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ORIGINAL ARTICLE

Five-year clinical outcomes of everolimus-eluting stents from the post marketing study of CoCr-EES (XIENCE V/PROMUS) in Japan

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Abstract

The Cobalt Chromium Everolimus-Eluting Stent (CoCr-EES) Post Marketing Surveillance (PMS) Japan study is a prospective multicenter registry designed to evaluate the safety and efficacy of XIENCE V/PROMUS everolimus-eluting stents in routine clinical practice at 47 centers representative of the clinical environment in Japan. We enrolled 2010 consecutive patients (2649 lesions) who underwent percutaneous coronary intervention using CoCr-EES. Clinical outcomes were evaluated through 5 years. Mean age was 68.8 years, 41.9% had diabetes, 4.9% received hemodialysis. Five-year clinical follow up was available for 1704 (84.8%) patients. Major adverse cardiovascular events (MACE) occurred in 10.7% of patients, including cardiac death (3.8%), myocardial infarction (1.8%), and clinically driven target lesion revascularization (TLR) (6.0%). Beyond 1 year, annual incidence of clinically driven TLR was 0.5–0.8%. Definite or probable stent thrombosis occurred in 9 (0.5%) patients at 5 years. After 1 year, definite stent thrombosis occurred in only 1 patient. Significant predictors for MACE were dialysis (ODDs ratio 4.58, 95% CI 2.75–7.64), prior cardiac intervention (ODDs ratio 2.47, 95% CI 1.75–3.49), total stent length (ODDs ratio 1.01, 95% CI 1.01–1.02), and number of diseased vessels (ODDs ratio 1.66, 95% CI 1.08–2.55). Five-year clinical outcomes from the CoCr-EES PMS Japan study demonstrated a low incidence of clinical events in the daily practice up to 5 years.
Clinical Trial Registration Information: https://clinicaltrials.gov/ct2/show/NCT01086228.

Keywords Everolimus · Stent · Restenosis · Thrombosis

Introduction

Several randomized studies have consistently shown robust 5-year safety and efficacy outcomes of cobalt–chromium everolimus-eluting stents (CoCr-EES) in patients with coronary artery disease [1–6]. However, there have been no sufficient data to evaluate whether these long-term favorable outcomes with CoCr-EES are consistent with the real-world clinical scenario in Japan. Five-year clinical outcomes of sirolimus-eluting stents (SES) in a Japanese post-marketing study raised concerns about the rate of very late stent thrombosis [7]. Previously, the current CoCr-EES Post Marketing

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Surveillance (PMS) Japan study reported 3-year clinical outcomes after CoCr-EES implantation [8]. To investigate further long-term outcomes, we report on the 5-year outcomes of the extended follow-up period of the current CoCr-EES PMS Japan study.

Methods

Patient population and follow-up

Details of the CoCr-EES PMS Japan study have been previously reported in the clinical literature [8]. In brief, CoCr-EES PMS Japan is a prospective multicenter registry. A total of 47 centers across Japan participated in the study. Patients were eligible for the study if one or more native coronary artery lesions were treated exclusively with CoCr-EES (XIENCE V or PROMUS) during the index percutaneous coronary intervention (PCI) procedure and written informed consent was obtained. Use of IVUS and Rotablator was at discretion of the operators in this registry. Clinical data were collected and documented in an electronic case report form (Medidata, New York, USA) and pre-specified clinical events such as death, myocardial infarction, and target lesion/vessel revascularization were adjudicated by an independent clinical event committee up to 3 years. Between 3 to 5 years, clinical events were counted by correcting self-report from participated sites.

Definitions

All deaths were considered as cardiac death unless an unequivocal non-cardiac cause was established. Myocardial infarction (MI) was defined as development of new, pathological Q waves on ECG, or elevation of creatinine kinase (CK) levels greater than or equal to two times the upper limit of normal (ULN) with elevated CK-MB in the absence of new pathological Q waves. Target lesion revascularization (TLR) was defined as any repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel performed for restenosis or other complication of the target lesion. All TLR events were classified prospectively as clinically indicated or non-clinically indicated by the physician prior to repeat angiography. Target vessel revascularization (TVR) was defined as any repeat percutaneous intervention or surgical bypass for any segment in the target vessel. Major adverse cardiac events (MACE) were defined as the composite of cardiac death, MI, clinical driven TLR. Target lesion failure (TLF) and target vessel failure (TVF) were defined as the composite of cardiac death, target vessel MI, clinical driven TLR, and the composite of cardiac death, MI, and TVR, respectively. Stent thrombosis was defined as definite, probable, and possible according to the Academic Research Consortium (ARC) definition.

