

Late Coronary Stent Thrombosis of DES in Routine Clinical Practice

- Data from a Large Two-Institutional Cohort Study-

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(Lancet in-press)

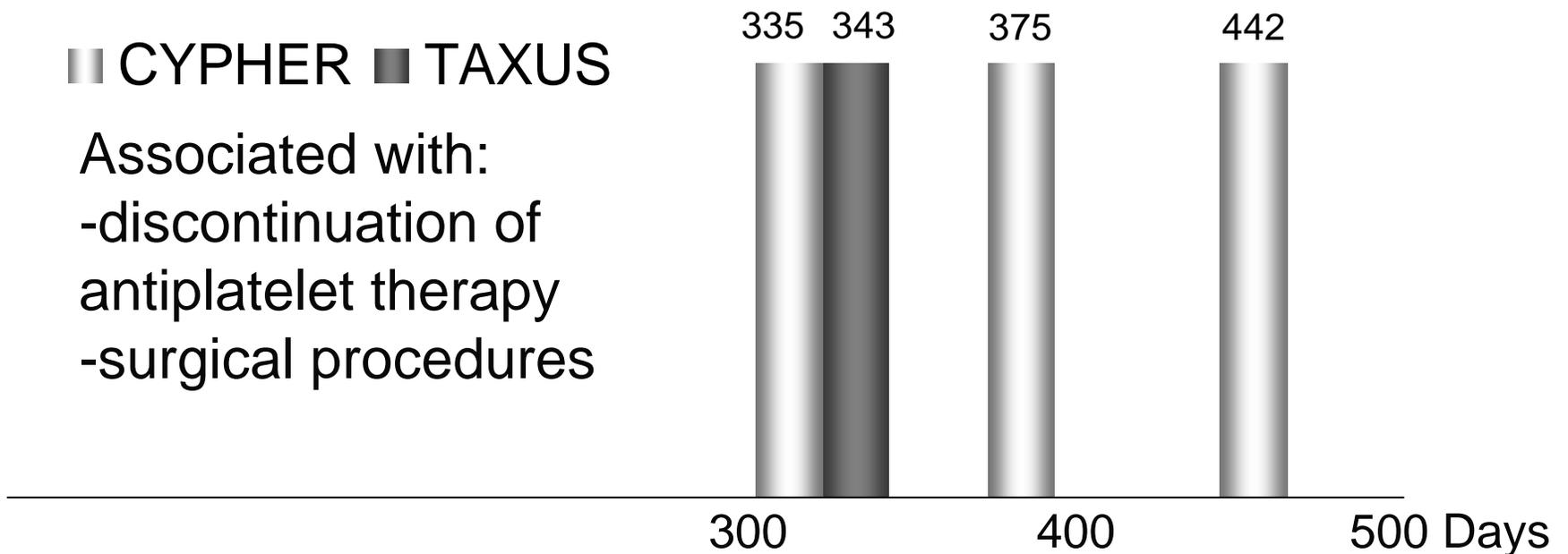
No conflict of interest to declare

Late Stent Thrombosis

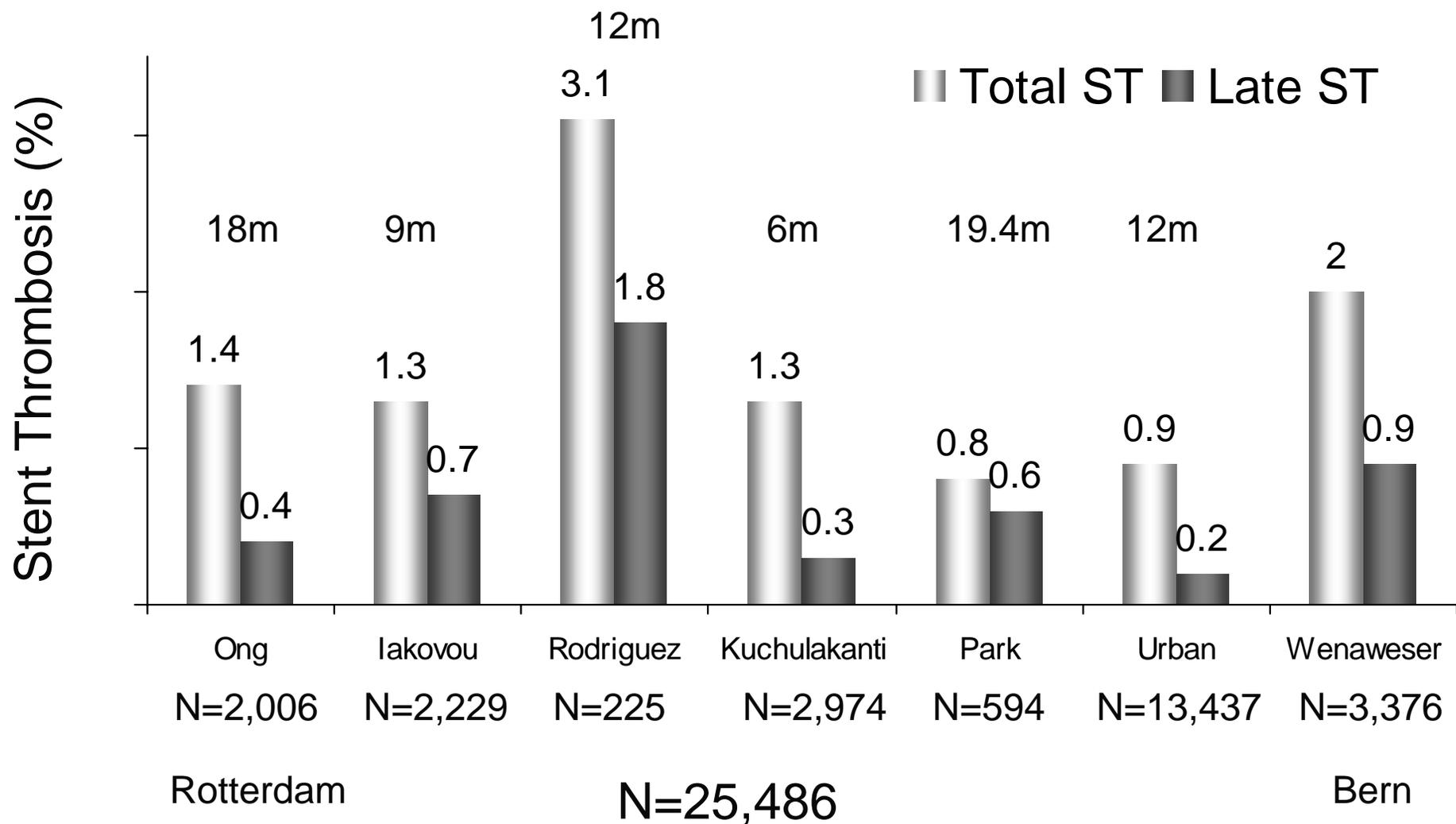
McFadden E et al. *Lancet* 2004;364:1519

