



***Preliminary Two-Year Outcome
After Sirolimus-eluting Stent Implantation
The j-Cypher Registry Update***

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on behalf of the j-Cypher Registry Investigators

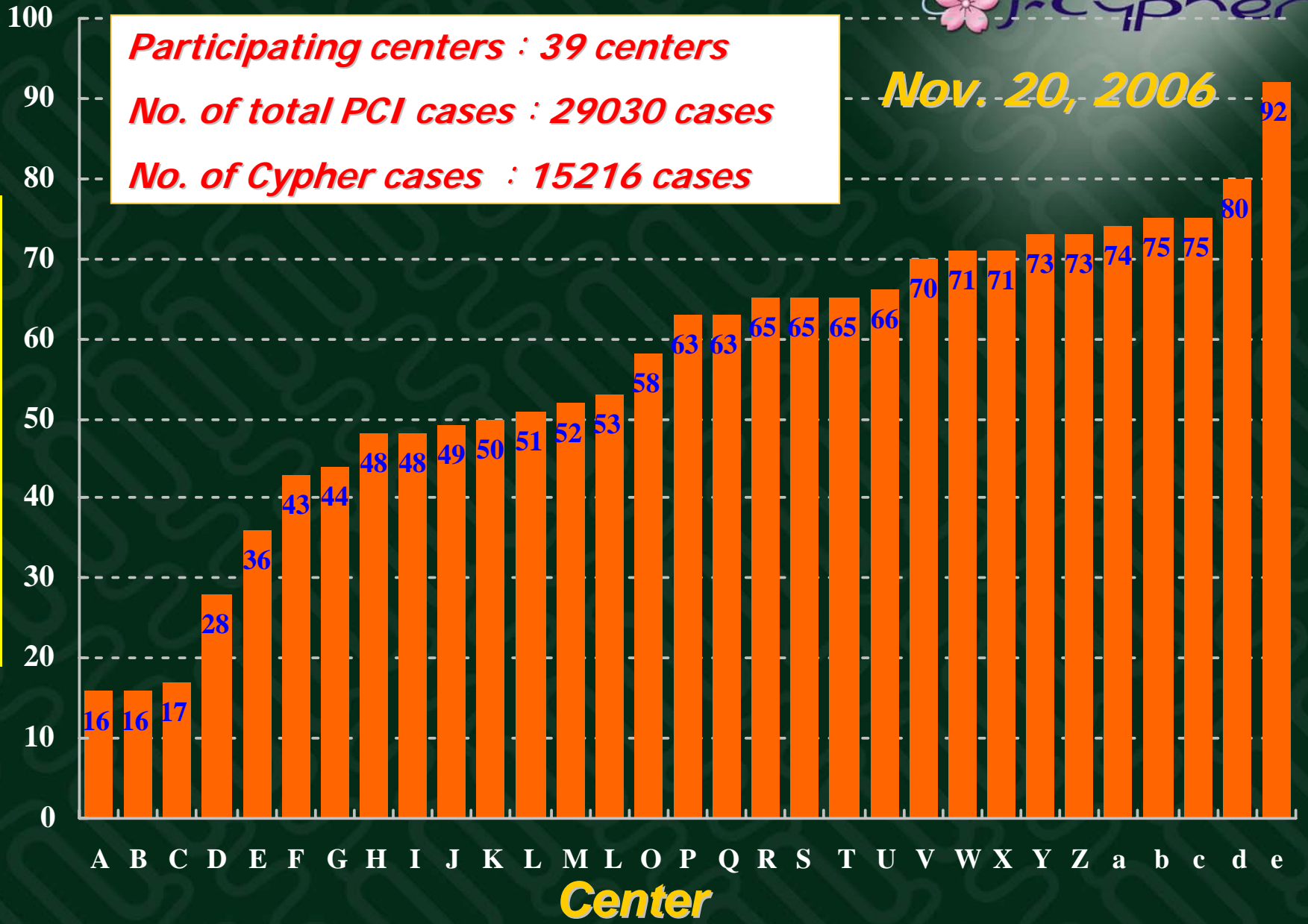
Penetration of the Cypher™ Stent



Nov. 20, 2006

Participating centers : 39 centers
No. of total PCI cases : 29030 cases
No. of Cypher cases : 15216 cases

Frequency of Cypher use



Baseline Characteristics



	<i>j-CYPHER</i>	<i>e-CYPHER</i>	<i>P Value</i>
	<i>N=6816</i>	<i>N=15157</i>	
<i>Age</i>	<i>68 ± 10</i>	<i>62 ± 11</i>	<i>0.0001</i>
<i>> 80 y.o.</i>	<i>12 %</i>	<i>4 %</i>	<i>0.0001</i>
<i>Male</i>	<i>75 %</i>	<i>78 %</i>	<i>0.0005</i>
<i>Diagnosis</i>			<i>0.0001</i>
<i>Stable Angina</i>	<i>51 %</i>	<i>42 %</i>	
<i>UAP / NSTEMI</i>	<i>15 %</i>	<i>33 %</i>	
<i>STEMI</i>	<i>8 %</i>	<i>13 %</i>	
<i>Silent Ischemia / OMI</i>	<i>21 %</i>	<i>10 %</i>	
<i>Coronary Stenosis</i>	<i>5 %</i>	<i>3 %</i>	
<i>Off-label Use</i>	<i>76%</i>		

