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Use of orbital atherectomy in coronary artery disease with severe calcification: A preliminary study

Short title: Orbital atherectomy in coronary artery disease

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INTRODUCTION

Severe coronary artery calcifications occur in about 10% patients undergoing percutaneous coronary intervention (PCI). They constitute a strong independent predictor of adverse cardiovascular events [1]. Even though the risk factors and pathomechanisms leading to severe coronary calcification are well understood, the options for effective treatment remain insufficient [2, 3].

In the presence of severe calcification, standard PCI has inferior immediate and long-term outcomes [4–6]. In this situation advanced lesion modification techniques are indispensable to improve PCI outcomes. Dedicated balloons and essentially ablative techniques are available. Rotational atherectomy (RA) is the oldest and best recognised ablative technique [7-9]. It is generally acknowledged that superficial modification of calcified atherosclerotic lesions is optimal mechanism of action in RA. Orbital atherectomy (OA) is the second ablative technique that applies the same procedural approach, albeit using a different device. OA was first introduced into clinical practice about 10 years ago in the US. Currently, in the US the number of interventions using OA and RA is comparable [10, 11]. For the past few years OA has been implemented in Europe, first procedure in Poland was performed in December 2021. The potential advantages of OA over RA include the ability to ablate calcifications both when the device is moved forward (anterograde) and backward (retrograde) (thus eliminating the risk of coronal entrapment within the lesion), lesser impact on circulatory hemodynamics (no drop in pressure during ablation, particularly beneficial in the case of hemodynamically unstable patients), more efficient ablation of calcifications, and lesser risk of microvascular obstruction during and after the procedure. On the other hand some data indicate higher rate of dissections and perforations with OA [12]. In present study we put out data on first cases with OA with the aim of showing immediate safety and efficacy of the procedure.

MATERIALS

The study included 25 consecutive patients who underwent coronary interventions with OA at referral cardiology centers in Bialystok, Krakow, and Zabrze between December 2021 and June 2022. The primary inclusion criterion was the presence of de novo stenosis ≥80% with severe calcification in a vessel of 2.5–4.0-mm diameter on angiography.

All the interventions were performed as elective procedures with OA as a primary approach. All stages of interventional treatment, including antiplatelet and perioperative therapy, were standard and remained in concordance with guidelines. Intravascular imaging was broadly recommended before the intervention and to assess the procedure's outcome. 1.25-mm ablative device (crown) was used at two standard speeds of 80 000 and 120 000 rpm, depending on the arterial anatomy and calcification pattern. Higher speed and slower coronal movement within the artery allowed for a greater degree of calcific modification. In OA effective action is possible while pushing on the stenosis and while withdrawing the device through the stenosis. Movement along the vessel was performed in a uniform motion at the recommended speed of about 1–3 mm/s.

After ablation, non-compliant balloon inflation was a routine, scoring/cutting balloons if necessary, followed by implantation of the drug eluting stents. Procedural success was defined as completing lesion modification with OA with subsequent stent placement. Evaluation of the intervention (the occurrence of major adverse cardiovascular events) was performed in the perioperative period.

RESULTS AND DISCUSSION

The basic characteristics of patients and treatment data are shown in Table 1.

All patients qualified for OA had complex atherosclerotic coronary lesions, median Syntax Score was 28 (23–33). The presence of severe calcifications was demonstrated in all patients in coronary angiography and/or intracoronary imaging. In concordance with the current guidelines in such case the application of modification methods (RA, OA or lithotripsy) is advised [13]. Radial access was used in 24 patients (96%), it allowed to minimize the risk of vascular complications, to reduce hospitalization time, and to maintain comparable procedural efficacy as in femoral access. There was a 100% success rate of the OA. All patients received DES optimally implanted, with an average length of 49 mm (30–66), and full TIMI3 flow in 24 patients (96%).

Next to more widely used RA, OA seems to have a couple of differences. In authors subjective opinion, comparing to RotaWire, the OA ViperWire Advance® guidewire allows superior deliverability and maneuverability. In most cases, the guidewire can be delivered directly without a micro catheter and as a result of its larger diameter, subsequent steps of intervention can be done easily with a single guidewire. Presumably OA can modify the calcified plaque to a greater extent by creating longer and deeper incisions. Finally, the plaque microparticles generated during OA are smaller than in RA (2 μm vs. 5 μm) [14]. Assuming its easier elimination from the microcirculation this may translate into the lower frequency of coronary flow disturbancies. Currently, no data prove the above differences as clinically significant [15]. In our study, only one patient showed transient flow impairment, the criteria for the diagnosis of IVa infarction were met in the postoperative period. It was the PCI with OA in dominant RCA with retrograde circulation to LCA, in patient with history of CABG with nonfunctioning venous bypasses. Fortunately patient was discharged in good condition after several additional days of hospitalization. Additionally at large, in two patients temporarily conduction disturbances not necessitating electrostimulation were observed, in another two cases minor forearm hematomas occurred not requiring surgical intervention.

