

Angioplasty Summit 2005, Korea

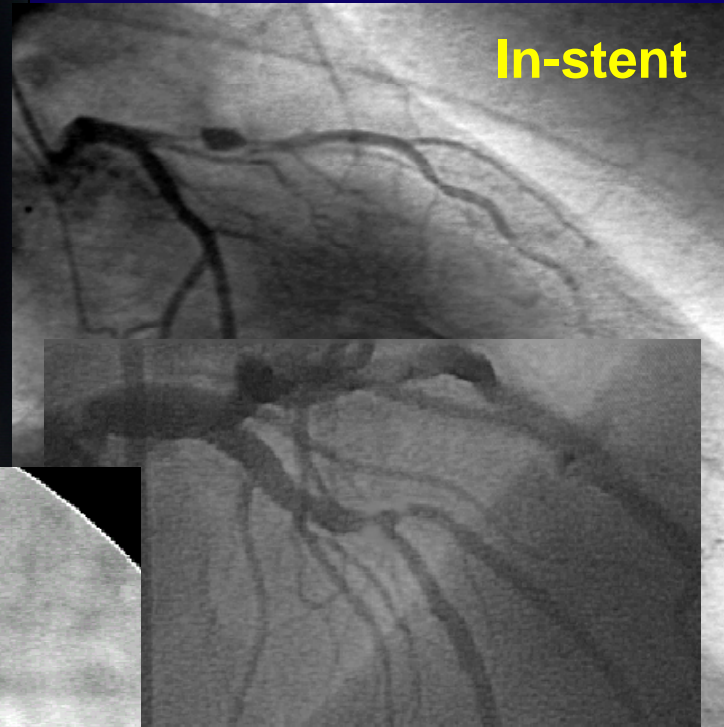
Is the TAXUS Stent Benefit Extended to the Most Complicated Patients and Lesions?

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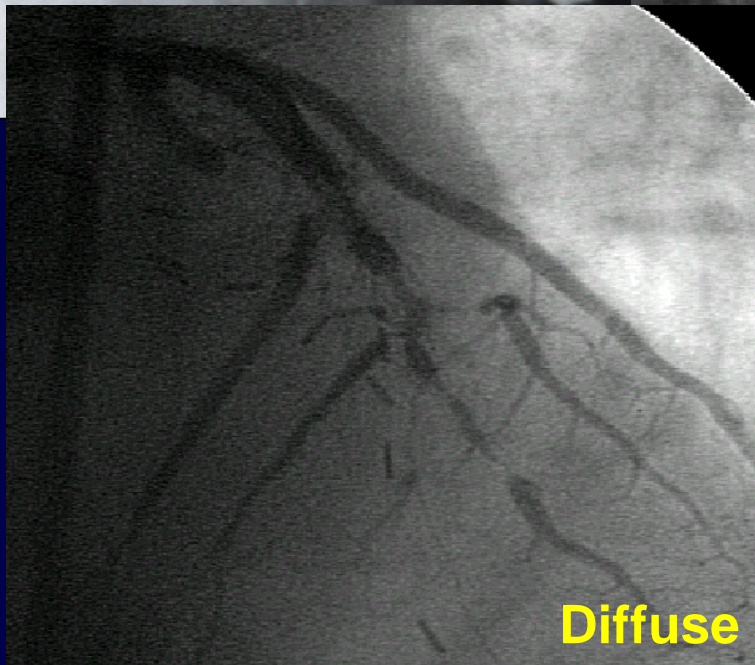
Heart Center Siegburg, Siegburg, Germany
Stanford University, School of Medicine, CA, USA



SVG



In-stent

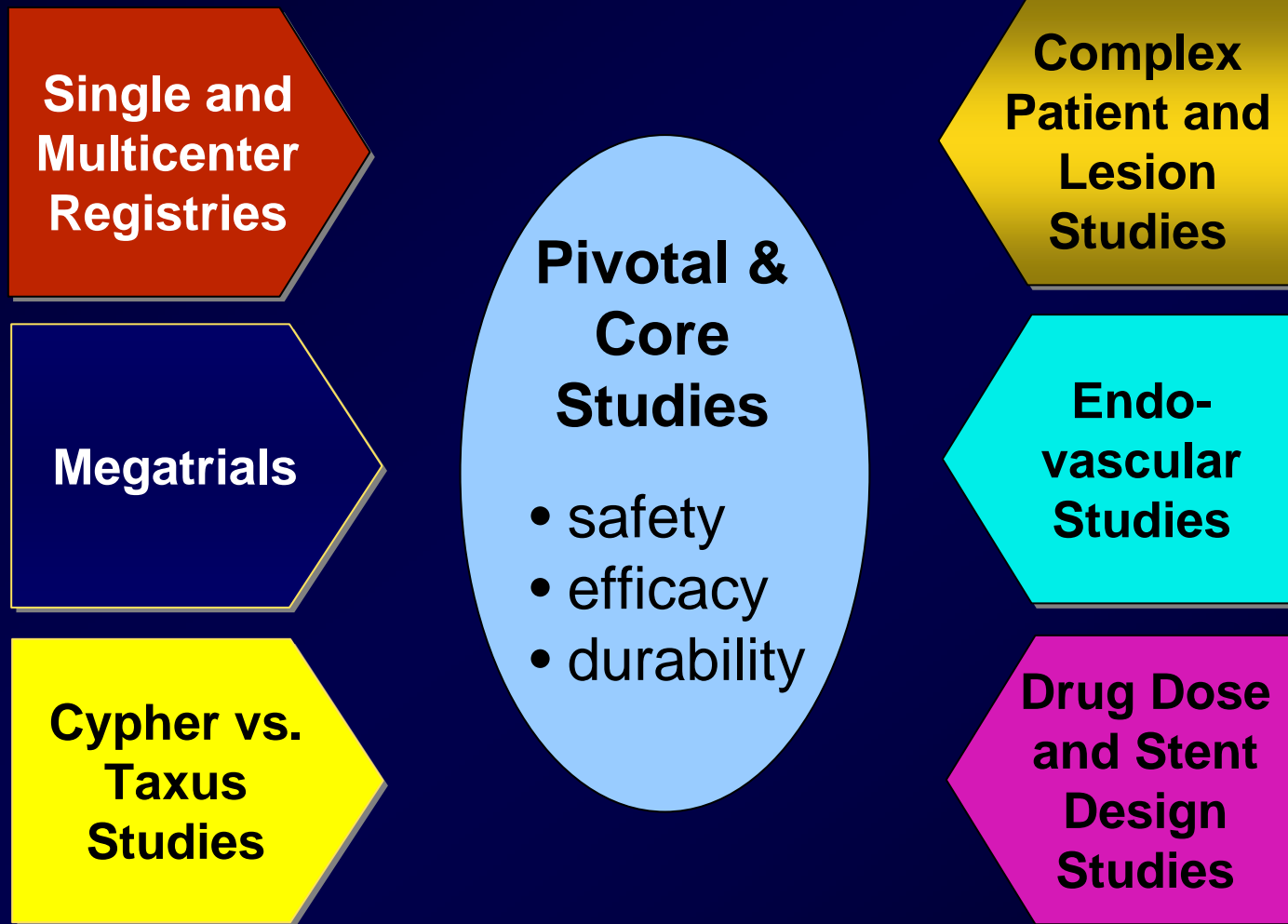


Diffuse



Bifurcation

DES Clinical Trial Programs



DES Clinical Trial Programs

Single and
Multicenter
Registries

Complex
Patient and
Lesion
Studies

TAXUS Clinical Development

Increasing complexity

	Stent Diameter	Lesion Length	Lesions	Vessels		Dose Formulation
				TV	non-TV	
TAXUS I	3.0-3.5 mm	10-12 mm	single	1	0	SR
TAXUS II	3.0-3.5 mm	10-12 mm	single	1	0	SR & MR
TAXUS III-ISR	3.0-3.5 mm	10-12 mm	ISR	1	0	SR
TAXUS IV	2.5-3.5 mm	10-28 mm	single	1	1	SR
TAXUS VI	2.5-3.5 mm	≤ 40 mm	multiple overlap	1	1	MR
TAXUS V	2.25-4.0 mm	≤ 46 mm	multiple overlap	1	1	SR
TAXUS V-ISR	2.5-4.0 mm	≤ 46 mm	ISR	1	1	SR

