Clinical Outcomes of Ultrathin Bioresorbable Polymer Sirolimus-Eluting Stents in Small Vessel Disease: A Retrospective Cohort Study

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Abstract

Aim: Percutaneous coronary intervention (PCI) in small vessel disease remains clinically challenging due to higher restenosis rate. The Orsiro stent, an ultrathin bioresorbable polymer sirolimus-eluting stent (SES), with thinner strut thickness may theoretically improve clinical outcome in small vessel disease PCI. We aimed to evaluate the long-term outcomes of SES in small vessel disease PCI.

Methods: We conducted a retrospective analysis in consecutive coronary artery disease patients who received PCI with ultrathin bioresorbable polymer SES implant between Jan 2017 and Dec 2017 in the National Taiwan University Hospital. All clinical information was collected by an independent interventionist. The primary measure was the incidence of major adverse cardiac and cerebrovascular events (MACCE), defined as death, acute coronary syndrome (including unstable angina), stroke or left ventricular failure requiring hospital admission and target lesion revascularization (TLR).

Results: A total of 191 patients received 297 ultrathin bioresorbable polymer SES in 219 vessel interventions. These patients were divided by lesion diameters into 2 groups. There were 92 patients in the small vessel disease (vessel size ≤ 2.5 mm) group and 99 patients in the non-small vessel disease group. All 297 SES were implanted successfully with a complication rate of 2.6%. After the median 17.2 months follow-up, the incidence of MACCE was 5.5% in the small vessel group and 11.0% in the non-small vessel group (P=0.110).

Conclusion: Small vessel PCI with bioresorbable polymers (SES) may be safe and effective.

Keywords: small vessel disease, percutaneous coronary intervention, outcomes, Orsiro

Introduction

Percutaneous coronary intervention (PCI) in small coronary arteries presents a challenge to intervention cardiologists. Small vessels are defined to with a reference vessel diameter

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(RVD) < 2.8 to 3.0 mm, and account for 30% to 50% of total coronary interventions.[1-4] Previous studies have demonstrated that coronary stenting significantly reduces the restenosis rate compared with balloon angioplasty.[5-7] However, these studies were mainly conducted with vessel sizes > 3.0 mm. Furthermore, there is no widely accepted consensus regarding the preferred intervention method for small coronary vessels. Currently, the decision to stent small vessels is based on vessel perfusion territories and lesion characteristics such as tortuosity and crossability. Small vessel intervention faces higher risks of dissection, perforation and restenosis.[8,9] The stent strut thickness is also an important predictor of restenosis in small coronary arteries and thinner-strutted stents are associated with lower incidence of restenosis compared with thick-strutted stents.[10-12]

Ultrathin bioresorbable polymer sirolimus-eluting stents (SES), such as the Orsiro sirolimus eluting coronary stent include thinner struts (60μm) and might improve cardiac outcomes and decrease the incidence of restenosis. The BIOFLOW V multicenter randomized control trial demonstrated that ultrathin bioresorbable polymer SES had lower incidence of target lesion revascularization (TLR) and target vessel-related myocardial infarction (MI) compared to thin strut (81 mm) durable polymer everolimus-eluting stent in small vessel disease (RVD about 2.6 mm) after 2 years follow-up.[13] However, data on the clinical outcomes of ultrathin bioresorbable polymer in Asian patients is lacking. To understand the performance of ultrathin bioresorbable polymer SES in Asian patients, we conducted this retrospective study investigating the safety and efficacy of ultrathin bioresorbable polymer SES in small vessel disease.

Methods

Patients

We retrospectively reviewed all patients who received ultrathin bioresorbable polymer SES implant between Jan 2017 and Dec 2017 in National Taiwan University Hospital. We classified them according to the diameters of implanted ultrathin bioresorbable polymer SES. Patients in the "non-small vessel group" received SES with diameter > 2.5 mm, while patients in the "small vessel group" received at least one SES diameter ≤ 2.5 mm. All clinical information was reviewed retrospectively through electronic medical records from National Taiwan University Hospital. Baseline demographics, past medical history, complete blood count, biochemistry studies, and medications were carefully recorded. Data on coronary angiograms, PCI procedures, interventional results, and procedural complications were carefully collected and reviewed by independent interventionists. Bifurcation stenting was defined as a 2-stent procedure in bifurcation lesions, while branch stenting was defined as stenting over branches over pericardial vessels, including diagonal artery, obtuse marginal artery, posterior descending artery or posterior lateral artery. Stent length was calculated by summation of the length of each stent.

