Thoraxcenter real world experience

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Thoraxcenter real world experience

Analysis performed by the department of Epidemiology of EMC (ERASMUS UNIVERSITY MEDICAL CENTER)
at the request of the board of the directors of the EMC
Preliminary data presented to the Board on November 23
Permission granted to present these preliminary data to the FDA panel 7-8 December

Thoraxcenter real world experience

Jan 2000 – Apr 2002	Apr 2002 – Feb 2003	Feb 2003 – Dec 2005
Bare metal stents	Sirolimus-eluting stents	Paclitaxel-eluting stents
N=2444	N=979	N=3019

6442 patients

13.150 stents

Thoraxcenter real world experience

Numbers at risk

BMS	SES	PES
	Baseline	
N=2444	N=979	N=3019
	30 days	
N=2211	N=955	N=2620
	1 year	
N=2126	N=936	N=2414
	2 year	
N=1990	N=888	N=1432
	3 years	
N=1862	N=833	N=491

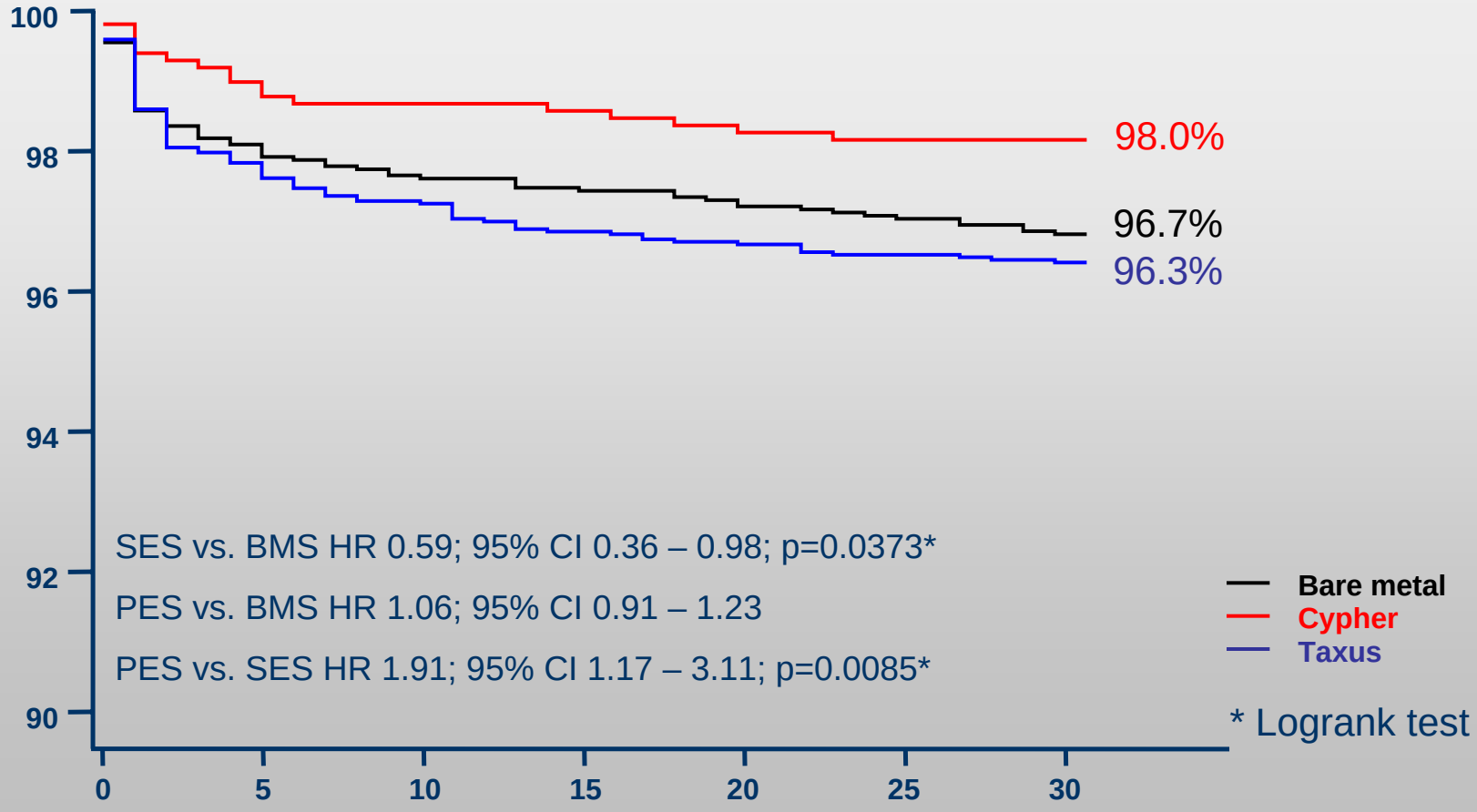
Baseline characteristics

	BMS (n=3823)	SES (n=979)	PES (n=3019)	P value
Age, mean±SD	61±12	62±11	62±11	0.064
