Long-term Safety of Drug Eluting Stent

Current Status of Stent Thrombosis Issue

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DES has Critical, Conceptual Flaw

Delayed Arterial Healing : Incomplete and Delayed Endothelialization

Pathology Findings:
SES and BMS from Different Coronary Arteries in the Same Patient (delayed healing)

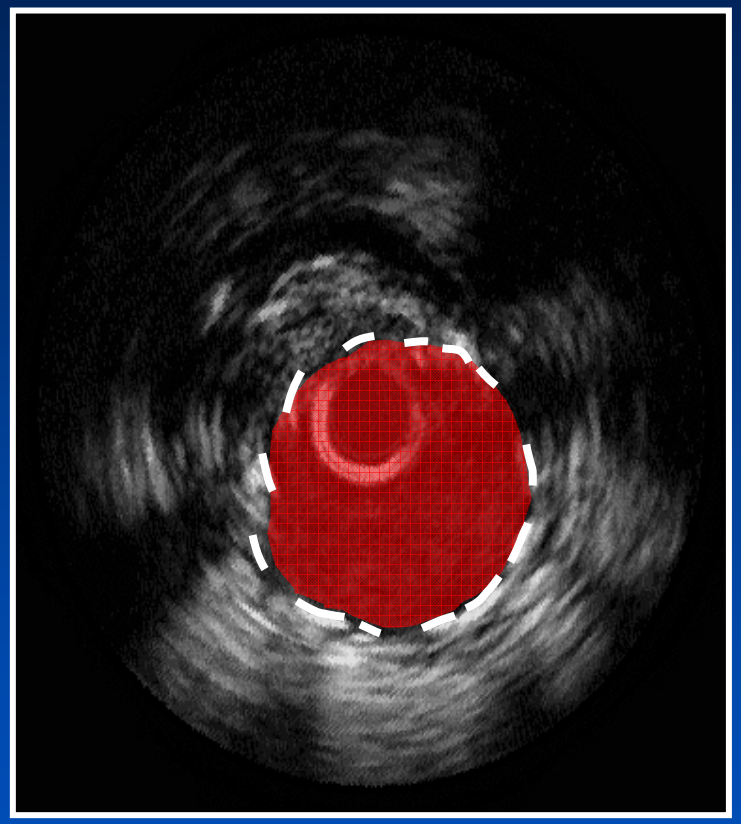
BMS 24 Months after Deployment

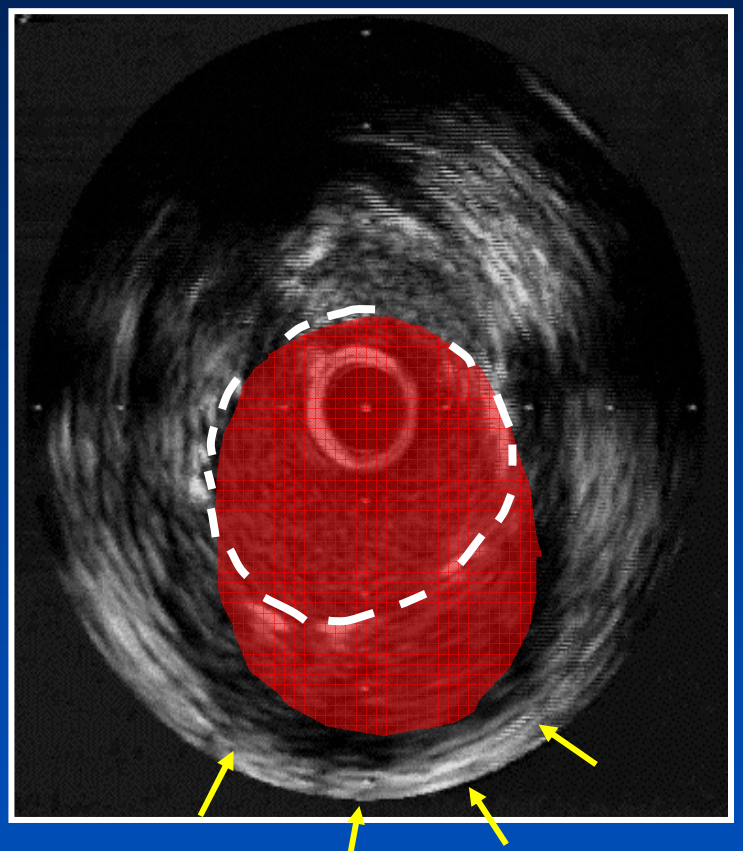
Cypher 16 Months after Deployment

G. Guagliumi et al. Circulation 2003;107:1340

Late Incomplete Apposition

Drug-eluting stent group

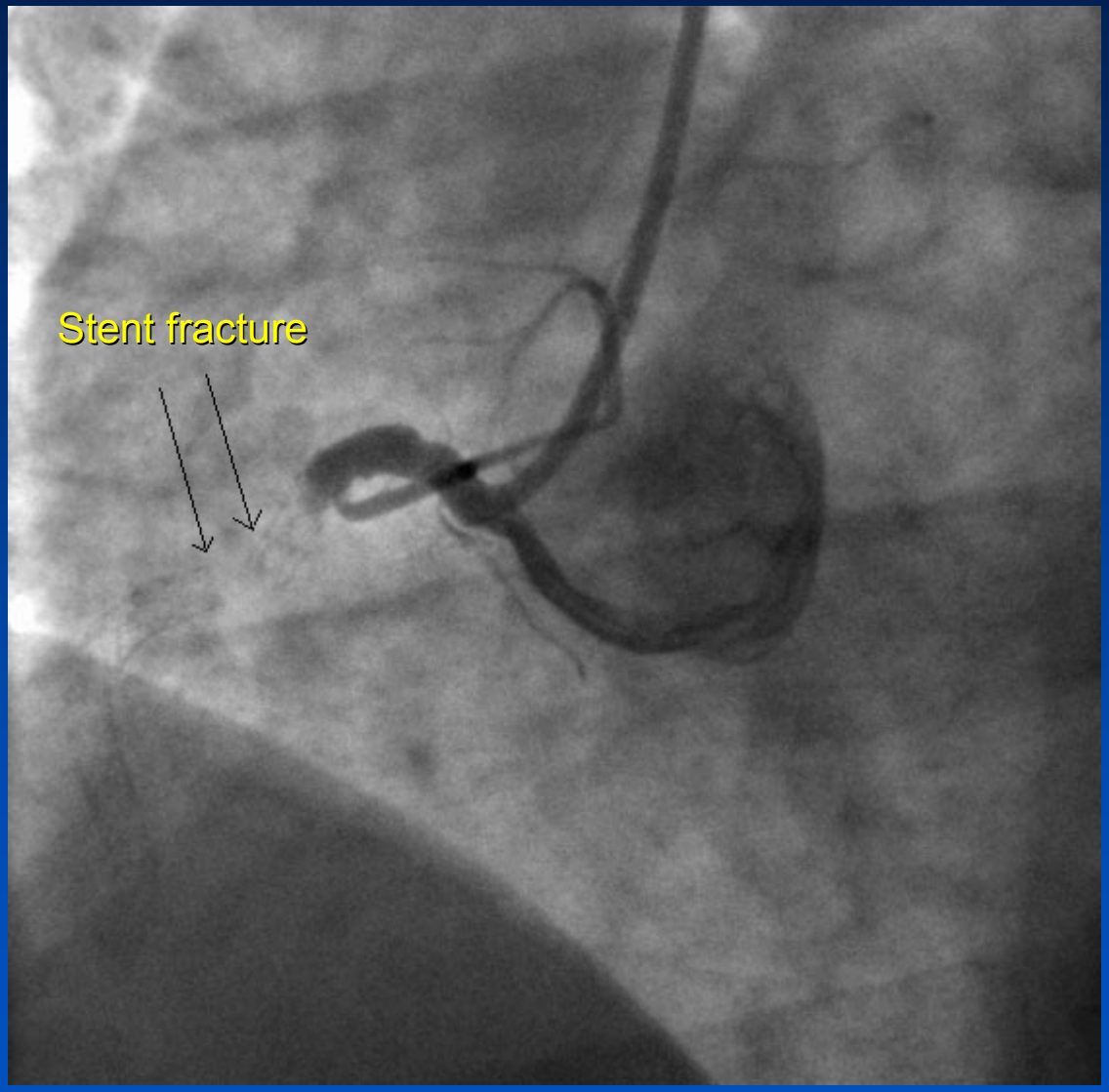




Baseline **Follow-up**

… vulnerable struts at the time when antiplatelets may not be taken

Stent fracture : Stent thrombosis 20 months after sirolimus-eluting stent implantation



Lee MS et al. AJC/TCT2006

Independent Predictors of ST
Multivariate Analysis

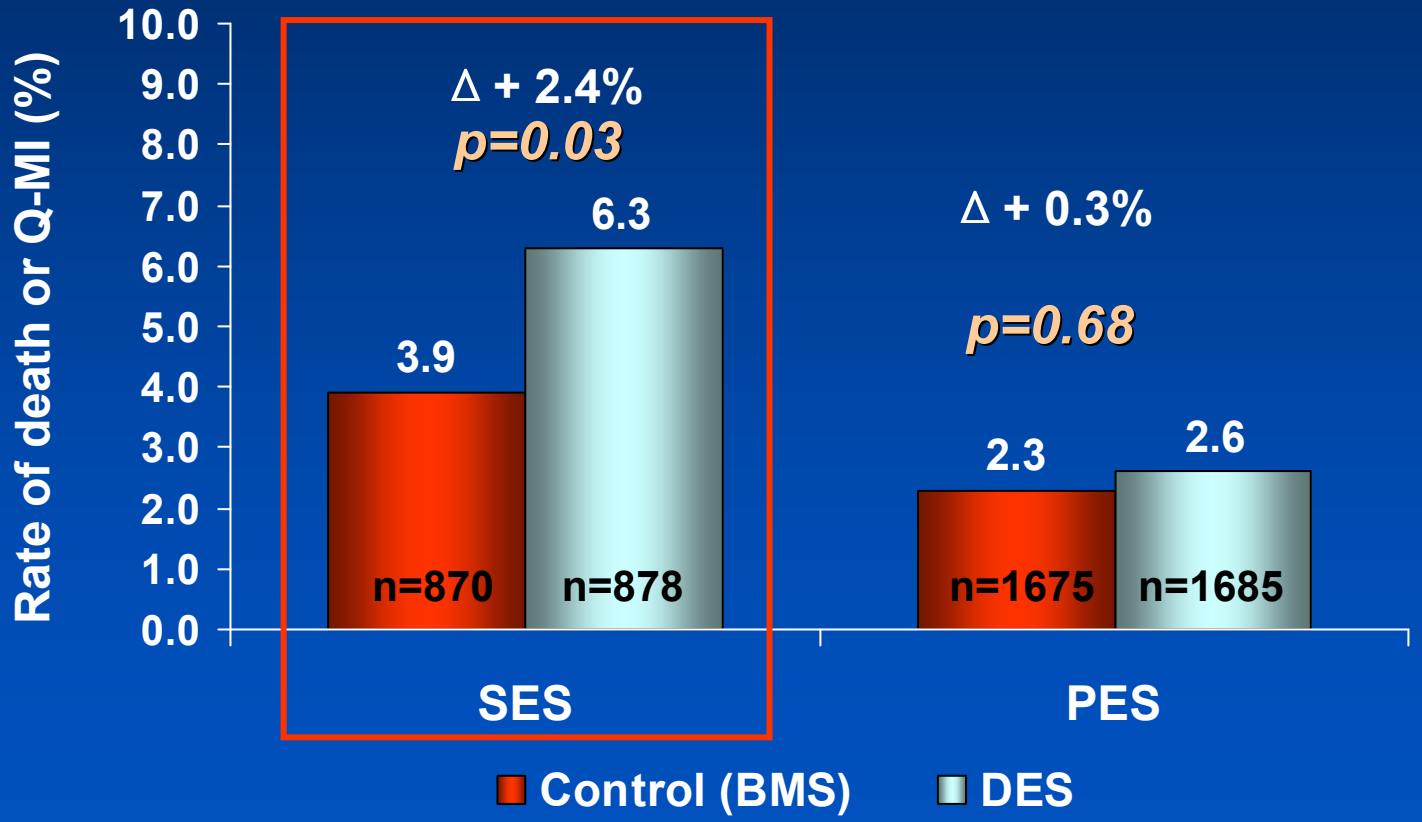
Variables	(95% CI)	P
Acute / subacute stent thrombosis		
• Primary stenting in acute MI	74.22 (5.89-861.45)	0.001
• Total stent length	1.04 (1.01-1.08)	0.048
Late stent thrombosis		
• Premature interruption of antiplatelet therapy	24.79 (7.51-81.84)	<0.001
• Renal failure	8.40 (1.81-39.09)	<0.001
Total stent thrombosis		
• Premature interruption of antiplatelet therapy	19.21 (5.63-65.51)	<0.001
• Primary stenting in acute MI	12.24 (1.67-89.71)	0.014
• Total stent length	1.02 (1.001-1.04)	0.037

Park, DW. AJC 2006;98:353-356

Stent Thrombosis:

First Issue
about DES safety

Increased Incidence of All Death or MI
All randomized studies up to latest available follow-up



Camenzind E, ESC 2006

Meta analysis
of RCTs and Registry Data

Academic Research Consortium (ARC) Proposed Standard Definitions

- **Definite/Confirmed**
  - Acute coronary syndrome AND
  - [Angiographic confirmation of thrombus or occlusion
    OR
  - Pathologic confirmation of acute thrombosis]
- **Probable**
  - Unexplained death within 30 days
  - Target vessel MI without angiographic confirmation of thrombosis or other identified culprit lesion
- **Possible**
  - Unexplained death after 30 days

Meta analysis
of RCTs and Registry Data

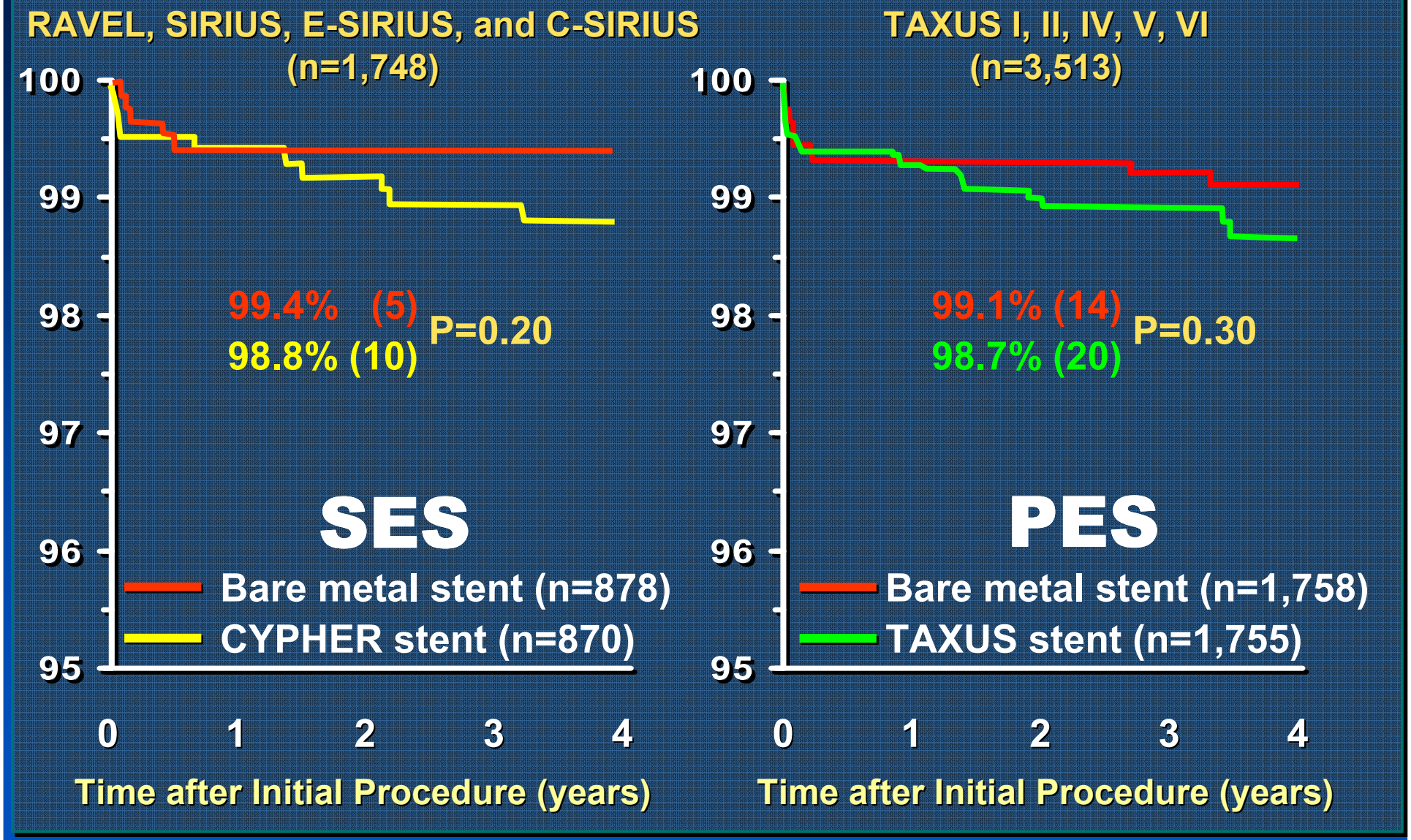
Series	Analysis	No. of patients	Comparison	F/U period	Death or MI difference
Spaulding et al	4 RCTs	878 / 870	SES / BMS	4	No
Kastrati et al	14 RCTs	2486 / 2472	SES / BMS	4	No
Mauri et al	8 RCTs	878 / 1400 / 2267	SES / PES / BMS	4	No
Stone et al	9 RCTs	878 / 1755/ 3513	SES / PES / BMS	4	No
Lagerqvist et al	Registry	6033/ 13738	DES / BMS	3	Yes

Five consecutive publications in NEJM 2007;356:989-1039

Meta analysis of Randomized Trials : On-Label Use (Relatively Simple Lesion)

DES vs. BMS

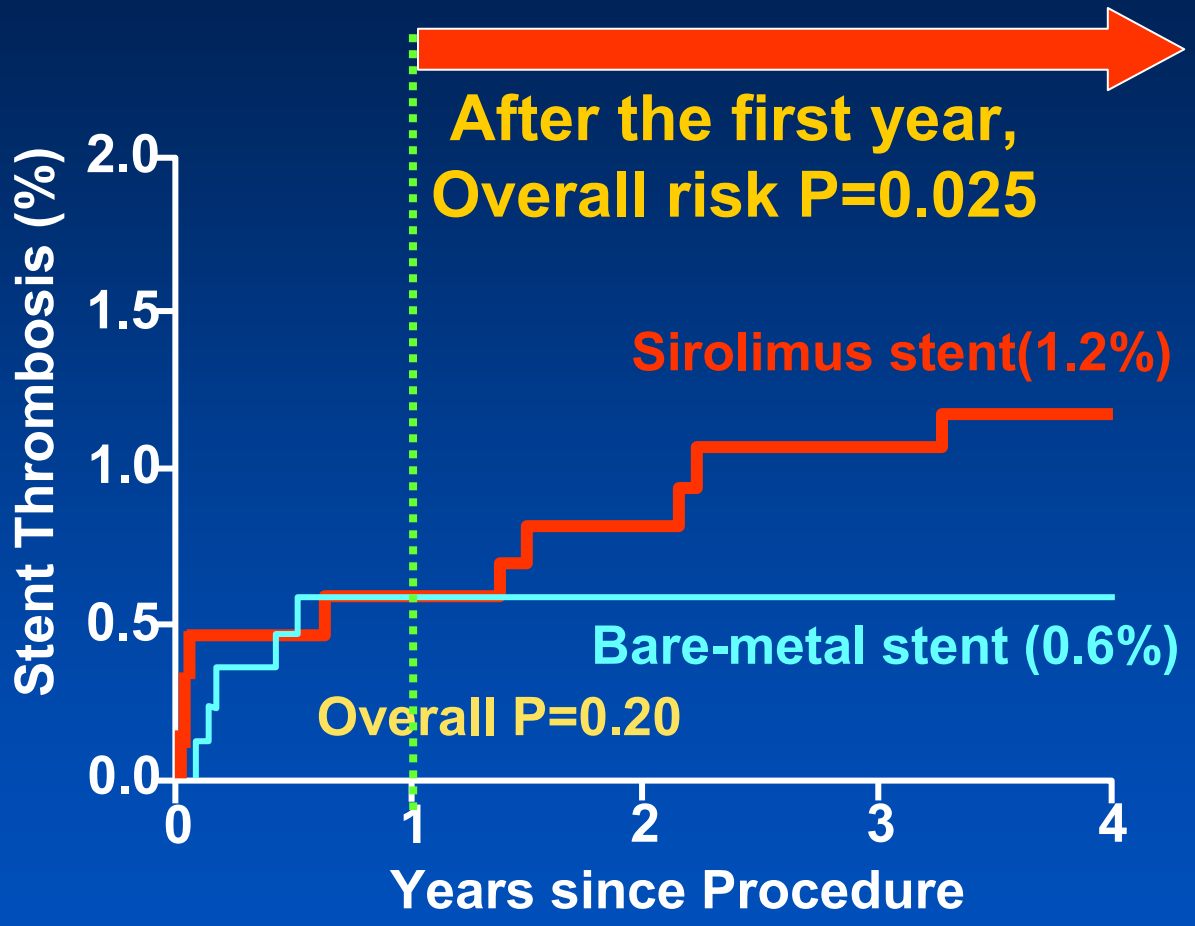
9 Prospective, Double-Blind, Randomized Trials
Freedom From (Protocol) Stent Thrombosis



Stone GW et al. NEJM 2007;356:998-1008

Stent Thrombosis After SES

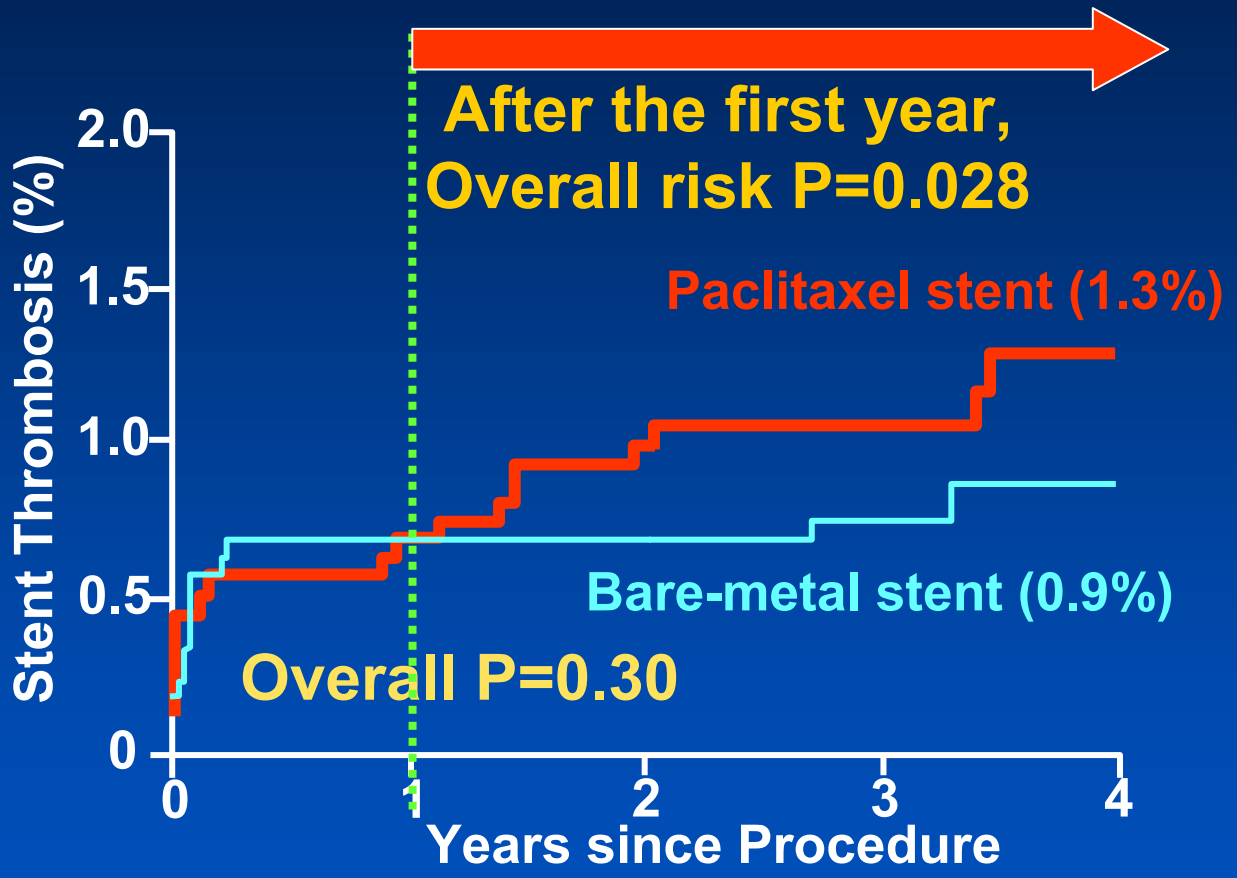
(Protocol Definition)



Stone GW et al. NEJM 2007;356:998-1008

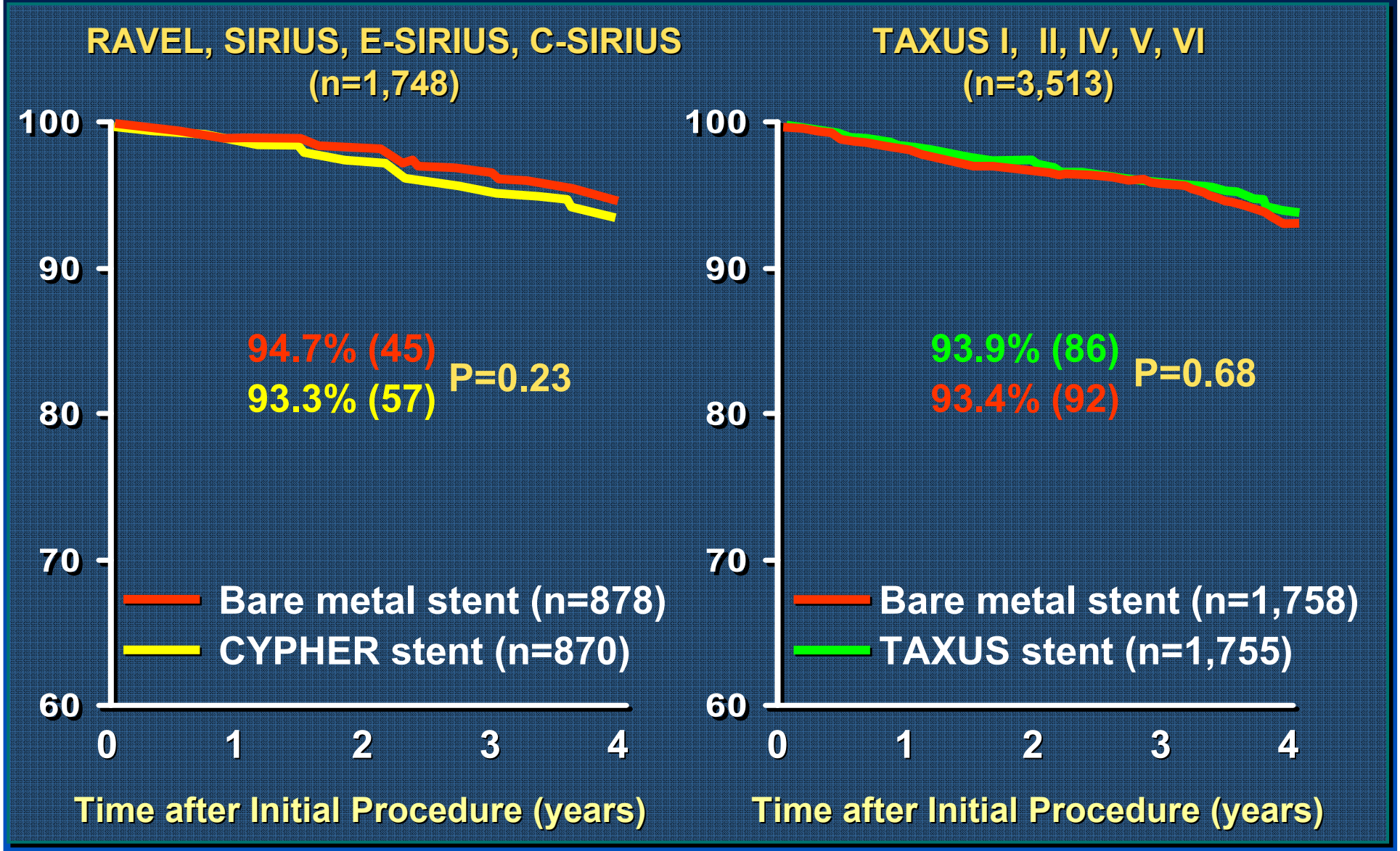
Stent Thrombosis After PES

(Protocol Definition)



