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**Boston Scientific Symposium**

**Better diabetic performance  
with TAXUS**

30 min

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# ARTS I Diabetics



## MACE at 5 years in Pts with Diabetes

	Stent diabetes (n=112)	Bypass diabetes (n=96)
Death	15(13.4%)	8(8.3%)
CVA	7(6.3%)	7(7.3%)
MI	12(10.7%)	7(7.3%)
Q-wave MI	9(8.0%)	4(4.2%)
Non-Q MI	3(2.7%)	3(3.1%)
Composite Death/CVA/MI	28(25.0%)	19(19.8%)
Re CABG	17(15.2%)	2(2.1%)
RE PTCA	34(30.4%)	9(9.4%)
Any Revascularization	48(42.9%)	10(10.4%)
Any MACCE	61(54.5%)	24(25.0%)

*Serruys et al JACC 2005*

# TAXUS<sup>®</sup> Stent Subgroup Analysis

Diabetics (N = 715)

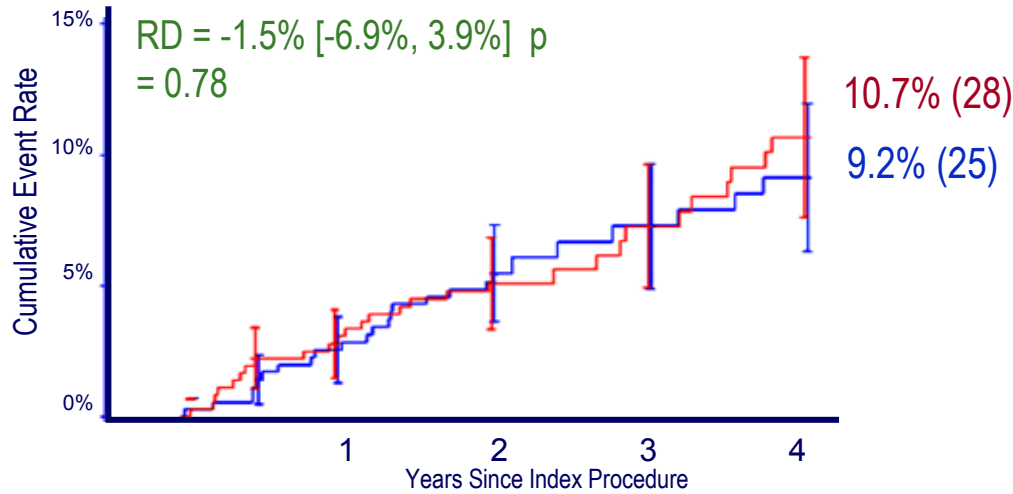
— TAXUS (N=356) — BMS (N=359)

