

**Late Stent Thrombosis  
Should It be Truly Concerned  
in Real World Practice ?  
10-Year Experience from AMC Registry**

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Asan Medical Center, *Seoul, Korea***



# DES

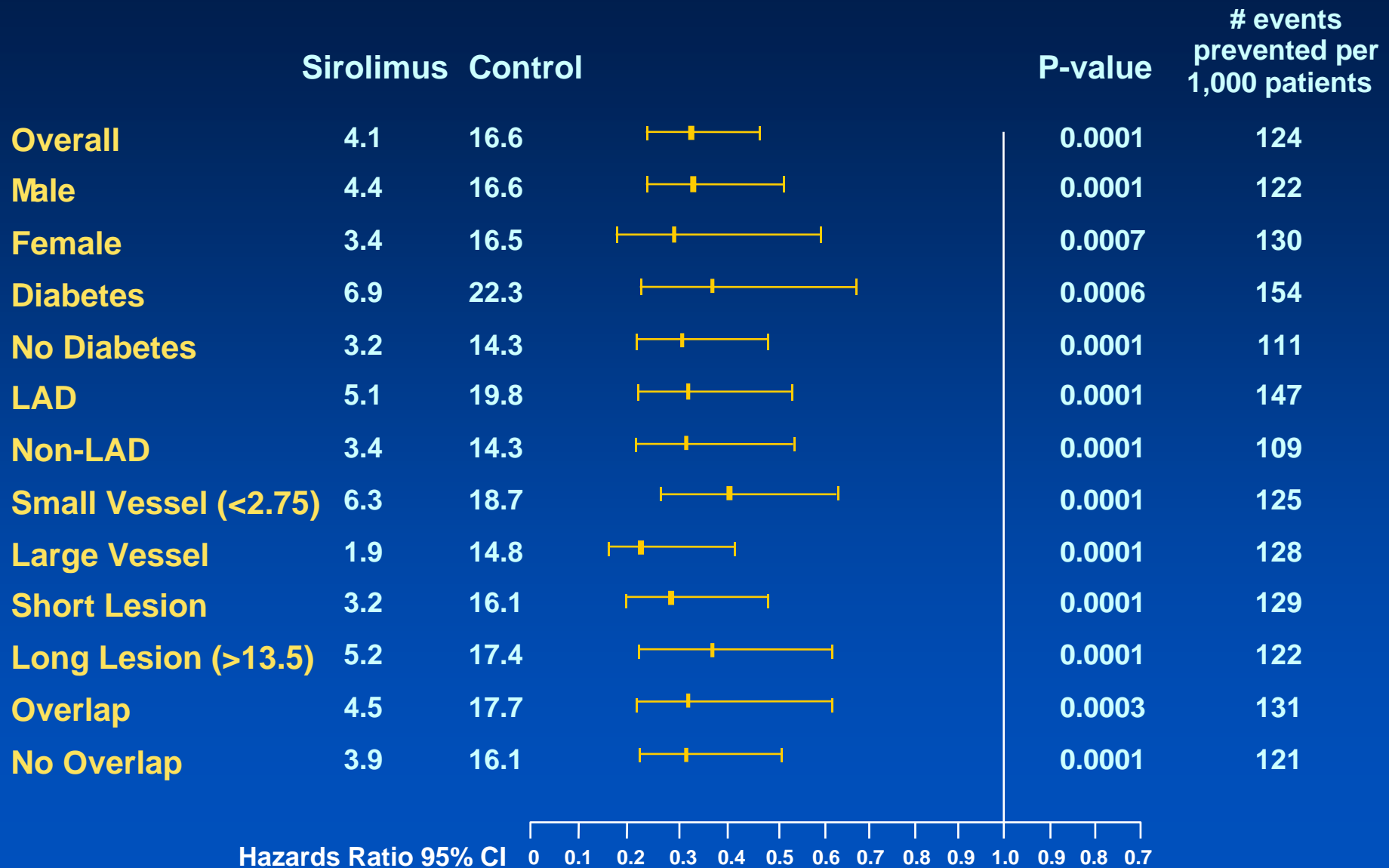


Marked reduction of TLR and restenosis rate compare to BMS

**Possible increase of late stent thrombosis and mortality ?**

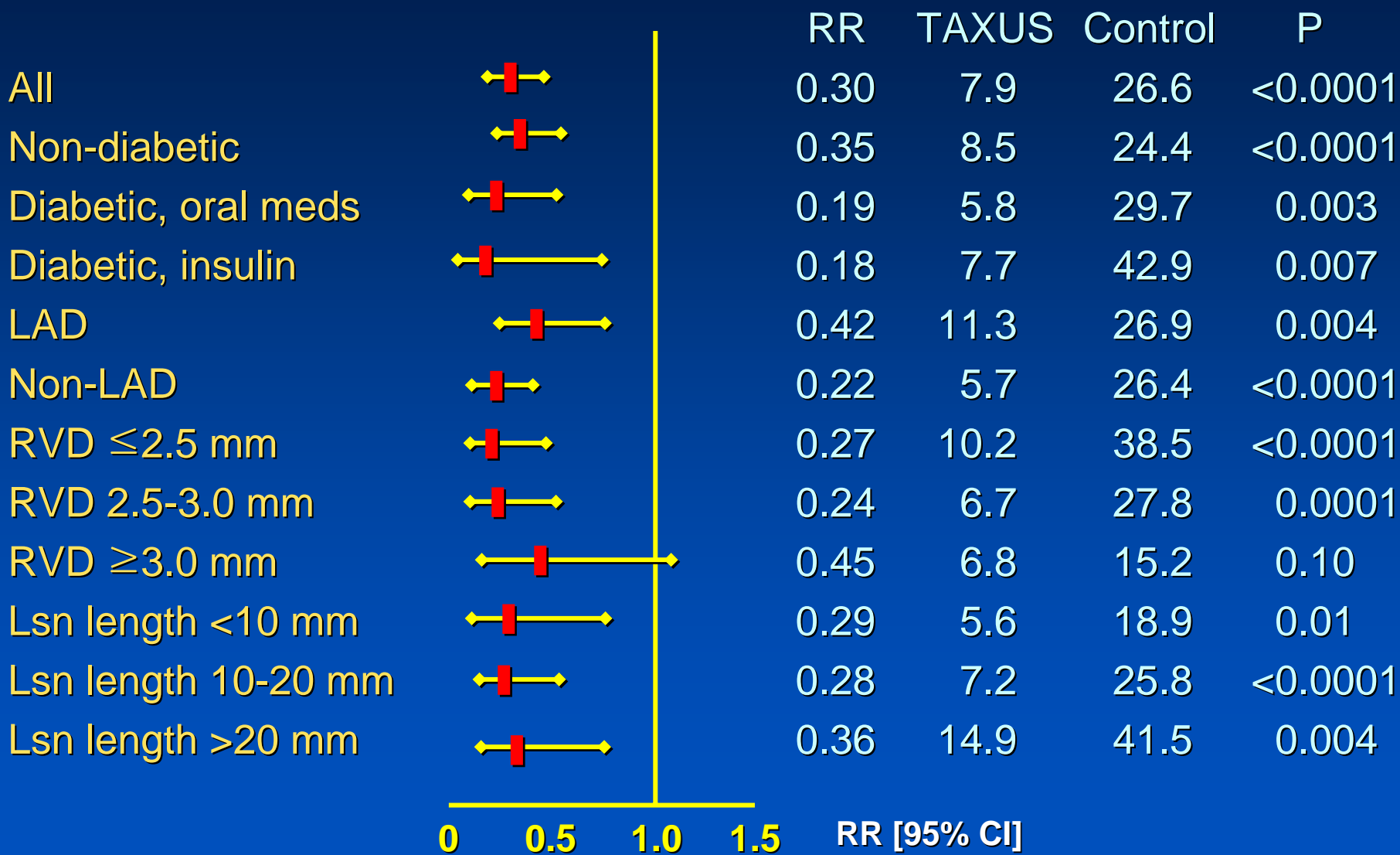
# TLR Rate

**SIRIUS**



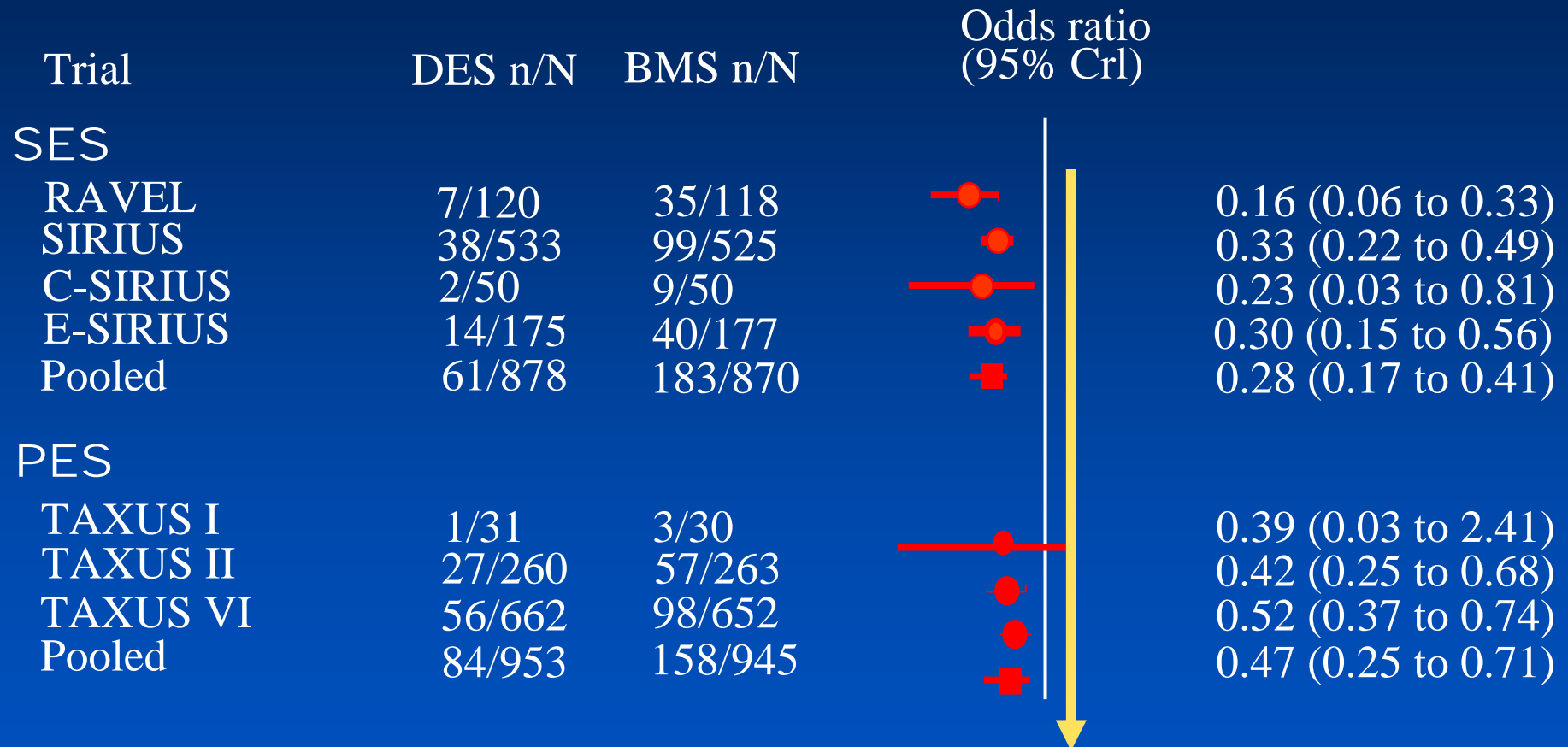
# Restenosis Rate

TAXUS,IV



# MACE of DES

## Meta Analysis of Large Randomized Trials



Babapulle MN et al. Lancet 2004;364:583

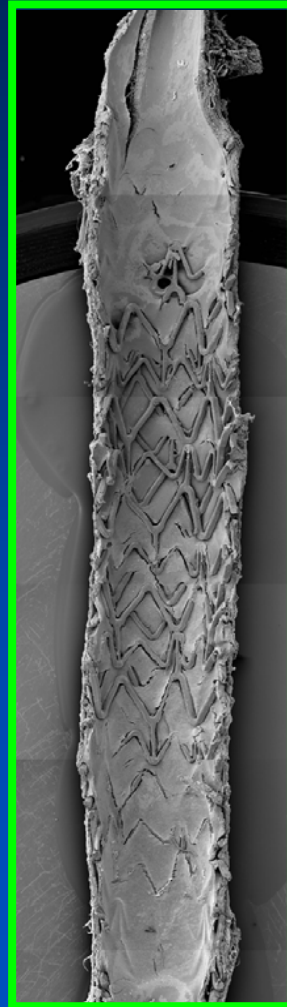
# DES is Better

# Critical, Conceptual Flaw of DES ; Incomplete and Delayed Endothelialization

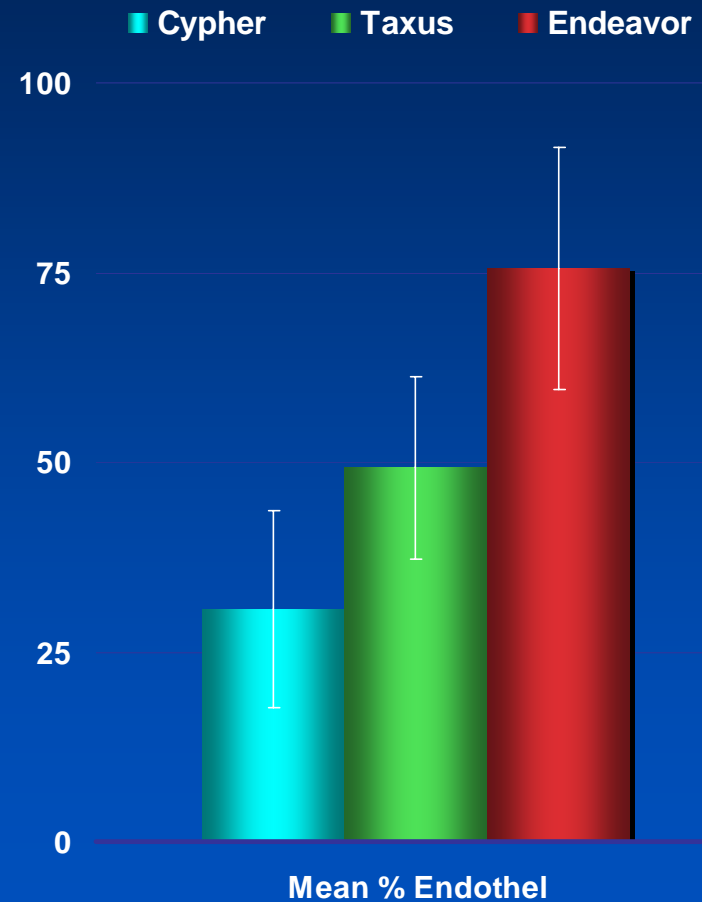
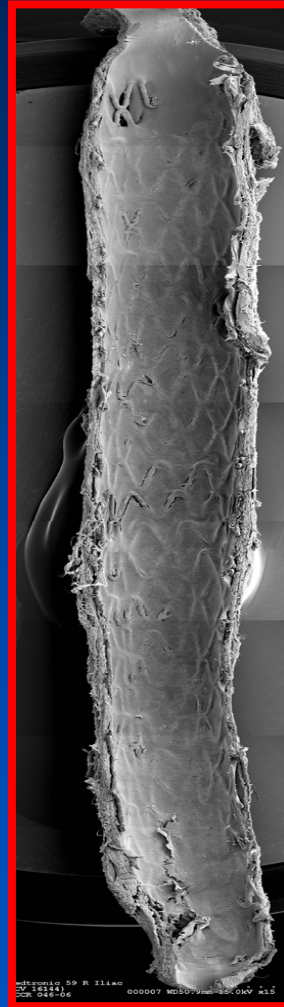
Cypher



Taxus

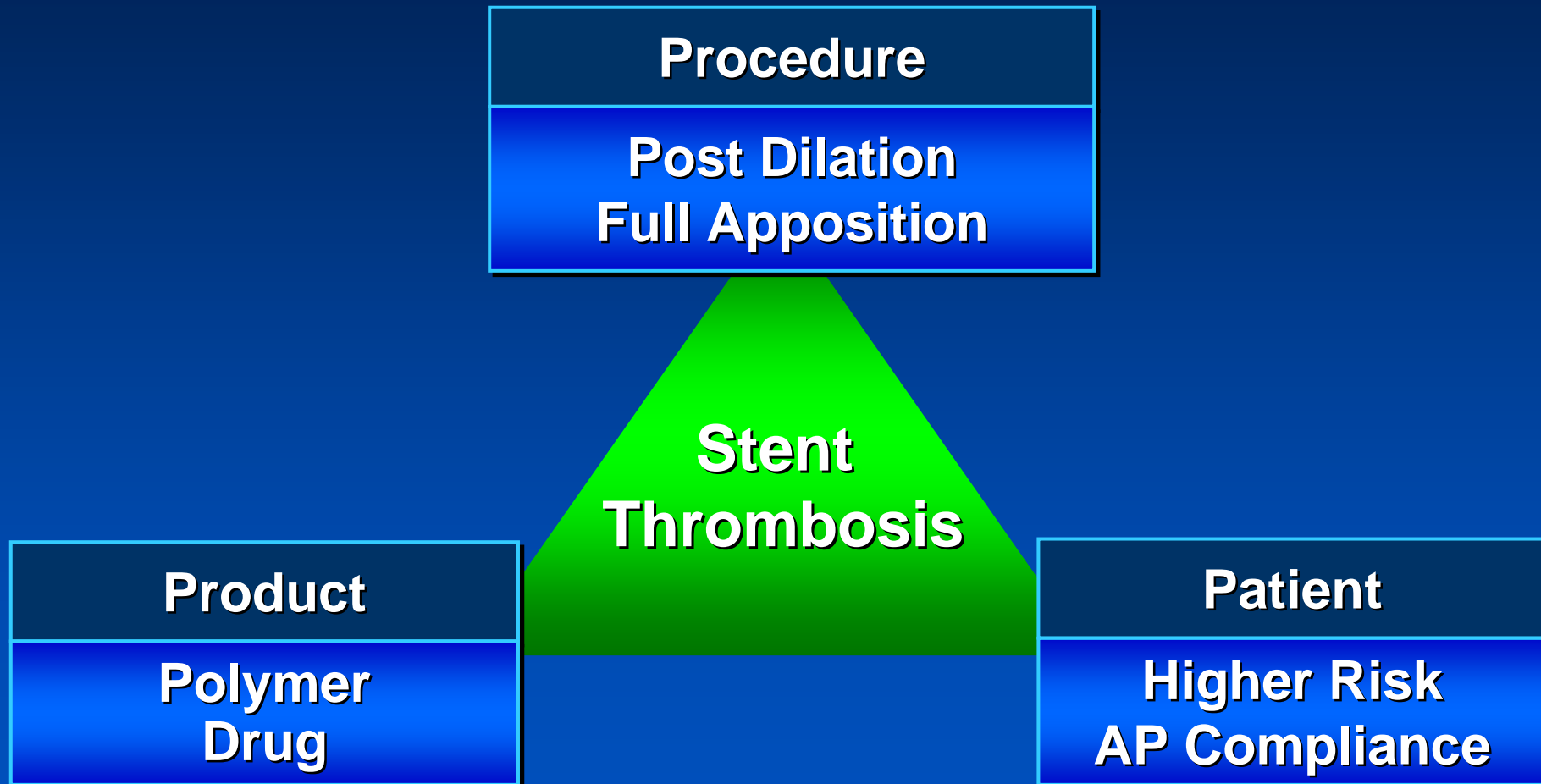


Endeavor



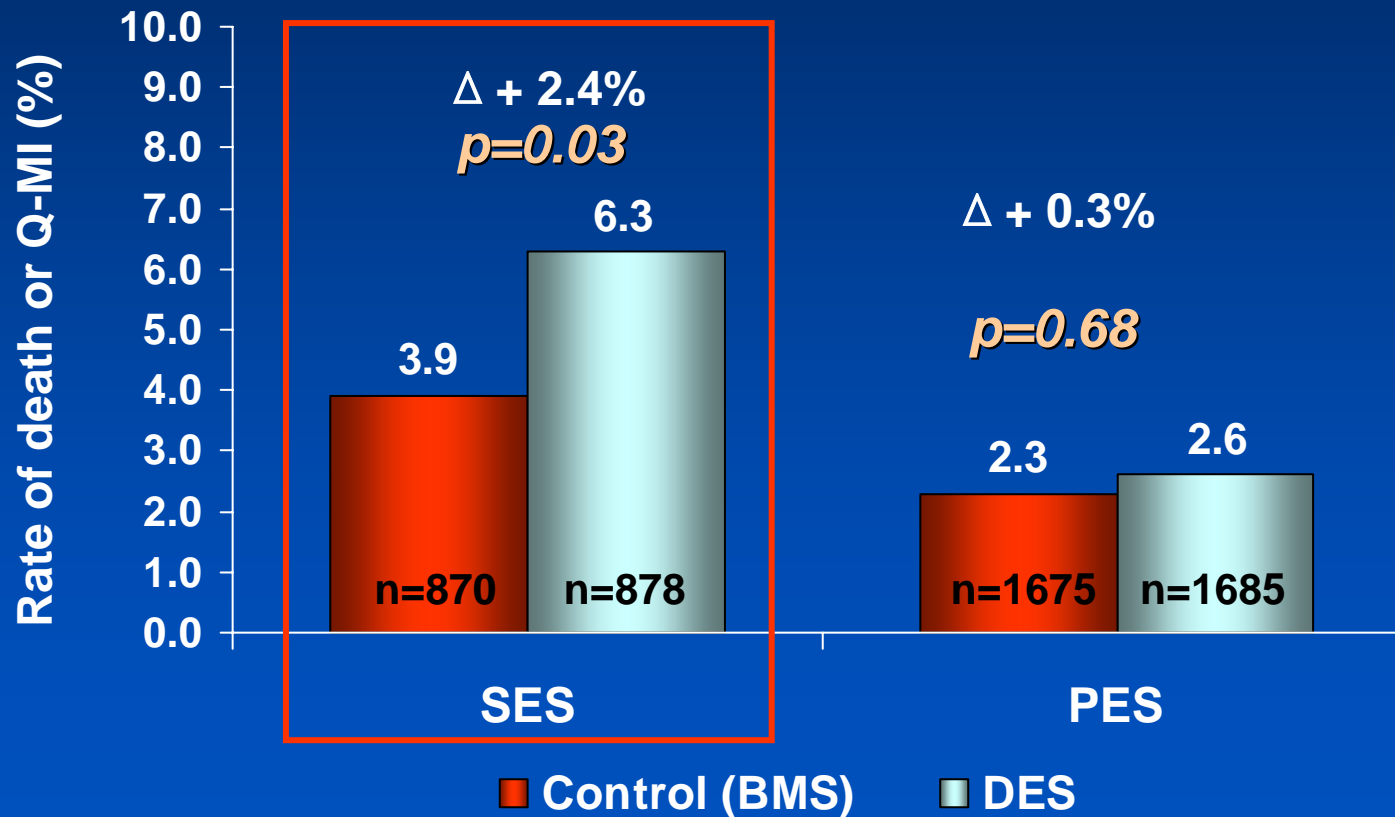
Vincentini et al. PCR 2006

# 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



# Concerns About this Analysis

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- Details and sources data used are unclear
- Sample size at different time points are not shown
- Rationale for choice of end points is unclear

# FDA Advisory Panel Meeting

## December 7-8, 2006

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- No increase of death or MI when DES are used on-label.
- Off-label use is associated with increased risk of stent thrombosis
- One-year use of clopidogrel is recommended to minimize the risk of stent thrombosis with DES.

# Academic Research Consortium (ARC) Proposed Standard Definitions

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- **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

# Stent Thrombosis

Potentially too specific

HCRI CEC  
Definition  
ST

Any ARC criteria

and clinical presentation

These agreed definitions should be used in all future reports of the data, and that events should be independently adjudicated in all trials and registries.

# 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	<b>No</b>
Kastrati et al	14 RCTs	2486 / 2472	SES / BMS	4	<b>No</b>
Mauri et al	8 RCTs	878 / 1400 / 2267	SES / PES / BMS	4	<b>No</b>
Stone et al	9 RCTs	878 / 1755 / 3513	SES / PES / BMS	4	<b>No</b>
Lagerqvist et al	Registry	6033 / 13738	DES / BMS	3	<b>Yes</b>

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

*The* NEW ENGLAND  
JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

MARCH 8, 2007

VOL. 356 NO. 10

A Pooled Analysis of Data Comparing Sirolimus-Eluting Stents  
with Bare-Metal Stents

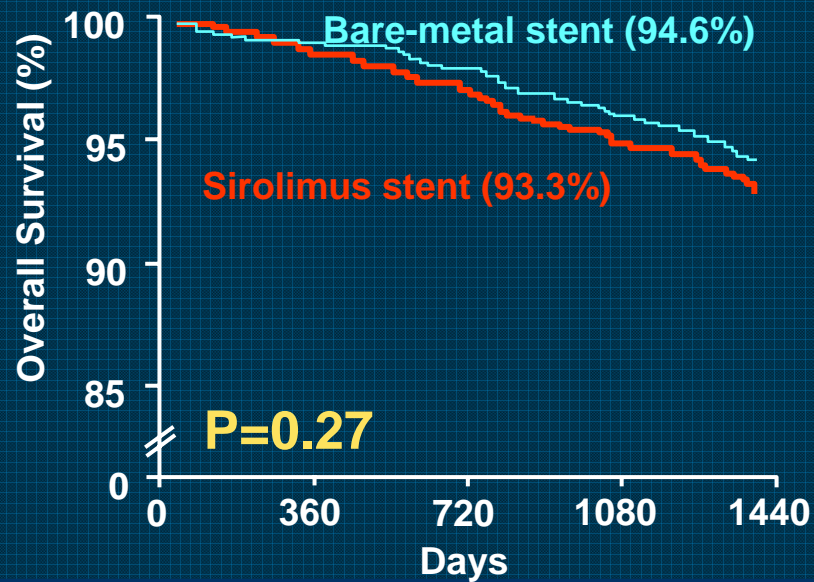
Christian Spaulding, M.D., Joost Daemen, M.D., Eric Boersma, Ph.D., Donald E. Cutlip, M.D.,  
and Patrick W. Serruys, M.D., Ph.D.

