Outcomes with drug-eluting stents in acute coronary syndromes

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Potential conflicts of interest

Speaker's name: Pawel Buszman, MD. PhD, FESC, FACC

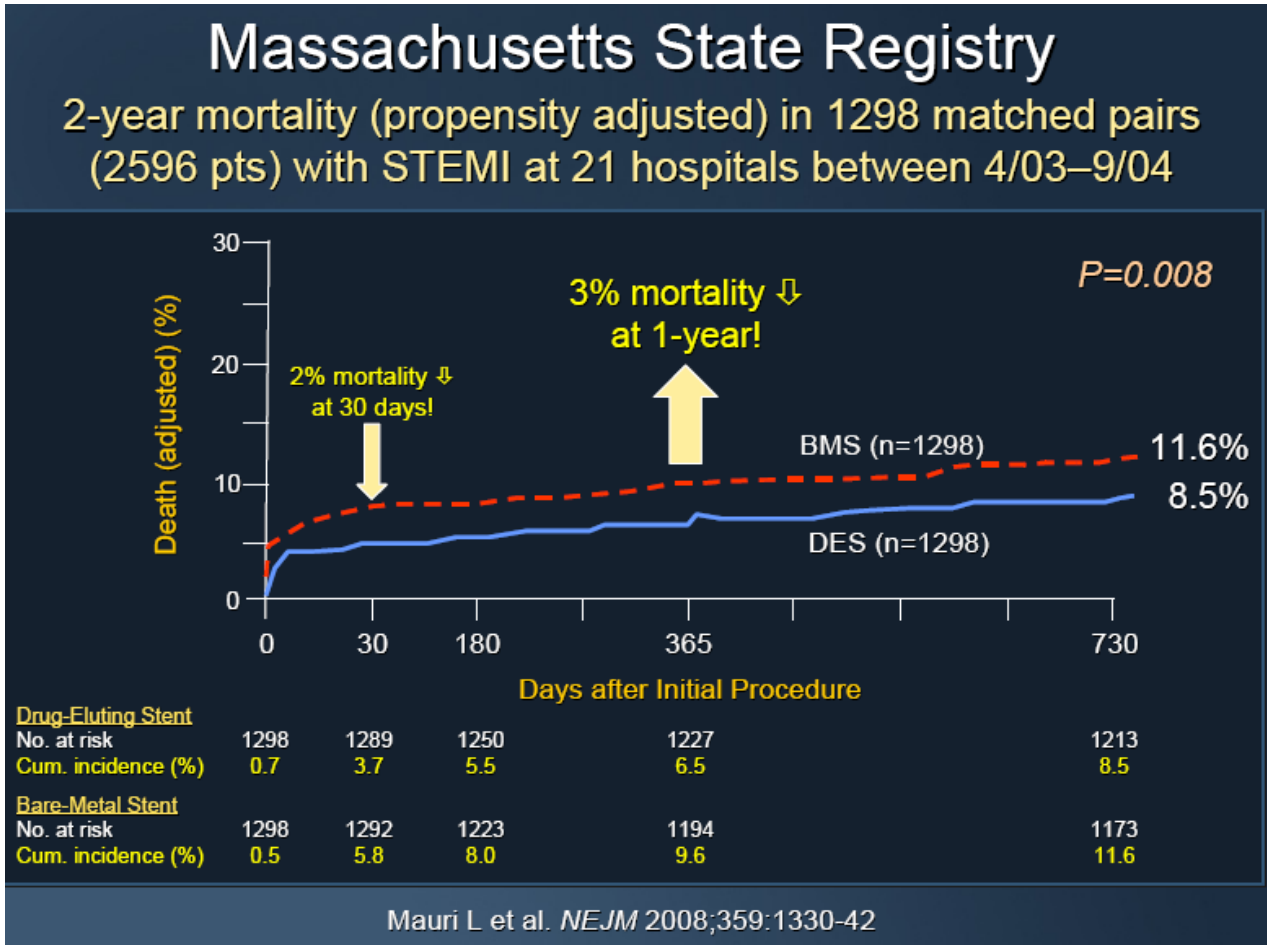
❑ **I have the following** potential conflicts of interest to report:

- ❑ Research contracts
- ❑ Consulting
- ❑ Employment in industry
- ❑ [X] Stockholder of a healthcare company
- ❑ [X] Owner of a healthcare company
- ❑ Other(s)

❑ **I do not have any potential conflict of interest**

EUROPCR09

BMS vs DES for STEMI



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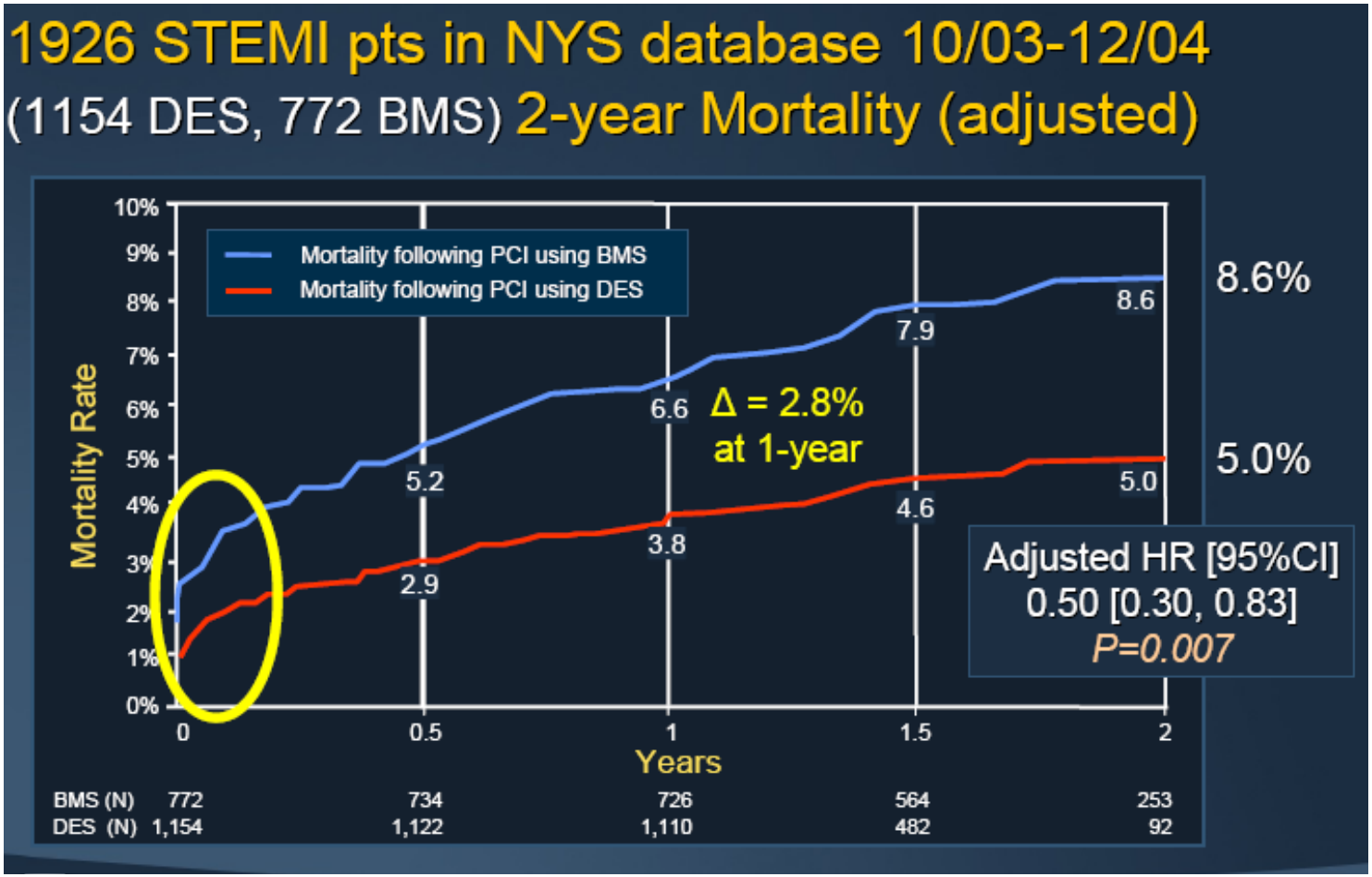
Adjusted AMI analysis



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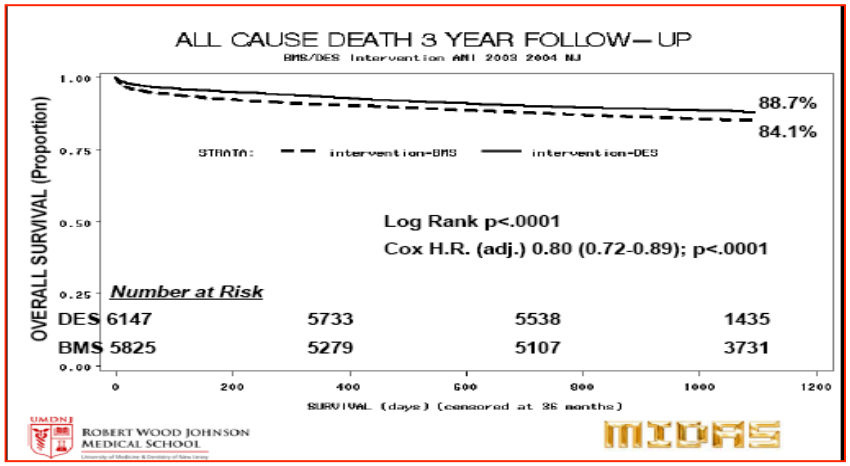
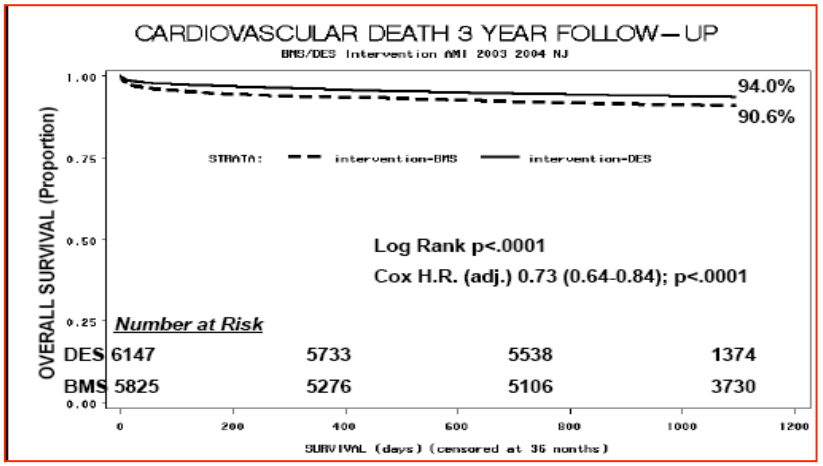
MIDAS Database: 2 year survival after AMI (BMS=5825, DES=6147)





CONCLUSIONS

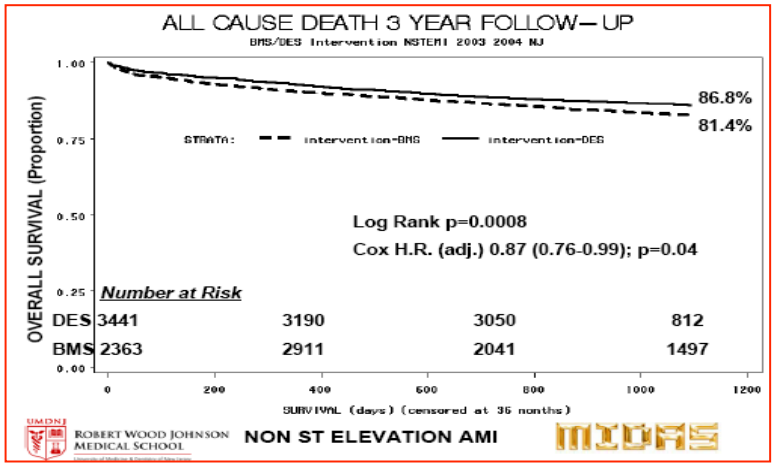
MIDAS DATA RECORDS FROM 2003 and 2004 SHOW THE USE OF DRUG ELUTING STENTS IN THE SETTING OF AMI WAS ASSOCIATED WITH SIGNIFICANT REDUCTIONS OF 3-YEAR ALL CAUSE MORTALITY AND CARDIOVASCULAR MORTALITY WHEN COMPARED WITH THE USE OF BARE METAL STENTS.

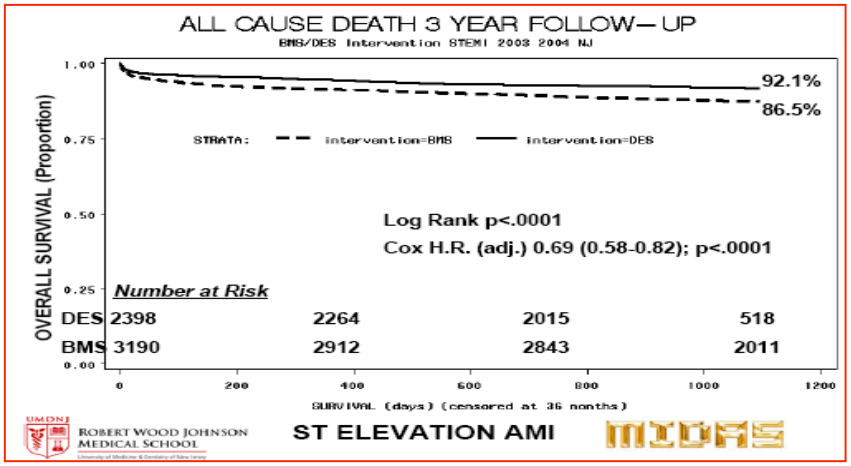
ROBERT WOOD JOHNSON MEDICAL SCHOOL

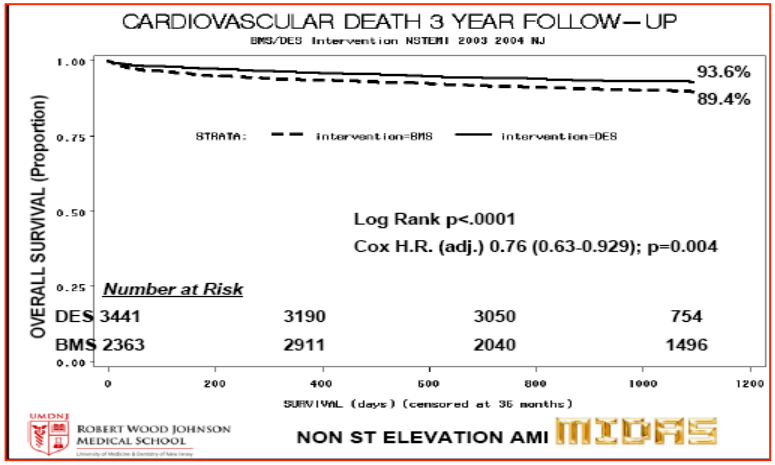
MIDAS

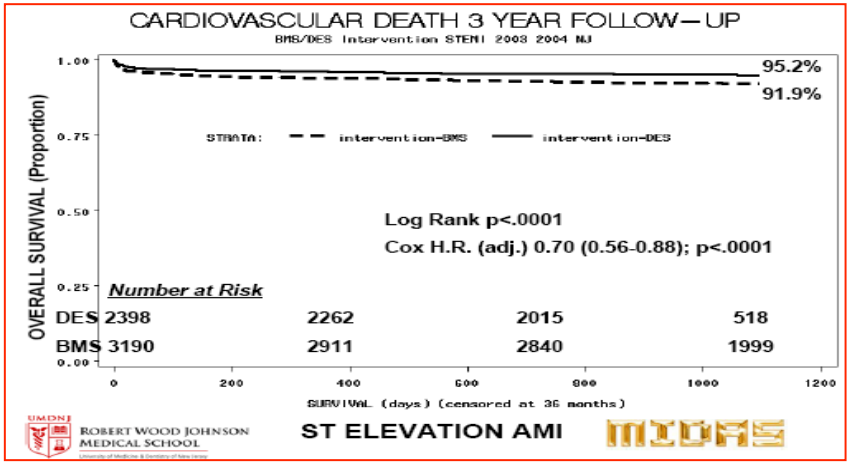
EUROPCR09

MIDAS Database: 2 year survival after AMI (BMS=5825, DES=6147)









