

# Sex-related differences and rotational atherectomy: Analysis of 5 177 percutaneous coronary interventions based on a large national registry from 2014 to 2020

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## Editorial

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## ABSTRACT

**Background:** Patients undergoing percutaneous coronary interventions (PCI) with rotational atherectomy (RA) have massively calcified coronary arteries and their prognosis differs between sexes.

**Aims:** The aim of the study was to evaluate the trends in the percentage of sexes in the subsequent years, to compare demographic characteristics between men and women, and to identify factors associated with the risk of periprocedural complications and death.

**Methods:** We analyzed data on 751 113 patients treated with PCI between 2014 and 2020 from the Polish National Registry of Percutaneous Coronary Interventions (ORPKI). We extracted data on 5 177 (0.7%) patients treated with RA of whom 3 552 (68.6%) were men. To determine risk factors of periprocedural complications and death, a multivariable analysis was performed.

**Results:** The proportion of PCIs involving RA increased between 2014 and 2020 ( $P < 0.001$ ). Almost twice as many RA procedures were performed on men (68.55%), and that proportion did not change in the following years. The female patients were older (75.2 [8.3] vs. 70.5 [9.2] years;  $P < 0.001$ ). When considering periprocedural complications, their overall rate (3.45% vs. 2.31%;  $P = 0.01$ ) and death rate (0.68% vs. 0.17%;  $P = 0.006$ ) were greater among women. Also, via multivariable analysis, female sex was found to be a risk factor for greater periprocedural mortality ( $P = 0.02$ ) and overall complication rate ( $P = 0.007$ ).

**Conclusions:** The majority of patients treated with RA are men and sex-related distribution was stable during the analyzed period. Female sex is a risk factor for greater periprocedural complications and mortality in patients treated with RA.

**Key words:** complications, mortality, percutaneous coronary intervention, rotational atherectomy, sex

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## INTRODUCTION

In the case of percutaneous coronary interventions (PCIs), years of practice have made indications for these procedures more common. Female sex is associated with poorer clinical outcomes after PCI including a higher risk of death, myocardial infarction or target vessel failure, and lesion failure in long-term follow-up [1–3]. Women who suffer from coronary artery disease are older with greater occurrence of comorbidities, which indicates sex-related differences in outcomes after PCI [4–7]. A narrow group of patients is characterized by the presence of massive calcifications in the coronary arteries during coronary artery procedures. In order to treat those patients, rotational atherectomy (RA) may be applicable to prevent stent under-expansion or malapposition [8, 9]. Despite the use of RA in interventional cardiology for over 3 decades, data regarding factors affecting the clinical outcomes of the use of RA is more and more frequent, and one of the main reasons is the extension of the indications towards more complex PCI procedures. Women undergoing PCI of calcified lesions tend to have a worse clinical profile and remain at increased ischemic risk, irrespective of new-generation, drug-eluting stents [10]. Coronary calcifications could be found less often among women compared to men [11]. RA usage varies among countries, but its average frequency is within the range of 0.8%–3.1% PCIs [12–14]. Due to this significant increase in the frequency of these procedures in recent years and the distinctiveness of this group of patients (PCI with RA) from other patients undergoing PCI, we have characterized the group according to sex.

The current study aimed to assess the number of male and female Polish patients undergoing PCI with RA and sex-related differences in both groups of patients between 2014 and 2020. We also assessed risk factors for periprocedural death and overall complications in patients treated with RA.

## METHODS

### *Study design and patient population*

This retrospective analysis was performed on prospectively collected data. Data were obtained from the National Registry of Percutaneous Coronary Interventions (ORPKI) maintained in cooperation with the Polish Cardiac Society's Association of Cardiovascular Interventions. The registry has been described in previously published papers [12]. The study covered data obtained from the registry between January 2014 and December 2020. We selected 5 177 patients treated with RA out of 751 113 individuals undergoing PCI during the analyzed period. The technical aspects of the procedure, such as the choice of access site, sheath size, and catheter size, were at the operator's discretion and complied with the current Polish and European recommendations [13, 15]. Furthermore, the periprocedural anticoagulation and indications for PCI, as well as the stent type, remained at the first operator's discretion and complied with the current guidelines of the European Society of Cardiology [16, 17]. The overall complications were calculated per patient, which means that a patient was found to have periprocedural complications if one or more periprocedural complications occurred. The protocol complied with the 1964 Declaration of Helsinki, and all participants provided their written, informed consent for participation in the percutaneous intervention. Due to the retrospective nature of the collected data and the registry, obtaining the consent of the Bioethics Committee was not required.