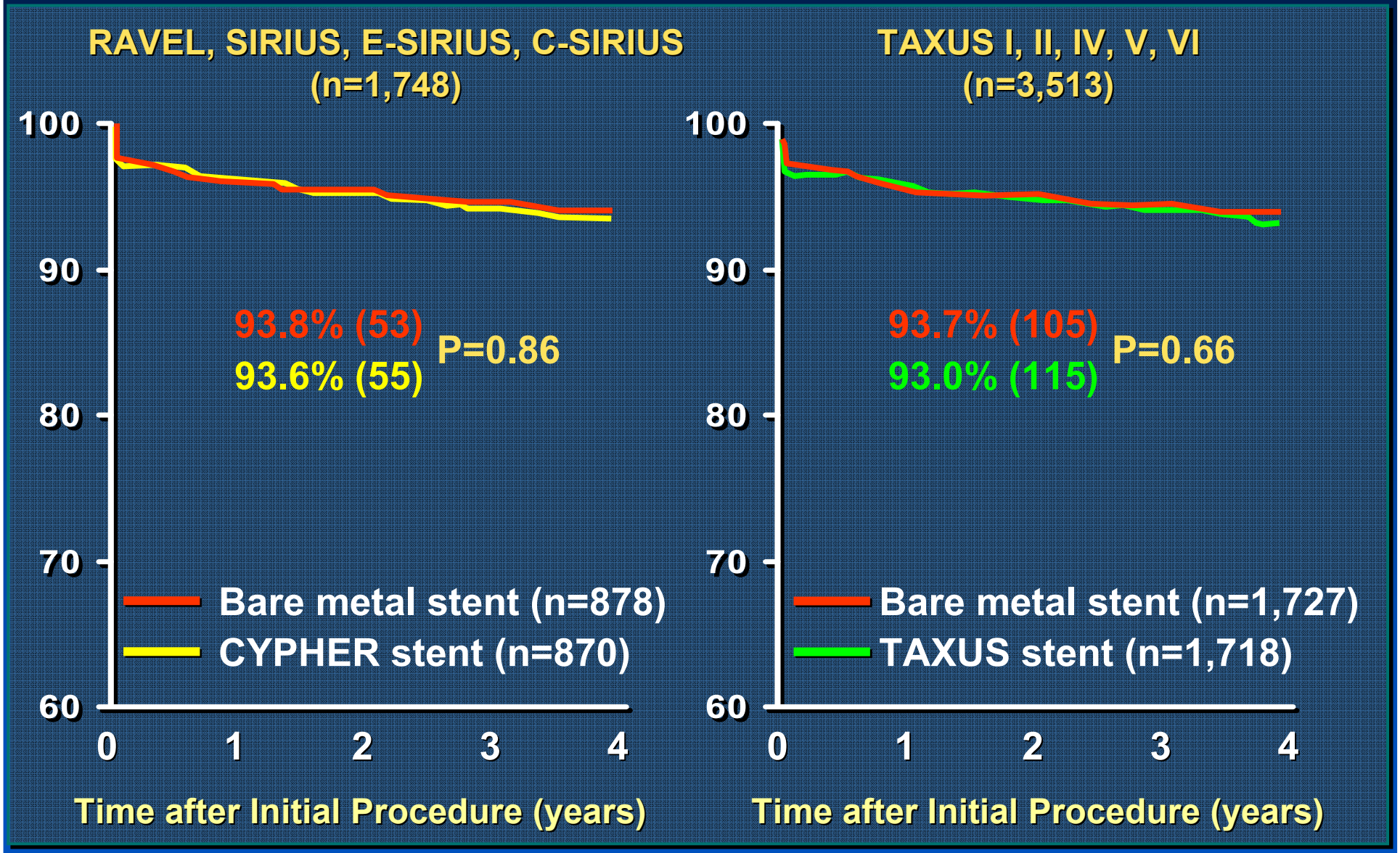
Stone GW et al. NEJM 2007;356:998-1008

Freedom From All Cause Death



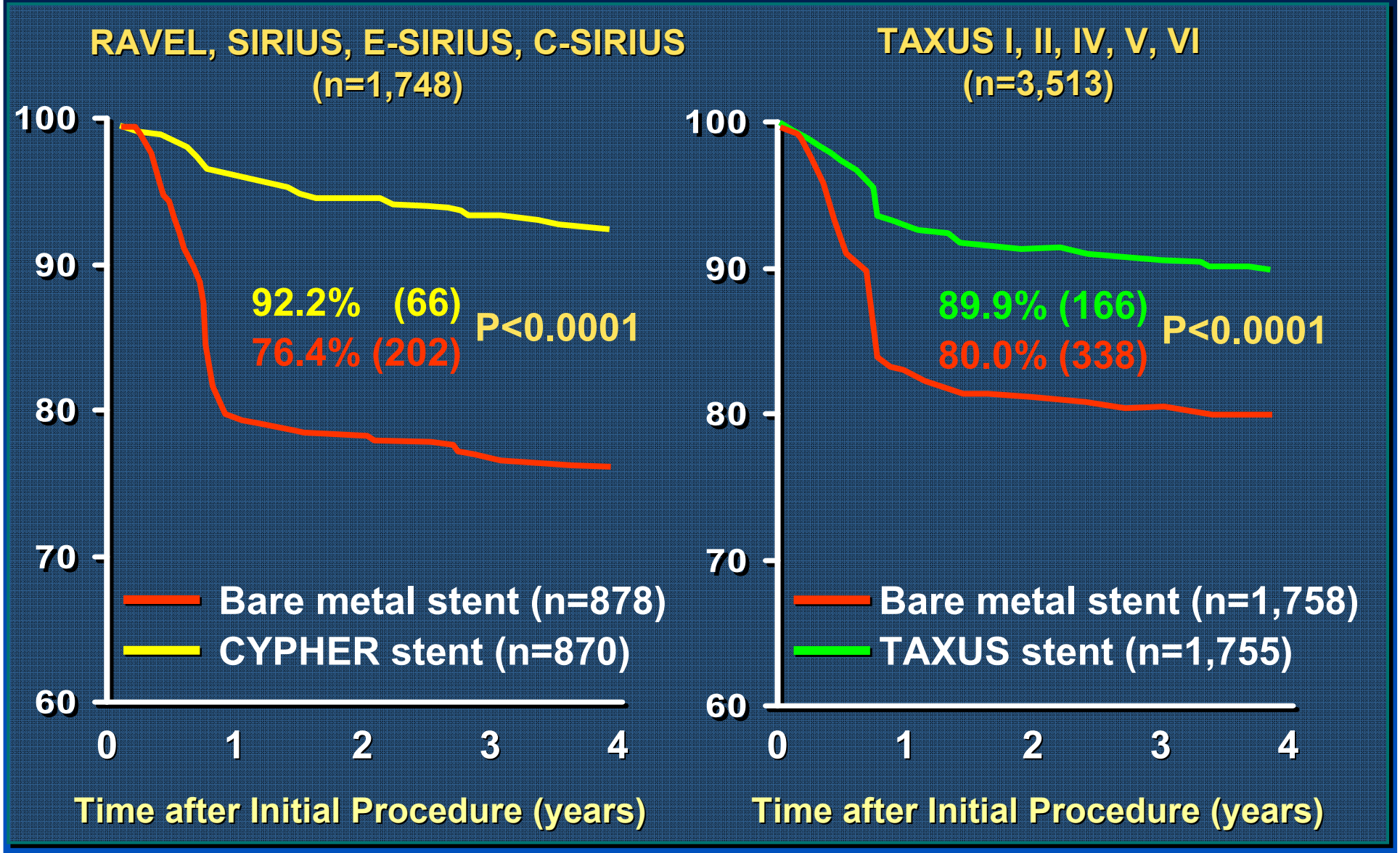
Stone GW et al. NEJM 2007;356:998-1008

Freedom From Myocardial Infarction



Stone GW et al. NEJM 2007;356:998-1008

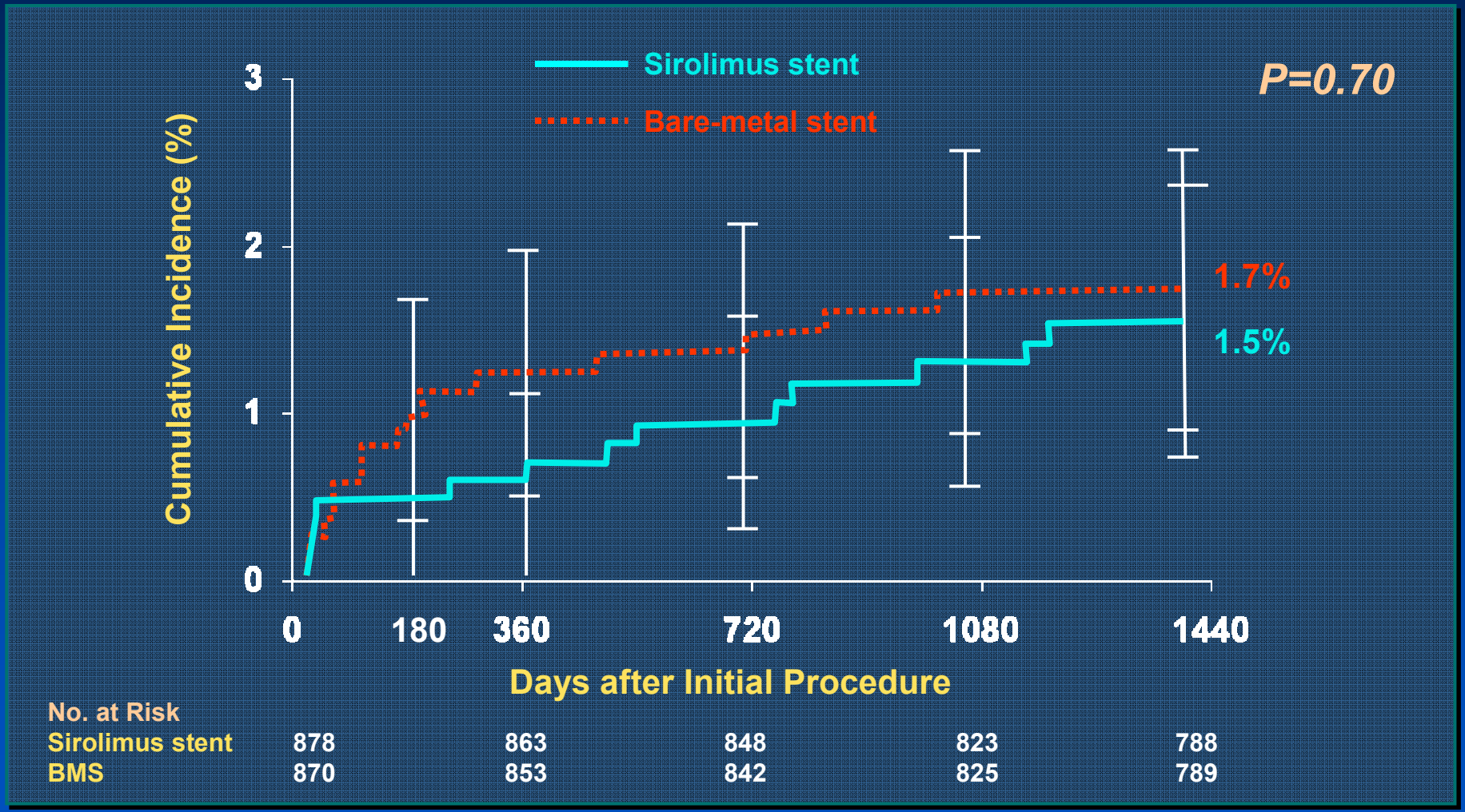
Freedom From Ischemic TLR



Stone GW et al. NEJM 2007;356:998-1008

Cumulative Incidence of Stent Thrombosis at 4 Years

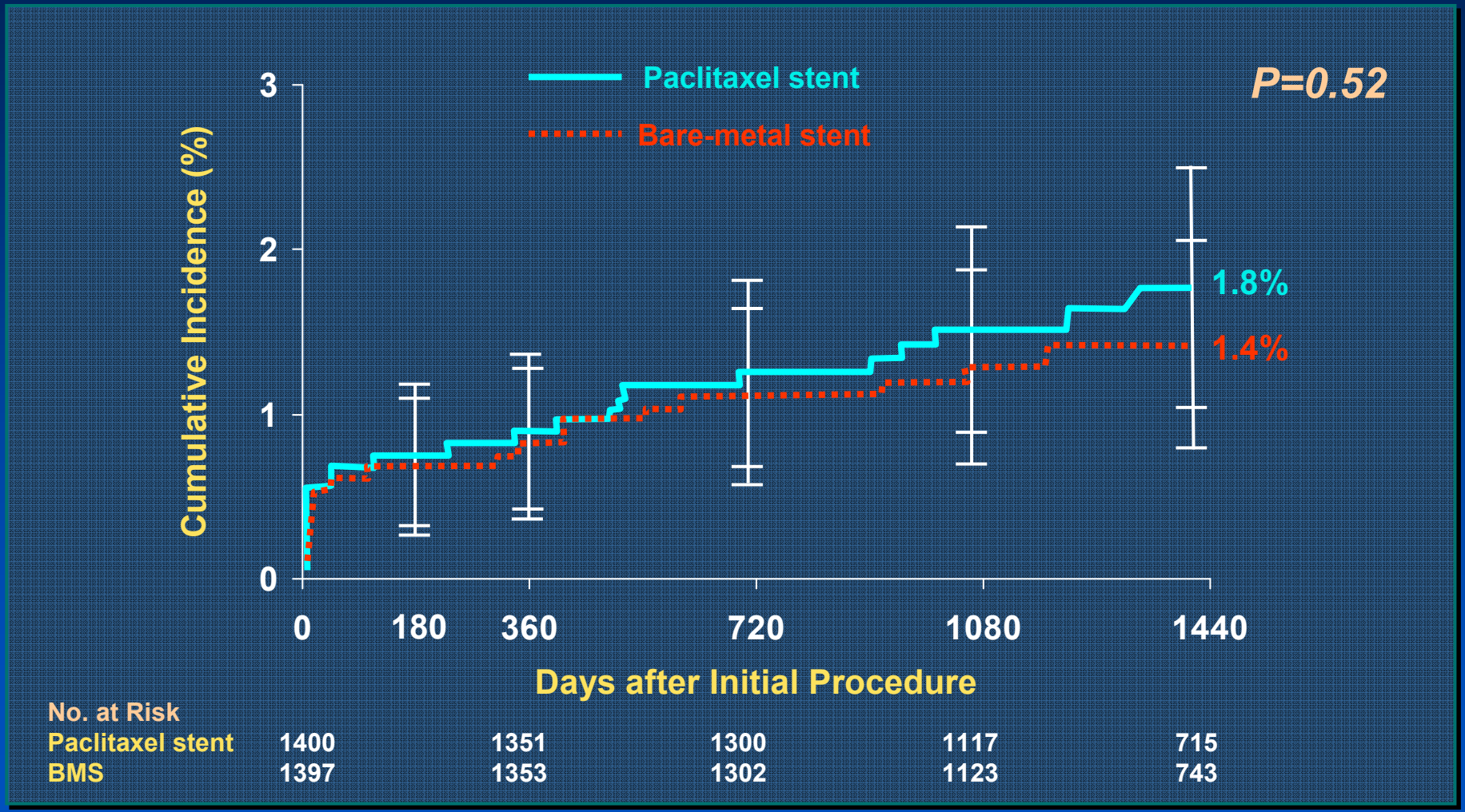
CYPHER (ARC Definite or Probable, 1° + 2°)



Mauri L, et al. *NEJM* 2007; 356: 1020-29

Cumulative Incidence of Stent Thrombosis at 4 Years

TAXUS (ARC Definite or Probable, 1° + 2°)

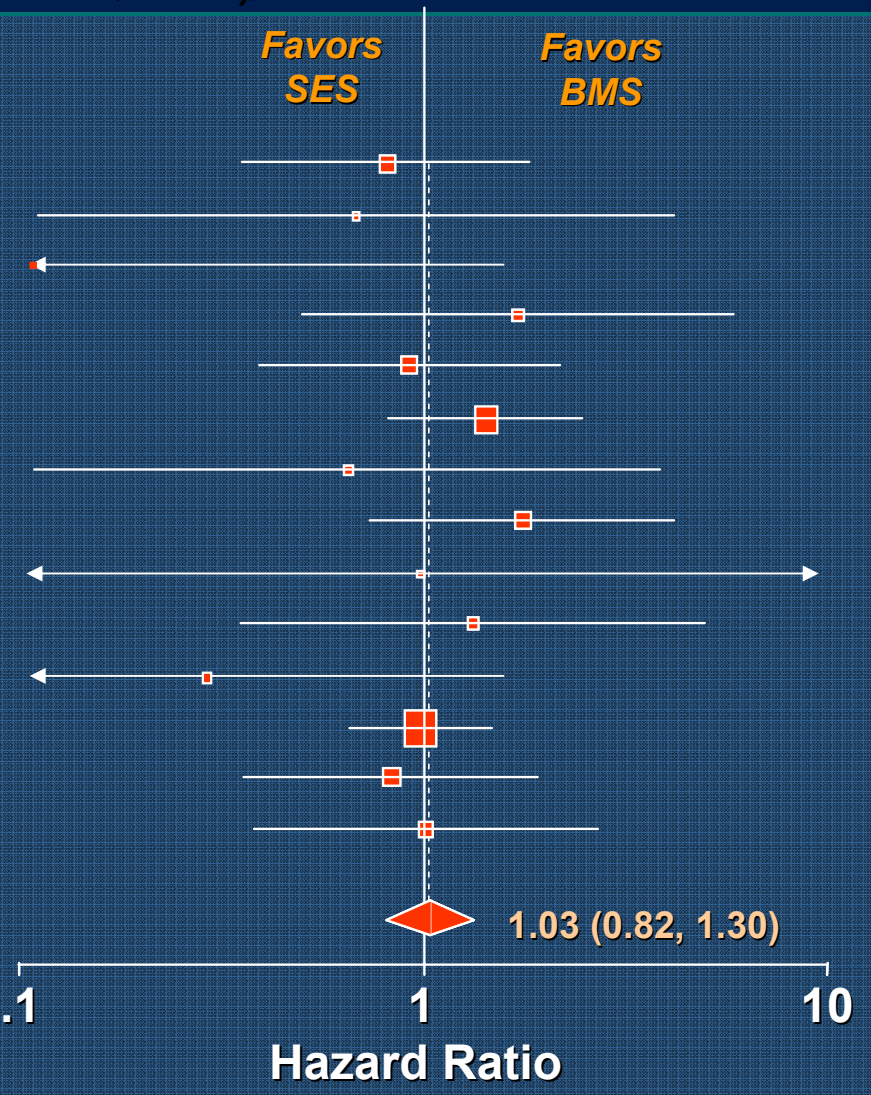


Mauri L, et al. *NEJM* 2007; 356: 1020-29

Meta analysis of Randomized Trials : On- and Off-Label Use (Relatively Complex Lesion)

Randomized Trial Mortality:
SES vs. BMS (N=4,958)

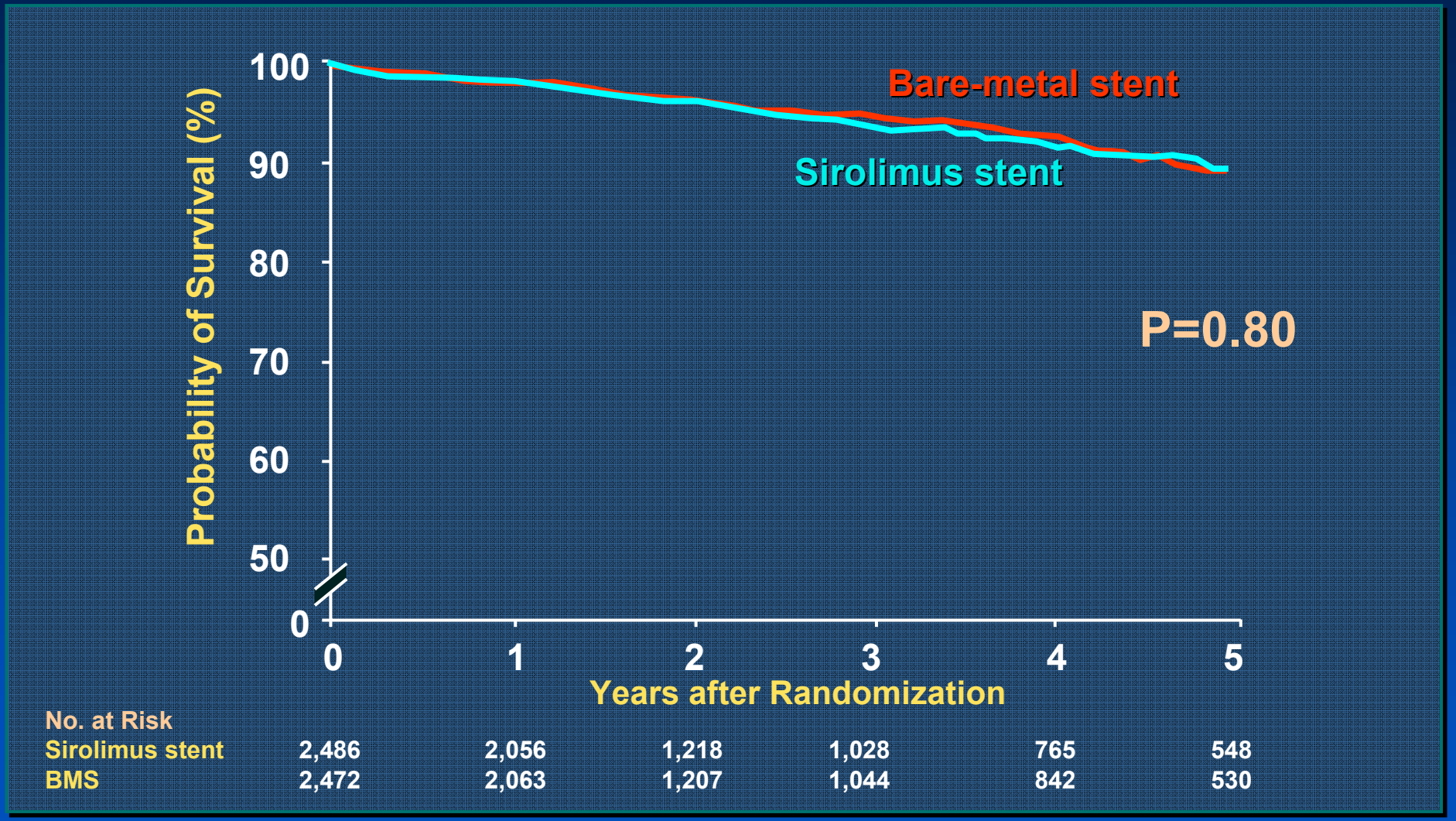
Trial (n=14)	SES group	BMSgroup
	No. of events / Total No. of patients	
BASKET	0/264	13/281
CSIRIUS	2/50	3/50
DECODE	0/54	2/29
DIABETES	7/80	5/80
ESIRIUS	10/175	11/177
PACHE	29/250	24/250
PRISON II	2/100	3/100
RAVEL	14/120	8/118
SCANDSTENT	1/163	1/159
SCORPIUS	5/95	4/98
SESAMI	3/160	7/160
SIRIUS	45/533	46/525
STRATEGY	0/87	12/88
TYPHOON	8/355	8/357
Overall	**146/2486**	**147/2472**



Test for Heterogeneity: Cochran Q=9.3 (d.f.=13) P=.75 . P (overall effect) = 0.80
Test for Inconsistency: I2 =0.0% Hazard Ratio

Kastrati A et al. NEJM 2007;356:1030-9

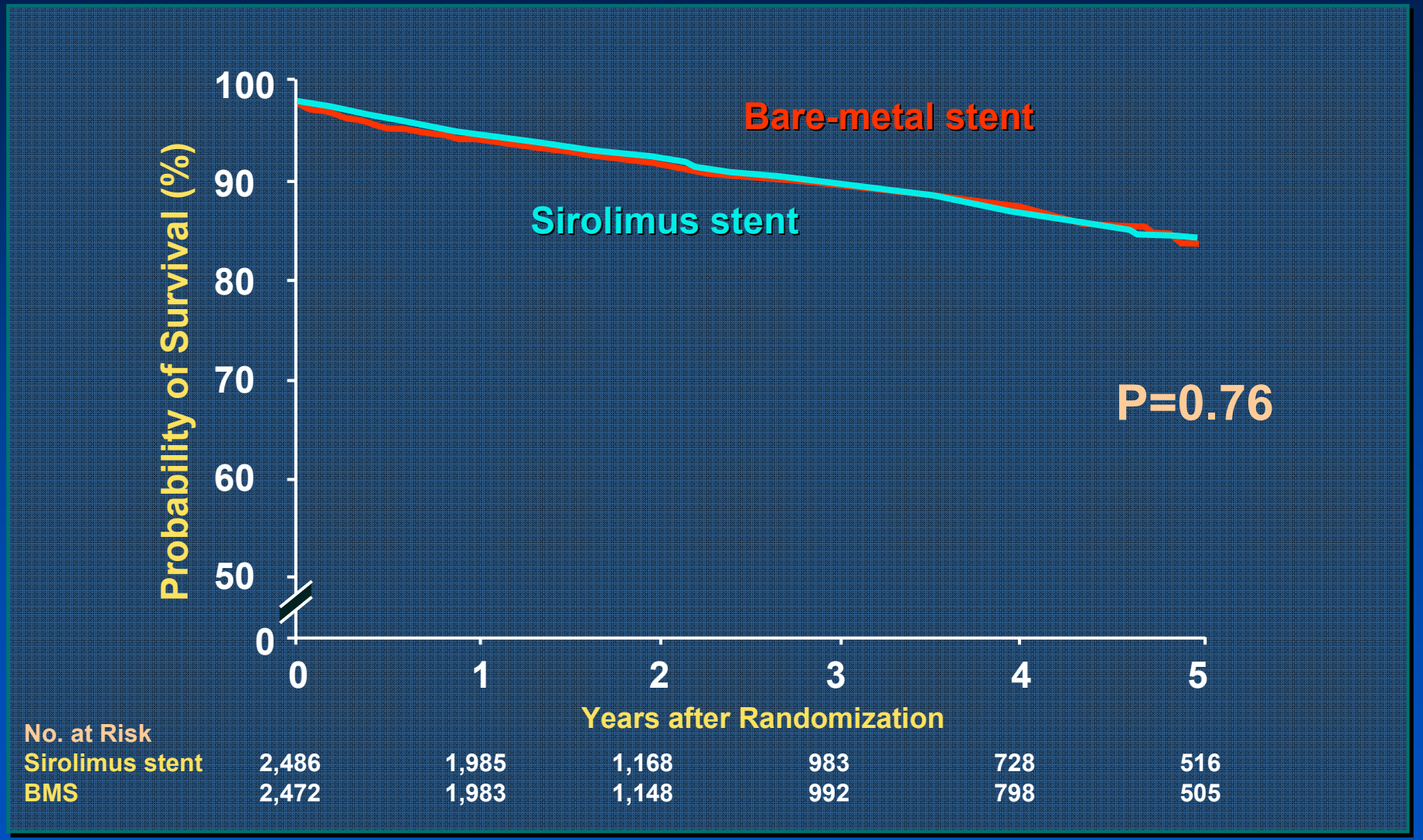
Freedom from Death
(n=4,958 randomized pts, propensity score adjusted)



Kastrati et al. *NEJM* 2007; 356: 1030-9

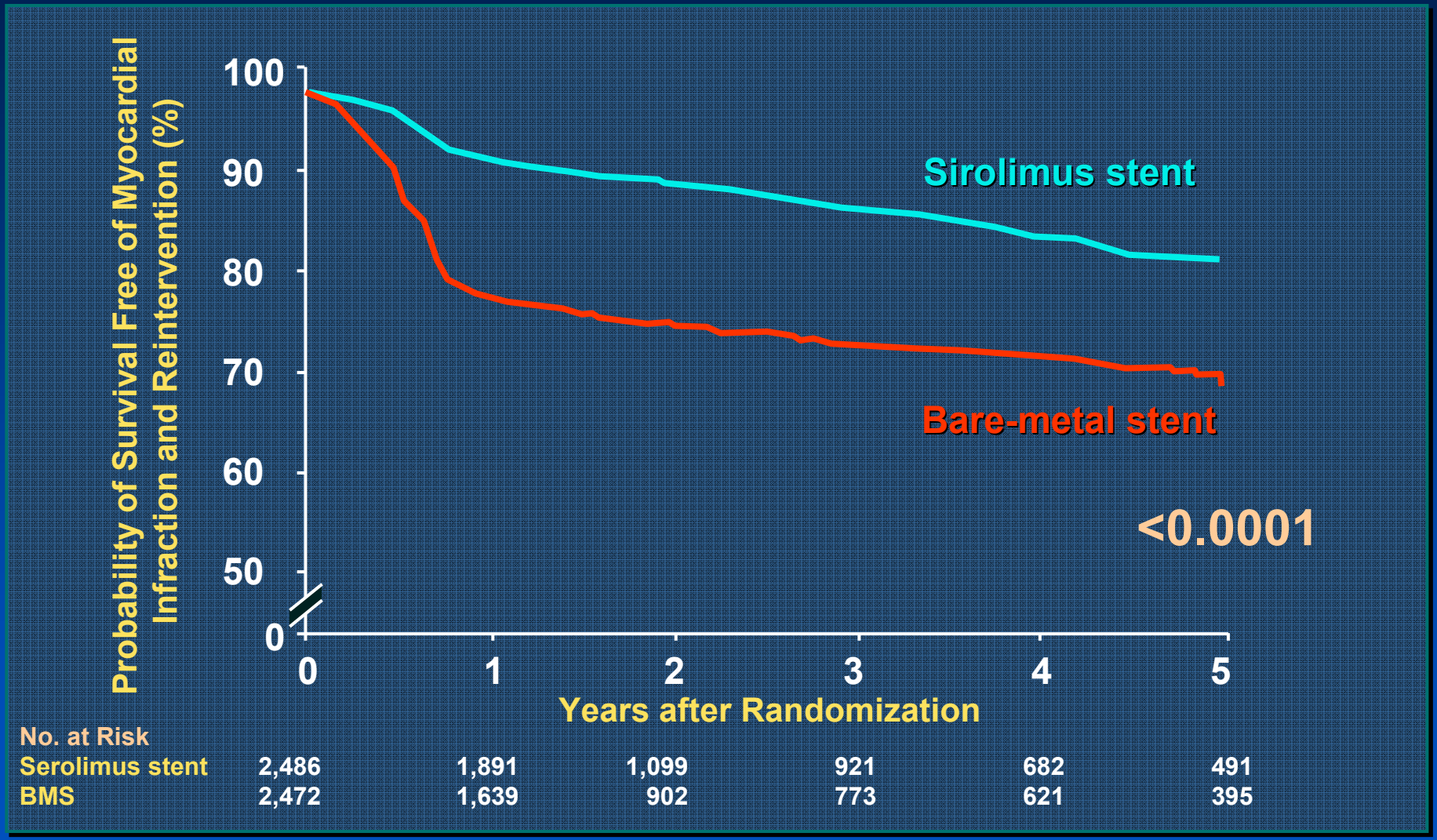
Freedom from Death or MI

(n=4,958 randomized pts)



Kastrati et al. *NEJM* 2007; 356: 1030-9

Freedom from Death/MI/Reintervention (n=4,958 randomized pts)



Kastrati et al. *NEJM* 2007; 356: 1030-9

Meta analysis of RCTs (On-and Off Label Use)

- Stent thrombosis after 1 year was **more common** with both DESs than with BMS.
- There were **no significant differences** in the cumulative rates of death or myocardial infarction at 4 years
- Both DESs (SES, PES) were associated with a **marked reduction in TLR.**

Registry Data Analysis
(Off-Label Use)

ORIGINAL ARTICLE

Long-Term Outcomes with Drug-Eluting Stents versus Bare-Metal Stents in Sweden

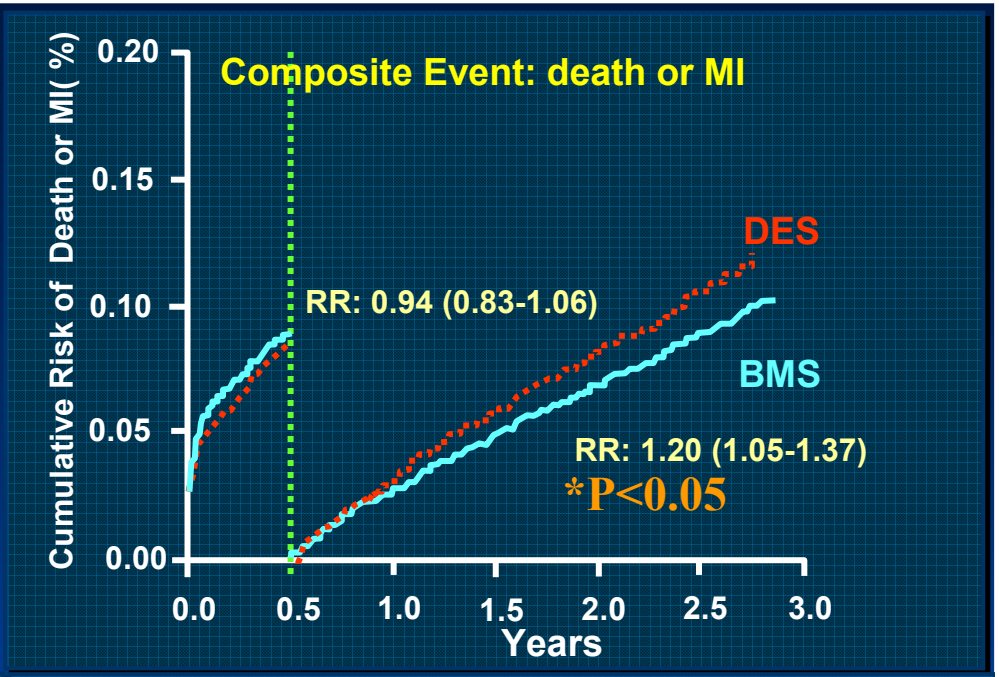
Bo Lagerqvist, M.D., Ph.D., Stefan K. James, M.D., Ph.D., Ulf Stenestrand, M.D., Ph.D., Johan Lindbäck, M.Sc., Tage Nilsson, M.D., Ph.D., and Lars Wallentin, M.D., Ph.D., for the SCAAR Study Group*

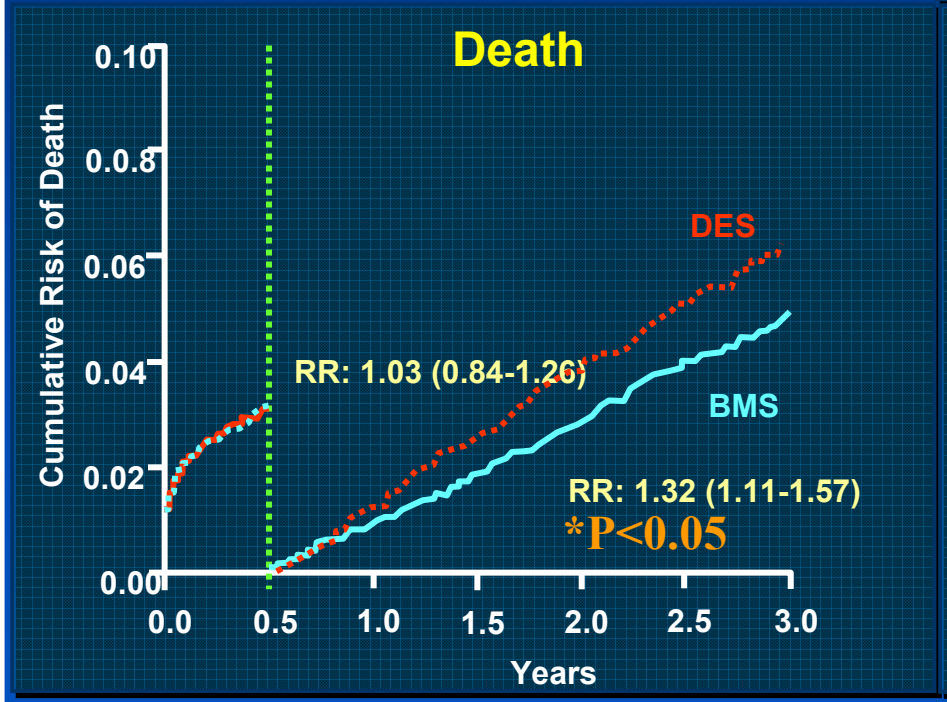
Pooled analysis of 6033 patients treated with DES and
13,738 patients treated with BMS
Data from Swedish Coronary Angiography and Angioplasty Registry

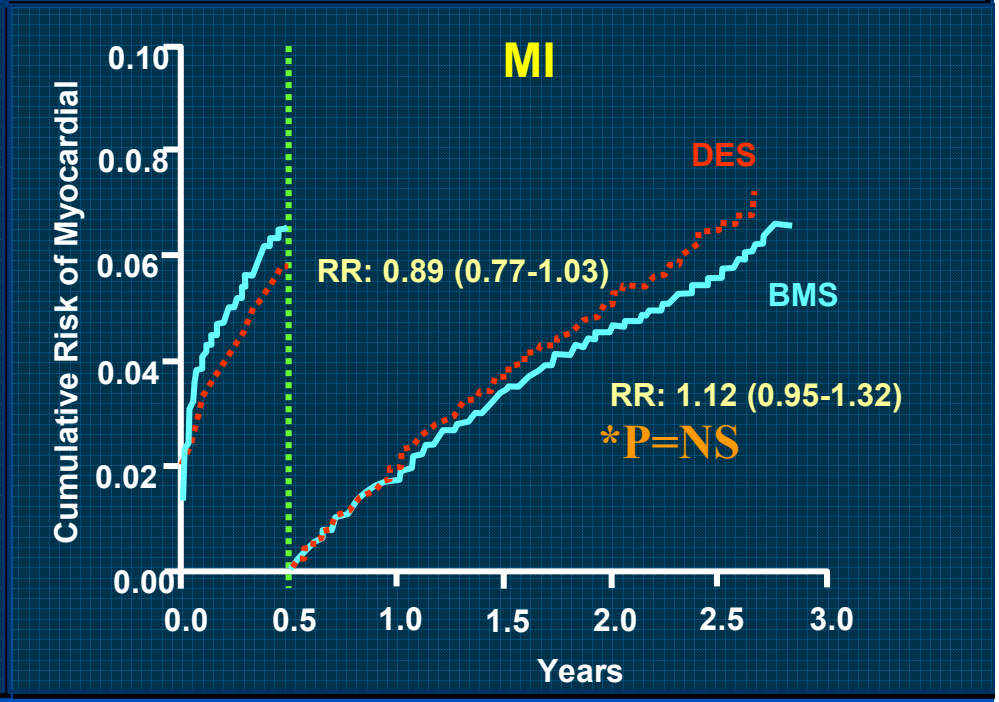
Outcome analysis was based on 1424 deaths and 2463 myocardial infarction during 3 years follow-up period and was adjusted for differences in baseline characteristics.

NEJM 2007;356:1009-19

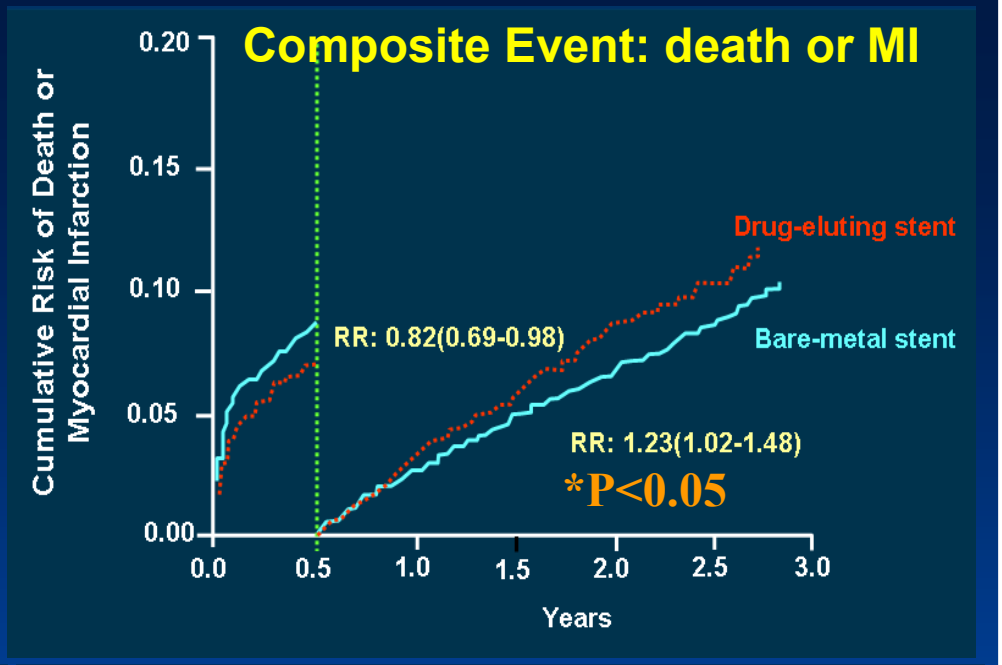
Landmark Analysis of the All Study Group

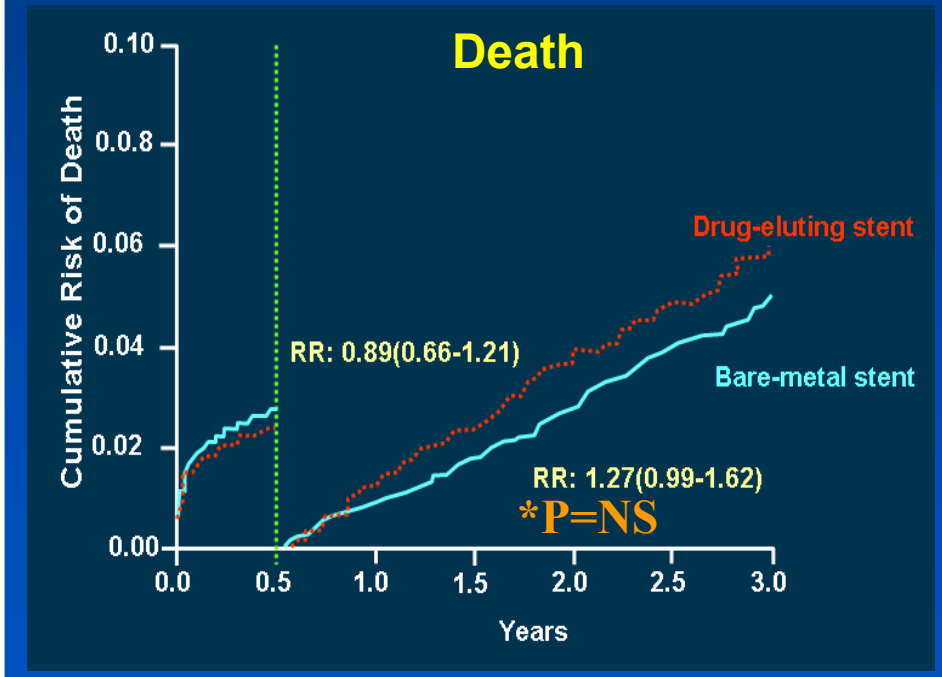


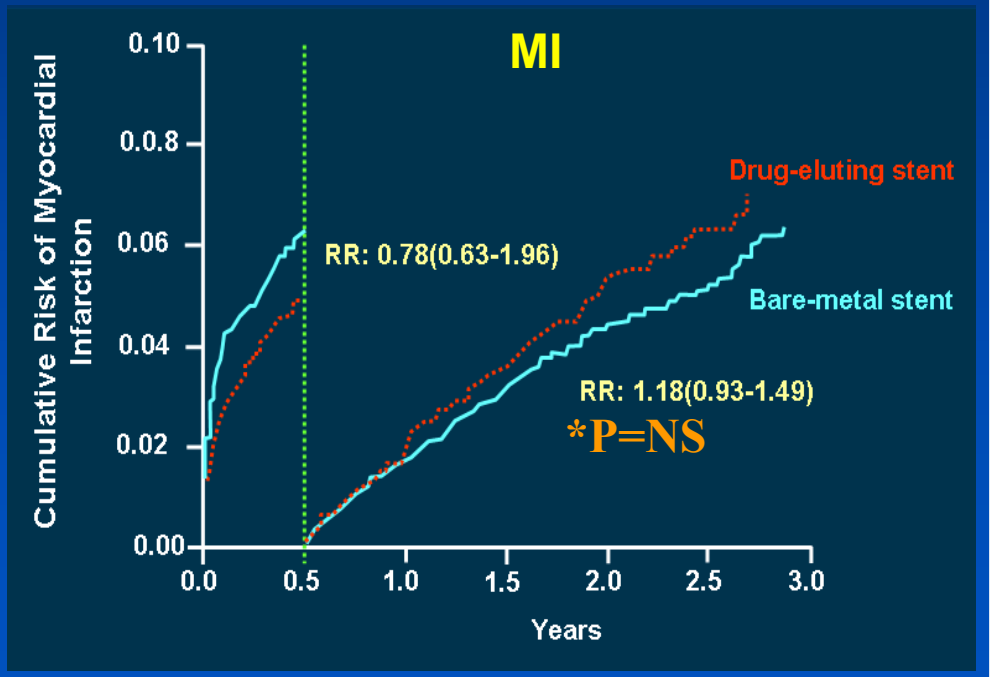




Landmark Analysis of the One-Stent Subgroup







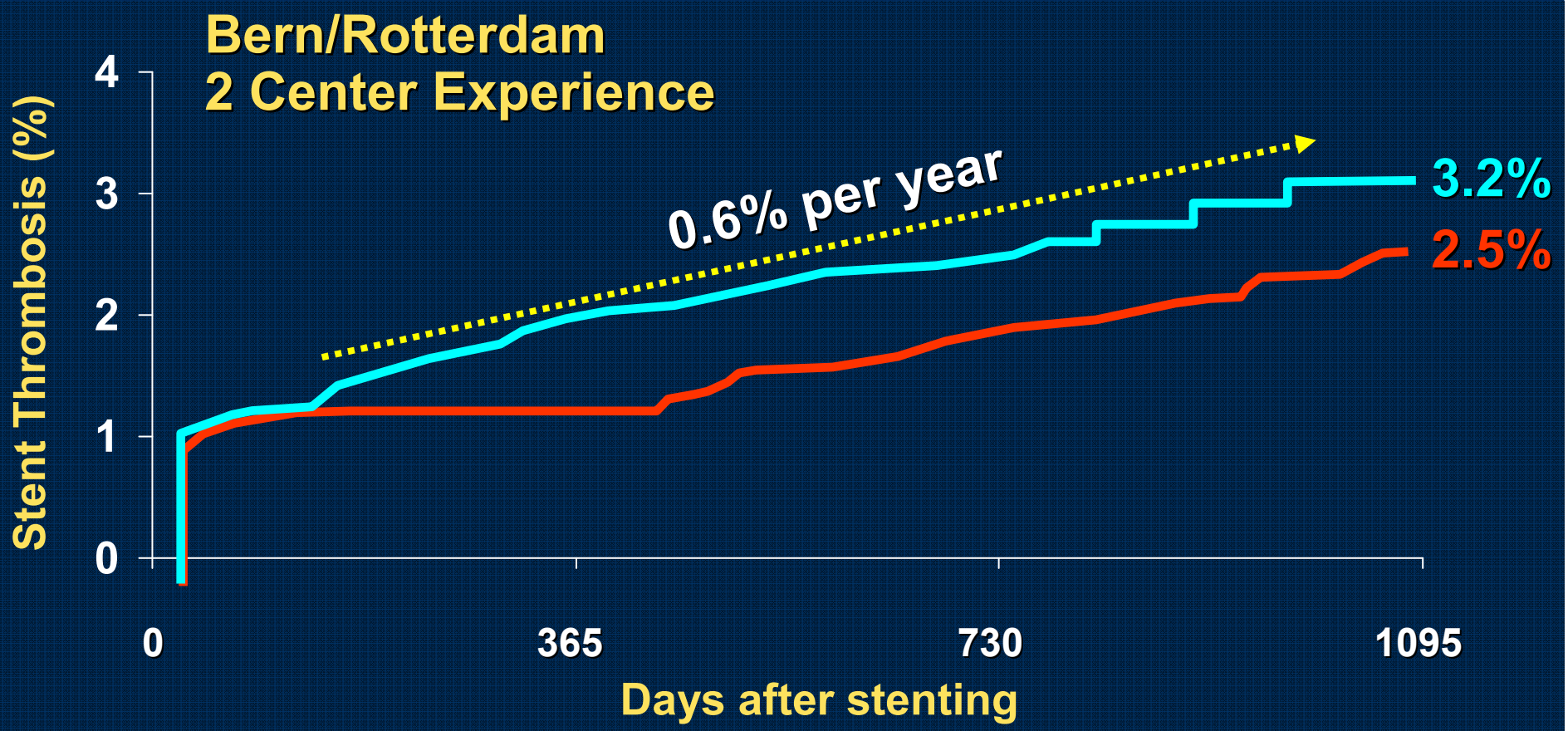
SCAAR: Patient Characteristics and Procedural Factors (ONE STENT)

	BMS	DES
STEMI (%)	25.8	17.7
Diabetes (%)	15.7	23.5
Previous PCI (%)	10.6	16.9
≥ 2 Stents (%)	24.9	39.7
Stent Diam < 3mm (%)	25.8	42.4
Stent Length ≥ 20 mm (%)	22.1	41.8
Restenotic Lesion (%)	1.2	6.7
LM Coronary (%)	1.0	2.3
LAD Location (%)	38.5	62.1

Differences all highly significant !

