Clinical value of drug-coated balloon angioplasty for *de novo* lesions in patients with coronary artery disease

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Structured Abstract

OBJECTIVES

The aim of this study was to investigate the efficacy of a drug-coated balloon (DCB) in the treatment of *de novo* coronary artery disease.

BACKGROUND

Despite the low restenosis rates of drug-eluting stents (DES), several problems remain, including stent thrombosis, stent fracture, and neo-atherosclerosis. 'Stent-less' (balloon alone) percutaneous coronary intervention (PCI) is still being used, and several clinical trials have supported the efficacy of DCB.

METHODS

We enrolled 60 consecutive patients who had been given elective PCI between May 2014 and June 2015. They were randomly assigned to a 'stent-less' group (n=30) and a 'stent' group (n=30). Twenty-seven patients were treated with DCB alone and 33 with DES, and then evaluated for target lesion revascularization (TLR) rate and by quantitative coronary angiography (QCA) eight months later.

RESULTS

TLR rates were similar in the two groups (DCB; 0.0%, DES; 6.1%, P = 0.169). In the QCA analysis, minimal lumen diameter (MLD) and acute gain were significantly smaller in the DCB group than in the DES group immediately after PCI (2.36±0.46 vs 2.64±0.37, P = 0.011, and 1.63±0.41 vs 2.08±0.37, P < 0.0001, respectively). Eight months after PCI, however, there was no significant difference in MLD or late lumen loss between the two groups.

CONCLUSIONS

A ‘stent-less’ PCI using DCB could be useful even in the DES era. After ‘stent-less’ PCI, antiplatelet agents might be reduced or discontinued more safely than after DES implantation.

Condensed Abstract

We compared the clinical outcomes and quantitative coronary angiography parameters after percutaneous coronary intervention (PCI) between a drug-coated balloon (DCB) group (n=27) and a drug-eluting stent (DES) group (n=33). Target lesion revascularization rate and late lumen loss after eight months were similar in the two groups. A DCB alone PCI (called ‘stent-less’ PCI) might be useful even in the DES era. Furthermore, ‘stent-less’ PCI might improve quality of life and long-term prognosis compared with DES by reducing early and late stent thrombosis and neo-atherosclerosis.

Keywords: ‘stent-less’ percutaneous coronary intervention, drug-coated balloon, drug-eluting stent, restenosis, stent thrombosis

Introduction

Percutaneous coronary intervention (PCI) is an effective treatment for patients with ischemic heart disease. Recent advances in drug-eluting stent (DES) technology have succeeded in reducing the restenosis rate. However, several problems remain, such as stent thrombosis, stent fracture, and neo-atherosclerosis (1). In addition, the use of DES is equivalent to that of bare metal stents in terms of long-term survival (2, 3). Stent materials represent foreign bodies, which whenever possible should not be left in the patient. Previously, we reported that 'stent-less' PCI was useful even in the DES era (4). Recently, several clinical trials have supported the efficacy of drug-coated balloons (DCB) in the treatment of stent restenosis and small vessel *de novo* lesions (5). The aim of the present study was to investigate the efficacy of DCB in the treatment of *de novo* coronary artery disease.

Methods

Strategy for PCI approach

The study was designed as a simple-randomization, open-label, single-center study, which included 60 consecutive patients with chronic coronary artery disease who had been subjected to elective PCI between May 2014 and June 2015. Patients on hemodialysis and those with restenosis lesions were excluded. Patients were also excluded if their lesion had severe calcification, was in the left main trunk, had produced chronic total occlusion, and/or extended over 25 mm or more. Coronary angiography was performed using AXIOM Artis dBC (Siemens Company Inc), and PCI was performed for lesions with significant stenosis. Lesions were classified according to

the modified American College of Cardiology (ACC)/American Heart Association (AHA) grading system (types A, B1, B2, and C). All patients were taking aspirin (100 mg) and clopidogrel bisulfate (75 mg), which were continued until the follow-up coronary angiogram (CAG). Drug treatment of risk factors (hypertension, dyslipidemia, and diabetes mellitus) was provided as appropriate. Statins were prescribed and continued in all patients independent of their lipid levels, except for those patients who found them intolerable or developed side-effects, with the aim of maintaining low-density lipoprotein (LDL) cholesterol below 100 mg/dl. For anti-hypertensive treatment, angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs) were given to all patients, except those who found them intolerable or in whom side-effects developed, with the aim of reducing blood pressure to below 130/80 mmHg. Beta-blockers and calcium channel-blockers were prescribed when clinically indicated. Diabetic patients were treated intensively with anti-diabetic agents, while avoiding hypoglycemic events.

