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# Evaluating the definition of severely injured patients: a Japanese nationwide 5-year retrospective study

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## ABSTRACT

**Objectives** The definition of severely injured patients lacks universal consensus based on quantitative measures. The most widely used definition of severe injury is based on the Injury Severity Score (ISS), which is calculated using the Abbreviated Injury Scale in Japan. This study aimed to compare the prevalence, in-hospital mortality and OR for mortality in patients with ISS ≥16, ISS ≥18 and ISS ≥26 by age groups.

**Design** Retrospective cohort study.

**Setting** Japan Trauma Data Bank, which is a nationwide trauma registry with data from 280 hospitals.

**Participants** We used data of 117 199 injured patients from a national database. We included injured patients who were transferred from the scene of injury by ambulance and/or physician.

**Primary and secondary outcome measures** Prevalence, in-hospital mortality and OR for mortality with respect to age and injury level (ISS group).

**Results** In all age categories, the in-hospital mortality of patient groups with an ISS ≥16, ISS ≥18 and ISS ≥26 was 13.3%, 17.4% and 23.5%, respectively. The in-hospital mortality for patients aged >75 years was the highest (20% greater than that of the other age groups). Moreover, in-hospital mortality for age group 5–14 years was the lowest (4.0–10.9%). In all the age groups, the OR for mortality for patients with ISS ≥16, ISS ≥18 and ISS ≥26 was 12.8, 11.0 and 8.4, respectively.

**Conclusions** Our results revealed the lack of an acceptable definition, with a high in-hospital mortality and high OR for mortality for all age groups.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ We used data from a large nationwide Japanese trauma registry to evaluate in-hospital mortality and OR for mortality in patients with severe injury according to age.
⇒ This is the first study to reveal that no definition of severe injury was acceptable, with not only high in-hospital mortality but also a high OR for mortality for all age groups.
⇒ The Japanese nationwide dataset with more missing data may have led to selection bias.

## INTRODUCTION

The terminology used to quantify anatomical injury severity has been vaguely described for many decades using various phrases, such as severely injured and major trauma.[1–5] Although the most widely used definitions continue to rely on patients who have a high mortality and morbidity risk and require intense medical resources, such as massive resuscitation, multiple surgical operations, intensive care and complex rehabilitation programmes,[4 5] the definition lacks a universal consensus with quantitative measures.[2 3]

The most widely used definition of severely injured patients is the Injury Severity Score (ISS),[6] which is calculated using the Abbreviated Injury Scale (AIS).[7] Thirty years ago, an ISS cut-off value of ≥16 was defined as 'severely injured' because patients with an ISS ≥16 had an expected mortality rate of >20%.[1] However, the mortality of patients with an ISS ≥16 and ISS ≥26 decreased from 12.4% to 9.3% and from 25.4% to 20.3%, respectively, during the 10-year study period, due to a reduction in mortality and/or morbidity associated with organised trauma systems.[8]

Research based on the Japanese nationwide trauma registry has also shown that the in-hospital mortality trend has decreased in injured patients.[9–11] Moreover, there are more age-related differences in the mortality of severely injured patients in Japan than that in the other developed countries because Japan has faced issues with the declining birth rate and ageing population.[11 12] To date, no study has evaluated the validity of the definition of severe injury in a Japanese cohort using a detailed classification of the definition cut-off values and age groups. We hypothesised that there would be differences in in-hospital mortality rate and risk among Japanese injured patients by age and anatomical injury severity. Therefore, this study aimed to compare the prevalence, in-hospital mortality and OR for mortality in patients with an ISS

≥16, ISS ≥18 and ISS ≥26 as the commonly used anatomical injury definitions by age group.[2]

