Final 5-Year Results in Unselected Patients Implanted With a Thin-Strut, Platinum-Chromium, Everolimus-Eluting Stent (from the PROMUS Element Plus US Post-Approval Study)

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PROMUS Element (PE) Plus post-approval study was a large prospective, observational, all-comers study designed to evaluate the safety and performance of a thin-strut platinum chromium everolimus-eluting PE Plus stent in everyday clinical practice. A total of 2,683 "real-world" patients with limited clinical or anatomic exclusion criteria were enrolled at 52 clinical sites in the United States. The study met its primary end point of 12-month cardiac death or myocardial infarction (CD/MI) compared with a prespecified performance goal ($p < 0.0001$). Five-year clinical outcomes were evaluated in overall PE Plus post-approval study patients and high-risk subgroups. During the 5-year follow-up period, CD/MI and stent thrombosis related to the PE Plus stent occurred in 9% and 2.2% overall patients, respectively. The reported all-cause mortality rate was 15%, with 7% classified as cardiac-related. A total of 18% patients underwent target vessel revascularization, and 11% were reported as target lesion revascularization. The rates of PE Plus stent-related CD/MI remained low in patients with medically treated diabetes (13%), small vessels (9%), and long stents (10%). PE Plus stent-related thrombosis through 5 years in patients with diabetes, small vessels and long stents was 4.2%, 2.2%, and 2.6%, respectively. The occurrence of target lesion revascularization was numerically higher in patients with diabetes (16%) and long lesions (18%) than the small vessels subgroup (11%). In conclusion, the final 5-year results establish the long-term safety and efficacy of the PE Plus stent in a broad, unselected patient population representative of "real-world" clinical practice. **(Am J Cardiol 2019;123:1765−1771)**

Everolimus-eluting stents (EES) have become a standard of comparison for drug-eluting stents (DES), as evidenced in both direct and indirect (network) comparative analyses demonstrating superior outcomes with EES compared with both bare metal and alternative DES.[1−3] The PROMUS Element Plus US Post-Approval Surveillance Study (PE Plus PAS) was a prospective, open-label, observational study[4] intended to (1) assess safety and efficacy in a broad, unselected patient population representative of everyday clinical practice, and (2) compare clinical outcomes with a prespecified performance goal after percutaneous coronary intervention (PCI) with the thin-strut, durable polymer PROMUS Element platinum chromium EES (PtCr-EES; Boston Scientific Corporation, Marlborough, Massachusetts). This study met the primary end point of 1-year cardiac death or myocardial infarction (CD/MI; 1.8%), which was significantly less than the prespecified performance goal (3.2%; based on PLATINUM[5] and SPIRIT IV[6] trial data; $p < 0.0001$).[4] The incidence of stent thrombosis (ST) and target lesion revascularization (TLR) at 1 year was low, and comparable to those reported in previous EES trials with more restrictive enrollment criteria.[5,6] As a post-approval regulatory requirement, the enrolled patients were followed through 5 years. This final report characterizes late patient-oriented and stent-related clinical outcomes among patients treated with PtCr-EES in everyday clinical practice.

Methods

The PE Plus PAS was a prospective, multicenter, observational, all-comers study designed to collect safety and clinical outcomes data in PE Plus stent implanted patients (Clinicaltrials.gov NCT01589978). The study design, methods, and primary end-point results of the PE Plus PAS have been previously described in detail.[4] Patients receiving 1 or more PtCr-EES as a part of routine PCI for any indication or lesion complexity were eligible for enrollment. Patients were considered enrolled only if they had signed an

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informed consent form and there had been an attempt to implant at least 1 commercial PtCr-EES. This study was approved by Institutional Review Board at each site before enrollment and complied with the principles of the Declaration of Helsinki and all applicable local and federal regulations. The data for this clinical trial may be made available to other researchers in accordance with the Boston Scientific Corporation Data Sharing Policy (http://www.bostonscientific.com/en-US/data-sharing-requests.html).