Patients were randomly assigned to two groups using a simple-randomization method (6): a ‘stent-less' group (n = 30) and a ‘stent’ group (n = 30). The ‘stent-less’ PCI strategy using a DCB was a balloon alone PCI without using a stent, and the ‘stent’ group was planned to receive a DES. For the ‘stent-less’ PCI strategy, an initial dilatation of the lesion was performed using an optimal size Lacrosse® non-slip element (NSE) balloon (Goodman Co., Ltd., Nagoya, Japan). The balloon size was 90% of vessel diameter as evaluated by intravascular ultrasound (IVUS) with its inflation pressure from nominal to rated burst (6–14 atm). The inflation time was 30–60 seconds, and the frequency of inflation was not limited. After that, we applied a drug to the vessel wall using DCB to reduce neo-intimal proliferation only when an optimal

dilatation result had been achieved after NSE balloon inflation as evaluated by both IVUS and CAG. The optimal dilatation result was defined as minimum lumen area ≥ 4.0 mm^2, and no major dissection (defined as length ≥ 20 mm or a decrease in lumen area > 30%) by both CAG and IVUS. The inflation pressure of the DCB was 7 atms, and the inflation time was 30 seconds. The DCB was the paclitaxel-coated balloon catheter (paclitaxel at a dose of 3 μg/mm^2 balloon surface; SeQuent Please; B Braun Melsungen, Germany). When an optimal dilatation result was not achieved, we used DES. All DESs used in this study were everolimus-eluting stents (EES: Xience Prime/Xpedition; Abbott Vascular, Santa Clara, CA, USA). We excluded PCI in cases of acute coronary syndrome (ACS) and restenosis lesions. The trial endpoints were the target lesion revascularization (TLR) rate and late lumen loss after eight months of follow-up after the PCI. In principle, TLR was performed in patients who had ≥75% diameter stenosis by quantitative coronary angiography (QCA) and/or had symptoms of ischemia.

The study was approved by the local medical ethics committee, and informed consent was obtained from each patient.

Quantitative coronary angiography

Coronary lesions were assessed by QCA using a computer-based QCA-CMS system (Medis, Leiden, Netherlands). The quantitative measurements were performed on end-diastolic frames from the angiograms by a single 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 the time of the follow-up CAG. On the basis of these measurements, values of percentage 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) were obtained for each lesion.

Statistical analysis

Data were expressed as mean ± SD. Inter-group comparisons were performed using the unpaired Student's t-test and the Mann-Whitney U test for continuous variables and the Chi square test for categorical variables. All analyses were performed using of StatView 5.0 (SAS Institute Inc.; Cary, NC). A P value <0.05 was considered statistically significant.

Results

Protocol (Figure 1)

In the 'stent-less' group of patients undergoing initial lesion dilation using a Lacrosse NSE balloon, optimal results by both CAG and IVUS were obtained in 27 patients (90.0%), and accordingly DCB was performed. There was no lesion for which provisional stenting was needed on account of unsatisfactory DCB balloon dilatation. Of the remaining three patients (10.0%), provisional stenting was performed owing to unsatisfactory NSE balloon dilatation, and DES was implanted. Overall, the DCB and DES groups consisted respectively of 27 and 33 patients with optimal results, all of whom received follow-up CAG evaluation.

Intention to treat (ITT) analyses of TLR and the patients' characteristics were

performed between the ‘stent-less’ group (n = 30) and the ‘stent group’ (n = 30), and per protocol set (PPS) analyses of TLR and QCA parameters were performed between the DCA group (n=27) and the DES group (n=33).

Clinical characteristics of the patients (Tables 1 and 2)

There were no significant differences between the two groups in age, gender, hypertension, dyslipidemia, diabetes mellitus, chronic kidney disease, family history or past history of smoking. Serum levels of triglycerides, high density lipoprotein-cholesterol, LDL-cholesterol, and hemoglobin A1c (HbA1c), and estimated glomerular filtration rate (eGFR) were similar in the two groups. Medications for hypertension (ACEI, ARB, calcium channel-blocker, beta-blocker), dyslipidemia (statin), and diabetes mellitus (sulfonylurea, alpha-glucosidase, thiazolidinedione, dipeptidyl peptidase-4 inhibitor, biganide, insulin) did not differ between the two groups.

Coronary angiographic characteristics (Table 3)

There were no significant differences between the two groups in lesion-related variables, classification according to the ACC/AHA grading system, device diameter, or device length.

Success rate

Successful PCI was achieved in all patients. There were no deaths or major cardiovascular events (acute myocardial infarction, congestive heart failure, coronary artery bypass-graft surgery, severe arrhythmia, stroke, etc.). There were also no

procedure-related complications (stent thrombosis, stent fracture, failure of stent deployment).