TAXUS Program

Clinical strategy

	Stent Diameter	Lesion Length	Lesions	Vessels		Dose Formulation
				TV	non-TV	
TAXUS I	3.0-3.5 mm	10-12 mm	single	1	0	SR
TAXUS II	3.0-3.5 mm	10-12 mm	single	1	0	SR & MR
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TAXUS V-ISR	2.5-4.0 mm	≤ 46 mm	ISR	1	1	SR

feasibility & safety

efficacy

pivotal

indication expansion

Complex Lesions

- Long Lesions
- Small vessels
- Multiple Stenting
- Chronic Total Occlusions
- Unprotected left mains
- Bifurcations
- ...

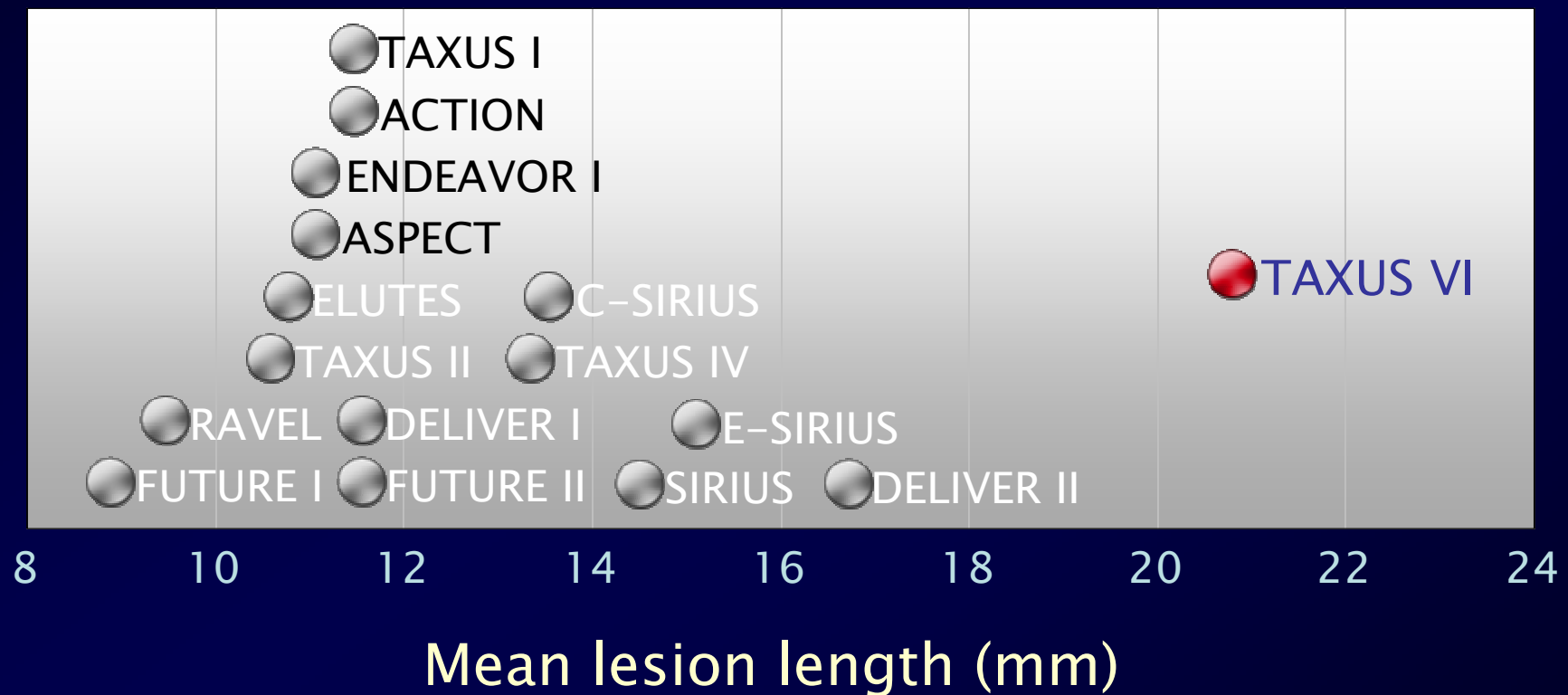
Complex Lesions

TAXUS VI

- Long Lesions
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- Chronic Total Occlusions
- Unprotected left mains
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- ...

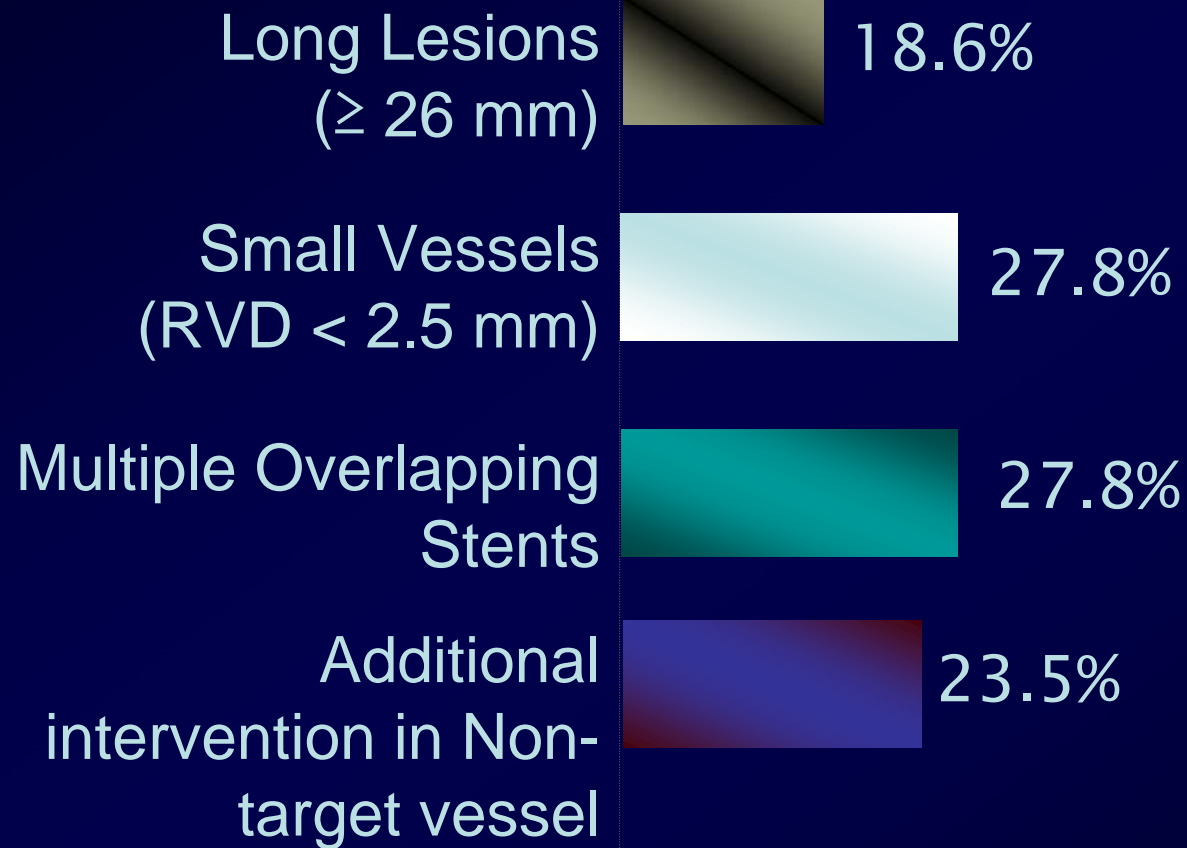
TAXUS VI:

