

Association between the mortality rate and operator volume in patients undergoing emergency or elective percutaneous coronary interventions

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KEY WORDS

acute coronary syndromes, mortality, operator volume, percutaneous coronary interventions, predictors

ABSTRACT

BACKGROUND Previous studies have suggested that low operator and institutional volume may be associated with an increased risk of adverse events in patients undergoing percutaneous coronary intervention (PCI).

AIMS The aim of the study was to assess the relationship between operator volume and procedure-related mortality in the emergent and elective settings.

METHODS Data were obtained from a national registry of PCIs, maintained in cooperation with the Association of Cardiovascular Interventions of the Polish Cardiac Society. Registry data for the period from January 2014 to December 2017 were collected. During the study, there were 162 active catheterization laboratories, in which a total of 456 732 PCIs were performed.

RESULTS The median number of PCIs performed in a single laboratory was 2643.5 (interquartile range [IQR], 1875–3598.5) over 4 years. The median number of PCIs performed by a single operator was 557 (IQR, 276.25–860.5) per year. We did not confirm a significant relationship between the operator volume and mortality in the overall group of patients treated with emergency and elective PCI. However, we noted a lower mortality rate for high-volume operators (odds ratio [OR], 0.79; 95% CI, 0.63–0.99; $P = 0.04$). When the operator volume was assessed as a continuous variable, there was a trend toward significance (OR, 0.94; 95% CI; 0.88–1.0007; $P = 0.052$) in patients treated with emergency PCI.

CONCLUSIONS High operator volume was associated with a lower periprocedural mortality rate than low operator volume in patients undergoing PCI due to acute coronary syndromes.

INTRODUCTION Previous research has indicated that low operator and institutional volume may be connected to a higher risk of adverse events in the setting of percutaneous coronary intervention (PCI).^{1,2} The current guidelines of the American College of Cardiology, American Heart Association, and the Society for Cardiovascular

Angiography and Intervention suggest that a minimum of 50 coronary interventional procedures have to be performed annually (over the averaged period of 2 years) to maintain competence (level of evidence C).³ In the United Kingdom, the British Cardiovascular Interventional Society supports the opinion that an independent operator

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WHAT'S NEW?

Low operator and institutional volume may be associated with a higher risk of adverse events in the setting of percutaneous coronary intervention (PCI). In many countries, the ratio of PCI has changed from predominantly elective to an increased proportion of emergency procedures for acute coronary syndromes. In addition, interventional devices, technologies, and pharmacology have improved; therefore, existing literature regarding the association between PCI volume and outcome may no longer apply to current practice. Therefore, we aimed to assess the relationship between the operator volume and procedure-related mortality in recent years. We demonstrated that operator volume is not associated with periprocedural mortality in the overall group of patients undergoing elective and emergency PCI. Primary interventions for acute coronary syndromes by high-volume operators were related to a lower mortality rate.

should perform a total of 150 procedures over a 2-year period to sustain proficiency.⁴ Similar recommendations (class IIa; level of evidence C) are provided in the European Society of Cardiology guidelines concerning operators performing PCIs for acute coronary syndromes (ACSs).⁵ However, the available data on this relationship are contradictory. Some studies reported a higher operator volume to be associated with improved outcomes such as a reduction in the number of in-hospital deaths or other adverse events, but no such link was revealed by other investigators.⁶⁻¹⁵

The aim of this study was to assess the relationship between the operator volume and procedure-related mortality rate for elective and emergency PCI.

METHODS **Materials** Data for the current study were obtained from a national registry of PCIs (Ogólnopolski Rejestr Procedur Kardiologii Inwazyjnej [ORPKI]), maintained in cooperation with the Association of Cardiovascular Interventions of the Polish Cardiac Society. The registry is free of charge and covers almost all catheterization laboratories performing PCIs in Poland. Detailed characteristics of the registry were published previously.¹⁶ Registry data for the period from January 2014 to December 2017 were collected.

