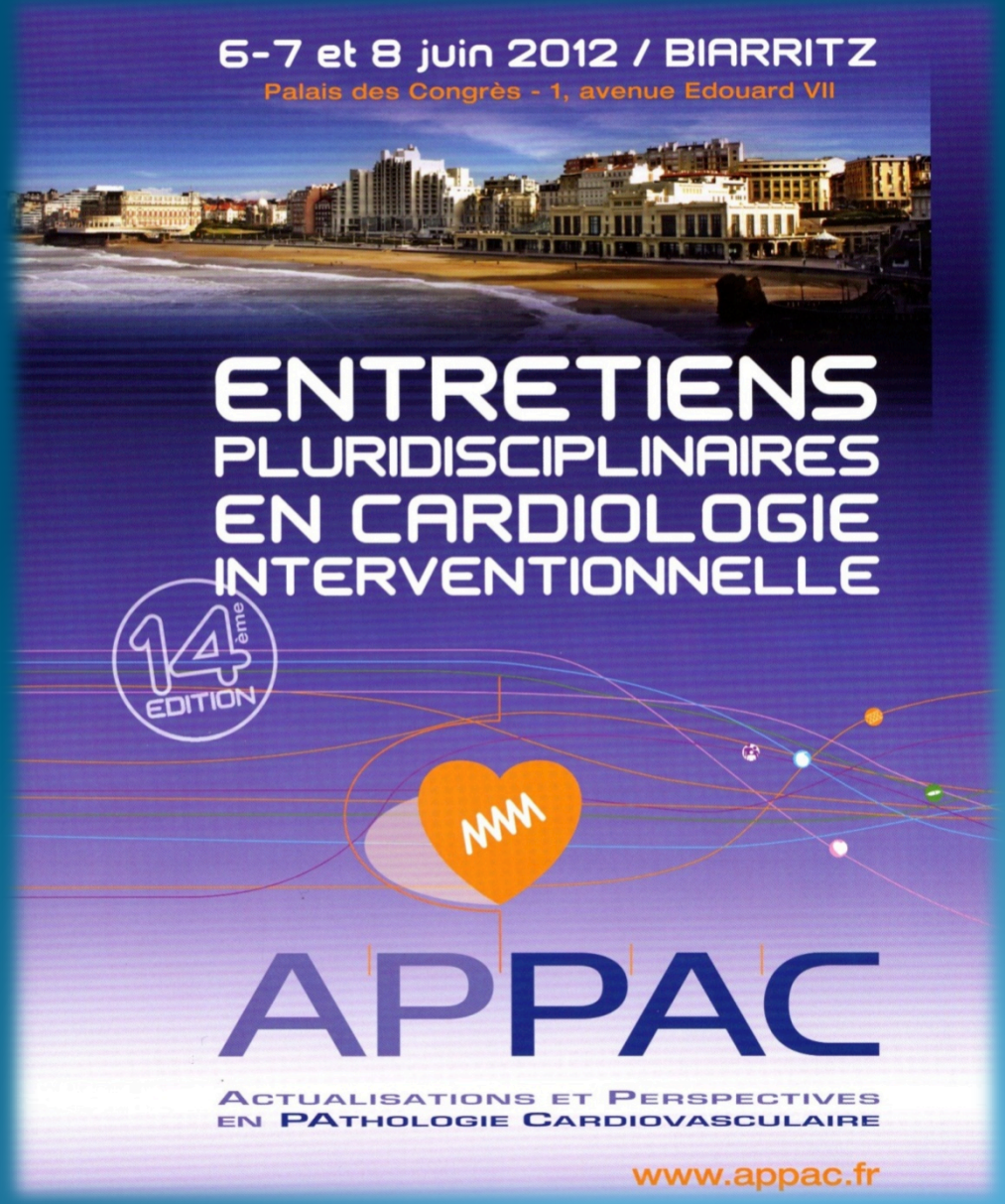


U.C.V.

Docteur B. VALEIX
Clinique Casamance
Aubagne

10h50-11h30

BIOSENSORS INTERNATIONAL

QUEL STENT EN PHASE AIGUE D'INFARCTUS ?

***Modérateurs : B. KARSENTY** (Pessac) - **B. VALEIX** (Marseille)*

• Cas clinique	***B. VALEIX** (Marseille)*
• Je choisis un BMS	***N. DELARCHE** (Pau)*
• Je choisis un DES	***P. MEYER** (St-Laurent du Var)*
• Futur et conclusions	***B. VALEIX** (Marseille)*

FUTUR ET CONCLUSIONS — **B. VALEIX (Marseille)**

Meta-Analysis of Long-Term Outcomes for Drug-Eluting Stents Versus Bare-Metal Stents in Primary Percutaneous Coronary Interventions for ST-Segment Elevation Myocardial Infarction.

Eric L. Wallace, DO[a], Ahmed Abdel-Latif, MD[a], Richard Charnigo, PhD[b], David J. Moliterno, MD[a], Bruce Brodie, MD[c], Rahul Matnani, MD[a], and Khaled M. Ziada, MD[a,*]

The use of drug-eluting stents (DESs) in primary percutaneous coronary intervention (PPCI) has shown early benefit over bare-metal stents (BMSs) in decreasing adverse cardiac events. However, there are concerns regarding the increased risk of late and very late stent thrombosis (ST) after DES use. With the paucity of ST events individual trials may have been underpowered to detect significant differences. We sought to perform a meta-analysis to evaluate the available literature examining the outcomes of DESs and BMSs in PPCI after ≥3 years of follow-up. We analyzed 8 randomized clinical trials (RCTs) and 5 observational studies comparing DESs to BMSs in PPCI. Clinical end-point data were analyzed for RCTs and observational studies separately using random-effect models. RCTs included 5,797 patients in whom first-generation DESs (sirolimus- or paclitaxel-eluting stents) were compared to BMS control arms. Patients receiving DESs had a significantly lower risk of target lesion revascularization (odds ratio [OR] 0.48, confidence interval [CI] 0.37 to 0.61), target vessel revascularization (OR 0.53, CI 0.42 to 0.66), and accordingly major adverse cardiac events (OR 0.69; CI 0.56 to 0.84). Incidence of ST was not different between groups (OR 1.02, CI 0.76 to 1.37). There was no significant difference in mortality (OR 0.88, CI 0.68 to 1.12) or recurrent myocardial infarction (OR 0.97; CI 0.61 to 1.54). Among observational studies (n = 4,650) fewer studies reported on target lesion revascularization and target vessel revascularization, but the trend remained in favor of DESs. A small but statistically significant increase in ST was noted with DES use (OR 1.62, CI 1.18 to 2.21) at ≥3 years of follow up, without evidence of recurrent myocardial infarction. Those receiving DESs had a significantly lower mortality compared to those receiving BMSs (OR, 0.65, 95% CI 0.53 to 0.80, p <0.001). In conclusion, this meta-analysis of RCTs examining the long-term outcomes of first-generation DESs versus BMSs in PPCI, DES use resulted in decreased repeat revascularization with no increase in ST, mortality, or recurrent myocardial infarction. (Am J Cardiol 2012;109:932–940)

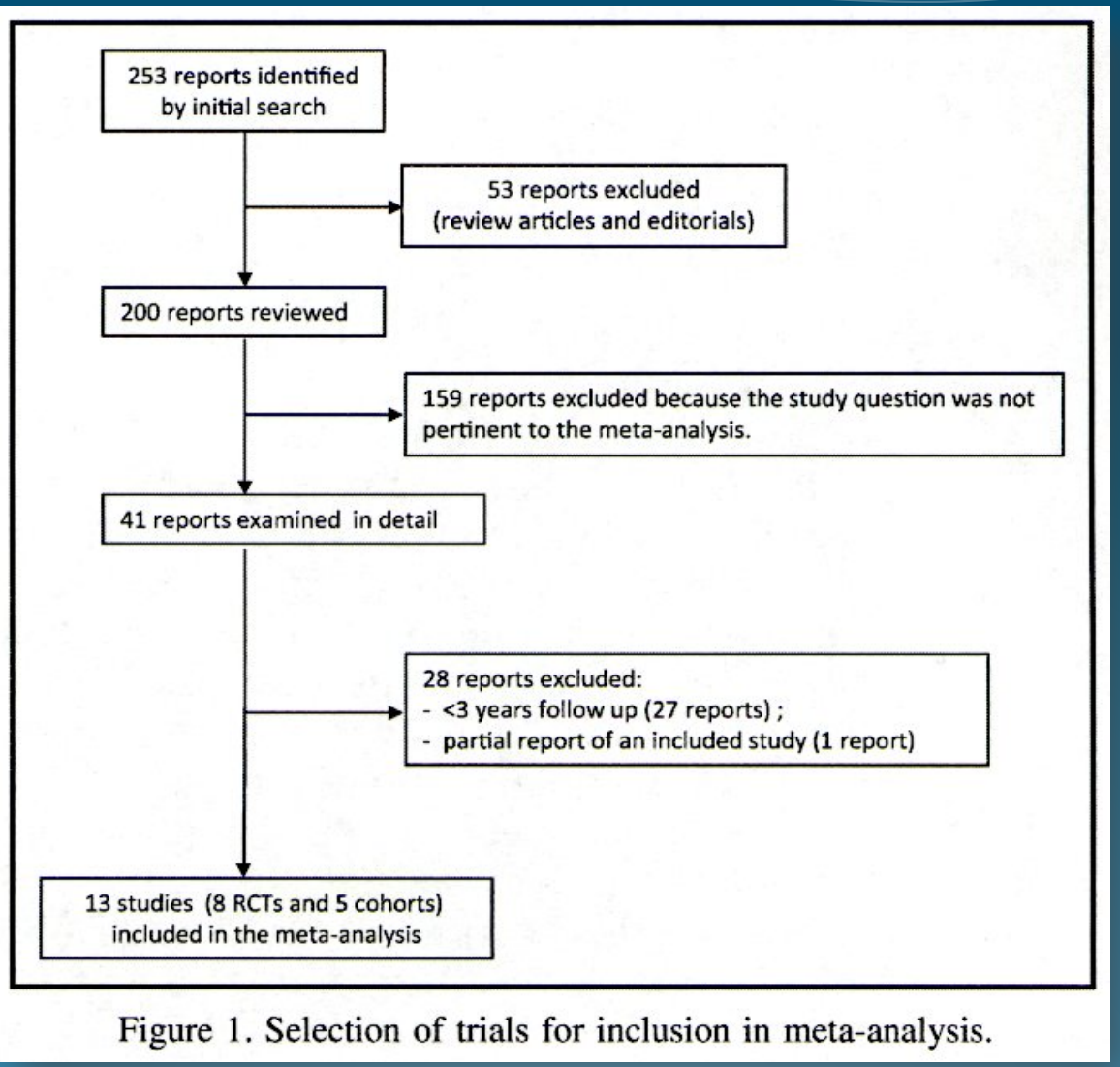


Figure 1. Selection of trials for inclusion in meta-analysis.

