Long-Term Outcomes of Coronary Stent Implantation versus Bypass Surgery for the Treatment of Unprotected Left Main Coronary Artery Disease

Revascularization for Unprotected Left *MAIN* Coronary Artery Stenosis: *COM*parison of *P*ercutaneous Coronary *A*ngioplasty versus Surgical *RE*vascularization from Multi-Center Registry:

The MAIN-COMPARE Study

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on Behalf of the MAIN-COMPARE Study Group

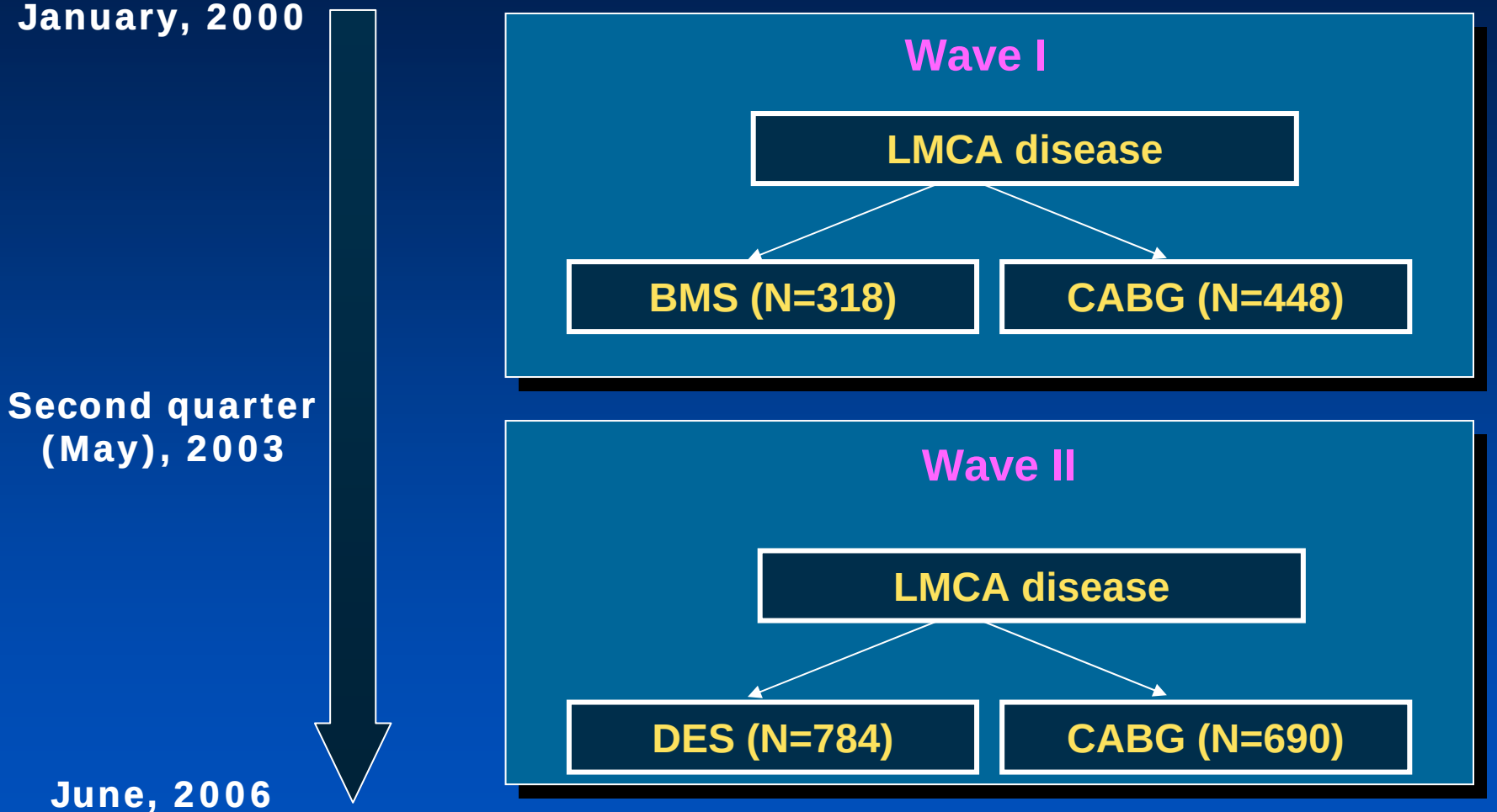
NEJM 2008;358.

Background

- Coronary stenting for LMCA disease suggested the favorable mid-term safety and feasibility, even with major limitation of angiographic restenosis and repeat revascularization.
- Current availability of DES has reduced the rates of restenosis and revascularization, and had led to a re-evaluation of the role of PCI for LMCA disease.
- We have very limited data about the efficacy comparison between PCI vs CABG in unprotected LM disease.

MAIN-COMPARE Study

Stenting (BMS or DES) vs. CABG



Total (N=2240) | **PCI (N=1102)** | **CABG(N=1138)**

Enrollment Criteria

Inclusion Criteria

- Patients with unprotected left main disease (defined as stenosis of more than 50%) who underwent stenting or isolated CABG

("Unprotected" is defined as no coronary artery bypass grafts to the LAD or the LCX artery)

Exclusion Criteria

- Prior CABG
- Concomitant valvular or aortic surgery
- ST-elevation MI
- Cardiogenic shock at presentation

Primary Outcome Measures

- Death
- Composite of death, Q-wave myocardial infarction, or stroke
- Target-vessel revascularization

Results

Baseline Characteristics

Variable	Stents (n=1102)	CABG (n=1138)	P Value
Demographic characteristics			
Age (yr)			<0.001
Median	62	64	
Interquartile range	52-70	57-70	
Male sex (%)	70.7	72.9	0.24
Cardiac or Coexisting conditions (%)			
Diabetes mellitus			
Any diabetes	29.7	34.7	0.01
Requiring insulin	6.8	8.2	0.22
Hypertension	49.5	49.4	0.94
Hyperlipidemia	28.5	32.6	0.04
Current smoker	25.6	29.8	0.03

Angiographic Characteristics

Variable	Stents (n=1102)	CABG (n=1138)	P Value
Involved location			0.04
Ostium and/or mid-shaft	50.6	46.2	
Distal bifurcation	49.4	53.8	
Extent of diseased vessel			<0.001
Left main only	25.2	6.2	
Left main plus single-vessel disease	24.0	10.5	
Left main plus double-vessel disease	26.0	26.3	
Left main plus triple-vessel disease	24.8	57.0	
Right coronary artery disease	35.9	70.7	<0.001
Restenotic lesion	2.9	1.2	0.005

After Propensity-Matching

Overall matched cohort (n=542 pairs)

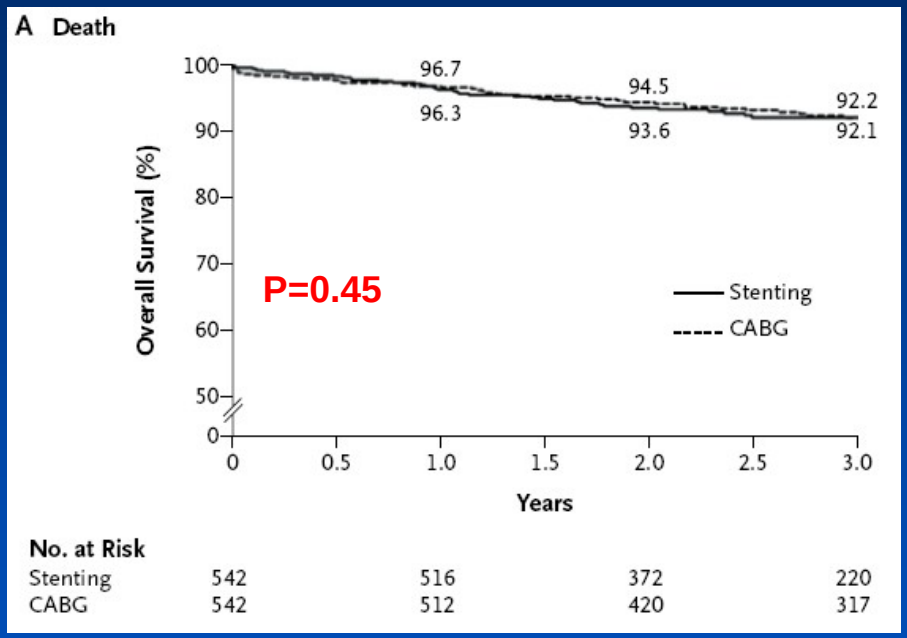
Wave 1; BMS vs. contemporary CABG (n=207 pairs)

Wave 2; DES vs. contemporary CABG (n=396 pairs)

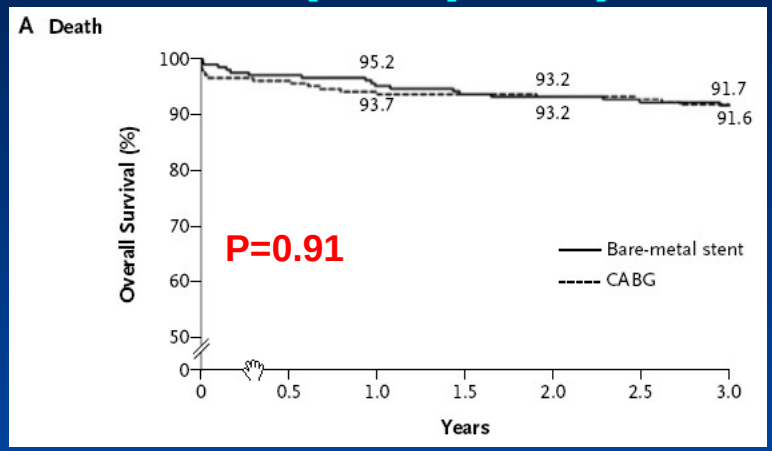
Comparable Incidence of Death

Propensity-Matched Populations

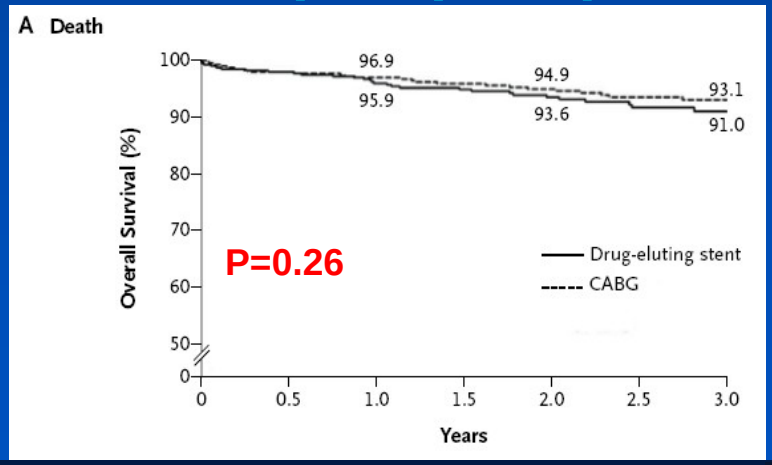
Overall (542 pairs)



