

관상동맥내 스텐트 시술시 Aspirin과 Cilostazol 2개월 병합요법

윤명호¹ · 탁승제¹ · 염철훈¹ · 장혁재¹ · 최소연¹ · 유상용¹
 안성균¹ · 고종훈¹ · 신준환¹ · 김한수¹ · 최병일¹

The Effects of Two-Month Combination Therapy of Cilostazol and Aspirin after Intracoronary Stenting

Myeong-Ho Yoon, MD¹, Seung-Jea Tahk, MD¹, Zhe-Xun Lian, MD¹, Hyuk-Jae Chang, MD¹,
 So-Yeon Choi, MD¹, Sang-Yong Yoo, MD¹, Sung-Gyun Ahn, MD¹, Jong-Hoon Koh, MD²,
 Joon-Han Shin, MD¹, Han-Soo Kim, MD¹ and Byung-Il W. Choi, MD¹

¹Department of Cardiology, Ajou University School of Medicine, Suwon, ²Department of Internal Medicine, Kwan Dong University School of Medicine, Kangreung, Korea

ABSTRACT

Background and Objectives : It is well known that anti-platelet agents decrease the rate of subacute thrombosis after intracoronary stenting significantly. The aim of this study is to assess the antithrombotic effect and safety of 2-month combined regimen of cilostazol and aspirin on intracoronary stenting. **Methods :** The study population consisted of 78 lesions of 57 patients (age : 58.1 ± 10.3 , male 47, female 10) with ischemic heart disease who were underwent successful intracoronary stenting. They were received cilostazol (200 mg/day) and aspirin (100 mg/day) two days before intracoronary stenting and continued for 8 weeks, and then aspirin was medicated continuously during the study. The laboratory and clinical findings were evaluated before cilostazol administration, 4 weeks, 8 weeks and 6 months after intervention. The treadmill exercise test was done at 6 months after intervention. **Results :** Subacute thrombosis occurred in 2 patients (3.5%). Target lesion revascularization (TLR) was done in 4 patients (7.3%). Clinical restenosis (symptomatic or positive stress test, subacute thrombosis and TLR) occurred in 15 patients (26.3%). There was no granulocytopenia, or severe liver dysfunction. HDL-cholesterol was increased significantly at 2 months (36.6 ± 7.4 mg/dl versus 41.6 ± 9.3 mg/dl, $p < 0.01$) and 6 months (36.6 ± 7.4 mg/dl versus 42.4 ± 10.6 mg/dl, $p < 0.01$) follow up. **Conclusion :** Two-month combined regimen of cilostazol and aspirin was effective and safe after intracoronary stenting. Subacute thrombosis and clinical restenosis rate were comparable with previous reports. Further large randomized trials are needed for the evaluation of favorable effect of cilostazol on lipid metabolism. (Korean Circulation J 2000; 30(8):927-936)

KEY WORDS : Cilostazol Intracoronary stenting Subacute thrombosis Target lesion revascularization.

서	론	intervention, PCI)	(subacute thrombosis)
	(percutaneous coronary	, ¹⁻³⁾	(subacute th -
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rombosis) 1% 4)5) 가 , ,
ticlopi - (<150,000/mm³), (3,000
dine, aspirin 3)6 - 10) . /mm³) .
ticlopidine 가 2.75 mm ,
1 .
(major adverse cardiovascular event(MACE) : 2 cilostazol 100 mg 1
(sudden death), (acute myocar - 2 aspirin 100 mg 1
dial infarction), (CABG), 1 aspirin
(repeat intervention for revascularizat - . ACT가 300 sec
ion)) heparin .
3)6 - 10) ,
(restenosis) 스텐트 시술
6 - 10) ticlopidine 7 French guiding catheter
(leukopenia)^{11 - 13)} ,
(thrombocytopenia)
가 . NIR (51 , 58.6%), MAC (25 , 28.7%),
Cilostazol GFX (9 , 10.4%) multilink (1 ,
14 - 16) 1.2%) cordis (1 , 1.2%) .
17)
18)
ticlopidine
19)20) .
30% 가 TIMI
6 cilostazol (thrombolysis in myocardial infarction) grade 3
20)21)
cilostazol 2
추적관찰
cilostazol as - 4
pirin 2
1 , 2 6
6 (treadmill
exercise test)
대상 및 방법
연구종료시기
환자 대상 및 약물 치료 6
1998 11 1999 6
cilostazol
57
(< 80,000/mm³),
가 , (<1,200/mm³)

