

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: COMparison of Percutaneous Coronary Angioplasty versus Surgical REvascularization from Multi-Center Registry:

The MAIN-COMPARE Study

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on behalf of the MAIN-COMPARE Study Group



MAIN-COMPARE Study – Disclosure Information

Supported by research grants from
the Korean Society of Interventional Cardiology
& CardioVascular Research Foundation (CVRF)

There was no industry involvement in the design,
conduct, or analysis of the study.



Background

- Based on clinical trials, showing survival benefit of coronary-artery bypass grafting (CABG) over medical therapy, CABG has been regarded as the standard therapy for patients with unprotected LMCA disease.
- 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.



Objective

- Data are limited regarding the long-term safety and effectiveness of PCI with bare-metal stents or drug-eluting stents, as compared with CABG for the treatment of unprotected LMCA disease.
- We therefore compared the long-term outcomes of coronary stenting and CABG among patients with unprotected LMCA disease in Korea, where left main stenting has been a more common clinical practice than in Western countries.



Study Population

- Consecutive patients with unprotected left main coronary disease who received stenting and underwent CABG between January 2000 and June 2006.
- From the second quarter of 2003 (May 2003), DES have been exclusively used as treatment device for PCI at participating centers.



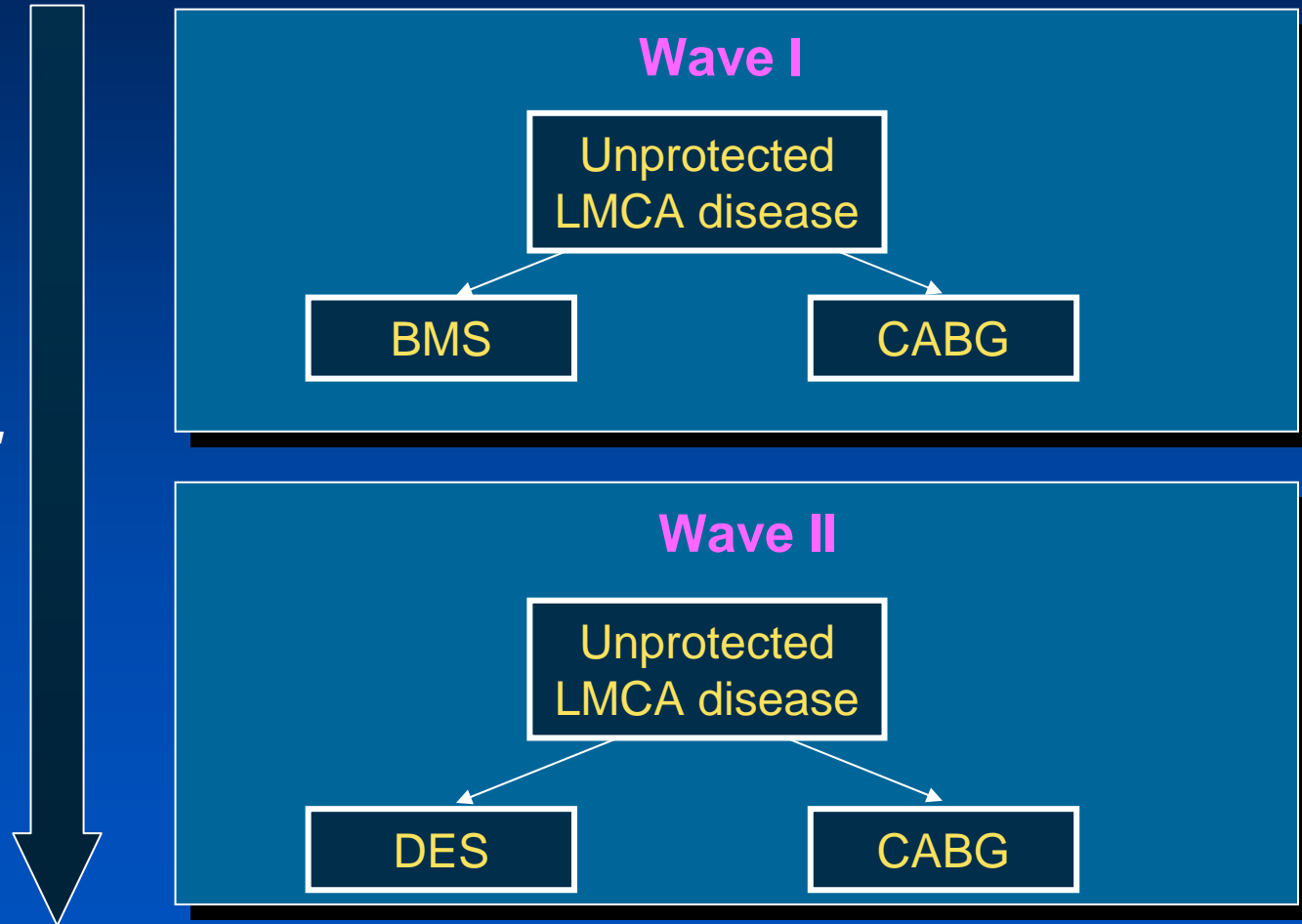
Study Design

MAIN-COMPARE Registry Stenting (BMS vs. DES) vs. CABG

January, 2000

Second quarter,
2003

June, 2006



Participating Centers

- **Co-P.I. :** Seung-Jung Park, MD, PhD, Asan Medical Center
- Ki-Bae Seung, MD, PhD, Kangnam St Mary's Hospital
- **Sponsors:** The Korean Society of Interventional Cardiology
CardioVasucular Research Foundation (CVRF)
- **Investigating centers (12 Major Cardiac Centers)**
 - Asan Medical Center
 - Kangnam St Mary's Hospital
 - Yoido St Mary's Hospital
 - Kyungpook National University Hospital
 - Gachon University Gil Medical Center
 - Seoul National University Hospital
 - Seoul National University Bundang Hospital
 - Samsung Medical Center
 - Ajou University Hospital
 - Yonsei University Medical Center
 - Chonnam National Univeristy Hospital
 - Chung-Nam University Hospital
- **Data analysis and management:** University of Ulsan Medical College, AMC.
- **Local independent event committee:** University of Ulsan Medical College, AMC.



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



Procedures

- Ostial or shaft lesions were attempted with a single stent placement.
- For bifurcation lesions, a single-stent technique was preferred in patients with diminutive or normal-appearing side branches, and two-stent techniques were considered in patients with diseased side branches.
- After the procedure, aspirin was continued indefinitely. Patients treated with bare-metal stents were prescribed clopidogrel or ticlopidine for at least 1 month and patients treated with drug-eluting stents were prescribed clopidogrel for at least 6 months.
- Surgical revascularization was performed using standard techniques. The internal thoracic artery was preferentially utilized for revascularization of the LAD artery.



Databases and Follow-up

- Clinical, angiographic, procedural or operative data, and outcome data were collected using the dedicated internet-based reporting system.
- All outcomes of interest were confirmed by source documentation collected at each hospital and were centrally adjudicated by the local events committee at the University of Ulsan College of Medicine, Asan Medical Center.
- Information about vital status was obtained (through July 15, 2007) from the Korea National Statistical Office using a unique personal identification number.



