

규정압력(Nominal Pressure)에 의한 관동맥 스텐트의 확장 정도 : 혈관내 초음파에 의한 연구

김기영¹ · 허승호² · 조용원³

Optimal Stent Expansion by Nominal Pressure Balloon Inflation : an Intravascular Ultrasound Study

Ki-Young Kim, MD¹, Seung-Ho Hur, MD² and Yong-Won Cho, MD³

¹Division of Cardiology, Heart Center, Colledge of Medicine, Konyang University, Daejeon,

²Department of Internal Medicine, ³Neurology, School of Medicine, Keimyung University, Daegu, Korea

ABSTRACT

Background and Objectives : Intravascular ultrasound (IVUS), following stent implantation, demonstrated a significant degree of underexpansion, despite the initial appearance of an angiographically successful deployment, in first-generation stents. With improvements in stent designs and delivery systems, the current-generation of stents appear to achieve optimal stent expansion. The purpose of this study was to evaluate optimal stent expansion, by nominal pressure balloon inflation, in the current generation of stents. **Subjects and Methods :** We evaluated 30 patients having had Nir-Sox, Tristar, S670 or Bx Velocity stents successfully deployed at nominal pressure (7 -10 atm) with delivery balloon system, between March and September 2001, using IVUS. IVUS criterion for optimal stent expansion was defined as a minimal stent area (MSA) ratio of 0.8 of the average reference lumen area. **Results :** The mean nominal balloon pressure was 8.87 ± 0.9 atmospheres and the mean stent size was 3.38 ± 0.45 mm. In reference segments, the minimal lumen diameter and average lumen area, found from the IVUS, were 3.18 ± 0.51 mm and 8.88 ± 2.92 mm², respectively. In stented segments, the minimal stent diameter and MSA were 2.55 ± 0.46 mm and 6.10 ± 2.08 mm², respectively. In only 11 of the 30 patients (36.7%) was the optimal stent expansion, by IVUS, achieved. **Conclusion :** Despite the development of a balloon delivery system for the current generation of stents, 63.3% of our study patients did not achieve optimal stent expansion, by IVUS, following nominal balloon inflation. Therefore, additional procedure will be required for optimal stent expansion in the current generation of stents. (**Korean Circulation J 2002;32(8):666-673**)

KEY WORDS : Ultrasonography, interventional ; Coronary disease.

서 론

taneous Coronary Intervention) 가

(Percu-

(ath-

: 2002 4 16

: 2002 5 31

: 2002 7 24

: , 700 - 712

194

: (053) 250 - 7949 · : (053) 250 - 7434 · E - mail : shur@dsmc.or.kr

eromatous plaque)

(IVUS : Intravascular ultrasound)

대상 및 방법

대상 환자

2001 3 2001 9

가

70%

¹⁾

30

가

가

스텐트 삽입술

¹⁾²⁾

가

2

Nakamura ²⁾ 1

Palmaz -

150 U/kg(

Schartz

10000 U)

80%

, Schiele ³⁾

/ 가 1 : 1

(12)

60%

(7 10

NIR - SOXTM(Boston Scientific Corp.) 7

; TRISTARTM(GUIDANT/Advanced Cardiovascular System Inc.) 8

; S670TM(Medtronic) 8

; Bx VELOCITYTM(Cordis/Johnson & Johnson)

10

(MSA : Minimal Stent

Area)

가

⁴⁻⁷⁾

관동맥 조영술

(QCA : quantitative coronary

angiography) computer - assisted

Digital Cardiac Imaging(PHILIPS)

(reference ves-

sel diameter), (% diameter stenosis),

(minimal lumen diameter)

가

, 1

가

radial strength,

2

가

¹⁰⁾

2

American College

of Cardiology/American Heart Association(ACC/

AHA) Task Force¹¹⁾

가

가

혈관내 조영파

CLEARVIEW(Cardiovascular Ima-

ging System/Boston Scientific Corp., San Jose, Cali-

(optimal stent expansion)

fornia) 30 MHz (3.2 Fr monorail ultrasound, single piezoelectric crystal transducer mechanically rotating at 1,800 rpm)

(CSA Index) , 가 0.8

200 (Fig. 1).