NSTEMI **STEMI**

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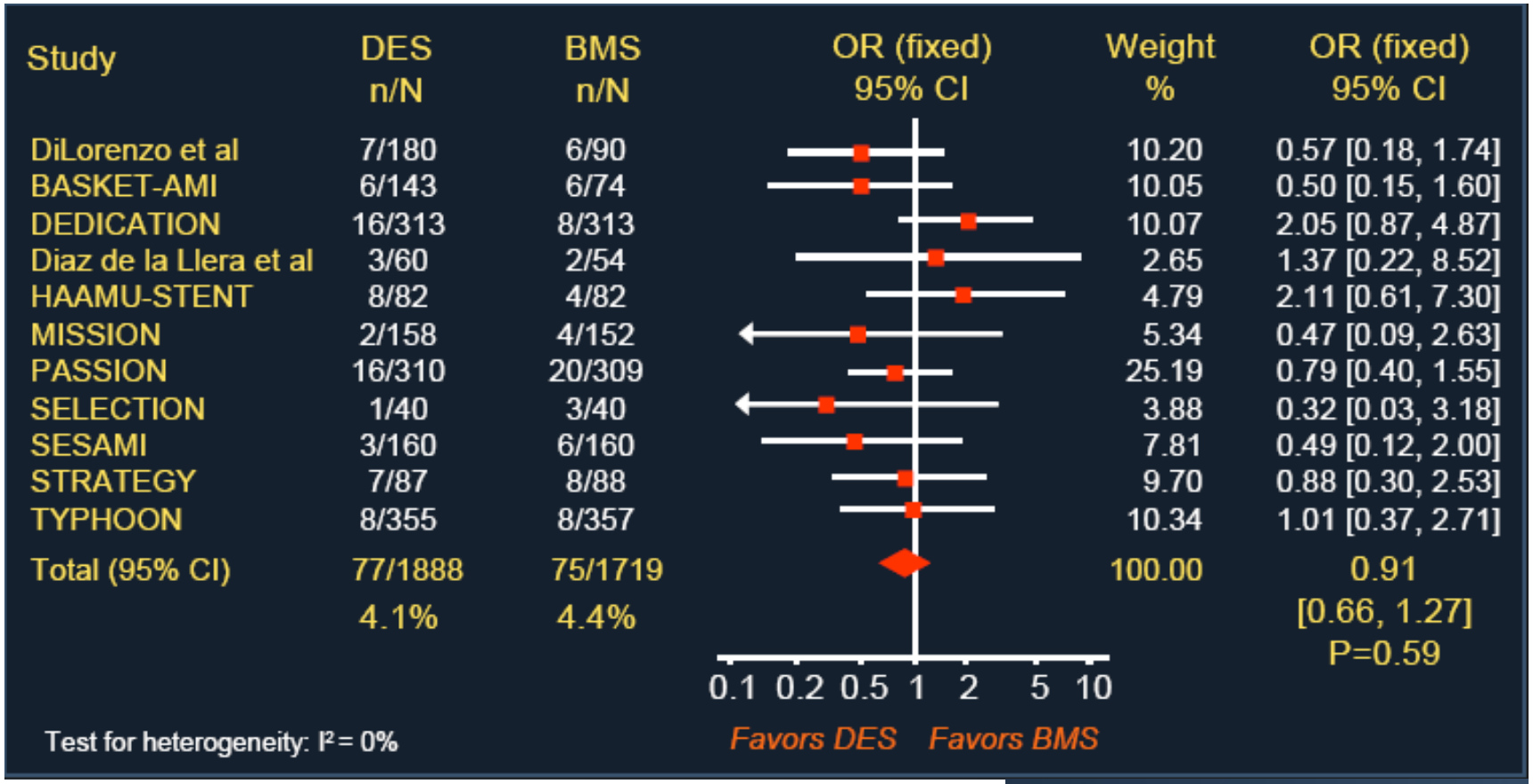
11 RCTs in AMI (n=3607) BMS vs DES

DEATH AT 12 MONTHS



De Luca G et al. *Int J Cardiol* 2008

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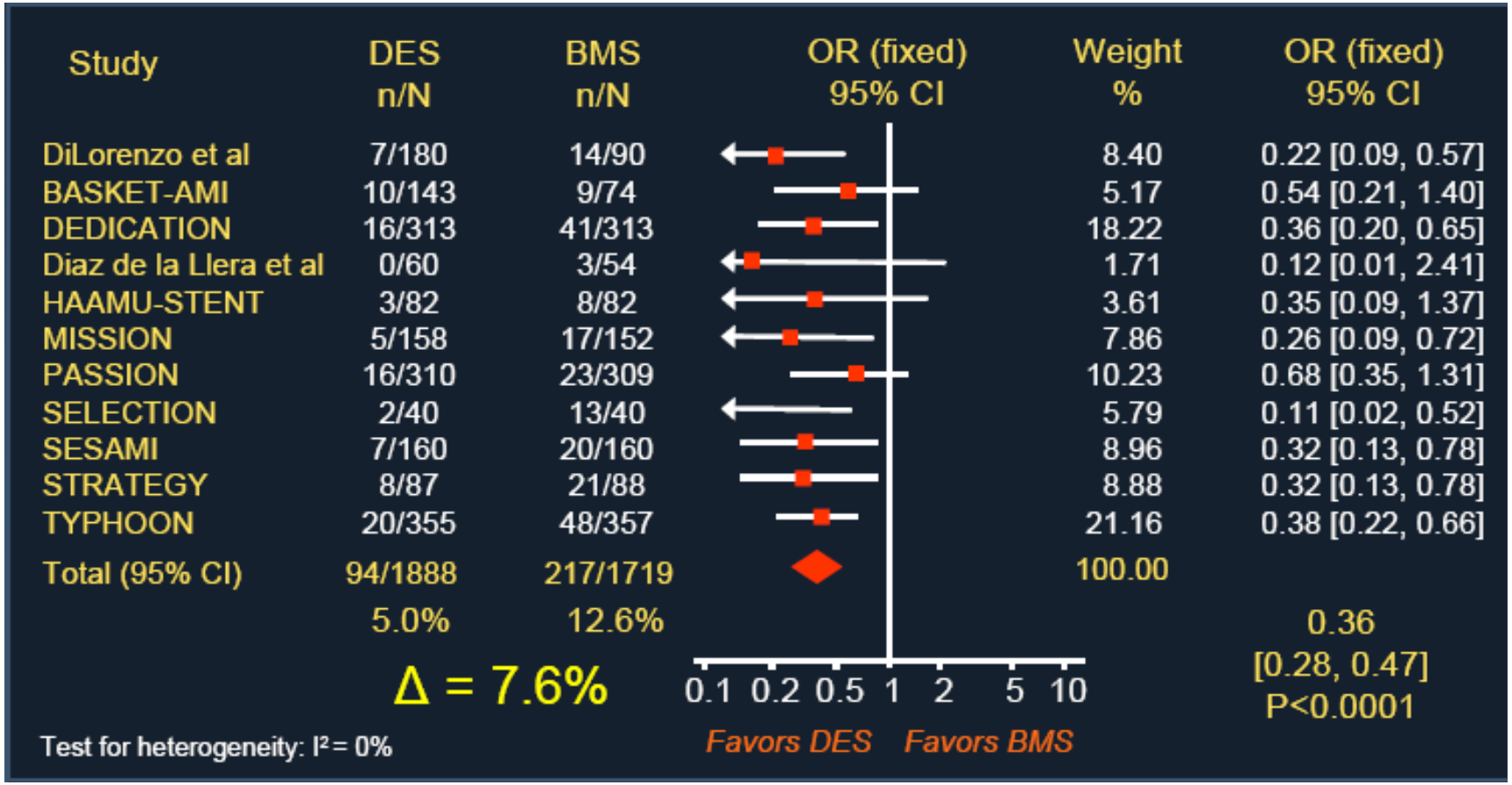
11 RCTs in AMI (n=3607) BMS vs DES

TVR AT 12 MONTHS



De Luca G et al. *Int J Cardiol* 2008

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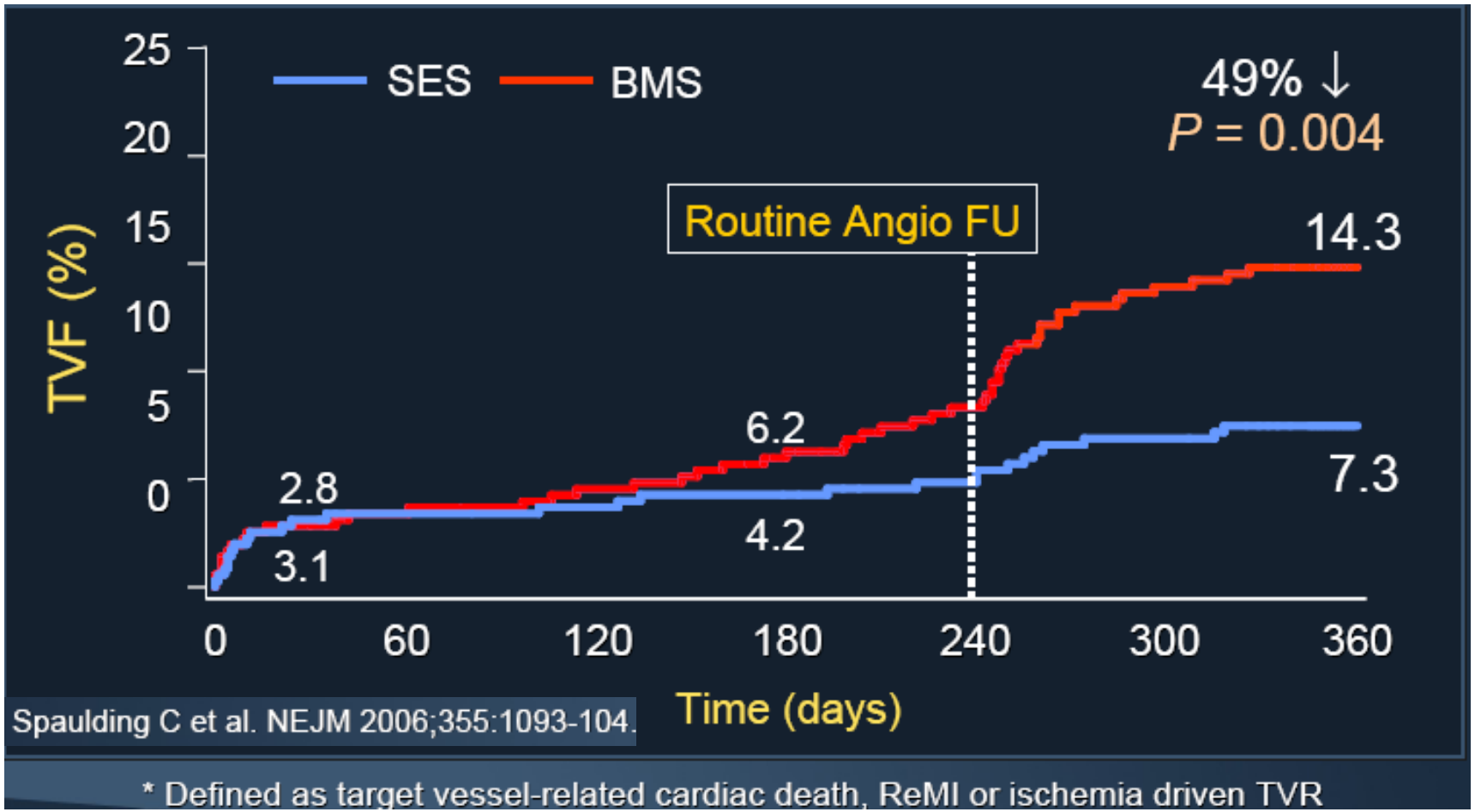
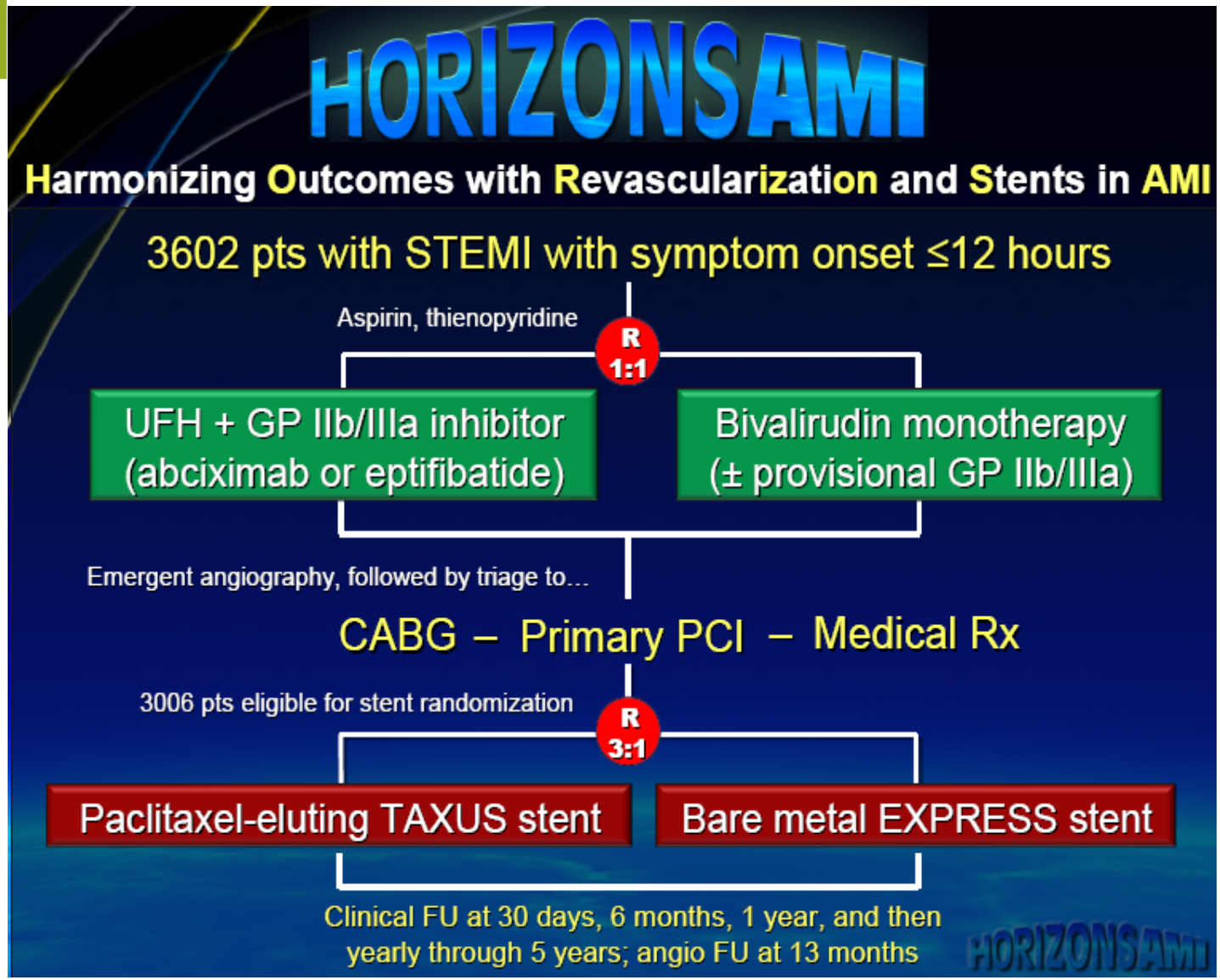
THE TYPHOON TRIAL

Primary endpoint (TVF) through 360 days




HORIZONS AMI
Harmonizing Outcomes with Revascularization and Stents in AMI
3602 pts with STEMI with symptom onset ≤12 hours
Aspirin, thienopyridine
R 1:1
UFH + GP IIb/IIIa inhibitor (abciximab or eptifibatide)
Bivalirudin monotherapy (± provisional GP IIb/IIIa)
Emergent angiography, followed by triage to…
CABG – Primary PCI – Medical Rx
3006 pts eligible for stent randomization
R 3:1
Paclitaxel-eluting TAXUS stent
Bare metal EXPRESS stent
Clinical FU at 30 days, 6 months, 1 year, and then yearly through 5 years; angio FU at 13 months
HORIZONS AMI

