International Journal of Cardiology 293 (2019) 91–100

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Relationship between operator and hospital volumes and short-term mortality for percutaneous coronary intervention in New York☆

Feng Qian *, Ye Zhong, Edward L. Hannan

Department of Health Policy, Management, and Behavior, School of Public Health, University at Albany-State University of New York, United States of America

ARTICLE INFO

Article history:
Received 3 January 2019
Received in revised form 28 March 2019
Accepted 2 May 2019
Available online 6 May 2019

Keywords:
Volume
Mortality
PCI
New York

ABSTRACT

Background: Recent studies have reported mixed findings regarding the inverse provider volume-outcome relationship for percutaneous coronary interventions (PCIs).
Methods: We included patients who underwent PCIs in New York during December 2012–November 2015. Using risk-adjusted in-hospital/30-day mortality rate and appropriateness of PCI, we tested for a continuous relationship and a variety of annual PCI volume cut points at hospital and operator levels in investigating volume-outcome relationships.
Results: There were 144,196 patients undergoing PCI procedures from 63 non-federal hospitals. There was a significant inverse association between risk-adjusted mortality and both annual hospital PCI volume and annual operator PCI volume. However, we did not find that there was an inverse hospital volume-outcome relationship for the 2013 ACCF/AHA/SCAI's hospital PCI volume cutoff value of 200 per year (AOR, 1.15, 95% CI, 0.88–1.51, $P = 0.32$) or a significant inverse operator volume-outcome relationship using the operator PCI volume cutoff value of 50 per year (AOR, 0.89, 95% CI, 0.70–1.12, $P = 0.32$) or for any other practical volume cutoffs. There was also no significant volume-outcome relationship for STEMI patients. Higher volume hospitals (>400) and operators (>200) tended to perform a higher percentage of inappropriate PCI procedures than their lower volume counterparts.
Conclusion: There were no significant PCI volume-mortality relationships for either hospitals or operators for any practical volume cuts. Higher volume hospitals and operators were associated with higher percentages of inappropriate PCIs.

1. Introduction

Coronary artery disease (CAD) is one of the most widespread and costly public health concerns in the United States. There are 16.5 million Americans suffering from CAD with an estimated annual total cost of $199.6 billion [1]. Percutaneous coronary intervention (PCI) is a viable non-surgical treatment option for CAD that has been commonly used by interventional cardiologists. Approximately 954,000 inpatient PCI procedures are performed annually in America although PCI volumes have slightly declined during recent years [1–3]. During the past 25 years, numerous studies have reported that both hospital PCI volume and operator PCI volume are inversely associated with short-term adverse outcomes for patients undergoing PCI [4–9]. These findings have led to the 2013 ACCF/AHA/SCAI minimum requirements for PCI performance at hospital level (≥200 PCIs per year per hospital) and operator level (≥50 PCIs per year per operator) [10].

Recently, a study using the U.S. National Cardiovascular Data Registry CathPCI database reported that an inverse relationship between PCI operator volume and in-hospital mortality exists [11]. However, three national studies using either the British Cardiovascular Intervention Society Registry or the Japanese PCI Registry failed to detect a significant inverse relationship between PCI operator volume and short-term mortality and/or an inverse relationship between hospital PCI volume and short-term mortality [12–14]. These mixed findings raise the question of whether inverse volume-outcome relationship still holds true at the hospital and operator level in contemporary real-world PCI practice. In this study, we aimed to address the question by using the statewide high-quality New York State PCI Registry [15]. We also expanded on these findings by separately examining volume-mortality relationships for patients with and without STEMI, and by examining the volume-appropriateness of PCI relationship.

Abbreviations: ACS, acute coronary syndrome; CABG, coronary artery bypass graft; CAD, coronary artery disease; PCI, percutaneous coronary intervention; LVEF, left ventricular ejection fraction; AOR, adjusted odds ratio; RAMR, risk adjusted mortality rate; STEMI, ST-segment elevation myocardial infarction; NYSDOH, New York State Department of Health.

☆ Statement: All these three authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

* Corresponding author at: Dept. of HPMB, School of Public Health, UAlbany-SUNY, One University Place, GEC Rm169, Rensselaer, NY 12144-3445, United States of America.
E-mail address: fqian@albany.edu (F. Qian).

https://doi.org/10.1016/j.ijcard.2019.05.005
0167-5273/

2. Methods

2.1. Study population

All patients who underwent PCI in all 63 non-federal hospitals in New York State between December 1, 2012 and November 30, 2015 were eligible study subjects. Cases were excluded due to the following reasons: (1) patients resided outside the United States, (2) patients' cardiac data validation process was incomplete due to hospital closure, (3) patients' 30-day mortality could not be attributed to a single PCI procedure, (4) patients had pre-procedure refractory cardiogenic shock, and (5) patients had hypoxic brain injury and expired under certain conditions.

2.2. Databases

An aggregated dataset was generated by linking the New York State's Percutaneous Coronary Intervention Reporting System (PCIRS) registry, the New York State Vital Statistics file and the National Death Index database with the goal of capturing both the post-PCI in-hospital mortality (from the PCIRS registry) and 30-day mortality following the index procedure (from the New York State Vital Statistics file and the National Death Index database). New York State's PCIRS database is an ongoing mandatory clinical registry developed by the New York State Department of Health. Since its inception in 1992, the PCIRS registry has been used to publish regular statewide public reports on cardiovascular care quality and outcomes for PCI procedures [15]. The PCIRS registry contains important information on patient demographics, baseline characteristics, pre-procedure risk factors, hemodynamic status, left ventricular function, coronary vessels diseased and attempted, coronary lesion information, procedure details, provider identifiers, post-procedure complications and discharge status. The advantages of the PCIRS registry include its completeness, real-world representation, accuracy, and reliability. Also, critical clinical variables are audited and their accuracy is ensured through well-structured systematic efforts [15]. The PCIRS registry has been continuously supervised by the New York State Cardiac Advisory Committee consisting of renowned cardiologists, cardiac surgeons, and experts in cardiovascular quality and outcomes research. The New York State Vital Statistics file contains death information for New York State residents, and the National Death Index as a centralized database of death record information provides death status for patients who were not New York State residents.

