Journal of
Cardio - Thoracic Medicine

http://jctm.mums.ac.ir

Optimal Stent Expansion by Stent Balloon Multiple Inflation at Nominal Pressure in Resistant Lesions: A New Technique

Amir Hossein Khosh Nasab[1], Mahmoud Mohammadzadeh Shabestri[2], Ali Eshraghi[2], Majid Jalalyazdi[2]*

[1] *Resident of Cardiology, Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran*
[2] *Cardiologist, Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran*

ARTICLE INFO

Article type:
Original Article

Article history:
Received: 5 May 2015
Revised: 21 May 2015
Accepted: 22 July 2015

Keywords:
Coronary Artery Disease
Interventional Cardiology
Stent

ABSTRACT

Introduction: This study aimed to evaluate the effects of four-time inflation of the stent balloon at nominal pressure on optimal stent expansion in resistant lesions.
Materials and Methods: This interventional study was conducted on 39 patients with coronary artery lesions, in whom Zotarolimus-eluting stents (N=20), Paclitaxel-eluting stents (N=11) and other stents (N=8) were deployed four times at nominal inflation pressure and increased inflation times (5, 15, 30 and 45 seconds). After the deployments, enhanced stent visualization imaging technique (IC stent) was used to assess stent placement and artery expansion.
Results: In this study, early success rate was estimated at 79.5% using the enhanced stent visualization imaging technique. In addition, major adverse cardiac event (MACE) was determined at 2.6%. Also, conventional methods resulted in lower success rate and higher MACE in resistant lesions.
Conclusion: According to the results of this study, four-time stent balloon inflation at nominal pressure could allow adequate stent expansion in resistant lesions leading to lower MACE.

►*Please cite this paper as:*
Khosh Nasab AH, Mohammadzadeh Shabestri M, Eshraghi A, Jalalyazdi M. Optimal Stent Expansion by Stent Balloon Multiple Inflation at Nominal Pressure in Resistant Lesions: A New Technique. J Cardiothorac Med. 2015; 3(3):340-343.

Introduction

Coronary stent under-expansion may lead to restenosis, or early and late stent thrombosis of the lesion after coronary interventions (1-5). Stent expansion has a close relationship with inflation pressure of the stent balloon. In one study, Stone et al. Observed that drug-eluting stents (DESs) could expand more as the inflation pressure increased from 12 to 18 atm (6). According to the literature, high-pressure inflation (20 atm) with 0.5-mm larger balloon could result in adequate DES expansion (7).

In this regard, the subsequent incidence of restenosis could be diminished using a focal expanding balloon for stent optimization (8). In addition to inflation pressure, several studies have investigated the relationship between balloon inflation time and stent expansion. For instance, in an in vitro experimental study, the use of plastic vials indicated that an inflation time of 30 seconds or more was adequate for the optimum stent deployment, expansion and apposition (9).

In human data, Asano et al. Reported that larger expansion of DES could be obtained by a 60-second inflation at the pressure of 14 atm, compared to a 10-second inflation (10). In another research, Kawasaki et al. Compared the expansion of Sirolimus-eluting stents (SES) and Paclitaxel-eluting stents (PES) at inflation times of 20 seconds and 60 seconds, concluding that a 60-second inflation time resulted in the optimal stent expansion (11).

**Corresponding author:* Majid Jalalyazdi, Mashhad University of Medical Sciences, Mashhad, Iran. Tel: +989155067246; Fax: +985138022748; E-mail: jalalyazdim@mums.ac.ir

High-pressure post-dilatation of stents with non-compliant balloons has been proposed as a method to avoid stent under-expansion and acute stent malapposition. However, this approach could lead to acute vessel wall injury (e.g., edge dissections), imposing additional costs for non-compliant balloons. If multiple, short inflations are able to provide better stent expansion, this method could be useful in performing percutaneous coronary intervention (PCI) for critical lesions.

On the other hand, if the four-time stent balloon inflation allows adequate stent expansion, there will be no need for another post-dilatation balloon in some cases, which could reduce the costs of coronary interventions, as well as the associated complications.

Materials and Methods

Study Population

This prospective interventional study compared multiple low pressure balloon stent inflation to conventional technique in stent deployment and inflation times were selected at 5, 15, 30 and 45 seconds based on our protocol. The study protocol was approved by the institutional review board of Mashhad University of Medical Sciences. The study population consisted of 39 patients presenting with de novo coronary artery lesions, in which coronary stents were placed during October 2013-October 2014 in Imam Reza Hospital of Mashhad, Iran. Patients with acute coronary syndrome, chronic total occlusion, hemodialysis and severe calcified lesions were excluded from this study.

