EXPEDITED REVIEW

The Unrestricted Use of Paclitaxel-Versus Sirolimus-Eluting Stents for Coronary Artery Disease in an Unselected Population

One-Year Results of the Taxus-Stent Evaluated At Rotterdam Cardiology Hospital (T-SEARCH) Registry

Andrew T. L. Ong, MBBS, FRACP, Patrick W. Serruys, MD, PhD, FACC, Jiro Aoki, MD, Angela Hoye, MBChB, MRCP, Carlos A. G. van Mieghem, MD, Gaston A. Rodriguez-Granillo, MD, Marco Valgimigli, MD, Karel Sonnenschein, Evelyn Regar, MD, PhD, Martin van der Ent, MD, PhD, Peter P. de Jaegere, MD, PhD, Eugene P. McFadden, MBChB, MD, FRCPI, FACC, Georgios Sianos, MD, PhD, Willem J. van der Giessen, MD, PhD, Pim J. de Feyter, MD, PhD, FACC, Ron T. van Domburg, PhD

Rotterdam, the Netherlands

OBJECTIVES
We investigated the efficacy of paclitaxel-eluting stents (PES) compared to sirolimus-eluting stents (SES) when used without restriction in unselected patients.

BACKGROUND
Both SES and PES have been separately shown to be efficacious when compared to bare stents. In unselected patients, no direct comparison between the two devices has been performed.

METHODS
Paclitaxel-eluting stents have been used as the stent of choice for all percutaneous coronary interventions in the prospective Taxus-Stent Evaluated At Rotterdam Cardiology Hospital (T-SEARCH) registry. A total of 576 consecutive patients with de novo coronary artery disease exclusively treated with PES were compared with 508 patients treated with SES from the Rapamycin-Eluting Stent Evaluated At Rotterdam Cardiology Hospital (RESEARCH) registry.

RESULTS
The PES patients were more frequently male, more frequently treated for acute myocardial infarction, had longer total stent lengths, and more frequently received glycoprotein IIb/IIIa inhibitors. At one year, the raw cumulative incidence of major adverse cardiac events was 13.9% in the PES group and 10.5% in the SES group (unadjusted hazard ratio [HR] 1.33, 95% confidence interval [CI] 0.95 to 1.88, p = 0.1). Correction for differences in the two groups resulted in an adjusted HR of 1.16 (95% CI 0.81 to 1.64, p = 0.4, using significant univariate variables) and an adjusted HR of 1.20 (95% CI 0.85 to 1.70, p = 0.3, using independent predictors). The one-year cumulative incidence of clinically driven target vessel revascularization was 5.4% versus 3.7%, respectively (HR 1.38, 95% CI 0.79 to 2.43, p = 0.3).

CONCLUSIONS
The universal use of PES in an unrestricted setting is safe and is associated with a similar adjusted outcome compared to SES. The inferior trend in crude outcome seen in PES was due to its higher-risk population. A larger, randomized study enrolling an unselected population may assist in determining the relative superiority of either device. (J Am Coll Cardiol 2005;45:1135–41) © 2005 by the American College of Cardiology Foundation
Abbreviations and Acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMS</td>
<td>bare-metal stent</td>
</tr>
<tr>
<td>CI</td>
<td>confidence interval</td>
</tr>
<tr>
<td>CK-MB</td>
<td>creatine kinase-MB</td>
</tr>
<tr>
<td>DES</td>
<td>drug-eluting stent</td>
</tr>
<tr>
<td>HR</td>
<td>hazard ratio</td>
</tr>
<tr>
<td>MACE</td>
<td>major adverse cardiac event</td>
</tr>
<tr>
<td>MI</td>
<td>myocardial infarction</td>
</tr>
<tr>
<td>PES</td>
<td>paclitaxel-eluting stent</td>
</tr>
<tr>
<td>RESEARCH</td>
<td>Rapamycin-Eluting Stent Evaluated At Rotterdam Cardiology Hospital</td>
</tr>
<tr>
<td>SES</td>
<td>sirolimus-eluting stent</td>
</tr>
<tr>
<td>TIMI</td>
<td>Thrombolysis In Myocardial Infarction</td>
</tr>
<tr>
<td>T-SEARCH</td>
<td>Taxus-Stent Evaluated At Rotterdam Cardiology Hospital</td>
</tr>
<tr>
<td>TVR</td>
<td>target vessel revascularization</td>
</tr>
</tbody>
</table>

on the results of randomized controlled trials (4,5). The beneficial effect of PES in patients treated in daily practice remains to be defined. The aim of this study was to report the one-year outcomes of unrestricted/universal use of PES in patients with de novo coronary artery lesions and to compare its efficacy against our historical SES cohort (3).