2.3. Outcomes

We chose in-hospital/30-day all-cause mortality (death at any time in the index admission, or within 30 days of the discharge date of the index procedure for patients discharged alive) as the primary outcome because it arguably represents the most important post-PCI short-term outcome. Also, it has been widely used in prior studies that investigated the inverse volume-outcome relationship for PCI procedures. We also looked at appropriateness of PCI as an outcome because inappropriate use of PCI has recently been demonstrated to be a concern [16–18].

2.4. Statistical analysis

We examined the distribution of patient demographics, pre-procedure risk factors, comorbidities, and coronary vessels affected for included patients. For hospital volume, we first examined the relationship between annul hospital PCI volume in hundreds and risk-adjusted short-term mortality. Then, we repeated our analysis to evaluate the relationship between annual operator PCI volume in fifties and risk-adjusted short-term mortality. Next, we calculated the mean annual PCI volume for each hospital and categorized annual hospital PCI volume using the cutoff value recommended by the 2013 ACCF/AHA/SCAI (as the new minimum requirement volume of 200 PCIs per year per hospital). Similarly, we calculated the mean annual PCI volume for each operator and then categorized it using the 2013 ACCF/AHA/SCAI recommended minimum volume of 50 PCIs per year. Moreover, we tested a variety of different annual hospital and operator PCI volume cut point values in creating the volume category variables to identify the optimal cut points as well as to determine whether multiple cut points yielded significant volume-mortality relationships. In addition, we examined the difference in risk adjusted mortality rates (RAMRs) when we used different simultaneous volume cut points at the hospital/operator level to define high-volume and low-volume categories. Annual PCI volume at hospital or/and operator level was used as a binary variable in the models for each of the cut-off points that were tested.

Cross-validated (using a 50% sample to build the model and the other half to validate) method was applied in our risk factor selection procedure. In both model building and model validating steps, logistic regression models with backward stepwise elimination were used to identify significant pre-procedural risk factors for in-hospital/30-day mortality following PCI. Candidate risk factors included age, body mass index, hemodynamic status, left ventricle ejection fraction, previous myocardial infarction, chronic lung disease, congestive heart failure, renal failure, and whether the patient had left main disease or not. All significant risk factors were used as control variables in the final logistic regression model. The generalized estimating equation (GEE) method was used to account for clustering within same hospital and within same operator.

Because ST-elevation myocardial infarction (STEMI) is associated with especially high mortality among PCI patients, we conducted separate analyses for patients with and without STEMI. According to New York Codes, Rules and Regulations for cardiac services, the annual threshold volume requirement for providing PCI procedure for patients with STEMI was 36/year at hospital level and 11/year at operator level, respectively [19]. Also, we looked at the "appropriateness" of the PCI procedures according to 2014 Appropriate Use Criteria (AUC) to examine whether high-volume operators and high-volume hospitals performed more inappropriate PCI procedures since appropriateness has been demonstrated to be an important concern in recent studies [16–18]. Our inappropriateness analysis was limited to patients without acute coronary syndrome (ACS) or previous coronary artery bypass graft (CABG) surgery because this is the group most likely to experience inappropriate PCIs and the group that was the subject of earlier studies [16–18].

We used SAS version 9.4 software (SAS Institute, Cary, North Carolina) for all descriptive and regression analyses, and 2-sided tests with a 0.05 significance level were used for hypothesis testing.

3. Results

The final study sample consisted of 144,196 patients undergoing PCI procedures from 63 non-federal hospitals in New York State during the study period of December 2012–November 2015. We sequentially excluded 112 cases because patients resided outside the United States, 331 cases because patients' data validation was incomplete due to hospital closure, 41 cases because patients' 30-day mortality could not be attributed to a single PCI procedure, 837 cases because patients had pre-procedure refractory cardiogenic shock, and 168 patients with hypoxic brain injury who expired under specified conditions.

The in-hospital/30-day mortality rate was 1.15%. About 30% of the patients were women and over 75% were either overweight or obese. >70% of patients had a LVEF of 50% or greater. Nearly 18% of the patients had a pre-procedural myocardial infarction within the last 24 h and 44% had a previous PCI. Nearly 20% of these patients had renal failure, 10% had peripheral vascular disease, 9% had cerebrovascular disease, 7% had congestive heart failure, and 6% had chronic lung disease (see Table 1).

Treating annual hospital PCI volume in hundreds or annual physician volume in fifties as a continuous variable in the multiple logistic regression model, we found that there was a significant inverse association between annual hospital volume (AOR, 0.987, 95% CI, 0.981–0.994, $P < 0.001$) or annual operator volume (AOR, 0.966, 95% CI, 0.952–0.982, $P < 0.001$) and short-term mortality (Table 1). However, Figures 1 and 2, which present risk-adjusted mortality rates for different ranges of hospital volumes and operator volumes, respectively, do not suggest evident inverse volume-outcome relationships (see Appendix Figures 1–2).

Also, we did not find that there was an inverse hospital volume-outcome relationship using the 2013 ACCF/AHA/SCAI's hospital PCI volume cutoff value of 200 per year (AOR, 1.15, 95% CI, 0.88–1.51, $P = 0.32$) or an inverse operator volume-outcome relationship using their cardiologist PCI volume cutoff value of 50 per year (AOR, 0.89, 95% CI, 0.70–1.12, $P = 0.32$). When we examined a variety of cut points, we found that hospital volume cut points between 700 and 1000 (Table 2), and operator volume cut points between 200 and 350 (Table 2) were associated with significant mortality differences between higher-volume and lower volume providers. From the standpoint of lowest *P*-values, the optimal cut point was 900 for hospitals (high-volume vs. low volume: AOR, 0.83, 95% CI, 0.73–0.94, $P = 0.004$) and 225 for operators (high-volume vs. low volume: AOR, 0.81, 95% CI, 0.69–0.95, $P = 0.011$). Also, the adjusted odds ratio did not decrease as the annual hospital/operator PCI volume cutoff value increased. When we examined the interactions between annual hospital and operator PCI volumes using 200/300/400 at hospital level and 75/100 at operator level, we did not find any statistically significant differences between other groups compared with the low-hospital and low-operator PCI volume combination reference group.

