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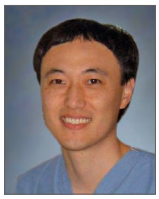
Orbital atherectomy treatment of severely calcified coronary lesions in patients with impaired left ventricular ejection fraction: one-year outcomes from the ORBIT II study



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KEYWORDS

- atherectomy
- calcified stenosis
- depressed left ventricular function

Abstract

Aims: Percutaneous coronary intervention (PCI) of severe coronary artery calcification (CAC) is challenging. The ORBIT II study demonstrated the safety and efficacy of orbital atherectomy (OA) in patients with severe CAC. Microparticulate liberated during OA may disturb the coronary microcirculation. In the present study, we evaluated OA treatment in patients with left ventricular systolic dysfunction.

Methods and results: Patients were grouped by left ventricular ejection fraction (LVEF): 26-40% (n=33), 41-50% (n=90), and >50% (n=314). Procedural success was similar (LVEF 26-40%: 90.9%, LVEF 41-50%: 88.9%, LVEF >50%: 88.4%). Rates of major adverse cardiac events (MACE), defined as cardiac death, myocardial infarction, and target vessel revascularisation, were similar in the LVEF 26-40%, 41-50%, and >50% groups, respectively, at 30 days (9.1%, 7.8%, 11.5%) and one year (18.2%, 19.1%, 16.0%). Although the 30-day cardiac death rate was 0% in patients with left ventricular dysfunction, one-year cardiac death was higher compared with patients with preserved left ventricular systolic function.

Conclusions: No patient with left ventricular systolic dysfunction experienced cardiac death at 30 days suggesting that OA was well tolerated without haemodynamic complication. However, one-year cardiac death was higher in patients with left ventricular systolic dysfunction, consistent with previous studies demonstrating the association between reduced left ventricular function and increased mortality after PCI. ClinicalTrials.gov Identifier: NCT01092416

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Abbreviations

ACC/AHA	American College of Cardiology/American Heart Association
CABG	coronary artery bypass grafting
CAC	coronary artery calcification
eGFR	estimated glomerular filtration rate
IMR	index of microcirculatory resistance
IVUS	intravascular ultrasound
LVEF	left ventricular ejection fraction
MACE	major adverse cardiac events
MI	myocardial infarction
OA	orbital atherectomy
OAS	orbital atherectomy system
PCI	percutaneous coronary intervention
RA	rotational atherectomy
TLR	target lesion revascularisation
TVR	target vessel revascularisation

Introduction

Severe coronary artery calcification (CAC) is present in 5.9% to 20% of patients undergoing percutaneous coronary intervention (PCI)[1,2]. Despite advances in interventional equipment and techniques, treating severe CAC remains a challenge, as it is associated with adverse outcomes including restenosis, target lesion revascularisation (TLR), vessel dissection, failure to deliver a stent or asymmetric stent expansion, balloon ruptures, undilatable lesions, death, and myocardial infarction (MI)[3-11]. Suboptimal stent expansion may increase the likelihood of stent thrombosis and restenosis[12]. Coronary artery rupture may occur due to repeated high-pressure inflations to ensure complete stent expansion[13]. Additionally, long-term ischaemic outcomes are significantly worse for patients with severely calcified coronary lesions compared to non-calcified lesions[1,2]. Patients with a low left ventricular ejection fraction (LVEF) have an increased risk of adverse events after PCI, including death[14-16].

The ORBIT II study evaluated the safety and efficacy of the Diamondback 360® Coronary Orbital Atherectomy System (OAS) (Cardiovascular Systems, Inc., St. Paul, MN, USA) in preparing *de novo*, severely calcified coronary lesions for stent placement and is the largest clinical study to date reporting exclusively on patients with severely calcified lesions. Major findings in the ORBIT II study included successful stent delivery in 97.7% of patients, residual stenosis of <50% observed in 98.6% of patients, and low rates of angiographic complications[17]. Adverse event rates up to one-year follow-up, including non-Q-wave and Q-wave MI, TLR, and death, were also much lower compared with prior studies evaluating severely calcified coronary lesions[17,18]. Although the OAS is a safe option for difficult-to-treat patients with various comorbidities, its performance in patients with left ventricular systolic dysfunction has not been studied[17]. We investigated the impact of left ventricular systolic dysfunction on clinical outcomes in patients with severe CAC who underwent orbital atherectomy.

