# One-Year Outcomes from an All-Comers Chinese Population of Patients Implanted With the Resolute *Zotarolimus*-Eluting Stent

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**The RESOLUTE China Registry is a prospective, multicenter, all-comers, observational study of patients in China implanted with the Resolute zotarolimus-eluting stent (R-ZES). R-ZES was commercially available before the enrollment began. All patients suitable for R-ZES implantation according to applicable guidelines were candidates for enrollment at 30 centers and were treated per standard hospital practice. Dual antiplatelet therapy (DAPT) was prescribed for a minimum of 6 months per current European Society of Cardiology guidelines and the device instructions for use. There were 1,800 patients enrolled with a mean age of 61.3 ± 10.9 years, 76% of patients were men, and 61% had complex disease. DAPT use was 94% at 1 year. Target lesion failure (cardiac death, target vessel myocardial infarction, or clinically driven target lesion revascularization) at 1 year was 3.5% (95% confidence interval 2.7% to 4.5%). The rate of cardiac death was 0.6%, target vessel myocardial infarction 2.3%, and clinically driven target lesion revascularization 0.9%. The 1-year rate of definite or probable stent thrombosis was 0.5% (8 of 1,750); 0.4% (7 of 1,750) occurred early (0 to 30 days) and 1 event occurred late (1 to 12 months). One stent thrombosis occurred in a patient who had an interruption of DAPT within the first month; all other stent thromboses occurred while on DAPT. Outcomes did not differ significantly between monitored and unmonitored patients (difference in target lesion failure, p = 0.264). In conclusion, the RESOLUTE China Registry confirms the safety and effectiveness of R-ZES in a large real-world Chinese population.**  **(Am J Cardiol 2014;113:613−620)**

From 1990 to 2010, coronary heart disease moved from the seventh to second leading cause of death in China.[1] The emerging challenge of treating cardiovascular disease in China has led to an increased interest in the assessment of outcomes in the Chinese population after drug-eluting stent (DES) implantation in this population. The Resolute zotarolimus-eluting stent (R-ZES; Medtronic Inc., Santa Rosa, California) has been shown to be safe and effective among all-comers populations in a European randomized study[2,3] and an international registry that did not include sites in China.[4] The RESOLUTE China Registry, the largest R-ZES study in the Chinese population, was designed to characterize real-world clinical outcomes of R-ZES in an all-comers population of Chinese patients requiring stent implantation. The 1-year outcomes of the RESOLUTE China Registry are described in this report.

## Methods

The RESOLUTE China Registry was a closed-cohort observational study that prospectively enrolled patients from 30 sites. Patients were enrolled from December 2010 to March 2012. Patient follow-up was planned at 30 days, 6 months, and annually through 5 years. The study conformed to the Declaration of Helsinki, the protocol was approved by independent ethics committees for all sites, and all patients provided written informed consent before enrollment. The RESOLUTE China Registry was registered in *ClinicalTrials.gov* (NCT01243749). The study design and oversight was directed by a steering committee of study investigators and a representative from the sponsor.

All patients who were aged ≥18 years and eligible for elective implantation of an R-ZES in ≥1 target lesions were candidates for enrollment. Patients were excluded if they had a known intolerance to materials or drugs used in the study, were pregnant or lactating, were highly unlikely to adhere to follow-up requirements, had a planned surgery within 6 months of the index procedure that required interruption of dual antiplatelet therapy (DAPT), or had previously enrolled in the RESOLUTE China Registry.

Stent implantation was done according to routine hospital practice, applicable guidelines, and the R-ZES instructions for use. Investigators were advised to attempt treatment of all lesions with R-ZES, but implantation of other stents was permitted. If delivery failure occurred or there were insufficient R-ZES available, any DES or bare-metal stent could be implanted. The protocol recommended DAPT using aspirin and clopidogrel 75 mg each for 3 days before procedure or a periprocedural loading dose of aspirin 250 to 500 mg and clopidogrel 300 to 600 mg. The protocol further

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This study was performed in clinical centers across China. See the online Supplementary Data for a list of centers and investigators.

This study was sponsored by Medtronic Inc., Shanghai, China. All investigators had access to the database.

See page 619 for disclosure information.

