"Long Cypher" Multicenter Registry Study in Korea

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Background

- Sirolimus eluting stent implantation has been demonstrated to dramatically diminish in-stent restenosis in elective patients with relatively simple coronary lesions.
- However, the impact of sirolimus eluting stent for very long coronary lesions is not well known.

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Objective

- The present study was performed to evaluate the safety and efficacy of the sirolimus eluting stent (Cypher™ stent; Cordis) for very long coronary lesion.
- And it was compared with a control group composed of patients with long coronary lesions treated with long bare metal stents in the same period.

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Investigating Centers (10 centers)

- Coordinating center : Asan Medical Center, *SJ Park*
- Collaborating centers

  Ajou University Medical Center, *SJ Tahk*
  Catholic University of Korea, St Mary's Hospital, *KB Seung*
  Chonnam Nat'l University Hospital, *MH Jeong*
  Keimyung University Dongsan Medical Center, *KS Kim*
  Korea University Kuro Hospital, *DJ Oh*
  Samsung Medical Center, *HC Gwon*
  Seoul National University Hospital, *Lee MM, Koo BK*
  Yonsei University Severance Hospital, *YS Jang*
  Yonsei University Wonju Christian Hospital, *JH Yoon*

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Inclusion Criteria

- The treated vessels were of 2.5-4.0 mm in diameter with ≥ 50% diameter stenosis, and had a lesion length ≥ 24 mm that could be covered by a single stent or multiple stents (total contiguous stent length ≥ 28 mm).

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Exclusion Criteria

- Contraindication to antiplatelet agents
- Left main coronary artery stenosis
- Grafted lesions
- In-stent restenotic lesions
- Primary angioplasty in acute myocardial infarction
- Left ventricular dysfunction (ejection fraction <40%)
- An inability to follow the protocol

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Study End Point

Primary end point

The incidence of major adverse cardiac events including death, nonfatal MI, target lesion revascularization or target vessel revascularization

Secondary end point

The angiographic restenosis rate and late loss at angiographic follow-up

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Follow Up

- Data were collected with a standardized case-report forms completed by the research coordinator at each site.
- All clinical events were monitored.
- Angiographic follow-up is being routinely performed at six months or earlier if a patient shows symptoms of recurrence.

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Subjects

February 19 ~ August 9

- The group treated with Cypher stents ;
  181 patients, 206 lesions

- The group treated with bare metal stents ;
  130 patients, 150 lesions

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Antiplatelet Regimens

Bare Metal Stent

- **Aspirin** indefinitely
- **Clopidogrel**

  300 mg loading, before intervention

  75 mg maintenance, for 1 month

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Antiplatelet Regimens

Cypher stent

Initial 100 patients	Following 81 patients
Aspirin lifelong	**Aspirin** lifelong
Cilostazol 100mg BID for 1 month (200mg loading)	**Clopidogrel** 75mg QD for 6 months (450mg loading)
Clopidogrel 75mg QD for 6 months (300mg loading)	

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Concerns of Antiplatelet Drugs in Long Cypher Study of Korea

- Triple or two drug combination with a higher loading dose of clopidogrel was used in the present study due to the following issues.
- The safety of long Cypher stent implantation was not known well.
- Triple regimen has been very effective to prevent stent thrombosis in coronary brachytherpy.
- Glycoprotein IIb/IIIa inhibitors can not be commonly used as other studies using drug eluting stents, due to the government's policy in Korea.

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Baseline Demographics

	Cypher (n=181)	Control (n=130)	P value
Age (years)	60 ± 10	60 ± 10	0.950
Man	130 (72%)	97 (75%)	0.614
Hypertension	101 (56%)	72 (55%)	0.968
Hypercholesterolemia	30 (16%)	23 (18%)	0.724
Diabetes mellitus	69 (38%)	39 (30%)	0.172
Smoking	54 (30%)	62 (48%)	0.002

