

The use of rotational atherectomy in high-risk patients: results from a high-volume centre

Piotr Kübler^{1,2}, Wojciech Zimoch^{1,2}, Michał Kosowski^{1,2}, Brunon Tomaszewicz^{1,2}, Oscar Rakotoarison¹, Artur Telichowski², Krzysztof Reczuch^{1,2}

¹Department of Heart Diseases, Wrocław Medical University, Wrocław, Poland

²Military Hospital, Wrocław, Poland

Abstract

Background: Rotational atherectomy (RA) is indicated for fibrocalcified lesions when traditional percutaneous coronary intervention (PCI) could not be successfully performed. In some of the high-risk patients the RA procedure is the last resort for successful revascularisation. Such patients are, among others, those in whom coronary artery bypass grafting (CABG) is not feasible.

Aim: The aim of the study was to assess in-hospital and one-year outcomes of PCI with RA in high-risk patients without other revascularisation options (RA-only group), in comparison to lower-risk patients undergoing RA.

Methods: We evaluated data of 207 consecutive patients who underwent PCI with RA. Primary endpoints were one-year all-cause mortality and one-year major adverse cardiac events (MACEs). Secondary endpoints were in-hospital outcomes.

Results: During the study 35% of patients fulfilled the inclusion criteria to the high-risk group. Those patients had significantly lower left ventricular ejection fraction, more often prior CABG, higher admission glucose level, and higher EuroSCORE II and Syntax Score. Procedural success was similar in both groups (85% in RA-only group vs. 91% in remaining patients, $p = 0.18$). In-hospital outcomes were similar, except more frequent no/slow-flow phenomenon in the RA-only group. The MACE and mortality rates in one-year follow-up were not statistically different in both groups (19% vs. 18%, $p = 0.82$ and 11% vs. 9%, $p = 0.64$, respectively).

Conclusions: Despite the high-risk characteristics of the study subgroup, no significant differences between in-hospital and one-year outcomes were found in comparison to lower-risk RA patients. Complex PCI with RA in patients without other revascularisation options should be taken into consideration.

Key words: rotablation, inoperable patients, calcified lesions

Kardiol Pol 2018; 76, 9: 1360–1368

INTRODUCTION

Rotational atherectomy (RA) is known as a bailout technique, and according to European and American recommendations it is indicated for calcified or massive fibrotic plaque modifications, when traditional balloon dilatations cannot be performed and optimal stent implantation is unavailable [1, 2]. Some of the patients with severe coronary artery disease constitute a high-risk population, and the RA procedure is their last resort for successful revascularisation. Such patients are, among others, those in whom coronary artery bypass grafting (CABG) is not feasible. The most common reasons for disqualification from CABG are major comorbidities increasing surgery risk, and challenging anatomy, including

poor periphery of coronary arteries or prior CABG with patent grafts [3–5]. Conservative treatment alone in cases of extensive symptomatic ischaemia also seems to be insufficient [6–8]. Hence, there is a group of patients in whom RA remains the only revascularisation option. Other potential methods for invasive treatment of heavily calcified lesions include orbital atherectomy and laser atherectomy, but they remain under investigation and are not available in every country.

Of note, in general the prognosis of patients with multi-vessel coronary disease who are ineligible or disputable for CABG, and who underwent percutaneous coronary intervention (PCI), is poor, which is associated with a complex clinical and coronary anatomy profile [9–12]. For this reason, an

Address for correspondence:

Piotr Kübler, MD, PhD, Department of Heart Diseases, Wrocław Medical University, ul. Weigla 5, 50–981 Wrocław, Poland, tel/fax: +48 261660250, e-mail: pkubler75@gmail.com

Received: 9.04.2018

Accepted: 29.06.2018

Available as AoP: 2.07.2018

Kardiologia Polska Copyright © Polish Cardiac Society 2018

initiative called Complex Higher-Risk and Indicated Patients (CHIP) Fellowship was created to advocate the necessity of special interventional training, including RA, so that high-risk PCI procedures can be performed with success.

Therefore, the purpose of this study was to assess the risk profile, safety, efficacy, and one-year outcomes of PCI with associated RA in patients with a high-risk profile and without other revascularisation options. A control group consisted of the remaining lower-risk all-comer patients undergoing RA in a high-volume centre.

METHODS

Study population

This single-, high-volume-centre observational study included all consecutive patients with symptomatic coronary artery disease who underwent PCI with RA in our institution from April 2008 to October 2015. During this time period an average of 1750 PCIs per year were performed, and were accompanied by RA in an average of ~2% of cases. There were no exclusion criteria. Baseline demographics, clinical characteristics, and detailed procedural data were collected, including indications for the procedure, urgency level, and lesion characteristics with basic quantitative coronary angiography parameters.

Preprocedural disqualification from CABG, if necessary, was undertaken by the local Heart Team, including at least one experienced cardiac surgeon, an experienced interventional cardiologist, and a general cardiologist who was in charge of the patient. Information on all postprocedural complications as well as in- and out-of-hospital major adverse cardiovascular events (MACEs) was collected. All patients gave informed consent to participate in the study. Follow-up data regarding all-cause mortality, recurrent hospitalisations, and MACEs was obtained from the Polish National Health Fund database, so no patient was lost to follow-up. The study protocol was accepted by the local Bioethics Committee and was in accordance with the Declaration of Helsinki.

Study definitions

A subgroup of high-risk patients (RA-only group) was subsequently distinguished from all study participants. It included patients in whom an attempt for traditional PCI was unsuccessful and who were concurrently disqualified from CABG by the Heart Team. The control group consisted of the remaining all-comer patients who underwent RA in our centre during the study period.