METHODS

Study design and patient population. The Taxus-Stent Evaluated At Rotterdam Cardiology Hospital (T-SEARCH) registry is a prospective single-center registry with the main purpose of evaluating the safety and efficacy of PES implantation for consecutive unselected patients treated in daily practice. Its conceptual design and methodology are similar to that of the RESEARCH registry (6) and follows the dynamic registry design described by Rothman and Greenland (7).

Since February 16, 2003, when PES was granted Conformité Européenne approval, it replaced SES as the default stent for every percutaneous coronary intervention. Up until September 30, 2003, a total of 576 patients with de novo lesions were treated exclusively with PES and are included in the present report (PES group). This comprised 83.7% of all patients with de novo disease who received coronary stents. In this period, only 12 patients received BMS exclusively (11 were due to requirement for stents >3.5mm, 1 patient had elevated liver enzymes that precluded long-term clopidogrel therapy). Patients treated with PES and BMS in the same procedure (20 patients), those treated with PES and SES (20 patients), those treated with SES only (15 patients), and patients enrolled in other drug-eluting trials (44 patients) were not included in the present report. The PES are available in diameters of 2.25 mm, 2.5 mm, 3.0 mm, and 3.5 mm and in lengths of 8 to 32 mm in 4-mm increments for each available diameter.

This PES group was compared with a control group that comprised the active arm of the RESEARCH registry, that is the 508 patients with de novo disease treated solely with SES (SES group). Thus, the report consists of 1,084 patients treated with DES, differentiated by the type of drug coating on the stent, either sirolimus or paclitaxel.

Procedures and postintervention medications. Interventions were performed according to current standard procedures, with the final interventional strategy (including direct stenting, postdilation, periprocedural glycoprotein IIb/IIIa inhibitor, and use of intravascular ultrasound) left entirely up to the operator’s discretion (6). Angiographic success was defined as residual stenosis ≤30% by visual analysis in the presence of Thrombolysis In Myocardial Infarction (TIMI) flow grade 3. Patients were advised to maintain lifelong aspirin (at least 80 mg/day) and were pretreated with 300 mg clopidogrel. Postprocedural clopidogrel treatment differed between the two groups. Patients treated with PES were prescribed at least six months of clopidogrel (75 mg/day), based on existing data from randomized, controlled trials (5). For patients treated with SES, clopidogrel was prescribed for at least three months, unless one of the following was present (in which case clopidogrel was maintained for at least six months): multiple SES implantation (≥3 stents), total stent length ≥36 mm, chronic total occlusion, and bifurcations.

End point definitions and clinical follow-up. The primary outcome was the occurrence of MACE, defined as a composite of: 1) all cause death, 2) nonfatal myocardial infarction (MI), or 3) TVR. Myocardial infarction was diagnosed by a rise in the creatine kinase-MB fraction (CK-MB) of more than three times the upper limit of normal according to American Heart Association/American College of Cardiology guidelines (8). In patients who underwent coronary artery bypass surgery during the follow-up period, a periprocedural MI was diagnosed by a rise in the CK-MB level of five times the upper limit of normal (9). For patients who presented with an acute MI, a diagnosis of re-MI in the acute phase required a fall and rise of CK-MB of 50% above the previous level (10). Target lesion revascularization was defined as a repeat intervention (surgical or percutaneous) to treat a luminal stenosis within the stent or in the 5-mm distal or proximal segments adjacent to the stent. Target vessel revascularization was defined as a re-intervention driven by any lesion located in the same epicardial vessel. Thrombotic stent occlusion was defined as angiographically documented complete occlusion (TIMI flow grade 0 or 1) or flow-limiting thrombus (TIMI flow grade 1 or 2) in a previously successfully treated artery. A committee of three cardiologists (A.O., J.A., and E.M.F.) reviewed all MACE.

