# Drug-Eluting Stent

## Real World Experience in Asan Medical Center

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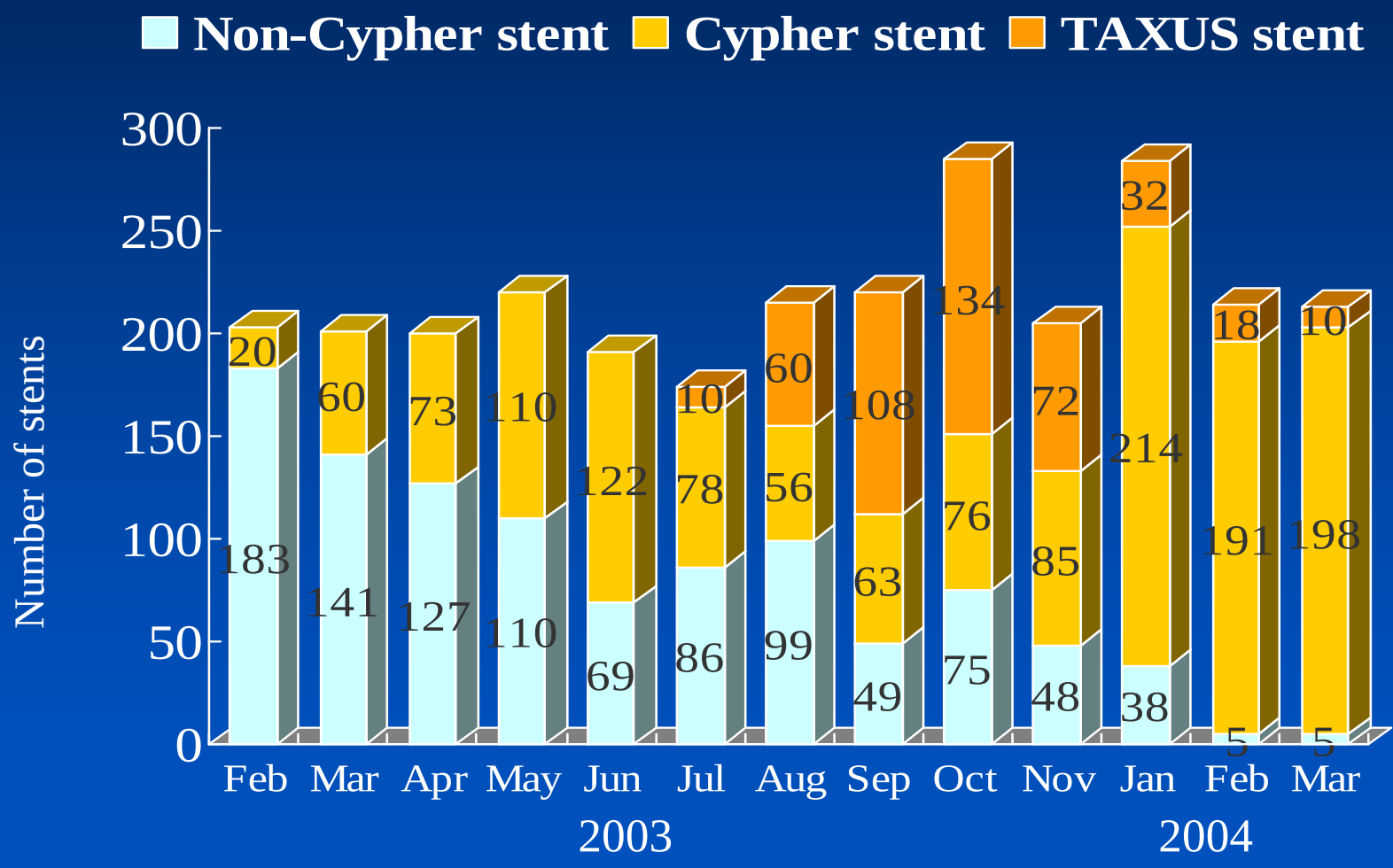
**Asan Medical Center, *Seoul, Korea***

# What a Big Changes ！

**DES have already changed the strategy of PCI in real world practice…**

ASAN Medical Center

# DES Use in AMC
## 95% penetration



# Why Global DES Use in AMC ?

**The reason why,**

**Global DES use would be the reasonable approach based on the data**

# Global DES use in is reasonable approach based on the data

Safety,
Efficacy,
Durability,
Cost Issue

# Safety Issue

**Subacute Thrombosis**

**Late stent Incomplete Apposition**

# Antiplatelet Regimens in AMC

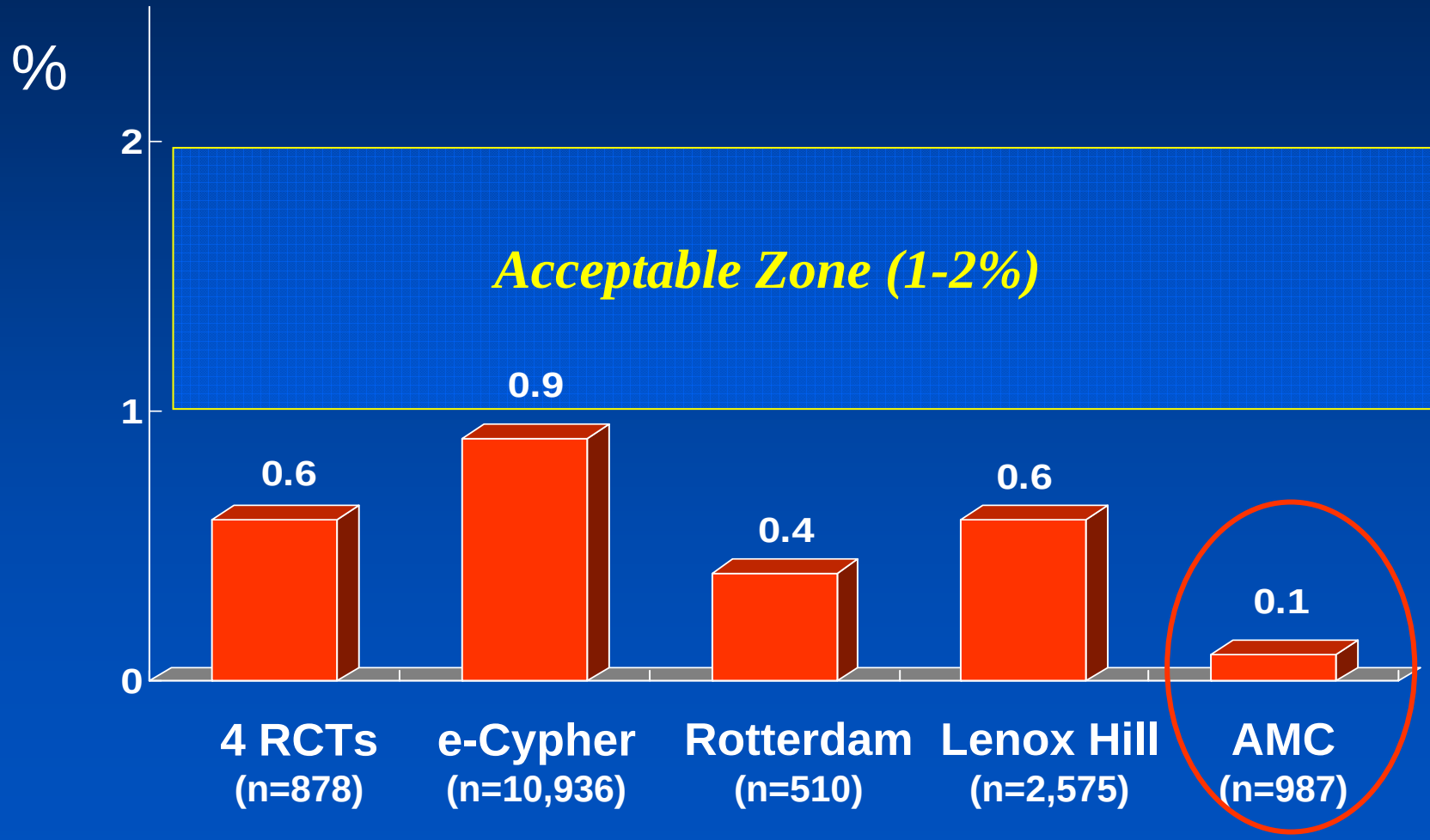
## Two combination

- **Aspirin** indefinitely
- **Clopidogrel 75 mg QD** at least for 6 months

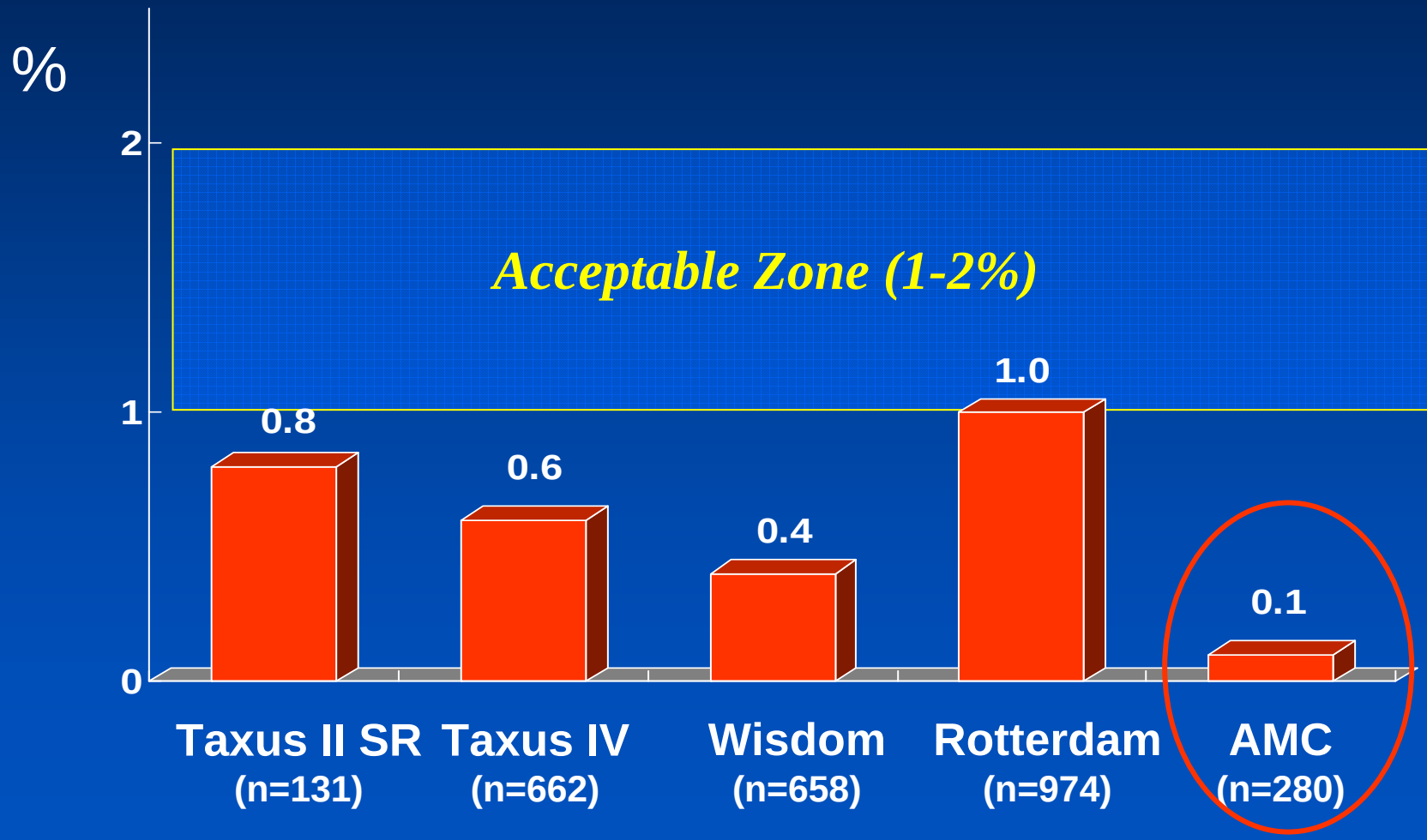
## Triple combination in cases of complex lesions

- **Aspirin** indefinitely
- **Cilostazol 100 mg BID** for 1 month
- **Clopidogrel 75 mg QD** at least for 6 month

# Cypher™ : SAT 0.1 %

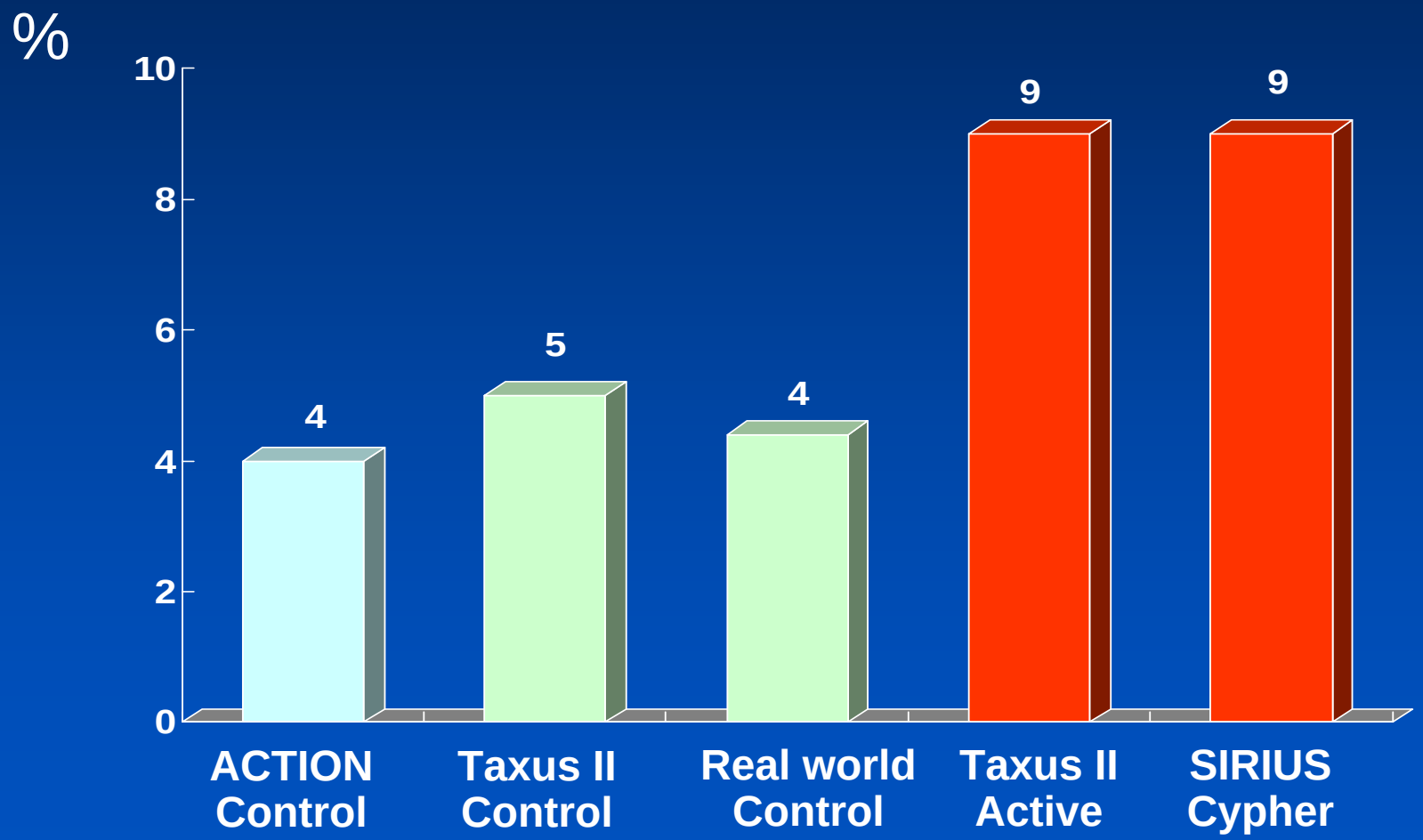


# Taxus™ : SAT 0.1 %


%
2
1
0
Acceptable Zone (1-2%)
0.8
0.6
0.4
1.0
0.1
Taxus II SR (n=131)
Taxus IV (n=662)
Wisdom (n=658)
Rotterdam (n=974)
AMC (n=280)

# Late Stent Incomplete Apposition

## No clinical events attributed…



# Safety Issue

**Subacute Thrombosis**
**Late stent Incomplete Apposition**

No more concerns about these…

# Efficacy Issue

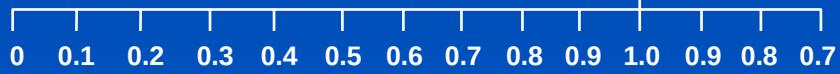
**Restenosis Rate**
**TLR**
**MACE**

We have lots of data…

# TLR Events

**SIRIUS**

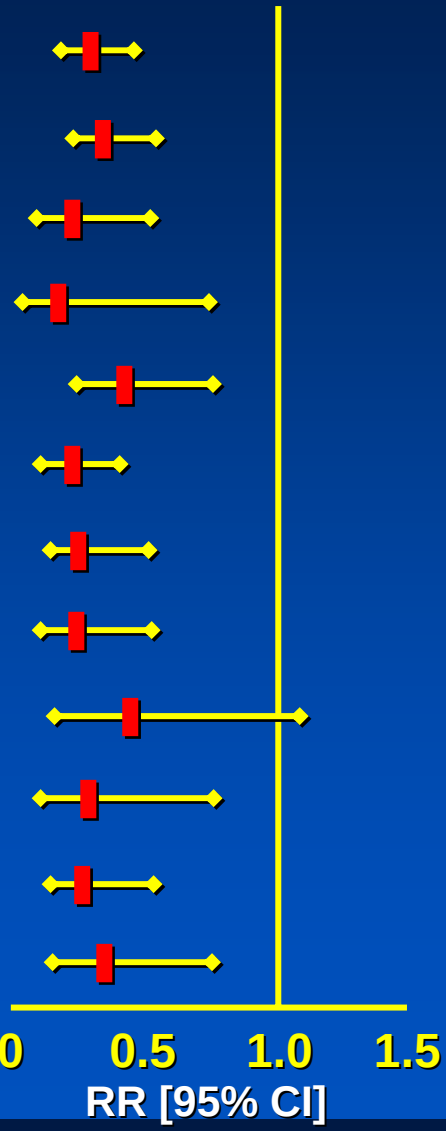
| | Sirolimus | Control | P-value | # events prevented per 1,000 patients |
|---|---|---|---|---|
| Overall | 4.1 | 16.6 | 0.0001 | 124 |
| Male | 4.4 | 16.6 | 0.0001 | 122 |
| Female | 3.4 | 16.5 | 0.0007 | 130 |
| Diabetes | 6.9 | 22.3 | 0.0006 | 154 |
| No Diabetes | 3.2 | 14.3 | 0.0001 | 111 |
| LAD | 5.1 | 19.8 | 0.0001 | 147 |
| Non-LAD | 3.4 | 14.3 | 0.0001 | 109 |
| Small Vessel (<2.75) | 6.3 | 18.7 | 0.0001 | 125 |
| Large Vessel | 1.9 | 14.8 | 0.0001 | 128 |
| Short Lesion | 3.2 | 16.1 | 0.0001 | 129 |
| Long Lesion (>13.5) | 5.2 | 17.4 | 0.0001 | 122 |
| Overlap | 4.5 | 17.7 | 0.0003 | 131 |
| No Overlap | 3.9 | 16.1 | 0.0001 | 121 |




***Sirolimus better***

# Restenosis Rate

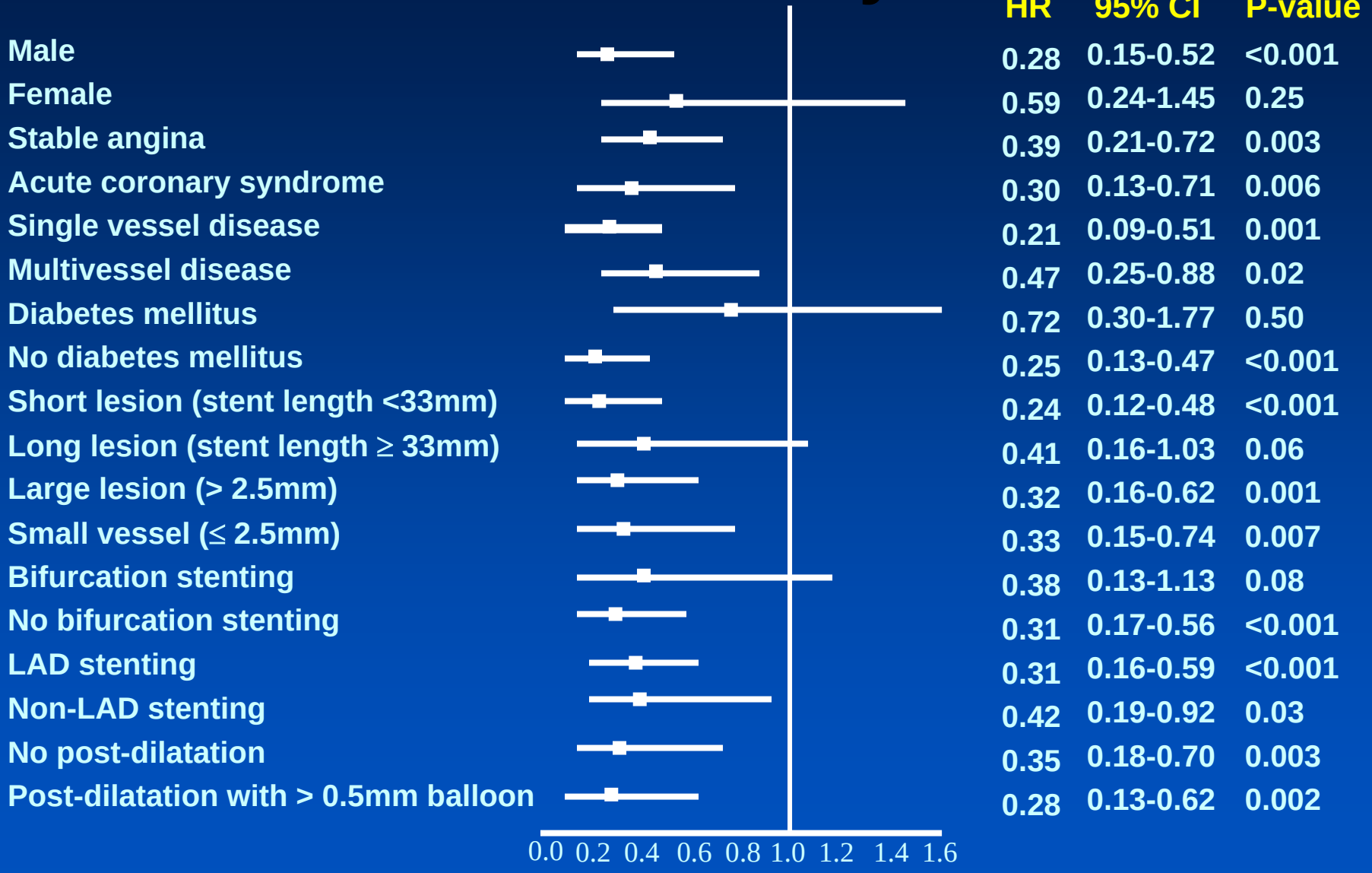
TAXUS IV

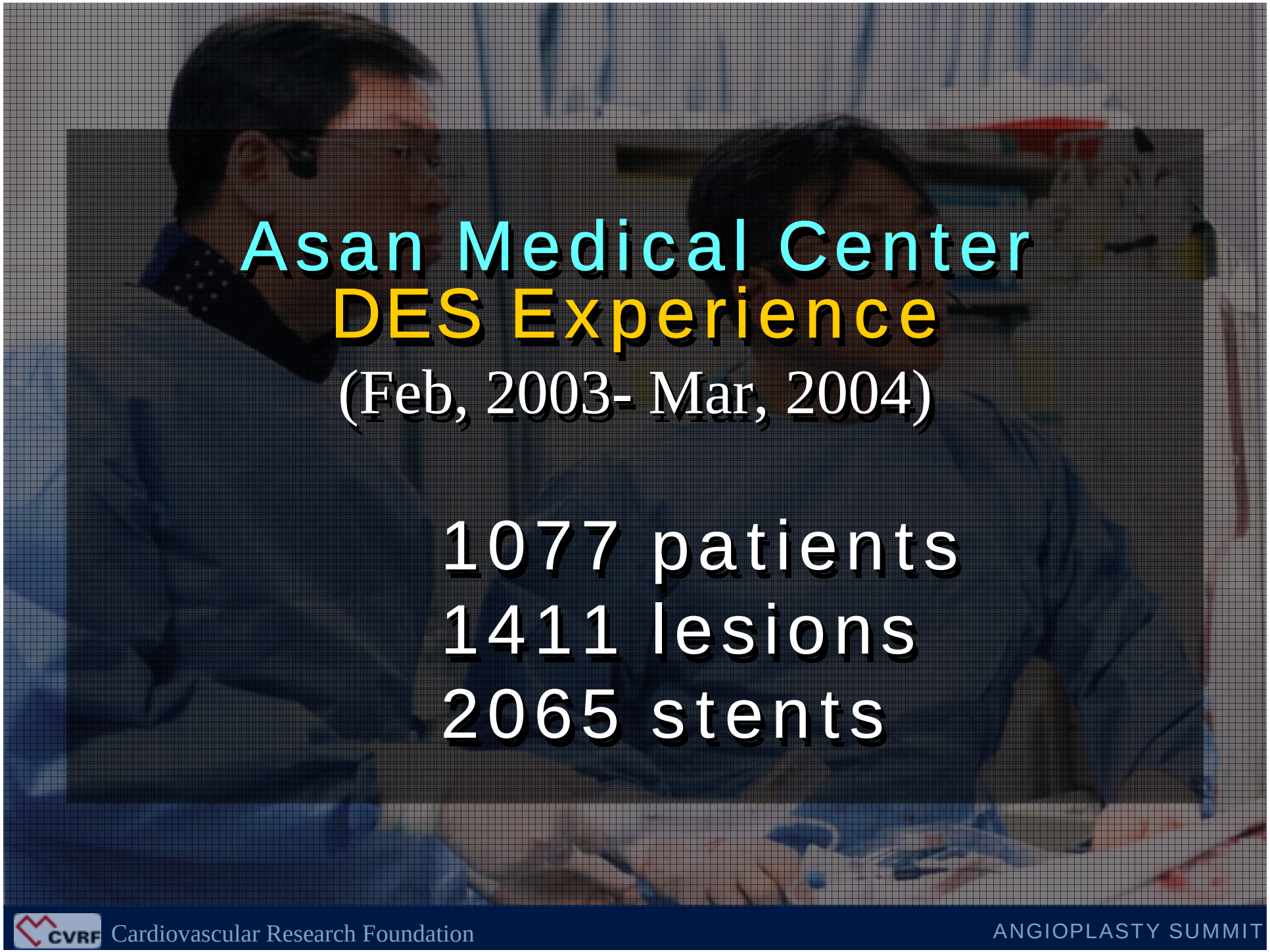



| | RR | TAXUS | Control | P |
|---|---|---|---|---|
| All | 0.30 | 7.9 | 26.6 | <0.0001 |
| Non-diabetic | 0.35 | 8.5 | 24.4 | <0.0001 |
| Diabetic, oral meds | 0.19 | 5.8 | 29.7 | 0.003 |
| Diabetic, insulin | 0.18 | 7.7 | 42.9 | 0.007 |
| LAD | 0.42 | 11.3 | 26.9 | 0.004 |
| Non-LAD | 0.22 | 5.7 | 26.4 | <0.0001 |
| RVD ≤2.5 mm | 0.27 | 10.2 | 38.5 | <0.0001 |
| RVD 2.5-3.0 mm | 0.24 | 6.7 | 27.8 | 0.0001 |
| RVD ≥3.0 mm | 0.45 | 6.8 | 15.2 | 0.10 |
| Lsn length <10 mm | 0.29 | 5.6 | 18.9 | 0.01 |
| Lsn length 10-20 mm | 0.28 | 7.2 | 25.8 | <0.0001 |
| Lsn length >20 mm | 0.36 | 14.9 | 41.5 | 0.004 |