BMS (207 pairs)



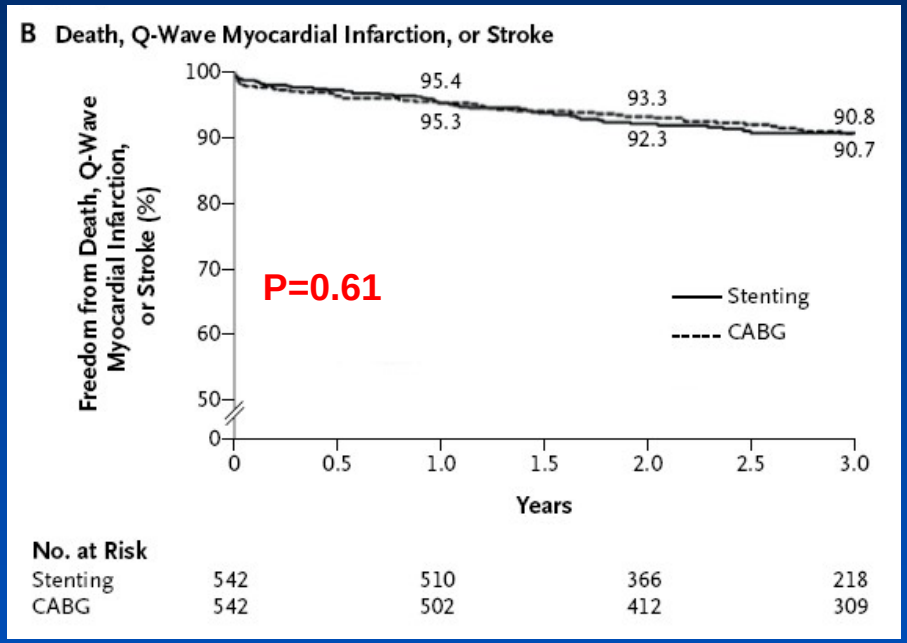
DES (396 pairs)



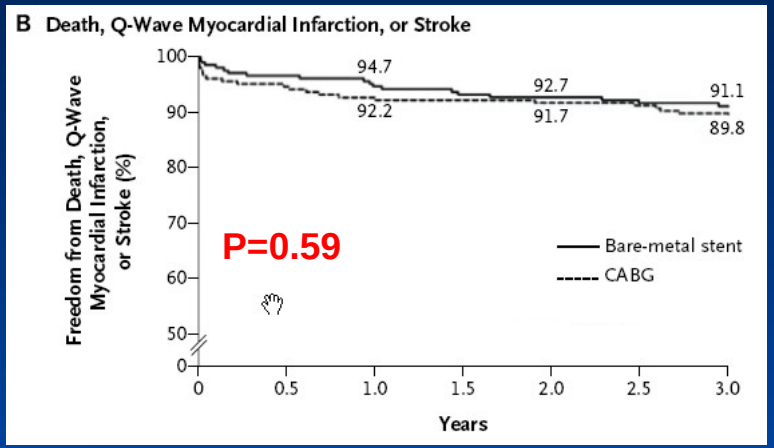
Comparable Incidence of Death/QMI/Stroke

Propensity-Matched Populations

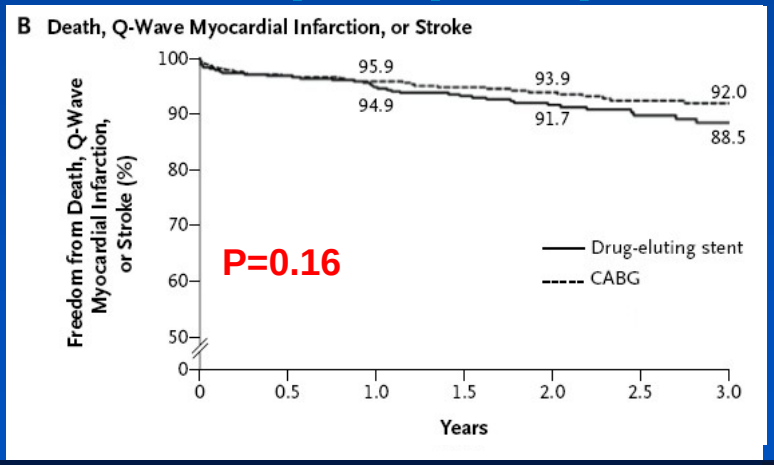
Overall (542 pairs)



BMS (207 pairs)



DES (396 pairs)



Hazard Ratios for Clinical Outcomes

(Overall PCI and CABG matched cohort: 542 pairs)

Outcome	Overall Patients (N=542 pairs)	
	Hazard Ratio* (95% CI)	P value
Death	1.18 (0.77-1.80)	0.45
Composite outcome (death, Q-wave myocardial infarction, or stroke)	1.10 (0.75-1.62)	0.61
Target-vessel revascularization	4.76 (2.80-8.11)	<0.001

***HR are for the stenting group, as compared with CABG group**

Hazard Ratios for Clinical Outcomes

(BMS and contemporary CABG matched cohort: 207pairs)

Outcome	Wave 1 (N=207 pairs) Hazard Ratio* (95% CI)	P value
Death	1.04 (0.59-1.83)	0.90
Composite outcome (death, Q-wave myocardial infarction, or stroke)	0.86 (0.50-1.49)	0.59
Target-vessel revascularization	10.70 (3.80-29.90)	<0.001

***HR are for the stenting group, as compared with CABG group**

Hazard Ratios for Clinical Outcomes

(DES and contemporary CABG matched cohort: 396 pairs)

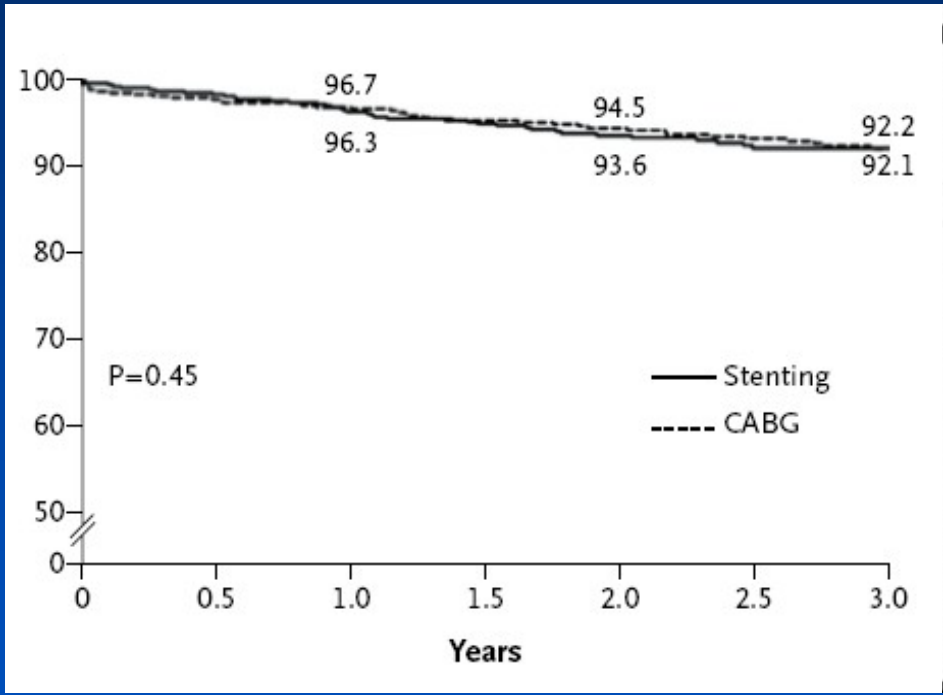
Outcome	Wave 2 (N=396 pairs) Hazard Ratio* (95% CI)	P value
Death	1.36 (0.80-2.30)	0.26
Composite outcome (death, Q-wave myocardial infarction, or stroke)	1.40 (0.88-2.22)	0.15
Target-vessel revascularization	5.96 (2.51-14.10)	<0.001

