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Comparison of Full Lesion Coverage versus Spot Drug-Eluting Stent Implantation for Coronary Artery Stenoses

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Purpose: The aim of this study was to evaluate and compare the long-term clinical outcomes of the spot drug-eluting stent (DES) implantation strategy, which is used to minimize implanted stent length and the number of stents, versus full lesion coverage for treatment of coronary artery stenoses. **Materials and Methods:** We evaluated 1-year clinical outcomes of 1619 patients with stent implantation for a single coronary lesion. They were divided into two groups: those treated by full lesion coverage (n=1200) and those treated with the spot stenting strategy (n=419). The combined occurrence of 1-year target vessel failure (TVF), including cardiac death, target-vessel related myocardial infarction, or ischemia-driven target-vessel revascularization was evaluated. **Results:** The spot DES implantation group had a shorter stent length (23.14±9.70 mm vs. 25.44±13.24 mm, respectively; $p<0.001$) and a fewer number of stents (1.09±0.30 vs. 1.16±0.41, respectively; $p<0.001$), even though the average lesion length was similar to the full lesion coverage group (21.36±10.30 mm vs. 20.58±10.97 mm, respectively; $p=0.206$). Spot DES implantation was superior to full DES coverage with respect to 1-year TVF (1.4% vs. 3.3%, $p=0.044$). Cox proportional hazard model analysis showed that the risk for 1-year TVF was almost 60% lower among patients who received spot DESs compared to those who received full DES coverage after adjustment for other risk factors (HR=0.40, 95% confidence interval=0.17-0.98; $p=0.046$). **Conclusion:** Minimizing stent length and the number of stents with overlapping by spot DES implantation may result in reduced rates of 1-year TVF, compared with full DES coverage.

Key Words: Drug-eluting stents, percutaneous coronary intervention, coronary artery disease

INTRODUCTION

To reduce the occurrence of restenosis, a strategy of full lesion coverage is recommended for percutaneous coronary intervention (PCI) of coronary lesions.[1-3] The

use of longer or multiple stents could be an inevitable consequence of spanning the full lesion between angiographically "healthy to healthy" segment.[4] However, longer stent length has been indicated as an independent prognostic factor predicting adverse clinical outcomes with an increased rate of stent thrombosis and restenosis, even in the era of the drug-eluting stent (DES).[5-7] To treat physically long coronary lesions in the era of the bare-metal stent, intravascular ultrasound-guided balloon angioplasty with provisional spot stenting was suggested, and the angiographic and clinical outcomes of this strategy were favorable compared to the matched control group treated with full lesion coverage.[8] Moreover, a recent randomized study examining the impact of length and multiple overlapping on DES effectiveness found favorable short- and long-term clinical outcomes in patients treated with spot DES implantation compared to those with full DES coverage in long coronary lesions.[4] However, data investigating the beneficial role of spot DES implantation are still insufficient. Particularly, the effect of this technique has not been systematically examined over all lesion lengths, including long lesions. Therefore, we examined the effect of spot DES implantation for treatment of not only long coronary lesions but all coronary lesions and compared the long-term clinical outcomes between full DES coverage and spot DES implantation in all DES-treated lesions.

MATERIALS AND METHODS

The real safety and efficacy of 3-month dual antiplatelet therapy (DAPT) following Endeavor zotarolimus-eluting stent (E-ZES; Medtronic, Inc., Santa Rosa, CA, USA) implantation trial (RESET trial) was a prospective, open label, randomized trial conducted at 26 sites in Korea.[9] The primary goal of this trial was to compare the safety and efficacy of two DES+DAPT implantation strategies: E-ZES+3-month DAPT versus standard therapy (other DES+12-month DAPT). Details regarding study design, inclusion and exclusion criteria, and primary outcomes are provided in a prior publication.[9] All participants were randomly assigned in a 1:1 ratio to receive either E-ZES+3-month DAPT (n=1059) or standard therapy (n=1058). Among 2117 patients, 1619 patients treated with stent implantation for a single coronary lesion were selected for this study; multi-vessel and multi-lesion PCI were excluded. Selected patients were then divided into two groups according to treatment strategies; full lesion coverage (n=1200) versus spot DES implantation (n=419). All study participants provided written, informed consent using documents approved by the Institutional Review Board at each participating center.

