



TAXUS Trials Meta Analysis

A Critical Analysis

Gregg W. Stone, MD

**Columbia University Medical Center
The Cardiovascular Research Foundation**

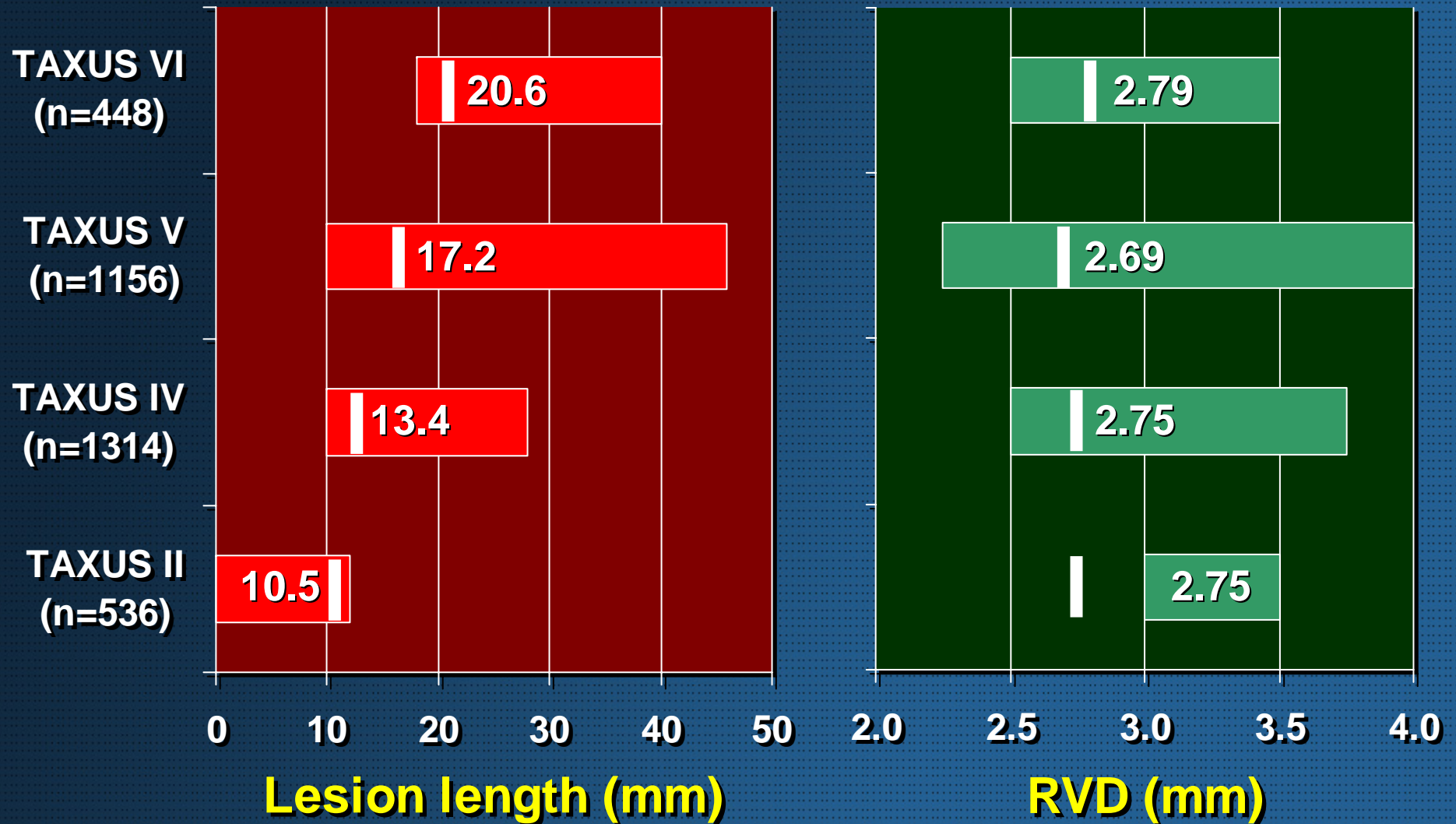


TAXUS Trial Designs

N = 3,445	TAXUS II (n=529)	TAXUS IV (n=1314)	TAXUS V (n=1156)	TAXUS VI (n=446)
Formulation	SR, MR	SR	SR	MR
Stent Platform	NIRx	Express	Express ²	Express
Geography	Europe	US	US	Europe
Primary Endpoint	6 month	9 month	9 month	9 month
Long-term F/U	2 years	2 years	9 months	1 year
Angio Core Lab	Cardialysis	B&WH	B&WH	B&WH
Angio F/U (%)	97.0	42.5	85.6	93.5