### *Study definitions*

In the current analysis, all periprocedural complications included death, myocardial infarction, no-reflow phenomenon, puncture-site bleeding, cardiac arrest, allergic reaction, coronary artery perforation, stroke, and coronary artery dissection.

## WHAT'S NEW?

Female sex is associated with poorer clinical outcomes after percutaneous coronary interventions (PCIs) including a higher risk of death, myocardial infarction or target vessel failure, and lesion failure in long-term follow-up. Patients undergoing PCI with rotational atherectomy (RA) have massively calcified coronary arteries and differ according to sex. We aimed to assess the trends in the percentage of sexes in the years 2014–2020, to compare demographic characteristics between men and women and to identify factors associated with the risk of periprocedural complications and death. Out of 751 113 patients treated with PCI between 2014 and 2020, we extracted data on 5 177 (0.7%) patients treated with RA of whom 3 552 (68.6%) were men. Sex-related distribution of patients treated with RA was stable during the analyzed period. Multivariable regression analysis confirmed that female sex is a risk factor of periprocedural complications and mortality in patients treated with PCI and RA.

### Study aims

The primary aim of the study was to assess the proportions of each sex, and sex-related differences, in the all-comers group of patients treated with PCI between 2014 and 2020. The secondary study aim included the assessment of possible risk factors for complications and death rate in patients treated with RA. We also assessed general trends regarding the frequency of RA use in the group of patients treated with PCI.

### Statistical analysis

Categorical variables are presented as numbers and percentages. Continuous variables are expressed as median (interquartile range [IQR]). The normality was assessed via the Shapiro-Wilk test. The equality of variance was evaluated using Levene's test. Differences between the 2 groups were compared using the Student's or Welch's *t*-test, depending on the equality of variance for normally distributed variables. Categorical variables were compared with Pearson's chi-squared or Fisher's exact test if 20% of cells had an expected count of less than 5 (Monte Carlo simulation for Fisher's test using tables of higher dimensions than  $2 \times 2$ ). All baseline/demographic characteristics were used as potential predictors of procedure-related complications and death in univariable logistic regression models. Then variables with *P*-value  $< 0.2$  or variables of clinical importance were included in the multivariable model. Final multivariable logistic regression models were constructed using the minimization of Akaike Information Criterion to find predictors of stroke in the DCA and PCI  $\pm$  DCA groups. Statistical analysis was performed using

the R, version 3.5.3 (R Foundation for Statistical Computing, Vienna, Austria) with the 'lme4', version 1.1-21 package.

