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Long-term clinical outcomes of permanent-polymer everolimus-eluting stent implantation following rotational atherectomy for severely calcified de novo coronary lesions: Results of a 22-center study (Tokyo-MD PCI Study)☆

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ABSTRACT

Background: Long-term clinical outcomes of permanent polymer everolimus-eluting stent (PP-EES) implantation after rotational atherectomy (RA) have not been fully evaluated. We sought to investigate the long-term clinical outcomes of PP-EES implantation after RA and assess the impact of hemodialysis on this treatment strategy.

Methods: Patients who underwent percutaneous coronary intervention (PCI) with PP-EES at 22 institutions between January 2010 and December 2011 were enrolled in this multicenter, observational trial. From a total of 1918 registered patients, 113 patients with 115 de-novo lesions who underwent PCI with PP-EES following RA were retrospectively analyzed. The primary endpoint was a major adverse cardiac event (MACE) defined as the composite of cardiac death, non-fatal myocardial infarction (MI), and clinically driven target lesion revascularization (TLR).

Results: Long-term follow-up was available for 112 patients (99.1%). The median follow-up period was 2.9 (interquartile range 1.9–3.6) years. The mean age of the patients was 72.3 ± 8.8 years and 64 patients (56.6%) had chronic kidney disease (≥stage 3, 42 on hemodialysis). The cumulative incidences of MACE, non-fatal MI, and TLR were 22.1%, 5.3%, and 10.6%, respectively. Cox's proportional hazards analysis showed that the independent predictors of TLR were hemodialysis and chronic total occlusion. (HR, 14.1; 95% CI, 1.74–155.5; $p = 0.01$, HR, 9.01; 95% CI, 1.34–62.5; $p = 0.02$).

Conclusions: PP-EES implantation after lesion modification by RA is considered to be a feasible treatment strategy for heavily calcified lesions. Hemodialysis and chronic total occlusion appeared to be associated with TLR.

1. Introduction

Coronary calcification is recognized as a clinical indicator of atherosclerosis, predictor of coronary artery disease, and is often found in patients with end-stage renal disease (ESRD) [1]. Previous studies on chronic kidney disease (CKD) have reported an increase in the number of patients with ESRD worldwide [2,3]. In the latest annual data reports on ESRD, approximately 460,000 patients in the United States, and approximately 320,000 patients in Japan were on hemodialysis (HD).

Rotational atherectomy (RA) can favorably modify severely calcified coronary lesions and facilitate stent delivery to establish optimal stent expansion [4,5]. First-generation drug-eluting stents (DES), including the sirolimus-eluting stent (SES; Cypher® Cordis Corp., Miami Lakes, Florida) and the paclitaxel-eluting stent (PES; Taxus® Boston Scientific, Maple Grove, Minnesota), have reduced restenosis [6–8], and some observational studies have reported a favorable outcome of first-generation DES implantation following RA [9,10]. Permanent polymer everolimus-eluting stents (PP-EES; Xience V® Abbott Vascular, Santa Clara, CA, USA and Promus®; Boston Scientific, Natick, MA, USA) are second-generation DES and have demonstrated a greater safety and efficacy than that of the first-generation DES [11–14]. In a recent clinical study, no significant difference in the long-term mortality rate was found when compared to PP-EES implantation with coronary artery bypass grafting (CABG), even in patients with multi-vessel coronary artery disease and CKD [15]; however, little information is available on the long-term clinical outcomes of PP-EES implantation after RA in patients with or without HD. The aim of this study was to clarify