Pooled analysis of 1748 patients in 4 RCTs  
comparing SES with BMS  
(Pivotal SES Trials: RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS)

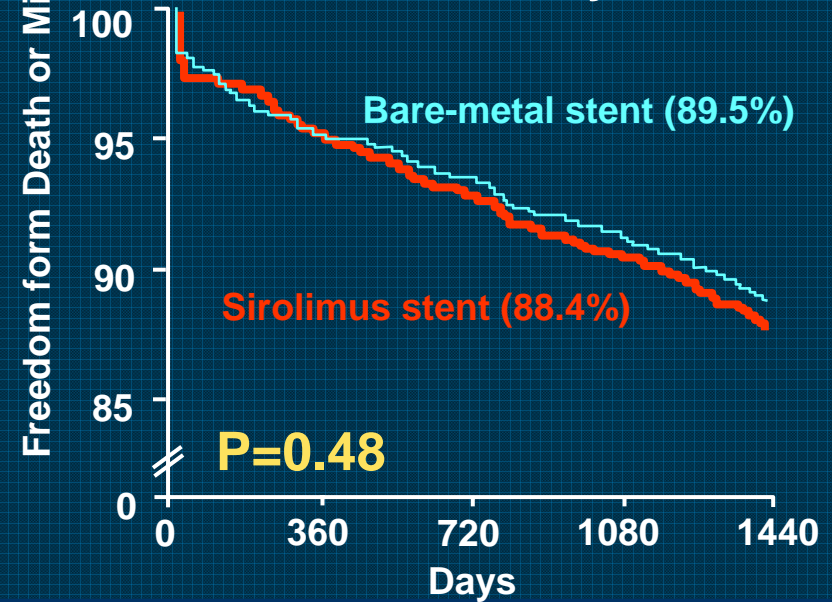
NEJM 2007;356:989-97



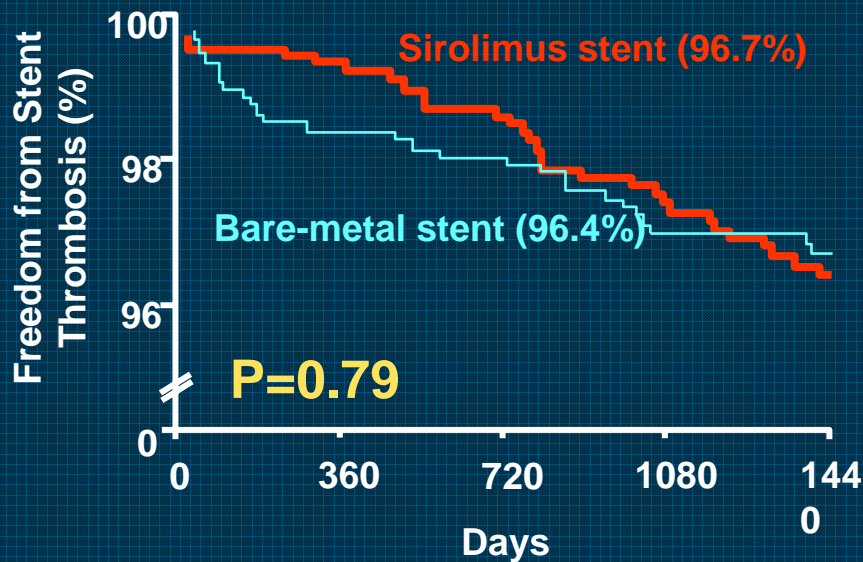
### Death at 4 yr F/U



### Death or MI at 4 yr F/U



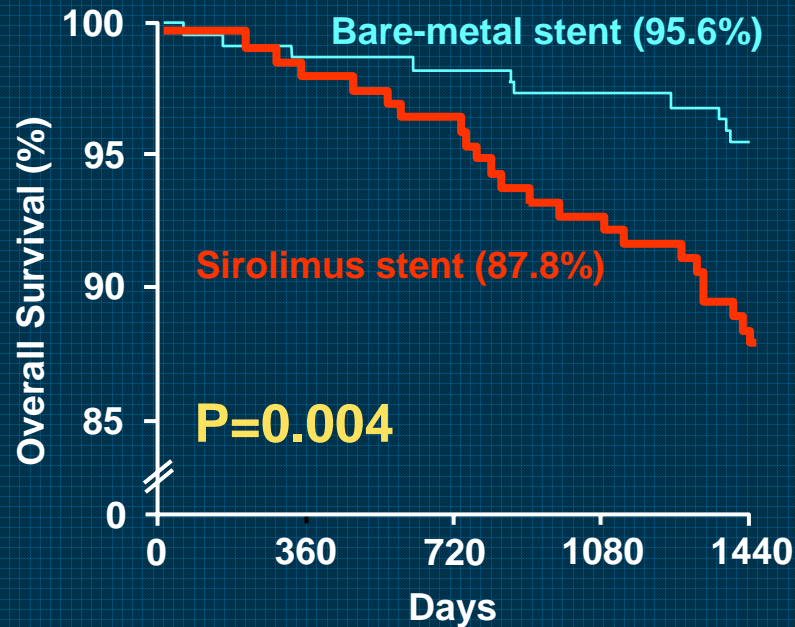
### ST (ARC) at 4 yr F/U



No difference in rates of death, MI, or stent thrombosis at 4 year

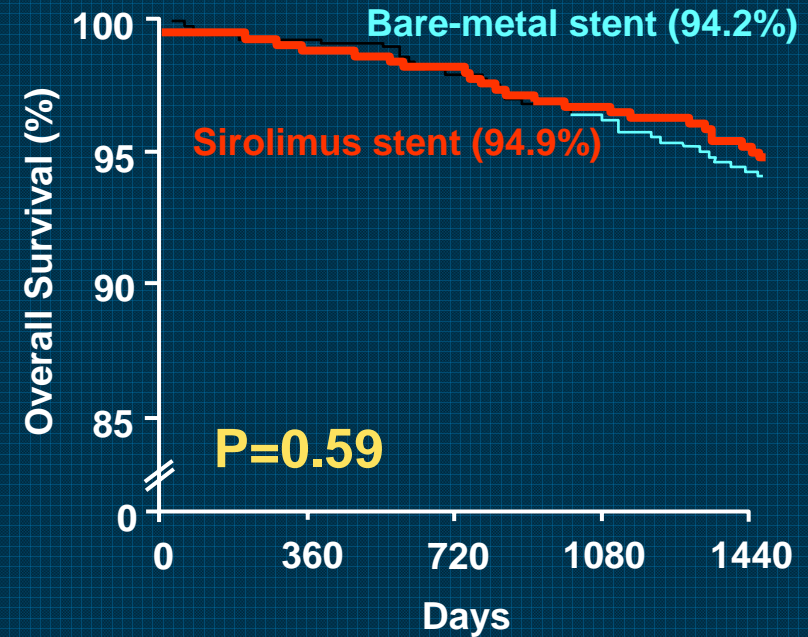
## Death at 4 yr F/U

Patients with Diabetes



## Death at 4 yr F/U

Patients without Diabetes



Significant difference in rates of deaths from both cardiovascular and noncardiovascular cause in **Diabetic Patients** at 4 year F/U



ORIGINAL ARTICLE

## Safety and Efficacy of Sirolimus- and Paclitaxel-Eluting Coronary Stents

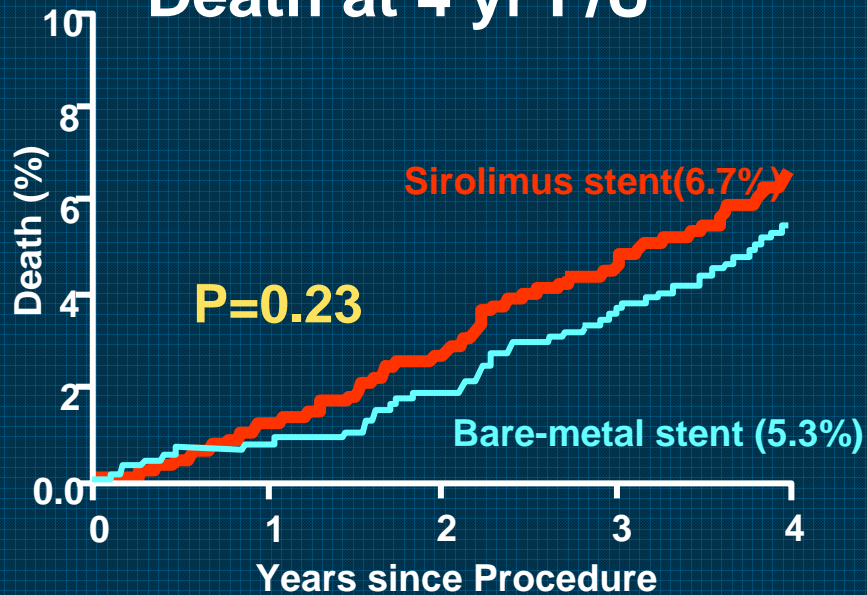
Gregg W. Stone, M.D., Jeffrey W. Moses, M.D., Stephen G. Ellis, M.D.,  
Joachim Schofer, M.D., Keith D. Dawkins, M.D., Marie-Claude Morice, M.D.,  
Antonio Colombo, M.D., Erick Schampaert, M.D., Eberhard Grube, M.D.,  
Ajay J. Kirtane, M.D., Donald E. Cutlip, M.D., Martin Fahy, M.Sc.,  
Stuart J. Pocock, Ph.D., Roxana Mehran, M.D., and Martin B. Leon, M.D.

Pooled analysis of 1748 patients in 4 RCTs between SES or BMS  
3513 patients in 5 RCTs between PES or BMS  
**(SES Trials: RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS)**  
**(PES Trials: TAXUS-I, TAXUS-II, TAXUS-IV, TAXUS-V, TAXUS VI)**

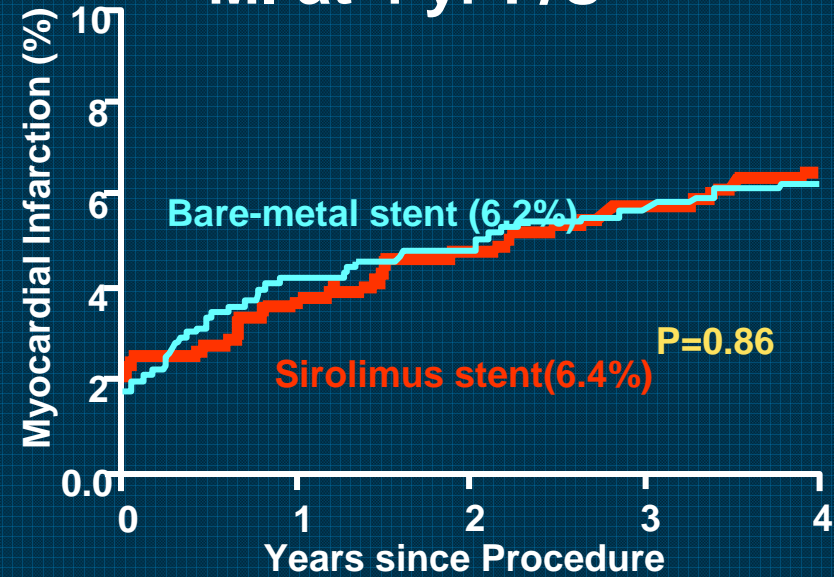
NEJM 2007;356:998-1008



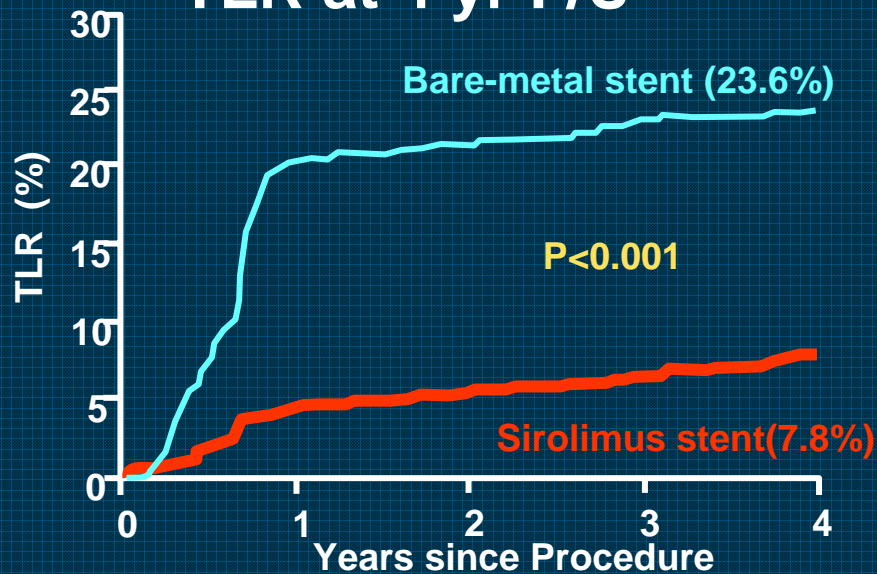
## Death at 4 yr F/U



## MI at 4 yr F/U

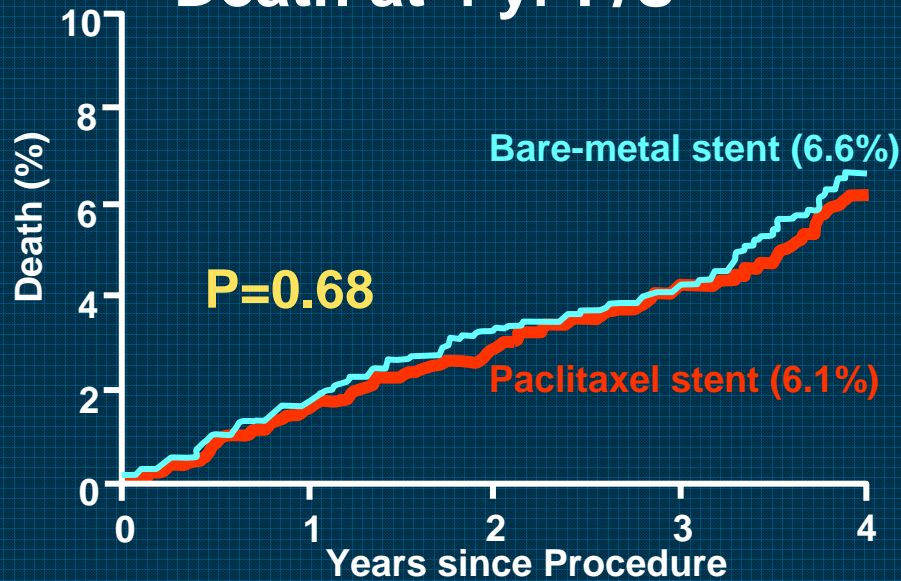


## TLR at 4 yr F/U

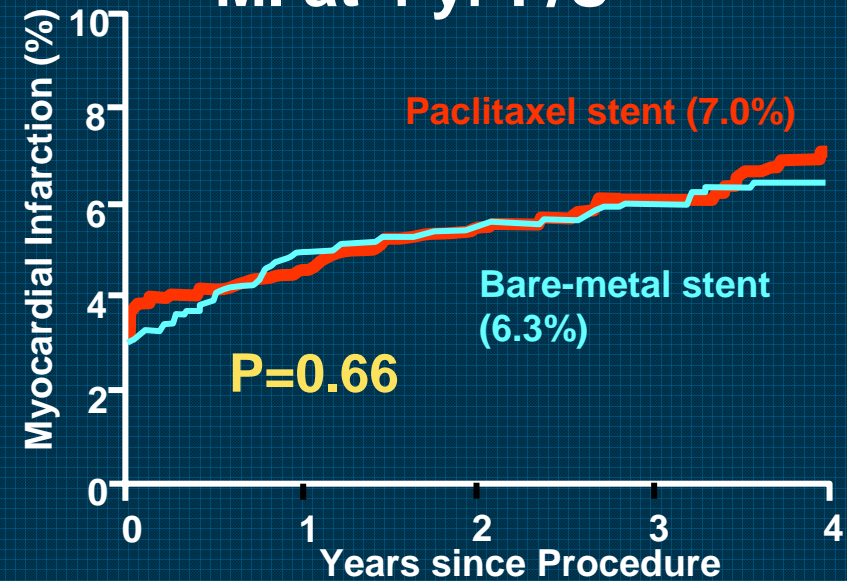


No difference in rates of death and MI. However, significant difference in TLR after SES

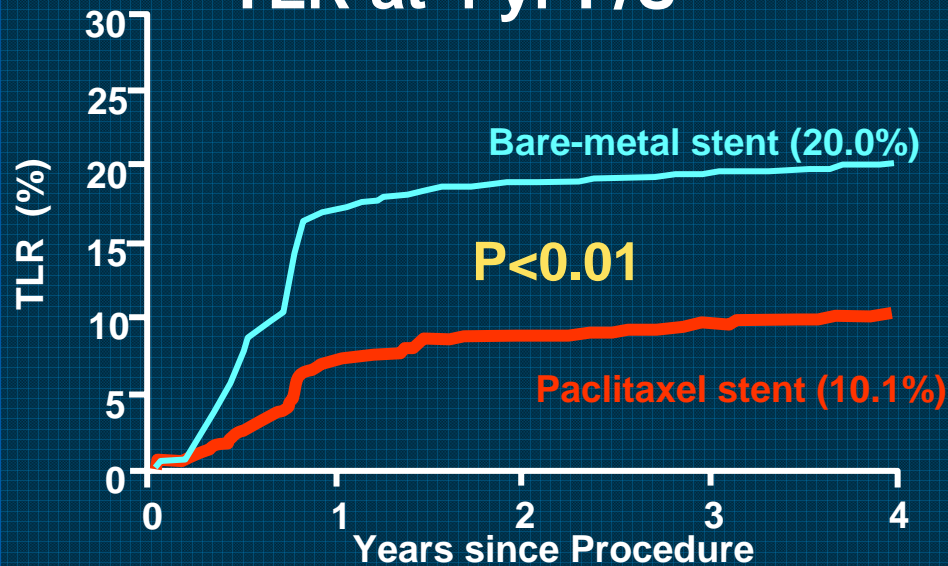
## Death at 4 yr F/U



## MI at 4 yr F/U

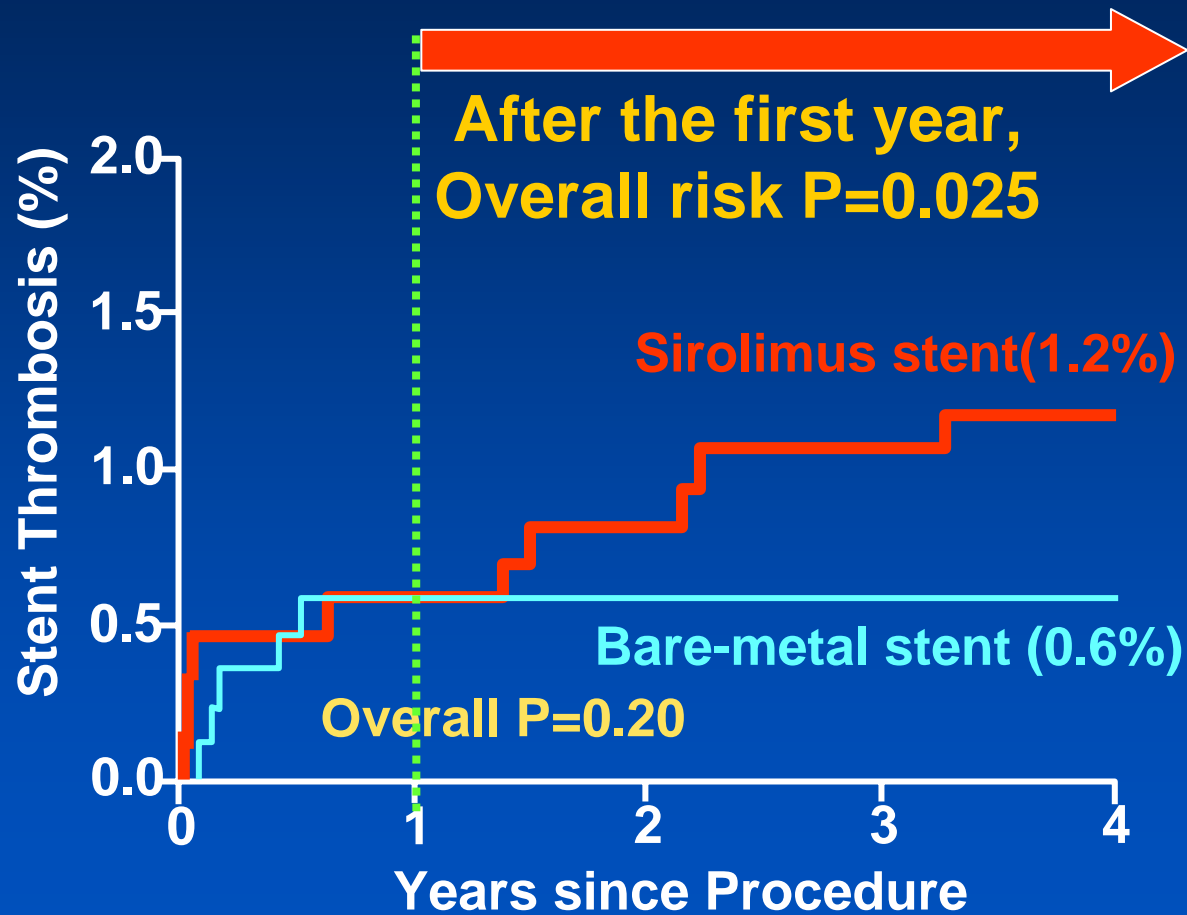


## TLR at 4 yr F/U

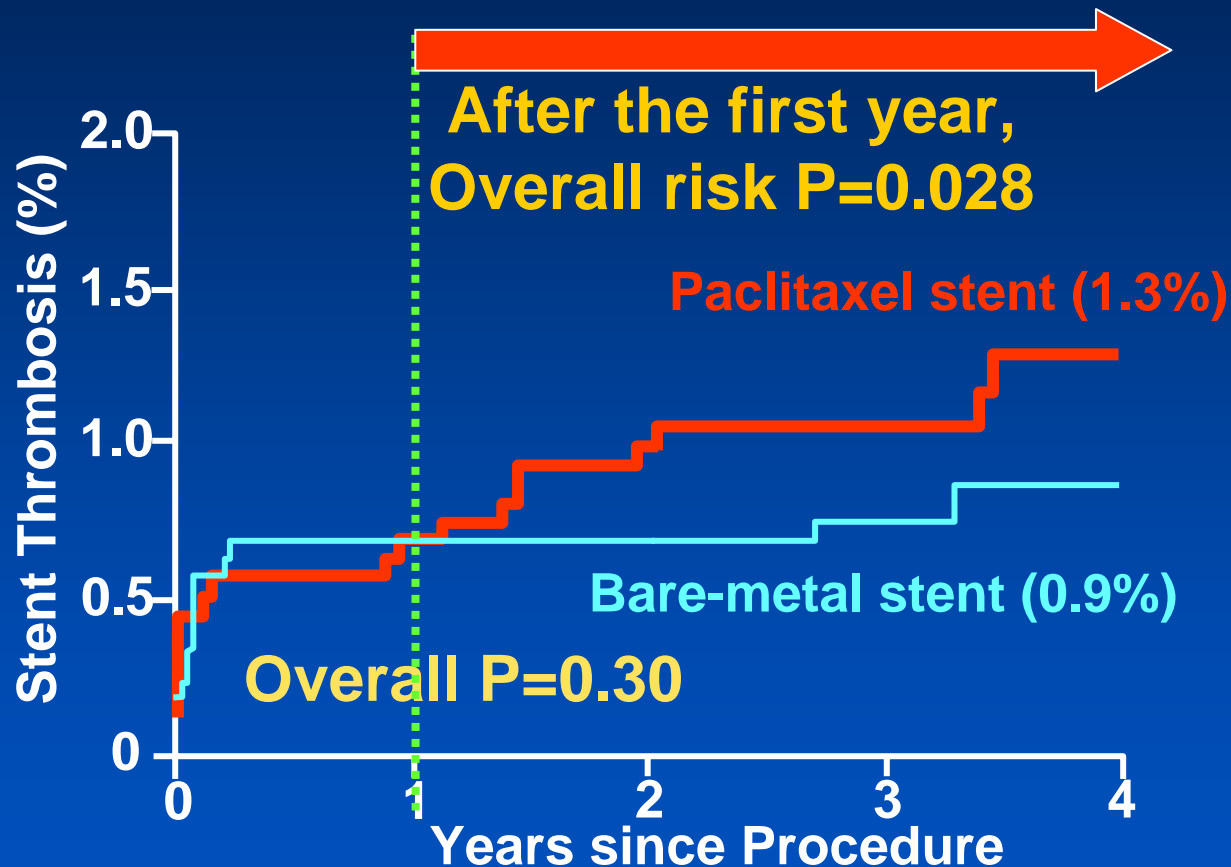


No difference in rates of death and MI. However, significant difference in TLR after PES

# Stent Thrombosis After SES (Protocol Definition)



# Stent Thrombosis After PES (Protocol Definition)



# Conclusions

## Pooled Data Analysis from RCTs

- 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.
- Stent thrombosis after 1 year was more common with both DESs than with BMS.

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\*

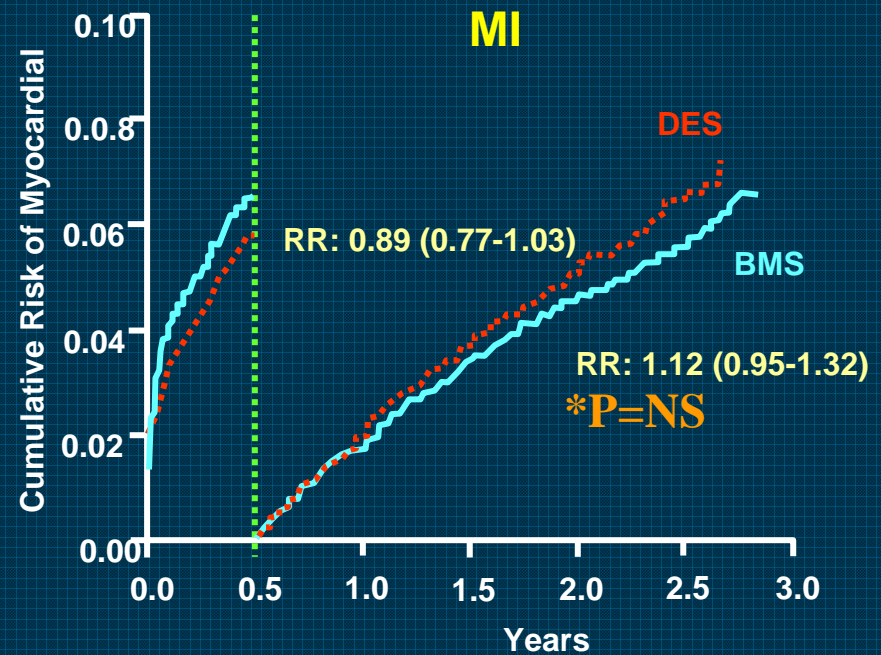
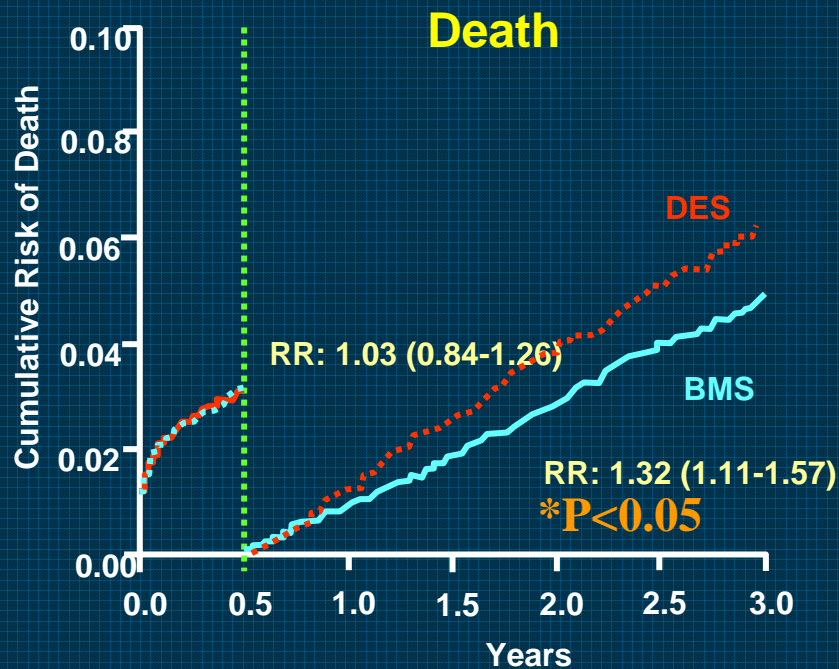
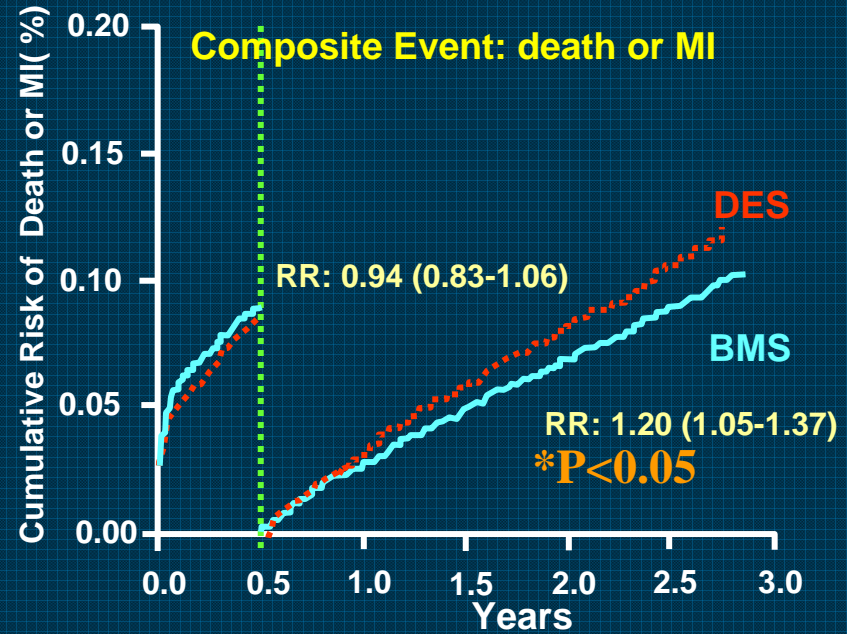
Pooled analysis of 6033 patients treated with DES and  
13,738 patients treated with BMS  
Data from Swedish Coronary Angiography and Angioplasty Registry