Outcome measures

The post-PCI follow-ups were reviewed from the electronic medical records. The primary measure of outcome was the incidence of major adverse cardiac and cerebrovascular events (MACCE), defined as death, acute coronary syndrome (including unstable angina), stroke or left ventricular failure requiring hospital admission and target lesion revascularization (TLR). TLR is defined as any repeat percutaneous intervention at the target lesion or bypass surgery of the target vessel performed due to restenosis or other complication of the target lesion. The secondary measure of outcome was all-cause mortality, cardiovascular (CV) related mortality, clinical driven TLR and acute coronary syndrome. This study was approved by the Institutional Review Board of National Taiwan University Hospital and was performed in accordance with relevant

guidelines and regulations.

Statistical analysis

Statistical analysis was performed using Stata/SE 14.0 for Windows (StataCorp LP, TX). A two-sided p-value less than 0.05 defined statistical significance. The measurement data were first tested for normality. Data with normal distribution were expressed as mean ± standard deviation and median (25th-75th interquartile range) was used for non-normally distributed numerical data. Categorical data were expressed as Number (%). Differences between proportions were calculated using the chi-square test or Fisher's exact test. Comparisons of data between 2 groups were performed using the independent T test (normally distributed data) and Mann-Whitney U test (non-normally distributed data). Kaplan–Meier survival curves were plotted and Cox regression model was used for outcome analysis. Patients who were lost to follow-up and those who completed 2 years follow-up were censored in the model.

Results

A total of 191 patients (150 men, mean age 66.0 ± 12.0 years) received 297 ultrathin bioresorbable polymer SES in 219 vessels by PCI during the period. There were 92 (48.2%) patients who received coronary intervention with at least one SES of diameter ≤ 2.5 mm, and who were classified as the "small vessel group". There were 99 (51.8%) patients who received coronary intervention, all with stent diameters > 2.5 mm and who were classified as the "non-small vessel group". Baseline characteristics regarding comorbidities, clinical presentation and history of coronary artery bypass graft (CABG), and blood tests, were similar between groups, except for gender, with fewer males in the small vessel group than the non-small vessel group (71.7% versus 84.8% respectively, P = 0.027). Medication use after SES PCI was also similar, except that a lower rate of nitrates use was observed in the small vessel group (29.3% versus 43.4%, P = 0.044).

The treatment target varied between the 2 groups. In the "small vessel group", LCX intervention was significantly higher compared to the "non-small vessel group" (40.2% vs. 22.2%, P = 0.007), and RCA intervention was significantly lower (18.5% vs. 34.3%, P = 0.013). The rates of LM and LAD intervention were similar between the groups. As regards the intervention procedure, although the number of vessels treated was similar in the 2 groups, in the small vessel group the total number of stents deployed was higher (1.7 ± 0.8 vs. 1.4 ± 0.7, P = 0.034) and the total stent length was longer (52.5 ± 26.2 mm vs. 44.3 ± 23.7 mm, P = 0.023). The rate of LM bifurcation stenting was similar, but there was a higher rate of non-LM bifurcation stenting in the "small vessel group" (13.0% vs. 3.0%, P = 0.01). Branch stentings involving diagonal branches, OM branches, RI, PDA or PLA were also higher in the small vessel group (38.0% vs. 17.1%, P = 0.001). All stents were successfully deployed to the lesions and the procedure success rate was 100%. The overall procedure complication rate was 3.3% in the small vessel group, which was similar to the non-small vessel group (2.0%) (P = 0.592). Two patients suffered complications with coronary extravasation, 2 patients with cardiogenic shock and 1 patient with periprocedural MI. There were no cases of stroke or mortality after the procedure.

Comparing the characteristics of the 218 target vessels treated, 98 (45.0%) vessels received coronary intervention with at least one stent of diameter ≤ 2.5 mm. There was a higher rate of LCX intervention (38.8% vs. 17.5%, P < 0.001), lower rate of RCA intervention (14.3% vs. 36.7%, P = 0.003), higher rate of branch stenting (32.7% vs. 11.7%, P < 0.001), higher rate of non-LM bifurcation stenting (11.2% vs. 3.3%, P = 0.022), and longer stent length per vessel (45.5 ± 20.7 mm vs. 39.9 ± 19.1 mm, P = 0.039) in target vessels treated with at least one SES of diameter ≤ 2.5 mm.