The RA procedure was performed mainly due to the presence of undilatable lesions (defined as lesions that could not be adequately dilated by a balloon during inflation) or uncrossable lesions (defined as lesions that could be crossed by a wire but could not be crossed by even the smallest balloons). The third primary reason to perform RA was its direct use in cases of severe massive calcifications of coronary vessels visible in angiography or failure of previous PCI for unclear reasons (in patients transferred from other catheterisation

laboratories). The clinical risk was assessed according to the logistic EuroSCORE II and baseline Syntax Score (SS) along with residual SS and SS II. SS was calculated by two interventional cardiologists, and in cases of inconsistency the third calculation was done by a supervising cardiologist. The Syntax Revascularisation Index (SRI) was calculated with the following formula: $SRI = (1 - [\text{residual SS}/\text{baseline SS}]) \times 100$ [13].

Endpoint definitions

Primary endpoints were one-year all-cause mortality and one-year MACE defined as the composite endpoint of all-cause mortality, follow-up myocardial infarction (MI), and stroke. Secondary endpoints were procedural success and in-hospital outcome.

Baseline and follow-up MI was defined according to the universal definition of MI [14]. Procedural success was defined as angiographic success (residual stenosis of < 30% after stent implantation with thrombolysis in myocardial infarction flow grade III) without periprocedural complications. Contrast-induced nephropathy (CIN) was defined as a relative increase in serum creatinine concentration > 25% or as an absolute increase in serum creatinine concentration > 0.5 mg/dL from baseline within 72 h of PCI. Relevant access site bleeding was defined as at least type 3a according to the Bleeding Academic Research Consortium [15].

Procedure

Rotational atherectomy procedure was performed using standard Boston Scientific Rotablator system (Boston Scientific, Marlborough, MA, USA). All procedures were performed by trained rotablator operators with a long experience in PCI. Radial or femoral route was used according to operator's discretion. Burr speed ranged from 140,000 to 180,000 rpm with a run duration of ~20 to 30 s. In all procedures an intracoronary continuous infusion of heparin, verapamil, and isosorbide dinitrate via a burr sheath was used. Heparin was given to maintain an activated clotting time > 250 s. All patients were pretreated with acetylsalicylic acid and clopidogrel, except three patients treated with ticagrelor and one treated with prasugrel. In-hospital treatment before and after RA was conducted according to current standards, including adequate pharmacotherapy in patients with comorbidities such as heart failure, atrial fibrillation, and diabetes mellitus, which was left to the discretion of physicians in charge of the patients.

Statistical analysis

Continuous variables with normal distribution are presented as mean \pm standard deviation, continuous variables with skewed distribution as median with interquartile range, and categorical variables as numbers and percentages. For continuous variables, intergroup differences were compared using Student t test or the Mann-Whitney U test, depending on the type of distribution. The χ^2 test was used to compare categorical variables. Univariate and multivariate Cox propor-

tional hazard models were used to determine the predicting factors of all-cause death and composite endpoint (MACE). The multivariate model included all variables with $p < 0.05$ in the univariate model. Survival and event-free survival curves were created using the Kaplan-Meier method. Differences in survival and event-free survival rates were compared using the log-rank test. A p -value < 0.05 was considered statistically significant. All statistical analyses were performed using Statistica 10.0 (StatSoft, Tulsa, OK, USA) software.

RESULTS

Patient characteristics

During the study period 73 (35%) out of 207 patients fulfilled the inclusion criteria to the high-risk (RA-only) group. The control group consisted of the remaining 134 (65%) all-comer patients, who underwent PCI with accompanying RA in the centre during this time. In the RA-only group 83% of patients were considered too high-risk for CABG, based on major comorbidities including extracardiac arteriopathy, chronic lung diseases, previous cardiac surgery, poor mobility, or mental status. The remaining 17% of patients had small or poor-quality peripheral vessels. The RA procedure was mainly performed due to the presence of uncrossable lesions (23%), undilatable lesions (52%), and severely calcified lesions or unsuccessful prior PCI attempt for unclear reasons (25%).

Baseline demographics, comorbidities, and laboratory results of the whole group and both subgroups are presented in Table 1. RA-only patients had worse left ventricular function with more frequent low left ventricular ejection fraction (LVEF) $< 35\%$ (25% vs. 13%, $p = 0.03$), more often prior CABG (40% vs. 1%, $p < 0.001$), and higher glucose level on admission (118 mg/dL vs. 106 mg/dL, $p = 0.02$). Both logistic EuroSCORE II (4.1 vs. 1.8, $p < 0.001$) and SS (23 vs. 16, $p < 0.001$) along with residual SS (12 vs. 6, $p < 0.001$) were significantly higher in the RA-only group, whereas SRI was lower (47 vs. 71, $p < 0.001$) in this subset of patients. The prevalence of other cardiovascular risk factors, multiple comorbidities, and medications at discharge was similar in both groups, apart from diuretics, which were used more often in the RA-only group.

Procedure characteristics

Procedure characteristics are summarised in Table 2. RA procedure was performed in an acute coronary syndrome setting more often in the RA-only group (31% vs. 14%, $p < 0.01$). There was a trend towards less frequent transradial approach (52% vs. 65%, $p = 0.07$) and more frequent mechanical circulatory support use (4% vs. 1%, $p = 0.09$) in RA-only patients, as well as longer fluoroscopy time (23 min vs. 20 min, $p = 0.08$). There were no differences in other procedural and lesion characteristics and no difference in procedural success between RA-only group and the remaining patients (85% vs. 91%, $p = 0.18$).

