ORIGINAL RESEARCH

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Does stent strut design impact clinical outcomes: comparative safety and efficacy of Endeavor Resolute versus Resolute Integrity zotarolimus-eluting stents

Abstract

Purpose: Percutaneous coronary intervention is the most commonly performed method of revascularizing obstructive coronary artery disease. The impact of stent strut design on clinical outcomes remains unclear. The Endeavour Resolute (ER-ZES) and the Resolute Integrity (RI-ZES) zotarolimus-eluting stents utilize identical polymers and anti-proliferative agents, differing only in their respective strut design. This study assessed the comparative safety and efficacy of these two stents in unrestricted contemporary real-world practice.

Methods: A total of 542 patients were identified, corresponding to 340 ER-ZES and 480 RI-ZES. The primary endpoint was major adverse cardiac events (MACE) defined by a composite of death, nonfatal myocardial infarction and stroke. Secondary endpoints included post-procedural length of stay, in-stent restenosis, target lesion revascularization, target vessel revascularization, coronary artery bypass grafting and stent thrombosis.

Results: MACE occurred in 3.2% of the ER-ZES cohort and 5.0% of the RI-ZES cohort ($p=0.43$). Adjusted analysis utilizing propensity score-adjusted odds ratio for MACE, was 1.37 (95% CI 0.46-4.07, $p=0.57$). The mortality rate (0.9% ER-ZES *vs.* 1.9% RI-ZES, $p=0.59$), non-fatal MI (2.3% ER-ZES *vs.* 3.1% RI-ZES, $p=0.75$) and stroke (0.0% ER-ZES *vs.* 0.3% RI-ZES, $p=0.85$) were not different. Additionally, there was no difference in any of secondary outcomes.

Conclusions: The clinical performance and safety of both ER-ZES and RI-ZES were not statistically different, despite differences in stent strut design.

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Percutaneous coronary intervention (PCI) is the most commonly performed method of revascularizing obstructive coronary artery disease (CAD) [1]. The current state-of-the-art in coronary stenting involves modern drug-eluting stents (DES) – composed of a metallic stent backbone covered in an engineered polymer that delivers a drug, over a prescribed period, to the vessel wall. Typically, the drug component is an anti-proliferative agent, which attenuates neointimal hyperplasia and which causes in-stent restenosis (ISR) [2]. First generation DES, eluting sirolimus and paclitaxel anti-proliferative agents, offered advancements over conventional bare metal stents (BMS), though concerns regarding the safety soon followed their introduction [3,4]. Indeed, first generation DES were noted to have higher rates of stent thrombosis (ST) over the traditional BMS, which were thought to be related to impaired arterial healing at the site of implantation, thereby leading to acute thrombotic events [5,6]. Accordingly, second generation DES were developed, offering numerous advancements in strut design, elution polymers and anti-proliferative agents to mitigate the risk of ISR, ST and, ultimately, mortality [7]. While data support the importance of polymer and drug design, it remains unclear if changes in the stent struts themselves impact clinical outcomes.

Two consecutive generations of DES, which share a common polymer and drug, are the Endeavor Resolute zotarolimus-eluting stent (ER-ZES) (Medtronic Cardiovascular, Santa Rosa, California, USA) and the Resolute Integrity zotarolimus-eluting stent (RI-ZES) (Medtronic Cardiovascular, Santa Rosa, California, USA). The ER-ZES uses a cobalt chromium Driver stent platform and a proprietary biostatic and biocompatible phosphorylchlorine polymer, known as BioLinx. This polymer is composed of three polymers: a hydrophobic C10 polymer to control drug release; a polyvinyl pyrrolidone polymer to improve initial drug delivery; and, a C19 hydrophilic layer for biocompatibility. BioLinx releases 85% of zotarolimus within 60 days of stent deployment, with the remaining 15% eluted by 180 days; thereby mitigating inflammation to a greater extent than the first generation polymers [8]. The more contemporary RI-ZES employs the same BioLinx polymer but is based upon an Integrity stent platform. Both the ER-ZES and RI-ZES stent platforms are 91 μm thick chromium cobalt, while the ER-ZES has a sinusoidal “out of phase” hoop design and the RI-ZES has a helical design. The newer platform was engineered to provide superior flexibility, smoother tracking and, hence, improved deliverability [9,10,11]; however, these small changes in design have been noted to dramatically alter the response of the stent to disruptive forces [12]. Specifically, the hoops of coronary stents are

designed to provide radial support and are held together by connectors. The balance between stent flexibility and integrity is related to the configuration of hoops and connectors; thus, differences in the configurations between the ER-ZES and RI-ZES could potentially contribute to compromises in stent integrity and ultimately predispose the patient to ISR or ST [12].