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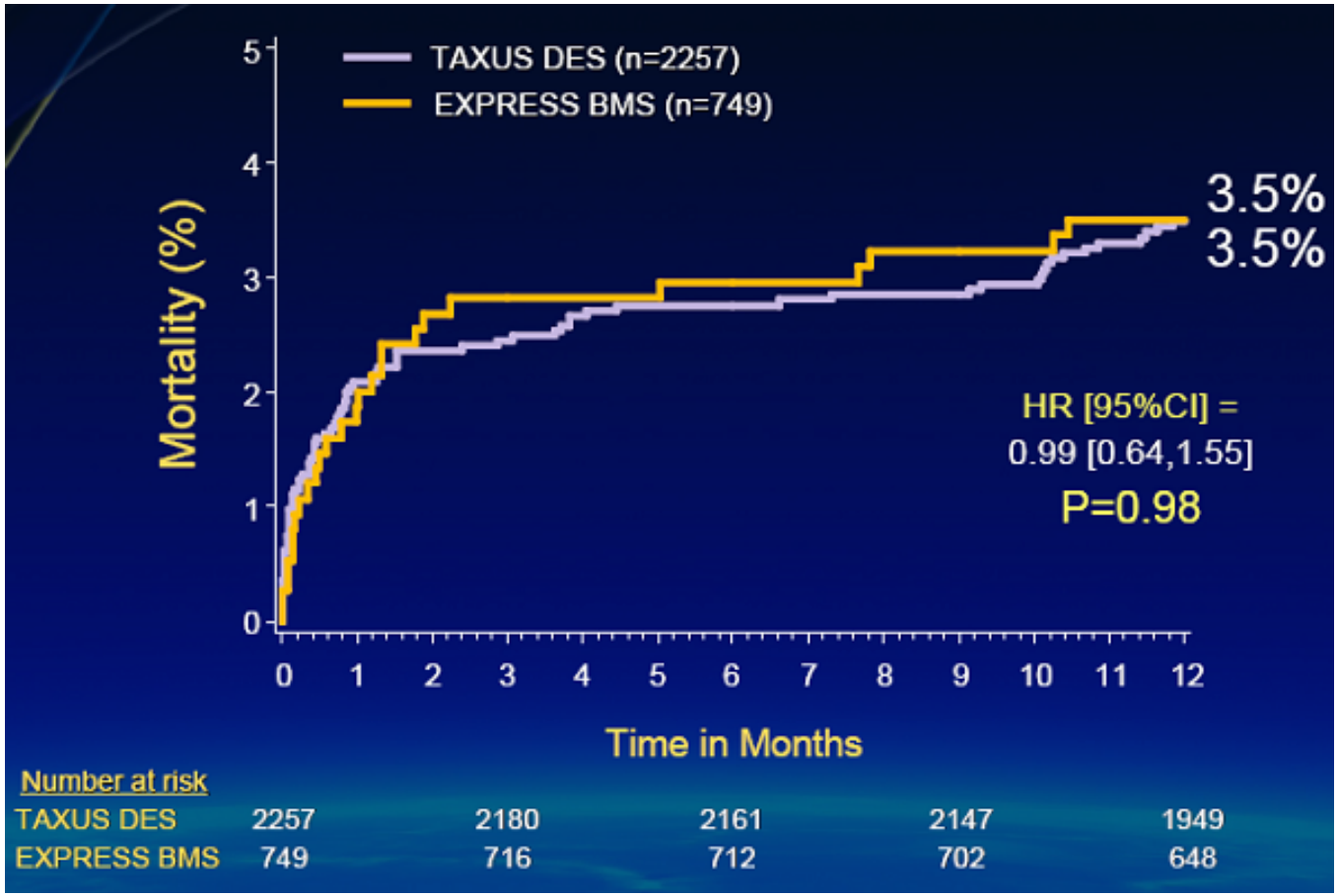
HORIZONS AMI
All-Cause Mortality



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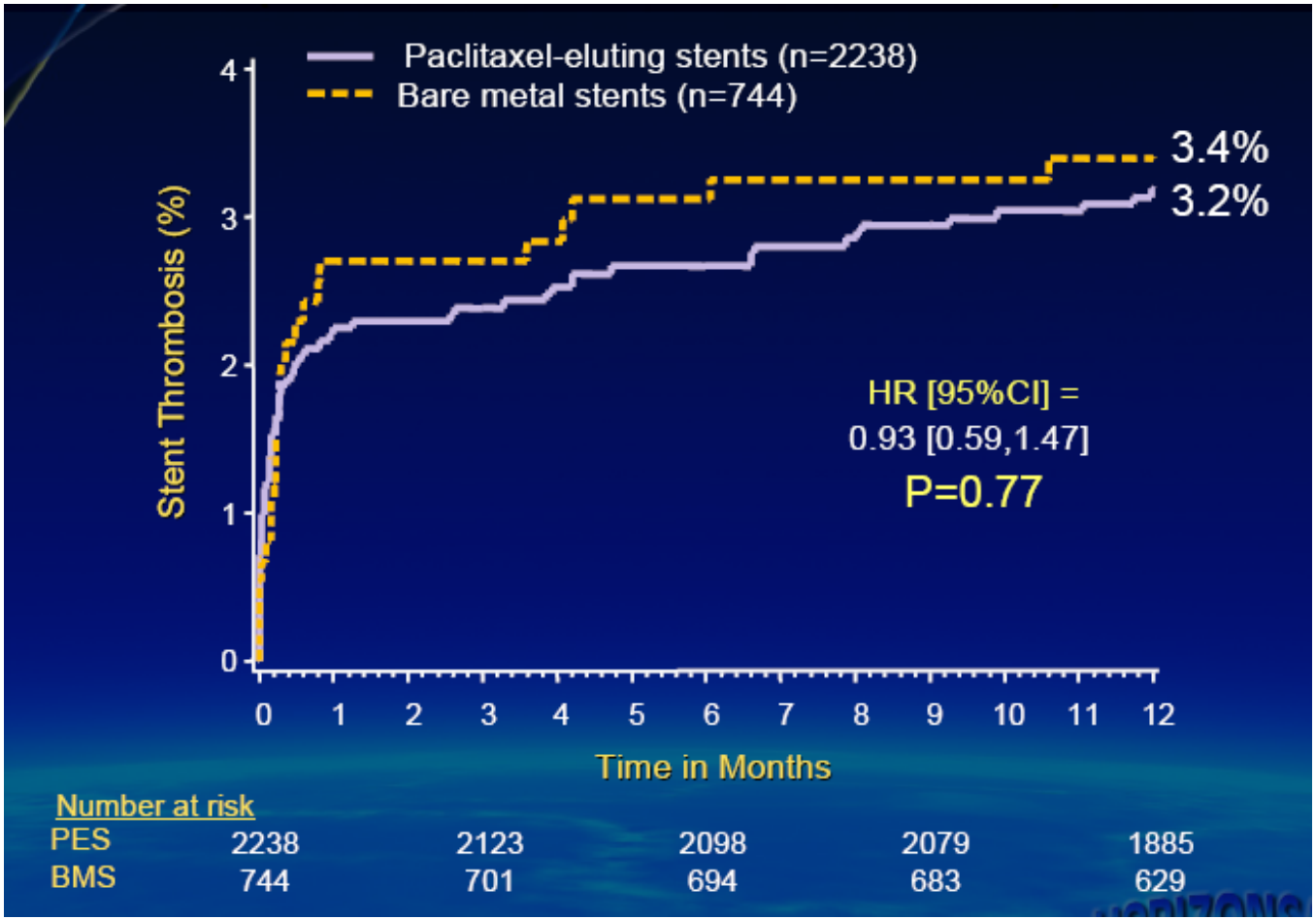
HORIZONS AMI
Stent thrombosis



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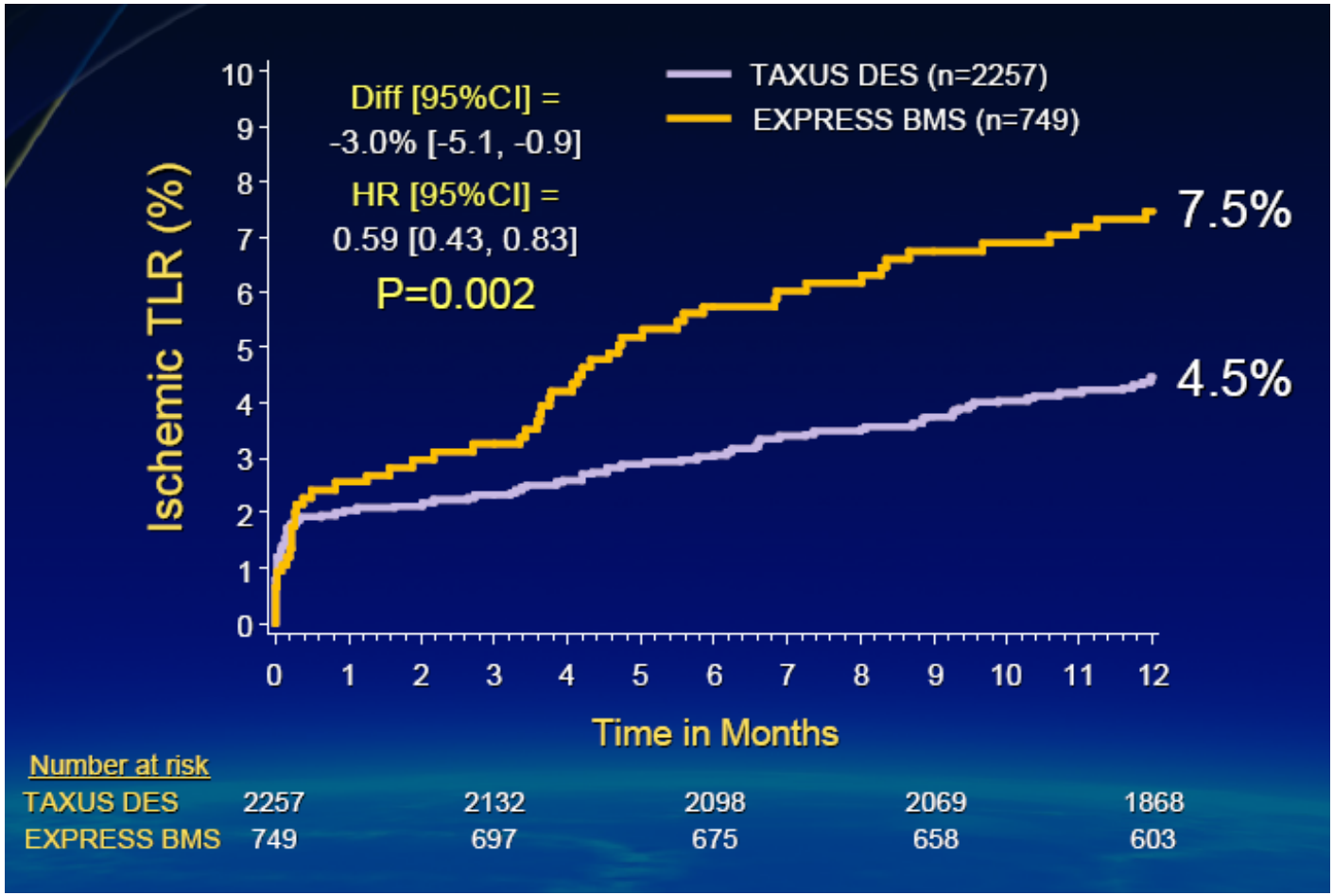
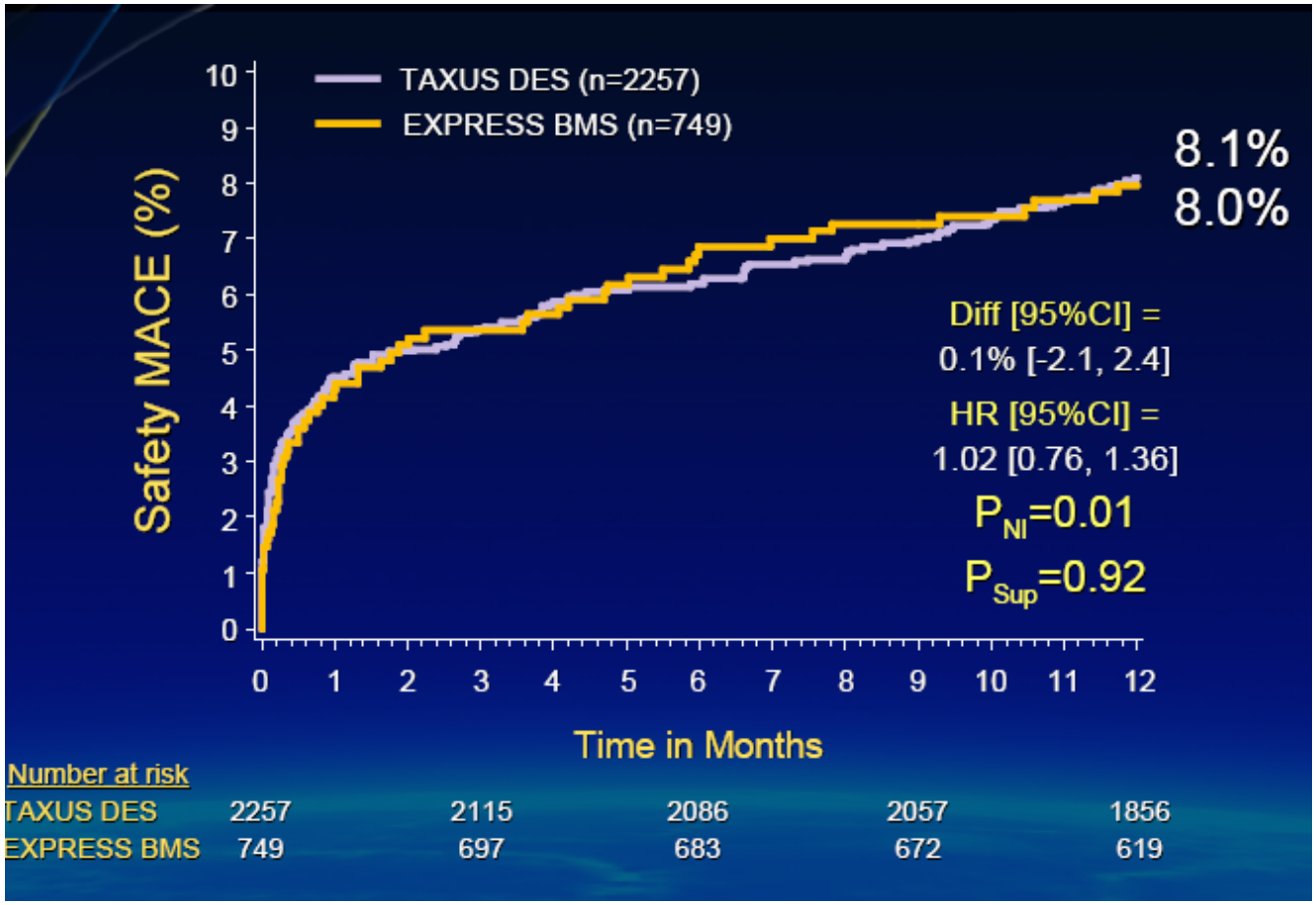
HORIZONS AMI: Clinically driven TVR