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Table 1
Baseline demographics and clinical characteristics

| Characteristic | All Patients (n = 1,800) | Monitored (n = 898) | Unmonitored (n = 902) | p Value* |
|---|---|---|---|---|
| Age (yrs) | 61.3 ± 10.9 | 61.1 ± 10.9 | 61.5 ± 10.8 | 0.458 |
| Men | 1,361 (76) | 672 (75) | 689 (76) | 0.476 |
| Current smoker | 644 (36) | 318 (35) | 326 (36) | 0.768 |
| Diabetes mellitus | 528 (29) | 265 (30) | 263 (29) | 0.877 |
| Insulin dependent | 19 (1) | 4 (<1) | 15 (2) | 0.019 |
| Hyperlipidemia | 735 (41) | 377 (42) | 358 (40) | 0.338 |
| Hypertension | 1,148 (64) | 579 (64) | 569 (63) | 0.556 |
| Previous myocardial infarction | 642/1,788 (36) | 323/891 (36) | 319/897 (36) | 0.768 |
| Revascularization for angina or myocardial infarction | | | | 0.607 |
| Silent angina | 45/1,783 (3) | 24/886 (3) | 21/897 (2) | |
| Stable angina | 133/1,783 (8) | 59/886 (7) | 74/897 (8) | |
| Unstable angina | 1,045/1,783 (58) | 524/886 (59) | 521/897 (58) | |
| Acute myocardial infarction | 560/1,783 (31) | 279/886 (32) | 281/897 (31) | |
| Serum creatinine (μmol/L) | 80.43 ± 31.80 | 78.74 ± 27.60 | 82.10 ± 35.41 | 0.029 |
| Complex patients† | 1,102 (61) | 537 (60) | 565 (63) | 0.227 |

Data are expressed as patients (%) or mean ± SD.
* Comparing monitored and unmonitored.
† Complex patients had 1,550 lesions (67%). Refer to the Methods section for the definition of complex patient status.

recommended aspirin 75 mg indefinitely and clopidogrel for at least 6 months (R-ZES instructions for use and European guidelines)[5] and up to 12 months (American guidelines).[6] DAPT use could be continued beyond 12 months by the physician's decision.

Site monitoring (R&G PharmaStudies Co Ltd, Shanghai, China) was prespecified to be conducted at all sites to verify 100% of informed consent forms and source data from 50% of patients. Additional monitoring was conducted based on clinical events committee−adjudicated events. Data management and statistical analysis were undertaken by the sponsor.

Clinical outcomes studied in this registry included target lesion failure (TLF; defined as cardiac death, target vessel myocardial infarction [Q wave and non−Q wave], or clinically driven target lesion revascularization) and Academic Research Consortium[7] definite or probable stent thrombosis. Other outcomes analyzed included target vessel failure (cardiac death, target vessel myocardial infarction, or clinically driven target vessel revascularization), major adverse cardiac events (MACEs; death, myocardial infarction, emergent coronary artery bypass graft, or clinically driven target lesion revascularization), a composite outcome (death, myocardial infarction, or any revascularization), significant bleeding complications, and the components of composite outcomes. Deaths were considered cardiac unless an unequivocal noncardiac cause could be established. Revascularization could have been by percutaneous or surgical methods. Target vessel myocardial infarction and myocardial infarction were adjudicated according to the extended historical definition.[8]

A bleeding complication was defined as a procedure-related hemorrhagic event that required a transfusion or surgical repair (including hematoma requiring treatment of retroperitoneal bleeding). A significant bleeding complication was defined as intracranial bleeding or bleeding that led to DAPT interruption, required transfusion, or resulted in substantial hemodynamic compromise requiring treatment.

Effectiveness was measured as attainment of <50% residual stenosis at the target lesion using any percutaneous method (lesion success), using only the assigned device (device success), or resulting in no in-hospital MACE (procedure success).

Complex patient status was defined as having ≥1 of the following characteristics: serum creatinine level ≥140 μmol/L, left ventricular ejection fraction <30%, acute myocardial infarction (within 72 hours), >1 lesion per vessel, ≥2 vessels stented, lesions of >27 mm, bifurcation, bypass graft, in-stent restenosis, unprotected left main, thrombus, or total occlusion.

Outcomes were adjudicated by an independent clinical events committee comprised of cardiologists who were not participants in the study. Clinical event adjudication definitions were the same as those used in other studies comprising the RESOLUTE Global Clinical Program. Safety oversight was provided by a data safety monitoring board composed of 2 cardiologists and a statistician not participating in the study. Safety data were reviewed on a regular basis, and the board could recommend early study closure to the sponsor and steering committee. The Cardiovascular Research Foundation (New York, New York) coordinated the clinical events committee and data safety monitoring board.

All analyses were conducted according to the intention-to-treat principle, and no data imputation for missing values was performed. Descriptive statistics and 95% confidence intervals were calculated for clinically relevant variables.

The sample size was calculated assuming a 1-year TLF rate of 6.8%, which was derived from the E-Five registry.[9] The E-Five registry used a similar all-comers registry design to the RESOLUTE China Registry, used the first-generation ZES approved in China at the time of sample size calculation (Endeavor, Medtronic Inc, Santa Rosa, California), and included sites in China.[9] A sample size of 1,800 patients would provide a 95% confidence interval with a 1.2% margin of error and would allow for a maximum of 5% rate of loss to follow-up.

