IVUS and PCI: Optimzing the Final Results

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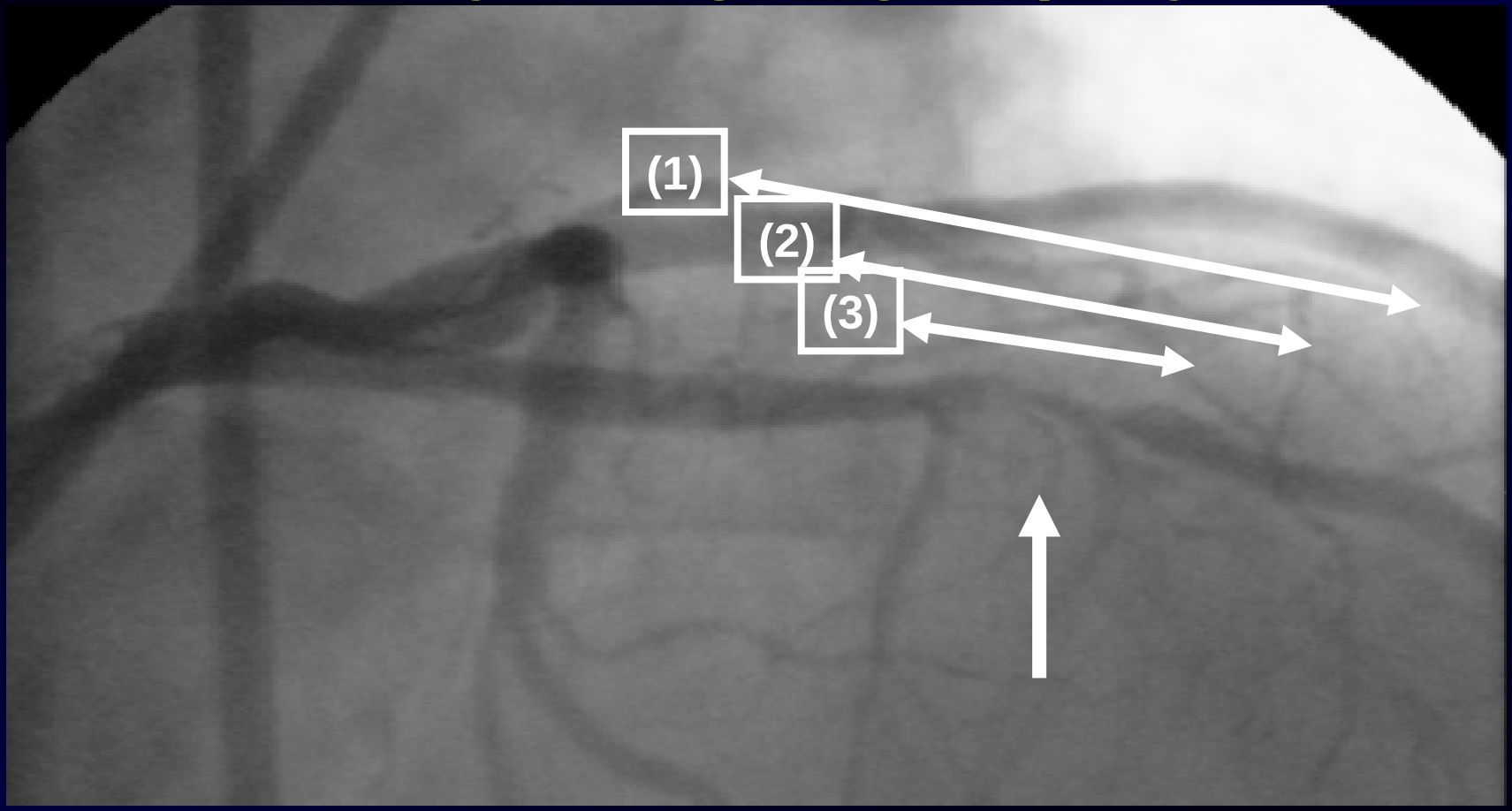
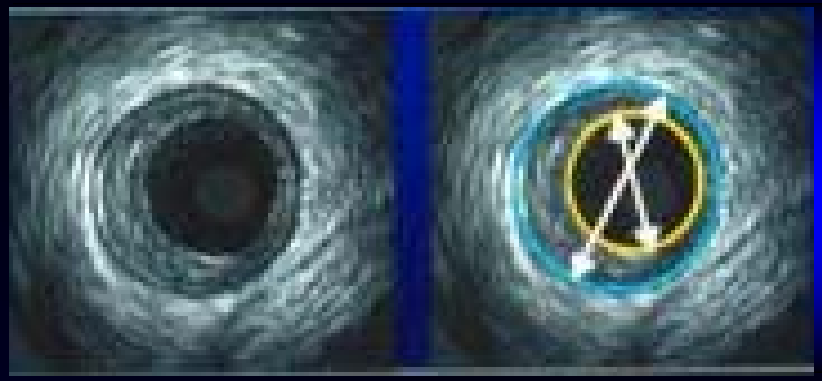
Coronary angiography

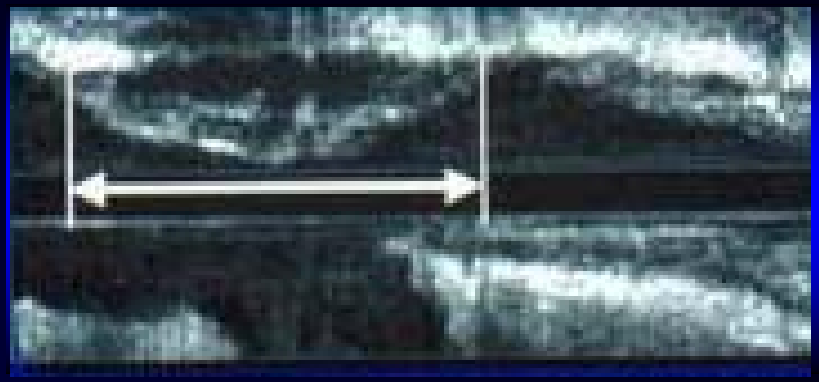


- **Lesion with Intermediate or short length**
- **Stent size and length ?**

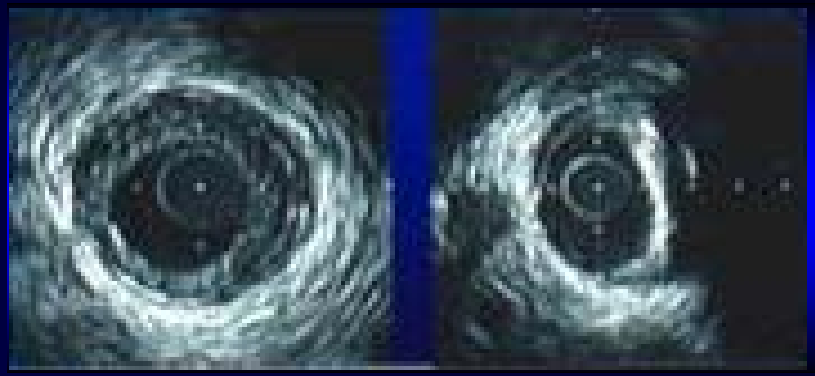
IVUS : Practical Uses in the Cath Lab



Size



Plaque Length



Plaque Type

Impact of preintervention IVUS on TCT strategies in 313 lesions

Change in therapy (n=124, 40%)

1. **Assessment of lesion severity leading to revascularization when none had been planned (6%)**
2. **Avoidance of surgery or TCT that had originally been planned (7%)**
3. **Assessment of lesion composition leading to a change in TCT (6%)**
4. **Selection of the revascularization strategy (20%)**

Mintz GS et al, Am J Cardiol 1994

Key Roles of IVUS in PCI

- Pre-intervention imaging
- Plaque morphology and calcium
- Post-intervention evaluation
- Complications
- Restenosis

IVUS in the BMS era

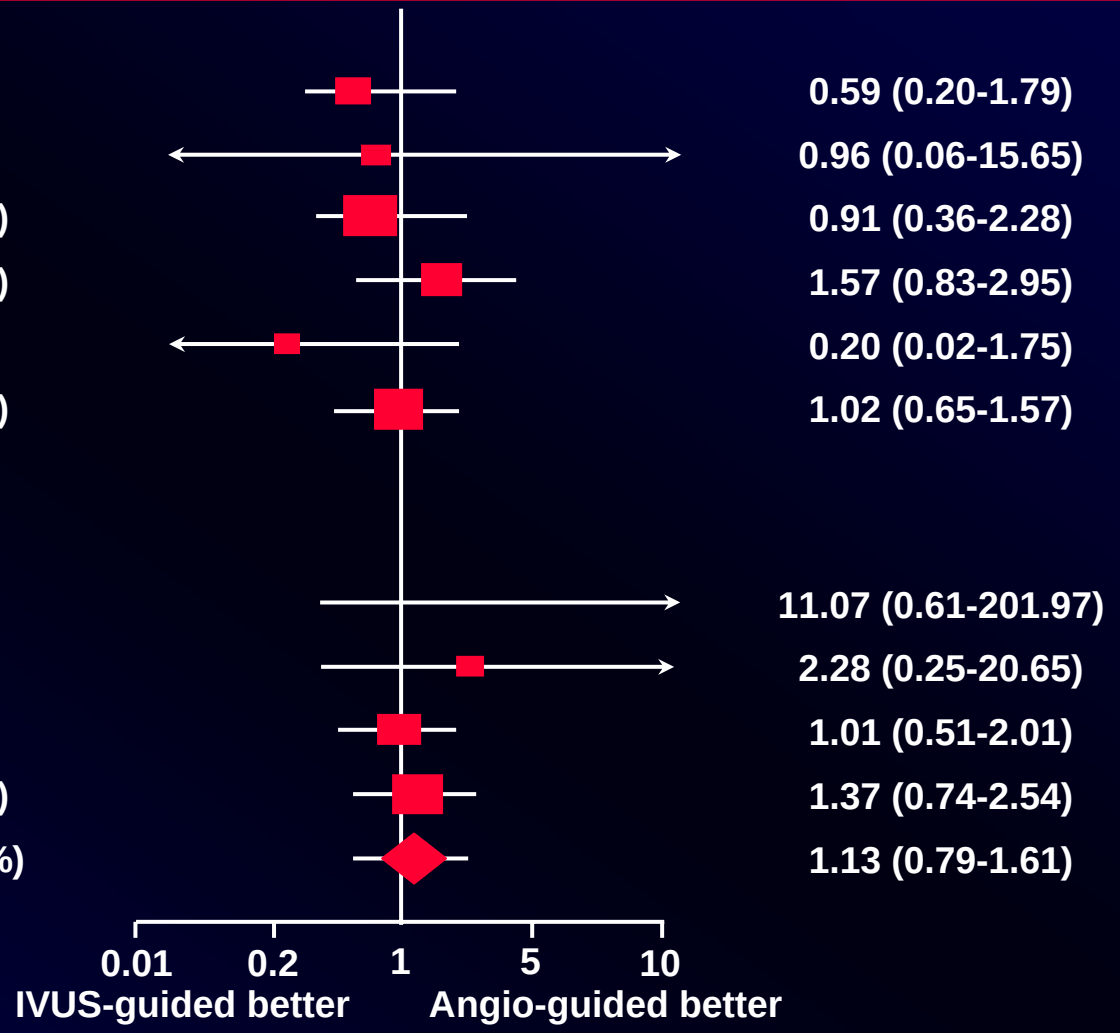
Studies supporting IVUS-guided Bare metal stenting is better?

	Angio Better	IVUS Better	IVUS also Cheaper
Choi et al (AHJ 2001;142:112-8)		X	
CRUSE (Circulation 2000;102523-30)		X	
SIPS (Circulation 2000;102:2497-502)		X	X
AVID (Circulation 1999;100:I-234)		X	
Gaster et al (Heart 2003;89:1043-9)		X	X
RESIST (JACC 1998;32:320-8)		X	
TULIP (Circulation 2003;107:62-7)		X	
BEST (Circulation 2003;107:545-551)		X	
OPTICUS (Circulation 2001;104:1343-9)	X		

Combined Endpoints (Death & MI)

Meta-analysis

Study	IVUS-guided	Angio-guided	Odds ratios and 95% CI Fixed
Randomized trials			
SIPS. 1996	5/121 (4.1%)	0/148 (6.7%)	0.59 (0.20-1.79)
RESIST. 1997	1/79 (1.2%)	1/76 (1.3%)	0.96 (0.06-15.65)
OPTICUS. 1998	9/273 (3.3%)	10/277 (3.6%)	0.91 (0.36-2.28)
AVID. 1999	25/372 (6.7%)	17/387 (4.4%)	1.57 (0.83-2.95)
TULIP. 2001	1/73 (1.3%)	5/77 (6.5%)	0.20 (0.02-1.75)
Subtotal	41/918 (4.4%)	43/965 (4.4%)	1.02 (0.65-1.57)
Registries			
Albiero et al. 1995	5/18 (3.1%)	0.154 (0%)	11.07 (0.61-201.97)
Choi et al. 1997	4/178 (2.2%)	1/100 (1%)	2.28 (0.25-20.65)
CRUISE. 2000	19/270 (7%)	16/229 (7%)	1.01 (0.51-2.01)
Subtotal	28/606 (4.6%)	17/483 (3.5%)	1.37 (0.74-2.54)
Total	69/1,524 (4.5)	60/1,448 (4.1%)	1.13 (0.79-1.61)