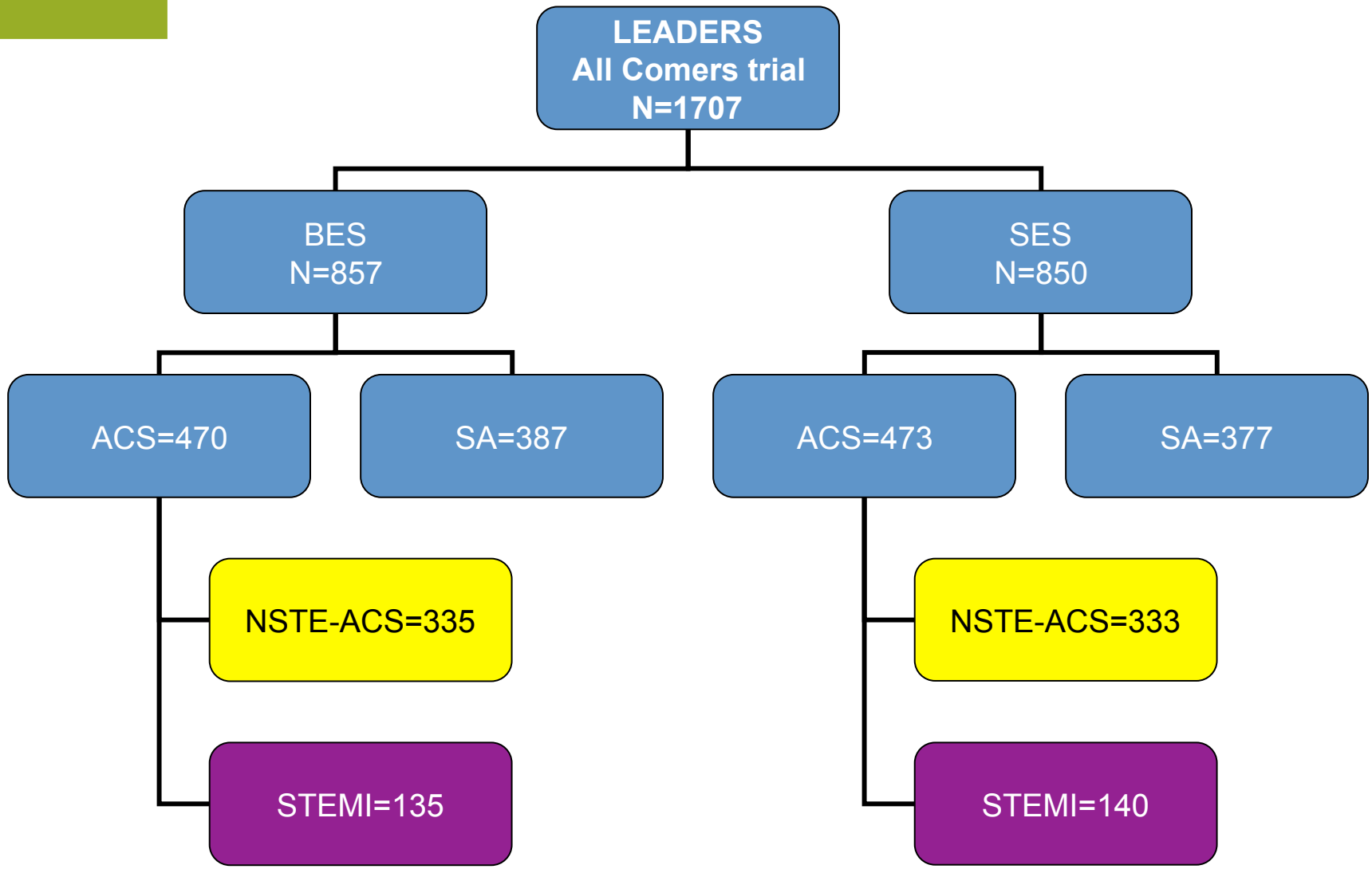


HORIZONS AMI

Primary Safety Endpoint: Safety MACE



Study population



Study endpoints

- Primary
  - Cardiac death (12 month)
  - Combined: cardiac death, MI, TVR (12 month)
- Secondary:
  - Cardiac death (one month)
  - Combined: cardiac death, MI, TVR (one month)
  - All cause mortality (one and 12 month)
  - Any TVR, TLR, repeat revascularization (one and 12 month)
  - NQMI, QMI (one and 12 month)
  - In stent thrombosis: acute, sub-acute, late

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STEMI vs NSTE-ACS
12 month follow-up

	STEMI				NSTE-ACS				
	BES (n = 135)	SES (n = 140)	Risk Ratio (95% CI)	P-value	BES (n = 722)	SES (n = 710)	Risk Ratio (95% CI)	P-value	P-value for interaction*
Death	5 (3.7)	10 (7.1)	0.51 (0.17,1.49)	0.21	22 (3.1)	18 (2.5)	1.21 (0.65,2.25)	0.56	0.17
Cardiac death	2 (1.5)	9 (6.4)	0.23 (0.05,1.05)	0.04	16 (2.2)	14 (2.0)	1.13 (0.55,2.31)	0.74	0.05
Myocardial infarction	3 (2.2)	7 (5.0)	0.43 (0.11,1.69)	0.22	47 (6.5)	32 (4.5)	1.46 (0.93,2.30)	0.10	0.08
Q-wave	2 (1.5)	2 (1.4)	1.03 (0.15,7.26)	0.98	2 (0.3)	5 (0.7)	0.39 (0.08,2.02)	0.25	0.45
Non-Q-wave	1 (0.7)	6 (4.3)	0.17 (0.02,1.41)	0.06	45 (6.2)	27 (3.8)	1.66 (1.03,2.70)	0.04	0.01
Clinically-indicated TLR	4 (3.0)	12 (8.6)	0.33 (0.11,1.02)	0.04	40 (5.5)	37 (5.2)	1.06 (0.68,1.67)	0.78	0.05
Percutaneous	4 (3.0)	10 (7.1)	0.40 (0.12,1.27)	0.11	38 (5.3)	36 (5.1)	1.04 (0.66,1.64)	0.86	0.12
Surgical	0 (0.0)	2 (1.4)	0.21 (0.01,4.28)	0.31	5 (0.7)	3 (0.4)	1.64 (0.39,6.86)	0.49	-
Any TLR	6 (4.4)	13 (9.3)	0.46 (0.17,1.21)	0.11	50 (6.9)	50 (7.0)	0.98 (0.66,1.45)	0.93	0.15
Percutaneous	5 (3.7)	11 (7.9)	0.46 (0.16,1.31)	0.14	47 (6.5)	48 (6.8)	0.96 (0.64,1.44)	0.86	0.19
Surgical	1 (0.7)	2 (1.4)	0.50 (0.05,5.60)	0.57	7 (1.0)	6 (0.9)	1.15 (0.39,3.41)	0.80	0.54
Clinically-indicated TVR	6 (4.4)	14 (10.0)	0.42 (0.16,1.10)	0.07	44 (6.1)	46 (6.5)	0.94 (0.62,1.42)	0.76	0.13
Percutaneous	5 (3.7)	12 (8.6)	0.41 (0.14,1.17)	0.09	42 (5.8)	44 (6.2)	0.94 (0.61,1.43)	0.77	0.15
Surgical	1 (0.7)	2 (1.4)	0.50 (0.05,5.60)	0.57	5 (0.7)	5 (0.7)	0.98 (0.29,3.40)	0.98	0.63
Any TVR	8 (5.9)	17 (12.1)	0.46 (0.20,1.07)	0.07	59 (8.2)	67 (9.4)	0.86 (0.61,1.22)	0.40	0.18
Percutaneous	6 (4.4)	15 (10.7)	0.40 (0.15,1.02)	0.05	54 (7.5)	60 (8.5)	0.88 (0.61,1.28)	0.51	0.12
Surgical	2 (1.5)	2 (1.4)	1.01 (0.14,7.20)	1.00	9 (1.3)	11 (1.6)	0.80 (0.33,1.94)	0.62	0.84
Any repeat revascularisation	8 (5.9)	18 (12.9)	0.43 (0.19,1.00)	0.04	59 (8.2)	68 (9.6)	0.85 (0.60,1.20)	0.35	0.14
Percutaneous	6 (4.4)	15 (10.7)	0.40 (0.15,1.02)	0.05	54 (7.5)	60 (8.5)	0.88 (0.61,1.28)	0.51	0.12
Surgical	2 (1.5)	3 (2.1)	0.67 (0.11,4.03)	0.66	9 (1.3)	12 (1.7)	0.74 (0.31,1.75)	0.48	0.92
Composite of death or MI	8 (5.9)	15 (10.7)	0.53 (0.23,1.26)	0.15	59 (8.2)	47 (6.6)	1.25 (0.85,1.84)	0.26	0.07
Composite of cardiac death or MI	5 (3.7)	14 (10.0)	0.36 (0.13,1.00)	0.04	54 (7.5)	44 (6.2)	1.22 (0.81,1.82)	0.34	0.02
Composite of cardiac death, MI, or clinicall indicated TLR	7 (5.2)	20 (14.3)	0.34 (0.14,0.81)	0.01	79 (10.9)	71 (10.0)	1.10 (0.80,1.52)	0.56	0.01
Composite of cardiac death, MI, or clinically-indicated TVR	9 (6.7)	22 (15.7)	0.40 (0.18,0.87)	0.02	82 (11.4)	80 (11.3)	1.01 (0.74,1.38)	0.94	0.03

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STEMI vs NSTE-ACS
12 month follow-up

	STEMI				NSTE-ACS				
	BES (n = 135)	SES (n = 140)	Risk Ratio (95% CI)	P-value	BES (n = 722)	SES (n = 710)	Risk Ratio (95% CI)	P-value	P-value for interaction*
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Myocardial infarction	3 (2.2)	7 (5.0)	0.43 (0.11,1.69)	0.22	47 (6.5)	32 (4.5)	1.46 (0.93,2.30	0.10	0.08
Q-wave	2 (1.5)	2 (1.4)	1.03 (0.15,7.26)	0.98	2 (0.3)	5 (0.7)	0.39 (0.08,2.02	0.25	0.45
Non-Q-wave	1 (0.7)	6 (4.3)	0.17 (0.02,1.41)	0.06	45 (6.2)	27 (3.8)	1.66 (1.03,2.70	0.04	0.01
Clinically-indicated TLR	4 (3.0)	12 (8.6)	0.33 (0.11,1.02)	0.04	40 (5.5)	37 (5.2)	1.06 (0.68,1.67	0.78	0.05
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Surgical	0 (0.0)	2 (1.4)	0.21 (0.01,4.28)	0.31	5 (0.7)	3 (0.4)	1.64 (0.39,6.86	0.49	-
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Clinically-indicated TVR	6 (4.4)	14 (10.0)	0.42 (0.16,1.10)	0.07	44 (6.1)	46 (6.5)	0.94 (0.62,1.42	0.76	0.13
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Surgical	1 (0.7)	2 (1.4)	0.50 (0.05,5.60)	0.57	5 (0.7)	5 (0.7)	0.98 (0.29,3.40	0.98	0.63
Any TVR	8 (5.9)	17 (12.1)	0.46 (0.20,1.07)	0.07	59 (8.2)	67 (9.4)	0.86 (0.61,1.22	0.40	0.18
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Surgical	2 (1.5)	2 (1.4)	1.01 (0.14,7.20)	1.00	9 (1.3)	11 (1.6)	0.80 (0.33,1.94	0.62	0.84
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Surgical	2 (1.5)	3 (2.1)	0.67 (0.11,4.03)	0.66	9 (1.3)	12 (1.7)	0.74 (0.31,1.75	0.48	0.92
Composite of death or MI	8 (5.9)	15 (10.7)	0.53 (0.23,1.26)	0.15	59 (8.2)	47 (6.6)	1.25 (0.85,1.84	0.26	0.07
Composite of cardiac death or MI	5 (3.7)	14 (10.0)	0.36 (0.13,1.00)	0.04	54 (7.5)	44 (6.2)	1.22 (0.81,1.82	0.34	0.02
Composite of cardiac death, MI, or clinicall indicated TLR	7 (5.2)	20 (14.3)	0.34 (0.14,0.81)	0.01	79 (10.9)	71 (10.0)	1.10 (0.80,1.52)	0.56	0.01
Composite of cardiac death, MI, or clinically-indicated TVR	9 (6.7)	22 (15.7)	0.40 (0.18,0.87)	0.02	82 (11.4)	80 (11.3)	1.01 (0.74,1.38)	0.94	0.03

STEMI vs NSTE-ACS
12 month follow-up

	STEMI				NSTE-ACS				P-value for interaction*
	BES (n = 135)	SES (n = 140)	Risk Ratio (95% CI)	P-value	BES (n = 722)	SES (n = 710)	Risk Ratio (95% CI)	P-value	
Cardiac death	7	10 (7.1)	0.51 (0.17,1.49)	0.04	(3.1)	18 (2.5)	1.21 (0.65,2.25)	0.56	0.17
	5)	9 (6.4)	0.23 (0.05,1.05)		(2.2)	14 (2.0)	1.13 (0.55,2.31)	0.74	0.05
Myocardial infarction	3 (2.2)	7 (5.0)	0.43 (0.11,1.69)	0.22	47 (6.5)	32 (4.5)	1.46 (0.93,2.30)	0.10	0.08
Clin.ind TLR	(1.5)	2 (1.4)	1.03 (0.15,7.26)	0.06	(0.3)	5 (0.7)	0.39 (0.08,2.02)	0.25	0.45
	(0.7)	6 (4.3)	0.17 (0.02,1.41)		(6.2)	27 (3.8)	1.66 (1.03,2.70)	0.04	0.01
	(3.0)	12 (8.6)	0.33 (0.11,1.02)		(5.5)	37 (5.2)	1.06 (0.68,1.67)	0.78	0.05
Percutaneous	4 (3.0)	10 (7.1)	0.40 (0.12,1.27)	0.11	38 (5.3)	36 (5.1)	1.04 (0.66,1.64)	0.86	0.12
Surgical	0 (0.0)	2 (1.4)	0.21 (0.01,4.28)	0.31	5 (0.7)	3 (0.4)	1.64 (0.39,6.86)	0.49	-
Clin.ind TVR	(4.4)	13 (9.3)	0.46 (0.17,1.21)	0.07	(6.9)	50 (7.0)	0.98 (0.66,1.45)	0.93	0.15
	(3.7)	11 (7.9)	0.46 (0.16,1.31)		(6.5)	48 (6.8)	0.96 (0.64,1.44)	0.86	0.19
	1 (0.7)	2 (1.4)	0.50 (0.05,5.60)	0.57	7 (1.0)	6 (0.9)	1.15 (0.39,3.41)	0.80	0.54
Clinically-indicated TVR	6 (4.4)	14 (10.0)	0.42 (0.16,1.10)	0.07	44 (6.1)	46 (6.5)	0.94 (0.62,1.42)	0.76	0.13
Any TVR	5 (3.7)	12 (8.6)	0.41 (0.14,1.17)	0.07	(5.8)	44 (6.2)	0.94 (0.61,1.43)	0.77	0.15
	1 (0.7)	2 (1.4)	0.50 (0.05,5.60)		(0.7)	5 (0.7)	0.98 (0.29,3.40)	0.98	0.63
	8 (5.9)	17 (12.1)	0.46 (0.20,1.07)	0.07	59 (8.2)	67 (9.4)	0.86 (0.61,1.22)	0.40	0.18
Any RePCI	6 (4.4)	15 (10.7)	0.40 (0.15,1.02)	0.04	(7.5)	60 (8.5)	0.88 (0.61,1.28)	0.51	0.12
	2 (1.5)	2 (1.4)	1.01 (0.14,7.20)		(1.3)	11 (1.6)	0.80 (0.33,1.94)	0.62	0.84
	8 (5.9)	18 (12.9)	0.43 (0.19,1.00)		(8.2)	68 (9.6)	0.85 (0.60,1.20)	0.35	0.14
Card death or MI	10.7)		0.40 (0.15,1.02)	0.04	(7.5)	60 (8.5)	0.88 (0.61,1.28)	0.51	0.12
	2.1)		0.67 (0.11,4.03)		(1.3)	12 (1.7)	0.74 (0.31,1.75)	0.48	0.92
	10.7)		0.53 (0.23,1.26)		(8.2)	47 (6.6)	1.25 (0.85,1.84)	0.26	0.07
Card death,MI or ciTLR	.1.00)			0.01	(7.5)	44 (6.2)	1.22 (0.81,1.82)	0.34	0.02
	.0.81)				(10.9)	71 (10.0)	1.10 (0.80,1.52)	0.56	0.01
Card death,MI or ciTVR	.0.87)			0.02	(11.4)	80 (11.3)	1.01 (0.74,1.38)	0.94	0.03

