

Clinical Outcome of Drug-eluting Stents in Japan

What We Have Learned

From The j-Cypher Registry

Takeshi Kimura MD.

Kyoto University Hospital

Takeshi Morimoto MD.

Kyoto University

Kazuaki Mitsudou MD.

Kurashiki Central Hospital

Masakiyo Nobuyoshi MD.

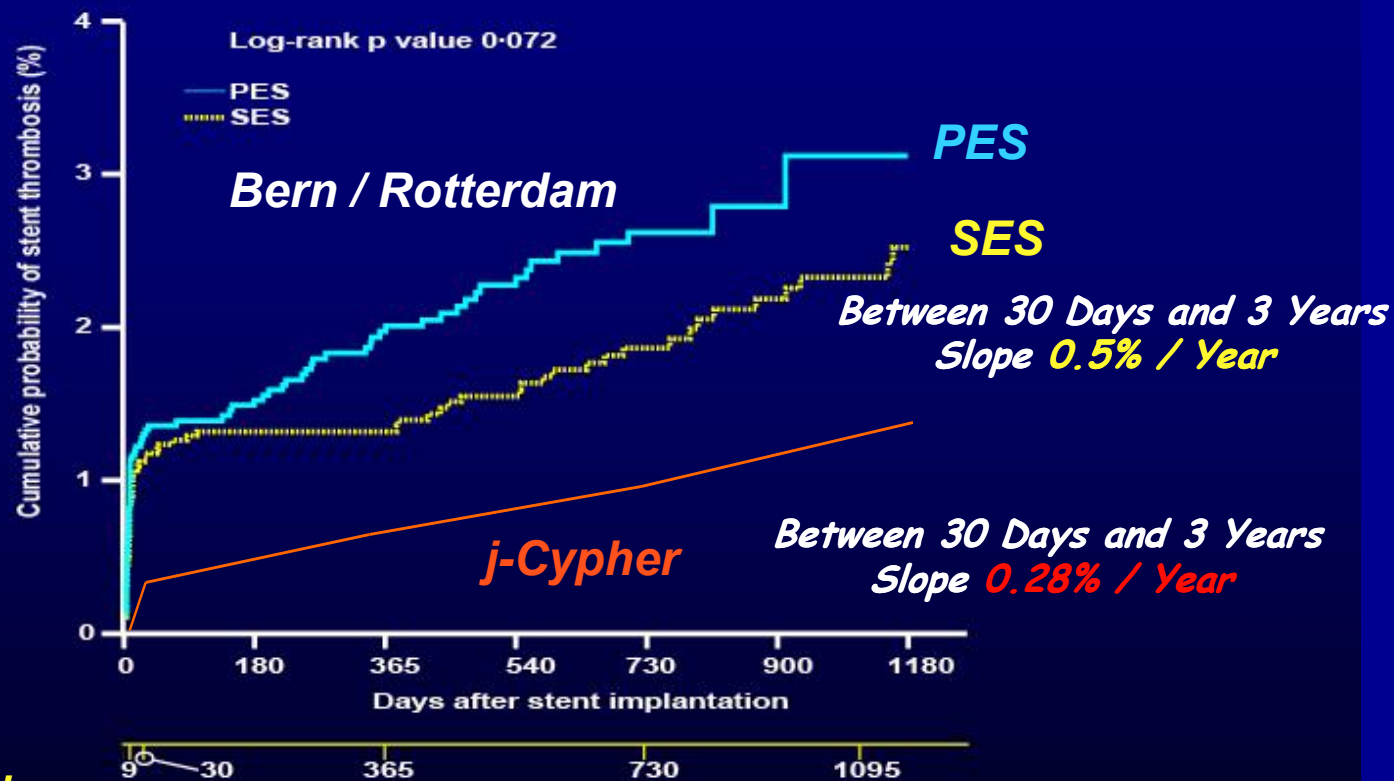
Kokura Memorial Hospital

on behalf of the j-Cypher Registry Investigators

Definite Stent Thrombosis

Bern/Rotterdam vs j-Cypher

A Collaborative study by the Bern/Rotterdam team and the j-Cypher group has already launched !!



Bern / Rotterdam

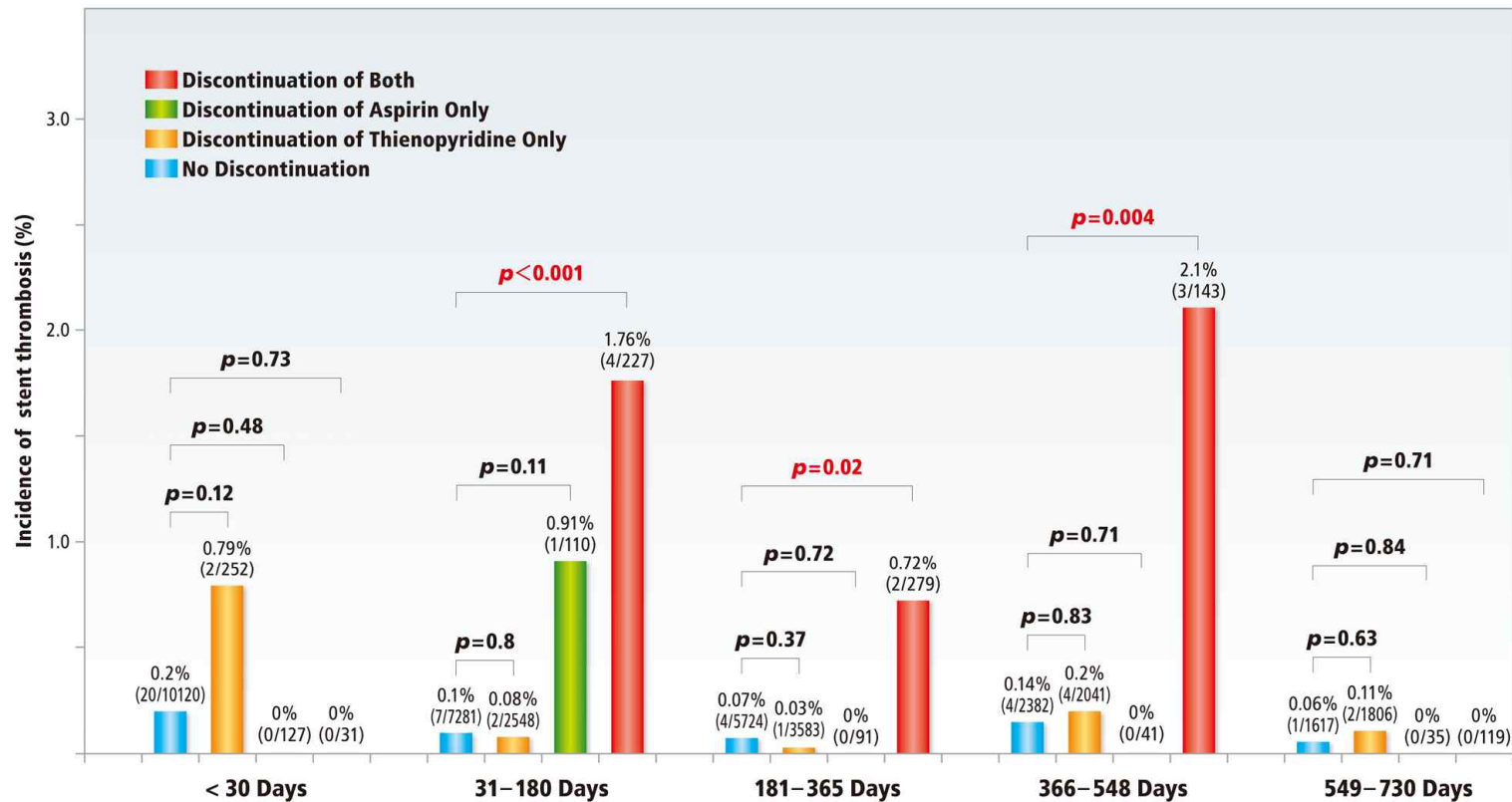
Incidence, PES (%)	1.2	1.3	2.0	2.7	3.2
Patients at risk (n)	3626	3493	2667	1131	68
Incidence, SES (%)	1.0	1.1	1.3	1.9	2.5
Patients at Risk (n)	3535	3508	2671	1710	903

j-Cypher

Cumulative Incidence (%)	0.3	0.4	0.6	0.8	1.2
Patients at Risk (n)	12682	12625	11843	9036	4191

Stent Thrombosis and Discontinuation of Aspirin and/or Thienopyridine

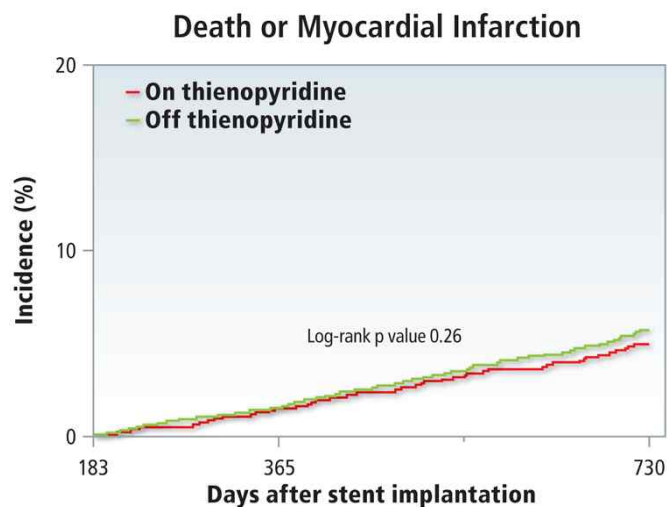
Incidence of Definite Stent Thrombosis



6-Month Landmark Analysis

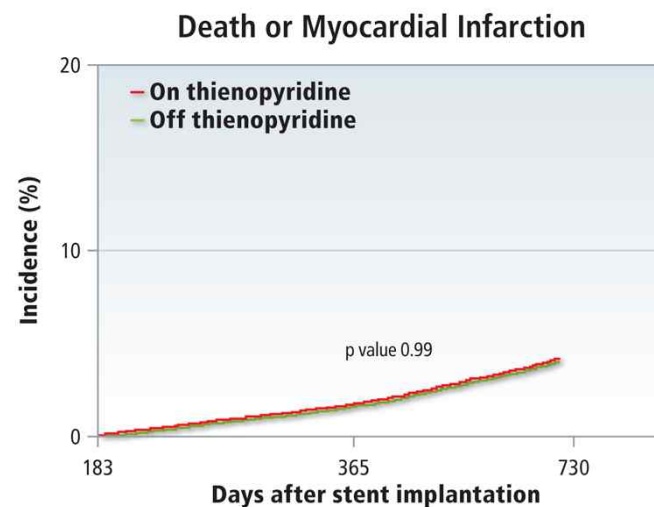
J-CYPHER Registry

A Unadjusted



Days after stent implantation	183	365	730
Cumulative incidence, On thienopyridine		1.6%	5.8%
Number of events		115	268
Number of patients at risk	7247	6918	2405
Cumulative incidence, Off thienopyridine		1.5%	5.0%
Number of events		39	91
Number of lesions at risk	2628	2533	1072

B Adjusted

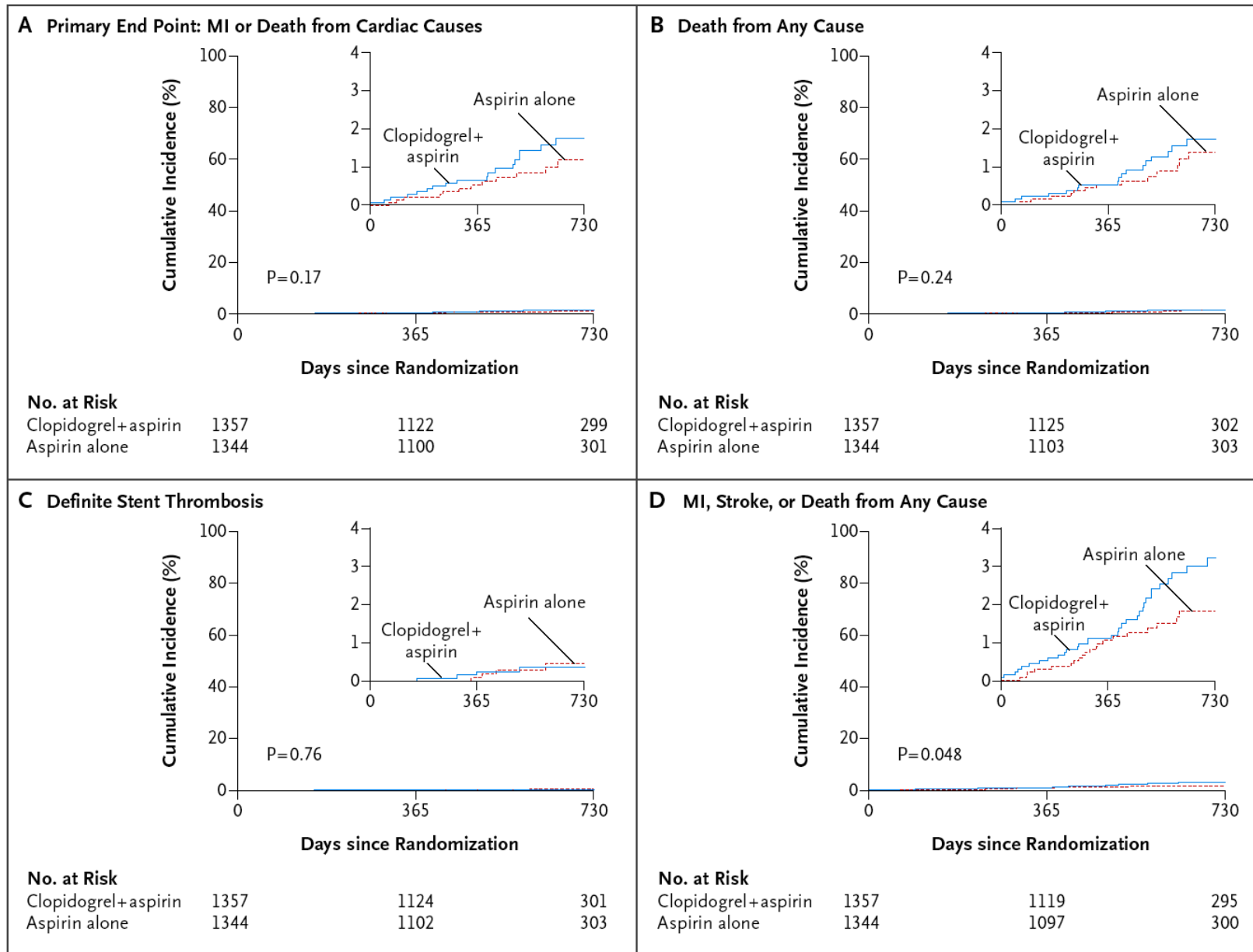


Days after stent implantation	183	365	730
Cumulative incidence, On thienopyridine		1.1%	4.1%
Cumulative incidence, Off thienopyridine		1.1%	4.1%

