International Journal of Cardiology 168 (2013) 3522–3526

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Long-term outcomes of patients receiving zotarolimus-eluting stents in ST elevation myocardial infarction, non-ST elevation acute coronary syndrome, and stable angina: Data from the Resolute program ☆,☆☆

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ARTICLE INFO

Article history:
Received 16 October 2012
Received in revised form 9 April 2013
Accepted 30 April 2013
Available online 22 May 2013

Keywords:
Myocardial infarction
Acute coronary syndrome
Angina pectoris
Zotarolimus-eluting stent
Coronary thrombosis

ABSTRACT

Background: Outcome data are limited in patients with ST-segment elevation acute myocardial infarction (STEMI) or other acute coronary syndromes (ACSs) who receive a drug-eluting stent (DES). Data suggest that first generation DES is associated with an increased risk of stent thrombosis when used in STEMI. Whether this observation persists with newer generation DES is unknown. The study objective was to analyze the two-year safety and effectiveness of Resolute™ zotarolimus-eluting stents (R-ZESs) implanted for STEMI, ACS without ST segment elevation (non-STEACS), and stable angina (SA).

Methods: Data from the Resolute program (Resolute All Comers and Resolute International) were pooled and patients with R-ZES implantation were categorized by indication: STEMI (n = 335), non-STEACS (n = 1416), and SA (n = 1260).

Results: Mean age was 59.8 ± 11.3 years (STEMI), 63.8 ± 11.6 (non-STEACS), and 64.9 ± 10.1 (SA). Fewer STEMI patients had diabetes (19.1% vs. 28.5% vs. 29.2%; $P < 0.001$), prior MI (11.3% vs. 27.2% vs. 29.4%; $P < 0.001$), or previous revascularization (11.3% vs. 27.9% vs. 37.6%; $P < 0.001$). Two-year definite/probable stent thrombosis occurred in 2.4% (STEMI), 1.2% (non-STEACS) and 1.1% (SA) of patients with late/very late stent thrombosis (days 31–720) rates of 0.6% (STEMI and non-STEACS) and 0.4% (SA) (P = NS). The two-year mortality rate was 2.1% (STEMI), 4.8% (non-STEACS) and 3.7% (SA) (P = NS). Death or target vessel re-infarction occurred in 3.9% (STEMI), 8.7% (non-STEACS) and 7.3% (SA) ($P = 0.012$).

Conclusion: R-ZES in STEMI and in other clinical presentations is effective and safe. Long term outcomes are favorable with an extremely rare incidence of late and very late stent thrombosis following R-ZES implantation across indications.

Introduction

The introduction of drug-eluting stents (DESs) significantly decreased restenosis rates after percutaneous coronary intervention (PCI) [1–4]. However, late and very late stent thrombosis (ST) emerged as a complication that was almost unknown with bare metal stents (BMSs) [5–8]. The reduced restenosis rates in the presence of an increased risk of late or very late ST raised concerns [9–12] and led to new research focused on improvements in stent technology designed to address these concerns. Two new generation DES, zotarolimus and everolimus-eluting stents, were subsequently introduced and demonstrated improved efficacy and encouraging long-term safety compared with early DES and BMS [13–17].

Because of potential safety concerns there are limited data in the literature on clinical outcomes in patients who present with ST-segment elevation acute myocardial infarction (STEMI) or other acute coronary syndromes (ACSs) and receive DES [18–20]. Recent data on patients presenting with ACS, and STEMI in particular,

☆ Grant Support: Preparation of this manuscript was partially supported by the Charles University research project UNCE nr. 204010.
☆☆ Conflicts of Interest: Prof. Widimsky receives occasional speaker's honoraria from Medtronic; Dr. Silber has received grant, travel and support from Medtronic; and Dr. Belardi serves as a consultant to Medtronic; all other authors have nothing to disclose.
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0167-5273/$ – see front matter
http://dx.doi.org/10.1016/j.ijcard.2013.04.209

indicate that these patients are at higher risk of ST after primary PCI when compared with other indications for stent implantation [21–24]. Research addressing the impact of new generation DES on clinical outcomes in these high-risk populations is minimal and differences in outcomes following DES implantation for patients presenting with STEMI versus non-STEMI or unstable angina (ACS without ST-segment elevations [non-STEACS]) versus stable angina (SA) are not well understood.

