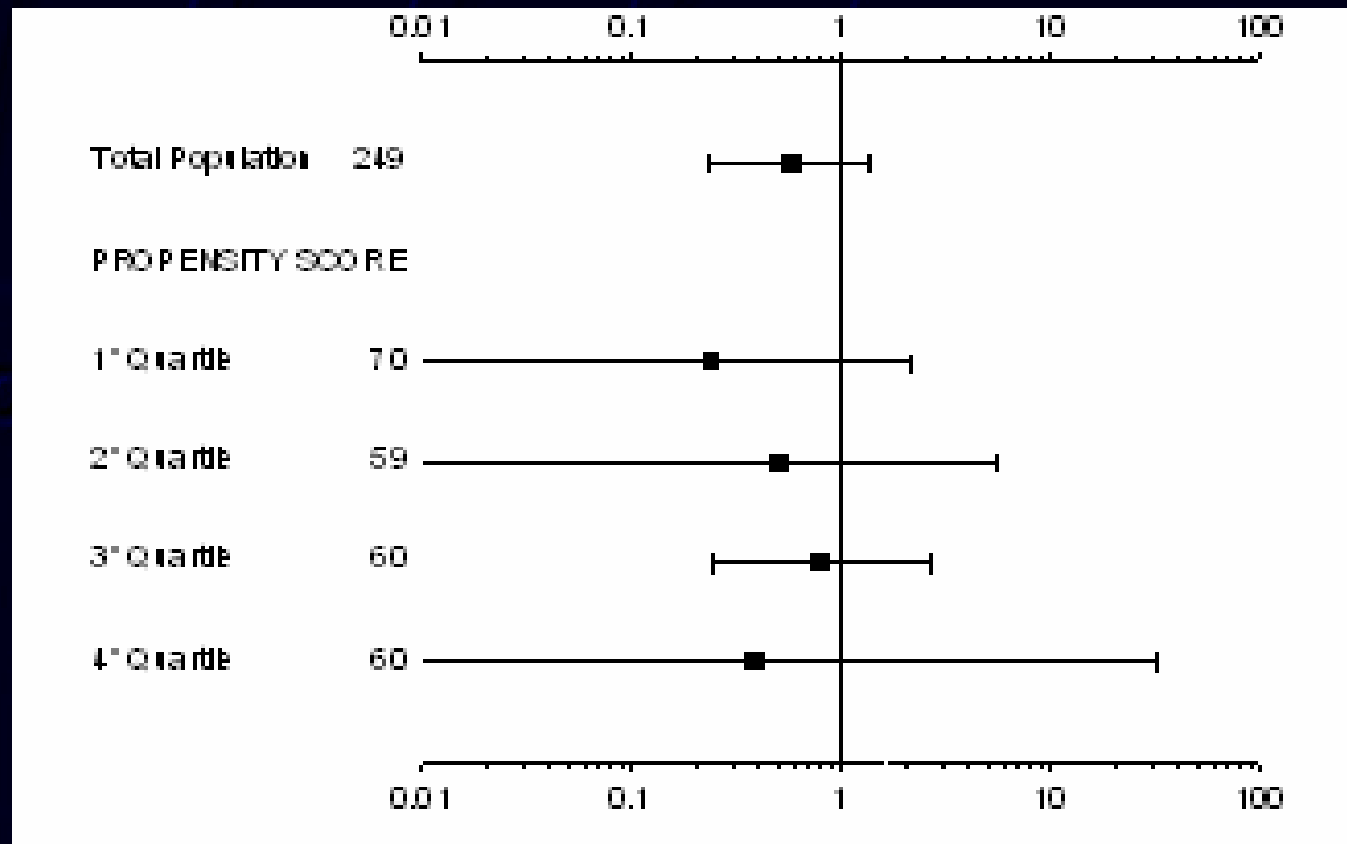
$P_{\text{noninferiority Taxus vs. Cypher}} < .001$