In-hospital and one-year outcomes

In-hospital and one-year outcomes are presented in Table 3 and Figure 1. The no/slow-flow phenomenon was observed more frequently in RA-only patients (4% vs. 0%, $p = 0.02$), and there was a trend towards more frequent access site bleedings in this group (11% vs. 4%, $p = 0.08$). There were no other differences in complication rates. In-hospital outcomes, including death, periprocedural MI, stroke, and CIN, were similar in both study groups.

At one-year follow-up the differences in mortality and MACE rates, including death, MI, and stroke, were not significant between the RA-only group and the remaining patients (11% vs. 9%, $p = 0.64$ and 19% vs. 18%, $p = 0.82$, respectively). Kaplan-Meier curves were plotted to assess survival data (Fig. 2) and MACE-free survival data (Fig. 3) for the RA-only group and the remaining patients. Values of the log-rank test comparison demonstrated non-significant differences in survival rates and MACE-free survival rates in both study groups.

Predictors of adverse events in one-year follow-up

In the whole study population, multivariate analysis revealed heart failure with LVEF $\leq 35\%$ (hazard ratio [HR] 4.85, 95% confidence interval [CI] 1.72–13.67, $p < 0.01$) and uncrossable lesion, as compared to undilatable lesion (HR 4.33, 95% CI 1.71–10.94, $p < 0.01$), as independent predictors of one-year mortality and one-year MACE (HR 2.85, 95% CI 1.38–5.86, $p < 0.01$ and HR 2.15, 95% CI 1.15–4.03, $p = 0.02$, respectively; Table 4). It should be emphasised that among study participants the qualification to the RA-only subgroup was not associated with significantly higher one-year mortality (HR 2.45, 95% CI 0.89–6.75, $p = 0.08$) or with higher MACE rate (HR 1.46, 95% CI 0.79–2.69, $p = 0.23$).

DISCUSSION

In the study we analysed the high-risk population of patients who underwent an RA procedure as the last resort for successful coronary revascularisation, in comparison to the remaining all-comer population undergoing RA. The main findings of the study are: 1) clinical and coronary high-risk patients without other revascularisation options apart from RA constitute a considerable population; 2) in-hospital and one-year outcomes are similar in high- and lower-risk patients after RA; 3) complex PCI with accompanying RA in patients without other revascularisation options has acceptable prognosis and should be taken into consideration.

One-third of the patients who underwent PCI with accompanying RA in our centre had a high-risk clinical and anatomical profile and had no revascularisation alternative. In this subgroup traditional PCI was unsuccessful because of the presence of tough fibrocalcified lesions that could not be crossed or dilated by conventional angioplasty balloons, which is considered the main indication to perform the more complex procedure of rotablation [1, 2]. Additionally, these

Table 1. Baseline clinical and laboratory characteristics

Parameters	All patients (n = 207)	RA-only (n = 73)	Remaining (n = 134)	p
Age [years]	71 ± 9	72 ± 9	70 ± 9	0.15
Male sex	137 (66)	51 (70)	86 (64)	0.41
Hypertension	170 (82)	59 (81)	111 (83)	0.72
Diabetes mellitus	88 (43)	36 (49)	52 (39)	0.14
Prior stroke/TIA	26 (13)	13 (18)	13 (10)	0.09
Hyperlipidaemia	96 (46)	31 (42)	65 (49)	0.40
Thyroid disease	28 (14)	8 (11)	20 (15)	0.43
Cancer	25 (12)	8 (11)	17 (13)	0.72
Asthma/COPD	14 (7)	7 (10)	7 (5)	0.23
Current smoker	15 (7)	2 (3)	13 (10)	0.06
Atrial fibrillation	44 (21)	14 (19)	30 (22)	0.59
Peripheral artery disease	64 (31)	28 (38)	36 (27)	0.09
Severe valve disease	19 (9)	8 (11)	11 (8)	0.51
LVEF [%]	55 (40–60)	45 (37–55)	55 (50–60)	< 0.001
LVEF ≤ 35%	35 (17)	18 (25)	17 (13)	0.03
Impaired renal function with eGFR < 60 mL/min	45 (22)	20 (27)	25 (19)	0.16
Dialysis	8 (4)	3 (4)	5 (4)	0.89
Prior acute coronary syndrome	130 (63)	50 (68)	80 (60)	0.21
Prior PCI	152 (73)	54 (74)	98 (73)	0.90
Prior CABG	31 (15)	29 (40)	2 (1)	< 0.001
Laboratory parameters:				
White blood cell count [10 ³ /μL]	7.7 ± 2.1	7.8 ± 2.3	7.7 ± 2.0	0.86
Red blood cell count [10 ⁶ /μL]	4.5 (4.1–4.8)	4.5 (4.0–4.8)	4.5 (4.2–4.8)	0.32
Haemoglobin [g/dL]	13.6 ± 1.4	13.4 ± 1.4	13.7 ± 1.4	0.12
Platelet count [10 ³ /μL]	205 (176–249)	203 (174–232)	210 (180–251)	0.24
Creatinine [mg/dL]	0.9 (0.8–1.1)	0.95 (0.8–1.2)	0.9 (0.8–1.1)	0.06
Glucose [mg/dL]	109 (96–134)	118 (102–140)	106 (96–130)	0.02
eGFR [mL/min/1.73 m ²]	80 (63–94)	77 (58–93)	82 (70–94)	0.10
Risk scores:				
Logistic EuroSCORE II	2.4 (1.4–4.9)	4.1 (2.4–7.1)	1.8 (1.2–3.5)	< 0.001
Syntax Score	17 (11–24)	23 (16–32)	16 (9–22)	< 0.001
Residual Syntax Score	8 (0–14)	12 (6–19)	6 (0–10)	< 0.001
Syntax Revascularisation Index [%]	59 (42–100)	47 (33–62)	71 (47–100)	< 0.001
Syntax Score II — PCI	5 (2)	1 (1)	4 (3)	0.47
Syntax Score II — CABG	45 (22)	24 (33)	21 (16)	< 0.01
Syntax Score II — both	157 (76)	48 (66)	109 (81)	0.01
Medication at discharge:				
ASA	201 (98)	70 (97)	131 (99)	0.53
P2Y ₁₂ inhibitor	203 (99)	70 (97)	133 (100)	0.06
β-blocker	195 (95)	70 (97)	125 (94)	0.30
ACEI/ARB	194 (94)	72 (99)	126 (95)	0.12
Statin	199 (96)	69 (94)	130 (97)	0.37
Diuretic	93 (45)	41 (57)	52 (39)	0.01
Nitrates	16 (8)	6 (8)	10 (8)	0.84
Oral anticoagulation	24 (12)	10 (14)	14 (11)	0.47
Proton pump inhibitor	100 (49)	36 (50)	64 (48)	0.84

