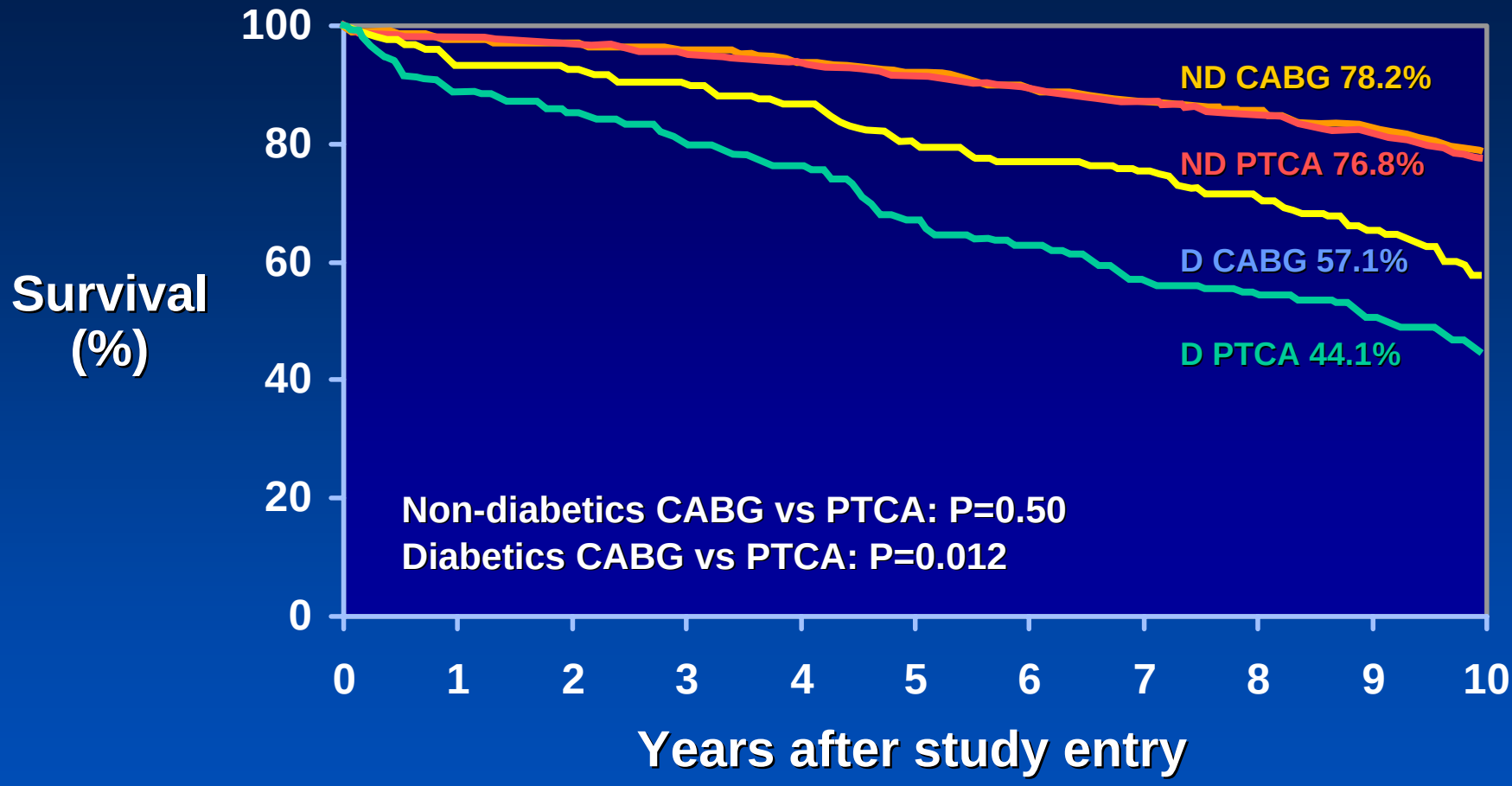
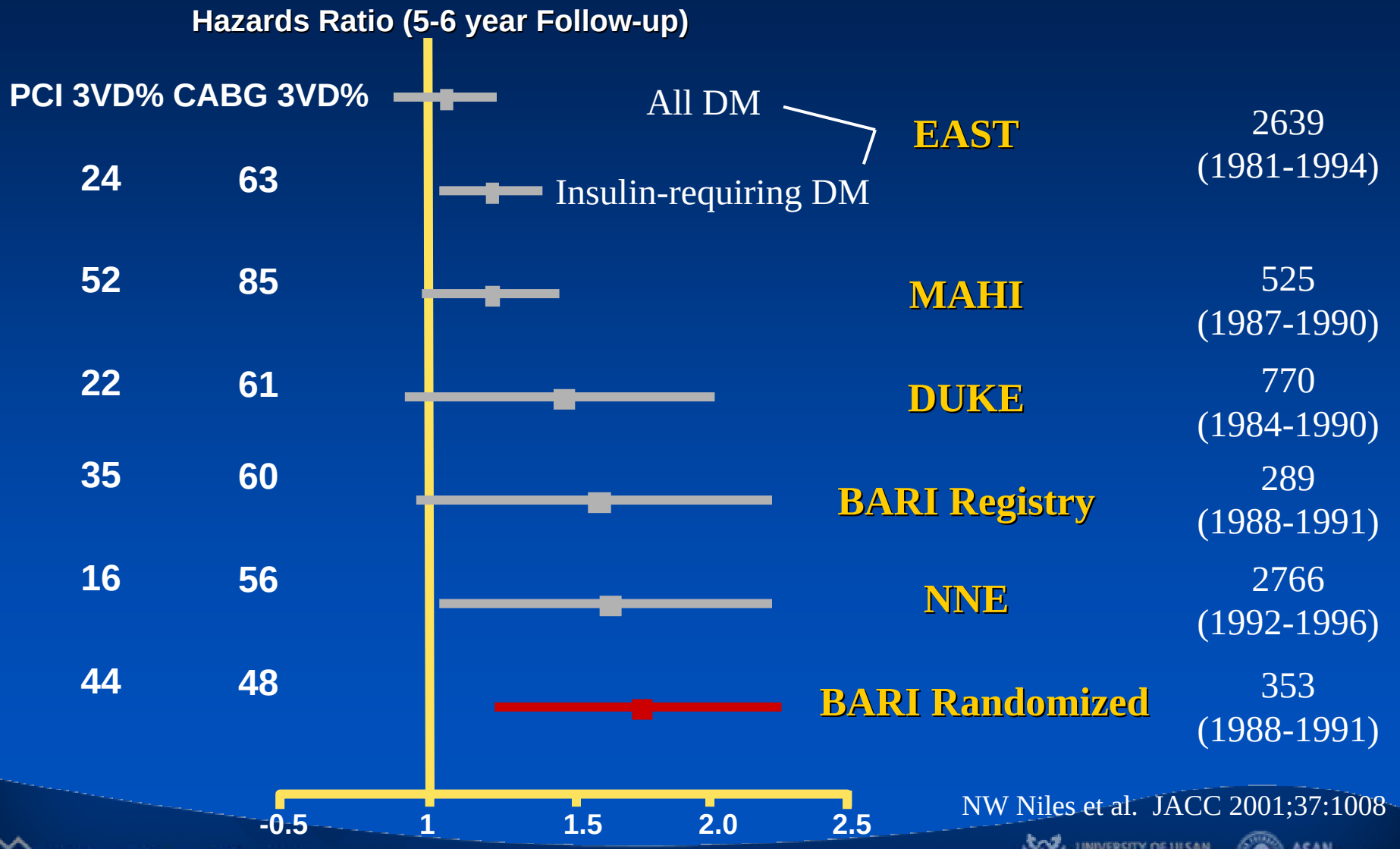
PCI vs. CABG

BARI Randomized Trial 10-Year Survival Stratified by Diabetes Status



J Am Coll Cardiol. 2007;49:1600–1606.

Diabetic Survival
PTCA vs CABG



NW Niles et al. JACC 2001;37:1008

5-year results from ART I

Diabetic subgroup

	Stent, n=112	CABG, n=96	RR (95% CI)	P
Death	13.4%	8.3%	1.61 (0.71-3.63)	0.27
CVA	6.3%	7.3%	0.86 (0.31-2.36)	0.79
MI	10.7%	7.3%	1.47 (0.60-3.59)	0.47
Q-MI	8.0%	4.2%	1.93 (0.61-6.07)	0.39
Non-Q MI	2.7%	3.1%	0.86 (0.18-4.15)	1.00
Death/CVA/MI	25%	19.8%	1.26 (0.76-2.11)	0.41
reCABG	15.2%	2.1%	7.29 (1.73-30.7)	0.001
re PCI	30.4%	9.4%	3.24 (1.64-6.41)	<0.001
Any revascular	42.9%	10.4%	4.11 (2.20-7.68)	<0.001
Any MACCE	54.5%	25%	2.18 (1.48-3.20)	<0.001

J Am Coll Cardiol. 2005;46:575–581.

ARTS-II Trial

607 patients
with multivessel coronary lesions
26.2% diabetic
54% 3 vessel disease
13.9% type C lesions

Historical Controls from ARTS I:
1202 patients
with multivessel coronary lesions
18.2% diabetic
28% 3 vessel disease
7.5% type C lesions

Cypher
3.7 stents per patient
Avg total length: 73 mm
n = 607

CABG
n = 602

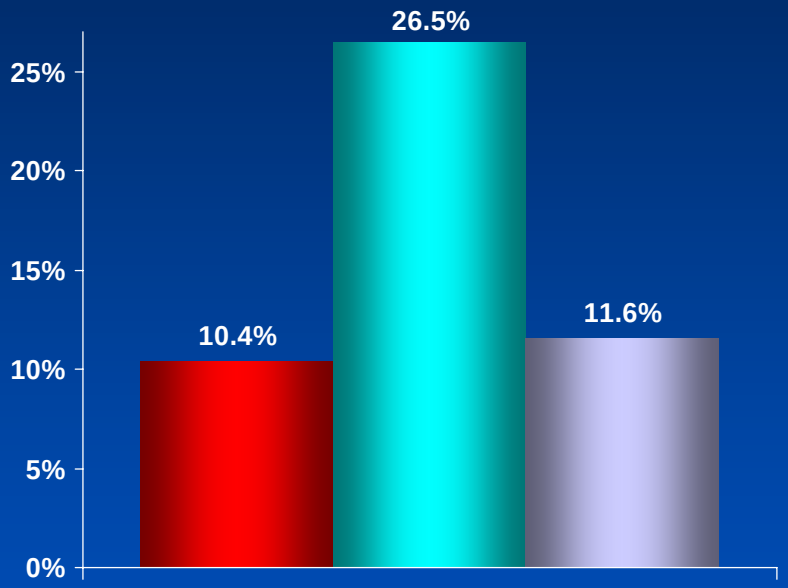
BMS
2.8 stents per patient
Avg total length: 48 mm
n = 600

Endpoints:

- **Primary** – Major adverse cardiac and cerebrovascular events (MACCE)
- **Secondary** – MACCE at 30 days, 6 months, 3 and 5 years.
  – Total cost at 30 days
  – Cost, cost effectiveness, quality of life at six mo, and 1, 3, and 5 years

ARTS II Trial

Death/ MI/ CVA/ Revascularization



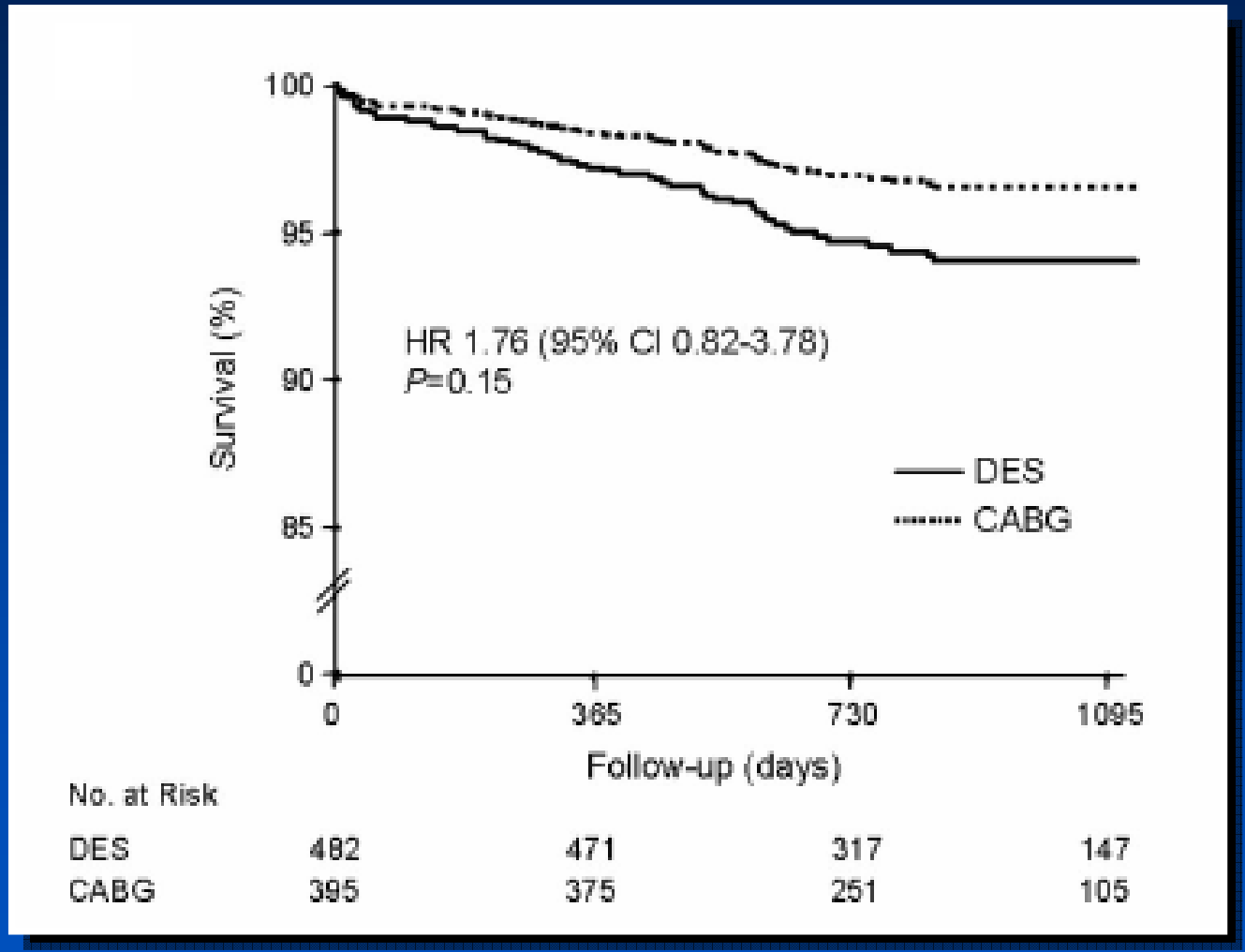
- There is no difference in the incidence of Death/MI/CVA between Cypher and CABG

- BMS group has a significantly higher revascularization rate than Cypher group

Cypher **BMS** **CABG**

Serruys PW, Eurointervention. 2005;1:147–156

DES vs. CABG
Three-year mortality in Diabetes



Park DW et al., Circulation 2008;117:2079-2086

SYNTAX Trial Design


62 EU Sites + 
23 US Sites

Heart Team (surgeon & interventionalist)

Amenable for both treatment options

Amenable for only one treatment approach

Stratification: LM and Diabetes

Randomized Arms
n=1800

CABG N=897 *vs* TAXUS* N=903

3VD 66.3% | LM 33.7%

3VD 65.4% | LM 34.6%

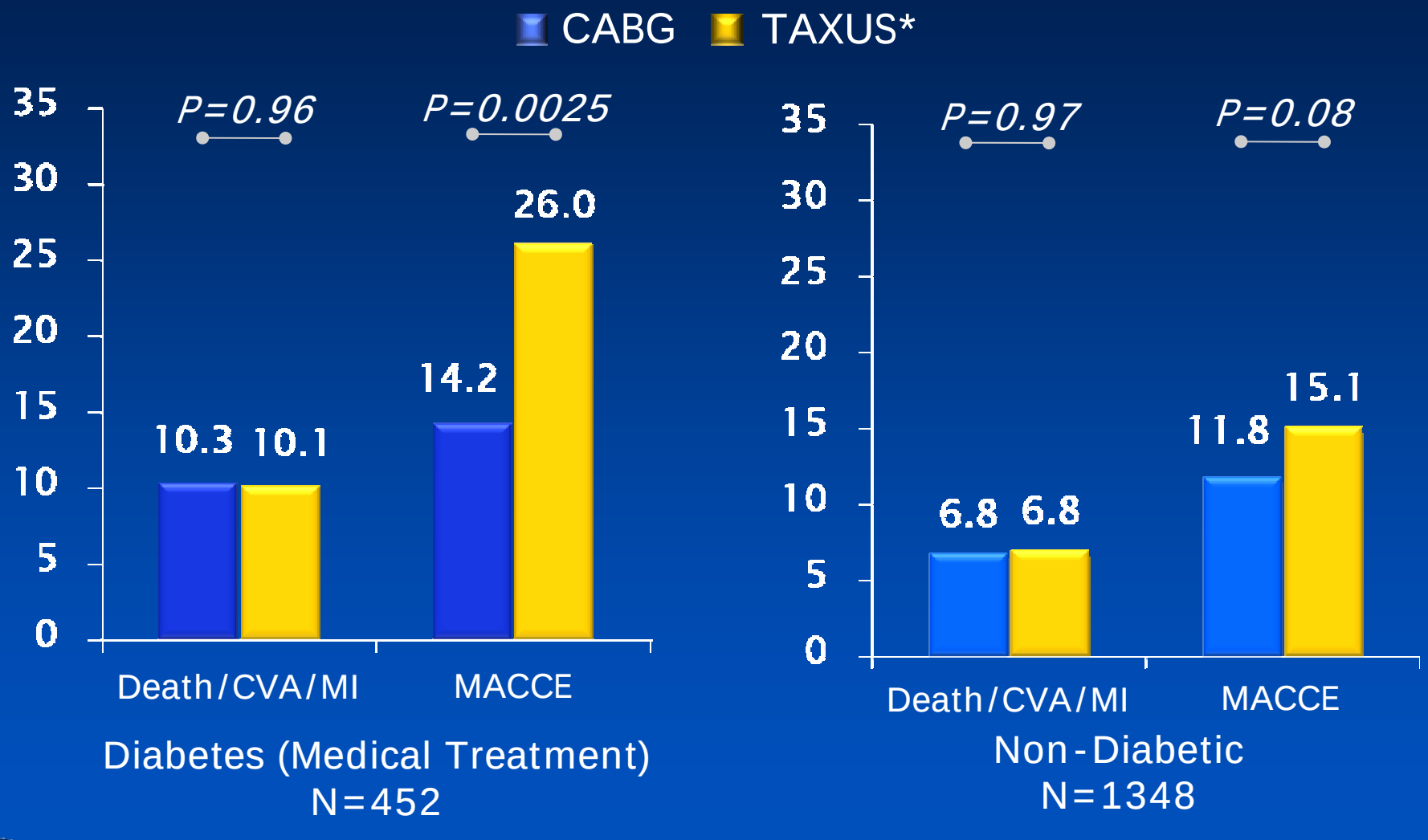
Two Registry Arms

CABG N=1077

PCI N=198

*TAXUS™ Express²™ Stent System

Medically Treated Diabetes and Non-Diabetic
All-Cause Death/CVA/MI and MACCE at 12 Months



ITT population

MACCE: death/CVA/MI/any revascularization

* TAXUS® Express® Stent System

CardioVascular Research Foundation

UNIVERSITY OF ULSAN COLLEGE MEDICINE

ASAN Medical Center

FREEDOM Trial

Eligibility : DM with MV-CAD eligible for stent or surgery
Exclude : Patients with acute STEMI, cardiogenic shock