On Courtesy of Dr Mehilli

Milan Experience CABG vs. DES

Cumulative MACCE at 1 Year



OR and
Exact 95% CI

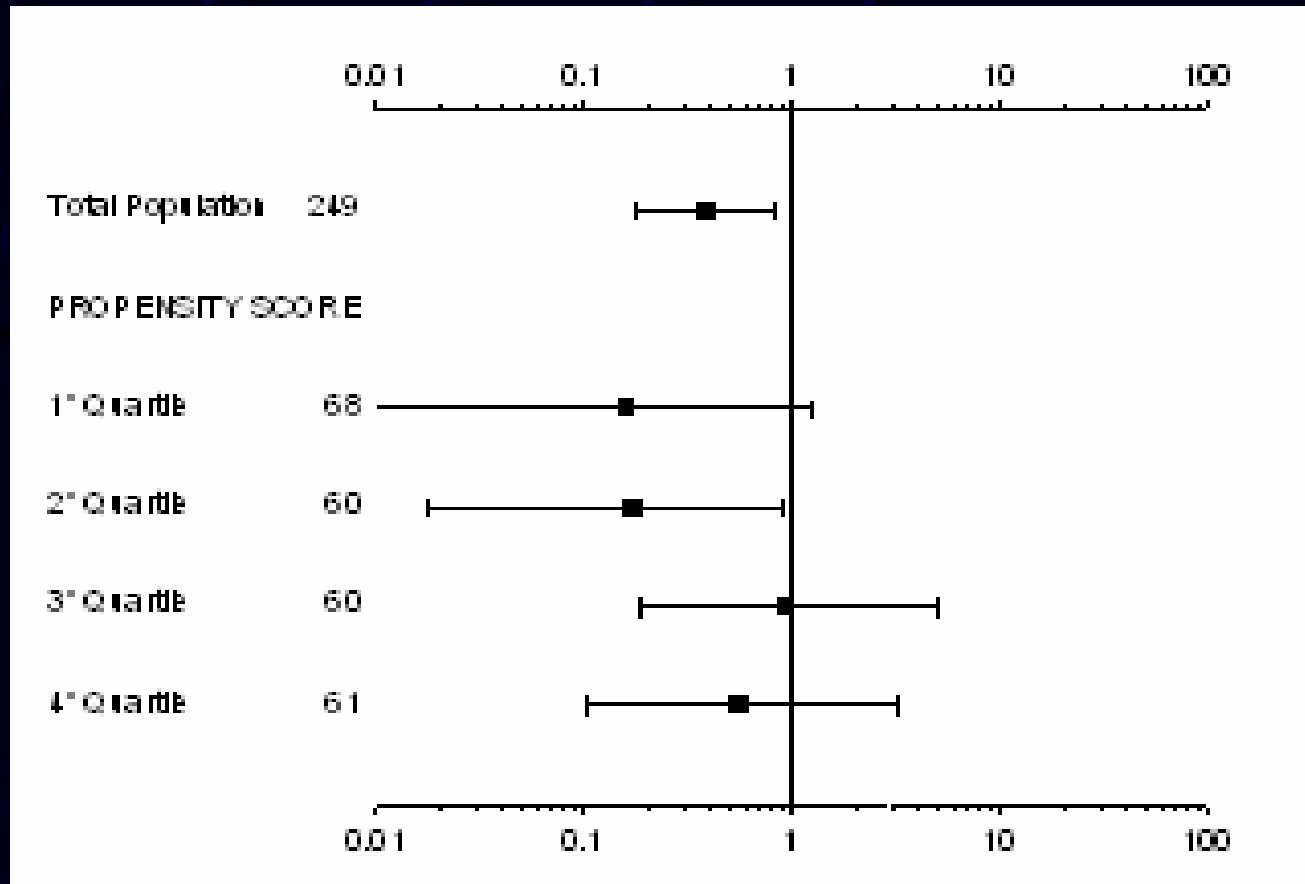
PCI better
n=107

CABG better
n=142

Chieffo et al Circulation 2007;116(2):158-62

CVE+MI+Death at 1 Year

OR and
Exact 95% CI