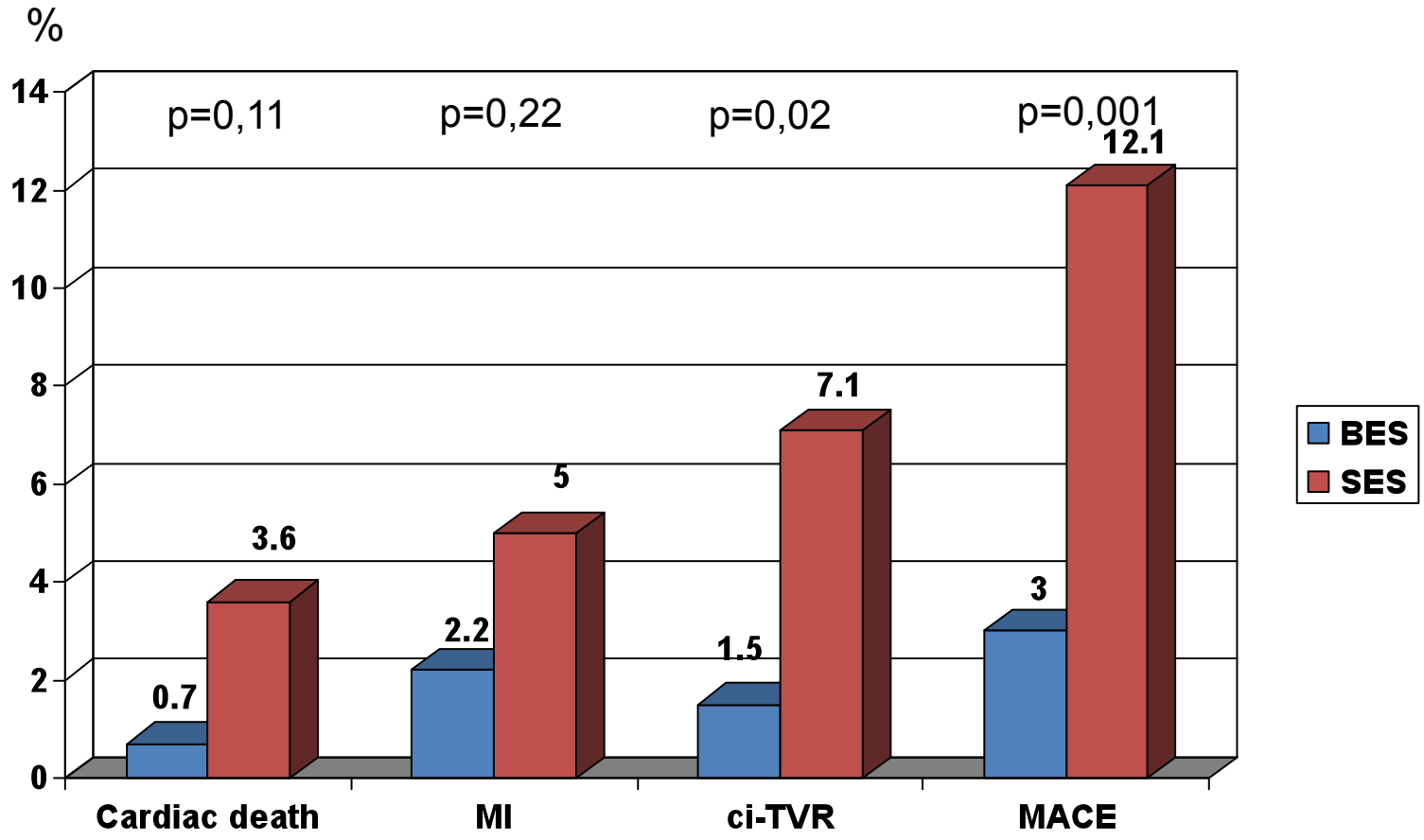
STEMI vs NSTE-ACS
12 month follow-up

- There is no significant difference between both groups for NSTE-ACS

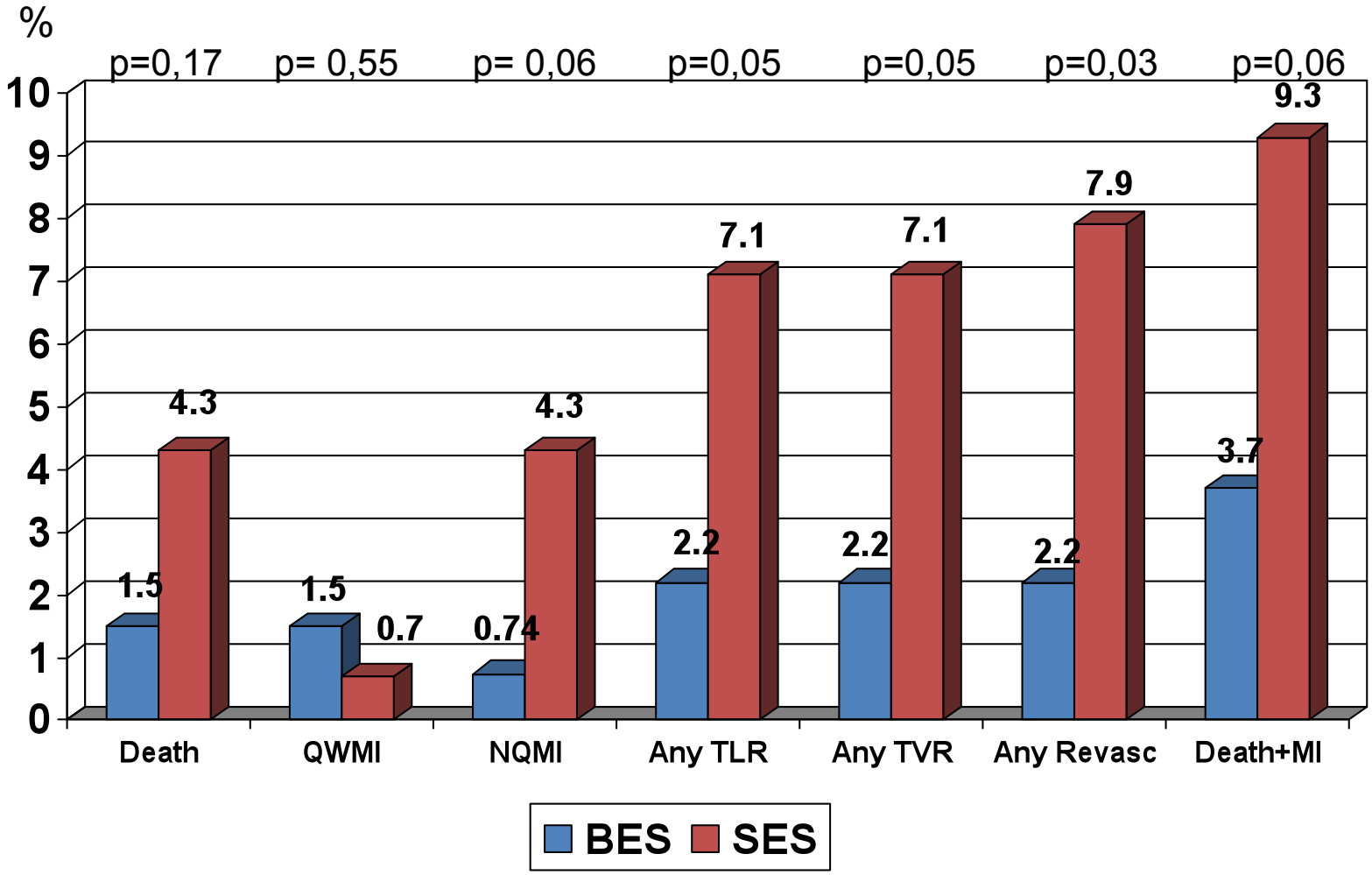
- Sginificant differences between the groups in respect to clinical outcomes in STEMI patients.