Study Procedures

Initially, a 6-Fr guiding catheter was placed in the coronary artery for PCI via the transradial or transfemoral sheaths, and heparin (8000 units) was dministered intravenously before the PCI procedure. After a 0.014-in guide wire crossed the stenotic lesions, the lesions were dilated using a balloon in all cases before stent placement. Stent diameters ranged between 2.1-3.3 mm (mean: 2.76±0.3 mm), and stent lengths ranged between 12-38 mm (mean: 22.9±8.4 mm).

In all studied patients, DES implantation was performed with the stents placed in the lesions and inflated four times at the nominal inflation pressure (mean: 11.3±2.3 atm). In this process, we used stent delivery balloons at inflation times of 5, 15, 30 and 45 seconds. After the fourth inflation, the stent lesions were examined by IC stent, and if adequate expansion was not obtained, non-compliant balloons were used.

Results

In total, 21 male and 18 female patients with the mean age of 59.5±11 years were enrolled in this study. Stent-delivered lesions had 75-99% stenosis, and the lesions (type C) were detected in the right coronary artery (RCA) in 15 cases, saphenous vein graft (SVG) in one case, left anterior descending artery (LAD) in 16 cases and left circumflex artery (LCX) in seven cases. Written informed consent was obtained from all the subjects prior to PCI.

We analyse data with SPSS software version 18. In this study, stent balloon multiple inflation was more successful in female patients; however, the difference between male and female subjects was not statistically significant (88.9% vs. 71.4%, P=0.24). Moreover, this new technique achieved more success in RCA (92.3%), LAD (85.7%) and LCX (80%), respectively; nevertheless, the difference was not considered to be statistically significant.

In 32 patients, the stenosis was detected in the main vessel, and the success rate was estimated at 87.5 %, while in seven patients, the stenosis was detected in the obtuse marginal or diagonal branches, with the success rate of 42.8%. According to the results of Fisher's exact test, lesion and stent lengths, as well as lesion calcifications, had no significant effects on the success rate (P=0.96). More details are listed in Table 1 and Table 2.

Discussion

According to the results of this study, adequate stent expansion is essential for maintaining satisfactory clinical outcomes after coronary stenting in patients with coronary artery disease.

Several studies have investigated the relationship between stent expansion and the inflation pressure of stent balloon. Stent expansion could be influenced by stent delivery pressure, as well as the stent structure. In onestudy, Javaid et al. Stated that based on the MUSIC criteria, stent expansion is inadequate in 80% of the patients with SES and 63% of the patients with PES (inflation pressure: 14 atm).

Table 1. Lesion characteristics

lesion characteristics		Number	Mean ± SD	*P* value
Lesion length	Success	31	20.42 ± 8.06	0.73
	Failed	8	19.25 ± 9.05	
Age	Success	31	59.10 ± 9.50	0.78
	Failed	8	61.00 ± 17.98	
Stent length	Success	31	23.03 ± 8.22	0.87
	Failed	8	22.50 ±9.68	
Stent diameter	Success	31	2.79 ± 0.28	0.28
	Failed	8	2.68 ± 0.40	
Max stent inflation force	Success	31	11.52 ± 1.21	0.97
	Failed	8	11.50 ± 1.41	

Table 2. Characteristics of patients and lesion

characteristics of patients and lesion		Success	Failed	*P* value
CRF	No	30 (78.9%)	8 (21.1%)	>0.99
	Yes	1(100%)	0 (0%)	
Smoking	No	27 (84.4%)	5 (15.6%)	>0.99
	Yes	4 (57.1%)	3 (42.9%)	
HTN	No	18 (69.2%)	8 (30.8%)	0.035
	Yes	13 (100%)	0 (0%)	
DM	No	28 (80%)	7 (20%)	>0.99
	Yes	3 (75%)	1 (25%)	
HLP	No	27 (77.1%)	8 (22.9%)	0.563
	Yes	4 (100%)	0 (0%)	
IHD	No	28 (77.8%)	8 (22.2%)	>0.99
	Yes	3 (100%)	0 (0%)	
Lesion calcification	No	23 (79.3%)	6 (20.7%)	0.96
	Yes	8 (80.0%)	2 (20.0%)	
NC Balloon	No	31 (86.1%)	5 (13.9%)	0.006
	Yes	0 (0%)	3 (100%)	

CFR: Chronic renal failure
HTN: Hypertension
DM: Diabetes mellitus
HLF: Hyperlipidemia
IHD: Ischaemic Heart Disease

Moreover, they claimed that stent expansion improved to 48% in SES and 34% in PES patients at the inflation pressure of 20 atm (12).

According to the findings of this study, high-pressure inflation (20 atm) with 0.5-mm larger balloon resulted in adequate SES expansion (7). In addition, the incidence of stenosis was significantly lower in the high-pressure inflation group (9%) compared to the subjects receiving normal pressure (22%) (8).

Early and late stent thrombosis could be associated with the under-expansion of stents. In a European study, the incidence rate of angiographically documented stent thrombosis in DES was reported to be 1.3 per 100 person-years (13), while it was estimated at 0.54 per 100 person-years in a multicenter study conducted in Japan (14). In the current study, we observed that the use of multiple stent balloon inflation at nominal pressure could result in the optimal expansion of DESs.