For the STEMI group analysis, there were a total of 17,049 patients (11.82% of full sample). We used the NYSDOH required minimum annual PCI volume of 36 at the hospital level and 11 at the operator level as initial cut points. We failed to detect a significant difference using these thresholds at the hospital level (≥36 vs <36: AOR: 0.61, 95% CI, 0.22–1.73, $P = 0.36$) or at the operator level (≥11 vs <11: AOR: 1.15, 95% CI, 0.85–1.56, $P = 0.36$) (see Table 3). In addition,

Table 1
Characteristics of 144,196 PCI patients in New York and PCI volume-outcome relationship with volume being a continuous variable (Dec 2012–Nov 2015).

Patient characteristics	Number	Percent/prevalence (%)
Demographic		
Age		
Less than 50	13,297	9.22
50–59	33,315	23.10
60–69	44,427	30.81
70–79	35,088	24.33
80 and above	18,069	12.53
Gender		
Female	42,831	29.70
Male	101,365	70.30
Body mass index (kg/m2)		
<18.5 kg/m2	1162	0.81
≥18.5 and <25 kg/m2	30,225	20.96
≥25 and <35 kg/m2	90,152	62.52
≥35 kg/m2	22,657	15.71
Hemodynamic status		
Non-refractory shock	678	0.47
Ventricular function		
Ejection fraction		
Ejection fraction 50% or greater	103,309	71.64
Ejection fraction less than 20%	1216	0.84
Ejection fraction 20–29%	5870	4.07
Ejection fraction 30–39%	11,459	7.95
Ejection fraction 40–49%	22,342	15.49
Pre-procedural MI		
No MI	68,750	47.68
MI with ST elevation		
MI < 6 h	14,363	9.96
MI 6–11 h	2397	1.66
MI 12–23 h	1194	0.83
MI without ST Elevation		
MI < 6 h	1155	0.80
MI 6–11 h	2045	1.42
MI 12–23 h	4427	3.07
MI with or without ST Elevation		
MI 1–14 days	23,445	16.26
MI > 14 days	26,420	18.32
Comorbidities		
Previous PCIs	63,200	43.83
Cerebrovascular disease (not TIA only)	11,833	8.21
Peripheral vascular disease	13,360	9.27
Congestive heart failure (CHF) (within 2 weeks)	9958	6.91
Chronic lung disease		
None	135,214	93.77
Mild	4912	3.41
Moderate	3552	2.46
Severe	518	0.36
Renal failure		
No renal dialysis and creatinine <1.2 mg/dL	102,206	70.88
Creatinine ≥1.2 and ≤1.5 mg/dL	28,093	19.48
Creatinine >1.5 and ≤2.0 mg/dL	6963	4.83
Creatinine >2.0 and ≤3.0 mg/dL	2231	1.15
Creatinine >3.0 mg/dL	772	0.54
Renal dialysis	3931	2.73
Contraindication to antiplatelet therapy		0.29
Vessels		
Left main disease	6434	4.46
Number of vessels diseased		
Fewer than two vessels diseased	78,508	54.44
Two vessels diseased	46,274	32.09
Three vessels diseased	19,414	13.46

Annual PCI volume	Adjusted odds ratio	95% confidence interval	*P* value
Hospital volume (in hundreds)	0.987	(0.981, 0.994)	<0.001
Operator volume (in fifties)	0.966	(0.952, 0.982)	<0.001

we examined several other volume cut points for annual hospital PCI volume for STEMI patients and did not find any significant association between hospital volume and mortality for PCI with STEMI patients. We also found no significant relationship at the required minimum operator volume of 11 per year, or at any of several other cut points that were tested.

There were 127, 147 patients without STEMI, which was 88.18% of the total patient population. Our regression analysis suggested

that for patients without STEMI, the annual PCI volume at the hospital level needs to be as high as 700 or higher to show a significant inverse volume-outcome relationship. Similarly, at the operator level, the annual PCI volume needs to reach 300 or above to demonstrate a significant inverse volume-outcome association. (Table 4).

Table 2
Empirical data exploration of optimal cut point for annual hospital/operator PCI volume.