## MATERIALS AND METHODS

### Study setting and population

This retrospective observational nationwide study was conducted based on data obtained from the Japan Trauma Data Bank (JTDB), which registers data of patients with an injury and/or burn, and records prehospitalisation-related and hospital-related information. The JTDB includes data on demographic characteristics, comorbidities, injury types, mechanism of injury, means of transportation, vital signs, AIS score, prehospital/in-hospital procedures, injury diagnosis as indicated by the AIS and clinical outcomes. In the most cases, physicians trained in AIS coding record the online registration of individual patient data. There were 280 participating hospitals in all 47 prefectures in Japan, including 92% of the Japanese government-approved tertiary emergency medical centres in March 2019. The Japan Association for the Surgery of Trauma permits open access and updating of existing medical information, and the Japan Correlation for Acute Medicine evaluates the submitted data.

In this study, we used the JTDB dataset that included information from 1 January 2014 to 31 December 2018, which initially yielded the data of 181 971 patients. The inclusion criterion for this study was injured patients who were transferred from the scene of injury by ambulance and/or physician. Patients with cardiac arrest on hospital arrival or with missing key data, such as mechanism, age, ISS and/or survival outcome, were excluded from this study. Figure 1 presents a flow diagram of the patient selection process in this study.

### Data collection

We collected information from the JTDB, including the following variables: demographic characteristics (age (years), sex, injury mechanism, transportation type and transfer process) and clinical parameters (AIS of the injured region and ISS). In the JTDB, a patient with an AIS of the injured region ≥3 was defined as a case of a severely injured region.

### Statistical analysis

The outcomes were as follows: prevalence, in-hospital mortality and OR for mortality with respect to age group (0–4, 5–14, 15–24, 25–34, 35–44, 45–54, 55–64, 65–74 and ≥75 years) and injury severity (ISS ≥16, ISS ≥18 and ISS ≥26); the ISSs of these groups were used as the definitions of anatomical injury in a previous review article.[2]

Continuous variables are presented as medians with IQR (IQR, Q1–Q3), and categorical variables are presented as the number and percentage of patients. The Mann-Whitney U test and Wilcoxon's rank-sum test were used to analyse continuous variables, whereas the $\chi^2$ test was used to analyse categorical variables. OR (95% CIs) for mortality was calculated using a logistic regression model. All statistical analyses were performed by using STATA/SE software (V.17.0; StataCorp). Statistical significance was defined as a two-tailed $p<0.05$.

