



## Trauma/Critical Care

# Volume–outcome relationship in severe operative trauma surgery: A retrospective cohort study using a Japanese nationwide administrative database



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## ABSTRACT

**Background:** The relationship between hospital case volume and in-hospital mortality, often referred to as the volume–outcome relationship, has been studied in various types of surgery. Despite its usefulness in policymaking, it has not been reported in operative trauma surgery. This study aimed to identify the volume–outcome relationship in severe operative trauma surgery.

**Methods:** A retrospective cohort study was conducted using a risk adjustment method based on the International Classification of Diseases 10th Revision Codes in a Japanese nationwide administrative database. Patients discharged from July 1, 2010, to March 31, 2015, who underwent severe operative trauma surgery, defined as having a mortality rate equal to or greater than 10%, were included. A logistic regression model with random effects was used for analysis. Annual hospital case volume was categorized into 4 groups: <6 (reference group), 6 to 11, 12 to 17, and  $\geq 18$ . Subgroup analysis on head and torso trauma surgery was conducted.

**Results:** The study population consisted of 18,382 patients from 964 hospitals. Overall mortality was 19.7%. The adjusted odds ratio for mortality did not reduce significantly in the higher hospital case volume category. Subgroup analysis revealed that the adjusted odds ratio reduced significantly in the subgroup of torso surgery (<6 cases/y [reference] vs  $\geq 6$  cases/y; adjusted odds ratio, 0.55; 95% confidence interval, 0.42–0.73), but not in the operative head trauma surgery subgroup.

**Conclusion:** A volume–outcome relationship was not identified in severe operative trauma surgery but was observed in the operative torso trauma surgery subgroup.

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## Introduction

An inverse association between hospital case volume and in-hospital mortality, often referred to as a “volume–outcome relationship,”<sup>1–4</sup> has been reported among various types of surgeries and diseases, particularly in surgeries with high mortality. Existing findings suggest that a high volume of cases is a proxy for the structures or processes in a hospital that lead to good outcomes. Furthermore, based on the assumption that higher hospital case volume leads to lower in-hospital mortality, centralizing patients in

high-volume hospitals has been suggested. For example, in the United States, level 1 trauma centers are required to have at least 1,200 trauma admissions and at least 240 admissions with an Injury Severity Score higher than 15.<sup>5</sup> Centralization requires systemic change, which is a fundamental strategy in quality improvement.<sup>6</sup> Such changes can yield a more consistent and widespread effect compared with localized or individual ones. Therefore, evidence on the volume–outcome relationship is particularly beneficial from a public health standpoint.

However, few studies have reported the volume–outcome relationship in operative trauma surgery, although mortality in trauma remains high and improving the quality of care is an urgent issue.<sup>7,8</sup> Meanwhile, an increasing proportion of trauma patients are managed non-operatively, leading to a decrease in the number of operative trauma surgeries performed by surgeons.<sup>9</sup> Therefore, setting a requirement for the minimum number of operative

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trauma surgeries will be required to maintain the quality of care. The volume–outcome relationship in trauma patients, regardless of surgical status, has been studied,<sup>10–13</sup> but analysis of operative trauma surgeries has not been reported. The American College of Surgeons Committee on Trauma has not set a requirement for the minimum number of operative trauma surgeries in trauma centers. This study aimed to identify the volume–outcome relationship in operative trauma surgery using a risk adjustment method based on the International Classification of Diseases 10th Revision Codes (ICD-10) in a Japanese nationwide administrative database.

## Methods

This study used a retrospective cohort study design to analyze the association between in-hospital mortality and the number of patients who underwent operative trauma surgery per hospital. The data were obtained from the Diagnostic Procedure Combination (DPC) database, an administrative inpatient database for billing purposes in Japan. The DPC database contains claims data from more than 1,100 hospitals, which covers about 50% of acute care hospitalizations in Japan. Hospitals that participate in the DPC payment system must be acute care hospitals and meet a certain level of nurse allocation (ie, a high number of nurses allocated compared to the number of patients admitted). Participation in the DPC payment system is voluntary; however, given that data is used for optimizing care, and participation is expected to increase profitability, many acute care hospitals participate in this system. All university hospitals and about 97% of tertiary emergency care centers participated in the DPC system during the study period. Patients who died in the outpatient setting (usually in the emergency room) are included in the database.