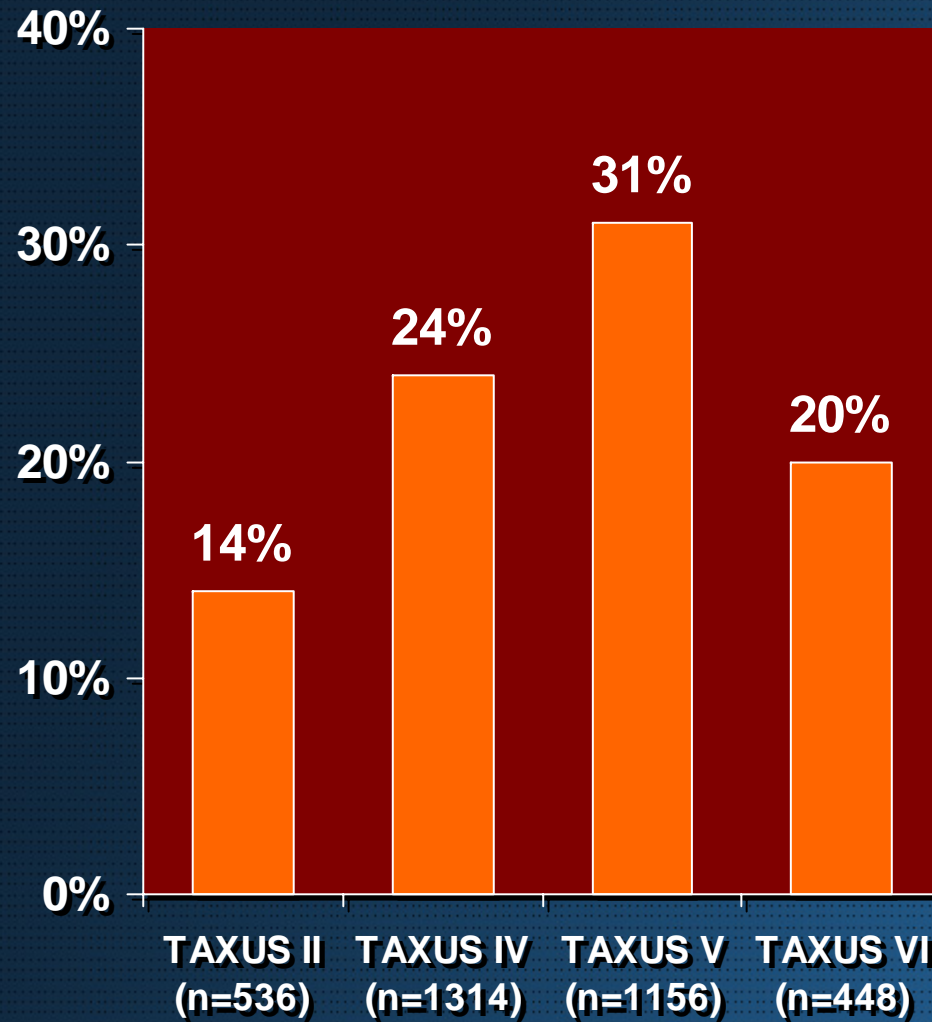


TAXUS II, IV, V, VI: N=3,445

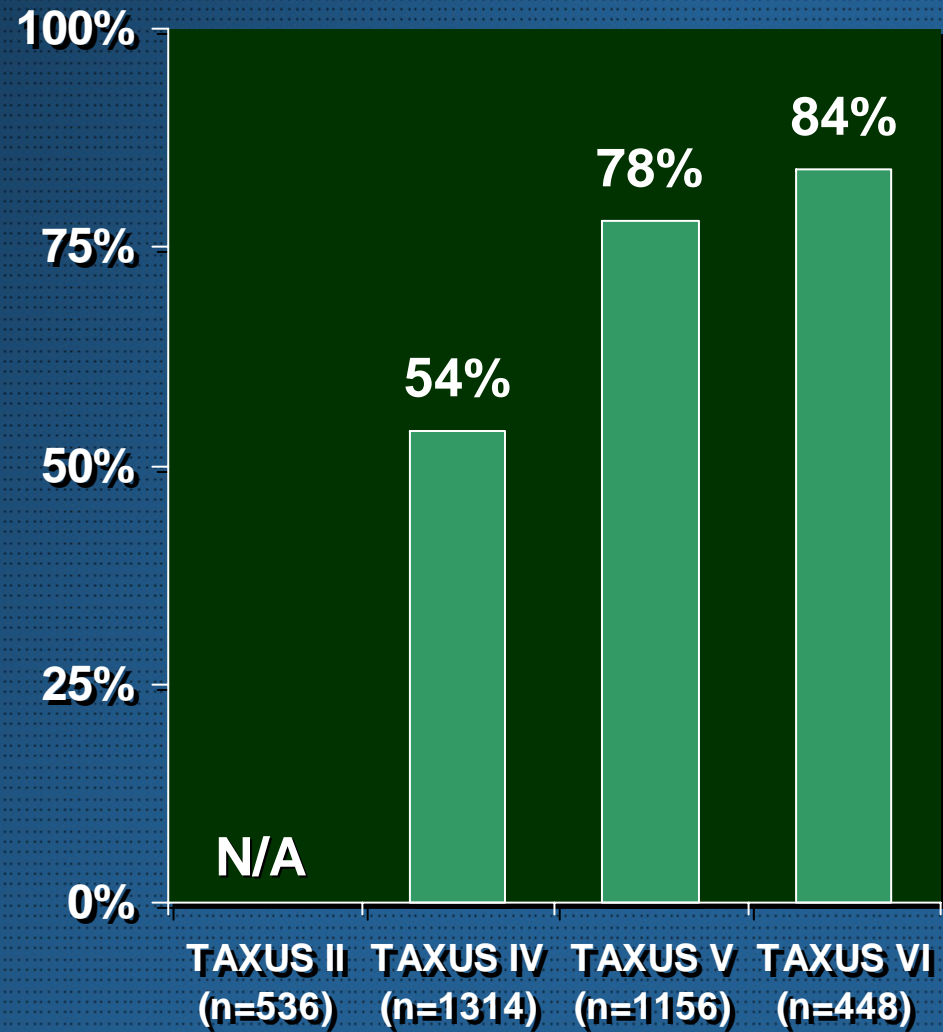




TAXUS II, IV, V, VI: **N=3,445**



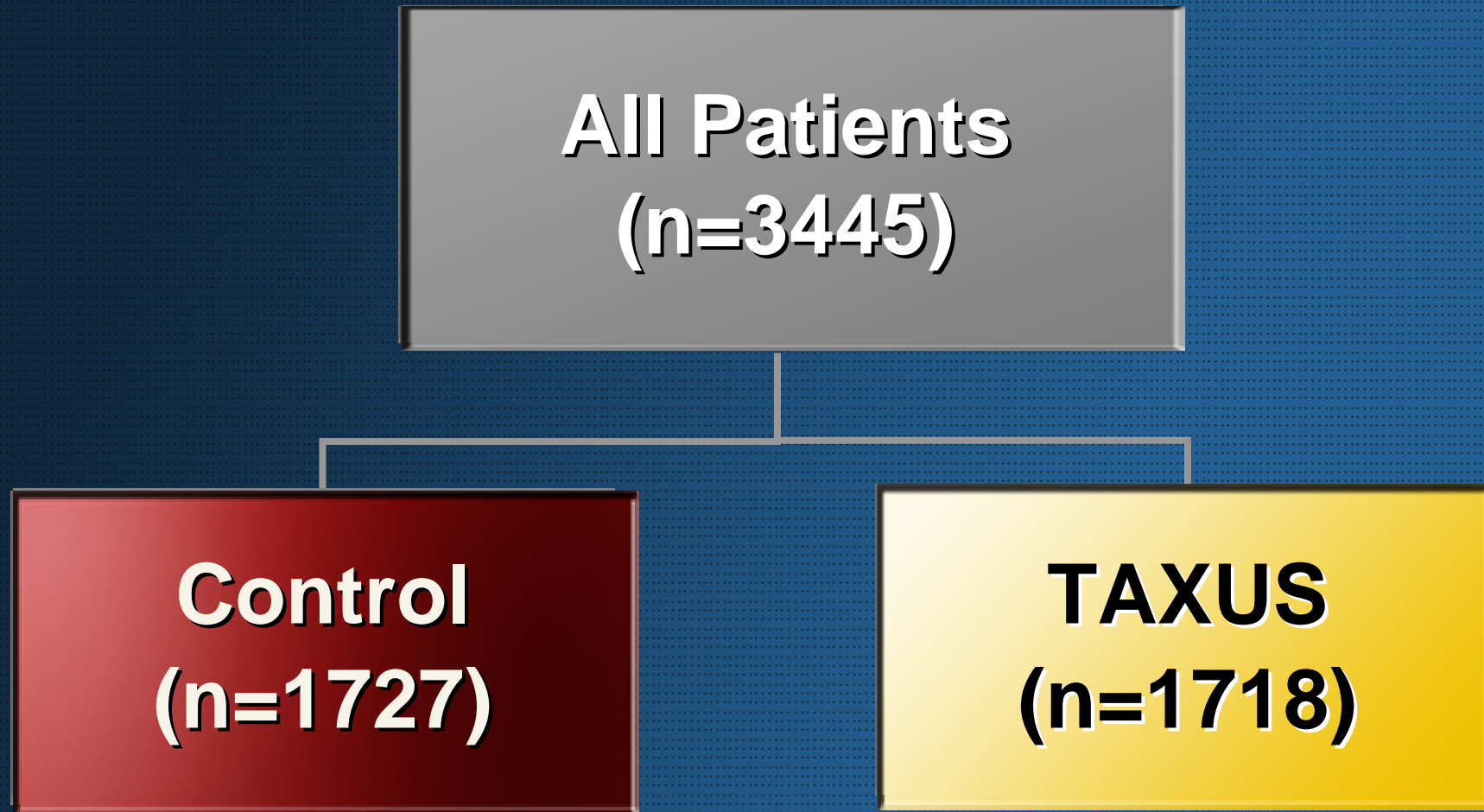
Diabetes



Type B2/C Lesions



Analysis of All Pts, TAXUS II, IV, V, VI





Baseline Characteristics (QCA)

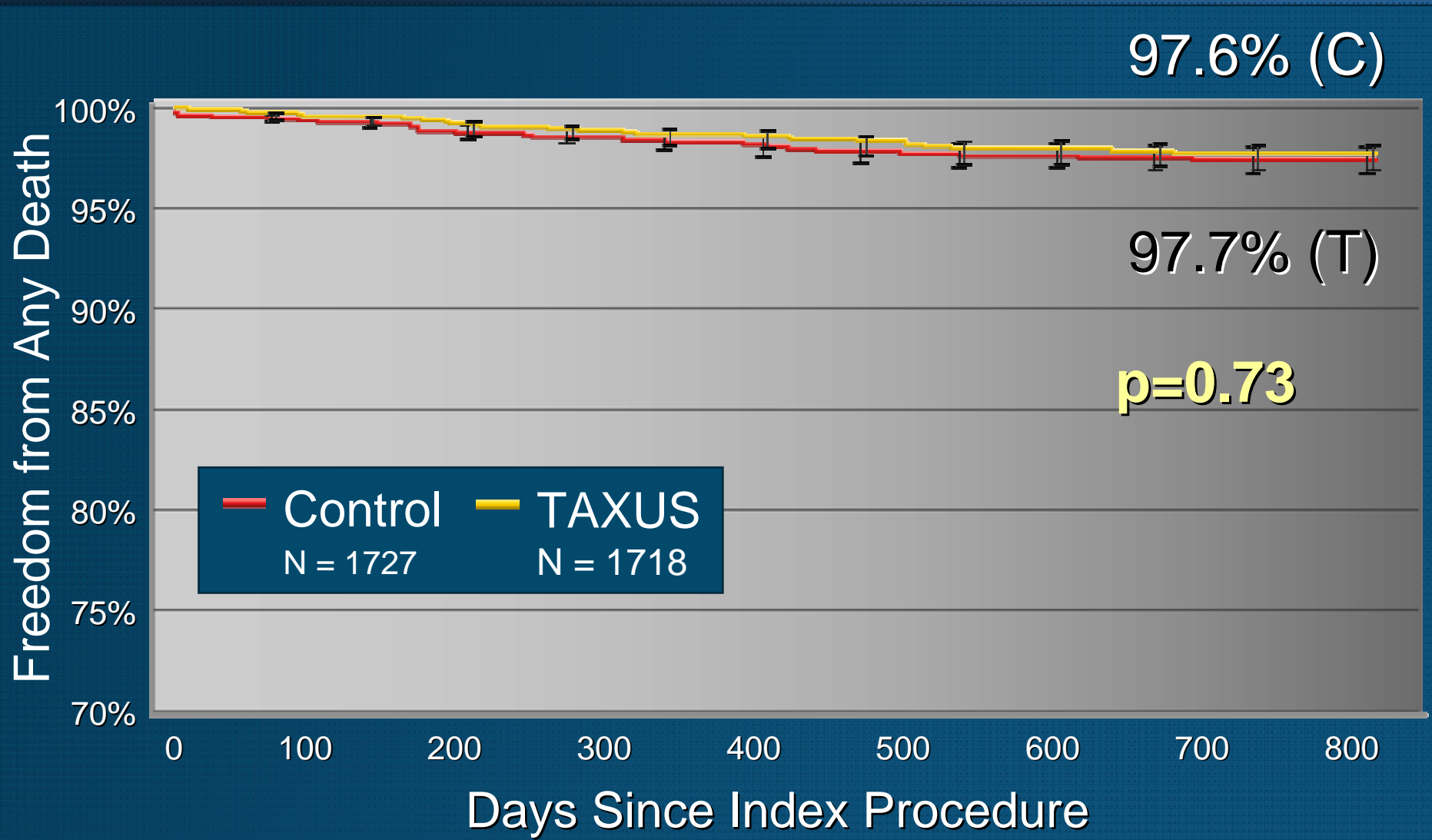
All Patients, TAXUS II, IV, V, VI (N=3,445)

	Control (n=1727)	TAXUS (n=1718)	P Value
Diabetes (%)	24.0	23.2	0.60
RVD (mm)	2.73 ± 0.51	2.74 ± 0.51	0.84
Lesion Length (mm)	15.1 ± 8.0	15.2 ± 7.9	0.85
Stent:Lesion Length	1.79 ± 0.82	1.80 ± 0.81	0.81



