



Data quality and patient coverage at Sina Hospital Trauma Registry affiliated with the National Trauma Registry of Iran

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Abstract

Background: The registry systems are a tool to provide information which can be used for improvement of medical care and preventive policies over time. The efficacy of trauma registries in improving the quality of care depends on the quality of their data.

Objectives: This study aimed to determine the completeness, reliability, validity, and patient coverage of the Sina Hospital Trauma Registry (SHTR).

Methods: The data collected in the SHTR by May 28, 2021, were used to assess the data completeness. A random sample of 250 patients was re-registered to evaluate the reliability and validity. The intraclass correlation coefficient (ICC) and the kappa and weighted kappa statistics were used to assess the reliability of data and agreement. The coverage was determined by comparing the list of trauma patients obtained from the trauma registry and the one from the hospital information system.

Results: The overall average completeness for all variables was 97.9%. The inter-rater agreement on important variables including Abbreviated Injury Scale (AIS), Injury Severity Score (ISS), and final outcomes was, respectively, perfect (kappa= 0.90) optimal (ICC = 0.72), and substantial (kappa= 0.71). The patient coverage was 79.6%.

Conclusion: The results confirm that the data quality and patient coverage were high. In addition, although the reliability of most variables was acceptable, the agreement between NTRI's data and the medical record for AIS codes and ISS was moderate.

Keywords: Trauma, Registry, Data quality, Coverage of registry, Validity.

Introduction

Trauma registries are databases that systematically document injured patients' information, including demographics, mechanism and features of injury, pre-hospital and in-hospital care and interventions, transport and timing, anatomic injury description, preexisting medical conditions, complications, and outcomes.^[1,2] The registry systems serve as a tool to provide information that can be used for the improvement of medical care and also preventive policies over time.^[3,4] In addition, this information makes it possible to compare the epidemiology and pattern of trauma at sub-national, national, and international levels.^[5] A review of the literature by Krishna Bommakanti et al. reported that regardless of barriers to setting up a qualified trauma registry in middle-income countries, running at least one

local trauma registry has improved injury surveillance and patient outcome.^[6]

Running such registries requires a substantial investment of money, time, and personnel. Regarding this requirement, data quality and patients capturing remain a challenge.^[6,7] The efficacy of trauma registries to implement improvement in the quality of care depends on the quality of their data.^[8,9] We should empower the quality and completeness of data and injured patients' coverage to enhance their value. Although all the registries tend to make methodological efforts to minimize missing data, there are still errors in every system. By the current trend, it is estimated that the use of trauma registries for research will go on.

Considering that trauma registries influence the assessment of trauma care performance, published

guidelines by Sterne et al. emphasized managing missing data to reduce this potential source of bias.^[10,11] One way to ascertain the coverage of a trauma registry is to link it to discharge databases to identify patients not included in the registry.^[12] Also, by reviewing medical records, the correctness and completeness of data can be evaluated,^[13,14] therefore, registries can identify causes of inaccuracy and incompleteness and prevent systematic errors. The national trauma registry of Iran (NTRI) is a multicenter hospital-based registry established in some of Iran's leading trauma centers with the support of the Ministry of Health and Medical Education. The NTRI was started at Sina Hospital, affiliated with Tehran University of Medical Sciences for the first time in 2016.^[5,15,16]

Objectives

This study evaluated data completeness, coverage, and data quality of the Sina Hospital Trauma Registry (SHTR) to fulfill this goal.

Methods

The NTRI is a dedicated trauma system that started in July 2016 and continues today.^[15] The NTRI has 25 collaborative centers from different cities across the country. However, in the present study, we only used the data from SHTR. Trauma patients who meet the NTRI inclusion criteria, i.e., hospital length of stay (LOS) more than 24 hours, death at the hospital, or transfer from intensive care units of other hospitals, are included in this registry.

A form based on the National Trauma Data Standard (NTDS) containing demographics, injury information, pre-hospital and emergency department information, interventions, diagnosis and ICD-10 codes, patient outcomes, and severity of injury indices, including the Abbreviated Injury Scale (AIS) and Injury Severity Score (ISS) was filled for all patients meeting the NTRI inclusion criteria.^[17]

In the registry, three approaches were used to collect data. Data related to age, gender, marital status, education, date and time of the accident, cause of injury, and transport mode were collected through interviews with the patient or patient's companion. Pulse rate, respiratory rate, GCS, temperature, systolic blood pressure, intubation attempt, and date and time of arrival to the emergency department are extracted from the medical records. AIS, ISS, ICU length of stay, hospital length of stay, and patient outcomes, including hospital death or discharge, discharge date, and payment method, were also extracted from the hospital information system (HIS).