Table 1
Clinical and angiographic characteristics of included studies

Study	Year	Total Number of Patients	Type of DES	Follow-Up (years)*	Age (years), mean ± SD	Women (%)	Diabetics (%)
Randomized trials							
DEDICATION[13]	2010	626	SES, PES	3	62 DES 63 BMS	27 DES 26 BMS	9 DES 11 BMS
HORIZONS-AMI[19]	2010	3,006	PES	3	60 DES 59 BMS	23 DES 24 BMS	16 DES 15 BMS
MISSION![10]	2010	310	SES	3	59 ± 11 DES 59 ± 12 BMS	25 DES 19 BMS	13 DES 7 BMS
PASEO[11]	2009	270	SES, PES	3.4	63 ± 15 DES 62 ± 17 BMS	31 DES 29 BMS	23 DES 26 BMS
PASSION[20]	2011	619	PES	5	61 ± 12 DES 61 ± 13 BMS	26 DES 22 BMS	10 DES 12 BMS
SESAMI[17]	2010	313	SES	3	63 DES 62 BMS	20 DES 20 BMS	18 DES 24 BMS
STRATEGY[18]	2009	175	SES	5	62 DES 63 BMS	23 DES 31 BMS	17 DES 12 BMS
TYPHOON[16]	2011	478	SES	4	58 ± 12 DES 61 ± 12 BMS	21 DES 22 BMS	16 DES 17 BMS
Observational studies							
BASKET[2]	2009	210	SES, PES	3	62 ± 13	20	16 SES 21 BMS
Brodie et al[5]	2011	1,463	SES, PES	NR	NR	28 DES 32 BMS	20 DES 14 BMS†
Ishikawa et al[12]	2010	555	SES	3.6 DES 5.0 BMS†	67 ± 12 DES 66 ± 12 BMS	29 DES 21 BMS	41 DES 38 BMS
Kukreja et al[14]	2008	1,738	SES, PES	4.2 SES 2.4 PES 5.8 BMS†	59 ± 12 SES 60 ± 12 PES 58 ± 12 BMS†	25 SES 22 PES 19 BMS	12 SES 10 PES 10 BMS
Park et al[15]	2010	684	SES, PES	2.1 DES 2.9 BMS	62 ± 13 DES 62 ± 13 BMS	27 DES 22 BMS	28 DES 29 BMS

BASKET = Basel Stent Cost-Effectiveness Trial; DEDICATION = Drug Elution and Distal Protection in Acute Myocardial Infarction; NR = not reported; PASEO = PaclitAxel or Sirolimus-Eluting stent versus bare metal stent in primary angioplasty; PASSION = Paclitaxel-Eluting Versus Conventional Stent in Myocardial Infarction with ST-Segment Elevation; PES = paclitaxel-eluting stent; SES = sirolimus-eluting stent; SESAMI = Sirolimus-Eluting Stent Versus Bare-Metal Stent in Acute Myocardial Infarction; STRATEGY = Single high-dose bolus TiRofiban versus Abciximab with sirolimus eluting sTEnt or Bare Metal Stent in Acute Myocardial Infarction studY.

* Many trials listed event rates at a defined interval and mean ± SD was not available.

† $p < 0.05$ cited by authors.

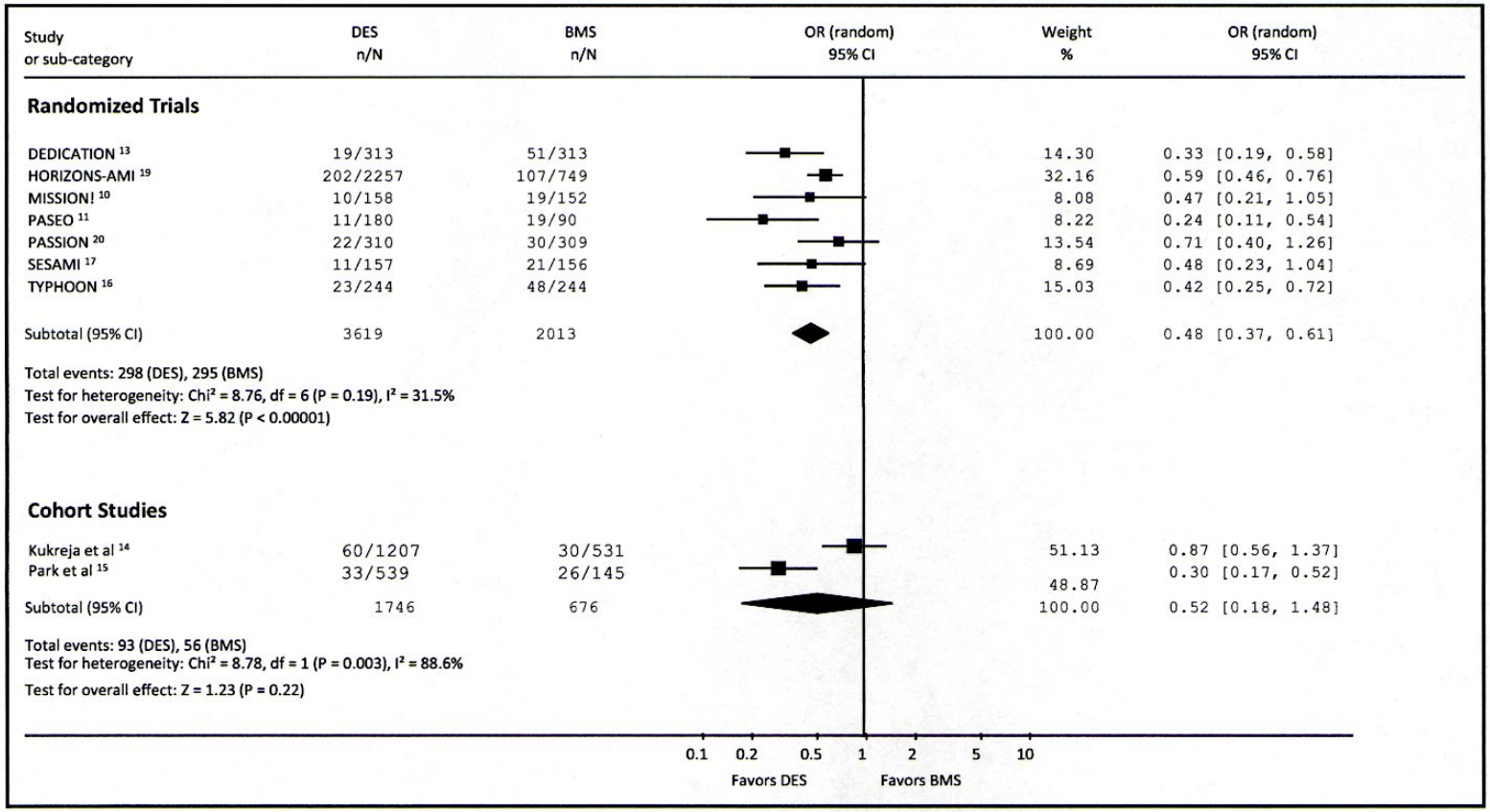


Figure 2. Forest plot of unadjusted odds ratios (95% confidence intervals) for target lesion revascularization after primary percutaneous coronary intervention in patients receiving drug-eluting stents compared to those receiving bare-metal stents. A significant decrease in target lesion revascularization is noted with drug-eluting stents in randomized clinical trials (odds ratio 0.48, 95% confidence interval 0.37 to 0.61, p <0.001) but not in observational studies (odds ratio 0.52, 95% confidence interval 0.18 to 1.48, p = 0.22). DEDICATION = Drug Elution and Distal Protection in Acute Myocardial Infarction; PASEO = PaclitAxel or Sirolimus-Eluting stent versus bare metal stent in primary angioplasty; PASSION = Paclitaxel-Eluting Versus Conventional Stent in Myocardial Infarction with ST-Segment Elevation; SESAMI = Sirolimus-Eluting Stent Versus Bare-Metal Stent in Acute Myocardial Infarction.

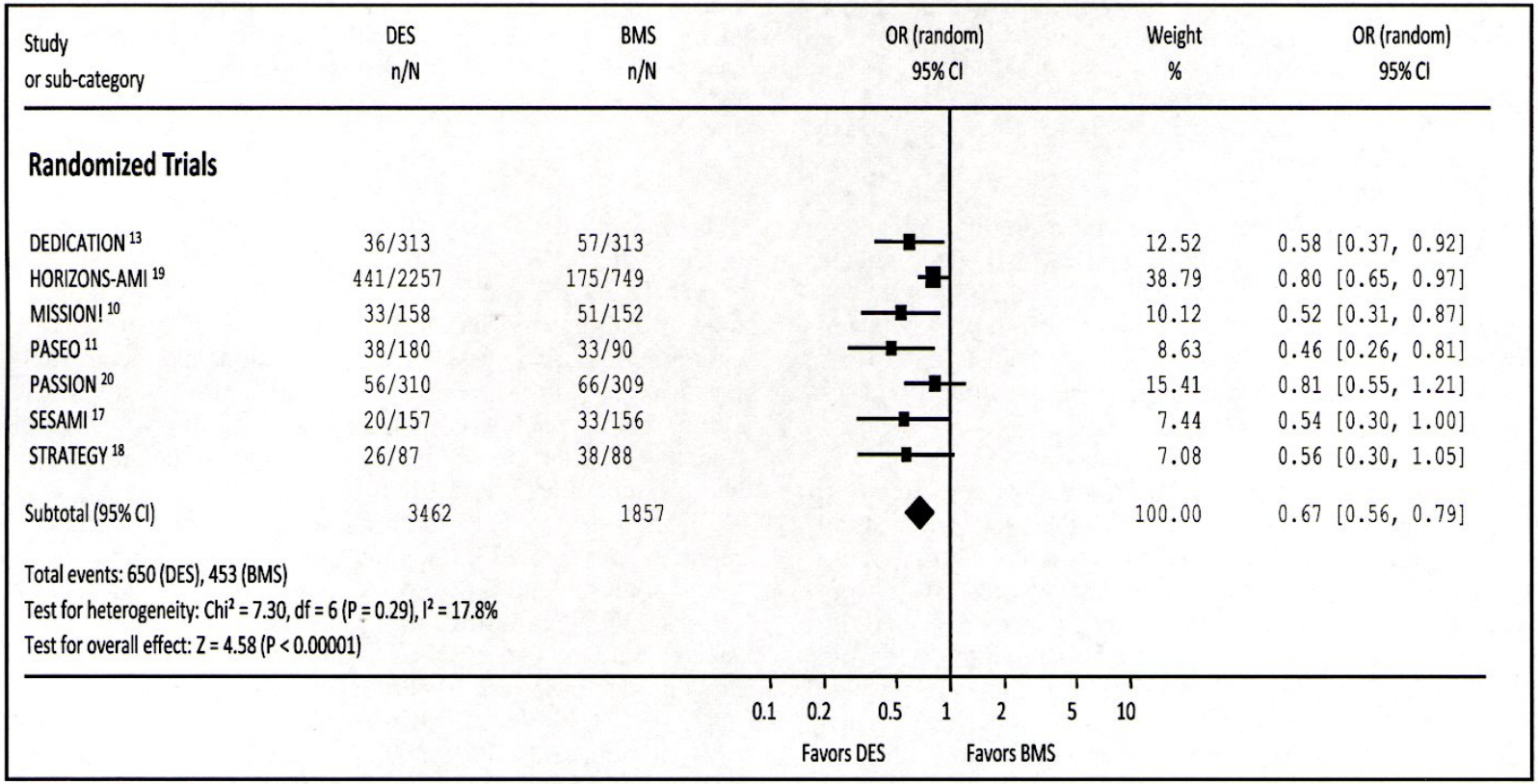


Figure 3. Forest plot of unadjusted odds ratio (95% confidence intervals) for major adverse cardiac events after primary percutaneous coronary intervention in patients receiving drug-eluting stents compared to those receiving bare-metal stents in randomized controlled trials. A significant decrease in major adverse cardiac events is noted with drug-eluting stents in randomized clinical trials (odds ratio 0.67, 95% confidence interval 0.56 to 0.79, p <0.001). STRATEGY = Single high-dose bolus TiRofiban versus Abciximab with sirolimus eluting sTEnt or Bare Metal Stent in Acute Myocardial Infarction studY. Other abbreviations as in Figure 2.

