# Bailout rotational atherectomy in patients with myocardial infarction is not associated with an increased periprocedural complication rate or poorer angiographic outcomes in comparison to elective procedures (from the ORPKI Polish National Registry 2015–2016)

# Rafał Januszek¹, Zbigniew Siudak², Artur Dziewierz³, Tomasz Rakowski³, Jacek Legutko³, Dariusz Dudek⁴, Stanisław Bartuś³

<sup>1</sup>2<sup>nd</sup> Department of Cardiology, University Hospital, Krakow, Poland <sup>2</sup>Faculty of Medicine and Health Sciences, Jan Kochanowski University, Kielce, Poland

<sup>3</sup>2<sup>nd</sup> Department of Cardiology, Jagiellonian University Medical College, Krakow, Poland

<sup>4</sup>Department of Interventional Cardiology, Jagiellonian University Medical College, Krakow, Poland

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#### Abstract

**Introduction:** Many years of experience and refinement of existing rotational atherectomy (RA) techniques have resulted in improved clinical outcomes and a tendency to broaden the spectrum of RA usage.

**Aim:** To compare the angiographic effectiveness and periprocedural complications in patients with stable angina (SA) and acute myocardial infarction (AMI) treated using RA.

**Material and methods:** Data were prospectively collected using the Polish Cardiovascular Intervention Society national registry (ORPKI) on all percutaneous coronary interventions (PCIs) performed in Poland in 2015 and 2016. In total, 975 RA procedures were recorded out of 221,187 PCI procedures.

**Results:** We compared angiographic effectiveness and periprocedural complications in 530 patients with SA and 245 with AMI in the RA group of patients, and 60,522 patients with SA and 91,985 with AMI in the non-RA group. The overall rate of periprocedural complications did not differ between SA and AMI patients in the RA group (2.3% vs. 2.0%; p = 0.84), while it was lower in AMI patients from the RA group compared to those from the non-RA group (2.0% vs. 3.0%; p = 0.34). The percentage of patients with angiographic success in the RA group was similar to the non-RA group in SA patients (97.3% vs. 97.1%; p = 0.75), whereas in the AMI group it was significantly higher compared to the non-RA group (96.7% vs. 92.6%; p < 0.001).

Conclusions: The angiographic effectiveness of PCI with RA in patients with AMI was not worse than in patients with SA.

Key words: percutaneous coronary intervention, angioplasty, acute myocardial infarction, rotablation, periprocedural complications, angiographic effectiveness.

### Introduction

Nowadays, in Europe, there is an increasing percentage of older patients in the general population. Due to that tendency, an increasing number of patients with heavily calcified coronary artery stenoses undergo percutaneous coronary interventions (PCIs). These lesions are a great challenge for successful percutaneous revascularization. Prevalence of coronary calcifications in patients undergoing PCI was estimated at 17% to 35% [1]. In selected patients, rotational atherectomy (RA) could serve as an alternative method for coronary artery by-pass grafting (CABG) operations. In accordance with the wider use of RA as a result of the improvement outcomes and procedural techniques, the range of indications also became wider [2]. We observe increased use of RA in acute coronary syndrome (ACS) patients

#### Corresponding author:

Stanisław Bartuś MD, PhD, 2<sup>nd</sup> Department of Cardiology, University Hospital, 17 Kopernika St, 31-501 Krakow, Poland, phone: +48 604 112 699, e-mail: stanislaw.bartus@uj.edu.pl

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including selected patients with ST-segment elevation myocardial infarction (STEMI) [3]. The appearance of this trend is present, even though the incidence of acute myocardial infarctions (AMI) decreases, and this trend is due to the drop in STEMI prevalence, while the incidence of non-ST-elevation myocardial infarctions increases slightly (NSTEMI) [4]. So far, it has been postulated that RA is relatively contraindicated in thrombogenic states such as ACS, especially in STEMI patients [5]. The use of RA in selected patients with STEMI and a patent culprit artery without thrombus blockade seems to be acceptable [2, 3].

### Aim

In this study, we aimed to assess whether the periprocedural complication rate and angiographic efficacy are poorer in patients with AMI compared to stable angina (SA) when treated using PCI and RA.

### Material and methods

We analyzed prospectively collected national data from all patients who underwent PCI in Poland between January 2015 and December 2016. Data on PCI practice in Poland were obtained from the ORPKI Polish National dataset, which is coordinated nationwide by the Jagiellonian University Medical College in cooperation with the AISN PTK (Association of Cardiovascular Interventions, Polish Cardiac Society). The ORPKI registry and RA patients were characterized in previously published studies [3]. In the current study, we concentrated on periprocedural results due to the fact that we did no collect all in-hospital and follow-up data following discharge. In the Polish National dataset, the definition of most periprocedural complications is left to the discretion of the operators. The baseline characteristics as well as periprocedural and outcome data were collected. The decision to perform RA was at the operators' discretion at each center according to the current European Recommendations [5]. All RA procedures were performed using the Rotablator rotational atherectomy system. All clinical decisions, such as vascular access, burr size, and treatment with glycoprotein IIb/IIIa inhibitors or bivalirudin were at the operators' discretion.

