



ORIGINAL RESEARCH

Volume-Outcome Relationships for Percutaneous Coronary Intervention in Acute Myocardial Infarction

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BACKGROUND: Lower primary percutaneous coronary intervention (PCI) volume is known to be associated with worse outcomes in patients with acute myocardial infarction (MI) at hospital level. The present study aimed to evaluate the relations of primary, elective, and total PCI volume and primary/total PCI volume ratio per hospital to in-hospital mortality in patients with acute MI undergoing primary PCI.

METHODS AND RESULTS: Using a large nationwide administrative database, we included a total of 83 076 patients from 154 hospitals in Japan undergoing PCI for either acute MI or elective cases. Relations of annual procedural volumes for primary, elective, and total PCI to in-hospital mortality after acute MI at hospital level were evaluated. The ratio of primary to total PCI volume per hospital was also assessed. The primary end point was the ratio of observed to predicted mortality. Of 83 076 patients, 26 913 (32.4%) underwent primary PCI for acute MI, among whom 1561 (5.8%) died during hospitalization. Overall, observed in-hospital mortality after acute MI and observed/predicted mortality ratio were higher in hospitals with lower primary, elective, and total PCI volumes. Observed/predicted in-hospital mortality ratio was higher in hospitals with low primary/total PCI volume ratio, even in those with high total PCI volume.

CONCLUSIONS: Primary, elective, and total PCI volume at hospitals were inversely associated with in-hospital mortality in patients with acute MI undergoing primary PCI. Lower ratio of primary to total PCI volume were related to higher in-hospital mortality, suggesting primary/total PCI volume ratio as an institutional indicator of quality of care for acute MI.

Key Words: mortality ■ myocardial infarction ■ percutaneous coronary intervention ■ volume-outcome relationship

Clinical outcomes of patients with acute myocardial infarction (MI) have considerably improved in recent decades with advances in early reperfusion therapy and established medical treatments, and primary percutaneous coronary intervention (PCI) has become a standard-of-care procedure in acute MI.^{1,2} To date, numerous studies have showed that total PCI volume at each institution is inversely associated with in-hospital mortality after the PCI procedures.³ In terms of PCI for acute MI, higher primary PCI volume reportedly contributes to a reduced risk of mortality and complications after acute MI.⁴⁻⁷ However, only a

few studies have reported the relation of total procedural volume including elective and primary PCI to outcomes of acute MI.^{8,9} A French registry, which included 37 848 total PCIs from 44 centers indicated an inverse relation between hospital total PCI volume and mortality for emergency PCIs.⁸ On the other hand, a recent Japanese nationwide database study demonstrated that annual number of patients with acute MI at hospitals rather than annual total PCI volume was associated with better 30-day mortality in patients with acute MI,¹⁰ suggesting the differences in expertise and skills needed between acute MI and elective cases. Because

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CLINICAL PERSPECTIVE

What Is New?

- Lower primary percutaneous coronary intervention (PCI) volume per hospital was associated with an increased risk of in-hospital mortality in patients with acute myocardial infarction.
- Lower elective and total PCI volume at hospitals were also associated with higher in-hospital mortality.
- Lower ratio of primary to total PCI volume was another factor related to higher in-hospital mortality in patients with acute myocardial infarction undergoing primary PCI.

What Are the Clinical Implications?

- Primary, elective, and total PCI volume and primary/total PCI volume ratio may be an institutional indicator of quality of care for acute myocardial infarction.

Nonstandard Abbreviations and Acronyms

DPC diagnosis procedure combination

patients with acute MI need specific medical care including immediate PCI with short door-to-balloon time, mechanical support, and post-reperfusion care, higher PCI volume for elective cases may not translate into better clinical outcomes in acute MI at hospital level. The aim of the present study was to evaluate the impact of PCI volume for acute MI and elective cases and their ratio on clinical outcomes of patients with acute MI undergoing primary PCI in a contemporary setting.

METHODS

Data Source

The data that support the findings of this study are available from the corresponding author upon reasonable request. The Diagnosis Procedure Combination (DPC) system is a case-mix classification system to calculate reimbursements from insurers to acute care hospitals in Japan. The present study used the DPC database, which consists of administrative claim data regularly collected from participating hospitals under the DPC system.¹¹ The DPC database includes inpatient information such as disease diagnosis, comorbidities, Killip class on admission, the use of mechanical support (intra-aortic balloon pumping and extracorporeal membrane oxygenation), and medications. Diseases were identified with the *International Classification of Disease, Tenth Revision*

(*ICD-10*) codes. The accuracy of the disease diagnosis of the DPC database with *ICD-10* codes was previously validated.¹² The database also includes information on the use of medical resources, diagnostic tests, and surgical procedures. This study was approved by the ethical committee of Chiba University (unique identifier: 3309). Because the data were fully anonymized, the requirement for informed consent was waived.

