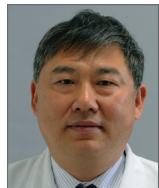


# Three-year outcomes from an all-comers Chinese population treated with the Resolute zotarolimus-eluting stent: RESOLUTE China Registry



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## KEYWORDS

- drug-eluting stent
- percutaneous coronary intervention
- Resolute zotarolimus-eluting stent

## Abstract

**Aims:** The Resolute™ zotarolimus-eluting stent (ZES) has been associated with excellent and sustained safety and efficacy in real-world populations undergoing percutaneous coronary intervention (PCI). However, limited real-world clinical outcome data beyond one year are available in an Asian population. The aim of this article is to report the three-year outcomes of the RESOLUTE China Registry.

**Methods and results:** The RESOLUTE China Registry is a prospective, observational registry conducted among patients with symptomatic coronary artery disease at 30 sites in China with minimal exclusion criteria. Among 1,800 patients enrolled, mean age was  $61 \pm 11$  years, 29% had a history of diabetes and 68% underwent PCI of long lesions ( $\geq 18$  mm), 43% of small vessels ( $\leq 2.75$  mm), and 7% of chronic total occlusions. Total stent length was  $42.2 \pm 28.3$  mm per patient. At three years, target lesion failure was 6.3%, with a 2.4% incidence of clinically driven target lesion revascularisation, 4.4% incidence of cardiac death or target vessel myocardial infarction, and 0.8% definite or probable stent thrombosis. Clinical outcomes were favourable across complex subsets, including patients with diabetes, chronic total occlusion, and small vessel treatment.

**Conclusions:** In the largest study of Asian patients treated with the Resolute ZES, the incidence of adverse cardiac events was low and sustained at three years, highlighting the continued safety and efficacy of the Resolute ZES in a real-world Chinese population.

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## Introduction

The Resolute™ zotarolimus-eluting stent (ZES) (Medtronic, Minneapolis, MN, USA) has been associated with excellent and sustained safety and efficacy in real-world populations undergoing percutaneous coronary intervention (PCI). In the RESOLUTE All-Comers trial of Resolute ZES (N=1,140) vs. XIENCE V™ everolimus-eluting stent (EES) (Abbott Vascular, Santa Clara, CA, USA; N=1,152), conducted in an all-comers population across Europe, target vessel failure (a composite of cardiac death, myocardial infarction [MI] not clearly attributable to a non-target vessel, and clinically indicated target vessel revascularisation) at five years was 20% with Resolute ZES (and no different from XIENCE V EES, 19%, p=0.60)<sup>1</sup>. Moreover, given the excellent safety and efficacy of current-generation drug-eluting stents, the stents are used to treat an increasingly complex patient population, including those with small vessels, bifurcation lesions, and chronic total occlusions. However, limited long-term real-world clinical outcome data are available in an Asian population, in particular among complex subsets. In contrast to the United States and Europe where mortality due to coronary artery disease is declining, mortality due to coronary artery disease is increasing in China<sup>2</sup>. Additionally, Asian patients are more likely to require re-admission to treat clinical restenosis as compared with white Europeans<sup>3</sup>.

The RESOLUTE China Registry is a large trial of Chinese patients implanted with the Resolute ZES in an all-comers population, providing a large sample size across complex subsets. Outcomes at one year have been previously reported<sup>4</sup>. In this manuscript we report the three-year outcomes.

## Methods

The design of and primary outcomes in the RESOLUTE China Registry have been previously reported<sup>4</sup>. Briefly, the RESOLUTE China Registry is a prospective, multicentre, observational study in an all-comers Chinese population. Limited inclusion/exclusion criteria were used. Subjects who were aged 18 years or older and eligible for elective implantation with Resolute ZES in at least one target lesion were included. Patient follow-up was planned at 30 days, six months, and annually up to five years.

