




Coronary orbital atherectomy treatment of Hispanic and Latino patients: A real-world comparative analysis

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Abstract

Objectives: To assess coronary orbital atherectomy (OA) use in Hispanic or Latino (HL) patients compared to non-HL patients.

Background: HL patients are at greater risk of cardiovascular disease mortality compared with Whites with similar coronary artery calcium (CAC) scores. The safety and efficacy of coronary atherectomy in the HL patient population is unknown due to the under-representation of minorities in clinical trial research.

Methods: A retrospective analysis of consecutive patients undergoing coronary OA treatment of severely calcified lesions at the Mount Sinai Medical Center, Miami Beach, Florida (MSMCMB) was completed. From January 2014 to September 2020, a total of 609 patients from MSMCMB who underwent percutaneous coronary intervention with OA were identified in the electronic health records.

Results: Of those identified, 350 (57.5%) had an ethnicity classification of HL. The overall mean age was 74 years and there was a high prevalence of diabetes in the HL group compared to the non-HL group (49.7% vs. 34.7%; $p = 0.0003$). Severe angiographic complications were uncommon and in-hospital freedom from major adverse cardiac events (MACE), a composite of cardiac death, MI, and stroke (ischemic or hemorrhagic cerebrovascular accidents), was 98.5% overall, with no significant difference between the HL and non-HL groups, despite the higher prevalence of diabetes in the HL group.

Conclusions: This study represents the largest real-world experience of OA use in HL versus non-HL patients. The main finding in this retrospective analysis is that OA can be performed safely and effectively in a high-risk population of HL patients.

KEYWORDS

atherectomy, coronary artery calcification, Hispanic/Latino, percutaneous coronary intervention

1 | INTRODUCTION

Individuals with Hispanic or Latino (HL) ethnicity are at greater risk for cardiovascular disease mortality compared with Whites with similar coronary artery calcium (CAC) scores and this risk is more pronounced with increasing CAC.^{1,2} In addition, given the higher prevalence and severity of coronary calcium in the HL population, patients requiring percutaneous coronary intervention (PCI) will likely require more frequent use of advanced atheroablative lesion preparation, such as with orbital atherectomy (OA). Despite this, the safety and efficacy of coronary atherectomy in the HL patient population is unknown due to the under-representation of minorities in clinical trial research. A review of cardiovascular trials at www.clinicaltrials.gov found that Hispanics comprised only 11% of the studied population.³ Since ethnic diversity in the United States is rapidly increasing^{2,4} and the non-Hispanic White population is projected to decline from about 60% of the US population in 2014 to about 44% by 2060,^{4,5} more attention should be paid to PCI treatment of severe CAC that includes atherectomy lesion modification in high-risk racial/ethnic minorities. Thus, we sought to assess the real-world experience of OA use in HL versus non-HL patients.

2 | METHODS

2.1 | Study design

Patients from Mount Sinai Medical Center, Miami Beach, Florida (MSMCMB) who underwent PCI with OA were identified in the electronic health records with no exclusion criteria. Data on consecutive patients from January 2014 to September 2020 was used for a retrospective analysis comparing the outcomes of patients with ethnicity of HL versus non-HL. The study was approved by the Mount Sinai Medical Center Institutional Review Board (IRB).

2.2 | Device description

The coronary OA device design has been previously described.^{6,7} Briefly, the device manufactured by Cardiovascular Systems, Inc. (CSI; St. Paul, MN) is a percutaneous OA system used to facilitate stent delivery in de novo, severely calcified coronary artery lesions. The device utilizes a high-speed orbiting diamond-coated crown that sands away the hard, calcific components of plaque. Meanwhile, the soft components of the plaque and vessel tissue flex away from the crown. In addition, there are OA pulsatile forces that fracture calcium in the coronary vessel wall.^{6,8} The dual mechanism of OA, sanding, and fracturing, subsequently changes the plaque morphology and vessel compliance allowing for adequate stent expansion.^{6,8} Lastly, OA is a time-dependent therapy and therefore traversing at 1 mm/s on low speed (80,000 rpm) will provide more orbital gain than 10 mm/s on high speed (120,000 rpm).⁶ Thus, the OA algorithm at MSMCMB discourages the use of high speed, unless the operator absolutely deems it necessary.