Table 2
Lesion, vessel, and procedural characteristics

| Characteristic | All Patients (n = 1,800 Patients; n = 2,320 Lesions) | Monitored (n = 898 Patients; n = 1,129 Lesions) | Unmonitored (n = 902 Patients; n = 1,191 Lesions) | p Value* |
|---|---|---|---|---|
| Vessel location (patients) | | | | |
| Left anterior descending | 1,120 (62) | 552 (62) | 568 (63) | 0.528 |
| Left circumflex | 416 (23) | 195 (22) | 221 (24) | 0.163 |
| Right | 577 (32) | 282 (31) | 295 (33) | 0.579 |
| Left main | 40 (2) | 19 (2) | 21 (2) | 0.873 |
| Saphenous vein graft | 13 (1) | 5 (1) | 8 (1) | 0.580 |
| Left/right internal mammary artery | 2 (<1) | 2 (<1) | 0 | 0.249 |
| Chronic total occlusion (lesions) | 167 (7) | 89 (8) | 78 (7) | 0.228 |
| Class B2/C (lesions) | 1,570 (68) | 756 (67) | 814 (68) | 0.478 |
| Bifurcation (lesions) | 345 (15) | 164 (15) | 181 (15) | 0.683 |
| Lesion length (mm) | 24.91 ± 13.73 | 24.93 ± 14.54 | 24.89 ± 12.93 | 0.945 |
| Preprocedural reference vessel diameter (mm) | 3.03 ± 0.50 | 3.02 ± 0.50 | 3.03 ± 0.51 | 0.846 |
| Preprocedural minimal lumen diameter (mm) | 0.49 ± 0.56 | 0.48 ± 0.53 | 0.50 ± 0.59 | 0.278 |
| Preprocedural diameter stenosis (%) | 84.06 ± 17.77 | 84.42 ± 17.00 | 83.71 ± 18.46 | 0.334 |
| Number of lesions treated per patient | 1.4 ± 0.7 | 1.4 ± 0.7 | 1.4 ± 0.7 | 0.836 |
| Total stent length per patient (mm) | 42.2 ± 28.3 | 42.14 ± 29.29 | 42.34 ± 27.31 | 0.878 |
| Total stent length per lesion (mm) | 29.5 ± 15.5 | 29.48 ± 16.16 | 29.51 ± 14.77 | 0.960 |
| Number of stents per patient | 1.8 ± 1.1 | 1.79 ± 1.07 | 1.79 ± 1.03 | 0.997 |
| Number of stents per lesion | 1.3 ± 0.5 | 1.26 ± 0.55 | 1.26 ± 0.52 | 0.784 |

Data are expressed as patients/lesions (%) or mean ± SD. Lesion characteristics were visually estimated and site reported.
* Comparing monitored and unmonitored.

Table 3
Clinical and safety events through 1 year after R-ZES implantation

| Clinical Event | All Patients (n = 1,750) | Monitored (n = 873) | Unmonitored (n = 877) | Adjusted p Value* |
|---|---|---|---|---|
| TLF | 61 (3.5) | 34 (3.9) | 27 (3.1) | 0.264 |
| Target vessel failure | 68 (3.9) | 37 (4.2) | 31 (3.5) | 0.331 |
| MACE | 70 (4.0) | 40 (4.6) | 30 (3.4) | 0.142 |
| Composite outcome | 109 (6.2) | 62 (7.1) | 47 (5.4) | 0.083 |
| Cardiac death or target vessel myocardial infarction | 52 (3.0) | 30 (3.4) | 22 (2.5) | 0.197 |
| Death or target vessel myocardial infarction | 60 (3.4) | 36 (4.1) | 24 (2.7) | 0.078 |
| Death | 20 (1.1) | 10 (1.1) | 10 (1.1) | 0.900 |
| Cardiac death | 11 (0.6) | 4 (0.5) | 7 (0.8) | 0.413 |
| Noncardiac death | 9 (0.5) | 6 (0.7) | 3 (0.3) | 0.283 |
| Target vessel myocardial infarction | 41 (2.3) | 26 (3.0) | 15 (1.7) | 0.062 |
| Clinically driven target lesion revascularization | 16 (0.9) | 6 (0.7) | 10 (1.1) | 0.396 |
| Clinically driven target vessel revascularization | 25 (1.4) | 10 (1.1) | 15 (1.7) | 0.412 |
| Definite/probable stent thrombosis | 8 (0.5) | 1 (0.1) | 7 (0.8) | 0.089 |
| Early (≤30 days) | 7 (0.4) | 1 (0.1) | 6 (0.7) | 0.126 |
| Late (31−360 days) | 1 (0.1) | 0 | 1 (0.1) | 0.902 |
| Significant bleeding | 25 (1.4) | 14 (1.6) | 11 (1.3) | 0.462 |

Data are expressed as patients (%). Refer to the Methods section for end point definitions.
* Comparing monitored and unmonitored.