Male, %	72.7	70.5	73.0	0.30
Indication				
Stable angina	41.4	46.0	39.2	0.01
Unstable angina	36.1	34.1	26.2	<0.001
Myocardial infarction	22.4	19.6	34.6	<0.001
Diabetes, %	13.1	18.4	17.3	<0.001
Smoking, %	24.1	27.9	25.7	<0.001
Hypertension, %	32.6	41.3	41.9	<0.001
Hypercholesterolemia, %	43.5	57.1	52.8	<0.001
Family history	21.5	30.9	34.4	<0.001
Prior MI, %	35.5	32.3	26.5	<0.001
Prior PCI, %	16.0	21.8	16.3	<0.001
Prior CABG, %	11.9	8.8	8.6	<0.001

Baseline characteristics

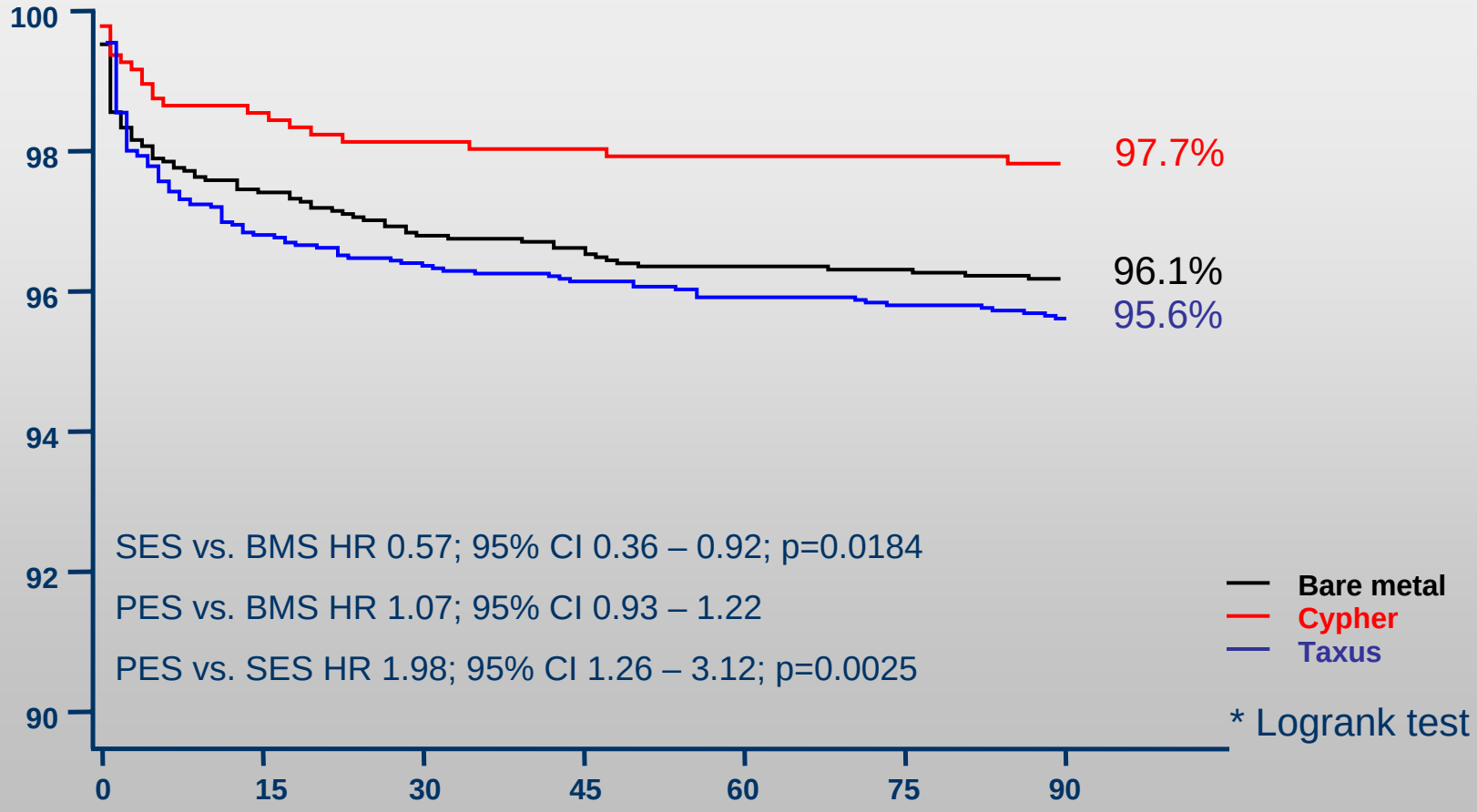
	BMS (n=3823)	SES (n=979)	PES (n=3019)	P value
Treated vessel				
RCA	39.3	39.3	37.3	0.26
LAD	53.1	57.8	52.0	0.007
LCX	30.1	32.8	29.2	0.10
LM	3.5	3.5	5.1	0.008
Bypass graft	5.6	2.7	3.9	<0.001
Bifurcation	3.6	10.5	12.6	<0.001
Multivessel disease	52.6	55.6	51.4	0.073
Number of stents (SD)	1.82 (1.18)	2.27 (1.44)	2.15 (1.39)	<0.001
Average stent diameter	3.3 (0.5)	2.8 (0.2)	3.0 (0.4)	<0.001
Total stented length	28.4 (20.0)	42.3 (30.4)	43.3 (30.6)	<0.001

