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WILEY

ORIGINAL STUDIES

Small-vessel PCI outcomes in men, women, and minorities following platinum chromium everolimus-eluting stents: Insights from the pooled PLATINUM Diversity and PROMUS Element Plus Post-Approval studies

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Abstract

Objective: We evaluated 1-year outcomes after platinum chromium everolimus-eluting stents (PtCr-EES) in small versus non-small coronary arteries within a large, diverse sample of men, women, and minorities.

Background: There exists limited outcomes data on the use of second-generation drug-eluting stent to treat small diameter coronary arteries.

Methods: We pooled patients from the PLATINUM Diversity and PROMUS Element Plus stent registries. Small-vessel percutaneous coronary intervention (SV-PCI) was defined as ≥1 target lesion with reference vessel diameter (RVD) ≤2.5 mm. Endpoints included major adverse cardiac event (MACE; death, myocardial infarction [MI] or target vessel revascularization [TVR]), target vessel failure (TVF; death related to the target vessel, target vessel MI or TVR) and definite/probable stent thrombosis (ST). Multivariable Cox regression was used to risk-adjust outcomes.

Results: We included 4,155/4,182 (99%) patients with available RVD, of which 1,607 (39%) underwent small-vessel PCI. SV-PCI was not associated with increased MACE (adjHR 1.02; 95% CI 0.81–1.30) or TVF (adjHR 1.07; 95%CI 0.82–1.39). MI risk was lower in white men compared to women and minorities, both in the setting of SV-PCI (adjHR 0.41; 95%CI 0.23–0.74 and adjHR 0.39; 95%CI 0.20–0.75, respectively) and for non-SV-PCI (adjHR 0.61; 95%CI 0.38–0.99 and adjHR 0.45; 95%CI 0.27–0.74, respectively). There was no significant interaction between RVD and sex or minority status for any endpoint.

Conclusion: In a large diverse contemporary PCI outcomes database, SV-PCI with PtCr-EES was not associated with increased MACE or TVR and did not account for the increased MI risk noted in women and minorities compared to white men.

Abbreviations: MACE, Major adverse cardiac event; MI, Myocardial infarction; PCI, Percutaneous coronary intervention; PtCr-EES, Platinum chromium everolimus-eluting stent; RVD, Reference vessel diameter; SV-PCI, Small vessel PCI; TLF, target lesion failure; TVR, target vessel revascularization.

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KEYWORDS
coronary artery disease, drug-eluting stent, percutaneous coronary intervention, platinum chromium everolimus-eluting stent, small coronary artery vessel, women and minority

1 | INTRODUCTION

The prevalence of small vessel coronary artery disease (CAD) in patients undergoing percutaneous coronary intervention (PCI) is as high as 50%, depending on its definition and the demographics of the patient population studied.[1] Although there exists no universally accepted definition for small vessel CAD, a reference vessel diameter (RVD) ≤2.5 for the target lesion has often been adopted.[2–4] Neointimal proliferation and local inflammation that follow PCI result in higher rates of in-stent restenosis and overall recurrent ischemic events in small vessels.[1,2,5,6] Compared to bare-metal stents, drug-eluting stents (DES) have been associated with reduced late lumen loss and improved clinical outcomes, with this benefit also applying to small vessel PCI (SV-PCI).[1,7–9] However, data regarding the performance of second-generation platinum chromium everolimus-eluting stents (PtCr-EES) in small coronary artery vessels are quite limited, particularly in women and minorities.[7] For example, women who more often present with small vessel CAD[10–12] have been underrepresented in PCI outcomes studies, often accounting for less than a quarter of overall enrollment.[2,3,7] Similarly, outcomes in minorities have also not been adequately evaluated in the context of SV-PCI.[13,14] We have recently shown that both women and minorities have higher risks of MACE following PCI with contemporary second generation PtCr-EES.[15] The extent to which this relates to vessel size is unknown. The purpose of this study was to evaluate the 1-year clinical outcomes after PtCr-EES implantation in SV-PCI versus non-SV-PCI within a large cohort of men, women, and minorities, while also examining the impact of sex and race.