To address the above mentioned limitations and concerns and to provide further insights on clinical outcomes after DES implantation across the spectrum of patient presentations, the two year pooled outcomes from the Resolute All Comers (RAC) and Resolute International (RINT) trials were evaluated.

Methods

RAC and RINT are part of the Resolute Global Clinical Trial Program and have similar data collection, endpoint definitions, adjudication processes, and methodologies for data evaluation and analyses. The detailed methods and eligibility criteria of these studies have been previously described [20,25]. Informed consent was obtained from each patient enrolled in these studies, and both study protocols conformed to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the institution's human research committee. The authors of this manuscript have certified that they comply with the Principles of Ethical Publishing in the International Journal of Cardiology.

In brief, both studies enrolled patients with a wide range of patient and lesion characteristics including stable coronary artery disease, and acute coronary syndromes with STEMI and non-STEMI. There were no exclusions based on number of treated lesions or vessels, lesion length, or number of stents implanted. Treated vessels had a reference vessel diameter of 2.25 to 4.0 mm. Only patients treated with a Resolute™ zotarolimus-eluting stent (R-ZES; Medtronic, Inc., Santa Rosa, California, USA) were included in this analysis. At discharge post-procedure all patients were prescribed aspirin 75 mg and clopidogrel 75 mg daily for a minimum of 6 months.

For the purposes of this analysis, we pooled patient level data from these two trials. Patients were stratified by their initial clinical presentation into one of three groups: STEMI within 24 h, non-STEACS, and SA. The primary safety endpoint of this analysis was ST, defined according to the Academic Research Consortium (ARC) [26]. The primary effectiveness endpoint was clinically-driven target vessel revascularization (TVR) defined as revascularization in the target vessel associated with a positive functional ischemia study or ischemic symptoms and an angiographic minimal lumen diameter stenosis ≥50% or revascularization of a target vessel with diameter stenosis ≥70% by quantitative angiography without angina or a positive functional study. Secondary endpoints included: all-cause mortality (defined as death by cardiac and non-cardiac causes), myocardial infarction (MI) (defined according to an extended historical protocol definition and according to 2007 ARC definitions [26,27]), and the composite of death or TVR. The extended historical definition of a Q wave MI required either 1) acute symptoms consistent with myocardial ischemia and new pathological Q waves in two or more contiguous ECG leads in the absence of timely cardiac enzyme data or, 2) new pathologic Q waves in two or more contiguous ECG leads and elevation of cardiac enzymes. In the absence of ECG data the CEC could adjudicate Q wave MI based on the clinical scenario and appropriate cardiac enzyme data. The extended historical definition of a non-Q wave MI required elevated CK ≥ 2× the laboratory upper limit of normal with any elevation of CK–MB in the absence of new pathological Q waves.

All serious adverse events including death, MI, revascularizations, and ST were adjudicated by an independent Clinical Events Committee (CEC). Additionally, a CEC Global Oversight Committee evaluated 100 primary endpoint events from each trial and made recommendations in cases of inconsistency in order to harmonize the interpretation of event definitions between the CECs.

Statistical analysis

All data were analyzed according to the intention to treat principle. Descriptive statistics were determined for baseline patient and lesion characteristics and data are presented as percentage or mean ± standard deviation. Linear regression was used in the analysis of continuous variables and Chi square test was used in the analysis of categorical variables. The cumulative incidence of events was analyzed using the Kaplan–Meier method. A P value of <0.05 was considered statistically significant. All statistical analyses were performed by the Harvard Clinical Research Institute, an independent clinical research organization, using SAS version 9.1 or higher (SAS Institute, Inc., Cary, North Carolina).