Inclusion criteria : Patients free from cardiovascular events (death/MI/Stroke/ST) and on aspirin at 6 months landmark

Kimura T, et al. Circulation. 2009;119:987-995

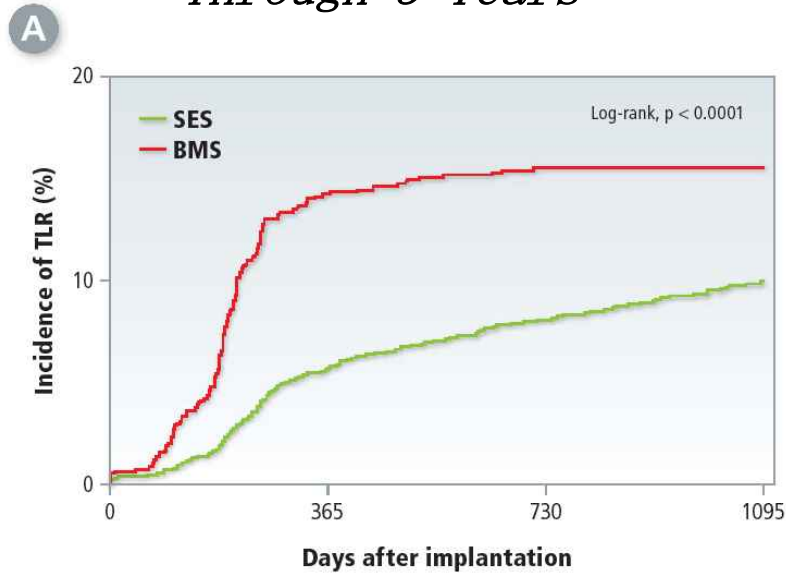
Duration of DAPT and Cardiovascular Events



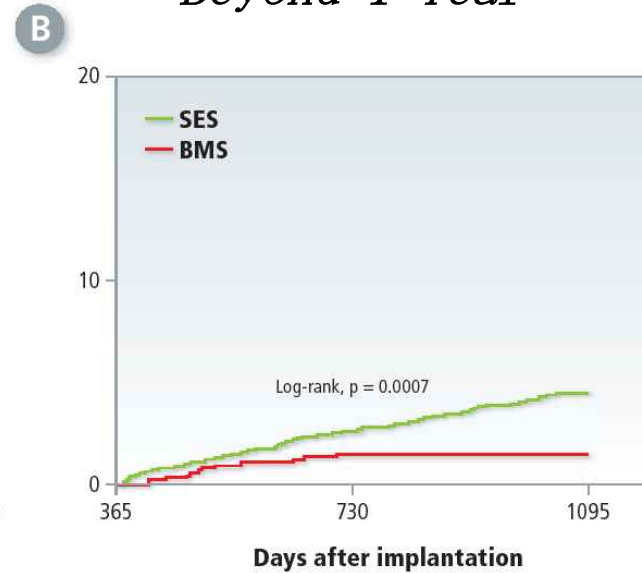
Late Catch-up Phenomenon

Incidences of TLR: SES vs. BMS

Through 3 Years



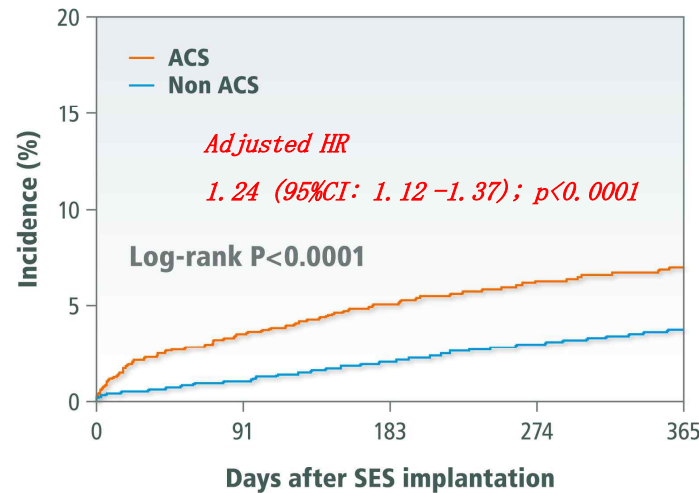
Beyond 1 Year



Days after implantation	0	365	730	1095	365	730	1095
Incidence of TLR							
SES	0%	5.7%	8.1%	10.0%	0%	2.6%	4.5%
BMS	0%	14.2%	15.5%	15.5%	0%	1.4%	1.4%
Number of events							
SES	0	926	1260	1409	0	334	483
BMS	0	169	181	181	0	12	12
Number of lesions at risk							
SES	17050	14944	11142	5054	14944	11142	5054
BMS	1259	980	721	329	980	721	329

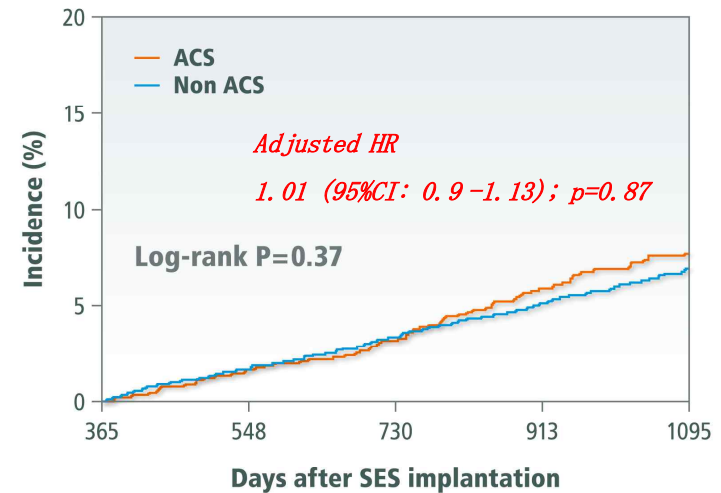
Death or Myocardial Infarction ACS vs. Non-ACS

(A) Event rate within 1 year



Days after SES implantation	0	91	183	365
Cumulative incidence, ACS		3.6%	5.2%	7.0%
Number of events		82	118	160
Number of patients at risk	2308	2198	2145	2057
Cumulative incidence, Non-ACS		1.1%	2.1%	3.8%
Number of events		94	180	318
Number of patients at risk	8470	8309	8193	7909

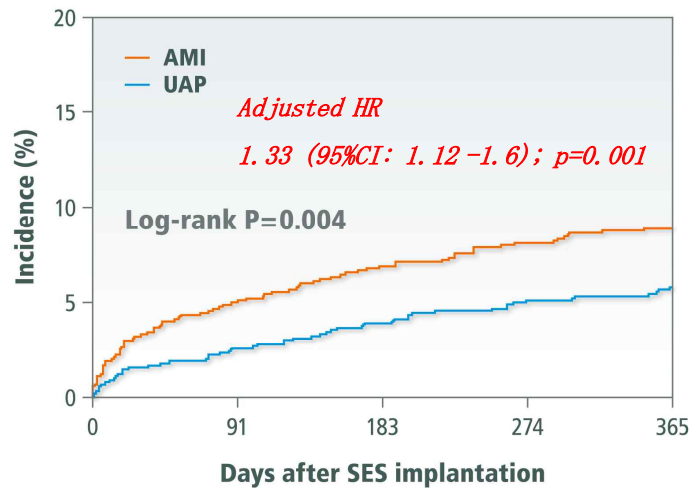
(B) Event rate beyond 1 year



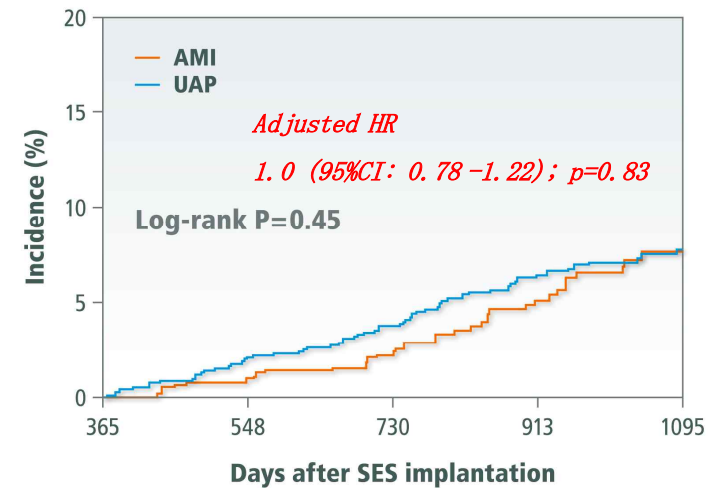
Days after SES implantation	365	730	1095
Cumulative incidence, ACS		3.2%	7.7%
Number of events		234	387
Number of patients at risk	2057	1521	633
Cumulative incidence, Non-ACS		3.4%	6.9%
Number of events		233	386
Number of patients at risk	7909	6088	2885

Death or Myocardial Infarction AMI vs. UAP

(A) Event rate within 1 year



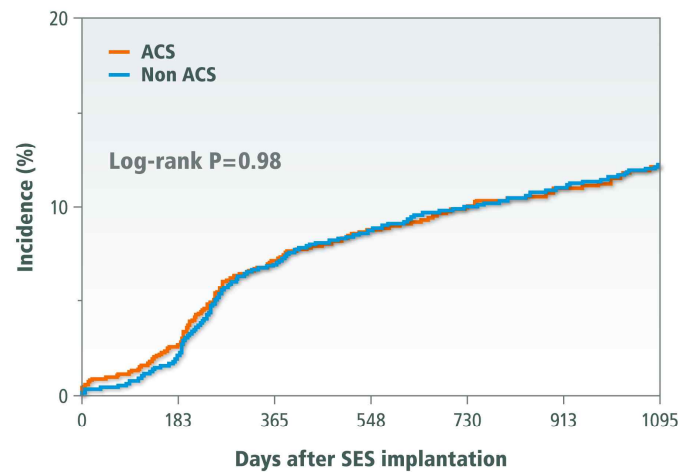
(B) Event rate beyond 1 year



Days after SES implantation	0	91	183	365
Cumulative incidence, AMI		5.1%	6.9%	8.9%
Number of events		48	65	83
Number of patients at risk	953	892	866	825
Cumulative incidence, UAP		2.5%	3.9%	5.8%
Number of events		34	53	77
Number of patients at risk	1355	1307	1281	1232

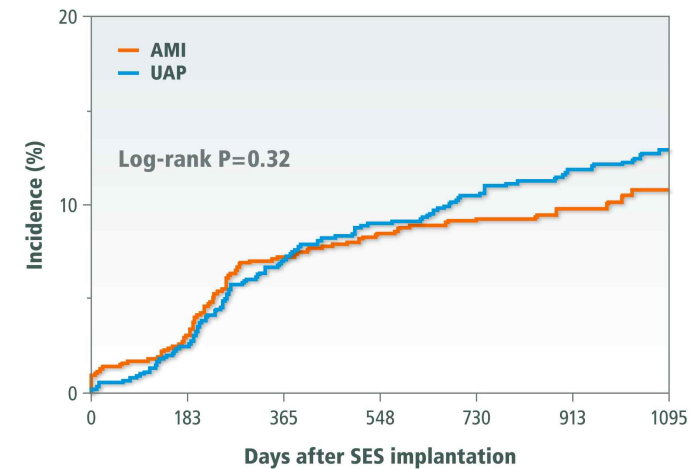
Days after SES implantation	365	730	1095
Cumulative incidence, AMI		2.2%	7.6%
Number of events		15	37
Number of patients at risk	825	600	230
Cumulative incidence, UAP		3.8%	7.8%
Number of events		40	67
Number of patients at risk	1233	921	403

Target Lesion Revascularization ACS vs. Non-ACS



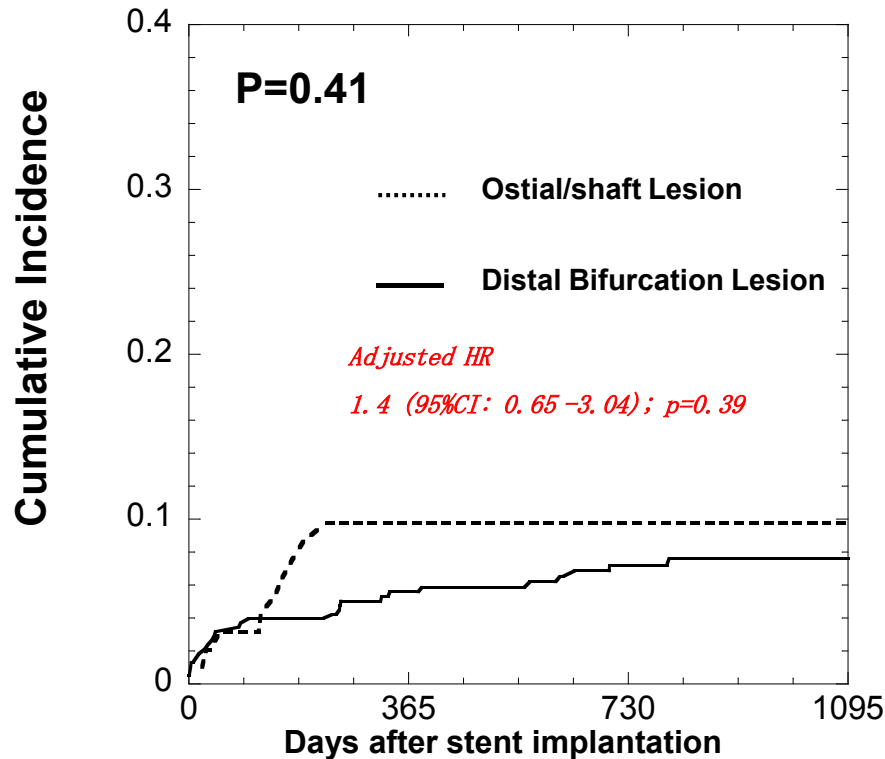
Days after SES implantation	0	183	365	730	1095
Cumulative incidence, ACS		2.7%	7.1%	10.0%	12.1%
Number of events		60	154	204	225
Number of patients at risk	2308	2104	1933	1393	578
Cumulative incidence, Non-ACS		2.2%	7.0%	10.0%	12.2%
Number of events		185	570	780	872
Number of patients at risk	8470	8046	7400	5534	2618