Databases and Follow-up

- Clinical follow-up was recommended at 1 month, 6 months, and 1 year, and then annually thereafter.
- Angiographic follow-up was routinely recommended for all PCI patients between 6 and 10 months. However, patients with a high risk of procedural complications and without ischemic symptoms or signs, as well as patients who refused, did not undergo routine follow-up angiography.
- For patients undergoing CABG, a recommendation for angiographic follow-up was restricted to patients having ischemic symptoms or signs during follow-up.



Primary Outcome Measures

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



Statistical Analysis

- We compared long-term outcomes between overall PCI and CABG patients.
- Additionally, we compared the outcomes of patients receiving bare-metal or drug-eluting stents with contemporary patients undergoing CABG.
- To reduce treatment selection biases and potential confounding, we performed adjustment for significant differences in the baseline characteristics using propensity-score matching.
- We created a propensity-score-matched pairs (a 1:1 match) using the Greedy 5→1 digit match algorithm.
- For each of concurrent comparisons (Wave 1 and Wave 2), a new propensity score for PCI versus CABG was incorporated for each analysis.



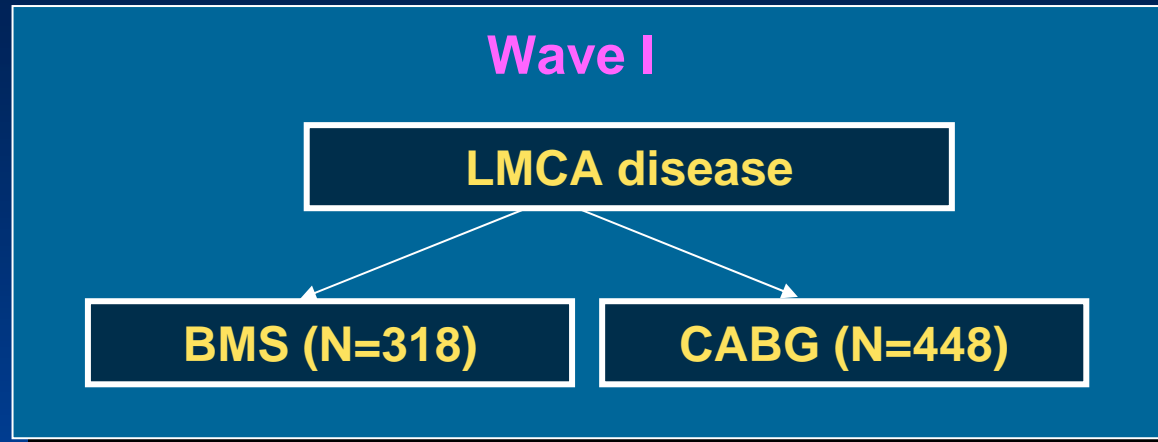
Results



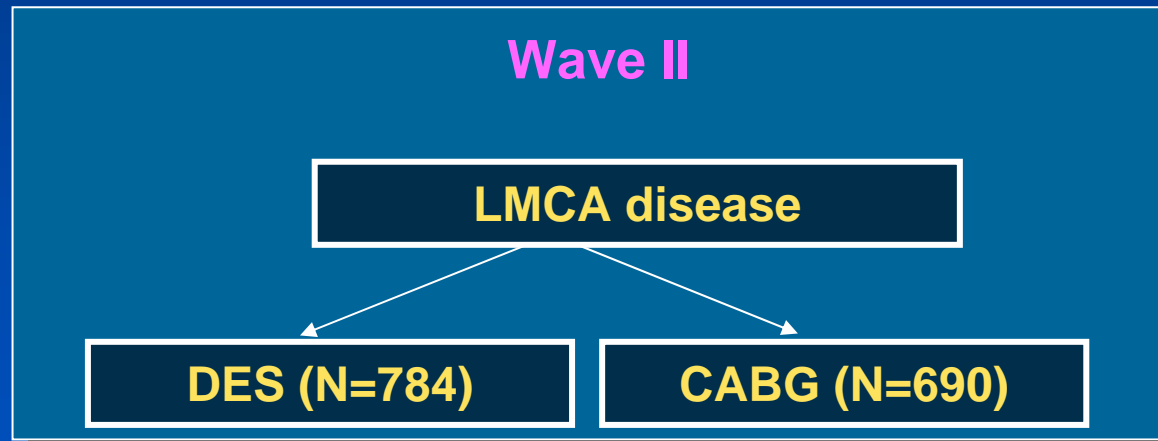
MAIN-COMPARE Study

Stenting (BMS or DES) vs. CABG

January, 2000



Second quarter
(May), 2003



June, 2006

Total (N=2240)

PCI (N=1102)

CABG(N=1138)

PCI patients (N=1102)

Reason for PCI

Physician's preference

- "good candidate for stenting or CABG" 1073 (97%)

Patient's preference/ Patient refused surgery

- "poor candidate for stenting"

Physician refused surgery

29 (3%)

- "poor candidates for CABG"

Age \geq 80 years and poor performance status

8

Limited life expectancy

3

Current malignancy

2

Concurrent severe medical illness

12

Without suitable bypass conduits

4



Procedural Characteristics

Variable	CABG (n = 1138)	PCI (n = 1102)
CABG Group		
Off-pump surgery (%)	42	-
At least one arterial conduit (%)	98	-
IMA to LAD Graft (%) in patients with arterial conduits	98	-
Grafts / Patients (Mean ± SD)	2.9±1.0	-
PCI Group		
Bare-metal stents(%)	-	29
Drug-eluting stents (%)	-	71
Sirolimus stents of DES (%)	-	(77)
Paclitaxel stents of DES (%)	-	(23)
Number of stents at LMCA lesions	-	1.2±0.5
Total length of stents at LMCA (mm)	-	28±21
Average stent diameter at LM site	-	3.5±0.4
Number of stents per patients (LMCA and other vessels)	-	1.9±1.1



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



Baseline Characteristics

Variable	Stents (n=1102)	CABG (n=1138)	P Value
Previous coronary angioplasty	18.1	11.0	<0.001
Previous myocardial infarction	8.1	11.6	0.005
Previous congestive heart failure	2.5	3.3	0.21
Chronic obstructive pulmonary disease	2.0	2.0	0.97
Cerebrovascular disease	7.1	7.3	0.84
Peripheral vascular disease	1.5	5.4	<0.001
Renal failure	2.7	3.0	0.71
Ejection fraction (%)			<0.001
Median	62	60	
Interquartile range	57-67	52-66	



Baseline Characteristics

Variable	Stents (n=1102)	CABG (n=1138)	P Value
Electrocardiographic findings			0.53
Sinus rhythm	97.8	97.1	
Atrial fibrillation	2.0	2.7	
Other	0.2	0.2	
Clinical indication (%)			<0.001
Silent ischemia	3.0	2.2	
Chronic stable angina	32.0	19.9	
Unstable angina	55.2	68.1	
NSTEMI	9.8	9.8	