All-cause mortality at 30 days



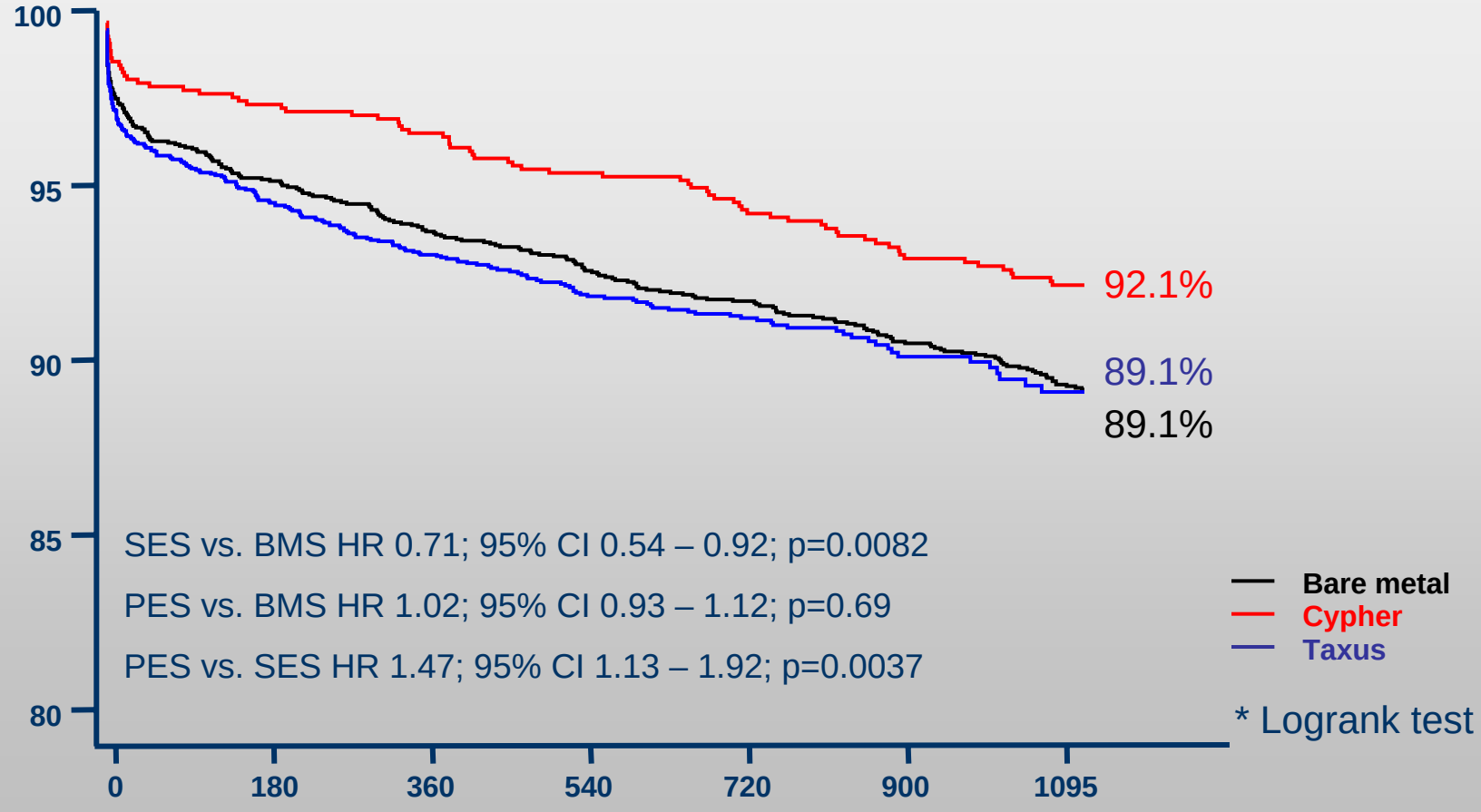
Group	0	30
BMS	2287	2211
SES	976	955
PES	2776	2620