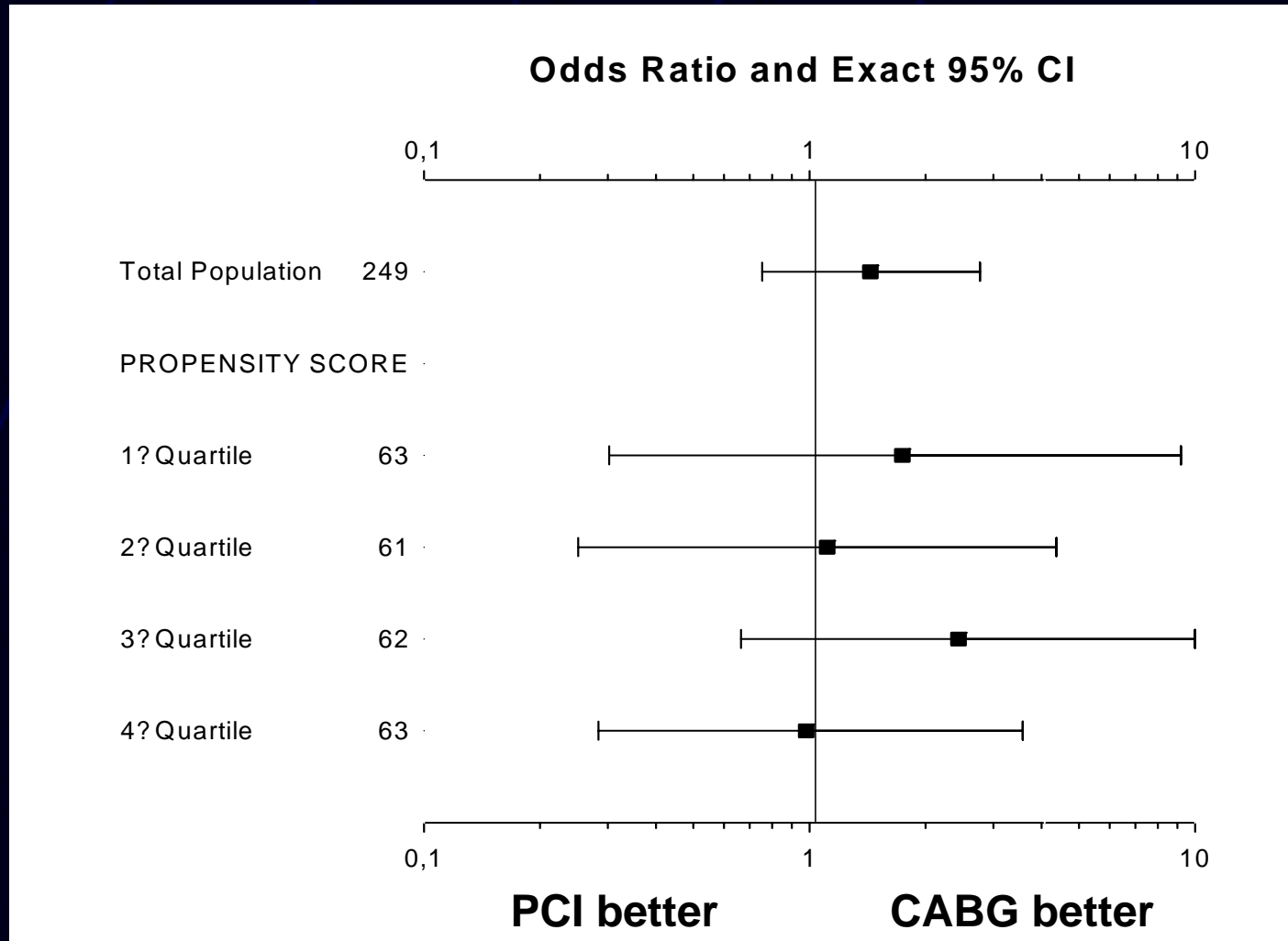


PCI better
n=107

CABG better
n=142

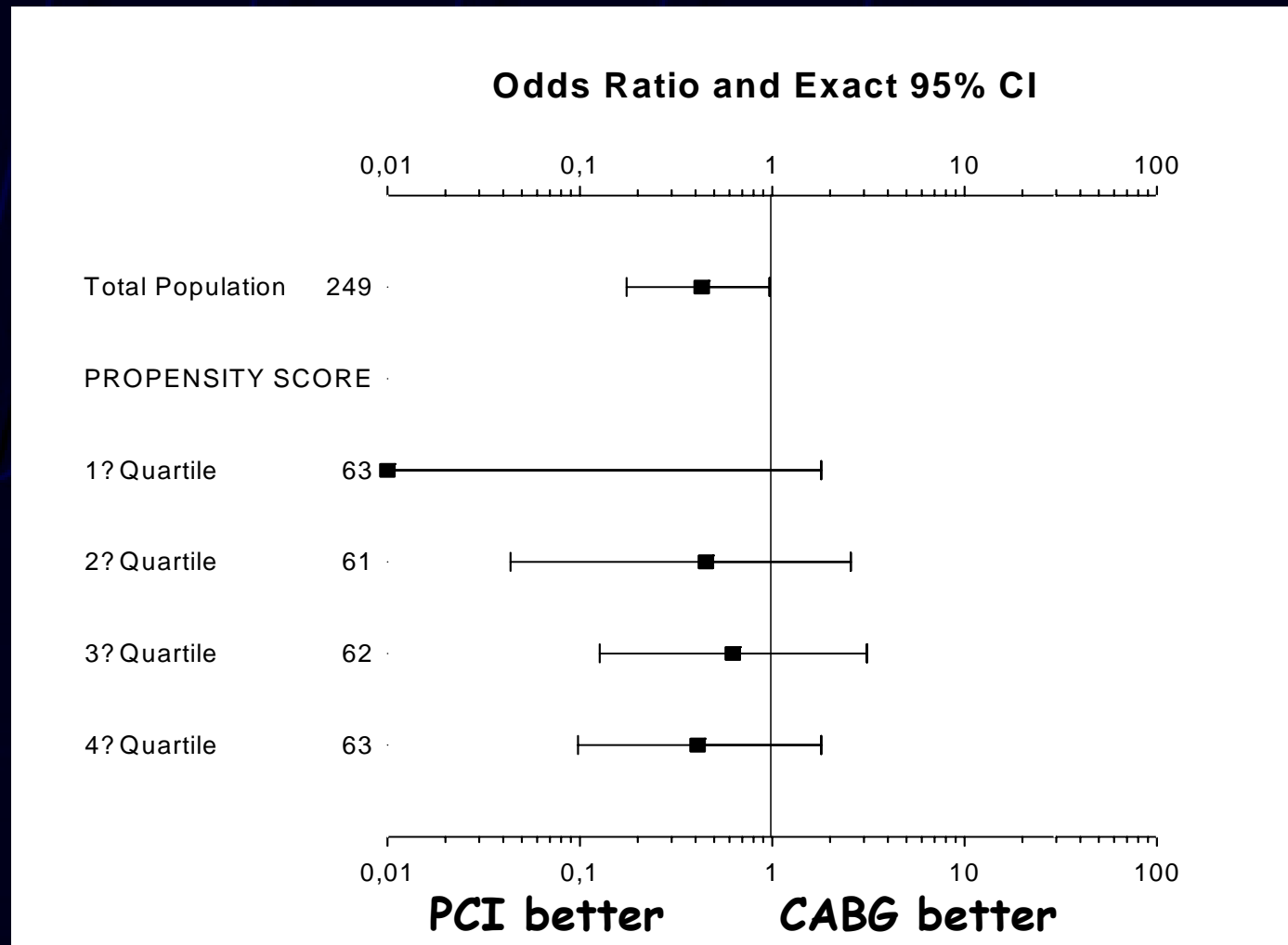
Milan Experience CABG vs. DES

MACCE at 4 years (including repeated revascularization)



36% in DES vs 28% in CABG
Adjusted OR 1.44 (95% CI 0.75 - 2.77; P=0.30)