EUROPCR09

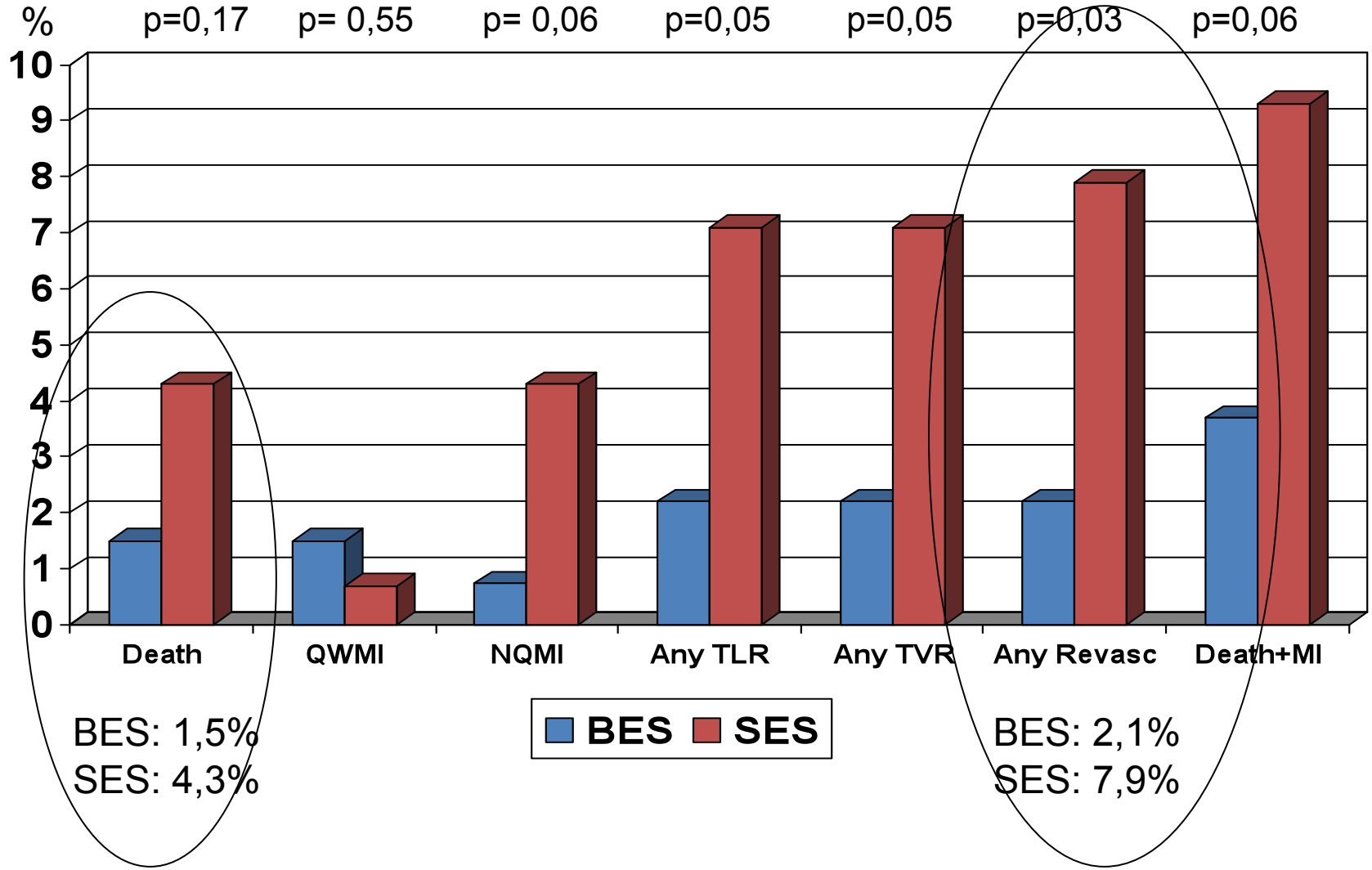
30 day MACE for STEMI



30 day events for STEMI

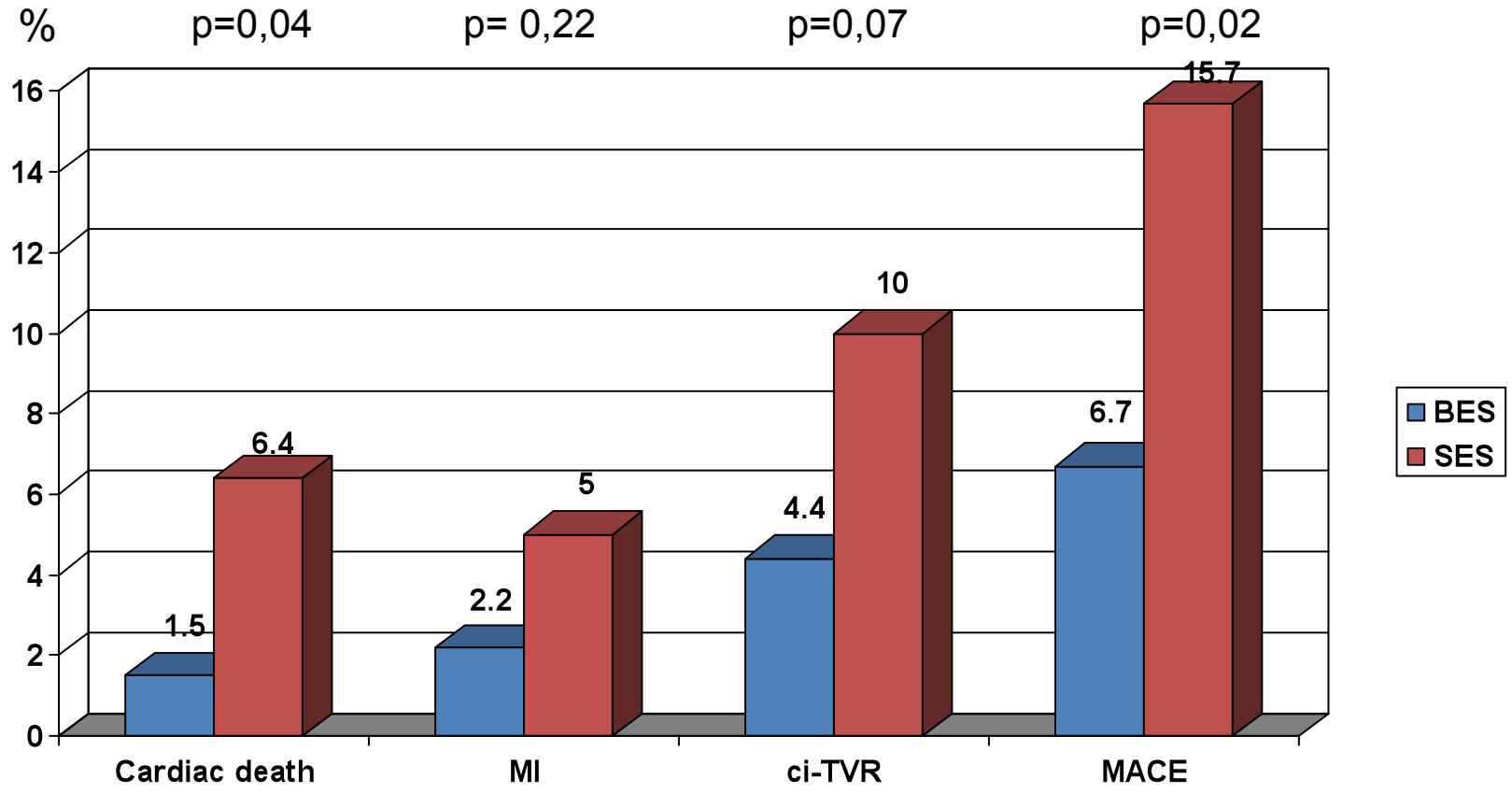


30 day events for STEMI

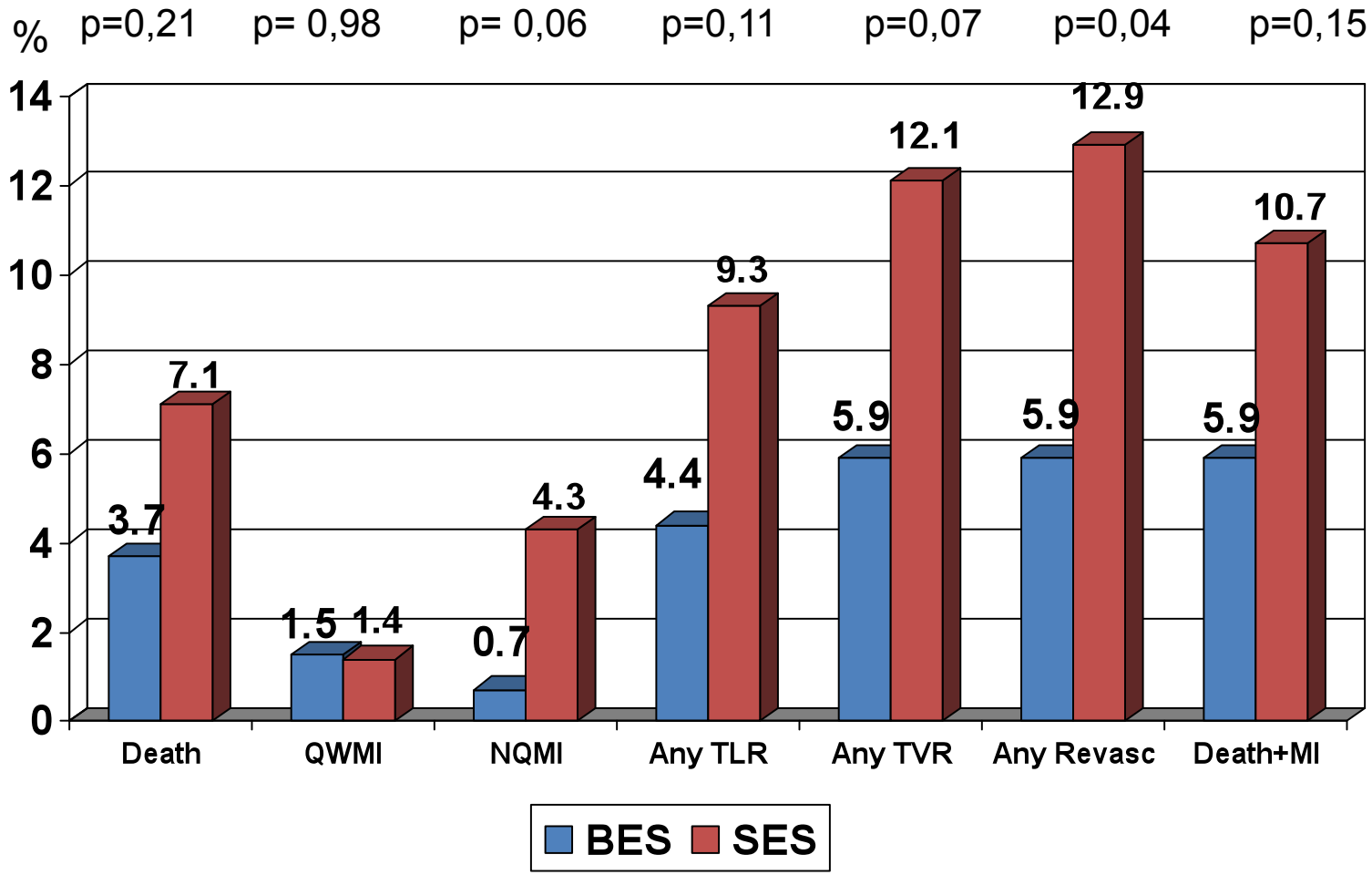


EUROPCR09

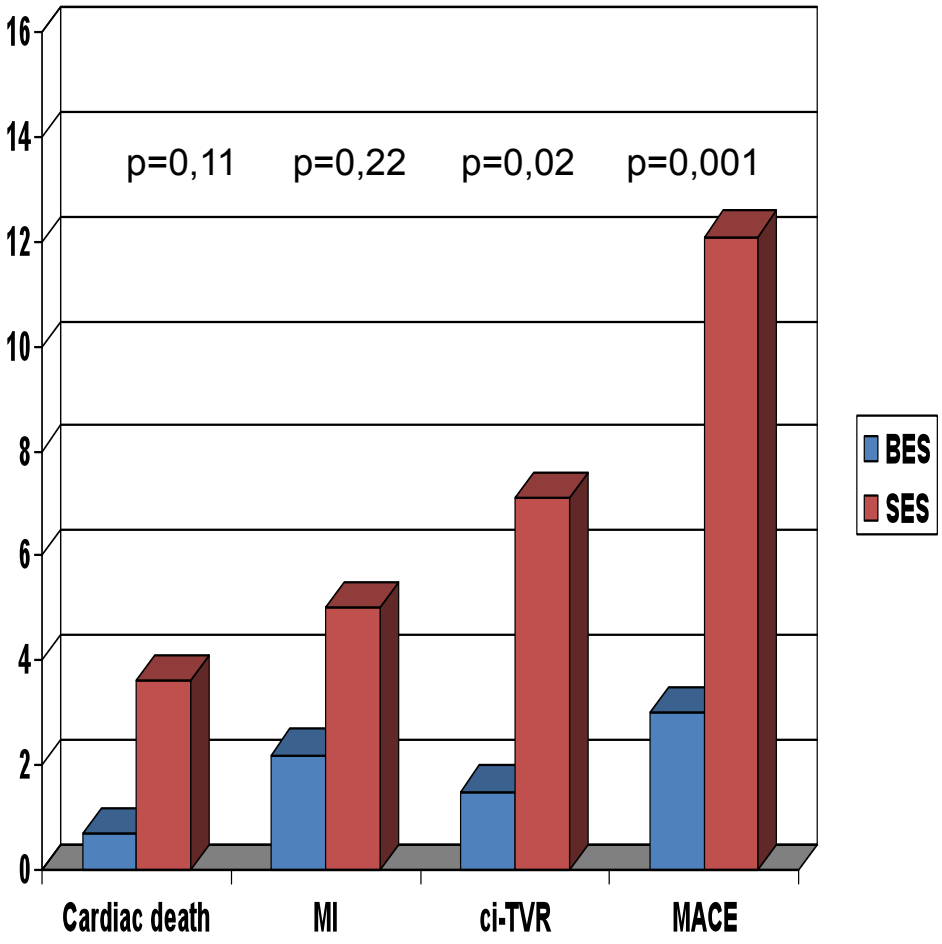
12 month MACE for STEMI



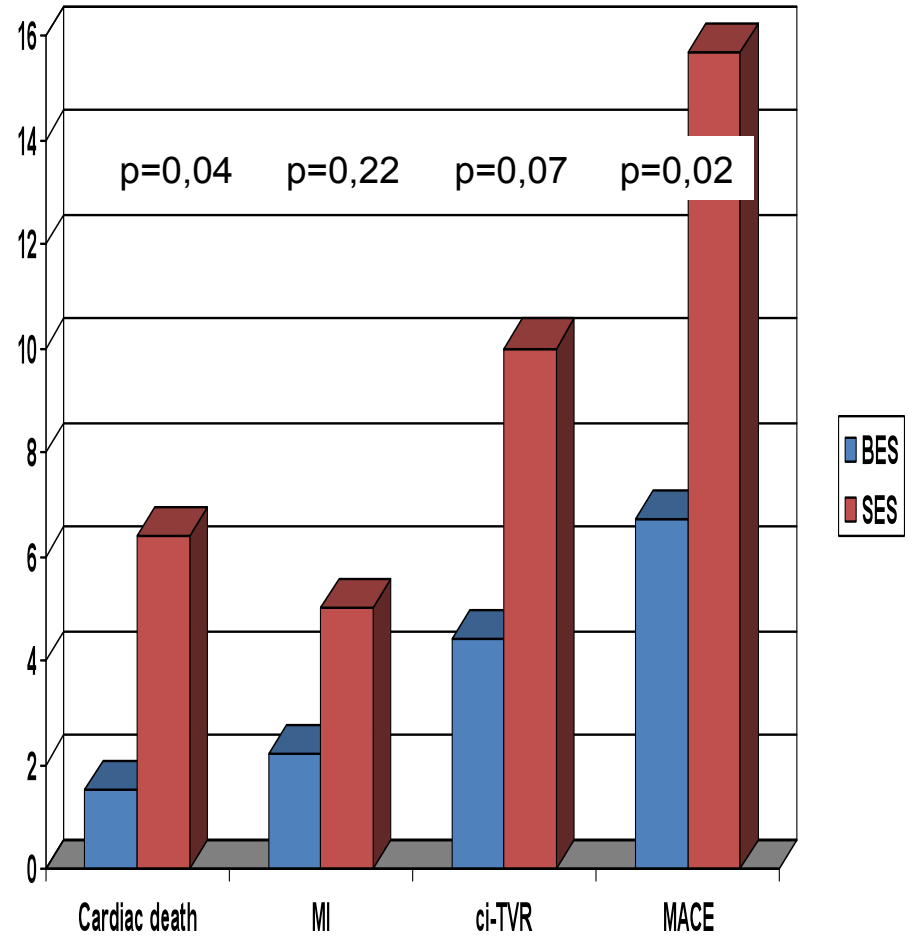
12 month events



30 day vs 12 month MACE in STEMI patients

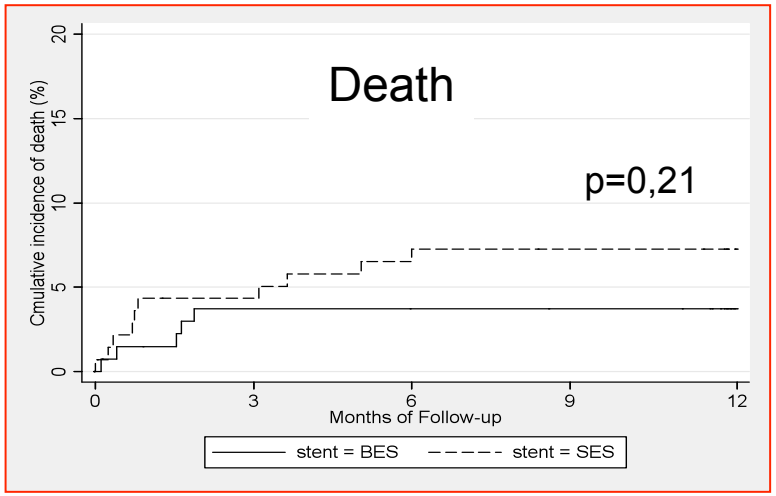


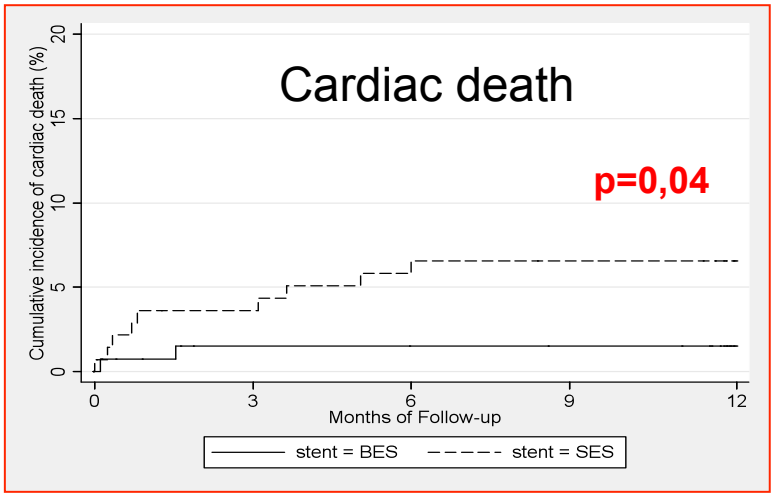
30 days

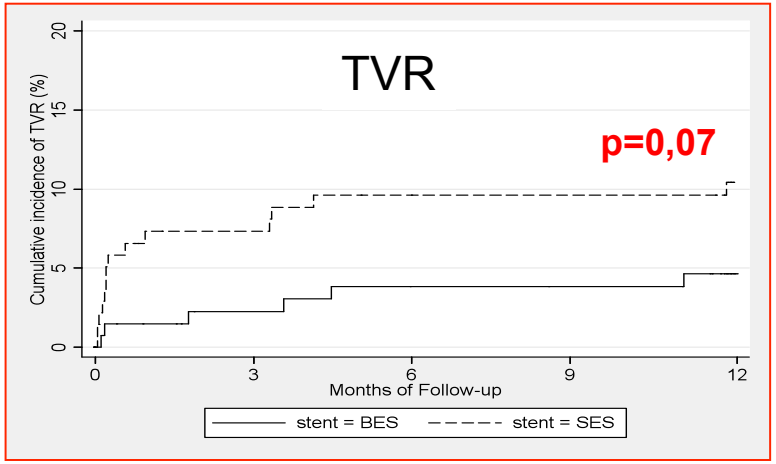


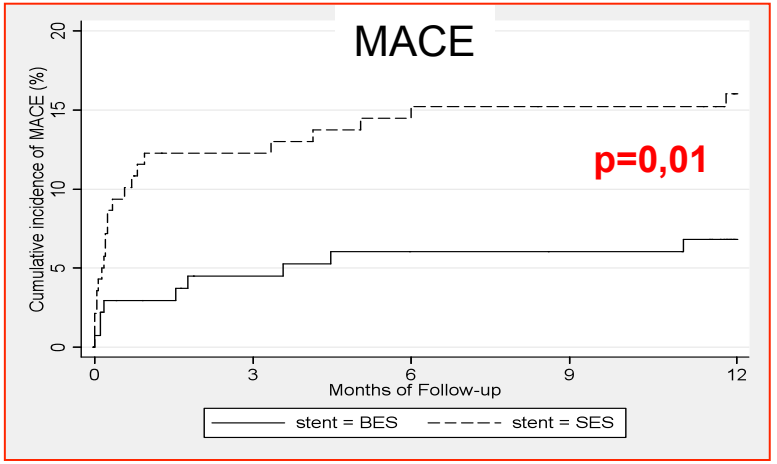
12 months

One-Year Cumulative Incidence of Death, Cardiac Death, TVR and MACE

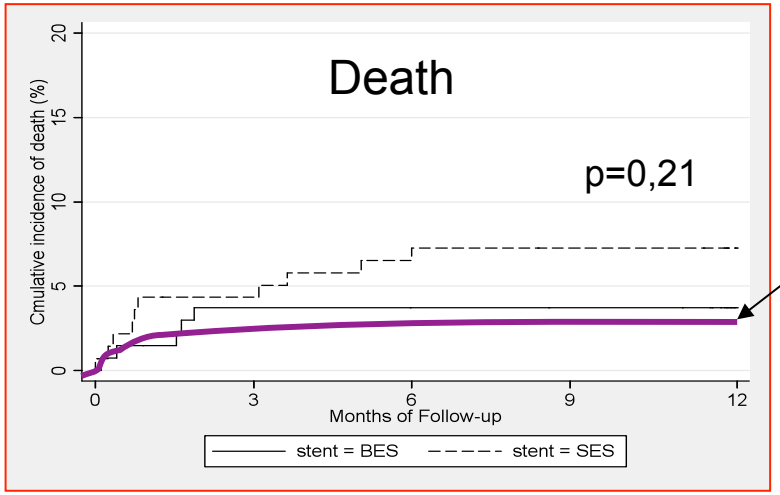




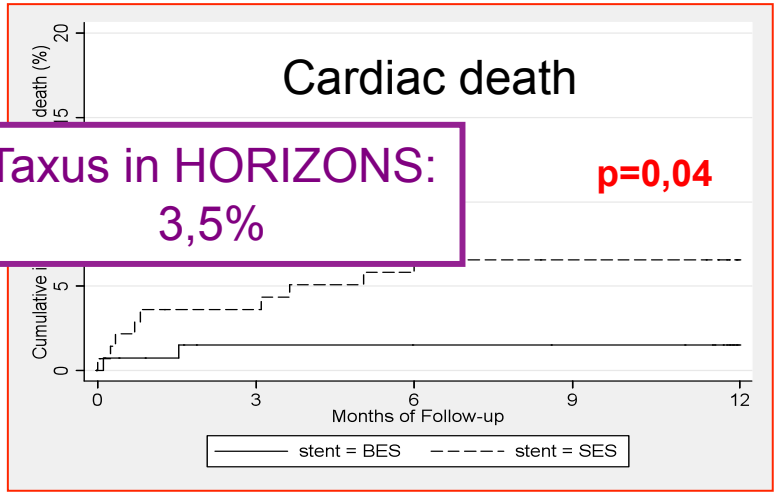


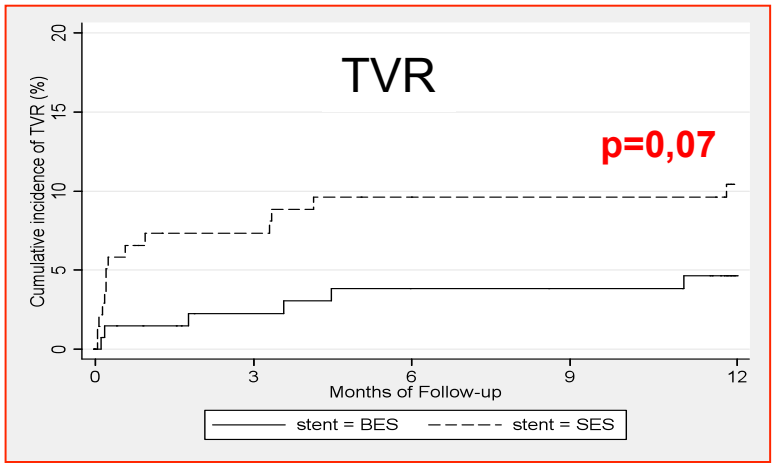


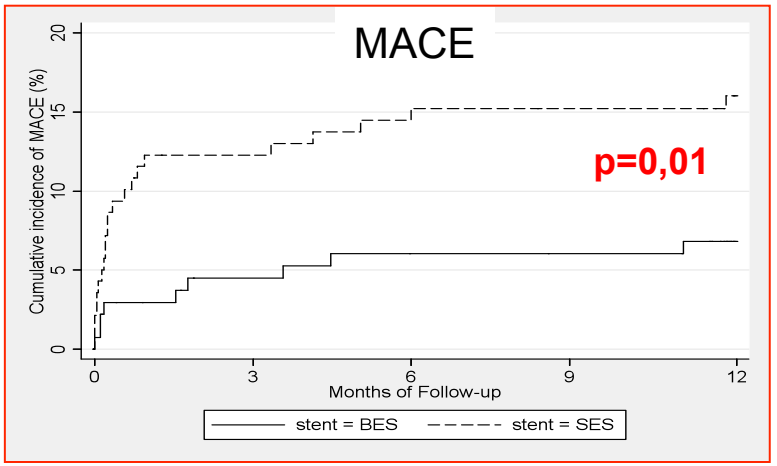
One-Year Cumulative Incidence of Death, Cardiac Death, TVR and MACE



