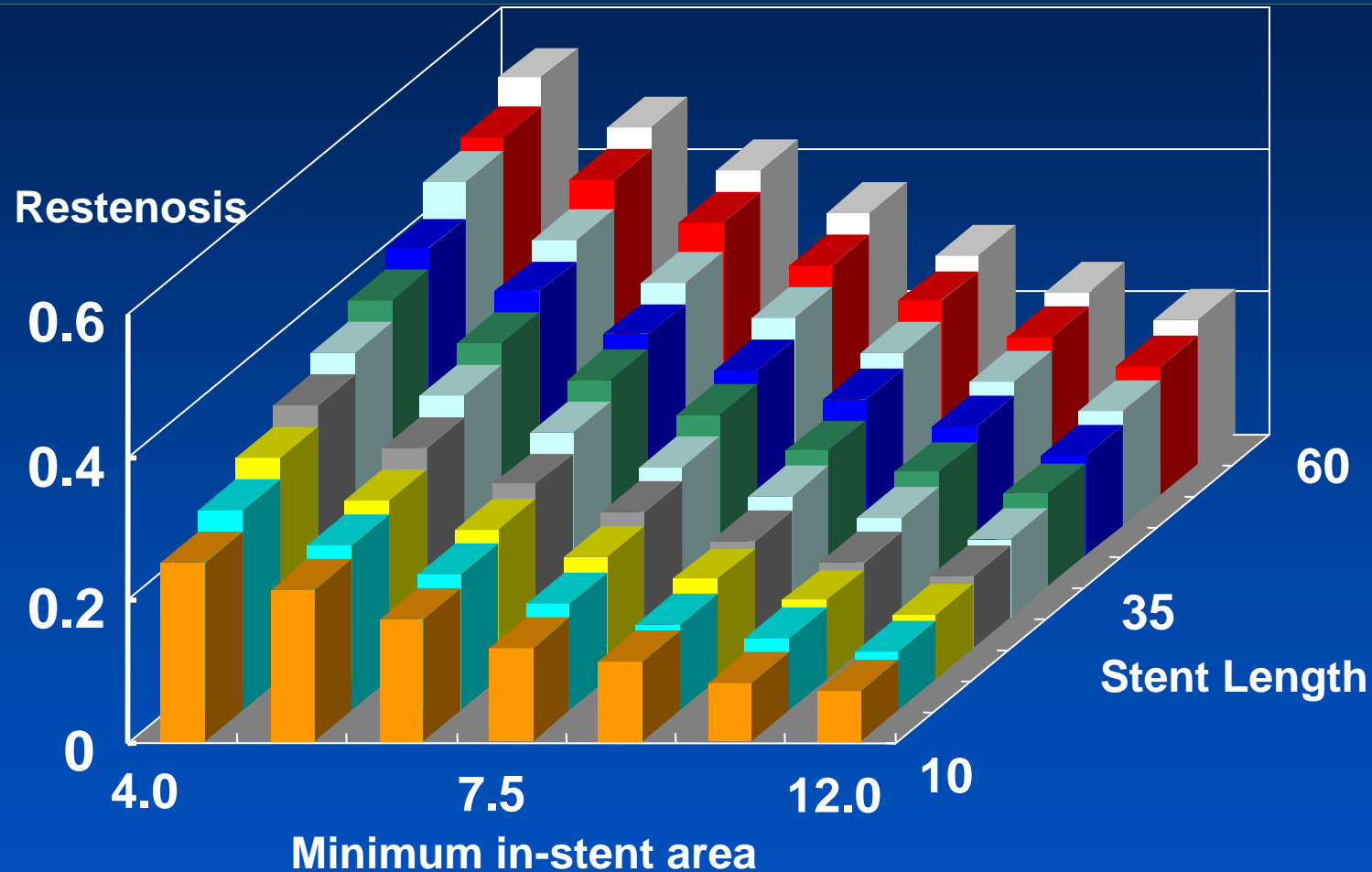


PCI for Long Coronary Lesion



In the Bare Metal Stent Era

Higher Restenosis Rate With Increasing Stent Length and Decreasing Stent Area



De Feyter. Circulation 1999; 100:1777-83

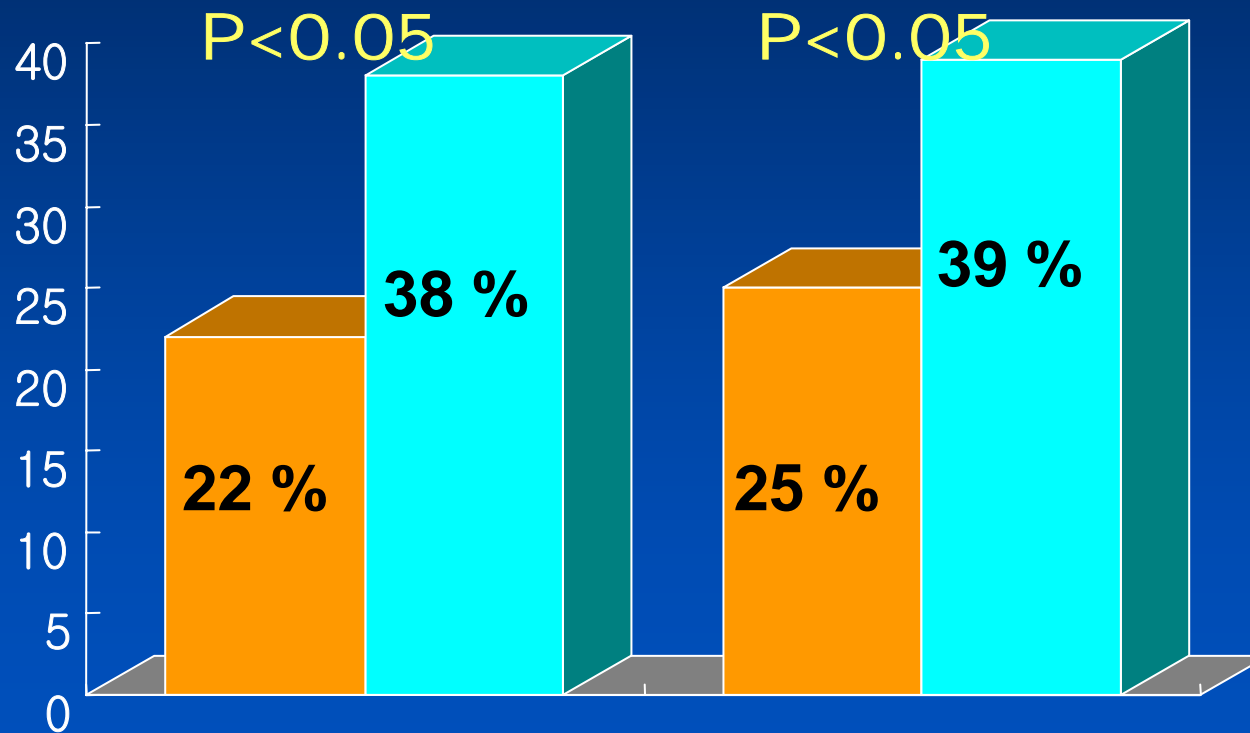
Spot Stenting vs. Long Stent

6 Months MACE

Restenosis Rate

■ Spot stenting

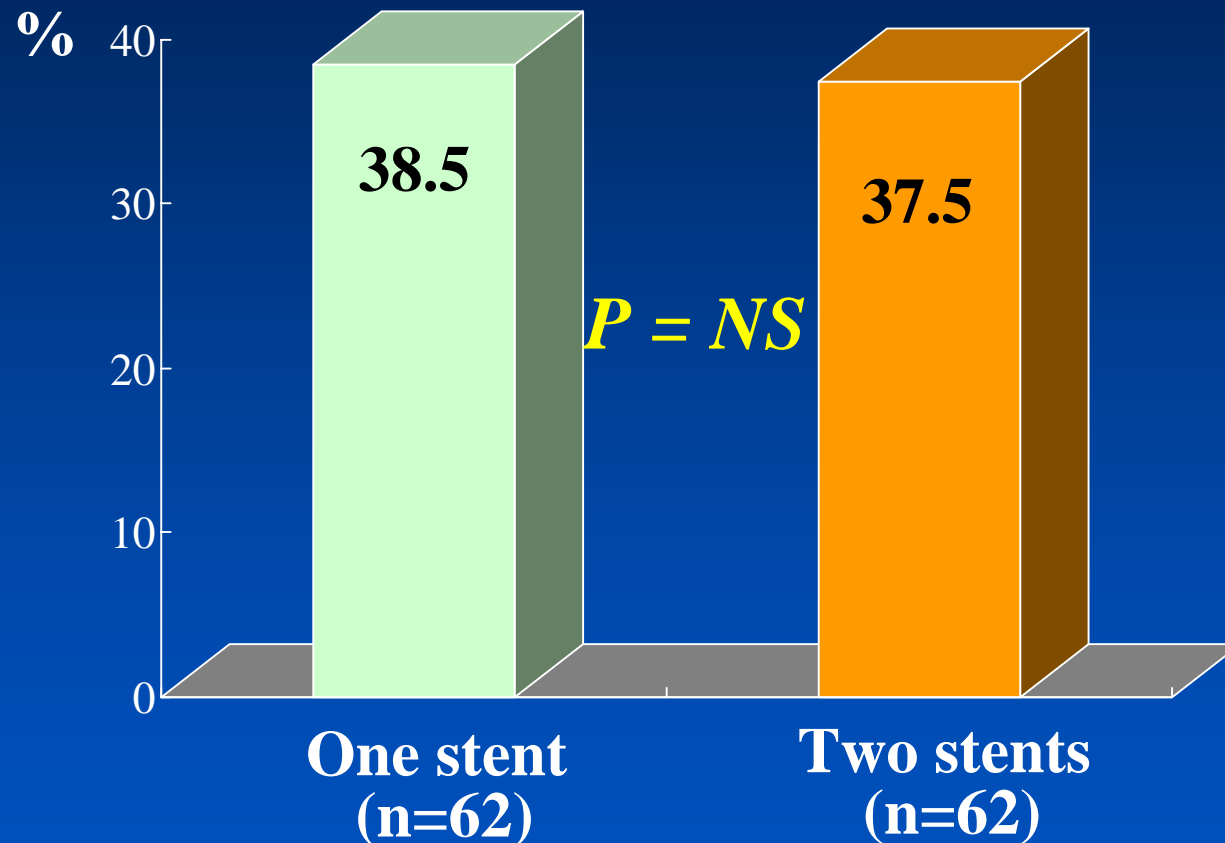
■ Long stenting



Colombo A et al, J Am Coll Cardiol 2001;38:1427-33

Single Stent vs. Multiple Stent

