

## 관동맥 중재적 시술 환자군에서 스텐트삽입술 도입에 따른 임상 결과 비교

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### A Comparison of Clinical Outcomes and Risks for Major Adverse Cardiac Events between the Pre- and Post-Stent Period

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#### ABSTRACT

**Background and Objectives** : Several studies have demonstrated improved outcomes achieved with stents vice balloon angioplasty. The purpose of this study was to compare the clinical outcomes and risk factors for major adverse cardiac events (MACE) between the pre- and post-stent period. **Subjects and Methods** : Clinical outcomes for 294 patients who had undergone balloon angioplasty alone in 1991 and 1992, were compared with those for 320 patients who underwent stent implantation in 1998. The duration of follow-up was 12 months. **Results** : There were more patients with diabetes and hyperlipidemia in the stent group ( $p < 0.05$ ). The stent group had significantly more 3-vessel diseases and complex lesion morphology ( $p < 0.05$ ). Cardiac event-free survival rates in the stent group at 1, 6, and 12 months were significantly higher than those in the balloon group (1, 6, 12 month : 97.0 vs 93.9%, 89.6 vs 82.3%, 83.7 vs 77.2%,  $p = 0.03$ ). MACE rates were highly associated with lesion morphology (OR = 2.6, 95% CI 1.4 -4.9) and angiotensin converting enzyme (ACE) inhibitors (OR = 2.4, 95% CI 1.3 -5.4) in the balloon group, and hypertension in the stent group (OR = 2.7, 95% CI 1.3 -5.6). Excluding acute myocardial infarction in the stent group, risk factors included diabetes (OR = 4.8, 95% CI 1.6 -14.2) and hypertension (OR = 4.4, 95% CI 1.2 -15.7). The stent group had significantly higher event-free survival rates in the complex lesions ( $p = 0.002$ ), but showed no difference in simple lesions. **Conclusion** : Compared with balloon angioplasty in the early 1990s, stent implantation in 1998 was associated with higher early and late cardiac event-free survival rates. Risk factors included complex lesion morphology and the use of ACE inhibitors in balloon angioplasty, and hypertension and diabetes in the stent group. (Korean Circulation J 2001;31(11):1123-1134)

**KEY WORDS** : Angioplasty, balloon ; Stents ; Disease-free survival.

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## 서 론

## 대상 및 방법

balloon angioplasty) Gruntzig <sup>1)</sup> 20 (balloon catheter) 대 상 1980

1991  
1990

가  
가 <sup>2)3)</sup> 1986 1991 1992 1998

<sup>4)</sup>

가 가 <sup>5)6)</sup> 가 60%

1

MACE(major adverse car -  
diac event) 50%

(directional or rotational atherectomy) 20%

<sup>7)</sup>

방 법

( ) <sup>8)</sup> , , ,

가 ( ) , 가

1 MACE , 1 , 6 , 12 , , ,

(cumulative cardiac event - free survival rate)

Q

자료분석 및 통계

chi - square test Fisher exact test

Kaplan - Meier log - rank test

2 mm 60%

Cox regression model

Cox regression model enter method forward conditional method SP-SS 9.0 for windows 95%

American College of Cardiology(ACC)/American Heart Association(AHA) type A, type B(type B<sub>1</sub> or type B<sub>2</sub>), type C<sup>9)</sup>

결 과

대상 환자의 임상적 특성

614 294 , 320 (Table 1).

가 25.6%, 28.1% ( ; 17.3%, ; 19.7%) 가 가

direct PTCA(percutaneous transluminal coronary angioplasty) , 가 (189.2±9.6 mg/dL vs 153.4±5.7 mg/dL) ,

추적관찰

MA - ble 1), Q Q (Ta - (38.8% vs 32.4%, p=0.04).

CE (target or non - target vessel revascularization) , MACE 가

1 , 6 , 12 MACE

가 95.1% (ticlopidine : 81%, cilostazol : 16%, others : 3%).