Target Lesion Revascularization AMI vs. UAP



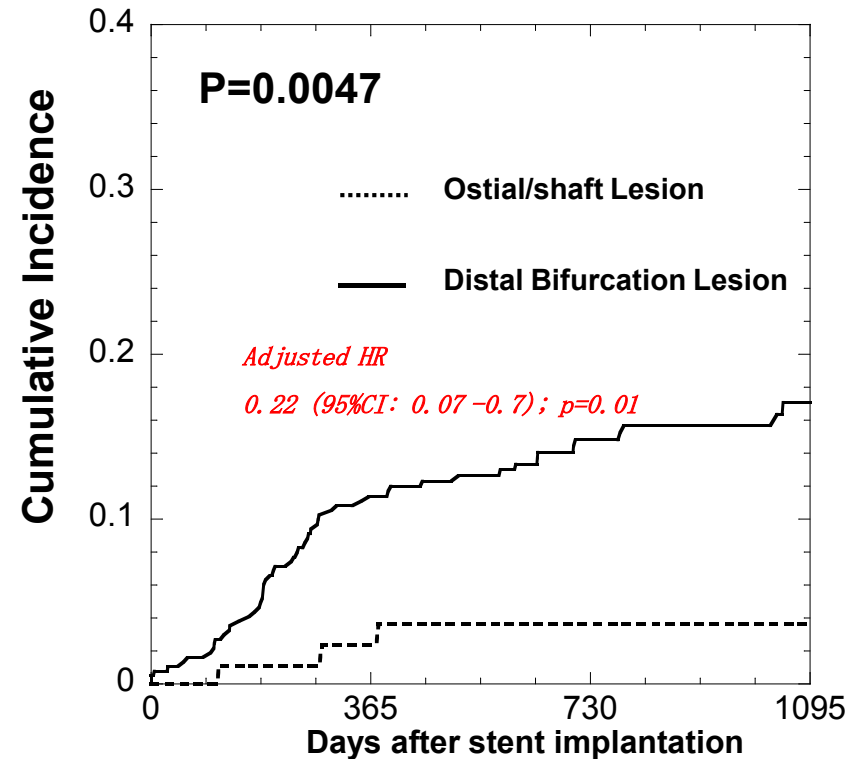
Days after SES implantation	0	183	365	730	1095
Cumulative incidence, AMI		2.9%	7.2%	9.3%	10.8%
Number of events		27	64	78	83
Number of patients at risk	953	851	776	553	213
Cumulative incidence, UAP		2.5%	7.0%	10.4%	12.9%
Number of events		33	90	126	142
Number of patients at risk	1353	1254	1157	840	365

(A) Cardiac Mortality



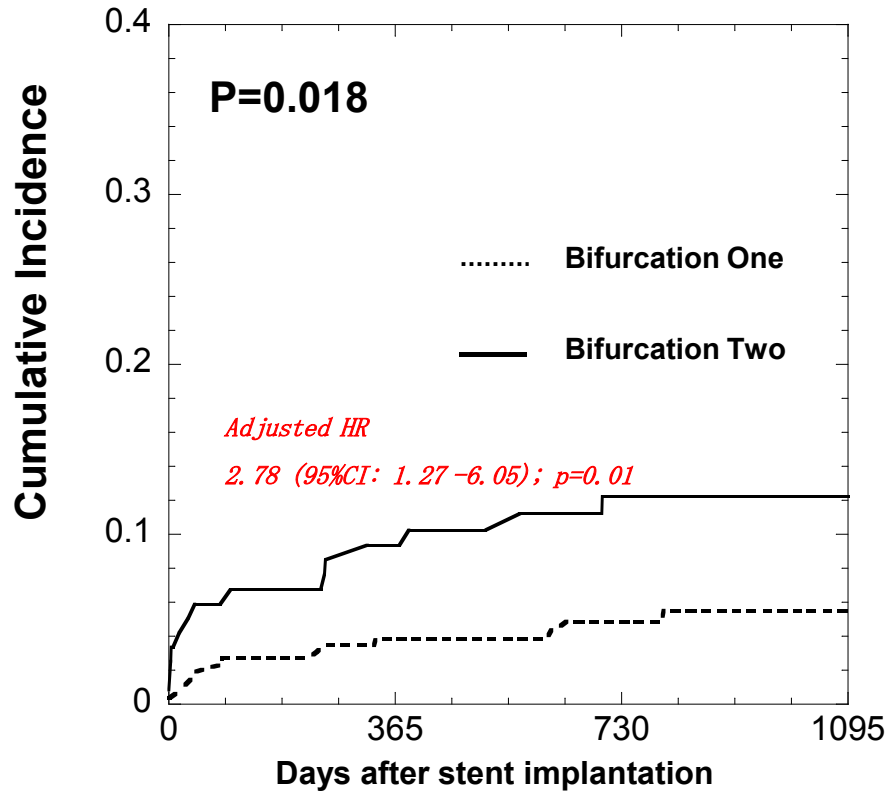
Interval (Days)	0	365	730	1095
Ostial/Shaft				
Incidence (%)		9.8	9.8	9.8
No. at risk	96	82	65	22
Distal Bifurcation				
Incidence (%)		5.6	7.2	7.6
No. at risk	380	347	266	138

(B) Target Lesion Revascularization



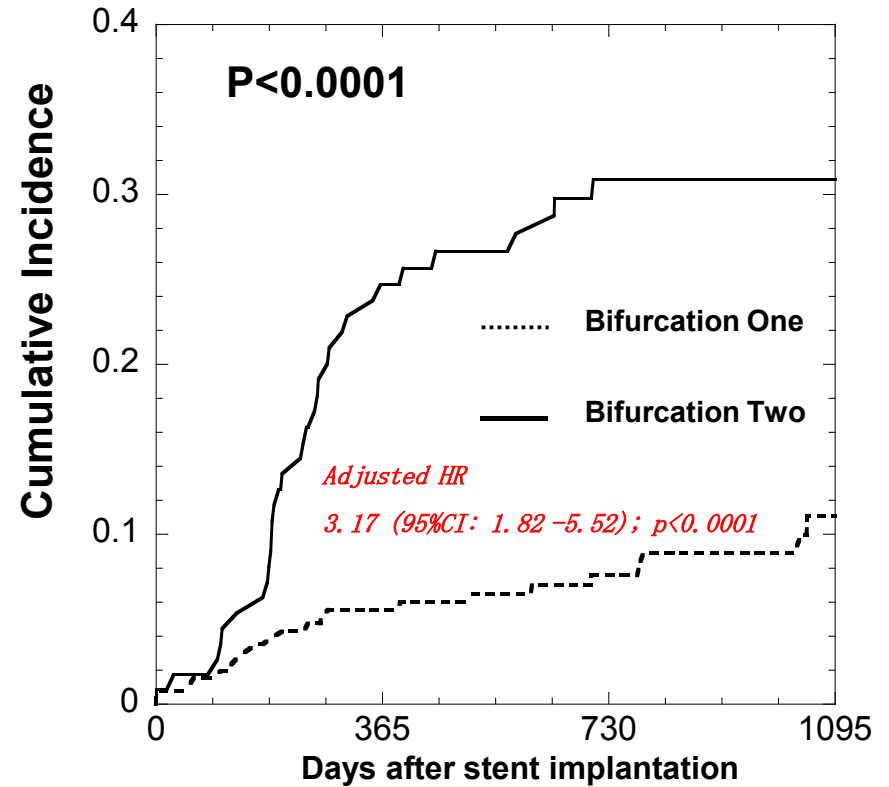
Interval (Days)	0	365	730	1095
Ostial/Shaft				
Incidence (%)		1.1	3.6	3.6
No. at risk	96	80	62	22
Distal Bifurcation				
Incidence (%)		11.4	14.8	17.1
No. at risk	380	309	222	113

(A) Cardiac Mortality



Day	0	365	730	1095
Bifurcation One				
Incidence (%)		3.9	4.9	5.5
No. at risk	261	242	180	86
Bifurcation Two				
Incidence (%)		9.4	12.2	12.2
No. at risk	119	105	86	52

(B) Target Lesion Revascularization

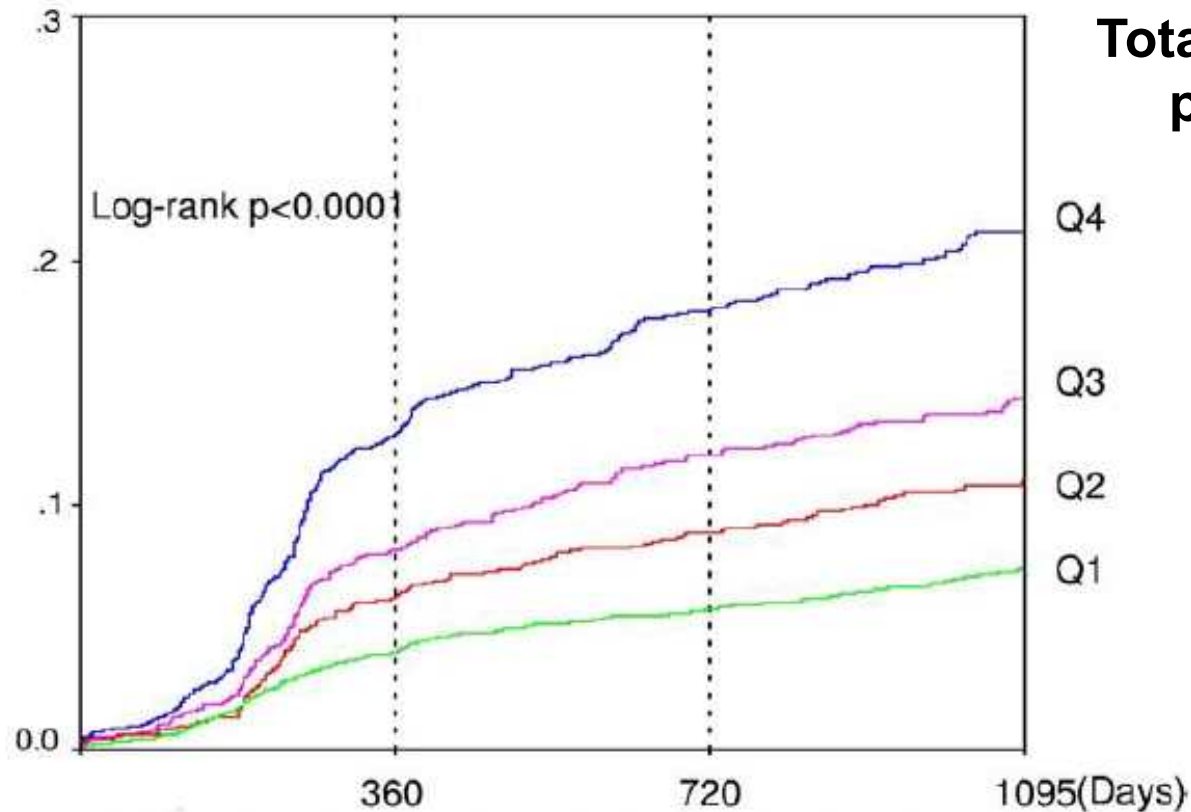


Day	0	365	730	1095
Bifurcation One				
Incidence (%)		5.6	7.6	11.1
No. at risk	261	229	161	76
Bifurcation Two				
Incidence (%)		24.6	30.9	30.9
No. at risk	119	81	62	37

Impact of Triple Vessel Disease

	ULMCA only	ULMCA+SVD	+DVD	+TVD	+CABG	P value
N	40	113	188	93	42	
Total Death (%)	21.4	11.2	14.0	21.7	9.5	0.15
Cardiac death (%)	2.5	7.3	7.8	15.1	0.0	0.033
Sudden Death (%)	0.0	1.9	1.7	3.5	0.0	0.56
MI (%)	4.4	2.1	4.9	5.6	0.0	0.57
Definite ST (%)	0.0	0.0	0.6	3.6	0.0	0.070
TLR (%)	2.6	7.1	18.7	18.9	15.6	0.027
Revascularization (%)	25.2	31.3	37.1	48.3	24.5	0.0016