Lagerqvist B. et al., NEJM 2007; 356:1009-19

ST rate Increased 0.6% per year…

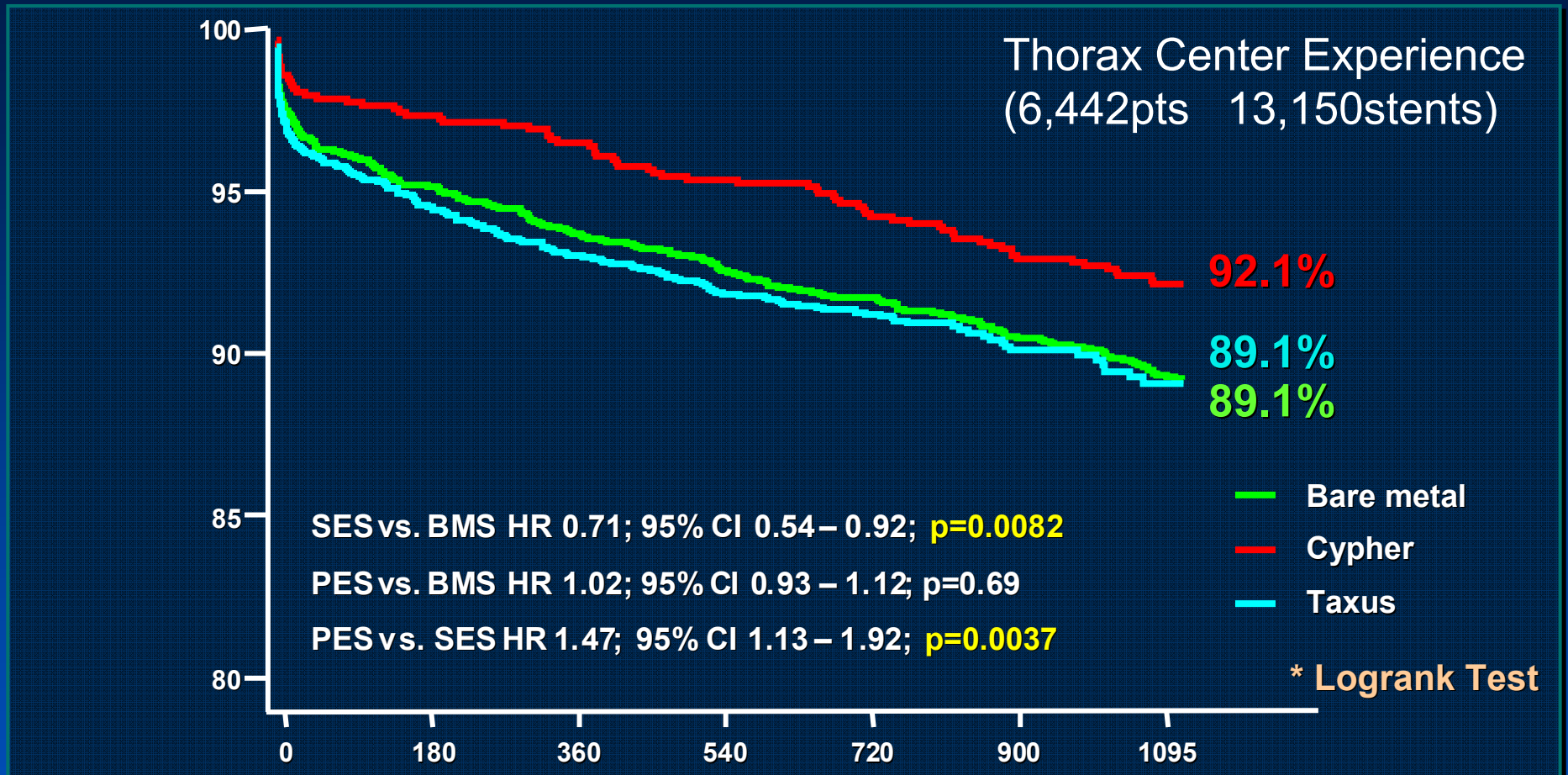


Days after PCI	9	30	365	730	1095
Incidence SES (%)	1.0	1.1	1.3	1.9	2.5
Incidence PES (%)	1.2	1.3	2.0	2.7	3.2
Pts at risk	8146	7162	7002	2841	971

Daemon J et al. Lancet 2007;369:667–78

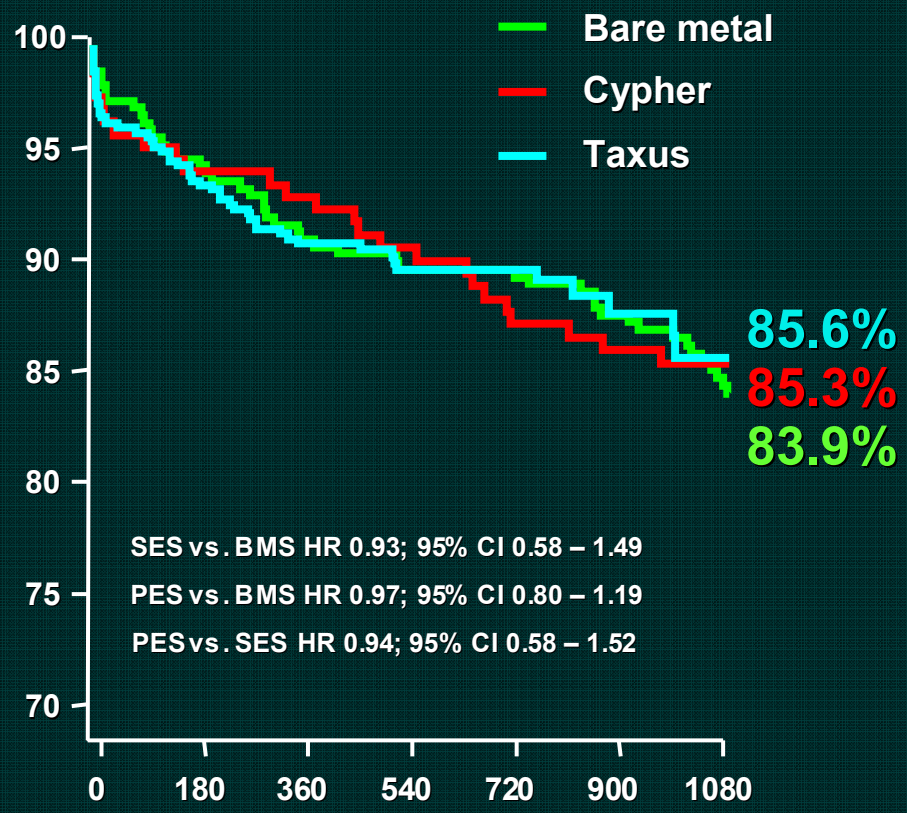
However, DES has better survival rather than BMS...

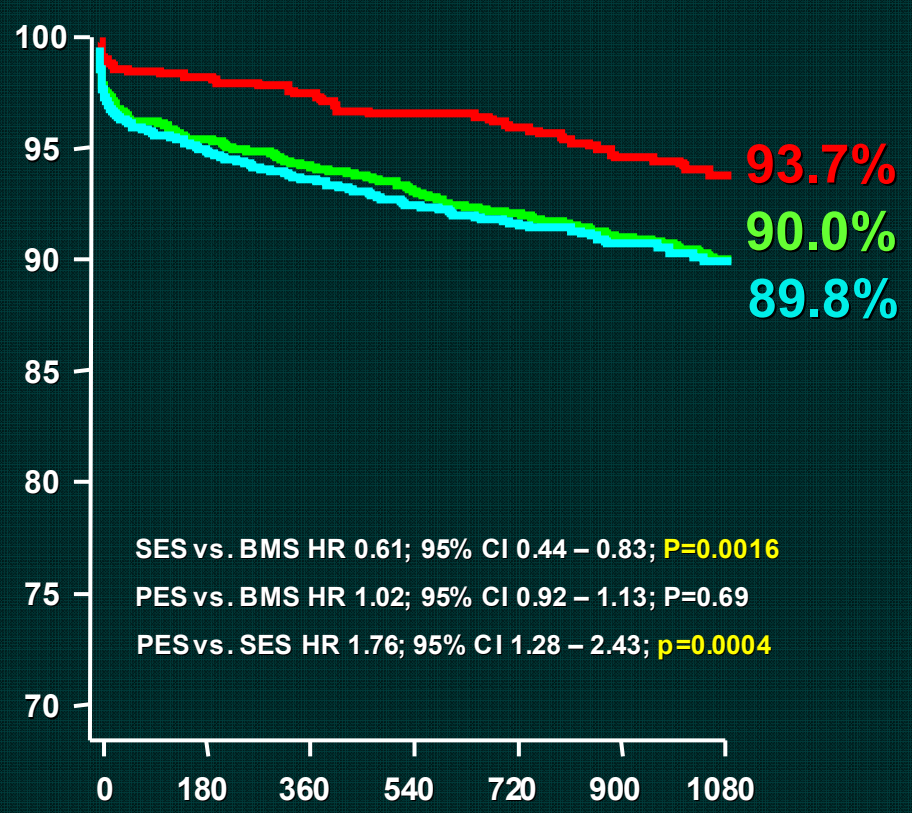
All-cause Mortality at 3 Years



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 at 3 Years



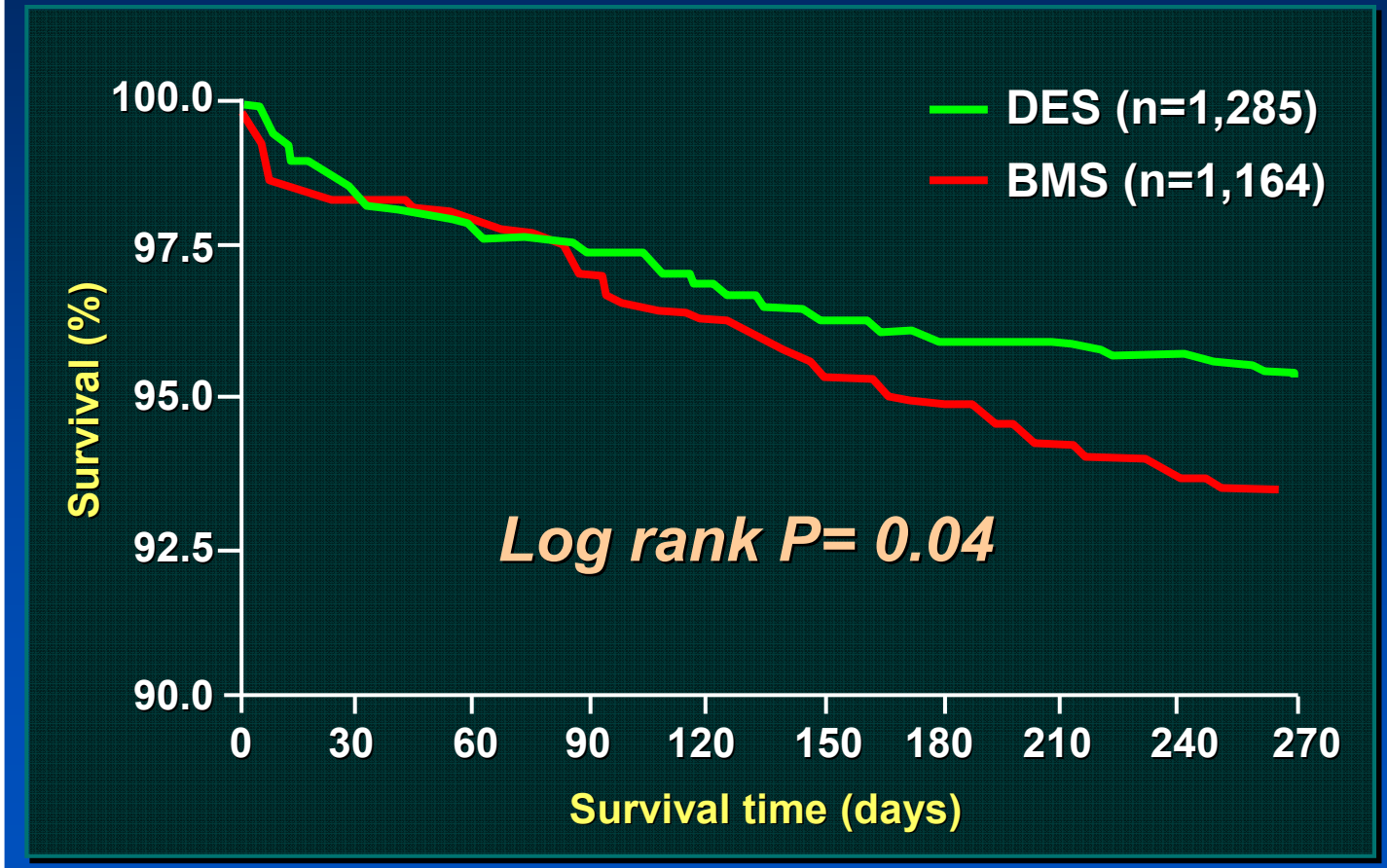


Group	0	180	360	720	1080
BMS	306	288	276	267	237
SES	179	168	165	152	142
PES	484	433	408	258	85

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

Wake Forest Experience (N=2,449)

BMS placed in 1164 pts
DES placed in 1,285 comparable pts
72% ACS; Propensity score adjusted Cox MV analysis

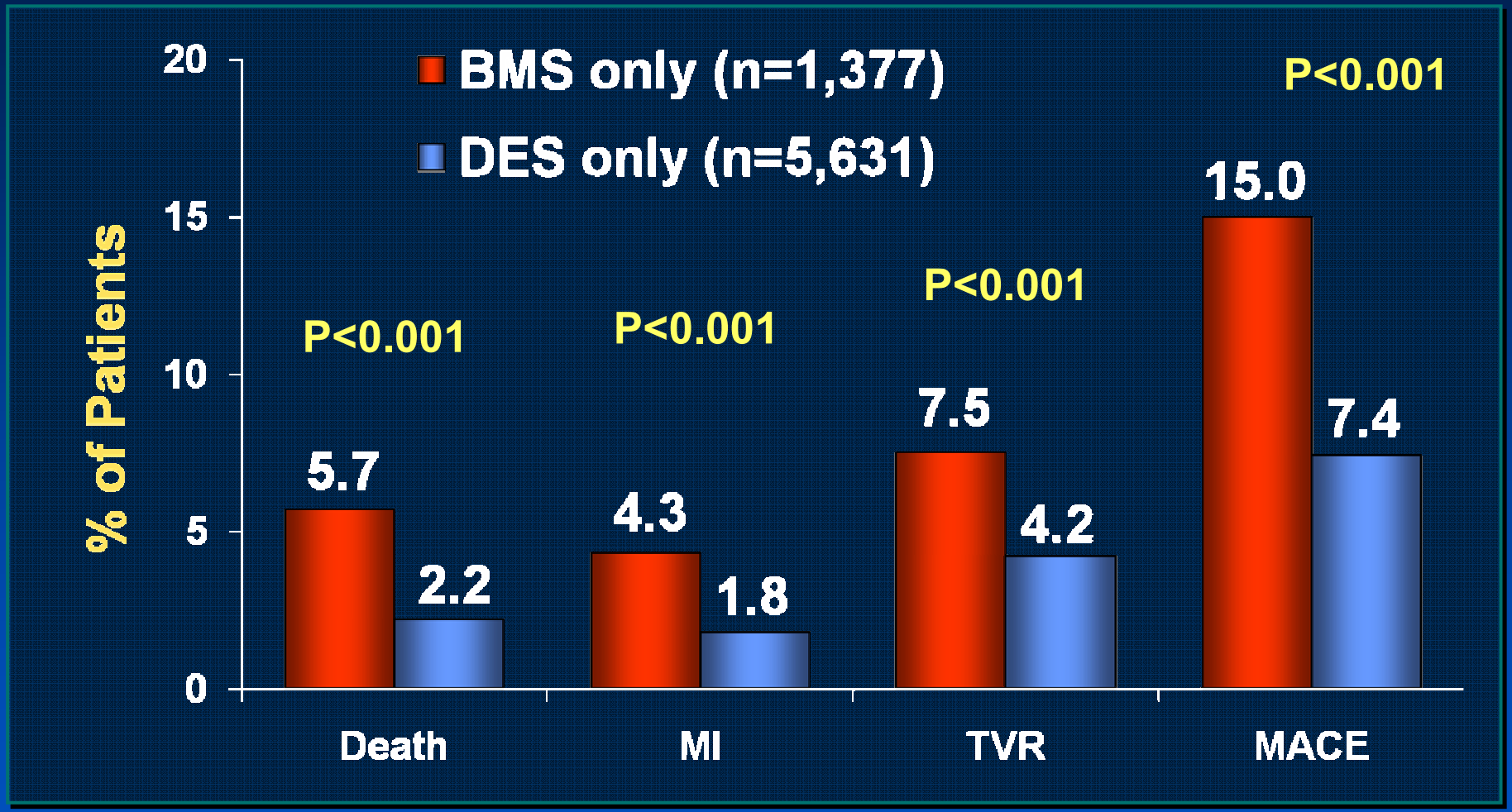


Mortality
4.9% DES
7.1% BMS
P=0.03

Propensity adjusted Cox
HR [95% CI] = 0.56 [0.36, 0.87]

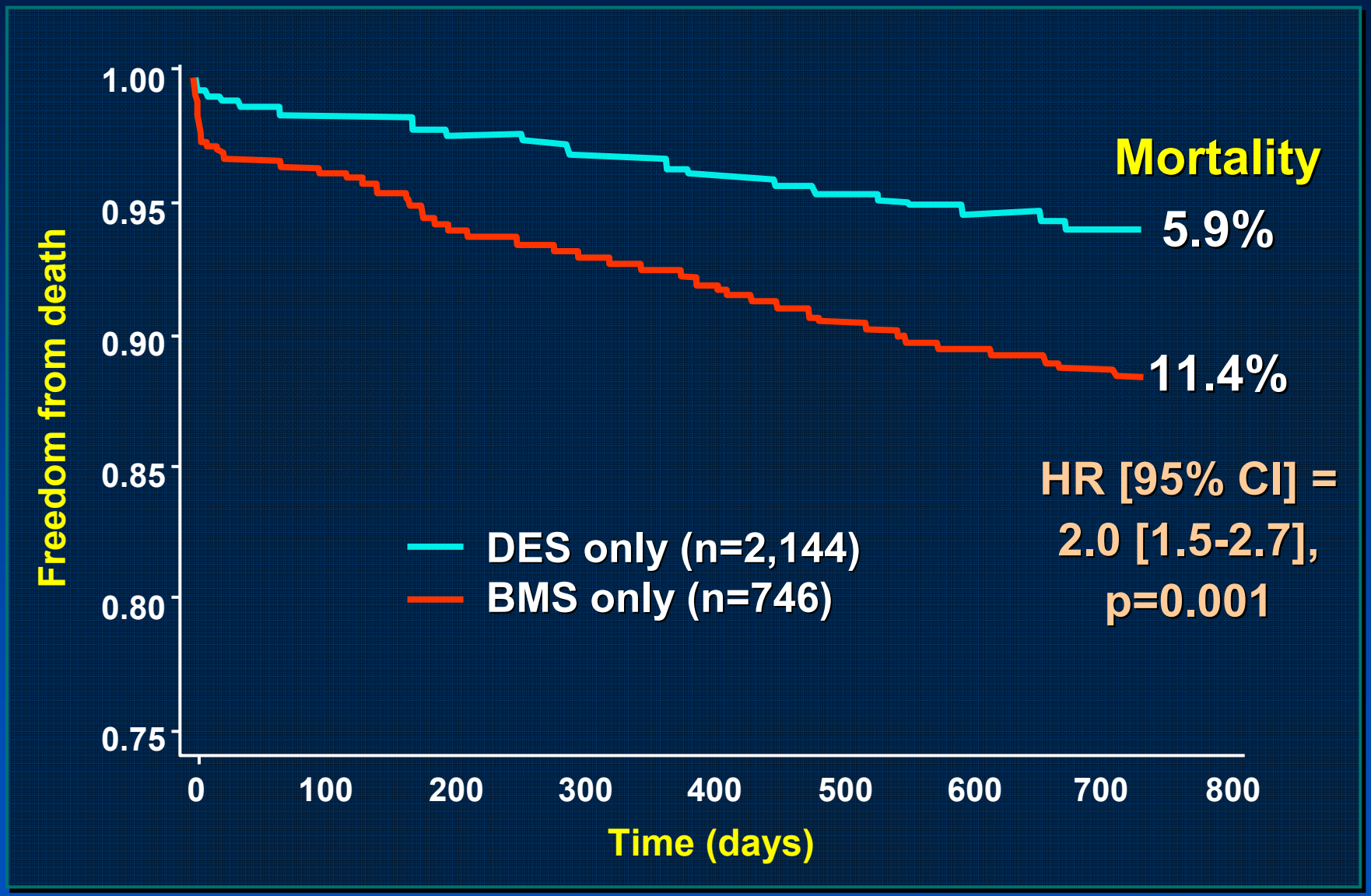
Applegate R et al. *AJC* 2007;99:333–338

STENT Registry (N=7,008): Nine Month Clinical Outcomes Comparing BMS and DES



Adjusted HR [95% CI] for death = 0.56 [0.40, 0.80]

DES vs. BMS: Mortality (completed 2 yr F/U)

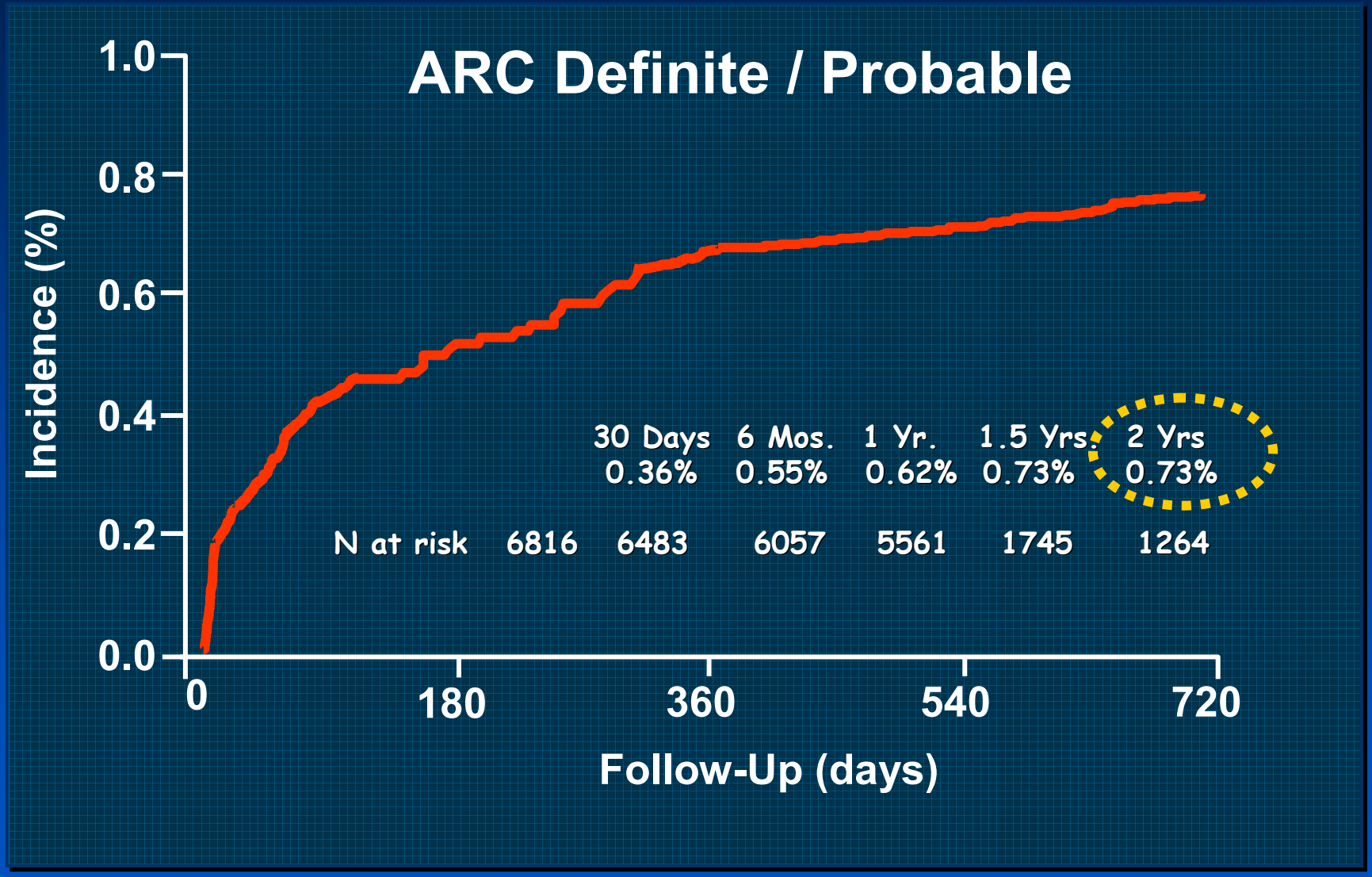


Chuck Simonton for the STENT Registry, March 2007

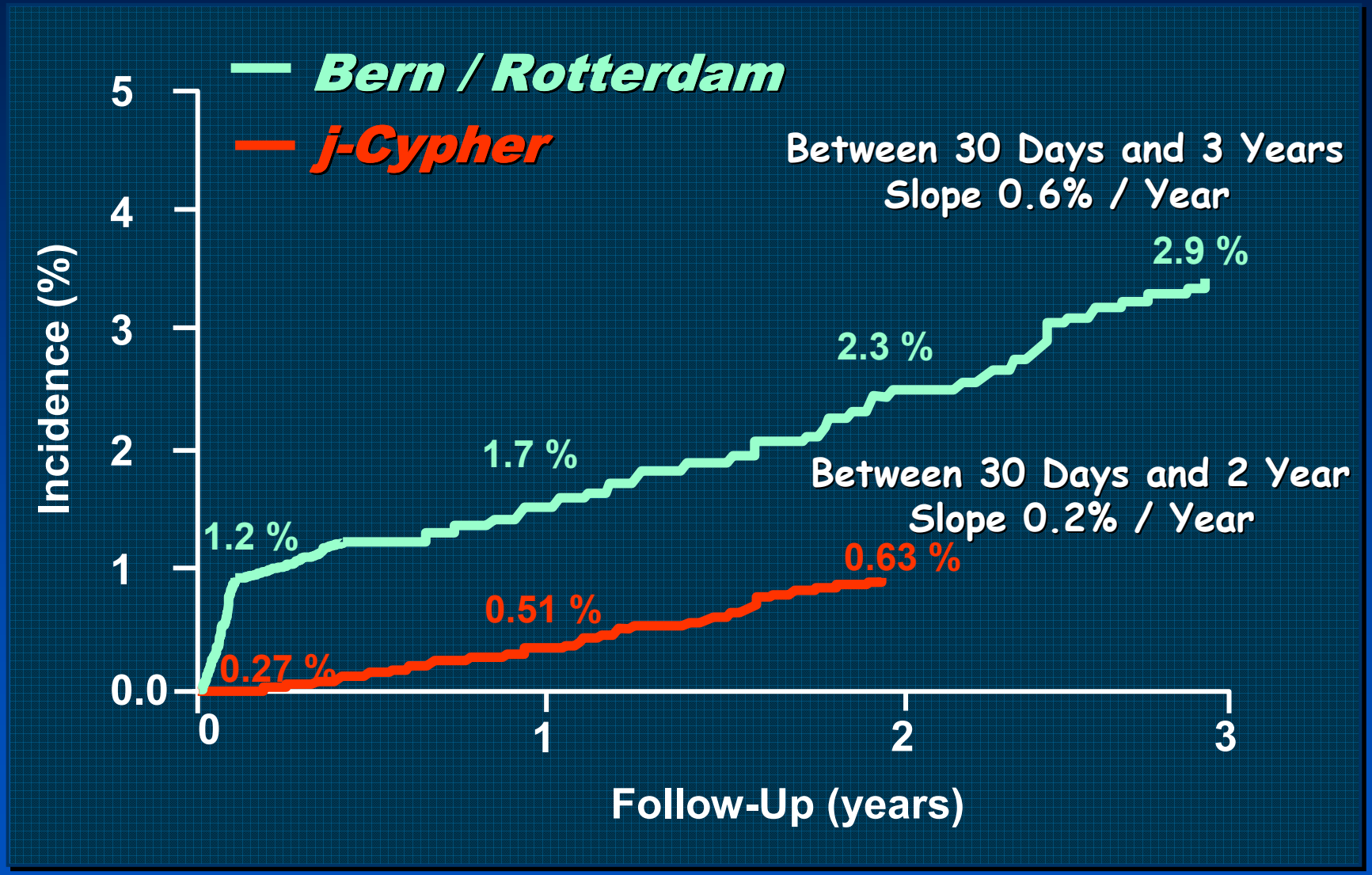
The j-Cypher Registry

Two-Year Outcome After Sirolimus-Eluting Stent Implantation

Stent Thrombosis
in j-Cypher at 2 year



Stent Thrombosis (Definite)

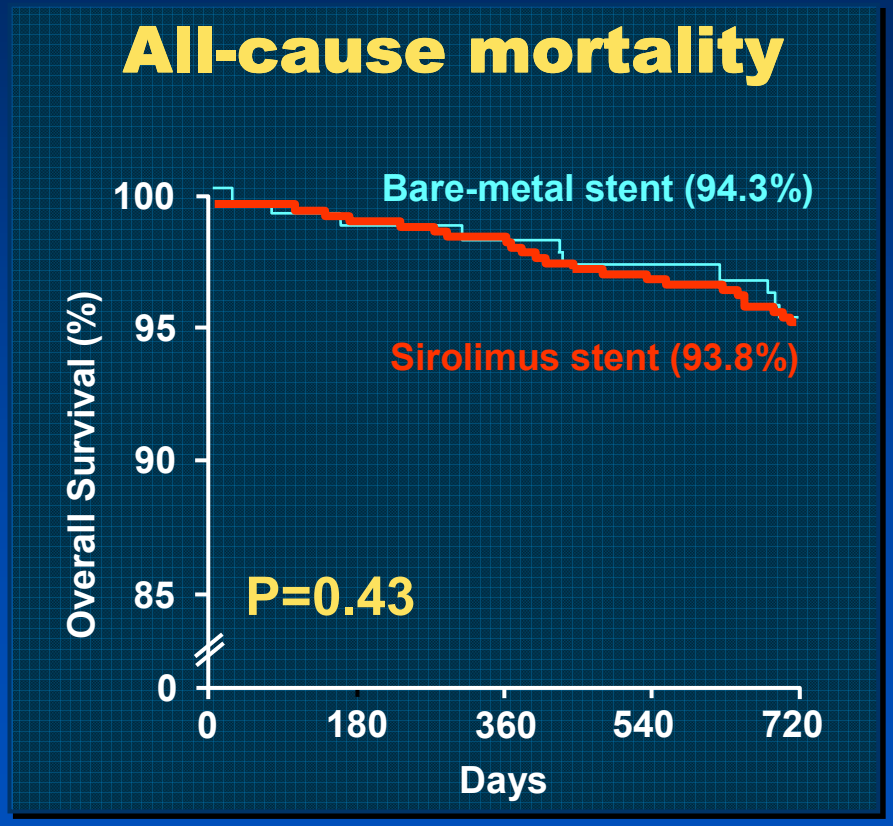


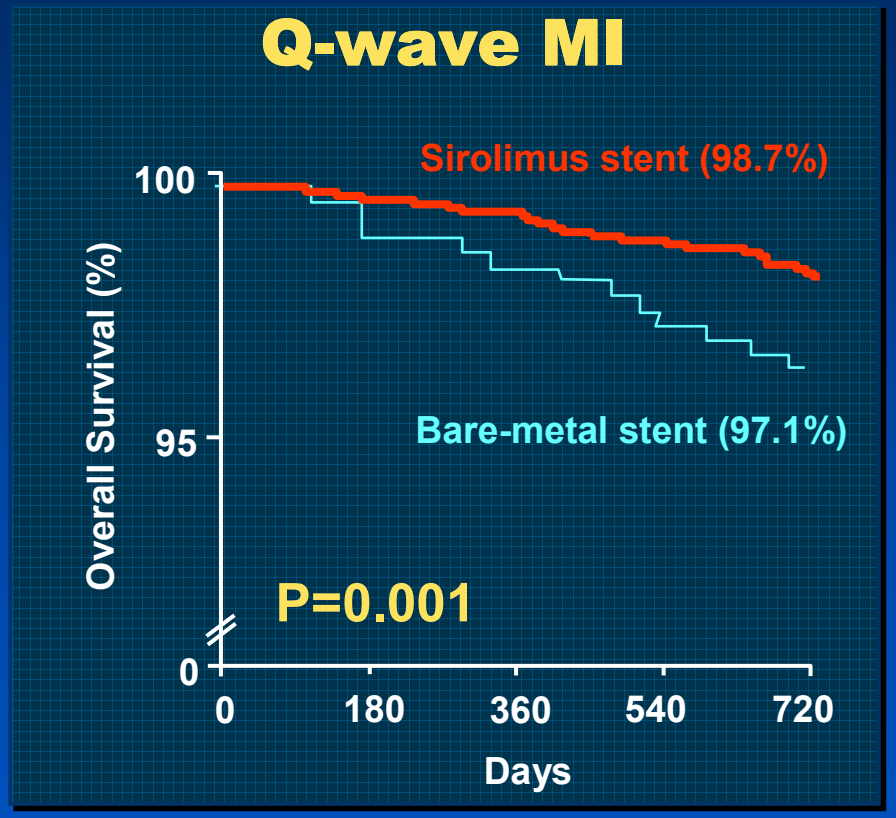
Historical Comparison
Between BMS and SES

	CREDO	j-Cypher	
N	5627	2767	P
Age	67.5±10.1	68.0±10.5	0.02
>80 yrs	11%	12%	0.09
Emergent PCI	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