2 | MATERIALS AND METHODS

2.1 | Study design and participants

The PLATINUM Diversity (PD) study (NCT02240810) was a prospective, multicenter, open-label observational study that enrolled patients who received ≥1 PROMUS PREMIER™ PtCr-EES (Boston Scientific, Marlborough, MA) and self-identified as having ≥1 of the following characteristics: female sex, black (of African heritage), Hispanic/Latino, or American Indian/Alaskan Native, without exclusion criteria. Patients were enrolled at 52 U.S. sites, from October 2014 to August 2015 and followed for 12 months by telephone or clinical visit. The PROMUS Element Plus Post-Approval (PE plus) Study (NCT01589978) was a prospective, multicenter, open-label observational registry completed in August 2014 across 52 U.S. sites, including an all-comer population of patients undergoing PCI with PROMUS Element Plus™ PtCr-EES (Boston Scientific).[16] Both the PD and PE Plus studies complied with the Declaration of Helsinki, were approved by each site's locally appointed ethics committee and both used an independent clinical events committee for adjudication of outcomes. Written informed consent was required within 24 hr of stent implantation. As previously described, the PD and PE Plus studies were pooled in a prespecified manner to create an unusually diverse PCI database with adequate representation of men, women, and minorities.[15] Both registries were supported by Boston Scientific, however, the authors independently performed and are solely responsible for the design and conduct of the present study, all study analyses, the drafting and editing of the article, and its final contents.

For the purpose of this study, SV-PCI was defined as the presence of ≥1 target lesion with a RVD ≤2.5 mm, as reported by the site investigator. There was no central angiographic core laboratory associated with the study.

2.2 | Device description

The stents used in the PD and PE Plus studies are thin-strut PtCr-EES with a permanent polyvinylidene fluoride-co-hexafluoropropene polymer. PROMUS PREMIER™ has a very similar scaffold design to PROMUS Element Plus™ stent with additional connectors within the proximal stent segments added to PROMUS PREMIER™. Both stents have demonstrated consistent safety and performance across the PD clinical trial program and in the PE Plus registry.[16–18]

2.3 | Endpoint definitions

We evaluated the 1-year cumulative rates of major adverse cardiac event (MACE; defined as the composite of all-cause death, myocardial infarction [MI] or target vessel revascularization [TVR]), and target vessel failure (TVF, defined as death related to the target vessel, any revascularization of the target vessel or target vessel MI). Additional endpoints evaluated included the individual components of the composite endpoints as well as definite or probable stent thrombosis (ST). All endpoints were adjudicated by an independent clinical event committee according to the common definitions used in the PD and PE Plus studies.[16,17]

2.4 | Statistical methods

Continuous data are presented as means and standard deviation (± SD) or median and interquartile range as appropriate and categorical data are presented as numbers and percentage. Two-sided Student's t-tests were used to compare continuous variables and chi-square tests were used for categorical variables. Cumulative event rates in the study groups were

calculated with the Kaplan–Meier method and compared using the log-rank test. The association between clinical outcomes and PCI in small coronary artery vessel was assessed using multivariable Cox regression adjusted for the following variables that include, but are not limited to the independent predictors of MACE from the pooled PD/PE Plus study[15]: age, male sex, minority status, diabetes mellitus, prior PCI, prior AF, prior hypertension, chronic kidney disease, prior peripheral artery disease, urgent or emergent PCI indication (vs. elective PCI), more than one target lesion treated (vs. only one target lesion treated). A *P*-value <0.05 was considered statistically significant. All data were analyzed using Stata version 14.0 (StataCorps, College Station, TX).