International Long Lesion Study

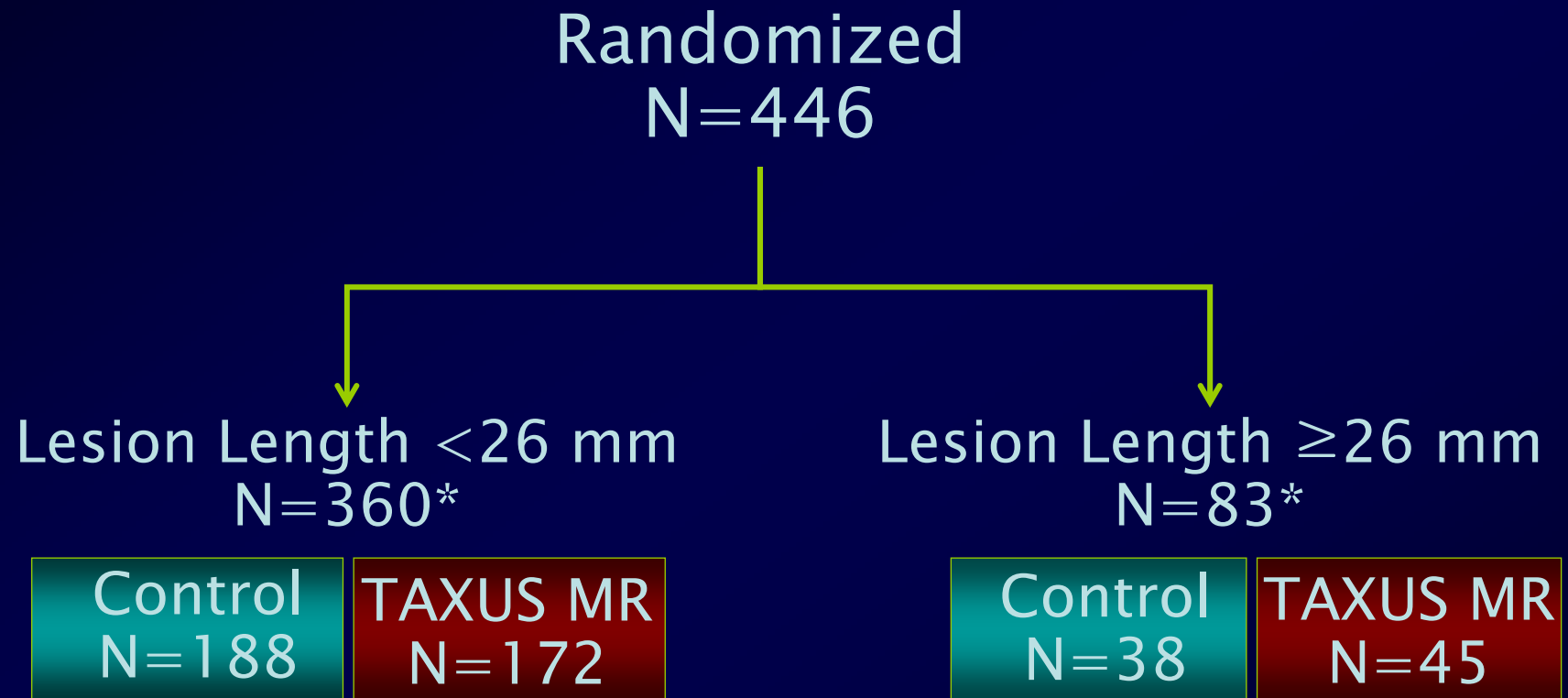


Complex Lesions & Procedures

% of Patients
N=446

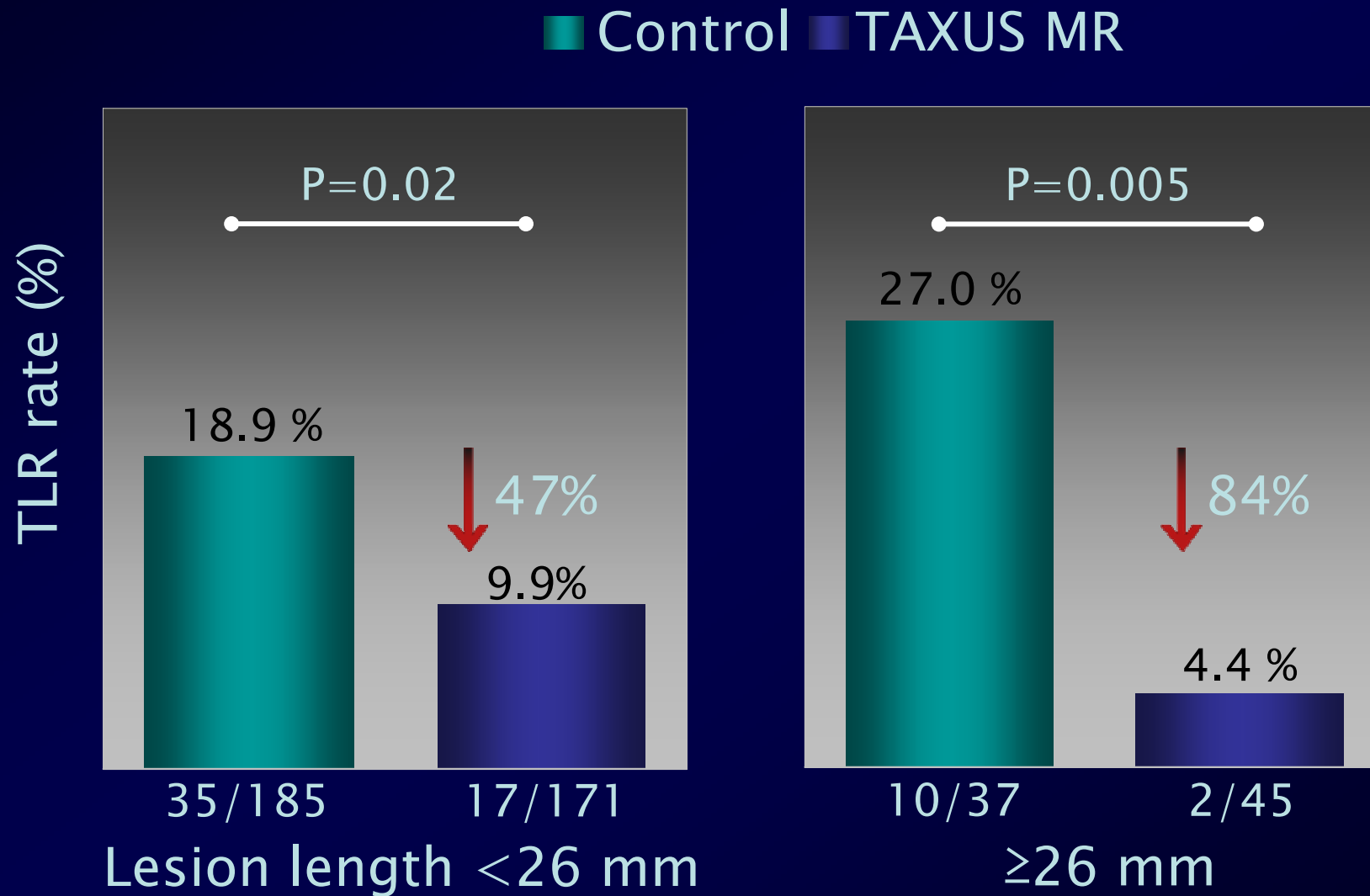


Long Lesions in TAXUS VI

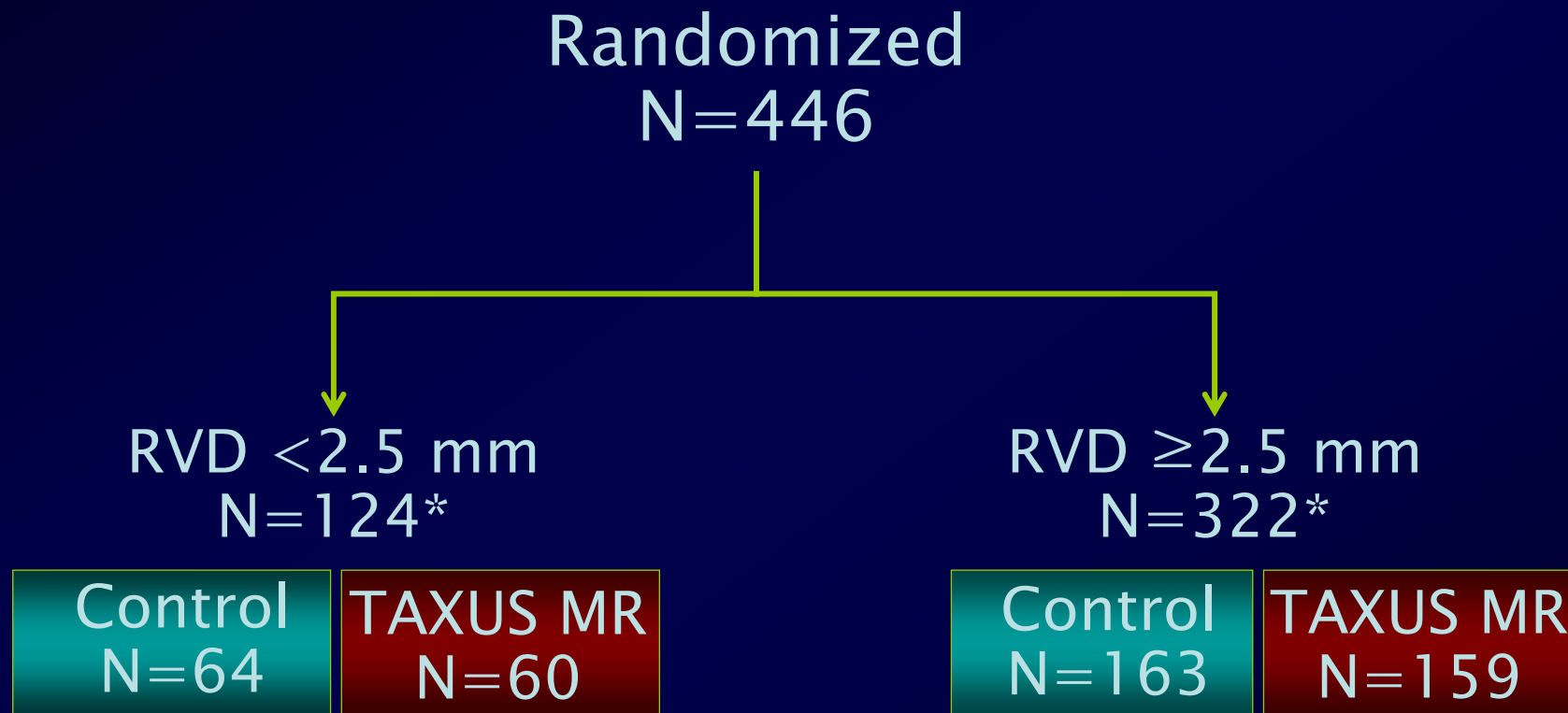


*Patients with 12-month follow-up

Impact of Lesion Length on TLR (12 Months)