6
1
Q 가 creatine kinase가 2
가 Q
kinase가 2 가 creatine Q
(periaccess site)

통계 및 분석

\pm
paired t - test
p 0.05

결 과

대상 환자, 관상동맥 조영술 및 스텐트 시술상의 특성

57 58.5 ± 10.3
, 가 47 (82.5%) (Table 1).

6 51 6

57 , 78

Table 2, 3

시술관련 합병증

Table 1. Clinical characteristics of the patients

	Numbers of case (%)
Enrolled patient number	57
6 months follow up patient number	51
Major adverse cardiovascular events	6
Age (years)	58.5 ± 10.3
Gender (M/F)	47/10
Diagnosis	
AMI	22(38.6%)
Stable angina	13(22.8%)
Unstable angina	19(33.3%)
Silent ischemia	3(5.3%)
Previous MI	5(8.8%)
Hypertension	22(38.6%)
Diabetes mellitus	17(29.8%)
Hypertlipidemia	11(19.3%)
Smoking	33(57.9%)

AMI : acute myocardial infarction
MI : myocardial infarction
Hyperlipidemia : total cholesterol > 220 mg/dl

Table 2. Angiographic characteristics of patients

Variables	Numbers of case (%)
Vessel disease	
1 vessel disease	35 (61.4%)
2 vessel disease	13 (22.8%)
3 vessel disease	9 (15.8%)
Target lesion site	
LAD	45 (57.7%)
RCA	18 (23.1%)
LCx	15 (19.2%)
ACC/AHA lesion type	1 (1.3%)
A	
B ₁	22 (28.2%)
B ₂	36 (46.2%)
C	19 (24.3%)

LAD : left anterior descending artery, LCx : left circumflex artery, RCA : right coronary artery ACC/AHA : American College of Cardiology/American Heart Association

2

아급성 스텐트 혈전증

57

2 (3.5%)

2 1 (4.0± . 2 1
 1.4) (tissue prolapse)
 2 가 1
 1 , 1
 1 .

Table 3. Stent pro cedural characteristics of the patients

Variables	Numbers of case (%)
Stent placement indication	
De-novo, elective	38 (48.7%)
Suboptimal result	39 (50.0%)
Bailout	1 (1.3%)
Stents per patients	1.5
Maximal balloon pressure (atm)	12.0± 1.9
Stent types	
NIR	51 (58.6%)
MAC	25 (28.7%)
GFX	9 (10.4%)
Others	2 (2.3%)
Stents per lesions	1.1
Stent length (mm)	18.0± 6.2
Dimensions before stenting	
Minimal lumen diameter (mm)	0.7± 0.4
Percent diameter stenosis (%)	78.5± 11.5
Dimensions after stenting	
Minimal lumen diameter (mm)	3.0± 0.5
Percent diameter stenosis (%)	8.4± 7.5
Reference diameter (mm)	3.3± 0.5
Lesion length (mm)	14.8± 9.3

초기 일반혈액검사 결과

4 8
 blood urea nitrogen, creatinine, bilirubin
 가
 (Table 4).
 alanine transaminase(ALT)
 aspartate transaminase(AST)
 가
 가
 (Table 5).
 cilostazol 4 total chol -
 esterol LDL - cholesterol
 HDL - cholesterol 가 8
 가 (Table 4)
 , (simv -
 astatin, atorvastatin)
 ,
 (32) HDL - chole -
 sterol 가 (Table 6).