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)



Baseline Characteristics of Propensity-Matched Patients (542 pairs)

Variable	Stents (n=542)	CABG (n=542)
Demographic characteristics		
Age (yr)		
Median	64	64
Interquartile range	56-71	56-70
Male sex (%)	71.6	71.2
Cardiac or Coexisting conditions (%)		
Diabetes mellitus		
Any diabetes	32.7	33.0
Requiring insulin	7.6	7.9
Hypertension	49.4	50.0
Hyperlipidemia	29.3	30.1
Current smoker	27.7	27.1



Baseline Characteristics of Propensity-Matched Patients (542 pairs)

Variable	Stents (n=542)	CABG (n=542)
Previous coronary angioplasty	14.8	15.1
Previous myocardial infarction	9.0	10.0
Previous congestive heart failure	2.8	3.0
Chronic obstructive pulmonary disease	2.6	2.2
Cerebrovascular disease	7.4	6.6
Peripheral vascular disease	2.0	2.0
Renal failure	3.7	3.9
Ejection fraction (%)		
Median	61	61
Interquartile range	54-66	55-66



Baseline Characteristics of Propensity-Matched Patients (542 pairs)

Variable	Stents (n=542)	CABG (n=542)
Electrocardiographic findings		
Sinus rhythm	97.6	96.7
Atrial fibrillation	2.4	3.1
Other	0.0	0.2
Clinical indication (%)		
Silent ischemia	2.8	2.6
Chronic stable angina	29.2	28.4
Unstable angina	57.4	57.9
NSTEMI	10.7	11.1



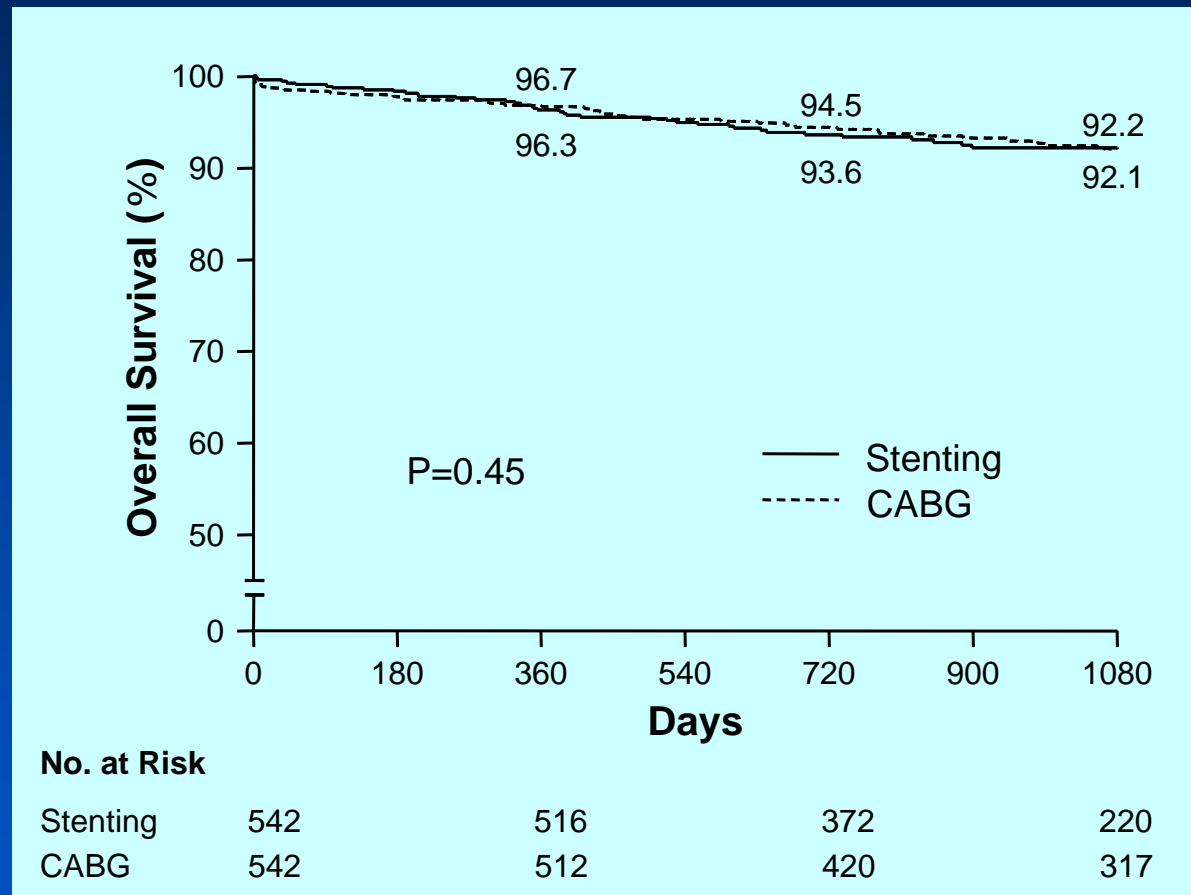
Baseline Characteristics of Propensity-Matched Patients (542 pairs)

Variable	Stents (n=542)	CABG (n=542)
Angiographic characteristics (%)		
Involved location		
Ostium and/or mid-shaft	48.3	47.8
Distal bifurcation	51.7	52.2
Extent of diseased vessel		
Left main only	11.8	11.1
Left main plus single-vessel disease	17.0	16.2
Left main plus double-vessel disease	31.7	33.9
Left main plus triple-vessel disease	39.5	38.7
Right coronary artery disease	53.7	53.7
Restenotic lesion	1.8	1.8