Randomized 1:1

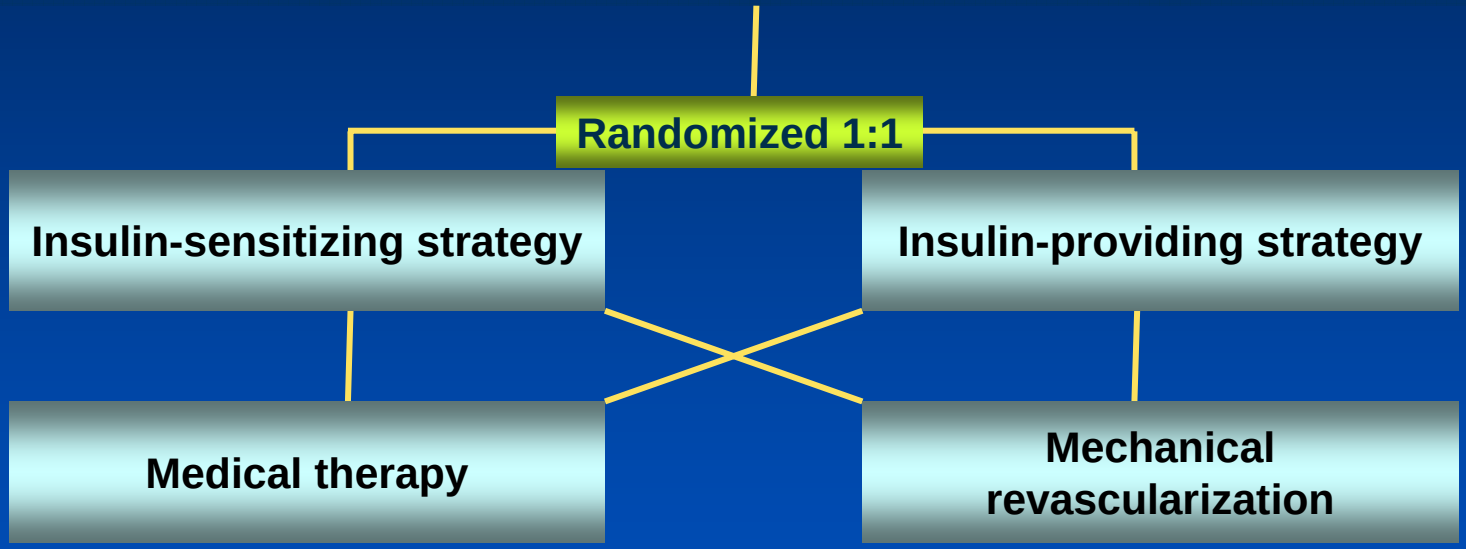
MV-stenting With DES and ReoPro	**CABG With or without CPB**

All concomitant Meds shown to be beneficial are encouraged, including : Plavix, ACE inhibitors, b-blockers, statins etc

PRIMARY: 5-year mortality
SECONDARY: 12-month MACCE, 5-year Quality of Life

BARI 2D Trial

Eligibility; DM patients (2000 pts)
with mild angina or documented myocardial ischemia and
> 1 significant (>50%) angiographic lesion



PRIMARY Endpoint: 5-year Mortality
SECONDARY Endpoints : 5-year Death, Q-wave MI, Stroke

PCI vs. CABG

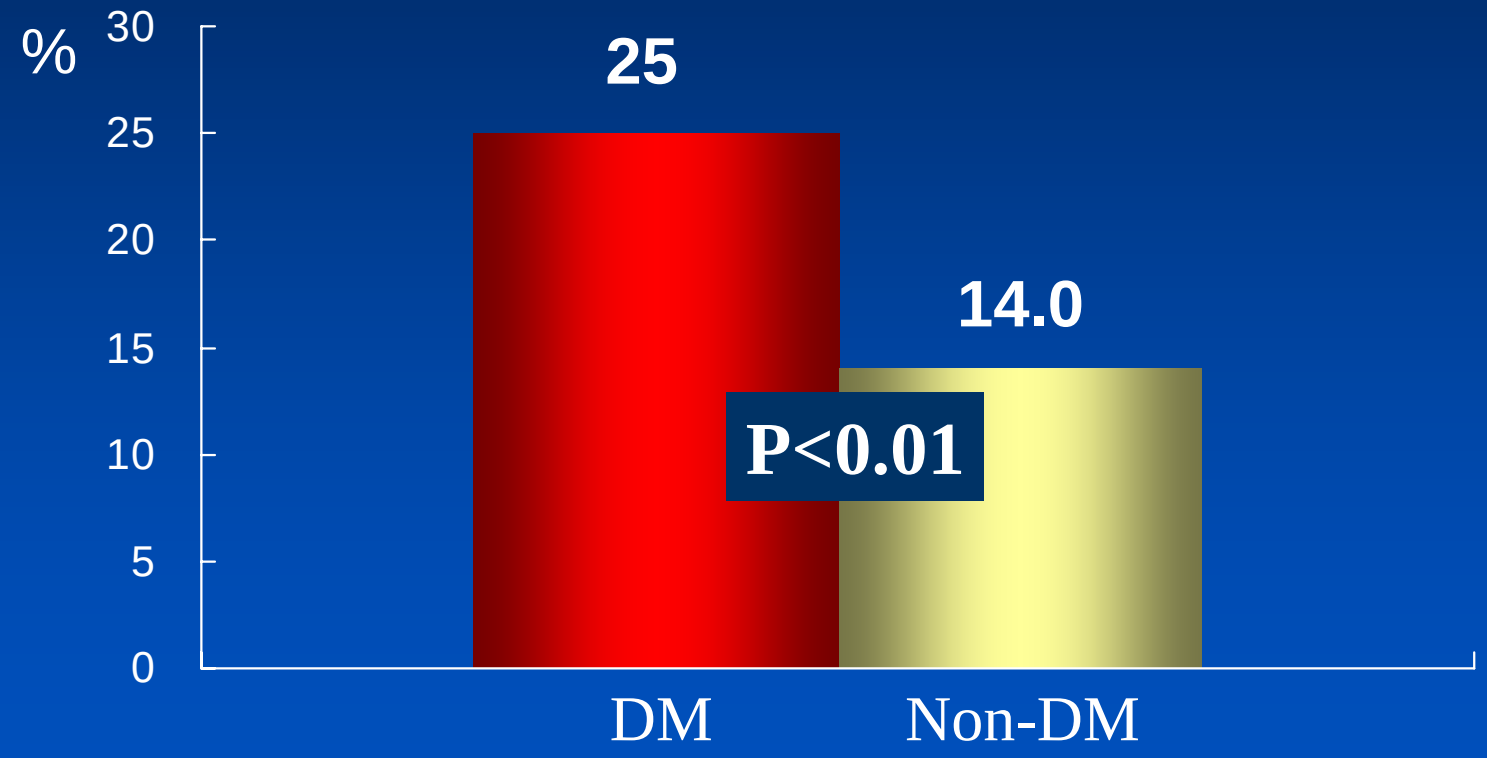
- Early randomized studies showed that reduced revascularization and mortality benefit were observed in CABG versus PCI in diabetic subgroup analysis in multivessel disease.
- With improvement of stent technology (BMS or DES) and pharmacologic therapy, the subgroup analysis of recent trials showed similar mortality rate in CABG and PCI with persistent reduction rate of revascularization in CABG
- On-going trials dedicated to diabetics will provide the most beneficial treatment strategy in diabetics.
- New trials of CABG and evolving DES as well as well done observational studies continue to be needed

Conclusions

- CABG is still standard therapy in patients with DM with multivessel disease in reducing adverse events.
- Based on the present data, patients with diabetes and an indication for PCI, a DES (preferably Cypher over Taxus) should be the treatment of choice.
- Aggressive medical treatment with glucose control, long-term clopidogrel treatment, triple antiplatelet therapy (DECLARE-DIABETES) could improve the long-term clinical outcomes after DES implantation.

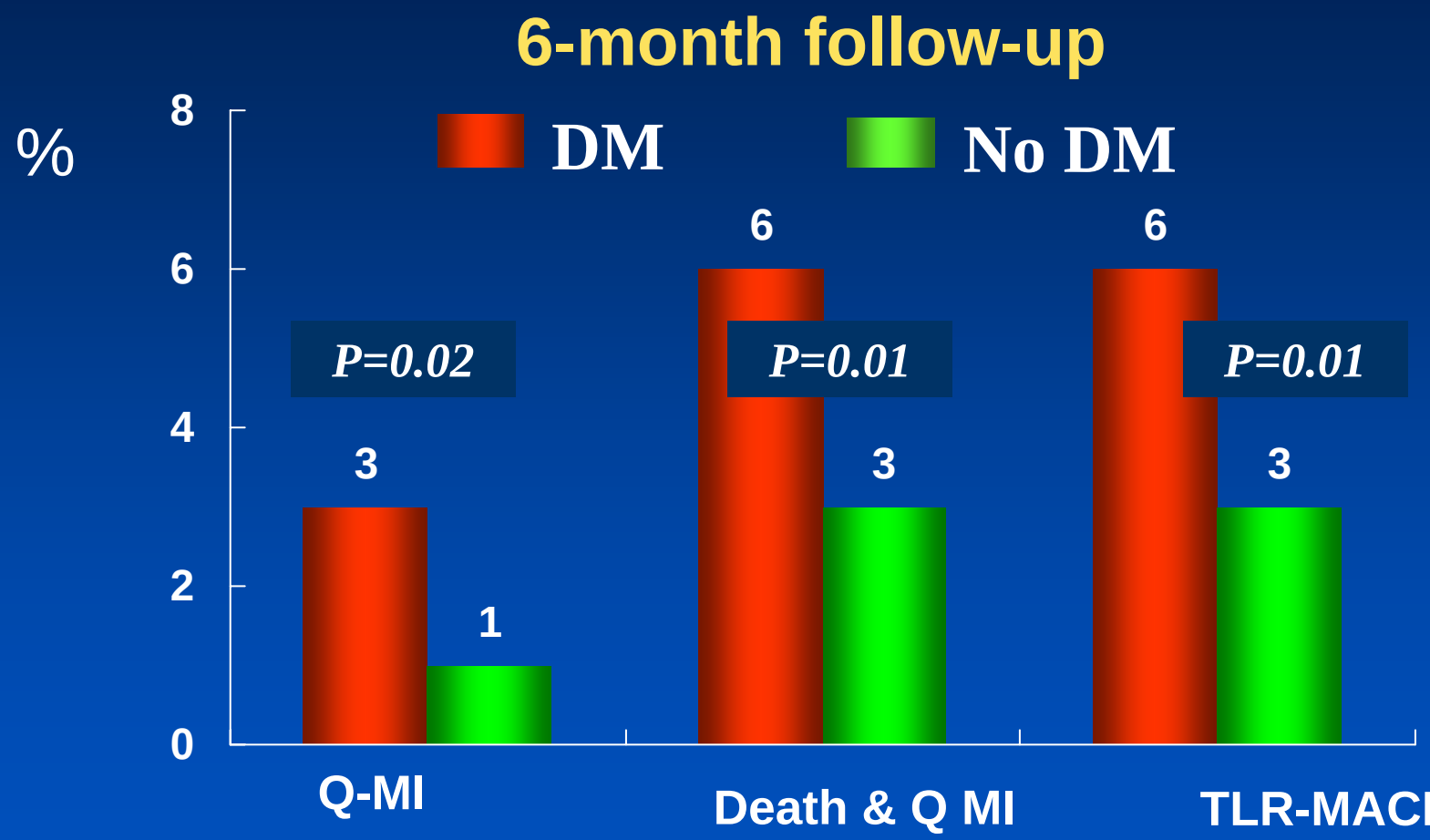
Impact of DM on Restenosis after DES Implantation

Matched comparison (192: 192)



Radke PW et al. Am J Cardiol 2006;98:1218

Impact of DM on clinical outcomes after SES



Kuchulakanti et al. Am J Cardiol 2005;96:1100

Impact of diabetes mellitus on long-term outcomes in the drug-eluting stent era

Raisuke Iijima, MD, Gjin Ndrepepa, MD, Julinda Mehilli, MD, Christina Markwardt, MD, Olga Bruskina, MD, Jürgen Pache, MD, Maryam Ibrahim, MD, Albert Schömig, MD, and Adnan Kastrati, MD *Munich, Germany*

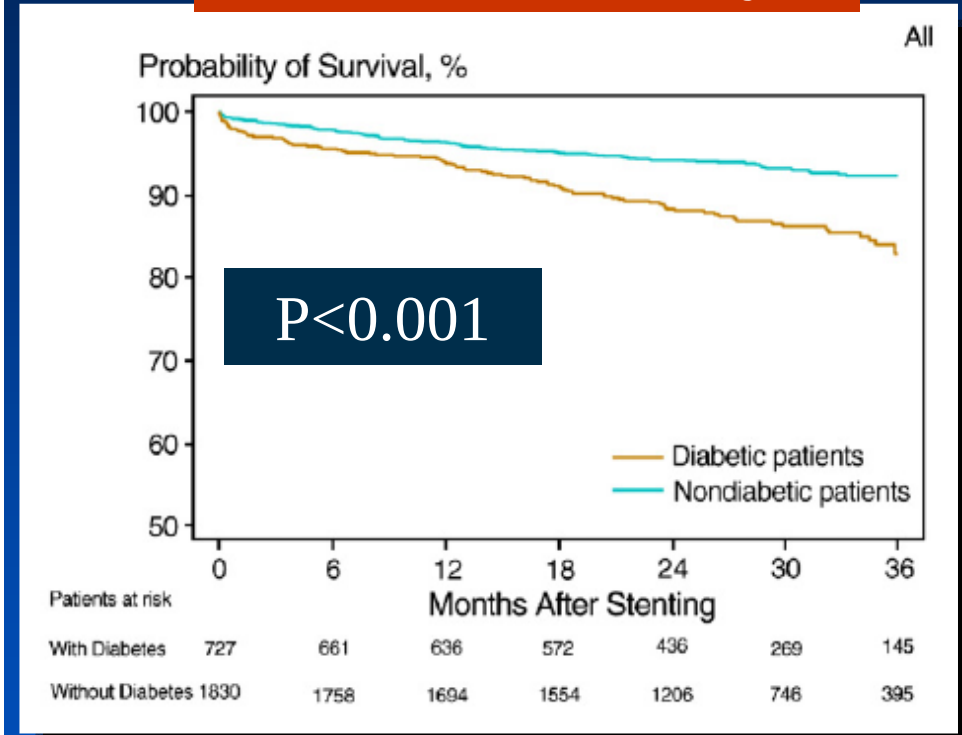
Prospective database of 2557 patients in 2 centers

: Diabetes (n=727) vs. Non-diabetes (n=1830)

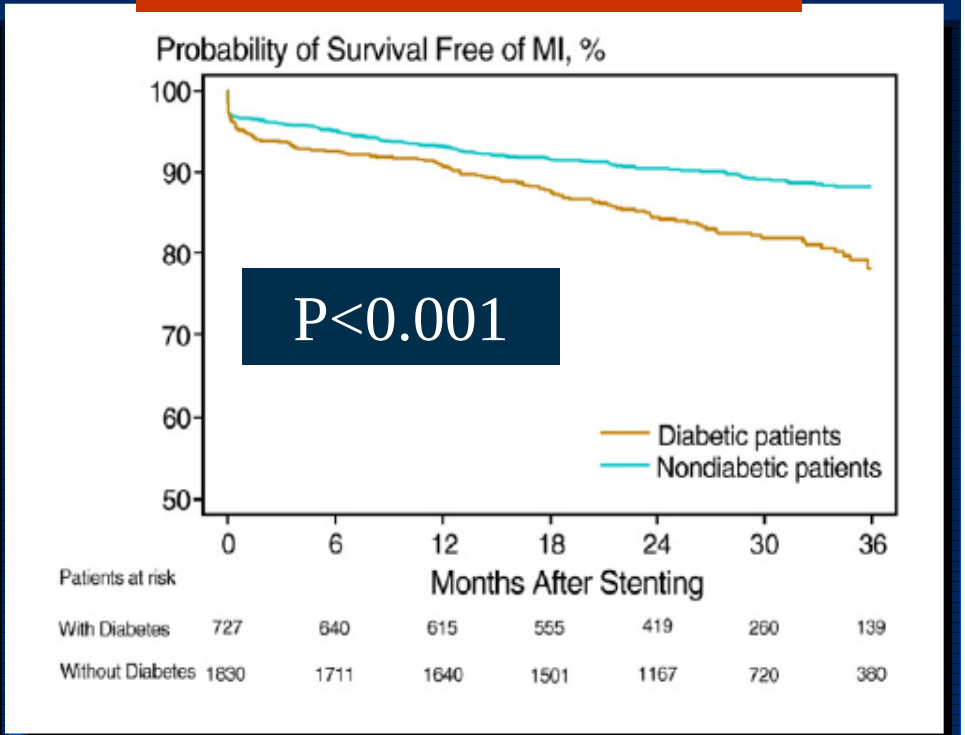
Am Hear J 2007;154:688-93

Long-term clinical outcome

All-cause mortality



Death or MI



Diabetes is independent predictor of 3-year mortality

Independent predictors of stent thrombosis

Incidence, Predictors, and Outcome of Thrombosis After Successful Implantation of Drug-Eluting Stents

- **Diabetes (HR 3.71, 95% CI, 1.74–7.89).**

JAMA 2005;293:2126-2130

Early and late coronary stent thrombosis of sirolimus-eluting and paclitaxel-eluting stents in routine clinical practice: data from a large two-institutional cohort study

Joost Daemen, Peter Wenaweser, Keiichi Tsuchida, Linda Abrecht, Sophia Vaina, Cyrill Morger, Neville Kukreja, Peter Jüni, Georgios Sianos, Gerrit Hellige, Ron T van Domburg, Otto M Hess, Eric Boersma, Bernhard Meier, Stephan Windecker, Patrick W Serruys

- **Diabetes (HR 2.03, 95% CI, 1.07–3.83).**

Lancet 2007;369: 667–78

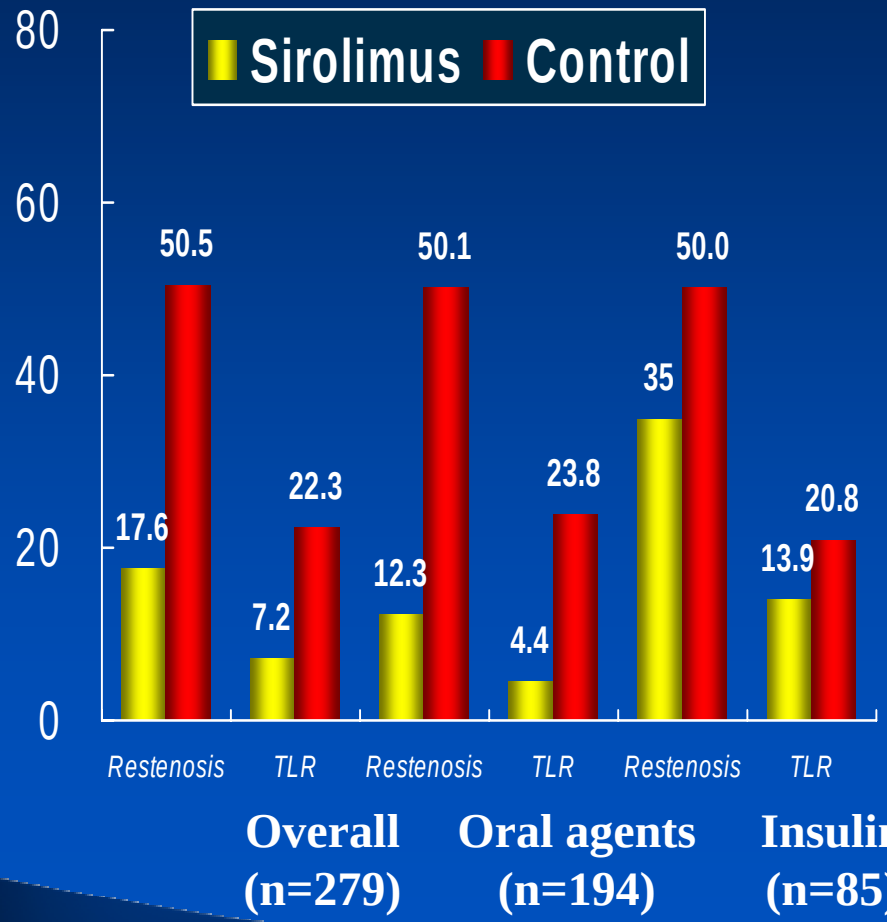
Diabetes on coronary artery disease

- Diabetic patients often present unfavorable coronary anatomy with small and diffusely diseased vessels and exhibit exaggerated neointimal hyperplasia after DES implantation as compared with nondiabetics.
- Presence of DM have been still associated with an increased risk of restenosis and unfavorable clinical outcomes in the era of DES.

