Zotarolimus- and Paclitaxel-Eluting Stents in an All-Comer Population in China

The RESOLUTE China Randomized Controlled Trial

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Objectives This study sought to compare clinical outcomes and angiographic findings using the Resolute zotarolimus-eluting stent (R-ZES) (Medtronic, Santa Rosa, California) versus the Taxus Liberte paclitaxel-eluting stent (PES) (Boston Scientific, Natick, Massachusetts) in an all-comer Chinese population.

Background Concerns regarding restenosis risk led to new-generation drug-eluting stents (DES) designed for use in patients with complex clinical or lesion characteristics. In-stent late lumen loss (LLL) is a measure of restenosis risk.

Methods Patients with an indication for treatment with a DES were randomized in a 1:1 ratio to placement of at least 1 R-ZES or PES with minimal exclusions. The primary endpoint was angiographic in-stent LLL at 9 months post-procedure. Clinical endpoints at 12 months are compared between the 2 stents.

Results A total of 198 patients received a R-ZES, and 202 patients received a PES. Most patients were male; 25.8% and 29.2% of R-ZES and PES patients, respectively, had diabetes. Over 70% of lesions in both cohorts were American College of Cardiology/American Heart Association lesion classification Type B2 and C (B2/C). In-stent LLL was 0.16 ± 0.38 mm for R-ZES and 0.33 ± 0.52 mm for PES at 9 months (p < 0.001; 95% confidence interval [CI]: −0.26 to −0.08). The rates of clinically driven target lesion revascularization were 1.5% for R-ZES and 7.0% for PES (p = 0.011). The rate of target lesion failure was 5.6% for R-ZES and 11% for PES (p = 0.068).

Conclusions In an all-comers Chinese population, 9-month in-stent LLL was significantly less with R-ZES compared with PES, which was reflected in lower revascularization rates at 12 months for the R-ZES patients. Results are consistent with previous clinical trials of the R-ZES in all-comer populations. (Resolute Zotarolimus-Eluting Stent Versus the Taxus Liberte Paclitaxel-Eluting Stent for Percutaneous Coronary Intervention in China [R-China RCT]; NCT01334268). (J Am Coll Cardiol Intv 2013; 6:664–70) © 2013 by the American College of Cardiology Foundation
The use of quantitative angiographic endpoints to better assess vascular response following stenting provides valuable data regarding the biological effects of different drug-eluting stents (DES). Late lumen loss (LLL) is an angiographic measure of neointimal hyperplasia, the pathological target of DES (1), and is considered a reasonable measure of clinical restenosis risk (2). Earlier studies that used LLL as a primary endpoint were done in simpler populations (3), but angiographic data for new-generation DES in all-comer populations are minimal. The RESOLUTE All-Comers (A Randomized Comparison of a Zotarolimus-Eluting Stent With an Everolimus-Eluting Stent for Percutaneous Coronary Intervention) trial (R-AC) included angiographic follow-up in only 20% of the patients, and a second similar randomized controlled trial did not include any angiographic follow-up (4,5).

We report here the first results of a randomized clinical trial comparing the Resolute zotarolimus-eluting stent (R-ZES) (Medtronic, Santa Rosa, California) with the Taxus Liberte paclitaxel-eluting stent (PES) (Boston Scientific, Natick, Massachusetts) in an all-comer Chinese population. The primary endpoint is in-stent LLL at 9 months. This study, the first randomized clinical trial of R-ZES conducted in China, was designed to confirm the consistency of R-ZES outcomes in real-world Chinese patients with coronary artery disease.

Methods

Study design and patient population. The RESOLUTE China Randomized Controlled Trial (R-China RCT) is a prospective, 2-arm, open-label study, designed to assess the non-inferiority of the R-ZES compared with the PES. Patients were enrolled in the trial at 16 sites from September 2011 to November 2011.

Ethics committees provided written approval for the protocol, and all patients gave written informed consent. The study was conducted in accordance with the Declaration of Helsinki and all local regulatory requirements.

Eligible patients were acceptable candidates for treatment with a DES with at least 1 R-ZES or PES. Patients were excluded if they were participating in an ongoing study or had planned surgery within 6 months of percutaneous coronary intervention. No limitations were placed on the number of vessels and lesions to be treated.