The study conformed to the Declaration of Helsinki, and the protocol was approved by independent ethics committees for all sites. All patients provided written informed consent before enrolment and prior to the PCI procedure. The study design and oversight were directed by a steering committee comprising study investigators and a representative from the sponsor. Outcomes were adjudicated by an independent clinical events committee (CEC) composed of cardiologists who were not study participants. Safety oversight was provided by a data safety monitoring board.

Site monitoring (R&G Pharma Studies Co. Ltd., Shanghai, China) was conducted at all sites to verify 100% of informed consent forms and source data from at least 50% of patients. Additionally, all serious adverse events were source verified

and also sent for CEC adjudication. The one-year report of the RESOLUTE China Registry showed no differences in outcomes between subjects who were monitored and those who were not<sup>4</sup>. Additional monitoring was conducted based on CEC-adjudicated events.

## STATISTICAL ANALYSIS

The primary endpoint was one-year target lesion failure (TLF), defined as a composite of cardiac death, target vessel MI (Q-wave and non-Q-wave) or clinically driven target lesion revascularisation (TLR) by percutaneous or surgical methods. Major adverse cardiac events (MACE) were defined as the composite of all death, MI, emergent coronary artery bypass graft, or clinically driven TLR. Deaths were considered cardiac unless an unequivocal non-cardiac cause could be established. All MI, including target vessel MI, were adjudicated according to the extended historical definition<sup>5</sup>.

The following pre-specified subset analyses are included: treatment of long lesions ( $\geq 18$  mm length), small vessels ( $\leq 2.75$  mm diameter), multiple vessels, and chronic total occlusion, as well as treatment in patients with a history of diabetes mellitus.

All analyses were conducted based on the intention to treat, and no data imputation for missing values was performed. Continuous variables are presented as mean $\pm$ standard deviation and nominal variables as percentages. The incidence of clinical events was calculated using the Kaplan-Meier method. A p-value  $<0.05$  was considered statistically significant. Statistical analyses were performed using SAS software, version 9.1 or later (SAS Institute, Cary, NC, USA).

## Results

Between 23 December 2010 and 6 March 2012, a total of 1,800 subjects were enrolled at 30 sites across China. Follow-up was available on 1,701 patients (95%) at three years. **Table 1** shows baseline patient and lesion characteristics, as reported previously. Mean age was  $61\pm 11$  years, 29% had a history of diabetes, 68% had acute coronary syndrome, 43% were treated for small vessels ( $\leq 2.75$  mm), 68% for long lesions ( $\geq 18$  mm), 28% of patients underwent multivessel treatment, 15% were treated for bifurcation lesions, and 7% for chronic total occlusions.

Total stent length was  $42.2\pm 28.3$  mm per patient and  $1.8\pm 1.1$  stents were implanted per patient. Predilatation was used in 82.8% of lesions. There was no post-procedure Thrombolysis In Myocardial Infarction (TIMI) grade 0 or 1, 0.3% grade 2 and 99.7% grade 3. Percent diameter stenosis was  $0.3\pm 2.4$ , based on operator estimate.

The three-year incidence of adverse cardiac events is shown in **Table 2** and **Figure 1**. At two years, TLF was 5.5% (96) and comprised 2.2% (39) clinically driven TLR and 3.7% (65) cardiac death or target vessel MI; between two and three years, there were two (0.1%) clinically driven TLRs and 10 (0.6%) cardiac deaths or target vessel MIs. Definite and probable stent thrombosis was low up to three years (**Table 2**).