Baseline characteristics and outcomes through 1 year of follow-up were compared between monitored and unmonitored patients, and descriptive statistics were done for key subgroups: men, women, bifurcation, diabetes, multivessel treatment, chronic total occlusion, acute coronary syndromes, long lesion (>27 mm), small vessel (<2.5 mm), ST-segment elevation myocardial infarction, and non−ST-segment elevation myocardial infarction or unstable angina. To adjust for differences in baseline patient characteristics between groups, propensity scores were calculated using logistic regression with treatment group as the dependent variable and the covariates as the predictors. The baseline characteristics included in the propensity score models were age, sex, diabetes, current smoker, hyperlipidemia, hypertension, previous myocardial infarction, previous coronary artery bypass graft, unstable angina or myocardial infarction, lesion in left ascending artery, B2/C lesion, moderate-to-severe calcification, tortuosity ≥45°, Thrombolysis In Myocardial Infarction flow 3, reference vessel diameter, lesion length, and percent diameter stenosis.

The effect of DAPT adherence on definite or probable stent thrombosis events through 1 year of follow-up was analyzed. Patients were grouped according to the time of first interruption of either aspirin or thienopyridine therapy

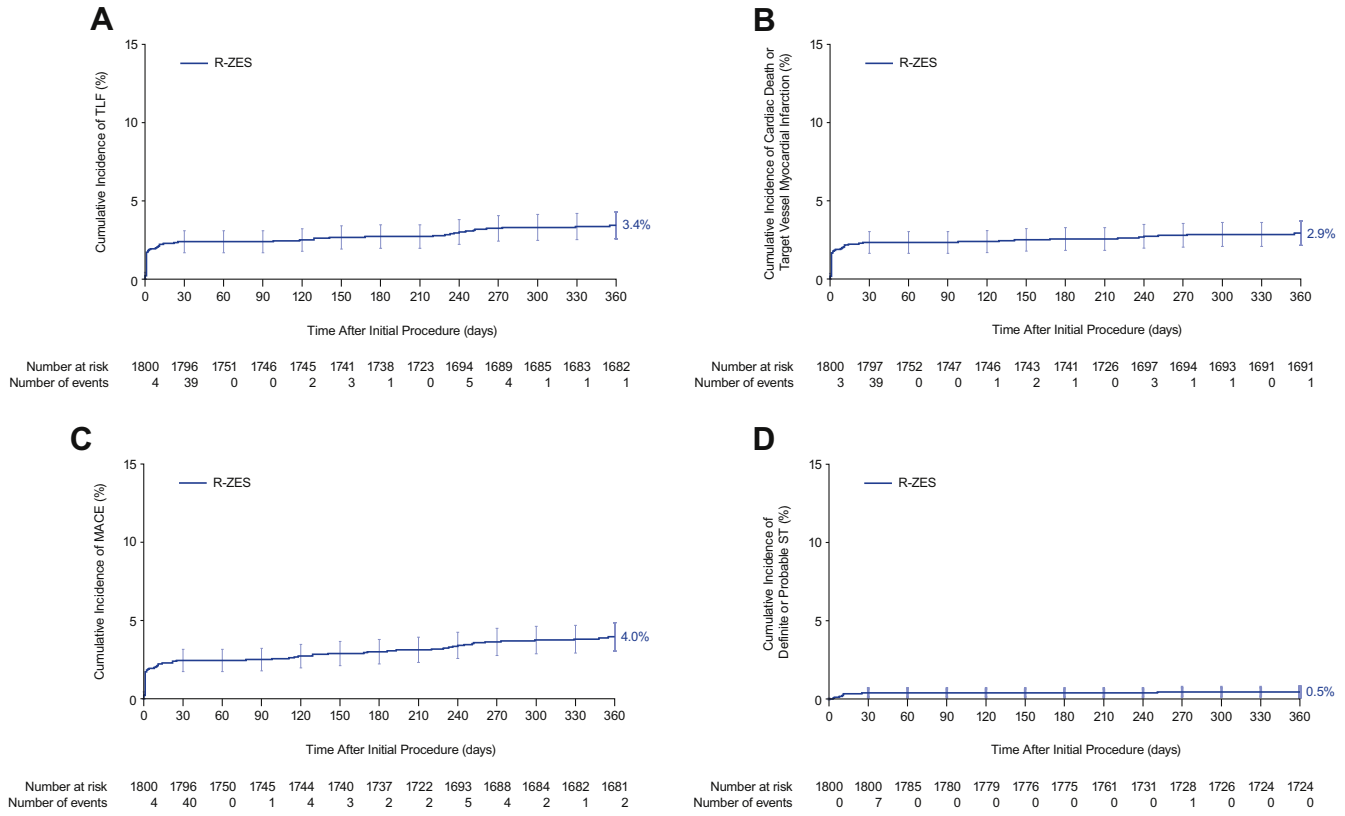



Figure 1. Cumulative incidence through 1 year after R-ZES implantation of *(A)* TLF, *(B)* cardiac death or target vessel myocardial infarction, *(C)* MACE, and *(D)* Academic Research Consortium definite or probable stent thrombosis (ST). Refer to the Methods section for outcome definitions.

