Relationship Between Hospital Volume and Outcomes Following Primary Percutaneous Coronary Intervention in Patients With Acute Myocardial Infarction

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**Background:** Primary percutaneous coronary intervention (PCI) is an important treatment option for patients with acute myocardial infarction (MI). Although an inverse association between a hospital's PCI volume and in-hospital mortality has been observed in Western studies, previous Japanese investigations have not found any such relationship.

**Methods and Results:** A retrospective analysis of 8,391 cases of acute MI, obtained from administrative data from 2006. The primary outcome was in-hospital mortality. Hospitals were divided into quartiles based on the number of PCI procedures per half-year (6–13, 14–22, 23–38, 39–134) and mortality rates were compared across the groups. Crude-mortality in the lowest-volume quartile was 7.0%, compared with 4.9% in the highest-volume quartile. An inverse association was found between primary PCI procedure volume and crude in-hospital mortality (P=0.016). After case-mix adjustment, a significant decrease in mortality risk for patients treated at high-volume (3rd and 4th quartile) hospitals compared to the lowest-volume (1st quartile) hospitals was found.

**Conclusions:** Based on this administrative data, there is an inverse association between a hospital's primary PCI volume and in-hospital mortality for patients with acute MI. Periodic outcomes research is necessary in conjunction with progress in PCI practice and technology to establish the recommended PCI volume and regionalization for improvements in care. (Circ J 2011; 75: 1107–1112)

**Key Words:** Acute myocardial infarction; Administrative data; In-hospital mortality; Percutaneous coronary intervention

For many surgical procedures there is a well-known inverse association between a hospital’s procedure volume and patient mortality. In cardiology, the association between hospitals’ percutaneous coronary intervention (PCI) volume and in-hospital mortality has been extensively investigated, and many earlier studies demonstrated that patients with acute myocardial infarction (MI) at hospitals performing more primary PCI procedures had lower mortality rates than those at hospitals with less primary PCI volume. Based on this evidence, the updated American College of Cardiology/American Heart Association/Society for Cardiovascular Angioplasty and Intervention (ACC/AHA/SCAI) PCI clinical practice guideline recommends that the minimum institutional volume requirement for hospitals offering PCI for ST-segment elevation MIs (STEMI) should be 400 elective and 36 primary PCI procedures per year.

It is well established that primary PCI is more effective than thrombolytic therapy for the treatment of STEMI. In Japan, primary PCI is widely favored over thrombolytic therapy as a treatment strategy for patients with acute MI, and compared with Western countries, the proportion of patients undergoing primary PCI in Japan is very high. The association between a hospital’s primary PCI volume and in-hospital mortality has also been assessed in Japan, but no studies to date have found the inverse association that has been demonstrated in many similar Western studies. However, there have been recent changes in PCI practice, with PCI with stent placement being performed more often than balloon angioplasty as coronary stent technology has progressed (eg, drug-eluting stents). We thus felt it important to reassess this potential association using a larger and more current patient sample.

The objective of this study was to assess the association between hospitals’ primary PCI procedure volumes and outcomes among patients with acute MI who underwent primary PCI in 2006.
Methods

Data Source and Study Population

The data source for this study consisted of discharge claim records from Japanese hospitals that were either using or preparing to implement the Diagnosis Procedure Combination (DPC) code as a payment scheme in 2006. The data were voluntarily offered to the DPC study group by the hospitals that agreed to be used for research by the DPC study group. The data were anonymous and could not be linked with any other information to identify patients when they were collected by the research group. The study was given prior approval by the Ethics Committee of Tokyo Medical and Dental University.

The data contained patient information on the most resource-consuming diseases, comorbidities, complications, demographics, procedures, medications, and materials. We used discharge data from July through December 2006. For the purposes of this study, we selected patients with MI if their DPC classification at discharge was MI-related (DPC code: 050030) and the most resource-consuming disease during their hospitalization was identified as acute MI (I21.0–21.9) by International Classification of Diseases (ICD-10) coding. We included patients who underwent a PCI procedure, and we excluded patients who received thrombolytic agents during their reperfusion therapy in order to limit the sample to primary PCI patients. Additionally, if patients were hospitalized more than once, only the data from the first hospitalization were used in order to maintain the independence of observations. Finally, patients who underwent PCI followed by coronary artery bypass grafting were also excluded. Of the 12,380 records with DPC code 050030, 12,157 records were found to indicate patients who were hospitalized for acute MI, and 8,555 patients who underwent a primary PCI were selected for inclusion.