Patients were randomized in a 1:1 ratio to stenting with a R-ZES or a PES using an interactive voice response system. The randomization was stratified by site. If more than 1 lesion was to be treated in a patient, all lesions were planned to be treated with the same assigned study stent type. The study management team, but not any of the study investigators, who participated in the study, was blinded to the assigned study stent. Dual antiplatelet therapy was to be administered according to hospital routine practice. The pre-procedural or periprocedural regimen was aspirin 100 mg and clopidogrel 75 mg for 3 days, or a loading dose of aspirin 300 to 600 mg and clopidogrel 300 to 600 mg. The post-procedural regimen was aspirin 100 mg daily (indefinitely) and 75 mg clopidogrel for at least 6 months.

Clinical follow-up was completed for 30 days, 6 and 9 months, and 1 year and is scheduled annually through 5 years. The angiographic follow-up was scheduled at 9 months post-procedure for all patients.

Endpoints and definitions. The primary endpoint was angiographic in-stent LLL at 9 months post-procedure, defined as the difference between the post-procedure minimal lumen diameter (MLD) and the follow-up MLD. Secondary angiographic endpoints included in-segment LLL, in-stent and in-segment percent diameter stenosis (%DS), in-stent and in-segment MLD, and in-stent and in-segment binary restenosis rate. Binary restenosis was defined as %DS of ≥50%.

Device, lesion, and procedure success have been previously defined (4). Clinical endpoint definitions were consistent with the prior RESOLUTE trials and included death, cardiac death, target vessel myocardial infarction (TVMI), cardiac death and TVMI, clinically driven target lesion revascularization (TLR), clinically driven target vessel revascularization (TVR), target vessel failure (TVF), target lesion failure (TLF), major adverse cardiac events, and stent thrombosis. Deaths were classified as cardiac death unless a noncardiac cause could be positively identified. Stent thrombosis was adjudicated according to the Academic Research Consortium definition (6).

Safety reporting. The trial was 100% monitored. A blinded angiographic core laboratory (Cardiovascular Research Foundation, New York, New York) reviewed all baseline, procedural, and 9-month follow-up assessments. An independent, blinded clinical events committee adjudicated all outcomes according to pre-specified definitions. An independent data safety monitoring board reviewed outcomes on a regular basis and could recommend study termination. The Cardiovascular Research Foundation coordinated the clinical events committee and data safety monitoring board.

Statistical analysis. This trial was powered to test whether R-ZES is noninferior to PES in the primary endpoint of in-stent LLL in the R-ZES group, with a noninferiority margin of 0.16 mm. This margin was based on the

**Abbreviations and Acronyms**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>%DS</td>
<td>percent diameter stenosis</td>
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<tr>
<td>CI</td>
<td>confidence interval</td>
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<td>DES</td>
<td>drug-eluting stent(s)</td>
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<td>LLL</td>
<td>late lumen loss</td>
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<tr>
<td>MI</td>
<td>myocardial infarction</td>
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<tr>
<td>MLD</td>
<td>minimal lumen diameter</td>
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<tr>
<td>PES</td>
<td>paclitaxel-eluting stent(s)</td>
</tr>
<tr>
<td>R-ZES</td>
<td>Resolute zotarolimus-eluting stent(s)</td>
</tr>
<tr>
<td>TLF</td>
<td>target lesion failure</td>
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<tr>
<td>TLR</td>
<td>target lesion revascularization</td>
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<tr>
<td>TVF</td>
<td>target vessel failure</td>
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<tr>
<td>TVMI</td>
<td>target vessel myocardial infarction</td>
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<tr>
<td>TVR</td>
<td>target vessel revascularization</td>
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**ENDEAVOR IV** (Randomized Comparison of Zotarolimus-Eluting and Paclitaxel-Eluting Stents in Patients with Coronary Artery Disease) study comparing the Endeavor zotarolimus-eluting stent to PES (7). R-ZES would be considered noninferior to PES if the upper limit of the 95% confidence interval (CI) of the difference of the primary endpoint was $<0.16$ mm.