The impact of stent strut design on clinical outcomes of coronary stenting remains unclear and has important clinical implications. The transition from the ER-ZES to the newer RI-ZES offered a unique opportunity to evaluate the impact of stent strut design on clinical outcomes; thus, the real-world impact of stent strut design on clinical outcomes was evaluated in our high volume cardiac centre.

Methods

Study Design, Data Source and Patients

A total of 746 patients were identified between January 1, 2012 and December 31, 2012 who had PCI performed with either stent of interest (303 patients received ER-ZES and 443 patients received RI-ZES) from the CAPITAL PCI registry [14,15]. From this initial cohort of 746 patients, a total of 1,136 stents were utilized. Exclusion criteria included patients with incomplete medical records (i.e., patients in whom index angiographic information was unavailable), those who received multiple stent types to the same coronary artery at the time of the index PCI, stents to non-native coronary arteries (i.e., to vein or arterial grafts), patients that presented with cardiac arrest or shock and/or those with previous stenting to the same vascular territory. This yielded a final sample of 542 patients (220 patients in the ER-ZES cohort and 322 patients in the RI-ZES cohort) with a total of 616 target lesions (254 treated with ER-ZES and 362 treated with RI-ZES) and 820 stents deployed (340 ER-ZES and 480 RI-ZES, Figure 1).

Procedural techniques and medications were used at the discretion of the individual operators in accordance with current clinical guidelines, including the use of intraaortic balloon pumps (IABPs), intravascular ultrasound (IVUS), fractional flow reserve (FFR) and/or optical coherence tomography (OCT). Procedural data were systematically extracted from the registry while post-procedural data were obtained from individual patient medical records. Length of stay was defined as in-hospital stay from index procedure until discharge from hospital. Following the index intervention, patients were maintained on dual antiplatelet therapy consisting of enteric-coated acetylsalicylic acid (EC-ASA) indefinitely and clopidogrel (Plavix)/ticagrelor (Brilinta)/prasugrel (Effient) for a minimum of 12 months. Review of records revealed that only one

FIGURE 1. Study Population. ER-ZES = Endeavor Resolute zotarolimus-eluting stent; RI-ZES = Resolute Integrity zotarolimus-eluting stent; multiple stent types = patients received multiple stent types at time of index PCI; stent for TLR/TVR = study stent deployed for target lesion revascularization or target vessel revascularization in a vascular territory where previous non-study stents have been utilized; wastage = stent was not deployed

patient discontinued their EC-ASA during the follow-up period. This study was approved by and conducted in accordance with the guidelines set out by The Ottawa Hospital Human Research Ethics Board.

Outcome Measures and Definitions

The follow-up period extended from the time of index procedure until the last available clinical evaluation on our institutional electronic medical record as of December 31, 2013. Our primary endpoint was the evaluation of major adverse cardiac events (MACE), as defined by a composite of all-cause death, nonfatal myocardial infarction (MI), and cerebrovascular accident (CVA). MI was defined as recurrent chest pain associated with ST segment or T wave changes and re-elevation of cardiac enzymes (twice the upper limit of the normal range) or angiographic documentation of reocclusion of the infarct-related

artery. CVA was defined as either ischemic or hemorrhagic stroke resulting in a new neurologic deficit of >24 hours' duration as diagnosed by a treating neurologist. Secondary endpoints included post-procedural length of stay, clinical ISR (defined as clinically driven repeat revascularization with angiographic evidence of >50% stenosis at site of stent deployment), target lesion revascularization (TLR), target vessel revascularization (TVR) and ST, all of which were defined by the Academic Research Consortium [16]. Coronary artery bypass grafting (CABG) was also a secondary endpoint defined as the need for revascularization via cardiac surgery post-index PCI.