## RESEARCH Registry

# Hazard Ratio of Clinically Driven TVR

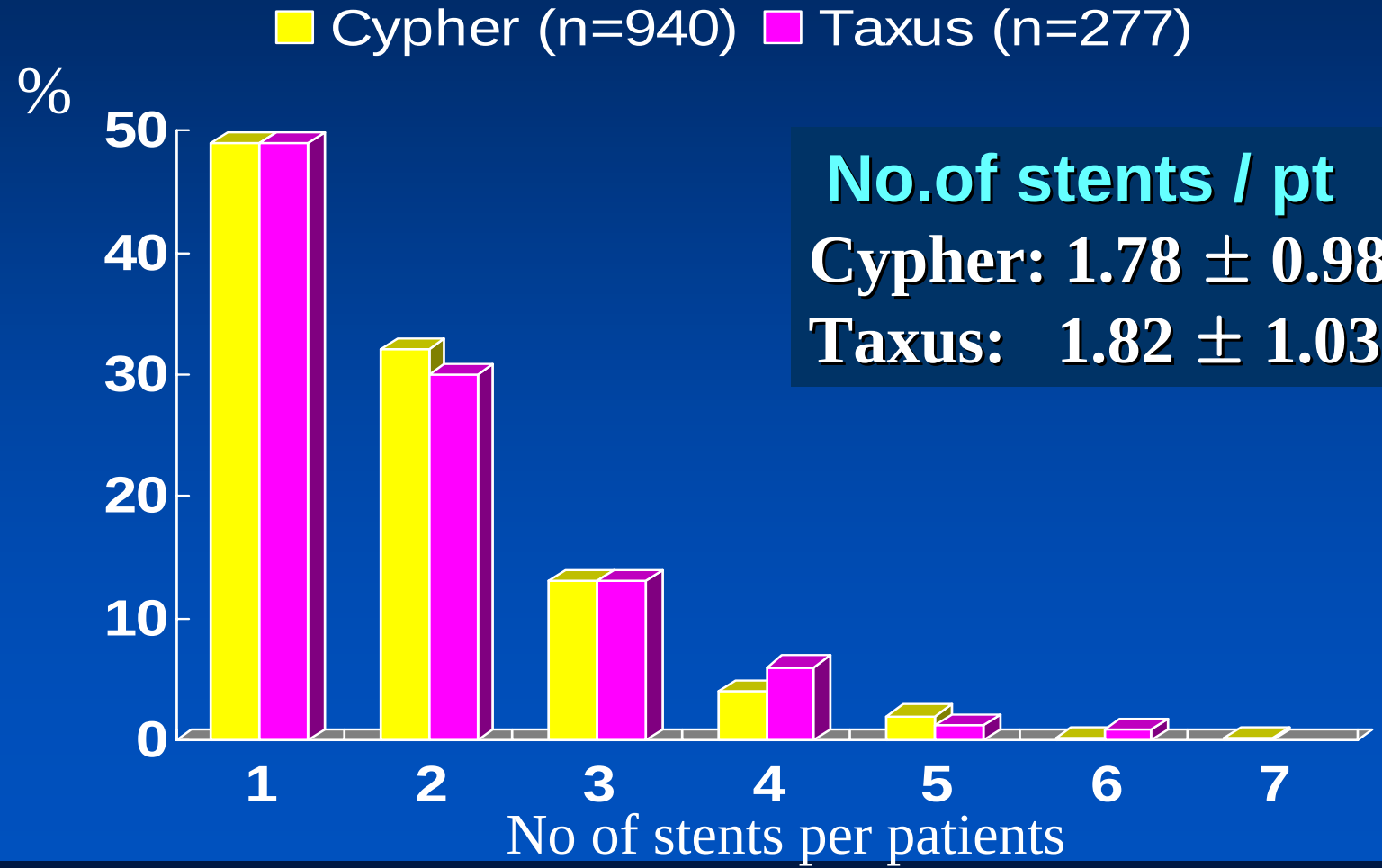



Asan Medical Center
DES Experience
(Feb, 2003- Mar, 2004)
1077 patients
1411 lesions
2065 stents

# What a Big Changes !

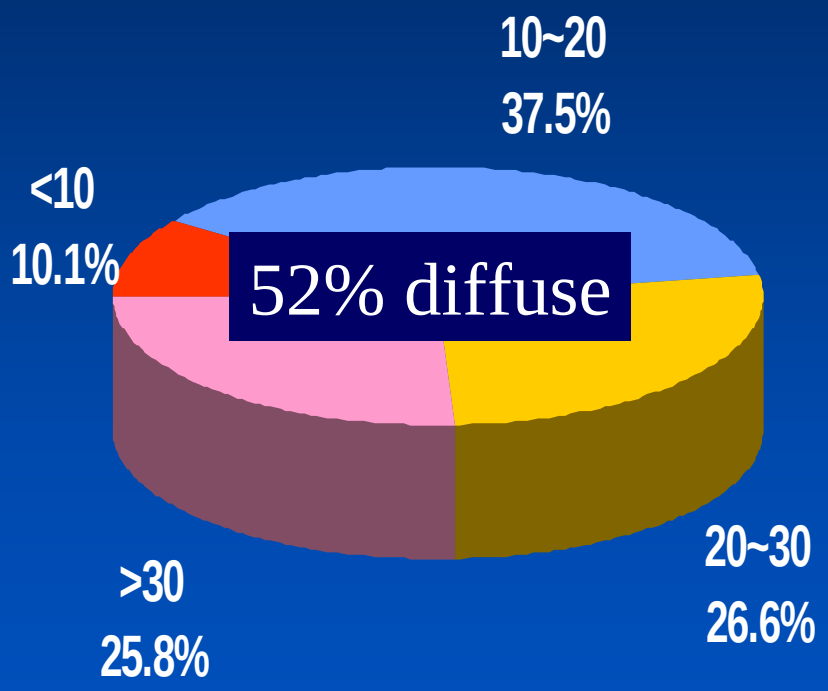
We have treated more complex patients and lesion subsets …

# Half (50%) of patients received multiple stents …



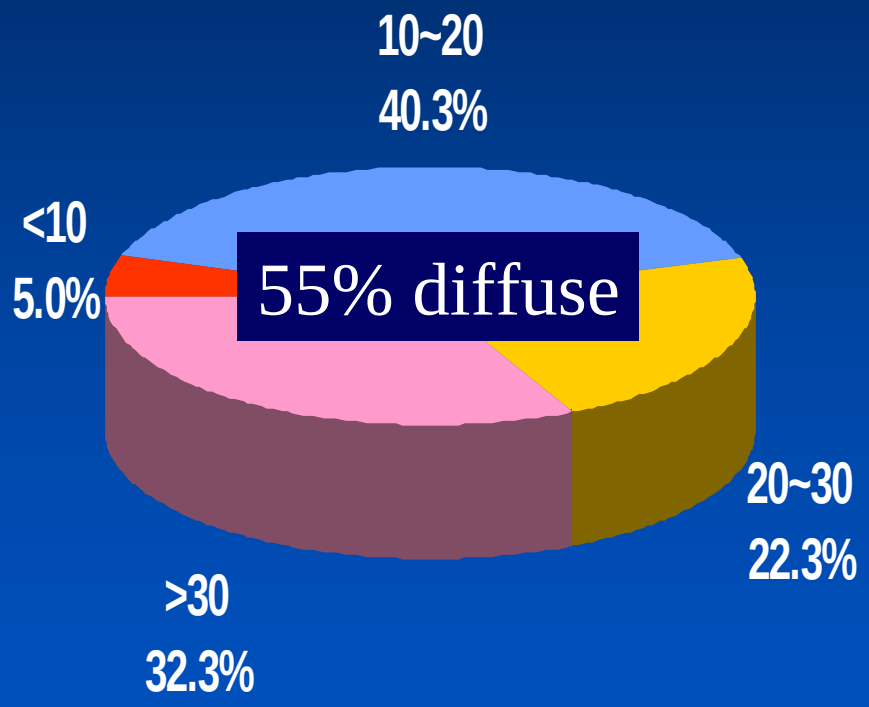
# Lesion Length

## Cypher Stent (n=1093)




**Mean: 24.2±14.3mm**

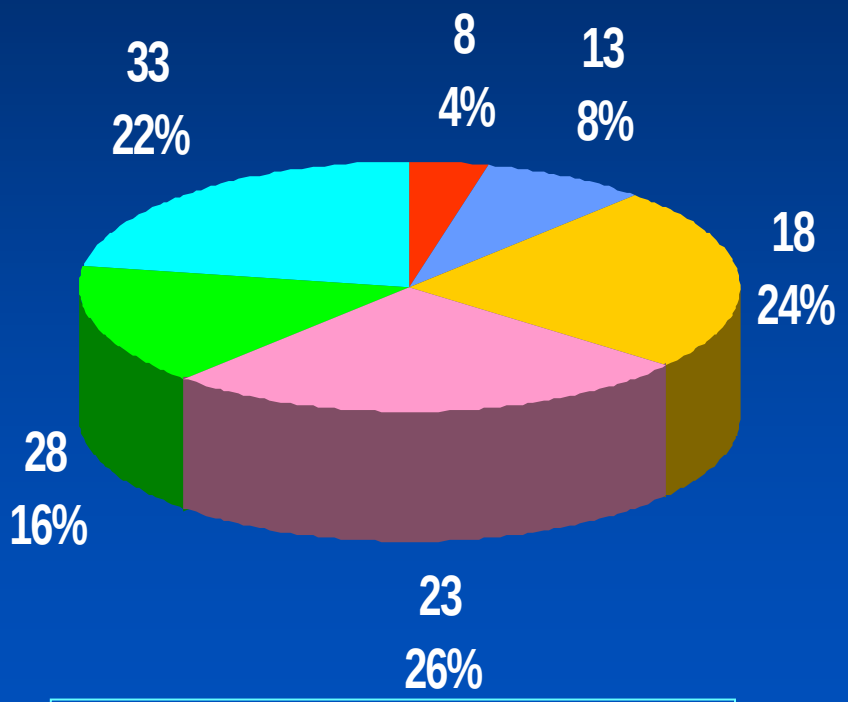
## Taxus Stent (n=318)




**Mean: 26.1±14.1mm**

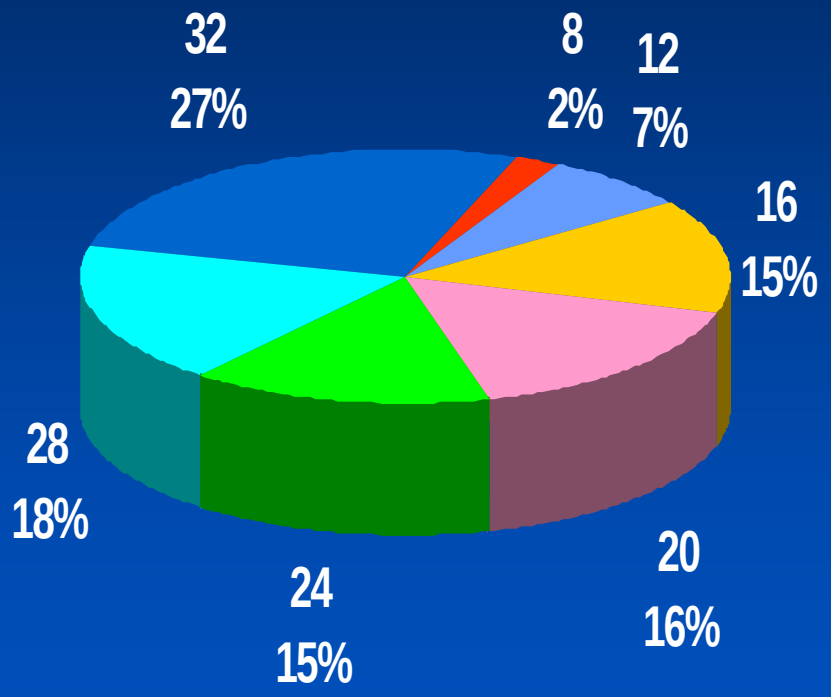
# Used Stent Length

## Cypher Stent (n=1593)




**Total stent length : 30.1±16.7 mm**

## Taxus Stent (n=472)

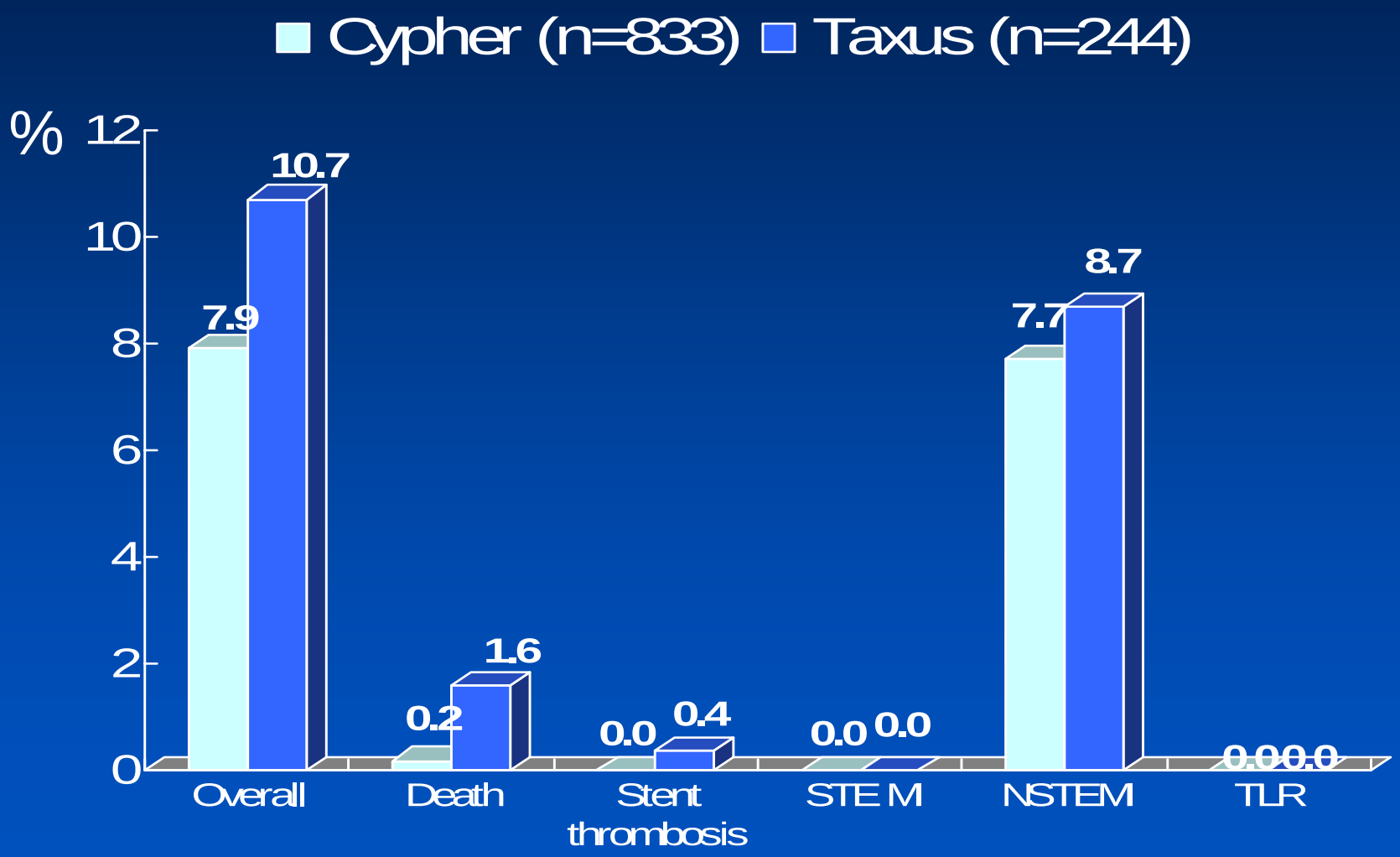



**Total stent length : 32.1±17.6 mm**

# Direct : 46%, Overlapping :28 %

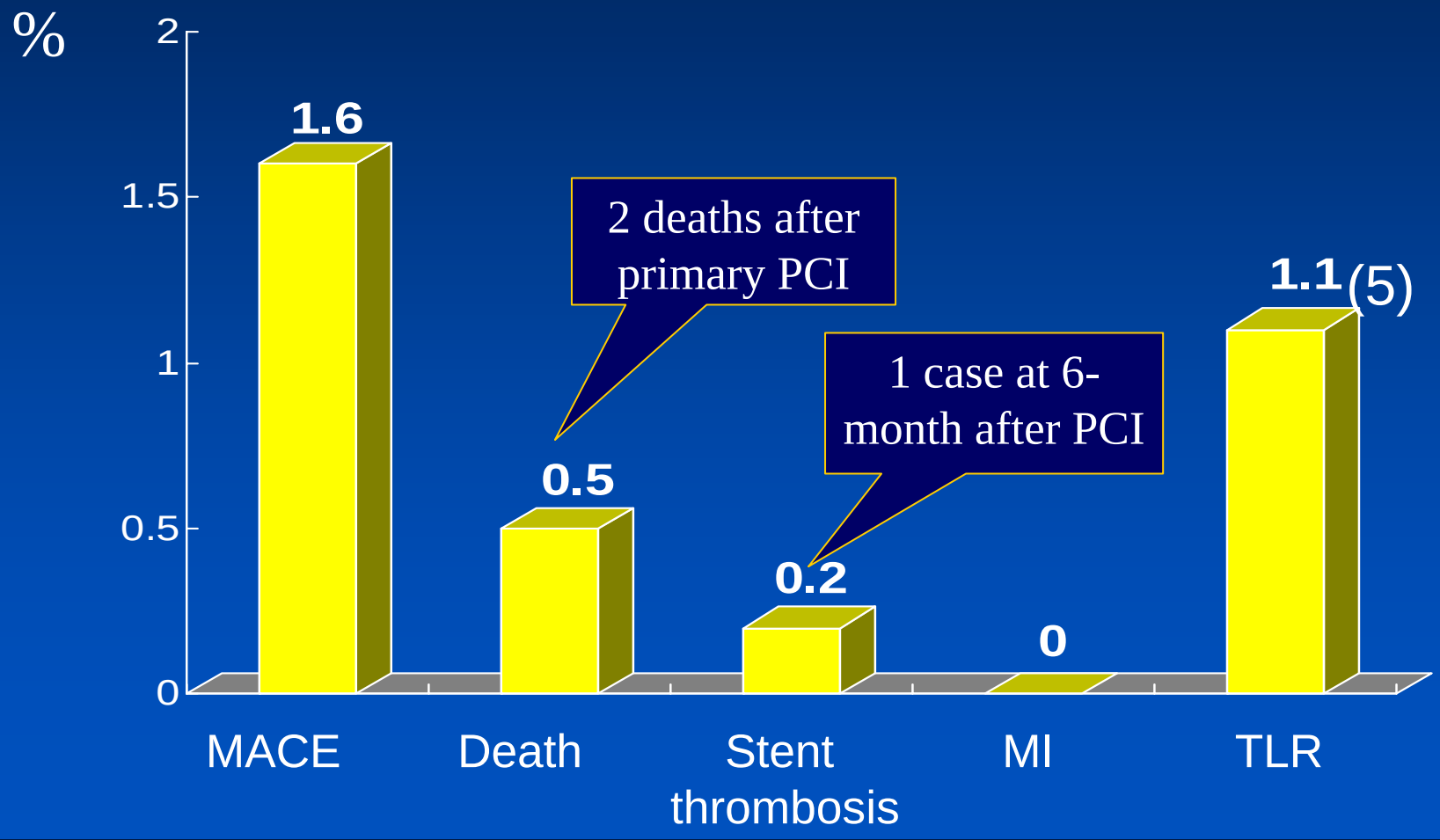
| | Cypher | Taxus |
|---|---|---|
| Direct stenting | 503 (46%) | 148 (47%) |
| Postdilatation with a new balloon | 226 (42 %) | 115 (46%) |
| Maximum inflation pressure (atm) | 16.7 ± 3.5 | 14.0 ± 3.9 |
| Balloon-to-artery ratio | 1.17 ± 0.42 | 1.16 ± 0.15 |
| Overlapping | 309 (28 %) | 91 (29%) |
| Use of Gp IIb/IIIa | 30 (3%) | 7 (2%) |

# In-Hospital Events



# 6-Month TLR : 1.1 %

Total 446 eligible patients with Cypher implantation

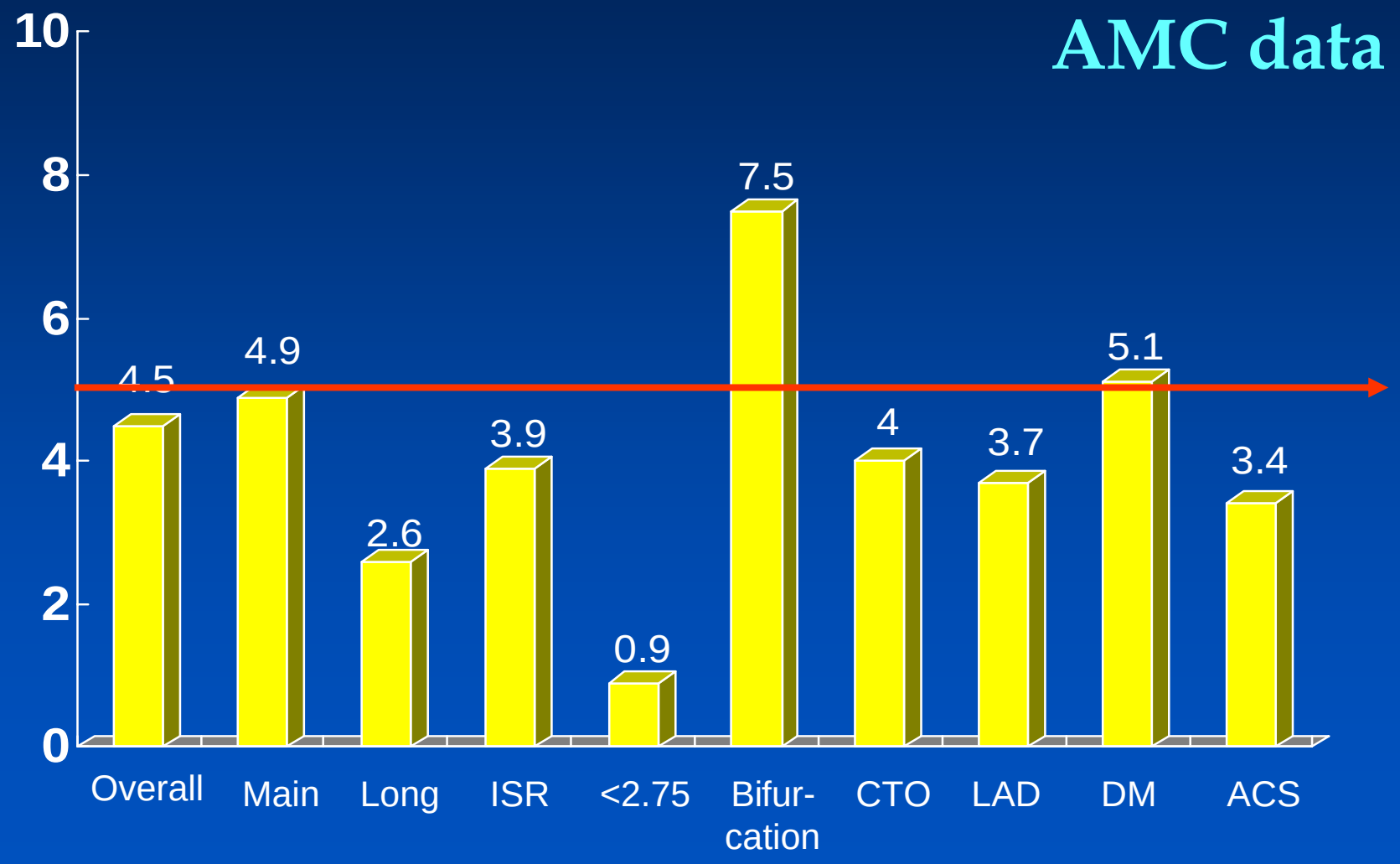


# 6-Month Restenosis : 4.5 %

| | 378 lesions (85%) |
|---|---|
| Reference vessel (mm) | 2.86 ± 0.54 |
| MLD (mm) | 2.66 ± 0.64 |
| Late loss (mm) | 0.30 ± 0.52 |
| Diameter stenosis (%) | 5.95 ± 19.74 |
| Binary restenosis (%) | 17 (4.5%) |
| Focal | 15 |
| Diffuse | 1 |
| Total | 1* |

* Total ISR after arterial graft intervention

# Restenosis Rate : 4.5 %



# Global DES Use is reasonable approach based on the data

Still have efficacy concerns about specific lesion and specific patient subsets…

We have small, but solid data

# Efficacy Concerns

## Specific lesion subsets

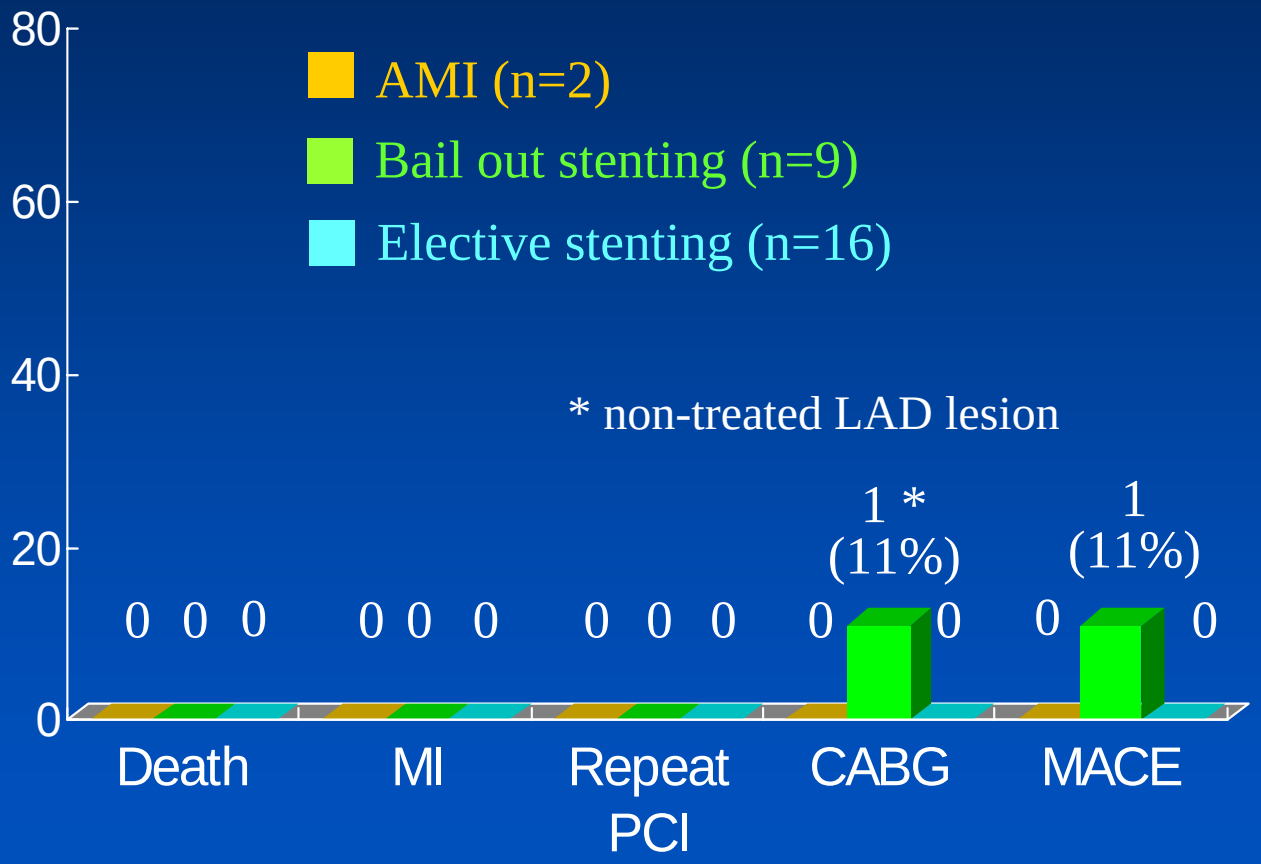
- Left main disease
- Long lesion
- In-stent restenosis
- Small vessel
- Bifurcation lesion
- CTO
- Saphenous vein graft