Statistics

Statistical analysis was performed using SAS software (version 9.3; SAS Institute; Cary, NC, USA). For binary variables, counts, percentages, and 95% confidence intervals (CI) were calculated. For continuous variables, means, standard deviations, and 95% CI for the mean were calculated. Cumulative event curves were estimated according to the Kaplan–Meier method and p value was based on log rank test. Logistic multivariate model was created using stepwise regression, where the variables were entered into the model at the 0.20 significance level and removed at the 0.05 level. The candidate predictors were selected from available data which seemed to be associated with clinical events, including age, gender, current tobacco use, diabetes, diabetes treated with insulin, hypertension, hypercholesterolemia, prior cardiac interventions, acute coronary syndrome, hemodialysis, prior myocardial infarction, number of treated lesions, number of diseased vessels, presence of thrombus, left anterior descending coronary artery, left main coronary artery, pre reference vessel diameter, pre minimal lumen diameter (MLD), lesion length, ACC/AHA B2/C, in-stent restenosis, ostial, stent overlap, chronic total occlusion, post reference vessel diameter, maximal balloon pressure, pre-dilatation, post-dilatation, number of implanted stents, 2.5 mm stent, total stent length per patients, and dual antiplatelet therapy less than 180 days.

Results

The flowchart of the study is presented in Fig. 1. A total 2010 patients (2649 lesions) constituted the current study population. Five-year clinical follow-up data were available for 1704 (84.8%) patients (Fig. 1). Patient, lesion and procedural characteristics were presented in Table 1. The average age was 68.8 ± 10.1 years. The prevalence of diabetes was 41.9% and hemodialysis was 4.9%. Dual antiplatelet therapy (DAPT) was continued in 84.6% of patients at 1 year, 71.5% at 2 years, and 64.0% at 3 years, respectively.

At 5 years, MACE occurred in 182 (10.7%) patients (Table 2). Cumulative incidences of cardiac death or MI, and clinically driven TLR were 4.9 and 5.5% at 5 years, respectively (Fig. 2). Annual incidence of late clinically driven TLR was below 1% beyond 1 year. Incidence of definite or probable stent thrombosis was 0.5% at 5 years (Table 2). Beyond 1 year, definite ST occurred in only one patient (Fig. 2). This patient was a 61-year-old man with dyslipidemia and diabetes. The initial PCI was performed due to ST elevated MI (STEMI). A Promus stent was implanted at the

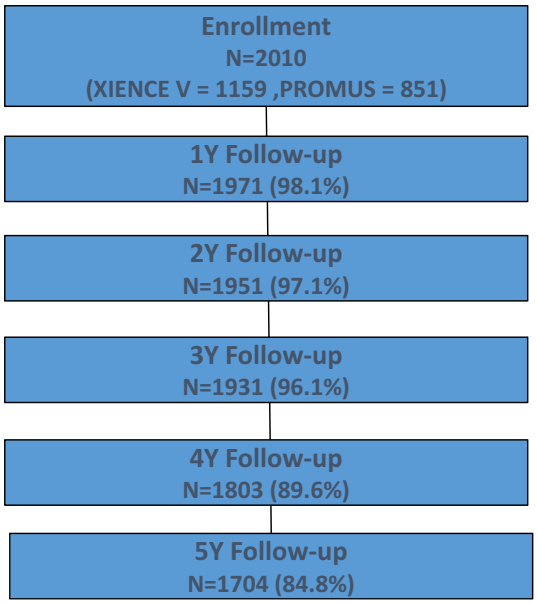

Fig. 1 Flow chart of the present study

distal RCA lesion. Post dilatation was performed and final in-stent diameter stenosis was 9%. On day 1767, the patient experienced chest discomfort and dorsal pain, and went to non-study hospital. On day 1773, he visited the emergency outpatient unit of the study site. Non-ST elevation myocardial infarction (Troponin T was positive) with stent thrombus occurred. PCI was successfully performed on the target lesion the following day and the condition resolved. The patient was discharged 2 days after the procedure.

