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Comparison of pre-dilation with a non-compliant balloon versus a dual wire scoring balloon for coronary stenting

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ABSTRACT

Purpose: The aim of this study was to determine the influence of lesion preparation using the dual wire scoring balloon on stent expansion and long-term outcomes. Methods: Forty-six consecutive de novo lesions treated with a single >2.5 mm drug-eluting stent under intravascular ultrasound guidance, using two implantation strategies, were randomly assigned to: 1) pre-dilation with a non-compliant balloon (NC group; n = 23) or 2) pre-dilation with a dual wire scoring balloon (DS group; n = 23). Results: Although the balloon size and the maximal dilation pressure for pre-dilatation was larger (3.33 ± 0.28 vs 3.09 ± 0.33 mm, p = 0.01) and higher (11.6 ± 3.2 vs 8.6 ± 2.7 atm, p < 0.01) in the NC group than the DS group, there were no significant differences in the stent expansion. Quantitative coronary angiography at the follow-up demonstrated a smaller in-stent late loss (0.71 ± 0.63 mm vs 0.23 ± 0.52 mm, p = 0.03) in the DS group. During the long-term follow-up, there were no significant differences in the major adverse cardiac event rates. Conclusions: Lesion preparation with a dual wire scoring balloon prior to drug-eluting stent implantation might therefore be a more feasible strategy than that using a non-compliant balloon.

Keywords: Intravascular Ultrasound; Stent; Coronary Artery Disease; Restenosis; Angioplasty

1. INTRODUCTION

Stent expansion remains an important predictor of restenosis and subacute thrombosis, even in the drug-eluting stent (DES) era. Plaque modification with rotational atherectomy or pre-dilation with a cutting balloon has been demonstrated to improve stent expansion [1-5]. Recently, pretreatment with the AngioSculpt balloon catheter (AngioScore, CA) has also been reported to enhance stent expansion [6]. However, the delivery of these devices to stenotic lesions is occasionally difficult, and thus, the use of these devices has not become widespread. The Scoreflex balloon (Orbus Neich, Hong Kong), which is a novel semi-compliant balloon with a dual wire system, is designed for use in focused force angioplasty, and is expected to allow the enhancement of luminal gain with modification of the plaque. Although the concept of both the scoring balloon catheters seems to be similar, the number of scoring elements is higher, with three in the AngioSculpt and two in the Scoreflex. Therefore, the Scoreflex balloon has the potential advantage in its deliverability through severely stenotic lesions. This study was conducted to determine the influence of lesion preparation using the dual wire scoring balloon on stent expansion and to examine the long-term outcomes.

2. METHODS

2.1. Study Population

The institutional review board approved this study. Written informed consent was obtained from all patients. Between December 2008 and September 2009, 46 consecutive patients who underwent elective DES implantation under intravascular ultrasound guidance were prospectively enrolled and randomly assigned to two implantation strategies: 1) pre-dilation with a non-compliant balloon (Hiryu, Terumo, Tokyo) (NC group; n = 23), and 2) pre-dilation with a dual wire scoring balloon (Scoreflex) (DS group; n = 23). Eligible patients were ≥18 years old with de novo lesions in native coronary arteries ≥ 2.5 mm in angiographic diameter (by visual assessment) and who were to receive a single DES. We excluded patients with acute coronary syndrome, total occlusion, bifurcation lesions with a significant side branch, and severely calcified lesions that an intravascular ultrasound (IVUS) catheter could not cross, or in which rotational atherectomy was needed.

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2.2. Techniques

All procedures were performed using the standard technique. Unfractionated heparin at 10,000 units was administered at the start of the procedure. Dual antiplatelet therapy with aspirin at 100 mg/day and clopidgrel at 75 mg/day was recommended to be continued for at least 12 months.

Three different commercially available DESs were used: sirolimus-eluting stents (Cypher, Cordis, FL), paclitaxel-eluting stents (Taxus, Boston Scientific, MA) and zotarolimus-eluting stents (Endeavor, Medtronic Vascular, CL). The selection of the DES type, size and length were left to the discretion of the operators. The stents were deployed at the same pressure of 14 atmosphere and inflated several times over 60 seconds in total to obtain an optimal stent expansion [7-9]. The non-compliant pre-dilation balloon was used in a diameter of 2.5 to 3.75 mm and a length of 15 mm. The dual wire scoring balloon catheter is a semi-compliant balloon with 2 wires that exert focused inflation forces. It can facilitate controlled plaque fractures, because the built-in integral wire and the coronary guide wire on the outside of the balloon create a focused force in a localized region of the plaque. The sizes used were 2.5 to 3.5 mm in a diameter, and 10 or 15 mm in a length. The pressure used for the pre-dilatation was left to the operators' discretion.

