13th Summit TCT Asia Pacific

Comparison of Drug-Eluting Stents with Bare Metal Stents In Acute Myocardial Infarction

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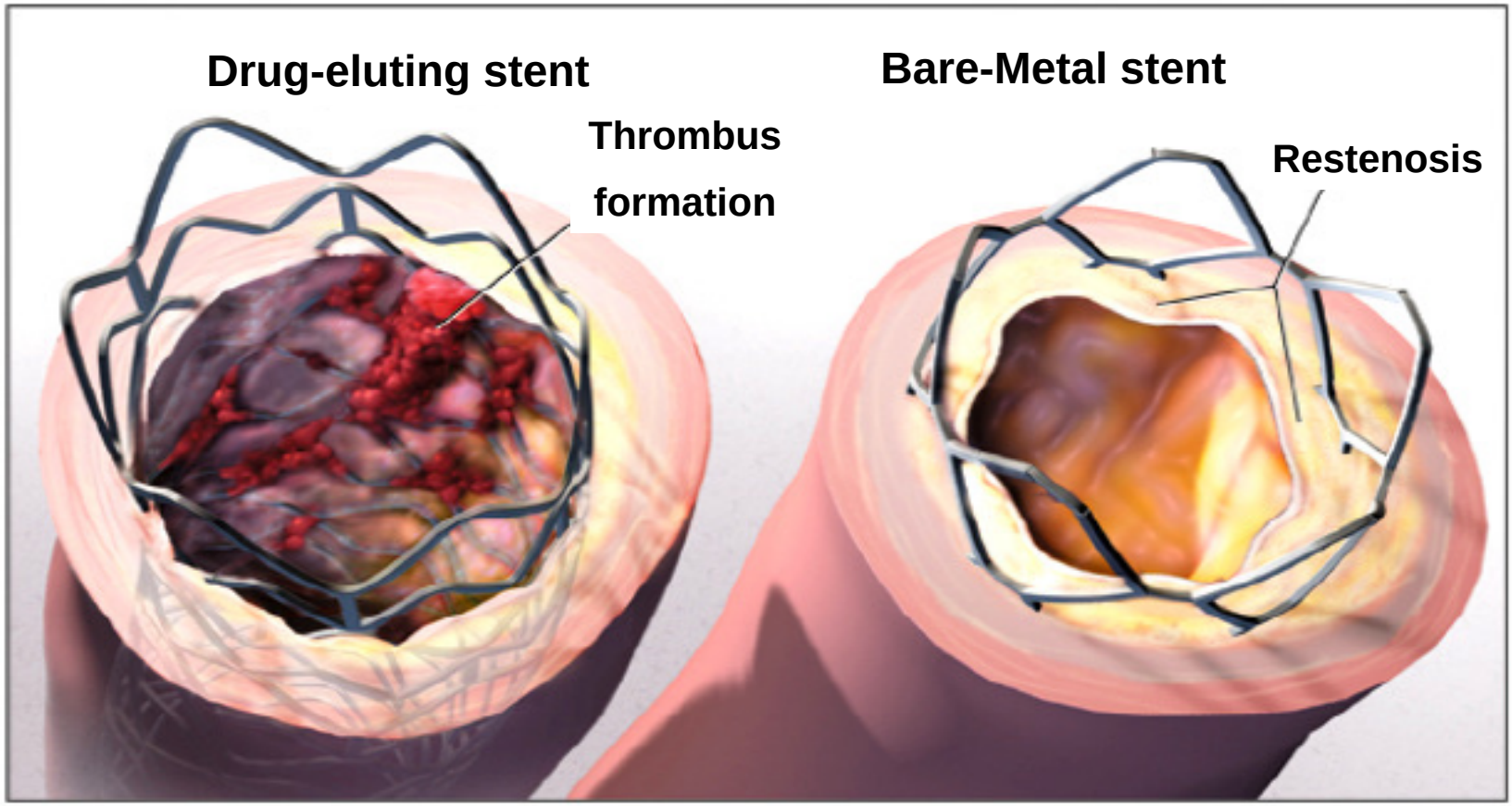
The Challenges of Percutaneous Coronary Interventions:

Restenosis and Stent Thrombosis



Shuchman M. N Engl J Med 2007;356:325-328

The Challenges of Percutaneous Coronary Interventions:

Heart implant warning

Drug-coated stents raise the risk of blood clots by 40 per cent, study finds

By Jonny Hope
Medical Correspondent

THOUSANDS of heart patients treated with tiny devices which hold arteries open are being warned they could be at higher risk of life-threatening blood clots.

Research suggests that stents raise the risk by nearly 40 per cent if they are coated with drugs.

It is estimated that more than 100,000 heart patients have had drug-coated stents implanted after a heart attack or narrowing of the blood vessels.

In the UK, diabetics are among those recommended to receive these stents, which release one of a range of drugs designed to prevent over-growth of new tissue which could re-block the artery. They have replaced the use of bare metal stents for around half of heart patients thought to be vulnerable to the problem, known as restenosis.

In these cases, patients might need to have another stent implanted as a result, which can itself be a risky procedure.

Concerns were raised two years ago that the first generation of drug-releasing stents were causing blood clots months or years after they had been implanted. In the latest study, researchers at the University Hospital of Ottawa re-examined the findings from trials on the drug-coated devices.

When the data were pooled, they revealed an increase in the risk of death or heart attack in patients given a stent called Cypher, made by the drug firm Johnson & Johnson.

Dr Edoardo Camenzind, who led the research, said the risk was increased by 40 per cent compared with bare metal stents. A separate study involving a stent made by the U.S. firm Boston Scientific showed a 36 per cent increase in risk of potentially fatal complications.

The risks appear to increase the longer the patient has the implant, suggesting new tissue might eventually cover the implant and narrow the blood vessel.

Experts s
ity of stent

and the second generation of drug-releasing stents might not have the same effect. But British doctors said patients might need to stay on anti-coagulant drugs for longer than the six months to one year currently advised.

Professor Peter Weissberg, medical director of the British Heart Foundation, urged cardiologists to use stents only when heart disease symptoms could not be controlled by drugs.

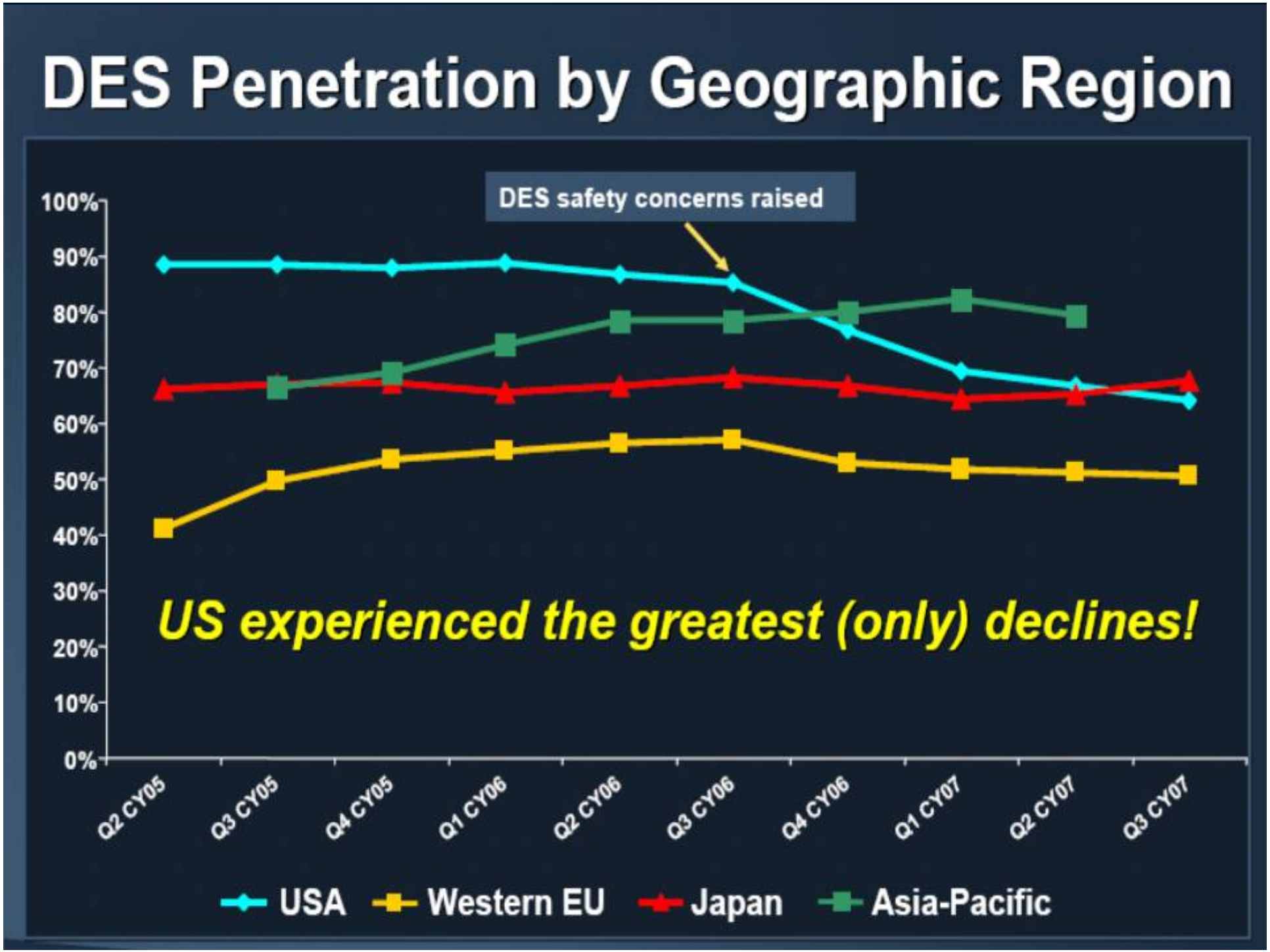
'These studies are far from conclusive but they indicate that further detailed research on the safety of drug-eluting stents should be carried out.'

The Medicines and Healthcare products Regulatory Agency, which oversees the safety of medical devices, said it was monitoring

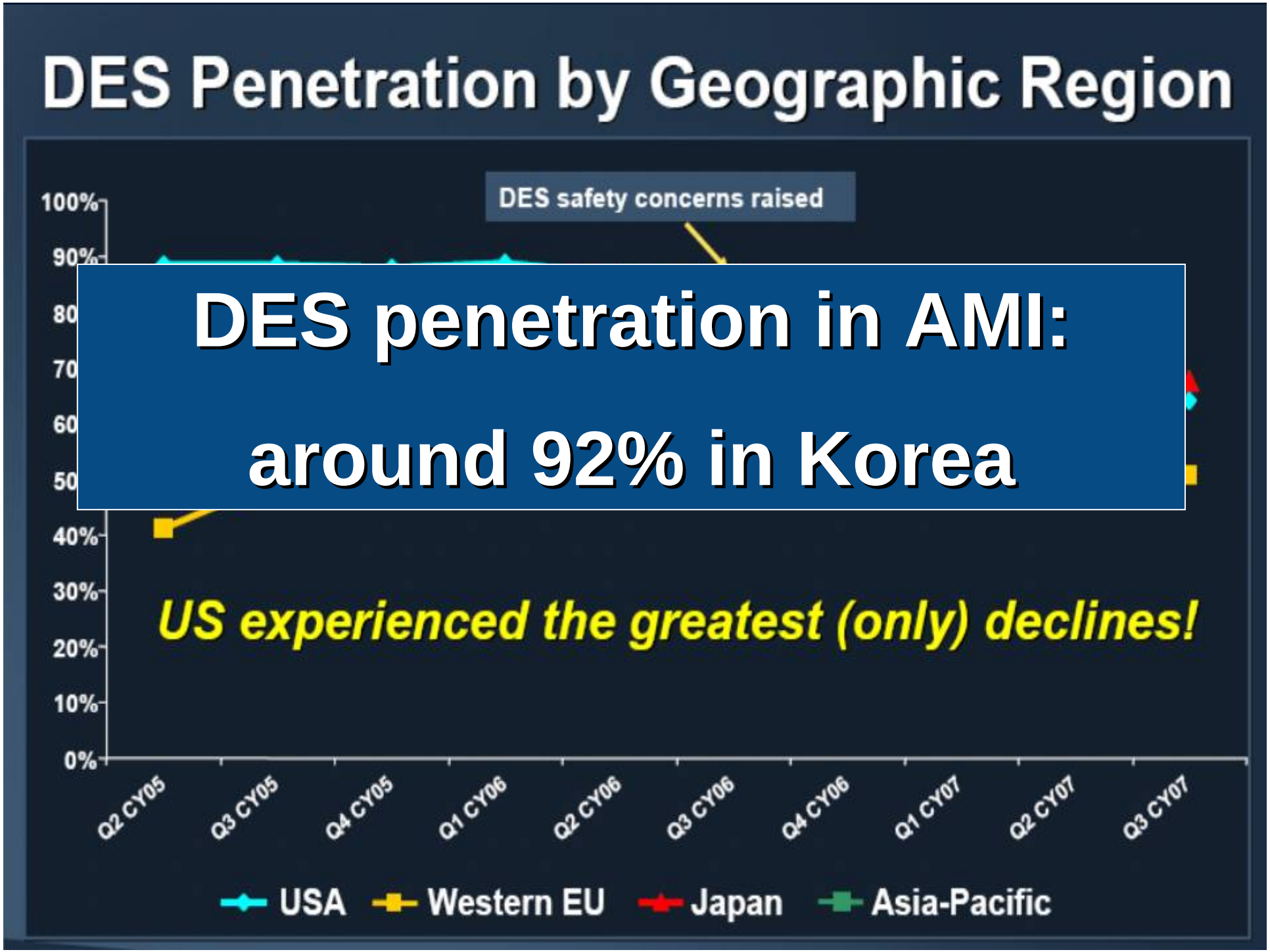
Daily Mail (London) – September 12, 2006

