

Impact of DES in STEMI

The Minneapolis Heart Institute

Level 1 MI Program



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Tim Henry, MD
Director of Research
Minneapolis Heart Institute Foundation

“MHI Level 1 MI” Program

- Based on the Trauma system
- Pilot program 2002, current program 2003
- Goals
 - **Standardize care**
 - **Improve outcomes**
 - **Research network of community/rural hospitals**
 - **Implementation of new data**
 - **Quality improvement program**
- To allow safe transfer of STEMI pts for Primary or Facilitated PCI, with a door (1st medical contact) to balloon time <120 min.

Level 1 MI Program

- STEMI diagnosis by emergency MD
- Single phone call to activate system
- Currently 30 hospitals trained
- 1121 consecutive patients over 39 months (528 Zone 1, 333 Zone 2, 260 AN)
- Currently 50+ patients/month
- **Inclusion:** STEMI < 24 hours or New LBBB
- **Exclusion:** None (including out-of-hospital cardiac arrest and cardiogenic shock)

Protocol focus:

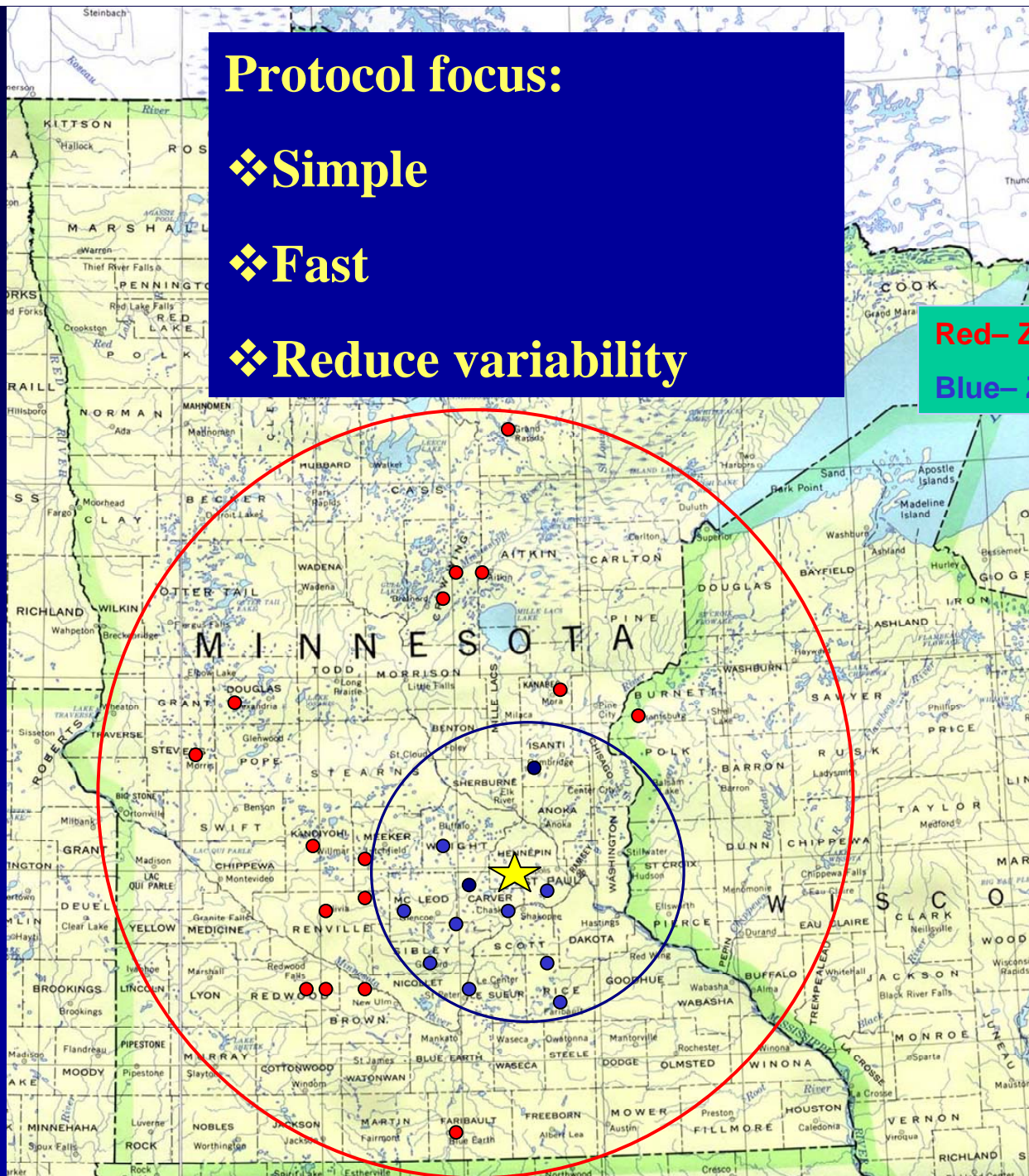
❖ Simple

❖ Fast

❖ Reduce variability

Red— Zone II (90-120 mins)

