Two-Year Clinical Outcomes of Biodegradable Polymer vs. Durable Polymer Drug-Eluting Stent Implantation in Patients With End-Stage Renal Disease on Dialysis

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Background: There are limited data comparing clinical outcomes between biodegradable polymer and durable polymer drug-eluting stents (BP-DES and DP-DES, respectively) in patients with end-stage renal disease (ESRD).

Methods and Results: This study enrolled 229 ESRD patients who underwent successful percutaneous coronary intervention (PCI) for 400 lesions with 472 DES, with 2-year clinical outcomes compared between the BP-DES and DP-DES groups. The primary outcome measure was the incidence of target lesion revascularization (TLR), whereas secondary outcome measures were the occurrence of cardiac death (CD), myocardial infarction (MI), stent thrombosis (ST), target vessel revascularization (TVR), non-TVR, and major adverse cardiac events (MACE), defined as a composite of CD, MI, and TVR. Multivariate analysis was used to identify predictors of TLR occurrence. The 2-year incidence of TLR did not differ significantly between the BP-DES and DP-DES groups (P=0.274). In addition, there were no significant differences in the 2-year incidence of CD (P=0.144), MI (P=0.812), ST (P=0.241), TVR (P=0.434), non-TVR (P=0.375), or MACE (P=0.841) between the 2 groups. Multivariate analysis showed that diabetes (P=0.021) was independently associated with TLR occurrence.

Conclusions: BP-DES and DP-DES had comparable safety and efficacy profiles over a 2-year follow-up period after PCI in ESRD patients.

Key Words: Biodegradable polymer drug-eluting stent; Coronary artery disease; Durable polymer drug-eluting stent; End-stage renal disease; Hemodialysis
Hospital Cardiovascular Center between July 2011 and March 2017 were evaluated. To be eligible for study inclusion, patients had to be ≥18 years of age and good candidates for PCI, as determined by the heart team of cardiologists and surgeons at the Kansai Rosai Hospital Cardiovascular Center. In addition, patients had to have clinical evidence of ischemic heart disease and/or a positive functional study.

The BP-DES used in this study was either a biodegradable polymer sirolimus-eluting stent (BP-SES; Ultimaster™; Terumo Corporation, Tokyo, Japan) or a biodegradable polymer everolimus-eluting stent (BP-EES; Synergy™; Boston Scientific, Natick, MA, USA). The DP-DES used in this study were either a durable polymer cobalt-chromium everolimus-eluting stent (DP-CoCr EES; Xience™; Abbott Vascular, Santa Clara, CA, USA), a durable polymer platinum-chromium everolimus-eluting stent (DP-PtCr EES; Promus Element stent; Boston Scientific), or a slow-release zotarolimus-eluting stent (ZES; Resolute™; Medtronic, Minneapolis, MN, USA).

Of the 365 ESRD patients (726 lesions) evaluated for this study, 136 patients (326 lesions) were excluded for the following reasons: failed PCI (5 patients, 11 lesions), PCI was not done (5 patients, 17 lesions), in-stent restenosis lesions (88 patients, 152 lesions), treatment with a bare metal stent (BMS) or drug-coated balloon (DCB; 6 patients, 22 lesions), and treatment with first-generation and drug-eluting stents (DES) other than BP-SES, BP-EES, DP-CoCr EES, DP-PtCr EES, and ZES (32 patients for 124 lesions). This left 229 ESRD patients who underwent successful PCI for 400 lesions with new-generation DES eligible for enrollment in this study, and these patients were divided into 2 groups, namely BP-DES and DP-DES groups (Figure 1). Patients were followed-up by means of telephone interviews, a review of hospital records, or through outpatient visits.

This study was conducted according to the ethical guidelines of the Declaration of Helsinki. The study protocol was approved by the Medical Ethics Committee of Kansai Rosai Hospital. All individual participants included in the study provided written informed consent prior to enrollment.

Study Procedures
PCI procedures were performed according to standard practice. All further procedures, lesion predilation, stenting or post-stenting dilation, and the use of debulking devices or imaging modalities were left to the operator’s discretion. All patients received dual antiplatelet therapy (DAPT) according to hospital practice. Continuation of DAPT was recommended for at least 12 months. Antiplatelet therapy beyond 12 months was at the discretion of the treating physician considering prevailing guidelines.

