Outcomes Following Coronary Stenting:
A National Study of Long Term, Real-World Outcomes of Bare-Metal and Drug-Eluting Stents

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Goal and Population

- **Goal**
  - To examine comparative effectiveness and safety of DES vs BMS in a national PCI cohort
- **Study population**
  - All PCI pts ≥ 65 yo in NCDR CathPCI 1/04-12/06
  - Follow up obtained through linkage to CMS inpatient claims data using indirect identifiers; 76% matched
- **Final cohort**
  - 262,700 pts
  - 83% DES; 46% Cypher, 55% Taxus

Analysis

- **30 month outcomes**
  - Death, MI, Stroke, Revascularization, Major bleeding
  - Overall and in important subgroups
- **Outcomes adjustments**
  - Inverse propensity weighted model (102 covariates)
  - Cox proportional hazards model (60 covariates)
- **Sensitivity analyses**
  - Results in ‘RCT-like’ population
  - Non-CV ‘cause’ of death

Patient Characteristics
DES (217,675) vs BMS (45,025)

	Unadjusted		IPW Adjusted	
	DES	BMS	DES	BMS
Age	74.5	75.3*	74.7	74.8
Female	43%	40%*	43%	43%
Caucasian	90%	91%*	90%	90%
Diabetes	32%	32%	32%	32%
Renal Failure	6%	8%*	7%	7%
Hypertension	80%	80%*	80%	81%
Prior PCI	28%	26%*	28%	28%
Prior CABG	22%	28%*	23%	23%
Urgent Status	38%	36%*	37%	38%
STEMI	10%	16%*	11%	11%

*p<0.0001 DES vs BMS

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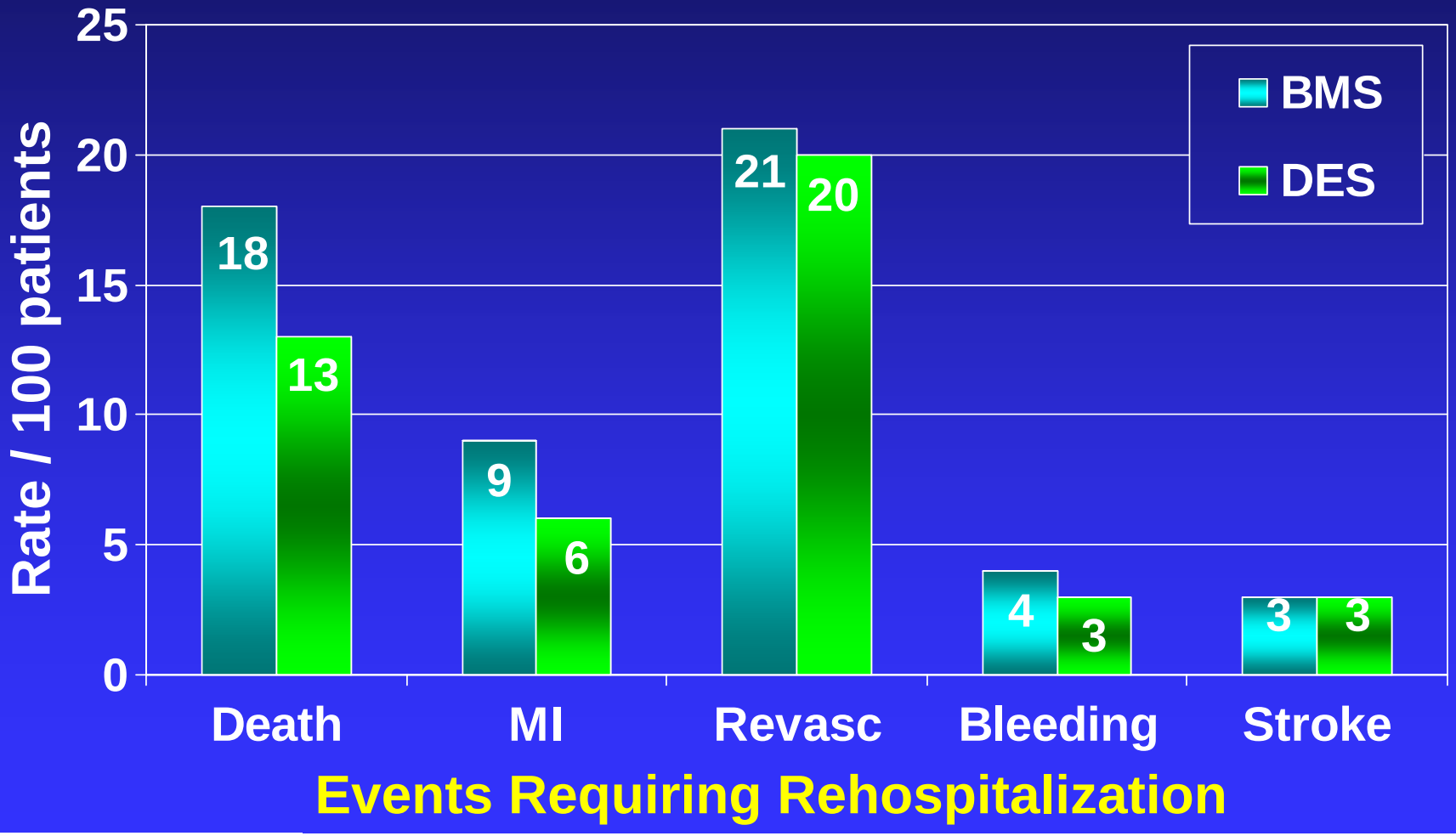
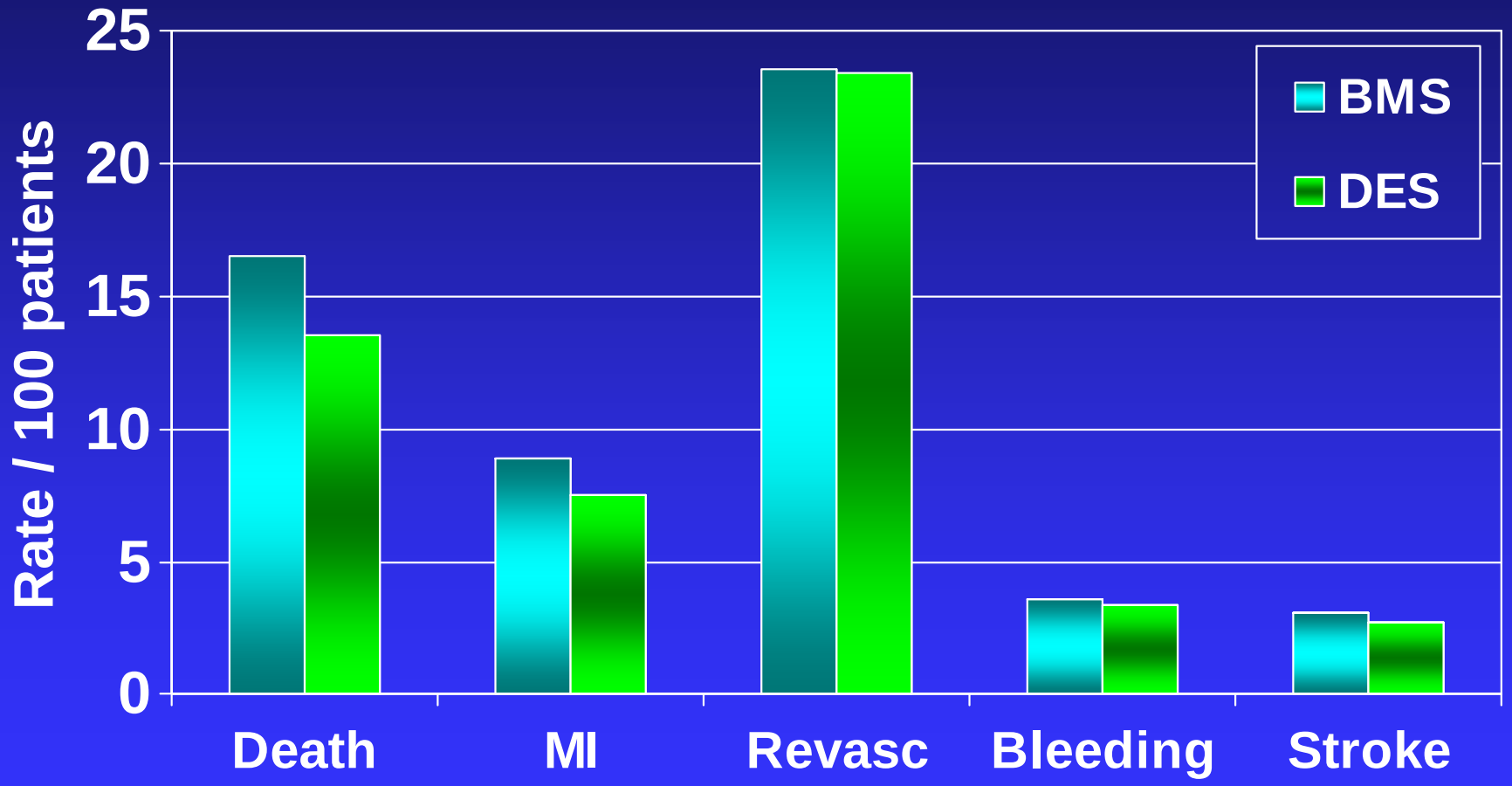
National Cardiovascular Data Registry

