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Research Article

Orbital Atherectomy for Treating Severely Calcified High-Risk Coronary Bifurcation Lesions: A Practical Approach

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- Atherectomy; Percutaneous coronary intervention; Coronary artery disease

Abstract

Background: Coronary bifurcation lesions account for 15-20% of lesions treated with percutaneous coronary intervention (PCI). Treatment of these lesions may be associated with increased complications. In calcified lesions orbital atherectomy (OA) facilitates stent delivery and improves overall procedural outcomes. However, its feasibility and safety preceding a planned two stent bifurcation strategy has not been established.

Methods: Between January 1, 2016 and September 30, 2019, patients undergoing OA prior to a planned two stent approach for complex calcified bifurcation lesions (medina 1:1:1, 0:1:1, 1:0:1) were retrospectively reviewed. Baseline patient characteristics, procedural variables and clinical outcomes were evaluated post procedure and at 30 days.

Results: Twenty-six (26) consecutive patients undergoing OA prior to stenting (OAptS) were treated with OA of both main and side branches prior to planned two stent bifurcation placement. These patients had advanced cardiovascular disease, multiple comorbidities and were not candidates for coronary artery bypass grafting. Hemodynamic support was used in 7 patients (26.9%). Despite this high-risk patient population, procedures were all successful without significant MACE or target vessel revascularization (TVR) immediately post procedure or at 30 days.

Conclusions: This retrospective study establishes the feasibility and safety of main branch (MB) and side branch (SB) OAptS for complex calcified coronary bifurcation lesions undergoing a pre-planned two stent treatment approach. In this high-risk, carefully selected patient population, OAptS was successfully used without significant MACE or TVR at 30 days.

ABBREVIATIONS

CABG: Coronary Artery bypass Grafting; ECMO: Extracorporeal Membrane Oxygenation; Fr; French; IC: Intracoronary; krpm: thousand rotations per minute; LAD: Left Anterior Descending Artery; LCx: Left Circumflex Artery; LMCA: Left Main Coronary Artery; LVEF: Left Ventricular Ejection Fraction; MACE: Major Adverse Cardiovascular Events; MB: Main branch; mm: millimeter; NSTEMI: non-ST Elevation Myocardial Infarction; NTG: Nitroglycerin; OA: Orbital Atherectomy; Oats: Orbital Atherectomy prior to stenting; OTW: over-the-wire; PCI: Percutaneous Coronary Intervention; RCA: Right Coronary Artery; SB: Side branch; TVR: Target Vessel Revascularization

INTRODUCTION

Treatment of calcified coronary bifurcation lesions remains challenging. In general, percutaneous intervention (PCI) of bifurcation lesions is associated with increased complication rates including periprocedural myocardial infarction (MI), coronary artery dissection, and death [1-3]. In patients undergoing PCI without atherectomy true bifurcation lesions have the highest overall MACE rates including stent thrombosis, emergent coronary artery bypass surgery (CABG), target vessel revascularization (TVR), and all-cause mortality [3,4]. This is largely due to lesion complexity, higher rates of lesion calcification, more extensive side branch involvement, and the propensity for plaque shift during treatment [5]. These lesions often require a pre-planned two stent technique for optimal outcomes. Orbital atherectomy prior to stenting (OAptS) has been generally shown to improve both stent delivery/deployment and outcomes for complex calcified lesions [6,7]. However, complex bifurcation lesions were excluded from the ORBIT II study [7]. Recently, the feasibility of OA for the treatment of calcified bifurcation lesions has been demonstrated, but these studies did not exclusively evaluate the most severe classes of bifurcation lesions. In these studies, most patients underwent provisional stent placement rather than a planned two stent approach [5,8,9]. Our study assesses the feasibility and procedural outcomes for OAptS in the highest risk, calcified, bifurcation lesions which required a planned two stent technique. It also provides limited safety and outcomes data in this patient cohort.