## Specific patient subsets

- Diabetes mellitus
- Acute MI

# Cypher for Unprotected LM

## Post-discharge Outcomes of 27 pts



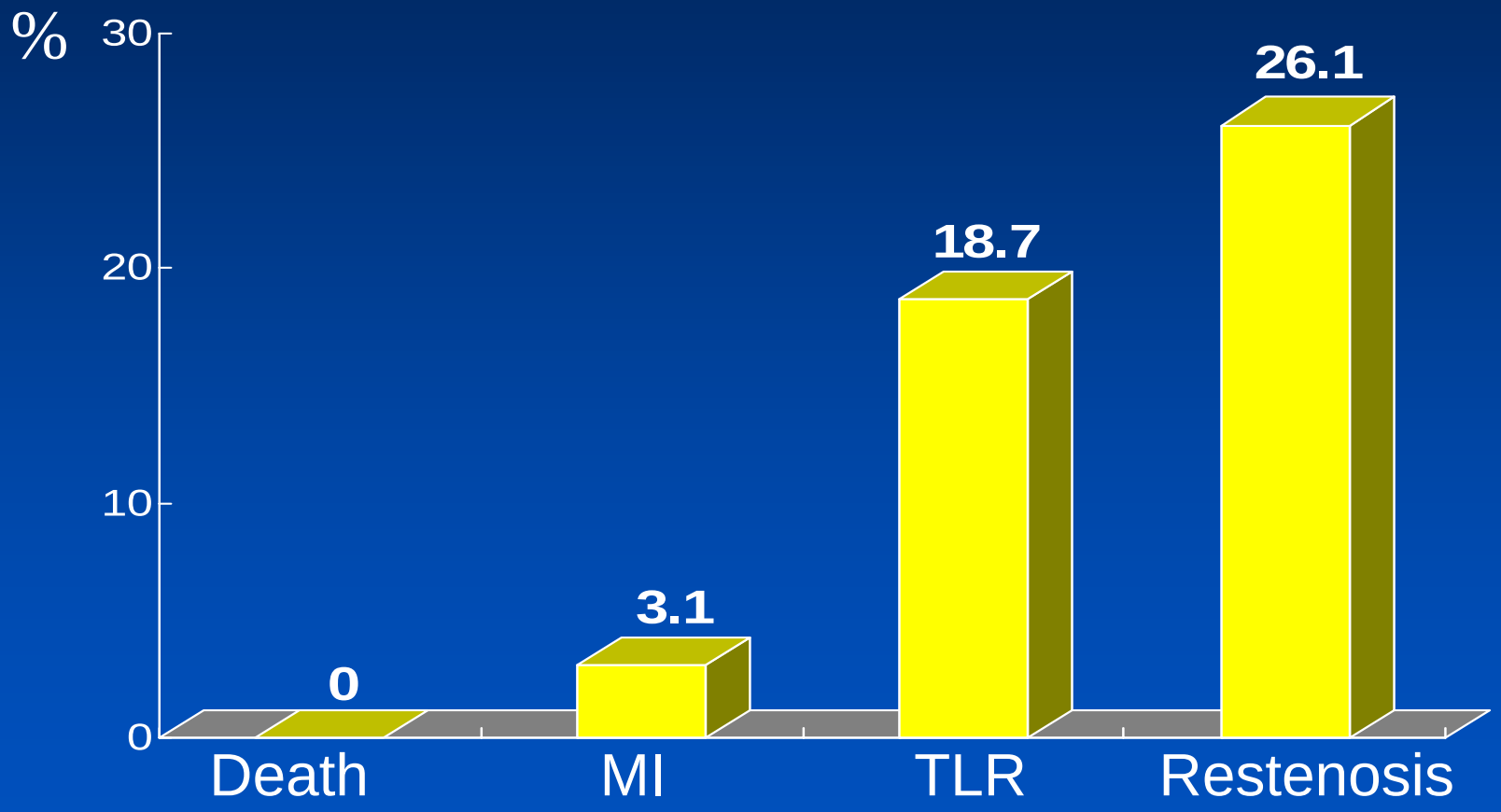

*Arampatzis CA et al. Am J Cardiol 2003;92:327*

Milan

# Cypher for Unprotected LM

## Total 32 pts (27 distal location)

Treated with Only 3.0mm Cypher




*ACC 2004*

# Cypher for Unprotected LM
## In AMC experience

**Total 109 patients**

| | |
|---|---|
| Proximal involvement | 28 (26 %) |
| Ostium | 24 |
| Shaft | 4 |
| Distal involvement | 81 (74 %) |

# Unprotected Left Main Stenting

## In the era of DES

## What is changing now ?

Historical Comparison
with Bare Metal Stenting
(1995-2002)

# Older age, more diabetics, lower EF in DES

| | BMS N=257 | DES N=109 |
|---|---|---|
| Age,yrs | 56±12 | 60 ± 11 (29-86) |
| Men | 172 (67%) | 81 (74 %) |
| Diabetes | 49 (19%) | 33 (30 %) |
| Hypertension | 82 (32%) | 46 (42 %) |
| Current smoker | 87 (34%) | 24 (22 %) |
| Hypercholesterolemia | 72 (28%) | 19 (17 %) |
| LVEF(%) | 62±8 | 59±10 (26-76) |

Yellow character: $p<0.05$

# More bifurcation lesions treated…

| | BMS N=257 | DES N=109 |
|---|---|---|
| Proximal involvement | 159 (62 %) | **28 (26 %)** |
| Ostium | 137 | **24** |
| Shaft | 22 | **4** |
| Distal involvement | 98 (38 %) | ✓ **81 (74 %)** |

✓ : $p<0.05$

# More multivessell disease, No more debulking…

| | BMS N=257 | DES N=109 |
|---|---|---|
| In-stent restenosis | 0 | 12 (13%) |
| Three vessel disease | 15 (6%) | 31 (27%) |
| Debulking before stenting | 95 (37%) | 3 (3%) |
| IVUS guidance | 159 (62%) | 95 (87%) |

# In-Hospital Outcomes : SAT 0 %

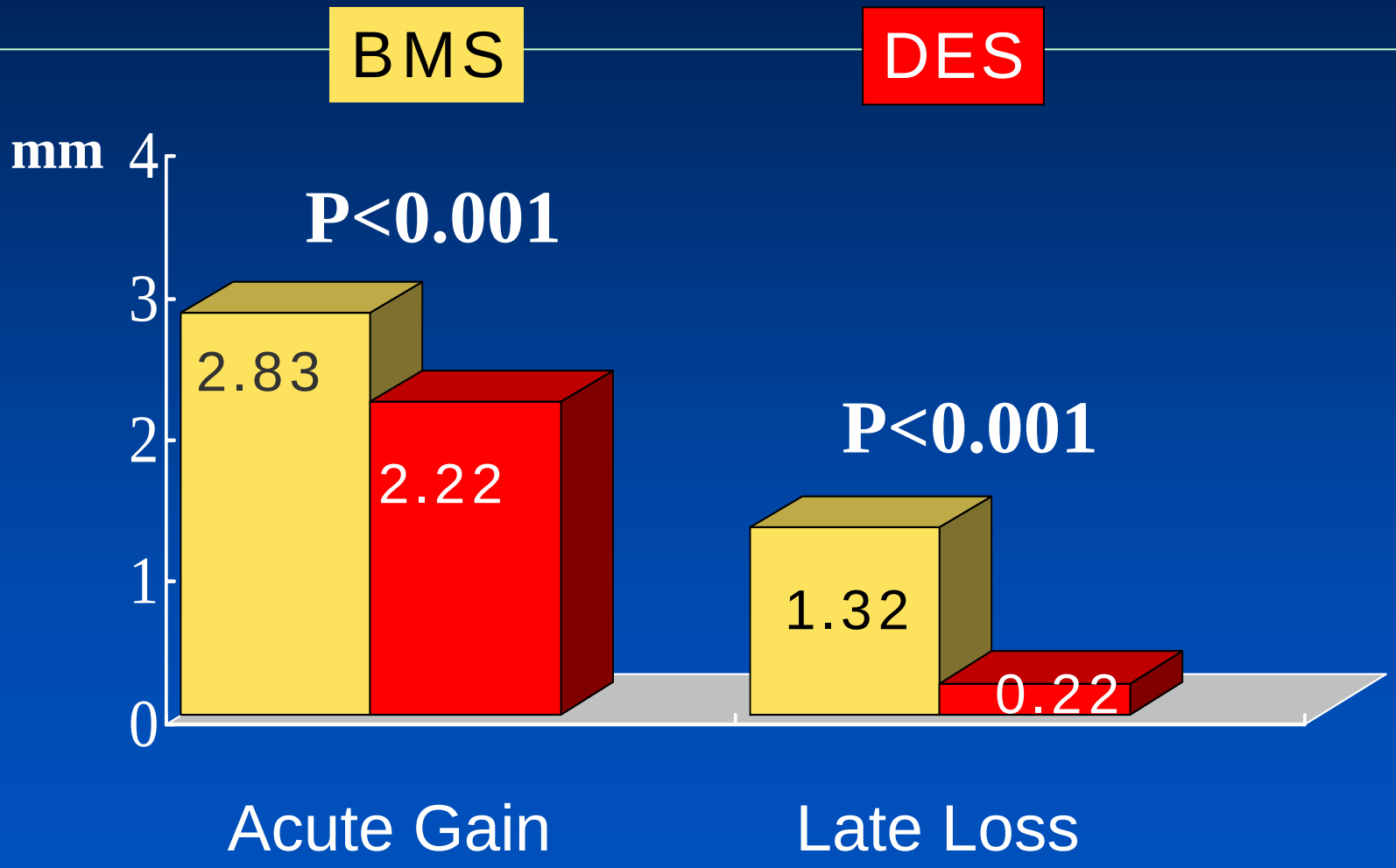
| | BMS N=257 | DES N=109 |
|---|---|---|
| Procedure Success (%) | 99.1 | 100 |
| Death | 0 | 0 |
| Q MI | 1 | 0 |
| Non-QMI | 19 (7%) | 11 (10 %) |
| SAT | 1 (0.9%) | 0 |
| Emergent CABG | 1 | 0 |
| Repeat PCI | 0 | 0 |

* All procedure related, CK-MB ≥ 3 times normal value

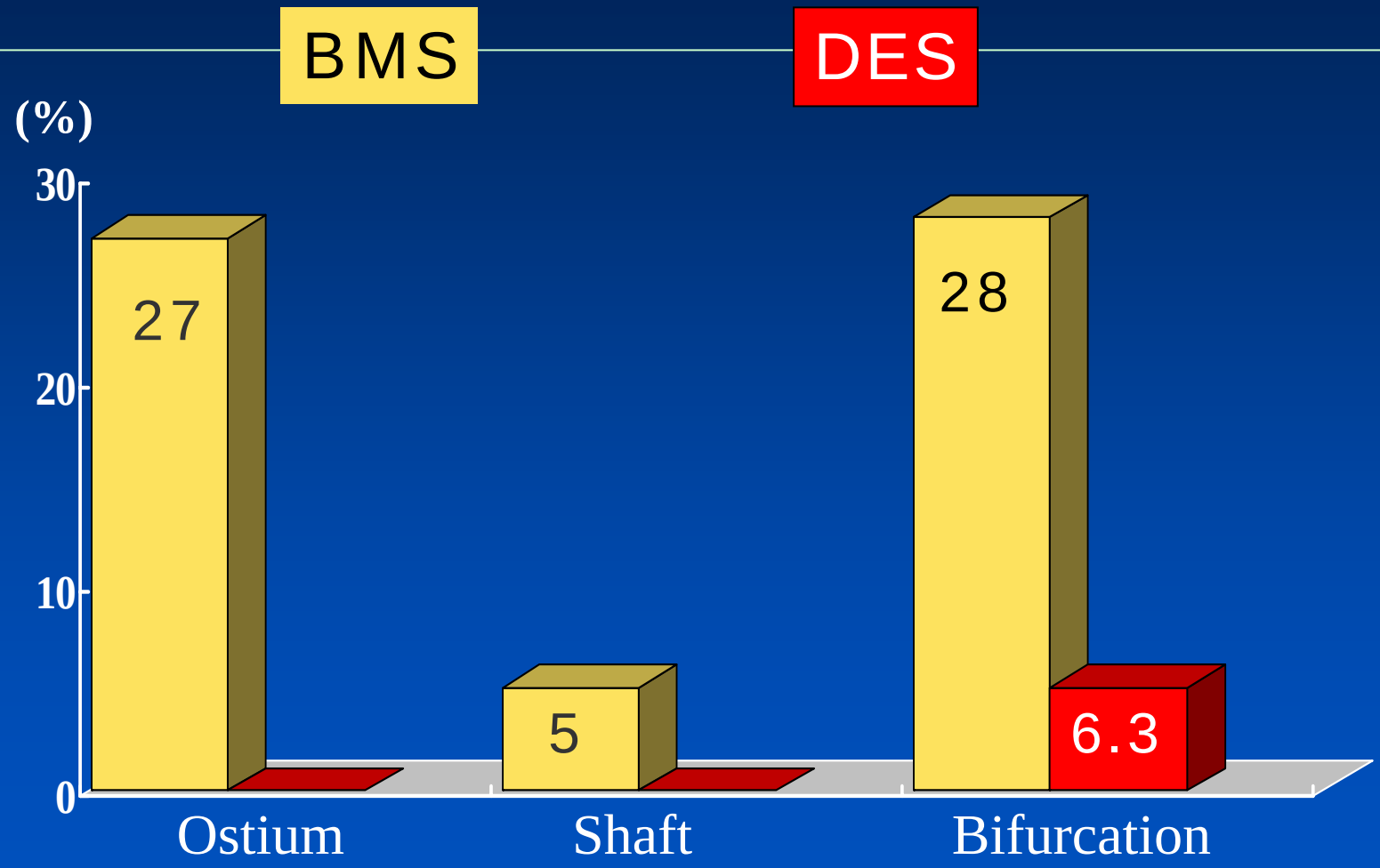
# 6 month Restenosis : 4.0 %

| | Proximal (n=17) | Distal (n=56) |
|---|---|---|
| Angiographic F/U | 13 (76%) | 48 (86%) |
| Reference vessel (mm) | 3.56±0.44 | 3.58±0.65 |
| MLD (mm) | 3.59±0.32 | 3.26±0.59 |
| Diameter stenosis (%) | -1.8±8.1 | 7.5±17.0 |
| Late loss (mm) | 0.17±0.21 | 0.23±0.50 |
| Restenosis | 0 % | 3 (6.3%) |

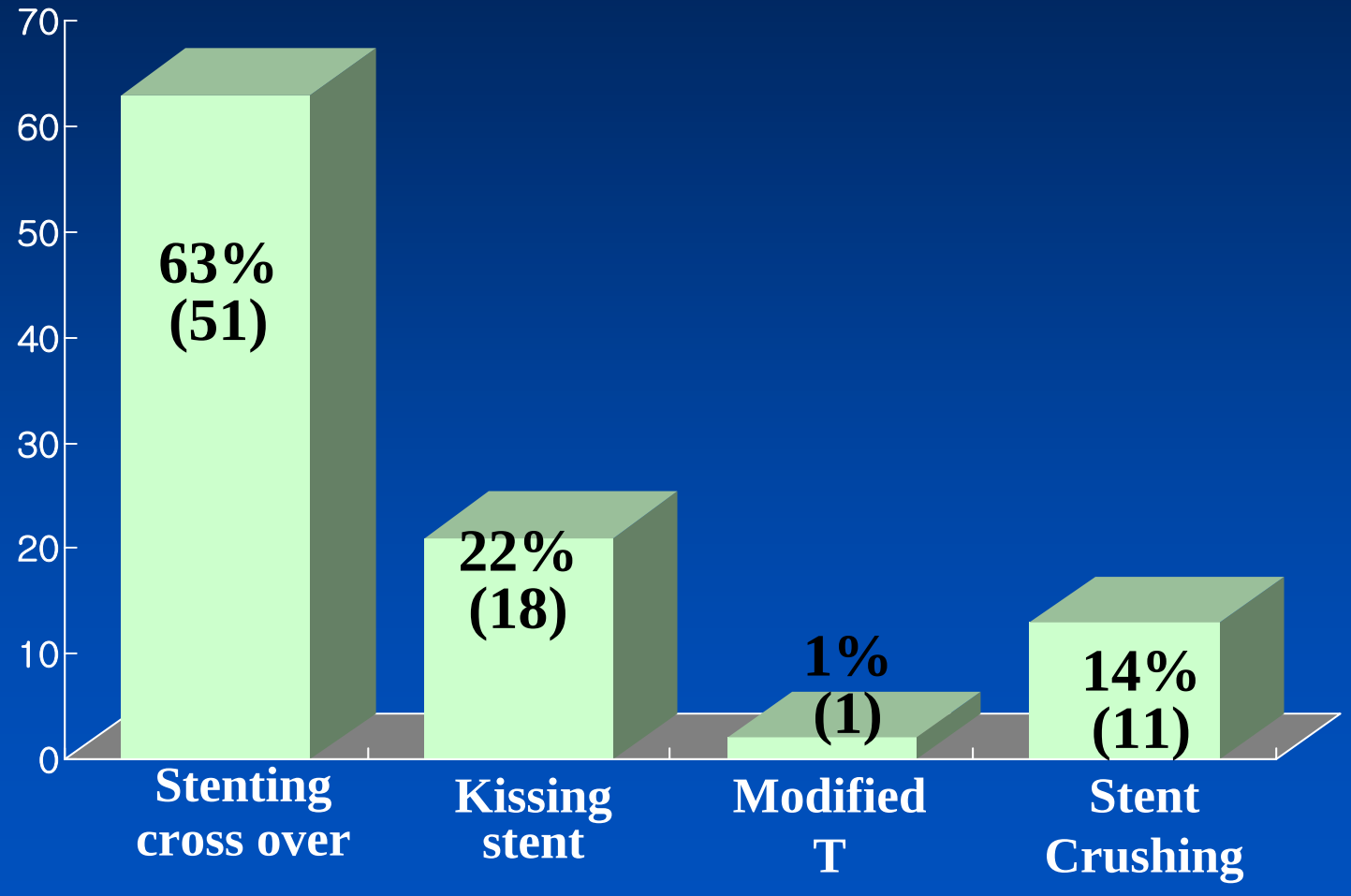
# Late Loss : 0.22 mm



# Restenosis Rate : 4 %

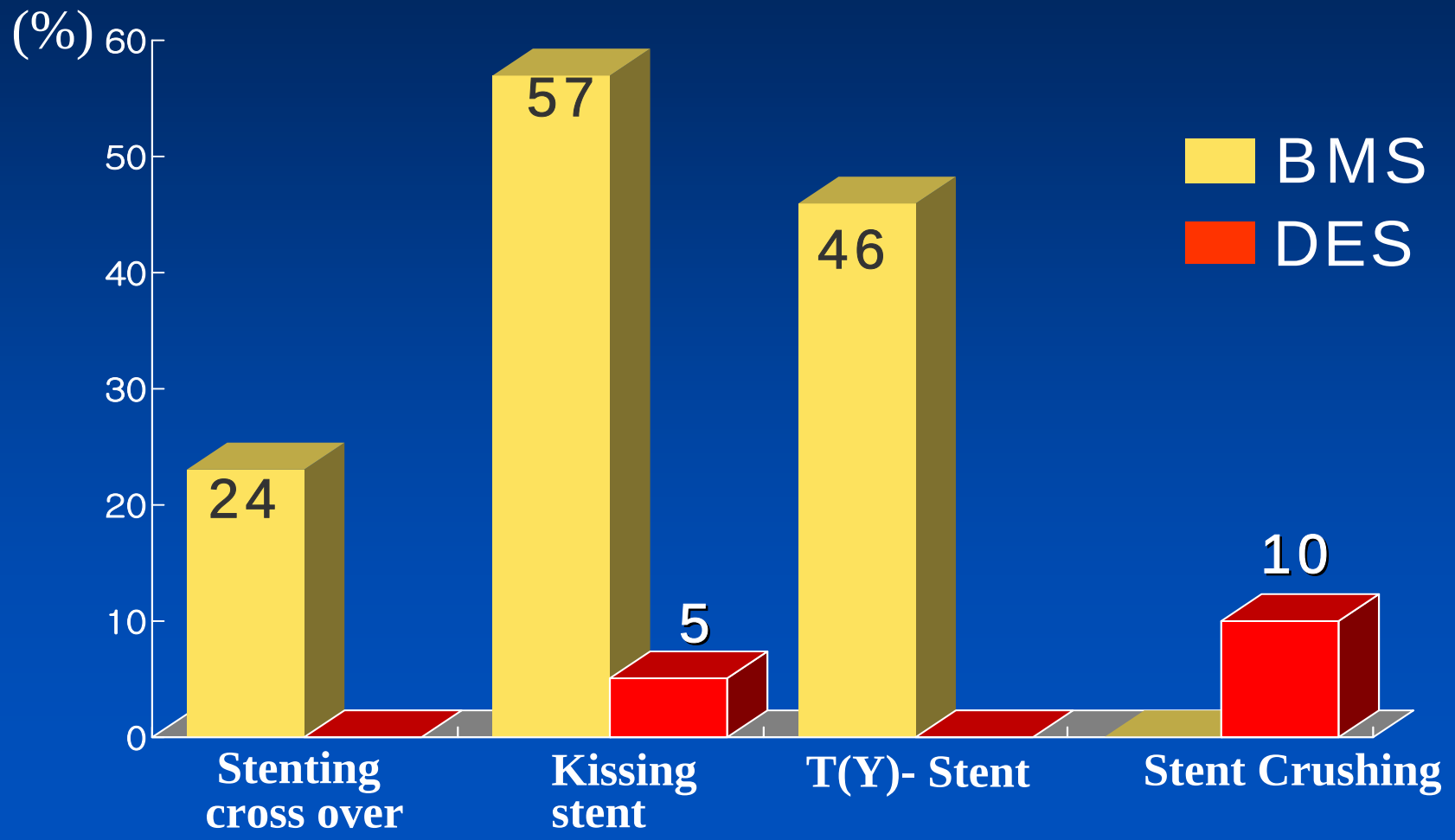


# Stenting Cross Over was most commonly used for distal LM bifurcaton (n=81)



# Restenosis Rate

## According to different strategy in distal LM



# Unprotected Left Main Stenting
## In the era of DES

## What is changing now ?

- We tackle more complex lesion groups
  (more LM distal bifurcation lesions, three vessel disease, longer lesions, higher risk patient)
- Simplified procedure – No more debulking…
- Excellent immediate and late clinical outcomes

# Global DES Use is reasonable approach based on the data

DES works for
the Left Main Disease…

# Efficacy Concerns

## Specific lesion subsets

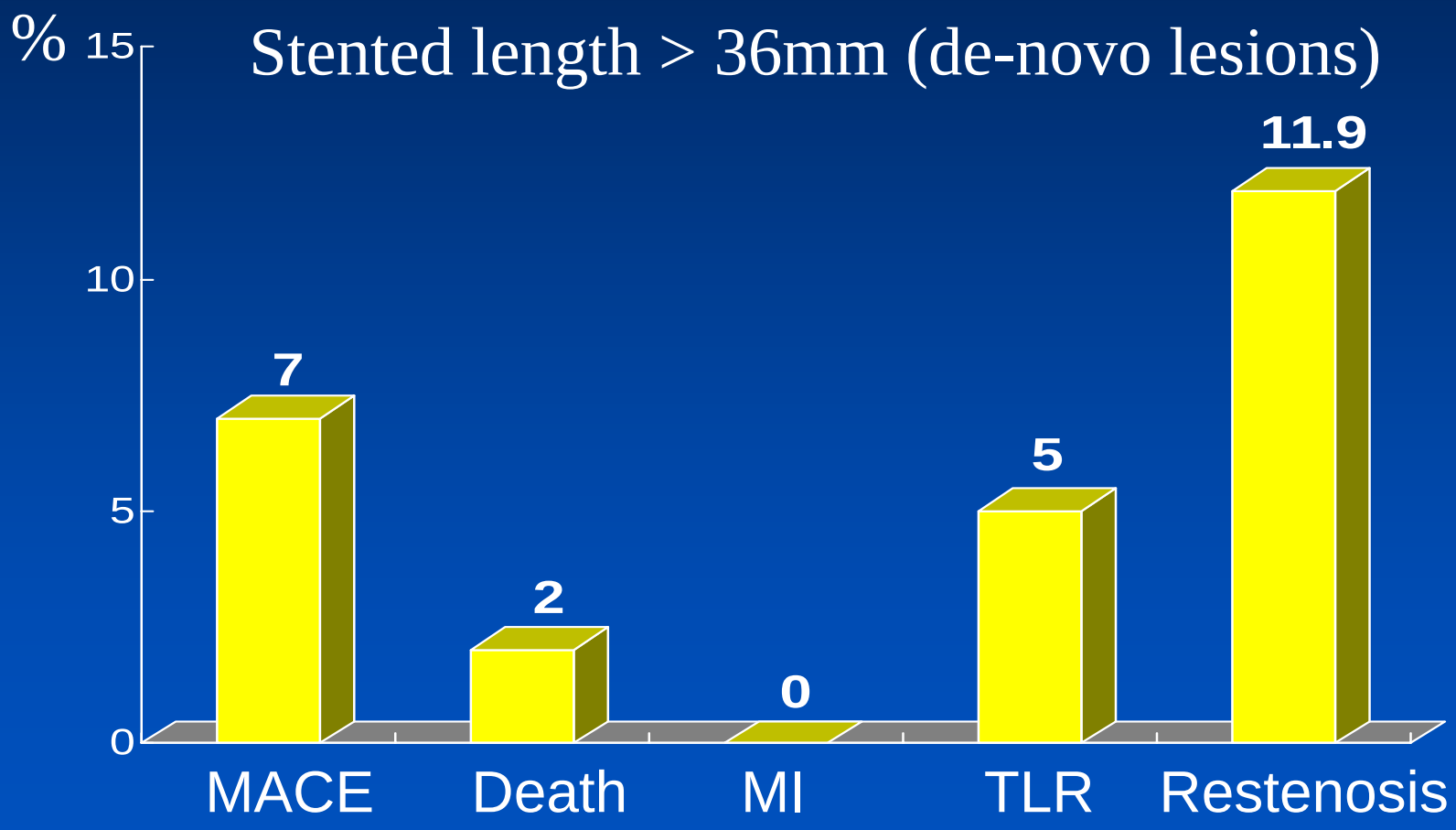
- Left main disease
- Long lesion
- In-stent restenosis
- Small vessel
- Bifurcation lesion
- CTO
- Saphenous vein graft