DES vs. BMS

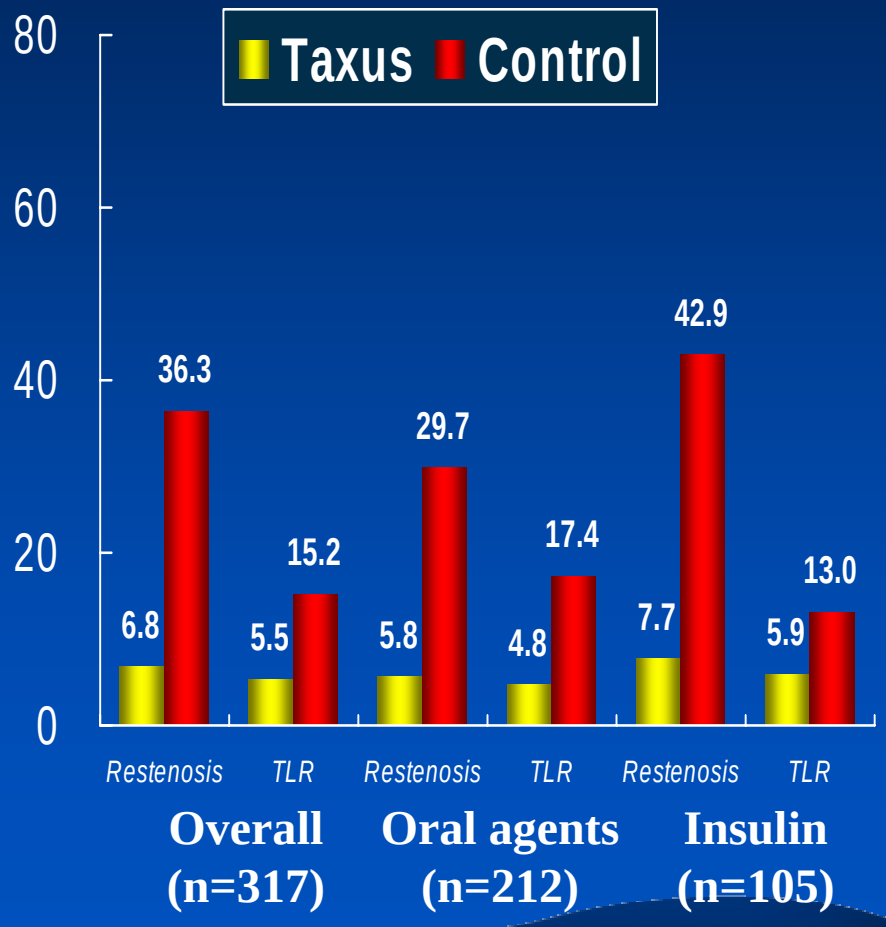
DES vs BMS in Diabetic patients

SIRIUS Trial
Diabetic Sub-analysis



Moses et al. NEJM 2003;349:1315

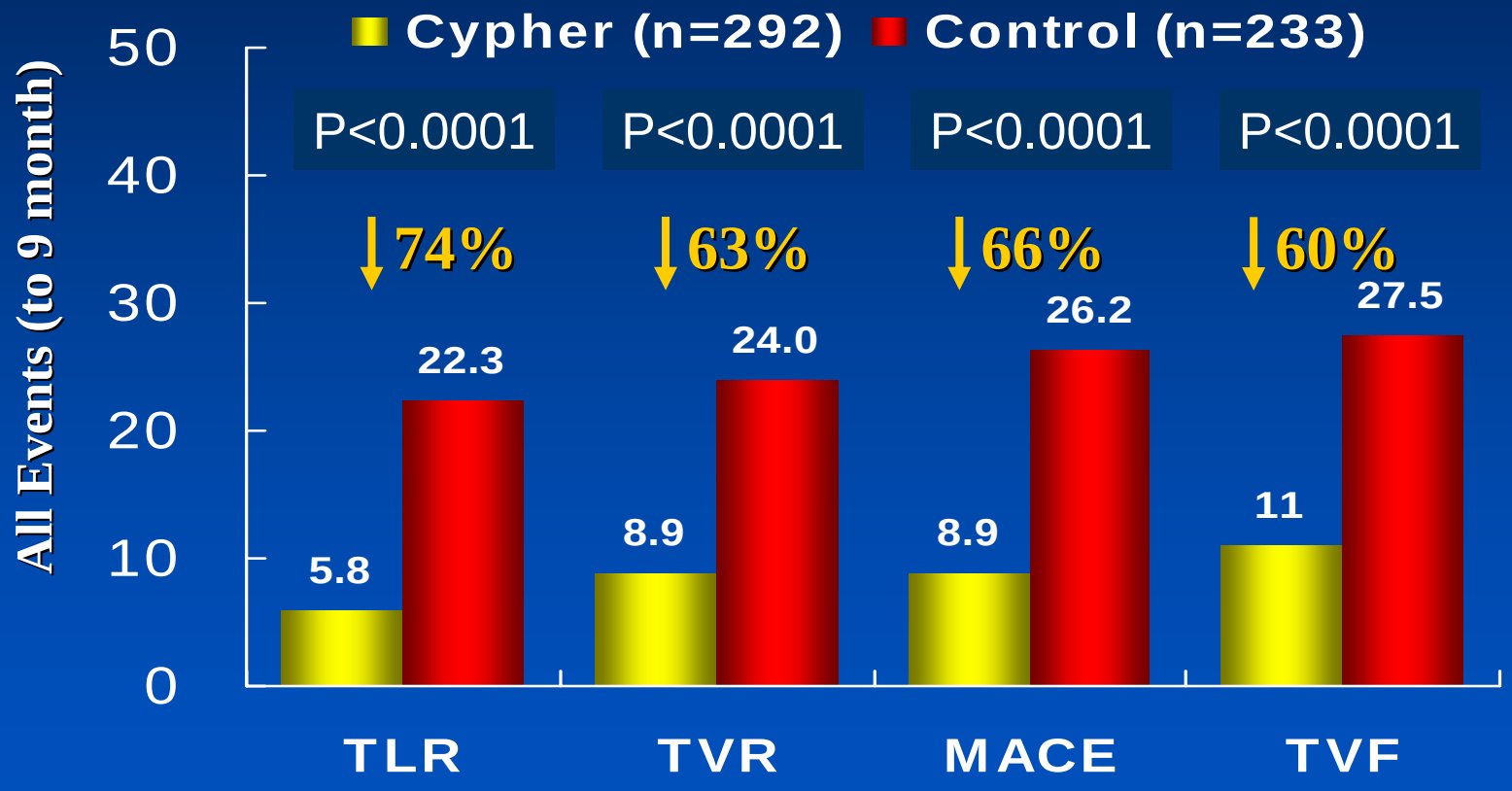
TAXUS IV Trial
Diabetic Sub-analysis



Stone et al. NEJM 2004;350:221.

CYPHER Trials Meta-Analysis in Diabetes

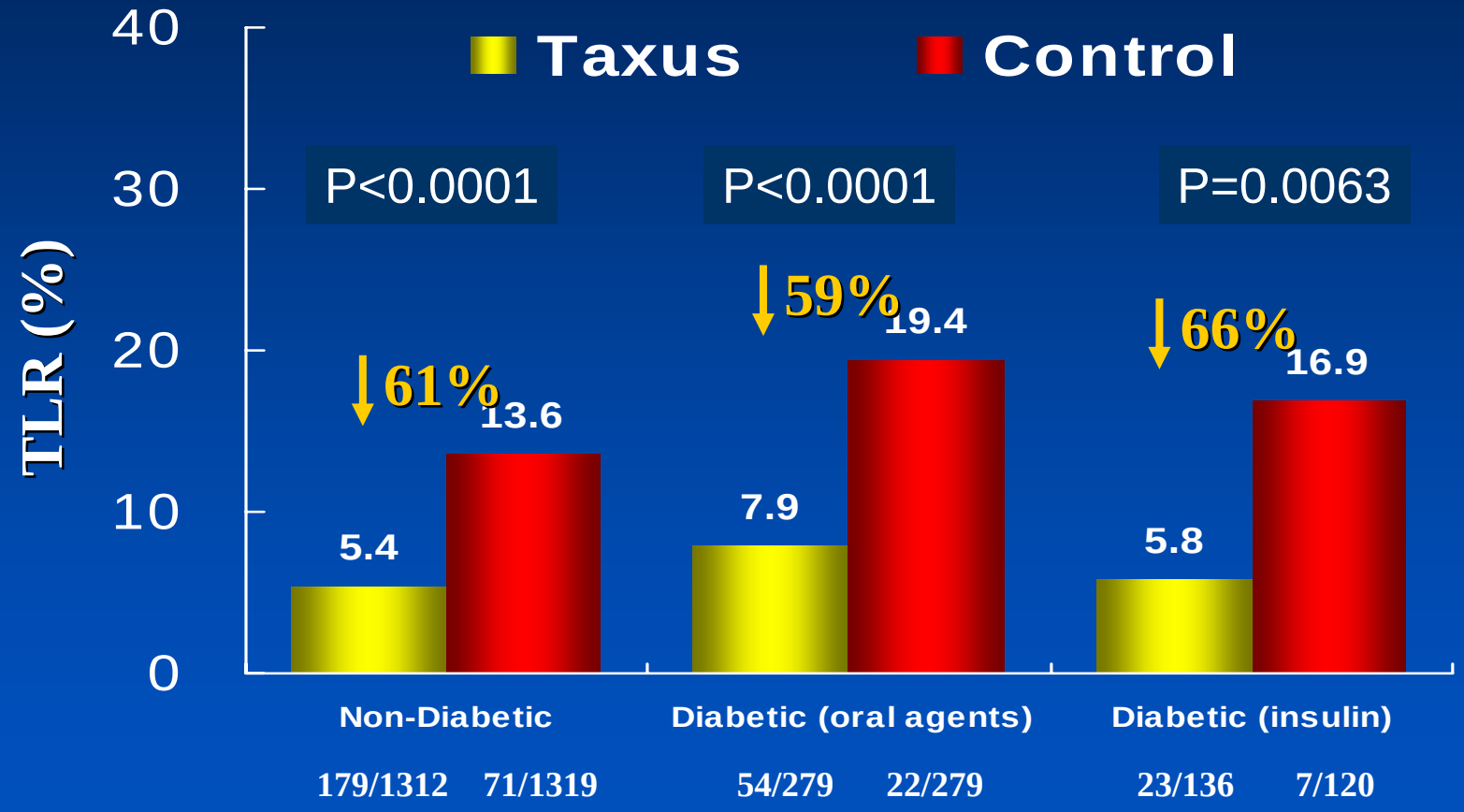
RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS, DIRECT, SVELTE



Abizaid et al. Anigoplasty Summit 2005

TAXUS Trials Meta-Analysis in Diabetes

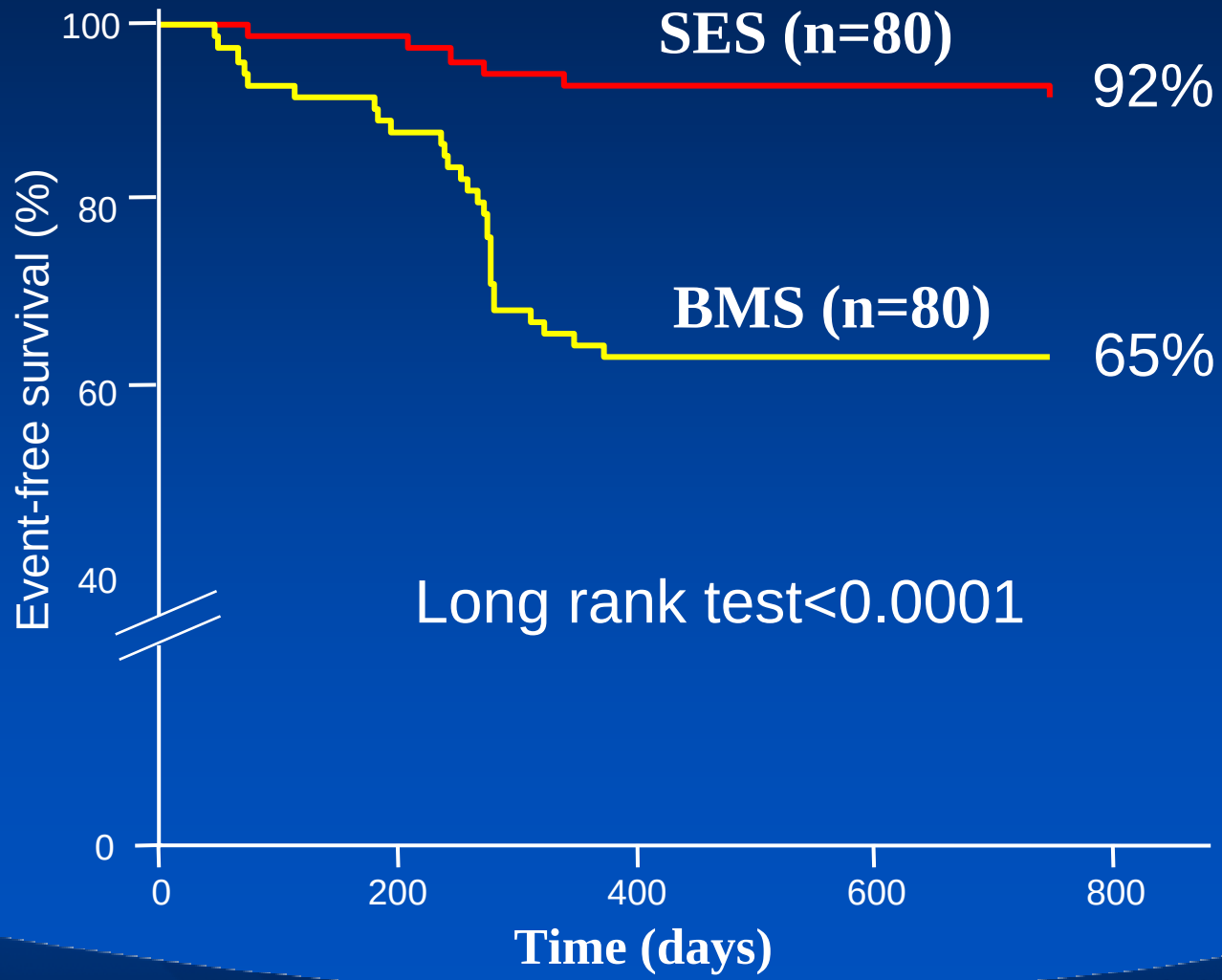
TAXUS II, IV, V, VI



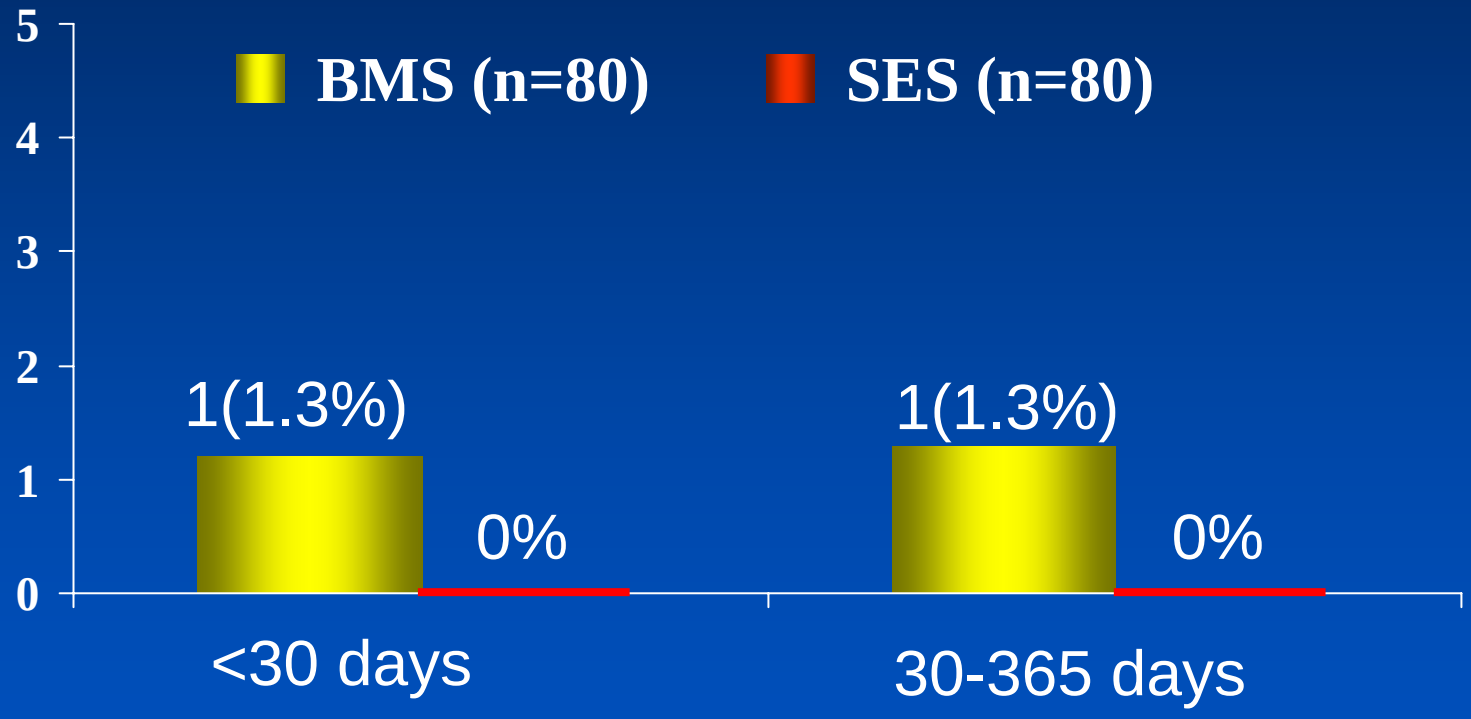
Stone GW et al. Anigoplasty Summit 2005

DIABETES trial

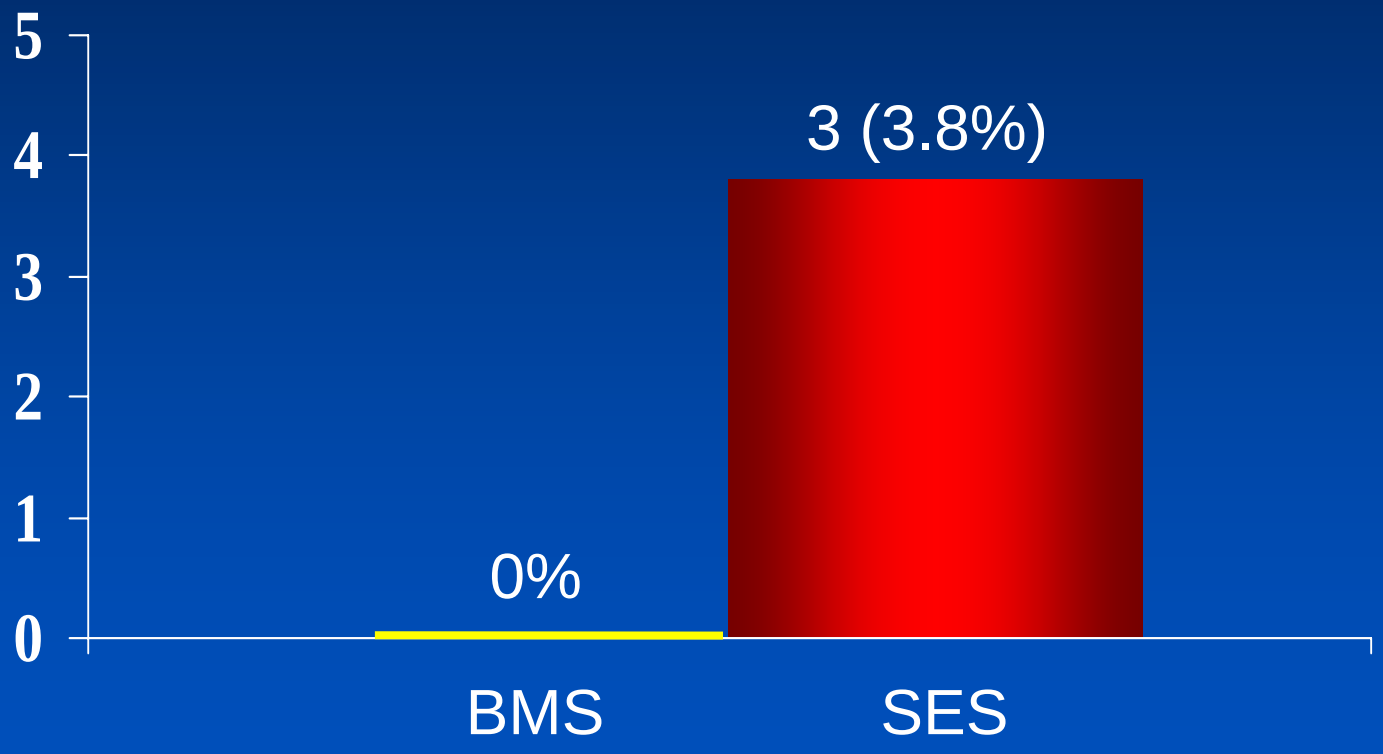
Two-year TLR-free survival



Stent thromboses during dual antiplatelet treatment (<1-year)