### Statistical analysis

All continuous variables were evaluated with the Kolmogorov-Smirnov test for distribution. Continuous variables are presented as mean ± standard deviation. Categorical variables are presented as numeric values and percentages. Continuous variables were compared using the two-tailed Student *t*-test and the Mann-Whitney U-test, whereas categorical variables were compared using the  $\chi^2$  test. To identify predictors of TIMI flow grade 3 after PCI, univariate and multivariate analyses were performed. Both univariate and multivariate regression models for major adverse cardiac and cerebrovascular events (MACCE) were constructed. A model based on the retrograde correction method was created. Statistical significance was accepted at a 0.05 level of probability. The statistical analyses were performed using Statistica 10.0 software (Dell Software, Inc., Round Rock, TX, USA) and SPSS Statistics 24 (IBM, USA).

### Results

### Patients' characteristics

The overall count of patients undergoing PCI in Poland in 2015 and 2016 was 221,187. Among them, there were 975 patients who underwent PCI with RA (0.44%) and 220,212 patients without RA. In the RA group, there were 530 cases with SA at admission (54.3%), which was a higher percentage compared to the non-RA group with 60,522 cases (27.5%; p < 0.001), while there were 245

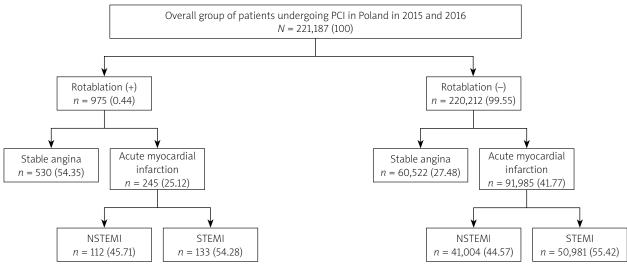


Figure 1. Subject flowchart

(25.1%) cases with AMI presentation of coronary artery disease (CAD) at admission, which was a significantly lower percentage as compared to the non-RA group of 91,985 (41.8%; p < 0.001). We also noted differences in the clinical presentation of CAD between the RA and non-RA groups. In the RA group, there was a higher percentage of patients with SA (530; 54.8%) compared to the non-RA group (60,522; 27.5%; p < 0.001), while the percentages of unstable angina (UA) (19.3% vs. 29.8%; p < 0.001), NSTEMI (11.6% vs. 18.6%; p < 0.001) and STEMI (13.7% vs. 23.2%; p < 0.001) patients were significantly lower. We excluded from further analysis patients with symptoms of unstable angina before PCI in both

investigated groups (Figure 1). Patients' characteristics and other indices including concomitant diseases, past percutaneous and cardiac procedures, as well as time of the procedure expressed as contrast dose and radiation exposure are presented in Table I.

### Periprocedural complications

The rate of periprocedural complications was significantly higher in patients treated with RA compared to non-RA procedures in the SA group (p = 0.003), while in the AMI group there was no such difference (p = 0.35). The incidence of individual complications in all observed groups is presented in Table I.