Maisel W. N Engl J Med 2007;356:981-984

DES Penetration by Geographic Region



DES Penetration by Geographic Region



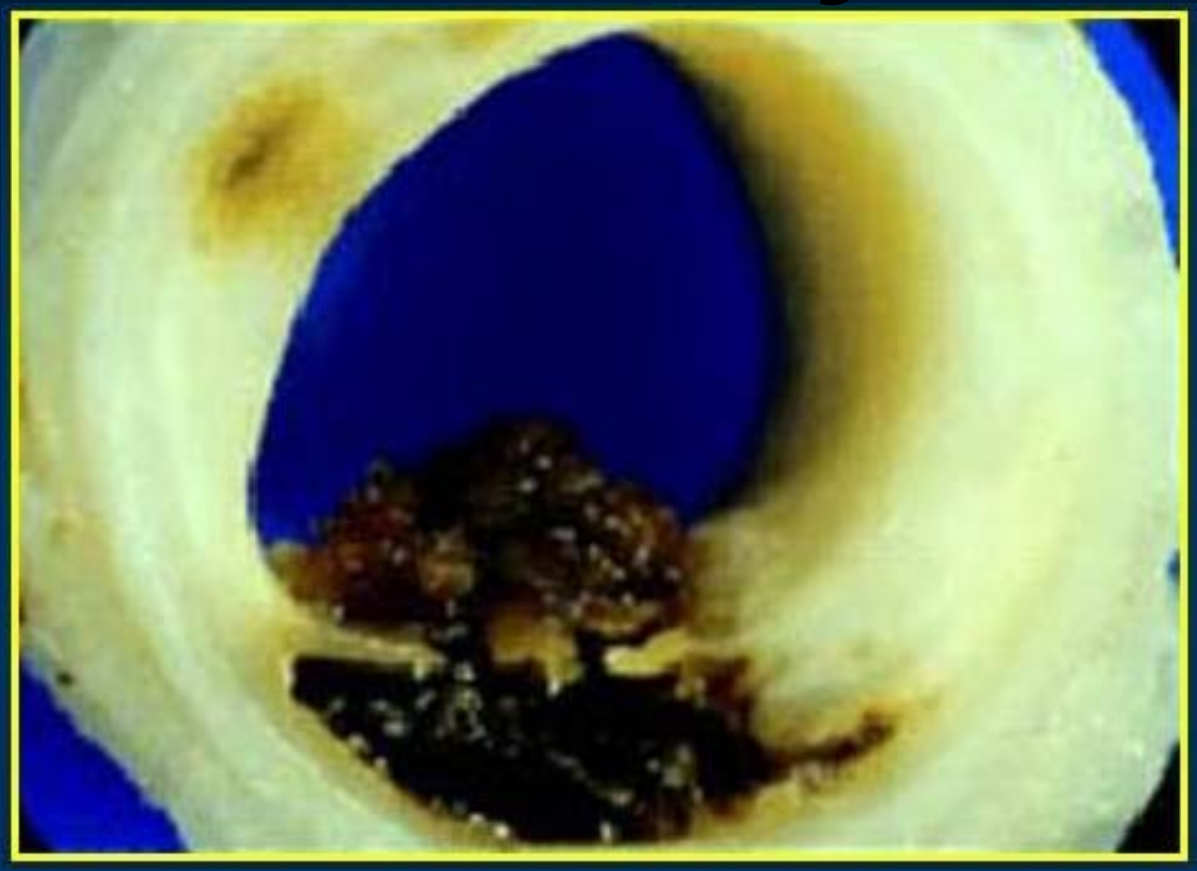
DES penetration in AMI: around 92% in Korea

US experienced the greatest (only) declines!

Unapproved/Unsettled Indications for DES

- Acute Myocardial Infarction
- Unprotected LMCA
- Bifurcation Lesions
- Chronic Total Occlusion
- Small-Vessel Disease and Long Lesions
- Saphenous Vein Grafts
- Multi-Vessel Disease

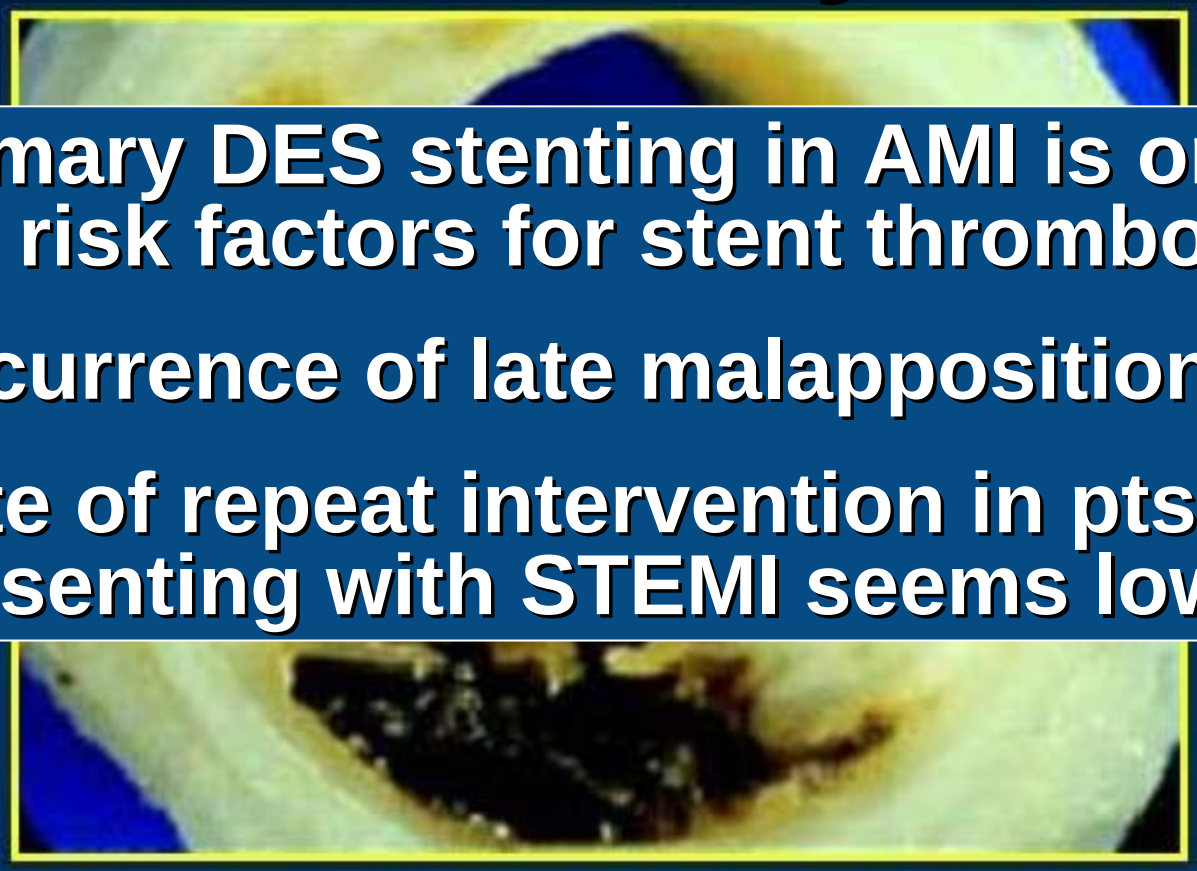
DES in AMI Patients: *Necessary?*



The culprit lesion:

Less plaque volume and more thrombus

DES in AMI Patients: *Necessary?*



1. Primary DES stenting in AMI is one of the risk factors for stent thrombosis.
2. Occurrence of late malapposition.
3. Rate of repeat intervention in pts with presenting with STEMI seems low.

The culprit lesion:

Less plaque volume and more thrombus

TYPHOON Trial: Study Design

712 patients with acute MI (prolonged chest pain with ST segment elevation) < 12 hours since onset, culprit lesion in a native suitable for stenting

Randomized, 22% female, mean age 59 years, mean follow-up 1 year

71% received Glycoprotien IIb/IIIa inhibitors, Door to balloon time=60 minutes

↓

Cardiac catheterization/primary PCI

↙ ↘

Cypher Stent Sirolimus-eluting
n=355

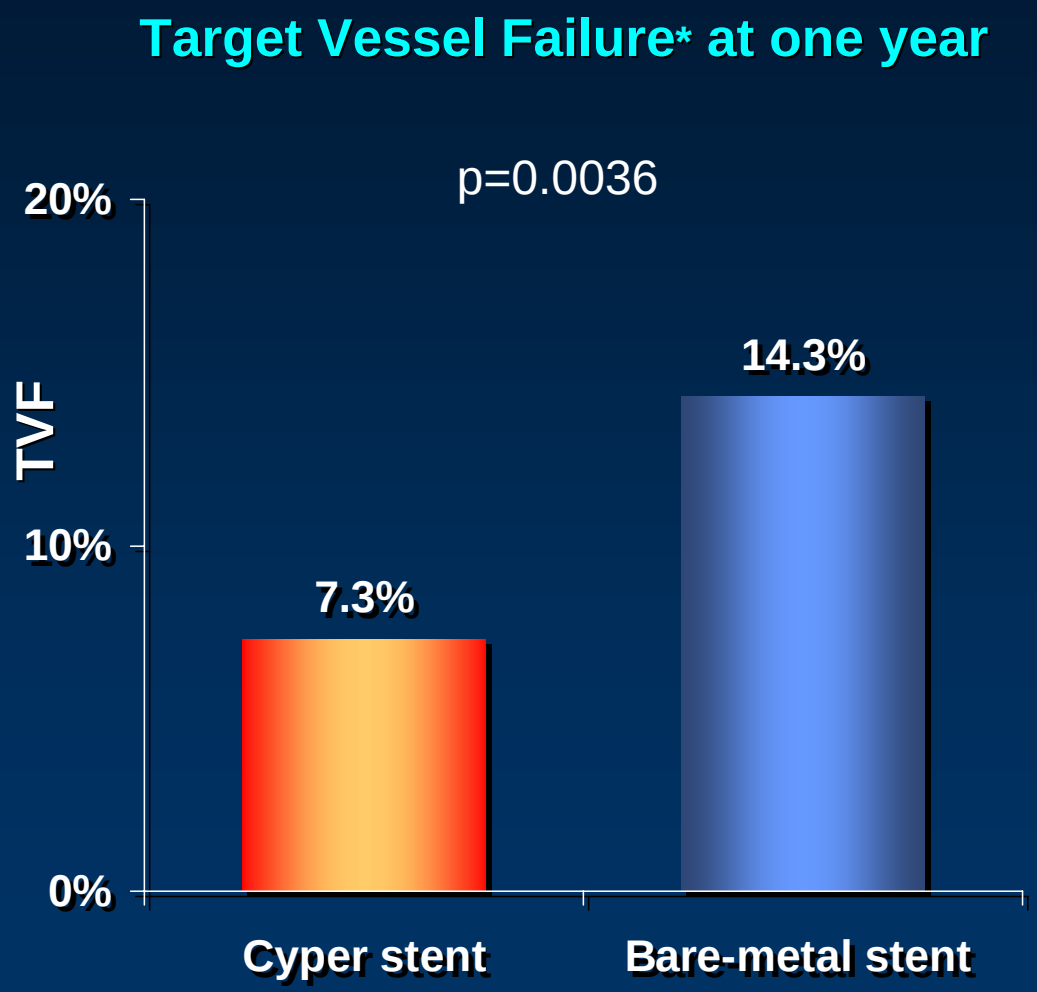
Bare-metal stent (any kind)
n=357

Concomitant Medications:
- Aspirin (≥100mg)
- Clopidogrel (300 mg load and 75 mg/day for 6 months)

- Primary Endpoint: Target vessel failure at one year, defined as target vessel revascularization, recurrent MI or cardiac death.
- Secondary Endpoint: In- hospital, 1, 6 & 12 months major adverse cardiac event

Spaulding C, et al. N Engl J Med 2006;355:1093-104

TYPHOON Trial: Primary Endpoint(s)



- Target vessel Failure (TVF) was lower in the SES compared to the BMS (7.3% vs 14.3%; p=0.0036) with no difference in death or MI.

* a composite of TVR, re-MI, TV-related cardiac death at 1 year

Spaulding C, et al. N Engl J Med 2006;355:1093-104

PASSION Trial: Study Design

619 patients with ST-elevation myocardial infarction with chest pain for > 20 minutes and ST-elevation in ≥2 contiguous leads; infarct related artery with a de novo lesion Randomized

24% female, mean age 61 years, mean follow-up 1 year

Use of GP IIb/IIIa inhibitors abciximab or tirofiban at discretion of physician

Time to balloon was 3.1 hours; LAD artery was the culprit in 50% of patients, 45% had multi-vessel disease.

Angiographic success was 96% in both groups; an average of 1.3 stents were used in both arms.