Statistical Analyses

All continuous variables were described as mean ($\pm$ standard deviation) or median (interquartile range) with categorical variables described as number (%). For the composite end

TABLE 1. Baseline clinical characteristics

	ER-ZES (n=220)	RI-ZES (n=322)	p value
Age – years (SD)	63.5 (11.7)	64.2 (12.5)	0.57
Males – no. (%)	157 (71.4)	237 (73.6)	0.63
Hypertension – no. (%)	140 (63.6)	200 (62.1)	0.79
Diabetes Mellitus – no. (%)	64 (29.1)	113 (35.1)	0.17
Dyslipidemia – no. (%)	141 (64.1)	224 (69.6)	0.21
Smoking – no. (%)	94 (42.7)	153 (47.5)	0.31
Family history of premature CAD* – no. (%)	39 (17.7)	63 (19.6)	0.67
Cardiovascular history – no. (%)			
MI†	28 (12.7)	59 (18.3)	0.10
CABG‡	10 (4.5)	21 (6.5)	0.43
PCI§	41 (18.6)	54 (16.8)	0.66
Stroke	12 (5.5)	14 (4.3)	0.70
Valve surgery	0 (0.0)	4 (1.2)	0.25
Renal function – GFR (SD)	105.2 (48.1)	104.2 (51.8)	0.68
BMI¶ – kg/m ² (SD)	28.6 (5.4)	28.9 (5.5)	0.46
Pre-procedure medications – no. (%)			
ACEI/ARB	145 (65.9)	191 (59.3)	0.14
Beta-blocker	153 (69.5)	235 (73.0)	0.44
Statin	186 (84.5)	291 (90.4)	0.06
ASA	208 (94.5)	309 (96.0)	0.57
Plavix	185 (84.1)	275 (85.4)	0.77
Ticagrelor	31 (14.1)	40 (12.4)	0.66
Prasugrel	1 (0.5)	5 (1.6)	0.43
GP IIb/IIIa inhibitors	3 (1.4)	6 (1.9)	0.92
Thrombolytics	14 (6.4)	18 (5.6)	0.85
Heparin	219 (99.5)	322 (100)	0.85
Bivalirudin	202 (91.8)	296 (91.9)	0.91
Indication for PCI – no. (%)			
Stable/elective	65 (29.5)	105 (32.6)	0.51
Unstable angina/NSTEMI**	102 (46.4)	151 (46.9)	0.97
STEMI††	53 (24.1)	66 (20.5)	0.38

*CAD- coronary artery disease; †MI- myocardial infarction;

‡CABG- coronary artery bypass graft; §PCI- percutaneous coronary intervention; ¶BMI- body mass index; ||ACEI/ARB- angiotensin converting enzyme inhibitor/angiotensin receptor blocker;

**NSTEMI – non-ST elevation myocardial infarction; ††STEMI – ST elevation myocardial infarction

point, all components are also reported individually. For patient and procedural characteristics, categorical variables were compared by Chi-square testing and continuous variables by analysis of variance or Mann-Whitney Rank Sum test. For adjusted analysis of the primary composite outcome, MACE, propensity score adjusted odds ratio (OR) was performed with 95% CI and the adjusted p value reported. Propensity score adjusted OR was also calculated for secondary outcomes. Independent variables demonstrating a $p < 0.05$, as well as clinically-relevant variables, were retained in the final adjusted models. All analyses were performed using SAS (SAS Institute Inc., North Carolina, USA).

Results

Population and Baseline Clinical Characteristics

From January 1, 2012 and December 31, 2012, 746 consecutive patients who received either the ER-ZES or RI-ZES were identified in the CAPITAL PCI registry (Figure 1). After exclusions, a final sample size of 542 patients (220 patients in the ER-ZES cohort and 322 patients in the RI-ZES cohort) with a total of 616 target lesions (254 treated with ER-ZES and 362 treated with RI-ZES) and 820 stents (340 ER-ZES and 480 RI-ZES) were included in the study. Between the RI-ZES and ER-ZES cohorts, the baseline clinical characteristics were similar (Table 1). Indications for angiography ranged from those with acute coronary syndrome (ACS), defined as those patients being evaluated for ST- elevation myocardial infarction (STEMI) (ER-ZES 24.1% *vs.* RI-ZES 20.5%, $p=0.38$) or non-ST-elevation MI (NSTEMI)/unstable angina (UA) (ER-ZES 46.4% *vs.* RI-ZES 46.9%, $p=0.97$), to those with stable angina with or without high risk noninvasive imaging (ER-ZES 29.5% *vs.* RI-ZES 32.6%, $p=0.51$).