Data are presented as numbers (percentages) for categorical variables, mean ± standard deviation for continuous variables with normal distribution, and median with interquartile range for continuous variables with skewed distribution. ACEI — angiotensin converting enzyme inhibitor; ARB — angiotensin receptor blocker; ASA — acetylsalicylic acid; CABG — coronary artery bypass grafting; COPD — chronic obstructive pulmonary disease; eGFR — estimated glomerular filtration rate; LVEF — left ventricular ejection fraction; PCI — percutaneous coronary intervention; RA — rotational atherectomy; TIA — transient ischaemic attack

Table 2. Procedure characteristics

Patients	All patients (n = 207)	RA-only (n = 73)	Remaining (n = 134)	p
Acute coronary syndrome	165 (80)	23 (31)	19 (14)	< 0.01
Radial access	125 (60)	38 (52)	87 (65)	0.07
Temporary pacing	19 (9)	13 (18)	26 (19)	0.78
MCS use	4 (2)	3 (4)	1 (1)	0.09
Reason for RA:				
Uncrossable lesion	48 (23)	17 (23)	31 (23)	0.98
Undilatable lesion	105 (51)	39 (52)	67 (50)	0.78
Direct/Unclear PCI failure	54 (26)	18 (25)	36 (27)	0.60
Target vessel:				
RCA	70 (34)	20 (27)	50 (37)	0.15
LM	11 (5)	6 (8)	5 (4)	0.17
LAD	92 (44)	32 (44)	60 (45)	0.90
Cx	29 (14)	15 (21)	14 (10)	0.05
Lesion characteristics:				
Lesion type B2/C	186 (90)	66 (90)	120 (90)	0.84
Aorto-ostial lesion	27 (13)	13 (18)	14 (10)	0.13
Bifurcation lesion	81 (39)	29 (40)	52 (39)	0.90
Chronic total occlusion	23 (11)	9 (12)	14 (10)	0.68
Severe calcifications	186 (90)	69 (95)	117 (87)	0.10
Diameter stenosis [%]	95 (90–99)	95 (90–99)	90 (90–99)	0.24
Lesion length [mm]	24 (15–35)	26 (16–36)	23 (14–35)	0.20
Minimum lumen diameter [mm]	0.175 (0–0.525)	0.15 (0–0.52)	0.23 (0.03–0.54)	0.19
Reference diameter [mm]	3.1 (2.75–3.6)	3.0 (2.5–3.5)	3.1 (2.75–3.6)	0.43
Procedural data:				
Predilatation	187 (92)	64 (89)	123 (93)	0.29
Postdilatation	108 (53)	38 (54)	70 (53)	0.95
More than one burr	41 (20)	11 (15)	30 (22)	0.20
Burr to artery ratio	0.43 (0.42–0.5)	0.43 (0.42–0.5)	0.43 (0.42–0.5)	0.58
Maximum burr diameter	1.5 ± 0.2	1.4 ± 0.2	1.5 ± 0.2	0.12
Number of stents	1.4 ± 0.9	1.4 ± 0.9	1.5 ± 0.8	0.43
DES implantations	184 (95)	63 (96)	121 (95)	0.78
Total contrast volume [mL]	250 (200–300)	250 (200–350)	250 (200–300)	0.15
Fluoroscopy time [min]	20 (15–29)	23 (16–30)	20 (14–28)	0.08
Procedure time [min]	85 (55–150)	90 (60–145)	85 (55–150)	0.45
Radiation exposure [μGy]	2623 (1686–4171)	2748 (1686–4429)	2483 (1717–4088)	0.42
Discharge after RA [days]	2 (1–4)	2 (2–5)	2 (1–3)	0.21
Procedural success	184 (89)	62 (85)	122 (91)	0.18

Data are presented as numbers and percentages for categorical variables, mean ± standard deviation for continuous variables with normal distribution and median with interquartile range for continuous variables with skewed distribution. Cx — circumflex artery; DES — drug-eluting stent; LAD — left anterior descending; LM — left main; MCS — mechanical circulatory support; PCI — percutaneous coronary intervention; RA — rotational atherectomy; RCA — right coronary artery

patients were disqualified from CABG. The main reasons were high-risk of surgery because of multiple comorbidities and challenging anatomy, including poor periphery of coronary arteries, which are acknowledged as contraindications [3–5].