The ICD-10 is used for coding diseases, and 4 primary diagnoses and a maximum of 4 concurrent diagnoses on admission is recorded. Surgical procedures are also recorded, with a maximum of 5 procedures that can be added to the record. The codes for surgeries and procedures are uniquely developed for billing purposes in Japan. Only 1 major surgery can be claimed for a single operation site. For example, either a colectomy or a small intestinal resection can be claimed for abdominal surgery. If the operation site differs, both surgeries, for example, a colectomy and pulmonary lobectomy, can be claimed. However, in certain cases, 2 surgeries can be claimed, even if they are performed at the same time. A list of those surgeries is provided in [Supplemental Text 1](#). More details on the DPC database are provided elsewhere.<sup>14</sup>

The requirement for obtaining informed consent for each participant was waived because all data were de-identified and handled anonymously. This study was approved by the ethics committee of the Tokyo Medical and Dental University (M2000-788).

### Patient Selection and Variables

Patients who were discharged from the hospital between July 1, 2010 and March 31, 2015 were included in the study. Patients were eligible if they had the following characteristics: diagnosis of trauma recorded in 1 of the 4 primary diagnoses, brought to the hospital by ambulance, 15 years old or older, discharged on day 3 or later, and underwent severe operative trauma surgery. The ICD-10 codes chosen for the diagnosis of trauma were S00.0 to T14.9. We did not include patients who were discharged on day 1 or 2 after admission because the conditions of those patients were considered too severe or too mild for their outcomes to be attributed to the quality of care at the hospital. Furthermore, by not including these patients, transfer cases who needed additional surgery in the

acute phase were excluded. Thus, overestimating care quality from sending hospitals was avoided.

In the present study, severe operative trauma surgery was defined as an operative trauma surgery with a mortality greater than or equal to 10% in a population that had at least 1 trauma disease code in the 4 primary diagnoses and was brought to the hospital by ambulance. We chose a population that was at high risk of dying by setting a threshold of mortality because volume–outcome relationships have been reported in relatively high-risk surgeries. The cutoff value for the high risk of dying was 10%, which has been used to describe major or severe trauma.<sup>15</sup> For each operative trauma surgery code, mortality was calculated. The number of deaths was divided by the number of patients who underwent that specific operative trauma surgery. Based on the mortality rate, trauma surgeries were classified as either severe or non-severe. Patients who underwent at least 1 surgery classified as severe were included in our study population.

Patients who were coded dead at hospital discharge were defined as non-survivors of the surgery. Patients with other discharge statuses, such as discharged home or transferred to another hospital, were defined as survivors. In addition, age, sex, Charlson Comorbidity Index (CCI), the number of severe operative trauma surgeries performed during a single hospital stay, and the Japan Coma Scale (JCS) score were compiled. The trauma risk index obtained from a previous study using the DPC database<sup>16</sup> was calculated and extracted from the database.

Age was categorized into 8 groups: 15 to 24 (reference), 25 to 34, 35 to 44, 45 to 54, 55 to 64, 65 to 74, 75 to 84, and  $\geq 85$ . The CCI score was assessed from the 4 concurrent diagnoses and categorized into 5 categories: 0 (reference), 1, 2, 3, and  $\geq 4$ .<sup>17,18</sup> The JCS is a scale that evaluates the consciousness of a patient and is comparable to the Glasgow Coma Scale (GCS).<sup>19</sup> Although the GCS score is a 3-axis evaluation system, the JCS score is a 1-axis evaluation system that assesses a patient's reaction to stimulation. A higher JCS score indicates a worse level of consciousness. If a patient is brought to the hospital by ambulance, the JCS score on arrival is recorded in the DPC database. GCS scores are not available from the DPC database. JCS scores were categorized into 4 groups: 0 (alert), 1 to 3 (responds without stimulus), 10 to 30 (responds with stimulus), and 100 to 300 (hardly responds or does not respond with stimulus). Wada et al.<sup>16</sup> developed and validated an ICD-10-based trauma risk model that had good discrimination and calibration using the DPC database. They used age, sex, CCI score, and 38 injury categories to predict in-hospital mortality among trauma patients. Our study used the variables of 38 injury categories to calculate the trauma risk index, which reflected the anatomical severity of trauma. The exponential of that index served as the odds ratio of death.

