

Safety and Effectiveness of Sirolimus Eluting Stent for Left Main Coronary Artery Stenosis

Seung-Jung Park, MD, PhD, FACC

Asan Medical Center, Seoul, Korea

Background

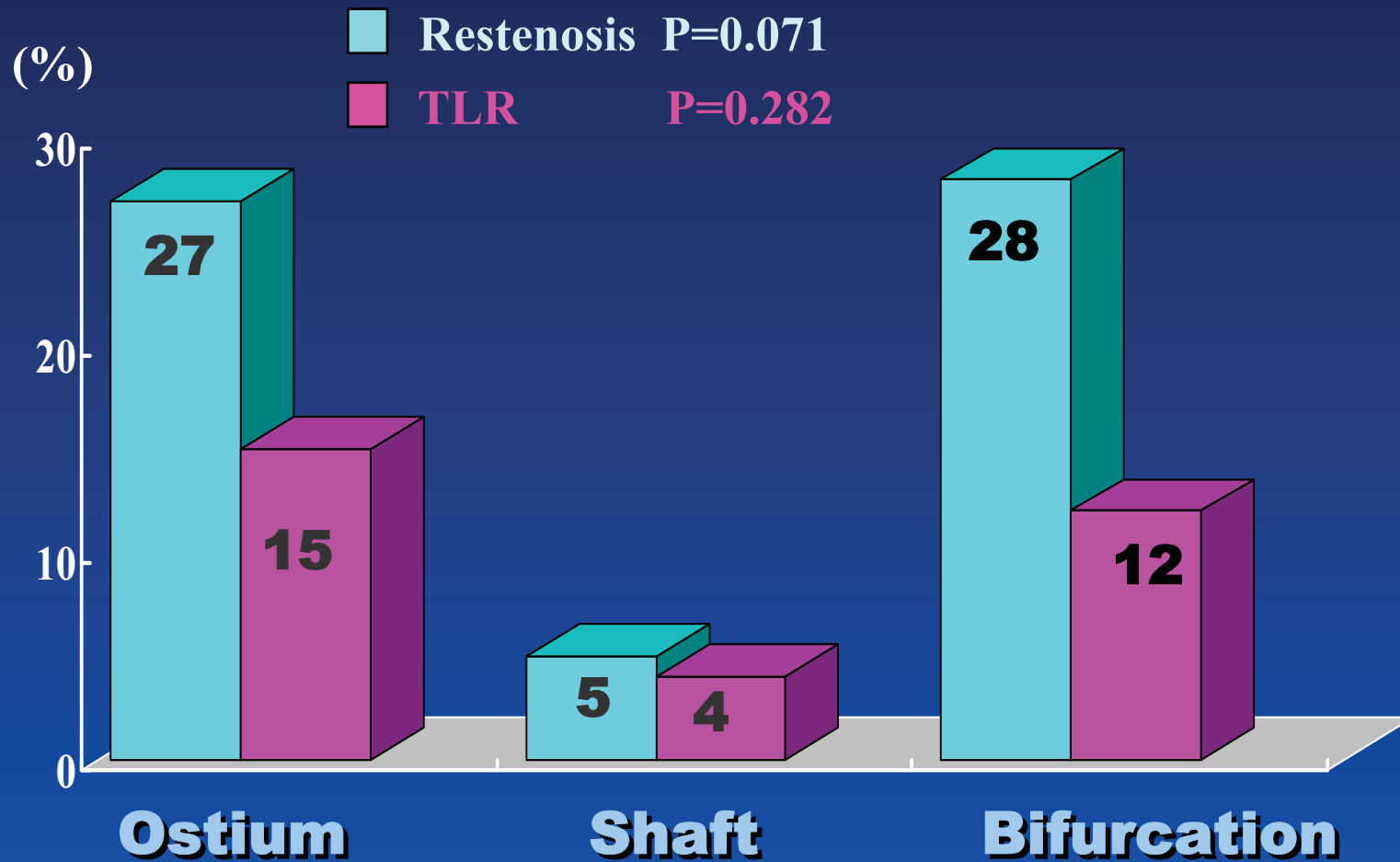
- Several trials have reported the safety and feasibility of stenting for left main coronary artery (LMCA) stenosis with favorable procedural and long-term outcomes in the era of bare metal stents(BMS).
- However, there was very limited data in the era of drug eluting stents

Background

- And, the restenosis remains the major problem limiting the late outcome after PCI in the era of BMS.