Annual hospital volume cut point	Number of patients (%)	Number of hospitals (%)	Adjusted odds ratio (high-volume vs. low-volume)	95% confidence interval	*P* value
200[a]			1.15	(0.88, 1.51)	0.32
<200	3043 (2.11)	10 (15.87)			
≥200	141,153 (97.89)	53 (84.13)			
300			0.91	(0.75, 1.10)	0.32
<300	10,019 (6.95)	19 (30.16)			
≥300	134,177 (93.05)	44 (69.84)			
400			0.91	(0.77, 1.06)	0.22
<400	13,833 (9.59)	23 (36.51)			
≥400	130,363 (90.41)	40 (63.49)			
500			0.99	(0.87, 1.14)	0.90
<500	24,763 (17.17)	31 (49.21)			
≥500	119,433 (82.83)	32 (50.79)			
600			0.94	(0.82, 1.07)	0.36
<600	31,391 (21.77)	35 (55.56)			
≥600	112,805 (78.23)	28 (44.44)			
700			0.85	(0.75, 0.97)	0.02
<700	43,565 (30.21)	41 (65.08)			
≥700	100,631 (69.79)	22 (34.92)			
800			0.84	(0.74, 0.96)	0.01
<800	45,958 (31.87)	42 (66.67)			
≥800	98,238 (68.13)	21 (33.33)			
900			0.83	(0.73, 0.94)	0.004
<900	53,417 (37.04)	45 (71.43)			
≥900	90,779 (62.96)	18 (28.57)			
1000			0.86	(0.76, 0.98)	0.03
<1000	59,174 (41.04)	47 (74.60)			
≥1000	85,022 (58.96)	16 (25.40)			
Annual operator volume cut point	**Number of patients (%)**	**Number of operators (%)**	**Adjusted odds ratio (high-volume vs. low-volume)**	**95% confidence interval**	***P* value**
50[a]			0.89	(0.70, 1.12)	0.32
<50	6949 (4.82)	132 (28.82)			
≥50	137,247 (95.18)	326 (71.18)			
75			0.86	(0.74, 1.00)	0.05
<75	16,608 (11.52)	193 (42.14)			
≥75	127,588 (88.48)	265 (57.86)			
100			0.94	(0.82, 1.06)	0.32
<100	29,963 (20.78)	255 (55.68)			
≥100	114,233 (79.22)	203 (44.32)			
125			1.01	(0.89, 1.15)	0.85
<125	42,088 (29.19)	297 (64.85)			
≥125	102,108 (70.81)	161 (35.15)			
150			0.91	(0.80, 1.03)	0.12
<150	57,837 (40.11)	339 (74.02)			
≥150	86,359 (59.89)	119 (25.98)			
175			0.94	(0.82, 1.07)	0.35
<175	73,497 (50.97)	374 (81.66)			
≥175	70,699 (49.03)	84 (18.34)			
200			0.87	(0.75, 0.99)	0.04
<200	80,534 (55.85)	389 (84.93)			
≥200	63,662 (44.15)	69 (15.07)			
225			0.81	(0.69, 0.95)	0.0105
<225	91,799 (63.66)	408 (89.08)			
≥225	52,397 (36.34)	50 (10.92)			
250			0.83	(0.70, 0.98)	0.03
<250	98,918 (68.60)	418 (91.27)			
≥250	45,278 (31.40)	40 (8.73)			
275			0.82	(0.69, 0.97)	0.02
<275	108,222 (75.05)	430 (93.89)			
≥275	35,974 (24.95)	28 (6.11)			
300			0.77	(0.64, 0.94)	0.011
<300	114,218 (79.21)	437 (95.41)			
≥300	29,978 (20.79)	21 (4.59)			
325			0.78	(0.62, 0.98)	0.03
<325	117,931 (81.79)	441 (96.29)			
≥325	26,265 (18.21)	17 (3.71)			
350			0.75	(0.58, 0.96)	0.02
<350	119,940 (83.18)	443 (96.72)			
≥350	24,256 (16.82)	15 (3.28)			

[a] Current guidelines' recommended minimum PCI volume at hospital/operator level.

Finally, we examined the appropriateness of PCI as a function of hospital and operator volumes. There were 28,832 patients included in the inappropriateness analysis and the overall inappropriateness rate was 10.01%. Based on our analysis of the association between hospital/operator annual PCI volume and PCI inappropriateness, we found that very high volume hospitals (e.g., >400) and operators (e.g., >200) were more likely to perform inappropriate PCIs (Appendix Table 5).

4. Discussion

Although volume-mortality relationships for many surgical procedures and specifically cardiac procedures have been demonstrated for >3 decades, some of the more recent studies have not found significant volume-outcome relationships [12–14]. For example, in a study using the British Cardiovascular Society Intervention Registry with 427,467 patients receiving PCI procedures between 2007 and 2013, O'Neill et al. did not find significant evidence of worse, or better 30-day mortality in low volume hospitals after adjustment for differences in case mix and clinical presentation [12]. In a study using the 2014–2015 Japanese national PCI registry with 323,322 PCIs, Inohara et al. found that after adjusting for patient level risk factors, the adjusted odds ratio for in-hospital mortality for hospitals in the lowest decile (10–149 annual hospital volume) was significantly higher than those in hospitals in the remaining deciles [13]. However, they did not detect significant volume-outcome relationship across volume deciles of operators. Most recently, Hulme et al. used the British Cardiovascular Intervention Society Registry data and found no relationship between 30-day mortality and operator PCI volume after adjusting for patient characteristics, hospital PCI volume, and interactions between operator PCI volume and hospital PCI volume [14].

One recent U.S. study did find an inverse PCI volume-outcome association at the operator level [11]. Fanaroff et al. analyzed July 2009–March 2015 National Cardiovascular Data Registry with 3,747,866 PCI procedures in 1584 sites. After risk adjustment, they found that patients receiving PCIs from low-volume (<50/year) and intermediate-volume (50–100/year) operators had significantly higher risk of in-hospital mortality than patients receiving PCIs from high-volume operators (AOR, 1.16, 95% CI: 1.12–1.21 for low-volume vs. high-volume; AOR, 1.05, 95% CI: 1.02–1.09 for intermediate-volume vs. high-volume). To compare our results with the ones from Fanaroff's study, we conducted extra analysis by using the same annual operator PCI volume categories (<50, 50–99, and ≥100). We found that patients receiving PCIs from low volume (<50/year) and intermediate-volume (50–100/year) operators did not have a significantly higher risk of risk-adjusted in-hospital/30-day mortality than patients receiving PCIs from high-volume (≥100/year) operators (AOR, 1.14, $P = 0.29$ for low-volume vs. high-volume; AOR, 1.06, $P = 0.50$ for intermediate-volume vs.

Table 3
STEMI data exploration of optimal cut point for annual hospital/operator PCI volume.

Annual hospital STEMI volume cut point	Number of patients (%)	Number of hospitals (%)	Adjusted odds ratio (high-volume vs. low-volume)	95% confidence interval	*P* value
36[a]			0.61	(0.22, 1.73)	0.36
<36	98 (0.57)	3 (4.76)			
≥36	16,951 (99.43)	60 (95.24)			
50			0.98	(0.65, 1.46)	0.91
<50	721 (4.23)	10 (15.87)			
≥50	16,328 (95.77)	53 (84.13)			
75			0.87	(0.71, 1.07)	0.20
<75	3948 (23.16)	29 (46.03)			
≥75	13,101 (76.84)	34 (53.97)			
100			0.93	(0.76, 1.13)	0.47
<100	6492 (38.08)	39 (61.90)			
≥100	10,557 (61.92)	24 (38.10)			
150			0.94	(0.74, 1.20)	0.63
<150	11,556 (67.78)	54 (85.71)			
≥150	5493 (32.22)	9 (14.29)			
200			1.19	(0.88, 1.61)	0.25
<200	14,767 (86.62)	60 (95.24)			
≥200	2282 (13.38)	3 (4.76)			
Annual operator STEMI volume cut point	**Number of patients (%)**	**Number of operators (%)**	**Adjusted odds ratio (high-volume vs. low-volume)**	**95% confidence interval**	***P* value**
10			1.06	(0.76, 1.48)	0.73
<10	1080 (6.33)	99 (26.26)			
≥10	15,969 (93.67)	278 (73.74)			
11[a]			1.15	(0.85, 1.56)	0.36
<11	1429 (8.38)	113 (29.97)			
≥11	15,620 (91.62)	264 (70.03)			
20			0.88	(0.73, 1.08)	0.22
<20	4366 (25.61)	222 (58.89)			
≥20	12,683 (74.39)	155 (41.11)			
30			0.93	(0.76, 1.14)	0.47
<30	8411 (49.33)	288 (76.39)			
≥30	8638 (50.67)	89 (23.61)			
40			1.02	(0.76, 1.38)	0.88
<40	13,409 (78.65)	345 (91.51)			
≥40	3640 (21.35)	32 (8.49)			
50			1.01	(0.57, 1.78)	0.98
<50	15,856 (93.00)	367 (97.65)			
≥50	1193 (7.00)	10 (2.65)			