Subgroup analyses were performed by stratifying the population based on the anatomical region of surgery because surgeries of the head, torso, and other parts of the body vary in terms of risk of dying and are performed by surgeons with different specialties. Further breakdown of severe operative trauma surgery was not deemed meaningful because in most cases, the detailed operative procedures that are necessary for the patient are unknown when deciding to transfer the patient to a higher-volume hospital.

Annual hospital case volume was divided based on the distribution of cases in each divided category and interpretability of the case volume (eg, 1 case per 2 months on average). Annual hospital case volume for severe operative trauma surgeries was divided into 4 categories:  $<6$  (reference), 6 to 11, 12 to 17, and  $\geq 18$ . For the head surgery subgroup, it was divided into 4 categories as well:  $<4$  (reference), 4 to 7, 8 to 11, and  $\geq 12$ . For torso surgeries, the annual hospital case volume was divided into 2 categories:  $<6$  (reference) and  $\geq 6$ . This was because the case volume in the lower-case volume

category was too small if the categories were divided into 4 categories. About one-fourth of the hospitals had performed only 1 severe operative trauma surgery annually on average. Furthermore, to confirm whether the categorization cutoffs and their numbers were appropriate, a generalized additive model plot was used as a visual inspection.<sup>20</sup> In the generalized additive model, the non-linear associations between case volumes and risk of death were examined.

**Statistical Analysis**

A logistic regression model with random effects was used to predict in-hospital mortality by annual hospital case volume. Other explanatory variables included age, sex, CCI score, trauma risk index, JCS score, and the number of severe operative trauma surgeries. The hospital identifier was used as the random intercept to account for unmeasured hospital-level characteristics. The validity of setting a random intercept was assessed with intraclass correlation coefficients (ICC).<sup>21</sup> ICCs reflect the proportion of variance explained by the random effect. A high ICC indicates a large variance within the random effect, that is, hospital level.

Model performance was assessed with the c-index and Brier score methods.<sup>22,23</sup> The Brier score is defined as the mean squared difference between the predicted mortality and actual mortality outcome (1 or 0). The score ranges from 0 to 1 and is used as a measure of model discrimination and calibration. Model performance is best as it approaches 0.

When comparing characteristics among annual hospital case volume categories, categorical variables were compared using the  $\chi^2$  test. Continuous variables were compared with the Kruskal-

Wallis test or Mann-Whitney *U* test, where data was assumed to be non-normal, and the analysis of variance or Student's *t* test, if assumed normal. All statistical analyses and visualization were conducted using the R software, version 3.4.2 (R Foundation for Statistical Computing, Vienna, Austria).

**Results**

The study population for analysis comprised 18,382 patients from 964 hospitals (Fig 1). Overall mortality was 19.7% (3,613 deaths). The number of patients who underwent only head and only torso surgeries were 13,137 and 5,032, respectively, and 92 patients underwent both head and torso surgeries.

A larger number of older, female patients were included in the lower annual hospital case volume category, as shown in Table 1. The CCI score was higher in those categories as well. In the higher annual hospital case volume category, the level of consciousness (ie, the JCS score) was worse, and the percentage of multiple, severe operative trauma surgeries performed was higher. The trauma risk index developed by Wada et al<sup>16</sup> ranged from -3.17 to 10.66, and the mean of that index was 2.96. Variability in crude mortality among hospitals was observed (Fig 2). In the study population, missing values were not observed in the variables used for analysis.

Seventy-one surgeries were identified as having a mortality of equal to or greater than 10%. The mortality of these surgeries ranged from 10% to 67%. The 5 most frequent surgeries were head trauma surgeries. Details of the frequency and mortality of the severe operative trauma surgeries are provided in Supplemental Table I.