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

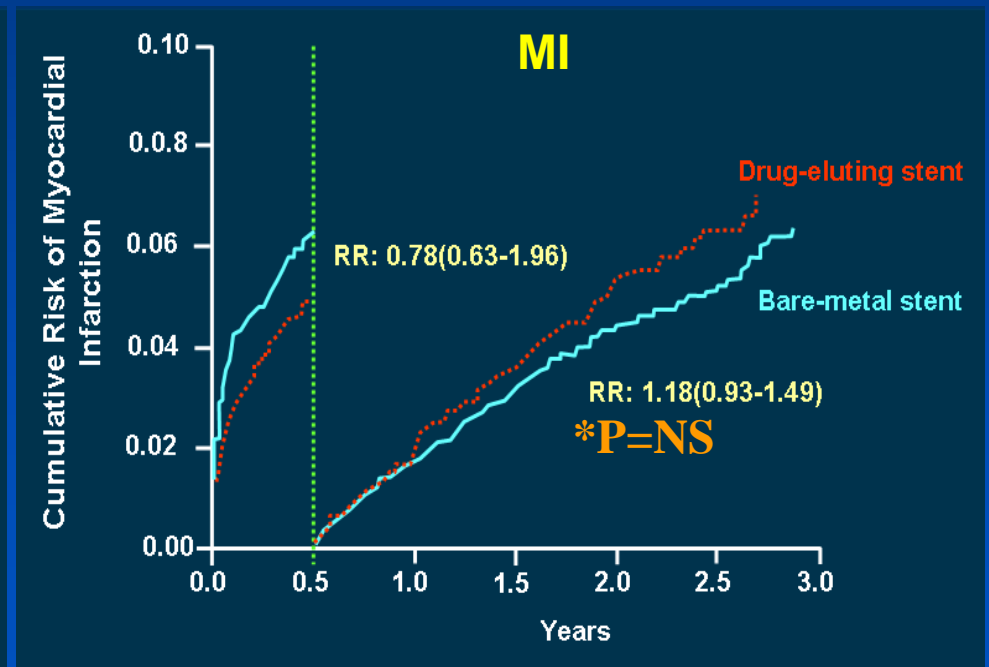
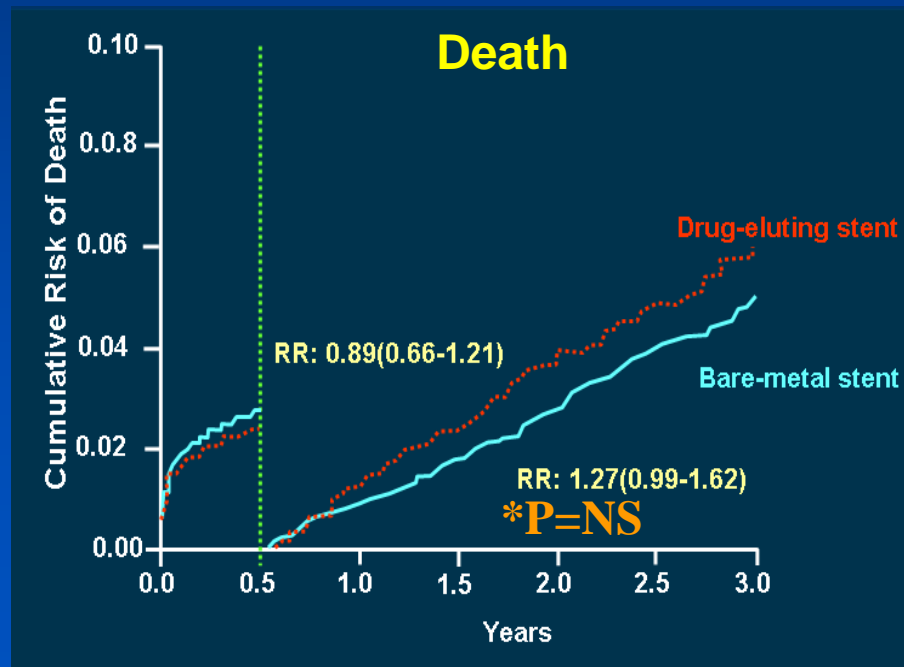
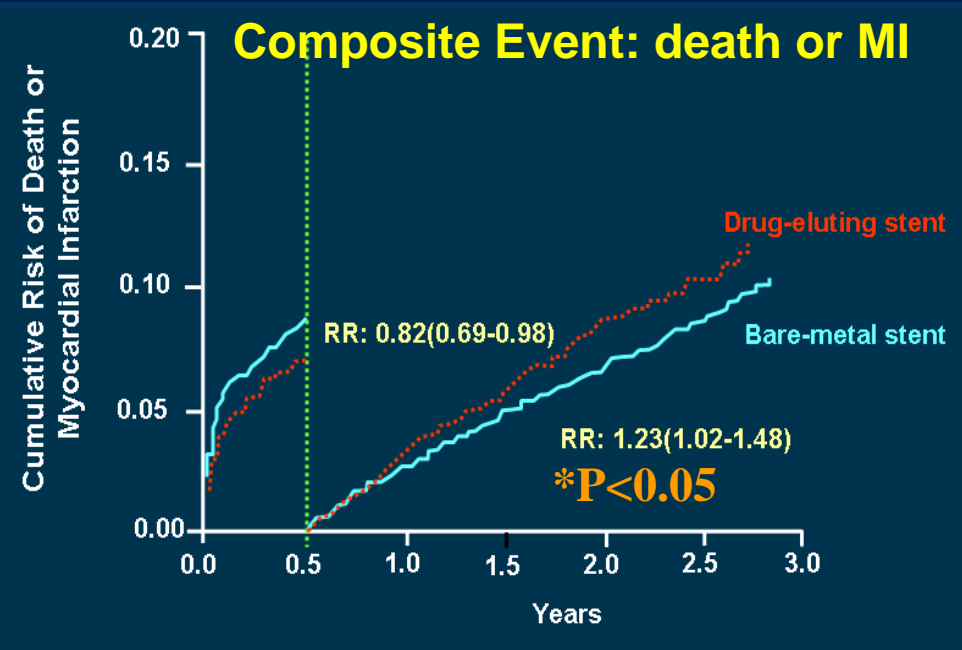


# Landmark Analysis of the All Study Group





# Landmark Analysis of the One-Stent Subgroup



# Conclusions

## Pooled Analysis from Registry Data (Sweden)

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- DESs were associated with an increased rate of death, as compared with BMSs after 6 months.
- The trend were appeared after 6 months, when the risk of death was 0.5 percentage point higher and a composite of death or myocardial infarction was 0.5 to 1.0 percentage point higher per year.
- The long-term outcome safety of DES needs to be ascertained in large, randomized trials

# One-Stent Subgroup

Stent length — no. (%)			Bare-Metal Stent (N = 10,319)	Drug-Eluting Stent (N = 3638)
<10 mm	64 (8.4)	182 (5.0)		
10–14 mm	74 (29.9)	792 (21.8)		
15–16 mm	67 (26.9)	796 (21.9)		
17–19 mm	13 (12.8)	341 (9.4)		
20–23 mm	92 (10.6)	675 (18.6)		
24–25 mm	16 (7.0)	382 (10.5)		
26–30 mm	04 (3.0)	187 (5.2)		
≥31 mm	53 (1.5)	272 (7.5)		
Restenotic lesion — no. (%)			121 (1.2)	243 (6.7)
Treated vessel — no. (%)				
Right coronary artery			3,463 (33.6)	557 (15.3)
Left main coronary artery			99 (1.0)	82 (2.3)
Left anterior descending artery			3,969 (38.5)	2260 (62.1)
Left circumflex artery			2,386 (23.1)	619 (17.0)
CABG graft			397 (3.8)	119 (3.3)

# One-Stent Subgroup

**They treated longer lesions,  
more LAD and more  
Diabetics. (more complex  
lesion and patients subsets)**

One-Stent Subgroup		
	Bare-Metal Stent (N= 10,319)	Drug-Eluting Stent (N= 3638)
Diabetes — no. (%)	1,618 (15.7)	855 (23.5)
Hypertension — no. (%)	4,368 (42.6)	1614 (44.7)
Previous PCI — no. (%)	1,068 (10.6)	606 (16.9)
Previous CABG — no. (%)	948 (9.5)	384 (10.7)
Previous myocardial infarction — no. (%)	3,693 (35.8)	1338 (36.8)
Aspirin before procedure — no. (%)	8,542 (82.8)	3161 (86.9)
Clopidogrel — no. (%)	5,248 (51.0)	2085 (57.4)

# Despite appropriate statistical adjustment,

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- Higher late-event rates in patients with DESs may be related with a higher proportion of high-risk patients.
- Another limitation is the lack of information about the duration of clopidogrel treatment in individual patients
- Also, changes in event rates over the time might have been influenced by the small number of patients with DESs early in the study period.

# Early and late coronary stent thrombosis of sirolimus-eluting and paclitaxel-eluting stents in routine clinical practice: data from a large two-institutional cohort study

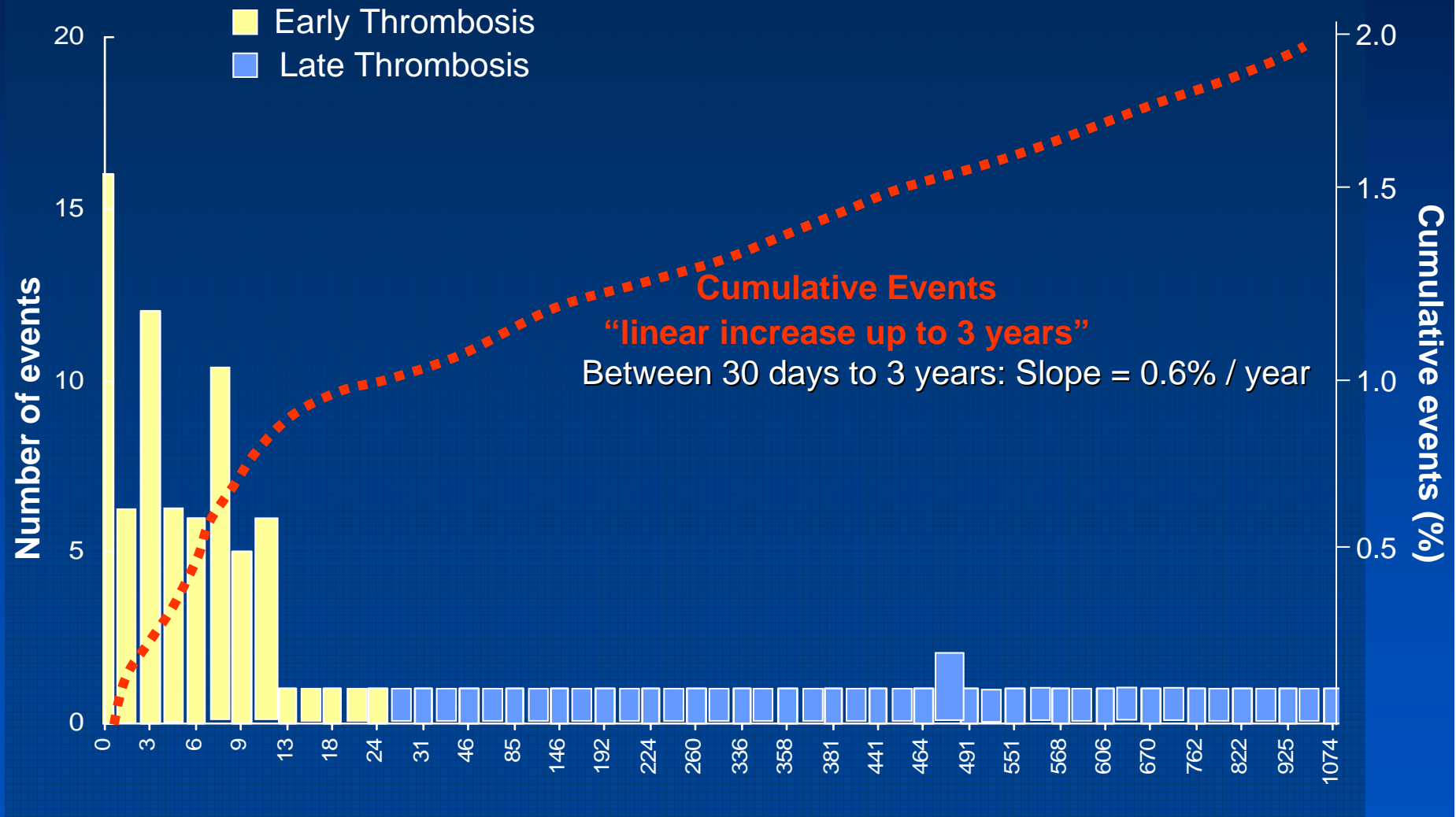
*Joost Daemen, Peter Wenaweser, Keiichi Tsuchida, Linda Abrecht, Sophia Vaina, Cyrill Morger, Neville Kukreja, Peter Juni, Georgios Sianos, Gerrit Hellige, Ron T van Domburg, Otto M Hess, Eric Boersma, Bernhard Meier, Stephan Windecker, Patrick W Serruys*

Pooled analysis of 8146 patients treated with SES (n=3823) or PES (n=4323): Data from University Hospital Bern, Switzerland and Erasmus Medical Center, Netherlands

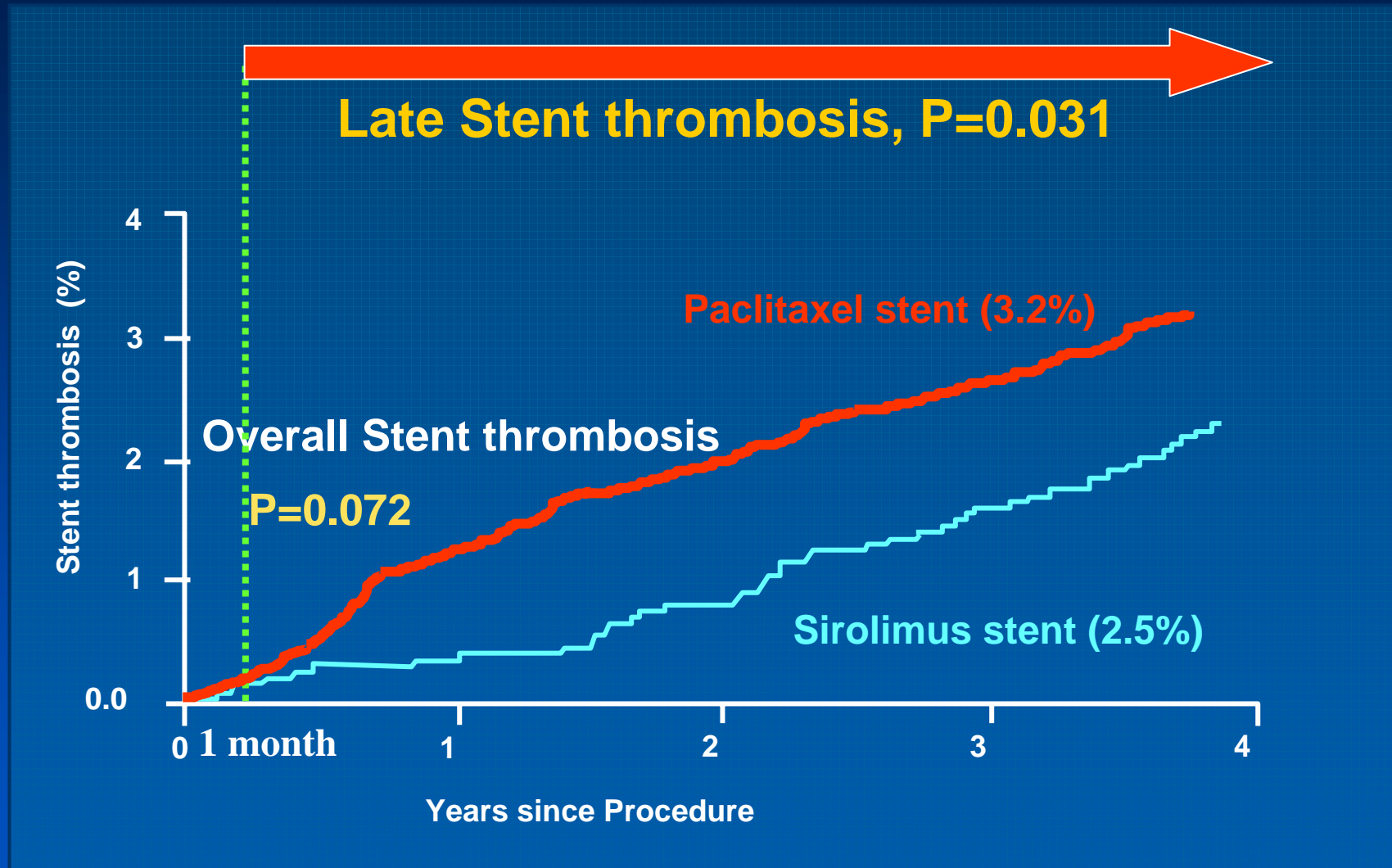
Angiographically documented stent thrombosis was assessed during 3 years follow-up period

Lancet 2007;369:667-678

# Occurrence of ST over time

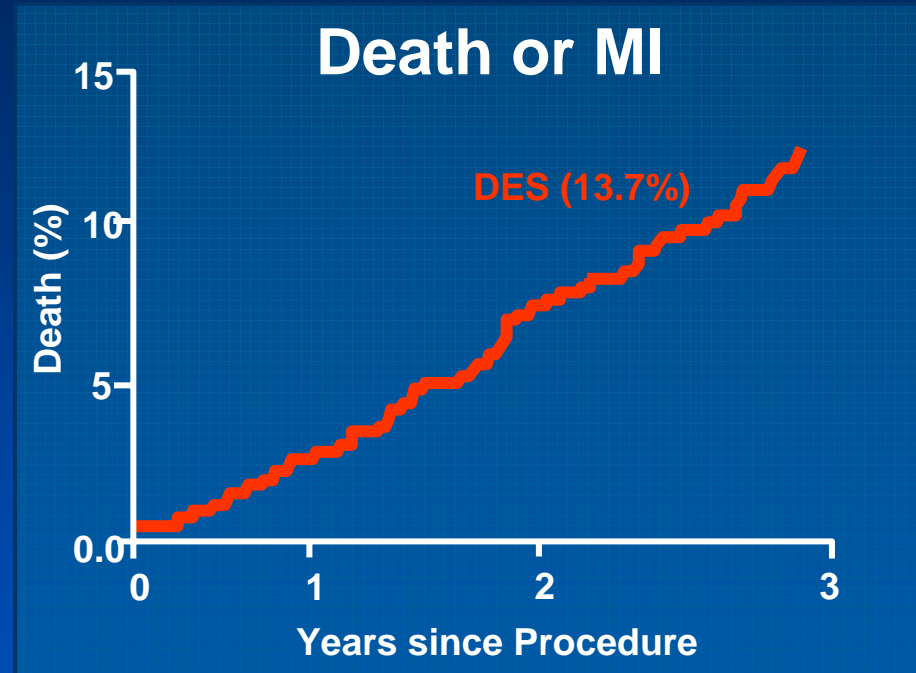
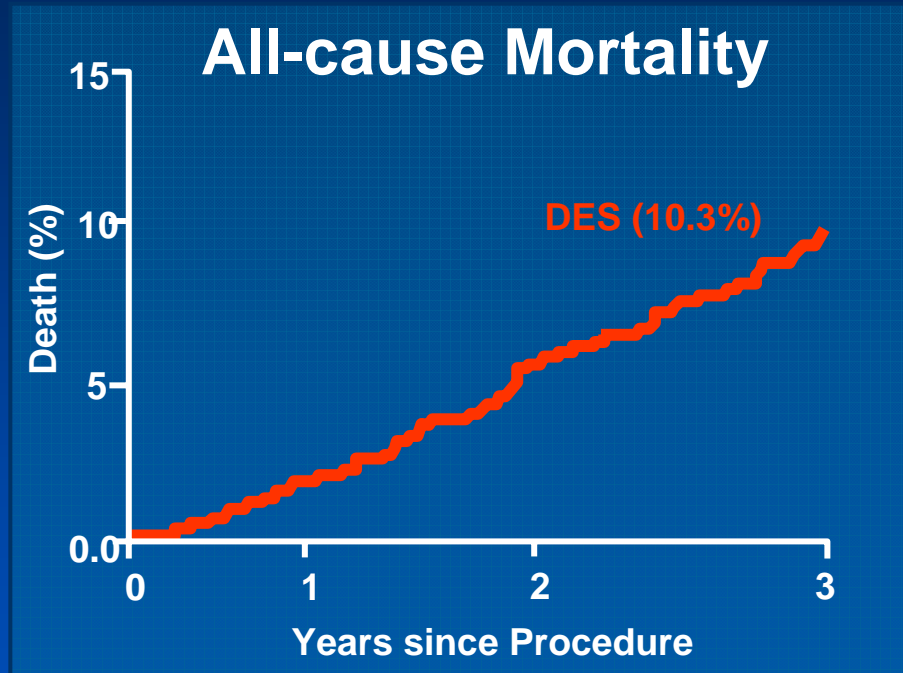


# Incidence of ST stratified by type of DES





# All-cause mortality or MI in overall population at 3 year F/U



# Conclusions

Pooled Analysis  
from Registry Data (Bern and  
Netherland Cohort)

- DESs only study
- The risk of stent thrombosis was 0.6 percentage increased per year.
- Higher mortality rate
- DM and acute coronary syndrome were independent predictors of stent thrombosis

# Clopidogrel Use and Long-term Clinical Outcomes After Drug-Eluting Stent Implantation

Eric L. Eisenstein, DBA

Kevin J. Anstrom, PhD

David F. Kong, MD

Linda K. Shaw, MS

Robert H. Tuttle, MSPH

**Context** Recent studies of drug-eluting intracoronary stents suggest that current antiplatelet regimens may not be sufficient to prevent late stent thrombosis.

**Objective** To assess the association between clopidogrel use and long-term clinical outcomes of patients receiving drug-eluting stents (DES) and bare-metal stents (BMS) for treatment of coronary artery disease.

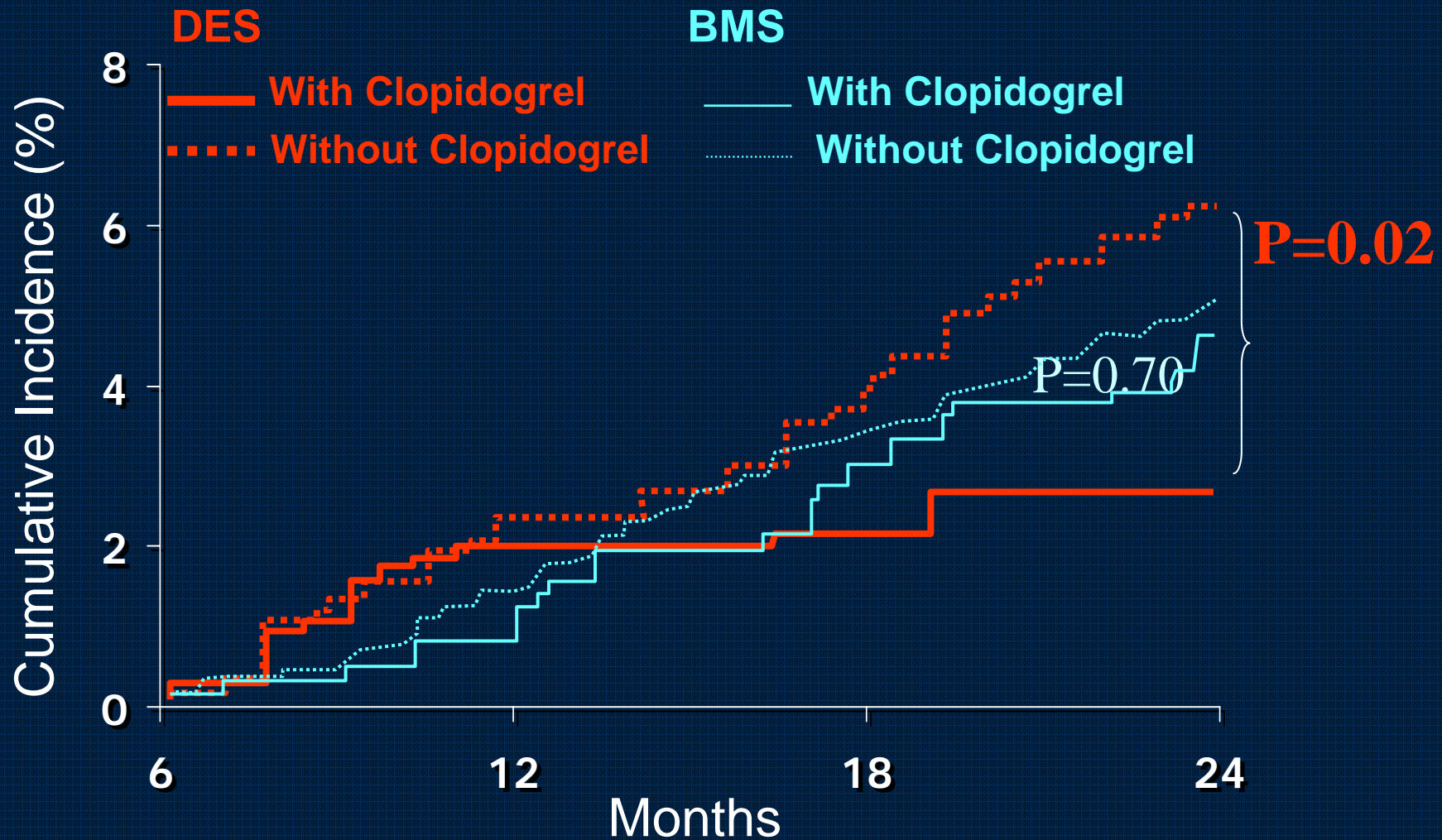
Pooled analysis of 4666 patients treated with DES (n=1501) or BMS (n=3165): Data from Duke Heart Center, USA

Landmark Analysis with or without clopidogrel use at 6-month and 12-month

JAMA 2007;297:159-68

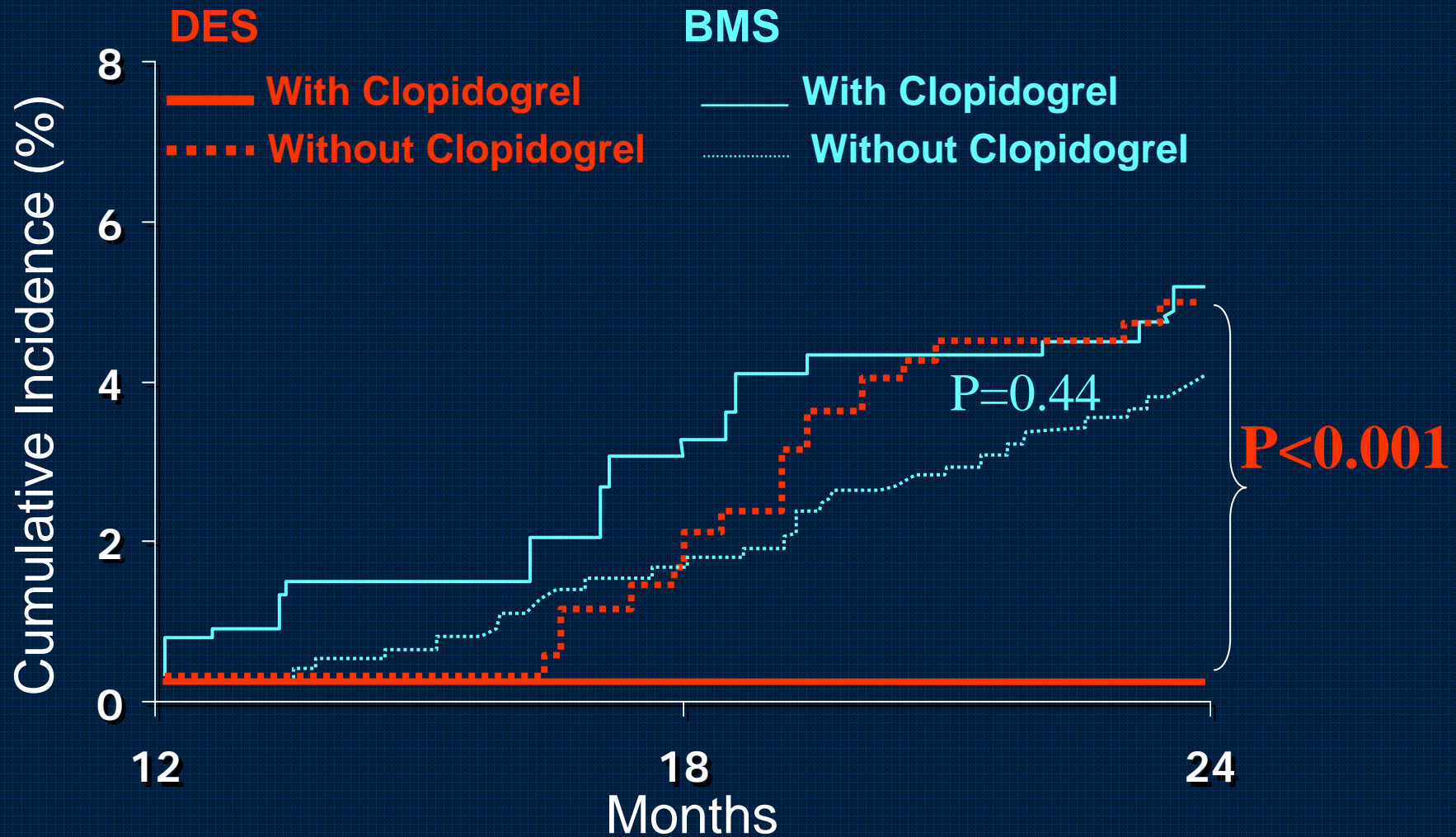


# Clopidogrel Use and Composite of Death or MI At 6-month Landmark



Eisenstein et al, JAMA 2007;297

# Clopidogrel Use and Composite of Death or MI At 12-month Landmark



Eisenstein et al, JAMA 2007;297

# Conclusions

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Pooled Analysis  
from Registry Data (Duke  
University, single center)

- Discontinued Clopidogrel was significantly associated with subsequent all cause death /MI.
- There may be selection bias between DES and BMS use in same period of registry.
- Detailed drug compliance was not monitored

# Long-Term Evaluation of Stent Thrombosis in Real World After DES vs. BMS Implantation

10-Year Experience  
from AMC Registry 2007

# Overall 10 Year Study Population

**7,217 Patients**  
**(10,193 Lesions, 12,038 Stents)**

Jan,1997

Mar,2003

Feb,2006

**BMS**

Default Treatment

**DES**

Default Treatment

**4,060 patients**

**5,705 lesions**

**5,867 stents**

**3,157 patients**

**4,488 lesions**

**6,171 stents**

**(4,766 SES    1,405 PES)**



# Population

- All patients in Asan Medical Center who had received coronary stent from Jan, 1997, to Mar, 2006, for whom complete follow-up data were available.
- The unit of analyses were based on the first recorded procedure, regardless of the number of repeated procedure.
- Patients who received at least one DES were assigned to the DES group.