3 | RESULTS

3.1 | Baseline characteristics

Of the 4,182 patients included in the pooled PD and PE Plus registries, the 4,155 (99%) who had RVD recorded for each target lesion

TABLE 1 Baseline clinical characteristics

		Small vessel PCI		
	Overall population (*n* = 4,155)	Yes (*n* = 1,607)	No (*n* = 2,548)	*P*-value
Demographics				
Age (years)	64 ± 11	65 ± 11	63 ± 11	**<0.001**
Women	1,855 (45%)	802 (50%)	1,053 (41%)	**<0.001**
Race				
African American	666 (16%)	250 (16%)	416 (16%)	0.51
Caucasian	3,033 (73%)	1,177 (73%)	1,856 (73%)	0.77
Asian	28 (0.7%)	9 (0.6%)	19 (0.7%)	0.47
Hispanic or Latino	353 (8.5%)	152 (9.5%)	201 (7.9%)	0.08
American Indian or Alaska native	37 (0.9%)	12 (0.7%)	25 (1.0%)	0.43
Native Hawaiian or other Pacific islander	11 (0.3%)	3 (0.2%)	8 (0.3%)	0.44
Race, ethnicity not disclosed	36 (0.9%)	11 (0.7%)	25 (1.0%)	0.32
Other race	33 (0.8%)	9 (0.6%)	24 (0.9%)	0.18
Minority	1,051 (25%)	412 (26%)	639 (25%)	0.68
Minority women	425 (10%)	179 (11%)	246 (9.7%)	0.12
Minority male	626 (15%)	233 (15%)	393 (15%)	0.42
History and risk factors				
Family history of CAD	2,450 (59%)	951 (59%)	1,499 (59%)	0.82
History of MI	1,845 (44%)	743 (46%)	1,102 (43%)	0.06
History of PCI	1,757 (42%)	779 (49%)	978 (38%)	**<0.001**
History of CABG	658 (16%)	279 (17%)	379 (15%)	**0.03**
History of atrial fibrillation	365 (8.8%)	156 (9.7%)	209 (8.2%)	0.10
History of CHF	489 (12%)	207 (13%)	282 (11%)	0.08
History of CVA	232 (5.6%)	107 (6.7%)	125 (4.9%)	**0.02**
History of TIA	193 (4.6%)	88 (5.5%)	105 (4.1%)	**0.04**
History of PVD	473 (11%)	207 (13%)	266 (10%)	**0.02**
History of renal disease	528 (13%)	210 (13%)	318 (12%)	0.58
History of multivessel disease	1,684 (40.5%)	768 (47.8%)	916 (35.9%)	**<0.001**
BMI (kg/m^2)	31 ± 6.8	31 ± 6.8	31 ± 6.7	0.50
Diabetes mellitus	1,660 (4%)	691 (43%)	696 (38%)	**0.006**
History of hyperlipidemia requiring medication	3,105 (75%)	1,265 (79%)	1,840 (72%)	**<0.001**
History of hypertension requiring medication	3,328 (80%)	1,335 (83%)	1,993 (78%)	**<0.001**
Current smoker	937 (23%)	313 (20%)	624 (24%)	**<0.001**
Clinical presentation				
NYHA classification III/IV	123 (3.0%)	61 (3.8%)	62 (2.4%)	**0.01**
Unstable angina	1,744 (42%)	629 (39%)	1,115 (44%)	**0.003**
Urgent/emergent intervention	1,628 (39%)	575 (36%)	1,053 (41%)	**<0.001**
MI within 72 h prior of index procedure	1,306 (31%)	459 (29%)	847 (33%)	**0.002**

Abbreviations: BMI, body mass index; CABG, coronary artery bypass graft; CAD, coronary artery disease; CHF, congestive heart failure; CVA, cerebral vascular accident; MI, myocardial infarction; NYHA, New York Heart Association classification; PCI, percutaneous coronary intervention; PVD, peripheral vascular disease; TIA, transient ischemic attack.
Bold value are for significant *p*-value.