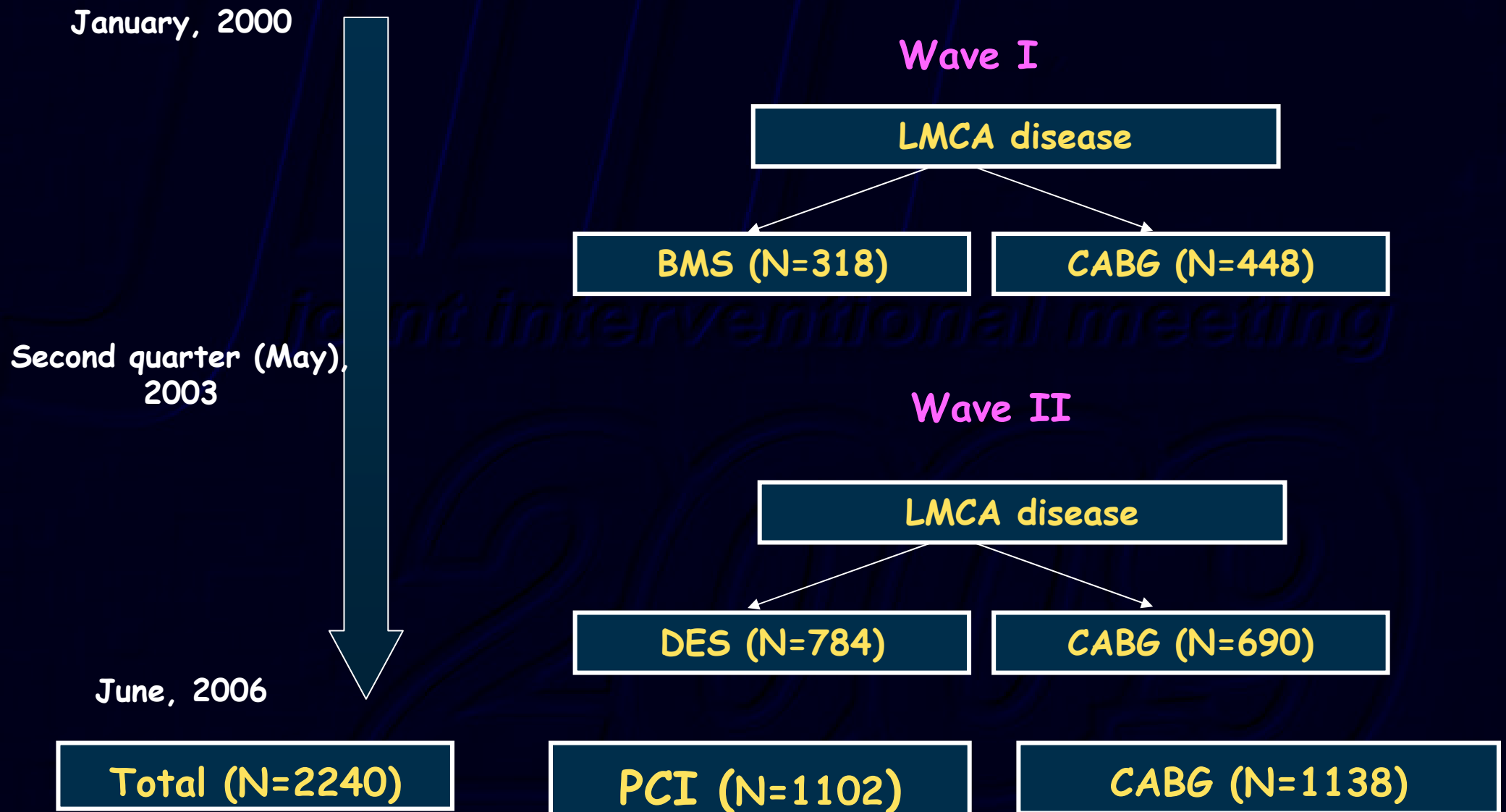
Milan Experience CABG vs. DES CVE+Death+MI at 4 years



14% in DES vs 22% in CABG
Adjusted OR= 0.43 (0.17- 0.97;P=0.04)