Blue— Zone I (< 90 mins)



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Demographics

N=1121

- Age: Median = 62
 $\geq 65 = 42.2\%$, $\geq 80 = 14.3\%$
- Sex: Male 72%
- Diabetes: 15%
- HTN: 54%
- Smoking: 63% (current 39%)
- Previous MI: 17%
- Previous revascularization: 18%
- Cardiogenic shock: 12%
- Cardiac Arrest: 10%
- Required ET intubation prior to PCI: 7%

Mortality (n=1121)

	Total	CV related
In hospital	45 (4.0%)	44 (3.9%)
30 day	53 (4.7%)	45 (4.0%)
1 year*	56 (7.6%)	39 (5.8%)

*Pts. with 1 year complete follow up included

Objective

1. Determine the % of Patients with STEMI who present with Stent Thrombosis
2. Determine the safety and efficacy of the use of DES in STEMI compared to BMS

The Changing Face of ST-elevation Myocardial Infarction

Trends in the Drug-Eluting Stent Era

Joseph A. Browning, M. Nicholas Burke, Katie M.
Menssen, Marc C. Newell, Michael R. Mooney, Daniel
L. Lips, Gabriela Vazquez-Benitez, Sue Duval, Timothy
D. Henry



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Methods

- 1177 consecutive STEMI patients from the MHI Level 1 Transfer Protocol from March 2003 to August 2006
- 218 patients with prior PCI
- 54 patients had a culprit lesion within a previously placed stent.
- Review of medical record to determine stent type and date of deployment, as well as clinical characteristics.