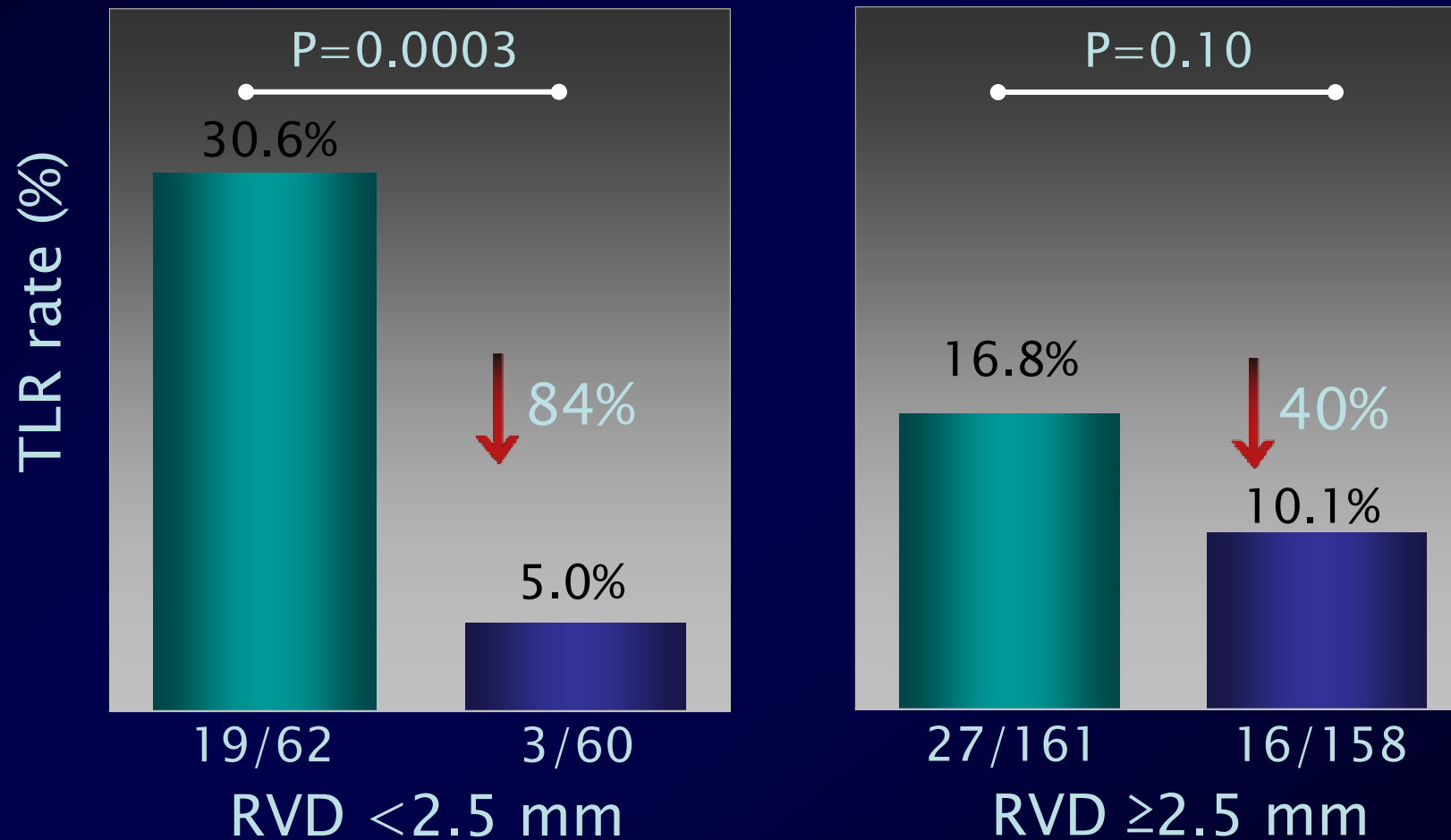
Small Vessels in TAXUS VI



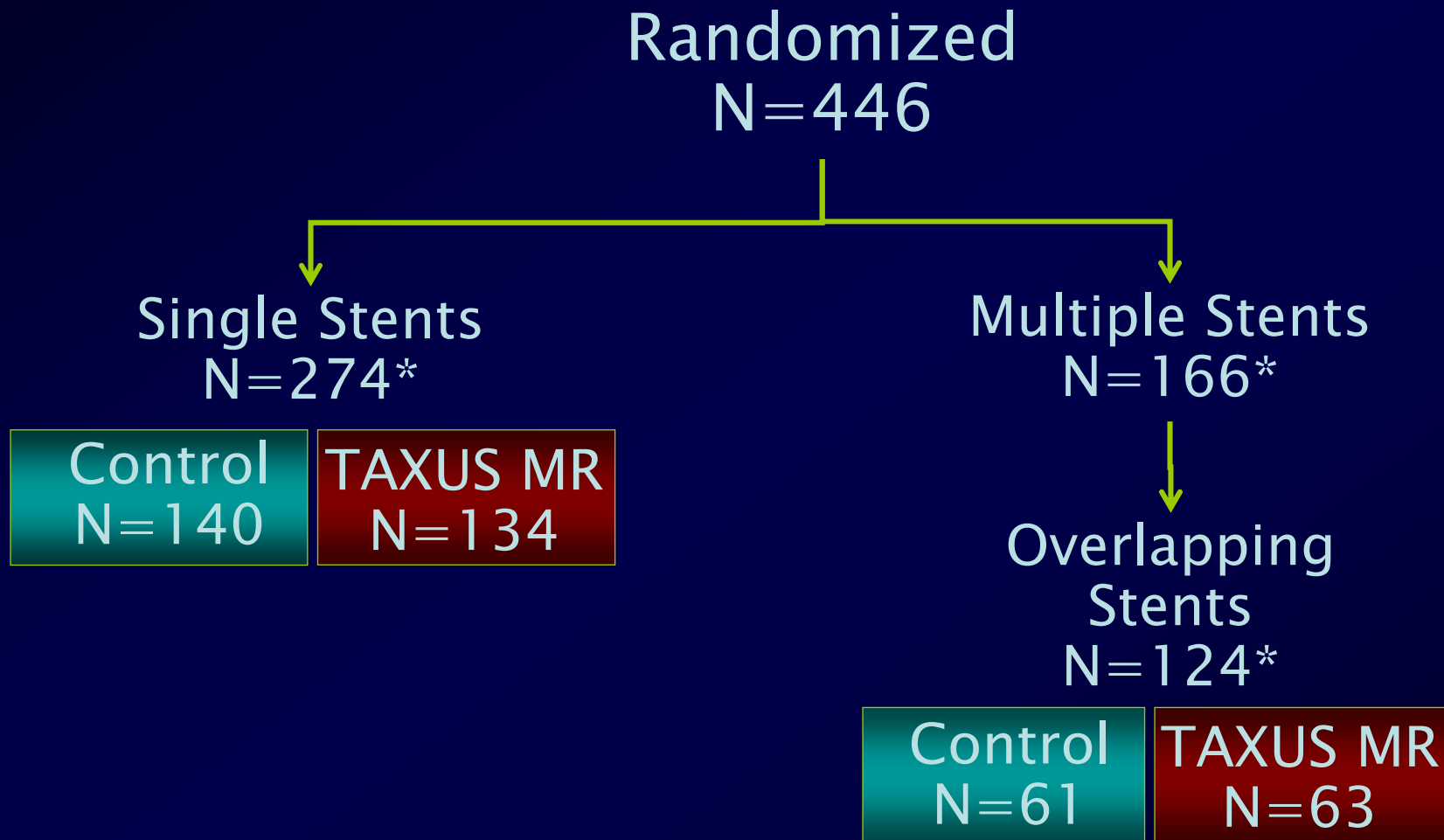
*Patients with 12-month follow-up

Impact of Vessel Size on TLR (12 Months)