Stent thromboses after clopidogrel withdrawal (> 1 year)



BMJ

RESEARCH

Drug eluting and bare metal stents in people with and without diabetes: collaborative network meta-analysis

35 trials in 3852 DM patients and 10947 non-DM patients

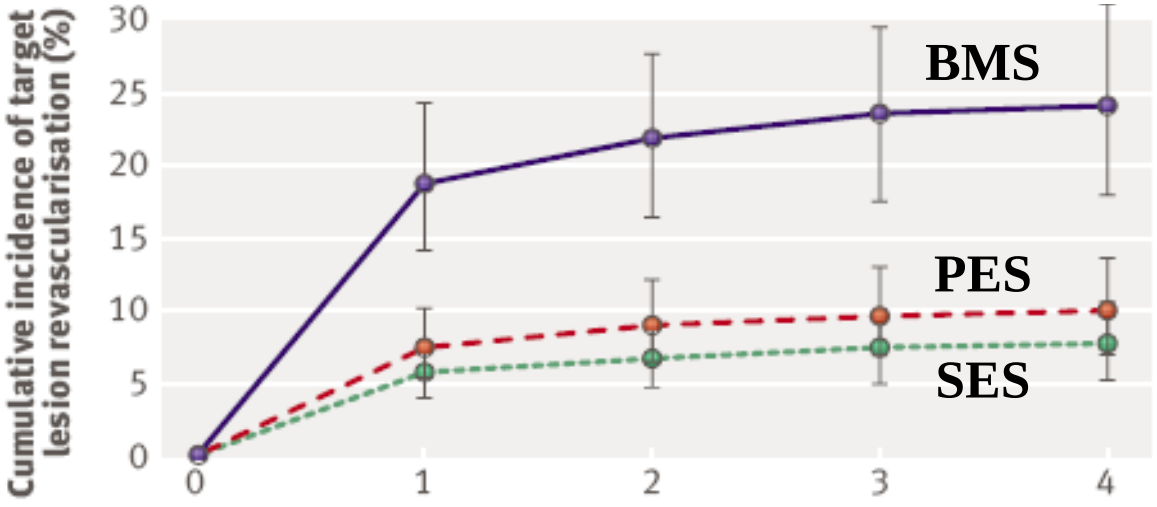
BMJ. 2008;337:a1331

Cumulative incidence of TLR

SES vs. BMS: Hazard Ratio 0.29 (0.19 to 0.45)

PES vs. BMS: Hazard Ratio 0.38 (0.26 to 0.56)

SES vs. PES: Hazard Ratio 0.78 (0.50 to 1.14)



		No of events/No of patients			
BMS	935	193/935	10/496	4/282	2/185
PES	1171	99/1171	21/946	3/487	3/146
SES	1122	80/1122	14/780	1/446	2/66

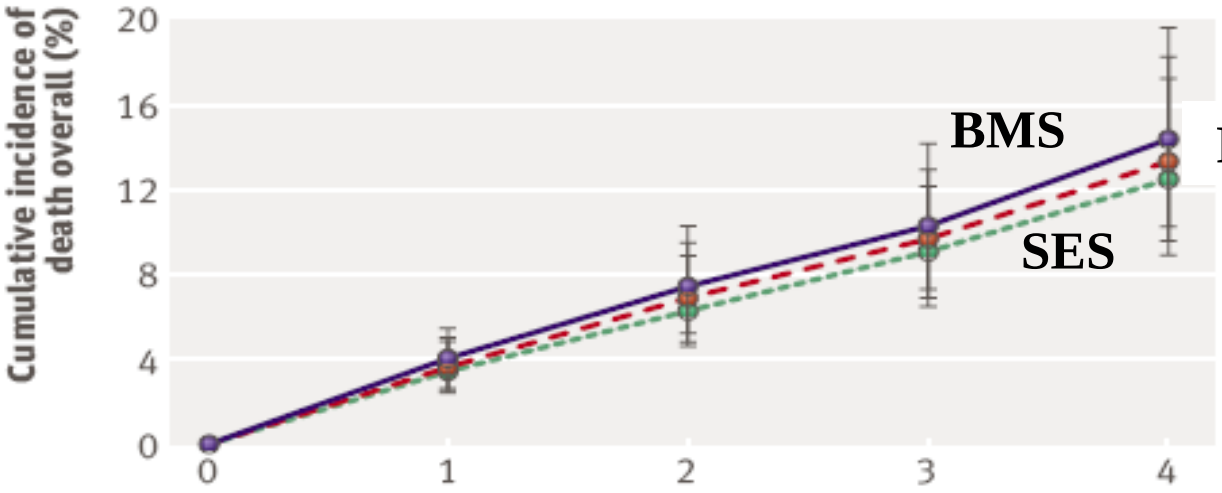
BMJ. 2008;337:a1331

Cumulative incidence of death

SES vs. BMS: Hazard Ratio 0.88 (0.55 to 1.30)

PES vs. BMS: Hazard Ratio 0.91 (0.26 to 1.38)

SES vs. PES: Hazard Ratio 0.95 (0.50 to 1.43)



		No of events/No of patients			
BMS	904	37/904	15/632	7/358	10/224
PES	1162	35/1162	40/1020	11/535	3/158
SES	1078	39/1078	26/830	12/497	1/73

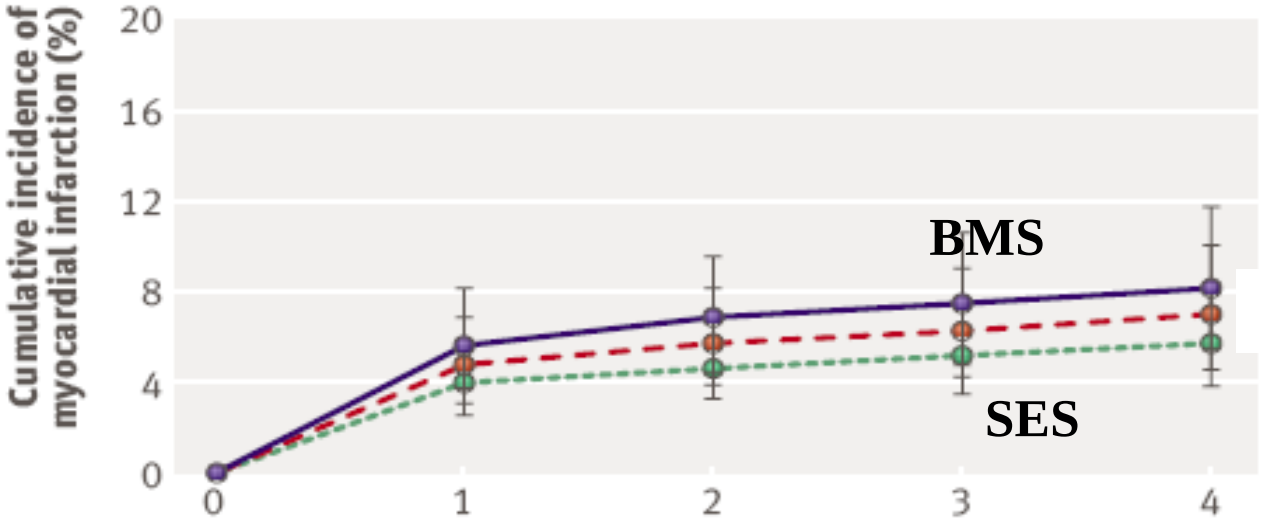
BMJ. 2008;337:a1331

Cumulative incidence of MI

SES vs. BMS: Hazard Ratio 0.68 (0.43 to 1.12)

PES vs. BMS: Hazard Ratio 0.85 (0.54 to 1.43)

SES vs. PES: Hazard Ratio 0.80 (0.55 to 1.27)



		No of events/No of patients			
BMS	867	54/867	6/585	2/336	2/209
PES	1160	55/1160	12/980	5/508	2/142
SES	1054	51/1054	2/792	1/460	0/56

BMJ. 2008;337:a1331

Risk of stent thrombosis

Variable	Events				Relative risks (95% credibility interval)		
	BMS	PES	SES	Total			SES *v* PES
ARC definite stent thrombosis*							
[redacted]	557	874	753	2184	[redacted]		
	13	17	9	39			0.40 (0.13 to 1.08)
	11	9	6	26			0.60 (0.12 to 3.36)
	2	8	3	13			0.20 (0.02 to 1.04)
Patients without diabetes:							
No of patients at risk	2439	3130	2647	8216			
0 days to 4 years	34	56	46	136	1.24 (0.58 to 3.08)	1.48 (0.69 to 3.40)	0.84 (0.41 to 1.88)
0-30 days	19	22	28	69	1.19 (0.43 to 3.09)	1.11 (0.38 to 2.97)	1.06 (0.41 to 2.90)
>30 days to 4 years	15	34	18	67	1.19 (0.43 to 4.13)	1.83 (0.67 to 5.85)	0.65 (0.26 to 1.70)
Per protocol definition of stent thrombosis†							
[redacted]	723	912	870	2505	[redacted]		
	16	18	7	41			0.27 (0.07 to 0.80)
	11	10	5	26			0.42 (0.07 to 1.89)
	5	8	2	15			0.11 (0.01 to 0.75)
Patients without diabetes:							
No of patients at risk	2577	3382	2625	8584			
0 days to 4 years	29	58	46	133	1.48 (0.74 to 3.41)	1.80 (0.89 to 3.67)	0.82 (0.44 to 1.73)
0-30 days	22	24	28	74	1.11 (0.47 to 2.81)	0.99 (0.44 to 2.33)	1.15 (0.48 to 2.72)
>30 days to 4 years	7	34	18	59	2.29 (0.83 to 7.77)	4.12 (1.55 to 13.1)	0.55 (0.25 to 1.27)

BMJ. 2008;337:a1331

Risk of Mortality according to duration of dual antiplatelet therapy

Table 2 | Overall mortality in patients with diabetes: evaluation of variation in network according to different trial characteristics

Characteristic	SES *v* bare metal stent		PES *v* bare metal stent		SES *v* PES	
	Relative risk (95% CI)	P value for interaction	Relative risk (95% CI)	P value for interaction	Relative risk (95% CI)	P value for interaction
Concealment of allocation:						
Adequate	1.30 (0.86 to 2.02)	0.16	1.22 (0.74 to 1.99)	0.72	1.06 (0.69 to 1.67)	—
Unclear	0.32 (0.03 to 2.27)		0.93 (0.21 to 4.33)		—	
Blind adjudication:						
Yes	1.30 (0.84 to 2.16)	0.37	1.17 (0.67 to 1.96)	0.96	1.11 (0.69 to 2.04)	0.78
No	0.72 (0.17 to 2.46)		1.24 (0.10 to 11.76)		0.94 (0.26 to 2.64)	
Intention to treat analysis:						
Yes	1.25 (0.81 to 2.02)	0.71	1.13 (0.65 to 1.92)	0.92	1.11 (0.71 to 1.87)	Not estimable*
No or unclear	0.97 (0.26 to 3.82)		1.08 (0.37 to 3.23)		0.14 (0.01 to 3.10)*	
High quality trial:						
Yes	1.40 (0.86 to 2.49)	0.27	1.28 (0.66 to 2.44)	0.61	1.08 (0.64 to 2.14)	0.80
No	0.70 (0.21 to 2.18)		0.97 (0.37 to 2.52)		0.93 (0.26 to 2.77)	
Length of follow-up:						
>2 years	1.37 (0.80 to 2.48)	0.51	1.30 (0.71 to 2.46)	0.54	1.05 (0.61 to 1.90)	0.97
≤2 years	1.01 (0.47 to 2.19)		0.91 (0.34 to 2.48)		1.02 (0.29 to 4.13)	
Patient recruitment:						
Completed Jan 2(						
Completed befor						

SES vs. BMS — **PES vs. BMS** — SES vs. PES —

BMJ. 2008;337:a1331

DES vs. BMS

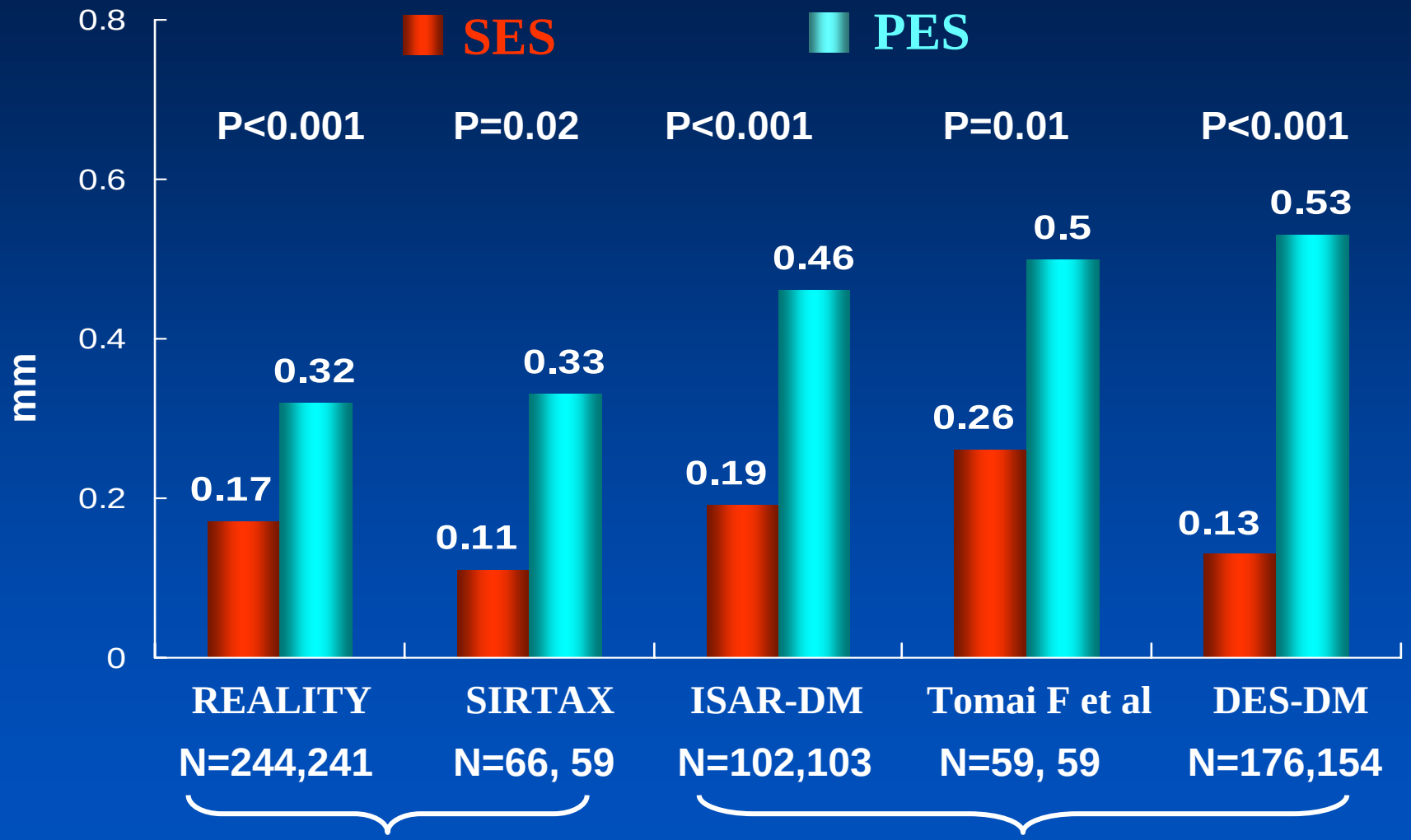
- DES implantation significantly reduced angiographic restenosis and long-term TLR without difference of death and MI compared to BMS in diabetic patients.
- The concern of late occurrence of stent thrombosis after DES exist, but long-term use of clopidogrel (≥ 6 months) could maintain its safety and effectiveness.

