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Comparison of platinum chromium everolimus-eluting stent with cobalt chromium everolimus-eluting stent in unselected patients undergoing percutaneous coronary intervention

R.-G. LI, C.-H. LEE[1], A. LOW[1], M. CHAN[1], K.H. CHAN[1], A.M. RICHARDS[1], X.-K. QU, W.-Y. FANG, H.C. TAN[1]

Department of Cardiology, Shanghai Chest Hospital Affiliated to Shanghai Jiaotong University, Shanghai, China
[1]National University Heart Centre, National University Health System, Singapore, Singapore

Abstract. – OBJECTIVE: The recent PLATINUM trial has demonstrated that the use of the new generation platinum chromium everolimus-eluting stents (PtCr-EES) yield clinical outcomes similar to those obtained by the use of cobalt chromium everolimus-eluting stents (CoCr-EES) in selected patients with 1 or 2 de novo coronary artery lesions. This study aimed to compare the safety and efficacy of the PtCr-EES and CoCr-EES in unselected patients from a real-life single-center registry.

PATIENTS AND METHODS: From July 2009 through November 2010, 788 consecutive patients in our institution with symptomatic coronary artery disease who were treated with the CoCr-EES (n = 410) or PtCr-EES (n = 378) were enrolled into this study. The primary endpoint of the study was target-lesion failure (TLF) at 12-month follow-up and the secondary endpoints were major adverse cardiovascular events and stent thrombosis.

RESULTS: The prevalence of TLF in the PtCr-EES group (4.5%) was similar to that in the CoCr-EES group (3.9%). In addition, there were no significant differences in the 12-month rates of cardiac death (2.1% vs. 1.5%), myocardial infarction (2.4% vs. 3.9%), ischemia-driven target lesion revascularization (2.4% vs. 2.2%), and definite or probable stent thrombosis (0.5% vs. 1.5%, all $p > 0.05$).

CONCLUSIONS: At 12-month follow-up, the PtCr-EES is comparable in safety and efficacy to the CoCr-EES in unselected patients with coronary artery diseases.

Keywords:
Everolimus-eluting stent, Percutaneous coronary intervention, Coronary artery diseases.

Introduction

The cobalt chromium everolimus-eluting stent (CoCr-EES, manufactured as XIENCE V by Abbott Vascular, Santa Clara, CA, USA; also distributed as PROMUS by Boston Scientific, Natick, MA, USA) is a second-generation drug-eluting stent (DES) used in percutaneous coronary intervention (PCI)[1,2]. Its clinical efficacy and safety have been well demonstrated in both randomized clinical trials and real-world registries[3-8]. The platinum chromium everolimus-eluting stent (PtCr-EES), also known as PROMUS Element (Boston Scientific, Natick, MA, USA), is a novel everolimus-eluting coronary stent system with the same anti-proliferative agent and polymer coating used in XIENCE V (PROMUS)[9-11]. This design is aimed to improve drug deliverability, radiopacity, and radial strength[12,13].

Recent results from the PLATINUM (A Prospective, Randomized, Multicenter Trial to Assess an Everolimus-Eluting Coronary Stent System for the Treatment of up to Two De Novo Coronary Artery Lesions) trial indicated that the safety and efficacy of the PtCr-EES were not inferior to those of the CoCr-EES at 1-year follow-up[14]. Owing to the strict inclusion and exclusion criteria, this pivotal trial excluded high-risk patients and complex lesions, including those with acute myocardial infarction (MI), chronic total occlusion, bifurcation, left main coronary artery lesions, saphenous vein graft lesions, ostial lesions and lesions with thrombus, excessive tortuosity, or calcification. Therefore, it remains unclear if these results can be extrapolated to a more varied patient population. In the present study, we aimed to test the hypothesis that the optimal design of the PtCr-EES may improve its clinical operability and provide similar levels – or higher levels – of safety and effectiveness than the CoCr-EES in unselected patients undergoing PCI in a real-world scenario.