Results

A total of 957 patients enrolled in RAC and 2054 from RINT provided 3011 patients for inclusion in this post-hoc analysis. The baseline clinical characteristics of these patients are presented in Table 1. Diabetes, hypertension, and hyperlipidemia were more commonly seen in patients in the non-STEACS and SA groups, while smoking was more common in patients in the STEMI group. The number of patients with prior MI and prior PCI was 2–3 fold higher, and prior CABG was 8–12 fold higher in the non-STEACS and SA groups compared with the STEMI group.

The lesion and procedure characteristics of the index PCI are presented in Table 2. Almost half of the patients in the STEMI group had totally occluded lesions, a proportion that was 5 fold higher than the other two groups. Patients presenting with STEMI also had a higher proportion of complex lesions (type C). Conversely, in-stent restenosis and multi-vessel stenting was less common in the STEMI group.

At 30 days and 1 year the majority of patients were receiving dual antiplatelet therapy (DAPT) (Table 3). At 2 years, the proportion of patients on DAPT, ranged from 28.9% to 41.5%.

Outcomes by indication for PCI

There was no significant difference across the 3 groups for all-cause mortality, MI, or definite and probable ST at 30 days, and 1, or 2 years

Table 1
Baseline characteristics of the study population.

	STEMI n = 335	Non-STEACS n = 1416	Stable CAD n = 1260	*P*-value
Mean age, years	59.8 ± 11.3	63.8 ± 11.6	64.9 ± 10.1	<0.001
Diabetes	19.1% (64/335)	28.5% (404/1416)	29.2% (368/1260)	<0.001
Females	23.9% (80/335)	23.1% (327/1416)	23.3% (294/1260)	0.953
Prior MI	11.3% (38/335)	27.2% (383/1406)	29.4% (369/1255)	<0.001
Prior PCI	11.3% (38/335)	27.9% (395/1416)	37.6% (474/1260)	<0.001
Prior CABG	0.9% (3/335)	8.0% (113/1416)	12.3% (155/1260)	<0.001
History of smoking	67.8% (227/335)	55.4% (784/1416)	55.2% (695/1260)	<0.001
Current smoker	45.7% (153/335)	26.2% (371/1416)	16.4% (207/1260)	<0.001
Hyperlipidemia	41.5% (139/335)	63.5% (899/1416)	71.3% (899/1260)	<0.001
Hypertension	51.9% (174/335)	69.1% (979/1416)	74.4% (938/1260)	<0.001
Serum creatinine, (μmol/L), mean ± SD	81.4 ± 27.06 (267)	88.9 ± 38.5 (1256)	90.1 ± 47.7 (1016)	0.009
LVEF				
<30%	4.5% (6/133)	2.9% (26/900)	2.2% (17/771)	<0.001
30–40%	24.1% (32/133)	9.0% (81/900)	6.2% (48/771)	
>40%	71.4% (95/133)	88.1% (793/900)	91.6% (706/771)	

All data presented as % unless otherwise noted. CABG, coronary artery bypass grafting; LVEF, left ventricular ejection fraction; MI, myocardial infarction; and PCI, percutaneous coronary intervention.

Table 2
Lesion and procedural characteristics of PCI.