**Table 1.** Difference of baseline characteristics between the balloon and the stent group

	Balloon angioplasty group (n=294)	Stent group (n=320)
Clinical		
Age (years)	56 ± 9.1	59 ± 9.9
Male (%)	73.1	73.1
Hypertension (%)	43.0	50.2
Diabetes (%)*	17.3	25.6
Smoker (%)	56.6	51.5
Hyperlipidemia (%)*	19.7	28.1
Family history of ischemic heart diseases (%)*	4.0	15.8
Past history of cerebral vascular accidents (%)	2.9	3.0
Laboratory value (mg/dL)		
Total cholesterol	206.0 ± 15.4	200.9 ± 20.1
Triglycerides*	189.2 ± 9.6	153.4 ± 5.7
HDL-cholesterol	37 ± 10	40 ± 10
LV ejection fraction (%)	55.5 ± 12.9	54.9 ± 13.2
Initial diagnosis*		
Stable angina (%)	17.4	13.3
Unstable angina (%)	48.0	42.7
Non-Q MI (%)	2.1	5.2
ST elevation QMI (%)	32.4	38.8
Location of acute MI		
Anterior and anteroapical (%)	44	48
Posterior and lateral (%)	10	9
Inferior (%)	46	43
Drug treatment		
Aspirin (%)	97.5	98.9
Anti-thrombotic agents (%)*	3.1	95.1
Beta blockades (%)*	24.3	65.1
ACE inhibitors (%)*	14.5	43.5
Calcium channel block (%)*	92.8	54.3
Nitrates	20.7	27.4

LV : left ventricle, HDL : high density lipoprotein, MI : myocardial infarction, QMI : Q-wave myocardial infarction, ACE : angiotensin converting enzyme. Results of continuous variables are mean ± SD. \* : p<0.05

(Table 1).

관동맥 조영술 검사소견과 중재적 시술 방법에 따른 분석 (Table 2)

vs 18.6%), (9.7% 가

**Table 2.** Difference of angiographic findings and procedural parameters between the balloon and the stent group

	Balloon angioplasty group (n=294)	Stent group (n=320)
Lesion severity (%)*		
1 vessel diseases	56.6	51.3
2 vessel diseases	33.7	30.1
3 vessel diseases	9.7	18.6
Vessels involved (%)		
Left anterior descending artery	53	51
Left circumflex artery	20	17
Right coronary artery	24	31
Lesion morphology (ACC/AHA)*		
Type A	12.5	4.2
Type B <sub>1</sub>	40.7	17.6
Type B <sub>2</sub>	34.4	46.6
Type C	12.5	31.6
Mean balloon diameter (mm)	2.8 ± 0.3	3.0 ± 0.4
Mean stent diameter (mm)		3.7 ± 0.3
Treatment modes of AMI*		
Direct PTCA (%)	10	32
Thrombolysis (%)	39	32
Conservative management (%)	51	36
Residual stenosis (%)*	19.4 ± 10.0	4.0 ± 6.0
Mean No. of lesion treated*	1.08 ± 0.27*	1.14 ± 0.35
Mean No. of vessels non-revascularized	0.50 ± 0.66	0.61 ± 0.70
Infarct related artery (%)		
Left anterior descending artery	47.3	48.5
Left circumflex artery	19.7	17.2
Right coronary artery	33.0	34.3

AMI : acute myocardial infarction, ACC/AHA : American college of cardiology/American heart association, PTCA : percutaneous transluminal coronary angioplasty, No. : number. \* : p<0.05