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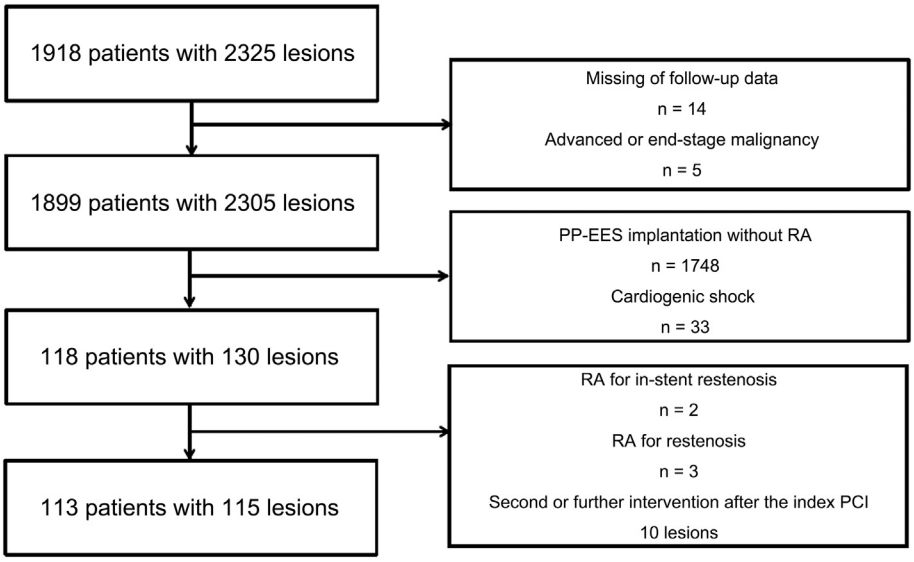

Fig. 1. Study flow chart. PP-EES: permanent polymer everolimus-eluting stents, RA: rotational atherectomy, PCI: percutaneous coronary intervention.

the clinical outcomes of PP-EES after RA in patients with severely calcified de novo coronary lesions and the impact of HD on this treatment strategy.

2. Methods

2.1. Study design and patient population

The Tokyo-MD PCI study is a physician-initiated, multicenter (22 institutions), observational cohort study in Japan to assess the clinical outcome of PP-EES implantation. A total of 1918 patients undergoing PP-EES implantation at 22 institutions between January 2010 and December 2011 were registered. There were no exclusion criteria for patient registration. Patient clinical characteristics were investigated through a retrospective analysis of clinical records, and adverse events were determined after PP-EES implantation. The Tokyo Medical and Dental University institutional ethics review board approved the study.

Patients who underwent first-time PCI with PP-EES using RA for de novo coronary lesions before stenting were retrospectively identified from the database of the Tokyo-MD PCI study. If a patient had a second or further intervention with PP-EES after the index PCI, only the first PCI was included in the analysis. The exclusion criteria of the present study were the following: 1) patients in cardiogenic shock before the PCI procedure, 2) patients who were treated with either RA without stenting, for in-stent restenosis, or for a combination of other stents, and 3) patients with advanced or end-stage malignancy. A study flow chart is shown in Fig. 1.

2.2. Procedural details

Indication for use of RA was determined by the operator based on a comprehensive assessment for severely calcified lesions. RA was performed with the Rotablator® coronary system (Rotablator, Boston Scientific, Natick, Massachusetts) by experienced interventional cardiologists according to standard techniques. The stent or guide wire selection and other decisions during the PCI were left to the operator's discretion. Rotational speed was set at 140,000–190,000 rpm, and care was taken to prevent any drop in rotational speed >5000 rpm. Procedural details of the RA have been reviewed elsewhere [16,17]. A continuous intracoronary infusion containing unfractionated heparin, isosorbide dinitrate, normal saline, and either verapamil or nicorandil, were routinely used for the prevention of slow flow.

2.3. Follow-up and definitions

Follow-up information was obtained either from medical records or by questionnaires obtained from local physicians. Severely calcified coronary lesions were defined visually as either an American College of Cardiology/American Heart Association (ACC/AHA) lesion classification type B or C due to coronary calcification and to either intra-vascular ultrasound (IVUS) findings or optical coherence tomography (OCT) findings as the presence of calcium in the vessel wall of the target lesion. Follow-up coronary angiography (CAG) was defined as the first CAG after the index PCI in the chronic phase. Major adverse cardiac events (MACE) were defined as the composite of cardiac death, non-fatal myocardial infarction (MI), and clinically driven target lesion revascularization (TLR). MI was defined as ischemic symptoms followed by typical increase in concentrations of troponin above the 99th percentile upper reference limit, or an increase in creatine kinase or creatine kinase-MB level to more than double the normal value. TLR was defined as any clinically driven repeat PCI or CABG of the target lesion.

