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Outcomes of patients with myocardial infarction who underwent orbital atherectomy for severely calcified lesions☆

Michael S. Lee [a,*], Evan Shlofmitz [b], Gentian Lluri [a], Jeremy Kong [a], Natalya Neverova [a], Richard Shlofmitz [c]

[a] Division of Cardiology, UCLA Medical Center, Los Angeles, CA, USA
[b] Department of Cardiology, Northwell Health, Manhasset, NY, USA
[c] Cardiology Department, St. Francis Hospital-The Heart Center, Roslyn, NY, USA

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ABSTRACT

Objectives: This study analyzed the outcomes of patients who presented with non-ST-elevation myocardial infarction (NSTEMI) and subsequently underwent orbital atherectomy for severe coronary artery calcification (CAC).
Background: Patients who present with NSTEMI have increased risk for death and recurrent MI after percutaneous coronary intervention (PCI). Patients with severe CAC have worse outcomes after PCI.Orbital atherectomy modifies calcified plaque, facilitating stent delivery and optimizing stent expansion. There are no data on these patients who present with NSTEMI who undergo orbital atherectomy.
Methods: Of the 454 consecutive real-world patients who underwent orbital atherectomy in our retrospective multicenter registry, 51 patients (11.2%) presented with NSTEMI. The primary safety endpoint was the rate of major adverse cardiac and cerebrovascular events (MACCE) at 30 days.
Results: Patients with NSTEMI had a higher prevalence of chronic kidney disease, lower mean ejection fraction, and required more vessels to be treated. The primary endpoint was similar in patients who presented with and without NSTEMI (2.0% vs. 2.2%, $p = 0.9$), as were the 30-day rates of death (2.0% vs. 1.2%, $p = 0.67$), MI (0% vs. 1.2%, $p = 0.42$), target vessel revascularization (0% vs. 0%, $p > 0.91$), and stroke (0% vs. 0.2%, $p = 0.72$). The rates of angiographic complications and stent thrombosis rate were low in both groups.
Conclusions: Despite having worse baseline characteristics, patients who presented with NSTEMI and subsequently underwent orbital atherectomy had similar clinical outcomes compared with patients without NSTEMI.

1. Introduction

Coronary artery calcification (CAC) is a marker of advanced atherosclerosis [1]. Percutaneous coronary intervention (PCI) of severe CAC is technically more demanding as attempts to treat undilatable lesions can lead to perforation, dissection, and ischemia [2]. These factors may explain the higher incidence of adverse cardiac events than in non-calcified lesions including death, myocardial infarction (MI), target vessel revascularization (TVR), and stent thrombosis [3]. Techniques to modify severe CAC before stent delivery and expansion are vital in decreasing mortality in these patients.

Although the ORBIT II trial reported excellent clinical outcomes following orbital atherectomy in 443 patients with severe CAC, patients with MI were excluded [4,5]. We previously reported the safety and efficacy of all comers undergoing orbital atherectomy followed by stenting in a real-world multicenter registry of patients with severe CAC [6]. Trials assessing rotational and orbital atherectomy have always excluded patients with thrombotic lesions. There are no data on outcomes of patients with MI who undergo orbital atherectomy. We report the outcomes of these high-risk patients with severe CAC who underwent orbital atherectomy.

2. Methods

2.1. Study population

This retrospective analysis included 454 consecutive real-world patients who underwent orbital atherectomy for severe CAC, defined by the presence of radio-opacities on fluoroscopy involving the vessel wall, between October 2013 and December 2015 at 3 centers (UCLA Medical Center, Los Angeles, CA, St. Francis Hospital, Roslyn, NY, and Northwell Health, Manhasset, NY).Patients were grouped by whether they underwent orbital atherectomy for non-ST-elevation MI ($n = 51$) and those who did not ($n = 403$). The institutional review board at each site approved the review of the data.

☆ Conflicts of interest: MSL, RS: honorarium from CSI; ES, GL, JK, NN: none.

* Corresponding author at: 100 Medical Plaza Suite 630, Los Angeles, CA 90095, USA. Tel.: +1 310 696 9523.
E-mail address: mslee@mednet.ucla.edu (M.S. Lee).

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2.2. Device description

The coronary orbital atherectomy device (Cardiovascular Systems, Inc. [CSI], St Paul, MN) has a 1.25-mm crown coated with 30-μm diamonds and rotates on a 0.014″ ViperWire (CSI).The ViperSlide (CSI) lubricant is infused through the drive shaft to reduce friction during device advancement and activation. The mechanism of action is centrifugal force, in which the eccentrically mounted crown expands laterally, resulting in debulking and plaque modification.

2.3. Procedure and adjunctive pharmacotherapy

Standard techniques were used to perform PCI via a 6 French guiding catheter in all cases. It was the discretion of the operator to insert temporary pacing lead, use a hemodynamic support device, and image with intravascular imaging (intravascular ultrasound or optical coherence tomography).After low-speed (80,000 rpm) atherectomy, high-speed (120,000 rpm) atherectomy was considered if the reference vessel diameter was ≥3 mm. The duration of each pass was ≤20 s.

Aspirin was continued indefinitely.A P2Y12 inhibitor was continued for at least one month after bare metal stenting and at least 12 months after drug-eluting stenting.The choice of P2Y12 inhibitor, antithrombotic therapy, and use of glycoprotein IIb/IIIa antagonist was left to the discretion of the operator.