Target Lesion Revascularization

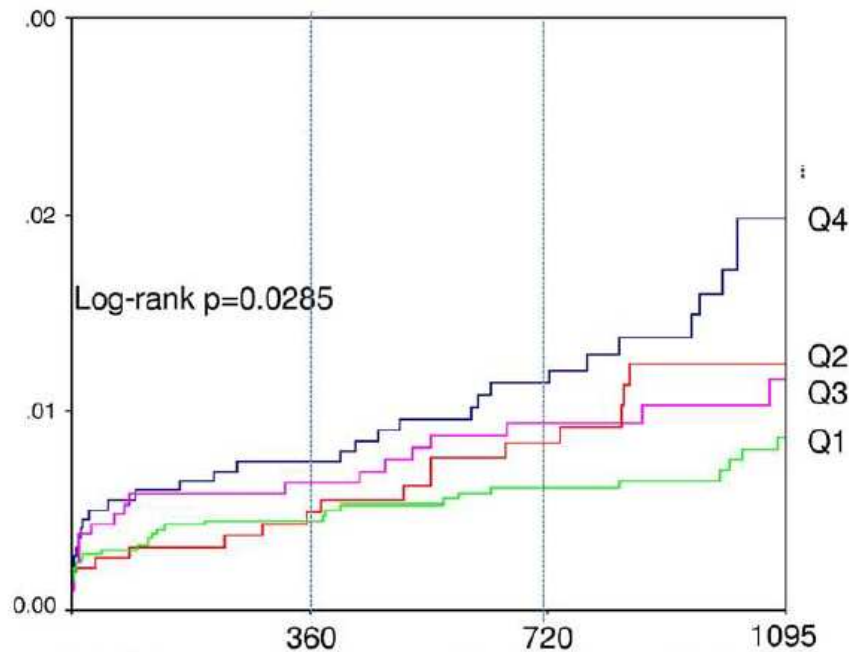


**Total stent length
per patient**

- Q4 **55-293 mm**
- Q3 **37-54 mm**
- Q2 **24-36 mm**
- Q1 **8-23 mm**

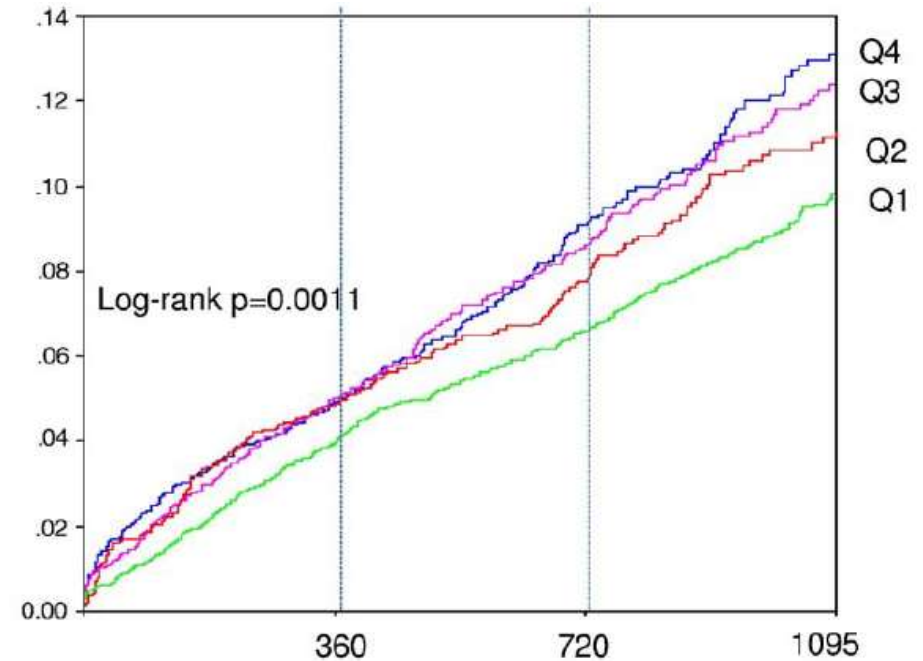
N at Risk	0	30	360	720	1095
Q	4647	4599	4187	3185	1481
Q2	1873	1833	1627	1187	545
Q3	2069	2035	1762	1336	633
Q4	2184	2134	1772	1262	535

Definite ST



N at Risk	0	30	360	720	1095
Q1	4647	4600	4337	3364	1589
Q2	1873	1838	1729	1289	593
Q3	2069	2037	1902	1499	718
Q4	2184	2139	2915	1531	657

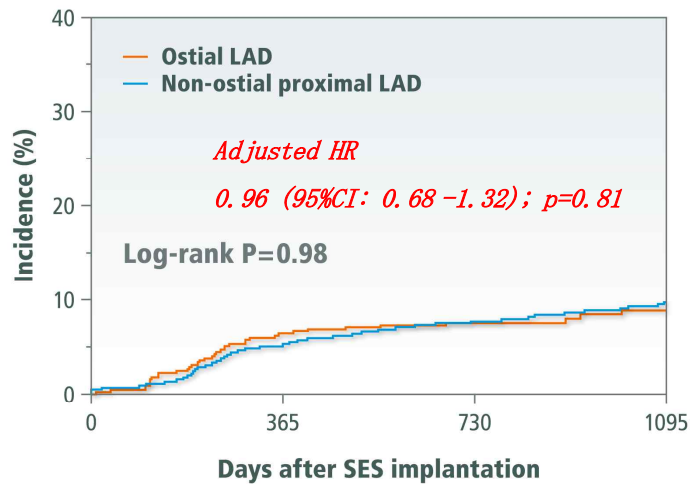
Death or MI



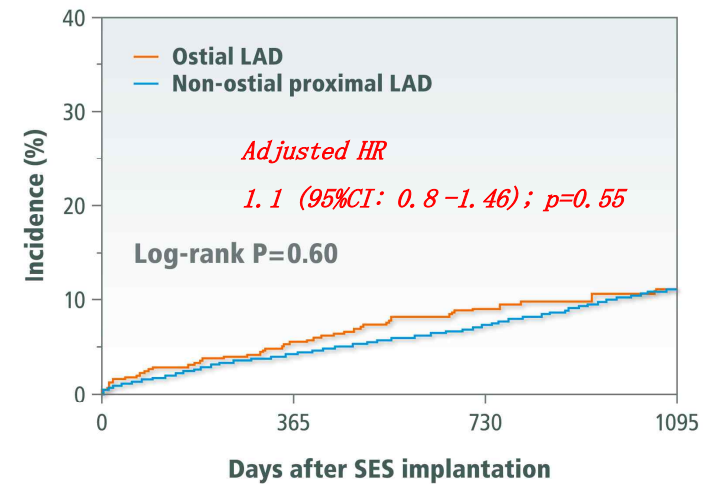
N at Risk	0	30	360	720	1095
Q1	4647	4601	4326	3349	1572
Q2	1873	1840	1727	1279	583
Q3	2069	2038	1899	1491	706
Q4	2184	2139	2010	1524	651

Ostial LAD vs. Non-ostial Proximal LAD

(A) Target Lesion Revascularization



(B) Death or Myocardial infarction

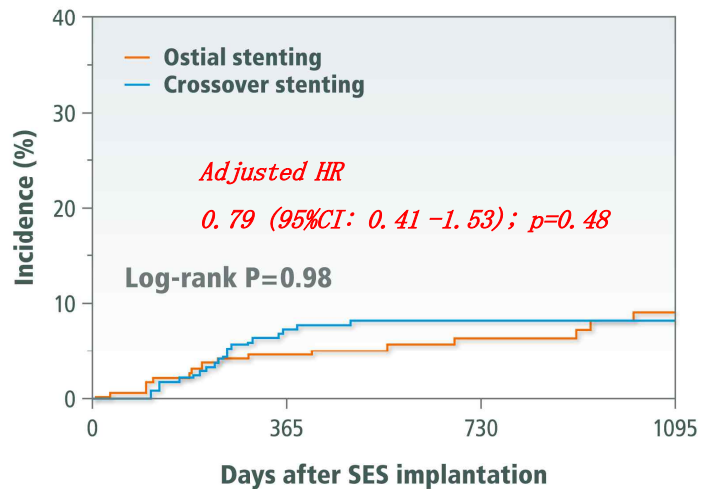


Days after SES implantation	0	365	730	1095
Ostial LAD				
Incidence		6.3%	7.6%	9.4%
No. of events		29	34	38
No. of patients at risk	481	417	316	170
Non-ostial proximal LAD				
Incidence		5.2%	7.7%	9.7%
No. of events		268	378	426
No. of patients at risk	5369	4727	3550	1562

Days after SES implantation	0	365	730	1095
Ostial LAD				
Incidence		5.7%	9.4%	11.3%
No. of events		27	42	47
No. of patients at risk	481	442	336	173
Non-ostial proximal LAD				
Incidence		4.5%	7.5%	11.3%
No. of events		237	373	479
No. of patients at risk	5369	4944	3797	1671

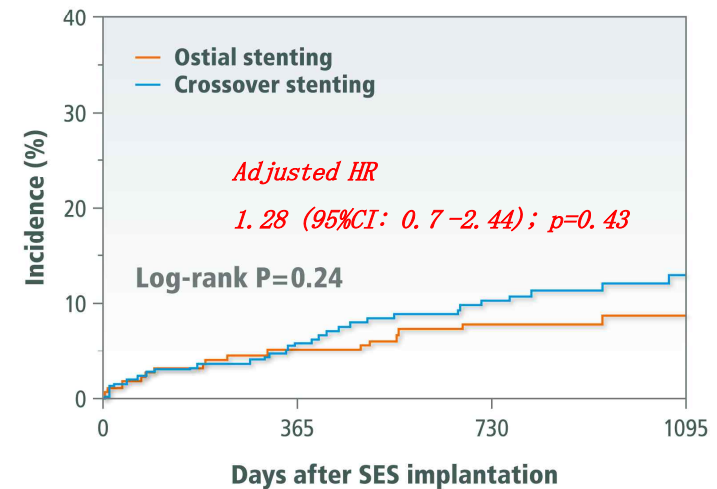
Ostial Stenting vs. Cross-over Stenting

(A) Target Lesion Revascularization



Days after SES implantation	0	365	730	1095
Ostial stenting				
Incidence		4.9%	6.7%	10.5%
No. of events		10	13	17
No. at risk	213	188	147	82
Crossover stenting				
Incidence		7.5%	8.4%	8.4%
No. of events		19	21	21
No. at risk	268	229	169	88

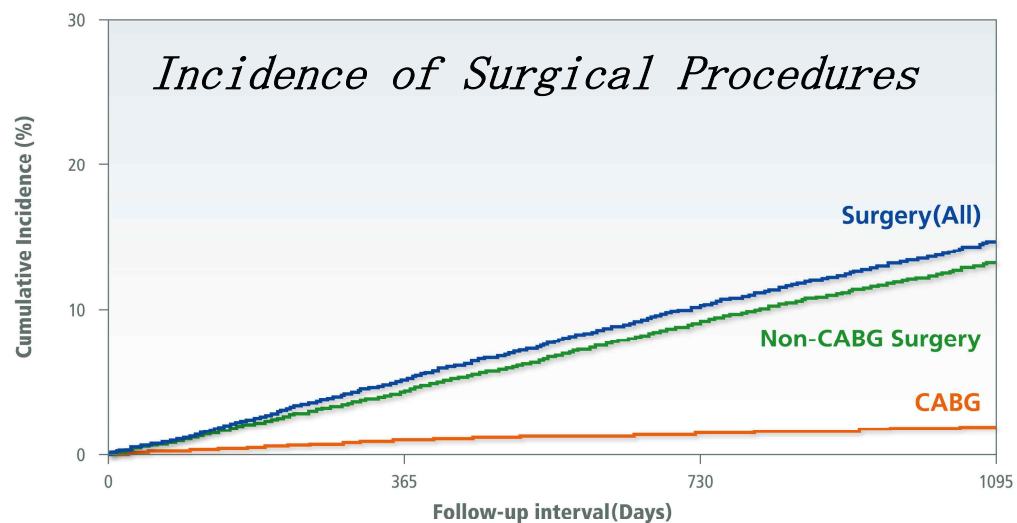
(B) Death or Myocardial infarction



Days after SES implantation	0	365	730	1095
Ostial stenting				
Incidence		5.2%	8.1%	8.9%
No. of events		11	16	17
No. at risk	213	195	151	81
Crossover stenting				
Incidence		6.1%	10.4%	13.1%
No. of events		16	26	30
No. at risk	268	247	185	92

Incidence and outcome of surgical procedures after sirolimus-eluting stent implantation: a report from the j-Cypher registry

Takeshi Kimura · Takaaki Isshiki · Yasuhiko Hayashi · Shigeru Oshima ·
 Masanobu Namura · Hitoshi Nakashima · Kazuya Kawai · Takahito Sone ·
 Ryozo Tatami · Taiichiro Meguro · Masakiyo Nobuyoshi · Kazuaki Mitsudo



Surgery(All)	60 Days	1 year	2 years	3 years
Incidence	0.7%	5.1%	10.2%	14.7%
Number of events	94	626	1146	1430
Number of patients at risk	12824	12492	11358	8264
Non-CABG Surgery				
Incidence	0.6%	4.3%	9.0%	13.3%
Number of events	75	526	1011	1275
Number of patients at risk	12824	12509	11448	8367
CABG				
Incidence	0.2%	0.9%	1.4%	1.9%
Number of events	20	111	161	189
Number of patients at risk	12824	12559	11814	8984

Cumulative Event Rates after Surgery OPER Registry

Endpoints	N of events (incidence)		
	30 days	1 year	2 years
Death / MI / ST (definite or probable)	38 (2.7%)	137 (11.4%)	181 (18.2%)
Death	33 (2.4%)	128 (10.7%)	171 (17.3%)
MI	9 (0.65%)	16 (1.3%)	18 (1.6%)
ST (definite or probable)	5 (0.35%)	7 (0.56%)	7 (0.56%)
ST (definite)	4 (0.28%)	6 (0.49%)	6 (0.49%)

MI = myocardial infarction and ST = stent thrombosis.