Corresponding Author: Huay Cheem Tan: Email: tanhc2014_11@163.com

Patients and methods

Study Population

Since 2002, all patients undergoing PCI for coronary artery diseases (CAD) in our institution have been registered in a single-center database. For the present study, all consecutive patients treated with either the PtCr-EES (i.e., PROMUS Element) or CoCr-EES (including XIENCE V and PROMUS) between July 2009 and November 2010 were recruited. All the patients provided informed consent for both the procedure and subsequent data collection and analysis for research purposes, and the study protocol was approved by the local Ethics Committee.

Device Description

The PROMUS Element PtCr-EES system is made of a platinum chromium alloy and an everolimus-eluting drug applied to the Element stent using the same combination of polymer layers of the XIENCE V (PROMUS) CoCr-EES system, with a drug dose density of 100 μ/cm^2. The polymer consists of a primer layer (n-butyl methacrylate) and a drug matrix layer (vinylidene fluoride-co-benaxfluoro-propylene) blended with everolimus to provide drug elution with nearly complete drug release in 90 days, similar to the XIENCE V (PROMUS) CoCr-EES.

PCI Procedure

All patients were pre-treated with 300 mg aspirin and 300 to 600 mg clopidogrel before the procedure. During the PCI procedure, a bolus dose of unfractionated heparin (100 IU/kg) was injected through the femoral or radial artery sheath, with repeated boli administered as needed to maintain an activated clotting time of 300 to 350 seconds. The PCI procedure and stent implantation were performed through a femoral or radial approach using standard methods. Lesions could have been pre-treated with balloon angioplasty or other devices, and received post-dilatation. Platelet glycoprotein IIb/IIIa receptor inhibitors and intravascular ultrasound examination were used at the operators' discretion. After the procedure, all the patients were maintained on dual anti-platelet therapy (aspirin 100 mg and clopidogrel 75 mg) for at least 12 months. The minimal lumen diameter, reference vessel diameter, and lesion length of the target vessels were assessed by two-dimensional quantifying coronary angiography (Kingstar Winning Pacs Thisview 3.0.2 Unicode).

Study Endpoints and Definitions

The primary endpoint of this study was the rate of target lesion failure (TLF) at 12-month follow-up. TLF is defined as cardiac death, MI related to the target vessel, or any ischemia-driven target lesion revascularization (TLR). Secondary endpoints were target vessel failure (TVF), major adverse cardiovascular event defined as all deaths, MI or target vessel revascularization (TVR), and stent thrombosis (defined as acute at <24 hours, subacute at 2-30 days, and late at >30 days). MI was classified as Q-wave when new pathological Q waves in 2 or more contiguous leads of the surface electrocardiogram were accompanied by a rise in cardiac troponin (cTN)-T or cTN-I concentrations of >3 times the upper limit of normal (ULN), and non-Q-wave when the cTN-T or cTN-I concentrations were >3 times the ULN in the absence of a new pathological Q-wave. Stent thrombosis was classified as definite and probable according to definitions proposed by the Academic Research Consortium.[15] TLR was defined as any repeat treatment of the target lesion or bypass graft surgery on the target vessel. TVR was defined as any repeat percutaneous or surgical treatment of the target vessel.

Statistical Analysis

Statistical analysis was performed using SAS software, version 9.1.3. Demographic characteristics, pre-existing risk factors, procedure-related variables and 1-year outcomes were summarized using the mean value with standard deviation for continuous variables, and the frequency and percentage were used for categorical variables. Differences in baseline, procedural, and follow-up data were compared between the CoCr-EES and PtCr-EES by chi-square test or Fisher's exact test, while continuous variables were compared using unpaired *t*-tests (normal distribution) and non-parametric Mann-Whitney *U* test (skew distribution). Survival curves for time-to-event variables were constructed on the basis of all available follow-up data with the use of Kaplan-Meier estimates, and were compared with the use of the log-rank test. In addition, logistic regression was used to determine whether the TLF at 12-month follow-up was consistent across important prespecified subgroups. A p value of < 0.05 was considered statistically significant.