Clinical follow-up was performed at 30 days, 180 days, and annually through 5 years after study stent implantation. The primary end-point evaluated at 12 months was the rate of CD/MI in PLATINUM-like patients who received PtCr-EES. PLATINUM-like patients were defined as patients without in-stent restenosis, acute MI, chronic total occlusion, graft stenting, 3-vessel stenting, cardiogenic shock, failed brachytherapy, left main disease, severe tortuosity, ostial or bifurcation lesions, moderate or severe calcification (visual estimate) in the target lesion or target vessel proximal to target lesion, or acute or chronic renal dysfunction (serum creatinine >2 mg/dl or subject on dialysis). Also, lesion length and reference vessel diameter (RVD) met 1 of 2 criteria: (1) lesion length ≤28 mm and RVD ≥2.25 mm and <2.5 mm, or (2) lesion length ≤24 mm and RVD ≥2.5 mm and ≤4.25 mm.

Additional prespecified end-points for the overall PE Plus PAS population included cardiac and non-cardiac death, MI (based on the definition used in the PLATINUM study[5]), target vessel revascularization (TVR) and target vessel failure (composite of MI, death, and TVR), major adverse cardiac events (defined as CD, MI, and TVR) and Academic Research Consortium definite/probable ST.[7] TLR was defined as PtCr-EES-related TVR. An independent clinical event committee reviewed and adjudicated all death, MI, TVR, and target vessel-related definite/probable ST events. Clinical outcomes were evaluated as Kaplan-Meier estimates with standard error using Greenwood's formula. Risk predictors and hazard ratios were evaluated using the Cox proportional hazards regression model. Statistical analyses were conducted using SAS Version 9.0 or later (SAS Institute, Cary, North Carolina).

Results

A total of 2,683 patients were enrolled at 52 US study sites between May 2012 and June 2013. Two of the enrolled patients had PtCr-EES implant failures and were followed through hospital discharge. Baseline clinical, lesion, and procedural characteristics have been reported previously.[4] Briefly, 70% of the enrolled patients were men, 33% had diabetes, 53% had previous MI, and 50% presented with unstable angina. Pre-procedure lesion length, RVD, and percent diameter stenosis (%DS) were 17.0 ± 10.3 mm, 2.9 ± 0.5 mm, and 86.7% ± 10.7%, respectively. Clinical procedural success defined as post-procedural %DS <30% in 2 near-orthogonal projections with Thrombolysis in Myocardial Infarction 3 flow (visual assessment), without the occurrence of in-hospital major adverse cardiac events was 99.0%. Technical success defined as successful delivery and deployment of the study stent to the target lesion, without balloon rupture or embolization was 99.9%.

Among the 2,681 patients implanted with the PE Plus stent, 5-year clinical follow-up was completed in 87.8% patients (Figure 1). As previously reported,[4] 1-year cardiac events in overall PE Plus PAS patients were favorably low: CD/MI 2.3% (1.8% PtCr-EES related) and 0.7% ST. Through 5 years, the patient-oriented rate of CD/MI was 10.9%, and including only MI events adjudicated to the PtCr-EES, the CD/MI rate was 8.6% (Figure 2). Additional clinical outcomes at 5 years postprocedure are shown in Figure 2 and Table 1. Target vessel failure was reported in 23% patients, with a 17% rate being related to the PtCr-EES. MI occurred in 5% of overall patients, and MI attributed to PtCr-EES was 3%. Mortality was reported in 15% patients, with 7% being cardiac-related. A total of 18% of