All patients underwent clinical follow-up. Information about the in-hospital outcomes was obtained from our institutional electronic clinical database and by review of the hospital records for those discharged to referring hospitals (patients were referred from a total of 14 local hospitals). Postdischarge survival status was obtained from the Municipal Civil Registries at 1, 6, and 12 months. All repeat interventions (surgical and percutaneous) and rehospitalizations were prospectively collected during the
follow-up. Questionnaires regarding adverse events, anginal status, and medication use were sent to all living patients at 6 and 12 months. Referring physicians and institutions were contacted for additional information if required.

In both groups, follow-up coronary angiography was clinically driven by symptoms or signs suggestive of myocardial ischemia or mandated by the operator at the end of the index procedure predominantly for complex procedures. In the PES group, three specific subgroups were restudied: left main stem stenting, crush-bifurcation procedures, and patients who were concomitantly in a vulnerable plaque study involving non-treated vessels (in total, 27% [n = 154] of PES patients underwent re-study during follow-up, including 14% [n = 81] that were clinically driven). In the SES group, the following “complex patient” subgroups were re-studied: bifurcation lesions, left main stem stenting, chronic total occlusions, very small vessels, long stent length (36 mm), and acute MI (in total, 40% [n = 204] of SES patients were re-studied, including 8% [n = 40] that were clinically driven). Because of the well-known effect of angiographic re-evaluation in increasing the incidence of repeat revascularization (11), all re-interventions were retrospectively adjudicated and classified as either clinically driven or non-clinically driven. Clinically driven repeat revascularization was defined as any intervention motivated by a significant luminal stenosis (≥50% diameter stenosis) in the presence of anginal symptoms and/or proven myocardial ischemia in the target vessel territory by noninvasive testing.

Statistical analysis. Continuous variables are presented as mean ± standard deviation, and were compared using the Student unpaired t test. Categorical variables are presented as counts and percentages and compared by means of the Fisher exact test. All statistical tests were two-tailed. Patients lost to follow-up were considered at risk until the date of last contact, at which point they were censored. The cumulative incidence of adverse events was estimated according to the Kaplan–Meier method, and Cox proportional hazards models were used to assess differences between the two strategies. Separate Cox regression analyses were performed to identify independent predictors of adverse events, using clinical, angiographic, and procedural variables contained in Tables 1 and 2. The Cox proportional hazards regression models were used to control for differences between groups, and the final results are presented as adjusted hazard ratios (HRs).

RESULTS

Baseline and procedural characteristics. The PES patients were more often male, had more MI as their presenting symptom, more cardiogenic shock, more complex lesions treated, longer total stent lengths, and more frequently received glycoprotein IIb/IIIa inhibitors (Tables 1 and 2). Fewer PES patients had a history of previous bypass surgery, and fewer segments per patient were stented, although the number of vessels treated per patient was identical. Other baseline and procedural characteristics were similar.

Clinical outcome. FIRST 30 DAYS. No significant differences were noted between groups with respect to the incidences of death, death or MI, TVR, or MACE in the first month (Table 3). Mortality in the first 30 days was 2.1% in the PES group and 1.6% in the SES group (p = 0.7). In both groups, most deaths occurred in patients with cardiogenic shock. Angiographically proven stent thrombosis occurred in six patients in the SES group, four of whom were treated for AMI, the other two presented with unstable angina. Two patients with AMI also underwent bifurcation stenting, as did one with unstable angina. In total, three patients with bifurcation stenting experienced stent thrombosis. In the SES group, two patients were diagnosed with stent thrombosis. One patient died as a result of stent thrombosis in the PES group.