[a] Current NYS hospital/operator level required minimum PCI volume for patients with STEMI.

Table 4
Patients without STEMI optimal cut point for annual hospital/operator PCI volume.

Annual hospital volume cut point	Number of patients (%)	Number of hospitals (%)	Adjusted odds ratio (high-volume vs. low-volume)	95% confidence interval	*P* value
200[a]			1.02	(0.66, 1.56)	0.95
<200	2153 (1.69)	10 (15.87)			
≥200	124,994 (98.31)	53 (84.13)			
300			0.84	(0.64, 1.10)	0.20
<300	7618 (5.99)	19 (30.16)			
≥300	119,529 (94.01)	44 (69.84)			
400			0.84	(0.67, 1.05)	0.12
<400	10,678 (8.40)	23 (36.51)			
≥400	116,469 (91.60)	40 (63.49)			
500			0.96	(0.85, 1.27)	0.67
<500	19,577 (15.40)	31 (49.21)			
≥500	107,570 (84.60)	32 (50.79)			
600			0.91	(0.82, 1.20)	0.28
<600	25,157 (19.79)	35 (55.56)			
≥600	101,990 (80.21)	28 (44.44)			
700			0.84	(0.71, 0.98)	0.03
<700	35,347 (27.80)	41 (65.08)			
≥700	91,800 (72.20)	22 (34.92)			
800			0.82	(0.70, 0.96)	0.0136
<800	37,458 (29.46)	42 (66.67)			
≥800	89,689 (70.54)	21 (33.33)			
900			0.83	(0.71, 0.96)	0.0138
<900	43,985 (34.59)	45 (71.43)			
≥900	83,162 (65.41)	18 (28.57)			
1000			0.84	(0.72, 0.97)	0.02
<1000	48,867 (38.43)	47 (74.60)			
≥1000	78,280 (61.57)	16 (25.40)			
Annual operator volume cut point	**Number of patients (%)**	**Number of operators (%)**	**Adjusted odds ratio (high-volume vs. low-volume)**	**95% confidence interval**	***P* value**
50[a]			0.93	(0.68, 1.27)	0.63
<50	6244 (4.91)	131 (28.67)			
≥50	120,903 (95.09)	326 (71.33)			
75			0.86	(0.71, 1.05)	0.14
<75	14,581 (11.47)	192 (42.01)			
≥75	112,566 (88.53)	265 (57.99)			
100			0.93	(0.79, 1.09)	0.36
<100	25,467 (20.03)	254 (55.58)			
≥100	101,680 (79.97)	203 (44.42)			
150			0.91	(0.79, 1.06)	0.22
<150	49,608 (39.02)	338 (73.96)			
≥150	77,539 (60.98)	119 (26.04)			
200			0.89	(0.76, 1.04)	0.15
<200	69,131 (54.37)	388 (84.90)			
≥200	58,016 (45.63)	69 (15.10)			
250			0.84	(0.69, 1.01)	0.06
<250	84,990 (66.84)	417 (91.25)			
≥250	42,157 (33.16)	40 (8.75)			
300			0.80	(0.64, 0.99)	0.04
<300	98,994 (77.86)	436 (95.40)			
≥300	28,153 (22.14)	21 (4.60)			
350			0.72	(0.57, 0.93)	0.01
<350	104,030 (81.82)	442 (96.72)			
≥350	23,117 (18.18)	15 (3.28)			
400			0.69	(0.52, 0.90)	0.007
<400	108,179 (85.08)	446 (97.59)			
≥400	18,968 (14.92)	11 (2.41)			
450			0.57	(0.42, 0.78)	0.0004
<400	115,366 (90.73)	452 (98.91)			
≥400	11,781 (9.27)	5 (1.09)			

[a] Current guidelines' recommended hospital/operator minimum PCI volume.

high-volume). However, it should be noted that the magnitudes of the AORs using our data were close to those reported in Fanaroff's (1.14 vs. 1.16, 1.06 vs. 1.05). Thus, we cannot rule out the possibility that our findings differed because of a lack of statistical power compared to the power in Fanaroff's national NCDR database.

The strengths of our study are that we included all patients receiving PCI from all non-federal hospitals in New York State and that we examined both the hospital level and operator level PCI volumes. Our main finding was that there were significant continuous relationships between mortality and both annual hospital volume and annual operator volume, but there were no significant relationships using the 2013 Guideline's recommended 200/year and 50/year volumes at the hospital and operator levels. Further analysis of different hospital and operator volume cut points showed that 900/year at the hospital level and 225/year at the operator level were the optimal volume cut points.

Since 900/year and 225/year cut points are more than four times higher than what is recommended by the guidelines and since these cut points are unrealistic in terms of having a high percentage of hospitals and operators with volumes that high, we

compared their impact on overall mortality with the impact of >300/year at the hospital level and 75/year at the operator level, both of which had reasonable (although not statistically significant) mortality benefits for higher volume providers. Our examination of the RAMR for of patients undergoing PCIs in hospitals with volumes of at least 900/year rather than 300/year showed that the former cut point could lead to one less short-term death per 1667 patients undergoing PCI procedures from high-volume hospitals. Also, using 225/year rather than 75/year to define high-volume operators would lead to one fewer short-term deaths per 834 patients receiving PCIs from high-volume operators. Thus, the added short-term mortality benefit of using unrealistically high volume cut points is minimal. Our further analysis including interaction term of annual hospital volume and annual operator volume did not show that compared with patients receiving PCI from both low-volume hospital and low-volume operators, patients receiving PCIs from other combination groups had significantly different short-term mortality.