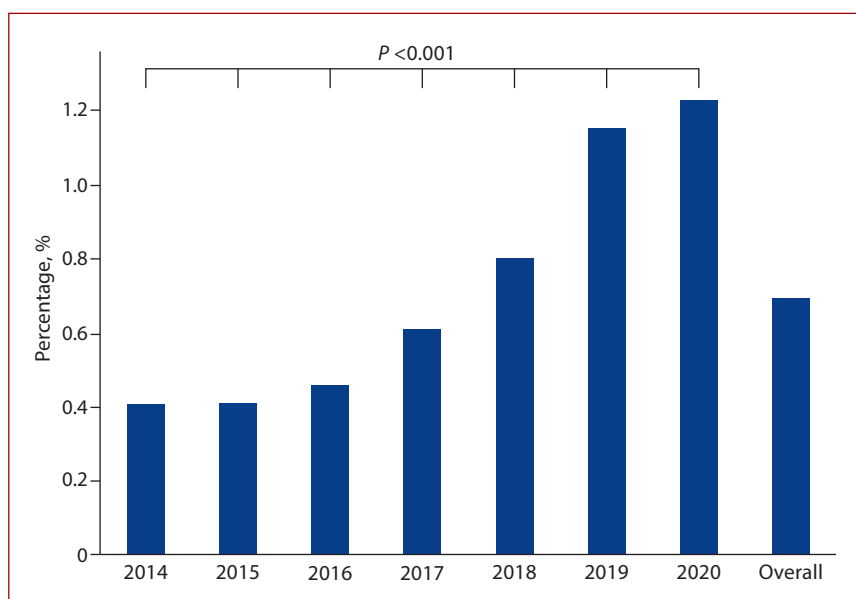
## RESULTS

### Population

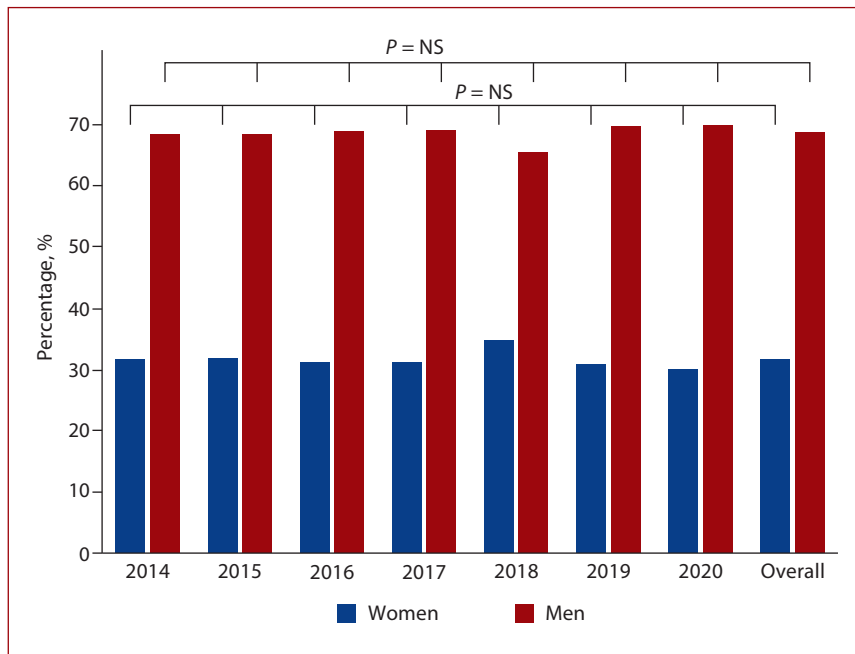
The study included patients treated with PCI and RA registered in the ORPKI database in the years 2014–2020. Out of 751 113 patients treated with PCI, we extracted data on 5 195 (0.69%) treated with RA. The percentage of patients with rotablation increased from 0.41% in 2014 to 1.23% in 2020 (Figure 1). In the group of patients analyzed in the current study and treated with PCI, there were 236 248 women (31.45%), and this number was comparable to the subgroup of patients treated with RA: 1 625 women (31.28%). The percentage of female patients in the group of patients treated with PCI did not change significantly from 2014 to 2020. It fluctuated around 30% and was similar to the group of RA, in which the ratio of men to women did not demonstrate statistically significant differences (Figure 2).

### Patient characteristics

Female patients treated with PCI and RA were older when compared to males ( $P < 0.001$ ). Also, women more often suffered from diabetes ( $P < 0.001$ ) and arterial hypertension ( $P = 0.001$ ). On the other hand, they less frequently had a history of prior PCI ( $P < 0.001$ ), coronary artery bypass grafting ( $P < 0.001$ ), and were less often smokers ( $P < 0.001$ ). Furthermore, clinical presentation at admission was different for male and female patients, as the women



**Figure 1.** Frequency of RA use among all-comers treated with PCI in Poland between 2014 and 2020 based on the ORPKI registry  
Abbreviations: ORPKI, National Registry of Percutaneous Coronary Interventions; PCI, outcomes after percutaneous coronary intervention; RA, rotational atherectomy



**Figure 2.** The percentage of men and women treated with and without PCI in Poland between 2014 and 2020 based on the ORPKI. Abbreviations: NS, not significant; other — see Figure 1

presented acute coronary syndromes more often than the men ( $P < 0.001$ ; Supplementary material, Table S1).