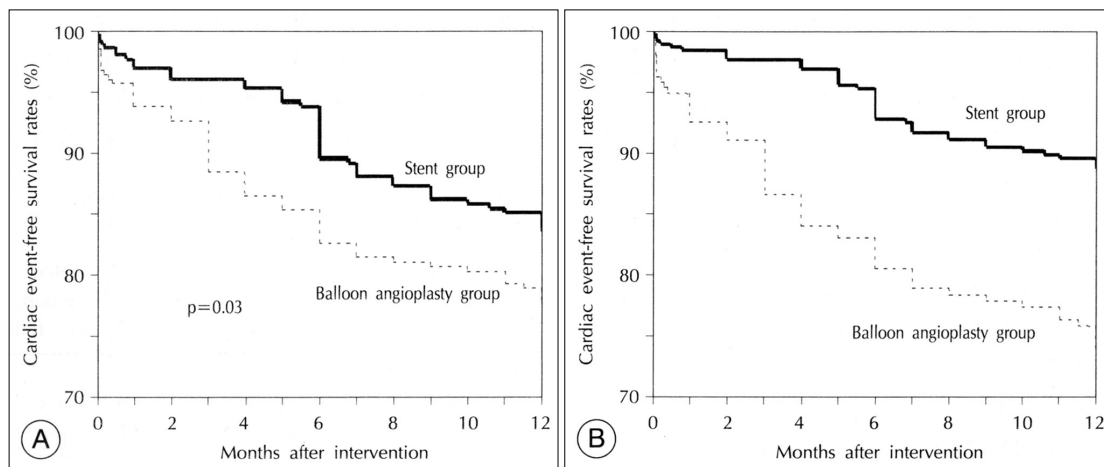
ACC/AHA type A  
(12.4%) (4.2%)  
type B<sub>2</sub> type C  
46.6% 31.6% 34.4%,  
12.5%  
(mean lu -  
minimal diameter)  
(1.14 ) (1.  
08 ) (Table 2).  
direct PTCA (32%)  
(10%)  
(4.0%) (19.4%)  
가  
(Table 2).  
추적관찰의 결과  
MACE  
, 1 , 6 , 12 M -  
ACE MACE Table 3  
Kaplan - Meier  
1 , 6 , 12  
97%, 90%, 84% 94%,  
82%, 77%  
(Table 3, Fig. 1A)(p=0.03, log rank test).  
1 6.8%,  
6 10.0%, 12 13.1% 1  
6.1%, 6 9.8%, 12 11.6% .  
1990  
가 가 Cox re -  
gression model  
(1 98.2% ; 6 93.0% ; 12 89.0%)  
(1 92.3% ; 6 80.5% ; 12 73.4%)  
(Fig. 1B). MA -  
CE ACC/AHA  
type B<sub>2</sub>, type C 2.6 MACE  
(odds ratio[OR] =2.6, 95% CI -

confidence interval[CI] 1.4 - 4.9 ; p=0.001)  
2.4  
MACE (OR =2.4, 95% CI 1.3 -

**Table 3.** Major adverse cardiac event and cardiac event-free survival rates

	Balloon angioplasty group (n=294)	Stent group (n=320)
MACE at in-hospital period		
Death (%)	0.7(2)	1.3
AMI (%)	1.1	0.6
CABG (%)	0.7	0.3
Target vessel revascularization (%)	1.1	0.3
Non-target vessel revascularization (%)	0.4	0.3
Total MACE (%)	4.0	2.8
MACE at 1 month		
Death (%)	0.7	1.3
AMI (%)	1.9	0.7
CABG (%)	0.7	0
Target vessel revascularization (%)	3.0	0.7
Non-target vessel revascularization (%)	0.4	1.0
Total MACE (%)	6.7	3.7
MACE at 6 month		
Death (%)	1.1	1.8
AMI (%)	3.1	1.4
CABG (%)	2.3	2.8
Target vessel revascularization (%)	11.9	6.7
Non-target vessel revascularization (%)	0.8	1.4
Total MACE (%)	19.2	14.0
MACE at 12 month		
Death (%)	1.2	1.8
AMI (%)	3.9	1.5
CABG (%)	2.4	2.9
Target vessel revascularization (%)	15.7	8.4
Non-target vessel revascularization (%)	0.8	2.5
Total MACE (%)	23.9	27.1
Cardiac event-free survival rates*		
1 month (%)	93.9	97.0
6 month (%)	82.3	89.6
12 month (%)	77.2	83.7

MACE percentage means cumulative counts of cardiac events. AMI : acute myocardial infarction, CABG : coronary artery bypass grafting, MACE : major adverse cardiac event, \* : p=0.03, log rank test. Cardiac event-free survival rates were analyzed by Kaplan-Meier method



**Fig. 1.** 12 months cumulative cardiac event-free survival rates using Kaplan-Meier Method (A) and Cox regression model (B).