2.4. Statistical analysis

Data for continuous variables are presented as either the mean ± standard deviation or median and interquartile range. The Mann-Whitney *U* test was used for comparison of the median and interquartile range. Categorical variables are expressed as frequencies with percentage and are compared using either the Chi-squared test or Fisher's exact test. The cumulative incidence of MACE, non-fatal MI, and TLR were calculated according to the Kaplan-Meier method, and the curves were compared using a log-rank test from the index PCI to the latest available follow-up data, respectively. Cox's proportional hazards analysis was performed to determine the independent predictor of TLR. Baseline clinical and procedural characteristics variables with a $p < 0.10$ in the univariate analysis were included in the multivariate analysis. The results were presented as hazard ratios with 95% confidence intervals. Statistical analyses were performed using SPSS for Windows, version 23 (IBM SPSS Inc., Chicago, IL, USA). $p < 0.05$ was considered significant.

3. Results

During the observation period, 113 patients with 115 lesions were treated with PP-EES following RA. The patients treated with a RA-PP-EES were old (mean age 72.3 ± 8.8 years), mostly male (69.9%), and

Table 1
Basic characteristics of study patients.

		Non-HD	HD	*p* value
Total population, n	113	71 (62.8)	42 (37.2)	
Age, (years)	72.3 ± 8.8	73.3 ± 9.2	70.6 ± 7.9	0.11
Male sex, n (%)	79 (69.9)	48	31	0.49
Hypertension, n (%)	84 (74.3)	54	30	0.59
Diabetes mellitus, n (%)	56 (49.6)	31	25	0.1
Insulin use, n (%)	27 (23.9)	12	15	0.02
Dyslipidemia, n (%)	80 (70.8)	55	25	0.04
Family history of coronary artery disease, n (%)	8 (7.1)	6	2	0.46
History of smoking, n (%)	38 (33.6)	26	12	0.38
Chronic kidney disease, n (%)	64 (56.6)	22	42	<0.001
Hemodialysis, n (%)	42 (37.2)	0	42	<0.001
Left ventricular EF <35%	7 (6.2)	3	4	0.26
Prior percutaneous coronary intervention, n (%)	56 (49.6)	36	20	0.75
Prior CABG, n (%)	10 (8.8)	6	4	0.84
OMI, n (%)	38 (33.6)	26	12	0.38
Presenting syndrome				
ACS, n (%)	25 (22.1)	18	7	0.28
Non-ACS, n (%)	88 (77.9)	53	35	0.28
No. of diseased vessels at admission				
3, without LMT	18 (15.9)	9	9	0.22
1, with LMT	8 (7.1)	5	3	0.7
2, with LMT	2 (1.8)	1	1	0.7
3, with LMT	1 (0.9)	2	0	0.27

Values are mean ± standard deviation or number and (%).
HD = hemodialysis; EF = ejection fraction; CABG = coronary artery bypass graft; OMI = old myocardial infarction; ACS = acute coronary syndrome; LMT = left main trunk.

had a high prevalence of diabetes mellitus (DM) (49.6%), CKD (56.6%), and HD (37.2%). Detailed patients baseline characteristics are shown in Table 1.

Tables 2 and 3 include the lesion and procedural characteristics, respectively. While complex lesions (AHA B2/C) accounted for 96.5% of the lesions, the left anterior descending artery was the target vessel in 51.3% of the cases, (numerically higher in the non-HD group); however, the right coronary artery was the target vessel significantly more frequently in the HD group. The average final burr size was 1.62 ± 0.20 mm. The average total stent length/patient was 33.9 ± 18.0 mm.

