

Long-term outcome after drug-eluting versus bare-metal stent implantation in patients with ST-elevation myocardial infarction

3 year follow-up of the randomised DEDICATION trial

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Disclosures

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Abbott, AstraZeneca, Aventis, Bayer, Bristol Myers Squibb, Eli-Lilly, Merck, Myogen, Medtronic, Mitsubishi Pharma, Nycomed, Organon, Pfizer, Pharmacia, Sanofi-Synthelabo, Searle, The Medicines Company.

Background

Implantation of drug eluting stents (DES) has proven to be both safe and efficient in most patients with coronary artery disease. However, long-term data are scarce with regard to their use in STEMI patients treated with PCI

Drug-Eluting vs Bare-Metal Stent Implantation during Primary PCI

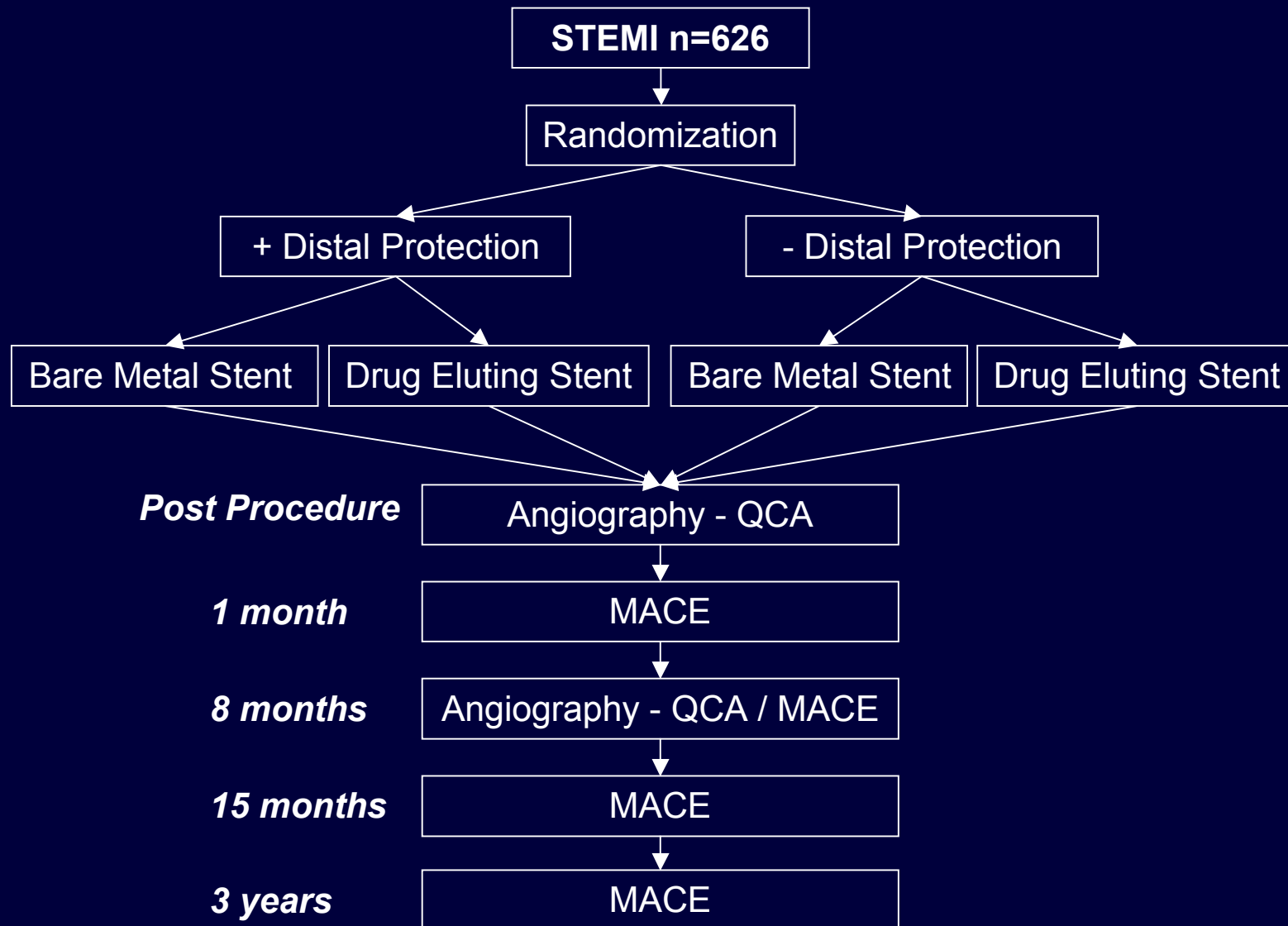
Previous published studies with ≥ 150 patients

Study	n	Invasive FU	RS,% DES/BMS	MACE,% DES/BMS	Primary endpoint	p
STRATEGY	175	133	8/28	18/32	MACCE	0.001
TYPHOON	712	170	7/20	7/14	TVF	0.004
PASSION	619	-	-	9/13	MACE	0.09
SESAMI	320	166	9/21	7/17	RS	0.03