Selection of a strategy and evaluation of the treatment for patients with severe coronary artery calcification is challenging. The clinical characteristics of patients and the complexity of atherosclerotic lesions undergoing PCI clearly predefine high cardiovascular risk. In addition, advanced and elaborated PCI techniques increase the risk of adverse events in the perioperative period. In this report, the prevalence of adverse events was low and comparable to the data from large registries [10, 11]. It should be emphasized that most complications during OA or RA procedures are the plain consequence of patients high clinical burden and the complexity of the lesions treated. In such difficult cases ablative methods very often are the sole treatment option. They are used not to generate complications but to overcome them and ensure optimal and effective treatment of patients. Currently, the ECLIPSE trial is recruiting patients to evaluate treatment strategies for severe coronary artery calcification by randomizing patients to OA or conventional angioplasty with implantation of DES stents [15]. The results of this trial will certainly provide important information for the application of OA.

In conclusion, in the analyzed group of patients, OA procedure proved to be effective and safe for modifying massively calcified coronary artery lesions. This procedure has a low and acceptable rate of adverse events. Further study in a large group of patients is needed to fully evaluate the procedure and to define the indications for its use. At present, the indications for OA overlaps with those of the more widely used RA.

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REFERENCES

1. Copeland-Halperin RS, Baber U, Aquino M, et al. Prevalence, correlates, and impact of coronary calcification on adverse events following PCI with newer-generation DES: Findings from a large multiethnic registry. Catheter Cardiovasc Interv. 2018; 91(5): 859–866, doi: 10.1002/ccd.27204, indexed in Pubmed: 28722295.
2. Gassett AJ, Sheppard L, McClelland RL, et al. Risk factors for long-term coronary artery calcium progression in the multi-ethnic study of atherosclerosis. J Am Heart Assoc. 2015; 4(8): e001726, doi: 10.1161/JAHA.114.001726, indexed in Pubmed: 26251281.
3. Mori H, Torii S, Kutyna M, et al. Coronary artery calcification and its progression: What does it really mean? JACC Cardiovasc Imaging. 2018; 11(1): 127–142, doi: 10.1016/j.jcmg.2017.10.012, indexed in Pubmed: 29301708.
4. Guedeney P, Claessen BE, Mehran R, et al. Coronary calcification and long-term outcomes according to drug-eluting stent generation. JACC Cardiovasc Interv. 2020; 13(12): 1417–1428, doi: 10.1016/j.jcin.2020.03.053, indexed in Pubmed: 32553329.
5. Kobayashi Y, Okura H, Kume T, et al. Impact of target lesion coronary calcification on stent expansion. Circ J. 2014; 78(9): 2209–2214, doi: 10.1253/circj.cj-14-0108, indexed in Pubmed: 25017740.
6. Généreux P, Madhavan MV, Mintz GS, et al. Relation between coronary calcium and major bleeding after percutaneous coronary intervention in acute coronary syndromes (from the Acute Catheterization and Urgent Intervention Triage Strategy and Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction Trials). J Am Coll Cardiol . 2014; 63(18): 1845–1854, doi: 10.1016/j.jacc.2014.01.034, indexed in Pubmed: 24561145.
7. Abdel-Wahab M, Richardt G, Joachim Büttner H, et al. High-speed rotational atherectomy before paclitaxel-eluting stent implantation in complex calcified coronary lesions: the randomized ROTAXUS (Rotational Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease) trial. JACC Cardiovasc Interv. 2013; 6(1): 10–19, doi: 10.1016/j.jcin.2012.07.017, indexed in Pubmed: 23266232.