RD = Rate Difference = TAXUS — BMS

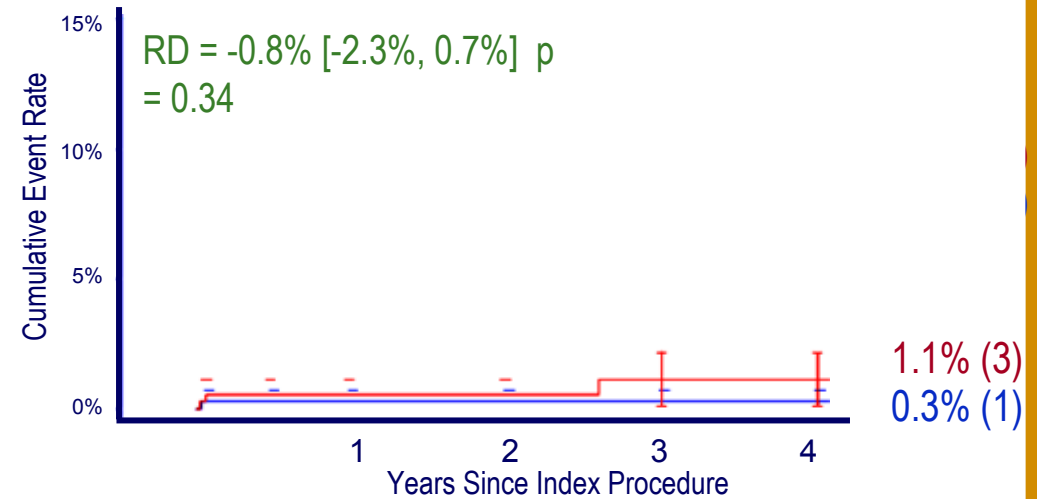
No increase

Increase

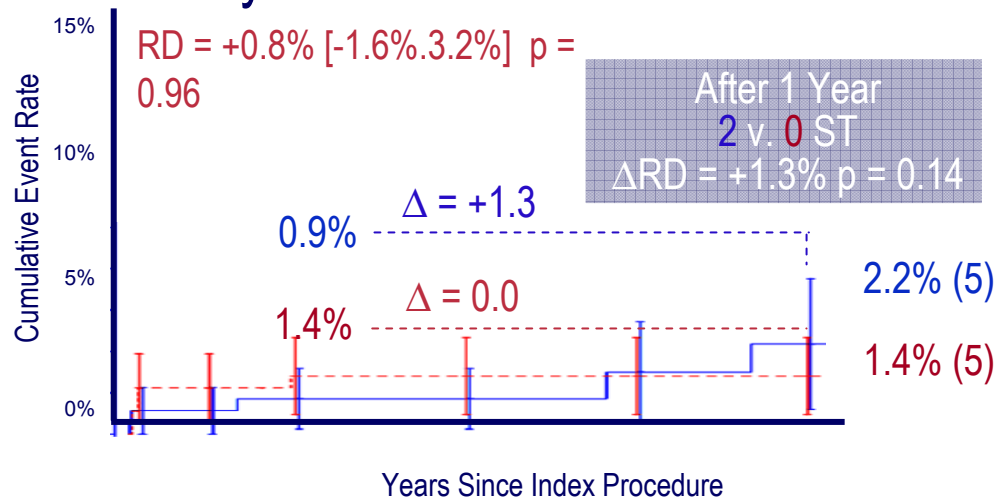
## All Death



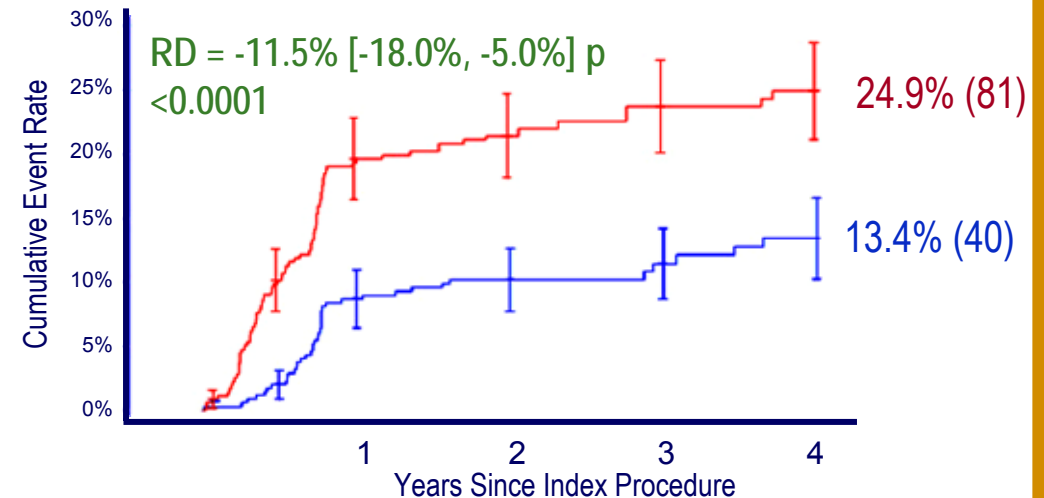
## Q Wave MI



## Primary ARC ST Definite/Probable



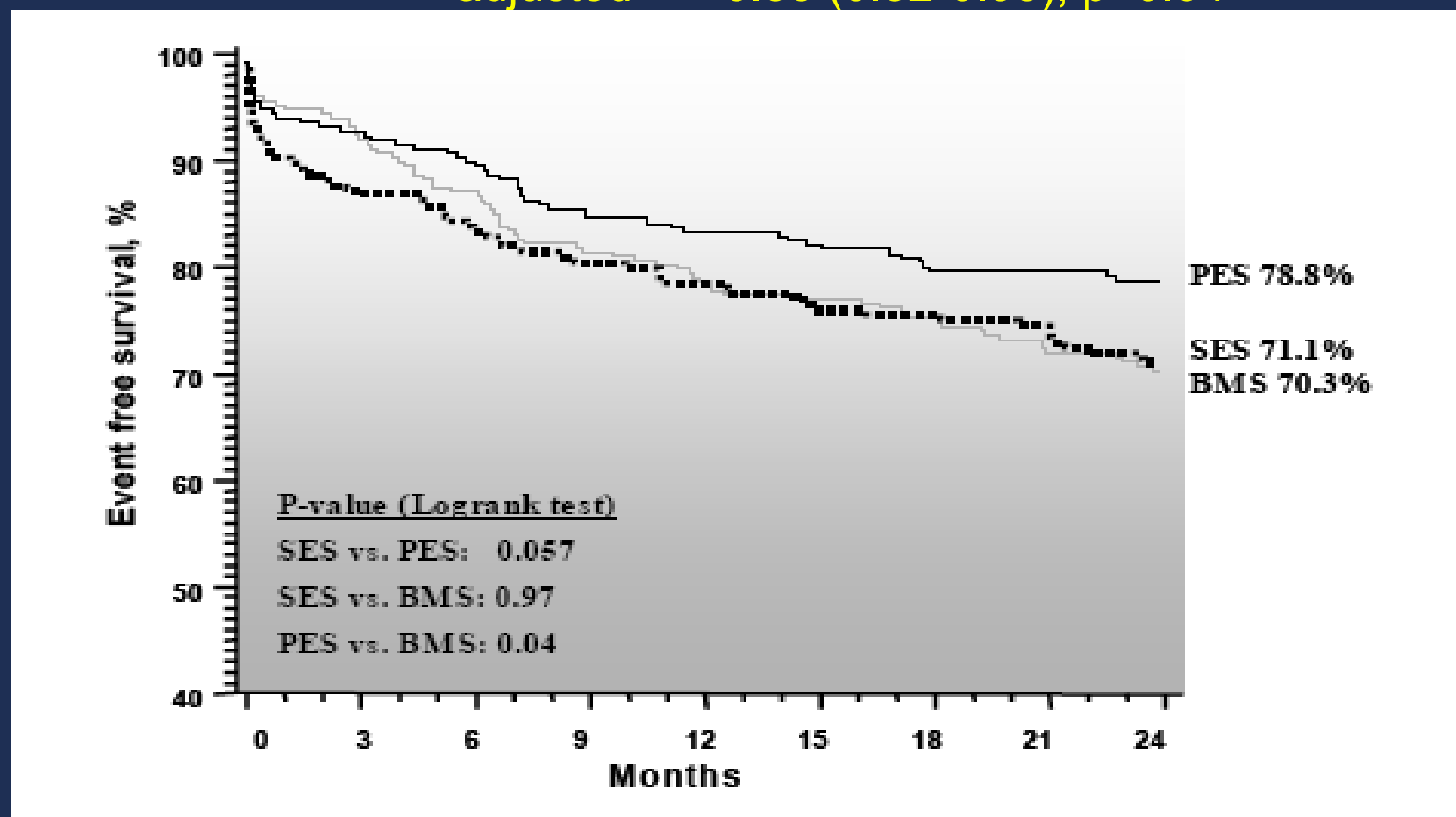
## TLR





# Thoraxcenter Diabetic data - MACE risk ratio for PES/SES

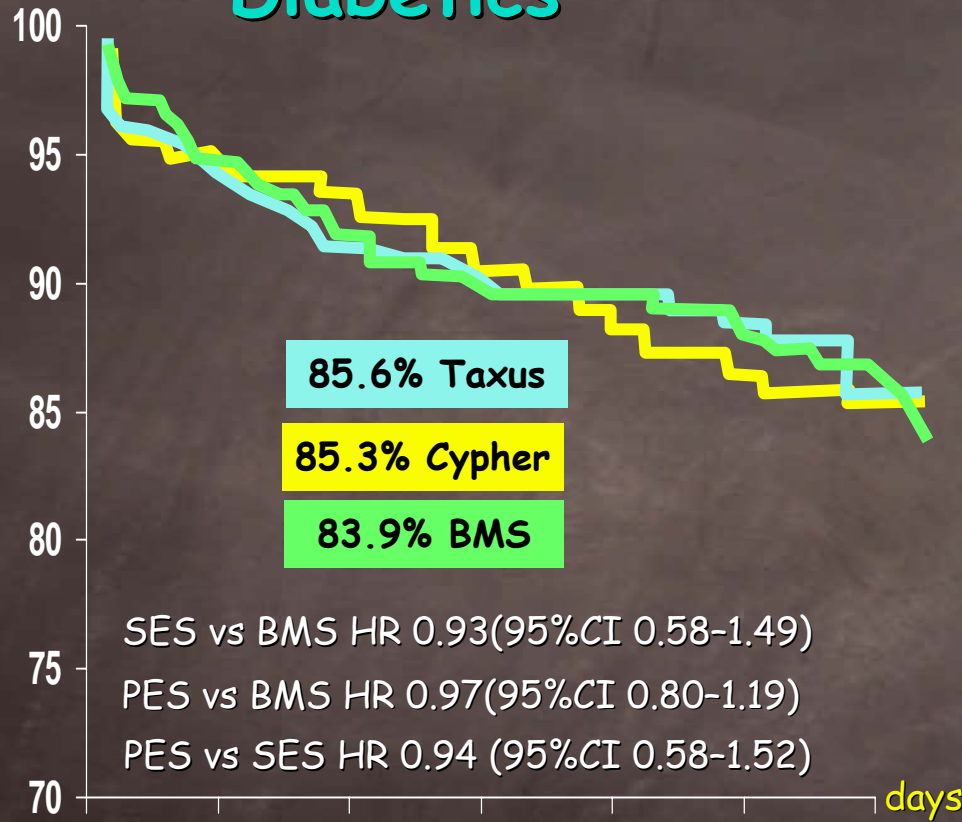
unadjusted 0.75 (0.49-1.15)  
adjusted 0.55 (0.32-0.95), p=0.04