after procedure. Patients were included in this analysis if they started on DAPT within 1 day after stent implantation, had no previous stent thrombosis events observed during the study, and had follow-up data available regarding the DAPT use. The association between DAPT adherence and stent thrombosis events was analyzed in 3 main groups: patients with no interruption, interruption during the first month after procedure, and interruption during 1 to 12 months after procedure.

Statistical analyses were performed using SAS software, version 9.1 or later (SAS Institute, Cary, North Carolina). p Values $<0.5$ were considered statistically significant.

## Results

There were 1,800 patients with 2,320 lesions enrolled, and follow-up at 1 year was 97% (n = 1,750). Baseline patient demographic and clinical characteristics are listed in Table 1, and lesion characteristics are listed in Table 2. The mean age of the patients was 61.3 ± 10.9 years, 76% were men, and 61% were complex. Most patients were treated in de novo lesions (98%, n = 2,281). Lesion success was 100% (2,319 of 2,320), device success was 97% (2,244 of 2,320), and procedure success was 98% (1,763 of 1,799). Predilatation was used in 83% (1,919 of 2,320) and direct stenting in 17% (401 of 2,320) of lesions. Overlapping stents were used in 20% (n = 368) of patients (507 lesions). Glycoprotein IIb/IIIa inhibitors were used in 16% (n = 317 of 1,937) of procedures. DAPT use was 96% (n = 1,712 of 1,780) at 6 months and 94% (n = 1,633 of 1,730) at 1 year.

The primary outcome of 1-year TLF was 3.5% (n = 61 of 1,750, 95% confidence interval 2.7% to 4.5%; Table 3 and Figure 1) and was primarily driven by target vessel myocardial infarction. There were 8 total events of definite or probable stent thrombosis: 7 early (≤30 days) and 1 late (31 to 360 days; Table 3 and Figure 1). The rate of significant bleeding complications was 1.4% (n = 25 of 1,750) at 1 year, and 5 of these 25 patients received glycoprotein IIb/IIIa inhibitors at stent implantation.

There were 898 patients who were monitored (902 were unmonitored). Baseline characteristics were similar between monitored and unmonitored patients, except for insulin-dependent diabetes and mean serum creatinine level. Clinical outcomes at 1 year were also similar between monitored and unmonitored patients (Table 3).

Subjects with MACE or stent thrombosis within the first month (n = 44) were compared with those who had neither event at that time (n = 1,754). The population of first-month MACE or patients with stent thrombosis had a greater proportion with diabetes (54% vs 29%, p <0.001), complex disease (86% vs 61%, p <0.001), and lesions in the left main artery (9% vs 2%, p = 0.015). The first-month MACE or stent thrombosis population also had higher mean number of lesions per patient (1.8 ± 0.8 vs 1.4 ± 0.7, p = 0.004), total stent length per patient (59.8 ± 37.4 vs 41.8 ± 27.9 mm, p = 0.003) and per lesion (35.19 ± 20.56 vs 29.32 ± 15.25 mm, p = 0.022), and total number of stents per

Table 4
Clinical outcomes for key subgroups at 1 year of follow-up

| Subgroup (Total Patients) | TLF | Cardiac Death or Target Vessel Myocardial Infarction | Clinically Driven Target Lesion Revascularization | MACE | Definite/Probable Stent Thrombosis |
|---|---|---|---|---|---|
| Men (n = 1,361) | 44 (3.3) | 39 (3.0) | 12 (0.9) | 52 (3.9) | 7 (0.5) |
| Women (n = 439) | 17 (3.9) | 13 (3.0) | 4 (0.9) | 18 (4.2) | 1 (0.2) |
| ≥1 Bifurcation lesion treated (n = 315) | 18 (6.0) | 14 (4.7) | 7 (2.3) | 19 (6.3) | 1 (0.3) |
| Diabetes (n = 528) | 33 (6.4) | 29 (5.6) | 8 (1.6) | 35 (6.8) | 4 (0.8) |
| Multivessel disease (n = 505) | 30 (6.1) | 27 (5.5) | 5 (1.0) | 31 (6.3) | 2 (0.4) |
| ≥1 Chronic total occlusion lesion treated (n = 157) | 7 (4.7) | 7 (4.7) | 1 (0.7) | 8 (5.3) | 1 (0.7) |
| Acute coronary syndromes (n = 1,190) | 40 (3.4) | 32 (2.7) | 14 (1.2) | 46 (3.9) | 5 (0.4) |
| ≥1 Long lesion treated, >27 mm (n = 576) | 35 (6.3) | 32 (5.7) | 8 (1.4) | 39 (7.0) | 6 (1.1) |
| ≥1 Small vessel treated, reference vessel diameter <2.5 mm (n = 183) | 8 (4.4) | 6 (3.3) | 4 (2.2) | 10 (5.5) | 3 (1.6) |

Data are expressed as patients (%). Refer to the Methods section for end point definitions.