TABLE 2 Baseline procedural characteristics

	Overall population (*n* = 4,155)	Small vessel PCI		*P*-value
		Yes (*n* = 1,607)	No (*n* = 2,548)	
Lesion description				
De novo lesions	3,801 (92%)	1,499 (93%)	2,302 (90%)	**0.001**
Tortuosity	678 (16%)	291 (18%)	387 (15%)	**0.013**
Moderate or severe coronary calcification	812 (20%)	331 (21%)	481 (19%)	0.17
Bifurcated lesion	323 (7.8%)	133 (8.3%)	190 (7.5%)	0.34
Ostial lesion	264 (6.4%)	107 (6.7%)	157 (6.2%)	0.53
Chronic Total occlusion	83 (2.0%)	51 (3.7%)	32 (1.3%)	**<0.001**
Thrombus	566 (14%)	148 (9.2%)	418 (16%)	**<0.001**
Maximal percent diameter stenosis (%)	89 ± 9.8	90 ± 9.0	88 ± 10	**<0.001**
Minimal reference vessel diameter (mm)	2.8 [2.5–3.0]	2.5 [2.3–2.5]	3.0 [3.0–3.5]	**<0.001**
Total lesion length (mm)	24 ± 17	27 ± 19	22 ± 15	**<0.001**
Number of target lesions treated:				**<0.001**
1	3,110 (75%)	971 (60%)	2,139 (84%)	
2	839 (20%)	483 (30%)	356 (14%)	
≥3	206 (5.0%)	153 (9.5%)	53 (2.1%)	
Lesion localization (*n* = 5,582)				**<0.001**
LMCA	89 (1.6%)	29 (1.1%)	60 (2.0%)	
LAD	2,108 (38%)	972 (39%)	1,136 (37%)	
LCx	1,318 (24%)	739 (29%)	579 (19%)	
RCA	1,827 (33%)	707 (28%)	1,120 (37%)	
Graft	239 (4.3%)	75 (3.0%)	164 (5.4%)	
Preprocedural TIMI flow (*n* = 5,582)				0.15
0	543 (9.7%)	233 (9.2%)	310 (10%)	
1	258 (4.6%)	135 (5.4%)	123 (4.0%)	
2	715 (13%)	325 (13%)	390 (13%)	
3	3,794 (68%)	1,710 (68%)	2,084 (68%)	
Unknown	272 (4.9%)	119 (4.7%)	153 (5.0%)	
Predilatation performed	2,934 (71%)	1,219 (76%)	1,715 (67%)	**<0.001**
Postdilatation performed	2,452 (59%)	911 (57%)	1,541 (61%)	**0.02**
Prestent IVUS performed	250 (6.0%)	71 (4.4%)	179 (7.0%)	**<0.001**
Poststent IVUS performed	216 (5.2%)	59 (3.7%)	157 (6.2%)	**<0.001**
Total number of study stents implanted:				**<0.001**
1	2,659 (64%)	806 (50%)	1,853 (73%)	
2	1,045 (25%)	504 (31%)	541 (21%)	
≥3	451 (11%)	297 (18%)	154 (6.1%)	
Total stent length (mm)	30 ± 21	35 ± 24	28 ± 18	**<0.001**
Discharge medication (PLATINUM diversity registry only)				
Aspirin	1,449 (97%)	588 (97%)	861 (96%)	0.35
P2Y12 inhibitors	1,465 (98%)	589 (97%)	976 (98%)	0.43
Statin	1,272 (85%)	515 (85%)	757 (85%)	0.81
RAAS	610 (41%)	247 (41%)	363 (41%)	0.93
Beta blocker	1,128 (75%)	454 (75%)	674 (75%)	0.88
Proton pump inhibitor	407 (27%)	171 (28%)	236 (26%)	0.42
Oral anticoagulant	83 (5.5%)	33 (5.5%)	50 (5.6%)	0.91

Abbreviations: IVUS, intravascular ultrasound; LAD, left anterior descending coronary artery; LCx, left circumflex; LMCA, left main coronary artery; RAAS, renin angiotensin aldosterone system inhibitor; RCA, right coronary artery.
Bold value are for significant *p*-value.

were included in the analysis. Of these, 1,607 (39%) presented with ≥1 lesion with RVD ≤ 2.5 mm. Patients undergoing SV-PCI were older, more likely to be women and presented with a greater burden of cardiovascular risk factors, including diabetes mellitus, systemic hypertension, peripheral vascular disease, and prior PCI (Table 1). Procedural characteristics are detailed in Table 2. Patients with small vessel