# All-cause Mortality at Three Years

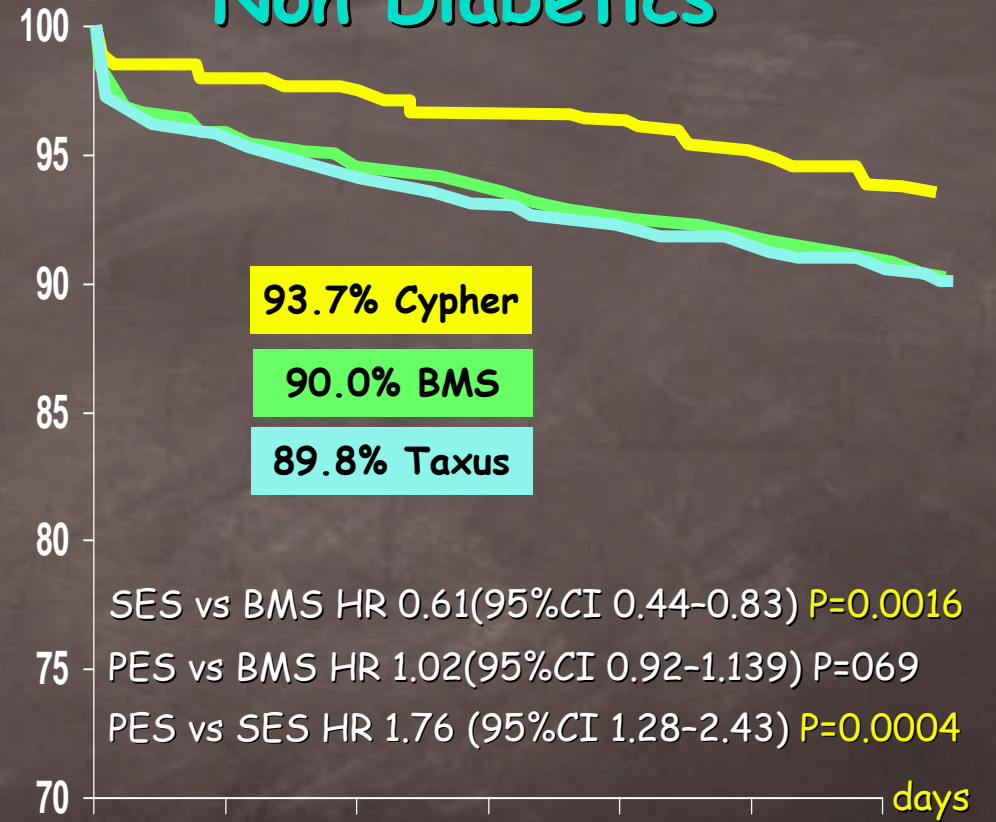


## Diabetics



	0	180	360	540	720	900	1080
<b>BMS</b>	306	288	276		267		237
<b>SES</b>	179	168	165		162		142
<b>PES</b>	484	433	408		258		85

## Non Diabetics



	0	180	360	540	720	900	1080
<b>BMS</b>	1980	1882	1850		1723		1625
<b>SES</b>	796	778	771		730		691
<b>PES</b>	2291	2066	2006		1174		402

