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# One-year outcomes following drug-eluting balloon use for coronary ostial restenosis

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ABSTRACT

*Aims:* The management of ostial lesions is one of the challenges of percutaneous coronary intervention (PCI) in recent medicine. Although stent implantation has increased the accuracy of the results and improved long-term outcomes, in-stent restenosis (ISR) occurs more frequency following the treatment of ostial lesions than the treatment of non-ostial lesions. When additional stenting is not desirable, PCI with drug-eluting balloons (DEBs) has emerged as an adjunctive strategy. However, little data regarding the effects of DEBs in ostial ISR lesions are available. Our study aimed to assess the efficacy of the use of DEBs in coronary ostial instent restenotic lesions.

*Methods and results:* From November of 2011 to May of 2014, 85 patients were diagnosed with coronary ostial ISR in our hospital. A total of 93 coronary ostial ISR lesions were treated with DEBs. More than half of the study patients had comorbidities, including hypertension, diabetes, and hyperlipidemia, 77.6% of the study patients had triple vessel coronary artery disease, and 54.1% of the study patients had left main coronary artery disease. In our study, target lesion revascularization were performed in 19.2% in all groups; 11.5% were in the ostial left anterior descending artery, 29.0% were in the ostial left circumflex artery, and 21.4% were in the ostial right coronary artery. Across all of the groups, 24.4% of the patients experienced major adverse cardiac cerebral events.

*Conclusion:* Percutaneous coronary intervention with drug-eluting balloons is an alternative strategy for coronary ostial instent restenosis when additional stenting is not desirable.

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## 1. Introduction

Flow-limiting ostial coronary lesions are clinically important because they subtend a large myocardial territory and may induce extensive myocardial ischemia. The diagnosis and treatment of these lesions have been challenging aspects of percutaneous coronary intervention (PCI) in recent era. The procedural success and clinical of these lesions outcomes are inferior to those of non-ostial lesions. The majority of ostial lesions are due to atherosclerotic coronary artery disease [1]. Fibrocellular and sclerotic fragments are the major tissue components that are found on histological analyses of specimens removed from right coronary artery ostial lesions by directional atherectomy, and lipid-rich components are infrequent [2]. Although stent implantation has improved the accuracy of the results and the long-term outcomes, in-stent restenosis (ISR) occurs more frequently following the treatment of ostial lesions that the treatment of non-ostial lesions. ISR is also related to poor clinical outcomes, particularly ostial restenosis. According to a previous study of the prevalence of coronary ostial instent restenosis following the use of CYPHER, TAXUS and BMS, the restenosis rates are 6%, 8%, and 33%, respectively [3]. 'Stent in stent' treatment causes lumen loss, and additional stenting may not be a desirable PCI for ostial ISR. The use of DEBs has emerged as an adjunctive strategy. Compared with DESs, the DEBs offer advantages, such as immediate and homogeneous drug release in the arterial wall and the absence of polymers that can induce chronic inflammatory reactions. To the best of my knowledge, no studies of strategies for coronary ostial ISR lesions have been published, and little data about the effect of DEBs in ostial ISR lesions are available. To address this gap in the published knowledge, our study aimed to assess the efficacy of the use of DEB for coronary ostial instent restenotic lesions.

## 2. Methods

### 2.1. Patient collection and groups

From November of 2011 to May of 2014, a total of 85 patients and 93 ostial ISR lesions were treated with DEBs in our hospital. A total of 28

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ostial left anterior descending artery (LAD) instent restenosis lesions, 32 ostial left circumflex artery (LCX) instent restenosis lesions and 33 ostial right coronary artery (RCA) instent restenosis lesions were included. The general demographics, clinical conditions, associated risk factors, characteristics of coronary artery disease, previous stents and characteristics of the DEBs were analyzed. Comprehensive inpatient and outpatient data from medical record abstractions and patient interviews were collected. The Institutional Review Committee on Human Research of our institution approved the study protocol.

### 2.2. Definitions

Ostial coronary lesions were defined as stenotic >50% of the lesion was within 3 mm of the orifices of the LAD, or LCX or RCA. Major adverse cerebral cardiac events (MACCEs) included myocardial infarction, target lesion revascularization, stroke and cardiovascular mortality.

### 2.3. Procedure and protocol

The SeQuent Please (B Braun Melsungen AG, Melsungen, Germany) was the only DEB used in our hospital. B. Braun Melsungen AG (Berlin, Germany) has licensed this technology for use in its SeQuent Please DEB catheter, but the coating procedure and balloon technology have been improved. Paccocath coating is stable during ethylene oxide sterilization, and the balloon has a shelf life of >1 year. More than 80% of the drug is retained during balloon delivery to the target lesion, and 10 to 15% of the initial dose is delivered to the vessel wall upon 60-second inflation. The DEBs were inflated at the ISR site for 30 to 60 s when the patients were able to tolerate this treatment.

### 2.4. Study end-points

The primary end-point of this study was target lesion revascularization. The secondary end-points of this study were myocardial infarction (ST elevation myocardial infarction and non-ST elevation myocardial infarction), stroke and cardiovascular mortality.