# Data Collection

- Baseline demographic and catheterization data was collected prospectively using the dedicated database.
- All patients were contacted at 1-, 6-, 12-months after the initial procedure, and annually thereafter.
- Complete data on vital status and date of death were obtained from the national population registry (on the basis of the unique personal ID number from “Ministry of Government Administration and Home Affairs”).
- Follow-up MI was based on clinical diagnosis by the patient’s physician and the screening of “ICD code”.

# Statistical Analysis

- Cumulative event rates were estimated by the Kaplan-Meier method and differences were assessed with the log-rank test.
- To compensate for the non-randomized design of observation study (“adjust the paradigm shift between BMS vs. DES”), we used propensity-score analyses.
- Adjusted relative risk were estimated from Cox-regression models in which the propensity score and the stent group as covariates .

# Landmark Analyses

- To provide separate descriptions of the early and late relative risks of event and evaluate the risk of very late stent thrombosis, we also performed a “landmark analysis” with a prespecified landmark set at 1 year

# Antiplatelet Regimens

## BMS Phase

Aspirin indefinitely

Clopidogrel 75 mg QD for at least 1 month or

Ticlopidine 500mg QD for at least 1 month

## DES Phase

Aspirin indefinitely

Clopidogrel 75 mg QD for at least 6 months

# Baseline Demographics

	<b>DES</b> <b>(n=3157)</b>	<b>BMS</b> <b>(n=4060)</b>	<b>P</b>
Age, yrs	60.5±10.3	59.2±10.1	<0.001
Male gender	2224 (71)	2902 (72)	0.4
Hypertension	1595 (51)	1674 (41)	<0.001
Diabetes mellitus	877 (28)	888 (22)	<0.001
Hypercholesterolemia	562 (25)	1460 (36)	<0.001
Current smoking	906 (29)	1641 (41)	<0.001
Left ventricular EF, %	58.5±8.8	59.1±10.3	0.032

# Baseline Demographics

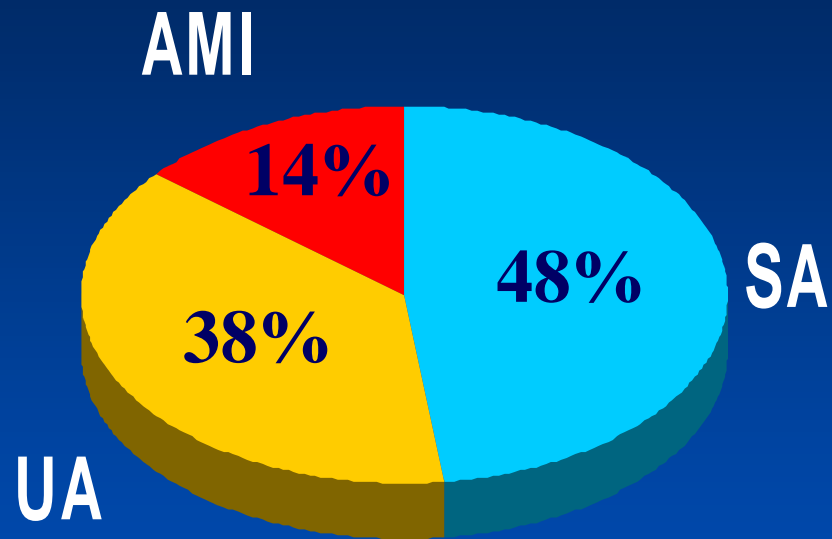
	DES (n=3157)	BMS (n=4060)	P
Previous PCI	539 (17)	135 (3)	<0.001
Previous CABG	81 (3)	24 (1)	<0.001
Previous MI	337 (12)	301 (7.4)	<0.001
Multi-vessel PCI	1053 (33)	1163 (29)	<0.001
Renal failure	95 (3)	41 (1)	<0.001
Duration of clopidogrel (months)	12.7±9.2	3.2±2.6	<0.001

# Lesion Characteristics

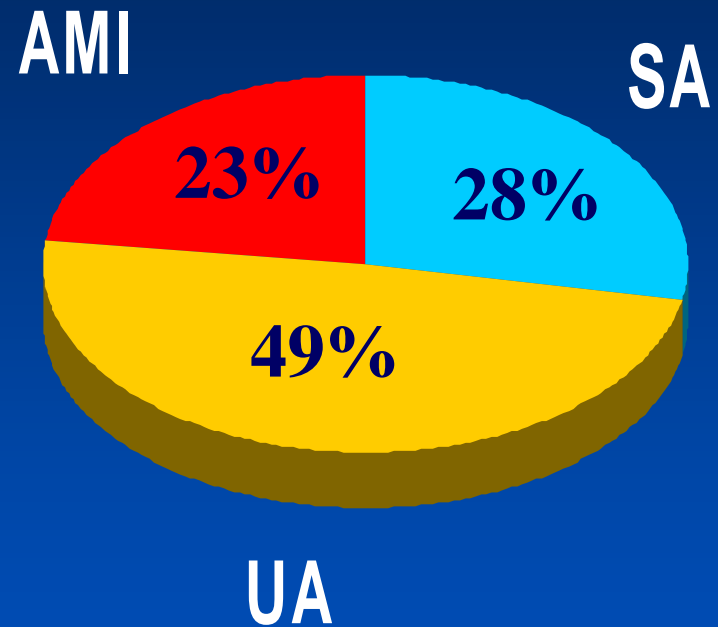
	DES (n=4488)	BMS (n=5705)	P
Chronic total occlusion	251 (6)	73 (1)	<0.001
In-stent restenosis	250 (6)	97 (2)	<0.001
Ostial lesion	354 (8)	497 (9)	0.2
Bifurcation	729 (16)	602 (11)	<0.001
B2/C type (ACC/AHA)	3291 (74)	3233 (57)	<0.001



# Clinical Indication



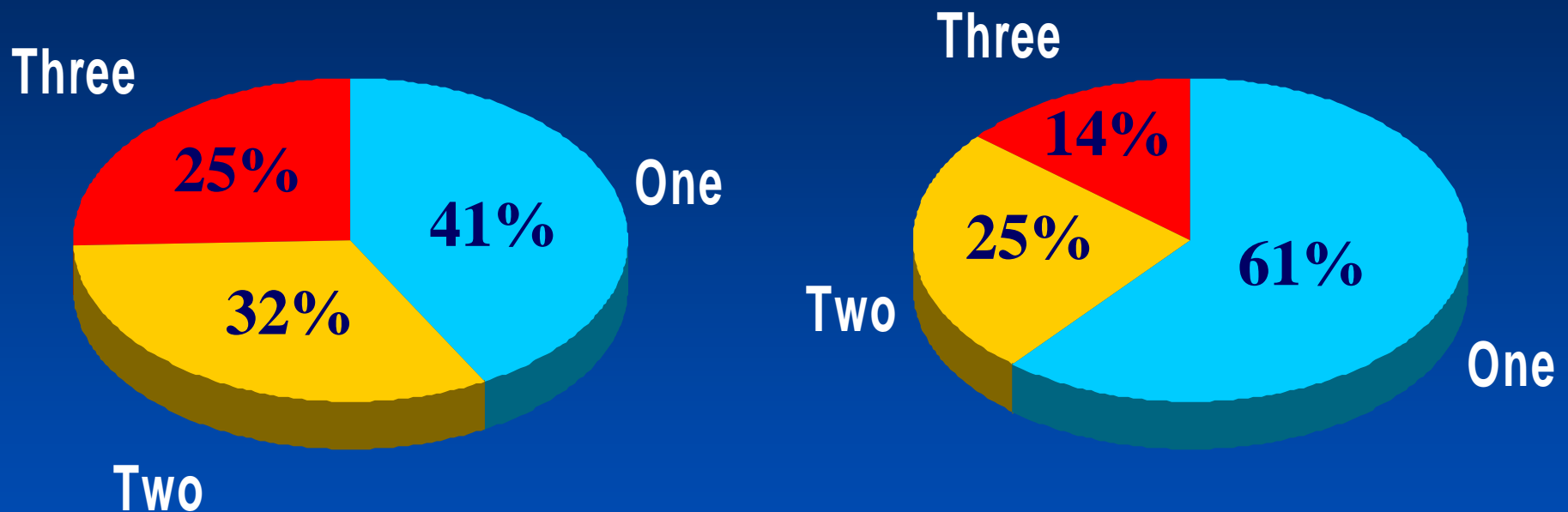
**DES**



**BMS**

**P<0.001**

# Number of diseased vessel

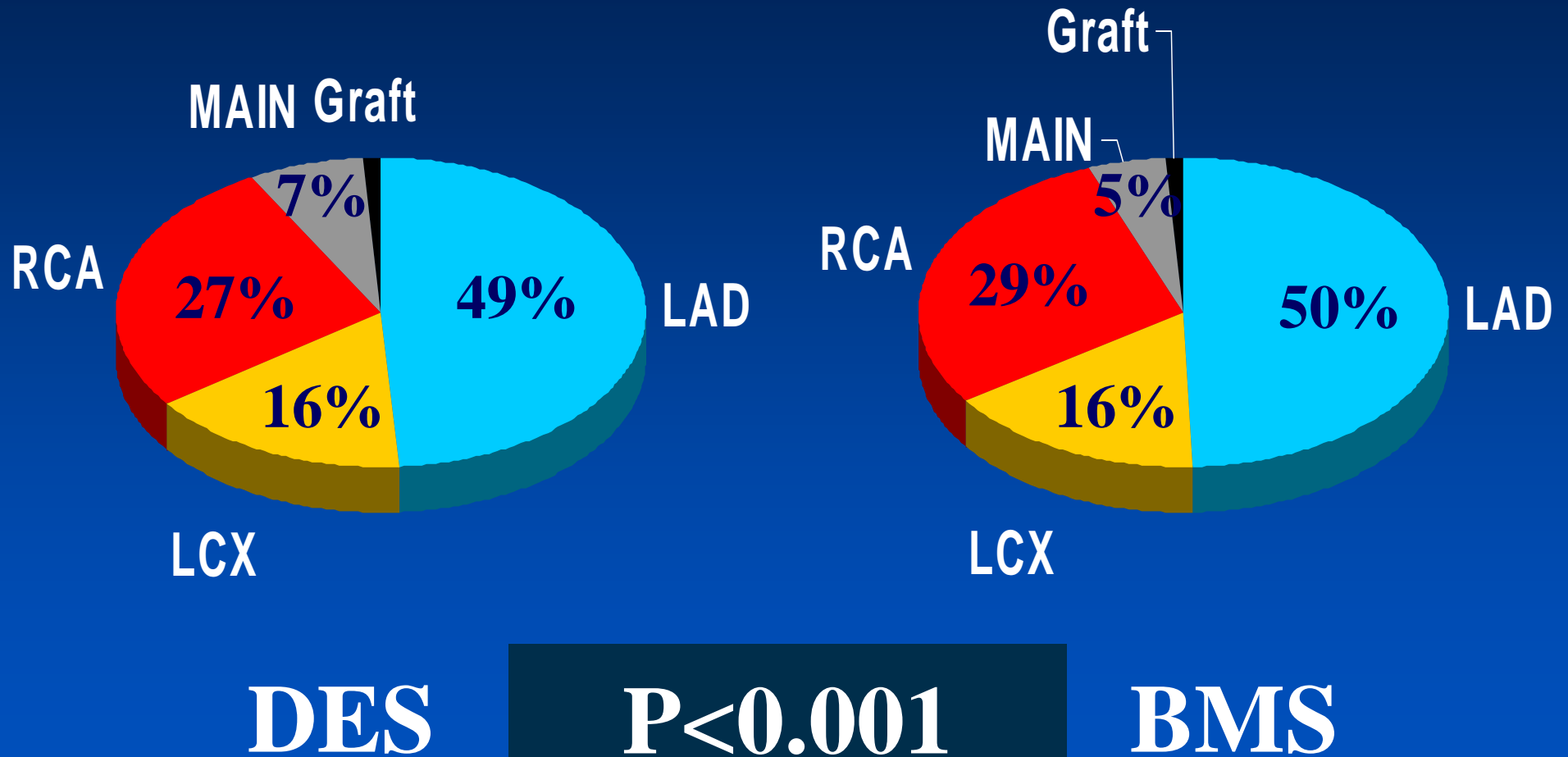


**DES**

**P<0.001**

**BMS**

# Treated Vessel



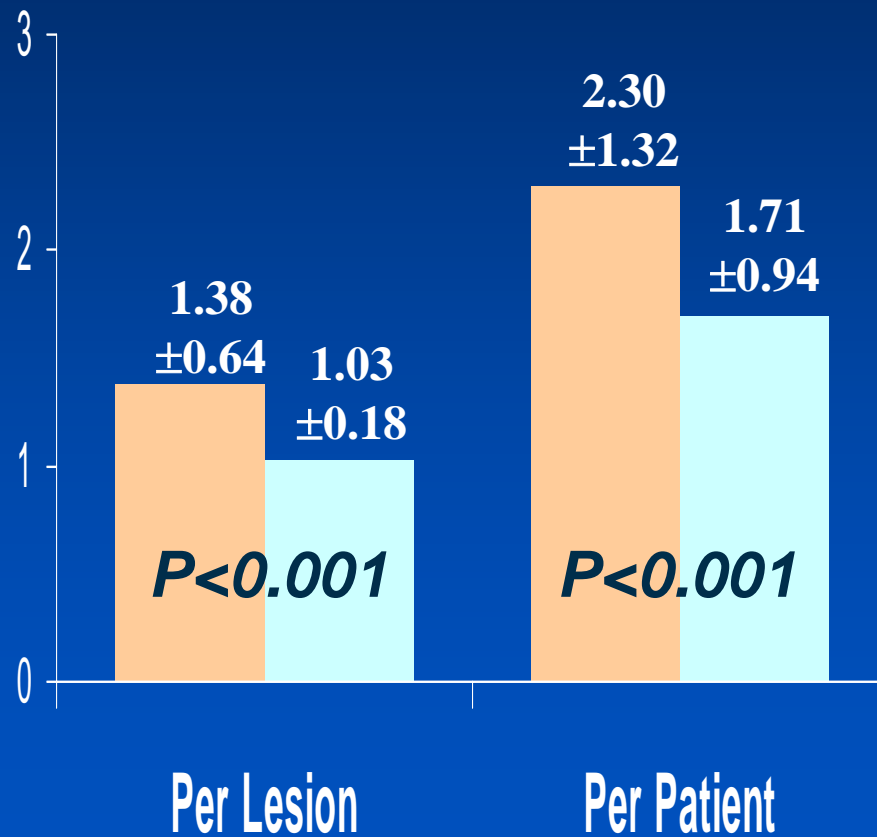
# Procedural Characteristics

	DES (n=4488)	BMS (n=5705)	P
Direct Stenting	2823 (64)	2675 (47)	<0.001
IVUS guidance	727 (17)	378 (7)	<0.001
Maximal device size	3.59±0.46	3.65±0.58	<0.001
Maximal inflation pressure	15.9±3.9	12.8±3.8	<0.001
Balloon-to-artery ratio	1.25±0.17	1.14±0.14	<0.001

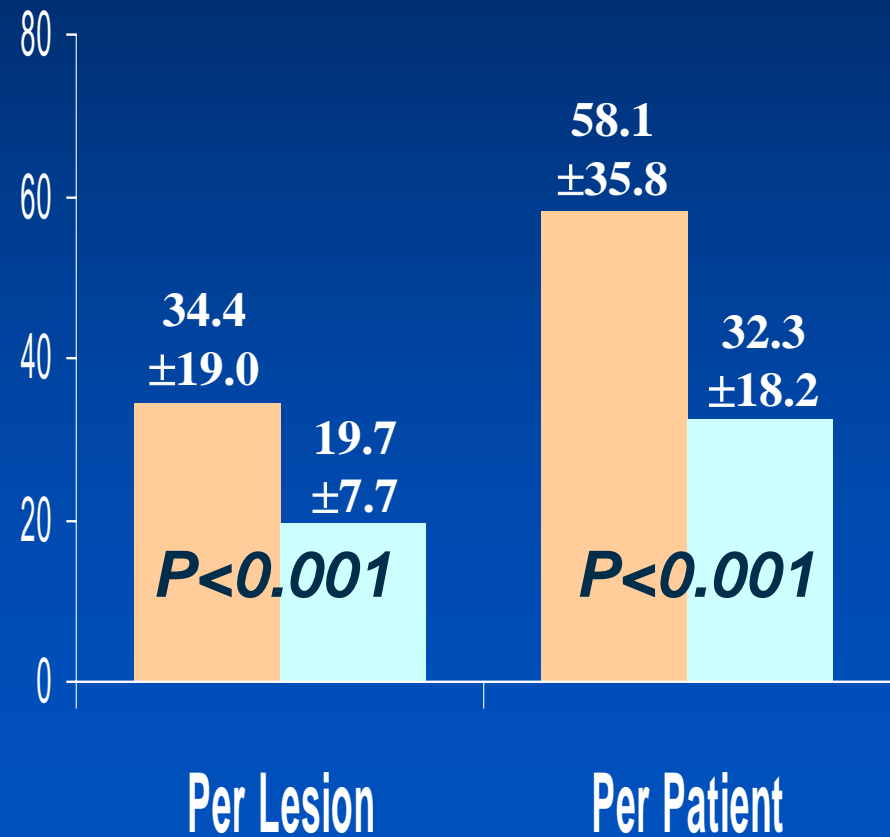
# Procedural Characteristics

■ DES ■ BMS

## Number of stents



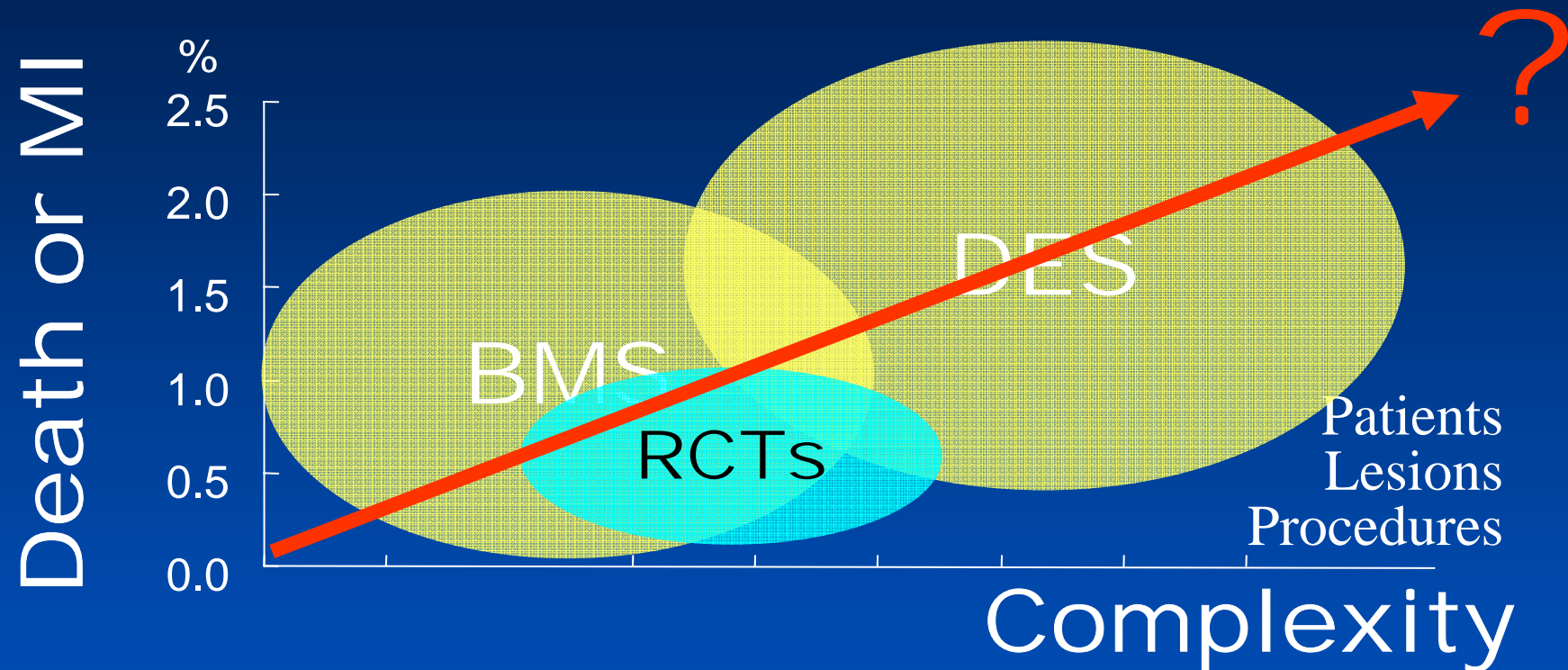
## Total stent length (mm)



# Pre/Post QCA Characteristics

	DES	BMS	P
Lesion length, mm	26.4±14.7	17.6±9.8	<0.001
Reference diameter, mm	2.90±0.49	3.25±0.57	<0.001
Pre - MLD, mm	0.90±0.55	0.79±0.53	<0.001
Post - MLD, mm	2.81±0.48	3.19±0.59	<0.001
Acute gain	1.90±0.59	2.40±0.70	<0.001
Pre - DS, %	68.2±17.2	76.5±15.5	<0.001
Post - DS, %	2.4±13.8	0.7±12.1	<0.001

# Paradigm Shift in Real World Practice



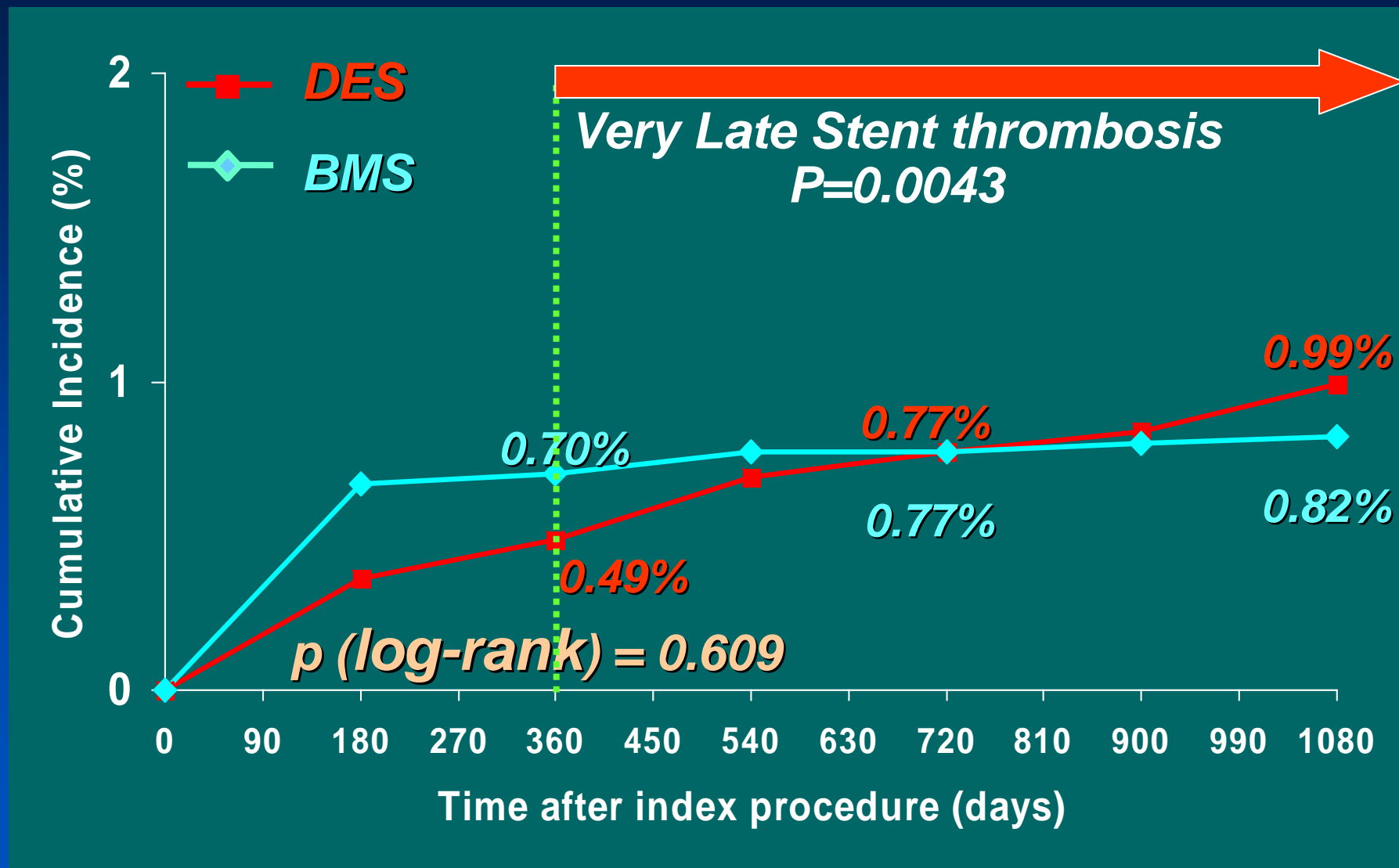
Patients treated with DES had more diabetes mellitus, multi-vessel, multi-lesion PCI, bifurcation location and low LV function, and more complex stenting procedures, which were typical traditional risk factors of unfavorable clinical outcomes.