***HR are for the stenting group, as compared with CABG group**

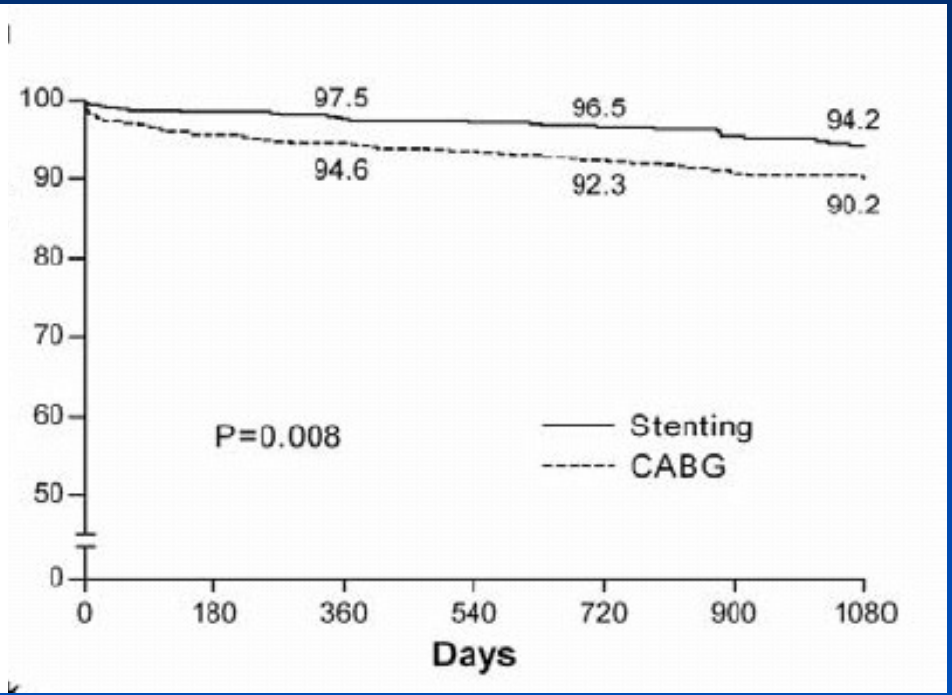
Incidence of Death

Matched and Unmatched Populations

Matched group

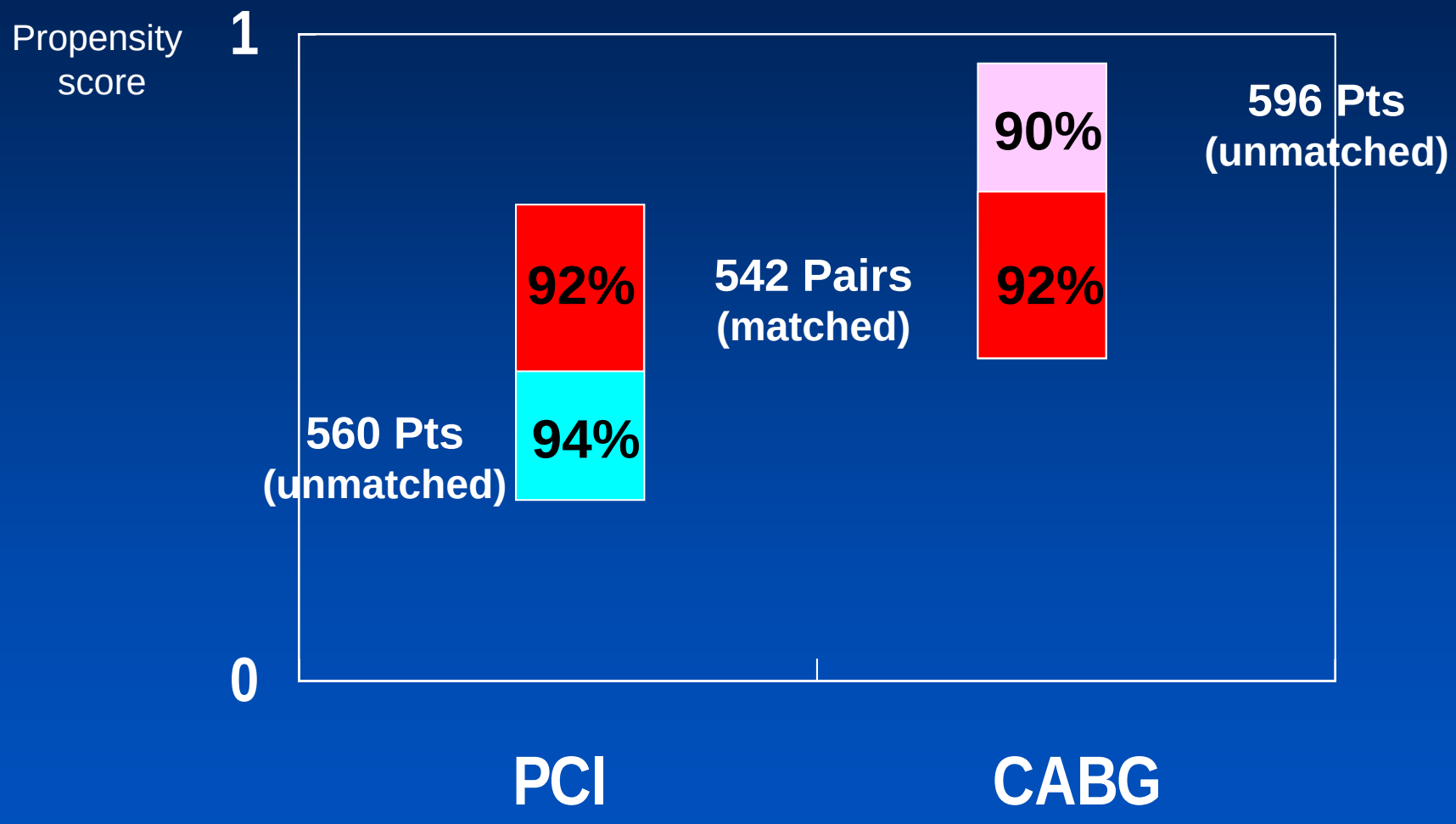


Un-matched group



Incidence of Death

Matched and Unmatched Populations



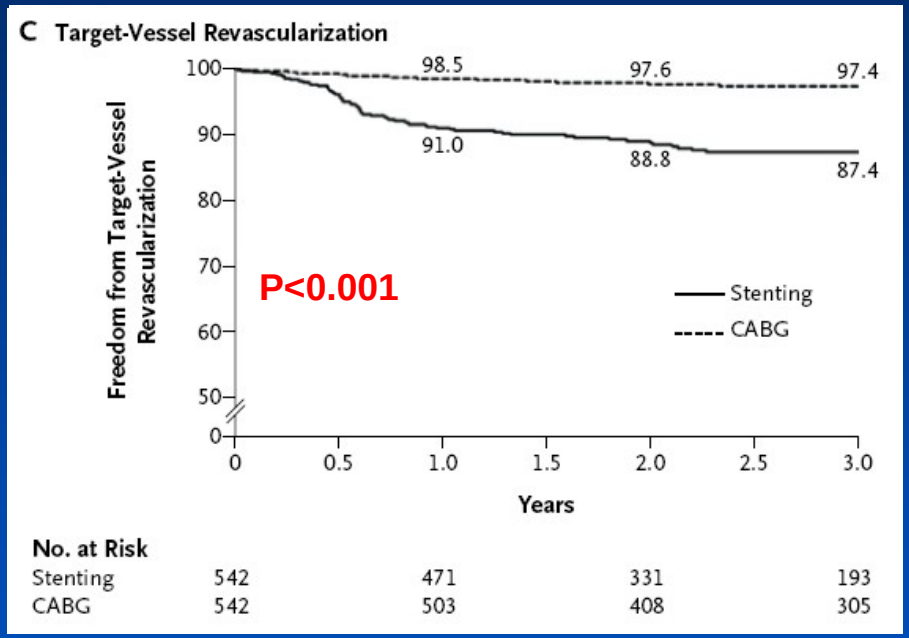
Safety of PCI for Unprotected LM Stenosis

- PCI for unprotected LM stenosis was comparably safe to CABG for patients at a low or moderate clinical risk.
- The risk of mortality was more dependent on the baseline clinical risk of patients than the type of treatment.

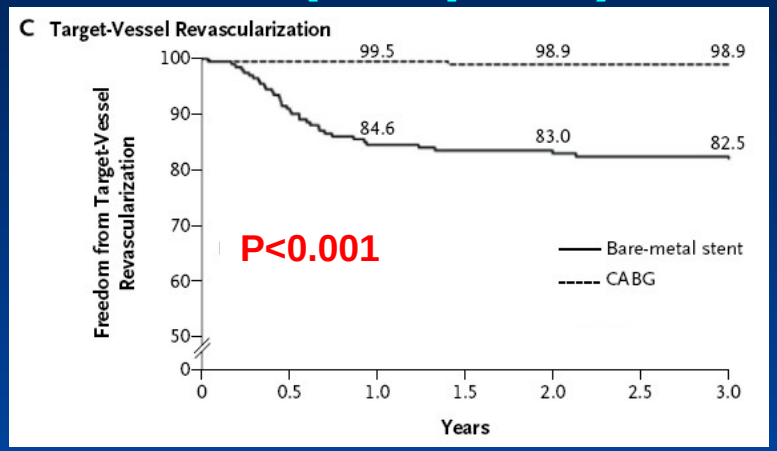
Lower Incidence of TVR By CABG

Propensity-Matched Populations

Overall (542 pairs)



BMS (207 pairs)



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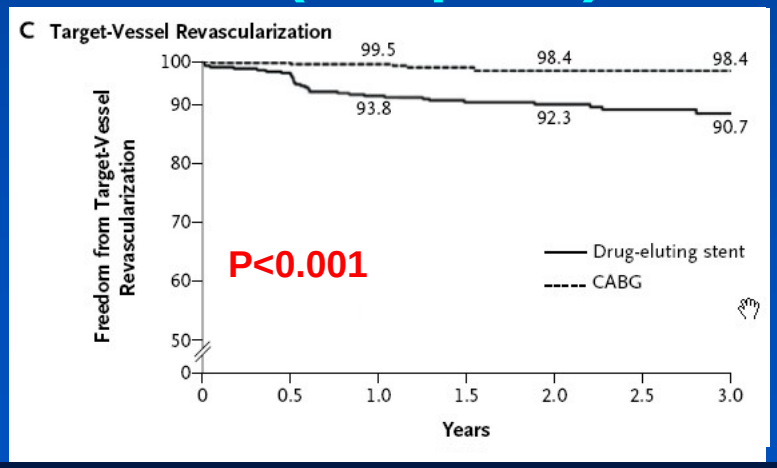
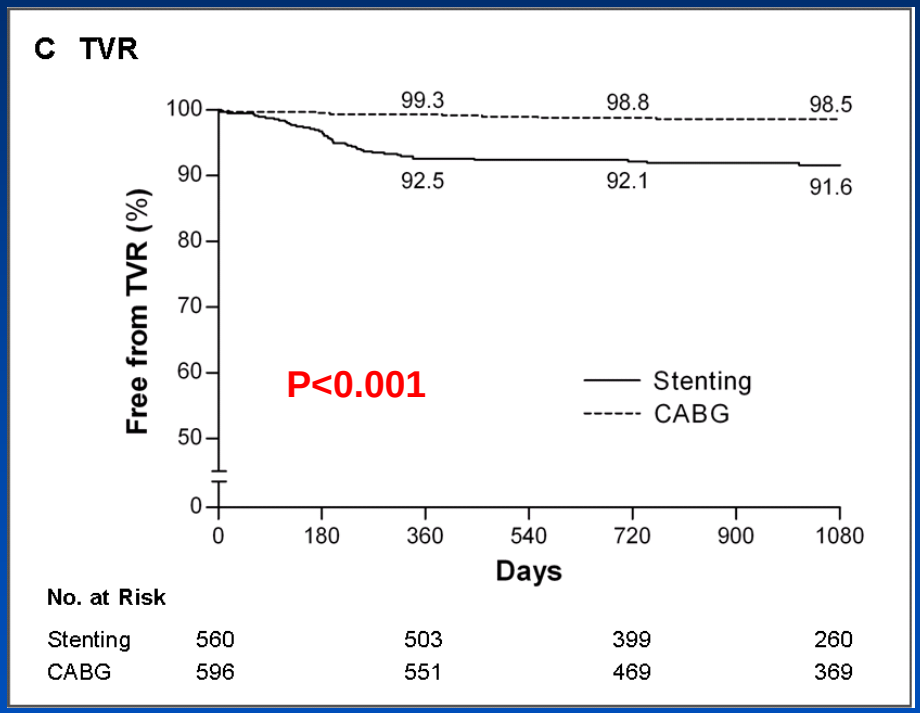