Study Population

From February 2014 to March 2018, a total of 96 396 patients (age ≥ 18 years) from 170 hospitals across entire regions of Japan underwent PCI for either acute MI including ST-segment and non ST-segment elevation MI or elective cases. Patients with no antithrombotic medications recorded ($n=12\ 608$) and patients from a hospital where in-hospital mortality was 0% ($n=702$) or no primary PCI for acute MI was performed ($n=10$) were excluded (Figure 1). Thus, the dataset included a total of 83 076 patients undergoing PCI from 154 hospitals, in which patients with acute MI were identified with following criteria: (1) *ICD-10* codes for acute MI (I21.0, I21.1, I21.2, I21.3, I21.4, and I21.9) and (2) patients who underwent primary PCI within 24 hours from hospital admission. In the present study, PCI procedures not for acute MI were considered as elective PCIs. The annual number of total PCI was defined as the number of primary PCI for acute MI plus elective PCI procedures per year at hospital level. The ratio of volume of primary to total PCI was calculated at each hospital as a primary metric.

Outcomes and Statistical Analysis

The primary outcome of the present study was in-hospital mortality in patients with acute MI undergoing primary PCI at hospital level. The associations of (1) primary PCI volume, (2) total PCI volume, and (3) primary/total PCI volume ratio, with in-hospital mortality after acute MI were evaluated. Statistical analysis was performed with SAS software version 9.4 (SAS Institute, Cary, USA). All data are expressed as mean \pm SD, median [interquartile range], or frequency (%). Continuous variables were assessed with Student *t* test, and categorical variables were compared with Fisher's exact test. Variables of baseline characteristics except for medications (Table), which were all significantly associated with in-hospital mortality, were used to calculate predicted mortality per patient with acute MI using a mixed-effects multivariate logistic regression model.¹³ The accuracy of the model was assessed with C-statistics. The model was applied to all patients with acute MI for predicting in-hospital mortality, and patient-level predicted mortality was averaged at each hospital. Observed in-hospital mortality was compared with predicted mortality at hospital

Table. Baseline Characteristics

Variable	All (n=26 913)	In-hospital death (+) (n=1561)	In-hospital death (-) (n=25 352)	P value
Age, y	69.2±12.7	75.7±12.0	68.8±12.7	<0.001
Male	20 422 (75.9%)	1066 (68.3%)	19 356 (76.4%)	<0.001
Body mass index, kg/m ²	24.0±3.8	23.2±4.0	24.0±3.8	<0.001
Hypertension	18 365 (68.2%)	449 (28.8%)	17 916 (70.7%)	<0.001
Diabetes	8469 (31.5%)	363 (23.3%)	8106 (32.0%)	<0.001
Dyslipidemia	19 255 (71.6%)	318 (20.4%)	18 937 (74.7%)	<0.001
Anterior MI	11 414 (42.4%)	774 (50.0%)	10 640 (42.0%)	<0.001
Killip class				<0.001
Killip 1	12 535 (46.6%)	142 (9.1%)	12 393 (48.9%)	
Killip 2	6578 (24.4%)	194 (12.4%)	6384 (25.2%)	
Killip 3	1881 (7.0%)	171 (11.0%)	1710 (6.8%)	
Killip 4	3249 (12.1%)	789 (50.5%)	2460 (9.7%)	
Undetermined	2670 (9.9%)	265 (17.0%)	2405 (9.5%)	
Cardiac arrest	967 (3.6%)	353 (22.6%)	614 (2.4%)	<0.001
IABP	3194 (11.9%)	701 (44.9%)	2493 (9.8%)	<0.001
ECMO	423 (1.6%)	278 (17.8%)	145 (0.6%)	<0.001
Medication				
Aspirin	26 367 (98.0%)	1344 (86.1%)	25 023 (98.7%)	<0.001
P2Y12 inhibitor	26 362 (98.0%)	1493 (95.6%)	24 869 (98.1%)	<0.001
Oral anticoagulant	3334 (12.4%)	159 (4.8%)	3175 (12.5%)	<0.001
Statin	23 443 (87.1%)	855 (54.8%)	22 588 (89.1%)	<0.001
ACEI or ARB	16 440 (61.1%)	371 (23.8%)	16 069 (63.4%)	<0.001
β-blocker	18 270 (67.9%)	466 (29.9%)	17 804 (70.2%)	<0.001
Proton pump inhibitor	23 380 (86.9%)	1032 (66.1%)	22 348 (88.2%)	<0.001
Mechanical complications	212 (0.8%)	108 (6.9%)	104 (0.4%)	<0.001

Data are mean±SD or n (%). Mechanical complication includes papillary muscle rupture, ventricular septal perforation, and free wall rupture. ACEI indicates angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pumping; and MI, myocardial infarction.

level, calculating observed/predicted in-hospital mortality ratio.¹⁴ The relations of primary and total PCI volumes and primary/total PCI ratio to observed and predicted mortality and observed/predicted mortality ratio were evaluated using the locally weighted scatterplot smoother plot (LOWESS) with 95% CIs. The 3-dimensional, smoothed surface plots were created using PROC G3GRID with spline interpolation as the smoothing algorithm. A $P < 0.05$ was considered statistically significant.