DES and BMS Event Rates: 30-month Unadjusted

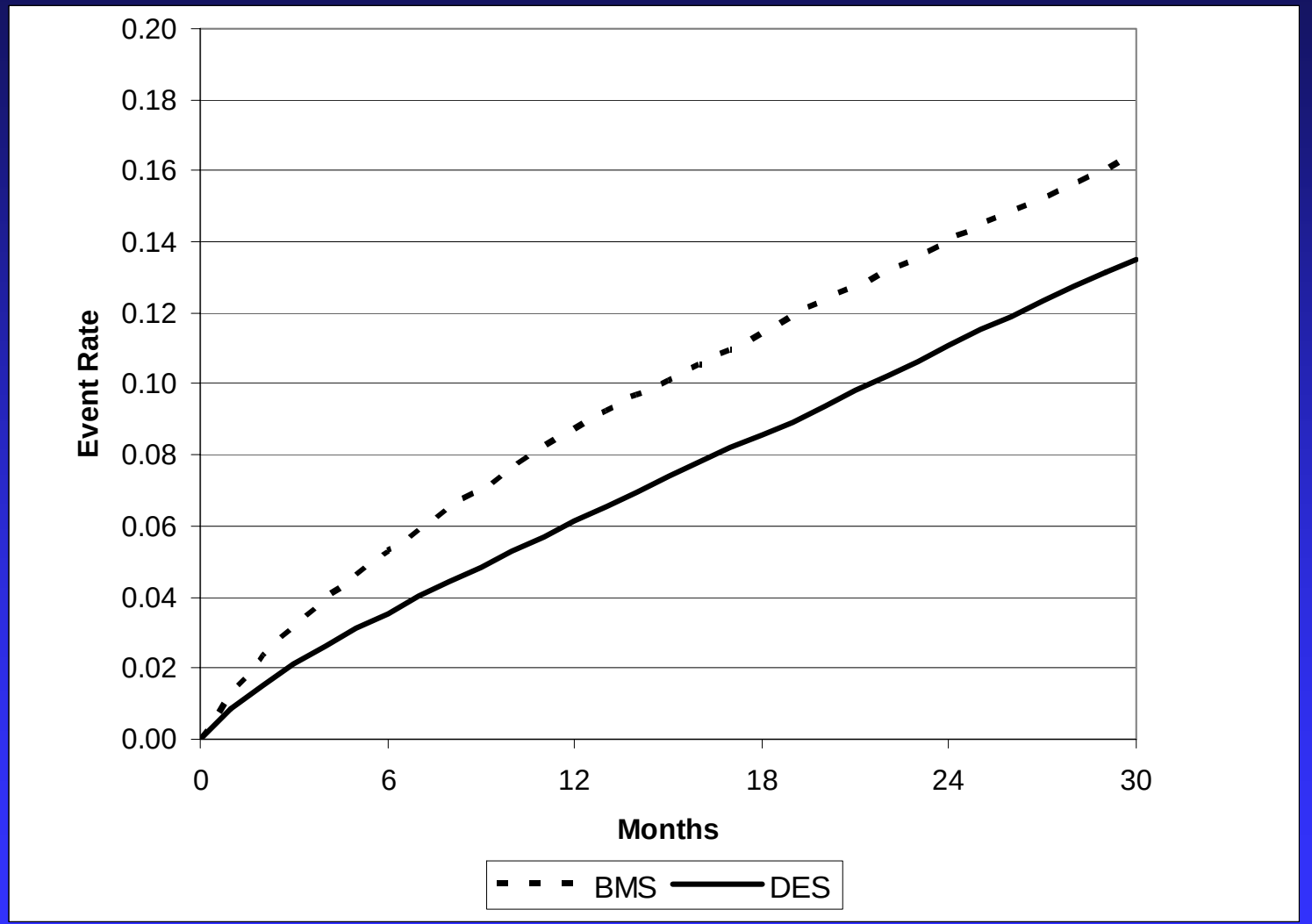


Events Requiring Rehospitalization

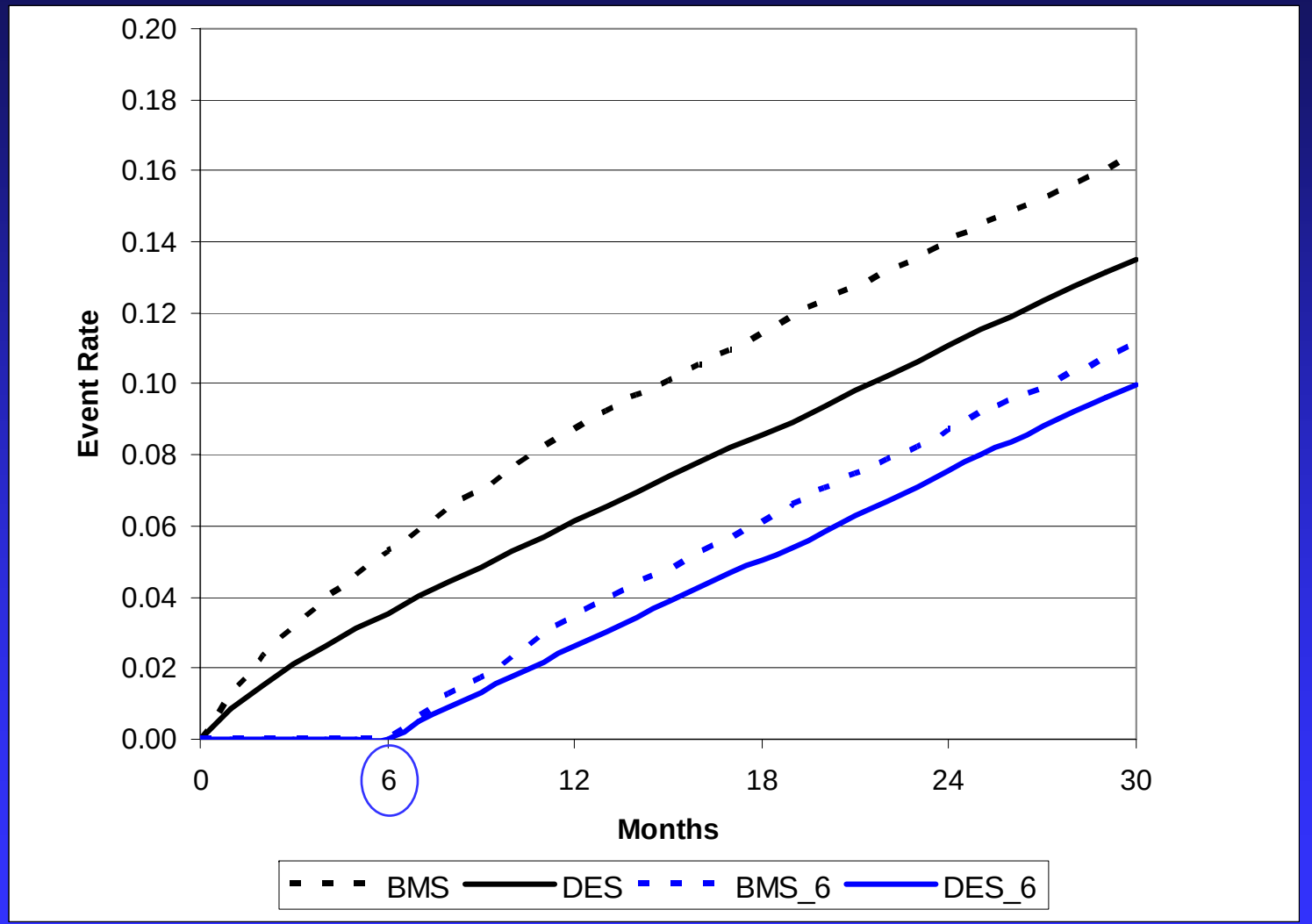
DES and BMS Event Rates: 30-month Adjusted



