

# **Drug-Eluting Stent Implantation for Unprotected Left Main Coronary Artery Stenosis in Patients at High Surgical Risk**

**Experience of Columbia University Hospital**

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# Background

- Previous studies have demonstrated the feasibility of PCI for unprotected left main coronary artery (LMCA) stenosis.
- DES has improved outcomes of PCI for such a lesion compared with BMS.
- However, the initial and long-term outcomes depend strongly on the patient clinical presentation and lesion characteristics.
- In particular, for patients at high surgical risks, the periprocedural and long-term outcomes have not been elucidated.

# Purpose

- **This study was aimed to evaluate the initial and long-term clinical outcomes of patients with unprotected LMCA stenosis undergoing PCI with DES at Columbia University Medical Center, who were at high risk for PCI.**



# Inclusion Criteria

- **Patients with a de novo  $\geq 50\%$  diameter stenosis of unprotected LMCA were treated with DES.**
- **Primary angioplasty for acute ST elevation MI was excluded.**
- **The LMCA was considered unprotected if there were no patent coronary artery bypass grafts to the left anterior descending artery or left circumflex artery.**
- **DES was implanted when PCI was considered the sole alternative for the treatment of LMCA stenosis, because these patients were at high surgical risk for CABG and/or refused CABG despite their physician's recommendation.**

# Patients

**Columbia PCI Registry between Oct 2004 to Apr 2006  
to Undergo PCI With N=3,214 pts**

**Unprotected LMCA  
N= 63 pts (1.9%)**

**Others  
N=3,151 pts (98.1%)**

- **Study endpoints:  
Death, cardiac death, stent thrombosis, MI, TLR, TVR,  
and MACE,**

# Definition of End Points

- MI was divided to Q-wave MI and non-Q-wave MI (an increase in the CK-MB level  $> 3 \times$  UNL without Q wave)
- Procedural success was defined as the achievement of a post-procedural DS at the LMCA  $< 50\%$  in the presence of TIMI flow grade 3, without death, Q-wave MI, or TLR during hospitalization
- TLR was defined as any repeat PCI or bypass surgery in the treated segment or within the adjacent 5 mm.
- TVR was defined as any repeat revascularization in LAD or LCX, as well as in the target segment.
- MACE was defined as any death, any MI, or TLR.
- Stent thrombosis included both the definite and probable ST defined by ARC.



# Demographics

Variable	63 patients
Age (yrs)	67.3 ± 14.3
Male	46 (73%)
History of smoking	32 (51%)
Hypertension	50 (79%)
Hyperlipidemia	50 (79%)
Diabetes mellitus	19 (30%)
Peripheral vascular disease	16 (25%)
History of CVA	6 (10%)
History of MI	17 (27%)
Previous PCI	32 (51%)
History of malignancy	7 (11%)



# Demographics

Variable	63 patients
History of nephropathy	9 (14%)
History of valve replacement	2 (3%)
Left ventricular EF (%)	50.4 ± 13.5
Acute MI within 2 weeks	3 (5%)
Unstable angina	36 (57%)
History of congestive heart failure	11 (18%)
EuroSCORE	6.9 ± 4.9
EuroSCORE > 6	35 (56%)
Parsonnet score	21.0 ± 11.8
Parsonnet score > 15	39 (62%)