## Specific patient subsets

- Diabetes mellitus
- Acute MI

# RESEARCH Registry

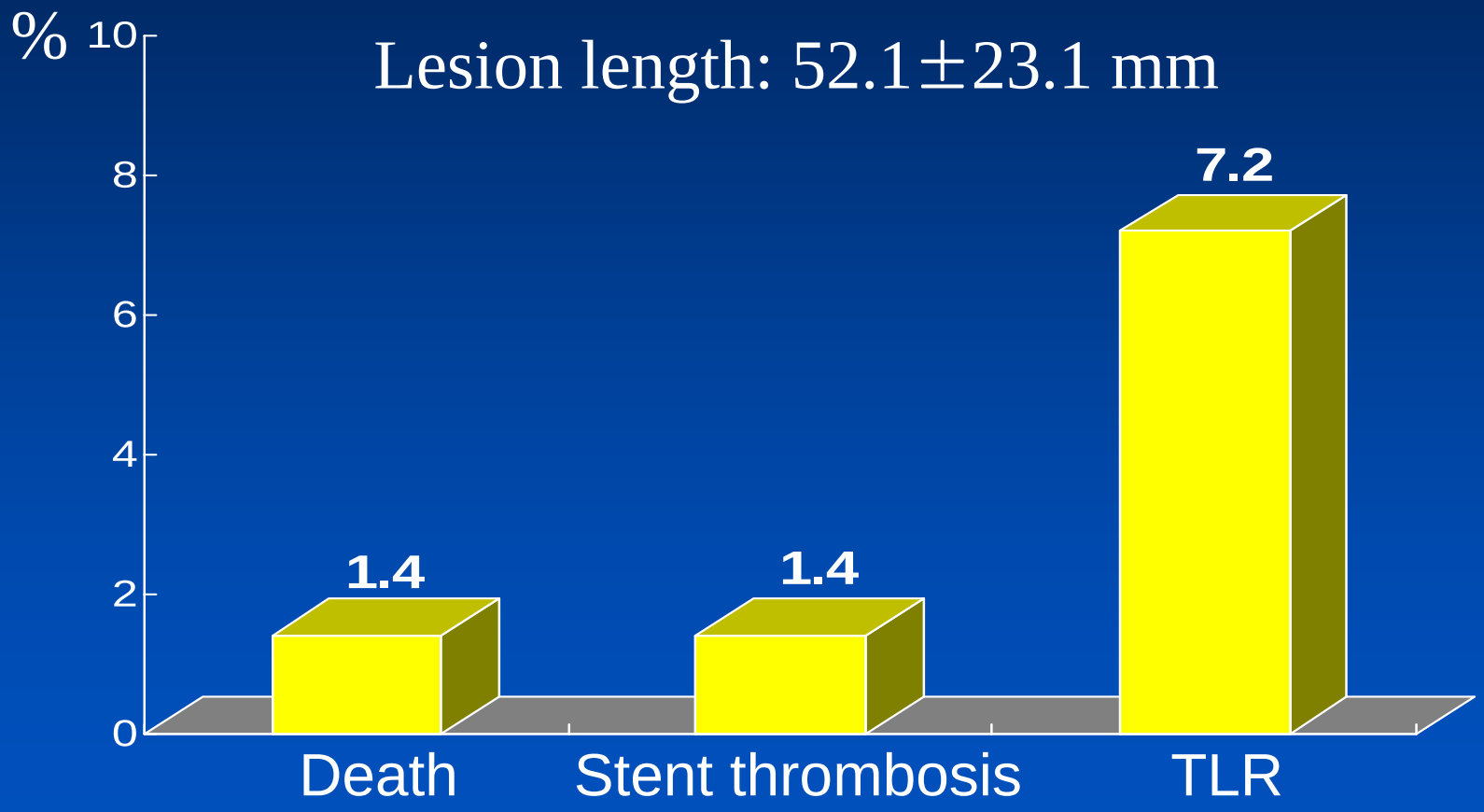
## 9-Months in 96 patients, 102 lesions




*PW Serruys, ACC 2004*

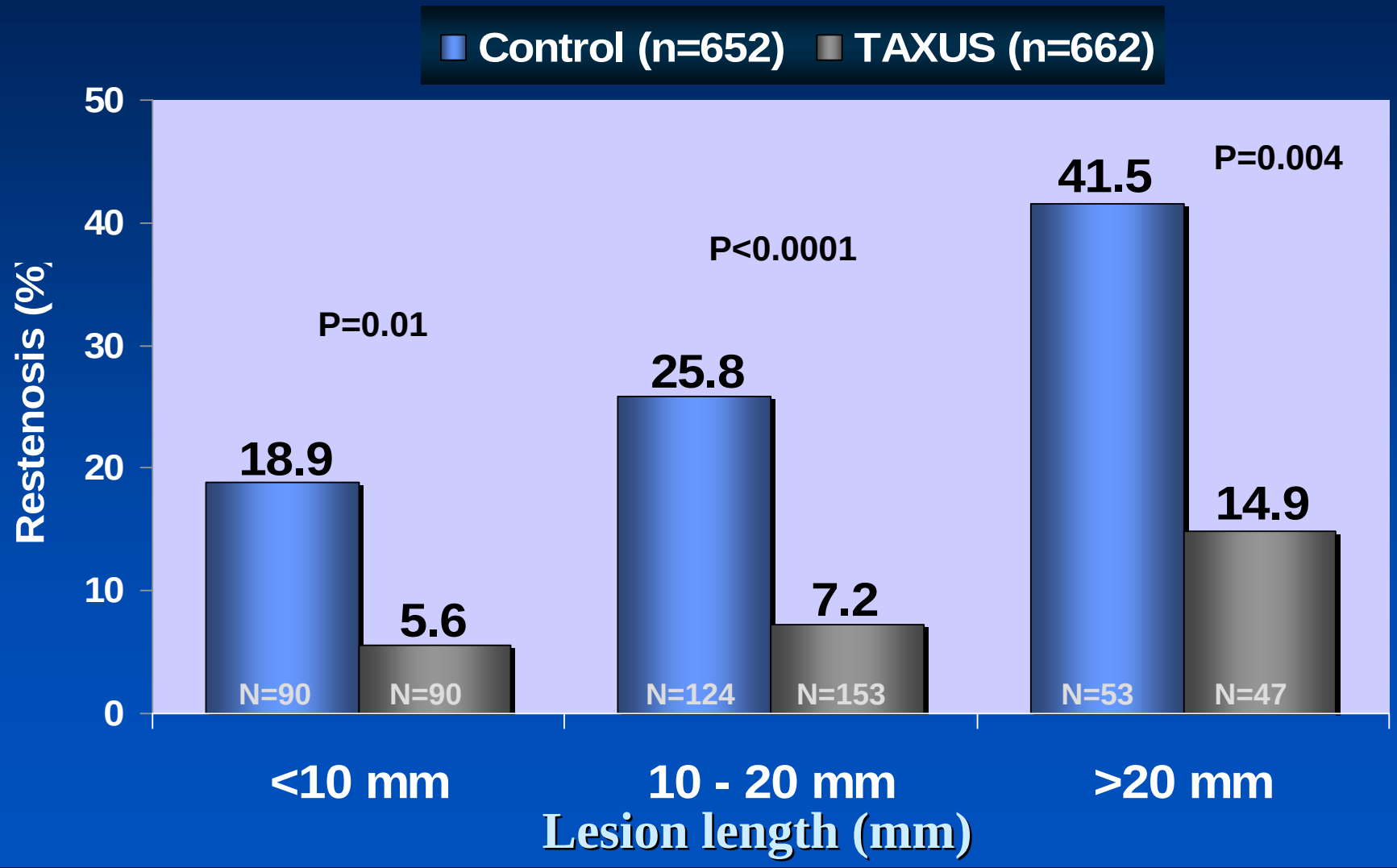
# Full Metal Jacket with Cypher

## 6-Month in 71 patients, 153 lesions




*Orlic D, ACC, 2004*

# Impact of Lesion Length in TAXUS IV
## Restenosis (analysis segment)



March 2003 - February 2004

# Enrollment

De-novo Lesions
(≥ 24mm)

**487 patients, 597 lesions**

Cypher stent
(≥ 28mm)

**338 patients, 424 lesions**
**Mean stent length : 41mm**
**(28- 92 mm)**

BMS stent
(≥ 28mm)

**149 patients, 173 lesions**
**Mean stent length : 37mm**
**(28 – 73 mm)**

# Diabetic patients : 36%

| | Cypher (n=338) | Control (n=149) | P value |
|---|---|---|---|
| Age (years) | 60 ± 10 | 60 ± 10 | 0.950 |
| Man | 243 (72%) | 112 (75%) | 0.614 |
| Hypertension | 193 (57%) | 79 (53%) | 0.488 |
| Hypercholesterolemia | 91 (27%) | 31 (21%) | 0.194 |
| Diabetes mellitus | 122 (36%) | 43 (29%) | 0.106 |
| Smoking | 108 (32%) | 73 (49%) | 0.001 |

# Unstable Angina : 44%

| | Cypher (n=338) | Control (n=149) | P value |
|---|---|---|---|
| LV ejection fraction (%) | 60 ± 10 | 56 ± 9 | <0.001 |
| Prior PCI | 37 (11%) | 21 (14%) | 0.323 |
| Prior CABG | 3 (2%) | 0 (0%) | 0.268 |
| Clinical diagnosis | | | 0.220 |
| Stable angina | 155 (46%) | 70 (47%) | |
| Unstable angina | 149 (44%) | 55 (37%) | |
| Acute MI | 34 (10%) | 24 (16%) | |

# Multivessel disease : 70%

| | Cypher (n=338) | Control (n=149) | P value |
|---|---|---|---|
| No of diseased vessels | | | 0.176 |
| 1 vessel | 118 (35%) | 41 (28%) | |
| 2 vessel | 124 (37%) | 55 (37%) | |
| 3 vessel | 96 (28%) | 53 (36%) | |

# LAD : 61%

| | Cypher (n=424) | Control (n=173) | P value |
|---|---|---|---|
| Lesion location | | | <0.001 |
| LAD | 259 (61%) | 72 (42%) | |
| LCX | 59 (14%) | 25 (20%) | |
| RCA | 110 (26%) | 53 (39%) | |
| Chronic total occlusion | 38 (9%) | 22 (13%) | 0.166 |
| Infarct related artery | 20 (5%) | 14 (8%) | 0.106 |

# Overlapping : 46%

| | Cypher (n=424) | Control (n=173) | P value |
|---|---|---|---|
| Used No of stents | 1.55 ± 0.68 | 1.29 ± 0.54 | <0.001 |
| Overlapping | 196 (46%) | 44 (25%) | <0.001 |
| √Contiguous stent length (mm) | 40.8 ± 15.0 | 36.6 ± 12.4 | 0.001 |
| Maximal inflation pressure (atm) | 15.4 ± 3.6 | 11.7 ± 3.3 | <0.001 |
| Maximal balloon size | 3.31 ± 0.38 | 3.41 ± 0.51 | 0.008 |
| Balloon-to-artery ratio | 1.11 ± 0.16 | 1.06 ± 0.14 | <0.001 |
| IVUS guidance | 303 (72%) | 71 (41%) | <0.001 |
| Use of Abciximab | 11 (3%) | 7 (4%) | 0.492 |

# In-Hospital Outcomes
# SAT : 0 %

| | Cypher (n=338) | Control (n=149) | P value |
|---|---|---|---|
| Procedural success * | 97.8% | 94.8% | 0.051 |
| Death | 0 | 1 (0.7%) ** | 1.000 |
| MI | 29 (9%) | 18 (12%) | 0.228 |
| Q wave | 0 | 0 | |
| Non-Q wave *** | 29 (9%) | 18 (12%) | |
| Stent thrombosis | 0 | 0 | 1.000 |
| TLR | 0 | 0 | 1.000 |
| TVR | 0 | 0 | 1.000 |

* Final TIMI flow ≥ 2 and residual diameter stenosis ≤ 30%
** No reflow after multivessel PCI , *** CK-MB ≥ 3 times normal value

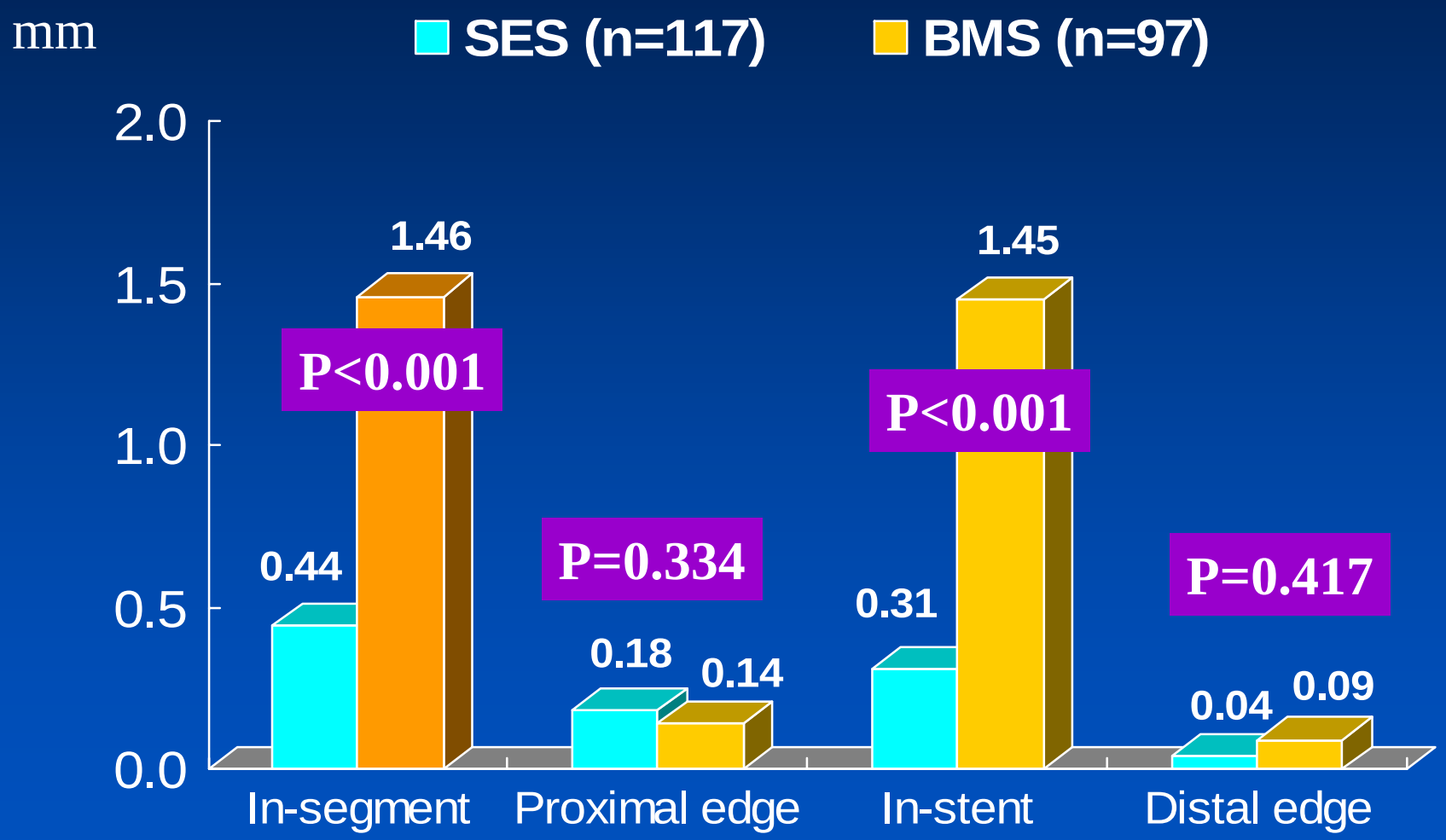
# TLR : 0.6 %

| | Cypher (n=162) | Control (n=127) | P value |
|---|---|---|---|
| Death | 1 (0.6%) | 1 (0.8%) | 1.000 |
| Non-cardiac | 1 (0.6%) | 0 | |
| Cardiac | 0 | 1 (0.8%) | |
| MI | 0 | 0 | 1.000 |
| Q wave | 0 | 0 | |
| Non-Q wave | 0 | 0 | |
| Stent thrombosis | 0 | 0 | 1.000 |
| TLR | 1 (0.6%) | 18 (14.2%) | <0.001 |
| Repeat PCI | 0 | 16 | |
| CABG | 1 | 2 | |
| MACE | 2 (1.1%) | 19 (15.0%) | <0.001 |

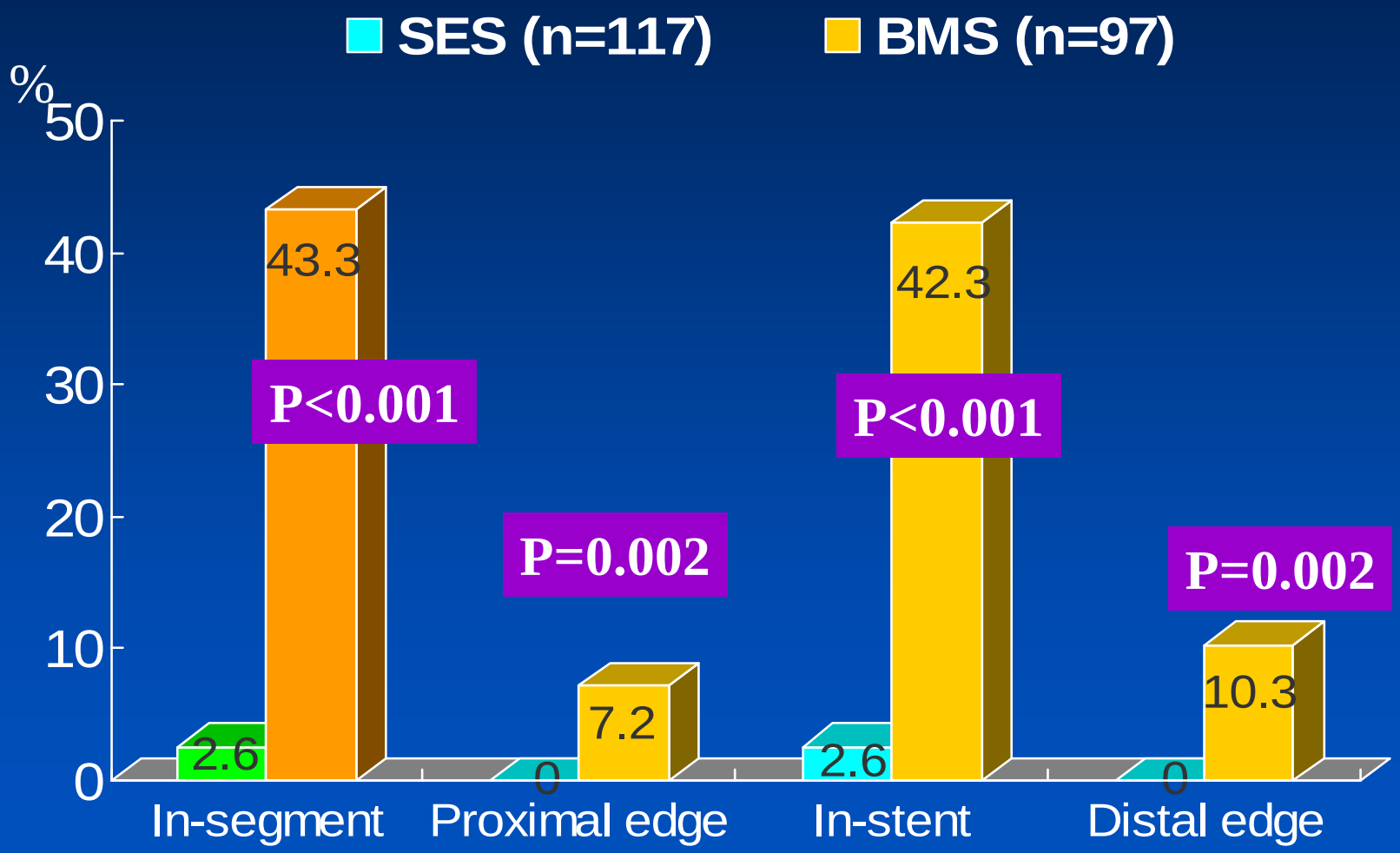
# Restenosis Rate : 2.6 %

| | Cypher (n=117) | Control (n=97) | P value |
|---|---|---|---|
| Proximal reference (mm) | 3.00 ± 0.49 | 3.64 ± 0.45 | 0.172 |
| Distal reference (mm) | 2.60 ± 0.43 | 2.69 ± 0.58 | 0.241 |
| MLD (mm) | 2.54 ± 0.53 | 1.53 ± 0.76 | <0.001 |
| Diameter stenosis (%) | 9.3 ± 17.4 | 48.0 ± 22.2 | <0.001 |
| Late loss (mm) | 0.31 ± 0.57 | 1.45 ± 0.72 | <0.001 |
| Restenosis | 3 (2.6%) | 42 (43.3%) | <0.001 |

# Late Loss :0.44 mm



# Restenosis Rate : 2.6 %



# Global DES Use is reasonable approach based on the data

DES works for
very Long Lesions…

# Efficacy Concerns

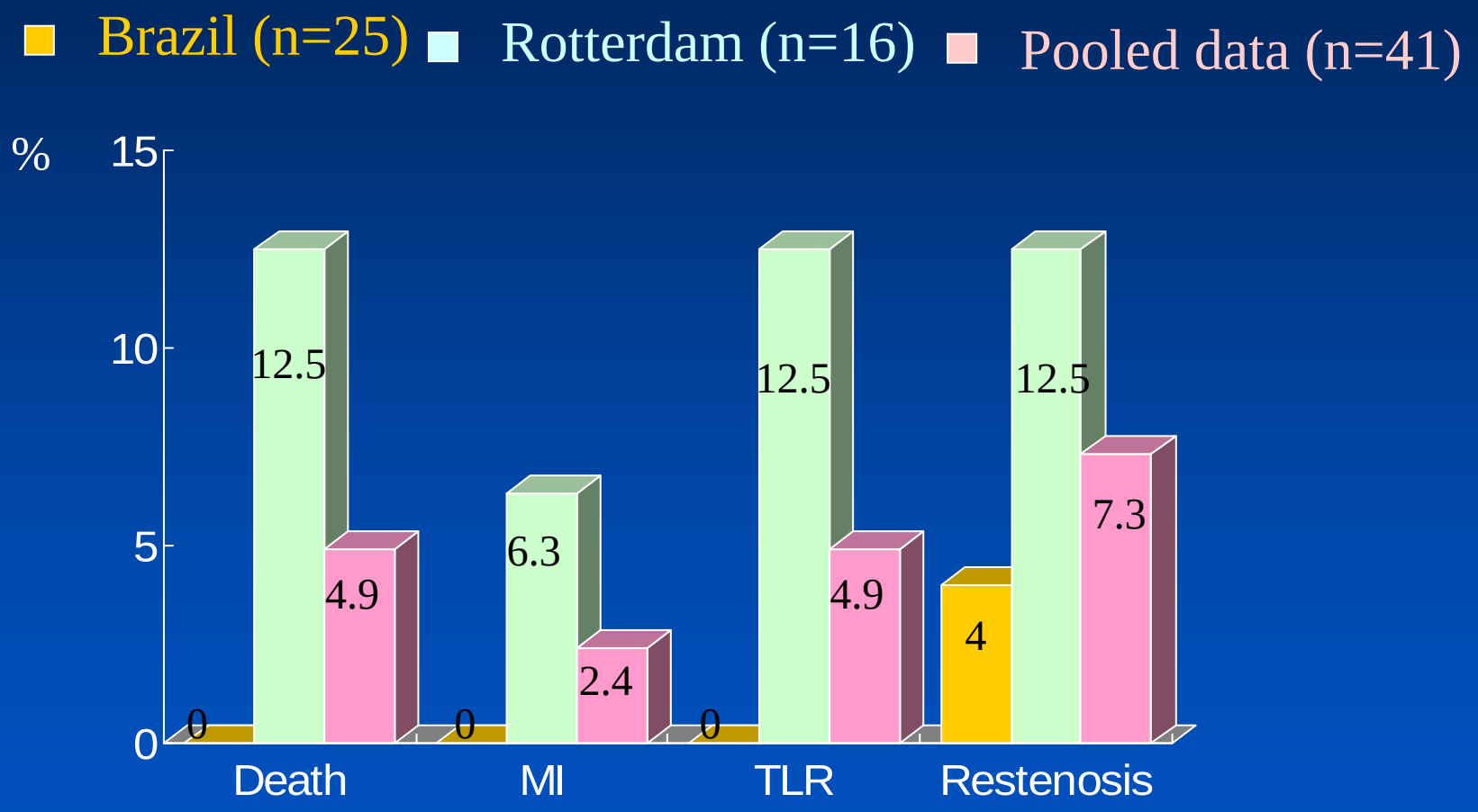
## Specific lesion subsets

- Left main disease
- Long lesion
- In-stent restenosis
- Small vessel
- Bifurcation lesion
- CTO
- Saphenous vein graft

## Specific patient subsets

- Diabetes mellitus
- Acute MI

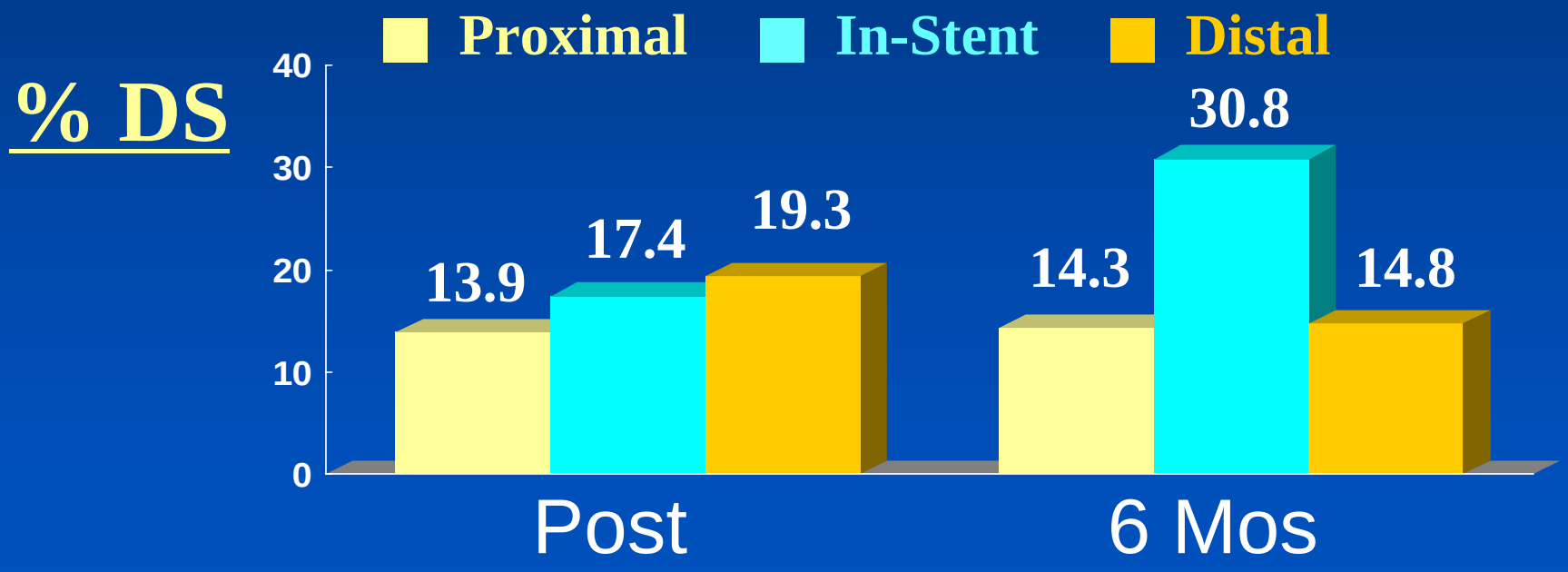
# First Study with Cypher 1-Year F/U : Restenosis : 7.3 %