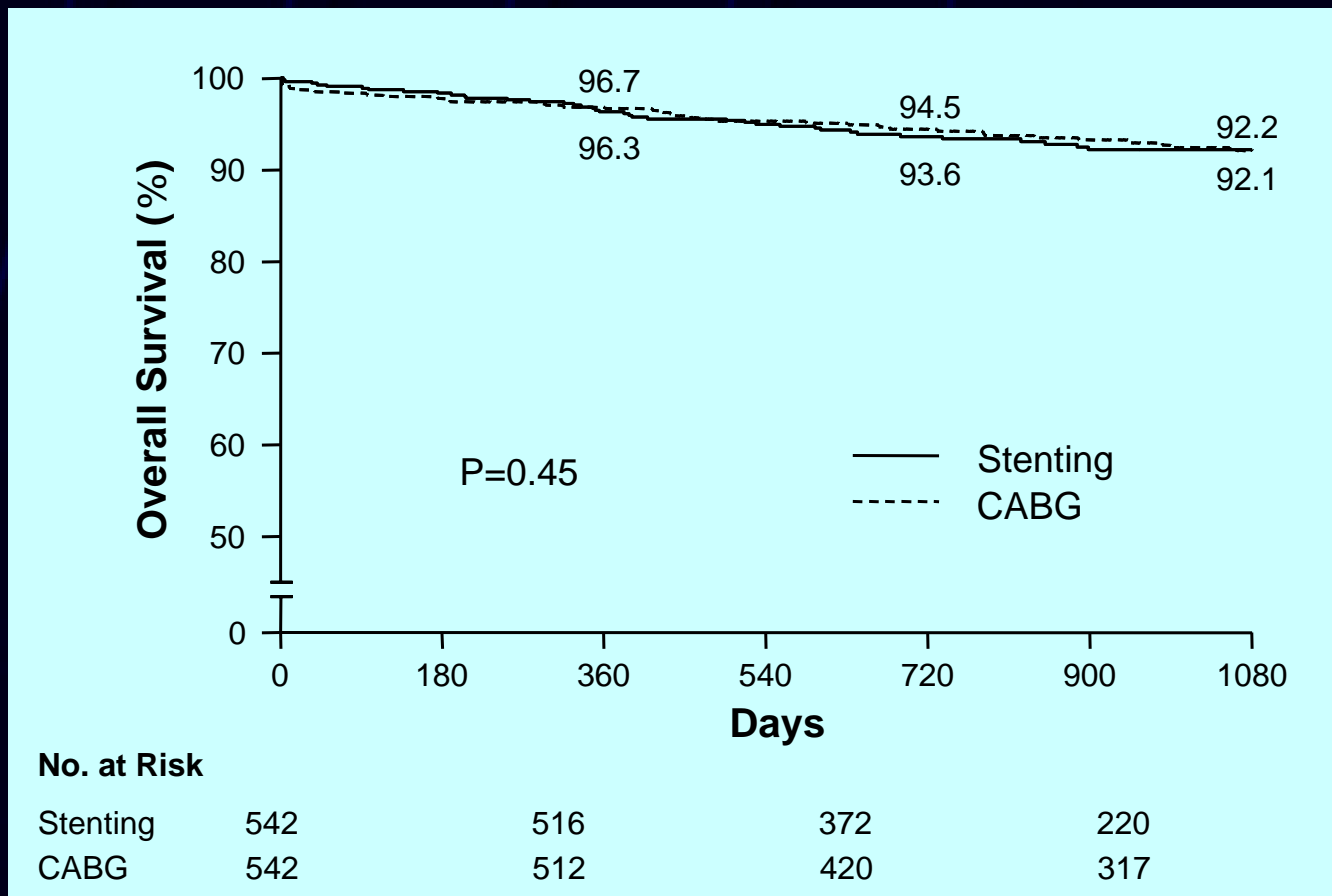
MAIN-COMPARE Study

Stenting (BMS or DES) vs. CABG



Death

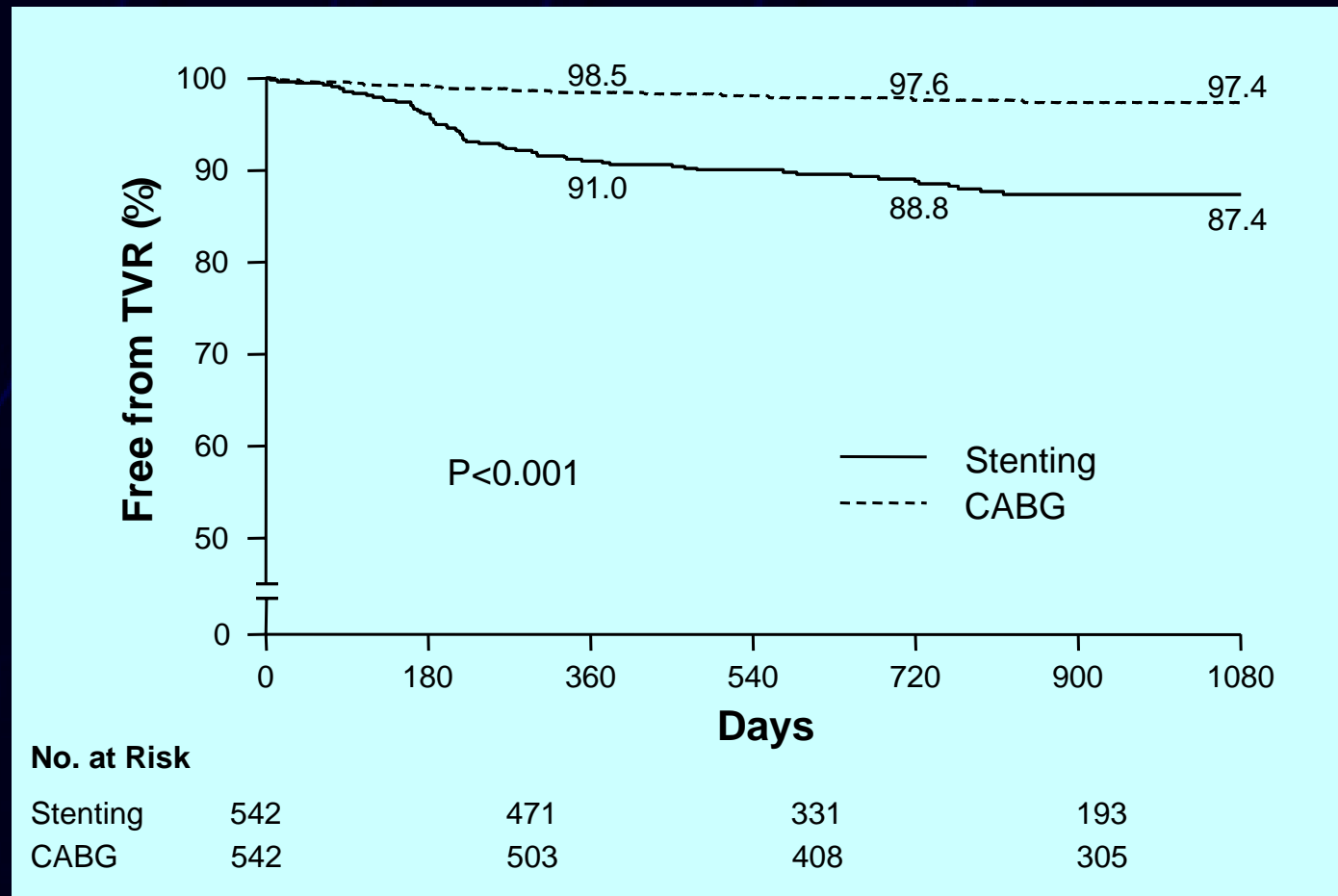
(Overall PCI and CABG matched cohort: 542 pairs)



Park et al N Engl J Med. 2008 Apr 24;358(17):1781-92

Target-vessel revascularization

(Overall PCI and CABG matched cohort: 542 pairs)



Park et al N Engl J Med. 2008 Apr 24;358(17):1781-92

SYNTAX Trial Design



62 EU Sites

+



23 US Sites

Heart Team (surgeon & interventionalist)