Angiographic and Procedural Characteristics

Baseline angiographic characteristics were described on a per lesion basis (Table 2). Of these variables, the length of the procedure was slightly longer in the RI-ZES cohort (55.6 ± 24.8 min *vs.* 51.8 ± 22.8 min, $p=0.04$). There were more interventions to the left circumflex territory in the ER-ZES group (29.9% *vs.* 21.0%, $p=0.02$). Additionally, the mean values of total stent length (26.3 ± 13.7 mm *vs.* 29.1 ± 16.1 mm, $p=0.03$), maximum pressure of stent deployment (15.4 ± 2.7 mmHg *vs.* 16.1 ± 2.6 mmHg, $p=0.01$), maximum post-deployment dilatation diameter (3.1 ± 0.5 mm *vs.* 3.2 ± 0.5 mm, $p<0.01$) and maximum post-deployment dilatation pressure (18.5 ± 3.0 mmHg *vs.* 19.2 ± 3.8 mmHg, $p=0.02$) also differed between the ER-ZES and RI-ZES cohorts, respec-

TABLE 2. Lesion angiographic characteristics

	ER-ZES (n=254)	RI-ZES (n=362)	p value
Target Lesion – no. (%)			
Left main	4 (1.6)	11 (3.0)	0.37
LAD*	84 (33.1)	137 (37.8)	0.26
LCx†	76 (29.9)	76 (21.0)	0.02
RCA‡	64 (25.2)	96 (26.5)	0.78
Bifurcations lesions	26 (10.2)	42 (11.6)	0.69
Bifurcation lesions – no. (%)	15 (5.9)	27 (7.5)	0.56
Medina classification			
0,0,0	0 (0.0)	0 (0.0)	1.00
0,0,1	1 (6.7)	0 (0.0)	0.86
0,1,0	0 (0.0)	0 (0.0)	1.00
0,1,1	0 (0.0)	2 (7.4)	0.64
1,0,0	2 (13.3)	0 (0.0)	0.33
1,0,1	1 (6.7)	0 (0.0)	0.86
1,1,0	4 (26.7)	5 (18.5)	0.89
1,1,1	7 (46.7)	20 (74.1)	0.18
Stenting technique			
Provisional	10 (66.7)	22 (81.5)	0.32
T-stent	4 (26.7)	3 (11.1)	0.64
Culotte	0 (0.0)	2 (7.4)	0.64
Mini crush	1 (6.7)	0 (0.0)	0.86
Side branch flow			
TIMI 0	0 (0.0)	1 (3.7)	0.86
TIMI 1	0 (0.0)	1 (3.7)	0.86
TIMI 2	1 (6.7)	2 (7.4)	0.76
TIMI 3	14 (93.3)	23 (85.2)	0.79
TIMI flow pre-PCI – no. (%)			
0	32 (12.6)	47 (13.0)	0.99
1	7 (2.8)	16 (4.4)	0.39
2	35 (13.8)	41 (11.3)	0.43
3	173 (68.1)	241 (66.6)	0.76
TIMI flow post-PCI – no. (%)			
0	0 (0.0)	0 (0.0)	1.00
1	1 (0.4)	0 (0.0)	0.86
2	1 (0.4)	2 (0.6)	0.76
3	245 (96.5)	342 (94.5)	0.34
ACC/AHA risk – no. (%)			
Low	4 (1.6)	3 (0.8)	0.64
Moderate	128 (50.4)	177 (48.9)	0.78
High	122 (48.0)	182 (50.3)	0.64
Procedure Time – min (SD)	51.8 (22.8)	55.6 (24.8)	0.04
Fluoroscopy Time – min (SD)	13.5 (7.2)	14.8 (8.7)	0.14
Volume of contrast – mL (SD)	236.9 (85.2)	248.9 (95.3)	0.19
IVUS§ – no. (%)	3 (1.2)	9 (2.5)	0.39
FFR¶ – no. (%)	9 (3.5)	9 (2.5)	0.60
IABP – no. (%)	0 (0.0)	2 (0.6)	0.64
Study stents deployed – no. (SD)	1.3 (0.9)	1.3 (0.6)	0.61
Total length of stents – mm (SD)	26.3 (13.7)	29.1 (16.1)	0.03
Max. stent diameter – mm (SD)	2.8 (0.4)	3.0 (1.5)	0.06
Max. pressure of stent deployment – mmHg (SD)	15.4 (2.7)	16.1 (2.6)	0.01
Max. post-deployment dilatation diameter – mm (SD)	3.1 (0.5)	3.2 (0.5)	<0.01
Max. post-deployment dilatation pressure – mmHg (SD)	18.5 (3.0)	19.2 (3.8)	0.02
Chronic Total Occlusion – no. (%)	3 (1.2)	7 (1.9)	0.69
Other methods of revascularization – no. (%)			
Rotablator	2 (0.8)	3 (0.8)	0.69
Thrombectomy	28 (11.0)	35 (9.7)	0.68
Dissection – no. (%)	4 (1.6)	4 (1.1)	0.88