Comparing the characteristics of the 297 SES used during PCI, a total of 108 (36.4%) SES

were ≤ 2.5 mm (7.1% with 2.25 mm SES, 29.3% with 2.5 mm SES).For those SES ≤ 2.5 mm, the rate of LM stenting was lower (0.9% vs. 12.2%, P = 0.001), the rate of LCX stenting was higher (34.3% vs. 16.9%, P = 0.001), the rate of RCA stenting was lower (13.9% vs. 32.3%, P < 0.001), the rate of branch stenting was higher (34.2% vs. 11.1%, P < 0.001) and the rate of LM bifurcation stenting was lower (0% vs. 5.3%, P = 0.015).

After the median 17.2 months follow-up, the incidence of MACCE was 5.5% in the small vessel group and 11.0% in the non-small vessel group (P = 0.110).The mortality rate, CV related mortality rate, TLR, and acute coronary syndrome were also similar in the two groups (Figure 1 and Table 4).

Discussion

In this real-world all-comers retrospective analysis, patients who received PCI with implantation of ultrathin bioresorbable polymer SES of diameter ≤ 2.5 mm had similar MACCE compared to patients who received larger diameter bioresorbable polymers SES implant. The MACCE rate in patients who received ultrathin bioresorbable polymer SES of diameter ≤ 2.5 mm was 5.5% after the median 17.2 months follow-up.

Small vessel disease intervention constitutes a large proportion of the daily practice of PCI and it remains a challenging task for intervention cardiologists.[14,15] These lesions are often combined with comorbidities such as diabetes mellitus,