TABLE 3 One-year outcomes after PCI in small versus larger coronary arteries

	Overall population (*n* = 4,155)	Small vessel PCI		*P*-value
		Yes (*n* = 1,607–38.7%)	No (*n* = 2,548–61.3%)	
Major adverse cardiac events	328 (8.3%)	138 (9.0%)	190 (8.0%)	0.21
Target vessel failure	256 (6.6%)	109 (7.1%)	147 (6.2%)	0.20
All-cause death	120 (3.0%)	49 (3.2%)	71 (3.0%)	0.64
Myocardial infarction	187 (4.6%)	82 (5.2%)	105 (4.2%)	0.14
Definite or probable stent thrombosis (ARC)	36 (0.88%)	16 (1.0%)	20 (0.80%)	0.48
Target vessel revascularization	200 (5.2%)	87 (5.7%)	113 (4.9%)	0.16

Results are given as number (Kaplan–Meier estimate); Abbreviations: ARC, Academic research consortium; PCI, percutaneous coronary intervention.
Bold value are for significant *p*-value.

CAD also presented with more lesions and received a higher number of stents compared to patients with non-SV-PCI.

3.2 | Outcomes after small vessel and non-small vessel PCI

One-year outcomes according to vessel size are detailed in Table 3 and Supporting Information Figures S1 and S2. There were no significant differences in the cumulative incidences of 1-year MACE, TLF, the individual components of these composite endpoints, as well as ST between patients undergoing SV-PCI versus non-SV-PCI. The risks remained comparable after adjusting for imbalances in baseline and procedural characteristics (Figure 1). Of note, results remained qualitatively similar when SV-PCI was defined as ≥1 target lesion with a RVD <3.0 mm (Supporting Information Table S1).

3.3 | Outcomes after small vessel and non-small vessel PCI according to sex and ethnicity

One-year outcomes according to vessel size, sex, and ethnicity are detailed in **Tables** 4 and 5. There were no differences in the adjusted 1-year risk of MACE and TLF between white men, women, and minorities undergoing SV-PCI (Figure 2). However, the adjusted risk of MI was lower in white men compared to women and minorities (adjHR 0.39; 95% CI 0.20–0.75 and adjHR 0.41; 95% CI 0.23–0.74, respectively) and the adjusted risk of ST was lower in white men compared to minorities (adjHR 0.23; 95%CI 0.06–0.91). A similar trend was noted for patients undergoing non-SV-PCI, whereby white men had a lower adjusted risk of MI compared to minorities and women (Figure 3). However, there was no significant interaction between RVD and sex or race/ethnicity regarding any of these outcomes.

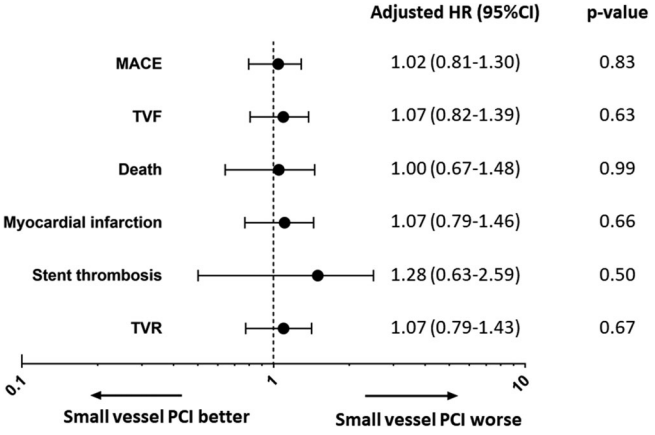

FIGURE 1 Risk adjusted 1-year outcomes after PCI in small versus larger coronary arteries. CI = confidence interval; HR = hazard ratio; MACE = major adverse cardiac event; PCI = percutaneous coronary intervention; TVF = target vessel failure; TVR = target vessel revascularization

4 | DISCUSSION

Given that minority and white women have a higher likelihood of undergoing SV-PCI,[12–14] it is crucial that SV-PCI outcomes studies include a heterogeneous and diverse cross-section of patients. By examining the PD/PE Plus pooled database,[15] our study took advantage of the only large, multicenter, diverse, prospectively collected and independently CEC adjudicated PCI patient outcomes database available in the U.S., thereby helping to provide a true "real world" reflection of SV-PCI outcomes in the setting of second generation PtCr-EES. Contrary to several prior studies from BMS and first-generation DES, we report that SV-PCI with a PtCr-EES was associated with no difference in 1-year outcomes compared to larger vessel PCI. SV-PCI was associated with older age, female sex and multiple cardiovascular risk factors, but not with any particular race or ethnicity. Although white men undergoing SV-PCI had a lower adjusted risk of MI compared to women and minorities and a lower risk of ST compared to minorities, overall MACE rates were similar across sex and race/ethnicity.

