Operator Volumes and In-Hospital Outcomes



An Analysis of 7,740 Rotational Atherectomy Procedures From the BCIS National Database

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ABSTRACT

OBJECTIVES The aims of this study were to use a national percutaneous coronary intervention (PCI) registry to study temporal changes in procedure volumes of PCI using rotational atherectomy (ROTA-PCI), the patient and procedural factors associated with differing quartiles of operator ROTA-PCI volume, and the relationship between operator ROTA-PCI volumes and in-hospital patient outcomes.

BACKGROUND Whether higher operator volume is associated with improved outcomes after ROTA-PCI is poorly defined.

METHODS Data from the British Cardiovascular Intervention Society national PCI database were analyzed for all ROTA-PCI procedures performed in the United Kingdom between 2013 and 2016. Individual logistic regressions were performed to quantify the independent association between annual operator ROTA-PCI volume and in-hospital outcomes.

RESULTS In total, 7,740 ROTA-PCI procedures were performed, with a negatively skewed distribution and an annualized operator volume median of 2.5 procedures/year (range 0.25 to 55.25). Higher volume operators undertook more complex procedures in patients with greater comorbid burdens than lower volume operators. A significant inverse association was observed between operator ROTA-PCI volume and in-hospital mortality (odds ratio [OR]: 0.986/case; 95% confidence interval [CI]: 0.975 to 0.996; p = 0.007) and major adverse cardiac and cerebral events (OR: 0.983/case; 95% CI: 0.975 to 0.993; p < 0.001). Additionally, lower rates of emergency cardiac surgery (OR: 0.964/case; 95% CI: 0.939 to 0.991; p = 0.008), arterial complications (OR: 0.975/case; 95% CI: 0.975 to 0.982; p < 0.001) and in-hospital major bleeding (OR: 0.985/case; 95% CI: 0.977 to 0.993; p < 0.001) were associated with higher ROTA-PCI operator volume. Sensitivity analyses in several subgroups demonstrated a consistency of improved outcomes as annual ROTA-PCI volume increased. An annual volume of <4 ROTA-PCI procedures/year was observed to be associated with increased major adverse cardiac and cerebral events, with 239 of 432 operators (55%) not exceeding this threshold.

CONCLUSIONS In-hospital adverse outcomes occurred less frequently as ROTA-PCI operator volume increased. These data suggest that operator volume is an important factor determining outcome after ROTA-PCI. (J Am Coll Cardiol Intv 2021;14:1423-30) © 2021 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

BCIS = British Cardiovascular Intervention Society

CI = confidence interval

IQR = interquartile range

- MACCE = major adverse cardiac and cerebral event(s)
- MI = myocardial infarction

OR = odds ratio

PCI = percutaneous coronary intervention

ROTA-PCI = rotational atherectomy during percutaneous coronary intervention

uLMS = unprotected left main stem

lthough higher operator percutaneous coronary intervention (PCI) volumes might lead to improved patient outcomes, research on this relationship has not provided consistent results (1-4). Two of the largest unselected series (i.e., in which all PCI procedures were included) failed to demonstrate an association between higher operator volume and improved patient outcomes, although an analysis of the National Cardiovascular Data Registry suggested that such a relationship might exist (5-7). However, more recent data suggest that the relationship between operator volume and patient outcomes in more complex PCI subsets may be more consistent (8,9).

Rotational atherectomy during PCI (ROTA-PCI) is a technically challenging procedure, with several factors essential to achieving procedural success and optimal patient outcomes (10–12). Operator volume and experience may therefore be important in improving outcomes after ROTA-PCI. However, there are few data on operator volume for ROTA-PCI and patient outcomes, with only small series published to date (13). Therefore, the aims of the present study were to use a national PCI registry to study temporal changes in ROTA-PCI procedure volumes, the patient and procedural factors associated with differing quartiles of operator ROTA-PCI volume, and the relationship between operator ROTA-PCI volumes and in-hospital patient outcomes.

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METHODS

STUDY SETTING AND SOURCES OF DATA. Data were derived from the British Cardiovascular Intervention Society (BCIS) National PCI Audit dataset, which records clinical, procedural, and outcome variables for every PCI performed in the United Kingdom. Entry of all PCI procedures by U.K. interventional operators is mandated as part of national audit and revalidation. The accuracy and quality of the BCIS dataset have previously been ascertained and reported (14,15). The study was approved by the National Institute for Cardiovascular Outcomes Research ethics committee, and data release was approved by the national Healthcare Quality Improvement Partnership.