Procedural non-fatal coronary perforation, slow flow phenomenon, and death during the peri-procedural period were each observed in one patient (0.9%). Table 4 shows the clinical outcomes. Clinical follow-up was available for 112 patients (99.1%), and the median follow-up period was 2.9 (interquartile range 1.9–3.6) years. Follow-up CAG was performed in 81.4% of the study patients who were in the chronic phase.

We found a 22.1% incidence of MACE (cardiac death was 9.7%, non-fatal MI was 5.3%, and clinically driven TLR was 10.6%), 14.2% (CABG 0.9%) incidence of any repeat revascularization, and a 3.5% incidence of stent thrombosis (ST) (Definite ST and Possible ST were each 1.8%)

Table 2
Lesion characteristics.

			Non-HD	HD	p value
Target vessel	Left main trunk, n (%)	3 (2.6)	2	1	0.88
	Left anterior descending artery, n (%)	59 (51.3)	42	17	0.05
	Left circumflex, n (%)	18 (15.7)	12	6	0.7
	Right coronary artery, n (%)	27 (23.5)	11	16	0.01
	LMT-LAD Cross over	8 (7.0)	5	3	0.99
Lesion classification AHA/ACC B2 or C, n (%)		111 (96.5)	69	42	0.6
CTO, n (%)		6 (5.2)	3	3	0.51
Ostial lesion, n (%)		24 (20.9)	16	8	0.64
Bifurcation, n (%)		39 (33.9)	27	12	0.29

Abbreviations as in Table 1. LAD = left anterior descending artery; CTO = chronic total occlusion.

Table 3
Procedural characteristics.

		Non-HD	HD	*p* value
Average final burr size (mm)	1.62 ± 0.20	1.62 ± 0.20	1.62 ± 0.20	0.99
Use of >1 burr, n (%)	9 (7.8)	6	3	0.79
Stent number	1.5 ± 0.7	1.51 ± 0.7	1.44 ± 0.73	0.59
Stent diameter (mm)	2.95 ± 0.36	2.89 ± 0.34	3.06 ± 0.36	0.0023
Stent length (mm)	22.4 ± 0.56	22.6 ± 5.5	22.2 ± 5.7	0.63
Total stent length/lesion (mm)	33.4 ± 17.9	34.2 ± 16.4	32.0 ± 20.2	0.52
Total stent length/patient (mm)	33.9 ± 18.0	34.4 ± 16.4	32.2 ± 20.4	0.59
Use of IVUS or OCT	111 (98.2)	69	42	0.27
Complications	12 (10.6)	9	3	0.36
Perforation, n (%)	1 (0.9)	1	0	0.44
Slow flow phenomenon, n (%)	1 (0.9)	1	0	0.44
Bleeding, n (%)	6 (5.3)	4	2	0.82
Cardiogenic shock, n (%)	1 (0.9)	1	0	0.44
Death, n (%)	1 (0.9)	0	1	0.19
Side branch occlusion	2 (1.8)	2	0	0.27
Complete revascularization at the time of after the index PCI	58 (51.3)	32	26	0.08

Values are mean ± SD.
Abbreviations as in Tables 1 and 2. IVUS = intravascular ultrasound; OCT = optical coherence tomography.

during the observation period. All ST occurred after PCI for RCA in patients on HD despite undergoing dual anti-platelet therapy (DAPT). Cases of definite ST included one late ST and one sub-acute ST. These cases were assessed by the incidence of MI and unstable angina pectoris after the index PCI (176 days and 28 days, respectively). All possible ST were assessed based upon the incidence of unexplained death 30 days after the index PCI (293 days and 430 days, respectively).

The Kaplan-Meier curve in Fig. 2 shows the cumulative incidence of MACE, nonfatal MI, and TLR. Subgroup analysis according to the HD status demonstrated that the incidence of MACE and TLR were significantly higher in the HD group than in the non-HD group (41.4% vs 4.2%, log-rank $p < 0.001$, 26.8% vs 1.4%, log-rank $p = 0.006$). There was no significant difference in the incidence of non-fatal MI (Fig. 3). The clinical outcomes of the HD group and non-HD group are also shown in Table 4. Cox's proportional hazards analysis which included CTO, HD, insulin use, statin use, and prior PCI as variables found that independent predictors of TLR were HD and CTO (HR, 14.1; 95% CI, 1.74–155.5; $p = 0.01$, HR, 9.01; 95% CI, 1.34–62.5; $p = 0.02$).