Materials and methods

STUDY DESIGN AND PATIENTS

The FDA mandated that ORBIT II be completed as a single-arm study since no comparable devices were approved for use in severely calcified coronary arteries in the USA. Details about the ORBIT II study design have been published previously[17,18]. Men and women, at least 18 years of age, with a *de novo*, severely calcified coronary lesion in a native coronary artery were enrolled in the study. Key inclusion criteria included: 1) target vessel reference diameter ≥2.5 mm and ≤4.0 mm with 70% to <100% stenosis or 50%-70% stenosis with evidence of clinical ischaemia; 2) target lesion length no longer than 40 mm; and 3) fluoroscopic or intravascular ultrasound (IVUS) evidence of severe calcium deposit at the lesion site. Severe calcium was defined as the angiographic presence of radiopacities noted without cardiac motion prior to contrast injection involving both sides of the arterial wall in at least one location and total length of calcium of at least 15 mm and extending partially into the target lesion, or the presence of ≥270° of calcium at one cross-section via IVUS. Key exclusion criteria included: 1) target vessel had a stent from previous PCI; 2) angiographically confirmed evidence of more than one lesion requiring intervention, unless the treatment of the lesions was staged; 3) target vessel was excessively tortuous; 4) patient had a recent MI (defined as CK-MB >1x upper limit of lab normal) within one month prior to procedure; 5) evidence of current LVEF ≤25% (where current was defined as the latest LVEF measurement completed within the last six months); and 6) NYHA Class III or IV heart failure. Only one target lesion was treated per subject. The operational treatment time was limited to five minutes per device, and each individual treatment interval was limited to 30±3 seconds. After the plaque modification, stent implantation was required.

The clinical study was conducted in the USA as per Good Clinical Practice and the applicable Code of Federal Regulations, and was approved by each institutional review committee. Subanalyses were performed for patients in three LVEF subgroups (LVEF 26-40%, 41-50%, and >50%).

DEVICE DESCRIPTION

The Coronary Orbital Atherectomy System is a percutaneous device designed to reduce severely calcified plaque prior to stent deployment **(Figure 1)**. The eccentrically mounted diamond-coated crown sands the plaque while rotating over the ViperWire Advance® Coronary Guidewire (Cardiovascular Systems, Inc.) to restore lumen patency. The crown's orbital diameter expands radially via centrifugal force, and an increase in rotational speed allows an increase in luminal gain. The soft tissue flexes away from the crown while the hard/calcified component of the plaque is reduced with each pass of the crown **(Moving image 1)**.

ENDPOINTS

The primary safety endpoint was major adverse cardiac events (MACE) at 30 days. MACE was defined as comprising cardiac

Figure 1. *Diamondback 360 Coronary Orbital Atherectomy System (OAS) device. Coronary OAS device handle and 1.25 mm classic crown.*

death, MI, and target vessel revascularisation (TVR). Myocardial infarction was defined as creatine kinase-myocardial band level >3x the upper limit of normal with or without a new pathologic Q-wave. Target vessel revascularisation was defined as any repeat revascularisation of the target vessel (inclusive of the target lesion) after completion of the index procedure. Procedural success was defined as success in facilitating stent delivery with a final residual stenosis of <50% and without in-hospital MACE. Angiographic success was defined as success in facilitating stent delivery with a residual stenosis of <50% and without the occurrence of a severe angiographic complication. An independent clinical events committee adjudicated adverse events and severe angiographic complications including persistent slow flow/no reflow and abrupt closure. An angiographic core laboratory (Cleveland Clinic Foundation, Cleveland, OH, USA) performed quantitative coronary analysis on procedural angiograms and reported minimum lumen diameter, final percent residual stenosis, as well as the presence and type of dissections and perforations.

STATISTICAL ANALYSIS

Statistical analyses were performed with either the SAS software system (SAS Institute Inc., Cary, NC, USA) or R (R Core Team-2012 [R: A language and environment for statistical computing; R Foundation for Statistical Computing, Vienna, Austria. ISBN 3-900051-07-0, URL http://www.R-project.org/]).