Paclitaxel-eluting stent
Taxus Express2 or Liberte Stent
n=309

Bare metal stent
Express2 or Liberte stent
n=310

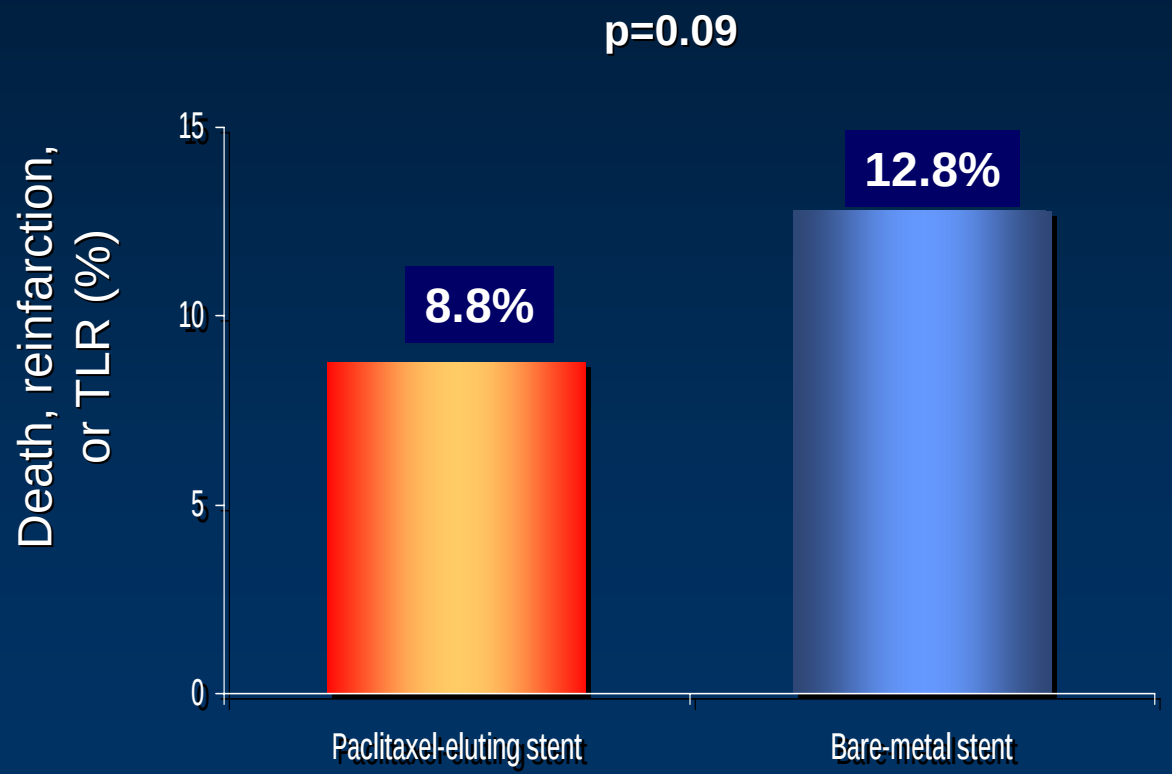
Concomitant medications: Aspirin (80-100 mg) and clopidogrel (300 mg loading dose followed by 75 mg/day for 6 months

- Primary Endpoint: Composite of cardiac death, recurrent MI, or ischemia-driven target lesion (within 5 mm of stent edges) revascularization (TLR) at one year

Laarman GJ, et al. N Engl J Med 2006;355:1105-13

PASSION Trial: Primary Endpoint

Composite endpoint of death, reinfarction, or TLR at one year (%)



- **The primary endpoint of death, reinfarction, or TLR did not differ significantly between treatment groups (Hazard ratio=0.63, p=0.09)**

Laarman GJ, et al. N Engl J Med 2006;355:1105-13

PASSION Trial: Summary

- Among patients undergoing primary PCI for ST-elevation MI, use of paclitaxel-eluting stents was not associated with a difference in the primary composite endpoint of death, MI or target lesion revascularization when compared to bare metal stents at one year.
- Occurrences of death or MI were not significantly different between the two groups (5.5% vs. 7.2%, p=0.40) nor was there a difference in TLR (5.3% vs. 7.8%, p=0.23).
- Although the TYPHOON trial showed that sirolimus-eluting stents significantly reduced target vessel failure compared with bare metal stents, it is difficult to compare these results since *PASSION enrolled patients with left main disease, bifurcation lesions, and large thrombus while TYPHOON excluded these patients.*
- *PASSION also used only the bare Express stent while TYPHOON used any bare metal stent.*

Laarman GJ, et al. N Engl J Med 2006;355:1105-13

SESAMI Trial: Study Design

320 patients with acute myocardial infarction to be treated with primary or rescue angioplasty without left main disease, saphenous vein grafts, and cardiogenic shock.

Randomized

19% female, mean age 61 years, follow-up 1 year

Primary or rescue angioplasty with **sirolimus-eluting stent** n=160

Primary or rescue angioplasty with **bare metal stent** n=160

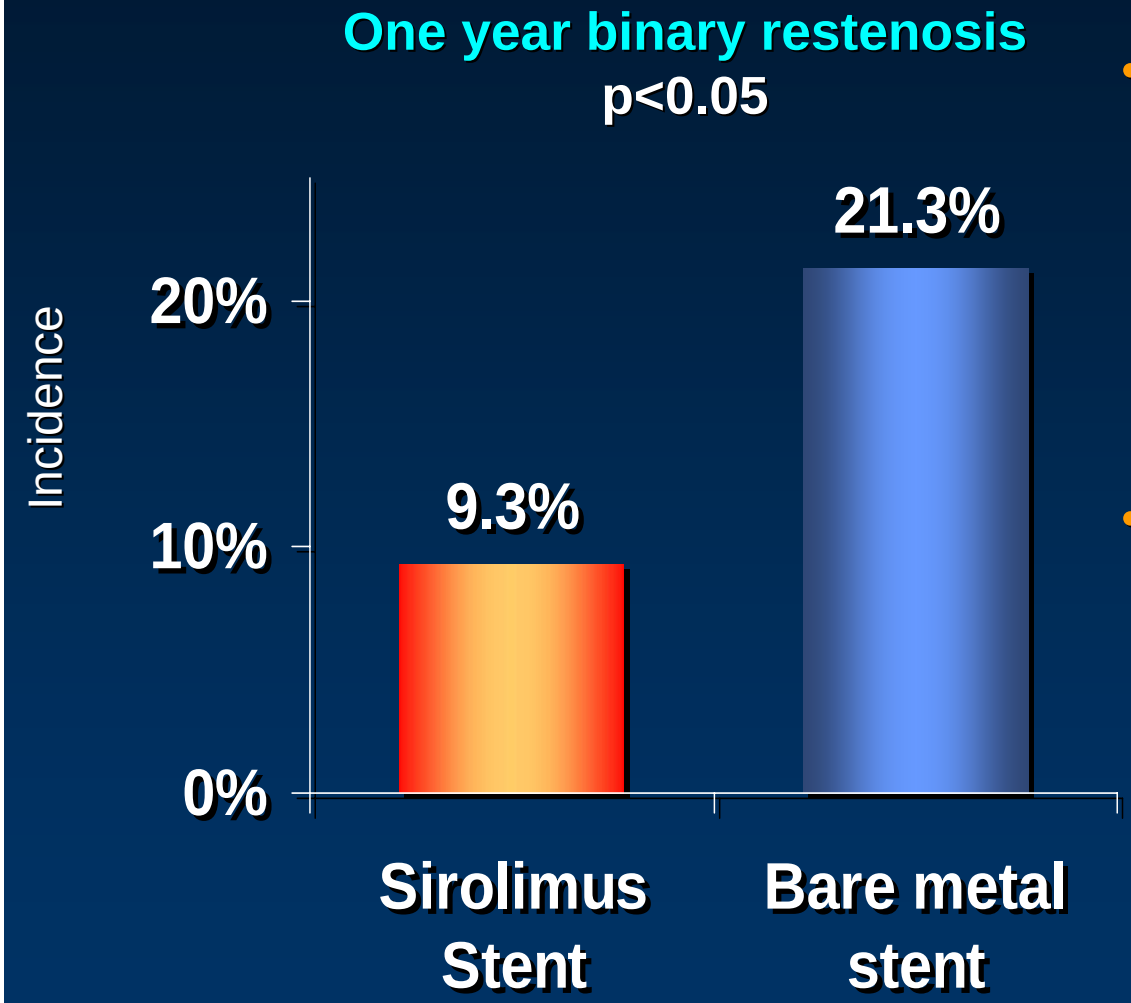
One year angiographic follow up

n=166

- Primary Endpoint: Angiographic binary restenosis at one year
- Secondary Endpoint: One year target lesion revascularization (TLR), target vessel revascularization (TVR), target lesion vessel failure (TVF) and major adverse cardiac events (MACE)

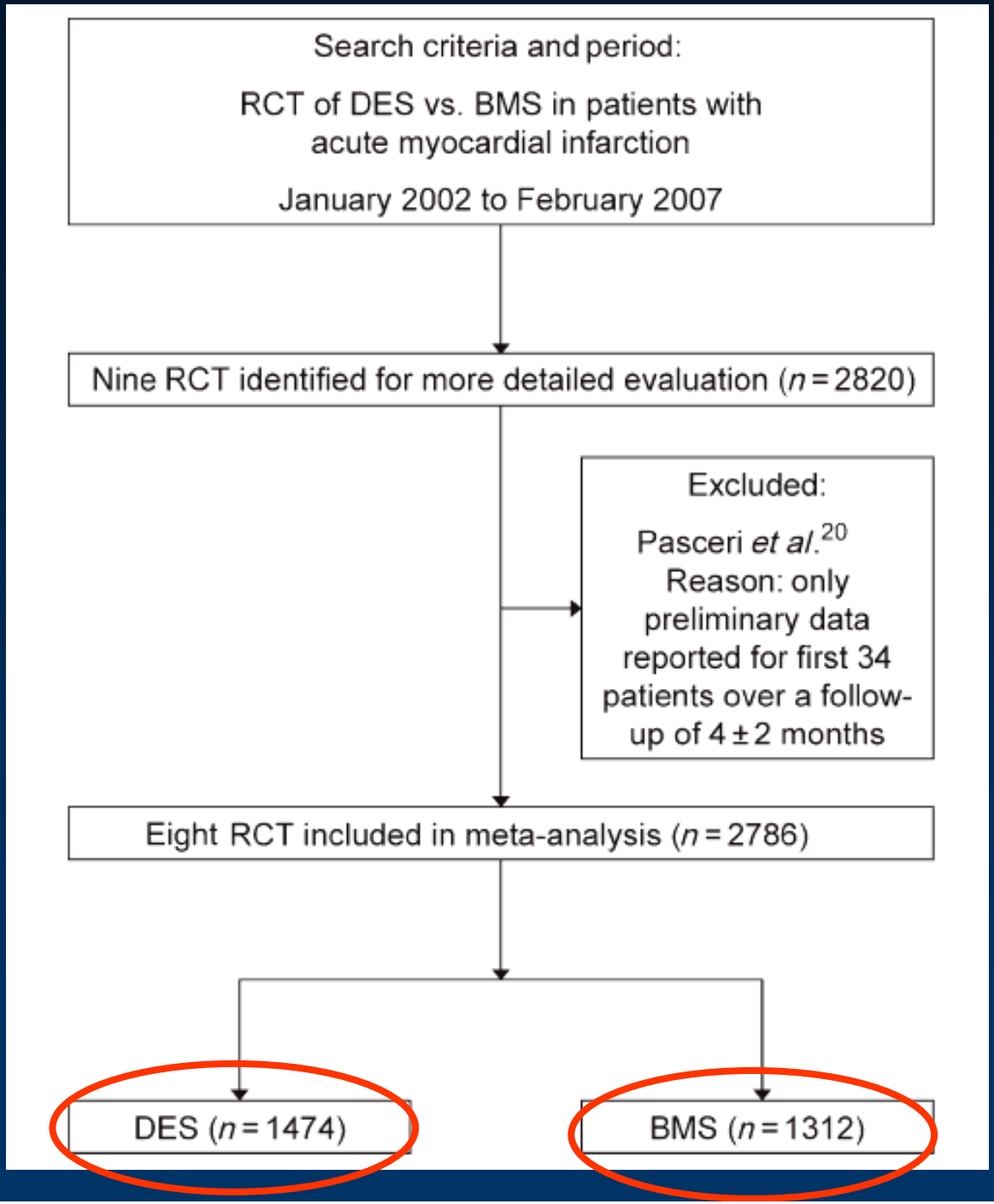
Menichelli M, et al. J Am Coll Cardiol 2007;49:1924-30

SESAMI Trial: Primary Endpoint



- The primary endpoint of one year binary restenosis on angiography occurred less often in the SES vs. the BMS (9.3% vs. 21.3%, relative risk reduction [RRR] 56%, p=0.032).
- Likewise, clinically driven restenosis was also lower in the SES (5.6% vs. 17.2%, RRR 64%, p<0.05).