2.4. Endpoints

The primary endpoint was the 30-day rate of major adverse cardiac and cerebrovascular events (MACCE), defined as the occurrence of death, MI, TVR, and stroke. Myocardial infarction was defined as recurrent ischemic symptoms with new ST-segment elevation or re-elevation of cardiac markers to at least twice the upper limit of normal. Target vessel revascularization was defined as repeat revascularization of the target vessel. Stent thrombosis was defined per the Academic Research Consortium definition [7]. Baseline demographic and procedural data and clinical outcomes were obtained from medical records and entered into a dedicated PCI database.

2.5. Statistical analysis

Continuous variables were expressed as mean and standard deviation and compared using Student *t* test. Categorical variables were expressed as percentages and compared using chi square test.A *p*-value < 0.05 was considered statistically significant.Statistical analysis was performed with GraphPad Prism 6 (GraphPad Software, Inc. La Jolla, CA).

3. Results

3.1. Baseline demographic and procedural characteristics

Patients with MI had a higher prevalence of chronic kidney disease (serum creatinine ≥ 1.5 mg/dl), history of MI, and lower mean ejection fraction (Table 1). Patients with MI had more vessels treated and were more often treated with a glycoprotein IIb/IIIa antagonist (Table 2).

3.2. Procedural results

No patient experienced stent loss (Table 3). Patients with MI had a higher dissection rate compared with patients without MI (3.9% vs. 0.5%, $p = 0.01$). The rate of coronary perforation (2.0% vs. 0.5%, $p = 0.22$) and no reflow (2.0% vs. 0.5%, $p = 0.22$) was not statistically different.

Table 1
Baseline characteristics.

	MI N = 51	No MI N = 403	*p*-Value
Age (years)	75.3 ± 1.6	73.5 ± 0.5	0.23
Male gender	30 (58.8)	282 (70.0)	0.11
Diabetes mellitus	26 (51.0)	164 (40.6)	0.17
Hypertension	48 (94.1)	345 (85.6)	0.09
Current smoker	4 (7.8)	17 (4.2)	0.25
Chronic kidney disease (creatinine ≥ 1.5 mg/dl)	20 (39.2)	68 (16.9)	<0.0001
History of myocardial infarction	13 (25.5)	58 (14.4)	0.04
Previous coronary artery bypass grafting	6 (11.8)	71 (17.6)	0.29
Previous percutaneous coronary intervention	12 (23.5)	150 (37.2)	0.06
Mean ejection fraction (%)	46.4 ± 2.4	52.7 ± 0.53	0.0003

Values are *n* (%) or mean ± SD.
MI = myocardial infarction.

3.3. 30-day clinical outcomes

Patients with MI and without MI had similar rates of 30-day MACCE (2.0% vs. 2.2%, $p = 0.9$), death (2.0% vs. 1.2%, $p = 0.67$), MI (0% vs. 1.2%, $p = 0.42$), TVR (0% vs. 0%, $p > 0.9$), and stroke (0% vs. 0.2%, $p = 0.72$) (Table 4). Stent thrombosis was similar in both groups (0% vs. 1.05, $p = 0.34$). Emergent coronary artery bypass grafting was uncommon in both groups (0% vs. 0.7%, $p = 0.53$).

4. Discussion

The main finding of this study was that orbital atherectomy in patients with severe CAC appears to be safe and effective in patients who presented with MI and provided similar outcomes compared with patients without MI.However, this analysis could be underpowered to find a significant difference between the groups due to the small number of patients with MI who underwent orbital atherectomy.

Patients who present with MI require timely PCI to revascularize severely stenotic coronary vessels and mitigate ongoing infarction. Patients who experience acute coronary syndrome are at risk for adverse clinical events. The 30-day mortality rate in patients who present with acute coronary syndromes is 2%–3% and rises to 5% if patients with unstable angina are excluded [8]. Patients with MI who underwent PCI are at increased risk for adverse events including death and recurrent MI compared with elective PCI [9,10]. Patients with acute coronary syndrome commonly have CAC. Target lesion CAC was severe in 5.9% and moderate in 26.1% in patients who presented with acute coronary syndromes and had significantly higher rates of death, stent thrombosis, and ischemic target lesion and vessel revascularization at 1 year compared with patients with no or mild CAC [11]. Severe CAC increases the level of complexity of PCI and increases the risk of stent deployment failure due to difficulty in advancing and optimally expanding stents. The incidence of failure in deploying drug-eluting stents was 5.8% in

Table 2
Angiographic and procedural characteristics.

	MI N = 51	No MI N = 403	*p*-Value
Vessels treated per case	1.3 ± 0.07	1.2 ± 0.02	0.02
Total stents used per case	2.3 ± 0.2	2.0 ± 0.1	0.15
Total stent length (mm)	49.1 ± 4.6	43.2 ± 1.4	0.19
Total volume of contrast used (ml)	189.5 ± 10.9	186.7 ± 4.6	0.84
Total fluoroscopy time (minutes)	23.1 ± 1.4	21.7 ± 0.9	0.61
Maximum stent pressure (atm)	16.5 ± 0.6	16.1 ± 0.2	0.5
Temporary pacemaker	1 (2.0)	25 (6.2)	0.22
Intravascular imaging	9 (17.7)	125 (31.0)	0.05
Glycoprotein IIb/IIa antagonist	10 (19.6)	13 (3.2)	<0.0001

MI = myocardial infarction.
Values are *n* (%) or mean ± SD.

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