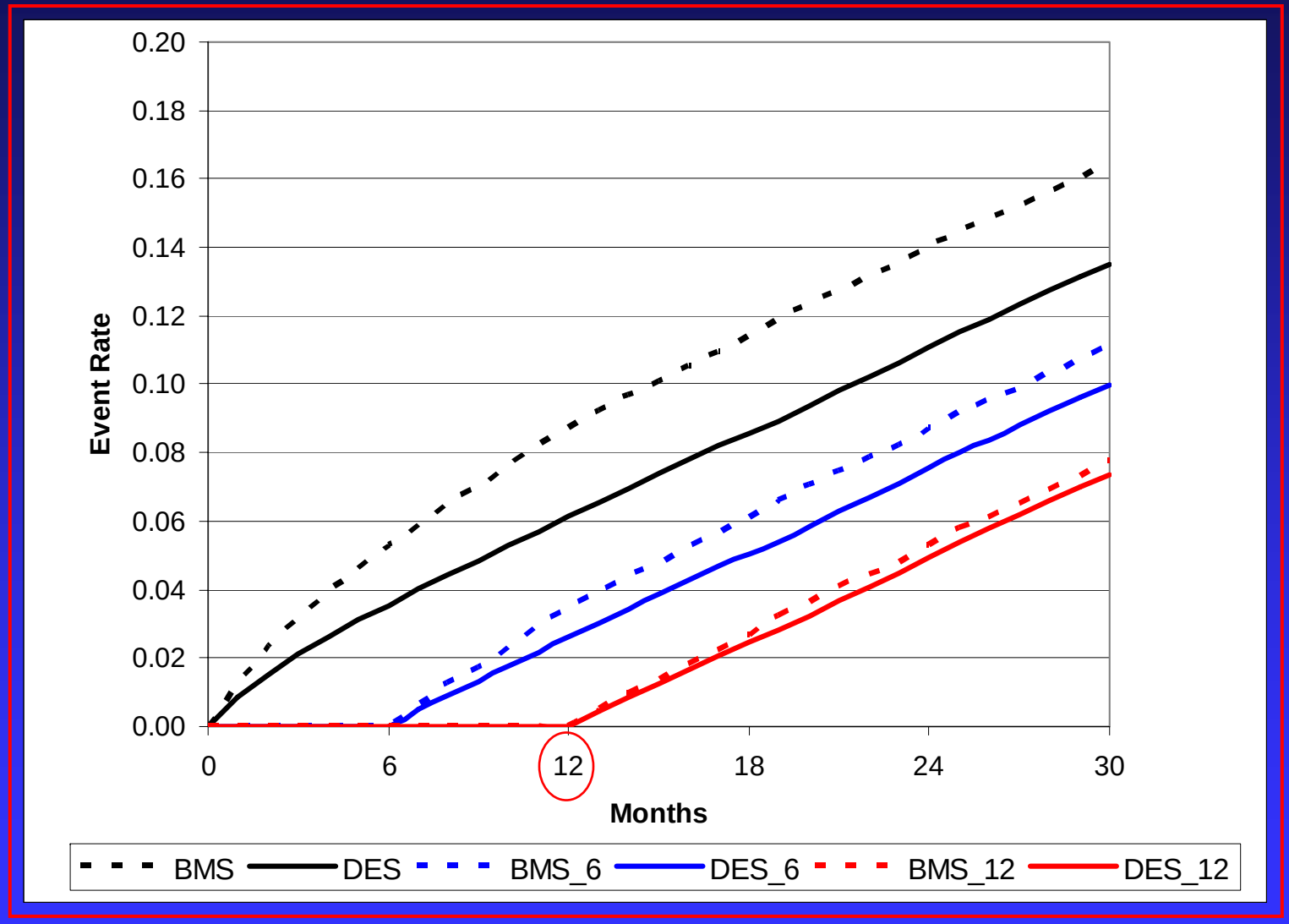
Landmark Display: Mortality



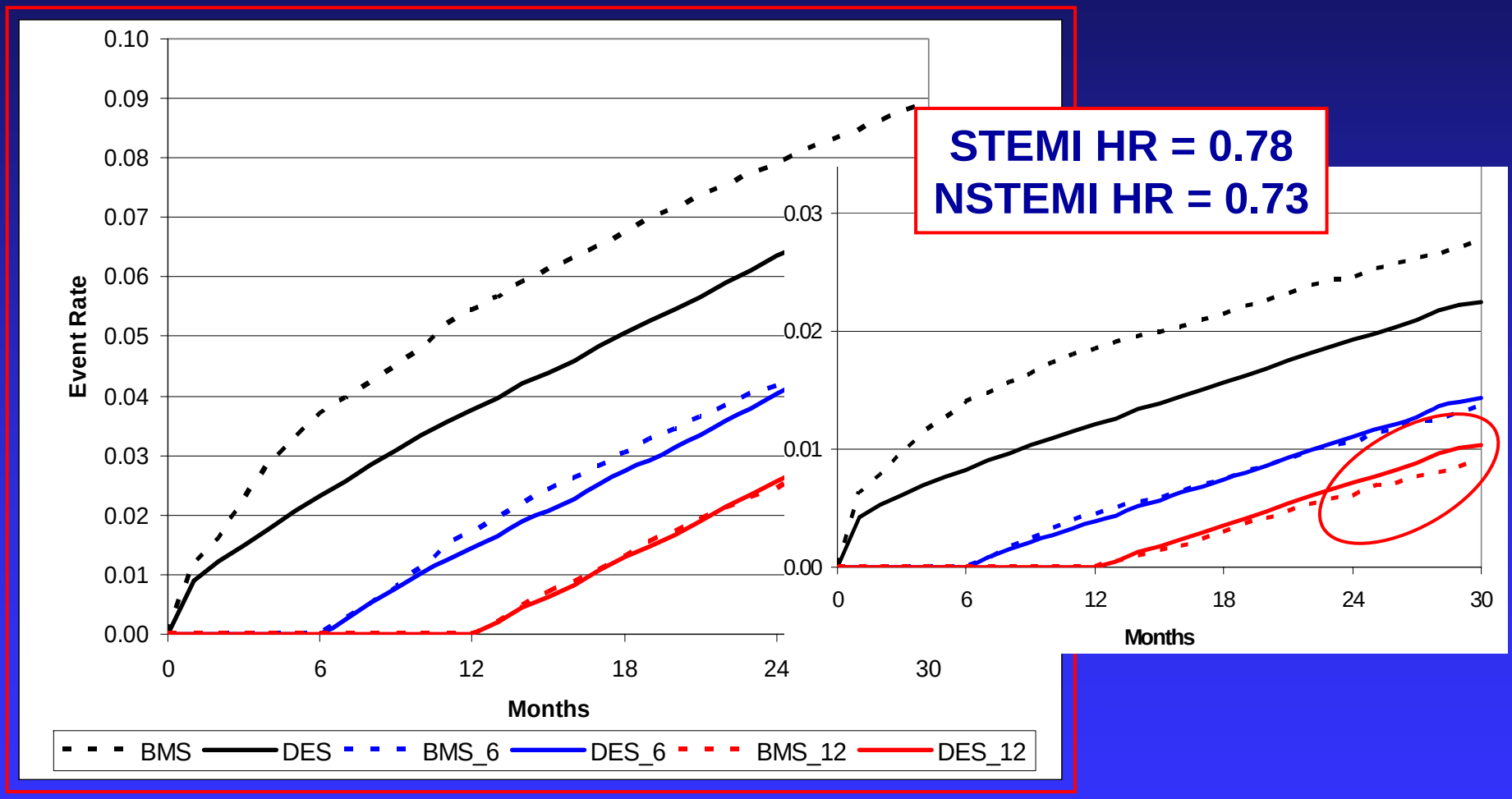
Landmark Display: Mortality



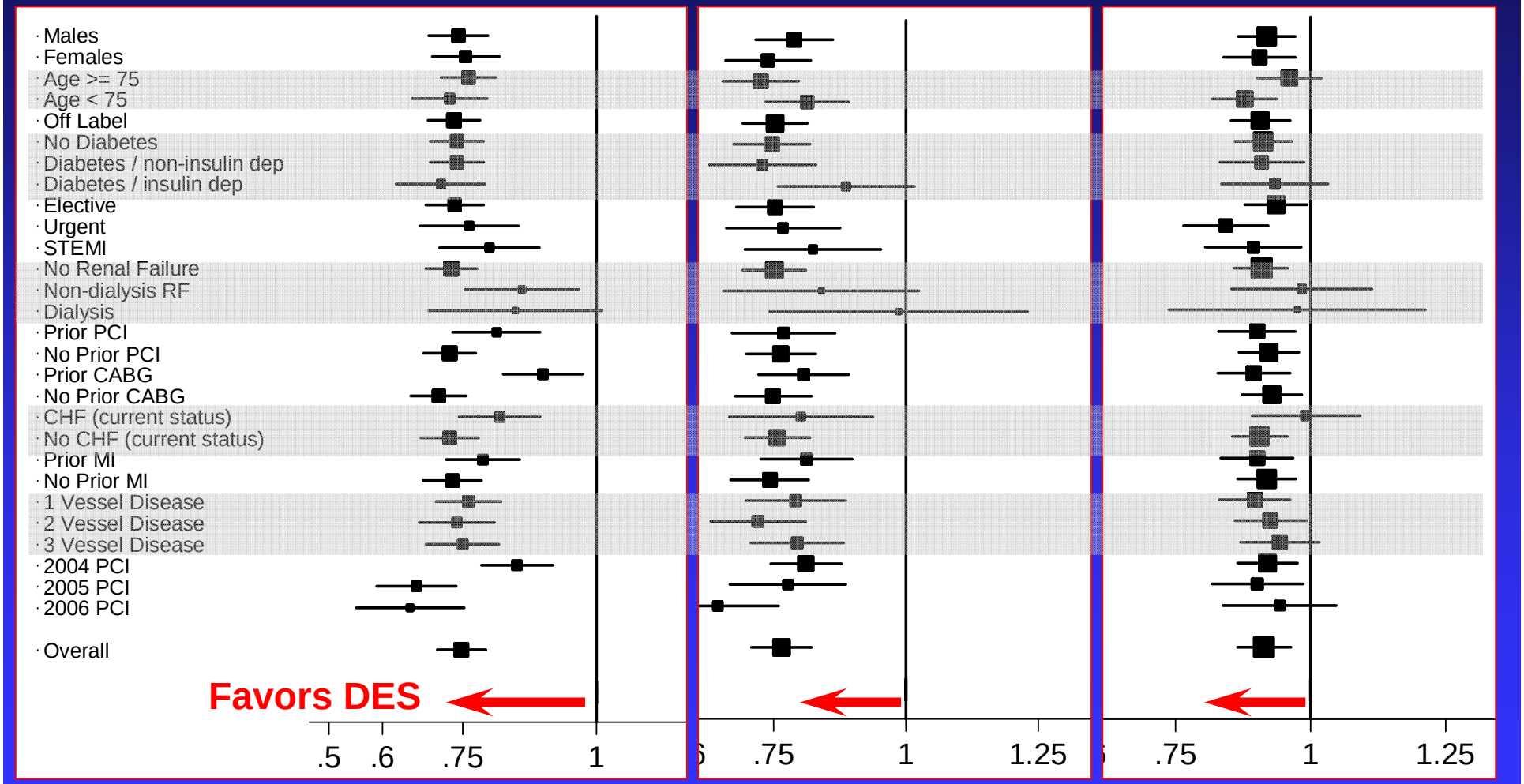
Landmark Display: Mortality



Landmark Analysis: MI

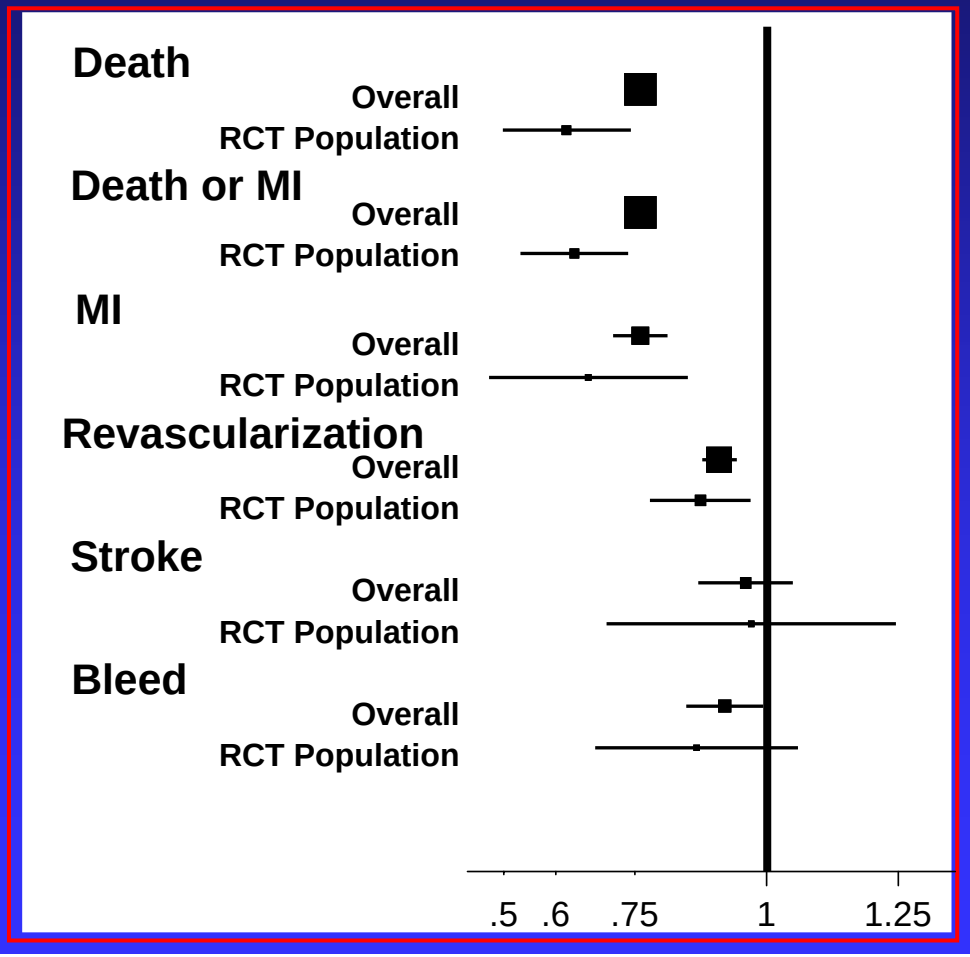


Subgroup Analyses

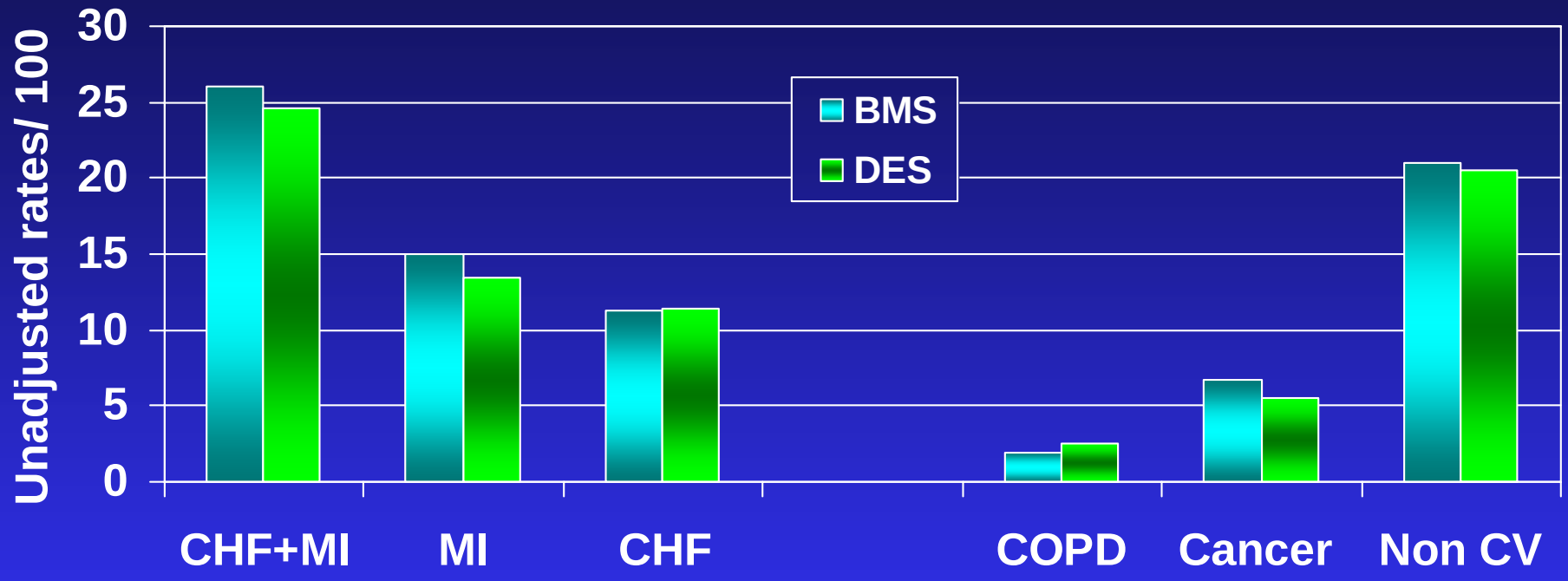


Sensitivity Analysis: Patient Selection

- RCT - like population
- N = 49,355 (19%)
- 'Inclusion' criteria
  - Elective PCI, ≤ 2 stents
  - Native vessel, de novo
  - Class A or B lesions
  - Lesion length, diameter
  - ASA, clopidogrel OK
  - No chronic renal disease



Sensitivity Analysis: Device Selection 'Cause of Death' in DES v BMS



- Using 1º hosp dx, 'cause' extracted in 90% deaths
- HR 0.80 favoring DES for CHF/MI death
- HR 0.74 favoring DES Non CV death
- 'Sicker' patients may preferentially receive BMS

Conclusions

- Linkage of clinically rich NCDR data to claims data is feasible; Data analysis allows a robust, longitudinal assessment of clinical effectiveness
- Comparing outcomes of DES to BMS at 30 mo:
  - No major DES safety concerns
  - Lower death and MI rates in DES patients
  - Slightly lower revascularization, bleeding rates
  - Similar stroke rates
- Results consistent among all patient subgroups
- Caveat: The apparent 'benefit' of DES may be affected by selection bias and unmeasured confounders present in this real world cohort

Krajská zdravotní, a.s.
- Masarykova nemocnice v Ústí nad Labem, o.z.

Randomized Comparison of Genous Stent Versus Chromium-Cobalt stent for Treatment of ST-Elevation Myocardial Infarction. 6-month Clinical, Angiographic and IVUS Follow-up. GENIUS-STEMI trial.