Statistical analysis Continuous variables were presented as mean (SD) and median (interquartile range [IQR]), depending on the normality of distribution assessed with the Kolmogorov-Smirnov test. Categorical variables were presented as numbers (percentages). Continuous variables were compared using the 2-tailed *t* test and the Mann-Whitney test, while categorical variables, using the χ^2 test or Fisher exact test when appropriate. To investigate the association between operator volume (defined as the total number of procedures the operator was responsible for in the previous 12 months) and periprocedural mortality in the presence of confounding and clustering effects (PCI operator), we used a multivariable mixed-effects logistic regression

model. The model was adjusted for patient demographic data, medical history, and procedural details (ie, age, sex, weight, diabetes, previous stroke, previous PCI, previous coronary artery bypass grafting, smoking, hypertension, kidney disease, year of procedure, total site volume, use of fractional flow reserve, use of intravascular ultrasound, use of optical coherence tomography, preprocedural Thrombolysis In Myocardial Infarction [TIMI], indication for a procedure, chronic total occlusion, bifurcation, access site, as well as radiation and contrast dose). To analyze nonlinear relationships with an annualized operator volume and risk-adjusted mortality rate per operator, we used local polynomial regression. Operator volume was assessed using quartiles and continuous variables with an intercept of 100 procedures. A *P* value of less than 0.05 was considered significant. Statistical analyses were performed using the R software version 3.5.3 and the 'lme4' version 1.1-21 and 'tidyverse' version 1.2.1 packages (RStudio, Boston, Massachusetts, United States).

RESULTS The current analysis included all PCI procedures performed in Poland between January 2014 and December 2017, which were available in the ORPKI database, covering more than 95% of all catheterization laboratories in Poland.

During the study, there were 162 active laboratories, in which a total of 456 732 PCI procedures were performed. The mean (SD) number of PCIs in a single laboratory was 2819.3 (1571.4) over 4 years, and the median number was 2643.5 (IQR, 1875-3598.5). The lowest number of PCIs per laboratory over 4 years was 23 and the highest was 10 663. The overall number of operators during the study was 744, which gives 4.59 operators per one laboratory. The mean (SD) number of PCIs performed by one operator was 613.88 (459.24) over 4 years, which translates to a mean (SD) of 153.4 (114.8) PCIs per one operator annually. After exclusion of 26 operators who performed fewer than 2 PCIs annually on average (8 PCIs/4 years), the mean (SD) number of PCIs performed by one operator was 636 (452.2) over 4 years and 159 (113.8) PCIs annually. Of the 744 operators, 542 (72.8%) performed more than 75 PCIs annually and 596 (80.1%) performed more than 50 PCIs annually.

Considering the number of PCI procedures performed by individual operators during the 4 years, the first quartile (Q1, 0-140 procedures/year) included 379 operators, the second (Q2, 141-212 procedures/year), 173 operators; the third (Q3, 213-305 procedures/year), 126 operators; and the fourth (Q4, \geq 306 procedures/year), 66 operators. Female operators performed 2.83% of all PCI procedures and had the largest share in Q1 and Q2, and the smallest, in Q3 and Q4 (4.08%, 5.23%, 0.83%, and 1.23% respectively, *P* < 0.001).

Baseline clinical characteristics Operators with a lower annual number of PCIs (Q1 and Q2), treated significantly younger patients in comparison with operators with a higher number of PCIs (Q3 and Q4). In general, potentially more difficult procedures, reflected by a higher number of patients after previous PCI, coronary artery bypass grafting, and prior myocardial infarction, were performed by high-volume operators (Q3 and Q4). Moreover, high-volume operators treated patients with stable and unstable angina significantly more often, while low-volume operators generally more frequently treated patients with acute myocardial infarction and ACS. Similarly, patients with comorbidities such as diabetes and kidney failure as well as a smoking habit were more often treated by low-volume operators (TABLE 1).

Procedure-related parameters Both a general and detailed assessment of vascular access revealed that high-volume operators used radial arteries significantly more often than low-volume ones. More advanced procedures such as PCI of chronic total occlusions, PCI

of bifurcated lesions, or rotational ablations, were significantly more often performed by high-volume operators. Other procedure-related parameters are presented in TABLE 2.