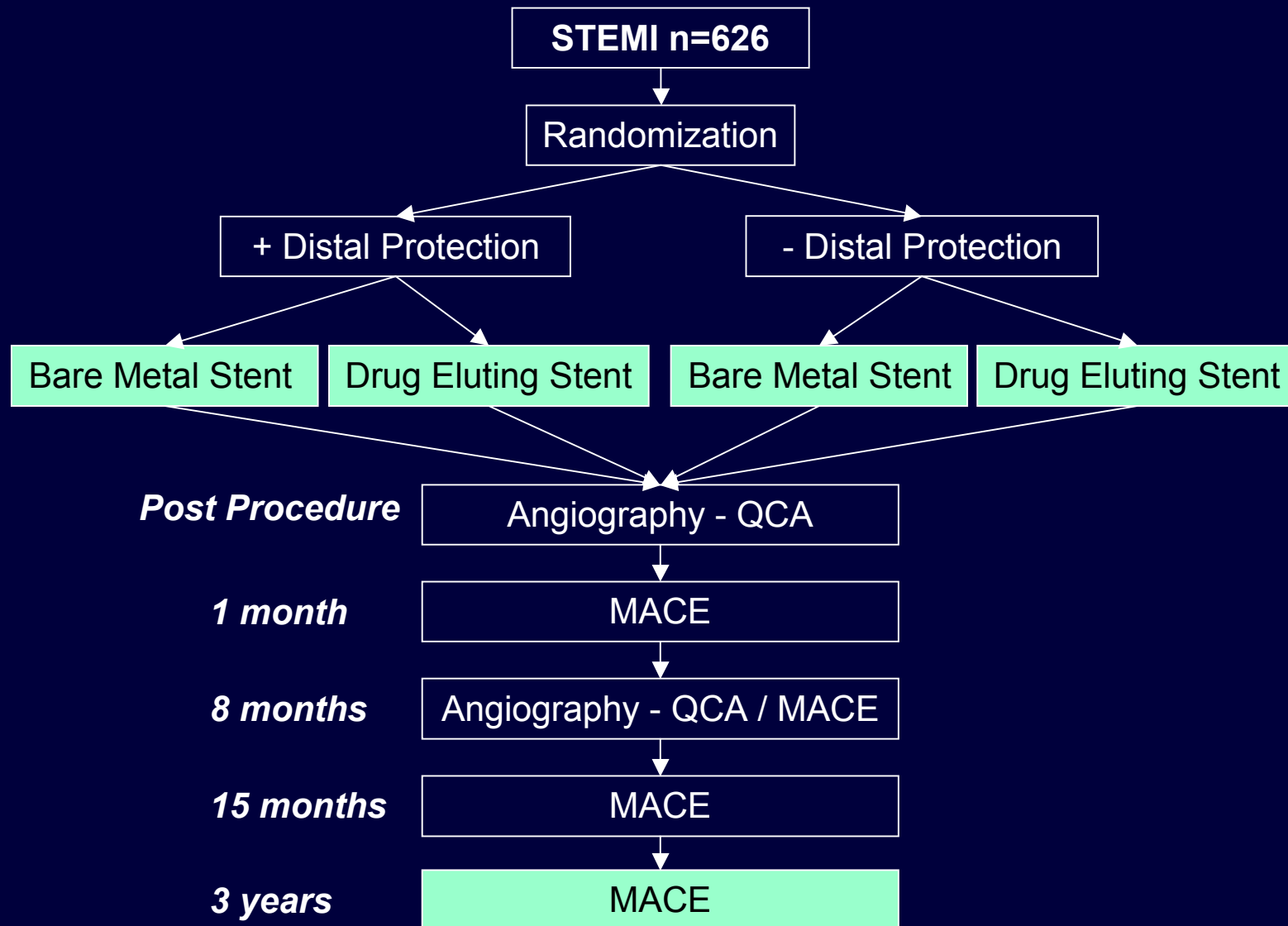
Purpose

The purpose of this study was to evaluate the clinical results 3 years after implantation of DES vs BMS in STEMI patients treated with primary PCI

Flow chart



Flow chart



Endpoints

- MACE (cardiac death, re-infarction, TLR) at 3 years
- Cardiac death at 3 years
- Total mortality
- MI
- TLR
- TVR
- Stroke