Quantitative Coronary Angiography (QCA)
Coronary angiography was performed in at least 10 projections. The view showing the most severe stenosis was selected for QCA, which was subsequently performed using a computerized angiographic analysis system (CAAS Workstation 5.11; Pie Medical Imaging, Maastricht, Netherlands) at the same angle of projection prior to and immediately after PCI.

Outcome Measures and Definitions
The primary outcome measure was the incidence of target lesion revascularization (TLR) at 2 years. Secondary out-
come measures were the occurrence of cardiac death (CD), ST, myocardial infarction (MI), target vessel revascularization (TVR), non-TVr, and major adverse cardiac events (MACE), defined as a composite of CD, MI, and TVR, at 2 years. TLR was defined as clinically driven repeat revascularization caused by a >50% stenosis within the stent or within a 5-mm border proximal or distal to the stent. CD was defined as any death resulting from an evident cardiac cause, any death related to PCI, an unwitnessed death, or death from unknown causes. ST was defined as definite stent thrombosis according to the Academic Research Consortium definition. MI was defined as Type 1–Type 3 or Type 4b based on the Third Universal Definition of Myocardial Infarction. TVR was defined as any repeat PCI or surgical bypass of any segment within the entire major coronary vessel that was proximal or distal to a target lesion, including upstream and downstream branches, and the target lesion itself. Non-TVr was defined as any repeat PCI or surgical bypass of any segment of the non-target coronary artery.

**Statistical Analysis**

Data are expressed as the mean±SD or as counts and percentages. For discrete variables, the significance of differences between 2 groups were analyzed using $X^2$ or Fisher’s exact tests, as appropriate. Multivariable Cox proportional hazards regression analysis, which includes baseline confounding factors, was conducted. Various clinical outcomes were estimated using Kaplan-Meier curves, and differences between groups were compared with the log-rank test. The following available variables were tested for potential relevance to TLR occurrence: sex (male), hypertension, dyslipidemia, diabetes, hyperuremia, current smoker, previous MI, previous PCI, previous coronary artery bypass grafting, acute coronary syndrome, chronic heart failure, atrial fibrillation, cerebrovascular disease, peripheral arterial disease, malignancy, aortic dissection, lesion location, American College of Cardiology (ACC)/American Heart Association (AHA) lesion types, chronic total occlusion, ostial, ostial right coronary artery, bifurcation, multivessel disease, direct stenting, the use of rotational atherectomy, BP-DES, and stent length $\geq$32 mm and vessel size $\leq$2.5 mm, which were defined based on the diameter of the stent used and post-dilation. Two-tailed $P<0.05$ was considered statistically significant. All statistical analyses were performed using SPSS version 25 (IBM Corp., Armonk, NY, USA).

**Results**

**Baseline Patient, Lesion and Procedural Characteristics**

In all, 229 ESRD patients who underwent successful PCI for 400 lesions with new-generation DES were enrolled in the study. Baseline patient characteristics are summarized in Table 1 and were similar between the BP-DES and DP-DES groups. Lesion and procedural characteristics are summarized in Table 2; again, there were no significant differences between the 2 groups. Approximately 80% of the lesions were ACC/AHA Type B2/C and multivessel disease in ESRD patients. All patients underwent PCI using an intravascular imaging device (intravascular ultrasound or optical coherence tomography) and approximately 20% of the patients underwent rotational atherectomy.
Clinical Outcomes

The cumulative incidence of clinical outcomes at 2 years is listed in Table 4 and shown in Figure 2. The 2-year incidence of TLR was not significantly different between the BP-DES and DP-DES groups (16.7% vs. 23.3%, respectively; P=0.274; Figure 2A). Similarly, there were no significant differences between BP-DES and DP-DES groups in the 2-year incidence of CD (18.5% vs. 12.0%, respectively; P=0.144; Figure 2B), MI (6.5% vs. 6.1%, respectively; P=0.812; Figure 2C), ST (0% vs. 0%, respectively; P=0.241), TVR (23.4% vs. 28.7%, respectively; P=0.434).

