Annual Operator Volume Among Patients Treated Using Percutaneous Coronary Interventions With Rotational Atherectomy and Procedural Outcomes - Analysis Based on a Large National Registry

Rafał Januszek, MD

University Hospital in Kraków, Poland

Introduction

- Low operator and institutional volume are associated with poorer procedural and long-term clinical outcomes in the general population of patients treated with percutaneous coronary interventions (PCI).

Aim

- The objective of this study is assessment of the relationship between operator volume and overall periprocedural complication count in patients with PCI and RA.
- We also aimed to calculate predictors of selected factors characterising procedural outcomes found as operator-volume dependent.

Materials and Methods

- Data for conducting the current analysis were obtained from the national registry of percutaneous coronary interventions (ORPKI), maintained in cooperation with the Association of Cardiovascular Interventions (AISN) of the Polish Cardiac Society.
- The register is free-of-charge and covers almost all catheter laboratories (CathLabs) performing PCIs in Poland.
- The study covers data obtained from the registry between January 2014 and December 2020.

Materials and Methods

- The overall complications were defined as the sum of particular complications diagnosed and reported after PCI by the operator and included: in-hospital death, myocardial infarction, no-reflow phenomenon, cardiac arrest, allergic reaction, coronary artery perforation and puncture-site bleeding.
- As the RA operator, we considered the one who performed at least one RA procedure as first operator during the analysed period of time.