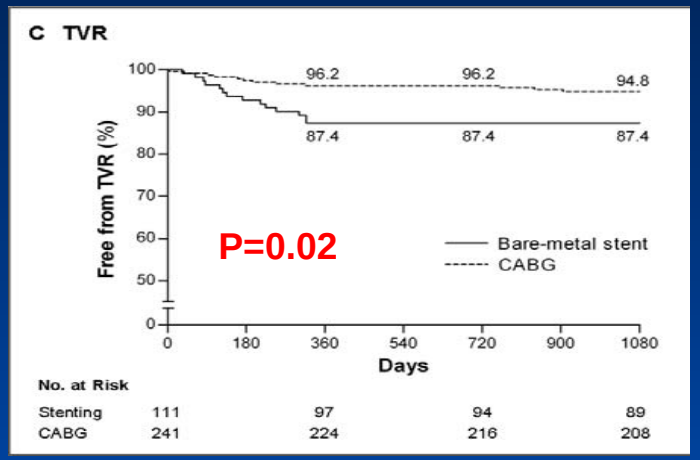
Lower Incidence of TVR By CABG

Propensity-Unmatched Populations

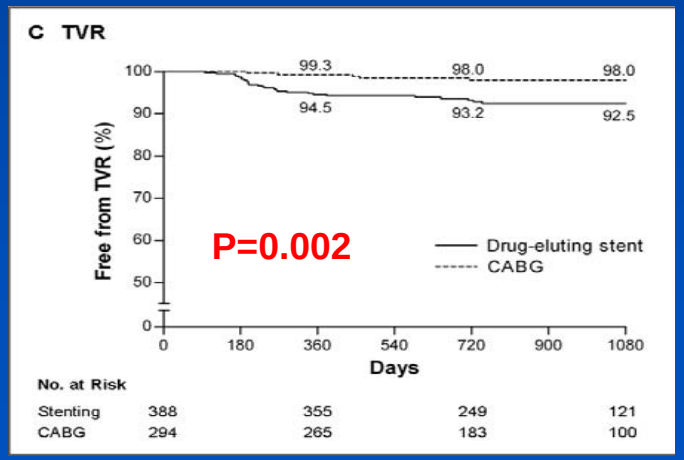
Overall



BMS Era



DES Era



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(BMS and contemporary CABG matched cohort: 207pairs)

Outcome	Wave 1 (N=207 pairs) Hazard Ratio* (95% CI)	P value
Death	1.04 (0.59-1.83)	0.90
Composite outcome (death, Q-wave myocardial infarction, or stroke)	0.86 (0.50-1.49)	0.59
Target-vessel revascularization	10.70 (3.80-29.90)	<0.001

***HR are for the stenting group, as compared with CABG group**

Hazard Ratios for Clinical Outcomes

(DES and contemporary CABG matched cohort: 396 pairs)

Outcome	Wave 2 (N=396 pairs) Hazard Ratio* (95% CI)	P value
Death	1.36 (0.80-2.30)	0.26
Composite outcome (death, Q-wave myocardial infarction, or stroke)	1.40 (0.88-2.22)	0.15
Target-vessel revascularization	5.96 (2.51-14.10)	<0.001

***HR are for the stenting group, as compared with CABG group**

Efficacy of PCI for Unprotected LM Stenosis

- The risk of repeat revascularization is lower with use of CABG than PCI.
- However, repeat revascularization is one of outcomes assessing the efficacy of a certain strategy.
- The majority of restenosis at the LM was treated with PCI.
- The safety and efficacy of PCI was consistently approved in diverse subgroups of patients.

Special Issue

Clinical Impact of IVUS Guidance on Outcomes of Left Main PCI:

Lessons from MAIN-COMPARE Registry

Results

- A total of 975 patients were included in this analysis:
  - 756 patients (77.5%) received IVUS-guided stenting
  - 219 patients (22.5%) received angiography-guided stenting

Baseline Clinical Characteristics

Variable	IVUS (n=756)	Angiography (n=219)	*P*
Age (years)	59.7±11.5	65.4±11.1	**<0.001**
Male gender	522 (69.0)	159 (72.6)	0.31
Diabetes			
Any type	204 (27.0)	72 (32.9)	0.09
Insulin-treated	39 (5.2)	21 (9.6)	**0.02**
Hypertension	360 (47.6)	120 (54.8)	0.06
Hyperlipidemia	229 (30.3)	59 (26.9)	0.34
Current smoker	191 (25.3)	49 (22.4)	0.38
Family history of coronary artery disease	58 (7.7)	11 (5.0)	0.18
Previous myocardial infarction	56 (7.4)	16 (7.3)	0.96
Previous coronary angioplasty	130 (17.2)	52 (23.7)	**0.03**
Previous congestive heart failure	6 (0.8)	7 (3.2)	**0.006**

Baseline Clinical Characteristics

Variable	IVUS (n=756)	Angiography (n=219)	*P*
Cerebrovascular disease	50 (6.6)	22 (10.0)	0.09
Peripheral vascular disease	9 (1.2)	7 (3.2)	**0.04**
Chronic lung disease	15 (2.0)	4 (1.8)	0.88
Renal failure	14 (1.9)	9 (4.1)	0.05
Atrial fibrillation	9 (1.2)	6 (2.7)	0.10
Unstable angina	466 (61.6)	133 (60.7)	0.81
Ejection fraction (%)	62.7±8.5	59.4±12.2	**0.001**
Euro SCORE			
Mean	3.4±2.2	4.4±2.4	**<0.001**
High score ≥ 6	124 (16.4)	71 (32.4)	**<0.001**

Angiographic Characteristics

Variable	IVUS (n=756)	Angiography (n=219)	*P*
Lesion location			0.26
Ostium or shaft	392 (51.9)	104 (47.5)	
Bifurcation	364 (48.1)	115 (52.5)	
Extent of diseased vessel			**<0.001**
LM only	227 (30.0)	31 (14.2)	
LM plus 1 VD	184 (24.3)	47 (21.5)	
LM plus 2 VD	187 (24.7)	67 (30.6)	
LM plus 3 VD	158 (20.9)	74 (33.7)	
Right coronary artery disease	239 (31.6)	101 (46.1)	**<0.001**
Restenotic lesion	24 (3.2)	5 (2.3)	0.49

After Propensity-Matching

Overall: IVUS vs. Angiography (n=201 pairs)

DES: IVUS vs. Angiography (n=145 pairs)

BMS; IVUS vs. Angiography (n=47 pairs)

Baseline Characteristics of Propensity-Matched Patients: All PCI (201pairs)

	IVUS-guidance	Angio-guidance	P
Age (yr)	65.28±10.50	64.31±10.66	0.259
Male gender	139 (69.2)	146 (72.6)	0.520
Diabetes			
Any type	70 (34.8)	63 (31.3)	0.520
Insuline-treated	18 (9.0)	17 (8.5)	1.000
Hypertension	116 (57.7)	104 (51.7)	0.256
Hyperlipidemia	62 (30.9)	53 (26.4)	0.380
Current smoker	44 (21.9)	46 (22.9)	0.904
Family history of coronary artery disease	10 (5.0)	9 (4.5)	1.000
Previous myocardial infarction	18 (9.0)	16 (8.0)	0.851
Previous coronary angioplasty	43 (21.4)	46 (22.9)	0.795
Previous congestive heart failure	3 (1.5)	3 (1.5)	1.000

Baseline Characteristics of Propensity-Matched Patients: All PCI (201pairs)

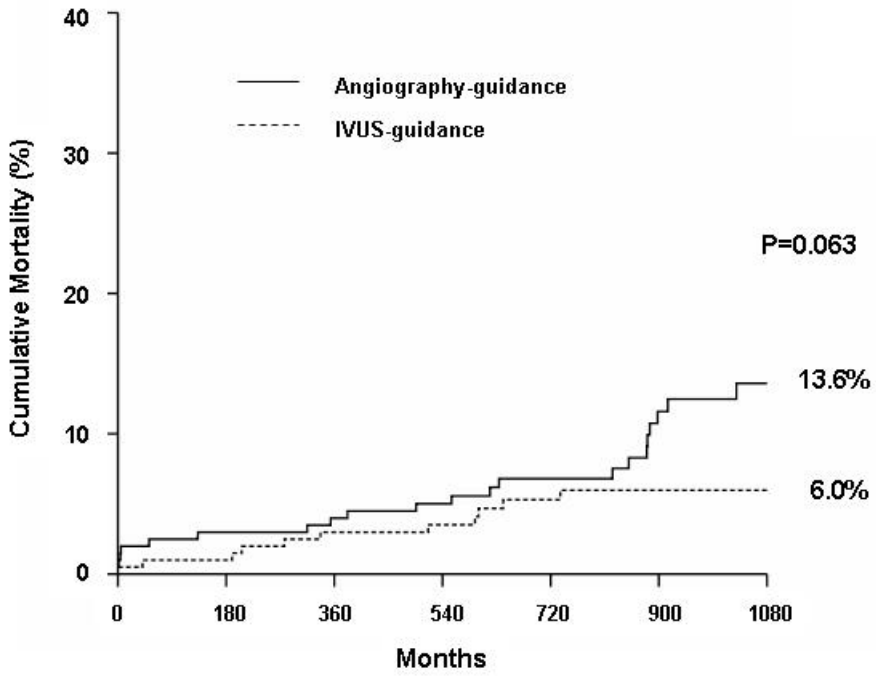
	IVUS-guidance	Angio-guidance	P
Cerebrovascular disease	17 (8.5)	16 (8.0)	1.000
Peripheral vascular disease	5 (2.5)	5 (2.5)	1.000
Chronic lung disease	3(1.5)	3(1.5)	1.000
Chronic renal failure	7(3.5)	5(2.5)	0.774
Atrial fibrillation	6(3.0)	5(2.5)	1.000
Acute coronary syndrome	122(60.7)	124(61.7)	0.923
Left ventricular ejection fraction (%)	61.47±10.62	61.38±10.20	0.229
Left main location			0.832
Ostium or shaft	93(46.3)	96(47.8)	
Bifurcation	108(53.7)	105(52.2)	

Baseline Characteristics of Propensity-Matched Patients: All PCI (201pairs)

	IVUS-guidance	Angio-guidance	P
Extent of diseased vessel			0.364
Left main only	28(13.9)	29(14.4)	
Left main plus single-vessel disease	53(26.4)	45(22.4)	
Left main plus two-vessel disease	59(29.4)	62(30.9)	
Left main plus three-vessel disease	61(30.4)	65(32.3)	
Right coronary artery disease	76(37.8)	93(64.3)	0.082
De novo lesions	196(97.5)	196(97.5)	1.000
Number of stents implanted at left main	1.18±0.46	1.20±0.50	0.620
Total stent length at left main	29.09±20.81	30.41±21.03	0.535
Complex stenting	45(22.4)	45(22.4)	1.000