4. Discussion

Our study found that: 1) PP-EES implantation after lesion modification by RA is an appropriate treatment strategy for heavily calcified lesions, 2) the patients on HD showed a higher incidence of TLR after implantation of PP-EES following RA, and 3) the incidence of ST was significantly higher in HD patients compared with non-HD patients.

There are few RA-DES studies with a follow-up period longer than 2 years. Tamekiyo et al. reported clinical outcome of RA-SES at 2 years, with the rate of TLR being 25% [18]. In our study, which exclusively used PP-EES following RA, we documented a TLR incidence of 10.6%, a TVR incidence of 14.2%, and a MACE incidence of 22.1% at 2.9 years. Thus, we demonstrated acceptable long-term results given the severity of the patients' characteristics and complex lesions requiring RA. Moreover, this finding is consistent with a recent review on RA-DES [17]. Abdel-Wahab et al., Benezet et al., and Furuichi et al. [10,19–20] reported rates of MACE between 12.7% and 17.7% at 15 months. The rate of MACE was close to that observed in RA-DES studies although the follow-up period of our study was longer (34.7 months) than that of the other studies (between 14.7 and 15 months), and the patients in our study were higher risk, particularly in their prevalence of 49% DM, 56.6% CKD, and 37.2% HD compared with prior studies. Procedural complications were consistent with those reported in ROTA-stenting studies [16].

Table 4
Clinical outcomes.

		Non-HD	HD	*p* value
Clinical follow-up rate, n (%)	112 (99.1)	71	41	0.19
Follow-up period, (days)	1041 (698–1302)	1052 (685–1305)	1030.7 (734–1283)	0.96
Binary restenosis (>50% diameter stenosis), n (%)	13 (11.5)	1	12	<0.001
Target lesion revascularization (TLR), n (%)	12 (10.6)	1	11	<0.001
CABG, n (%)	1 (0.9)	0	1	0.19
Target vessel revascularization (TVR), n (%)	16 (14.2)	3	13	<0.001
Any repeat revascularization, n (%)	16 (14.2)	3	13	<0.001
Myocardial infarction, n (%)	8 (7.1)	4	4	0.44
Fatal, n (%)	2 (1.8)	1	1	0.7
Non-fatal, n (%)	6 (5.3)	3	3	0.5
Myocardial infarction (attributable to target vessel), n (%)	1 (0.9)	0	1	0.19
Unstable angina (attributable to target vessel), n (%)	3 (2.7)	0	3	0.02
Stent thrombosis, n (%)	4 (3.5)	0	4	0.01
Definite, n (%)	2 (1.8)	0	2	0.06
Possible, n (%)	2 (1.8)	0	2	0.06
Hospitalization of heart failure, n (%)	12 (10.6)	7	5	0.73
Sustained VT/VF, n (%)	4 (3.5)	2	2	0.59
All-cause death, n (%)	28 (24.8)	13	15	0.04
Cardiovascular death, n (%)	11 (9.7)	2	9	0.01
Composite MACE (cardiac death, non-fatal MI, TLR)	25 (22.1)	6	19	<0.001
Follow-up CAG, n (%)	92 (81.4)	54	38	0.06

Values are median (interquartile range).
Abbreviations as in Tables 1 and 2. VT; ventricular tachycardia; VF = ventricular fibrillation; MACE = major adverse cardiac event; CAG = coronary angiography.