**Table 1. Baseline patient and lesion characteristics.**

|   |   | <b>RESOLUTE China Registry (N=1,800 subjects; 2,321 lesions)</b> |
|---|---|--|
| <b>Patient characteristics</b>  |   |  |
| Age, years  |   | 61±11  |
| Men, %  |   | 76 (1,361)   |
| Current smoker, %   |   | 36 (645)   |
| Diabetes mellitus, %  |   | 29 (645)   |
| Hyperlipidemia, %   |   | 41 (733)   |
| Hypertension, %   |   | 64 (1,150)   |
| Prior myocardial infarction, %  |   | 36 (638)   |
| Reason for revascularisation, %   | Unstable angina                                 | 59 (1,045)   |
|   | Acute myocardial infarction                     | 31 (560)   |
|   | Stable angina                                   | 8 (134)  |
|   | Silent angina                                   | 3 (45)   |
| Complex patients, %*  |   | 61 (1,102)   |
| <b>Lesion characteristics</b>   |   |  |
| Vessel location (per lesion), %   | Left anterior descending                        | 51 (1,194)   |
|   | Left circumflex                                 | 19 (432)   |
|   | Right coronary artery                           | 28 (642)   |
|   | Left main                                       | 2 (40)   |
|   | Saphenous vein graft or internal mammary artery | 0.6 (13)   |
| Lesion length, mm   |   | 24.9±13.7 (n=2,263)  |
| Pre-procedure reference vessel diameter, mm   |   | 3.0±0.5  |
| Pre-procedure TIMI, %   | 0   | 14.0   |
|   | 1   | 4.1  |
|   | 2   | 13.6   |
|   | 3   | 68.3   |
| Pre-procedure diameter stenosis, %  |   | 86.0±13.3 (2,321)  |
| Long lesion ( $\geq 18$ mm length), %   |   | 68 (1,230)   |
| Small vessels ( $\leq 2.75$ mm diameter), %   |   | 43 (769)   |
| AHA/ACC Class B2/C lesion, %  |   | 68 (1,571)   |
| Chronic total occlusion, %  |   | 7 (167)  |
| Bifurcation lesion, %   |   | 15 (345)   |
| Number of lesions treated per subject   |   | 1.4±0.7  |
| Number of stents per subject  |   | 1.8±1.1  |
| Total stent length per lesion, mm   |   | 29.5±15.4  |
| Total stent length per subject, mm  |   | 42.2±28.3  |
| Results presented as mean±standard deviation or % (n). *Subjects are considered “complex” if they have at least one of the following characteristics: total occlusion, bifurcation, saphenous vein graft, in-stent restenosis, acute myocardial infarction ( $\leq 72$ hours from index procedure), left ventricular ejection fraction $<30\%$ , unprotected left main, more than two vessels stented, renal insufficiency or failure (creatinine $\geq 140$ µmol/L), lesion length $>27$ mm, more than one lesion per vessel, or pre-procedure thrombus. AHA/ACC: American Heart Association/American College of Cardiology. |   |  |

Dual antiplatelet use at one, two and three years was 94%, 51%, and 40%, respectively. Academic Research Consortium (ARC) definite or probable stent thrombosis at one year, and between one and three years was 0.5% and 0.3%, respectively.

## SUBSET ANALYSES

**Figure 2** demonstrates the incidence of adverse cardiac events across several complex subsets. The three-year rate of TLF was 7.4% in subjects with long lesions ( $\geq 18$  mm length, total stent length  $50\pm 29$  mm per subject), 8.4% in small vessels ( $\leq 2.75$  mm diameter), 10.5% in multivessel treatment, 9.0% in subjects with diabetes mellitus, 11.1% in subjects treated at a bifurcation lesion, and 8.7% in subjects treated for chronic total occlusion (lesion length  $31\pm 18$  mm).

## Discussion

The RESOLUTE China Registry is the largest study of Asian patients (1,800 patients) treated with second-generation Resolute ZES in real-world clinical practice, allowing a robust evaluation of clinical outcomes across a broad spectrum of patients. Despite this complex patient population, the three-year incidence of all major adverse clinical events remained low. Between two and three years, only two subjects underwent TLR and, at three years, the incidence of TLF was 6.3% (due to 2.4% clinically driven TLR and 4.4% cardiac death or target vessel MI), and the incidence of ARC definite or probable stent thrombosis was 0.8%. These results highlight the long-term safety and efficacy of this second-generation drug-eluting stent in a large, real-world Chinese population.

