Orbital atherectomy for treatment of calcified coronary artery lesions. First experiences in Poland: Short-term outcomes of the Lower-Silesia Orbital Atherectomy Registry (LOAR)

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INTRODUCTION

Coronary artery calcifications (CAC) have a strong negative impact on the clinical outcomes of percutaneous coronary intervention (PCI). The prevalence of CAC is relatively high and reaches up to 40% when the diagnosis is made based on angiographic assessment and even up to 70% when intravascular ultrasound (IVUS) is used [1, 2]. Adequate lesion preparation before drug-eluting stent (DES) implantation is a crucial point of the PCI procedure to achieve satisfying results. Several dedicated devices (non-compliant [NC], ultra-high pressure, cutting, or scoring balloon catheters along with rotational and laser atherectomy modalities) have been used in contemporary practice as part of the lesion preparation strategy. Still, each of the mentioned devices has its unique proprieties and limitations. Therefore, novel treatment methods are in continuous development. Recently Diamondback 360° Coronary Orbital Atherectomy (OA) System (Cardiovascular Systems Inc., Saint Paul, US) has been introduced into clinical practice [3]. In this brief report, we present the short-term outcomes of the OA registry — the Lower-Silesia Orbital Atherectomy Registry (LOAR).

METHODS

The study population consisted of 36 consecutive patients with a clinical indication for PCI and the presence of severely calcified lesions who underwent an OA procedure between May and September 2022 in two cooperating Cardiac Departments in the Lower Silesia Region. The decision to perform OA after detection of a moderate/severely calcified lesion was left to the operator's discretion. Angiographic calcification was defined as moderate when it involved between 30% and 50% of the reference lesion diameter and as severe when it involved over 50% of the reference diameter. When initial assessment was based on IVUS findings, lesions had to reach at least 2 points in the IVUS calcium score [4]. There were no angiographic exclusion criteria regarding lesion anatomy such as the length, tortuosity, severity, or location. All procedural features (use of an additional lesion preparation technique; stent implantation parameters, periprocedural pharmacological therapy, use of intravascular imaging along with the left ventricular support device) were left to the discretion of the operator.

The study had two primary endpoints: clinical success and safety outcomes. Clinical success was defined as an effective stent deployment without significant stent underexpansion (in accordance with the European Association of Percutaneous Cardiovascular Interventions consensus [5]) and the presence of Thrombolysis in Myocardial Infarction (TIMI) 3 flow at the end of the procedure.

The safety outcomes were defined as procedural complications (coronary perforation, slow- or no-reflow, new coronary thrombus, ventricular arrhythmias, vessel closure, and device failure). Also, adverse cardiac and cerebrovascular events (MACCE) were evaluated. MACCE was defined as acute coronary syndrome, cerebrovascular events, major bleeding, and need for repeated revascularization or death. Clinical follow-up was obtained via telephone 30 days after the index procedure.

Statistical analysis

Depending on the normality of distribution (assessed by the Shapiro-Wilk test), the data are presented as mean and standard deviation (SD) or median and interquartile range (IQR). All calculations were made with the R language.

RESULTS AND DISCUSSION

We retrospectively analyzed 36 consecutive OA PCI patients, mainly acute coronary syndrome (ACS) cases (69.4%), performed between May and September 2022. The vast majority of patients were male (77.8%) with an average age of 70.7 years and a high prevalence of cardiovascular risk factors (hypercholesterolemia [97.5%], hypertension [94.4%], and diabetes mellitus [57.7%]). All clinical data are presented in Table 1.

In 24 cases, OA was used as a primary debulking device. In the remaining cases, OA was part of bail-out therapy after initial unsuccessful treatment (seven cases of uncrossable lesions and five undilatable). The study subpopulation was rather high-risk, with a median SYNTAX Score II of 38.9 points and estimated 4-year PCI mortality at a level of 19.1%. Despite aggressive lesion preparation (in 58.3% of cases OA was used in a high-speed mode), in two cases significant underexpansion of the device (first DES, second NC balloon) used after OA was observed. In those subjects, additional rescue shockwave intravascular lithotripsy (S-IVL) was performed with a satisfying final result. Despite the initial anatomical advancement of coronary artery disease (CAD) (SYNTAX Score 22.6), only 3 patients required periprocedural therapy with catecholamines. Additionally, in one case (PCI of last remaining vessel; low ejection fraction), we used the Impella Pump support.

In terms of safety endpoints, one patient developed a short episode of periprocedural ventricular arrhythmia aborted with defibrillation. None of the slow/no-flow phenomenon episodes was observed. During the observation period, we noticed two MACCEs — one stroke 3 days after the index procedure and one episode of lethal subacute stent thrombosis 14 days after the initial procedure.

Despite significant advances in interventional cardiology, CAC remains a major challenge to achieving optimal results with percutaneous revascularization. Recently two novel devices, S-IVL [6] and OA [7] focused on calcium management have been introduced into practice. We present one of the first Polish experiences with OA.