The primary and secondary endpoints were calculated using an intention-to-treat population. Enrollment of 400 patients (assuming a 20% loss to follow-up rate) would provide a power of 83% to demonstrate that R-ZES was noninferior in the primary endpoint. Secondary outcomes were compared between R-ZES and PES using the Fisher exact test for categorical outcomes and a 2-sample $t$ test for continuous outcomes. Baseline characteristics were compared between R-ZES and PES using the Fisher exact test or Cochran-Mantel-Haenszel test for categorical variables and a 2-sample $t$ test for continuous outcomes. The Kaplan-Meier method was used to analyze the time-sensitive nature of TLF.

The 1-year TLF rate was compared between the 2 arms for a few pre-defined subgroups. The risk ratios and 95% CIs were calculated for those subgroups. The outcomes for patients with and without diabetes were also compared.

SAS software version 9.1 or later (SAS Institute; Cary, North Carolina) was used for all statistical analyses. Values $p < 0.05$ were considered statistically significant.

**Results**

**Patient disposition and characteristics.** There were 400 patients randomized, 198 (264 lesions) to R-ZES and 202 (260 lesions) to PES. Nine-month angiographic follow-up is available for 148 R-ZES patients (74.7%) and 148 PES patients (73.3%). Clinical follow-up data at 12 months were available for 98.5% of R-ZES and 98% of PES patients (Fig. 1). Dual antiplatelet therapy use at 12 months was high in both groups (96.9% for R-ZES and 95.5% for PES).
Patients had a mean age of 60 years, most were male (79%), and 28% had diabetes mellitus. Baseline characteristics were similar between groups (Table 1). A mean of 1.7 stents per patient were used, and over 70% of lesions in both groups were B2/C (Table 2). Device, lesion, and procedure success were high for both stents (Table 2).

Primary and secondary angiographic endpoint. In-stent LLL was 0.16 mm ± 0.38 mm in the R-ZES group and 0.33 mm ± 0.52 mm in the PES group at 9 months (Table 3, Fig. 2). The primary endpoint was met (p < 0.001 for both noninferiority and superiority; 95% CI: −0.26 to −0.08).

The in-stent MLD of the PES group was significantly less than that seen in the R-ZES group (2.26 ± 0.68 mm vs. 2.44 ± 0.56 mm, p = 0.004). Additionally, in-stent and in-segment %DS and binary restenosis were significantly lower in the R-ZES group compared with the PES group (Table 3).

The rates of clinically driven TLR (1.5% vs. 7%, p = 0.011) and TVR (2% vs. 9%, p = 0.003) were significantly less in the R-ZES group compared with the PES group (Table 4, Fig. 3). Cardiac death and TVMI were similar (p = 0.809).

SUBGROUP ANALYSIS. The relative risk for TLF at 12 months for the overall population and selected subgroups are shown in Figure 3. Baseline characteristics of the R-ZES and PES patients with and without diabetes were similar. There were no significant differences in 9-month angiographic and any 12-month clinical endpoints between patients with and without diabetes in either group.

Discussion

R-China RCT represents the largest reported population of real-world R-ZES patients with angiographic follow-up in the RESOLUTE global clinical program. The primary endpoint of in-stent LLL was significantly lower following percutaneous coronary intervention with the R-ZES compared with the PES and met the noninferiority criteria of the trial (0.16 ± 0.38 mm vs. 0.33 ± 0.52 mm, 2-sided 95% CI: −0.26 to −0.08, p < 0.001).

The use of quantitative angiographic criteria of lumen deterioration, namely, late loss, more closely reflects the magnitude of the reactive intimal hyperplasia after stenting (8). A review examining the relationship between mean LLL and restenosis among different DES concluded that LLL is an excellent predictor of angiographic (binary restenosis) and clinical (TVR) measures of restenosis with no threshold phenomenon observed, suggesting that a lower mean LLL correlates with a lower risk for revascularization over time (9).