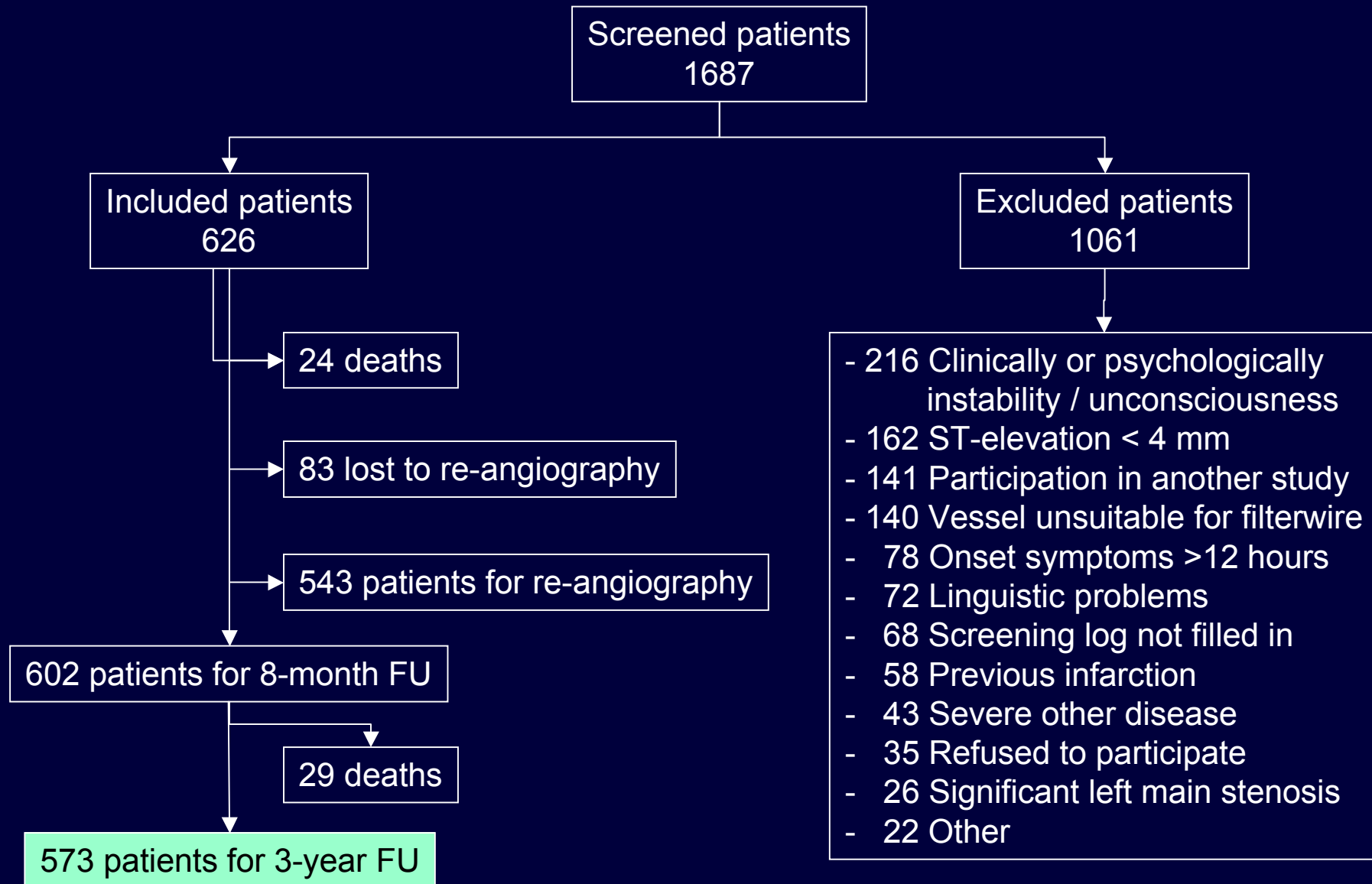
Major inclusion criteria

- Patients who presented with the symptoms and signs of a first time large STEMI
- Chest pain \leq 12 hours duration
- ST-elevation $>$ 4 mm in contiguous leads
- High grade stenosis/occlusion of a native coronary artery that could be crossed with a guidewire