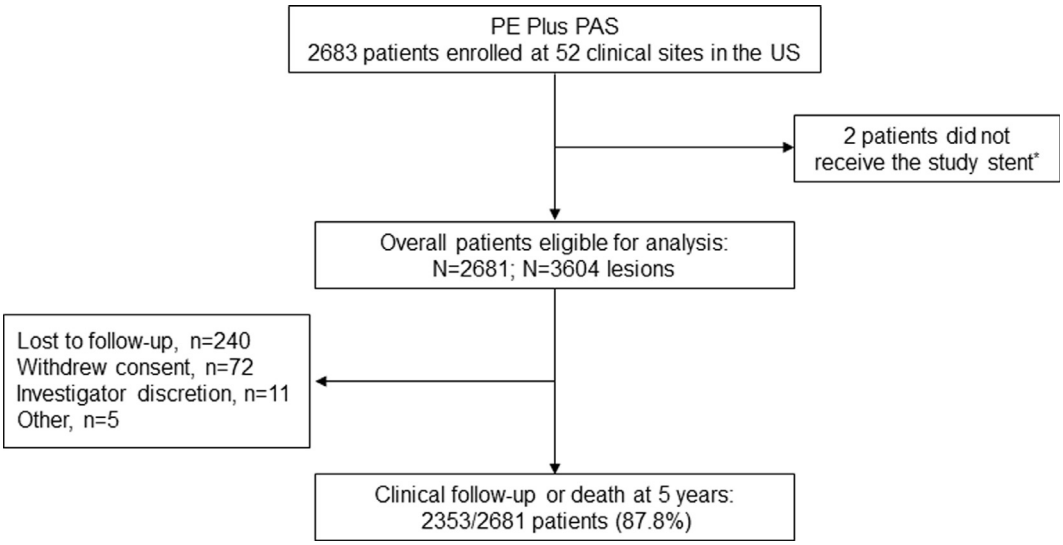

Figure 1. PE Plus PAS enrollment and follow-up. *2 patients not eligible for analysis due to implant failure (stent could not cross lesion). PE = PROMUS Element; PAS = Post-Approval Study.