RESULTS

Of 83 076 patients, 26 913 (32.4%) from 154 hospitals underwent primary PCI for acute MI, among whom 1561 (5.8%) died during the hospitalization (Figure 1). Table lists baseline characteristics. Annual PCI volumes for acute MI, elective cases, and both at each hospital are shown in Figure 2. The median ratio of volume of primary to total PCI volume was 0.30 [0.20, 0.40] (Figure 2). The relation between annual total PCI

volume and primary/total PCI volume ratio at hospital is shown in Figure S1. All variables listed in Table except for medications were used to calculate predicted mortality, resulting in C-index of 0.934 (95% CI, 0.923–0.941) for estimating observed mortality (Table S1). The relations of primary, elective, and total PCI volume per year per hospital to observed and predicted mortality and observed/predicted mortality ratio are shown in Figure 3. Overall, observed mortality and observed/predicted mortality ratio were higher in hospitals with lower annual PCI volumes. Figure 4 displays that hospitals with lower ratio of volume of primary to total PCI were likely to have higher predicted mortality, while hospitals with higher primary/total PCI volume ratio tended to treat lower-risk MI patients. Observed/predicted in-hospital mortality ratio was higher in hospitals with lower primary/total PCI volume ratio irrespective of annual total PCI volume, and facilities with higher primary/total PCI volume ratio especially in those with low annual total PCI volume (Figure 4). As a sensitivity analysis, we excluded hospitals with annual primary

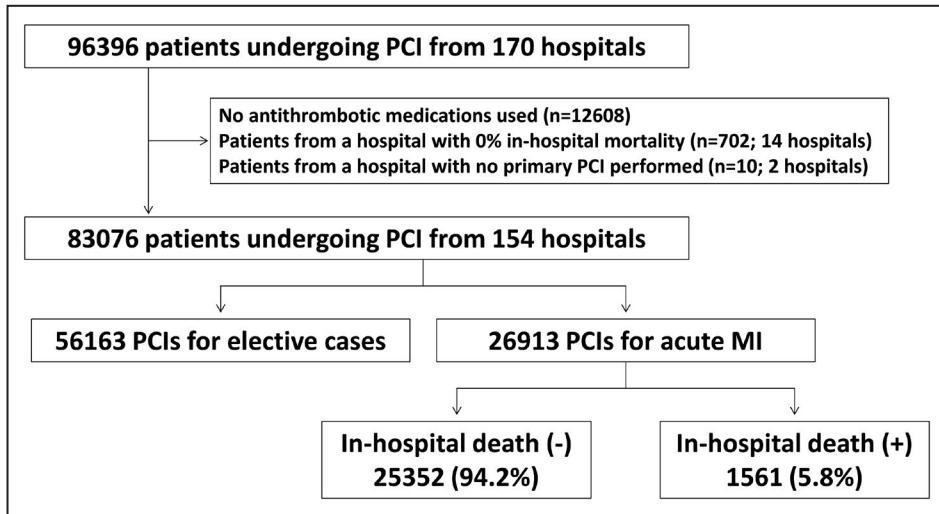


Figure 1. Study flow.
MI indicates myocardial infarction; and PCI, percutaneous coronary intervention.

PCI volume <10, showing similar results as displayed in Figure S2.

DISCUSSION

The present study confirmed the fact that the number of PCI procedures performed in each hospital ranged widely, and observed in-hospital mortality compared with predicted mortality was higher in hospitals with lower primary PCI volume per year

than those with higher primary PCI volume. This study also demonstrated that lower PCI volume for elective cases was associated with an increased risk of in-hospital death after primary PCI for acute MI at hospital level. However, even if many elective PCI procedures were performed, lower primary/total PCI volume ratio was associated with higher observed/predicted in-hospital mortality ratio, suggesting primary/total PCI volume ratio as a surrogate for quality of care for acute MI.