All interventions were performed according to standard interventional techniques. In the full DES coverage group, stents were deployed to cover the full length of the atherosclerotic lesion without residual stenosis in the reference segment by angiographic analysis. In the spot DES implantation group, selective stent implantation sites of hemodynamically significant portions of the lesions (defined as diameter stenosis >50%), as identified by angiographic analysis, were chosen.[4] Pre-PCI, all patients received at least 75 mg of aspirin. A loading dose of 300 mg clopidogrel was administered at least 12 hours pre-PCI. However, in cases when clopidogrel was not administered 12 hours in advance, the patient received a 600 mg loading dose in the catheterization laboratory prior to PCI. Unfractionated heparin was administered to maintain the activated clotting time >250 seconds. The use of the glycoprotein IIb/IIIa inhibitors was left to the operator's discretion. After stent implantation, aspirin (100 mg/day) was prescribed indefinitely, and the duration of clopidogrel (75 mg/day) depended on the randomization assignment: 3-month duration following E-ZES implantation vs.12-month duration following other DES implantation. The use of cilostazol was not allowed.

Quantitative coronary angiography analysis was performed using an off-line quantitative coronary angiographic system (CASS system, Pie Medical Instruments, Maastricht, the Netherlands) before and after stent implantation. Analysts in an independent core laboratory at the Cardiovascular Research Center, Seoul, Korea were blinded to clinical information. The stented segment plus 5-mm distal and proximal reference segments were selected for analysis. Using the guiding catheter for magnification-calibration, the diameters of the reference vessel (the average of the proximal and distal reference lumen diameters), the minimal luminal diameter, lesion length, and the percent diameter stenosis were measured before and after stenting from diastolic frames in a single, matched view showing the smallest minimal luminal diameter. Lesion length was defined as the distance from the proximal to the distal segment of the lesion site; that is between the segments with no stenosis evident in the projection assessed by angiogram.

Post-procedure clinical assessment was performed in-hospital and 1, 3, 6, and 12 months after index procedure either by a clinical visit or a telephone interview. Target vessel failure (TVF), defined as the combined occurrence of car-

diovascular death, target vessel-related myocardial infarction, or target vessel revascularization at one year post-procedure, was compared between the two groups. The patients were not scheduled for routine angiographic follow-up. Clinical events were defined according to the Academic Research Consortium.[10] All deaths were considered cardiovascular deaths unless a definite non-cardiovascular cause was established. Myocardial infarction was defined as the presence of clinical symptoms, electrocardiographic changes, or abnormal imaging findings of myocardial infarction. Findings were further substantiated with the presence of either an increase in the creatine kinase myocardial band fraction to greater than three times the upper limit of the normal range or an increase in troponin-T/troponin-I to more than the 99th percentile of the upper normal limit, unrelated to an interventional procedure.[10] Target-vessel revascularization was defined as a repeat PCI or bypass surgery of the target vessel with either 1) ischemic symptoms or a positive stress test and angiographic diameter stenosis ≥50% by quantitative coronary angiographic analysis or 2) angiographic diameter stenosis ≥70% by quantitative coronary angiographic analysis without ischemic symptoms or a positive stress test. All clinical events were independently monitored and assessed by a Clinical Event Committee.

Statistical analysis

Continuous variables are expressed as mean±standard deviation, and categorical variables are expressed as number (%). Categorical variables were compared using χ^2 statistics and Fisher's exact test. Student's t-test or the Mann-Whitney U test was used to compare continuous variables. We estimated the cumulative event rate using the Kaplan-Meier method and calculated absolute differences and 95% confidence intervals (CIs). The log-rank test was used to assess the significance of different incidences. A multivariable Cox proportional hazards model was used to evaluate the association between the different stenting strategies (i.e., full DES coverage versus spot DES implantation) and TVF. The proportional hazards assumption was evaluated for all variables by generating log-log survival plots for each predictor from the Cox regression model. Statistical analyses were performed using the Statistical Package for the Social Sciences (version 18.0, SPSS Inc., Chicago, IL, USA). A p-value <0.05 was considered statistically significant.