STUDY DESIGN AND PARTICIPANTS. The study patient flow is illustrated in **Supplemental Figure 1**. From 2012 onward, the unique General Medical Council number for the consultant responsible for the PCI was added to each PCI procedure, allowing an

analysis of operator volume. Anonymized operatorlinked volumes and outcomes for the study years of 2013 to 2016 were available and used as the final study population.

STUDY DEFINITIONS AND ENDPOINTS. Study definitions were used as in the BCIS National PCI Audit (available at https://www.bcis.org.uk/resources/ bcis-ccad-database-resources/datasets-history/). The clinical outcomes of interest were in-hospital mortality, in-hospital major adverse cardiac and cerebral events (MACCE) (defined as death, in-hospital cerebrovascular accident, or myocardial infarction [MI]), in-hospital bleeding (defined as gastrointestinal bleeding, intracerebral bleeding, retroperitoneal hematoma, blood or platelet transfusion, access-site hemorrhage, or an arterial access-site complication requiring surgery), emergency coronary artery surgery (coronary artery bypass grafting) or repeat PCI, and acute coronary procedural complications (no flow, perforation, dissection, and major side-branch loss).

DATA ANALYSES. All database years (2007 to 2016) are presented to study temporal changes in ROTA-PCI versus non-ROTA-PCI volumes of procedures and percentage of total PCI procedures represented by ROTA-PCI. Individual ROTA-PCI operator volume was then calculated for each of the 4 years of the study period (between 2013 and 2016 when operator General Medical Council number was linked to each procedure) and averaged to create an annualized average operator ROTA-PCI volume. We then divided all ROTA-PCI procedures into 4 almost equally sized procedural number quartiles categorized by annualized average operator ROTA-PCI volume (quartiles 1 to 4). Cochran-Armitage 2-sided alternative hypotheses were used for trend analyses of categorical variables and analysis of variance for trend analyses of continuous variables.

For clinical outcomes, we performed individual logistic regressions on the imputed dataset for each of the MACCE to quantify the independent association between annualized operator volume and patient outcomes. We used all available baseline and procedural characteristics in adjustment, including all procedural and baseline variables in the analysis including age, sex, comorbidity, clinical syndrome, shock, Canadian Cardiovascular Society class, New York Heart Association functional class, body mass index, previous PCI, previous coronary artery bypass graft surgery, ejection fraction, last remaining vessel PCI, number of vessels attempted, baseline disease, target vessel, chronic total occlusion PCI, restenosis PCI, access site, and imaging use. To correct for missing values, we imputed missing data on baseline



covariates using multiple imputations with chained equations to adjust for missing data (Supplemental Table 1). Weights were then included in the logistic regression using proc surveylogistic in SAS (SAS Institute, Cary, North Carolina). All statistical analyses were done using SAS version 9.4 and R version 3.4.1 (R Foundation for Statistical Computing, Vienna, Austria). We also generated smoothed curves that showed clinical events (mortality, in-hospital MACCE, in-hospital bleeding, and MI) against volume to explore possible nonlinear relationships. Restricted cubic splines with 5 knots located midway between quintiles were used. We used the same approach to study the possible nonlinear relationship between different subgroups. Interaction p values were obtained from a likelihood ratio test between a model with and without interaction. A mediation analysis was also performed to explore the relationship among bleeding, access site, and glycoprotein IIb/IIIa inhibitor use.

RESULTS

ROTA-PCI VOLUMES BETWEEN 2006 AND 2016. Between 2006 and 2016, 14,612 ROTA-PCI procedures were undertaken in the United Kingdom, with the crude number of annual ROTA-PCI procedures increasing significantly, as did ROTA-PCI activity as a percentage of annual total PCI volume (increasing from 0.7% in 2006 to 2.4% in 2016; p < 0.001 for trend) (Supplemental Figure 2). Between 2013 and 2016, a total of 7,740 ROTA-PCI cases were performed, with a negatively skewed distribution and an annualized median of 2.5 procedures/year (Figure 1). Annualized ROTA-PCI operator volume ranged from 0.25 to 55.25 ROTA-PCI procedures/year. Within quartile 1, 303 operators performed a median of 1 ROTA-PCI procedures/ year (interquartile range [IQR]: 0.5 to 2.8); in quartile 2, 69 operators performed a median of 6.75 ROTA-PCI procedures/year (IQR: 4 to 6); in quartile 3, 59 operators performed a mean of 11.5 ROTA-PCI procedures/ year (IQR: 10.1 to 15.2 ROTA-PCI procedures/year); and in quartile 4, 17 operators performed a mean of 16 ROTA-PCI procedures/year (IQR: 23.3 to 33.0 ROTA-PCI procedures/year).