Restenosis Rate

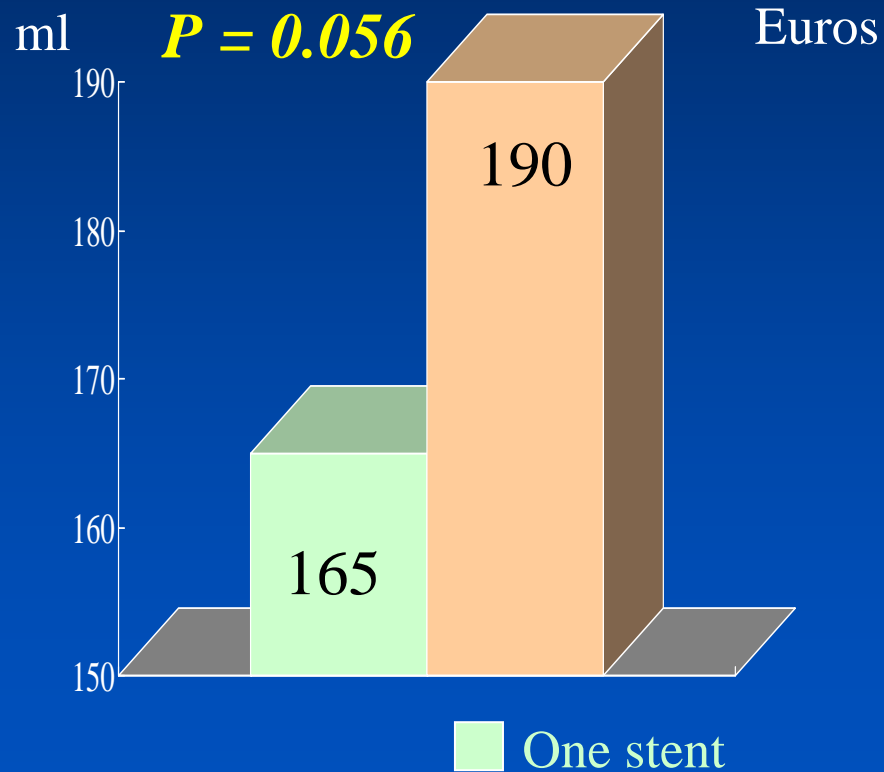


Hoffmann R, et al. Am J Cardiol 2002;90:460-464

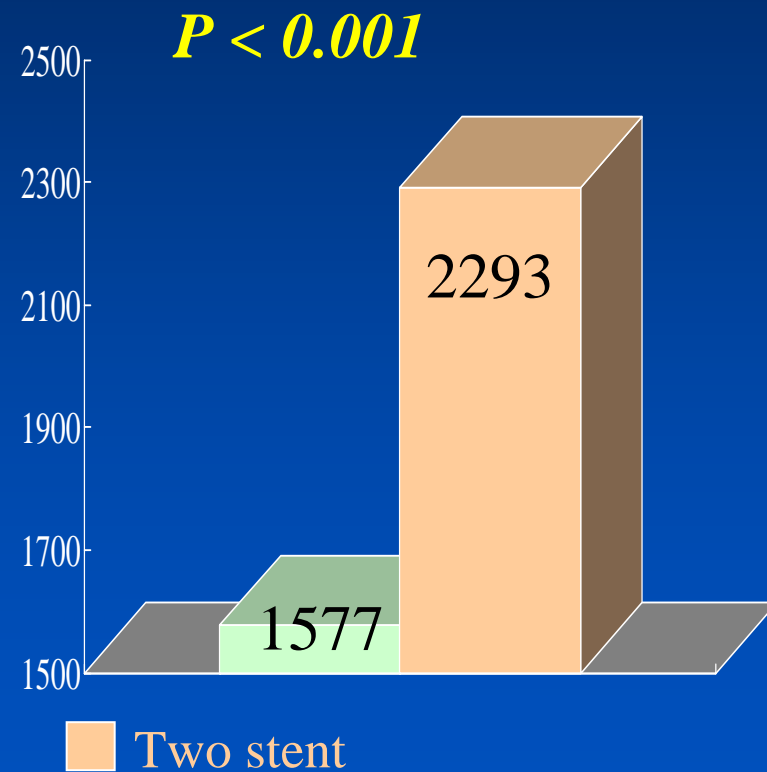
Single Stent vs. Multiple Stent

Cost-Effectiveness

Contrast agent



Intervention Cost



Hoffmann R, et al. Am J Cardiol 2002;90:460-464

Stenting with Bare Metal Stent for Long Coronary Lesion

It was suggested that...

- Spot stenting
- Single stent

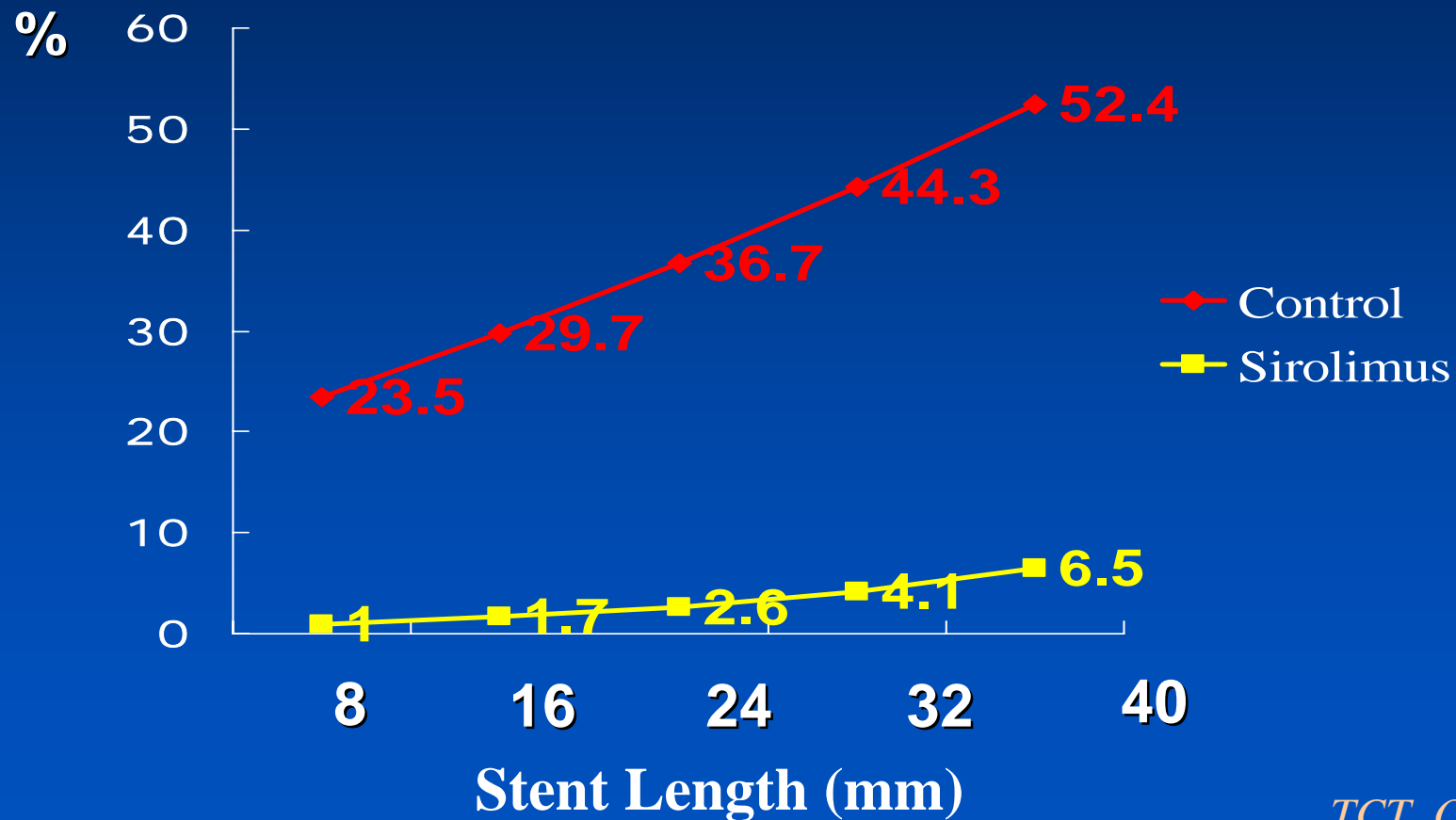
What is changing ?