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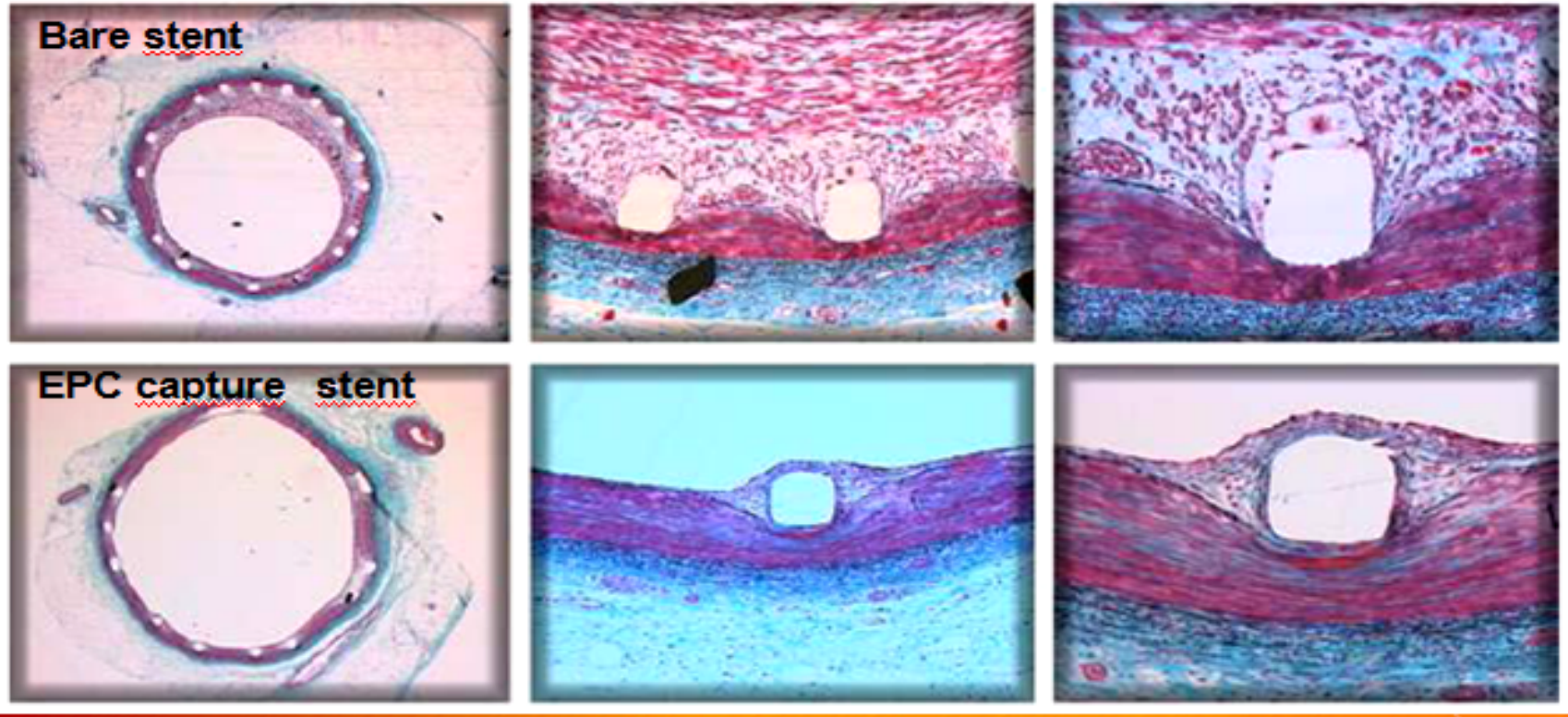
ACC.09 i2 summit 2009

(Orlando, 28th March,2008)

GENIUS-STEMI

Krajská zdravotní, a.s.
- Masarykova nemocnice v Ústí nad Labem, o.z.

Histopathologic analysis: 28 days



Mature neointima with minimal inflammation

EPC = Endothelial progenitor cells

GENIUS-STEMI

Krajská zdravotní, a.s.
- Masarykova nemocnice v Ústí nad Labem, o.z.

➢ Method

Between August and December 2007,
100 consecutive patients with STEMI and single vessel disease were randomly assigned (sealed envelope) to receive either EPC capture stent (N=50) (Genous™ stent) or chromium-cobalt stent (N=50)
(either Driver™ or Coroflex Blue™)

Dual antiplatelet treatment was administered for 30 days in both groups.

A 6-month clinical, angiographic and IVUS follow-ups were assessed in both groups.

GENIUS-STEMI

Krajská zdravotní, a.s.
- Masarykova nemocnice v Ústí nad Labem, o.z.

➢ Endpoints

MACEs' (CV death, MI, clinically driven TLR)
at 6 month FU

Late lumen loss at 6-month FU

Neointimal hyperplasia inside the stent at 6-month FU

GENIUS-STEMI

Krajská zdravotní, a.s.
- Masarykova nemocnice v Ústí nad Labem, o.z.

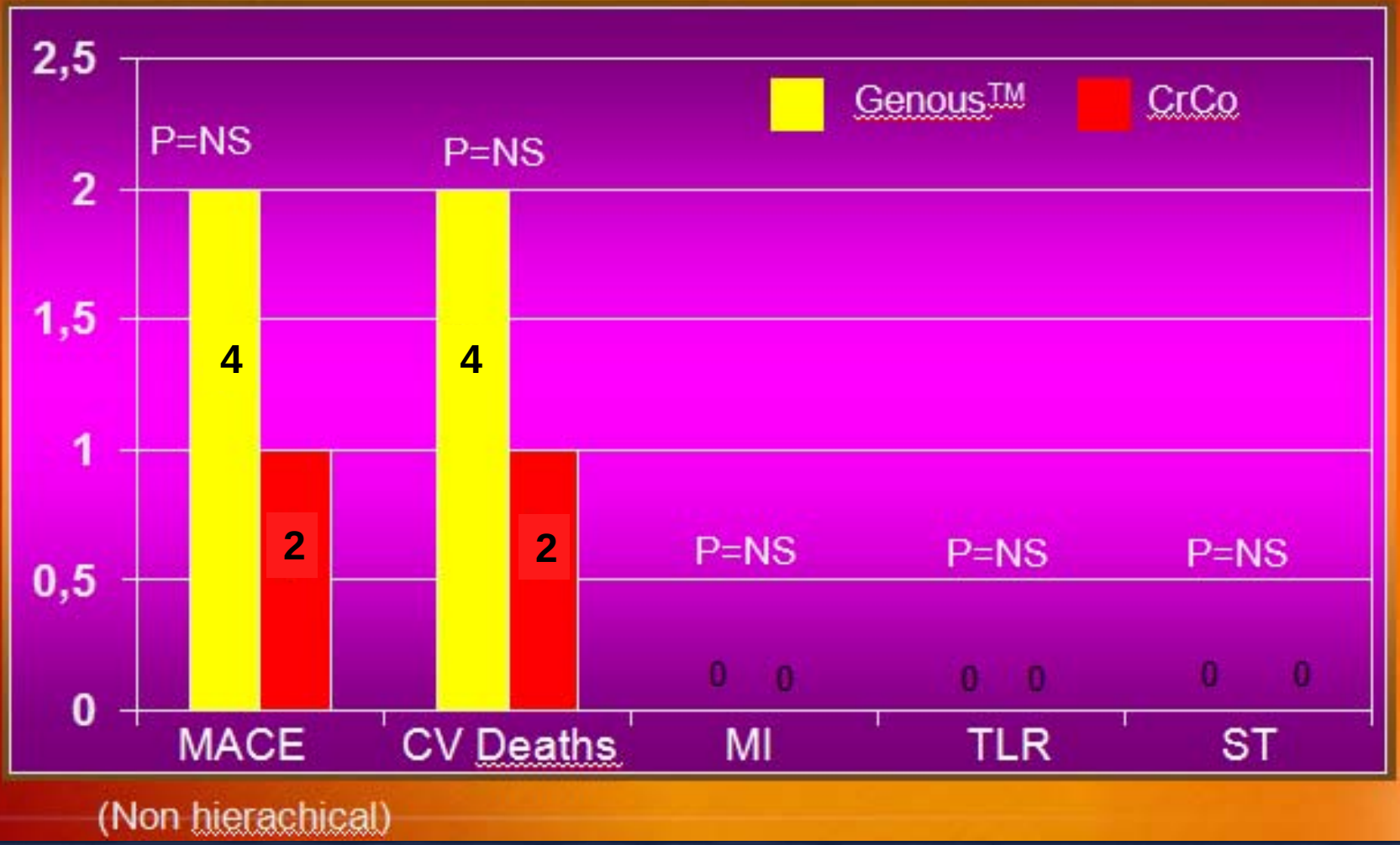
➢ Procedural characteristics

	Genous	Cr-Co	P value
	N=50	N=50	
Stenosis (%)	5.2±4.5	3.9±3.7	NS
MLD (mm)	3.56±0.42	3.62±0.39	NS
TIMI flow			
0-1 (%)	0	0	NS
2	6	3	NS
3	94	97	NS
Number of stents	1.20	1.26	NS
Length of the stents (mm)	20.42	22.30	NS
GP IIb/IIIa inhibitors (%)	32	22	NS
Thromboaspiration (%)	17	25	NS

GENIUS-STEMI

Krajská zdravotní, a.s.
- Masarykova nemocnice v Ústí nad Labem, o.z.