Significant independent multivariable predictors for MACE were identified as hemodialysis, prior coronary intervention, total implanted stent length, and number of diseased vessels (Table 3). Although severe or moderate calcification was more frequent in the patients on hemodialysis compared to the patients without hemodialysis (40.9 versus 21.0%, $p < 0.0001$), in-stent % diameter stenosis (DS) (13.9 ± 8.3 versus 13.8 ± 7.6%, $p = 0.98$) and MLD (2.55 ± 0.50 versus 2.54 ± 0.50 mm, $p = 0.93$) at post procedure as well as acute gain (1.73 ± 0.50 versus 1.77 ± 0.54 mm, $p = 0.42$) were comparable between the 2 groups. Nonetheless, 5-year MACE rate for patients on hemodialysis was significantly higher compared to patients not on hemodialysis (33.8 versus 8.7%, $p < 0.0001$, Fig. 3).

Discussion

Major findings of the CoCr-EES PMS Japan study were: major findings of the CoCr-EES PMS Japan study were: (1) late TLR rate beyond 1 year was 0.5–0.8% per year in routine daily practice, which is less than half of the rates observed with the first-generation DES PMS; (2) very late definite or probable stent thrombosis occurred in only 1 patient beyond 1 year; (3) hemodialysis was the strongest independent predictor for 5-year MACE.

Several randomized trials presented the sustained clinical benefits after EES implantation. Five-year outcomes of EES arm in the SPIRIT II, SPIRIT III, COMPARE, SORT OUT IV, Resolute All comers, and TWENTE randomized trials showed 4.7–8.6% clinically driven TLR rates, and 0.3–3.1% definite or probable ST (Table 4) [1–6]. However, most of the western randomized excluded patients with ST elevation MI or severe renal dysfunction including hemodialysis. The current registry represented the real-world clinical data including patients with ST elevated MI or with renal dysfunction including hemodialysis. The present registry further confirmed the sustained low clinically driven TLR (6.0%) and low late ST rates (0.5%) after EES implantations. Beyond 3 years, clinically driven TLR occurred in 0.8% per year and definite ST occurred in only 1 patient. Even after bare-metal stent implantation, late stent thrombosis and late restenosis were observed possibly due to plaque progression and rupture in the in-stent neoatherosclerosis [9–12]. In the first-generation DES, polymer caused chronic inflammation. However, the polymer of CoCr-EES is different from the polymer of the first-generation DES. CoCr-EES strut platform was coated with 7.8 um thick durable fluorinated copolymer. Fluorinated copolymer of CoCr-EES consists of vinylidene fluoride and hexafluoropropylene, which is used clinically for permanent surgical sutures and proven to be biocompatible [13]. In a porcine coronary model, CoCr-EES was associated with decreasing inflammatory response was observed overtime, whereas as an escalation of inflammation was observed after SES implantation [14]. In human, CoCr-EES showed a lower inflammation score with no hypersensitivity and less fibrin deposition compared to the first-generation DES [15]. Biocompatible durable thromboresistant fluoride and hexafluoropropylene polymer on EES might contribute to protect progression of neoatherosclerosis and minimalize in-stent plaque rupture [15–17].

However, this sustained benefit disappeared in patients on hemodialysis. Patients on hemodialysis tend to have multi-vessel, diffuse, and calcified coronary artery disease [18]. Rigid calcified coronary arteries hamper the successful delivery of a coronary stent, and stent expansion. Stent under-expansion is one of the main risk factors for stent restenosis and stent thrombosis [19, 20]. However, stent expansion was not inferior in hemodialysis patients compared to non-hemodialysis patients in this registry. Other physiological factors such as severe endothelial dysfunction, enhanced platelet activation, and poor response to antiplatelet drugs in this patient population might contribute to the poor outcomes after coronary stent implantation [21, 22]. Nonetheless, CoCr-EES seem to have better