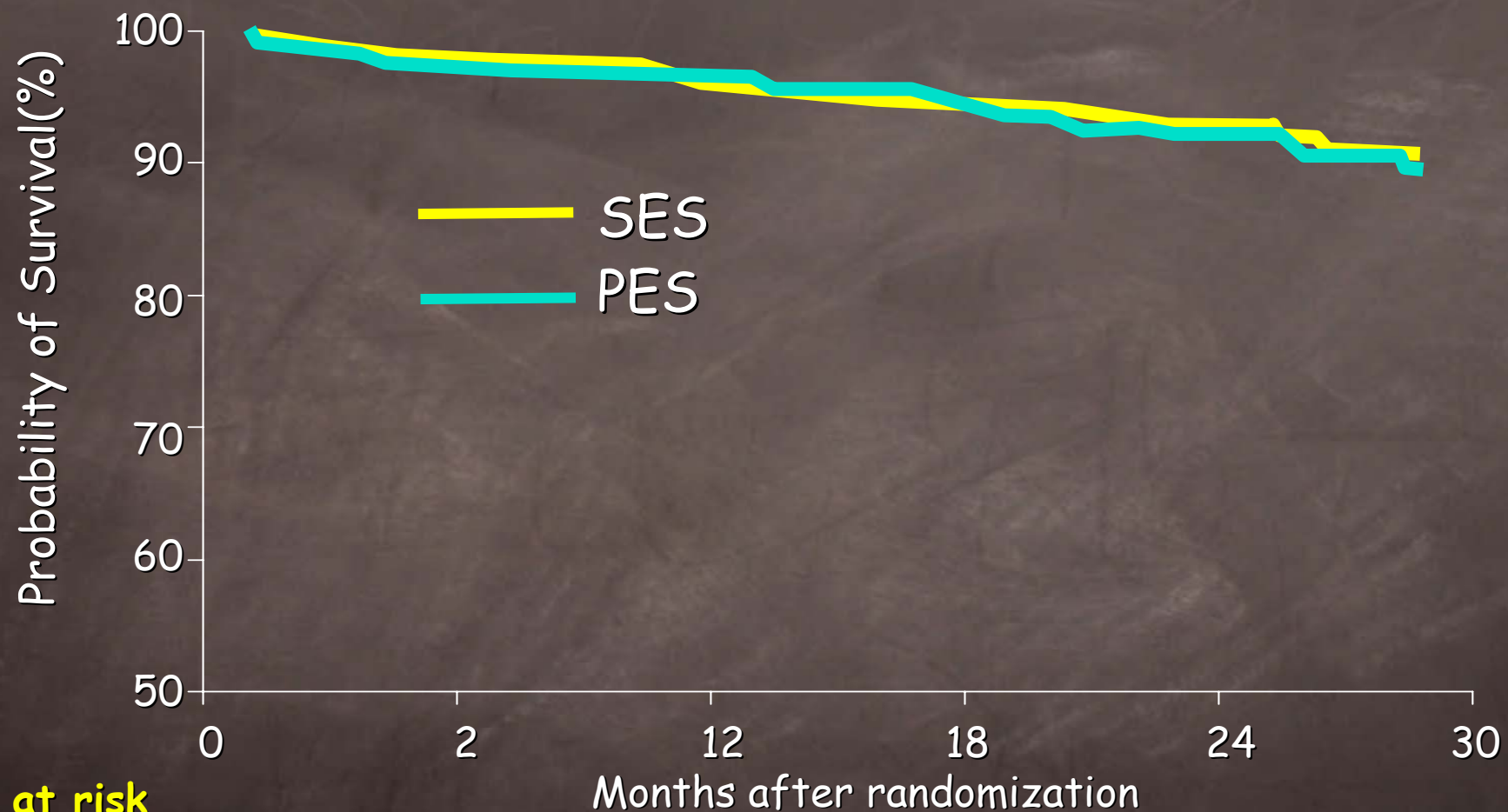
## 9 Randomized SES vs PES Trials



N = 5,074 (including diabetics n=1,418)

Trial	Total nr of pts	Total nr diabetic pts	Mean clinical FU in months	Notes
BASKET	545	93	18.2	All comers
CORPAL	652	202	30.5	
ISAR-DESIRE	200	58	33.9	Bare metal in-stent restenosis
ISAR-DIABETES	250	250	32.1	Diabetic pts
ISAR-SMART3	360	0	33.9	Small vessels, no diabetic
LONGDES II	500	166	13.0	Very long les
REALITY	1353	379	24.1	Small vessels, long lesions
SIRTAX	1012	201	24.2	50% ACS
TAXI	202	69	36.9	
Overall	5054	1418	25.1	