**In the Era of
Drug Eluting Stent**



Minimal Increase of Restenosis With Increasing SES length

SIRIUS



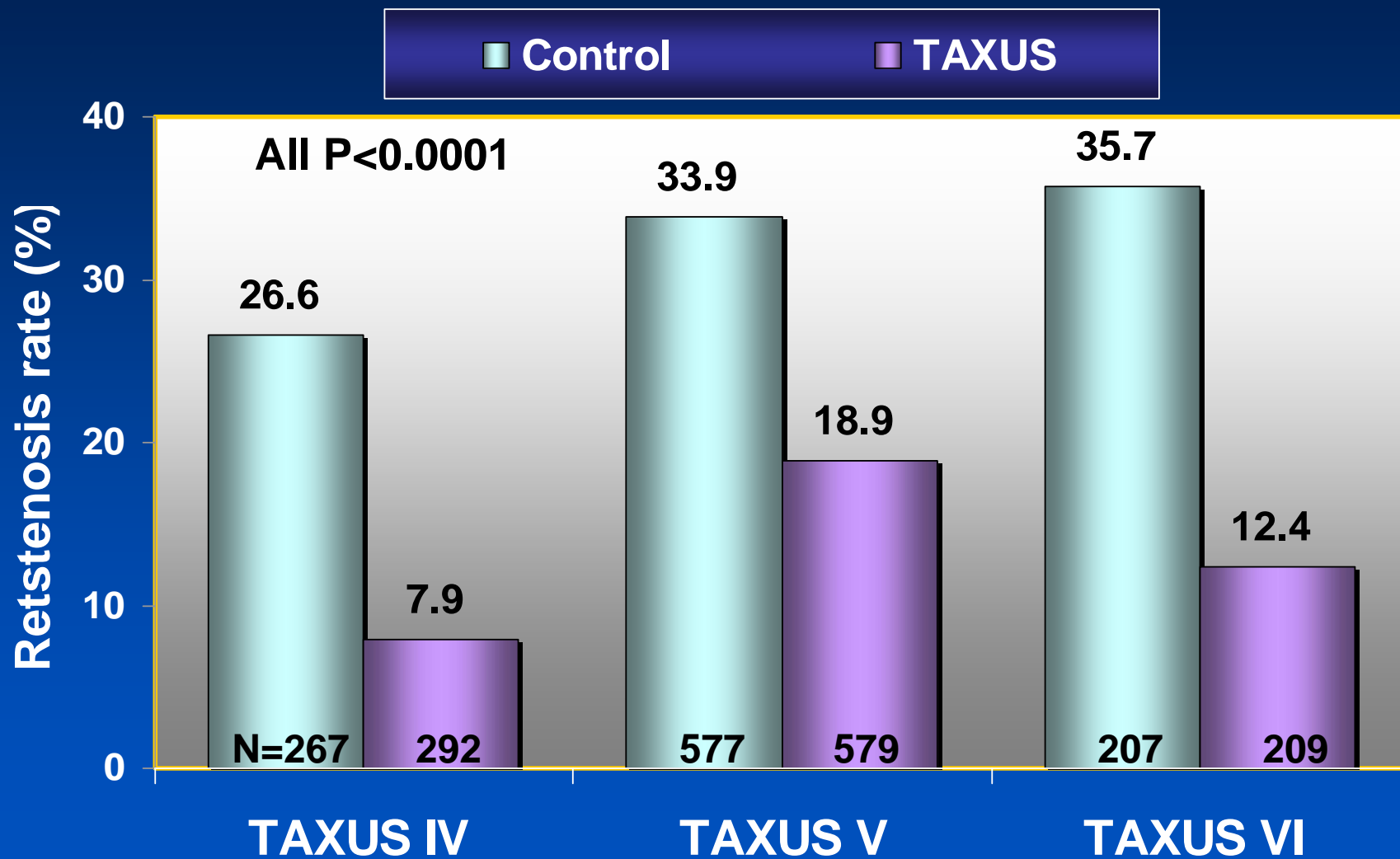
TCT, Oct 2002



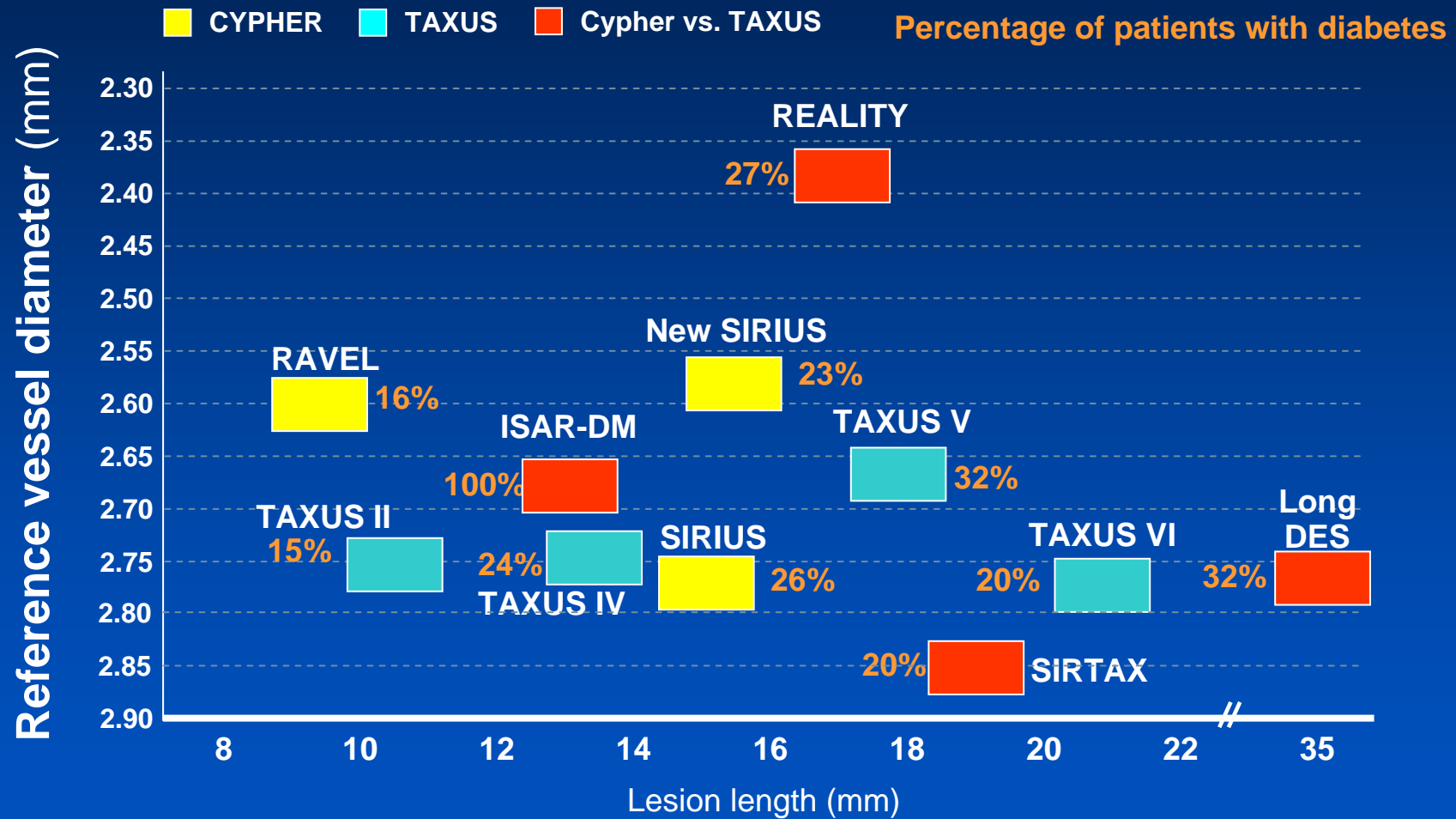
Taxus IV vs. V vs. VI

	TAXUS IV	TAXUS V	TAXUS VI
No of patients	1,314	1,156	446
Lesion length (mm)	14.4	17.3	20.6
Stent length (mm)	21.9	28.7	33.4
AHA/ACC type C lesions (%)	20.3	36.8	55.6
Small vessels (<2.5mm) (%)	32.1	18.7	27.8
Overlapping stent (%)	Not permit	29.1	27.8
Non-target vessel intervention (%)	20.8	NA	23.5
Diabetes mellitus (%)	23.4	31.7	20.0