The outcomes in the RESOLUTE China Registry are similar to those observed in studies of EES in a Chinese population. In PLATINUM China, TLR at one year was 2.2% with the PROMUS Element™ EES (Boston Scientific, Marlborough, MA, USA) (N=373)<sup>6</sup>, similar to that observed with Resolute ZES in the RESOLUTE China Registry at one year (1.3%). Long-term outcomes in PLATINUM China are not available.

The RESOLUTE China Registry is unique in providing a large study population of all-comer subjects to analyse complex subsets in a Chinese population. In subjects with diabetes mellitus, clinically driven TLR and TLF were 2.9% and 9.0% at three years, respectively. TLF is similar to that observed in a meta-analysis from the SPIRIT Clinical Trial Program among subjects with diabetes mellitus treated with EES (11.7% TLF at three years)<sup>7</sup>. Additionally, in the RESOLUTE China Registry, 150 subjects were treated for chronic total occlusion with an average lesion length of  $31\pm 18$  mm. Among these subjects, TLF at three years was 8.7%, which is similar to that reported at three years in subjects treated with the Resolute ZES for chronic total occlusion in both TWENTE (13.6% in a pooled analysis of Resolute ZES and XIENCE V EES)<sup>8</sup> and a pooled analysis in RESOLUTE All Comers and RESOLUTE International (9.1% at two years)<sup>9</sup>. Furthermore, in both TWENTE and the pooled analysis, TLF was similar in both subjects treated and not treated for