Such patients can undergo further conservative treatment alone, which in the case of extensive symptomatic ischaemia has a poor prognosis [6–8]. The use of RA, even though it is a demanding technique for experienced operators, gives

Table 3. In-hospital and one-year follow-up adverse events

Patients	All patients (n = 207)	RA-only (n = 73)	Remaining (n = 134)	p
Periprocedural complications:				
Slow/no-flow	3 (1)	3 (4)	0 (0)	0.02
Side branch occlusion	5 (2)	3 (4)	2 (1)	0.24
Dissection	8 (4)	3 (4)	5 (4)	0.89
Perforation	3 (1)	0 (0)	3 (2)	0.20
Emergency CABG	0 (0)	0 (0)	0 (0)	NS
Permanent pacing	0 (0)	0 (0)	0 (0)	NS
In-hospital outcomes:				
Death	2 (1)	1 (1)	1 (1)	0.66
Periprocedural MI	28 (14)	9 (12)	19 (14)	0.71
Stroke/TIA	1 (0.5)	0 (0)	1 (1)	0.46
Target vessel revascularisation	1 (0.5)	0 (0)	1 (1)	0.46
Contrast-induced nephropathy	6 (3)	3 (4)	3 (2)	0.44
Access site bleedings	14 (7)	8 (11)	6 (4)	0.08
Clinical outcomes at one-year follow-up:				
Death	20 (10)	8 (11)	12 (9)	0.64
Follow-up MI	20 (10)	8 (11)	12 (9)	0.64
Stroke	2 (1)	0 (0)	2 (1)	0.29
MACE	38 (18)	14 (19)	24 (18)	0.82

Data are presented as numbers (percentages). CABG — coronary artery bypass grafting; MACE — major adverse cardiac events; MI — myocardial infarction; NS — non-significant; RA — rotational atherectomy; TIA — transient ischaemic attack

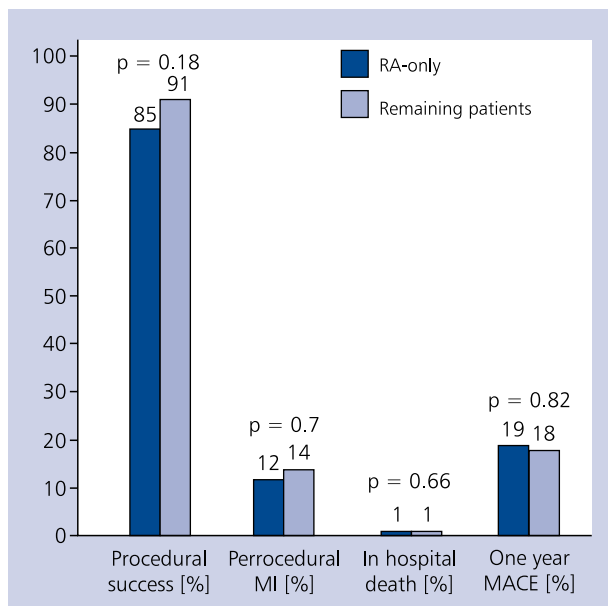


Figure 1. Outcomes in patients after rotational atherectomy; MACE — major adverse cardiac events; MI — myocardial infarction; RA — rotational atherectomy

the patients the opportunity of successful revascularisation. Potential optimal evidence of RA efficacy in such a high-risk subgroup might be verified in a trial. However, randomising patients to PCI with RA and to optimal medical treatment alone seems difficult to perform, also from an ethical point of view, so all remaining patients who underwent RA were classified as a control group.

A large majority of the study group comprised higher-risk patients, with more frequent low LVEF < 35% (25% vs. 13%, $p = 0.03$), more often after CABG (40% vs. 1%, $p < 0.001$), and more often with acute coronary syndrome on admission (31% vs. 14%, $p < 0.01$), as compared to the control group. The presence of heart failure with decreased LVEF is a well-documented independent predictor of mortality, following not only conventional PCI procedure, but also PCI with accompanying RA [16, 17]. Patients with decreased LVEF undergoing complex PCI along with RA could be referred for more specialised treatment, such as the use of mechanical circulatory support (4% of our RA-only patients). The clinical status of the RA-only group was reflected by higher EuroSCORE II (4.1 vs. 1.8, $p < 0.001$) and the coronary status by higher SS (23 vs. 16, $p < 0.001$). In another trial patients

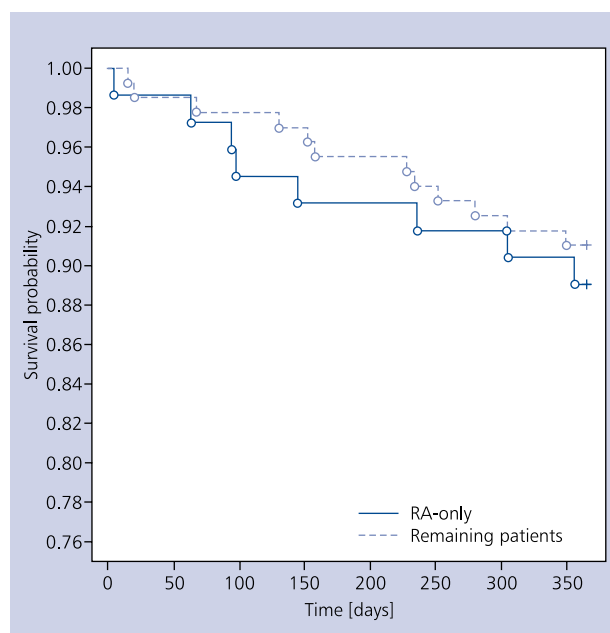


Figure 2. Kaplan-Meier survival curves, log-rank $p = 0.63$; RA — rotational atherectomy