Table 1 Baseline and procedural characteristics

	$N = 2010$ patients $N = 2649$ lesions	95% CI[a]
Age (years)	68.8 ± 10.1	68.4, 69.2
Gender, male (%)	76.1	74.1, 77.9
Current tobacco use (%)	23.2	21.3, 25.1
Hypertension (%)	78.7	76.8, 80.4
Dyslipidemia (%)	67.5	65.4, 69.5
Diabetes mellitus (%)	41.9	39.7, 44.1
Treated with insulin (%)	9.1	7.9, 10.4
Hemodialysis (%)	4.9	4.0, 5.9
Clinical presentation		
Stable angina (%)	45.4	43.1, 47.7
Unstable angina (%)	19.5	17.7, 21.3
Acute myocardial infarction (%)	8.5	7.3, 9.9
ST segment elevated myocardial infarction (%)	5.8	4.8, 7.0
Silent ischemia (%)	20.3	18.5, 22.2
Angiographic stenosis only (%)	6.3	5.2, 7.5
Target vessel		
LAD (%)	48.0	46.1, 49.9
LCX (%)	18.3	16.9, 19.8
RCA (%)	30.2	28.4, 32.0
LMCA (%)	2.8	2.2, 3.5
Graft (%)	0.6	0.4, 1.0
Lesion type		
De novo (%)	89.0	87.8, 90.2
Restenosis (%)	11.0	9.8, 12.2
Type B2/C lesion (%)	81.9	80.1, 83.6
Number of implanted stents (per patient)	1.5 ± 0.8	1.5, 1.6
Number of implanted stents (per lesion)	1.2 ± 0.5	1.2, 1.2
Pre QCA analysis		
Reference vessel diameter (mm)	2.57 ± 1.63	2.50, 2.65
Minimal lumen diameter (mm)	0.77 ± 0.44	0.75, 0.79
% Diameter stenosis (%)	69.6 ± 15.4	68.9, 70.3
Post QCA analysis		
In-stent minimal lumen diameter (mm)	2.54 ± 0.50	2.52, 2.56
In-stent % diameter stenosis (%)	13.9 ± 7.6	13.5, 14.2

LAD left anterior descending coronary artery, *LCX* left circumflex coronary artery, *RCA* right coronary artery, *LMCA* left main coronary artery, *QCA* quantitative coronary analysis

[a]By normal approximation for continuous variables and by Clopper-Pearson exact confidence interval for binary variables

angiographic outcomes compared to first-generation DES in the previous reports. In the consecutive 100 hemodialysis patients, CoCr-EES were associated with significant lower late loss (0.26 versus 0.53 mm, $p = 0.03$) and binary restenosis rate (8.7 versus 21.2%, $p = 0.04$) compared to SES at 1 year [23]. This significant effect to prohibit neointimal growth was consistent with the multicenter registry in Japan (OUCH-PRO registry) [24]. In OUCH-PRO registry, average rate loss was 0.37 mm and binary restenosis rate was 16%. Incidence of target lesion failure was 18% and no stent thrombosis was recorded at 1 year in 123 hemodialysis patients. However, there have been few reports to investigate whether CoCr-EES significantly improve long clinical outcomes compared to first-generation DES or not. Otsuka et al. compared clinical outcomes between CoCr-EES ($N = 102$) and paclitaxel-eluting stents (PES, $N = 107$) in hemodialysis patients. Incidence of 3-year MACE was 13.2% in the EES group and 17.4% in the PES group ($p = 0.25$) [25]. No significant difference was observed in this study. Currently available DES including CoCr-EES cannot achieve the acceptable clinical outcomes in hemodialysis patients. Further study

Table 2 Clinical outcomes through 5 years ($N = 2010$)

	1 year (0–365 days) $N = 1971$	2 years (0–730 days) $N = 1951$	3 years (0–1095 days) $N = 1931$	4 years (0–1460 days) $N = 1803$	5 years (0–1825 days) $N = 1704$
Clinical outcomes, % (number)					
Death	2.4 (47)	4.1 (80)	5.9 (113)	8.3 (149)	11.3 (193)
Cardiac death	0.9 (17)	1.4 (28)	2 (39)	2.7 (48)	3.8 (65)
All MI %	1.0 (20)	1.5 (29)	1.6 (30)	1.7 (30)	1.8 (31)
Target vessel MI	0.8 (15)	1.0 (19)	1.0 (20)	1.1 (20)	1.2 (21)
All TLR	3.7 (72)	4.8 (93)	5.4 (105)	6.4 (115)	7.2 (123)
Clinical driven TLR	3.0 (59)	3.8 (75)	4.4 (84)	5.2 (94)	6.0 (102)
All TVR	5.7 (113)	7.5 (147)	8.8 (169)	10.6 (191)	12.3 (209)
Composite outcomes, % (number)					
MACE	4.6 (90)	6.3 (123)	7.4 (142)	8.8 (159)	10.7 (182)
TLF	4.4 (86)	5.8 (114)	6.9 (133)	8.3 (150)	10.2 (173)
TVF	7.2 (141)	9.6 (188)	11.4 (220)	13.8 (249)	16.4 (280)
Stent thrombosis, % (number)					
Definite	0.36 (7)	0.36 (7)	0.36 (7)	0.39 (7)	0.47 (8)
Probable	0.05 (1)	0.05 (1)	0.05 (1)	0.06 (1)	0.06 (1)
Definite or probable	0.41 (8)	0.41 (8)	0.41 (8)	0.44 (8)	0.53 (9)