Unprotected Left Main Stenting

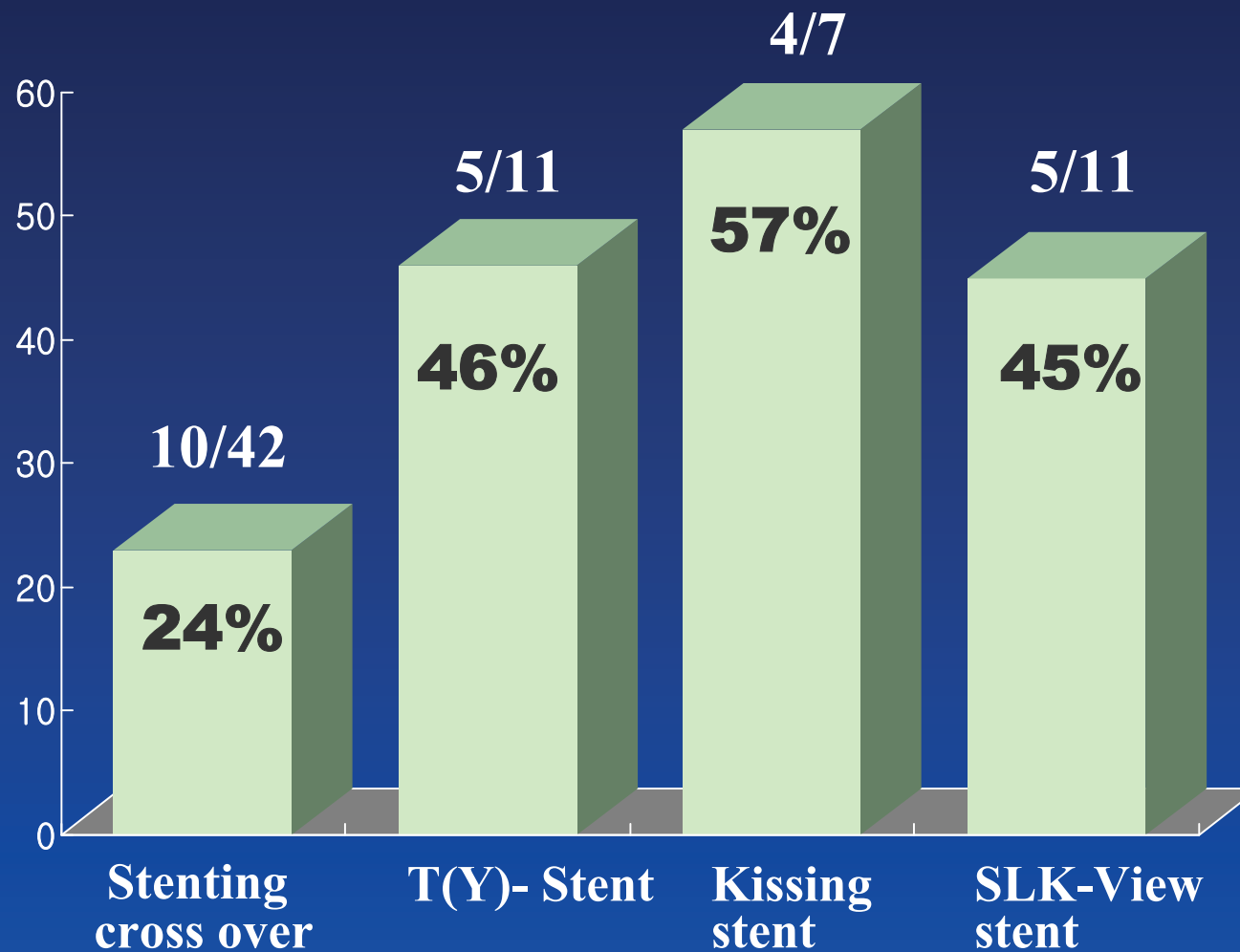
Restenosis Rate & TLR at overall



Park SJ, Am J Cardiol 2003;

6 month Angiographic Restenosis

According to different strategy



Park SJ, Am J Cardiol 2003;

Objective

- The present study was performed to evaluate the safety and efficacy of the sirolimus eluting stent (Cypher™ stent; Cordis) for unprotected LMCA narrowing in selected patients.