Procedure-related complications In the current study, the overall mortality rate was 0.46%, while the rate of no-reflow was 0.51%; cardiac arrest, 0.41%; coronary artery perforations, 0.17%; allergic reactions, 0.14%; and bleeding at puncture site, 0.09%. No-reflow phenomenon occurred significantly more often in patients treated by low-volume operators (Q1 and Q2). A similar negative correlation was observed between the operator volume and cardiac arrest ($P < 0.001$), allergic reactions ($P < 0.01$), and puncture-site bleeding ($P < 0.001$).

Predictors of mortality in the overall group of patients In the overall group of patients treated with PCI, the multivariable analysis demonstrated no significant correlations between the operator volume and procedure-related mortality, regardless of the method

TABLE 1 Relationships between the number of percutaneous coronary interventions according to quartile and selected parameters during the 4-year follow-up (2014–2017)

Parameter	Total (n = 456732)	Q1: 0–140 (n = 113587)	Q2: 141–212 (n = 113396)	Q3: 213–305 (n = 113295)	Q4: ≥306 (n = 116454)	P value
Age, y, mean (SD)	67.08 (10.7)	66.86 (10.8)	66.97 (10.8)	67.25 (10.8)	67.25 (10.6)	<0.001
Male sex	308425 (67.9)	75646 (67.9)	76851 (67.8)	76729 (67.7)	79199 (68)	0.45
Diabetes	110010 (24.1)	27233 (24)	27966 (24.7)	27068 (23.9)	27743 (23.8)	<0.001
Prior cerebral stroke	14940 (3.27)	3646 (3.21)	3592 (3.17)	3889 (3.43)	3813 (3.27)	0.002
Prior MI	141437 (31)	31694 (27.9)	35441 (31.2)	36244 (32)	38058 (32.7)	<0.001
Prior PCI	170440 (37.3)	38036 (33.5)	41072 (36.2)	42630 (37.6)	48702 (41.8)	<0.001
Prior CABG	28572 (6.26)	6864 (6.04)	6888 (6.07)	7511 (6.6)	7309 (6.3)	<0.001
Smoking	88913 (19.5)	24723 (21.8)	21607 (19.05)	21242 (18.75)	21341 (18.3)	<0.001
Psoriasis	1803 (0.39)	462 (0.41)	536 (0.47)	399 (0.35)	406 (0.35)	<0.001
Hypertension	325031 (71.16)	80950 (71.3)	80412 (71)	80833 (71.3)	82836 (71.1)	0.1
Kidney disease	24822 (5.4)	6454 (5.68)	6276 (5.5)	6233 (5.5)	5859 (5.03)	<0.001
Indication						
Stable angina	122111 (26.8)	27349 (24.2)	28408 (25.1)	31675 (28)	34679 (29.)	<0.001
Unstable angina	130303 (28.6)	30137 (26.7)	32681 (28.9)	30820 (27.2)	36665 (31.5)	
NSTEMI	87433 (19.2)	23839 (21.1)	22237 (19.6)	21864 (19.3)	19493 (16.8)	
STEMI	111782 (24.5)	30565 (27.1)	28907 (25.5)	27769 (24.5)	24541 (21.1)	
Others	3880 (0.85)	1030 (0.91)	980 (0.86)	984 (0.86)	886 (0.76)	

Data are presented as number (percentage) unless otherwise indicated.

Abbreviations: CABG, coronary artery bypass grafting; MI, myocardial infarction; NSTEMI, non-ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; Q1, interval from the minimum to the first quartile; Q2, interval from the first quartile to the second quartile; Q3, interval from the second quartile to the third quartile; Q4, interval from the third quartile to the maximum; STEMI, ST-segment elevation myocardial infarction

TABLE 2 Relationships between the number of percutaneous coronary interventions according to quartile and procedure-related parameters during the 4-year follow-up (2014–2017)