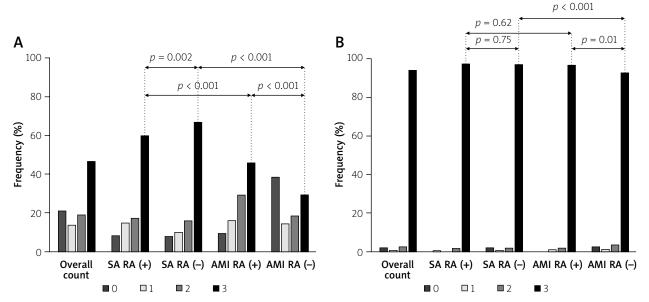
Variables	Overall group	SA		P-value	AMI		P-value
		Rota (+)	Rota (–)		Rota (+)	Rota (–)	
Age [years]	67.1 ±10.8	71.4 ±9.2	66.9 ±9.7	< 0.001	73.1 ±10.4*	66.7 ±11.8 <sup>†</sup>	< 0.001
Gender, males	150,140 (67.9)	391 (73.8)	42,191 (69.7)	0.04	154 (62.8)*	62,058 (67.5)	0.12
Diabetes	52,677 (23.8)	178 (33.6)	15,828 (26.1)	< 0.001	84 (34.3)	19,918 (21.6)†	< 0.001
Hypertension	157,408 (71.2)	409 (77.2)	45,540 (75.2)	0.3	194 (79.2)	60,499 (65.8) <sup>†</sup>	< 0.001
Past cerebral stroke	7,290 (3.3)	16 (3.1)	1,876 (3.1)	0.98	15 (6.1)*	3,289 (3.6)	0.03
Previous MI	68,955 (31.2)	280 (52.8)	25,661 (42.4)	< 0.001	125 (51.0)	20,294 (22.1)†	< 0.001
Previous PCI	82,444 (37.3)	345 (65.5)	33,298 (55.0)	< 0.001	121 (49.4)*	20,290 (22.0)†	< 0.001
Previous CABG	14,092 (6.4)	90 (17.0)	4,336 (7.2)	< 0.001	29 (11.8)	3,862 (4.2)†	< 0.001
Current smoker	42,574 (19.2)	79 (14.9)	9,099 (15.0)	0.93	29 (11.8)	22,195 (24.1)†	< 0.001
Kidney failure	12,127 (5.5)	58 (10.9)	3,458 (5.7)	< 0.001	36 (14.7)	5,088 (5.5)	< 0.001
COPD	5,594 (2.5)	18 (3.4)	1,531 (2.5)	0.2	5 (2.0)	2,373 (2.6)	0.59
Complications:							
Overall/patient	4,266 (1.9)	12/530 (2.3)	596 (1.0)	0.003	5/245 (2.0)	2,804 (3.0)†	0.35
Overall/complication	4,776 (2.1)	14/530 (2.6)	644 (1.1)	< 0.001	6/245 (2.4)	3,384 (3.7)†	0.3
Arterial dissection	234 (0.1)	0/96 (0)	59 (0.1)	0.7	0/35 (0)	96 (0.1)	0.83
CAP	393 (0.2)	4/530 (0.7)	103 (0.2)	0.001	2/245 (0.8)	174 (0.2)	0.02
Cardiac arrest	1,413 (0.6)	3/530 (0.6)	91 (0.1)	0.01	2/245 (0.8)	1,101 (1.2)†	0.58
Death	1,018 (0.5)	0/530 (0)	24 (0.04)	0.64	0/245 (0)	842 (0.9)†	0.13
Allergic reaction	354 (0.2)	1 (0.2)	120 (0.2)	0.96	0 (0)	135 (0.1)	0.54
Cerebral stroke	18 (0.01)	0 (0)	3 (0.01)	0.84	0 (0)	12 (0.01)	0.85
Puncture-site bleeding	223 (0.1)	2 (0.4)	52 (0.08)	0.02	0 (0)	104 (0.1)	0.59
Time of the procedure:							
Radiation [mGy]	1,071.6 ±965.1	1,763.0 ±1,387.8	1,015.4 ±936.0	< 0.001	1,516.5 ±1,030.1	1,106.7 ±1,016.2 <sup>†</sup>	< 0.001
Contrast [ml]	176.2 ±79.0	221.1 ±96.5	169.8 ±79.3	< 0.001	225.9 ±100.6	180.1 ±79.0 <sup>†</sup>	< 0.001

### Table I. Patients' characteristics

Data are expressed as mean  $\pm$  SD or numbers (percentages). Student's t-test or the Mann-Whitney U test was used for continuous variables, and the  $\chi^2$  test was used for categorical variables. CABG – coronary artery bypass grafting surgery, CAP – coronary artery perforation, COPD – chronic obstructive pulmonary disease, MI – myocardial infarction, PCI – percutaneous coronary intervention. \*p < 0.05 when SA and AMI patients were compared in the RA (+) group. \*p < 0.05 when SA and AMI patients were compared in the RA (-) group.

# Angiographic effectiveness and procedural success

The percentage of patients with thrombolysis in myocardial infarction (TIMI) grade 3 flow was significantly higher in the non-RA group compared to the RA group at baseline (59.9% vs. 66.8%, p = 0.002) in SA patients, while it was significantly higher in the RA group compared to the non-RA in AMI patients (45.8% vs. 29.2%, p < 0.001). The percentage of patients with TIMI grade 0 flow at baseline was significantly lower in the AMI group in RA patients compared to non-RA patients (9.2% vs. 38.3%; p < 0.001; Figure 2 A).



**Figure 2. A** – Distribution of TIMI flow grade (0–3) percentages before percutaneous coronary intervention in the overall group of patients, stable angina (RA–), stable angina (RA+), acute myocardial infarction (RA–) and acute myocardial infarction (RA+). **B** – Distribution of TIMI flow grade (0–3) percentages after percutaneous coronary intervention in the overall group of patients, stable angina (RA–), stable angina (RA–), stable angina (RA+), acute myocardial infarction (RA+).