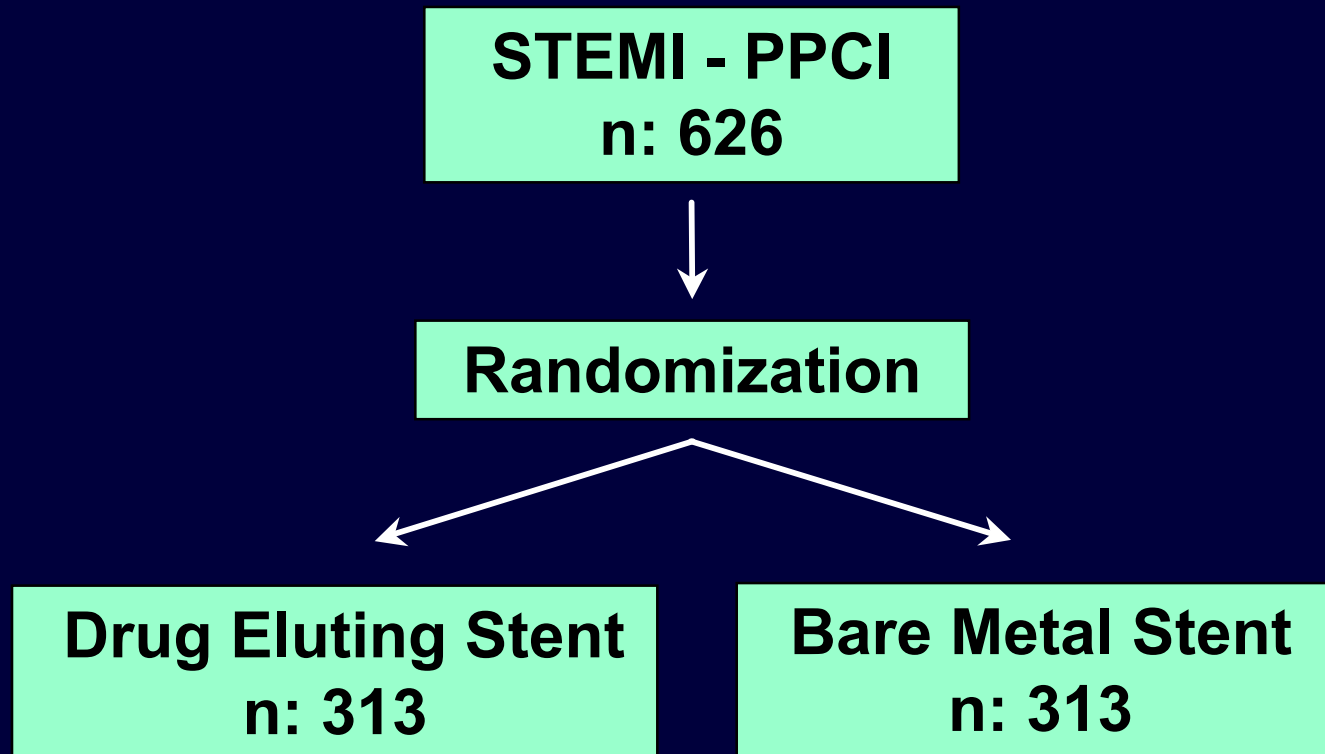
Major exclusion criteria

- History of a previous myocardial infarction
- Left main stem stenosis
- Gastrointestinal bleeding within 1 month
- Expected survival < 1 year
- Linguistic difficulties needing an interpreter

Study Flow



Number of Patients



Baseline clinical characteristics

	DES n=313	BMS n=313	p
Age (years)	62	63	0.41
Male gender (%)	72.8	73.5	0.93
Diabetes Mellitus (%)	9.3	11.5	0.30
Hypertension (%)	32.3	34.0	0.67
Hyperlipidemia (%)	18.7	21.4	0.54
Current smoker (%)	52.7	54.7	0.88
Family history of CAD (%)	37.3	38.2	0.87
Left ventricular ejection fraction	0.48	0.47	0.45
Previous myocardial infarction (%)	6.1	7.1	0.20
Previous PCI / CABG (%)	4.5	5.4	0.56
Symptom onset to arrival, min	197	200	0.69
Door-to-balloon, min	25	25	0.63