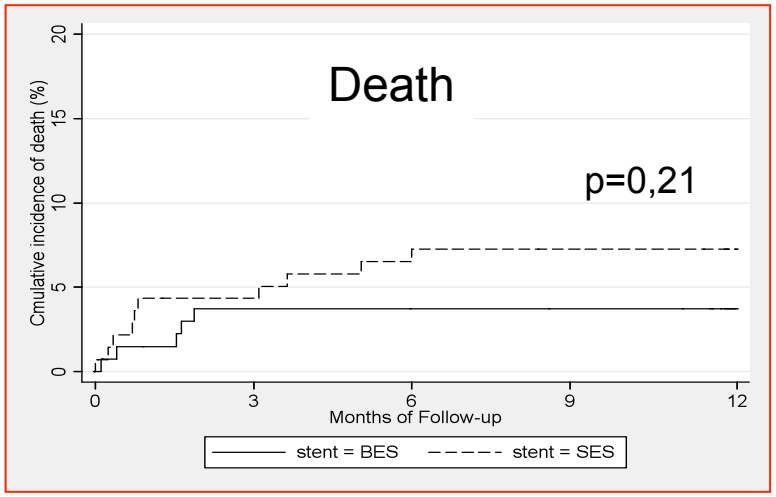
Taxus in HORIZONS: 3,5%

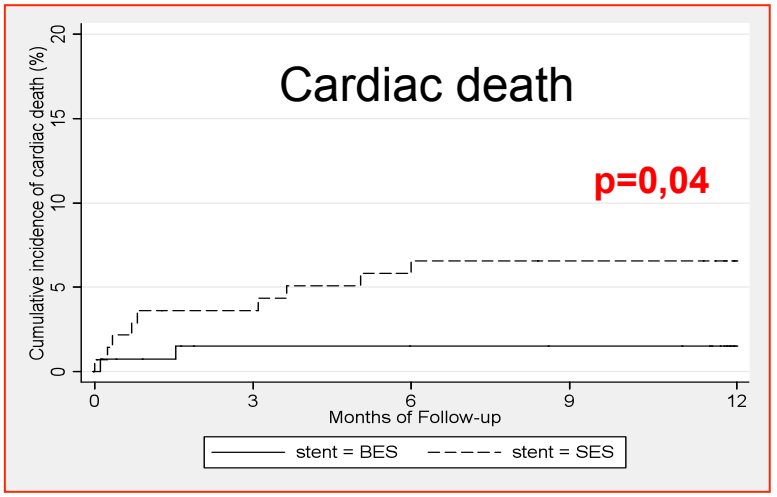


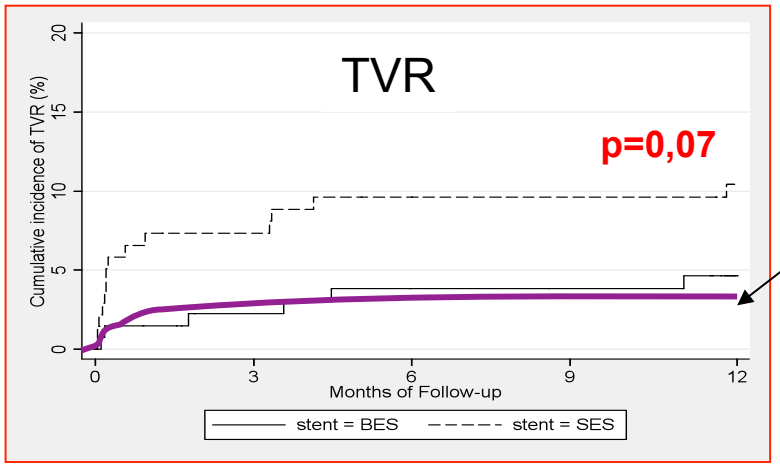




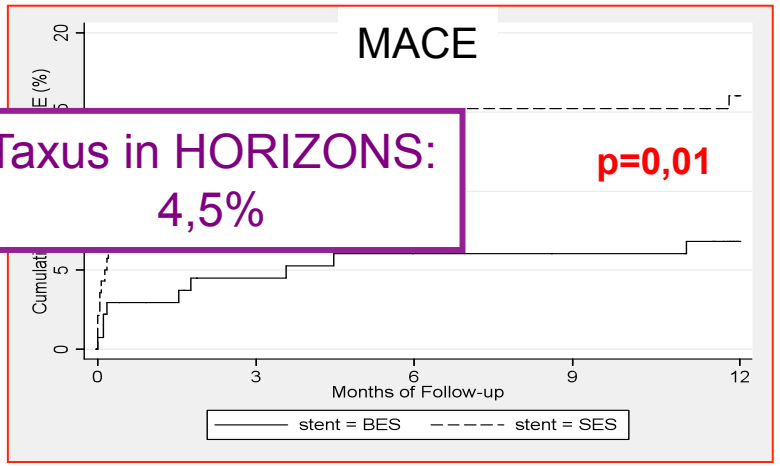
One-Year Cumulative Incidence of Death, Cardiac Death, TVR and MACE



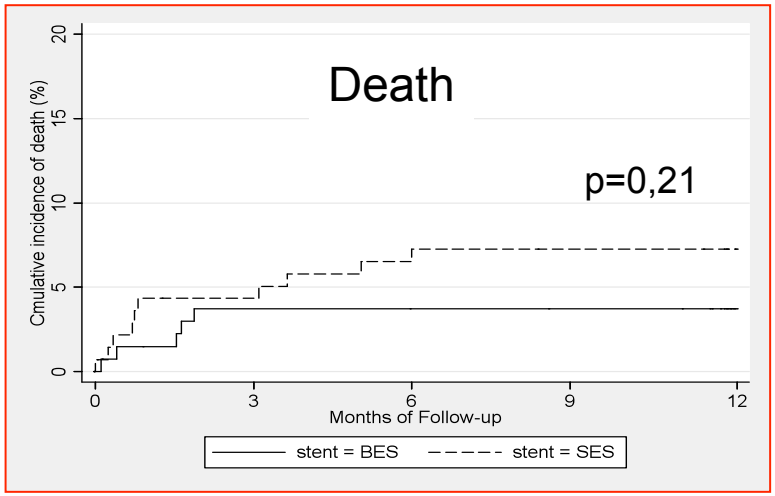


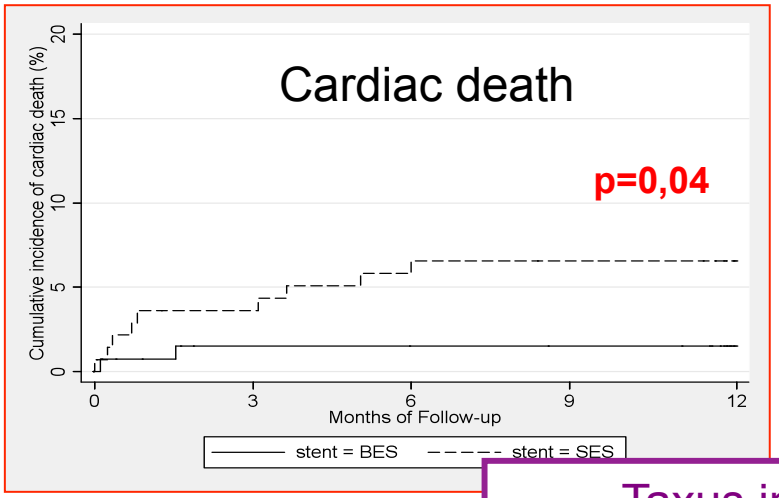


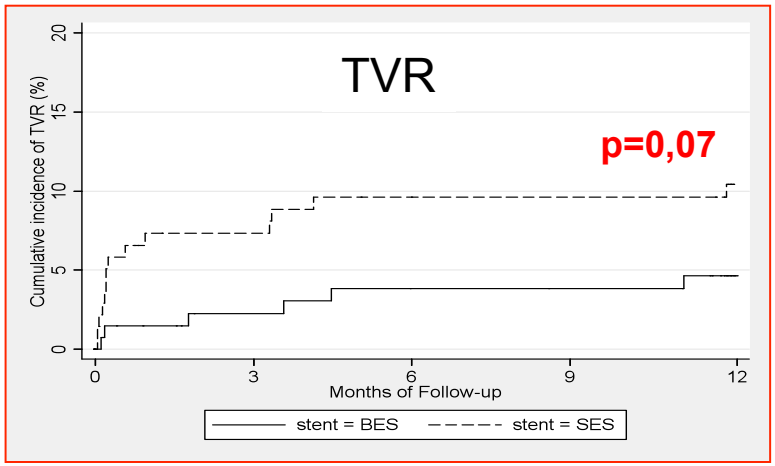
Taxus in HORIZONS: 4,5%

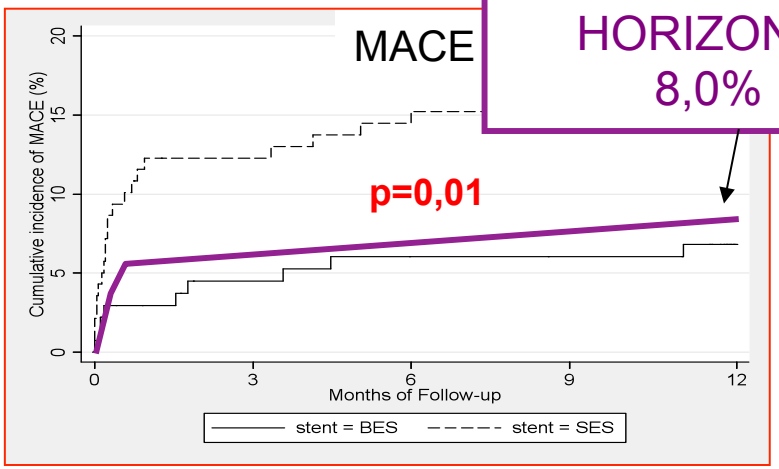


One-Year Cumulative Incidence of Death, Cardiac Death, TVR and MACE



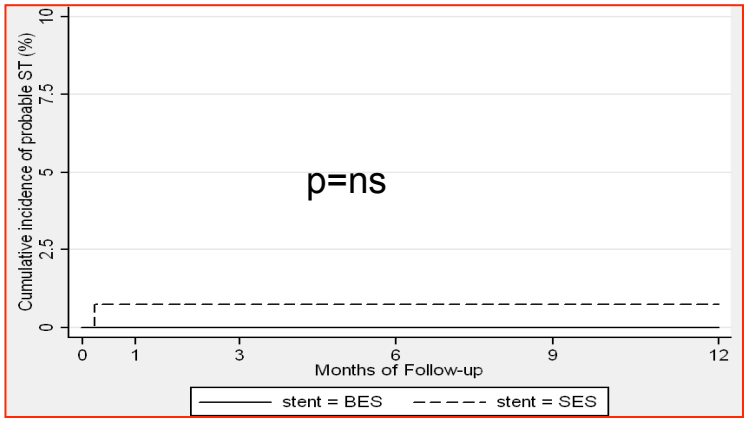




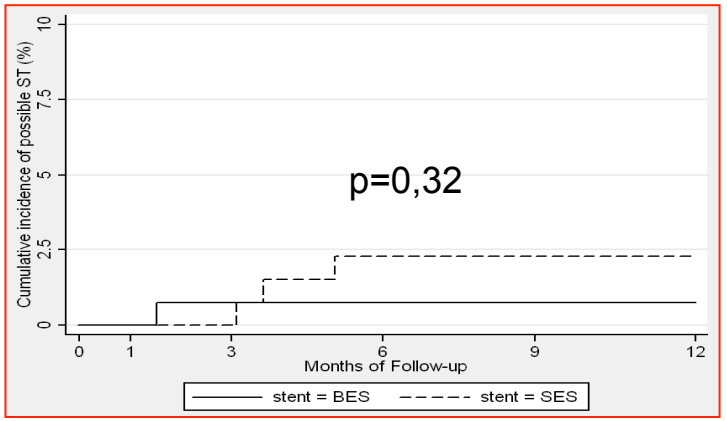


Taxus in HORIZONS: 8,0%

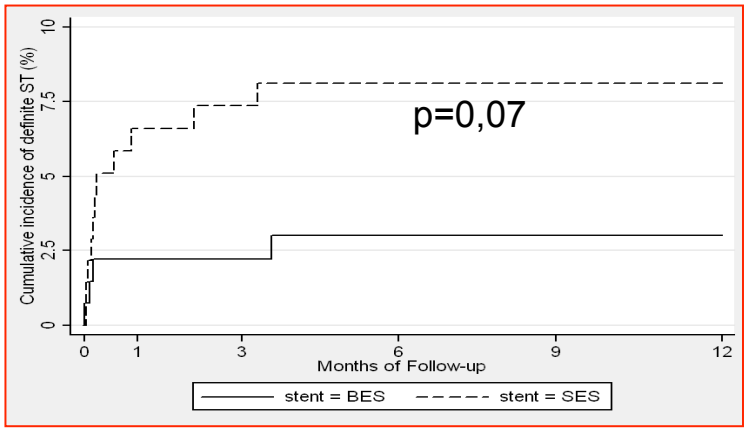
One-Year Cumulative Incidence of Stent thrombosis: BES vs SES in STEMI



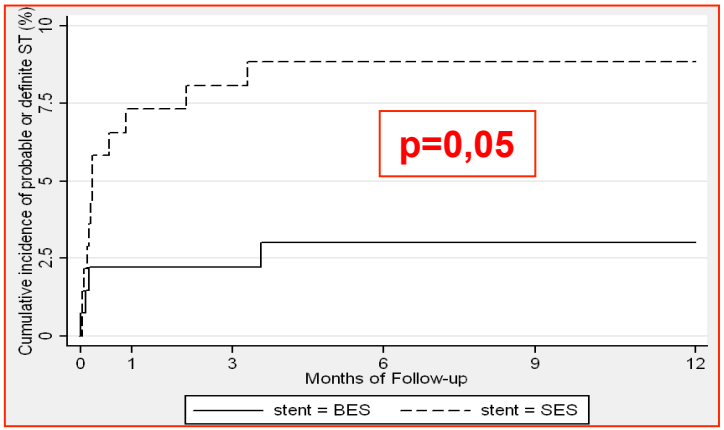
Probable ST



Possible ST



Definite ST



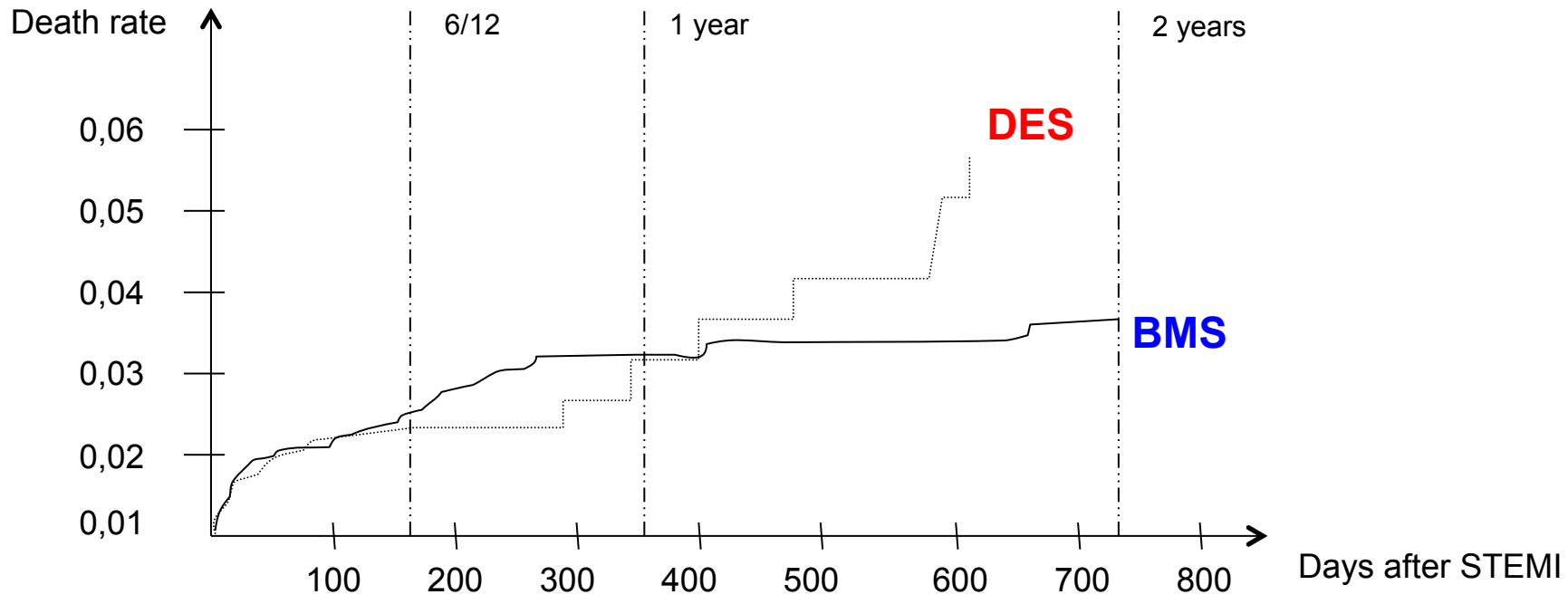
Possible or Definite ST

Why BioMatrix is better than Cypher for STEMI?

