



Outcomes after Atherectomy Treatment of Severely Calcified Coronary Bifurcation Lesions: A Single Center Experience



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ABSTRACT

Background: Coronary bifurcation and calcified lesions account for 15–20% and 6%–20% of percutaneous coronary interventions (PCI), respectively. Treatment of these lesions is associated with high periprocedural complication rates and unfavorable long-term clinical outcomes, including high rates of revascularization. This retrospective, single-center study evaluated the outcomes of atherectomy treatment for heavily calcified coronary bifurcation lesions.

Methods: Patients who underwent a coronary atherectomy procedure to treat a heavily calcified lesion between January 2010 and March 2016 at Metropolitan Heart and Vascular Institute (Minneapolis, MN) were included in this retrospective study. Data were stratified to compare atherectomy treatment of coronary bifurcation lesions vs non-bifurcation lesions. Additionally, data were compared based on type of atherectomy utilized during the index procedure, either orbital (OAS) or rotational (RA) atherectomy. Major adverse cardiac events (MACE), defined as a composite of death, myocardial infarction (MI), and target vessel revascularization (TVR), were assessed at 30 days post-procedure.

Results: Among the 177 patients treated with atherectomy, 72 patients had bifurcation lesions. Compared to patients with non-bifurcation lesions, patients with bifurcation lesions were more likely to have a history of prior PCI or coronary artery bypass grafting. Bifurcation lesions required a higher volume of contrast. There were similar low rates of slow flow/no-reflow (2.8% bifurcations vs 1.0% non-bifurcation; $p = 0.355$). The 30-day rates of death (1.4% vs 1.9%; $p = 0.794$), MI (0% vs 0%; $p = \text{NA}$), and TVR (0% vs 1.0%; $p = 0.406$) were similar in patients with bifurcation lesions versus those without, respectively. An atherectomy sub-analysis (OAS vs RA) of the patients with bifurcation lesions showed that OAS utilization was associated with shorter procedure time (81 min vs 109 min; $p = 0.026$) and fluoroscopy time (18 min vs 27 min; $p = 0.007$) compared to RA, respectively—no significant differences in baseline demographic or lesion characteristics were noted in the bifurcation atherectomy sub-groups, except for higher beta/calcium blocker use in RA bifurcation subjects.

Conclusions: The results of this study demonstrated that atherectomy treatment in patients with heavily calcified coronary bifurcation lesions is feasible, resulting in similar low 30-day MACE rates as compared to patients with non-bifurcation lesions. In addition, in this study OAS utilization versus RA in bifurcation lesions was associated with significantly shorter procedure and fluoroscopy time. Further studies are needed to assess the safety and efficacy of atherectomy in patients with severely calcified bifurcation lesions.

Summary for annotated table of contents: This retrospective, single-center study evaluated the outcomes of orbital and rotational atherectomy treatment for heavily calcified coronary bifurcation lesions as compared to non-bifurcation lesions. The results demonstrate that atherectomy treatment in patients with heavily calcified coronary bifurcation lesions is feasible, resulting in similarly low 30-day MACE rates as compared to patients with non-bifurcation lesions. In addition, in this study OAS utilization versus RA in bifurcation lesions was associated with significantly shorter procedure and fluoroscopy time.

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Abbreviations: CABG, coronary artery bypass grafting; CIN, contrast-induced nephropathy; Cx, circumflex artery; Dx, diagonal branch of LAD; IABP, intra-aortic balloon pump; IRB, institutional review board; ISR, in-stent restenosis; LAD, left anterior descending; LMCA, left main coronary artery; MACE, major adverse cardiac events; MI, myocardial infarction; OAS, orbital atherectomy system; OM, obtuse marginal; PCI, percutaneous coronary intervention; PDA, posterior descending artery; RA, rotational atherectomy; RCA, right coronary artery; SB, side branch; TVR, target vessel revascularization.

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1. Introduction

Coronary bifurcation and calcified lesions account for 15–20% [1,2] and 6%–20% [3,4] of percutaneous coronary interventions (PCI), respectively. Despite recent advances in interventional technology, treatment of these lesions is still associated with high periprocedural complication rates and unfavorable long-term clinical outcomes, including high rates of revascularization [5]. Further complications can arise when treating severely calcified bifurcation lesions, which commonly include vessel dissection and perforation [6]. This retrospective, single-center study evaluated the outcomes of orbital and rotational atherectomy treatment for heavily calcified coronary bifurcation lesions as compared to non-bifurcation lesions. The mechanisms, treatment algorithms, and general clinical outcomes of these atherectomy devices have been recently reviewed [7–10]. The data presented here provides new information for interventional cardiologists since bifurcation lesions were excluded from past controlled clinical trials, such as the pivotal ORBIT II trial [11].