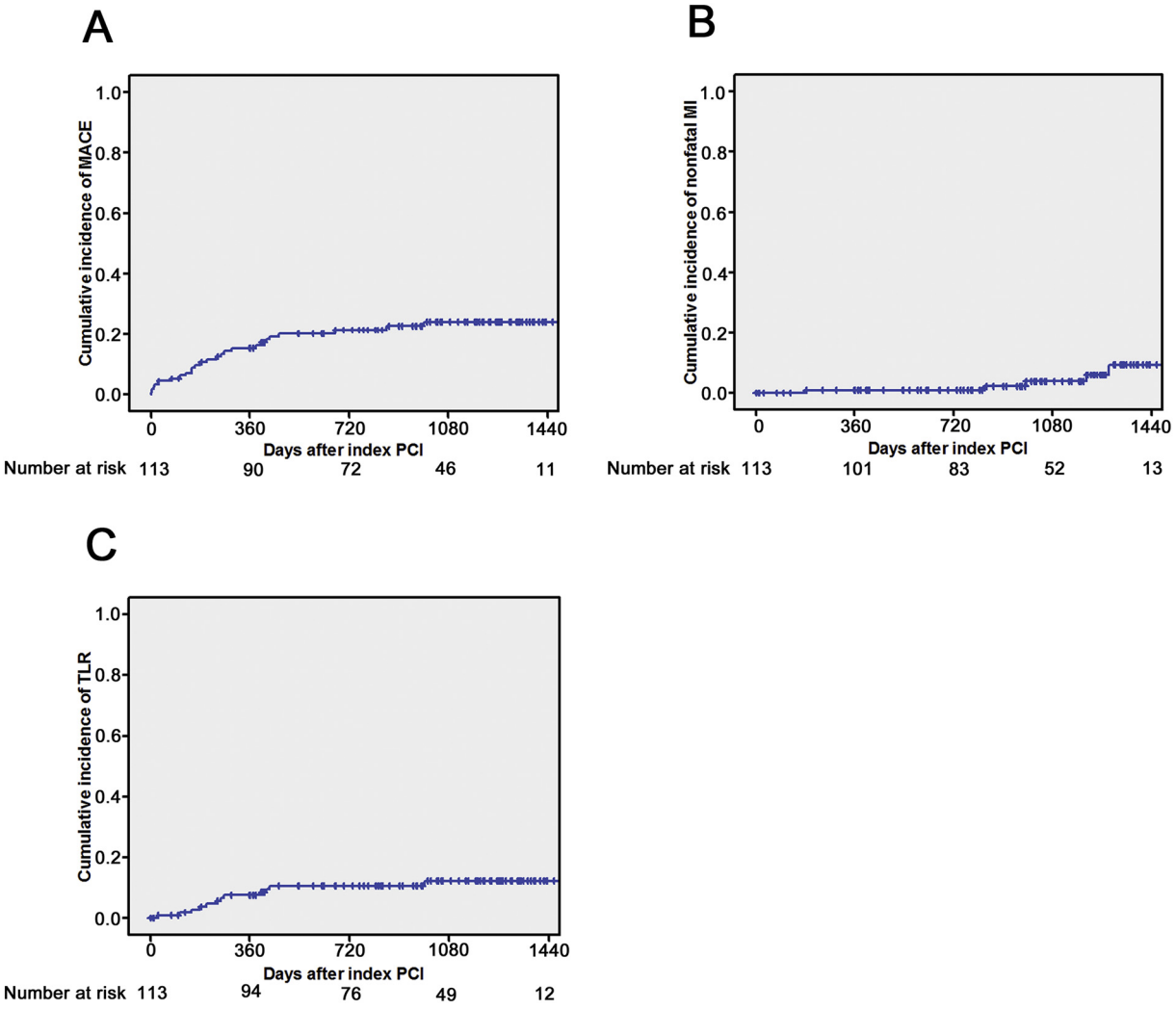

Fig. 2. Cumulative incidence for all patients. (A) Cumulative incidence of MACE, (B) cumulative incidence of nonfatal MI, (C) cumulative incidence of TLR. MACE: major adverse cardiac event, MI: myocardial infarction, TLR: target lesion revascularization.