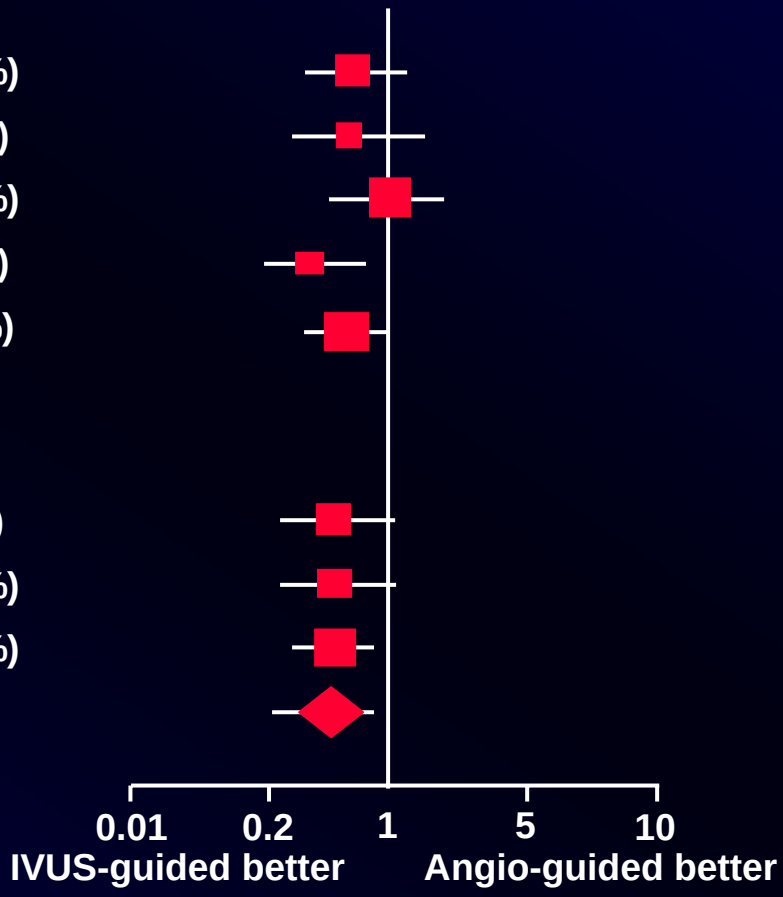


Gianni Casella et al, Cathet Cardiovasc Intervent 2003;59:314-321

Binary Restenosis

Meta-analysis

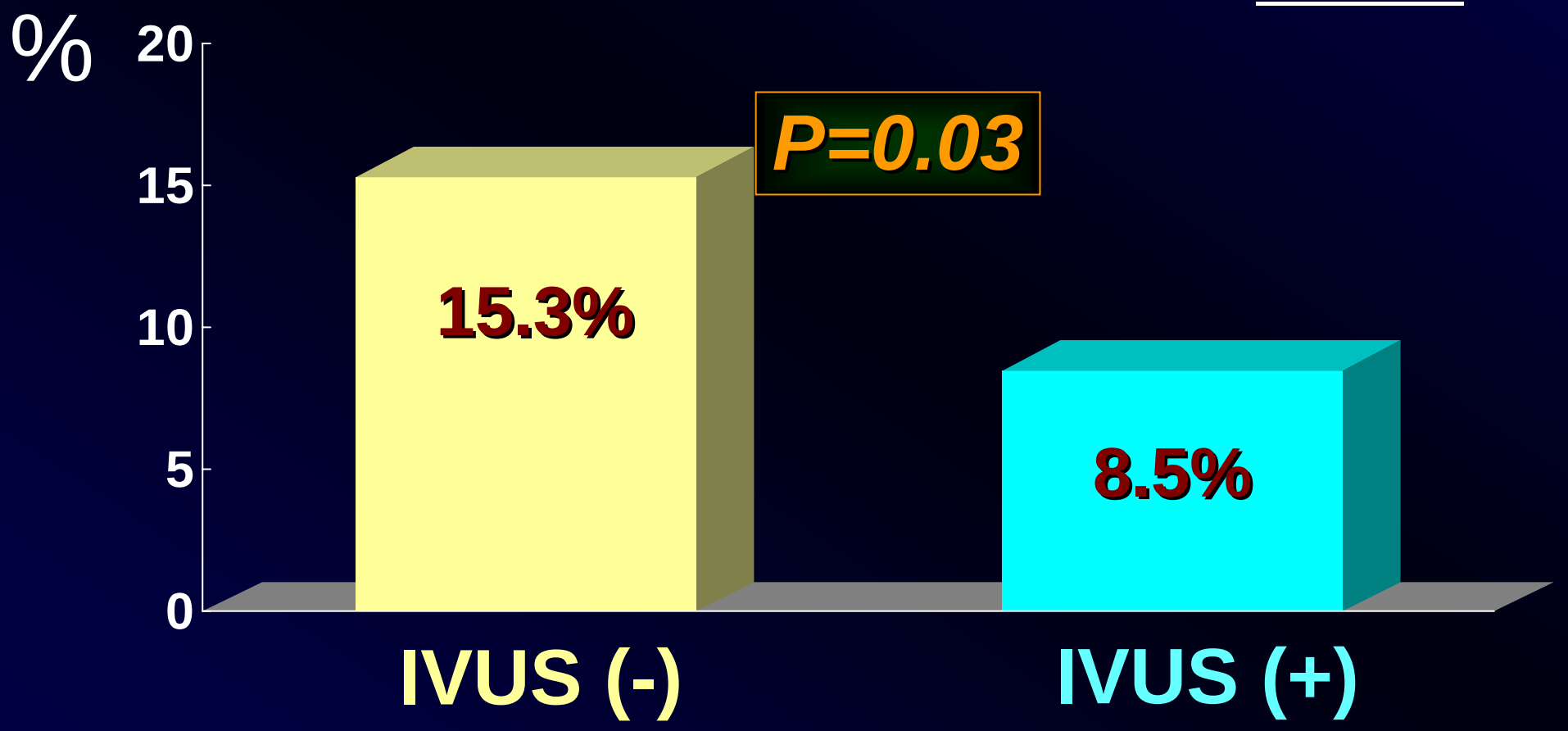
Study	IVUS-guided	Angio-guided	Odds ratios and 95% CI Fixed
Randomized trials			
SIPS. 1996	48/166 (29%)	66/190 (34.7%)	0.76 (0.49-1.20)
RESIST. 1997	16/71 (22.5%)	21/73 (28.7%)	0.72 (0.34-1.53)
OPTICUS. 1998	56/229 (24.4%)	52/228 (22.8%)	1.10 (0.71-1.69)
TULIP. 2001	15/73 (20.5%)	28/77 (36.4%)	0.45 (0.22-0.94)
Subtotal	135/539 (25%)	167/568 (29%)	0.81 (0.62-1.06)
Registries			
Albiero et al. 1995	29/158 (18.3%)	40/154 (26%)	0.64 (0.37-1.10)
Blasini et al. 1995	22/105 (20.9%)	32/107 (29.9%)	0.62 (0.33-1.16)
Subtotal	51/263 (19%)	72/261 (27.5%)	0.63 (0.42-0.95)
Total	186/806 (23%)	239/829 (28.8%)	0.75 (0.60-0.94)



Gianni Casella et al, Cathet Cardiovasc Intervent 2003;59:314-321

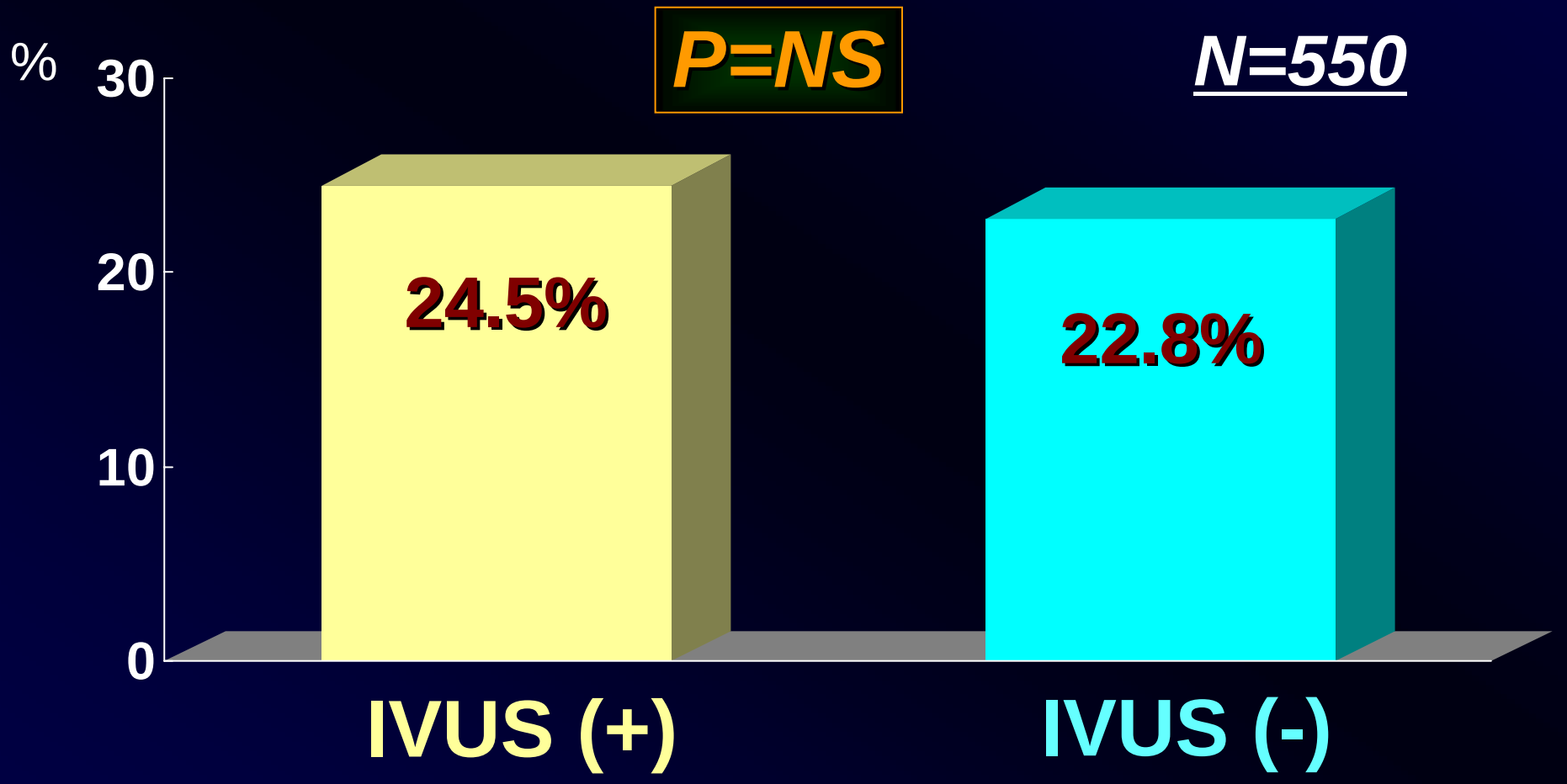
CRUISE: 9-Month TLR

N=499



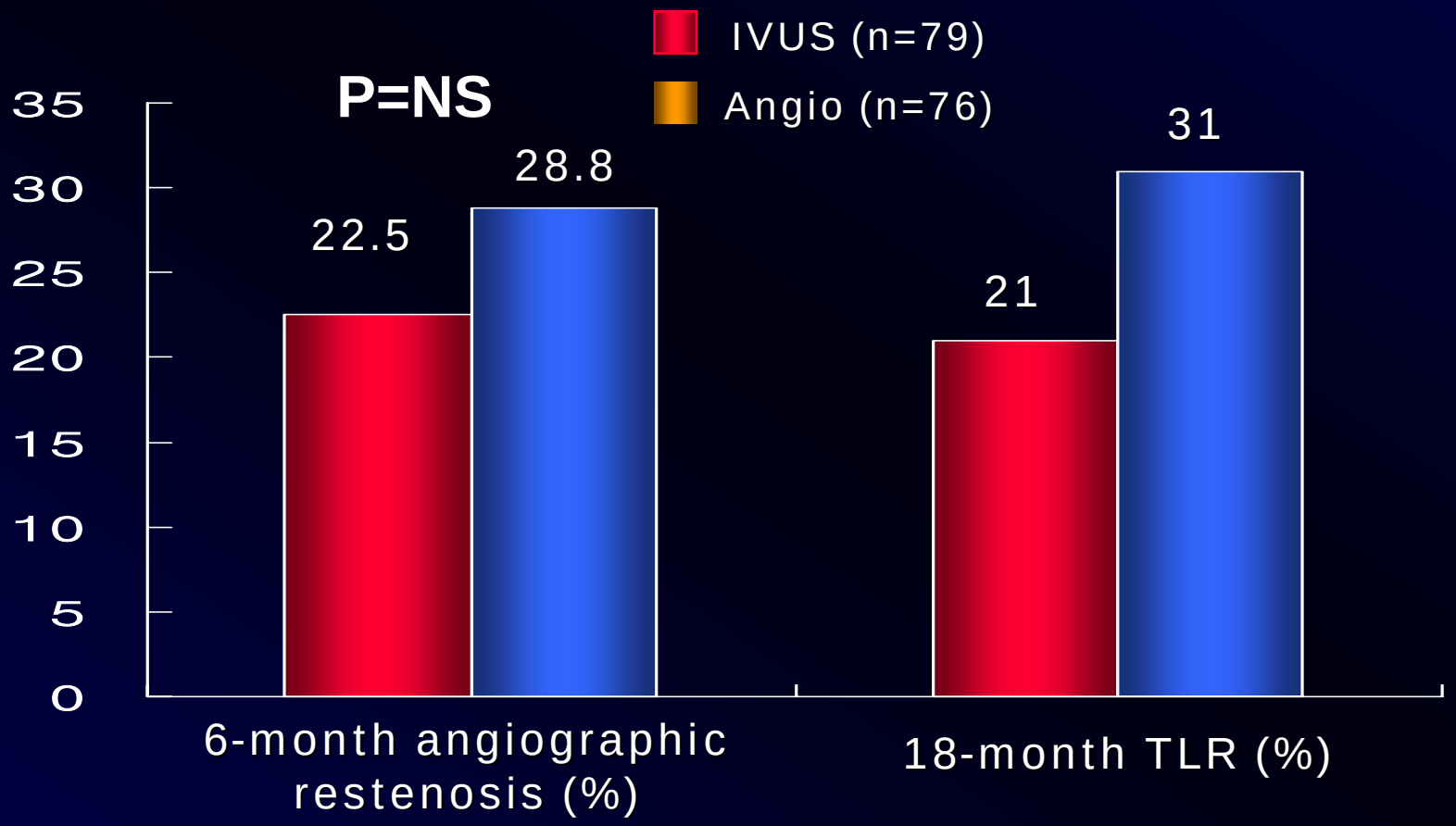
Fitzgerald PJ, et al. Circulation 2000;1002:523