Hospital Primary PCI Volume Group

We calculated the hospital primary PCI volume as the total number of patients who underwent primary PCI procedures at each hospital during the second half of 2006. Hospitals were excluded if the number of PCI procedures performed during the period of study was fewer than 6 (ie, fewer than 1 per month) because those hospitals could make coding errors and their performance may be inconsistent due to the low-volume. We considered using tertile, quartile, or quintile groupings as the threshold to categorize hospitals, but based on the distribution of hospital volumes (Figure), groupings by quartile were chosen, as the tertile threshold included quite a broad range of procedural experience and the quintile threshold included too narrow a range of procedural experience in the highest tertile. We defined the 1st and 2nd quartile groups as low-volume and the 3rd and 4th quartile groups as high-volume hospitals.

Variables for Analysis

The outcomes of interest were in-hospital mortality following primary PCI and the length of hospital stay (LOS). Patient characteristics such as urgency of admission, transport by ambulance, and the number of stents used were also analyzed. In order to adjust for the impact of patient comorbidity status on in-hospital mortality, the Charlson comorbidity index, which is widely used for risk adjustment in outcome studies using administrative data, was determined based on the Quan version. In addition, supplementary cardiac interventions and procedures during reperfusion therapy were assessed to compare hospital performance.

Statistical Analysis

Patients’ characteristics were compared across the 4 hospital primary PCI volume groups using a Mantel-Haenszel chi-
square test for trend (categorical variables) and analyses of variance (continuous variables). Supplementary interventions and procedures were also analyzed in the same manner. The mean and standard deviation (SD) LOS of each group were calculated and compared with the analysis of variance after transformation with a natural logarithm.

The in-hospital crude-mortality rate was compared with a Mantel-Haenszel chi-square test for trends to investigate any inverse association between hospital volume and in-hospital mortality. An unadjusted logistic regression model was used to assess any increase in the risk of in-hospital mortality compared with the lowest quartile group’s performance. Multivariate logistic regression models, adjusting for patient characteristics, were then created to assess the association between in-hospital mortality and hospital primary PCI volume. We used the generalized estimating equation approach for the logistic regression model in order to account for any clustering effects within each hospital. All analyses were carried out using SAS 9.1 (SAS Institute Inc, Cary, NC, USA) statistical software. A 2-sided P-value <0.05 was considered statistically significant.

**Results**

**Patients’ Characteristics**
The original target population was 8,555 patients, but the final analysis included 8,391 patients from 303 hospitals after excluding 164 patients from 59 hospitals, each of which performed fewer than 6 PCI procedures in the 6 months under review. The hospital primary PCI volume ranged from 6 to 134 patients, with a mean of 27.7 and a median of 22 procedures. As presented in Table 1, 776 (9.3%) patients were treated at 83 hospitals in the 1st (lowest-volume) quartile group, 1,245 (14.8%) were treated at 69 hospitals in the 2nd quartile group, 2,328 (27.7%) were treated at 78 hospitals in the 3rd quartile group, and 4,042 (48.2%) were treated at 73 hospitals in the 4th (highest volume) quartile group.

**Supplementary Procedures**
As presented in Table 3, rates of supplementary cardiac interventions and procedures were not significantly different among the 4 groups.
In-Hospital Mortality

The mean LOS was 20.0 (SD=17.4) days for all patients, 23.3 (19.8) days for the 1st quartile group, 22.8 (19.3) days for the 2nd quartile group, 19.3 (16.1) days for the 3rd quartile group, and 18.9 (16.7) days for the 4th quartile group. Hospitals in the high-volume quartile groups had a mean LOS close to 19 days, and hospitals in the low-volume quartile groups had a mean LOS close to 23 days. The treatment duration for hospitals in the high-volume hospitals were 17% shorter than in the low-volume hospitals. The mean LOS was significantly different across the 4 groups (P<0.001).