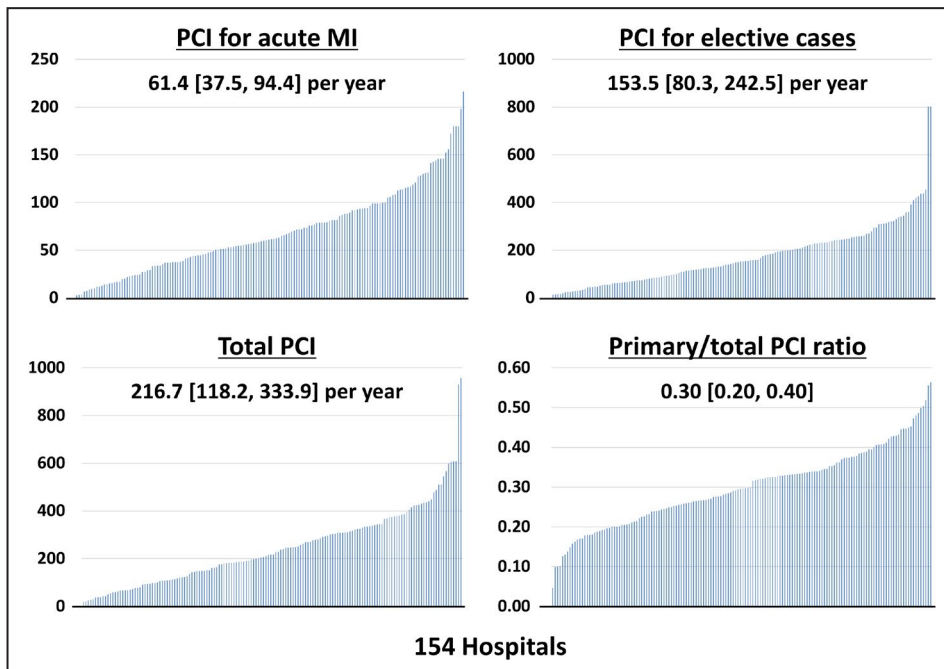


Figure 2. Volumes of primary, elective, and total PCI, and ratio of primary to total PCI volume at hospitals.
MI indicates myocardial infarction; and PCI, percutaneous coronary intervention.