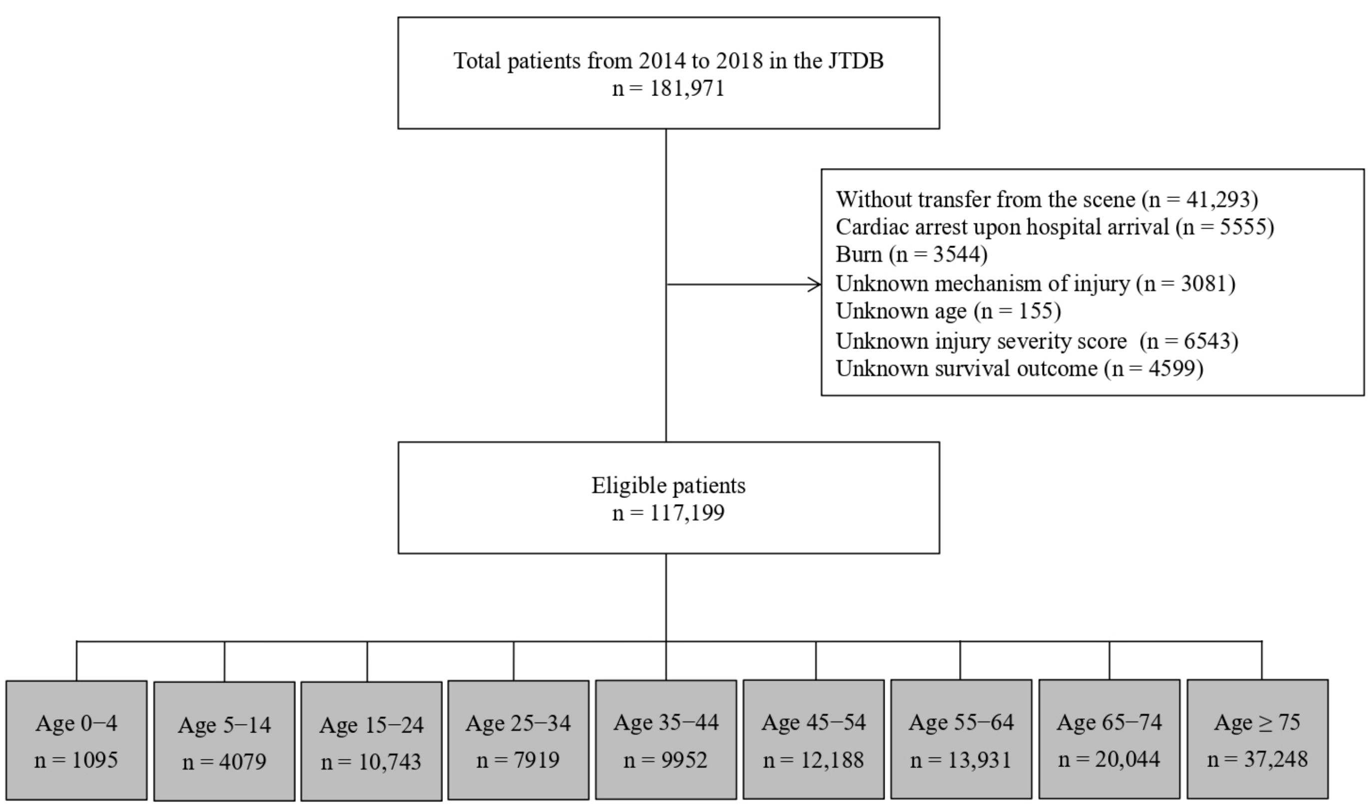


**Figure 1** Flow diagram of the patient selection process. JTDB, Japanese Trauma Data Bank.

### Patient and public involvement

Patients and the public were not involved in the design, conduct, reporting or dissemination of this research. We will not directly disseminate our findings to involved participants. However, we plan to disseminate them through the publication of an article.

## RESULTS

During the 5-year study period, we analysed the data of 117 199 injured patients transferred from the scene of injury; 113 435 (97%) of them had blunt trauma (figure 1, table 1). The median age and ISS score were 64 years (IQR, 41–78) and 10 (IQR, 9–19), respectively. The overall in-hospital mortality rate was 6.1%.

Table 1 shows the characteristics by age group and injury severity group during the 5-year study period. The number of patients with ISS ≥16, ISS ≥18 and ISS ≥26 was 48 028 (41% of all the patients), 32 225 (28%) and 15 343 (13%), respectively.

Figure 2 shows in-hospital mortality and OR for mortality with respect to age group and injury severity. In all age categories, the in-hospital mortality of patients with ISS ≥16, ISS ≥18 and ISS ≥26 was 13.3%, 17.4% and 23.5%, respectively. In each age category, the in-hospital mortality for patients aged >55 years was higher than that for younger age groups, and that of patients aged >75 years was higher (by more than 20%) than that of all patient groups for each level of injury severity. In-hospital mortality for the 5–14 years age group was 4.0%–10.9% and lower than that for the other age groups.

In all age categories, the OR for mortality by patient group was 12.8 (11.9–13.8), 11.0 (10.4–11.6) and 8.4 (8.0–8.8), respectively, for the three levels of injury severity and the OR in patients with ISS ≥16 or ISS ≥18 was higher than that in patients group ISS ≥26.