Variables	Overall group	SA		P-value	А	AMI	
	-	Rota (+)	Rota (–)		Rota (+)	Rota (–)	
Angiography:							
Single-vessel disease	138,701 (69.0)	324 (72.0)	40,405 (74.0)	0.33	41 (51.9)*	51,825 (64.7)†	0.02
MVD, LMCA (–)	52,256 (26.0)	72 (16.0)	11,992 (21.9)	0.002	26 (32.9)*	23,794 (29.7)†	0.53
MVD, LMCA (+)	8,100 (4.0)	45 (10.0)	1,706 (3.1)	< 0.001	10 (12.6)	3,839 (4.8)†	0.001
Isolated LMCA	1,819 (0.9)	9 (2.0)	510 (0.9)	0.02	2 (2.5)	611 (0.8)	0.07
Vascular access:							
Femoral artery	56,636 (25.6)	174 (32.8)	13,604 (22.5)	< 0.001	113 (46.1)*	25,277 (27.5)†	< 0.001
Left radial artery	36,799 (16.6)	53 (10.0)	10,423 (17.2)	< 0.001	23 (9.4)	14,604 (15.9)	0.005
Right radial artery	126,129 (57.0)	297 (56.0)	35,979 (59.4)	0.11	108 (44.1)*	51,513 (56.0)†	< 0.001
Other	1,643 (0.7)	6 (1.1)	516 (0.8)	0.48	1 (0.4)	591 (0.6)	0.64
Bifurcation	11,894 (5.4)	49 (9.2)	4,058 (6.7)	0.02	14 (5.7)	4,029 (4.4)†	0.3
Chronic total occlusion	9,320 (4.2)	31 (5.8)	3,775 (6.2)	0.71	10 (4.1)	2,757 (3.0)†	0.32
Fractional flow reserve	3,258 (1.5)	9 (1.7)	2,348 (3.9)	0.009	1 (0.4)	283 (0.3) <sup>†</sup>	0.77
Intravascular ultrasound	1,882 (0.8)	24 (4.5)	976 (1.6)	< 0.001	7 (2.8)	439 (0.5) <sup>†</sup>	< 0.001
OCT	400 (1.8)	3 (0.6)	210 (0.3)	0.39	2 (0.8)	89 (0.1)†	< 0.001

Table II. Procedural indices

Data are expressed as numbers (percentages). Student's t-test or the Mann-Whitney U test was used for continuous variables, and the  $\chi^2$  test was used for categorical variables. LMCA – left main coronary artery, MVD – multi-vessel disease, OCT – optical coherence tomography. \*p < 0.05 when SA and AMI patients were compared in the RA (+) group. \*p < 0.05 when SA and AMI patients were compared in the RA (-) group.

After PCI, the percentage of patients with TIMI grade 3 flow in the RA group was similar to the non-RA group in SA patients (97.3% vs. 97.1%, p = 0.75) and to the RA group with AMI (97.3% vs. 96.7%; p = 0.62). However, the percentage of patients with TIMI grade 3 flow in the AMI group treated with RA was higher than in the non-RA group (96.7% vs. 92.6%; *p* < 0.001; Figure 2 B). We were not able to assess procedural success due to the lack of specific data. It was indirectly determined based on the performed type of PCI. The group of patients with plain old balloon angioplasty (POBA) and failed PCI could be considered as representing unsuccessful procedures. On this basis, the rate of failed RA procedures was significantly lower in SA compared to AMI patients (1.9% vs. 6.9%; p < 0.001). A similar relationship was noted in the non-RA group when comparing SA and AMI patients (6.7% vs. 8.9%; *p* < 0.001). The frequency of POBA/failed PCI in the RA group was lower in this group as compared to the non-RA in SA and AMI groups (Table II).

### Lesion characteristics

Α 100

Frequency (%)

98

96

94

92

90 10

8

6

4

2

0

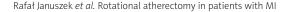
Overall

count

DCB restenosis

DES restenosis

Both in the SA and AMI groups, PCI of the left main coronary artery (LMCA) was more often performed in the RA group compared to the non-RA group (p < 0.001). The rate of drug-eluting stent (DES) restenosis and bare-metal stent (BMS) restenosis was significantly lower in the RA group compared to the non-RA group in SA patients, whereas it was not significantly lower in AMI patients (Figure 3 A). De-novo lesions were more often treated in the RA group compared to the non-RA group (p < 0.001), while restenosis lesions were less often treated in RA pa-



tients (p < 0.001), in the SA and AMI groups (Figure 3 B). Location of culprit arteries is presented in Table III.

### **Procedure characteristics**

All procedural indices including coronary angiography, vascular access, lesion type and additional devices used during the PCI are presented in Table II.

### Predictors of TIMI grade 3 flow after PCI

Multivariable analysis revealed that the positive predictors of TIMI grade 3 flow after PCI in the overall group of patients undergoing RA included older age (odds ratio (OR) = 1.037; 95% confidence interval (CI): 1.029–1.045; p < 0.001) and patent culprit artery (TIMI grade 2 or 3 flow) before PCI (OR = 3.76; 95% CI: 1.823-7.755; p < 0.001). In the SA group of patients treated with RA, the positive predictors of TIMI grade 3 flow after PCI also included older age (OR = 1.038; 95% CI: 1.027-1.049; p < 0.001) and patent culprit artery (TIMI grade 2 or 3 flow) before PCI (OR = 4.169; 95% CI: 1.5–11.593; p = 0.06). Among the positive predictors of TIMI grade 3 flow after PCI in patients with AMI treated with RA we also confirmed older age (OR = 1.035; 95% CI: 1.022–1.049; p < 0.001), whereas the patent culprit artery (TIMI grade 2 or 3 flow) before PCI was only of borderline significance (OR = 3.691; 95% CI: 0.95–14.345; p = 0.059).