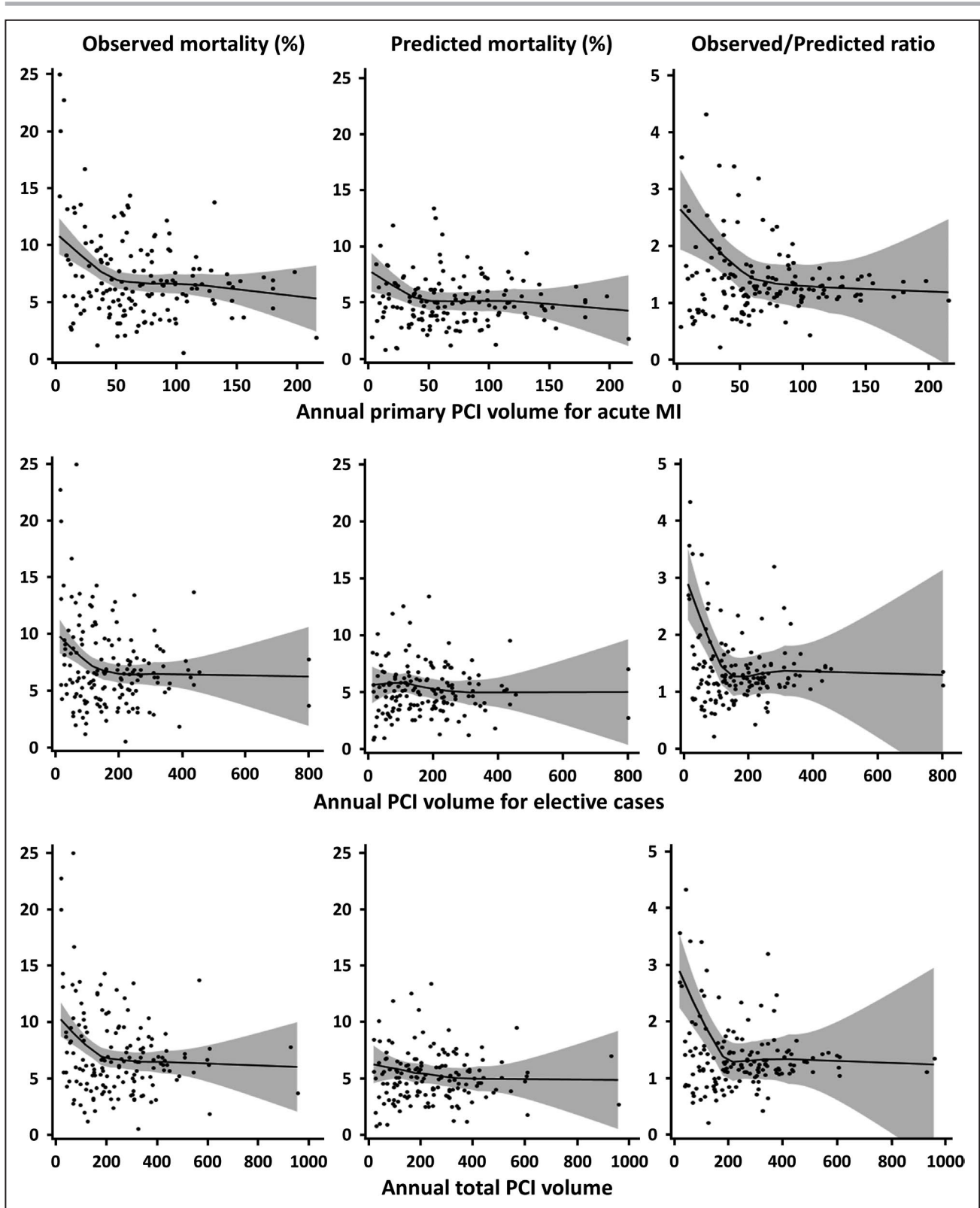


Figure 3. Relations of primary, elective, and total PCI volumes to observed and predicted in-hospital mortality and observed/predicted mortality ratio after acute MI. MI indicates myocardial infarction; and PCI, percutaneous coronary intervention.

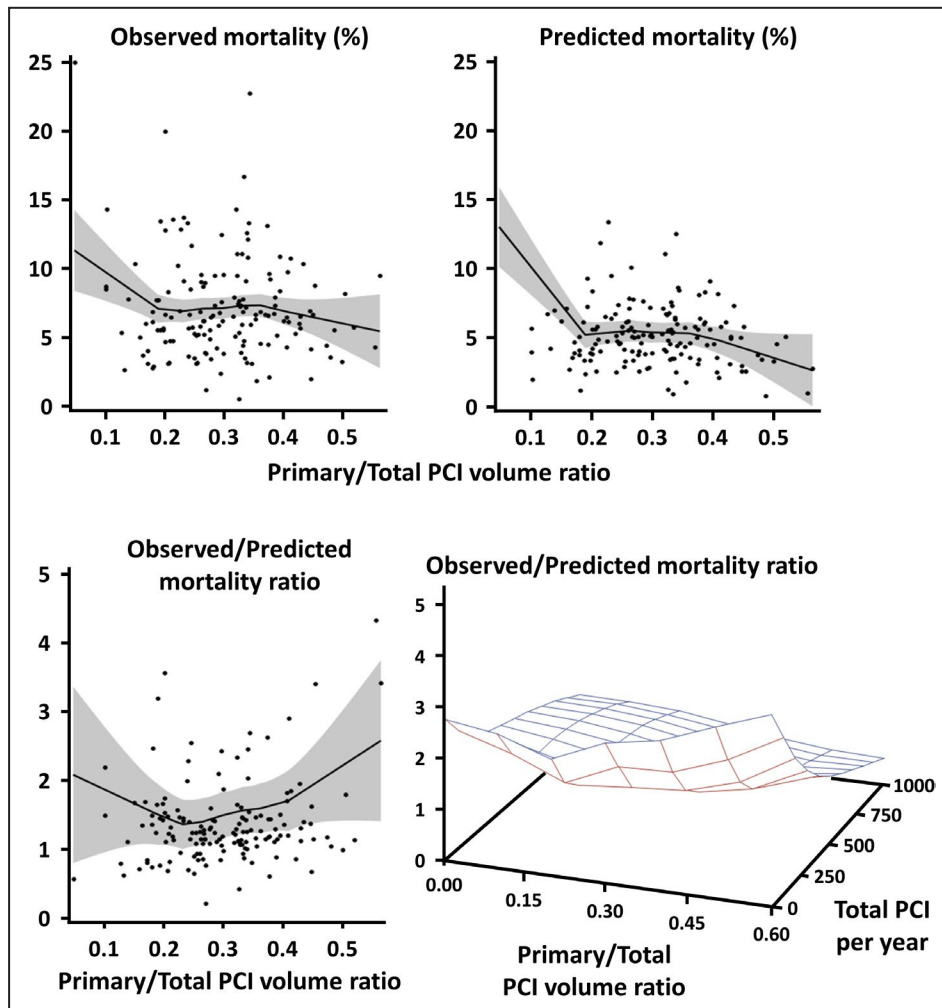


Figure 4. Relations of primary/total PCI volume ratio to observed and predicted in-hospital mortality after MI.

MI indicates myocardial infarction; and PCI, percutaneous coronary intervention.