MI myocardial Infarction, *TLR* target lesion revascularization, *TVR* target vessel revascularization, *MACE* major adverse cardiac events, *TLF* target lesion failure, *TVF* target vessel failure

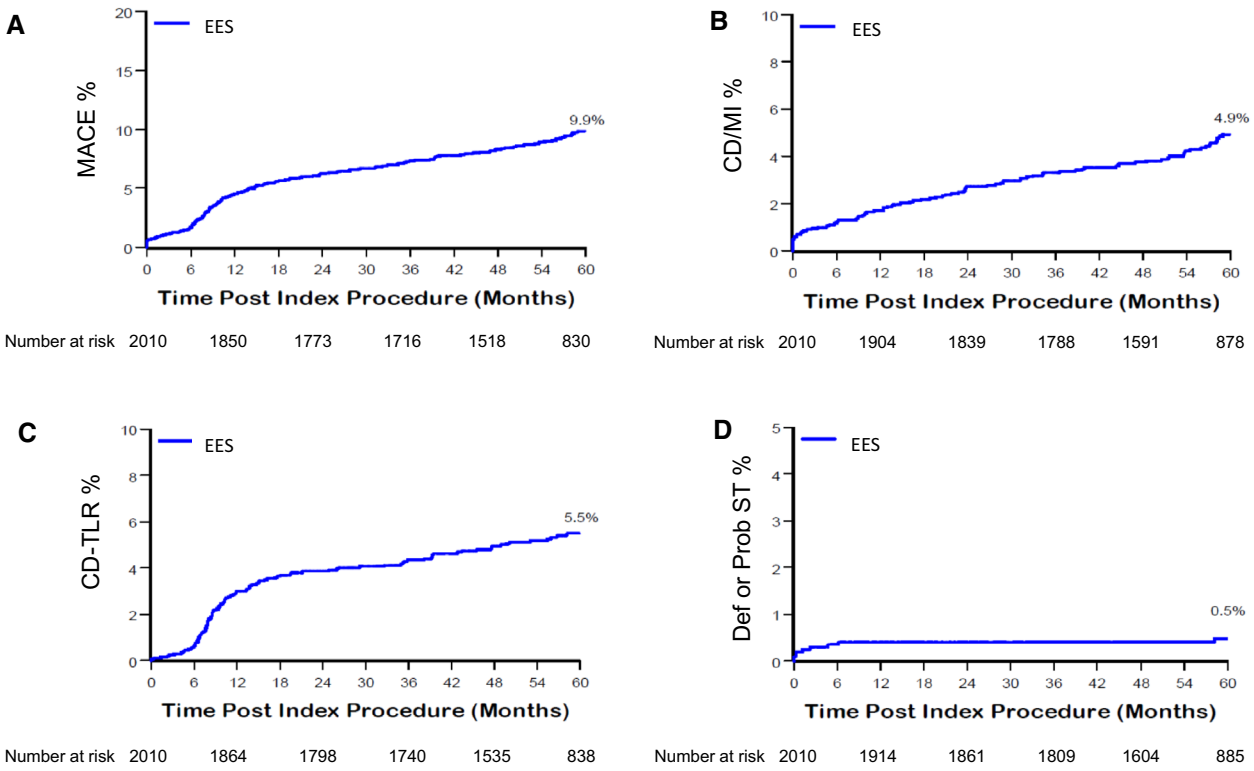

Fig. 2 Kaplan–Meier estimated curves for major adverse cardiac events (**a**), cardiac death or myocardial infarction (**b**), clinically driven target lesion revascularization (**c**), and definite or probable stent thrombosis (**d**) through 5 years

Table 3 Significant predictors of 5-year MACE from multivariate stepwise logistic regression analysis

Predictors	ODDs ratio (95% CI)	*p* value
Dialysis	4.58 (2.75–7.64)	< 0.0001
Prior cardiac intervention	2.47 (1.75–3.49)	< 0.0001
Total stent length	1.01 (1.01–1.02)	0.0007
Number of diseased vessels	1.66 (1.08–2.55)	0.0220

is warranted to improve clinical outcomes in hemodialysis patients with coronary artery disease.