### Discussion

The main finding of the current study is that the use of RA in selected patients with AMI may not increase the periprocedural complication rate and is not associated

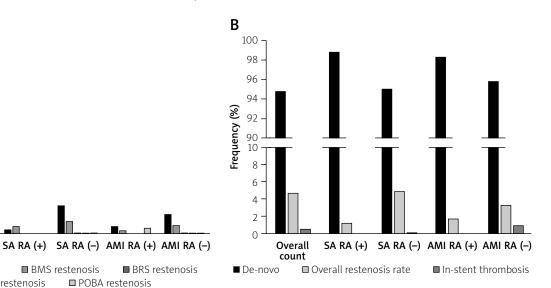


Figure 3. A – Distribution of DES-, BMS-, BRS-, DCB- and POBA-restenosis percentages in the overall group of patients, stable angina (RA–), stable angina (RA+), acute myocardial infarction (RA–) and acute myocardial infarction (RA+).  $\mathbf{B}$  – Distribution of de-novo lesion, restensis and in-stent thrombosis percentages in the overall group of patients, stable angina (RA-), stable angina (RA+), acute myocardial infarction (RA-) and acute myocardial infarction (RA+)

BMS – bare-metal stent, BRS – bioresorbable scaffold, DCB – drug-coated balloon, DES – drug-eluting stent, POBA – plain old balloon angioplasty.

BRS restenosis

■ POBA restenosis

BMS restenosis

Variable	Overall group	SA		P-value	AMI		P-value
	-	Rota (+)	Rota (–)		Rota (+)	Rota (–)	
Culprit artery:							
Left main coronary artery	6,697 (3.2)	56 (10.6)	1,672 (3.0)	< 0.001	41 (16.7)*	2,740 (3.1)	< 0.001
Left anterior descending artery	79,411 (38.3)	226 (42.6)	20,954 (37.5)	0.01	109 (44.5)	33,606 (38.6) <sup>†</sup>	0.06
Circumflex artery	47,183 (22.7)	106 (20.0)	13,603 (24.3)	0.02	47 (19.2)	18,792 (21.6)†	0.36
Intermediate artery	3,451 (1.7)	2 (0.4)	1,041 (1.9)	0.01	3 (1.2)	1,298 (1.5)†	0.73
Right coronary artery	67,618 (32.6)	181 (34.1)	17,895 (32.0)	0.29	71 (29.0)	29,629 (34.0)†	0.09
Saphenous vein graft	2,616 (1.3)	1 (0.2)	582 (1.0)	0.05	0 (0)	940 (1.1)	0.1
Internal mammary artery	442 (0.2)	0 (0)	114 (0.2)	0.29	0 (0)	134 (0.1) <sup>†</sup>	0.53
Type of PCI:							
Drug-eluting stent	189,553 (85.7)	507 (95.7)	52,908 (87.4)	< 0.001	221 (90.2)*	77,317 (84.0)†	0.008
Bare-metal stent	7,271 (3.3)	0 (0)	1,089 (1.8)	0.002	3 (1.2)*	4,304 (4.7) <sup>†</sup>	0.01
Bioresorbable scaffold	2,934 (1.3)	3 (0.6)	1,100 (1.8)	0.03	6 (2.4)*	1,028 (1.1)†	0.04
Drug-coated balloon	4,834 (2.2)	11 (2.1)	1,477 (2.4)	0.58	2 (1.2)	1,564 (1.7)†	0.28
POBA/failed	17,249 (7.8)	10 (1.9)	4,070 (6.7)	< 0.001	17 (6.9)*	8,151 (8.9)†	0.28

Table III. Location of culprit lesion, type of PCI and periprocedural complications

Data are expressed as numbers (percentages). The  $\chi^2$  test was used for categorical variables. PCI – percutaneous coronary intervention, POBA – plain old balloon angioplasty. \*p < 0.05 when SA and AMI patients were compared in the RA (+) group. \*p < 0.05 when SA and AMI patients were compared in the RA (-) group.

with poorer angiographic efficacy compared to patients with SA. Moreover, the angiographic success rate in patients with AMI treated with RA was higher as compared to patients with AMI from the non-RA group.

Despite the fact that intra-arterial thrombus is recognized as a contraindication to RA in AMI patients, especially in STEMI patients, the use of RA in this group is becoming more and more widespread [6]. It is associated, among other reasons, with the evolution of the profile of patients and culprit lesions in countries with well-developed networks of interventional cardiology facilities and frequent PCIs. Recently in these countries, STEMI patients more often present complex and calcified target lesions, they suffer from many comorbidities and are at increased risk of cardiac operations. Due to this, those patients are being transferred from the CABG group to the PCI with RA group more often in recent years, especially when they are unstable and regular devices are not able to cross well-calcified lesions.

