Cardiovascular Revascularization Medicine xxx (2017) xxx–xxx

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

Orbital atherectomy treatment of severely calcified native coronary lesions in patients with prior coronary artery bypass grafting: Acute and one-year outcomes from the ORBIT II trial☆

Michael S. Lee [a,*], Bynthia M. Anose [b], Brad J. Martinsen [b], Arthur C. Lee [c], Richard A. Shlofmitz [d], Jeffrey W. Chambers [e]

[a] UCLA Medical Center, Los Angeles, CA, United States
[b] Cardiovascular Systems, Inc. (CSI), Saint Paul, MN, United States
[c] The Cardiac and Vascular Institute, Gainesville, FL, United States
[d] St. Francis Hospital–The Heart Center, Roslyn, NY, United States
[e] Metropolitan Heart and Vascular Institute, Mercy Hospital, Minneapolis, MN, United States

ARTICLE INFO

Article history:
Received 30 September 2017
Accepted 23 October 2017
Available online xxxx

Keywords:
Prior CABG
Calcified stenosis
Atherectomy
Coronary artery disease

ABSTRACT

Aims: Patients undergoing percutaneous coronary intervention (PCI), with a history of coronary artery bypass grafting (CABG), may be at increased risk for mortality and repeat revascularization, compared with patients without prior CABG. In this post-hoc analysis of the ORBIT II trial, safety and efficacy of coronary orbital atherectomy (OA) to modify severe coronary artery calcium, prior to stent placement, was evaluated in subjects based on history of CABG.

Methods and results: Comorbidities: diabetes, dyslipidemia, hypertension, and history of myocardial infarction (MI) were more prevalent in the CABG group. The in-hospital major adverse cardiac event (MACE) rate, defined as a composite of cardiac death, MI (CK-MB > 3× ULN), and target vessel revascularization (TVR), was higher in the CABG group (16.9% vs. 8.5%, p = 0.04), driven primarily by a higher incidence of MI (16.9% vs. 8.0%, p = 0.03); however, Q-wave rates were low at 1.5% vs 0.5%, (p = 0.38). There was no significant difference in rates of cardiac death (6.2% vs. 2.7%, p = 0.17) and TVR (7.9% vs. 5.5%, p = 0.47).

Conclusions: Low rates of TVR, cardiac death, and Q-wave MI, suggest OA treatment to facilitate stent delivery is successful and provides durable outcomes in subjects with and without prior CABG.

Condensed abstract: Patients with history of CABG have extensive coronary artery disease. Those who undergo PCI may be at increased risk for mortality and repeat revascularization, compared with patients without prior CABG. This post-hoc analysis of ORBIT II trial evaluated safety and efficacy of coronary OA to modify severe coronary artery calcium, prior to stent placement, based on subject history of CABG. The MACE rate was higher in the CABG group, driven by higher incidence of MI; however, Q-wave rates were low. OA treatment to facilitate stent delivery is successful, but higher incidence of non-Q-wave MI in CABG patients warrants further study.

1. Introduction

For patients who undergo coronary artery bypass grafting (CABG), the need for repeat revascularization is common [1]. By 10 years post-CABG, 12% of patients undergo repeat revascularization. Severe coronary artery calcification is frequently found in patients who undergo CABG—nearly 33% of subjects in the SYNTAX CABG registry had heavily calcified lesions [2]. Further, severe lesion calcification is associated with increased mortality related to myocardial infarction (MI) in patients undergoing CABG [3]. Patients with a history of CABG are typically excluded from percutaneous coronary intervention (PCI) trials [4]. PCI of severely calcified coronary lesions often results in poor outcomes: procedural failure, coronary dissection and thrombosis, MI, restenosis, death, target lesion revascularization (TLR), and other major adverse cardiac events (MACE) [4–9]. The impact of CABG on patient outcomes has not previously been studied for PCI involving severely calcified native coronary arteries. The ORBIT II trial assessed the safety and efficacy of the coronary Orbital Atherectomy System (OAS) in preparing de novo, severely calcified coronary lesions for stent placement [8]. In

☆ Conflicts of interest: Dr. Arthur Lee has received consulting and training fees from, and owns stock in, Cardiovascular Systems, Inc. (CSI); Drs. Michael Lee, Richard Shlofmitz, and Jeff Chambers receive consulting fees from CSI; Drs. Brad Martinsen and Bynthia Anose are employed by, and own stock in, CSI.