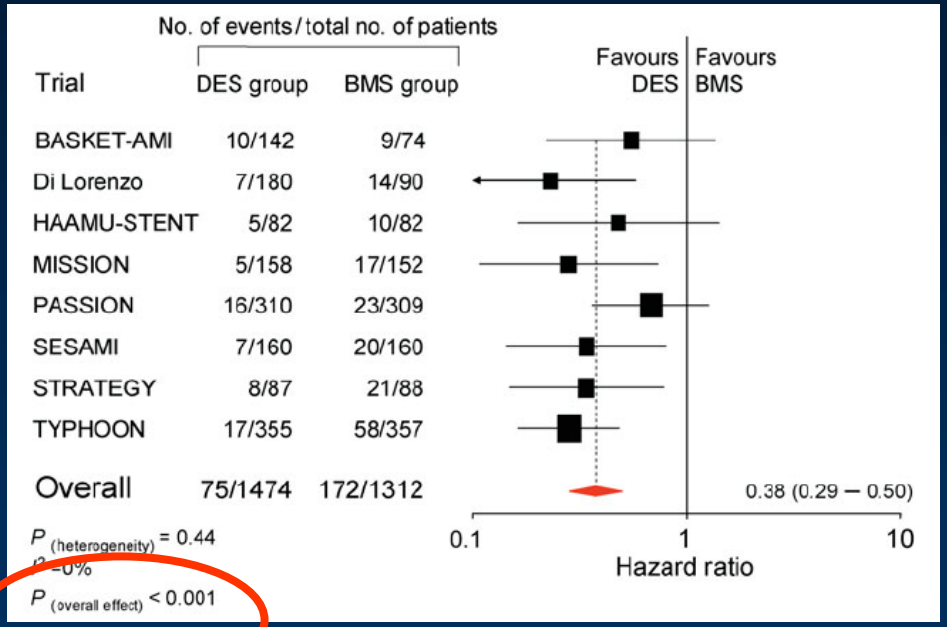
Menichelli M, et al. J Am Coll Cardiol 2007;49:1924-30