All-cause mortality at 3 months



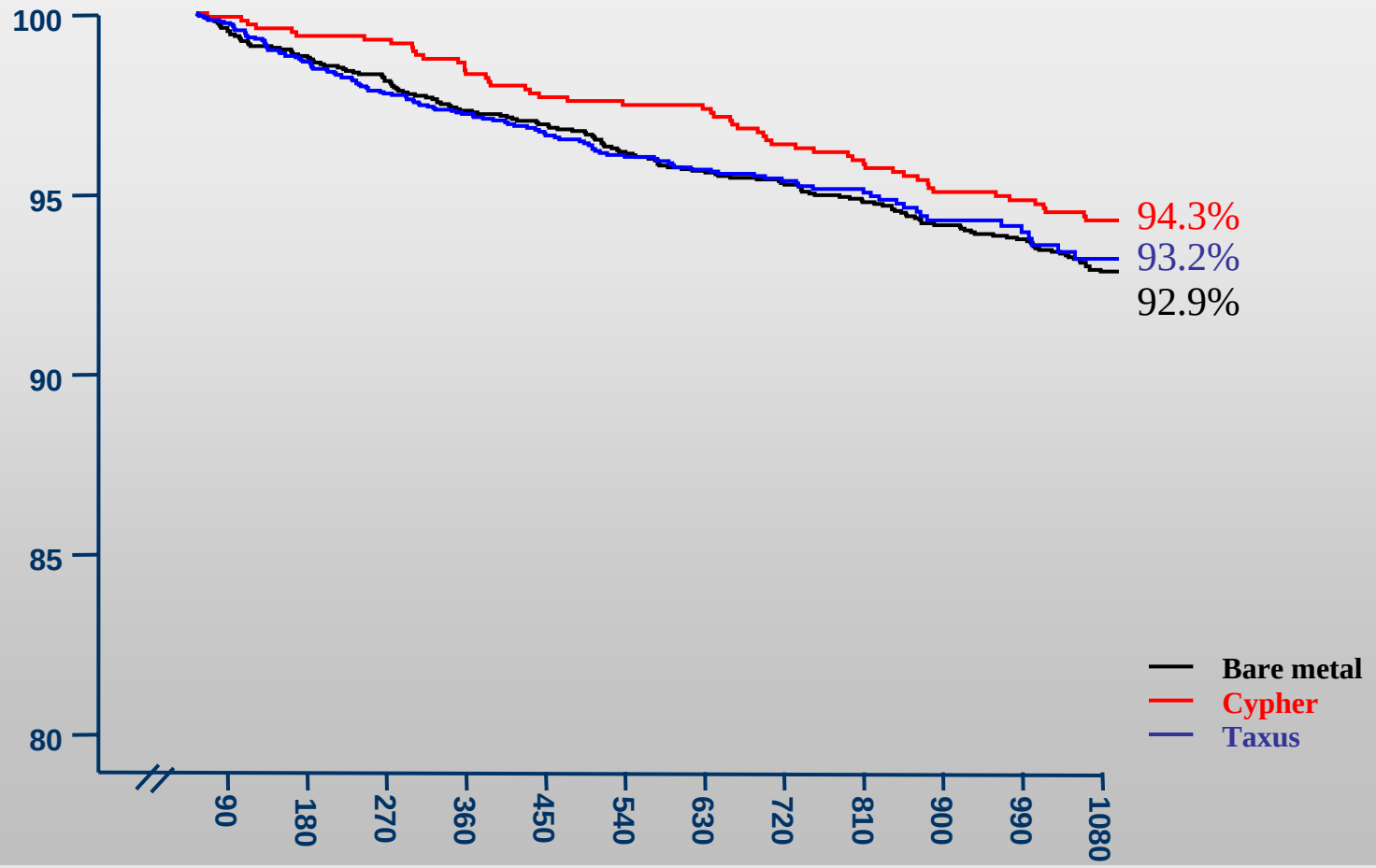
Group	0	30	90	180	360	720	1080	1440
BMS	2287	2211	2195					
SES	976	955	951					
PES	2776	2620	2537					