Inclusion Criteria

- The patients who had unprotected LMCA stenosis (diameter stenosis $\geq 50\%$) with normal LV function and refused surgery were included.

Exclusion Criteria

- Contraindication to antiplatelet agents
- Bailout stenting
- Primary angioplasty in acute myocardial infarction
- Left ventricular dysfunction (ejection fraction $<40\%$)
- An inability to follow the protocol

Follow Up

- Follow-up information was obtained by regular outpatient evaluation and by telephone contact.
- Angiographic follow-up is being routinely performed at six months or earlier if a patient shows symptoms of recurrence.

Subjects

February 19 ~ October 4

Total 74 patients with normal LV function who underwent elective stenting for unprotected LMCA stenosis were included.

Unprotected Left Main Stenting

Antiplatelet Regimens

Triple combination

Aspirin indefinitely

Cilostazol 100 mg BID for 1 month

Clopidogrel 75 mg QD for 6 month

* Use of Reopro : 3 cases (7 %) at operator's discretion

Baseline Demographics

n=74

Age,yrs	58 ± 12 (33-88)
Men	54 (73 %)
Diabetes	20 (27 %)
Hypertension	23 (31 %)
Current smoker	18 (24 %)
Hypercholesterolemia	4 (6 %)
LV ejection fraction (%)	58 ± 9

Unprotected Left Main Stenting

Lesion Location

Total 74 patients

Proximal involvement *	17 (23 %)
------------------------	-----------

Distal involvement	57 (77 %)
--------------------	-----------

* Include 2 case confined to LMCA shaft

Baseline Demographics

	Proximal (n=17)	Distal (n=57)
Prior PCI	5 (29%)	14 (25%)
Clinical diagnosis		
Stable angina	5 (29%)	18 (31%)
Unstable angina	9 (53%)	34 (60%)
Acute MI	3 (18%)	5 (9%)

Lesion Characteristics

	Proximal (n=17)	Distal (n=57)
In-stent restenosis	1 (7%)	9 (21%)
Diseased vessel		
1 vessel	4 (24%)	20 (35%)
2 vessel	4 (24%)	14 (25%)
3 vessel	5 (29%)	9 (16%)
LMCA only	4 (24%)	14 (25%)

Lesion Characteristics

	Proximal (n=17)	Distal (n=57)
Proximal reference (mm)		4.0 ± 0.6
Distal reference (mm)	3.6 ± 0.6	2.9 ± 0.5 *
Lesion length (mm)	7.6 ± 2.7	22.4 ± 14.4
Minimal lumen diameter (mm)	1.6 ± 0.5	1.2 ± 0.5
Diameter stenosis (%)	55.9 ± 9.6	63.7 ± 15.6