2. Material and methods

Patients who underwent a coronary atherectomy procedure to treat heavily calcified lesions between January 2010 and March 2016 at Metropolitan Heart and Vascular Institute (Minneapolis, MN) were consecutively included in this retrospective study. IRB waiver was obtained. Subjects were stratified into two main cohorts: those with bifurcation versus non-bifurcation lesions. All lesions were true bifurcations, Medina classification (1, 1, 1), (1, 0, 1), or (0, 1, 1). Characterization of these lesions as ostial was not tracked in this study. Additionally, in-stent restenosis (ISR) lesions were excluded as this is a contraindication for orbital atherectomy. These main cohorts were also subdivided based on the type of atherectomy utilized during the index procedure, either the orbital atherectomy system (OAS) (Cardiovascular Systems, Inc., St. Paul, MN) or rotational atherectomy (RA) (Boston Scientific Corporation, Marlborough, MA). Major adverse cardiac events (MACE), defined as a composite of death, myocardial infarction (MI), and target vessel revascularization (TVR), were assessed at 30 days post-procedure. Procedural success was defined as adequate ablation of intimal calcification to facilitate proper placement of a stent. Statistical analyses were performed using SOFA Statistics (Version 1.4.6; Paton-Simpson & Associates Ltd., Auckland, New Zealand) and XLSTAT (Version 2018.3; Data Analysis and Statistical Solution for Microsoft Excel. Addinsoft, Paris,

France). Data were summarized using descriptive statistics for continuous data presented as mean \pm standard deviation and proportions for categorical data. Data were compared using Mann Whitney *U* Test for continuous parameters and Pearson's Chi Square Test for categorical parameters, and any *p*-value < 0.05 was considered significant.

3. Results

3.1. Demographic, vessel, and lesion characteristics

Among the 177 consecutive patients treated with atherectomy, 72 patients had bifurcation lesions, and of those, 33 were treated with OAS and 39 with RA (Table I). There were no significant differences between the overall bifurcation and non-bifurcation cohorts, except for the significantly higher rates of prior PCI and coronary artery bypass grafting (CABG) seen in the bifurcation cohort (Table I). When comparing OAS and RA subgroups, RA had a significantly higher rate of beta/calcium blocker utilization as compared to OAS in the bifurcation cohort—otherwise similar demographic rates were noted (Table I). Lastly, there were no significant vessel or lesion characteristic differences noted between the bifurcation and non-bifurcation cohorts, nor the OAS versus RA subgroups in the bifurcation cohort (Table II).

3.2. Procedural and 30-day outcomes

The bifurcation and non-bifurcation cohorts both resulted in a 100% atherectomy and stent implantation success rate, as well as similar final post-procedure stenosis rates, as visually estimated from the cine at the time of procedure (Table III). In addition, there were similar low rates of slow flow/no-reflow between the cohorts (2.8% vs 1.0%; *p* = 0.355); however, bifurcation lesions required a higher volume of contrast during the procedure (251 mL vs 219 mL; *p* = 0.026). An atherectomy sub-analysis (OAS vs RA) of the patients with bifurcation lesions showed that OAS utilization was associated with shorter procedure time (81 min vs 109 min; *p* = 0.026) and fluoroscopy time (18 min vs 27 min; *p* = 0.007) compared to RA, respectively (Table III). A similar trend was noted in the non-bifurcation cohort: procedures involving OAS were shorter (73 min vs 100 min; *p* < 0.001), and required less fluoroscopy (15 min vs 28 min; *p* < 0.001) than procedures using RA (Table III).

Table I
Baseline characteristics.