Late thrombosis in drug-eluting coronary stents after discontinuation of antiplatelet therapy

Eugène P McFadden, Eugenio Stabile, Evelyn Regar, Edouard Cheneau, Andrew T L Ong, Timothy Kinnaird, William O Suddath, Neil J Weissman, Rebecca Torguson, Kenneth M Kent, August D Pichard, Lowell F Satler, Ron Waksman, Patrick W Serruys



Incidence of Late Stent Thrombosis Drug-Eluting Stents



Definition of Stent Thrombosis

Only patients with angiographic ST were included:

Angiographic definition

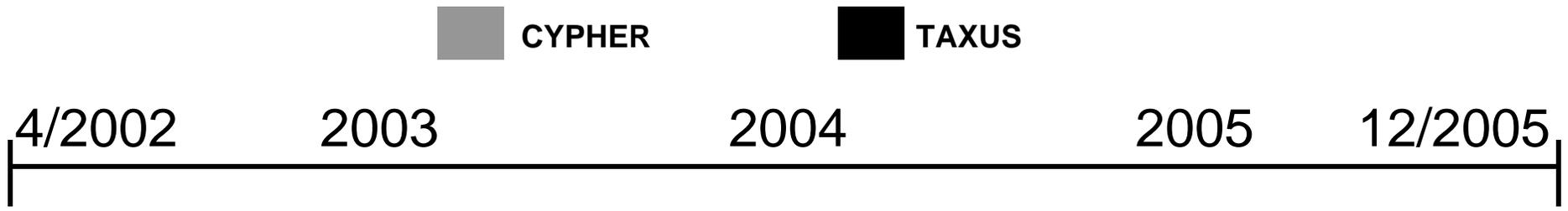
- Angiographically proven partial or total thrombotic occlusion within the peri-stent region
 - a. TIMI flow 0 with occlusion originating in the peri-stent region
 - b. TIMI flow 1,2 or 3 in the presence of a thrombus originating in the peri-stent region

AND at least ONE of the following, additional criteria:

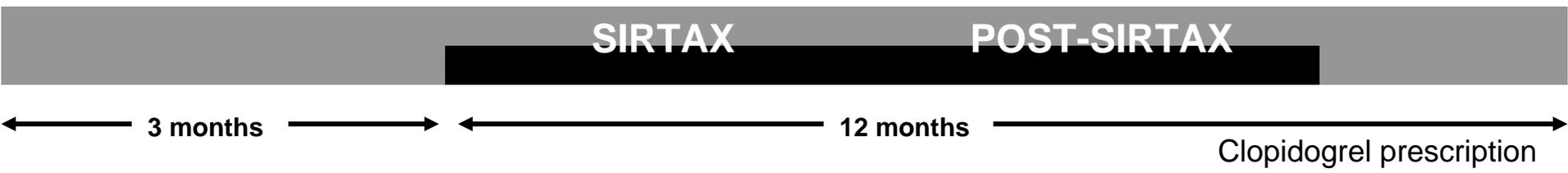
- Acute ischemic symptoms
- Ischemic ECG changes
- Elevated cardiac biomarkers

