Mortality after PCI with BMS and DES from the Thoraxcenter Database

Patrick Serruys, M.D., Ph.D.
Yoshinobu Onuma, MD
Joost Daemen, MD

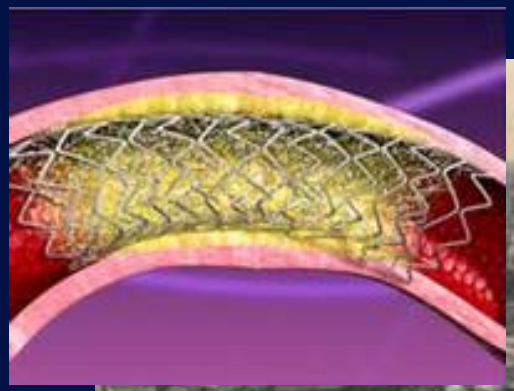
15:30-45 April 23rd, 2008
Main Arena

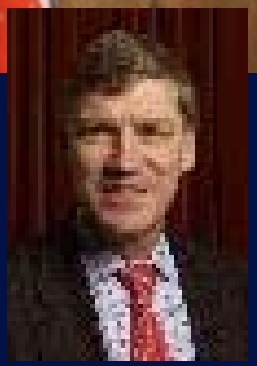
Professor Serruys declares no conflict of interest

An Epidemiological Analysis Requested by the Directing Board of a Dutch Tertiary Medical Center

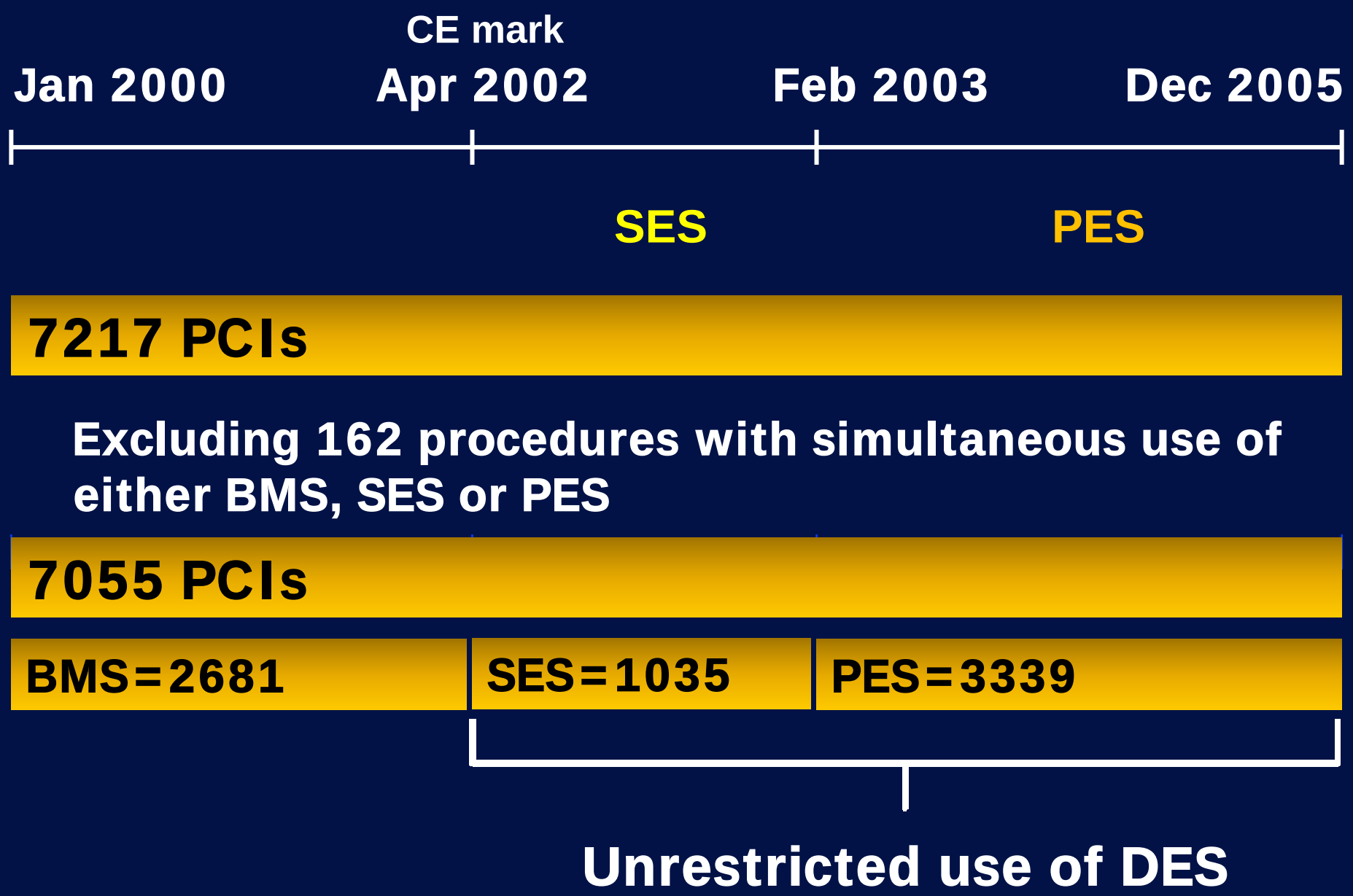
THE THORAXCENTER EXPERIENCE

2000-2005





THORAXCENTER REAL WORLD EXPERIENCE



Follow-up and causes of death

Survival status obtained via municipal civil registries

Causes of death:

- obtained via Central Bureau of Statistics
- stratified according to the International Classification of Diseases and Related Health Problems, 10th Revision (ICD-10).
- Cardiac: I-20 to I-25; I-46; R-96; I-50
- Cancer: C-00 to C-97
- Other causes

Baseline characteristics

	Overall (n=6129)	BMS (n=2428)	SES (n=866)	PES (n=2835)	P-value
Age (±SD)	61.8 ± 12	61.5 ±12	61.5 ±11	62.2 ±12	0.04
Male gender, %	72.5	72.8	70.3	72.9	0.30
Presentation, %					
Stable angina	40.0	41.4	43.3	37.8	0.003
Unstable angina	31.4	36.2	35.2	26.1	<0.001
AMI	28.6	22.4	21.6	36.1	<0.001
Diabetes	15.3	13.2	17.3	16.5	0.001
Hypertension, %	37.9	32.7	41.2	41.3	<0.001
Hypercholesterolemia	49.0	43.5	55.3	51.7	<0.001
Previous PCI, %	13.1	15.9	11.8	11.2	<0.001
Previous CABG, %	9.4	11.9	7.1	8.0	<0.001
Previous AMI, %	30.0	35.2	31.3	25.1	<0.001
Multivessel disease, %	52.2	52.8	54.3	51.0	0.18

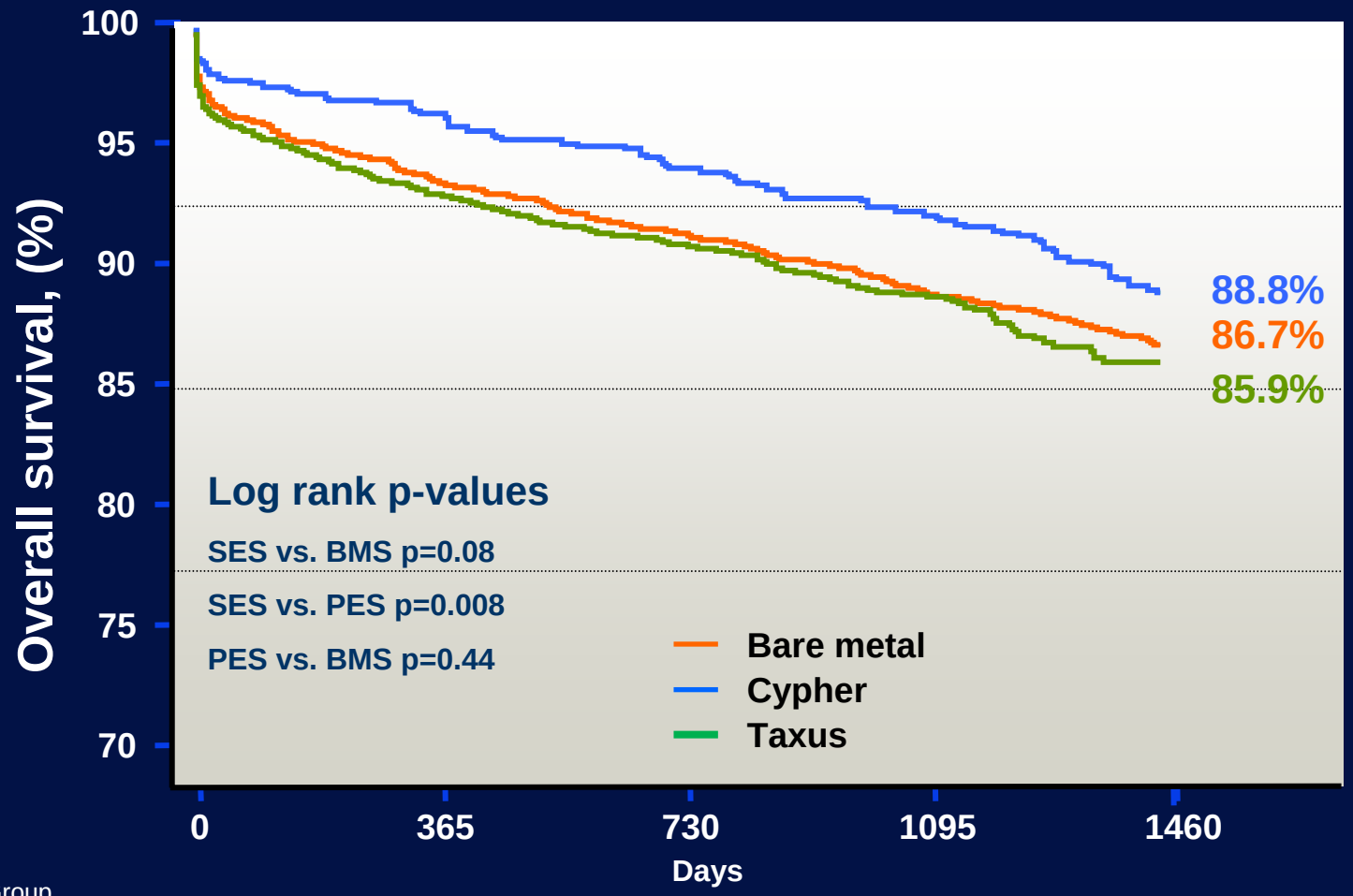
Baseline characteristics

	Overall (n=6129)	BMS (n=2428)	SES (n=866)	PES (n=2835)	P-value
Age (±SD)	61.8 ± 12	61.5 ±12	61.5 ±11	62.2 ±12	0.04
Male gender, %	72.5	72.8	70.3	72.9	0.30
Presentation, %					
Stable angina	40.0	41.4	43.3	37.8	0.003
Unstable angina	31.4	36.2	35.2	26.1	<0.001
AMI	28.6	22.4	21.6	36.1	<0.001
Diabetes	15.3	13.2	17.3	16.5	0.001
Hypertension, %	37.9	32.7	41.2	41.3	<0.001
Hypercholesterolemia	49.0	43.5	55.3	51.7	<0.001
Previous PCI, %	13.1	15.9	11.8	11.2	<0.001
Previous CABG, %	9.4	11.9	7.1	8.0	<0.001
Previous AMI, %	30.0	35.2	31.3	25.1	<0.001
Multivessel disease, %	52.2	52.8	54.3	51.0	0.18