Table 4. Serial follow-up of routine chemistry of 57 patients

	Base	4 week	8 week	6 months
BUN (mg/dl)	16.3 ± 5.2	14.4 ± 4.4*	15.4 ± 5.4	16.8 ± 5.7
Creatinine(mg/dl)	1.0 ± 0.3	1.1 ± 0.2*	1.1 ± 0.2 [†]	1.1 ± 0.2 [†]
Total bilirubin (mg/dl)	0.54 ± 0.22	0.63 ± 0.24*	0.61 ± 0.23	0.73 ± 0.25 [†]
Alk. phosphatase (U/l)	77.5 ± 26.4	80.0 ± 25.7	80.9 ± 23.6	85.4 ± 23.0*
ALT (U/l)	35.1 ± 25.3	27.8 ± 13.8*	25.1 ± 15.3	28.1 ± 13.9
AST (U/l)	52.5 ± 61.9	20.4 ± 5.8 [†]	20.0 ± 6.6 [†]	24.4 ± 8.5 [†]
T. cholesterol (mg/dl)	200.0 ± 33.9	187.8 ± 33.9	178.3 ± 31.4*	186.6 ± 36.4
Triglyceride (mg/dl)	169.3 ± 114.6	134.8 ± 47.6	128.9 ± 71.5	161.7 ± 85.4
HDL-cholesterol (mg/dl)	36.6 ± 7.4	40.6 ± 9.7 [†]	41.6 ± 9.3 [†]	42.4 ± 10.6 [†]
LDL-cholesterol (mg/dl)	133.4 ± 32.4	122.3 ± 26.7	113.2 ± 27.2 [†]	111.9 ± 27.7 [†]

BUN : blood urea nitrogen, ALT : alanine transaminase, AST : aspartate transaminase

HDL : high-density lipoprotein and LDL : low-density lipoprotein

* : p<0.05 base vs 4 week, 8 week, 6 months, † : p<0.01 base vs 4 week, 8 week, 6 months

Table 5. Serial follow-up of peripheral blood cell counts in 57 patients

	Base	4 week	8 week	6 months
Hemoglobin (g/dl)	13.75 ± 1.59	13.89 ± 1.42	14.13 ± 1.57*	14.33 ± 1.57 [†]
Hematocrit (%)	40.41 ± 4.67	40.86 ± 4.23	41.50 ± 4.68*	42.04 ± 4.51 [†]
Platelet (× 103/μl)	225.1 ± 57.3	224.6 ± 58.6	230.3 ± 58.0	236.2 ± 51.8
WBC (× 103/μl)	9.34 ± 4.17	6.72 ± 1.46 [†]	7.23 ± 4.07 [†]	7.35 ± 1.85 [†]

WBC : white blood cell

* : p<0.05 base vs 4 week, 8 week, 6 months, † : p<0.01 base vs 4 week, 8 week, 6 months

Table 6. Serial follow up of lipid profile except for patients receiving lipid lowering agents (n = 32)

	Base	4 week	8 week	6 months
T. cholesterol (mg/dl)	182.6 ± 21.6	191.7 ± 32.4	184.3 ± 31.1	196.4 ± 39.4
Triglyceride (mg/dl)	148.3 ± 82.1	142.1 ± 49.0	140.3 ± 87.4	167.2 ± 103.9
HDL-cholesterol (mg/dl)	37.4 ± 8.8	40.0 ± 10.8	42.0 ± 10.7*	44.8 ± 12.1 [†]
LDL-cholesterol (mg/dl)	119.4 ± 23.3	126.9 ± 25.2	116.7 ± 27.1	117.5 ± 27.1

* : p<0.05 base vs 4 week, 8 week, 6 months, † : p<0.01 base vs 4 week, 8 week, 6 months

장기 일반혈액검사 결과

creatinine, total bilirubin	6	(PTCA)
가		(direct coro-
(Table 4). LDL - cholesterol	2	
HDL - cholesterol		가 2
가		
HDL - cholesterol	가	1
ALT, AST		
		6
		51

장기 임상결과

57	7 (13.7%)	
2	6	4
		6
		2
	(tar -	7 (
get lesion revascularization, TLR)	57	1)
6	10.5%	24.6%
4	4	
(3.4±1.7)		기타 약물 부작용
(3 :	, 1	AST 가가 가 1
:)	cilostazol 2 ALT가 92 U/L
		가
가 2		6
3 ,	1	54 U/l
3 ,	1	2
	2	1 ,
		1

Table 7. Incidence of complication of cilostazol

Symptoms and laboratory abnormalities	Numbers of case (%)
Clinical symptoms	
Headache	3 (5.2%)
Gastrointestinal disturbance	3 (5.2%)
Palpitation	1 (1.8%)
Facial edema	1 (1.8%)
Laboratory abnormalities	
Elevation of AST	1 (1.8%)

(Table 7) 가 ,

고 찰

²²⁾²³⁾ de novo lesion (vein graft lesion) (restenosis rate) ²⁴⁾²⁵⁾ , 가 .