We also conducted separate analyses for patients with and without STEMI to examine the volume-outcome relationship. We did not observe any significant inverse volume-outcome association using various volume cutoff values for STEMI patients. For patients without STEMI, similar to our main findings using the full sample, only very high cutoff values (700 and above at the hospital level and 300 and above at the operator level) showed a significant inverse volume-outcome relationship. Finally, we applied 2014 AUC criteria to investigate whether inappropriate use of PCI was related to hospital or operator volume. We found that there was a tendency for higher volume hospitals (>400 PCIs/year) and higher volume operators (>200 PCIs/year) to perform a higher percentage of inappropriate PCI procedures than their lower volume counterparts.

There are several possible explanations for our negative findings using the Guidelines' recommended minimum volume cutoffs. First, the quality and outcome improvement could result from effective education and training, enhanced compliance with the practice guidelines, and continuous quality improvement effort. Second, procedure volume might be most pertinent when the new procedure begins to diffuse into real practice. As PCI procedures have been widely used, the recommended minimum volume cutoffs at hospital and operator level might not be able to distinguish low-quality care from high-quality care in the real-world setting. Using empirical data-driven higher volume cutoffs allowed us to detect the inverse volume-outcome relationship at very high volume levels, although it is practically impossible to recommend such high volume criteria as a requirement for offering PCI procedures. Third, short-term mortality rates are quite low for PCI and other measures such as target vessel revascularization would have to be used to detect volume-outcome relationships. Also, it should be noted that when examining short-term mortality for patients with STEMI at the NYSDOH required minimum hospital volume of 36/year, we found that only 3 hospitals had PCI STEMI volumes below 36, and only 0.6% of patients with STEMI underwent PCI in those hospitals. Thus, it was impossible to accurately compare performance for hospitals on either side of that cut point, and the cut point may be quite effective in achieving high-quality outcomes.

Our study has several limitations. First, this project was a nonrandomized retrospective observational study. We cannot rule out the possibility of selection bias and residual confounders although we adjusted for available patient-level risk factors in our analysis. Second, the study was limited to patients receiving PCI procedures in New York State, and our findings may not be reproducible in other states. Third, we defined annul PCI volume by calendar year, which might not be able to fully capture the most recent experience/skills of the hospital/operator. A better alternative approach might be to define the annual volume by using the volume from the previous 365 days for the hospital/operator. However, when we used the previous 365 days' volume for hospital/operator in our regression analysis, we obtained similar findings. Fourth, we focused on the in-hospital/30-day mortality after PCI procedure and did not examine other relevant outcomes such as 30-day hospital readmission and post procedural complications. Future research is suggested to include a more comprehensive set of outcome measures in studying the volume-outcome relationship in PCI.

Our study suggests that there is no practical cutoff value for minimum hospital or operator volume to use by federal or state governments for quality and outcomes regulatory purposes. This finding itself is valuable because prior studies in New York and elsewhere did find that there were minimum volume cutoff points for which significant mortality differences occurred. Thus, our study has found a change in the volume-mortality relationship for PCI in contemporary practice. Our additional finding that volume-outcome relationships do occur at volumes too high to use for regulatory purposes (because the impact on current hospitals would be too disruptive and because patients' travel times would increase substantially) is also important. It implies that individual patients could have higher survival probabilities by using very high-volume PCI hospitals and operators if the travel distance is not too daunting for them.

In conclusion, this study examined the volume and outcome relationship at both hospital and operator levels for PCI procedures using a contemporary PCI registry in New York. We found a continuous volume-outcome relationship for both hospital volume and operator volume, but we failed to detect significant inverse volume-outcome relationship at the 2013 ACCF/AHA/SCAI Guidelines' recommended minimum PCI volume cutoff values for hospitals and operators or at any other practical volume cutoff points. And, we observed significant inverse volume-outcome associations at both hospital and operator levels when much higher PCI volume cut points were selected. Overall, our findings are consistent with some recent large-scale registry-based observational studies that found no volume-mortality differences at lower volume levels. Nevertheless, we think it is critically important to keep monitoring the PCI volume-outcome relationship as PCI procedures evolve over time. Further studies are needed using longer-term outcomes as well as other clinically meaningful measures.

Grant support

None.

Conflicts of interest

None.

Acknowledgements

We thank the New York State Cardiac Advisory Committee for their encouragement and support of this study; and thank Kimberly S. Cozzens, Cynthia L. Johnson, and the cardiac surgery departments and cardiac-catheterization laboratories of the participating hospitals for their tireless efforts to ensure the timeliness, completeness, and accuracy of the PCI and CSRS registries.

Disclosure

Dr. Qian serves as a medical advisor for Kenzen Inc.

Appendix A

Table 5
Annual hospital/operator PCI volume and inappropriate PCI rate.