In-Hospital Mortality

As shown in Table 4, the trend test revealed an inverse association between hospital primary PCI volume and crude in-hospital mortality (P=0.016). The lowest crude in-hospital mortality was 4.9% in the 4th (highest-volume) quartile group, which was approximately 30% lower than the 1st (lowest-volume) quartile group, in which the in-hospital mortality was 7.0%.

Unadjusted odds ratios showed that patients treated at hospitals in the 4th (highest-volume) quartile group had a significantly decreased risk of in-hospital mortality when compared with hospitals in the 1st (lowest-volume) quartile group (odds ratio (OR) 0.70, 95% confidence interval (CI) 0.51–0.95) (Table 5). Although there was no change in risk between the 4th and 1st quartile groups after adjustment for age and sex, the multivariate adjustment model showed that patients treated at hospitals in the high-volume quartile groups had a significantly decreased risk of in-hospital mortality when compared with hospitals in the 1st (lowest-volume) group (OR 0.70, 95%CI 0.50–0.98; OR 0.66, 95%CI 0.47–0.93, respectively). Patients treated at the 2nd quartile group hospitals did not show any decreased risk for in-hospital mortality in any unadjusted or adjusted models. The multivariate model also found older age (OR 1.90 per 10-year increase, 95%CI 1.71–2.12), female sex (OR 1.31, 95%CI 1.05–1.62), and arrival by ambulance (OR 1.86, 95%CI 1.47–2.35) to be significant risk factors after adjusting for case mix. On the other hand, both single and multivessel stent use were associated with a decreased risk of in-hospital mortality when compared to no stent use (OR 0.52, 95%CI 0.39–0.70; OR 0.68, 95%CI 0.50–0.94, respectively).

We also performed additional analyses using other group thresholds to check the consistency of these results. Using tertile thresholds (6–16, 17–31, 32–134), similar results for in-hospital mortality were obtained (6.4%, 5.5%, 5.1% in low-, medium-, and high-volume groups, respectively). Although not statistically significant, high-volume hospitals showed a trend toward reduced risk of mortality compared to low-volume hospitals (OR 0.75 95%CI 0.55–1.01, P=0.054). Using quintile thresholds (6–11, 12–19, 20–28, 29–41, 42–134), hospital PCI volume was analyzed as a continuous variable because of the relatively narrow range of hospital volumes. When this continuous variable was entered in the multivariate adjusted model, the odds ratio for a 10-procedure increase in primary PCI volume was 0.94 (95%CI 0.89–0.99, P=0.012). Finally, we repeated the analyses to determine any influence of the largest volume hospital (134 PCIs) on the results. After excluding the hospital, crude in-hospital mortality was the same and the OR in the high-volume quartile groups also showed a significantly decreased risk of in-hospital mortality.
Discussion

The present study is the first from Japan to demonstrate an inverse association between primary PCI volume and in-hospital mortality in patients with acute MI. To perform this analysis, we accessed a large patient dataset from geographically diverse hospitals with a wide range of experience in primary PCI. Of note, patients treated at hospitals in the high-volume quartile groups were found to have a significantly lower risk for in-hospital mortality compared with hospitals in the lowest-volume quartile group after adjusting for patient case mix. Since the LOS in high-volume quartile hospitals was shorter than in low-volume quartile hospitals, high-volume hospitals appear to have treated patients in a more cost-effective manner.

There are several possible interpretations of the inverse association between procedure volume and in-hospital mortality. First, physicians and hospital personnel at high-volume hospitals generally have more experience treating a wide variety of patients, which consequently increases their level of individual and organizational skill. The inverse relationship between LOS and PCI volume could also imply that clinical paths are well-followed by high-volume hospitals, suggesting that those hospitals have their own protocols for the treatment of patients from the time of patient presentation to the completion of reperfusion therapy. Time to primary PCI is strongly associated with mortality risk and is an important factor, regardless of time from symptom onset to presentation. However, door-to-balloon time (DBT) data were not available for our current analyses, it has been reported in both Japan and the US that the DBT at high-volume hospitals is shorter than that at low-volume hospitals. That factor may have contributed to the favorable outcomes for high-volume hospitals.