■ Control ■ TAXUS MR

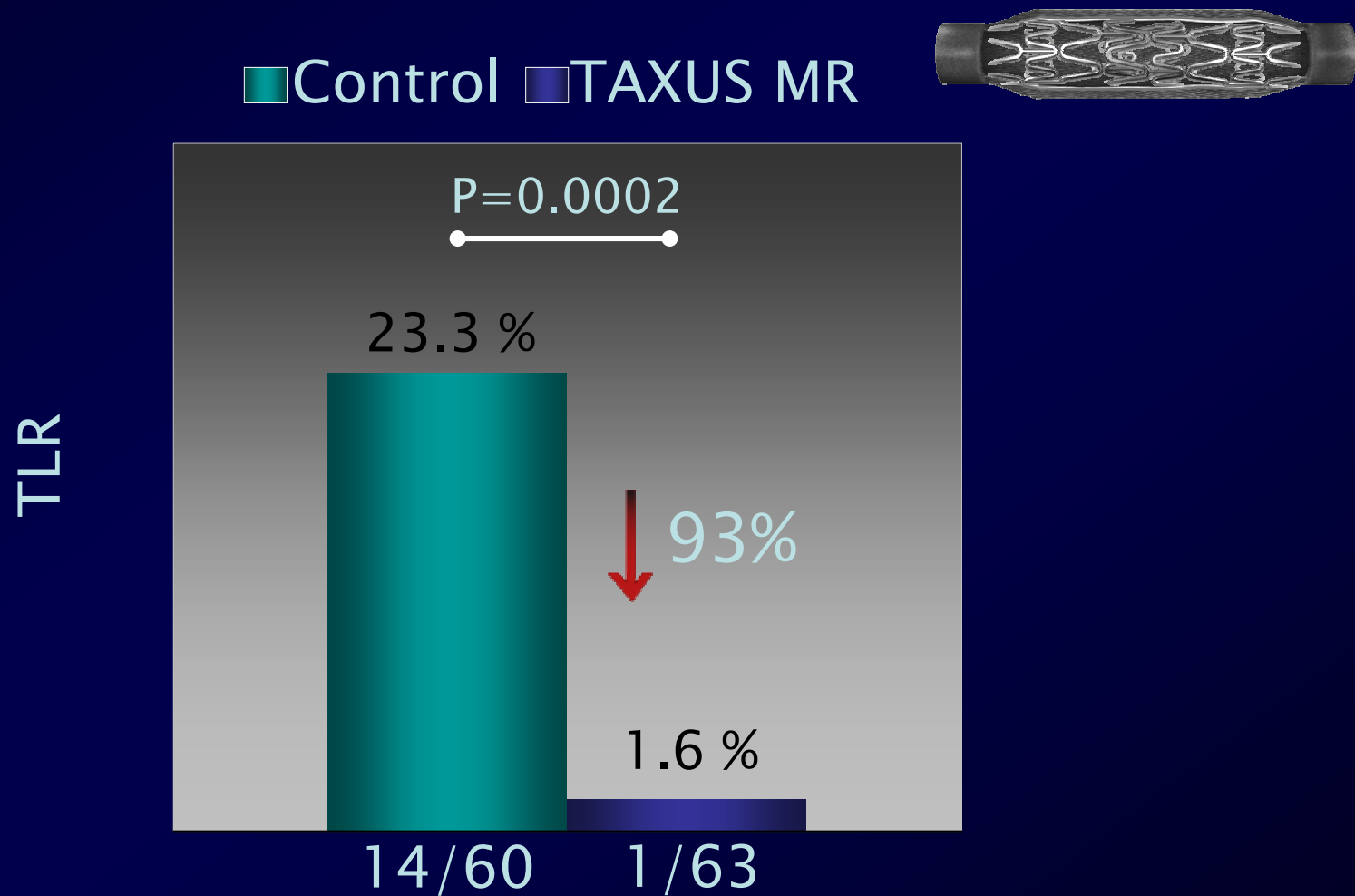


Multiple Overlapping Stents in TAXUS VI

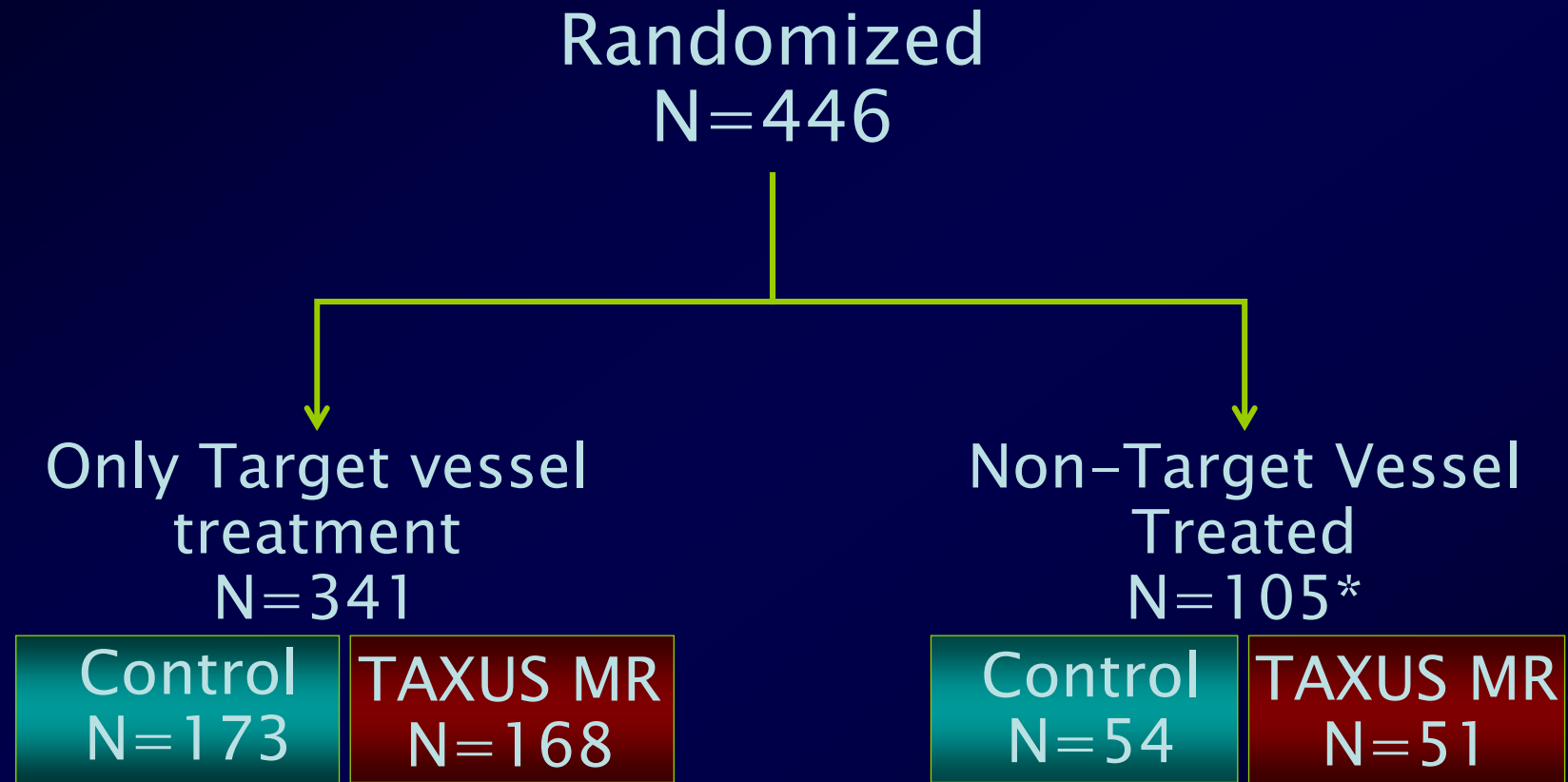