### 2.5. Statistical analysis

The data are expressed as percentages and the means ± the standard deviations. The categorical variables were compared using chi-square tests. The continuous variables were compared using an analyses of variance (ANOVAs) test. The differences in the continuous variables between the two groups were analyzed using a one-way analyses of variance. A Kaplan–Meier survival curve was performed for the outcomes of target lesion revascularization at one-year follow-up duration. P values below 0.05 were considered statistically significant. All statistical analyses were performed using SPSS 22.0 software (SPSS, Inc., Chicago, Illinois).

## 3. Results

### 3.1. Baseline characteristics of the study patients (Table 1)

The average age of the patients was 66.76 ± 9.85 years with a range of 33 to 89 years, and 68.2% of the patients were male. The major clinical condition of the patients was unstable angina (56.5%). Other patients exhibited clinical problem, such as ST elevation myocardial infarction (STEMI, 1.2%), non-ST elevation myocardial infarction (NSTEMI, 24.7%) and stable angina (17.6%). The majority of patients had hypertension (90.6%), diabetes (61.2%) and hyperlipidemia (61.8%). Forty-one point two percent of the patients had medical histories of prior myocardial infarction, 30.6% had histories of heart failure, and 32.9% had ESRD. The average of serum creatinine level of the non-hemodialysis patients was 1.36 ± 1.32 mg/dL. The lesion-related arteries involved the LAD (30.1%), LCX (35.5%) and RCA (34.4%). The majority of patients had multiple vessel diseases (97.6%) and left main artery disease (54.1%). Among all patients, 77.6% had triple vessel coronary artery disease, 20% had double vessel coronary artery disease, and 2.4% had single vessel coronary artery disease. The previously used stents included bare-metal stents (BMSs, 37.6%) and drug-eluting stents (DESs, 62.4%).

Angiography revealed a pre-PCI stenosis of 77.26 ± 13.43%, a pre-PCI minimal luminal diameter (MLD) of 0.71 ± 0.44 mm and a pre-PCI reference luminal diameter (RLD) of 3.19 ± 0.54 mm. The post-PCI stenosis was 17.70 ± 8.71%, the post-PCI MLD was 2.59 ± 0.47 mm, and the post-PCI RLD was 3.19 ± 0.54 mm. The average DEB length was 25.98 ± 4.34 mm, and the average DEB diameter was 3.25 ± 0.40 mm. Peri-procedure intravascular ultrasound was utilized

**Table 1**
Baseline characteristics of study patients[a].

| | Ostial lesion (N = 93) |
|---|---|
| Patient number | 85 |
| Lesion number | 93 |
| General demographics | |
| Age (year) | 66.76 ± 9.85 |
| Male gender (%) | 68.2 |
| Clinical condition | |
| STEMI (%) | 1.2 |
| NSTEMI (%) | 24.7 |
| Unstable angina (%) | 56.5 |
| Stable angina (%) | 17.6 |
| Risk factors | |
| Hypertension (%) | 90.6 |
| Diabetes (%) | 61.2 |
| Current smoker (%) | 37.6 |
| Old myocardial infarction (%) | 41.2 |
| Old stroke (%) | 4.7 |
| PAOD (%) | 8.2 |
| Hyperlipidemia (%) | 61.8 |
| Heart failure (%) | 30.6 |
| Prior CABG (%) | 9.4 |
| ESRD on maintenance hemodialysis (%) | 32.9 |
| Laboratory examination | |
| Creatinine (mg/dL) (exclude ESRD) | 1.36 ± 1.32 |
| Lesion-related artery (%) | |
| Left anterior descending artery | 30.1 |
| Left circumflex artery | 35.5 |
| Right coronary artery | 34.4 |
| Characteristics of coronary artery disease | |
| Single- or multiple-vessel disease (%) | |
| Single vessel disease | 2.4 |
| Double vessel disease | 20 |
| Triple vessel disease | 77.6 |
| Left main disease (%) | 54.1 |
| Previous stent | |
| Bare metal stent (%) | 37.6 |
| Drug eluting stent (%) | 62.4 |
| Pre-PCI angiography | |
| Pre-PCI stenosis (%) | 77.26 ± 13.43 |
| Pre-PCI MLD (mm) | 0.71 ± 0.44 |
| Pre-PCI RLD (mm) | 3.10 ± 0.54 |
| Post-PCI angiography | |
| Post-PCI stenosis (%) | 17.70 ± 8.71 |
| Post-PCI MLD (mm) | 2.59 ± 0.47 |
| Post-PCI RLD (mm) | 3.19 ± 0.54 |
| DEB | |
| Diameter (mm) | 3.25 ± 0.40 |
| Length (mm) | 25.98 ± 4.34 |
| IVUS use (%) | 43 |
| Complication of PCI (%) | 0 |
| F/U time (days) | 601.13 ± 291.06 |

Data are expressed as mean ± SD or as number (percentage).
[a] Abbreviation: STEMI: ST segment elevation myocardial infarction; NSTEMI: non ST segment elevation myocardial infarction; PAOD: peripheral arterial occlusive disease; CABG: coronary artery bypass grafting; ESRD: end stage renal disease; MLD: minimal luminal diameter; RLD: reference luminal diameter; IVUS: intravascular ultrasound; PCI: percutaneous intervention; F/U: follow-up.

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