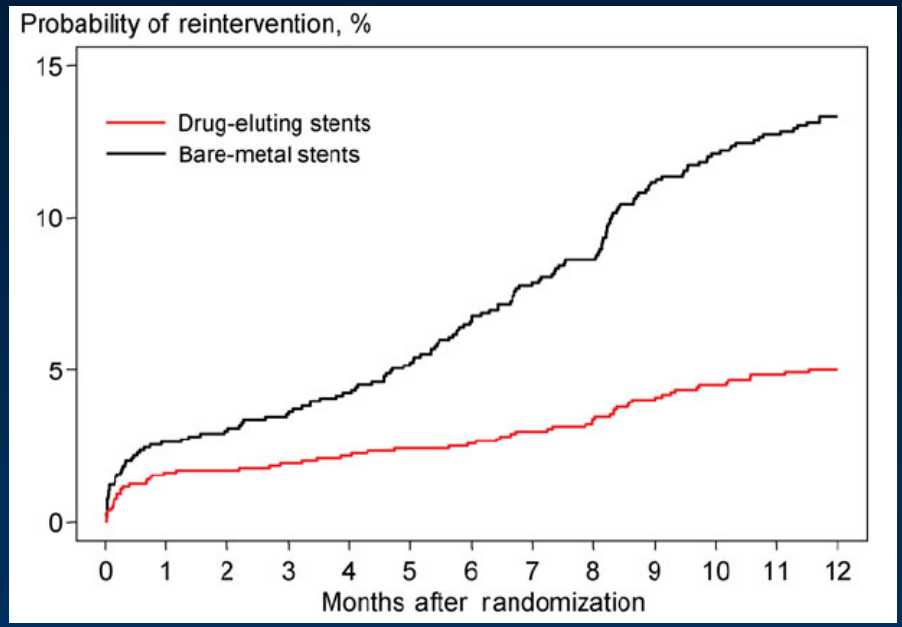


Follow-up duration: 12.0 to 24.2 months

Kastrati A et al. Eur Heart J 2007;28:2706–2713

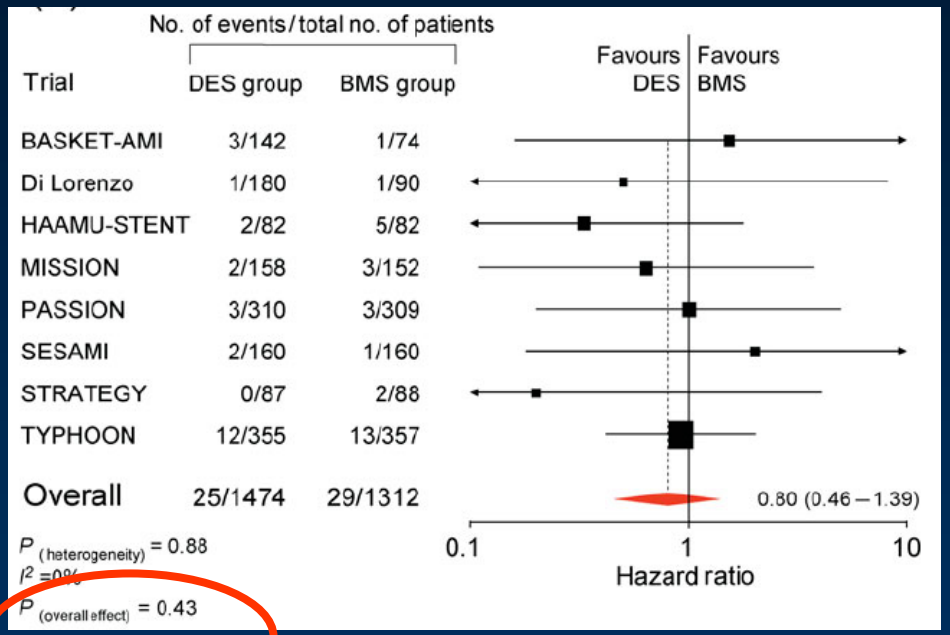
Re-intervention

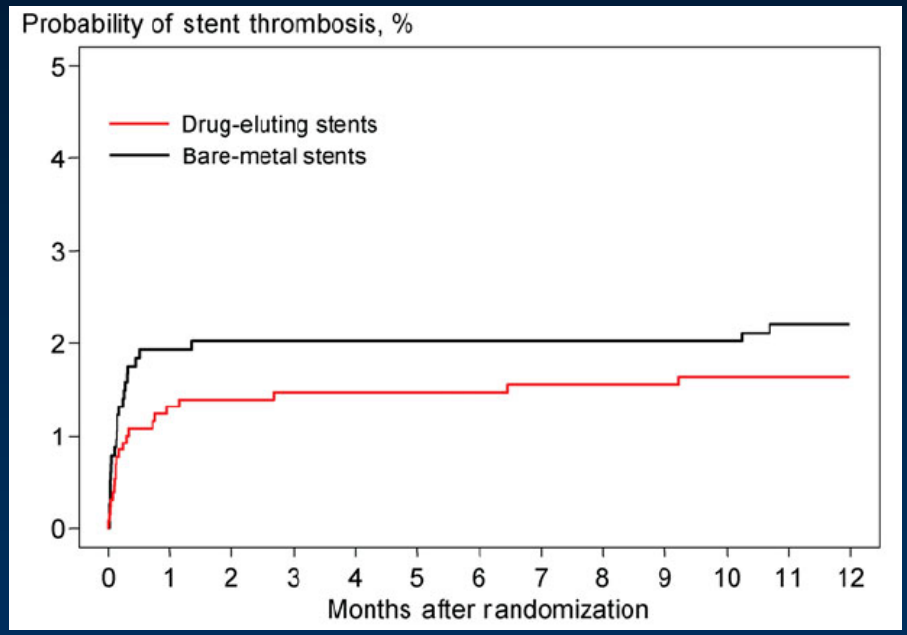




Kastrati A et al. Eur Heart J 2007;28:2706–2713

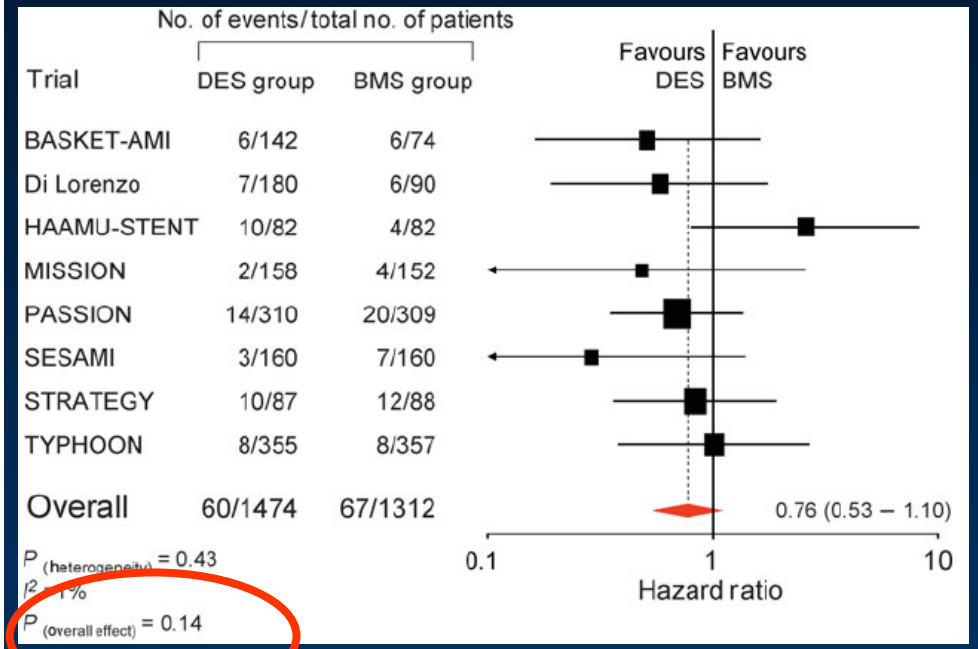
Stent Thrombosis

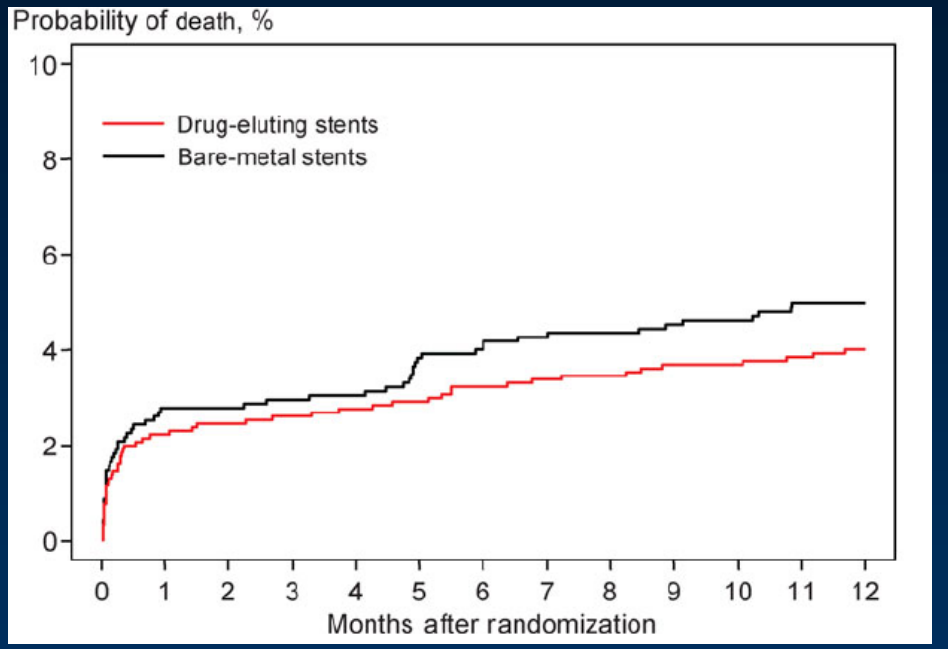




Kastrati A et al. Eur Heart J 2007;28:2706–2713

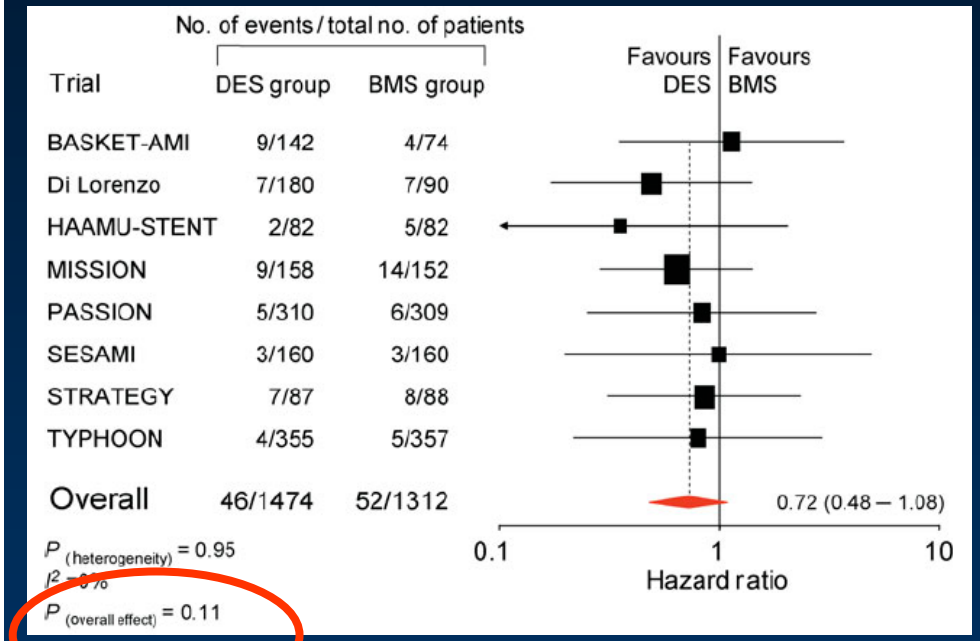
Death

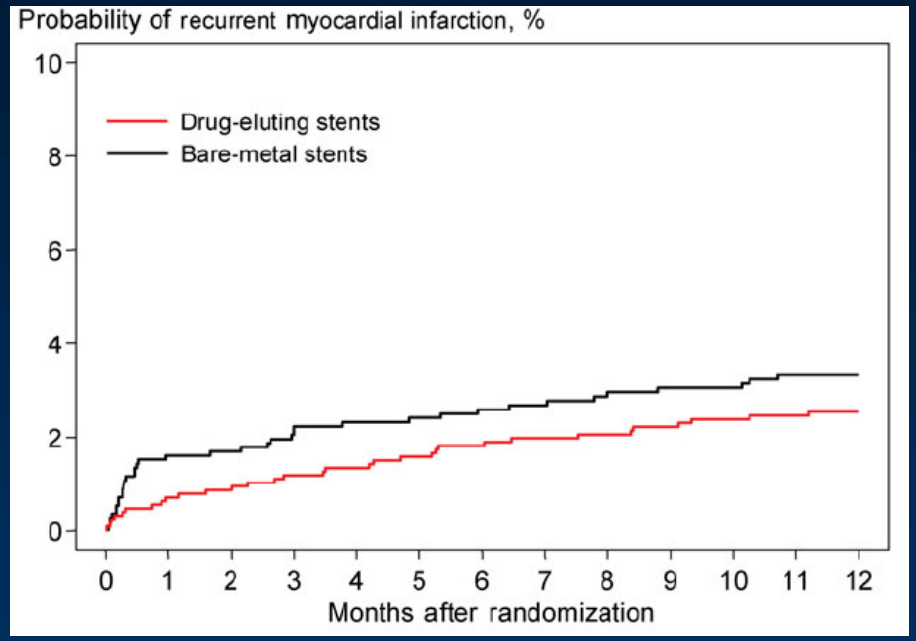




Kastrati A et al. Eur Heart J 2007;28:2706–2713

Recurrent MI





DES in patients with AMI is safe and improves clinical outcomes by reducing risk of reintervention compared with BMS

Kastrati A et al. Eur Heart J 2007;28:2706–2713

The Safety and Efficacy of Drug-Eluting Stents Compared With Bare-Metal Stents In Patients with Acute Myocardial Infarction

Youngkeun Ahn, Myung Ho Jeong, Hae-Chang Jeong, Shung Chull Chae, Seung Ho Hur, Taek Jong Hong, Young Jo Kim, In Whan Seong, Jei Keon Chae, Jay Young Rhew, In Ho Chae, Myeong Chan Cho, Jang Ho Bae, Seung Woon Rha, Chong Jin Kim, Donghoon Choi, Yang Soo Jang, Junghan Yoon, Wook Sung Chung, Jeong Gwan Cho, Ki Bae Seung, Seung Jung Park and other Korea Acute Myocardial Infarction Registry Investigators

Korea Acute Myocardial infarction Registry (KAMIR) Study Group of Korean Circulation Society

- 27% female
- Mean age 64 years
- Follow-up duration 1 year
- Use of GP IIb/IIIa inhibitors 14%
- LAD artery was the culprit in 40%
- 55% had multi-vessel disease
- Angiographic success was 96%
- Average of 1.4 stents were used

Baseline Clinical Characteristics-1

Characteristics	BMS (n=478)	DES (n=5563)	P
Mean Age (years)	63.8±12.9	63.6±12.4	0.715
Male (%)	346 (73.6)	3923 (72.4)	0.565
Body mass index (kg/m^2)	25.8±22.9	24.3±8.2	0.159
Past history (%)			
Hypertension	227 (49.5)	2489 (47.5)	0.413
Diabetes mellitus	101 (21.9)	1422 (27.1)	0.015
Current Smoking	293 (63.8)	3120 (59.9)	0.101
Hyperlipidemia	33 (7.2)	455 (8.7)	0.263
Family history of heart disease	35 (7.6)	360 (6.9)	0.562
Prior angina	33 (40.2)	286 (39.3)	0.866
Prior myocardial infarction	17 (20.7)	163 (22.4)	0.732
Prior percutaneous coronary intervention	31 (37.8)	250 (34.3)	0.532
Prior coronary artery bypass graft	1 (1.2)	29 (4.0)	0.351
Symptom to door time (min)	511.1±730.5	523.6±731.3	0.738

Baseline Clinical Characteristics-2

Symptoms and hemodynamic on admission	BMS (n=478)	DES (n=5563)	P
Chest pain (%)	387 (83.9)	4569 (86.8)	0.083
Dyspnea (%)	112 (24.3)	1312 (24.9)	0.777
Heart rate (beats/min)	76.0±47.8	76.4±23.0	0.855
Killip class (%)			
I	351 (77.5)	3900 (76.1)	0.520
II	54 (11.9)	693 (13.5)	0.335
III	31 (6.8)	328 (6.4)	0.715
IV	17 (3.8)	201 (3.9)	0.857
Final diagnosis (%)			
STEMI	315 (65.9)	3577 (64.3)	0.476
Non-STEMI	163 (34.1)	1986 (35.7)	0.246
Echocardiogram findings			
Left ventricular EF (%)	55.0±21.8	51.9±19.2	0.001
Total wall motion score	20.3±10.6	18.4±10.6	0.002

Baseline Clinical Characteristics-3

Laboratory findings	BMS (n=478)	DES (n=5563)	P
Total cholesterol (mg/dl)	179.0±40.6	184.9±45.7	0.004
Triglyceride (mg/dl)	142.0±158.4	129.3±103.9	0.101
High density lipoprotein-cholesterol (mg/dl)	45.2±47.1	45.5±24.8	0.790
Low density lipoprotein-cholesterol (mg/dl)	117.3±56.4	119.5±45.0	0.359
N-terminal pro-brain natriuretic peptide (pg/ml)	2565.6±6112.5	2278.3±5702.7	0.406

Medical therapy on admission

Medical therapy (%)	BMS (n=478)	DES (n=5563)	P
Aspirin	459 (96.0)	5272 (94.8)	0.232
Clopidogrel	457 (95.6)	5256 (94.5)	0.297
Cilostazol	101 (21.1)	2095 (37.7)	<0.001
Unfractionated heparin	263 (55.0)	3090 (55.5)	0.825
Low molecular weight heparin	197 (41.2)	2045 (36.8)	0.053
Platelet glycoprotein IIb/IIIa inhibitor	89 (18.6)	648 (11.6)	<0.001
Beta blocker	349 (73.0)	3800 (68.3)	0.033
Angiotensin converting enzyme inhibitor	356 (74.5)	3692 (66.4)	<0.001
Angiotensin receptor blocker	72 (15.1)	866 (15.6)	0.770
Statin	346 (72.4)	3998 (71.9)	0.809

Baseline coronary angiographic variables-1

Variable	BMS (n=478)	DES (n=5563)	p
Coronary artery disease (%)			
1 vessel	213 (44.6)	2314 (41.6)	0.188
2 vessels	142 (29.7)	1796 (32.3)	0.235
3 vessels	107 (22.4)	1338 (24.1)	0.395
Left main, isolated	2 (0.4)	20 (0.3)	0.840
Left main, complex	14 (2.9)	95 (1.7)	0.055
Infarct-related artery (%)			
Left main stem	6 (1.3)	89 (1.6)	0.558
Left anterior descending artery	146 (30.5)	2816 (50.6)	<0.001
Right coronary artery	231 (48.3)	1810 (32.5)	<0.001
Left circumflex artery	95 (19.9)	848 (15.3)	0.008

Baseline coronary angiographic variables-2

Lesion type (%)	BMS (n=478)	DES (n=5563)	
A	25 (5.2)	236 (4.2)	0.316
B1	86 (18.0)	891 (16.0)	0.274
B2	129 (27.0)	1434 (25.8)	0.592
C	238 (49.8)	3002 (54.0)	0.087
TIMI flow grade (%)			
0	213 (44.6)	2416 (43.4)	0.364
1	67 (14.0)	704 (12.7)	0.478
2	75 (15.7)	875 (15.7)	0.856
3	123 (25.7)	1568 (28.2)	0.169

Procedural characteristics-1

Variable	BMS (n=478)	DES (n=5563)	p
Prior thrombolysis (%)	39 (8.2)	402 (7.5)	0.555
Door to balloon time (minute)	757.0±1017.7	813.8±1132.6	0.311
Type of PCI			
Primary PCI in STEMI	229 (49.5)	2822 (53.7)	0.080
Early PCI, but not primary in STEMI	55 (11.9)	845 (16.1)	0.017
Rescue after thrombolysis in STEMI	21 (4.5)	135 (2.6)	0.013
Early invasive strategy in NSTEMI	1 (0.2)	36 (0.7)	0.228
Rescue after conservative in STEMI/NSTEMI	17 (3.7)	288 (5.5)	0.097
Elective PCI	140 (30.2)	1130 (21.5)	<0.001

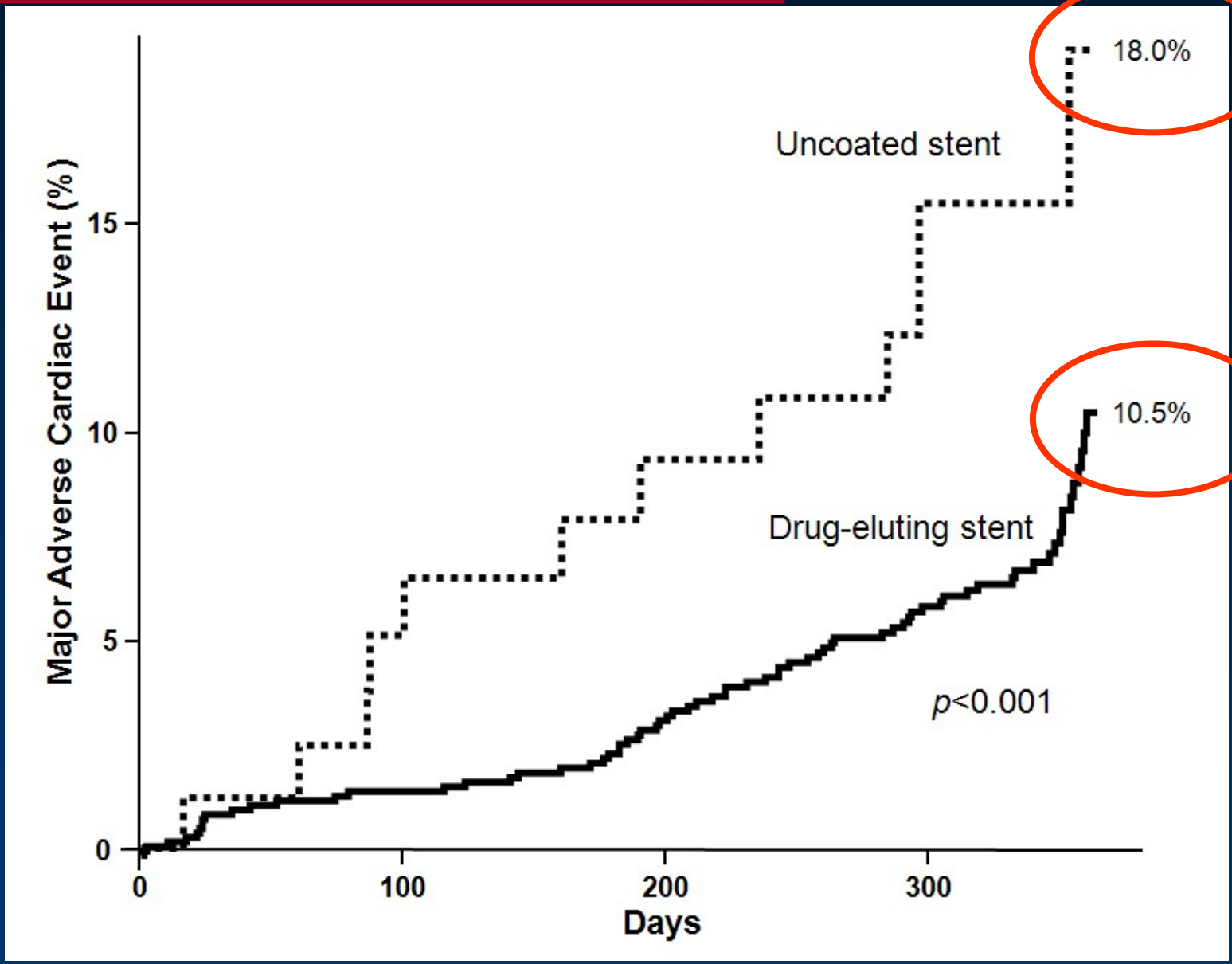
Procedural characteristics-2

Variable	BMS (n=478)	DES (n=5563)	p
Stent size (mm)	3.45±0.62	3.11±0.39	<0.001
Stent length (mm)	21.99±6.13	25.90±6.50	<0.001
Number of stents implanted per patients	1.42±0.79	1.54±0.87	0.002
Final TIMI flow grade (%)			
0	4 (0.8)	52 (1.0)	0.797
1	7 (1.5)	30 (0.5)	0.015
2	17 (3.6)	207 (3.7)	0.785
3	450 (94.1)	5274 (94.8)	0.612
Procedural success (%)	459 (96.0)	5409 (97.2)	0.241
Revascularization (%)			
Total revascularization	56 (11.7)	664 (11.9)	0.723
Revascularization of single IRA	215 (45.0)	2591 (46.6)	0.964
Revascularization of only IRA in multi-vessel	140 (29.3)	1596 (28.7)	0.926
Multi-vessel revascularization	55 (11.5)	633 (11.4)	0.901
No revascularization of IRA	12 (25.1)	79 (1.4)	0.074