Procedural characteristics

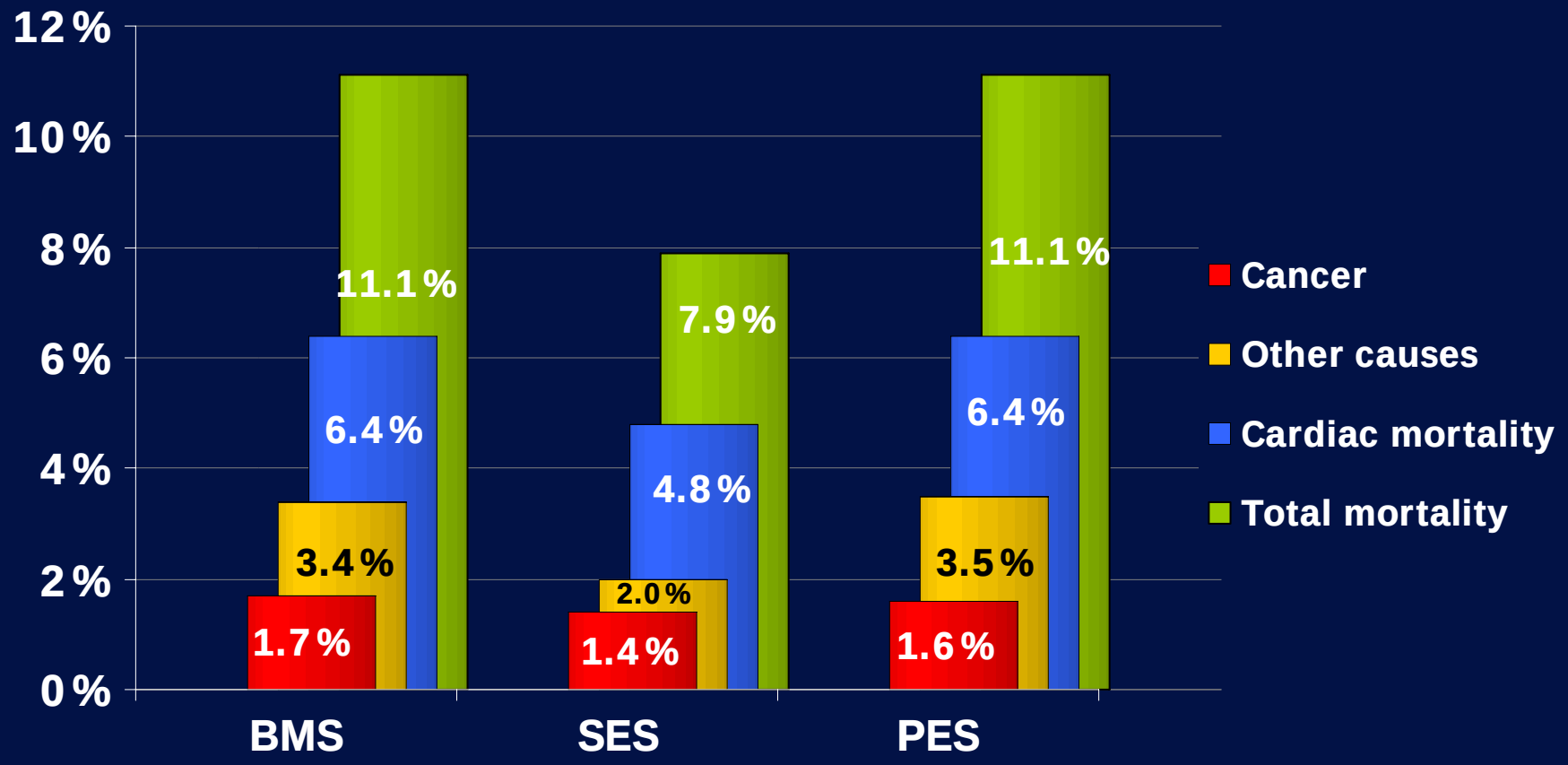
	Overall (n=6129)	BMS (n=2428)	SES (n=866)	PES (n=2835)	P-value
Vessel					
RCA, %	38.7	39.4	40.5	37.5	0.18
LAD, %	53.8	53.2	59.4	52.7	0.002
LCX, %	30.1	30.1	32.7	29.3	0.17
LM, %	4.2	3.5	3.1	5.2	0.003
Bypass graft, %	4.1	5.6	2.0	3.6	<0.001
Lesion type B2/C, %	73.8	71.9	77.9	74.1	0.002
Bifurcation, %	8.5	3.6	10.2	12.3	<0.001
Nr of stents (±SD)	2.0±1.3	1.8±1.1	2.2±1.5	2.2±1.4	<0.001
Av. Stent diam (±SD)	3.1±0.6	3.3±0.6	2.8±0.3	2.9±0.6	<0.001
Stented length (±SD)	37.0±28	28.3±20	42.8±30	42.7±31	<0.001
Clopidogrel (months)	4.6±3.6	2.5 ±2.3	4.5 ±3.2	6.6 ±3.4	<0.001

All-cause survival at 4 years



Group					
BMS	2428	2202	2128	2051	1973
SES	866	825	790	759	582
PES	2835	2511	2105	1018	280

Causes of Death



BMS
- Total = 251
- •Cardiac = 143
- •Cancer = 36
- •Other = 72

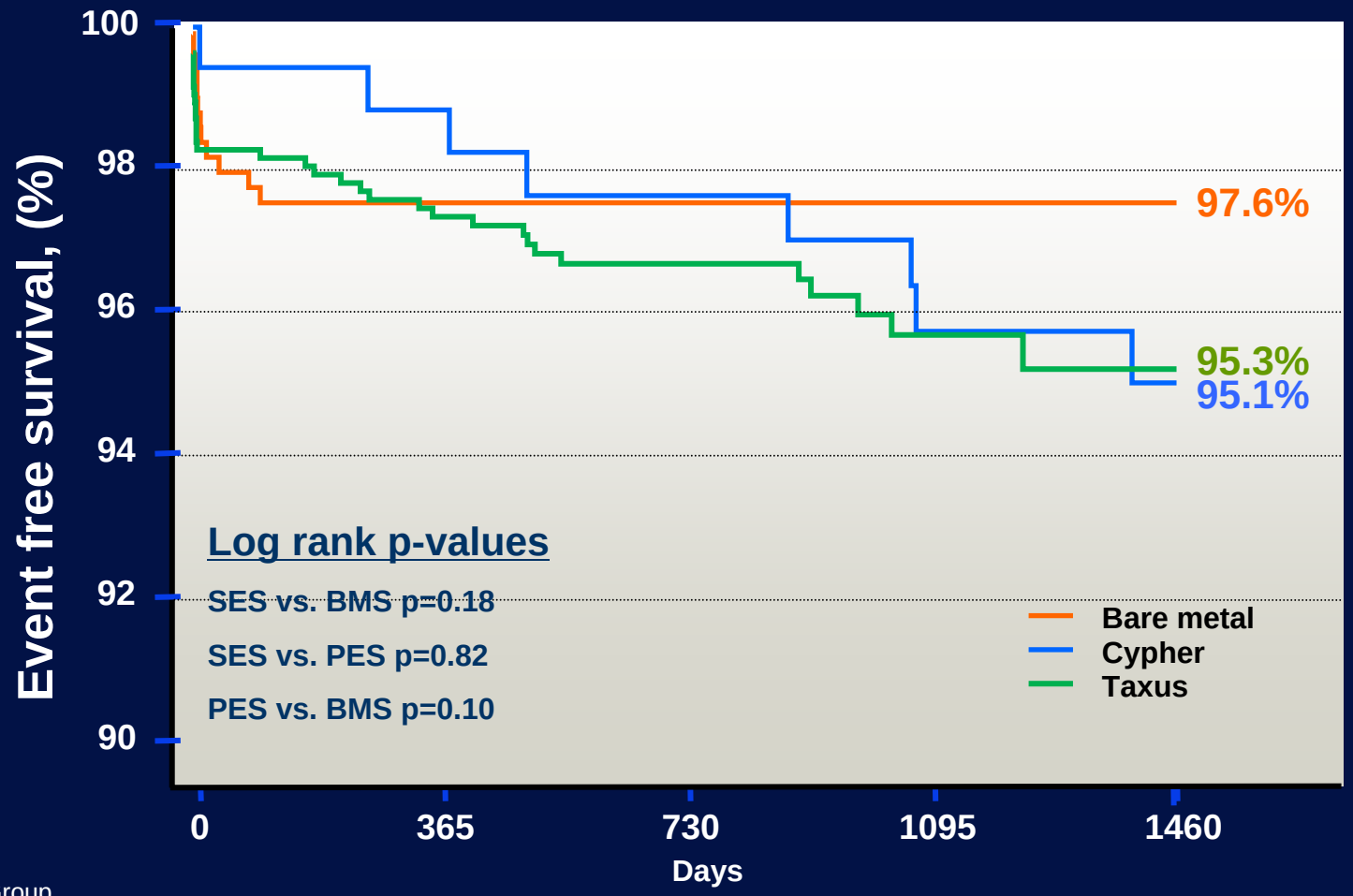
SES
- Total = 67
- •Cardiac = 40
- •Cancer = 11
- •Other = 16