Early stent thrombosis = 0 - 30 days after stent implantation

Late stent thrombosis = > 30 days after stent implantation



BERN



ROTTERDAM

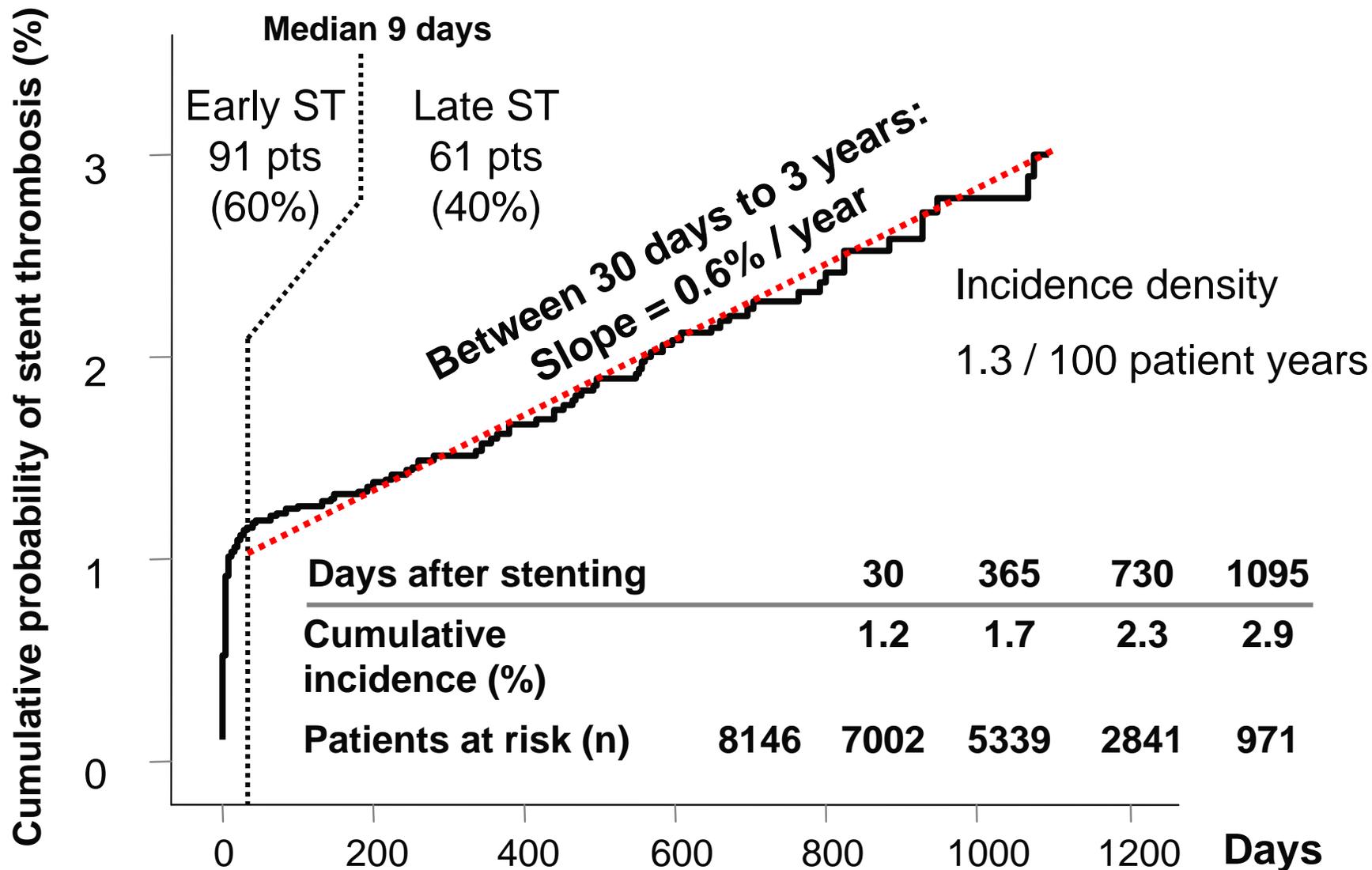


Baseline Characteristics Overall Population

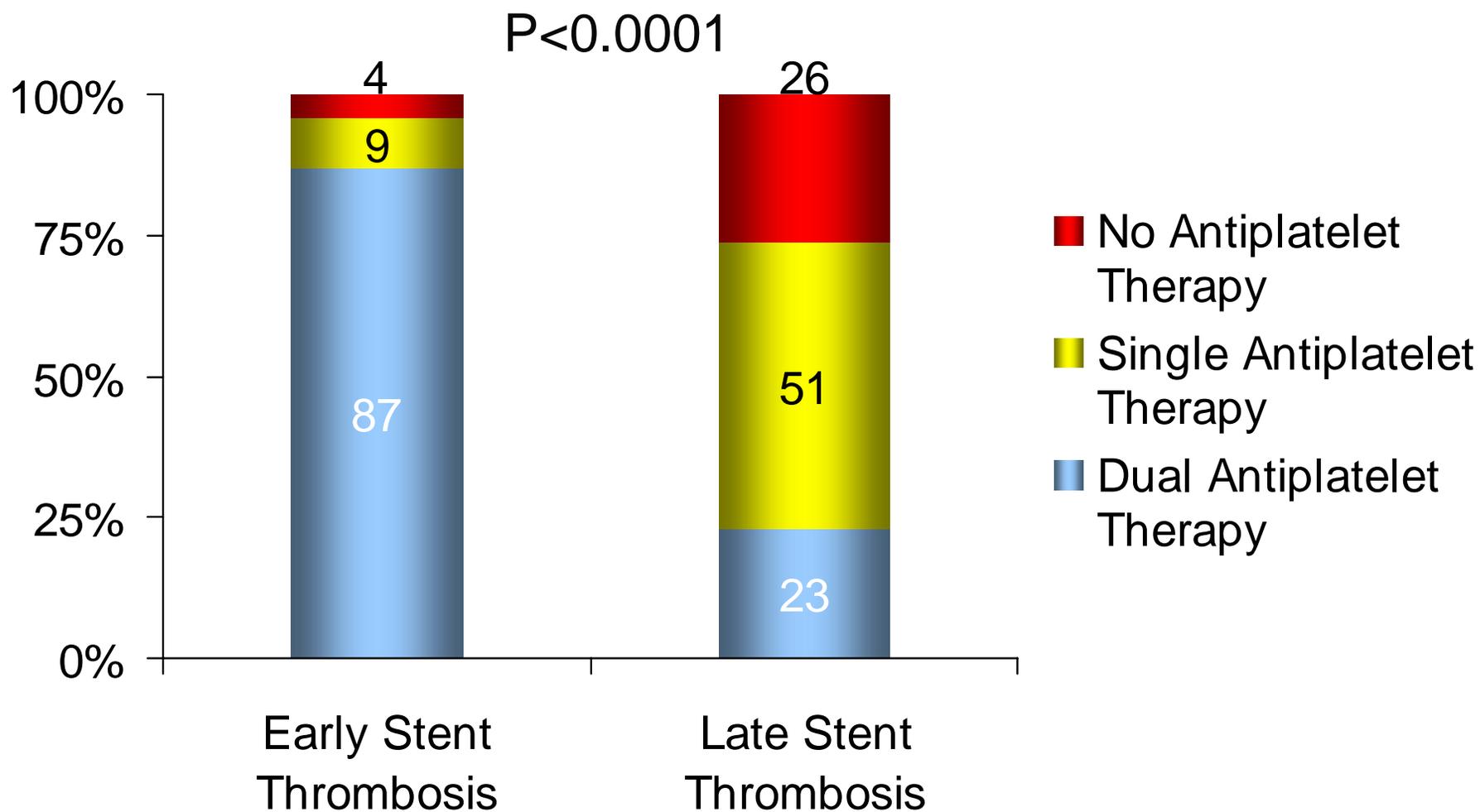
8,146 consecutive DES patients enrolled between 04/2002 and 12/2005

	Stent Thrombosis (N=152)	No Stent Thrombosis (N=7994)	<i>P</i>
Age	60±12	63±12	0.014
Male gender	76%	74%	0.78
Hypertension	41%	46%	0.29
Current smoking	38%	37%	0.87
Family history of CHD	29%	28%	0.79
Dyslipidemia	49%	50%	0.74
Diabetes	19%	16%	0.32
Left ventricular EF	52±12%	55±12%	0.07
Renal impairment	6%	4%	1.00
ACS at time of index procedure	71%	59%	0.020
Bifurcation treatment	28%	16%	0.003
Total stent length/patient	42.3±34mm	35.8±25mm	0.002
Number of stents per patient	2.35±1.7	1.95±1.2	<0.001
Average stent diameter per patient	2.83±0.4	2.93±1.4	0.48

Angiographic DES Stent Thrombosis: Bern - Rotterdam Cohort Study: N = 8146 pts (Lancet in-press)