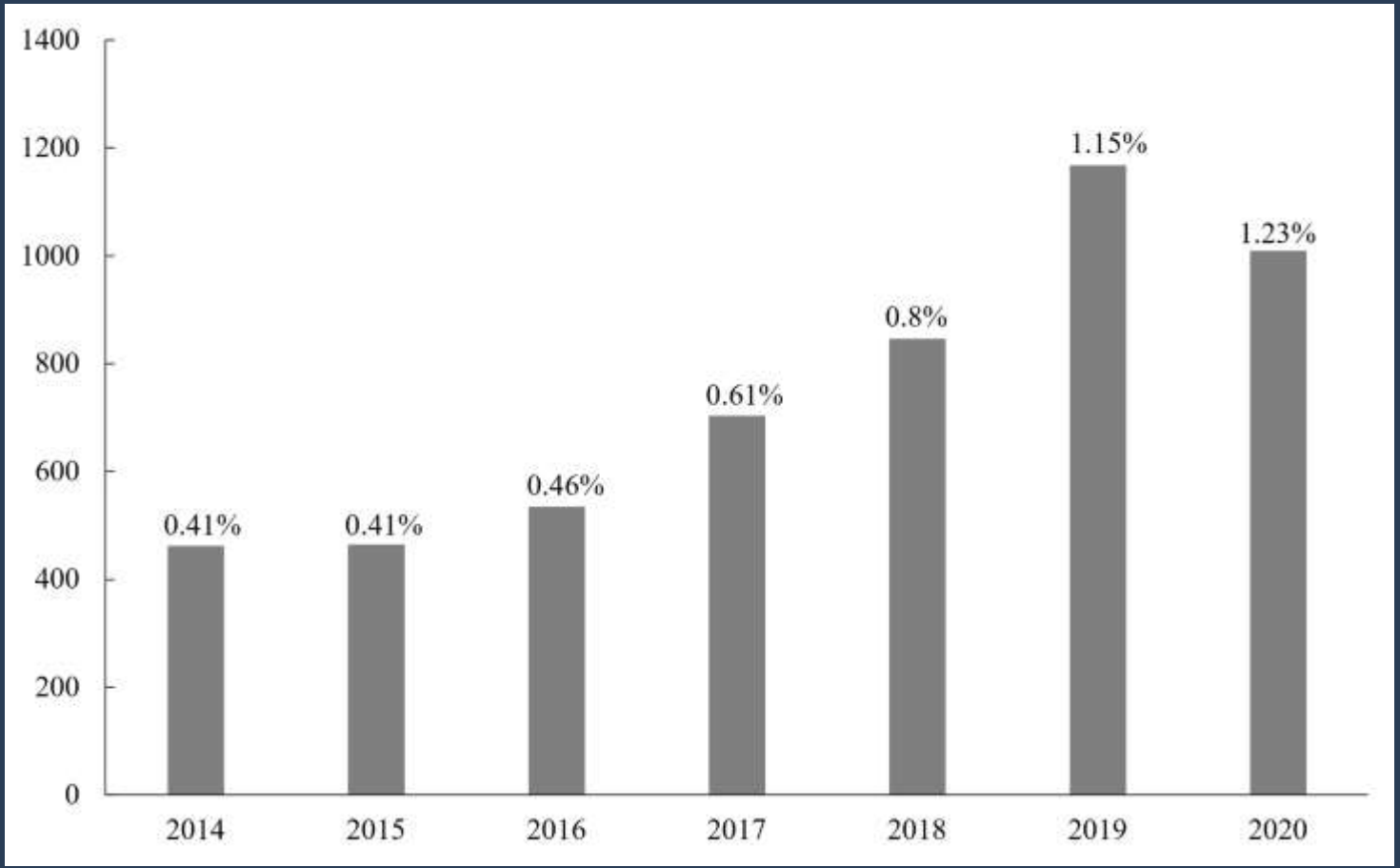
Materials and Methods

- The current analysis included all PCI procedures performed in Poland between January 2014 and December 2020, which were available in the Polish national ORPKI database registry, covering more than 95% of all CathLabs in Poland.
- During the investigated period, there were 162 active CathLabs, at which 747,033 PCI procedures were performed during the time of observation.
- The mean number of PCIs carried out at one CathLab was 4,318.1 ± 2,568.3 over 7 years, and the median and interquartile range was 4,224.5 [2,546 ÷ 5,717] PCIs/7 years.
- The minimal PCI count/CathLab/7 years was 1 and the maximum was 14,884. The overall number of operators during the observational period was 851, which gives 5.25 operators per one CathLab.
- All 5,188 PCIs with rotablation were performed by 377 RA operators (44.3% of all PCI first operators); average 30±61 per site/7 years (Me: 3; Q1-Q3: 0-31); 6±18 per operator/7 years (Me: 0; Q1-Q3: 0-3).