QCA

The QCA findings are summarized in Table 3. Lesion length was longer in the BP-DES than DP-DES group and, at the preprocedural assessment, diameter stenosis was smaller in the BP-DES than DP-DES group. However, reference vessel diameter and minimum lumen diameter at the post-procedural assessment were larger in the BP-DES than DP-DES group. Consequently, diameter stenosis was not significantly different between the 2 groups (P=0.141).

Table 2. Lesion and Procedural Characteristics

| Lesion characteristics          | BP-DES (n=138) | DP-DES (n=262) | P value |
|--------------------------------|----------------|----------------|---------|
| Lesion location                |                |                | 0.170   |
| LAD                            | 47 (34.1)      | 85 (32.4)      |         |
| LCX                            | 28 (20.3)      | 66 (25.2)      |         |
| RCA                            | 47 (34.1)      | 93 (35.5)      |         |
| LMT                            | 16 (11.5)      | 18 (6.9)       |         |
| ACC/AHA Type B2/C              | 118 (85.5)     | 209 (79.8)     | 0.175   |
| Chronic total occlusion        | 4 (2.9)        | 3 (1.1)        | 0.240   |
| Ostial                         | 22 (15.9)      | 38 (14.5)      | 0.769   |
| Bifurcation                    | 56 (40.6)      | 86 (32.8)      | 0.126   |
| Multivessel disease            | 114 (82.6)     | 207 (79.0)     | 0.430   |

Preprocedural QCA

| Reference vessel diameter (mm) | 2.55±0.65 | 2.55±0.74 | 0.213 |
| Minimal lumen diameter (mm)   | 0.90±0.46  | 0.96±0.47  | 0.996 |
| Lesion length (mm)            | 21.7±13.1  | 18.7±12.1  | 0.022 |
| Diameter stenosis (%)         | 66.6±14.0  | 62.9±14.1  | 0.013 |

Post-procedural QCA

| Reference vessel diameter (mm) | 3.04±0.51  | 2.85±0.62  | 0.003 |
| Minimal lumen diameter (mm)   | 2.57±0.48  | 2.37±0.51  | <0.001 |
| Diameter stenosis (%)         | 15.6±5.8   | 16.6±8.3   | 0.141 |

Table 3. Quantitative Coronary Angiography (QCA)

Data are given as the mean±SD. Abbreviations as in Table 1.
In this study we compared 2-year clinical outcomes between BP-DES and DP-DES in ESRD patients with coronary artery disease after PCI. The main findings of this study are that: (1) there was no significant difference between the BP-DES and DP-DES groups in the 2-year incidence of TLR (16.7% vs. 23.3%, respectively; P=0.274); (2) there was no significant difference between the BP-DES and DP-DES groups in the 2-year incidence of non-TVR (25.8% vs. 31.4%, respectively; P=0.375), and MACE (38.2% vs. 41.1%, respectively; P=0.841; Figure 2D).

After multivariate analysis, diabetes (hazard ratio [HR] 2.09; 95% confidence interval [CI] 1.12–3.88; P=0.021) was found to be independently associated with TLR occurrence in ESRD patients on dialysis (Table 5).

**Table 4. Two-Year Cumulative Incidence of Clinical Outcomes Between the BP-DES and DP-DES Groups, Determined by Kaplan-Meier Analysis**

|                | BP-DES (72 patients, 138 lesions) | DP-DES (157 patients, 262 lesions) | P value |
|----------------|-----------------------------------|------------------------------------|---------|
| TLR            | 16.7                              | 23.3                               | 0.274   |
| CD             | 18.5                              | 12.0                               | 0.144   |
| ST             | 0                                 | 0                                  | 0.241   |
| MI             | 6.5                               | 6.1                                | 0.812   |
| TVR            | 23.4                              | 28.7                               | 0.434   |
| Non-TVR        | 25.8                              | 31.4                               | 0.375   |
| MACE           | 38.2                              | 41.1                               | 0.841   |

CD, cardiac death; MACE, major adverse cardiac events; ST, stent thrombosis; TLR, target lesion revascularization; TVR, target vessel revascularization. Other abbreviations as in Table 1.