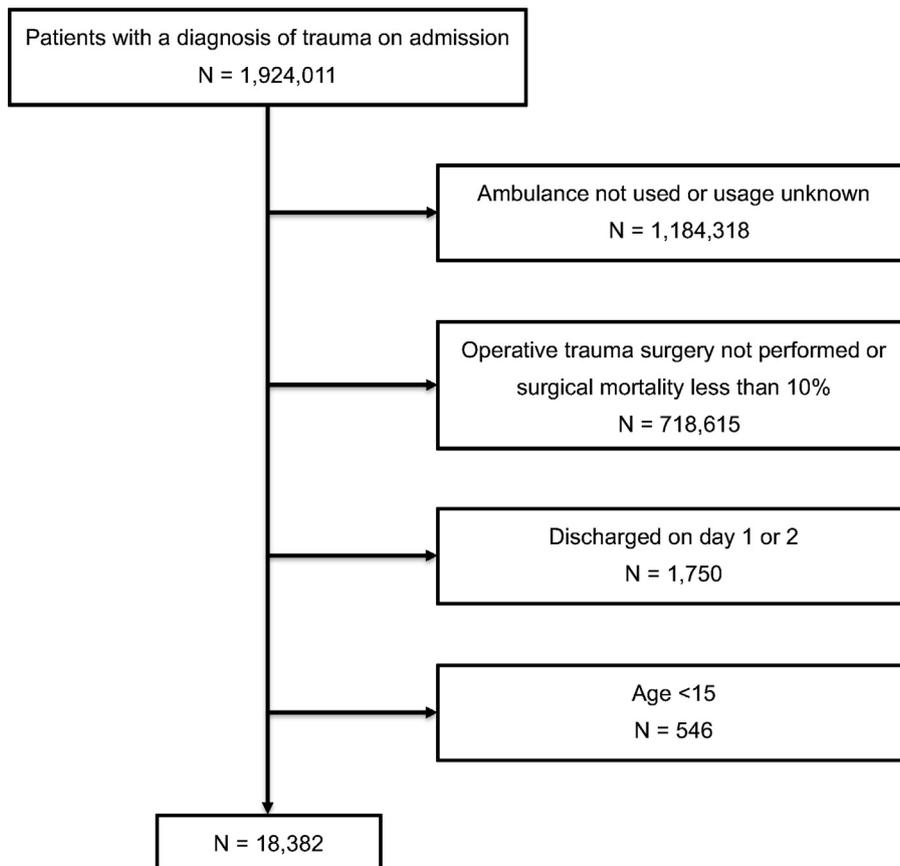


Fig 1. Study population flowchart.

**Table I**  
Patient characteristics by hospital case volume category

	Annual hospital case volume				P value
	<6	6–11	12–17	≥18	
Number of cases, n	5,288	5,540	3,236	4,318	
Number of hospitals, n	700	169	55	40	
Age (years), median (IQR)	74 (62–82)	70 (54–80)	66 (45–78)	63 (40–75)	< .001
Age category (%)					
15–24	177 (3.3)	337 (6.1)	246 (7.6)	427 (9.9)	< .001
25–34	147 (2.8)	308 (5.6)	200 (6.2)	347 (8.0)	
35–44	202 (3.8)	381 (6.9)	259 (8.0)	408 (9.4)	
45–54	339 (6.4)	426 (7.7)	307 (9.5)	425 (9.8)	
55–64	680 (12.9)	718 (13.0)	490 (15.1)	637 (14.8)	
65–74	1,174 (22.2)	1,174 (21.2)	709 (21.9)	916 (21.2)	
75–84	1,707 (32.3)	1,538 (27.8)	748 (23.1)	876 (20.3)	
≥85	862 (16.3)	658 (11.9)	277 (8.6)	282 (6.5)	
Female, n (%)	1,980 (37.4)	1,948 (35.2)	1,070 (33.1)	1,380 (32.0)	< .001
CCI score, n (%)					
0	2,647 (50.1)	3,336 (60.2)	2,140 (66.1)	3,161 (73.2)	< .001
1	1,344 (25.4)	1,201 (21.7)	615 (19.0)	709 (16.4)	
2	776 (14.7)	612 (11.0)	290 (9.0)	271 (6.3)	
3	311 (5.9)	241 (4.4)	124 (3.8)	109 (2.5)	
≥4	210 (4.0)	150 (2.7)	67 (2.1)	68 (1.6)	
Trauma risk index, mean (SD)	2.66 (1.42)	2.92 (1.51)	3.08 (1.65)	3.28 (1.79)	< .001
JCS score, n (%)					
0	1,406 (26.6)	1,259 (22.7)	605 (18.7)	642 (14.9)	< .001
1–3	1,238 (23.4)	1,194 (21.6)	722 (22.3)	883 (20.4)	
10–30	936 (17.7)	922 (16.6)	559 (17.3)	750 (17.4)	
100–300	1,708 (32.3)	2,165 (39.1)	1,350 (41.7)	2,043 (47.3)	
Number of severe operative trauma surgeries, n (%)					
1	4,684 (88.6)	4,798 (86.6)	2,658 (82.1)	3,212 (74.4)	< .001
2	552 (10.4)	652 (11.8)	475 (14.7)	835 (19.3)	
3	47 (0.9)	80 (1.4)	88 (2.7)	211 (4.9)	
≥4	5 (0.1)	10 (0.2)	15 (0.5)	60 (1.4)	
Length of stay (days), median (IQR)	43 (21–74)	38 (17–62)	35 (16–60)	35 (15–59)	< .001