Death

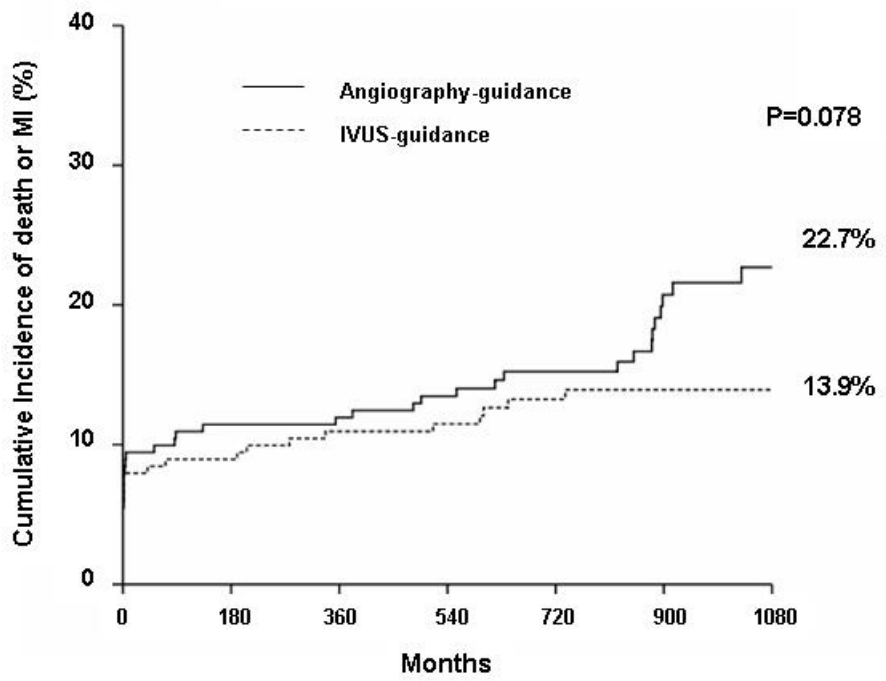
Overall



Patients at risk

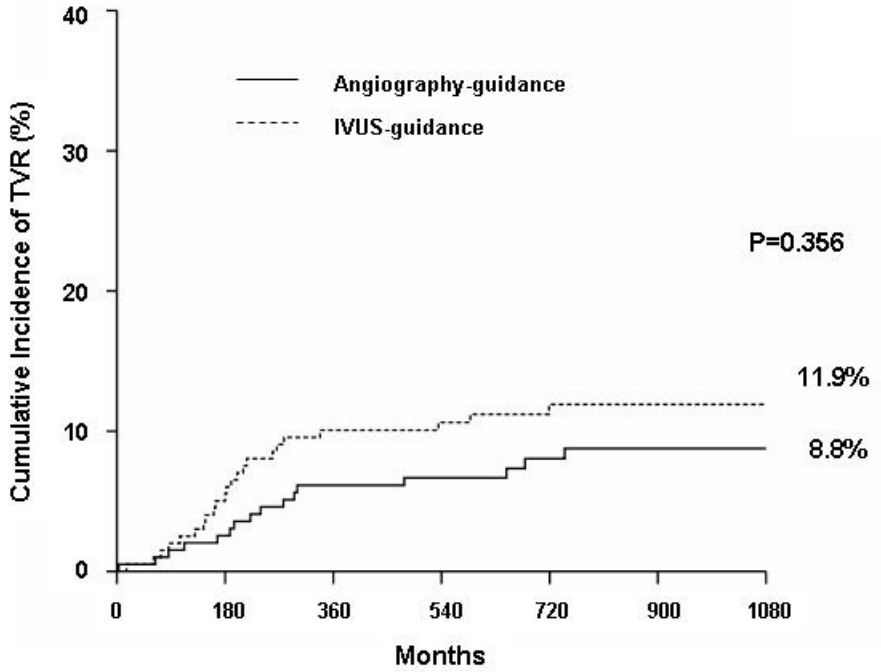
IVUS-guidance	201	194	143	88
Angiography-guidance	201	191	138	64

Death or MI



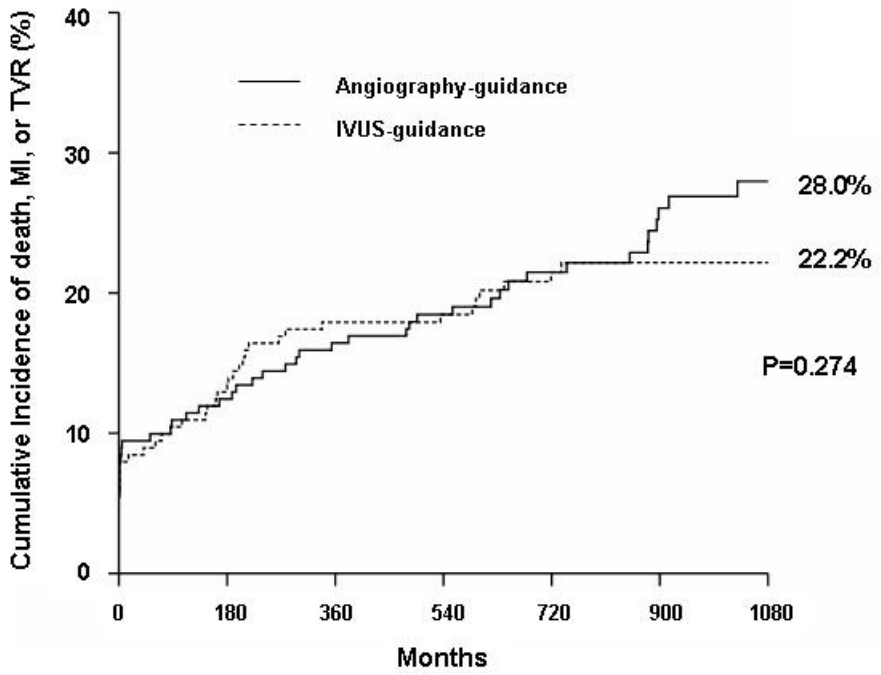
Patients at risk				
IVUS-guidance	201	178	131	82
Angiography-guidance	201	175	128	67

TVR



Patients at risk				
IVUS-guidance	201	176	125	18
Angiography-guidance	201	179	129	70

Death, MI, or TVR



Patients at risk				
IVUS-guidance	201	164	116	74
Angiography-guidance	201	166	120	64

Hazard Ratios for Clinical Outcomes

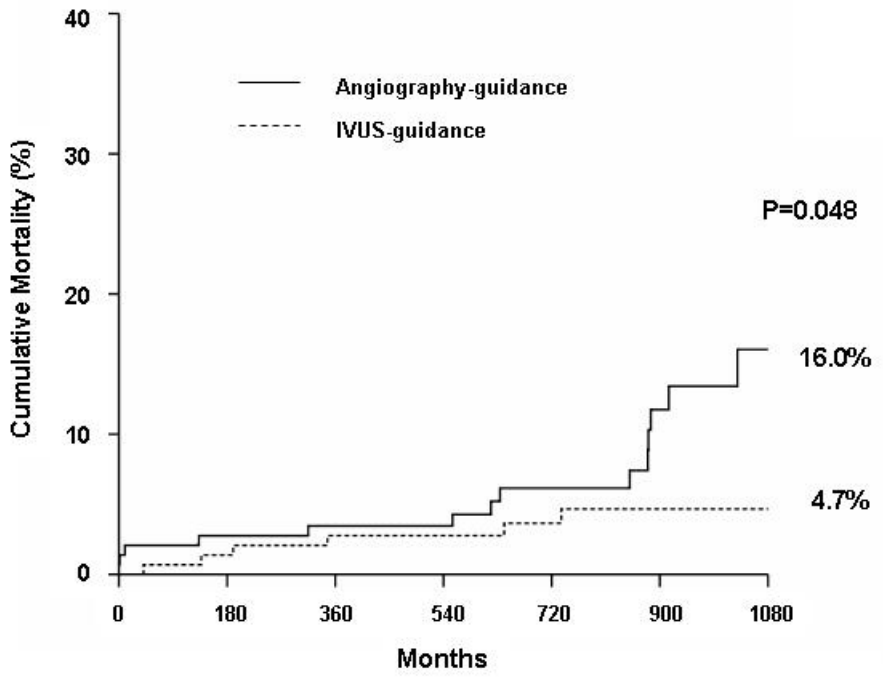
(Overall IVUS vs. Angiography matched cohort: 201 pairs)

Outcome	HR	95% CI	p-value
Death	0.54	0.28-1.03	0.061
MI	0.76	0.41-1.40	0.38
Death or MI	0.66	0.42-1.04	0.071
TVR	1.33	0.72-2.48	0.37
Death, MI, or TVR	0.80	0.54-1.19	0.28

***HR are for the IVUS group, as compared with the Angiography group**

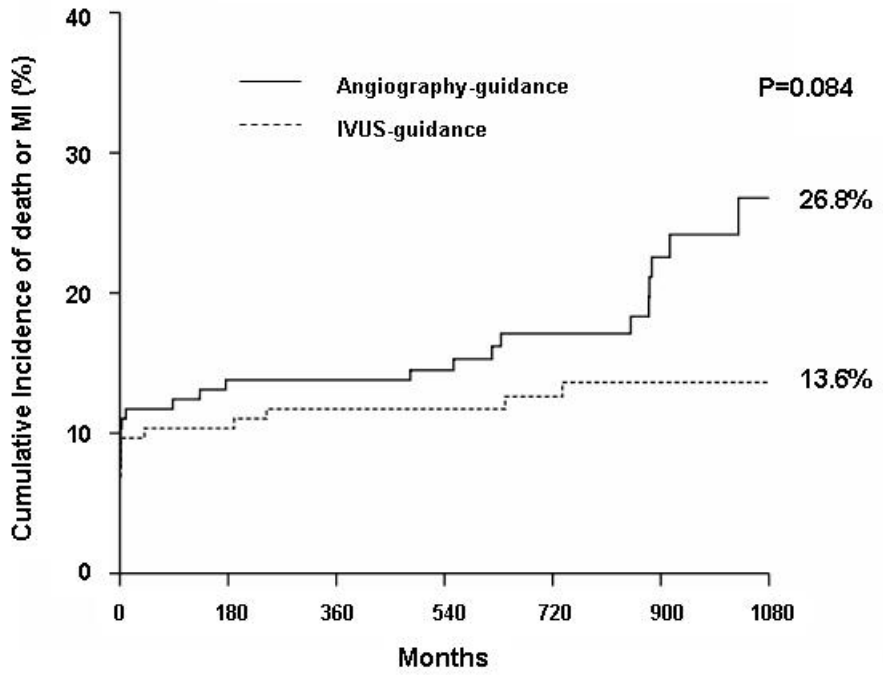
DES

Death



Patients at risk				
IVUS-guidance	145	140	98	37
Angiography-guidance	145	137	88	29