RESULTS

Baseline clinical and angiographic characteristics of the two groups are shown in Table 1 and 2, respectively. Compared to the full DES coverage group, the spot DES implantation group had shorter stent length (25.44±13.24 mm vs. 23.14±9.70 mm, respectively; p<0.001) and fewer the number of stents (1.16±0.41 vs. 1.09±0.30, respectively; p<0.001), even

Table 1. Baseline Clinical Characteristics

Variables	Full DES coverage (n=1200)	Spot DES implantation (n=419)	p value
Age (yrs)	61.8±9.7	62.9±9.6	0.055
Male sex (%)	758 (63.2)	247 (58.9)	0.126
Dyslipidemia (%)	716 (59.7)	242 (57.8)	0.493
Current smoker (%)	279 (23.3)	96 (22.9)	0.713
Hypertension (%)	725 (60.4)	274 (65.4)	0.071
Diabetes mellitus (%)	313 (26.1)	121 (28.9)	0.266
Previous myocardial infarction (%)	25 (2.1)	4 (1.0)	0.134
Previous PCI (%)	45 (3.8)	11 (2.6)	0.278
No. of diseased vessels (%)			0.115
One	847 (70.6)	297 (70.9)	
Two	258 (21.5)	77 (18.4)	
Three	95 (7.9)	45 (10.7)	
Ejection fraction (%)	64.34±8.95	64.52±9.44	0.743
Clinical presentation (%)			0.311
Stable angina	541 (45.1)	172 (41.1)	
Unstable angina	502 (41.8)	184 (43.9)	
Acute myocardial infarction	157 (13.1)	63 (15.0)	

PCI, percutaneous coronary intervention; DES, drug-eluting stent.
Values are presented as n (%) or mean±standard deviation.

Table 2. Angiographic and Procedural Characteristics

Variables	Full DES coverage (%)	Spot DES implantation (%)	*p* value
Treated artery			0.930
Left anterior descending artery	731 (60.9)	259 (61.8)	
Right coronary artery	271 (22.6)	91 (21.7)	
Left circumflex artery	198 (16.5)	69 (16.5)	
No. of stents	1.16±0.41	1.09±0.30	<0.001
Type of stents			0.253
E-ZES	587 (48.9)	226 (53.9)	
Endeavor resolute	257 (21.4)	88 (21.0)	
Xience	127 (10.6)	35 (8.4)	
Cypher	229 (19.1)	70 (16.7)	
Lesion length (mm)	20.58±10.97	21.36±10.30	0.206
Percent diameter stenosis (%)			
Pre-intervention	64.54±14.31	67.38±14.35	0.001
Post-intervention	11.50±7.70	12.02±7.50	0.231
Reference diameter (mm)			
Pre-intervention	3.04±0.53	3.02±0.50	0.652
Post-intervention	3.10±0.52	3.09±0.49	0.898
Minimal lumen diameter (mm)			
Pre-intervention	1.09±0.48	1.00±0.47	0.001
Post-intervention	2.75±0.44	2.73±0.40	0.335
Use of intravascular ultrasound	556 (46.3)	205 (48.9)	0.360
Nominal stent length (mm)	25.44±13.24	23.14±9.70	<0.001

DES, drug-eluting stent; E-ZES, Endeavor zotarolimus-eluting stent.
Values are presented as n (%) or mean±standard deviation.

though the average lesion length was similar between the two groups (20.58±10.97 mm vs. 21.36±10.30 mm, respectively; p=0.206). Pre-intervention minimal lumen diameter was significantly smaller in the spot DES implantation group (1.00±0.47 mm vs. 1.09±0.48 mm, p=0.001), and the percent diameter stenosis pre-PCI was significantly greater (67.38±14.35% vs. 64.54±14.31%, p=0.001).

Clinical outcomes through 1-year follow-up are summarized in Table 3. At 1 year, the rate of TVF was significantly lower in the spot DES implantation group (1.4% vs. 3.3%, p=0.044). Outcomes for the individual components of TVF at 1-year follow-up were similar between the two groups, except a lower rate of target vessel revascularization in the spot DES implantation group was observed (1.2% vs. 3.0%, p=0.043). A log-rank test revealed that the cumulative incidence of TVF at 1-year was significantly lower in patients who underwent spot DES implantation than those subjected to full DES coverage (p=0.041) (Fig. 1). This association remained significant even after controlling for other risk factors including age, hypertension, lesion length, the DES type used, etc. (HR=0.40, 95% CI=0.17-0.98; p=0.046) (Table 4). The Cox proportional hazard model found the risk for TVF to be almost 58% lower in patients subjected to spot DES implantation compared to those subjected to full DES coverage (HR=0.42, 95% CI=0.18-0.99, p=0.048) (Fig. 2). Subgroup analysis showed that the beneficial effects of spot DES implantation appeared to be more prominent in the elderly and those with hypertension (Fig. 2).