All the patients underwent baseline and post-stent deployment intravascular ultrasound using a commercially available catheter (Atlantis Pro, Boston Scientific, MA or Revolution, Volcano, CA) with motorized transducer pullback (0.5 mm/s). Quantitative coronary ultrasound was performed in all the lesions. Stent expansion was defined as the ratio of the intravascular ultrasound-measured stent area in the lesion to the manufacturer's predicted stent area. After the post-stent deployment intravascular ultrasound, the addition of post-dilation was also left to the discretion of the operators.

2.3. Patient Follow-Up

Patients were followed up at six months after the procedure and once a year routinely, unless symptoms or events required earlier consultation. Angiographic follow-up at eight months was encouraged for all the patients. The follow-up data were collected until February 2013. Major adverse cardiac events were defined as cardiac death, non-fatal myocardial infarction, target lesion revascularization and stent thrombosis.

2.4. Statistical Analysis

Quantitative data are presented as the mean values ± SD or the medians [the interquartile range], and qualitative data as frequencies. Continuous variables between two groups were compared using a Mann-Whitney test. Categorical variables were compared with the chi-square test. The Kaplan-Meier method and log-rank test were used to assess the time to major adverse cardiac events. All probability values were 2-tailed and a value of $p < 0.05$ was considered to be statistically significant. All statistical analyses were performed with the SPSS software program (SPSS, Inc, Chicago, Ill).

3. RESULTS

All the procedures were successful, while an additional stent was needed in a patient in the NC group due to coronary dissection. The clinical and procedural characteristics are shown in **Table 1**. All the patients were diagnosed to have angina pectoris or silent myocardial ischemia. Although the clinical background of the patients was similar, the balloon size (3.33 ± 0.28 vs 3.09 ± 0.33 mm, $p = 0.01$) and maximal dilation pressure (11.6 ± 3.2 vs 8.6 ± 2.7 atm, $p < 0.01$) for the pre-dilation were significantly different between the NC group and the DS group. The pre-interventional quantitative coronary angiography and intravascular ultrasound, and the post-stent deployment and post-interventional quantitative data are shown in **Table 2**. There were no differences in the angiographic or ultrasound data. The percentage of stents that had minimum stent areas > 5.0 mm^2 (a commonly accepted criterion for adequate DES expansion) was 87% in both groups. Post-dilation was added for four lesions (17.4%) in the NC group and seven lesions (30.4%) in the DS group ($p = 0.30$). Clinical follow-up data at 1-year were obtained for all patients in the NC group and 20 patients in the DS group, and the durations to the final clinical follow-up were 1197 [813 - 1271] and 1206 [642 - 1301] days, respectively. During the follow-up period, 43 patients (93.5%) were assessed using some imaging modality, such as myocardial scintigraphy, computed tomography or coronary angiography. Follow-up coronary angiography was performed in 33 patients (71.7 %), and the periods from the index coronary intervention until angiography consisted of 258 [215 - 297] days in the NC group ($n = 16$) and 273 [252 - 383] days in the DS group ($n = 17$). Quantitative coronary angiography demonstrated a significantly lower in-stent late loss in the DS group (0.71 ± 0.63 mm vs 0.23 ± 0.52 mm, $p = 0.03$; **Figure 1**), and the other parameters including the in-stent % diameter stenosis, in-segment % diameter stenosis, and binary restenosis rate all tended to be lower in the DS group (**Table 3**). The incidence of major adverse cardiovascular events was also lower in the DS group, although the difference was insignificant (**Table 3**, **Figure 2**). Non-cardiac death occurred in one patient in the NC group and four in the DS group.

4. DISCUSSION

Focused-force angioplasty is a technique in which the

Table 1. Clinical and procedural characteristics.

	Non-compliant balloon (n = 23)	Dual wire scoring balloon (n = 23)	p value
Age (years)	70.7 ± 9.4	66.2 ± 10.1	0.10
Male	12 (52.2%)	17 (73.9%)	0.13
Diabetes mellitus	10 (43.5%)	12 (52.2%)	0.56
Hypertension	22 (95.7%)	19 (82.6%)	0.35
Dyslipidemia	13 (56.5%)	17 (73.9%)	0.22
Coronary artery treated			0.91
LAD/LCx/RCA	12/5/6	12/6/5	
Lesion complexity			0.13
Type A/B1	6 (26.1%)	11 (47.8%)	
Type B2/C	17 (73.9%)	12 (52.2%)	
Procedure			
Balloon size (mm)	3.33 ± 0.28	3.09 ± 0.33	0.01
Maximal inflation pressure (atm)	11.6 ± 3.2	8.6 ± 2.7	<0.01
Stent type (SES/PES/ZES)	10/11/2	11/11/1	0.83
Stent size (mm)	3.33 ± 0.24	3.25 ± 0.31	0.43
Stent length (mm)	22.6 ± 7.0	21.5 ± 7.5	0.51

LAD = left anterior descending artery; LCx = circumflex artery; RCA = right coronary artery; SES = sirolimus-eluting stent; PES = paclitaxel-eluting stent; ZES = zotarolimus-eluting stent.