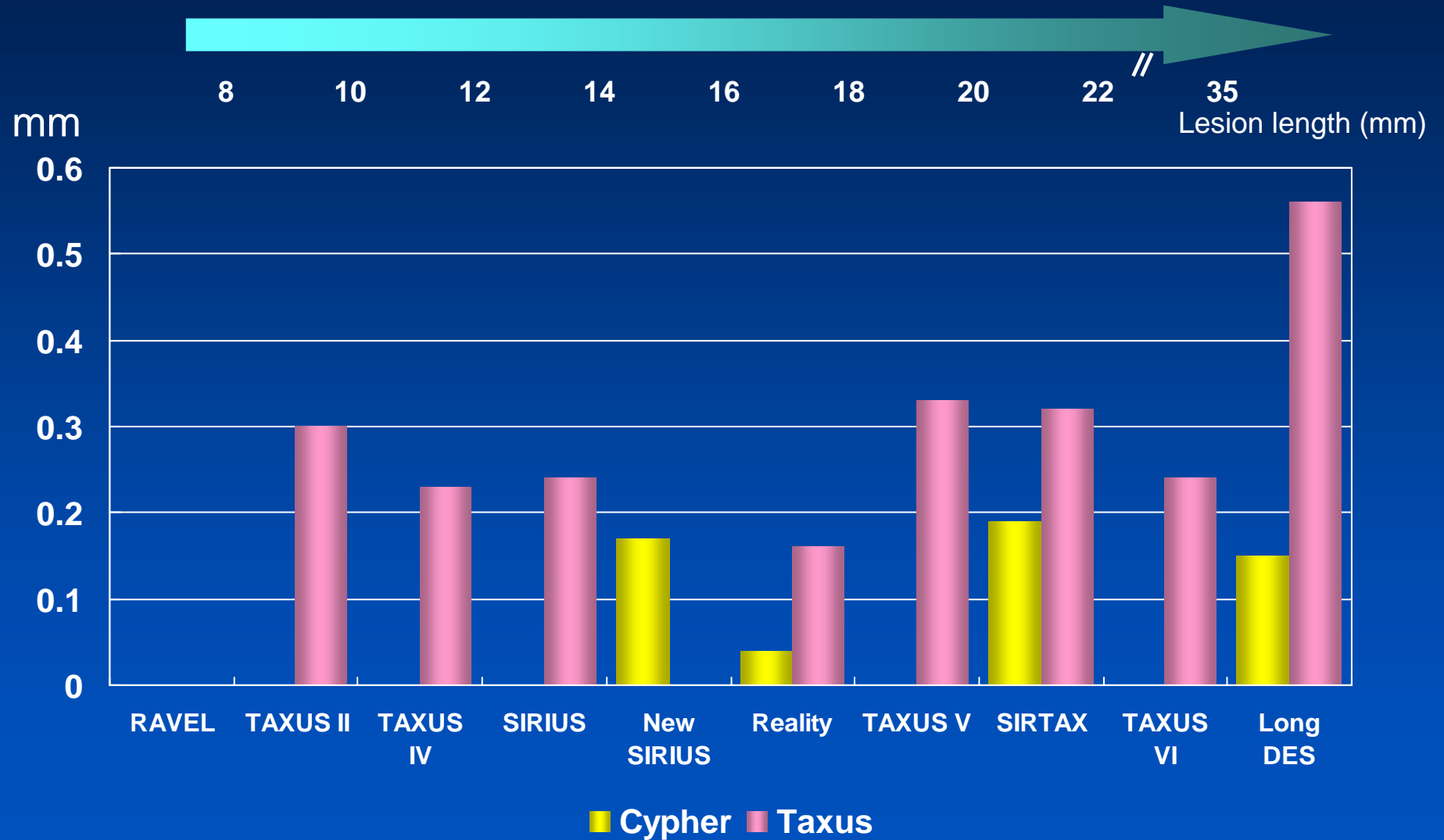
Restenosis of In-Segment



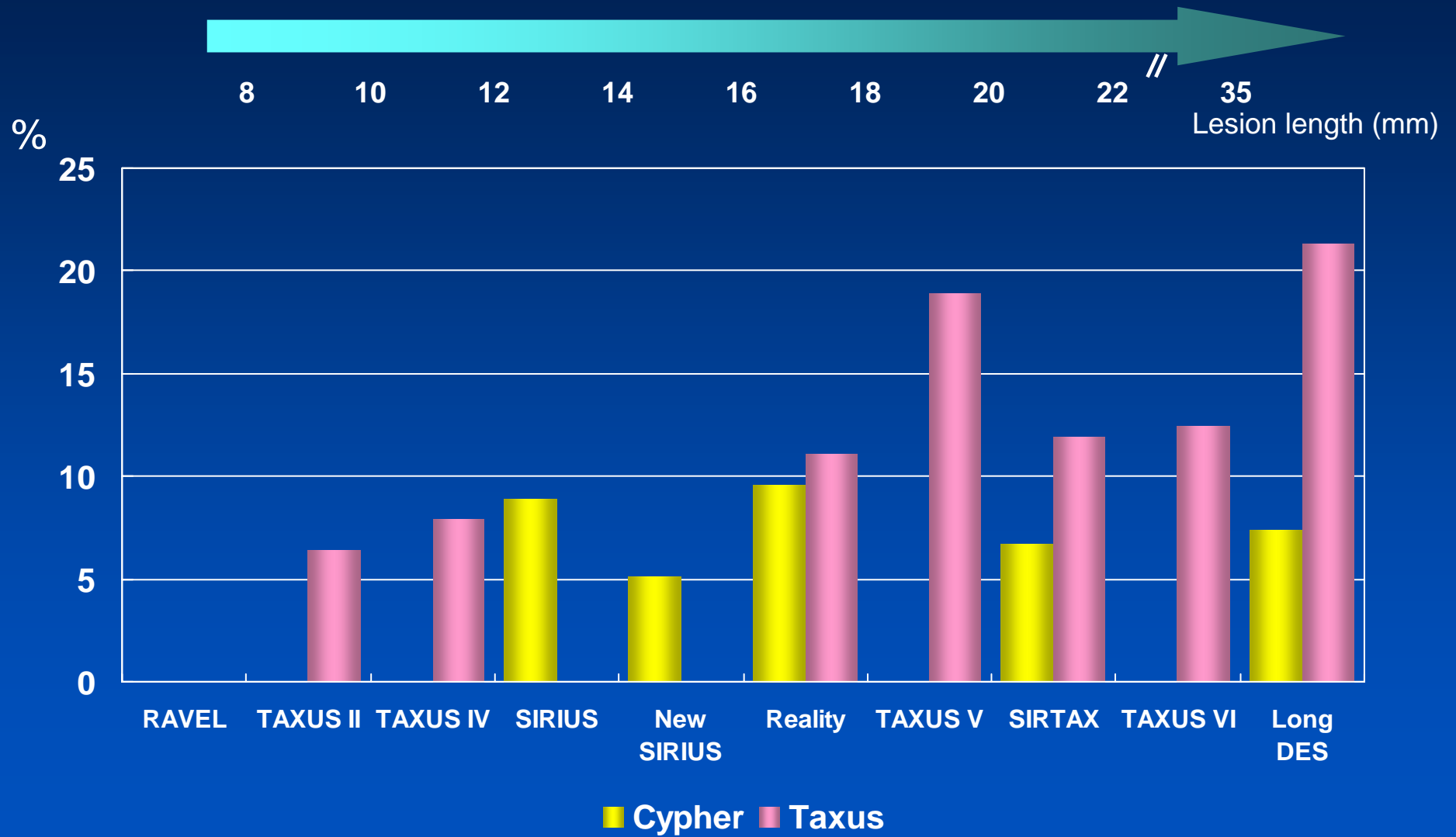
Comparison of Major DES Trials Using Cypher vs. Taxus



In-segment Late Loss



In-segment Restenosis



Full Metal Jacket with Cypher

71 patients (153 lesion, 209 SES)

Lesion length : 52.1 ± 23.1 mm

- Reference vessel diameter: 2.59 ± 0.58 mm
- Stented segment : 83.6 ± 23.9 mm
- Glycoprotein IIb/IIIa inhibitors: 65%

Orlic D, ACC, 2004

Full Metal Jacket with Cypher

	Sirolimus (n=71)
In-hospital events (postprocedure)	
Q-MI	1(1.4%)
Non Q-MI (CK-MB>3 normal)	15(21.1%)
30 days outcomes	
Subacute stent thrombosis	1(1.4%)
Death due to MI	1(1.4%)
6-month follow-up	
TLR	7.2%

Orlic D, ACC, 2004



Very Long Lesion with Cypher in RESEARCH Registry

Stented length > 36 mm (de novo lesion)

Study population	96 pts(102 lesions)
Stented length	62 ± 21mm(41-134 mm)
Stents per lesion	2.7 ± 0.9 (2-6)
6-month angiography	67 patients (71%)

Binary restenosis (DS > 50%) : 11.9%

Serruys PW ACC, 2004



6-month Angiographic Follow-Up

RESEARCH registry

	Proximal	In-stent	Distal
Reference vs1 diameter	3.30	2.82	2.63
Minimal lumen diameter	2.74	2.04	2.12
% diameter stenosis	17	27	19
Late lumen loss	0.02	0.13	-0.16