MATERIAL AND METHODS

Between January 1, 2016 and September 30, 2019, a total of 3246 patients underwent PCI at our institution with 299 patients (9.2% of all PCI) undergoing atherectomy (laser, orbital, rotational). Of the 299 atherectomies, 271 were orbital atherectomy. Based on Medina criteria, 43 patients undergoing OA (15.8%) were identified to have complex bifurcation lesions which might require a two-stent strategy for treatment. Of the 43 patients with bifurcation lesions, 26 (9.6% of all orbital atherectomy patients) had Medina 1:1:1, 0:1:1, 1:0:1 lesions with extensive main branch (MB) and side branch (SB) stenosis requiring a pre-planned two stent treatment strategy. The other 17 patients were treated with MB OA and provisional bifurcation stenting and were not included in this analysis. Clinical data and coronary angiograms for these 26 patients were retrospectively reviewed. Baseline patient characteristics, procedural variables, major adverse cardiovascular event (MACE) rates (defined as cardiac death, myocardial infarction and target vessel revascularization) and bleeding/vascular complications were compiled. Only true bifurcation lesions with visible calcification in both the MB and SB and a SB lesion involving the ostium and extending greater than 15mm were included for analysis. All other bifurcation lesions were excluded from analysis. IVUS and OCT were not routinely used in this patient population. Anecdotally, most of these lesions were unfavorable for imaging devices because of their complexity, tortuosity, and dense calcification. Fluoroscopy likely underestimates lesion calcification [10,11]. Therefore, dense circumferential and/or eccentric vessel calcification by fluoroscopy were felt to indicate the need for atherectomy. Procedures were performed using either transradial (65.4%) or transfemoral approach (34.6%). Both 6 Fr and 7 Fr guide catheter sizes were utilized depending on access site, coronary anatomy, and aortic arch configuration. Due to lesion complexity, operators expected to treat these lesions using a planned two stent bifurcation strategy, rather than provisional stenting, following both MB and SB OA. All patients received drug-eluting stents.

Orbital atherectomy of both the MB and SB was performed prior to bifurcation stenting. Only low atherectomy speed (80 krpm) was used in each branch to minimize the risk of dissection, perforation. or plaque shift between MB and SB before, during and after stent delivery and deployment. In general, 2-4 passes (forward and back = pass) were performed in each branch, so long as no angiographic evidence of dissection or slow flow was detected between passes by test angiography. Debulking was not quantified prior to stenting. Rather, we relied on OA pulsatile force generation and calcium ablation (debulking) to sufficiently modify calcific plaque and facilitate stent delivery and deployment. Planned two stent bifurcation techniques used included classic crush, mini-crush, culotte, V-stent and modified T-stent [6]. All patients underwent final kissing balloon angioplasty following stent deployment.

The MB was generally treated first, unless the wire preferentially took the SB due to a favorable approach angle. First, the MB branch was wired directly using a *ViperWire Advance®* or a suitable workhorse coronary guidewire. If a workhorse wire was used, it was exchanged for a *ViperWire Advance®* using an uninflated, low-profile over-the-wire (OTW) balloon or a suitable exchange catheter (i.e. Teleport, Finecross, etc.). Next, MB OA was performed at low speed with care taken to assess for dissection or slow flow using test angiography between passes. The *ViperWire Advance®* was removed and redirected into the second branch after administering intracoronary nitroglycerin (IC NTG) 200-400 mcg depending on systemic blood pressure, and OA was performed. In general, it proved easier to wire the SB (after MB OA) with a workhorse wire, then exchange it for a *ViperWire Advance®*. Again, assessment for dissection or slow flow was performed using test angiography after wire placement in the second branch and between OA passes. After completing SB OA, additional IC NTG was administered, and a workhorse coronary wire placed into the MB. A second workhorse wire was then placed into the SB and the *ViperWire Advance®* removed. Bifurcation stent placement was then performed followed by kissing balloon angioplasty. Either MB or SB angioplasty was avoided until OA of both branches had been successfully completed.