PCI Volume and Outcomes

It is well known that the number of PCI procedures performed in each hospital widely varies worldwide. In the present study, median annual total PCI volume per hospital was 216.7 [118.2, 333.9], which is quite concordant with a different nationwide cohort study in Japan (ie, 216 [121, 332]),¹⁵ but the number is much lower than that in Western countries.^{14,16} Previous studies have demonstrated that hospitals with higher primary PCI volume have an advantage in better clinical outcomes in patients with acute MI compared with institutions with lower primary PCI volume, which may be explained by skills in primary PCI including shorter door-balloon time, hospital processes of care, and interdepartmental and interdisciplinary co-ordination.⁴⁻⁷ Suggested cut-off values for the number of annual primary PCI per hospital reportedly include 20, 36, 40, 50, 60, and 115,^{5,17-19} and previous guidelines indicated 36 as the cut-off value for annual primary PCI volume

at facilities.³ The present study showed that observed/predicted mortality ratio was increased especially in hospitals with annual primary PCI volume <50 to 60 cases on visual assessment on the LOWESS analysis, which is in line with previous reports. A recent retrospective observational study in Japan indicated 115 as the cut-off value,⁵ but in fact, the in-hospital mortality after acute MI at each hospital rapidly increased in institutions with primary PCI volume <50 to 60/year in that Japanese study.⁵ Taken together, the optimal cut-off value for annual primary PCI volume per hospital may be around 50, although a specific threshold was undetermined.

Beyond the relation between primary PCI volume and clinical outcomes following acute MI, the present study found that elective and total PCI volume were also inversely associated with in-hospital mortality after primary PCI for acute MI. Larger PCI volume for elective cases may be translated into higher-quality primary

PCI and improved outcomes in acute MI, but expertise and skills needed in acute MI and elective cases are different. Thus, even though some studies done in 2 decades ago alluded the association of larger PCI volume for elective cases with better outcomes in acute MI at hospital level,^{8,9} it remains to be established. In this context, the present study demonstrated that lower elective and total PCI volume was significantly associated with higher observed/predicted mortality ratio after acute MI in a contemporary and standardized setting of primary PCI in Japan. Therefore, it is conceivable that primary PCI-capable hospitals should ideally perform both primary and elective PCI procedures in a certain volume (eg, >50 and 150 cases per year for primary and elective procedures in Japan).

Ratio of Primary to Total PCI Volume

One of the most important findings of the present study was the relation between primary/total PCI volume ratio per hospital and clinical outcomes after primary PCI for acute MI. The median ratio was 0.30 [0.20, 0.40] in the present study as well as other previous studies in Japan, which was lower than that in Western countries (ie, 0.6–0.7).¹⁶ Elective PCIs are unlikely to be considered appropriate procedures compared with those for acute coronary syndrome.²⁰ Given that high PCI volume centers are predisposed to perform more elective PCI procedures than those for acute MI, these hospitals seem to perform more “may be appropriate” and “rarely appropriate” PCI procedures.²¹ Although whether appropriate use of PCI is associated with clinical outcomes after the procedures remains uncertain,^{22–24} the primary/total PCI volume ratio may be a surrogate of PCI appropriateness and could be an indicator of clinical outcomes after primary PCI for acute MI at hospital level. Indeed, in the present study, when a hospital performed PCI in a certain volume but predominantly with elective cases (eg, primary/total PCI volume ratio <0.2), observed/predicted in-hospital mortality ratio after primary PCI for acute MI was high. Interestingly, hospitals with higher primary/total PCI volume ratio tended to treat more patients with acute MI with low predicted mortality, and the higher primary/total PCI ratio was also associated with a slightly increased observed/predicted mortality ratio especially in low total PCI volume centers. These findings suggest that even if a hospital perform primary PCI in a certain volume for low-risk acute MI, this may not be translated into better medical care in high-risk MI patients. Lower and higher cut-off values of primary/total PCI ratio should be different in various settings (eg, Eastern versus Western countries), and further studies are needed to confirm our results and to determine the thresholds.

Limitations

Several limitations to our study should be considered. This was a retrospective study using the DPC administrative database, which does not provide detailed clinical information including laboratory findings, ST-segment elevation on ECG, and door-to-balloon time. The sample size is large to reflect clinical practice for acute MI in Japan,^{25–29} but there may be residual confounding factors. CIs of the LOWESS were wide, especially in higher volume hospitals (Figure 3). In the present study, subgroup analyses including different age groups and Killip classes were not performed. Despite the previous validation of the DPC database,¹² the data in part may not accurately reflect the presence and severity of clinical conditions due to the nature of claims database studies. Killip class was undetermined in ≈10% of patients in the present study, which is in line with a previous study using DPC database.¹⁰ In addition, operator volume data are not available, although it is controversial whether operator rather than hospital volume for PCI procedures is associated with in-hospital mortality.¹⁵ Because of the nature of observational study, the present investigation does not indicate causal relations of primary and total PCI volume, and primary/total PCI volume ratio to in-hospital mortality after primary PCI for acute MI.