# Angiographic Findings

**Variable** **63 patients**

## Coronary disease outside LMCA

**LAD** **33 (62%)**

**LCX** **29 (46%)**

**RCA** **30 (48%)**

**RI** **8 (13%)**

**Multi-vessel ( $\geq 2$ ) disease except LMCA** **31 (49%)**

**Three vessel disease except LMCA** **14 (22%)**

**Number of diseased vessels except LMCA** **1.5  $\pm$  1.0**

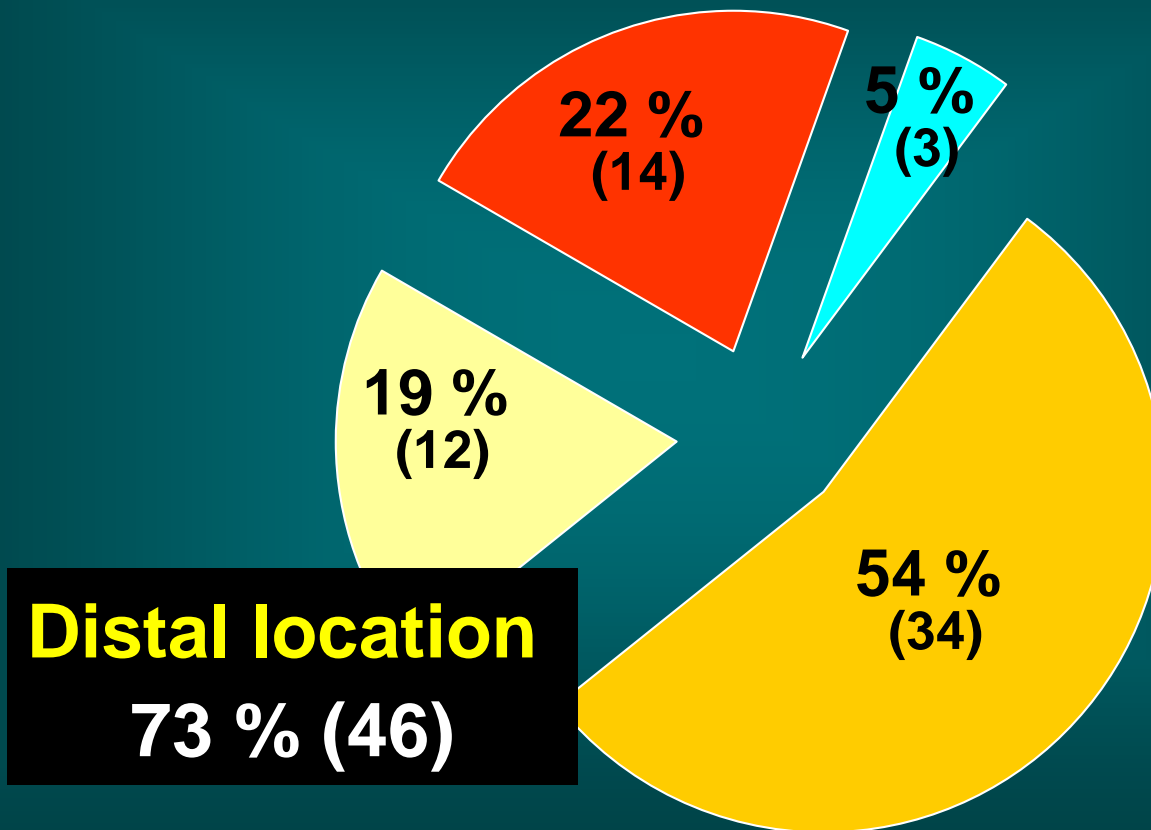
# Angiographic Findings

Variable	63 patients
CTO in the RCA	4 (6%)
Any CTO in major epicardial coronary	8 (13%)
TIMI flow grade	
3	56 (89%)
2	5 (8%)
1 or 0	2 (3%)
Eccentric lesion	23 (34%)
Thrombus	2 (3%)
Moderate to severe calcium	29 (46%)
Moderate to severe tortuosity	4 (6%)



# Lesion Location

■ Ostium    ■ Shaft    ■ Bifurcation    ■ Diffuse

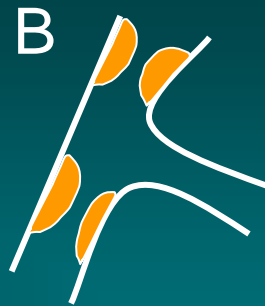


# Bifurcation Types (Medina Classification)

Total 46 bifurcations



19 (41%)



25 (54%)



1 (2%)



0



1 (2%)



0



0



# QCA Before PCI

	Main vessel	Side branch
Interpolated reference, mm	$3.33 \pm 0.65$	$2.96 \pm 0.47$
Proximal reference, mm	$3.90 \pm 0.58$	-
Distal reference, mm	$2.87 \pm 0.65$	$2.67 \pm 0.55$
Lesion length, mm	$22.8 \pm 20.1$	$6.3 \pm 4.8$
MLD, mm	$1.34 \pm 0.61$	$1.96 \pm 0.69$
Diameter stenosis, %	$60.1 \pm 16.3$	$33.2 \pm 21.1$