In some cases, initial vessel wire placement with the *ViperWire Advance®* was technically challenging because of its relative stiffness and somewhat inflexible tip, thereby making it suboptimal for navigating more complex vessel anatomy. This potentially increases the risk of both vessel wall injury (i.e. haziness, reduced flow) and visible dissection during initial guide wire placement which would limit the use of OA. Therefore, we chose to mitigate this potential risk in some patients by first wiring the target vessel with a workhorse coronary wire, then exchanging for a *ViperWire Advance®* using a suitable exchange catheter or over-the-wire-balloon. It should be noted, however, that no vessel injury or dissection was actually observed in our patients when using the *ViperWire Advance®* for initial target vessel wire placement. Also, current availability of the *ViperWire Advance®* with Flex Tip, a newer, more flexible and steerable OA coronary guide wire, may significantly reduce the potential risk of vessel wall injury/dissection in complex or tortuous vessel anatomy because of its improved design (note: this guide wire was not commercially available at the time this case series was completed). If either vessel wall injury or dissection would have been detected by test angiography following the initial *ViperWire Advance®* placement or between OA passes, no further OA would have been performed. Instead, the injured vessel would have been stabilized with balloon angioplasty and/or stent placement, as appropriate. Further treatment of the bifurcation lesion would then proceed using conventional balloon and stent techniques without further atherectomy. Hemodynamic support in the form of *Impella-CP*® or extracorporeal membrane oxygenation (ECMO) was used in patients undergoing left main-left anterior descending-left circumflex (LMCA–LAD–LCx) intervention if they had severely reduced ejection fraction <20%, an occluded RCA, and/or a moderately reduced ejection fraction <35% with severe RCA disease. No statistical analysis was attempted in this proof-of-concept study since no independent or dependent variables were compared.

RESULTS

Study Population

Patient characteristics are shown in Table 1. The mean age was 68.9 ± 12.2 years with a male preponderance (84.6%). Most patients were 50 years or older (96.2%). The left ventricular ejection fraction (LVEF) ranged from 15-65% with a mean of 48.2 ± 14.6%. In general, patients had multiple coronary risk factors and well-established cardiovascular disease. Most notably, 17 patients (65%) were diabetic, and 22 patients (84.6%) were smokers. Furthermore, there was a high incidence of previous PCI (50%), MI (42.3%) and CABG (11.5%). Because of disease complexity, 14 (53.8%) patients were referred for CABG, but were deemed suboptimal candidates because of poor distal targets, depressed LVEF and/or multiple comorbidities. Eight patients (30.7%) underwent staged PCI procedures for treatment of other coronary lesions prior to treating their bifurcation lesion. Two patients (7.7%) had treatment of a bifurcation lesion prior to transcatheter aortic valve replacement. Finally, 12 patients (46.2%) were not referred for CABG because they refused or had no clear clinical benefit from CABG compared to PCI. Hemodynamic support in the form of *Impella-CP*® or extracorporeal membrane oxygenation (ECMO) was used in 7 patients (26.9%), all undergoing LMCA–LAD–LCx intervention. Of the patients requiring hemodynamic support, four had an occluded RCA, one had severe aortic stenosis, one had severely reduced systolic function (ejection fraction <25%) with severe RCA disease, and one had moderately reduced systolic function (ejection fraction 30%). Of the four patients with occluded RCA, one had severely reduced systolic function (ejection fraction <25%), one had mildly reduced systolic function (ejection fraction 40%), two had normal systolic function but complex LMCA stenosis.