Annual hospital volume cut point	Number of patients (%)	Number of hospitals (%)	Inappropriateness rate (%)	*P* value
200[a]				0.29
<200[b,c]	378 (1.31)	10 (15.87)	9.98	
≥200	28,454 (98.69)	53 (84.13)	11.64	
300				0.09
<300	1382 (4.79)	19 (30.16)	8.68	
≥300	27,450 (95.21)	44 (69.84)	10.07	
400				0.0022
<400	1940 (6.73)	23 (36.51)	7.99	
≥400	26,892 (93.27)	40 (63.49)	10.15	
500				<0.0001
<500	3484 (12.08)	31 (49.21)	7.52	
≥500	25,348 (87.92)	32 (50.79)	10.35	
600				<0.0001
<600	4415 (15.31)	35 (55.56)	7.36	
≥600	24,417 (84.69)	28 (44.44)	10.48	
700				0.006
<700	6166 (21.39)	41 (65.08)	9.07	
≥700	22,666 (78.61)	22 (34.92)	10.26	
800				<0.0001
<800	6547 (22.71)	42 (66.67)	8.71	
≥800	22,285 (77.29)	21 (33.33)	10.39	
900				<0.0001
<900	7975 (27.66)	45 (71.43)	8.54	
≥900	20,857 (72.34)	18 (28.57)	10.57	
1000				<0.0001
<1000	9366 (32.48)	47 (74.60)	8.54	
≥1000	19,466 (67.52)	16 (25.40)	10.71	
Annual operator volume cut point	**Number of patients (%)**	**Number of operators (%)**	**Inappropriateness rate (%)**	***P* value**
50[a]				0.46
<50	1506 (5.22)	109 (25.17)	10.56	
≥50	27,326 (94.78)	324 (74.83)	9.98	
75				0.06
<75	3135 (10.87)	169 (39.03)	10.94	
≥75	25,697 (89.13)	264 (60.97)	9.89	
100				0.30
<100	5343 (18.53)	231 (53.35)	10.39	
≥100	23,489 (81.47)	202 (46.65)	9.92	
150				0.82
<150	10,639 (36.90)	314 (72.52)	9.95	
≥150	18,193 (63.10)	119 (27.48)	10.04	
200				0.0004
<200	15,243 (52.87)	364 (84.06)	9.42	
≥200	13,589 (47.13)	69 (15.94)	10.66	
250				0.002
<250	18,767 (65.09)	393 (90.76)	9.60	
≥250	10,065 (34.91)	40 (9.24)	10.77	
300				0.0002
<300	22,462 (77.91)	413 (95.15)	9.65	
≥300	6370 (22.09)	21 (4.85)	11.26	
350				<0.0001
<350	23,085 (80.07)	418 (96.54)	9.66	
≥350	5747 (19.93)	15 (3.46)	11.41	
400				0.0003
<400	23,793 (82.52)	422 (97.46)	9.71	
≥400	5039 (17.48)	11 (2.54)	11.41	
450				<0.0001
<400	25,774 (89.39)	428 (98.85)	9.52	
≥400	3058 (10.61)	5 (1.15)	14.13	

[a] Current guideline's recommended hospital/operator minimum PCI volume.
[b] The correlation between hospital inappropriate rate and hospital volume: Pearson Correlation Coefficient $r = -0.0733$ ($P = 0.57$).
[c] The correlation between operator inappropriate rate and operator volume: Pearson Correlation Coefficient $r = -0.0129$ ($P = 0.79$).

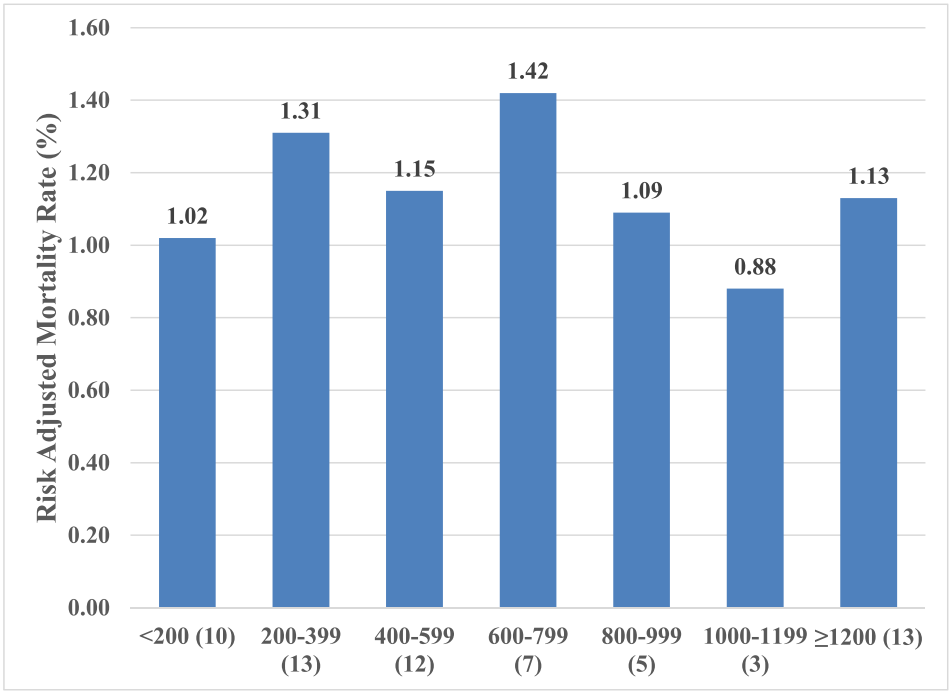

Fig. 1. Risk-adjusted mortality rate for hospitals with different annual PCI volume (Dec 2012–Nov 2015). *Annual hospital PCI volume and the number of hospitals (in the parenthesis) are listed under each bar.