# Procedural Findings

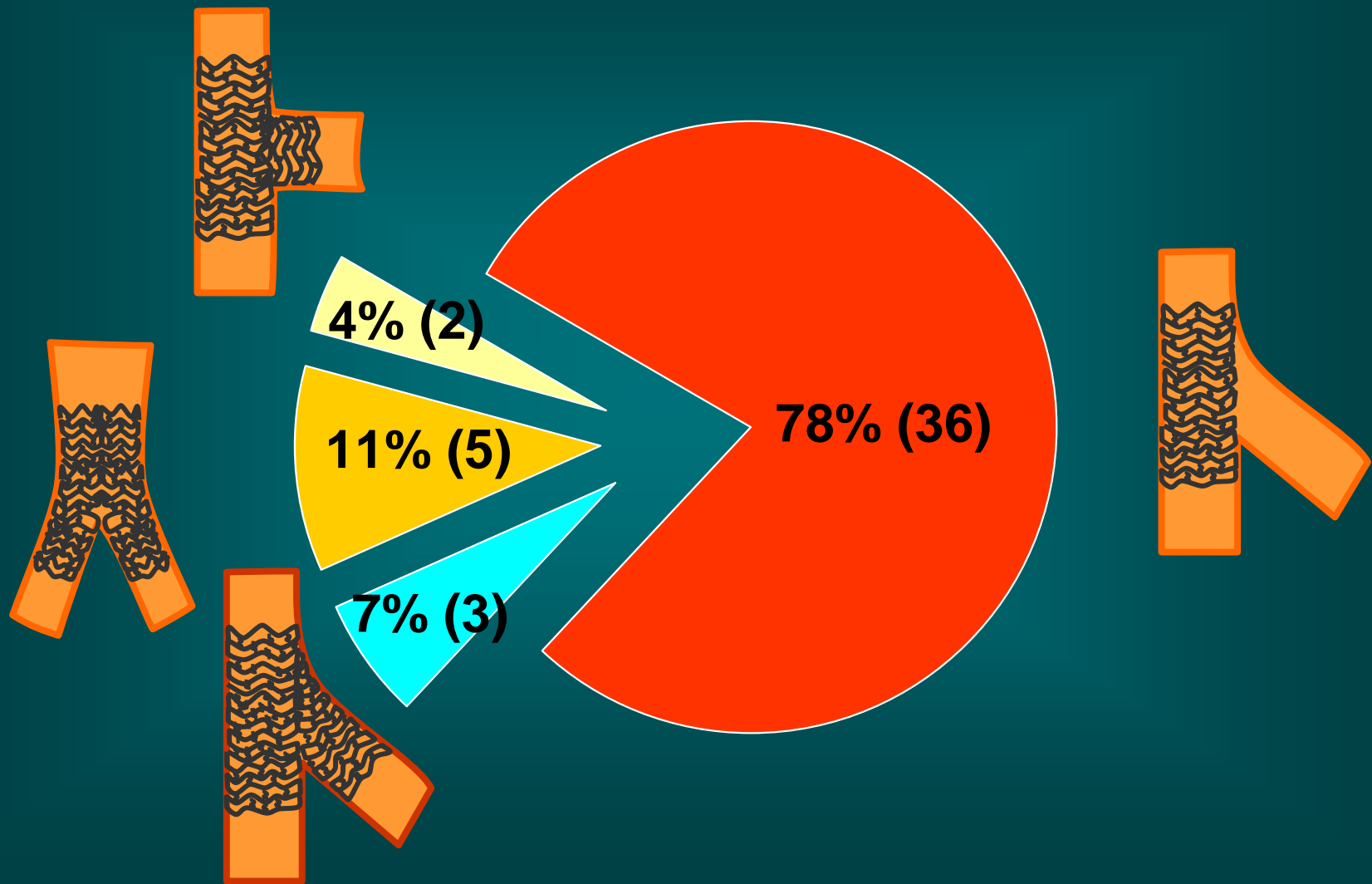
Variable	63 patients
Urgent PCI within 24 hours post-procedure	6 (10%)
Number of used DESs at left main	1.7 ± 1.1
Number of total used stents	2.9 ± 1.7
Intra-aortic balloon pump	4 (6%)
Glycoprotein IIb/IIIa inhibitor	8 (13%)
Bivalirudin	56 (89%)

# Procedural Findings

Variable	63 patients
IVUS guidance	51 (81%)
Cutting balloon angioplasty	1 (2%)
Directional coronary atherectomy	0
Rotabating atherectomy	1 (2%)
Cypher	52 (83%)
Taxus	11 (17%)
Final kissing balloon technique	27 (43%)
Direct stenting	28 (44%)