### Periprocedural complications

Periprocedural complications typical for RA are similar to those common for PCI and include vascular access complications, stroke, MI, urgent CABG surgery, death, coronary artery perforation (CAP), artery dissection (AD), short-term closure, side branch loss and the slow-flow/no-reflow phenomenon [7]. The frequency of these periprocedural complications depends on several factors, with the most influential including type of PCI, study population and year of study [6]. In recent years, RA techniques have changed. Smaller burr sizing reduces angiographic complications [5, 8, 9]. The incidence of particular complications in patients undergoing RA is estimated at 0-4% for death, 1-19.8% for MI, 0-0.8% for urgent CABG, 1.7–5.9% for CAD, 0–2% for CAP and 0-2.6% for slow flow/no-reflow [10-12]. Complications typical for RA include vasospasm (1.6% to 6.6%) and burr entrapment (0.5% to 1%). However, a recently published study including a large number of participants (13,335 RA cases) reported that primary composite outcomes, including in-hospital death, tamponade, and emergent surgery, occurred in 1.31% of patients [13]. Most available publications reported predictors of periprocedural complications in the overall group of patients treated with RA. For example, it was demonstrated that women and older patients were at increased risk of CAP [14]. Additional risk factors include the use of clopidogrel, kidney failure, hypertension, previous CABG, history of congestive heart failure including dialysis therapy, peripheral vascular disease, ACC/AHA type C lesion, radial access and multi-vessel disease (MVD) [14]. Rotational atherectomy was also found to be an independent predictor of CAP in the overall group of patients undergoing PCI [3]. We presented the results concerning predictors of selected periprocedural complications in the overall group of patients treated with RA in a previously published study [4]. Critics of RA PCI focus on the high complication rates reported in older trials and registries. However, data reported by Sakakura et al. were provided in 2014 and 2015 and come from Japan, where interventional cardiology is recognized to be well developed [13]. Nevertheless, RA strategies in the past included large burr diameters, high burr speeds, large caliber catheters and no dual antiplatelet therapy or DES therapies enabling productive comparisons. Several studies compared periprocedural complication rates between RA patients and non-RA patients, as well as the different PCI technologies. For example, Cockburn et al. reported that selected complications occurred more often in the RA group such as AD (3.6% vs. 2.2%; p < 0.001), CAP (1.1% vs. 0.3%; *p* < 0.001), cardiac tamponade (0.2%) vs. 0.1%; *p* = 0.02), and non-Q wave MI (1.1% vs. 0.4%; p < 0.001 [15]. A review by Cavusoglu *et al.* listed the following complication rates: death 1%, emergency CABG 1-2%, abrupt vessel closure 10-13%)and CAP 1.5% [7]. Another study completed by Kawamoto et al. included 1,076 consecutive patients treated with RA [16]. Exclusion criteria included recent STEMI and lesions with angiographic evidence of thrombus. The leading complication was residual AD (7.0%). CAP was observed in 1.0% of all cases, and 1 patient died. The rate of periprocedural complications was lower in the BMS group (2.6%) then in the DES group (2.4%) [8]. The study published by Rathore et al. demonstrated an acceptable in-hospital MACE rate (8.3%) when only considering patients receiving newer-generation DES following RA. In support of previous studies, the rate of in-hospital MACE was principally driven by periprocedural MI, while the mortality rate was low (0.6%) [11]. Similar relationships were presented in other studies [12, 17]. Rotational atherectomy was used more frequently for LMCA intervention. The higher percentage of LMCA PCI shows an increased rate of patients transferred from the CABG group and higher perioperative risk. It could be suspected that it should worsen clinical and procedural outcomes in comparison to regular patients undergoing PCI. This highlights the complexity of many RA interventions. The higher incidence of the elective intra-aortic balloon pump procedural support in the RA group compared to the non-RA group could be proof of this [15]. One of the few published studies comparing the use of RA in patients with NSTEMI and SA was the registry published by Iannaccone et al., which included 1,308 patients, 37% in the NSTEMI group and 63% in the SA group. Procedural complications were more frequent in the NSTEMI group compared with the SA group, driven mainly by a higher rate of slow flow/no-flow (3.3% vs. 1.4%; p = 0.02), while in-hospital death and MACE did not differ significantly (1.2% vs. 0.3% and 5.7% vs. 5.8%) [18] The largest study on RA, published by Sakakura et al., demonstrated that among others well-known factors related to increased rate of periprocedural complications such as age, gender, kidney function, number of diseased vessels, and volume of the institution, there was also emergent PCI, which increased the probability of composite study endpoints almost four times [13]. Our analysis revealed different results. It could be

due, at least in part, to the higher rate of periprocedural complications in patients with unstable angina (2.7%). Those patients were excluded from the current analysis. Also, it is difficult to compare the patients' characteristics with our study, because they compared complication and non-complication groups, which could substantially blur the conclusions. The frequency of RA use in Japan is greater than that in Poland, which may also reflect better operator's skills in performing RA procedures. Another issue is that culprit lesions in AMI patients qualified for RA are partially prepared for PCI. The artery has to be patent enough for the guidewire's passage. This, by definition, reduces the risk of periprocedural complications in comparison to regular PCI in AMI patients.