- Biodegradable polymer and abluminal coating?
- Mechanical futures of the stent platform?
  - Symmetric strut deployment
  - Stent apposition and sealing of the soft plaque and thrombus

GRACE-AMI

- Survival up to 2 years: BMS vs DES



G. Stegg et al. EHJ (2009) 30, 321-329

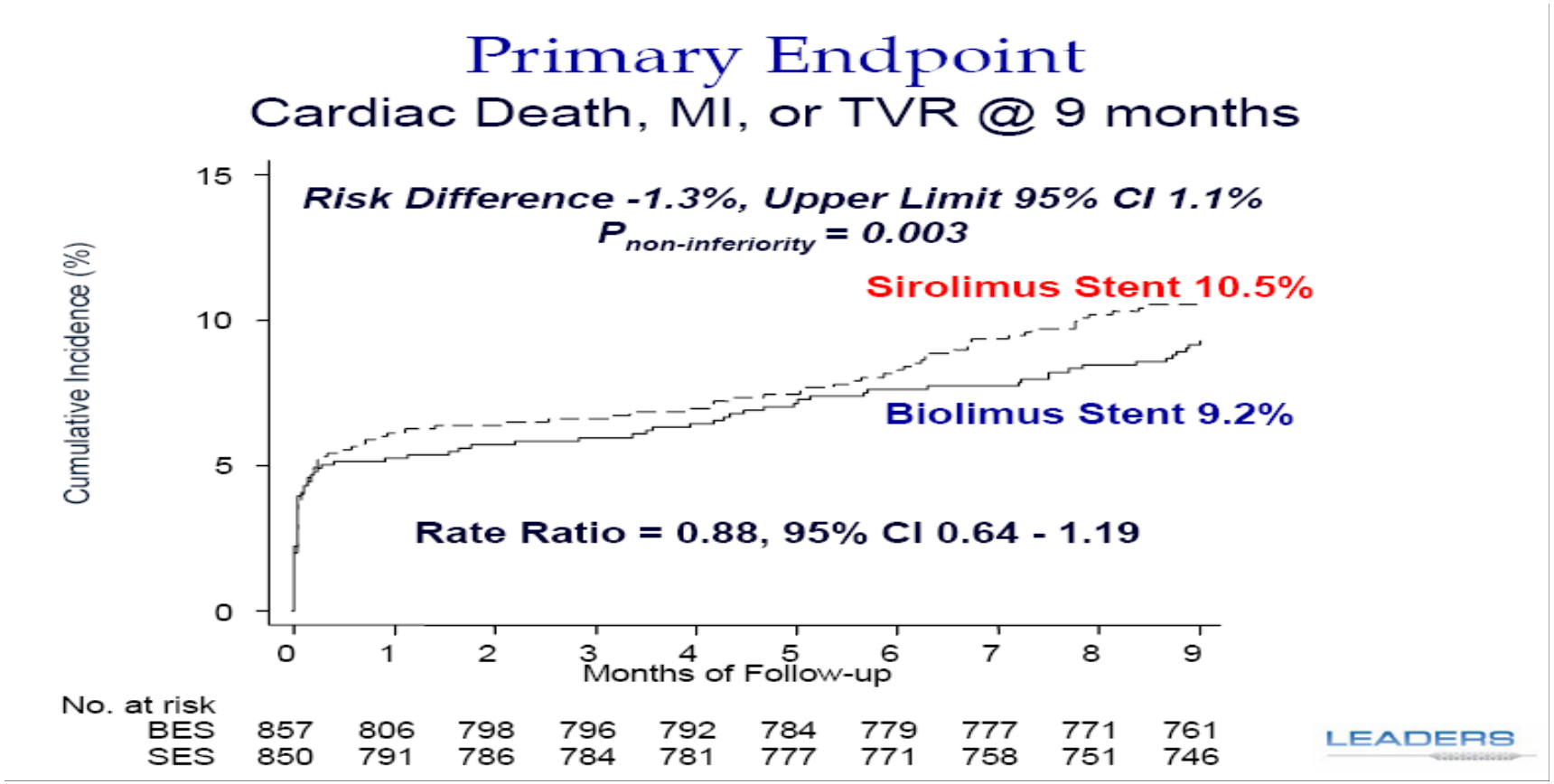
Summary

- There was no differerences in clinical outcome between SES and BES in NST-ACS patients.
- In BES patients a significant lower incidence of MACE and cardiac death rate at 12 month was observed in STEMI subgroups.
- The difference between BES and SES patients in STEMI are related mainly to subacute ST and TVR occuring during first 30 days.
- Long term follow-up (2 year and longer) is mandatory to assess safety profile of both stents.

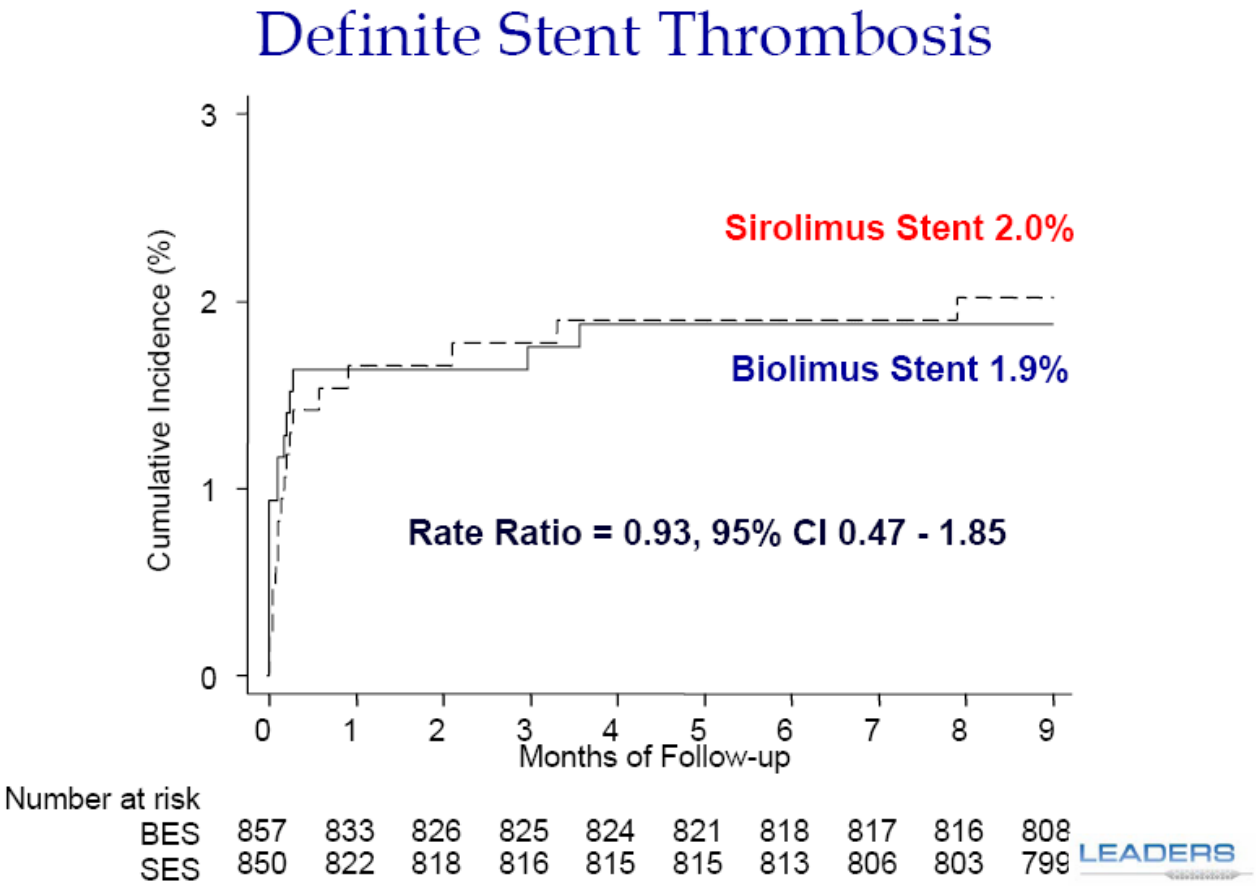
SES vs BES in STEMI

- The significant difference between SES and BES are related mainly to subacute ST and TVR occuring during first 30 days.

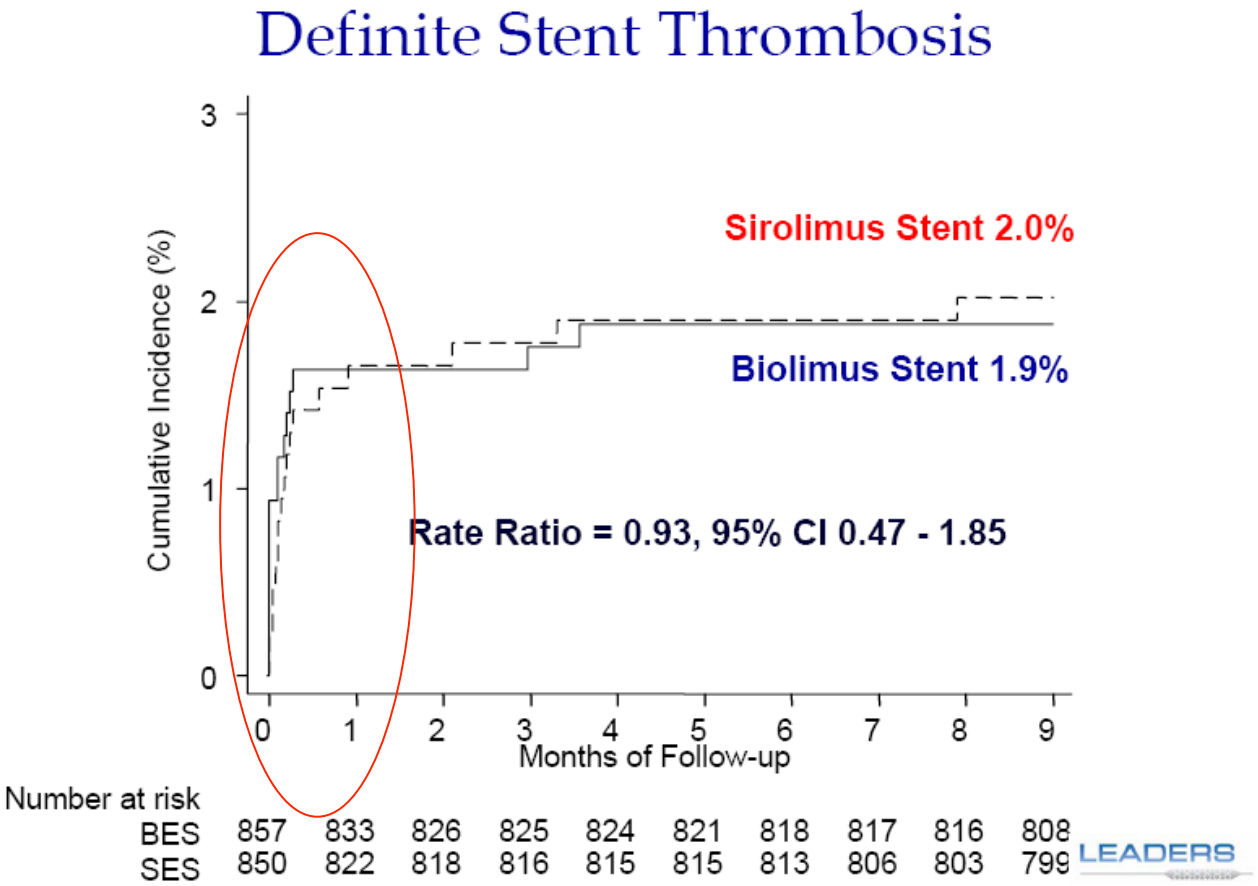
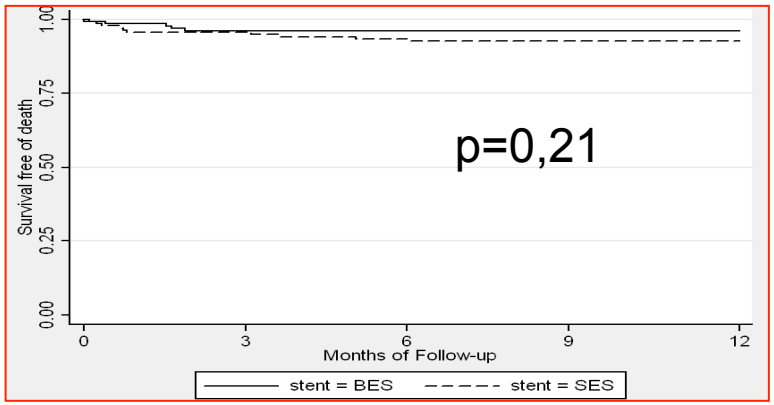
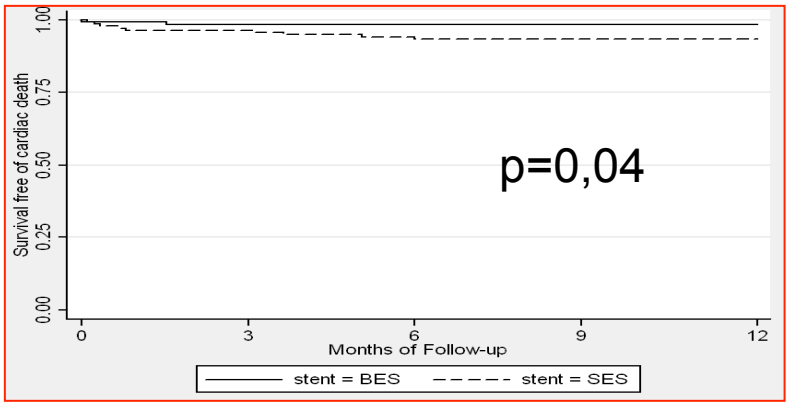
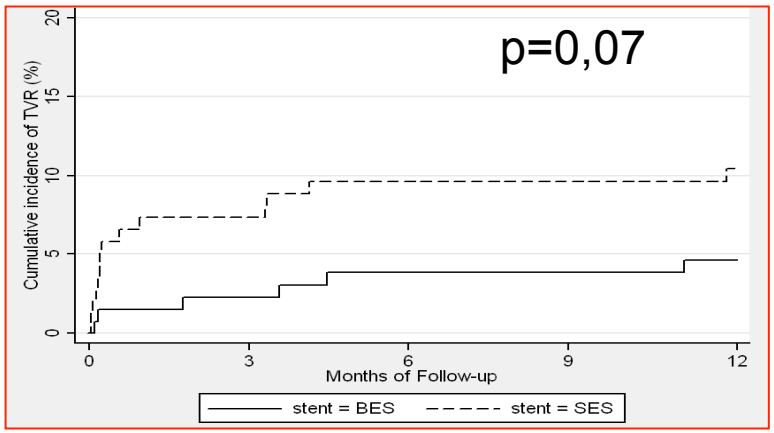
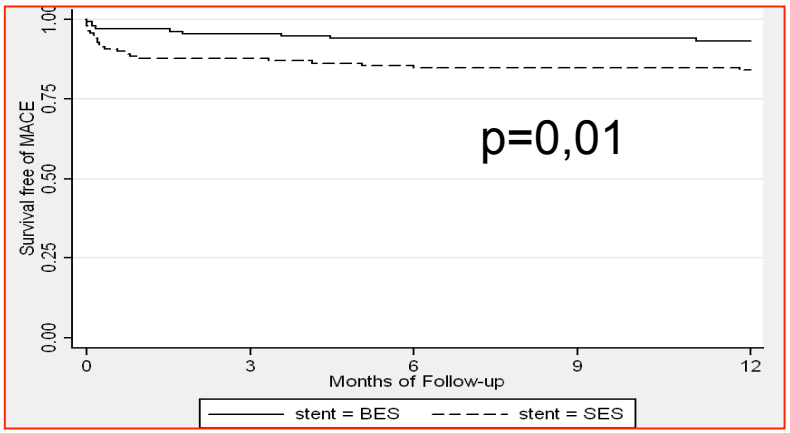
Timing of occurence of primary endpoints in all patients



In-stent Thrombosis: all patients



In-stent Thrombosis: all patients



Survival curves and cumulative incidence of TVR