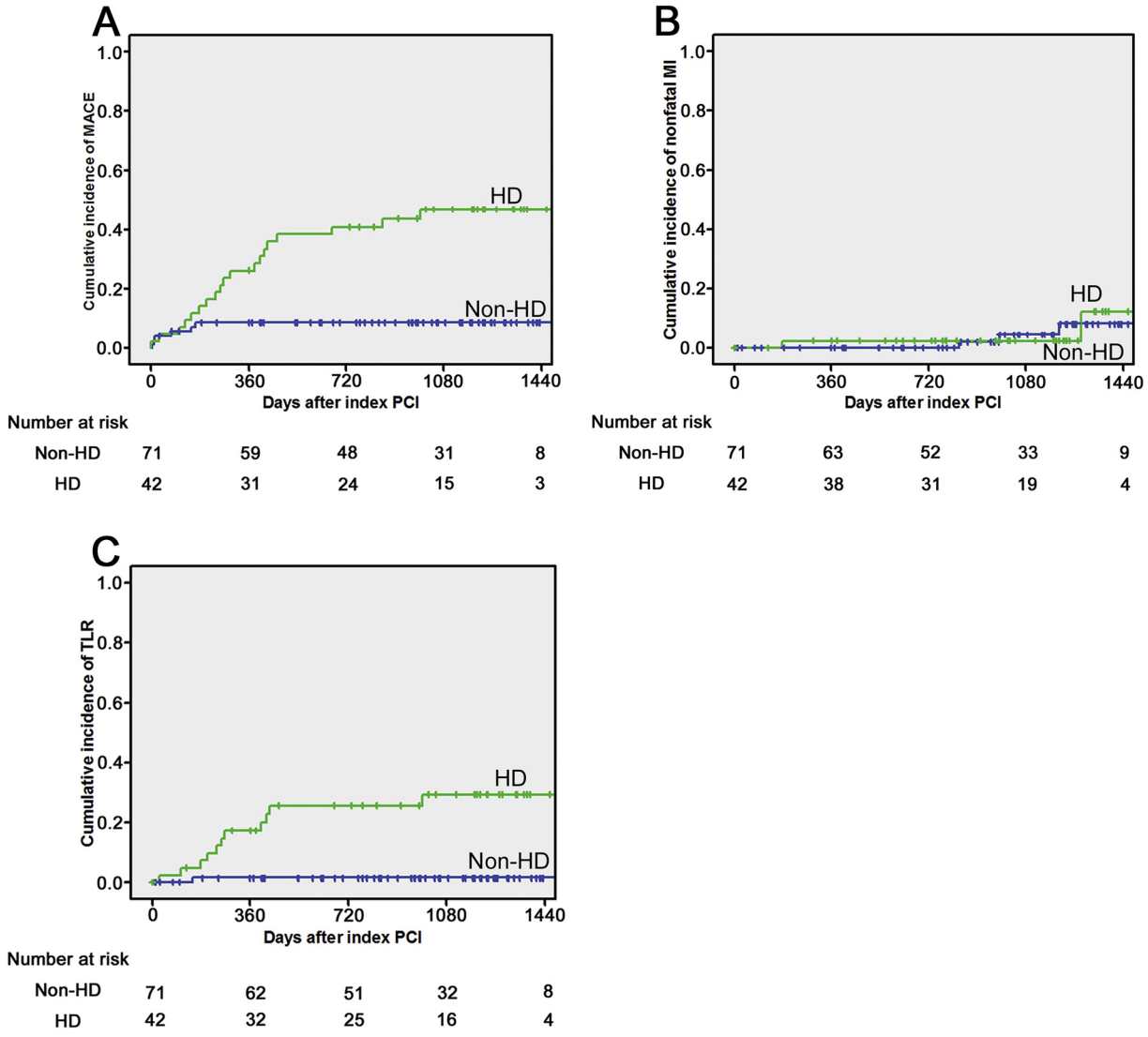

Fig. 3. Comparison of cumulative incidence between HD and non-HD patients. (A) Cumulative incidence of MACE, (B) cumulative incidence of nonfatal MI, (C) cumulative incidence of TLR. HD: hemodialysis, MACE: major adverse cardiac event, MI: myocardial infarction, TLR: target lesion revascularization.