μg 10 20 mm automatic pull - back system 0.5 mm/sec S - VHS off - line

(1) incomplete stent apposition(가) (2) plaque protrusion() (3) edge dissection(가) (4) thrombus(echolucent mass)

가 가

통계적 분석 SPSS version 10.0(SPSS Inc., Chicago, Illinois)

혈관내 조음파 분석

(1) (CSA : cross sectional area) (minimal stent diameter) (2) (maximal stent diameter) (3) (reference lumen CSA) 가 5 10 mm

paired student's t-test wilcoxon signed rank test p 0.05 가 가

결 과

대상 환자군의 임상적 특징

30 21 (70%), 9 (30%) 58.2 ± 8.6 8 (27%), 8 (27%) 2 (7%), 3

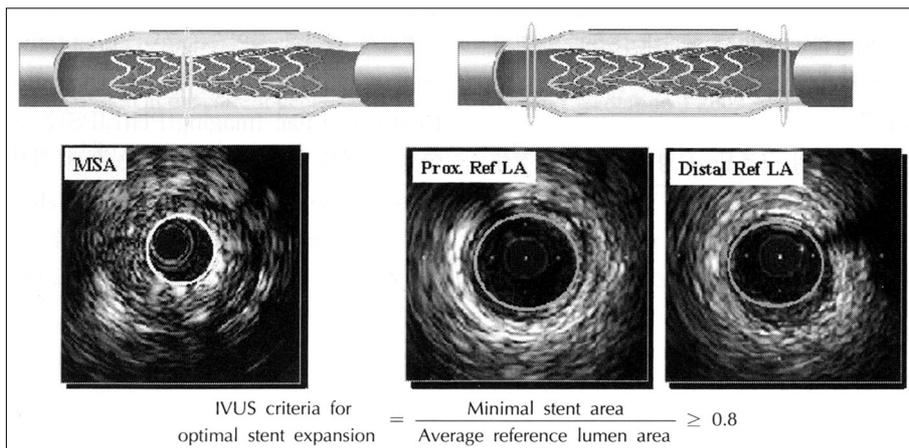


Fig. 1. Intravascular ultrasound criteria for optimal stent expansion. MSA : minimal stent area, Prox. Ref LA : proximal reference lumen area, Distal Ref LA : distal reference lumen area, IVUS : intravascular ultrasound.

(10%)
 17 (57%), 7 (23%),
 6 (20%) . NIR -
 SOX™(Boston Scientific Corp.) 10 (33%), TRIS-
 TAR™(GUIDANT/Advanced Cardiovascular System
 Inc.) 8 (27%), Bx VELOCITY™(Cordis/Johnson &
 Johnson) 8 (27%), S670™(Medtronic) 4 (13%)
 (Table 1).

관동맥 조영술 및 시술 결과

ACC/AHA
 A 6 (20%), B1 10 (33%), B2 7
 (23%), C 7 (23%) ,
 16 (53%), 4 (13%), 10
 (33%) .
 3.52 ± 0.48 mm,

Table 1. Clinical and angiographic characteristics of patients

| | |
|--------------------------|------------------------------|
| Number | 30 |
| Age (years) | 58.2 ± 8.6 |
| Male/Female | 21 (70)/9 (30) |
| ACC/AHA class (%) | |
| A/B1/B2/C | 6 (20)/10 (33)/7 (23)/7 (23) |
| Diagnosis (%) | |
| SA/UA/AMI | 17 (57)/7 (23)/6 (20) |
| Medical history (%) | |
| Diabetes | 8 (27) |
| Hypertension | 8 (27) |
| Smoking | 19 (63) |
| Prior MI | 2 (7) |
| Prior PTCA or CABG | 3 (10) |
| Multi-vessel disease (%) | 7 (23) |
| Coronary artery (%) | |
| LAD/LCX/RCA | 16 (53)/4 (13)/10 (33) |
| Stent type (%) | |
| NIR | 10 (33) |
| TRISTAR | 8 (27) |
| Bx VELOCITY | 8 (27) |
| S670 | 4 (13) |

ACC/AHA : American College of Cardiology/American Heart Association, SA : stable angina, UA : unstable angina, AMI : acute myocardial infarction, PTCA : percutaneous transluminal coronary angioplasty, CABG : coronary artery bypass graft, LAD : left anterior descending, LCX : left circumflex, RCA : right coronary artery

77.7 ± 13.7%, 0.81 ±
 0.42 mm . 3.38 ± 0.45 mm,
 17.50 ± 4.77 mm, /
 1.05 ± 0.1, 8.87 ± 0.90
 . 0.81 ± 0.42 mm
 3.05 ± 0.54 mm , 77.7 ± 13.7%
 9.3 ± 11.6% 가
 (p<0.05)(Table 2).