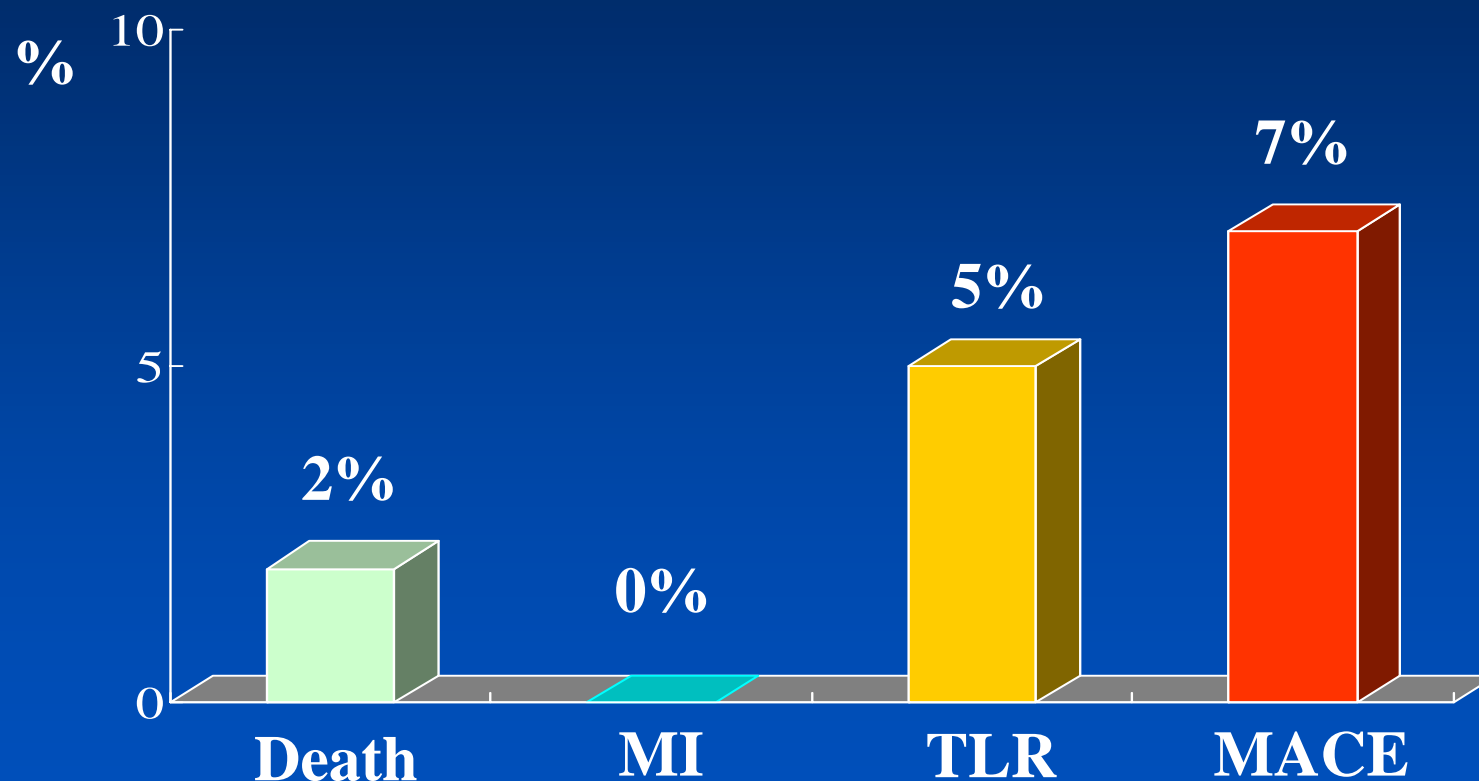
In-lesion binary restenosis : 11.9%

Serruys PW ACC, 2004



Clinical Follow-Up at 320 Days

RESEARCH registry



Serruys PW ACC, 2004



Long DES Study

From March 2003 - to February 2004

De-novo Lesions
($\geq 24\text{mm}$)

637 patients, 739 lesions

CYPHER
($\geq 28\text{mm}$)

294 patients
344 lesions

TAXUS
($\geq 28\text{mm}$)

166 patients
194 lesions

Bare Metal
($\geq 28\text{mm}$)

177 patients
201 lesions

Study End Points

Primary end point

Six-month in-segment restenosis rate

Secondary end points

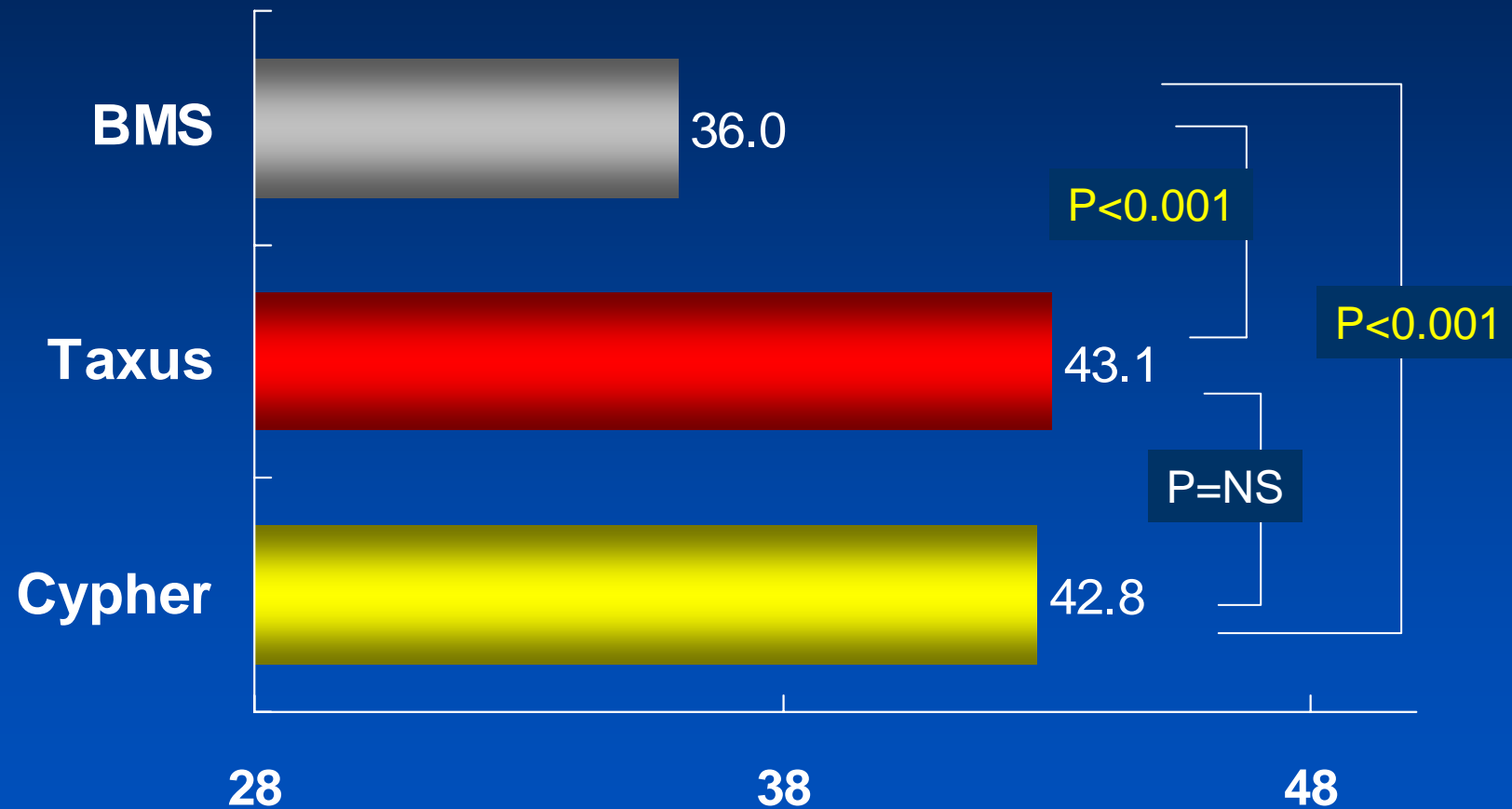
1. In-segment late loss
2. Major adverse cardiac events including death, MI, or TLR

Baseline QCA

	Cypher (n=337)	Taxus (n=194)	BMS (n=201)	P value
Reference, mm				
Proximal	3.01±0.49 #	3.10±0.49 **	3.27±0.55	<0.001
Distal	2.59±0.45 * #	2.71±0.53	2.84±0.57	<0.001
Mean	2.80±0.41 * #	2.90±0.48 **	3.10±0.54	<0.001
Lesion length, (mm)	35.3±14.3 #	36.3±14.5 **	32.0±12.3	0.004
MLD, (mm)	0.76±0.47	0.77±0.49	0.78±0.54	0.942
DS, %	72.5±16.6	73.6±16.2	74.4±17.0	0.450

Between groups: * p<0.025 Cypher vs Taxus; # p<0.025 Cypher vs BMS; **, p<0.025 Taxus vs. BMS

Total Stent Length Treated



Procedural Characteristics

	Cypher (n=337)	Taxus (n=194)	Control (n=201)	P value
Used stents	1.65±0.71 #	1.63±0.70 **	1.28±0.49	<0.001
Overlapping	179 (53) #	100 (52) **	52 (26)	<0.001
Maximal pressure, (atm)	16.0±3.6 * #	13.2±3.9 **	12.0±3.3	<0.001
Maximal device diameter, (mm)	3.35±0.37 *	3.40±0.41	3.47±0.52	0.014
IVUS guidance	266 (79) #	144 (74) **	96 (48)	<0.001
Use of Abciximab	8 (3)	2 (1)	7 (4)	0.266