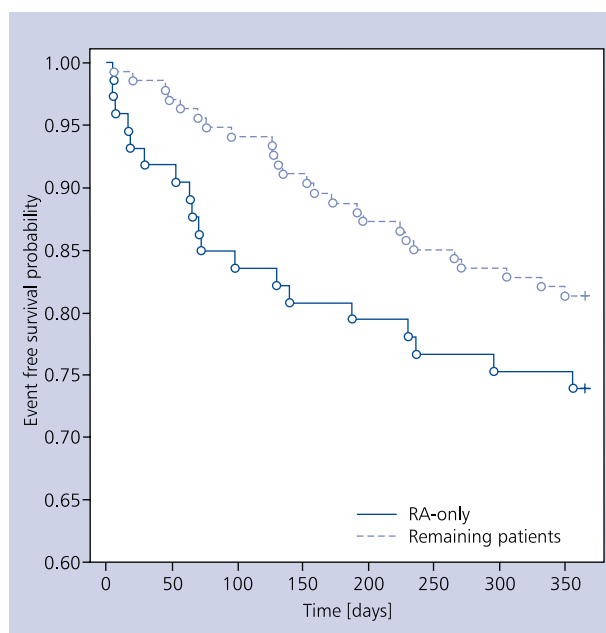


Figure 3. Kaplan-Meier major adverse cardiac event-free survival curves, log-rank $p = 0.17$; RA — rotational atherectomy

Table 4. Predictors of outcome in Cox regression models

	Univariate model			Multivariate model		
	HR	95% CI	p	HR	95% CI	p
Predictors of all-cause death:						
LVEF $\leq 35\%$	5.64	2.34–13.55	< 0.001	4.85	1.72–13.67	< 0.01
Uncrossable lesion	3.64	1.51–8.74	< 0.01	4.33	1.71–10.94	< 0.01
Syntax Score	1.04	1.00–1.08	0.03	0.99	0.94–1.04	0.66
eGFR < 60 mL/min	2.58	1.05–6.31	0.04	1.36	0.47–3.93	0.57
EuroSCORE II	1.09	1.03–1.15	< 0.01	1.07	0.98–1.17	0.16
Predictors of major adverse cardiac events:						
LVEF $\leq 35\%$	3.25	1.76–6.02	< 0.001	2.85	1.38–5.86	< 0.01
Uncrossable lesion	2.01	1.11–3.81	0.02	2.15	1.15–4.03	0.02
Syntax Score	1.03	1.01–1.06	0.01	0.99	0.97–1.03	0.81
Age	1.04	1.01–1.08	0.01	1.03	0.99–1.07	0.09
Diabetes mellitus	1.93	1.06–3.49	0.03	1.82	0.99–3.35	0.06
EuroSCORE II	1.07	1.03–1.12	< 0.01	1.03	0.98–1.10	0.26

CI — confidence interval; eGFR — estimated glomerular filtration rate; HR — hazard ratio; LVEF — left ventricular ejection fraction

deemed by the Heart Team as inoperable also constituted a high-risk population, reaching 7.7 ± 9.0 in logistic EuroSCORE and 31.6 ± 12.3 in SS, and in another RA registry high EuroSCORE II had a significant association with MACE in long-term observation [9, 18].

Additionally, the level of incomplete revascularisation with the use of residual SS and SRI was assessed. The impor-

tance of incomplete revascularisation after PCI and its influence on prognosis have been raised in recent trials, indicating that high residual SS was associated with worse prognosis [19, 20]. The SRI was introduced to assess reasonable incomplete revascularisation as well [21]. Both the abovementioned scales indicated the higher level of incomplete revascularisation in the study group compared to the control group. Fewer lesions

were stented, presumably because mainly culprit lesions were treated whereas other lesions remained untouched, resulting in residual SS of 12 (vs. 6, $p < 0.001$) and SRI of 47% (vs. 71%, $p < 0.001$). Interestingly, according to SS II, which adds a few clinical parameters to the initial SS, one-third of our patients from the RA-only group might have better prognosis after potential CABG than after PCI. It highlights the impact of other comorbidities and overall status of the patient on Heart Team's judgement regardless of different scores.

Thus, our clinical and coronary high-risk subpopulation had an unfavourable prognosis. Despite significant differences in characteristics between the high-risk and control groups, patients who underwent RA as the last resort for revascularisation had similar rates of procedural success as well as in-hospital and one-year outcomes, including mortality, along with cardiovascular morbidity. RA-only criteria in regression analysis were also not associated with worse prognosis, and even partial revascularisation seemed reasonable in this selected subgroup. The rate of periprocedural complications was relatively low and the only unfavourable parameter was more frequent no/slow-flow phenomenon (4% vs. 0%, respectively, $p = 0.02$) in the RA-only group, which was probably associated with the presence of complex atherosclerotic coronary lesions and did not have subsequent impact on in-hospital and one-year outcomes. Longer-term follow-up is warranted.

