Journal of Cardiology 63 (2014) 19–23

Contents lists available at ScienceDirect

Journal of Cardiology

journal homepage: www.elsevier.com/locate/jjcc

Original article

Clinical significance of non-slip element balloon angioplasty for patients of coronary artery disease: A preliminary report

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ARTICLE INFO

Article history:
Received 20 November 2012
Received in revised form 31 May 2013
Accepted 19 June 2013
Available online 29 July 2013

Keywords:
'Stentless' percutaneous coronary intervention
Lacrosse® non-slip element balloon
Drug-eluting stent
Restenosis

ABSTRACT

Background: Recent advances in drug-eluting stent (DES) technology have succeeded in reducing restenosis. However, the use of DES is reportedly equivalent to bare metal stents in terms of long-term survival. In addition, stent materials represent foreign bodies, which if possible should not ideally be left within the patient. On these bases, an investigation was performed into the feasibility of a new approach, 'stentless' percutaneous coronary intervention (PCI), using a Lacrosse® non-slip element (NSE) balloon (Goodman Co., Ltd., Nagoya, Japan).

Methods and results: In our 'stentless' approach, the NSE balloon is used for target lesion dilation in patients with low risk factors and simple target lesions. No stenting was performed once an optimal dilatation result was achieved, as evaluated by intravascular ultrasound (IVUS). In a total of 340 lesions in 304 patients, in whom the follow-up study was completed, the 'stentless' PCI by NSE balloon alone was achieved in 52 lesions (15%). Target lesion revascularization (TLR) was performed for 5 (9.6%) of the 52 'stentless' lesions. In the comparison between the 52 'stentless' lesions and the 31 DES lesions selected under the statistical matching of the patient profiles and baseline lesion characteristics, the TLR rate (9.6% vs 6.5%, $p = 0.616$) and late lumen loss (0.52 ± 0.26 mm vs 0.48 ± 0.21 mm, $p = 0.347$) were similar. In the 52 'stentless' lesions, IVUS parameters such as vessel area, minimal lumen area, and plaque area at both before and immediately after PCI were similar between the 5 TLR lesions and the 47 non TLR lesions.

Conclusions: It is believed that the 'stentless' approach is applicable even in the DES era.

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Introduction

Recent advances in drug-eluting stent (DES) technology have succeeded in reducing restenosis, which has long been a major weakness of percutaneous coronary intervention (PCI). However, the use of DES is reportedly equivalent to bare metal stents (BMS) in terms of long-term survival [1,2]. A new concern beyond restenosis has arisen due to the potential for delayed vessel wall healing by the impairment of reendothelialization, i.e. endothelial regeneration on the surface of the stent strut after DES stenting [3–6]. Also, recent evidence suggests that DES impairs the endothelial function in the distal segment of the stented site [7–9] and/or in the microvasculature of the DES-implanted coronary artery [10]. Anatomical as well as functional endothelial impairment may in part account for the fact that the DES does not contribute to improvements in long-term prognosis.

In addition, not only DES but also BMS have the limitations of metallic implants such as artifacts in in-stent lumen visualization by standard magnetic resonance and computed tomography angiography, problems of post-PCI coronary artery bypass grafting, metal allergy, and other unknown long-term adverse effects. On these bases, it is hypothesized that a 'stentless' approach (balloon angioplasty alone) should be given careful consideration as a choice for PCI strategy, even in the DES era.

Previously, patients undergoing balloon angioplasty alone incurred restenosis rates of approximately 40–50%. Therefore, even in the era of balloon angioplasty alone, 50–60% of patients were free from restenosis. Post-angioplasty intravascular ultrasound (IVUS) findings such as large plaque burden, cross-sectional luminal narrowing, and major dissection were noted to predict development of restenosis after balloon angioplasty [11,12].

The Lacrosse® non-slip element (NSE) balloon (Goodman Co., Ltd., Nagoya, Japan) is an angioplasty catheter with 3 longitudinal elements attached directly proximal and distal to the balloon that produces 3 endovascular surgical incisions during balloon dilation.

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http://dx.doi.org/10.1016/j.jjcc.2013.06.009

Lesion dilation under surgical incisions may be expected to reduce hoop stress during the dilation, and thus, resulting in plaque reduction and large luminal gain.

We have actively undertaken the 'stentless' approach using an NSE balloon in appropriate cases as an initial PCI strategy. To verify our hypothesis, this time we investigated the feasibility of this new approach.