An important feature of R-China RCT is that the patients were enrolled within a 2-month period, suggesting that the majority of patients may have been concurrently

<table>
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<th>Table 1. Baseline Characteristics</th>
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<tbody>
<tr>
<td>Characteristic</td>
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<tr>
<td>Age, yrs</td>
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<tr>
<td>Male</td>
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<tr>
<td>Current smoker</td>
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<td>Diabetes mellitus</td>
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<tr>
<td>Hyperlipidemia</td>
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<tr>
<td>Hypertension</td>
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<tr>
<td>Previous MI</td>
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<tr>
<td>Complex</td>
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<tr>
<td>Stable angina</td>
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<tr>
<td>Unstable angina</td>
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<tr>
<td>Acute MI</td>
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<tr>
<td>Acute MI (within 72 h)</td>
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<tr>
<td>Complex*</td>
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<tr>
<th>Table 2. Baseline Lesion, Device, and Procedure Characteristics</th>
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<tr>
<td>Characteristics</td>
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<tr>
<td>Calcification, moderate/severe</td>
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<tr>
<td>Bifurcation</td>
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<tr>
<td>Small vessel (RVD ≤2.75 mm)</td>
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<tr>
<td>Left main</td>
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<tr>
<td>CTO</td>
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<tr>
<td>Vessel location per patient</td>
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<tr>
<td>LAD</td>
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<tr>
<td>LCX</td>
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<tr>
<td>RCA</td>
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<tr>
<td>Left main</td>
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<tr>
<td>Multivessel treatment</td>
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<tr>
<td>Stents per patient</td>
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<tr>
<td>Lesions treated per patient</td>
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<tr>
<td>Device success</td>
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<tr>
<td>Lesion success</td>
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<tr>
<td>Procedural success</td>
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Values are mean ± 5D or % (n/N). *Complex patients were defined by the presence of at least 1 of the following clinical or lesion characteristics: renal insufficiency (serum creatinine ≥140 μmol/l), left ventricular ejection fraction <30%, acute MI (≤72 h), >1 lesion per vessel, ≥2 vessels stented, lesions ≤27 mm, bifurcations, bypass grafts, in-stent restenosis, unprotected left main coronary artery, lesions with thrombus or total occlusion.

CTO = chronic total occlusion; LAD = left anterior descending coronary artery; LCX = left circumflex; MLD = minimal lumen diameter; RCA = right coronary artery; RVD = reference vessel diameter; other abbreviations as in Table 1.
enrolled and were truly all-comers. Complex lesions (type B2/C) occurred in 70% of the study population, and 55% of the population met the criteria for complex, with 26% diabetic patients, 37% current smokers, and 27% undergoing revascularization following an acute myocardial infarction (MI), which is similar to the study populations enrolled in the TWENTE (the Real-World Endeavor Resolute Versus XIENCE V Drug-Eluting Stent Study in Twente) trial (70% B2/C lesions, 22% diabetic patients, 28% with acute MI) and the R-AC trial (67% complex, 24% diabetic patients, 27% current smokers, and 34% with acute MI) (4,5). The Chinese all-comer population is also comparable with the RESOLUTE International (R-Int) trial population (n = 2,349); 30.4% had diabetes, 24.2% were current smokers, and 29.7% had acute MI (10).

Compared with the LLL outcomes of R-China RCT, the R-FIM (RESOLUTE First-in-Man) trial enrolled fewer complex patients and reported 9-month in-stent LLL of 0.22 ± 0.27 mm (3).

The R-US (RESOLUTE US) trial also enrolled a less complex population although 34% of patients had diabetes. In the angiographic cohort, the mean in-stent LLL at 8 months was 0.30 ± 0.54 mm (11). R-Japan (RESOLUTE Japan) reported a 9-month in-stent LLL of 0.12 ± 0.22 mm. The lower LLL in R-China RCT and R-Japan may be attributed to differences in procedural techniques utilized in these countries, which include use of adjunctive post-dilation at a higher pressure after expansion.