* Reference vessel size of LAD

Used Cypher Stents

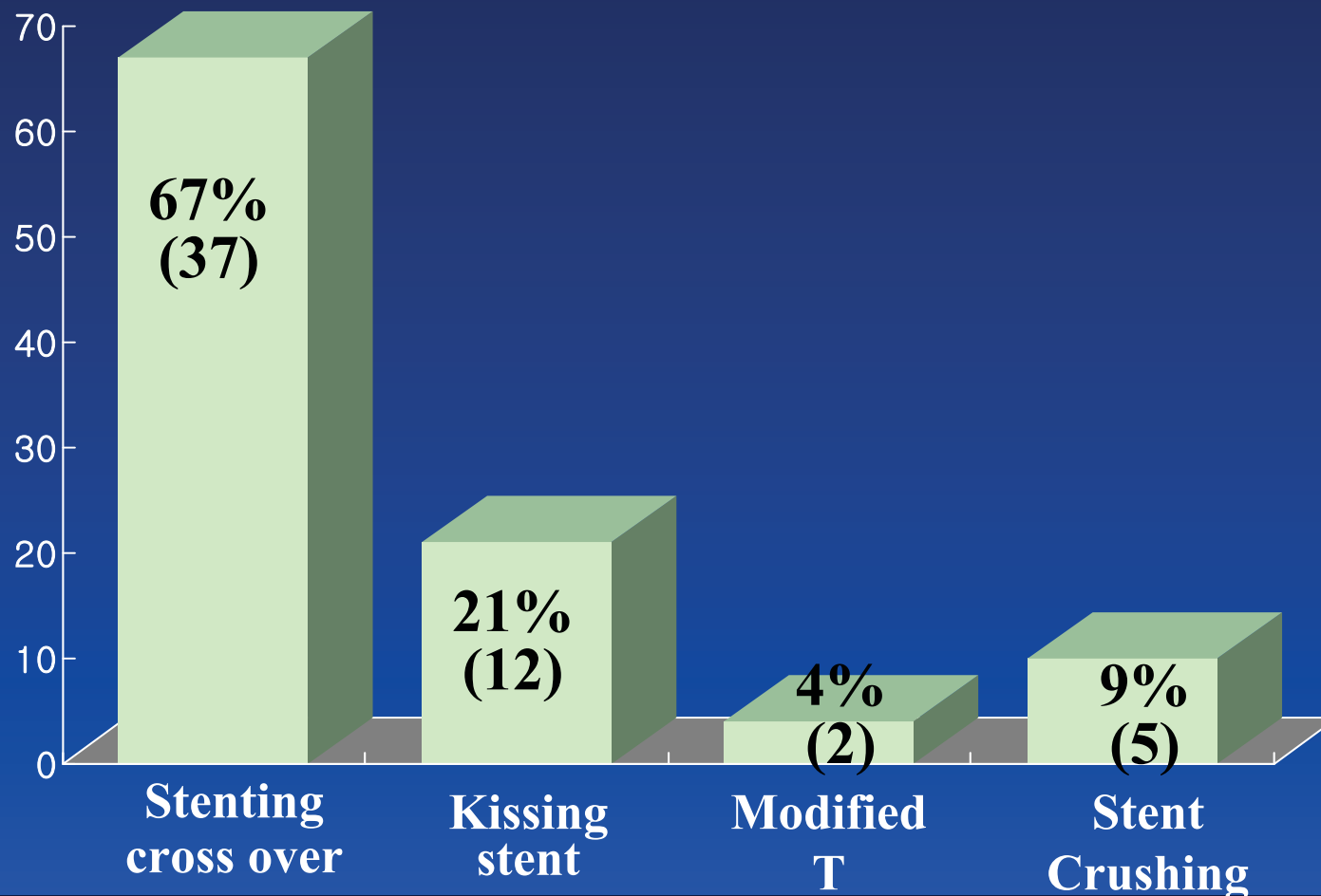
	Proximal (n=17)	Distal (n=57)
Used No. of stents	17	89
Single stent	17 (100%)	32 (56%)
Two stents	0	19 (33%)
≥ Three stents	0	6 (11%)
Used stent size		
2.5 mm	0	3 (3%)
2.75 mm	0	6 (7%)
3.0 mm	6 (35%)	35 (39%)
3.5 mm	11 (65%)	45 (51%)