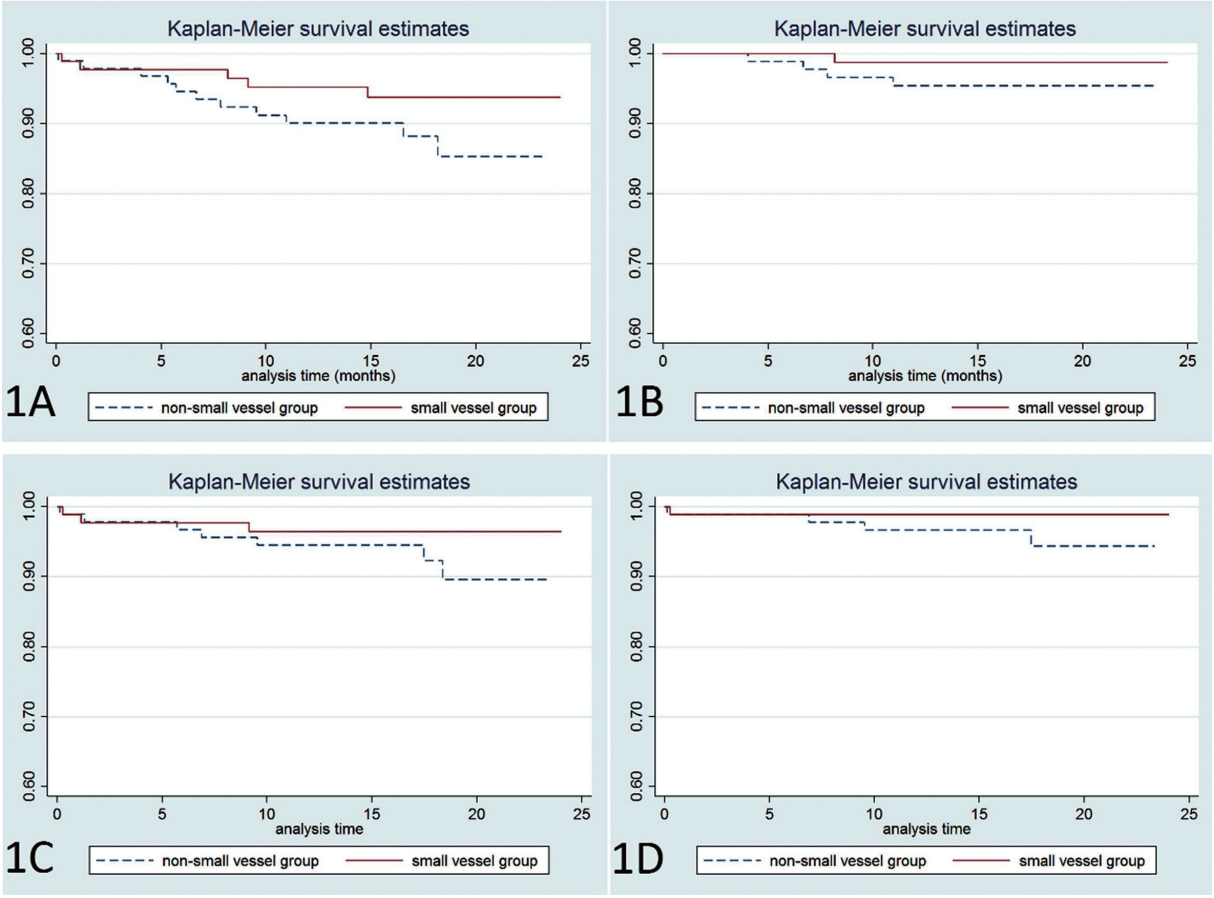

Figure 1. Kaplan-Meier survival estimates for clinical outcome in the small vessel and non-small vessel group.

Kaplan-Meier survival estimates for cumulative incidence of MACCE in 1A (P = 0.159), TLR in 1B (P = 0.242), mortality in 1C (P = 0.238) and CV related mortality in 1D (P = 0.238) in small and non-small vessel groups.

Table 1. Patient characteristics and procedure result

	Small vessel group (n=92)	Non-small vessel group (n=99)	Total patients (n=191)	P value
Age, years	66.4 ± 11.1	65.6 ± 12.8	66.0 ± 12.0	0.657
Male gender, n (%)	66 (71.7%)	84 (84.8%)	150 (78.5%)	0.027
Body mass index, Kg/cm^2	26.0 ± 3.6	25.5 ± 3.5	25.7 ± 3.6	0.292
Diabetes mellitus, n (%)	47 (51.1%)	41 (41.4%)	88 (46.1%)	0.180
Hypertension, n (%)	70 (76.1%)	76 (76.8%)	146 (76.4%)	0.912
Dyslipidemia, n (%)	60 (65.2%)	65 (65.7%)	125 (65.4%)	0.950
End stage renal disease, n (%)	9 (9.8%)	16 (16.2%)	25 (13.1%)	0.192
History of CABG, n (%)	7 (7.6%)	6 (6.1%)	13 (6.8%)	0.671
Acute coronary syndrome, n (%)	14 (15.2%)	20 (20.2%)	34 (17.8%)	0.368
Hemoglobin, g/dL	13.4 ± 2.2	13.3 ± 2.2	13.3 ± 2.2	0.754
Platelet, K/uL	217.5±63.0	219.8±57.3	218.7±60.0	0.785
Creatinine, mg/dL	1.7±2.1	1.9±2.5	1.8±2.3	0.432
Fasting glucose, mg/dL	116.6 ± 38.4	119.4 ± 40.4	118.1 ± 39.4	0.620
HbA1c, %*	6.6 ± 1.1	6.4 ± 1.2	6.5 ± 1.2	0.370
Total cholesterol, mg/dL	161.3 ± 38.2	161.1 ± 35.4	161.2 ± 36.7	0.963
Triglyceride, mg/dL	128.2 ± 62.8	144.0 ± 106.0	136.4 ± 88.0	0.214
LDL-C, mg/dL	94.2 ± 34.4	93.3 ± 28.9	93.8 ± 31.5	0.852
HDL-C, mg/dL	42.9 ± 9.7	42.1 ± 9.3	42.5 ± 9.5	0.565
Treatment target				
LM, n (%)	7 (7.6%)	12 (12.1%)	19 (9.9%)	0.298
LAD, n (%)	50 (56.5%)	52 (50.5%)	102 (53.4%)	0.405
LCX, n (%)	37 (40.2%)	22 (22.2%)	59 (30.9%)	0.007
RCA, n (%)	17 (18.5%)	34 (34.3%)	51 (8.9%)	0.013
Multi-vessel intervention, n (%)	15 (16.3%)	10 (10.1%)	26 (13.1%)	0.204
Number of stents used	1.7 ± 0.8	1.4 ± 0.7	1.5 ± 0.7	0.034
Total stent length, mm	52.5 ± 26.2	44.3 ± 23.7	48.2 ± 25.2	0.023
Bifurcation stenting, n (%)	13 (14.1%)	7 (7.1%)	20 (8.9%)	0.113
LM bifurcation stenting, n (%)	1 (1.1%)	4 (4.0%)	6 (3.1%)	0.203
Non-LM bifurcation stenting, n (%)	12 (13.0%)	3 (3.0%)	15 (7.6%)	0.010
Branch stenting, n (%)	34 (38.0%)	18 (17.1%)	52 (27.2%)	0.001
Rotation use, n (%)	4 (4.3%)	2 (2.0%)	6 (3.1%)	0357
IVUS use, n (%)	48 (52.1%)	49 (49.4%)	97 (50.8%)	0.711
CTO lesion, n (%)	14 (15.2%)	11 (11.1%)	25 (13.1%)	0.401
Periprocedural complication, n (%)	3 (3.3%)	2 (2.0%)	5 (2.6%)	0.592
Medication after PCI				
Beta blocker, n (%)	65 (70.7%)	74 (74.7%)	139 (72.8%)	0.525
Statin, n (%)	67 (72.8%)	77 (77.8%)	144 (75.4%)	0.427
Ezetimibe, n (%)	9 (9.8%)	7 (7.0%)	16 (8.4%)	0.471
ACEI/ARB, n (%)	50 (54.9%)	62 (62.0%)	112 (58.6%)	0.323
Calcium channel blocker, n (%)	27 (29.3%)	31 (31.3%)	58 (30.4%)	0.769
Nitrate, n (%)	27 (29.3%)	43 (43.4%)	70 (36.6%)	0.044
Aspirin, n (%)	85 (92.4%)	90 (90.9%)	175 (91.6%)	0.712
Clopidogrel, n (%)	80 (86.9%)	86 (86.9%)	166 (86.9%)	0.986
Ticagrelor, n (%)	12 (13.0%)	12 (12.1%)	24 (12.5%)	0.848
DAPT, n (%)	85 (92.3%)	90 (90.9%)	175 (91.6%)	0.712
Oral anti-coagulant, n (%)	2 (2.2%)	4 (4.0%)	6 (3.1%)	0.460