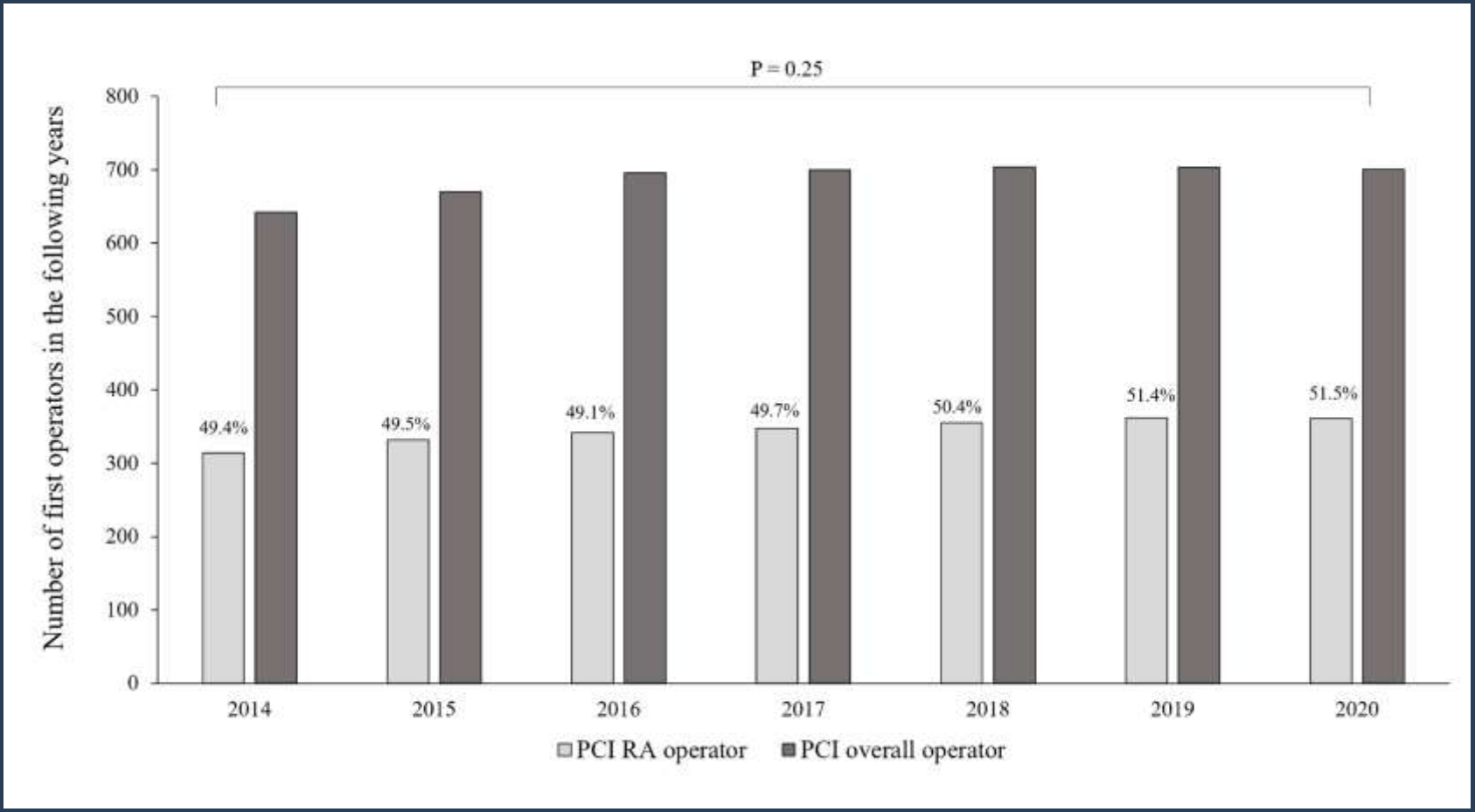
Materials and Methods

- Continuous variables are presented as median ÷ interquartile range, depending on normality of distribution, assessed using the Kolmogorov-Smirnov test. Categorical variables are presented as counts (percentages).
- Continuous variables were compared using the ANOVA or Kruskal-Wallis tests as necessary, with corresponding post hoc tests, whereas categorical variables via the χ^2 test or Fisher Exact test when appropriate.
- To investigate the association between operator (defined as the annual average number of PCIs with RA for which the consultant was responsible) and all periprocedural complications in the presence of confounding and clustering effects (PCI operator), we used multivariable, mixed effects logistic regression modelling.
- All patient demographics, medical history as well as procedure details were considered as potential predictors. Then, the final models were constructed using the stepwise approach with minimisation of Bayesian Information Criterion as the target.
- To analyse nonlinear relationships of annualised operator PCIs with RA volume and adjusted outcome rates, we used local polynomial regression. A *p* value lower than 0.05 was considered significant.
- Statistical analyses were performed using R version 3.5.3 as well as the 'lme4' - version 1.1-21 and 'tidyverse' - version 1.2.1 packages.