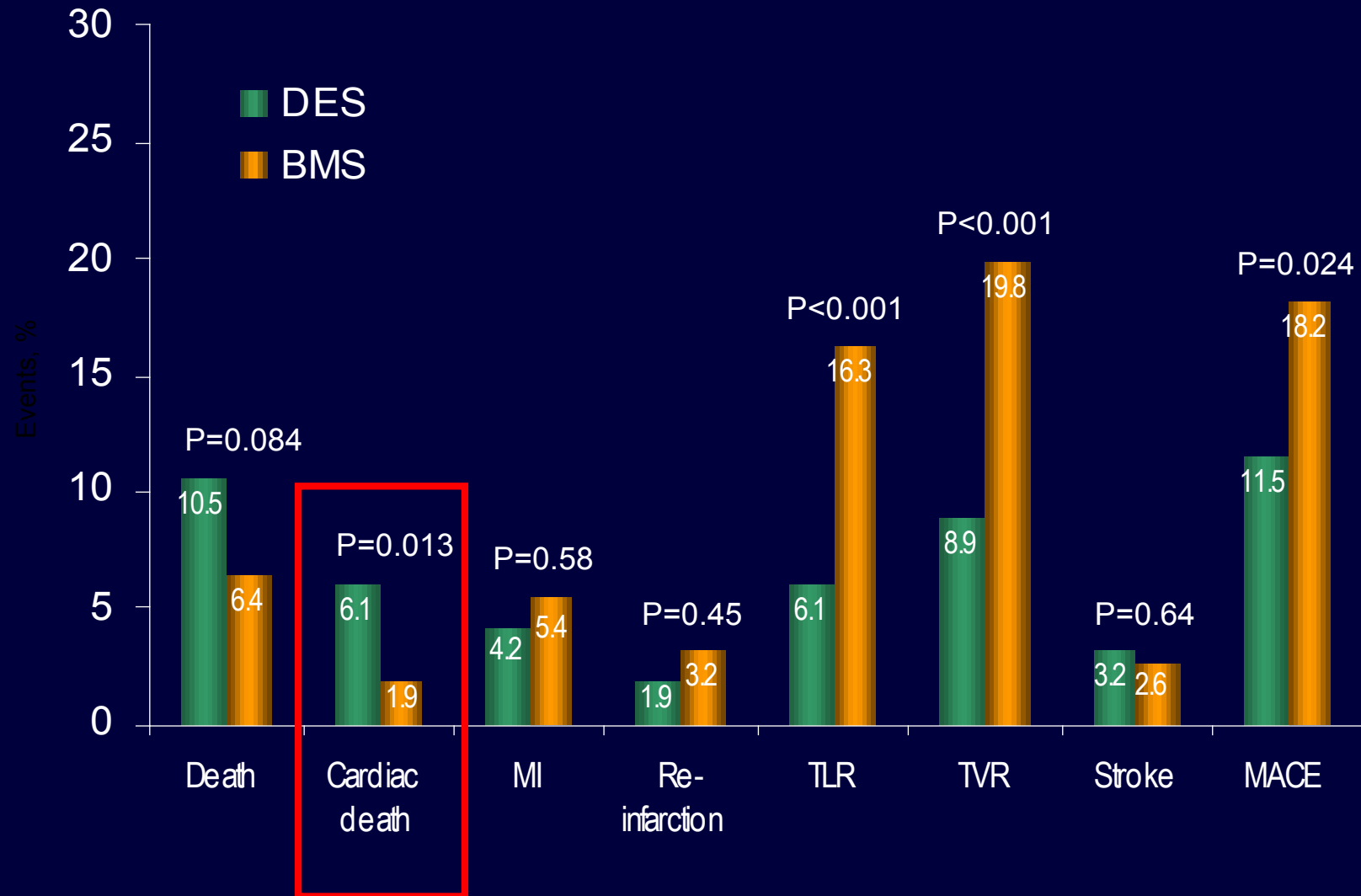
Baseline lesion characteristics

	DES n=313	BMS n=313	p
<hr/>			
Infarct related coronary artery (%)			
LAD	44	38	
CX	11	14	0.57
RCA	45	48	
Number of diseased vessel (%)			
1 vessel disease	65	61	
2 vessel disease	25	29	0.47
3 vessel disease	10	10	
Baseline TIMI flow			
TIMI 0-1	65	70	
TIMI 2-3	35	30	0.27
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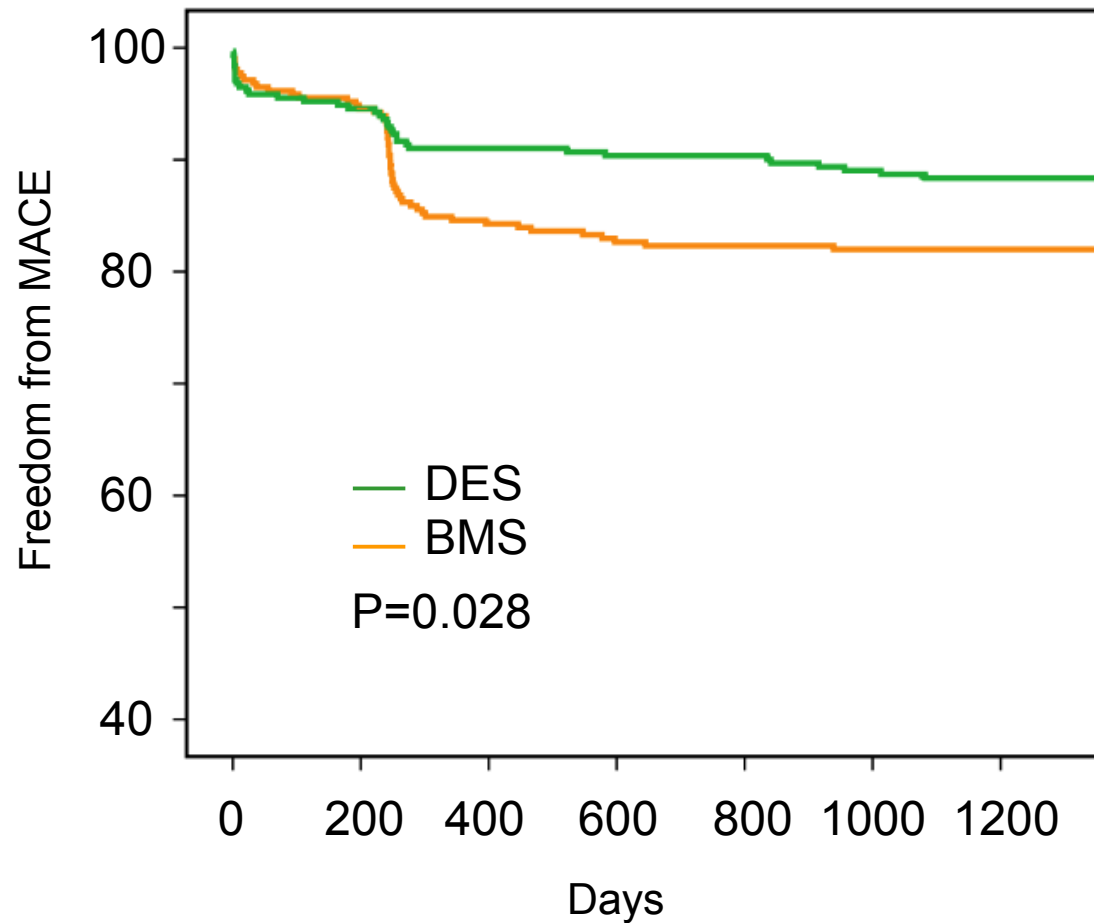
Procedural results