## DISCUSSION

To the best of our knowledge, this is the first nationwide study in Japan to evaluate in-hospital mortality and OR for mortality in patients with severe injury according to age. Our study showed that in all three groups with ISS ≥16, ISS ≥18 and ISS ≥26, which are the commonly used anatomical injury definitions, in-hospital mortality for patients aged <55 years was between 4.0% and 17.7% for each level of injury severity. Moreover, after evaluating the validity of the definition for severely injured patients in a Japanese cohort via the detailed classification of the definition cut-off values and age groups, there was no acceptable definition, with not only a high in-hospital mortality, but also a high OR for mortality for all age groups.

Previous studies demonstrated that in 1990 when severe injury was defined as an ISS cut-off of ≥16 points, the mortality of patients with an ISS ≥16 was more than 20%; however, the mortality of these patients decreased; therefore, an ISS cut-off of ≥18 or 26 might be suitable for defining severely injured patients with a high mortality rate.[1–3 8] This study also showed that patients with ISS ≥26 had the highest in-hospital mortality in all age categories. However, the OR for mortality in patients with ISS ≥26 was lower than that in patients with ISS ≥16 and ISS ≥18. There are possible explanations for the lack of an accepted definition with a high in-hospital mortality and high OR for mortality in a Japanese cohort.

First, there are differences in the study era and/or cohorts at the time of development.[1] A previous 10-year nationwide study using the JTDB dataset from 2004 to 2013 demonstrated that the in-hospital mortality of patients with ISS ≥16 decreased from 28.5% to 15.7% owning to improvements in trauma care and medical ambulance services.[9] Moreover, in the Japanese cohort, unlike the ageing population in the rest of the world, the characteristics and survival outcome of severely injured patients varied widely according to age, and the mortality risk of elderly patients with severe injury was higher than that of the other age groups.[12] A previous Japanese nationwide study showed that the incidence rate of severe traumatic brain injury among severely injured patients aged >65 years was high (40.7%).[13] Moreover, the in-hospital mortality of these patients was higher than that of the other age groups.[13] These results suggest that the elderly patient groups had a higher mortality because of the high proportion and mortality of severe traumatic head injury. This study also showed that the prevalence and in-hospital mortality of severely injured patients aged 55–64, 65–75 and ≥75 years increased stepwise. On the other hand, previous studies suggested that the ISS cut-off of ≥16 in adult patients was equivalent to a cut-off of ≥26 in paediatric patients aged <16 years.[14 15] This study showed different results from those of a previous study,[15] where the in-hospital mortality of paediatric patients aged 0–4 years with an ISS ≥26 was high (17.7%) and that of paediatric patients aged 5–14 years with an ISS ≥26 was low (10.9%), as shown in figure 2. Moreover, a previous study showed that there was a difference in the optimal cut-off value of ISS in predicting severely injury mortality risk by region and/or mechanism of injury among paediatric patients. Therefore, it is important to develop an acceptable definition of severe injury by considering the age-related characteristics and mortality risks in a Japanese cohort. Moreover, this study showed that the mortality rate and risk of injured patients in Japan differed by age groups and did not have a linear correlation with age in years. For a better predictive accuracy in mortality, it may be effective to add age categories as a predictive variable for mortality and to calculate the coefficient for coded value according to mortality risk by each age group, as shown in the Trauma and Injury Severity Score methodology.[16] Second, there was a limitation in evaluating only anatomical injury severity as a definition of severe injury. A more recent approach suggests that the addition of other physiological variables to the anatomical injury severity score has the advantage of identifying severely injured patients with a high mortality risk.[2 17 18] Although the mortality of patients with ISS ≥16 was 18.7%, that of

