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Impact of age following treatment of severely calcified coronary lesions with the orbital atherectomy system: 3-year follow-up☆

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ABSTRACT

Objectives: We investigated the safety and efficacy of coronary orbital atherectomy to treat severely calcified lesions prior to stenting based upon age.
Background: The ORBIT II study reported the safety and efficacy with orbital atherectomy in 443 patients with severely calcified lesions. Elderly patients undergoing percutaneous coronary intervention may be at increased risk for major adverse cardiac events (MACE) and death compared with younger patients.
Methods: Patients were stratified according to age (≥75 year old [174/443, 39.3%] vs. <75 year old [269/443, 60.7%]). The MACE rate, defined as cardiac death, myocardial infarction (CK-MB > 3X ULN), and target vessel revascularization, was examined at 30-day and 3-year follow-up.
Results: Elderly and non-elderly groups had similar rates of procedural (87.9% vs. 89.5%, p = 0.64) and angiographic success (91.4% vs. 91.4%, p = 1.00). Severe angiographic complications were also similar in both groups (6.9% vs. 7.4%, p = 1.00). There was no statistically significant difference in MACE rates in the elderly and younger groups at 30 days (10.9% vs. 10.1%; p = 0.76) and 3 years (27.8% vs. 20.7%, p = 0.13). The individual endpoints of cardiac death (9.1% vs. 5.1%, p = 0.14), myocardial infarction (13.4% vs. 9.7%, p = 0.27), and target vessel revascularization (10.6% vs. 10.0%, p = 0.91) were also similar in both groups at 3 years.
Conclusions: The rates of adverse clinical events in elderly patients who underwent orbital atherectomy were low and similar to the non-elderly patients, suggesting that it could be a reasonable treatment strategy for elderly patients with severely calcified lesions.

1. Introduction

In the U.S., >43 million of the 322 million people are >65 years old, and the fastest growing age group is those >85 years old [1]. By 2050, the population aged 65 years old is expected to double to 83.7 million. The prevalence of coronary artery disease will continue to grow as the elderly population grows.

Severely calcified coronary lesions, which are commonly observed in patients with diabetes, advanced age, end-stage renal disease on dialysis, and smokers, may preclude stent delivery and optimal stent expansion, are associated with increased risk of death, myocardial infarction (MI), target vessel revascularization (TVR), and stent thrombosis after percutaneous coronary intervention (PCI) [2–4]. Elderly patients who undergo PCI commonly have more comorbidities, have increased frailty, and have increased mortality compared to their younger counterparts [5–7]. Furthermore, elderly patients are often excluded from PCI clinical trials; therefore, data are lacking to guide optimal PCI treatment for older patients [8,9].

Orbital atherectomy may be used to treat de novo, severely calcified coronary lesions prior to stent placement; however, data are limited regarding the use of orbital atherectomy in elderly patients [10]. Therefore we sought to evaluate the impact of age on clinical outcomes in patients who underwent orbital atherectomy for severely calcified coronary lesions in the ORBIT II study.

2. Methods

2.1. Study design

A total of 443 patients were enrolled at 49 U.S. centers in the prospective, single-arm ORBIT II study that assessed the clinical outcomes

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of orbital atherectomy in de novo, severely calcified coronary lesions prior to stent placement (Clinical Trials.gov Identifier: NCT01092416). The ORBIT II study design was previously described [11]. Each site received approval from the institutional review board to enroll patients after informed consent was obtained. For this analysis, patients were stratified by age (≥75 years of age [elderly] vs. <75 years of age [younger]).

2.2. Study population and treatment

The ORBIT II study enrolled both male and female patients with de novo, severely calcified lesions in a native coronary artery. The inclusion criteria included: 1) target vessel reference diameter ≥ 2.5 mm and ≤4.0 mm with a stenosis ≥ 70% and <100% or a stenosis ≥ 50% and <70% with evidence of clinical ischemia via positive stress test, or fractional flow reserve value ≤ 0.8, or intravascular ultrasound (IVUS) minimum lumen area ≤ 4.0 mm^2; 2) target lesion length ≤ 40 mm; 3) evidence of severe calcium deposit at the lesion site as assessed by the operator based on angiographic presence of radio-opacities involving both sides of the arterial wall in at least one location, total length of calcium ≥15 mm and extending partially into the target lesion, or presence of >270° of calcium at 1 cross section via IVUS. Key exclusion criteria included: 1) the target vessel had a stent from previous PCI; 2) target vessel was excessively tortuous; 3) target lesion was in an ostial location; 4) target lesion was a bifurcation; 5) recent MI, defined as creatine kinase-myocardial band >1× upper limit of normal within 30 days prior to index procedure; 6) they were diagnosed with chronic renal failure unless under hemodialysis, or had a serum creatinine level > 2.5 mg/dl; 7) there was evidence of current left ventricular ejection fraction ≤25%.

One target lesion was treated per patient. Stent implantation was required after atherectomy. Post-atherectomy predilatation and post-stent post-dilatation was left to the discretion of the operator. Patient follow-up included a clinic visit at 30 days and telephone call or clinic visit at 1, 2, and 3 years post index procedure.