ONE YEAR. The MACE components are presented in Figures 1 and 2. At one year, 5.3% of patients in the PES group and 3.4% in the SES group had died (HR 1.69, 95% confidence interval [CI] 0.93 to 3.00, p = 0.08). In total, 8.8% of patients in the PES group versus 7.0% in the SES group had either died or suffered a nonfatal re-MI (HR 1.28, 95% CI 0.84 to 1.95, p = 0.3). The incidence of TVR was similar in the SES and PES groups: 7.3% versus 5.1% (HR 1.31, 95% CI 0.81 to 2.13, p = 0.3). Clinically driven TVR was reduced by a similar magnitude in both groups, specifically 3.7% versus 5.4%, respectively (HR 1.38, 95% CI 0.79 to 2.43, p = 0.3). Post-hoc analysis of clinically driven TVR demonstrates that confidence limits crossed unity, with point estimates close to unity in the subgroups

### Table 1. Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>SES Group (n = 508)</th>
<th>PES Group (n = 576)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male, %</td>
<td>68</td>
<td>74</td>
<td>0.04</td>
</tr>
<tr>
<td>Age, yrs ± SD</td>
<td>61 ± 11</td>
<td>62 ± 11</td>
<td>0.4</td>
</tr>
<tr>
<td>Diabetes, %</td>
<td>18</td>
<td>18</td>
<td>0.8</td>
</tr>
<tr>
<td>Non-insulin-dependent, %</td>
<td>12</td>
<td>13</td>
<td>0.5</td>
</tr>
<tr>
<td>Insulin-dependent, %</td>
<td>6</td>
<td>5</td>
<td>0.7</td>
</tr>
<tr>
<td>Hypertension, %</td>
<td>41</td>
<td>42</td>
<td>0.9</td>
</tr>
<tr>
<td>Hypercholesterolemia, %</td>
<td>56</td>
<td>62</td>
<td>0.03</td>
</tr>
<tr>
<td>Current smoking, %</td>
<td>31</td>
<td>29</td>
<td>0.6</td>
</tr>
<tr>
<td>Previous myocardial infarction, %</td>
<td>30</td>
<td>35</td>
<td>0.13</td>
</tr>
<tr>
<td>Previous angioplasty, %</td>
<td>19</td>
<td>18</td>
<td>0.8</td>
</tr>
<tr>
<td>Previous coronary bypass surgery, %</td>
<td>9</td>
<td>6</td>
<td>0.05</td>
</tr>
<tr>
<td>Single-vessel disease, %</td>
<td>46</td>
<td>44</td>
<td>0.5</td>
</tr>
<tr>
<td>Multivessel disease, %</td>
<td>54</td>
<td>56</td>
<td>0.5</td>
</tr>
<tr>
<td>Clinical presentation</td>
<td></td>
<td></td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Stable angina, %</td>
<td>45</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>Unstable angina, %</td>
<td>37</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td>Acute myocardial infarction, %</td>
<td>18</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>Cardiogenic shock, %</td>
<td>10</td>
<td>13</td>
<td></td>
</tr>
</tbody>
</table>

*Relative to patients with acute myocardial infarction.

PES = paclitaxel-eluting stent; SES = sirolimus-eluting stent.
analyzed (Fig. 3). Regarding the primary end point of MACE (the composite of death, MI, or TVR), Kaplan-Meier estimates were 13.9% in the PES group versus 10.5% in the SES group (unadjusted HR 1.33, 95% CI 0.95 to 1.88, p = 0.10).

There were two cases of late (>6 months to 1 year) stent thrombosis documented angiographically in the PES group. In one, it occurred eight months after the index procedure while the patient was on antiplatelet monotherapy with aspirin. The second occurred 11 months after the index procedure after the patient had temporarily suspended antiplatelet therapy (aspirin) for noncardiac surgery.

Predictors of adverse events. To assess the independent predictors of MACE at one year, two separate multivariate analyses were performed. First, a model was built using all baseline and procedural characteristics shown in Tables 1 and 2. Forward stepwise regression was performed with entry and stay criteria of 0.05 and 0.10, respectively. The following variables were significant: cardiogenic shock, female gender, multivessel disease, diabetes mellitus, left main stenting, bifurcation stenting, and lesion type B2/C (Table 4). A second model built using the same variables with the end point of TVR at one year revealed bifurcation stenting was the only significant independent predictor of TVR.