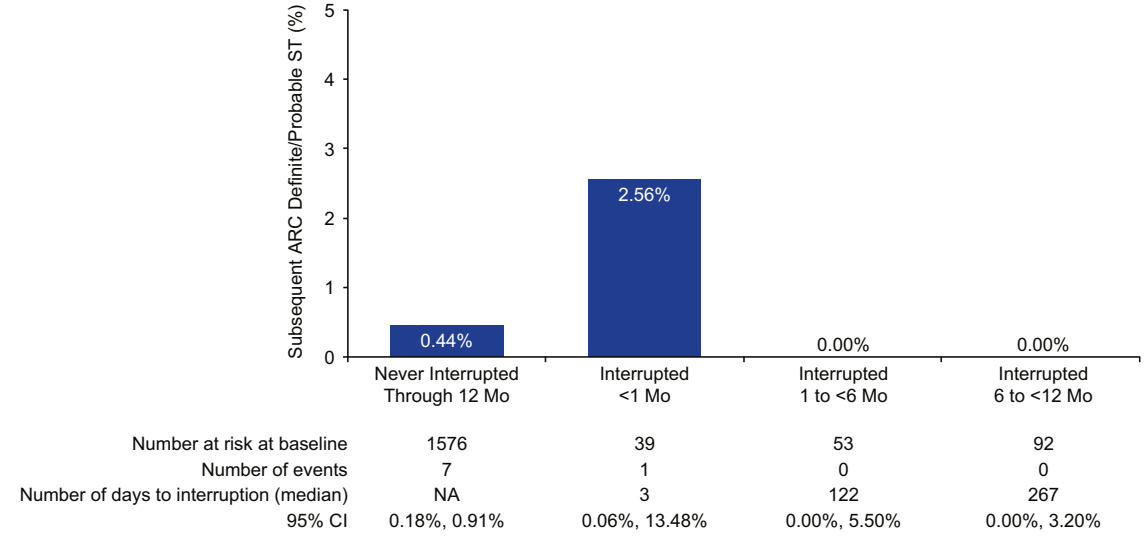



Figure 2. Academic Research Consortium (ARC) definite or probable stent thrombosis (ST) rates through 1 year according to the DAPT status. The never interrupted group included those who had no interruptions except for ST occurring while on DAPT. CI = confidence interval.

patient (2.4 ± 1.4 vs 1.8 ± 1.0, p = 0.004) and per lesion (1.43 ± 0.67 vs 1.25 ± 0.53, p = 0.031). All other baseline patient and lesion characteristics were similar between these groups (data not shown).

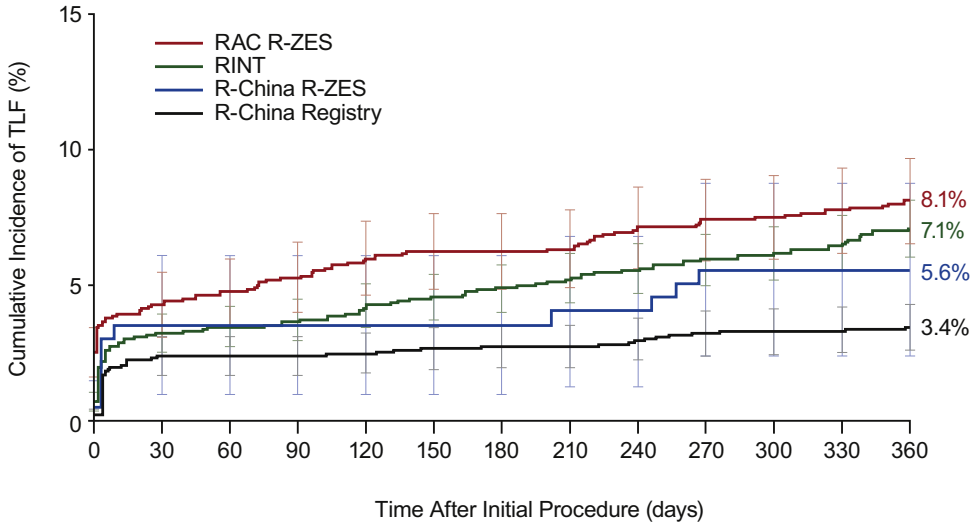
Clinically important subgroups were analyzed for key 1-year outcomes. The results of these analyses are presented in Table 4.