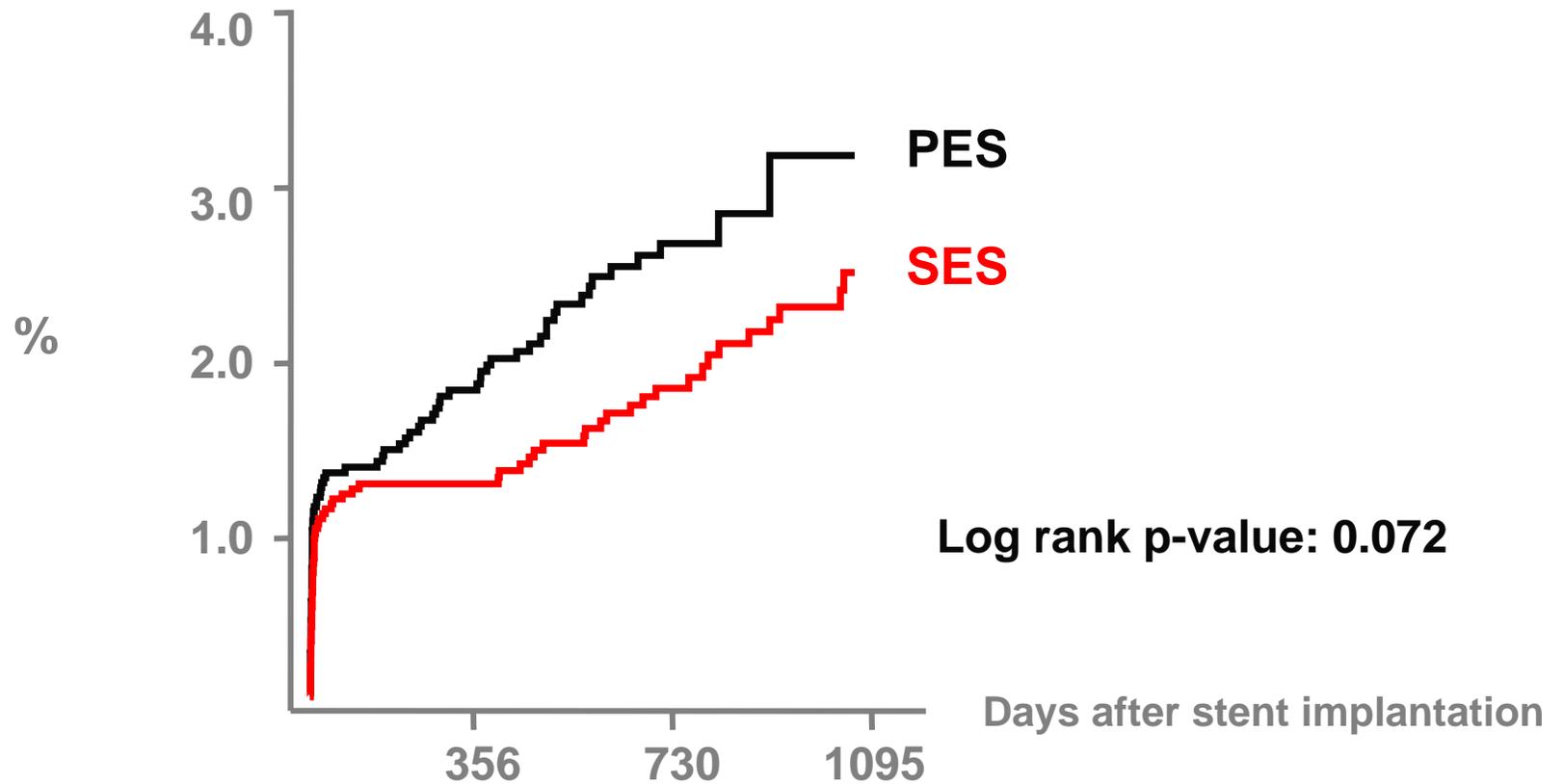
Antiplatelet Treatment at Time of Stent Thrombosis



Baseline Characteristics SES vs. PES

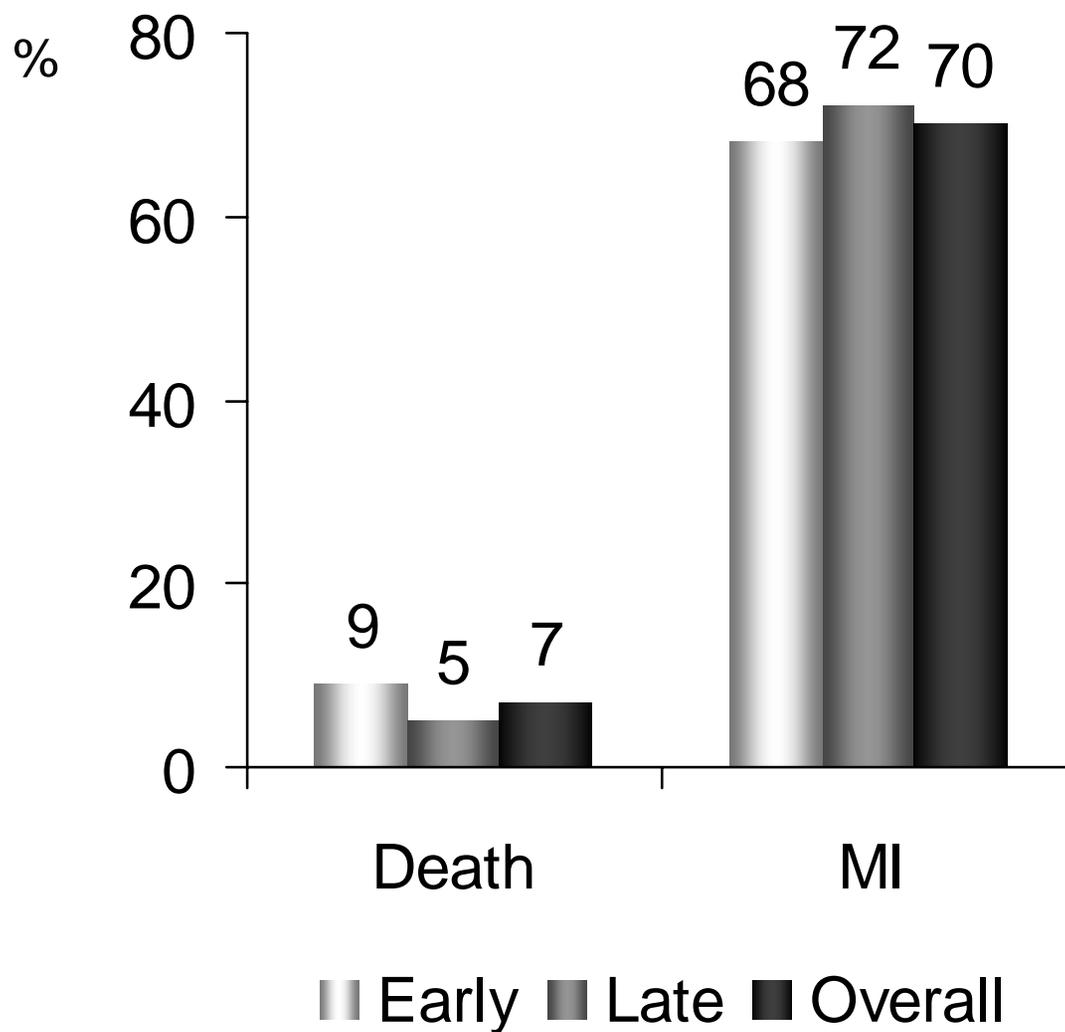
	SES		PES	P
	(N=3823)		(N=4323)	
Age	63±12		63±12	0.31
Male gender	75%		74%	0.53
Hypertension	51%	>	41%	<0.0001
Current smoking	45%	>	29%	<0.0001
Dyslipidemia	55%	>	46%	<0.0001
Diabetes	18%	>	14%	<0.0001
Family history	29%	>	27%	0.036
Average stent diameter/patient	2.9±2.1mm		3.0±0.5mm	0.11
Total stent length/patient	33.6±22.6mm	<	38.0±27.4mm	<0.0001
Stents per patient	1.9±1.1	<	2.0±1.3	<0.0001
Renal impairment	4%		4%	0.30
Left ventricular EF	54±12%		55±11%	0.01
ACS at time of presentation	54%	<	61%	<0.0001
Bifurcation treatment	18%	>	15%	0.014
Duration of clopidogrel prescription (m)	4.7	<	6.4	<0.0001