# Results

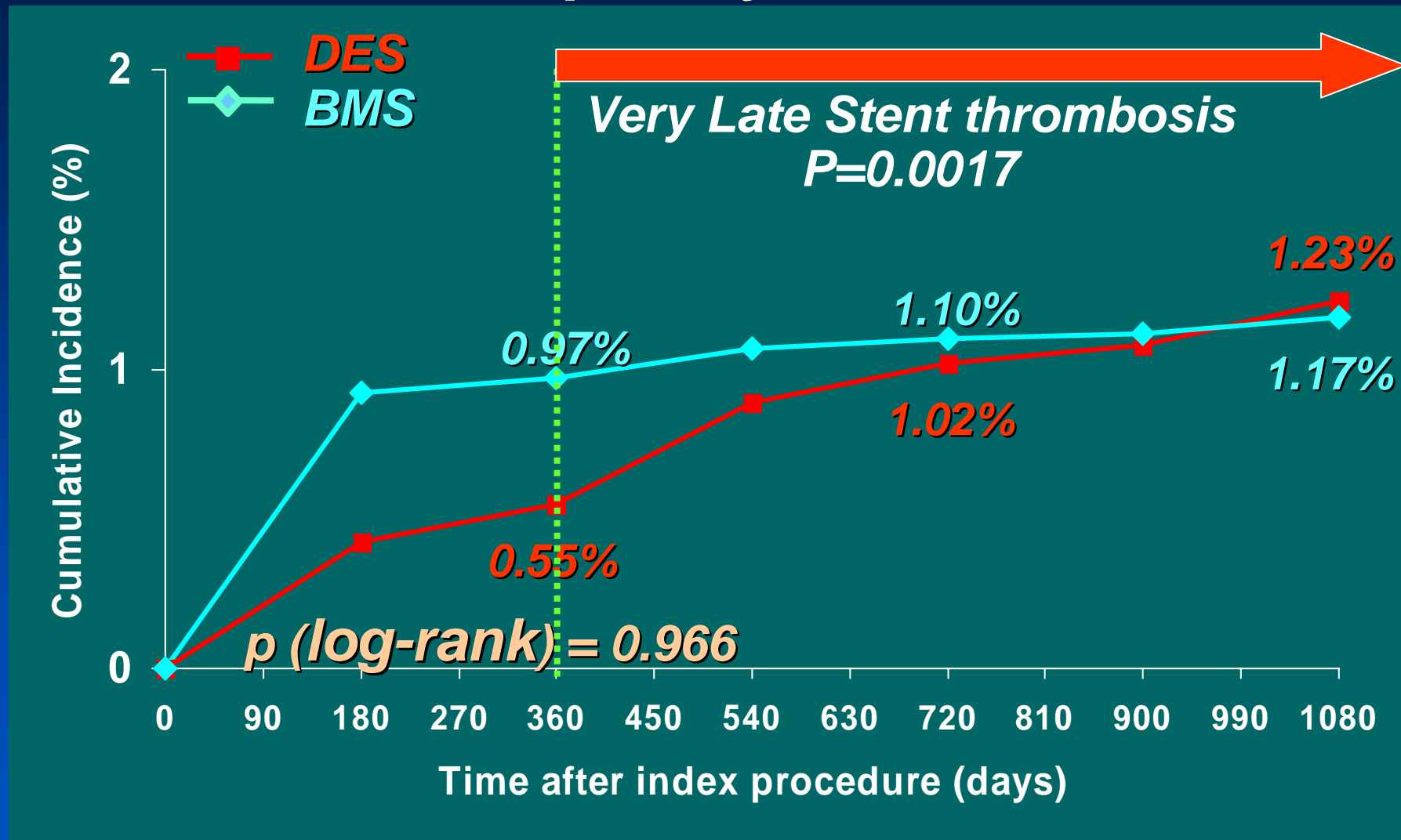
- Stent Thrombosis (ST)  
Death  
MI



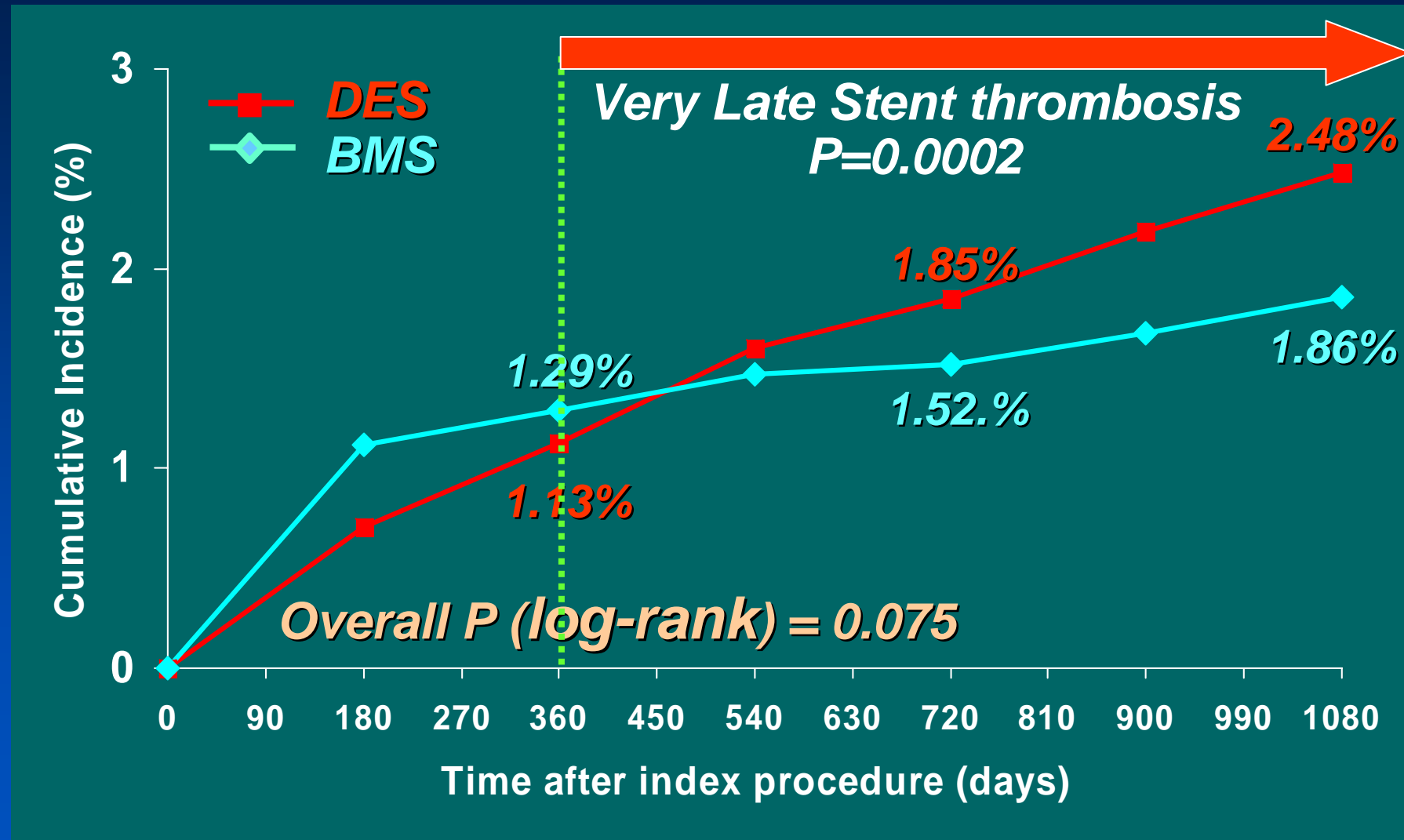
# Incidence of ST (ARC: Definite) upto 3 years



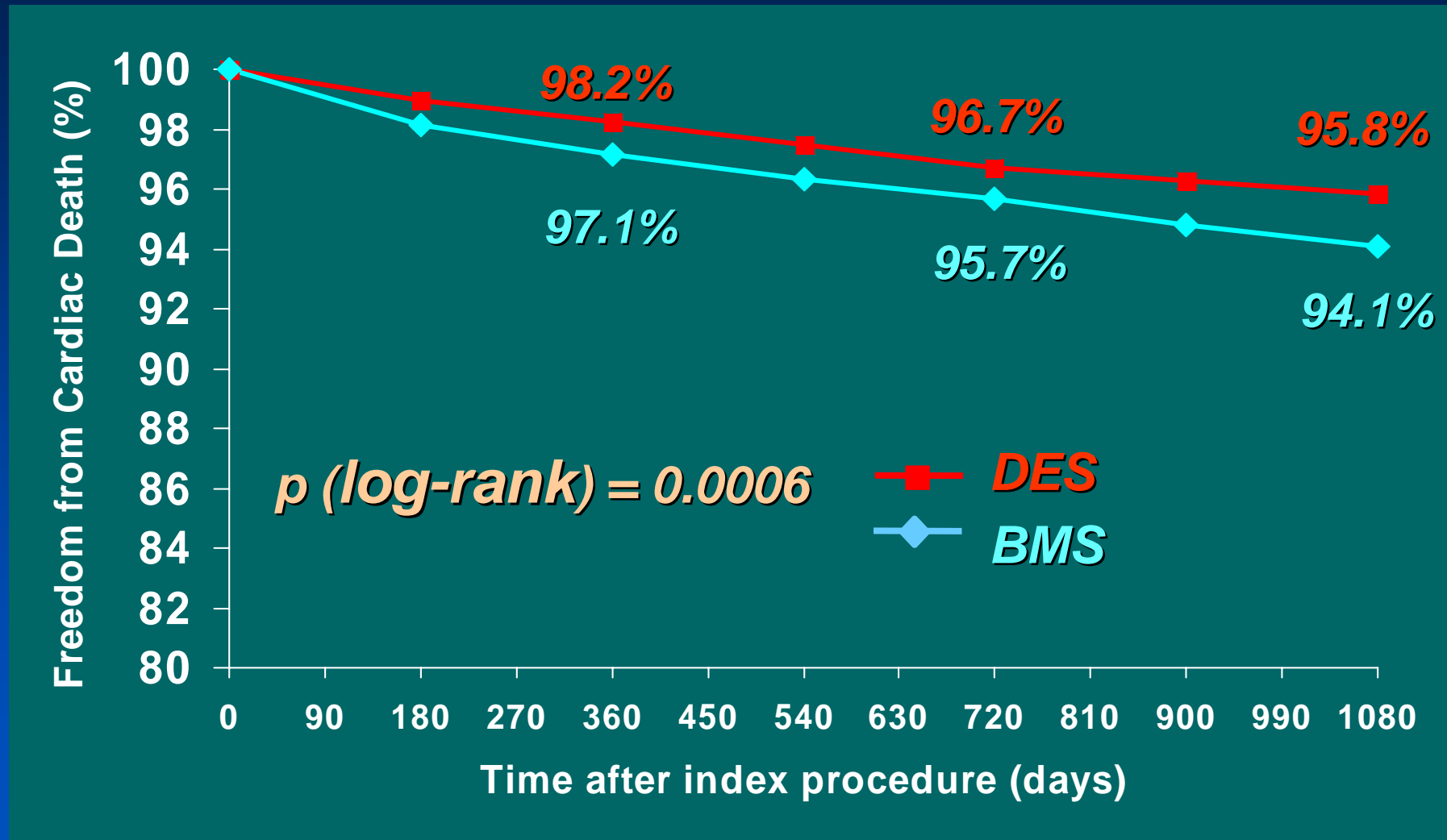
# Incidence of ST (ARC: Definite + Probable) upto 3 years



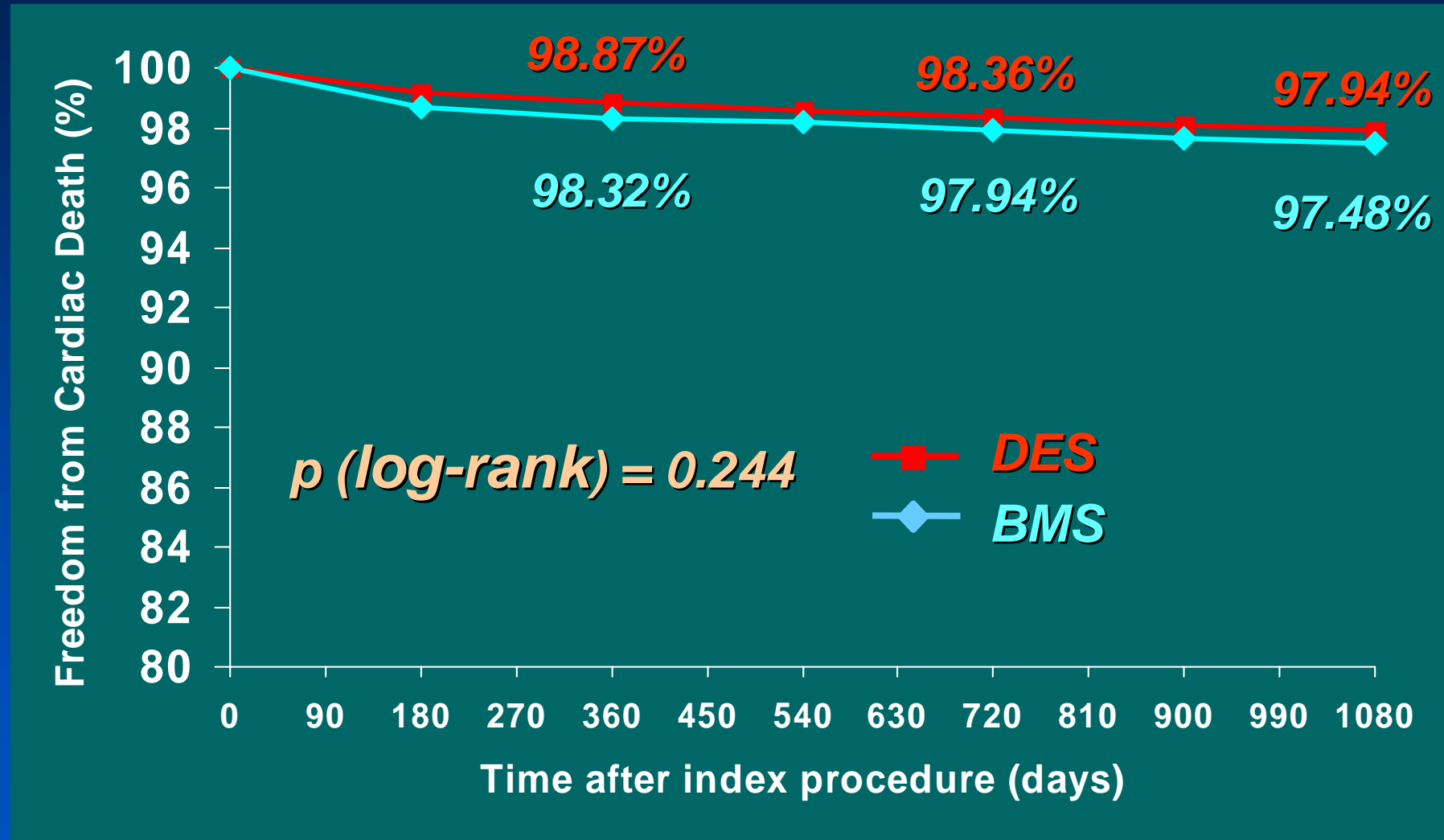
# Incidence of ST (Any ARC Criteria) upto 3 years



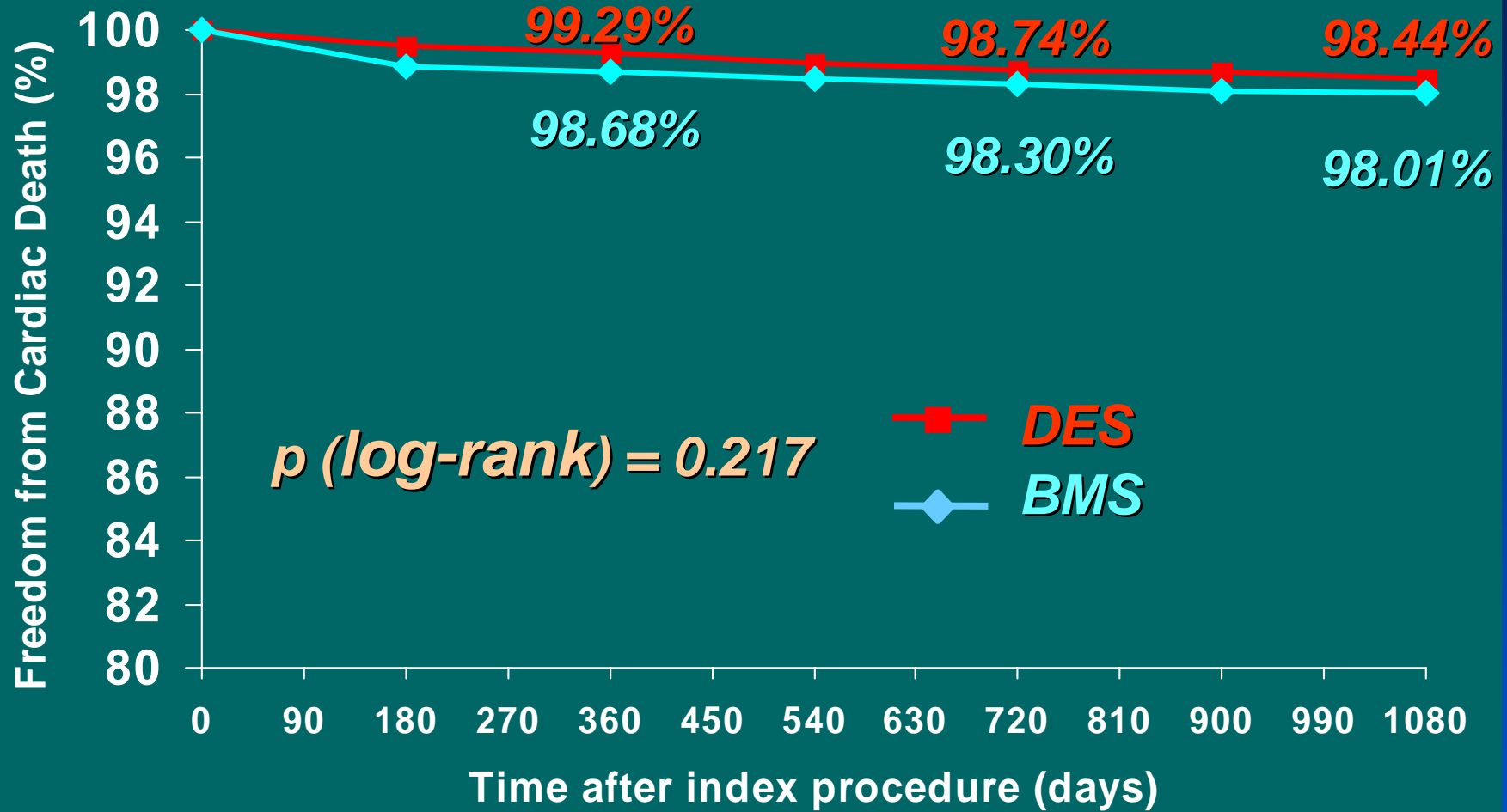
# Survival-Free from All-cause Mortality up to 3 years



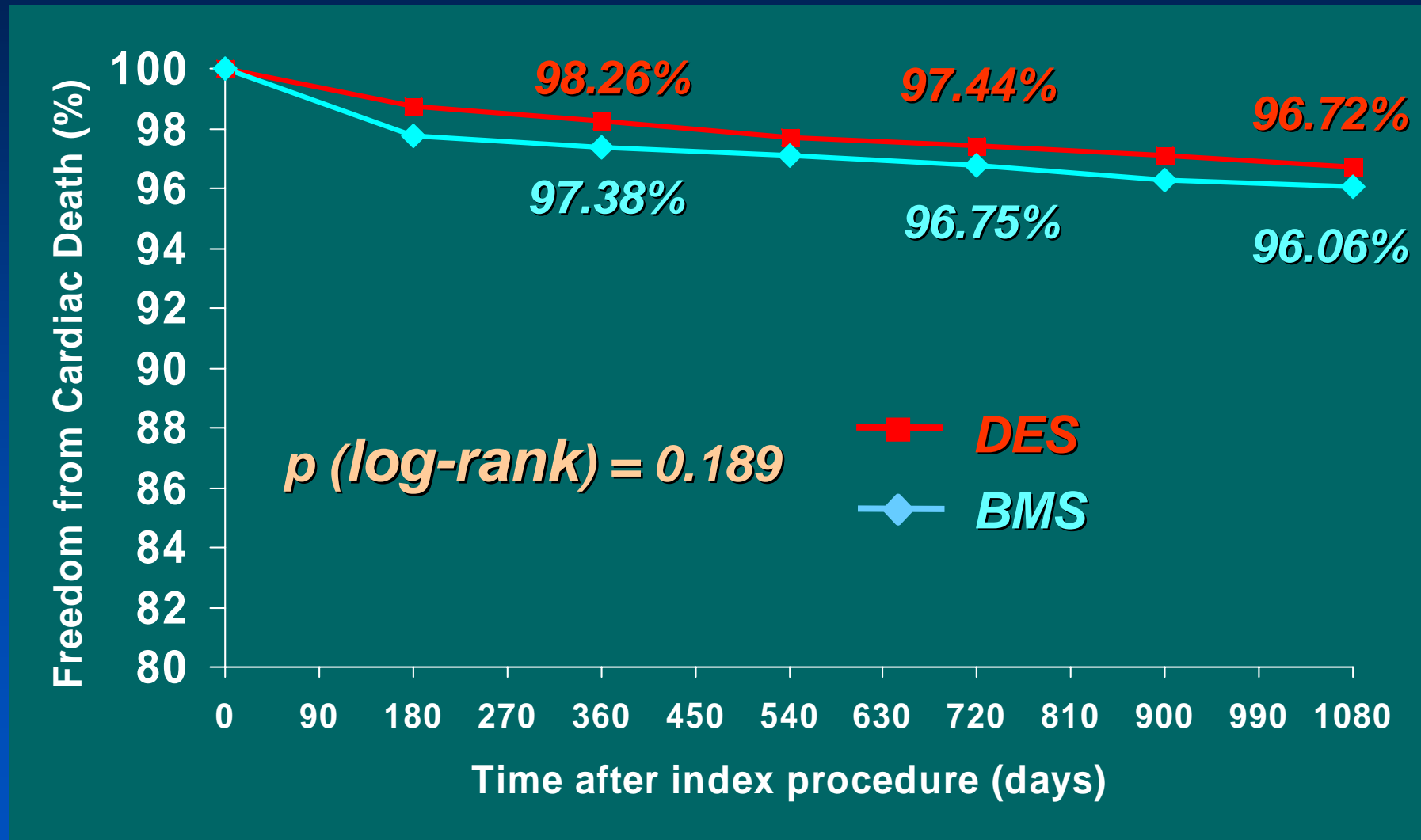
# Survival-Free from Cardiac Death up to 3 years



# Survival-Free from MI up to 3 years



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

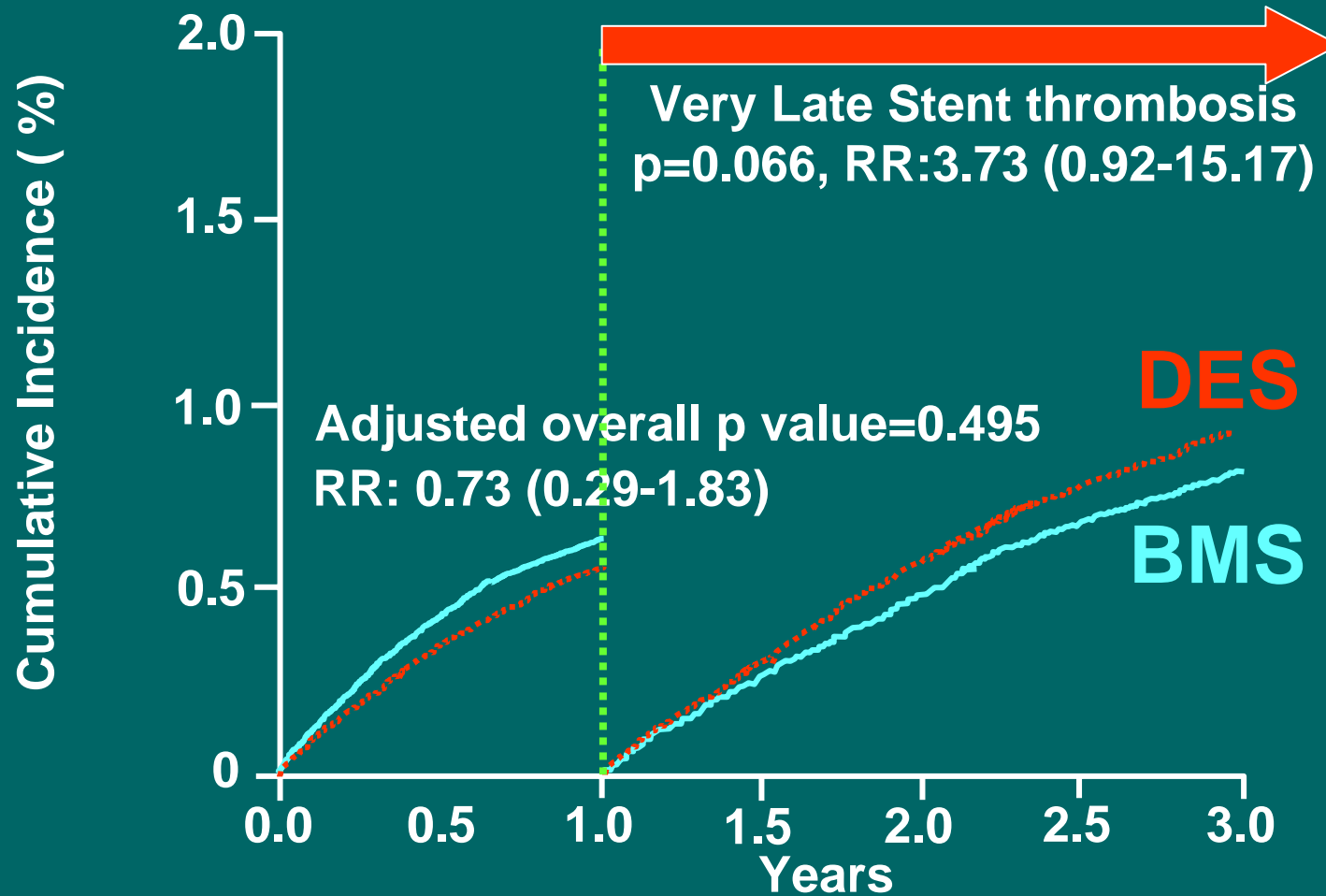


# DES

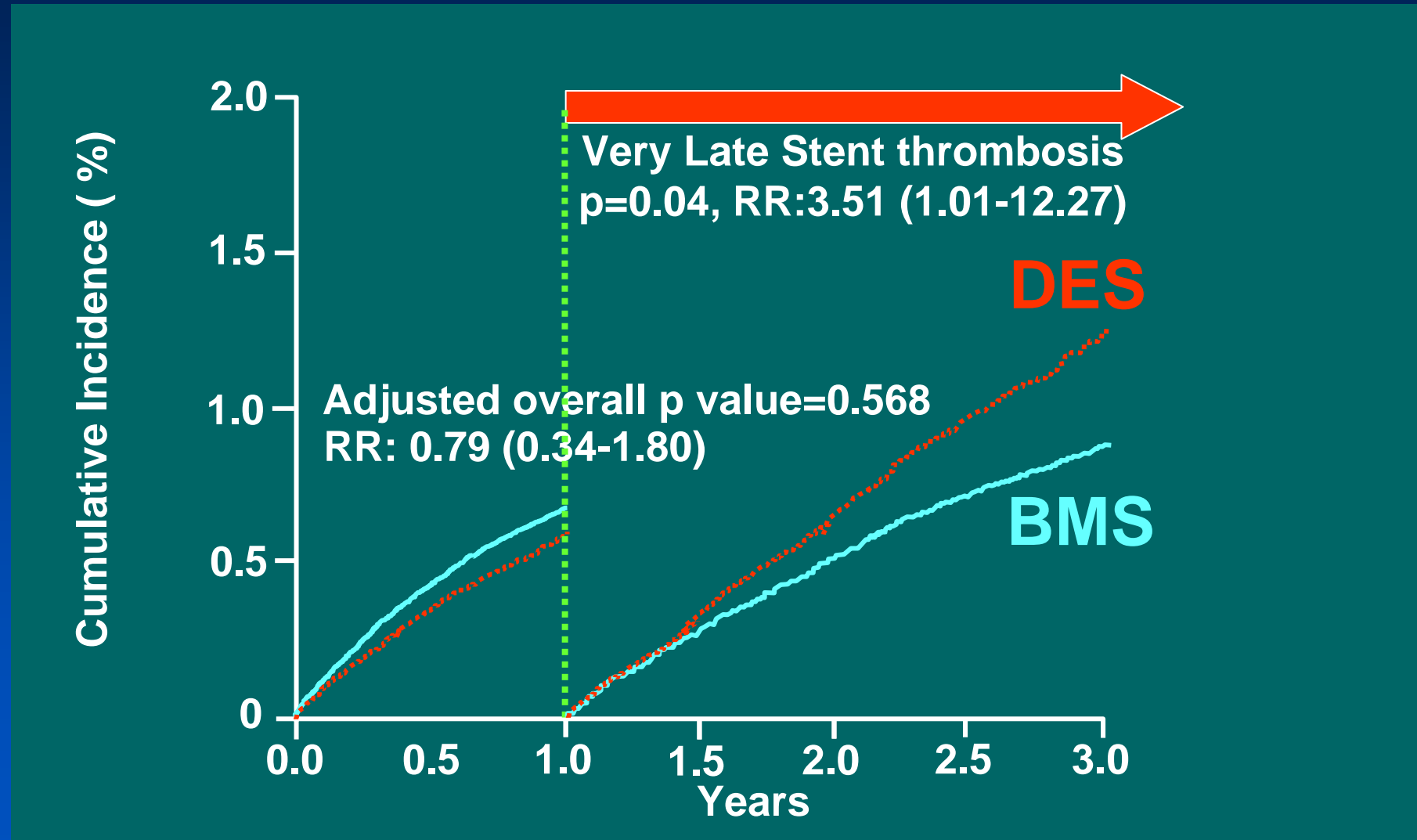
After risk adjustment  
using propensity-score-adjusted  
Cox regression analyses