### Procedural indices

Men undergoing PCI and RA were more often treated due to chronic total occlusion ( $P = 0.03$ ), which was reflected in the different distribution of thrombolysis in the myocardial infarction (TIMI) grade as compared to women ( $P < 0.001$ ), different contrast use ( $P < 0.001$ ) and radiation exposition ( $P < 0.001$ ). Female patients were more often treated within the right coronary artery area in comparison to men ( $P = 0.002$ ) (Supplementary material, Table S2).

### Periprocedural complications

Considering periprocedural complications, the overall rate was greater in women compared to men ( $P = 0.02$ ). The rates of periprocedural death ( $P = 0.006$ ) and cardiac arrest ( $P = 0.04$ ) were also higher in female patients compared to males (Supplementary material, Table S3).

### Periprocedural death

Among risk factors for an increased rate of periprocedural death assessed by multivariable analysis in patients treated with PCI and RA, we found the following risk factors: female sex ( $P = 0.02$ ), multi-vessel disease ( $P = 0.009$ ), cardiac arrest at baseline ( $P < 0.001$ ), and radial vascular access in comparison to femoral ( $P = 0.019$ ). Among factors related to decreased rate of periprocedural deaths, we confirmed patent coronary artery after PCI assessed by TIMI flow scale as grade 3 ( $P < 0.001$ ) (Figure 3).

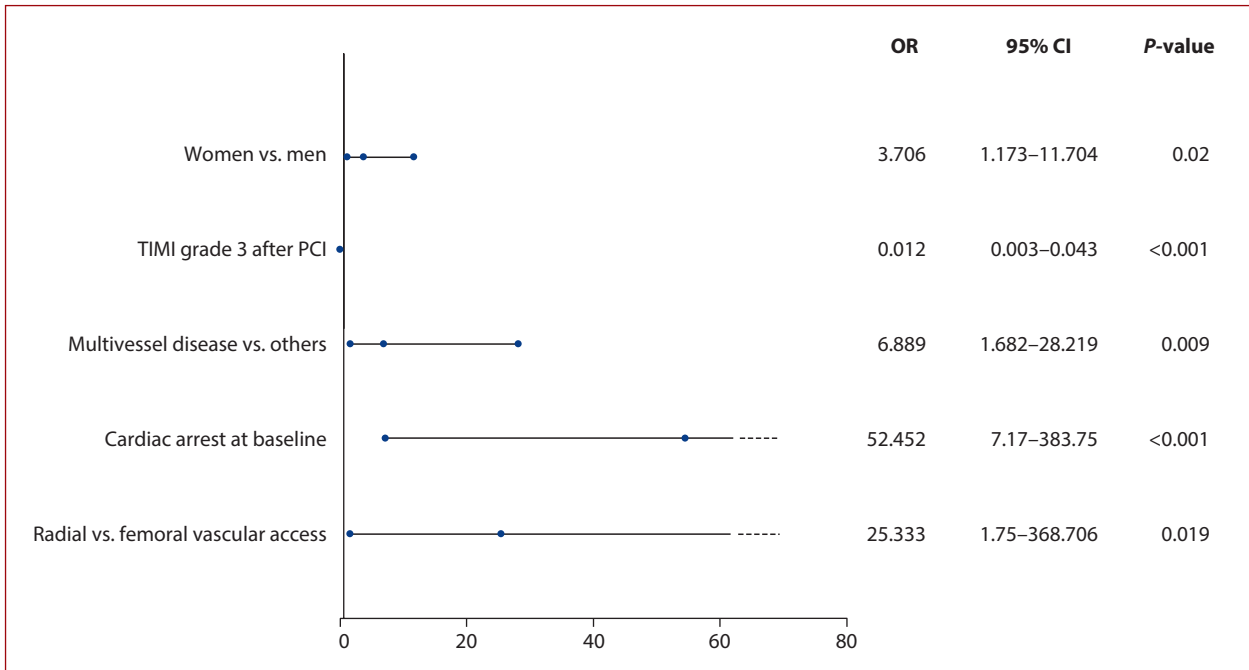
### Overall periprocedural complications