	STEMI	Non-STEACS	Stable CAD	*P*-value
Multi vessel stenting	12.2% (41/335)	20.4% (289/1416)	16.5% (208/1260)	<0.001
Lesion type				<0.001
A	5.2% (23/445)	8.5% (171/2009)	8.1% (137/16870)	
B1	21.1% (94/445)	28.9% (581/2009)	29.9% (505/1687)	
B2	27.9% (124/445)	31.7% (636/2009)	32.3% (545/1687)	
C	45.8% (204/445)	30.9% (621/2009)	29.6% (500/1687)	
RVD (mm)	2.89 ± 0.51 (359)	2.85 ± 0.51 (1922)	2.83 ± 0.52 (1621)	0.200
MLD (mm)	0.40 ± 0.51 (442)	0.63 ± 0.49 (1999)	0.65 ± 0.48 (1677)	<0.001
% Diameter stenosis	85.48 ± 17.87 (442)	77.21 ± 17.02 (1999)	76.49 ± 17.25 (1677)	<0.001
Lesion length (mm)	16.82 ± 8.95 (356)	16.45 ± 9.61 (1915)	16.71 ± 11.44 (1606)	0.692
Small vessel ≤2.75 mm	48.0% (132/275)	51.2% (699/1366)	53.4% (650/1217)	0.216
Bifurcation	20.3% (68/335)	20.1% (284/1413)	20.8% (260/1252)	0.912
Total occlusion	49.9% (167/335)	11.1% (157/1416)	8.8% (111/1258)	<0.001
In-stent restenosis	4.5% (15/335)	8.3% (1117/1413)	9.6% (120/1252)	0.011
Number of stents per patient	1.69 ± 1.07 (335)	1.72 ± 1.07 (1416)	1.68 ± 1.04 (1260)	0.668

All data presented as mean ± SD (n) or % (#/n). RVD, reference vessel diameter; and MLD, minimum lumen diameter.

after stent placement (Table 4). The STEMI group had a higher rate of early definite and probable ST than the other 2 groups but rates were very low after 30 days in all patients (Table 4, Fig. 1). Clinically-driven TVR at 361–720 days was significantly different across the 3 indications with 0.3% in STEMI, 2.6% in non-STEACS, and 2.5% in SA patients ($P = 0.016$). Death or target vessel re-infarction occurring between 30 and 720 days was also statistically significant and occurred in 3.9%, 8.7% and 7.3% of patients with STEMI, non-STEACS, and SA, respectively ($P = 0.012$).

Discussion

The implantation of an R-ZES in the acute phase of STEMI as well as in other clinical presentations appears to be safe and effective, with favorable outcomes up to 2 years. All-cause mortality and recurrent MI did not differ according to PCI indication. Importantly, the risk of late and very late ST was very low and did not differ significantly by the initial clinical presentation. It is notable that DAPT use was low in all indications by 2 years (Table 3). The rate of clinically-driven TVR through two years was ≤7% in all groups, which is a satisfactory rate for this all-comers study that included a significant proportion of patients with diabetes mellitus, type-C lesions, and multivessel stenting.

Patients with STEMI have generally been excluded from pivotal trials of DES. However, some studies have described a higher risk of ST among patients who received first generation DES during primary PCI for STEMI [22,23,28,29]. The highest rates of late and very late ST have been described after implantation of paclitaxel-eluting stents (PESs) [30]. This has been linked to the delayed healing with DES in the setting of plaque rupture versus SA and to the potential of the thrombus to modify the delivery of compounds from the DES into the vessel wall [31,32].

Two meta-analyses compared the efficacy and safety of DES with that of BMS in patients who experienced acute STEMI and underwent primary PCI in 13 randomized trials and 18 registries. Both analyses concluded that DES significantly reduces TVR compared with BMS without an increase in death, MI or ST within 2 years of the index procedure [33,34]. However, these meta-analyses were limited to the study of outcomes in the STEMI setting and did not provide insights on the safety and efficacy of the same stent in patients with various clinical presentations such as non-STEACS. Another meta-analysis of 15 randomized controlled trials representing 7867 patients with follow-up from 6 months to 7 years also found a lower rate of TVR in STEMI patients treated with first generation DES compared to BMS. An interaction between ST and time was observed such that the risk of ST within the first year was similar for DES and BMS treated patients (HR 0.8, 95% CI 0.58–1.12). However, the risk of ST was higher for DES as compared to BMS during subsequent years of follow-up (HR 2.1, 95% CI 1.20–3.69) [35].