PES
- Total = 237
- •Cardiac = 145
- •Cancer = 28
- •Other =64

* ICD: I-20 to I-25; I-46; R-96; I-50

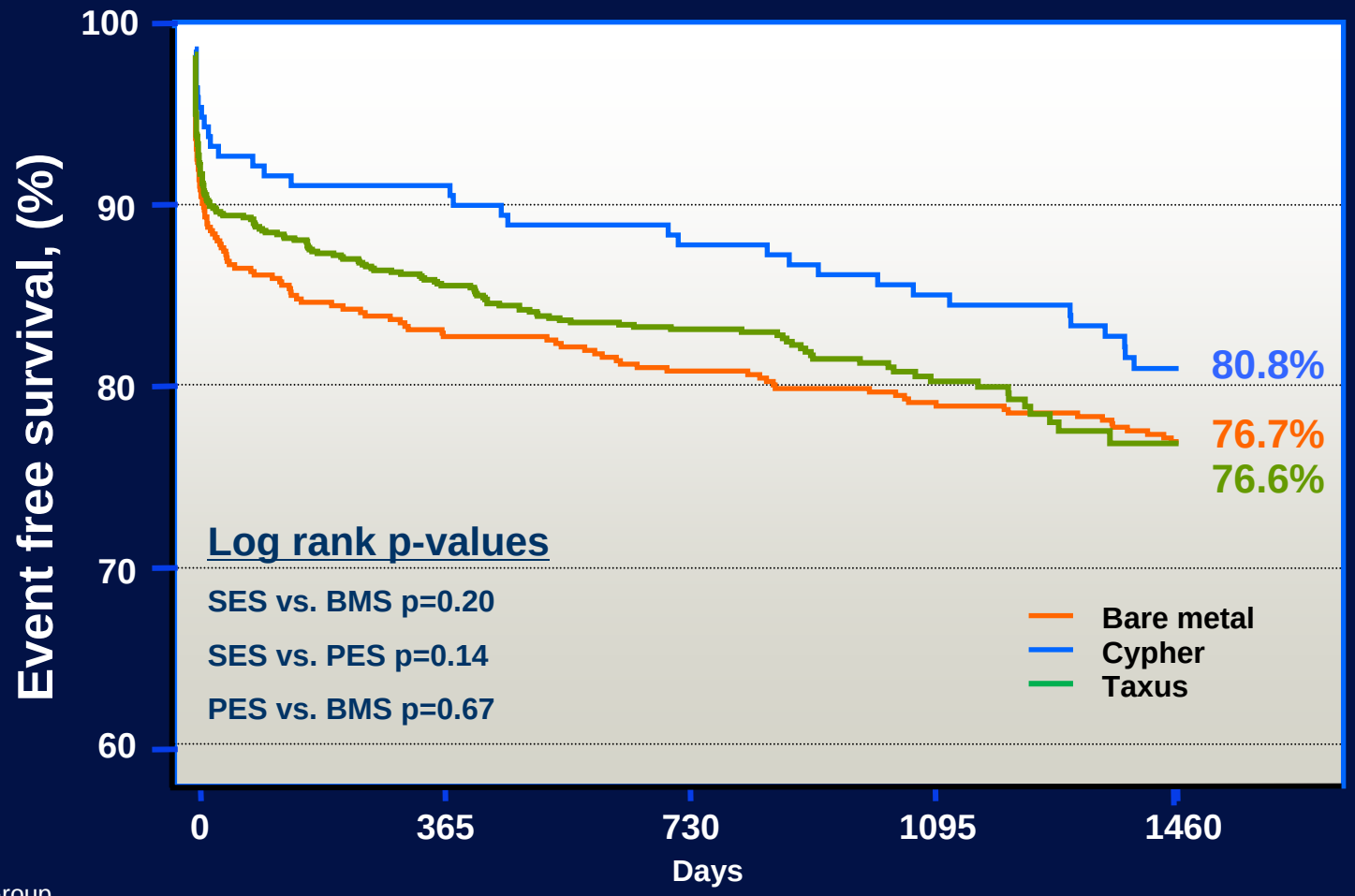
** ICD: C-00 to C-97

Stent thrombosis



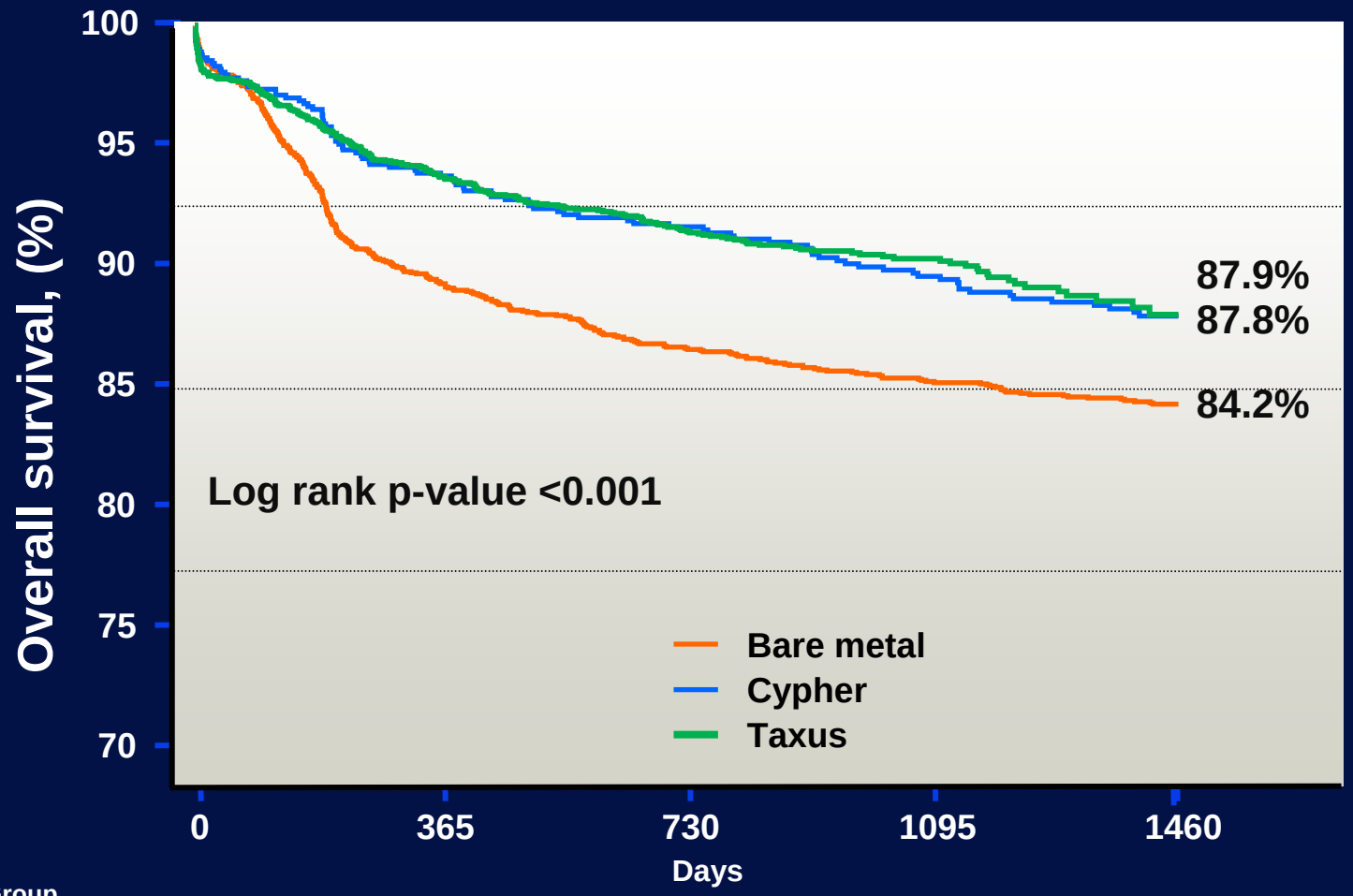
Group					
BMS	545	449	483	422	403
SES	186	168	160	151	116
PES	1021	821	652	295	84

Death/MI free survival



Group					
BMS	545	439	421	409	390
SES	186	167	160	151	116
PES	1021	807	643	290	82

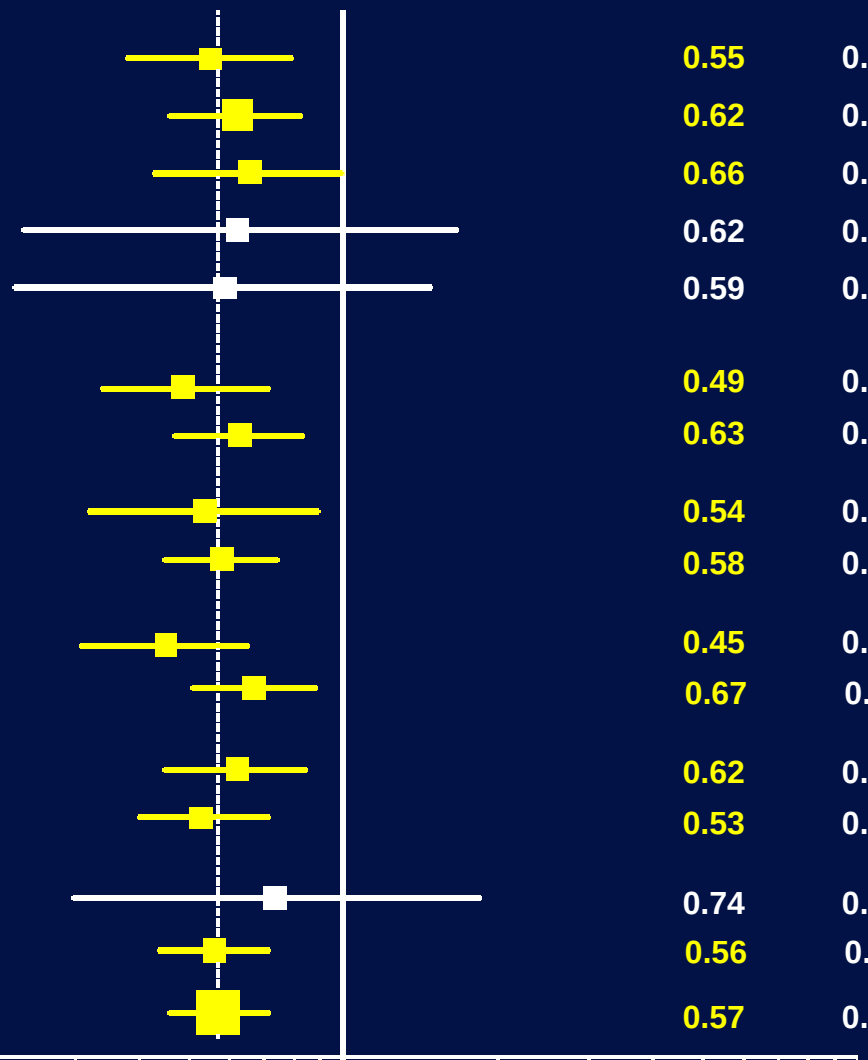
Target vessel revascularization



Group					
BMS	2370	1971	1851	1764	1678
SES	856	774	725	685	517
PES	2745	2365	1958	942	269