Stenting Procedure

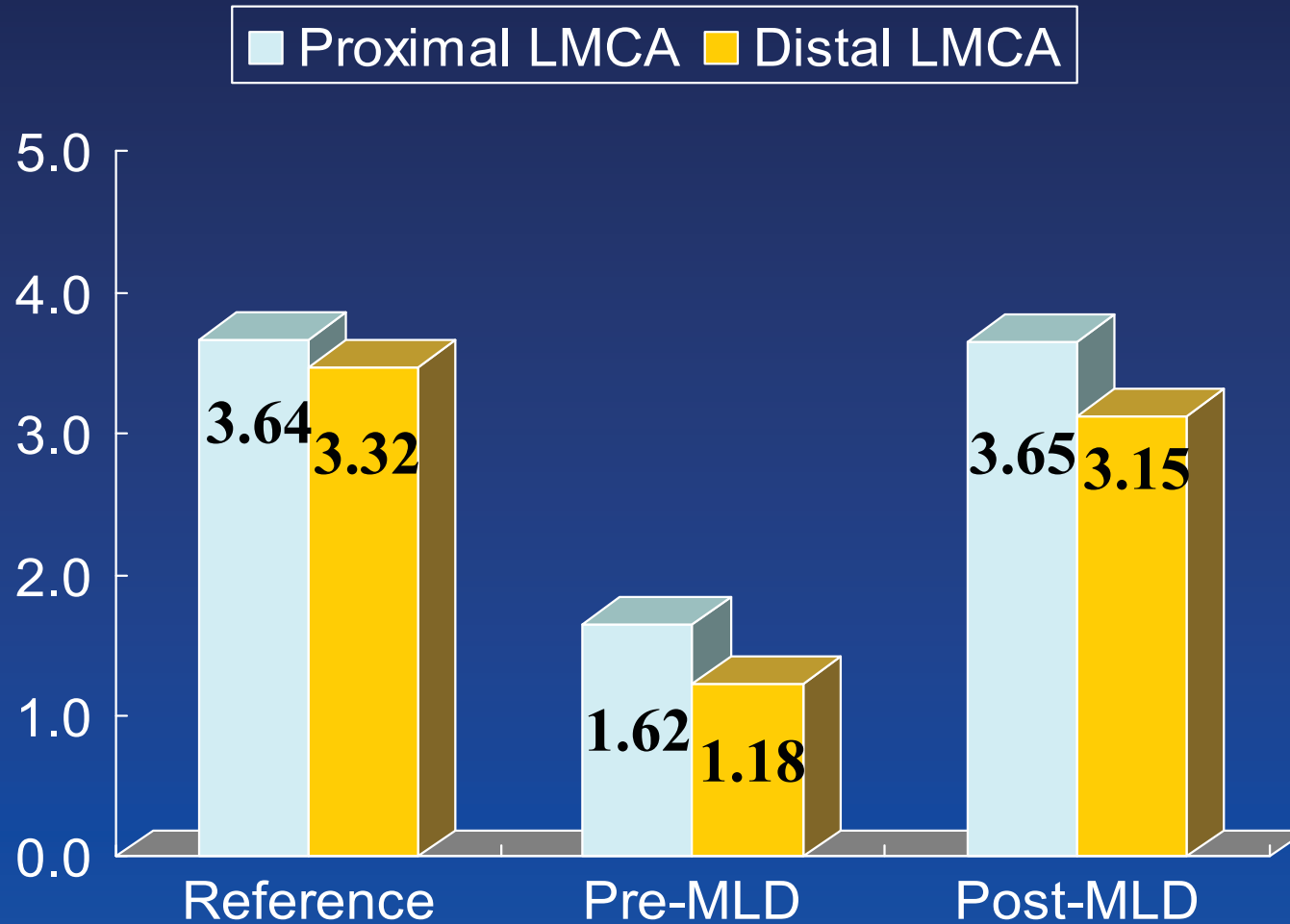
	Proximal (n=17)	Distal (n=57)
Use of Abciximab	1 (6%)	4 (7%)
Debulking atherectomy	0	2 (4%)
IVUS guidance	14 (82%)	53 (93%)
Direct stenting	9 (53%)	24 (42%)
Use of a additional high pressure balloon	13 (77%)	30 (54%)
Maximal inflation pressure (atm)	18.7 ± 2.4	18.5 ± 3.7
Maximal balloon diameter (mm)	3.8 ± 0.3	4.1 ± 2.8
Balloon-to-artery ratio	1.1 ± 0.1	1.1 ± 0.1