Cumulative Incidence of Stent Thrombosis



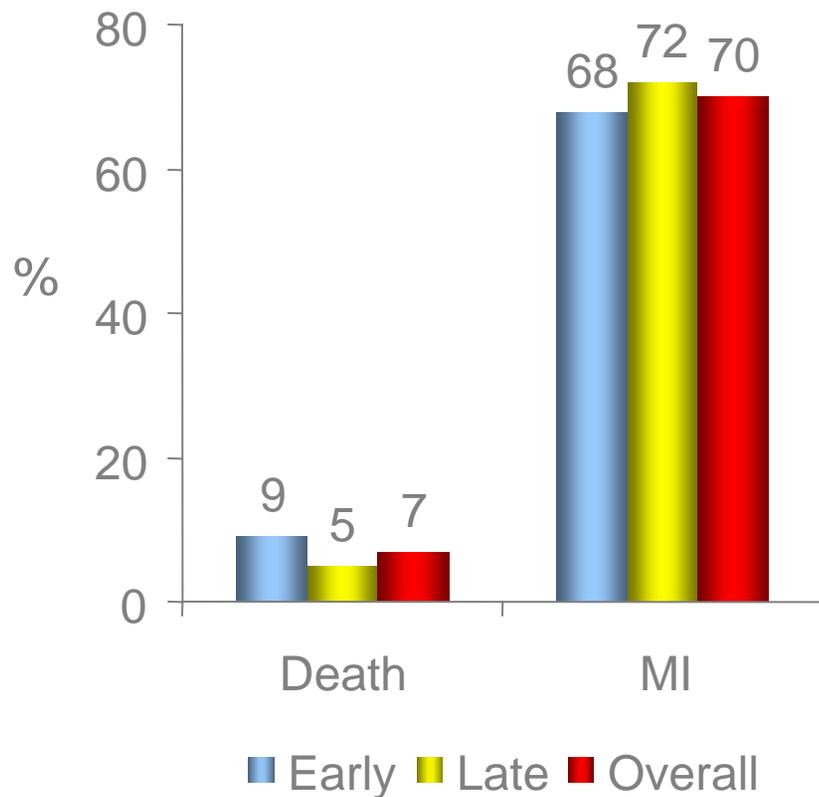
Days after PCI	9	30	365	730	1095
Incidence-SES (%)	1.0	1.1	1.3	1.9	2.5
Incidence-PES (%)	1.2	1.3	2.0	2.7	3.2