IQR, interquartile range; SD, standard deviation.

The adjusted odds ratio (AOR) of hospital case volume for mortality did not decrease significantly as the volume increased (Table II). In the subgroup analysis, severe head surgery did not show a significant reduction in AOR either. However, in torso

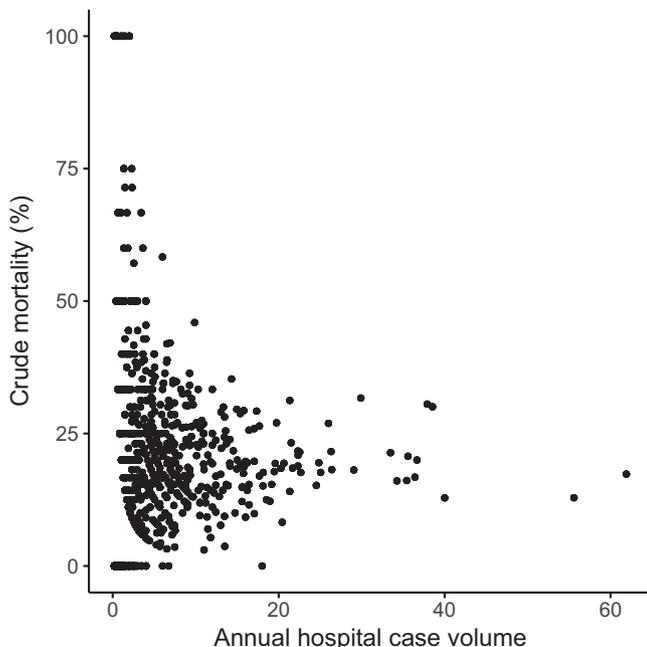
surgery, the AOR decreased significantly when the annual case volume was equal to or greater than 6 compared with the reference category (<6 cases/y). The AOR was 0.55 (95% confidence interval [CI], 0.42–0.73;  $P < .001$ ). Details on the patient characteristics in the subgroup analysis are provided in Supplemental Tables II and III. The plots of the generalized additive model, which were used for visual inspection to check the non-linear relationship between case volume and risk of death, are provided in Supplemental Text 2.

The ICC for the severe operative trauma surgery model was 0.02. In the subgroup analyses, the ICC was 0.02 and 0.03 for head and torso operative trauma surgeries, respectively. The c-index for severe operative trauma surgery was 0.72 (95% CI, 0.71–0.73), whereas it was 0.68 (95% CI, 0.67–0.69) and 0.81 (95% CI, 0.79–0.83) for head and torso surgery, respectively. The Brier score for severe operative trauma surgery was 0.143 (95% CI, 0.140–0.146); for the head and torso subgroups, it was 0.168 (95% CI, 0.164–0.172) and 0.071 (95% CI, 0.065–0.076), respectively.