# Stenting Technique for 46 Bifurcations





■ Crossover ■ Cruch ■ Kissing ■ T stenting





# Bifurcation Stenting Technique

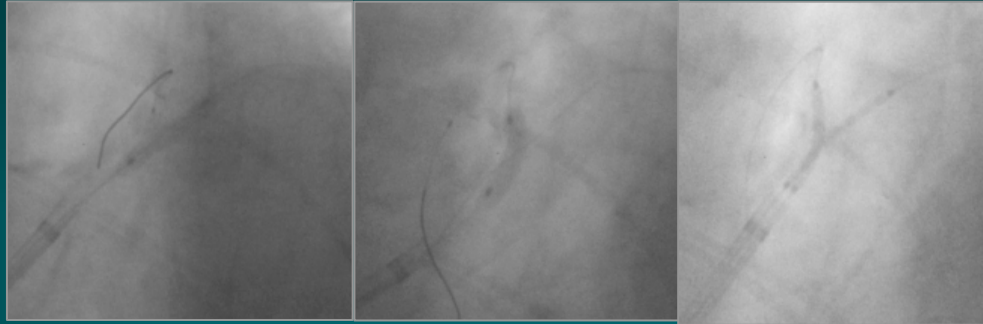
## According to Bifurcation Type

		Stenting in MV	Stenting in MV and SB
Type A (N=19)		58 % (11)	42 % (8)
Type C (N=25)		92 % (23)	8 % (2)
Type D (N=1)		100 % (1)	0
Type F (N=1)		100 % (1)	0

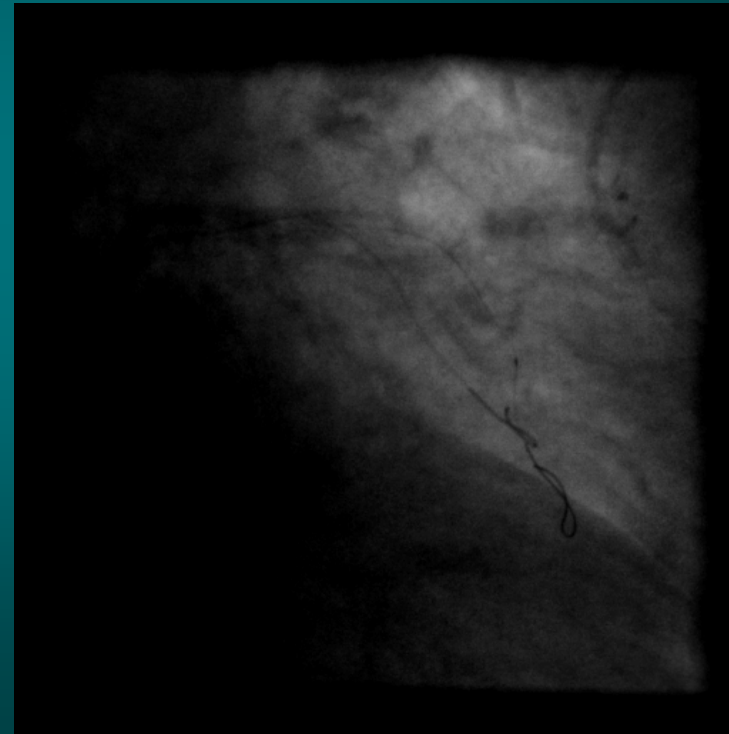


# Kissing Stenting with Two Cyphers after Predilation

Predilation  
and Stenting



3.5 X 23 mm  
& 3.0 X 18 mm



# QCA After PCI

	Main vessel	Side branch
Interpolated reference, mm	$3.15 \pm 0.62$	$2.96 \pm 0.46$
<b>In-segment</b>		
MLD, mm	$2.64 \pm 0.58$	$2.30 \pm 0.54$
DS, %	$16.2 \pm 10.3$	$21.8 \pm 16.2$
<b>In-stent</b>		
MLD, mm	$3.02 \pm 0.56$	$2.64 \pm 0.35$
DS, %	$13.8 \pm 9.9$	$15.2 \pm 7.2$
Acute gain, mm	$1.30 \pm 0.61$	$0.34 \pm 0.73$
Stent length, mm	$25.0 \pm 21.8$	$15.9 \pm 3.5$