Various definitions of small vessel CAD have been previously published. In the era of bare metal stents (BMS) and first-generation DES, a RVD ≤3 mm has often been used as cut-off.[7,19,20] However, in more recent years, as smaller stent diameters have become available, lower thresholds for RVD (e.g., <2.75 mm or ≤2.5 mm), have more frequently been used to define small vessel PCI.[4,21–23] Consequently, for this study we used RVD ≤2.5 mm to define SV-PCI.[9,24,25] Similar to prior reports, we observed that patients undergoing SV-PCI were more likely to be older, female and present with a greater burden of cardiovascular risk factors, particularly diabetes mellitus and hypertension.[2,4,26] It is, therefore, not surprising that SV-PCI patients in our study also presented with more coronary lesions and greater vessel tortuosity.

PCI in small vessels has previously been associated with restenosis and repeat revascularization.[6] Small coronary arteries have less capacity to accommodate neointimal hyperplasia after PCI, resulting in a higher

TABLE 4 One-year outcomes after small vessel PCI according to sex and race/ethnicity

	White men (*n* = 557)	Minorities (*n* = 412)	Women (*n* = 802)	White men vs. minorities *P*-value	White men vs. women *P*-value
Major adverse cardiac events	44 (8.1%)	42 (11%)	69 (9.1%)	0.23	0.66
Target vessel failure	37 (6.8%)	34 (8.7%)	51 (6.9%)	0.36	0.82
All-cause death	15 (2.8%)	15 (3.7%)	24 (3.2%)	0.40	0.75
Myocardial infarction	15 (2.8%)	28 (6.9%)	52 (6.6%)	**0.002**	**0.0014**
Definite or probable stent thrombosis (ARC)	3 (0.55%)	7 (1.7%)	8 (1.0%)	0.077	0.35
Target vessel revascularization	31 (5.8%)	27 (7.0%)	41 (5.5%)	0.53	0.71

Results are given as number (Kaplan–Meier estimate); Abbreviation: ARC, Academic research consortium.
Bold value are for significant *p*-value.

TABLE 5 One-year outcomes after non-small vessel PCI according to sex and race/ethnicity

	White men (*n* = 1,056)	Minorities (*n* = 639)	Women (*n* = 1,053)	White men vs. minorities *P*-value	White men vs. women *P*-value
Major adverse cardiac events	74 (7.8%)	57 (9.2%)	86 (8.6%)	0.19	0.37
Target vessel failure	64 (6.9%)	40 (6.4%)	59 (5.9%)	0.95	0.59
All-cause death	20 (2.0%)	23 (4.0%)	38 (3.9%)	**0.039**	**0.02**
Myocardial infarction	28 (2.7%)	46 (7.3%)	49 (4.8%)	**<0.001**	**0.015**
Definite or probable stent thrombosis (ARC)	8 (0.78%)	5 (0.80%)	8 (0.77%)	0.96	0.99
Target vessel revascularization	53 (5.8%)	29 (4.7%)	43 (4.3%)	0.60	0.27

Results are given as number (Kaplan–Meier estimate); Abbreviation: ARC, Academic research consortium.
Bold value are for significant *p*-value.