All-cause mortality at 3 years



Group	0	30	90	180	360	720	1095
BMS	2287	2211	2195	2170	2126	1990	1862
SES	976	955	951	946	936	888	833
PES	2776	2620	2537	2499	2414	1432	491

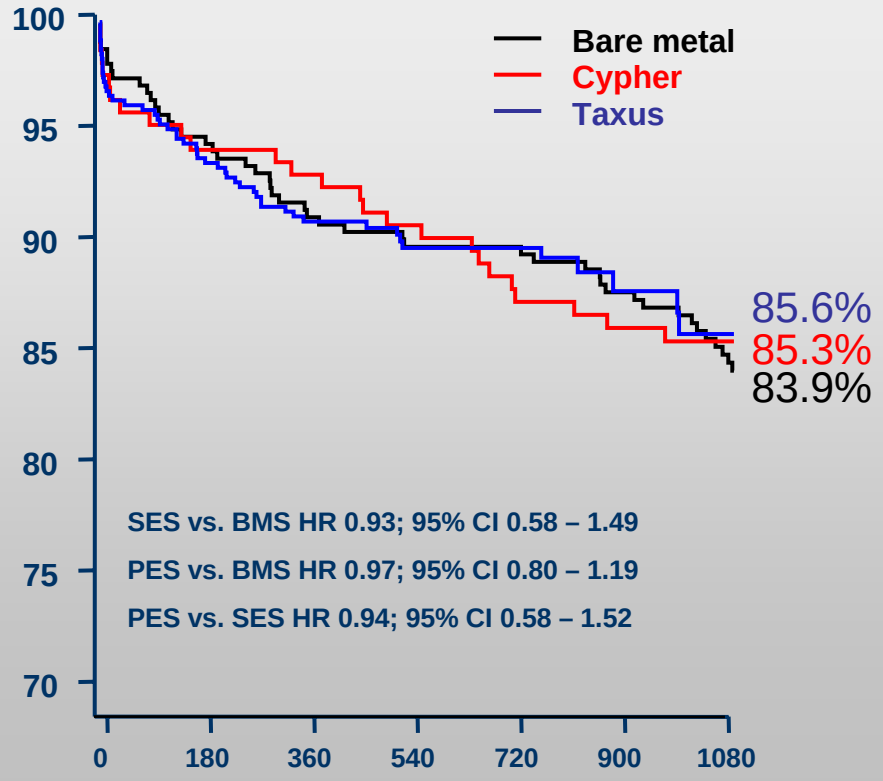
All-cause mortality from 90 to 1080 days



Group	-	180	360	720	1080
BMS	2194	2170	2126	1990	1862
SES	950	946	936	888	833
PES	2536	2499	2414	2432	487

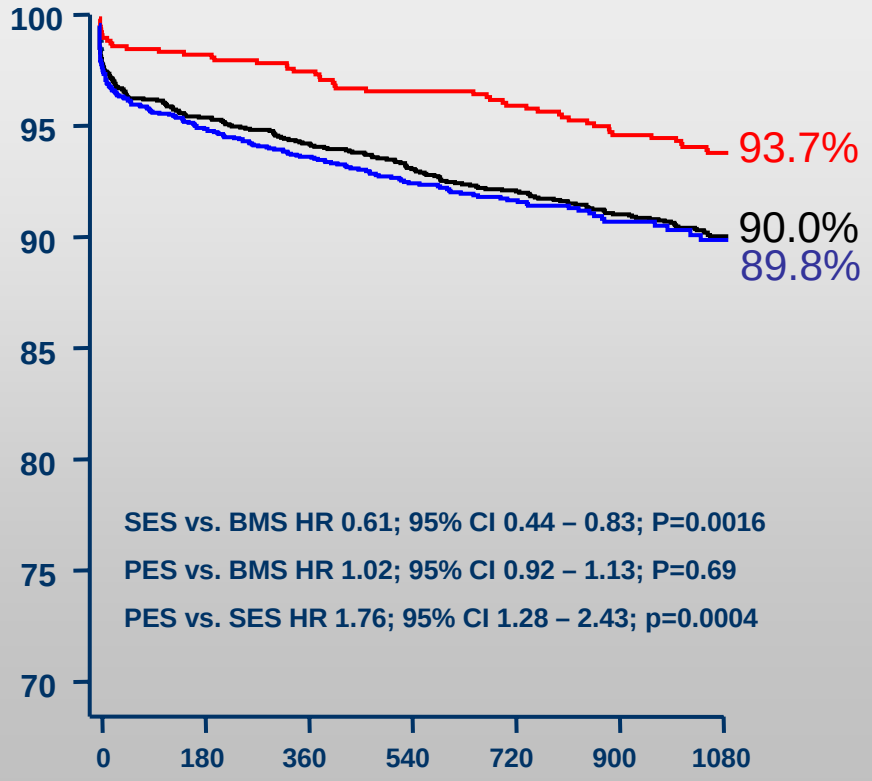
All-cause mortality at 3 years

Diabetics



Group	0	180	360	720	1080
BMS	306	288	276	267	237
SES	179	168	165	152	142
PES	484	433	408	258	85