# Survival: SES vs PES Diabetics (n=1,418)



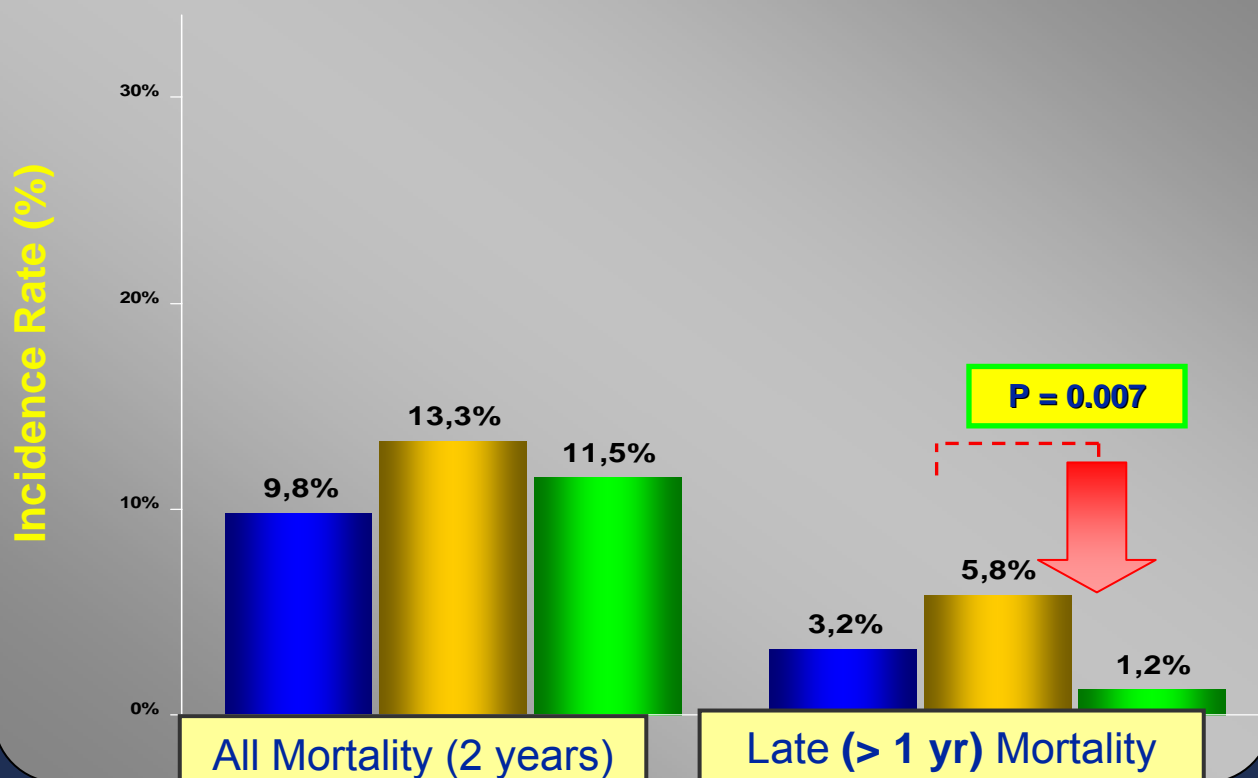
**Pts at risk**

<b>SES</b>	704	687	641	577	475	207
<b>PES</b>	714	686	634	572	439	186

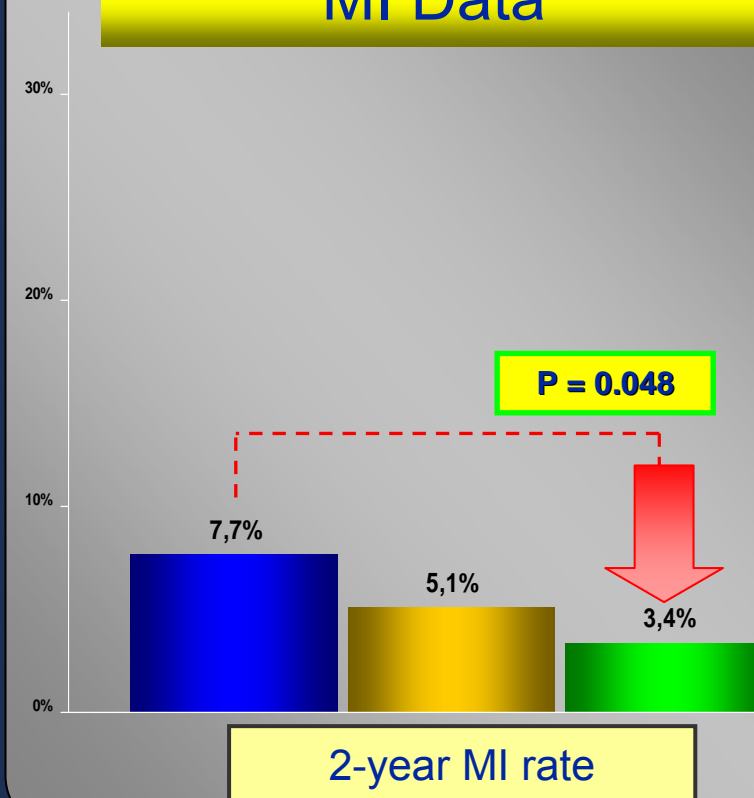


# The TAXUS™ Stent is as safe as BMS despite being used in more complex\* lesions

## Mortality Data



## MI Data



■ Bare Metal Stents (N = 252)    ■ TAXUS™ Stent (N = 250)    ■ Cypher™ Stent (N = 206)

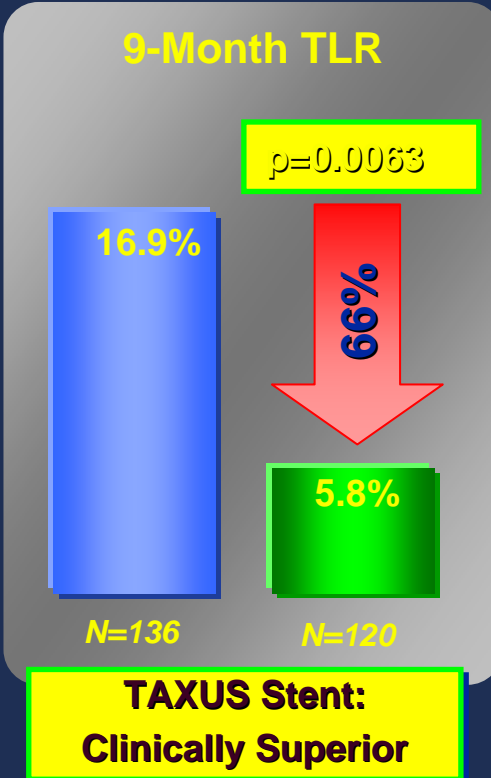
TSEASRCH/RESEARCH Data presented by Joost Daemen; European Society of Cardiology, Nov. 2006. No p-values other than the ones indicated were significant. P-values were not reported for PES vs. BMS or SES vs. BMS for Late (> 1 yr.) mortality. P-values were not reported for PES vs. BMS or SES vs. PES for MI. In the T-SEARCH/RESEARCH Diabetic registry, patients who received the TAXUS Stent had more type C lesions, higher incidence of multivessel treatment, higher number of stented vessels, longer stented length, and more CTOs. The TAXUS™ Express<sup>2</sup> Stent is contraindicated for use in patients with total occlusion of target vessel.



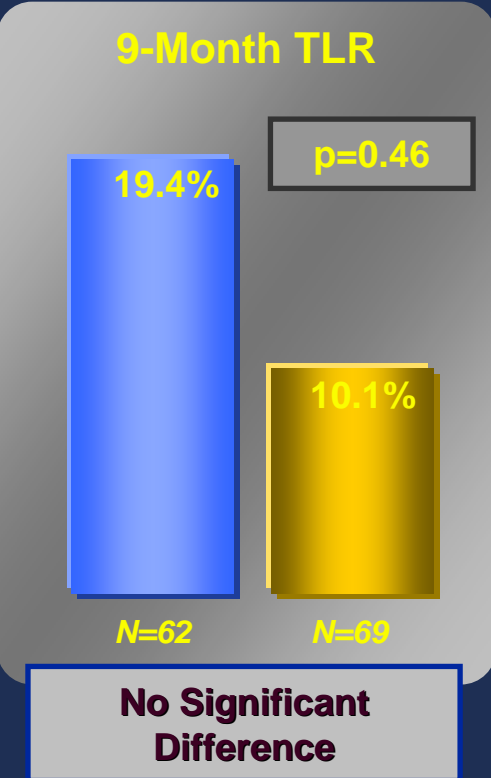
# TAXUS™ Stent: Statistically Significant TLR reduction in Insulin-treated patients\*\*



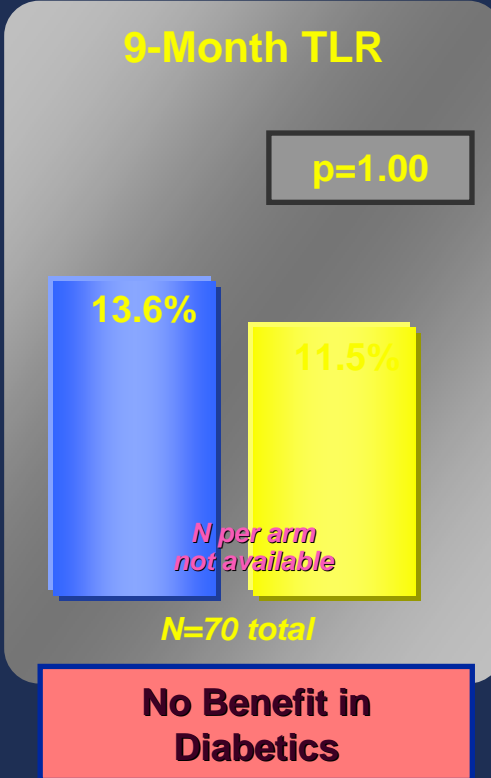
**TAXUS Stent** \*\*  
Meta-Analysis



**Cypher™ Stent** \*  
Integrated Analysis



**Endeavor™ Stent**  
ENDEAVOR II Study



■ TAXUS Stent     
 ■ Cypher Stent     
 ■ Endeavor Stent     
 ■ BMS Controls

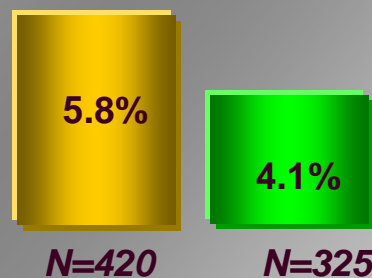
Cypher™ is a trademark of J&J/Cordis Corp. Endeavor™ is a trademark of Medtronic Corp. ENDEAVOR II study data published in *Circulation*. 2006;114:798:806. \*Trials included in Cypher™ Integrated Analysis: RAVEL, SIRIUS, E SIRIUS and C SIRIUS all studies sponsored by J&J-Cordis: Results published on TCTMD.com, Oct 17, 2005 \*\*TAXUS 4 year meta-analysis, presented by Dr. Baim, TCT 2006.