relative reduction of lumen diameter for a given amount of neointimal thickening compared to larger vessels.[7] However, the majority of studies evaluating outcomes after SV-PCI were performed in the setting of drug coated balloons, BMS or first generation DES, with only limited data on the performance of second generation DES.[7] Therefore, by demonstrating uniformity of outcomes across both small and larger vessel sizes, our study supports the notion that current second generation DES, like PtCr-EES, may be more efficacious and safe in treating small vessels than prior stent designs. Our findings are consistent with Tama et al., who also found no difference in early or late restenosis after PCI with cobalt-chromium EES (XIENCE V™ [Abbot vascular, Abbott Park, IL]).[26] Caputo et al., also reported the Zotarolimus-eluting stent (RESOLUTE™ [Medtronic Inc, Santa Rosa, CA]) to be efficacious in SV-PCI (defined as RVD ≤2.5 mm), with no difference in TLR in the first 2-years post PCI.[4] The reduced strut thickness and width of second-generation stents, high radial strength, effective drug delivery, and more biocompatible polymers may account for these more favorable and durable outcomes.[27] Nevertheless, such results have not been entirely consistent. For example, Van der Heijden et al., within the TWENTE II trial (comparing the RESOLUTE Integrity zotarolimus-eluting cobalt chromium stent to the PROMUS Element stent), found small vessel diameter (RVD <2.5 mm) to be independently associated with TLF at 2 year follow-up.[2]

Enrolling a more diverse cohort of patients compared to prior PCI studies afforded us the unique opportunity to examine relationships between sex, race/ethnicity, vessel size, and clinical outcomes. First, we found that women were more likely to have SV-PCI. However, SV-PCI was not associated with race or ethnicity. Furthermore, we found no differences in the 1-year risk of MACE and TLF between

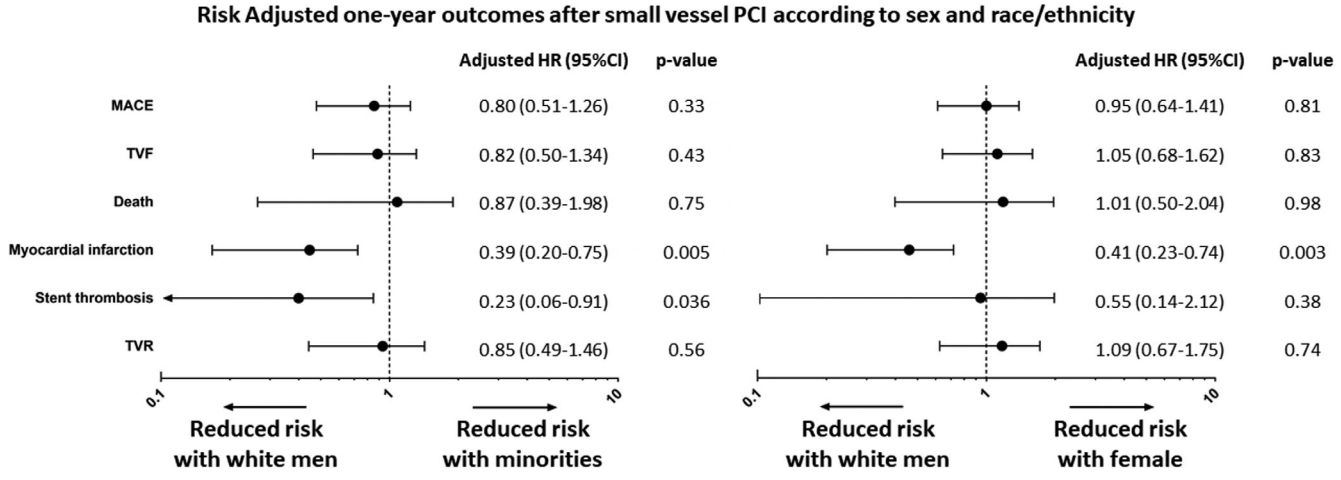

FIGURE 2 Risk adjusted 1-year outcomes after small vessel PCI according to sex and race/ethnicity. Abbreviations are the same as Figure 1