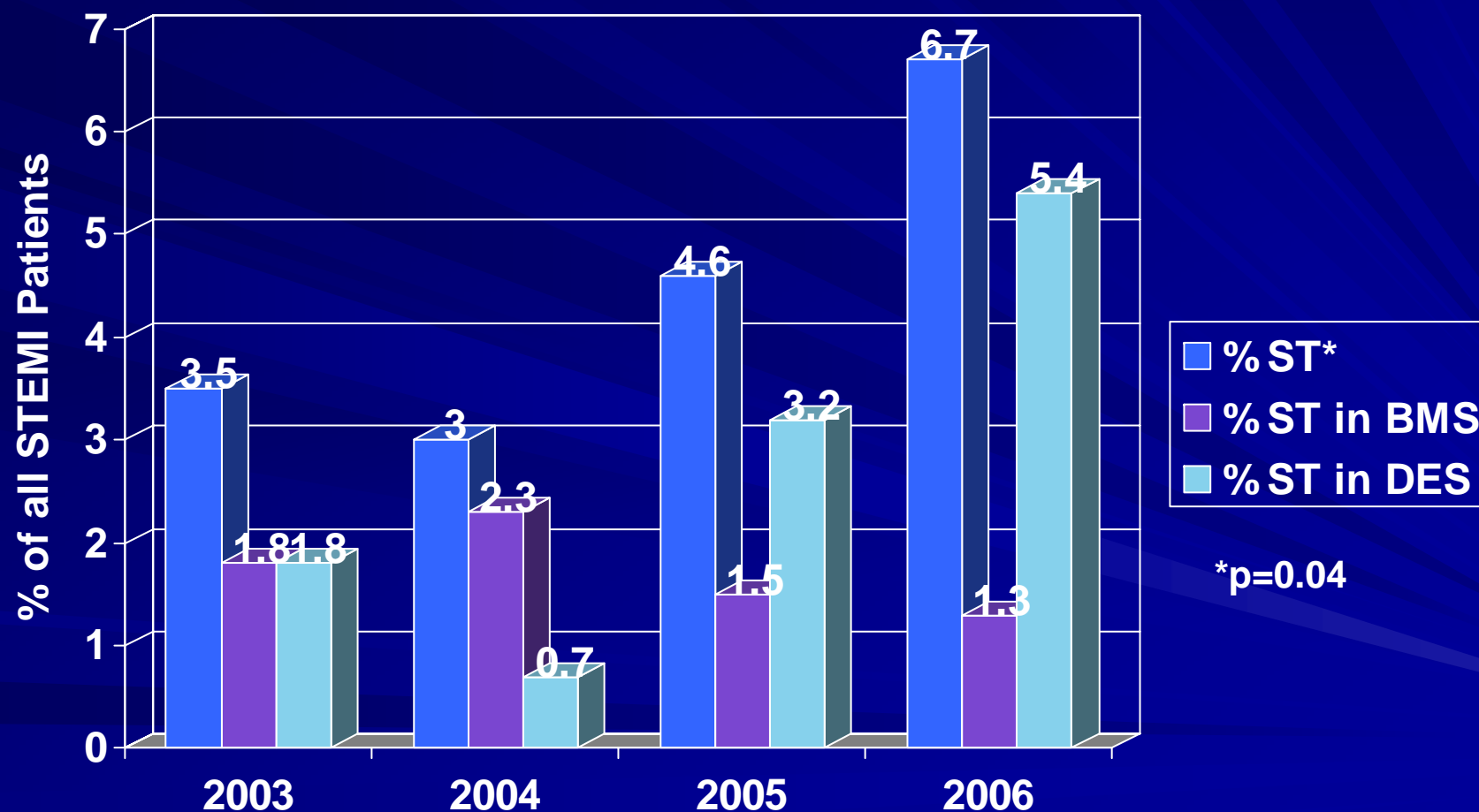
Results

Year	# Stent Thrombosis*	# ST in BMS	# ST in DES
2003 N=171 (%)	6 (3.5)	3 (1.8)	3 (1.8)
2004 N=298 (%)	9 (3.0)	7 (2.3)	2 (0.7)
2005 N=411 (%)	19 (4.6)	6 (1.5)	13 (3.2)
2006 N=297 (%)	20 (6.7)	4 (1.3)	16 (5.4)