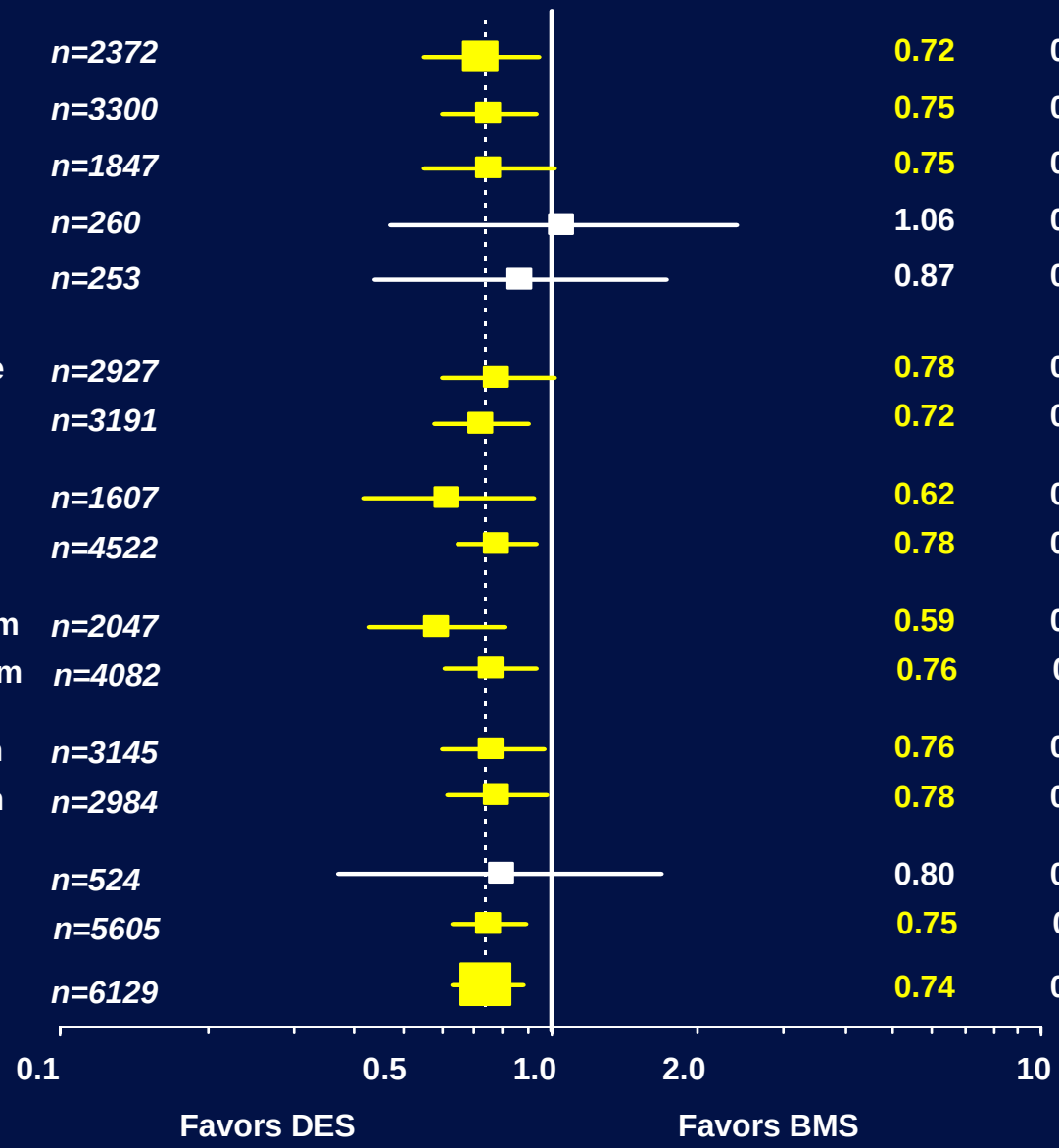
Adjusted hazard ratio and 95% CI for target vessel revascularization at 1 year (Treatment effect ranges from 55 % to 33 %)

Variable	Number	HR	95% CI	P-Value
RCA	n=2372	0.55	0.38-0.79	0.001
LAD	n=3300	0.62	0.46-0.82	0.001
LCX	n=1847	0.66	0.43-0.99	0.046
LM	n=260	0.62	0.24-1.65	0.62
Bypass graft	n=253	0.59	0.23-1.47	0.25
Single vessel disease	n=2927	0.49	0.34-0.71	<0.001
Multivessel disease	n=3191	0.63	0.47-0.83	0.001
Lesion type A/B1	n=1607	0.54	0.32-0.89	0.016
Lesion type B2/C	n=4522	0.58	0.45-0.74	<0.001
Vessel diameter ≤3mm	n=2047	0.45	0.31-0.65	<0.001
Vessel diameter >3mm	n=4082	0.67	0.51-0.88	0.004
Lesion length ≤30mm	n=3145	0.62	0.45-0.84	0.002
Lesion length >30mm	n=2984	0.53	0.40-0.71	<0.001
Bifurcation	n=524	0.74	0.30-1.82	0.51
No bifurcation	n=5605	0.56	0.44-0.71	<0.001
All patients	n=6129	0.57	0.46-0.71	<0.001



Adjusted hazard ratio and 95% CI for target vessel revascularization at 4 year (Treatment effect ranges from 41 % to 22 %)

Variable	Number	HR	95% CI	P-Value
RCA	n=2372	0.72	0.55-0.95	0.022
LAD	n=3300	0.75	0.60-0.93	0.009
LCX	n=1847	0.75	0.55-1.02	0.071
LM	n=260	1.06	0.47-2.39	0.89
Bypass graft	n=253	0.87	0.44-1.72	0.70
Single vessel disease	n=2927	0.78	0.60-1.02	0.07
Multivessel disease	n=3191	0.72	0.58-0.90	0.003
Lesion type A/B1	n=1607	0.62	0.42-0.92	0.016
Lesion type B2/C	n=4522	0.78	0.65-0.94	0.011
Vessel diameter ≤3mm	n=2047	0.59	0.43-0.81	0.001
Vessel diameter >3mm	n=4082	0.76	0.61-0.94	0.013
Lesion length ≤30mm	n=3145	0.76	0.60-0.97	0.026
Lesion length >30mm	n=2984	0.78	0.62-0.98	0.030
Bifurcation	n=524	0.80	0.37-1.69	0.55
No bifurcation	n=5605	0.75	0.63-0.89	0.001
All patients	n=6129	0.74	0.63-0.88	0.50

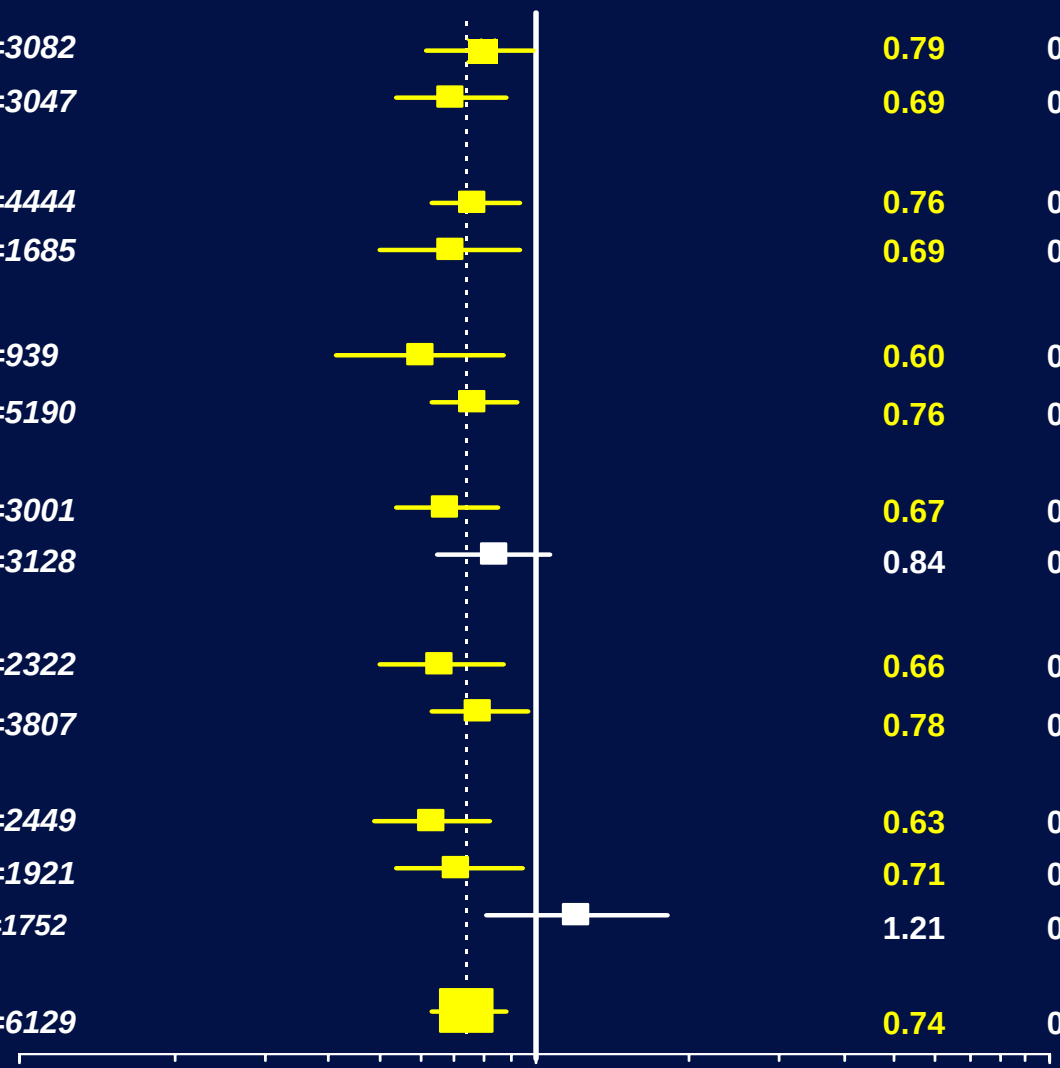


Adjusted hazard ratio and 95% CI for target vessel revascularization at 1 year (Treatment effect ranges from 44 % to 39 %)

Variable	Number	HR	95% CI	P-Value
Age ≤62 years	*n=3082*	0.55	0.40-0.75	<0.001
Age >62 years	*n=3047*	0.58	0.42-0.80	0.001
Men	*n=4444*	0.56	0.43-0.72	<0.001
Women	*n=1685*	0.59	0.38-0.89	0.013
Diabetes	*n=939*	0.61	0.37-0.99	0.047
No diabetes	*n=5190*	0.54	0.42-0.70	<0.001
Dyslipidemia	*n=3001*	0.56	0.41-0.76	<0.001
No dyslipidemia	*n=3128*	0.60	0.44-0.83	0.002
Hypertension	*n=2322*	0.57	0.39-0.83	0.003
No hypertension	*n=3807*	0.58	0.44-0.76	<0.001
Stable angina	*n=2449*	0.56	0.40-0.80	0.001
Unstable angina	*n=1921*	0.46	0.32-0.67	<0.001
Myocardial infarction	*n=1752*	0.83	0.49-1.41	0.48
All patients	*n=6129*	0.57	0.46-0.71	<0.001

Adjusted hazard ratio and 95% CI for target vessel revascularization at 4 year (Treatment effect ranges from 40 % to 21 %)

Variable	Number	HR	95% CI	P-Value
Age ≤62 years	n=3082	0.79	0.62-0.99	0.044
Age >62 years	n=3047	0.69	0.54-0.88	0.003
Men	n=4444	0.76	0.63-0.93	0.008
Women	n=1685	0.69	0.50-0.94	0.021
Diabetes	n=939	0.60	0.41-0.87	0.008
No diabetes	n=5190	0.76	0.63-0.92	0.004
Dyslipidemia	n=3001	0.67	0.54-0.85	0.001
No dyslipidemia	n=3128	0.84	0.65-1.07	0.16
Hypertension	n=2322	0.66	0.50-0.87	0.003
No hypertension	n=3807	0.78	0.63-0.97	0.026
Stable angina	n=2449	0.63	0.49-0.82	0.001
Unstable angina	n=1921	0.71	0.54-0.95	0.018
Myocardial infarction	n=1752	1.21	0.81-1.80	0.35
All patients	n=6129	0.74	0.63-0.88	<0.001