There were 1,760 patients included in the DAPT analysis (Figure 2); 1,576 patients had no interruption of their DAPT during the year after R-ZES implantation. After R-ZES treatment, 39 patients had a DAPT interruption from implantation to 1 month, 53 patients from 1 to 6 months, and 92 patients from 6 to 12 months. There were 7 definite or probable stent thrombosis events in patients with no DAPT interruption and 1 stent thrombosis event in a patient with DAPT interrupted within 1 month of treatment. No patient with an interruption from 1 to 6 or 6 to 12 months experienced a stent thrombosis (Figure 2).

## Discussion

We report 1-year results from a large, national, all-comers registry of R-ZES use in Chinese patients. The previously reported RESOLUTE China Randomized Controlled Trial (RCT)[10] compared the R-ZES and the paclitaxel-eluting stent in an all-comers Chinese population. The study found that R-ZES had significantly lower in-stent late luminal loss at 9 months. The clinical and safety end points at 9 months and 1 year after R-ZES implantation were also similar to those observed in other studies comprising the RESOLUTE Global Clinical Program. Results from the RESOLUTE China RCT suggest that R-ZES is as safe and effective in Chinese patients as in previously studied populations. Patients in the RESOLUTE China Registry experienced a low rate of TLF and definite or probable stent thrombosis; these outcomes were consistent with the results observed among R-ZES patients in the RESOLUTE China RCT. Most events occurred within the first 30 days after the index procedure. DAPT interruption was not associated with late stent thrombosis. Clinical outcomes did not differ between monitored and unmonitored patients.

Because of its all-comers design, the population in our study included a mix of patients with complex and simple diseases. As in other RESOLUTE studies with all-comers designs,[2,4,10] the protocol did not restrict enrollment for

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **RAC R-ZES** | | | | | | | | | | | | | |
| Number at risk | 1140 | 1107 | 1083 | 1077 | 1071 | 1063 | 1060 | 1058 | 1056 | 1047 | 1043 | 1042 | 1039 |
| Number of events | 29 | 20 | 5 | 6 | 8 | 3 | 0 | 1 | 9 | 3 | 1 | 3 | 4 |
| **RINT** | | | | | | | | | | | | | |
| Number at risk | 2349 | 2329 | 2265 | 2256 | 2247 | 2232 | 2221 | 2208 | 2199 | 2190 | 2181 | 2171 | 2158 |
| Number of events | 17 | 59 | 5 | 6 | 13 | 7 | 8 | 8 | 8 | 8 | 6 | 8 | 12 |
| **R-China R-ZES** | | | | | | | | | | | | | |
| Number at risk | 198 | 197 | 190 | 190 | 190 | 190 | 190 | 190 | 189 | 189 | 186 | 186 | 144 |
| Number of events | 1 | 6 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 3 | 0 | 0 | 0 |
| **R-China Registry** | | | | | | | | | | | | | |
| Number at risk | 1800 | 1793 | 1749 | 1746 | 1744 | 1741 | 1731 | 1709 | 1694 | 1689 | 1685 | 1683 | 1366 |
| Number of events | 4 | 39 | 0 | 0 | 2 | 3 | 1 | 0 | 5 | 4 | 1 | 1 | 1 |

Figure 3. Cumulative incidence through 1 year after R-ZES implantation of TLF in the RESOLUTE All Comers (RAC) R-ZES group, RESOLUTE International (RINT), RESOLUTE China Randomized Controlled Trial (R-China RCT) R-ZES, and RESOLUTE China Registry (R-China Registry). Refer to the Methods section for outcome definitions.

either complex or simple (e.g., stable angina) disease states. A high proportion (61%) had complex disease according to prespecified criteria, a rate that is consistent with the other RESOLUTE studies with all-comers designs: RESOLUTE China RCT (55.1%), RESOLUTE All Comers (67.0%), and RESOLUTE International (67.5%).[2,4,10] The all-comers design of this study increased the likelihood that we would enroll a population that would be representative of real-world PCI practice in China.

The rates of clinical events observed in our study were lower than those in other all-comers studies in the RESOLUTE Global Clinical Program: RESOLUTE China RCT (n = 198),[10] RESOLUTE All Comers (n = 1,140),[2] and RESOLUTE International[4] (n = 2,349; Figure 3). Outcome definitions and adjudication practices were harmonized across studies in this program, ensuring similar criteria for reported outcomes despite differences in population or study conduct. In all these studies, most TLF occurred within the first 30 days (Figure 3). Lesions treated per patient did not vary greatly among these studies, but mean total lesion length in RESOLUTE China Registry was considerably lower. The apparent difference in lesion length may have led to the comparably lower clinical event rates in the RESOLUTE China Registry.