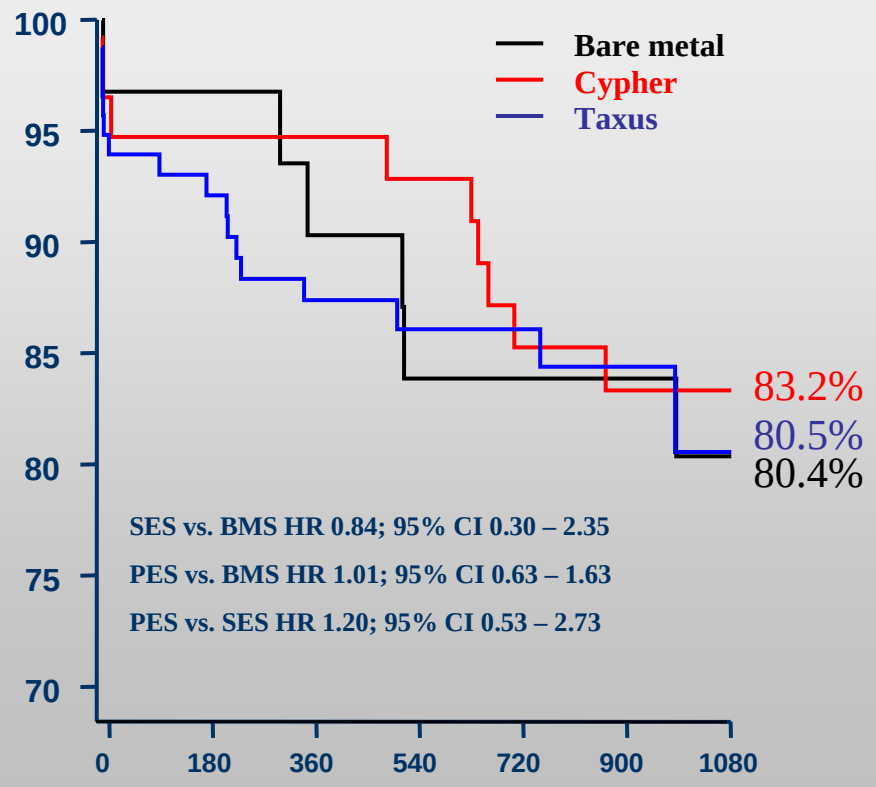
Non-Diabetics



Group	0	180	360	720	1080
BMS	1980	1882	1850	1723	1625
SES	796	778	771	730	691
PES	2291	2066	2006	1174	402