Amenable for both
treatment options

Amenable for only one
treatment approach

Stratification:
LM and Diabetes

Randomized Arms
N=1800

Two Registry Arms
N=1275

CABG
N=897

vs

TAXUS*
N=903

CABG
N=1077

PCI
N=198

DM
28.5%

Non DM
71.5%

DM
28.2%

NonDM
71.8%

*TAXUS Express

MACCE to 12 Months

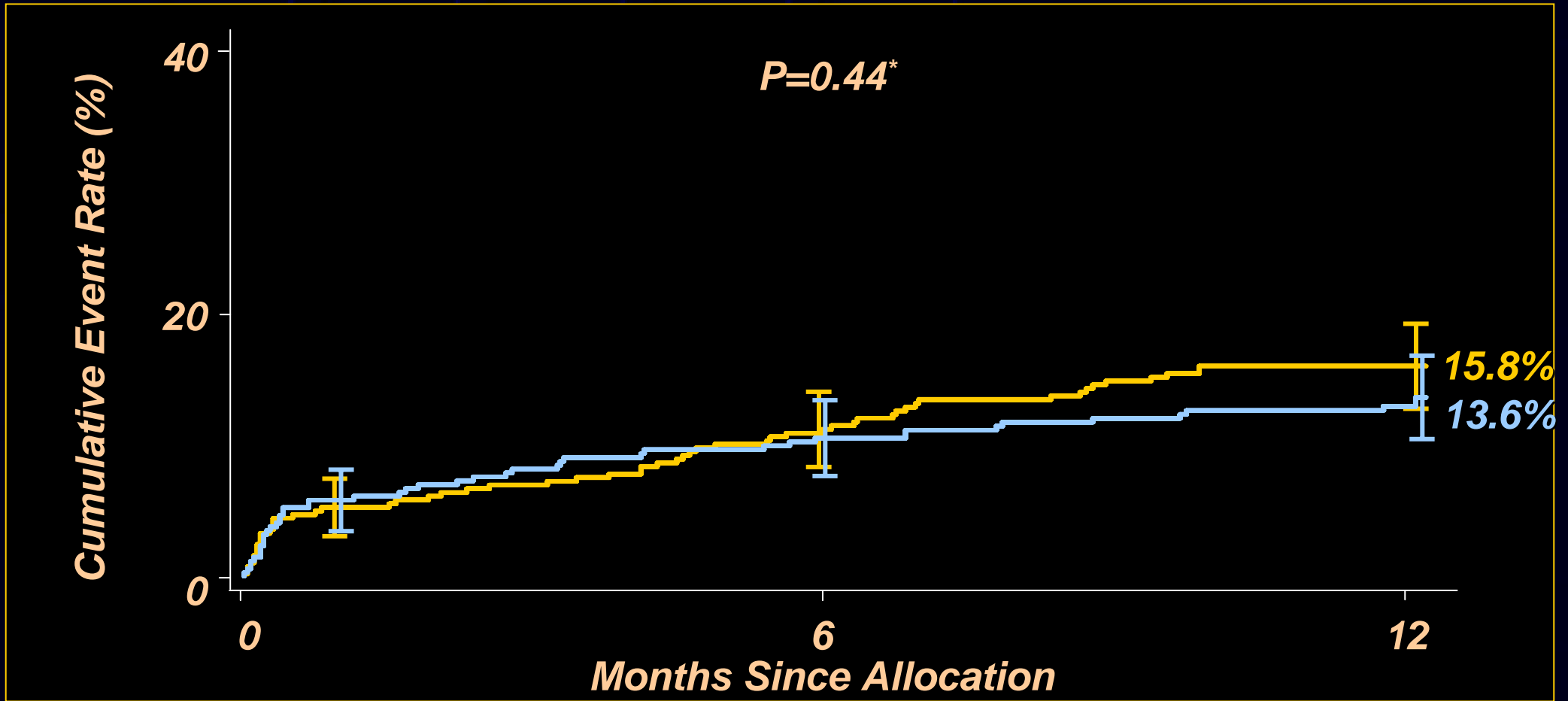
Left Main Subset



CABG (N=348)



TAXUS (N=357)



Event rate \pm 1.5 SE, *Fisher exact test

ITT population

Death/CVA/MI to 12 Months

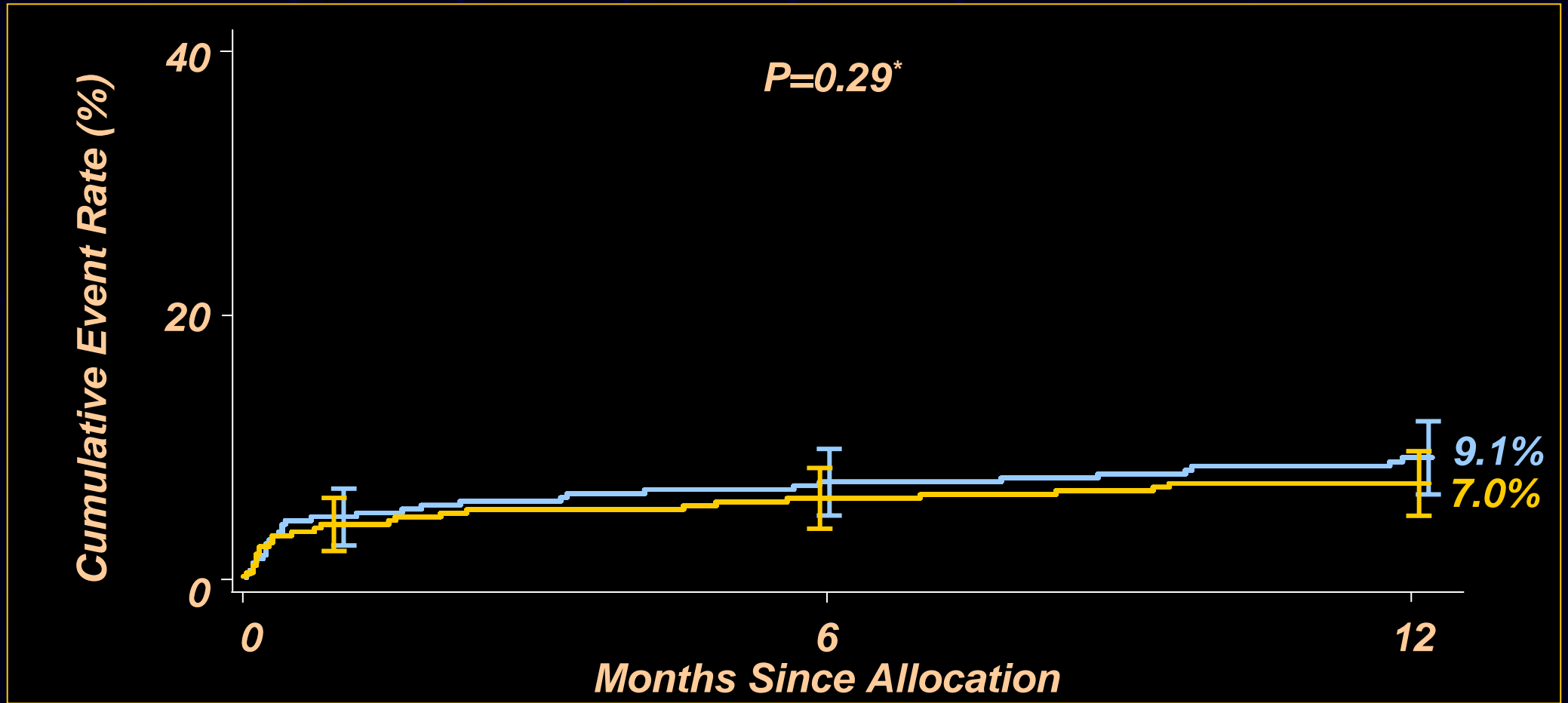
SYNTAX Left Main Subset



CABG (N=348)