Freedom from Any Death to 2-Years

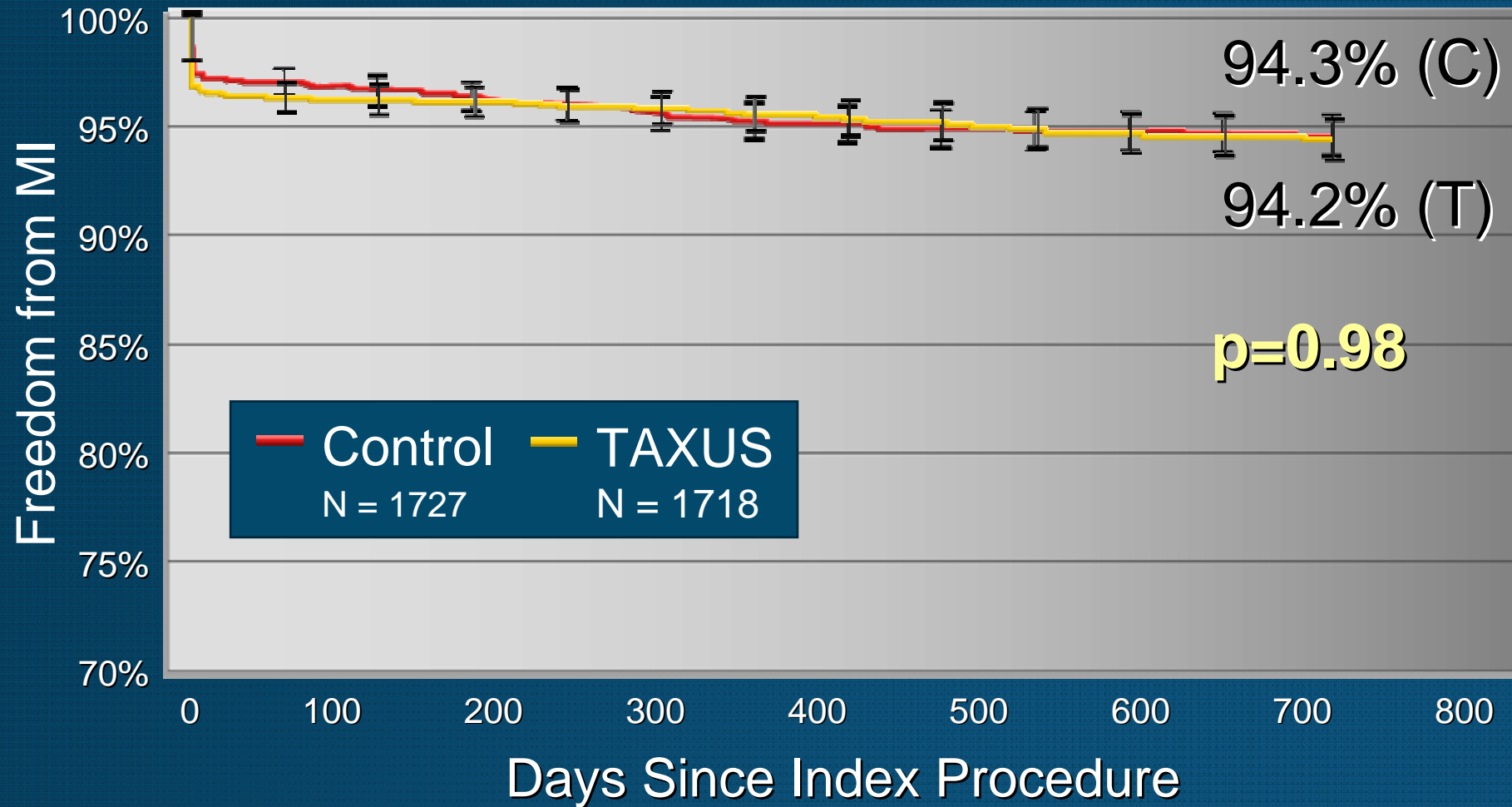
All Patients, TAXUS II, IV, V, VI





Freedom from MI to 2-Years

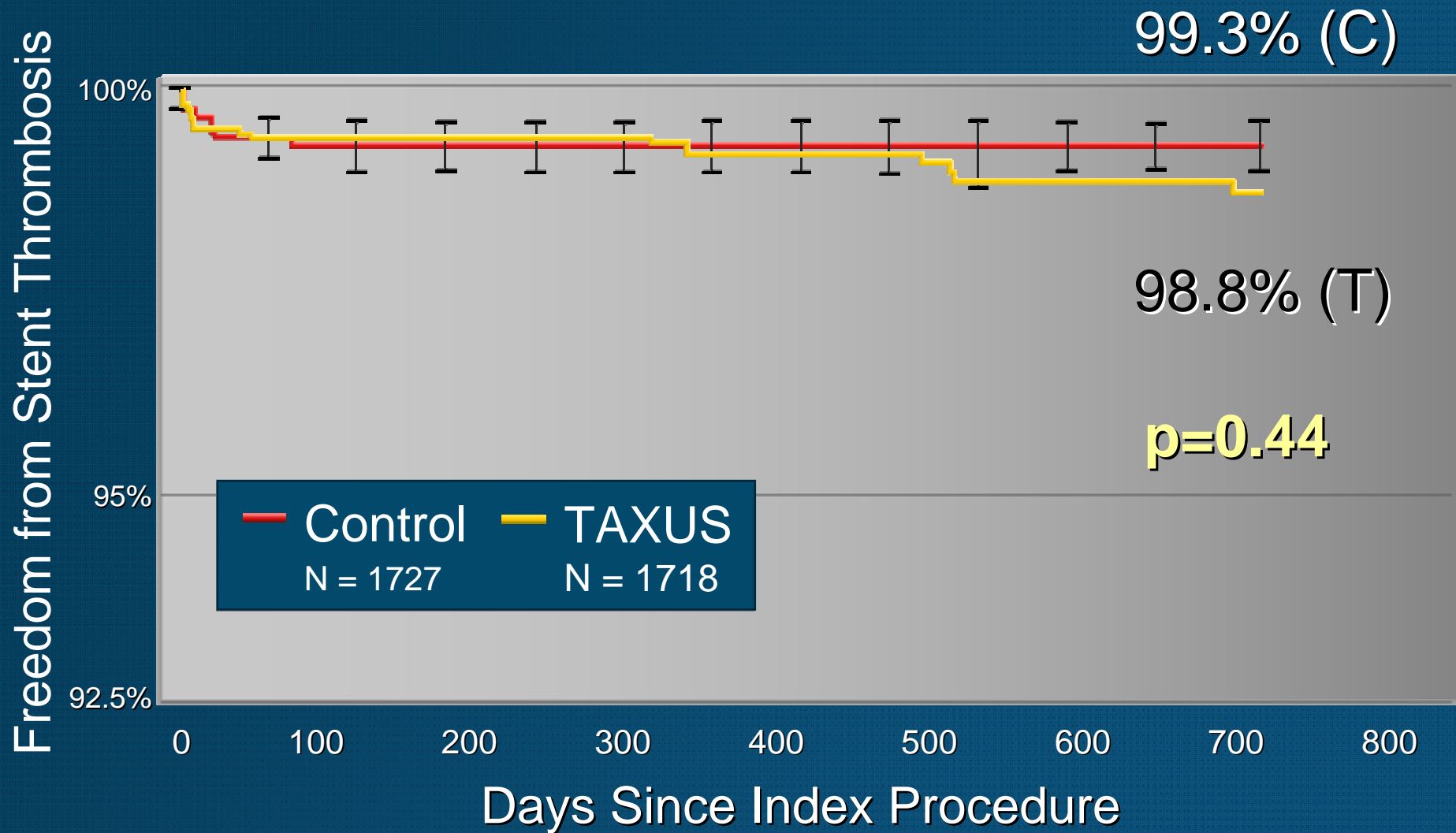
All Patients, TAXUS II, IV, V, VI





Stent Thrombosis to 2-Years

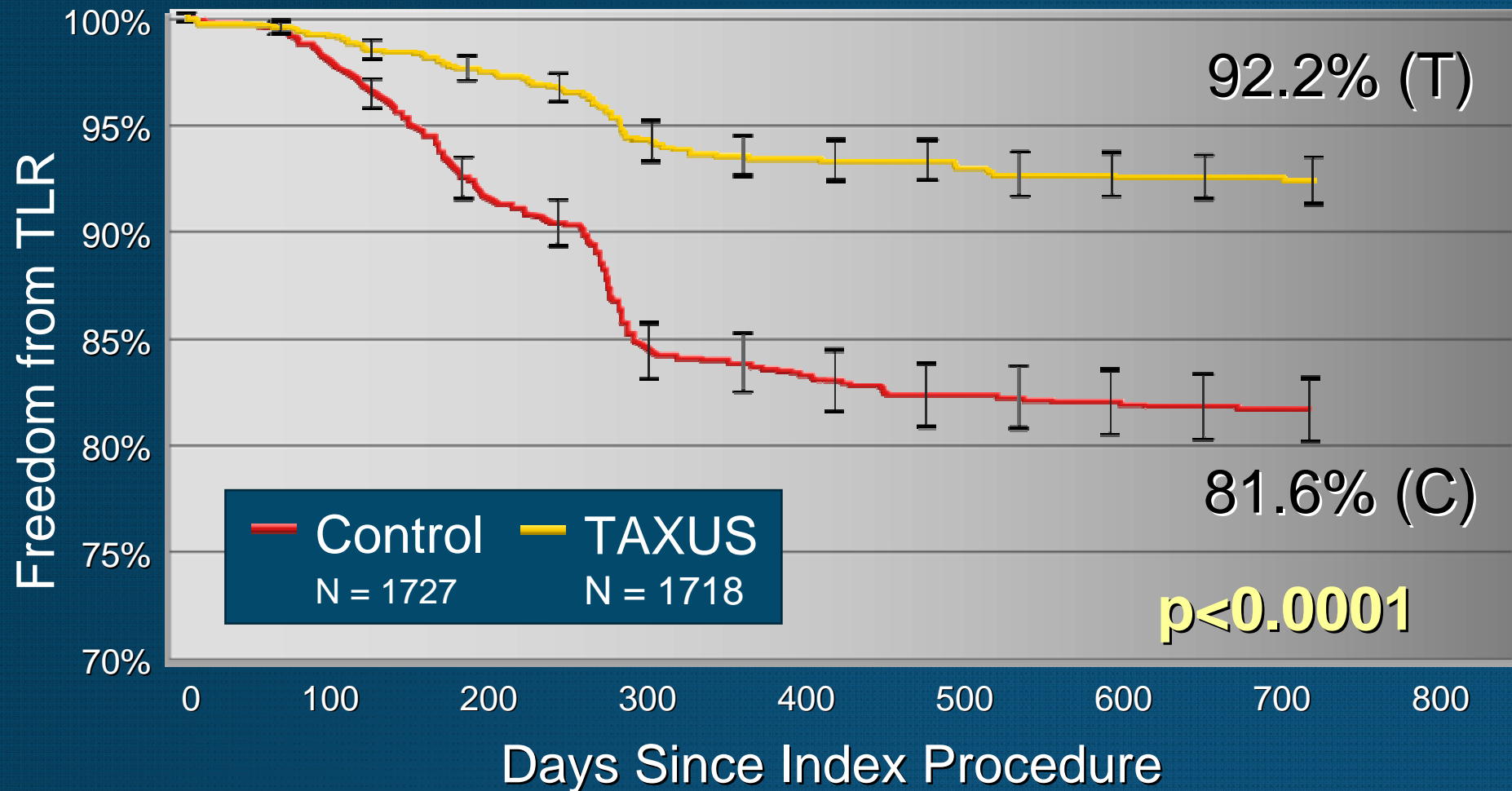