Vessel and lesion characteristics

Examples of treated bifurcation lesions are demonstrated in Figure 1 and Figure 2. The lesions most often treated were LAD–diagonal bifurcations in 13 patients (50%), LMCA–LAD–LCx bifurcations in 7 patients (26.9%), LCx-OM bifurcations in 4 patients (15.4%) and distal RCA bifurcation in 2 patients (7.7%). Significant lesion calcification was visible angiographically in all lesions. Total MB stented length was 24.4 ± 7.3 mm (range 16 to 38 mm) and total SB stented length was 21.9 ± 14.3 mm (range 16 to 75 mm). Procedural variables including procedure time, fluoroscopy time and contrast volume are shown in Table 2. Finally, the mean angles for individual treated vessel bifurcations are shown in Table 3. In general, these angles were between 30° and 70°, but there was wide angle variation with a range of 15° to 130°. More extreme bifurcation angulation was often noted in LMCA–LAD–LCx and RCA bifurcations.

Procedural outcomes

Outcomes were evaluated in all patients by review of the

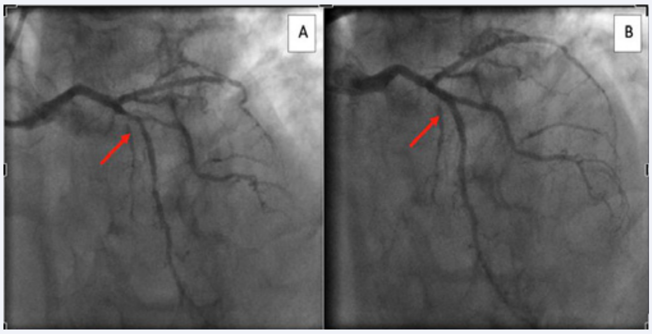

Figure 1 Complex, calcified LAD-Diagonal 1 bifurcation lesion in an anterior-posterior cranial projection in a patient prior to planned transcatheter aortic valve insertion for severe, calcific aortic stenosis. Panel A shows the pre-treatment lesion (arrow) and Panel B shows the lesion after atherectomy and stenting (arrow).

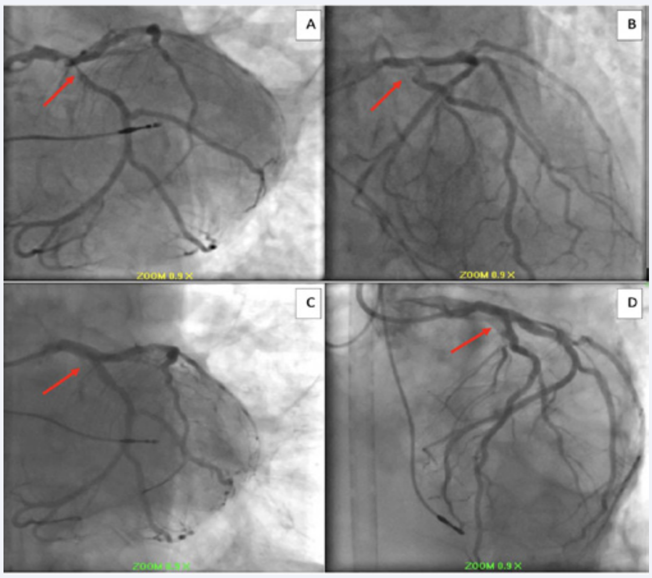

Figure 2 Panel A and Panel B show initial anterior-posterior caudal and left anterior oblique angiograms (respectively) of a calcified distal LMCA lesion involving the ostia/proximal segments of both the LAD and LCx (arrows) in a patient presenting with NSTEMI who was deemed too high-risk for CABG. Panel C and Panel D show post treatment angiograms in the same angiographic views after orbital atherectomy of distal LMCA, proximal LAD and proximal LCx followed by a simultaneous kissing stent placement and final kissing balloon angioplasty (arrows). Elective hemodynamic support with extracorporeal membrane oxygenation (ECMO) was used due to complex, proximal target lesion anatomy in a left dominant coronary system and severely reduced global LV systolic function (LVEF 20%).