2.3. Device description

The Orbital Atherectomy System manufactured by Cardiovascular Systems, Inc. (CSI, St. Paul, MN) is a percutaneous coronary orbital atherectomy device that facilitates stent delivery in coronary arteries with severe calcification. A diamond-coated crown orbits at high velocity to modify heavily calcified plaque while minimizing trauma to the soft, healthy vessel wall which flexes away from the orbiting crown.

2.4. Endpoints

The primary safety endpoint was major adverse cardiac events (MACE) at 30-days. The primary efficacy endpoint was procedural success, defined as successful stent delivery with a final residual stenosis of <50% and without in-hospital MACE. MACE was defined as the composite of cardiac death, MI, and TVR. Myocardial infarction was defined as creatine kinase-myocardial band level > 3 times upper limit of normal with or without a new pathologic Q-wave. Target vessel revascularization was defined as repeat revascularization of the target vessel (inclusive of the target lesion) after completion of the index procedure. Angiographic success was defined as successfully stent delivery with residual stenosis < 50% without a severe angiographic complication including severe dissection (types C to F), perforation, persistent slow flow, persistent no reflow, and abrupt closure. An angiographic core laboratory (Cleveland Clinic Foundation, Cleveland, Ohio) analyzed the procedural angiograms and reported the minimum lumen diameter and final percentage of residual stenosis as well as the presence and type of dissections and perforations.

Table 1
Baseline characteristics.

	Elderly (≥75 years) (n = 174)	Younger (<75 years) (n = 269)	p Value
Female	74/174 (42.5)	83/269 (30.9)	0.01
Age (years)	80.7 ± 4.2	65.4 ± 7.5	<0.0001
Diabetes mellitus	47/174 (27.0)	113/269 (42.0)	0.002
Dyslipidemia	159/174 (91.4)	248/269 (92.2)	0.83
Hypertension	166/174 (95.4)	240/269 (89.2)	0.02
eGFR	67.2 ± 22.4	81.3 ± 27.0	<0.0001
Prior stroke/TIA	22/174 (12.6)	17/269 (6.3)	0.03
Prior MI	33/174 (19.0)	66/269 (24.5)	0.28
History of angina	137/174 (78.7)	211/269 (78.4)	1.00
Prior CABG	25/174 (14.4)	40/269 (14.9)	1.00
Body mass index	28.0 ± 5.0	30.3 ± 6.3	<0.0001
Smoking			<0.0001
No, never	65/174 (37.4)	85/269 (31.6)	
Yes, current	10/174 (5.7)	65/269 (24.2)	
Yes, former	99/174 (56.9)	119/269 (44.2)	

Values n/N (%) or mean ± standard deviation; CABG = coronary artery bypass grafting; eGFR = estimated glomerular filtration rate; MI = myocardial infarction; TIA = transient ischemic attack.

2.5. Statistical analysis

Continuous variables are expressed as mean ± standard deviation and compared using Wilcoxon rank-sum test. Categorical variables are expressed as percentages and compared using Fisher's exact test. MACE event rates were estimated with Kaplan-Meier analysis. Statistical analyses were performed with either SAS Software System (SAS Institute Inc., Cary, NC, USA) or R (R Core Team-2012).

3. Results

3.1. Demographics

In this post-hoc sub-analysis, the 443 patients in the ORBIT II study were divided into two groups: elderly (174/443) or younger (269/443) (Table 1). The elderly group had a higher prevalence of females (42.5% vs. 30.9%, p = 0.01), lower body mass index (28.0 ± 5.0 vs. 30.3 ± 6.3, p < 0.0001), lower estimated glomerular filtration rate (67.2 ± 22.4 vs. 81.3 ± 27.0, p < 0.0001), lower prevalence of diabetes (27.0% vs. 42.0%, p = 0.002), fewer current smokers (5.7% vs.

Table 2
Vessel and lesion characteristics.

	Elderly (≥75 years) (n = 174)	Younger (<75 years) (n = 266)	p Value
Patients with OAS inserted	174	266	
Target lesion vessel			0.29
LAD	84/174 (48.3)	143/266 (53.8)	
LCX	23/174 (13.2)	41/266 (15.4)	
Left Main	4/174 (2.3)	6/266 (2.3)	
RCA	58/174 (33.3)	74/266 (27.8)	
Ramus	5/174 (2.9)	2/266 (0.8)	
ACC/AHA lesion classification			0.30
A	0/174 (0.0)	0/266 (0.0)	
B1	38/174 (21.8)	76/266 (28.6)	
B2	84/174 (48.3)	113/266 (42.5)	
C	52/174 (29.9)	77/266 (28.9)	
Pre-procedure MLD (mm)	0.5 ± 0.3	0.5 ± 0.3	0.06
Pre-procedure target lesion length (mm)	19.0 ± 9.3	18.9 ± 8.7	0.95
Pre-procedure average reference vessel diameter (mm)	3.1 ± 0.4	3.1 ± 0.4	0.40
Pre-procedure percent stenosis	85.1 ± 9.4	83.9 ± 8.6	0.11

Values n/N (%) or mean ± standard deviation; MLD = minimum lumen diameter; OAS = orbital atherectomy system.

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