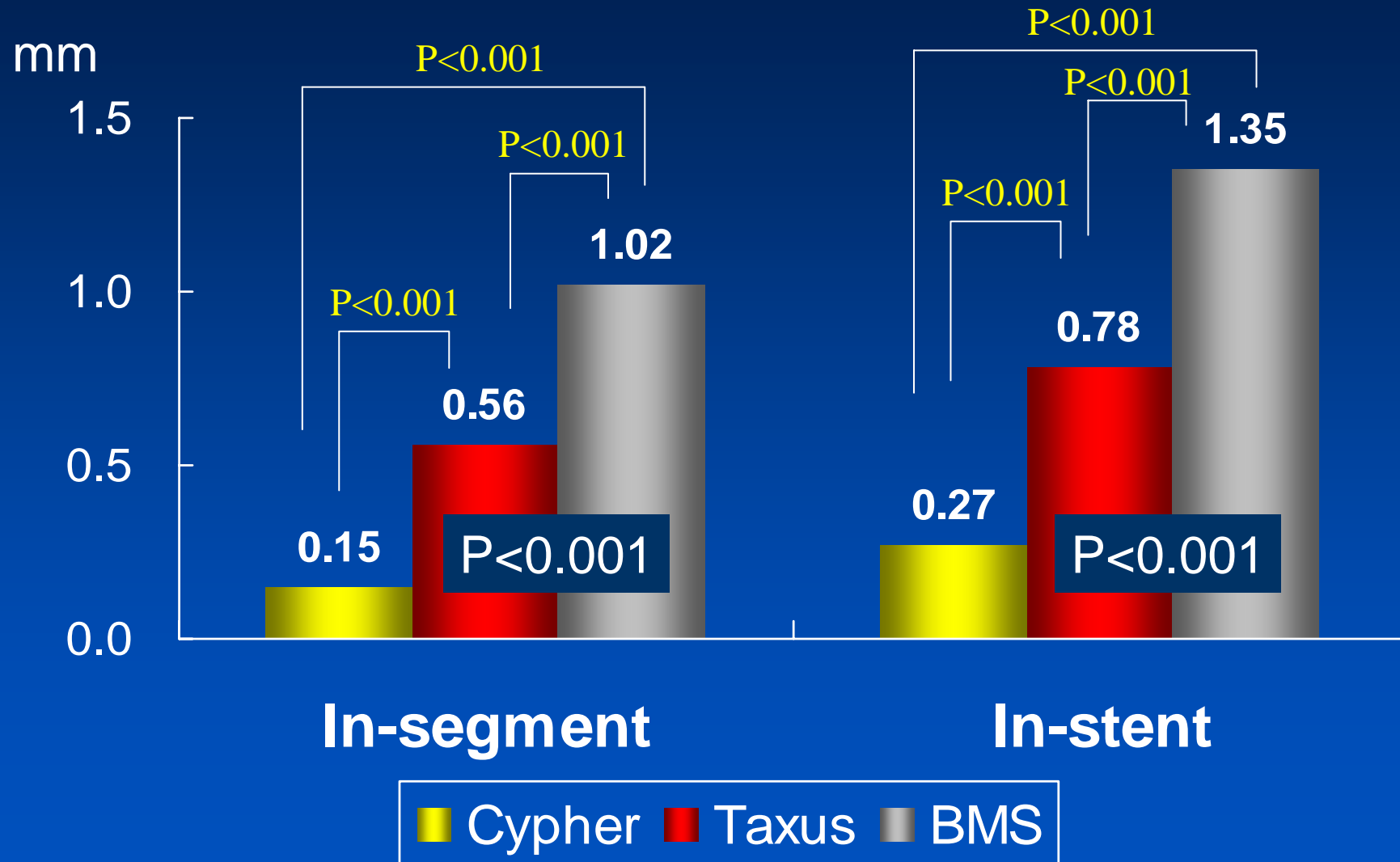
Between groups: * p<0.025 Cypher vs Taxus; # p<0.025 Cypher vs BMS;**, p<0.025 Taxus vs. BMS

In-Hospital Outcomes

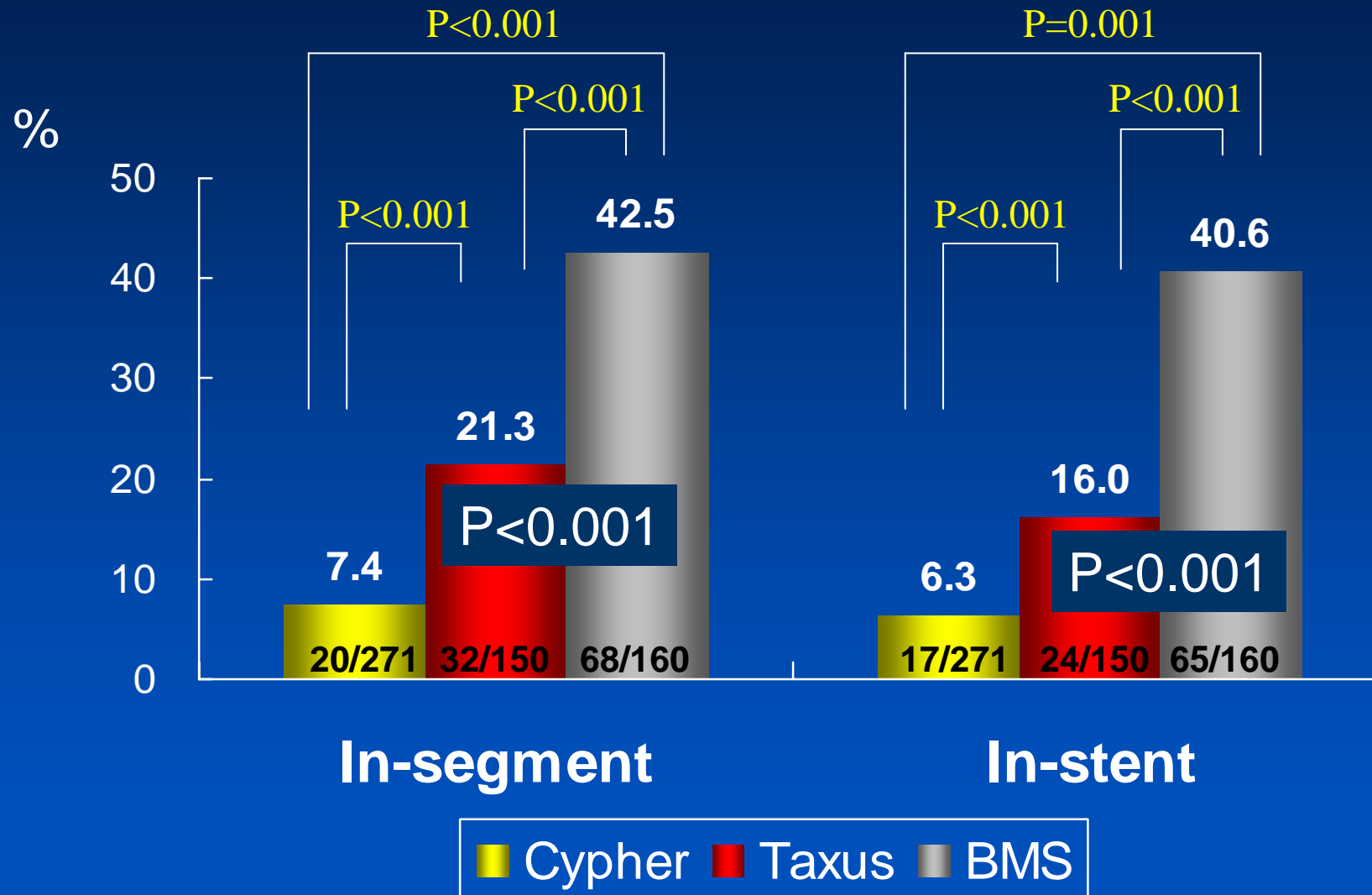
	Cypher (n=294)	Taxus (n=166)	Control (n=177)	P value
Angiographic success (%)	329 (98)	191 (99)	193 (96)	0.296
Death	0 (0)	0 (0)	1 (0.6)	0.422
MI				
Q wave	0 (0)	0 (0)	1 (0.6)	0.272
Non-Q wave	26 (8.8)	16 (9.6)	14 (7.9)	0.852
Stent thrombosis	0 (0)	0 (0)	1 (0.6)	0.272
TLR	0 (0)	0 (0)	1 (0.6)	0.272
MACE	26 (8.8)	16 (9.6)	15 (8.5)	0.928

Between groups: * p<0.025 Cypher vs Taxus; # p<0.025 Cypher vs BMS;**, p<0.025 Taxus vs. BMS