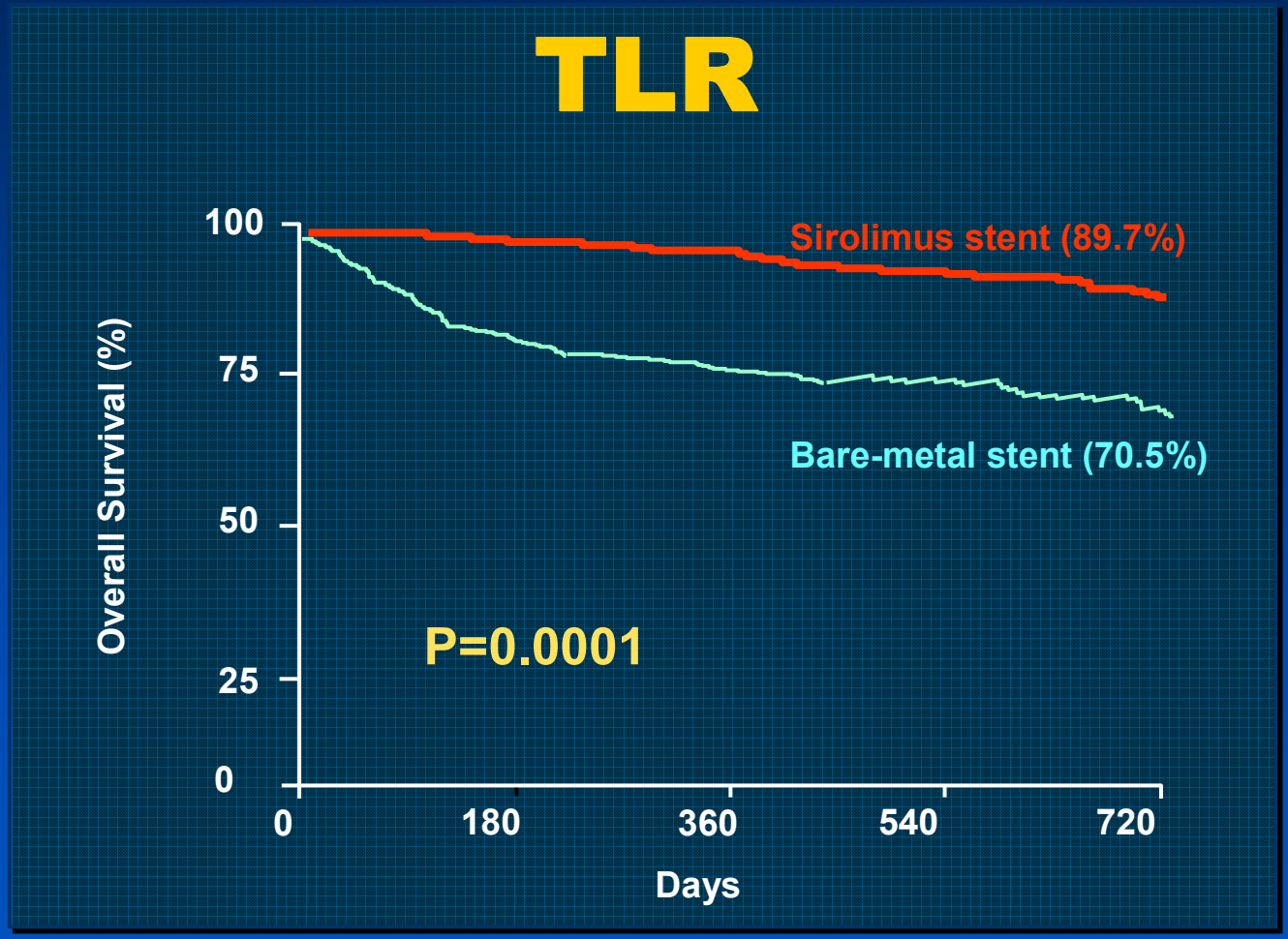
CREDO vs j-Cypher





Comparison Between BMS and SES Using Historical Control

CREDO vs j-Cypher



3 year F/U (BMS vs DES) of AMC Registry Data

7,221 Patients
(10,193 Lesions, 12,038 Stents)

Jan,1998 — Mar,2003 — Feb,2006

BMS → Default Treatment

4,061 patients
5,702 lesions
5,867 stents

DES → Default Treatment

3,160 patients
4,491 lesions
6,171 stents
(4,766 SES, 405 PES)

Baseline Demographics

	DES (n=3157)	BMS (n=4060)	P
Age, yrs	60.5±10.3	59.2±10.1	<0.001
Male gender	2229 (71)	2903 (72)	0.4
Hypertension	1599 (51)	1674 (41)	<0.001
Diabetes mellitus	865 (24)	835 (21)	<0.001
Hypercholesterolemia	759 (24)	1469 (36)	<0.001
Current smoking	920 (29)	1642 (40)	<0.001
Left ventricular EF, %	58.4±8.8	59.2±9.6	0.001

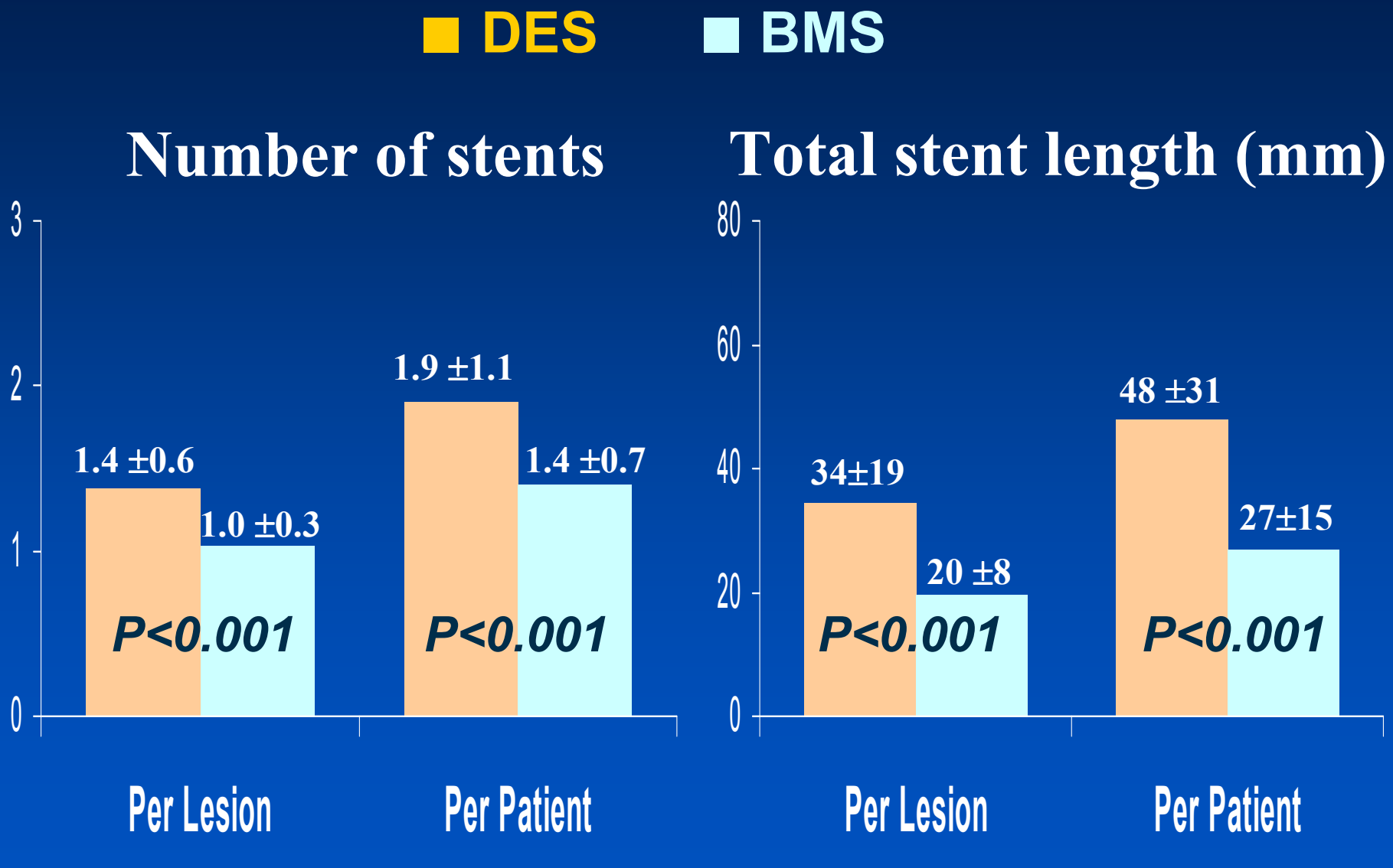
Baseline Demographics

	DES (n=3157)	BMS (n=4060)	P
Previous PCI	544 (17)	373 (9)	<0.001
Previous CABG	84 (3)	65 (2)	0.002
Previous MI	297 (9)	304 (8)	0.004
Multi-vessel disease	1865 (59)	1656 (41)	<0.001
Renal failure	80 (3)	82 (2)	0.13
Duration of clopidogrel (months)	11.8±8.0	3.2±2.6	<0.001

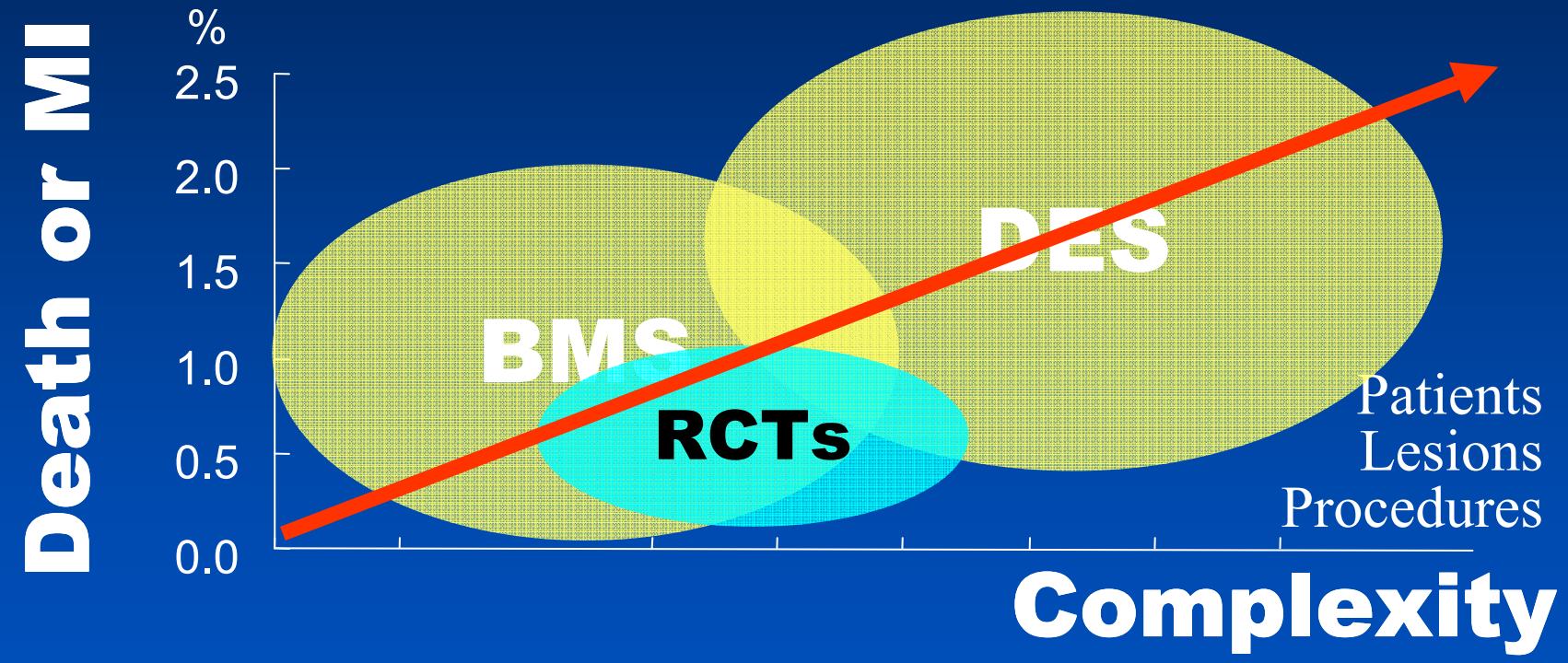
Lesion Characteristics

	DES (n=4491)	BMS (n=5702)	P
Chronic total occlusion	251 (6)	217 (4)	<0.001
In-stent restenosis	251 (6)	175 (3)	<0.001
Ostial lesion	475 (11)	427 (8)	<0.001
Bifurcation	732 (16)	602 (11)	<0.001
B2/C type (ACC/AHA)	3338 (74)	3250 (57)	<0.001

Procedural Characteristics



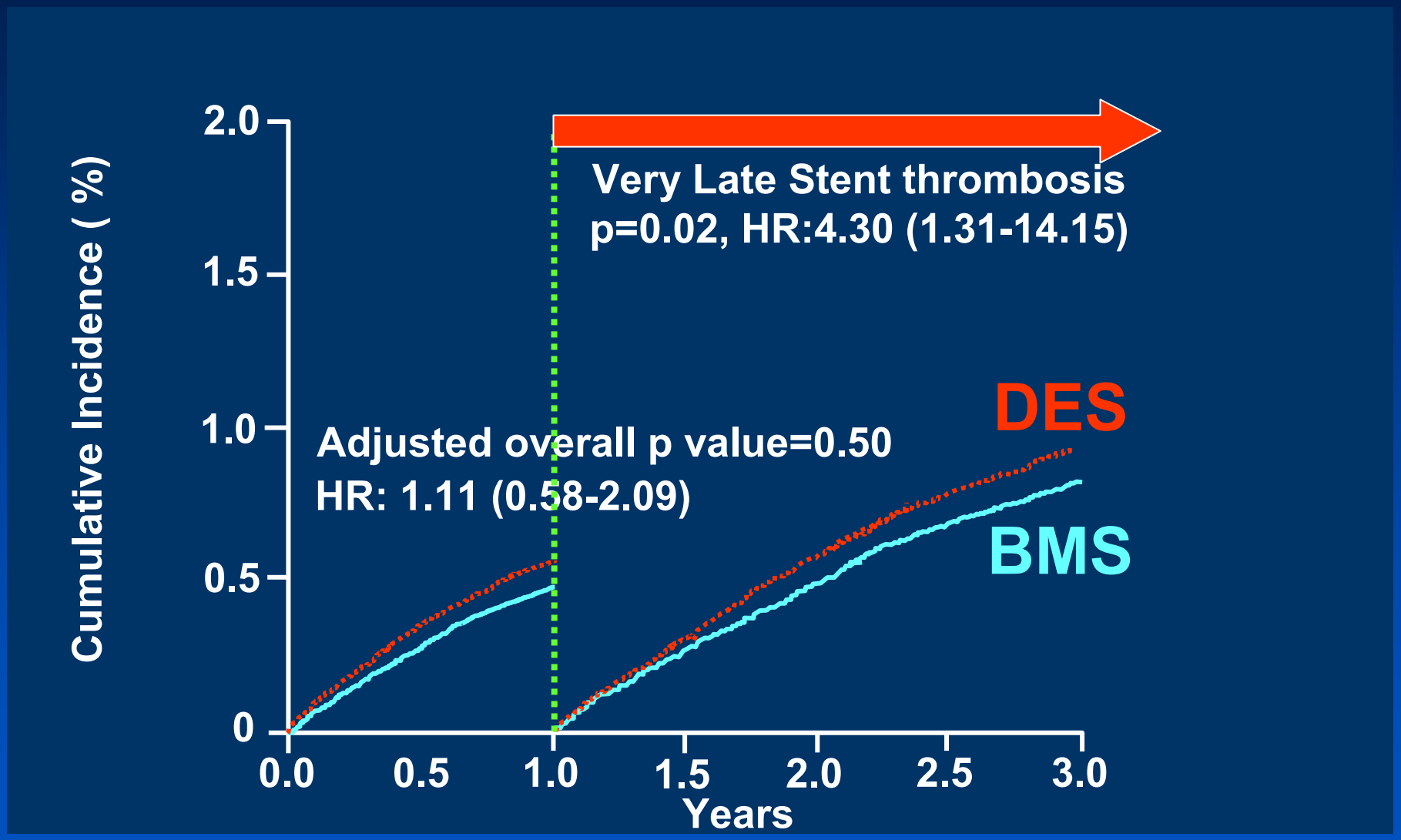
Paradigm Shift
in Real World Practice (Registry Data)



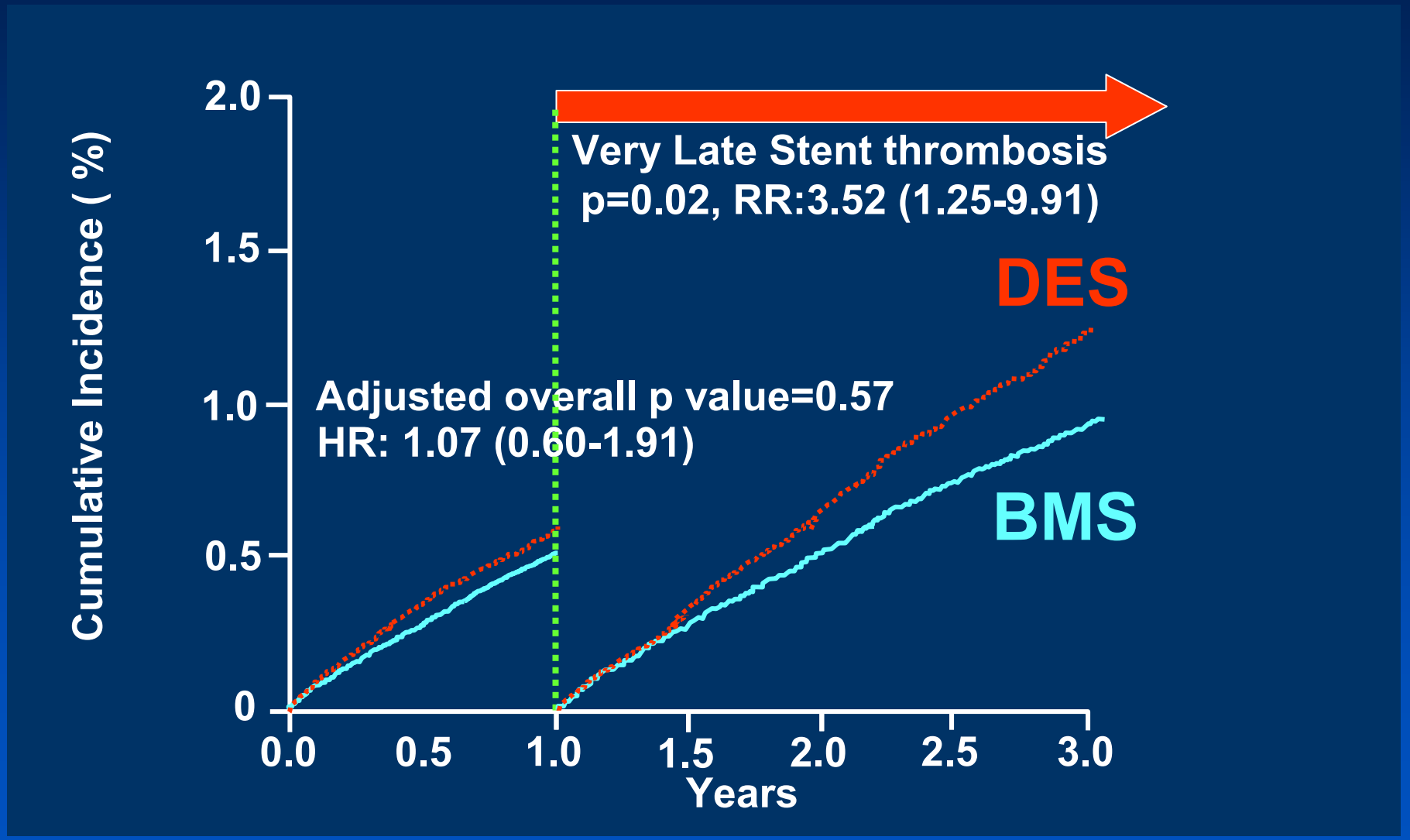
Results

After risk adjustment using propensity-score-adjusted Cox regression analyses

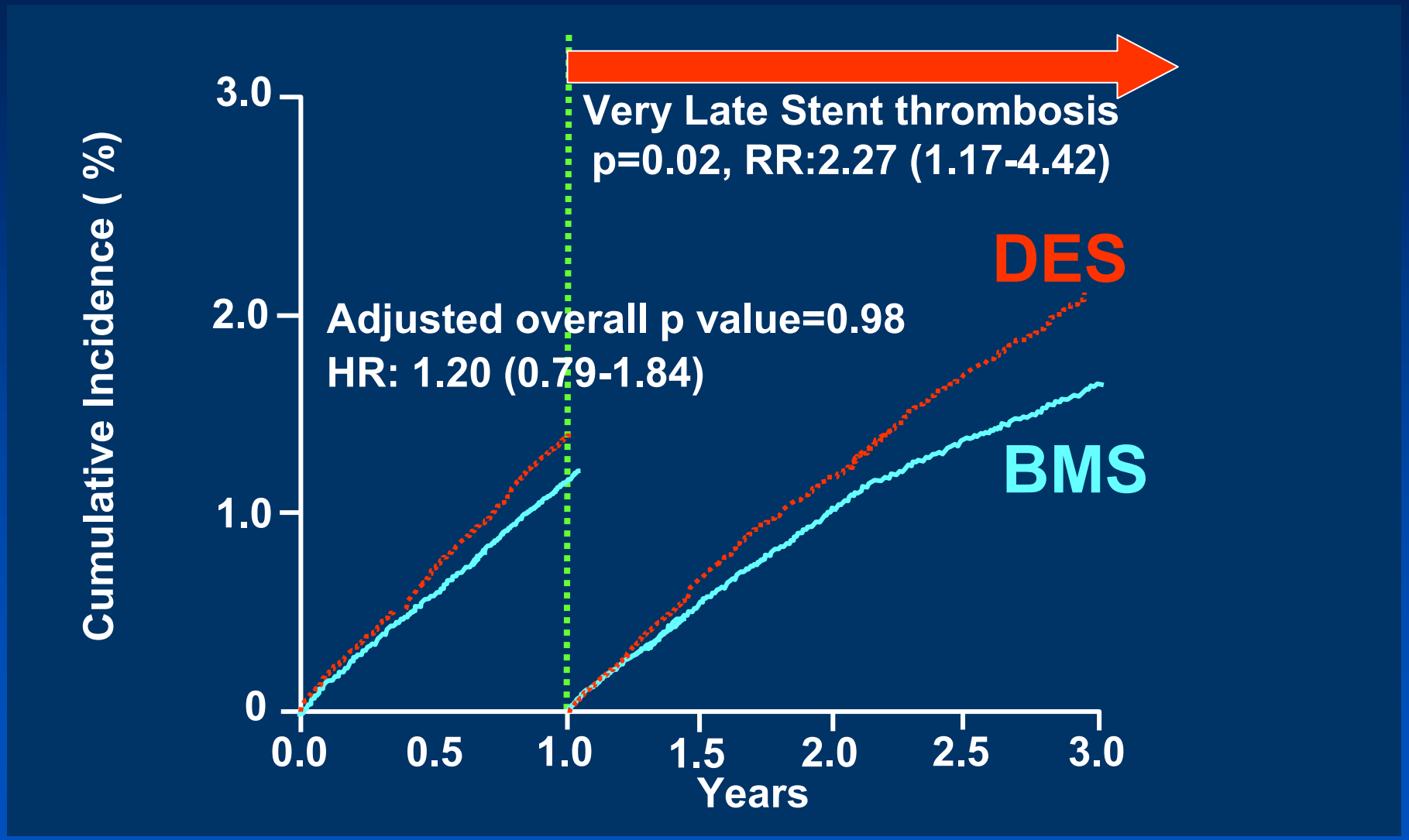
Incidence of ST (ARC: Definite) up to 3 years



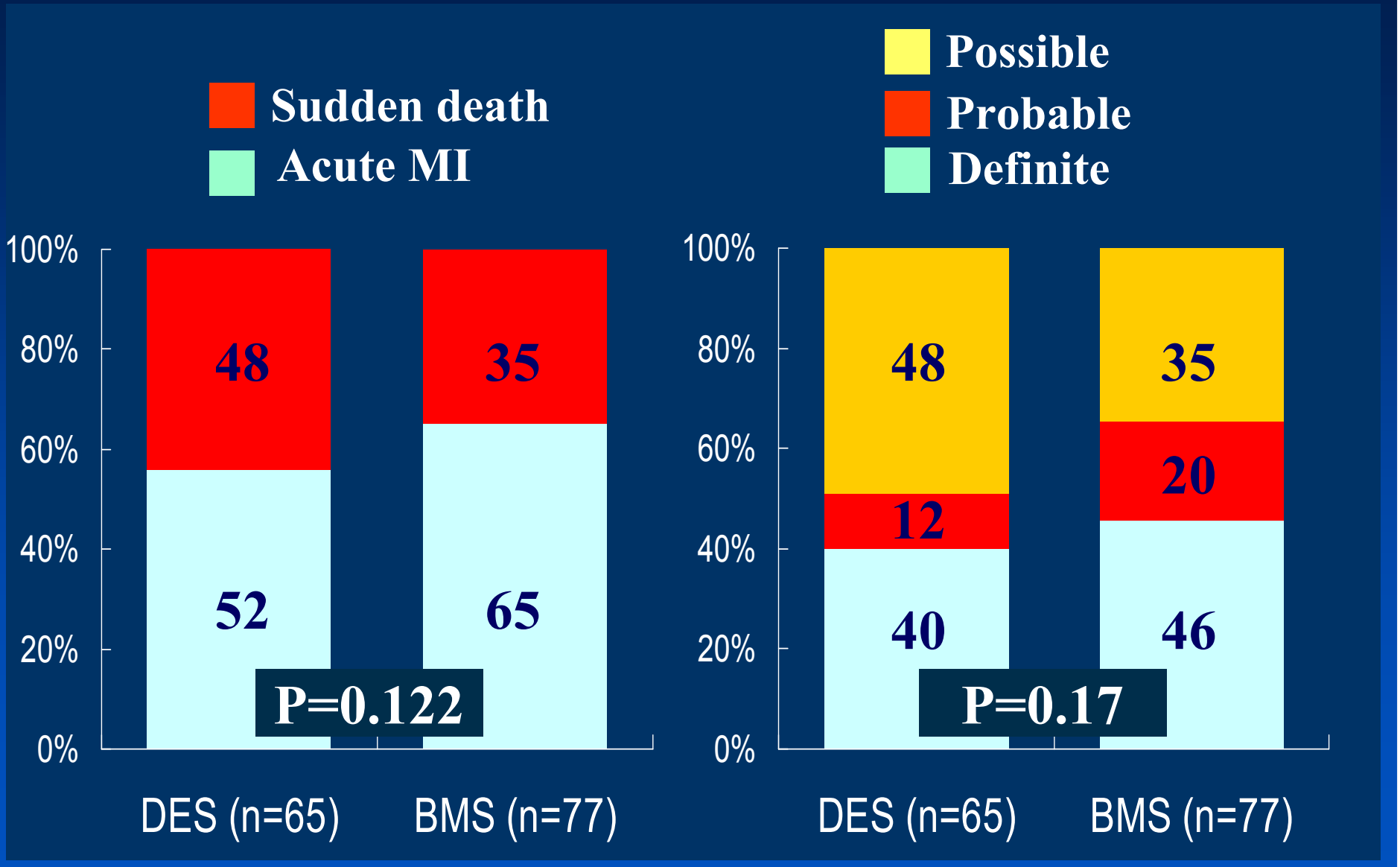
Incidence of ST (ARC: Definite + Probable) up to 3 years



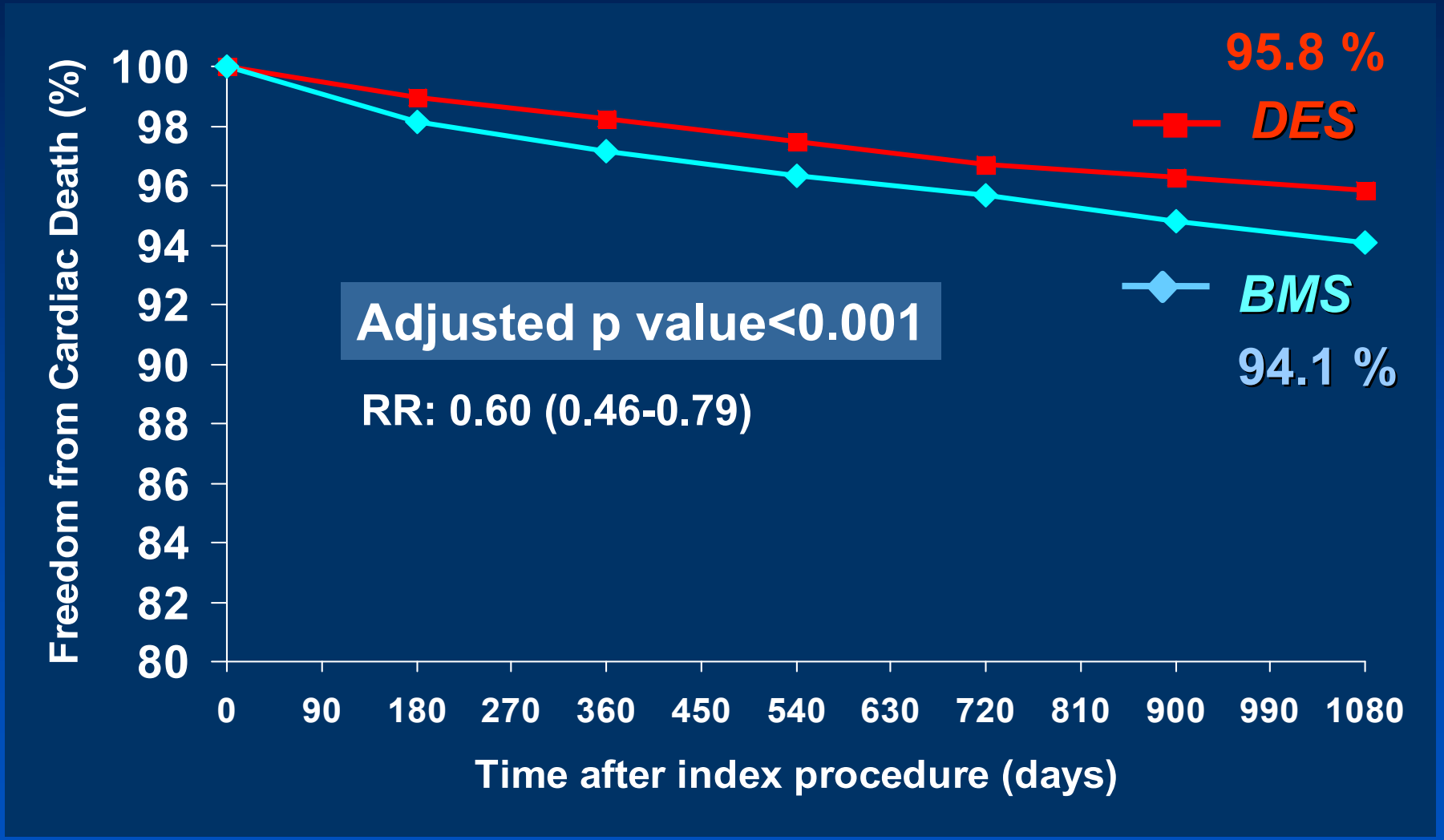
Incidence of ST (Any ARC Criteria) upto 3 years



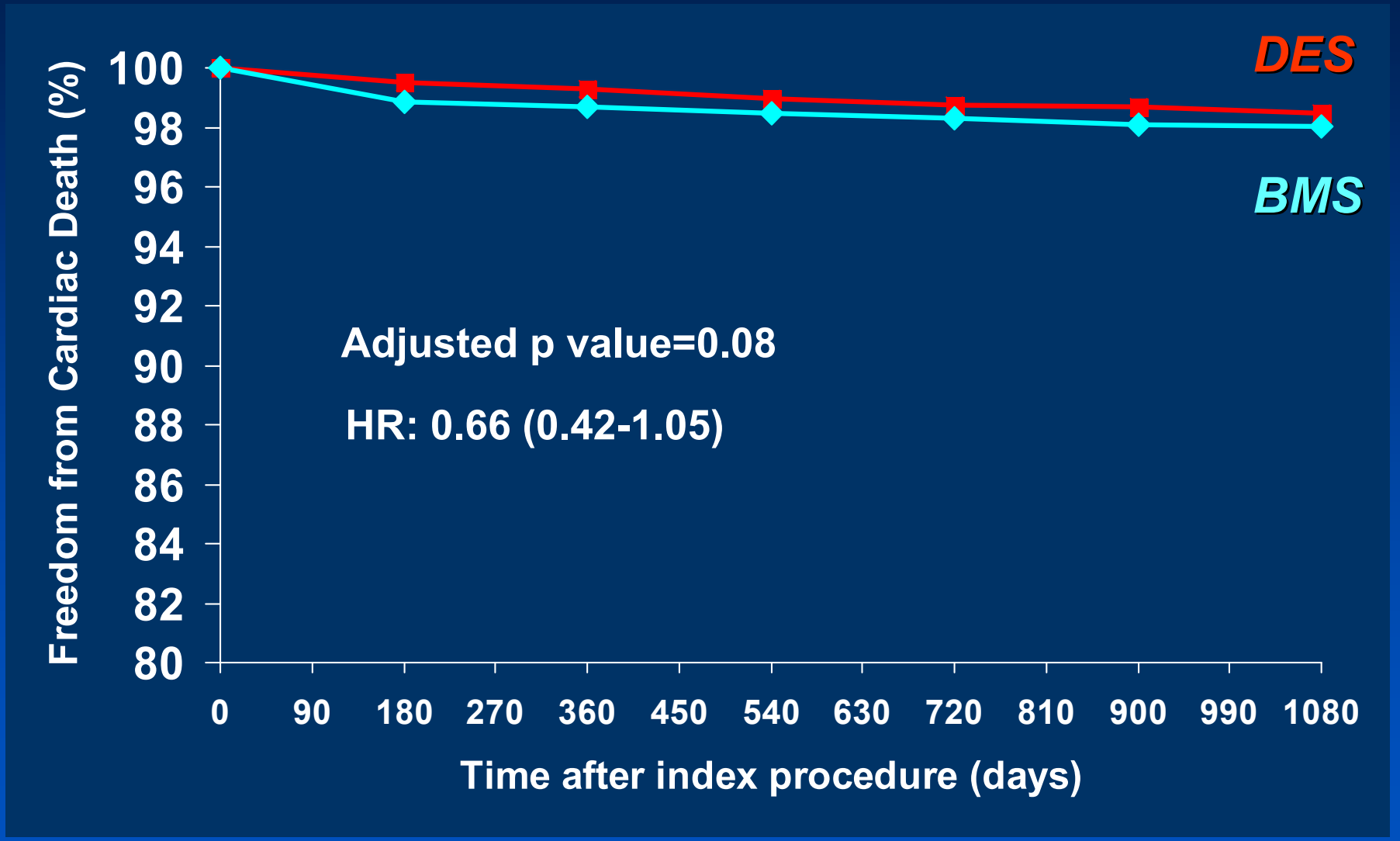
Presentation of ST (any ARC)



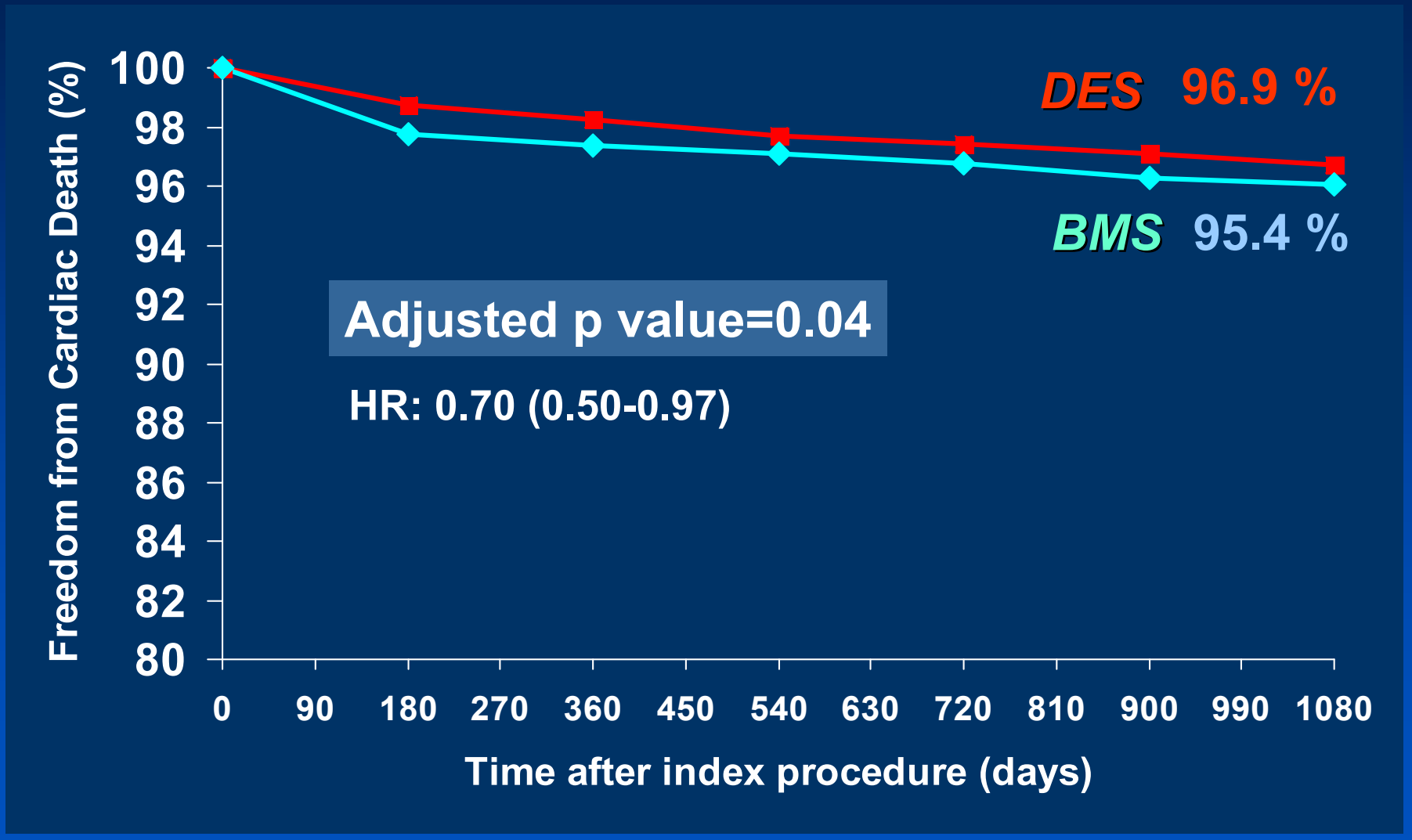
Survival-Free from All-cause Mortality (up to 3 years)



Survival-Free from MI (up to 3 years)



Survival-Free from Cardiac Death + MI (up to 3 years)



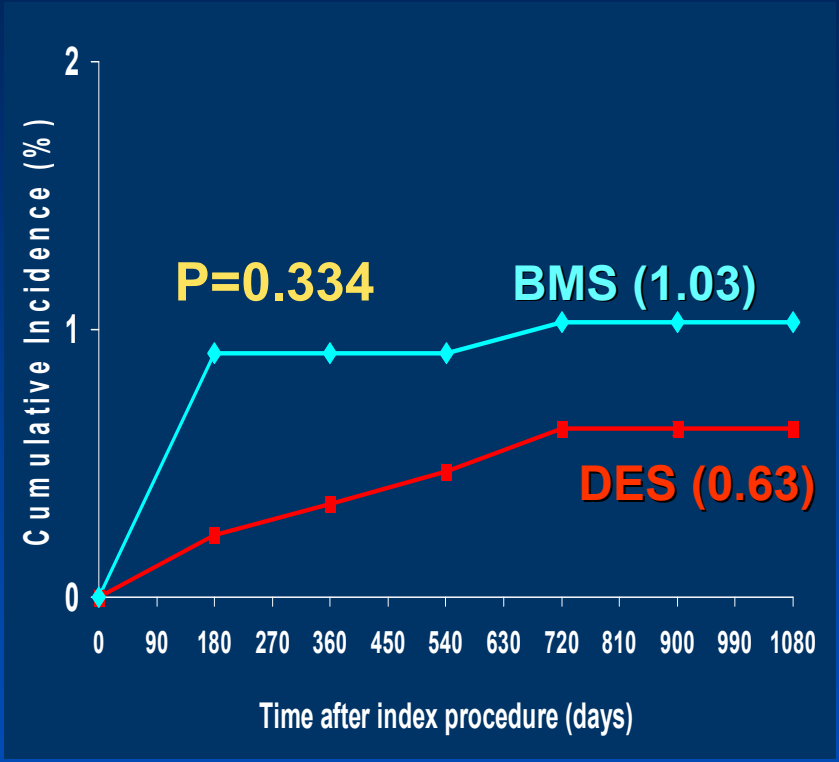
Registry Data Analysis
(Off-Label Use)

- Stent thrombosis Rate **might increase per year** with both DESs (Cyphr and Taxus) than with BMS.
- There were no significant differences in the cumulative rates of death or myocardial infarction, **even better** with DES.