**Table 2.** Event rates at 1, 2 and 3 years in the RESOLUTE China Registry.

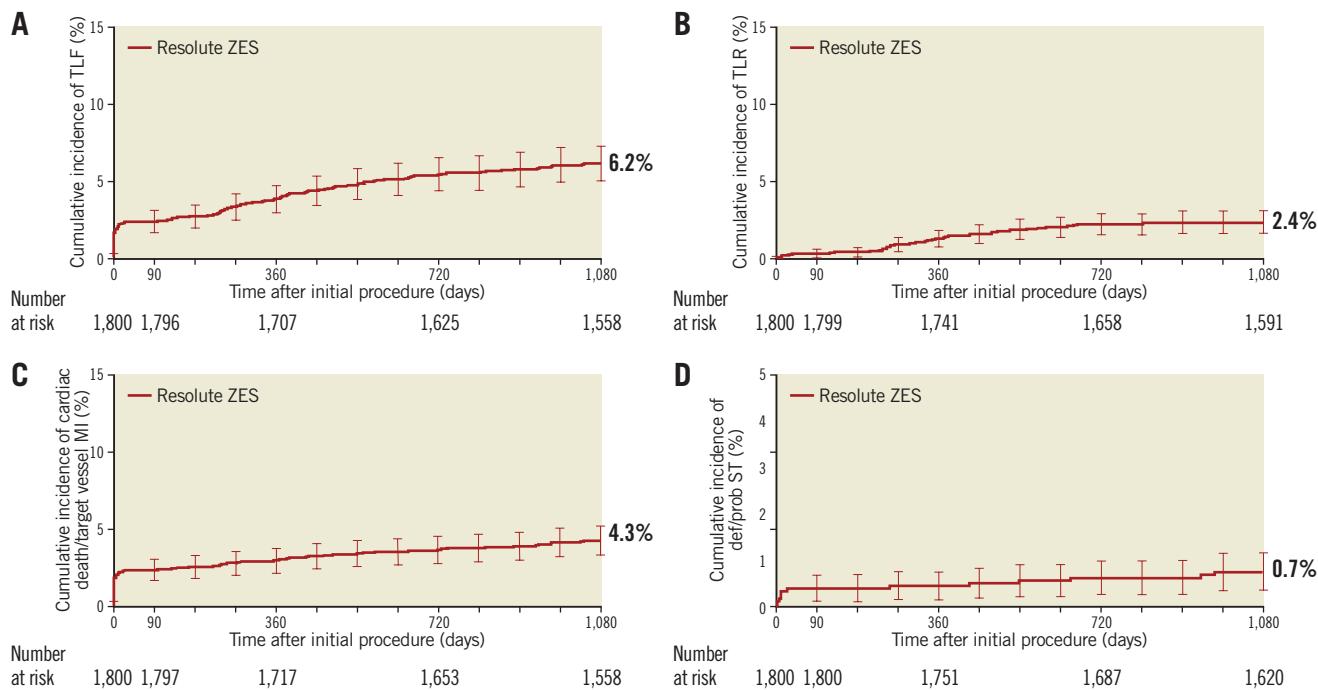
|  | 1 year<br>% (n)<br>(n=1,774) | 95% CI       | 2 years<br>% (n)<br>(n=1,742) | 95% CI       | 3 years<br>% (n)<br>(n=1,701) | 95% CI       |
|--|------------------------------|--------------|-------------------------------|--------------|-------------------------------|--------------|
| Target lesion failure                    | 3.9 (69)                     | (3.0%, 4.9%) | 5.5 (96)                      | (4.5%, 6.7%) | 6.3 (108)                     | (5.2%, 7.5%) |
| Target vessel failure                    | 4.3 (76)                     | (3.4%, 5.3%) | 6.0 (105)                     | (5.0%, 7.3%) | 6.9 (118)                     | (5.8%, 8.3%) |
| MACE                                     | 4.5 (79)                     | (3.5%, 5.5%) | 6.8 (119)                     | (5.7%, 8.1%) | 8.2 (140)                     | (7.0%, 9.6%) |
| Cardiac death or target vessel MI        | 3.0 (53)                     | (2.3%, 3.9%) | 3.7 (65)                      | (2.9%, 4.7%) | 4.4 (75)                      | (3.5%, 5.5%) |
| Death                                    | 1.2 (22)                     | (0.8%, 1.9%) | 2.8 (48)                      | (2.0%, 3.6%) | 3.9 (67)                      | (3.1%, 5.0%) |
| Cardiac death                            | 0.7 (12)                     | (0.4%, 1.2%) | 1.3 (23)                      | (0.8%, 2.0%) | 1.9 (33)                      | (1.3%, 2.7%) |
| Target vessel MI                         | 2.3 (41)                     | (1.7%, 3.1%) | 2.6 (45)                      | (1.9%, 3.4%) | 2.8 (47)                      | (2.0%, 3.7%) |
| Clinically driven TLR                    | 1.3 (23)                     | (0.8%, 1.9%) | 2.2 (39)                      | (1.6%, 3.1%) | 2.4 (41)                      | (1.7%, 3.3%) |
| Clinically driven TVR                    | 1.8 (32)                     | (1.2%, 2.5%) | 2.9 (50)                      | (2.1%, 3.8%) | 3.1 (53)                      | (2.3%, 4.1%) |
| Stent thrombosis (ARC) definite/probable | 0.5 (8)                      | (0.2%, 0.9%) | 0.6 (11)                      | (0.3%, 1.1%) | 0.8 (13)                      | (0.4%, 1.3%) |
| Acute (0-1 day) definite/probable        | 0.0 (0)                      | (0.0%, 0.2%) |                               |              |                               |              |
| Definite                                 | 0.0 (0)                      | (0.0%, 0.2%) |                               |              |                               |              |
| Probable                                 | 0.0 (0)                      | (0.0%, 0.2%) |                               |              |                               |              |
| Subacute (2-30 days) definite/probable   | 0.4 (7)                      | (0.2%, 0.8%) |                               |              |                               |              |
| Definite                                 | 0.2 (3)                      | (0.0%, 0.5%) |                               |              |                               |              |
| Probable                                 | 0.3 (5)                      | (0.1%, 0.7%) |                               |              |                               |              |
| Early (0-30 days) definite/probable      | 0.4 (7)                      | (0.2%, 0.8%) |                               |              |                               |              |
| Definite                                 | 0.2 (3)                      | (0.0%, 0.5%) |                               |              |                               |              |
| Probable                                 | 0.3 (5)                      | (0.1%, 0.7%) |                               |              |                               |              |
| Late (31-360 days) definite/probable     | 0.1 (1)                      | (0.0%, 0.3%) |                               |              |                               |              |
| Definite                                 | 0.1 (1)                      | (0.0%, 0.3%) |                               |              |                               |              |
| Probable                                 | 0.0 (0)                      | (0.0%, 0.2%) |                               |              |                               |              |
| Very late (>361 days) definite/probable  |                              |              |                               |              | 0.1 (6)                       | (0.1%, 0.8%) |
| Definite                                 |                              |              |                               |              | 0.0 (1)                       | (0.0%, 0.3%) |
| Probable                                 |                              |              |                               |              | 0.1 (5)                       | (0.1%, 0.7%) |
| Significant bleeding complications       | 1.5 (27)                     | (1.0%, 2.2%) | 1.7 (29)                      | (1.1%, 2.4%) | 1.9 (32)                      | (1.3%, 2.7%) |
| Stroke                                   | 0.8 (15)                     | (0.5%, 1.4%) | 1.3 (23)                      | (0.8%, 2.0%) | 1.9 (32)                      | (1.3%, 2.7%) |