Patient demographics, medical history, risk factors, pre- and post-procedure lesion characteristics, procedure characteristics, and outcome variables were summarised using descriptive statistics for continuous variables presented as mean±standard error and frequency tables or proportions for discrete variables. Data were compared using the Wilcoxon rank-sum test for continuous parameters and Fisher's exact test for categorical parameters. Kaplan-Meier methods were used to obtain estimates of the 30-day and one-year event rates; p-values were calculated using Cox proportional hazards models. A multivariable Cox proportional hazards regression model was fit to assess the relationship of LVEF and one-year cardiac death after adjusting for other baseline covariates. The baseline covariates included in the model were: history of coronary artery bypass grafting (CABG), gender, history of diabetes, and history of MI.

Results

PATIENT DEMOGRAPHICS AND LESION CHARACTERISTICS

The ORBIT II study population comprised 443 patients enrolled at 49 sites. Approximately 99% (437/443) of ORBIT II patients had LVEF assessed at baseline. Patients were grouped by LVEF: 26-40% (n=33), 41-50% (n=90), and >50% (n=314) **(Table 1)**. Patients with left ventricular systolic dysfunction

Table 1. Baseline patient characteristics.

	LVEF 26-40% (n=33)	LVEF 41-50% (n=90)	LVEF >50% (n=314)	*p*-value
Mean age (years)	71.3±1.9	71.7±1.1	71.3±0.5	0.79
Female gender	5/33 (15.2)	22/90 (24.4)	126/314 (40.1)	0.0008
eGFR (mL/min/1.73 m^2)	78.3±6.2	73.4±2.6 (n=89)	76.1±1.4 (n=313)	0.82
Clinical history				
Diabetes mellitus	14/33 (42.4)	42/90 (46.7)	104/314 (33.1)	<0.05
Dyslipidaemia	29/33 (87.9)	83/89 (93.3)	290/314 (92.4)	0.56
Hypertension	30/33 (90.9)	82/90 (91.1)	288/314 (91.7)	0.88
Stroke/transient ischaemic attack	3/33 (9.1)	9/90 (10.0)	26/313 (8.3)	0.81
Myocardial infarction	17/32 (53.1)	33/88 (37.5)	48/312 (15.4)	<0.0001
CABG	11/33 (33.3)	16/90 (17.8)	37/314 (11.8)	0.005
Angina	24/33 (72.7)	72/90 (80.0)	247/314 (78.7)	0.65
Smoker (current or former)	25/33 (75.8)	67/90 (74.4)	197/314 (62.7)	0.06

Values are n/N (%) or mean±standard error. CABG: coronary artery bypass grafting; eGFR: estimated glomerular filtration rate; LVEF: left ventricular ejection fraction

were more likely to be male (p=0.0008) had a higher prevalence of diabetes mellitus (p<0.05), history of MI (p<0.0001), and history of prior CABG (p=0.005). No significant differences in vessel and lesion characteristics were noted among the LVEF subgroups **(Table 2)**.

PROCEDURAL RESULTS

Procedural success was similar in LVEF subgroups (LVEF 26-40%: 90.9%, LVEF 41-50%: 88.9%, LVEF >50%: 88.4%; p=1.0). No significant differences in overall procedural results **(Table 3, Table 4)** were observed among the LVEF subgroups.

SAFETY

The in-hospital and 30-day MACE rates were similar in the LVEF subgroups **(Table 5)**. The Kaplan-Meier estimates of one-year major adverse cardiac events (MACE) are shown in **Figure 2.** The MACE rate at one year was similar among the LVEF subgroups (p=0.83) **(Figure 2A)**, as was MI (p=0.55) **(Figure 2C)**, and target vessel revascularisation (p=0.70) **(Figure 2D)**. However, cardiac death was increased in patients with left ventricular systolic dysfunction, with a stepwise increase in mortality with lower LVEF (LVEF >50%: 1.6%, LVEF 41-50%: 6.9%, LVEF 26-40%: 9.1%, p=0.02) **(Figure 2B)**. The results of the multivariable model

Table 2. Vessel and lesion characteristics.