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Baseline Demographics

	Cypher (n=181)	Control (n=130)	P value
LV ejection fraction (%)	60 ± 11	55 ± 10	0.045
Prior PCI	19 (11%)	14 (11%)	0.939
Prior CABG	3 (2%)	0 (0%)	0.268
Clinical diagnosis			0.548
Stable angina	72 (40%)	56 (43%)	
Unstable angina	94 (52%)	54 (41%)	
Acute MI	14 (8%)	20 (16%)	

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Baseline Demographics

	Cypher (n=181)	Control (n=130)	P value
No of diseased vessels			0.356
1 vessel	69 (38%)	(30%)	
2 vessel	66 (37%)	(39%)	
3 vessel	46 (25%)	(30%)	

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Lesion Characteristics

	Cypher (n=206)	Control (n=150)	P value
Lesion location			0.004
LAD	136 (66%)	72 (48%)	
LCX	21 (10%)	25 (17%)	
RCA	49 (24%)	53 (35%)	
Chronic total occlusion	21 (10%)	21 (14%)	0.272
Bifurcation lesion (side branch ≥ 2.0mm)	53 (26%)	21 (14%)	0.007
Infarct related artery	10 (5%)	18 (12%)	0.015

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Lesion Characteristics

	Cypher (n=206)	Control (n=150)	P value
Lesion length (mm)	33 ± 13	30 ± 14	0.046
Proximal reference (mm)	3.2 ± 0.5	3.4 ± 0.6	0.002
Distal reference (mm)	2.7 ± 0.5	2.9 ± 0.6	0.038
MLD (mm)	0.7 ± 0.5	0.7 ± 0.6	0.638
Diameter stenosis (%)	76.3 ± 15.8	75.0 ± 21.0	0.575

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Stenting Procedure

	Cypher (n=206)	Control (n=150)	P value
Used No of stents	1.5 ± 0.7	1.3 ± 0.5	0.001
Overlapping	87 (42%)	41 (27%)	0.008
Contiguous stent length (mm)	38.3 ± 13.1	35.9 ± 11.7	0.071
Contiguous stent length ≥56mm	33 (16%)	17 (11%)	0.209
Maximal inflation pressure (atm)	15.8 ± 3.7	11.8 ± 3.2	< 0.001
Maximal balloon size	3.2 ± 0.3	3.5 ± 0.5	< 0.001
Balloon-to-artery ratio	1.1 ± 0.2	1.1 ± 0.1	0.242
IVUS guidance	148 (72%)	77 (51%)	< 0.001
Use of Abciximab	9 (4%)	7 (5%)	0.893