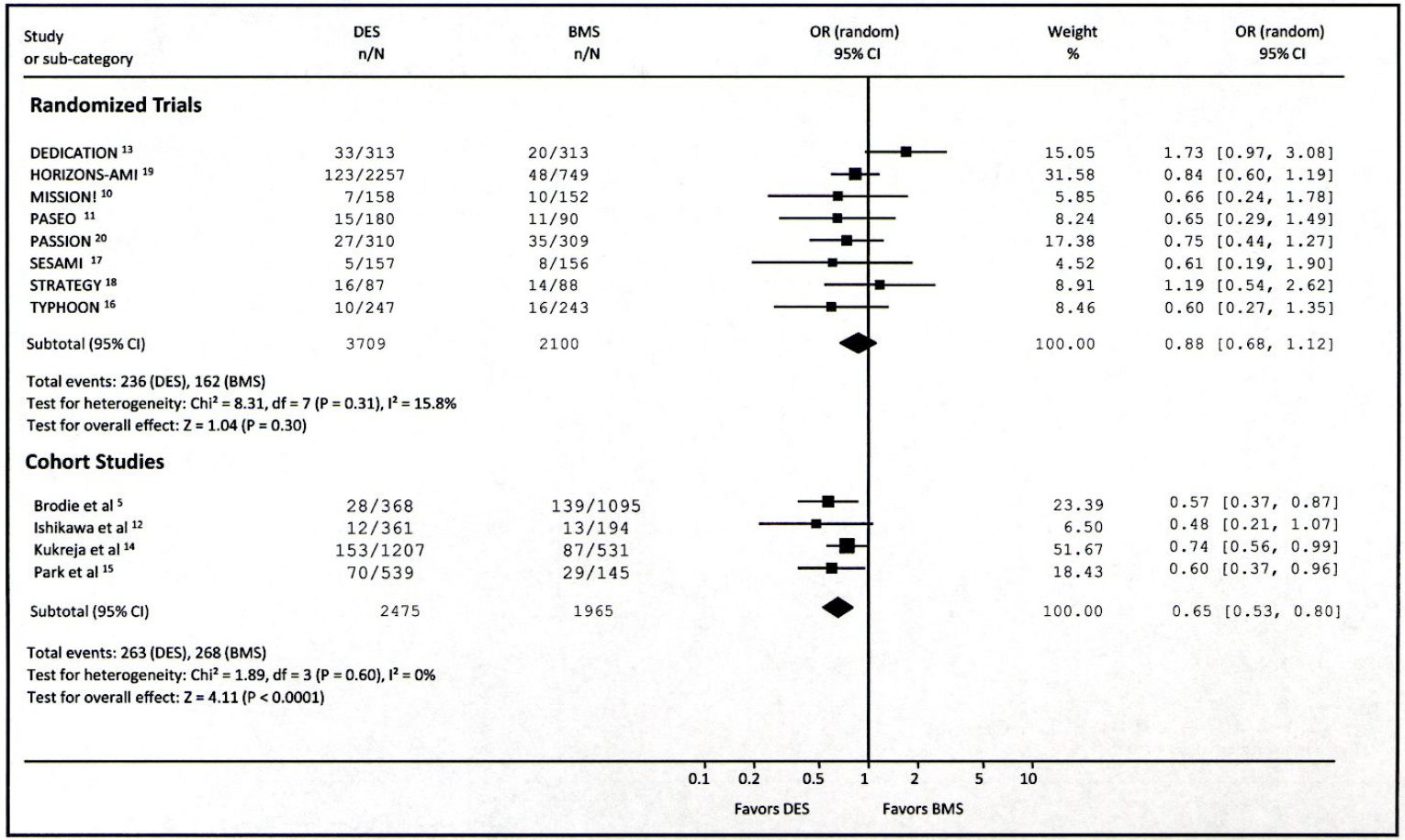


Figure 4. Forest plot of unadjusted odds ratios (95% confidence intervals) for mortality after primary percutaneous coronary intervention in patients receiving drug-eluting stents compared to those receiving bare-metal stents. No decrease in mortality is seen with drug-eluting stents in randomized clinical trials (odds ratio 0.88, 95% confidence interval 0.68 to 1.12, p = 0.30), but a decrease in mortality is noted with drug-eluting stents in observational studies (odds ratio 0.65, 95% confidence interval 0.53 to 0.80, p <0.001). Abbreviations as in Figures 2 and 3.

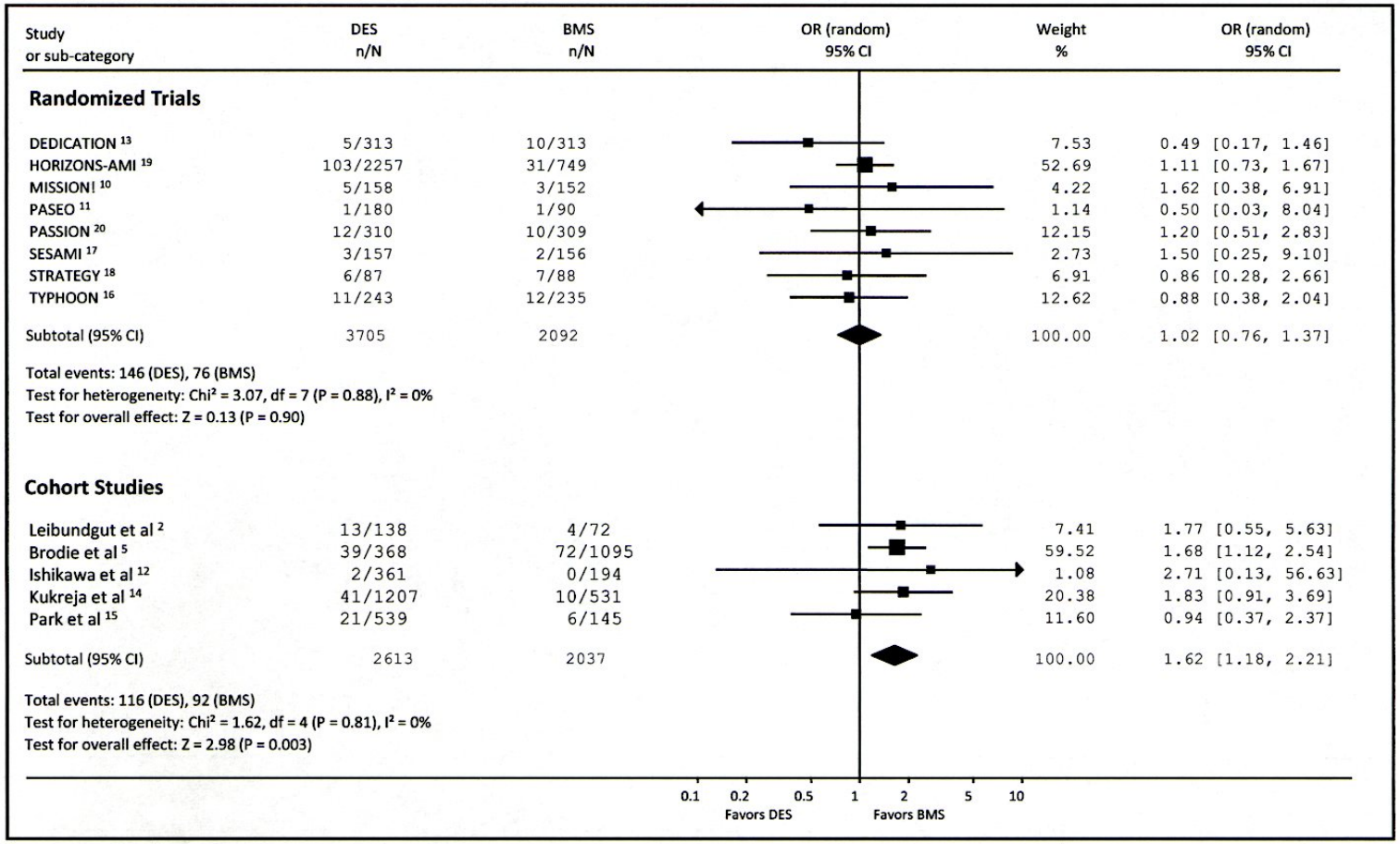


Figure 5. Forest plot of unadjusted odds ratios (95% confidence intervals) for stent thrombosis after primary percutaneous coronary intervention in patients receiving drug-eluting stents compared to those receiving bare-metal stents. There was no significant difference in stent thrombosis between drug-eluting and bare-metal stent randomized clinical trials (odds ratio 1.02, 95% confidence interval 0.76 to 1.37, p = 0.90), but there was a significantly higher incidence of stent thrombosis with drug-eluting stents in registry trials (odds ratio 1.62, 95% confidence interval 1.18 to 2.21, p = 0.003). Abbreviations as in Figures 2 and 3.