OPTICUS: 6-month angiographic restenosis rate



Harald Mudra et al, Circulation. 2001;104:1343-9

The RESIST Randomized Trial



Schiele et al, JACC 1998;32:320-8 and Circulation 2000;102:II-547

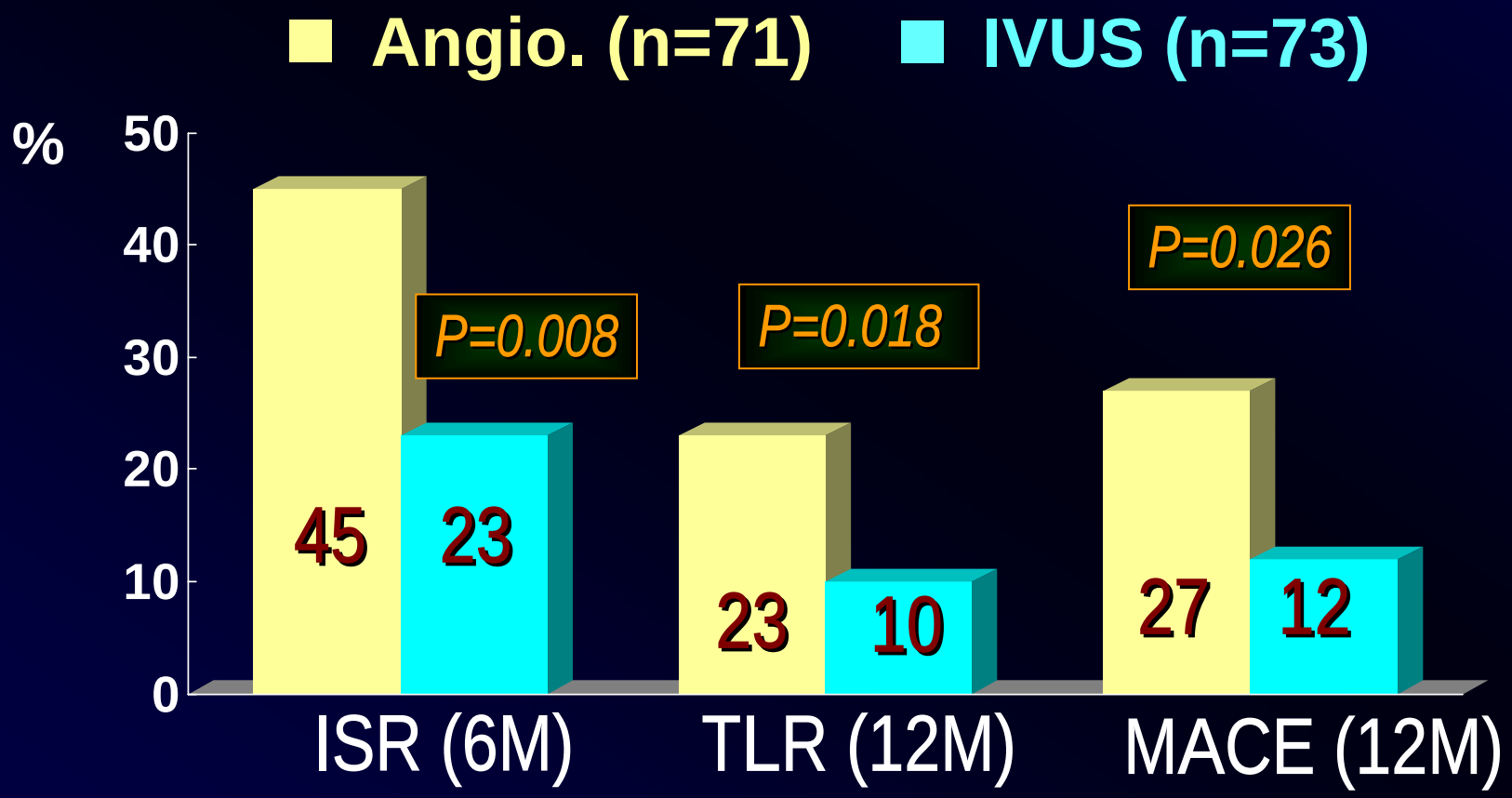
Value of IVUS in simple or relatively simple lesions?

acorn

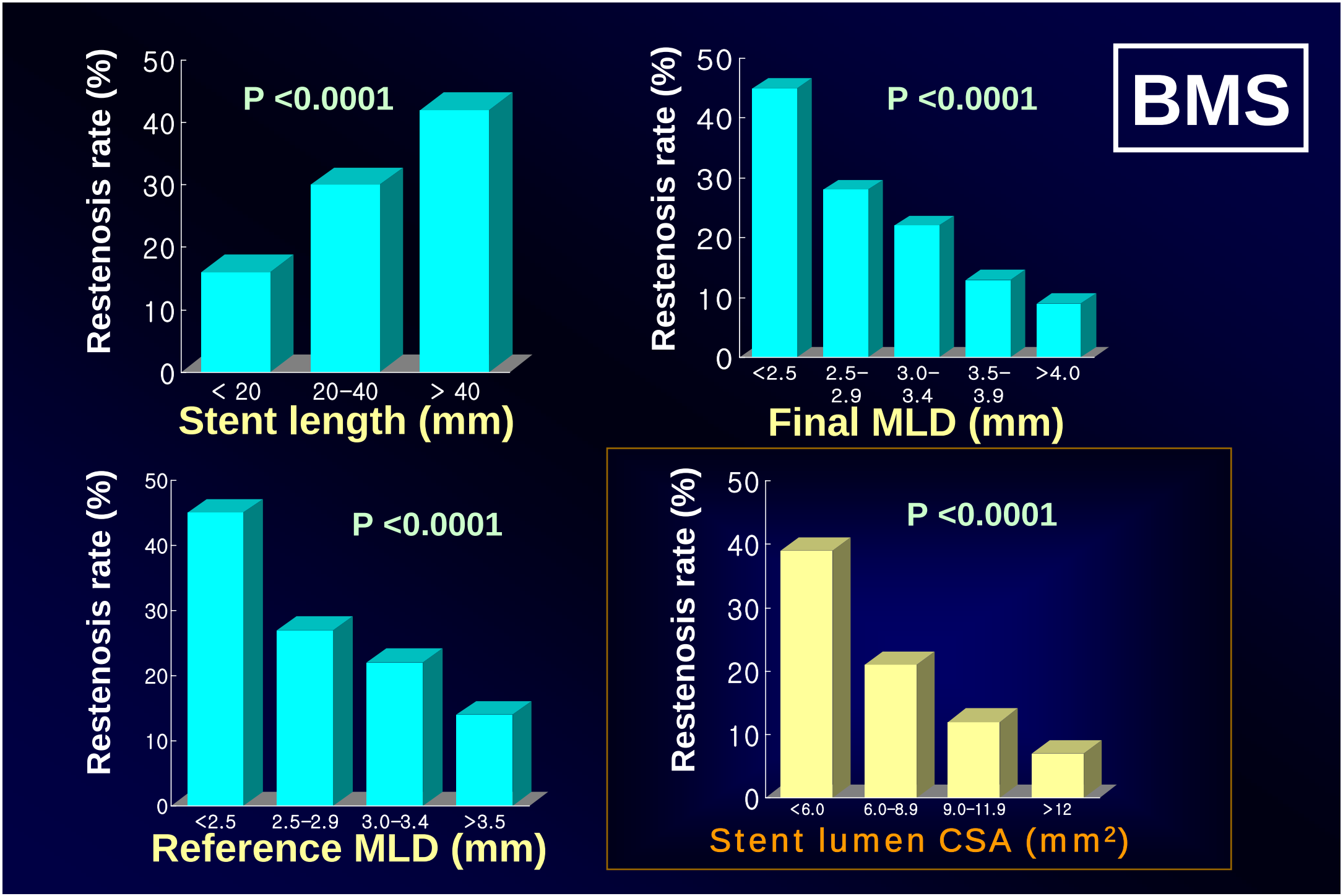
There is more or less on the same level and no one is outstanding *in simple lesions*

How about use of IVUS in complex lesions?

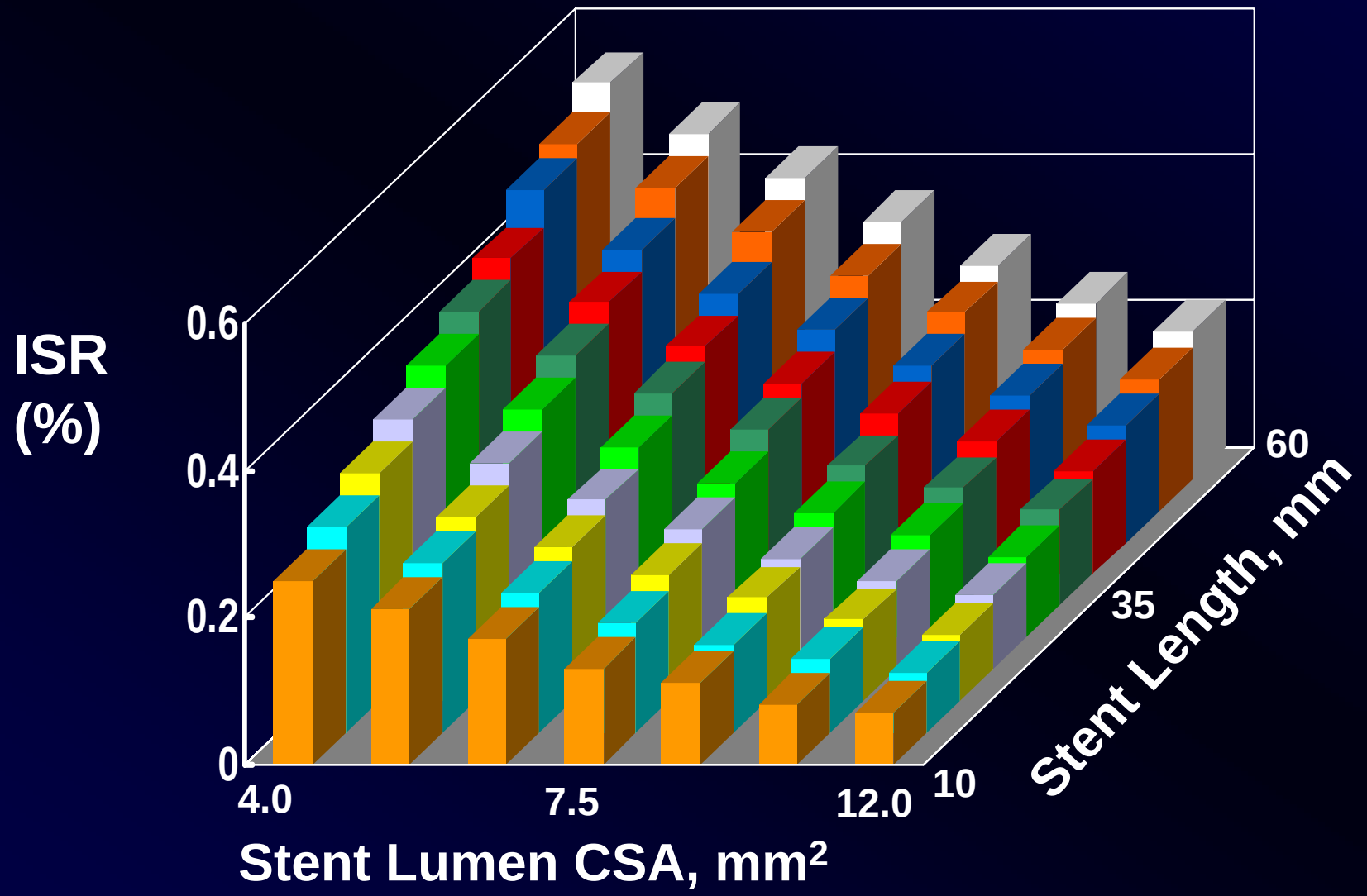
Impact of IVUS after Stenting of Long Coronary Lesion: TULIP Trial



Oemrawsingh et al, Circulation 2003;107:62-67

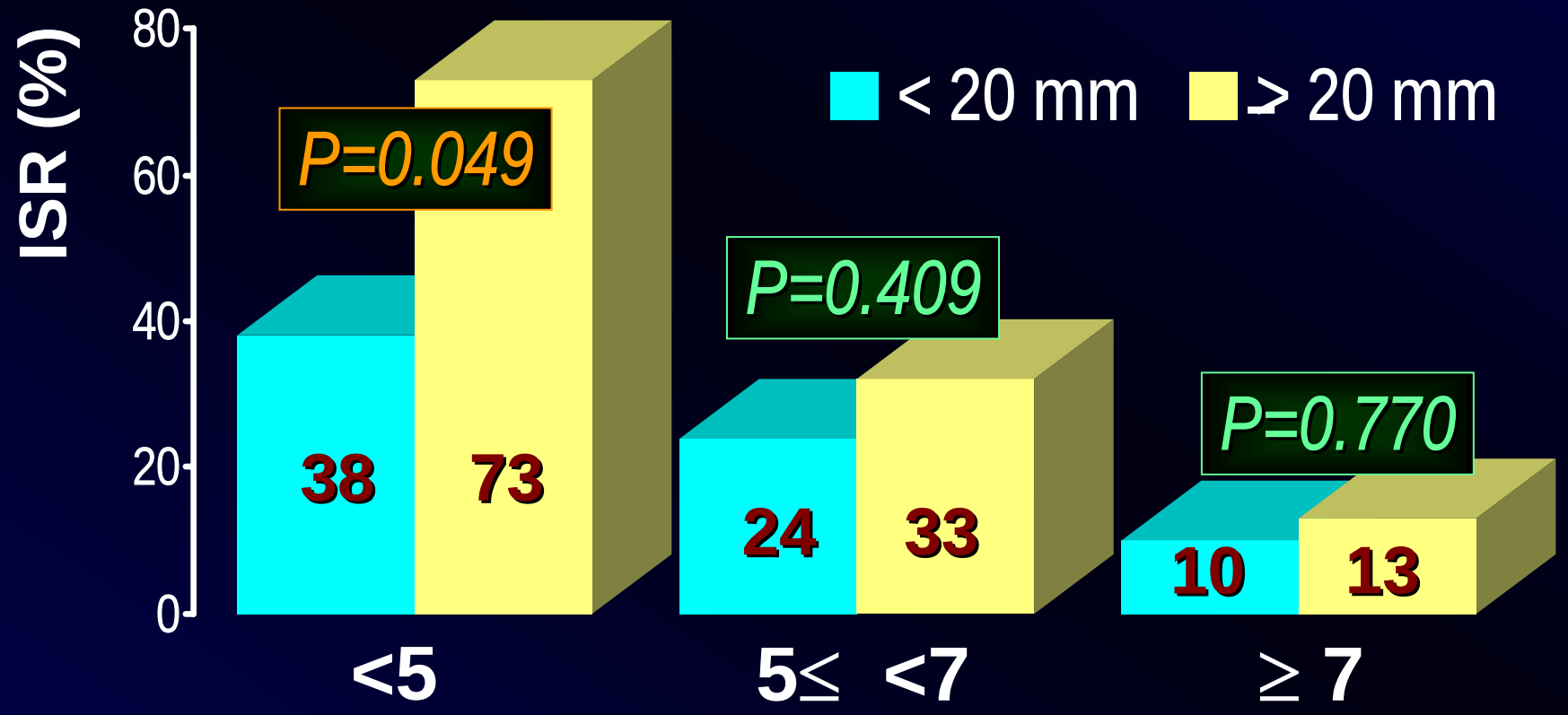

BMS
Restenosis rate (%)
50
40
30
20
10
0
P <0.0001
< 20
20–40
> 40
Stent length (mm)
Restenosis rate (%)
P <0.0001
<2.5
2.5–2.9
3.0–3.4
3.5–3.9
>4.0
Final MLD (mm)
Restenosis rate (%)
P <0.0001
<2.5
2.5–2.9
3.0–3.4
>3.5
Reference MLD (mm)
Restenosis rate (%)
P <0.0001
<6.0
6.0–8.9
9.0–11.9
>12
Stent lumen CSA (mm²)