The results of the study may have practical implications and permit a more aggressive approach in selected high-risk patients, in whom conventional procedures are contraindicated and conservative treatment is insufficient. Additional consultation in a centre specialising in treatment of patients recognised as CHIP should be considered not only by physicians from low-volume centres, where complex procedures like rotational atherectomy are not performed, but also by members of the Heart Team.

The study was a nonrandomised observational registry from a single high-volume centre. The sample size was relatively small, and the analyses should be considered as explorative. Only all-cause mortality was reported during follow-up without differentiating the group of cardiac death patients.

To conclude, in clinical and coronary high-risk patients, no significant difference between in-hospital and one-year outcomes was found, in comparison to the remaining lower-risk patients undergoing RA. Complex PCI including RA in patients without other revascularisation options seems to be a safe and effective procedure with acceptable prognosis and should be taken into consideration.

Conflict of interest: none declared

References

- Barbato E, Carrié D, Dardas P, et al. European Association of Percutaneous Cardiovascular Interventions. European expert consensus on rotational atherectomy. *EuroIntervention*. 2015; 11(1): 30–36, doi: [10.4244/EIJV11I1A6](https://doi.org/10.4244/EIJV11I1A6), indexed in Pubmed: [25982648](https://pubmed.ncbi.nlm.nih.gov/25982648/).
- Tomey MI, Kini AS, Sharma SK. Current status of rotational atherectomy. *JACC Cardiovasc Interv*. 2014; 7(4): 345–353, doi: [10.1016/j.jcin.2013.12.196](https://doi.org/10.1016/j.jcin.2013.12.196), indexed in Pubmed: [24630879](https://pubmed.ncbi.nlm.nih.gov/24630879/).
- Windecker S, Kolh P, Alfonso F, et al. 2014 ESC/EACTS Guidelines on myocardial revascularization: The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) Developed with the special contribution of the European Association of Percutaneous Cardiovascular Interventions (EAPCI). *Eur Heart J*. 2014; 35(37): 2541–2619, doi: [10.1093/eurheartj/ehu278](https://doi.org/10.1093/eurheartj/ehu278), indexed in Pubmed: [25173339](https://pubmed.ncbi.nlm.nih.gov/25173339/).
- Christenson JT, Schmuziger M, Simonet F. Reoperative coronary artery bypass procedures: risk factors for early mortality and late survival. *Eur J Cardiothorac Surg*. 1997; 11(1): 129–133, indexed in Pubmed: [9030801](https://pubmed.ncbi.nlm.nih.gov/9030801/).
- Yap CH, Sposato L, Akowuah E, et al. Contemporary results show repeat coronary artery bypass grafting remains a risk factor for operative mortality. *Ann Thorac Surg*. 2009; 87(5): 1386–1391, doi: [10.1016/j.athoracsur.2009.02.006](https://doi.org/10.1016/j.athoracsur.2009.02.006), indexed in Pubmed: [19379870](https://pubmed.ncbi.nlm.nih.gov/19379870/).
- Pfisterer M. Long-term outcome in elderly patients with chronic angina managed invasively versus by optimized medical therapy: four-year follow-up of the randomized Trial of Invasive versus Medical therapy in Elderly patients (TIME). *Circulation*. 2004; 110(10): 1213–1218, doi: [10.1161/01.CIR.0000140983.69571.BA](https://doi.org/10.1161/01.CIR.0000140983.69571.BA), indexed in Pubmed: [15337691](https://pubmed.ncbi.nlm.nih.gov/15337691/).
- Rogers W, Bourassa M, Andrews T, et al. Asymptomatic cardiac ischemia pilot (ACIP) study: Outcome at 1 year for patients with asymptomatic cardiac ischemia randomized to medical therapy or revascularization. *J Am Coll Cardiol*. 1995; 26(3): 594–605, doi: [10.1016/0735-1097\(95\)00228-v](https://doi.org/10.1016/0735-1097(95)00228-v).
- Erne P, Schoenenberger A, Burckhardt D, et al. Effects of Percutaneous Coronary Interventions in Silent Ischemia After Myocardial Infarction. *JAMA*. 2007; 297(18): 1985–1991, doi: [10.1001/jama.297.18.1985](https://doi.org/10.1001/jama.297.18.1985).
- Head SJ, Holmes DR, Mack MJ, et al. Risk profile and 3-year outcomes from the SYNTAX percutaneous coronary intervention and coronary artery bypass grafting nested registries. *JACC Cardiovasc Interv*. 2012; 5(6): 618–625, doi: [10.1016/j.jcin.2012.02.013](https://doi.org/10.1016/j.jcin.2012.02.013), indexed in Pubmed: [22721656](https://pubmed.ncbi.nlm.nih.gov/22721656/).
- Hlatky MA, Boothroyd DB, Bravata DM, et al. Coronary artery bypass surgery compared with percutaneous coronary interventions for multivessel disease: a collaborative analysis of individual patient data from ten randomised trials. *Lancet*. 2009; 373(9670): 1190–1197, doi: [10.1016/S0140-6736\(09\)60552-3](https://doi.org/10.1016/S0140-6736(09)60552-3), indexed in Pubmed: [19303634](https://pubmed.ncbi.nlm.nih.gov/19303634/).
- Serruys PW, Morice MC, Kappetein AP, et al. Percutaneous coronary intervention versus coronary-artery bypass grafting for severe coronary artery disease. *N Engl J Med*. 2009; 360(10): 961–972, doi: [10.1056/NEJMoa0804626](https://doi.org/10.1056/NEJMoa0804626), indexed in Pubmed: [19228612](https://pubmed.ncbi.nlm.nih.gov/19228612/).
- Kapur A, Hall RJ, Malik IS, et al. Randomized comparison of percutaneous coronary intervention with coronary artery bypass grafting in diabetic patients. 1-year results of the CARDia (Coronary Artery Revascularization in Diabetes) trial. *J Am Coll Cardiol*. 2010; 55(5): 432–440, doi: [10.1016/j.jacc.2009.10.014](https://doi.org/10.1016/j.jacc.2009.10.014), indexed in Pubmed: [20117456](https://pubmed.ncbi.nlm.nih.gov/20117456/).
- Généreux P, Campos CM, Yadav M, et al. Reasonable incomplete revascularisation after percutaneous coronary intervention: the SYNTAX Revascularisation Index. *EuroIntervention*. 2015; 11(6): 634–642, doi: [10.4244/EIJY14M10_05](https://doi.org/10.4244/EIJY14M10_05), indexed in Pubmed: [25308300](https://pubmed.ncbi.nlm.nih.gov/25308300/).
- Thygesen K, Alpert J, White H. Joint ESC/ACCF/AHA/WHF Task Force for the Redefinition of Myocardial Infarction. Universal Definition of Myocardial Infarction. *J Am Coll Cardiol*. 2007; 50(22): 2173–2195, doi: [10.1016/j.jacc.2007.09.011](https://doi.org/10.1016/j.jacc.2007.09.011).