* Corresponding author at: 100 Medical Plaza Suite 630, Los Angeles, CA 90095, United States.
E-mail address: mslee@mednet.ucla.edu (M.S. Lee).

https://doi.org/10.1016/j.carrev.2017.10.009
1553-8389/

this post-hoc analysis, the ORBIT II data were evaluated to investigate the effect of subject history of CABG on clinical outcomes.

2. Methods

The ORBIT II trial design was previously published [8,10]. Briefly, ORBIT II was a prospective, single arm, multi-center study designed to demonstrate that in the treatment of de novo, severely calcified coronary lesions: (1) the Diamondback 360® Coronary OAS (Cardiovascular Systems, Inc. [CSI]; St. Paul, MN) is safe and (2) the OAS successfully facilitates stent delivery. No patients underwent orbital atherectomy of bypass grafts. The study enrolled 443 subjects at 49 U.S. institutions from May 25, 2010 to November 26, 2012. Key inclusion criteria were: (1) target vessel must be a native coronary artery; (2) target lesion must have fluoroscopic or intravascular ultrasound (IVUS) evidence of severe calcium deposit at lesion site; (3) target vessel reference diameter ≥ 2.5 mm and ≤4.0 mm; and (4) target lesion ≤ 40 mm in length. Severe calcium was defined as (a) presence of radiopacities noted without cardiac motion prior to contrast injection, involving both sides of the arterial wall, with calcification length of ≥15 mm and extension partially into the target lesion, or (b) presence of ≥270° of calcium at one cross section via IVUS.

Key exclusion criteria included: (1) acute MI (STEMI or non-STEMI: CK-MB > Upper Limit of Normal (ULN)) within 30 days prior to index procedure; (2) subject diagnosed with chronic renal failure (creatinine (CR) > 2.5 mg/dl) unless under hemodialysis; (3) evidence of current left ventricular ejection fraction ≤ 25%; (4) more than one lesion requiring intervention unless the lesions are staged; (5) in-stent treatment; and (6) target lesion in ostial location, bifurcation, or has a ≥1.5 mm side branch. There were no required/mandated medications per the study protocol, and post-OAS/pre-stent percutaneous transluminal coronary angioplasty (PTCA) was optional. The ORBIT II trial was conducted per Good Clinical Practice (GCP) and applicable Code of Federal Regulations (CFR), and was approved by each institutional review committee.

Procedural success was defined as success in facilitating stent delivery with a final residual stenosis < 50% and without in-hospital MACE. MACE was defined as a composite of cardiac death, target vessel revascularization (TVR), and MI (CK-MB > 3× ULN with or without new pathologic Q-wave). An independent Clinical Events Committee adjudicated adverse events and persistent slow flow, persistent no flow, and abrupt closure complications. An Angiographic Core Laboratory (Cleveland Clinic Foundation, Cleveland, OH) analyzed procedural angiograms and reported final minimum lumen diameter, final percent residual stenosis, and the presence and type of dissections and perforations. Angiographic success was defined as success in facilitating stent delivery with a residual stenosis of <50% without severe angiographic complications, defined as persistent slow flow, persistent no flow, abrupt closure, Type C-F dissections, and perforations. Subjects were followed in clinic at 30 days and by phone or in clinic at 1 year post-procedure.

The coronary OAS manufactured by CSI is a catheter-based device indicated to facilitate stent delivery in patients with coronary artery disease, who are acceptable candidates for stenting due to de novo, severely calcified, coronary artery lesions. The OAS tracks and rotates over the ViperWire® (CSI) guidewire and modifies coronary plaque on the vessel wall by using a diamond-coated crown. The crown's orbital diameter expands laterally via centrifugal force and sands away the hard components of the plaque, allowing the soft components of the plaque and vessel wall to flex away from the crown. In the ORBIT II trial, two OAS configurations were used: Pneumatic (1.25 mm, 1.50 mm, 1.75 mm. 2.00 mm crowns) and Electric (1.25 mm and 1.50 mm crowns).