IVUS predictors of ISR (BMS)



De Feyter, et al. Circulation 1999;100:1777

Angiographic ISR According to Stent Lumen CSA and Stent Length (BMS)



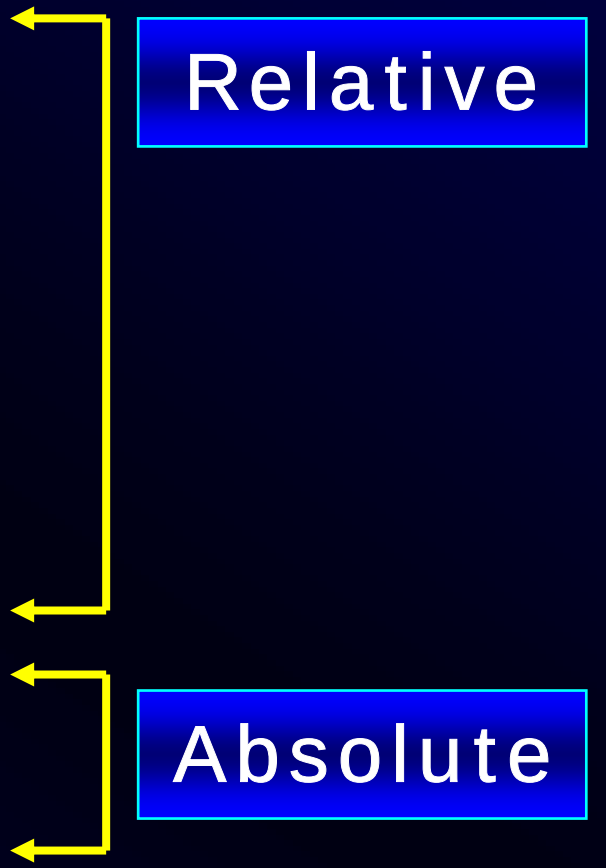
→ *p=0.001*

Hong MK, et al. 2000 AJC;85:441-445

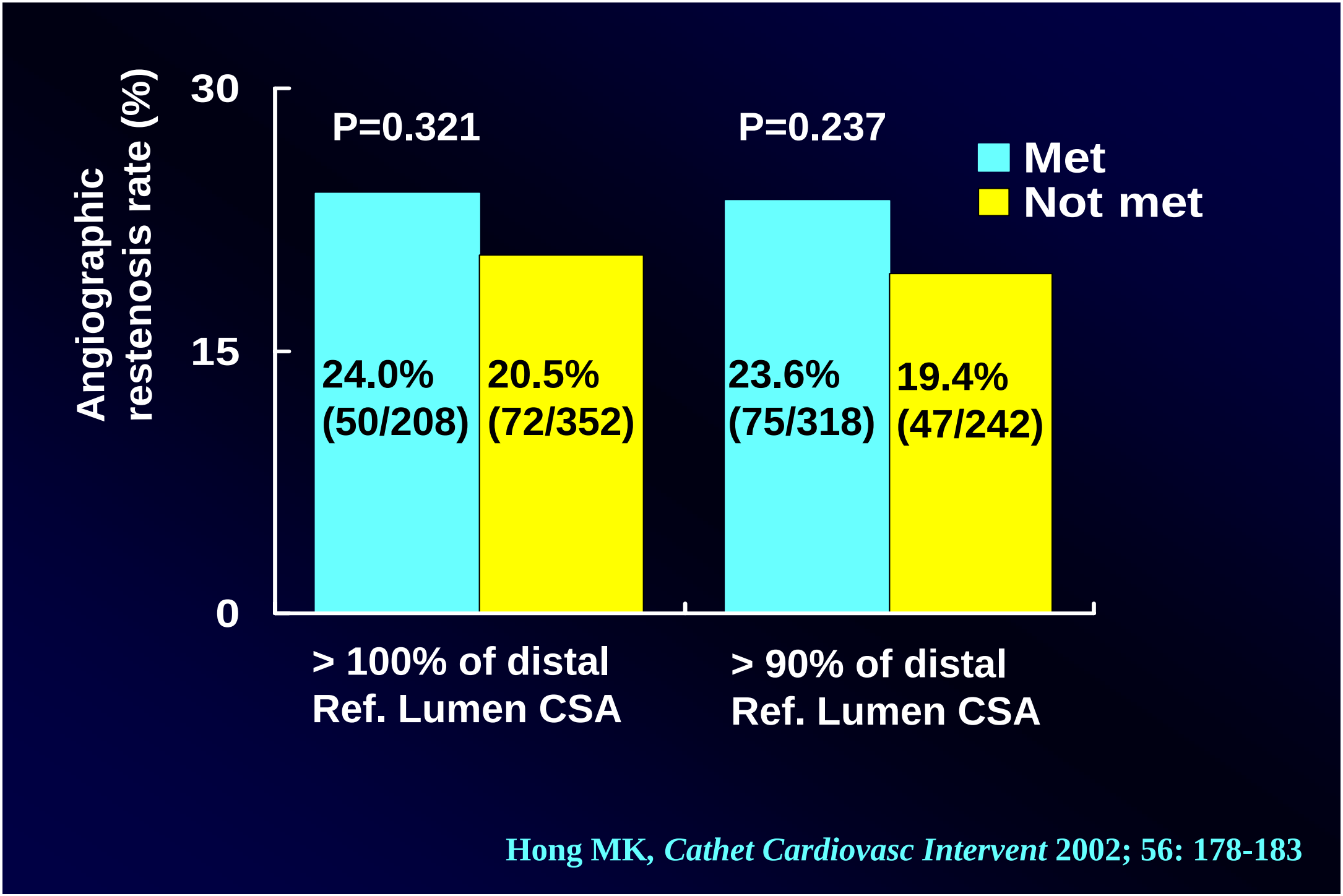
Seven IVUS Criteria

Stent CSA at lesion segment

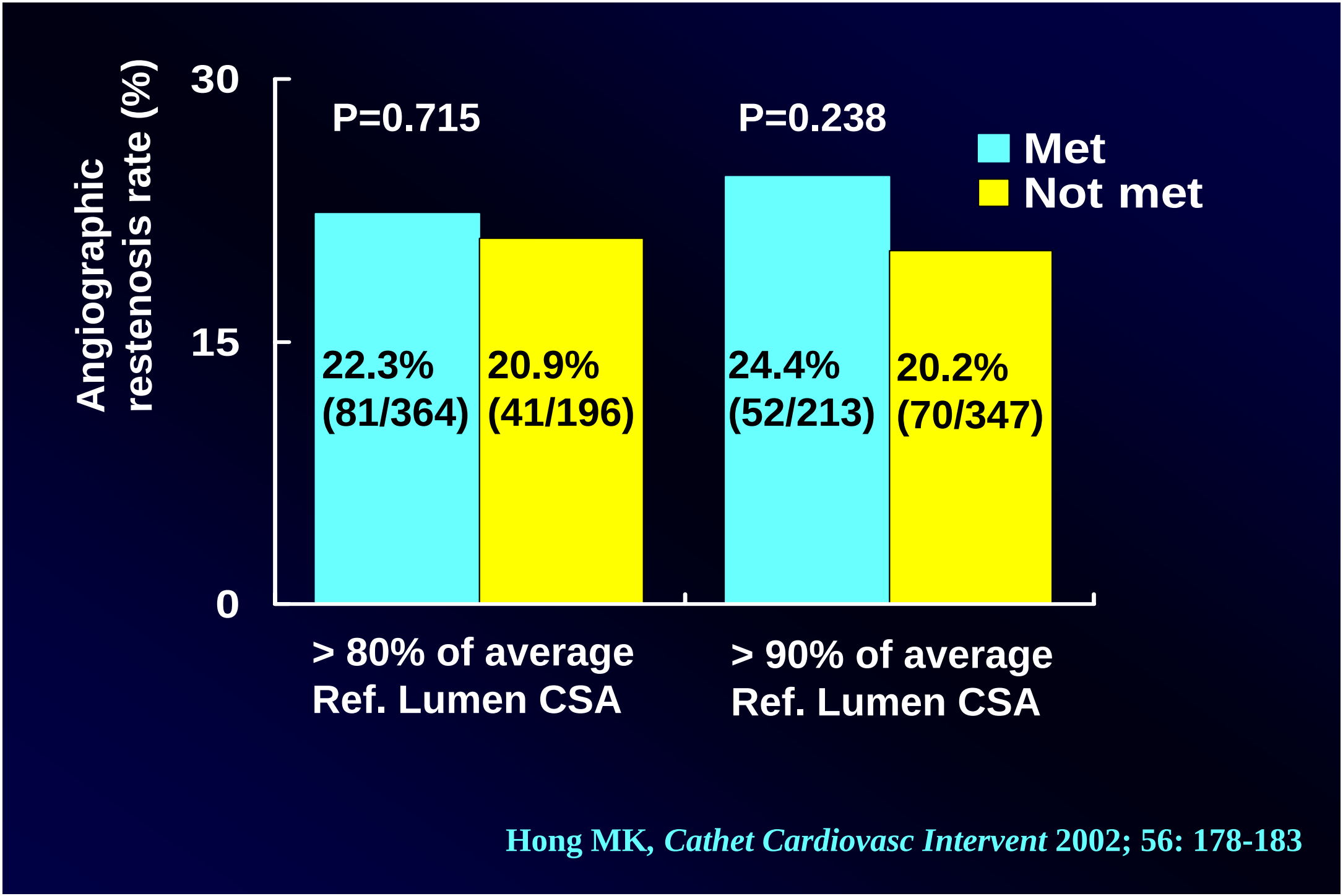
1. ≥ 100% of distal ref. lumen CSA.
2. ≥ 90% of distal ref. lumen CSA.
3. ≥ 80% of average ref. lumen CSA.
4. ≥ 90% of average ref. lumen CSA.
5. ≥ 55% of average ref. EEM CSA.
6. ≥ 7 mm^2.
7. ≥ 9 mm^2.



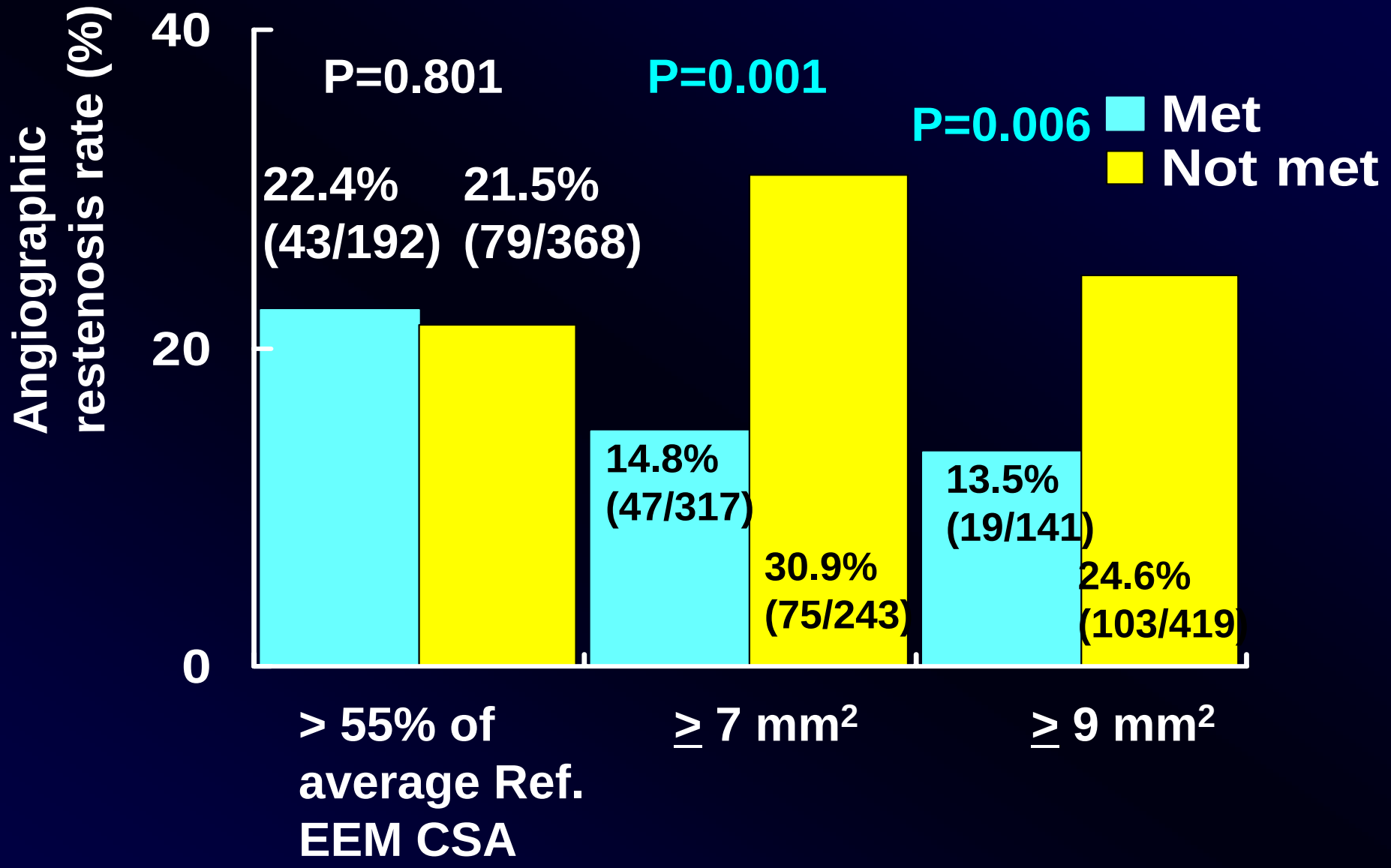
Hong MK, *Cathet Cardiovasc Intervent* 2002; 56: 178-183