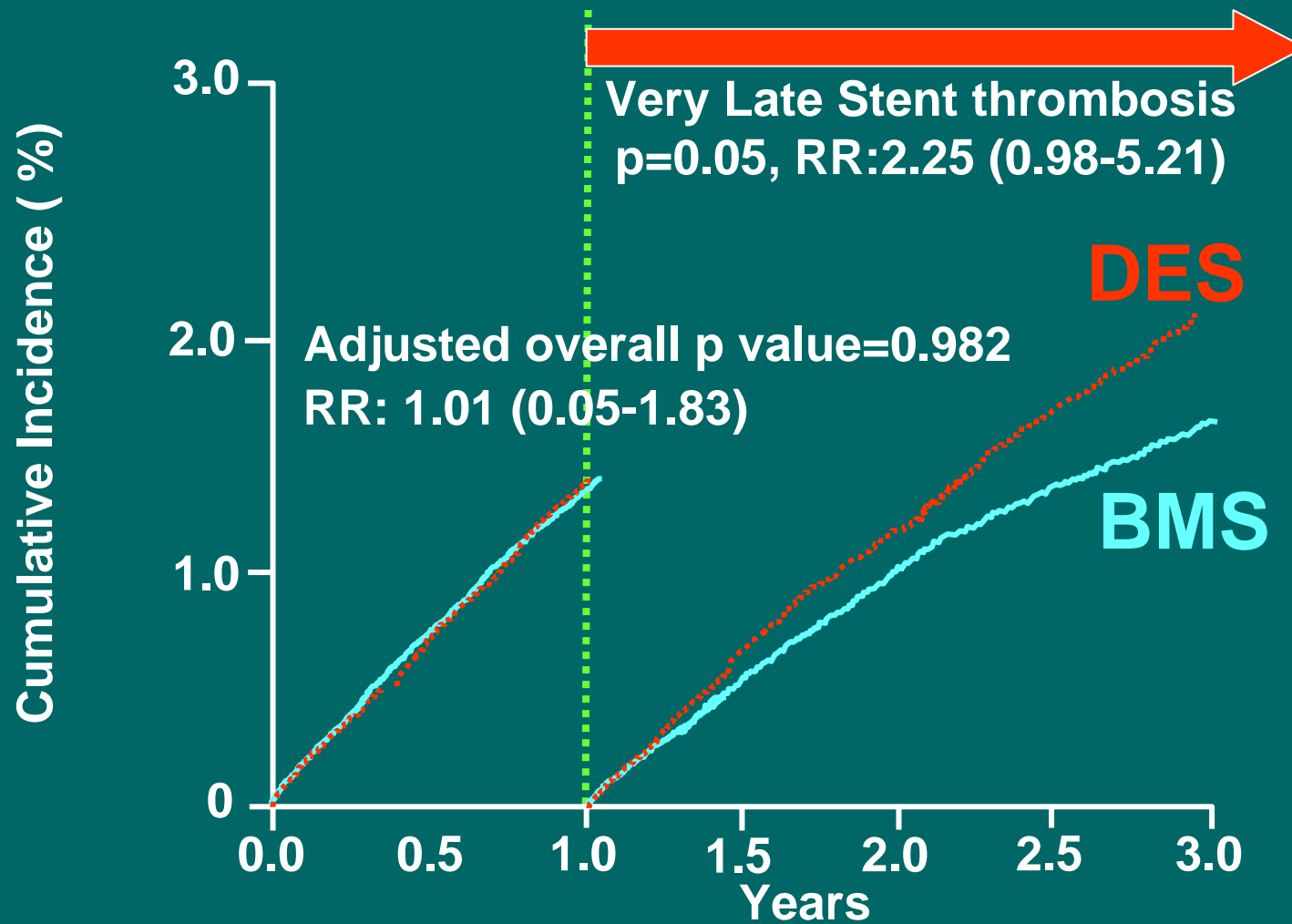
# Incidence of ST (ARC: Definite) upto 3 years



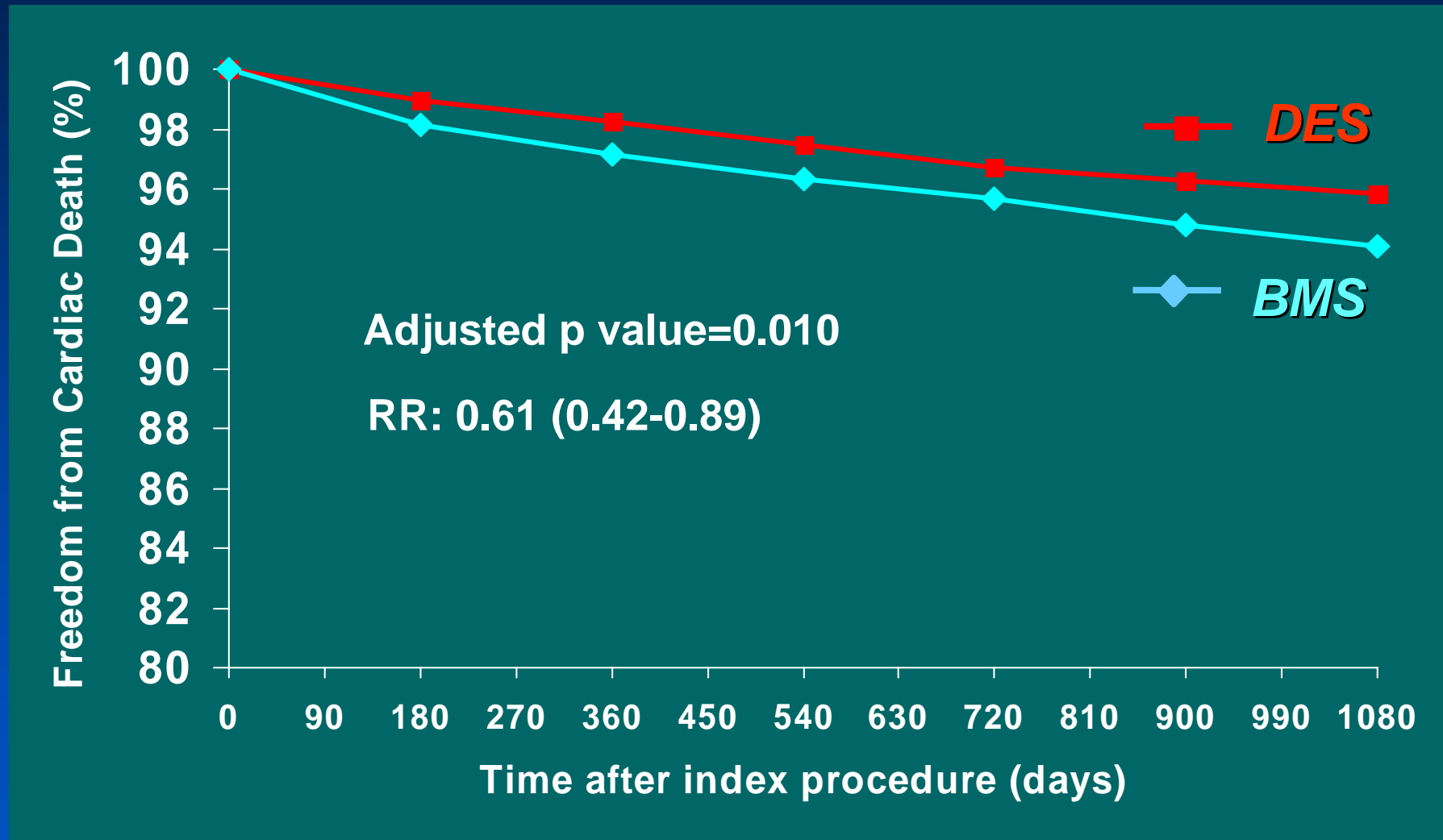
# Incidence of ST (ARC: Definite+Probable) upto 3 years



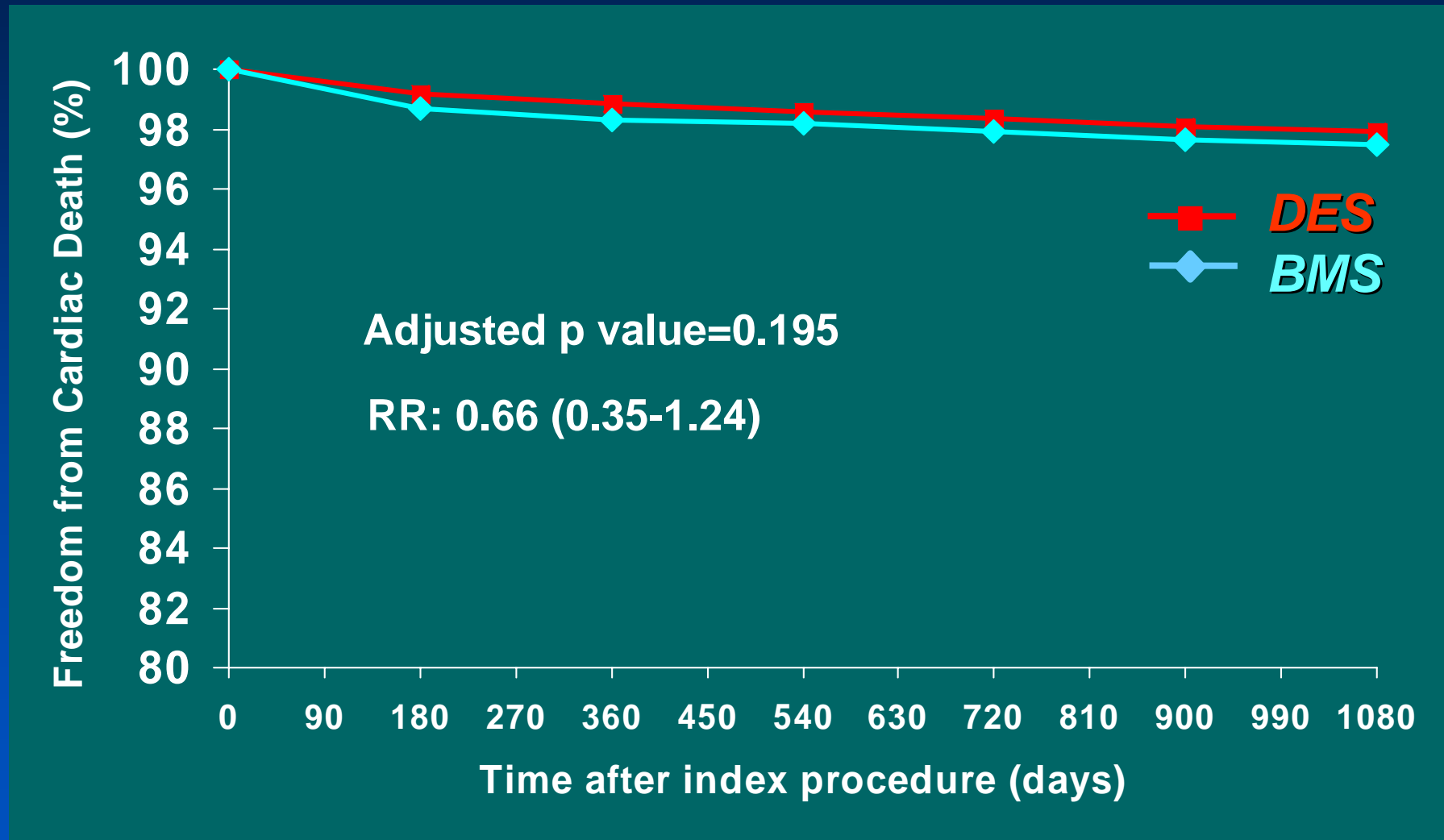
# Incidence of ST (Any ARC Criteria) upto 3 years



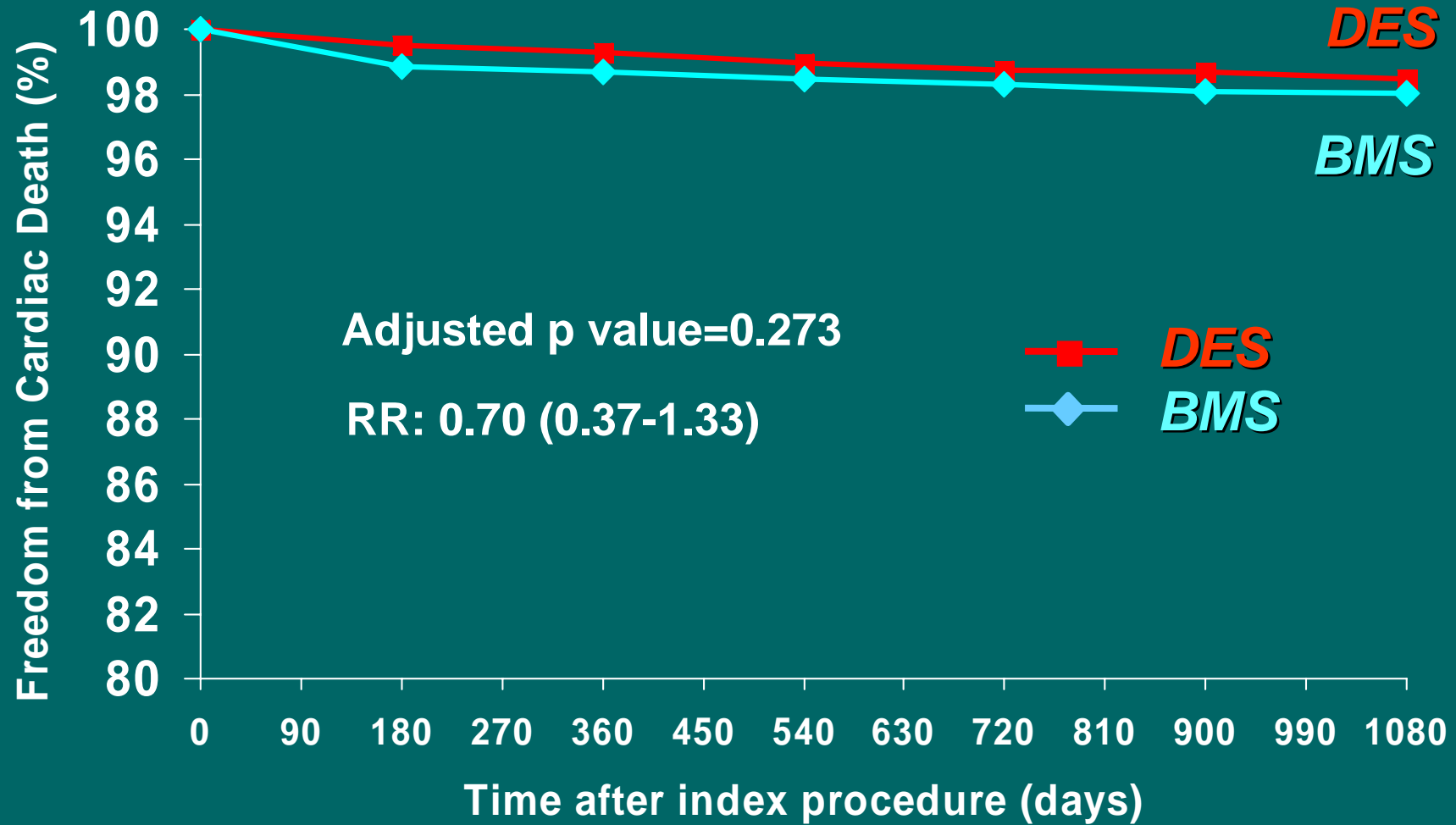
# Survival-Free from All-cause Mortality (up to 3 years)



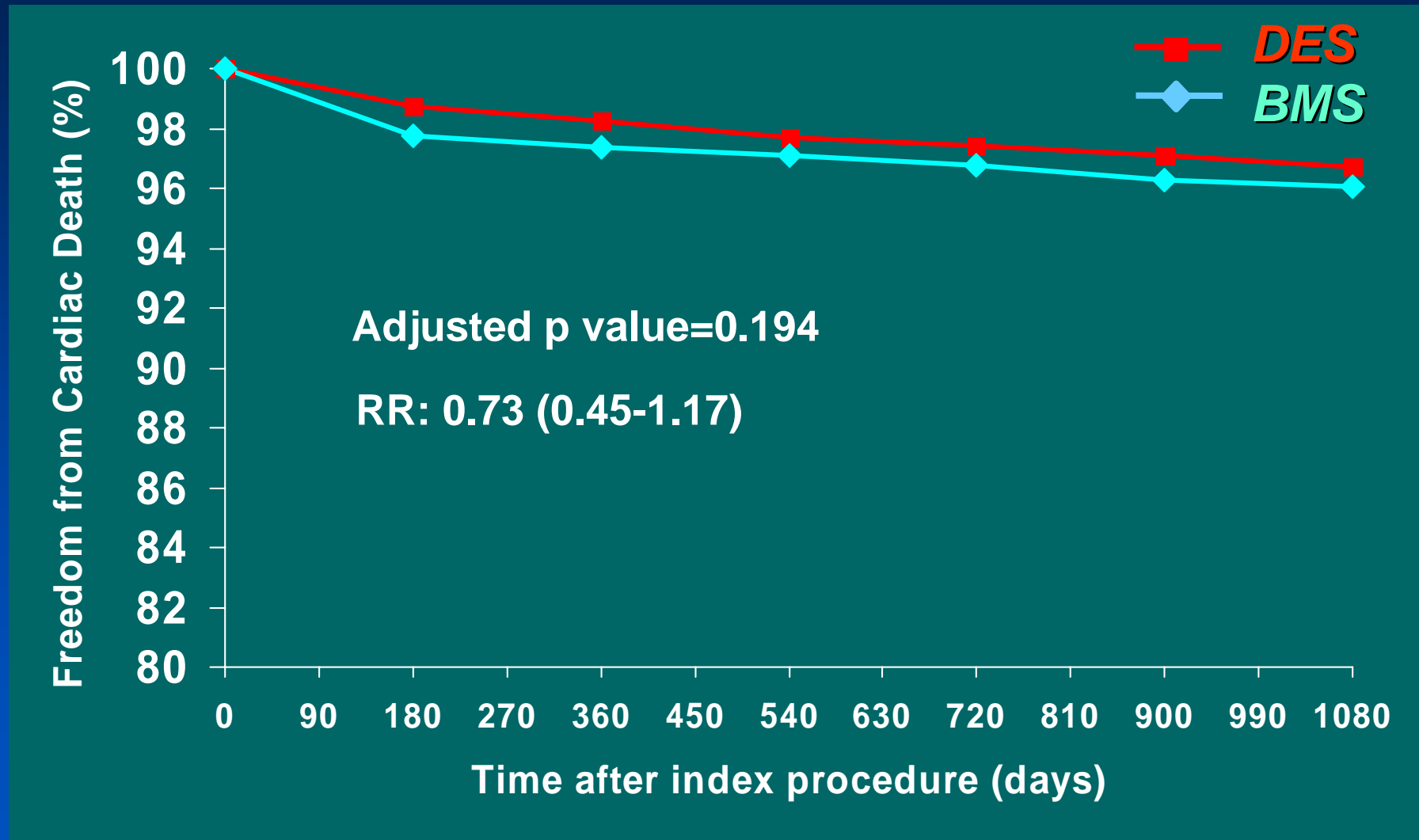
# Survival-Free from Cardiac Death (up to 3 years)



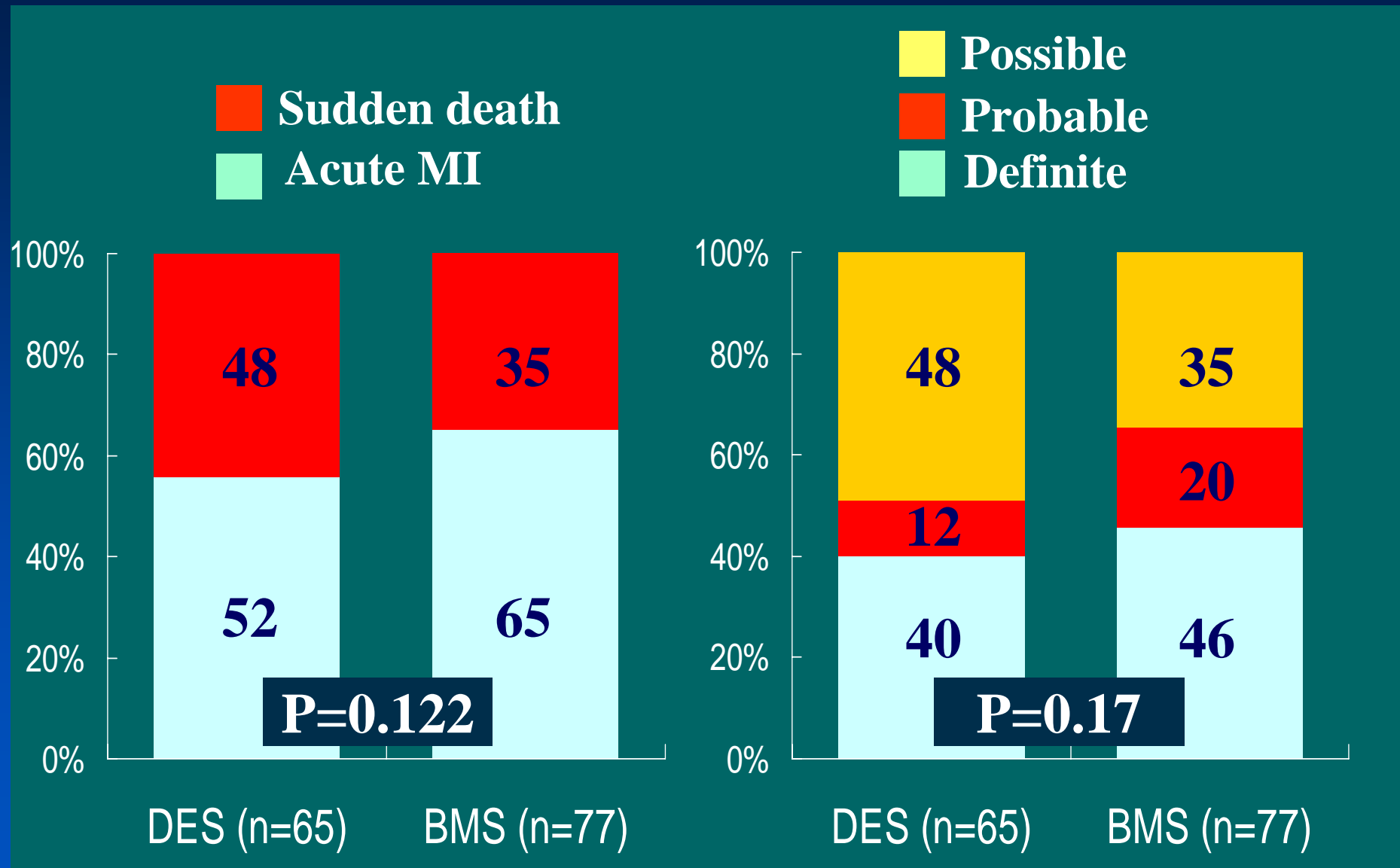
# Survival-Free from MI (up to 3 years)