Late Loss

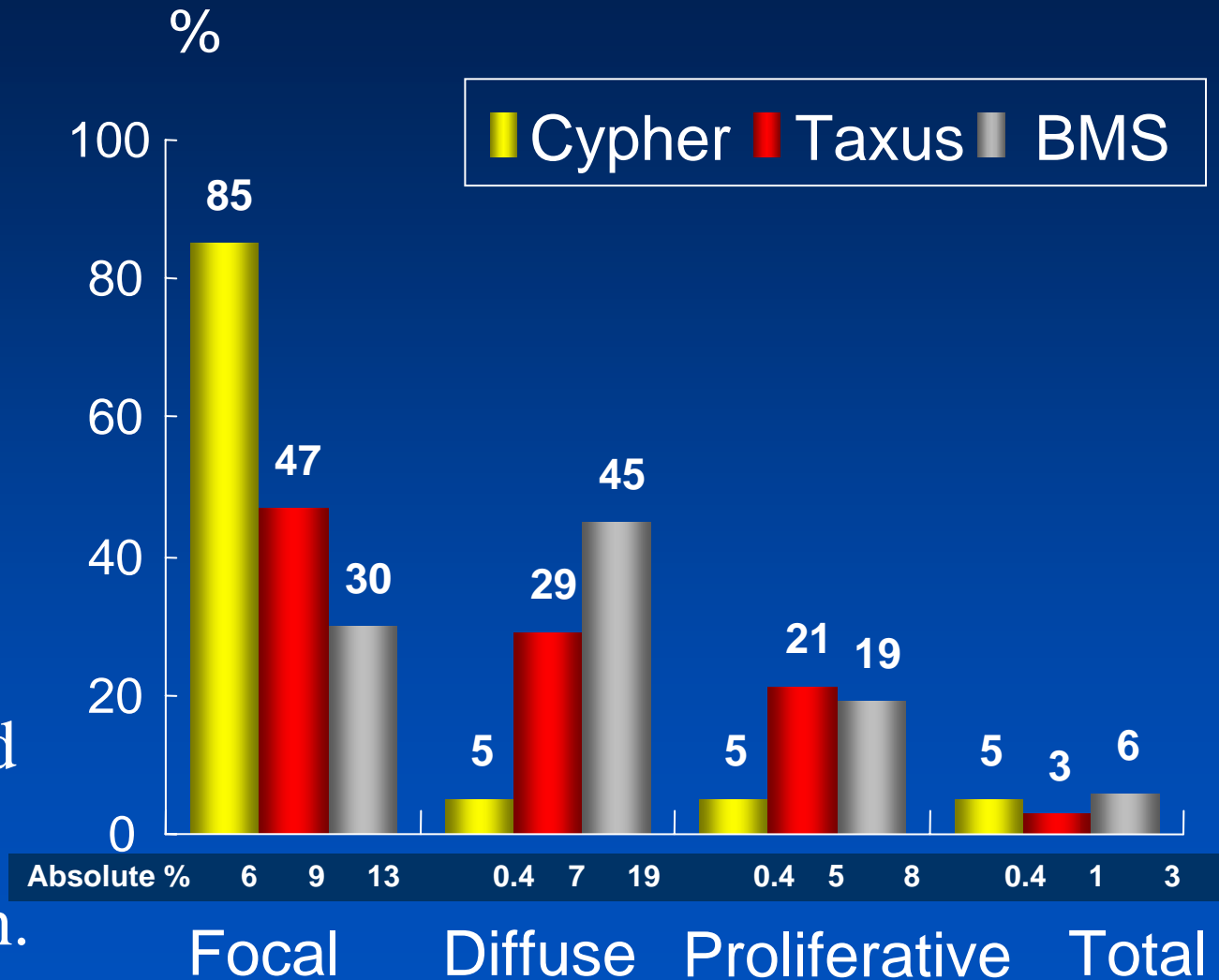


Restenosis Rate



Restenosis Pattern

- The majority of restenosis in the Cypher occurred as a localized lesion.
- However, the Taxus and BMS restenosis commonly occurred as a diffuse or proliferative pattern.



Predictors of Restenosis

by Multivariate Analysis



Predictors of Restenosis Overall

Variables	Relative Risk	95% C.I.	P value
■ Bare metal stent	8.01	4.90-13.11	<0.001
■ Lesion length (10mm)	1.29	1.10-1.51	0.002
■ MLD after procedure (mm)	0.32	0.19-0.53	<0.001

Predictors of Restenosis DES subgroup

Variables	Relative Risk	95% C.I.	P value
■ Taxus stent	3.65	1.96-6.79	<0.001
■ Lesion length (10mm)	1.31	1.08-1.60	0.006
■ MLD after procedure (mm)	0.29	0.13-0.61	0.001

Predictors of Restenosis

Cypher or Taxus subgroup

		R.R	95% C.I.	P value
Cypher	■ Multiples stent	5.62	1.60-19.68	0.007
Taxus	■ MLD after procedure (mm)	0.19	0.05-0.57	0.004
	■ Lesion length (10mm)	1.36	1.02-1.82	0.037
BMS	■ MLD after procedure (mm)	0.31	0.15-0.64	0.001
	■ Diabetes mellitus	2.00	1.01-3.98	0.048

Summary : Restenosis Predictors

- The traditional risk factors of restenosis in the BMS era (multiple stents, lesion length, MLD after procedure) remained important determinants of restenosis in long DES implantation.
- The principles of coronary intervention in the BMS era - “the bigger, the better” or “the shorter, the better”- may be applied to the DES era in long lesion intervention. However, the clinical impact of such risk factors in the DES may not be as large as the BMS because of low absolute number of restenosis.

Angiographic Restenosis : DES vs BMS

	DES	BMS		P-value
Overall	12.4	42.5		<0.0001
Male	12.1	45.6		<0.0001
Female	13.9	31.4		0.019
Diabetes	15.2	52.7		<0.0001
No Diabetes	11.1	37.1		<0.0001
LAD	10.3	45.9		<0.0001
Non-LAD	14.8	34.7		<0.0001
Small Vessel (≤ 2.75)	15.0	56.6		<0.0001
Large Vessel	10.1	35.5		<0.0001
Stent length >45mm	18.4	44.0		0.004
Stent length ≤ 45 mm	8.5	42.2		<0.0001
Multiple stent	15.8	45.2		<0.0001
Single	8.5	41.5		<0.0001

" DES Better "



Angiographic Restenosis : Cypher vs Taxus

	Cypher	Taxus		P-value
Overall	7.4	24.3		<0.0001
Male	6.6	21.3		<0.0001
Female	10.5	21.9		0.119
Diabetes	9.9	23.5		0.033
No Diabetes	6.3	20.2		<0.0001
LAD	5.7	20.5		0.001
Non-LAD	9.8	22.1		0.020
Small Vessel (≤ 2.75)	9.2	27.0		0.001
Large Vessel	5.7	17.2		0.005
Stent length >45mm	13.9	25.8		0.056
Stent length ≤ 45 mm	3.5	18.2		<0.0001
Multiple stent	12.1	22.5		0.041
Single	2.3	20.0		<0.0001

“ Cypher Better ”

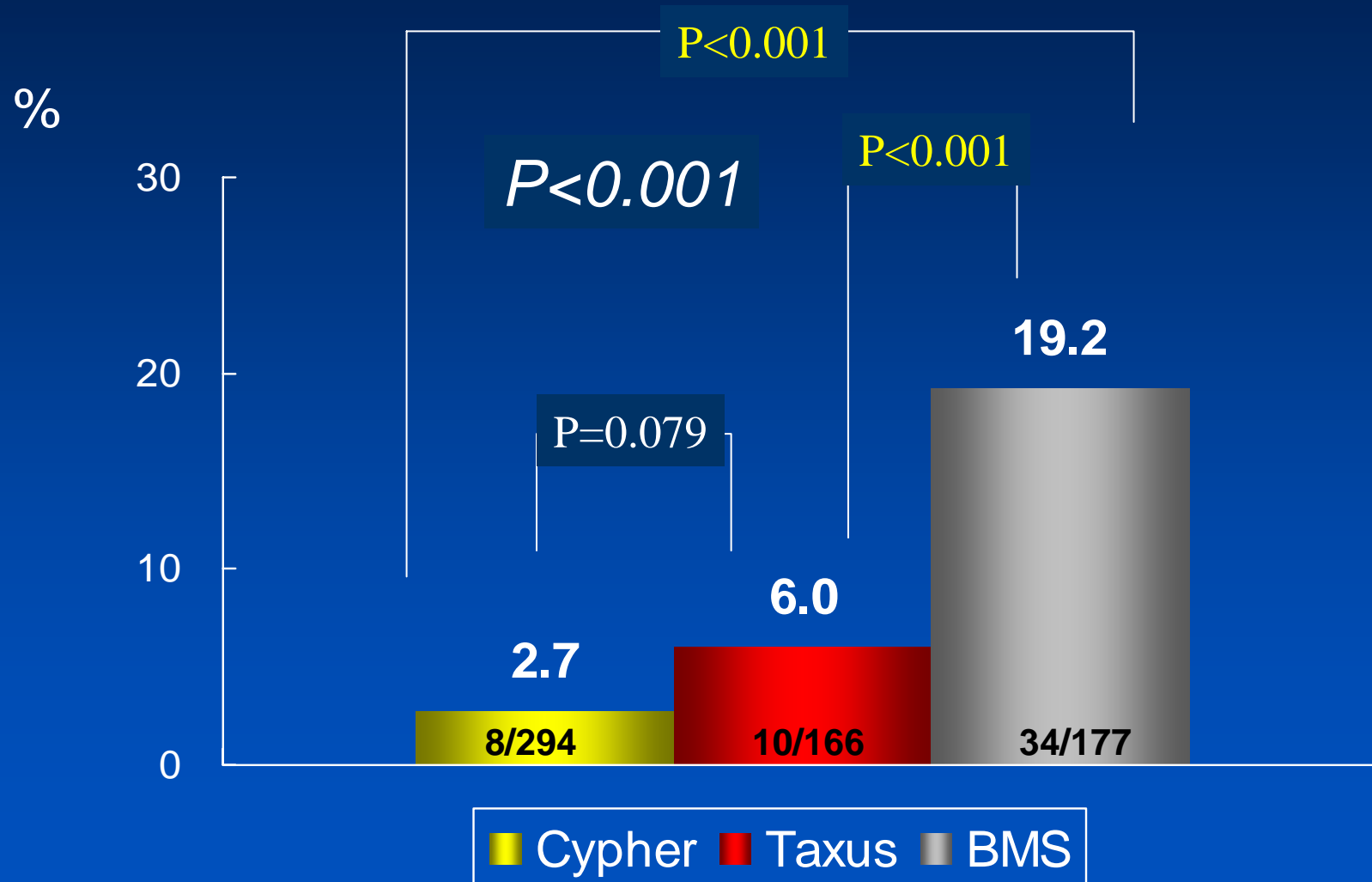
0.3 0.4 0.5 0.6 0.7 0.8 0.9 1.0 0.9 0.8 0.7