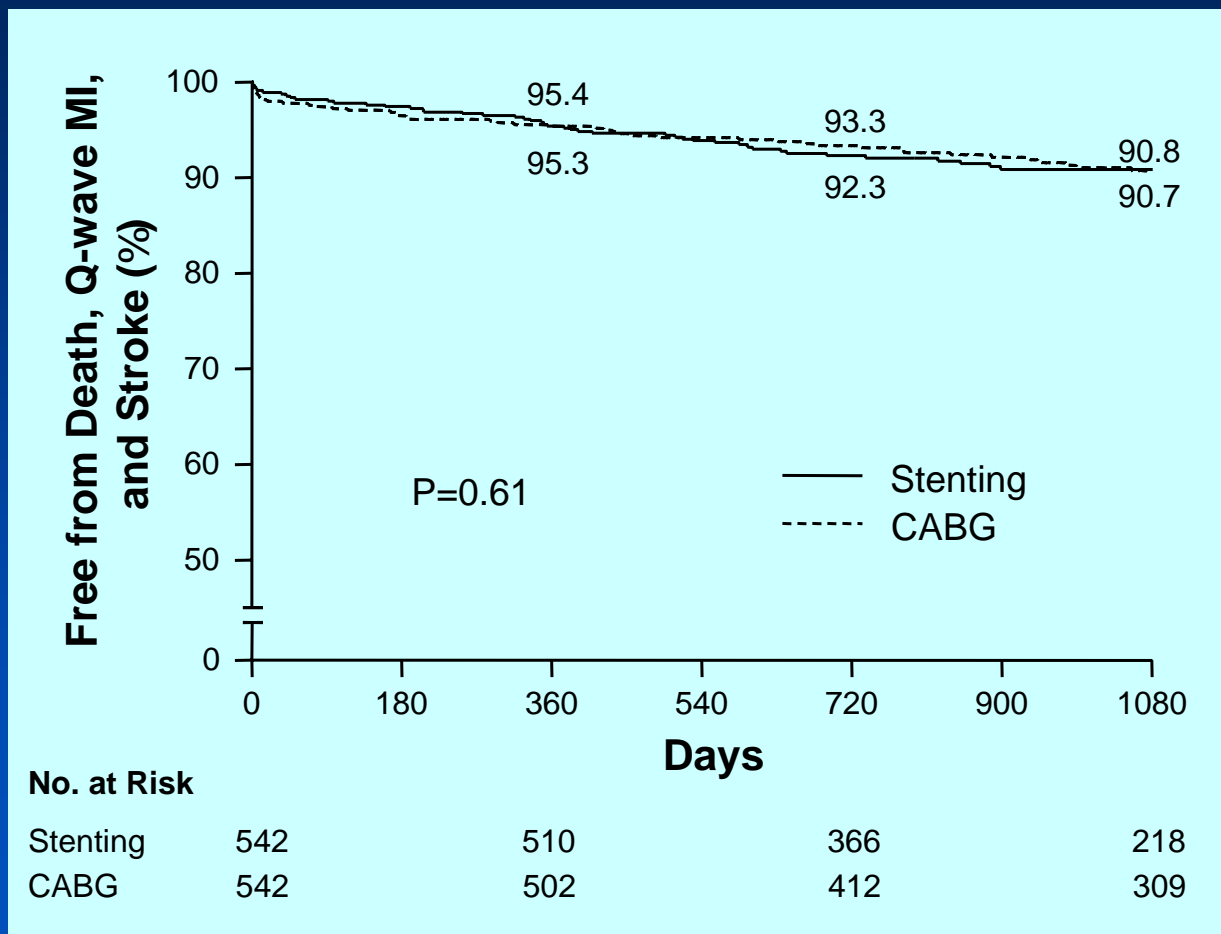
Death

(Overall PCI and CABG matched cohort: 542 pairs)



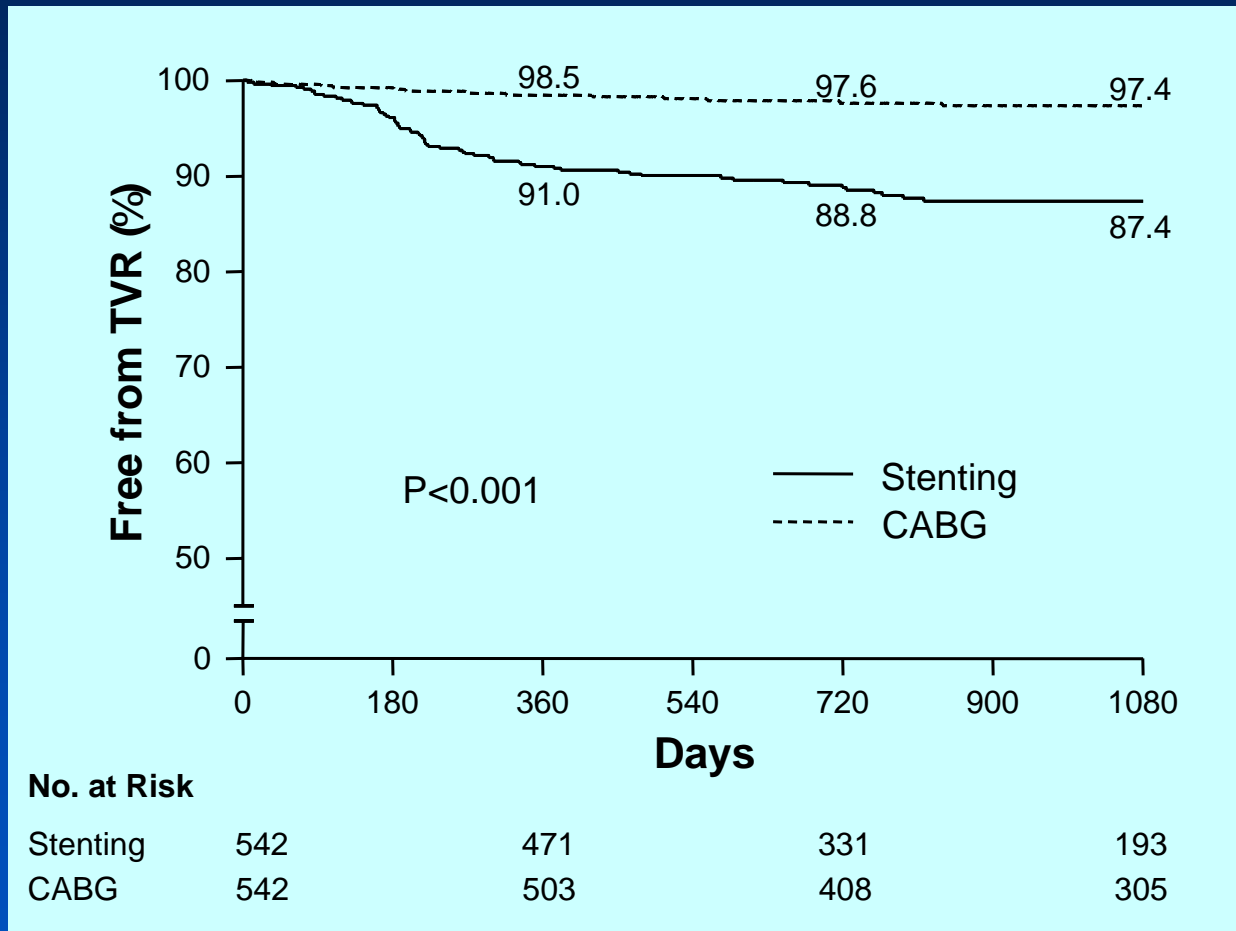
Death, Q-MI, or Stroke

(Overall PCI and CABG matched cohort: 542 pairs)



Target-vessel revascularization

(Overall PCI and CABG matched cohort: 542 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



Baseline Characteristics of Matched Cohort : BMS vs. contemporary CABG (207 pairs)

Variable	BMS (n=207)	CABG (n=207)
Demographic characteristics		
Age (yr)		
Median	61	61
Interquartile range	51-69	53-67
Male sex (%)	72.0	71.0
Cardiac or Coexisting conditions (%)		
Diabetes mellitus		
Any diabetes	26.1	26.6
Requiring insulin	4.8	5.3
Hypertension	44.9	45.4
Hyperlipidemia	27.1	27.1
Current smoker	28.5	28.0