2.3 | Endpoints

The primary study outcome was in-hospital freedom from major adverse cardiac events (MACE), defined as a composite of in-hospital mortality, periprocedural MI, or stroke (ischemic or hemorrhagic cerebrovascular accident). Secondary outcomes were severe angiographic complications (severe dissection type C-F, perforation, and persistent slow flow/no reflow), bleeding events, and successful stent placement.

2.4 | Statistical analysis

Baseline and procedural characteristics are presented as *n* (%) for binary variables or mean \pm standard deviation for continuous variables. Freedom from MACE and bleeding values (via Kaplan-Meier and Peto's method) are % (95% confidence interval). Missing data for baseline characteristics were imputed via single imputation using the Markov Chain Monte Carlo method with a single chain. The starting value for the chain was computed from the expectation-maximization algorithm. Resulting *p* value of the comparison of HL versus non-HL was calculated via Fisher's Exact test for frequency variables or Student's *t* test for continuous variables. A *p* < 0.05 was considered statistically significant. Analyses were conducted in SAS Version 9.4.

3 | RESULTS

3.1 | Demographics

A total of 609 patients from MSMCMB who underwent PCI with OA were identified in the electronic health records and 350 (57.5%) of them had an ethnicity classification of Hispanic or Latino (Table 1). Overall, the mean age was 74 years and 64% were men. Patients frequently had diabetes, dyslipidemia, and hypertension, as well as a prior history of myocardial infarction (MI) and coronary artery bypass grafting (CABG) (Table 1). HL patients compared to non-HL were significantly more likely to be diabetic, hypertensive, and female (Table 1). There was no significant difference in PCI indication between cohorts—the majority were indicated due to stable ischemic heart disease (SIHD) or acute coronary syndrome with unstable angina (Table 1).

3.2 | Procedural results

Overall, the most common vessels treated were the left anterior descending artery (LAD), the right coronary artery (RCA), and the left circumflex artery (LCX) (Table 2). HL patients compared to non-HL were significantly more likely to have RCA lesions treated. Overall, on average the lesions were highly stenotic (85.8%), long (22.6 mm), and complex with over 50% of the lesions classified as type C via the American College of Cardiology/American Heart Association (ACC/AHA) lesion classification system (Table 2). All patients were treated

TABLE 1 Baseline characteristics

	Overall	HL	Non-HL	p Value
Number of patients treated with OA	609	350	259	-
Age, years	74.0 ± 9.3	74.4 ± 9.6	73.4 ± 8.8	0.19
Male	387 (63.5)	209 (59.7)	178 (68.7)	0.0267
Race				
Caucasian	506 (83.1)	303 (86.6)	203 (78.4)	0.0087
Black or African American	35 (5.7)	13 (3.7)	22 (8.5)	0.0138
Asian	5 (0.8)	1 (0.3)	4 (1.5)	0.17
Native American	29 (4.8)	27 (7.7)	2 (0.8)	<0.0001
Other or not reported	36 (5.9)	8 (2.3)	28 (10.8)	<0.0001
Ethnicity				
Hispanic or Latino	350 (57.5)	350 (100)	0 (0.0)	-
History of diabetes mellitus	264 (43.3)	174 (49.7)	90 (34.7)	0.0003
History of dyslipidemia	462 (75.9)	266 (76.0)	196 (75.7)	0.92
History of hypertension	555 (91.1)	327 (93.4)	228 (88.0)	0.0297
Currently on dialysis	28 (4.5)	14 (3.9)	14 (5.3)	0.52
Prior MI	144 (23.6)	78 (22.3)	66 (25.5)	0.39
Prior CABG	85 (14.0)	42 (12.0)	43 (16.6)	0.12
Smoker (current or former)	102 (16.7)	62 (17.7)	40 (15.4)	0.51
PCI indication				0.85
SIHD (no or stable angina)	164 (26.9)	95 (27.3)	69 (26.5)	
ACS-unstable angina	361 (59.2)	200 (57.1)	158 (60.9)	
ACS-NSTEMI	81 (13.3)	52 (14.7)	32 (12.2)	
ACS-STEMI	4 (0.6)	3 (0.9)	1 (0.4)	