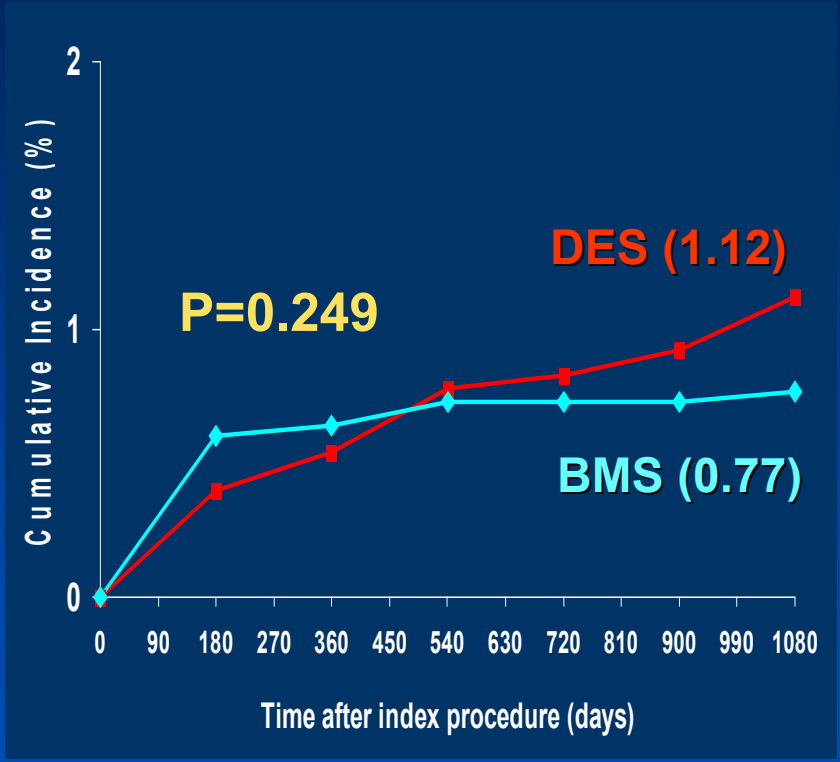
Impact of Diabetes Mellitus ?

Incidence of ST (ARC: Definite) up to 3 Years

Patients with Diabetes



Patients without Diabetes

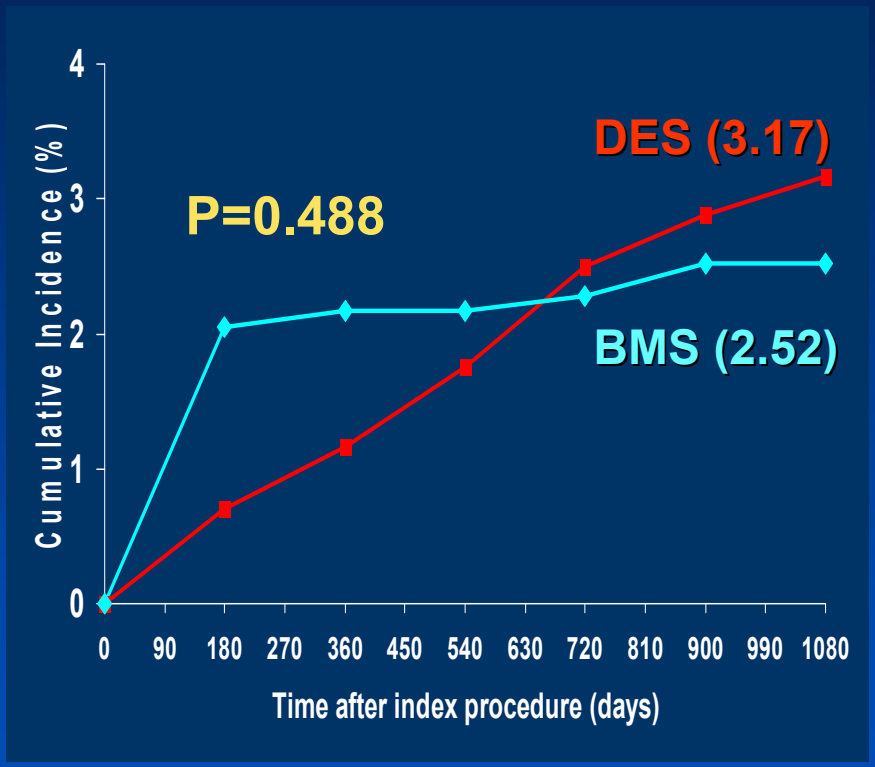


Interaction P value (DM * Stent type) = 0.598

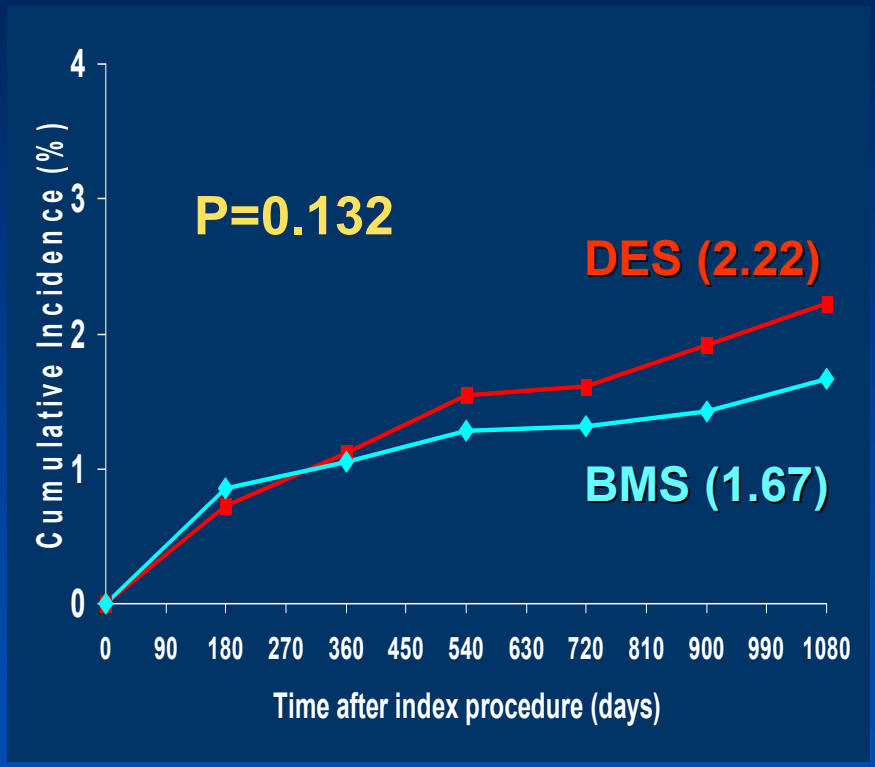
AMC registry Data 2007

Incidence of ST (Any ARC Criteria) upto 3 Years

Patients with **Diabetes**



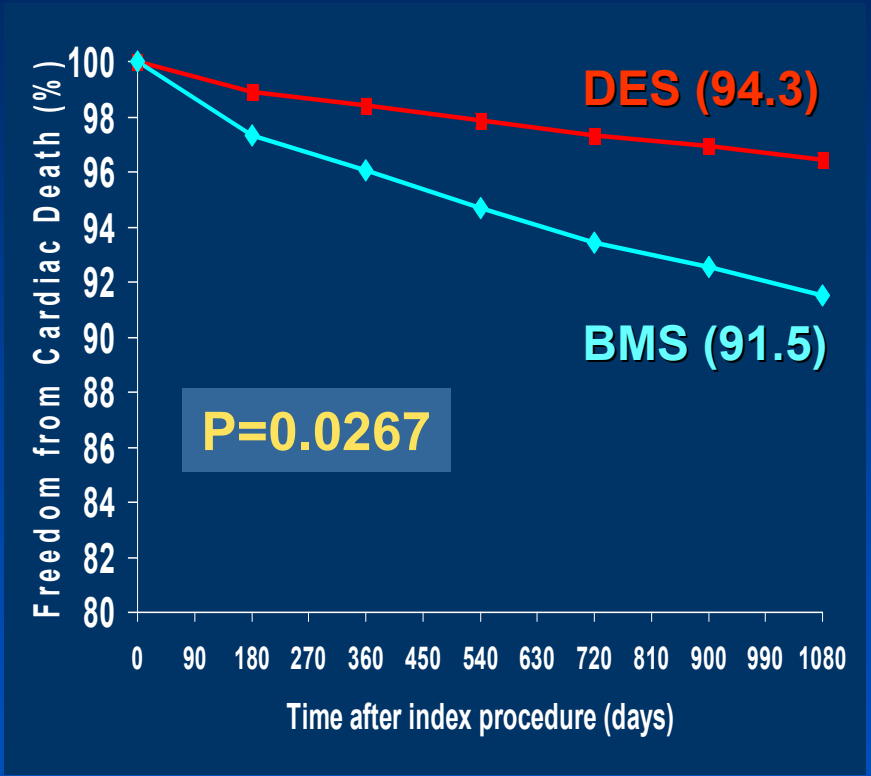
Patients without Diabetes



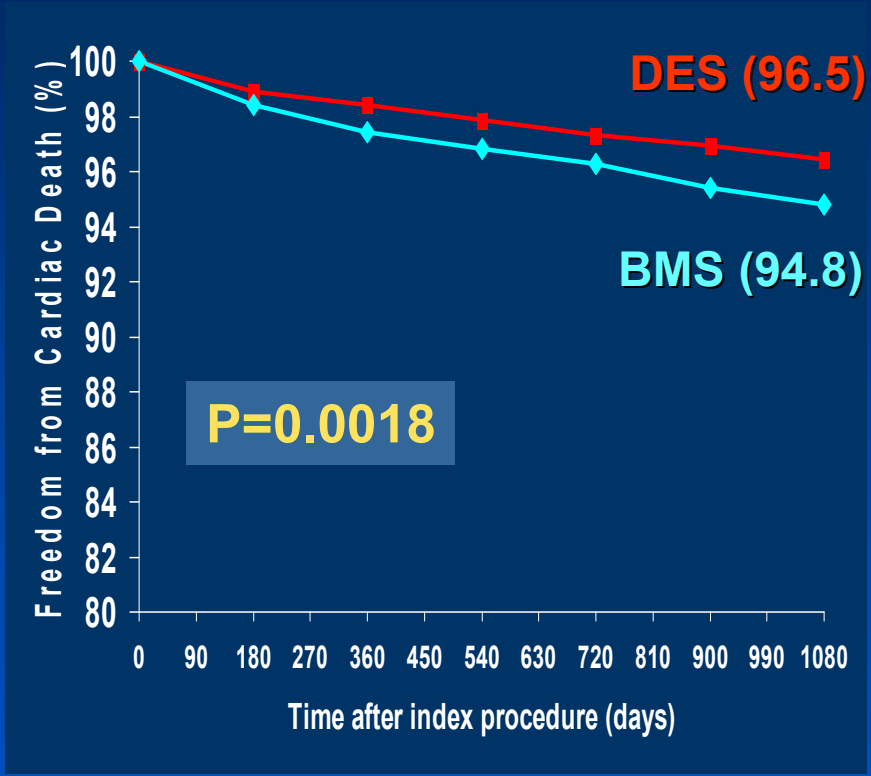
Interaction P value (DM * Stent type) = 0.103

Survival-Free from All-cause Mortality up to 3 years

Patients with **Diabetes**



Patients without Diabetes

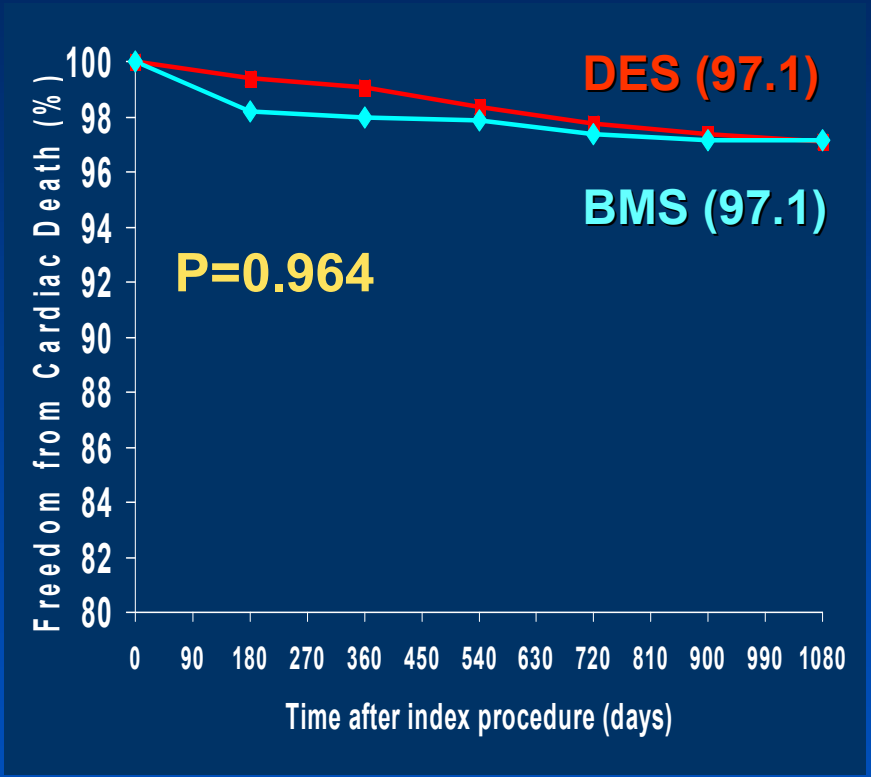


Interaction P value (DM * Stent type) = 0.0001

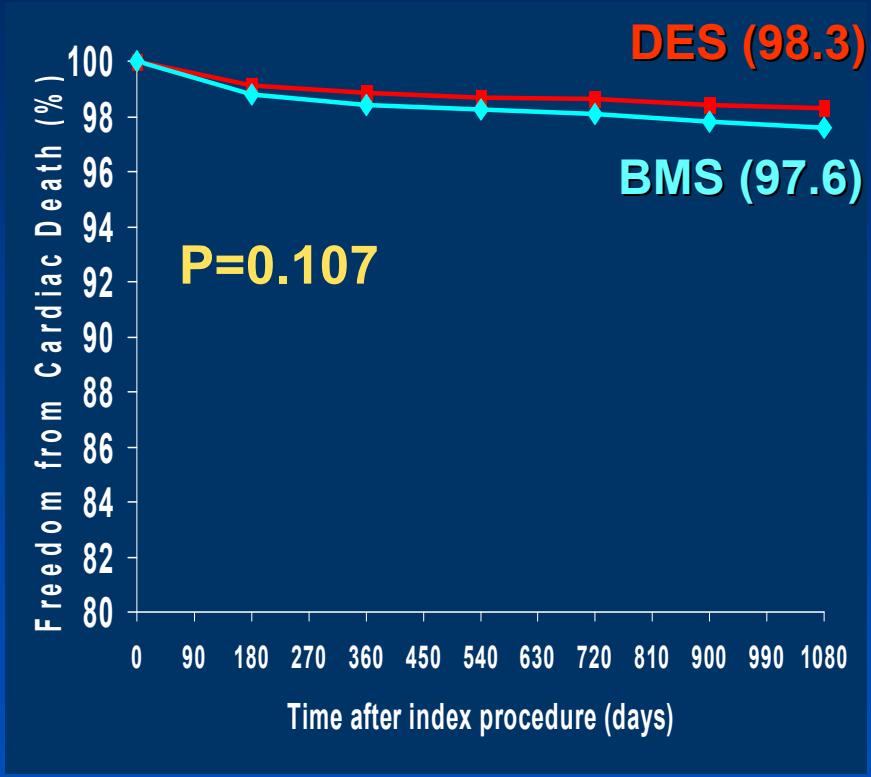
AMC registry Data 2007

Survival-Free from Cardiac Death up to 3 years

Patients with **Diabetes**

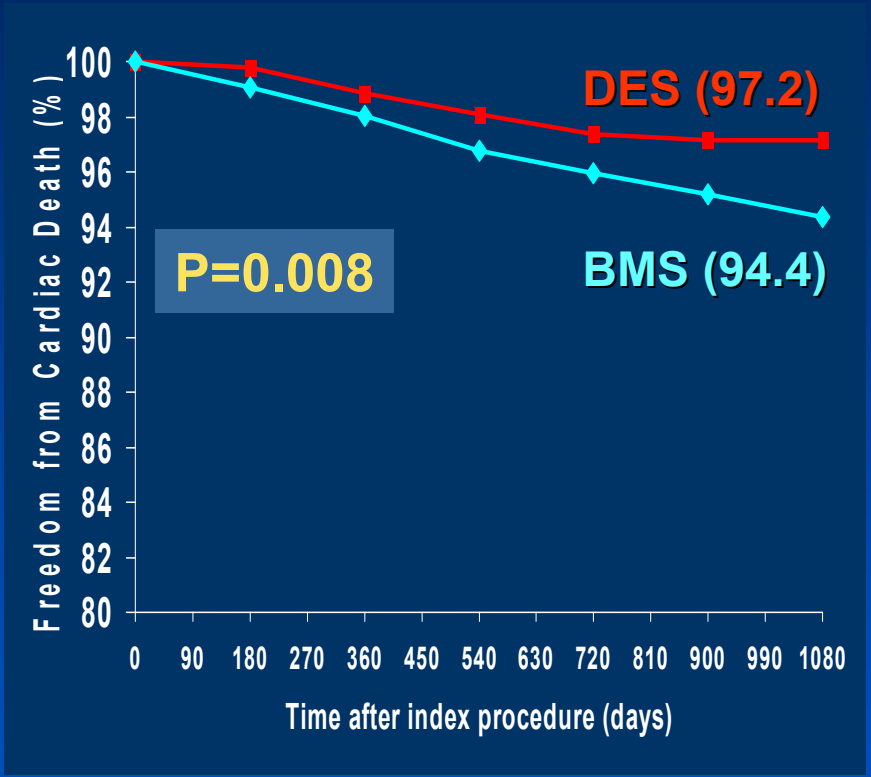


Patients without Diabetes

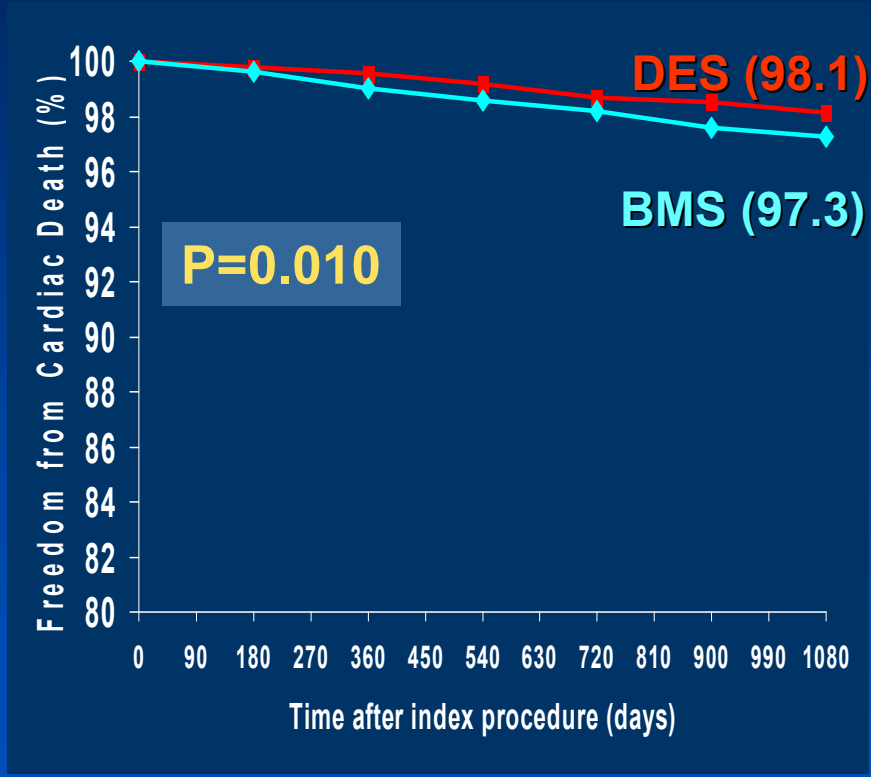


Survival-Free from Non-Cardiac Death up to 3 years

Patients with **Diabetes**

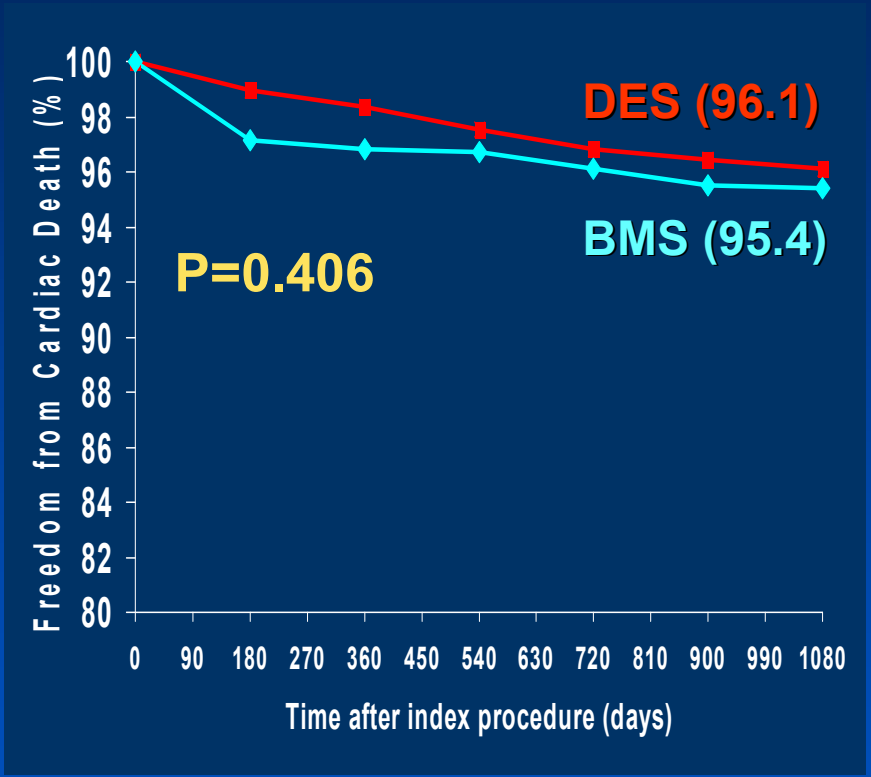


Patients without Diabetes

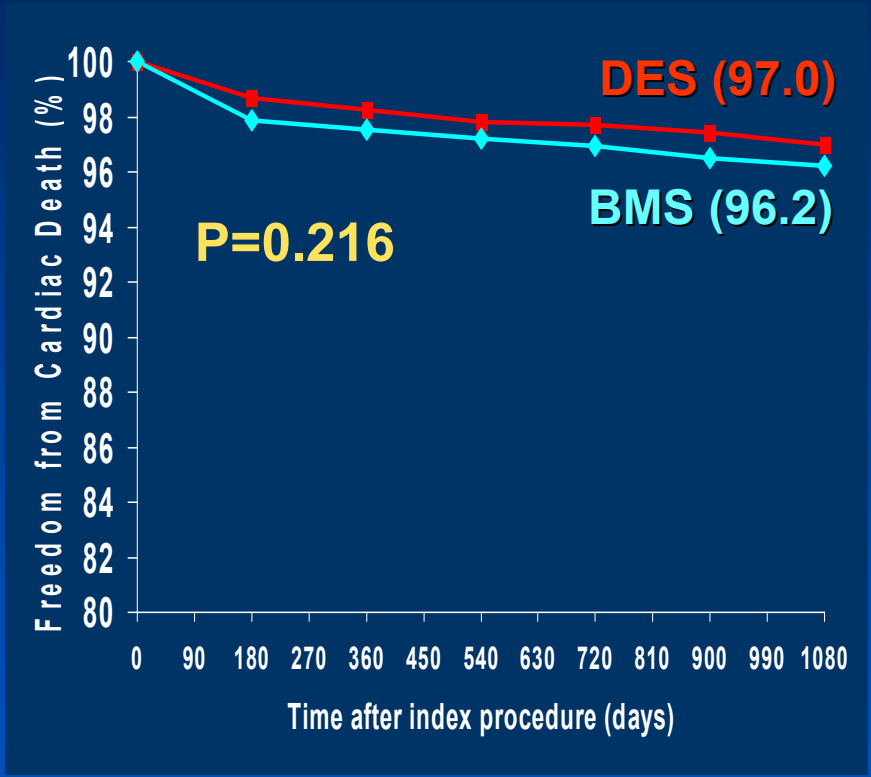


Survival-Free from Cardiac Death + MI up to 3 years

Patients with **Diabetes**



Patients without Diabetes



Interaction P value (DM * Stent type) = 0.136

Any differences of stent thrombosis pattern between Asia and Western country

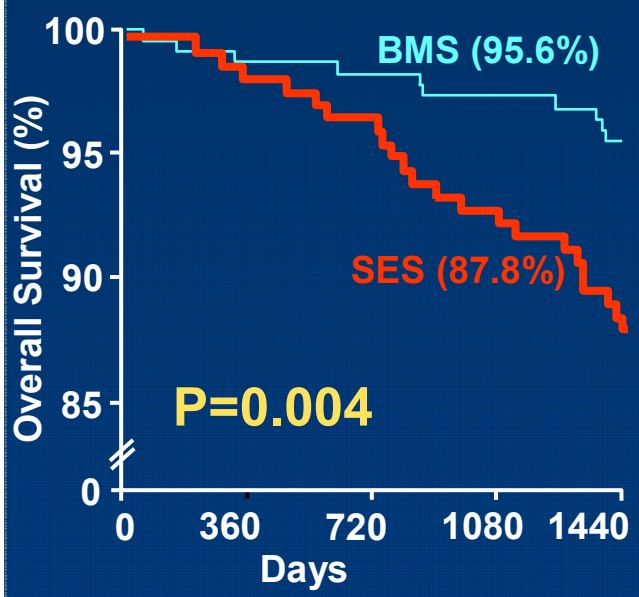
?

Impact of Diabetes

All-Cause Mortality

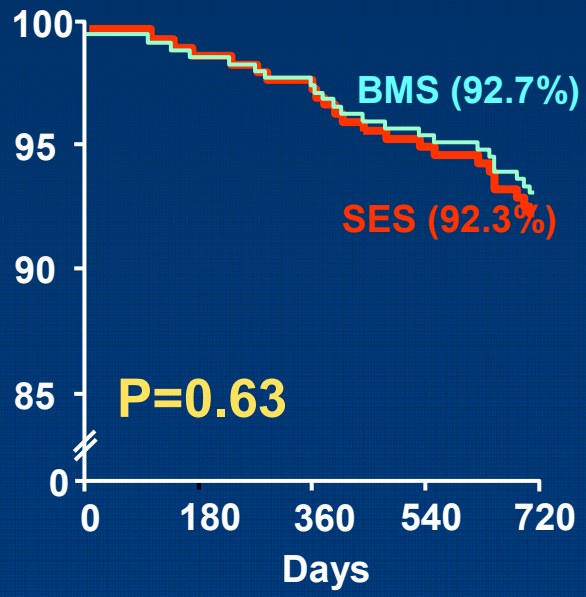
Death at 4 yr F/U

Patients with Diabetes



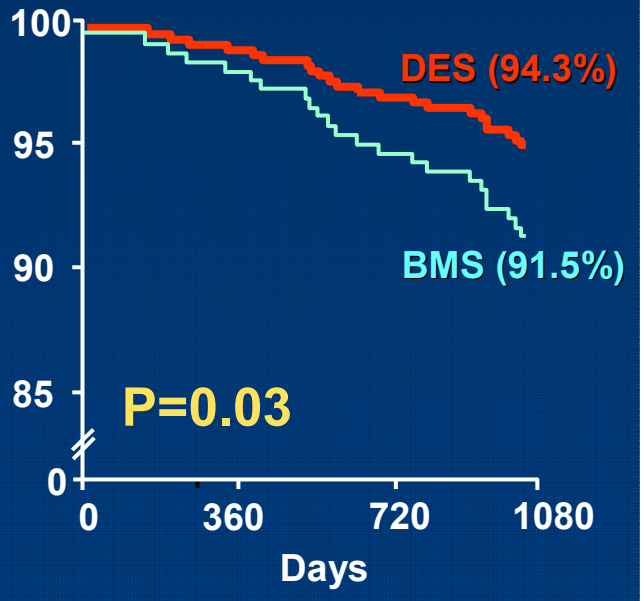
Death at 2 yr F/U

Patients with Diabetes



Death at 3 yr F/U

Patients with Diabetes

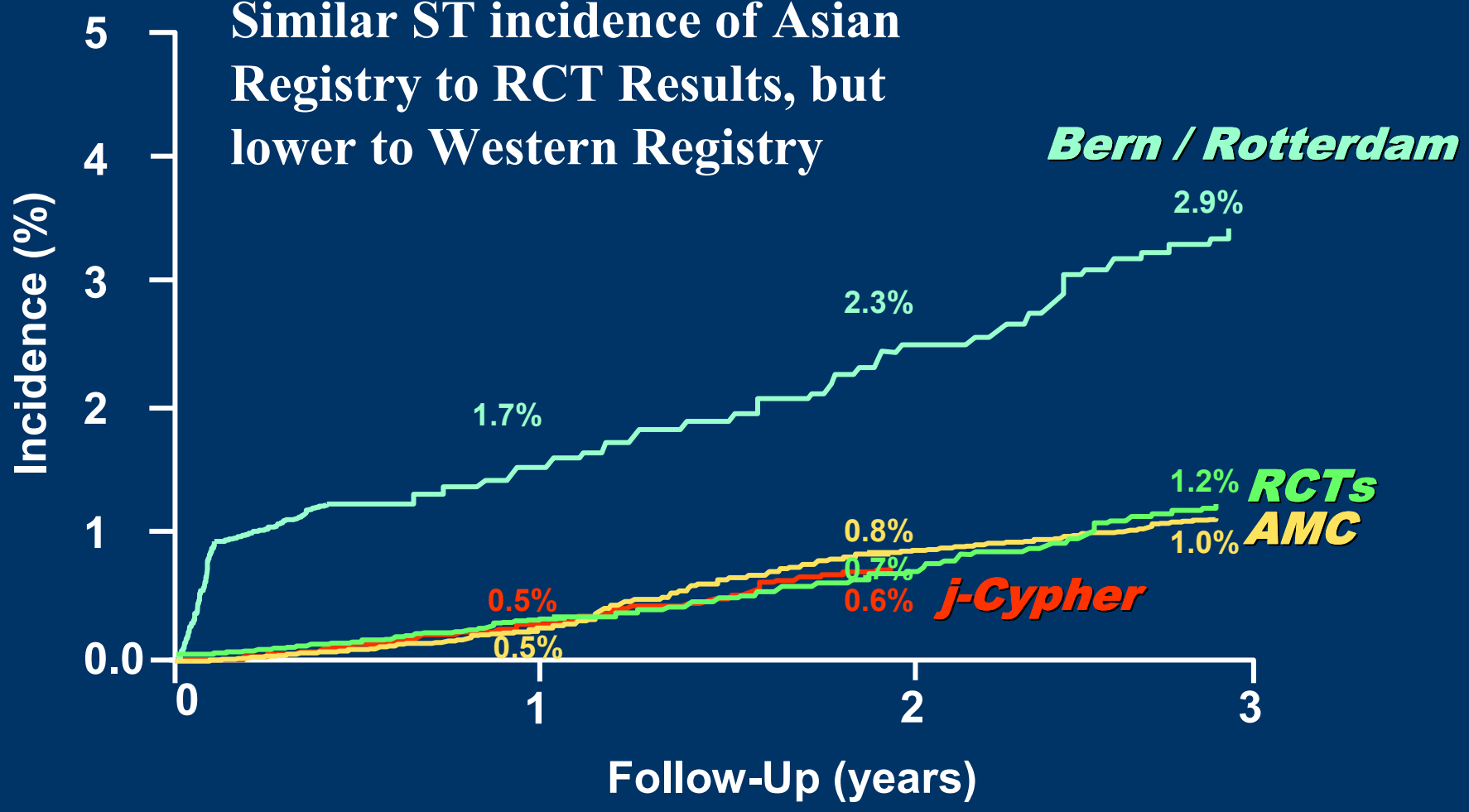


RCTs
(RAVEL, SIRIUS,
E-SIRIUS, C-SIRUS)