# In-Hospital Outcomes

Variable	Overall (N=63)	Non-bifur. (N=17)	Bifur. (N=46)
Proc. success	100 %		
Death	0 %		
Q MI	0 %		
Non-Q MI	10 % (6)	6 % (1) *	11 % (5)
TLR	0 %		
TVR	0 %		

\* p=NS

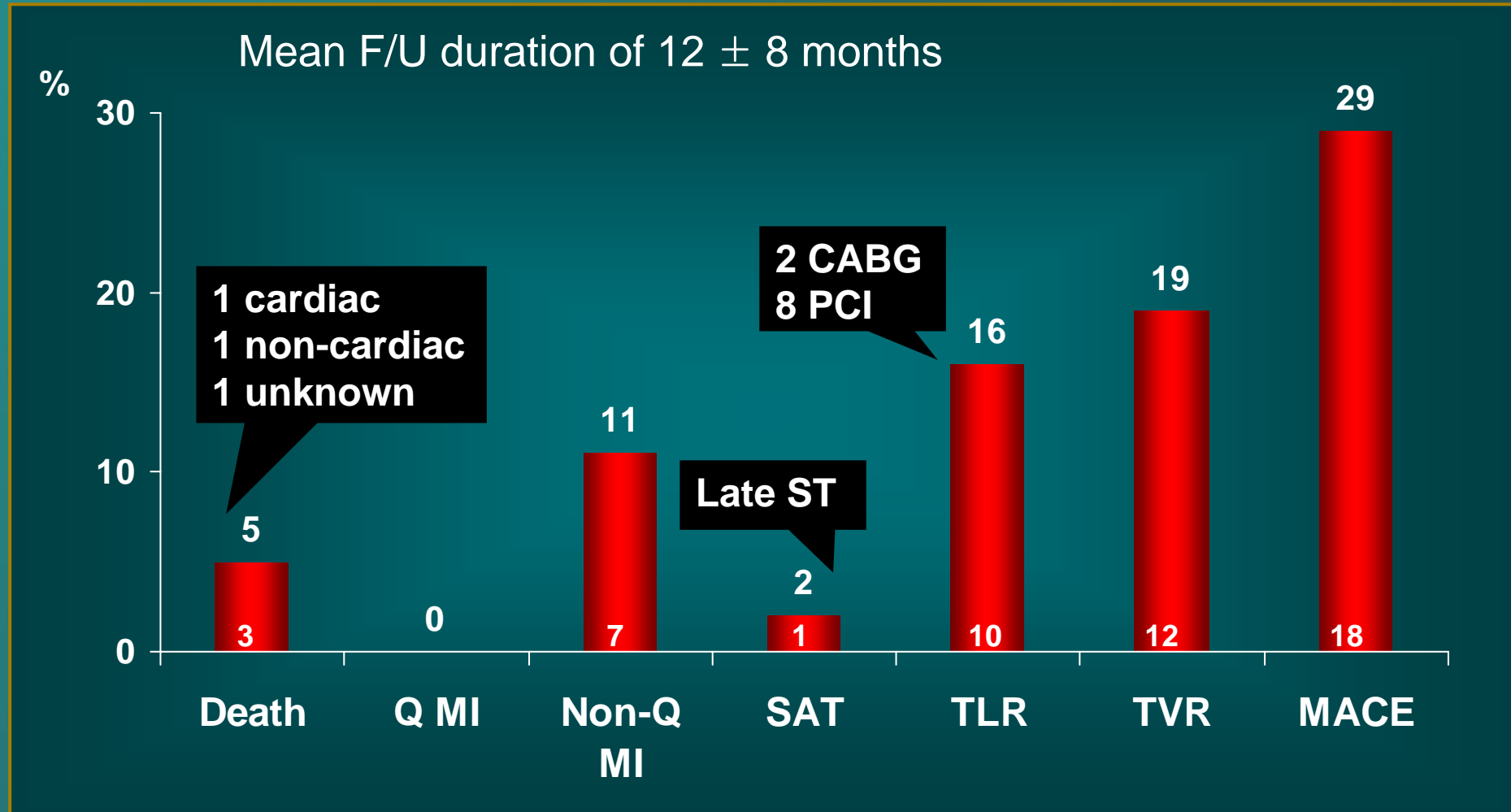


# QCA at Follow-Up

	Main vessel	Side branch
<b>Follow-up</b>	<b>33 patients (52%)</b>	
<b>Interpolated reference, mm</b>	<b>3.21 ± 0.67</b>	<b>3.02 ± 0.54</b>
<b>In-segment</b>		
<b>MLD, mm</b>	<b>2.39 ± 0.75</b>	<b>1.88 ± 0.68</b>
<b>DS, %</b>	<b>24.5 ± 21.6</b>	<b>36.2 ± 22.0</b>