Note: Values are *n* (%) or mean ± standard deviation.

Abbreviations: ACS, acute coronary syndrome; CABG, Coronary artery bypass graft surgery; HL, Hispanic or Latino; MI, Myocardial Infarction; NSTEMI, non-STEMI; OA, Orbital atherectomy; PCI, percutaneous coronary intervention; *p* Value, comparison of HL versus non-HL; SIHD, stable ischemic heart disease; STEMI, ST-elevation MI.

with OA to optimize stent placement and expansion during PCI, resulting in drug-eluting stent (DES) placement in all patients with the majority successfully placed at the <50% and <20% residual stenosis (RS) threshold levels (Table 3). Severe angiographic complications and bleeding events were uncommon for both HL and non-HL

TABLE 2 Lesion and vessel characteristics

	Overall	HL	Non-HL	p Value
Number of lesions	970	559	411	-
Lesion length (mm)	22.6 ± 9.4	22.8 ± 9.6	22.5 ± 9.2	0.70
Preintervention stenosis	85.8 ± 9.7	86.5 ± 9.9	84.9 ± 9.3	0.0112
Postintervention residual stenosis	0.8 ± 6.7	1.0 ± 7.9	0.5 ± 4.8	0.34
ACC/AHA lesion class				
Type A/B1/B2 (Non-C)	446 (46.0)	252 (45.1)	194 (47.2)	0.52
Type C	524 (54.0)	307 (54.9)	217 (52.8)	0.52
Target vessel				
Left anterior descending artery	491 (50.6)	268 (47.9)	223 (54.3)	0.06
Left circumflex artery	213 (22.0)	121 (21.6)	92 (22.4)	0.81
Left main artery	42 (4.3)	26 (4.7)	16 (3.9)	0.63
Right coronary artery	234 (24.1)	155 (27.7)	79 (19.2)	0.0024
Ramus	6 (0.6)	4 (0.7)	2 (0.5)	1.00

Note: Values are *n* (%) or mean ± standard deviation.

Abbreviations: ACC, American College of Cardiology; AHA, American Heart Association; HL, Hispanic or Latino; *p* value, comparison of HL versus non-HL.

patients—in particular, there were no occurrences of persistent slow flow/no reflow (Table 3).

3.3 | In-hospital MACE

The in-hospital freedom from MACE, a composite of cardiac death, MI, and stroke (ischemic or hemorrhagic cerebrovascular accidents), was 98.5% overall, with no significant difference between HL and non-HL patients (Table 4).

4 | DISCUSSION

This study represents the largest real-world experience of OA use in a patient population with a high proportion of HL ethnicity. Despite the higher cardiovascular risk for mortality in the HL population compared with whites, especially in those with severe CAC,^{1,2} the outcomes in this OA analysis showed no difference between HL and non-HL patients. Percutaneous interventional cardiovascular therapies are often underutilized in Hispanics and that may contribute to excess morbidity and mortality in this vulnerable population.^{9,10} Overall, HL patients are more likely to present with comorbidities,