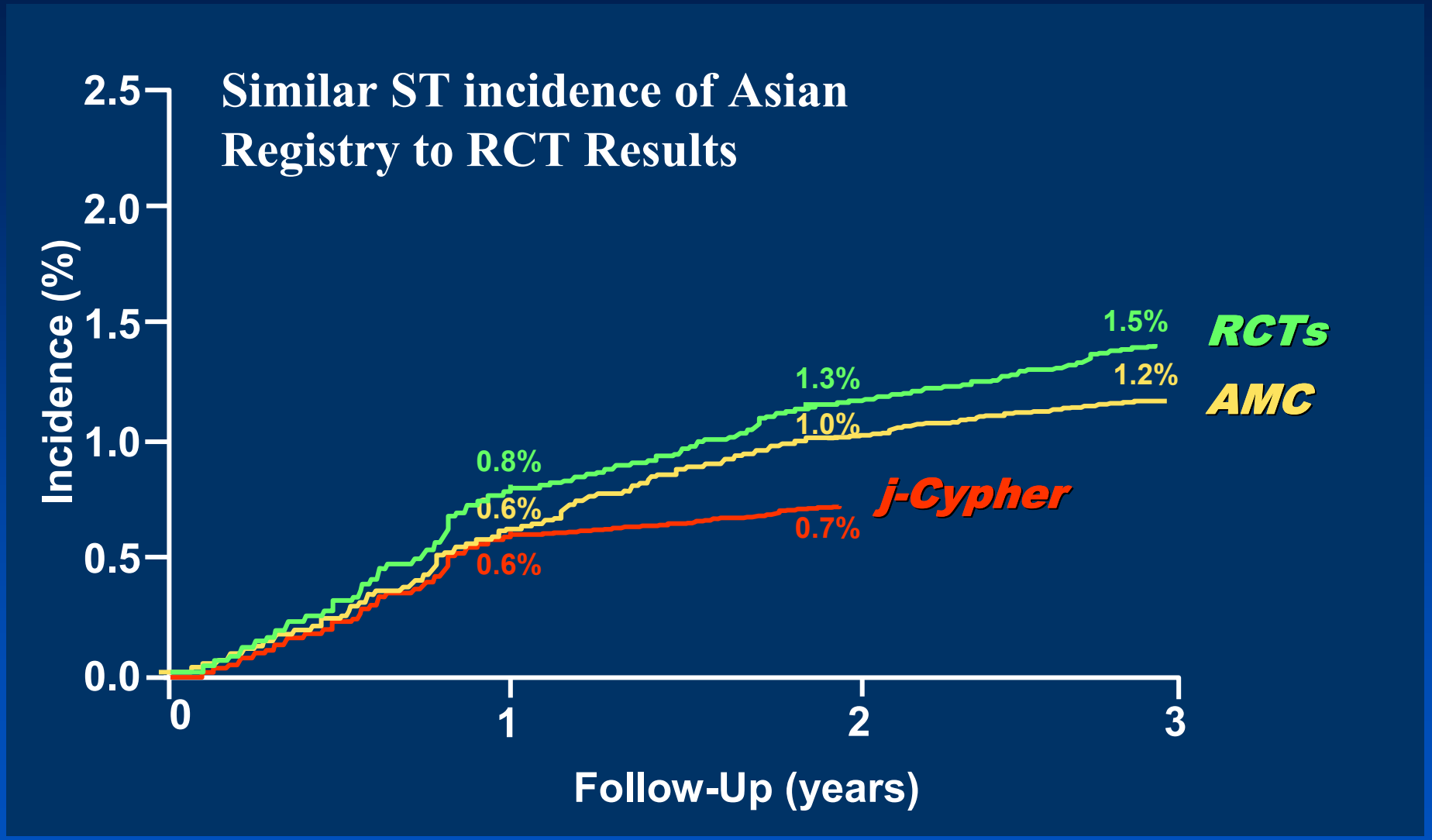
J-Cypher

AMC Registry

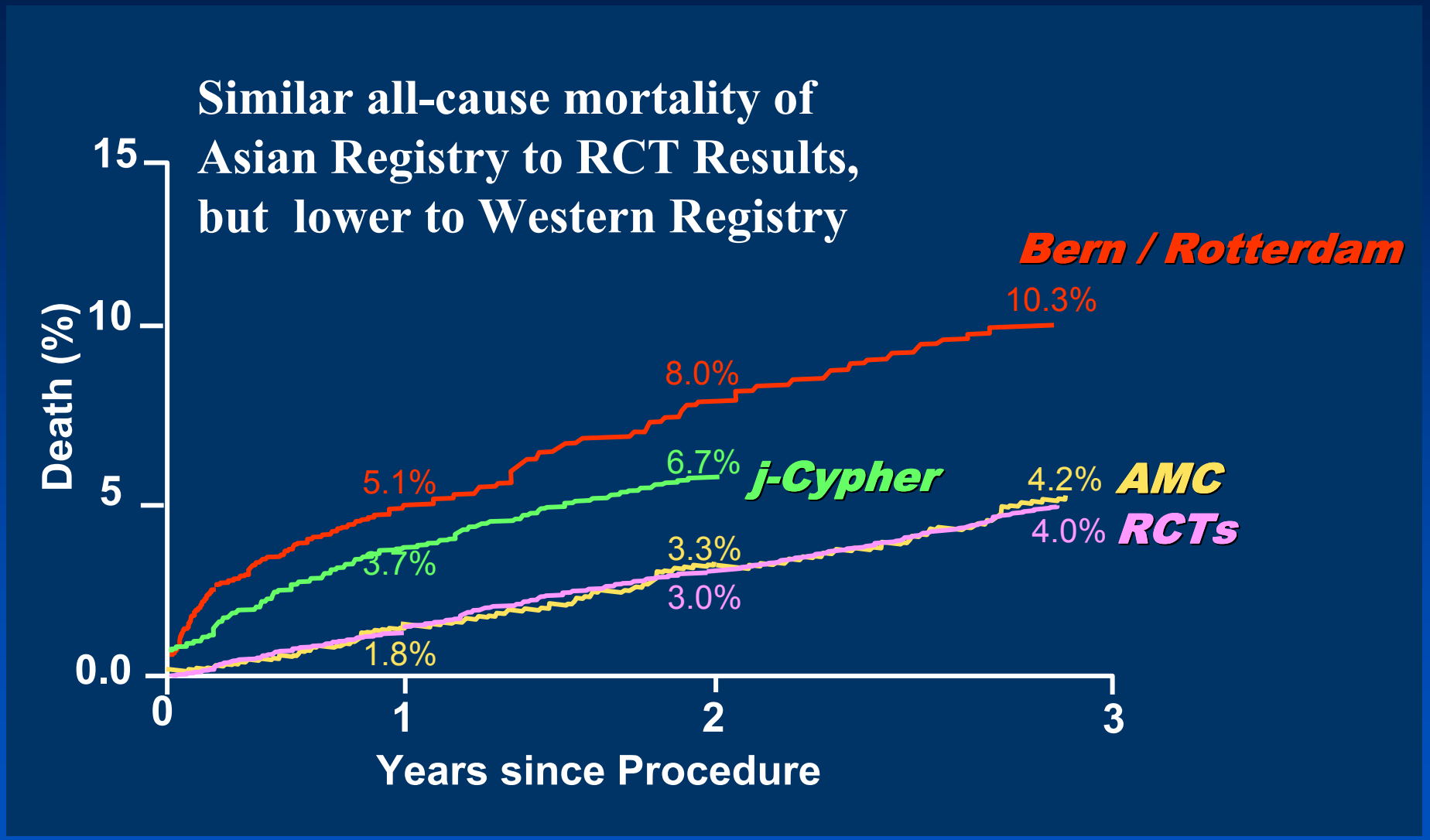
Incidence of Angiographic ST



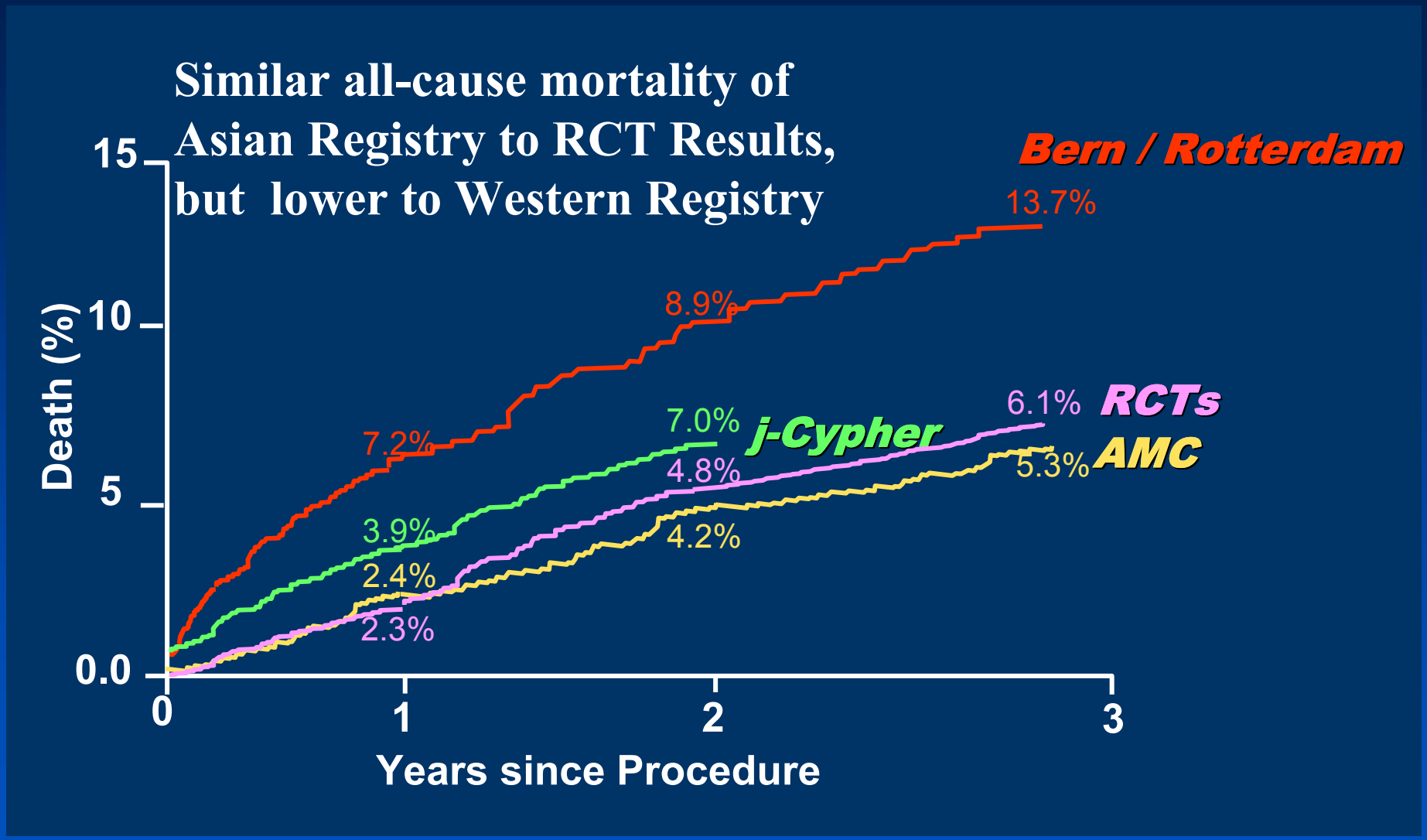
Incidence of ST (Definite+Probable)



All-Cause Mortality



Death or MI


Similar all-cause mortality of
Asian Registry to RCT Results,
but lower to Western Registry
Bern / Rotterdam
13.7%
8.9%
7.2%
7.0%
j-Cypher
6.1%
RCTs
4.8%
3.9%
AMC
5.3%
2.4%
4.2%
2.3%
Death (%)
15
10
5
0.0
0
1
2
3
Years since Procedure

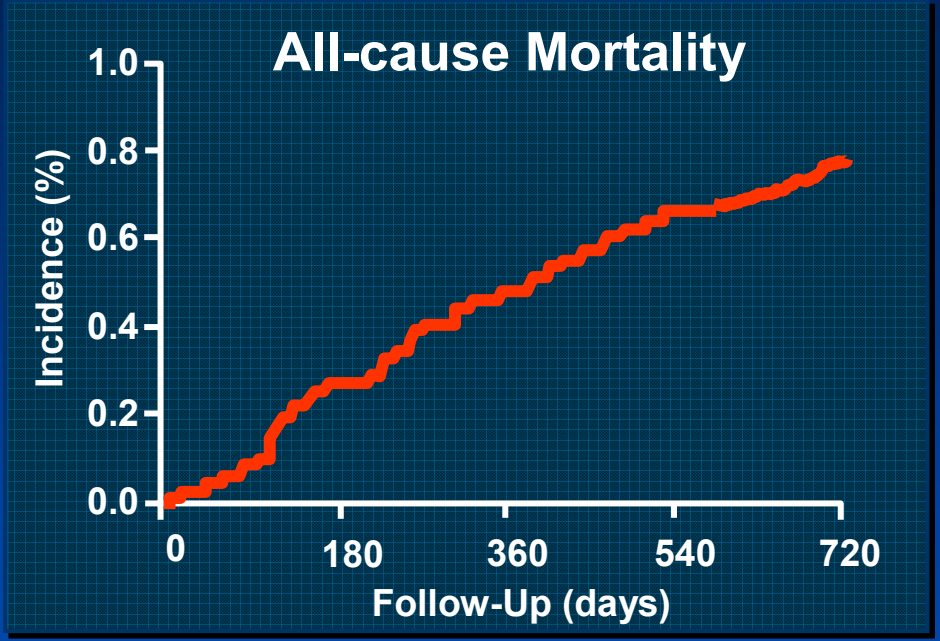
Any differences of stent thrombosis pattern between Asia and Western country ?

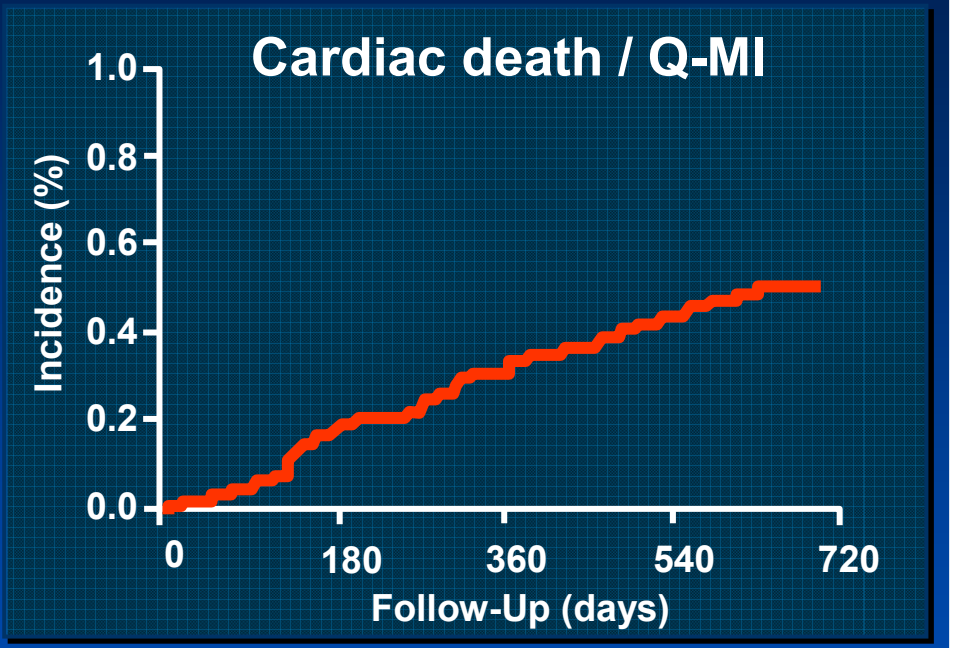
- Absolute incidence of stent thrombosis and all-cause mortality of Asian registry was lower than those of Western registry data ?
- Impact of diabetes on the long-term outcomes in Asia was very modest, compared to the features from Western data. ?

Impact of Long-Term Use of Clopidogrel Beyond 1 Year

?

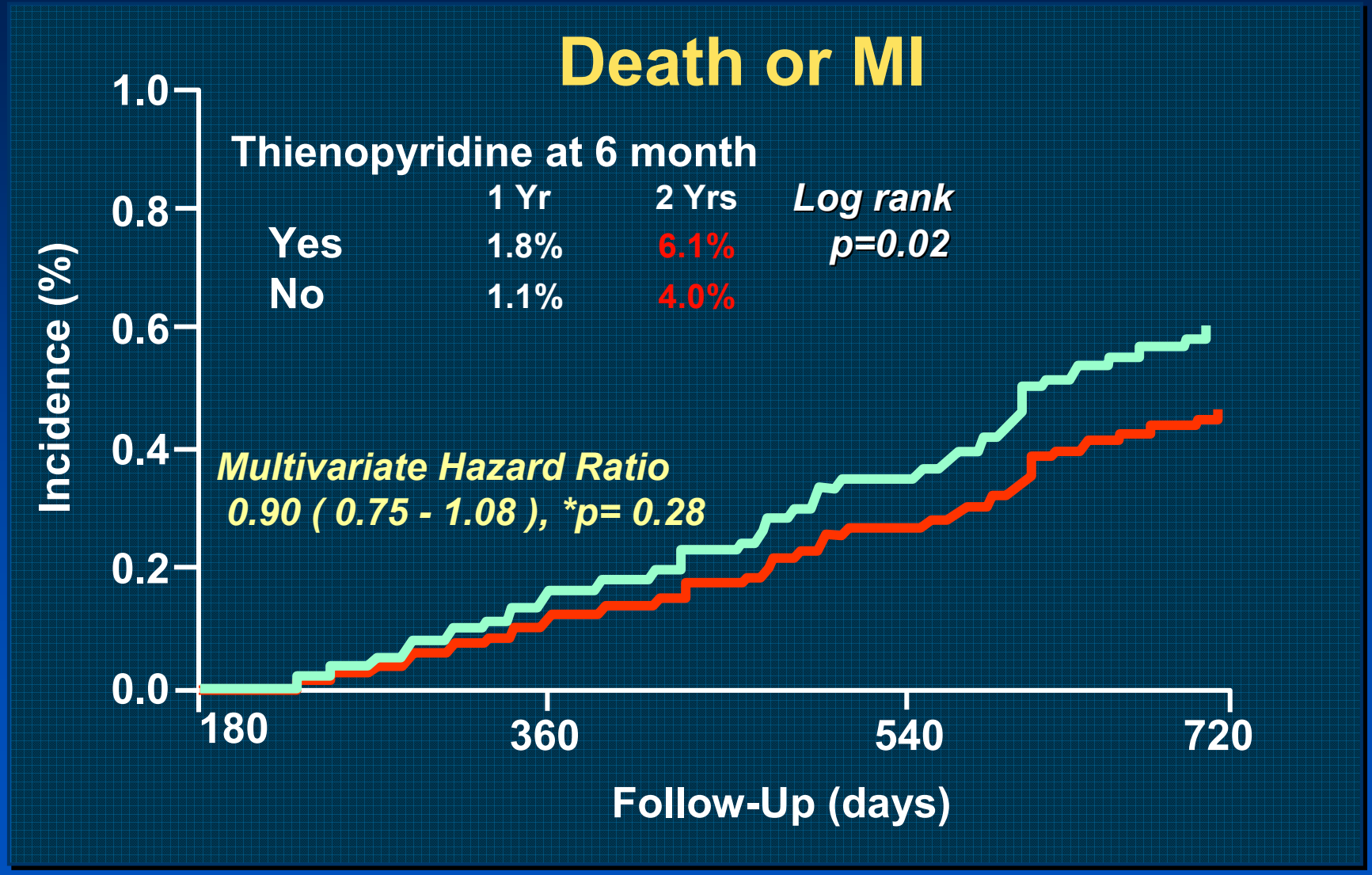
Two year event rates in j-Cypher



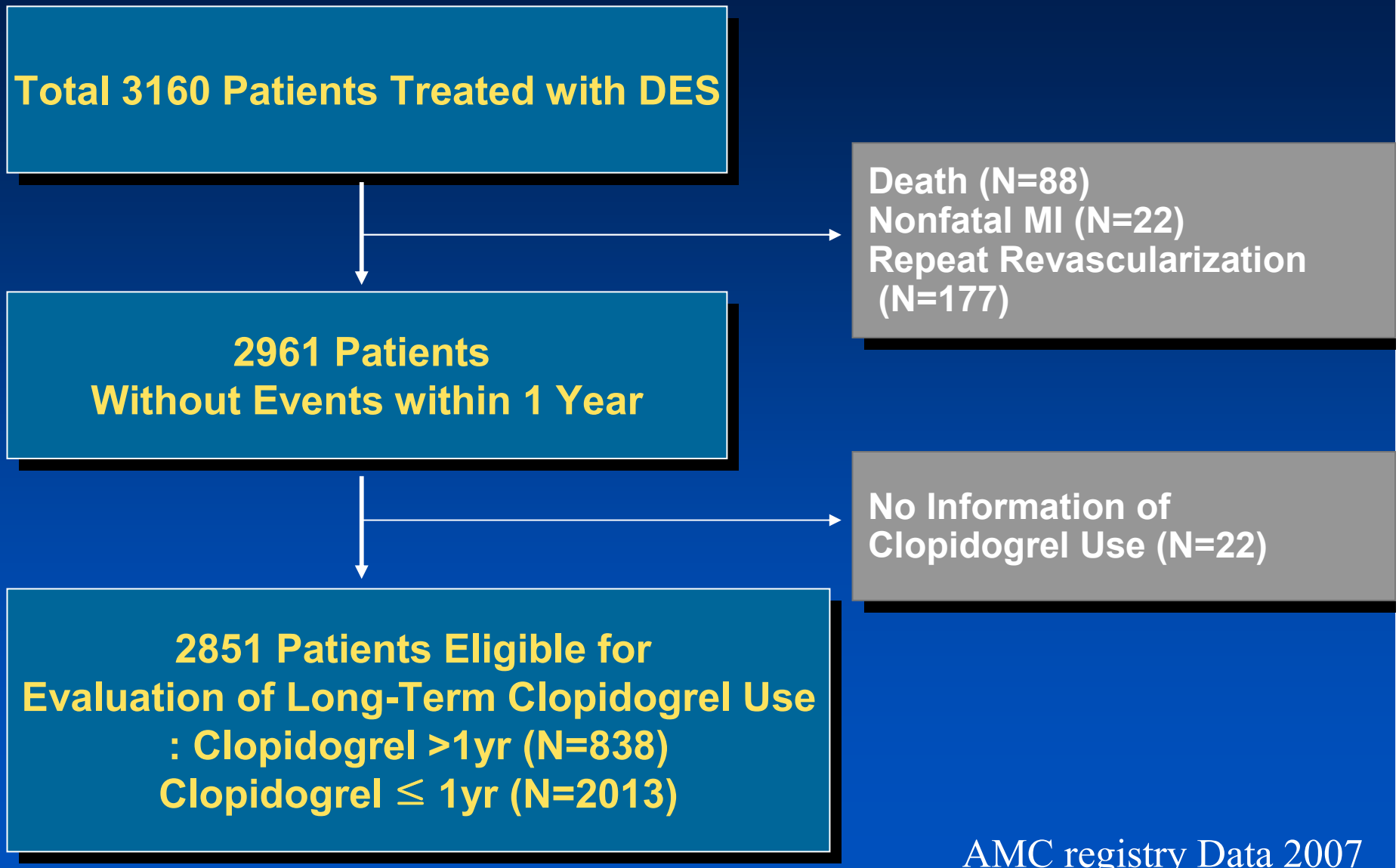


		30 Days	6 Mos.	1 Yr.	1.5 Yr.	2 Yrs.
All-cause mortality		0.62%	2.2%	3.7%	5.6%	6.7%
Cardiac death / Q wave MI		0.84%	2.0%	2.6%	3.6%	4.5%
n of pts at risk	6816	6488	6056	5552	1735	1251

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

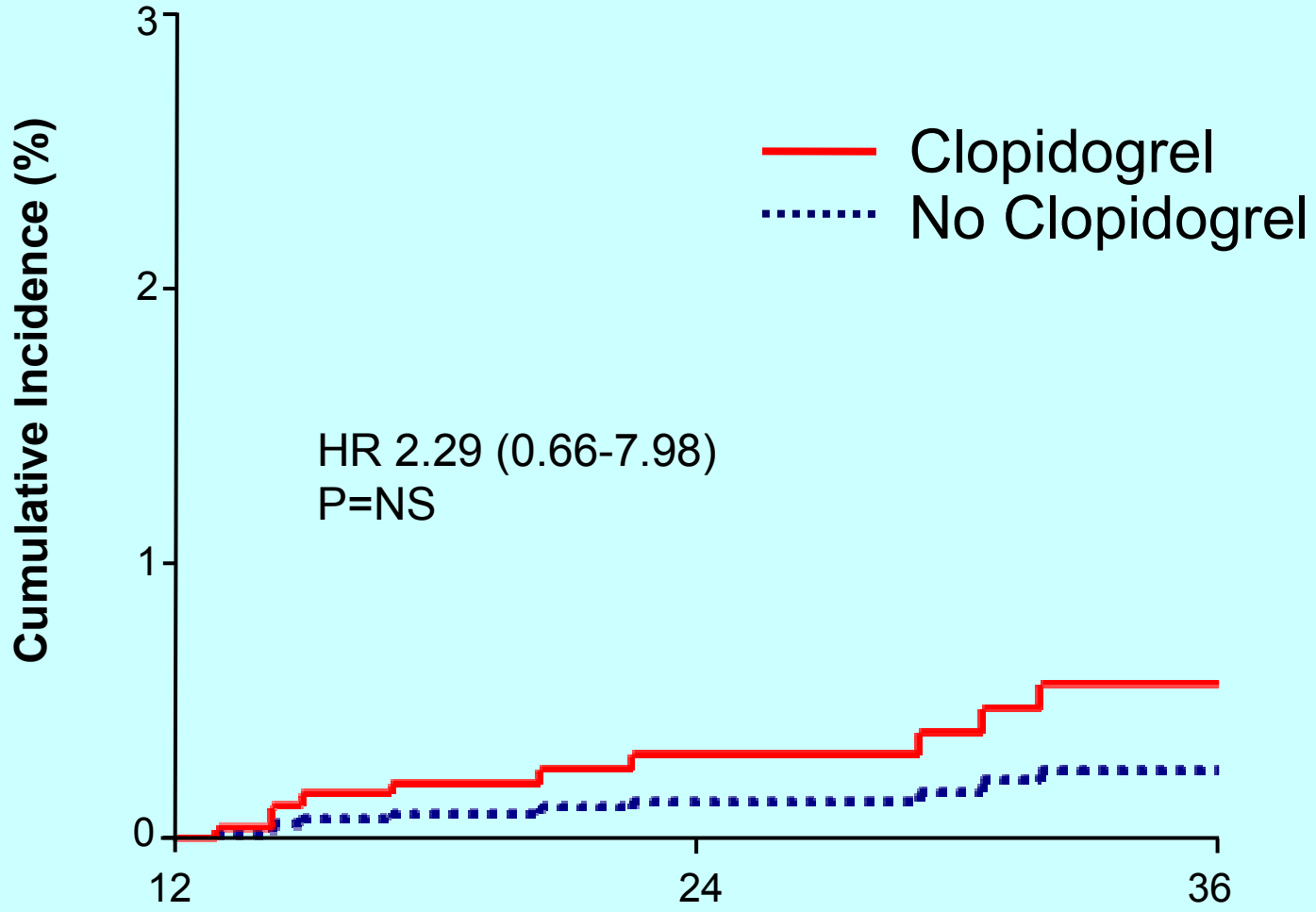


Eligible Patients



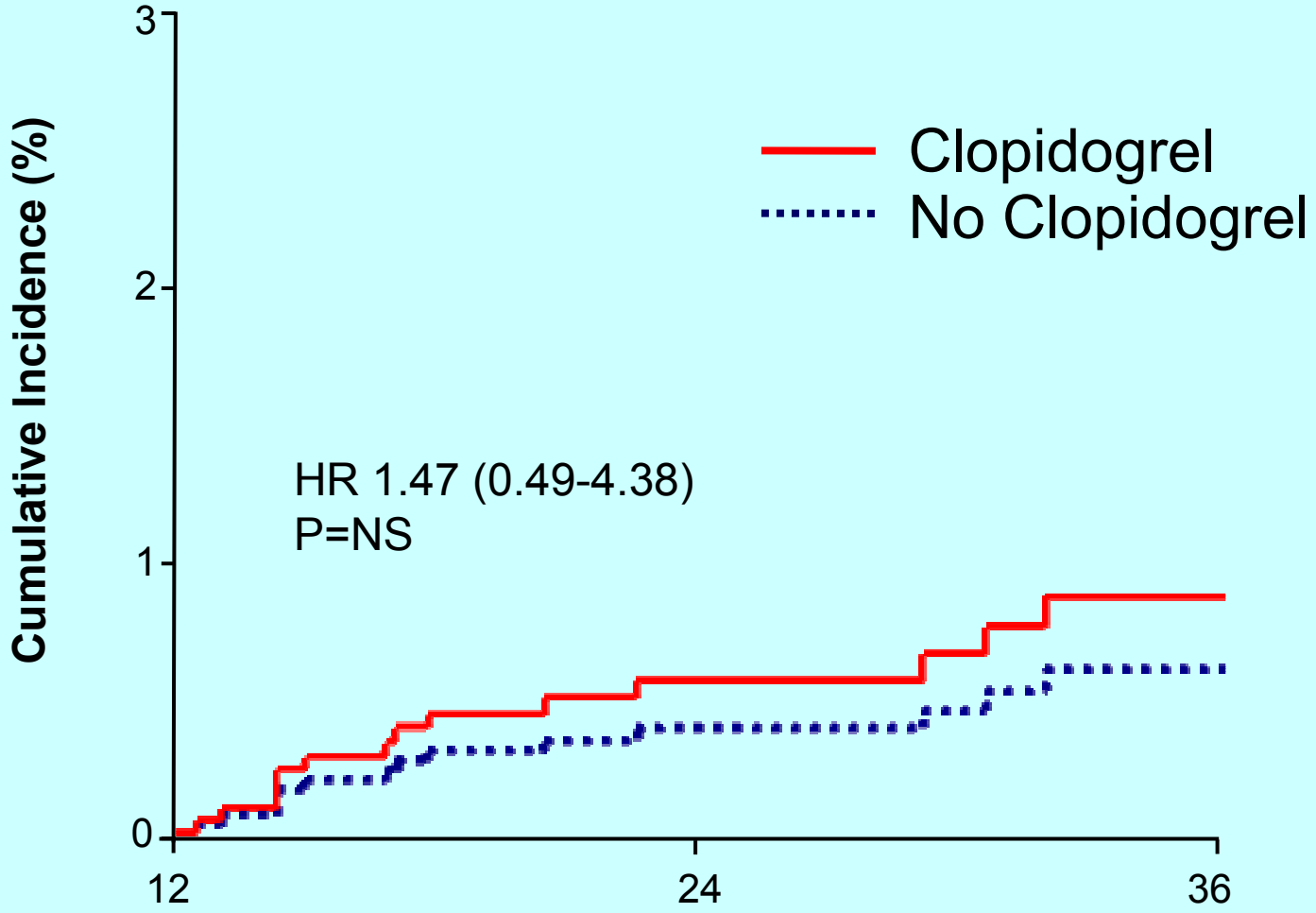
AMC registry Data 2007

Stent Thrombosis (Definite)



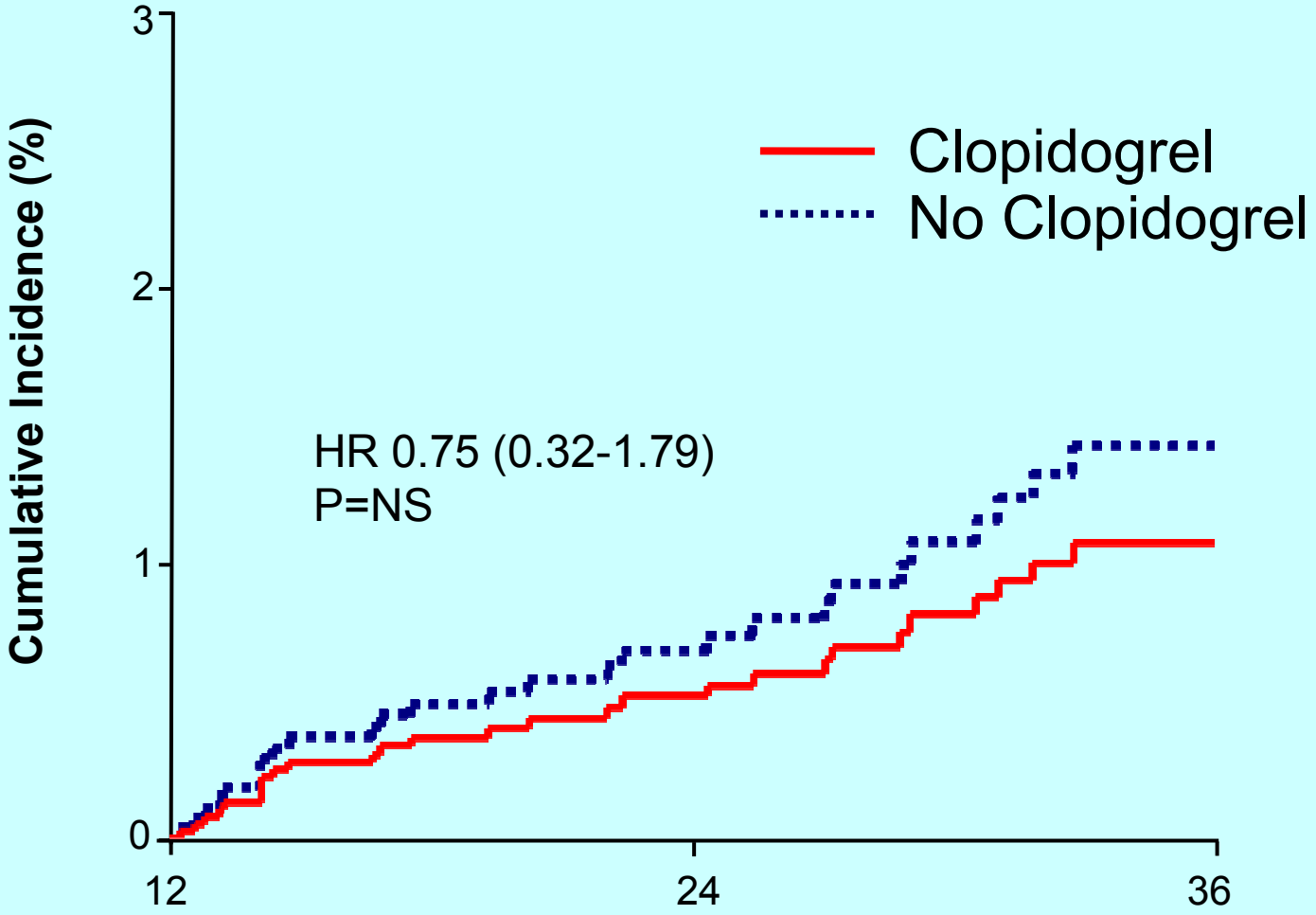
No. at Risk			
Clopidogrel	838	457	194
No Clopidogrel	2013	1459	654

Stent Thrombosis (Definite or Probable)



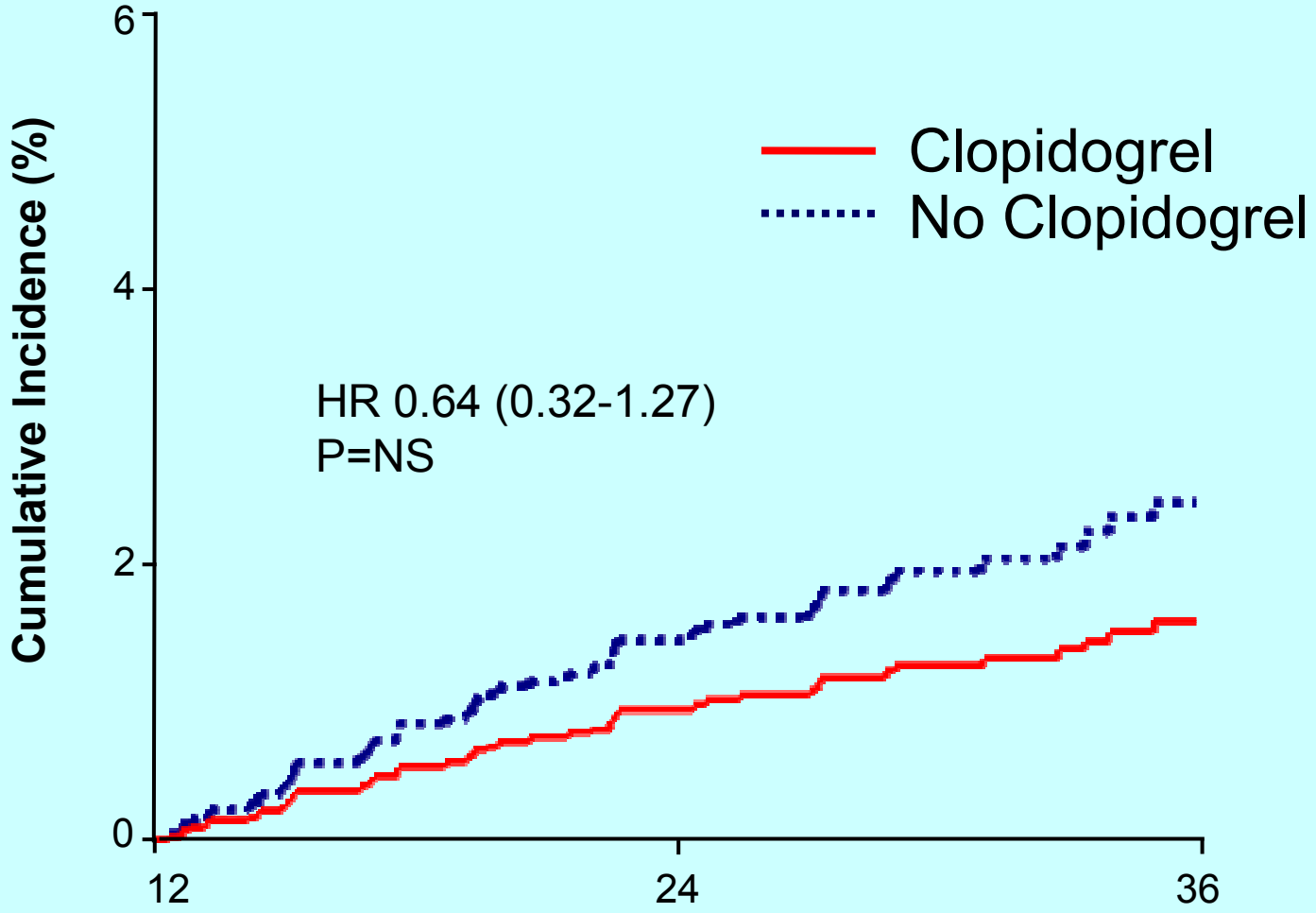
No. at Risk			
Clopidogrel	838	457	194
No Clopidogrel	2013	1459	654

Stent Thrombosis (Any ARC Criteria)



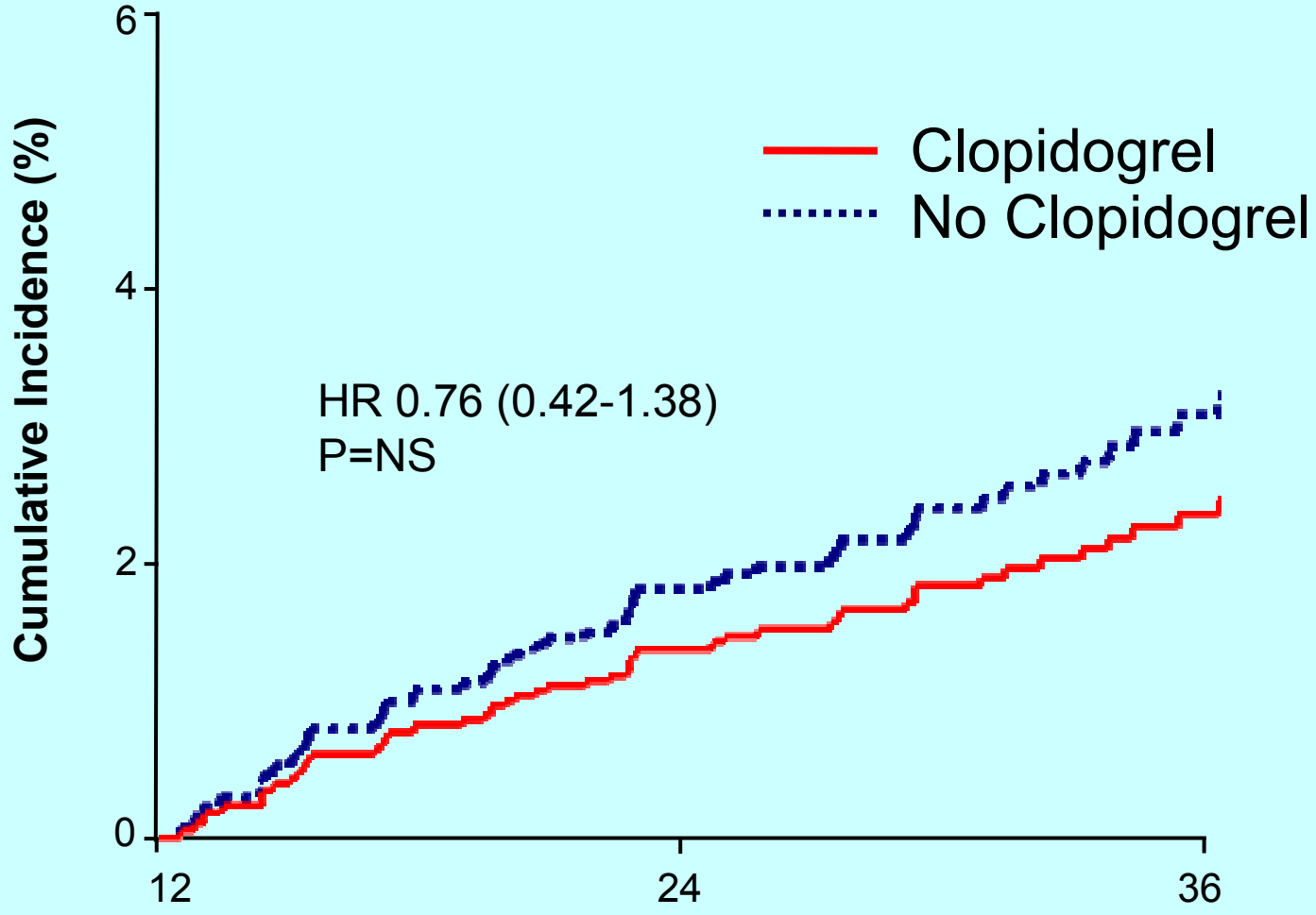
No. at Risk			
Clopidogrel	838	457	194
No Clopidogrel	2013	1459	654

All-Cause Mortality



No. at Risk			
Clopidogrel	838	458	195
No Clopidogrel	2013	1463	658

Composite of Death or MI



No. at Risk			
Clopidogrel	838	457	194
No Clopidogrel	2013	1459	654

Impact of Long-Term Use of Clopidogrel Beyond 1 Year

We need more data, RCTs

SES vs PES

?