BASELINE DEMOGRAPHICS AND PROCEDURAL CHARACTERISTICS BY OPERATOR ROTA-PCI VOLUMES, 2013 TO 2016. The baseline patient demographics categorized by operator ROTA-PCI volume quartiles are presented in **Table 1.** Higher volume operators undertook procedures in older patients (p < 0.001 for trend) with greater comorbid burdens, including chronic renal disease (p < 0.001), previous MI

TABLE 1 Baseline Patient Characteristics by Quartile of ROTA-PCI Operator Volume, 2013 to 2016 Volume, 2013 to 2016

	Q1 (n = 2,024)	Q2 (n = 1,876)	Q3 (n = 1,999)	Q4 (n = 1,934)	p Value
Age (yrs)	73.7 ± 9.4	$\textbf{73.9} \pm \textbf{9.5}$	74.6 ± 9.3	$\textbf{75.0} \pm \textbf{9.4}$	<0.001
Female	529 (26.2)	492 (26.3)	562 (28.1)	497 (25.7)	< 0.001
Hypertension	1,482 (73.8)	1,395 (75.6)	1,487 (77.3)	1,387 (74.9)	0.651
Diabetes mellitus	677 (34.0)	624 (34.0)	647 (33.7)	578 (30.3)	0.096
Previous MI	743 (37.5)	778 (42.9)	862 (43.9)	800 (43.5)	0.034
Previous CVA/PVD	303 (15.1)	347 (18.7)	329 (17.1)	349 (18.8)	< 0.001
Renal disease	105 (5.3)	119 (6.5)	149 (7.7)	137 (7.3)	< 0.001
Valvular heart disease	88 (4.4)	89 (4.8)	94 (4.9)	91 (4.9)	0.456
Previous CABG	312 (15.6)	308 (16.7)	301 (15.2)	301 (15.7)	0.752
Previous PCI	681 (34.2)	637 (34.8)	683 (34.6)	718 (37.7)	0.148
ACS presentation	854 (42.2)	784 (41.8)	873 (43.7)	741 (38.3)	0.213
Shock pre-procedure	29 (1.9)	36 (2.3)	28 (1.6)	14 (0.9)	0.012
Ejection fraction <30%	98 (7.9)	119 (9.1)	144 (10.9)	114 (9.4)	0.015
NYHA functional class ≥III	366 (29.2)	355 (27.8)	430 (29.9)	405 (28.8)	0.893
Left main stem disease pre-PCI	302 (18.6)	308 (19.4)	381 (22.9)	466 (28.6)	<0.001
Number of diseased vessels	$\textbf{1.63} \pm \textbf{0.87}$	$\textbf{1.73} \pm \textbf{0.89}$	$\textbf{1.74} \pm \textbf{0.92}$	1.75 ± 0.95	<0.001

Values are mean \pm SD or n (%).

ACS = acute coronary syndrome; CABG = coronary artery bypass graft; CVA = cerebrovascular accident; MI = myocardial infarction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention;PVD = peripheral vascular disease; Q = quartile; ROTA-PCI = percutaneous coronary intervention with rotationalatherectomy.

> (p = 0.034), peripheral vascular disease or previous cerebrovascular accident (p < 0.001), and ejection fraction <30% (p = 0.015). Higher quartiles of ROTA-PCI volume were associated with greater baseline disease burden, and a greater likelihood of left main stem disease (p < 0.001).

> Procedural characteristics categorized by ROTA-PCI operator quartile are presented in Table 2. Higher volume ROTA-PCI operators undertook increasingly complex procedures, with more vessels and lesions treated (p < 0.001 for both trends). The target vessel was more likely to be the left main stem (p < 0.001) as operator ROTA-PCI volumes increased, with the procedure more likely to be associated with the use of microcatheters (p = 0.032), laser atherectomy (p < 0.001), atherectomy balloons (p < 0.001), pressure wires (p = 0.16), and intravascular imaging (p < 0.001). Higher volume operators were less likely to use glycoprotein inhibitors (p < 0.001) but used more stents of longer lengths (p < 0.001 for both trends). Higher volume operators were less likely to use femoral access (47.1% for quartile 1 vs. 36.1% for quartile 4; p < 0.001 for trend).