	DES n=313	BMS n=313	p
Use of GP IIb/IIIa inhibitor, %	97	95	0.21
Visible thrombus, %	74	72	0.33
Filterwire used, %	40	42	0.38
Stent implanted, %	99	98	0.29
Number of stents per lesion	1.3	1.3	0.52
Stented length, mm	22.2	21.0	0.13
Stent diameter, mm	3.54	3.53	0.86
Max deployment pressure, mm Hg	16.7	16.3	0.20
TIMI III post procedure	90	90	1.00
Procedural success, %	98	99	0.73

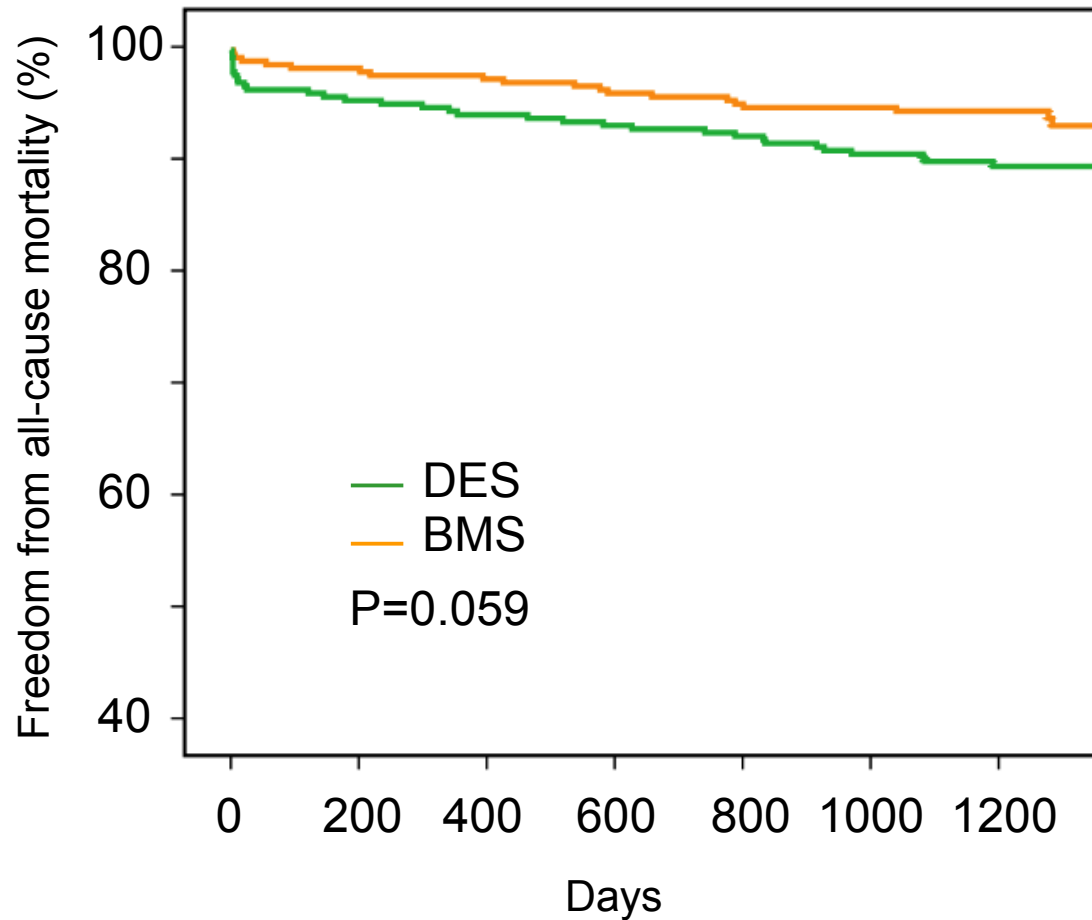
MACE during 3 years



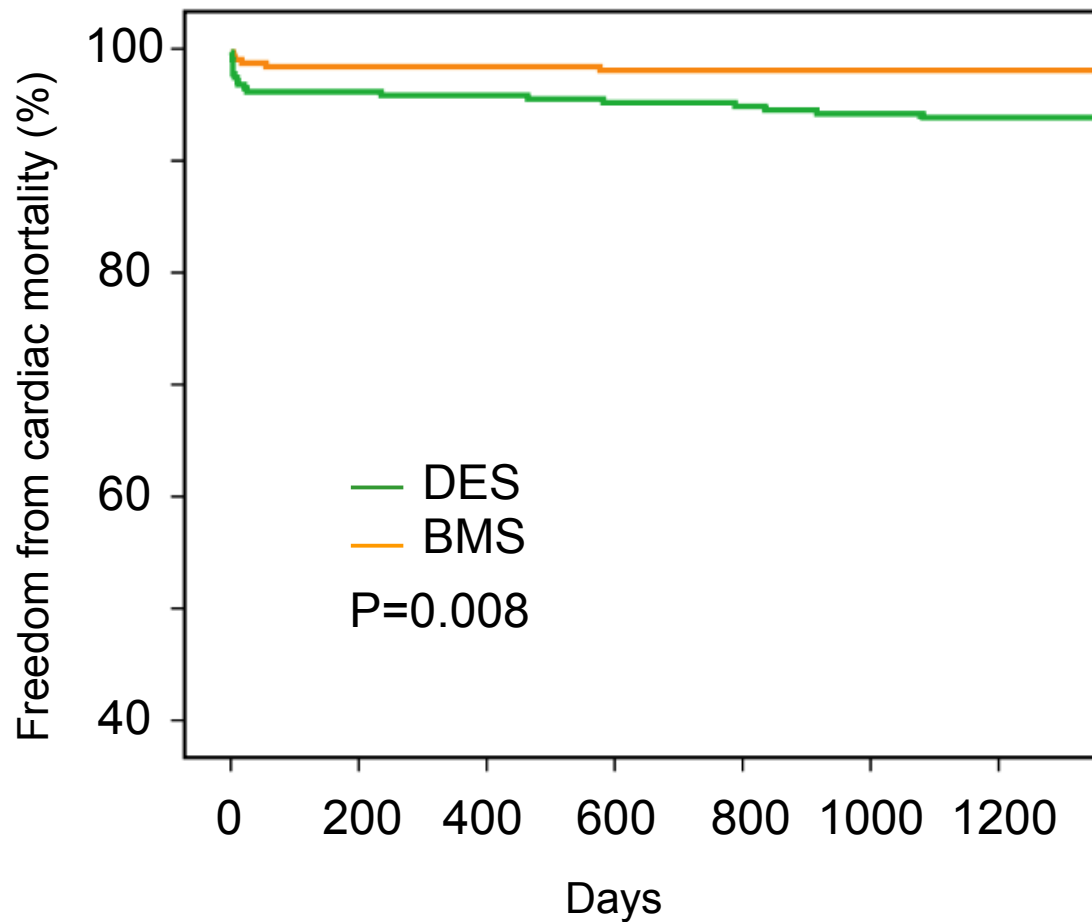
Freedom from MACE