**Discussion**

In this study we compared 2-year clinical outcomes between BP-DES and DP-DES in ESRD patients with coronary artery disease after PCI. The main findings of this study are that: (1) there was no significant difference between the BP-DES and DP-DES groups in the 2-year incidence of TLR (16.7% vs. 23.3%, respectively; P=0.274); (2) there was no significant difference between the BP-DES
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A patient-level pooled analysis on 12,426 patients undergoing PCI using second-generation DES showed that the cumulative incidence of target lesion failure was 24.1% during the study period (median follow-up duration 1,046 days) in ESRD patients on dialysis. The outcomes of that study, including the cumulative incidence of TLR, CD, and MI, were also consistent with those of the present study. Data from retrospective analyses of >35,000 dialysis patients over a 7-year period noted a significant reduction in death, death or MI, and death, MI, or repeat revascularization at 1 year among patients receiving DES compared with those receiving BMS.11,12

However, there are few studies comparing BP-DES and DP-DES in patients with ESRD on dialysis. In the present study, we found that the 2-year clinical outcomes were not significantly different between these 2 groups.

The polymer in BP-DES consists of polylactic acid that fully degrades into carbon dioxide and water within 3–4 months. Despite this particular advantage of BP-DES, the long-term clinical outcomes are debatable compared with DP-DES. Although BP-DES are expected to improve clinical outcomes compared with DP-DES because of their thin struts, which reduce stent thrombogenicity,13 and the biodegradable polymer, it was reported that BP-DES induced a severe histiolymphocytic and fibromuscular reaction.14,15 In a meta-analysis of RCTs, BP-DES had similar 1-year clinical outcomes to contemporary DP-DES.16 Furthermore, BP-DES were found to have similar safety and efficacy profiles to DP-DES in another meta-analysis of RCTs at the longest available follow-up (mean duration 26 months).17 The present study also showed that the incidence of TLR (HR 0.709; 95% CI 0.381–1.318; P=0.274) was similar for BP-DES and DP-DES in ESRD patients on dialysis. This suggests that we may expand the results of the previous meta-analysis to ESRD patients. In addition, the incidence of TLR is very high in both groups of ESRD patients because of: (1) insufficient drug penetration for calcified lesions; (2) the loss of polymer during delivery for calcified lesions; (3) stent fracture; and (4) stent underexpansion.18 These issues are not resolved even if BP-DES are used instead of DP-DES, and clinical outcomes in the present study were similar between the 2 groups of ESRD patients.

### Table 5. Predictors of TLR

| Unadjusted HR | Adjusted HR |
|---------------|-------------|
| HR (95% CI)   | P value     | HR (95% CI) | P value |
| Male sex      | 0.89 (0.50–1.57) | 0.687 |                      |
| Hypertension  | 1.57 (0.67–3.67) | 0.296 |                      |
| Dyslipidemia  | 1.10 (0.65–1.86) | 0.724 |                      |
| Diabetes      | 2.18 (1.17–4.06) | 0.014 | 2.09 (1.12–3.88) | 0.021 |
| Hyperuremia   | 1.55 (0.82–2.93) | 0.179 |                      |
| Current smoker| 0.75 (0.35–1.58) | 0.441 |                      |
| Previous MI   | 1.32 (0.69–2.56) | 0.404 |                      |
| Previous PCI  | 1.59 (0.94–2.68) | 0.086 |                      |
| Previous CABG | 1.23 (0.49–3.07) | 0.665 |                      |
| ACS           | 1.67 (0.95–2.93) | 0.073 |                      |
| Chronic heart failure | 0.65 (0.28–1.51) | 0.316 |                      |
| Atrial fibrillation | 0.99 (0.43–2.32) | 0.990 |                      |
| Cerebrovascular disease | 1.41 (0.51–3.91) | 0.506 |                      |
| Peripheral arterial disease | 1.51 (0.88–2.57) | 0.136 |                      |
| Malignancy    | 0.75 (0.35–1.58) | 0.441 |                      |
| Aortic dissection | 0.05 (0.00–30.1) | 0.354 |                      |
| Lesion location| 1.17 (0.95–1.46) | 0.146 |                      |
| ACC/AHA Type B2/C | 2.91 (1.05–8.05) | 0.040 | 2.23 (0.78–6.38) | 0.136 |
| Chronic total occlusion | 1.14 (0.16–8.25) | 0.897 |                      |
| Ostial        | 0.85 (0.39–1.88) | 0.691 |                      |
| Ostial right coronary artery | 1.13 (0.35–3.63) | 0.833 |                      |
| Bifurcation   | 1.77 (1.04–2.99) | 0.033 | 1.51 (0.89–2.58) | 0.128 |
| Multivessel disease | 2.25 (0.96–5.25) | 0.061 |                      |
| Direct stenting | 0.36 (0.09–1.47) | 0.153 |                      |
| Rotational atherectomy | 0.73 (0.33–1.61) | 0.437 |                      |
| BP-DES        | 0.71 (0.38–1.32) | 0.277 |                      |
| Stent length ≥32 mm | 1.80 (1.04–3.14) | 0.037 | 1.47 (0.84–2.59) | 0.180 |
| Vessel size ≤2.5 mm | 1.56 (0.88–2.75) | 0.129 |                      |
| Post-dilation | 1.60 (0.69–3.73) | 0.276 |                      |