In this analysis of patients with STEMI who were treated with the R-ZES in the RAC and RINT trials, the overall ARC definite and probable ST rate at 2 years was 2.4%, all-cause mortality was 2.1%, and myocardial reinfarction was 2.7%. At the 2-year follow-up time point in the Harmonizing Outcomes with Revascularization and Stents in Acute Myocardial Infarction (HORIZONS AMI) trial, the reported rate of ST was 4.1% in patients treated with either PES or BMS for STEMI, all-cause mortality rates were 5.3% for BMS and 4.3% for PES, and the 2-year myocardial reinfarction rates were 6.0% for BMS and 5.7%

Table 3
Dual antiplatelet therapy use.

DAPT	STEMI	Non-STEACS	Stable CAD
30 days	98.2% (324/330)	97% (1366/1408)	95.1% (1194/1256)
1 year	92.3% (301/326)	90.8% (1245/1371)	87.0% (1073/1233)
2 years	30.5% (97/318)	41.5% (548/1321)	28.9% (342/1184)

DAPT consisted of aspirin plus clopidogrel or ticlopidine.

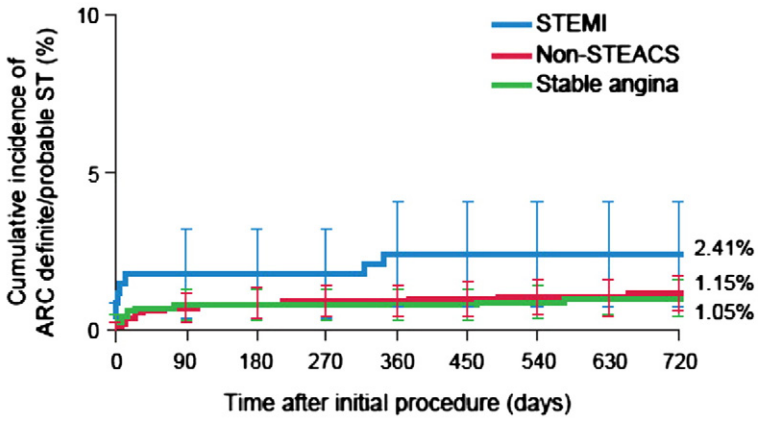
Table 4
Two year outcomes per original indication for PCI.

	STEMI	Non-STEACS	Stable CAD
N	335	1416	1260
All cause mortality			
30-day	0.6% (2/332)	0.4% (6/1412)	0.1% (1/1257)
1-year	1.2% (4/332)	2.6% (37/1405)	1.6% (20/1253)
2-year	2.1% (7/329)	4.8% (66/1387)	3.7% (46/1235)
Myocardial (re-)infarction			
30 days	1.2% (4/332)	2.9% (41/1412)	3.3% (42/1257)
1-year	1.8% (6/332)	4.2% (59/1405)	3.7% (46/1253)
2-year	2.7% (9/329)	5.0% (69/1387)	4.5% (55/1235)
ST (def/prob)			
Early (0–30 days)	1.8% (6/329)	0.6% (8/1387)	0.7% (9/1235)
Late (31–360 days)	0.6 (2/329)	0.4% (5/1387)	0.2% (2/1235)
Very late (361–720 days)	0% (0/329)	0.2% (3/1387)	0.2% (2/1235)
2-year	2.4 (8/329)	1.2% (16/1387)	1.1% (13/1235)
Clinically driven TVR			
0–360 days	6.6% (22/332)	4.2% (59/1405)	4.4% (55/1253)
361–720 days*	0.3% (1/329)	2.6% (36/1387)	2.5% (31/1235)
2-year	7.0% (23/329)	6.8% (95/1387)	7.0% (86/1235)
Death or target vessel re-infarction			
30–720 days**	2.1% (7/329)	5.6% (77/1387)	4.0% (49/1235)
Stroke or TIA at 1 year	0.0% (0/329)	0.8% (11/1389)	0.8% (10/1245)

ARC, Academic Research Consortium; ST, stent thrombosis; TIA, transient ischaemic attack; and TVR, target vessel revascularization.

* $P = 0.016$.