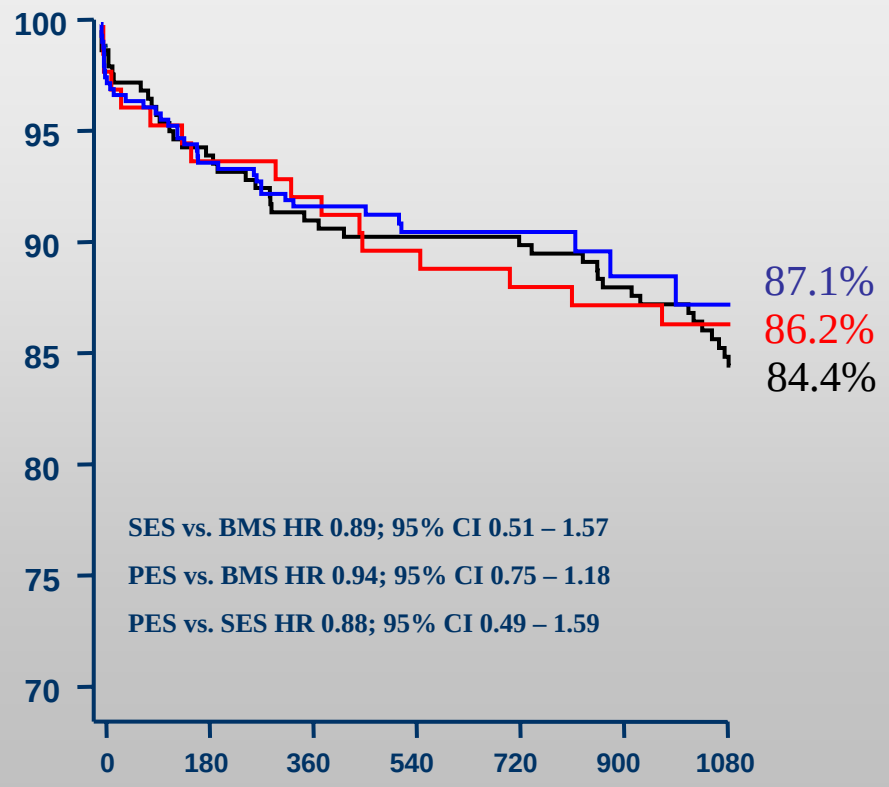
All-cause mortality at 3 years

Insulin dependent



Group	0	180	360	720	1080
BMS	30	30	28	26	33
SES	55	53	52	45	42
PES	113	101	91	61	20

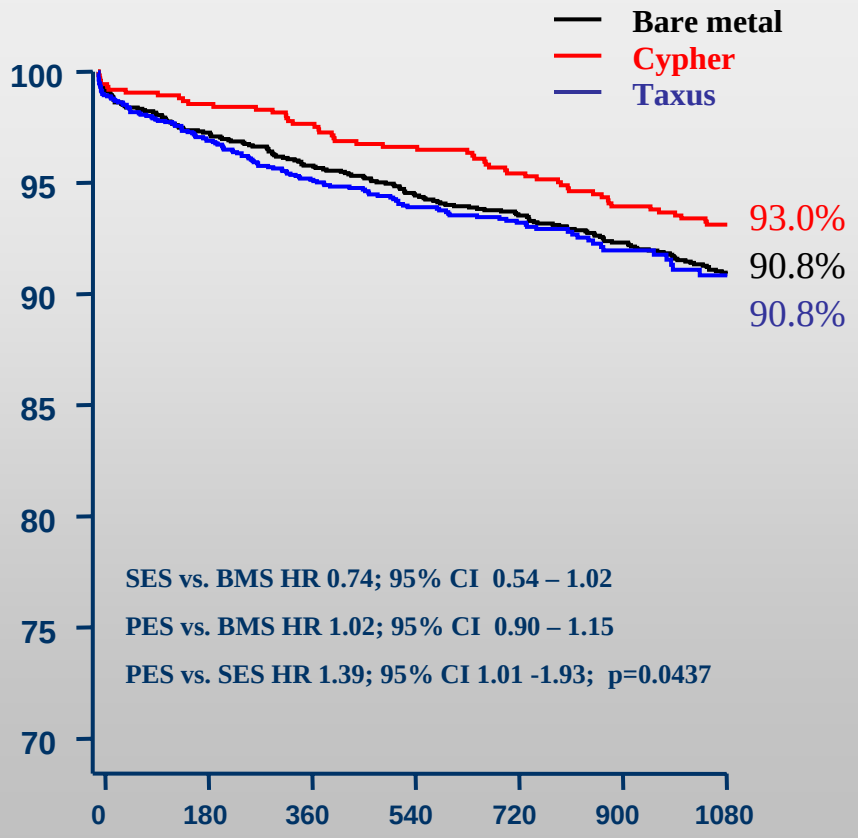
Non-Insulin dependent



Group	0	180	360	720	1080
BMS	275	258	248	241	214
SES	124	116	114	108	101
PES	376	337	322	197	65