# Prior efficacy data trended in favor of TAXUS™ Stent in Diabetic Patients



## SOLACI registry

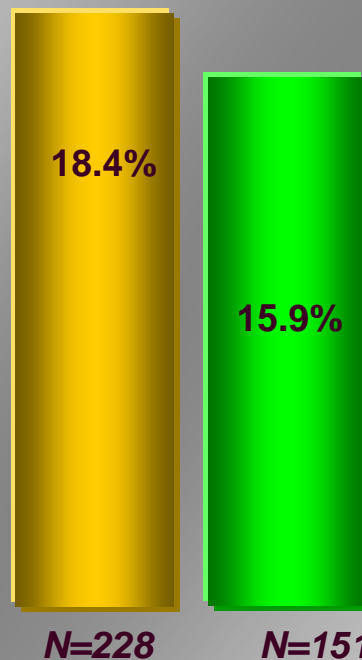
12-Month TVR  
p=n.s.



Trend favors TAXUS Stent

## MILAN registry

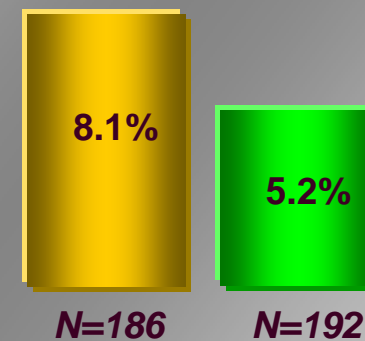
9-Month TLR  
p=n.s.



Trend favors TAXUS Stent

## REALITY study

12-Month TLR  
p= n.s.



Trend favors TAXUS Stent

Cypher Stent

TAXUS Stent

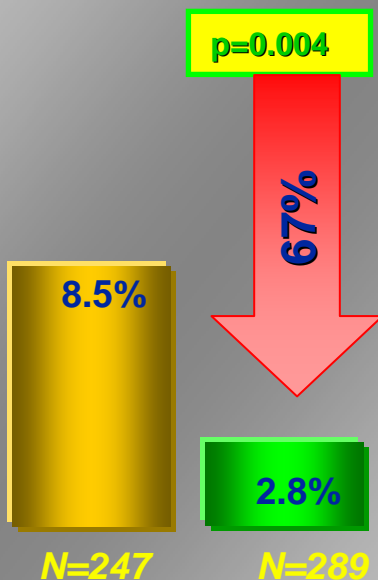
# New data confirm that the TAXUS™ Stent is Superior in Diabetics