Limitation

Several study limitations were identified: (1) the single arm study design prevents the direct comparison to treatment with other therapies. (2) Five-year clinical follow-up data were available in only 84.8% of patients. (3) Beyond 3 years, clinical events were only counted by correcting self-report from participated sites. Event rates might be under-evaluated. (4) The study sample size was not sufficient for evaluating the incidence of stent thrombosis, although the rates of stent thrombosis, very late stent thrombosis in particular, was remarkably low in the present study. (4) The data on the prevalence of use of intracoronary imaging devices and Rotablator were not available. (5) Additionally, important data such as DAPT use beyond 3 years was not available. However, this is the first large-scale multicenter study to report long-term outcomes of second-generation EES based on routine clinical practice in Japan.

Conclusions

Five-year clinical outcomes of the CoCr-EES PMS Japan study demonstrated a low incidence of clinical events in routine clinical practice in Japan. There were no major concerns about very late stent thrombosis and late catch-up phenomenon at least up to 5-year follow-up.

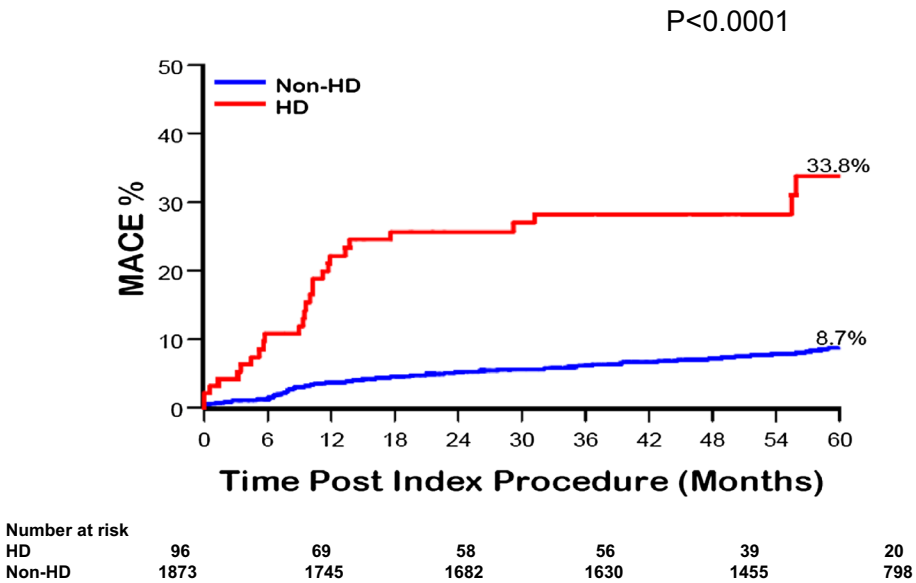

Fig. 3 Kaplan–Meier estimated curves for major adverse cardiac events in patients with or without dialysis through 5 years

Table 4 Five-year clinical events in the EES arm in the randomized control trials

Clinical event	PMS (present study)	SPIRIT II EES arm	SPIRIT III EES arm	COMPARE EES arm	SORTOUT IV EES arm	RESOLUTE AC EES arm	TWNTE EES arm
CD-TLR	6.0	4.7	8.6	5.0	–	7.1	7.7
Def or prob ST	0.5	0.9	0.3	3.1	0.9	1.7	0.6

PMS post marketing surveillance, *EES* everolimus-eluting stent, *CD-TLR* clinical driven-target lesion revascularization, *Def or prob ST* definite or probable stent thrombosis

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Compliance with ethical standards

Conflict of interest Ken Kozuma and Kengo Tanabe receive remuneration from Abbott Vascular, Kusano Hajime is an employee of Abbott Vascular and has stocks of Abbott Vascular, Hong Nie is an employee of Abbott Vascular, and Takeshi Kimura receives research and scholar funds from Abbott Vascular. Others have no disclosure related to this manuscript.

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