MACE at 1 Year Between DES and BMS

Follow-up at 1 year	BMS (n=400)	DES (n=4620)	p
Composite	72 (18.0)	483 (10.5)	<0.001
Cardiac death	26 (6.5)	177 (3.8)	0.009
Non-cardiac death	10 (2.5)	49 (1.1)	0.024
MI	2 (0.5)	40 (0.9)	0.771
Re-PCI	32 (6.8)	212 (3.9)	0.002
TVR	5 (1.3)	31 (0.7)	0.204
Non-TVR	10 (2.5)	115 (2.5)	1.000
TLR	18 (4.5)	67 (1.5)	<0.001
CABG	2 (0.5)	12 (0.3)	0.308

Composite primary end point of death from cardiac or non cardiac causes, recurrent MI, revascularization at 1 year



Multi-variate predictors of 1-year MACE

	Odd ratio	95% confidence interval		P
		Lower	Upper	
Use of BMS	2.762	1.356	5.623	0.005
Large stent diameter	0.484	0.226	1.035	0.061
High level of troponin I	1.004	0.990	1.001	0.125
High level of troponin T	1.024	0.991	1.058	0.163
ACEI treatment	0.622	0.285	1.354	0.231
Old age	1.014	0.962	1.010	0.250
GP IIb-IIIa inhibitor treatment	0.739	0.746	2.455	0.320
High EF	1.013	0.958	1.017	0.382
High level of hs-CRP	1.006	0.971	1.016	0.574
High regional wall motion score	1.017	0.958	1.080	0.577
Beta blocker treatment	0.809	0.326	2.006	0.647
Long stent length	1.005	0.954	1.058	0.860
Atrioventricular block	1.104	0.304	4.010	0.880
Diabetes mellitus	1.015	0.560	1.838	0.961

Subgroup analysis among DES

Follow-up at 1 year	SES (n=2495)	PES (n=1720)	ZES (n=405)	*p*
Composite	254 (10.2)	194 (11.3)	35 (8.6)	0.971
Cardiac death	94 (3.8)	67 (3.9)	16 (4.0)	0.807
Non-cardiac death	23 (0.9)	23 (1.3)	3 (0.7)	0.632
Myocardial infarction	23 (0.9)	15 (0.9)	2 (0.5)	0.478
Re-PCI	110 (3.8)	89 (4.3)	13 (2.5)	0.601
TVR	20 (0.8)	10 (0.6)	2 (0.2)	0.168
Non-TVR	64 (2.6)	42 (2.4)	9 (2.2)	0.666
TLR	26 (1.0)	38 (2.2)	3 (0.7)	0.167
CABG	8 (0.3)	3 (0.2)	1 (0.2)	0.485

SES=Sirolimus-eluting stents. PES-Paclitaxel-eluting stents. ZES=Zotarolimus-eluting stents

Comparison of Effectiveness of Bare Metal Stents vs. Drug-Eluting Stents in Patients with Acute Myocardial Infarction Who Underwent Single-vessel Percutaneous Coronary Intervention in Large Coronary Arteries

TCT 2007

Subjects and Methods (I)

A total of 1,340 patients from the KAMI Registry who underwent single-vessel PCI in large coronary arteries (>= 3.5 mm) without long lesions (< 25mm) between Nov 2005 and Sept 2006 were divided into two groups.

Group 1: patients who received DES, N = 1,151

Group 2: patients who received BMS, N = 189

Subjects and Methods (II)

Study end points were the composite of MACE, including death, MI, and urgent revascularization at 30 days and six months.

Baseline Clinical Characteristics

	DES Group (N=1,151)	BMS Group (N=189)	*P*
Age (yrs)	60±13	59±13	0.814
Male	915 (79.5%)	151 (79.9%)	0.962
Risk factors			
Smoking	746 (64.8%)	82 (66.1%)	0.970
Hypertension	458 (39.8%)	79 (41.8%)	0.939
Hyperlipidemia	91 (7.9%)	16 (8.5%)	0.759
Diabetes	249 (21.6%)	28 (14.8%)	0.193
Family history	74 (6.4%)	12 (6.3%)	0.954
ST-elevation MI	802 (69.7%)	132 (69.8%)	0.964
Non ST-elevation MI	349 (30.3%)	57 (30.2%)	0.964
Cardiogenic shock	39 (3.4%)	7 (3.7%)	0.825
Ejection fraction	0.53±0.23	0.54±0.10	0.690

Procedural Characteristics

	DES Group (N = 1,151)	BMS Group (N = 189)	*P*
Treated coronary vessel			
Left anterior descending artery	572 (49.7%)	51 (27.0%)	<0.0005
Left circumflex artery	120 (10.4%)	23 (12.2%)	0.472
Right coronary artery	426 (37.0%)	112 (59.3%)	<0.0005
Left main	33 (2.9%)	3 (1.6%)	0.313
ACC/AHA lesion type			
A	65 (5.6%)	14 (7.4%)	0.341
B1	287 (24.9%)	41 (21.7%)	0.337
B2	336 (29.2%)	67 (35.4%)	0.082
C	396 (34.4%)	52 (27.5%)	0.063
TIMI flow			
0	447 (38.8%)	82 (43.4%)	0.236
1	119 (10.3%)	27 (14.3%)	0.107
2	202 (17.5%)	33 (17.5%)	0.976
3	347 (30.1%)	45 (23.8%)	0.076
Stent diameter (mm)	3.58±0.27	3.98±0.44	<0.0005
Stent length (mm)	20.4±3.42	19.5±3.60	0.002

In-hospital mortality

	DES Group (N=1,151)	BMS Group (N=189)	*P*
Cardiac death	17 (1.5%)	5 (2.6%)	0.228
Non-cardiac death	0	0	

30-day Clinical Outcomes

	DES Group (N=692)	BMS Group (N=124)	*P*
Cardiac death	0	1 (0.8%)	0.152
Non-cardiac death	1 (0.1%)	1 (0.8%)	0.281
Acute MI	0	1 (0.8%)	0.152
TLR	0	1 (0.8%)	0.152
Non-TLR	6 (0.9%)	1 (0.8%)	0.989
CABG	1 (0.1%)	0	0.672
Stent thrombosis	0	0	
Total MACE	8 (1.2%)	5 (4.0%)	0.472

Six-month Clinical Outcomes

	DES Group (N=380)	BMS Group (N=75)	*P*
Cardiac death	0	1 (1.3%)	0.141
Non-cardiac death	2 (0.5%)	1 (1.3%)	0.366
Acute MI	0	1 (1.3%)	0.141
TLR	6 (1.6%)	3 (4.0%)	0.122
Non-TLR	8 (2.1%)	0	0.610
CABG	1 (0.2%)	0	1.000
Total MACE	17 (4.4%)	6 (8.0%)	0.176

Discussion

There were no differences in outcomes of acute MI patients treated by BMS or DES in large coronary arteries without long lesions.

Given a similar degree of neointimal proliferation around a stent of any diameter, neointimal growth occurring in large vessels would be less likely to cause clinically or angiographically significant restenosis.

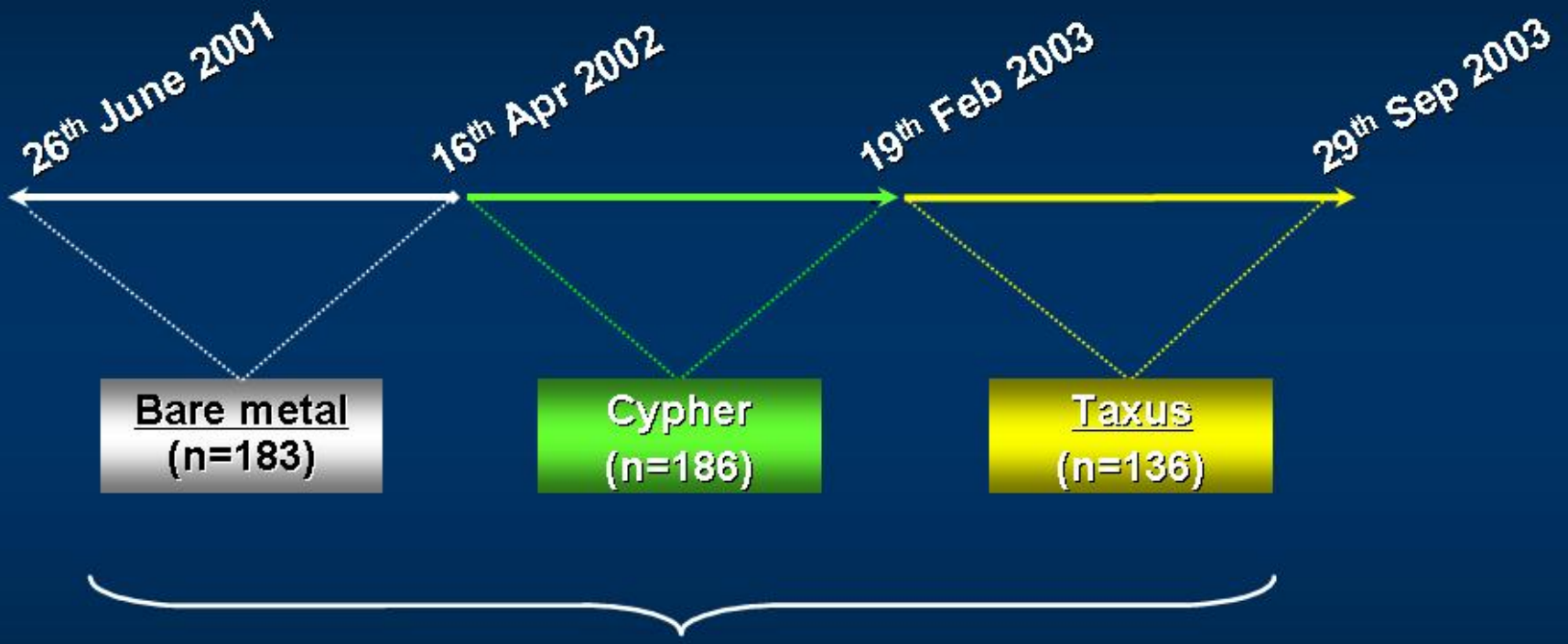
Conclusion

Clinical outcomes of BMS were comparable with those of DES in patients with acute MI who underwent single-vessel PCI in large coronary arteries without long lesions.

Do Drug-Eluting Stents Remain Superior to Bare Metal Stents in Patients with Acute Myocardial Infarction after 3 Years of Follow-Up?

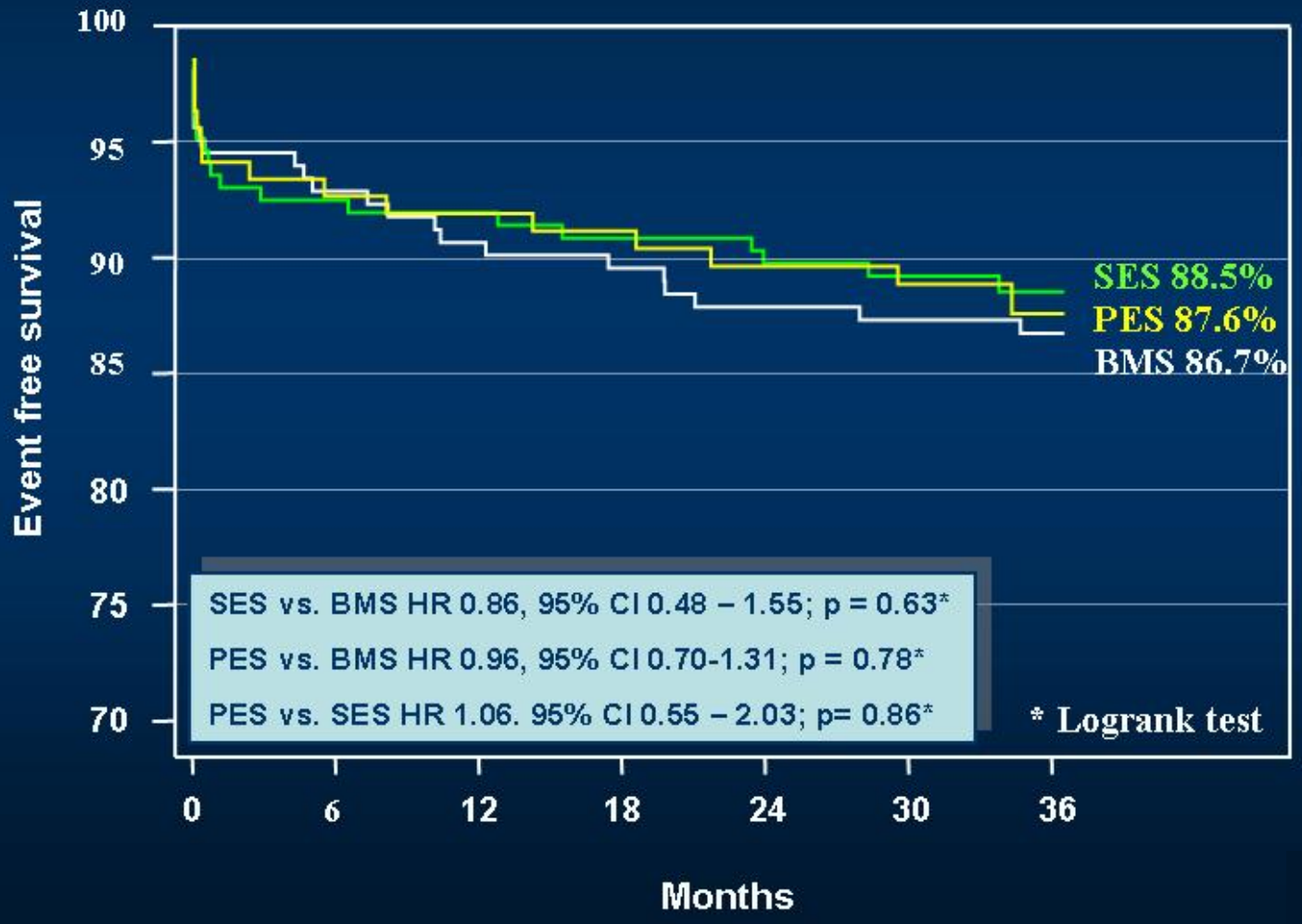
Insights into the RESEARCH and T-SEARCH registries