DISCUSSION

This study shows a lower rate of 1-year TVF in long lesions as well as other lesions in patients treated with a spot DES implantation compared with those treated with a full length DES. Lesion length was similar between the two groups. Therefore, we propose that efforts to minimize the implanted stent length and the number of stents with overlapping during PCI procedures should be made regardless of lesion length.

In the era of bare-metal stent, longer stent length was found to be an independent factor predicting restenosis, and multiple or physically longer stent implantations have been associated with an increased risk of major adverse cardiac

Table 3. Clinical Outcomes of Through 1 Year

Variables	Full DES coverage (%)	Spot DES implantation (%)	*p* value
Composite events			
Target-vessel failure	40 (3.3)	6 (1.4)	0.044
Death from any cause, myocardial infarction, or stent thrombosis	10 (0.8)	3 (0.7)	0.999
Death from cardiovascular cause or myocardial infarction	7 (0.6)	1 (0.2)	0.688
Individual components			
Death			
From any cause	6 (0.5)	2 (0.5)	0.999
From cardiovascular cause	4 (0.3)	0 (0.0)	0.578
Myocardial infarction	4 (0.3)	1 (0.2)	0.999
Target-vessel revascularization	36 (3.0)	5 (1.2)	0.043
Non-target vessel revascularization	14 (1.2)	7 (1.7)	0.432
Stent thrombosis, definite or probable	5 (0.4)	0 (0.0)	0.336
Bleeding			
Major or minor	7 (0.6)	3 (0.7)	0.725
Major	3 (0.3)	1 (0.2)	0.999
Cerebrovascular accidents	7 (0.6)	2 (0.5)	0.999

DES, drug-eluting stent.
Values are presented as n (%).

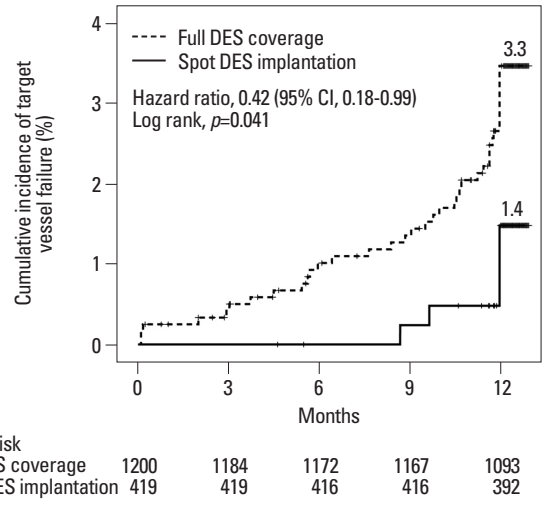

Fig. 1. Cumulative incidence of target vessel failure at 1 year. One year time-to-event curves are shown for target vessel failure in patients treated with full DES coverage versus spot DES implantation. Event rates represent Kaplan-Meier estimates. The *p* values are based on the log-rank test. CI, confidence interval; DES, drug-eluting stent.

events.[11-13] However, previous studies have shown that treatment of long coronary lesions by a DES significantly reduced the rates of restenosis and the need for target lesion revascularization compared with the use of bare-metal stent.[14-17] An intravascular ultrasound study reported that the residual edge plaque burden was an independent predictor of angiographic edge restenosis after bare-metal and paclitaxel-eluting stent implantation; the cutoff value of the residual edge plaque burden was 47.7% and 47.1%, respectively.[18] Therefore, with the advent of the DES, the most considerable change in the implantation strategy is that longer or multiple DES implantations for full lesion coverage have usually been performed in an effort to minimize edge restenosis.