➢ 30 day outcome



(Non hierachical)

GENIUS-STEMI

Krajská zdravotní, a.s.
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➢6 month angio and IVUS data

	Genous	Cr-Co	P value
ANGIO DATA	**N=44**	**N=47**	
Late lumen loss (mm)	0.89±0.59	0.79±0.47	NS
Restenosis (>50%)	20	13	NS
(QCA: Pie Medical Im)			
IVUS	***N=41***	***N=42***	
mean in-stent NIH (mm^3)	49.7±48	40.0±22.8	NS
(Volcano, pull back 0.5%mm/s)			
(QIVA Pie Medical Im)			

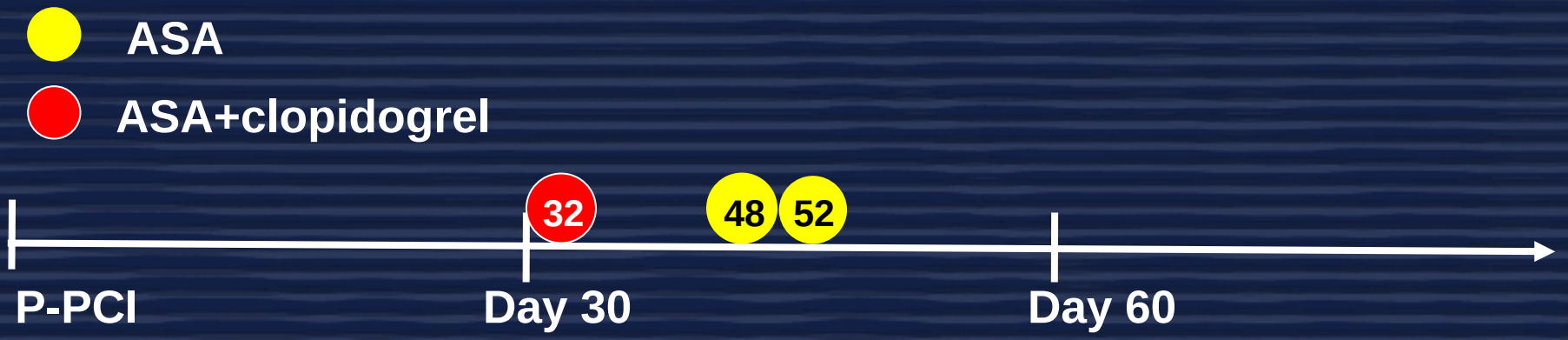
GENIUS-STEMI

Krajská zdravotní, a.s.
- Masarykova nemocnice v Ústí nad Labem, o.z.

➢ Stent thrombosis in Genous™ group

Patient	Age	TIMI	Thrombus	iGP IIb/IIa	Vessel	EF	Stent	Days	Treatment	Dual T	Stát.
J.J.	61	3	Y	Y	RCA	60	1; 2.75/23	48	dPOBA	N	Alive
P.U.	26	3	Y	Y	LAD	45	1; 3/23	32	dPCI+G	Y	Alive
J.T.	47	2	Y	Y	RCA	52	2; 3.5/23+18	52	dPOBA	N	Alive

ARC definition: 3x definite; 3x late



GENIUS-STEMI

Krajská zdravotní, a.s.
- Masarykova nemocnice v Ústí nad Labem, o.z.

➢ Conclusions:

The use of EPC capture stents in the setting of STEMI is feasible and save.

However, the rate of MACE at 6-month FU was significantly higher in Genous™ group when compare to CrCo stents.

Warrisome is the rate of late stent thrombosis in EPCs capture stent group.

Larger randomized trials are mandatory.

Caveats:

Small, single center trial

Underpowered for MACE

No core lab

Comparison of the Efficacy and Safety of *Z*otarolimus-*E*luting Stent versus *S*irolimus-Eluting Stent and Pacli*T*axel-Eluting Stent for Coronary Lesions:

The ZEST Trial

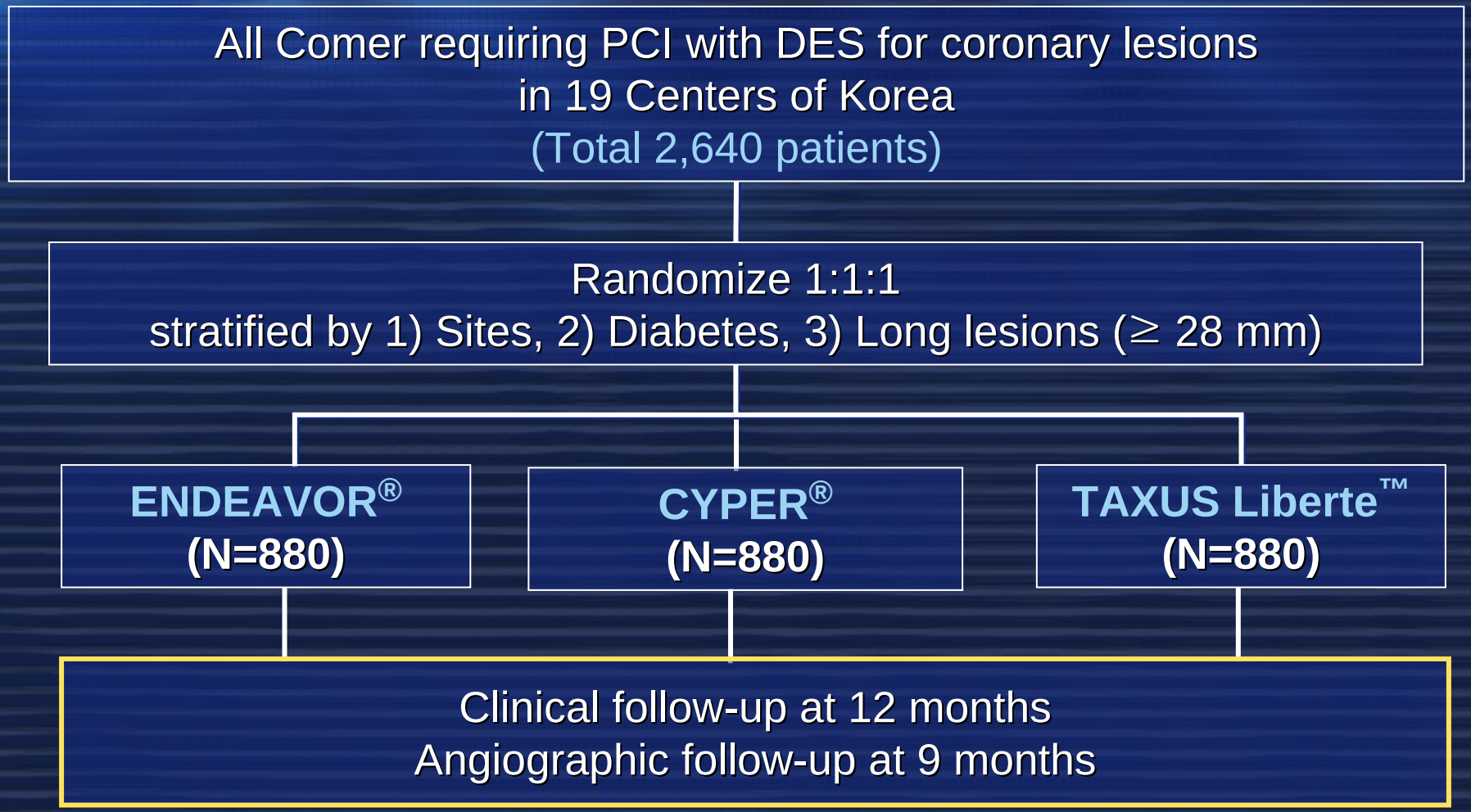
Seung-Jung Park, MD, PhD
on behalf of the ZEST investigators

Objective

- To establish the safety and effectiveness of coronary stenting with zotarolimus-eluting stent (Endeavor, Medtronic) as compared with sirolimus-eluting stent (Cypher, Cordis Johnson & Johnson) and paclitaxel-eluting stent (Taxus, Boston Scientific) in a multicenter, randomized clinical trial for unselected patients in the real world.

Intention-to-Treat Analyses

Study Design



Primary Study Endpoint

- The composite clinical outcome of
  - Death from any cause
  - Myocardial infarction (MI)
  - Ischemia-driven target-vessel revascularization (TVR)

at 12 months after the index procedure.