<b>Late loss, mm</b>	<b>0.30 ± 0.70</b>	<b>0.39 ± 0.60</b>
<b>In-stent</b>		
<b>MLD, mm</b>	<b>2.59 ± 0.82</b>	-
<b>DS, %</b>	<b>25.6 ± 20.3</b>	-
<b>Late loss, mm</b>	<b>0.37 ± 0.76</b>	-
<b>Restenosis</b>	<b>7 (21%)</b>	<b>10 (30%)</b>
<b>Overall restenosis</b>	<b>12 (36%)</b>	

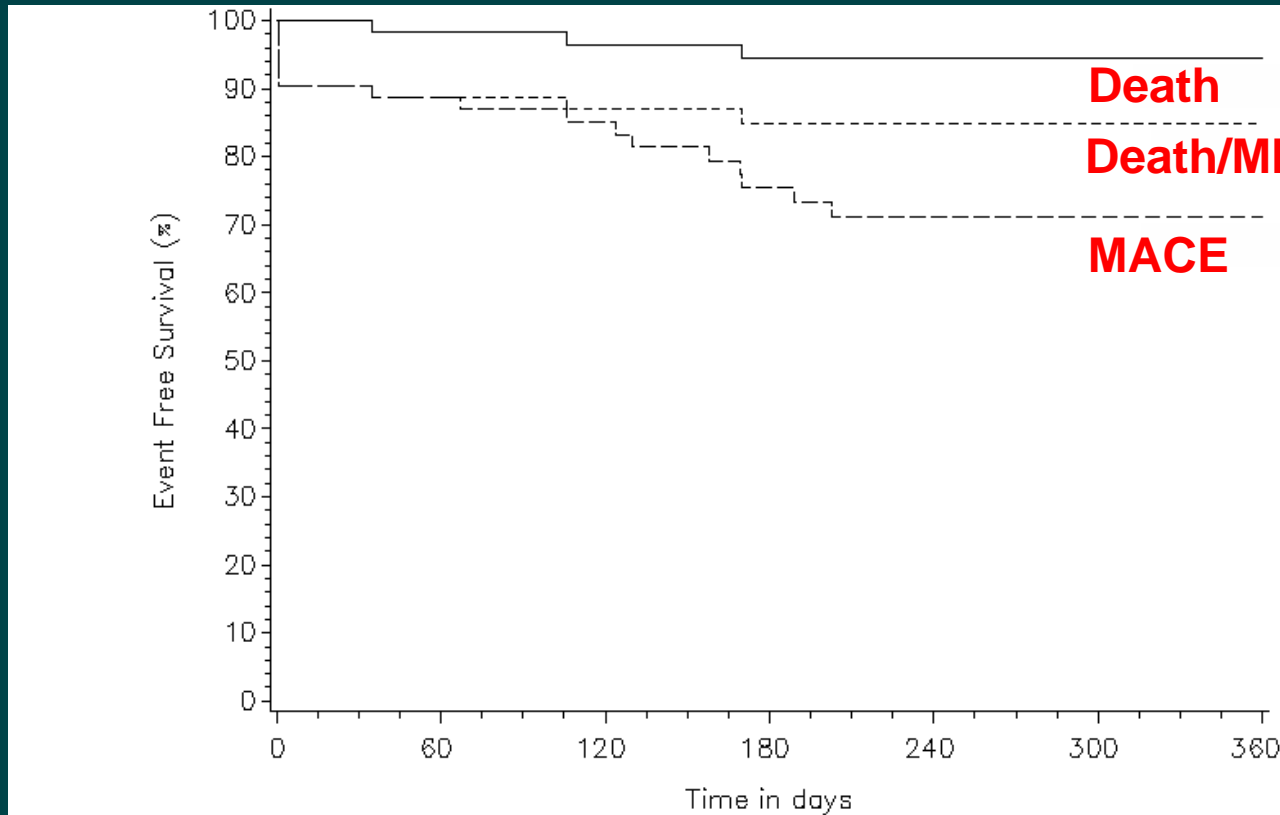


# Long-term Outcomes



\* One patient had non-Q MI due to late ST at 36 days post-procedure and was successfully treated with PCI for ST at the LCX Cypher.