## Discussion

This study investigated the volume–outcome relationship in severe operative trauma surgery and did not find any such relationship among those patients. Subgroup analysis also did not identify any relationship in severe operative head trauma surgery, but the relationship was observed in severe operative torso trauma surgery.

These results can be integrated with previous findings on the volume–outcome relationship in trauma using the DPC database. Wada et al<sup>24</sup> did not find a significant relationship between volume and outcome among severe head trauma patients, which included both operative and nonoperative cases. One possible reason that a



**Fig 2.** Association between the annual hospital case volume of severe operative trauma surgery and crude mortality.

**Table II**  
Odds ratio of annual hospital case volume for mortality

Annual hospital case volume	Number of deaths (%)	Unadjusted odds ratio (95% CI)	P value	Adjusted odds ratio (95% CI)	P value
Severe operative trauma surgery (N = 18,382)	3,613 (19.7)				
<6 (n = 5,288)	1,040 (19.7)	Reference		Reference	
6–11 (n = 5,540)	1,112 (20.1)	1.03 (0.93–1.13)	.60	1.01 (0.90–1.12)	.92
12–18 (n = 3,236)	624 (19.3)	0.98 (0.87–1.09)	.66	0.95 (0.83–1.10)	.49
≥18 (n = 4,318)	837 (19.4)	0.98 (0.89–1.09)	.73	0.88 (0.76–1.02)	.084
Severe operative head trauma surgery (N = 13,137)	3,119 (23.7)				
<4 (n = 3,238)	733 (22.6)	Reference		Reference	
4–7 (n = 4,140)	983 (23.7)	1.06 (0.95–1.19)	.26	1.01 (0.90–1.14)	.85
8–11 (n = 2,358)	551 (23.4)	1.04 (0.92–1.18)	.52	0.96 (0.83–1.12)	.61
≥12 (n = 3,401)	852 (25.1)	1.14 (1.02–1.28)	.021	1.01 (0.87–1.16)	.95
Severe operative torso trauma surgery (N = 5,032)	442 (8.8)				
<6 (n = 3,450)	343 (9.9)	Reference		Reference	
≥6 (n = 1,582)	99 (6.3)	0.60 (0.48–0.76)	< .001	0.55 (0.42–0.73)	< .001

volume–outcome relationship in severe operative trauma surgery was not identified in our study may be that about 70% of the study population consisted of head surgery patients. We also speculate that nonoperative cases of severe head trauma do not show a volume–outcome relationship. Furthermore, Wada et al<sup>25</sup> identified a volume–outcome relationship in severe torso trauma patients irrespective of surgical status. Endo et al<sup>26</sup> confirmed it in severe trauma patients, including nonoperative cases. Their results and our findings combined may indicate a volume–outcome effect in nonoperative cases as well. Hospitals that see many nonoperative cases may have more experience and expertise in treating torso trauma patients nonoperatively and operating as necessary.

These findings and interpretations of the volume–outcome relationship among the subgroups possibly indicate the heterogeneity of severe trauma patients. The relationship will be masked if the subset population is not selected as a homogenous group of trauma patients. Therefore, a reasonable approach is to set standards for the minimum number of a certain homogenous trauma population, rather than for trauma irrespective of type and severity. The combined results of previous studies and our study suggest that differentiation is needed between operative and nonoperative cases and between head and torso trauma.

Severe injuries requiring operative procedures continue to have an adverse outcome even after years of implementing trauma education programs in Japan.<sup>27</sup> Our research findings serve as additional evidence of areas in which improvement is needed. Severe operative torso trauma surgery has been found to result in a bad outcome if performed in lower-volume hospitals (<6 cases/y). Therefore, transferring trauma patients, who are at high risk of torso surgery, to higher-volume hospitals may improve the outcome of trauma care in that area. Nonetheless, although a volume–outcome relationship in severe operative torso trauma surgery was observed in our study and implications could be drawn, several limitations exist when interpreting the results further.