CONCLUSIONS

The present Japanese nationwide observational study reinforced that hospital primary PCI volume inversely associated with in-hospital mortality in patients with acute MI undergoing PCI. In addition, hospitals with lower elective and total PCI volumes had higher observed in-hospital mortality than predicted. A lower ratio of primary to total PCI volume per hospital was associated with higher observed/predicted in-hospital mortality ratio irrespective of total PCI volume, suggesting primary/total PCI volume ratio as an institutional indicator of quality of care for acute MI.

ARTICLE INFORMATION

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None.

Disclosures

None.

Supplemental Material

Table S1

Figures S1–S2

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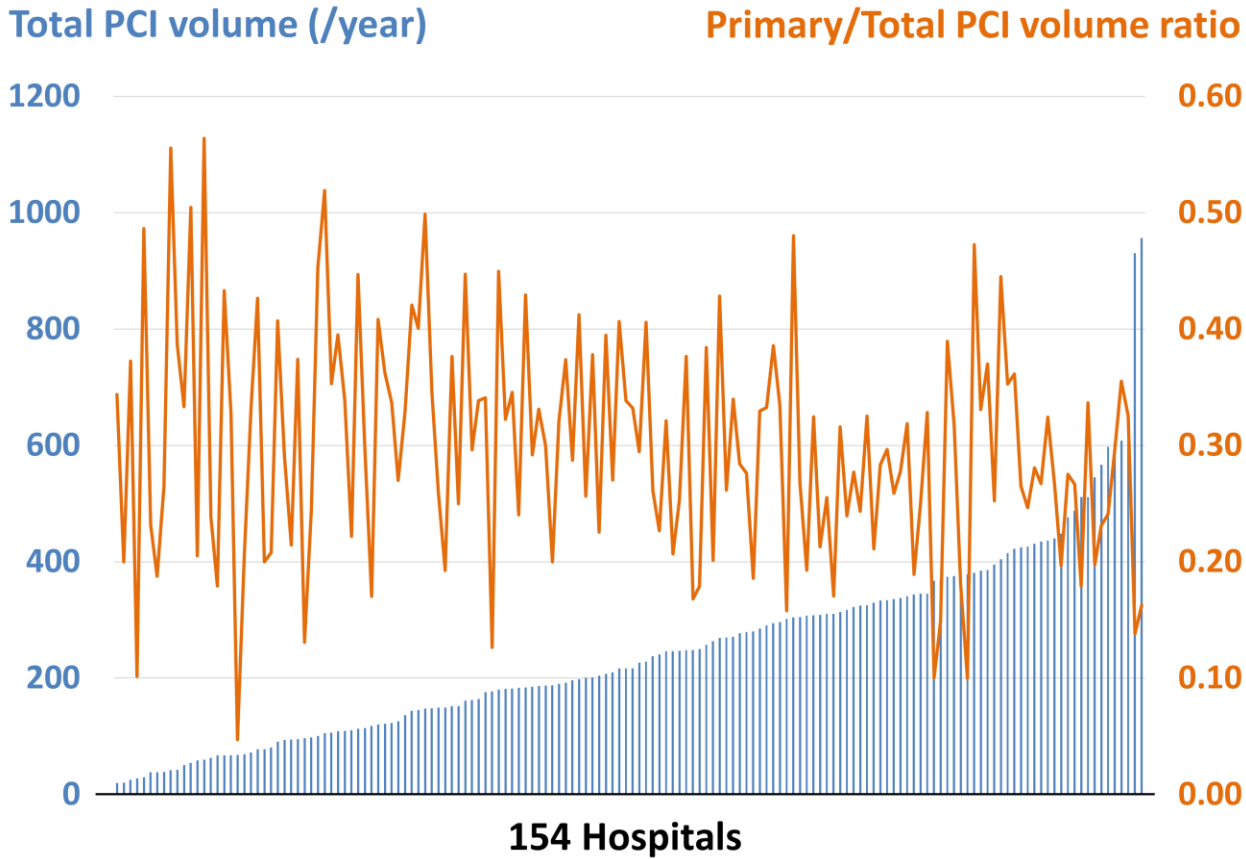
SUPPLEMENTAL MATERIAL

Table S1. Multivariate Logistic Regression for In-Hospital Mortality.