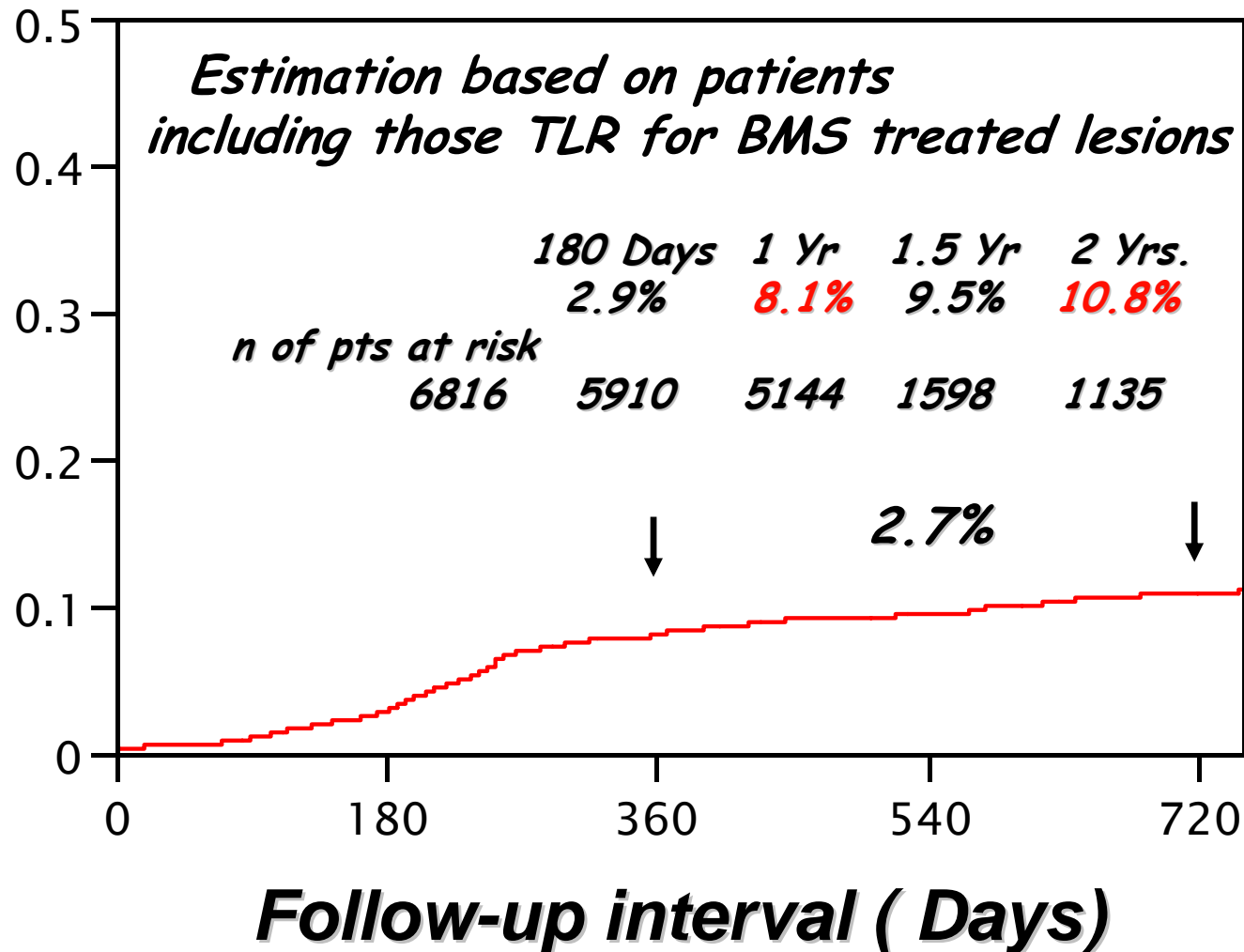
Baseline Characteristics



	<i>j-CYPHER</i>	<i>e-CYPHER</i>	<i>P Value</i>
	<i>N=6816</i>	<i>N=15157</i>	
<i>Prior PCI</i>	<i>49 %</i>	<i>29 %</i>	<i>0.0001</i>
<i>Prior CABG</i>	<i>8 %</i>	<i>11 %</i>	<i>0.0001</i>
<i>Multi-vessel Disease</i>	<i>55 %</i>	<i>57 %</i>	<i>0.0001</i>
<i>Unprotected LMCA</i>	<i>4 %</i>	<i>N.A.</i>	
<i>Diabetes</i>	<i>44 %</i>	<i>29 %</i>	<i>0.0001</i>
<i>On Insulin</i>	<i>10 %</i>	<i>10 %</i>	<i>1.0</i>
<i>CKD (CCr < 60)</i>	<i>50 %</i>	<i>N.A.</i>	
<i>Hemodialysis</i>	<i>5 %</i>	<i>N.A.</i>	
<i>Hx of Heart Failure</i>	<i>12 %</i>	<i>N.A.</i>	
<i>PVD</i>	<i>12%</i>	<i>7 %</i>	<i>0.0001</i>
<i>Hx of Stroke</i>	<i>8 %</i>	<i>3 %</i>	<i>0.0001</i>