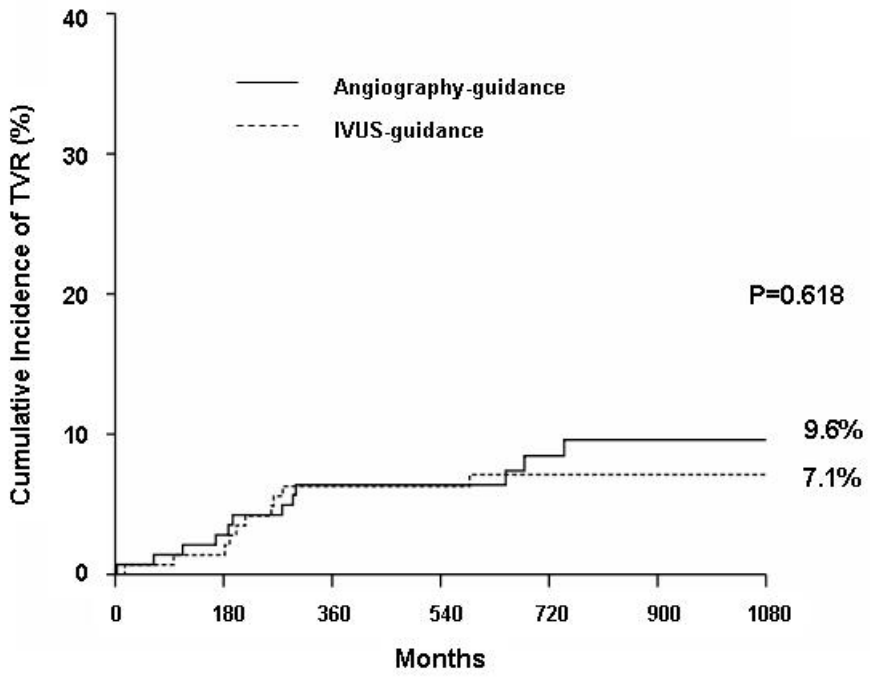
Death or MI



Patients at risk

IVUS-guidance	145	127	88	24
Angiography-guidance	145	123	80	25

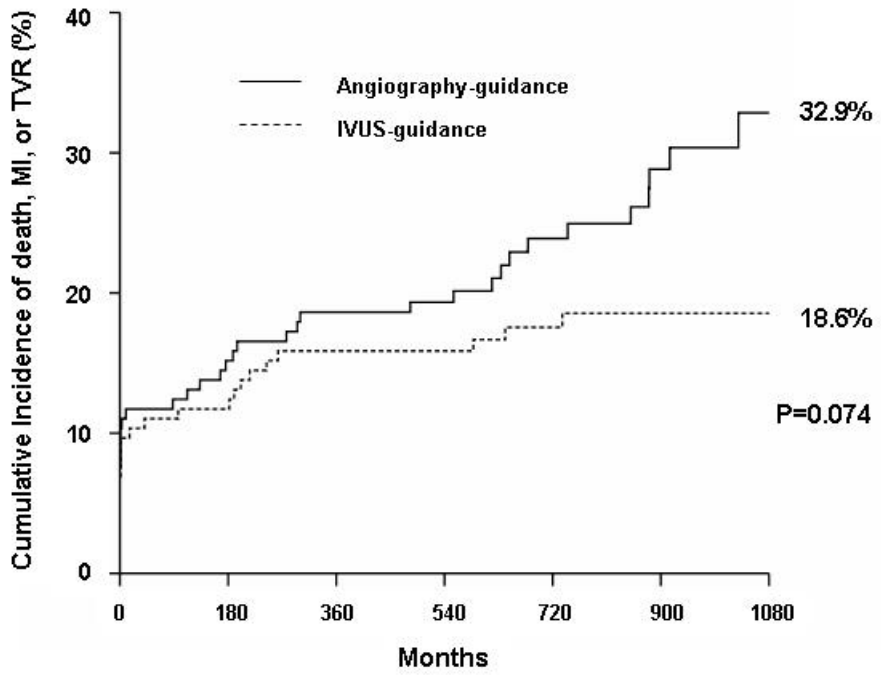
TVR



Patients at risk

IVUS-guidance	145	132	91	35
Angiography-guidance	145	128	83	28

Death, MI, or TVR



Patients at risk				
IVUS-guidance	145	121	83	23
Angiography-guidance	145	116	75	24

Hazard Ratios for Clinical Outcomes

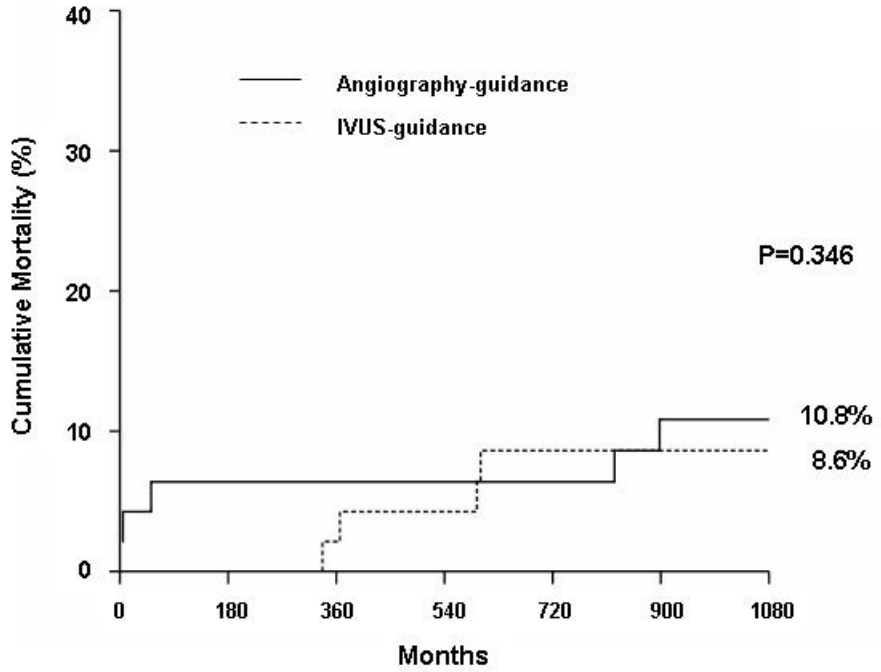
(DES IVUS vs. Angiography matched cohort: 145 pairs)

Outcome	HR	95% CI	p-value
Death	0.39	0.15-1.02	0.05
MI	0.83	0.43-1.57	0.56
Death or MI	0.61	0.35-1.07	0.082
TVR	0.8	0.35-1.86	0.62
Death, MI, or TVR	0.64	0.39-1.04	0.074

***HR are for the IVUS group, as compared with the Angiography group**

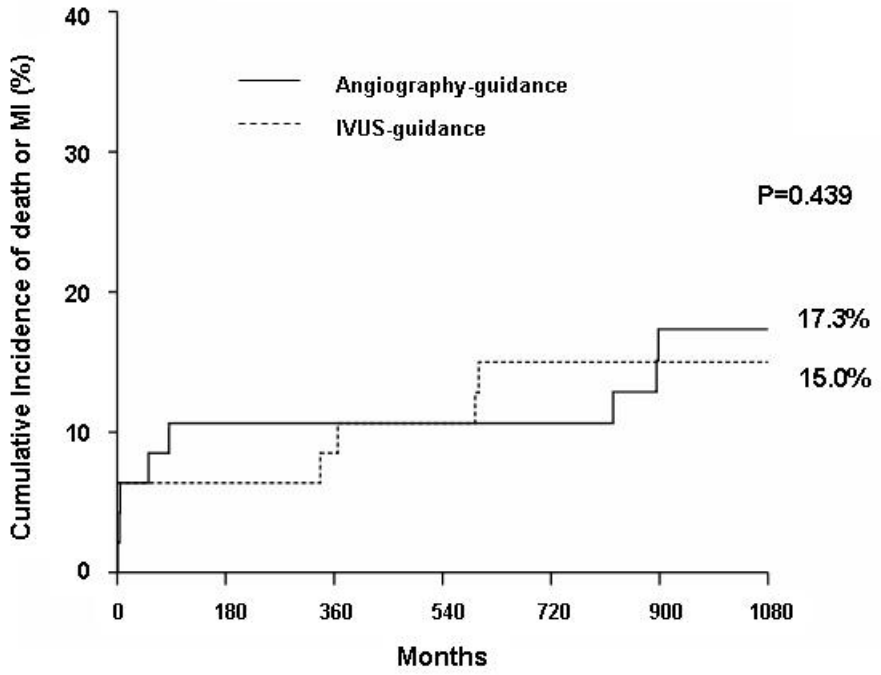
Death

BMS



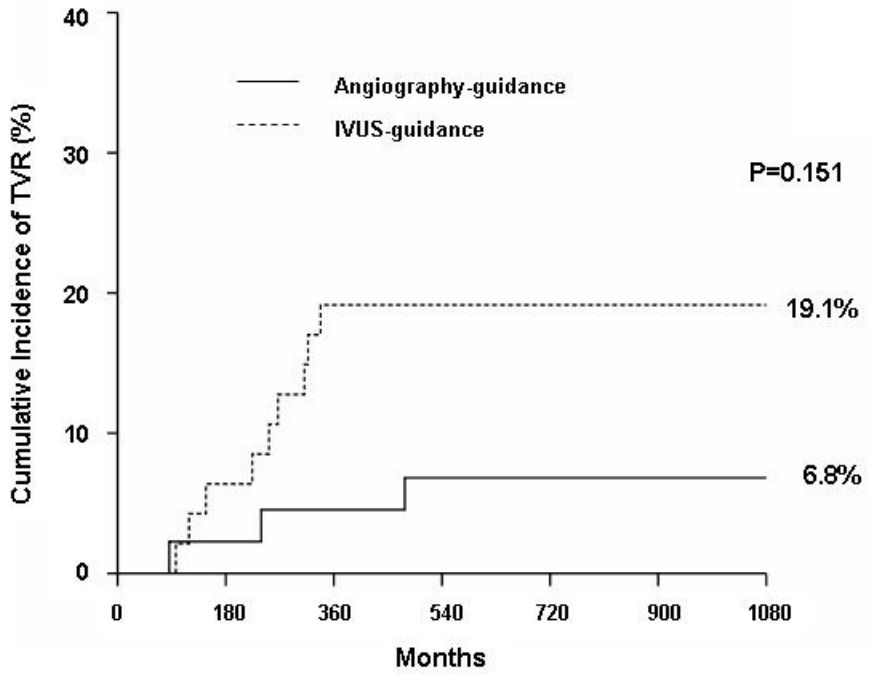
Patients at risk				
IVUS-guidance	47	46	42	41
Angiography-guidance	47	44	42	38