All Patients, TAXUS II, IV, V, VI





Freedom from TLR to 2-Years

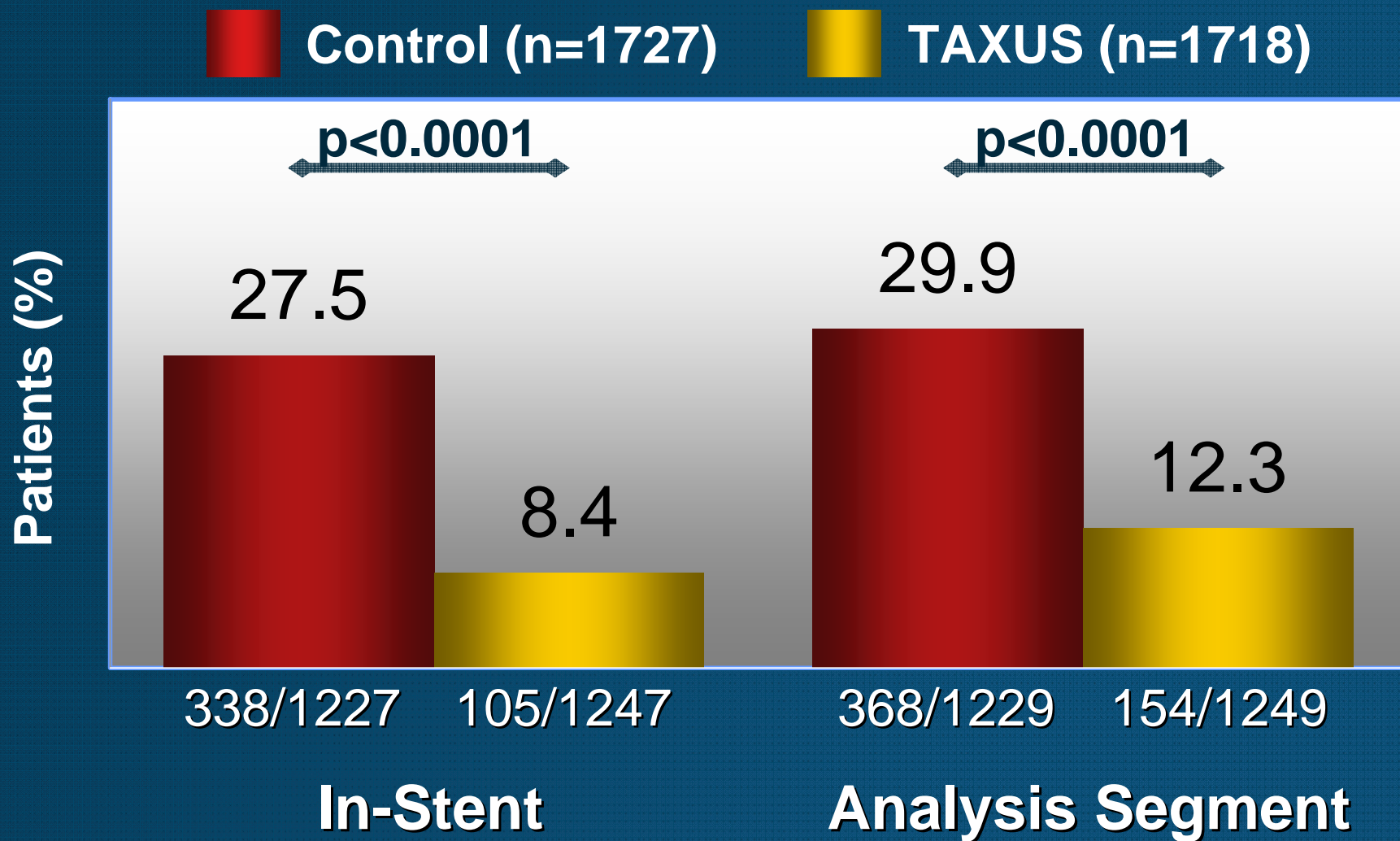
All Patients, TAXUS II, IV, V, VI





% Binary Restenosis at 6-9 Months

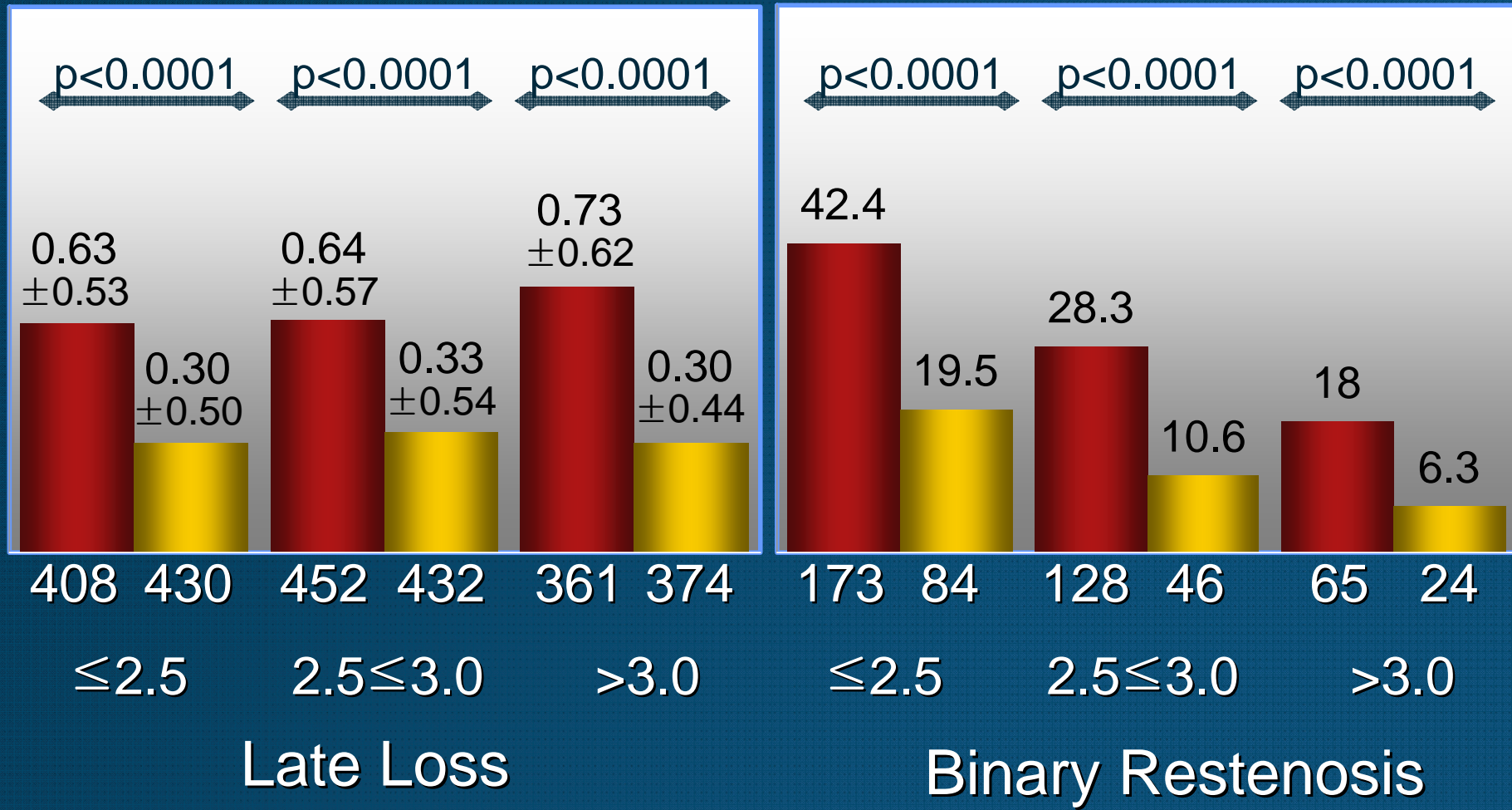
All Patients, TAXUS II, IV, V, VI (N=3,445)