THORAXCENTER REAL WORLD EXPERIENCE

A subgroup analysis of 1779 STEMI Patients

CE mark

Jan 2000 | Apr 2002 | Feb 2003 | Dec 2005

STEMI Primary PCI

BMS=569	SES=189	PES=1021

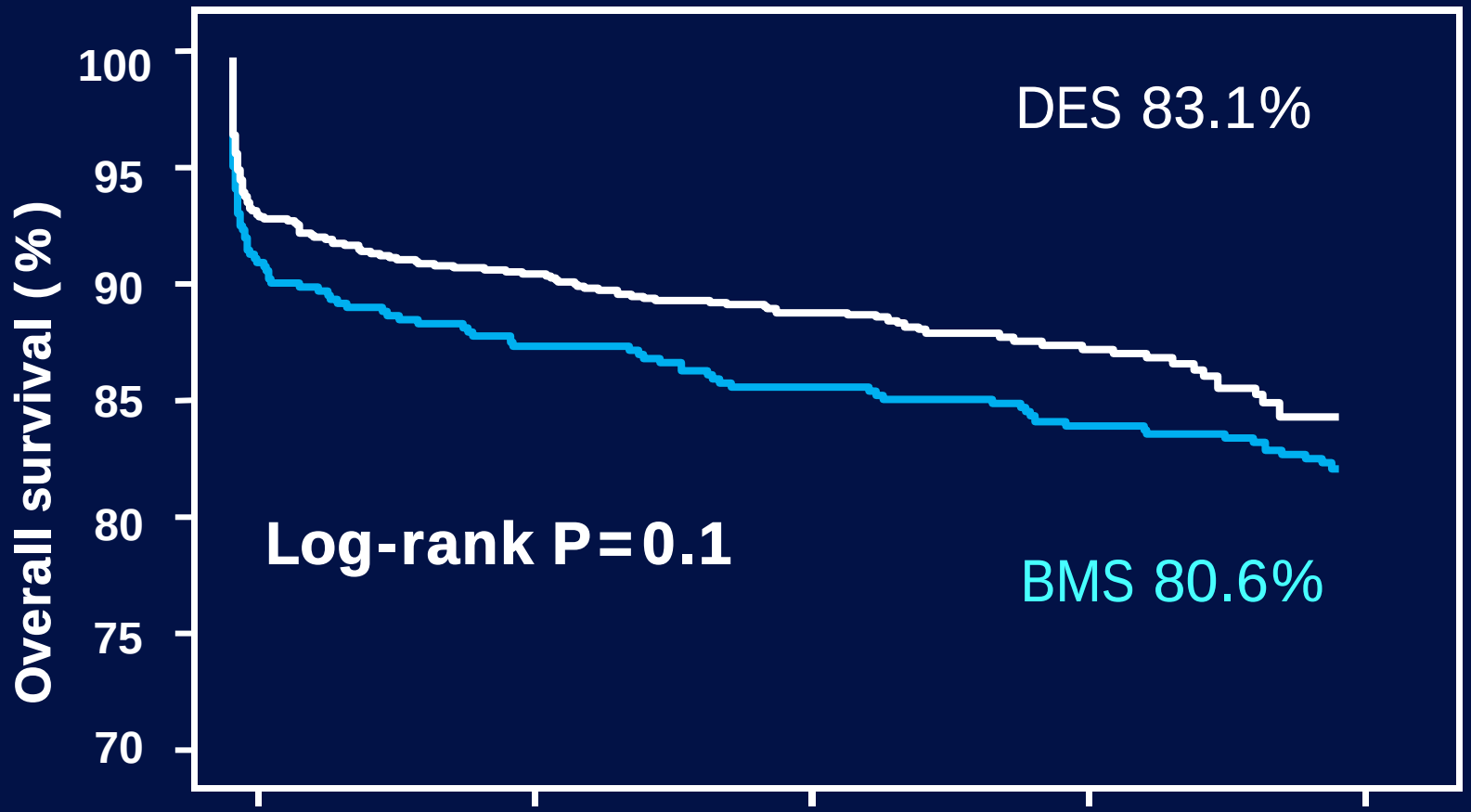
Baseline characteristics

	BMS (n=569)	DES (n=1210)	P-value
Age (±SD)	58 ±12	60 ±12	0.001
Male gender, %	81	78	0.09
Shock, %	5	6	0.4
Diabetes, %	10	10	1.0
Hypertension, %	22	29	0.002
Current smoker, %	36	40	0.1
Hypercholesterolemia	26	32	<0.01
Family history of CAD	20	27	0.003
Previous PCI, %	7	4	0.02
Previous CABG, %	4	2	0.01
Previous MI, %	22	10	<0.001

Baseline characteristics

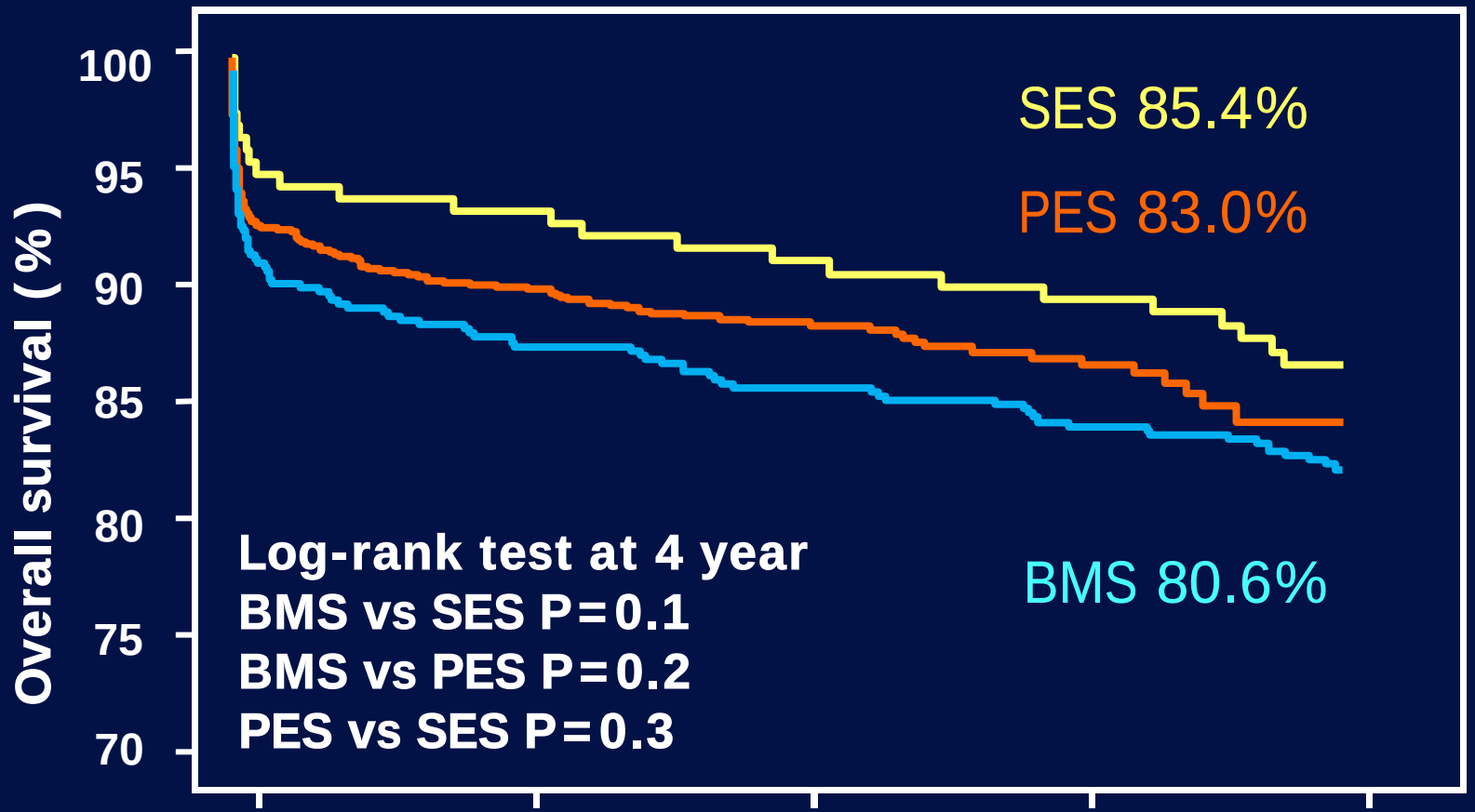
	BMS (n=569)	DES (n=1210)	P-value
Vessel			
RCA, %	39	41	0.5
LAD, %	58	50	0.003
LCX, %	17	16	0.6
LM, %	4	3	0.5
Bypass graft, %	3	1	<0.01
Lesion type B2/C, %	78	77	1.0
Bifurcation, %	4	7	0.001
Nr of stents (±SD)	1.7±1.0	1.8±1.1	0.1
Av. Stent diam (±SD)	3.4±0.5	3.1±0.4	<0.001
Stented length (±SD)	28±19	35±23	<0.001

Freedom from All-cause death at 4 years



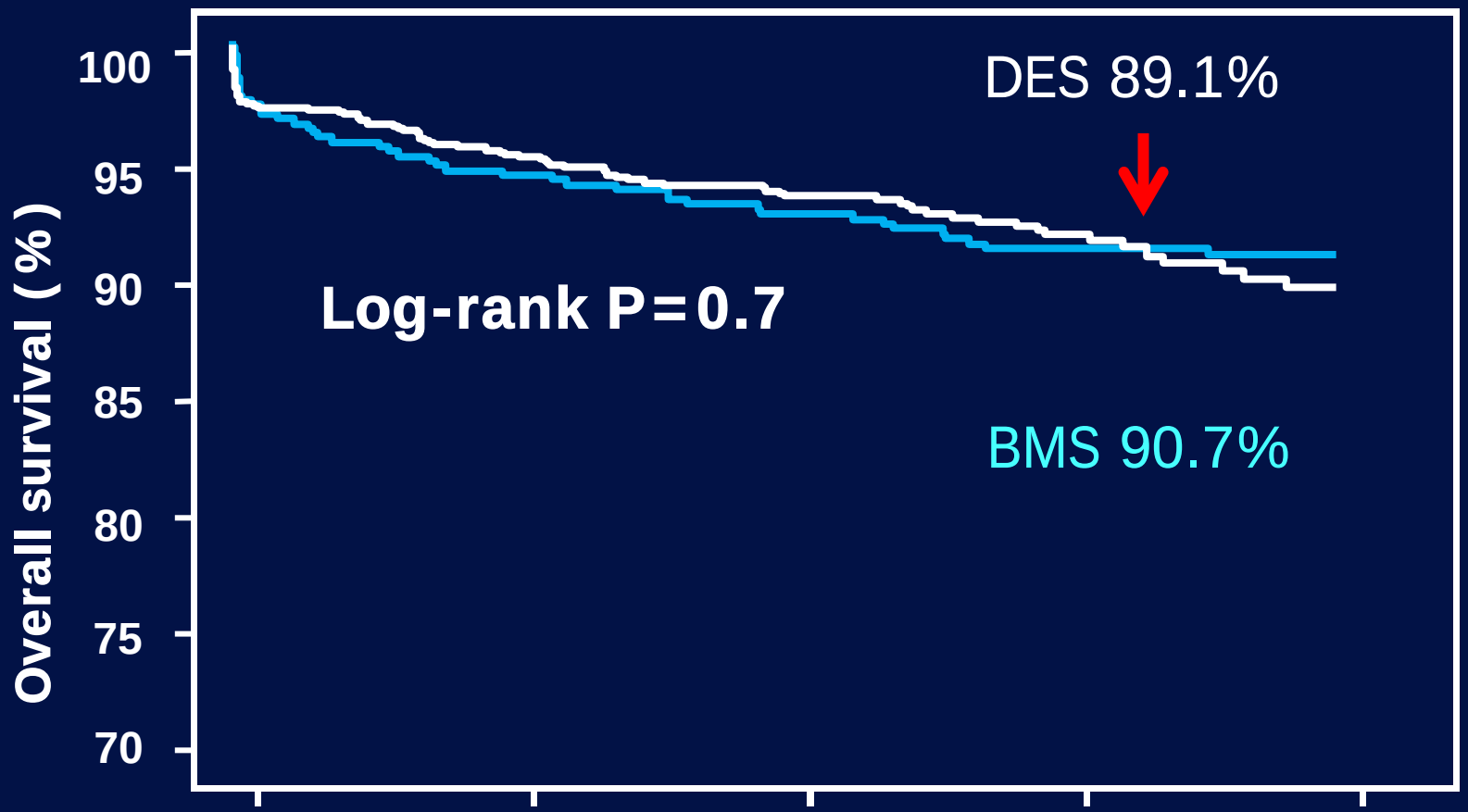
Pts at risk	0	365	730	1095	1460
BMS	562	482	464	453	432
SES	189	173	167	161	126
PES	982	856	686	311	89