SES vs. PES

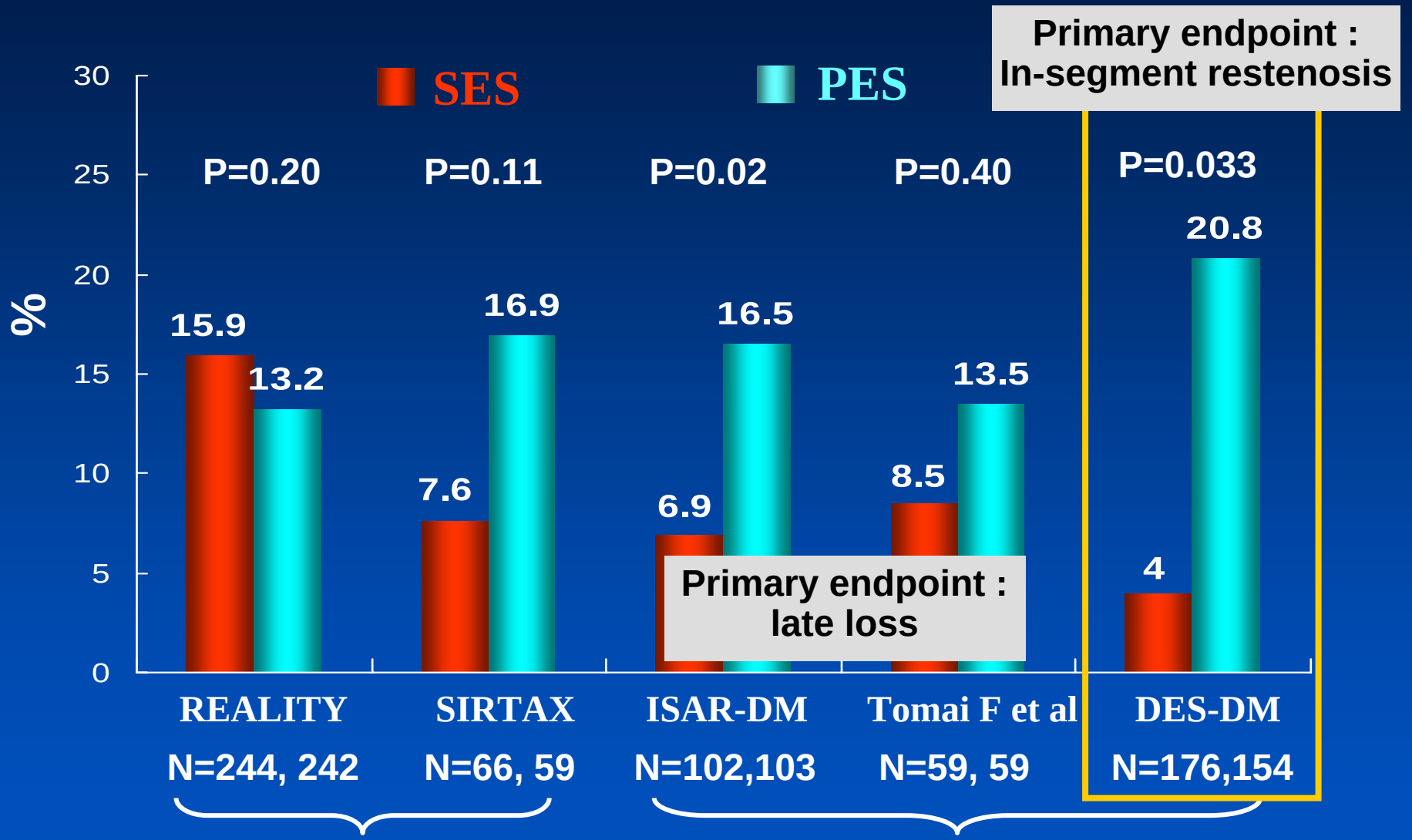
SES vs. PES

Angiographic analysis

In-stent late loss



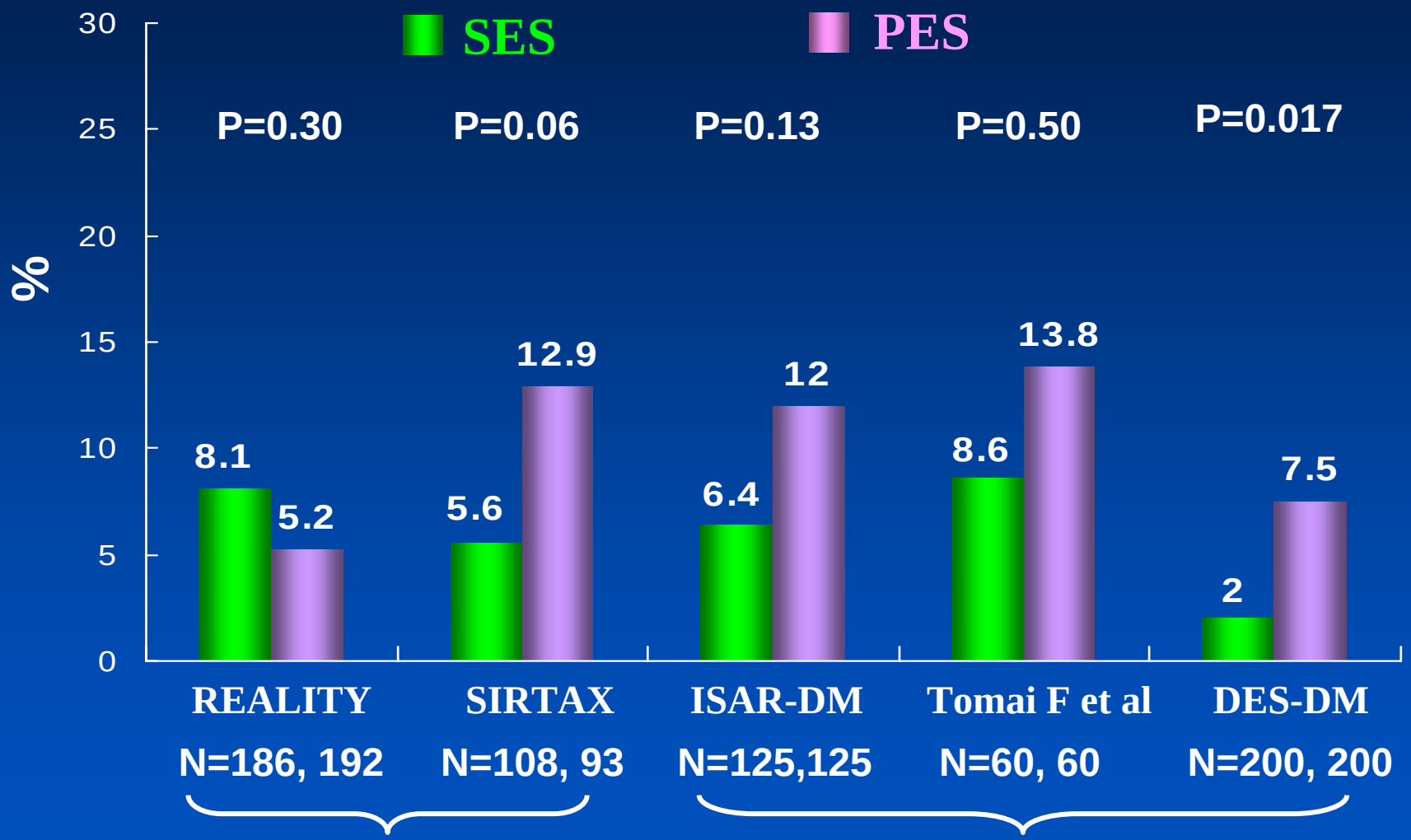
In-segment restenosis



SES vs. PES

Mid-term Clinical outcomes

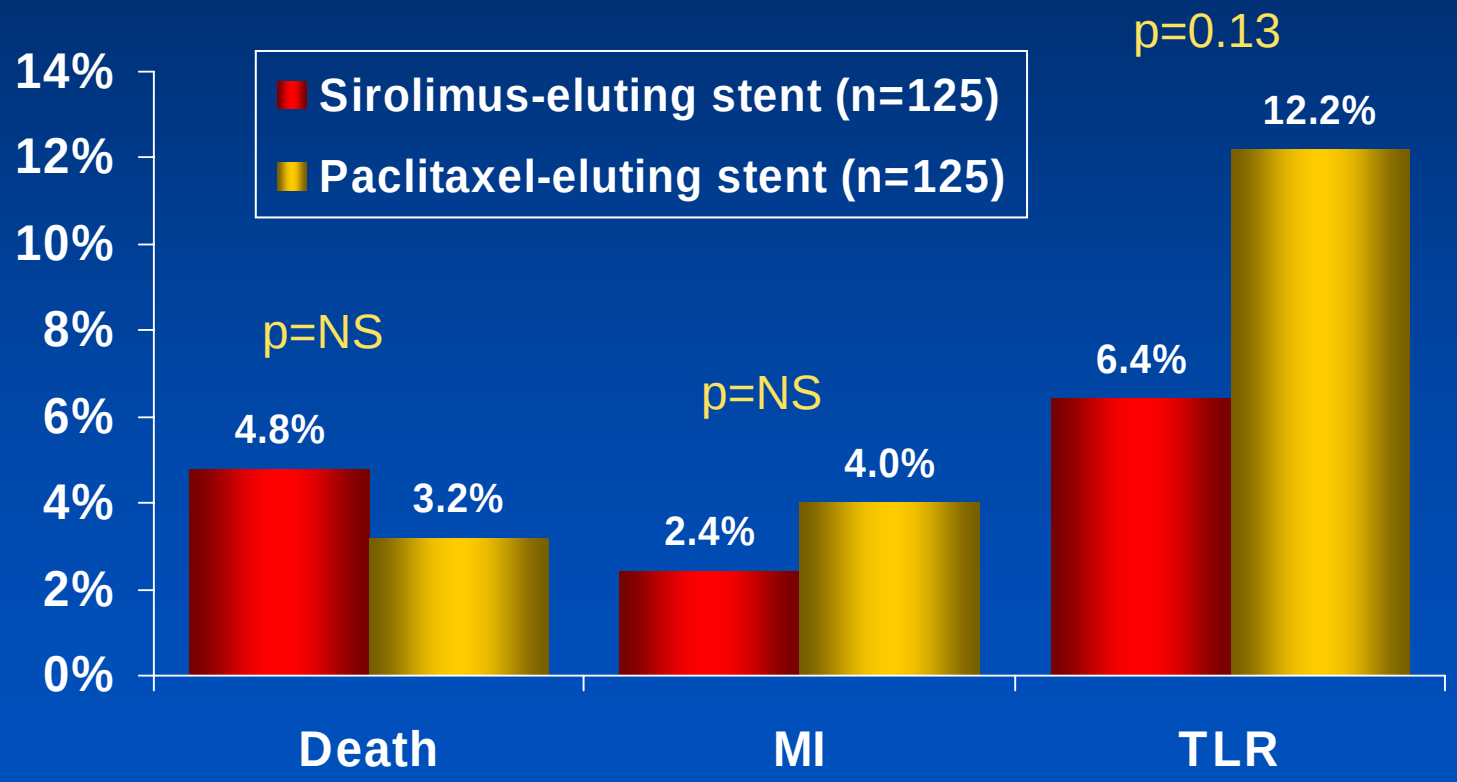
TLR at 9 to 12 months



ISAR-DIABETES Trial

Nine-month outcomes

SES showed significant reduction of restenosis,
which did not translated into improved clinical outcomes
owing to small population

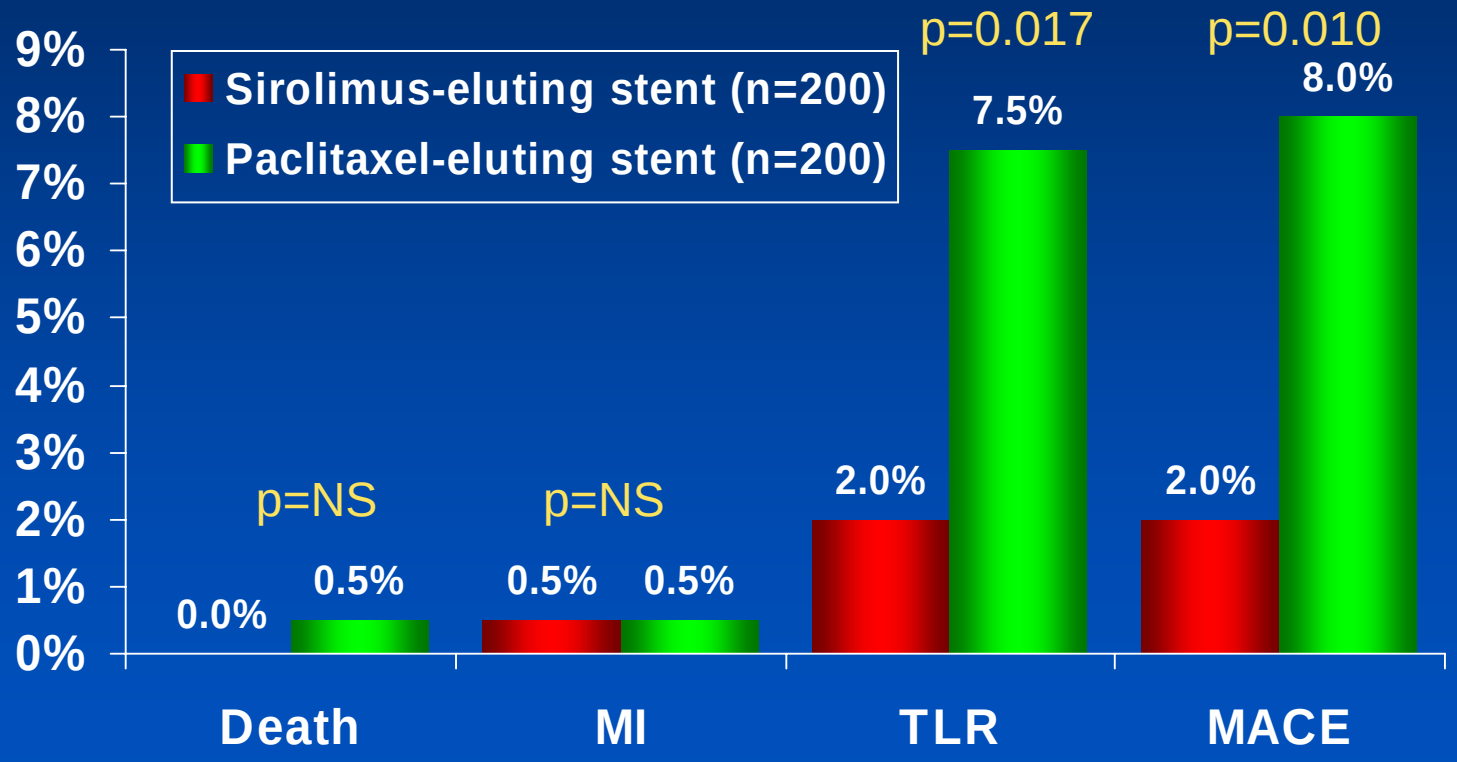


Kastrati et al., NEJM 2005;353:663-70

DES-DIABETES Trial

Nine-month outcomes

SES showed significant reduction of restenosis, which translated into improved clinical outcomes



Lee SW, Park SW et al., J Am Coll Cardiol 2008;52:727-33

SES vs. PES

Long-term Clinical outcomes

SES vs. PES

Two-year outcomes

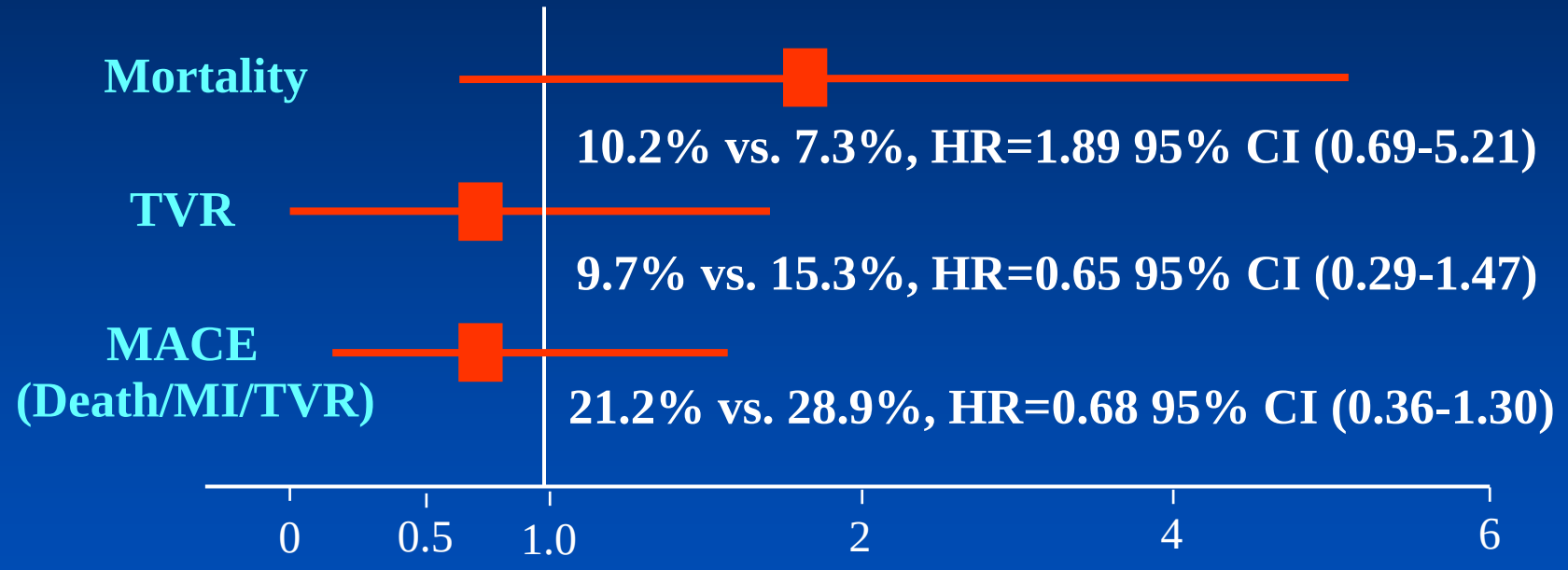
- RESEARCH and T-SEARCH } **REGISTRY**
- SIRTAX subgroup analysis } **RANDOMIZED STUDY**
- DES-DIABETES } **RANDOMIZED STUDY**