		LVEF 26-40%	LVEF 41-50%	LVEF >50%	*p*-value
Subjects with OAS inserted, n		33	90	311	
Target lesion vessel	Left anterior descending artery	15/33 (45.5)	44/90 (48.9)	166/311 (53.4)	0.35
	Left circumflex artery	5/33 (15.2)	13/90 (14.4)	43/311 (13.8)	
	Left main artery	3/33 (9.1)	3/90 (3.3)	4/311 (1.3)	
	Right coronary artery	10/33 (30.3)	28/90 (31.1)	93/311 (29.9)	
	Ramus	0/33 (0.0)	2/90 (2.2)	5/311 (1.6)	
ACC/AHA lesion classification	Type A	0/33 (0.0)	0/90 (0.0)	0/311 (0.0)	0.15
	Type B1	6/33 (18.2)	25/90 (27.8)	82/311 (26.4)	
	Type B2	12/33 (36.4)	38/90 (42.2)	144/311 (46.3)	
	Type C	15/33 (45.5)	27/90 (30.0)	85/311 (27.3)	
Mean lesion length (mm)		19.4±1.8	18.8±1.0	19.0±0.5	0.86
Mean percent stenosis		86.3±1.7	84.9±0.9	84.2±0.5	0.38
Mean reference vessel diameter (mm)		3.1±0.1	3.1±0.1	3.1±0.1	0.34
Mean minimum lumen diameter (mm)		0.4±0.1	0.5±0.0	0.5±0.0	0.47
Number of subjects with calcification determined by angiography only		33/33 (100.0)	85/90 (94.4)	282/311 (90.7)	0.12
Total length of calcium (including segmented) (mm)		27.2±3.2	27.9±1.6	29.0±0.9	0.35
Number of subjects with calcium visible on both sides of vessel		33/33 (100.0)	85/85 (100.0)	282/282 (100.0)	
Subjects with calcification determined by IVUS		0/33 (0.0)	5/90 (5.6)	29/311 (9.3)	0.12
Maximum degree of calcium via IVUS (°)		–	318.0±18.0	291.2±6.6	0.07

Values are n/N (%) or mean±standard error unless otherwise indicated. ACC/AHA: American College of Cardiology/American Heart Association; IVUS: intravascular ultrasound; LVEF: left ventricular ejection fraction; OAS: Orbital Atherectomy System

Table 3. Overall procedural results.

	LVEF 26-40%	LVEF 41-50%	LVEF >50%	*p*-value
Subjects where OAS was inserted, n	33	90	311	
Subjects treated with OAS, n	32	86	308	
Post-OAS minimum lumen diameter (mm)	1.1±0.1	1.3±0.1	1.3±0.0	0.25
Post-OAS residual stenosis	64.8±3.3	59.2±2.0	58.0±1.0	0.15
Subjects treated with post-OAS/pre-stent balloon dilations	19/33 (57.6)	41/90 (45.6)	119/311 (38.3)	0.07
Maximum inflation pressure (atm)	13.0±0.7 (n=18)	12.0±0.6 (n=41)	11.9±0.4 (n=119)	0.39
Mean post-OAS balloon angioplasty residual stenosis	40.3±4.5 (n=19)	42.9±3.8 (n=41)	42.8±1.8 (n=117)	0.83
Subjects with stent placed	33/33 (100.0)	85/90 (94.4)	308/311 (99.0)	0.03
Post-OAS stents used per subject	1.5±0.2	1.2±0.1	1.2±0.0	0.35

Values are n/N (%) or mean±standard error. LVEF: left ventricular ejection fraction; OAS: Orbital Atherectomy System