Secondary Study Endpoint

- Death (all-cause or cardiac)
- MI
- Composite of death or MI
- TVR (all- and ischemia-driven)
- TLR (all- and ischemia-driven)
- Composite of death, MI, ischemia-driven TLR
- Stent thrombosis by ARC definition
- Late loss in both in-stent and in-segment at 9 mths
- Restenosis in both in-stent and in-segment at 9 mths
- Procedural success rate

Antiplatelet Regimen

Pre-Procedure

- Aspirin (≥ 100mg)
- Clopidogrel (loading dose) : 300 or 600 mg

During Procedure

- Heparin: IV bolus + boluses to maintain ACT > 250 s
- GP IIb/IIIa inhibitors: at physician's discretion

After Discharge

- Aspirin: 100-325 mg /day indefinitely
- Clopidogrel: 75 mg once daily for ≥ at least 12 months

Results

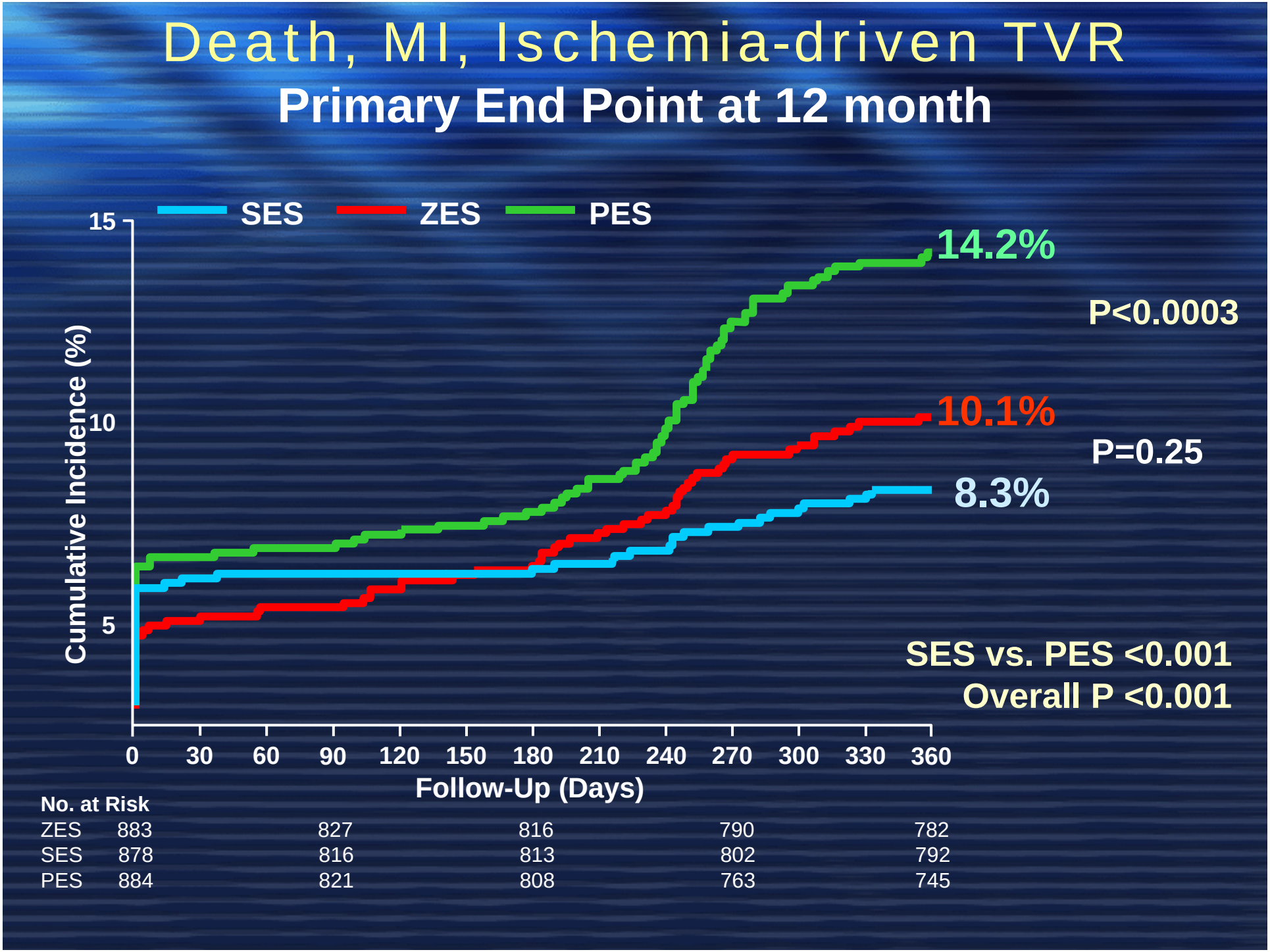
Baseline and lesion characteristics are similar in the three patient groups

Procedure Characteristics

Lesions	ZES (n=1190)	SES (n=1218)	PES (n=1205)	P value
No. of stents per lesion	1.2±0.4	1.2±0.4	1.2±0.4	0.35
No. of stents per patient	1.6±0.9	1.6±0.9	1.6±0.9	0.92
Length of stents per lesion	27.9±13.1	28.9±13.5	28.9±14.3	0.12
Length of stents per patients	39.7±26.8	38.3±24.3	38.9±25.2	0.45
Maximal stent diameter	3.4±0.7	3.4±0.7	3.5±0.6	0.03
Maximal pressure	16.3±4.2	16.3±4.1	16.2±4.2	0.95
Direct stenting	84 (7)	109 (9)	89 (7)	0.24
Use of IVUS	488 (41)	514 (42)	491 (41)	0.62
Use of glycoprotein IIb-IIIa inhibitors	19 (2)	15 (2)	14 (2)	0.64