Hong MK, *Cathet Cardiovasc Intervent* 2002; 56: 178-183

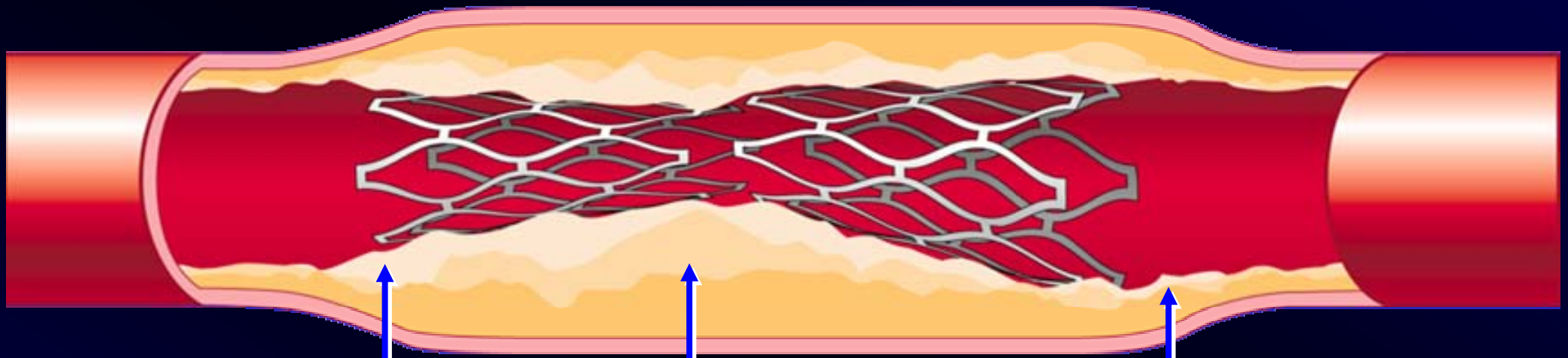


Hong MK, *Cathet Cardiovasc Intervent* 2002; 56: 178-183



Hong MK, *Cathet Cardiovasc Intervent* 2002; 56: 178-183

Problems after Stenting



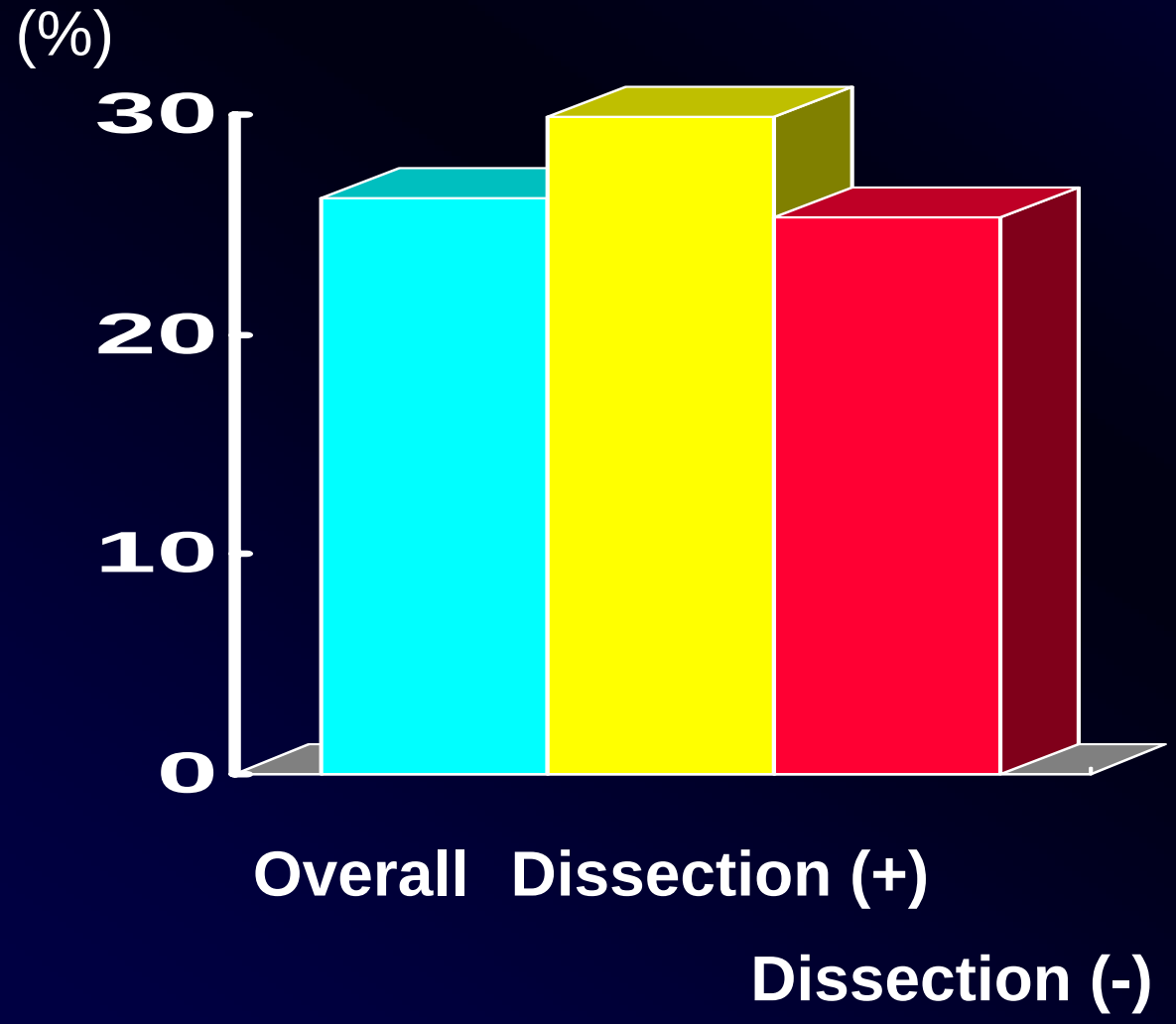
Stent under-expansion,

Plaque prolapse within the stent

Incomplete stent apposition

Edge dissection

Minor edge dissection vs. angiographic restenosis (BMS)



Overall: 26.2% (91/ 348)

With dissection

29.9% (20/67)

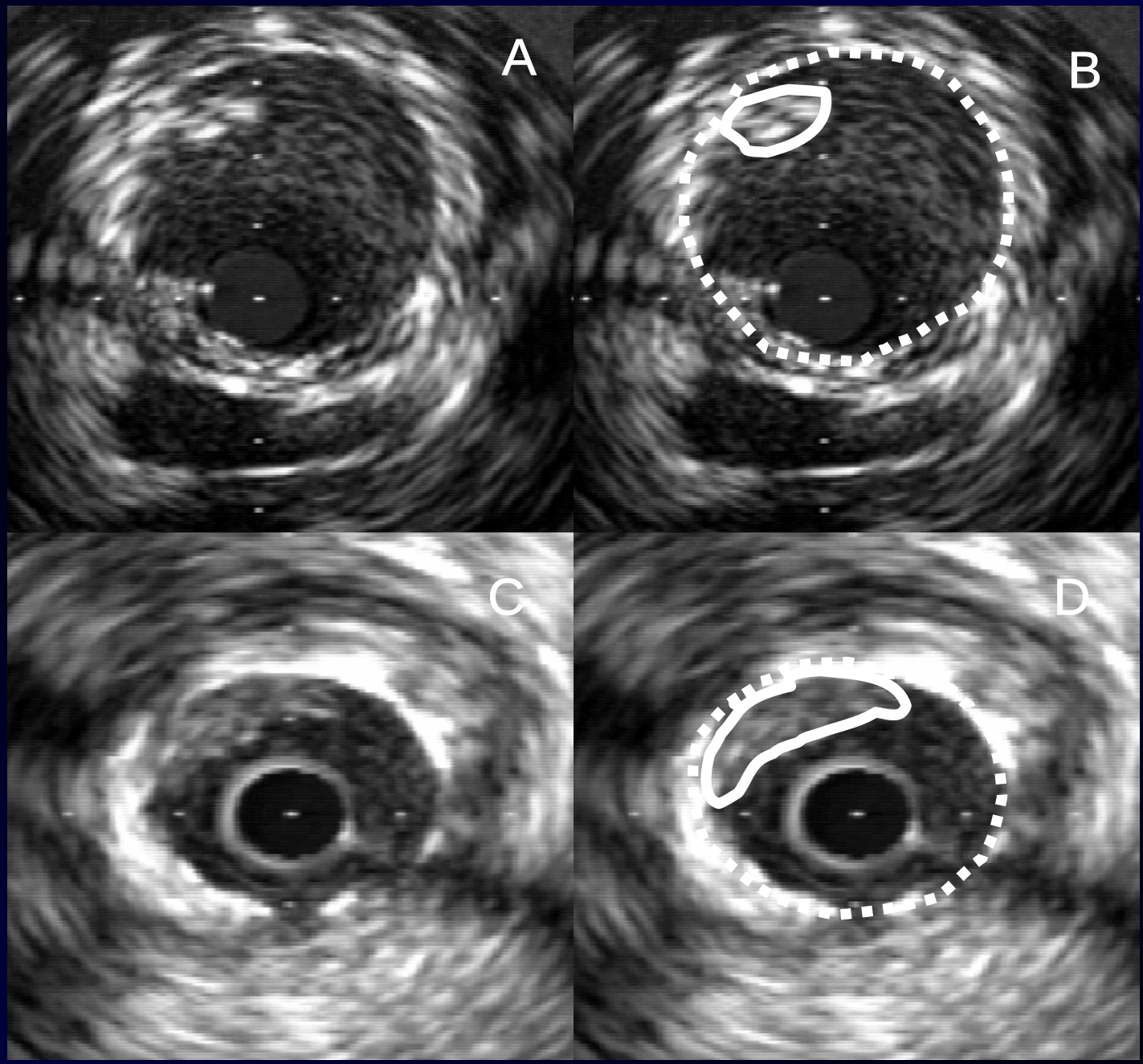
Without dissection

25.3% (71/281)

P=0.540

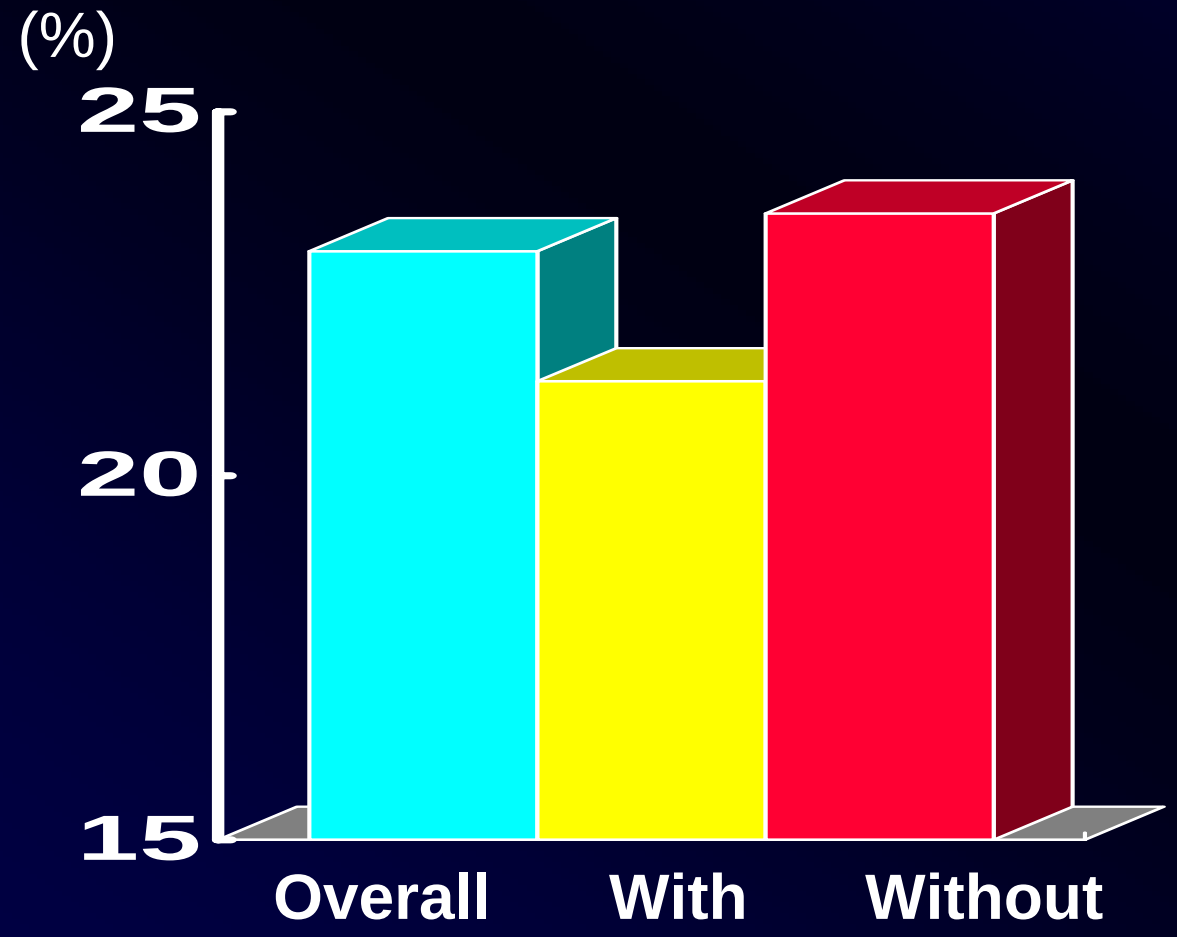
Hong MK, Am J Cardiol 2000; 86: 791-795

Minor Plaque Prolapse



The extent of plaque prolapse < 25% of stent CSA

Minor plaque prolapse vs. angiographic restenosis (BMS)



Overall: 23.1%

With prolapse 21.3%

Without prolapse 23.6%

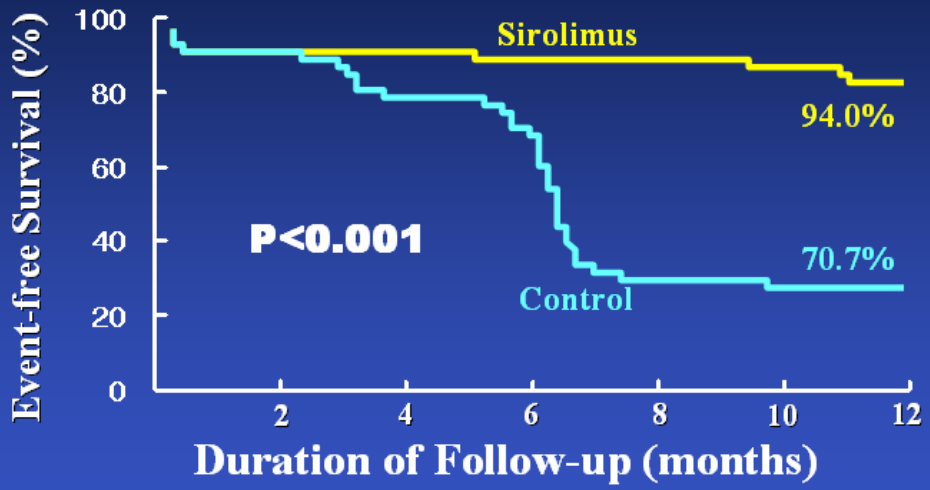
P=0.806

Hong MH, Cathet Cardiovasc Intervent **2000; 51: 22-26**

IVUS in the DES era

Event-free Survival in RAVEL:

Death, MI, CABG, Re-PCI



Morice MC et al, NEJM 2002;346:17

TLR Events

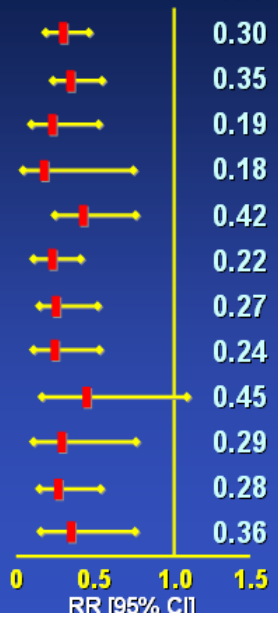
SIRIUS

	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

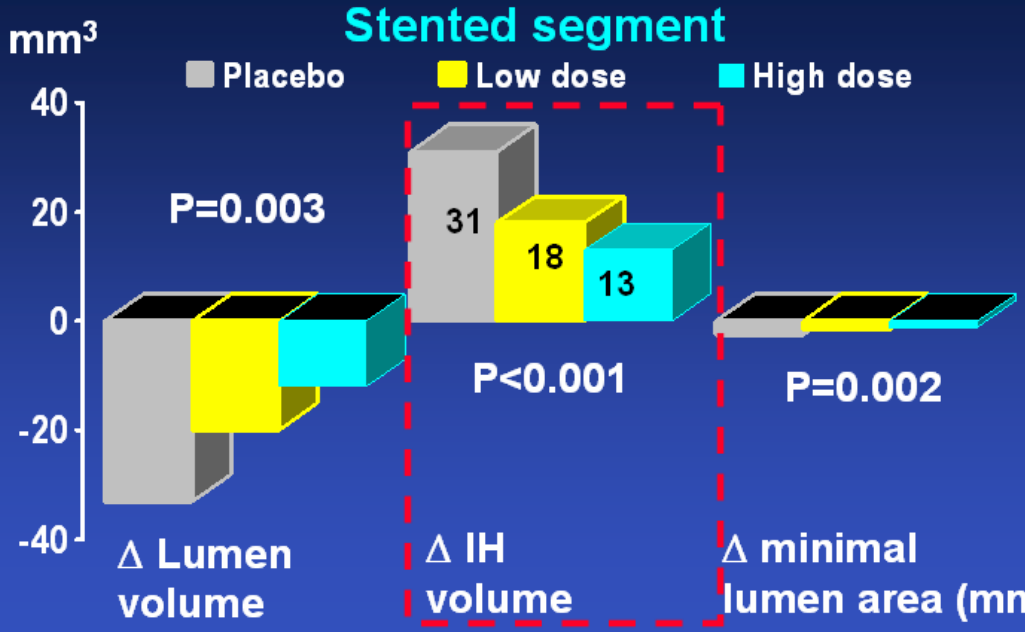
Restenosis Rate

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



IVUS analysis (Δ: comparison)

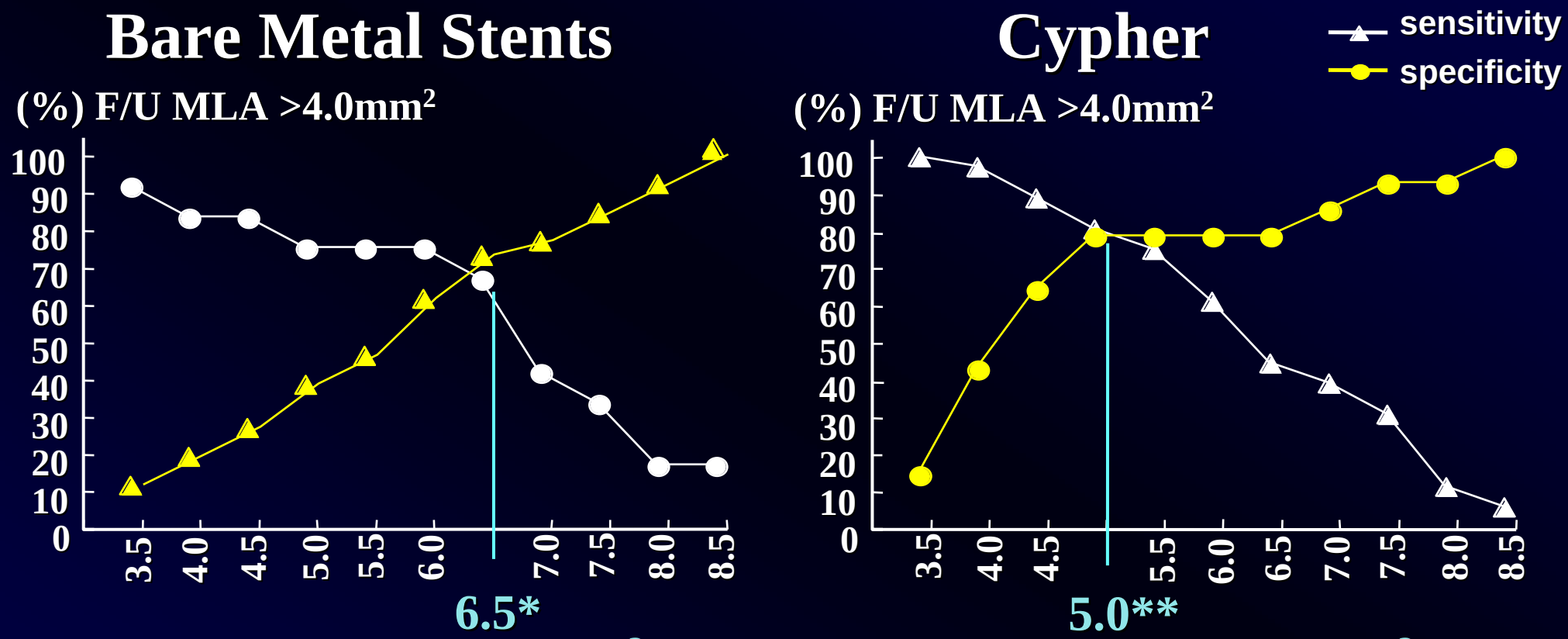


Hong MK, et al. Circulation 2003; 107: 517-520

Minimal Stent CSA and Stent Length

Are the minimal stent area by IVUS and stent length still important in the era of DES?

"Optimal" MSA (from SIRIUS)



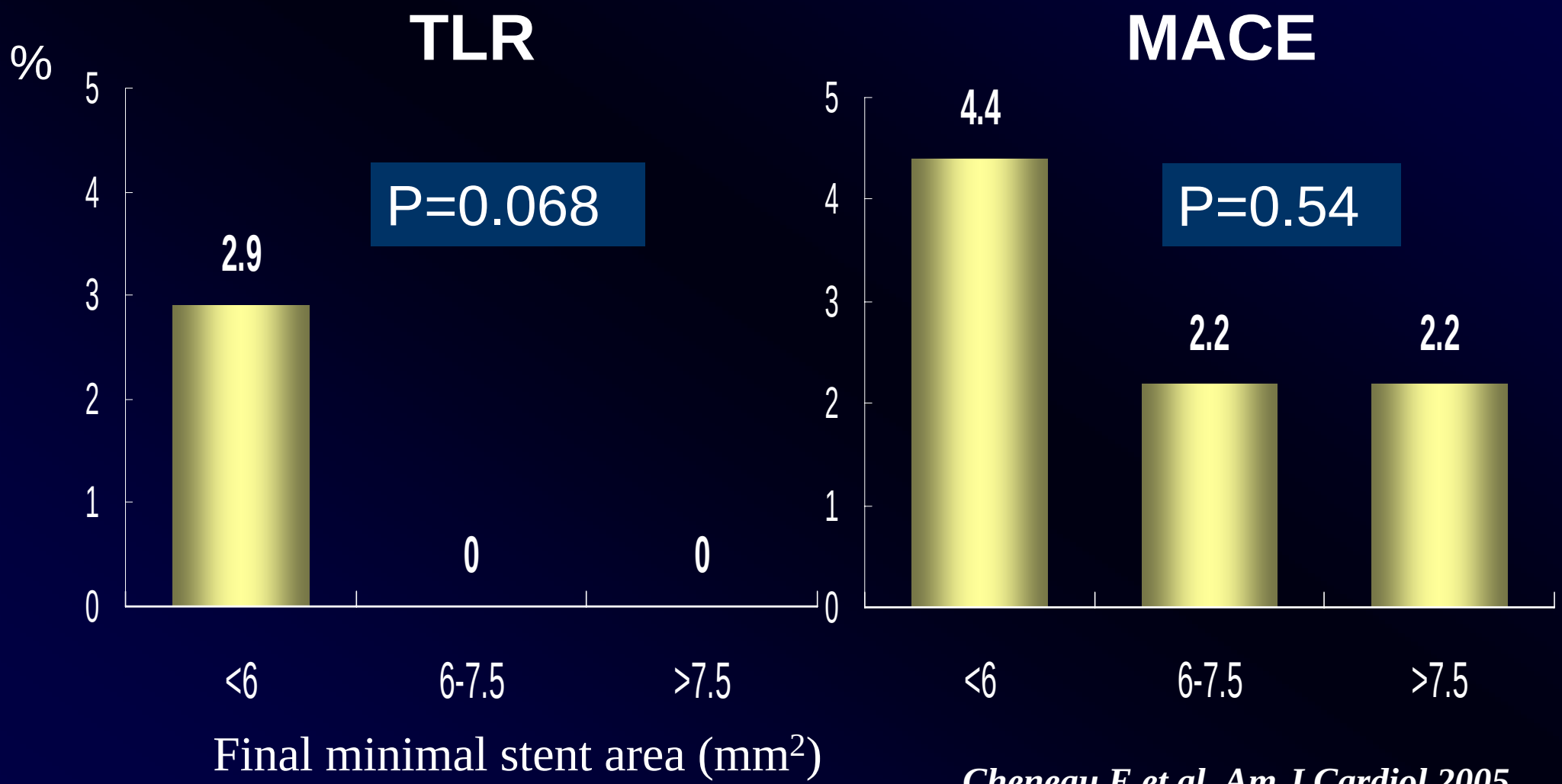
*predictive value=56%

**predictive value=90%

Sonoda et al. JACC 2004;43:1959-63

Optimal Stent Expansion

Total 219 patients



Cheneau E et al. Am J Cardiol 2005

IVUS predictors of angiographic restenosis after SES.

Independent predictors by multivariate logistic regression analysis

1. IVUS minimum stent CSA (odds ratio=0.584, 95% CI 0.385–0.885, p=0.011),

2.Total stent length measured by IVUS (odds ratio=1.028, 95% CI 1.002–1.055, p=0.038).

Hong MK, et al. Eur Heart J 2006; 27: 1305-1310

IVUS predictors of angiographic restenosis after SES.

Angiographic restenosis rate

Stent length	Total	Stent CSA < 5.5 mm^2	Stent CSA ≥ 5.5 mm^2	p
Total	21/543 (3.9%)	14/189 (7.4%)	7/354 (2.0%)	0.002
< 40 mm	4/411 (1.0%)	3/127 (2.4%)	1/284 (0.4%)	0.090
≥ 40 mm	17/132 (12.9%)	11/62 (17.7%)	6/70 (8.6%)	0.116
p	<0.001	<0.001	<0.001	

Hong MK, et al. Eur Heart J 2006; 27: 1305-1310

Importance of Full-lesion Coverage

SIRIUS

	Edge Stenosis		p
	Yes (n=6)	No (n=162)	
Reference area, mm^2	10.7±3.8	10.7±3.8	0.156
Reference plaque, mm^2	6.7±3.3	7.0±3.2	0.891
Reference minimum lumen area, mm^2	**4.7±2.3**	**6.4±2.3**	**0.0498**
Edge stent area, mm^2	6.8±3.2	7.3±2.1	0.358
Maximum reference plaque area, %	**60.5±9.0**	**48.8±11.5**	**0.030**
Edge teat or dissection	0	2 (1%)	1.000

Sakurai R et al. Am J Cardiol 2005;96:1251

IVUS analysis of DES failure

- **121 patients, >30days after Cypher stent implantation**
- **Angiographic restenosis in 20 lesions in 19 pts**
  - **Proximal edge restenosis in 6 lesions**
  - **Intra-stent restenosis in 14 lesions**
- **Of 14 intra-stent restenosis lesions, IVUS analysis in 8 lesions**
  - **2 Stent underexpansion**
  - **4 Strut fractures**

Lemos et al., Circulation 2003

Contribution of Stent Underexpansion to Recurrence After SES Implantation for ISR

- **41 pts with ISR treated with SES and IVUS**
- **Recurrence in 11 lesions (all focal)**
- **Stent underexpansion by IVUS compared with 16pts (19 lesions) without recurrence as documented by angiography**

  - 9/11 recurrent lesions had MSA <5.0mm^2 in vs 5/19 non-recurrent lesions (p=0.003)