Baseline Characteristics of Matched Cohort : BMS vs. contemporary CABG (207 pairs)

Variable	BMS (n=207)	CABG (n=207)
Previous coronary angioplasty	14.0	14.5
Previous myocardial infarction	9.7	10.6
Previous congestive heart failure	2.4	2.9
Chronic obstructive pulmonary disease	2.4	1.9
Cerebrovascular disease	6.8	6.3
Peripheral vascular disease	1.0	1.0
Renal failure	1.9	2.4
Ejection fraction (%)		
Median	61	61
Interquartile range	57-67	56-66



Baseline Characteristics of Matched Cohort : BMS vs. contemporary CABG (207 pairs)

Variable	BMS (n=207)	CABG (n=207)
Electrocardiographic findings		
Sinus rhythm	97.6	97.1
Atrial fibrillation	2.4	2.9
Other	0.0	0.0
Clinical indication (%)		
Silent ischemia	2.9	3.4
Chronic stable angina	16.6	16.4
Unstable angina	69.6	69.6
NSTEMI	11.1	10.6



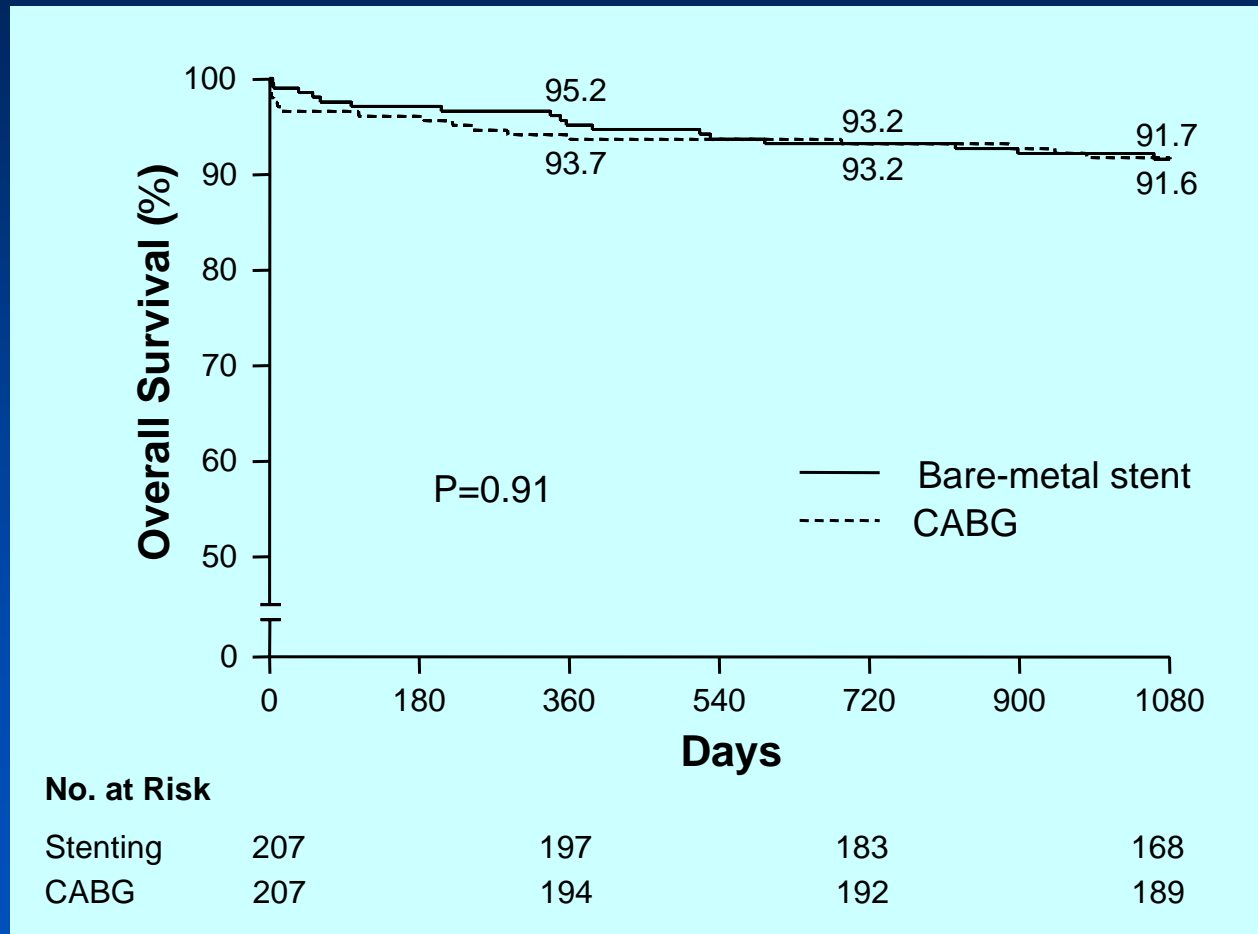
Baseline Characteristics of Matched Cohort : BMS vs. contemporary CABG (207 pairs)

Variable	BMS (n=207)	CABG (n=207)
Angiographic characteristics (%)		
Involved location		
Ostium and/or mid-shaft	61.8	61.4
Distal bifurcation	38.2	38.6
Extent of diseased vessel		
Left main only	21.3	21.3
Left main plus single-vessel disease	29.0	29.0
Left main plus double-vessel disease	33.8	33.8
Left main plus triple-vessel disease	15.9	15.9
Right coronary artery disease	29.5	29.5
Restenotic lesion	1.9	2.4



