

관동맥내 Stent 삽입술시 고압력 확장술의 유용성에 대한 재평가

이은미 · 오동주 · 김현철 · 김병희 · 김수미 · 황교승 · 안정천
송우혁 · 임도선 · 박창규 · 김영훈 · 서홍석 · 심완주 · 노영무

Optimal Balloon Inflation Pressures for Stent Deployment -High Pressure is Always Good?

Eun Mi Lee, MD, Dong Joo Oh, MD, Hyun Chul Kim, MD, Byung Hoe Kim, MD,
Soo Mi Kim, MD, Gyo Seung Hwang, MD, Jeong Cheon Ahn, MD, Woo Hyuk Song, MD,
Do Sun Lim, MD, Chang Hyu Park, MD, Young Hoon Kim, MD,
Wan Joo Shim, MD, Hong Seog Seo, MD and Young Moo Ro, MD

Department of Internal Medicine, College of Medicine, Korea University, Seoul, Korea

ABSTRACT

Background and Objectives : To reduce the subacute stent thrombosis, the use of high pressure final balloon dilatations and confirmation of adequate stent expansion by intravascular ultrasound has been recommended. The purpose of this study is to compare incidence of stent thrombosis and major cardiac events (MACE) between high and moderate pressure balloon technique without using intravascular ultrasound (IVUS) guidance. **Materials and Methods :** We prospectively studied 147 patients (110 males & 37 females, mean ; 56.9 ± 9.9 years, 154 lesions) who were deployed intracoronary stents with the use of conventional technique except IVUS guidance. According to inflation pressure, patients were divided into two groups ; G1 (moderate pressure group, maximum inflation balloon pressure <14 ATM, 77 lesion) & G2 (high pressure group, maximum inflation balloon pressure ≥ 14 ATM, 77 lesions). We investigated the incidence of stent thrombosis and MACE between two groups during the 10 month follow up examination. **Results :** 1) The mean inflation pressure is different between two groups by definition (G1 : G2 10.2 ± 1.8 ; 15.2 ± 1.3 ATM $p < 0.001$). 2) The stenotic lesion lengths of the group of patients treated with the moderate pressure technique were longer than those treated under the high pressure technique (G1 : G2 19.8 ± 7.1 mm ; 16.3 ± 4.1 mm $p = 0.002$). 3) There were no significant differences between the moderate pressure group and the high pressure group during the 10 month follow-up examination in terms of MACE [early event (0 -14D) -subacute thrombosis G1 : G2 0 : 0 death G1 ; G2 1 : 1/late events (15D -10M) -repeat revascularization : G1 ; G2 8 ; 7, CABG G1 ; G2 1 ; 0, Q.M.I G1 ; G2 1 ; 0] . **Conclusion :** On selected patients, it is possible to consider moderate pressure technique as an other option for coronary stenting. (**Korean Circulation J 1998;28(8):1272-1279**)

KEY WORDS : Stent · Moderate pressure balloon technique high pressure balloon technique · Major adverse cardiac events.

: 1998 7 3
: 1998 8 21
: , 152 - 050 80
: (02) 818 - 6633 · : (02) 864 - 3062
E - mail : parkcg@unitel.co.kr

서 론
 1986
 1-4)
 가
 (high pressure
 balloon technique)
 5-8)
 16
 가 가 9-12)
 147
 (IVUS)
 (subacute stent thrombosis)
 (major adverse cardiac
 event, MACE)
 가
 재 료 및 방 법
 대 상
 가 147
 , 154
 50 , 48 ,
 49
 , 10
 50
 정 의
 1) (1 , moderate pressure ba-
 lloon inflation group)
 14 , (2 , high
 pressure balloon inflation group) 14
 2) 30 2
 0.04 Q ,
 ST creatinine kinase
 CK-MB 2
 Braunwald 2
 1 mm ST T
 가
 3)
 National Heart Lung and Blood Instit-
 ute(NHLBI) A, B, C
 D1 ,
 NHLBI D2, E F
 Thrombolysis in Myoc-
 ar dial Infarction(TIMI) grade 0 TIMI grade 1
 (ele-
 ctive,) [(subo-
 ptimal) , (elastic recoil)
 TIMI 0 TIMI 1 (bailout)]
 4) , ,
 (3) , ,
 (45 °)
 (discrete) (diffuse)
 5) 2
 (2)
 , 가 (, Q
 (2 10)
 (,),
 , Q ,
 스텐트의 종류
 Gianturco-Roubin Cordis wire coil

, Palmaz-Schatz Scimed NIR slot -
ted tube , Microstent wire zigzag

관동맥 풍선확장술과 스텐트 삽입술
10,000
IU ,
72 500 mg

200 mg 2
1 ,
(Pr -
mary PTCA and Stenting)