Parameter	Total (n = 456732)	Q1: 0–140 (n = 113587)	Q2: 141–212 (n = 113396)	Q3: 213–305 (n = 113295)	Q4: ≥306 (n = 116454)	P value
FFR	3997 (0.88)	968 (0.85)	1026 (0.9)	975 (0.86)	1028 (0.88)	0.53
IVUS	3688 (0.81)	1158 (1.02)	977 (0.86)	707 (0.62)	846 (0.73)	<0.001
OCT	688 (0.15)	157 (0.14)	204 (0.18)	165 (0.15)	162 (0.14)	0.03
Thrombectomy	15587 (3.4)	4125 (3.63)	3693 (3.26)	3752 (3.3)	4017 (3.45)	<0.001
Rotational ablation	2159 (0.47)	473 (0.42)	505 (0.45)	538 (0.47)	643 (0.55)	<0.01
TIMI before PCI	1.91 (1.2)	1.86 (1.21)	1.86 (1.21)	1.92 (1.2)	2 (1.16)	<0.001
TIMI after PCI	2.88 (0.52)	2.88 (0.52)	2.87 (0.54)	2.88 (0.52)	2.90 (0.48)	<0.001
Contrast volume	183.96 (80.5)	177.71 (79.03)	170.34 (74.6)	161.84 (74.1)	173.4 (77.5)	<0.001
Radiation dose	1087.3 (1006.5)	1101.8 (897.8)	1100.6 (1021.9)	1121.3 (1039.7)	1026.4 (1052.7)	<0.001
Female PCI operator	12935 (2.83)	4638 (4.08)	5928 (5.23)	939 (0.83)	1430 (1.23)	<0.001
Vascular access (detailed)						
Femoral	123524 (27.1)	38387 (33.9)	32243 (28.5)	25517 (22.6)	27377 (23.5)	<0.001
Radial right	254486 (55.8)	57128 (50.4)	60700 (53.6)	67331 (59.57)	69327 (59.6)	
Radial left	74255 (16.3)	16942 (14.9)	19510 (17.2)	19154 (16.9)	18649 (16)	
Other	3533 (0.78)	890 (0.79)	702 (0.62)	1020 (0.9)	921 (0.79)	
Chronic total occlusion	10635 (2.3)	1927 (1.7)	2740 (2.4)	2953 (2.6)	3015 (2.6)	<0.001
Bifurcation	21010 (4.6)	4370 (3.8)	4907 (4.3)	5003 (4.4)	6730 (5.8)	<0.001
Type of PCI						
BMS only	20218 (4.43)	6230 (5.48)	5563 (4.9)	4483 (3.96)	3942 (3.39)	<0.001
BVS and BMS	25 (0.01)	7 (0.01)	2 (0)	5 (0)	11 (0.01)	
BVS only	4397 (0.96)	846 (0.74)	974 (0.86)	1273 (1.12)	1304 (1.12)	
DES and BMS	2092 (0.46)	421 (0.37)	532 (0.47)	649 (0.57)	490 (0.42)	
DES and BVS	433 (0.09)	74 (0.07)	129 (0.11)	127 (0.11)	103 (0.09)	
DES, BVS, and BMS	3 (0)	0 (0)	2 (0)	0 (0)	1 (0)	
DES only	377392 (82.6)	90963 (80.1)	93779 (82.7)	94772 (83.6)	97878 (84)	
No stent	51425 (11.3)	14638 (12.9)	12287 (10.8)	11872 (10.5)	12628 (10.8)	
Unknown type	747 (0.16)	408 (0.36)	128 (0.11)	114 (0.1)	97 (0.08)	

Data are presented as number (percentage).

Abbreviations: BMS, bare metal stent; BVS, bioresorbable vascular scaffold; DES, drug-eluting stent; FFR, fractional flow reserve; IVUS, intravascular ultrasound; OCT, optical coherence tomography; TIMI, Thrombolysis In Myocardial Infarction; others, see TABLE 1

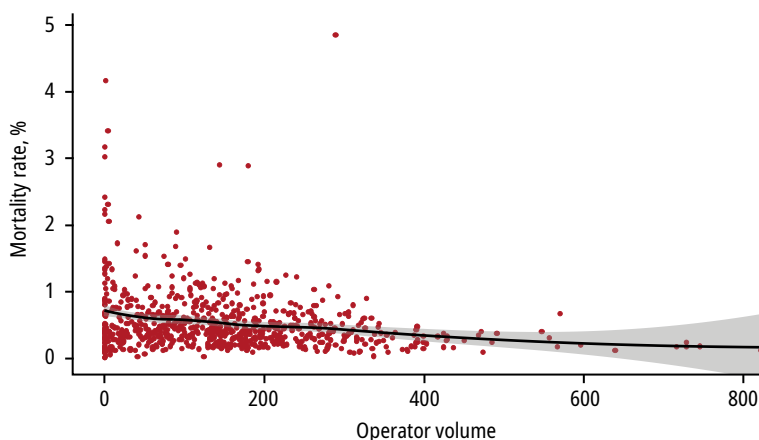


FIGURE 1 Nonlinear relationship with annualized operator volume and risk-adjusted mortality rate per operator: a local polynomial regression analysis