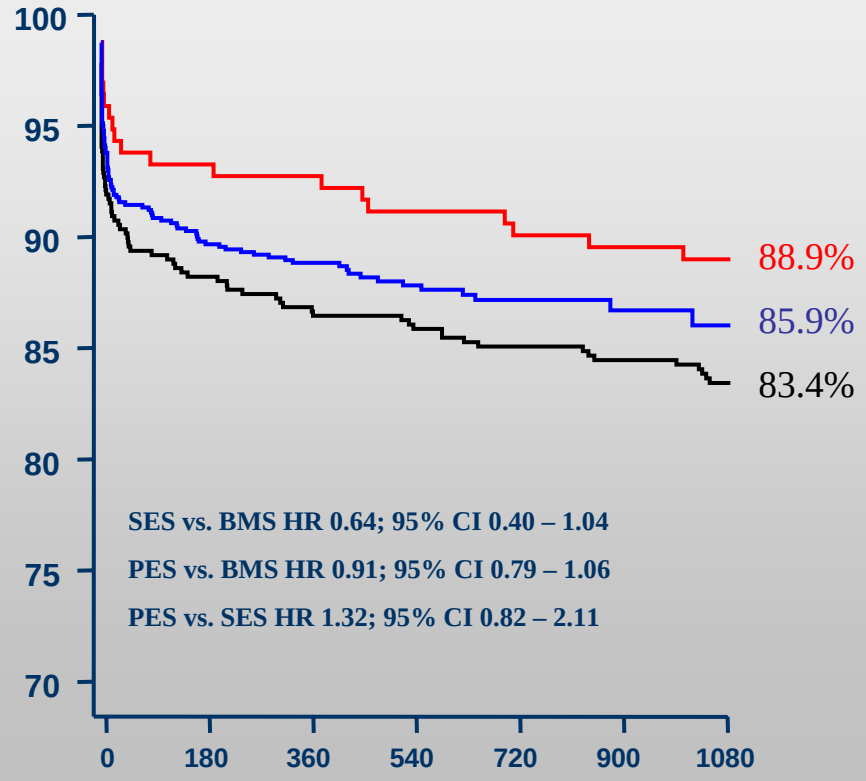
All-cause mortality at 3 years

Stable or Unstable



Group	0	180	360	720	1080
BMS	1771	1715	1679	1565	1460
SES	783	769	760	719	673
PES	1856	1728	1673	1105	365

Acute MI



Group	0	180	360	720	1080
BMS	513	453	445	424	402
SES	190	176	175	168	159
PES	905	759	729	324	122

Multivariate analysis
SES VS. BMS

	Hazard Ratio	Confidence interval	P-value
Age	1.05	1.04 – 1.07	0.016
Indication			
Stable angina (ref)	-	-	-
Unstable angina	1.61	1.20 – 2.15	0.001
Myocardial infarction	3.59	2.63 – 4.89	0.001
Diabetes	1.77	1.34 – 2.34	<0.001
Previous MI	1.52	1.19 – 1.93	0.001
Left main treatment	2.47	1.66 – 3.66	<0.001
Multivessel disease	1.81	1.39 – 2.36	<0.001
Sirolimus-eluting stent	0.71	0.54 – 0.94	0.016

PRELIMINARY ANALYSIS

Multivariate analysis
SES VS. BMS

	Hazard Ratio	Confidence interval	P-value
Age	1.05	1.04 – 1.07	0.016
Indication			
Stable angina (ref)	-	-	-
Unstable angina	1.61	1.20 – 2.15	0.001
Myocardial infarction	3.59	2.63 – 4.89	0.001
Diabetes	1.77	1.34 – 2.34	<0.001
Hypercholesterolemia	0.76	0.59 – 0.98	0.036
Family history	0.74	0.52 – 1.03	0.079
Previous MI	1.52	1.19 – 1.93	0.001
RCA treatment	0.67	0.52 – 0.87	0.002
Left main treatment	2.47	1.66 – 3.66	<0.001
Multivessel disease	1.81	1.39 – 2.36	<0.001
Sirolimus-eluting stent	0.71	0.54 – 0.94	0.016

PRELIMINARY ANALYSIS

Multivariate analysis
PES VS. BMS

	Hazard Ratio	Confidence interval	P-value
Age	1.05	1.04 – 1.06	<0.001
Indication			
Stable angina (ref)	-	-	-
Unstable angina	1.30	1.02 – 1.66	0.032
Myocardial infarction	3.13	2.45 – 3.99	<0.001
Diabetes	1.49	1.17 – 1.89	0.001
Previous MI	1.63	1.33 – 2.00	<0.001
Left main treatment	2.27	1.67 – 3.10	<0.001
Multivessel disease	1.77	1.43 – 2.20	<0.001
Paclitaxel-eluting stent	0.98	0.89 – 1.08	0.73

PRELIMINARY ANALYSIS

Multivariate analysis
PES VS. SES

	Hazard Ratio	Confidence interval	P-value
Age	1.05	1.04 – 1.07	<0.001
Indication			
Stable angina (ref)	-	-	-
Unstable angina	1.40	1.04 – 1.89	0.028
Myocardial infarction	2.89	2.13 – 3.93	<0.001
Diabetes	1.75	1.32 – 2.32	<0.001
Hypercholesterolemia	0.57	0.44 – 0.74	<0.001
Family history	0.70	0.52 – 0.95	0.021
Previous MI	1.45	1.12 – 1.87	0.004
Left main treatment	2.26	1.54 – 3.32	<0.001
Bypass graft treatment	1.60	0.99 – 2.56	0.052
Multivessel disease	1.73	1.32 – 2.26	<0.001
Paclitaxel-eluting stent	1.38	1.04 – 1.83	0.024

PRELIMINARY ANALYSIS