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Table 5 Causes of death within 30 days after surgical procedures

Causes of death	Number of cases
Cardiac death	15
MI, probable ST	1
Sudden cardiac death (post CABG)	1
Postoperative MI, no evidence of ST	3
Heart failure, no evidence of MI	5
Complications of preoperative MI	4
Unknown	1
Non-cardiac death	18
Infection	7
Renal failure	3
Stroke	3
Bleeding	1
Others	4

CABG coronary artery bypass grafting surgery, *MI* myocardial infarction, *ST* stent thrombosis

Incidence and outcome of surgical procedures after sirolimus-eluting stent implantation: a report from the j-Cypher registry

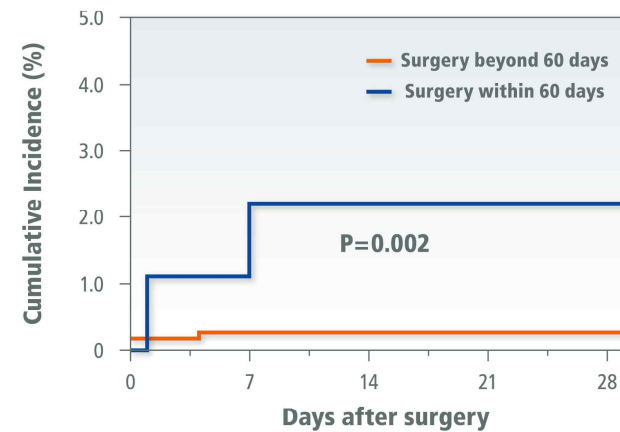
Takeshi Kimura · Takaaki Isshiki · Yasuhiko Hayashi · Shigeru Oshima · Masanobu Namura · Hitoshi Nakashima · Kazuya Kawai · Takahito Sone · Ryozo Tatami · Taiichiro Meguro · Masakiyo Nobuyoshi · Kazuaki Mitsudo

(A) Death / MI / ST



Surgery within 60 days	7 Days	30 Days
Incidence	6.4%	6.4%
Number of events	6	6
Number of patients at risk	94	89
Surgery beyond 60 days		
Incidence	0.8%	2.5%
Number of events	10	32
Number of patients at risk	1336	1306

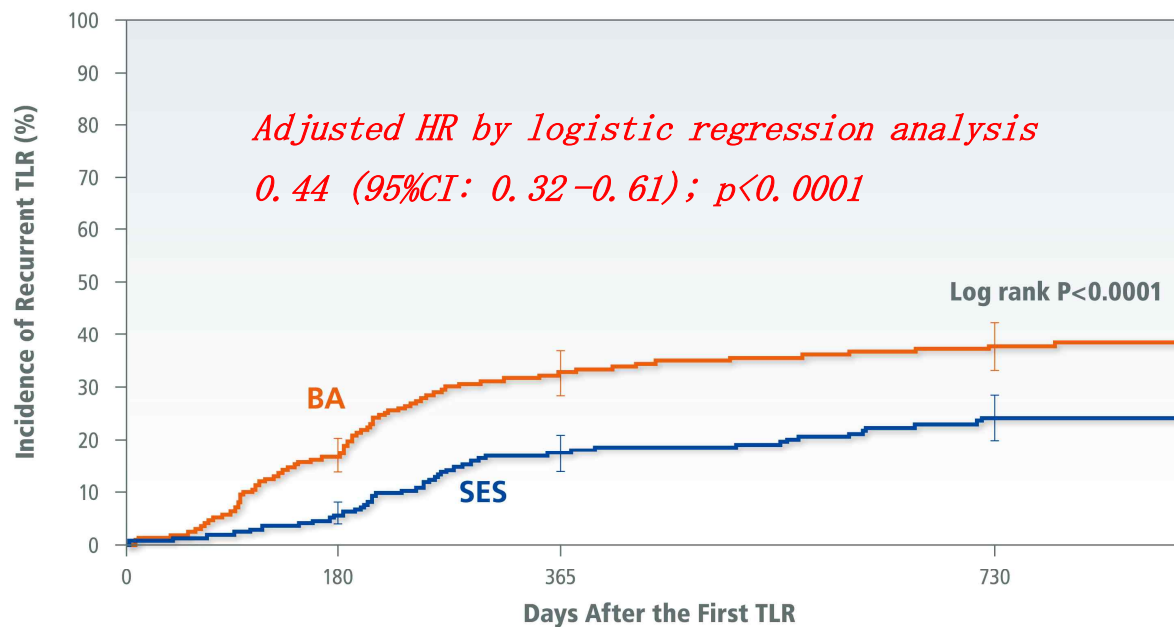
(B) ST



Surgery within 60 days	7 Days	30 Days
Incidence	2.2%	2.2%
Number of events	2	2
Number of patients at risk	94	89
Surgery beyond 60 days		
Incidence	0.23%	0.23%
Number of events	3	3
Number of patients at risk	1336	1306

Incidences of Recurrent TLR

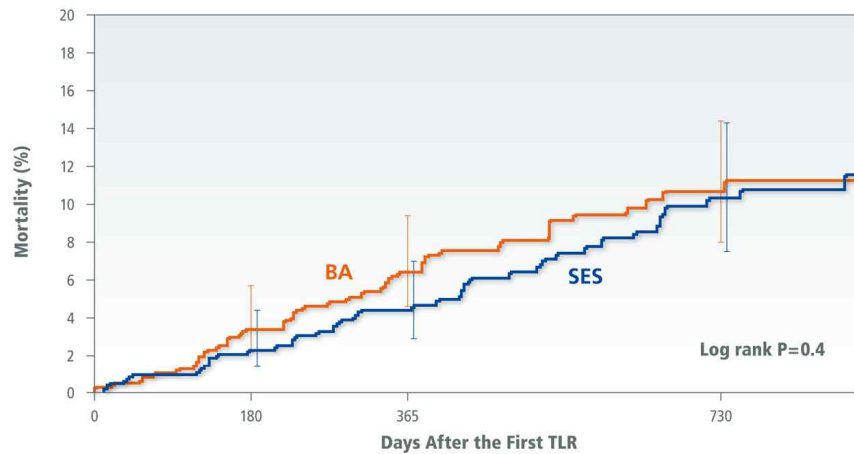
Repeated SES Implantation vs. Balloon Angioplasty



Days after the First TLR	0	180	365	730
BA				
Cumulative incidence		16.8%	32.4%	37.7%
Number of events		85	154	171
Number of lesions at risk	557	387	270	123
SES				
Cumulative incidence		5.7%	17.0%	23.8%
Number of events		28	77	97
Number of lesions at risk	537	440	327	156

Repeated SES Implantation vs. Balloon Angioplasty

Death



Days after the First TLR	0	180	365	730
BA				
Overall mortality		3.5%	6.6%	10.8%
Number of events		16	28	41
Number of patients at risk	491	414	354	174
SES				
Overall mortality		2.5%	4.5%	10.4%
Number of events		11	19	36
Number of patients at risk	475	414	350	186

Stent Thrombosis



Days after the First TLR	0	180	365	730
BA				
Cumulative incidence		0.4%	0.6%	0.6%
Number of events		2	3	3
Number of lesions at risk	557	462	393	191
SES				
Cumulative incidence		0.2%	0.2%	0.6%
Number of events		1	1	2
Number of lesions at risk	537	464	393	209

Conclusions

- *Long-term follow-up results from the j-Cypher registry demonstrated acceptable outcome of PCI in the real world clinical practice in Japan.*
- *Remaining issues to be addressed include stent thrombosis, particularly very late stent thrombosis, late catch -up phenomenon, optimization of left main bifurcation stenting and management of DES restenosis.*

Event Rates at 30 Days after Surgery

According to Perioperative Status of APT

J-CYPER Registry

Endpoints	N of events (incidence)				P value
	Dual APT	Aspirin alone	Thienopyridine alone	None	
	N=400	N=434	N=19	N=577	
Death / MI / ST (definite or probable)	15 (3.8%)	12 (2.9%)	0 (0%)	11 (1.9%)	0.3
Death	15 (3.8%)	10 (2,4%)	0 (0%)	8 (1,4%)	0.09
MI	2 (0.53%)	3 (0,7%)	0 (0%)	4 (0.7%)	0.96
ST (definite or probable)	0 (0%)	2 (0.47%)	0 (0%)	3 (0.52%)	0.55
ST (definite)	0 (0%)	2 (0.47%)	0 (0%)	2 (0.35%)	0.62

The j-Cypher Registry Investigators

J-CYPHER Registry

【愛媛県立中央病院】	風谷 幸男	平松 伸一	沖野 綾
【大垣市民病院】	曾根 孝仁	林 英次郎	奥村 恭巳
【大阪市立総合医療センター】	土師 一夫	伊藤 彰	
【大阪赤十字病院】	田中 昌	稲田 司	高田 晴子
【済生会野江病院】	馬場 雄治	武 俊介	矢野 智子
【金沢循環器病院】	名村 正伸	土谷 武嗣	山本 基善
【湘南鎌倉総合病院】	齋藤 滋	高橋 佐枝子	竹谷 善雄
【川崎社会保険病院】	村松 俊哉	伊藤 良明	
【岸和田徳洲会病院】	横井 良明	森岡 信行	石川 隆司
【鹿児島医療センター】	中島 均	瀬戸口 学	長友 雅彦
【京都大学病院】	木村 剛	田村 俊寛	太田 悦雄
	中川 義久		
【京都第二赤十字病院】	井上 直人	藤田 博	松尾 あきこ
【倉敷中央病院】	光藤 和明	門田 一繁	清水 速人
【群馬県立心臓血管センター】	大島 茂	星崎 洋	河口 廉
【公立能登総合病院】	村田 義治		森田 絹代
【小倉記念病院】	延吉 正清	安本 均	湯田 逸雄
【国立循環器病センター】	宮崎 俊一	川村 淳	横山 博典
【済生会熊本病院】	本田 喬	堀内 賢二	
【静岡県立総合病院】	土井 修	為清 博道	

The j-Cypher Registry Investigators

J-CYPHER Registry

【新古賀病院】	川崎 友裕		千代島 雅志
【新別府病院】	中村 夏樹	菊田 浩一	田中 秀憲
【仙台厚生病院】	目黒 泰一郎	本田 英彦	下山田 恵
【土谷総合病院】	林 康彦	豊福 守	石橋 徹
【帝京大学病院】	一色 高明	上妻 謙	
【徳島赤十字病院】	日浅 芳一	岸 宏一	
【南風病院】	山口 浩士	豊寫 慎一郎	
【福岡大学病院】	朔 啓二郎	白井 和之	
【福山循環器病院】	治田 精一	赤沼 博	松田 憲尚
【藤田保健衛生大学 坂文種報徳会病院】	野村 雅則	横井 博厚	三川 雅人
【北光記念病院】	櫻井 正之	野崎 洋一	玉澤 充
【舞鶴共済病院】	多々見 良三	蘆田 欣也	北井 高明
【松江赤十字病院】	塩出 宣雄		
【三重ハートセンター】	西川 英郎	内田 文也	
【宮崎市郡医師会病院】	柴田 剛徳	野村 勝政	
【山口大学医学部附属病院】	松崎 益徳	山田 寿太郎	岡村 誉之
【日本赤十社和歌山医療センター】	三浦 彰	坂本 裕樹	城 崇友
【近森病院】	川井 和哉	関 秀一	

Interventional Cardiology

Three-Year Outcomes After Sirolimus-Eluting Stent Implantation for Unprotected Left Main Coronary Artery Disease Insights From the j-Cypher Registry

Mamoru Toyofuku, MD; Takeshi Kimura, MD; Takeshi Morimoto, MD; Yasuhiko Hayashi, MD;
Hiroaki Ueda, MD; Kazuya Kawai, MD; Yoichi Nozaki, MD; Shinichi Hiramatsu, MD;
Akira Miura, MD; Yoshiaki Yokoi, MD; Shinichiro Toyoshima, MD; Hitoshi Nakashima, MD;
Kazuo Haze, MD; Masaru Tanaka, MD; Shunsuke Take, MD; Shigeru Saito, MD;
Takaaki Isshiki, MD; Kazuaki Mitsudo, MD; on Behalf of the j-Cypher Registry Investigators

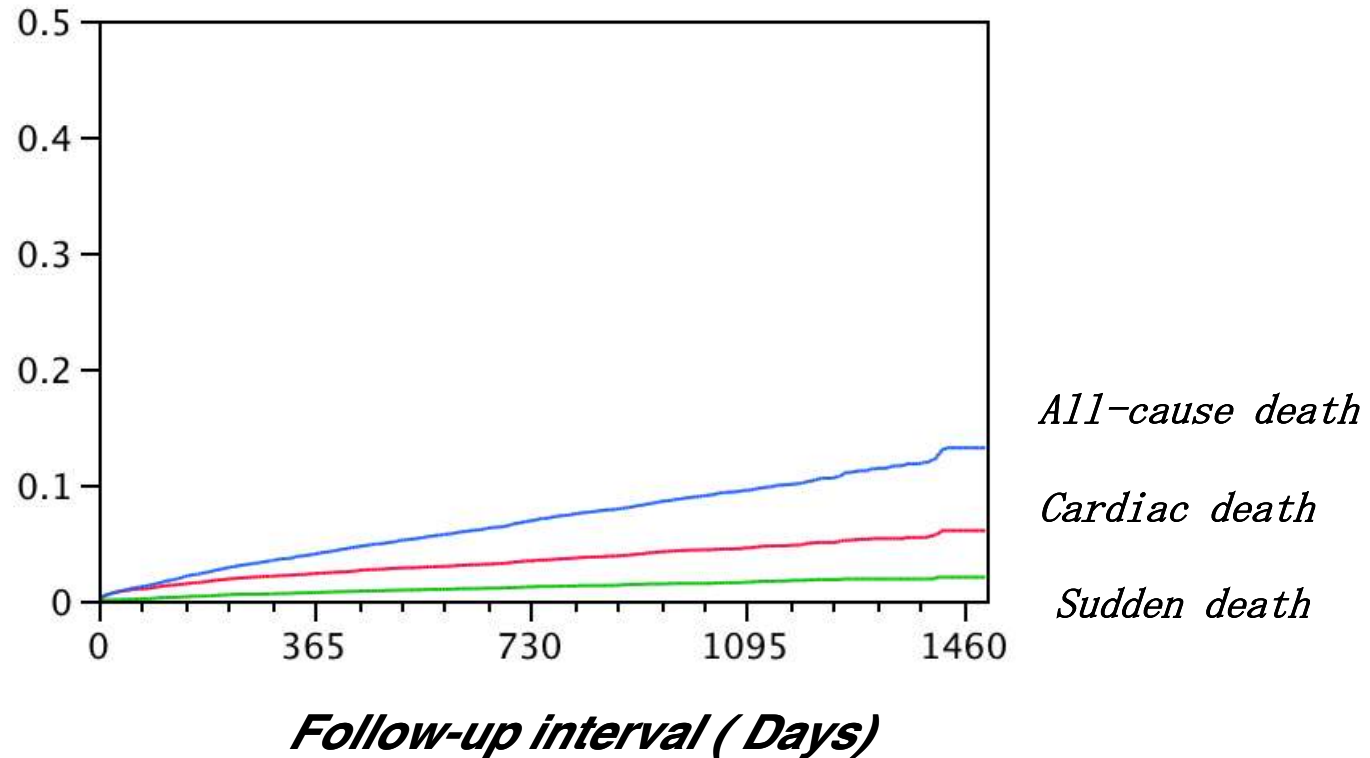
Background—Long-term outcomes after stenting of an unprotected left main coronary artery (ULMCA) with drug-eluting stents have not been addressed adequately despite the growing popularity of this procedure.