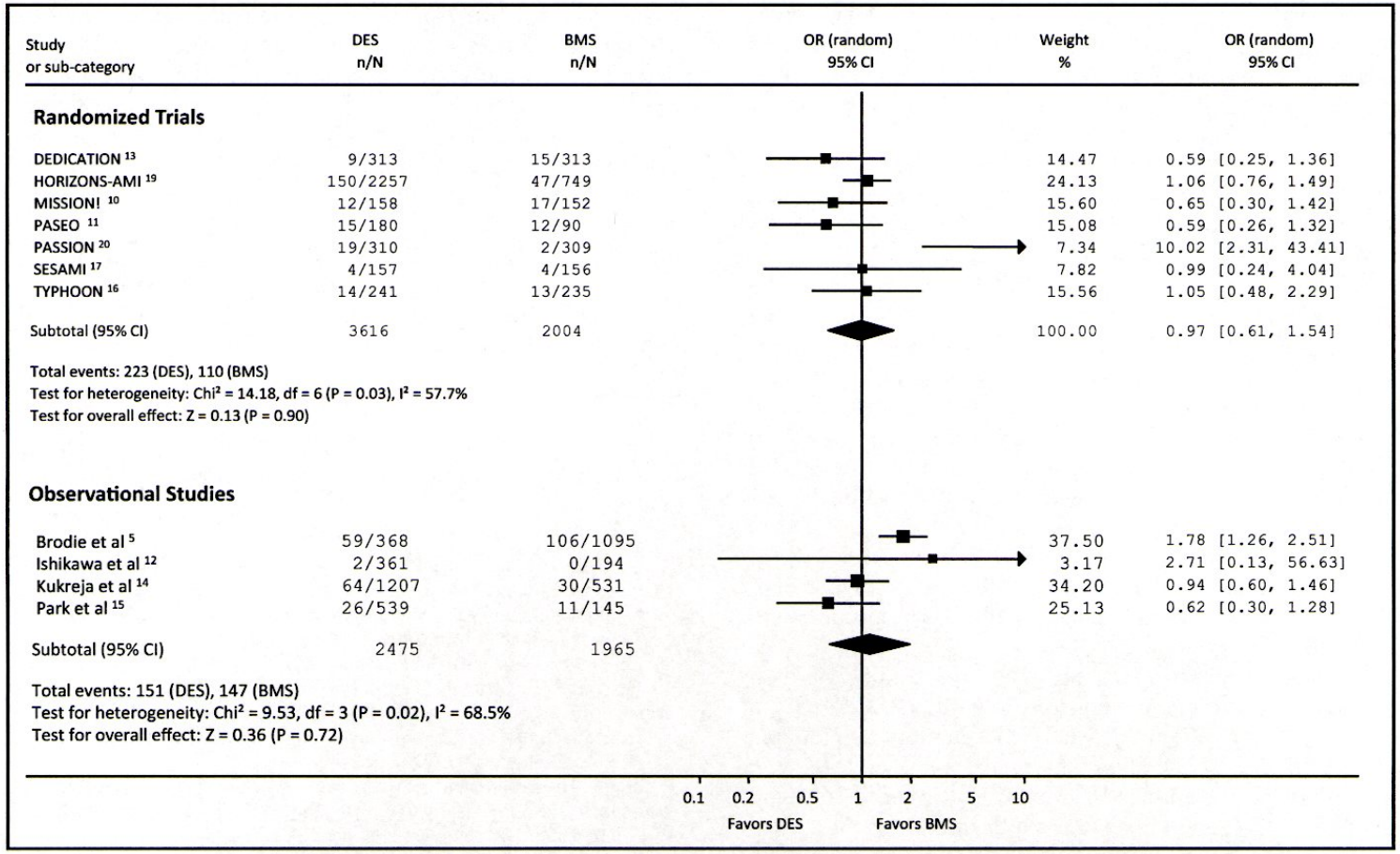


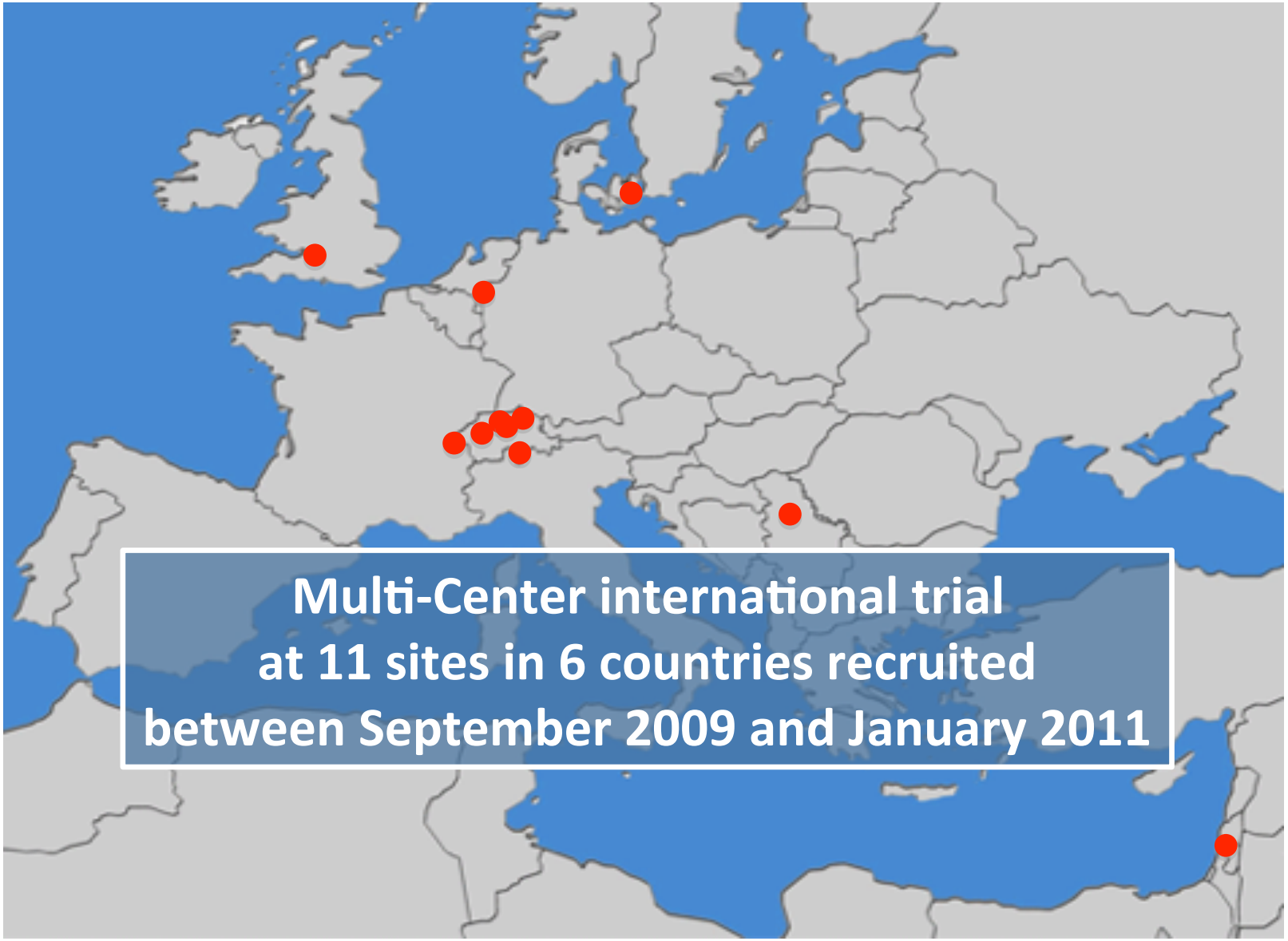
Figure 6. Forest plot of unadjusted odds ratios (95% confidence intervals) for recurrent myocardial infarction after primary percutaneous coronary intervention in patients receiving drug-eluting stents compared to those receiving bare-metal stents. No significant decrease or increase in recurrent myocardial infarction was noted with drug-eluting stents in randomized clinical trials (odds ratio 0.97, 95% confidence interval 0.61 to 1.54, p = 0.90) or cohort studies (odds ratio 1.11, 95% confidence interval 0.63 to 1.95, p = 0.72). Abbreviations as in Figure 2.

Biolimus-Eluting Stents With Biodegradable Polymer Versus Bare Metal Stents in Acute Myocardial Infarction: the COMFORTABLE AMI Trial

Lorenz Räber, Henning Kelbæk, Miodrag Ostojic, Andreas Baumbach, David Tüller, Clemens v. Birgelen, Dik Heg, Marco Roffi, Aris Moschovitis, Ahmed A. Khattab, Peter Wenaweser, Robert Bonvini, Giovanni Pedrazzini, Ran Kornowski, Klaus Weber, Thomas F. Lüscher, Masanori Taniwaki, Bernhard Meier, Peter Jüni, Stephan Windecker

NTC00962416

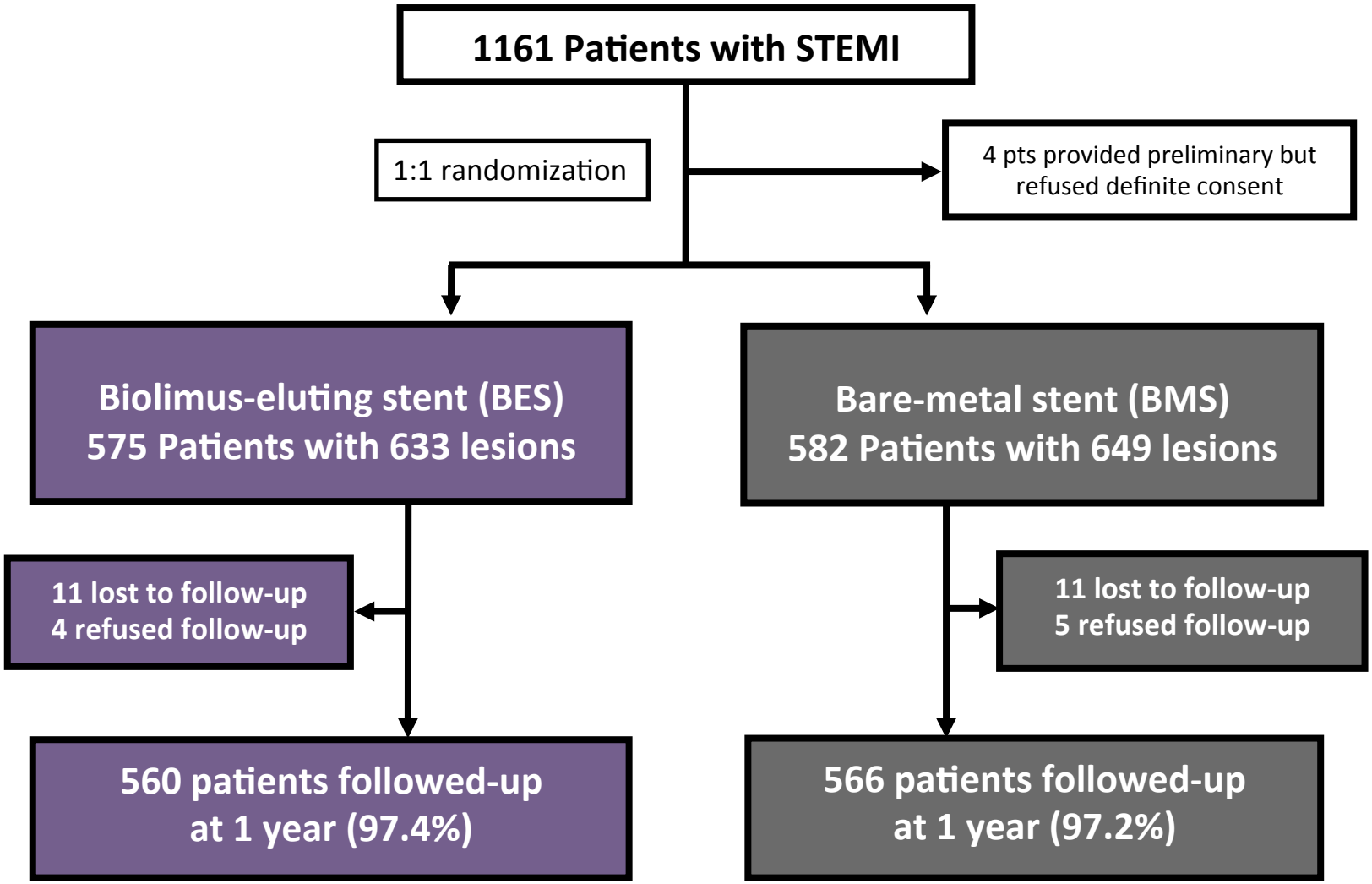
Enrollment Centers and Inclusion Numbers