The increased overall rate of periprocedural complications assessed by multivariable analysis in the group of patients treated with PCI and RA was related to (1) greater contrast amount ( $P < 0.001$ ), (2) PCI within bifurcation ( $P = 0.009$ ), (3) radial vascular access ( $P = 0.02$ ), (4) treatment with low-molecular-weight heparin ( $P = 0.02$ ), (5) aspiration thrombectomy during PCI ( $P < 0.001$ ), (6) PCI within the proximal right coronary artery (RCA) ( $P < 0.001$ ), (7) cardiac arrest at baseline ( $P = 0.04$ ), (8) multi-vessel disease ( $P = 0.007$ ), (9) TIMI grade 3 assessed before PCI ( $P = 0.01$ ), and (10) female sex ( $P = 0.007$ ). The decreased rate of periprocedural complications was associated with TIMI grade flow 3 assessed after PCI ( $P < 0.001$ ). These findings are presented in Figure 4.

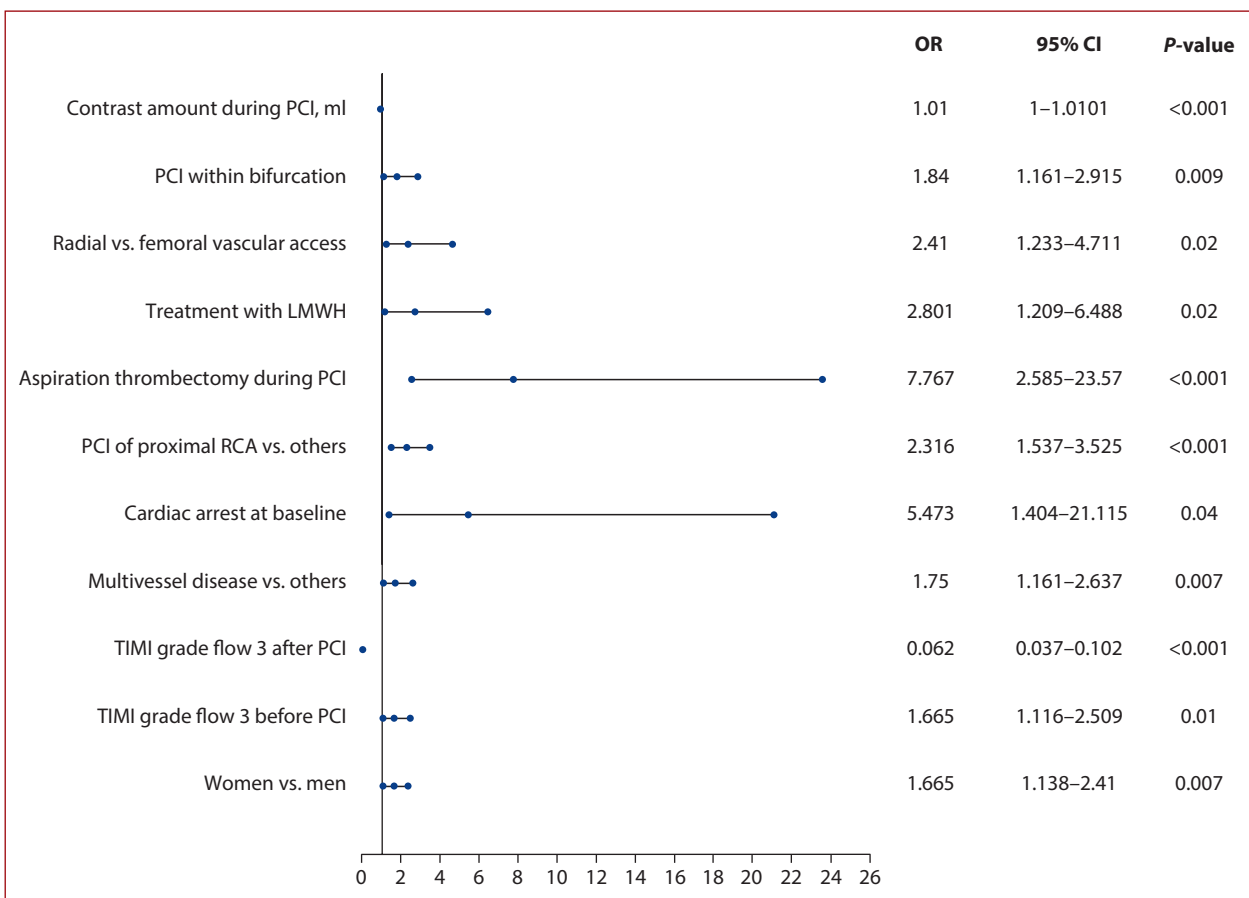
## DISCUSSION

The current analysis allowed us to confirm that the percentage of RA among all PCIs in Poland has been growing in recent years. Secondly, the majority of patients treated with RA are men. Thirdly, sex-related distribution did not change significantly among patients treated with PCI with or without RA during the analyzed period and did not differ significantly between those 2 groups. Fourthly, using multiple regression analysis, we confirmed that female sex is an independent predictor of greater periprocedural death rate and overall complication count among patients treated with PCI and RA.

An analysis of RA use from 2014 to 2020 in the entire group of patients undergoing PCI, based on a large national



**Figure 3.** The risk of periprocedural cardiovascular death among patients treated with PCI and RA assessed by multivariable analysis  
Abbreviations: CI, confidence interval; OR, odds ratio; other — see Figure 1



**Figure 4.** Risk factors of periprocedural complications in patients treated with PCI and RA assessed by multivariable analysis  
Abbreviations: LMWH, low-molecular-weight heparin; RCA, right coronary artery; TIMI, thrombolysis in myocardial infarction; other — see Figures 1 and 3

registry, confirms that the upward trend in RA percentage among all PCI procedures continues [14, 18].

Like in previously published articles, in the current analysis, we demonstrated that women treated with PCI and RA were older than men and presented acute coronary syndrome (ACS) more often [19]. While there were no significant differences in vascular access, in other publications, it was suggested that female patients were more often treated from femoral vascular access [19]. According to multivariable analysis, a greater burden of periprocedural cardiovascular death and complications was presented in female patients, which is in accordance with the data from previously published papers [19]. This might be, at least