In-hospital death and MI in stent thrombosis patients

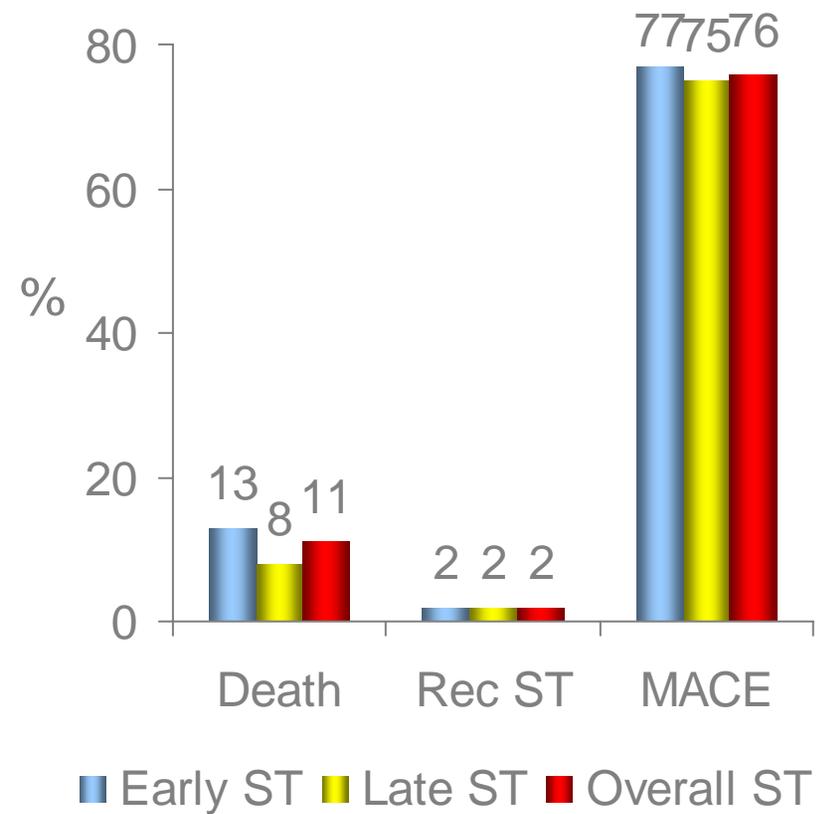


Clinical Outcome of ST Patients at 6 Months

In-Hospital MACE



6 Months MACE



	Bern		Rotterdam	
	Univariate	Multivariate	Univariate	Multivariate
	Hazard Ratio [95% CI]	Hazard Ratio [95% CI]	Hazard Ratio [95% CI]	Hazard Ratio [95% CI]
Overall stent thrombosis				
Age, year	0.99 [0.97 – 1.00]	0.98 [0.96 – 1.01]	0.98 [0.96 – 1.00]	0.97 [0.95 – 1.00]
Male gender	1.06 [0.63 – 1.79]	1.32 [0.65 – 2.66]	1.05 [0.62 – 1.75]	0.90 [0.51 – 1.58]
Family history	0.74 [0.44 – 1.25]	0.67 [0.35 – 1.28]	1.25 [0.77 – 2.02]	1.21 [0.74 – 2.15]
Diabetes	1.04 [0.58 – 1.85]	1.30 [0.67 – 2.51]	1.43 [0.81 – 2.53]	2.03 [1.07 – 3.83]
Hypertension	0.83 [0.54 – 1.30]	0.78 [0.45 – 1.34]	0.72 [0.44 – 1.19]	0.68 [0.38 – 1.21]
Smoking	1.05 [0.67 – 1.63]	0.87 [0.50 – 1.51]	0.89 [0.51 – 1.55]	0.78 [0.43 – 1.44]
Dyslipidemia	0.77 [0.50 – 1.20]	0.76 [0.44 – 1.30]	0.93 [0.58 – 1.47]	1.07 [0.63 – 1.82]
Left ventricular ejection fraction	0.98 [0.96 – 0.99]	*	‡	‡
Renal failure†	1.00 [0.24 – 4.10]	0.96 [0.23 – 3.99]	‡	‡
Acute coronary syndrome at presentation	‡	‡	1.80 [1.07 – 3.05]	2.28 [1.29 – 4.03]
Bifurcation treatment	‡	‡	1.87 [1.04 – 3.37]	1.47 [0.79 – 2.72]
Paclitaxel-eluting stents	1.26 [0.80 – 1.97]	1.25 [0.73 – 2.12]	1.47 [0.86 – 2.51]	1.38 [0.79 – 2.44]
Number of stents per patient	1.21 [0.97 – 1.51]	1.11 [0.74 – 1.67]	1.27 [1.12 – 1.43]	1.27 [0.98 – 1.64]
Total stent length per patient, mm	1.01 [1.00 – 1.02]	1.01 [0.98 – 1.03]	1.01 [1.01 – 1.02]	1.00 [0.99 – 1.01]
Average stent diameter per patient, mm	0.64 [0.26 – 1.60]	‡	0.70 [0.46 – 1.07]	0.72 [0.42 – 1.22]
Lack of clopidogrel	‡	‡	0.59 [0.77 – 4.48]	0.77 [0.09 – 6.24]