of operator-volume estimation (FIGURE 1). However, a significant relationship was demonstrated for a number of other factors, which coincided both in the case of the operator volume assessed using quartiles and continuous variables with an intercept of 100 procedures. Other factors related to the mortality rate are presented in TABLE 3.

Predictors of mortality in patients with stable angina

In patients with stable angina, the operator volume was not significantly related to mortality, regardless of the assessment method (quartiles, continuous variables). Factors associated with the mortality rate are presented in TABLE 4.

TABLE 3 Multivariable analysis of the relationship between the operator volume in the overall group of patients treated with percutaneous coronary interventions and procedure-related mortality rate

Parameter	Operator volume per quartile			Operator volume per 100 PCIs		
	OR	95% CI	P value	OR	95% CI	P value
Site volume	0.89	0.83–0.95	<0.001	0.89	0.84–0.95	<0.001
Operator volume						
Q2	0.91	0.76–1.08	0.3	–	–	–
Q3	1.04	0.86–1.25	0.66	–	–	–
Q4	0.81	0.65–1.01	0.9	–	–	–
Per 100 PCIs	–	–	–	0.95	0.9–1.006	0.08
Clinical and anthropometric characteristics						
Weight, kg	0.92	0.88–0.97	0.006	0.92	0.88–0.97	0.006
Age, y	1.44	1.37–1.51	<0.001	1.44	1.37–1.51	<0.001
Diabetes	1.49	1.34–1.66	<0.001	1.49	1.34–1.66	<0.001
Prior stroke	1.6	1.34–1.91	<0.001	1.61	1.34–1.92	<0.001
Prior myocardial infarction	1.71	1.5–1.96	<0.001	1.71	1.5–1.96	<0.001
Prior PCI	0.59	0.51–0.69	<0.001	0.59	0.51–0.69	<0.001
Prior CABG	0.5	0.38–0.64	<0.001	0.5	0.38–0.64	<0.001
Smoking	0.79	0.69–0.91	<0.001	0.79	0.69–0.91	<0.001
Psoriasis	1.76	1.02–3.05	0.04	1.76	1.02–3.03	0.04
Hypertension	0.57	0.51–0.63	<0.001	0.57	0.51–0.63	<0.001
Kidney failure	1.59	1.36–1.85	<0.001	1.58	1.36–1.85	<0.001
Year of PCI (2014–2017)						
2015	1.17	1.03–1.33	0.01	1.17	1.03–1.33	0.01
2016	1.36	1.19–1.55	<0.001	1.36	1.19–1.55	<0.001
2017	1.32	1.15–1.51	<0.001	1.33	1.16–1.52	<0.001
TIMI grade flow before PCI						
I	0.6	0.52–0.68	<0.001	0.6	0.52–0.68	<0.001
II	0.4	0.35–0.47	<0.001	0.4	0.35–0.47	<0.001
III	0.17	0.15–0.2	<0.001	0.17	0.15–0.2	<0.001
Indication						
Valvular heart disease before PCI	16.6	3.14–87.7	<0.001	16.6	3.51–78.6	<0.001
Cardiac arrest before PCI	11.19	2.05–60.96	0.005	11.19	2.29–54.6	0.002
Chronic total occlusion	0.55	0.4–0.76	<0.001	0.55	0.4–0.76	<0.001
Vascular access						
Radial right	0.18	0.16–0.2	<0.001	0.18	0.16–0.2	<0.001
Radial left	0.15	0.12–0.18	<0.001	0.15	0.12–0.19	<0.001
Radiation dose, Gy	1.2	1.15–1.26	<0.001	1.21	1.15–1.26	<0.001
Contrast amount, ml	0.88	0.83–0.93	<0.001	0.88	0.83–0.93	<0.001