Materials and Methods



Materials and Methods



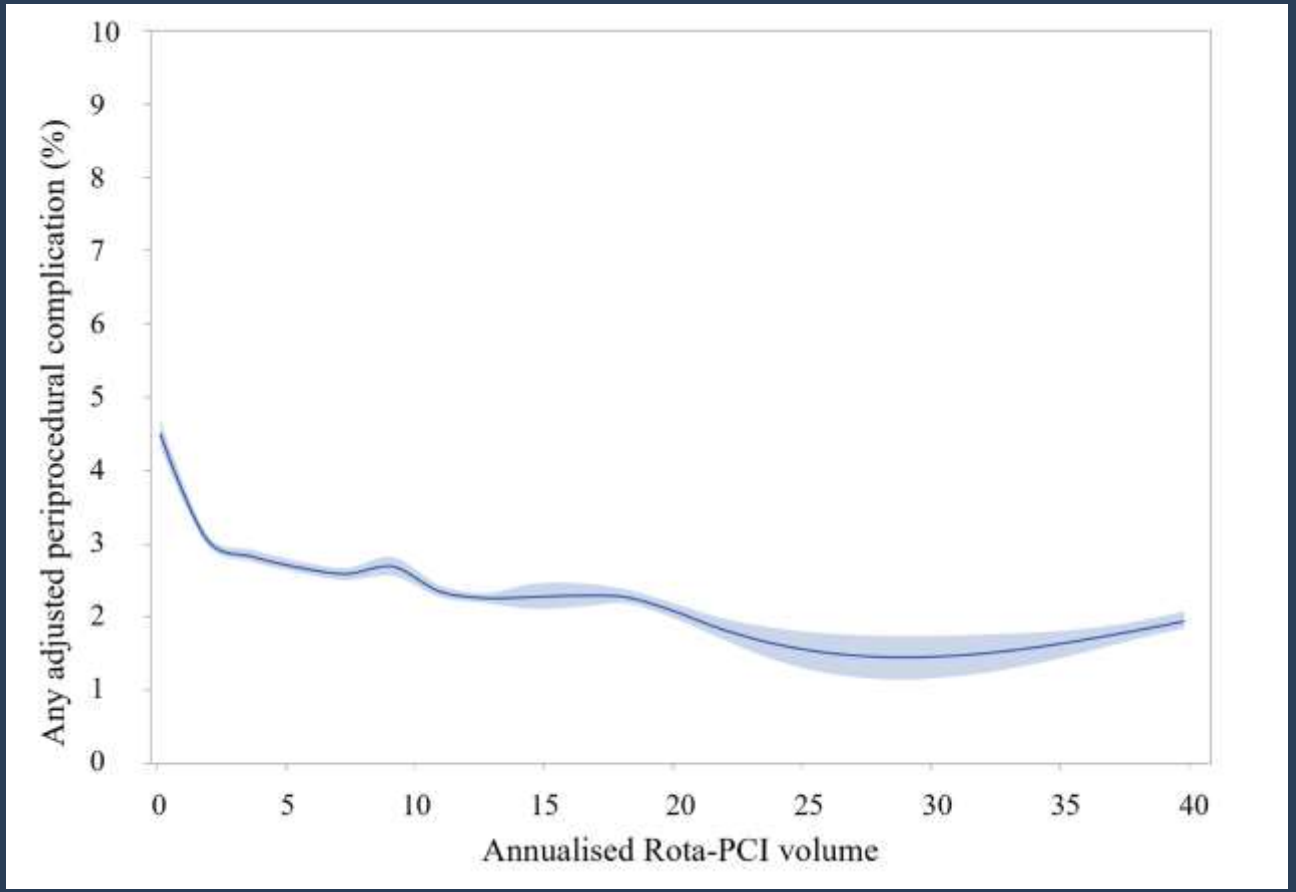
Results

Variable	Total N = 5,177	Q1: N = 1,364	Q2: N =1,233	Q3: N =1,363	Q4: ≥ N =1,217	P value
Age, years	72 (66 ÷ 79)	72 (66 ÷ 78)	72 (66 ÷ 79)	72 (65 ÷ 79)	72 (66 ÷ 79)	0.62
Gender, males	1,625 (31.4)	422 (31.1)	367 (29.8)	455 (33.4)	381 (31.3)	0.26
Diabetes	1,682 (32.4)	418 (30.6)	409 (33.1)	514 (37.6)	341 (28)	<0.001
Prior stroke	211 (4.1)	51 (3.7)	55 (4.45)	59 (4.3)	46 (3.8)	0.72
Prior MI	2,475 (47.7)	597 (43.7)	600 (48.50)	683 (50)	595 (48.8)	0.006
Prior PCI	2,857 (55.1)	711 (52)	665 (53.8)	744 (54.5)	737 (60.5)	<0.001
Prior CABG	680 (13.1)	174 (12.7)	159 (12.8)	204 (14.9)	143 (11.7)	0.09
Smoking	809 (15.6)	202 (14.8)	229 (18.5)	248 (18.2)	130 (10.7)	<0.001
Hypertension	3,868 (74.6)	1008 (73.7)	976 (78.9)	1058 (77.4)	826 (67.8)	<0.001
Kidney disease	631 (12.2)	143 (10.5)	207 (16.73)	171 (12.5)	110 (9)	<0.001
COPD	188 (3.6)	29 (2.1)	69 (5.6)	52 (3.8)	38 (3.1)	<0.001

Results

Variable	Total N = 5,177	Q1: N = 1,364	Q2: N = 1,233	Q3: N = 1,363	Q4: ≥ N = 1,217	P value
All complications	143 (2.76)	49 (3.58)	34 (2.75)	31 (2.27)	29 (2.38)	0.16
Death	17 (0.33)	9 (0.66)	1 (0.08)	2 (0.15)	5 (0.41)	0.04
Myocardial infarction	22 (0.42)	8 (0.59)	6 (0.49)	5 (0.37)	3 (0.25)	0.59
No-reflow phenomenon	36 (0.69)	9 (0.66)	10 (0.81)	12 (0.88)	5 (0.41)	0.49
Cardiac arrest	23 (0.44)	8 (0.59)	4 (0.32)	4 (0.29)	7 (0.57)	0.52
Allergic reaction	3 (0.06)	3 (0.22)	0 (0)	0 (0)	0 (0)	0.06
Coronary artery perforation	45 (0.87)	8 (0.59)	10 (0.81)	12 (0.88)	15 (1.23)	0.37
Puncture site bleeding	10 (0.19)	5 (0.37)	1 (0.08)	2 (0.15)	2 (0.16)	0.42

Results



Nonlinear relationship with annualised percutaneous coronary intervention with rotablation operator volume and risk-adjusted periprocedural complication rate per operator - local polynomial regression analysis (*p* for trend = 0.019)

Results

Predictors of increased rate of all periprocedural complications assessed by multivariable analysis

Selected indices	OR	95% CI	P value
All complications			
Log2 PCI rota per year (per unit)	0.89	0.81-0.98	0.02
Prior PCI (yes vs. no)	0.66	0.45-0.96	0.03

Conclusion

- High-volume rotablation operators are related to lower overall periprocedural complication occurrence in patients treated with RA in comparison to low-volume operators.
- There were no significance for such a relationship between periprocedural moratlity and procedural success assessed by coronary artery patency by TIMI flow grade scale and operator volume