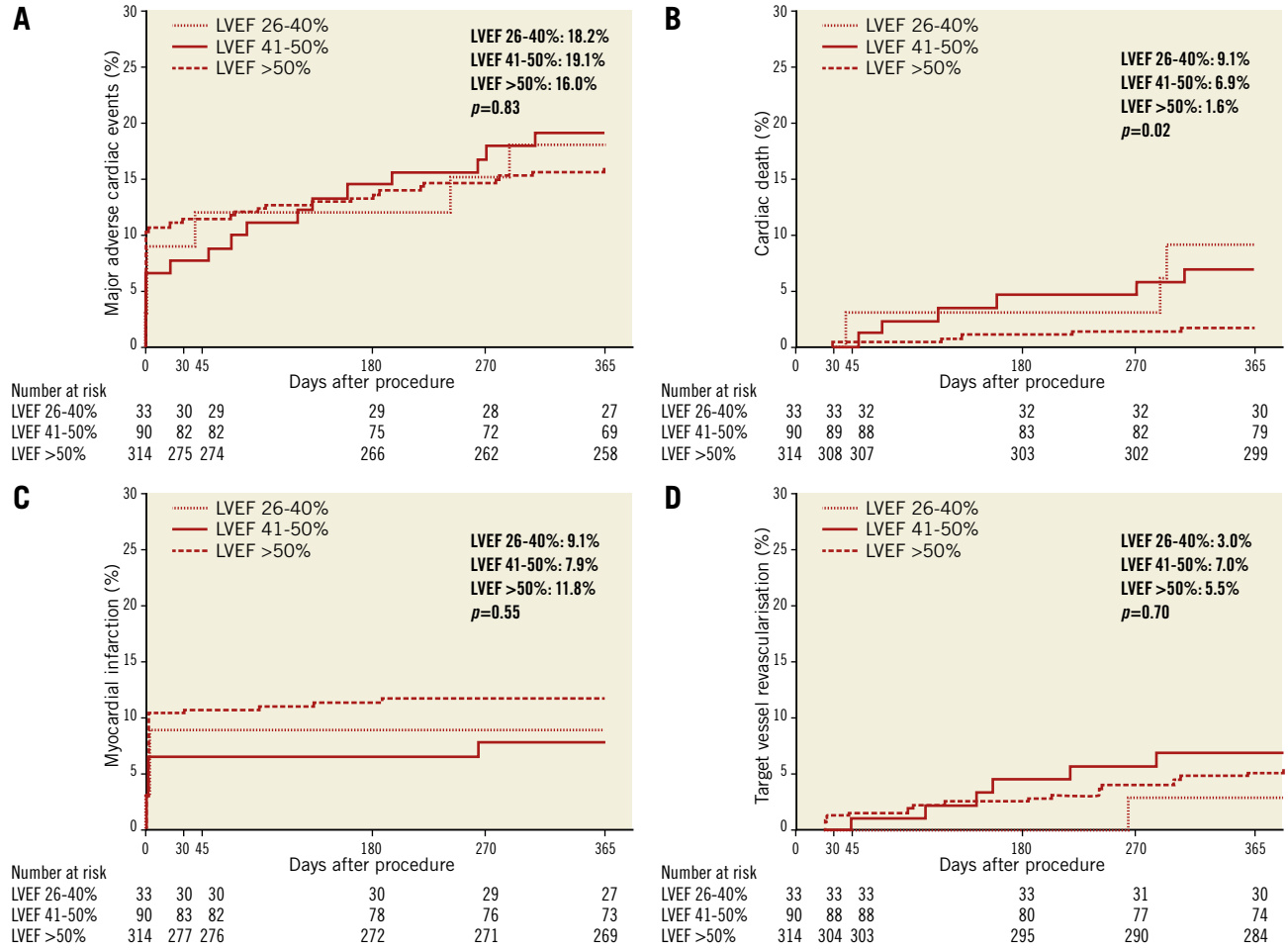

Figure 2. *Kaplan-Meier estimates of one-year major adverse cardiac events (MACE). Estimates of major adverse cardiac events (MACE) (A), including cardiac death (B), myocardial infarction (C), and target vessel revascularisation (D) are presented for patients with left ventricular ejection fraction (LVEF) volume 26-40%, LVEF 41-50%, or LVEF >50%.*

indicate that, even after adjustment for baseline covariates, there was a statistically significant difference across LVEF subgroups in the risk of cardiac death at one year (p=0.01). Angiographic success and severe angiographic complications were not significantly different among the LVEF subgroups **(Table 6)**.

Discussion

Current treatment options for severely calcified coronary lesions include PCI and CABG. Compared to non-calcified lesions, percutaneous or surgical revascularisation of severely calcified lesions is associated with an increased risk of death and adverse events[1,2,19,20]. Recently published data demonstrate that orbital atherectomy treatment of severely calcified coronary lesions prior to stent placement is a promising strategy for these historically difficult-to-treat lesions[17,18,21]. In light of the recent findings of the STICH trial related to the survival benefit associated with CABG in coronary artery disease patients with heart failure and severe left ventricular systolic dysfunction, we sought to understand the

Table 4. Final overall procedural results.