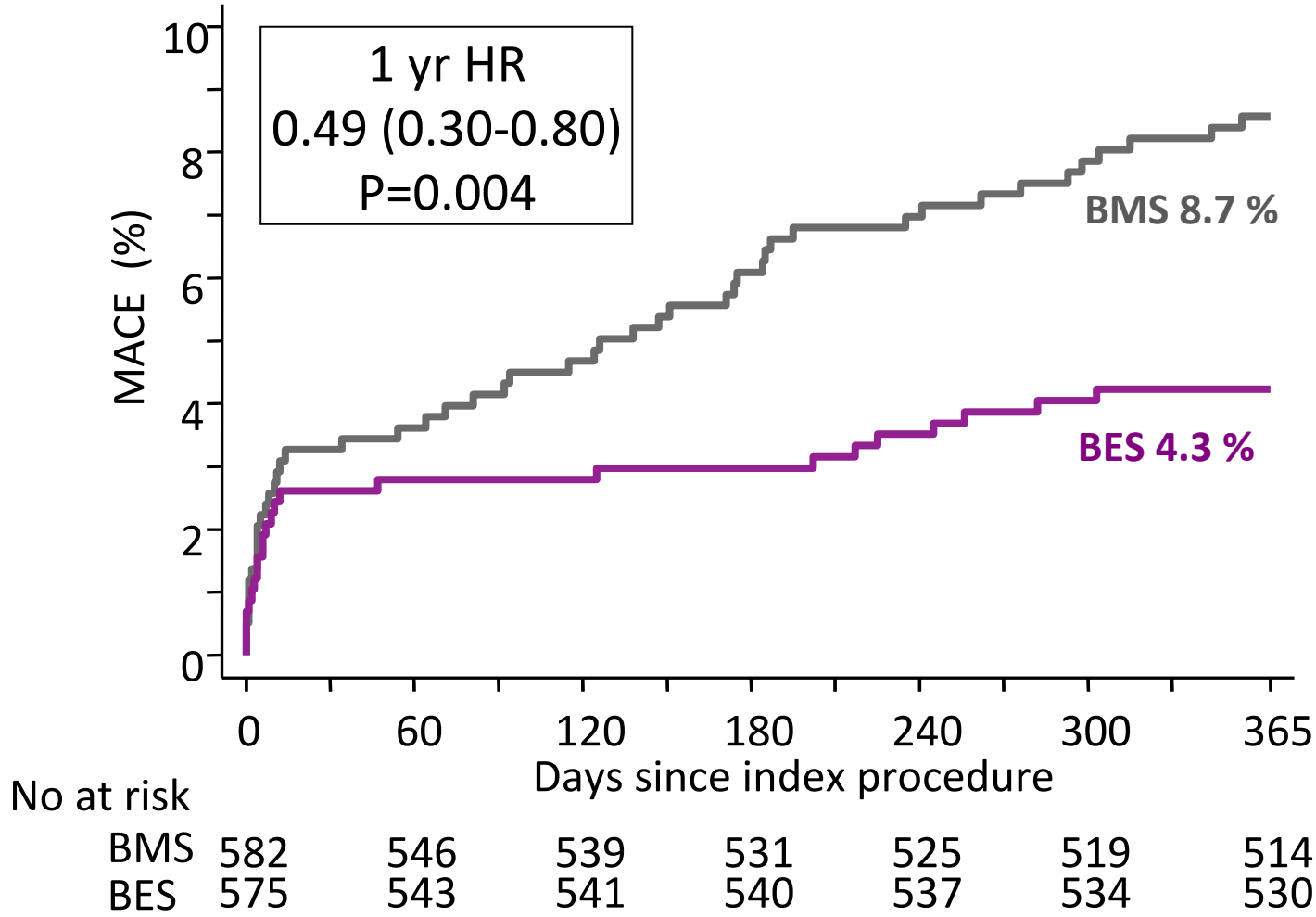
CENTER	INVESTIGATOR	No of Pts recruited
Bern, Switzerland		250
Copenhagen, Danmark	Henning Kelbaek	173
Belgrade, Serbia	Miodrag Ostoijc	172
Zurich Triemli, Switzerland	David Tüller	110
Bristol, United Kingdom	Andreas Baumbach	109
Enschede, Netherlands	Clemens von Birgelen	100
Geneva, Switzerland	Marco Roffi	83
Lugano, Switzerland	Giovanni Pedrazzini	56
Tel Aviv, Israel	Ran Kornowski	48
Zurich USZ, Switzerland	Thomas F. Lüscher	44
Kreuzlingen, Switzerland	Klaus Weber	16