Effect of Vessel Size on 9m QCA In-Segment, TAXUS II, IV, V, VI MetaAnalysis

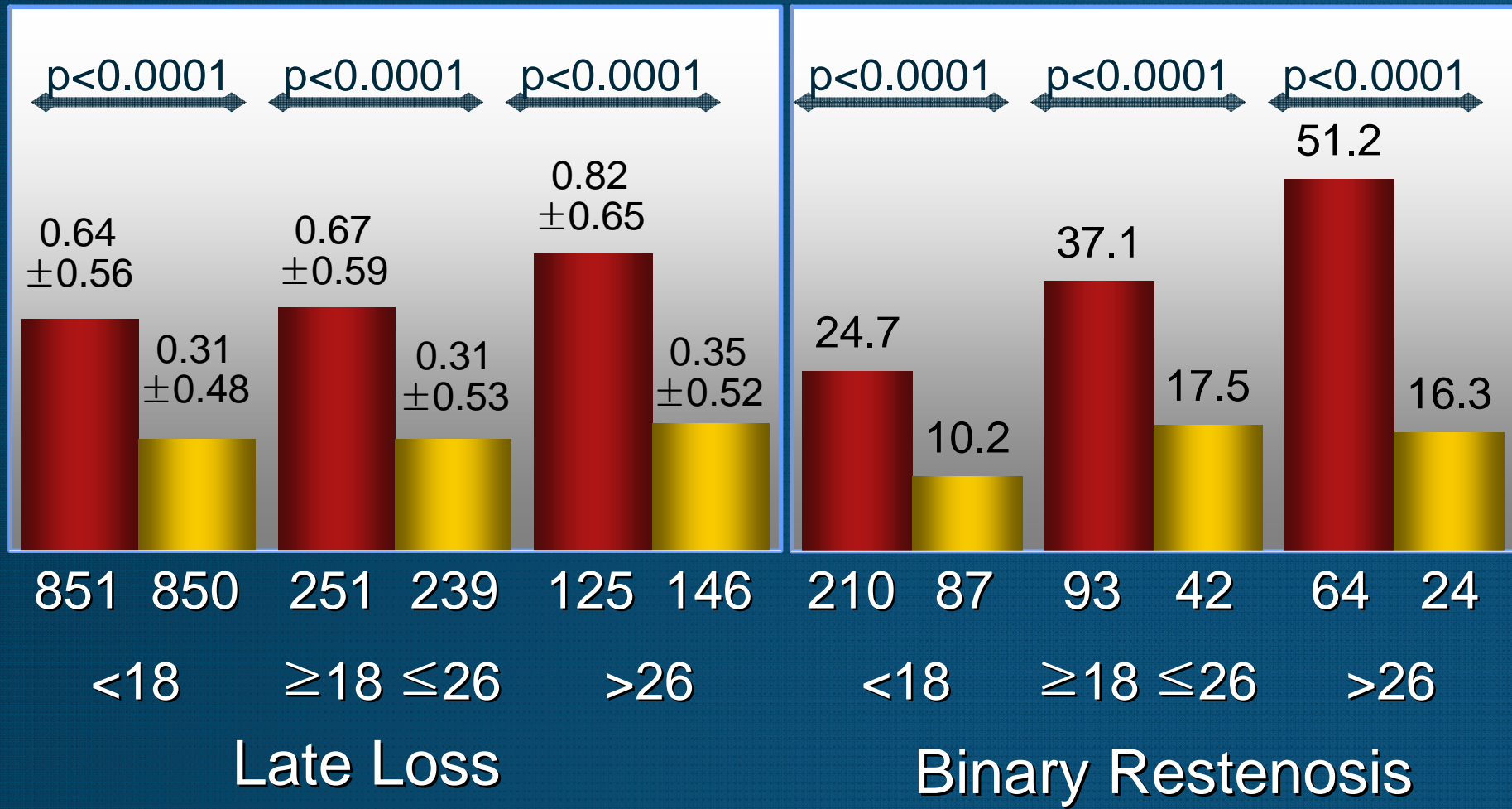
Control **TAXUS**





Effect of Lesion Length on 9m QCA In-Segment, TAXUS II, IV, V, VI MetaAnalysis

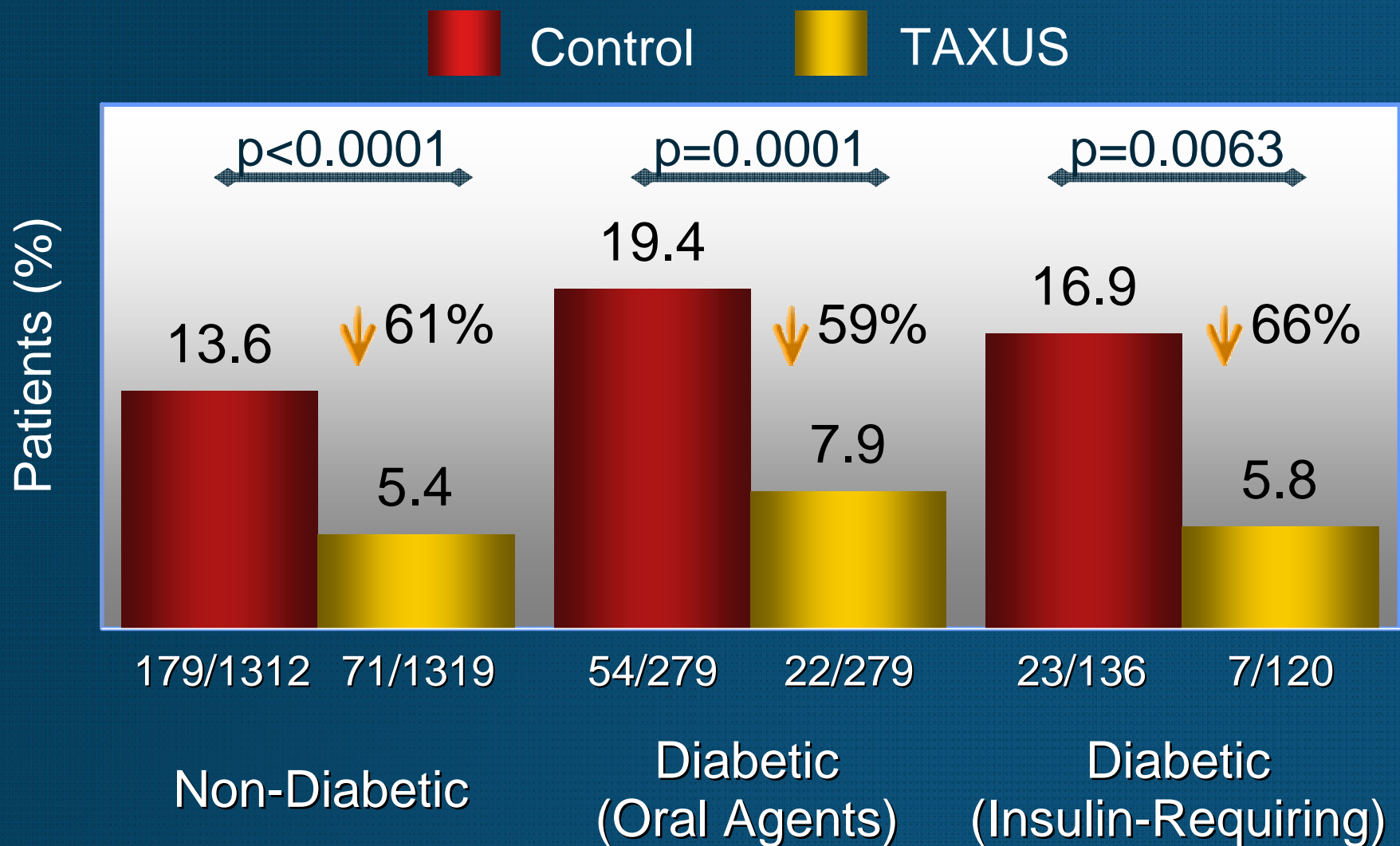
Control TAXUS





Effect of Diabetic Status on 9-Month TLR

TAXUS II, IV, V, VI MetaAnalysis





Multiple Stent Analysis

TAXUS II, IV, V, VI MetaAnalysis





Baseline Characteristics

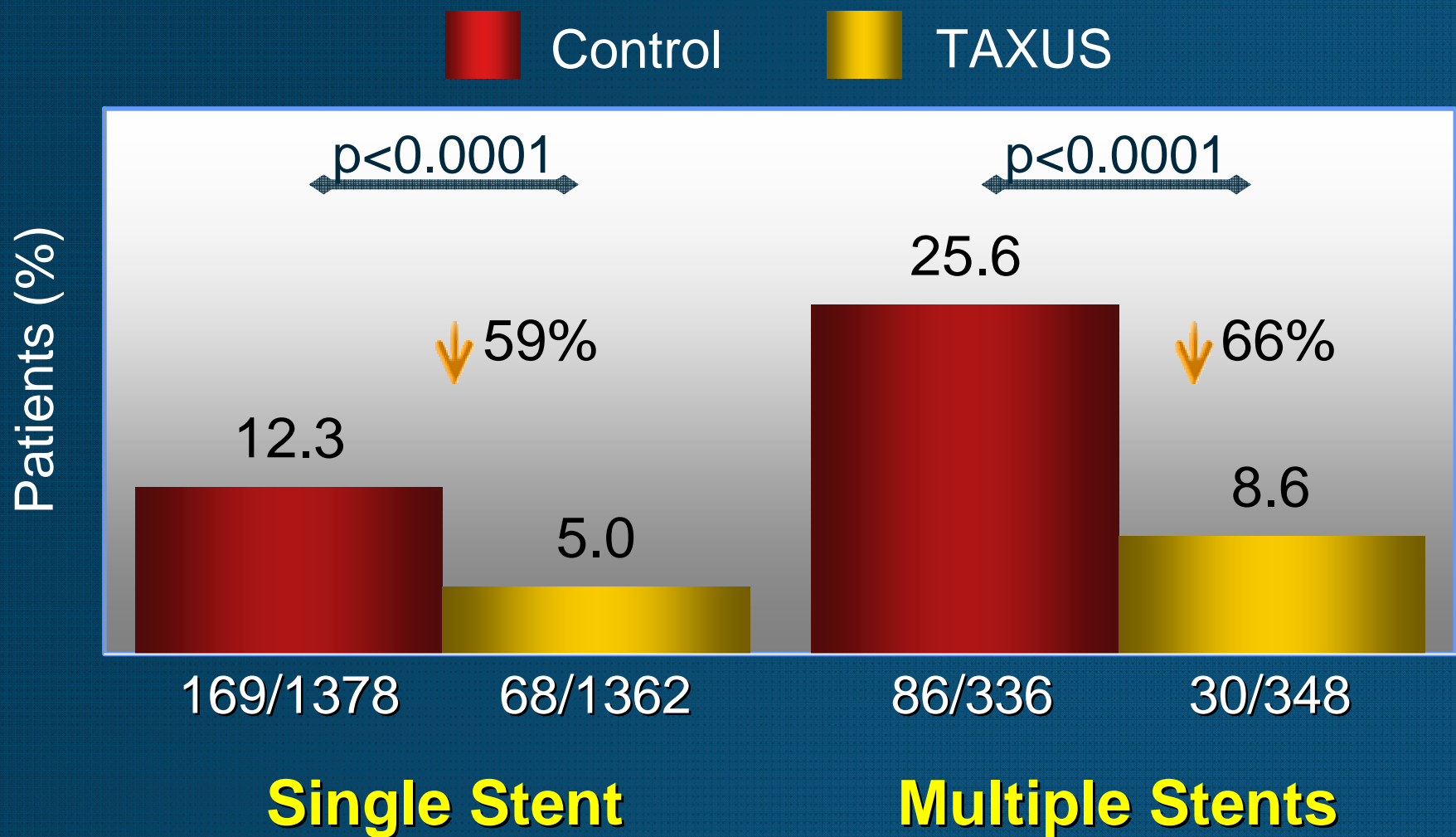
Single vs. Multiple Stents (pooled), TAXUS II, IV, V, VI