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



# Presentation of ST (any ARC)

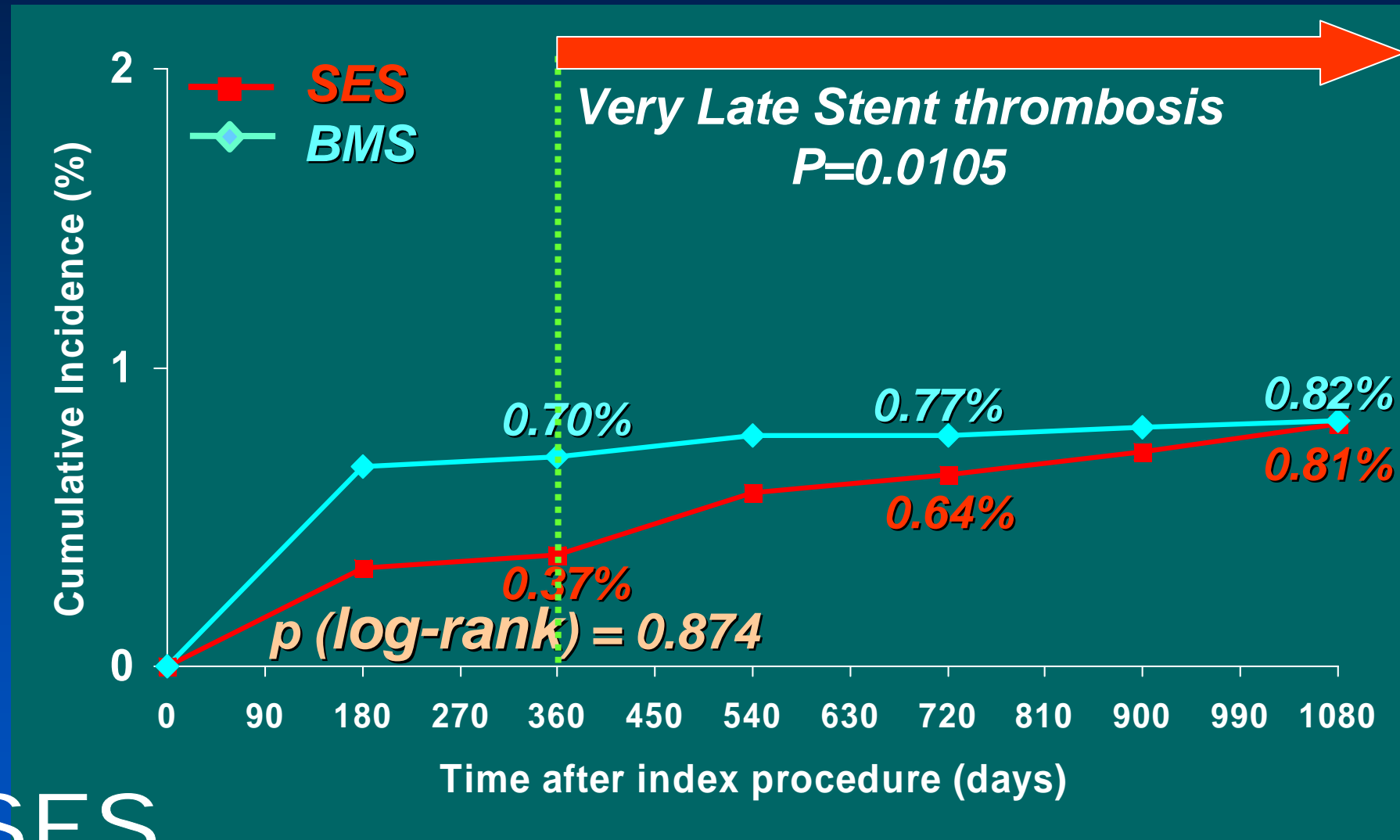




# SES

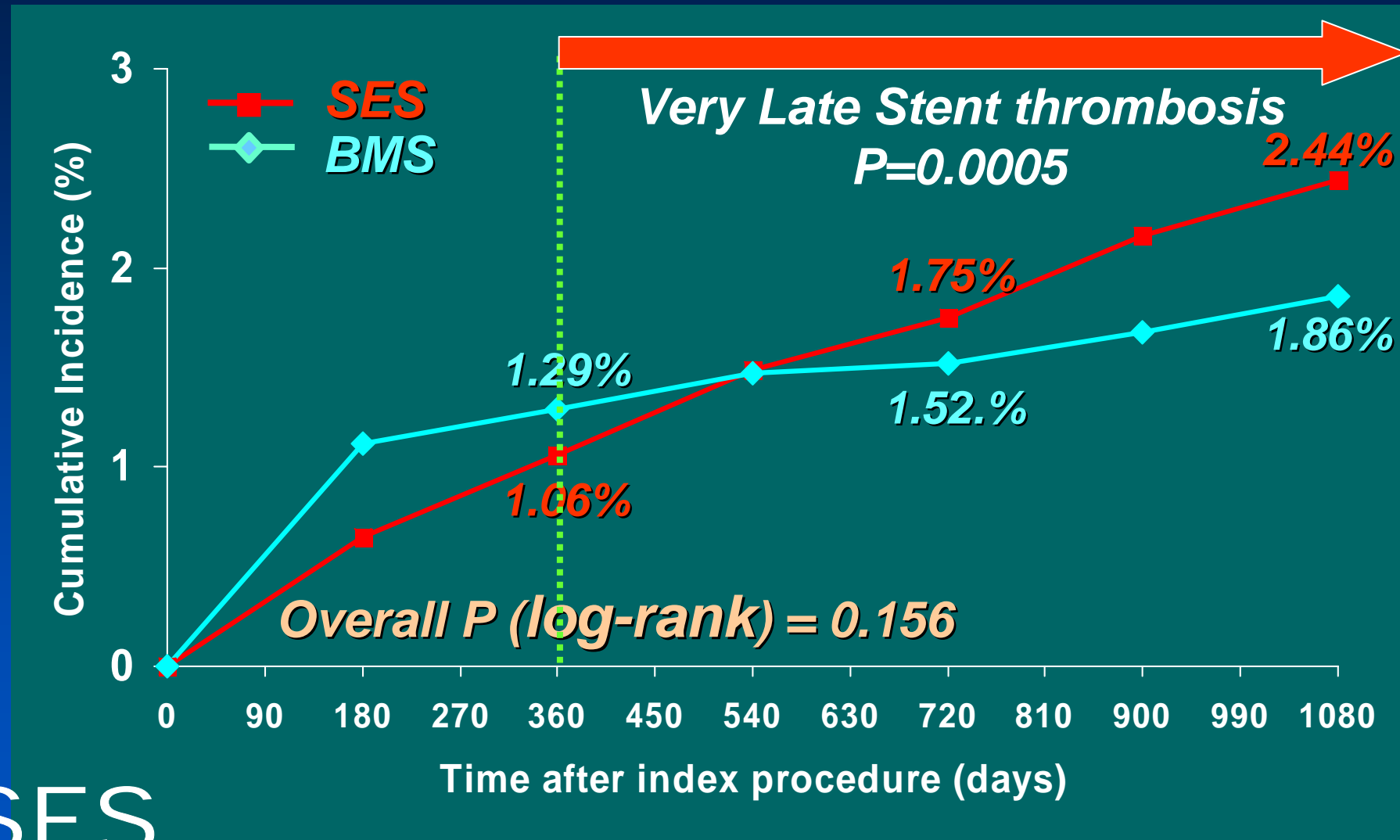


# Incidence of ST (ARC: Definite) upto 3 years



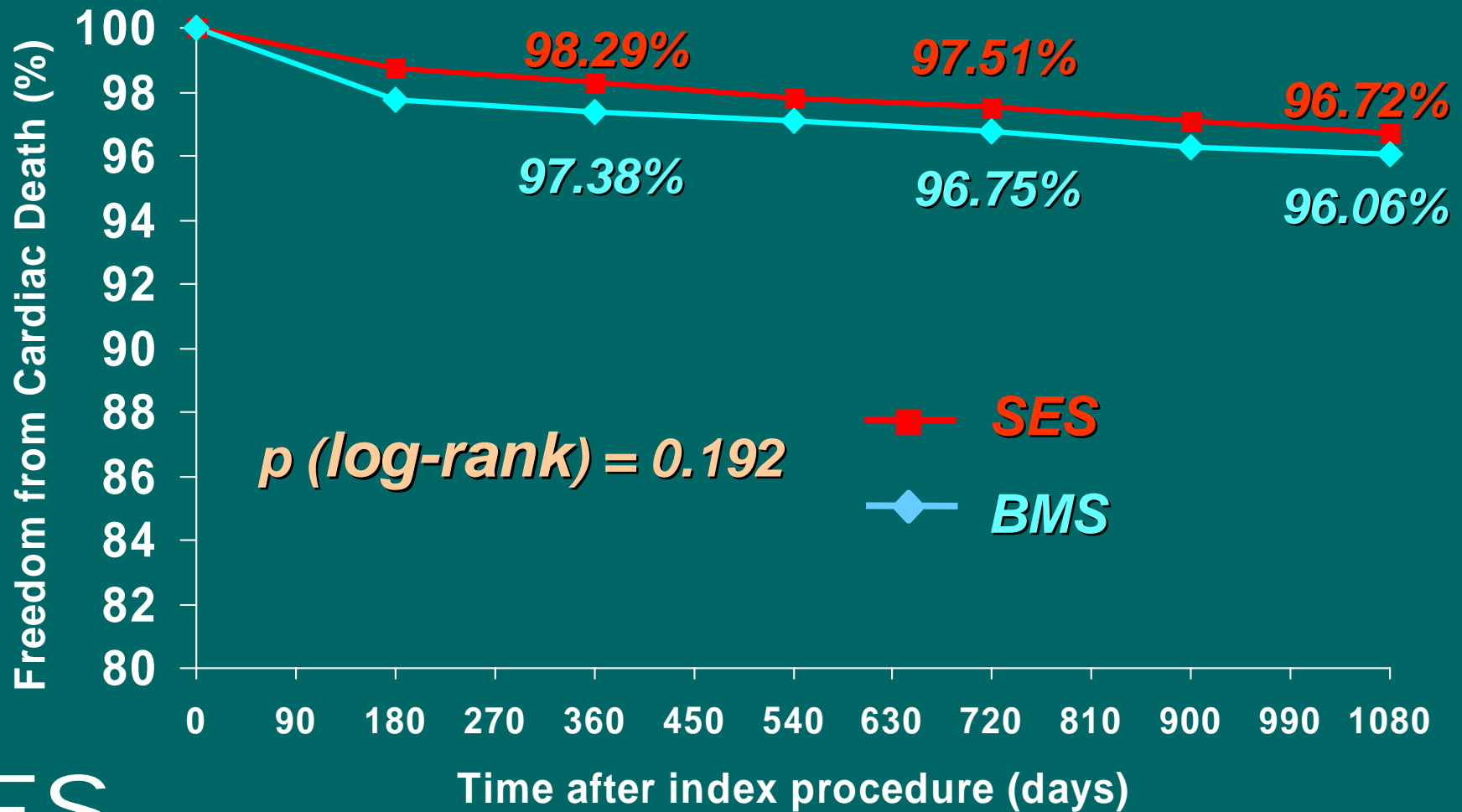
SES

# Incidence of ST (Any ARC Criteria) upto 3 years



SES

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

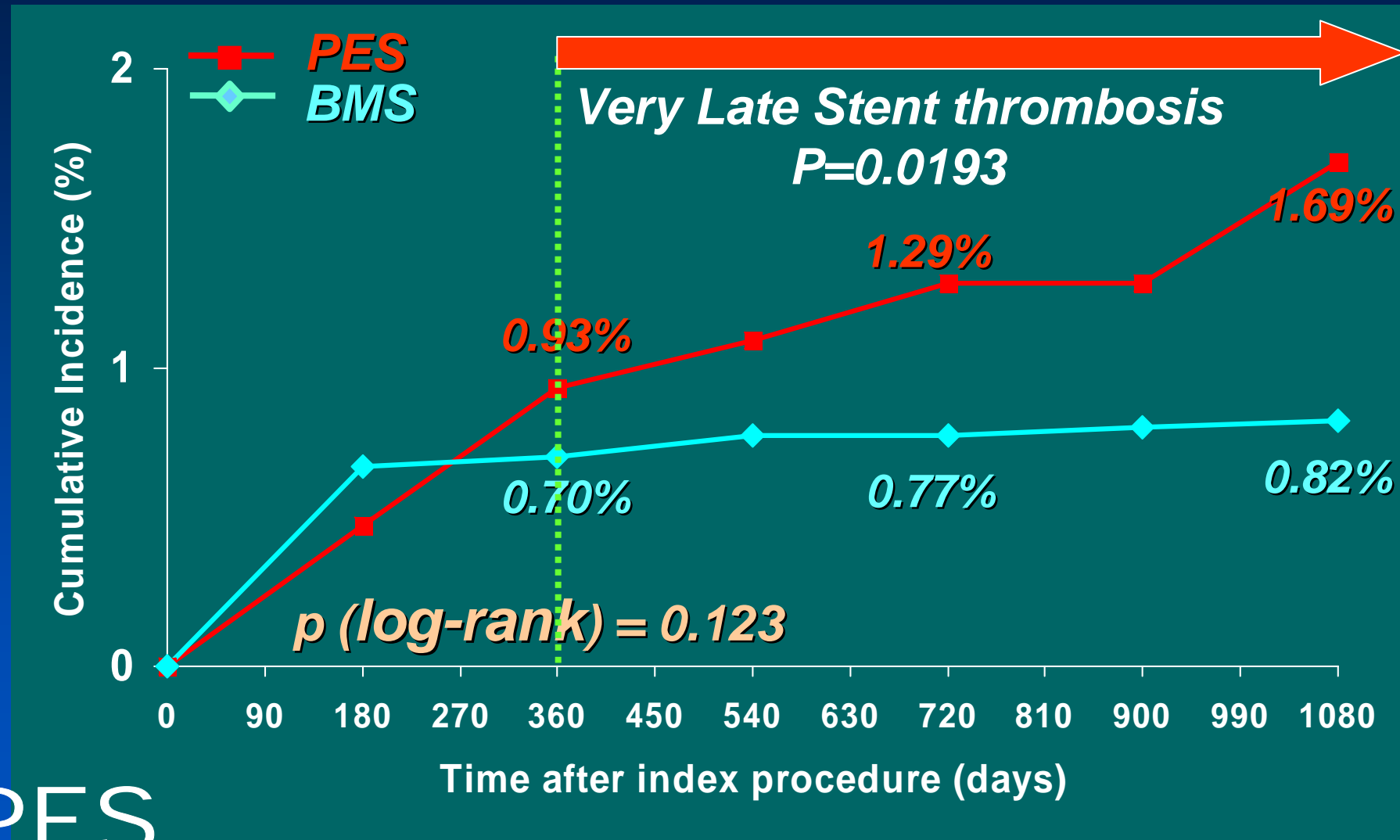


SES

# PES

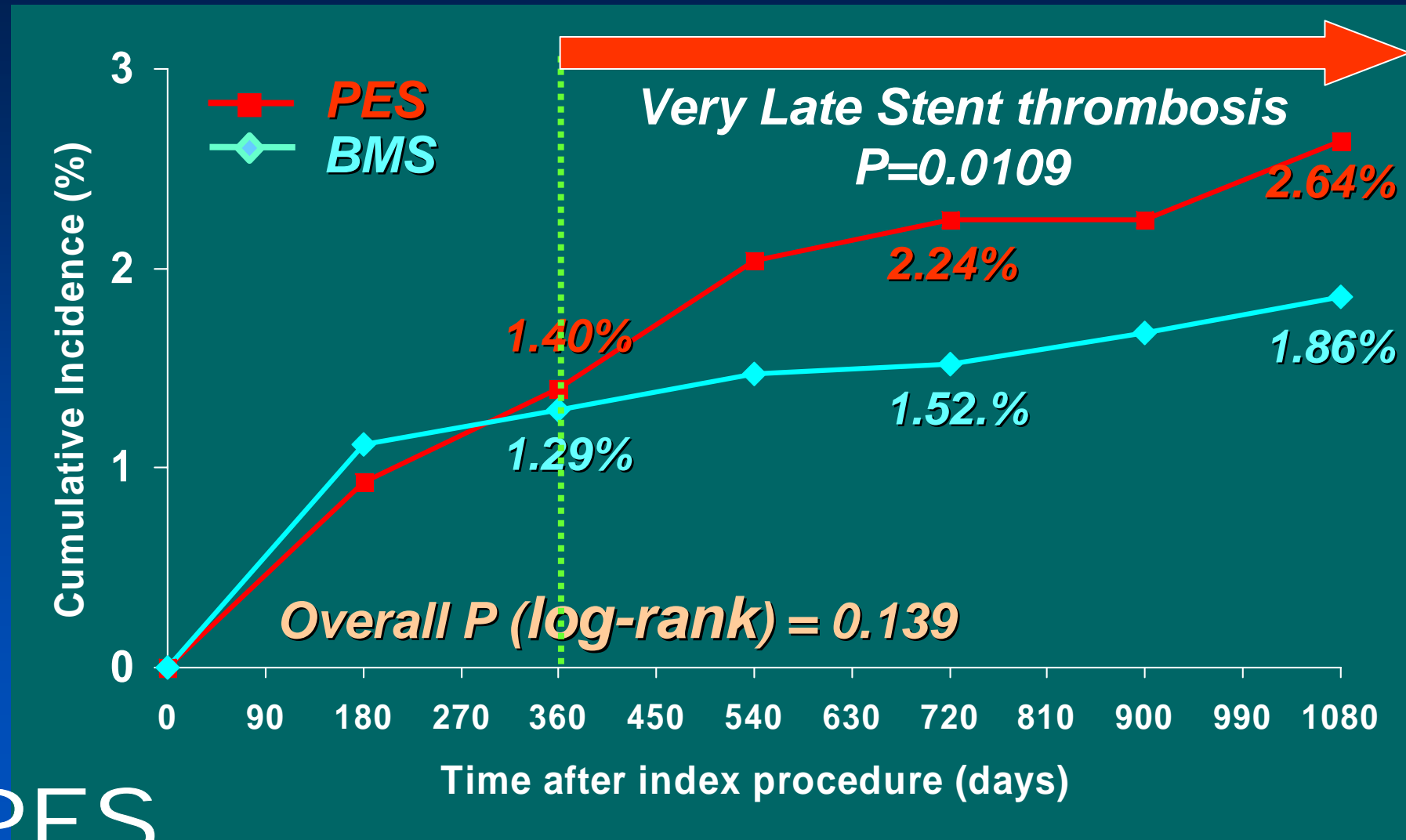


# Incidence of ST (ARC: Definite) upto 3 years



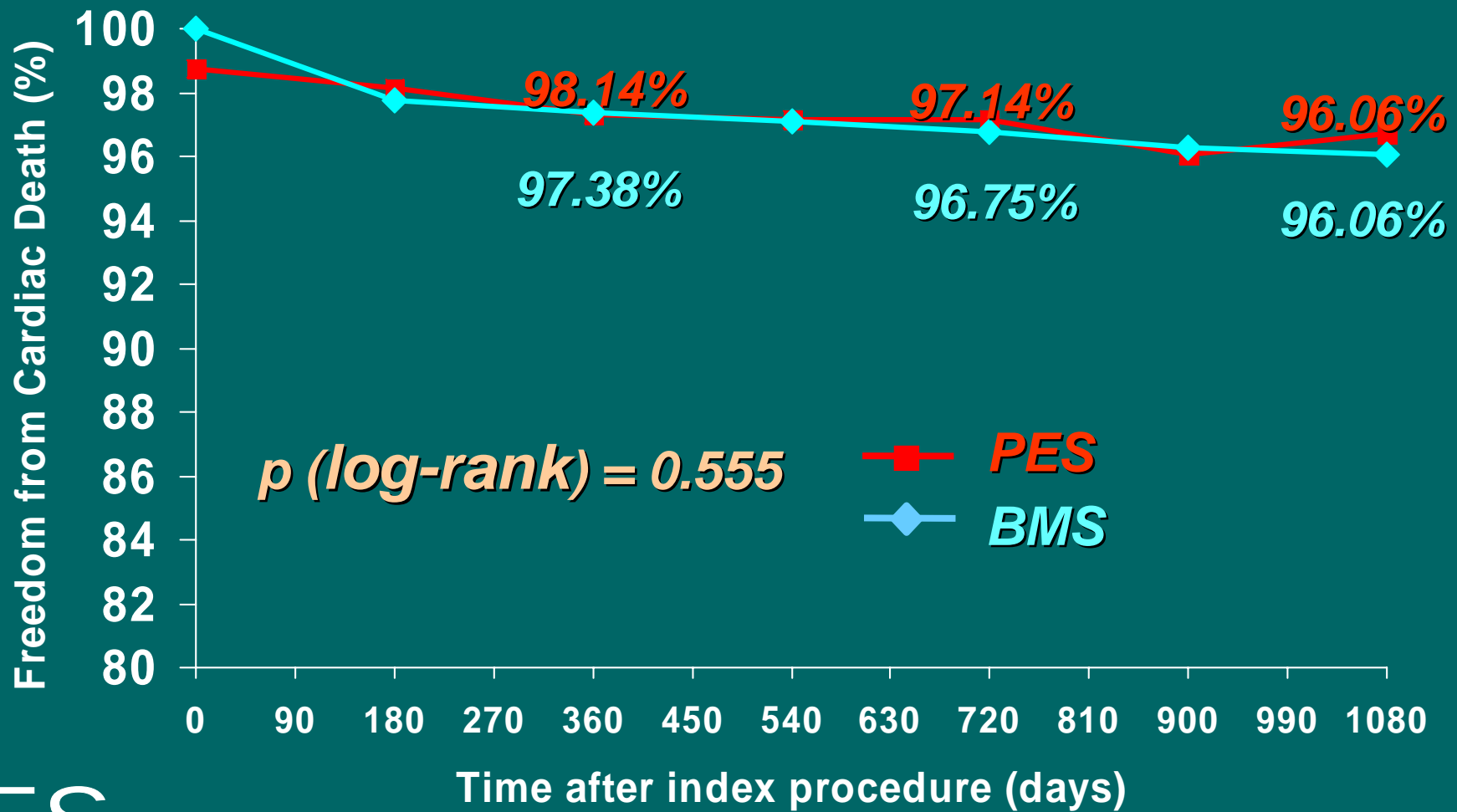
PES

# Incidence of ST (Any ARC Criteria) upto 3 years



PES

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

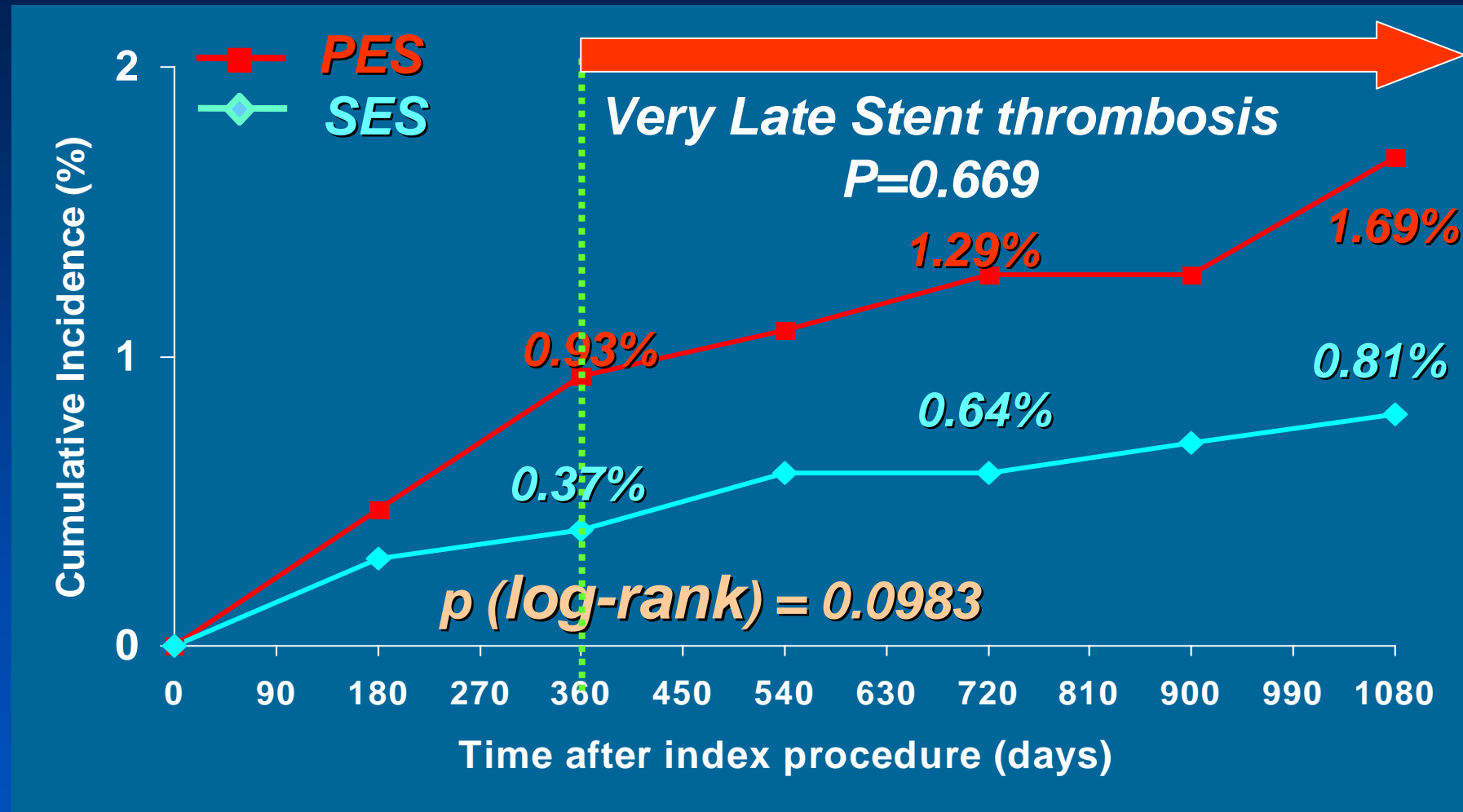


PES



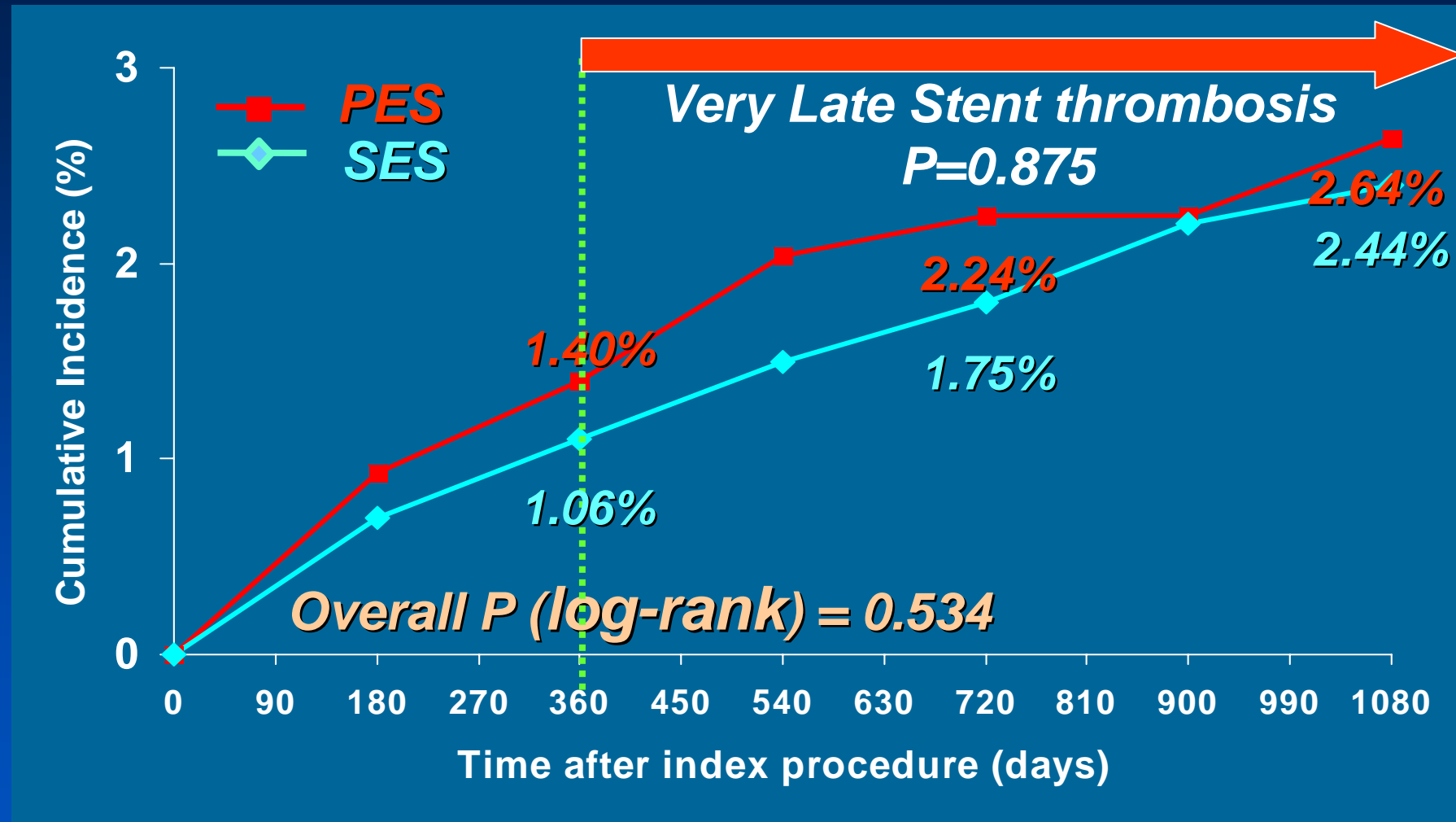
# SES vs. PES

# Incidence of ST (ARC: Definite) upto 3 Years



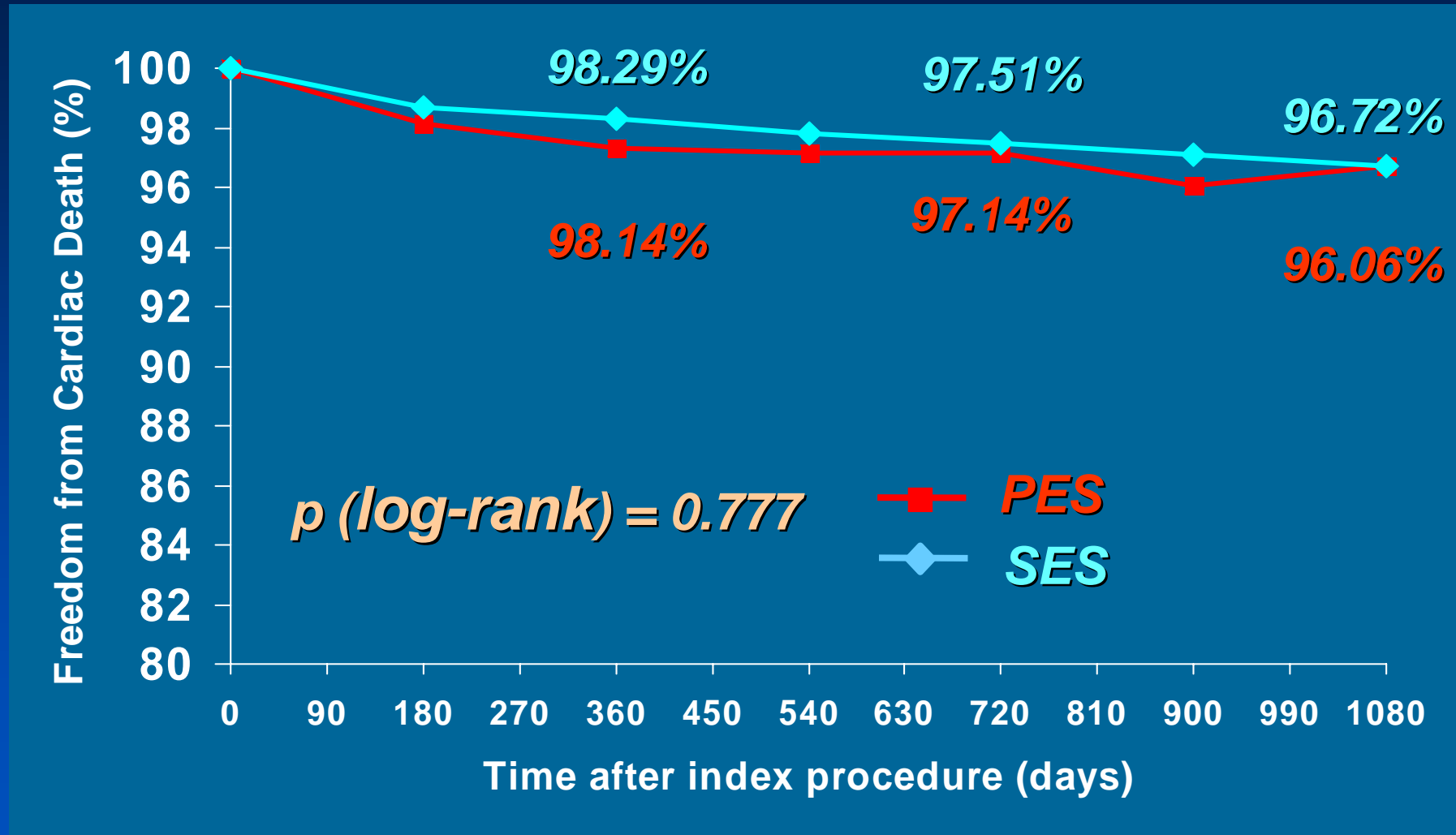
SES vs PES

# Incidence of ST (Any ARC Criteria) upto 3 Years



SES vs PES

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



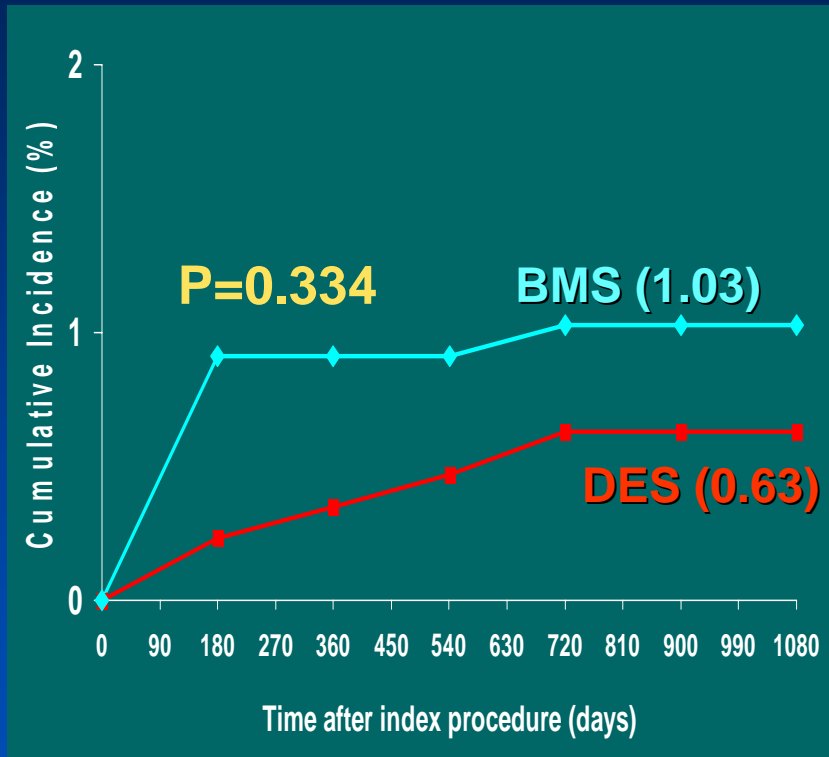
SES vs PES

# Diabetics

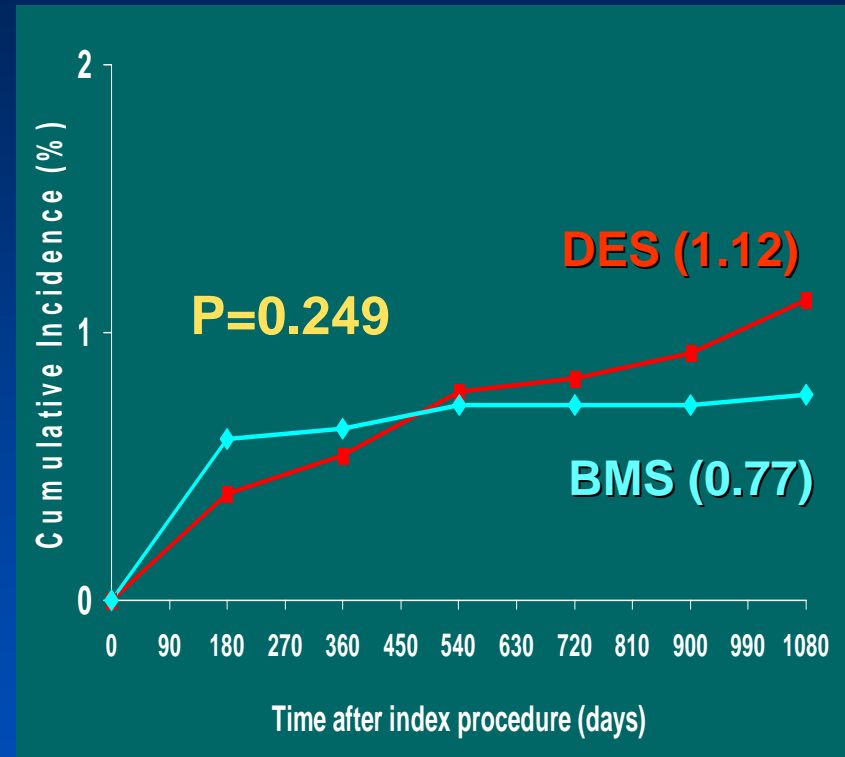


# Incidence of ST (ARC: Definite) up to 3 Years

## Patients with Diabetes



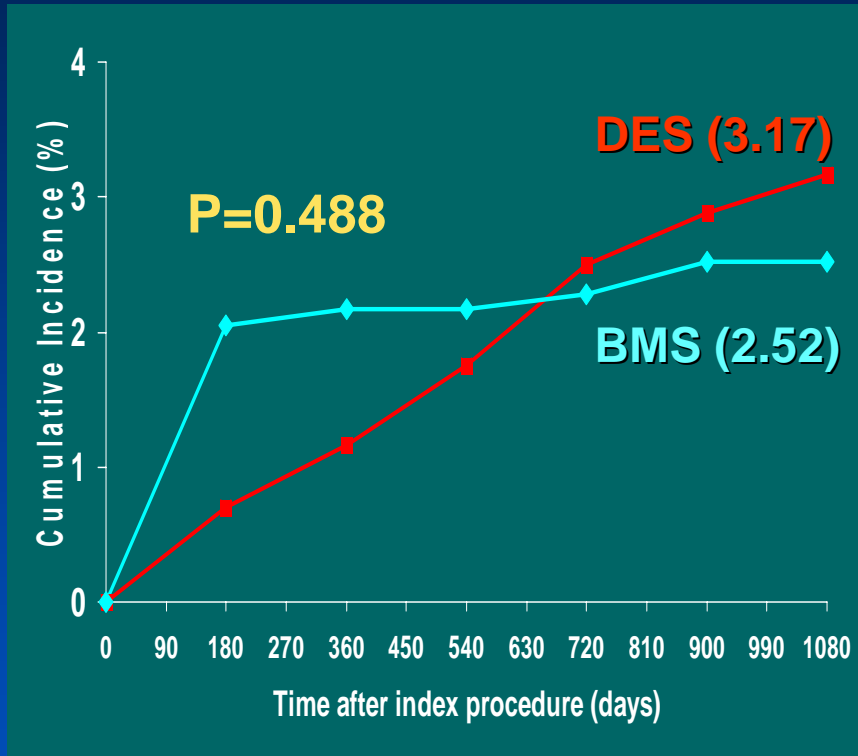
## Patients without Diabetes



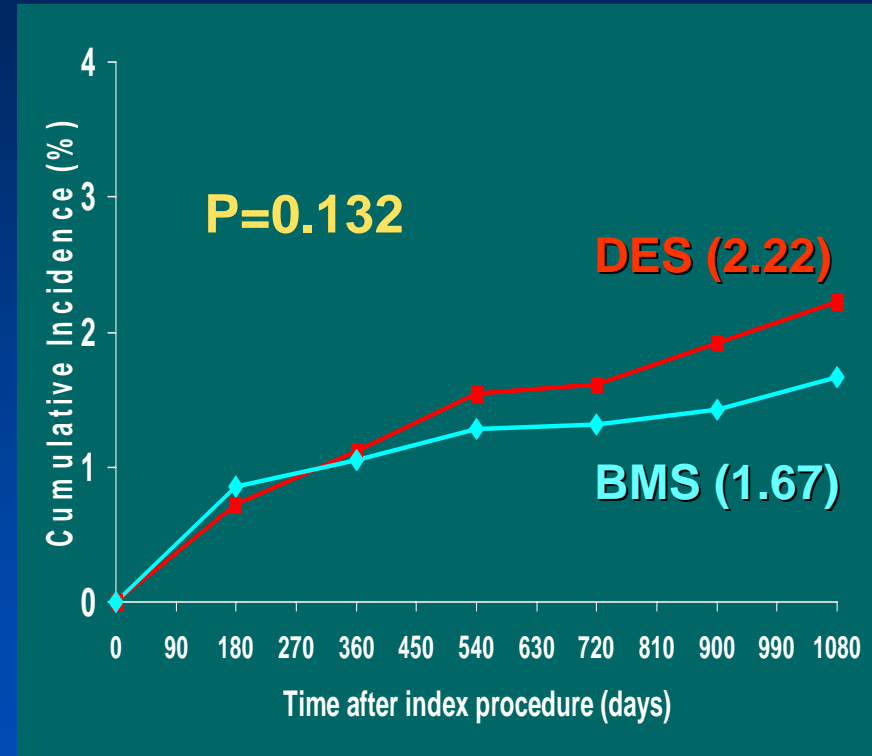
Interaction P value (DM \* Stent type) = 0.598

# Incidence of ST (Any ARC Criteria) upto 3 Years

## Patients with Diabetes



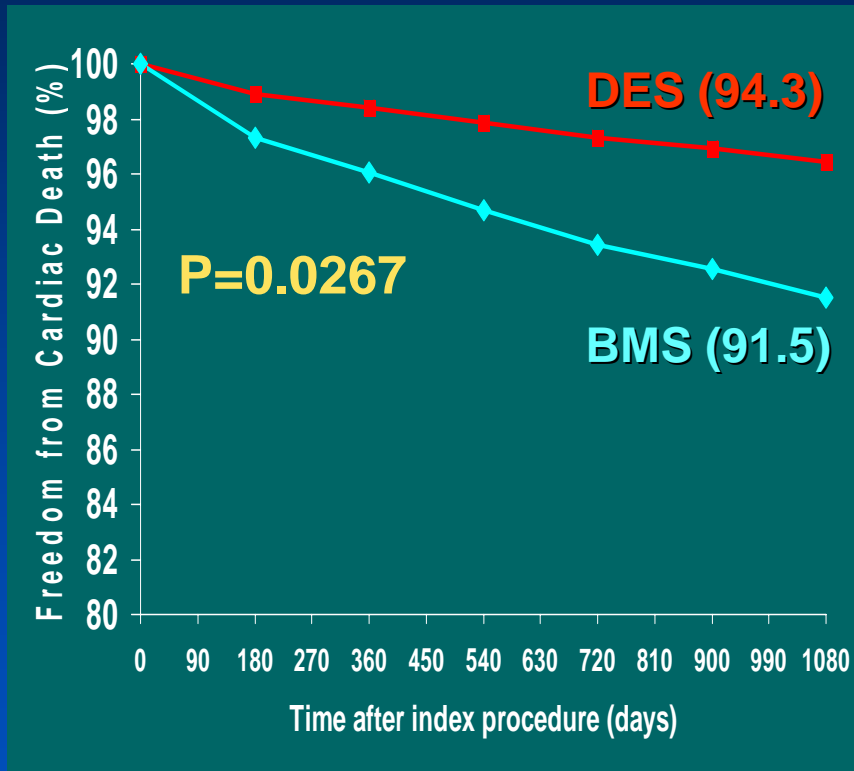
## Patients without Diabetes



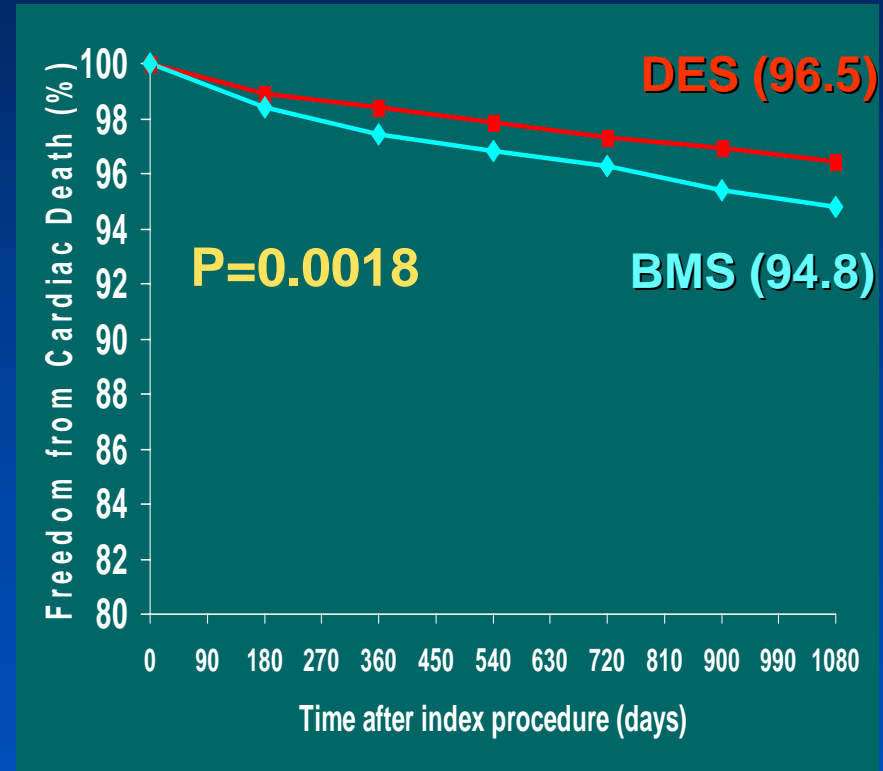
**Interaction P value (DM \* Stent type) = 0.103**

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

## Patients with Diabetes



## Patients without Diabetes

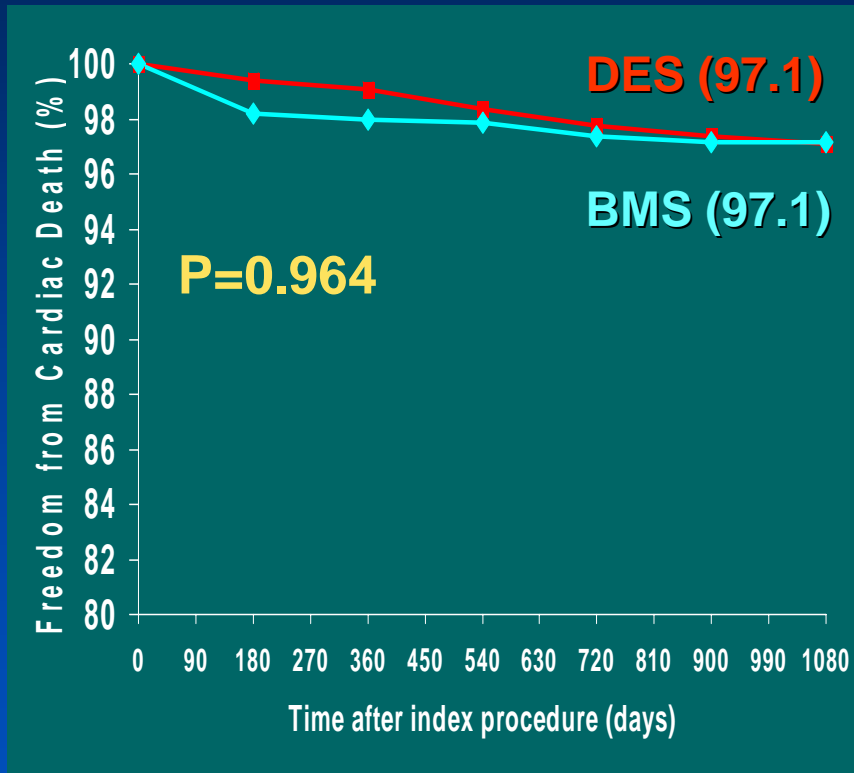


Interaction P value (DM \* Stent type) = 0.0001

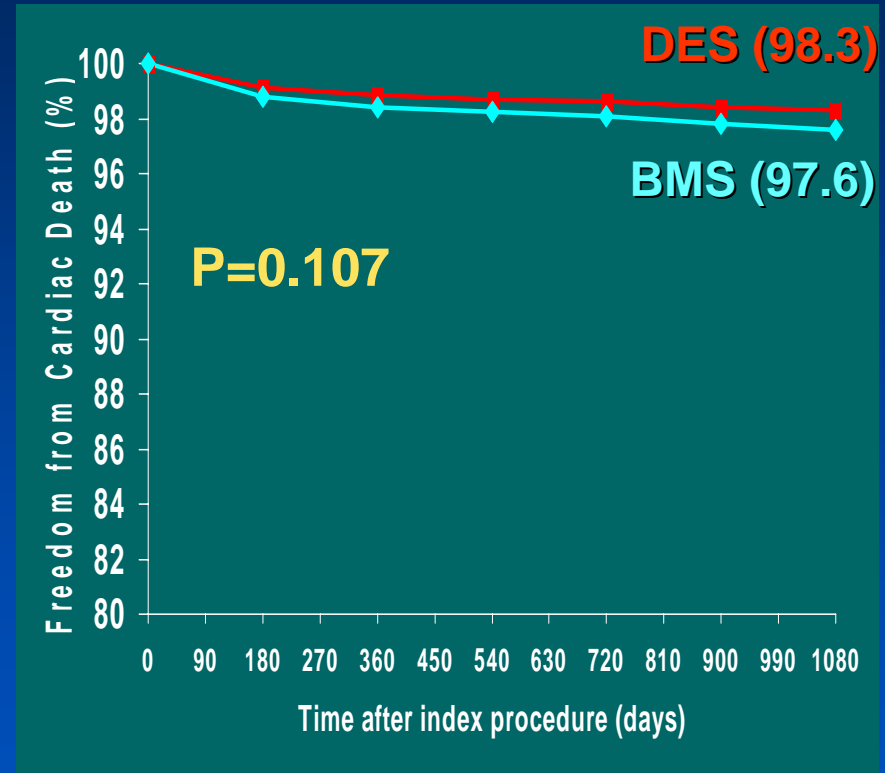


# Survival-Free from Cardiac Death up to 3 years

## Patients with Diabetes

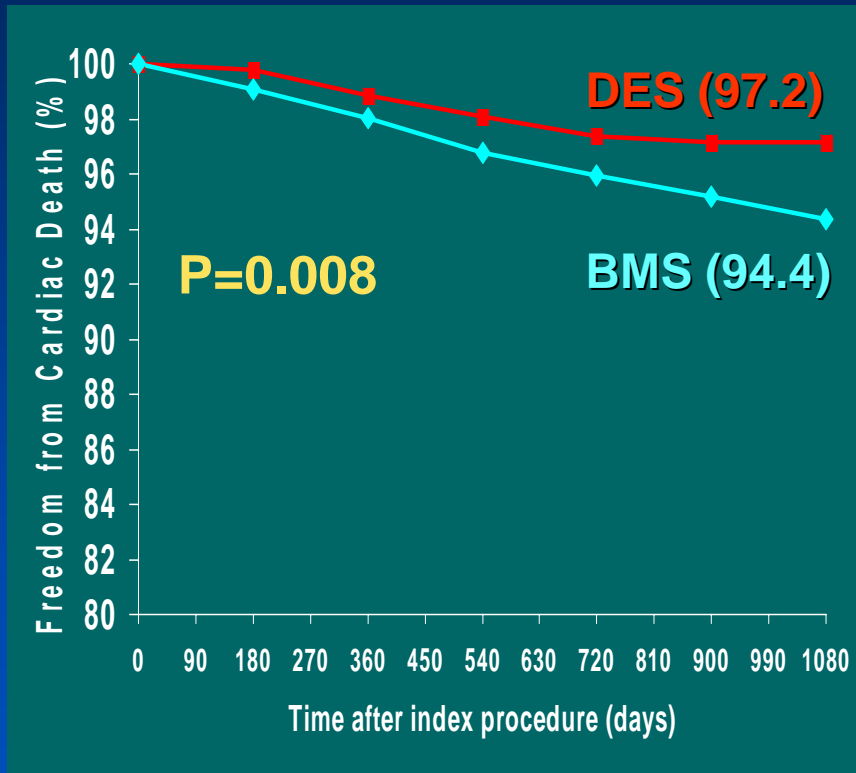


## Patients without Diabetes

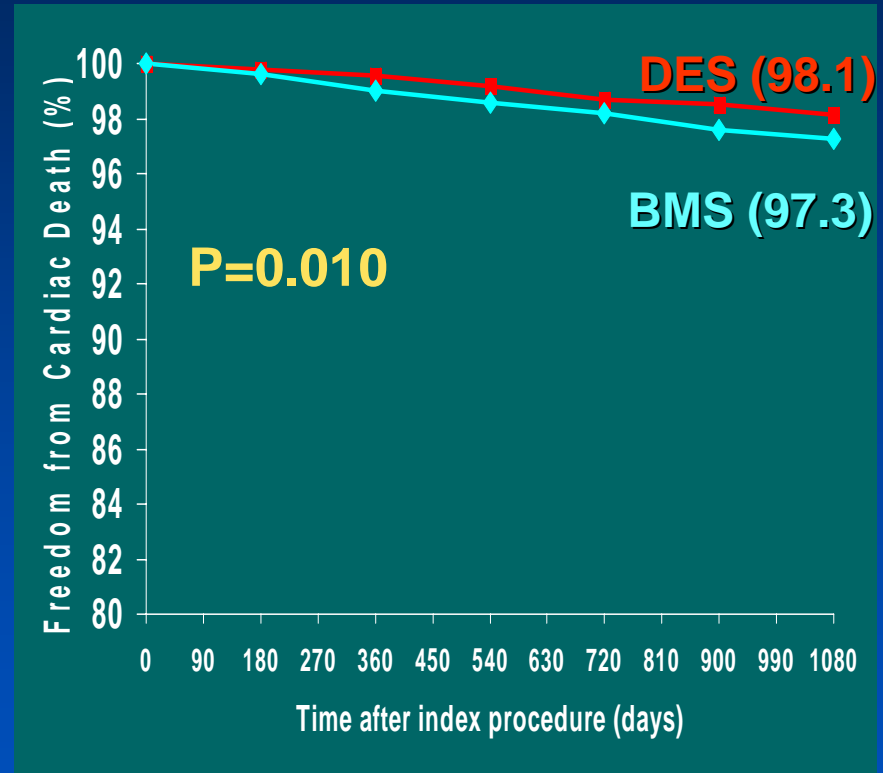


# Survival-Free from Non-Cardiac Death up to 3 years

## Patients with Diabetes

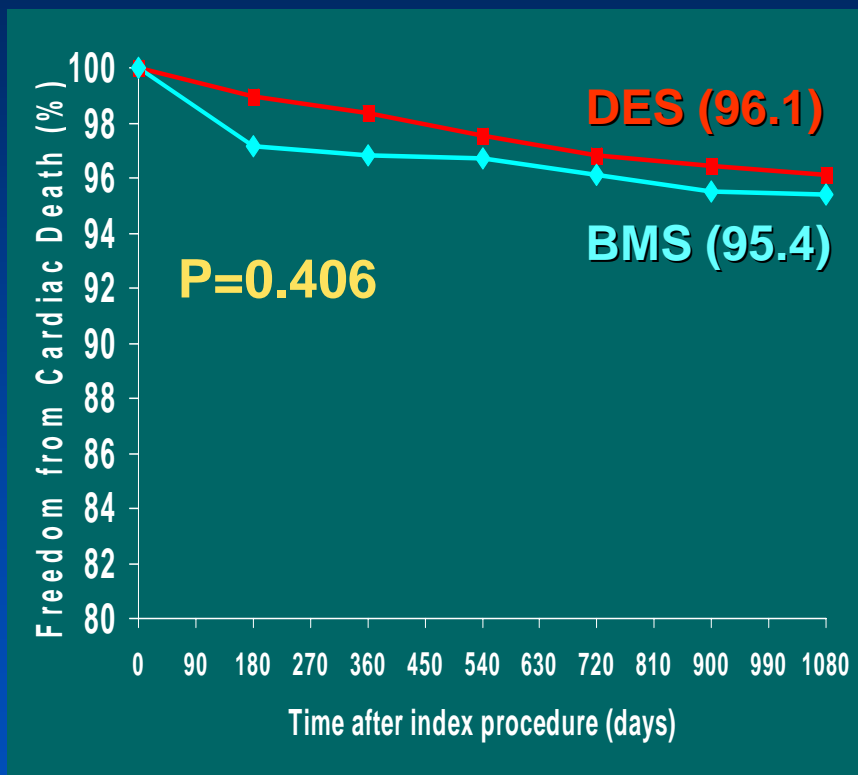


## Patients without Diabetes

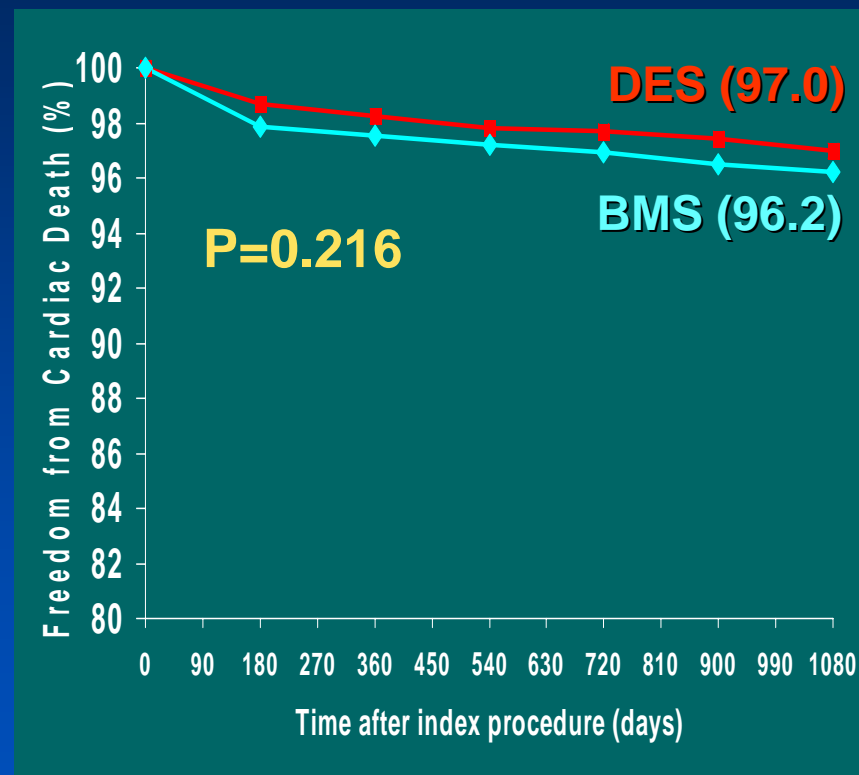