Although our study is primarily an angiographic study, we found consistent clinical outcomes compared with other trials included in the RESOLUTE global clinical program. A comparison of the cumulative incidence of TLF at 12 months for the 6 RESOLUTE trials illustrates this point (Fig. 4). Given the outcomes observed in R-China RCT, there does not appear to be an oculo-stenotic reflex affecting

<table>
<thead>
<tr>
<th>Table 3. Angiographic Outcomes</th>
<th>R-ZES (n = 198 Patients, n = 264 Lesions)</th>
<th>PES (n = 202 Patients, n = 260 Lesions)</th>
<th>p Value</th>
</tr>
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<tbody>
<tr>
<td>Pre-procedure</td>
<td></td>
<td></td>
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<tr>
<td>RVD, mm 2.84 ± 0.49</td>
<td>2.80 ± 0.50</td>
<td>0.411</td>
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<tr>
<td>Lesion length, mm 19.09 ± 10.18</td>
<td>18.16 ± 10.18</td>
<td>0.309</td>
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<tr>
<td>MLD, mm 0.77 ± 0.44</td>
<td>0.81 ± 0.43</td>
<td>0.289</td>
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<tr>
<td>Diameter stenosis, % 72.81 ± 14.34</td>
<td>71.11 ± 14.09</td>
<td>0.173</td>
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<tr>
<td>Post-procedure</td>
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<tr>
<td>RVD, mm 2.88 ± 0.48</td>
<td>2.86 ± 0.51</td>
<td>0.564</td>
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<tr>
<td>In-segment</td>
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<tr>
<td>MLD, mm 2.61 ± 0.44</td>
<td>2.57 ± 0.46</td>
<td>0.308</td>
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<tr>
<td>Diameter stenosis, % 9.15 ± 7.39</td>
<td>9.51 ± 8.59</td>
<td>0.605</td>
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<tr>
<td>In-segment</td>
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<tr>
<td>MLD, mm 2.38 ± 0.48</td>
<td>2.35 ± 0.47</td>
<td>0.496</td>
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<tr>
<td>Diameter stenosis, % 17.60 ± 8.78</td>
<td>17.67 ± 8.84</td>
<td>0.924</td>
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<tr>
<td>9-month follow-up</td>
<td></td>
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<tr>
<td>RVD, mm 2.83 ± 0.44</td>
<td>2.88 ± 0.48</td>
<td>0.328</td>
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</tr>
<tr>
<td>In-segment</td>
<td></td>
<td></td>
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<tr>
<td>Late lumen loss, mm 0.16 ± 0.38</td>
<td>0.33 ± 0.52</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>MLD, mm 2.44 ± 0.56</td>
<td>2.26 ± 0.68</td>
<td>0.004</td>
<td></td>
</tr>
<tr>
<td>Diameter stenosis, % 13.77 ± 14.19</td>
<td>21.70 ± 18.70</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Binary restenosis*</td>
<td>2.5% (5/203)</td>
<td>10.7% (21/196)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>In-segment</td>
<td></td>
<td></td>
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<tr>
<td>Late lumen loss, mm 0.15 ± 0.41</td>
<td>0.24 ± 0.49</td>
<td>0.062</td>
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</tr>
<tr>
<td>MLD, mm 2.21 ± 0.56</td>
<td>2.13 ± 0.68</td>
<td>0.201</td>
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<tr>
<td>Diameter stenosis, % 21.99 ± 14.41</td>
<td>26.52 ± 18.01</td>
<td>0.006</td>
<td></td>
</tr>
<tr>
<td>Binary restenosis*</td>
<td>3.9% (8/205)</td>
<td>12.2% (24/196)</td>
<td>0.003</td>
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</tbody>
</table>

Values are mean ± SD or % (n/N).
Abbreviations as in Tables 1 and 2.