	Bifurcation			P*	Non-bifurcation			P*	P**
	OAS (N = 33)	RA (N = 39)	Total (N = 72)		OAS (N = 45)	RA (N = 60)	Total (N = 105)		
Age (years)	69.5 \pm 8.9	71.6 \pm 8.3	70.6 \pm 8.6	0.530	69.6 \pm 9.7	72.2 \pm 9.8	71.1 \pm 9.8	0.147	0.506
Male gender	26 (78.8)	28 (71.8)	54 (75.0)	0.495	33 (73.3)	33 (55.0)	66 (62.9)	0.054	0.089
Ethnicity				0.354				0.314	0.318
Caucasian	33 (100.0)	38 (97.4)	71 (98.6)		45 (100.0)	57 (95.0)	102 (97.1)		
African American	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (1.7)	1 (1.0)		
Asian	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	2 (3.3)	2 (1.9)		
Native American	0 (0.0)	1 (2.6)	1 (1.4)		0 (0.0)	0 (0.0)	0 (0.0)		
Creatinine	1.01 \pm 0.2	1.30 \pm 1.2	1.17 \pm 0.9	0.202	1.15 \pm 1.0	1.44 \pm 2.0	1.31 \pm 1.7	0.503	0.150
eGFR (mL/min/1.73 m ²)	78.1 \pm 19.9	68.6 \pm 21.9	73.0 \pm 21.4	0.086	76.6 \pm 24.0	72.6 \pm 26.1	74.3 \pm 25.2	0.720	0.560
Hemodialysis	0 (0.0)	2 (5.1)	2 (2.8)	0.187	0 (0.0)	5 (8.3)	5 (4.8)	0.047	0.506
Diabetes	12 (36.4)	20 (51.3)	32 (44.4)	0.204	22 (48.9)	21 (35.0)	43 (41.0)	0.152	0.644
Heart failure	6 (18.2)	8 (20.5)	14 (19.4)	0.803	6 (13.3)	10 (16.7)	16 (15.2)	0.638	0.464
History of hyperlipidemia	29 (87.9)	33 (84.6)	62 (86.1)	0.690	37 (82.2)	53 (88.3)	90 (85.7)	0.376	0.941
History of hypertension	31 (93.9)	36 (92.3)	67 (93.1)	0.786	39 (86.7)	54 (90.0)	93 (88.6)	0.595	0.320
Beta/calcium blocker use	7 (21.2)	21 (53.8)	28 (38.9)	0.005	8 (17.8)	41 (68.3)	49 (46.7)	<0.001	0.305
History of MI	15 (45.5)	10 (25.6)	25 (34.7)	0.078	8 (17.8)	17 (28.3)	25 (23.8)	0.209	0.113
History of PCI	20 (60.6)	27 (69.2)	47 (65.3)	0.444	19 (42.2)	27 (45.0)	46 (43.8)	0.777	0.005
History of CABG	12 (36.4)	20 (51.3)	32 (44.4)	0.204	9 (20.0)	17 (28.3)	26 (24.8)	0.328	0.006
Smoker	29 (87.9)	27 (69.2)	56 (77.8)	0.058	34 (75.6)	44 (73.3)	78 (74.3)	0.797	0.595

Values are n (%) or mean \pm standard deviation. Missing data imputed using mean imputation method [creatinine (N = 4)].

P* = OAS vs RA; P** total bifurcation vs total non-bifurcation.

CABG = coronary artery bypass graft; MI = myocardial infarction; OAS = orbital atherectomy system; PCI = percutaneous coronary intervention; RA = rotational atherectomy.

Table II
Vessel and lesion characteristics.

	Bifurcation				Non-bifurcation				P**	
	OAS (N = 33)	RA (N = 39)	Total (N = 72)	P*	OAS (N = 45)	RA (N = 60)	Total (N = 105)	P*		
Pre-procedure stenosis (%)	87.5 ± 7.3	89.3 ± 6.9	88.4 ± 7.1	0.300	85.0 ± 6.9	91.5 ± 7.7	88.7 ± 8.0		<0.001	0.715
Pre-procedure target lesion length (mm)	23.1 ± 11.9	25.0 ± 14.5	24.2 ± 13.3	0.701	24.1 ± 16.9	33.2 ± 19.9	29.3 ± 19.1		0.008	0.192
Target lesion vessel				0.276					0.051	0.331
Cx	2 (6.1)	6 (15.4)	8 (11.1)		8 (17.8)	4 (6.7)	12 (11.4)			
Dx	0 (0.0)	4 (10.3)	4 (5.6)		1 (2.2)	0 (0.0)	1 (1.0)			
LAD	12 (36.4)	10 (25.6)	22 (30.6)		21 (46.7)	20 (33.3)	41 (39.0)			
LMCA	10 (30.3)	12 (30.8)	22 (30.6)		0 (0.0)	0 (0.0)	0 (0.0)			
OM	2 (6.1)	3 (7.7)	5 (6.9)		0 (0.0)	4 (6.7)	4 (3.8)			
PDA	1 (3.0)	0 (0.0)	1 (1.4)		0 (0.0)	0 (0.0)	0 (0.0)			
Ramus	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (1.7)	1 (1.0)			
RCA	6 (18.2)	4 (10.3)	10 (13.9)		15 (33.3)	31 (51.7)	46 (43.8)			