Variable	OR (95% CI)	
Age (years)	1.06 (1.05-1.07)	<0.001
Male	1.00 (0.85-1.17)	>0.99
Body mass index (kg/m ²)	1.01 (0.99-1.03)	0.18
Hypertension	0.42 (0.36-0.49)	<0.001
Diabetes mellitus	0.72 (0.61-0.84)	<0.001
Dyslipidemia	0.24 (0.20-0.28)	<0.001
Anterior MI	1.20 (1.04-1.38)	0.01
Killip class		
Killip 1	0.13 (0.10-0.16)	<0.001
Killip 2	0.26 (0.21-0.32)	<0.001
Killip 3	0.64 (0.51-0.80)	<0.001
Killip 4	Reference	
Undetermined	0.52 (0.40-0.66)	<0.001
Cardiac arrest	2.39 (1.91-2.99)	<0.001
IABP	2.81 (2.39-3.29)	<0.001
ECMO	9.66 (7.25-12.87)	<0.001
Mechanical complications	10.74 (7.49-15.40)	<0.001

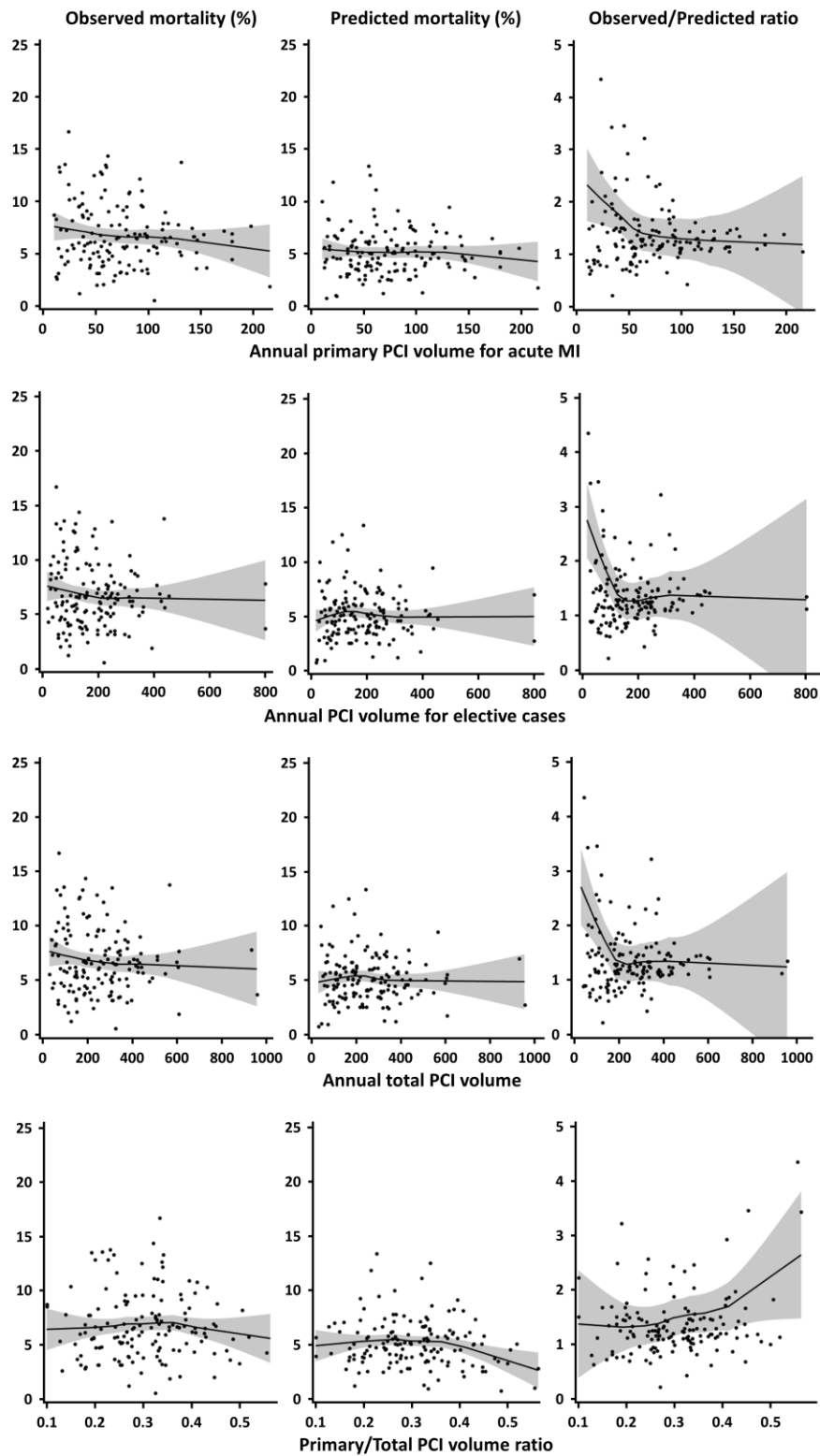
CI, confidence interval; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pumping; MI, myocardial infarction; OR, odds ratio.

Figure S1. Relation Between Total PCI Volume and Primary/Total PCI Volume Ratio.



PCI, percutaneous coronary intervention.

Figure S2. Relations of Primary, Elective, and Total PCI Volumes and Primary/Total PCI Volume Ratio to Observed and Predicted Mortality and Observed/Predicted Mortality Ratio.



MI, myocardial infarction; PCI, percutaneous coronary intervention.