*Patients with 12-month follow-up

TLR with Overlapping Stents

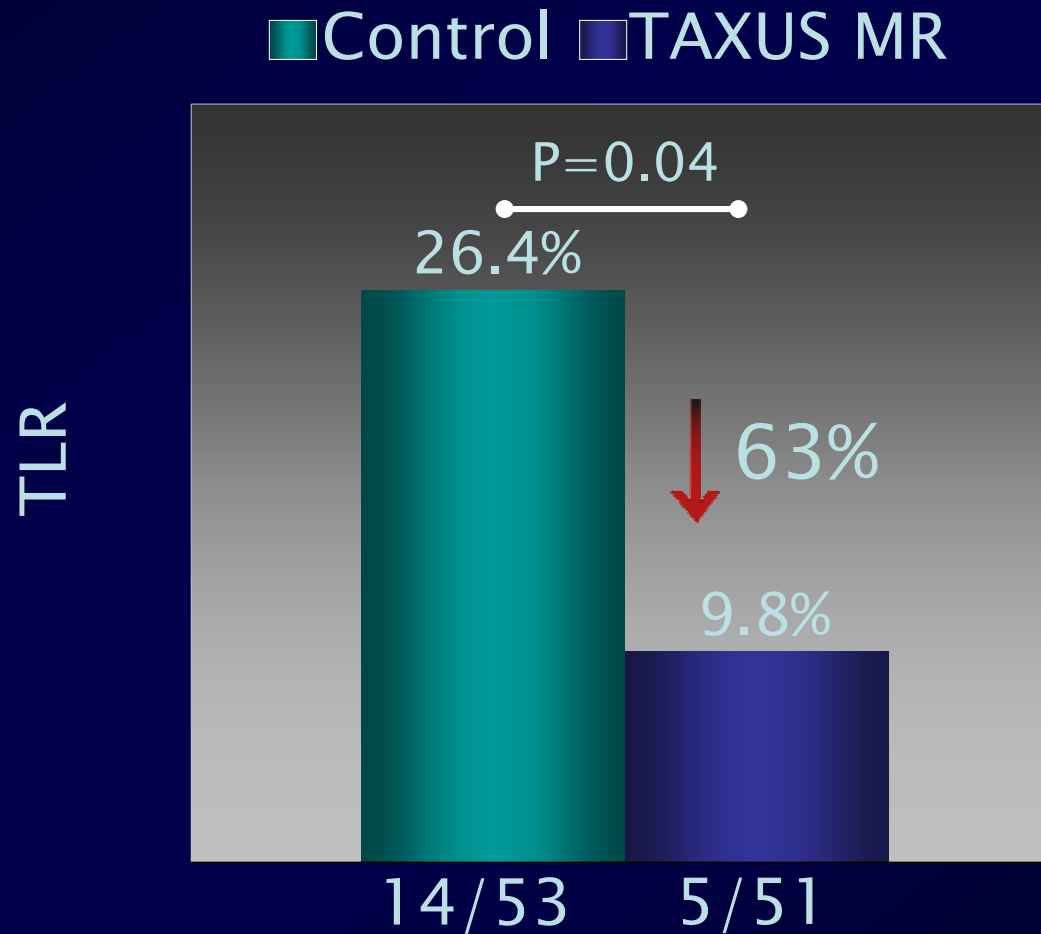


Multi-Vessel Procedures

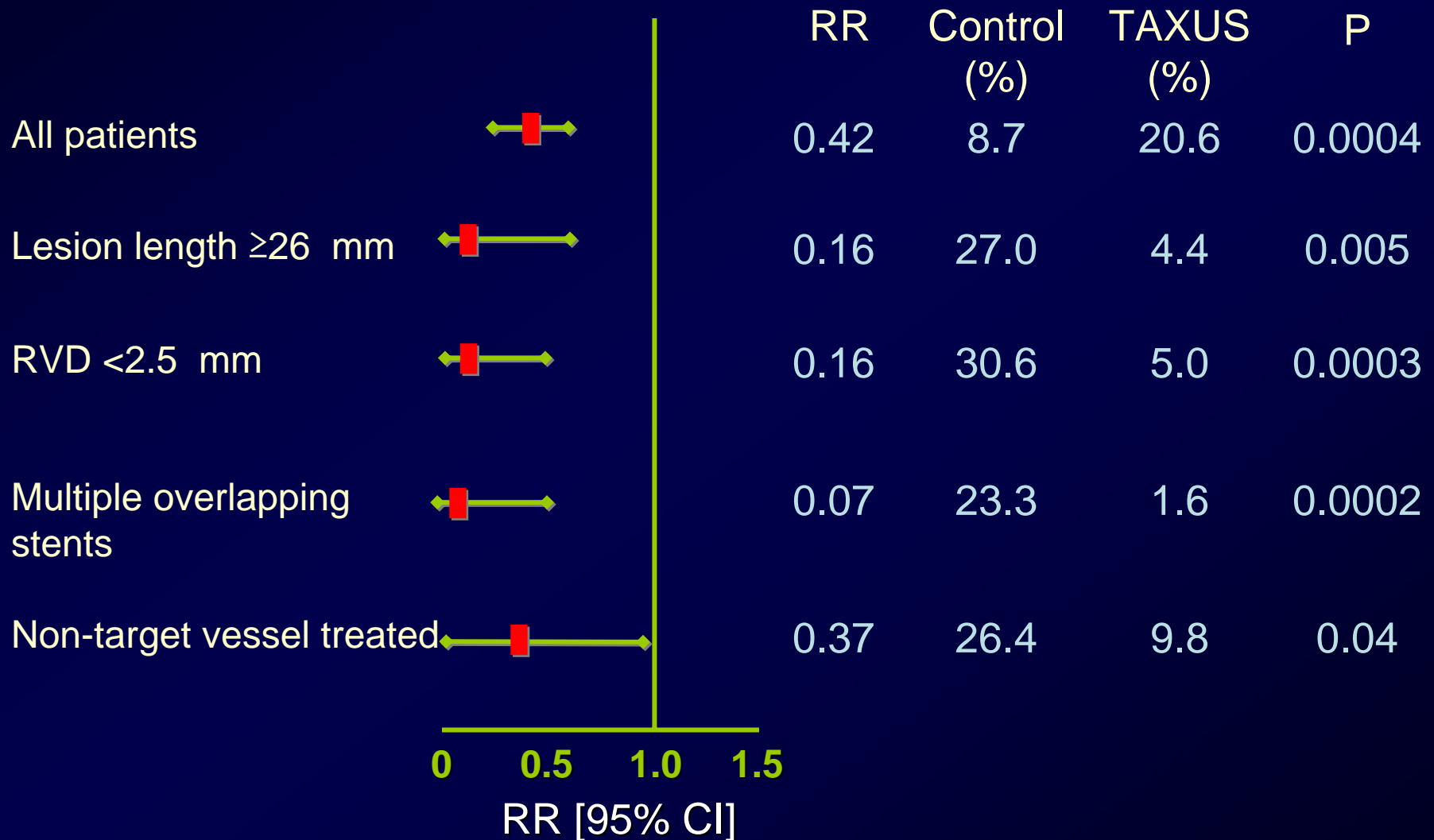