Four-year outcomes

- Network meta-analysis

Adjusted Hazard Ratios for 2-year Outcomes Comparing PES and SES

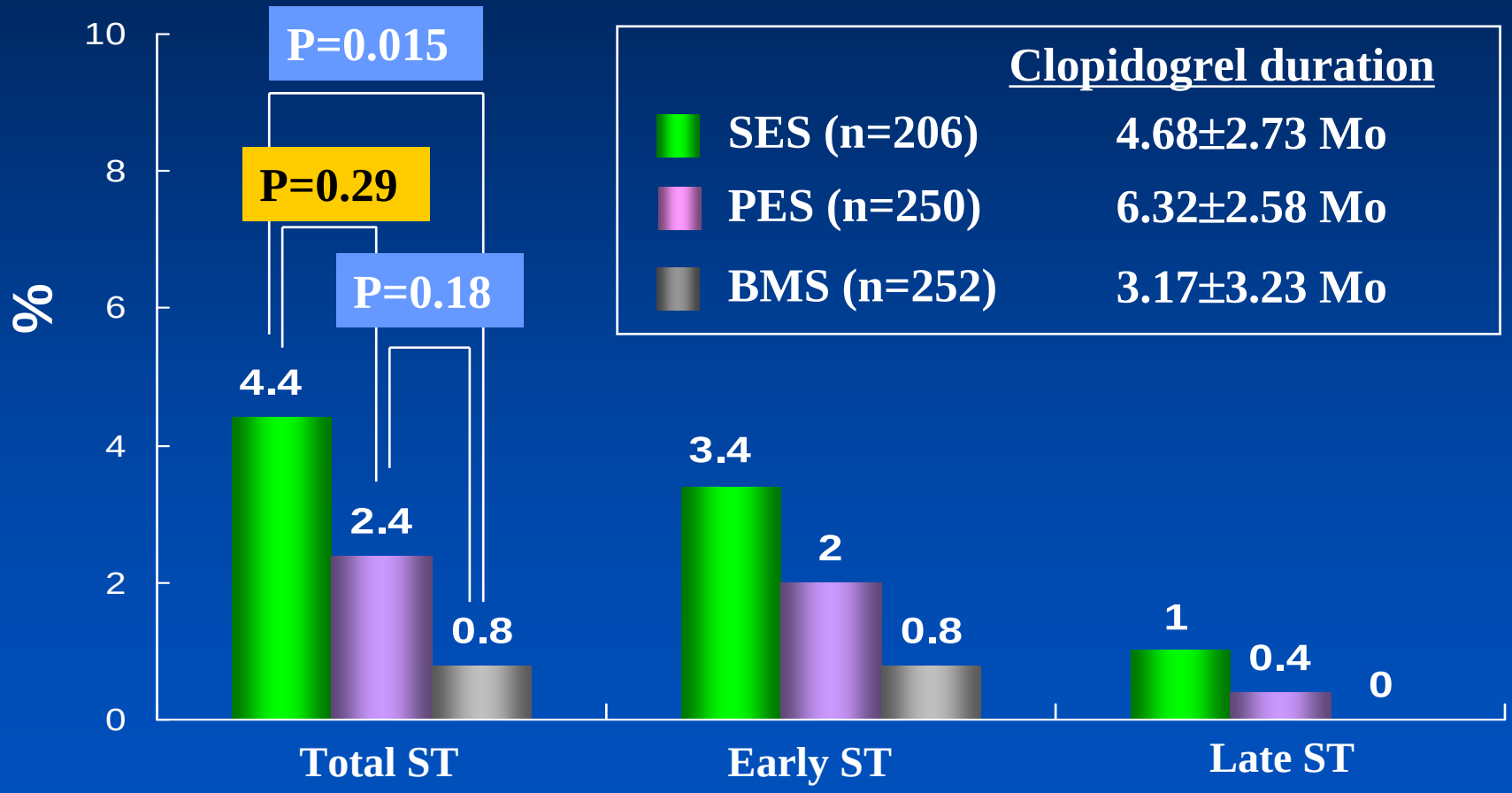
Adjustment with propensity score



Daemen J et al., Eur H Journal 2008;28:26-32

Two-year stent thrombosis

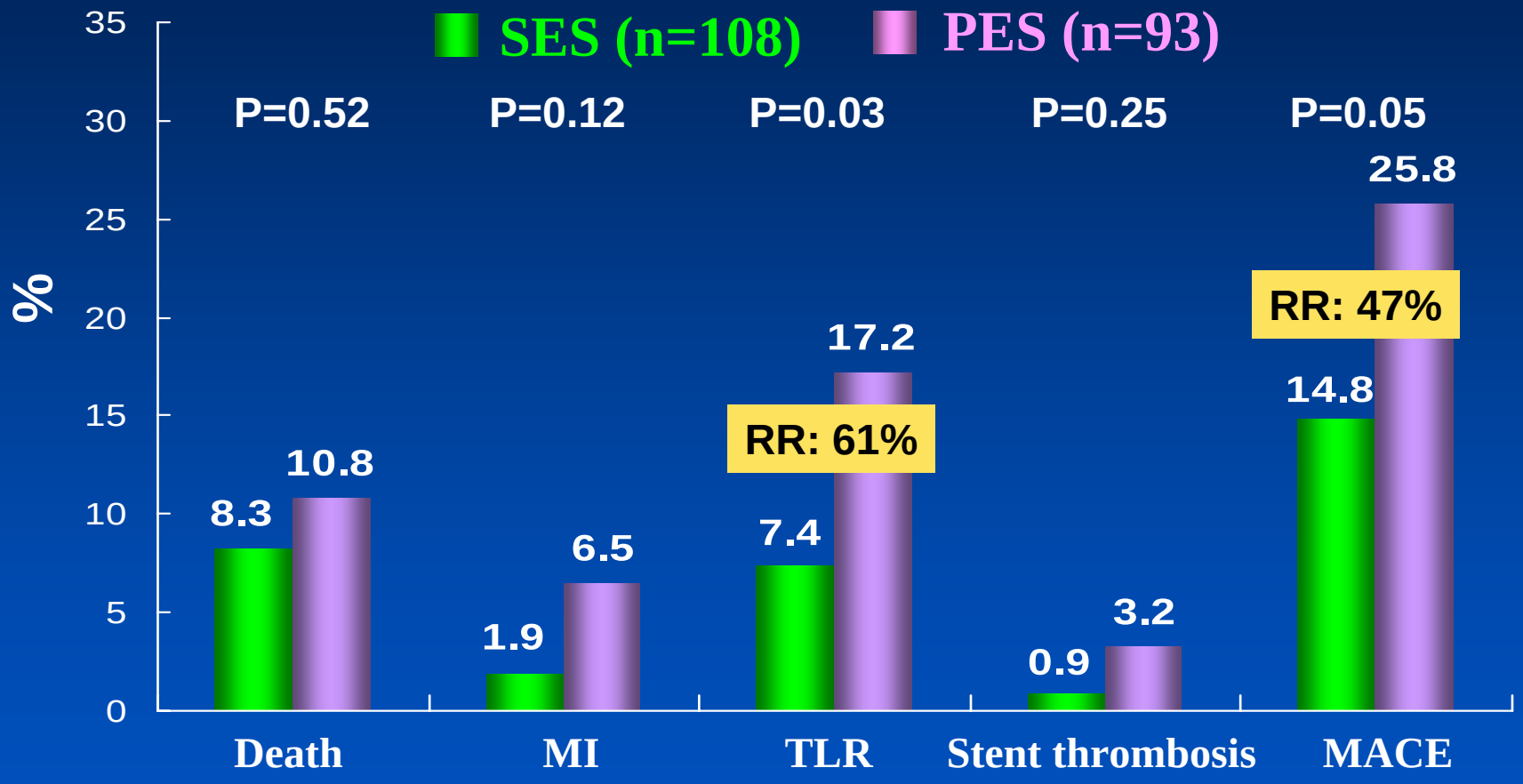
SES appeared to have high incidence of ST, but risk of stent thrombosis was not adjusted according to clinical and angiographic factors



Daemen J et al., Eur H Journal 2008;28:26-32

SIRTAX Trial

Two-year outcomes in diabetic subgroup



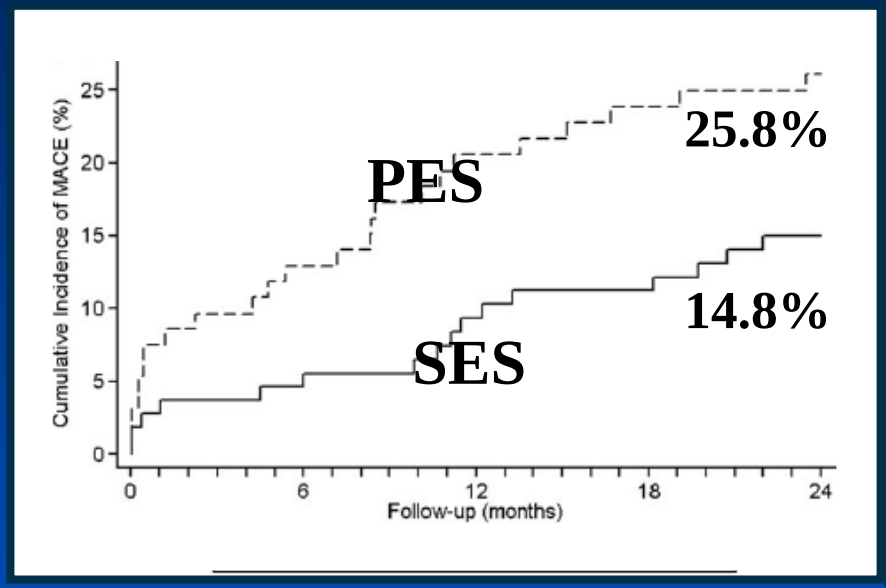
MACE: Death/MI/TLR

Billinger M et al., Eur H Journal 2008;29:718-25

SIRTAX Trial

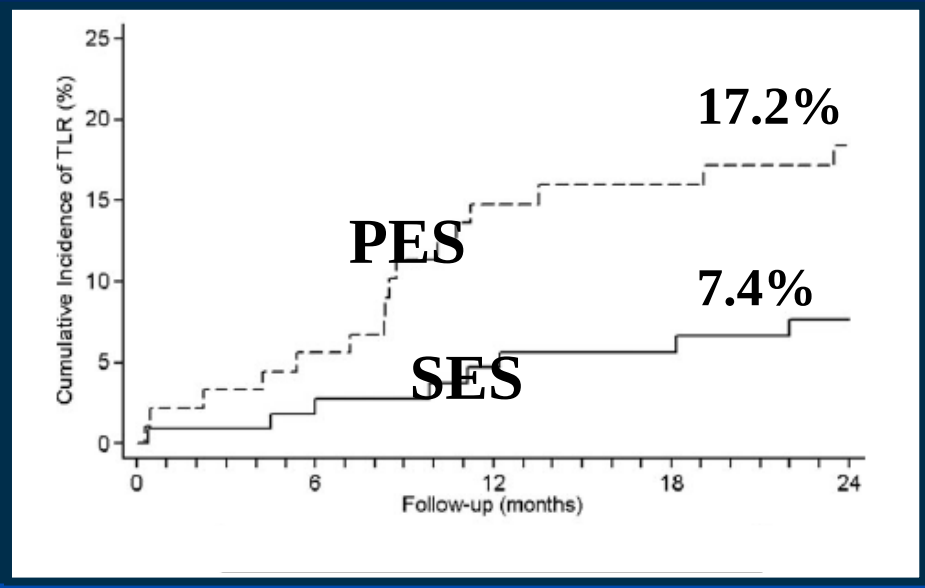
Two-year outcomes in diabetic subgroup

MACE



HR=0.52; 95% CI 0.28–0.99; P=0.05

TLR



HR=0.39; 95% CI 0.17–0.90; P=0.03

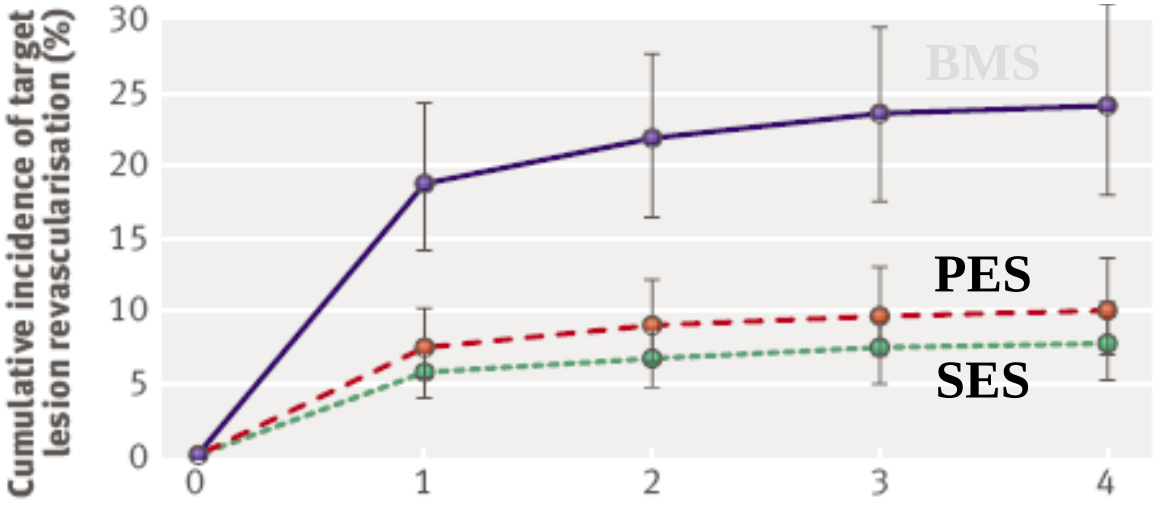
Billinger M et al., Eur H Journal 2008;29:718-25

Cumulative incidence of TLR

SES vs. BMS: Hazard Ratio 0.29 (0.19 to 0.45)

PES vs. BMS: Hazard Ratio 0.38 (0.26 to 0.56)

SES vs. PES: Hazard Ratio 0.78 (0.50 to 1.14)



		No of events/No of patients			
BMS	935	193/935	10/496	4/282	2/185
PES	1171	99/1171	21/946	3/487	3/146
SES	1122	80/1122	14/780	1/446	2/66

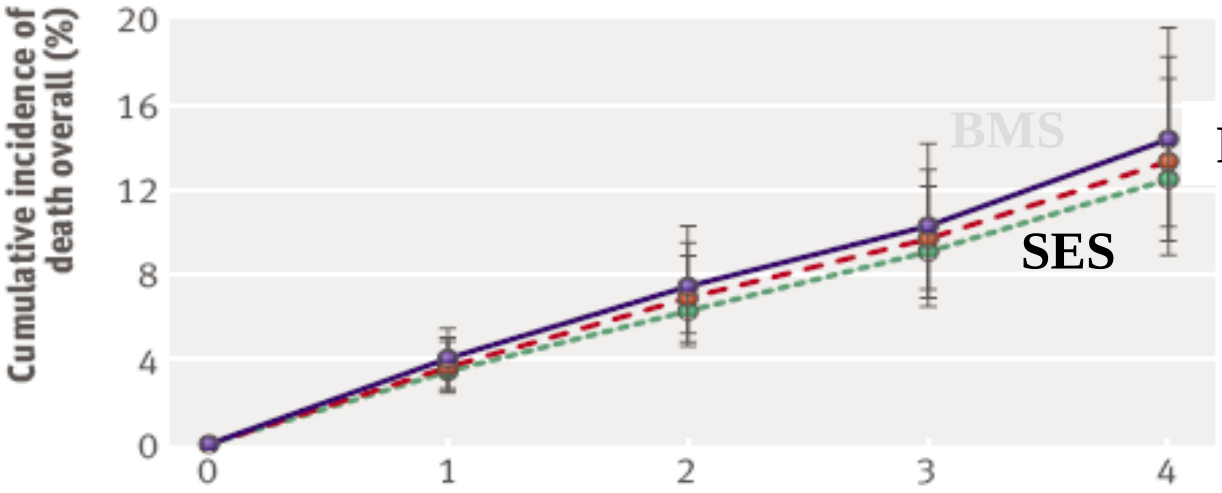
BMJ. 2008;337:a1331

Cumulative incidence of death

SES vs. BMS: Hazard Ratio 0.88 (0.55 to 1.30)

PES vs. BMS: Hazard Ratio 0.91 (0.26 to 1.38)

SES vs. PES: Hazard Ratio 0.95 (0.50 to 1.43)



		No of events/No of patients			
BMS	904	37/904	15/632	7/358	10/224
PES	1162	35/1162	40/1020	11/535	3/158
SES	1078	39/1078	26/830	12/497	1/73

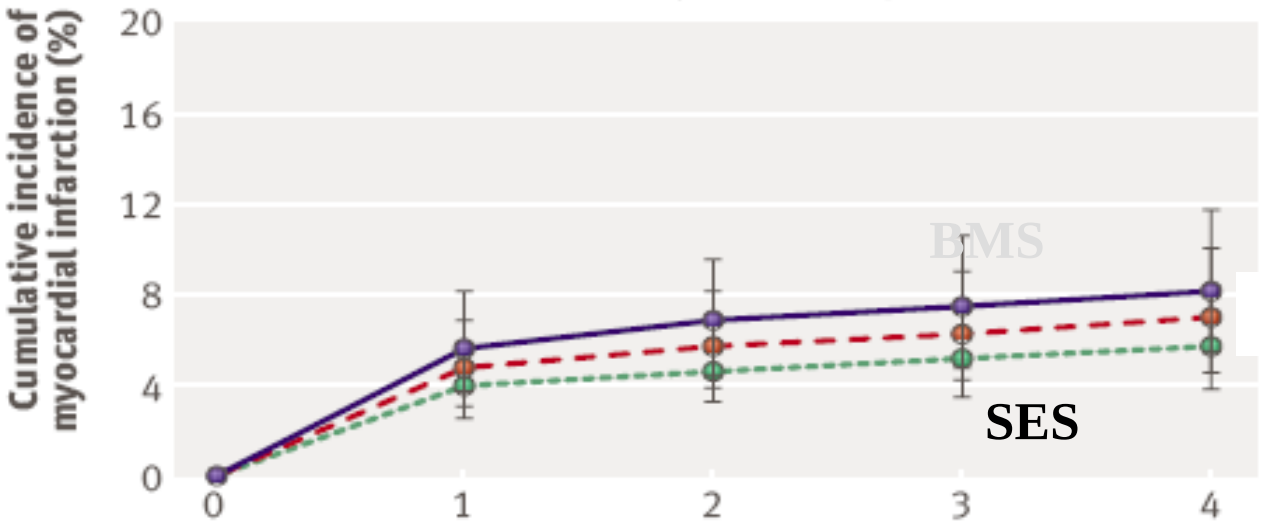
BMJ. 2008;337:a1331

Cumulative incidence of MI

SES vs. BMS: Hazard Ratio 0.68 (0.43 to 1.12)

PES vs. BMS: Hazard Ratio 0.85 (0.54 to 1.43)

SES vs. PES: Hazard Ratio 0.80 (0.55 to 1.27)



		No of events/No of patients			
BMS	867	54/867	6/585	2/336	2/209
PES	1160	55/1160	12/980	5/508	2/142
SES	1054	51/1054	2/792	1/460	0/56

BMJ. 2008;337:a1331

Risk of stent thrombosis

Variable	Events				Relative risks (95% credibility interval)		
	BMS	PES	SES	Total	SES *v* BMS	PES *v* BMS	
ARC definite stent thrombosis*							
	557	874	753	2184			
	13	17	9	39	0.33 (0.09 to 1.09)	0.82 (0.23 to 3.09)	
	11	9	6	26	0.25 (0.04 to 1.11)	0.39 (0.05 to 2.36)	
	2	8	3	13	0.72 (0.04 to 10.8)	3.54 (0.23 to 78.6)	
Patients without diabetes:							
No of patients at risk	2439	3130	2647	8216			
0 days to 4 years	34	56	46	136	1.24 (0.58 to 3.08)	1.48 (0.69 to 3.40)	0.84 (0.41 to 1.88)
0-30 days	19	22	28	69	1.19 (0.43 to 3.09)	1.11 (0.38 to 2.97)	1.06 (0.41 to 2.90)
>30 days to 4 years	15	34	18	67	1.19 (0.43 to 4.13)	1.83 (0.67 to 5.85)	0.65 (0.26 to 1.70)
Per protocol definition of stent thrombosis†							
	723	912	870	2505			
	16	18	7	41	0.20 (0.05 to 0.68)	0.73 (0.19 to 2.80)	
	11	10	5	26	0.23 (0.03 to 1.08)	0.55 (0.09 to 3.05)	
	5	8	2	15	0.10 (0.01 to 0.93)	0.87 (0.06 to 10.3)	
Patients without diabetes:							
No of patients at risk	2577	3382	2625	8584			
0 days to 4 years	29	58	46	133	1.48 (0.74 to 3.41)	1.80 (0.89 to 3.67)	0.82 (0.44 to 1.73)
0-30 days	22	24	28	74	1.11 (0.47 to 2.81)	0.99 (0.44 to 2.33)	1.15 (0.48 to 2.72)
>30 days to 4 years	7	34	18	59	2.29 (0.83 to 7.77)	4.12 (1.55 to 13.1)	0.55 (0.25 to 1.27)

BMJ. 2008;337:a1331

Risk of Mortality according to duration of dual antiplatelet therapy

Table 2 | Overall mortality in patients with diabetes: evaluation of variation in network according to different trial characteristics