> **PROCEDURAL AND CLINICAL OUTCOMES BY OPERATOR ROTA-PCI VOLUMES, 2013 TO 2016.** The crude unadjusted procedural and clinical outcomes are presented

in Table 3. The adjusted clinical outcomes are presented in Table 4 and illustrate a significant inverse association between operator ROTA-PCI volume and in-hospital mortality (odds ratio [OR]: 0.986/case; 95% confidence interval [CI]: 0.975 to 0.996; p = 0.007), MACCE (OR: 0.983/case; 95% CI: 0.975 to 0.993; p < 0.001), emergency cardiac surgery (OR: 0.964/case; 95% CI: 0.939 to 0.991; p = 0.008), arterial complications (OR: 0.975/case; 95% CI: 0.975 to 0.982; p < 0.001), and in-hospital major bleeding (OR: 0.985/ case; 95% CI: 0.977 to 0.993; p < 0.001). The Central Illustration plots smoothed curves of the relationship between adjusted in-hospital MACCE, major bleeding, and annualized operator ROTA-PCI volume. Supplemental Figure 3 plots a smoothed curve of the relationship between adjusted in-hospital mortality and annualized operator ROTA-PCI volume. An annual volume of <4 ROTA-PCI procedures/year compared with higher volumes was observed to be associated with increased MACCE (p < 0.05), with 239 of 432 operators (55%) not exceeding this threshold. Sensitivity analyses showed a significant interaction by female sex (p for interaction = 0.044) and acute coronary syndrome presentation (p = 0.033), whereas left main stem ROTA-PCI versus non-left main stem ROTA-PCI (p = 0.476), and age (>80 years vs. <80 years; p = 0.267), did not demonstrate differential outcomes (Supplemental Figure 4). No interaction was observed between increased operator ROTA-PCI volume and reduced major bleeding in all subgroups analyzed (Supplemental Figure 5). In a mediation analysis of major bleeding, glycoprotein IIb/IIIa inhibitor use became nonsignificant, with the effect of access site remaining highly significant and of the same magnitude (OR: ~3.0).

DISCUSSION

Data associating operator PCI volume and patient outcomes differ between all-comers and selected PCI subsets. In all-comers studies, the data are not consistent. An analysis of 133,970 PCI procedures using data derived from the BCIS database revealed no association between operator volume and 30-day mortality (5). Similarly, an analysis of 323,322 procedures from the Japanese PCI Registry showed no differences in in-hospital mortality across varying operator volumes (6). In contrast, an analysis of the National Cardiovascular Data Registry did demonstrate an association between operator volume and mortality, although operator volumes were generally lower than seen in other studies (7). Possible explanations for the lack of a consistent association between higher operator PCI volume and improved

patient outcomes may include low event rates in all-comers PCI and that many PCI procedures are not a particular technical challenge, and for these cases, operator experience is less important. Thus, the potential benefits of operator expertise in treating the minority of more complex lesions would be diluted in these observational studies.

However, in complex PCI subsets, data are increasingly supportive of the "practice-makes-perfect" hypothesis. Previous studies correlating operator experience and outcomes after unprotected left main stem (uLMS) PCI have shown improved outcomes with greater operator volumes. In an analysis of the BCIS dataset, in-hospital survival (OR: 0.30; 95% CI: 0.14 to 0.56; p < 0.001), in-hospital MACCE (OR: 0.40; 95% CI: 0.24 to 0.66; p < 0.001), and 12month survival (OR: 0.53; 95% CI: 0.36 to 0.79; p < 0.001) were significantly lower in the highest quartile of operator uLMS PCI procedural volume compared with the lowest quartile (8). Data from a single high-volume Chinese PCI center also supported these findings, with patients treated by higher uLMS PCI volume operators having a lower rate of cardiac death at 30 days (adjusted hazard ratio: 0.22; 95% CI: 0.09 to 0.59; p = 0.003) and at 3 years (adjusted hazard ratio: 0.49; 95% CI: 0.29 to 0.84; p = 0.009) compared with lower volume operators (16). Most recently, an analysis of the Blue Cross Blue Shield of Michigan Cardiovascular Consortium registry evaluated the association of operator and hospital experience with procedural success. Among 210,172 patients enrolled in the registry, chronic total occlusion PCI success increased as operator volume increased and was highest for high-volume operators at highvolume centers and lowest for low-volume operators at low-volume centers (9).