	Single n=2740	Multiple n=684	P value
Age	62.0 ± 10.8	62.9 ± 10.5	0.052
Type C lesions	21.9	69.4	<0.0001
Silent Ischemia	19.6	11.1	<0.0001
RVD (mm)	2.74 ± 0.50	2.71 ± 0.53	0.15
Lesion length (mm)	13.0 ± 5.6	23.6 ± 10.1	<0.0001
Stent length (mm)	20.1 ± 6.0	41.7 ± 11.0	<0.0001
Stent:Lesion Ratio	1.73 ± 0.70	2.07 ± 1.12	<0.0001



Effect of Multiple Stenting on 9-Month TLR

TAXUS II, IV, V, VI MetaAnalysis





30 Day MACE

Single Stent Patients, TAXUS II, IV, V, VI (N=2,740)

	Control n=1378	TAXUS n=1362	P value
MACE, Overall (%)	3.2	2.9	0.74
Cardiac Death	0.2	0.1	0.62
MI	2.9	2.7	0.82
Q-wave	0.3	0.3	1.00
Non Q-wave	2.6	2.4	0.81
TVR	0.4	0.4	1.00
TLR	0.4	0.3	0.75



30 Day MACE

Multiple Stent Patients, TAXUS II, IV, V, VI (n=684)

	Control n=336	TAXUS n=348	P value
MACE, Overall (%)	4.2	8.3	0.027
Cardiac Death	0.3	0.3	1.00
MI	3.9	8.0	0.024
Q-wave	0.9	0.9	1.00
Non Q-wave	3.0	7.2	0.015
TVR	0.9	1.1	1.00
TLR	0.6	1.1	0.69

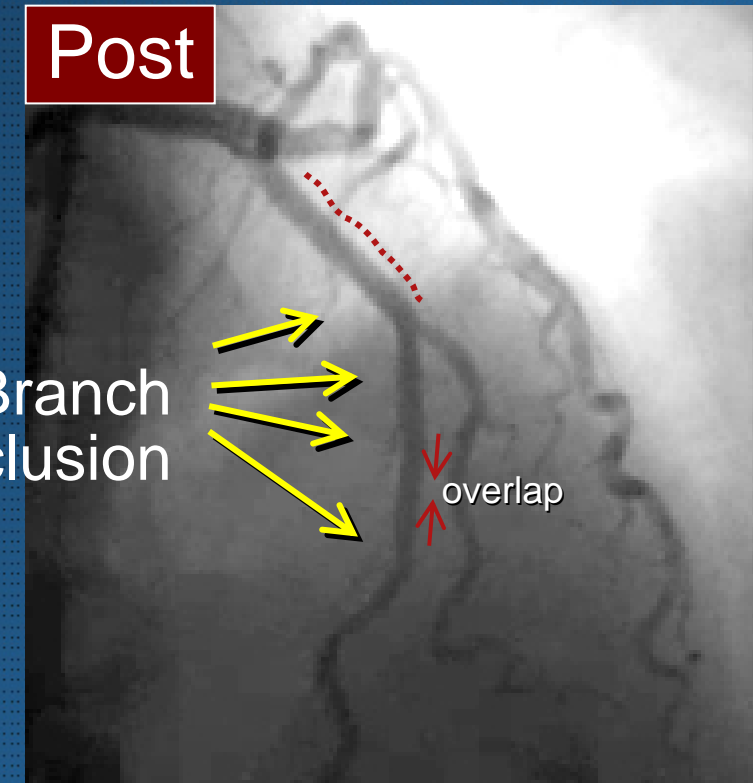
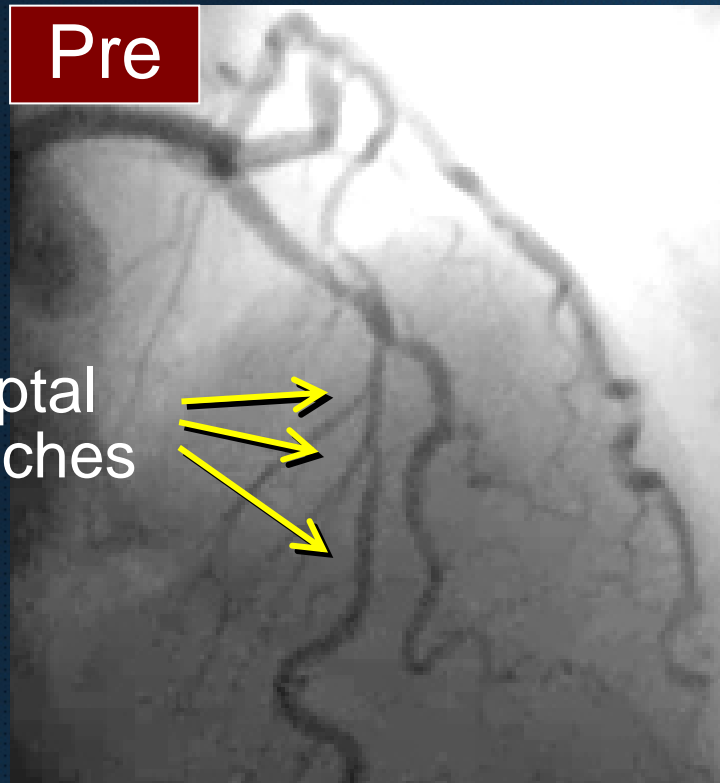


Side Branch Analysis in Multiple Stenting

Core Laboratory Analysis (blinded)

Per Patient	Control n=184	TAXUS n=188	P value
Branch TIMI Flow Reduction (anytime)	28.6 (42/147)	41.9 (65/155)	0.016
Any Side Branch Narrowing (by >70% or to 100%)	30.6 (45/147)	42.6 (66/155)	0.033
Any Side Branch Occlusion	20.4 (30/147)	27.1 (42/155)	0.18

Case 1 – Side branch loss

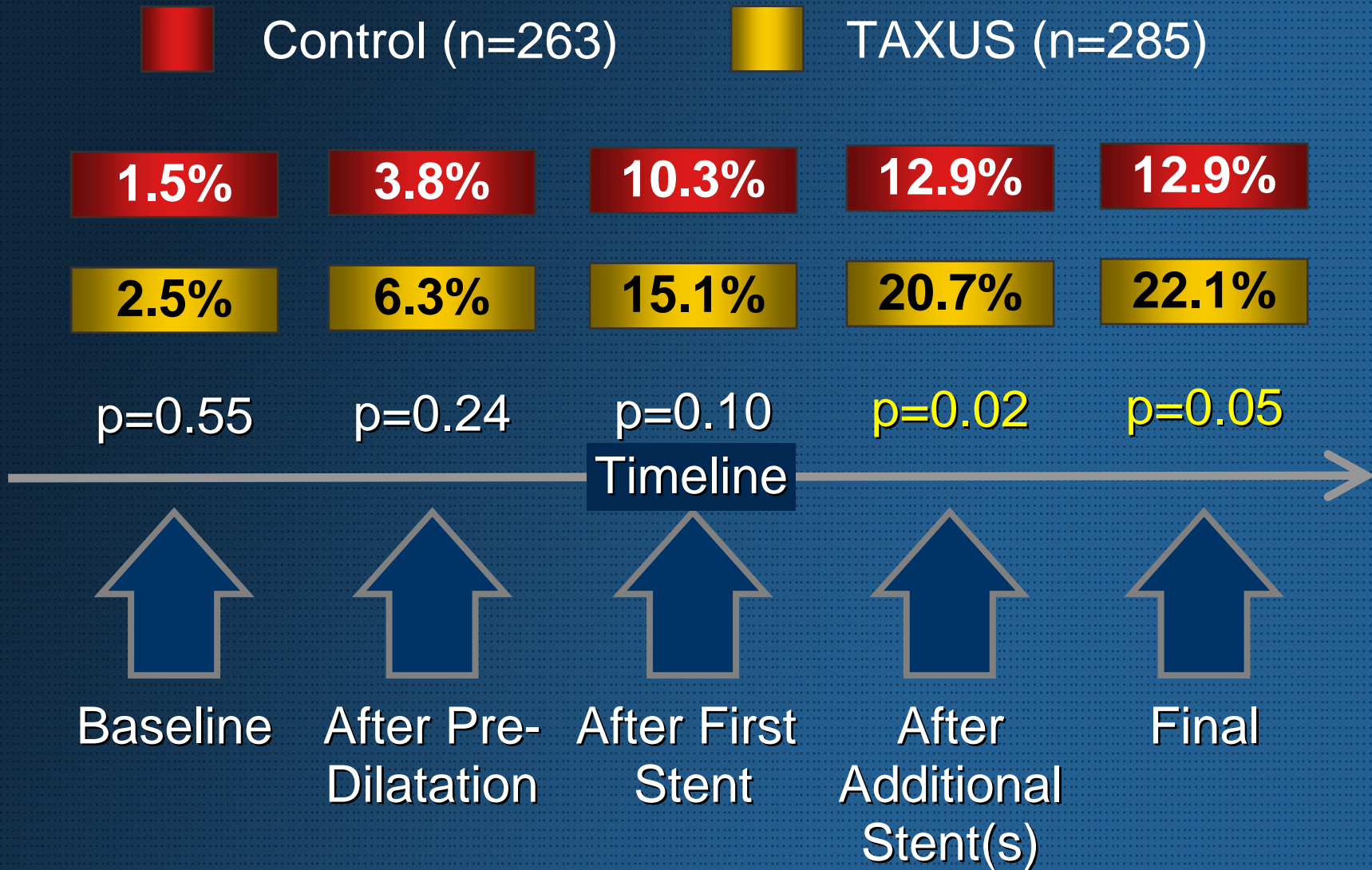


- Loss of 2 septal branches after implantation of first MLAD stent
- Implantation of second MLAD stent to cover distal dissection led to loss of the third septal branch (in non overlap zone)
- Implantation of a third stent in PLAD resulted in loss of 4th small septal branch