Characteristic	SES *v* bare metal stent		PES *v* bare metal stent		SES *v* PES	
	Relative risk (95% CI)	P value for interaction	Relative risk (95% CI)	P value for interaction	Relative risk (95% CI)	P value for interaction
Concealment of allocation:						
Adequate	1.30 (0.86 to 2.02)	0.16	1.22 (0.74 to 1.99)	0.72	1.06 (0.69 to 1.67)	—
Unclear	0.32 (0.03 to 2.27)		0.93 (0.21 to 4.33)		—	
Blind adjudication:						
Yes	1.30 (0.84 to 2.16)	0.37	1.17 (0.67 to 1.96)	0.96	1.11 (0.69 to 2.04)	0.78
No	0.72 (0.17 to 2.46)		1.24 (0.10 to 11.76)		0.94 (0.26 to 2.64)	
Intention to treat analysis:						
Yes	1.25 (0.81 to 2.02)	0.71	1.13 (0.65 to 1.92)	0.92	1.11 (0.71 to 1.87)	Not estimable*
No or unclear	0.97 (0.26 to 3.82)		1.08 (0.37 to 3.23)		0.14 (0.01 to 3.10)*	
High quality trial:						
Yes	1.40 (0.86 to 2.49)	0.27	1.28 (0.66 to 2.44)	0.61	1.08 (0.64 to 2.14)	0.80
No	0.70 (0.21 to 2.18)		0.97 (0.37 to 2.52)		0.93 (0.26 to 2.77)	
Length of follow-up:						
>2 years	1.37 (0.80 to 2.48)	0.51	1.30 (0.71 to 2.46)	0.54	1.05 (0.61 to 1.90)	0.97
≤2 years	1.01 (0.47 to 2.19)		0.91 (0.34 to 2.48)		1.02 (0.29 to 4.13)	
Patient recruitment:						
Completed Jan 2(						
Completed befor						

SES vs. BMS — PES vs. BMS — **SES vs. PES**

BMJ. 2008;337:a1331

A Randomized Comparison of Sirolimus-versus Paclitaxel-eluting stent implantation in Patients with Diabetes Mellitus

:*D*rug-*E*luting *S*tenting for Patients with *Diabetes* mellitus

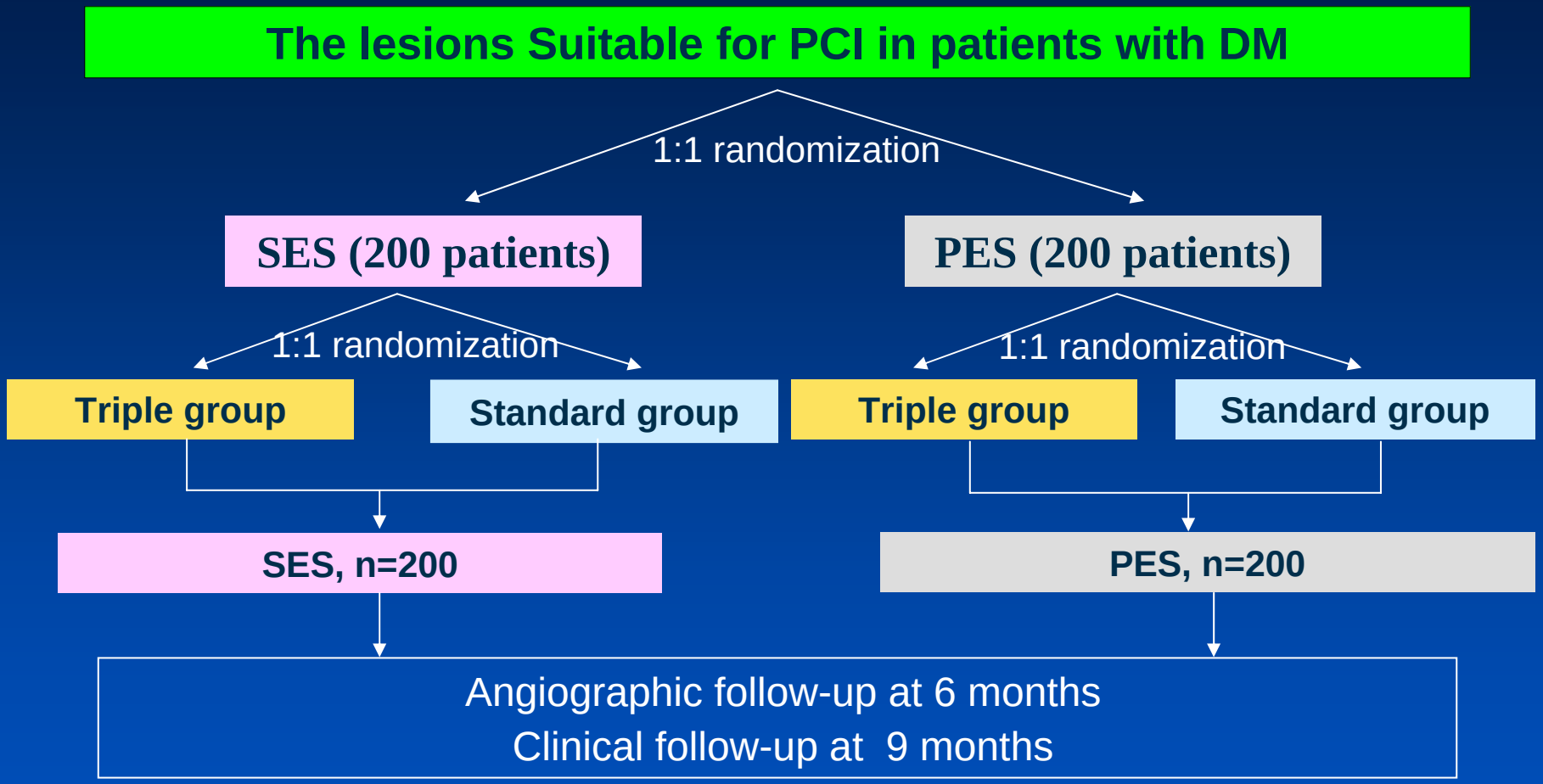
The DES-DIABETES Trial

Seong-Wook Park, MD, PhD, FACC
for the DES-DIABETES Study investigators

Asan Medical Center,
University of Ulsan College of Medicine, Seoul, Korea

Lee SW, Park SW et al., J Am Coll Cardiol 2008;52:727-33

DES-DIABETES Trial Design



* Randomization – Stratification according to DES types
* Blinding – Patients, Outcome assessors
* Pre-specified angiographic primary endpoint
* Intention-to-treat analysis

DES-DIABETES Trial Design

The lesions Suitable for PCI in patients with DM

1:1 randomization

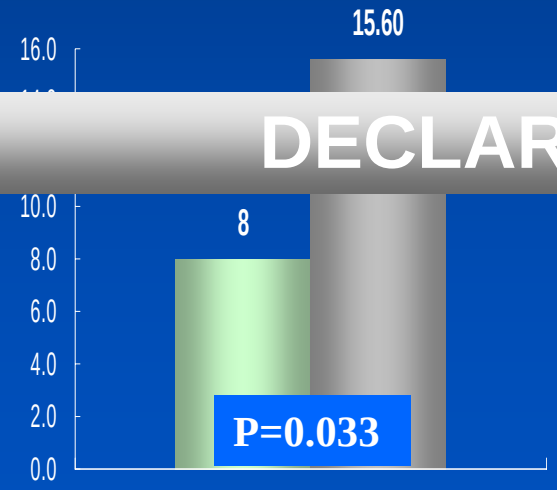
SES (200 patients) | **PES (200 patients)**

1:1 randomization | 1:1 randomization

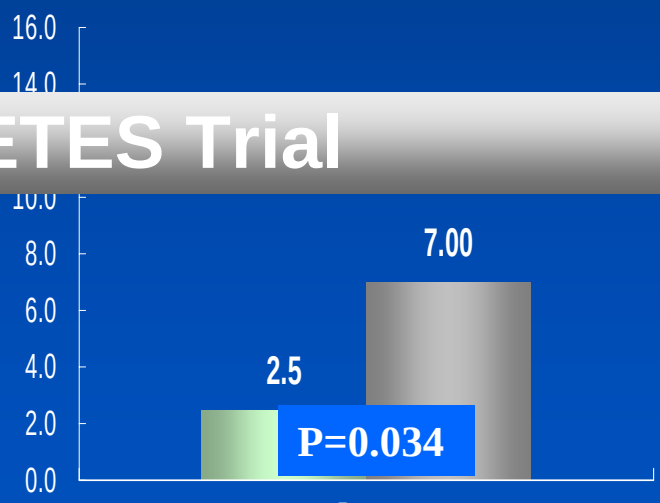
Triple group | **Standard group** | **Triple group** | **Standard group**

Triple (aspirin, clopidogrel, cilostazol) **Standard (aspirin, clopidogrel)**

DECLARE-DIABETES Trial



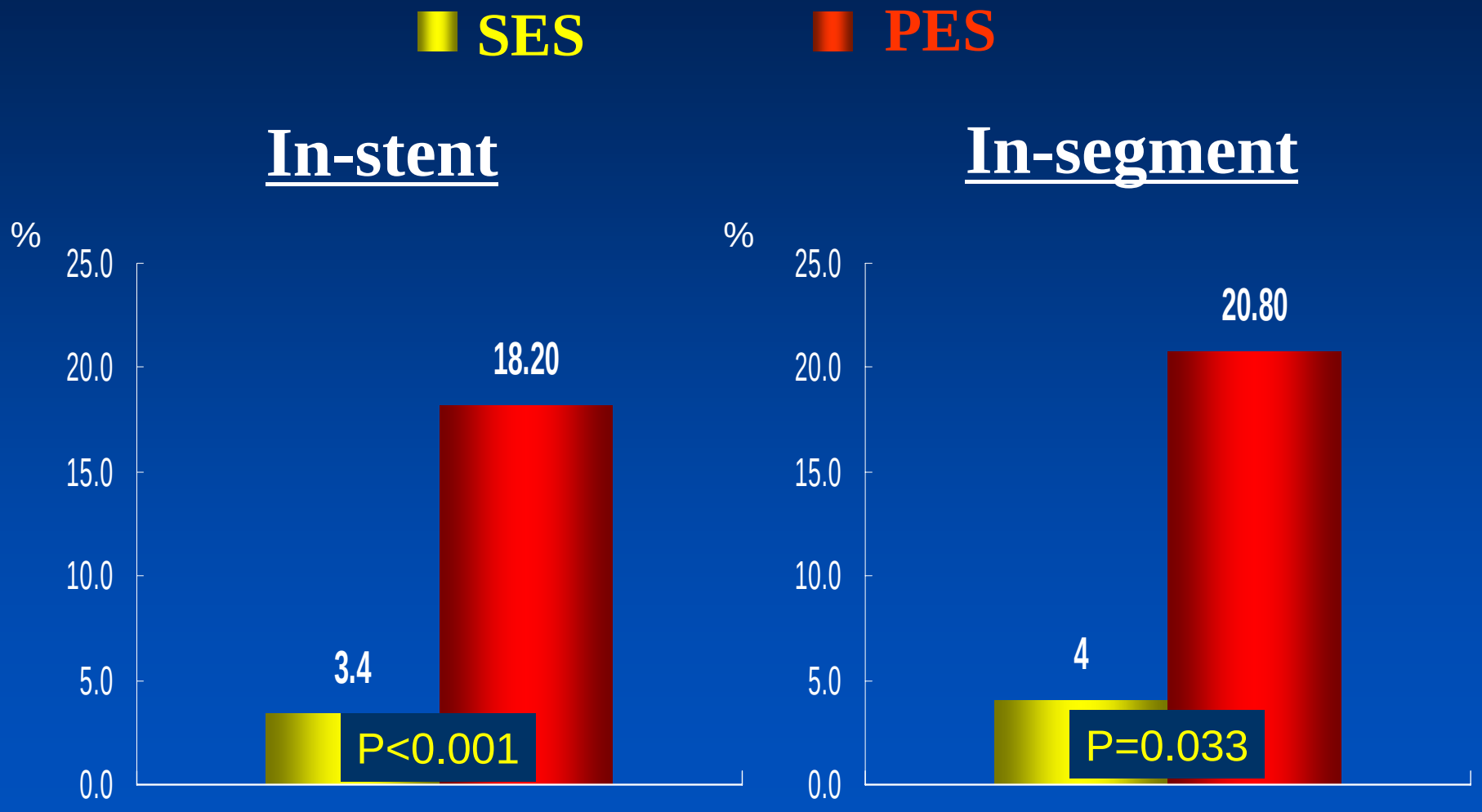
Restenosis rate



9-month TLR

Lee SW, Park SW et al., J Am Coll Cardiol 2008;51:1181-7

Restenosis rate

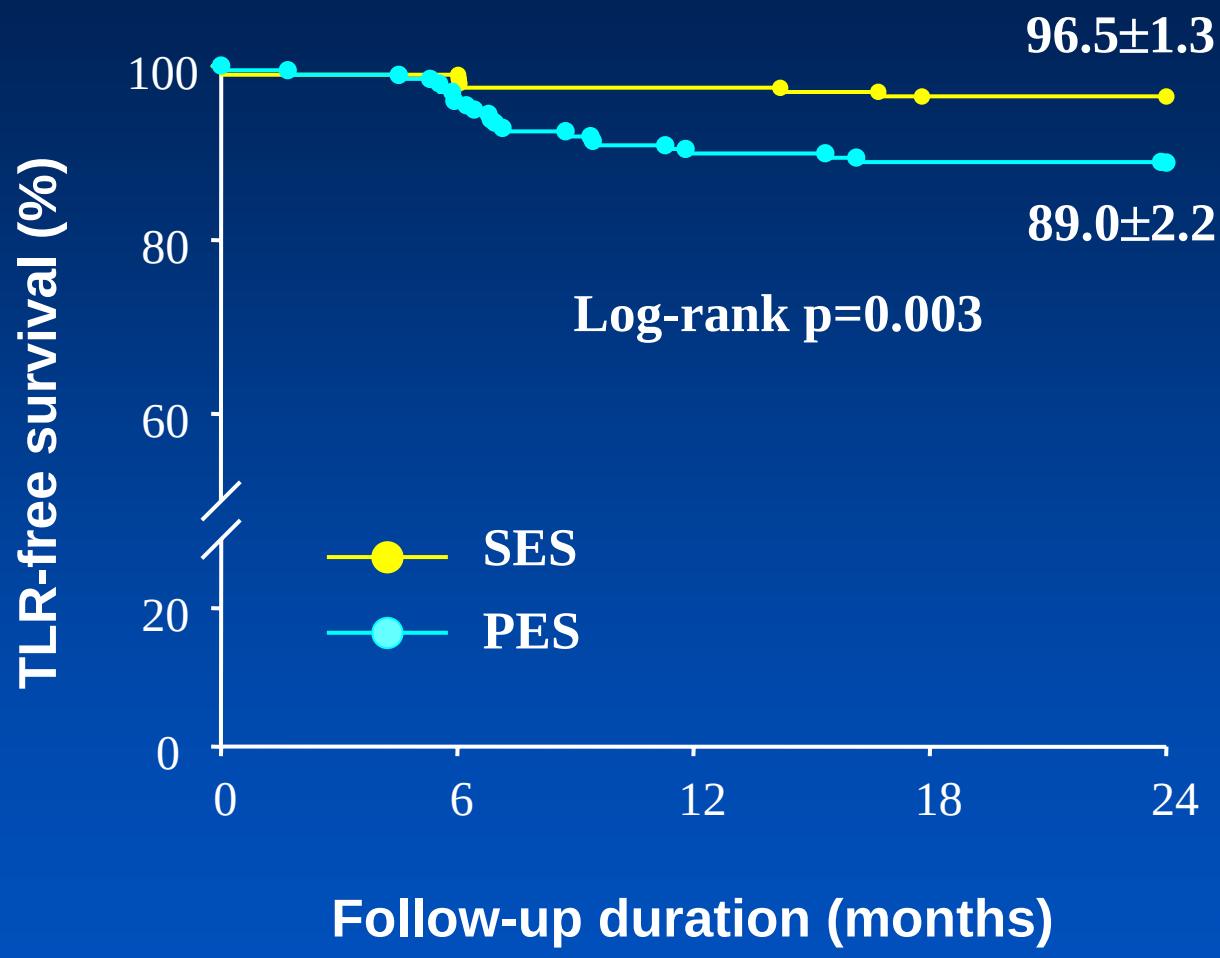


MACE at 9-Months

DES-DIABETES

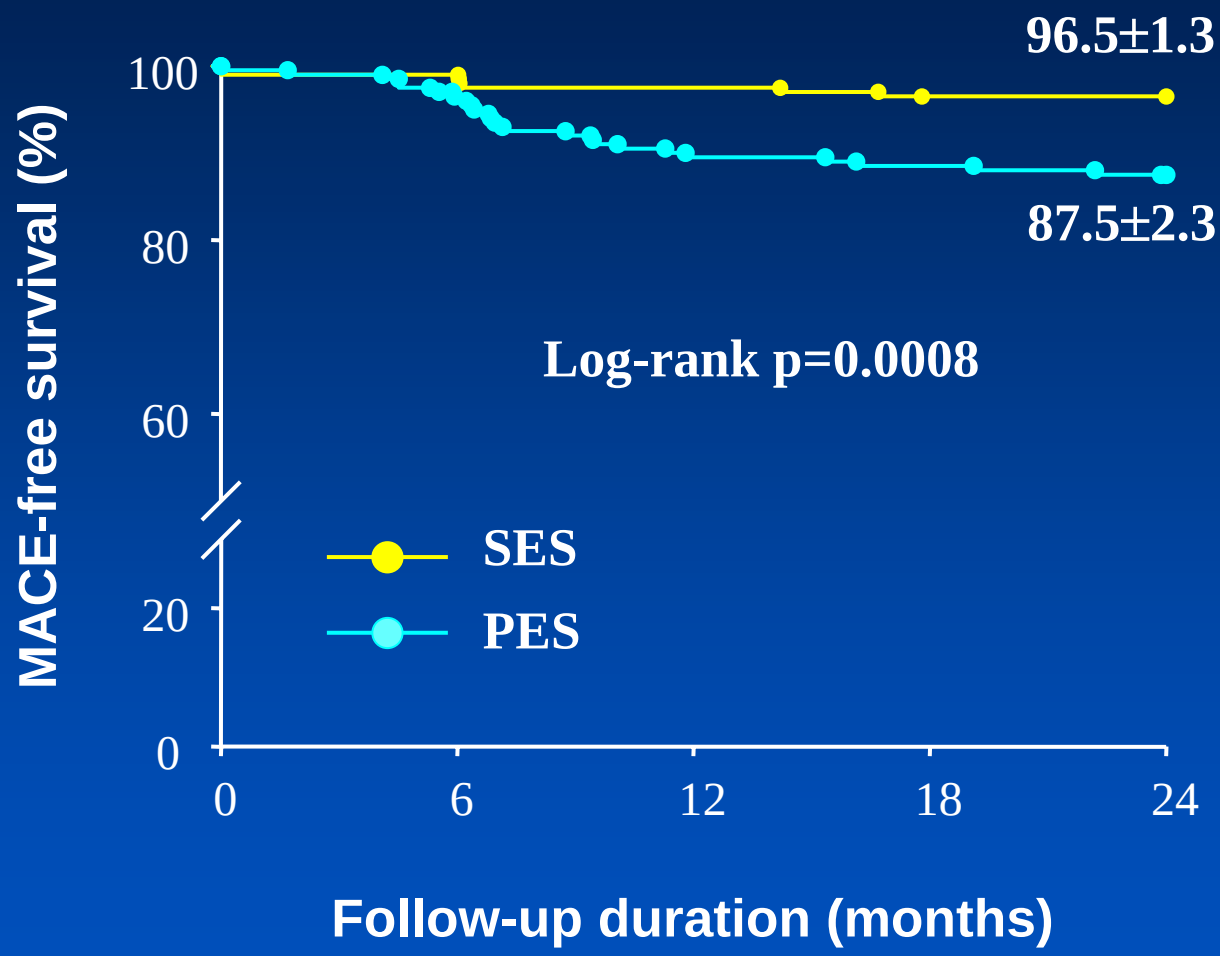
	SES	PES	P
Patients	200	200	
Death	0	1(0.5%)	0.999
Cardiac	0	1(0.5%)	
Non-cardiac	0	0	
MI	1 (0.5%)	1 (0.5%)	0.999
Stent thrombosis	1 (0.5%)	0	0.999
Acute	1 (0.5%)	1	
Subacute	0	0	
Late	0	0	
TLR	4 (2.0%)	15 (7.5%)	0.017
Death/MI/TVR	7 (3.5%)	17 (8.5%)	0.035
MACE (Death/MI/TLR)	4 (2.0%)	16 (8.0%)	0.010

Two-year TLR-free survival



Lee SW, Park SW et al., J Am Coll Cardiol (in press)

Two-year MACE-free survival



MACE: Death/MI/TLR

Lee SW, Park SW et al., J Am Coll Cardiol (in press)

DES-DIABETES

MACE at 2-years

	SES	PES	P
Patients	200	200	
Death	0	3(1.5%)	0.248
Cardiac	0	2(1.0%)	
Non-cardiac	0	1(0.5%)	
MI	1 (0.5%)	2 (1.0%)	0.999
Stent thrombosis	2 (1.0%)	0	0.499
Acute	1 (0.5%)	1	
Subacute	0	0	
Late	1 (0.5%)	0	
TLR	7 (3.5%)	22 (11.0%)	0.004
Death/MI/TVR	11 (5.5%)	28 (14.0%)	0.004
MACE (Death/MI/TLR)	7 (3.5%)	25 (12.5%)	0.001

Lee SW, Park SW et al., J Am Coll Cardiol (in press)

Conclusions

- SES implantation is associated with reduced angiographic restenosis and 9-month TLR and MACE, and showed sustained reduction of 2-year TLR and MACE compared to PES implantation with no difference of death or MI

- The use of SES was negative independent predictors of angiographic restenosis, 2-year risks of TLR and MACE.