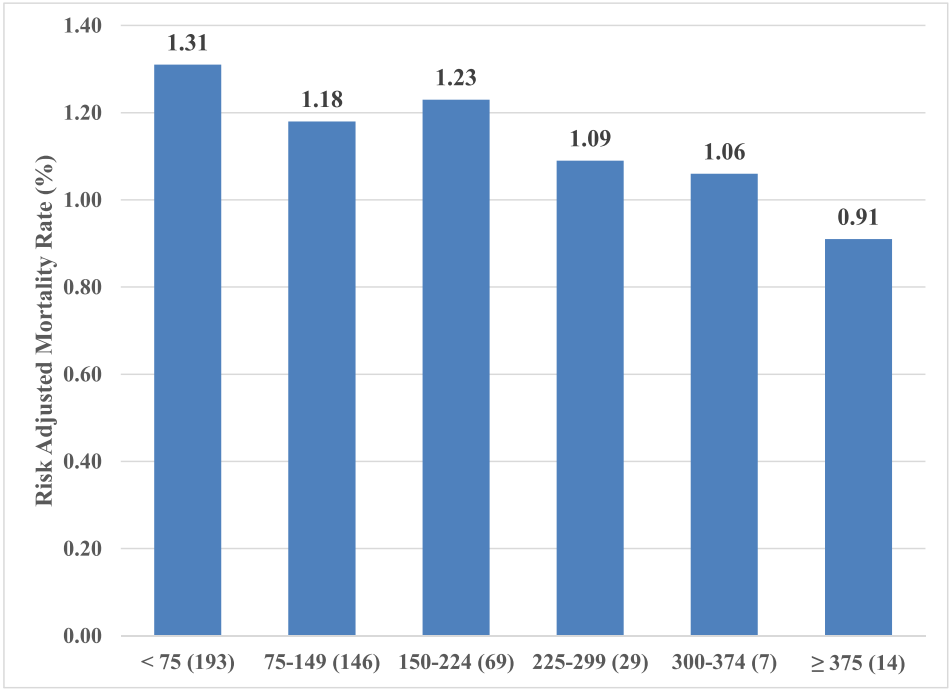

Fig. 2. Risk-adjusted mortality rate for operators with different annual PCI volume (Dec 2012–Nov 2015). *Annual operator PCI volume and the number of operators (in the parenthesis) are listed under each bar.

References

[1] E.J. Benjamin, M.J. Blaha, S.E. Chiuve, et al., Heart disease and stroke statistics-2017 update: a report from the American Heart Association, Circulation 135 (10) (Mar 7 2017) e146–e603.

[2] D.H. Howard, Y.C. Shen, Trends in PCI volume after negative results from the COURAGE trial, Health Serv. Res. 49 (1) (Feb 2014) 153–170.

[3] J. Maroney, S. Khan, W. Powell, L.W. Klein, Current operator volumes of invasive coronary procedures in Medicare patients: implications for future manpower needs in the catheterization laboratory, Catheter. Cardiovasc. Interv. 81 (1) (Jan 1 2013) 34–39.

[4] E.L. Hannan, M. Racz, T.J. Ryan, et al., Coronary angioplasty volume-outcome relationships for hospitals and cardiologists, JAMA 277 (11) (Mar 19 1997) 892–898.

[5] E.L. Hannan, C. Wu, G. Walford, et al., Volume-outcome relationships for percutaneous coronary interventions in the stent era, Circulation 112 (8) (Aug 23 2005) 1171–1179.

[6] P.D. McGrath, D.E. Wennberg, D.J. Malenka, et al., Operator volume and outcomes in 12,998 percutaneous coronary interventions. Northern New England Cardiovascular Disease Study Group, J. Am. Coll. Cardiol. 31 (3) (Mar 1 1998) 570–576.

[7] P.D. McGrath, D.E. Wennberg, J.D. Dickens Jr., et al., Relation between operator and hospital volume and outcomes following percutaneous coronary interventions in the era of the coronary stent, JAMA 284 (24) (Dec 27 2000) 3139–3144.

[8] M. Moscucci, D. Share, D. Smith, et al., Relationship between operator volume and adverse outcome in contemporary percutaneous coronary intervention practice: an analysis of a quality-controlled multicenter percutaneous coronary intervention clinical database, J. Am. Coll. Cardiol. 46 (4) (Aug 16 2005) 625–632.

[9] A.O. Badheka, N.J. Patel, P. Grover, et al., Impact of annual operator and institutional volume on percutaneous coronary intervention outcomes: a 5-year United States experience (2005–2009), Circulation 130 (16) (Oct 14 2014) 1392–1406.

[10] J.G. Harold, T.A. Bass, T.M. Bashore, et al., ACCF/AHA/SCAI 2013 update of the clinical competence statement on coronary artery interventional procedures: a report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training (Writing Committee to Revise the 2007 Clinical Competence Statement on Cardiac Interventional Procedures), J. Am. Coll. Cardiol. 62 (4) (Jul 23 2013) 357–396.

[11] A.C. Fanaroff, P. Zakroysky, D. Dai, et al., Outcomes of PCI in relation to procedural characteristics and operator volumes in the United States, J. Am. Coll. Cardiol. 69 (24) (Jun 20 2017) 2913–2924.

[12] D. O'Neill, O. Nicholas, C.P. Gale, et al., Total center percutaneous coronary intervention volume and 30-day mortality: a contemporary national cohort study of 427 467 elective, urgent, and emergency cases, Circ. Cardiovasc. Qual. Outcomes 10 (3) (Mar 2017).

[13] T. Inohara, S. Kohsaka, K. Yamaji, et al., Impact of institutional and operator volume on short-term outcomes of percutaneous coronary intervention: a report from the Japanese Nationwide Registry, JACC. Cardiovascular interventions 10 (9) (May 8 2017) 918–927.

[14] W. Hulme, M. Sperrin, N. Curzen, et al., Operator volume is not associated with mortality following percutaneous coronary intervention: insights from the British Cardiovascular Intervention Society registry, Eur. Heart J. 39 (18) (2018 May 7) 1623–1634.

[15] E.L. Hannan, K. Cozzens, S.B. King 3rd, G. Walford, N.R. Shah, The New York State cardiac registries: history, contributions, limitations, and lessons for future efforts to assess and publicly report healthcare outcomes, J. Am. Coll. Cardiol. 59 (25) (Jun 19 2012) 2309–2316.

[16] E.L. Hannan, K. Cozzens, Z. Samadashvili, et al., Appropriateness of coronary revascularization for patients without acute coronary syndromes, J. Am. Coll. Cardiol. 59 (21) (May 22 2012) 1870–1876.

[17] E.L. Hannan, Z. Samadashvili, K. Cozzens, et al., 2017 versus 2012 appropriate use criteria for percutaneous coronary interventions: impact on appropriateness ratings, JACC. Cardiovascular interventions 11 (5) (Mar 12 2018) 473–478.

[18] N. Desai, S. Bradley, C. Parzynski, et al., Appropriate use criteria for coronary revascularization and trends in utilization, patient selection, and appropriateness of percutaneous coronary intervention – findings from the NCDR- CathPCI Registry, JAMA 314 (19) (2015 Nov 17) 2045–2053.

[19] New York State Department of Health. New York Codes, Rules, and Regulations Title 10. CRR-NY 405.29 Cardiac Services (https://www.health.ny.gov/regulations/nycrr/title_10/; Access March 23, 2019).