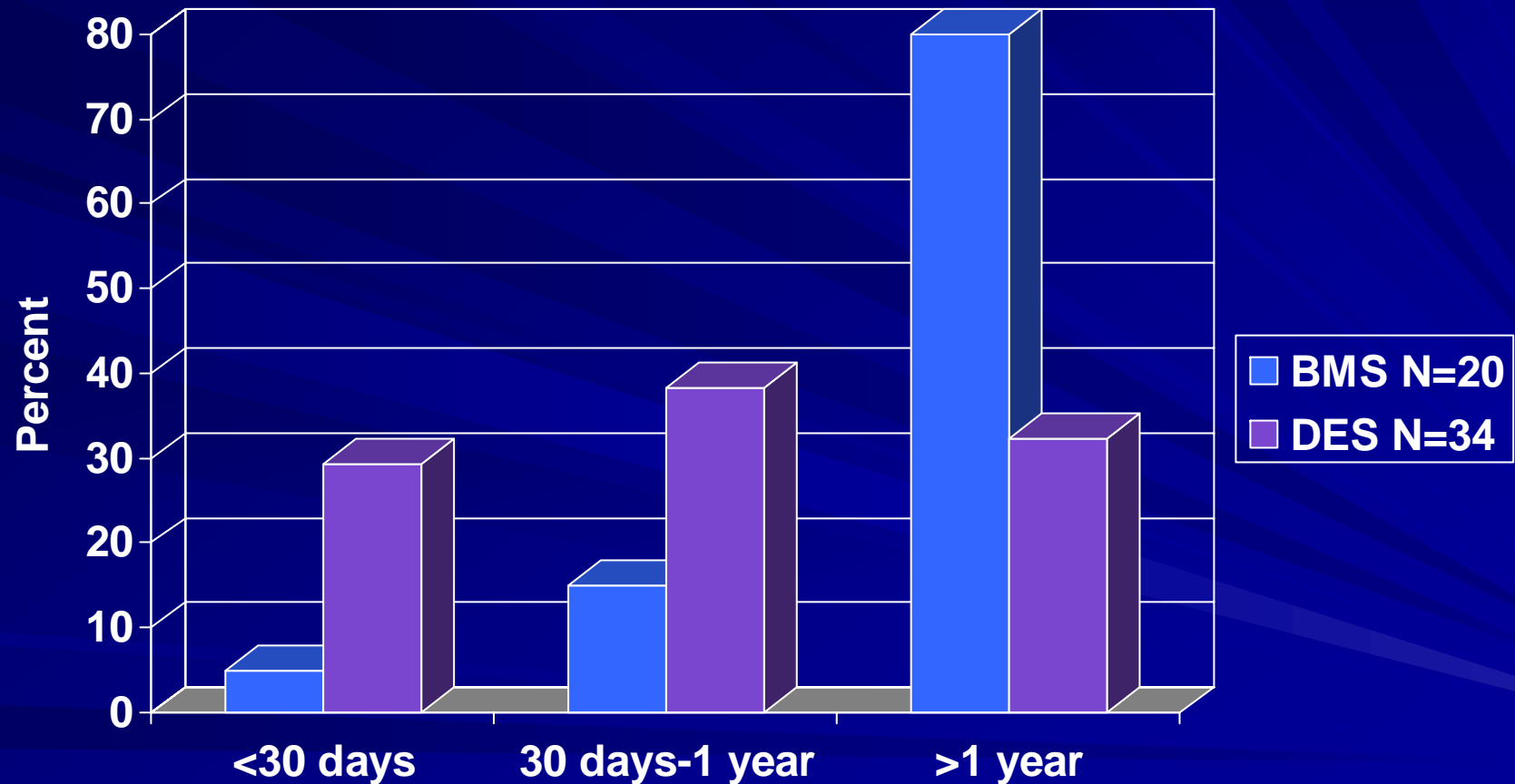
*p=0.04 for increase over time

STEMI due to Stent Thrombosis

(angiographic evidence of occlusion in a previously placed Stent)



Timing of Stent Thrombosis



Mortality

■ 30-day mortality:

- STEMI due to ST: 1.9%
- STEMI *not* due to ST: 4.8%

Conclusions

- The % of pts with STEMI due to stent thrombosis has significantly increased from 2003-2006.
- Stent thrombosis occurs in pts with both BMS and DES but the timing and pathophysiology is different.
- In contrast to previous reports, mortality of pts with STEMI due to stent thrombosis is lower than those without stent thrombosis.

Long-term Outcomes of Drug-Eluting and Bare Metal Stents in ST-elevation Myocardial Infarction

Joseph A. Browning MD, Andrey G. Zenovich MSc, Katie M. Menssen, Marc C. Newell MD, Christopher R. Henry, Michael M. Mooney MD, Daniel L. Lips MD, Jay H. Traverse MD, David M. Larson MD, Timothy D. Henry MD



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Methods

- 858 consecutive patients with STEMI treated with Primary PCI via the MHI Level 1 MI protocol from March 2003 to August 2006.
- Stent type and IIb/IIIa inhibitor use were at the discretion of interventional physician (SES from 4/03, PES from 3/04).
- Patients were classified based on the type of stent deployed in the culprit (infarct-related) artery.

Methods

- The occurrence of major adverse cardiac events (MACE): death (all-cause), nonfatal myocardial infarction, target lesion revascularization (TLR) and stent thrombosis were assessed in hospital, 30 days, one year, and beyond.
- Stent thrombosis defined as any of following:
 - Clinical presentation of ACS with angiographic evidence.
 - Nonfatal reinfarction in distribution of treated vessel.
 - Death without other identifiable cause.
- Patients will be followed for 5 years

Patient Presentation

	BMS N=157	SES N=224	PES N=477	p-value (group)	p-value (PES & SES)
Male (%)	104 (66.2)	166 (74.1)	358 (75.1)	0.09	0.79
Age (Mean yrs ± SD)	66.5±14.5	60.9±13.5	61.3±13.9	<0.001	0.75
Current Tobacco Use (%)	63 (40.4)	100 (44.8)	201 (42.2)	0.67	0.52
Hypertension (%)	94 (59.9)	118 (52.9)	255 (53.5)	0.32	0.89
Dyslipidemia (%)*	74 (49.3)	133 (61.3)	279 (63.3)	0.01	0.62
BMI (mean±SD)	28.7±6.7	28.4±5.1	29.0±5.5	0.43	0.19
Diabetes (%)	27 (17.3)	29 (13.0)	82 (17.2)	0.32	0.15