*K Tanabe, Circulation 2003;107*

# TAXUS III for ISR :
# **Re-Restenosis :16%**

## 2 Clinical Centers (n=28 pts)

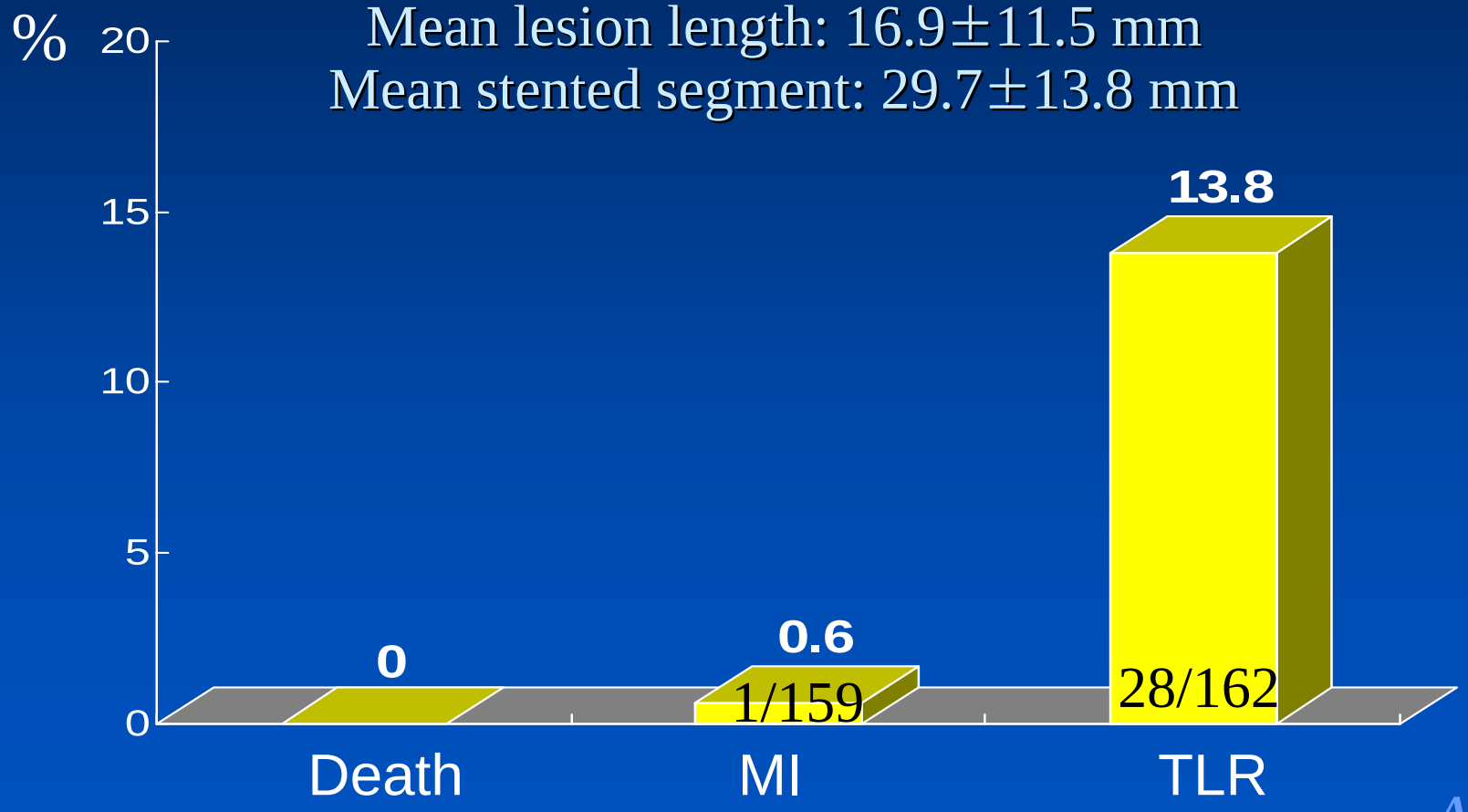



*K Tanabe, Circulation 2003;107*

# Cypher for ISR in Milan : TLR 14 %

## Immediate and mid-term results

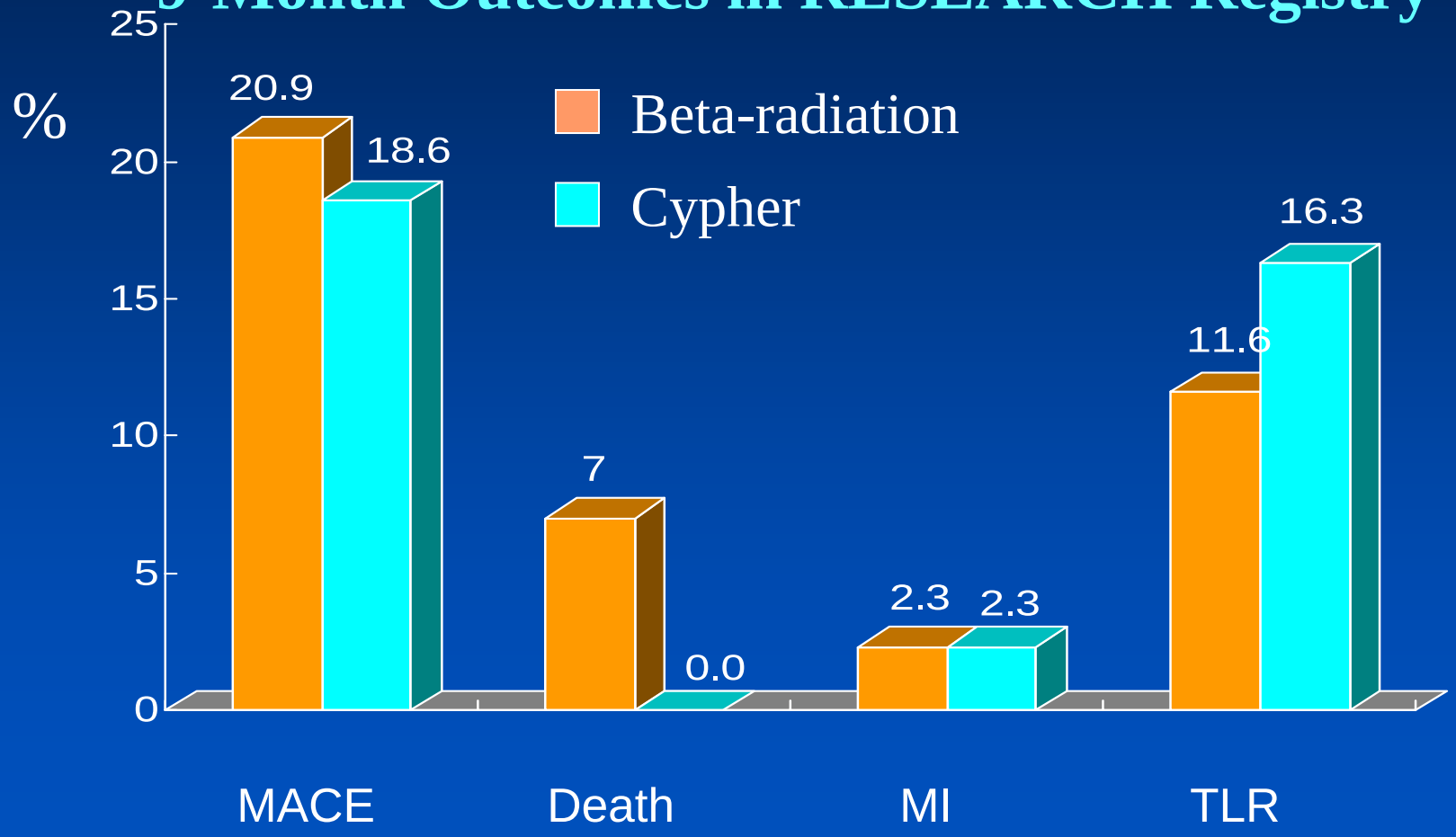
206 ISR, 159 patients
Mean lesion length: 16.9±11.5 mm
Mean stented segment: 29.7±13.8 mm




*ACC 2004*

# Similar TLR; Cypher vs. RT for ISR

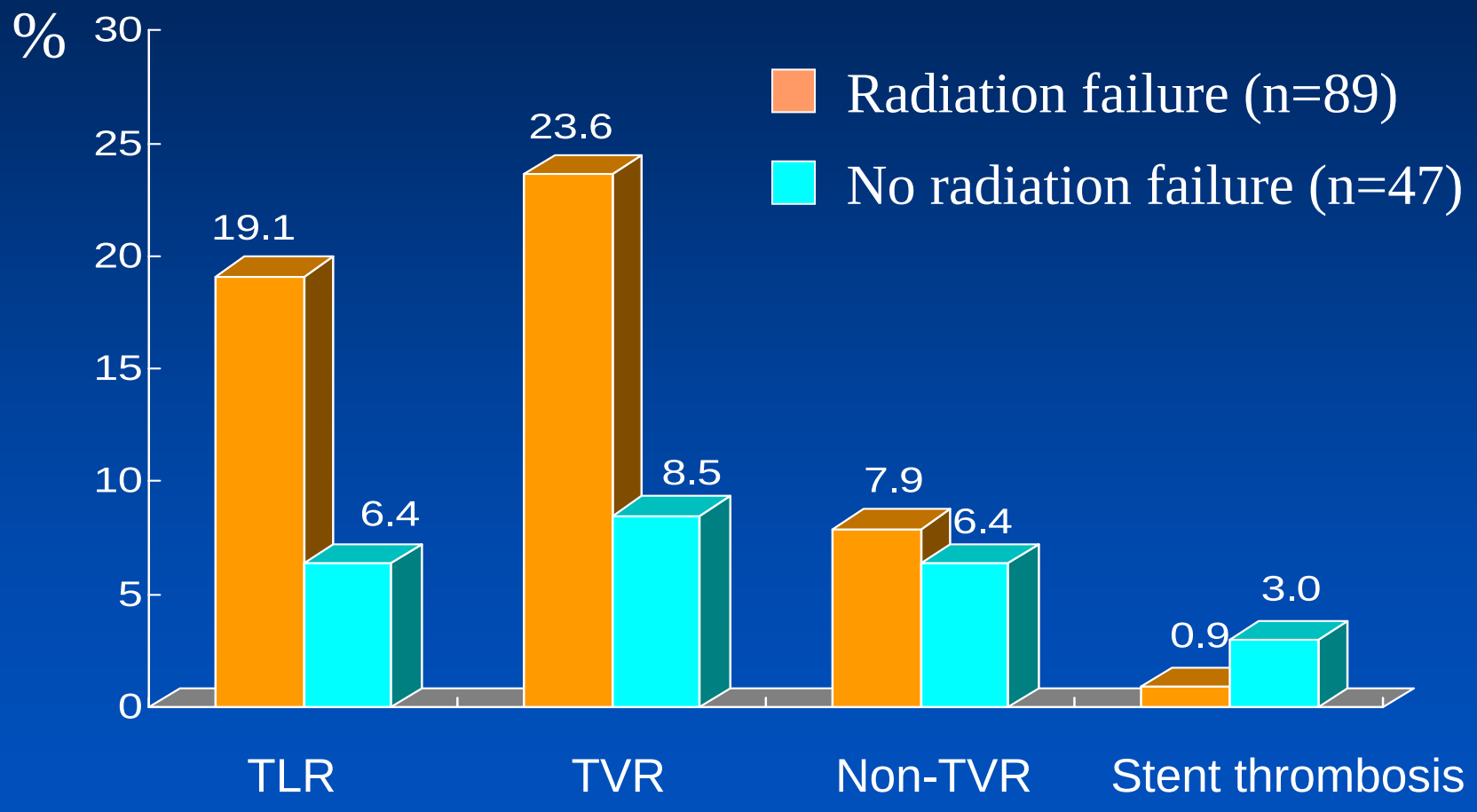
## 9-Month Outcomes in RESEARCH Registry




*Saia F et al. Catheter Cardiovasc Interven (In press)*

# High TLR : Cypher for RT Failure

## 6-Month Outcomes in SECURE registry




*Teirstein PS et al. AHA 2003*

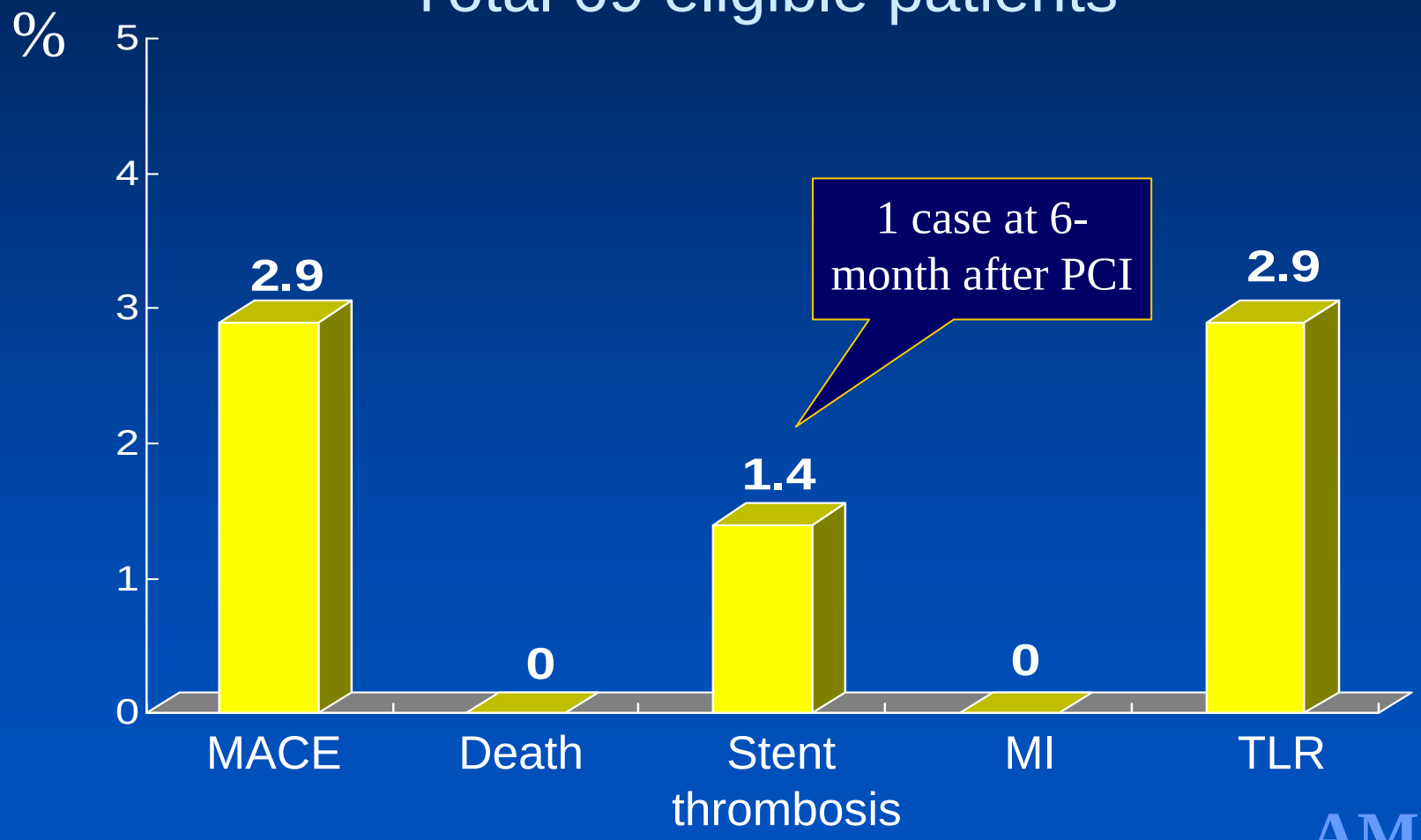
# 6-Month Restenosis : 3.8 %

| | 52 / 69 eligible lesions (75%) |
|---|---|
| Reference vessel (mm) | 2.77 ± 0.48 |
| MLD (mm) | 2.40 ± 0.66 |
| Late loss (mm) | 0.55 ± 0.42 |
| Diameter stenosis (%) | 12.8 ± 21.7 |
| Binary restenosis (%) | 2 (3.8%) |
| Focal | 1 |
| Diffuse | 1 |

AMC-ISR

# 6-Month TLR : 2.9 %

Total 69 eligible patients




AMC-ISR

# Randomized Comparison of Cypher vs. RT

**From February 2003 till March 2004**

Diffuse (≥ 10mm) In-Stent Restenosis

**Randomization (1:1)**

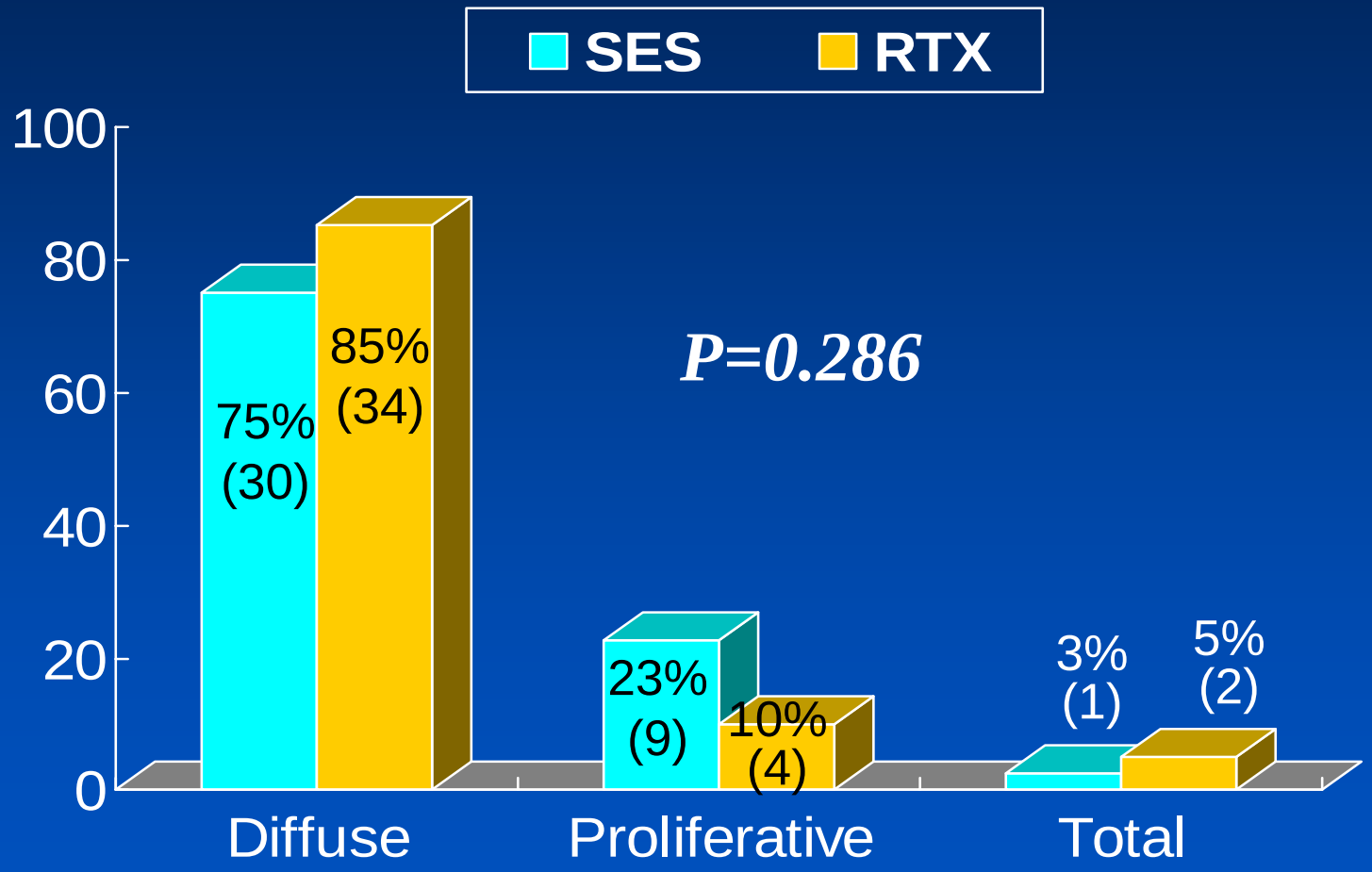
Cypher (N=40)

Complete lesion coverage with Cypher

Brachytherapy with $^{188}$Re after cutting balloon angioplasty (N=40)

Radiation dose of **20 Gy at a depth of 1.0 mm** into the vessel wall

# Diffuse ISR (≥ 10mm) were included




AMC-ISR

# Lesion Length : 32 mm

| | Cypher | RT | P value |
|---|---|---|---|
| **Pre-procedure** | | | |
| Reference vessel (mm) | 2.96±0.55 | 2.86±0.56 | 0.446 |
| MLD (mm) | 0.89±0.43 | 0.83±0.35 | 0.473 |
| Diameter stenosis (%) | 69.9±13.8 | 70.6±12.6 | 0.831 |
| Lesion length (mm) | 31.7±12.4 | 32.8±16.6 | 0.744 |
| **Post-procedure** | | | |
| MLD (mm) | 2.92±0.45 | 2.42±0.44 | <0.001 |
| Diameter stenosis (%) | 0.19±13.6 | 14.2±14.1 | <0.001 |
| Acute gain (mm) | 2.02±0.51 | 1.59±0.52 | <0.001 |

AMC-SES/RT

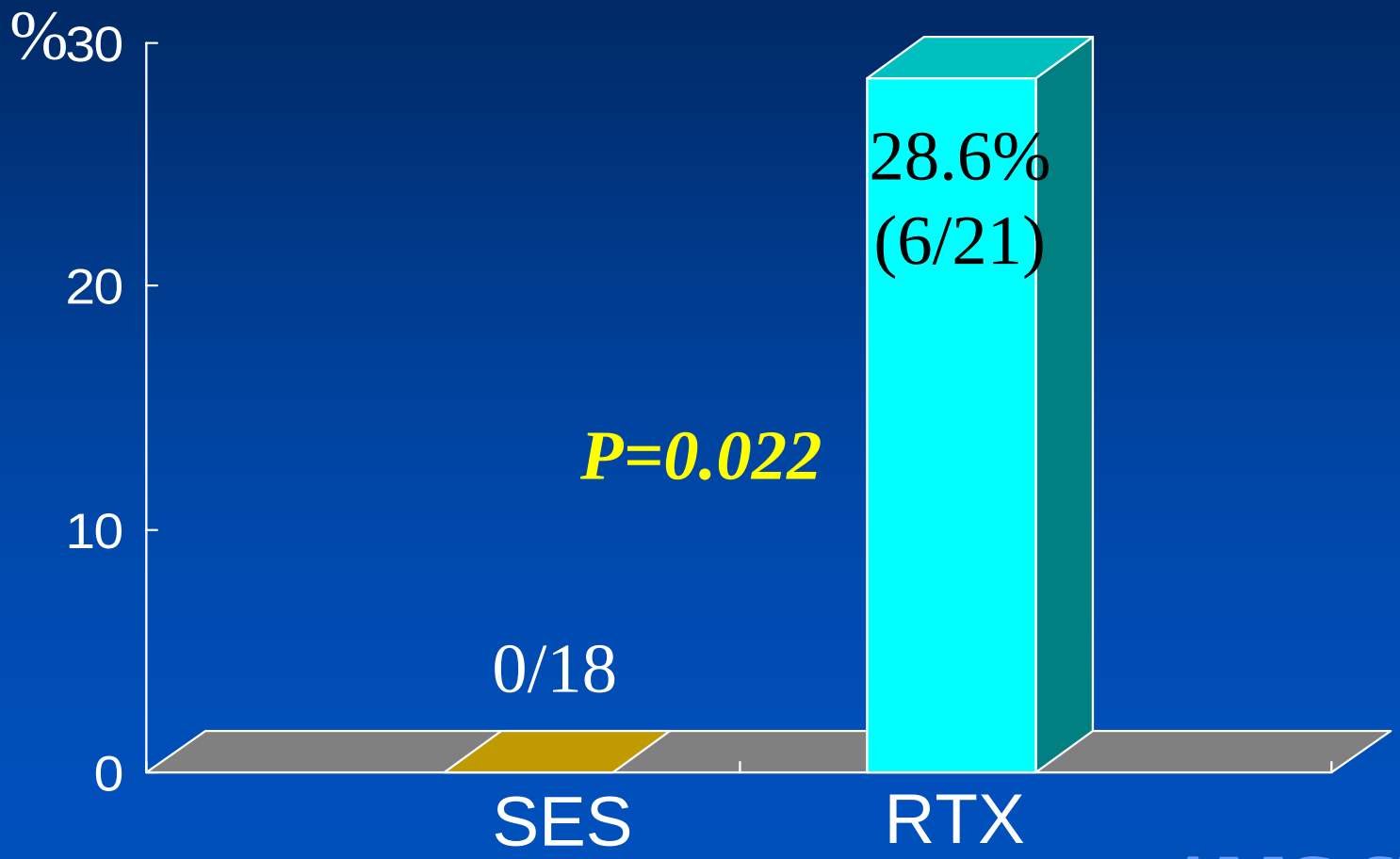
# QCA Analysis

## Follow-UP Results

| | Cypher | RT | p |
|---|---|---|---|
| Follow-up | 18 | 21 | |
| Reference (mm) | 2.83±0.44 | 2.74±0.36 | 0.606 |
| MLD (mm) | 2.38±0.66 | 1.67±0.73 | 0.017 |
| DS (%) | 15.4±19.9 | 39.6±24.0 | 0.012 |
| Late loss (mm) | 0.75±0.39 | 0.94±0.66 | 0.388 |

AMC-SES/RT

# Restenosis Rate : 0 %




AMC-SES/RT

# 6-Month TLR : 4 %

| | Cypher | RT | P value |
|---|---|---|---|
| Eligible | 24 | 27 | |
| Death | 0 | 0 | |
| MI | 0 | 0 | |
| Q-wave | | | |
| Non-Q-wave | | | |
| Thrombosis | 1 (4%) | 0 | 1.000 |
| TLR | 1 (4%) | 3 (11%) | 0.612 |
| MACE | 1 (4%) | 3 (11%) | 0.612 |

AMC-SES/RT

# Global DES Use is reasonable approach based on the data

DES works for ISR.

The efficacy would be comparable with that of brachytherapy

# Efficacy Concerns

## Specific lesion subsets

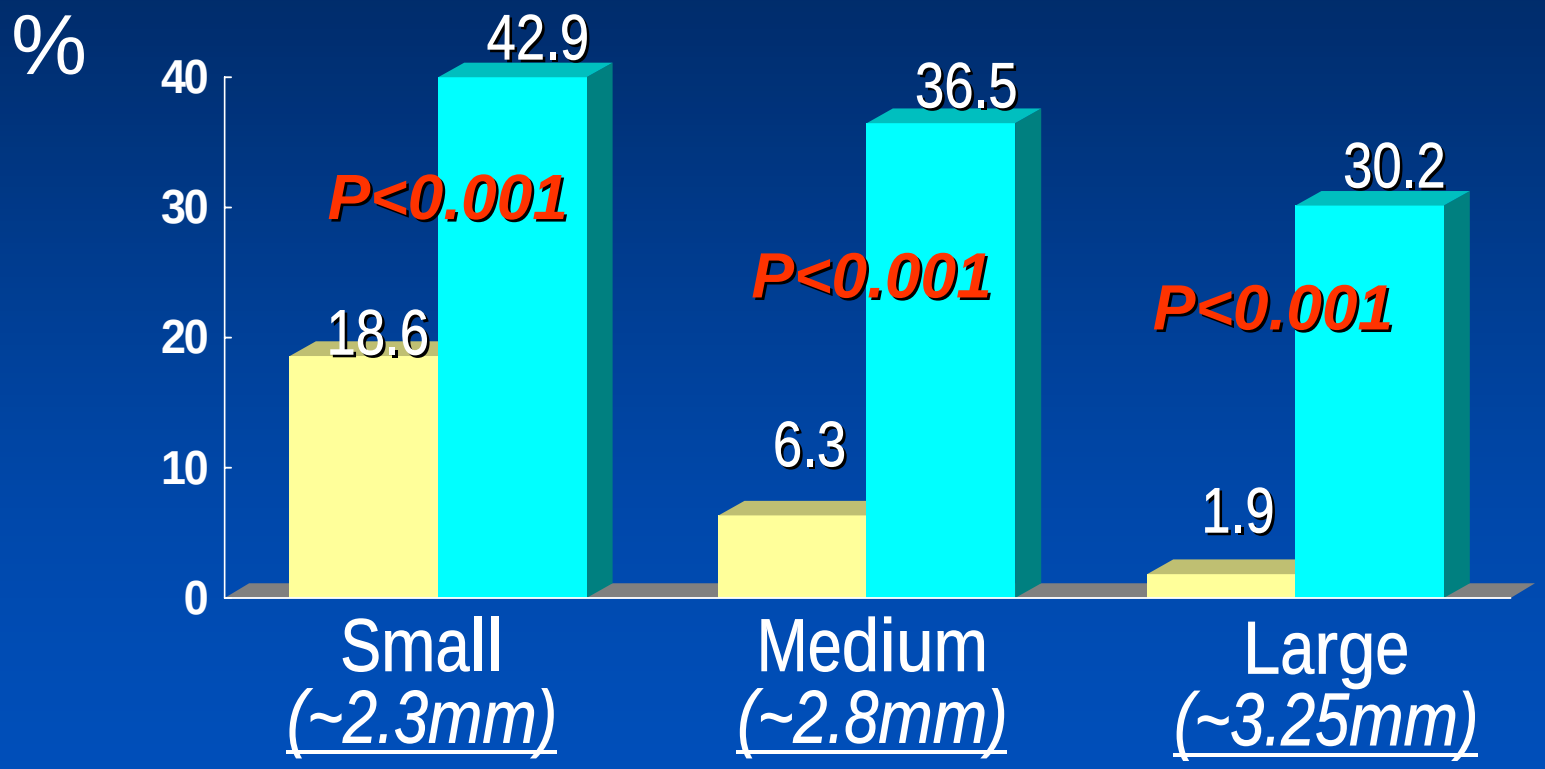
- Left main disease
- Long lesion
- In-stent restenosis
- Small vessel
- Bifurcation lesion
- CTO
- Saphenous vein graft