TLR rate and QCA analysis (Table4, Figure 2, 3A and 3B)

TLR rates after eight months in the two groups were similar: zero patients (0.0%) in the DCB group and two (6.1%) in the DES group (P = 0.193). There was no restenosis in the three patients in the 'stent-less' group who received provisional DES implantation owing to suboptimal results of NSE balloon dilation. Therefore, regarding the ITT analysis, TLR rates were also similar in the two groups ('stent-less' group, 0.0%; 'stent' group, 6.7%; P = 0.130).

The QCA parameters before PCI, including lesion length, reference diameter, minimal lumen diameter (MLD) and % stenosis, showed no significant differences between the two groups. However, MLD and acute gain in the DCB group were significantly smaller (2.36±0.46 vs 2.64±0.37, P=0.011, and 1.63±0.41 vs 2.08±0.37, P<0.0001, respectively) than those in the DES group immediately after PCI. MLD and late lumen loss after eight months were similar in the two groups.

Discussion

The present study demonstrated that the TLR rates eight months after PCI were similar in the DCB and DES groups, and that in the QCA analysis there was no significant difference in MLD or late lumen loss between the two groups. These findings suggest that both the 'stent-less' strategy and DES implantation were safe and efficient.

Stent-less PCI and DCB

The increase in vessel lumen after conventional angioplasty is achieved by compression of soft atheromatous material, stretching of the artery wall, and ultimately disruption of the intima and often also the media. Such intimal dissections are visible on angiography in about 20–40% of PTCA procedures (7).

Formerly in the era of balloon angioplasty alone, no bail-out tools were available when acute vessel occlusion resulting from elastic recoil or dissection occurred. Furthermore, essential imaging tools for vessel wall assessment, such as IVUS and optical coherence tomography, were not available. Previously, we reported that a "stent-less PCI" strategy was of value even in the DES era. We reported that dilatation by Lacrosse NSE balloon, confirmation of optimal results after PCI evaluated by IVUS, and intensive medical therapy substantially reduced the restenosis rate compared with that in the era of balloon alone PCI (4). The NSE balloon is an angioplasty catheter, in which three longitudinal synthetic resin elements mounted on the balloon surface prevent the balloon slip phenomenon during balloon inflation. Simultaneously, the longitudinal elements produce three endovascular surgical incisions during balloon dilatation because of their sharp geometry. As a result, it is theoretically feasible that elastic recoil can be partly prevented, and traumatic vessel wall injury and dissection can be limited. Thus, the concept of lesion dilatation by an NSE balloon is similar to that of a cutting balloon. The cutting balloon, on which three or four microtome sharp metal blades are mounted, was designed by Barath et al (8). The three or four radially directed micro-surgical blades create longitudinal vascular incisions before the balloon inflation is completed, and the balloon pressure serves primarily to propagate these incisions. Thus, unfavorable vascular injury is controlled and localized to the area of the incisions, and inter-incisional segments are spared. Cutting balloon angioplasty prior to

BMS has been reported to have some impact on restenosis reduction in the Japanese trial, REstenosis reDUction on Cutting balloon Evaluation trial III (REDUCE III) (9). However, the cutting balloon has a limitation in crossability through the lesion on account of the metal blade component. By contrast, the NSE balloon demonstrates several advantages over the cutting balloon in terms of its flexibility and profile characteristics that exhibit better crossability. Inoue et al (10) reported that cutting balloon angioplasty reduced the PCI-induced local inflammatory response as indicated by less up-regulation of integrin Mac-1(CD11b/CD18) on the surface of neutrophils, compared with conventional balloon angioplasty. Further observations indicated that PCI-induced Mac-1 up-regulation was greater with BMS stenting than with conventional balloon angioplasty (11). Therefore, the NSE balloon would be expected to produce further reduction of the inflammatory response.

Recently, paclitaxel-coated angioplasty balloon catheters based on a new matrix coating technique have shown reproducible efficacy in the treatment and prevention of restenosis in the porcine coronary model, in coronary in-stent restenosis, and in small vessel *de novo* lesions in patients and human peripheral arteries (12-19). The coating includes an X-ray contrast medium (iopromide), which improves the solubility of the drug and its transfer into the vessel wall (12). In view of these favorable results, it is assumed that the drug-coated balloon will also have beneficial effects in the treatment of *de novo* coronary stenosis. In the present study, ‘stent-less’ PCI using DCB strategy was found to be of greater value than the conventional ‘stent-less’ strategy that we previously reported. One of the reasons for this excellent result is that we were careful to avoid ‘geographical mismatch’ during ballooning. In the PEPCAD-1 study, a major limitation was the high incidence of ‘geographical mismatch’ in patients with additional