# Survival-Free from Cardiac Death + MI up to 3 years

## Patients with Diabetes



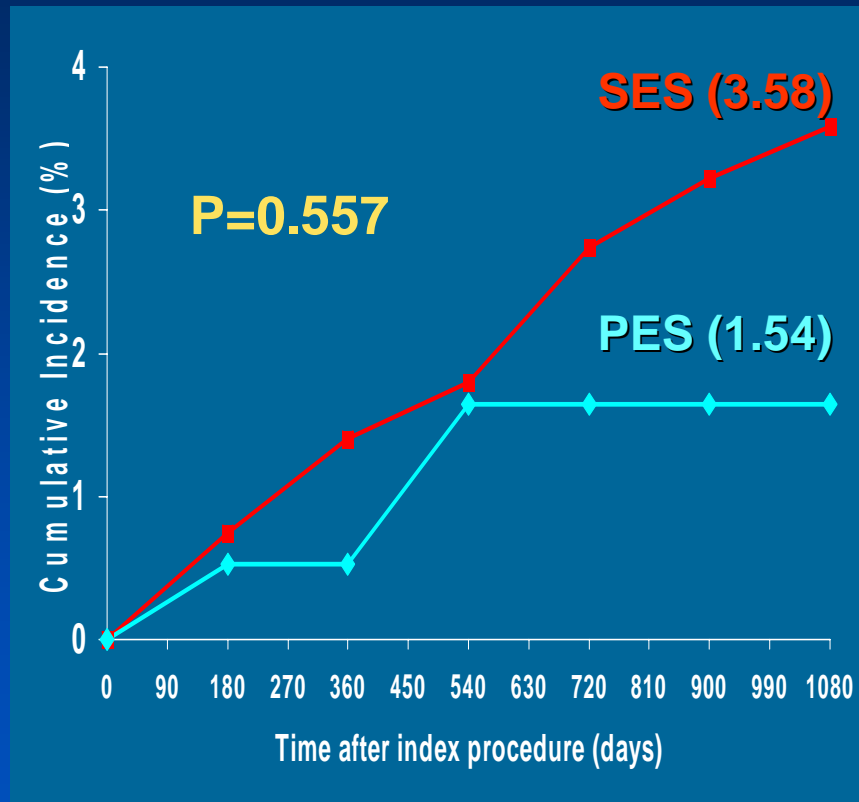
## Patients without Diabetes



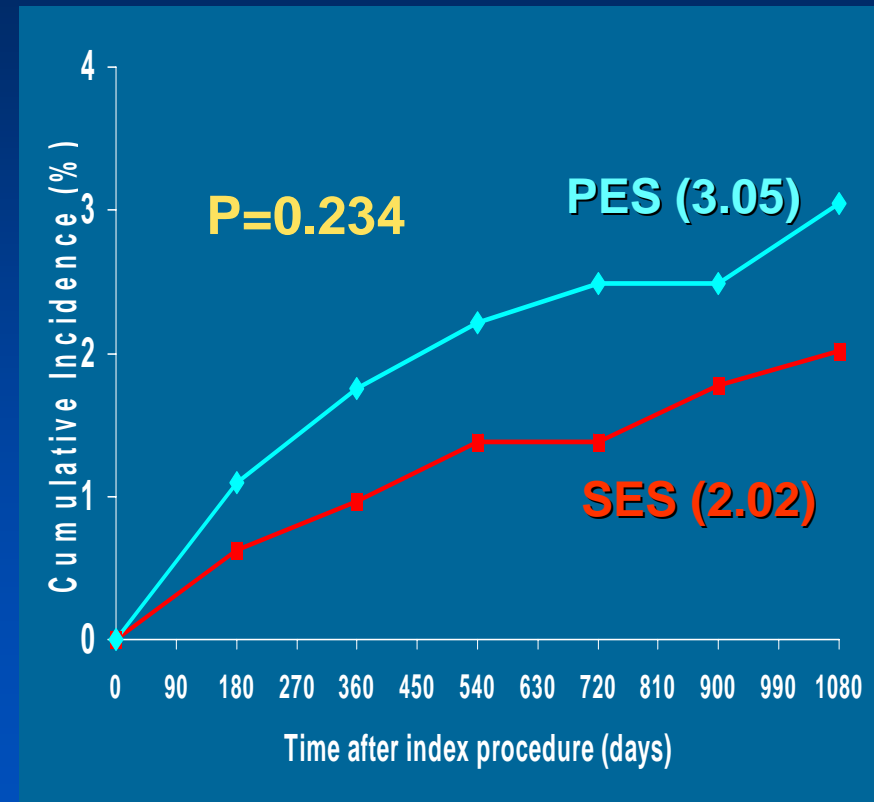
Interaction P value (DM \* Stent type) = 0.136

# Incidence of ST (Any ARC Criteria) upto 3 Years in the DES group

## Patients with Diabetes



## Patients without Diabetes



**SES vs PES**

# Predictors of DES Stent Thrombosis by Univariate and Multivariate Cox Proportional Hazards Analysis

# 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 $\geq$ 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

# Multivariate Analysis for ST (Definite)

	HR	95% CI	<i>p</i> -value
Age	0.92	0.87-0.96	0.001

# 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 $\geq$ 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



# Multivariate Analysis for ST (Any Criteria)

	HR	95% CI	<i>p</i> -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

# 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 $\geq$ 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

# Multivariate Analysis for Cardiac death or MI

	HR	95% CI	<i>p</i> -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

# Conclusions

Pooled Analysis  
from AMC Registry Data 2007

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- There was significant paradigm shift of practice toward more complex patient and lesion subsets in the era of DES.
- Stent thrombosis after 1 year was more common with both SES and PES than with BMS.
- There were no significant differences in the cumulative rates of cardiac death or MI up to 3 years.

# Conclusions

Pooled Analysis  
from AMC Registry Data 2007

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- In diabetic patients, there was higher all-cause mortality of BMS, however, no differences in cardiac death or MI between DES and BMS.
- There was no difference between the two DES (SES and PES) in the rate of death or MI and stent thrombosis upto 3 year follow-up.
- Absence of Clopidogrel was not independent predictor in occurrence of stent thrombosis (any ARC criteria).

# Late Stent Thrombosis Is it Truth or Myth ?

- Increase late stent thrombosis: Yes / No
- Higher Mortality : No
- Randomized Trial would be almost impossible in the complex patients and lesion subsets ?
- How long should we use antiplatelet therapy ?
- We need a Smart DES.