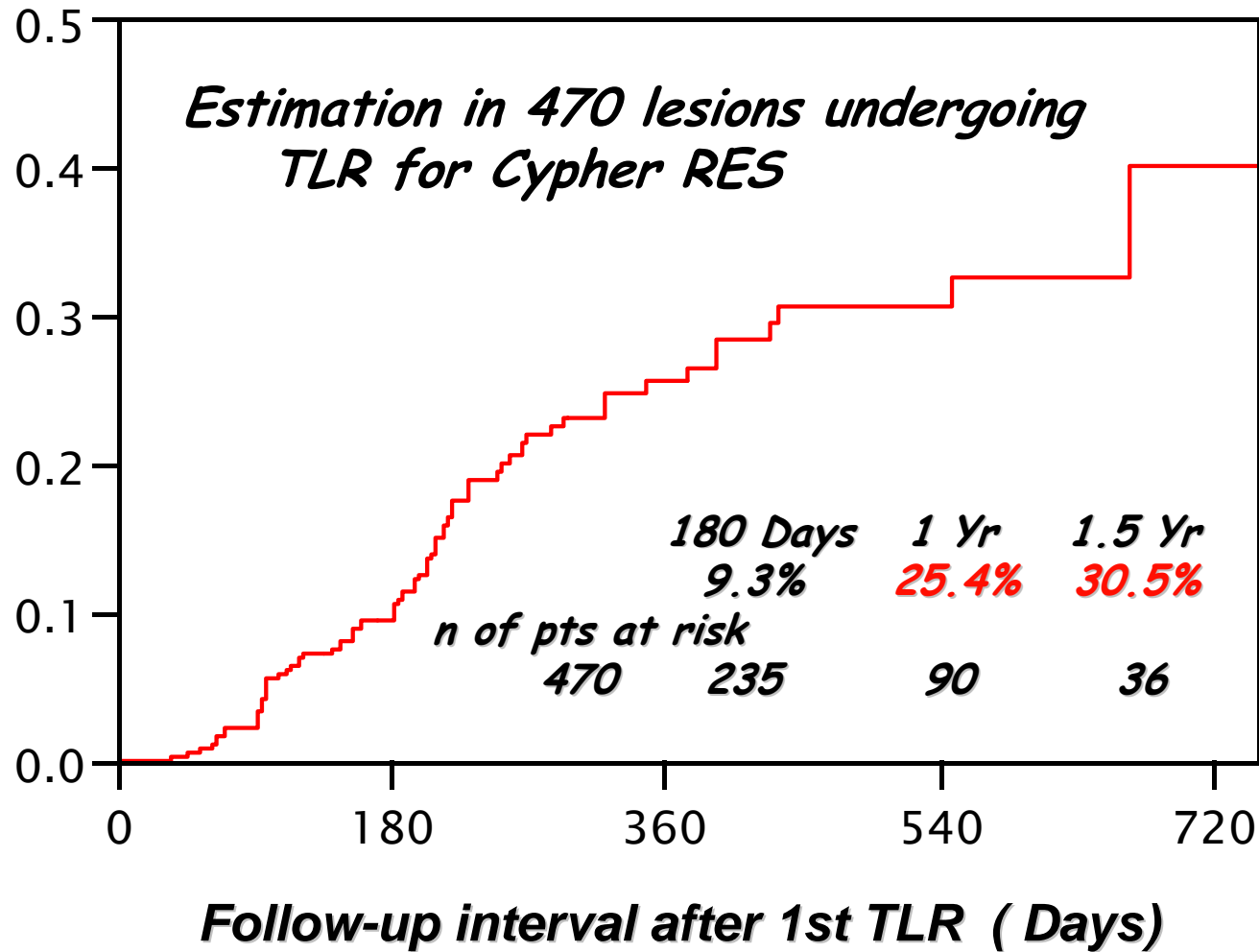
Two-Year Event Rate in j-Cypher

Target Lesion Revascularization



Fate of Restenosis of Cypher

Second Target Lesion Revascularization

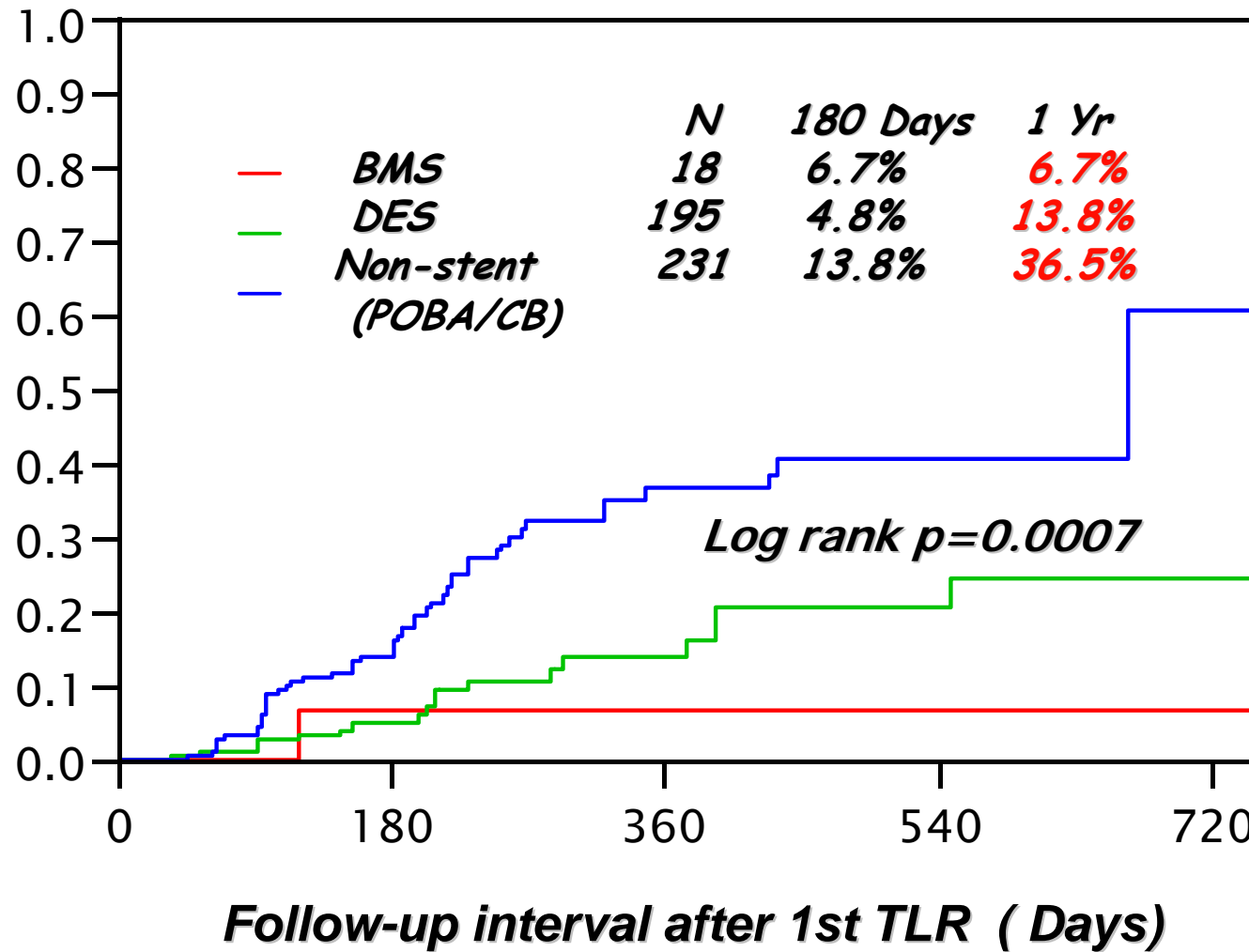


Fate of Restenosis of Cypher

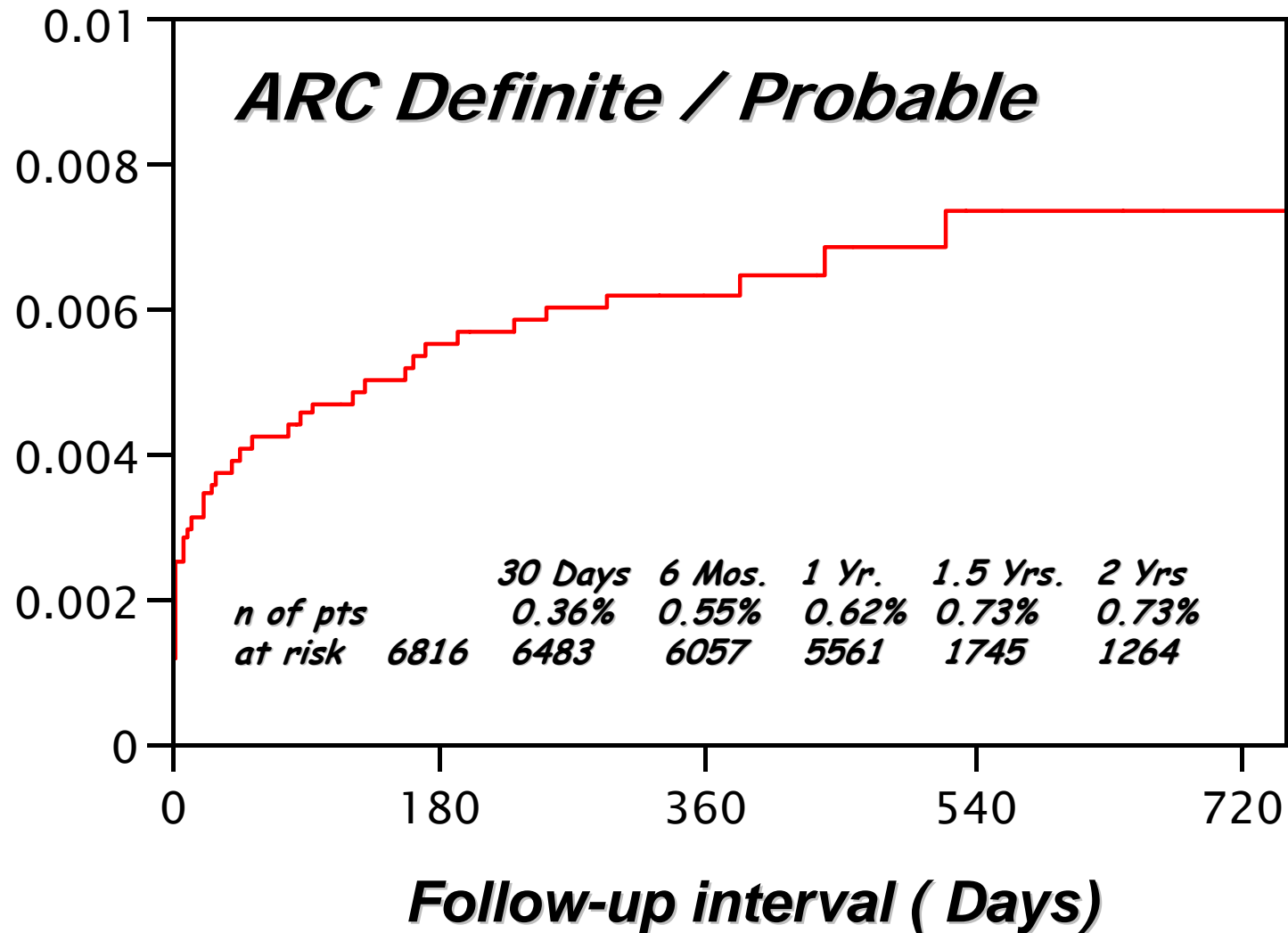
Second Target Lesion Revascularization