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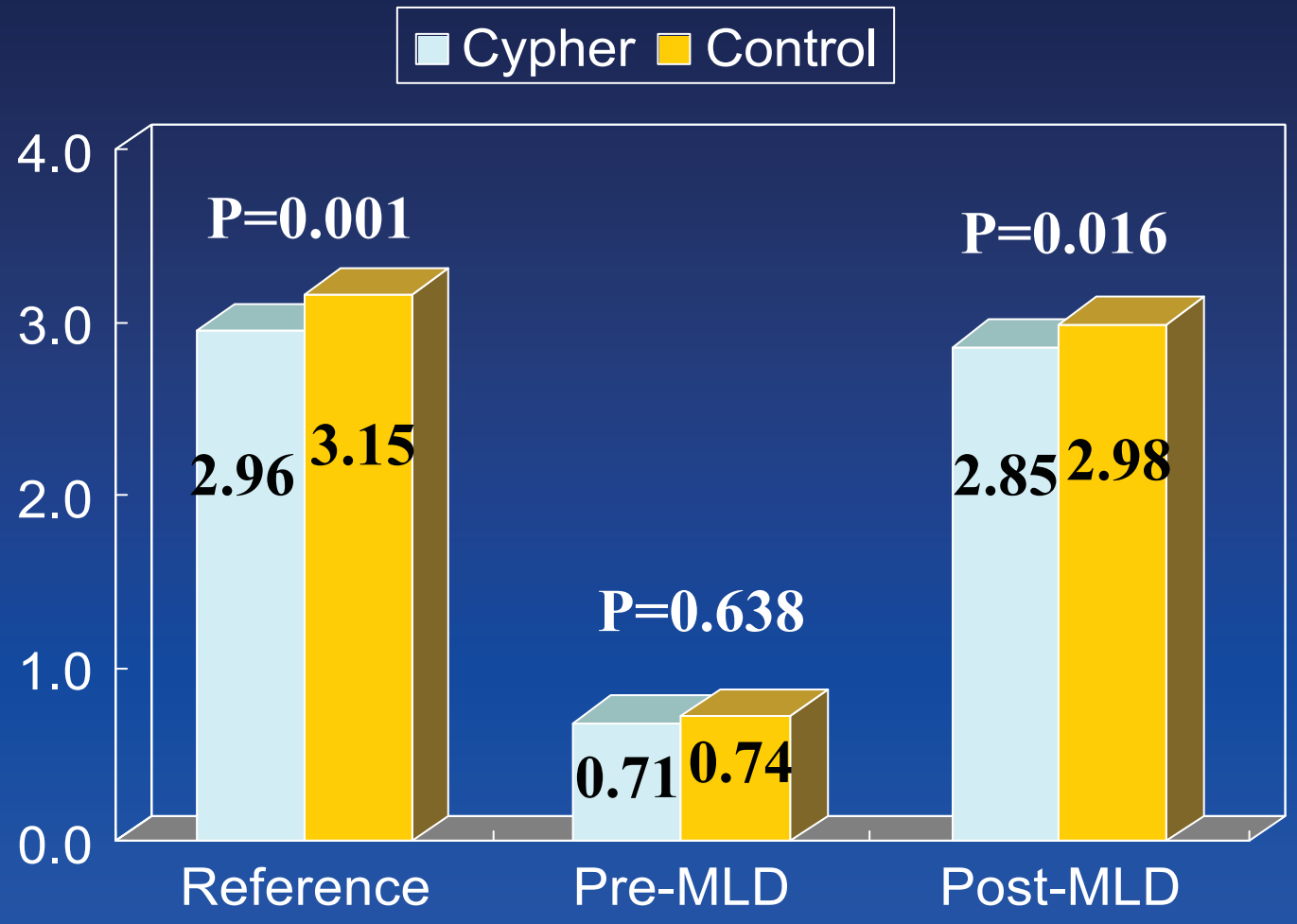
Minimal Lumen Diameter