Abbreviations: OR, odds ratio; others, see TABLES 1 and 2

Predictors of mortality in patients with acute coronary syndromes Contrary to the above findings, in patients with ACS, procedure volume was associated with mortality. High-volume

operators (Q4) were related to lower mortality in the multivariable analysis. Also, when assessing the procedure volume as a continuous variable, we noted borderline significance for

TABLE 4 Multivariable analysis of the relationship between selected parameters in patients with stable angina treated with percutaneous coronary interventions and procedure-related mortality rate

Parameter	Intercept – quartile			Intercept – 100 PCIs		
	OR	95% CI	P value	OR	95% CI	P value
Weight, kg	0.63	0.41–0.98	0.04	0.63	0.41–0.98	0.04
Left radial vascular access	0.06	0.004–0.94	0.04	0.06	0.004–0.92	0.04
Operator volume						
Q2	1.65	0.14–18.37	0.68	–	–	–
Q3	1.09	0.07–15.3	0.95	–	–	–
Q4	0.8	0.05–12.98	0.9	–	–	–
Per 100 PCIs	–	–	–	0.97	0.5–1.86	0.92
TIMI grade flow before PCI						
I	0.18	0.058–0.59	0.004	0.18	0.059–0.59	0.004
II	0.28	0.08–0.96	0.04	0.28	0.08–0.95	0.04
III	0.13	0.04–0.38	<0.001	0.13	0.04–0.38	<0.001

Abbreviations: see TABLES 1–3

the correlation between high-volume operators and lower mortality rate. The significance of other factors assessed by the multivariable analysis did not differ when the operator volume was assessed by quartiles or continuous variables. Other factors related to the mortality rate are presented in TABLE 5.

DISCUSSION The present study showed that there was no significant correlation between the operator volume and procedure-related mortality rate in the overall group of patients undergoing PCIs. Similar results were obtained for patients with stable angina. Of note, the mortality rate in the case of high-volume operators (Q4) was significantly lower among patients undergoing PCI for ACS. Nonetheless, when the operator volume was evaluated as a continuous variable, this correlation did not reach significance. Furthermore, we demonstrated that specific procedure-related complications were negatively correlated with the operator volume. We also established a negative association between the site (catheterization laboratory) volume and procedure-related mortality rate, independent of whether the PCI procedure was primary or elective.

The current literature on the relationship of the operator volume with post-PCI outcomes provides contradictory data. Some studies reported an increase in the rate of adverse events with regard to a lower operator volume following risk adjustment, while other studies did not reveal such a link.^{6–15} Hulme et al¹⁷ did not confirm a relationship between the 30-day in-hospital mortality rate and operator volume. This was

observed both when the operator volume was demonstrated continuously and when it was dichotomized at the level of 50 or 75 PCIs annually. This analysis comprised all PCIs performed over a specified period of time, including elective and emergent procedures.

In a large meta-analysis including 23 studies and a total of 1 109 103 patients, no strong evidence for the correlation between the operator volume and a reduction in short-term mortality was shown, although some evidence concerning a decrease in major adverse cardiac events for high-volume operators was revealed. For this volume, the mean follow-up time was 2.8 years.¹⁸

A study by Badheka et al⁸ included 457 498 procedures registered in the National Inpatient Sample (NIS) database between 2005 and 2009. These procedures were associated with a lower in-hospital mortality rate in higher-volume quartiles (>100 PCIs annually) in comparison with the lowest quartile (1–15 PCIs annually). The highest-volume quartile was connected with the greatest reduction. This research was based on procedures undertaken no later than in 2010. The significance of older investigators in providing information about current best practice is weakened and should be interpreted with caution. In particular, this period witnessed a rapid shift from the use of transfemoral to that of transradial vascular access.