7 8 French
:
1 : 1 1.2 : 1

(1) 14
(2)
14

가 10%

95 9 98 7 ,
10

통계적 검증
IBM PC SPSSWIN 7.0

±
unpaired t
Chi -
quare P 0.05

결 과

환자구성
147 (1)
72 , (2) 75 ,

Table 1. Baseline clinical characteristics (147 patients)

	Group 1 (72) (<14ATM)	Group 2 (75) (≥ 14ATM)
Diagnosis(n)		
AMI	23	27
Unstable AP	21	7
Stable AP	28	21
Stent number(n)	77	77
Mean age(year)	56.7 ± 10.0	57.1 ± 9.8
Male sex(n)	51	59
Risk factors(n)	36	
Current smoker		40
Diabetes mellitus	16	12
Hypertension	30	31
Hyperlipidemia	9	17
Previous PTCA(n)	12	12
LVEF(%)	56.4 ± 9.5	53.7 ± 10.2
Number of diseased vessels(n)		
1	40	48
2	22	21
3	10	6

AMI = acute myocardial infarction ; AP = angina pec-
toris ; PTCA = percutaneous transluminal coronary
angioplasty ; LVEF = left ventricular ejection fraction
No significant difference between two groups in all
variables

56.9 ± 9.9
가 (; 1 70%, 2 78%).

환자들의 기본 특성 (Table 1)

(1) 23 ,
21 , 28 ,
(2) 27 ,
27 , 28

. 1 72 5 , 2
75 2 2

(slotted tube)
(wire coil, wire zigzag)

. 1 25%(18

), 2 16%(12)
, 1 56%(40), 2 64%(48)

확장 압력에 따른 시술결과

1
(elective) 55%(45) ,
(
30%
) 29%(22),
가 16%(10) , 2
69%(52) ,
17%(13) ,
가 14%(10)
(Table 2).
가 (1 42 , 2 59)
가 (1 36 ,
2 42),
, 3
, 45 , 20 mm
가
, (multiple lumen irregularities)
1 (1 51 , 2 15 p=0.04)
Table 3). 1 slotted
tube가 , 2 wire coil wire zigzag
. 1 19.8±7.1 mm,
2 16.3±4.1 mm 1
, 1 10.2±1.8
, 2 15.2±1.3
(p=0.001).
(1 3.2±0.4, 2 3.2
±0.3 mm),
(1 24±12.8 , 2 21.5±8.3)(Table 4).
2
, 1

Table 2. Indications for stenting (154 lesions)

	Group1	Group 2	Total
Elective	41	48	89
Restenosis	4	6	10
Suboptimal	22	13	35
Bailout	10	10	20

Bailout stenting means stenting due to dissection and acute elastic recoil.

ATM = atmosphere

No significant difference between two groups in all variables by Chi-square test

3 , 가 3 , Q
1 Q
. 2

Table 3. Angiographic Characteristics (n = 154 lesions)

Vessel dilated(n)	Group1 (<14ATM) n = 77	Group2 (≥14ATM) n = 77
LAD	42	59
LCX	15	7
RCA	19	11
Ramus	1	0
Lesion site(n)		
Ostial	1	3
Oroximal	36	42
Mid	35	31
Distal	5	1
Lesion characteristics(n)		
Calcified	3	3
Multiple lumen irregularities*	51	15
Thrombus	12	54
Occlusion†	6	6
Angle >45 °	15	16
Long lesion	14	19

LAD = left anterior descending artery ; LCX = left circumflex artery ; RCA = right coronary artery long lesion = longer than 20 mm

† All occlusion is not associated with acute myocardial infarction.

*p = 0.04 group 1 vs group 2 by Chi-square test

Table 4. Procedural characteristics between moderate and high pressure group (154 lesions)

Vessel dilated(n)	Group1 (<14ATM) n = 77	Group2 (≥14ATM) n = 77
Type and number of stents(n)		
Slotted tube	33	68*
Wire coil	18	1
Wire zigzag	26	8
Largest balloon size(mm)	3.2± 0.4	3.2±0.3
Stent length(mm)	19.8± 7.1†	16.3±4.1
Maximum pressure(mm) (ATM)	10.2± 1.8†	15.2±1.3
Total inflation time(sec)	24 ±12.8	21.5±8.3

ATM = atmosphere

Slotted tube stent means NIR and Palmaz-Schatz stent.

Wire coil stent means Gianturco-Roubin, and Cordis stent.

Wire zigzag stent means microstent.