Nine-Month Outcomes

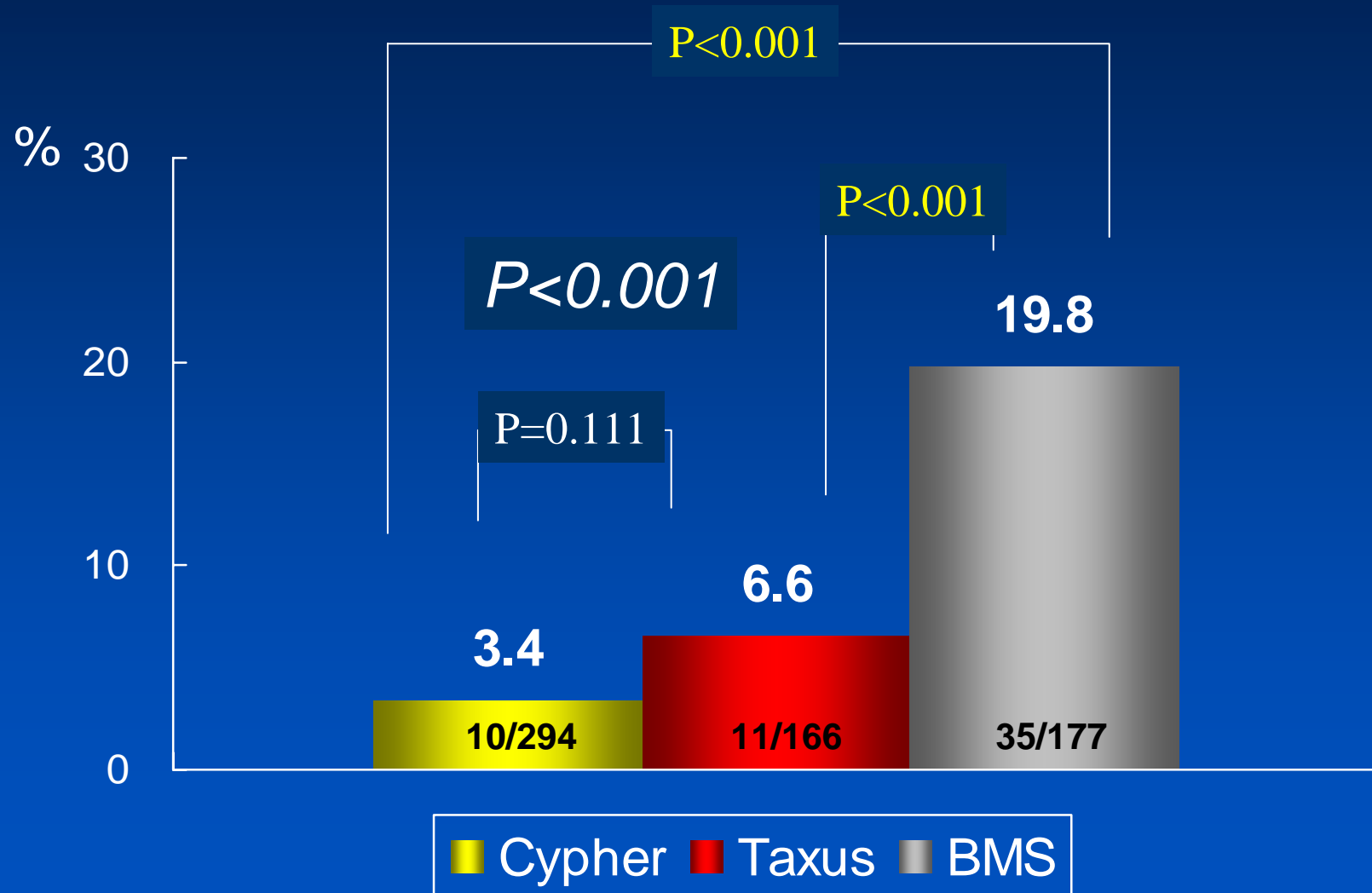
	Cypher (n=294)	Taxus (n=166)	Control (n=177)	P value
Death	2 (0.7)	1 (0.6)	1 (0.6)	0.987
MI	0 (0)	0 (0)	1 (0.6)	0.272
Q wave	0 (0)	0 (0)	1 (0.6)	
Non-Q wave	0 (0)	0 (0)	0 (0)	
Stent thrombosis	0 (0)	0 (0)	1 (0.6)	0.272
TLR	8 (2.7) #	10 (6.0) **	34 (19.2)	<0.001
Repeat PCI	7	7	32	
CABG	1	2	2	
MACE	10 (3.4) #	11 (6.6) **	35 (19.8)	<0.001

Between groups: * p<0.025 Cypher vs Taxus; # p<0.025 Cypher vs BMS; **, p<0.025 Taxus vs. BMS

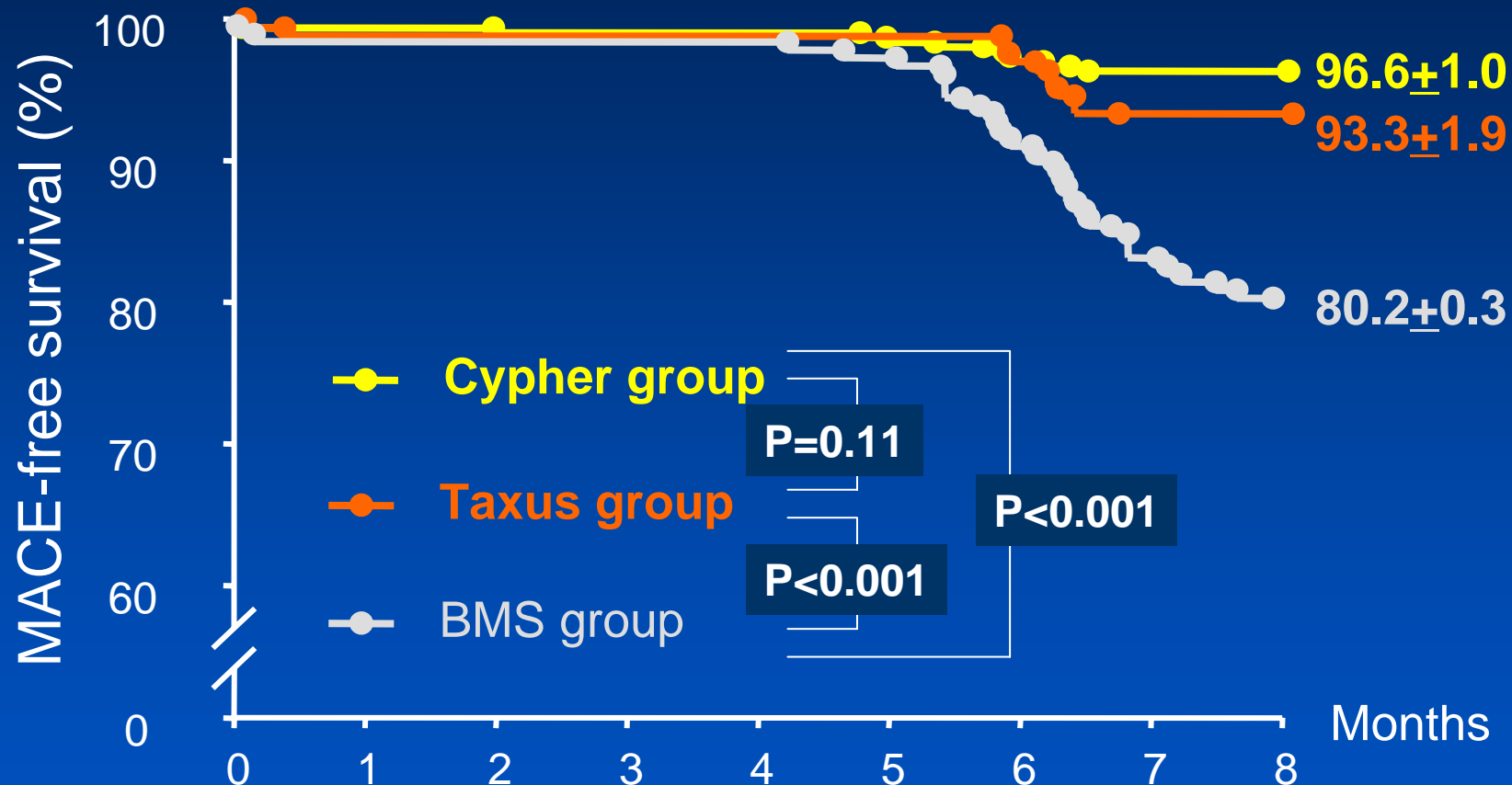
Nine-Month TLR



Nine-Month MACE



MACE-free Survival



Conclusions: DES vs. BMS

- Two leading DES including Cypher[®] sirolimus-eluting stent and Taxus[™] paclitaxel-eluting stent implantation for long coronary lesions was safe with no incidents of death, stent thrombosis, or Q wave myocardial infarction.
- Both DES was associated with low rate of in-segment restenosis and TLR for long coronary lesions compared to BMS.

Conclusions: Cypher vs. Taxus

- Even though the Cypher group had narrower vessels at baseline and after procedure, those patients had less late loss and lower restenosis rate than the Taxus stent.
- However, the superior benefit of the Cypher stent in terms of late loss and restenosis rate was not translated into lower repeat revascularization rate, compared to the Taxus stent.