혈관내 초음파 결과

8.88 ±
 2.92 mm², 3.18 ± 0.51 mm
 , 2.56 ± 0.46 mm,
 2.90 ± 0.44 mm, 0.88 ± 0.07,
 6.10 ± 2.08 mm² (Ta-
 ble 3).

Table 2. Results of quantitative coronary angiography

| | |
|------------------------------------|--------------|
| Reference vessel diameter (mm) | 3.52 ± 0.48 |
| Minimal lumen diameter (mm) | |
| pre-intervention | 0.81 ± 0.33 |
| post-stent | 3.05 ± 0.54* |
| Lesion stenosis (%) | |
| pre-intervention | 77.7 ± 13.7 |
| post-stent | 9.3 ± 11.6* |
| Mean stent length (mm) | 17.50 ± 4.77 |
| Mean stent size (mm) | 3.38 ± 0.45 |
| Mean norminal pressure (atm) | 8.87 ± 0.90 |
| Stent balloon inflation time (sec) | 28.0 ± 11.9 |
| Stent balloon/artery ratio | 1.05 ± 0.1 |

* : p<0.05 vs pre-intervention

Table 3. Results of post-stent quantitative intravascular ultrasound

| | |
|---------------------------------------|-------------|
| Reference segment | |
| Minimal diameter (mm) | 3.18 ± 0.51 |
| Average lumen area (mm ²) | 8.88 ± 2.92 |
| Stented segment | |
| Minimal diameter (mm) | 2.55 ± 0.46 |
| Maximal diameter (mm) | 2.90 ± 0.44 |
| Symmetry index | 0.88 ± 0.07 |
| Minimal stent area (mm ²) | 6.10 ± 2.08 |

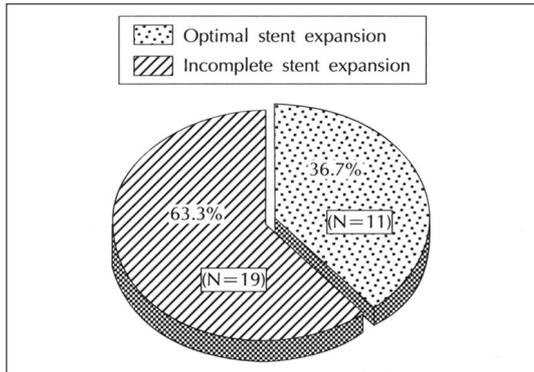


Fig. 2. Percents of optimal stent expansion in intravascular ultrasound. N : number of patients.

(CSA Index>0.8) 30 11 (37%)
 , 19 (63%)
 (Fig. 2).
 19 가 가 16
 (84%) 가
 (adjunctive balloon dilatation) (
 : 3.39 ± 0.38 mm, : 13.74 ± 1.15
 mm)

2.85 ± 0.43 mm 3.16 ± 0.47 mm
 14.3%가,
 5.85 ± 1.76 mm² 7.36 ± 1.72 mm² 27.6%가
 가 가
 (p<0.001).

가 (p>0.05).

(3.52 ± 0.51 vs 2.98 ± 1.10, p>0.05).

가 (p>0.05)

(9.81 ± 2.84 vs 7.29 ± 2.42 mm², p<0.05)

Table 4. Clinical, stent, angiographic and IVUS characteristics in the optimal stent expansion and incomplete stent expansion groups