# K-M Survival Curves at 1 year



**94.5±3.1%**

**84.9±4.7%**

**71.2±6.2%**

Number at risk

Death	63	56	52	46	38	33	28
Death/MI	63	50	46	42	35	30	26
Death/MI/TLR	63	50	45	37	28	25	21



# Predictors of Adverse Outcomes

## Using Cox Regression Model

	Hazard ratio	95% CI	p
<b>Death/MI</b>			
Age	1.13	1.03 to 1.23	0.0081
Use of bivalirudin	0.21	0.05 to 0.97	0.0462
Male	0.15	0.03 to 0.68	0.0139
<b>Death/MI/TLR (MACE)</b>			
Male	0.11	0.03 to 0.40	0.0008
Unstable angina	5.37	1.44 to 20.13	0.0126
Age	1.08	1.01 to 1.16	0.0192
Direct stenting	0.28	0.09 to 0.87	0.0275
Bifurcation involvement	12.90	1.36 to 122.45	0.0259





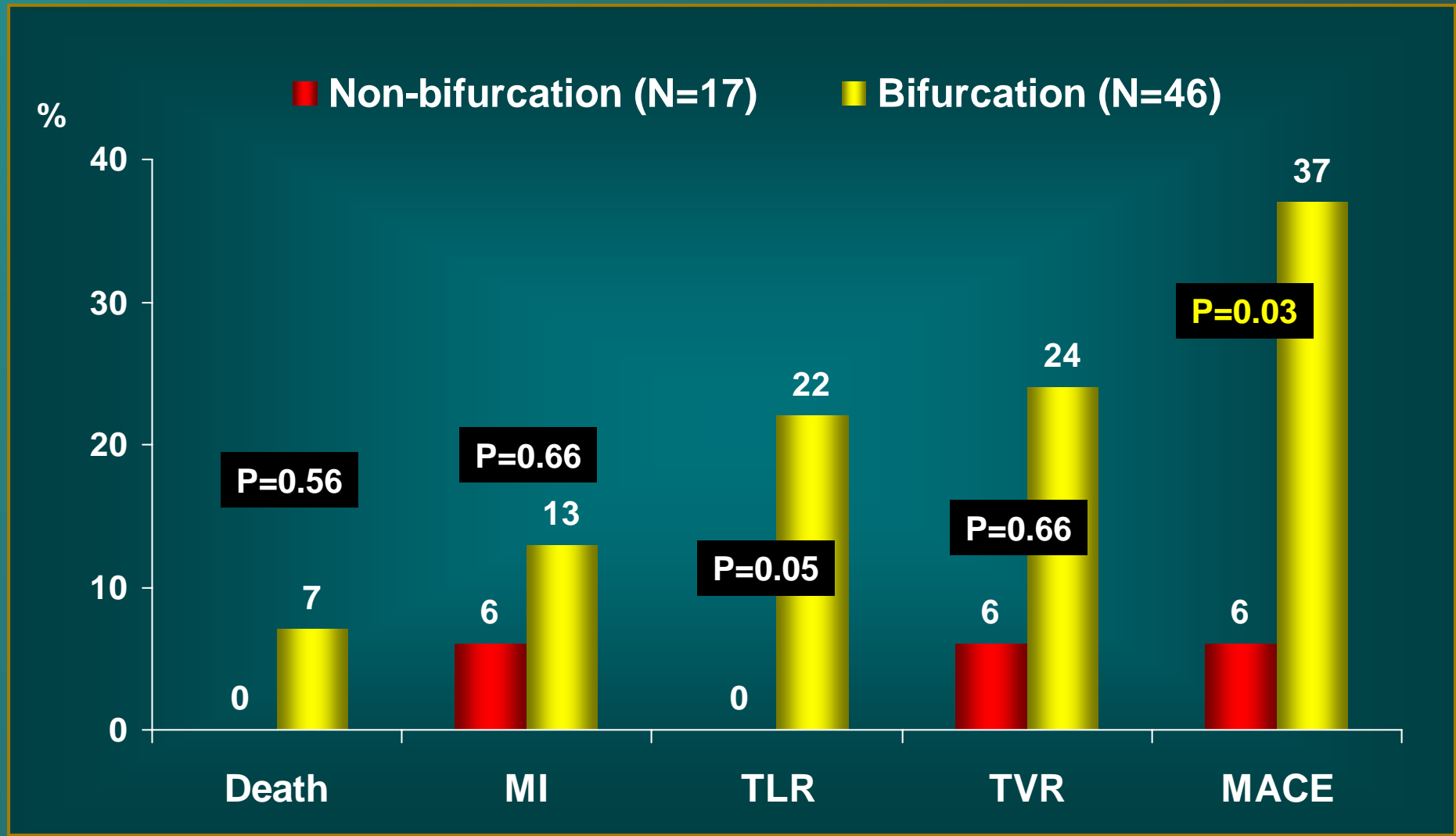
# Bifurcation vs. Non-bifurcation

	Bifurcation (N=46)	Non-bifurcation (N=17)	p *
Final kissing	25 (54%)	2 (12%)	0.003
Side branch stenting	10 (22%)	0	0.050
Cypher	35 (76%)	17 (100%)	0.027
Direct stenting	14 (30%)	14 (82%)	<0.001
LMCA stent number	2.0 (1.0, 2.3)	1.0 (1.0, 1.0)	<0.001
Lesion length	23.2 (12.3, 39.0)	7.6 (4.7, 11.6)	<0.001
Stent length	28.4 (13.0, 39.4)	7.8 (6.0, 11.8)	<0.001
Post-procedure MLD	2.50 (2.07, 2.86)	3.17 (2.81, 3.28)	<0.001
Post-procedure DS	16.1 (9.2, 24.1)	10.0 (5.4, 16.3)	<0.001
EuroSCORE	6.0 (2.8, 10.0)	6.0 (4.0, 9.0)	0.858

\* Fisher exact for categorical and Wilcoxon-sum for continuous variables

# Long-Term Outcomes

## Bifurcation vs. Non-bifurcation



## Comparison of Recent DES Studies For LM stenting using DES

	Milan (Chieffo)	Seoul (Park)	Rotterd. (Valgimigli)	California (Price)	Columbia
<b>Number</b>	85	102	95	50	63
<b>Age</b>	63	60	64	69	68
<b>EF</b>	51	60	41	-	50
<b>Bifurcation</b>	69	72	65	94	75
<b>EuroSCORE</b>	4.4	2.9	-	-	6.9