As noted in other health care systems, the frequency of ROTA-PCI use in the United Kingdom increased over time, driven presumably a combination of an ageing population (and thus increasingly calcified coronary arteries) and an expansion of PCI indications into more complex anatomic settings (17,18). ROTA-PCI can be technically challenging with even the initial step of distal placement of the rota guidewire in some cases being difficult. Given its unwieldy nature, most operators in contemporary practice use a more standard guidewire first, with subsequent wire exchange using a variety of techniques, including over-the-wire balloons, microcatheters, and trapping balloons. In the calcific milieu in which ROTA-PCI is used, distal guidewire placement requires a certain level of operator skill and a knowledge of the problem-solving algorithms required. Once set up for atherectomy, acute

TABLE 2 Procedural Variables by Quartile of ROTA-PCI Operator Volume, 2013 to 2016					
	Q1 (n = 2,024)	Q2 (n = 1,876)	Q3 (n = 1,999)	Q4 (n = 1,934)	p Value
Operator ROTA-PCI volume, procedures/yr	1 (0.5-2.8)	6.75 (5.8-7.8)	11.5 (10.1-15.2)	25 (23.3-33)	-
Number of operators	304	69	39	16	-
Number of vessels attempted	$\textbf{1.29} \pm \textbf{0.58}$	1.35 ± 0.61	1.41 ± 0.66	$\textbf{1.53} \pm \textbf{0.79}$	<0.001
Number of lesions attempted	$\textbf{1.56} \pm \textbf{0.79}$	$\textbf{1.63} \pm \textbf{0.80}$	1.70 ± 0.86	$\textbf{1.69} \pm \textbf{0.91}$	<0.001
CTO attempted	140 (7.4)	157 (8.6)	153 (7.9)	222 (11.7)	<0.001
Last remaining vessel	65 (3.9)	61 (3.8)	82 (4.9)	67 (4.1)	0.509
Femoral access	943 (47.1)	786 (42.4)	991 (50.1)	693 (36.1)	<0.001
Circulatory support	39 (2.0)	42 (2.3)	40 (2.1)	29 (1.7)	0.512
Pressure wire	74 (3.8)	79 (4.3)	79 (4.0)	101 (5.7)	0.016
Intracoronary imaging	285 (14.5)	300 (16.4)	239 (12.2)	401 (22.6)	<0.001
Target vessel Left main coronary artery	283 (14.0)	301 (16.1)	366 (18.4)	471 (24.4)	<0.001
Left anterior descending coronary artery	1,041 (51.7)	1029 (55.0)	1,153 (57.9)	1,085 (56.3)	0.066
Circumflex coronary artery	392 (19.5)	387 (20.7)	409 (20.6)	439 (22.8)	0.052
Right coronary artery	741 (36.8)	654 (35.0)	650 (32.7)	661 (34.4)	0.153
Atherectomy balloon	119 (5.9)	177 (9.4)	229 (11.5)	171 (8.8)	<0.001
Microcatheter	445 (22.0)	417 (22.2)	367 (18.4)	381 (19.7)	0.032
Laser atherectomy	10 (0.5)	25 (1.3)	19 (1.0)	44 (2.3)	<0.001
Glycoprotein inhibitor	87 (4.6)	119 (6.7)	67 (3.5)	53 (2.8)	<0.001
Stent not used	104 (5.1)	74 (4.9)	60 (3.0)	148 (2.2)	0.003
Longest stent (mm)	$\textbf{35.6} \pm \textbf{20.4}$	$\textbf{36.3} \pm \textbf{20.2}$	$\textbf{34.5} \pm \textbf{18.3}$	$\textbf{42.7} \pm \textbf{25.1}$	<0.001
Number of stents used	1.88 ± 1.12	1.96 ± 1.10	1.95 ± 1.12	$\textbf{2.31} \pm \textbf{1.35}$	<0.001

Values are median (IQR), or mean \pm SD, or n (%).