Data were presented as mean ± standard deviation or number (percentage).
Abbreviation: LDL-C: low-density lipoprotein cholesterol, HDL-C: high density lipoprotein cholesterol, LM: left main coronary artery, LAD: left anterior descending artery, LCX: left circumflex artery, RCA: right coronary artery, IVUS: intravascular ultrasound, CTO: chronic total occlusion, ACEI: angiotensin converting enzyme inhibitors, ARB: angiotensin receptor blockers, DAPT: dual antiplatelet therapy.
* n=90 in patient with stent > 2.5 mm, n = 79 in patients with stent ≤ 2.5 mm.

Table 2. Procedure results in target vessel

	Target vessel treated with stent ≤2.5 mm (n=98)	Target vessel treated with stent > 2.5mm (n=120)	Total target vessels (n=218)	P-value
LM, n (%)	7 (7.1%)	17 (14.1%)	24 (11.0%)	0.10
LAD, n (%)	45 (45.9%)	57 (47.5%)	102 (46.8%)	0.816
LCX, n (%)	38 (38.8%)	21 (17.5%)	59 (27.1%)	<0.001
RCA, n (%)	14 (14.3%)	38 (36.7%)	76 (23.9%)	0.003
SVG, n (%)	1 (1.0%)	3 (2.5%)	6 (1.8%)	0.418
Branch stenting, n (%)	32 (32.7%)	14 (11.7%)	46 (21.1%)	<0.001
Diagonal stenting, n (%)	13 (13.3%)	2 (1.7%)	15 (6.9%)	0.001
OM stenting n (%)	14 (14.3%)	6 (5.0%)	20 (7.9%)	0.018
PDA or PLA stenting, n (%)	6 (6.1%)	6 (5.0%)	12 (5.5%)	0.718
Ramus intermediate, n (%)	2 (2.0%)	1 (0.8%)	3 (1.3%)	0.447
Bifurcation stenting, n (%)	13 (13.3%)	12 (10.0%)	25 (11.5%)	0.452
LM bifurcation stenting, n (%)	3 (3.1%)	8 (6.6%)	11 (5.0%)	0.226
Non-LM bifurcation stenting, n (%)	11 (11.2%)	4 (3.3%)	14 (6.4%)	0.022
Stent length per vessel, mm	45.5 ± 20.7	39.9 ± 19.1	42.4 ± 20.0	0.039
Number of stents per vessel	1.4 ± 0.6	1.3 ± 0.6	1.2 ± 0.5	0.082
Minimal stent diameter, mm	2.45 ± 0.10	3.19 ± 0.37	2.85 ± 0.47	<0.001
Maximum stent diameter, mm	2.65 ± 0.39	3.28 ± 0.39	3.00 ± 0.49	<0.001