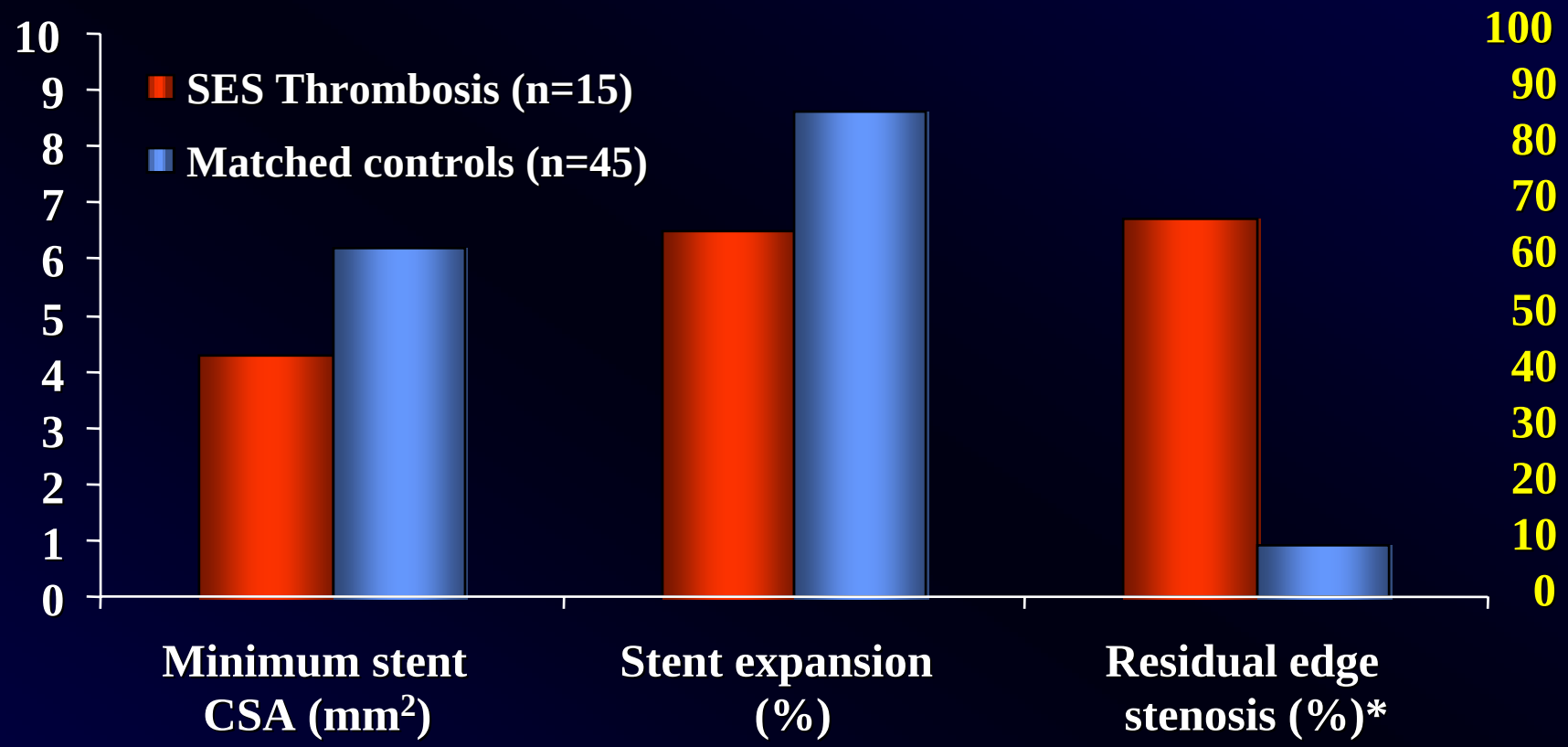
  - 7/11 recurrent lesions had MSA <4.0mm^2 in vs 4/19 non-recurrent lesions (p=0.02)

  - 4/11 recurrent lesions had MSA <3.0mm^2 in vs 1/19 non-recurrent lesions (p=0.03)
- **Gap between multiple stents: 3/11 recurrent lesions vs 1/19 non-recurrent lesion (p=0.005)**

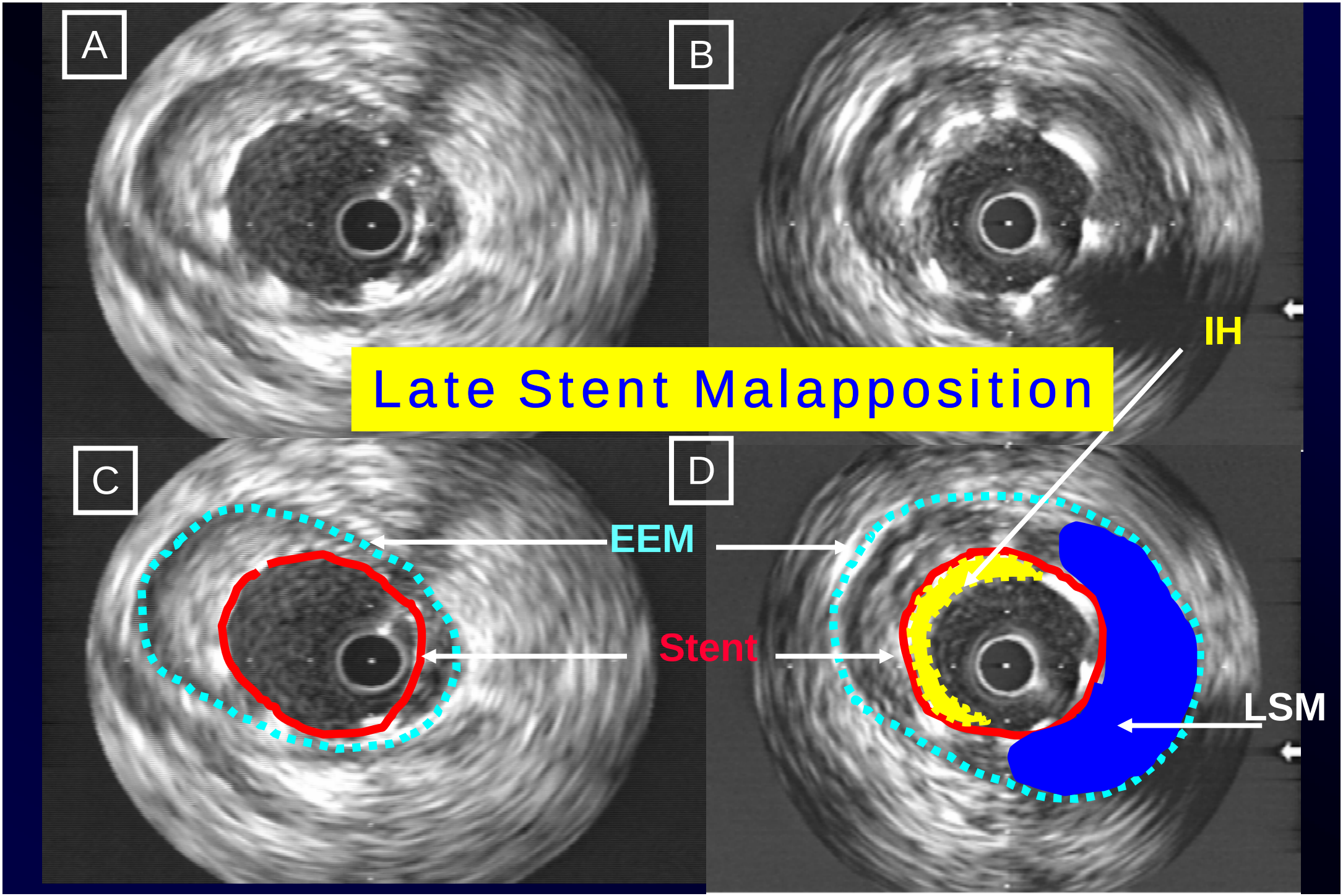
-> Complete lesion coverage and adequate stent expansion are important in the DES treatment of ISR

Fujii et al. Circulation 2004

IVUS predictors of Cypher Thrombosis



- 2,575 patients were treated with 4,722 Cypher stents.
- 21 (0.8%) had stent thrombosis of whom 15 had IVUS
- 12/15 SES thrombosis lesions has stent CSA <5.0mm² (vs 13/45 controls)


A
B
Late Stent Malapposition
IH
C
D
EEM
Stent
LSM

Stent malapposition in SIRIUS

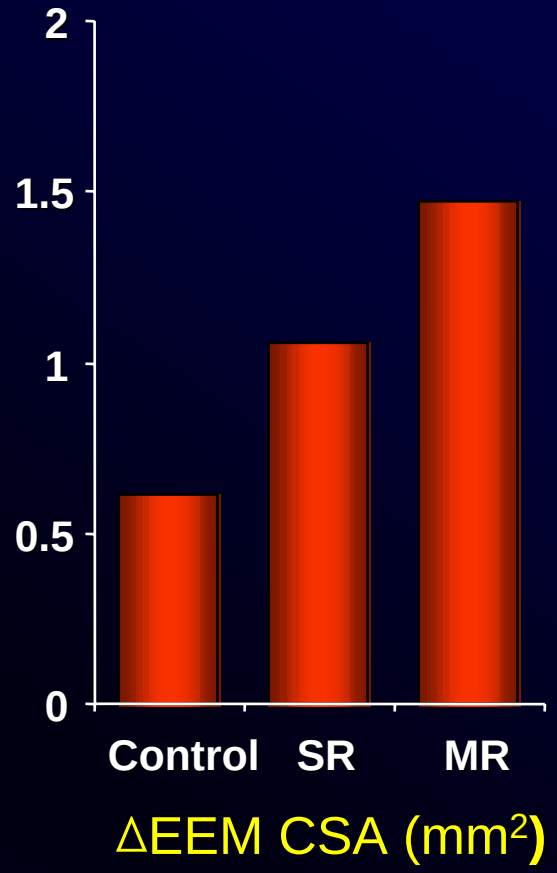
	Cypher Stent (n=80)	Bare Stent (n=61)
Baseline malapposition	**13 (16.3%)**	**9 (14.7%)**
Resolved	**7**	**3**
Persistent	**6**	**6**
New late malappositon	**7 (8.7%)***	**0 (0%)**

p<0.05, but without events at 6-months

Stent Malapposition in TAXUS-II

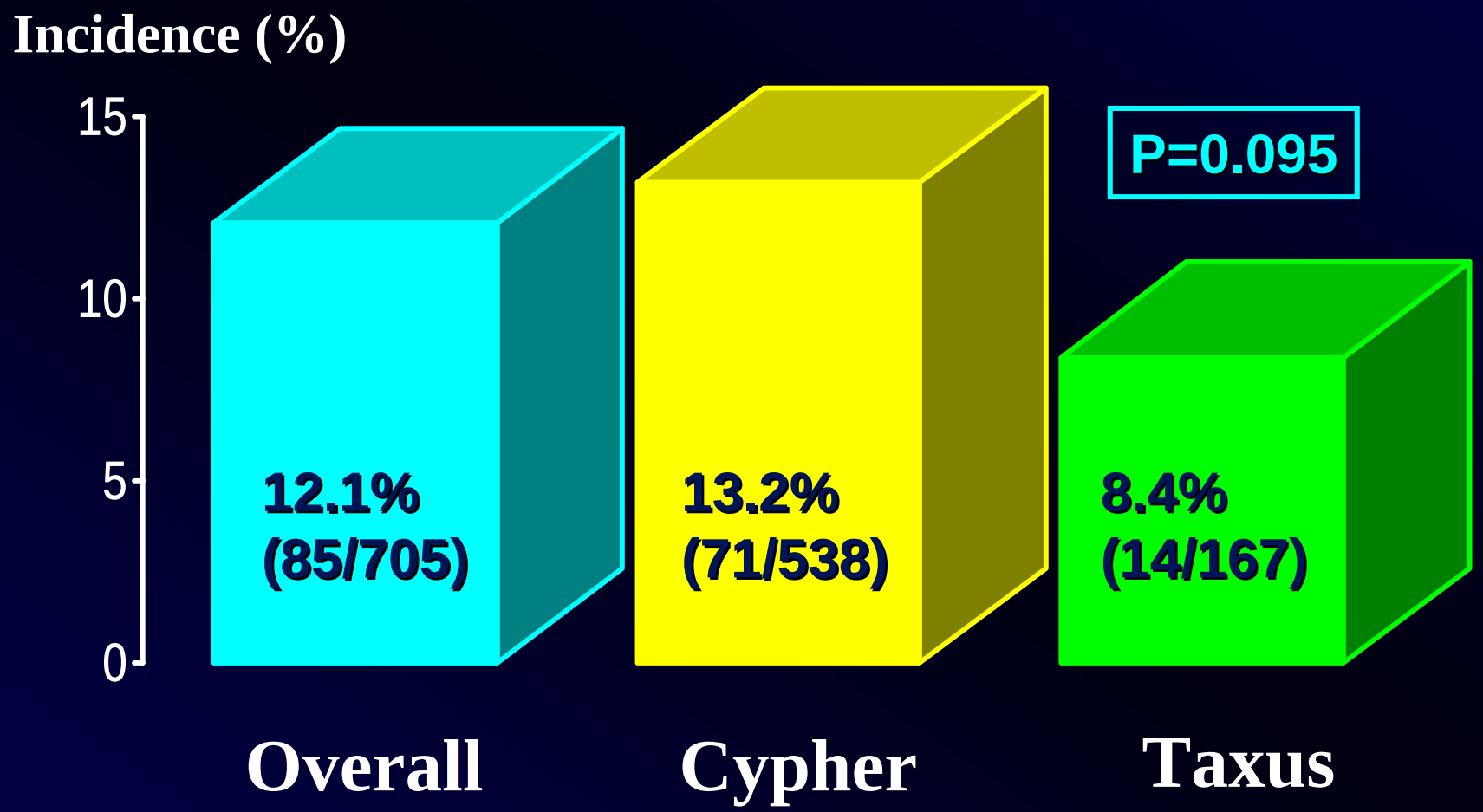
	Control (n=240)	SR (n=114)	MR (n=116)	p
Resolved	4.6% (11/240)	7.0% (8/114)	2.6% (3/116)	0.3
Persistent	3.3% (8/240)	4.4% (5/114)	0.0% (0/116)	0.0564
Acquired	**5.4% (13/240)**	**8.8% (10/114)**	**9.5% (11/116)**	**0.3***

*P=0.15 when SR and MR are combined



No increase in *6-month* events in patients with late stent malapposition

Incidence of LSM after DES



Hong MK, et al. Circulation 2006;113:414-419

Long-term clinical follow-up: MACE after detection of LSM after DES

- **TLR at 6-month: in 20 patients with 22 lesions in the non-LSM group, but in none of the LSM patients (p=0.095).**
- **Mean duration of long-term clinical follow-up after 6-month angiogram was 10.9±4.4 and 10.1±3.9 months in LSM and non-LSM group, respectively (p=0.100).**
- **Death from cardiac origin in 1 patient in the non-LSM group (sudden death at 2.6 months after the 6-month follow-up angiogram).**
- **Except for only one death in non-LSM group, no MACE occurred in both LSM and non-LSM groups during a mean 10.2 months follow-up after detection of LSM.**

Hong MK, et al. Circulation 2006;113:414-419

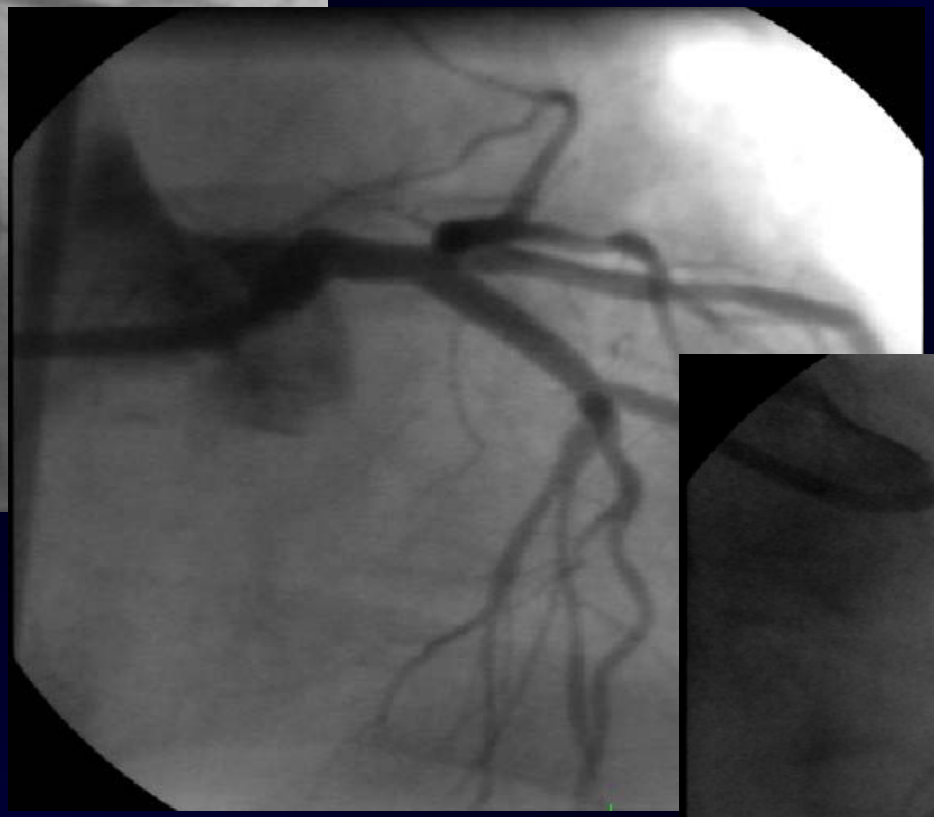
How to treat coronary lesions with DES and IVUS guidance ?