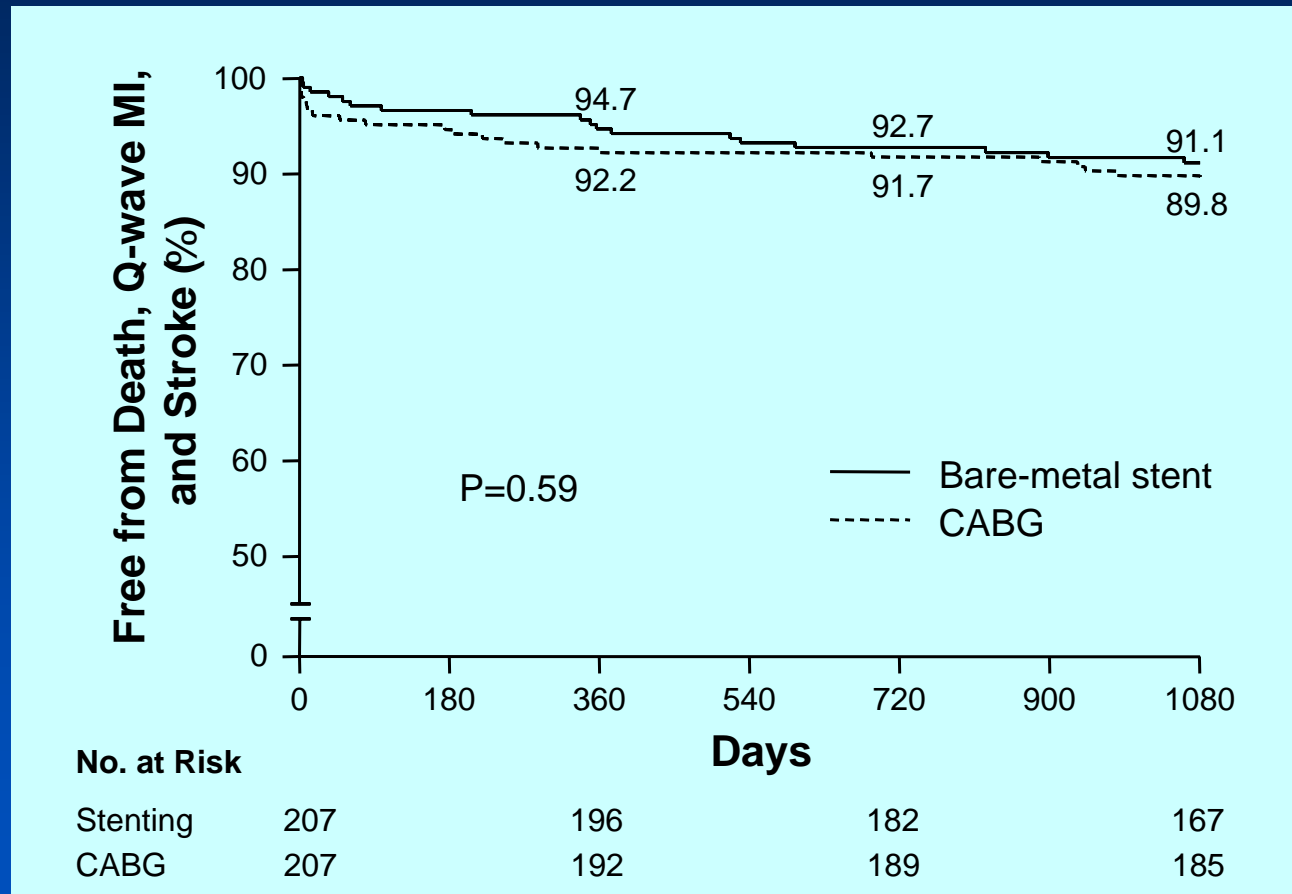
Death

(BMS and contemporary CABG matched cohort: 207pairs)



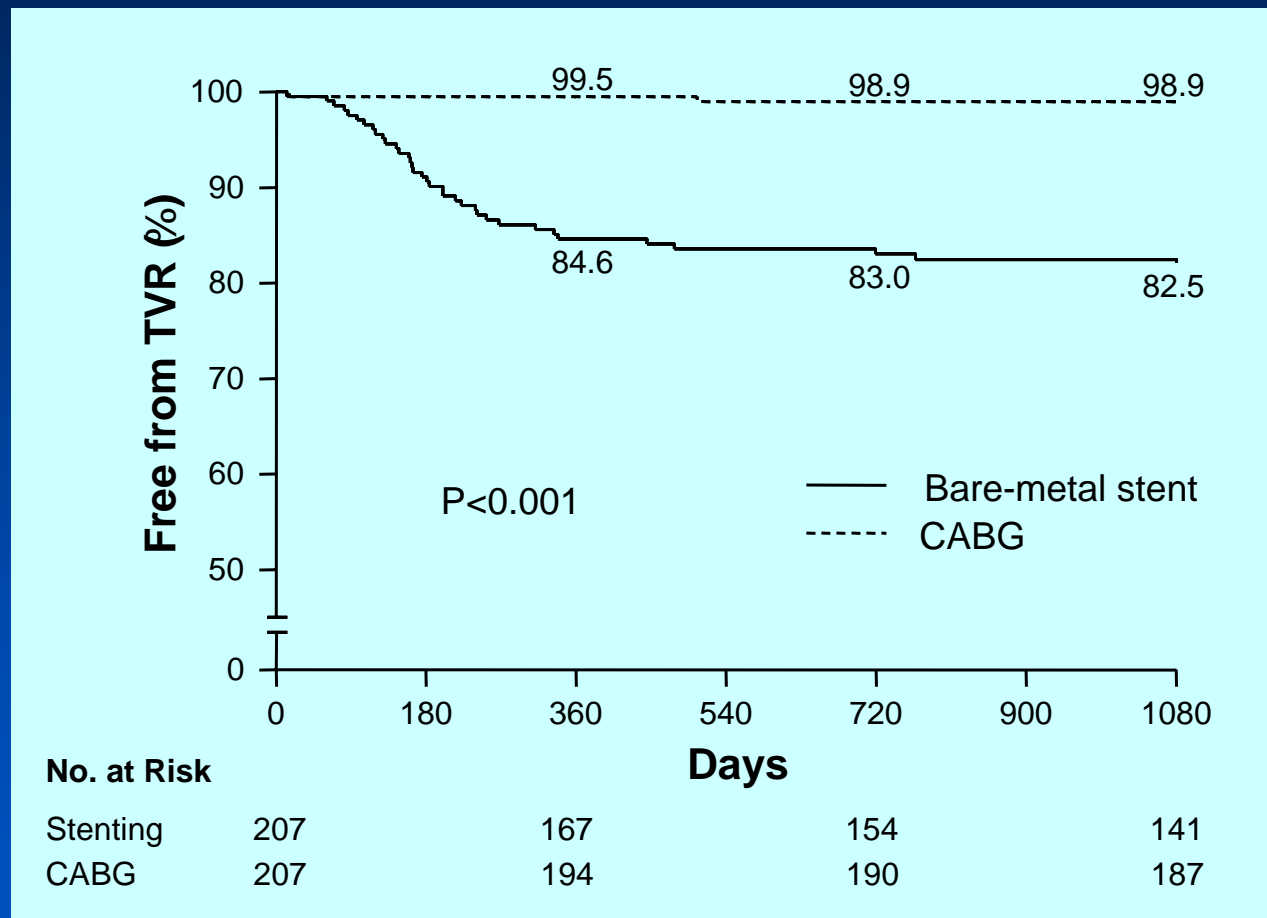
Death, Q-MI, or Stroke

(BMS and contemporary CABG matched cohort: 207pairs)



Target-vessel revascularization

(BMS and contemporary CABG matched cohort: 207pairs)



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



Baseline Characteristics of Matched Cohort : DES vs. contemporary CABG (396 pairs)

Variable	DES (n=396)	CABG (n=396)
Demographic characteristics		
Age (yr)		
Median	66	66
Interquartile range	57-72	58-70
Male sex (%)	71.5	71.7
Cardiac or Coexisting conditions (%)		
Diabetes mellitus		
Any diabetes	36.1	36.9
Requiring insulin	10.1	10.9
Hypertension	52.3	53.0
Hyperlipidemia	32.6	33.6
Current smoker	26.3	25.5



Baseline Characteristics of Matched Cohort : DES vs. contemporary CABG (396 pairs)