euro PCR 2012

Patient Flow

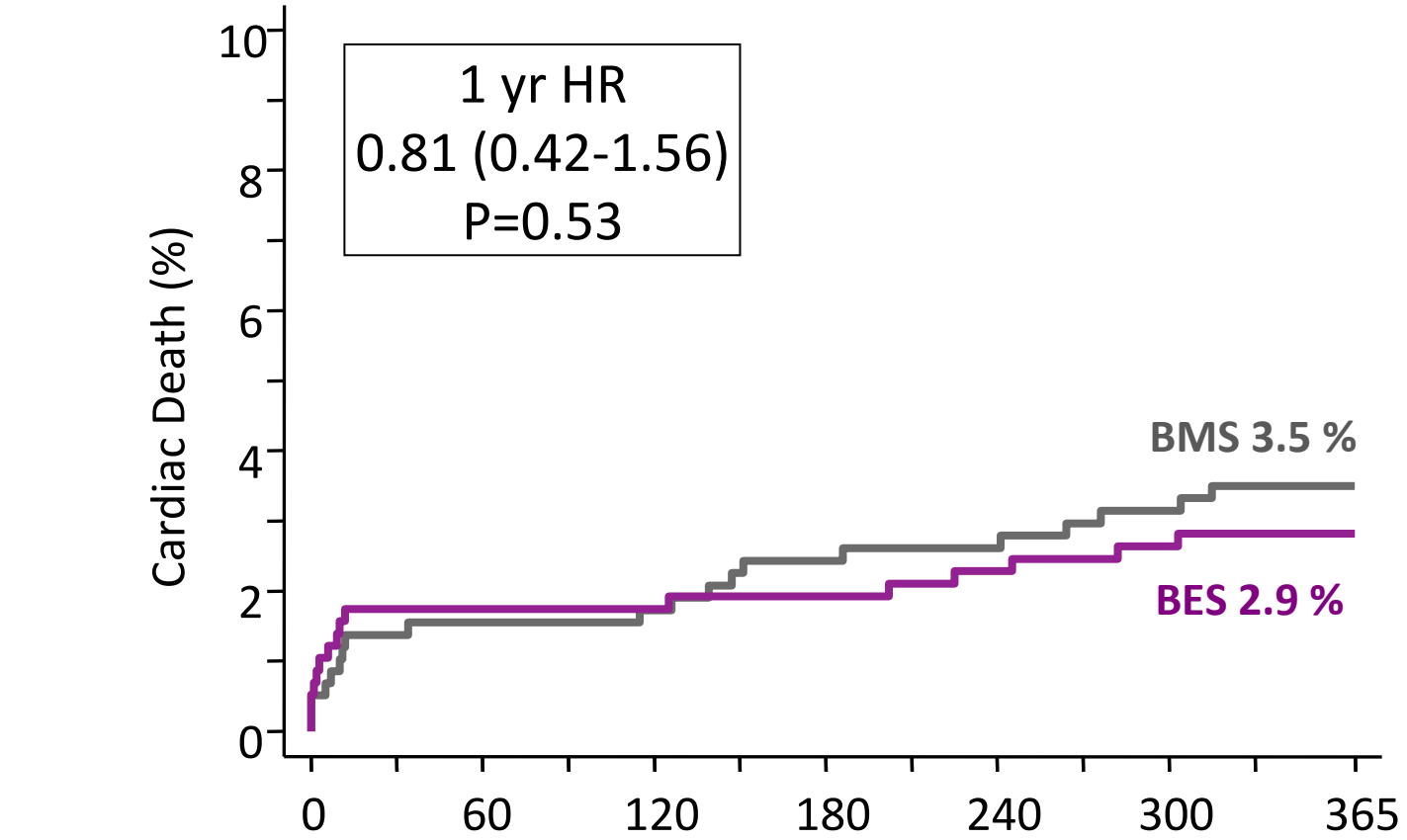


Primary Endpoint – MACE @ 1 Year



Clinical outcomes were adjudicated by an independent and blinded CEC

2nd Endpoint – Cardiac Death

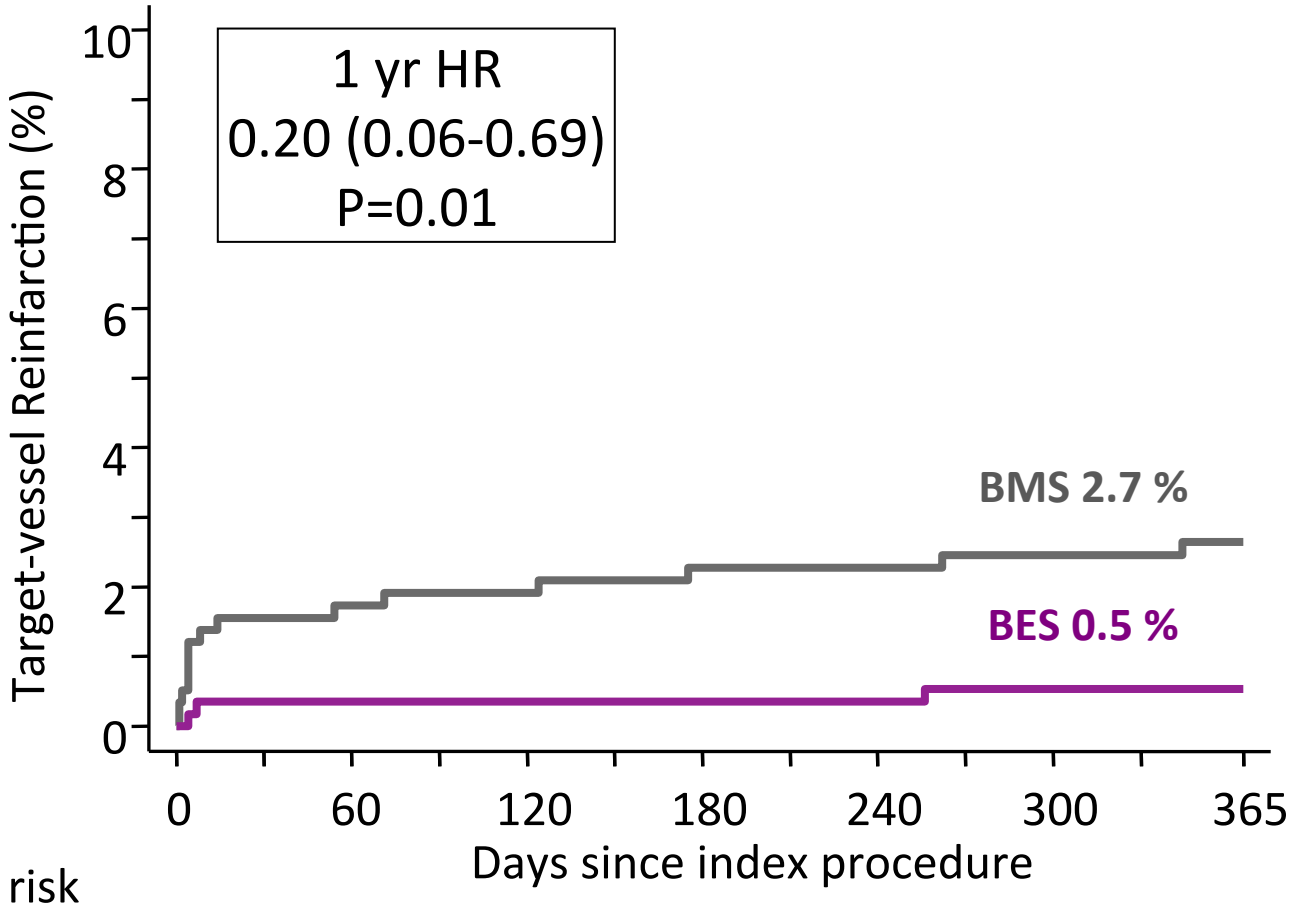


No at risk

BMS	582	558	556	551	549	545	542
BES	575	549	547	546	544	542	538

Clinical outcomes were adjudicated by an independent and blinded CEC

2nd Endpoint – TV-Reinfarction

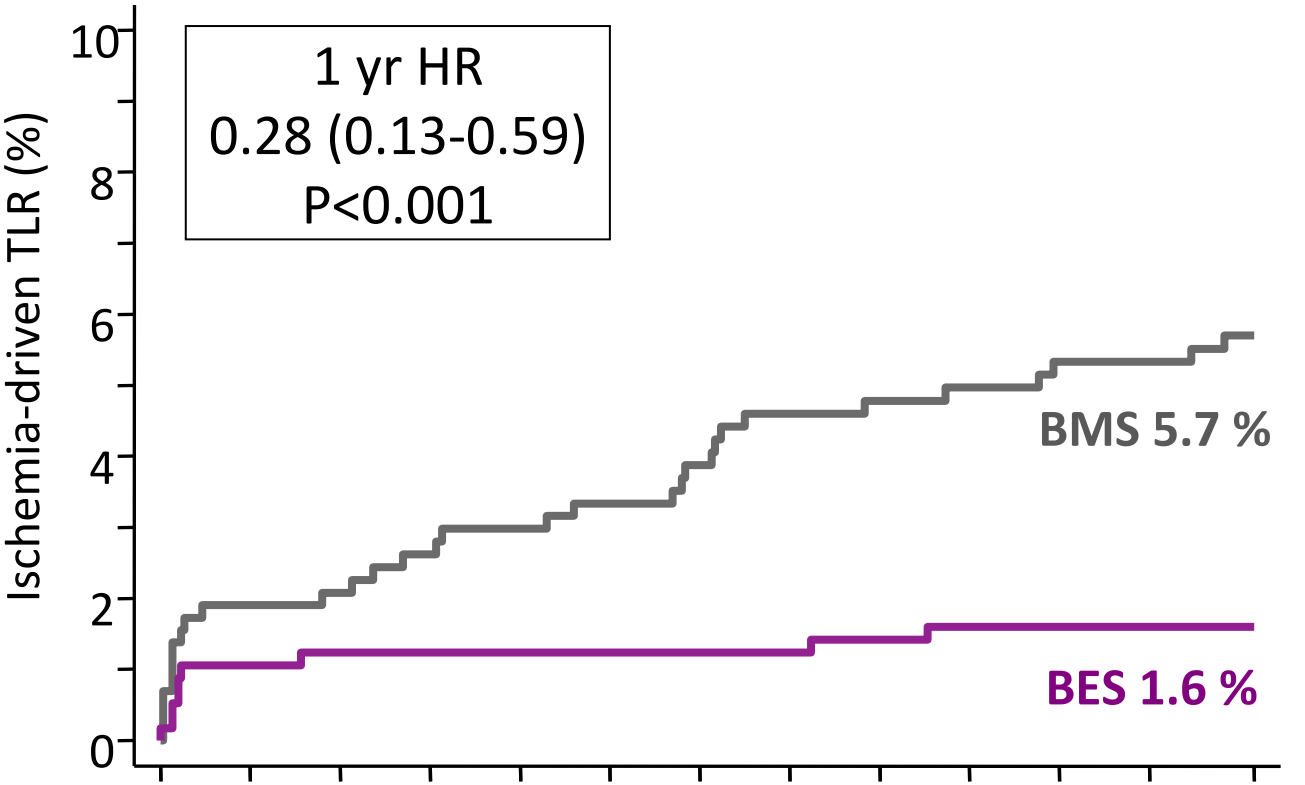


No at risk

BMS	582	548	545	539	538	534	530
BES	575	547	545	544	542	539	535

Clinical outcomes were adjudicated by an independent and blinded CEC

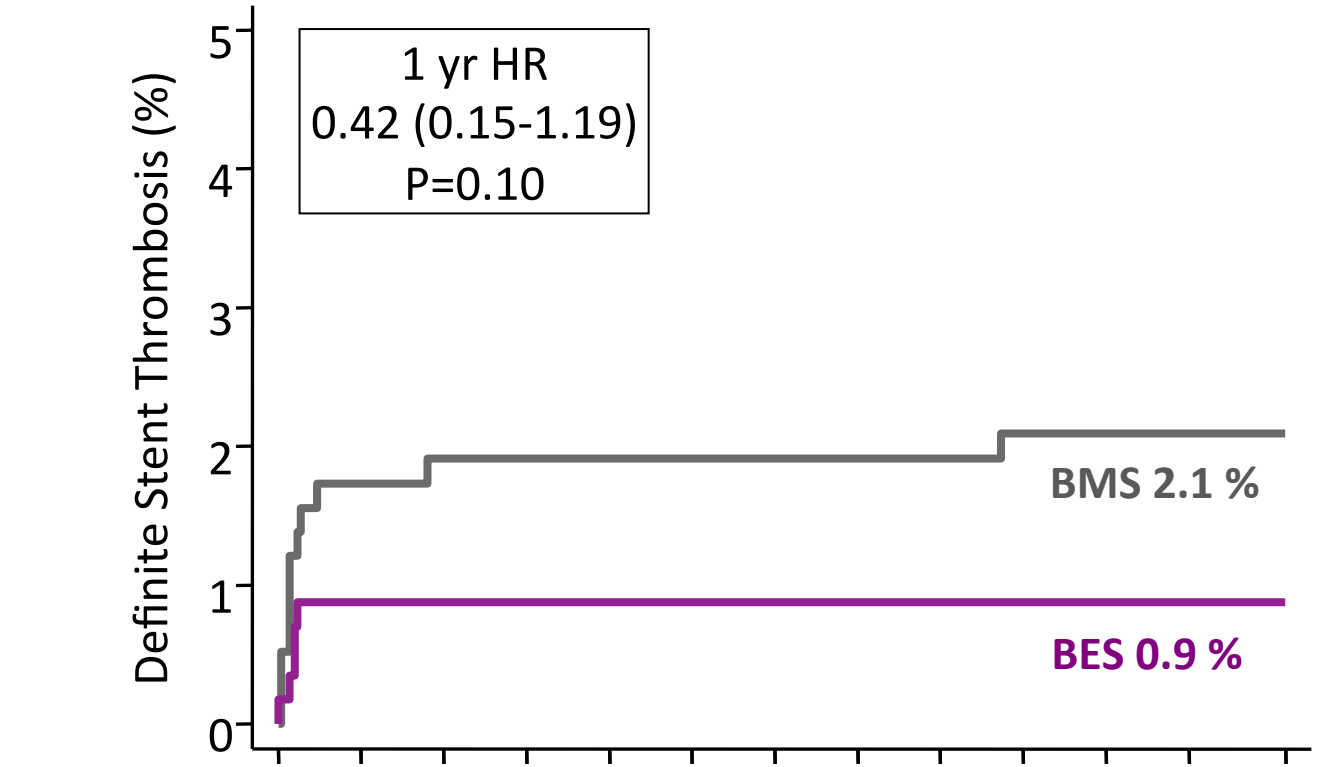
2nd Endpoint – ID-TLR



No at risk							
BMS	582	547	540	532	526	520	515
BES	575	543	541	540	537	534	530

Clinical outcomes were adjudicated by an independent and blinded CEC

ARC Definite Stent Thrombosis



No at risk							
BMS	582	547	545	540	538	534	481
BES	575	545	543	542	540	538	494

Clinical outcomes were adjudicated by an independent and blinded CEC

euro PCR 2012

Conclusion

The use of stents eluting biolimus from a biodegradable polymer is more effective and safe than bare metal stents in STEMI patients undergoing primary PCI at one year.

LEADERS 4 years

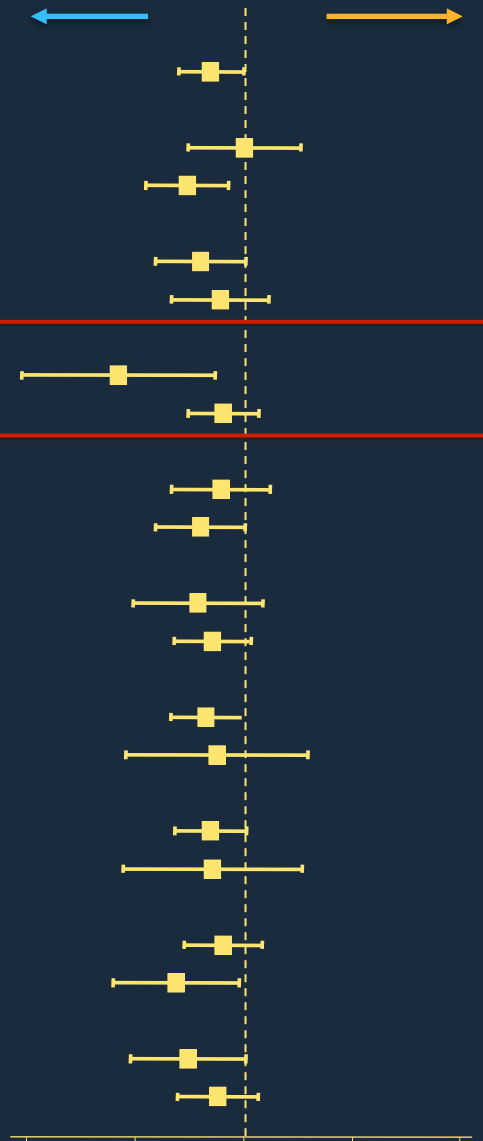
STEMI subgroup analysis

LEADERS 4 years

STEMI subgroup analysis

Stratified Analysis of MACE @ 4 Years

	BES	SES	RR (95%CI)	P*	P for interaction
Overall	160/857	192/850	0.81 (0.66 to 1.00)	0.05	
Diabetes mellitus					ns
Yes	65/223	56/191	1.00 (0.70 to 1.44)	0.98	
No	94 /634	136/659	0.70 (0.54 to 0.91)	0.007	
ACS					ns
Yes	82/470	106/473	0.76 (0.57 to 1.01)	0.06	
No	77/387	86/377	0.86 (0.63 to 1.17)	0.34	
ST elevation MI					**0.043**
Yes	**15/135**	**32/140**	**0.45 (0.24 to 0.83)**	**0.009**	
No	**144/722**	**160/710**	**0.88 (0.70 to 1.10)**	**0.26**	
Left anterior descending					ns
Yes	73/407	85/417	0.86 (0.63 to 1.18)	0.36	
No	86/449	107/431	0.76 (0.57 to 1.01)	0.06	
Multivessel disease					ns
Yes	44/209	48/176	0.75 (0.49 to 1.13)	0.16	
No	115/648	144/674	0.82 (0.64 to 1.05)	0.11	
Off label use					ns
Yes	139/696	165/665	0.79 (0.63 to 0.99)	0.037	
No	20/160	27/183	0.84 (0.47 to 1.51)	0.56	
De-novo lesions					ns
Yes	138/788	165/774	0.81 (0.64 to 1.01)	0.07	
No	21/68	27/74	0.82 (0.46 to 1.45)	0.49	
Small-vessel disease					ns
Yes	119/585	131/568	0.88 (0.68 to 1.12)	0.30	
No	40/271	61/280	0.65 (0.44 to 0.97)	0.033	
Long lesions					ns
Yes	53/262	63/225	0.70 (0.49 to 1.01)	0.06	
No	106/594	129/623	0.85 (0.65 to 1.10)	0.21	



