



The Content Validity and Reliability of Injury Severity Parameters in Data Collection Tool for Developing a National Trauma Prognostic Scale (TPS)

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Abstract

Background: Trauma injuries are a health threat to the whole world and according to 2016 WHO report, are one of the top ten causes of death. This study aimed to determine the content validity and inter-rater reliability of a data collection tool used to develop a national trauma prognostic scale (TPS).

Methods: The study was conducted in three stages including the development of the primary tool, assessment of the validity tool, and assessment of the reliability. The content validity, inter-rater reliability, and intra-rater reliability were assessed. For reliability assessment, 45 trauma patients from three trauma specialty centers in Tehran and Tabriz metropolises participated in the study.

Results: The final data collection tool had a total of 51 items in six parts as demographic (part A with 9 items); past medical history (part B with 14 items); type of patients' transferring (Part C with 3 items); pre-hospital measures (part D with 9 items); physiological indicators of injury severity (part E with 9 items), and anatomical indicators of injury severity (part F with 7 items). The content validity of the tool was confirmed with a total scale-level content validity ($S-CVI = 0.93$, $S-CVI = 0.92$ for part A, $S-CVI = 0.90$ for part B, $S-CVI = 1.000$ for part C, $S-CVI = 0.90$ for part D, $S-CVI = 0.95$ for part E, and $S-CVI = 0.91$ for part F. Spearman correlation was above 0.7 for all items.

Conclusions: The content validity, and inter-rater test-retest reliability of the data collection tool for the developed TPS was confirmed.

Keywords: Trauma, Injury, Prognostic, Validity, Reliability.

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Introduction

Trauma injuries are a health threat to the whole world and according to 2016 WHO report, are one of the top ten causes of death.^{1,2} Trauma is a growing problem for most of the world's societies and is one of the leading causes of human. Disability³⁻⁵ Based on WHO reports, about 1.2 million people die each year due to road traffic trauma and about 50 million are injured.⁶ Trauma is also the leading cause of death and disability in children and adolescents.⁷ In low-income countries, 11% of all lost years are due to trauma disability.⁸ In developing countries, trauma is among the main causes of disability in the active population, which results in a high economic burden.^{9,10}

The use of a valid scoring index for trauma severity plays an important role in determining the prognosis of trauma patients.¹¹ In general, there are three types of scoring scales for the prediction of trauma-related deaths; 1) scales based on patients' physiological responses; 2) scales based on patients' anatomical status; 3) combination scales that use both physiological and anatomical indicators.^{12,13} These scoring scales apply for 1) predicting the consequences of trauma; 2) triage in pre-hospital trauma; 3) ensuring the quality of care; 4) trauma death audit; 5) resource allocation; 6) assessing trauma care quality between trauma centers; 7) trauma care research; 8) strengthening trauma registration systems.¹³ There are about 256 scales of trauma scoring in the world, each of which has been built based on specific conditions of countries and available facilities in hospitals.^{13,14}

Iran has the leading rank for the frequency of trauma cases in the Middle East.¹⁵ This is the largest number among Middle East countries and is above the world average number. Despite this fact, there is no appropriate national scale for trauma severity so far in Iran. To develop a national trauma prognostic scale (TPS) a study was conducted in the Iran emergency medicine organization in collaboration with Tabriz university of medical sciences. This article reports the reliability and validity study of the final tool used for gathering trauma patients data needed in the development of Iran's national TPS.

Materials and Methods

This study generally consists of three stages including the development of the primary tool, content validity, and Inter-rater reliability assessment.

Development of the primary tool: In the first step, a literature review was conducted to identify the items which are important in predicting trauma-related deaths. Studies that used trauma scores/scales at the hospital or prehospital levels as well as important indexes in predicting trauma-related deaths were included in the review. From each individual score/scale or index, only one article was selected and entered to review. The search databases included PubMed, ProQuest, Ovid, EBSCO, EMBASE, Science Direct, Web of Science, Wiley, Scopus, and Google Scholar. Table 1 summarizes the search strategy.

After the literature review, a primary checklist was developed by the research team and sent for review to an expert panel. The primary expert panel included five specialists in the

fields of epidemiology and emergency medicine with at least 10 years of experience in trauma research. The expert panel evaluated items/scores of the primary checklist for relevance and feasibility. They also asked for introducing other indicators that were not included but could have been important in predicting trauma-related deaths if necessary. Getting feedback from the expert panel and eliminating unfeasible items, the primary tool was created.

Content validity assessment: The created primary tool was sent to a secondary expert panel for assessment of the content validity. The secondary expert panel consisted of 15 trauma scientists with at least 10 years of trauma research and clinical experience including three specialists in epidemiology and biostatistics, five in emergency medicine, one in orthopedics, one in psychiatry, two in neuroscience, two in general surgery, and one in anesthesia. They were asked to evaluate the item's relevance through a four-choice question including 1) irrelevant, 2) relevant but needs a serious review, 3) relevant but needs minor review, and 4) completely relevant. They also requested to assess the necessity of the item's existence in the form using a three-choice question including 1) necessary, 2) useful but unnecessary, and 3) unnecessary. After these steps, the final tools were developed.