| | Optimal stent expansion (n=11) | Incomplete stent expansion (n=19) |
|-----------------------------|--------------------------------|-----------------------------------|
| Clinical | | |
| Sex (M/F) | 9/2 | 12/7 |
| Age (yrs) | 58.7 ± 7.9 | 57.9 ± 9.1 |
| Smoker | 6 (55%) | 13 (63%) |
| Diabetes | 4 (36%) | 4 (21%) |
| Hypertension | 3 (27%) | 5 (26%) |
| Previous MI | 0 (0%) | 2 (11%) |
| Stent | | |
| type | | |
| Bx | 2 (18%) | 6 (32%) |
| NIR | 3 (27%) | 7 (37%) |
| S670 | 1 (9%) | 3 (16%) |
| Tristar | 5 (46%) | 3 (16%) |
| size (mm) | 3.32 ± 0.46 | 3.42 ± 0.45 |
| length (mm) | 7.55 ± 4.68 | 17.47 ± 4.95* |
| nominal pr. (atm) | 8.82 ± 0.87 | 8.89 ± 0.94 |
| Angiographic | | |
| pre-MLD (mm) | 0.69 ± 0.44 | 0.79 ± 0.44 |
| post-MLD (mm) | 2.91 ± 0.59 | 3.10 ± 0.53 |
| re-DS (%) | 77.5 ± 15.9 | 77.7 ± 12.7 |
| post-DS (%) | 10.6 ± 6.8 | 14.8 ± 8.8 |
| ref. LD (mm) | 2.98 ± 1.10 | 3.52 ± 0.51 |
| IVUS | | |
| MSD (mm) | 2.56 ± 0.38 | 2.56 ± 0.52 |
| SI | 0.89 ± 0.06 | 0.88 ± 0.08 |
| ref. CSA (mm ²) | 7.29 ± 2.42 | 9.81 ± 2.84 [†] |
| MSA (mm ²) | 6.12 ± 1.95 | 6.10 ± 2.21 |
| stent expansion (%) | 84.6 ± 5.75 | 62.41 ± 1.65 [‡] |

* : p<0.05 optimal stent expansion, † : p<0.05 vs optimal stent expansion, ‡ : p<0.001 vs optimal stent expansion, MI : myocardial infarction, pr. : pressure, atm : atmosphere, MLD : minimal lumen diameter, DS : diameter stenosis, ref. LD : reference lumen diameter, IVUS : intravascular ultra-sound, MSD : minimal stent diameter, SI : symmetry index, ref. CSA : reference cross sectional area, MSA : minimal stent area

(62.3 ± 11.6 vs 84.6 ± 5.75, p<0.001) (Table 4).

incomplete apposition 4 (13%), edge dissection 2 (7%), plaque protrusion 2 (7%), thrombi 0

고찰

10% 가 0.8 or 0.9 ,⁶⁾ Gap() 0.1 mm 가 0.7 ,⁵⁾ 9 mm² FFR(Fractional Flow Reserve) 0.96 가¹⁵⁾

12) Palmaz - Scharz Hoffmann 291 9.3 ± 11.6% 6.10 ± 2.08 mm²

Blasini¹³⁾ (10) (14 16) Takano¹⁶⁾ 32 Palmaz - Scharz 225 (% of the manufacturer 's expected stent area) 62%

3.05 ± 0.54 mm 2.55 ± 0.46 mm (7 10) (p<0.05). CRUISE(Can Routine Ultrasound Influence Stent Expansion) 2.56 ± 0.46 mm 3.38 ± 0.45 mm 75.6%

가) 9 (Target Vessel Revascularization)⁹⁾ 6.10 ± 2.08 mm² 9.14 ± 2.41 mm² 67% Takano¹⁶⁾