* P values for superiority

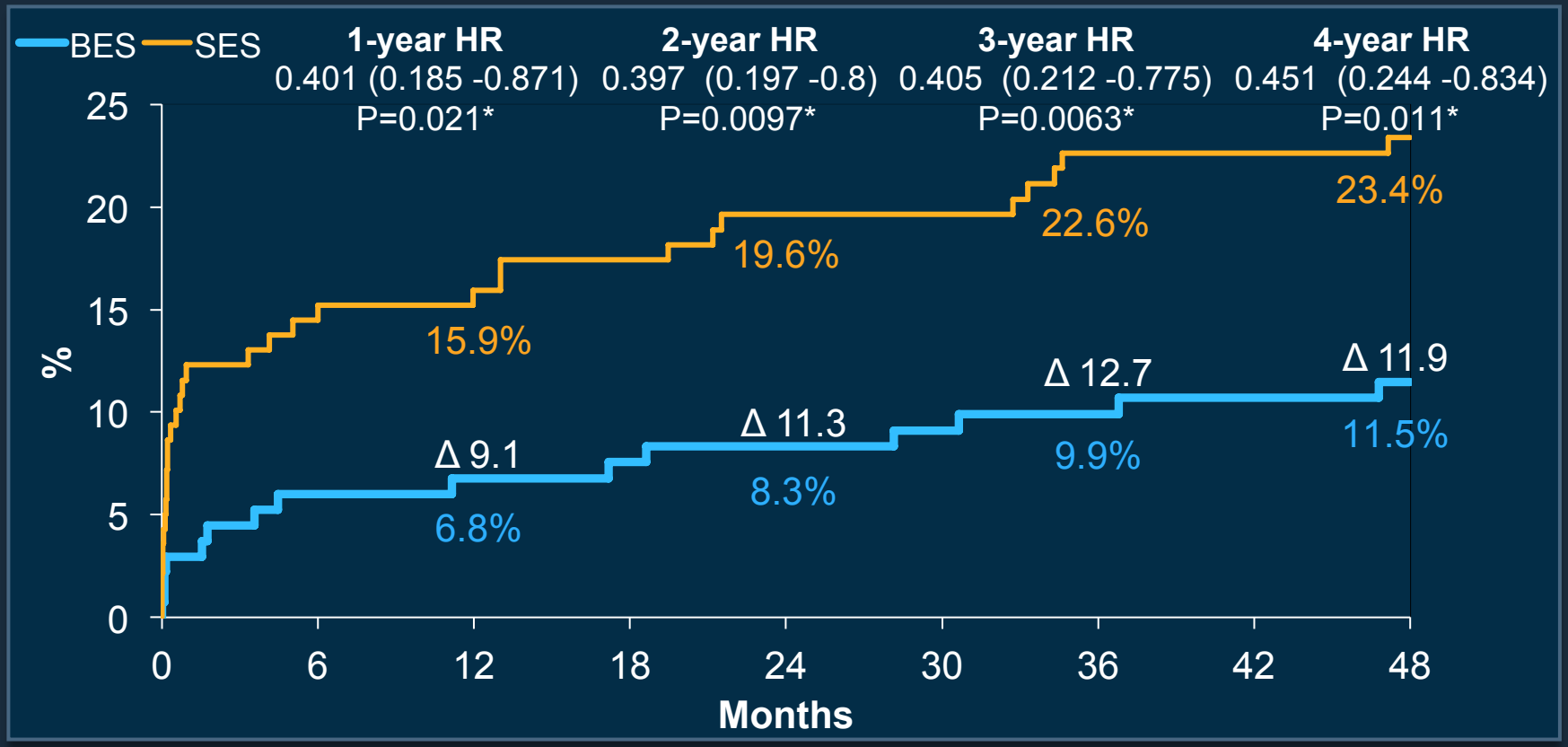
Stefanini G. et al., The Lancet, 2011

Ischinger et al., oral presentation, TCT 2011

LEADERS

LEADERS-STEMI subgroup

MACE (cardiac death, MI, ci-TVR)



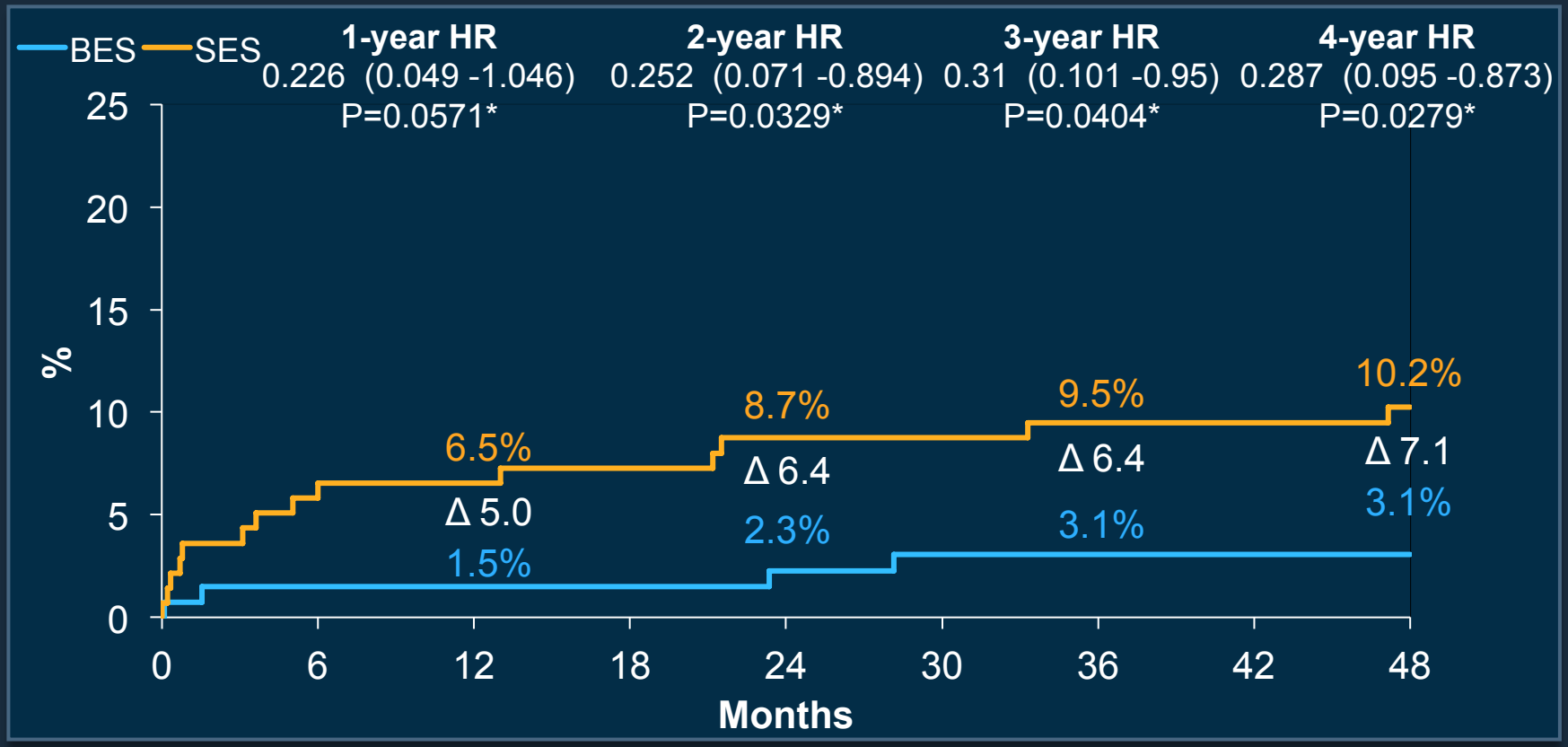
Numbers at risk

BES	135	122	121	119	118	116	114	113	111
SES	140	116	115	112	108	107	103	103	102

Windecker S., oral presentation, EuroPCR 2011
* p-values for superiority

LEADERS

LEADERS-STEMI subgroup
Cardiac death



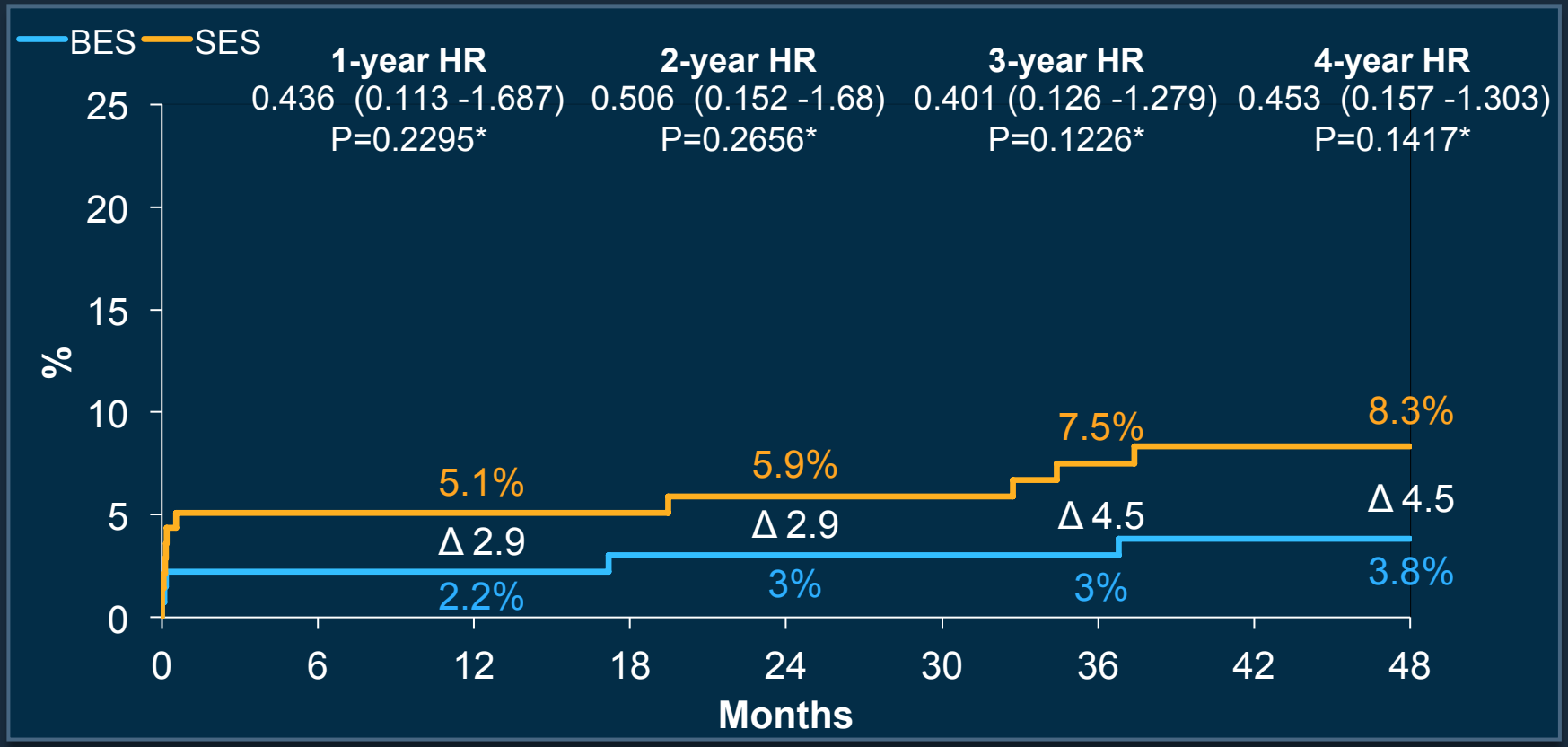
Numbers at risk

BES	135	128	128	127	126	124	122	122	121
SES	140	128	128	126	123	122	120	120	119

* p-values for superiority

LEADERS

LEADERS- STEMI subgroup
Myocardial infarction (MI)