Table I. Characteristics of the Patients at Baseline.

Characteristics	CoCr-EES (n = 410)	PtCr-EES (n = 378)	*p* value
Age (yrs)	59 ± 9.6	58 ± 10.6	0.452
Ethnicity			0.384
– Chinese (%)	268 (65.4%)	225 (59.5%)	
– Indian (%)	45 (11.0%)	48 (12.7%)	
– Malay (%)	61 (14.9%)	63 (16.7%)	
– Others (%)	36 (8.8%)	42 (11.15%)	
Male	334 (81.5%)	320 (84.7%)	0.233
Height (cm)	165 ± 7.0	165 ± 7.3	0.924
Body weight (kg)	70 ± 11.9	70 ± 12.2	0.587
Body surface area (m^2)	2 ± 0.2	2 ± 0.2	0.816
Systolic blood pressure (mmHg)	141 ± 27.1	140 ± 29	0.449
Diastolic blood pressure (mmHg)	76 ± 12	79 ± 13.2	0.008
Heart rate (beats per minute)	71 ± 14.6	72 ± 14.1	0.421
Hypertension	281 (68.5%)	246 (65.1%)	0.303
Diabetes mellitus			
– Any	173 (42.2%)	140 (37.0%)	0.139
– Requiring insulin	84 (20.5%)	85 (22.5%)	0.495
Hypercholesterolemia	313 (76.4%)	267 (70.6%)	0.069
Premature CAD	31 (7.6%)	11 (2.9%)	0.004
Current Smoker	112 (27.3%)	101 (26.7%)	0.866
History of percutaneous coronary intervention	85 (20.7%)	86 (22.8%)	0.492
History of coronary bypass grafting	22 (5.4%)	24 (6.3%)	0.556
Cerebrovascular accident	17 (4.1%)	17 (4.3%)	0.865
Chronic renal failure on dialysis	7 (1.7%)	8 (2.1%)	0.675
Acute myocardial infarction	74 (18.0%)	99 (26.2%)	0.006
Number of target lesions	1.49 ± 0.77	1.45 ± 0.71	0.443
1-lesion (%)	263 (63.5%)	252 (64.5%)	
2-lesion (%)	113 (27.3%)	109 (27.9%)	
3-lesion (%)	38 (9.2%)	30 (7.7%)	
Target vessel location			0.498
– Left anterior descending (%)	302 (59.3%)	285 (58.0%)	
– Left circumflex (%)	82 (16.1%)	80 (16.3%)	
– Right coronary artery (%)	103 (20.2%)	101 (20.6%)	
– Left main (%)	2 (0.4%)	13 (2.6%)	
– Bypass graft (%)	14 (2.8%)	8 (1.6%)	

Results

Patient Characteristics

From July 2009 through November 2010, a total of 788 patients with CAD underwent PCI with the PtCr-EES (n = 378) or CoCr-EES (n = 410). The baseline characteristics of the study patients are listed in Table I. Compared with those undergoing CoCr-EES implantation, patients with PtCr-EES implantation had higher diastolic blood pressures, higher prevalence of premature coronary artery disease, and were more likely to be admitted for acute MI (all $p < 0.05$). The other baseline characteristics of the 2 groups were similar.

Angiographic Lesion Characteristics and Stent Procedure

The majority of the lesions treated were de novo stenosis (96.2%). Compared with the CoCr-EES group, the target vessels in the PtCr-EES group showed larger reference vessel diameters, more type C lesions and less type A/B lesions (all $p < 0.05$). After stent implantation, the ratio of the stent-to-lesion length in the PtCr-EES group was significantly smaller than that in the CoCr-EES group (p = 0.002). By contrast, post-procedural residual diameter stenosis in the PtCr-EES group was higher than that in the CoCr-EES group (p = 0.025). However, the contrast volume used in the PtCr-EES-treated patients was significantly lower than that in the CoCr-EES group. The other procedural characteristics between the 2 groups were similar (Table II).