TCT 2006

TC WYRE Registry

12-Month TVR

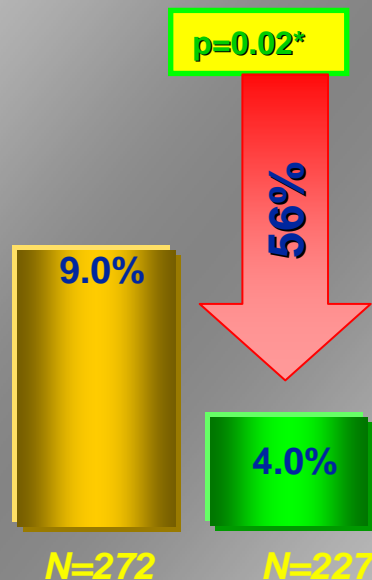


**TAXUS Stent:  
Clinically Superior**

TCT 2006

Kaiser Permanente Registry

12-Month  
Death, MI, TVR

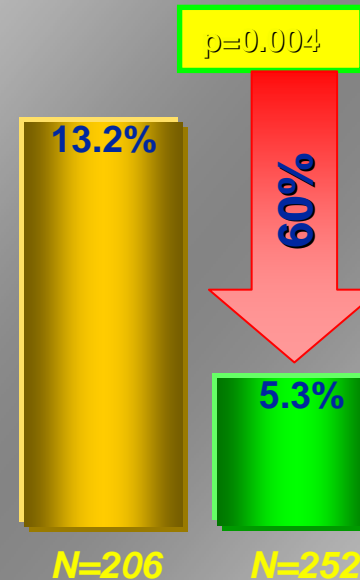


**TAXUS Stent:  
Clinically Superior**

AHA 2006

T-SEARCH/RESEARCH Registry

24-Month TLR



**TAXUS Stent:  
Clinically Superior**

**New  
Data**

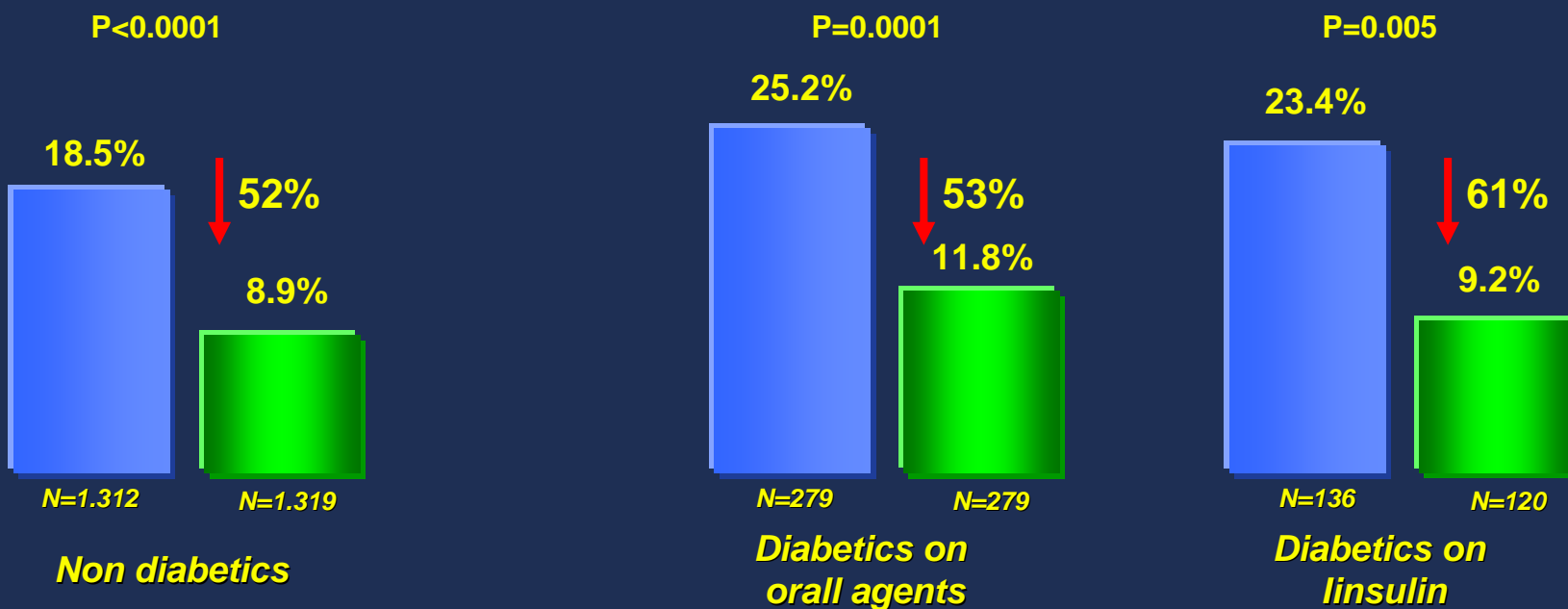
Cypher™ Stent      TAXUS Stent

TC WYRE registry data presented by Dr. Kandzari and Dr. O'Neill at TCT 2006. Kaiser Permanente registry data presented by Dr. Brar at TCT 2006. Prairie Heart Institute registry data presented by Dr. Mishkel et al. TCT 2006. T-Search/Research registry presented by Dr. Daemen at AHA 2006. Cypher is a registered trademark of J&J/ Cordis Corp. \* Log-Rank p-value.



## results in diabetics treated with insulin

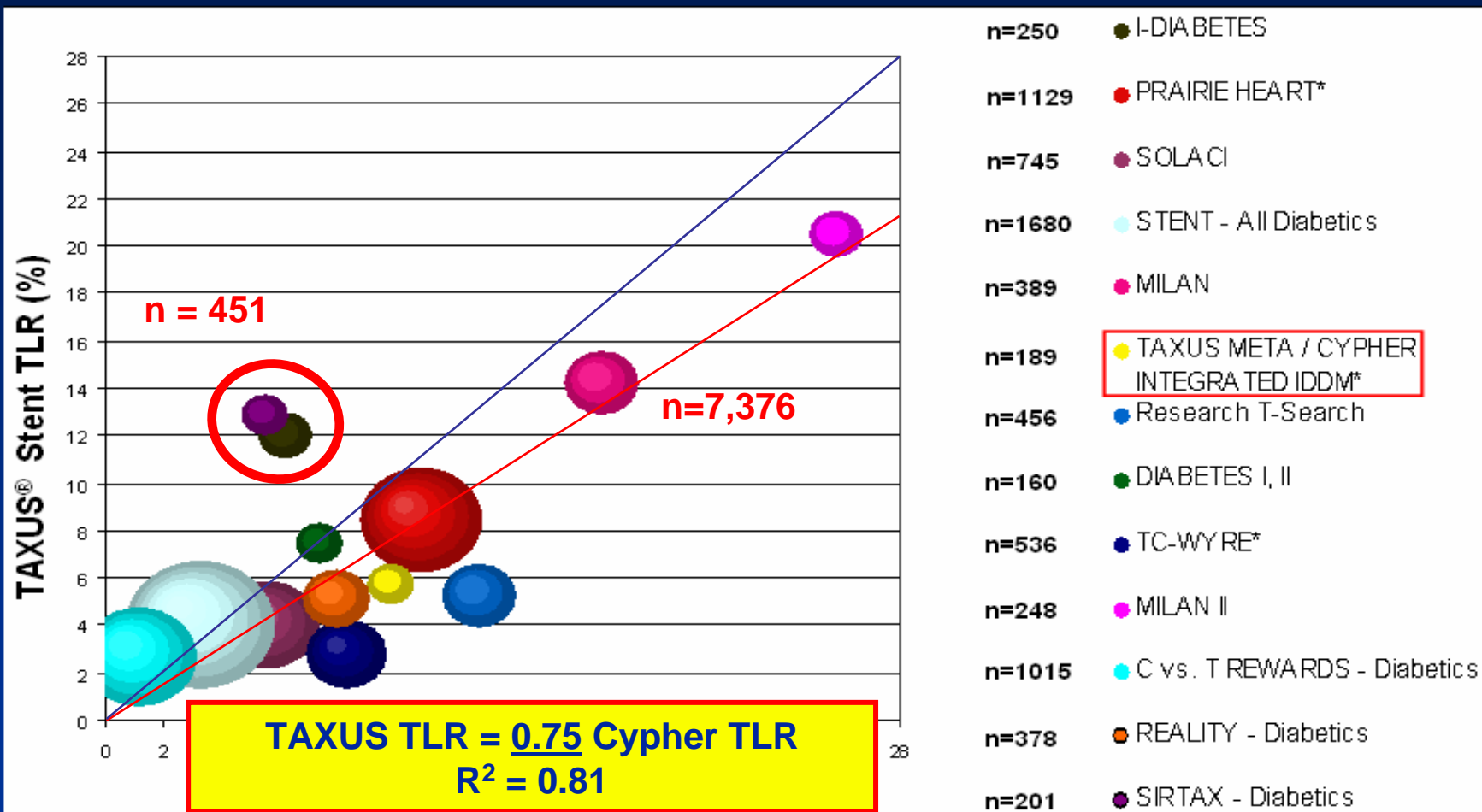
### Meta-Analysis TAXUS™ II, IV, V, VI



# Diabetic Evidence

Weight the Studies According to Trial Size...

**ISAR-Diabetes and SIRTAX are Outliers**



Size of circle adjusted for number of patients.

\* STENT- all Diabetic, SOLACI, TC-WYRE and PRAIRIE HEART are TVR

Data points represent similar lesion types from the two referenced trials, but are not head to head trials.

The safety and effectiveness of the TAXUS® Express® Stent and Cypher® Stent have not been established in patients with diabetes.



