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Comparison of angiographic patterns of in-stent restenosis between sirolimus- and paclitaxel-eluting stent

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Abstract

Background: Angiographic pattern of in-stent restenosis (ISR) after drug-eluting stent (DES) implantation was known to be different to that after bare metal stent (BMS) implantation. But the different angiographic patterns of ISR and its prognosis between sirolimus-eluting stent (SES) and paclitaxel-eluting stent (PES) has not been properly addressed in large scale studies.
Objectives and methods: We evaluated the angiographic pattern of ISR and their subsequent clinical outcomes in 177 ISR lesions of 163 consecutive patients previously treated with SES ($n=97$) or PES ($n=80$) from February 2003 to April 2005.
Results: In angiographic ISR pattern, diffuse ISR was more common in PES implantation (SES vs PES; 23.7% vs 48.7%, $p=0.001$) mainly because of higher incidence of diffuse intrastent ISR (8.2% vs 33.8%, $p<0.001$, respectively) whereas focal ISR was more common in SES implantation (76.3% vs 51.3%, $p=0.001$, respectively) mainly because of higher incidence of focal margin ISR (27.8% vs 2.5%, $p<0.001$, respectively). Among 177 ISR lesions, clinically driven target lesion revascularization (TLR) was performed in 53.6% in SES implantation and 56.3% in PES implantation ($p=0.725$).
Conclusion: Angiographic pattern of ISR differed after SES and PES implantation, but their subsequent TLR rate was similar to both types of DES.

Keywords: Stents; Angioplasty; Coronary restenosis

1. Introduction

Routine stent implantation has been shown to have a better procedural success rate and clinical outcome than balloon angioplasty [1,2]. However, restenosis and repeat revascularization remain significant clinical problems limiting the long-term success of stent implantation [1–3]. The recent introduction of drug-eluting stent (DES) has reduced the incidence of stent-related restenosis to less than 10%, but did not eliminate it completely [4,5]. Previous reports [6,7] showed that the pattern of in-stent restenosis (ISR) has changed into a predominantly focal ISR after DES implantation but the number of patients was small and those results were restricted to sirolimus-eluting stents (SES). Furthermore, any difference of angiographic restenotic pattern and their subsequent clinical outcome between SES and paclitaxel-eluting stent (PES) were rarely known.

Therefore, we evaluated and compared the characteristics of angiographic pattern of ISR and their clinical outcomes after SES and PES implantation.

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2. Materials and methods

2.1. Patients

Between February 2003 and April 2005, 2317 consecutive patients underwent coronary DES implantation in 3329 lesions at Asan Medical Center. Follow-up angiography after coronary stenting was acquired in mean 6.6±1.7 months after procedure. Angiographic follow-up data were obtained in 2454 lesions of 1673 patients (follow-up rate, 72.2%), and overall angiographic restenotic rate was 7.9% (193 lesions). Of these patients, 177 ISR lesions in 163 patients were enrolled for this study. Patients were excluded from this study if the treatment site was in the left main coronary artery (n=12) or venous bypass graft (n=4). The study was approved by our institutional review board.

2.2. Stenting procedure

SES (Cypher™, Cordis Corporation, Miami, FL) or PES (Taxus™, Boston Scientific, Natric, MA) was used in all patients. Stent implantation was performed according to standard techniques [8], and stents were selected by the operator. Complete lesion coverage was recommended as well as angiographic optimization with <20% residual stenosis by visual estimate. During the procedure, patients received a bolus of 100 IU/kg of heparin, with repeated bolus of 2000 IU heparin to maintain the activated clotting time ≥300 s. All patients were treated with aspirin 100–200 mg a day indefinitely and clopidogrel 75 mg a day for at least 6 months.

Repeat revascularization was performed in patients with a symptomatic or restenotic diameter stenosis ≥70%. Asymptomatic patients with angiographically intermediate ISR lesion underwent a non-invasive functional test such as treadmill test or thallium SPECT. Patients with positive stress test underwent revascularization.

2.3. Angiographic analysis

Coronary angiograms were analyzed by two experienced investigators who were not aware of the study purpose. The reference vessel diameter, percent diameter stenosis, and the minimal luminal diameter using an on-line quantitative coronary angiographic system (Xelera Cath 1.1, Philips, Netherland) were determined at baseline, after the procedure, and at follow-up. Angiographic measurement was made during end diastole after intracoronary nitroglycerin administration. Lesion length was measured as the distance from the proximal shoulder to distal shoulder in the projection with least amount of foreshortening [15].

2.4. Definition

All demographic, clinical, angiographic and procedural characteristics were prospectively entered into the Asan Medical Center angiographic database. Angiographic restenosis was defined as diameter stenosis of ≥50% occurring in the segment inside the stent or 5 mm segment proximal or distal to the stent at follow-up angiography. Patterns of restenosis were classified, according to what Mehran et al. [9] suggested, with an angiographic classification of ISR according to the geographic distribution of intimal hyperplasia; pattern I (focal ISR): 1A (gap), 1B (margin), 1C (focal body), 1D (multifocal), pattern II–IV (diffuse ISR): pattern II (intrastent ISR), pattern III (proliferative ISR) and pattern IV (totally occluded ISR). Clinically driven target lesion revascularization (TLR) was defined as either surgical or percutaneous reintervention driven by significant (≥50%) luminal narrowing, within or 5 mm proximal or distal to the stent, together with angina symptoms or objective evidence of ischemia.

2.5. Statistical analysis

Data were expressed as mean±SD for continuous variables and frequencies for categorical variables. Continuous variables were compared by unpaired Student's t test and categorical variables by chi-square test. Statistical significance was defined as a two-sided value of $p<0.05$.

3. Results

ISR after PES and SES implantation occurred in 80 and 97 lesions, respectively. Clinical, angiographic, and procedural variables were analyzed and summarized in Tables 1 and 2. There was no significant difference of clinical variables in both types of DES except for tendency of higher incidence of prior coronary intervention in SES group. But in angiographic variables, SES group showed significantly a longer lesion length (SES vs PES; 41.0±21.6 mm vs 33.4±17.9 mm, p=0.013), more mean number of implanted stent

Table 1
Clinical characteristics of sirolimus- and paclitaxel-eluting stents

	SES (n=90)	PES (n=73)	p value
Age, years	58.4±10.3	60.4±10.9	0.242
Sex, male	67 (74.4%)	50 (68.5%)	0.401
Diabetes mellitus	25 (27.8%)	16 (21.9%)	0.391
Hypertension	45 (50%)	34 (46.6%)	0.664
Current smoking	27 (30.0%)	25 (34.2%)	0.563
Hypercholesterolemia (≥200 mg/dL)	25 (27.8%)	20 (27.4%)	0.445
Prior PCI	25 (27.8%)	12 (16.4%)	0.086
Prior CABG	1 (1.1%)	0 (0%)	1.000
Clinical presentation			0.604
Stable angina	53 (58.9%)	42 (57.5%)	
Unstable angina	20 (22.2%)	15 (20.5%)	
Acute myocardial infarction	17 (18.9%)	16 (21.9%)	
Use of statin	58 (64.4%)	44 (60.3%)	0.584
LVEF (%)	59.4±8.5	58.1±8.7	0.370
Multivessel disease	43 (47.8%)	37 (50.7%)	0.712

Abbreviations: SES, sirolimus-eluting stent, PES, paclitaxel-eluting stent, PCI, percutaneous coronary intervention, CABG, coronary artery bypass surgery, LVEF, left ventricular ejection fraction.