Data are given as unadjusted or adjusted hazard ratios (HRs) for target lesion revascularization with 95% confidence intervals (CIs). Abbreviations as in Tables 1,2,4.
CKD patients were left main or 3-vessel disease lesions and multivessel PCI, old age, male sex, peripheral vascular disease, diabetes, and clinical presentation of acute MI. In the present study, diabetes was independently associated with TLR occurrence in ESRD patients, which is in line with the previous study. It has been reported that the metabolic abnormalities that characterize diabetes, such as hyperglycemia, increased free fatty acids, and insulin resistance, each provoke molecular mechanisms that contribute to vascular dysfunction. This may contribute to the cellular events that cause atherosclerosis and subsequently increase the risk of adverse cardiovascular events that occur in patients with diabetes and atherosclerosis. ESRD Patients with diabetes had worse outcomes than ESRD patients without diabetes, and more careful follow-up was needed for diabetic ESRD patients.

ST did not occur in either group in the present study. It has been reported that one of the causes of early ST, defined ST occurring within 1 month after stent implantation, was stent underexpansion. In the present study, patients underwent PCI using imaging devices, and approximately 20% of patients underwent rotational atherectomy. Lesion preparation to minimize underexpansion may have been crucial in avoiding early ST in ESRD patients on dialysis. Very late ST (VLST), defined as ST occurring >1 year after stent implantation, has been reported. It may have been crucial in avoiding early ST in ESRD patients. Very late ST, defined ST occurring >1 year after stent implantation, was not detected in the present study. It has been reported that an abnormal vascular response causes VLST after DES implantation. BP-DES has been expected to decrease the occurrence of VLST because the polymer, which is suspected as one of the causes of VLST, is completely absorbed within 3–4 months after stent implantation. Although ST was not detected in either group in this study, possibly due to the limited sample size, further studies are needed to evaluate the incidence of VLST after BP-DES vs. DP-DES implantation.

Study Limitations
This study has several limitations. First, the present study was a single-center non-randomized observational study; thus, there may be some under-reporting and/or missed data. Second, even though multivariate analysis was performed, variables not included in the analysis may have affected the study outcomes. Finally, because this study enrolled only Japanese patients and used imaging devices in all patients, the results may not be generalizable to patients of other ethnicities in different parts of the world.

Conclusions
In conclusion, BP-DES had comparable safety and efficacy profiles to DP-DES over a 2-year follow-up period after PCI in patients with ESRD on dialysis. However, further development of DES is necessary because the adverse event rate was still high, even with BP-DES.

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None.

Data Availability
This manuscript does not report on the results of clinical trials.

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Disclosures
None.

IRB Information
This study was approved by the Medical Ethics Committee of Kansai Rosai Hospital (15D081).

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