Three previous investigations in Japan did not find an association between PCI volume and in-hospital mortality. One possible reason for this discrepancy is the larger sample size of our study, which may have allowed us to detect the reported inverse association. Additionally, we involved over 300 hospitals in our analyses, a much larger number than previous studies, which allowed for a sufficient number of hospitals within each stratum. Although we used different thresholds than previous studies, analyses with alternative thresholds and a continuous approach both showed similar results. We also excluded 59 hospitals that performed fewer than 6 primary PCI procedures per half-year, which may have been a factor in the difference between our study and previous studies. Finally, the timing of data collection may also be a reason for this difference; for example, I study used national registry analyzed data from 1997, since when the practise and technology of PCI (especially with regard to the frequency of stent use) has improved, notably in the past decade. Interestingly, high-volume hospitals were more likely to use stents in that registry, whereas low-volume hospitals were more likely to use stents in our dataset. Collectively, these reasons make direct comparisons between our report and prior studies difficult.

We believe our findings have important implications for health policy decision-makers, especially with respect to regionalization of hospitals offering primary PCI and the consequent provision of higher quality PCI. Currently, there is no recommendation regarding primary PCI volume for acute MI patients in Japan. Our original data included 174 (48%) of 362 hospitals that would not meet the ACC/AHA recommended minimum volume of 36 primary PCI procedures per year. As evidence to support low-volume hospitals, previous research in the US indicates that low-volume hospitals are likely to treat patients with more severe disease. This finding could be explained by patients having difficulty accessing high-volume hospitals due to geographic constraints or patient preference for hospitals closer to home, ultimately leading low-volume hospitals to accept patients with more severe disease who would otherwise go to high-volume hospitals. However, we did not see such a trend in our dataset. Indeed, high-volume hospitals receiving patients from other hospitals showed better outcomes, indicating that patient transfer is a possible route for improving PCI quality. European randomized trials also support transferring patients from community hospitals to tertiary PCI centers for primary PCI. From a clinical perspective, recent registry study also revealed an increased number of elderly patients with AMI and suggested appropriate treatment for such patients. Given this evidence, there is a need for better strategic approaches from both the clinical and health policy standpoints for the treatment of acute MI patients. These strategies should be based not only on establishing a recommended volume of primary PCI procedures but also on developing regional protocols regarding patient transfers and further controlling coronary risk factors. These improvements will result in improved primary PCI care for patients with acute MI.

Study Limitations

The most serious limitation was a lack of detailed clinical information concerning acute MI. We were limited to administrative data, so clinical data that could have influenced our understanding of in-hospital mortality were not taken into consideration. If clinical data were included in the multivariate model, the differences between the lowest- and high-volume quartiles might have been attenuated. Second, we did not account for information about individual physician PCI volume in calculating the association between hospital volume and in-hospital mortality. The association between physician PCI volume and outcome has not been investigated in Japan, so it is difficult to speculate on what effect this variable might have had on our results. Third, because our sample came from DPC hospitals, the results could have been influenced by selection bias. Especially, our data were collected from voluntary hospitals; therefore, they might have been different from other DPC hospitals that did not offer data. Fourth, our study population possibly excluded severe patients because the choice of DPC code was based on the most resource-consuming disease. In the severe cases with comorbidity such as heart failure, patients may not be defined as DPC 0500030. If those severe cases were included in the study, the results may be different. Finally but importantly, we evaluated only short-term outcomes and were not able to include outcomes such as revascularization rates and longer-term mortality. To assess the effect of primary PCI volume more precisely, these outcomes should be investigated in future evaluations.

In conclusion, based on administrative data from 2006, there is an inverse association between the primary PCI volume of hospitals and both in-hospital mortality and LOS in patients with acute MI. The high-volume group had a significantly reduced risk of mortality compared to the lowest volume group. Periodic research, in conjunction with progress in PCI practice and technology, is necessary to determine recommended PCI volume levels and regionalization for optimal improvements in the quality of care for MI.
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References