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EXPEDITED PUBLICATIONS

A Meta-Analysis of 16 Randomized Trials of Sirolimus-Eluting Stents Versus Paclitaxel-Eluting Stents in Patients With Coronary Artery Disease

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Munich, Germany; Bern, Basel, and Lausanne, Switzerland; Córdoba, Spain; Seoul and Daejeon, Korea; and Avellino, Italy

A Meta-Analysis of 16 Randomized Trials Comparing Sirolimus-Eluting Stents with Paclitaxel-Eluting Stents

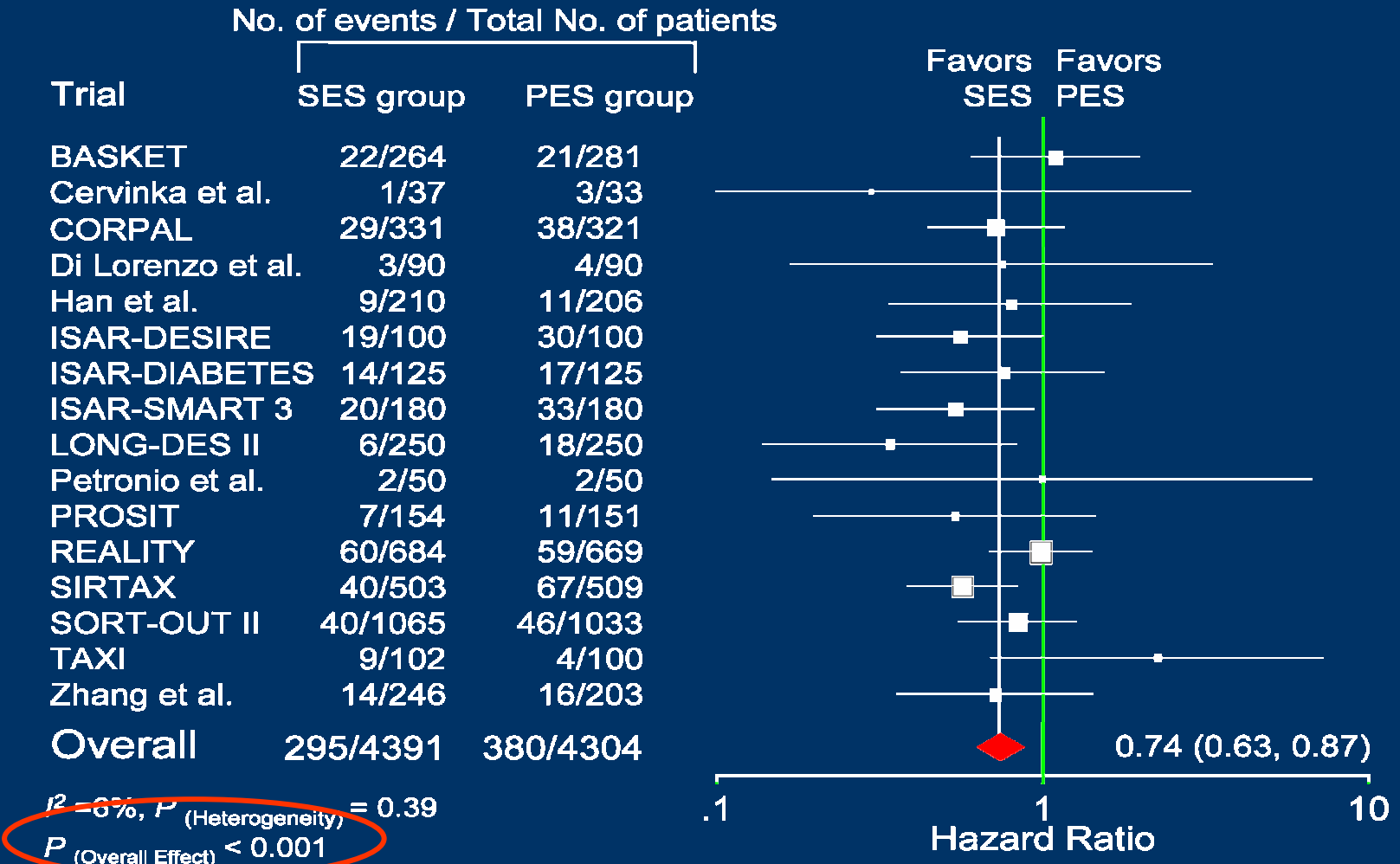
Shõmig et al, J Am Coll Cardiol 2007;50: e-publication (August 21, 2007)

Summary of 16 RCTs

	# of pts	Patient Profile	Primary Endpoint	Length of Dual APT: SES/PES (m)	Mean Follow-up
Di Lorenzo, et al.*	180	AMI	MACE	6/6	12
ISAR-DESIRE	200	ISR	Angiographic Restenosis	6/6	34
TAXi*	202	All-Comer	MACE	12/12	37
ISAR-DIABETES	250	Diabetics	Late Loss	6/6	32
PROSIT	308	AMI	MACE	6/6	26
ISAR-SMART 3	360	Small-Vessels (non-DM)	Late Loss	6/6	34
Long DES II	500	Long-lesions	Angiographic Restenosis	6/6	13
BASKET*	545	All-Comer	HECON based on MACE	6/6	18
CORPAL	652	All-Comer	Angiographic Restenosis	12/12	31
SIRTAX	1,012	All-Comer	MACE	12/12	24
REALITY	1,353	Relatively Unrestricted	Angiographic Restenosis	2/6	24
Cervinka, et al.	70	Complex	NI Volume (IVUS)	6/6	24
Petronio, et al.	100	Complex	NI Volume (IVUS)	6/6	36
Han, et al.*	416	MVD	MACE	9/9	20
Zhang, et al.*	449	All-Comer	MACE	9/12	12
SORT OUT II*	2,098	All-Comer	MACE	9/9	9

Shõmig et al, J Am Coll Cardiol 2007;50: e-publication (August 21, 2007)

Primary Efficacy Endpoint
Reintervention
Through Latest Follow-up

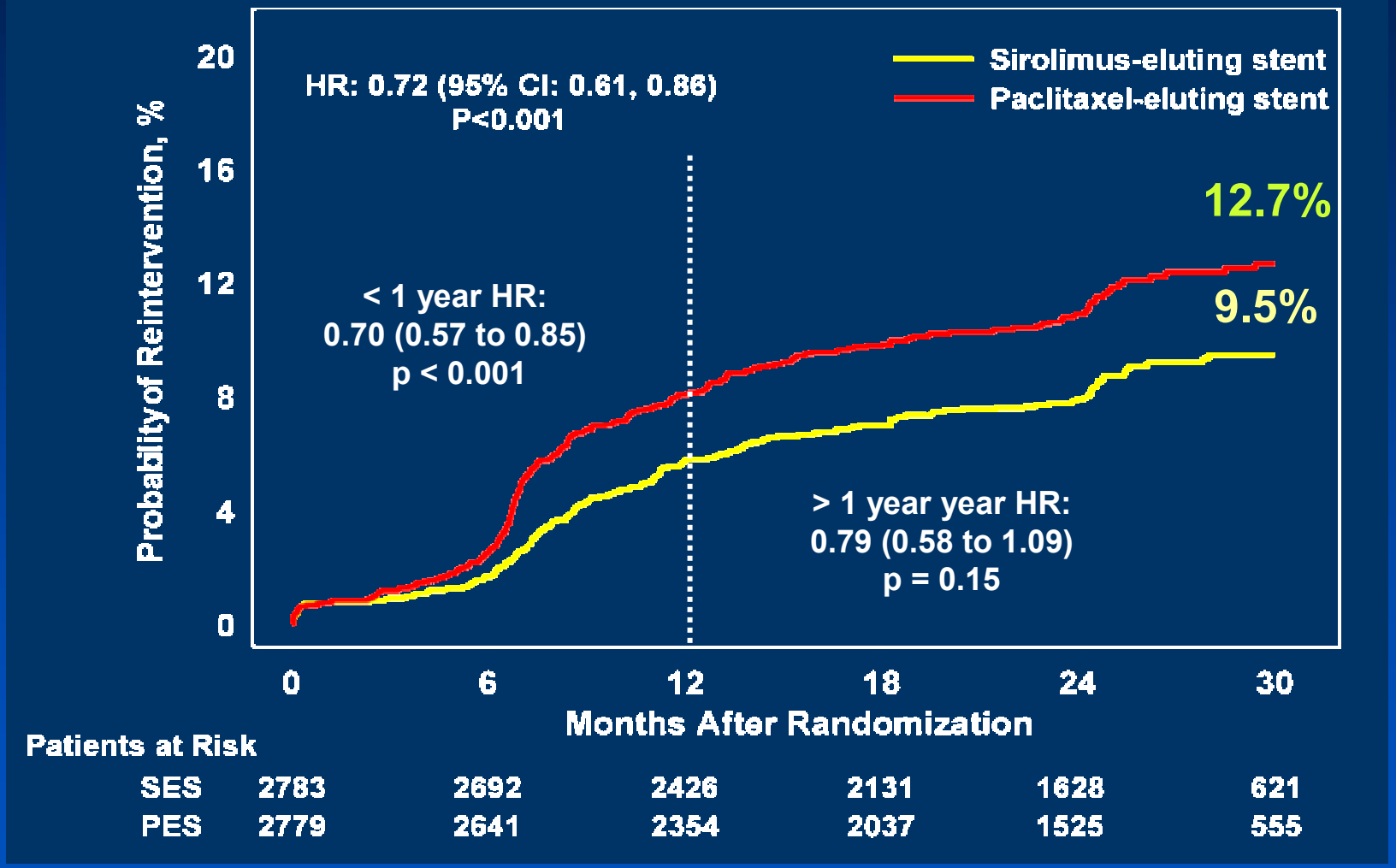


Shõmig et al, J Am Coll Cardiol 2007;50: e-publication (August 21, 2007)

Trials with Patient-level Data

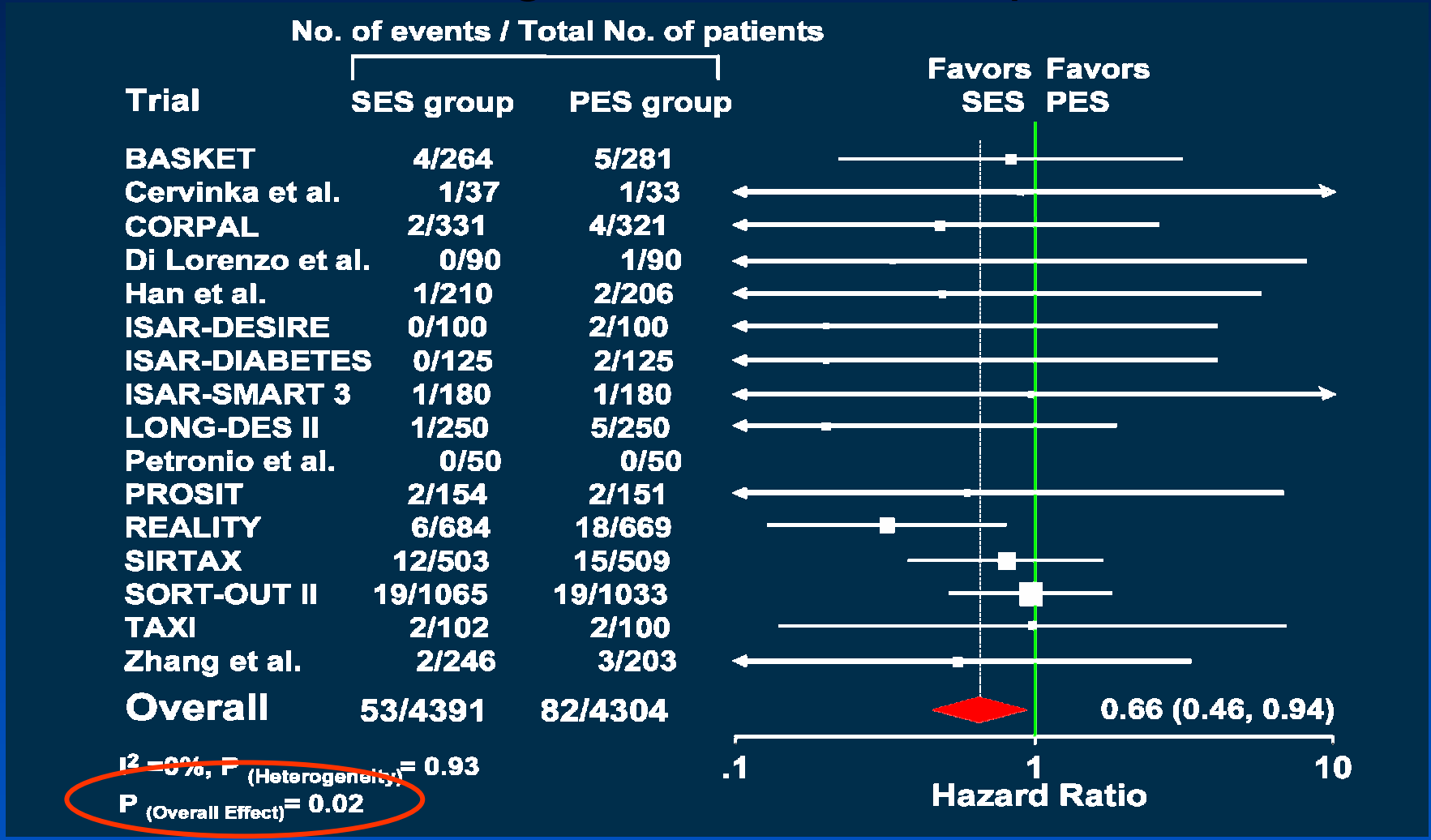
Reintervention

Through Latest Follow-up



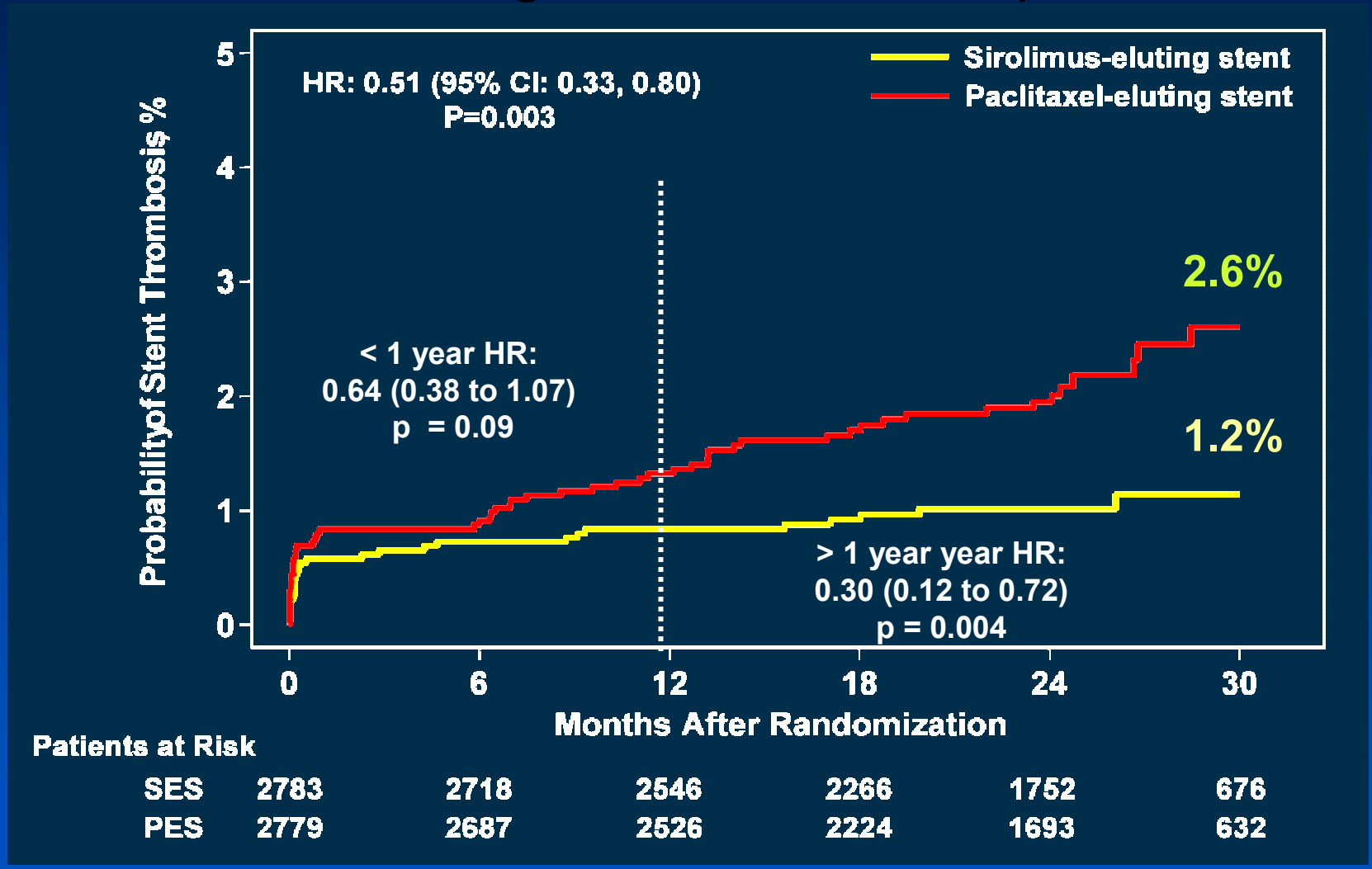
Shõmig et al, J Am Coll Cardiol 2007;50: e-publication (August 21, 2007)

Primary Safety Endpoint
Stent Thrombosis
Through Latest Follow-up



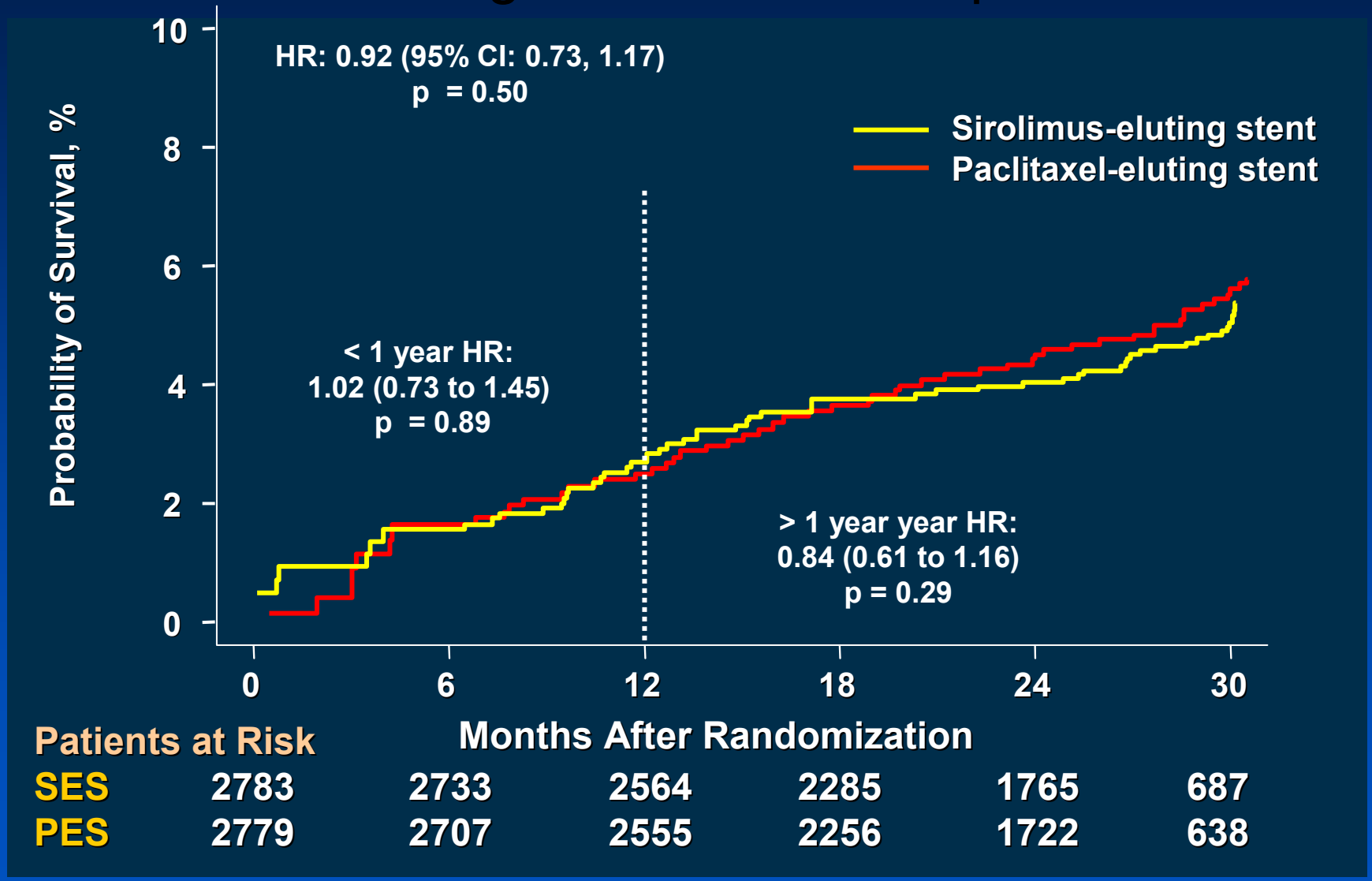
Shõmig et al, J Am Coll Cardiol 2007;50: e-publication (August 21, 2007)

Trials with Patient-level Data
Stent Thrombosis
Through Latest Follow-up



Shõmig et al, J Am Coll Cardiol 2007;50: e-publication (August 21, 2007)

Trials with Patient-level Data
Mortality
Through Latest Follow-up

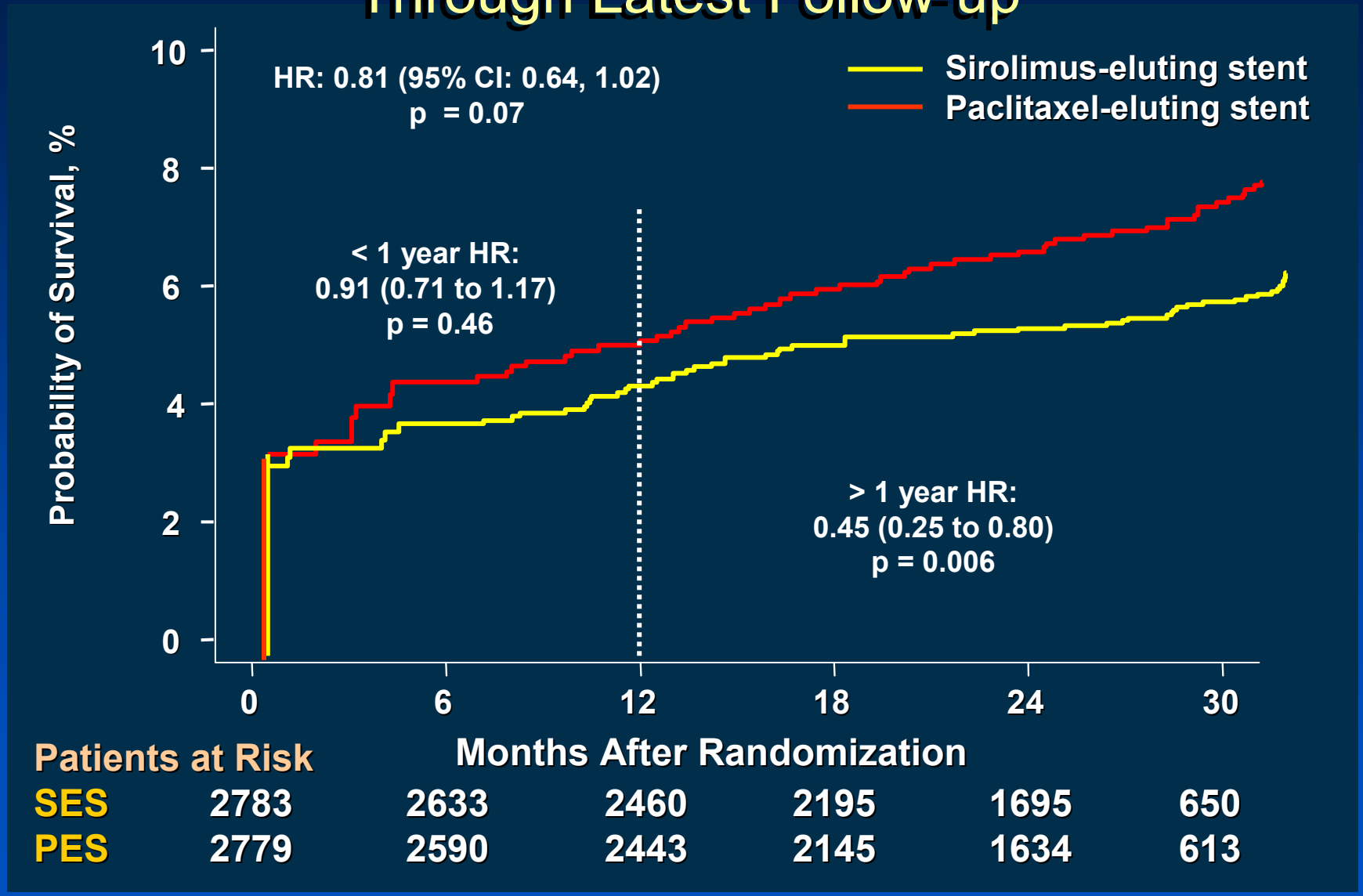


Patients at Risk						
SES	2783	2733	2564	2285	1765	687
PES	2779	2707	2555	2256	1722	638

Trials with Patient-level Data

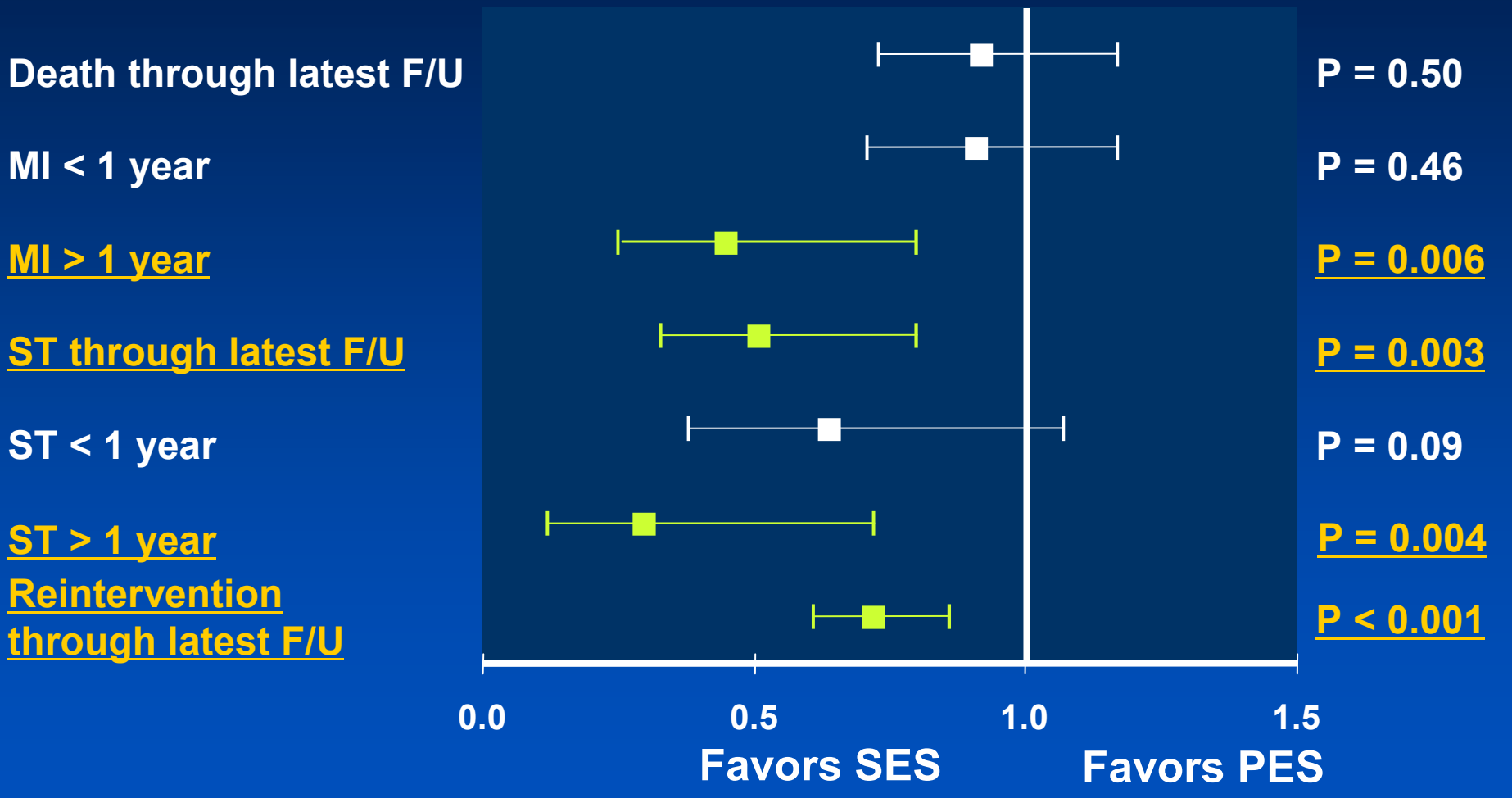
MI

Through Latest Follow-up



Patients at Risk						
SES	2783	2633	2460	2195	1695	650
PES	2779	2590	2443	2145	1634	613

Trials with Patient-level Data
Summary of Meta-analysis Findings



Shõmig et al, J Am Coll Cardiol 2007;50: e-publication (August 21, 2007)

Lancet 2007; 370: 937–48

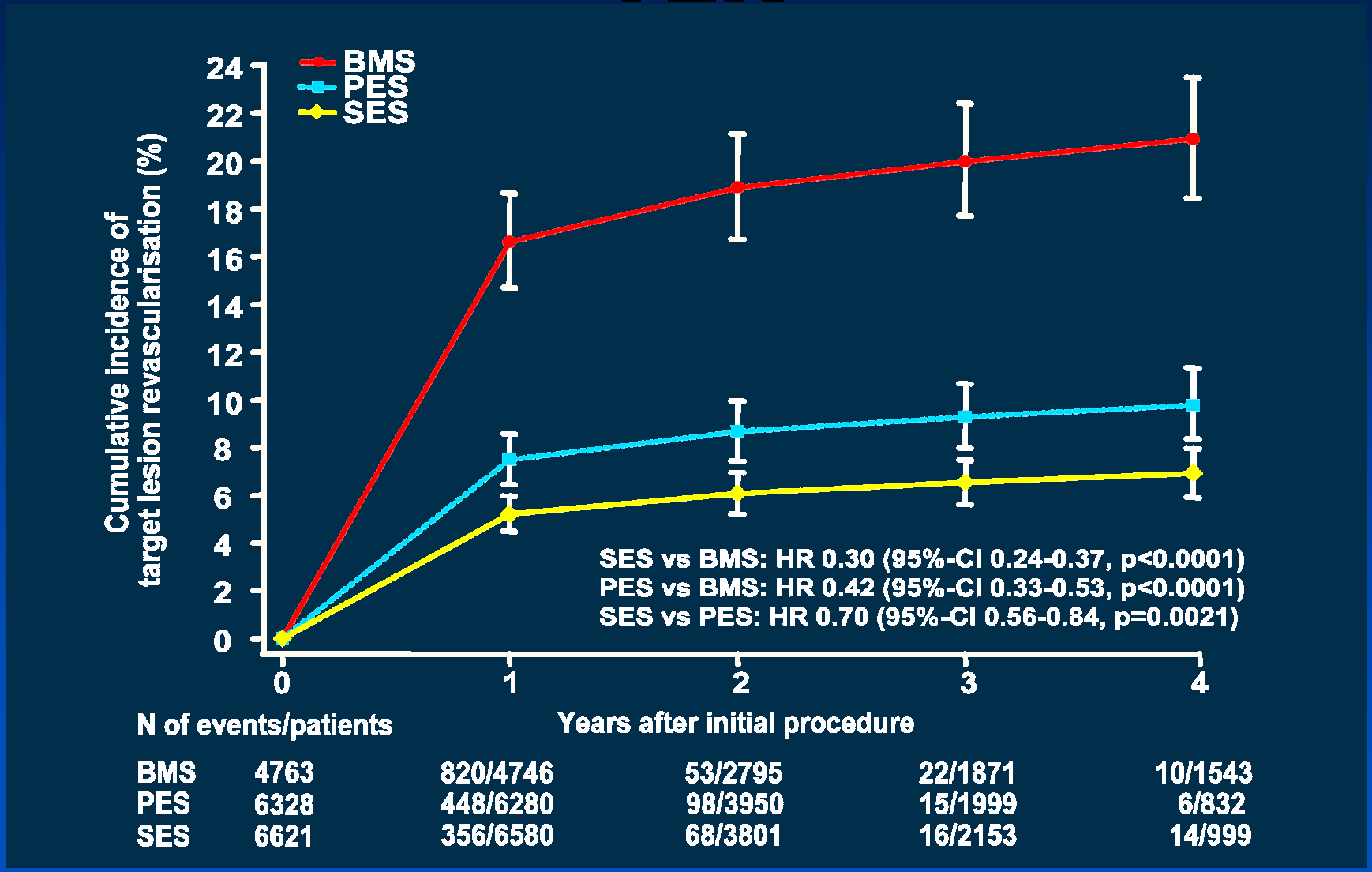
Outcomes associated with drug-eluting and bare-metal stents: a collaborative network meta-analysis