Table 1: Baseline Characteristics

	All Subjects N=26
Age (years)	68.9 ± 12.2
	Range: 31-85
<49	1(3.8)
50-65	10(38.5)
>65	15(57.7)
Gender	
Male	22 (84.6)
Female	4 (15.4)
LVEF (%)	48.2
	± 14.6
	Range: 15-65
<35%	5 (19.2)
35-49%	5 (19.2)
>50%	16 (61.5)
Hypertension	25 (96.2)
Hyperlipidemia	24 (92.3)
Smoker	22 (84.6)
Diabetes	17 (65.4)
PAD	12 (46.2)
CKD	10 (38.5)
ESRD	2 (7.7)
CABG	3 (11.5)
PCI	13 (50)
MI	11 (42.3)
Stroke	4 (15.4)

The data is expressed as n (%) or mean ± standard deviation. Abbreviations: CABG, coronary artery bypass grafting; CKD, chronic kidney disease; ESRD, end stage renal disease; LVEF, left ventricular ejection fraction; MI, myocardial infarction; PAD, peripheral arterial disease; PCI, percutaneous coronary intervention.

Table 2: Procedural Outcomes

	Outcomes (N=26)
30-Day MACE	0
MI	0
Bleeding	0
TVR	0
Cardiac death	0
30-Day non-cardiac death	1(3.8)
1-year MACE	0
MI	0
Bleeding	0
TVR	0
Cardiac death	0
1-year non-cardiac death	3(11.5)
AKI	1(3.8)
Procedure Time (minutes)	102.5 ± 30.1
Fluoroscopy Time (minutes)	34.5 ± 9.6
Contrast Volume (ml)	271.3 ± 57.1

The data is expressed as n (%) or mean ± standard deviation. Abbreviations: MACE, major adverse cardiovascular events; MI, myocardial infarction; ml, milliliter; TVR, target vessel revascularization; AKI, acute kidney injury.

electronic medical record and at clinic follow up. Despite lesion complexity, short term procedural and clinical outcomes were generally good as shown in Table 2. There were no procedural/vascular complications, major bleeding, or MACE events at 30 days. One patient, however, did require transient hemodialysis for contrast-induced nephropathy. Clinical follow-up data was

Table 3: Bifurcation Angle of Treated Vessels

Vessel	Bifurcation Angle (Degrees)
LMCA-LAD-LCx	71 ± 30 deg
LAD - Diagonal	37 ± 14 deg
LCx – OM	33 ± 6 deg
RCA	70 ± 20 deg

Data are expressed as mean ± standard deviation.
Abbreviations: deg, degrees; LAD, left anterior descending artery; LCx, left circumflex artery; LMCA, left main coronary artery; OM, obtuse marginal artery; RCA, right coronary artery.

available on all 26 patients by chart review at one year and no cardiac deaths, MACE, or TVR events occurred. There were 4 total non-cardiac deaths: one patient died 25 days post procedure from sepsis and 3 other patients suffered non-cardiac death between 30 days and one year.

DISCUSSION

Coronary bifurcation lesions account for 15-20% of all lesions treated with PCI [6,12,13]. Calcified bifurcation lesions are associated with the highest restenosis and complication rates [1-3]. While a provisional stent strategy is considered guideline directed therapy for most bifurcation lesions, a preplanned two stent approach for adequately treating the highest risk bifurcation lesions is often necessary. In these lesions SB treatment may be a critical part of the intervention. SB stenting should be considered: 1) when there is significant SB flow impairment (TIMI flow grade <3); 2) in the presence of a major SB dissection; 3) when the SB is diseased and large enough to lead to significant residual ischemia; or 4) when future SB access may be important [6]. A two-stent bifurcation technique is usually considered for bifurcation lesions when the SB is >2.5mm with >50% stenosis extending >5mm beyond the SB ostium [6]. However, this strategy may be associated with unique complications and optimal stent expansion and deployment is required to optimize coronary flow dynamics and improve overall outcomes [14]. When dealing with heavily calcified bifurcation lesions optimal vessel preparation is imperative to facilitate device delivery and stent strut apposition [15]. Furthermore, plaque shift between MB and SB may hinder stent delivery and deployment ultimately leading to worse outcomes. Therefore, prior plaque modification with calcium ablation (debulking) may significantly limit lesion plaque shift and improve overall outcomes. In general, OAptS has been proven safe and effective for treating calcified coronary lesions [7-9]. However, its efficacy in complex bifurcation lesions requiring a two-stent approach is uncertain.