<table>
<thead>
<tr>
<th>Table 4. Clinical and Safety Outcomes at 12 Months</th>
<th>R-ZES (n = 197)</th>
<th>PES (n = 200)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLF</td>
<td>5.6 (11)</td>
<td>11.0 (22)</td>
<td>0.068</td>
</tr>
<tr>
<td>TVF</td>
<td>6.1 (12)</td>
<td>13.0 (26)</td>
<td>0.026</td>
</tr>
<tr>
<td>MACE</td>
<td>5.6 (11)</td>
<td>12.0 (24)</td>
<td>0.033</td>
</tr>
<tr>
<td>Cardiac death or TVMI</td>
<td>4.6 (9)</td>
<td>4.0 (8)</td>
<td>0.809</td>
</tr>
<tr>
<td>Death</td>
<td>1.0 (2)</td>
<td>1.0 (2)</td>
<td>1.000</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>1.0 (2)</td>
<td>0.5 (1)</td>
<td>0.621</td>
</tr>
<tr>
<td>All MI</td>
<td>3.6 (7)</td>
<td>4.0 (8)</td>
<td>1.000</td>
</tr>
<tr>
<td>TVMI</td>
<td>3.6 (7)</td>
<td>3.5 (7)</td>
<td>1.000</td>
</tr>
<tr>
<td>All TLR</td>
<td>2.0 (4)</td>
<td>9.0 (18)</td>
<td>0.003</td>
</tr>
<tr>
<td>Clinically driven TLR</td>
<td>1.5 (3)</td>
<td>7.0 (14)</td>
<td>0.011</td>
</tr>
<tr>
<td>All TVR</td>
<td>2.5 (5)</td>
<td>11.0 (22)</td>
<td>0.001</td>
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<tr>
<td>Clinically driven TVR</td>
<td>2.0 (4)</td>
<td>9.0 (18)</td>
<td>0.003</td>
</tr>
<tr>
<td>ARC def/prob stent thrombosis</td>
<td>0.5 (1)</td>
<td>1.0 (2)</td>
<td>1.000</td>
</tr>
<tr>
<td>Late thrombosis (31–360 days)</td>
<td>0.0% (0)</td>
<td>0.5% (1)</td>
<td>1.000</td>
</tr>
</tbody>
</table>

Values are % (n).
ARC def/prob = Academic Research Consortium definite/probable; MACE = major adverse cardiac events; TLF = target lesion failure; TVR = time to revascularization; TVF = target vessel failure; TVMI = target vessel myocardial infarction; other abbreviations as in Table 1.
12-month clinical outcomes for R-ZES as evidenced by the fact that no additional events occurred between 9 and 12 months and might be attributed to the fact that improved angiographic outcomes are less susceptible to the oculo-stenotic reflex (12–15). However, the rates of TVF, clinically driven TLR, and clinically driven TVR were significantly increased in the PES arm of our trial at 12 months.

The rates of TLF for selected subgroups between patients in each stent group showed results consistent with those observed between the stents overall. The post hoc analysis comparing R-ZES patients with and without diabetes observed similar clinical and angiographic outcomes that are consistent with results reported from the pooled global RESOLUTE clinical program. Patients with diabetes who are not treated with insulin have comparable safety and effectiveness to nondiabetic patients treated with a R-ZES (16). These data are in contrast to earlier publications suggesting that patients with diabetes have a higher risk for restenosis than nondiabetic patients following bare-metal stent or DES placement (17,18).

**Study limitations.** The sample size is small in terms of clinical comparisons; however, R-China RCT was primarily designed as an angiographic study and uses a sample size similar to other studies with angiographic primary end-
points (19). The small size of subgroups also limits the ability to detect differences in clinical outcomes. Although a higher rate of angiographic follow-up is desirable to fully evaluate the angiographic outcomes, the statistical power of the trial was preserved at 80% (20). Furthermore, the present study enrolled a unique cohort of all-comer patients with complex procedures, which differs from patients usually included in randomized trials and may limit the compliance for angiographic restudy. The comparison is to a first-generation DES currently less in use, rather than a newer-generation DES. Longer-term follow-up will be needed to confirm observed differences in revascularization.

Conclusions

This prospective, randomized, multicenter trial comparing the R-ZES with the PES in an all-comer Chinese population demonstrates a significantly lower in-stent LLL for the R-ZES. The 12-month clinical outcomes are consistent with other trials in the RESOLUTE global clinical program and are significantly better than the comparator arm of the trial.

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REFERENCES


Key Words: all-comer population • China • drug-eluting stent • paclitaxel-eluting stent • randomized controlled trial • Resolute zotarolimus-eluting stent.

APPENDIX

For an expanded acknowledgment section, please see the online version of this paper.