The clinical event rates observed in the RESOLUTE China Registry were comparable with those of other all-comers new-generation DES registries. The XIENCE V USA[11] study of real-world patients treated with the everolimus-eluting stent (EES; XIENCE V, Abbott Laboratories, Santa Clara, California) reported a 1-year TLF rate of 6.7%, similar to RESOLUTE International. This study analyzed standard-risk (on label) and extended-risk (higher risk characteristics) patients; TLF was 3.5% compared with 8.5% in these groups, respectively. The EXCELLENT (Efficacy of Xience/promus versus Cypher to rEduce Late Loss after stENTing) registry[12] conducted in Korea analyzed outcomes in 3,056 patients after treatment with EES. The 1-year rate of TLF was 2.7%. The proportion of complex patients (reported as those with at least 1 off-label indication) was 73%. The outcomes of the EXCELLENT registry were compared with the RESOLUTE-Korea registry, which prospectively enrolled 1,998 patients treated with the R-ZES without exclusions. The results of this registry were similar with a 1-year TLF rate of 2.9% ($p = 0.662$ compared with EES), although the proportion of complex patients was significantly greater than in EXCELLENT (81%, $p < 0.001$). All clinical event rates were similar between the 2 registries.[12] The RESOLUTE China, EXCELLENT, and RESOLUTE-Korea registries were similar in lesion characteristics. The mean age, proportion of male patients, proportion of patients with diabetes and hypertension, total stent length per patient or lesion, and the number of stents per patient or lesion appeared to be similar between the 3 studies. Such similarities in baseline characteristics and follow-up

outcomes indicate that the results of the RESOLUTE China Registry are generalizable to Asian populations implanted with new-generation DESs.

The RESOLUTE China Registry extends the growing body of evidence that rates of stent thrombosis are low in new-generation DESs through 1 year of real-world follow-up. We observed a rate of definite or probable stent thrombosis of 0.5%. In the aforementioned RESOLUTE Global Clinical Program all-comers studies,[2,4,10] rates of definite or probable stent thrombosis ranged from 0.5% to 1.3%. Definite or probable stent thrombosis occurred in 0.8% of patients treated with an EES in the XIENCE V USA registry[11] through 1 year, which is similar to the rate of 0.6% reported for EES in EXCELLENT.[12] These rates of stent thrombosis appear to be similar to the rate of 0.5% in our study and 0.4% reported in the RESOLUTE-Korea registry.[12] DAPT usage was 97% at 6 months and 85% at 1 year in the Korea registries,[12] 79% at 1 year in XIENCE V USA,[11] and 94% at 1 year in the RESOLUTE China Registry.

Our observation that most stent thrombosis events occur early (<30 days) is consistent across all DES studies, but the effect of DAPT adherence is not well understood—especially in new-generation DESs. We found that there were no stent thrombosis events in patients with a DAPT interruption after 1 month. This is consistent with results from an analysis of a larger R-ZES data set from the RESOLUTE Clinical Global Program recently reported at the American College of Cardiology.[13] There were 32 (0.8%) of 3,827 stent thrombosis events in patients with no DAPT interruption, 6 (3.6%) of 166 stent thrombosis events in patients with DAPT interrupted 0 to 1 month after R-ZES treatment, and 1 (0.1%) of 903 in patients with DAPT interrupted between 1 and 12 months. A prolonged use of antiplatelet drugs is a known risk for bleeding events, and there is evidence to suggest that for some patients, DAPT extension beyond 3 months confers no additional benefit in terms of reduction in stent thrombosis events but is associated with more major bleeding events.[14]

There was no control group in the RESOLUTE China Registry, and clinical monitoring was less than that used in randomized controlled clinical trials. However, outcomes did not differ significantly between monitored and unmonitored patients, and the monitoring rate of 50% was higher than that in other large registries. Another limitation is that the study reflected common clinical practice by relying on site-reported visual assessments of angiographic data.

The RESOLUTE China Registry is a prospective, multicenter, all-comers registry that provides valuable insight into patient characteristics, usage patterns, and clinical outcomes in routine interventional cardiology practice. The RESOLUTE China Registry demonstrated a low rate of cardiac events, including low definite or probable stent thrombosis. The results observed in this registry confirm the results seen in the RESOLUTE China RCT and are consistent with those in other registries conducted in Asian populations. This large real-world study further supports the favorable performance of the R-ZES in China.

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## Disclosures

The authors have no conflicts of interest to disclose.

## Supplementary Data

Supplementary data related to this article can be found, in the online version, at http://dx.doi.org/10.1016/j.amjcard.2013.10.042

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