First, the interpretations above are all based on Japanese data. Volume–outcome relationships have been well studied,<sup>1–4,10–13</sup> but the results have varied among countries and several studies have even revealed nonsignificant relationships.<sup>28,29</sup> In 1 study, the United States and Japan demonstrated a different pattern in terms of the volume–outcome relationship for coronary artery bypass grafting.<sup>30</sup> We presume that the number of cases for low- and high-volume hospitals differs across healthcare systems. In the subgroup of patients undergoing operative torso trauma surgery in our study, if we divided the population into 4 categories so that each category had nearly the same case volume, the lowest case volume category

had an annual case volume of only 1 case. This reflects the unique healthcare system in Japan, where severe trauma patients are scattered across regions and seen in hospitals that may not have much experience. Trauma centers in Japan are not as strictly designated as they are in the United States<sup>5</sup> and Germany.<sup>13</sup> Therefore, studies comparing other countries and Japan may yield different results with respect to the volume–outcome relationship in trauma. As such, it is important to conduct research on the volume–outcome relationship in each country or healthcare setting. It is highly possible that heterogeneity exists in trauma care among different regions, even if the type and severity score are the same.

Second, confounding factors may still exist after our risk adjustment, affecting volume and outcome. Hospitals that performed fewer severe operative trauma surgeries had an older patient profile, which may indicate that these hospitals were in rural areas where transfer time was longer. Therefore, without adjusting for transfer time, the true association between volume and outcome may not be known. Mixed results on transfer time and outcome have been reported<sup>31–33</sup>; therefore, further research is required to clarify the association. However, the level of consciousness, which was included in our analysis, may work as a proxy for transfer time because it will deteriorate with a longer transfer time if the patient is in shock or has a severe head injury. Furthermore, volume for the nontrauma surgeries that require similar surgical skills and experience in simulation training might have affected hospital volume and outcomes. Although the effect of these factors on the final outcome could be mediated by trauma surgery volume (as trauma surgeries are quite different from nontrauma surgeries or participating in simulations), examining the effects of nontrauma surgery volume and experience with simulation training is required in future studies.

Third, the causal relationship between volume and outcome is unknown. More practice may lead to better outcomes, or selective referral to high-quality hospitals may lead to greater volume.<sup>34</sup> The referrals from other hospitals for operative trauma surgery are limited compared with other surgeries, such as cancer surgeries, because transferring patients may not be feasible, owing to hemorrhagic shock or coma. However, emergency medical service personnel may transfer to hospitals that see many trauma patients and provide a high quality of care, which is a similar patient flow to selective referral. Therefore, it is unknown whether higher volume improves outcomes or better outcomes lead to higher volume. Theoretically, because these effects are not mutually exclusive, the relationship may be bidirectional. To ensure quality improvement in operative trauma surgery, we suggest trauma patients be

centralized in existing higher-volume hospitals because patients will benefit from the high quality of care offered. Such high quality of care may already be established or derived from the learning effect attributable to more practice. Certainly, both scenarios will improve the outcome of operative trauma surgery in a particular geographical area.

Last, a technical limitation may exist when using data from an ICD-based administrative database, which has been considered different from databases that collect ISSs.<sup>35</sup> Although ICD-10-based risk adjustment has been proven to be valid in predicting mortality, controversy remains among researchers.<sup>36</sup> The trauma risk model developed by Wada et al<sup>16</sup> has good discrimination and calibration for predicting in-hospital mortality. In our analysis, the level of consciousness and number of severe operative trauma surgeries were added to improve model performance. The c-index and Brier score of the models indicated fair to good performances. Noticeably, the model for torso trauma surgery in which a volume–outcome relationship was observed, had a good performance. Considering the severe conditions of our study population, patient-level factors on admission would not fully account for the clinical outcome. Therefore, we assume that the risk adjustment method using ISSs, which is usually a score derived on admission, would not improve model performance as much as our ICD-10-based model.

In conclusion, the volume–outcome relationship was not identified in severe operative trauma surgeries but was observed in the subgroup of severe operative torso surgeries in a Japanese administrative database using an ICD-10-based risk adjustment method. Transferring patients who potentially require operative torso trauma surgery to higher-volume hospitals may be warranted to improve trauma care.

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### Conflict of interest/Disclosure

The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article.

### Supplementary materials

Supplementary material associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.surg.2019.06.002>.

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