* Data missing on 50 patients: 7 BMS, 7 SES, 36 PES

Patient Characteristics

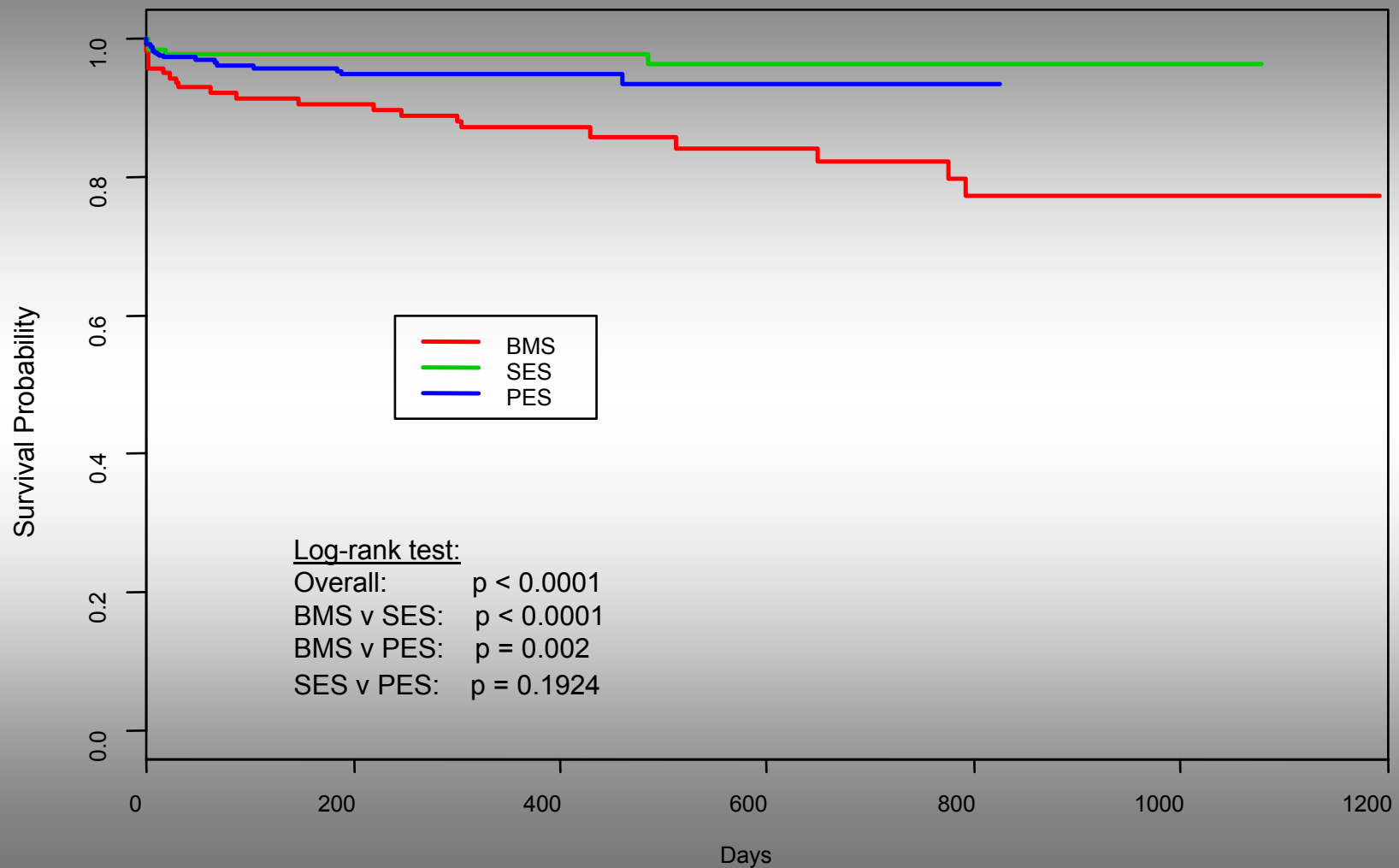
	BMS N=157	SES N=224	PES N=477	p-value (group)	p-value (PES & SES)
Cardiogenic Shock (%)	27 (17.2)	28 (12.5)	49 (10.3)	0.07	0.38
Cardiac Arrest (%)	24 (15.3)	24 (10.7)	36 (7.5)	0.17	0.17
Killip Class (mean±SD)	1.52±1.14	1.41±0.94	1.34 ±0.92	0.14	0.41
EF (Mean %±SD)	47±0.13	47±0.12	48±0.12	0.79	0.84
Peak CK (Mean±SD)	1764±2085	1522±1630	1627±3945	0.10	0.25
Peak TnT (Mean±SD)	3.96±5.28	3.01±3.92	3.52±7.26	0.38	0.35
Creatinine Clearance (Mean ± SD)	81.8±43.0	89.3±37.8	90.1±37.9	0.10	0.80