4-7) de Feyter⁵⁾ 가 0.8 11 (36.7%) 6 19 (63.3%) Mo-

ussa⁶⁾ 425 (496) 가 16 (84.2%) 가 Hur¹⁷⁾

Ellis¹⁴⁾ 781 가 가 가 12 , 36 가 가

REFERENCES

- 1) Fischman DL, Leon MB, Baim DS, Schatz RA, Savage MP, Penn I, Detre K, Veltri L, Ricci D, Nobuyoshi M. *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.*
- 2) Nakamura S, Colombo A, Gaglione A, Almagor Y, Goldberg SL, Maiello L, Finci L, Tobis JM. *Intracoronary ultra-sound observation during stent implantation. Circulation 1994;89:2026-34.*
- 3) Schiele F, Meneveau N, Vuilleminot A, Zhang DD, Gupta S, Mercier M, Danchin N, Bertrand B, Bassand JP. *Impact of intravascular ultrasound guidance in stent deployment on 6-month restenosis rate: a multicenter, randomized study comparing two strategies-with and without intravascular ultrasound guidance. Am Coll Cardiol 1998;32:320-8.*
- 4) Albiero R, Rau T, Schuler M, di Mario C, Reimers B, Mathey DG, Tobis JM, Schofer J, Colombo A. *Comparison of immediate and intermediate-term results of intravascular ultra-sound versus angiography guided Palmaz-Schatz stent implantation in matched lesions. Circulation 1997;96:2997-3005.*
- 5) de Feyter PJ, Kay P, Disco C, Serruys PW. *Reference chart derived from post-stent-implantation intravascular ultrasound predictors of 6-month expected restenosis on quantitative coronary angiography. Circulation 1999;100:1777-83.*
- 6) Moussa I, Moses J, di Mario C, Albiero R, de Gregori J, Adamian M, di Francesco L, Colombo A. *Does the specific intravascular ultrasound criterion used to optimize stent expansion have an impact on the probability of stent restenosis? Am J Cardiol 1999;83:1012-7.*
- 7) Mintz GS, Popma JJ, Pichard AD, Kent KM, Satler LF, Chuang YC, Griffin J, Leon MB. *Intravascular ultrasound predictors of restenosis after percutaneous transcatheter coronary revascularization. J Am Coll Cardiol 1996;27:1678-87.*
- 8) Stone GW, Hodgson JM, St Goar FG, Frey A, Mudra H, Sheehan H, Linnemeier TJ. *Improved procedural results of coronary angioplasty with intravascular ultrasound-guided balloon sizing. Circulation 1997;95:2044-52.*
- 9) Fitzgerald PJ, Oshima A, Hayase M, Metz JA, Bailey SR, Baim DS, Cleman MW, Deutsch E, Diver DJ, Leon MB, Moses JW, Oesterle SN, Overlie PA, Pepine CJ, Safian RD, Shani J, Simonton CA, Smalling RW, Teirstein PS, Zidar JP, Yeung AC, Kuntz RE, Yock PG. *Final results of the can routine ultrasound influence stent expansion (CRUISE) study. Circulation 2000;102:523-30.*
- 10) Gorge G, Haude M, Ge J, Voegele E, Gerber T, Rupprecht HJ, Meyer J, Erbel R. *Intravascular ultrasound after low and high inflation pressure coronary stent implantation. J Am Coll Cardiol 1995;26:725-30.*
- 11) Ryan T, Faxon D, Gunnar R. *Guidelines for percutaneous transluminal coronary angioplasty: a report of American College of Cardiology/American Heart Association Task Force on Assessment of diagnosis and Therapeutic Cardiovascular Procedures. J Am Coll Cardiol 1988;12:529-45.*
- 12) Hoffmann R, Mintz GS, Mehran R, Pichard AD, Kent KM, Satler LF, Popma JJ, Wu H, Leon MB. *Intravascular ultrasound predictors of angiographic restenosis in lesions treated with Palmaz-Schatz stents. J Am Coll Cardiol 1998;31:43-9.*
- 13) Blasini R, Neumann FJ, Schmitt C, Bokenkamp J, Schomig A. *Comparison of angiography and intravascular ultrasound for the assessment of lumen size after coronary stent placement: impact of dilatation pressures. Cathet Cardiovasc Diagn 1997;42:113-9.*
- 14) Ellis SG, Brown KJ, Ellert R, Howell GL, Miller DP, Flowers NM, Ott PA, Keys T, Loop FD, Topol EJ. *Cost of cardiac care in the three years after coronary catheterization in a contained care system: critical determinants and implications. J Am Coll Cardiol 1998;31:1306-13.*
- 15) Fearon WF, Luna J, Samady H, Powers ER, Feldman T, Dib N, Tuzcu M, Cleman MW, Chou TM, Cohen DJ, Ragosta M, Takagi A, Jeremias A, Fitzgerald PJ, Yeung AC, Kern MJ, Yock PG. *Fractional flow reserve compared with intravascular ultrasound guidance for optimal stent deployment. Circulation 2001;104:1917-22.*
- 16) Takano Y, Yeatman LA, Higgins JR, Currier JW, Ascencio E, Kopelson KA, Tobis JM. *Optimizing stent expansion with new stent delivery systems. J Am Coll Cardiol 2001;38:1622-7.*
- 17) Hur SH, Kitamura K, Morino Y, Honda Y, Jones M, Korr KS, Reen B 3rd, Cooper CJ, Niess GS, Christie L, Corey W, Messenger J, Yock PG, Cummins F, Fitzgerald PJ. *Efficacy of post-deployment balloon dilatation for current generation stent as assessed by intravascular ultrasound. Am J Cardiol 2001;88:1114-9.*