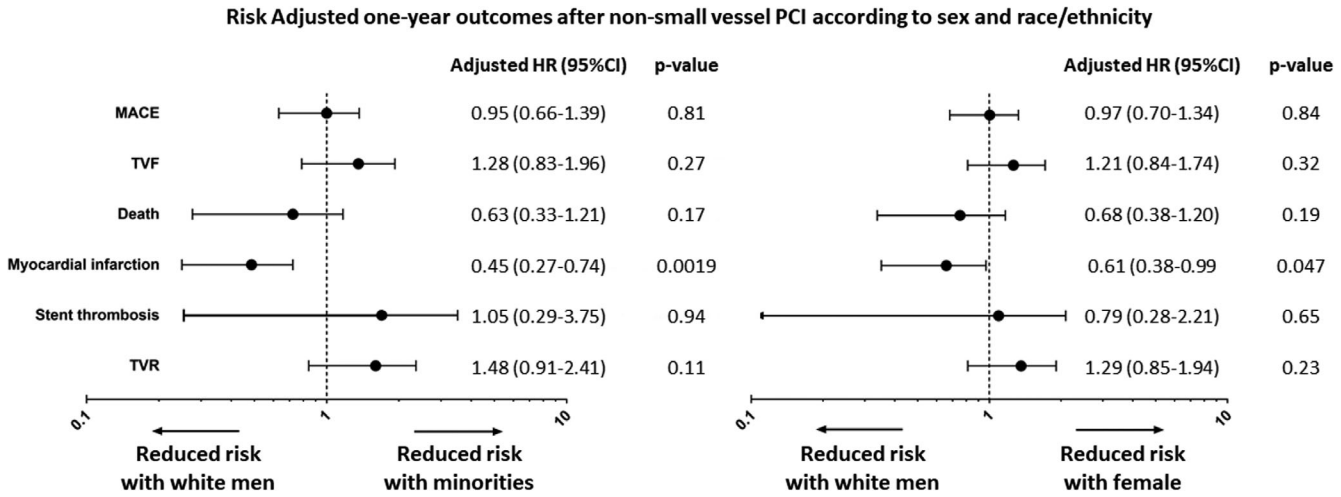

FIGURE 3 Risk adjusted 1-year outcomes after non-small vessel PCI according to sex and race/ethnicity. Abbreviations are the same as Figure 1

white men and women or minorities undergoing both small-vessel and non-SV-PCI. However, for SV-PCI, the adjusted risk of MI was lower in white men compared to women and minorities and the risk of ST lower in white men compared to minorities; differences that prevailed despite comparable patient-reported adherence to dual antiplatelet therapy. The lack of interaction between RVD and sex or race/ethnicity for all outcomes studied suggests that it was not small vessel size, but other factors that accounted for the between group differences in ischemic endpoints. These findings are consistent with those reported from the overall PD/PE Plus pooled analysis and several other prior studies.[15,28–30] We suspect that other factors such as social determinants of health, healthcare insurance, thrombogenicity, and/or other unmeasured factors play a greater role.[31]

4.1 | Limitations

First, this is a retrospective analysis of two prospective registries. Therefore, despite the use of multivariate risk adjustment, the results may have been impacted by unmeasured confounders. Second, angiographic variables, including RVD were assessed solely by site investigators, *with low rates of intravascular ultrasound use* and were not adjudicated by an independent core laboratory. However, this is representative of real-life conditions and considering the large number of sites (n = 52) and patients enrolled, we believe that the risk of a systematic bias based on sex or race/ethnicity is unlikely. Small vessel PCI was defined by the presence of at least one target lesion with RVD ≤2.5 mm, thus patients who underwent concomitant PCI of larger vessel were also included in this group which may have impacted the result. Finally, adherence to antiplatelet therapy was patient-reported and therefore also potentially prone to unrecognized bias.

5 | CONCLUSIONS

In a uniquely diverse sample of men, women, and minorities undergoing PCI with PtCr-EES, small vessel size was associated with older age, female sex, and a greater burden of cardiovascular risk factors. However, SV-PCI did not confer an increased risk of adverse 1-year outcomes. Although white men undergoing SV-PCI experienced a lower risk of MI than women and minorities and a lower risk of ST than minorities, overall MACE rates were similar across all groups and this phenomenon was independent of vessel size.

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DISCLOSURES

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CONFLICT OF INTEREST

All other authors have no conflict of interest relative to this publication to report.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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