On the other hand, few studies have focused on the relationship between balloon inflation time and stent expansion. In an experimental study, Trindade et al. used plastic vials with 3.5-mm internal diameter to examine stainless-steel stent expansions with balloon inflation times between 5-60 seconds. According to their results, the inflation time of 30 seconds or more was adequate for the optimum stent deployment, expansion and apposition (9).

In the present study, the most effective inflation time was up to 45 seconds, and optimal expansion could be achieved by multiple stent inflation using a stent balloon, instead of another high-pressure balloon, after deployment. Therefore, it was concluded that additional stent expansion could be obtained using multiple stent balloon inflation, and longer inflation times resulted in the more adequate expansion of the stents.

Conclusion

According to the findings of the current study, multiple low-pressure balloon inflation may be better than high-pressure inflation and result in better stent expansion. Therefore, it is recommended that routine multiple low-pressure stent balloon inflation be used for stent delivery. Recently, many specialists tend to use another high-pressure balloon after stent deployment in order to prevent stent malapposition, especially in DESs. In the present study, additional high-pressure inflation by the same stent balloon was required in 7% of the patients. In conclusion, multiple low-pressure stent balloon inflation could reduce the costs of PCI and the associated complications by decreasing the number of PCI balloons.

Conflict of Interest

The authors declare no conflict of interest.

References

1. Hoffmann R, Mintz GS, Mehran R, Pichard AD, Kent KM, Satler LF, et al. Intravascular ultrasound predictors of angiographic restenosis in lesions treated with Palmaz-Schatz stents. J Am Coll Cardiol. 1998; 31:43-9.
2. Kastrati A, Schomig A, Elezi S, Schuhlen H, Dirschinger J, Hadamitzky M, et al. Predictive factors of restenosis after coronary stent placement. J Am Coll Cardiol. 1997; 30:1428-36.
3. Kasaoka S, Tobis JM, Akiyama T, Reimers B, Di Mario C, Wong ND, et al. Angiographic and intravascular ultrasound predictors of in-stent restenosis. J Am Coll Cardiol. 1998; 32:1630-5.
4. Nakazawa G. Stent thrombosis of drug eluting stent: pathological perspective. J Cardiol. 2011; 58:84-91.
5. Takayama T, Hiro T, Hirayama A. Stent thrombosis and drugeluting stents. J Cardiol. 2011; 58:92-8.
6. Stone GW, St Goar FG, Hodgson JM, Fitzgerald PJ, Alderman EL, Yock PG, et al. Analysis of the relation between stent implantation pressure and expansion. Optimal Stent Implantation (OSTI) Investigators. Am J Cardiol. 1999; 83:1397-400.
7. Cheneau E, Satler LF, Escolar E, Suddath WO, Kent KM, Weissman NJ, et al. Underexpansion of sirolimus-eluting stents: incidence and relationship

to delivery pressure. Catheter Cardiovasc Interv. 2005; 65:222-6.
8. Mori F, Tsurumi Y, Hagiwara N, Kasanuki H. Impact of postdilatation with a focal expanding balloon for optimization of intracoronary stenting. Heart Vessels. 2007; 22:152-7.
9. Trindade IS, Sarmento-Leite R, Santos de Freitas M, Gottschall CA. Determination of the minimum inflation time necessary for total stent expansion and apposition: an in vitro study. J Invasive Cardiol. 2008; 20:396-8.
10. Asano T, Kobayashi Y, Fukushima K, Iwata Y, Kitahara H, Ishio N, et al. Effect of balloon inflation time on expansion of sirolimus-eluting stent. Heart Vessels. 2009; 24:335-9.
11. Kawasaki T, Koga H, Serikawa T, Orita Y, Ikeda S, Mito T, et al. Impact of a prolonged delivery inflation time for optimal drug-eluting stent expansion. Catheter Cardiovasc Interv. 2009; 73:205-11.
12. Javaid A, Chu WW, Cheneau E, Clavijo LC, Satler LF, Kent KM, et al. Comparison of Paclitaxel-eluting stent and sirolimus-eluting stent expansion at incremental delivery pressures. Cardiovasc Revasc Med. 2006; 7:208-11.
13. Daemen J, Wenaweser P, Tsuchida K, Abrecht L, Vaina S, Morger C, et al. Early and late coronary stent thrombosis of sirolimus-eluting and Paclitaxel-eluting stents in routine clinical practice: data from a large two-institutional cohort study. Lancet. 2007; 369:667-78.
14. Kimura T, Morimoto T, Nakagawa Y, Tamura T, Kadota K, Yasumoto H, et al. Antiplatelet therapy and stent thrombosis after sirolimus-eluting stent implantation. Circulation. 2009; 119:987-95.