TABLE 3 Procedural outcomes

	Overall	HL	Non-HL	p Value
Number of patients treated with OA	609	350	259	-
DES placed	609 (100)	350 (100)	259 (100)	-
Successful DES placed (<50% RS)	603 (99)	345 (98.6)	258 (99.6)	0.41
Successful DES placed (<20% RS)	600 (98.5)	344 (98.3)	256 (98.8)	1.00
Freedom from bleeding				
Type 3	100 [99.4, 100]	100 [99.0, 100]	100 [98.6, 100]	-
Type 2	99.5 [98.6, 99.9]	99.4 [98.0, 99.9]	99.6 [97.9, 100]	1.00
Type 1	98.5 [97.2, 99.3]	98.3 [96.3, 99.4]	98.8 [96.7, 99.8]	0.74
Number of procedures	656	380	276	-
Total fluoroscopy time (min)	19.7 ± 12.5	19.0 ± 11.6	20.6 ± 13.6	0.12
Total volume of contrast used (ml)	213 ± 79	208 ± 77	218 ± 81	0.10
Severe Angiographic Complications				
Severe dissection (type C, D, E, F)	3 (0.5)	2 (0.5)	1 (0.4)	1.00
Perforation	5 (0.8)	1 (0.3)	4 (1.4)	0.17
Persistent slow flow/no reflow	0 (0.0)	0 (0.0)	0 (0.0)	-

Note: Values are *n* (%) or mean ± standard deviation. Freedom from bleeding values (via Kaplan-Meier and Peto's method) are % [95% confidence interval]. Bleeding definitions: Type 3 = postbleeding event with tamponade and transfusion; Type 2 = postbleeding event with transfusion, not included as Type 3; Type 1 = postbleeding event not included as Type 3.

Abbreviations: DES, drug-eluting stent; HL, Hispanic or Latino; OA, orbital atherectomy; *p* Value, comparison of HL versus non-HL; RS, residual stenosis.

TABLE 4 In-hospital MACE outcomes

	Overall	HL	Non-HL	p Value
Freedom from MACE	98.5 [97.2, 99.3]	98.6 [96.7, 99.5]	98.5 [96.1, 99.6]	1.00
Freedom from cardiac death	99.3 [98.3, 99.8]	99.4 [98.0, 99.9]	99.2 [97.2, 99.9]	1.00
Freedom from MI	99.2 [98.1, 99.7]	99.1 [97.5, 99.8]	99.2 [97.2, 99.9]	1.00
Freedom from ischemic CVA	99.7 [98.8, 100]	99.7 [98.4, 100]	99.6 [97.9, 100]	1.00
Freedom from hemorrhagic CVA	100 [99.4, 100]	100 [99.0, 100]	100 [98.6, 100]	-

Note: Values are *n* (%) or mean ± standard deviation. MACE values (via Kaplan-Meier and Peto's method) are % [95% confidence interval].

Abbreviations: CVA, cerebrovascular accident; HL, Hispanic or Latino; MACE, major adverse cardiac event (composite of cardiac death, MI, ischemic CVA, or hemorrhagic CVA); MI, myocardial infarction; *p* Value, comparison of HL versus non-HL.

experience longer delays before treatment, and suffer worse outcomes when compared with non-HL white patients.^{10,11} Since the HL population is often underrepresented in prospective PCI clinical trials,^{3,7} we sought to retrospectively assess the in-hospital safety and efficacy of OA in heavily calcified coronary lesions of HL patients compared to non-HL patients.

4.1 | Baseline demographic comparison of HL versus non-HL patients

The demographic characteristics of HL patients in our study were similar to previous studies showing that HL PCI patients are significantly more likely to be female, diabetic, and hypertensive

than non-HL patients.^{4,11} In addition, the HL cohort was 86.6% Caucasian, significantly higher than the non-HL group; however, this high percentage matches the overall Florida State statistics showing that 84.3% of the HL population is Caucasian.¹²

Both the HL and non-HL cohorts had highly stenotic long lesions, with the majority classified as ACC/AHA type C and located in the LAD. HL patients, however, had a significantly higher mean percent diameter stenosis at baseline than non-HL patients. In addition, HL patients were significantly more likely to have lesions located in the RCA than non-HL patients. Due to the paucity of longitudinal studies describing the geographical incidence of atherosclerosis in the coronary arteries, it is difficult to ascertain the importance of this.¹³ Pathological studies have shown that the prevalence and burden of atherosclerosis is typically higher in the LAD, followed by the RCA and then the LCX. Other studies, however, observed roughly equal frequency of atherosclerosis in the LAD and the RCA, and lower frequency in the LCX.¹³