3~4%
가 .

ticlopidine aspirin (wafarin)
aspirin
1% 가 ³⁾⁶⁻⁹⁾ , ticlopidine

가 0.8~2.1% ¹¹⁻¹³⁾ . Cilostazol in vitro dipyridamole ticl -
²⁶⁾ in vivo ²⁷⁾ . Cilostazol c - AMP ph -
osphodiesterase III

c - AMP 가
가
cilostazol 가 가
c - AMP 가 3H - thymidine uptake 가
DNA

¹⁸⁾가
c - AMP 가 endogenous
nitric oxide(NO) synthetase 가 lipo -
protein lipase 가

²⁸⁾
가 HDL -
¹⁷⁾
c - AMP 가

cilostazol
가

cilostazol
¹⁹⁾²⁰⁾²⁹⁾³⁰⁾
Park ³¹⁾ 490
30 ticlopidine 6 cilostazol
30
가 ticlopid -
ine 0.4% , cilostazol

0.8% 가
Yoon ³²⁾ 300
cilostazol ticlopidine 30
cilostazol
1.4% ticlopidine 가

0.7%
, Ochiai ¹⁹⁾ 71 84
cilostazol 1 1
,
, Yoshitomi Y ²⁹⁾ 83
, 93 3

cilostazol 6
 1 (skin rash) . 6 1
 , 가 cilostazol 2 ALT
 , 가가
 , 6
 , 6
 .
 cilostazol
 ticlo -
 pidine
 57 2 (3.5%) Sekiya ²¹⁾ 6
 cilostazol 1
 ticlopidine 1 ³⁾⁵⁾¹⁹⁾³²⁾ cilostzol aspirin
 0~1% 가 31.7% 12.5%
 1 9.5% , probucol
 가 cilostazol
 가 , Kunishima ³⁰⁾ 70
 2 , 82 Palmaz - Shatz
 cilostazol 5.1
 ticlopidine
^{3)5 - 10)} aspirin 26.8% 8.6% cilost -
³⁾¹³⁾ azol . Cilostazol
 가
 19)29) , , 1% 10% ²¹⁾³⁰⁾ 20~30%
 . Kimura ³³⁾
 0.7%~5.3% 143 , 147 3
 8 12.6%, 1 14.7%, 3
 16.8%
 , Makaya ³⁴⁾ 259
 15.8% 1 10%
 10~20%
 가 2 cilostazol aspirin
 가 6
 cilostazol 57
 가 2
 , 6 (10.5%)

1998 11 1999 6

2 (1 cilost -

) azol 57 .

7 57 14 2 cilostazol 100 mg 1

24.6% 2 aspirin 100 mg 1

. cilostazol Ts - 1 ACT가 300 sec

utusi³⁵⁾ heparin .

가 HDL - 4 , 1 , 2

가 (total chole - 6 6

sterol), LDL - (triglyceride) .

HDL - 가

cilostazol 결 과 :

1) 58.5 ± 10.3 가 47

(82.5%) .

2) BUN, Cr, bilirubin

, LDL - 가

(triglyceride) .

HDL - 가

가 57

2 cil - 9 (15.8%)

ostazol aspirin .

4)

32 8 6 HDL -

cholesterol 가 .

5) 57 2

(3.5%) 2

6 (10.5%) 6

ticlopi -

dine 가 2 (1

)

7 14

. Cilostazol 24.6%

cilostazol 6

결 론 :

가 2 cilostzol as -

cilostazol aspirin 2 pirin

cilostazol

cilostazol aspirin 2

대상 및 방법 :

cilostazol

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