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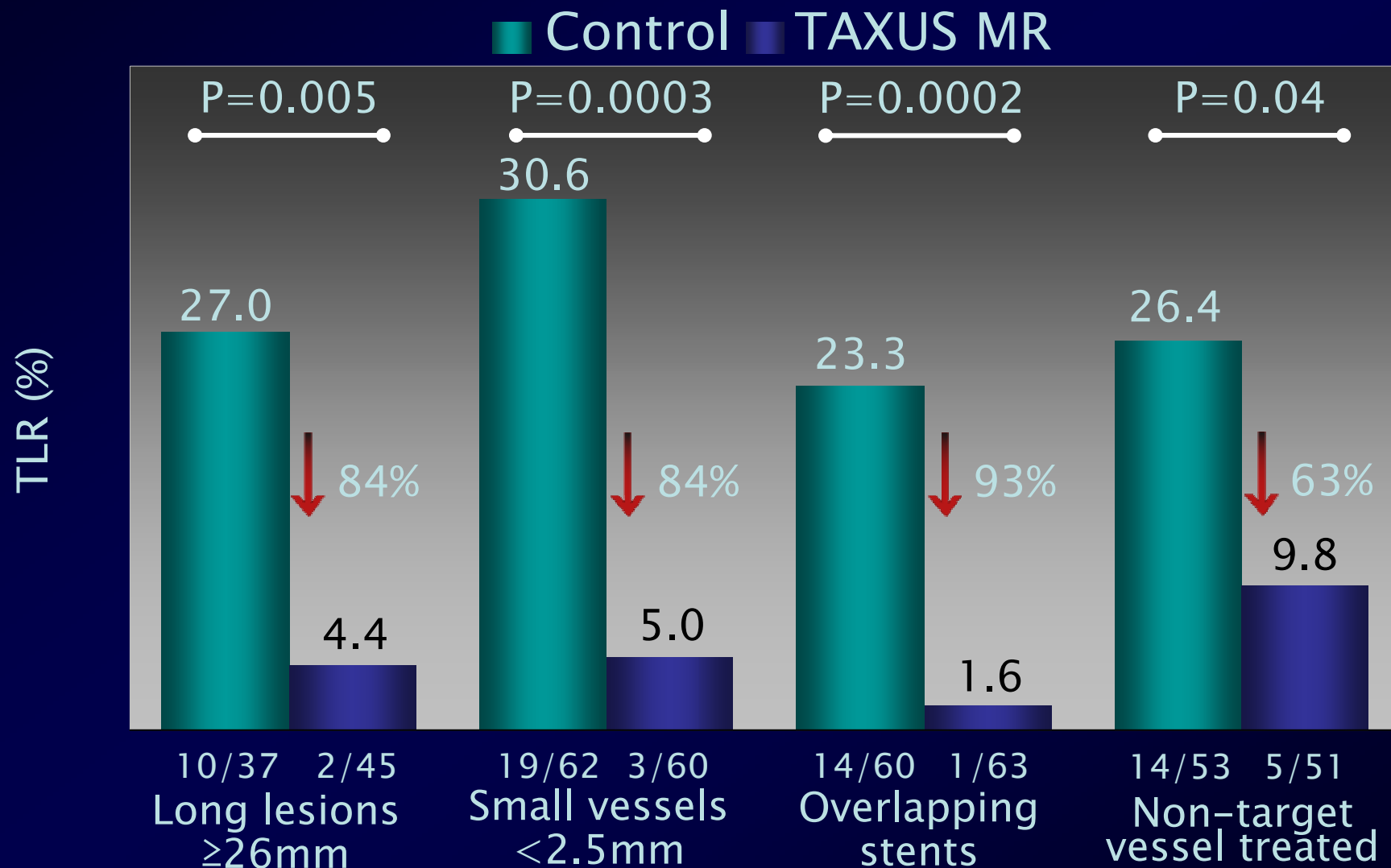
TLR in Patients with Non-Target Vessel Treated