Values are n (%) or mean ± standard deviation. Missing data imputed using mean imputation method [pre-procedure stenosis (N = 1) and pre-procedure target lesion length (N = 6)]. P* = OAS vs RA; P** total bifurcation vs total non-bifurcation.

Cx = circumflex; Dx = diagonal branch of LAD; LAD = left anterior descending; LMCA = left main coronary artery; OAS = orbital atherectomy system; OM = obtuse marginal; PDA = posterior descending artery; RA = rotational atherectomy; RCA = right coronary artery.

As shown in Table IV, the 30-day MACE rates, including death, MI and TVR, were similar in the bifurcation cohort versus the non-bifurcation cohort (1.4% vs 1.9%, respectively; $p = 0.794$). There were also no significant differences between OAS and RA subgroups regarding MACE rates (Table IV).

4. Discussion

In previous studies involving the use of balloon angioplasty, cutting balloons, atherectomy and stents, it has been commonplace to associate the treatment of calcified bifurcation lesions with low success and high restenosis rates [5,12,13]. Improved stent designs and implantation techniques have been developed for bifurcation lesions, but with limited success [5,14]. In particular, past methods of atherectomy were associated with modestly improved angiography results and lower post-procedure stenosis, but with the cost of significant increases in early and late MACE rates, and a high rate of periprocedural complications [13,15]. Although RA has been associated with a higher rate of complications, such as side branch (SB) perforations and contrast-induced nephropathy (CIN) [15], RA has been shown to limit SB occlusion by ablating calcific plaque instead of shifting it into the SB, as is common when balloon angioplasty is used without atherectomy to treat bifurcation lesions [16].

The results of this retrospective study further demonstrate that atherectomy treatment in subjects with heavily calcified coronary bifurcation lesions is feasible, resulting in similarly low 30-day MACE rates as

compared to subjects with non-bifurcation lesions. In addition, since bifurcations were excluded from the ORBIT II OAS device approval study [11], this retrospective study provides the first published data of OAS use in bifurcation lesions. Although OAS and RA had successful procedural and 30-day outcomes, there were differences noted between these devices that may have patient treatment implications. For example, OAS utilization versus RA in bifurcation lesions was associated with significantly shorter procedure and fluoroscopy time. Although not shown here, previous studies have shown associations between prolonged fluoroscopy time and increases in rates of in-hospital death, CABG, hematoma, and contrast-induced nephropathy [13]. Thus, further studies are warranted to understand the differences between OAS and RA devices, as well as to further assess the safety and efficacy of atherectomy in patients with severely calcified bifurcation lesions.

5. Conclusions

The results of this study demonstrate that atherectomy treatment in patients with heavily calcified coronary bifurcation lesions is feasible, resulting in similarly low 30-day MACE rates as compared to patients with non-bifurcation lesions. In addition, in this study OAS utilization versus RA in bifurcation lesions was associated with significantly shorter procedure and fluoroscopy time. Further studies are needed to assess the safety and efficacy of atherectomy in patients with severely calcified bifurcation lesions.

Table III
Procedural results.