Abbreviation: SVG: saphenous vein graft, OM: obtuse marginal, PDA: posterior descending artery, PLA: posterior lateral artery.

Table 3. Procedure results in target lesion

	Target lesion treated by stent ≤2.5 mm (n=108)	Target lesion treated by stent >2.5 mm (n=189)	Total target lesions (n=297)	P-value
LM, n (%)	1 (0.9%)	23 (12.2%)	24 (8.1%)	0.001
LAD, n (%)	53 (49.1%)	88 (46.6%)	141 (47.3%)	0.677
LCX, n (%)	37 (34.3%)	32 (16.9%)	69 (23.2%)	0.001
RCA, n (%)	15 (13.9%)	61 (32.3%)	76 (25.5%)	<0.001
SVG, n (%)	1 (0.9%)	5 (2.6%)	6 (2.0%)	0.311
Branch stenting, n (%)	37 (34.2%)	21 (11.1%)	58 (19.5%)	<0.001
Diagonal stenting, n (%)	15 (13.9%)	2 (1.1%)	17 (5.7%)	<0.001
OM stenting, n (%)	13 (12.0%)	7 (3.7%)	20 (6.7%)	0.007
PDA or PLA stenting, n (%)	7 (6.5%)	11 (5.8%)	18 (6.1%)	0.818
Ramus intermediate, n (%)	2 (1.9%)	1 (0.5%)	3 (1.0%)	0.273
Bifurcation stenting, n (%)	15 (13.9%)	25 (13.2%)	40 (13.5%)	0.873
LM bifurcation stenting, n (%)	0 (0)	10 (5.3%)	10 (3.4%)	0.015
Non-LM bifurcation stenting, n (%)	15 (13.9%)	15 (7.9%)	30 (10.1%)	0.102
Stent length, mm	32.0 ± 7.9	30.8 ± 8.9	31.2 ± 8.5	0.218
Stent Diameters, mm	2.45 ± 0.10	3.21 ± 0.36	2.94 ± 0.47	<0.001
2.25 mm stent, n (%)	21 (19.4%)	0 (0.0%)	21 (7.0%)	<0.001
2.5 mm stent, n (%)	87 (80.6%)	0 (0.0%)	87 (29.2%)	
2.75 mm stent, n (%)	0 (0.0%)	26 (13.8%)	26 (8.7%)	
3.0 mm stent, n (%)	0 (0.0%)	85 (45.0%)	85 (28.5%)	
3.5 mm stent, n (%)	0 (0.0%)	61 (32.3%)	61 (20.5%)	
4.0 mm stent, n (%)	0 (0.0%)	17 (9.0%)	17 (5.7%)	

Table 4. Clinical outcomes

	Stent ≤ 2.5 mm (n=92)	Stent > 2.5 mm (n=89)	aHR (95 CI)*	P-value
MACCE	5.5%	11.0%	0.40 (0.13-1.23)	0.110
TLR	1.1%	4.0%	0.34 (0.03-3.33)	0.352
All-cause mortality	3.3%	7.0%	0.37 (0.09-1.57)	0.178
CV related mortality	1.1%	4.0%	0.19 (0.02-1.85)	0.151
Acute coronary syndrome	1.1%	3.0%	0.20 (0.02-2.52)	0.205

*Cox regression analysis after adjusting for age, sex, total stents and total stent length.
Abbreviation: CV: cardiovascular, TLR: target lesion revascularization, MACCE: major adverse cardiac and cerebrovascular events.

multi-vessel disease, and complex and longer lesions. All of these conditions are associated with poor outcomes.[16] Previous studies have defined 3.0 mm as the threshold for small vessels which is associated with worse outcomes after stenting. However, thanks to developments in stent technology, including new metal alloys, antiproliferative agents, thinner struts, improvement in polymer biocompatibility and the development of bioresorbable polymers,[17] the clinical outcomes of small vessel intervention are improving.[13,18,19]

The TWENTE II trial used new-generation drug-eluting stents (DES) and showed that MACE and target lesion failure (TLF) were significantly more frequent in small vessels (< 2.5 mm) than in large vessels after 2 years follow-up20. It also showed that a vessel diameter < 2.5 mm may be regarded as a threshold for small vessel disease to predict clinical outcomes after subgroup analysis. In this study, we also used 2.5 mm as the threshold of RVD for small vessel disease.