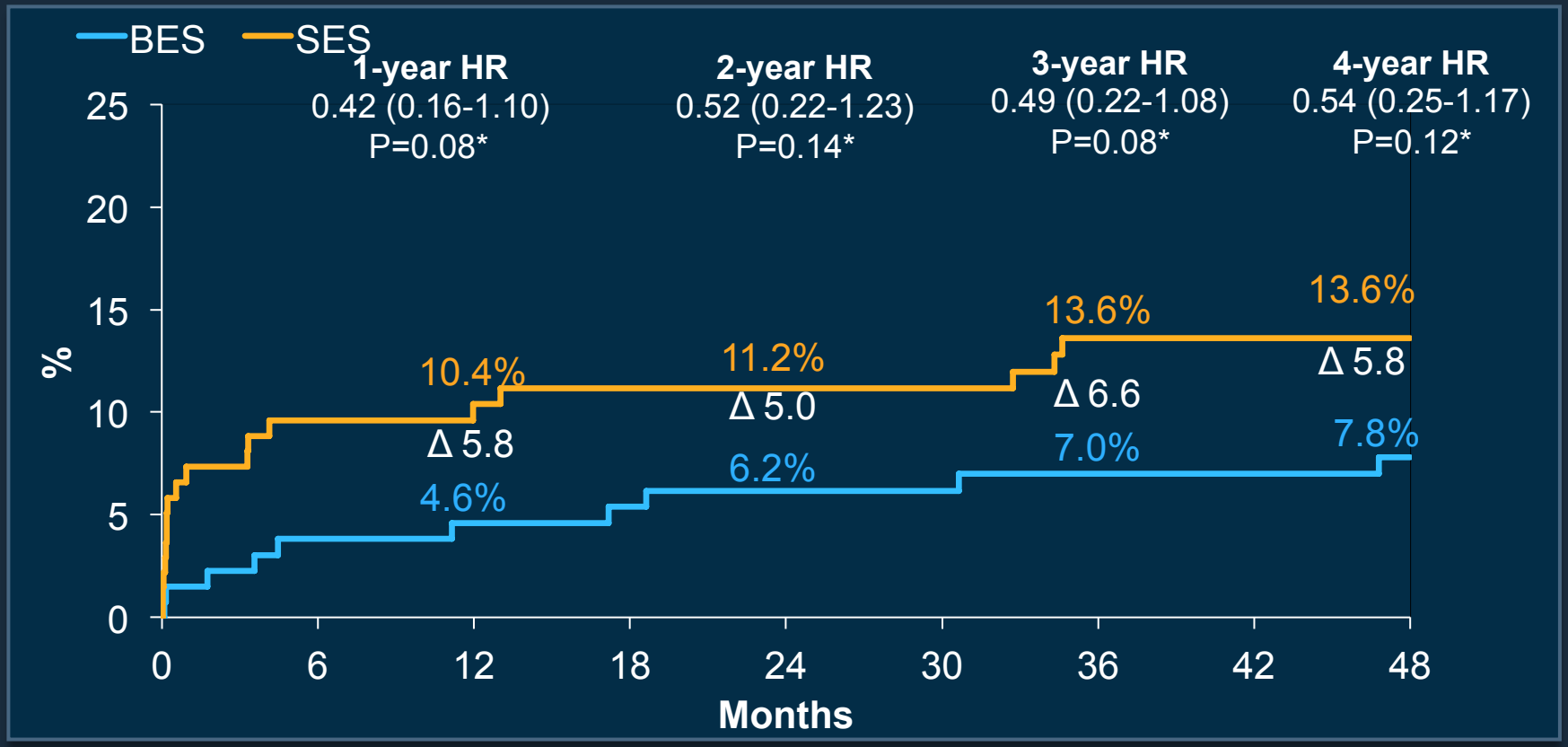
Numbers at risk

BES	135	125	125	123	123	121	120	119	118
SES	140	123	123	121	117	116	113	112	111

* p-values for superiority

LEADERS

LEADERS- STEMI subgroup clinically-indicated TVR



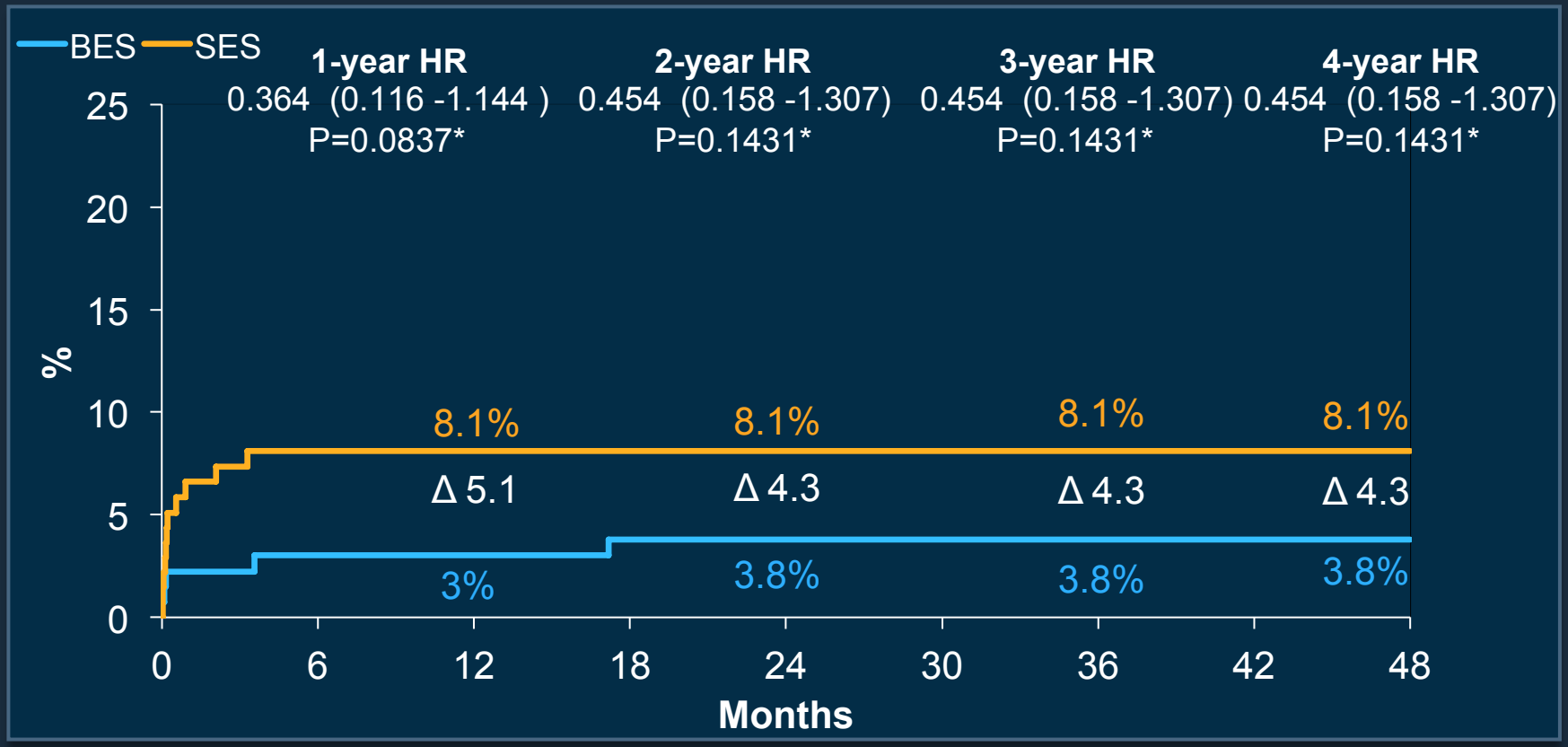
Numbers at risk

BES	135	123	122	120	118	116	114	114	112
SES	140	117	116	113	110	109	105	105	104

* p-values for superiority

LEADERS

LEADERS – STEMI subgroup
Definite Stent thrombosis (ARC)



Numbers at risk

BES	135	124	124	122	121	119	118	118	117
SES	140	119	119	117	114	113	111	111	110

* p-values for superiority

LEADERS

CE APPROVED

MGUARD Prime

Net Protective Co-Cr Stent

APPAC 14 EDITION

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APPAC 14 EDITION
Actualisations et Perspectives en Pathologie Cardiovasculaire

U.C.V.

NOUVEAUTES TECHNIQUES (STENTS ET IDM)

♦ MGUARD Prime (Co-Cr – 80 microns)

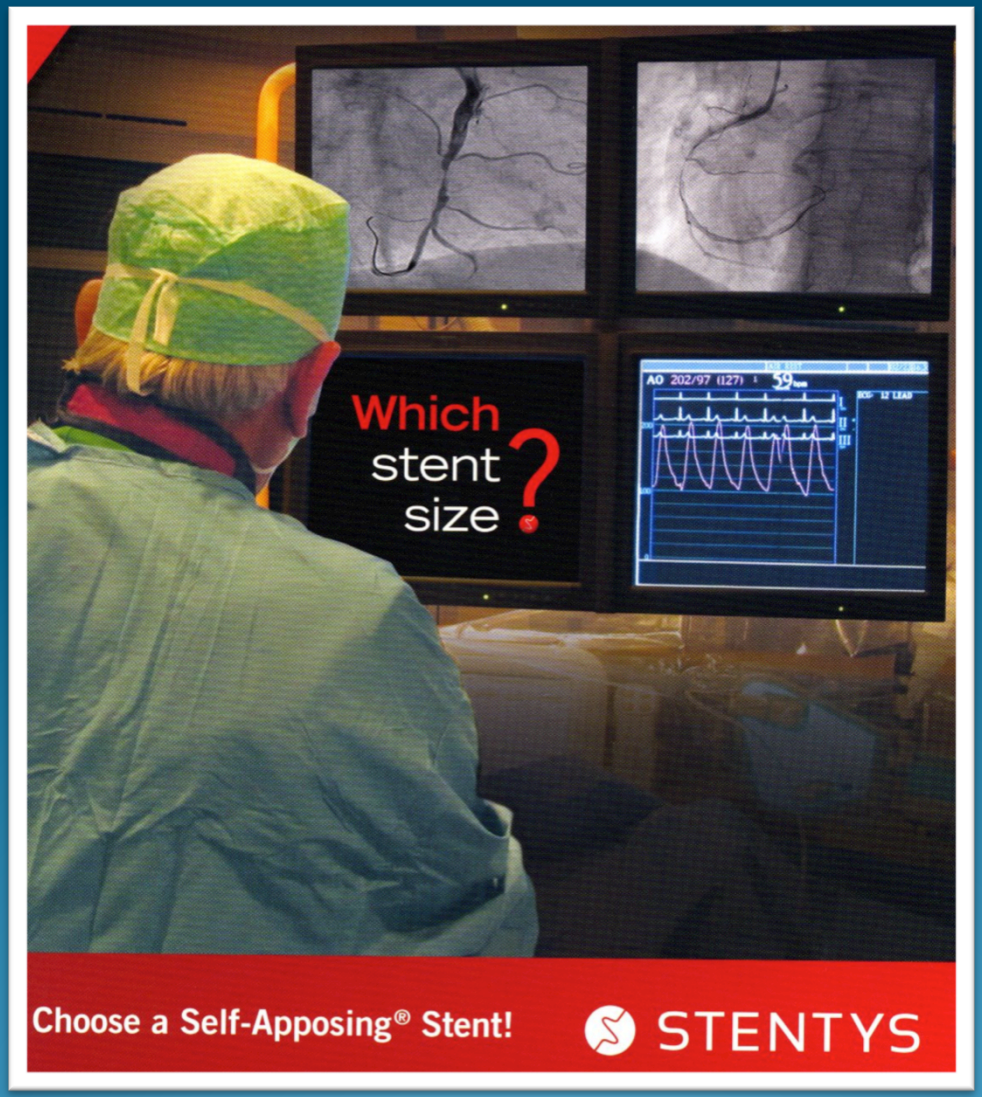
1/ Maillage externe +++	(PET / 20 microns).

2/ Avantages :	- réduction des embolies distales.
	- MACE à 6 mois 1.7 % (STEMI)
	- MACE à 30 j 3.3 % (PAC)

NOUVEAUTES TECHNIQUES (STENTS ET IDM)

♦ MGUARD Prime

* Indications :	- SCA ST ⊕
	- SCA avec thrombus visible
	- PAC


Which
stent
size ?
Choose a Self-Apposing® Stent!
STENTYS

FUTUR (STENTS ET IDM)

♦ INFUSE AMI.		
* 500 patients	ReoPro	Aspiration
* IDM antérieurs arrivés tôt	Gregg Stone	Mike Gibson

1/ ReoPro IC in situ +++

- réduction de la taille de l'IDM (IRM / mesure à 1 mois)

- Flux / Blush / réduction ST pas d' effet.

2/ Thrombo-aspiration (Persistance de points d'interrogation)

- Pas d'effet sur la taille de l'IDM.

FUTUR (STENTS ET IDM)

♦ BMS	- toujours très employés
	- surtout chez les sujets âgés
	- cicatrisation plus rapide.

♦ DES	- augmentation de leur usage
	- réduction des TVR
	- très recommandé chez : * les jeunes * les diabétiques (surtout ID)