## Specific patient subsets

- Diabetes mellitus
- Acute MI

# Impact of Vessel Diameter in SIRIUS

## Restenosis (analysis segment)

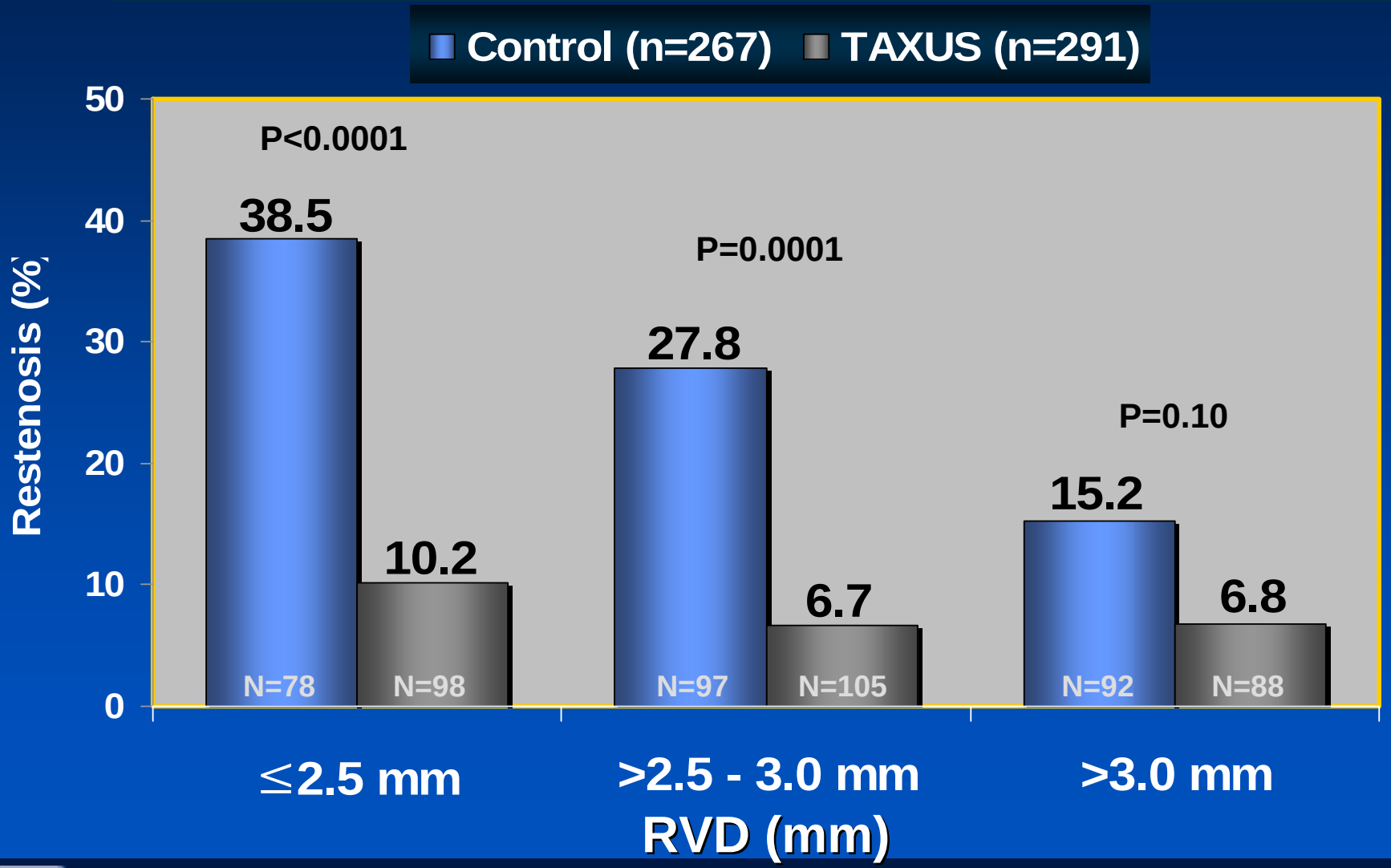



■ Sirolimus (n=533) ■ Control (n=525)

*TCT, Oct 2002*

# Impact of Vessel Diameter in TAXUS IV

## Restenosis (analysis segment)



# SES-SMART Randomized Trial in Small Vessels (≤ 2.75mm)

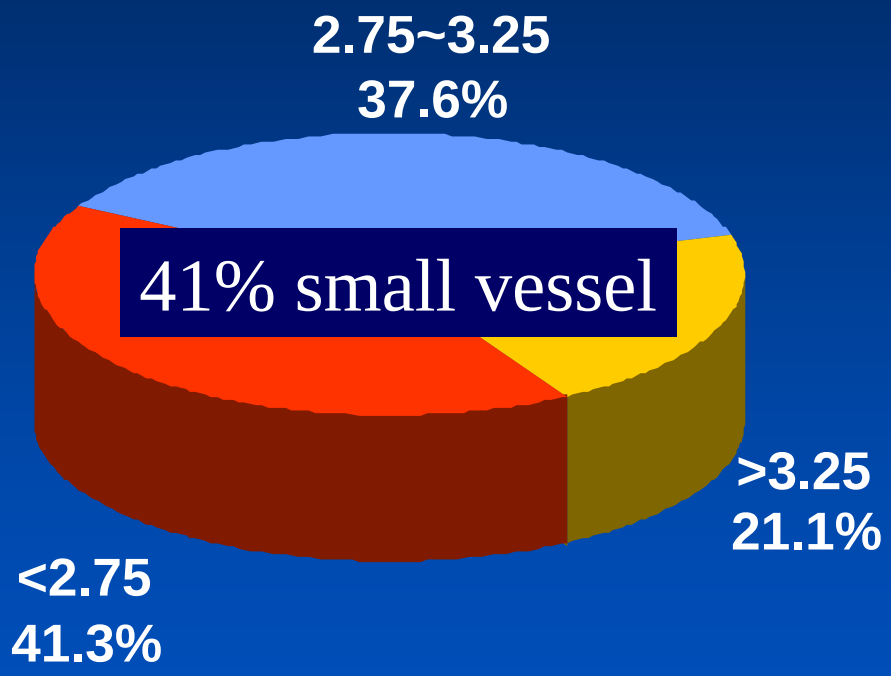
## 8 month Results

| | Sirolimus Group (n=129) | Uncoated Stent (n=128) | P Value |
|---|---|---|---|
| Binary Restenosis (in-segment) | 9.8% | 53.1% | < 0.001 |
| Late Loss | 0.16 mm | 0.69 mm | < 0.001 |
| Loss Index | 0.11 | 0.68 | < 0.001 |
| MLD – pre-procedure | 0.73 ± 0.23 | 0.71 ± 0.23 | No diff |
| MLD – post-procedure | 2.16 ± 0.24 | 2.14 ± 0.24 | No diff |
| MLD – at 8months | 2.01 ± 0.43 | 1.2 ± 0.64 | < 0.001 |
| TLR (all) | 7.0% | 21.1% | 0.0021 |
| TLR-PCI | 7.0% | 19.5% | 0.0053 |
| MACE | 9.3% | 31.3% | < 0.001 |

*ACC 2004*

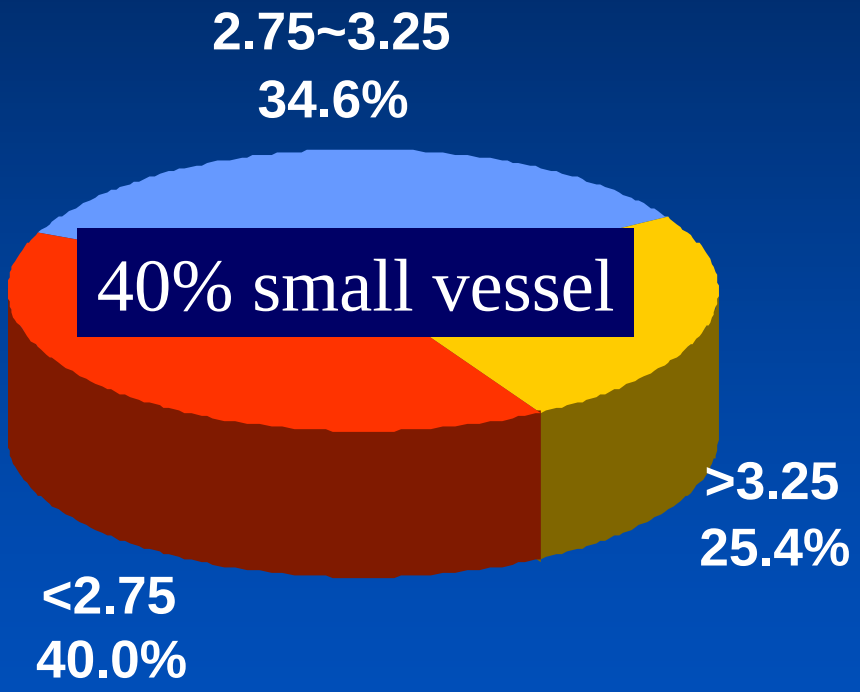
# Reference Vessel Size in AMC

## Cypher Stent (n=1093)




**Mean: 2.91±0.48mm**

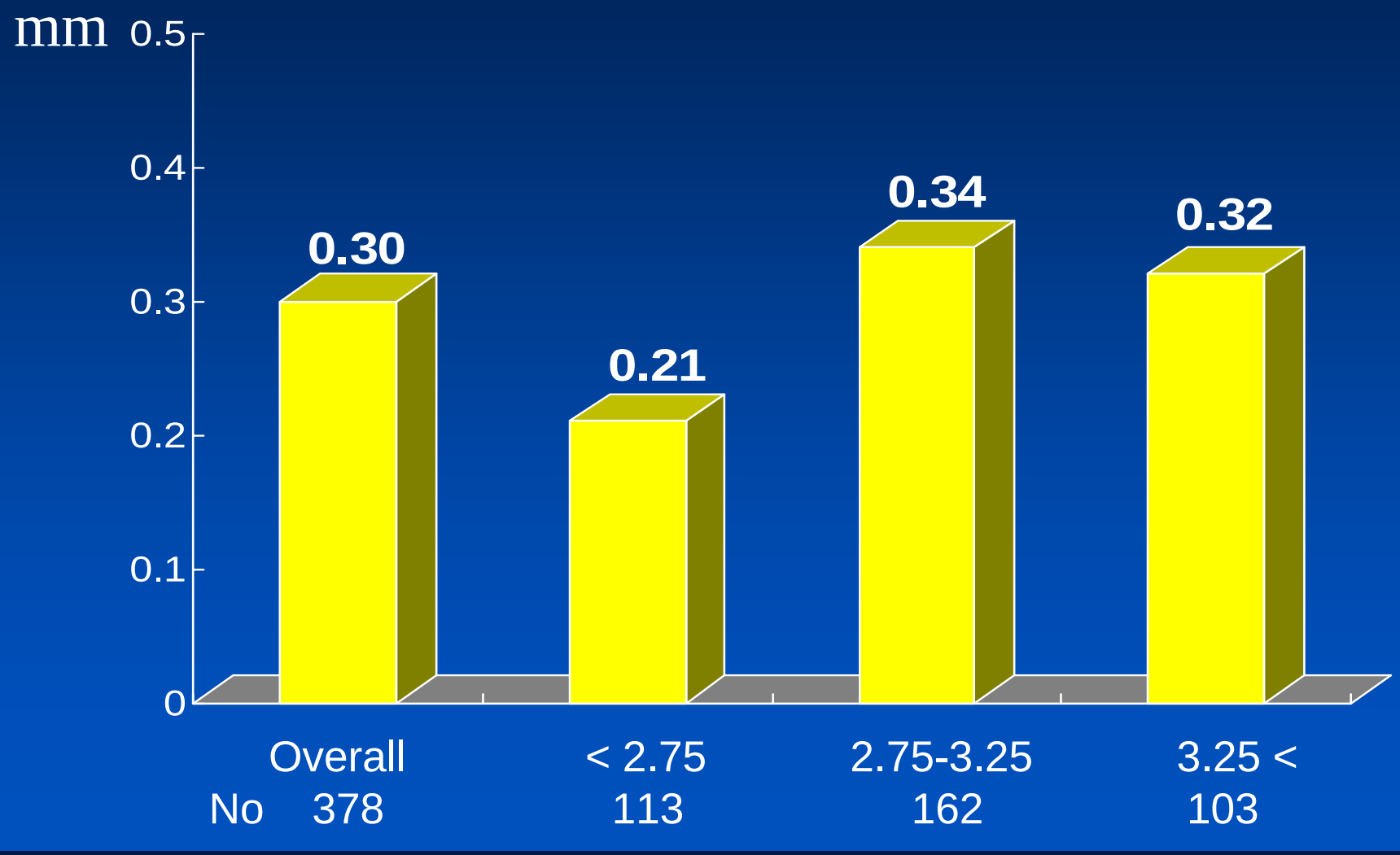
## Taxus Stent (n=318)



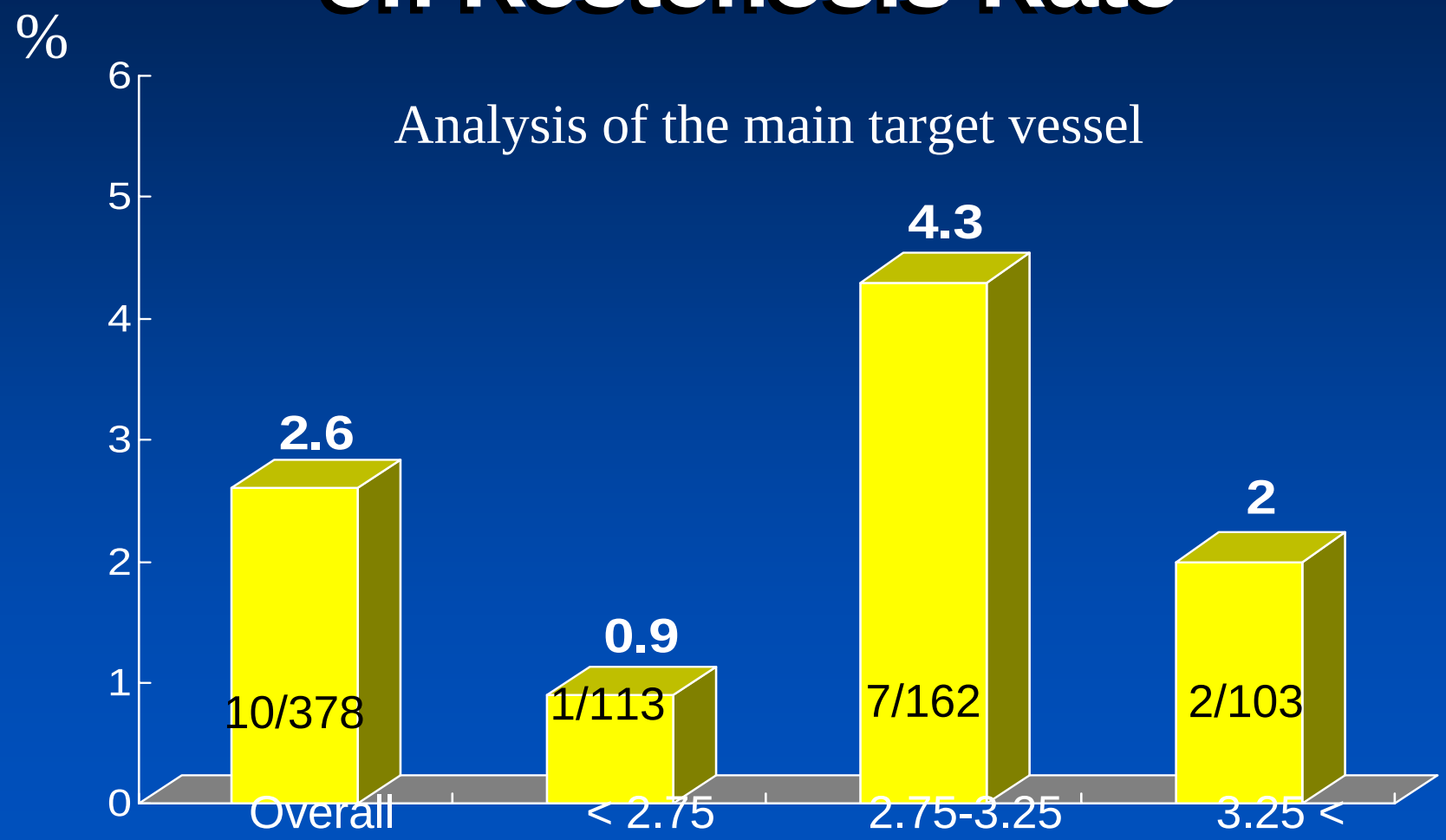

**Mean: 2.93±0.52mm**

# AMC-Small Vessel

## Late Loss : 0.30 mm



# Impact of Vessel Size on Restenosis Rate



# Global DES Use is reasonable approach based on the data

DES works for small vessel disease

# Efficacy Concerns

## Specific lesion subsets

- Left main disease
- Long lesion
- In-stent restenosis
- Small vessel
- Bifurcation lesion
- CTO
- Saphenous vein graft

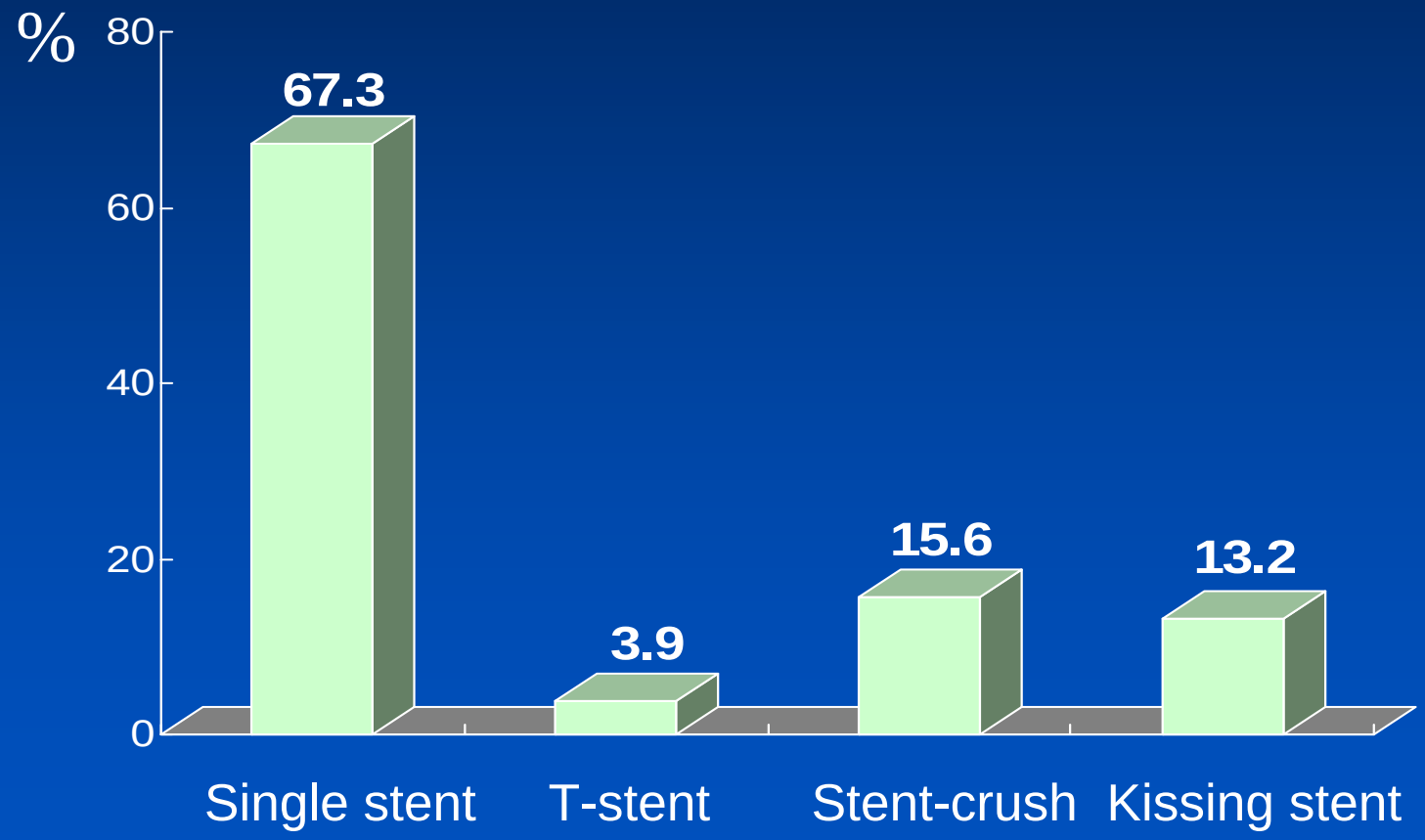
## Specific patient subsets

- Diabetes mellitus
- Acute MI

# Bifurcation Lesions in AMC

## Treatment Strategies

### Total 205 lesions with side branch ≥ 2.5mm



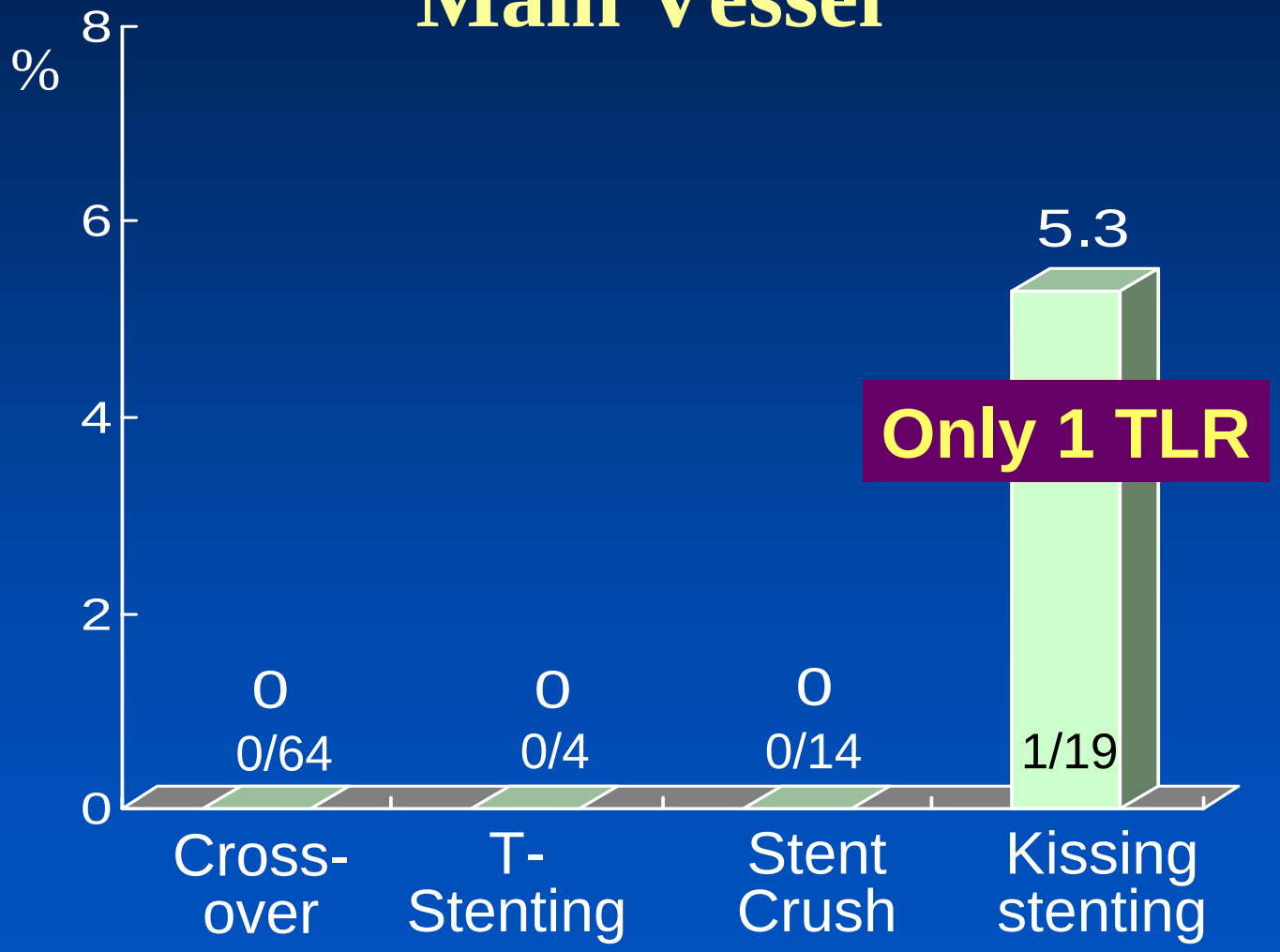
# Late Loss
## at 6-month angiography

| | No | Main vessel | Side branch |
|---|---|---|---|
| Single stent | 62 | 0.21±0.46 | 0.06±0.44 |
| T-stent | 4 | 0.21±0.46 | 0.16±0.49 |
| Stent-crush | 14 | 0.16±0.45 | 0.51±0.88 |
| Kissing stent | 19 | 0.55±0.60 | 0.34±0.34 |