Christoph Stettler,* Simon Wandel,* Sabin Allemann, Adnan Kastrati, Marie Claude Morice, Albert Schömig, Matthias E Pfisterer, Gregg W Stone, Martin B Leon, José Suarez de Lezo, Jean-Jacques Goy, Seung-Jung Park, Manel Sabaté, Maarten J Suttorp, Henning Kelbaek, Christian Spaulding, Maurizio Menichelli, Paul Vermeersch, Maurits T Dirksen, Pavel Cervinka, Anna Sonia Petronio, Alain J Nordmann, Peter Diem, Bernhard Meier, Marcel Zwahlen, Stephan Reichenbach, Sven Trelle, Stephan Windecker, Peter Jüni

A Meta-Analysis of 38 Randomized Trials Comparing Sirolimus-Eluting Stents, Bare Metal Stents and Paclitaxel-Eluting Stents

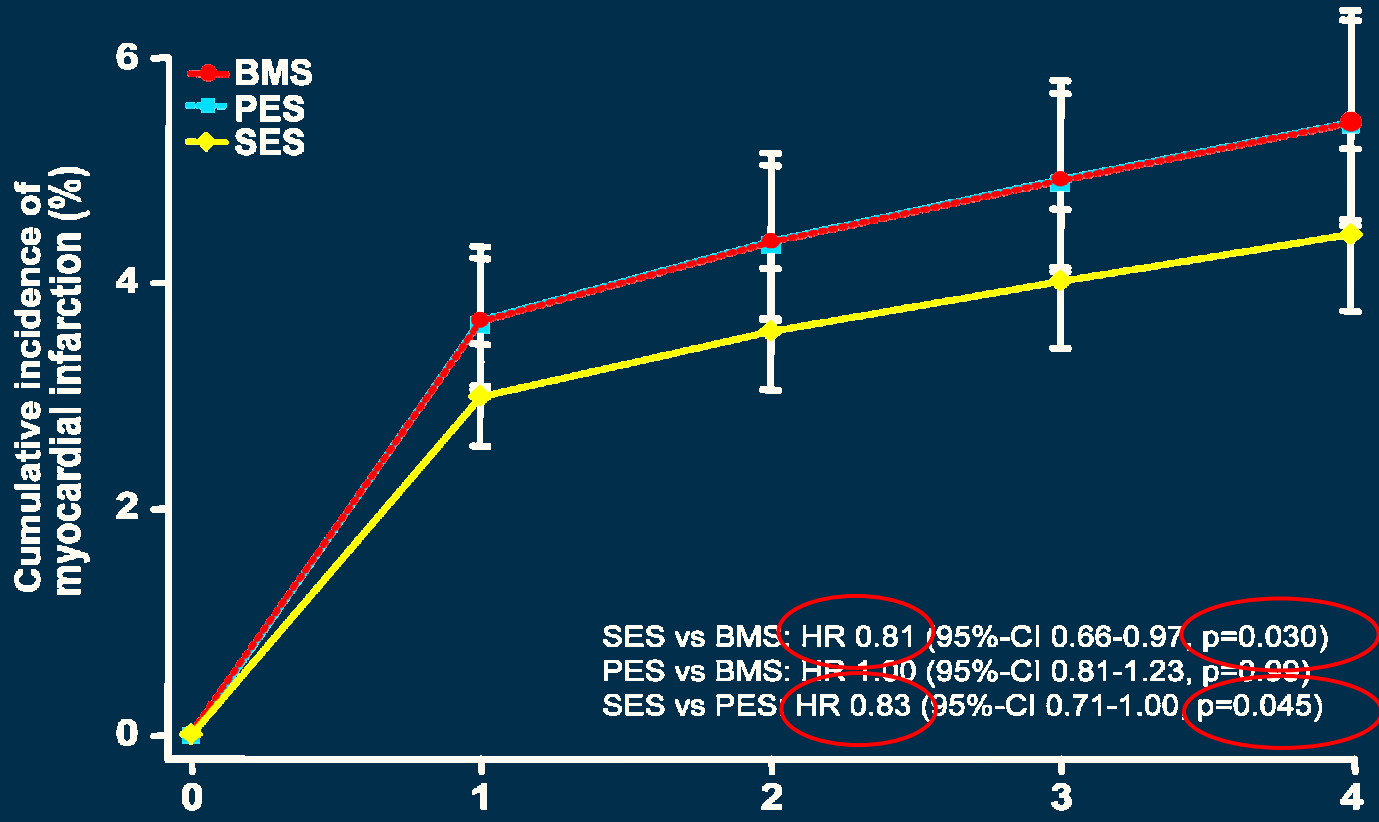
Stettler C., et al., Lancet 2007

Cumulative Incidence of TLR



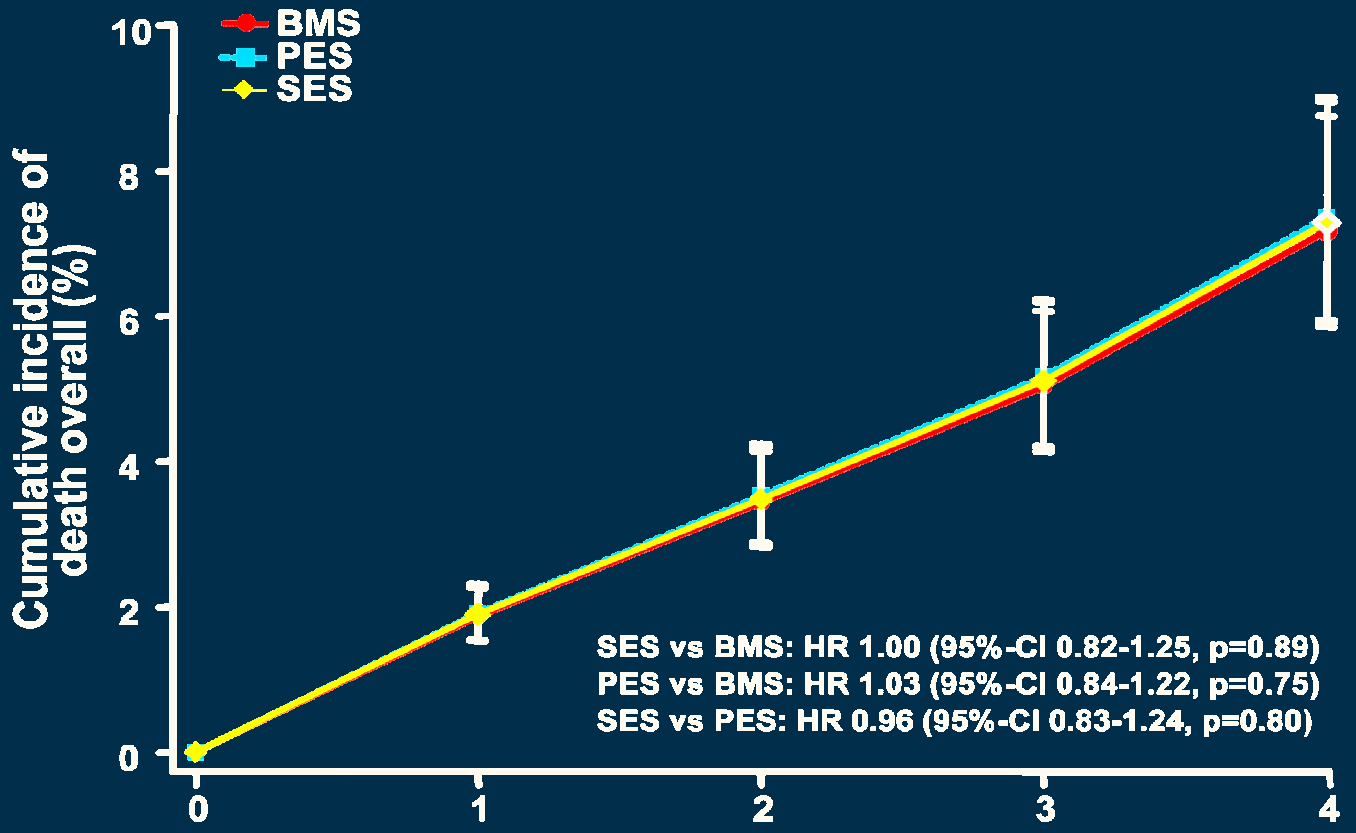
TVR was used as a proxy for 3 studies

Cumulative Incidence of Myocardial Infarction



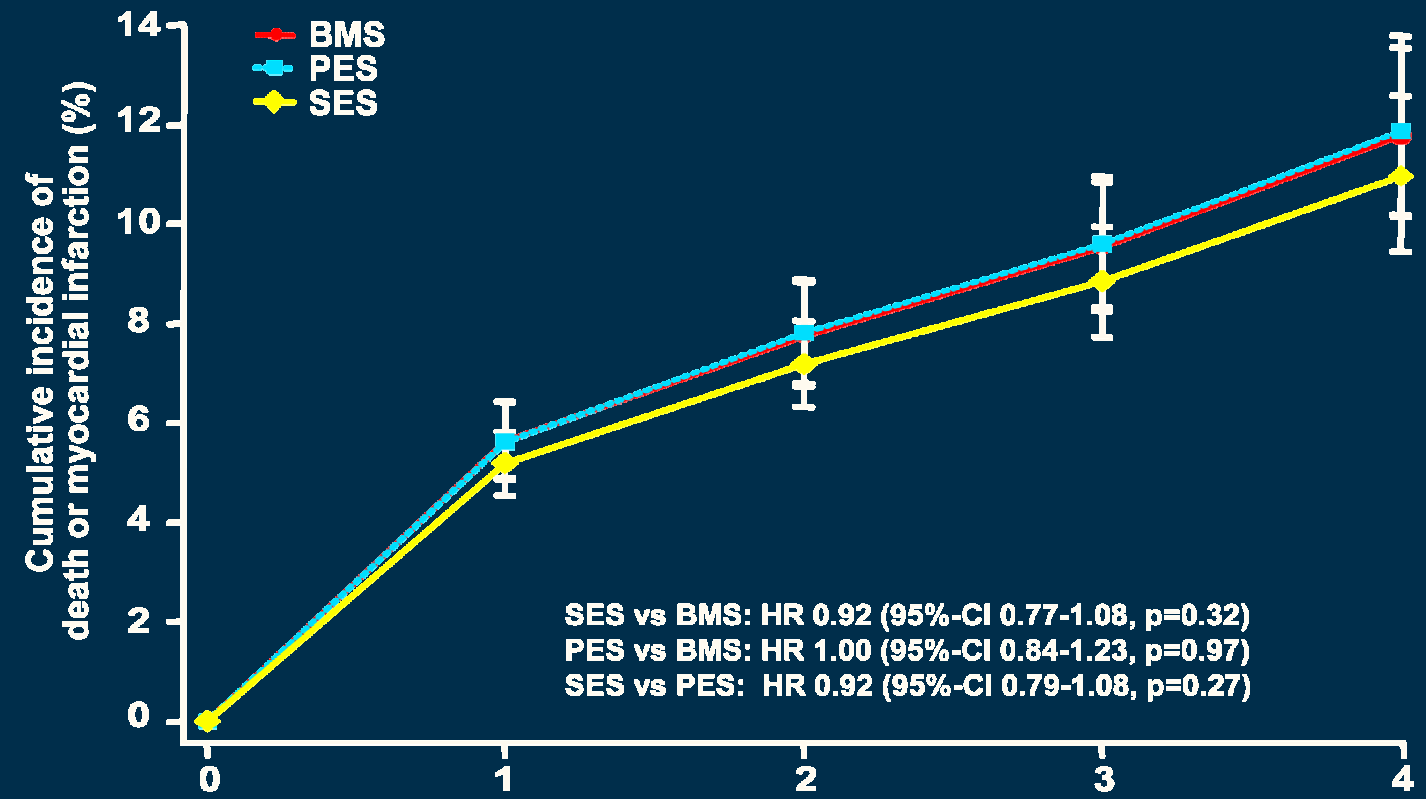
N of events/patients					
BMS	4891	210/4874	20/3174	17/2129	9/1745
PES	6300	249/6252	47/4057	15/2054	8/805
SES	6771	232/6730	25/3884	11/2236	7/1025

Cumulative Incidence of All Death



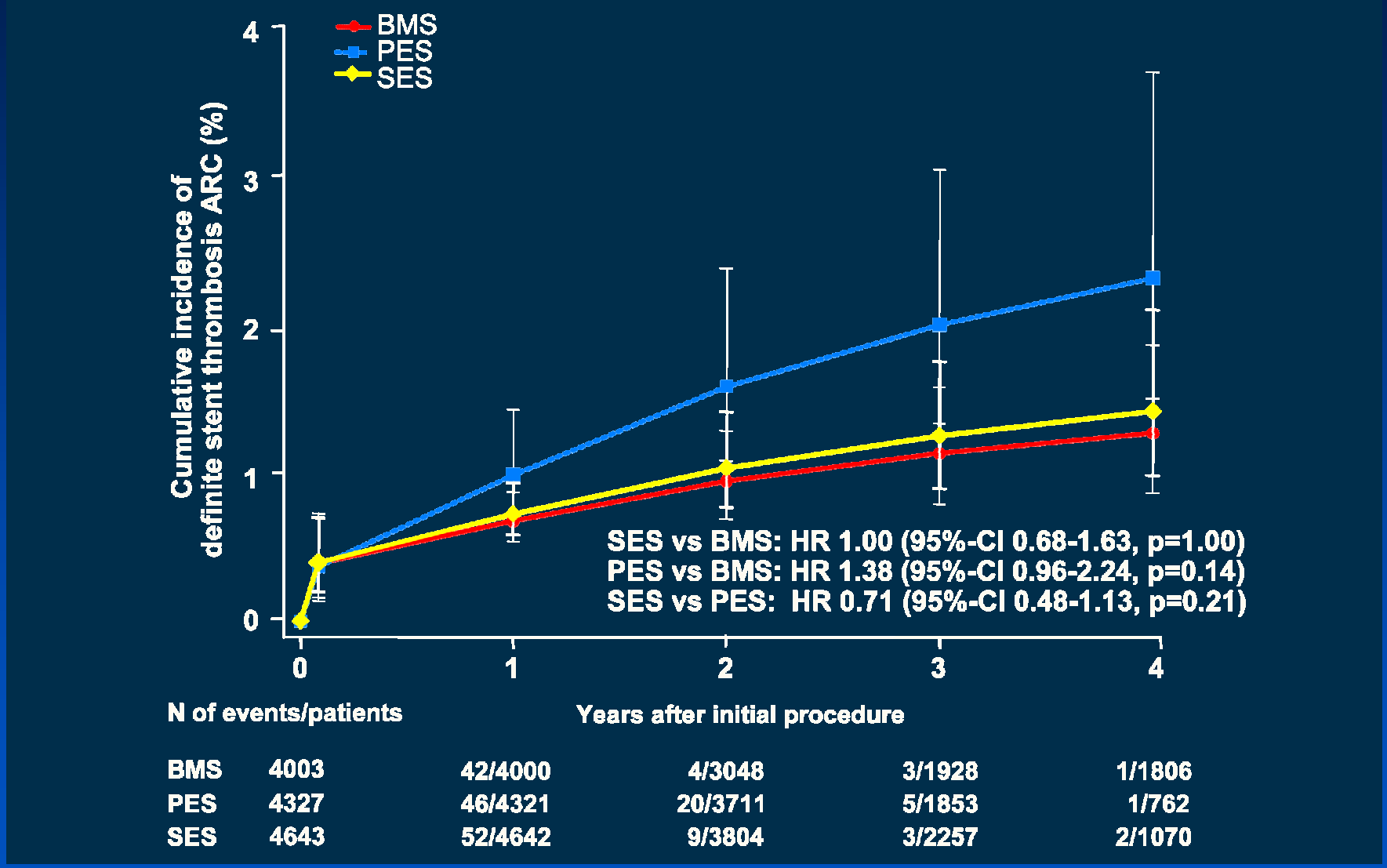
N of events/patients					
BMS	4921	109/4904	48/3340	31/2264	44/1875
PES	6331	138/6283	78/4263	32/2187	15/869
SES	6771	139/6730	72/4041	38/2340	24/1081

Cumulative Incidence of Death or Myocardial Infarction



N of events/patients					
BMS	4921	301/4904	62/3208	45/2161	46/1780
PES	6331	376/6283	115/4087	43/2082	22/833
SES	6771	356/6730	86/3888	44/2241	28/1032

Cumulative Incidence of ARC Definite Stent Thrombosis



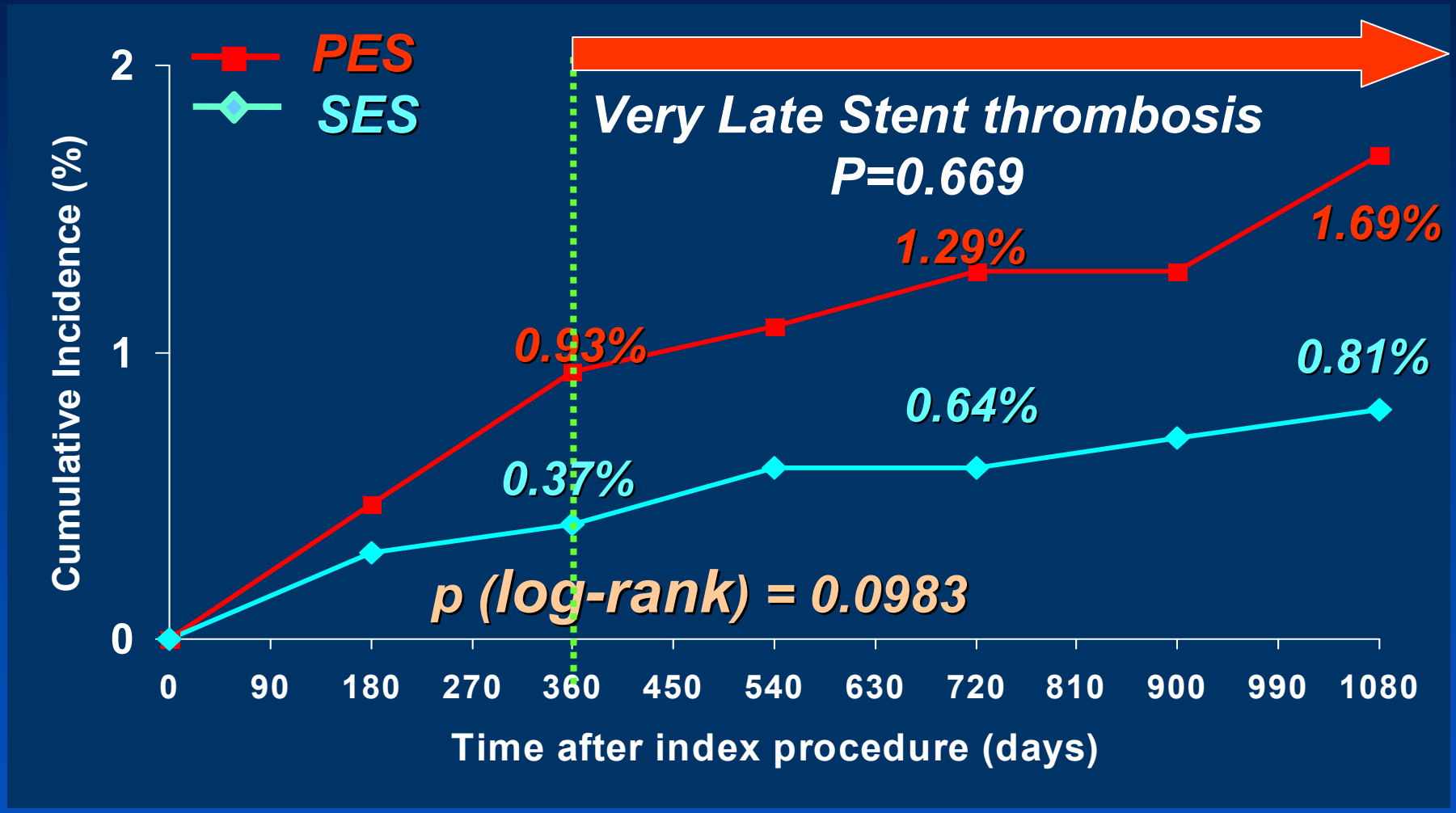
BMS	4003	42/4000	4/3048	3/1928	1/1806
PES	4327	46/4321	20/3711	5/1853	1/762
SES	4643	52/4642	9/3804	3/2257	2/1070

Summary of Key Network Analysis Findings

	PES vs. BMS HR (95% CI)	SES vs. BMS HR (95% CI)	SES vs. PES HR (95% CI)
ARC-Definite LST	2.11 (1.19-4.23) p = 0.017	1.14 (0.62-2.26) p = 0.71	0.54 (0.26-0.98) p = 0.041
ARC-Definite VLST	3.57 (0.86-16.85) p = 0.071	1.43 (0.27-6.24) p = 0.64	0.39 (0.09-1.32) p = 0.10
Protocol-Defined LST	2.36 (1.23-7.00) p = 0.011	1.13 (0.66-2.81) p = 0.57	0.45 (0.25-0.79) p = 0.011
Protocol-Defined VLST	20.02 (3.92-221.7) p = 0.001	5.82 (0.88-76.89) p = 0.07	0.30 (0.05-0.98) p = 0.046

Stettler C., et al., Lancet 2007

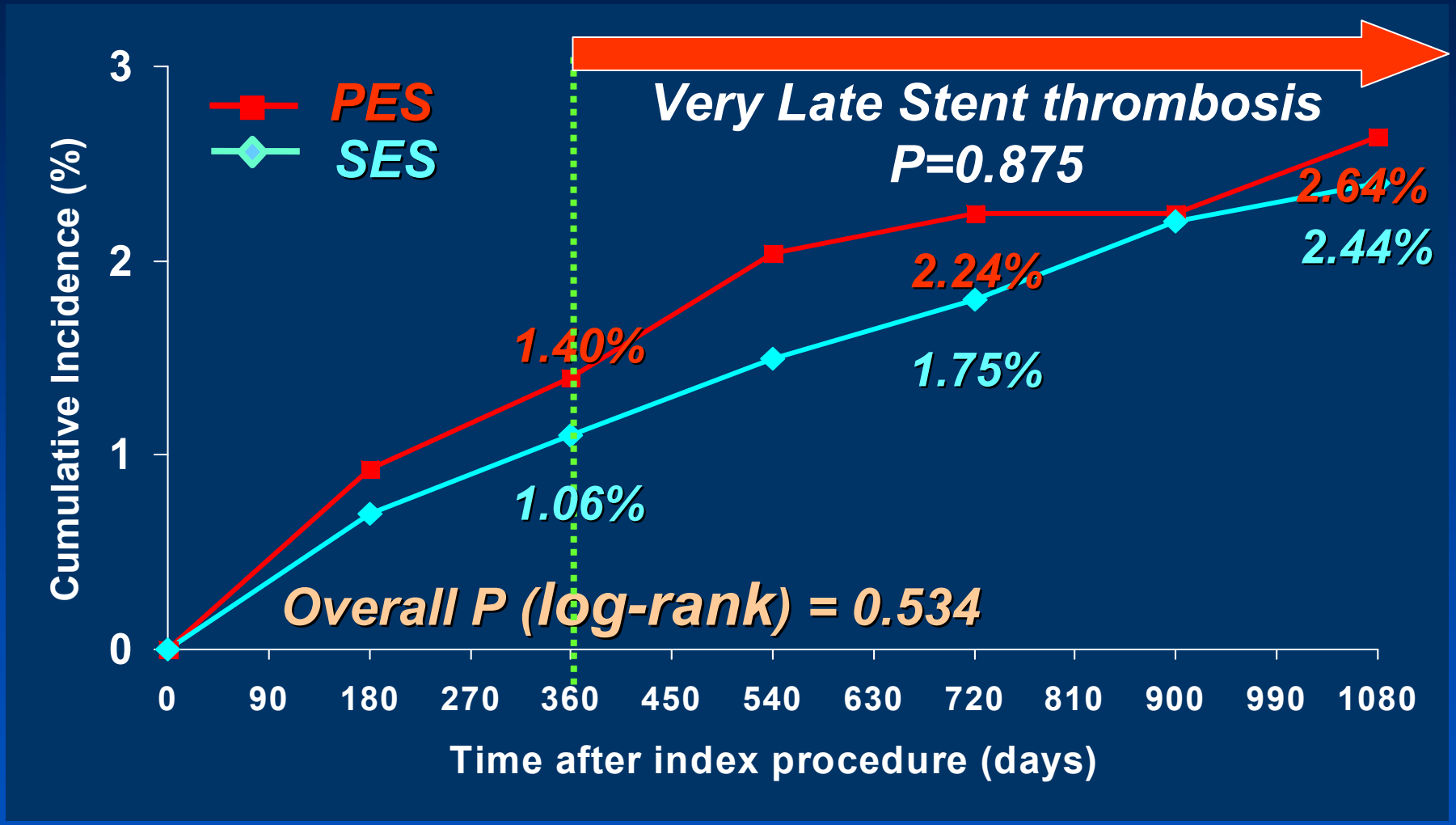
Incidence of ST (ARC: Definite) upto 3 Years



SES vs **PES**

AMC registry Data 2007

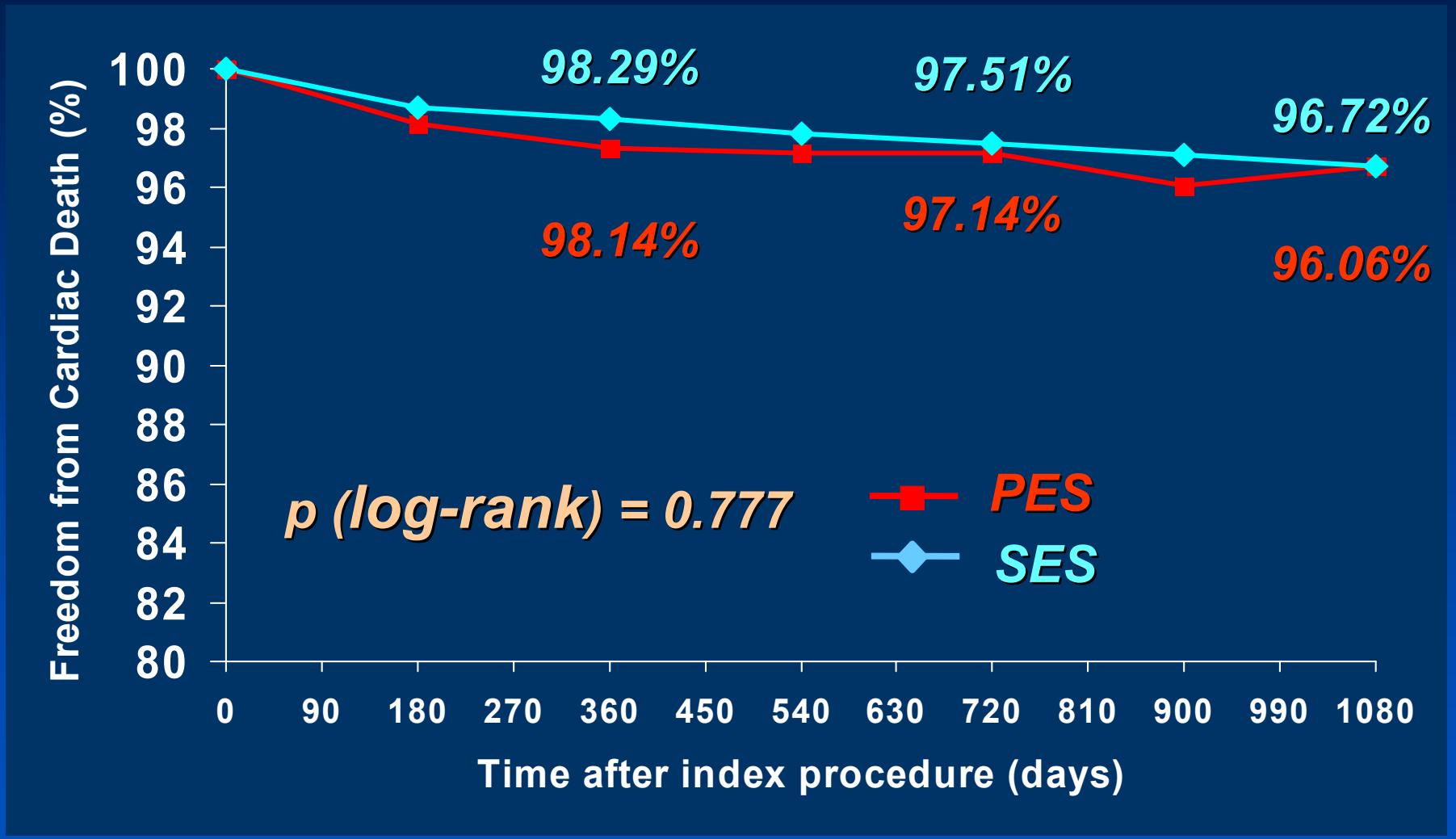
Incidence of ST (Any ARC Criteria) upto 3 Years



SES vs **PES**

AMC registry Data 2007

Survival-Free from Cardiac Death + MI up to 3 Years



SES vs **PES**

AMC registry Data 2007

SES vs PES

- There were **no differences** in the cumulative rates of death or myocardial infarction between SES vs. PES vs. BMS.

- SES seem to be clinically better than BMS and PES, in terms of TLR and incidence of definite LST…

Predictors of DES Stent Thrombosis

by Univariate and Multivariate Cox Proportional Hazards Analysis

AMC registry Data 2007

Multivariate Analysis **for ST (Definite)**

	HR	95% CI	*p*-value
Age	0.92	0.87-0.96	0.001

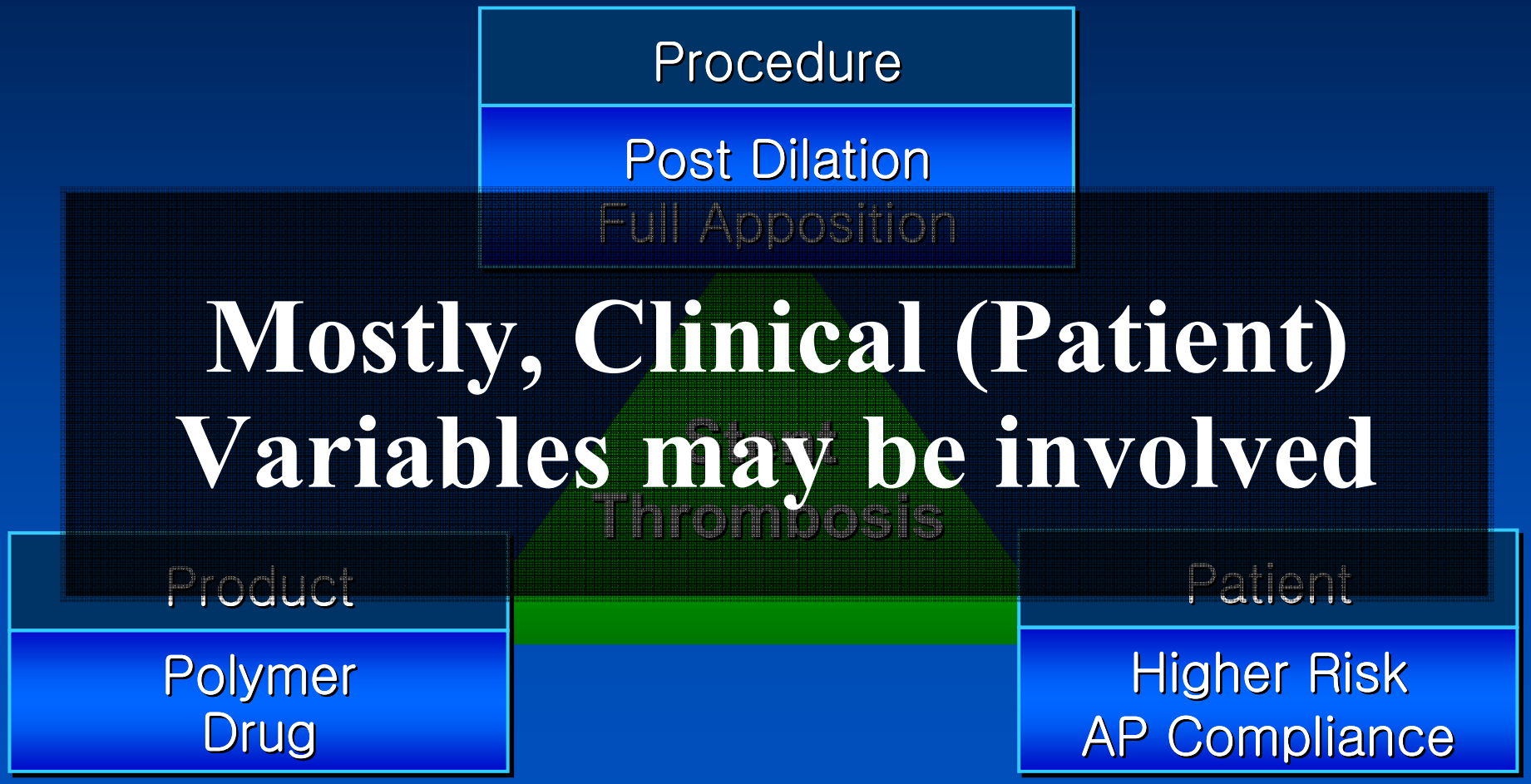
Multivariate Analysis **for ST (Any Criteria)**

	HR	95% CI	*p*-value
Left ventricular EF	0.97	0.94-0.99	0.013
Renal failure	5.68	2.24-14.41	<0.001
Total stent length per patient	1.01	1.002—1.02	0.018

Multivariate Analysis for Cardiac death or MI

	HR	95% CI	*p*-value
Left ventricular EF	0.96	0.94-0.99	0.007
Renal failure	6.10	2.71-13.76	<0.001
Multi-vessel disease	2.34	1.16-4.71	0.018

Stent Thrombosis:



Late Stent Thrombosis
Is it Truth or Myth ?

- Increase late stent thrombosis: **Yes**
- Higher Mortality : **No**

- Randomized Trial would be almost impossible in the complex patients and lesion subsets ?
- How long should we use antiplatelet therapy ?

Late Stent Thrombosis

Is it Truth or Myth ?

We need a Smart DES.


Thank You !!

Univariate Analysis for ST (Definite)

	HR	95% CI	*p*-value
Age	0.93	0.89-0.96	<0.001
Left ventricular ejection fraction	0.96	0.92-0.99	0.021
Diabetes	0.59	0.22-1.56	0.290
Renal failure	3.07	0.41-23.30	0.278
Multi-vessel disease	1.02	0.47-2.20	0.96
Acute coronary syndrome at presentation	2.31	1.01-5.28	0.047
Complex lesion criteria (ACC/AHA ≥B2/C)	1.15	0.44-3.04	0.778
Bifurcation treatment	0.92	0.35-2.44	0.865
Intervention with IVUS guidance	0.98	0.43-2.26	0.965
Paclitaxel-eluting stent	1.94	0.87-4.32	0.102
Number of stents per patient	1.02	0.73-1.42	0.927
Total stent length per patient	1.01	0.99-1.02	0.530
Average stent diameter per patient	1.10	0.90-1.35	0.349
Premature discontinuation of antiplatelet drug (<6 months)	1.19	0.41-0.34	0.747

Univariate Analysis for ST (Any Criteria)

	HR	95% CI	*p*-value
Age	0.99	0.97-1.01	0.408
Left ventricular ejection fraction	0.95	0.93-0.97	<0.001
Diabetes	1.42	0.86-2.34	0.167
Renal failure	8.59	3.83-19.26	<0.001
Multi-vessel disease	1.29	0.79-2.12	0.315
Acute coronary syndrome at presentation	1.99	1.20-3.32	0.008
Complex lesion criteria (ACC/AHA ≥B2/C)	1.10	0.60-2.02	0.750
Bifurcation treatment	0.93	0.51-1.70	0.805
Intervention with IVUS guidance	0.60	0.37-0.98	0.040
Paclitaxel-eluting stent	1.19	0.68-2.09	0.535
Number of stents per patient	1.18	0.97-1.42	0.096
Total stent length per patient	1.01	1.002-1.02	0.010
Average stent diameter per patient	1.07	0.89-1.29	0.494
Premature discontinuation of antiplatelet drug (<6 months)	2.66	1.57-4.52	<0.001

Univariate Analysis for Cardiac death or MI

	HR	95% CI	*p*-value
Age	1.01	0.99-1.03	0.619
Left ventricular ejection fraction	0.94	0.92-0.96	<0.001
Diabetes	1.26	0.82-1.95	0.297
Renal failure	7.70	4.27-17.72	<0.001
Multi-vessel disease	1.56	1.01-2.41	0.047
Acute coronary syndrome at presentation	2.33	1.49-3.65	<0.001
Complex lesion criteria (ACC/AHA ≥B2/C)	1.10	0.66-1.83	0.727
Bifurcation treatment	0.87	0.51-1.48	0.607
Intervention with IVUS guidance	0.47	0.31-0.71	<0.001
Paclitaxel-eluting stent	1.07	0.66-1.76	0.777
Number of stents per patient	1.06	0.89-1.26	0.526
Total stent length per patient	1.01	0.99-1.01	0.131
Average stent diameter per patient	1.06	0.89-1.26	0.499
Premature discontinuation of antiplatelet drug (<6 months)	3.76	2.46-5.75	<0.001