Variable	DES (n=396)	CABG (n=396)
Previous coronary angioplasty	15.4	15.4
Previous myocardial infarction	8.8	9.3
Previous congestive heart failure	3.0	3.3
Chronic obstructive pulmonary disease	2.8	2.5
Cerebrovascular disease	8.1	7.3
Peripheral vascular disease	2.5	3.3
Renal failure	5.3	4.8
Ejection fraction (%)		
Median	60	60
Interquartile range	55-66	56-66



Baseline Characteristics of Matched Cohort : DES vs. contemporary CABG (396 pairs)

Variable	DES (n=396)	CABG (n=396)
Electrocardiographic findings		
Sinus rhythm	97.7	96.5
Atrial fibrillation	2.3	3.0
Other	0.0	0.5
Clinical indication (%)		
Silent ischemia	2.3	2.8
Chronic stable angina	30.1	28.8
Unstable angina	57.8	57.8
NSTEMI	9.8	10.6



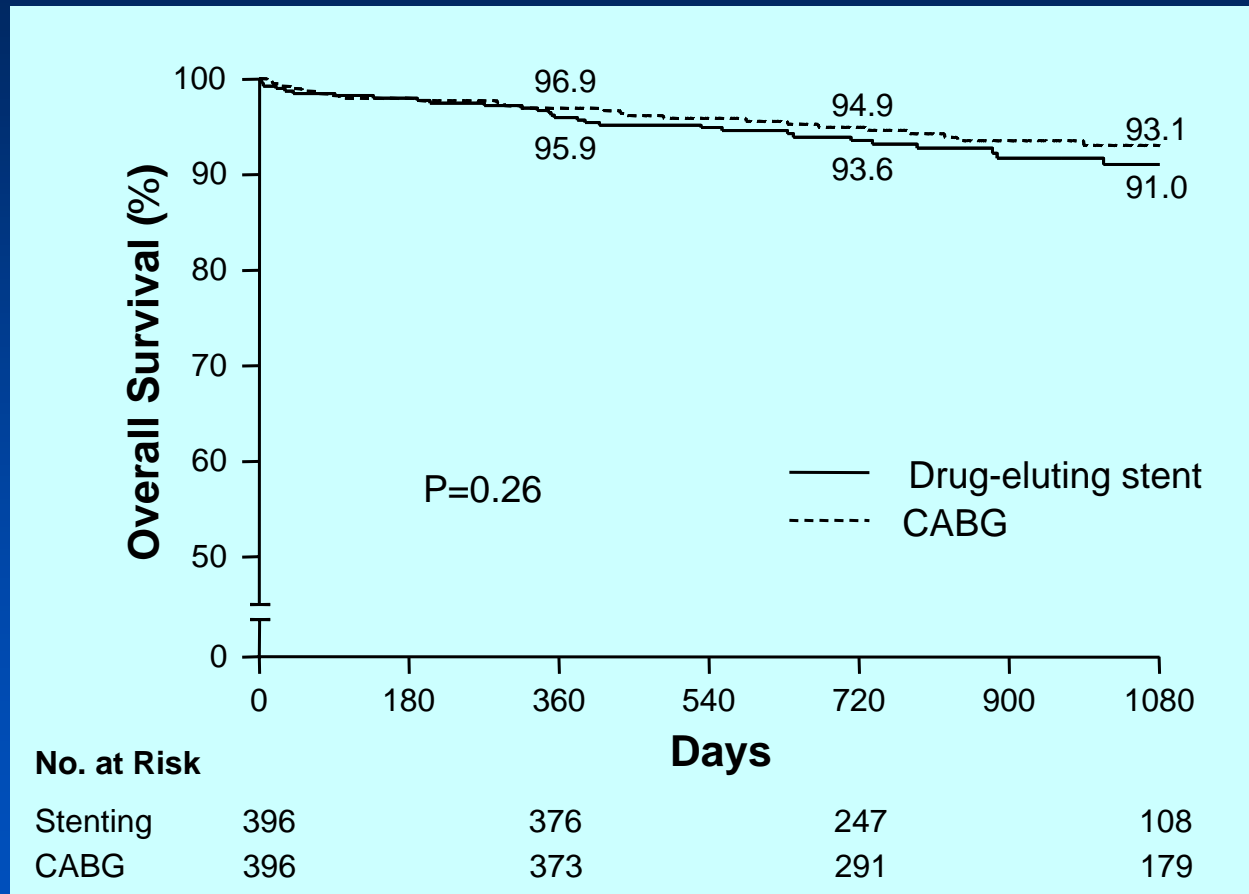
Baseline Characteristics of Matched Cohort : DES vs. contemporary CABG (396 pairs)

Variable	DES (n=396)	CABG (n=396)
Angiographic characteristics (%)		
Involved location		
Ostium and/or mid-shaft	39.4	38.9
Distal bifurcation	60.6	61.1
Extent of diseased vessel		
Left main only	5.8	5.8
Left main plus single-vessel disease	12.4	11.6
Left main plus double-vessel disease	29.0	29.5
Left main plus triple-vessel disease	52.8	53.0
Right coronary artery disease	65.9	66.9
Restenotic lesion	1.8	1.3