Finally, data forms were filled out and uploaded to the NTRI web-based portal by three dedicated registrars. They created a record for each new patient and entered the required data in case report forms. Each patient has a unique identifier. Therefore, one record is created for each patient in the system. After data entry and submission of patient records in the system by registrars, quality reviewers checked data for completeness, consistency, and accuracy. If there were a problem with each data element, it was specified with a comment by the quality reviewer. Then, the record was returned electronically to the corresponding registrar for correction. Otherwise, the submitted data were verified by the quality reviewer. Details of variables and how to collect them have been previously described in detail.^[15,16,18]

The data collected in the SHTR by May 28, 2021, were used in the study to determine completeness. According to the data, the missing percentages in variables of age, gender, marital status, education, date and time of incident, date and time of arrival to the emergency department, date and time of hospital admission, cause of injury, transport mode, pulse rate, respiratory rate, GCS, AIS, ISS, intubation attempt, ICU length of stay, hospital length of stay, and outcomes including in-hospital death or discharge, discharge date and time and the payment method were calculated.

To evaluate the reliability of the data, 250 patients registered in the NTRI were selected from the registry using a simple random sampling strategy. In the next step, all data registration processes were re-conducted for the 250 patients. Two nursing experts conducted the registration. To assess reliability, the data collected in this step were compared to those registered in the NTRI. Data recorded in the HIS, including AIS, ISS, ICU length of stay, hospital length of stay, outcome, and payment method were compared with medical records.

Sina Hospital is equipped with a HIS in which all patient's data admitted to the hospital are registered. The list of trauma patients obtained from the trauma registry was compared to the one obtained from HIS to estimate the coverage. Accordingly, 60 days were randomly selected out of the active days in the trauma registry. Then, all patients who satisfied the NTRI inclusion criteria according to HIS during these 60 days were considered the fraction's denominator. The fraction's numerator comprised those registered in the Trauma Registry in these 60 days.

Statistical analysis

The quantitative variables with normal distribution were expressed as the mean \pm SD, and the categorical variables

were presented as a percentage and frequency. The intra-class correlation coefficient (ICC) and the kappa and weighted kappa statistics were used to evaluate quantitative and categorical data reliability and agreement. Also, a confidence interval of 95% was presented for these indices. For the ICC, values greater than 0.70 were considered optimal agreement. Also, kappa and weighted kappa statistics were interpreted based on Koch's classification indicating 0.01 to 0.20 as slight agreement, 0.21 to 0.40 as fair agreement, 0.41 to 0.60 as moderate agreement, 0.61 to 0.80 as substantial agreement, and above 0.80 as almost perfect agreement. Analyses were performed using STATA 14.0 (StataCorp LLC, College Station, Texas, USA).

Ethical considerations

The Ethics Committee of Tehran University of Medical Sciences has ethically approved this study with code number 97-03-38-345. All methods were performed in accordance with the ethical standards as laid down in the Declaration of Helsinki and its later amendments or comparable ethical standards. Also, Informed consent was obtained from all individual participants included in the study.

Results

Five thousand four hundred ninety-eight trauma patients had been included in the registry until May 28, 2021. Table 1 shows the missing percentage for each of the variables. The overall average completeness for all variables was 97.9%. The percentages of missing data ranged from 0.0% to 15.7%. The highest percentage of missing values was observed in the ISS variable (15.7%) and the lowest percentage in the cause of injury. Accordingly, the results showed that ISS was not registered for 861 out of the 5498 patients.