chronic total occlusion<sup>8,9</sup>. In the EXPERT CTO multicenter trial (Evaluation of the XIENCE Coronary Stent, Performance, and Technique in Chronic Total Occlusions), TLF was 9.1%<sup>10</sup> at one year after implantation of XIENCE V EES in 250 subjects with chronic total occlusion.

The advent of drug-eluting stents has increased the use of stenting for more complex lesions, including small vessels<sup>11</sup>; however, historically, late lumen loss was more likely to result in the need for repeat revascularisation in small vessels as compared with large vessels<sup>12</sup>. Among subjects with small vessel treatment ( $\leq 2.75$  mm reference vessel diameter) in the RESOLUTE China Registry, TLR was low at 3.4% (25/734) at three years, which is similar to the rate observed with EES implantation in small coronary vessels (RVD  $<2.77$  mm) in a pooled analysis of SPIRIT II and III (3.0% [11/366] at one year)<sup>13</sup>. Given concerns about rising mortality due to coronary artery disease in China<sup>2</sup> and high re-admission rates to treat clinical restenosis among Asian patients<sup>3</sup>, using drug-eluting stents to reduce the risk of restenosis is of

critical importance in China. Treatment of small vessels can be problematic as late lumen loss may be less tolerated in small vessels. The low adverse event rates associated with Resolute ZES in the RESOLUTE China Registry, including among subjects with small vessels, makes Resolute ZES an important option in the treatment of coronary artery disease in China.

Dual antiplatelet use in the RESOLUTE China Registry at one, two, and three years was 94%, 51% and 40%, respectively. This rate is higher than that observed in RESOLUTE All Comers conducted in Europe, in which dual antiplatelet use after implantation with Resolute ZES at one, two, and three years was 84%, 18%, and 13%, respectively<sup>14</sup>, suggesting that long-term dual antiplatelet therapy may be prescribed more commonly in Asian populations. Use of dual antiplatelet therapy in RESOLUTE Asia (conducted across Asia) at one and two years was 91% and 94% in the 38 mm cohort and 66% and 78% in the dual vessel cohort, respectively<sup>15</sup>. Despite possible geographical differences in dual antiplatelet usage, ARC definite or probable stent