	Bifurcation				Non-bifurcation				P**	
	OAS (N = 33)	RA (N = 39)	Total (N = 72)	P*	OAS (N = 45)	RA (N = 60)	Total (N = 105)	P*		
Bradycardia or heart block	0 (0.0)	0 (0.0)	0 (0.0)	–	0 (0.0)	0 (0.0)	0 (0.0)	–	–	–
Temporary pacer placement	0 (0.0)	1 (2.6)	1 (1.4)	0.354	1 (2.2)	5 (8.3)	6 (5.7)	0.182	0.147	
Temporary pacer activation	0 (0.0)	0 (0.0)	0 (0.0)	–	1 (2.2)	3 (5.0)	4 (3.8)	0.462	0.094	
Slow flow/no-reflow	1 (3.0)	1 (2.6)	2 (2.8)	0.905	0 (0.0)	1 (1.7)	1 (1.0)	0.384	0.355	
IABP use	0 (0.0)	1 (2.6)	1 (1.4)	0.354	0 (0.0)	0 (0.0)	0 (0.0)	–	0.226	
Impella use	1 (3.0)	0 (0.0)	1 (1.4)	0.274	0 (0.0)	0 (0.0)	0 (0.0)	–	0.226	
Successful atherectomy	33 (100.0)	39 (100.0)	72 (100.0)	–	45 (100.0)	60 (100.0)	105 (100.0)	–	–	
Total number of lesions treated	1.2 ± 0.4	1.3 ± 0.6	1.3 ± 0.5	0.963	1.2 ± 0.4	1.3 ± 0.4	1.2 ± 0.4	0.777	0.986	
Total procedure time (minutes)	80.8 ± 27.2	108.6 ± 70.0	95.9 ± 56.2	0.026	73.4 ± 24.8	100.1 ± 39.5	88.6 ± 36.4	<0.001	0.521	
Total fluoroscopy time (minutes)	17.9 ± 7.8	27.3 ± 20.1	23.0 ± 16.3	0.007	15.2 ± 7.3	27.5 ± 15.5	22.2 ± 14.0	<0.001	0.737	
Total length of stay (days)	2.6 ± 4.8	2.1 ± 2.1	2.4 ± 3.5	0.405	1.7 ± 1.0	2.5 ± 2.5	2.2 ± 2.0	0.309	0.317	
Total volume of contrast used (mL)	236.9 ± 88.1	263.5 ± 100.7	251.3 ± 95.4	0.306	216.3 ± 78.0	221.2 ± 86.4	219.1 ± 82.5	0.751	0.026	
Final post-procedure stenosis (%)	0.3 ± 1.7	1.9 ± 6.4	1.2 ± 4.9	0.464	0.5 ± 2.1	1.0 ± 5.3 (N = 59)	0.7 ± 4.2 (N = 104)	0.530	0.963	

Values are n or mean ± standard deviation. Missing data imputed using mean imputation method [total procedure time (N = 1), total fluoroscopy time (N = 8), total volume of contrast used (N = 2), final procedure stenosis (N = 9)].

P* = OAS vs RA; P** total bifurcation vs total non-bifurcation.

IABP = intra-aortic balloon pump; OAS = orbital atherectomy system; RA = rotational atherectomy.

Table IV
Thirty day outcomes.

	Bifurcation				Non-bifurcation				P**
	OAS (N = 33)	RA (N = 39)	Total (N = 72)	P*	OAS (N = 45)	RA (N = 60)	Total (N = 105)	P*	
30-Day MACE	1 (3.0)	0 (0.0)	1 (1.4)	0.274	1 (2.2)	1 (1.7)	2 (1.9)	0.837	0.794
Death	1 (3.0)	0 (0.0)	1 (1.4)	0.274	1 (2.2)	1 (1.7)	2 (1.9)	0.837	0.794
MI	0 (0.0)	0 (0.0)	0 (0.0)	–	0 (0.0)	0 (0.0)	0 (0.0)	–	–
TVR	0 (0.0)	0 (0.0)	0 (0.0)	–	1 (2.2)	0 (0.0)	1 (1.0)	0.246	0.406

Values are n (%). P* = OAS vs RA; P** total bifurcation vs total non-bifurcation.

MACE = major adverse cardiac events; MI = myocardial infarction; TLR = target lesion revascularization; TVR = target vessel revascularization; OAS = orbital atherectomy system; RA = rotational atherectomy.

6. Limitations

This was a non-randomized, observational, single center, retrospective study. This study was not powered due to the limited sample size. Patient selection may be operator dependent and therefore the results may not be generalizable outside of this observational study. Cardiac enzymes were not routinely measured after PCI, therefore, some periprocedural non-ST elevation MIs may not have been detected.

Conflict of interest

JWC has a consulting agreement with Cardiovascular Systems, Inc. ANB, DTW, and BJM are employees of Cardiovascular Systems, Inc. in the Scientific and Clinical Affairs Department. CW and JC have no conflicts of interest to report.

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