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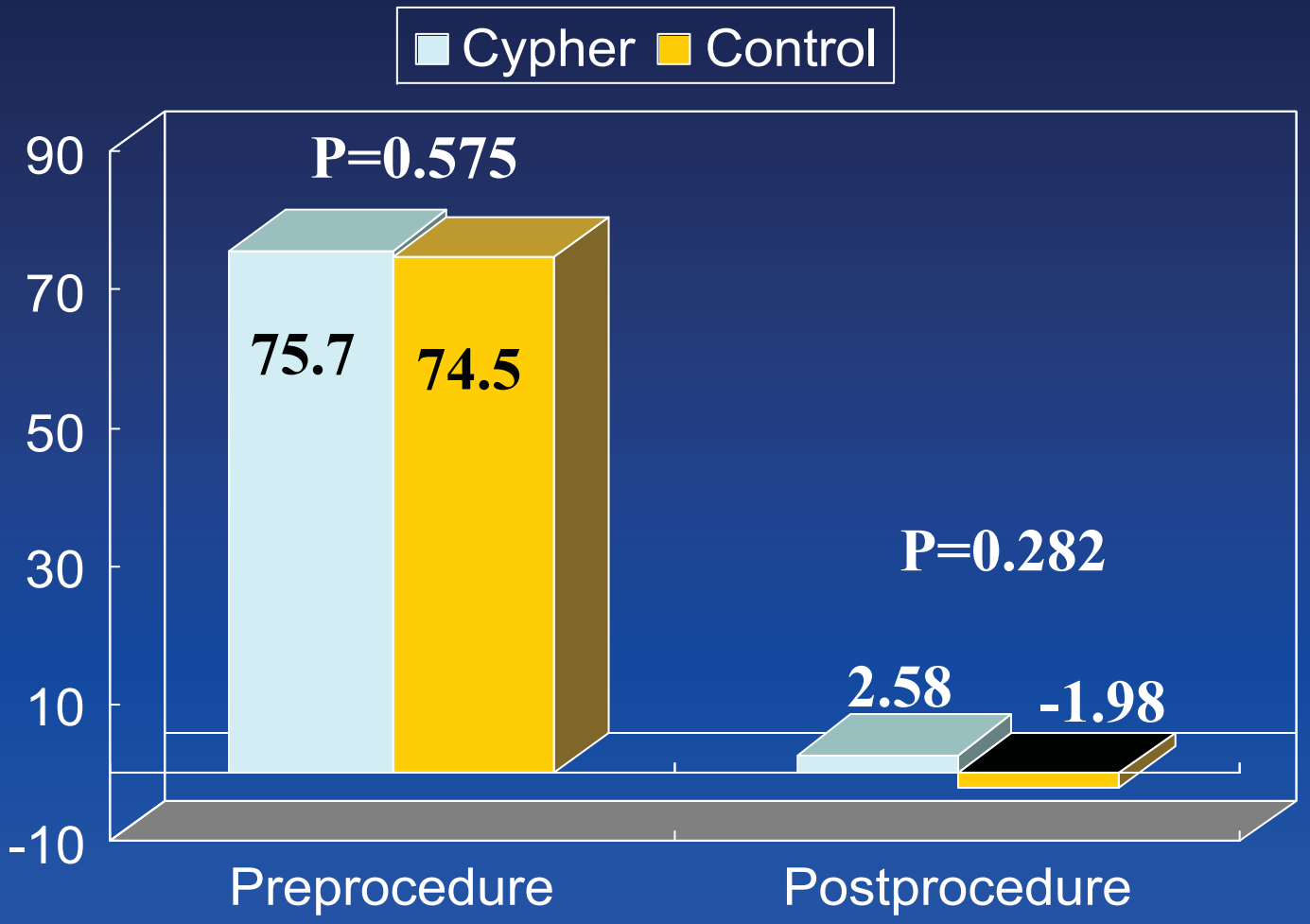
Diameter Stenosis



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In-Hospital Outcomes

	Cypher (n=181)	Control (n=130)	P value
Procedural success *	99%	94%	0.010
Death	0	0	1.000
MI	16 (9%)	15 (12%)	0.634
Q wave	0	0	
Non-Q wave **	16 (9%)	15 (12%)	
TLR	0	0	1.000
TVR	0	0	1.000

* Final TIMI flow ≥ 2 and residual diameter stenosis ≤ 30%
** CK-MB ≥ 3 times normal value (≤5 IU/mL)

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30-Day Outcomes

	Cypher (n=175)	Control (n=124)	P value
Death	1 (0.6%) *	0	1.000
Noncardiac	1 (0.6%)	0	
Cardiac	0	0	
MI	16 (9%)	15 (12%)	0.634
Q wave	0	0	
Non-Q wave **	16 (9%)	15 (12%)	
TLR	0	0	1.000
TVR	0	0	1.000

* Due to intracranial hemorrhage, 5 days after intervention

** All procedure related, no occurrence after discharge

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Conclusions

- Bare stents were implanted more commonly in patients with low LV ejection fraction and recent history of acute myocardial infarction than Cypher stents.
- Cypher stents were more preferred in lesions at a high risk of restenosis, such as LAD lesions and very long lesions with small diameter.

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Conclusions

- Cypher stents were implanted with a similar balloon-to-artery ratio (1.1:1) to bare metal stents with a high pressure balloon dilatation.
- IVUS guidance was more commonly used in Cypher stent implantation to evaluate the exact lesion characteristics and to prevent stent inapposition.

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Conclusions

- Sirolimus eluting stent implantation for very long coronary lesions was safe with early outcomes comparable to conventional bare metal stent.
- Long-term angiographic and clinical results will be presented in next year.

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