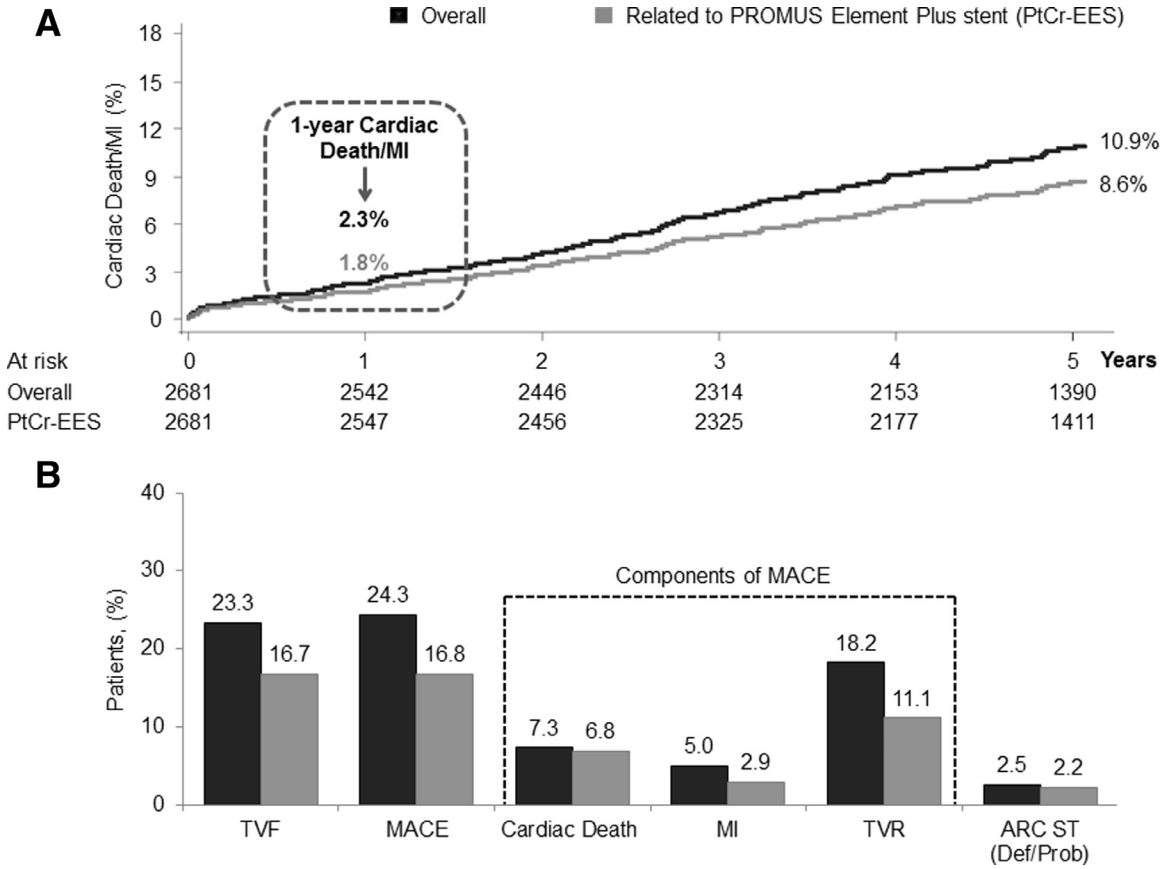

Figure 2. (A) Cumulative Kaplan-Meier curve for cardiac death/myocardial infarction (CD/MI) through 5 years. (B) Cumulative time-to-event rates for additional clinical outcomes at 5 years. ARC ST (def/prob) = Academic Research Consortium definite/probable stent thrombosis; MACE = major adverse cardiac events; MI = myocardial infarction; PE = PROMUS Element; TVF = target vessel failure; TVR = target vessel revascularization.

patients underwent TVR and 11% were reported as being TLR. The 5-year cumulative rate of ARC definite/probable ST was 2.5% (1.6% cases >1 to 5 years were PtCr-EES related). Adherence to dual antiplatelet therapy declined from 94% at discharge to 62% at 2 years, and 49% at 5 years (Figure 3). Clinical outcomes at 5-year follow-up were also evaluated in high-risk patient subgroups, including patients with medically treated diabetes, small vessels (at least 1 target lesion diameter ≥2.25 mm and <2.5 mm) and long stents (at least one 32 mm or 38 mm PtCr-EES; Table 1).

Multivariate predictors of CD, MI, TVR, and ST up to 5 years are shown in Figure 4. The most significant baseline predictors of CD (Figure 4) were congestive heart failure, a history of renal disease, and current smoking status. The predicted risk of CD increased 5% with an increase in age by 1 year. Medically treated diabetes and a history of renal disease were identified as the strongest predictors of MI (Figure 4). The strongest predictor of TVR was previous PCI, followed by the number of lesions treated and medically treated diabetes (Figure 4). Previous PCI and diabetes increased the risk of definite/probable ST (Figure 4).

Discussion

As a final 5-year completion of a post-approval trial, these results extend our understanding of PtCr-EES to a broad, unselected patient population representative of "real-world" clinical practice, demonstrating a low incidence of late-term CD/MI, TLR, and ST. Despite limited enrollment criteria, long-term outcomes are similar to those observed in both previous randomized and observational studies with EES.[8–13] Specifically, cumulative 5-year rates of TLR and ST were 11% and 2.5%, respectively. In addition, favorable event rates were maintained in patients with higher risk lesions or clinical complexity.

After more than a decade of iterative DES development, clinical studies have been challenged to keep pace, shifting focus from angiographic to patient-oriented clinical events and inclusion of broader lesion complexities and clinical indications. With current DES trials reporting favorable efficacy and safety outcomes to date, end-point event rates have migrated even lower over the past decade. To provide a more complete perspective of DES efficacy and safety in real-world clinical practice, a larger sample size representative of greater patient and lesion complexity is necessary. Despite best intent, even trials randomizing "all-comers" without restrictions generally do not enroll all eligible patients and include a lower risk population than patients followed in non-randomized, observational studies.[14] To this purpose, the present trial enrolled a broad, unselected patient population representative of routine clinical practice with limited clinical or anatomic exclusion criteria. Despite greater clinical risk and lesion complexity, the rate of 1-year CD/MI (PE Plus PAS primary end point) and measures

Table 1
Clinical outcomes at 5 years in the PE Plus overall population and high-risk subgroups