*LAD-left anterior descending; †LCx- left circumflex; ‡RCA-right coronary artery; §IVUS- intravascular ultrasound; ¶FFR- fractional flow reserve; ||IABP- intraaortic balloon pump

FIGURE 2. Comparable outcomes between Endeavor Resolute (ER-ZES) and Resolute Integrity (RI-ZES). Propensity score-adjusted odds ratios demonstrated no differences in MACE (composite of all-cause death, nonfatal myocardial infarction and cerebrovascular accident), ISR (in stent restenosis), TLR (target lesion revascularization) or TVR (target vessel revascularization).

TABLE 3. Unadjusted clinical outcomes

	ER-ZES (n=220)	RI-ZES (n=322)	p value
Length of stay – days (SD)	2.54 (3.6)	3.96 (7.7)	0.08
MACE* – no (%)	7 (3.2)	16 (5.0)	0.43
MI†	5 (2.3)	10 (3.1)	0.75
Stroke	0 (0.0)	1 (0.3)	0.85
Death	2 (0.9)	6 (1.9)	0.59
CABG‡	2 (0.9)	7 (2.2)	0.43
Median follow up – days (IQR)§	262 (85-408.5)	272 (61-447)	0.22

*MACE- major adverse cardiac events defined as a composite of myocardial infarction, stroke and death; †MI-myocardial infarction; ‡CABG- coronary artery bypass graft; §IQR- interquartile range

TABLE 4. Unadjusted lesion outcomes

	ER-ZES (n=254)	RI-ZES (n=362)	p value
ISR* – no (%)	7 (2.8)	17 (4.7)	0.31
TLR† – no (%)	10 (3.9)	22 (6.1)	0.32
TVR‡ – no (%)	13 (5.1)	27 (7.5)	0.32
ST§ – no (%)	2 (0.8)	2 (0.6)	0.88

*ISR- in-stent restenosis; †TLR- target lesion revascularization; ‡TVR- target vessel revascularization; §ST- stent thrombosis

tively.

Clinical Outcomes

The incidence of MACE was similar between the ER-ZES and the RI-ZES cohorts suggesting no impact of the differing stent design on safety (3.2% *vs.* 5.0%, $p=0.43$, Table 3). Importantly, there were no differences in post-procedural length of stay or time to last-known follow-up. On a per lesion basis, the rates of ISR, TLR, TVR and ST were consistent with expected incidences and no significant differences between the outcomes were observed (Table 3).

To adjust for confounders of our primary and important secondary outcomes, a propensity score adjusted analysis was performed. The odds ratios (OR) for the adjusted analysis are shown in Figure 2. As in the unadjusted analyses, our primary composite outcome of MACE was not different between the cohorts (1.37, 95% CI 0.46 – 4.07, $p=0.57$). There was also no difference in any secondary outcomes, including ISR (1.37, 95% CI 0.53 – 3.54, $p=0.52$), TLR (1.38, 95% CI 0.59 – 3.20, $p=0.46$) and TVR (1.31, 95% CI 0.62 – 2.74, $p=0.48$). Adjusted ORs for ST could not be calculated as the incidence of this outcome was too sparse for analysis (ER-ZES 0.8% *vs.* RI-ZES 0.6%, $p=0.88$ with unadjusted analysis).