in part, a result of the more difficult treatment of coronary artery disease among women due to the higher percentage of diabetes and ACS, which are related, generally, to the higher risk of death. Diabetes itself might be an individual predictor of periprocedural complications during RA [20]. ACS was presented as an individual risk factor for major adverse cardiovascular events during RA procedures in similar studies [21, 22].

It is also worth mentioning that multi-vessel disease (MVD) is related to a higher risk of death and periprocedural complications. A multi-vessel disease often leads to worse heart function, more complex and difficult PCIs, which often demand the use of left ventricular function support devices and can lead to dissections, perforations, and higher contrast doses. Additionally, patients presenting MVD are more often burdened with comorbidities influencing PCIs, such as kidney failure, peripheral atherosclerosis, or diabetes. All these factors, as well as arterial hypertension and age, contribute to vessels being more tortuous and fragile and could result in a greater rate of coronary artery perforations and dissections. Another significant factor is cardiac arrest at baseline. As previously mentioned, ACS itself is a risk factor for many major adverse cardiovascular events. It is also related to a higher percentage of deaths during PCI procedures.

Another significant factor is vascular access. Transradial access was found to be associated with a lower risk of all-cause mortality, major bleeding, and vascular complications compared with transfemoral access in PCI patients with ST-segment elevation myocardial infarction [23]. However, an opposite correlation was suggested in the group of RA patients, where transradial access was found to be significantly related to greater coronary artery perforation rate, with no significance for periprocedural mortality, overall complication count, or other periprocedural complications [18]. Women weigh less than men, which was confirmed in the presented analysis, which is related to smaller vessels that are potentially more fragile. This can also translate into a greater rate of vascular complications. Also, vascular access in women is smaller in diameter. Other implications concerning vascular access in patients treated with RA were discussed more widely in the previous publication [18]. These include, *inter alia*, puncture of arteries under

ultrasound control, the use of guiding catheters with hydrophilic sheaths, so-called sheathless guiding catheters, and the so-called balloon-assisted tracking, which allows the passage of diagnostic and rescue catheters through often narrow and tortuous vessels, which further facilitates the maintenance of radial access and avoiding conversion to, for example, femoral access [24–26].