**Table 4.** Cox regression analysis of major risk factors for major adverse cardiac events

	Balloon group		Stent group	
	Odds Ratio	95% Confidence Interval	Odds Ratio	95% Confidence Interval
Age (per year)	1.0	0.9 - 1.1	0.9	0.9 - 1.0
Male sex	1.0	0.4 - 2.1	1.1	0.4 - 2.9
Diabetes	1.4	0.7 - 3.6	1.5	0.7 - 3.0
Hypertension	1.1	0.6 - 1.9	2.7*	1.3 - 5.6
Smoking	1.0	0.5 - 2.0	1.9	0.8 - 4.5
Use of ACE inhibitors	2.4*	1.3 - 5.4	0.9	0.5 - 1.9
Use of beta blockades	1.2	0.6 - 2.0	0.9	0.5 - 1.8
Use of antithrombotics	1.2	0.9 - 1.4	0.5	0.3 - 1.3
Acute myocardial infarction	1.1	0.6 - 1.9	1.8	0.9 - 3.4
Lesion morphology (complex lesions)	2.6*	1.4 - 4.9	2.3	0.8 - 6.6
Reference diameter	0.8	0.3 - 1.9	0.7	0.3 - 1.8
Number of lesion treated	1.1	0.4 - 3.0	1.0	0.4 - 1.5
Number of non-revascularized vessels	1.4	0.7 - 2.5	1.9	0.9 - 4.2
Residual stenosis (%)	1.0	1.0 - 1.2	1.0	0.9 - 1.2

ACE : angiotensin converting enzyme, \* : the most significant risk factor in the balloon angioplasty group

5.4 ;  $p=0.001$ ), 가 (Ta - , ble 4).

MACE

2.7

(OR=2.7, 95% CI 1.3 - 5.6 ;  $p=0.005$ ) ,

(Table 5).

ACC/AHA

171

183

(OR=3.0, 95% CI 1.7 - 5.3,  $p=0.0001$ ) .

Kaplan - Meier

가

(OR=2.3, 95% CI

(1 98.

1.4 - 3.7,  $p=0.0008$ ).

2% ; 6

93.2% ; 12

87.3%)

(1

95.0% ; 6 82.0% ; 12 76.5%)  
 . Forward method MACE  
 ACC/AHA  
 2.42 MACE  
 (OR = 2.42, 95% CI 1.20 - 4.91, p = 0.01)  
 가 .  
 MACE 가  
 4.8 (OR =

4.8, 95% CI 1.6 - 14.2, p = 0.005)  
 (OR = 4.4, 95% CI 1.2 - 15.7, p = 0.009)  
 ACC/AHA  
 type B<sub>1</sub> B<sub>2</sub> B

**Table 5.** Difference of 12 months cardiac event-free survival rates in the balloon group according to lesion morphology : those with ACC/AHA classification type A, B (B<sub>1</sub>, B<sub>2</sub>), C, or simple (type A, B<sub>1</sub>), complex (type B<sub>2</sub>, C) lesions, perceiving balloon angioplasty in 1991 - 1992