However, a physically longer DES length was still associated with poor clinical outcomes. The main problems of longer length of DES are associated with an increased risk of "hard" clinical outcomes (i.e., stent thrombosis) as well as "soft" clinical outcomes (i.e., restenosis).[5-7] In addition, previous studies revealed that DES overlap was an independent predictor of overall stent thrombosis and was associated with impaired angiographic and long-term clinical outcome.[19,20] Prolonged duration of DAPT would be associated with an increased risk of bleeding after longer DES implantation because of increased potential of stent thrombosis. Indeed, a large-scale multicenter registry study with 301 patients with definite stent thrombosis (from 23500 DES-treated patients) showed that longer stent length was one of the independent predictors of stent thrombosis.[5] Another study with 3145 patients (4667 DES-treated lesions) showed that the threshold of stent length for predicting stent thrombosis was 31.5 mm; stent lengths greater than or equal to 31.5 mm were associated with higher rates of stent thrombosis at 3 years, compared with stent length less than 31.5 mm (4.0% vs. 0.7%, respectively, $p<0.001$).[6]

The provisional spot stenting technique was initially pro-

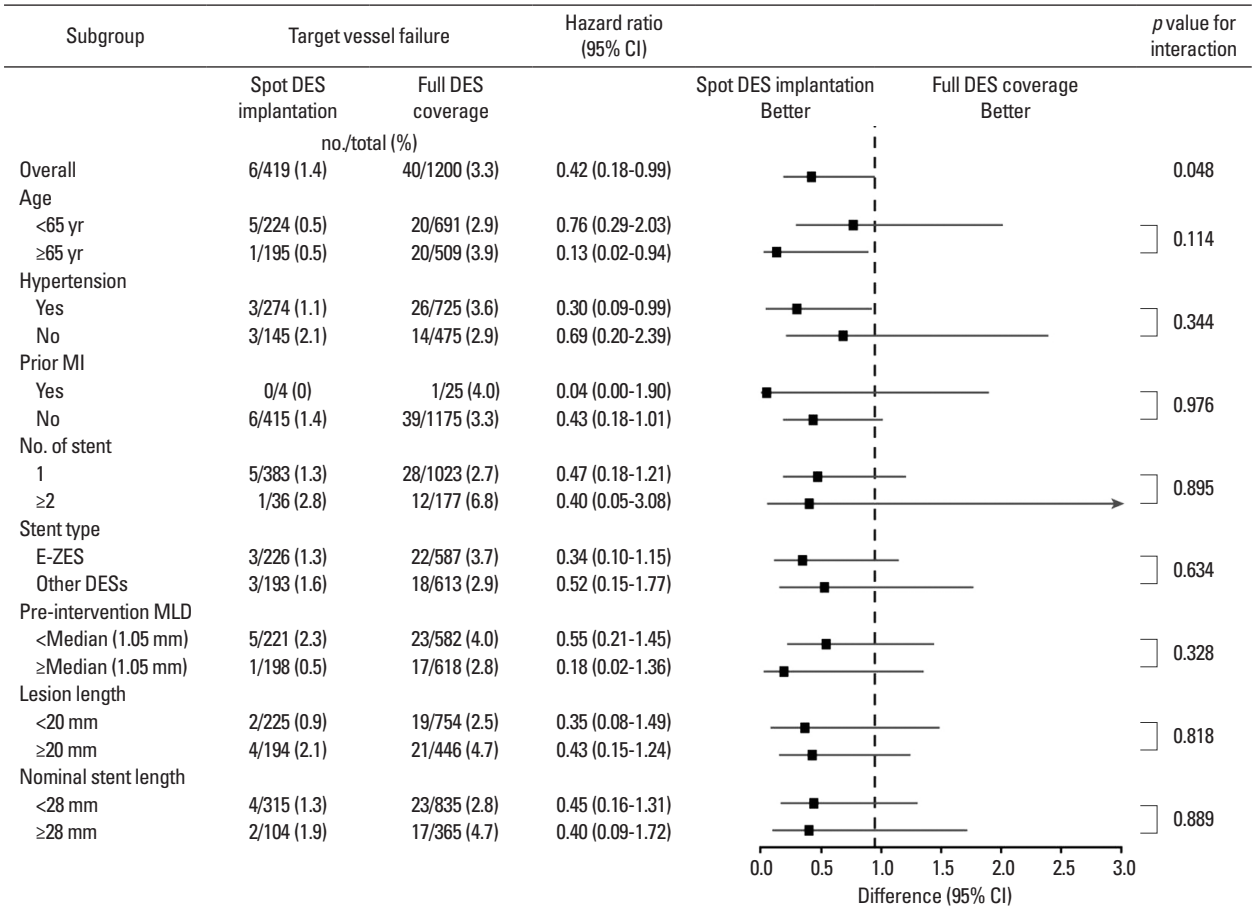

Fig. 2. Subgroup analyses of the 1-year rates of target vessel failure. Subgroup analyses are shown for the target vessel failure at 1 year among subgroups of patients treated with full DES coverage versus spot DES implantation. The *p* value for interaction represents the likelihood of interaction between the variable and the relative treatment effect. CI, confidence interval; DES, drug-eluting stent; E-ZES, Endeavor zotarolimus-eluting stent; MI, myocardial infarction; MLD, minimal lumen diameter.