Freedom from All-cause death at 4 years



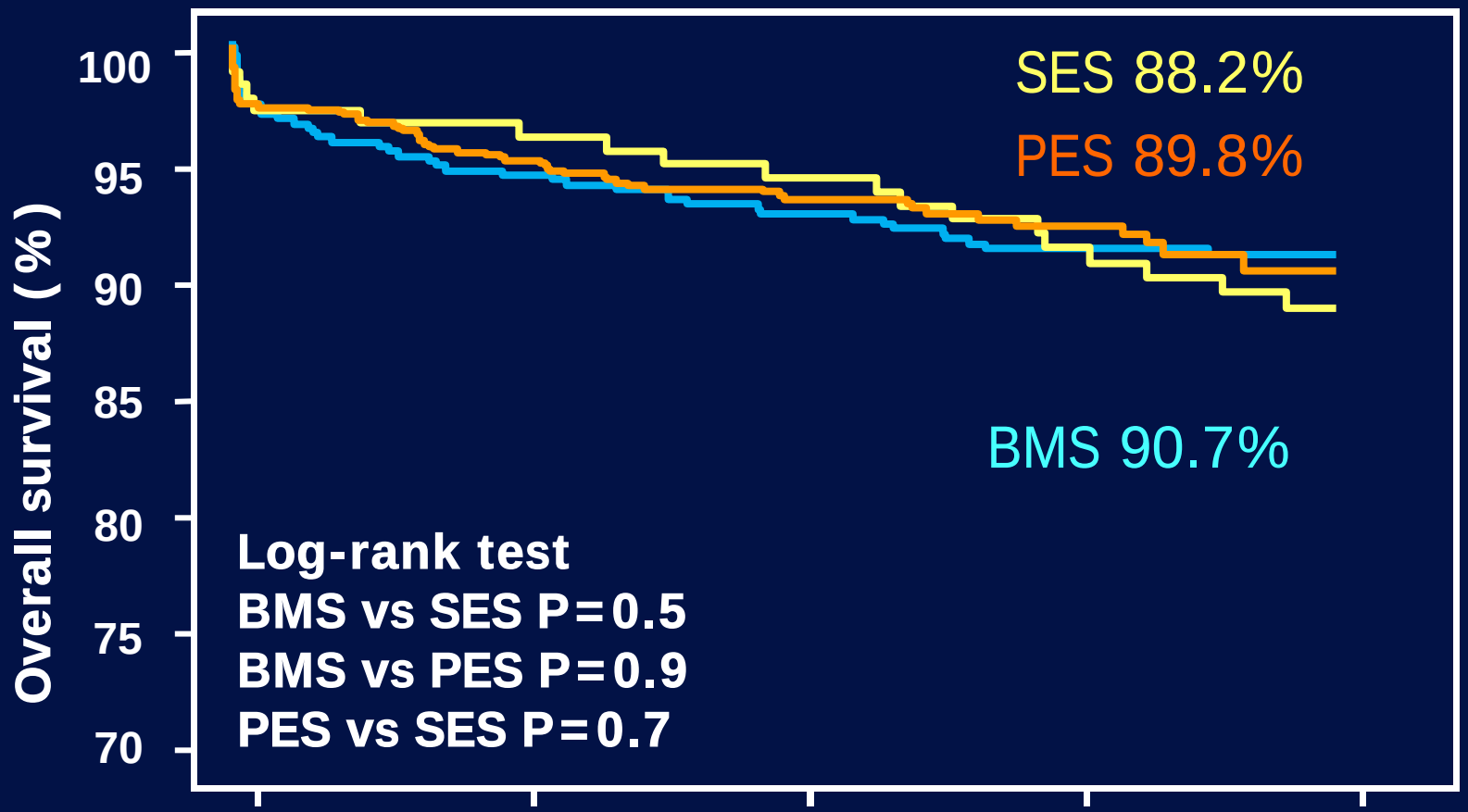
Pts at risk	0	365	730	1095	1460
BMS	562	482	464	453	432
SES	189	173	167	161	126
PES	982	856	686	311	89

Freedom from TVR at 4 years



Pts at risk	0	365	730	1095	1460
BMS	562	455	430	414	393
SES	189	167	157	147	113
PES	982	815	645	290	83

Freedom from TVR at 4 years



Pts at risk	0	365	730	1095	1460
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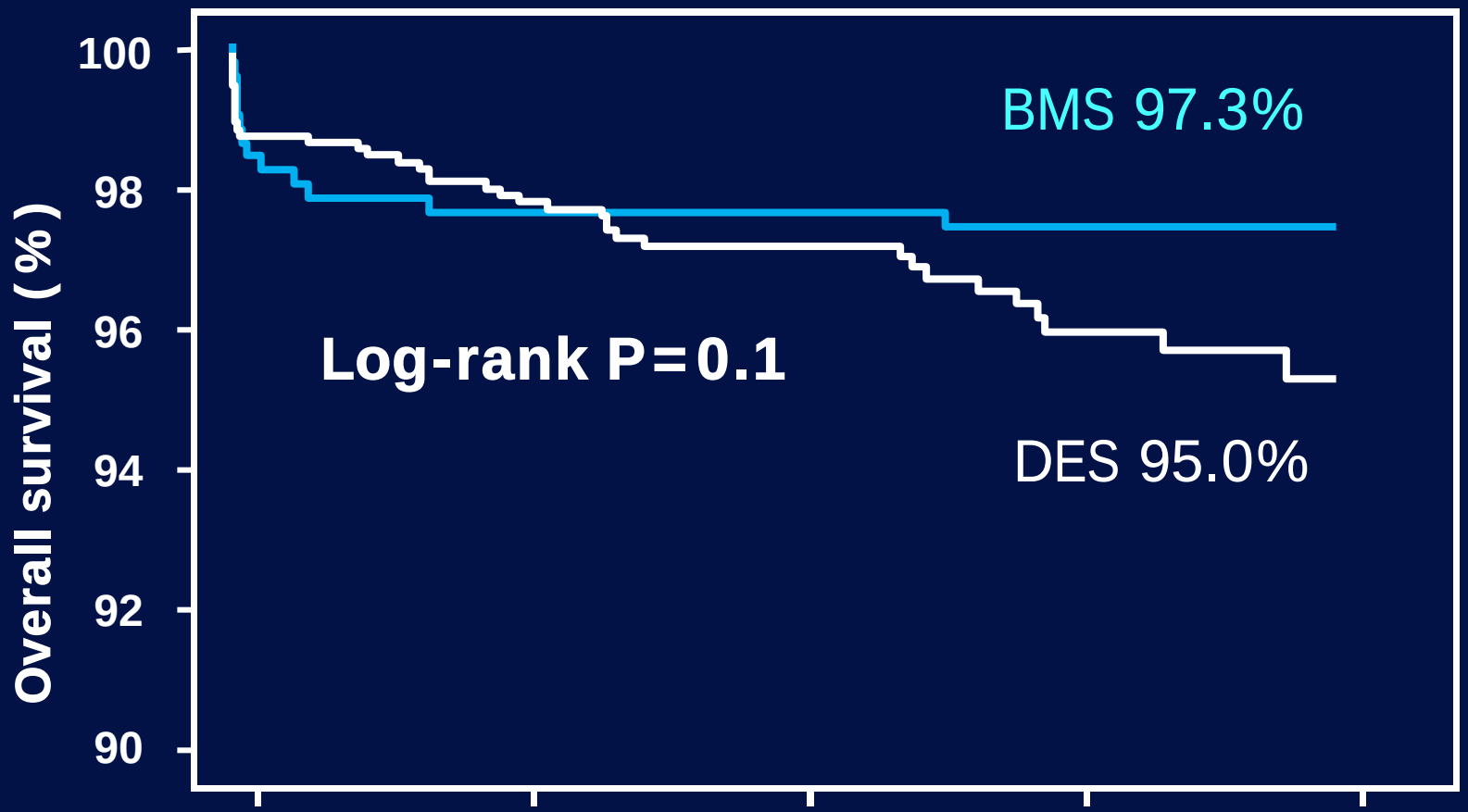
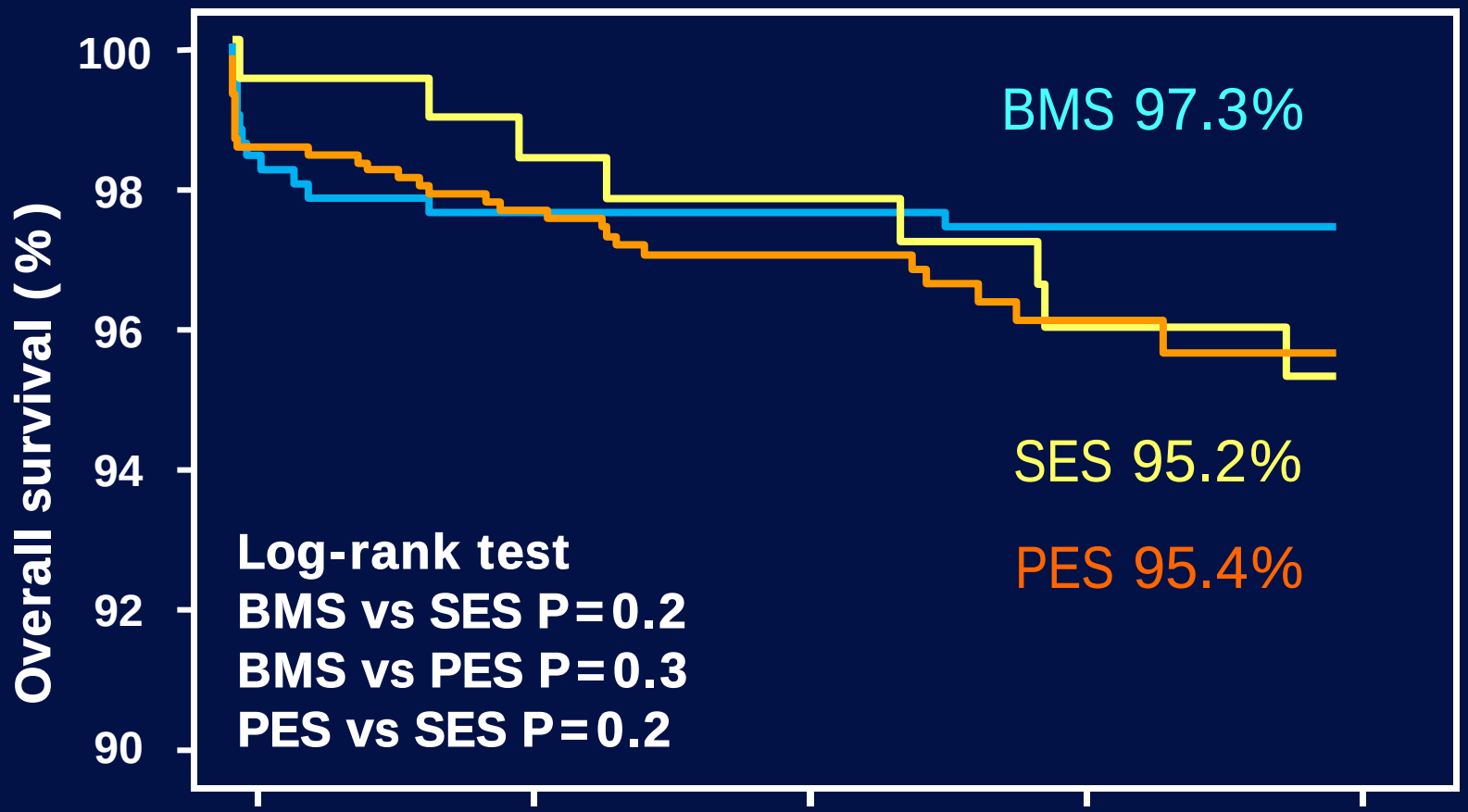
SES	189	167	157	147	113
PES	982	815	645	290	83