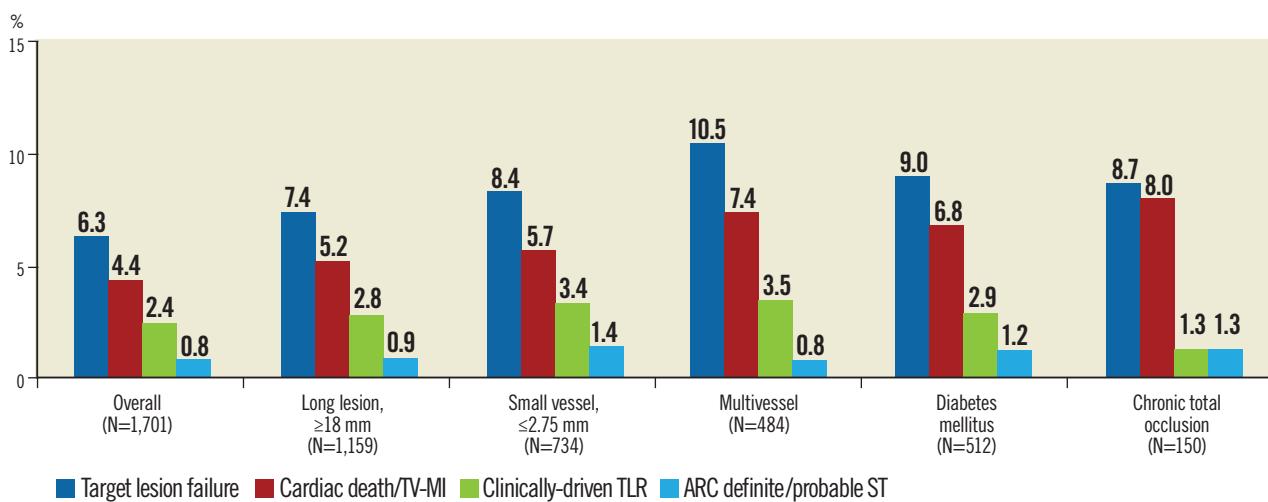
**Figure 1.** Three-year cumulative incidence of events. A) Target lesion failure. B) Clinically driven target lesion revascularisation. C) Cardiac death/target vessel myocardial infarction. D) Academic Research Consortium definite or probable stent thrombosis.

thrombosis remains low across the RESOLUTE Global Clinical Trial Program<sup>1,16-18</sup> including the RESOLUTE China Trial, in which stent thrombosis was 0.5% at one year and 0.3% between one and three years.

## Limitations

As a registry, the RESOLUTE China Registry did not include a control group. The registry also did not collect intravascular ultrasound and optical coherence tomography data as these

imaging procedures were not in common practice in China at the time this study was initiated. Additionally, clinical monitoring was not 100%; however, a previous analysis at one year found no differences in outcomes between the monitored and unmonitored subjects<sup>4</sup>. Furthermore, while subset analyses were pre-specified, a randomised controlled trial comparing subsets would be required to confirm results. Results from this study may be specific to China and therefore may not necessarily be indicative of results in other Asian or Western countries.



**Figure 2.** Three-year events across complex subsets. ARC: Academic Research Consortium; TV-MI: target vessel myocardial infarction; ST: stent thrombosis; TLR: target lesion revascularisation

## Conclusion

The prospective, multicentre RESOLUTE China Registry is the largest study of Asian patients treated with the second-generation Resolute ZES. The incidence of adverse cardiac events remained low and sustained, demonstrating the three-year safety and efficacy of this second-generation DES in a large, real-world, complex patient population.

## Impact on daily practice

Given concerns about rising mortality due to coronary artery disease in China and high re-admission rates to treat clinical restenosis among Asian patients, using drug-eluting stents to reduce the risk of restenosis is of critical importance in China. Unfortunately, clinical outcome data beyond one year for Asian populations undergoing percutaneous coronary intervention are limited. This study documented a low incidence of adverse cardiac events at three years among real-world Chinese patients treated with the Resolute zotarolimus-eluting stent, demonstrating the continued safety and efficacy of this stent.

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## Conflict of interest statement

The authors have no conflicts of interest to declare.

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