CTO = chronic total occlusion; other abbreviations as in Table 1.

procedural complications are relatively frequent, with coronary perforation, coronary or aortic dissection, and slow flow all more common than during PCI not involving rotational atherectomy (11,12,19). Furthermore, the potentially disastrous stuck rota burr requires a high degree of technical skill to retrieve and rescue the situation (20,21). Thus, ROTA-PCI may represent a particular subset of PCI procedures in which operator volume and experience might influence patient outcomes. The present study supports this hypothesis, observing a relationship between higher annual operator ROTA-PCI volume and in-hospital MACCE (driven mainly by periprocedural MI) and also in-hospital major bleeding and arterial complications. In the current published research, few data are available on ROTA-PCI operator volume, although several studies have reported an association between higher center ROTA-PCI volume and improved patient outcomes (22,23). These previous studies and the present study are therefore consistent in suggesting that procedural ROTA-PCI procedural

Operator Volume, 2013 to 2016						
	Q1 (n = 2,024)	Q2 (n = 1,876)	Q3 (n = 1,999)	Q4 (n = 1,934)	p Value	
Immediate procedural outcomes						
Number of successful lesions	1.49 ± 0.81	$\textbf{1.57} \pm \textbf{0.81}$	1.65 ± 0.87	$\textbf{1.64} \pm \textbf{0.91}$	<0.001	
Emergency cardiac surgery/PCI	11 (0.6)	8 (0.5)	9 (0.5)	3 (0.2)	0.012	
Coronary perforation	31 (1.6)	24 (1.3)	16 (0.9)	25 (1.4)	0.381	
Tamponade	11 (0.6)	8 (0.4)	5 (0.3)	7 (0.4)	0.242	
Heart block	8 (0.4)	8 (0.4)	3 (0.2)	7 (0.4)	0.588	
Coronary dissection	41 (2.1)	64 (3.5)	40 (2.1)	44 (2.5)	0.951	
Slow flow	19 (1.0)	22 (1.2)	19 (1.1)	20 (1.1)	0.783	
Major side-branch loss	16 (0.8)	18 (1.0)	26 (1.4)	12 (0.7)	0.959	
All coronary complications	110 (5.6)	131 (7.2)	101 (5.4)	108 (6.1)	0.921	
Access-site complication	35 (1.8)	90 (4.9)	71 (3.7)	12 (0.6)	0.007	
Access-site hemorrhage	19 (1.0)	15 (0.8)	18 (0.9)	6 (0.3)	0.035	
Clinical outcomes						
Transfusion	23 (1.2)	12 (0.7)	9 (0.5)	11 (0.6)	0.021	
In-hospital major bleed	42 (2.1)	33 (1.8)	28 (1.4)	22 (1.1)	0.012	
Periprocedural CVA	1 (0.1)	1 (0.1)	1 (0.1)	1 (0.1)	0.991	
Periprocedural MI	12 (0.6)	17 (0.9)	14 (0.7)	7 (0.4)	0.068	
In-hospital mortality	44 (2.2)	39 (2.1)	33 (1.7)	37 (1.9)	0.134	
In-hospital MACCE	61 (3.0)	61 (3.3)	50 (2.5)	44 (2.3)	0.004	
Length of stay (days)	$\textbf{2.2} \pm \textbf{11.1}$	$\textbf{2.1} \pm \textbf{10.8}$	1.9 ± 3.6	1.8 ± 5.3	0.006	

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Values are mean \pm SD or n (%).

MACCE = major adverse cardiac and cerebral event(s); other abbreviations as in Table 1.

volume may be an important factor in determining patient outcomes.

In considering the mechanism underpinning these observations, there are several plausible explanations. First, MIs were less common in the highest operator quartile, an association that might be explained by greater operator experience, leading to improved procedural planning and execution. Second, major bleeding was significantly less frequent, and the adverse effects of this endpoint on clinical

TABLE 4Multivariate Analysis of In-Hospital Clinical Outcomesby Actual Operator ROTA-PCI Volume (as a Continuous Variable)					
	Odds Ratio	95% CI	p Value		
Emergency cardiac surgery	0.964	0.939-0.991	0.008		
Cardiac tamponade	0.972	0.948-0.996	0.021		
Acute kidney injury	0.996	0.932-1.002	0.062		
Transfusion	0.941	0.918-0.964	< 0.001		
Arterial complication	0.968	0.958-0.979	< 0.001		
Post-procedural CVA	0.990	0.929-1.055	0.755		
Post-procedural MI	0.978	0.958-0.999	0.037		
In-hospital mortality	0.986	0.975-0.996	0.007		
In-hospital MACCE	0.983	0.975-0.993	< 0.001		
In-hospital bleeding	0.967	0.953-0.980	<0.001		
CI = confidence interval: other abbreviations as in Tables 1 and 3 .					