Estimation in 444 lesions undergoing successful PCI for Cypher RES

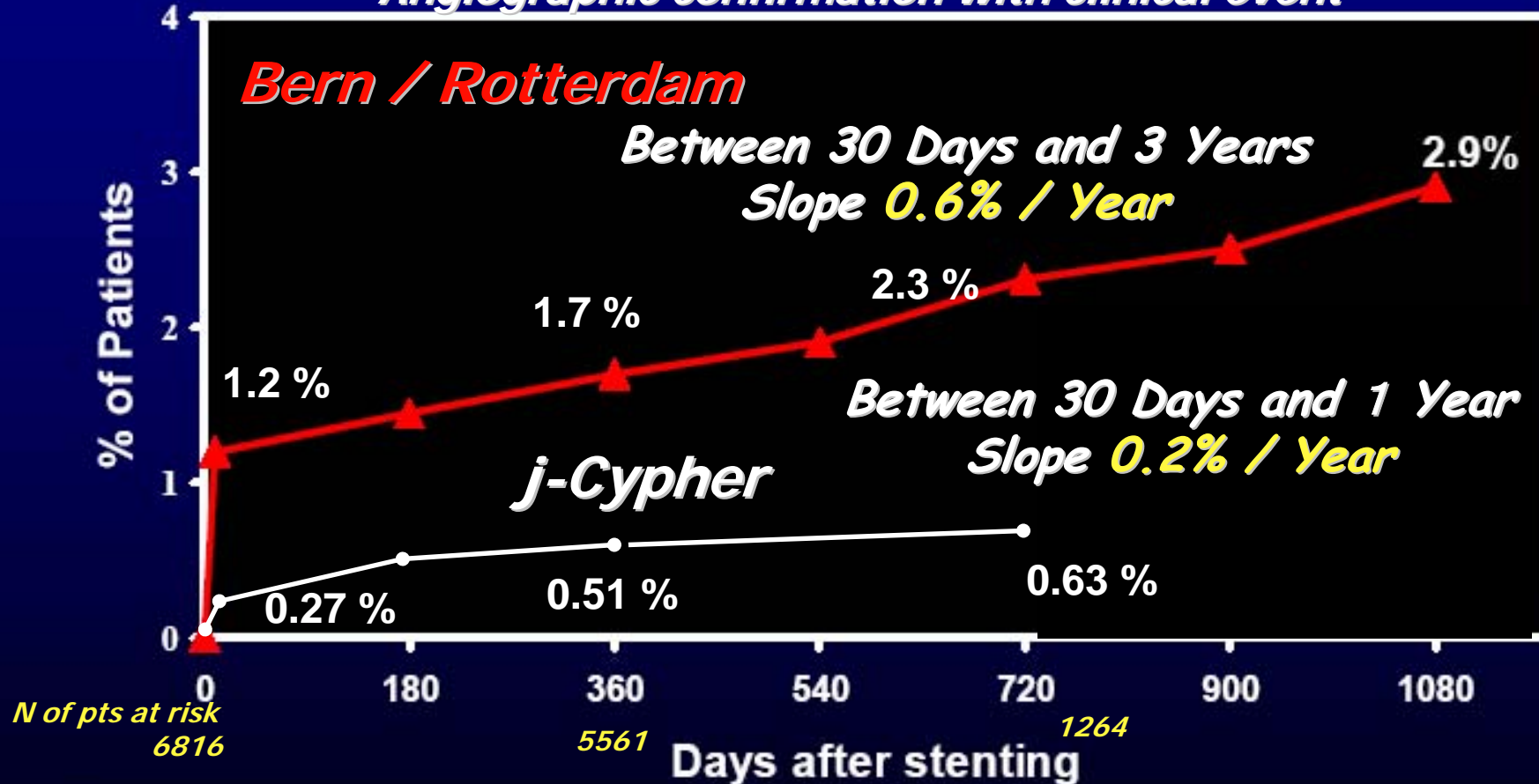


Stent Thrombosis in j-Cypher



Cumulative Incidence of Stent Thrombosis

Angiographic confirmation with clinical event

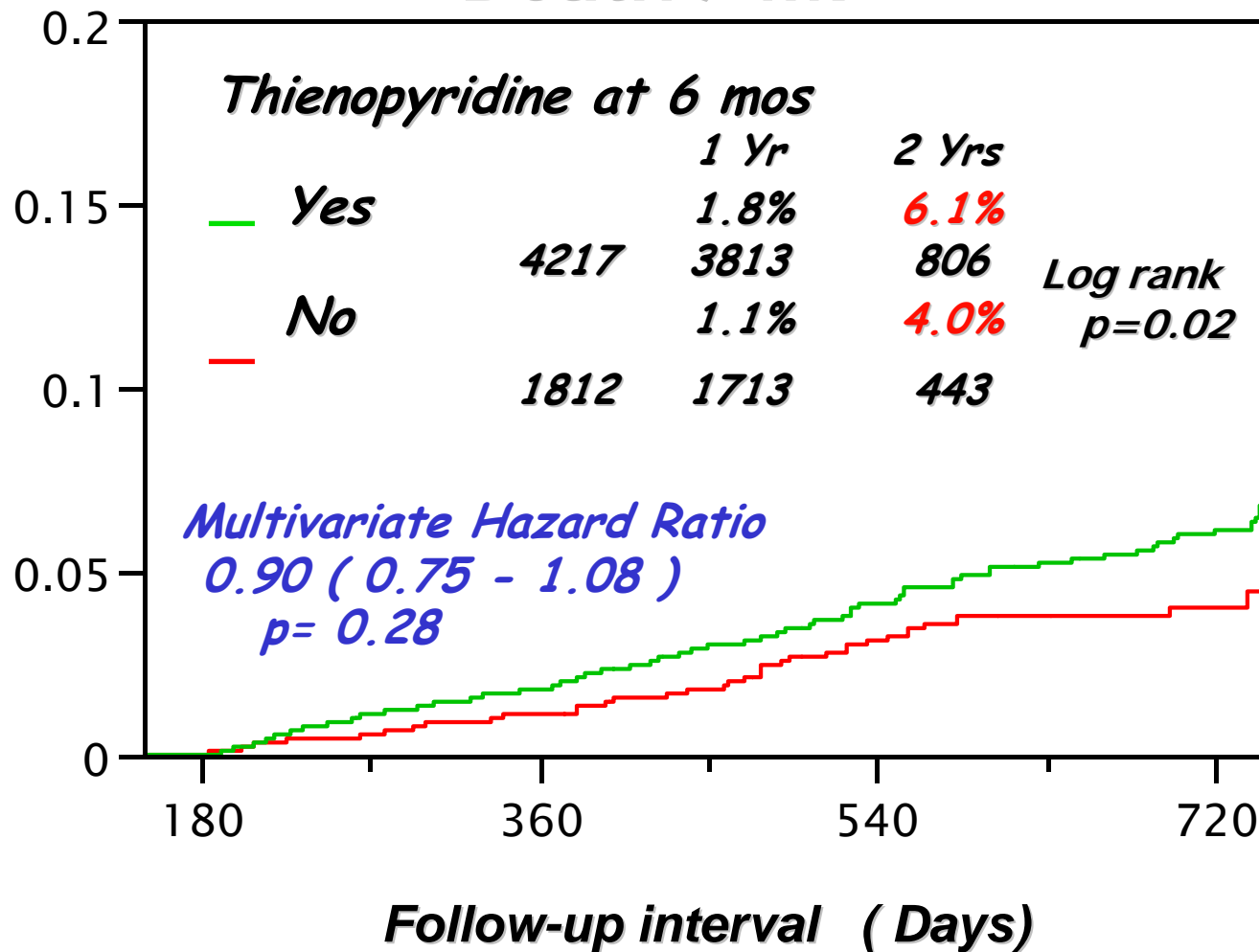


Days after stenting	0	9	30	365	720	1095
Cumulative incidence (%)		1.1	1.2	1.7	2.3	2.9