12-Month TLR: Subset Summary



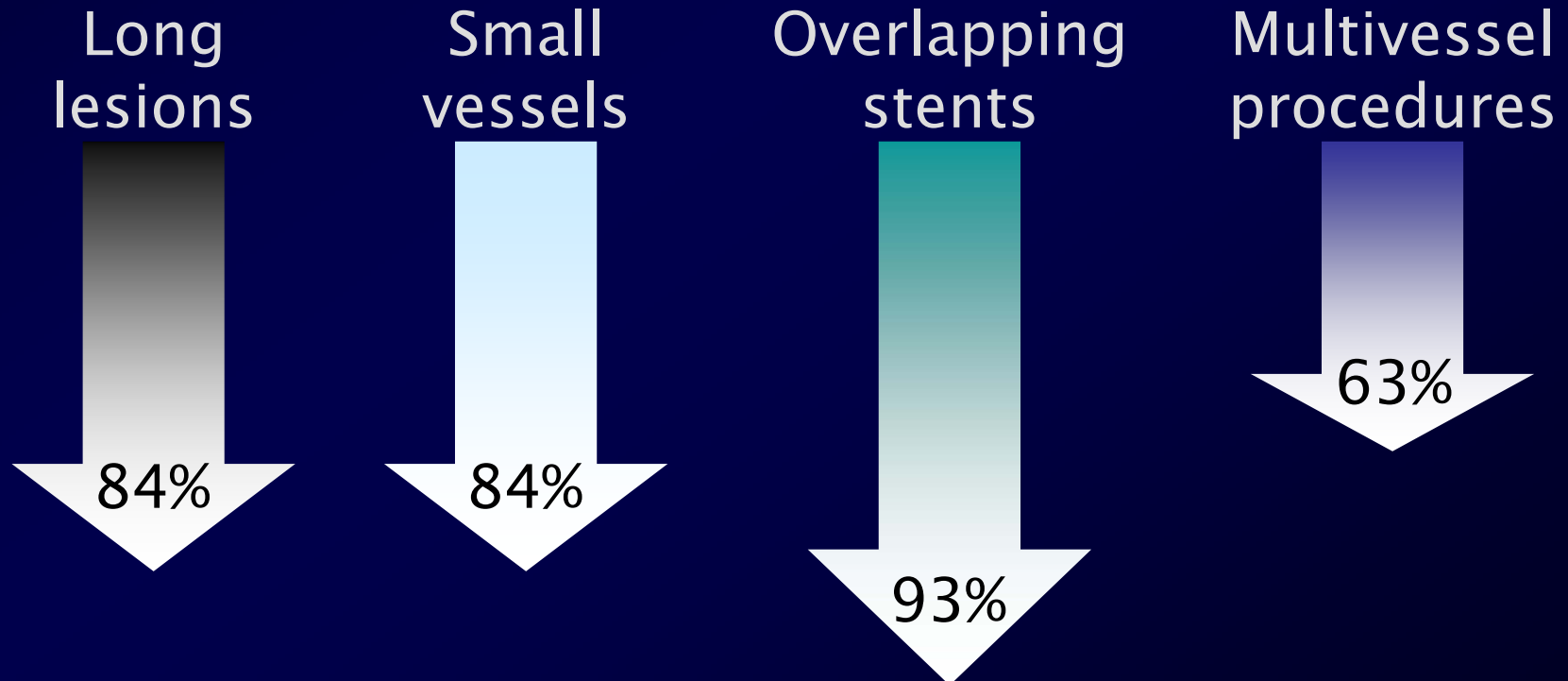
TLR Independent of Classic Risk Factors



TAXUS VI Summary

TAXUS benefit in TAXUS VI trial is independent of classic risk factors

TLR reductions in...



Siegburg Taxus ISR Registry

94 patients with 104 lesions over a 12 months period

Type of stent used in previous intervention, n (%)

Bare metal stent	89 (85.6%)
Drug-eluting stents	15 (14.4%)
Paclitaxel-eluting	9
Tacrolimus-eluting	5
Everolimus-eluting	1

Siegburg Taxus ISR Registry

6-MONTH CLINICAL FOLLOW-UP (n=94 pts)

Target lesion revascularization, n (%)	7 (7.4%)
PCI with DES	3 (3.2%)
PCI with balloon angioplasty	2 (2.1%)
CABG	1 (1.1%)
Brachytherapy	1 (1.1%)
Stent thrombosis, n (%)	1 (1.1%)
Myocardial infarction, n	0
Death, n	0

Siegburg Taxus ISR Registry

6-MONTH FOLLOW-UP (n=104 lesions)

Late loss, mm

proximal	0.35 ± 0.65
in-stent	0.30 ± 0.50
distal	0.09 ± 0.66
in-segment	0.49 ± 0.61

Binary restenosis, n (%)

proximal	5 (4.8%)
in-stent	4 (3.8%)
distal	4 (3.8%)
in-segment	8 (7.6%)

Siegburg Taxus ISR Registry

PATTERN OF IN-STENT RESTENOSIS, n (%)

	PRE	6-m FU
Mehran I (Focal)	34 (32.7%)	4 (3.8%)
Mehran II (Diffuse intra-stent)	50 (48.1%)	0
Mehran III (Diffuse proliferative)	15 (14.4%)	2 (1.9%)
Mehran IV (Total occlusion)	5 (4.8%)	2 (1.9%)

Conclusions

- Efficacy of the TAXUS stent in the overall is extended to patients with classic risk factors for restenosis
- Larger studies are needed to prospectively evaluate contemporary DES use in high-risk cases