**Table 1** Characteristics by the nine age groups and three levels of injury severity groups

| Variables | Overall n=117 199 | Age 0–4 n=1095 | Age 5–14 n=4079 | Age 15–24 n=10 743 | Age 25–34 n=7919 | Age 35–44 n=9952 | Age 45–54 n=12 188 | Age 55–64 n=13 931 | Age 65–74 n=20 044 | Age≥75 n=36 248 |
|---|---|---|---|---|---|---|---|---|---|---|
| Age, years | 64 (41–78) | 2 (1–3) | 10 (7–12) | 20 (17–22) | 29 (27–32) | 40 (38–42) | 49 (47–52) | 60 (57–62) | 69 (67–72) | 83 (79–87) |
| Male | 73 680 (63) | 675 (62) | 2985 (73) | 8095 (75) | 6008 (75) | 7710 (77) | 9211 (76) | 10 017 (72) | 12 662 (63) | 16 317 (44) |
| Mechanism of injury | | | | | | | | | | |
| Blunt | 113 435 (97) | 1073 (98) | 4020 (99) | 10 477 (98) | 7508 (95) | 9361 (94) | 11 475 (94) | 13 383 (96) | 19 433 (97) | 36 705 (99) |
| Injury region | | | | | | | | | | |
| Head injury with AIS ≥3 | 36 244 (31) | 439 (40) | 1213 (30) | 2798 (26) | 1933 (24) | 2527 (25) | 3363 (28) | 4451 (32) | 7384 (37) | 12 136 (33) |
| Facial injury with AIS ≥3 | 940 (0.8) | 4 (0.4) | 33 (0.8) | 150 (1.4) | 109 (1.4) | 128 (1.3) | 124 (1.0) | 123 (0.9) | 133 (0.7) | 136 (0.4) |
| Neck injury with AIS ≥3 | 478 (0.4) | 6 (0.6) | 2 (0.1) | 27 (0.3) | 39 (0.5) | 55 (0.6) | 70 (0.6) | 77 (0.6) | 110 (0.6) | 92 (0.3) |
| Chest injury with AIS ≥3 | 25 723 (22) | 148 (14) | 622 (15) | 2831 (26) | 2110 (27) | 2759 (28) | 3485 (29) | 3726 (27) | 4594 (23) | 5448 (15) |
| Abdominal and pelvic injury with AIS ≥3 | 5407 (5) | 27 (2) | 185 (5) | 805 (7) | 591 (7) | 682 (7) | 709 (6) | 684 (5) | 831 (4) | 893 (2) |
| Spinal injury with AIS ≥3 | 13 146 (10) | 12 (1) | 128 (3) | 861 (8) | 788 (10) | 1120 (11) | 1530 (13) | 2106 (15) | 3053 (15) | 3548 (10) |
| Upper extremity injury with AIS ≥3 | 6562 (6) | 57 (5) | 590 (14) | 581 (5) | 522 (7) | 711 (7) | 849 (7) | 798 (6) | 1026 (5) | 1428 (4) |
| Lower extremity injury with AIS ≥3 | 31 526 (27) | 124 (11) | 634 (16) | 2143 (20) | 1660 (21) | 2055 (21) | 2404 (20) | 2691 (19) | 4358 (22) | 15 457 (42) |
| Injury Severity Score | 10 (9–19) | 9 (4–16) | 9 (5–16) | 10 (5–19) | 10 (6–20) | 13 (9–20) | 13 (9–21) | 14 (9–21) | 14 (9–21) | 9 (9–17) |
| Actual in-hospital mortality | 7201 (6.1) | 23 (2.1) | 48 (1.2) | 354 (3.3) | 310 (3.9) | 372 (3.7) | 533 (4.4) | 762 (5.5) | 1438 (7.2) | 3361 (9.0) |
| Injury Severity Score ≥16 | 48 028 (41) | 376 (34) | 1166 (29) | 3878 (36) | 3043 (38) | 4076 (41) | 5297 (43) | 6541 (47) | 9711 (48) | 13 940 (37) |
| Injury Severity Score ≥18 | 32 225 (28) | 187 (17) | 747 (18) | 2954 (28) | 2305 (29) | 2985 (30) | 3793 (31) | 4372 (31) | 6256 (31) | 8626 (23) |
| Injury Severity Score ≥26 | 15 343 (13) | 62 (6) | 367 (9) | 1595 (15) | 1129 (14) | 1481 (15) | 1823 (15) | 2038 (15) | 2910 (15) | 3938 (11) |

Data are presented as number (percentage) or median (IQR Q1–Q3).
AIS, Abbreviated Injury Scale.