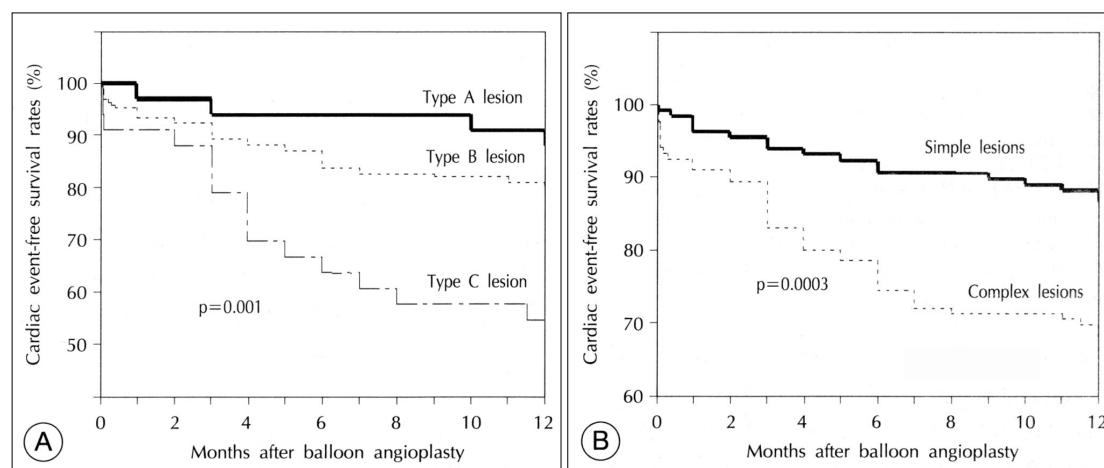
	Type A (n=36)	Type B (n=221)	Type C (n=37)
Cardiac event-free survival rates*			
1 month (%)	97.1	93.6	91.2
6 month (%)	94.0	83.9	63.8
12 month (%)	88.0	79.4	54.7
	Simple lesions (n=156)	Complex lesions (n=138)	
Cardiac event-free survival rates†			
1 month (%)	96.3	91.0	
6 month (%)	90.7	74.5	
12 month (%)	86.6	68.0	

\* : p = 0.001, Kaplan-Meier method, log rank test, † : p = 0.0003, Kaplan-Meier method, log rank test, ACC/AHA : American college of cardiology/American heart association

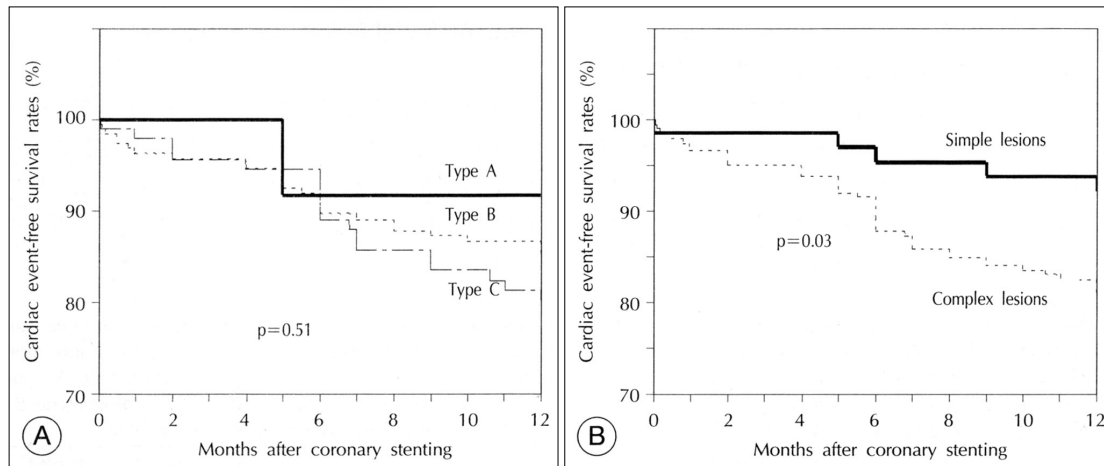
**Table 6.** Difference of 12 months cardiac event-free survival rates in the stent group according to lesion morphology : those with ACC/AHA classification type A, type B (B<sub>1</sub>, B<sub>2</sub>), type C, or simple (type A, B<sub>1</sub>), complex (type B<sub>2</sub>, C) lesions, perceiving stent implantation in 1998

	Type A (n=13)	Type B (n=205)	Type C (n=102)
Cardiac event-free survival rates*			
1 month (%)	100.0	96.4	97.7
6 month (%)	91.6	89.6	89.1
12 month (%)	91.6	84.9	80.2
	Simple lesions (n=70)	Complex lesions (n=250)	
Cardiac event-free survival rates†			
1 month (%)	96.4	97.5	
6 month (%)	95.4	87.8	
12 month (%)	92.1	81.1	