# AMC-Bifurcation

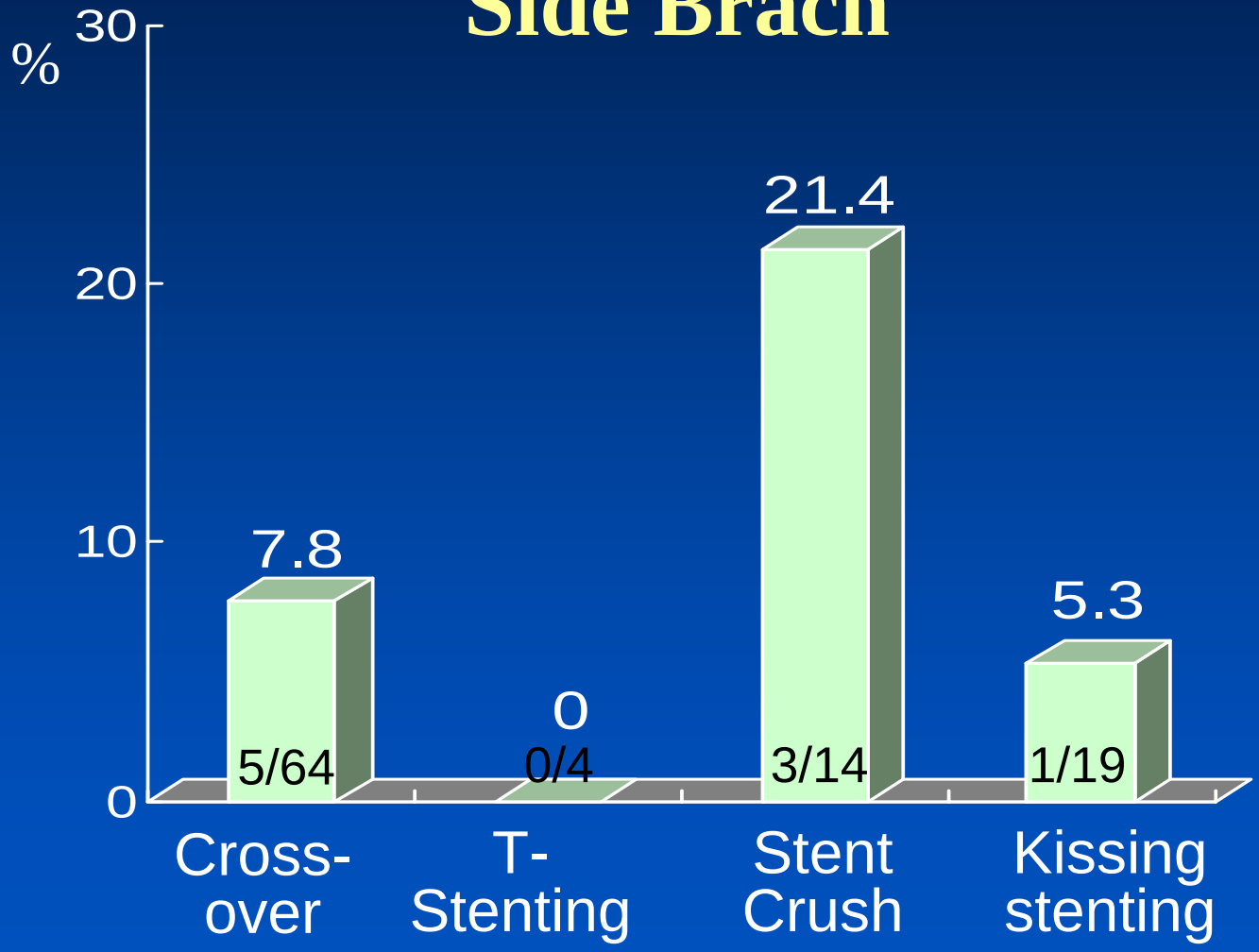
# Restenosis Rate : 5.3 %

## Main Vessel



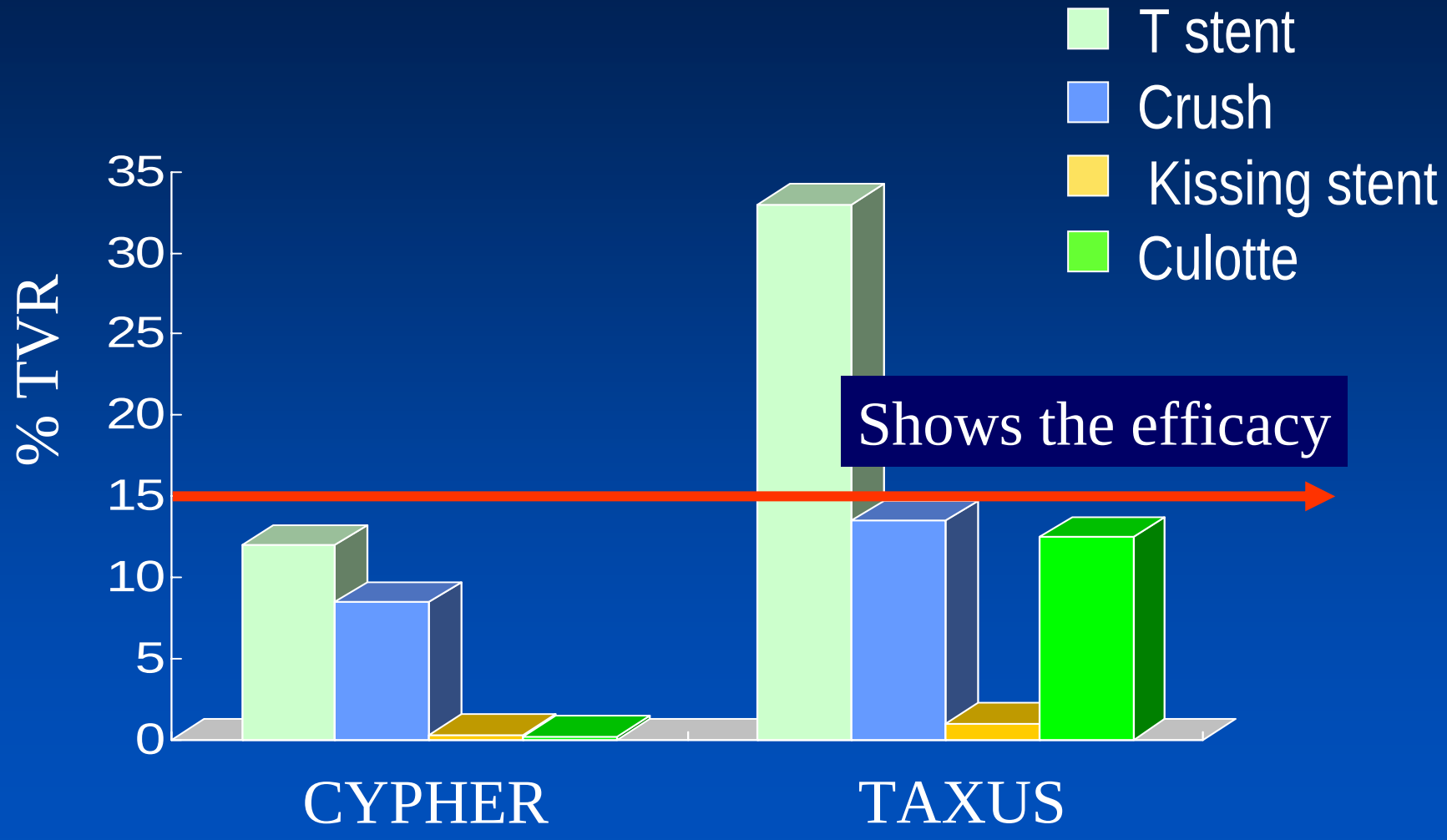
# Restenosis Rate

## Side Brach



# TVR in RESEARCH Bifurcation

## CYPHER vs. TAXUS




*PW Serruys et al, ACC 2004*

# Global DES Use is reasonable approach based on the data

For the bifurcation lesion,

DES may be promising if appropriately performed the procedure…

# Efficacy Concerns

## Specific lesion subsets

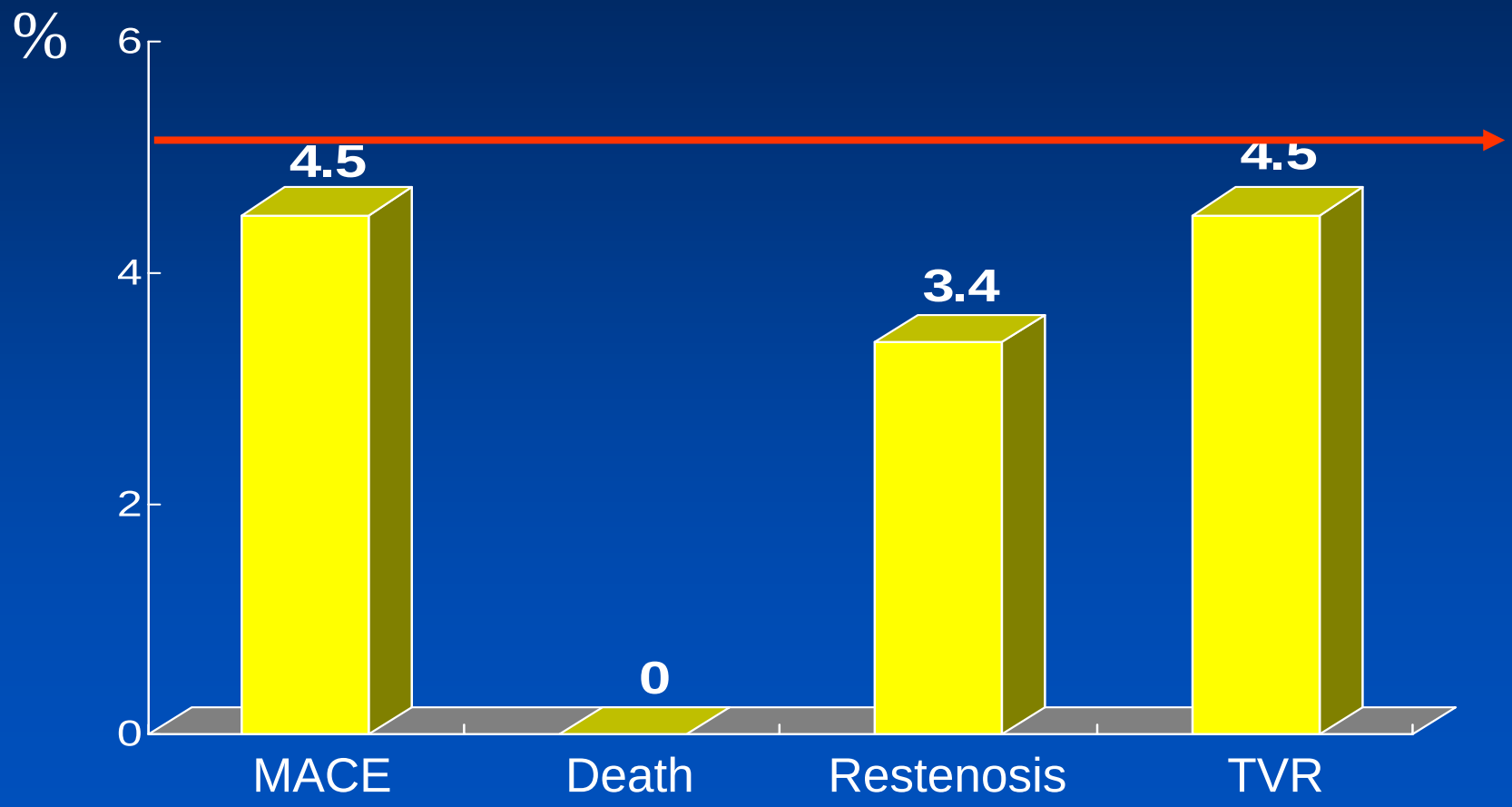
- Left main disease
- Long lesion
- In-stent restenosis
- Small vessel
- Bifurcation lesion
- CTO
- LAD lesion
- Saphenous vein graft

## Specific patient subsets

- Diabetes mellitus
- Acute MI

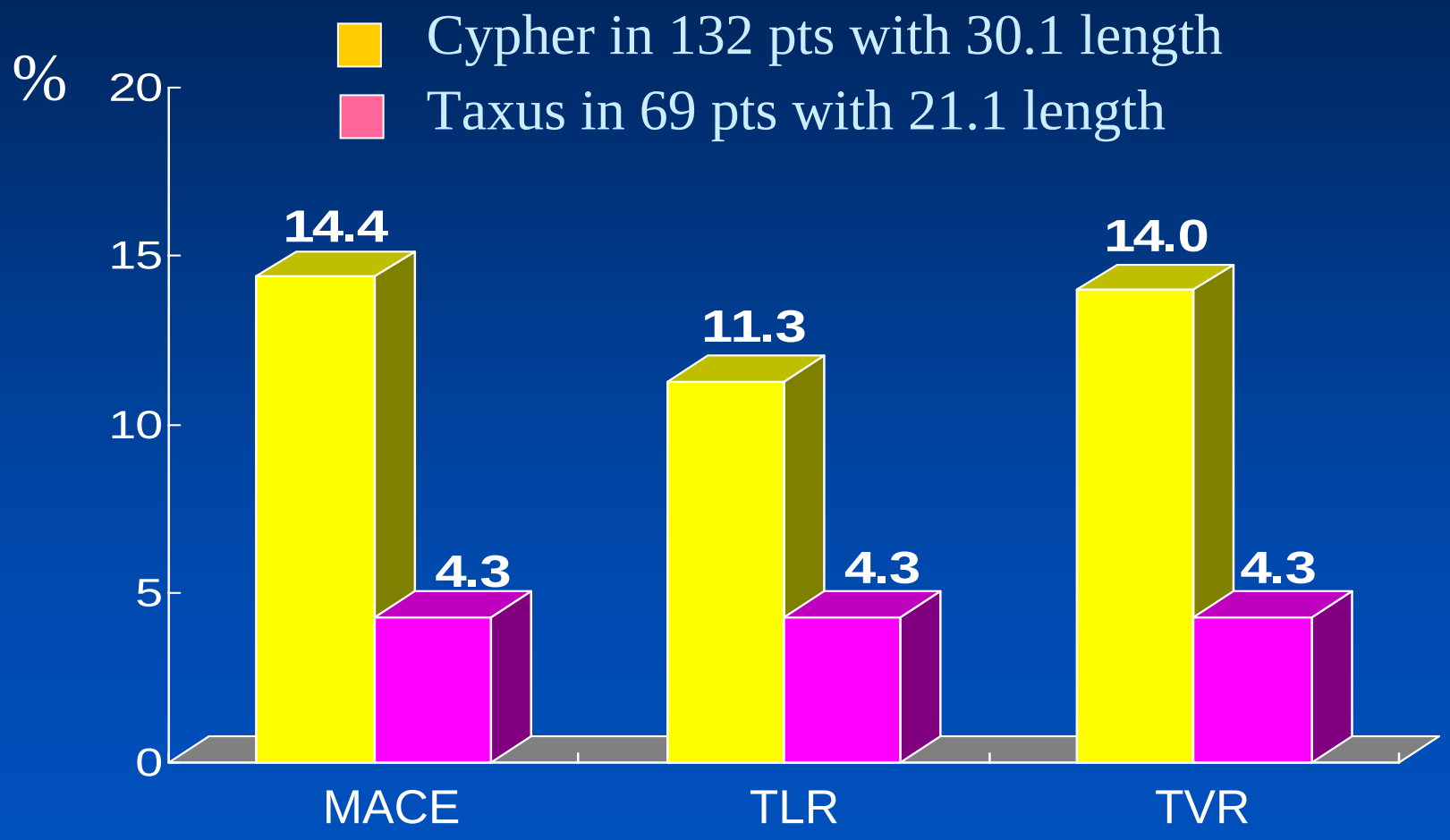
# CTO in 5 Asian Center

## Total 88 pts with 102 CTOs treated with Cypher




*Nakamura et al, ACC 2004*

# TLR : CTO in Milan




*Colombo et al, ACC 2004*

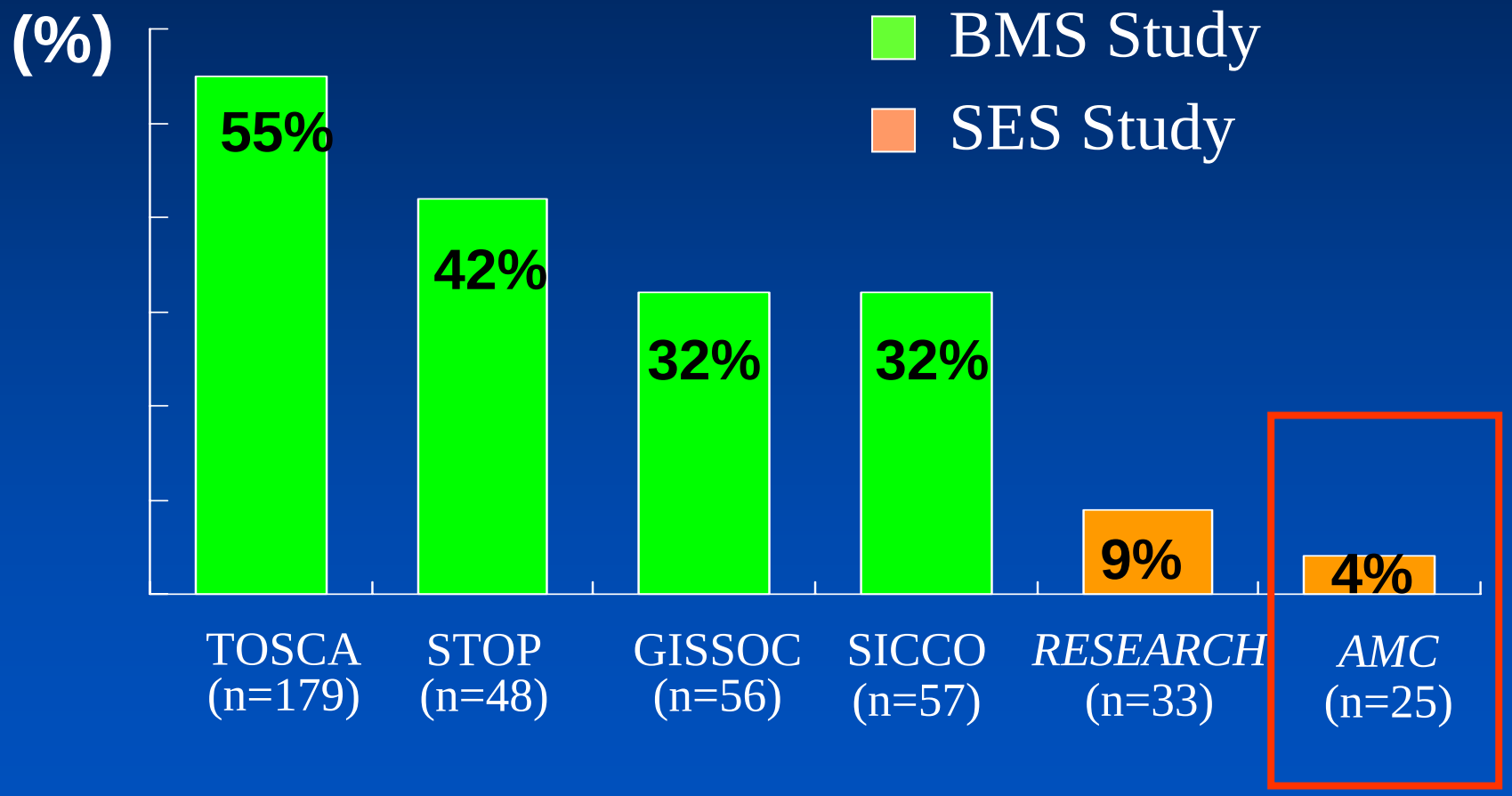
# CTO in AMC

## 6-Month QCA Analysis from 57 lesions with Cypher implantation

| 6-month follow-up | 25 / 32 eligible lesions (78%) |
|---|---|
| Reference vessel (mm) | 2.95 ± 0.57 |
| MLD (mm) | 2.58 ± 0.79 |
| Late loss (mm) | 0.30 ± 0.69 |
| Diameter stenosis (%) | 12.2 ± 23.0 |
| Binary restenosis (%) | 1 (4%) |

# Historical Comparison

## 6 Month Restenosis Rate




*Serruys et al, ACC 2004*

# Global DES Use is reasonable approach based on the data

DES works for CTO

# Efficacy Concerns

## Specific lesion subsets

- Left main disease
- Long lesion
- In-stent restenosis
- Small vessel
- Bifurcation lesion
- CTO
- Saphenous vein graft

## Specific patient subsets

- Diabetes mellitus
- Acute MI

# DES for Saphenous Graft

We do not have appropriate stents for SVG. We are waiting for the suitable device and data.

# Efficacy Concerns

## Specific lesion subsets

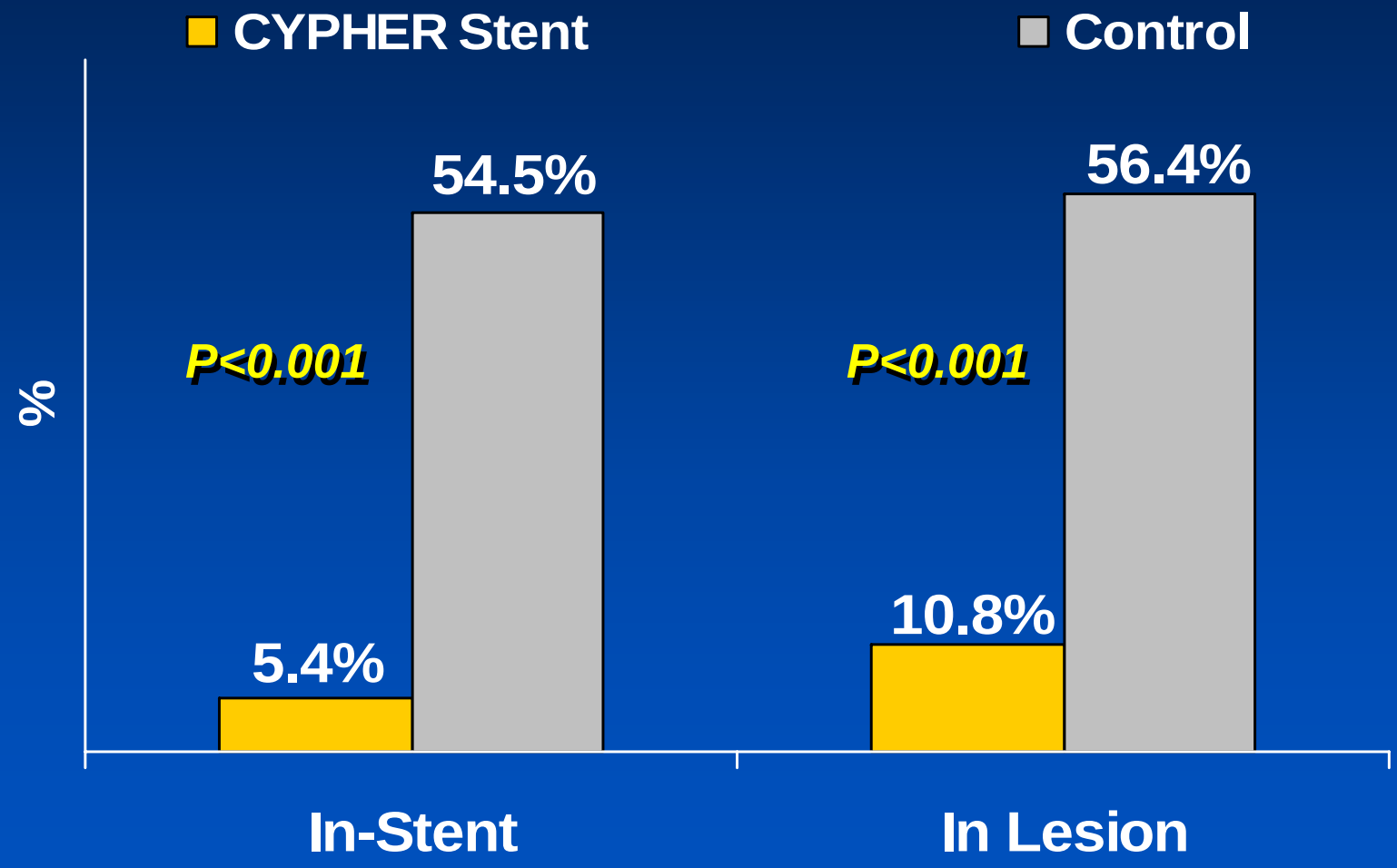
- Left main disease
- Long lesion
- In-stent restenosis
- Small vessel
- Bifurcation lesion
- CTO
- LAD lesion
- Saphenous vein graft

## Specific patient subsets

- Diabetes mellitus
- Acute MI

# Restenosis in Diabetic Subgroup

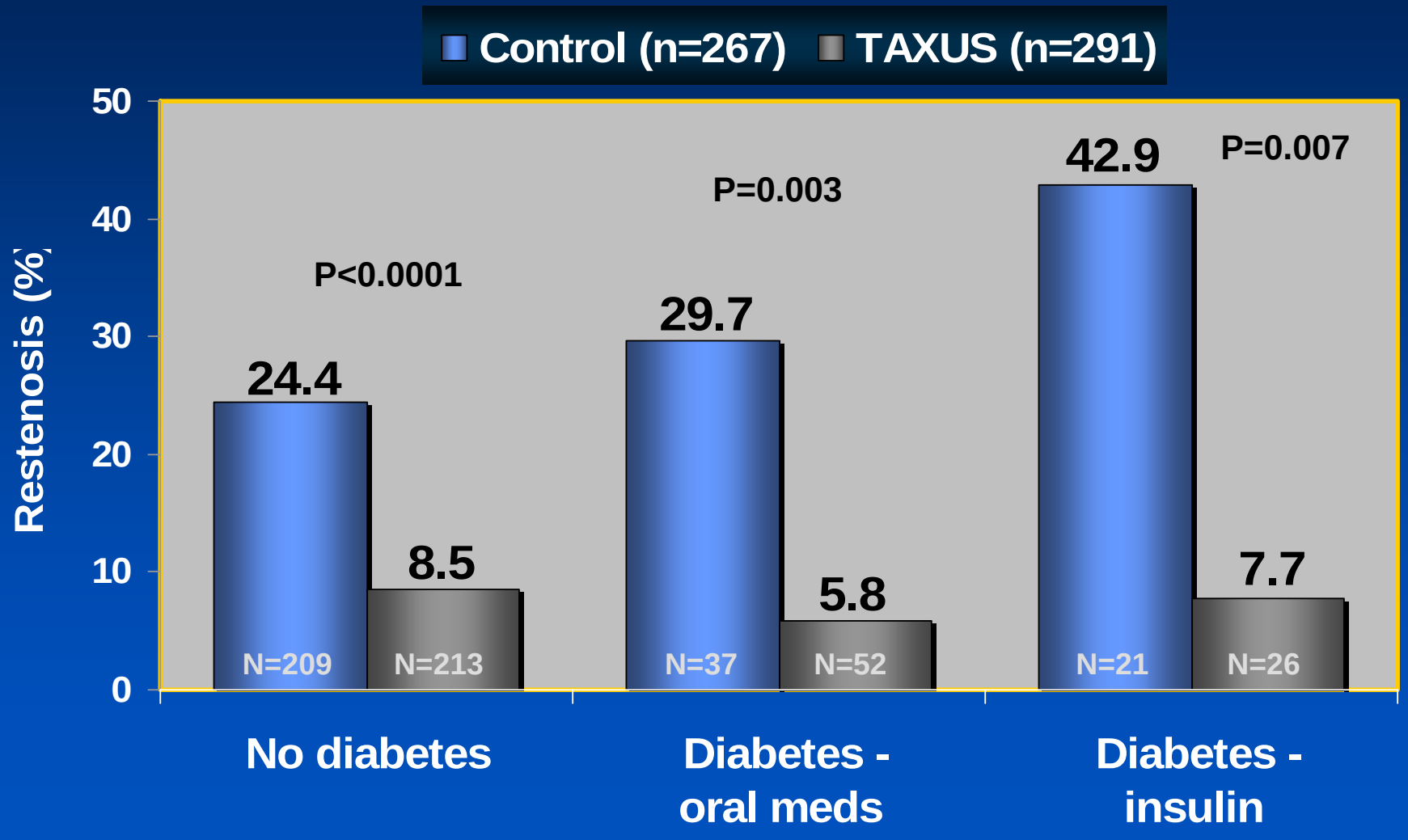
## New-SIRIUS




* Pooled data from the E- & C-SIRIUS trials, 8 mos. angiographic and 9 mos. clinical follow-up