Adjustment for differences between groups. The Cox regression models were used to adjust the two groups by correcting for multiple potential confounders in the baseline and procedural characteristics. First, a model was built forcing stent type and all independent predictors from Table 4 (see Table 5). All previously significant variables remained significant except for lesion type B2/C. The adjusted HR for use of PES became even less significant, decreasing from 1.33 (95% CI 0.95 to 1.88, p = 0.10) to 1.20 (95% CI 0.85 to 1.70, p = 0.3), after controlling for the increased complexity in the PES group.

A second model was then built forcing stent type and significant univariable predictors (independent predictors plus total stent length and number of stents), and the adjusted outcome of MACE at one year was similar between SES and PES (adjusted HR 1.16, 95% CI 0.81 to 1.64, p = 0.4). Finally, stent type was also not a significant predictor of TVR when adjusted for bifurcation stenting (adjusted HR 1.33, 95% CI 0.82 to 2.15, p = 0.25).

**DISCUSSION**

The major finding of this report is that the unrestricted use of PES in de novo lesions is associated with a nonsignificant difference in outcome compared to SES, both unadjusted and when controlled for significant baseline and procedural characteristics. The trend toward an inferior crude outcome

---

### Table 2. Procedural Characteristics

<table>
<thead>
<tr>
<th></th>
<th>SES Group (n = 508)</th>
<th>PES Group (n = 576)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treated vessel</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left anterior descending, %</td>
<td>59</td>
<td>55</td>
<td>0.3</td>
</tr>
<tr>
<td>Left circumflex, %</td>
<td>32</td>
<td>33</td>
<td>0.6</td>
</tr>
<tr>
<td>Right coronary artery, %</td>
<td>39</td>
<td>38</td>
<td>0.9</td>
</tr>
<tr>
<td>Left main coronary, %</td>
<td>3</td>
<td>4</td>
<td>0.3</td>
</tr>
<tr>
<td>Bypass graft, %</td>
<td>3</td>
<td>3</td>
<td>1.0</td>
</tr>
<tr>
<td>Lesion type*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type A or B1, %</td>
<td>47</td>
<td>32</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Type B2 or C, %</td>
<td>76</td>
<td>87</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Multivessel treatment, %</td>
<td>32</td>
<td>29</td>
<td>0.3</td>
</tr>
<tr>
<td>Glycoprotein IIb/IIIa inhibitor, %</td>
<td>19</td>
<td>28</td>
<td>0.002</td>
</tr>
<tr>
<td>Clopidogrel prescription, months ± SD</td>
<td>4.0 ± 2.0</td>
<td>6 ± 0</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Bifurcation stenting, %</td>
<td>16</td>
<td>16</td>
<td>0.9</td>
</tr>
<tr>
<td>No. of stented segments ± SD</td>
<td>2.0 ± 1.0</td>
<td>1.7 ± 0.9</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>No. of stented vessels ± SD</td>
<td>1.3 ± 0.6</td>
<td>1.3 ± 0.6</td>
<td>0.8</td>
</tr>
<tr>
<td>No. of implanted stents ± SD</td>
<td>2.1 ± 1.4</td>
<td>2.2 ± 1.5</td>
<td>0.09</td>
</tr>
<tr>
<td>Total stented length per patient, mm ± SD</td>
<td>38.7 ± 23.7</td>
<td>42.9 ± 31.2</td>
<td>0.02</td>
</tr>
<tr>
<td>Nominal stent diameter ≥2.5 mm, %</td>
<td>36</td>
<td>35</td>
<td>0.7</td>
</tr>
<tr>
<td>Total stent length ≥33 mm, %</td>
<td>45</td>
<td>48</td>
<td>0.5</td>
</tr>
<tr>
<td>Angiographic success of all lesions, %</td>
<td>97</td>
<td>97</td>
<td>0.9</td>
</tr>
</tbody>
</table>

*Percentage of patients with at least 1 lesion type within the category. Abbreviations as in Table 1.