Clinical Outcomes at 12-Month Follow-up

At follow-up 12 months later, the primary endpoint (TLF) was similar between the 2 groups (4.5% for PtCr-EES and 3.9% for CoCr-EES, p = 0.68) (Table III).

Table II. Angiographic Outcomes and Stent Procedure.

Variable	CoCr-EES (n = 410)	PtCr-EES (n = 378)	*p* value
Before index procedure			
Minimal lumen diameter, mm	0.50 ± 0.27	0.47 ± 0.28	0.356
Reference vessel diameter, mm	2.56 ± 0.53	2.63 ± 0.47	0.025
Diameter stenosis, %	84.30 ± 12.02	85.20 ± 11.38	0.222
Lesion length, mm	25.65 ± 38.43	26.14 ± 12.19	0.783
Type of lesion			0.003
– Type A	9 (2.2%)	5(1.3%)	
– Type B	143 (34.9%)	97 (25.7%)	
– Type C	258 (62.9%)	276 (73.0%)	
Procedure variables			
No. of treated lesions per patient	1.49 ± 0.77	1.45 ± 0.71	0.443
No. of stents per patient	1.56 ± 0.77	1.57 ± 0.83	0.776
No. of stents per lesion	1.22 ± 0.49	1.27 ± 0.59	0.168
Diameter of stent	2.79 ± 0.36	2.80 ± 0.39	0.890
Length of stent	23.32 ± 7.07	23.99 ± 8.15	0.119
Maximum stent diameter, mm	2.82 ± 0.36	2.81 ± 0.38	0.557
Total stent length per lesion, mm	31.23 ± 14.61	31.27 ± 14.38	0.961
Total stent to lesion length ratio, %	136.4 ± 56.4	125.1 ± 58.0	0.002
Fluoroscopy time (min)	20.8 ± 52.2	26.3 ± 89.0	0.312
Contrast used (ml)	176.4 ± 72.2	163.0 ± 72.0	0.009
After index procedure			
Minimal lumen diameter, mm	2.90 ± 0.37	2.89 ± 0.42	0.523
Reference vessel diameter, mm	3.01 ± 0.39	3.00 ± 0.43	0.070
Residual stenosis, %	3.28 ± 3.49	3.94 ± 5.47	0.025
Acute gain, mm	2.40 ± 0.42	2.41 ± 0.46	0.596

Table III. Clinical Outcome at 12 Months.

Outcome	CoCr-EES (n = 410)	PtCr-EES (n = 378)	*p* value
Death			
Any reason	9 (2.2%)	12 (3.2%)	0.394
Cardiac death	6 (1.5%)	8 (2.1%)	0.488
TV cardiac death	5 (1.2%)	3 (0.8%)	0.810
Non TV cardiac death	1 (0.2%)	5 (1.3%)	0.183
Myocardial infarction (MI)			
Q-wave	6 (1.5%)	4 (1.1%)	0.850
Non-Q-wave	10 (2.4%)	5 (1.3%)	0.252
Related to TV MI	11 (2.7%)	6 (1.6%)	0.290
Non-related to TV MI	5 (1.2%)	3 (0.8%)	0.810
Stent thrombosis	8 (1.95%)	5 (1.32%)	0.489
Acute (0–1 day)	0 (0.00%)	1 (0.27%)	
Subacute (2–30 day)	5 (1.22%)	1 (0.27%)	
Late (>30 day)	3 (0.73%)	3 (0.79%)	
Definite	4 (0.98%)	2 (0.53%)	
Probable	4 (0.98%)	3 (0.79%)	
Target lesion failure (TLF)	16 (3.9%)	17 (4.5%)	0.677
Target vessel failure (TVF)	17 (4.1%)	17 (4.5%)	0.809
Target vessel revascularization (TVR)			
Any	11 (2.7%)	9 (2.4%)	0.788
Non-TLR TVR	2 (0.5%)	0 (0.0%)	0.500
Target lesion revascularization (TLR)	9 (2.2%)	9 (2.4%)	0.862
TLR-CABG	1 (0.2%)	1 (0.3%)	1.000
TLR-PCI	8 (2.0%)	8 (2.1%)	0.870
Major adverse cardiac event	24 (5.9%)	22 (5.8%)	0.984