Inter-rater reliability (IRR): Patients' data were collected separately by three trained general practitioners under the supervision of an emergency medicine resident using the above-mentioned tool. Each physician evaluated 15 trauma patients with 5 patients in each trauma specialty center. Patients received informed consent to participate in this study. Inclusion criteria for patients were trauma-based referral to any of the three trauma specialty centers; a maximum of 24 hours elapsed since the occurrence of the trauma; referral to trauma centers with trauma as the chief complaint excluding referrals due to trauma complications.

Statistical analysis: Indicators' item-level content validity index (I-CVI), scale-level content validity (S-CVI), content validity ratio (CVR), and modified CVI (modified kappa) were used to evaluate the content validity. If the CVI score is higher than 0.79 and the CVR score is higher than 0.49, the validity of the item/scale content is confirmed [16].

To calculate CVR statistic, the following formula was used:

$$CVR = \left[N - \frac{N}{2} \right] / \left[\frac{N}{2} \right]$$

Where N is the number of specialists who have to choose the "necessary" option, and N is the total number of specialists.

To calculate the modified content validity (modified kappa) statistic, the probability of chance agreement was calculated for each item using the following formula:

$$PC = \left[\frac{N!}{A! (N-A)!} \right] * 5^N =$$

Where N stands for the number of experts and A shows the number of agreeing specialists. Modified kappa was computed by entering the numerical values of the probability of chance agreement (PC) in the following formula:

$$K = (I_CVI - PC) / 1 - PC$$

Where K is the modified kappa. Evaluation criteria for modified kappa are Excellent (K >0.74); Good (K between 0.60–0.74); Fair (K between 0.40–0.59) [17]. Statistical analyses were conducted using Stata software version 14 descriptive.

For intra-rater reliability (IRR) assessment, the spearman correlation was calculated.

Results

Search in scientific databases resulted in 512 articles 447 of which were removed by reviewing the titles and abstracts. The items of the primary checklist were extracted from the 65 remained articles. This checklist consisted of a total of 63 items in six parts including demographic (part A with 15 items) and past medical history (part B with 17 items), type of patients' transferring (Part C with 4 items), pre-hospital measures (part D with 10 items), physiological indicators of injury severity (part E with 8 items) and anatomical indicators of injury severity (part F with 9 items). Through investigating the feasibility of measurement items/scores in part A, weight and height items were removed from the primary tool because only 26.67% of the expert panel approved their feasibility for the current setting. Similarly, the collision speed item in part C was also removed due to an expert panel consensus of 40.00 % on its feasibility. In part D, 73.33 % of the expert panel members stated that measurement of the time between the trauma occurrence and the arrival of the ambulance at the scene is not possible. Therefore, this item was removed. The items regarding the depth of wound or scratch and the amount of lost blood in part F, gained an expert panel consensus of 40.00 % and 20.00% respectively, and therefore excluded from the primary tool. As a result, parts A, C, D, and F kept 13, 3, 9, and 7 items respectively.

The CVR value was higher than 0.49 for 90.00% of items in part A, 82.36% of items in part B, and 100.00 % of items in other parts. The value of I-CVI was higher or equal to 0.80 for 90.0% of items in part A, 82.36 % of items in part B, and 100.00 % of items in other parts. The value of modified content validity was more than 0.80 for all items in all parts. The content validity of the tool was confirmed with a total scale-level content validity (S-CVI) = 0.93, S-CVI= 0.92 for part A, S-CVI= 0.90 for part B, S-CVI= 1.000 for part C, S-CVI= 0.90 for part D, S-CVI= 0.95 for part E, S-CVI= 0.91 for part F. The content validity analysis resulted in the elimination of the treating physician name in part A, and Rheumatism disease, Osteoporosis disease, and urological disorders in part B as they didn't score the needed points (table 2).

The content validity of the tool was confirmed with an S-CVI= 0.948 for part E and S-CVI= 0.914 for part F (table 3).

At the end of the content validity analysis, the final tool kept 51 items in six parts including part A with nine items, part B with 14 items, part C with three items, part D with nine items, part E with nine items, and part F with seven items. According to the expert panel, the follow-up of each patient was considered in three phases of "on admission", "24 hours after admission", and "one month after admission".

Forty-five trauma patients from three trauma specialty centers in Tehran and Tabriz participated in the study. Out of these, 32 (71.10%) patients were male and the mean age of

patients was 34.06 ± 16.9 . None of the patients died due to trauma (table 4).

Due to the results of spearman correlation analysis, there is a high correlation between the values measured by general practitioners and the values measured by the emergency resident. Therefore, the final tool was found to be reliable. The lowest spearman correlation coefficient, 0.6 belonged to the trauma mechanism. The Spearman correlation coefficient was in a range of 0.7 to 0.9 for Body temperature, AIS, FIO₂, Specific organ damage, and O₂ Saturation. The coefficient was highest in a range of 0.9-0.99 for most of the items including GCS, 4 scores, systolic blood pressure, diastolic blood pressure, pulse rate, ISS, NISS, MISS, and PTS.