Death or MI



Patients at risk				
IVUS-guidance	47	43	39	39
Angiography-guidance	47	42	40	35

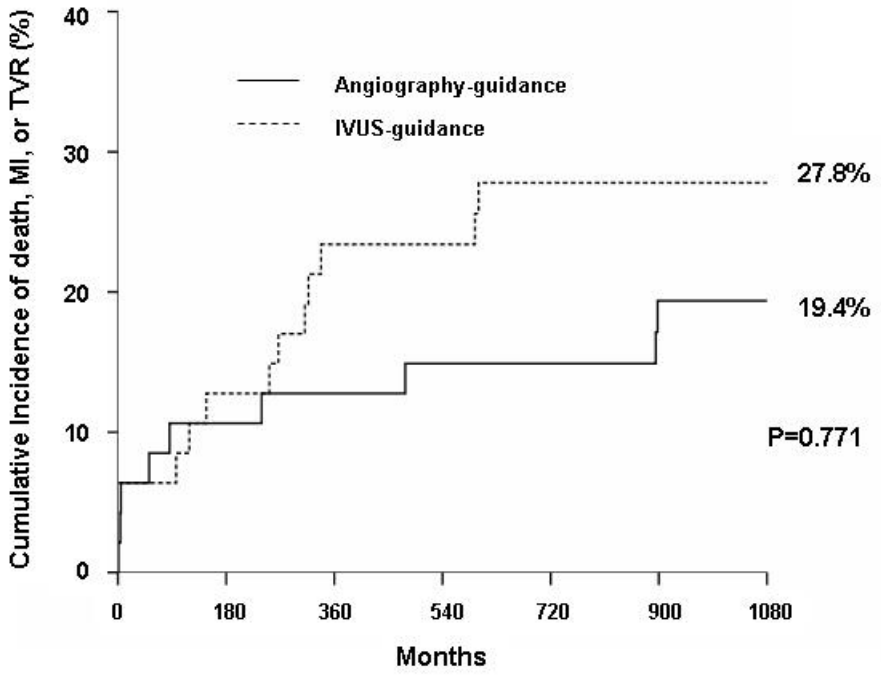
TVR



Patients at risk

IVUS-guidance	47	38	35	34
Angiography-guidance	47	42	39	36

Death, MI, or TVR



Patients at risk				
IVUS-guidance	47	36	33	33
Angiography-guidance	47	41	38	34

Hazard Ratios for Clinical Outcomes

(BMS IVUS vs. Angiography matched cohort: 47 pairs)

Outcome	HR	95% CI	p-value
Death	0.59	0.18-1.91	0.38
MI	0.97	0.23-4.16	0.97
Death or MI	0.70	0.27-1.8	0.46
TVR	2.31	0.68-7.9	0.18
Death, MI, or TVR	1.12	0.520-2.41	0.78

***HR are for the IVUS group, as compared with the Angiography group**

Conclusion

- IVUS-guided stenting are associated with reduced long-term mortality rate compared with conventional angiography-guided stenting for unprotected LMCA stenosis.
- In addition, this trend was identified only in patients receiving DES, but not in those receiving BMS.
- Contrasted with an improvement of survival, the risk of repeat revascularization was not modified by use of IVUS.

Special Issue

BMS vs. DES
in LM disease intervention

Subgroup Analyses from
MAIN-COMPARE Registry

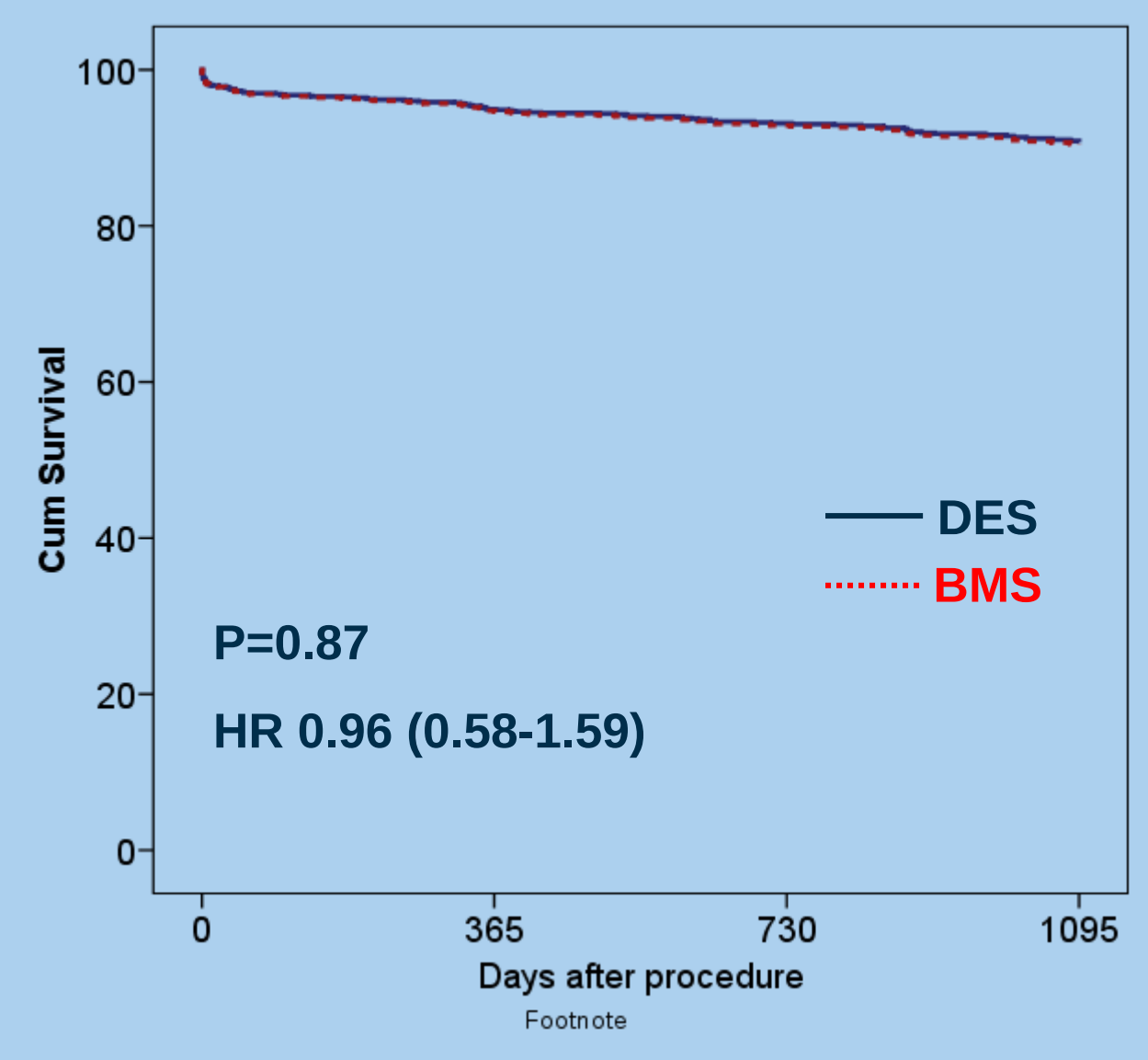
Baseline Characteristics

Variable	BMS (n=353)	DES (n=864)	*P*
Age (years)	59.1±12.7	62.7±11.2	<0.001
Male gender	253 (71.7)	619 (71.6)	0.99
Diabetes	84 (23.8)	279 (32.3)	0.003
Hypertension	147 (41.6)	452 (52.3)	0.001
Hyperlipidemia	80 (22.7)	252 (29.2)	0.02
Current smoker	101 (28.6)	224 (25.9)	0.34
Previous myocardial infarction	32 (9.1)	70 (8.1)	0.58
Previous coronary angioplasty	43 (12.2)	167 (19.3)	0.003
Previous congestive heart failure	7 (2.0)	25 (2.9)	0.37
Peripheral vascular disease	3 (0.8)	17 (2.0)	0.16
Chronic lung disease	2 (0.6)	28 (3.2)	0.006
Renal failure	8 (2.3)	36 (4.2)	0.11
Ejection fraction (%)	60.3±10.9	59.4±11.7	0.26

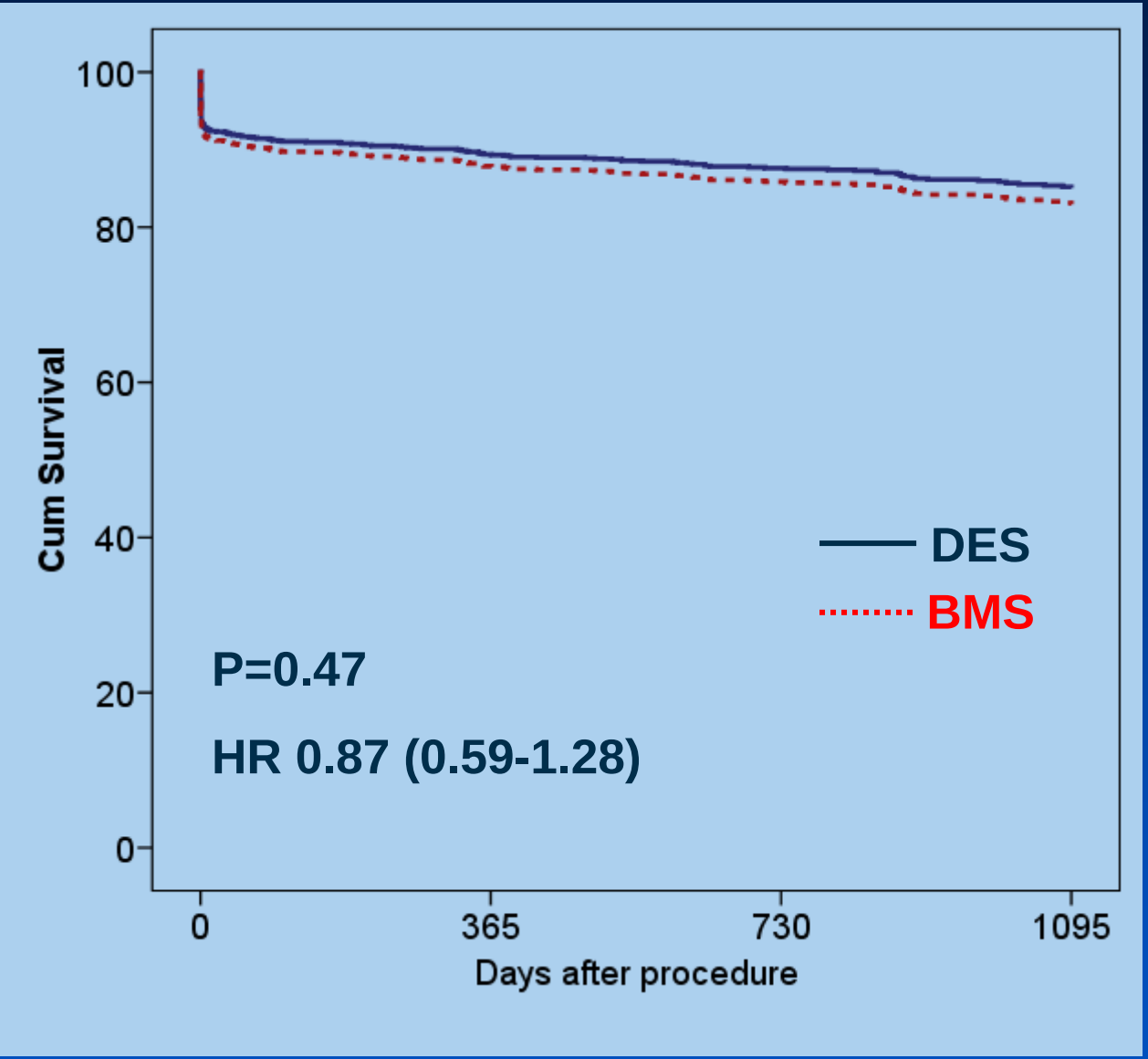
Outcomes of Overall Patients (BMS vs. DES)