The individual endpoints of all death or cardiac death, MI, TVR, and TLR showed no significant differences between the 2 groups. The secondary endpoints such as TVF and total major adverse cardiovascular events also remained similar between the 2 groups at all time points (Table III, Figures 1 and 2). It was noted that the rate of Academic Research Consortium-defined stent thrombosis was lower in the PtCr-EES group (1.32%) than in the CoCr-EES group (1.95%), which was primarily related to a lower rate of definite/probable stent thrombosis.

Subgroup Analysis and Predictors of TLF

To further determine whether the TLF at 12 months in the PtCr-EES and CoCr-EES stents was consistent across important prespecified subgroups, we performed a logistic-regression analysis with interaction testing. As shown in Figure 3, there were no significant interactions between the type of stent used and TLF at 12 months in the 7 subgroups.

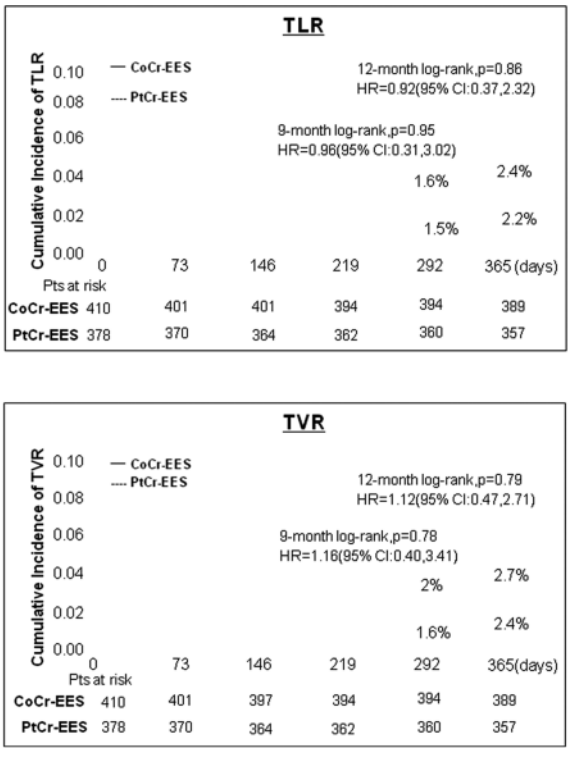

Figure 1. Cumulative prevalence of target-vessel failure (TVR) and target-lesion revascularization (TLR). Time-to-event curves are shown for TVR (**A**) and ischemia-driven TLR (**B**) between patients who received the platinum chromium everolimus-eluting stent (PtCr-EES) and those who received the cobalt chromium everolimus-eluting stent (CoCr-EES). CI: confidence interval; HR: hazard ratio; Pts: patients.

Discussion

The present registry study was conducted to evaluate the relative safety and efficacy of the PtCr-EES versus CoCr-EES in daily practice. Herein, a comparison of the clinical outcomes between unselected patients undergoing PCI treatment for coronary lesions using the novel PtCr-EES and those treated using the CoCr-EES yield similar results for the 2 groups at 12-month follow-up. This was despite differences in the design of the stent platform and the stent material used between the 2 stents. Not only were the composite endpoints comparable and favorable in both groups, so were the individual components of the primary endpoint. Accordingly, this study suggests that the new-generation platinum chromium stent platform is not inferior to the cobalt chromium stent platform used in routine clinical practice.