TAXUS (N=357)

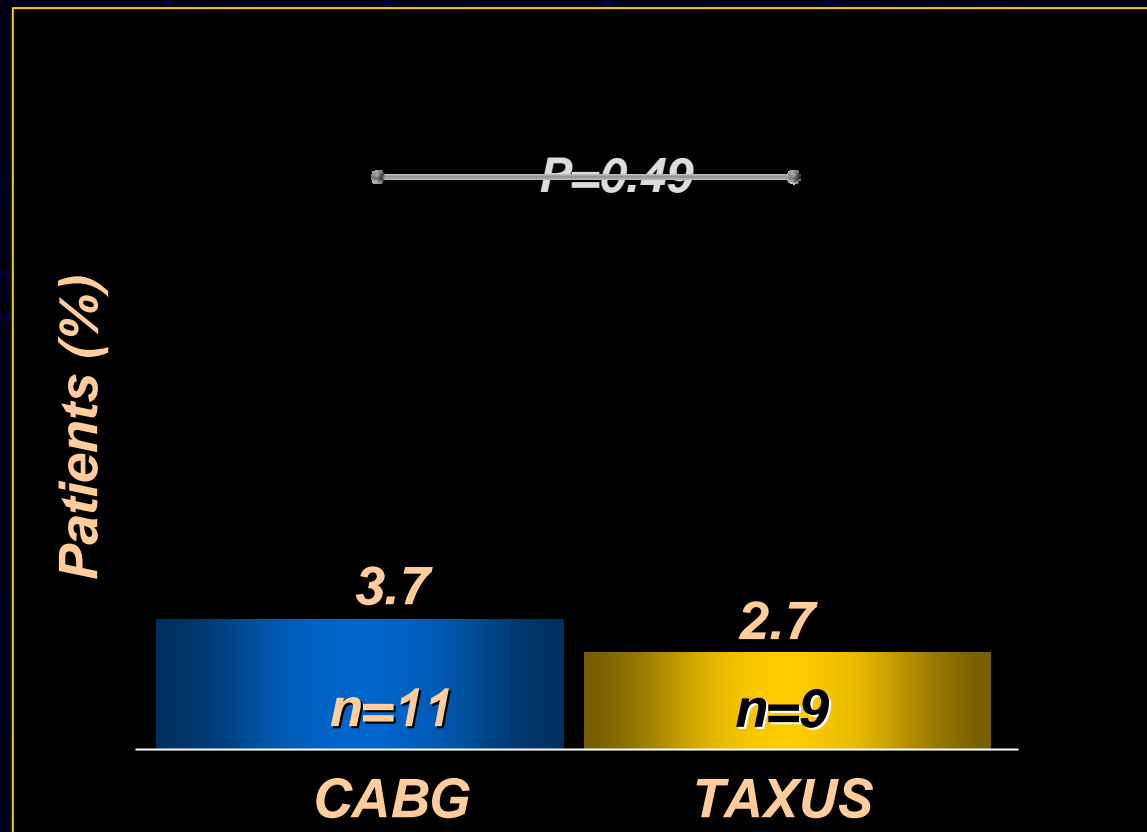


Event rate \pm 1.5 SE, *Fisher exact test

ITT population

Symptomatic Graft Occlusion & Stent Thrombosis to 12 Months *Left Main Subset*

■ CABG (n=348) ■ TAXUS (n=357)