Side Branch Analysis in Multiple Stenting

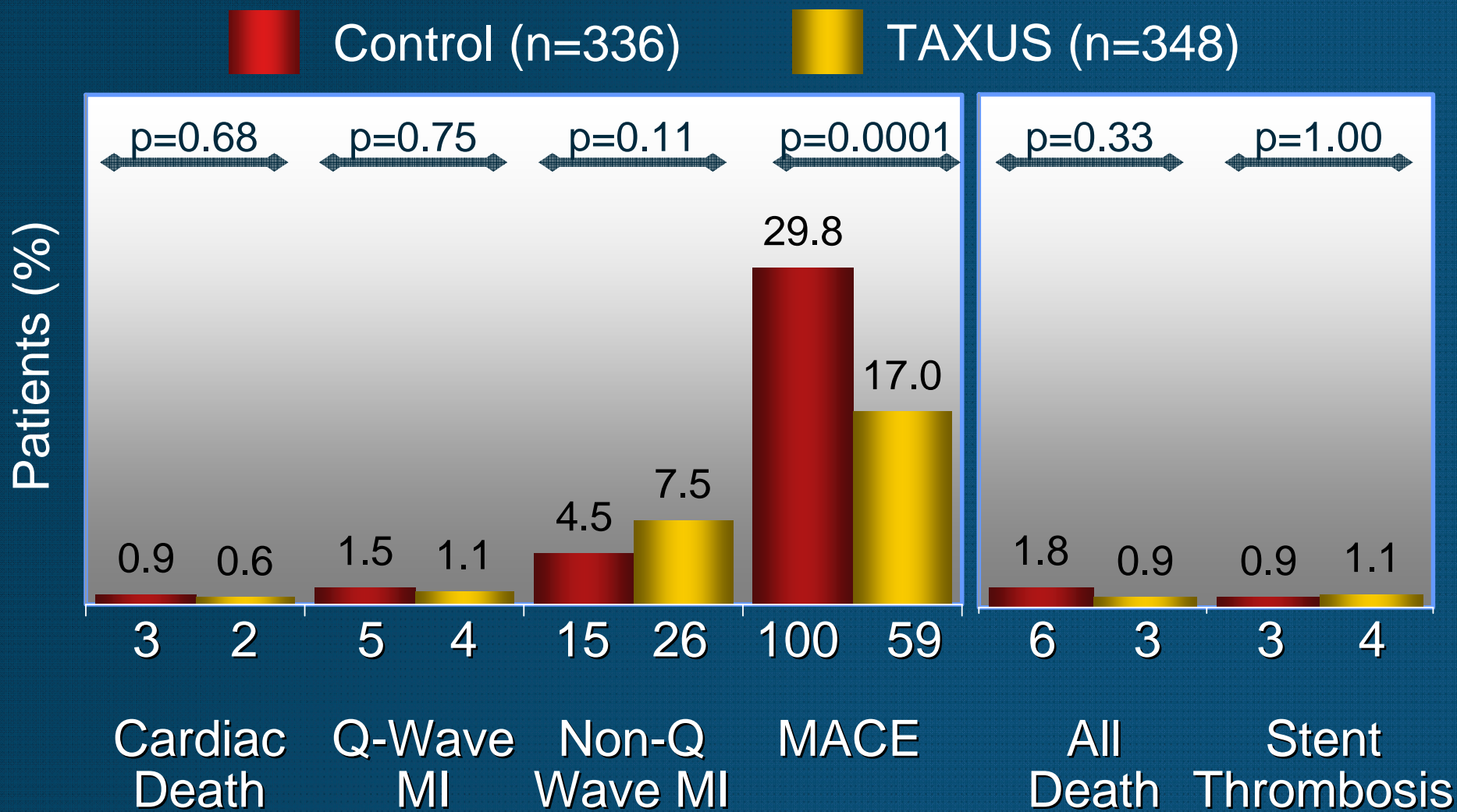
TIMI Flow ↓: Timing, Any Time Point





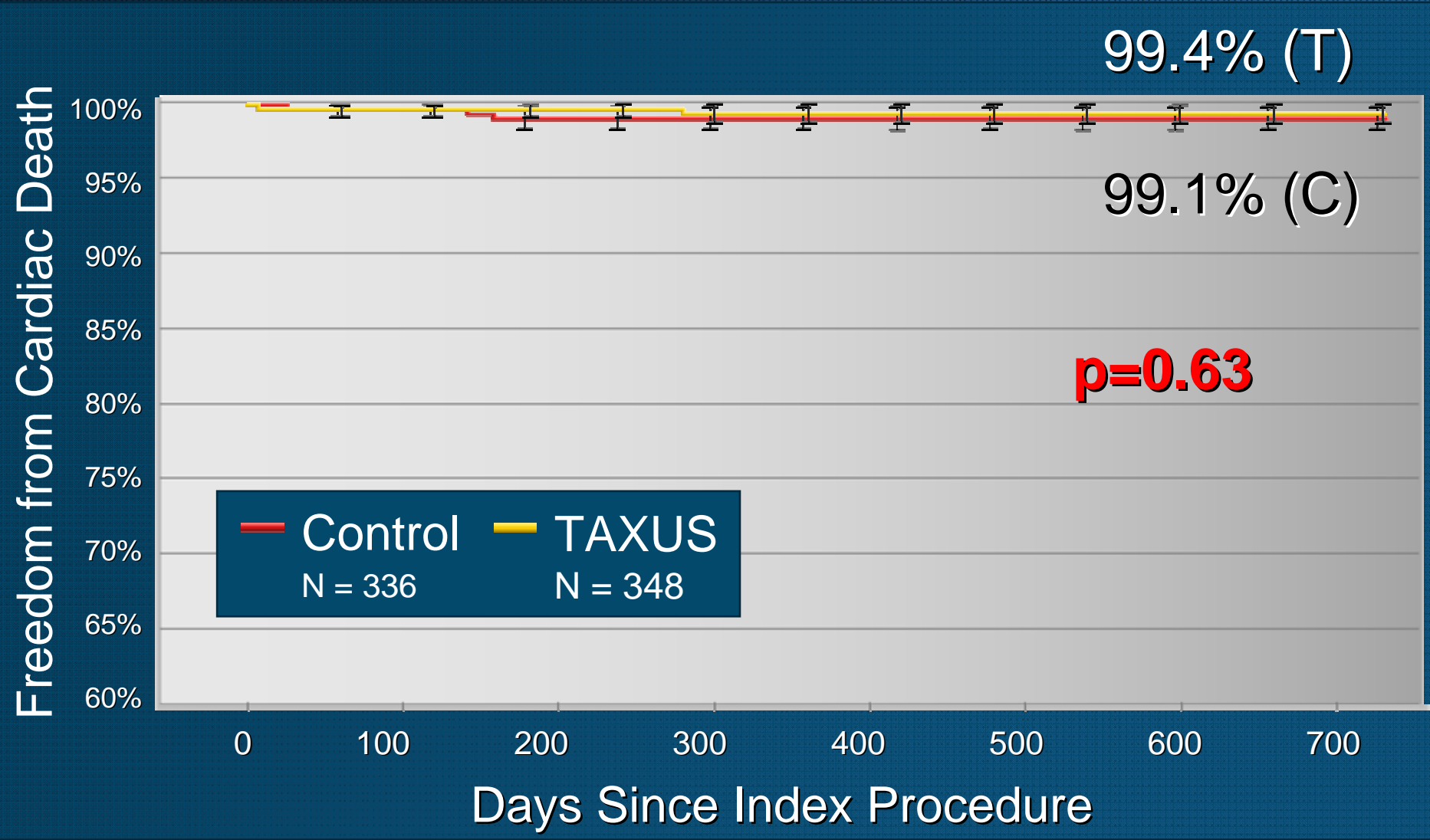
9-Month **Safety** Summary

Multiple Stent Patients, TAXUS II, IV, V, VI



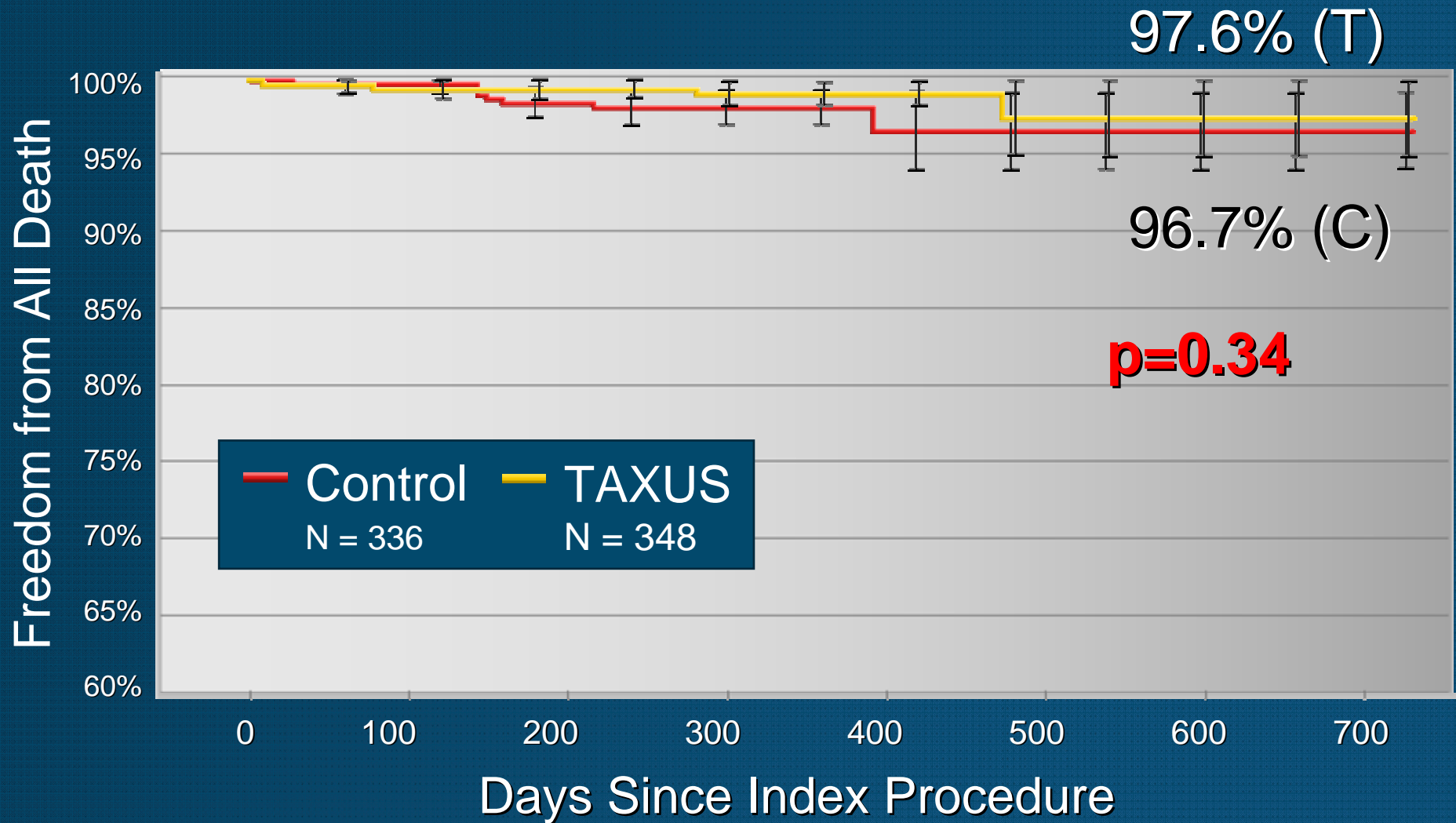


Freedom from **Cardiac Death** to 2-Years Multiple Stent Patients, TAXUS II, IV, V, VI



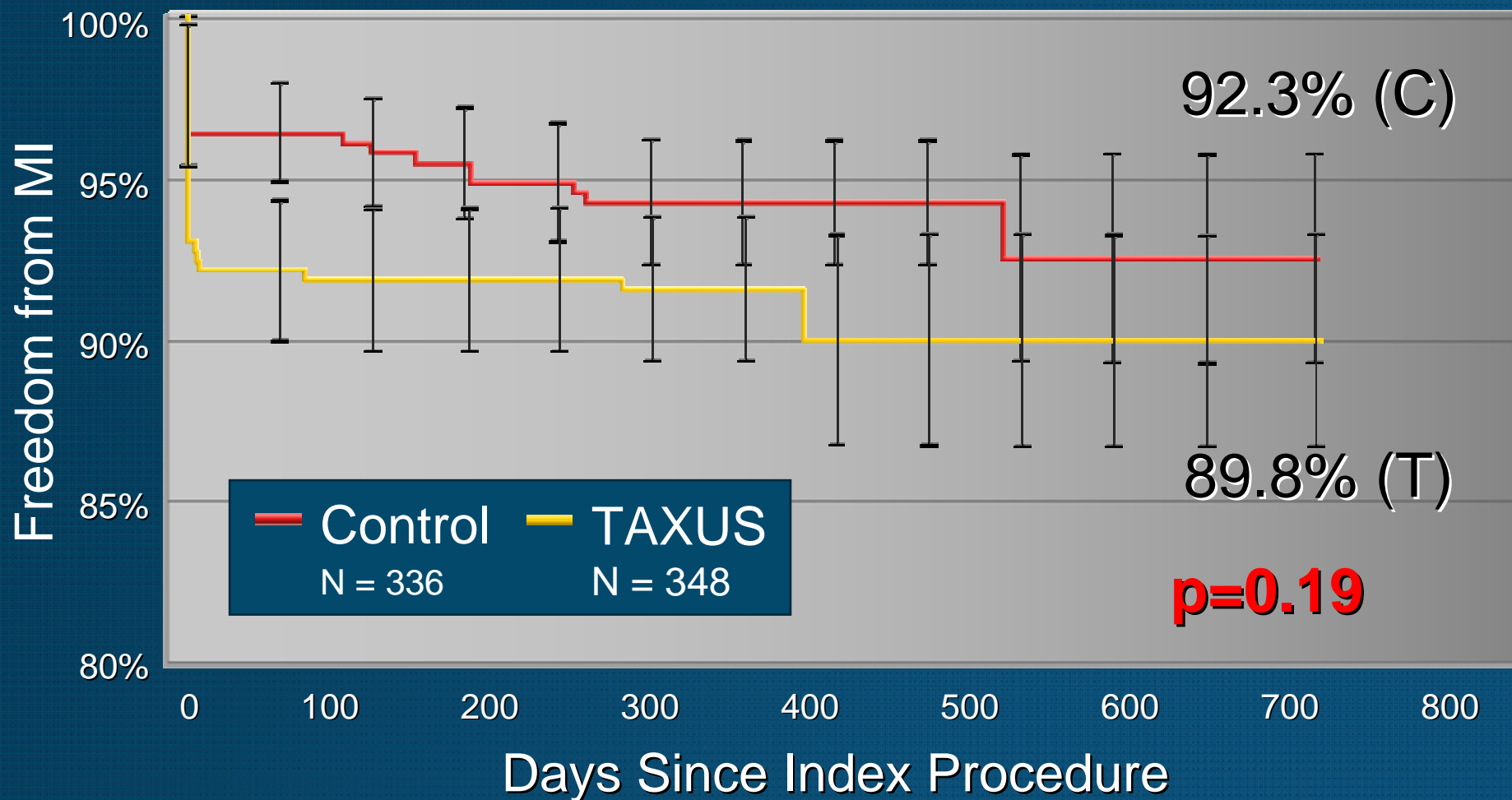


Freedom from **All Death** to 2-Years **Multiple Stent Patients**, TAXUS II, IV, V, VI



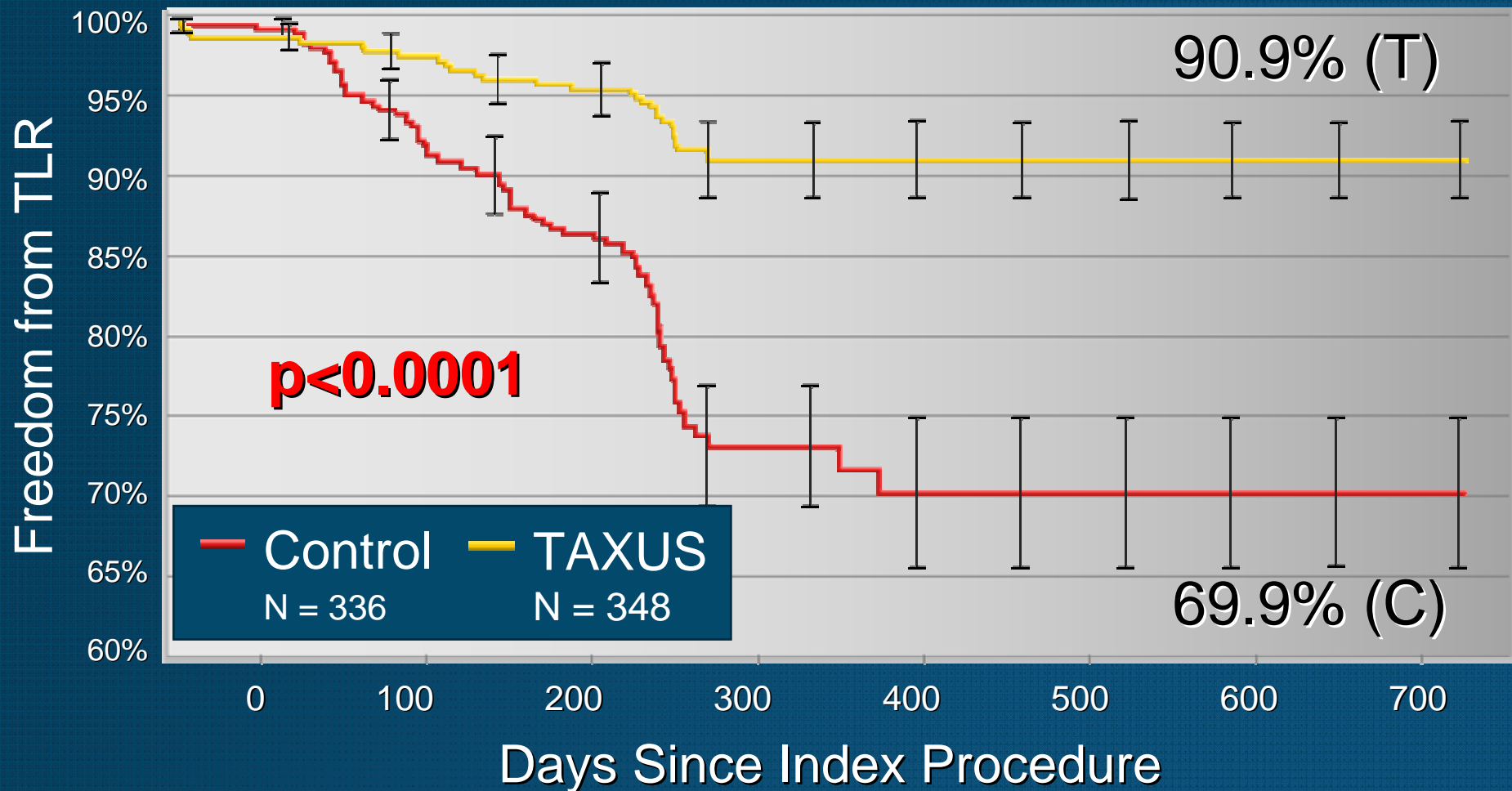


Freedom from MI to 2-Years Multiple Stent Patients, TAXUS II, IV, V, VI





Freedom from TLR to 2-Years Multiple Stent Patients, TAXUS II, IV, V, VI





TAXUS Meta-Analysis Conclusions

● Overall Efficacy to 2 Years

- Marked ↓ TLR and TVR
- Marked ↓ late loss and restenosis

● Overall Safety to 2 Years

- No risk of early stent thrombosis
- ? Increase in late stent thrombosis (n=6)
- No increase in death, cardiac death, or MI

● Subgroups

- Effective at all vessel sizes
- Effective at all lesion lengths
- Effective in all diabetic classes and non diabetics
- Multiple stents: Increase peri-procedural NQMI, with marked ↓ TLR and restenosis, with similar survival