15. Mehran R, Rao SV, Bhatt DL, et al. Standardized bleeding definitions for cardiovascular clinical trials: a consensus report from the Bleeding Academic Research Consortium. *Circulation*. 2011; 123(23): 2736–2747, doi: [10.1161/CIRCULATIONAHA.110.009449](https://doi.org/10.1161/CIRCULATIONAHA.110.009449), indexed in Pubmed: [21670242](https://pubmed.ncbi.nlm.nih.gov/21670242/).
16. Wu C, Camacho FT, King SB, et al. Risk stratification for long-term mortality after percutaneous coronary intervention. *Circ Cardiovasc Interv*. 2014; 7(1): 80–87, doi: [10.1161/CIRCINTERVENTIONS.113.000475](https://doi.org/10.1161/CIRCINTERVENTIONS.113.000475), indexed in Pubmed: [24425588](https://pubmed.ncbi.nlm.nih.gov/24425588/).
17. Édes IF, Ruzsa Z, Szabó G, et al. Clinical predictors of mortality following rotational atherectomy and stent implantation in high-risk patients: A single center experience. *Catheter Cardiovasc Interv*. 2015; 86(4): 634–641, doi: [10.1002/ccd.25945](https://doi.org/10.1002/ccd.25945), indexed in Pubmed: [26032270](https://pubmed.ncbi.nlm.nih.gov/26032270/).
18. 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(6): 564–572, doi: [10.5603/KP.a2017.0042](https://doi.org/10.5603/KP.a2017.0042), indexed in Pubmed: [28631258](https://pubmed.ncbi.nlm.nih.gov/28631258/).
19. Farooq V, Serruys PW, Bourantas CV, et al. Quantification of incomplete revascularization and its association with five-year mortality in the synergy between percutaneous coronary intervention with taxus and cardiac surgery (SYNTAX) trial validation of the residual SYNTAX score. *Circulation*. 2013; 128(2): 141–151, doi: [10.1161/CIRCULATIONAHA.113.001803](https://doi.org/10.1161/CIRCULATIONAHA.113.001803), indexed in Pubmed: [23766350](https://pubmed.ncbi.nlm.nih.gov/23766350/).
20. Park KW, Kang J, Kang SH, et al. The impact of residual coronary lesions on clinical outcomes after percutaneous coronary intervention: Residual SYNTAX score after percutaneous coronary intervention in patients from the Efficacy of Xience/Promus versus Cypher in rEducating Late Loss after stENTing (EXCELLENT) registry. *Am Heart J*. 2014; 167(3): 384–392.e5, doi: [10.1016/j.ahj.2013.09.015](https://doi.org/10.1016/j.ahj.2013.09.015), indexed in Pubmed: [24576524](https://pubmed.ncbi.nlm.nih.gov/24576524/).
21. Généreux P, Campos CM, Farooq V, et al. Validation of the SYNTAX revascularization index to quantify reasonable level of incomplete revascularization after percutaneous coronary intervention. *Am J Cardiol*. 2015; 116(2): 174–186, doi: [10.1016/j.amjcard.2015.03.056](https://doi.org/10.1016/j.amjcard.2015.03.056), indexed in Pubmed: [25983123](https://pubmed.ncbi.nlm.nih.gov/25983123/).

Cite this article as: Kübler P, Zimoch W, Kosowski M, et al. The use of rotational atherectomy in high-risk patients: results from a high-volume centre. *Kardiol Pol*. 2018; 76(9): 1360–1368, doi: [10.5603/KP.a2018.0144](https://doi.org/10.5603/KP.a2018.0144).

WHAT IS NEW?

Some of the patients with severe coronary artery disease constitute a high-risk population and the procedure of rotational atherectomy is their last resort for successful revascularisation. The study revealed that procedural success and one-year outcomes in such high-risk groups are similar to those in lower-risk routine rotablation groups in a high-volume centre. The results of the study may have practical implications and permit a more aggressive approach in selected high-risk patients, in whom conventional procedures are contraindicated and conservative treatment is insufficient. Additional consultation in a centre treating high-risk patients should be considered not only by specialists from low-volume centres, where complex procedures like rotational atherectomy are not performed, but also by members of the Heart Team.