Methods and Results—j-Cypher is a multicenter prospective registry of consecutive patients undergoing sirolimus-eluting stent implantation in Japan. Among 12 824 patients enrolled in the j-Cypher registry, the unadjusted mortality rate at 3 years was significantly higher in patients with ULMCA stenting (n=582) than in patients without ULMCA stenting (n=12 242; 14.6% versus 9.2%, respectively; $P<0.0001$); however, there was no significant difference between the 2 groups in the adjusted risk of death (hazard ratio 1.23, 95% confidence interval 0.95 to 1.60, $P=0.12$). Among 476 patients whose ULMCA lesions were treated exclusively with a sirolimus-eluting stent, patients with ostial/shaft lesions (n=96) compared with those with bifurcation lesions (n=380) had a significantly lower rate of target-lesion revascularization for the ULMCA lesions (3.6% versus 17.1%, $P=0.005$), with similar cardiac death rates at 3 years (9.8% versus 7.6%, $P=0.41$). Among patients with bifurcation lesions, patients with stenting of both the main and side branches (n=119) had significantly higher rates of cardiac death (12.2% versus 5.5%; $P=0.02$) and target-lesion revascularization (30.9% versus 11.1%; $P<0.0001$) than those with main-branch stenting alone (n=261).

Conclusions—The higher unadjusted mortality rate of patients undergoing ULMCA stenting with a sirolimus-eluting stent did not appear to be related to ULMCA treatment itself but rather to the patients' high-risk profile. Although long-term outcomes in patients with ostial/shaft ULMCA lesions were favorable, outcomes in patients with bifurcation lesions treated with stenting of both the main and side branches appeared unacceptable. (*Circulation*. 2009;120:1866-1874.)

Four-Year Mortality

J-CYPHER Registry

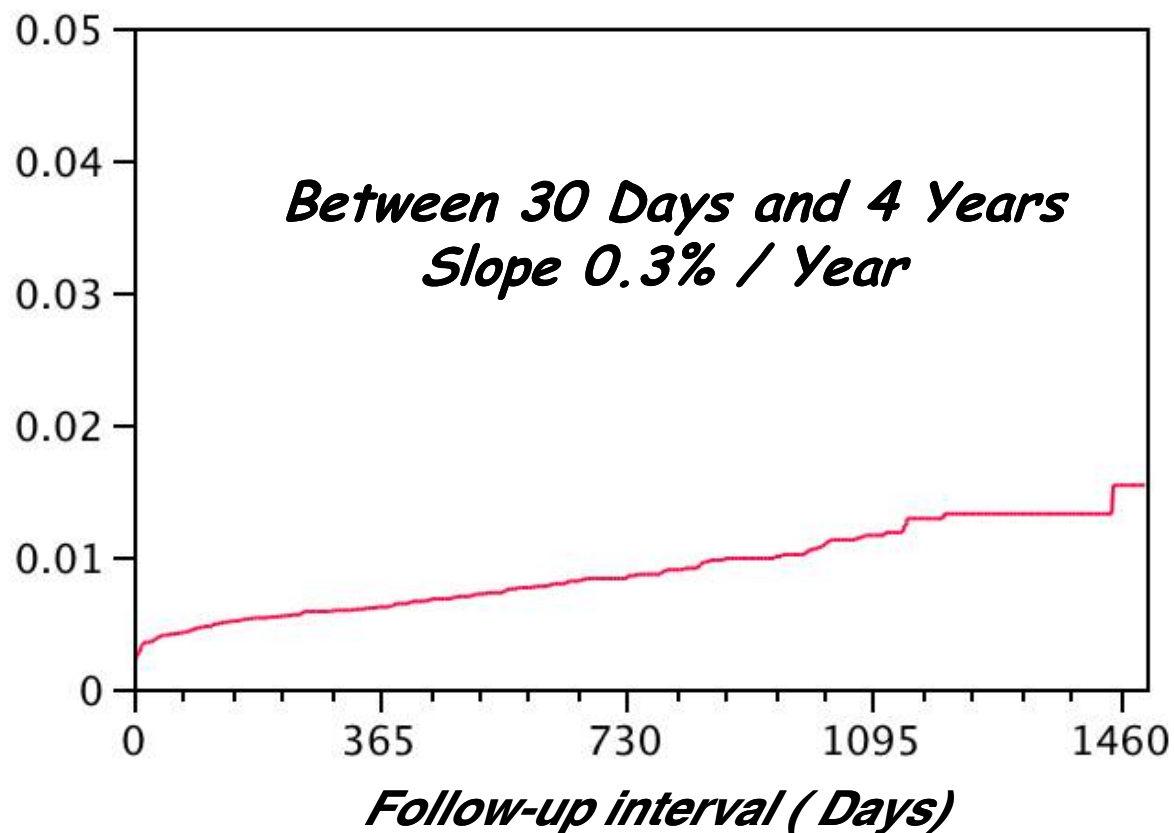


	30 Days	1 Yr.	2 Yrs.	3 Yrs.	4 Yrs.
<i>All-cause death</i>	0.7%	4.0%	6.9%	9.5%	13.2%
<i>Cardiac death</i>	0.7%	2.3%	3.4%	4.5%	6.0%
<i>Sudden death</i>	0.1%	0.7%	1.2%	1.6%	2.0%
<i>n of pts at risk</i>	12824	12677	11961	9749	5650

Stent Thrombosis

J-CYPHER Registry

ARC Definite



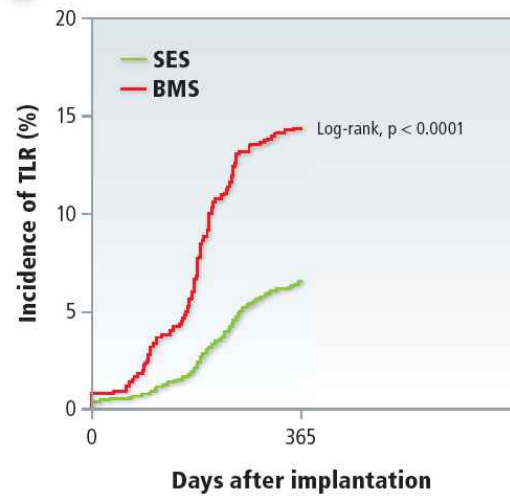
	30 Days	1 Yr.	2 Yrs.	3 Yrs.	4 Yrs.
Cumulative incidences	0.37%	0.62%	0.83%	1.16%	1.54%
n of pts at risk	12824	12632	11892	9646	5392

Events: Not yet fully adjudicated

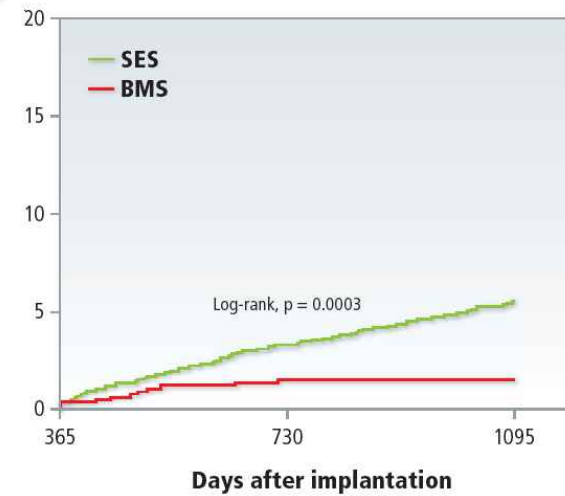
Incidences of TLR: SES vs. BMS

Off-label indication

A *Within the First Year*



B *Beyond 1 Year*

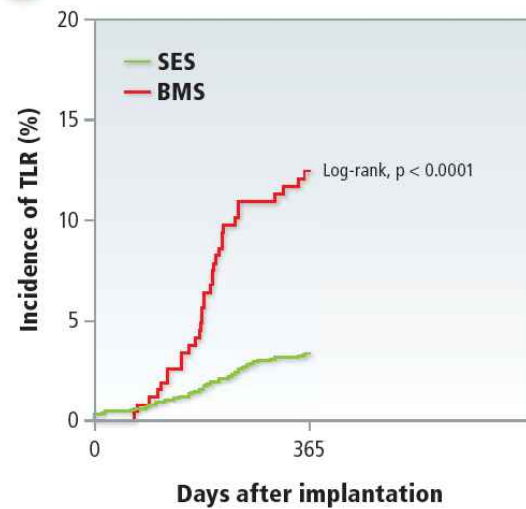


Days after implantation	0	365	365	730	1095
Incidence of TLR					
SES	0%	6.6%	0%	2.9%	5.1%
BMS	0%	14.8%	0%	1.2%	1.2%
Number of events					
SES	0	779	0	271	386
BMS	0	137	0	8	8
Number of lesions at risk					
SES	12368	10701	10701	7903	3574
BMS	983	757	757	555	262

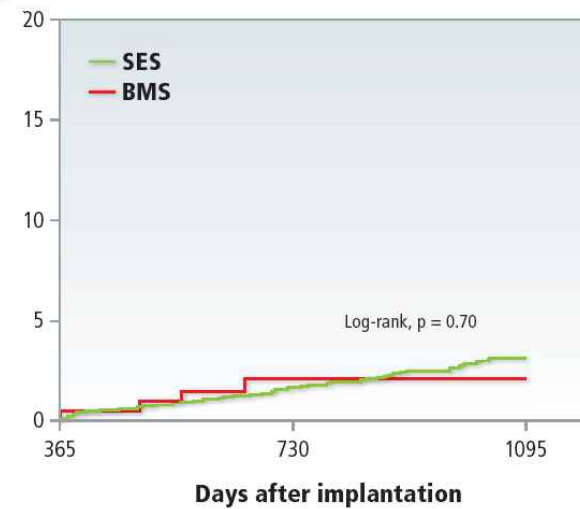
Incidences of TLR: SES vs. BMS

On-label indication

A *Within the First Year*



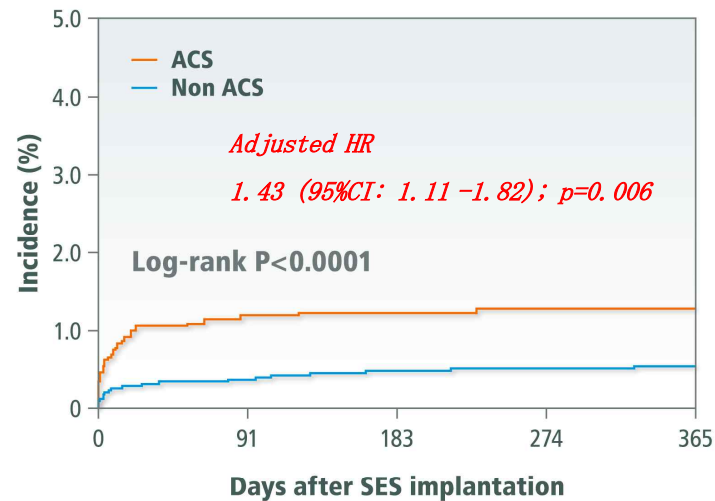
B *Beyond 1 Year*



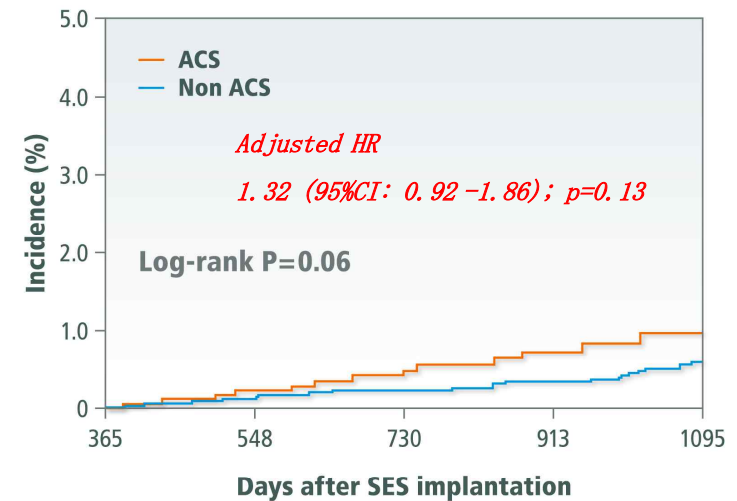
Days after implantation	0	365	365	730	1095
Incidence of TLR					
SES	0%	3.3%	0%	1.7%	3.3%
BMS	0%	12.3%	0%	2.1%	2.1%
Number of events					
SES	0	147	0	63	97
BMS	0	32	0	4	4
Number of lesions at risk					
SES	4682	4243	4243	3239	1480
BMS	276	223	223	166	67

Stent Thrombosis (Definite or Probable) ACS vs. Non-ACS

(A) Event rate within 1 year



(B) Event rate beyond 1 year

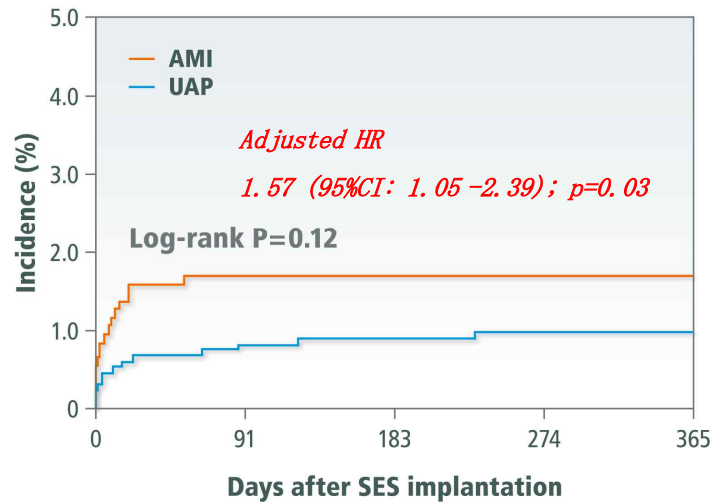


Days after SES implantation	0	91	183	365
Cumulative incidence, ACS		1.2%	1.2%	1.3%
Number of events		27	28	29
Number of patients at risk	2308	2193	2146	2061
Cumulative incidence, Non-ACS		0.4%	0.5%	0.5%
Number of events		31	39	45
Number of patients at risk	8470	8313	8201	7927