implantation of a bare metal stent after pre-treatment with the drug-coated balloon. ‘Geographical mismatch’ occurs when the BMS is in part deployed in vessel areas that have not previously been treated with the DCB, possibly increasing the restenosis rate. Therefore, in the present study, we selected the length of the drug-coated balloon so that ‘geographical mismatch’ would be avoided. Drug-eluting stents significantly reduce the restenosis rates compared with uncoated stents (20-22). However, the use of DES is reportedly equivalent to bare metal stents in terms of long-term survival. In addition, several problems still remain, such as stent thrombosis, stent fracture and neo-atherosclerosis. In this ‘stent-less’ PCI strategy, stent materials cannot be left in the patient. Therefore, these problems are not expected to occur.

Drug treatment and DCB

In the BARI study, the PTCA group had substantially greater subsequent revascularization rates than the CABG group (23). However, optimal medical treatment and an accurate evaluation of the result post PCI had not been carried out. The COURAGE trial revealed that optimal medical therapy was very important to reduce major cerebral cardiac events (MACCE) in ischemic heart disease patients. Especially, statins and ACEIs/ARBs, now utilized as anti-atherosclerotic agents, were well known to reduce MACCE. The JUPITER trial revealed that in healthy persons without hyperlipidemia but with elevated high-sensitivity C-reactive protein levels, statin therapy significantly reduced the incidence of MACCE (24). The HOPE trial showed that ACEIs significantly reduced the incidence of both mortality and MACCE (25). Therefore, the patients in the present study were given adequate ACEIs/ARBs and statin

treatment. We think that intensive medical therapy might also lead to a reduction of the TLR rate.

The DESs are characterized by a long-lasting release of anti-proliferative agents from the stent struts, resulting in delayed or absent endothelialization and possible local inflammation due to polymeric coatings (26,27). Therefore, dual antiplatelet therapy after implantation of DES is necessary. In the DAPT trial, more than 12 months of DAPT treatment reduced cardiovascular events, whereas bleeding events were more common than with single anti-platelet therapy. The concept of a DCB allows for a homogenous drug application to the artery wall, which might avoid long-lasting drug exposure of the stent struts and the use of polymers. In the future, this ‘stent-less’ DCB strategy might shorten the DAPT period.

Kimura et al (28) reported that surgical procedures were performed commonly and constantly (annual rate of 5%) after PCI using DES. The cumulative incidence rates of surgical procedures were 5.1% at 1 year, 10.2% at 2 years and 14.7% at 3 years. A significant number of patients with DES implantation might worry about the risk of DAPT discontinuation in the future. That fear for coronary events following DAPT discontinuation might be eradicated by ‘stent-less’ PCI, which would also be expected to prevent a neo-atherosclerosis (1) after DES implantation. Therefore, we believe that the ‘stent-less’ PCI improves the quality of life and the long-term prognosis of patients post PCI.

Study limitations

As this was a single center study with a small sample size, a prospective randomized multicenter trial with a large number of participants will be needed to confirm the value

of PCI using DCB. In the present study, IVUS was performed only for evaluation of the optimal result after PCI. In future studies, IVUS parameters including volume data at every point would be needed.

Conclusion

From the present results, it is envisioned that metallic implants might be avoided in some patients undergoing PCI, selected on the basis of clinical criteria and lesion type, if IVUS were to be used to assess the vessel wall and luminal gain, combined with optimal medical treatments. Thus, we believe a 'stent-less' PCI using DCB could be a useful strategy even in the DES era.

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Figure Legends

Figure 1: Protocol

Between May 2014 and June 2015, a total of 30 patients underwent elective PCI under the strategy for a ‘stent-less' approach, and a total of 30 patients underwent elective PCI under the strategy for a ‘stent’ approach. In three patients (10.0%) provisional stenting was performed due to unsatisfactory NSE balloon dilatation results, and DES was implanted. Overall, ‘stent-less' PCI using DCB (DCB group) was accomplished in 27 patients, and PCI using DES (DES group) in 33 patients.

Figure 2: Clinical driven TLR rate between the two groups

TLR rate eight months after PCI was zero patients (0.0%) in the DCB group and two patients (6.1%) in the DES group. There were no significant differences between the two groups (P=0.193).

Figure 3A and 3B: QCA analysis.

In the DCA group, MLD and acute gain were significantly smaller (2.36±0.46 vs 2.64±0.37, P= 0.011; 1.63±0.41 vs 2.08±0.37, P<0.0001; respectively) than in the DES group immediately after PCI. However, after eight months, MLD and late lumen loss were similar in the two groups.