	Crude		Multivariable adjusted†		Adjusted for propensity	
Outcome	Hazard Ratio (95% CI)	*P*	Hazard Ratio (95% CI)	*P*	Hazard Ratio (95% CI)	*P*
Death	0.93 (0.61–1.41)	0.73	0.85 (0.53–1.38)	0.51	0.96 (0.58–1.59)	0.87
Cardiac	0.89 (0.55–1.42)	0.62	0.92 (0.54–1.60)	0.78	0.91 (0.51–1.61)	0.74
Noncardiac	1.10 (0.45–2.68)	0.84	0.69 (0.23–1.13)	0.51	1.16 (0.40–3.38)	0.79
Myocardial Infarction	1.22 (0.76–1.96)	0.42	1.00 (0.58–1.76)	0.98	0.89 (0.50–1.56)	0.68
TLR	0.39 (0.26–0.60)	<0.001	0.34 (0.19–0.59)	<0.001	0.33 (0.19–0.55)	<0.001
TVR	0.55 (0.38–0.78)	0.001	0.35 (0.22–0.55)	<0.001	0.37 (0.24–0.57)	<0.001
Death/MI	1.04 (0.75–1.44)	0.81	0.90 (0.62–1.30)	0.58	0.87 (0.59–1.28)	0.47
Death/MI/TLR	0.84 (0.64–1.10)	0.20	0.75 (0.55–1.02)	0.07	0.70 (0.51–0.97)	0.03
Death/MI/TVR	0.84 (0.66–1.09)	0.19	0.67 (0.50–0.90)	0.008	0.65 (0.48–0.89)	0.006

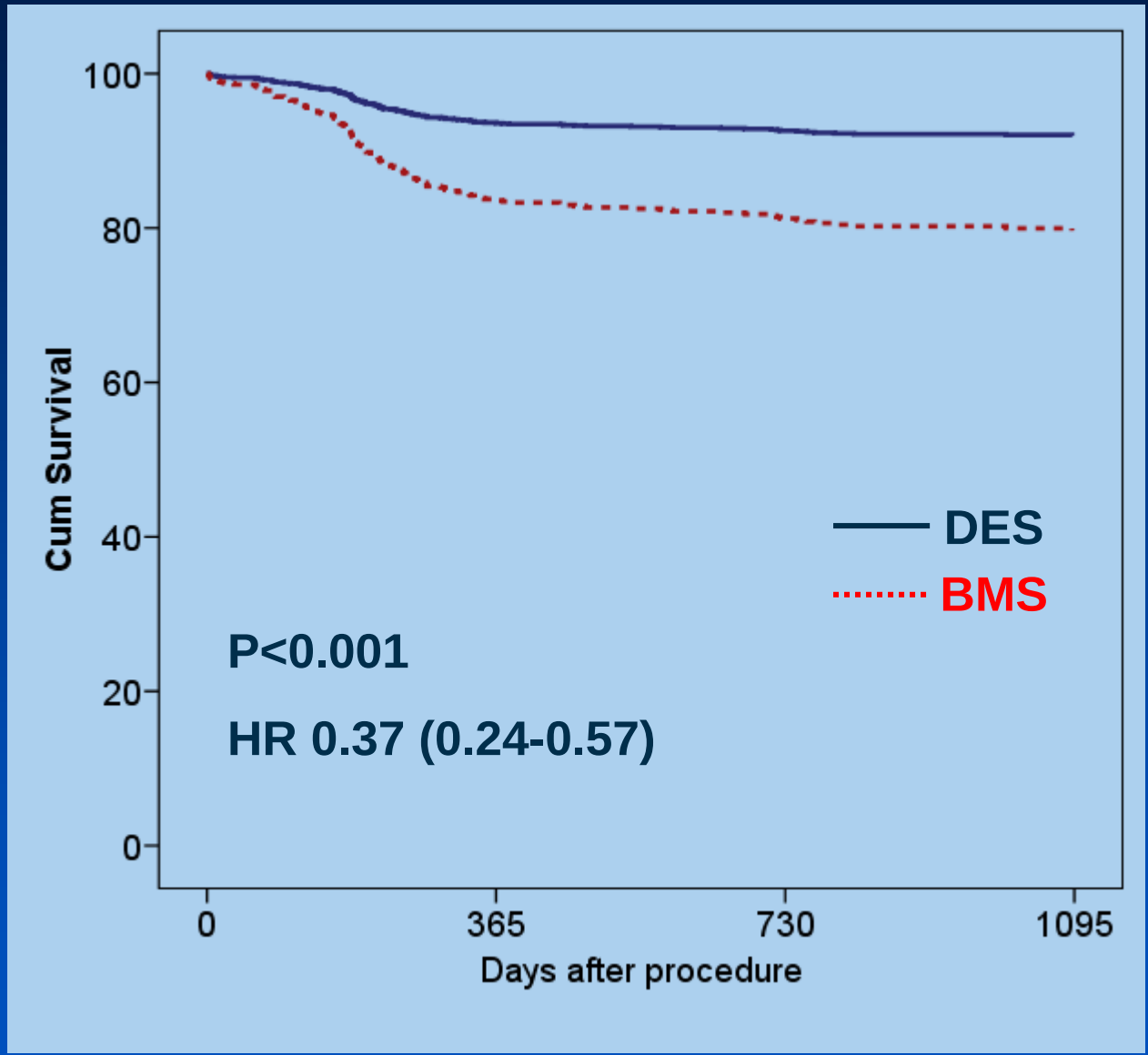
Adjusted Curves for Death



Adjusted Curves for Death or MI



Adjusted Curves for TVR



Outcomes of Non-Bifurcation Lesions (BMS vs. DES)

	Crude		Multivariable adjusted†		Adjusted for propensity	
Outcome	Hazard Ratio (95% CI)	*P*	Hazard Ratio (95% CI)	*P*	Hazard Ratio (95% CI)	*P*
Death	1.16 (0.67–2.00)	0.60	1.08 (0.56–2.14)	0.79	1.12 (0.60–2.11)	0.72
Cardiac	1.33 (0.71–2.49)	0.38	1.36 (0.63–2.94)	0.43	1.20 (0.58–2.46)	0.63
Noncardiac	0.70 (0.21–2.31)	0.55	0.78 (0.20–3.89)	0.35	0.89 (0.23–3.50)	0.87
Myocardial Infarction	1.35 (0.61–3.02)	0.46	1.30 (0.48–3.51)	0.60	0.98 (0.39–2.47)	0.96
TLR	0.30 (0.15–0.61)	0.001	0.25 (0.10–0.62)	0.003	0.30 (0.13–0.69)	0.004
TVR	0.43 (0.25–0.77)	0.004	0.27 (0.13–0.57)	0.001	0.37 (0.19–0.70)	0.003
Death/MI	1.25 (0.78–2.01)	0.36	1.16 (0.66–2.04)	0.61	1.06 (0.61–1.83)	0.85
Death/MI/TLR	0.85 (0.58–1.25)	0.40	0.80 (0.51–1.27)	0.35	0.76 (0.49–1.19)	0.23
Death/MI/TVR	0.85 (0.59–1.23)	0.40	0.73 (0.47–1.13)	0.15	0.72 (0.47–1.11)	0.13

Outcomes of Bifurcation Lesions (BMS vs. DES)

	Crude		Multivariable adjusted†		Adjusted for propensity	
Outcome	Hazard Ratio (95% CI)	*P*	Hazard Ratio (95% CI)	*P*	Hazard Ratio (95% CI)	*P*
Death	0.70 (0.36–1.36)	0..30	0.69 (0.61–1.54)	0.36	0.70 (0.33–1.50)	0.36
Cardiac	0.53 (0.26–1.08)	0.08	0.41 (0.16–1.07)	0.07	0.48 (0.21–1.10)	0.08
Noncardiac	2.61 (0.34–20.3)	0.36	1.91 (0.12–29.75)	0.65	3.66 (0.39–34.28)	0.26
Myocardial Infarction	0.79 (0.44–1.44)	0.45	0.85 (0.42–1.72)	0.65	0.89 (0.45–1.78)	0.74
TLR	0.36 (0.20–0.65)	0.001	0.30 (0.14–0.65)	0.002	0.37 (0.19–0.74)	0.004
TVR	0.47 (0.29–0.76)	0.002	0.34 (0.18–0.62)	<0.001	0.45 (0.25–0.78)	0.005
Death/MI	0.71 (0.45–1.12)	0.14	0.72 (0.43–1.22)	0.22	0.73 (0.44–1.24)	0.24
Death/MI/TLR	0.68 (0.46–1.01)	0.054	0.66 (0.42–1.04)	0.07	0.70 (0.44–1.09)	0.11
Death/MI/TVR	0.66 (0.46–0.95)	0.02	0.59 (0.39–0.90)	0.01	0.65 (0.43–0.98)	0.04

Cypher vs. TAXUS
in LM disease intervention

Subgroup Analyses from MAIN-COMPARE Registry

Baseline Characteristics

Variable	Sirolimus Stent (n=669)	Paclitaxel Stent (n=189)	*P*
Demographic characteristics			
Age (years)	62.1±11.2	64.9±10.8	0.002
Male gender	483 (72.2)	133 (70.4)	0.62
Coexisting conditions or other risk factors			
Diabetes			
Any type	211 (31.5)	65 (34.4)	0.46
Insulin-treated	52 (7.8)	18 (9.5)	0.44
Hypertension	346 (51.7)	101 (53.4)	0.68
Hyperlipidemia	197 (29.4)	52 (27.5)	0.61
Current smoker	174 (26.0)	49 (25.9)	0.98

Crude and Adjusted HRs of Clinical Outcomes According to Stent Group (Cpher vs. TAXUS)

	Crude		Multivariable adjusted†		Adjusted for propensity	
Outcome	Hazard Ratio (95% CI)	*P*	Hazard Ratio (95% CI)	*P*	Hazard Ratio (95% CI)	*P*
Death	0.88 (0.49–1.56)	0.66	0.92 (0.47–1.80)	0.82	0.93 (0.50–1.71)	0.81
MI	0.95 (0.54–1.70)	0.87	0.80 (0.43–1.48)	0.47	0.87 (0.48–1.59)	0.66
TVR	1.27 (0.64–2.51)	0.49	1.10 (0.53–2.29)	0.81	1.11 (0.55–2.26)	0.77
Death or MI	0.89 (0.58–1.36)	0.59	0.80 (0.50–1.26)	0.34	0.88 (0.56–1.38)	0.58
Death, MI, or TVR	1.02 (0.71–1.49)	0.90	0.95 (0.64–1.41)	0.79	0.99 (0.67–1.46)	0.95

Conclusion

- In a cohort of patients with unprotected left main coronary artery disease, we found no statistical significant difference in the risk of death and serious composite outcomes (death, Q-wave myocardial infarction, or stroke) between patients receiving stenting and those undergoing CABG.

- However, the rate of target-vessel revascularization was significantly lower in the CABG group than in the PCI group, regardless of stent type.