Different Stenting Technique for Distal LMCA Narrowing

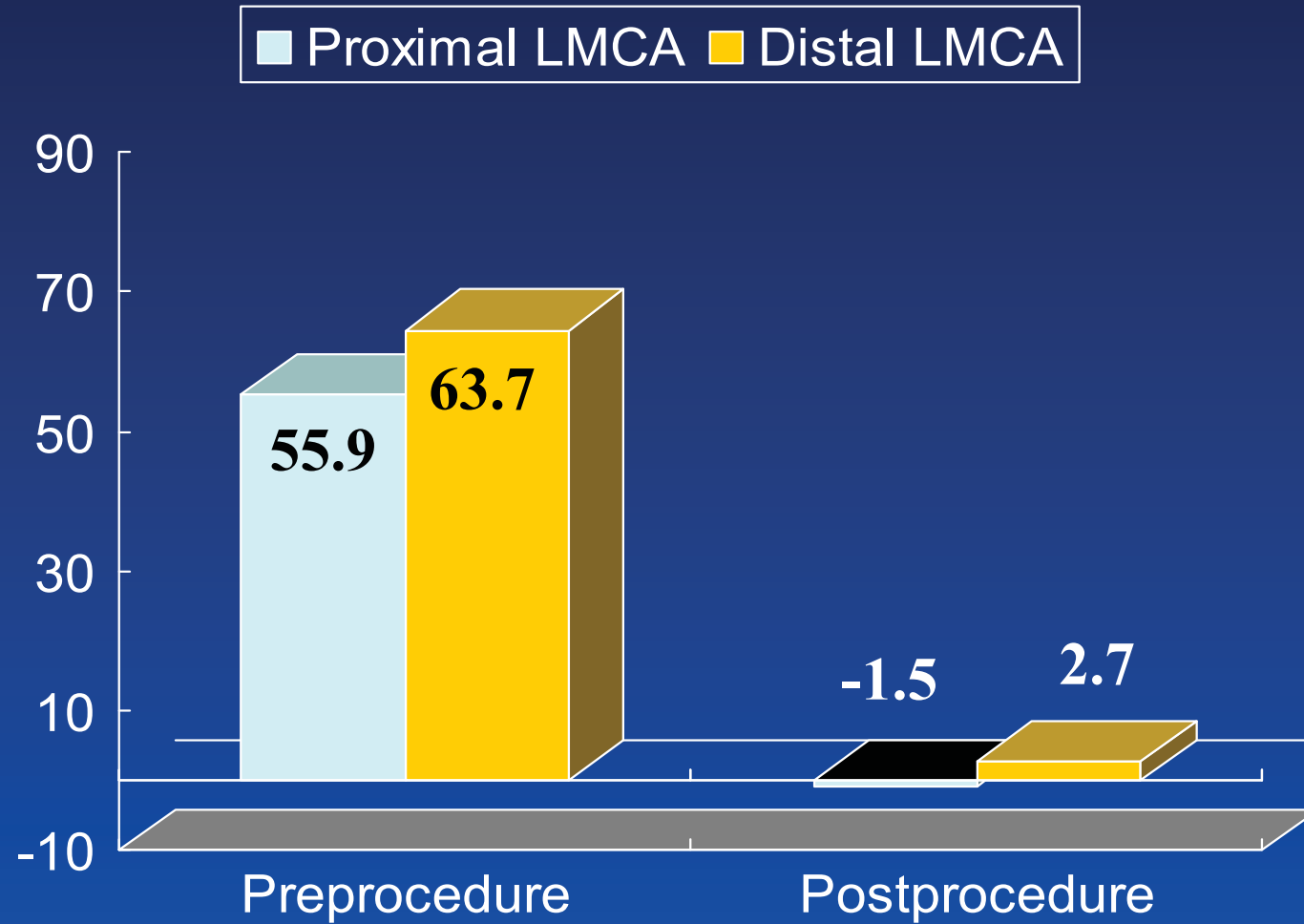
Final kissing balloon inflation : 30 pts (53%)



Minimal Lumen Diameter



Diameter Stenosis



Immediate Outcomes

in 30 days

Procedural success 100%

Death	0
Q MI	0
Non Q MI *	4 (5 %)
Emergent CABG	0
Repeat PCI	0

* All procedure related, CK-MB \geq 3 times normal value

Angiographic Follow-Up

at 6 Months

**Performed in 4 patients
without restenosis**

IVUS Analysis

	Baseline	Postprocedure
Vulnerable plaque	34 %	
Proximal reference		
EEM CSA	19.9 ± 5.3	22.4 ± 0.2
Lumen CSA	11.1 ± 2.9	12.2 ± 0.6
Target segment		
EEM CSA	18.5 ± 5.3	19.7 ± 6.0
Lumen CSA	3.0 ± 0.7	9.3 ± 2.3
Distal reference segment		
EEM CSA	17.1 ± 5.0	16.9 ± 5.4
Lumen CSA	10.1 ± 3.3	10.4 ± 4.3
Stent inapposition		18 %

EEM=external elastic membrane, CSA=cross sectional area

Conclusions

- Sirolimus eluting stent implantation for unprotected LMCA stenosis was safe with favorable early outcome.
- Long-term angiographic and clinical results will be presented in next year.