Table 2. Angiographic and intravascular ultrasound data.

	Non-compliant balloon (n = 23)	Dual wire scoring balloon (n = 23)	p value
Pre-interventional coronary angiography			
Reference vessel diameter (mm)	2.75 ± 0.55	2.60 ± 0.58	0.18
Minimal lumen diameter (mm)	1.16 ± 0.39	1.07 ± 0.36	0.31
% diameter stenosis	56.5 ± 16.5	54.9 ± 18.4	0.90
Lesion length (mm)	11.50 ± 5.81	9.54 ± 3.95	0.20
Pre-interventional intravascular ultrasound			
Plaque morphology			
Soft/Fibrous/Calcified/Mixed	5/2/3/13	2/8/4/9	0.12
Superficial lesion calcium	17	14	0.35
Arc of lesion calcium			0.55
No	6	9	
<90	9	7	
90 - 180	4	4	
180 - 270	2	0	
>270	2	3	
External elastic membrane area (mm^2)	11.17 ± 3.59	11.35 ± 5.03	0.77
Luminal area (mm^2)	2.23 ± 0.77	2.21 ± 0.78	0.85
Plaque and media area (mm^2)	8.89 ± 3.67	9.14 ± 4.73	0.91
Plaque burden (%)	78.2 ± 9.4	78.1 ± 10.0	0.88
Post-stent deployment intravascular ultrasound			
Minimal stent diameter (mm)	2.70 ± 0.34	2.58 ± 0.38	0.21
Minimal stent cross sectional area (mm^2)	6.98 ± 1.48	6.54 ± 1.68	0.18
Stent expansion (%)	70.7 ± 11.2	69.1 ± 11.1	0.52
Post-interventional coronary angiography			
Minimal lumen diameter in stent (mm)	2.81 ± 0.43	2.65 ± 0.47	0.17
Minimal lumen diameter in segment (mm)	2.21 ± 0.49	2.33 ± 0.57	0.73

Table 3. Clinical and Angiographic outcome.

	Non-compliant balloon (n = 23)	Dual wire scoring balloon (n = 23)	p value
Major adverse cardiac event			0.30
Cardiac death	0	0	
Non-fatal myocardial infarction	1	1	
Target lesion revascularization	2	0	
Stent thrombosis	0	0	
Coronary angiography at follow-up	n=16	n = 17	
In-stent			
Minimal lumen diameter (mm)	2.03 ± 0.77	2.38 ± 0.59	0.31
% diameter stenosis	29.7 ± 22.7	17.5 ± 11.0	0.16
In-segment			
Minimal lumen diameter (mm)	1.80 ± 0.66	2.00 ± 0.56	0.42
% diameter stenosis	37.9 ± 18.9	26.9 ± 11.4	0.09
Binary restenosis	3	0	0.07

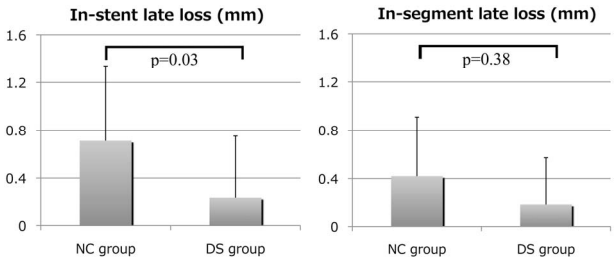

Figure 1. In-stent (left panel) and in-segment (right panel) late loss of the NC group (pre-dilation with the non-compliant balloon) and DS group (pre-dilation with the dual wire scoring balloon) observed at the follow-up coronary angiographic examinations.

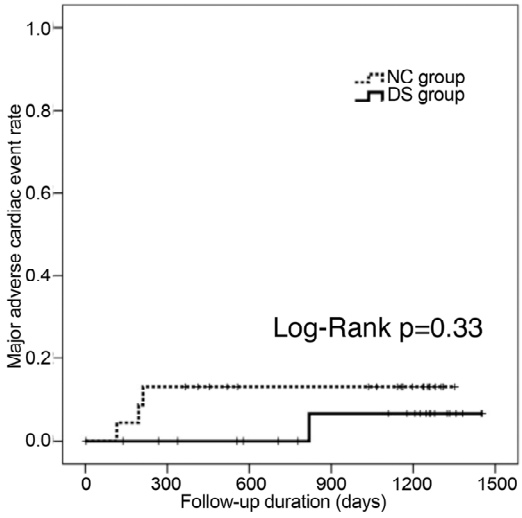

Figure 2. The major adverse cardiac event rate during the follow-up period of the NC group (pre-dilation with the non-compliant balloon) and the DS group (pre-dilation with the dual wire scoring balloon).