The new generation PtCr-EES incorporates a novel thin-strut platinum chromium alloy platform designed to enhance visibility, conformability, and drug delivery in coronary vessels[11,12]. Bench testing has demonstrated that platinum chromium alloy has enhanced radial strength relative to stainless steel and less stent recoil than cobalt chromium.[16] However, occurrences of longitudinal stent deformation as a result of its stent geometric design have been reported[17]. In our study, 2 patients in the PtCr-EES group developed stent deformation during the procedure as a result of the use of ancillary devices: one, a noncompliant balloon for post-stent dilation, and the other, an intravascular ultrasound

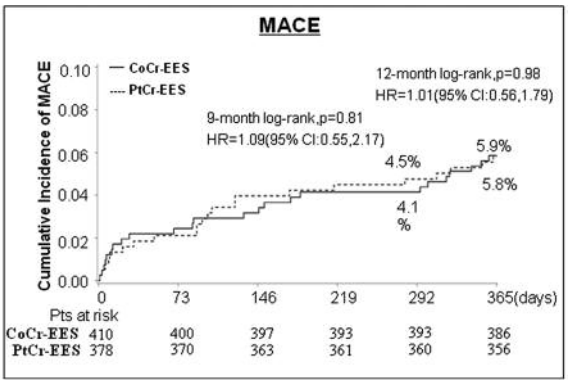

Figure 2. Cumulative prevalence of major adverse cardiovascular event (MACE). Time-to-event curves are shown for MACE between patients who received the platinum chromium everolimus-eluting stent (PtCr-EES) and those who received the cobalt chromium everolimus-eluting stent (CoCr-EES). CI: confidence interval; HR: hazard ratio; Pts: patients.

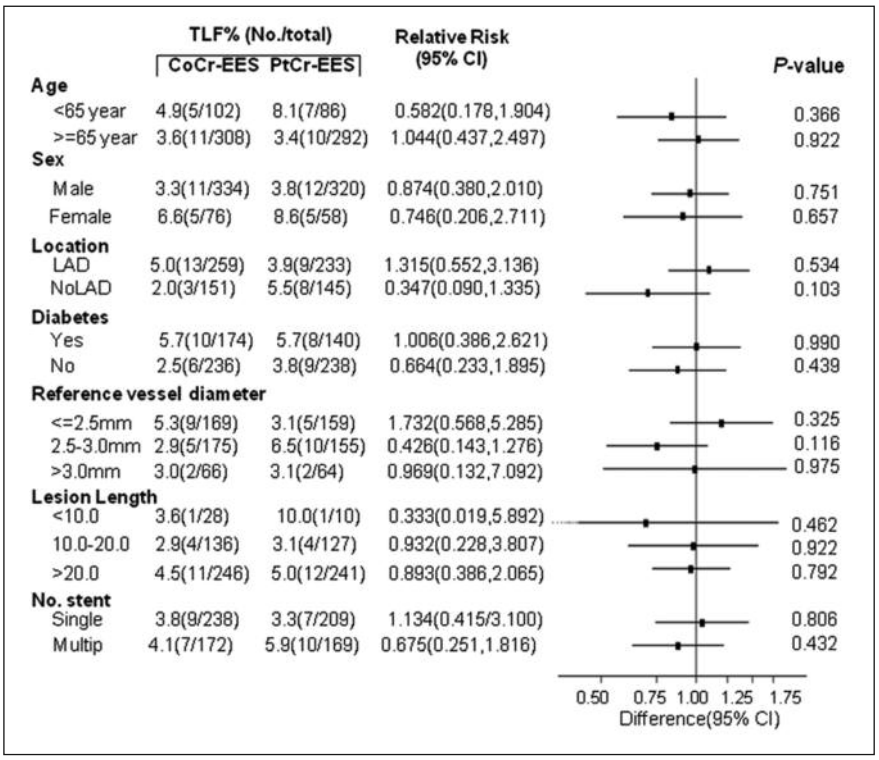

Figure 3. Subgroup analysis of target-lesion failure (TLF). Subgroup analyses are shown, with relative risks and 95% confidence intervals, for the primary endpoint of target-lesion failure at 12 months between the platinum chromium everolimus-eluting stent (PtCr-EES) and cobalt chromium everolimus-eluting stent (CoCr-EES) groups. The *p* value for interaction represents the likelihood of interaction between the variable and the relative treatment effect.

catheter. The former was treated with another stent implantation and the latter with further post-stent balloon dilatation. Neither of the patients developed any subsequent serious adverse events. There were no cases of stent deformation in the CoCr-EES group.