Event	PE Plus Overall (n = 2,681)	Small Vessels (n = 356)	Medically Treated Diabetes (n = 885)	Long Stents (n = 343)
MACE	595 (24%)	84 (26%)	250 (31%)	90 (29%)
Related to PE Plus	408 (17%)	52 (16%)	186 (24%)	75 (24%)
Cardiac death or MI	263 (11%)	43 (13%)	119 (15%)	39 (13%)
Related to PE Plus	208 (9%)	28 (9%)	99 (13%)	32 (10%)
Death	341 (15%)	50 (16%)	151 (23%)	50 (17%)
Cardiac death	172 (7%)	24 (7%)	80 (10%)	28 (10%)
Related to PE Plus	159 (7%)	21 (7%)	75 (10%)	27 (10%)
Noncardiac Death	169 (8%)	26 (9%)	71 (14%)	22 (7%)
MI	117 (5%)	23 (8%)	53 (7%)	17 (6%)
Related to PE Plus	68 (3%)	10 (3%)	33 (4%)	10 (3%)
Q-wave MI	31 (1%)	6 (2%)	17 (2%)	5 (2%)
Related to PE Plus	19 (0.8%)	3 (0.9%)	11 (1%)	2 (0.6%)
Non Q-wave MI	90 (4%)	18 (6%)	39 (5%)	13 (5%)
Related to PE Plus	50 (2%)	7 (2%)	23 (3%)	9 (3%)
TVR	435 (18%)	64 (20%)	186 (24%)	66 (22%)
TLR	265 (11%)	37 (11%)	123 (16%)	54 (18%)
TVF	568 (23%)	78 (24%)	244 (31%)	87 (28%)
TLF	407 (17%)	52 (16%)	185 (23%)	75 (24%)
ARC ST (Definite/Probable)	59 (2.5%)	9 (2.9%)	35 (4.5%)	11 (3.6%)
Related to PE Plus	54 (2.2%)	7 (2.2%)	33 (4.2%)	8 (2.6%)
Acute (0-1 days)	2 (0.1%)	0 (0%)	0 (0%)	0 (0%)
Subacute (2-30 days)	8 (0.3%)	1 (0.3%)	5 (0.6%)	2 (0.6%)
Late (31-365 days)	10 (0.4%)	0 (0%)	5 (0.6%)	2 (0.6%)
Very Late (>1-year)	36 (1.6%)	6 (2.0%)	23 (3.1%)	4 (1.4%)

Values are n (%); Time to event analysis.

Relatedness to PE Plus stent was adjudicated and determined by the Clinical Events Committee for each event.

ARC = Academic Research Consortium; MACE = major adverse cardiac events; MI = myocardial infarction; ST = stent thrombosis; TLF = target lesion failure; TLR = target lesion revascularization; TVF = target vessel failure; TVR = target vessel revascularization.

Major adverse cardiac events were defined as cardiac death, MI, or TVR; TVF was defined as TVR, target vessel MI, or death related to the target vessel. All MI and composite events related to MI use PLATINUM MI definition.

of long-term interest, including ST and repeat revascularization at 5 years, are comparable to and externally validate the results from randomized trials comparing contemporary DES.[8–13]

Dedicated longitudinal follow-up in clinical trials also offer greater insight to the effectiveness of DES, and the accrual of events amplifies the ability to describe the long-term performance of a DES. Specifically, the overall TLF