Death, MI, Ischemia-driven TVR

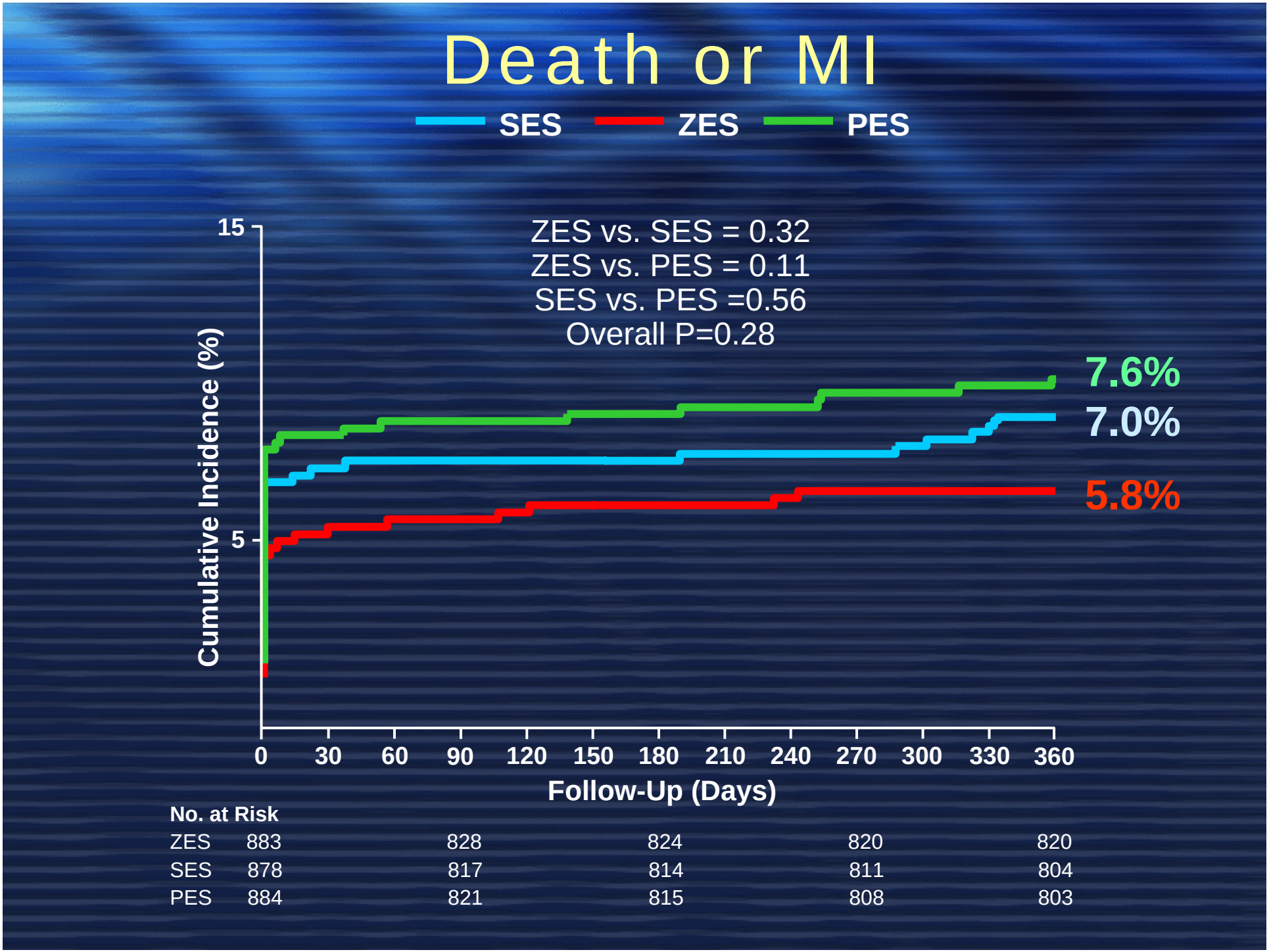
Primary End Point at 12 month



No. at Risk

ZES	883	827	816	790	782
SES	878	816	813	802	792
PES	884	821	808	763	745

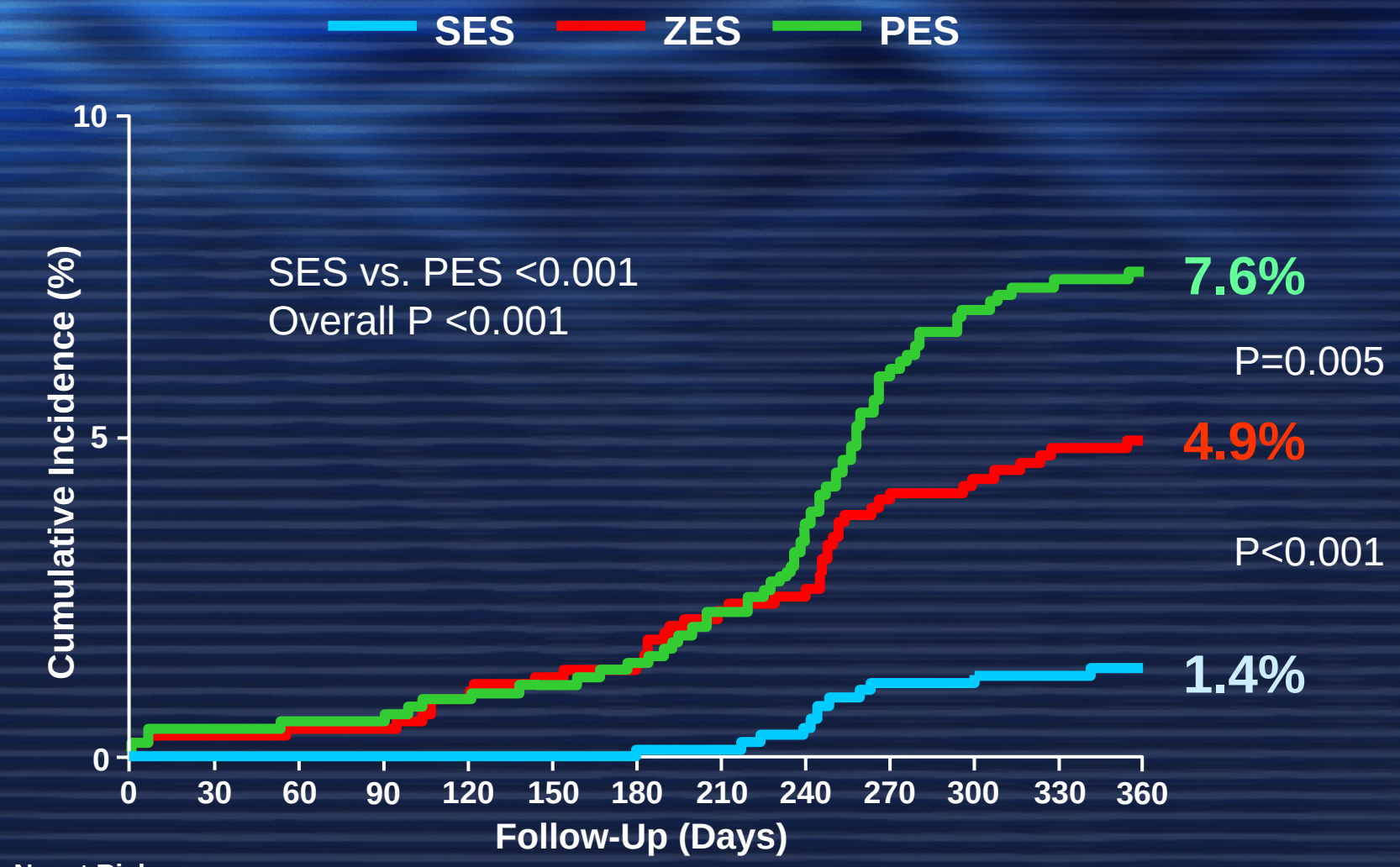
Death or MI



No. at Risk

ZES	883	828	824	820	820
SES	878	817	814	811	804
PES	884	821	815	808	803

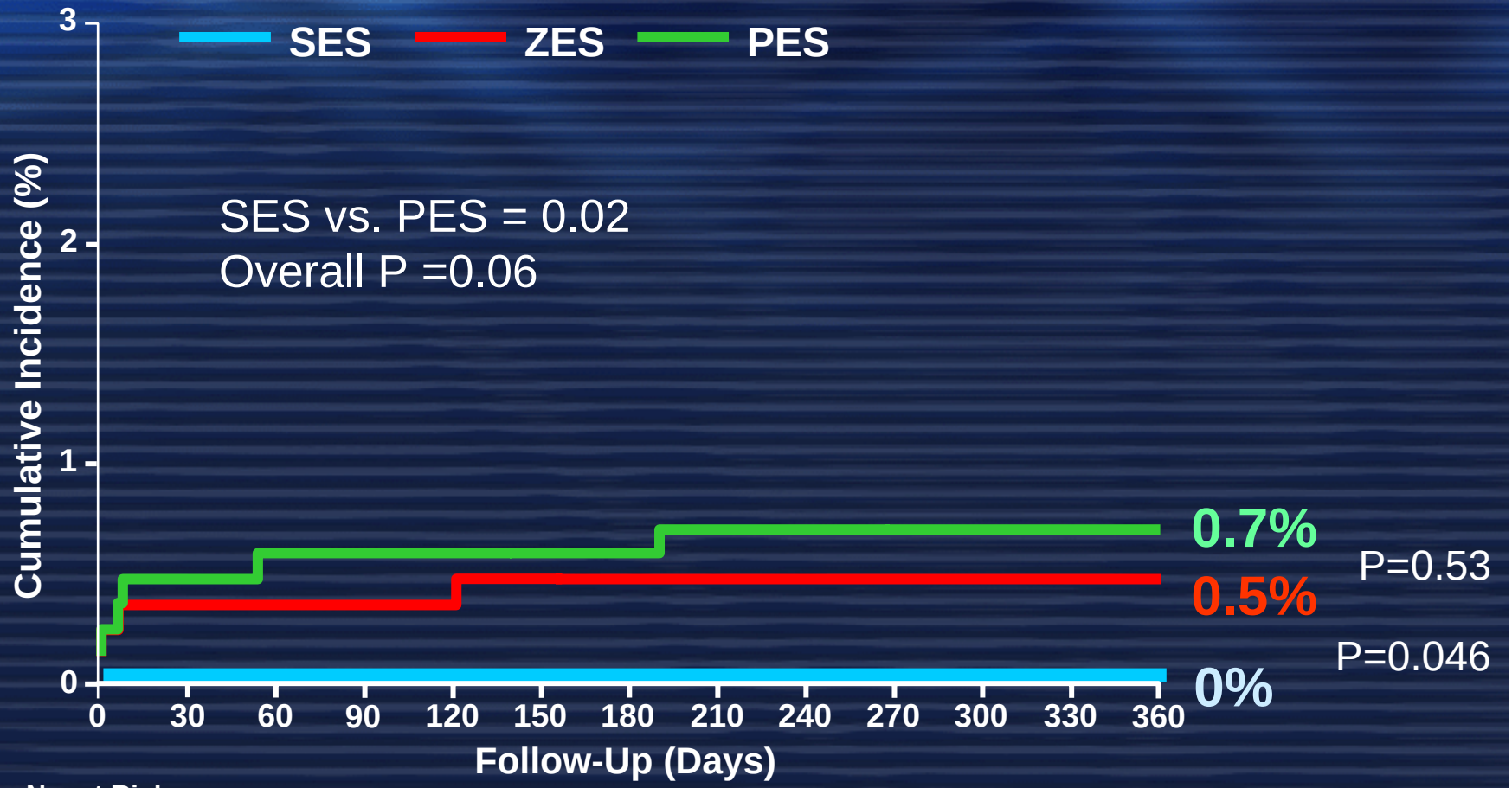
Ischemic driven TLR



No. at Risk					
ZES	883	868	857	829	822
SES	878	869	866	853	845
PES	884	875	861	813	794

Stent Thrombosis

: ARC Definite Criteria



No. at Risk

ZES	883	869	866	861	861
SES	878	869	867	863	857
PES	884	875	868	859	853

Conclusion

- As compared with first-generation DES (SES and PES), the use of ZES results in similar major adverse cardiac events with reference to SES, but in fewer major adverse cardiac events with reference to PES.

Conclusion

- There was a trend toward lower rates of death or MI in the ZES group as compared with the SES and PES group.
- The rates of Ischemia-driven TLR and TVR in the ZES group was significantly lower than the PES group, but higher than in the SES group.
- The rate of stent thrombosis in the ZES group was similar with the PES group, but higher than in the SES group.