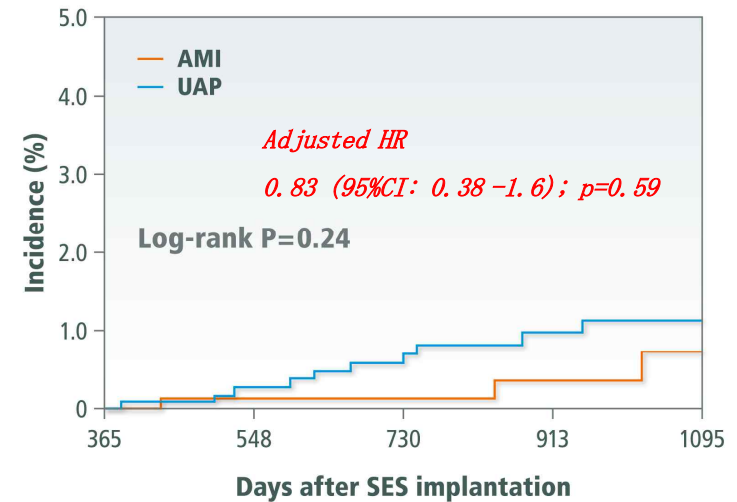
Days after SES implantation	365	730	1095
Cumulative incidence, ACS		0.4%	1.0%
Number of events		7	11
Number of patients at risk	2061	1526	643
Cumulative incidence, Non-ACS		0.2%	0.6%
Number of events		16	29
Number of patients at risk	7927	6123	2920

Stent Thrombosis (Definite or Probable) AMI vs. UAP

(A) Event rate within 1 year



(B) Event rate beyond 1 year

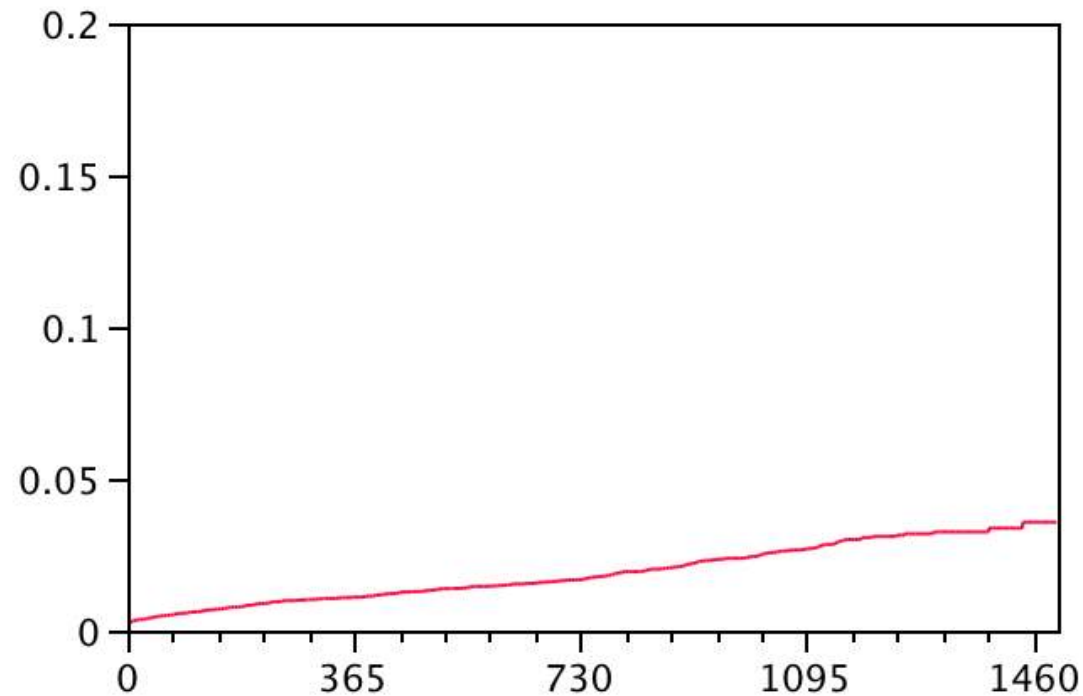


Days after SES implantation	0	91	183	365
Cumulative incidence, AMI		1.7%	1.7%	1.7%
Number of events		16	16	16
Number of patients at risk	953	888	866	825
Cumulative incidence, UAP		0.8%	0.9%	1.0%
Number of events		11	12	13
Number of patients at risk	1355	1306	1281	1236

Days after SES implantation	365	730	1095
Cumulative incidence, AMI		0.1%	0.7%
Number of events		1	3
Number of patients at risk	825	600	234
Cumulative incidence, UAP		0.6%	1.2%
Number of events		6	10
Number of patients at risk	1236	926	409

Myocardial Infarction

J-CYPHER Registry



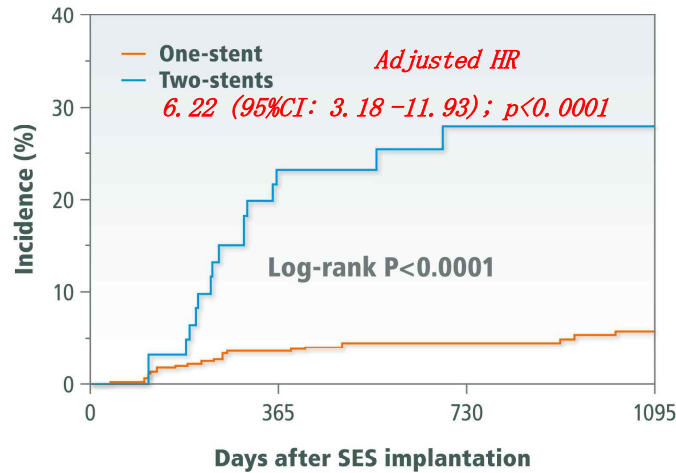
Follow-up interval (Days)

	30 Days	1 Yr.	2 Yrs.	3 Yrs.	4 Yrs.
Cumulative incidences	0.4%	1.1%	1.7%	2.7%	3.6%
n of pts at risk	12824	12636	11856	9588	434

Events: Not yet fully adjudicated

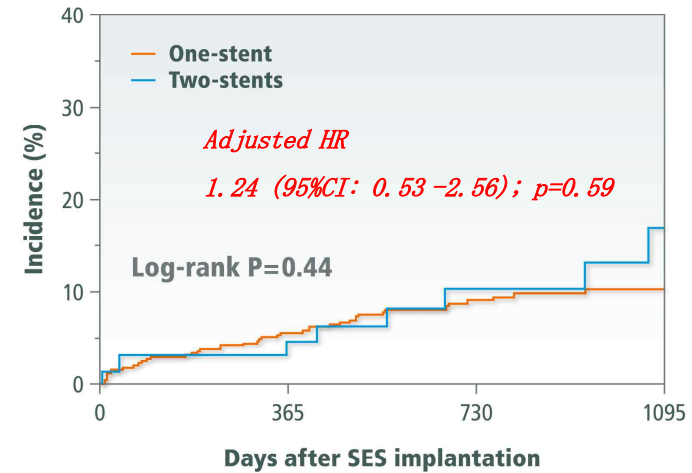
One-stent vs. Two-stents

(A) Target Lesion Revascularization



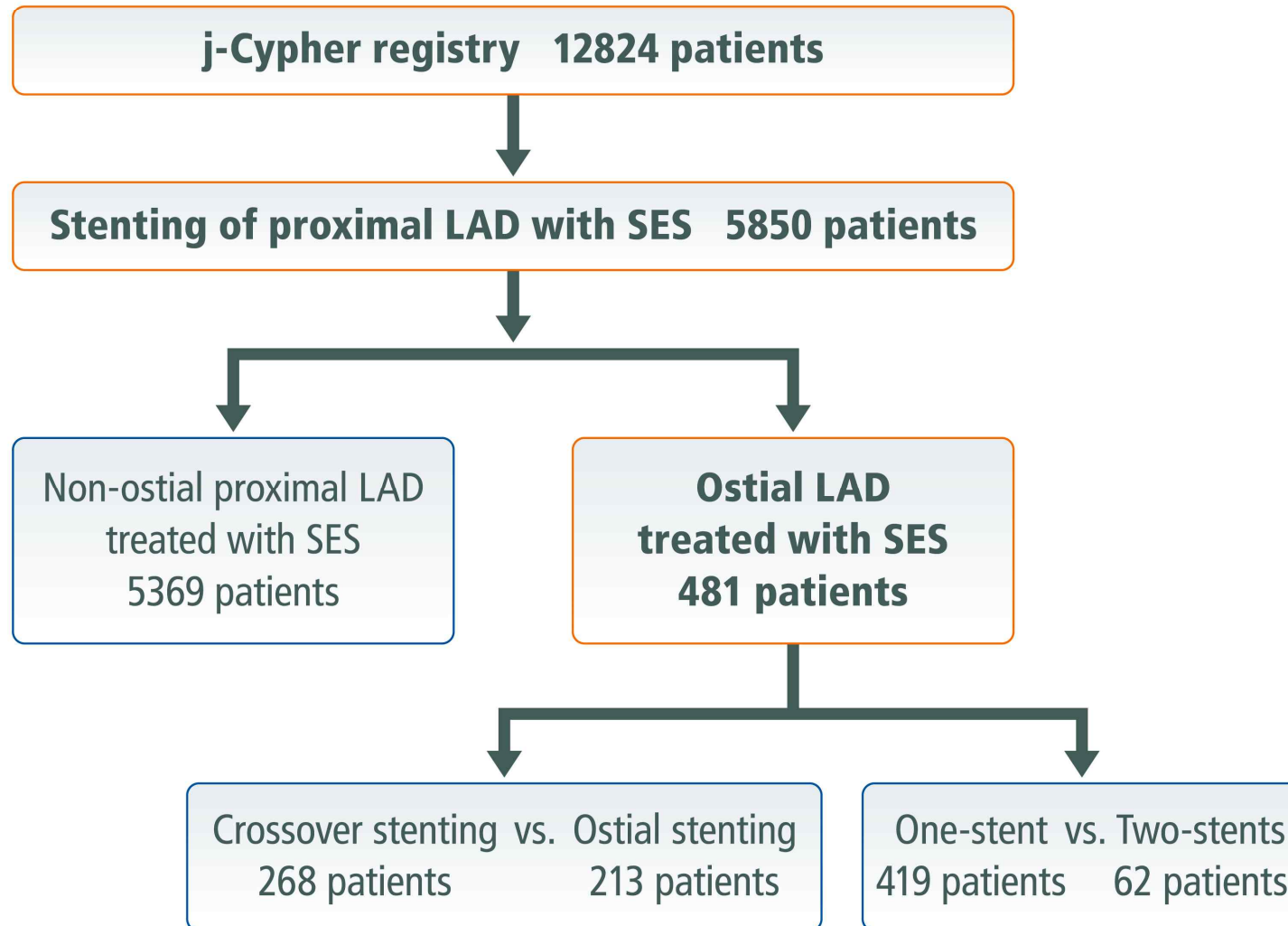
Days after SES implantation	0	365	730	1095
One-stenting				
Incidence		3.8%	4.6%	6.6%
No. of events		15	18	22
No. at risk	419	372	287	155
Two-stenting				
Incidence		23.3%	28.1%	28.1%
No. of events		14	16	16
No. at risk	62	47	30	15

(B) Death or Myocardial infarction

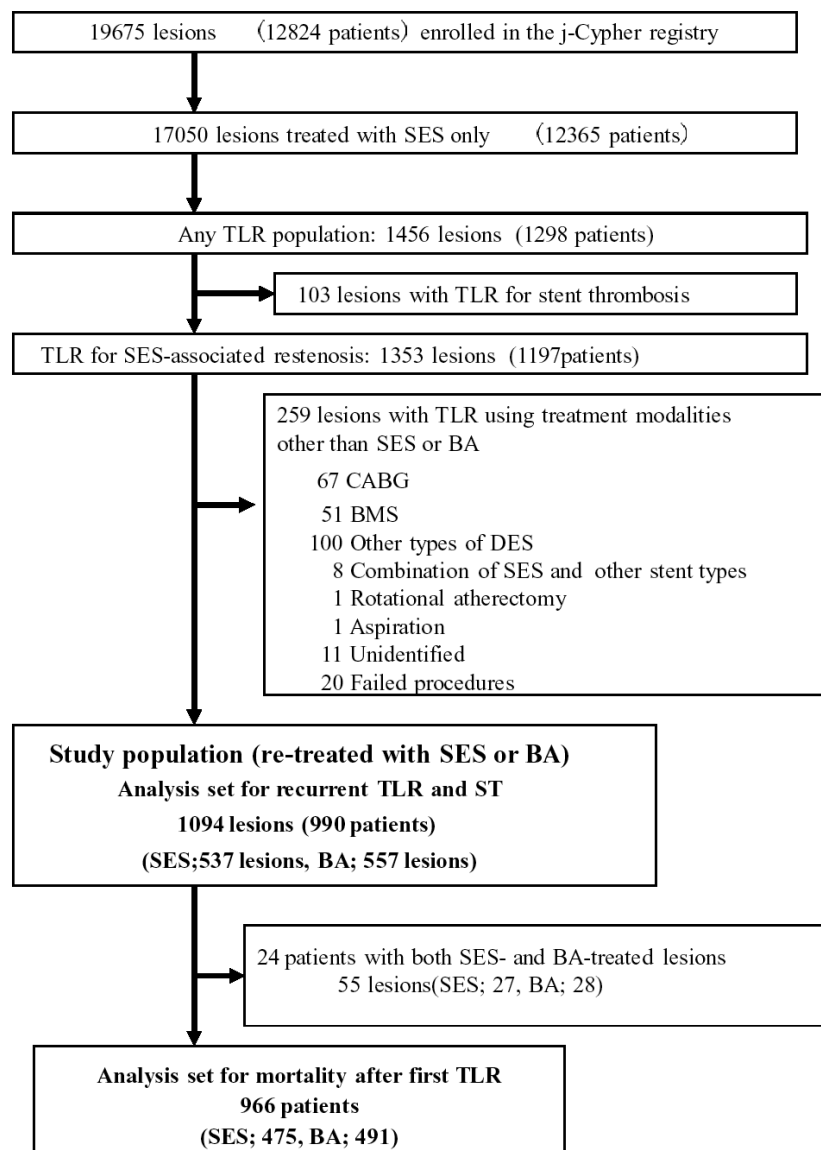


Days after SES implantation	0	365	730	1095
One-stenting				
Incidence		5.8%	9.2%	10.4%
No. of events		24	36	39
No. at risk	419	383	293	154
Two-stenting				
Incidence		4.8%	10.5%	17.2%
No. of events		3	6	8
No. at risk	62	60	44	19

Study Flow Chart



Repeated SES Implantation vs. Balloon Angioplasty



Unprotected LMCA Stenting with SES

J-CYPHER Registry

j-Cypher registry (August 2004-November 2006)
12824 patients with first registration

Main-Analysis

582 patients underwent
PCI for ULMCA
(4.5% of whole population)

Vs.