Patients at risk (n)	8146	7162	7002	5339	2641	971

Landmark Analysis of Duration of Dual Anti-platelet Thrapy in j-Cypher



Death / MI

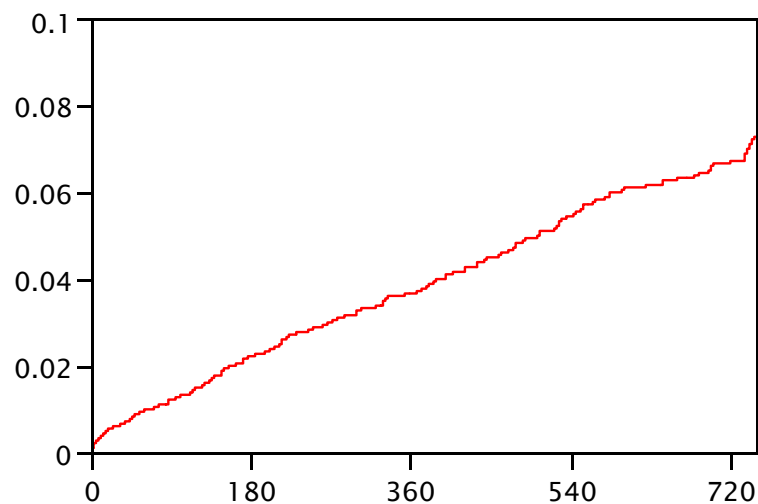


Two-Year Event Rate in j-Cypher

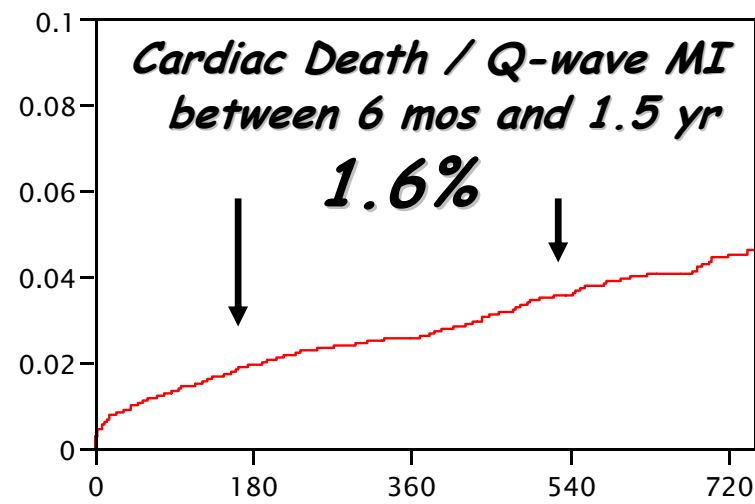


All-cause mortality

Cardiac Death / Q-wave MI



Follow-up interval (Days)