Event Rates

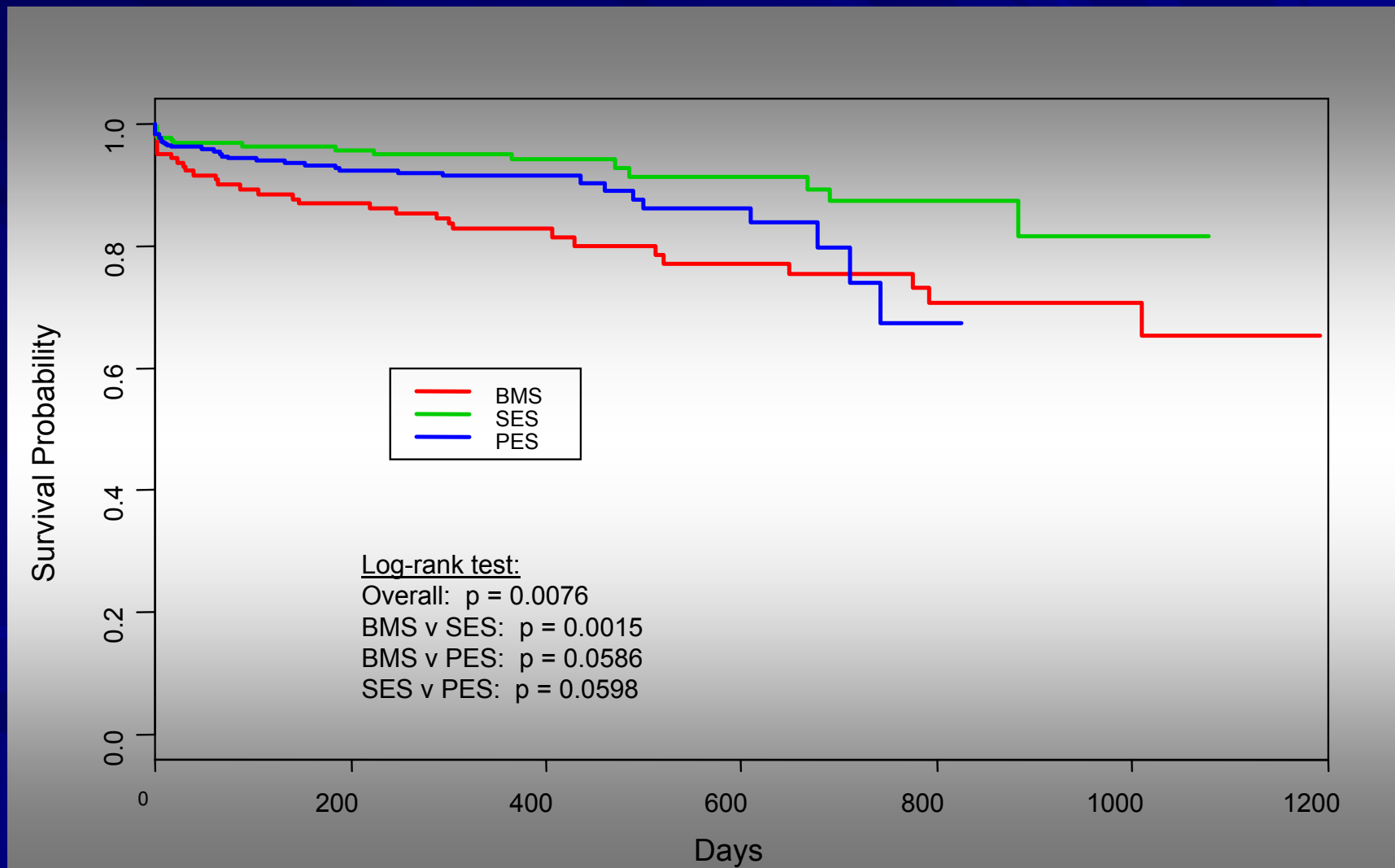
	BMS N=157	SES N=224	PES N=477	p-value (group)*	p-value (PES & SES)*
Mortality					
30 Day	7.1%	2.3%	2.8%	<0.001	0.19
1 Year	12.9%	2.3%	5.3%		
MACE					
30 Day	7.7%	3.2%	3.9%	0.001	0.03
1 Year	17.2%	5.8%	8.6%		
Stent Thrombosis					
30 Day	1.33%	0.9%	1.95%	0.01	0.009
1 Year	1.33%	0.9%	3.7%		

* Derived from log-rank test.