Table 1. Clinical, procedural, and postprocedural characteristics of the study population

	Overall (n = 36)
Age, mean (SD)	70.7 (7.3)
Male sex, n (%)	28 (77.8)
Diagnosis	
Stable angina, n (%)	11 (30.6)
Unstable angina, n (%)	3 (8.3)
NSTEMI, n (%)	22 (61.1)
STEMI, n (%)	0 (0)
Hypercholesterolemia, n (%)	35 (97.2)
Diabetes, n (%)	17 (47.2)
Hypertension, n (%)	34 (94.4)
Kidney failure, n (%)	7 (19.4)
History of stroke, n (%)	6 (16.7)
COPD, n (%)	11 (30.6)
Post PCI status, n (%)	18 (50)
Post CABG status, n (%)	2 (5.6)
Primary diagnosis MI, n (%)	18 (50)
Moderate/severe aortic valvular stenosis, n (%)	4 (11.1)
SYNTAX score, median (IQR)	22.6 (17–25)
LVEF, %, mean (SD)	47.4 (13.8)
Treated vessel	
LM, n (%)	11 (30.6)
LAD, n (%)	14 (38.9)
Cx, n (%)	4 (11.1)
RCA, n (%)	7 (19.4)
Primary atherectomy, n (%)	24 (66.7)
Uncrossable lesion, n (%)	7 (19.4)
Undilatable lesion, n (%)	5 (13.9)
Bifurcations, n (%)	16 (44.4)
Initial diameter stenosis (%), mean (SD)	83.8 (7.7)
Final diameter stenosis (%), median (IQR)	11 (0–14)
Time of ablation (s), mean (SD)	263 (110)
Use of high-speed (120 000 rpm) rotation; n (%)	21 (58.3)
Postdilatation, n (%)	35 (97.2)
Number of DES per procedure, mean (SD)	1.7 (0.4)
Total DES length per procedure, median (IQR)	52.6 (32–68)
OCT/IVUS guided PCI, n (%)	20 (55.6)
Clinical success of orbital atherectomy, n (%)	34 (94.4)
Radial access, n (%)	32 (88.9)
Femoral access, n (%)	4 (11.1)
6 F guide catheter, n (%)	31 (86.1)
7 F guide catheter, n (%)	5 (13.8)
Radiation doses, mGy, median (IQR)	1192 (566–1454)
Contrast amount, ml, median (IQR)	226 (140–246)
In-hospital MACCE, n (%)	2 (5.6)
MACCE 30 days after procedure, n (%)	2 (5.6)

Abbreviations: CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; Cx, circumflex artery; DEB, drug eluting balloon; DES, drug-eluting stent; LAD, left anterior descending; IVUS, intravascular ultrasound, LM, left main; LVEF, left ventricular ejection fraction; MACCE, major adverse cardiac and cerebrovascular event; NSTEMI, non-ST-segment elevation myocardial infarction; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; RCA, right coronary artery; STEMI, ST-segment elevation myocardial infarction

The OA system is a debulking device composed of a 1.25 mm diamond-coated crown that can sand bidirectionally with speed selection options for low-speed (80 000 rpm), high-speed (120 000 rpm), or Glide-Assist (5 000 rpm). The elliptical orbital movement allows for continuous flow of saline and blood during treatment and produces small particle sizes during pulverization.

This specific mechanism of action might result in greater plaque modification with a coincidental decrease in the periprocedural slow/no-flow phenomenon rate, yet it might also increase the dissection rate [3, 8, 9]. The results of our study partially support earlier findings. In our high-risk cohort (one out of three cases referred to left main disease; diffused CAD-average DES length approximately 53 mm) with coexisting highly prothrombotic ACS settings (up to 70% of all cases) we did not observe any periprocedural slow-flow phenomena. Furthermore, such anatomical features of the lesions (high SYNTAX score, long, sequential, with acuity angulation) have been additionally defined as predictors of atherectomy (rotational) failure [10]. Interestingly, despite demanding clinical scenarios, the PCI success rate reached 94.4% (34 out of 36 cases). The two remaining exceptions required additional plaque modification with S-IVL (orbital-lithotripsy). A similar bail-out modality was described earlier in relation to rotational atherectomy [11, 12]. Moreover, our study cohort contained a large number (19.4%) of highly demanding "uncrossable" lesions. In our opinion, thanks to the excellent trackability of the OA wire and easy handling of the OA system, it may become an alternative to rotational atherectomy in these no-option patients.

Our initial data support the safety of OA procedures. This fact might be related to a low vascular access complication rate [13]. Contrary to classical RA [14], the OA burr is fully compatible with 6F guiding, and there is no need to increase the size of the burr or guiding during the procedure. Consequently, the majority of cases are suitable for standard 6F radial access (in our cohort over 85% of all cases). A similar effect was previously observed in the context of other novel debulk devices (S-IVL) [15].

Initial data from the LOAR suggest OA is a relatively safe and effective calcified plaque modification method in short-term observation. Still, future studies with a high number of patients are necessary to evaluate short and long-term results.

Article information

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