We demonstrated that a patent target artery after PCI expressed as TIMI grade 3 flow was a negative predictor for both periprocedural complications and death. Better flow presented in the TIMI scale suggests both successful treatment and a better prognosis. Patients qualified for RA with STEMI or chronic total occlusion are burdened with a higher risk of complications a priori, including coronary artery perforations. Those in chronic total occlusion have a higher risk of mortality and morbidity [27].

The range of procedures also plays a key role in increasing the risk of complications. PCI within bifurcation comes first. PCI within bifurcations, alongside PCI within the left main coronary artery or calcified coronary arteries, are considered high-risk PCIs. They are associated with a higher dose of contrast and a burden of comorbidities including, among others, chronic kidney disease, diabetes, arterial hypertension, and MVD, as well as lower left ventricular ejection fraction and smoking. It seems more difficult to explain the relationship between PCI within proximal RCA and the increased number of periprocedural complications. One of the possibilities might be that this segment of the artery is relatively close to the aortic bulb. In the case of the proximal vessel, this may cause continuity of dissection to the abovementioned structure [28]. Another possibility is that RA in RCA is the second most frequent procedure in our database. Also, complications related to the PCI within RCA involve cardiac arrest and heart block.

Furthermore, periprocedural use of low-molecular-weight heparin and aspiration thrombectomy also increase the chances of developing complications during RA procedures. It is strongly connected to comorbidities. Patients treated with low-molecular-weight heparin might suffer from other comorbidities, such as atrial fibrillation, or have a history of thromboembolic diseases, which increases the procedure risk and could be related to the frequency of periprocedural complications, especially the ones associated with bleeding. Aspirational thrombectomy, on the other hand, is used more often in ACS patients [29]. Their prognosis, in general, is worse, especially if they suffer from calcification in the coronary artery, which occurs in RA patients [30].

Another risk factor for increased periprocedural complication rate observed in the current analysis is the use of a larger amount of contrast. We would rather attribute this risk to the fact that a higher dose of contrast means a longer procedure and consequently, more complicated, usually high-risk PCI, which is, a priori, related to a more frequent occurrence of periprocedural complications.



### Strengths and limitations

First of all, we would like to underline that the greatest strength of the presented study is the large group of the examined patients because analyses carried out among such a large group of patients using RA are rare. However, the study has a few limitations, and those that should be addressed in the first place include the nature of the analysis. The study was retrospective, conducted on the data from a prospectively collected registry. Firstly, the event rates were low. This is reflected in the very large confidence intervals in the multivariable models. Many of the disadvantages of such a registry include, but are not limited to, estimating the frequency of periprocedural complications arising from the registry itself, which further includes complications only during the time of the procedure and the early post-procedural period when the patient is still in the catheterization laboratory. Another important issue is the fact that recognizing periprocedural complications was at the discretion of the operator and depended on his/her knowledge, habits, or inclinations, which, unfortunately, imposes bias. We were not able to include other well-recognized risk factors of periprocedural complications in patients treated with RA into the current analysis, which included lesion and target vessel indices (length, diameter, location, tortuosity, bifurcations, trifurcation, etc.), or the burr size or type of rotawire due to lack of data. We also did not have access to the data on previous attempts of PCIs, and the use of other typical devices such as scoring, cutting, or high-pressure balloons. These missing values could significantly affect the results and cause some bias. Another issue is connected to periprocedural complications and the risk of death. We were not able to identify certain reasons for higher complication frequency regarding proximal RCA. The lack of periprocedural data mentioned above leads only to speculations on this topic.

### CONCLUSIONS

The current analysis allows us to confirm that the percentage of RA among PCI all-comers in Poland has been growing in the recent decade. The majority of patients treated with RA are men. Distribution according to sex also did not change significantly among patients treated with PCI, with and without RA, during the analyzed period and did not differ significantly between those 2 groups. Female sex, among other factors, is a predictor of a greater periprocedural complication rate and mortality in patients treated with PCI and RA.

### Supplementary material

Supplementary material is available at [https://journals.viamedica.pl/kardiologia\\_polska](https://journals.viamedica.pl/kardiologia_polska).

### Article information

**Conflict of interest:** None declared.

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