Statistical analyses were performed with either the SAS Software System (SAS Institute Inc., Cary, NC) or R (R Core Team-2012). Subject demographics, pre- and post-procedure lesion characteristics, procedural characteristics, and outcome variables were summarized using descriptive statistics for continuous variables (presented as mean ± SE) and frequency tables or proportions for discrete variables. Data were compared using 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 event rates; comparisons were made using Cox proportional hazards models. p-Values < 0.05 were considered statistically significant.

3. Results

Of the 443 subjects in the ORBIT II study, 65 subjects had a history of CABG (Table 1). This CABG group contained a greater proportion of subjects with history of diabetes mellitus, dyslipidemia, hypertension, and MI than did the group with no prior history of CABG.

Subjects with prior CABG had smaller minimum lumen diameter (0.4 ± 0.0 mm vs. 0.5 ± 0.0 mm, p = 0.002) and larger mean diameter stenosis (87.4% ± 1.0% vs. 83.8% ± 0.5%, p = 0.004) than those without a history of CABG (Table 2). The OAS was inserted in 65 (100%) subjects with prior CABG and 375 (99.2%) subjects with no-prior-CABG (Table 3). The mean number of stents used post-OAS, was significantly higher in subjects with prior CABG (1.4 ± 0.1 vs. 1.2 ± 0.0, p = 0.02), as was final procedure stenosis (8.9% ± 2.2% vs. 3.9% ± 0.7%, p = 0.01).

Although the angiographic success rate and the incidence of severe angiographic complications were similar in both groups, there was an increased rate of severe dissection (Type C-F) in subjects with prior CABG (7.7% vs 2.6%, p = 0.05) (Table 4). The in-hospital MACE rate was also higher in the CABG group (16.9% vs. 8.5%, p = 0.04) (Table 5). This was driven primarily by the higher rate of MI (16.9% vs. 8.0%, p = 0.03); however, Q-wave rates were low (1.5% vs 0.5%, p = 0.38). When utilizing the current Society for Cardiac Angiography and Interventions (SCAI) definition of MI, there was no significant difference in rates of MI between the two groups (3.1% vs 1.9%, p = 0.63) [11].

The CABG patients had higher rates of 1-year MACE (27.7% vs. 15.0%, p = 0.01) and MI (18.5% vs. 9.3%, p = 0.03) (Table 5 and Fig. 1A, C). However, there was no significant difference in rates of cardiac death (6.2% vs. 2.7%, p = 0.17) or TVR (7.9% vs. 5.5%, p = 0.47) between the two groups at 1 year (Fig. 1B, D). The rate of TLR at 1 year was also similar (6.3% vs. 4.4%, p = 0.52) in both groups.

4. Discussion

This post hoc analysis of the ORBIT II trial revealed patients with a history of CABG who underwent orbital atherectomy of severely calcified native coronary lesions was associated with a significantly higher

Table 1
Baseline subject characteristics.

	Prior CABG	No prior CABG	p value*
Number of subjects	N = 65[a]	N = 378[a]	
Age (years)	71.9 ± 1.2	71.3 ± 0.5	0.82
eGFR (mL/min/1.73 m^2)	78.3 ± 3.3	75.3 ± 1.3 (N = 376)	0.57
Male gender	52 (80.0%)	234 (61.9%)	0.005
History of:			
Diabetes mellitus	32 (49.2%)	128 (33.9%)	0.02
Dyslipidemia	65 (100.0%)	342/377 (90.7%)	0.005
Hypertension	64 (98.5%)	342 (90.5%)	0.03
Stroke/transient ischemic attack	8 (12.3%)	31/377 (8.2%)	0.34
Myocardial infarction	26/62 (41.9%)	73/376 (19.4%)	<0.001
Angina	53 (81.5%)	295 (78.0%)	0.62
Smoker (current or former)	45 (69.2%)	248 (65.6%)	0.67

CABG = coronary artery bypass grafting.
Values are n (%) or mean ± SE.
* p-Values from Wilcoxon rank-sum test (continuous parameters) and Fisher's exact test (categorical parameters).
[a] Unless otherwise indicated.

Please cite this article as: Lee MS, et al, Orbital atherectomy treatment of severely calcified native coronary lesions in patients with prior coronary artery bypass grafting..., Cardiovasc Revasc Med (2017), https://doi.org/10.1016/j.carrev.2017.10.009