Table 4. Independent Predictors of 1-Year Target Vessel Failure in Cox's Regression Analysis

Predictors	Hazard ratio (95% CI)	*p* value
Age (yrs)	1.01 (0.98-1.04)	0.678
History of hypertension	1.10 (0.60-2.02)	0.762
History of prior myocardial infarction	1.25 (0.17-9.19)	0.827
No. of diseased coronary arteries	0.90 (0.57-1.43)	0.652
No. of stents	1.61 (0.51-5.03)	0.416
E-ZES (vs. other DESs)	1.27 (0.71-2.28)	0.421
Pre-intervention MLD (mm)	0.65 (0.35-1.21)	0.170
Lesion length (mm)	1.02 (0.96-1.10)	0.507
Nominal stent length (mm)	0.99 (0.92-1.07)	0.822
Spot DES implantation (vs. full DES coverage)	0.40 (0.17-0.98)	0.046

CI, confidence interval; DES, drug-eluting stent; E-ZES, Endeavor-zotarolimus-eluting stent; MLD, minimal lumen diameter.
Values are presented as n (%) or mean±SD.

posed by Colombo, et al.[8] and performed to minimize stented length for treatment of long coronary lesions in the era of the bare-metal stent. The target lesion revascularization rate was significantly lower in the provisional spot stenting group (n=130 lesions) compared with the traditional stenting group (n=143 lesions) (19% vs. 34%, respectively, $p<0.05$).[8]

In the DES era, data on the spot DES implantation are scarce. One randomized study investigating the treatment of long coronary lesions with DESs showed that the 3-year major adverse cardiac event rate was significantly lower in the spot DES implantation group (n=89 patients) compared to the full DES coverage group (n=90 patients) (7.8% vs. 20%, re-

spectively, p=0.019).[4] However, no studies have investigated the effect of spot DES implantation on all DES-treated lesions, not just long lesions. In the present study, we made such an analysis, showing a lower rate of 1-year TVF in all DES-treated lesions treated with spot DES implantation.

A previous, randomized study showed that PCI as an initial management strategy did not significantly reduce the composite risk of death, myocardial infarction, and other major cardiovascular events when added to optimal medical therapy in patients with stable coronary disease (20.0% vs. 19.5%, respectively, p=0.62),[21] and an another randomized study reported that event-free survival was similar between the deferral and PCI groups in a patient population with moderate coronary stenosis for whom PCI was planned when fractional flow reserve was greater than 0.75.[22] These studies suggest that reducing unnecessary stent implantation and minimizing the stent length could be associated with improved clinical outcomes after PCI. An angiographic follow-up study found edge restenosis in 27.8% of in-stent restenosis cases utilizing a sirolimus-eluting stent and in 2.5% of in-stent restenosis cases utilizing a paclitaxel-eluting stent.[23] Because the rate of target vessel revascularization was 3.0% in full DES coverage and 1.2% in spot DES implantation in this study, we believe that actual incidence of edge restenosis might be quite lower among the overall study population. Therefore, considering the low incidence of edge restenosis and the balance between in-stent restenosis and stent thrombosis, spot DES implantation should be considered as an appropriate strategy alternative to full DES coverage, offering a favorable clinical outcome in all DES-treated lesions.

There are some limitations in this study. First, this was a retrospectively analyzed cohort study. The nature of the nonrandomized subgroup analysis may have resulted in a selection bias and restricted power due to the methodological limitations. Nonetheless, a significant strength of the current study is that it has a relatively large sample size compared with other randomized trials. Second, the spot DES implantation group could be underestimated because the two groups were divided based on the measurements of quantitative coronary angiographic analysis alone without reference to other modalities such as intravascular ultrasound or fractional flow reserve. Third, there was no data in the present study regarding platelet function assessment or the effects by using new antiplatelet agents besides clopidogrel. Finally, the findings of this study could be underpowered as a result of relatively lower event rates and the small number of patients in the spot DES implantation group.

In conclusion, minimizing the stent length and the number of stents with overlapping by spot DES implantation should be considered in the treatment of all lesions regardless of lesion length.

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