forces resulting from inflating an angioplasty balloon in a stenotic lesion are concentrated and focused at one or more locations within the stenosis [10]. This technique, including the conventional buddy wire technique and cutting balloon, have been shown to be useful for resolving resistant stenosis. Recently, several scoring balloon catheters developed based on the concept of focused-force angioplasty have been in use, however, the clinical data on the scoring balloon have been limited [11]. The similar type of the dual wire scoring balloon catheter used in the present study has previously been demonstrated to be superior to the buddy wire technique for resistant calcified lesions [12]. Thus, scoring balloon catheters could potentially be used to treat fibrocalcific or undilatable lesions that have failed treatment with conventional balloon catheters.

The AngioSculpt Scoring balloon catheter, the other type of scoring balloon, consists of a minimally compliant balloon encircled by three nitinol spiral elements, and several case reports have demonstrated the scoring effect on intravascular ultrasound or optical coherence tomography [13-15]. An observational, nonrandomized study using intravascular ultrasound has demonstrated that pre-dilation with the AngioSculpt balloon increased the final stent diameter and the area of the expansion of drug eluting stents [6], although no randomized investigations have so far confirmed this result. The cutting balloon consists of a balloon catheter with three or four blades that create longitudinal incisions in the atherosclerotic lesion during balloon inflation. The microtome sharp metal blades mounted on the cutting balloon are expected to provide better stent expansion than the scoring elements attached to the other scoring balloons. In fact, a

randomized study showed that the cutting balloon yielded greater luminal diameters with less inflation pressure compared with conventional balloon angioplasty for the treatment of calcified coronary lesions [1]. However, this advantage was not demonstrated for the treatment of non-calcified lesions. The present study also did not demonstrate significant superiority of the pre-dilation with a dual wire scoring balloon in terms of the stent area or expansion, although the smaller balloon size and the lower inflation pressure used in the DS group might have affected the acute gain. Therefore, it remains unclear whether pre-dilation by a scoring balloon with the same balloon size would lead to a larger stent expansion than the pre-dilation using a conventional balloon.

The less traumatic ballooning with the smaller balloon size and the lower inflation pressure associated with the DS group might therefore have led to the significantly less in-stent late loss observed in this study. A high inflation pressure is important with regard to the risk of vessel stretching and edge injuries [16]. Several animal and human studies have suggested that aggressive stent inflation with high pressures caused deeper injury of the vessel wall, with rupture of the intima or media, and might result in a long-term inflammatory response with a greater neointimal proliferative response and an increased restenosis rate [17,18]. Moreover, a SIRIUS substudy suggested that more injury to the contiguous vasoelastic normal wall, coupled with a drug that delays the healing process, could contribute to late stent malapposition owing to focal positive vessel remodeling [19]. Therefore, the less traumatic ballooning using the dual wire scoring balloon might be a more feasible strategy for pre-dilation prior to stent implantation than conventional ballooning in order to obtain an equivalent acute gain, while also resulting in less late loss. Further investigations are needed to confirm the effectiveness of this less traumatic ballooning strategy.

A large-scale randomized study investigating the usefulness of the lesion preparation prior to coronary stent implantation is lacking, while rotational atherectomy or a cutting balloon have been demonstrated to yield a greater acute gain in selected cases [1-4]. A high-pressure pre-dilation stenting strategy was also shown to lead to superior stent expansion compared to a direct or non-agressive pre-dilation strategy in patients with bare-metal stent restenosis in a non-randomized study [20]. These results suggest that the lesion preparation prior to coronary stenting may modify the vessel compliance and conesquently improve the stent expansion. In fact, in some cases, lesion preparation is absolutely necessary to avoid stent thrombosis and restenosis due to stent underexpansion. In daily practice, it is difficult to differentiate the cases needing lesion preparation prior to the procedure, and stent underexpansion is often undetectable angiographically. Therefore, high-pressure pre-dilation seems to be one of the most practical strategies to gain appropriate stent expansion, and the present study supports pre-dilation with a dual wire scoring balloon because it is an easy and feasible option.

There are some important limitations asociated with our study: 1) our study involved a small number of subjects at a single institution; 2) the drug-eluting stents used in the present study were first-generation stents and are no longer being used as contemporary coronary stents. The improved characteristics of the stent platform might minimize the validity of the plaque modification prior to stent implantation; 3) follow-up coronary angiography was not performed in all of the patients, and thus, the follow-up results might be biased to some degree.

5. CONCLUSION

In this study, pretreatment using a dual wire scoring balloon was found to be associated with less in-stent late loss at follow-up coronary angiography compared to that using a non-compliant balloon, although the lesion preparation did not demonstrate any significant superiority in acute stent expansion.

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