The Orsiro coronary stent consists of an ultrathin cobalt chromium strut (60 μm) with a bioresorbable, poly-lactic acid polymer coating that elutes the antiproliferative drug sirolimus. This ultrathin bioresorbable polymer sirolimus-eluting stent has thinner stent and bioresorbable polymers which possibly contribute to the good clinical results.[13,17]

Some studies have been conducted to compare the outcomes between bioresorbable and durable polymers. In the LEADERS trial comparing 5-year clinical outcomes, the bioresorbable polymer stents and durable polymer stents showed similar rates of cardiac death, MI and clinically driven TLR, despite significantly lower very late stent thrombosis in the bioresorbable polymer.[21] In the recent BIOFLOW V trial, ultrathin bioresorbable polymer sirolimus-eluting stent had significantly lower rates of TLF, ischemia driven TLR, target vessel-related MI and late/very late definite stent thrombosis, when compared with thin strut (81 μm) durable polymer everolimus-eluting stent after 2 years follow-up.[13] In addition to the beneficial effects of bioresorbable polymers, the ultrathin strut of the Orsiro stent may also improve clinical outcomes.

The ISAR STEREO 2 study demonstrated that the ultrathin strut (50 μm) produced less angiographic and clinical restenosis compared with thick strut (140 μm) bare-metal stent.[11] Micaela Iantorno et al conducted a meta-analysis to assess the impact of stent struts in DES. Stents with thinner struts have less angiographic restenosis compared with those with thicker struts (17.9% vs 31.4%, RR: 0.57, p < 0.001). Furthermore, thinner struts were found to have less TVR compared with thicker struts (12.3% vs 21.9%, RR: 0.56, P = 0.002).[12] In the present study, the TLR in small vessels (< 2.5 mm) was 1.1%, which was lower than the 4.8% result from the TWENTE II trial after 2 years follow-up. The frequency of MACE was also lower in our study

compared with the TWENTE II trial (5.5% vs 10.8%).[20] In the recent BIOFLOW V trial, the TLR and MACE rates were also higher compared to our results; 1.1% TLR in our small vessel group, compared with 2.9% in the BIOFLOW V trial (mean RVD: 2.59 ± 0.54).[13]

Small vessel disease is often associated with complex lesions and there are many technical difficulties during small vessel intervention. It is important to confirm the actual vessel diameters for optimal stenting and to prevent complications. IVUS is useful in assessing the luminal diameter and improving outcomes.[22,23] IVUS was frequently used in our study to guide the small vessel intervention. In this study, 15.2% of patients with small vessel lesions had CTO, and the stent lengths per target vessel with small vessel lesions were longer compared with those in the BIOFLOW V trial (45.5 mm versus 20.8 mm).[13] Both CTO and long lesions are associated with restenosis and worse outcomes.[24,25] Despite the challenges of PCI performed in these complex lesions, the Orsiro stent demonstrated excellent results in real-world practice.

There are several limitations to this study. First, this was a small retrospective study with a limited number of cases. Further large prospective studies with longer follow-up time are needed to support our findings. Second, detailed angiographic characteristics were relatively limited in this retrospective study. Further prospective study should document the lesion characteristics more comprehensively. Third, not all patients received the complete 2 years follow-up and the data in this study should therefore be interpreted with caution.

Conclusion

Patients who received PCI with implantation of ultrathin bioresorbable polymer SES of diameter ≤ 2.5 mm had similar MACCE, TLR, acute coronary syndrome, all-cause mortality and CV related mortality, compared to patients who received SES implant of diameter > 2.5 mm, after long-term follow-up. Small vessel PCI with bioresorbable polymer SES may be safe and effective.

Conflict of Interest

The authors declare no conflicts of interest.

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