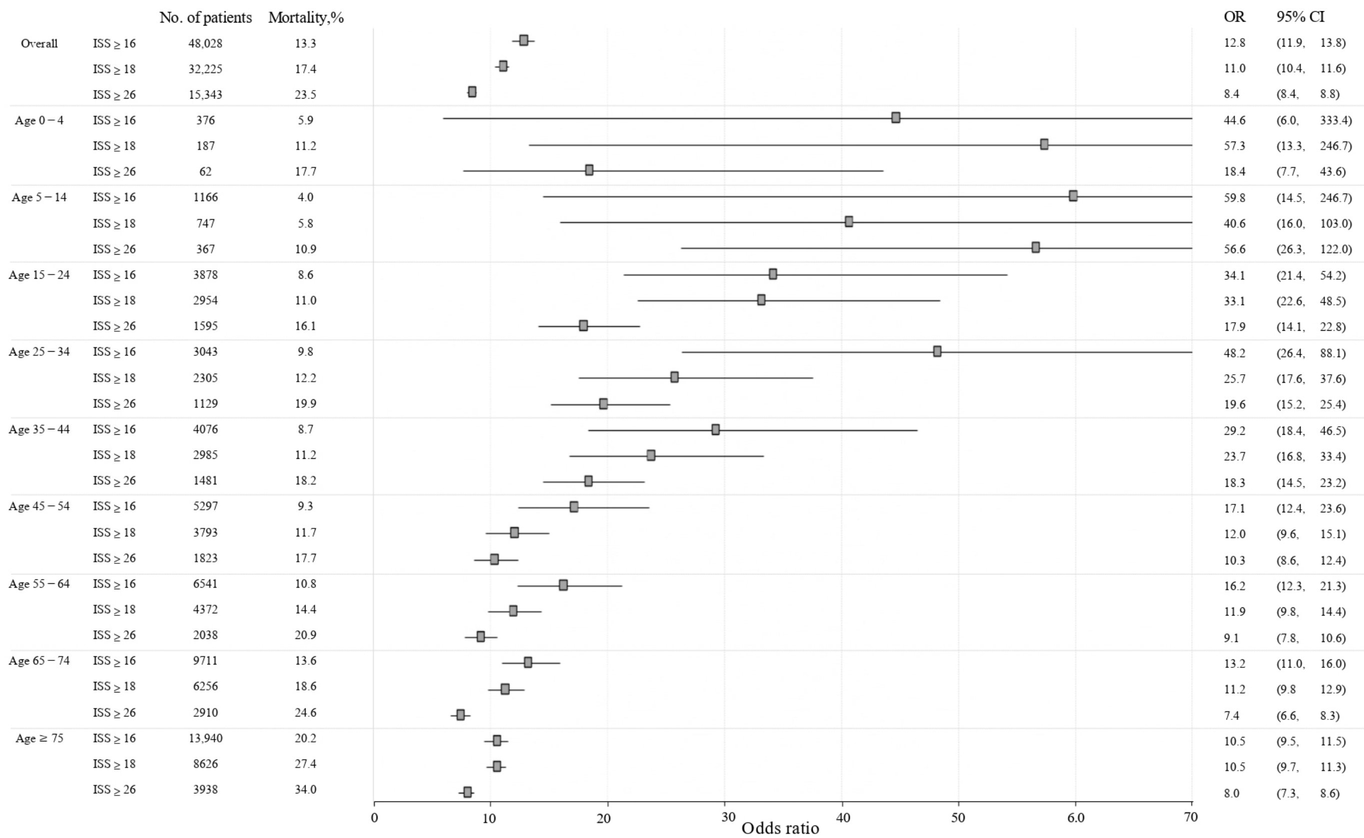


**Figure 2** Association between OR for in-hospital mortality and age groups by patients with Injury Severity Score (ISS) ≥16, ISS ≥18 and ISS ≥26. In a Japanese cohort, using the detailed definition cut-off values and age groups, there was no acceptable definition, with not only a high in-hospital mortality, but also a high OR for mortality for all age groups.