Freedom from Angiographic Stent Thrombosis at 4 years



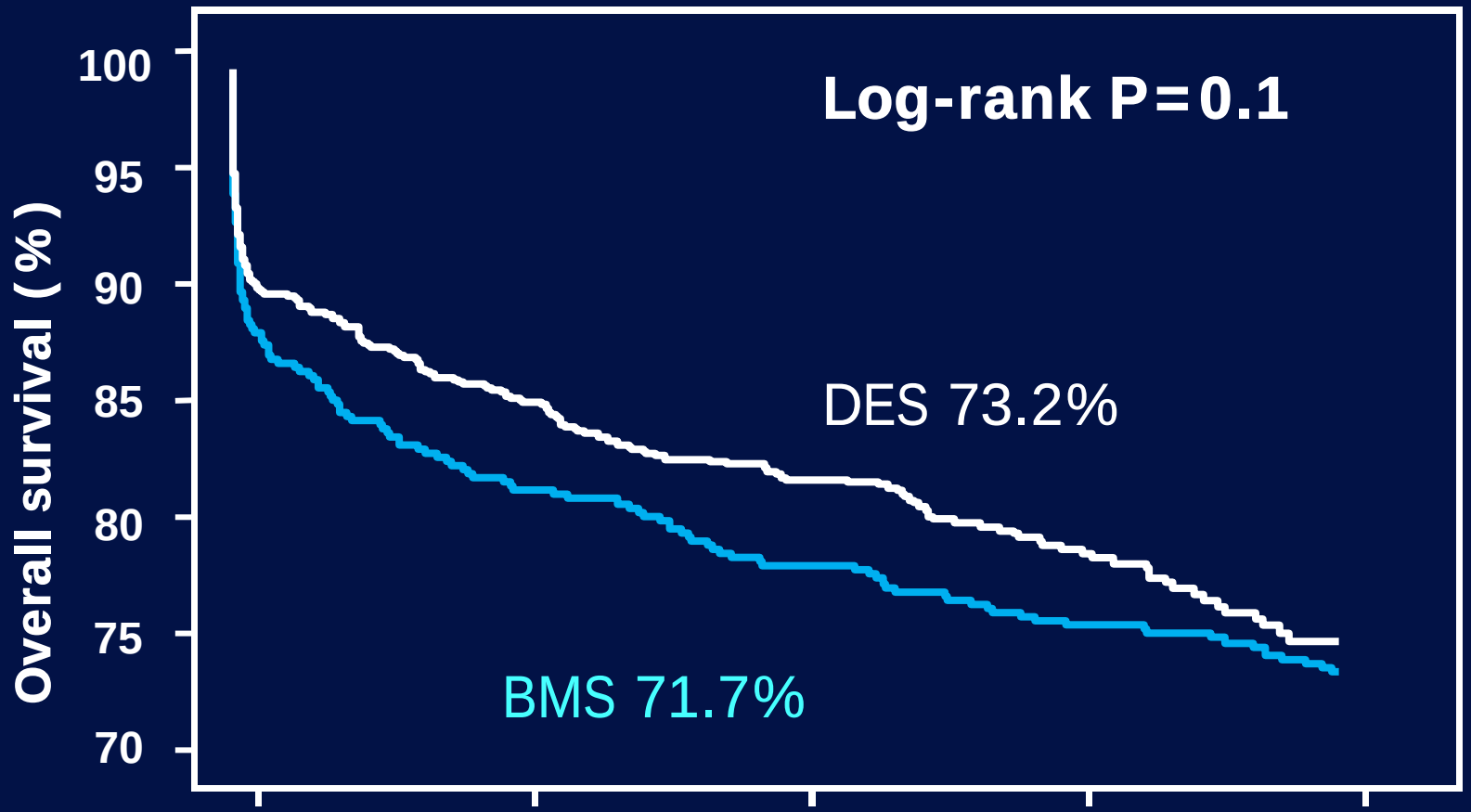
Pts at risk	0	365	730	1095	1460
BMS	532	470	452	441	420
SES	189	171	163	154	119
PES	982	837	669	302	85

Freedom from Angiographic Stent Thrombosis at 4 years



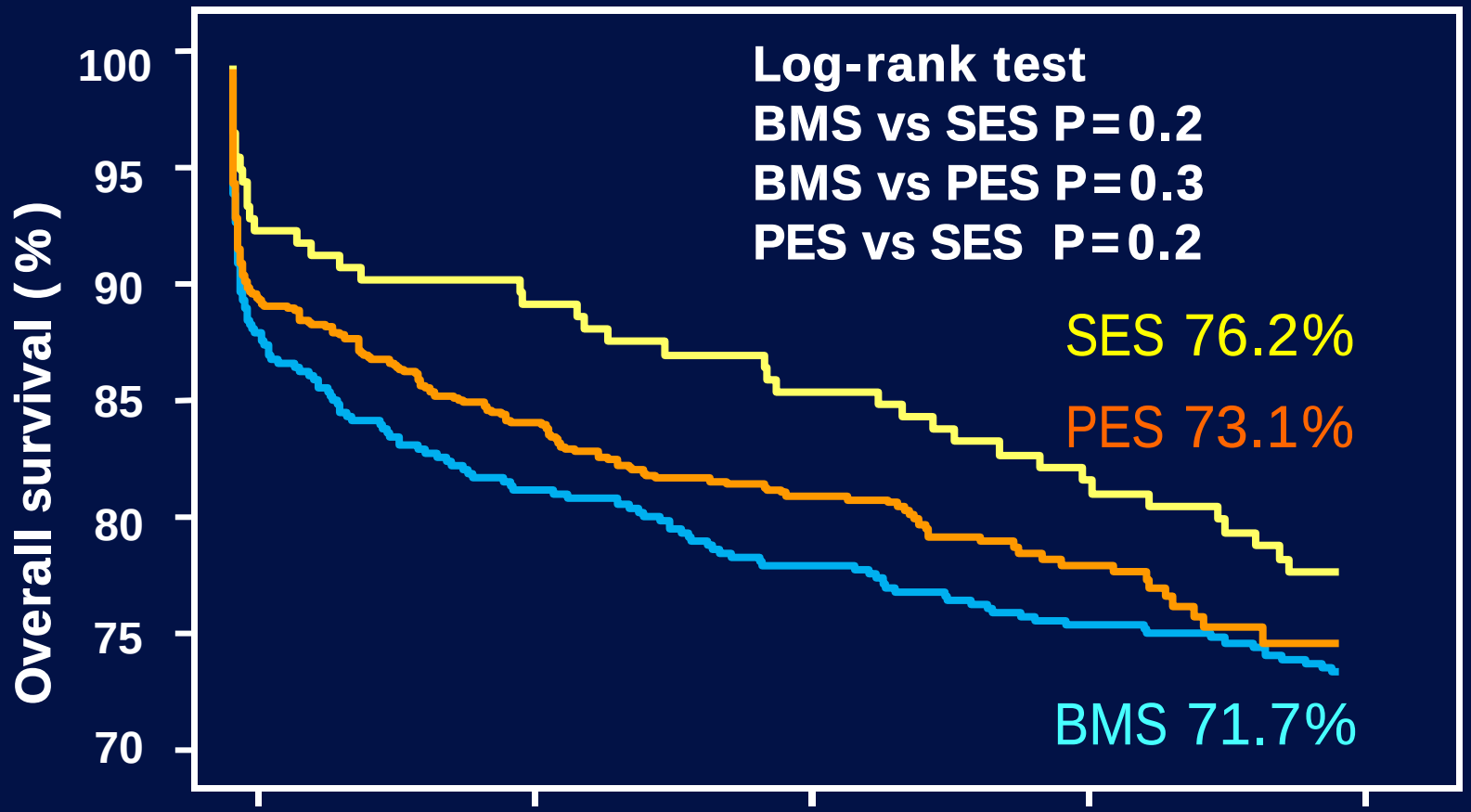
Pts at risk	0	365	730	1095	1460
BMS	532	470	452	441	420
SES	189	171	163	154	119
PES	982	837	669	302	85

Freedom from MACE at 4 years



Pts at risk	0	365	730	1095	1460
BMS	562	446	420	405	385
SES	189	166	156	146	112
PES	982	798	633	283	81

Freedom from MACE at 4 years



Pts at risk	0	365	730	1095	1460
BMS	562	446	420	405	385
SES	189	166	156	146	112
PES	982	798	633	283	81

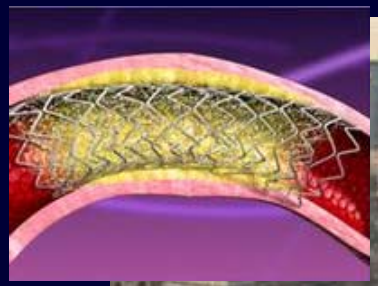
Based on our personal 4-year experience,

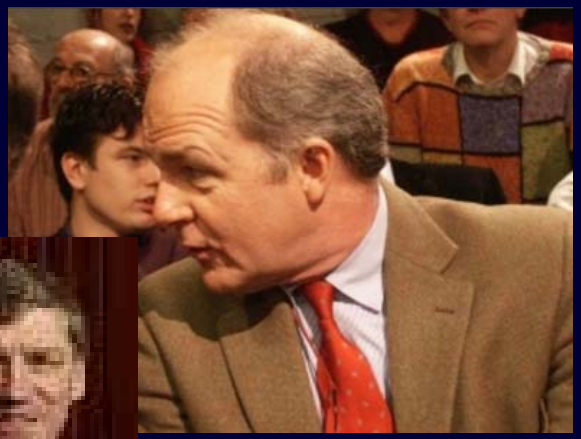
- In patients with drug-eluting stents (in particular SES), the survival rate at 4 year is improved by 3.2% and the risk of TLR at 4 year is reduced by a minimum of 20% up to a maximum of 41% for almost all subset of syndromes and lesions.