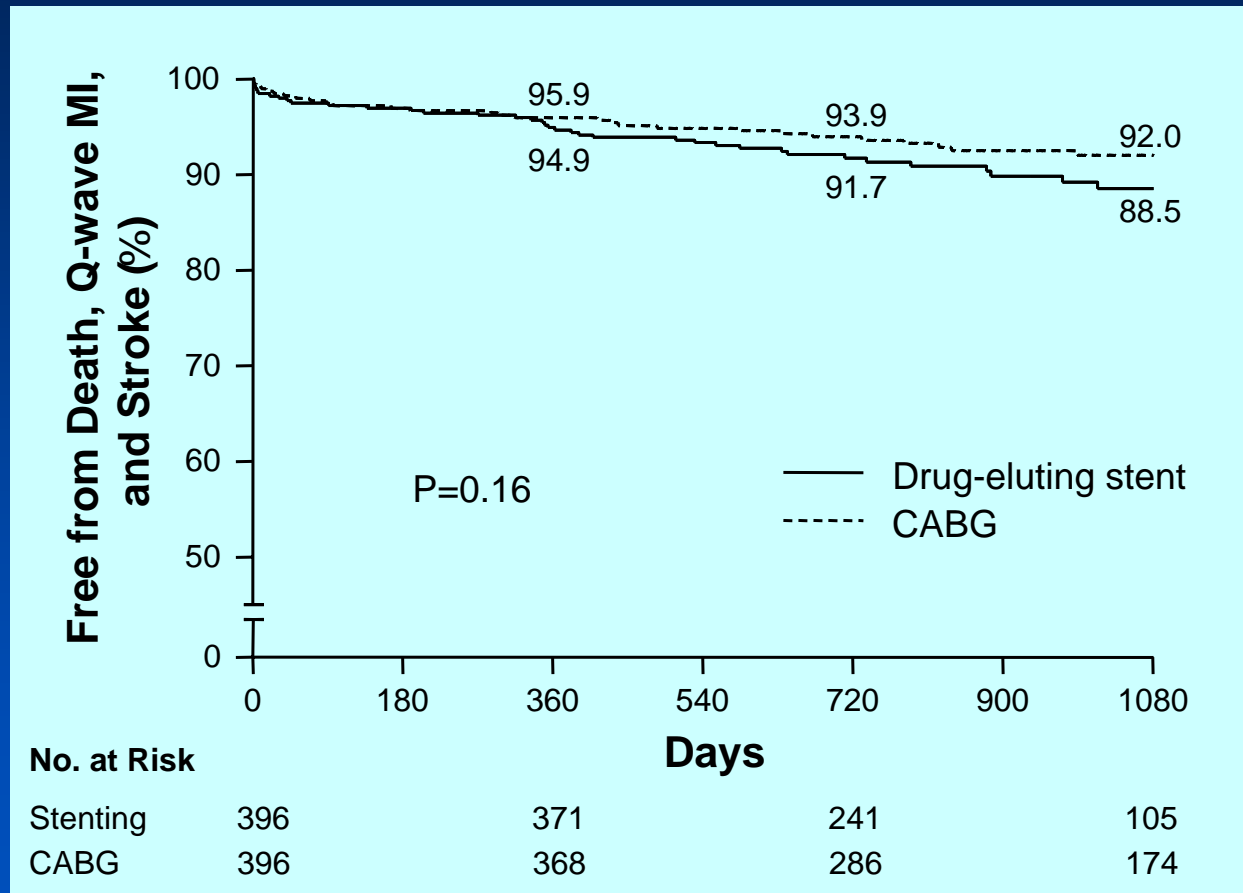
Death

(DES and contemporary CABG matched cohort: 396 pairs)



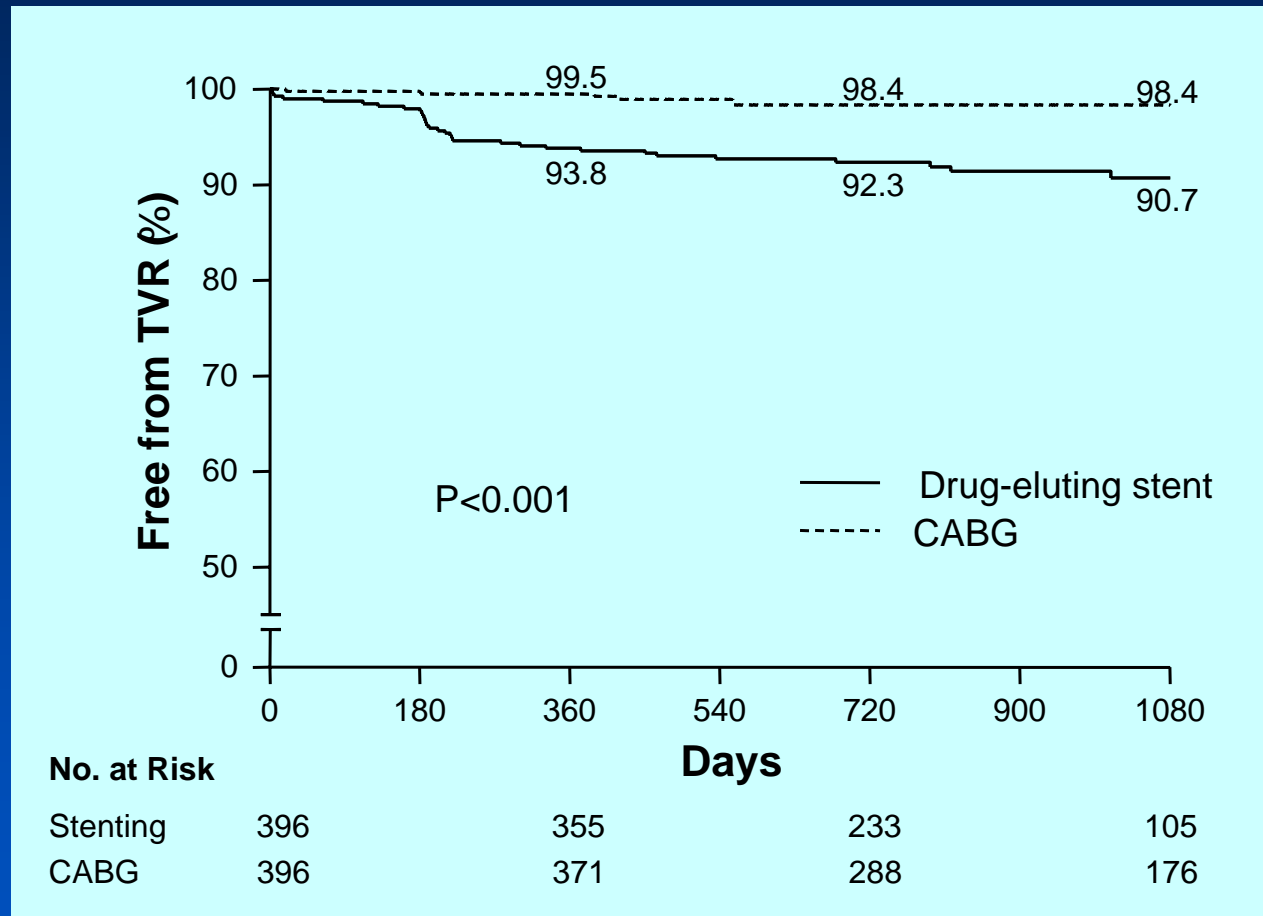
Death, Q-MI, or Stroke

(DES and contemporary CABG matched cohort: 396 pairs)



Target-vessel revascularization

(DES and contemporary CABG matched cohort: 396 pairs)



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



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.
- These results were consistent when comparing bare-metal stents or drug-eluting stents with concurrent CABG controls, although a statistically nonsignificant trend was noted toward higher risk in the analysis for drug-eluting stents.
- However, the rate of target-vessel revascularization was significantly lower in the CABG group than in the PCI group, regardless of stent type.



Concerns about a statistically non-significant trend of higher mortality in DES group compare to CABG

- This study is observational data. In DES group, more than 80% of left main disease combined with 2-3 vessel disease, 65% of concomitant RCA disease, and only 5.8% of patients had LM only disease. These angiographic findings was quite similar with those of unadjusted surgery group. This comparison would not be realistic in real world practice if as a randomized fashion.



Concerns about a statistically non-significant trend of higher mortality in DES group compare to CABG

- We did not analyze the baseline angiographic morphologic findings in detail how much suitable for PCI.
- That means, just for mechanical matching with propensity score from registry data, patients with “poor candidate for surgery” and “poor candidate for stenting” should be included in DES group. It might be related with nonsignificant trend of higher mortality in DES group.



A blue-tinted landscape of rolling hills and mountains covered in dense evergreen forests. The text "Thank You !!" is overlaid in the center in a dark blue, sans-serif font.

Thank You !!