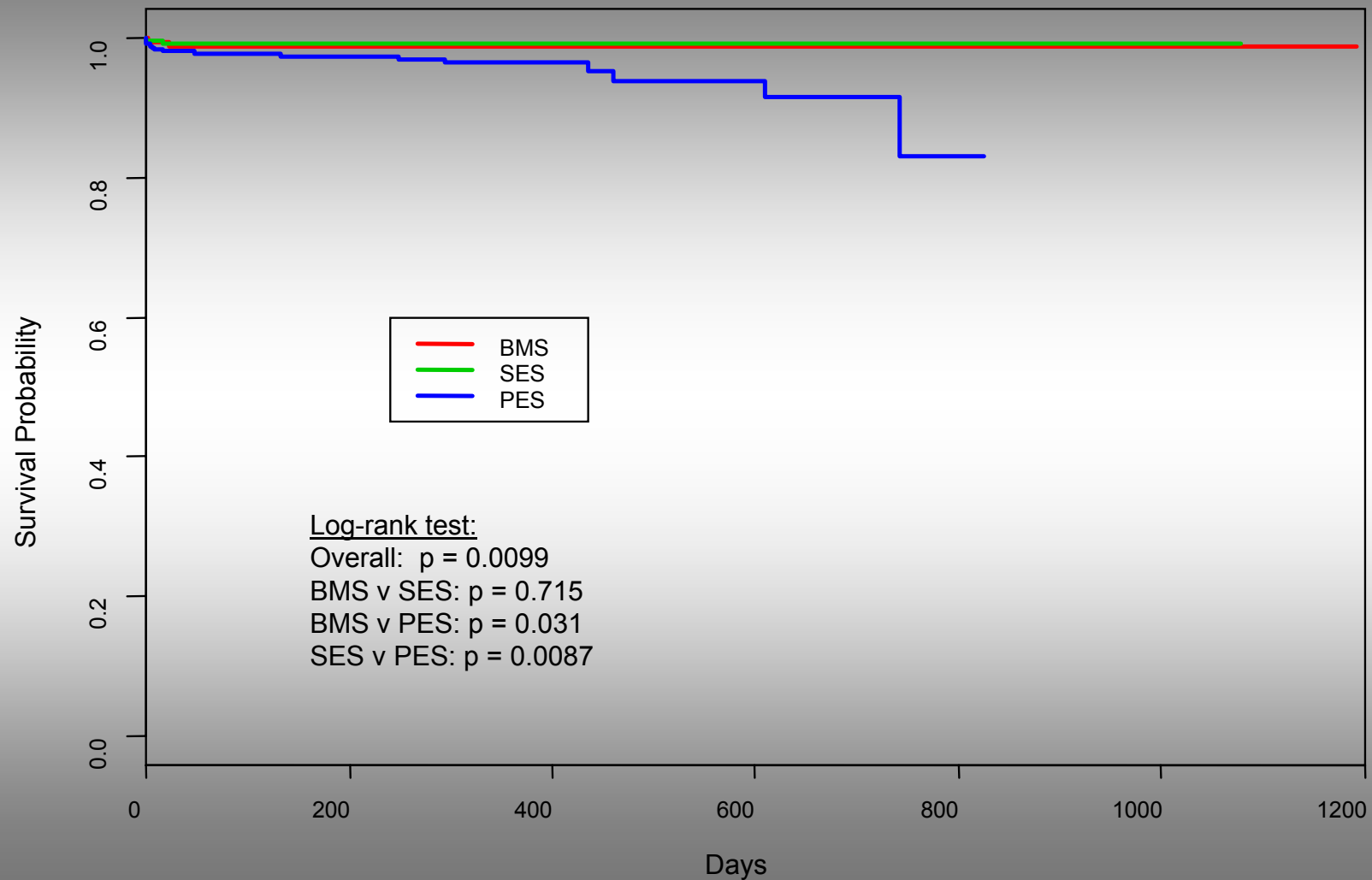
Kaplan-Meier Curve: Mortality



Kaplan-Meier Curve: MACE



Kaplan-Meier Curve: Stent Thrombosis



Propensity Analysis

- **For predictors of propensity, the following covariates were included:**
 - Gender
 - Age
 - Current tobacco use
 - Hypertension
 - Hyperlipidemia
 - Diabetes
 - Cardiogenic shock
 - Cardiac Arrest
 - Facilitated PCI
 - Peak creatinine
 - Killip class
 - BMI
 - Ejection Fraction
- **Due to missing data on some patients, a reduced cohort of 747 patients were used for propensity analysis. This affected the outcomes numerically, but not qualitatively.**

Event Rates Adjusted by Propensity Scores

Mortality

Comparison	Hazard Ratio	p-value
SES vs. BMS	0.26	0.03
PES vs. BMS	0.85	0.43
PES vs. SES	3.30	0.49

MACE

Comparison	Hazard Ratio	p-value
SES vs. BMS	0.45	0.03
PES vs. BMS	0.90	0.48
PES vs. SES	2.11	0.04