Discussion

The current study sought to evaluate the impact of stent design on clinical outcomes. The transition from the ER-ZES to the RI-ZES offered a unique opportunity to evaluate this impact, as these stents share an identical zotarolimus drug and BioLinX polymer, differing only in their respective stent platforms [8]. No significant differences in clinical outcomes were seen between patients treated with the ER-ZES and those treated with the RI-ZES platform. Moreover, when analyzed on a per lesion basis, the rates of ISR, TLR and TVR did not differ between the stent platforms, consistent with the analysis of clinical outcomes. Thus, the findings of this analysis suggest comparable safety and efficacy with the ER-ZES and RI-ZES and infer that modifications to stent platform design likely do not translate into differences in clinical outcomes.

To date only a single study has performed a similar analysis using a metallic DES platform. In their report, Ishikawa *et al.* [13] compared outcomes between the TAXUS Liberte and TAXUS Express stent platform, finding no differences in either patient outcomes or in the incidence of binary ISR. Similar to our study, the difference in the platforms was solely in stent design, with the Liberte stent having a thinner strut and greater spacing to improve homogeneity of drug delivery. While small

imaging-based studies suggested that neointima inhibition with the Liberte platform may be greater when evaluated by IVUS and OCT, these findings have failed to translate into improved clinical outcomes [17,18]. Indeed, although admittedly underpowered, the TAXUS ATLAS trial demonstrated that the Liberte did not prove to be inferior to the TAXUS Express, with nearly identical 9-month MACE rates. Our data now corroborates these findings in a second metallic based DES, showing no differences in clinical outcomes or in clinical effectiveness between the ER-ZES and the RI-ZES systems.

Admittedly, differences between the aforementioned stent platforms are small and important clinical differences owing to differences in stent design may yet exist. To date, findings from two studies have supported the importance of stent strut thickness on clinical outcomes. First, in the ISAR STEREO study, native coronary lesions were stented with either the ACS Rx Multi-Link stent (strut thickness 50 μm) or the ACS Multi-Link RX Duet (strut thickness 140 μm), resulting in a reduction in angiographic restenosis from 25.8% to 15.0% [19]. Second, in the ISAR-STEREO-2 trial, two platforms were tested that had identical designs but differed only in strut thickness [20]. There are two important caveats to these studies: the findings seem to be restricted to studies of BMS in the absence of a polymer/drug combination; and, hard clinical outcomes were not different in either of the studies performed. Thus, to date, only evidence from BMS studies support the hypothesis that stent design is important and our study adds to the concept that, with modern polymers and anti-proliferative agents, the design of metallic stent scaffolds may not be important.

Certainly, this study is not without limitations. First, the selection of patients and stents was not prospectively randomized and is therefore subject to the inherent limitations of a retrospective analysis. While baseline clinical characteristics did not differ between cohorts, specific procedural and technical factors, although unlikely, may have influenced the choice of stent employed; however, clinically the ER-ZES and RI-ZES represent sequential generation of devices and it is unlikely that one device would be preferentially selected over the other. Second, the follow-up period for the current cohort was out to one year and, therefore, very late ST or ISR beyond this period may not be accounted for; however, we previously reported no ST beyond one year with up to three years of follow-up, making significant differences beyond this point unlikely [21]. Furthermore, while this study included all available patients, the sample size was limited and this study is underpowered to detect small but perhaps still clinically significant differences. Last, there are numerous patient and procedural factors that

may influence outcomes following PCI. To account for the differences in baseline clinical and angiographic characteristics, we performed a propensity adjusted analysis and found no differences in the adjusted odds-ratios the primary and important secondary outcomes. Thus, it is unlikely that these potential confounders impacted the outcome of the analysis.

Conclusion

Both ER-ZES and RI-ZES demonstrated excellent clinical performance and safety in a real-world cohort. No differences in major adverse cardiac events or secondary outcomes were identified. In this setting, stent strut design does not appear to significantly influence clinical safety or performance.

Conflicts of Interest

Dr. Christopher Glover is a proctor for the Medtronic TAVI program. No other conflicts of interest to declare.

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