- **Full lesion coverage covering the adjacent diseased segment with IVUS guidance**

- **Achievement of the optimal final lumen area at least 5-5.5mm^2 and/or stent length <40 mm**

DES implantation with angiographic guidance

Pre-DES

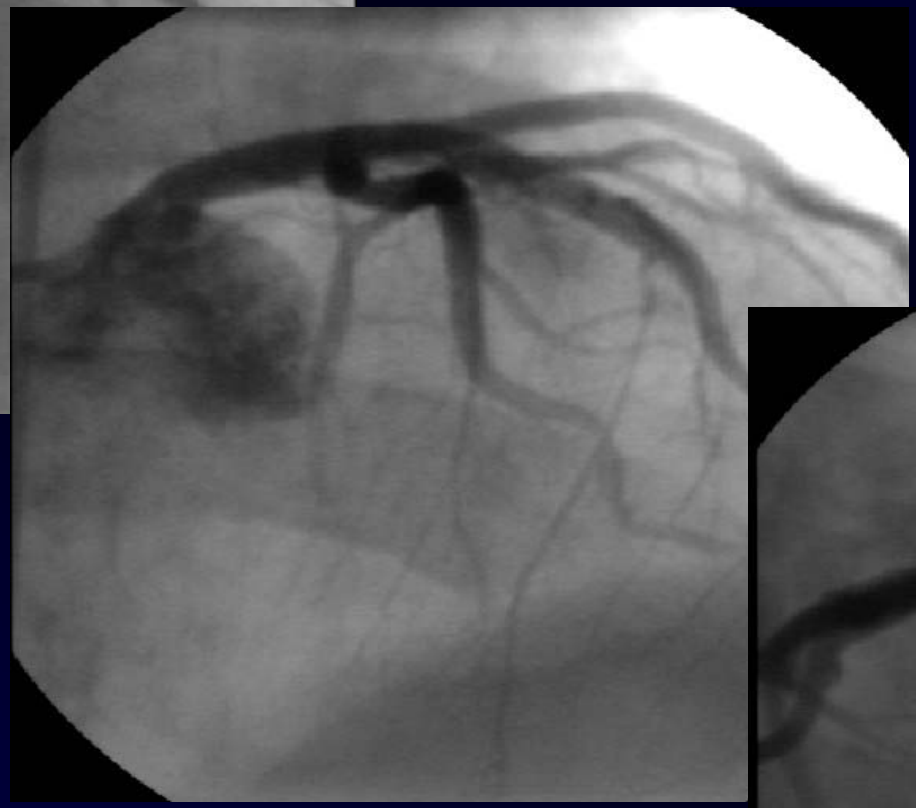


Post-DES

6-month follow-up

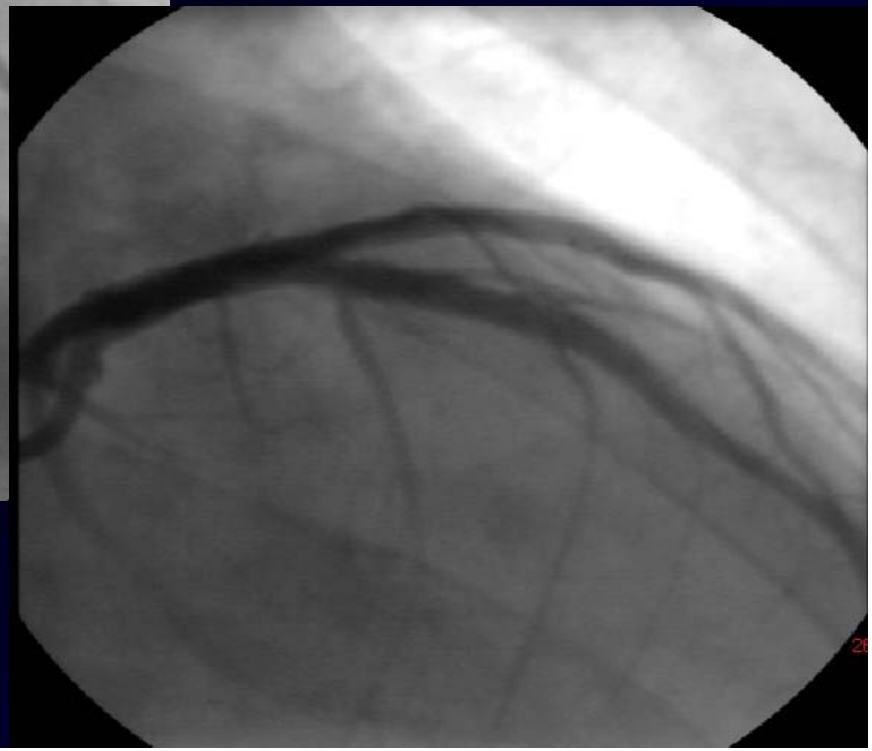
DES implantation with IVUS guidance

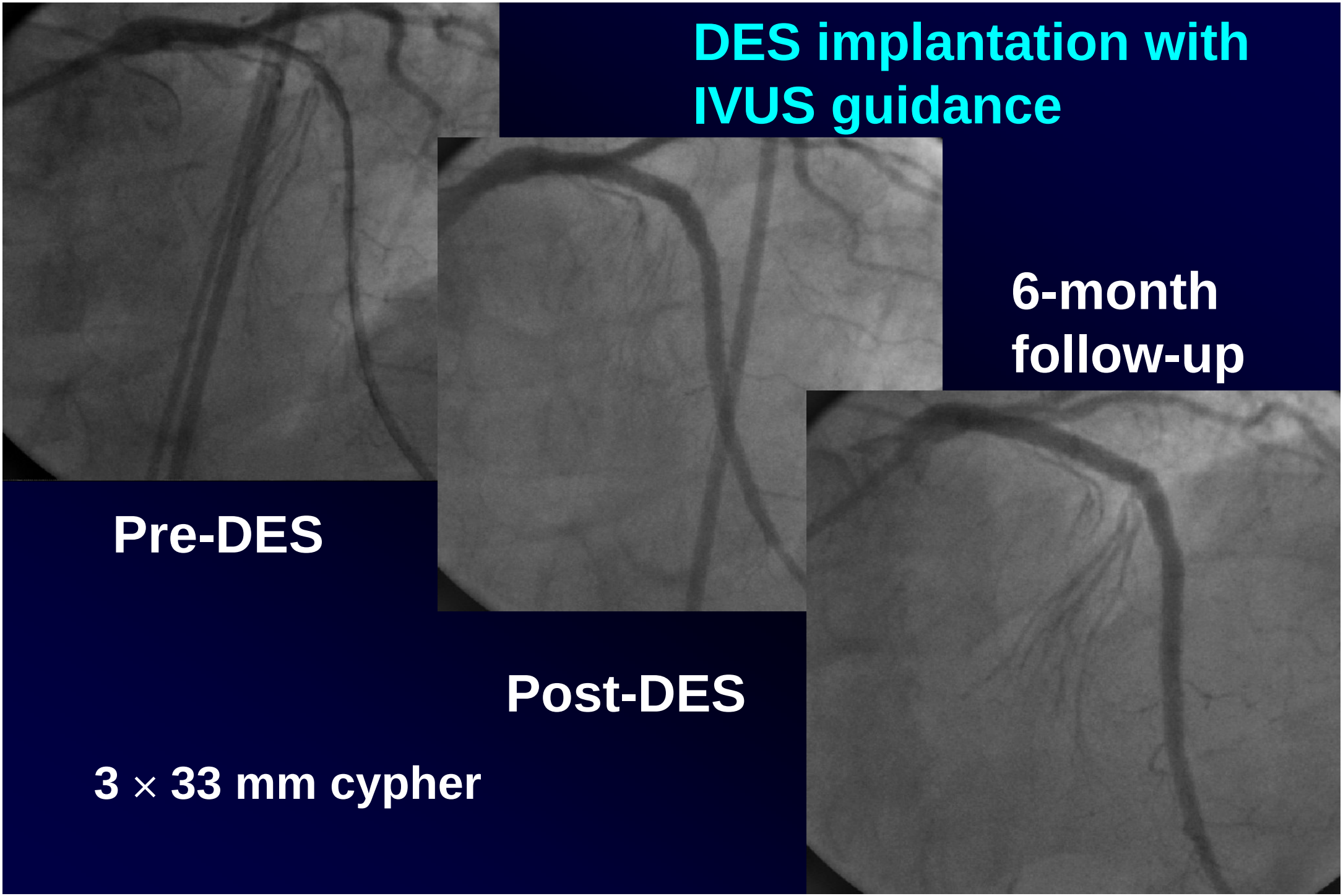
Pre-DES



Post-DES

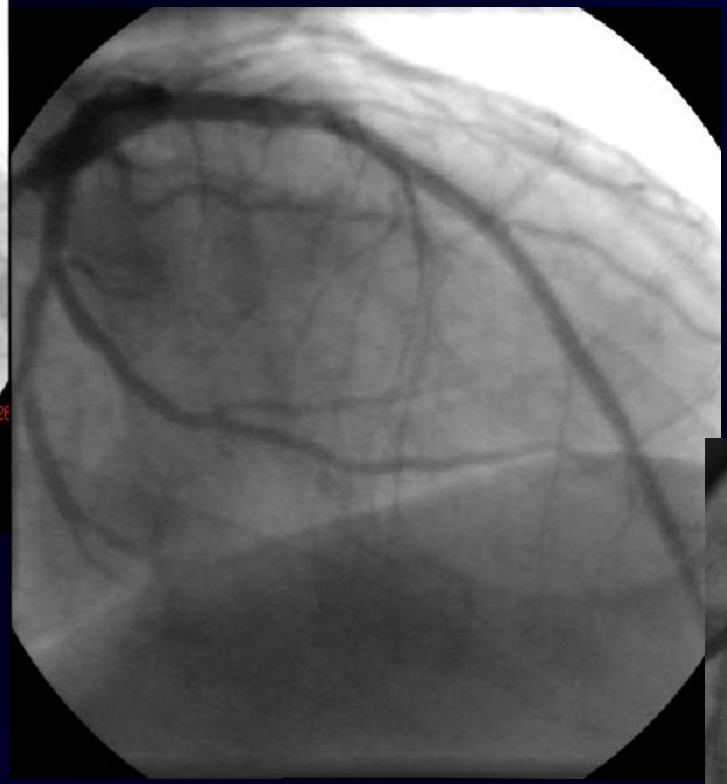
6-month follow-up



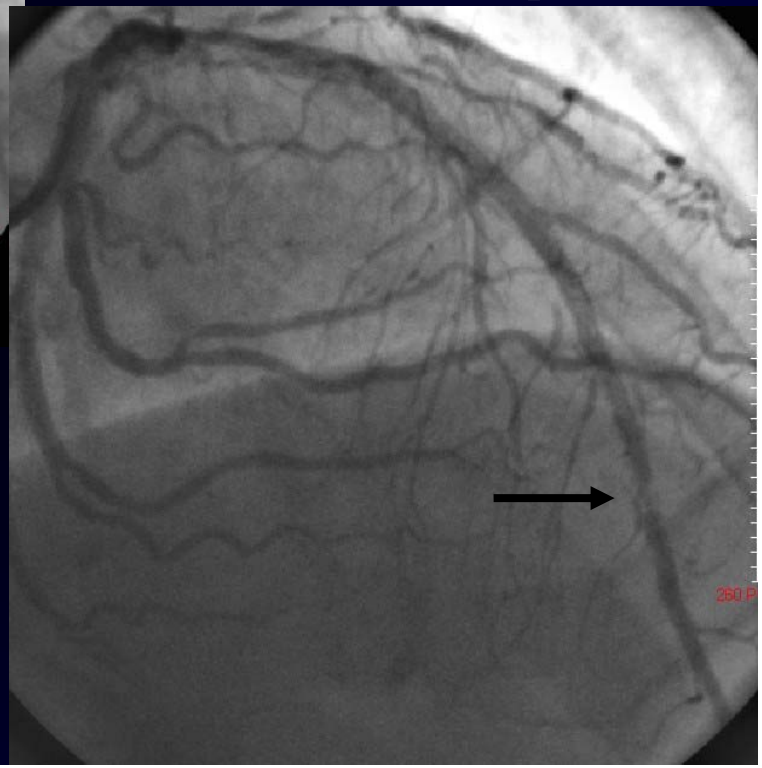

DES implantation with
IVUS guidance
6-month
follow-up
Pre-DES
Post-DES
3 × 33 mm cypher

DES implantation with angiographic guidance

Pre-DES



Post-DES



6-month follow-up

3 × 33 mm cypher

DES Stenting with IVUS

- **Select a stent length based upon the “diseased zone” and not the >50% stenosis -full lesion coverage**
- **Stent from “disease free” to “disease free” (or proximal to distal normal reference)**
- **Choose a “safe landing zone”, 3-5 mm outside the shoulders of the lesion, to position the stent edges**
- **Expect that overall stent lengths will be 5-10 mm longer than with previous bare stent techniques**
- **IVUS are helpful tool to select optimal stent length**

Conclusion: IVUS-Guided Intervention in the world of DES

- **Simple lesion (type A lesions): IVUS-guidance may not be necessary.**

- **Complex lesions (type B2/C lesions) including very long lesions, CTO lesions, bifurcation lesions, LM lesions, ISR lesions and diabetic patients: IVUS-guidance may be very helpful to reduce long-term restenosis rate and MACE rate.**