Table 2. The agreement on the different variables between the initial and audit registrars in the population sample (n = 250), intra-class correlation coefficient (ICC) and 95% confidence intervals (CI)

	ICC	95% CI for ICC
Age	0.99	0.98 to 0.99
Education	0.91	0.85 to 0.97
Pulse rate	0.60	0.52 to 0.68
Respiratory rate	0.65	0.56 to 0.73
Systolic blood pressure	0.69	0.62 to 0.75
Glasgow Coma Scale	0.99	0.99 to 1.00
Injury Severity Score (ISS)	0.72	0.66 to 0.81
Temperature	0.88	0.85 to 0.91
Hospital length of stay	0.88	0.84 to 0.91
ICU length of stay	0.84	0.80 to 0.87

The comparison of data registered in the trauma registry and the re-registered data in the audit phase are shown in Tables 2 and 3. Based on the ICC, optimal reliability was observed in age, education, GCS, ISS, AIS, body temperature, hospital LOS, and ICU LOS. Hence, the inter-rater agreement on the ISS as an essential indicator of injury severity was 0.72 (95% CI: 0.66 to 0.81) [Table 2].

Table 1. Missing data for variables included in the completeness of trauma registry of Iran (Total patients=5498)

	Missing, N (%)
Age	6 (0.1)
Gender	3 (0.1)
Marital status	96 (1.8)
Education	267 (4.9)
Date of incident	5 (0.1)
Date of arrival to emergency department	6 (0.1)
Date of admission	7 (0.1)
Cause of injury	0 (0)
Transport mode	74 (1.3)
Field/On-scene GCS	245 (4.4)
Pulse rate	178 (3.2)
Temperature	118 (2.1)
Respiratory rate	164 (2.9)
Systolic blood pressure	74 (1.3)
Hospital GCS	112 (2.0)
Abbreviated Injury Scale (AIS)	24 (0.4)
Injury Severity Score (ISS)	861 (15.7)
Intubation	122 (2.2)
Hospital length of stay	23 (0.4)
ICU length of stay (n=863)*	21 (2.4)
Discharge status (patient outcome)	54 (1.0)
Discharge date	16 (0.3)
Payment method	51 (1.0)

GCS: Glasgow Coma Scale, ICU: Intensive Care Unit, *Number of patients admitted to the intensive care unit (n=863)

Based on the kappa statistics, the reliability of gender, cause of injury, transport mode, AIS, discharge status, and payment method were almost perfect. Accordingly, the inter-rater agreement on the AIS as a vital indicator of injury severity was almost perfect (ICC: 0.90, 95% CI: 0.83 to 0.97) [Table 3]. Also, marital status and intubation had moderate or substantial reliability.

Comparing HIS data with medical records showed that the variables of AIS, discharge status, and payment method between these two sources have a moderate agreement. Hence, the kappa statistic showed that 63%

(95% CI: 56% to 70%) of the AIS codes registered in the HIS matched the codes registered in the medical records [Table 4].

Finally, comparing the list of trauma patients who satisfied the inclusion criteria to the trauma registry with the list obtained from HIS showed that the SHTR had identified 79.6% of the total patients who had the inclusion criteria to enter this registry. In other words, out of 312 trauma patients based on HIS, 248 patients (79.6%) were registered in the trauma registry.

Table 3. The agreement on the different variables between the initial and audit registrars in the population sample (n = 250), kappa score and 95% confidence intervals (CI)

	Kappa score	95% CI for Kappa
Gender	0.98	0.86 to 1.00
Marital status	0.65	0.56 to 0.73
Cause of injury	0.83	0.76 to 0.91
Transport mode	0.91	0.79 to 1.00
Abbreviated Injury Scale (AIS)	0.90	0.83 to 0.97
Intubation	0.61	0.50 to 0.72
Discharge status (patient outcome)	0.71	0.67 to 0.76
Payment method	0.95	0.87 to 1.00

Table 4. The agreement between data recorded in National Trauma Registry of Iran compared with that from a medical record

	Kappa (95% CI)	ICC (95% CI)
Abbreviated Injury Scale (AIS)	0.64 (0.56 to 0.70)	-
Discharge status (patient outcome)	0.72 (0.65 to 0.78)	-
Payment method	0.69 (0.57 to 0.78)	-
Injury Severity Score (ISS)	-	0.60 (0.52 to 0.68)
Hospital length of stay	-	0.67 (0.58 to 0.75)
ICU length of stay	-	0.63 (0.55 to 0.70)

Discussion

This study aimed to investigate the coverage of the National Trauma Registry of Iran and assess the completeness and reliability of its data. The results showed that the SHTR has successfully registered 79.6% of eligible patients. Also, on average, the variables were fully recorded for more than 97% of patients. Reliability indices also showed that essential variables such as ISS, AIS, and discharge status (patient outcome) had optimal reliability.