Follow-up interval (Days)

	30 Days	6 Mos.	1 Yr.	1.5 Yr.	2 Yrs.	
All-cause mortality	0.62%	2.2%	3.7%	5.6%	6.7%	
Cardiac death / Q wave MI	0.84%	2.0%	2.6%	3.6%	4.5%	
n of pts at risk	6816	6488	6056	5552	1735	1251

Comparison Between BMS and SES Using Historical Control



CREDO-Kyoto Registry 9873 pts

j-Cypher Registry
Current Analysis 6816 pts

CABG

*Prior
PCI / CABG*

PCI without stent

STEMI

PCI using BMS
5627 pts

PCI using SES
2767 pts

Comparison Between BMS and SES Using Historical Control

CREDO-Kyoto versus j-Cypher



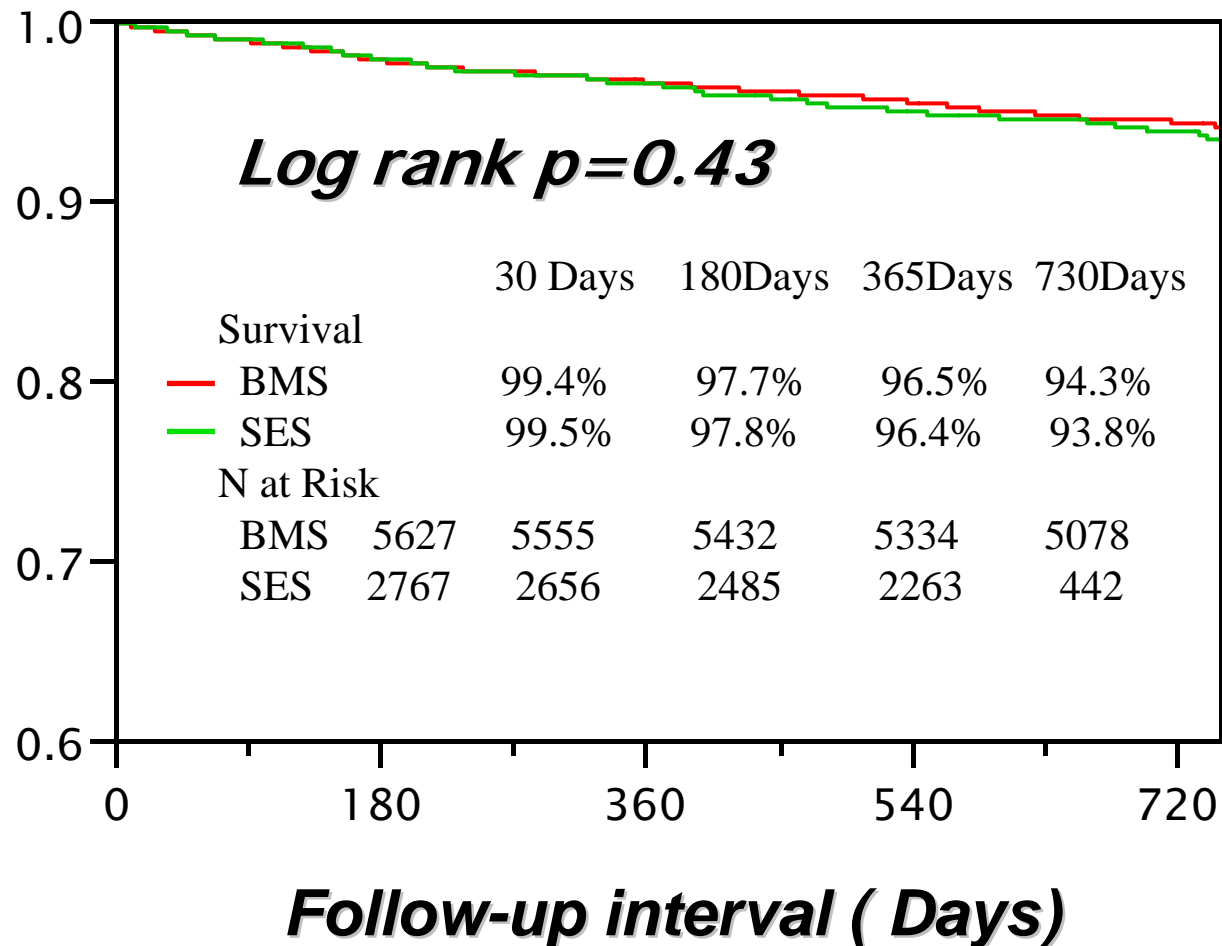
Baseline characteristics

	CREDO	j-Cypher	p Value
N	5627	2767	
Age	67.5±10.1	68.0±10.5	0.02
≥ 80 yrs	11%	12%	0.09
Emergency	5.8%	8.1%	0.03
Diabetes	36%	41%	0.0001
Hemodialysis	3.4%	5.2%	0.0001
CCr < 60	39%	49%	0.0001
EF < 40%	6.5%	8.3%	0.0002
Target LMCA	2.0%	4.7%	0.0001
N of target vessels	1.32±0.55	1.34±0.59	0.33
Statin at discharge	32%	43%	0.0001