12242 patients underwent
PCI for non-ULMCA

Patients excluded:
74 patients with non-SES treatment for ULMCA
(non-stent, BMS or other type of DES)

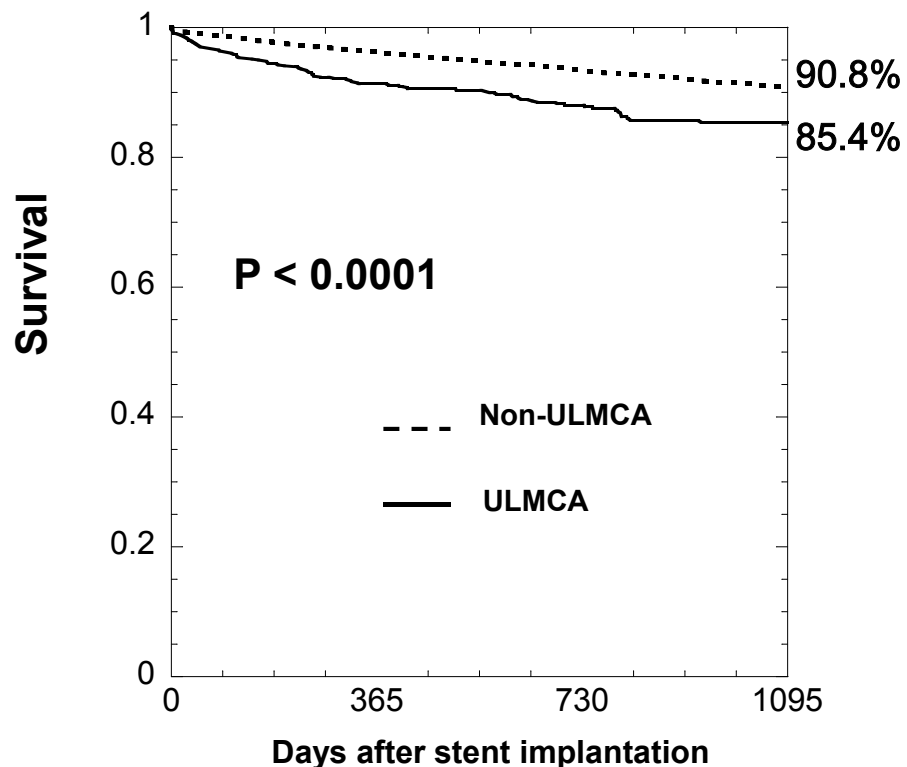
Patients excluded:
28 patients with hybrid treatment for ULMCA
(SES and BMS or other type of DES)

Patients excluded:
4 patients missing information on lesion location
of ULMCA or bifurcation stent strategy

Sub-Analysis

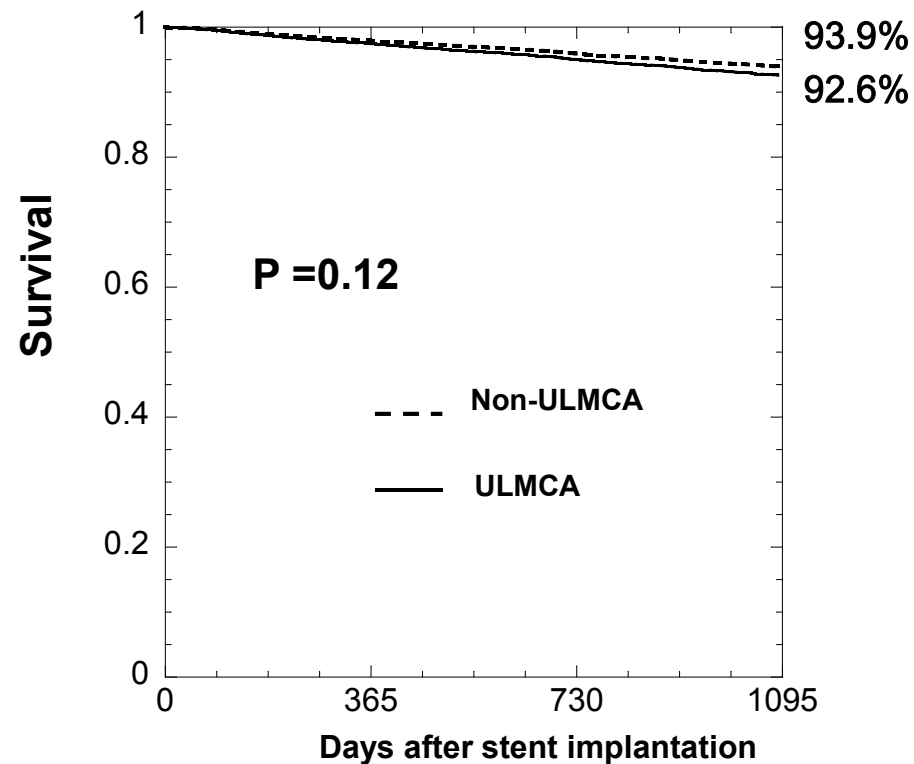
476 patients treated exclusively with SES for ULMCA

Unadjusted survival curve



Interval(Days)	0	365	730	1095
Non-ULMCA				
Incidence (%)		3.8	6.6	9.2
No. at risk	12242	11394	8737	4055
ULMCA				
Incidence (%)		8.7	9.2	14.8
No. at risk	582	517	396	188

Adjusted survival curve



Interval(Days)	0	365	730	1095
Non-ULMCA				
Incidence (%)		2.1	4.1	6.1
ULMCA				
Incidence (%)		2.5	5.0	7.4

*Incidence of stent thrombosis in two large registries in Europe and Japan:
a patient level data analysis from the Bern -Rotterdam and J-CYPHER registries*

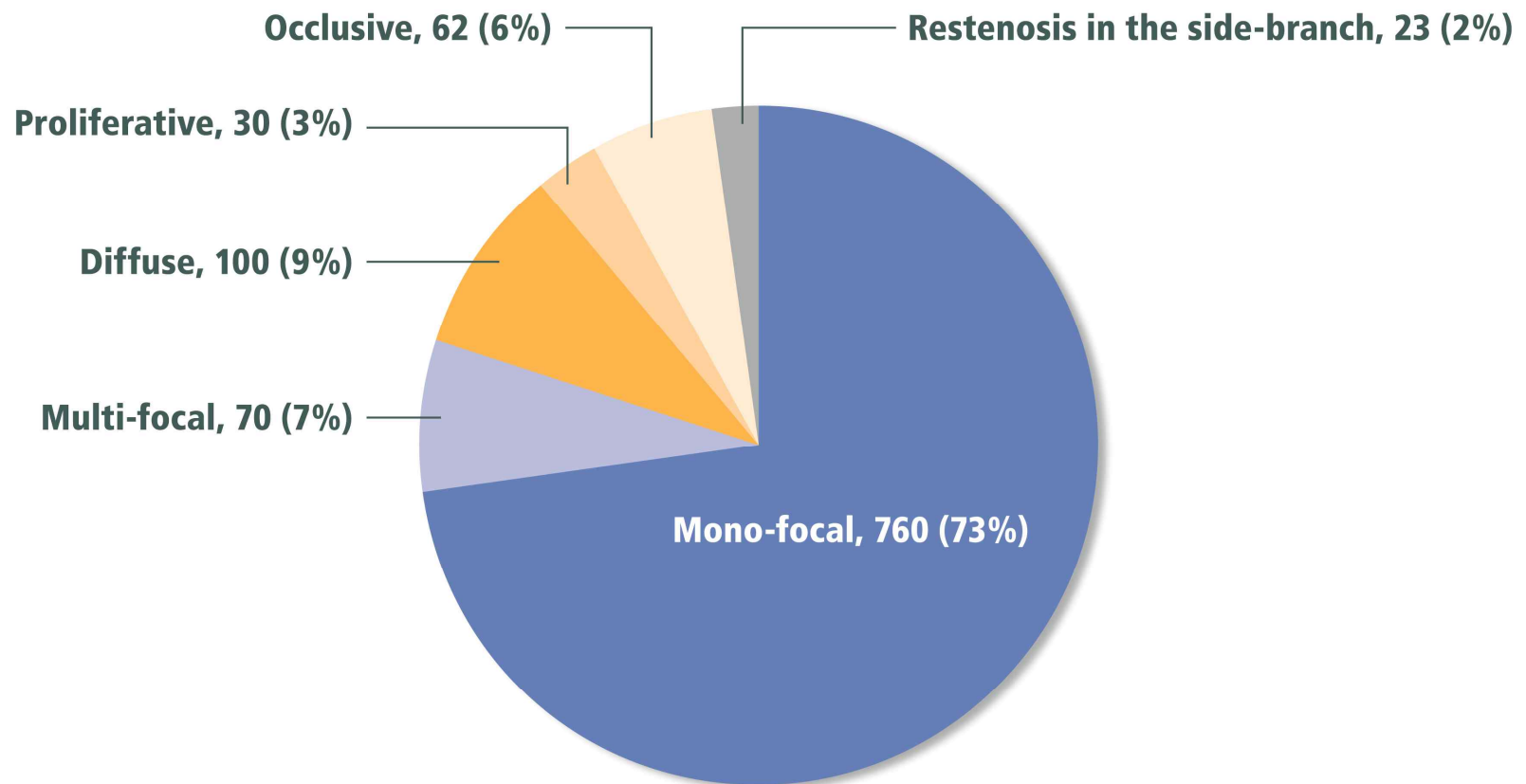
Yoshinobu Onuma MD^{1*}; Takeshi Kimura MD²; Stephan Windecker MD³; Ron van Domburg PhD¹;
Kazuaki Mitsudo MD⁴ ; Patrick Serruys MD, PhD¹

On behalf of investigators of the Bern-Rotterdam and J-Cypher Registries

Results: ~~The p~~Patients in BR were **younger (BR-62.8 vs. JC-68.3 year old, p<0.01)**, and more frequently had ~~current smoking habit~~**smokers (37% vs. 20%, p<0.001)**, had a higher rate of and-dyslipidemia (51% vs. 45%, p<0.001) and presented more frequently presented with acute coronary syndromes (55% vs. 24%, p<0.001) ~~than the patients in JC,~~ Conversely, while JC patients more frequently had **diabetes (16% vs. 42%, p<0.001)** and **hypertension (47% vs. 75%, p<0.001)** ~~than BR patients.~~ At 2 years, definite stent thrombosis ST and mortality rate were significantly lower in JC than BR (**ST: 0.8% vs. 2.1%, logrank-p<0.001, mortality: 6.3% vs. 7.5 %, logrank-p=0.02**), while TVR rate was significantly higher in JC than in BR (15.7% vs. 10.7%, logrank-p<0.01). **After adjustment of pre-procedural characteristics using Cox regression model, definite stent thrombosis was remained lower in JC than in BR (HR 0.56 [95%_CI 0.39-0.79]).**

Repeated SES Implantation vs. Balloon Angioplasty

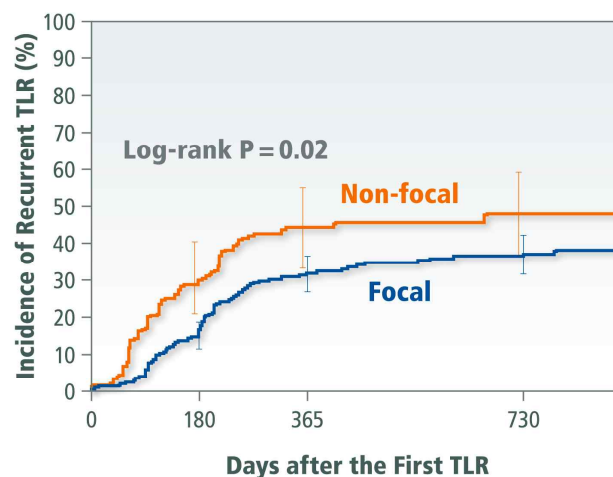
Patterns of SES-associated Restenosis



Incidences of Recurrent TLR

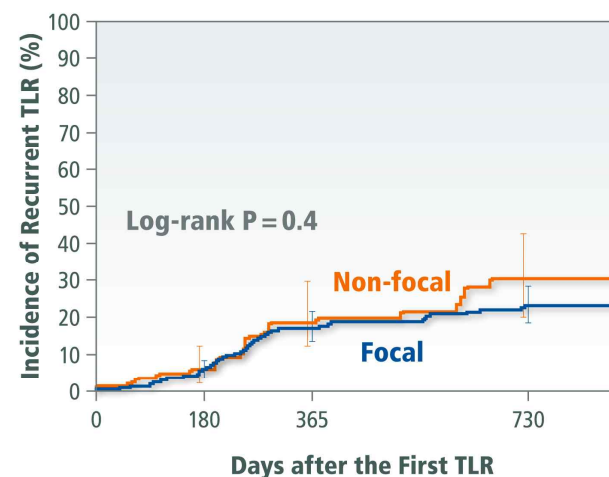
Repeated SES Implantation vs. Balloon Angioplasty

(A) BA-treated Lesions



Days after the First TLR	0	180	365	730
Non-focal				
Cumulative incidence		29.8%	43.8%	47.7%
Number of events		25	35	37
Number of lesions at risk	92	54	38	22
Focal				
Cumulative incidence		14.7%	31.5%	36.8%
Number of events		56	112	125
Number of lesions at risk	422	301	206	90

(B) SES-treated Lesions



Days after the First TLR	0	180	365	730
Non-focal				
Cumulative incidence		5.4%	19.5%	30.1%
Number of events		5	16	21
Number of lesions at risk	100	80	59	23
Focal				
Cumulative incidence		5.6%	16.8%	23.0%
Number of events		21	58	72
Number of lesions at risk	408	337	249	120