* ; p<0.001 group 1 vs group 2 by Chi-square test

† ; p<0.001 group 1 vs group 2 by unpaired t-test

Table 5. Frequency of major adverse cardiac events (147 patients)

	Group 1 (< 14ATM) n = 72	Group 2 (14ATM) n = 75
Early events(0 - 14D)		
Spasm	0	1
Subacute thrombosis	0	0
Additive stent	0	1
Q.MI	3	0
Death	1	1
Late events(15D - 10M)		
Repeat PTCA	8	7
CABG	1	0
Q.MI	1	0
Death	0	0

D = day ; M = month ;
PTCA = percutaneous transluminal coronary angioplasty ;
CABG = coronary artery bypass graft ;
Q.MI = Q myocardial infarction
No significant difference between two groups in all variables by Chi-square test

1 , 가 1
6 Q
1
Q
2 10
1 8 ,
1 , Q 1 , 2
7
(Table 5).
50 15
8(53%)

스텐트 종류에 따른 시술 결과

가
slotted tube , slotted tube
가 (wire zigzag 1 ,
wire coil 5 , slotted tube 20 , p = 0.001).
가
가 slotted tube (wire zi -
gzag 1 , wire coil 3 , slotted tube 16 p = 0.05).

Table 6. Procedural characteristics between stent types (154 lesions)

	Wire zigzag (n = 35)	Wire coil (n = 19)	Slotted tube (n = 100)
Largest balloon size (mm)	3.2 ± 0.3	3.3 ± 0.5	3.2 ± 0.4
Stent length (mm)	24.9 ± 6.1 [#]	15.6 ± 8.9	16.3 ± 4.7
Maximum pressure (ATM)	11.1 ± 2.3	10.7 ± 1.9	13.6 ± 2.9*
Total inflation time (sec)	21.6 ± 12.9	25.6 ± 8.9 §	22.6 ± 10.5

[#]p = 0.05 wire zigzag vs wire coil group

*p = 0.000 wire coil vs slotted tube group

§p = 0.05 wire zigzag vs wire coil group

p value < 0.05 by ANOVA test between wire zigzag, wire coil, & slotted tube groups

slotted tube
slotted tube
(wire zigzag 13 , wire coil
11 , slotted tube 45), wire zigzag
(wire zigzag 8 (27%), wire coil 1
(6%), slotted tube 8 (8%) p = 0.042).

, 3
45 , 20 mm
가
3
가 , wire zigzag
, slotted tube
가 , wire coil 가
(Table 6).

2
wire zigzag Q
1 , wire coil Q
1 , slotted tube
4 , 가 4
2 10
wire zigzag 3 ,
wire coil 2 , slotted tube 10
, slotted tube 1 , Q
wire coil 1
(Table 7).

Table 7. Frequency of major cardiac event between stent types (147 patients)

	Wire zigzag (n = 34)	Wire coil (n = 17)	Slotted tube (n = 96)
Early events(0 - 14D)			
Spasm	0	0	4
Subacute thrombosis	0	0	0
Additive stent	0	0	4
Q.MI	0	0	0
Death	1	1	0
Late events(15D - 10M)			
Repeat PTCA	3	2	10
CABG	0	0	1
Q.MI	0	1	0
Death	0	0	0

D = day ; M = month ;
PTCA = percutaneous transluminal coronary angioplasty ;
CABG = coronary artery bypass graft ;
Q.MI = Q myocardial infarction
No significant difference between three groups in all variables by ANOVA test

고찰

(MACE)

가

가

wire zigzag

가

1977 Gruentzig

2% 10%

(20 8%),

(20 56%),

(20 35%) 6

30% 60%

7)(8)(13)

8 15%

(10 30%)

¹³⁾ 1993

Colombo

가

가 가

14

가 가

5 - 6)

King Angiography versus Intravas -
cular Ultrasound - directed Stent Placement (AV -
ID)

16

가 , 58%
9 - 12)

Palmaz - Schatz 16
(8 12)

14 - 17)

slotted tube Palmaz - Schatz
(trackability)

가

147 , 154
가
wire coil wire zigzag ,
slotted tube NIR
가 slotted tube Palmaz - Shaltz
가
3.2 mm 가 가
가
Palmaz - Schatz wire coil , wire zigzag
가

15.2
10.2
1
wire coil
wire zigzag
slotted tube
4
가 3
nitroglycerin , NIR 가
12 1
2 가
nitroglycerin 147 가
50 15
4 slotted tube
wire coil wire zigzag
가
0% 가
15 8 , 요 약
7
서 론 :
8 3 (37.5%),
7 5 (71%)
King 가
8 7 Palmaz - Schatz
1 wire coil cordis 가 Pal -
maz - Schatz
147 , 154
가
wire coil 1 14 (72 , 77
) , 2 14 (75 , 77
)
3 10

2 , 가
 , Q. 2
 10 ,
 , Q. .
 결 과 :
 1) (1)
 10.2 ± 1.8 , 15.2 ± 1.3
 (p=0.001).
 2)
 (51 , 15 p=0.04),
 가 (19.8 ±
 7.1 mm : 16.3 ± 4.1 mm p=0.002).
 3) wire coil wire zigzag
 , slotted tube
 (wire coil 1 ; 2 18 : 1, wire zigzag 1 ;
 2 26 ; 8, slotted tube 1 ; 2 33 ; 68).
 4)
 (2
 0 , 1 ,
 2 10 1 8 ,
 2 7 , Q. 1
 1).
 결 론 :
 wire coil
 wire zigzag ,
 가 .
 중심 단어 : .