### Angiographic and procedural effectiveness

The procedural success of RA in published studies ranges from 72.2% to 100%. It depends on the type of PCI and the year of the study. The improvement in results in recent years is attributed to modern techniques and new equipment [19, 20]. For example, Benezet et al. published a study in a group of patients treated with RA, which included 102 patients at the mean age of 68.8 years. The procedure was successful in 97% [10]. Cockburn et al. compared the clinical outcomes of RA and non-RA PCI procedures performed in the UK, which included 2,125 patients after RA from a total of 221,669 patients undergoing PCI. Patients undergoing RA procedures were older (71.7 vs. 64.1 years; p < 0.001) and suffered from concomitant diseases more often, which was also similar in our group of patients. Furthermore, clinical presentation of CAD, vascular access and the frequencies of particular culprit arteries were similar to the results obtained in our study [15]. Procedural success was poorer in the RA group compared to the non-RA group (90.3% vs. 94.6%; p < 0.001 [15]. Rathore *et al.* compared procedural outcomes and angiographic follow-ups in a group of 516 patients treated with RA [11]. Angiographic success (defined as < 30% residual stenosis and TIMI grade 3 flow) was achieved in 97.1% of cases. Another study reported that angiographic success (defined as 20% residual stenosis and TIMI grade 3 flow) was achieved in 96.7% of cases in both groups [12]. In the study published by Kawamoto et al., final TIMI grade 3 flow was achieved in 99.1% of patients even though slow- or no-flow was observed in 1.1% [16]. In their analyses, most of the published studies compared patients treated with RA and regular PCI, or with a different type of stents, or stents in comparison to POBA. Only a few studies have compared SA with other clinical presentations of CAD. Iannaccone et al. reported that the mean post-procedure TIMI grade flow (2.9 ±0.3 vs. 2.98  $\pm$ 0.2; p = 0.058) and angiographic success (98.8% vs. 99.2%, p = 0.57) were not significantly different [18]. However, despite the fact that the authors compared the NSTEMI and SA groups, the indication for RA was elective in about half of the cases in both groups (49.2% vs. 50.9%; p = 0.73). This was different than in our population, where patients in the SA group were all elective, whereas in the STEMI group, all were urgent. It was demonstrated that vasculopathy, MVD, bifurcation lesions and low TIMI grade flow were among the independent predictors for RA in bailout cases [18]. We did not perform multivariable analysis of factors influencing bailout RA due to the fact that it would be the equivalent of AMI predictors in the RA group. Similar results were obtained in the DART trial, which achieved a procedural success rate of 91.6% [17]. A more recent paper published by Benezet et al. reported comparable angiographic success as our data [10]. Tamura et al. compared BMS implantation with DES implantation, where angiographic success was 100% in both groups, while the procedural success was 96.6% and 97.2%, respectively [19]. The high angiographic effectiveness of RA for the STEMI group in the current study can certainly be attributed to the natural exclusion of patients with a large thrombus load and the consequent inability to visualize some parts of the culprit artery due to slowflow or no-reflow. On the other hand, STEMI patients with multi-segmental and calcified atherosclerosis, and who are more likely to undergo PCI of the LMCA and LAD, are at increased procedural risk at baseline. Another issue is that the angiographic effectiveness was higher in RA patients with AMI compared to procedural effectiveness. First, angiographic effectiveness assessed as TIMI grade 3 flow after the procedure does not mean that the procedure was effective. We are not in possession of exact data on procedural effectiveness. It was estimated as POBA and failed PCI, whereas POBA does not always mean that the procedure was not effective in all cases. Among predictors of angiographic effectiveness we found TIMI flow before PCI and age. While poorer TIMI flow before PCI could obviously impact the final effectiveness, worse angiographic effectiveness in younger patients remains unclear. Possibly, it could be explained by the low number of patients with impaired TIMI flow after PCI and those dichotomous variables could be over-fitted.

The decision whether to perform RA or not was at the operators' discretion. Definitions of periprocedural complications also depended on the operators. No propensity score matching analysis was performed due to limited availability of angiographic data including calcification severity, vessel size, thrombus load, etc. Underreported periprocedural complications including periprocedural myocardial infarctions and no-reflows were removed from the analysis. Estimation of the number of no-reflows in a selected group of AMI patients treated with RA is difficult and largely depends on the operator. Also, it seems that finally greater TIMI grade 3 flow in RA patients compared to non-RA in the AMI group is substantially influenced by the specific bias selection. The RA procedure could be performed in patients where the guidewire has

crossed the lesion and an unsuccessful attempt of predilatation was undertaken. If the guidewire did not cross the culprit lesion, the operators could not use RA.