** $P = 0.012$, all other comparisons are non-significant across the 3 groups.



STEMI									
at risk	335	332	325	324	323	321	315	315	314
% CI	0.30	1.80	1.80	1.80	2.41	2.41	2.41	2.41	2.41
Non-STEACS									
at risk	1416	1414	1387	1375	1367	1357	1332	1323	1318
% CI	0.14	0.71	0.85	0.92	0.92	1.00	1.07	1.07	1.15
Stable angina									
at risk	1260	1257	1239	1233	1228	1214	1198	1188	1183
% CI	0.24	0.80	0.80	0.80	0.80	0.80	0.88	1.05	1.05

Fig. 1. Kaplan–Meier estimates of the cumulative incidence of ARC definite or probable stent thrombosis through 720 days.

for PES [28]. In the Single High Dose Bolus Tirofiban and Sirolimus Eluting Stent vs. Abciximab and Bare Metal Stent in Myocardial Infarction (STRATEGY) trial of STEMI patients treated with a sirolimus-eluting stent (SES) or BMS, ARC definite and probable ST rates between 30 and 720 days were also higher (1.1% for SES, and 2.2% for BMS) than observed in our analysis for R-ZES over the same length of follow-up [29]. These observations are supportive of the hypothesis that R-ZES is not associated with an increased risk of ST in patients with STEMI, but definitive conclusions cannot be drawn from such cross-trial comparisons.

Patients with ACS are generally considered at higher risk of subsequent clinical events after PCI, but some evidence suggests that this risk is related to factors other than the ACS presentation. In an analysis of 1923 patients undergoing PCI (n = 970 elective and n = 953 ACS), ACS was a univariate predictor of mortality with follow-up to 4 years. After multivariate adjustment, only age and renal impairment remained significant predictors of long-term mortality, suggesting that an ACS may not be the driver of mortality after PCI [36]. However, ACS patients do appear to be at higher risk of ST following PCI compared to patients with chronic, stable angina. Patients with either non-STEACS or STEMI had a higher propensity-score adjusted rate of any ST as compared to patients with SA in an analysis of 5816 consecutive patients (3485 with ACS) undergoing PCI who were followed for almost 4 years (propensity score adjusted HR for non-STEACS vs. SA 2.58, 95% CI 1.52–4.39; STEMI vs. SA HR 3.10, 95% CI 1.80–5.34) [37]. STEMI and non-STEACS were independent predictors of any ST. Approximately 60% of patients received either an SES or PES. The risk of ST among ACS patients was observed in patients treated with either DES or BMS, although the majority of very late ST events occurred in patients who received a DES. BMS was independently associated with a lower risk of very late ST [37].

The findings of this analysis do not suggest an increased risk of very late ST in STEMI or non-STEACS patients treated with R-ZES. This observation may be related to an improved safety profile of second generation DES as compared to first generation DES, where the majority of data demonstrating an increased risk of very late ST exists.

Study limitations

This study is a post-hoc analysis of pooled data from 2 studies. However, the studies used a similar design, process for data collection, and endpoint definitions. Differences in baseline characteristics, risk factors, and comorbidities were observed across the groups of STEMI, non-STEACS, and SA, and these differences could have influenced the study outcomes. These data include follow-up to 2 years. It is possible that ST events may have accrued beyond this time point, and continued evaluation of these data will be important to confirm the observed safety of R-ZES in patients with STEMI.

Conclusions

The implantation of R-ZES in the acute phase of STEMI as well as in other clinical presentations is effective and safe. The long term outcomes are also favorable. Late and very late ST are extremely rare irrespective of the initial presentation.

Acknowledgments

Preparation of this manuscript was partially supported by the Charles University research project UNCE nr. 204010. Editorial support was provided by Colleen Gilbert, PharmD an employee of Medtronic and Wendy Gattis Stough, PharmD. Statistical analysis support was provided by Minglei Liu, PhD and Yun Peng PhD, both employees of Medtronic.

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