In previous studies, data completeness of trauma registries varied from excellent to very poor.^[10,13,19,20] The high data completeness in the NTRI can be justified by the precise control of the data collection process by dedicated registrars and quality reviewers. The results of a study by M. Heinänen et al., which was conducted to investigate the quality of the Helsinki Trauma Registry, showed that the coverage of this registry was 97.1%, and AIS codes had

been recorded for 99% of individuals.^[19] Also, 90% of the AIS codes in the registry were confirmed with a verifiable source. The coverage in our registry was 79.6%, which is lower than the Helsinki Trauma Registry. One of the possible reasons for this inconsistency could be the difference in the inclusion criteria of the two registries. According to the Helsinki Trauma Registry, people with New Injury Severity Scores (NISS) higher than 15 are included in the study. In other words, the present study is limited to severe trauma. However, in the present study, all trauma patients with any ISS can meet the criteria for entry into the registry.^[19] Also, the agreement of AIS codes between NTRI's data compared with that from medical records was lower than that of M. Heinänen et al. The low agreement of AIS codes cannot affect the registry coverage. However, it can lead to incorrect calculation of the ISS and, ultimately, errors in statistical analysis.

Although AIS codes were recorded for 99.6% of patients, the ISS was not recorded for 15.7% of patients. One of the reasons could be that the AIS codes are not registered correctly. The results of Bismil Ali Ali et al.'s study showed that in the Major Trauma Registry of Navarra, the average completeness of data for all variables was about 92.8%. Also, on average, 98.0% of the variables registered corresponded to the patient's medical files. The highest discordancy between the registry system and the patients' medical files was observed in the AIS codes (6.0%) and ISS (5.0%).^[13]

This study has strengths and considerations. It is the first study that assessed the completeness and quality of the NTRI data. A review of the literature shows that one of the common approaches to measuring the data validity of a registry is to compare the data recorded in the registry with the patients' medical records.^[21] We used the same approach in the present study. However, it is essential to note that the data recorded in the medical files may not be entirely valid. Also, in the present study, it should be noted that a considerable part of the data is extracted from the medical files and entered into the registry system. As a result, only reliability indicators can be reported for this data. Due to the lack of evidence in the country about the validity of medical records, assessing the validity of medical records in Iran and specifically medical records of trauma patients in future studies can be necessary. Comparing the present study results with those of the previous studies shows that the NTRI has acceptable reliability, especially in essential variables such as AIS codes and ISS.

Conclusions

Findings of this study show that the NTRI data completeness is excellent. In addition, most of the variables, especially ISS and AIS codes, had acceptable reliability. However, there was moderate agreement between NTRI's data and the medical record data for AIS codes and ISS.

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None.

Competing interests

Mohammad Reza Zafarghandi is the director of the national trauma registry of Iran. Also, Payman Salamati is the executive director of the national trauma registry of Iran. The other authors declare that there is no conflict of interest.

Abbreviations

Abbreviated Injury Scale: AIS;
Injury Severity Score: ISS;
New Injury Severity Scores: NISS;
Intraclass correlation coefficient: ICC;
Length of stay: LOS;
Glasgow Coma Scale: GCS;
Intensive Care Unit: ICU.

Authors' contributions

PS, VB, and MKH made substantial contributions to the study conception and design, the acquisition, analysis, and interpretation of data, drafting the manuscript, and revising the manuscript critically for important intellectual content. MRZ and VRM contributed to the study design and interpretation of data and revised the manuscript critically. All authors read and approved the final manuscript. All authors take responsibility for the integrity of the data and the accuracy of the data analysis.

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Role of the funding source

None.

Availability of data and materials

The data used in this study are available from the corresponding author on request.

Ethics approval and consent to participate

The Ethics Committee of Tehran University of Medical Sciences has ethically approved this study with code number 97-03-38-345. All methods were performed in accordance with the ethical standards as laid down in the Declaration of Helsinki and its later amendments or comparable ethical standards. Also, Informed consent was obtained from all individual participants included in the study.

Consent for publication

By submitting this document, the authors declare their consent for the final accepted version of the manuscript to be considered for publication.

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