To date, prior studies with observation periods of >2 years on clinical outcomes of RA-specific DES, including patients with HD, are limited. Tamekiyo et al. reported that the TLR was 36% with the RA-SES strategy (43% on HD) at 24 months in subgroup analysis [18]. On the other hand, Naito et al. reported that the rate of TLR in RA-SES and RA-PES strategy (13% on HD) at 630 days was 4.9% and 9.8%, respectively [21]. Based on the results of recent studies for clinical outcomes of PCI for HD patients, Otsuka et al. reported that SES has a significantly higher incidence of MACE in HD patients compared with that in non-HD patients [22], while Ota et al. demonstrated that HD was an independent predictor of 2-year MACE [23].

In the present study, we also found that HD was associated with TLR even after implantation of the second-generation DES following RA. Furthermore, all cases of definite ST occurred in the HD group after PCI for RCA despite all of the deployed stents having been 3.5 mm in diameter, procedure was performed under IVUS-guidance and DAPT was continued at the time of the events. In patients with definite ST, we found one subacute ST and one late ST. Both patients had highly complex lesions (total stent length > 70 mm, one patient had an ostial CTO lesion) in the RCA. Thus, lesion complexity, stent length and stent under-expansion or malapposition might contribute to ST [24].

In a previous randomized RA-DES trial, Abdel-Wahab et al. demonstrated that despite higher procedural success and acute lumen gain in the RA-DES strategy group, the incidence of TLR at 9 months was similar in the RA-DES group and in the DES implantation without RA group [24]. In that trial, a first-generation DES (PES) was exclusively used for stenting, so the differences in stent specifications should be considered when we compare these findings to current clinical settings in which second-generation DES is mostly used. The SPIRIT II and SPIRIT III studies reported that PP-EES was superior to PES in terms of late luminal loss, which indicated that PP-EES more efficiently suppressed neointimal hyperplasia than did PES [25,26]. In a previous pathological study of PP-EES, Otsuka et al. reported that a CoCr-PP-EES demonstrated less inflammation, fibrin deposition, and late and very late stent thrombosis [27]. Moreover, the long-term safety and efficacy of PP-EES when compared with that of PES were demonstrated in the 5-year results of the COMPARE trial [28]. Furthermore, recent studies suggested that the presumed mechanisms of the poor outcomes after DES implantation for HD patients were multifactorial as follows [22,29]: 1) the drug is not effective for calcified atherosclerotic lesions or insufficient doses of the drug for calcified lesion, 2) polymer damage decreased the efficacy of the drug, 3) stent fracture due to the high pressure dilatation, 4) suboptimal stent expansion, and 5) vessel trauma and inflammation caused by the RA.

The mechanism for the poor long-term clinical outcome of DES implantation for patients with chronic HD is still unclear, since large

scale clinical studies exclude patients with ESRD. Thus, it is necessary to further evaluate the safety and efficacy of RA-PP-EES.

4.1. Study limitations

This study has some limitations. First, this was a non-randomized, multicenter, observational study. Second, the sample size was relatively small, and the follow-up CAG in the chronic phase was obtained from 81.4% of the study patients. Third, any additional procedures used for lesion modification after RA (e.g., cutting balloon angioplasty) could not be analyzed. Fourth, the results of this study should not be applied to other types of second-generation DES, such as a polymer degradable drug-eluting stent or a newer-generation DES and other types of atherectomy devices.

5. Conclusions

PP-EES implantation after lesion modification with RA is one feasible treatment strategy for severely calcified coronary lesions in the current clinical setting. The present study showed that the rate of TLR was not as high as previously reported clinical trials of RA-first generation DES implantation, which included patients with ESRD. HD and CTO appeared to be associated with TLR. Further studies are required to improve treatment outcomes of heavily calcified coronary lesions.

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