<b>In-hospital mortality</b>	0%	0%	10% (30d)	0%	0%
<b>Long-term outcomes (months)</b>	6m	12	16	13	12
<b>Cardiac mortality</b>	4%	0%	8%	2%	2%
<b>Stent thrombosis</b>	1%	0%	0%	0%	2%
<b>TVR</b>	<b>19%</b>	<b>2%</b>	<b>6%</b>	<b>38%</b>	<b>19%</b>

# Summary

- In the PCI registry of Columbia University Hospital, elective PCI with DES for unprotected LMCA was performed in 2% of patients.
- Since PCI for unprotected LMCA stenosis was reserved to patients at high surgical risk, the study population consisted of very complex patients with a high incidence of comorbidities.
- Nevertheless, peri-procedural outcome was excellent.
- Simple stenting strategy, in which single stent placement crossover LCX, was mostly preferred.
- Over the 1-year follow, the incidence of death, death/MI or stent thrombosis was low.
- The TLR (16%) was also acceptably low, but it was predominantly performed in bifurcation stenosis.

# Conclusions

- **In this small single center series of patients at high surgical risk who had unprotected LMCA stenosis and were treated with DES, we observed:**
  - **Favorable early (in-hospital) and long-term outcomes**
  - **And the outcomes were comparable to those of previous studies for relatively low risk population**
- **Single stent treatment whenever possible should be the preferred strategy to improve outcomes.**
- **However, further studies to evaluate optimal stenting technique or dedicated bifurcated stents for bifurcation stenosis need to be performed.**
- **Moreover, a large randomized trial with comparison to the CABG should be performed to further assess safety and efficacy of DES in such complex coronary lesions.**