Inclusion period

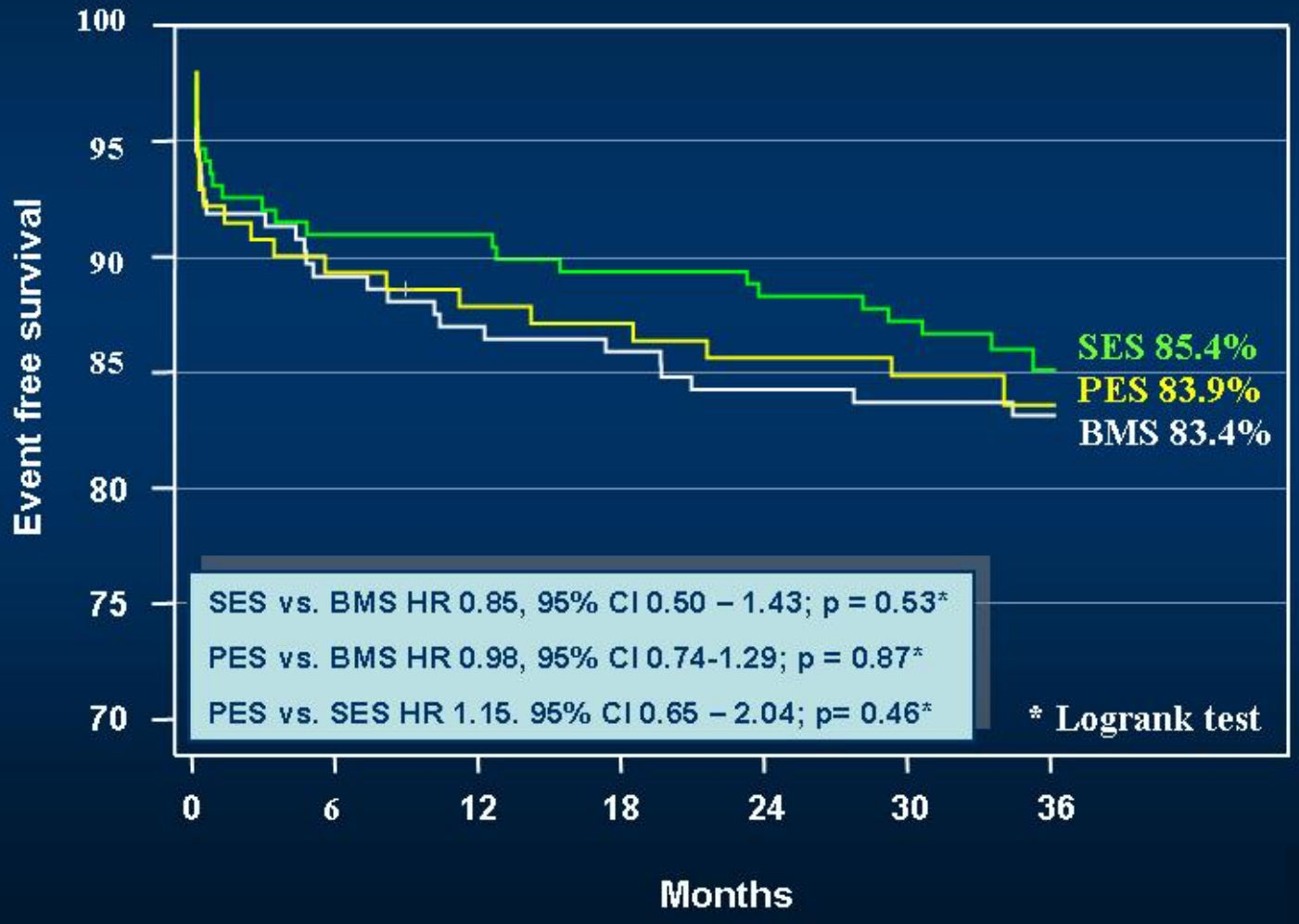


505 consecutive patients treated with primary PCI for ST-segment myocardial infarction