The analysis of 323 322 procedures performed in 2014 and 2015, registered in a Japanese PCI registry, showed no significant differences in terms of the in-hospital mortality rate or a composite of periprocedural complications in connection with the operator volume.¹⁴ However, although the data covered a similar time and

TABLE 5 Multivariable analysis of the relationship between selected parameter in patients with acute coronary syndromes treated with percutaneous coronary interventions and procedure-related mortality rate

Parameter	Intercept – quartile			Intercept – 100 PCIs		
	OR	95% CI	P value	OR	95% CI	P value
Site volume	1.24	1.08–1.43	0.001	0.88	0.83–0.95	<0.001
Chronic total occlusion	0.47	0.33–0.66	0.001	0.47	0.33–0.66	0.001
Operator volume						
Q2	0.89	0.73–1.07	0.22	–	–	–
Q3	1.04	0.85–1.27	0.68	–	–	–
Q4	0.79	0.63–0.99	0.04	–	–	–
Per 100 PCIs	–	–	–	0.94	0.88–1.0007	0.05
Clinical and anthropometric characteristics						
Weight, kg	0.92	0.87–0.97	0.003	0.92	0.87–0.97	0.003
Age, y	1.48	1.41–1.56	<0.001	1.48	1.41–1.56	<0.001
Diabetes	1.47	1.31–1.64	<0.001	1.47	1.31–1.64	<0.001
Prior cerebral stroke	1.72	1.43–2.06	<0.001	1.72	1.43–2.06	<0.001
Prior myocardial infarction	1.63	1.42–1.86	<0.001	1.63	1.42–1.86	<0.001
Prior PCI	0.52	0.44–0.6	<0.001	0.52	0.44–0.6	<0.001
Prior CABG	0.38	0.28–0.5	<0.001	0.38	0.28–0.5	<0.001
Smoking	0.84	0.73–0.96	0.01	0.84	0.73–0.96	0.01
Psoriasis	1.89	1.09–3.26	0.02	1.88	1.09–3.25	0.02
Hypertension	0.54	0.48–0.6	<0.001	0.54	0.48–0.59	<0.001
Kidney failure	1.58	1.35–1.85	<0.001	1.58	1.35–1.85	<0.001
Year of PCI (2014–2017)						
2016	1.24	1.08–1.42	0.001	1.24	1.08–1.42	0.001
2017	1.24	1.08–1.43	0.001	1.25	1.09–1.43	0.001
TIMI grade flow before PCI						
I	0.48	0.42–0.55	<0.001	0.48	0.42–0.55	<0.001
II	0.29	0.25–0.34	<0.001	0.29	0.25–0.34	<0.001
III	0.11	0.1–0.14	<0.001	0.11	0.1–0.14	<0.001
Vascular access						
Radial right	0.16	0.14–0.18	<0.001	0.16	0.14–0.19	<0.001
Radial left	0.14	0.11–0.17	<0.001	0.14	0.11–0.17	<0.001
Radiation dose, Gy	1.21	1.15–1.27	<0.001	1.21	1.15–1.27	<0.001
Contrast amount, ml	0.89	0.84–0.94	<0.001	0.89	0.84–0.94	<0.001

Abbreviations: see TABLES 1–3

the studies showed similar rates of radial access (61.3% vs 67.5% in our study), cultural differences and the levels of operator volume make it difficult to translate the Japanese findings to the European context.

In the present study, the average annual number of procedures conducted by a single operator was 159. This is considerably higher than the number provided in the NIS database in the United States (between 33 and 58 PCIs

annually), the CathPCI Registry (59 PCIs annually; IQR, 21–106), and in the J-PCI registry in Japan (28 PCIs annually; IQR, 10–56).^{8,9,14} Moreover, in the CathPCI registry, 44% of operators performed fewer than 50 PCIs annually, while in our study, more than 72% of operators performed more than 75 PCIs annually, while 80% of operators or more conducted more than 50 PCIs annually. Two studies investigating this relationship revealed a post-adjustment

decrease in the in-hospital mortality rate in the case of operators performing over 10 or 11 primary procedures per year.^{6,11} In the study on CathPCI, the correlation between operator volume and in-hospital mortality rate was significant among patients with ST-segment elevation myocardial infarction (STEMI). Over the past 10 years, PCI volumes have declined, and numerous operators have noted a corresponding decrease in the number of conducted procedures.¹⁹

The study by Fanaroff et al⁹ reported significant differences also in patient-related characteristics for PCIs performed by low-, intermediate-, and high-volume operators. Cardiovascular comorbidities were less likely to occur in patients who underwent PCI by low-volume operators than in those subjected to PCI by intermediate- or high-volume operators. In contrast, PCIs performed by low-volume operators were more common among patients with STEMI than those performed by intermediate- or high-volume operators, and these were usually emergency PCIs. A similar relationship was noted in our study.