Methods

Strategy for a 'stentless' PCI approach

Since September, 2009, initial elective PCI for patients with chronic coronary artery disease that satisfied the following enrolment criteria was performed at our facility: patient criteria including no poor-controlled diabetes defined as a hemoglobin A1c level over 6.5% by the National Glycohemoglobin Standardization Program (NGSP) criteria with or without diabetic treatments and without undergoing hemodialysis treatment; target lesion criteria including no evidence of calcification, chronic total occlusion or bifurcated lesions; lesion length < 20 mm and reference diameter ≥ 3.0 mm. Initial dilatation of the lesions was performed using an optimal size NSE balloon. Balloon size was determined as 90% of vessel diameter evaluated by IVUS with balloon inflation pressure from nominal to rated burst (6–14 atm). Inflation time was 30–60 s, and frequency of inflation was not limited. Once an optimal dilatation result was achieved, as evaluated by intravascular ultrasound (IVUS) in addition to coronary angiography (CAG) findings, no stenting was undertaken. The optimal dilatation result was defined as: minimum lumen area ≥ 5.0 mm^2; no major dissection (defined as length ≥ 20 mm or a decrease in lumen area > 30%) by both CAG and IVUS. If an optimal lesion dilation result was not achieved, a BMS or DES was implanted. For those lesions that did not satisfy the lesion criteria for a 'stentless' approach, planned stenting using a BMS or DES was the primary treatment strategy. In patients who had poorly controlled diabetes, who were undergoing hemodialysis and/or who had only complex lesions including small vessels, long lesions, chronic total occlusive lesions, bifurcated lesions, and/or severe calcified lesions as the target lesions, planned stenting with the BMS or DES (Fig. 1) was determined as the primary treatment strategy. The choice of BMS or DES was based upon operator discretion, given a concept of DES avoidance due to the impairment of the wound healing response after DES placement. PCI for acute coronary syndrome (ACS) and restenosis lesions were excluded from this strategy. The trial endpoint is the target lesion revascularization (TLR) rate and late lumen loss at the 6–12 month follow-up period. In principle, TLR was performed in patients who experienced ≥75% diameter stenosis by quantitative coronary angiographic (QCA) measurements and/or given ischemic symptoms.

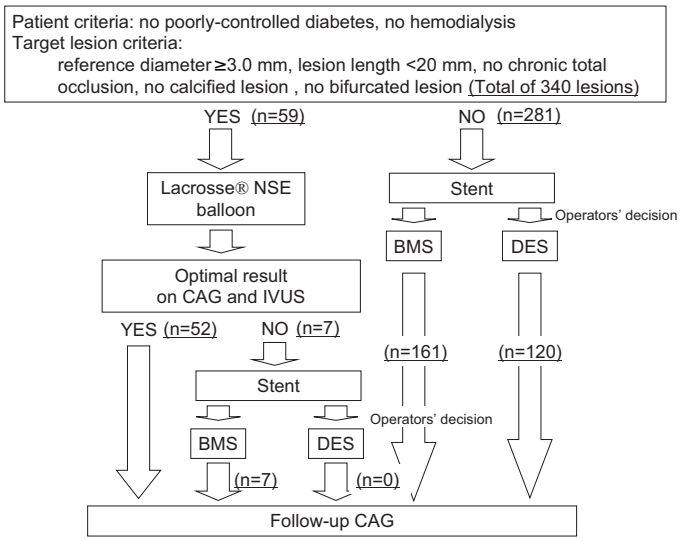

Fig. 1. Protocol of 'stentless' percutaneous coronary intervention approach shown in a flow-chart and detailed number of lesions in each flow. NSE, non-slip element; BMS, bare metal stent; DES, drug-eluting stent; CAG, coronary angiography; IVUS, intravascular ultrasound.

All of the patients received optimal medical therapies including anti-platelet therapy, anti-hypertensive therapy, anti-diabetic therapy, and lipid-lowering therapy, in addition to PCI. All patients received aspirin and clopidogrel was further included in cases with implanted stents. The anti-platelet agents were continued until follow-up CAG. Statins were administered and continued in all patients except for those in whom side effects appeared and/or tolerability was lacking, independent of their lipid levels, with the aim being to reduce low-density lipoprotein (LDL) cholesterol levels < 70 mg/dl [13], and the patients with LDL cholesterol level < 70 mg/dl received minimum dose of strong statins or standard dose of mild statins [14]. For anti-hypertensive treatment, angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs) were administered to all patients except for those in whom side effects appeared and/or tolerability was lacking, with the aim to reduce patients' blood pressure to <130/80 mmHg. Diabetic patients were aggressively treated with anti-diabetic agents, while avoiding hypoglycemic events.

Quantitative coronary angiographic analysis

Coronary lesions were assessed by QCA measurements using a computer-based QCA-CMS system (Medis, Leiden, Netherlands). The quantitative measurements were performed on end-diastolic frames from the angiograms by one investigator who was unaware of the study design. The reference diameter, lesion length, and minimal lumen diameter were measured before and after PCI, and also at time of follow-up CAG. On the basis of these measurements, values of percent diameter stenosis, acute gain (minimal lumen diameter immediately after PCI minus minimal lumen diameter before PCI), net gain (minimal lumen diameter at follow-up angiography minus minimal lumen diameter before PCI), and late lumen loss (minimal lumen diameter immediately after PCI minus minimal lumen diameter at follow-up angiography) was obtained for each lesion.

IVUS procedure

IVUS data were acquired with a 20-MHz, 2.9 Fr, phased-array IVUS catheter (Eagle Eye Gold, Volcano Corp., Rancho Cordova, CA, USA) and a dedicated console (IVG3, Volcano Corp.). The catheter probe was advanced ≥10 mm distal to the most distal side branch. Angiographic cine runs were performed to define the position of the IVUS catheter. Manual pullback was performed after intracoronary administration of isosorbide dinitrate (2.5 mg) at before and immediately after NSE balloon angioplasty, and measured vessel area, lumen area, and plaque area and evaluated whether major coronary dissection had occurred.

Statistical analysis

Values are expressed as the mean ± SD. Intergroup comparisons were performed using unpaired *t* tests for continuous variables and chi square tests for categorical variables. A *p*-value < 0.05 was considered to be statistically significant.

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