- In patients with myocardial infarction, there is no evidence of benefit at 4 years for TVR, but their survival and MACE rate still showed more favorable trend with SES. Late stent thrombosis is responsible for this late "erosion" of the clinical benefit of DES.

Recommendation of the board

- **The board of directors kept endorsing the policy of an unrestricted DES use considering the better survival in a population at higher risk than the bare metal stent provided the use of drug-eluting stents has no unfavorable economical impact on the budget of the hospital.**





Based on our personal 4-year experience,

- I have to say to (almost) all my patients that with drug-eluting stents (in particular SES) the survival rate at 4 year is improved by 3.2% and that the risk of TVR at 4 year is reduced by a minimum of 20% to a maximum of 41%

- I have to say to my patients with myocardial infarction that there is no evidence of benefit at 4 years.

- I have to say to my patients with bifurcation that a risk reduction of 20% is not significant and that the risk reduction depends on the technique used (2 stents/1stent, kissing, new techniques).

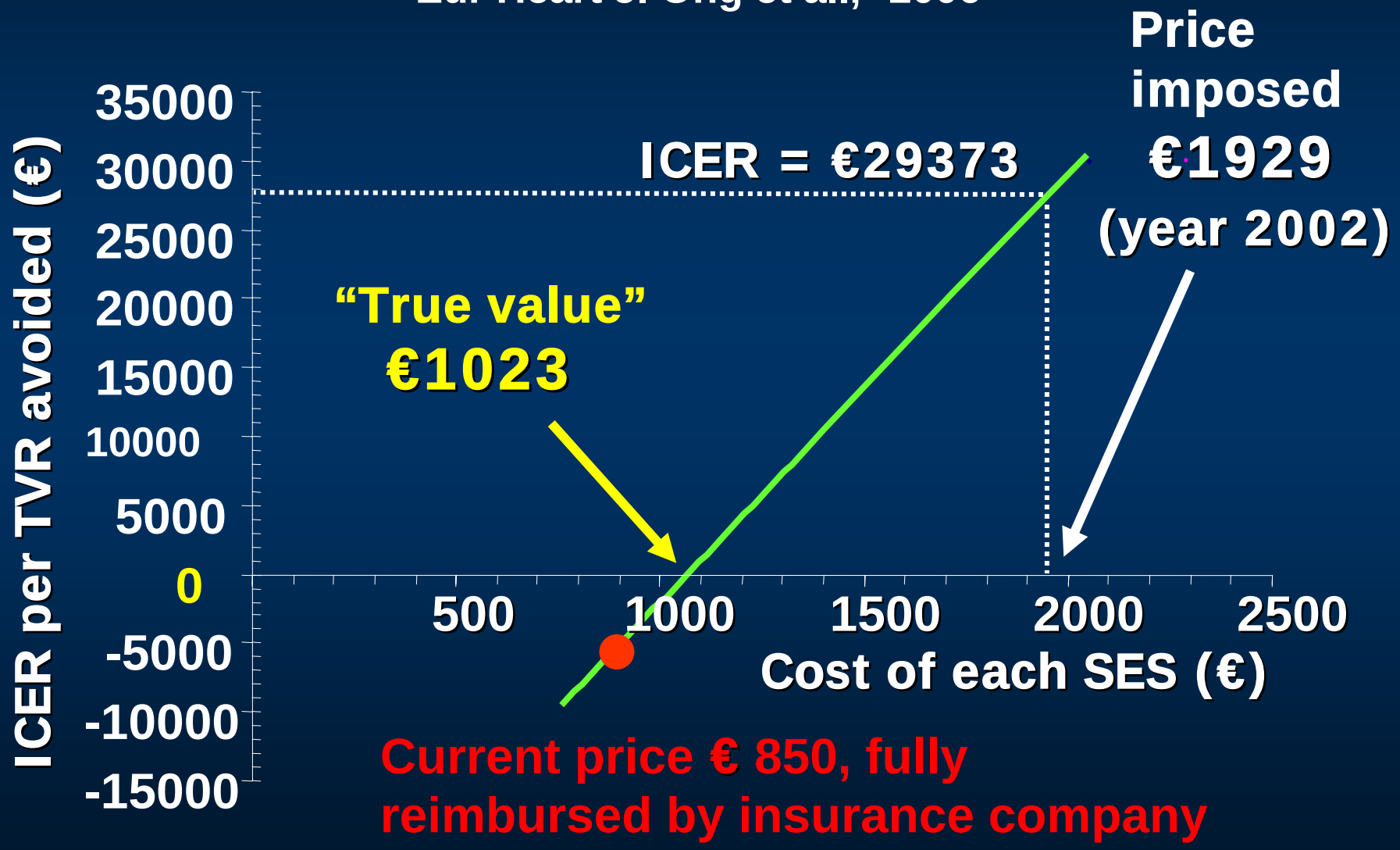
Recommendation of the board

- **The board of directors kept endorsing the policy of an unrestricted DES use considering the better survival in a population at higher risk than the bare metal stent provided the use of drug-eluting stents has no unfavorable economical impact on the budget of the hospital.**

This is why I use DES as the first choice for most of my patients

Cost-effective Price of SES: 1 Year Follow-up (BMS=€692)

Eur Heart J. Ong et all, 2006



In general, debates are a waste of time and energy and are close to an exercise in futility. However, debates keep the audience entertained by artificially discussing issues which are going to be resolved spontaneously.

Why you should use DES as the first choice for most patients

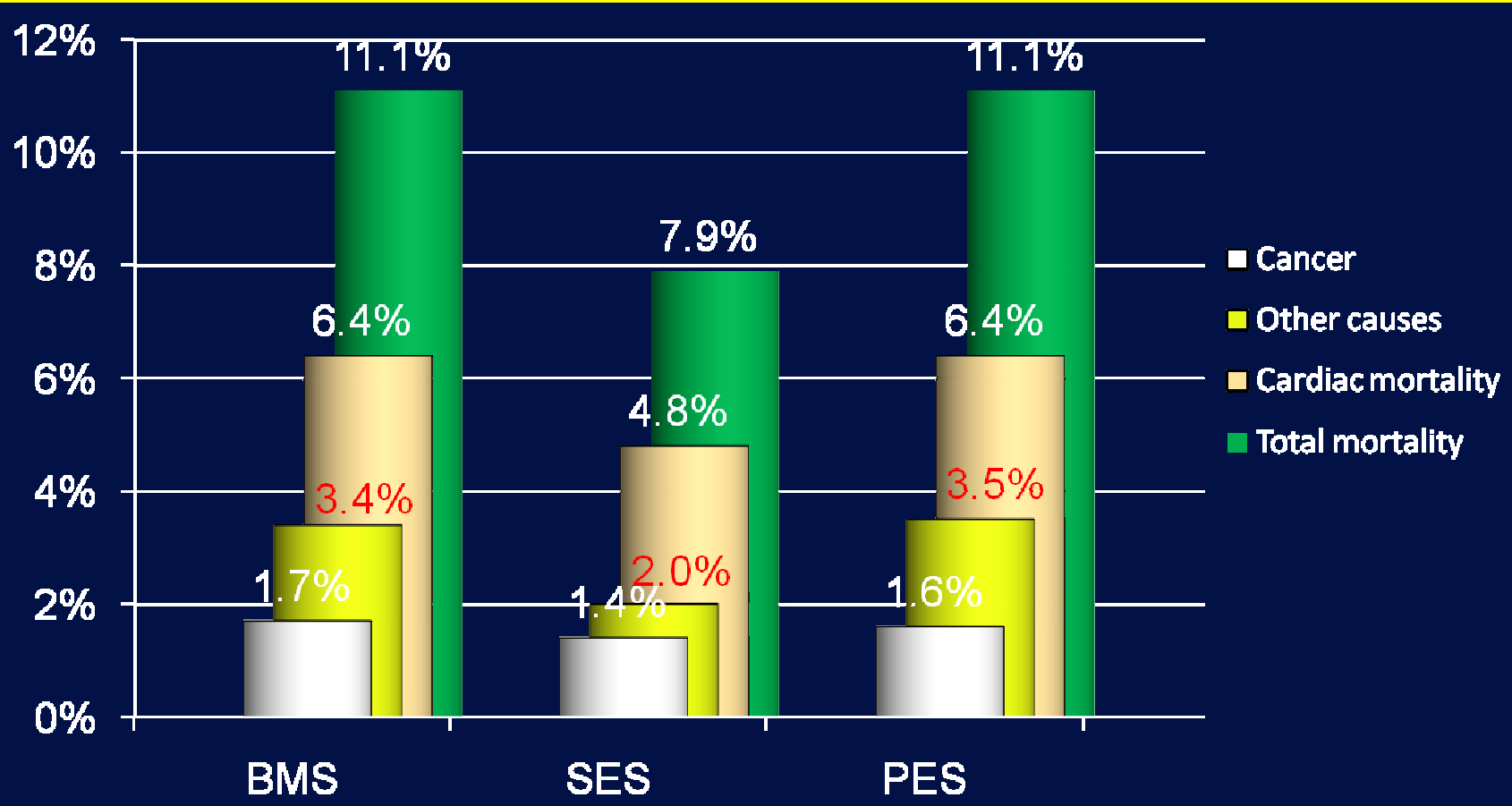
1. Meta-analysis of RTs showed no increase in mortality, no increase in stent thrombosis and a 58 to 70% treatment effect with an absolute reduction in TLR of 12 to 14%.

2. Evidence based form the most recent multicenter registry– Ontario registry (NEJM)

3. Evidence based from the “oldest” monocenter registry– RESEARCH, T-SEARCH (ESC)

4. Cost-effectiveness in all comers : our personal experience, Research (EHJ)

Follow-up and causes of death



BMS

Total = 251

- **Cardiac = 143**
- **Cancer = 36**
- **Other = 72**

SES

Total = 67

- **Cardiac = 40**
- **Cancer = 11**
- **Other = 16**

PES

Total = 237

- **Cardiac = 145**
- **Cancer = 28**
- **Other =64**

*** ICD: I-20 to I-25; I-46; R-96; I-50**

**** ICD: C-00 to C-97**