The main finding of the study by Fanaroff et al⁹ was that the majority of operators performed an average of 50 PCIs or fewer annually. Compared with high- and intermediate-volume operators (>100 and 50–100 PCIs/year, respectively), low-volume operators (<50 PCIs/year) performed a higher number of PCIs in emergency settings, but a lower number of anatomically complex PCIs, treating patients with fewer comorbidities and less often operating multiple lesions during a single visit to the catheterization laboratory. In comparison, in our research, low-volume operators had a tendency to perform PCIs more frequently in patients with acute myocardial infarction, which showed a correlation with the higher number of patients with a lower TIMI flow grade before and after the procedure. Fanaroff et al⁹ also demonstrated that in the case of low-volume operators, the hospital PCI volume was associated with in-hospital mortality rates. For low-volume hospitals, higher mortality rates were noted than for high-volume hospitals. Using the clinical and procedural data from the CathPCI registry, they also noted that low-volume operators tended to use radial access less frequently, because the use of greater amounts of contrast dye and fluoroscopy took more time. Notably, these operators also commonly practiced at lower-volume hospitals, treating patients with fewer comorbidities but with more acute presentations and managing less complex lesions than in the case of higher-volume operators. Similar correlations were noted in our study, which was conducted during a similar time.

Moscucci et al,²⁰ using data from PCIs performed in Michigan (2002), proposed a classification of operators into quintiles based on an

annual volume. They noted a higher rate of major adverse cardiac events (but not deaths) among patients treated by operators from the 2 lower quintiles. We noted a similar relationship regarding procedure-related cardiac arrest, allergic reactions, bleeding at puncture site, and no-reflow phenomenon.

Badheka et al⁸ showed higher risk-adjusted mortality in patients undergoing PCIs performed by low- (<16 PCIs/year) in comparison with high-volume operators (>100 PCIs/year). Nonetheless, the overall in-hospital mortality rate was not high, reaching only 1.08%, while in our research, the procedure-related mortality rate was 0.46%. Nevertheless, this number did not include all in-hospital deaths. Fanaroff et al⁹ also showed a linear increase in in-hospital mortality following PCI along with a decrease in the operator volume. This curve does not have a marked inflection point suggesting a minimal annual PCI number. Following adjustment for procedure-related indices (ie, radial access, antithrombotic agent), differences in mortality rates between high-, intermediate-, and low-volume operators decreased, indicating that high-volume operators apply specific strategies that, in some cases, may improve outcomes. This is in line with our findings. Additionally, it is possible that some low-volume operators practice at high-volume centers.⁷ Fanaroff et al⁹ also stated that operator volume may sometimes play a greater role among lower-risk patients, whereas patient factors may have excessive impact on the consequences of the operator volume for the outcomes of patients with STEMI. Low-volume operators perform an inconsistent number of PCIs in the emergency setting as well as primary PCIs for STEMI, which suggests that they may take on a significant role in maintaining PCI access.

Limitations Although previous studies have shown discrepancies in cardiovascular outcomes according to race and socioeconomic variables, these variables were not included in our model or other adjustment models used for public reporting. Another important limitation is the lack of follow-up, including all in-hospital complications, as well as short- and long-term follow-up after discharge. An additional factor that may affect the study results is the lack of correction for confounders associated with increased cardiovascular risk burden in patients with ACS undergoing PCI, which can undoubtedly affect the bias associated with an apparent increase in mortality in this group of patients.

Conclusions The operator volume is not associated with periprocedural mortality in the overall group of patients treated with PCI and in patients treated with elective PCI. Nonetheless, high operator volume is associated with a lower procedure-related mortality rate among patients

undergoing primary PCI for ACS, as compared with low operator volume. High-volume catheterization laboratories are associated with lower procedure-related mortality in the overall group of patients treated with PCI. In these group of patients, high operator volume is also related to a lower rate of procedure-related complications.

ARTICLE INFORMATION

CONFLICT OF INTEREST None declared.

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