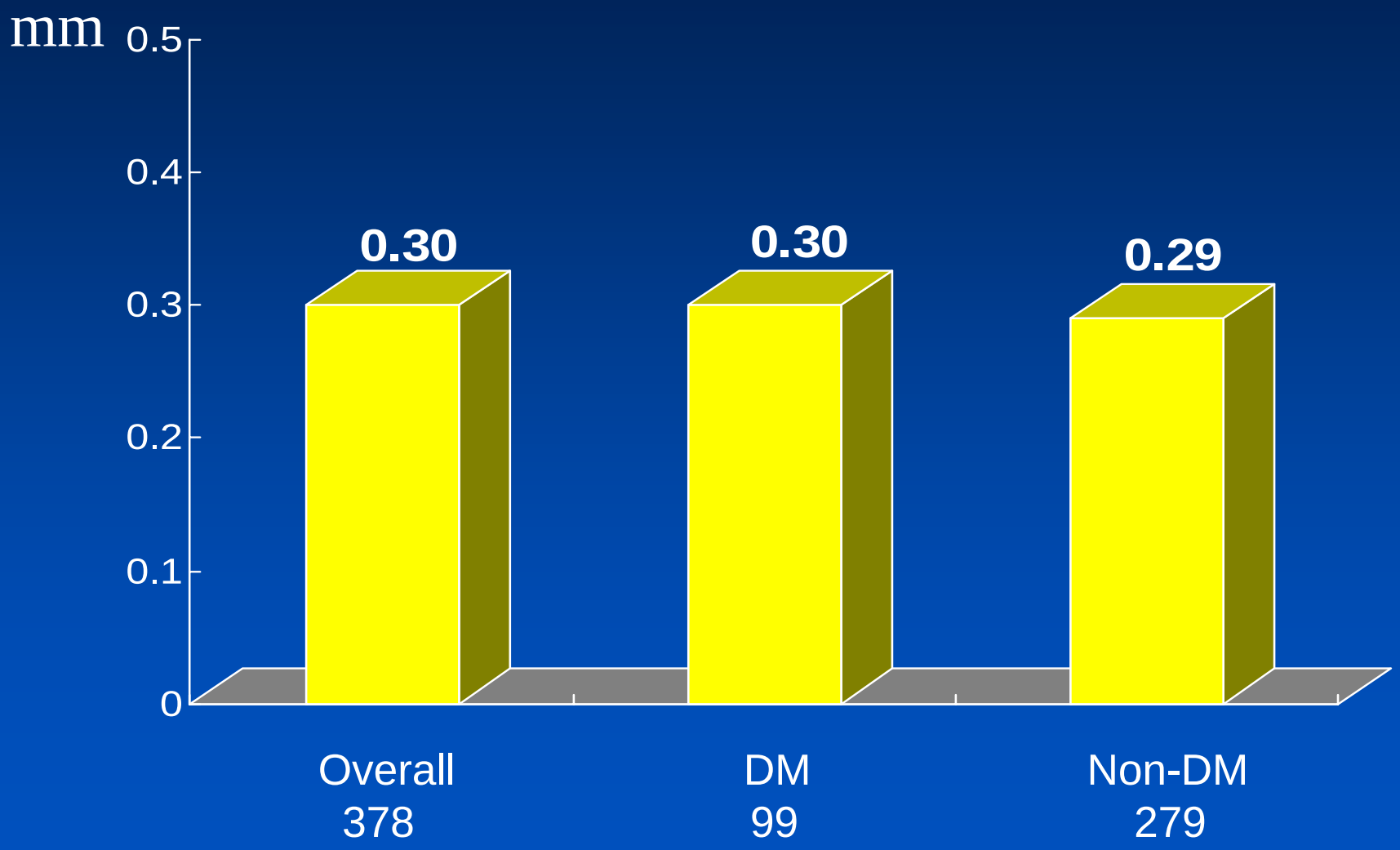
# Restenosis in Diabetic Subgroup

## TAXUS IV



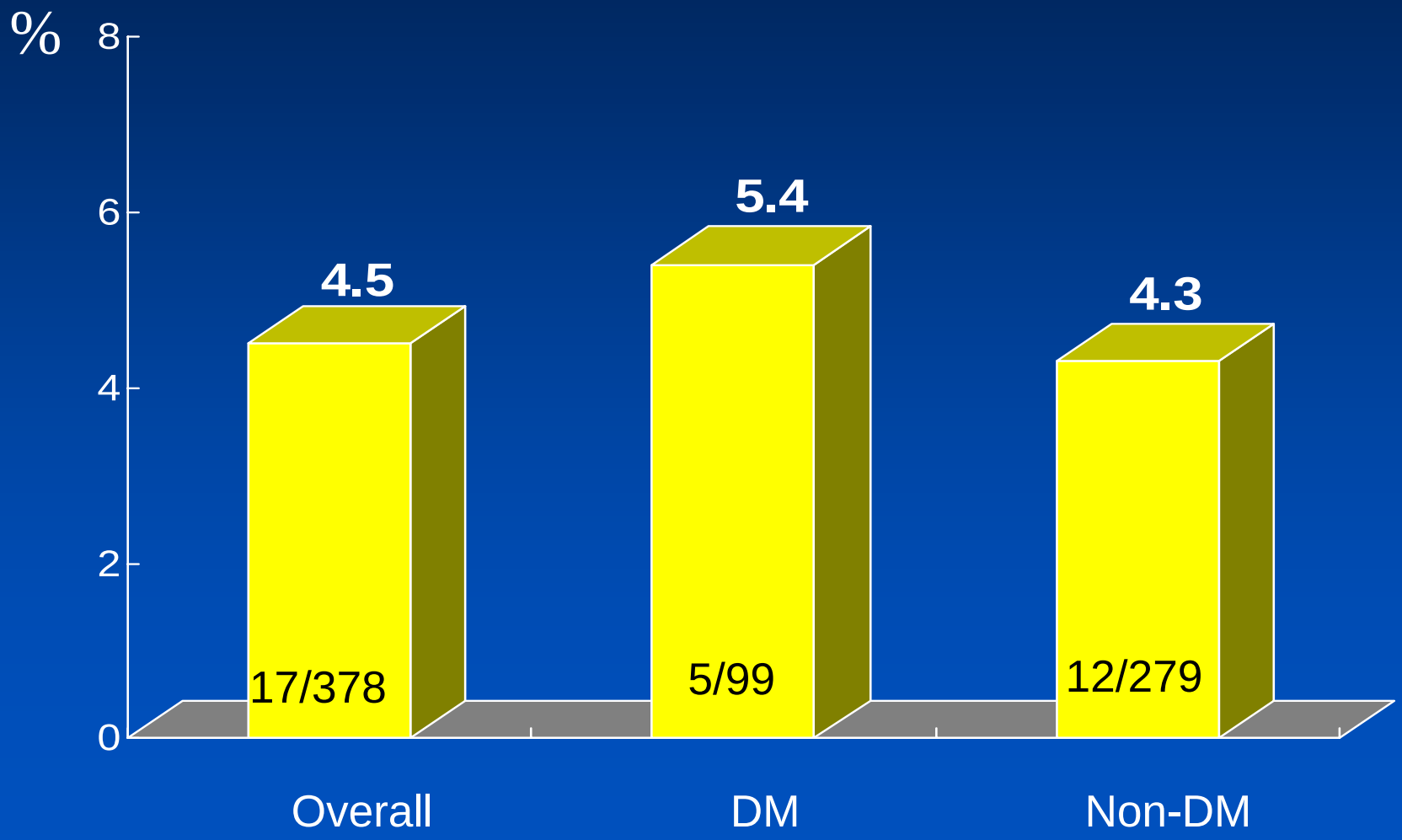
AMC-DM

# Impact of DM on Late Loss



AMC-DM

# Restenosis Rate in DM : 5.4 %



# Efficacy Concerns

## Specific lesion subsets

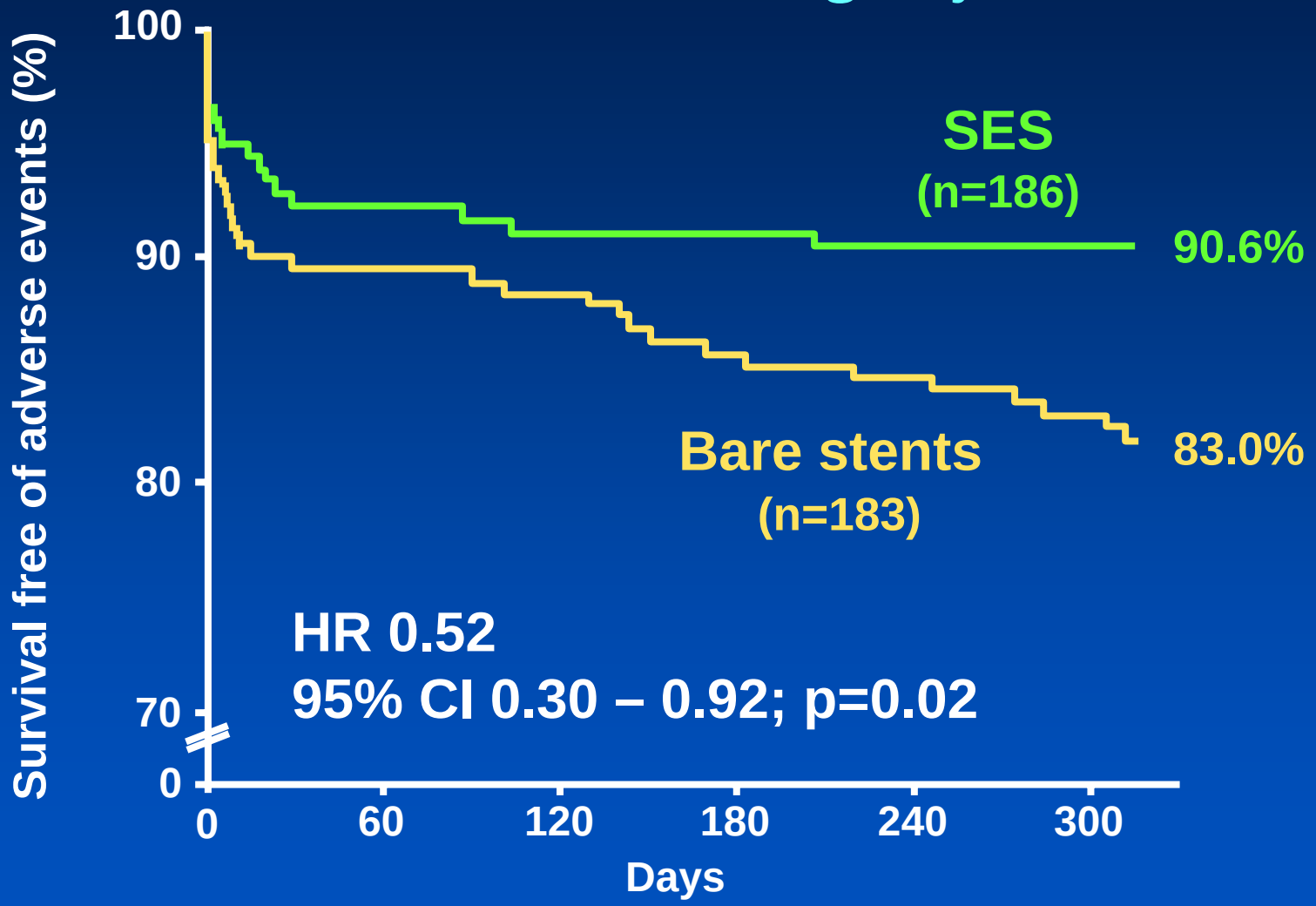
- Left main disease
- Long lesion
- In-stent restenosis
- Small vessel
- Bifurcation lesion
- CTO
- LAD lesion
- Saphenous vein graft

## Specific patient subsets

- Diabetes mellitus
- Acute MI

# MACE Free Survival in AMI

## RESEARCH Registry




*Saia et al. Circulation 2003*

# Primary Stenting for AMI in AMC

**22 patients, 26 lesions for the past 3 months**

- Death: 2 cases after procedure
- Recurrent MI: None
- TLR: None

# Efficacy Concerns

**Efficacy has been widely accepted in all lesions and patients. Except…**

## Specific lesion subsets

- Left main disease
- Long lesion
- In-stent restenosis
- Small vessel
- Bifurcation lesion
- CTO
- Saphenous vein graft

## Specific patient subsets

…ns

More user-friendly and better outcomes (?) than RT

Maybe promising, if appropriately performed

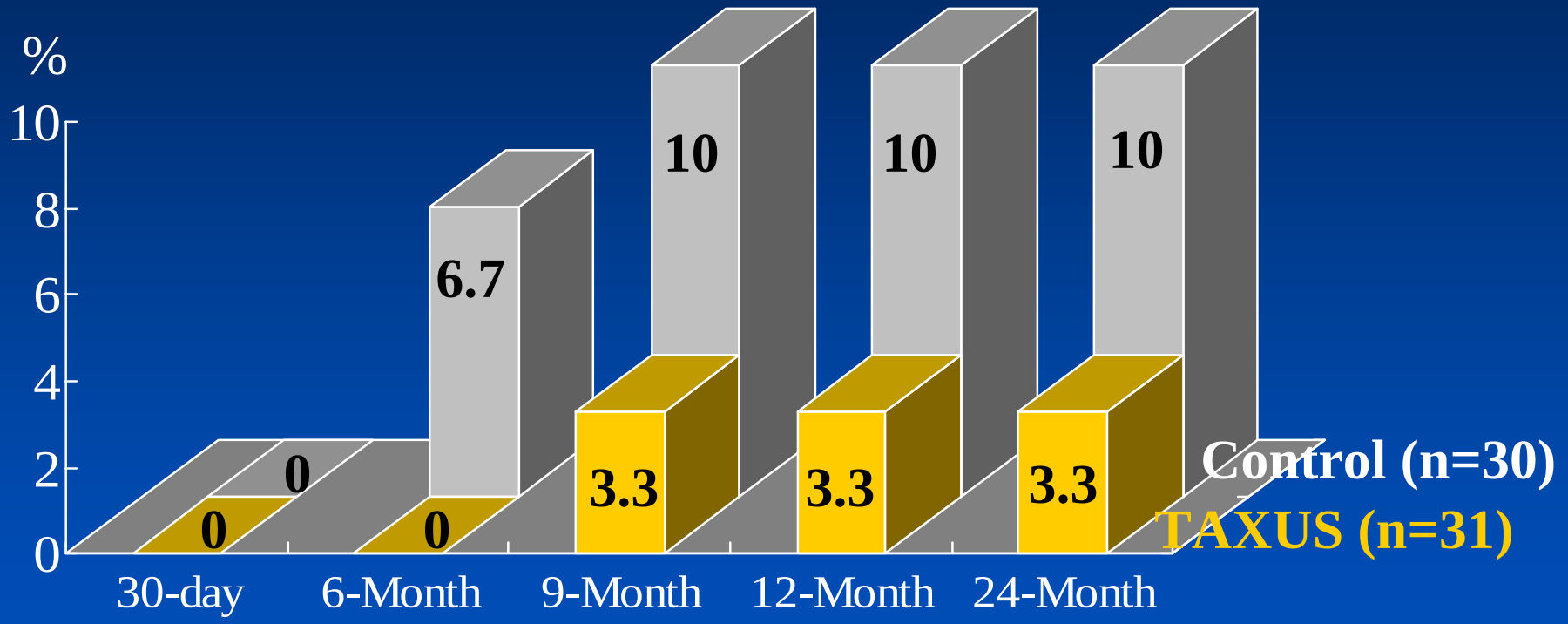
Waiting for the device and data

# Global DES use is reasonable approach based on the data

Safety,
Efficacy,
Durability,
Cost Issue

# Long-term Durability ?

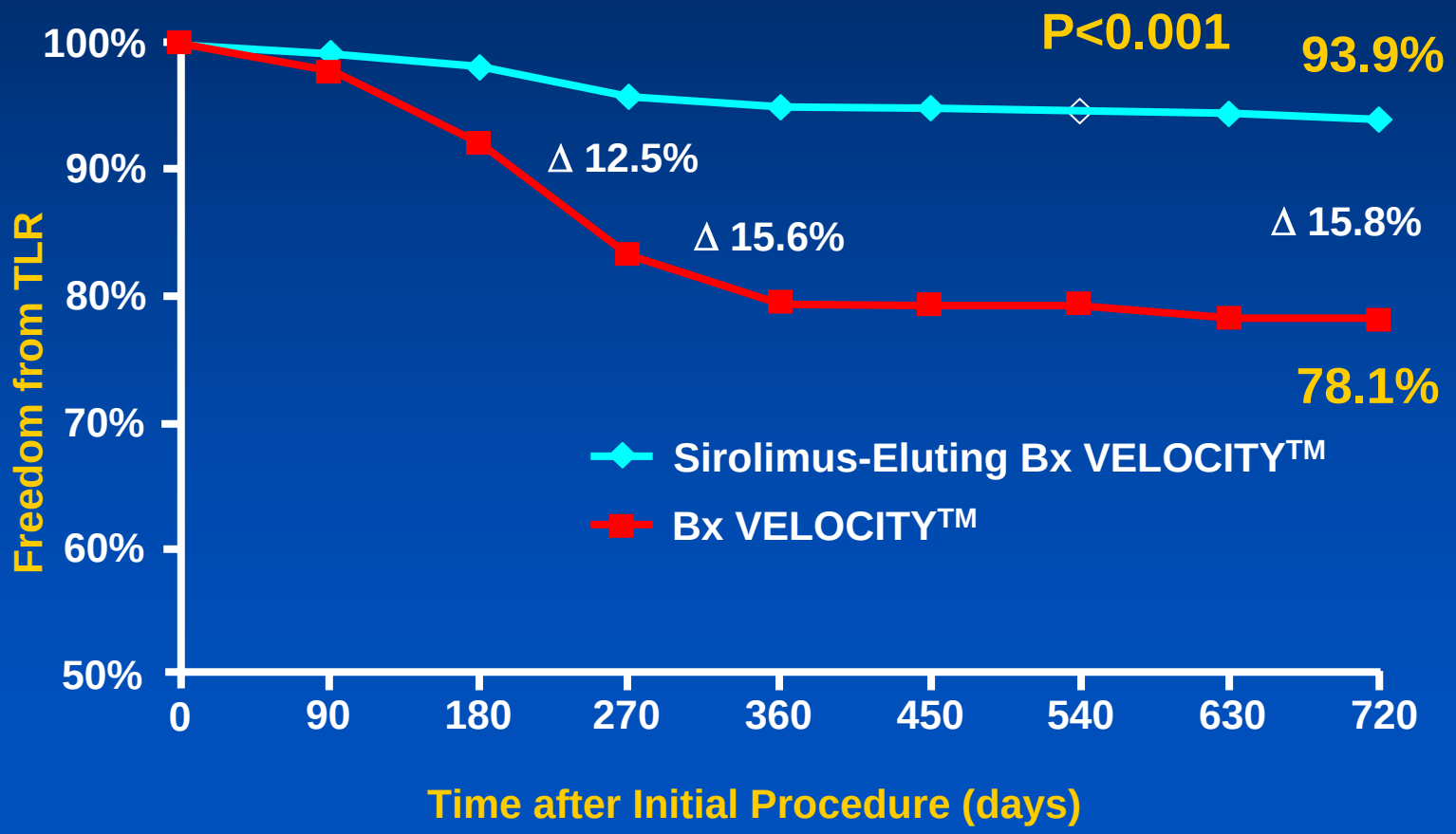
## 2-Year MACE in TAXUS I




Sustained benefit of TAXUS SR over 2 years

# Long-term Durability ?

## 4-Year TLR Free Survival in First Cypher Stent Study



# DES and Cost

- Price is determined by the market (supply, demand, competition, etc)
- Only two DES are available at the present time.
- Cost can be reduced by the market with time.
- It is reducing, NOW.
- Importance of the issue depends on the individual countries.

However, this problem should be transient...

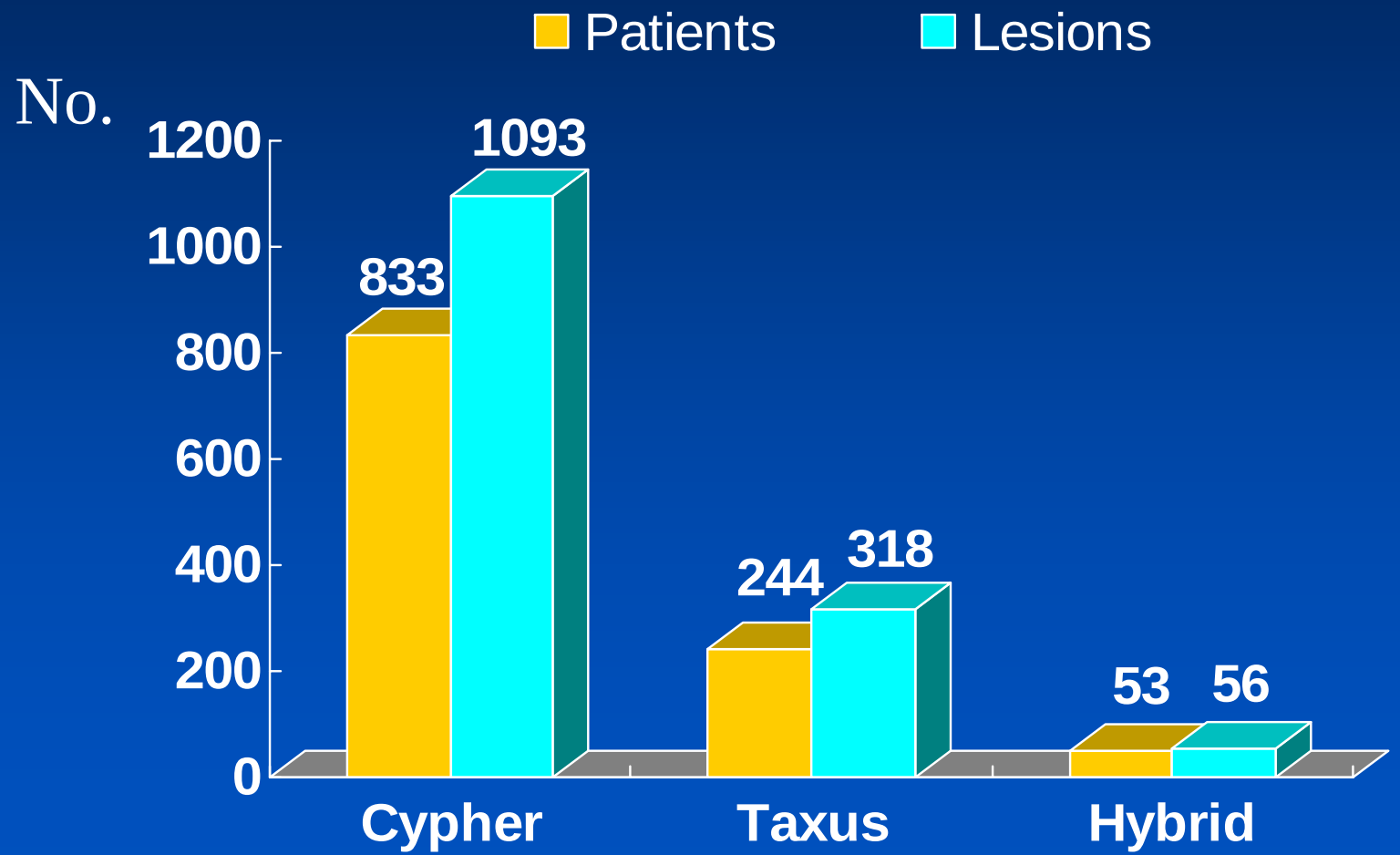
# Why Global DES Use in AMC ?

- **DES is definitely safe.** There is no evidence that it is associated with high rate of acute complications.
- **Effectiveness has been proved.** The effectiveness of DES is extended to all the patient and lesion subsets.
- **Cost issue will be gone.** It is transient problem, not in the near future.

# If you know something, How can you select ?

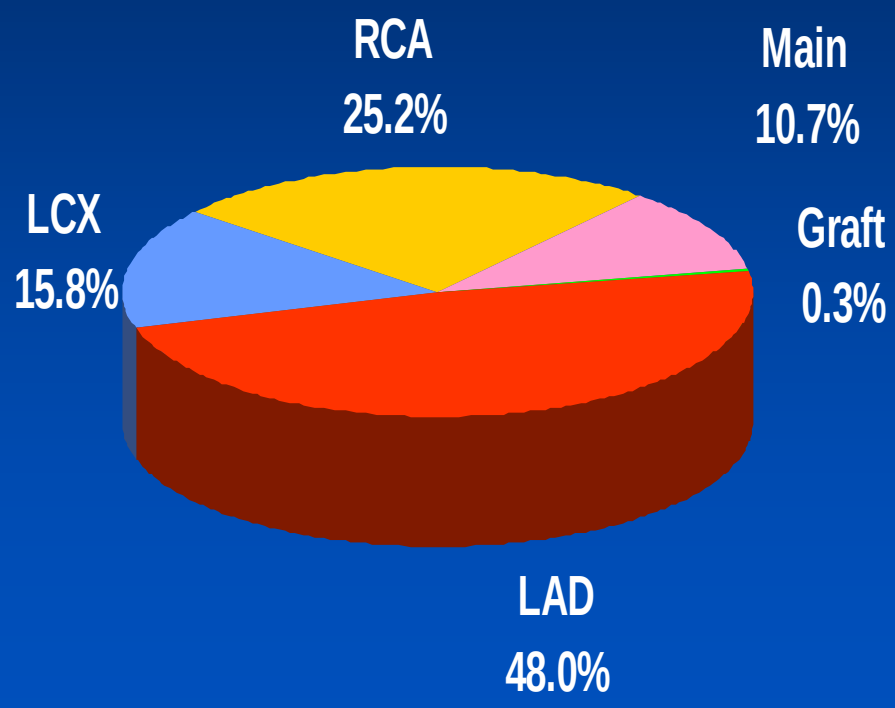
# Patients with DES Implantation

## From February 2003 till March 2004

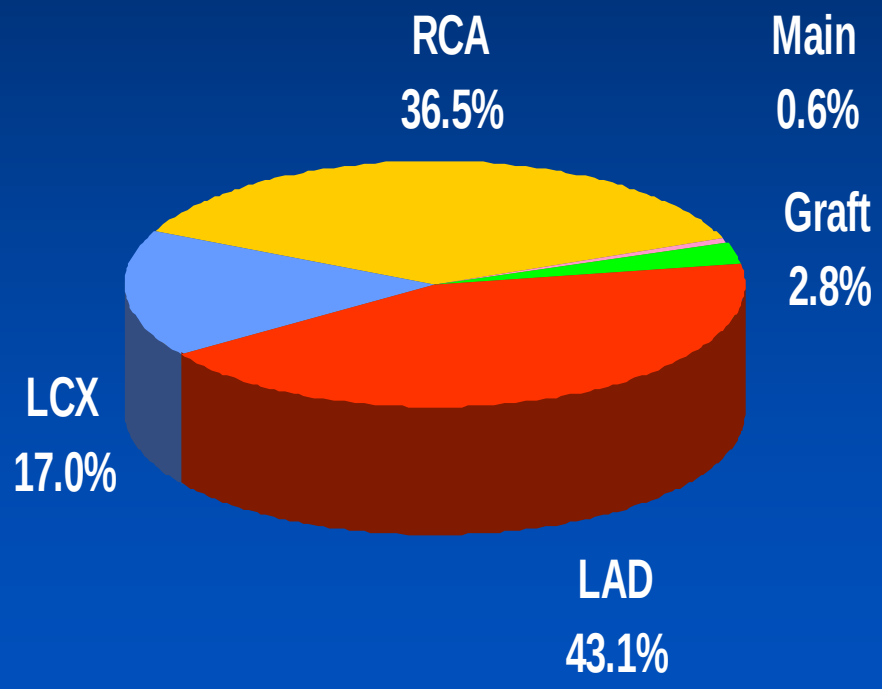


# Lesion Site in AMC

## Cypher Stent (n=1093)

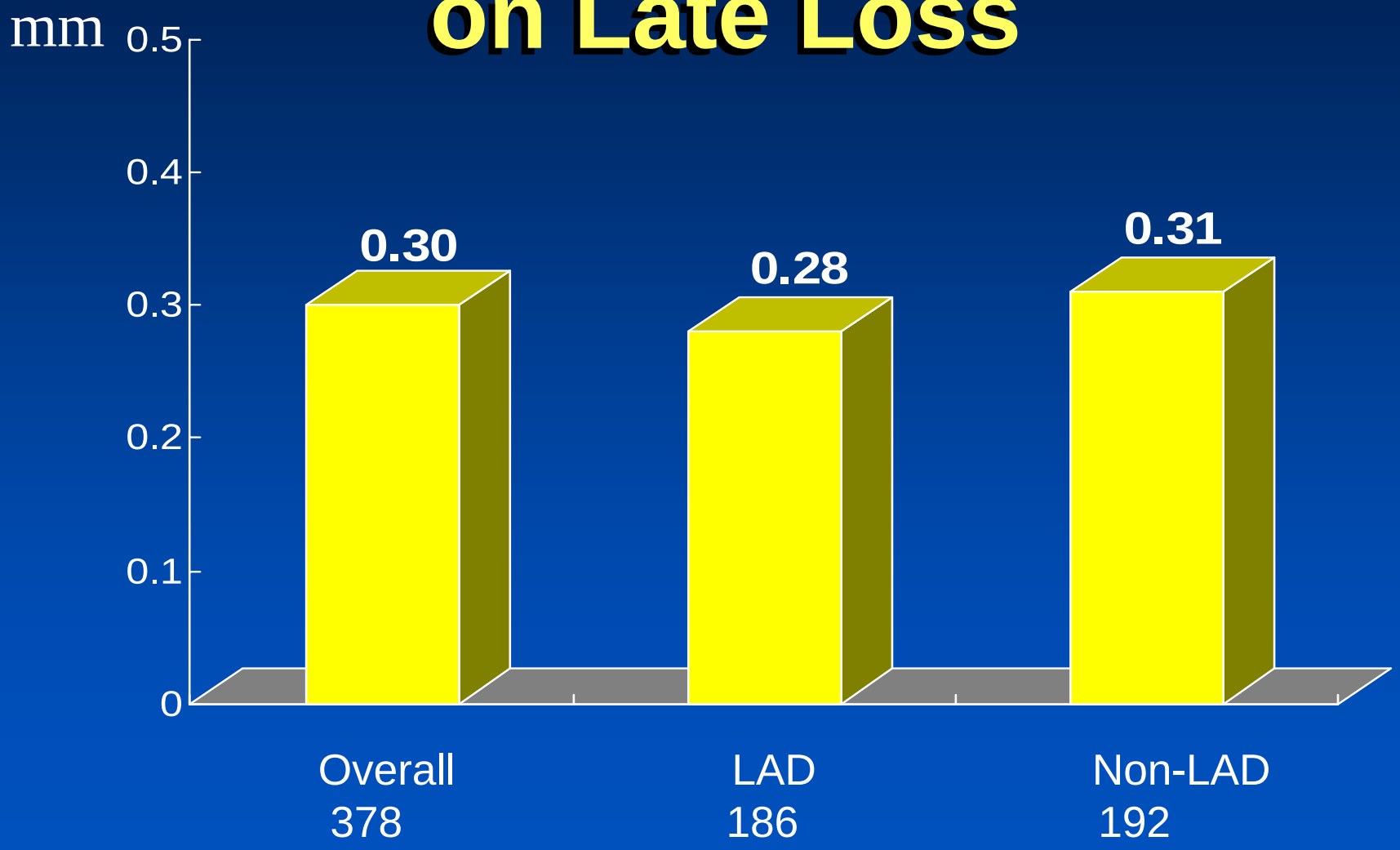



## Taxus Stent (n=318)



AMC-LAD

# Impact of Lesion site on Late Loss



AMC-LAD

# Impact of Lesion site on Restenosis Rate