MACCE to 12 Months by SYNTAX Score Tertile

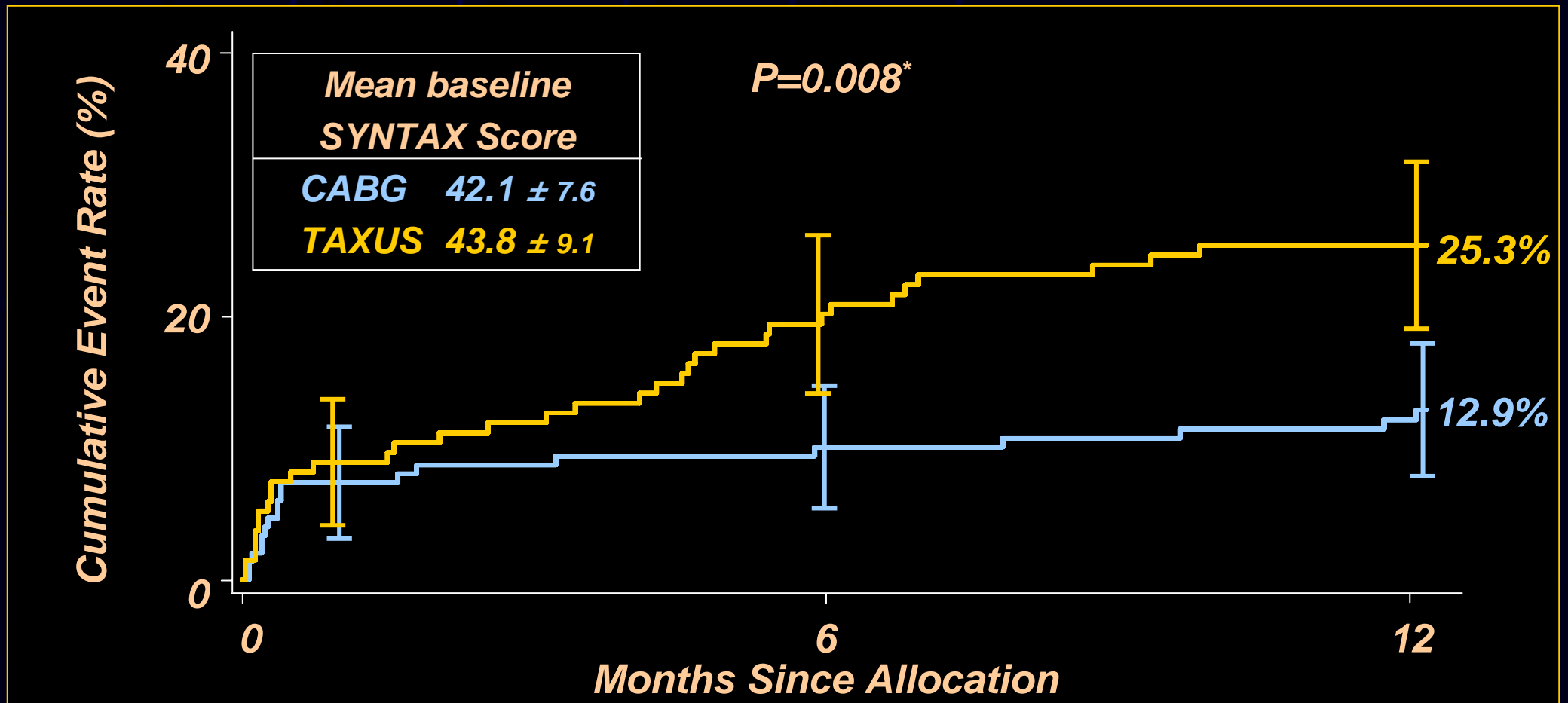
High Scores (≥ 33) Left Main Subset



CABG (N=150)



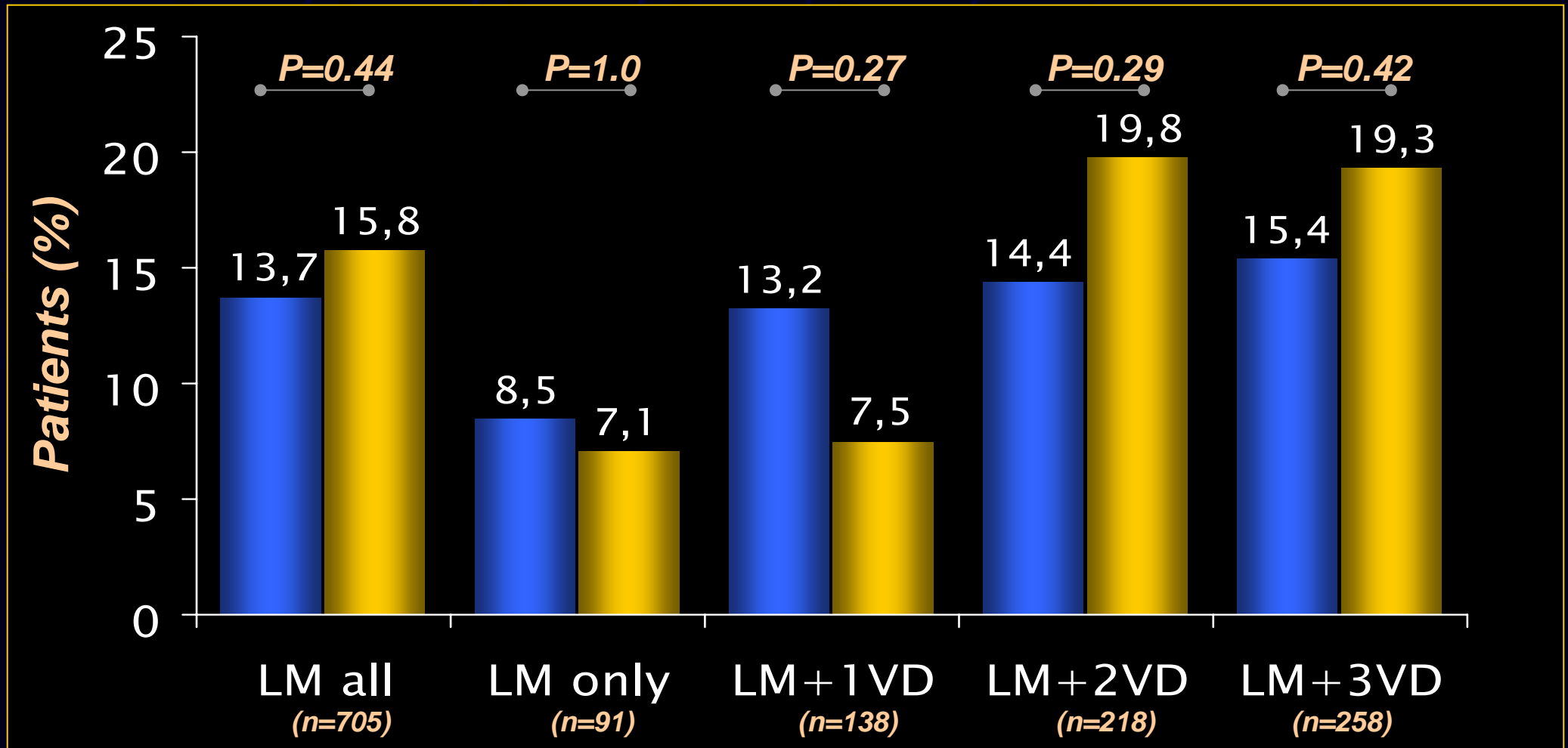
TAXUS (N=135)



Event rate ± 1.5 SE, *Fisher exact test

Overall MACCE at 12 Months *Left Main Subset*

CABG **TAXUS**



Conclusions I

- PCI on unprotected LMCA lesions should be performed electively by experienced interventional operators in selected institutions.

joint interventional meeting

- At present, patients should be fully informed of the potential risks of the procedure in the context of limited data.

Conclusions II

- Careful patient and lesion selection is necessary in percutaneous treatment of unprotected LMCA.
- Conclusive information about the optimal treatment of LMCA will come only from prospective, randomized trial comparing CABG vs PCI with extended follow-up at least until 5 years