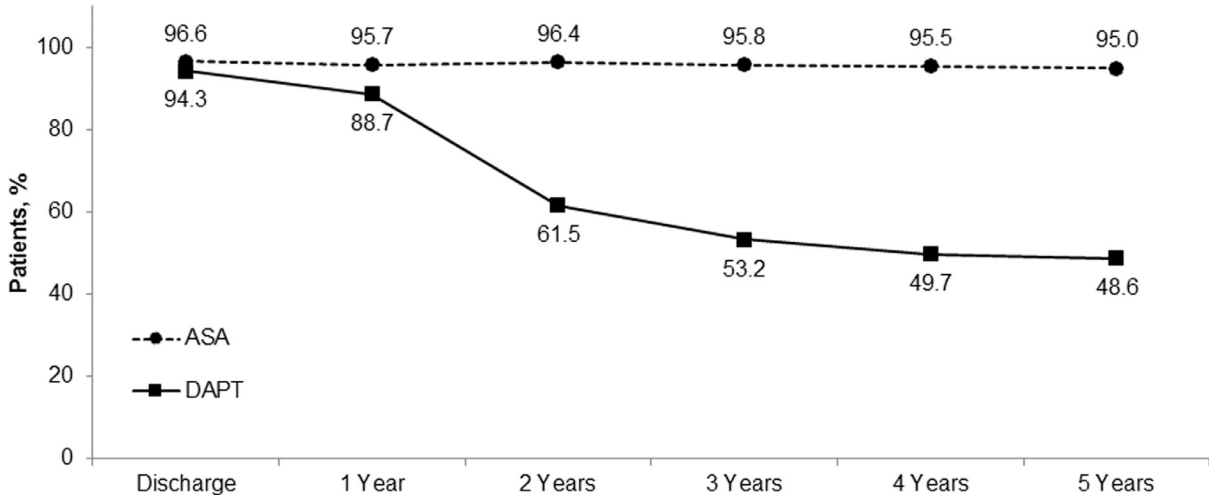

Figure 3. Antiplatelet medications through 5-year follow-up. Acetylsalicylic acid (ASA) and dual antiplatelet therapy (DAPT) use for the PROMUS Element Plus stent at discharge and annually through 5 years post-stent implantation. DAPT consisted of ASA + thienopyridine (Clopidogrel, Prasugrel, Ticagrelor, Ticlopidine).