Lee SW, Park SW et al., J Am Coll Cardiol (in press)

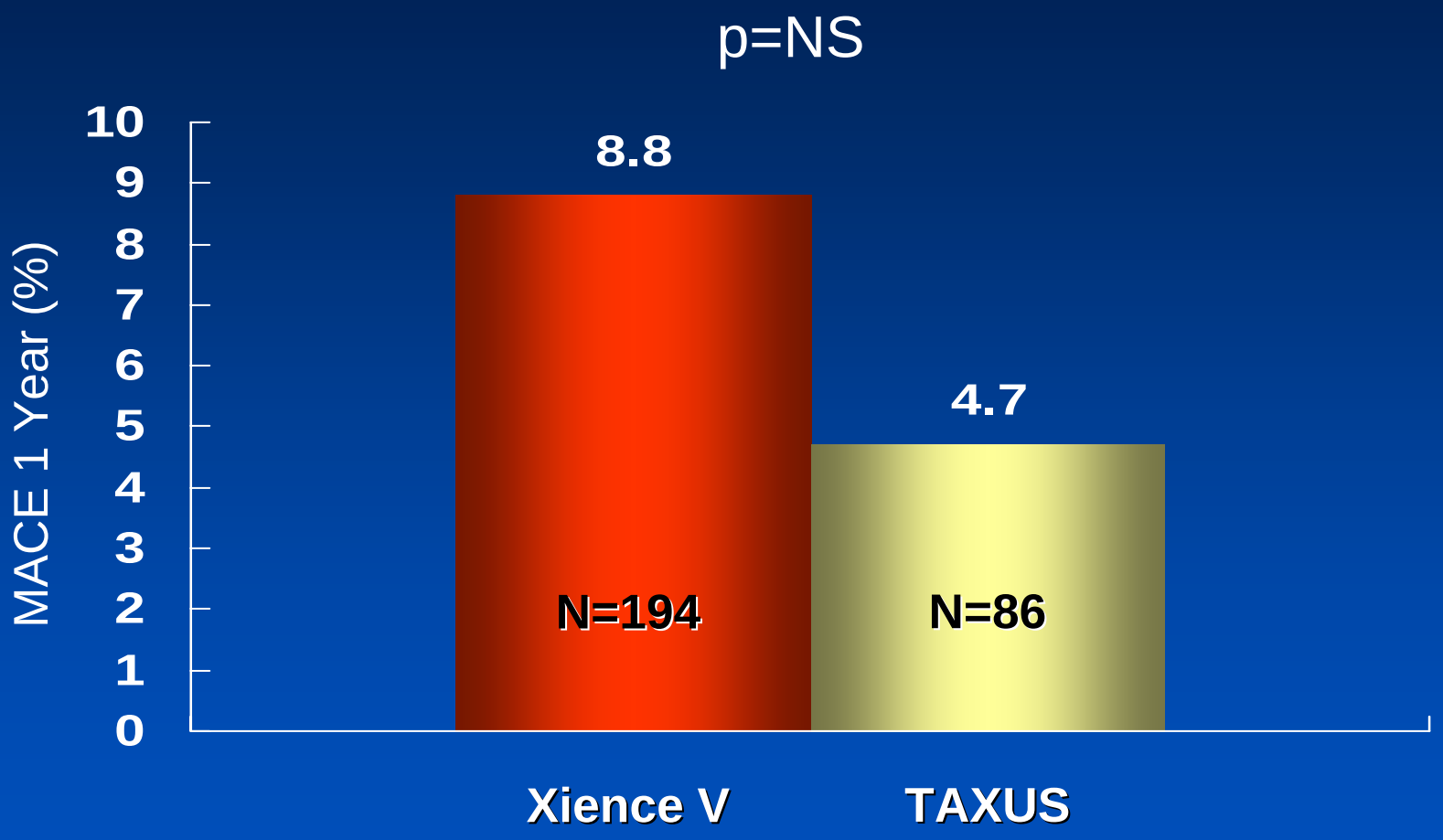
SES vs. PES

- There has been heterogeneous clinical outcomes, but SES showed consistent superiority of late loss and angiographic restenosis, which is translated to improved clinical outcomes (SIRTAX, DES-DIABETES) without difference of death, MI, and stent thrombosis.

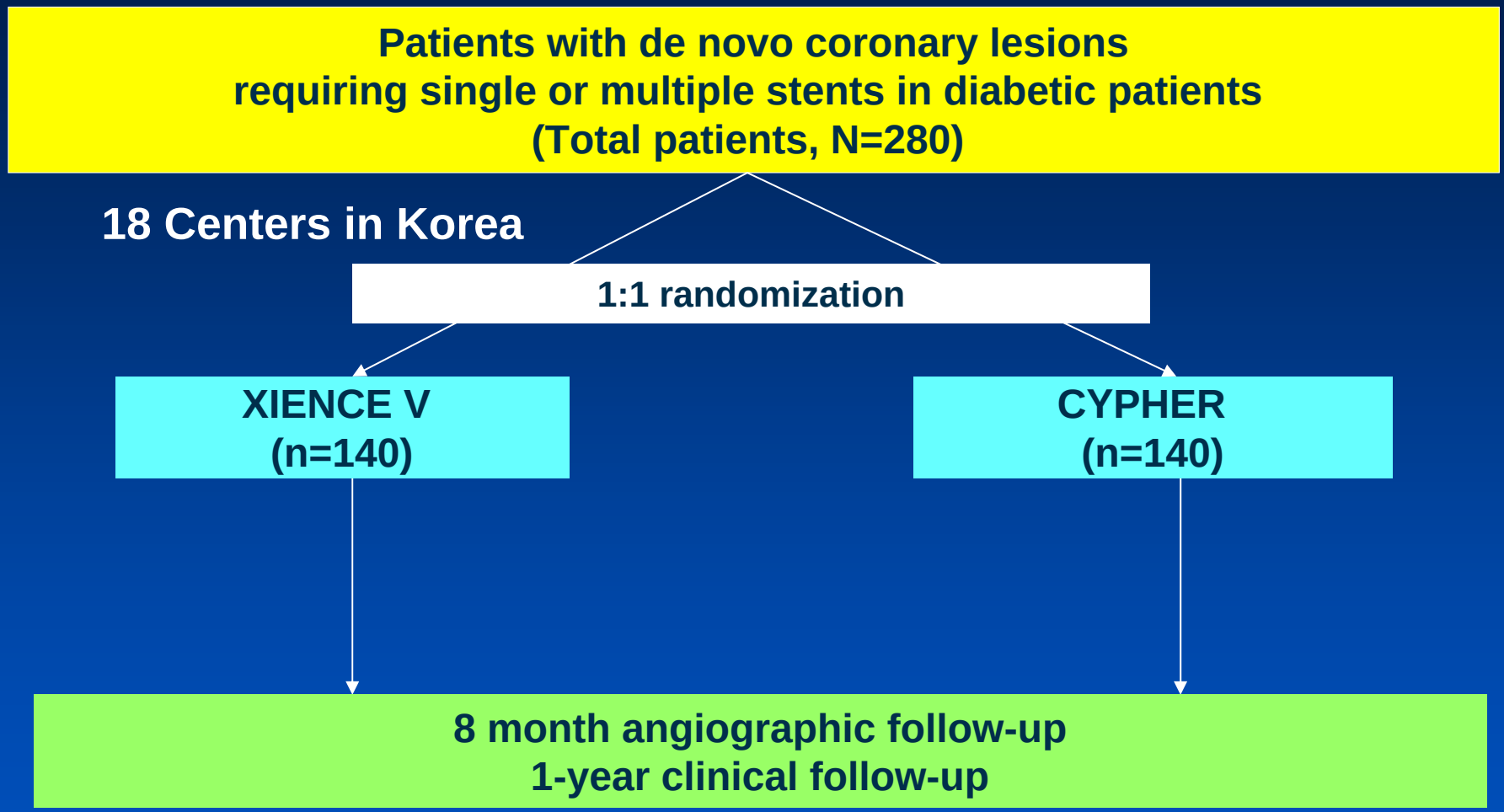
- Network meta-analysis showed similar TLR up to 4 years (HR 0.78, 95% CI,0.50 to 1.14), but HR favoring SES explained possible superiority of SES over PES, which was demonstrated in randomized trial (DES-DIABETES) dedicated for diabetic patients

SES vs. Everolimus-eluting stent

SPIRIT III Diabetes



ESSENCE-DIABETES Trial



Primary end-point: Angiographic in-segment late loss at 8-month angiography
Secondary end-point: Clinical outcomes at 12 month follow-up
IVUS results at 8 month angiographic follow-up (selected center)

PI: Seong-Wook Park, MD, PhD, FACC

21 DES ever received CE-Certificate !

CE 0086

cypher

TAXUS

ENDEAVOR

Xience V Promus™

AXXION™ DES

translumina®
YUKON™ Choice DES
Drug Eluting Stent

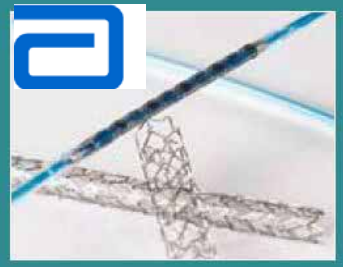
PICO Elite
amg International
Paclitaxel-Eluting Coronary Stent

JANUS
Tacrolimus eluting Carbostent™

Eurocor
TAXCOR®
Paclitaxel-Eluting
Coronary Stent System

Coroflex LEASE

Infinnium
PACLITAXEL - ELUTING STENT



Dexamet

APOLLO
Paclitaxel Eluting
Coronary Stent

euca TAX
Paclitaxel Eluting Coronary
Stentsystem

Endeavor
Resolute Stent

NOBORI™

BIOMATRIX®
DRUG ELUTING CORONARY STENT SYSTEM
Uncompromised Patient Benefit
through the Combination of Safety and Efficacy

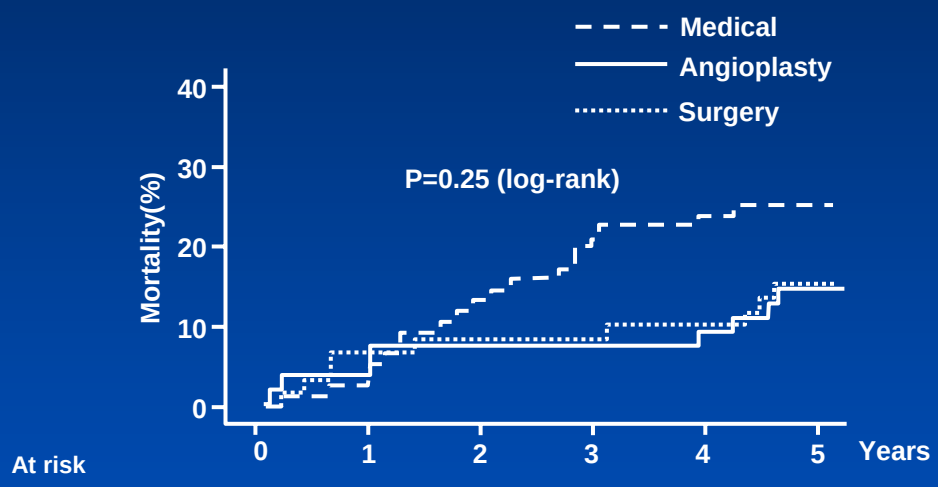
CardioVascular Research Foundation

UNIVERSITY OF ULSAN
COLLEGE MEDICINE

ASAN
Medical Center

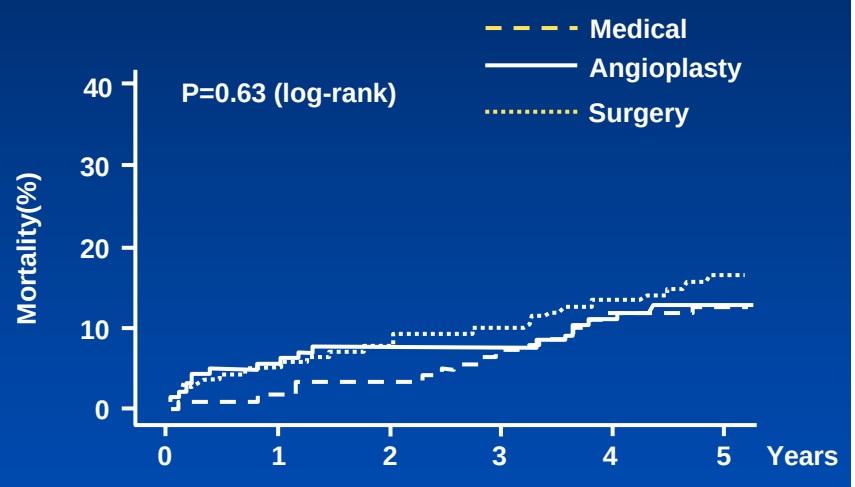
Medical vs. PCI or CABG
MASS II

Diabetic



At risk						
Medical	75	73	65	59	57	56
Angioplasty	56	53	51	51	50	47
Surgery	59	55	54	54	53	50

Nondiabetic



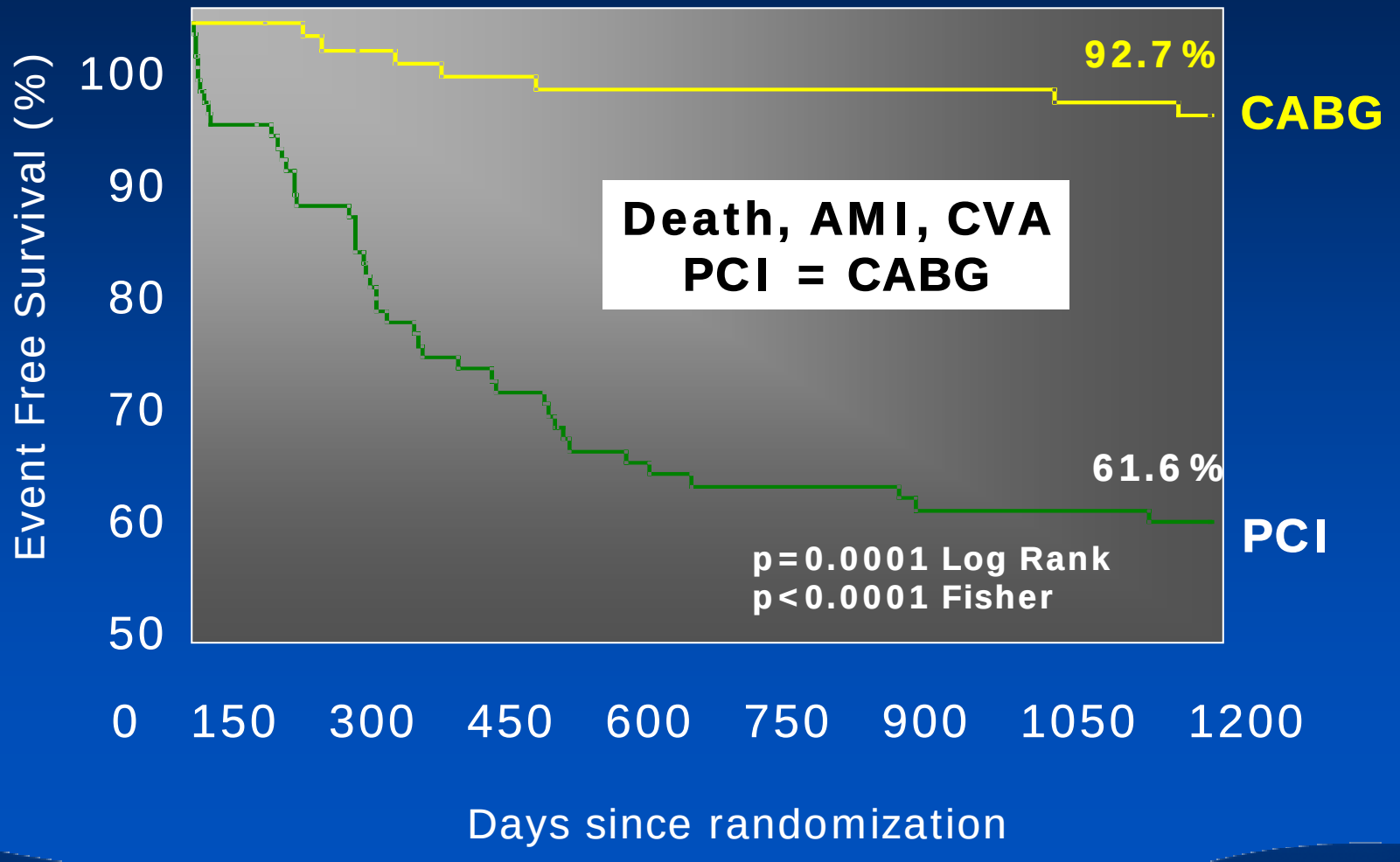
At risk						
Medical	128	126	124	119	113	112
Angioplasty		141	128	138	133	130
Surgery	144	137	133	130	125	121

Soares, PR et al. Circulation 2006; 114:I420

ARTS I trial (CABG *v.* PCI)

Three year Follow-up (Diabetic subgroup)

Repeat revascularization



Multivessel Disease

Survival at 1 year from ARTS I study

89% internal thoracic artery use, stent used but bare metal stent

N(%)	Diabetes			Non-diabetes		
	Stent (n=112)	CABG (n=96)	p	Stent (n=488)	CABG (n=509)	p
Death	7 (6.3)	3 (3.1)	0.294	8 (1.6)	14 (2.8)	0.412
CVA	2 (1.8)	6 (6.3)	0.096	7 (1.4)	6 (1.2)	0.722
MI	7 (6.3)	3 (3.1)	0.294	25 (5.1)	21 (4.1)	0.453
Re-CABG	9 (8.0)	0	< 0.001	19 (3.9)	3 (0.6)	< 0.001
Re-PTCA	16 (14.3)	3 (3.1)	< 0.001	57 (11.7)	15 (2.9)	< 0.001
Event free	71 (63.4)	81 (84.4)	< 0.001	372 (76.2)	450 (88.4)	< 0.001