REFERENCES

- 1) Schatz RS, Baim D, Leon M, Ellis SG, Goldberg S, Hirshfeld JW, et al. Clinical experience with the Palmaz-Schatz coronary stent (initial results of a multicenter study). *Circulation* 1991;83:148-61.
- 2) Roubin GS, Cannon AD, Agrawal SK, Macander PJ, Dean LS, Baxley WA, et al. Intracoronary stenting for acute and threatened closure complicating percutaneous transluminal coronary angioplasty. *Circulation* 1992;85:916-27.
- 3) Serruys PW, Jaegere P, Kiemeneij F, Macaya C, Rutsch W, Heyndrickx G, et al. A comparison of balloon-expandable-stent implantation with balloon angioplasty in patients with coronary artery disease. Benestent study group. *N Engl J Med* 1994;331 (8):489-95.
- 4) Fischman DL, Leon MB, Baim DS, Schatz RA, Savage MP, Penn I, et al. A randomized comparison of coronary-stent placement and balloon angioplasty in the treatment of coronary artery disease. *N Engl J Med* 1994;331:496-501.
- 5) Goldberg SL, Colombo A, Nakamura S, Almagor Y, Maiello L, Tobis JM. Benefit of intracoronary ultrasound in the deployment of Palmaz-Schatz stents. *J Am Coll Cardiol* 1994;24 (4):996-1003.
- 6) Colombo A, Hall P, Nakamura S, Almagor Y, Maiello L, Martini G, et al. Intracoronary stenting without anticoagulation accomplished with intravascular ultrasound guidance. *Circulation* 1995;91:1676-88.
- 7) Jaegere PPT, Eefting FD, Popma J, Serruys PW. Clinical trials on intracoronary stenting. *Semin Intervent Cardiol* 1996;1:233-45.
- 8) Leon MB, Popma JJ, Mintz GS, Pichard AD, Satler LF, Kent KM. An overview of US coronary stent trials. *Semin Intervent Cardiol* 1996;1:247-54.
- 9) Rosso RJ, Teirstein PS, for AVID Investigators. Angiography versus intravascular ultrasound-directed stent placement. *J Am Coll Cardiol* 1996;27:306A.
- 10) Waksman R, Shen Y, Ghazzal Z, Scott NA, Douglass J, King III AB. Optimal balloon inflation pressures for stent deployment and correlates of stent thrombosis and in stent restenosis. *Circulation (supplement)* 1996;94 (8):1511S.
- 11) Vardi GM, Fishman RF, Ailwadi GA, Parker MA, Meyers SN, Davidson CJ. Interaction of balloon size and pressure for optimal stent deployment using intracoronary ultrasound guidance. *Circulation (supplement)* 1996;94 (8):1531S.
- 12) Sainous J, Silvestri M, Bayet G, Simeoni JB, Roquerbert PO, Quatre JM, et al. Coronary artery stenting without anticoagulation, intravascular ultrasound or high pressure balloon: Immediate results and one month follow-up. *Circulation (supplement)* 94 (8):1996:1532S.
- 13) Leon MB, Wong SC. Intracoronary stents: A breakthrough technology or just another small step. *Circulation* 1994;89 (3):1323-27.
- 14) Elezi S, Kastrati A, Pache J, Dirschinger J, Schomig A. Is high pressure inflation necessary for optimal stenting? *J Am Coll Cardiol (abstracts-poster)* 1998:16A (1005-78).
- 15) Dirschinger J, Hausleiter J, Schuhler J, Giehl W, Walter H, Pache J, et al. High versus normal balloon pressure dilatation for coronary stent placement. 6-month clinical and angiographic results from a randomized multicenter trial. *J Am Coll Cardiol (abstracts-poster)* 1998:16A (1005-79).
- 16) Stratiev V, Chevalier B, Hlatt B, Guyon P, Royer T. Does systematic high pressure deployment improve clinical outcome after PalmazSchatz coronary stent implantation? *J Am Coll Cardiol (abstracts-poster)* 1998:16A (1005-80).
- 17) Blanco J, Weintraub WS, Shen Y, Chronos H, McAdams D, Chronos N, et al. Cost impact of high pressure inflation and therapy with aspirin and ticlopidine after coronary stenting. *J Am Coll Cardiol (abstracts-poster)* 1998:16A (1005-80).