outcomes are well documented (24,25). In a mediation analysis, the main driver of bleeding reduction with operator volume was increased use of radial access rather than less glycoprotein IIb/IIIa inhibitor use, implying that appropriate attention to access site may diminish bleeding complications significantly. Third, higher operator volumes were associated with greater use of supporting technologies such as atherectomy balloons, pressure wires, and intravascular ultrasound. Thus, vessel preparation, physiological assessment, complete lesion coverage, and optimal stent expansion and apposition may be enhanced as operator volume increases. These factors have been correlated in previous studies with lower rates of acute and late stent thrombosis (16,26,27).

The present data suggest that when the minimum operator ROTA-PCI annual volume was <4 cases/year, in-hospital MACCE increased. Given the negatively skewed volume distribution, 55% of operators were below this threshold of annual ROTA-PCI volume. Although a consensus document from a number of European and U.S. experts did not explicitly state a minimum volume, it was argued that optimal outcomes for rotational atherectomy procedures are achieved by regular users of the technology, and it was recommended that due consideration of referral to a high-volume center experienced in rotational atherectomy should be given (10). Thus, operators within PCI centers with sufficient ROTA-PCI volume should consider working in a collegiate fashion to subspecialize and identify ROTA-PCI operators. At PCI centers without sufficient ROTA-PCI volume, these data support a network or regional strategy with case referral among hospitals in an effort to improve patient outcomes. In light of the guidelines of professional societies that support discussion of the management of complex coronary disease in a multidisciplinary team setting, this could provide the opportunity to factor local operator ROTA-PCI volumes into the decision-making process but could also facilitate referral among colleagues. In contrast, continuing traditional practice with a heavily negatively skewed distribution of operator ROTA-PCI volume could represent suboptimal patient care and lead to adverse clinical outcomes.

STUDY LIMITATIONS. First, as observational data were used in this study, the possibility of unmeasured confounders' influencing the findings cannot be excluded causality cannot be implied. Second, burr size is not captured in the BCIS database, although with no robust data linking burr size and outcomes, the relevance of this parameter to operator volume and MACCE would be uncertain at best.



adverse cardiac and cerebral events (MACCE). (**Right**) Smoothed curve of ROTA-PCI operator volume per year and in-hospital major bleeding MACCE. **Dotted lines** indicate 95% confidence intervals. MACCE = major adverse cardiac and cerebral events; ROTA-PCI = percutaneous coronary intervention with rotational atherectomy.

Third, certain procedural factors including procedure time, contrast volume, and radiation dose are not included in the current iteration of the BCIS database, and the effect of operator volume on these endpoints cannot be ascertained. Finally, the present study presents only in-hospital outcomes, as 12month survival is not currently available. However, for a technically demanding intervention such as rotational atherectomy, in-hospital complications and clinical outcomes are an important endpoint with respect to operator volume.

CONCLUSIONS

Higher volume ROTA-PCI operators undertake more complex procedures in higher risk patients. Despite this, in-hospital outcomes including MACCE and major bleeding were observed to occur less frequently as ROTA-PCI operator volume increased. These data suggest that operator volume is an important factor determining outcome after ROTA-PCI.

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PERSPECTIVES

WHAT IS KNOWN? Although in unselected PCI cohorts, higher operator procedural volumes are not consistently associated with improved patient outcomes, in more complex PCI subsets such as rotational atherectomy, higher operator volumes might be important.

WHAT IS NEW? Higher volume operators undertook procedures in more complex patients and undertook increasingly complex procedures with more vessels and lesions treated, and the left main stem was increasingly likely to be the target vessel. Despite this, reductions in in-hospital mortality, MACCE, emergency surgery, and major bleeding were observed as operator ROTA-PCI volume increased.

WHAT IS NEXT? These data should encourage health care systems to define ROTA-PCI specialists to optimize patient outcomes.

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KEY WORDS complications, national database, operator volume, outcomes, rotational atherectomy

APPENDIX For supplemental figures and a table, please see the online version of this paper.