### Conclusions

Rotational atherectomy used during urgent PCI in patients with AMI facilitates complex procedures rather than increasing the periprocedural complication rate or contributing to poorer angiographic procedural results when compared to the treatment of patients with SA in an elective manner.

## Conflict of interest

The authors declare no conflict of interest.

### References

- 1. Kawaguchi R, Tsurugaya H, Hoshizaki H, et al. Impact of lesion calcification on clinical and angiographic outcome after sirolimus-eluting stent implantation in real-world patients. Cardiovasc Revasc Med 2008; 9: 2-8.
- Bartuś S, Januszek R, Legutko J, et al. Long-term effects of rotational atherectomy in patients with heavy calcified coronary artery lesions: a single-centre experience. Kardiol Pol 2017; 75: 564-72.
- 3. Januszek R, Siudak Z, Dziewierz A, et al. Predictors of in-hospital effectiveness and complications of rotational atherectomy (from the ORPKI Polish National Registry 2014-2016). Catheter Cardiovasc Interv 2017 in press doi: 10.1002/ccd.27372.
- Yeh RW, Sidney S, Chandra M, et al. Population trends in the incidence and outcomes of acute myocardial infarction. N Engl J Med 2010; 362: 2155-65.
- Barbato E, Carrié D, Dardas P, et al.; European Association of Percutaneous Cardiovascular Interventions. European expert consensus on rotational atherectomy. EuroIntervention 2015; 11: 30-6.
- 6. Tomey MI, Kini AS, Sharma SK. Current status of rotational atherectomy. JACC Cardiovasc Interv 2014; 7: 345-53.
- 7. Cavusoglu E, Kini AS, Marmur JD, et al. Current status of rotational atherectomy. Catheter Cardiovasc Interv 2004; 62: 485-98.
- 8. Safian RD, Feldman T, Muller DW, et al. Coronary Angioplasty and Rotablator Atherectomy Trial (CARAT). Immediate and late results of a prospective multicenter randomized trial. Catheter Cardiovasc Interv 2001; 53: 213-20.
- 9. Doyle BJ, Ting HH, Bell MR, et al. Major femoral bleeding complications after percutaneous coronary intervention: incidence, predictors, and impact on long-term survival among 17,901 patients treated at the Mayo Clinic from 1994 to 2005. JACC Cardiovasc Interv 2008; 1: 202-9.
- Benezet J, Diaz de la Llera LS, Cubero JM, et al. Drug-eluting stents following rotational atherectomy for heavily calcified coronary lesions: long-term clinical outcomes. J Invasive Cardiol 2011; 23: 28-32.
- 11. Rathore S, Matsuo H, Terashima M, et al. Rotational atherectomy for fibro-calcific coronary artery disease in drug eluting stent era: procedural outcomes and angiographic follow-up results. Catheter Cardiovasc Interv 2010; 75: 919-27.
- 12. Abdel-Wahab M, Richardt G, Joachim Büttner H, et al. Highspeed 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: 10-9.

- 13. Sakakura K, Inohara T, Kohsaka S, et al. Incidence and determinants of complications in rotational atherectomy: insights from the National Clinical Data (J-PCI Registry). Circ Cardiovasc Interv 2016; 9: pii: e004278.
- 14. Fasseas P, Orford JL, Panetta CJ, et al. Incidence, correlates, management, and clinical outcome of coronary perforation: analysis of 16,298 procedures. Am Heart J 2004; 147: 140-5.
- 15. Cockburn J, Hildick-Smith D, Cotton J, et al. Contemporary clinical outcomes of patients treated with or without rotational coronary atherectomy: an analysis of the UK central cardiac audit database. Int J Cardiol 2014; 170: 381-7.
- 16. 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: 1448-56.
- 17. Mauri L, Reisman M, Buchbinder M, et al. Comparison of rotational atherectomy with conventional balloon angioplasty in the prevention of restenosis of small coronary arteries: results of the Dilatation vs Ablation Revascularization Trial Targeting Restenosis (DART). Am Heart J 2003; 145: 847-54.
- Iannaccone M, Piazza F, Boccuzzi GG, et al. ROTational AThErectomy in acute coronary syndrome: early and midterm outcomes from a multicentre registry. EuroIntervention 2016; 12: 1457-64.
- 19. Tamura H, Miyauchi K, Dohi T, et al. Comparison of clinical and angiographic outcomes after bare metal stents and drug-eluting stents following rotational atherectomy. Int Heart J 2016; 57: 150-7.
- 20. Sharma SK, Kini A, Mehran R, et al. Randomised trial of rotational atherectomy versus balloon angioplasty for diffuse in-stent restenosis (ROOSTER). Am Heart J 2004; 147: 16-22.