---

### Table 3. Major Adverse Cardiac Events in the First Month Following Stent Implantation

<table>
<thead>
<tr>
<th></th>
<th>0 to 1 Month</th>
<th>SES Group (n = 508)</th>
<th>PES Group (n = 576)</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death, n (%)</td>
<td></td>
<td>8 (1.6)</td>
<td>12 (2.1)</td>
<td>0.7</td>
</tr>
<tr>
<td>Nonfatal myocardial infarction, n (%)</td>
<td>12 (2.4)</td>
<td>17 (3.0)</td>
<td>0.6</td>
<td></td>
</tr>
<tr>
<td>Target lesion revascularization, n (%)</td>
<td>6 (1.2)</td>
<td>7 (1.2)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Target vessel revascularization, n (%)†</td>
<td>6 (1.2)</td>
<td>13 (2.3)</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Any event, n (%)</td>
<td></td>
<td>23 (4.5)</td>
<td>34 (5.9)</td>
<td>0.3</td>
</tr>
<tr>
<td>Stent thrombosis, n (%)‡</td>
<td></td>
<td>2 (0.4)</td>
<td>6 (1.0)</td>
<td>0.3</td>
</tr>
</tbody>
</table>

*By Fisher exact test. †Includes target lesion revascularization. ‡Angiographically documented stent thrombosis requiring repeat intervention. Abbreviations as in Table 1.
with PES was due to the more complex characteristics of the group.

The two sequential registries were separated by a four-month interval. Several differences in baseline characteristics were noted. More MIs including patients in cardiogenic shock were treated in the T-SEARCH registry because of the implementation of a local pre-hospital protocol that triaged more patients to primary percutaneous coronary intervention. More complex lesions were treated in the T-SEARCH registry, with a shift from type A/B1 to B2/C lesions, with more stents being implanted in the T-SEARCH registry. This in part reflects the increased complexity of cases being performed with time and as operators and referring physicians becoming more aware and familiar with DES.

The primary end point of this trial was overall MACE, and the results for this comparison are presented both unadjusted and following adjustment for significant predictive variables (Table 5). With the commercialization of PES, our institution switched completely from SES to PES, precluding randomization. Therefore, it was intuitive to present the data as such and imperative to statistically correct by using significant predictive variables to account for the increased complexity seen in the PES group. To preserve the prospective, consecutive, and unselected nature of both registries, and the requirement to control for multiple significant variables, the Cox regression model was used. Our results demonstrate that, following adjustment, the HR was closer to unity compared to the crude result, further confirming the increased complexity in the PES group.

The multivariate analysis (Table 4) for independent predictors of MACE is unique as it is an analysis of 1,084 DES patients treated in an unrestricted setting. In a total cohort of DES patients, cardiogenic shock, female gender, multivessel disease, diabetes mellitus, left main stenting,
bifurcation stenting, and treatment of a complex lesion significantly predicted an adverse outcome. From this list, patients who possess these characteristics should undergo more regular clinical surveillance.

The major advantage of DES has been to reduce the need for repeat revascularization (1–3). In our study, the incidence TVR at one year with PES was not significantly different from the results obtained with SES. Furthermore, when the adjusted end point of clinically driven TVR was used (Fig. 2), similar outcomes were reproduced, thus confirming that both drug-eluting systems serve to reduce clinical restenosis in an unselected population.

A nonsignificantly higher incidence of angiographic stent thrombosis in the first 30 days was noted in the PES cohort (1.0% in SES vs. 0.4% in PES, \( p \leq 0.3 \)). However, it is important to emphasize that, owing to the infrequent occurrence of this event, large numbers of patients are required to assess this complication properly. We have shown that in a larger population, the incidence rates in both DES were in the same range: 1.0% (95% CI 0.6% to 1.9%) in PES and 1.0% (95% CI 0.5% to 1.8%) in SES (12).

At the time the T-SEARCH registry was conducted, TAXUS II (5) and the Randomized Comparison of a Sirolimus-Eluting Stent with a Standard Stent for Coronary Revascularization (RAVEL) (13) were the two published trials available with one-year MACE results from the eluting stent arms of 10.9% (slow-release arm) and 5.8%, respectively. Based on those results, the group sample sizes of our study would have been adequately powered to show a difference.