## Baseline Patient Characteristics

	SES	PES	P-value
Patients, n	171	171	
Age, ys	64.4 ± 9.8	63.1 ± 9.9	0.22
<b>Diabetes Mellitus</b>			
- Diet controlled	11.7%	14.0%	0.63
- Oral Agents	66.7%	52.0%	0.008
- Insulin	21.6%	33.9%	0.016
EF, %	50.1 ± 10.9	51.9 ± 10.7	0.15
Pre CABG	21.1%	24.0%	0.6
Renal impairment	10.5%	9.4%	0.86



## Lesion Characteristics

	SES	PES	P-value
Lesions, n	323	324	
Bifurcations	14.2%	13.3%	0.73
Occlusions	9.3%	8.3%	0.68
Calcified lesions	22.0%	24.4%	0.52
Stent Length, mm	29.5 ± 12.5	28.9 ± 13.6	0.56
Stent Diameter, mm	2.95 ± 0.41	2.96 ± 0.37	0.79
Stents per lesion, n	1.13 ± 0.38	1.14 ± 0.44	0.72



## QCA Measurements (I)

	SES	PES	P-value
Lesions, n	323	324	
<b>Pre-procedural</b>			
RVD, mm	2.62 ± 0.69	2.62 ± 0.60	0.86
MLD, mm	0.83 ± 0.50	0.87 ± 0.49	0.35
DS, %	67.9 ± 18.0	67.3 ± 16.8	0.62
Lesion Length, mm	14.3 ± 9.1	14.2 ± 9.1	0.90
<b>Post-procedural</b>			
RVD, mm	3.10 ± 0.62	3.12 ± 0.49	0.33
MLD, mm	2.69 ± 0.60	2.78 ± 0.50	0.06
DS, %	12.5 ± 8.8	11.0 ± 7.9	0.04
Acute gain, mm	1.86 ± 0.66	1.91 ± 0.56	0.28





## QCA Measurements (II)

	SES	PES	P-value
Follow-up			
Lesions, n	235	236	
RVD, mm	3.06 ± 0.60	2.86 ± 0.53	0.001
MLD, mm	2.41 ± 0.94	2.23 ± 0.76	0.06
DS, %	22.8 ± 22.8	22.7 ± 21.9	0.97
Late lumen loss, mm	0.34 ± 0.82	0.61 ± 0.68	0.002
Median (IQR)	0.2 (-0.2-0.69)	0.5 (0.14-0.9)	0.0001
Angiographic restenosis	25.5%	21.2%	0.28



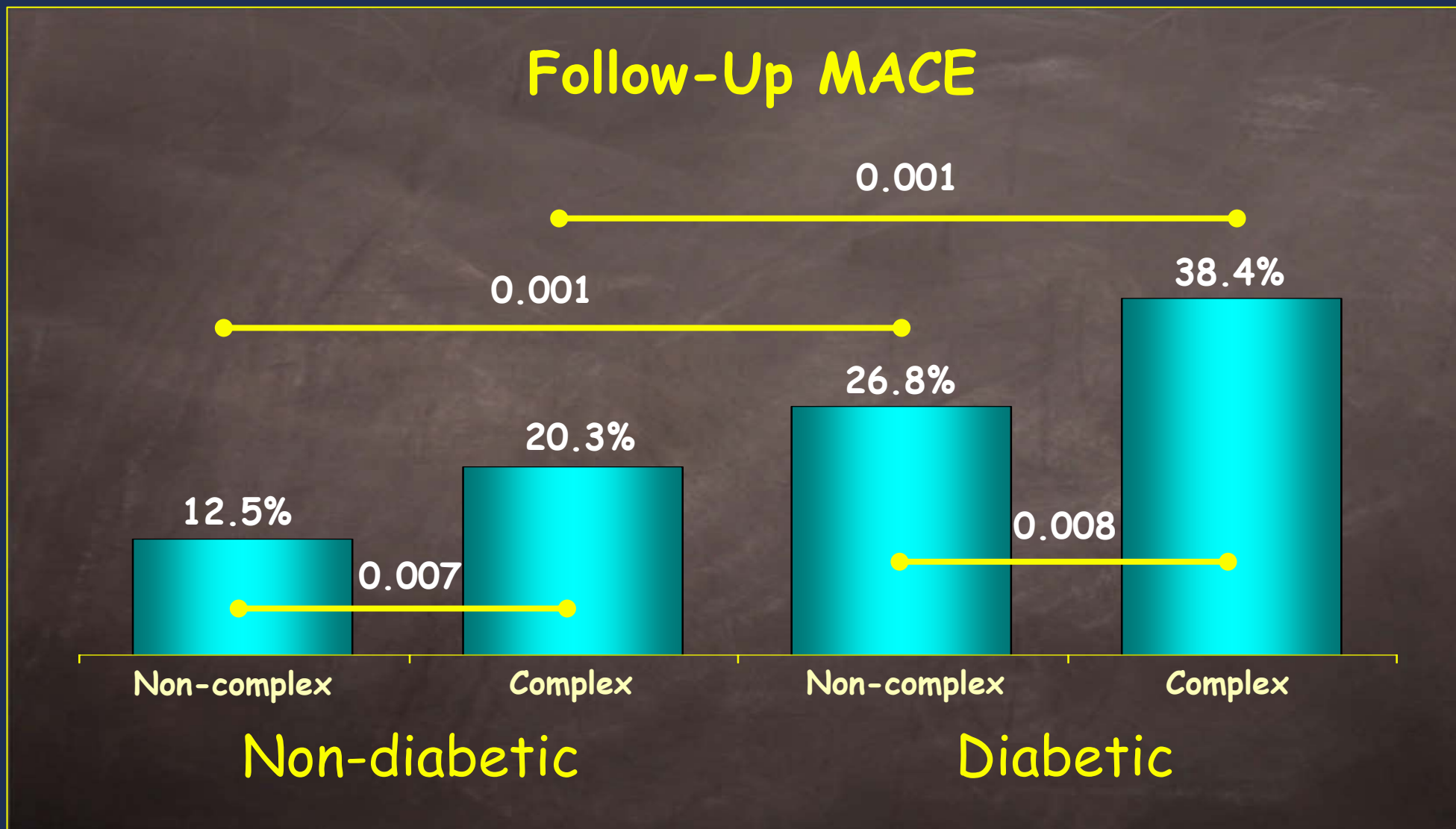
## Clinical Outcomes (per patient)<sup>§</sup>

	<b>SES</b>	<b>PES</b>	<b>P-value</b>
Angio follow-up patients, n	71.9% (123)	73.1% (125)	0.72
Total Death	6.4% (11)	3.5% (6)	0.32
Cardiac death	5.8% (10)	2.9% (5)	0.29
Myocardial infarction*	2.9% (5)	4.1% (7)	0.77
Late thrombosis*	0.6% (1)	1.8% (3)	0.37
TLR	25.7 % (44)	20.5% (35)	0.31
TVR	31.0% (53)	26.3% (45)	0.4
MACE	35.7% (61)	31.0% (53)	0.42
CABG	1.2% (2)	1.8% (3)	0.69
Multiple MACE	4.1% (7)	3.5% (6)	1.0

<sup>§</sup> Median clinical follow-up: 13.9 months (IQR 11.5-17.5)



## Diabetes and Disease Complexity



## Conclusions



- Both stent platforms perform reasonably well in diabetic patients
- PCI in this complex subset even with DES is associated with a significant MACE rate.
- The advantage in late lumen loss for SES does not translate into a measurable clinical benefit.
- In some registries it appears that Taxus may have an advantage over Cypher regarding restenosis
- Presently there is no dedicated and powered study addressing this issue