Stent Thrombosis

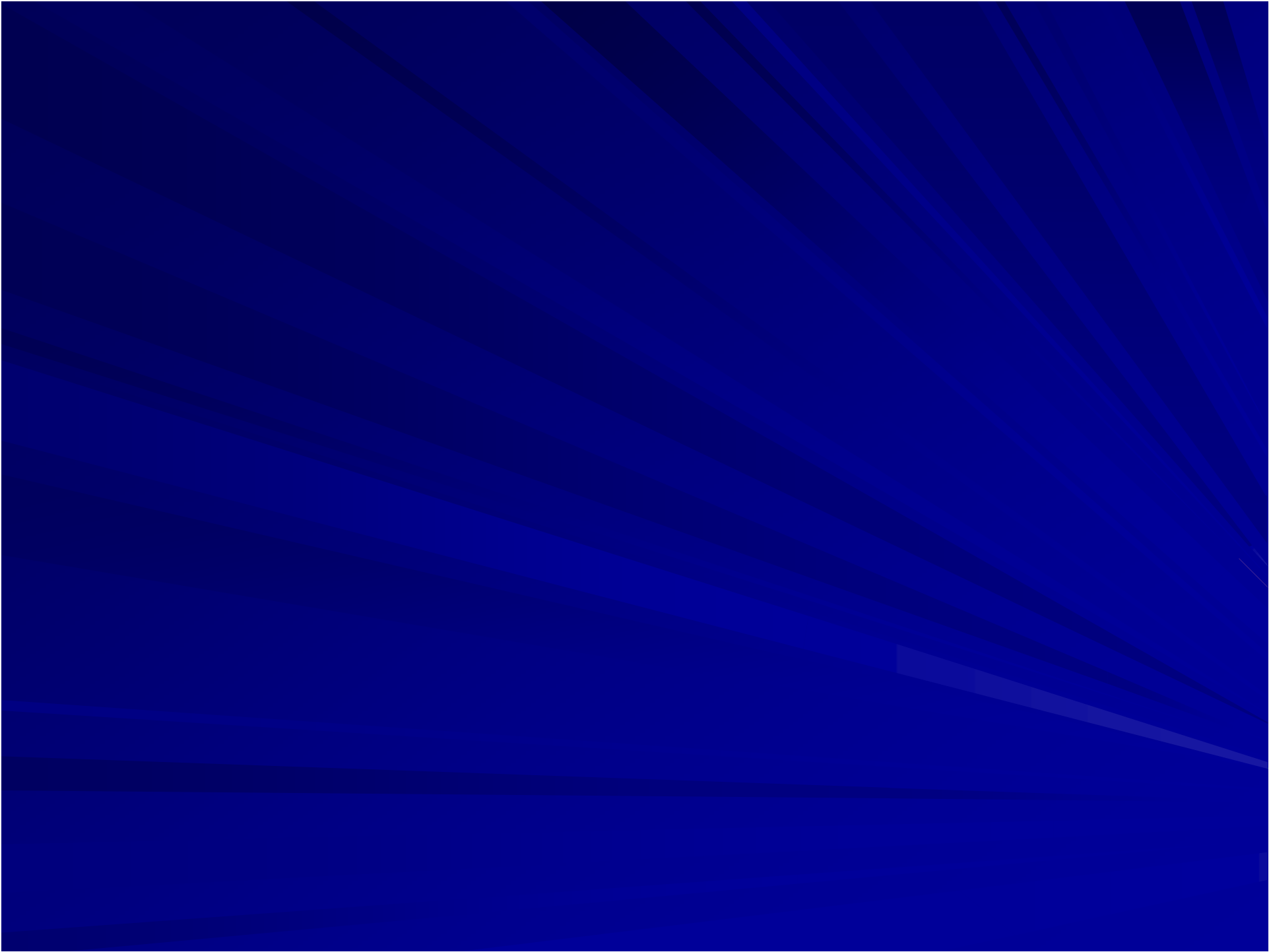
Comparison	Hazard Ratio	p-value
SES vs. BMS	0.69	0.72
PES vs. BMS	1.77	0.12
PES vs. SES	4.50	0.03

Caveats

- Non-randomized, with significant baseline differences among the groups.
- Patients receiving BMS were higher risk relative to patients receiving DES, which may influence outcomes.
- Propensity analysis may not control for all variables.

Conclusions

- DES reduce all-cause mortality when compared with BMS in STEMI.
- DES use in patients with STEMI reduces the rate of MACE when compared with BMS.
- Stent thrombosis was significantly higher in PES compared to SES and BMS.
- After adjusting for propensities, SES significantly improved mortality and MACE over BMS and PES.
- After adjusting for propensities, PES was not significantly better than BMS in any outcomes studied.



Objectives

- Determine if the percentage of patients with stent thrombosis as a cause for STEMI is increasing over time.
- Evaluate clinical and angiographic characteristics of those with stent thrombosis to determine potential predictors of stent thrombosis.

Background-1

- The overall number of ST-elevation MIs is decreasing.
 - Statin use
 - Antiplatelet therapy
- Increase in DES use over BMS
- Concern over increased risk of stent thrombosis (ST) in DES vs. BMS.
- Timing and characteristics of stent thrombosis continues to be controversial.

Background-2

- PCI has been shown to be superior to fibrinolytics in ST-elevation myocardial infarction (STEMI).
- Bare Metal Stents (BMS) are superior to PTCA in STEMI
- Drug-eluting stents (DES) are superior to BMS in elective PCI
- This has led to widespread adoption of DES in settings in which they have not been exclusively studied, including STEMI.