Subsequent to that, the results of larger trials of both devices—TAXUS IV and Sirolimus-Eluting Stent in Coro-

nary Lesions (SIRIUS)—were published and demonstrated a smaller difference (8.4% vs. 7.1%, respectively).

The population of this registry is an all-inclusive unre-

stricted one, a sample that is representative of the popula-

tion seen in a tertiary catheterization laboratory. Therefore, this population is directly comparable to daily practice and the results do not require extrapolation as for randomized trials. The results of this registry complement published randomized trials.

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>HR</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>1.38</td>
<td>(0.79-2.45)</td>
<td>0.3</td>
</tr>
<tr>
<td>Age &gt; 65</td>
<td>0.87</td>
<td>(0.36-2.13)</td>
<td>0.7</td>
</tr>
<tr>
<td>Age ≤ 65</td>
<td>1.84</td>
<td>(0.89-3.82)</td>
<td>0.1</td>
</tr>
<tr>
<td>Male</td>
<td>1.06</td>
<td>(0.52-2.22)</td>
<td>0.8</td>
</tr>
<tr>
<td>Female</td>
<td>2.28</td>
<td>(0.98-5.40)</td>
<td>0.1</td>
</tr>
<tr>
<td>Stable angina</td>
<td>0.80</td>
<td>(0.38-1.71)</td>
<td>0.6</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>3.49</td>
<td>(1.11-10.96)</td>
<td>0.03</td>
</tr>
<tr>
<td>Acute MI</td>
<td>2.0</td>
<td>(0.41-9.61)</td>
<td>0.4</td>
</tr>
<tr>
<td>1 vessel disease</td>
<td>1.38</td>
<td>(0.49-3.87)</td>
<td>0.5</td>
</tr>
<tr>
<td>Multivessel disease</td>
<td>1.38</td>
<td>(0.72-2.69)</td>
<td>0.4</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>0.62</td>
<td>(0.22-1.80)</td>
<td>0.4</td>
</tr>
<tr>
<td>Use of IBB or inhibitor</td>
<td>1.24</td>
<td>(0.51-2.97)</td>
<td>0.8</td>
</tr>
<tr>
<td>1 vessel treatment</td>
<td>1.15</td>
<td>(0.53-2.51)</td>
<td>0.7</td>
</tr>
<tr>
<td>Multivessel treatment</td>
<td>1.79</td>
<td>(0.79-4.06)</td>
<td>0.2</td>
</tr>
<tr>
<td>Restenosis</td>
<td>1.72</td>
<td>(0.63-4.64)</td>
<td>0.3</td>
</tr>
<tr>
<td>&gt; 2 stents implanted</td>
<td>0.76</td>
<td>(0.32-1.84)</td>
<td>0.5</td>
</tr>
<tr>
<td>≤ 2 stents implanted</td>
<td>2.15</td>
<td>(0.99-4.66)</td>
<td>0.06</td>
</tr>
<tr>
<td>Lesion type A/B1</td>
<td>1.84</td>
<td>(0.74-4.57)</td>
<td>0.2</td>
</tr>
<tr>
<td>Lesion type B2/C</td>
<td>1.13</td>
<td>(0.64-1.99)</td>
<td>0.7</td>
</tr>
</tbody>
</table>

*Major adverse cardiac events: death, myocardial infarction, or target vessel revascu-

larization. CI = confidence interval; HR = hazard ratio.
CONCLUSIONS

The universal use of PES in an unrestricted setting is safe, and associated with a non-significant adjusted difference in outcome at one year compared to SES, with a trend toward worse outcomes in the PES cohort, in part owing to its higher-risk profile. Both DES reduce the need for repeat intervention in the real world setting of complex patient and procedural characteristics.

Reprint requests and correspondence: Prof. Patrick W. Serruys, Thoraxcenter, Bd-406, Dr. Molewaterplein 40, 3015-GD Rotterdam, the Netherlands. E-mail: p.w.j.c.serruys@erasusmc.nl.

REFERENCES