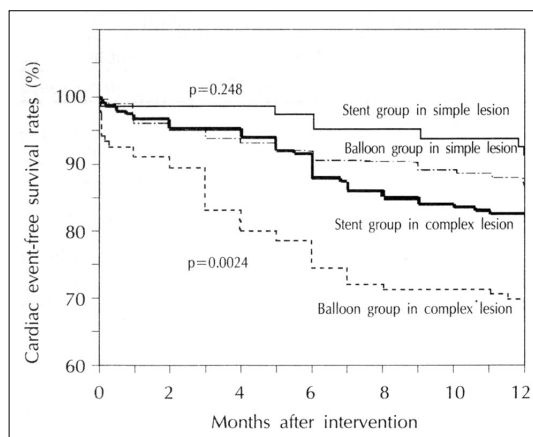
\* : p = 0.51, Kaplan-Meier method, not significant by log rank test, † : p = 0.003, Kaplan-Meier method, log rank test, ACC/AHA : American college of cardiology/American heart association



**Fig. 2.** 12 months cardiac event-free survival rates in the balloon group according to lesion morphology : those with ACC/AHA classification type A, those with type B (B<sub>1</sub>, B<sub>2</sub>), and those with type C (A). Simple lesions are type A and type B. Complex lesions are type C (B). The survival difference was statistically significant by log rank test. ACC/AHA : American college of cardiology/American heart association.



**Fig. 3.** 12 months cardiac event-free survival rates in the stent group according to lesion morphology : those with ACC/AHA classification type A, those with type B ( $B_1$ ,  $B_2$ ), and those with type C (A). Simple lesions are type A and type B. Complex lesions are type C (B). The survival difference was not significant by log rank test. ACC/AHA : American college of cardiology/American heart association.



**Fig. 4.** Difference of 12 months cumulative cardiac event-free survival rates between the balloon group and the stent group by coronary lesion morphology : simple lesions are ACC/AHA classification type A and type  $B_1$ . Complex lesions are ACC/AHA classification type  $B_2$  and C. The survival difference in simple lesions was not statistically significant but significant in complex lesions by log rank test. ACC/AHA : American college of cardiology/American heart association.

type A  $B_1$  , type  $B_2$   
C  
Kaplan - Meier (Table 5, Fig. 2A)  
type A가 가  
type B type C가 가

( $p=0.001$ , log rank test),  
(Table 5, Fig. 2B)  
1 , 6 , 12  
96.3%, 90.7% 86.6% 91.0%,  
74. 5%, 68.0%  
( $p=0.0003$ , log rank test).  
type A, B, C  
가 (Table 6, Fig.  
3A)  
1 , 6 , 12  
96.4%, 95.4%, 92.1% (1 :  
97.5%, 6 : 87.8%, 12 : 81.1%)  
(Table 6,  
Fig. 3B).

ACC/AHA

ACC/AHA

1 , 6 , 12  
98.5%, 95.4%, 92.1%  
(1 : 96.3%, 6 : 90.7%, 12  
: 86.6%)  
가 ( $p=0.248$ , log rank test)



(Fig. 4).

1, 6, 12 96.  
6%, 87.8%, 81.2% 1990  
(1 : 91.0%, 6 : 74.5%, 12 : 68.0%) ACC/AHA type  
( $p = 0.0024$ , log B<sub>2</sub> type C 가 ,  
rank test)(Fig. 5).

## 고찰

1986 1991  
4) 1990 , 가 ,  
가 , 가  
가 1990 가  
30 50% ,  
2-4)  
1990 12 MACE  
1991 multicenter European re - , , ,  
gistry 20% . 1994  
1994 Benestent I trial 3. STRESS trials 96.  
5% .<sup>10)11)</sup> , 1994 1% 7  
80.5% .<sup>16)</sup>  
Benestent II trial 30% MACE 7  
79.9% .<sup>17)</sup>  
1% .<sup>18)</sup>  
14) 6 84 89%  
ACC/AHA classification type C 35  
mm 75%  
19)  
15) 6 , 12 89.6% 83.7%  
ACC/AHA  
MACE 가  
MACE 가  
MACE 가  
1998 가 ACC/AHA

Korean Circulation J 2001;31(11):1123-1134

가

결 론 :

가

MACE

가

MACE

## 요 약

배경 및 목적 :

중심 단어 :

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1991

1992

1998

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