Summary

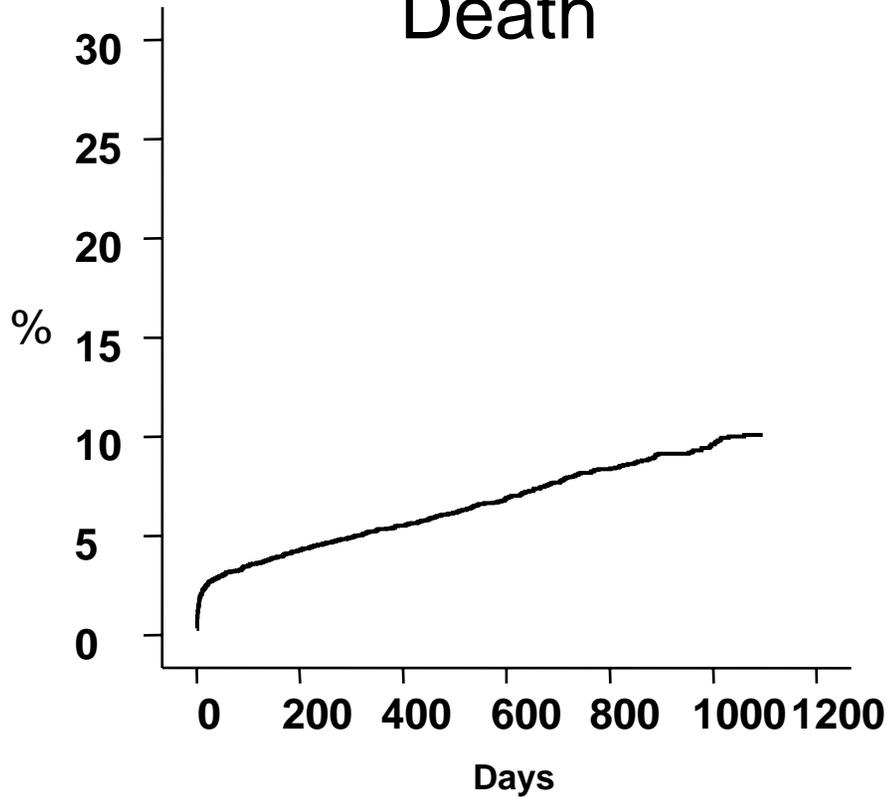
- Angiographic stent thrombosis with DES (SES and PES) occurred with an incidence density of 1.3/100 patient years and a cumulative incidence of 2.9% at 3 years
- The incidence of late stent thrombosis did not diminish but rather continued at a steady rate of 0.6%/year during the first 3 years
- Early and late ST was encountered with both DES without significant differences between stent types

Limitations

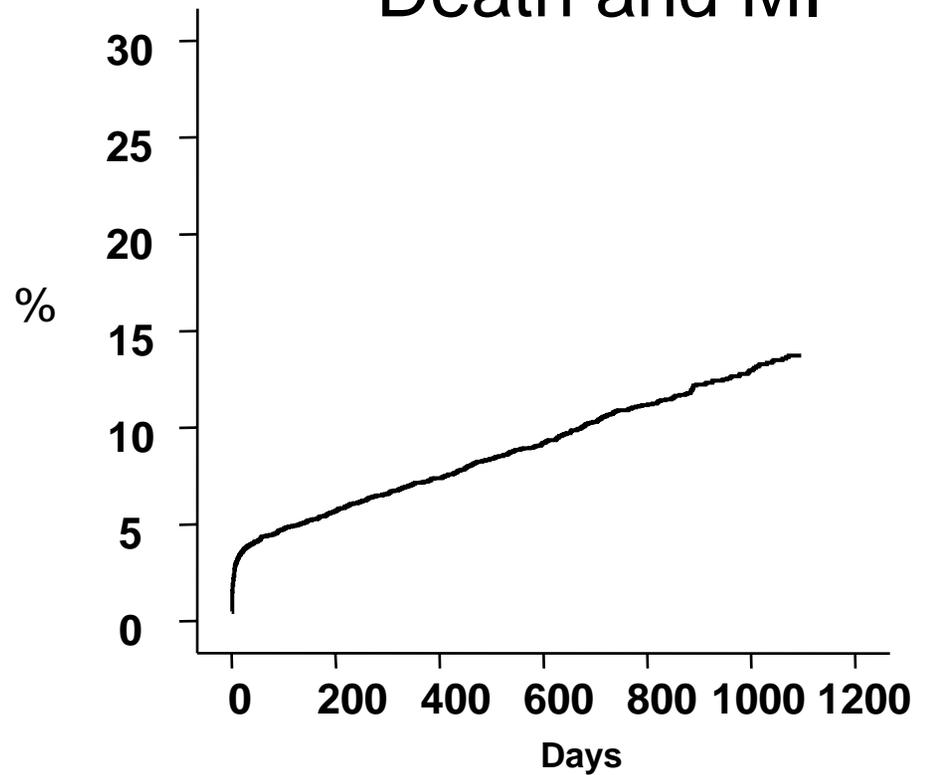
- Non-randomized cohort study of two tertiary care centers
- Stent type and antiplatelet therapy determined by local institutional practice
- Analysis limited to angiographic stent thrombosis
- IVUS not routinely performed in ST patients
- No direct comparison with a BMS patient population

Major Adverse Clinical Events

Death



Death and MI



Days after PCI	0	9	30	365	730	1095
Cumulative incidence (%)	-	2.1	2.7	4.3	8.0	10.1
Cumulative events		152	203	378	500	542
Patients at risk (n)	8146	7244	7118	5633	2904	1009

Days after PCI	0	9	30	365	730	1095
Cumulative incidence (%)	-	3.0	3.8	7.2	10.7	13.7
Cumulative events		224	284	507	669	729
Patients at risk (n)	8146	7173	7039	5522	2824	974