Preclinical testing has also supported the vascular compatibility of platinum chromium[9,12]. In addition, the higher density of platinum, compared with iron or cobalt, contributes to enhancement of the radiopacity of the platinum chromium alloy, compared with stainless steel or cobalt chromium. Thus, the thinner stent strut design of the PtCr-EES did not cause a reduction in stent visibility. In the present study, we found that the contrast volume used in the PtCr-EES group was significantly reduced compared with that in the CoCr-EES group. It is conceivable that this reduction is mainly due to the improved visualization of the PtCr-EES under fluoroscopy, which might have helped to reduce the need for angiography during stent placement and balloon post-dilatation.

Although the clinical event rates in this study are higher than that in the PLATINUM trial undertaken in selected patients[14], the rates are basically similar to the results from a large-scale sample study, the SCAAR trial, where the rates of TVR (2.8%) and stent thrombosis (0.2%) were comparable to that obtained in our results (2.4% and 0.5%, respectively)[18]. Compared with the PLATINUM trial, our study's registry design allowed for inclusion of any patient eligible for PCI. In particular, this study included a high proportion of patients with complex clinical and lesion characteristics. As shown in Table II, the proportion of type C lesions in PtCr-EES treatment was significantly higher than that in CoCr-EES treatment. Since the PtCr-EES has better deliverability and radial strength than CoCr-EES, it is likely that physicians prefer to use the PtCr-EES for complex type C lesions.

Stent thrombosis has become a critical concern in the era of drug eluting stents[19]. Emerging evidence has shown that late stent malapposition may play a role in the formation of in-stent thrombi, especially for late and very late stent thrombosis, which could be caused by the accumulation of local platelets and red blood cells in the residual interspaces between stent struts and the vascular wall[20,21]. However, late stent malapposition is hard to detect at the time of stent implantation and is often only confirmed by intravascular ultrasound or optical coherence tomography during post-procedure follow-up. In

this work, the rate of stent thrombosis after PtCr-EES implantation in this registry was relatively low. This is especially significant as more PtCr-EES than CoCr-EES were implanted in patients (28.0% vs. 26.2%, $p = 0.006$). Although this result needs to be further investigated with a dedicated, large-scale study, more recent researches have demonstrated that PtCr-EES has a low occurrence of late malapposition and higher radial force[13]. Therefore, the favorable features we identified in this study provide a rationale for further examination.

Although the patients with PtCr-EES implantation in this study had several unfavorable clinical features such as more frequent admission for acute MI and histories of coronary bypass surgery and diabetes, our logistic regression analysis showed that the variables did not result in any significant differences between the rates of various clinical outcomes (i.e., TLF) of the 2 devices up to 12-month follow-up (Figure 3). These results suggest that the favorable performance of the PtCr-EES seen in the pivotal PLATINUM trial is retained in a broader patient population.

There were, however, some criticisms to our study. These include those inherent to all observational registries, such as the existence of potentially confounding variables. The clinical follow-up period of this study was only 12 months, and thus not long enough to make conclusions regarding the long-term durability of the PtCr-EES. Furthermore, it was a single-center study with a relatively small study population. Patients in whom the delivery of the stents was unsuccessful were not included in the analysis.

Conclusions

The new-generation PtCr-EES does not seem to be inferior to the CoCr-EES in the treatment of unselected patients in routine clinical practice. Further multi-center registries and randomized controlled trials with larger patient populations and longer follow-up periods are needed to provide further confirmation of the clinical efficacy of the PtCr-EES in PCI of real-world patients.

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Conflict of Interest

The Authors declare that there are no conflicts of interest.

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