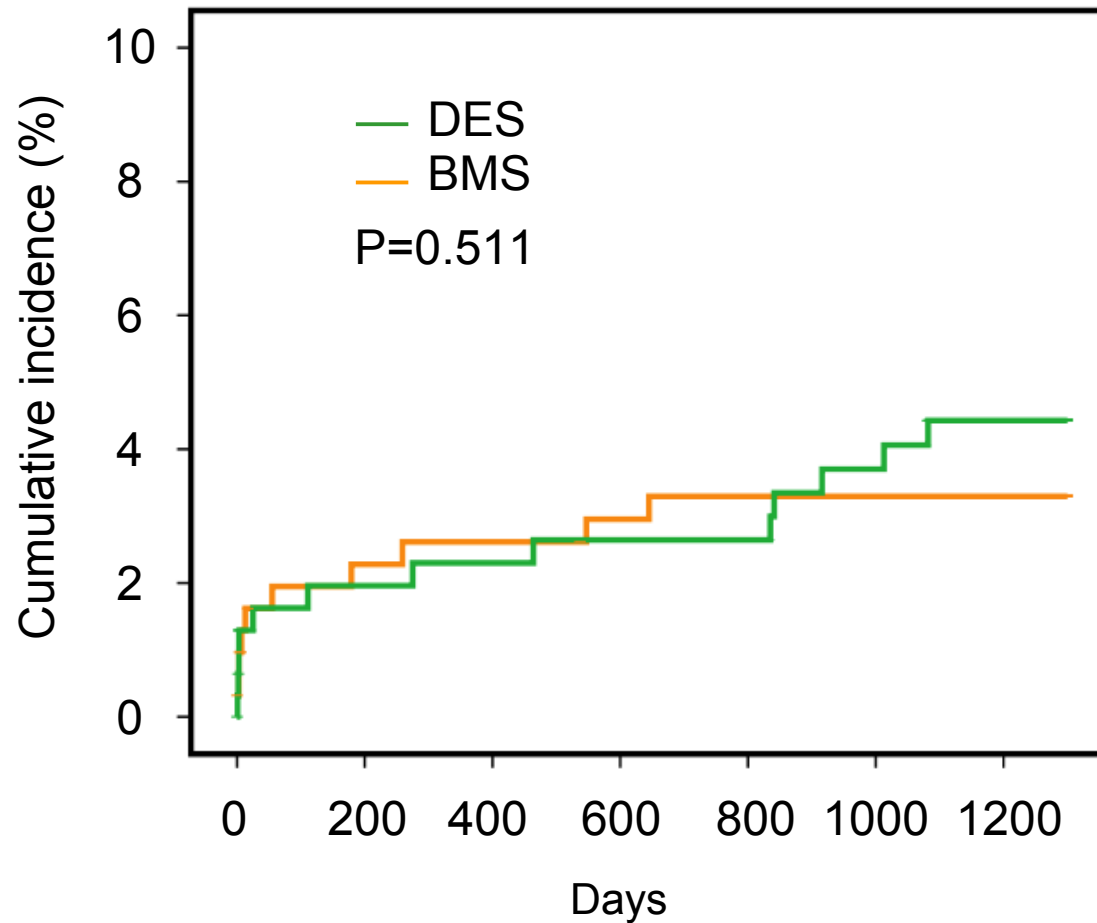
Freedom from all-cause mortality



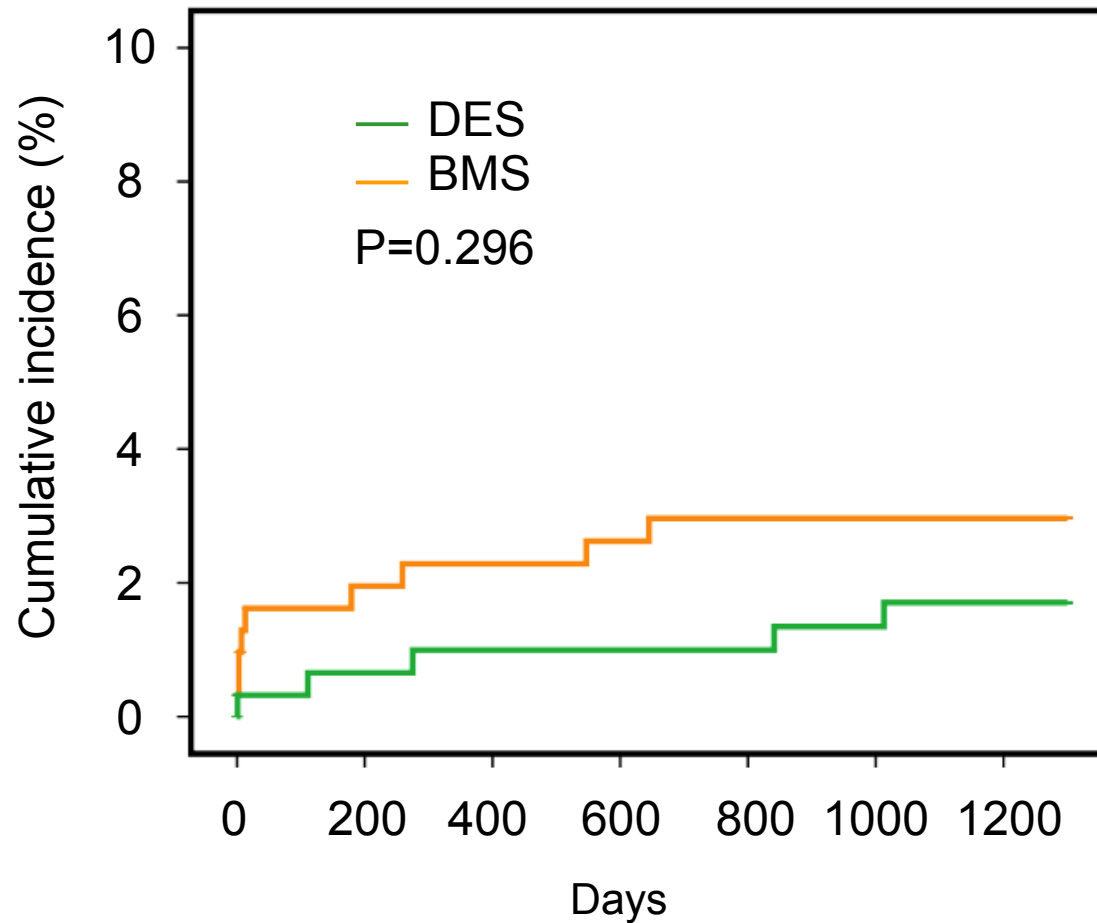
Freedom from cardiac mortality



Any stent thrombosis



Definite stent thrombosis



Subgroup analysis

Group	n	Rate of MACE (%)		Odds Ratio (95% CI)
		DES	BMS	
All	626	11.5	18.2	
Age < 63	315	9.4	19.4	
Age ≥ 63	311	13.7	17.1	
Male	458	11.8	16.1	
Female	168	10.6	24.1	
DM	65	13.8	22.2	
no DM	561	11.3	17.7	
Ref D > 3.1 mm	317	9.6	15.6	
Ref D ≤ 3.1 mm	299	12.0	20.8	
Visible thrombus	458	11.6	15.9	
No visible thrombus	168	11.1	24.1	
Stent length > 18 mm	309	12.9	17.8	
Stent length ≤ 18 mm	310	9.5	17.9	
LAD	258	14.8	20.6	
CX / RCA	368	9.4	16.4	

0 0.5 1.0 0.5 2.0
 DES better BMS better

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Conclusions

In the DEDICATION trial implantation of DES (compared with BMS) in STEMI patients

- reduced the rate of MACE and the need for repeat revascularization
- was not associated with an increased rate of myocardial infarction or stent thrombosis
- was associated with an increased risk of cardiac death