8. Kawamoto H, Latib A, Ruparelia N, et al. In-hospital and midterm clinical outcomes of rotational atherectomy followed by stent implantation: the ROTATE multicentre registry. EuroIntervention. 2016; 12(12): 1448–1456, doi: 10.4244/EIJ-D-16-00386, indexed in Pubmed: 27998836.
9. Bouisset F, Barbato E, Reczuch K, et al. Clinical outcomes of PCI with rotational atherectomy: the European multicentre Euro4C registry. EuroIntervention. 2020; 16(4): e305–e312, doi: 10.4244/EIJ-D-19-01129, indexed in Pubmed: 32250249.
10. Lee M, Généreux P, Shlofmitz R, et al. Pivotal trial to evaluate the safety and efficacy of the orbital atherectomy system in treating de novo, severely calcified coronary lesions (ORBIT II). JACC Cardiovasc Interv. 2014; 7(5): 510–518, doi: 10.1016/j.jcin.2014.01.158, indexed in Pubmed: 24852804.
11. Aggarwal D, Seth M, Perdoncin E, et al. Trends in utilization, and comparative safety and effectiveness of orbital and rotational atherectomy. JACC Cardiovasc Interv. 2020; 13(1): 146–148, doi: 10.1016/j.jcin.2019.09.027, indexed in Pubmed: 31918938.
12. Karimi Galougahi K, Shlofmitz E, Jeremias A, et al. Therapeutic approach to calcified coronary lesions: disruptive technologies. Curr Cardiol Rep. 2021; 23(4): 33, doi: 10.1007/s11886-021-01458-7, indexed in Pubmed: 33666772.
13. Dobrzycki S, Reczuch K, Legutko J, et al. Rotational atherectomy in everyday clinical practice. Association of Cardiovascular Interventions of the Polish Society of Cardiology. Expert opinion. Kardiol Pol. 2018; 76(11): 1576–1584, doi: 10.5603/KP.2018.0225, indexed in Pubmed: 30460675.
14. Sotomi Y, Shlofmitz RA, Colombo A, et al. Patient selection and procedural considerations for coronary orbital atherectomy system. Interv Cardiol. 2016; 11(1): 33–38, doi: 10.15420/icr.2015:19:2, indexed in Pubmed: 29588702.
15. Généreux P, Kirtane AJ, Kandzari DE, et al. Randomized evaluation of vessel preparation with orbital atherectomy prior to drug-eluting stent implantation in severely calcified coronary artery lesions: Design and rationale of the ECLIPSE trial. Am Heart J. 2022; 249: 1–11, doi: 10.1016/j.ahj.2022.03.003, indexed in Pubmed: 35288105.

Table 1. Characteristics of the study participants

Baseline characteristics (n = 25)

Age, years, median (IQR)	71 (68.5–72.5)
Male, n (%)	23 (92)
EuroSCORE II, median (IQR)	2.4 (1.5–4)
BMI, kg/m^2, median (IQR)	27.8 (27–32.3)
LVEF, %, median (IQR)	54 (43–60)
Previous PCI, n (%)	17 (68)
Previous CABG, n (%)	9 (36)
Previous ACS, n (%)	8 (32)
Previous stroke, n (%)	3 (12)
Atrial fibrillation, n (%)	10 (40)
Diabetes mellitus, n (%)	10 (40)
Chronic kidney disease, n (%)	6 (24)
Peripheral artery disease, n (%)	8 (32)
Angiographic details	
SYNTAX I, median (IQR)	28 (23–33)
SYTNAX II CABG, median (IQR)	31 (28.5–44)/35.9 (28.8–50.8)
SYTNAX II PCI, median (IQR)	
Single vessel CCS, n (%)	3 (12)
Multivessel CCS, n (%)	14 (56)
Chronic total occlusion, n (%)	(3) 12
Procedural details	
Procedural success, n (%)	25 (100)
Radial access, n (%)	24 (95)
Treated artery	
Left main, n (%)	6 (24)
Left anterior descending artery, n (%)	12 (48)
Circumflex artery, n (%)	3 (12)
Right coronary artery, n (%)	4 (16)
PCI in CTO, n (%)	3 (12)
PCI in bifurcation, n (%)	4 (16)

IVUS, n (%)	21 (84)
OCT, n (%)	4 (16)
Scoring balloon, n (%)	2 (8)
Cutting balloon, n (%)	1 (4)
Length of all stents, mm, median (IQR)	49 (30–66)
Average diameter of all stents, mm, median (IQR)	3.5 (3–3.5)
Total procedure time, min, median (IQR)	90 (80–105)
Total fluoroscopy time, min, median (IQR)	25.6 (18.7–32)
K, mGy, median (IQR)	1029 (679–1538)
Contrast volume, ml, median (IQR)	170 (150–230)
TIMI 3 score post procedure, n (%)	24 (96)
Acetylsalicylic acid prescribed at discharge, n (%)	25 (100)
Clopidogrel prescribed at discharge, n (%)	25 (100)
Postprocedural complications	
Slow flow, n (%)	2 (8)
No flow, n (%)	0 (0)
Coronary perforation, n (%)	0 (0)
Tamponade, n (%)	0 (0)
Atrioventricular block, n (%)	2 (8)
Acute kidney injury, n (%)	0 (0)
Vascular complications of PCI, n (%)	2 (8)
IVa myocardial infarction, n (%)	1 (4)
In hospital MACE, n (%)	1 (4)

Chronic kidney disease was defined as the presence of kidney damage or an estimated glomerular filtration rate (eGFR) less than 60 ml/min/1.73 m^2, persisting for three months or more, irrespective of the cause

Abbreviations: ACS, acute coronary syndrome; BMI, body mass index; CABG, coronary artery bypass grafting; CCS, chronic coronary syndrome; CTO, chronic total occlusion; IQR, interquartile range; IVUS, intravascular ultrasound; K, kinetic energy released per mass unit; LVEF, left ventricular ejection fraction; MACE, major adverse cardiovascular events; Me;

median; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; TIMI, thrombolysis in myocardial Infarction grade flow