patients with ISS ≥16 in addition to one other physiological parameter increased from 35% to 38%.[2] Moreover, patients with an increasing number of the physiological variable, such as the Glasgow Coma Scale, hypotension and laboratory values (eg, acidosis and/or coagulopathy), may have an increased risk of mortality.[17–19] However, we could not evaluate the variables according to physiological parameters and findings of blood tests. Therefore, it seems important to evaluate these parameters together with the anatomical injury severity used in this study to develop a well-validated definition of severely injured patients.

Our study had some limitations. First, there was selection bias because not all Japanese hospitals that treat severely injured patients are registered in the JTDB. The 280 tertiary centres equivalent to level I trauma centres in the USA participated, including 92% of the Japanese government-approved tertiary emergency medical centres in March 2019. Therefore, the JTDB is not a population-based sample of injured patients and the data are registered voluntarily. Moreover, the JTDB dataset has missing data, especially for paediatric patients.[20] A number of paediatric patients were lower than that of adult patients. Therefore, missing data may have a more significant influence on the analysis of the paediatric patients' data than that of the adult patients' data. A high-quality Japanese nationwide dataset with less missing data should be constructed to improve the accuracy of predicting the survival of injured patients in the data analysis for all age categories. Second, because the number of patients aged 0–4 and 5–14 years was small (0.9% and 3.5% of all the patients, respectively), it is possible that the ORs of these patient groups with small sample sizes were overestimated. In addition, the number of participating hospitals differed across the study period. Furthermore, the JTDB used AIS 90 until 2018 and is now using the AIS 2005 updated 2008 coding scale. Similar studies need to be conducted using the newest measure to verify our results. Last, we did not evaluate which definition would be effective for each age group. A recent study showed significant discrepancies in the mortality risk of severely injured patients by each injury region.[21] We intend to calculate the coefficient for the coded value according to mortality risk by age group and injury region for a better mortality estimate.

## CONCLUSIONS

This is the first nationwide study in Japan to evaluate the prevalence, in-hospital mortality and OR for mortality in patients with severe injury according to age categories. This study showed that there were differences in in-hospital mortality rate and risk among Japanese injured patients by age and anatomical injury severity; therefore, the use of correlation between mortality and injury severity score, such as the ISS, may be hardly justified in the definition of severely injured patients in all age categories. In the future, it will be important to evaluate the other parameters, such as age, physiological variables and laboratory variables, together with the anatomical injury severity by using the population-based database to develop a well-validated definition of severely injured patients.

**Collaborators** None.

**Contributors** Conceptualisation: CT and TM; methodology, CT; software, CT and TA; validation, CT, TM, TA, MG and MS; formal analysis, CT; investigation, CT, TM, MS, MG and TA; resources, CT and TA; data curation, CT and TA; writing—original draft preparation, CT; writing—review and editing, CT, TM, MS, MG, TA and IT; visualisation, CT; supervision, IT; project administration and funding acquisition, CT. All authors have read and agreed to the published version of the manuscript. Guarantor: CT.

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** The requirement for informed consent from the patients was waived owning to the observational nature of the study design.

**Ethics approval** This study was approved by the hospital ethics committee of Yokohama City University Medical Center (approval no. B170900003). The approval authority for data access was provided by the Japanese Association for the Surgery of Trauma (Trauma Registry Committee). The requirement for informed consent from the patients was waived owing to the observational nature of the study.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** No data are available. The approving authority for data access was the Japanese Association for the Surgery of Trauma (Trauma Registry Committee).



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