This retrospective analysis demonstrates the relative feasibility and efficacy for OAptS in a high-risk coronary bifurcation lesion subset. It includes a wide spectrum of patients who were not CABG candidates because of poor distal targets, multiple comorbidities and/or severely reduced LVEF. In some patients with complex coronary anatomy and poor LVEF, hemodynamic support was safely utilized to facilitate OA and stent placement without increasing overall procedural risk. Despite the high-risk patient population, all procedures were successful without MACE or TVR at 30 days. Also, no cardiac deaths were observed in this patient group despite their unfavorable clinical and anatomical characteristics. While these outcomes are preliminary, they are comparable to prior studies using OA to treat less complex lesions and patients [7,16]. Compared to prior studies evaluating OA treatment of bifurcation lesions, treatment of high-risk coronary bifurcation lesions was associated with slightly higher contrast volume, procedural time, and fluoroscopy time but equally good procedural/clinical outcomes [8,9].

The dual action of OA lends itself well to treating true bifurcation lesions. Mechanistically, lesion debulking and plaque modification has been shown to facilitate stent delivery, more complete stent expansion, and less stent strut malposition [17]. Furthermore, the smooth vessel lumen created by OA treatment allows unencumbered passage of the guidewires, balloons, and stents [17]. In these patients with complex bifurcation lesions, we observed improved SB access for guidewire placement and stent delivery following MB OA. Also, SB guidewire and balloon delivery was facilitated for final kissing balloon angioplasty. Finally, atherectomy and coronary guidewires can be easily exchanged at various stages during the procedure, so long as no angiographic evidence of dissection is noted [18]. Most importantly, the lesion can be safely treated using a single guide catheter system without requiring any additional coronary guidewires or protective devices.

Caution should be exercised in treating bifurcation angles approaching or exceeding 90 degrees. During OA unintended guidewire bias could produce excessive pulsatile force transmission into a calcified and sharply angulated vessel wall. This could increase the risk of proximal vessel or target lesion dissection. Hence, meticulous attention to optimal technique is necessary to achieve the desired procedural outcome in these lesions. This caution should also be exercised when treating sharply angulated, calcified lesions in general.

CONCLUSION

This small retrospective study examines the feasibility and safety of using of OAptS for high risk calcified coronary bifurcation lesions. Despite the high-risk patient population, OA in both bifurcation branches (MB and SB) prior to stenting was successful without MACE or TVR at 30 days. Furthermore, no cardiac deaths were observed in this patient group despite their unfavorable clinical and anatomical characteristics. The atherectomy and stenting techniques described in these patients appear feasible and safe; however, these complex lesions may require longer procedure/fluoroscopy time, and increased contrast volume.

LIMITATIONS

This is a non-randomized, single center retrospective experience which includes a relatively small sample size and no statistical analysis. It should be considered a “proof of concept” observational report. The patient population was high-risk and carefully selected. This technique requires further study and may not be applicable nor recommended for the treatment of calcified bifurcation lesions, in general.

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DATA AVAILABILITY STATEMENT

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

ETHICS APPROVAL STATEMENT

This trial was approved by the Indiana University Institutional Review board.

CONFLICTS OF INTEREST

Dr. Revtyak is a consultant (ad hoc) for Cardiovascular Systems, Inc.

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