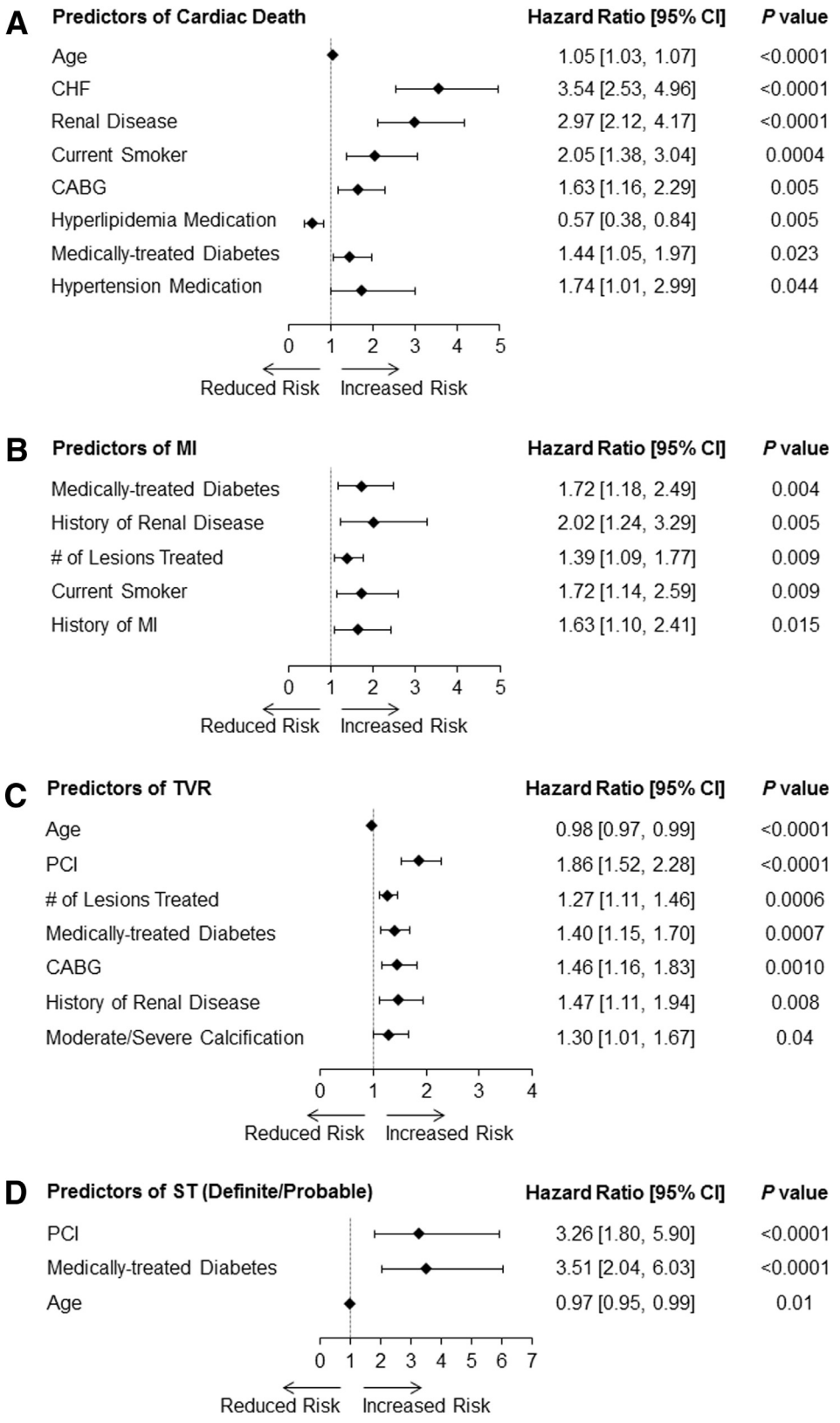

Figure 4. Multivariate predictors of (A) cardiac death, (B) MI, (C) TVR, and (D) ST (definite/probable) at 5 years. CABG = coronary artery bypass grafting; CHF = congestive heart failure; MI = myocardial infarction; PCI = percutaneous coronary intervention; TVR = target vessel revascularization; ST = stent thrombosis.

rate of 17% in the PE Plus PAS compares well with 5-year event rates ranging from 9% to 20% across contemporary comparative DES trials. In the RESOLUTE all-comers[8] and BIOSCIENCE randomized[9] trials, for example, rates of TLF at 5 years in the EES cohorts were 16% and 19%, respectively. Similarly, the observed rate of definite/probable ST in the present study (2.2%) also compares well with rates that range from 1.3% to 3.1% with EES in previous trials over a similar follow-up period.[8,10–13]

Beyond consideration of stent-specific outcomes alone, an additional advantage of long-term follow-up is to identify high-risk patient subgroups and observe trends in clinical outcomes among these selected patient populations. For example, cumulative 5-year rates of CD/MI remain higher in patients with small vessel disease, long lesions or diabetes than the overall population. Furthermore, the occurrence of TLR and ST is considerably higher among patients with diabetes and long lesions compared with the overall study population. Especially among those with diabetes, these findings are consistent with other contemporary studies demonstrating a persistent higher risk of adverse events despite treatment with contemporary DES.[15]

As a limitation of this trial, the study design was open label with no active comparator, as is common for post-market evaluations. Second, the study was not powered for individual clinical end points at 1 year, although similarity of the results to other trials as previously described is reassuring regarding stent-specific long-term events.

Consistent with the rapidity of device evolution, PtCr-EES have been succeeded by commercialization of bioresorbable polymer EES in many geographies, yet the relevance of these findings to current practice remains. First, among relatively limited reports of long-term outcomes with contemporary DES, the results affirm observations from recent randomized trials supporting the achievement of best outcomes to date with PCI. Second, the report extends the generalizability of these results, reflecting a broad representation of patients with considerable variance in clinical and lesion complexity, many of whom would be systematically excluded from participation in more traditional clinical trials. Finally, among selected patients with high clinical risk or lesion complexity, adverse events remain high, confirming expectations regarding outcomes in the context of clinical practice.

Disclosures

Dr. Kandzari received grant support and consulting fees from Boston Scientific Corporation, Medtronic and Biotronik. Drs. Underwood, Allocco, and Meredith are full-time employees with equity interest in Boston Scientific Corporation. All other authors have no conflicts of interest to declare.

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