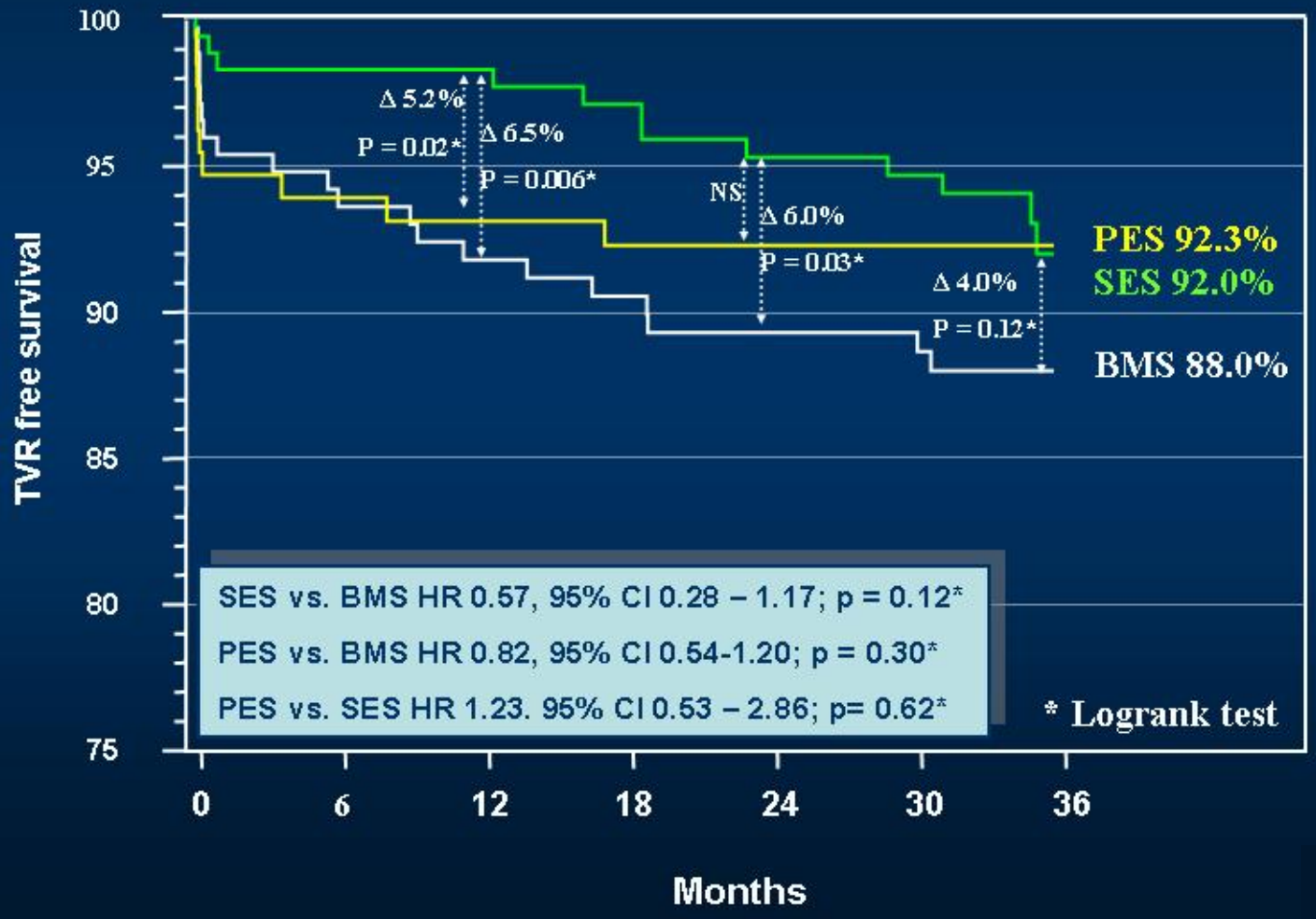
All cause mortality



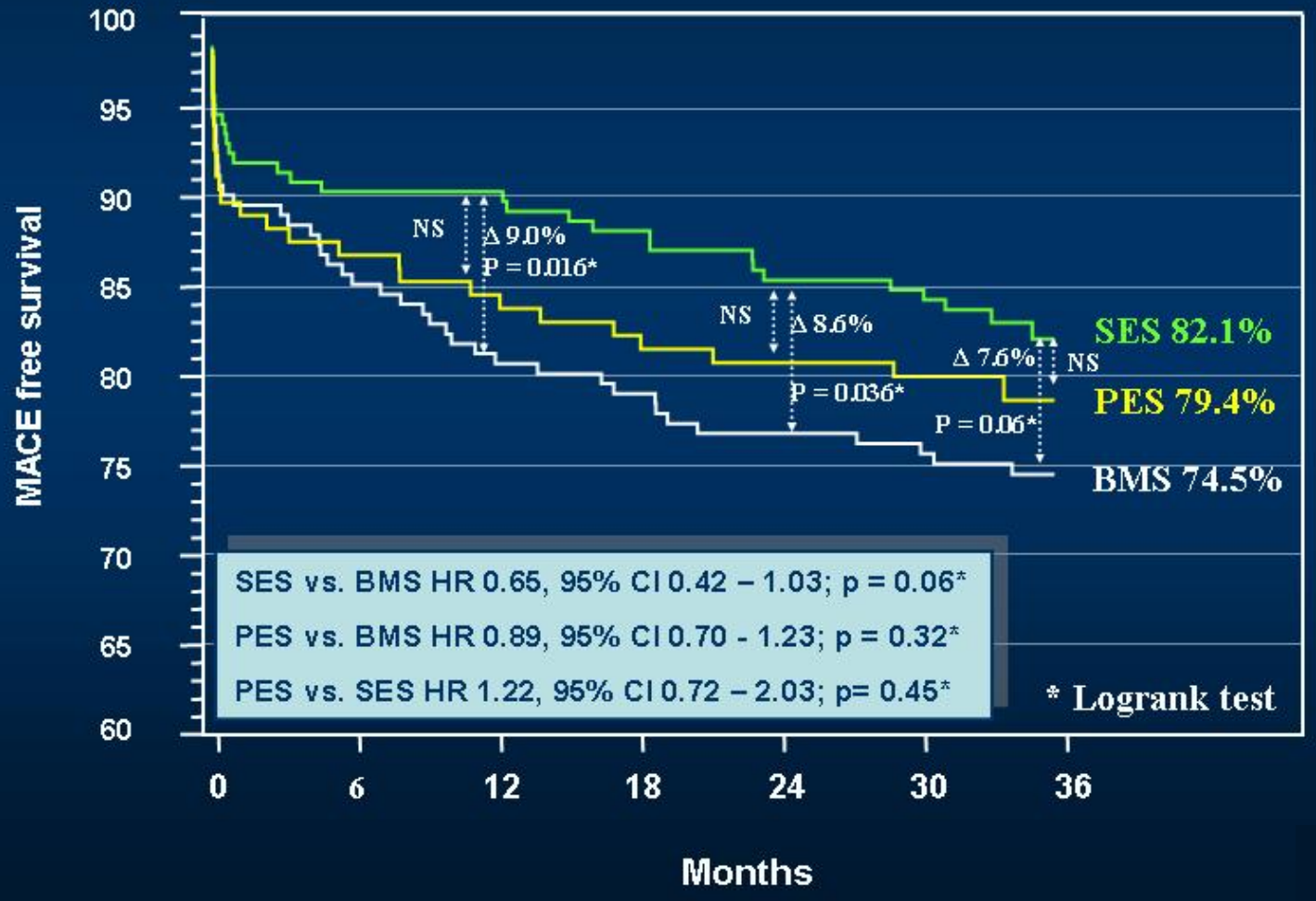
All cause mortality or MI



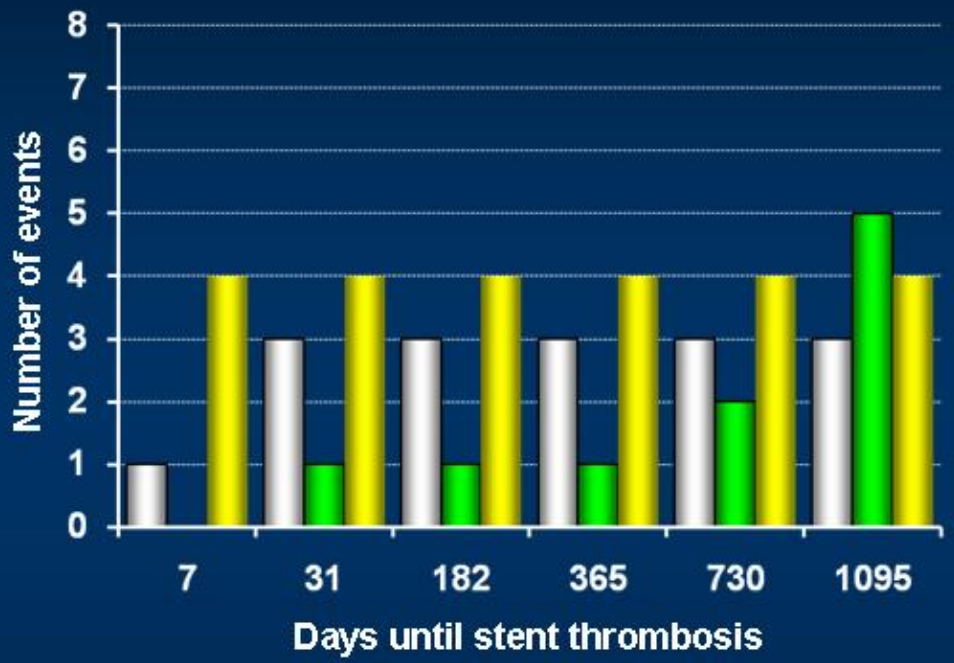
TVR

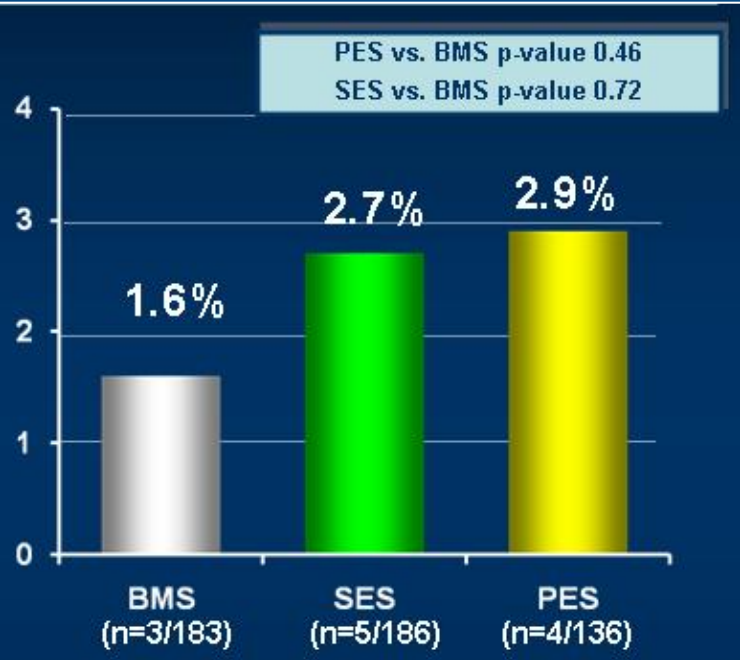

100
95
90
85
80
75
TVR free survival
0
6
12
18
24
30
36
Months
Δ 5.2%
P = 0.02*
Δ 6.5%
P = 0.006*
NS
Δ 6.0%
P = 0.03*
Δ 4.0%
P = 0.12*
PES 92.3%
SES 92.0%
BMS 88.0%
SES vs. BMS HR 0.57, 95% CI 0.28 – 1.17; p = 0.12*
PES vs. BMS HR 0.82, 95% CI 0.54-1.20; p = 0.30*
PES vs. SES HR 1.23. 95% CI 0.53 – 2.86; p= 0.62*
* Logrank test

MACE


MACE free survival
100
95
90
85
80
75
70
65
60
0
6
12
18
24
30
36
Months
NS
Δ 9.0%
P = 0.016*
NS
Δ 8.6%
P = 0.036*
Δ 7.6%
NS
P = 0.06*
SES 82.1%
PES 79.4%
BMS 74.5%
SES vs. BMS HR 0.65, 95% CI 0.42 – 1.03; p = 0.06*
PES vs. BMS HR 0.89, 95% CI 0.70 - 1.23; p = 0.32*
PES vs. SES HR 1.22, 95% CI 0.72 – 2.03; p= 0.45*
* Logrank test

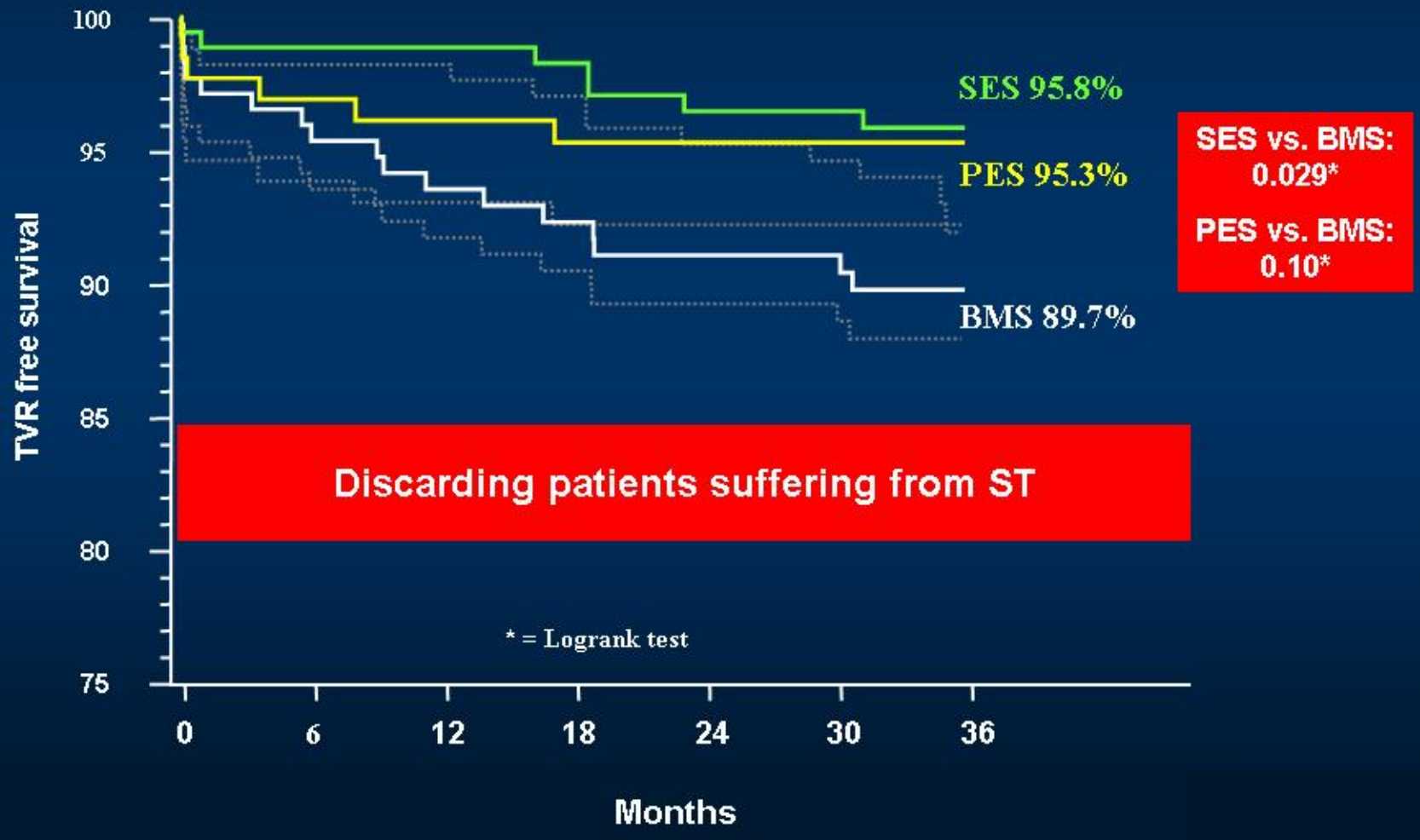
Stent thrombosis



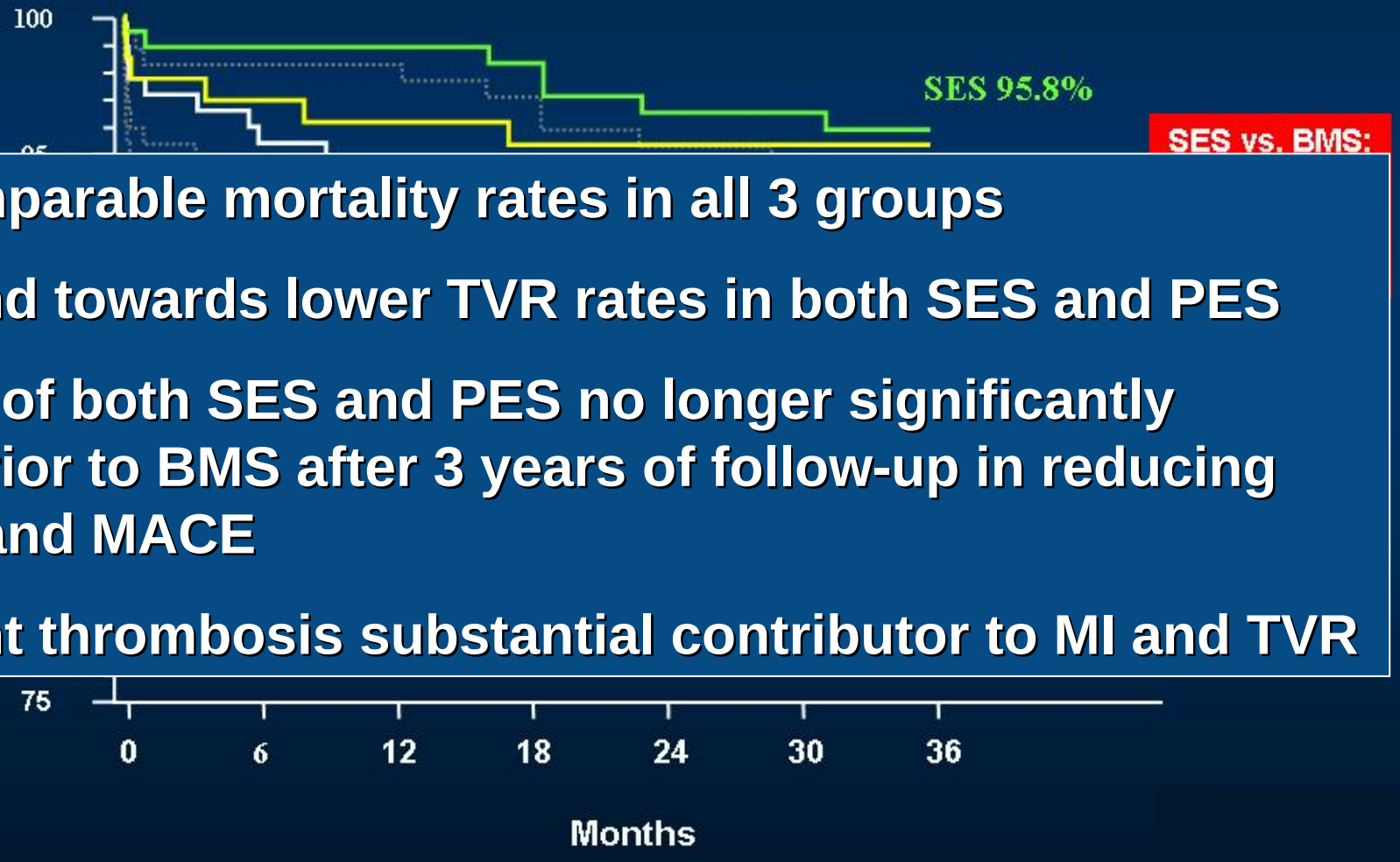


- All 3 BMS patients on dual antiplatelet therapy at time of ST
- Three SES patients on single antiplatelet therapy with aspirin, 1 on dual antiplatelet therapy and 1 patient stopped aspirin 2 days before the event
- All 4 PES patients on dual antiplatelet therapy at time of ST

Cumulative incidence of TVR



Cumulative incidence of TVR



- Comparable mortality rates in all 3 groups
- Trend towards lower TVR rates in both SES and PES
- Use of both SES and PES no longer significantly superior to BMS after 3 years of follow-up in reducing TVR and MACE
- Stent thrombosis substantial contributor to MI and TVR

Drug-Eluting Stents in Acute MI
- Summary-

- DES in AMI are feasible and safe.
- Rapid restoration of blood flow by primary PCI per se is more important for the clinical course after STEMI than the reduction of in-stent restenosis.
- Although the randomized studies performed so far have limitations regarding study designs, these initial findings support the use of DES in STEMI.
- Nevertheless, there is a tendency for physicians to select a BMS rather than a DES in STEMI patients.
- One of the possible reasons may be that in STEMI patients, it is difficult to rule out our circumstances limiting the long-term intake of clopidogrel.

Drug-Eluting Stents in Acute MI
- Summary-

Innovation is needed to overcome the stent problems:

stent thrombosis, restenosis

- Different coatings (e.g. „pro-healing“ strategies)
- New polymers
- Bioabsorbable stents
- New antiplatelet strategies (prolonged therapy?)
- New antiplatelet drugs (minimise drug resistance)
- More selective use of DES (avoid „off-label“)