Interestingly, it has been hypothesized that calcium deposition occurs earlier in atherosclerotic lesions of the LAD compared to lesions of other coronary arteries (RCA, LCX, and LM).¹³ Thus, it may be possible that the HL patients in our retrospective study had delayed access to care and therefore presented with more advanced coronary disease in regard to calcium deposition beyond the LAD. The presence of lesions requiring atherectomy treatment in the RCA may put HL patients at higher risk of pacing issues during PCI—although not tracked in this OA analysis, a previous rotational atherectomy study did show an increased need for pacemaker placement when treating the RCA.¹⁴

Lastly, recent intravascular imaging studies indicate that calcified nodules are more likely found in the RCA, resulting in a higher risk of stent under expansion and more adverse events compared to calcified lesions without a calcified nodule.^{15,16} Although optical coherence tomography and intravascular ultrasound imaging were not tracked in this analysis, previous studies have shown that imaging optimizes and improves PCI results regardless of lesion location and ethnicity.^{17,18} However, we hypothesize that patients with RCA lesions, such as the HL patients in our retrospective analysis, may especially require intravascular imaging to better characterize the calcified lesions to properly plan for vessel preparation to obtain optimal results.

4.2 | HL versus non-HL cohort outcomes

Despite the noted differences in baseline patient, lesion, and vessel characteristics between the HL and non-HL cohorts, 100% successful stent placement was achieved in both cohorts with high freedom from angiographic complications and bleeding events. In particular, there was no persistent slow flow/no reflow events in either cohort. In addition, freedom from MACE was high in both the HL and non-HL cohorts (98.6% vs. 98.5%; $p = 1.00$). These outcomes are favorable compared to a previous NCDR CathPCI Registry study of coronary

atherectomy¹⁹ and to the coronary OA pivotal approval study ORBIT II⁷—whether this is due to a refinement in procedural technique or differences in endpoint ascertainment across studies is not known. We hypothesize that our institution's algorithmic use of OA as a primary/upfront-planned treatment of severely calcified lesions, instead of bail-out use, may have leveled any risk differences between the HL and non-HL cohorts, resulting in similar MACE outcomes.

5 | LIMITATIONS

There are inherent limitations of this retrospective study. First, this high-volume center analysis may limit the generalizability of these results to lower volume and less experienced nontertiary centers. Second, no adjustments for confounding between HL and non-HL patients, such as a propensity score-matched analysis, were completed. Third, only in-hospital data were available for analysis. Lastly, these data were not derived from a prospective randomized trial and thus should be viewed as observational in nature. The ongoing ECLIPSE trial (OA vs. conventional angioplasty; 2000 patients; Clinicaltrials.gov identifier NCT03108456) will provide the opportunity to analyze prospective comparative data regarding the safety and efficacy of OA over balloon angioplasty in subpopulations.

6 | CONCLUSIONS

HL individuals are at greater risk for cardiovascular disease mortality compared with non-HLs with similar CAC scores. In this large real-world OA study, the in-hospital freedom from MACE rates in HL patients who underwent OA were high and similar to non-HL patients. This study suggests OA is a reasonable treatment strategy for HL patients with severe CAC. Prospective randomized trials with greater inclusion of racial/ethnic minorities are needed to determine the ideal revascularization strategy for HL patients with severe CAC.

CONFLICTS OF INTEREST

Drs. Beohar, Stone, Leon, and Kirtane report receiving consulting fees from Cardiovascular Systems, Inc. (CSI). Dr. Martinsen is employed by and owns stock in CSI. No other potential conflict of interest relevant to this article was reported.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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