Comparison Between BMS and SES Using Historical Control

CREDO-Kyoto versus j-Cypher

All-cause Mortality

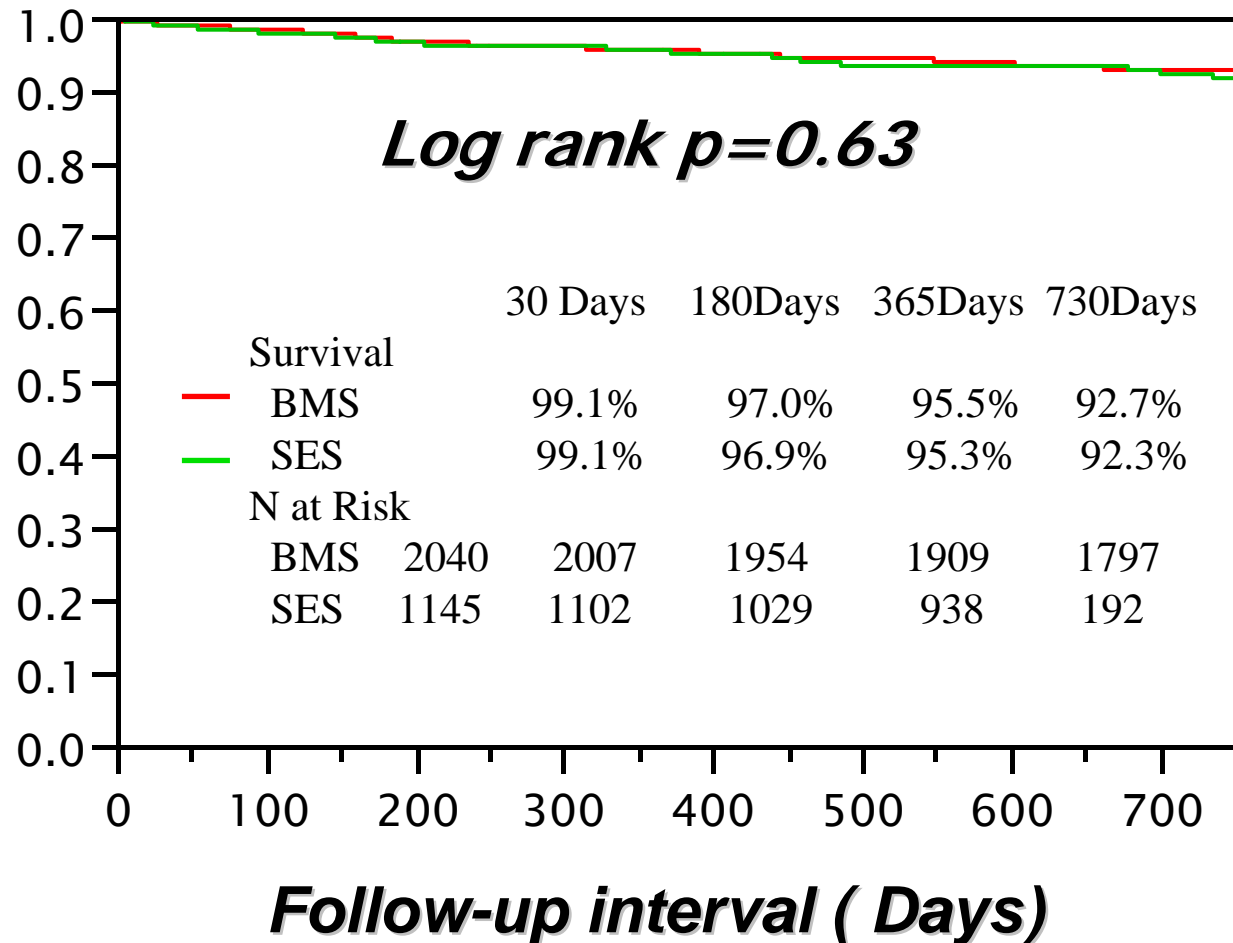


Comparison Between BMS and SES Using Historical Control

CREDO-Kyoto versus j-Cypher



All-cause Mortality in Diabetic Patients

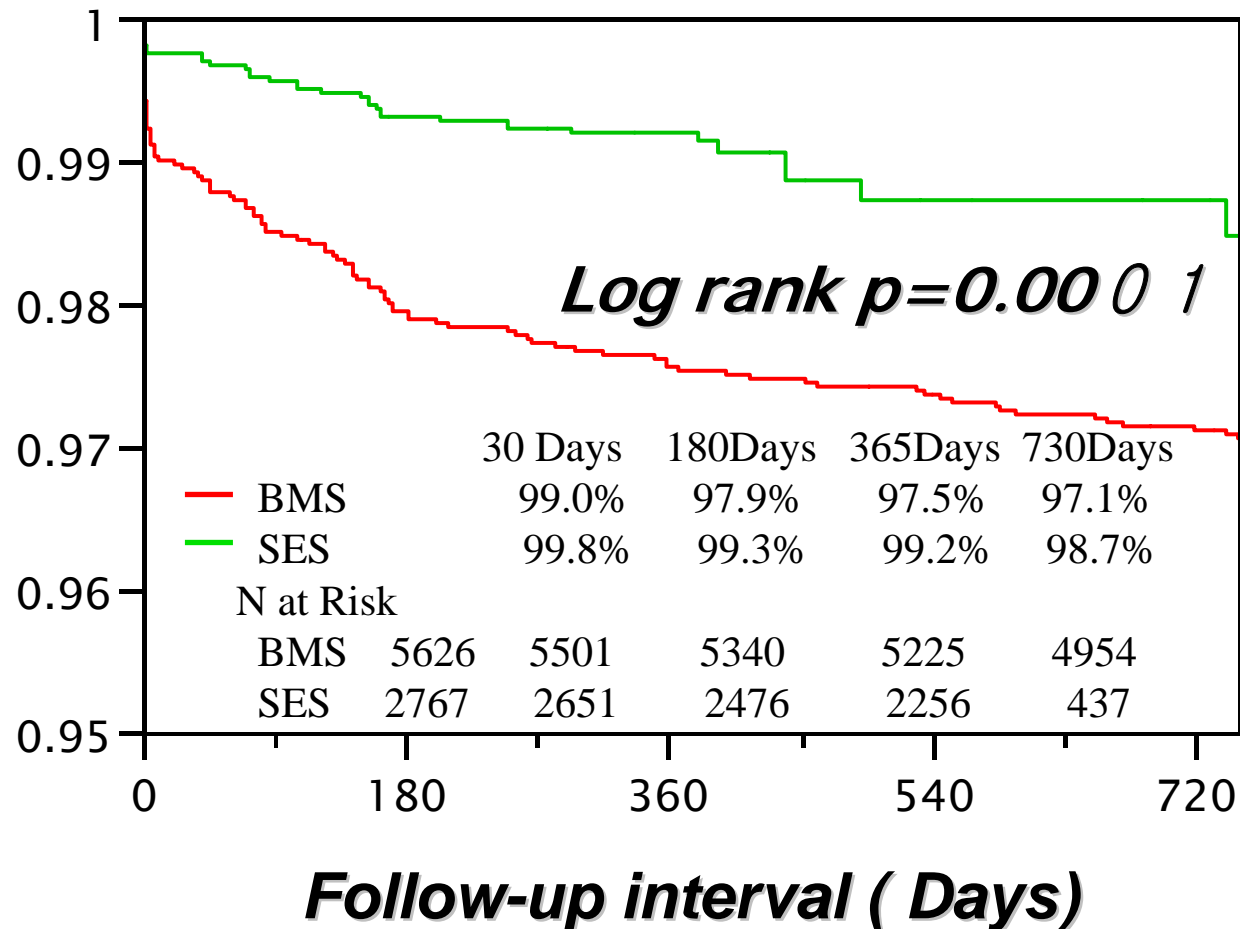


Comparison Between BMS and SES Using Historical Control

CREDO-Kyoto versus j-Cypher



Q-wave MI

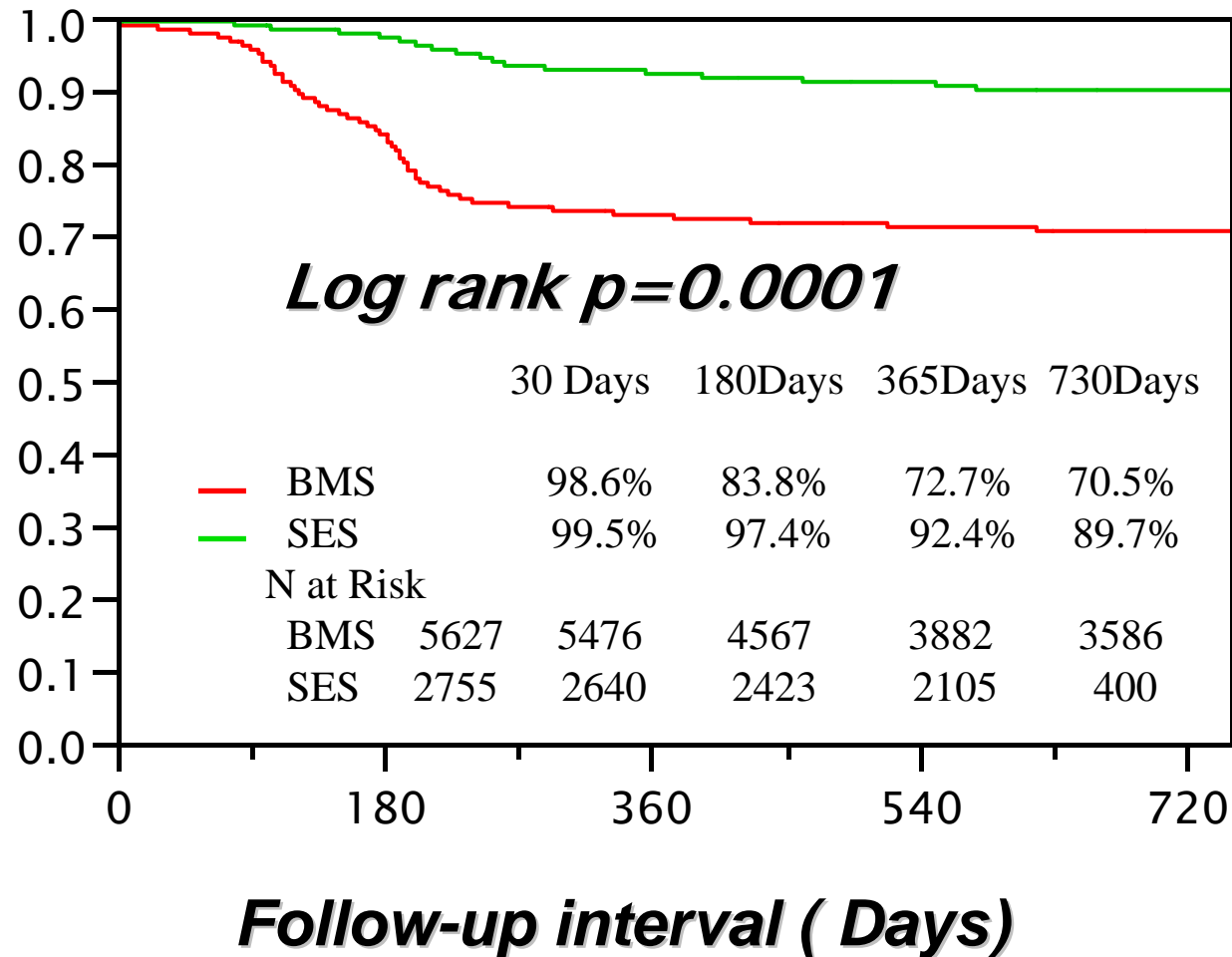


Comparison Between BMS and SES Using Historical Control

CREDO-Kyoto versus j-Cypher



Target Lesion Revascularization



Summary



Preliminary Two-year Result from the j-Cypher Registry suggests

- 1. Efficacy of SES in preventing clinical restenosis was clearly demonstrated in the real world clinical practice in Japan. However, repeated TLR after TLR for restenosis of SES is not uncommon. Regarding the strategy of TLR for restenosis of SES, placement of additional Cypher™ stents seemed to be associated with less repeated TLR as compared with non-stent strategies.*
- 2. Stent thrombosis rate up to 2 years under Ticlopidine anti-platelet regimen in Japan seemed to be lower as compared with those reported from other registries in the real world, despite the fact that high risk patients such as diabetes and CKD were more prevalent in the j-Cypher registry.*

Summary



Preliminary One-year Result from the j-Cypher Registry suggests

- 4. Extended dual anti-platelet therapy beyond 6 months as compared to discontinuation of thienopyridine within 6 months did not have favorable effect on the incidence of death / MI.*
- 5. Compared to a historical control of BMS, PCI using SES in the j-Cypher registry was associated with similar mortality, less myocardial infarction, and strikingly less TLR at 1 year, despite prevalence of more morbid patients such as diabetes, CKD, elderly, and left main stenting in the SES group.*