	LVEF 26-40%	LVEF 41-50%	LVEF >50%	*p*-value
Total procedure time (min)	51.2±4.6 (n=33)	57.4±3.6 (n=90)	51.6±1.6 (n=310)	0.54
Total fluoroscopy time (min)	18.0±1.7 (n=33)	21.6±1.8 (n=88)	17.4±0.6 (n=309)	0.25
Total volume of contrast used (ml)	164.2±12.4 (n=33)	177.8±9.5 (n=89)	174.7±5.0 (n=310)	0.83
Final procedure minimum lumen diameter (mm)	3.1±0.1 (n=31)	2.9±0.1 (n=87)	2.8±0.0 (n=301)	0.06
Final procedure stenosis (%)	5.9±1.9 (n=33)	4.8±1.6 (n=90)	4.6±0.8 (n=310)	0.70
Values are mean±standard error. LVEF: left ventricular ejection fraction; OAS: Orbital Atherectomy System				

Table 5. MACE rates.

	LVEF 26-40%	LVEF 41-50%	LVEF >50%	*p*-value
In-hospital MACE	3/33 (9.1)	7/90 (7.8)	33/311 (10.6)	0.74
Cardiac death	0/33	1/90 (1.1)	0/311	0.28
MI	3/33 (9.1)	6/90 (6.7)	32/311 (10.3)	0.64
Q-wave MI	0/33	0/90	3/311 (1.0)	1.0
Non-Q-wave MI	3/33 (9.1)	6/90 (6.7)	29/311 (9.3)	0.77
Target vessel revascularisation	0/33	0/90	3/311 (1.0)	1.00
30-day MACE	9.1	7.8	11.5	0.60
Cardiac death	0	0	0.3	1.0
MI	9.1	6.7	10.8	0.53
Q-wave MI	0	0	1.3	1.00
Non-Q-wave MI	9.1	6.7	9.6	0.72
Target vessel revascularisation	0	1.1	1.6	0.95
1-year MACE	18.2	19.1	16.0	0.83
Cardiac death	9.1	6.9	1.6	0.02
MI	9.1	7.9	11.8	1.0
Q-wave MI	0.0	0.0	1.3	1.0
Non-Q-wave MI	9.1	7.9	10.5	0.75
Target vessel revascularisation	3.0	7.0	5.5	0.70

Values are n/N (%) or % as estimated by Kaplan-Meier. LVEF: left ventricular ejection fraction; MACE: major adverse cardiac events; MI: myocardial infarction

outcomes of OAS-mediated PCI not only in patients with severely calcified lesions but also in those with left ventricular systolic dysfunction[22,23].

The main finding of this sub-analysis of the ORBIT II study was that patients with severe CAC and left ventricular systolic dysfunction who underwent orbital atherectomy had similar MACE rates at one-year follow-up as well as procedural results and angiographic success compared with patients with preserved left ventricular systolic function. Although there were no cardiac deaths in patients with left ventricular systolic dysfunction at 30 days, cardiac death at one year was higher compared with patients with preserved left ventricular systolic function.

The in-hospital and 30-day MACE rates, which were predominantly driven by periprocedural non-Q-wave MI, were similar in the three groups. No patients with left ventricular systolic dysfunction had a Q-wave MI within 30 days of the procedure. Furthermore, no patients with left ventricular systolic dysfunction suffered Q-wave MI at one-year follow-up. At one year, the rate of MI was similar in all three groups.

In-hospital and 30-day TVR did not occur in any patient with left ventricular systolic dysfunction. The rate of TVR at one year was similar in the groups. Only one patient (3.1%) with LVEF 26-40% had TVR at one year.

No patients with left ventricular dysfunction experienced cardiac death periprocedurally or within 30 days post procedure. Patients with left ventricular systolic dysfunction were able to tolerate orbital atherectomy without significant haemodynamic complications, despite reduced physiological reserve and microparticulate debris liberated during orbital atherectomy which may disturb the coronary microcirculation. However, patients with left ventricular

Table 6. Angiographic success and complications.

	LVEF 26-40%	LVEF 41-50%	LVEF >50%	*p*-value
Angiographic success	31/33 (93.9)	83/90 (92.2)	285/314 (90.8)	0.88
<50% residual stenosis	33/33 (100.0)	88/90 (97.8)	310/314 (98.7)	0.76
Severe angiographic complications	2/33 (6.1)	3/90 (3.3)	27/314 (8.6)	0.27
Severe dissection (Type C, D, E, and F)	1/33 (3.0)	1/90 (1.1)	13/314 (4.1)	0.43
Perforation	1/33 (3.0)	1/90 (1.1)	6/314 (1.9)	0.67
Persistent slow flow/no reflow	1/33 (3.0)	0/90 (0.0)	3/314 (1.0)	0.30
Abrupt closure	0/33 (0.0)	1/90 (1.1)	7/314 (2.2)	0.84

Values are n/N (%). LVEF: left ventricular ejection fraction

systolic dysfunction had increased cardiac mortality compared with patients with preserved left ventricular systolic function at one-year follow-up. An analysis of >230,000 PCI procedures reported a strong relationship between left ventricular function and mortality following PCI, with worsening left ventricular function associated with worse 30-day and longer-term mortality[24]. Analysis from the National Heart, Lung, and Blood Institute-sponsored Percutaneous Transluminal Coronary Angioplasty and Dynamic Registries, National Cardiovascular Data Registry, and the HORIZONS-AMI trial also demonstrated that impaired left ventricular function predicted mortality[25-27].

Assessment of left ventricular function is helpful to risk stratify patients undergoing PCI. Inclusion of left ventricular function as one of six clinical parameters to the anatomical SYNTAX score (to form the SYNTAX II score) enhanced the ability of the model to predict four-year mortality following percutaneous or surgical revascularisation[28]. Each 10% increase in left ventricular function was independently associated with a 44% reduction in four-year mortality after PCI.

The effect of left ventricular systolic dysfunction has not been adequately studied with other atherectomy devices for severe CAC. The data with rotational atherectomy in patients with left ventricular dysfunction are limited. In a retrospective study of 23 patients with LVEF <30% who underwent rotational atherectomy, MACE-free survival at 30 days was 100%[29]. Long-term clinical outcomes were not reported. The mechanism of action of orbital atherectomy is different from rotational atherectomy (RA); the OAS utilises an orbital motion instead of a drill motion like that of RA. The orbital motion allows continuous flushing of particulate instead of one bolus release, as seen with RA. This difference in mechanism of action probably results in the lower rates of slow flow/no reflow with OAS (0.7%-0.9%) as compared to Rotablator™ (0%-29.9%) (Boston Scientific, Marlborough, MA, USA)[17,21,30-34].

Study limitations

The ORBIT II study was designed as a non-randomised, prospective clinical study and lacks a control arm. Future studies are needed to examine the efficacy of the OAS versus other PCI treatments. The ORBIT II study was not powered to determine OAS efficacy and safety in this sub-analysis. In addition, the number of patients with left ventricular systolic dysfunction was low. Patients with severe left ventricular dysfunction (LVEF ≤25%) were excluded from the ORBIT II study and therefore the outcomes of these patients are unknown. Data on the concomitant use of haemodynamic support devices such as intra-aortic balloon pump or Impella® (Abiomed, Danvers, MA, USA) were not available.

Conclusions

In the first and only assessment of patients with left ventricular dysfunction who underwent orbital atherectomy for severe CAC, the MACE rate at one-year follow-up was similar compared with patients with preserved left ventricular systolic function. There were no cardiac deaths in patients with left ventricular systolic dysfunction at 30 days, suggesting that patients tolerated orbital atherectomy without any significant haemodynamic complications. However, cardiac death at one year was higher in patients with left ventricular systolic dysfunction, consistent with previous studies reporting reduced left ventricular function and increased mortality after PCI. Left ventricular function should be assessed prior to orbital atherectomy given its importance in risk stratification to quantify risk accurately.

Impact on daily practice

In the ORBIT II study of orbital atherectomy treatment for severely calcified coronary lesions prior to stent placement, patients with left ventricular systolic dysfunction who underwent orbital atherectomy had a similar MACE rate at one-year follow-up as well as procedural results and angiographic success compared with patients with preserved left ventricular systolic function. Left ventricular function should be assessed prior to orbital atherectomy given its importance in risk stratification to quantify risk accurately. These findings suggest that orbital atherectomy may be an appropriate revascularisation strategy in patients with left ventricular systolic dysfunction and severe coronary artery calcification.

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Conflict of interest statement

M. Lee, A. Lee, R. Shlofmitz, E. Shlofmitz, and J. Chambers have consulting agreements with Cardiovascular Systems, Inc. B. Martinsen is employed by and owns stock in Cardiovascular Systems, Inc.

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Supplementary data

Moving image 1. Animation of FDA-approved Coronary Orbital Atherectomy System.

The supplementary data are published online at: http://www.pcronline.com/eurointervention/118th_issue/51