Discussion

In this study, we used the expert panel group to make tools, including various specialties involved in providing services to patients with trauma. The system of providing services to patients with trauma includes different levels. At each of these levels, specialists, including emergency medicine, orthopedics, neurology, surgery, and general practitioners, provide services to patients with trauma.¹³ It is a necessity to consider the opinion of different specialists providing services to trauma patients. This will increase the efficiency of the trauma scoring index and refer patients more accurately between different levels. In this study, before evaluating the validity and reliability, we first examined the items in the primary tool in terms of the possibility of measuring at different levels from the perspective of different experts and removed items that could not be measured from the tool. Deleting these items allows the tool to develop indicators specific to each level of service delivery. To make this tool, we used 52 items, including physiological and anatomical items. These 52 items are used in various international scoring indicators (at different levels of care for trauma patients). This makes it possible for the research project to provide item comparison and modeling in a wider range of measurements in order to compare various types of current scales. The use of these various items makes it possible for the existing tools to develop indicators specific to each level in Iran and drawers with similar conditions in terms of facilities available at different levels of service for patients with trauma. In this study, all age groups were considered and it was tried to use the items in the international scoring indicators have been created for all age groups and specific age groups in making the tools of this study. The use of these items makes the indicators developed by this tool usable for different age groups. There is a wide range of trauma scores/scales in the world, each of which uses different items to measure and score trauma. These scores/scales are based on the facilities available in developing countries, which makes it difficult to use them in other countries with different levels of facilities to provide to trauma patients.³⁻¹⁸ For example, some of these scores/scales are provided for screening and triage of trauma patients at the pre-hospital level and not may be the best choices for use in other levels of service delivery to patients with trauma. Among these scores/scales, we can mention GAP and PHI scores.^{19,20} The GAP index consists of three items of GCS (Consciousness Level Index, which consists of sub-items of eye, verbal, and motor, this score is scored between 3 and 15), the patient's systolic blood pressure, and the patient's age.¹⁹ The PHI score

consists of GCS, systolic blood pressure, and heart rate.²⁰ Both of these scores are suitable scores for the pre-hospital stage and patient triage, while they are not suitable for the hospital level.²¹ Among the scores/scales used at the hospital level to score and evaluate patients with trauma are TRISS (Trauma Injury Severity Score), PTS (Pediatric Trauma Score), and ICSS (ICD-derived ISS).^{22,23} The TRISS score is a composite score consisting of ISS (Injury Severity Score), RTS (Revised Trauma Score), and age. The RTS score also includes GCS, patient systolic blood pressure, and heart rate. Although the RTS score is a useful score for scoring in patients with trauma,²⁴ an important part of the RTS score depends on the respiratory rate. Since measuring the respiratory rate is a qualitative item, it makes the RTS score not very reliable. Although TRISS is a comprehensive composite score, its ISS part requires accurate anatomical clinical diagnosis, which also requires the use of radiology, ultrasound, and CT scans, while these tools are not available in all general hospitals for patients with trauma. On the other hand, score TRISS lacks item O₂ Saturation.²⁵⁻²⁸ The evidence shows that the O₂ Saturation index is a good indicator for predicting the care needs of patients, including trauma patients.²⁹ Considering the importance of index O₂ saturation in predicting the required services for patients with trauma and considering that the pulse dosimeter is available in different levels of medical services in Iran for patients with trauma and is easily available to the treatment staff, it O₂ Saturation index can be easily measured for patients with trauma. That's why we put the O₂ Saturation index in the tool. The PTS score is a combination of both anatomical and physiological items including weight, airway status, systolic blood pressure, wound status, central nervous system (CNS) status and fracture status that is developed for use in assessing pediatric trauma.³⁰ Although TPS is a very comprehensive score for assessing and scoring trauma in children, this index cannot be used for scoring adults, so it cannot be used alone for all patients with trauma.^{23,31,32} The ICSS score is another anatomical score that, like the ISS, rates trauma based on trauma anatomy status. This score is scored based on ICD codes. At first this score was a risk adjustment model when recording injuries using ICD-9-CM encoding (TPM-ICD9). Although the TPM-ICD9 score is statistically accurate it is not mathematically accurate. This index tends to overestimate the severity of the injury. For this reason, this index was updated again using ninth edition, clinical modification (ICD-9-CM). The IMP-ICDX has better discrimination and calibration compared to ISS.³³ The codes of IMP-ICDX are easily available and have advantages over the ISS index, which is also present in the TRISS combined score, which includes covering all injuries and the simplicity of training in scoring this index for the physicians who perform the evaluation. But as we mentioned, ICSS is just an anatomical score and does not include physiological items, and on the other hand, it is not suitable for scoring trauma at the pre-hospital level.²² To the best of our knowledge, there is yet no trauma prognostic score/scale of approved for widespread use in Iran applicable for different levels of trauma care including pre-hospital level, general hospital level, and trauma specialty centers.¹³ This study was conducted to determine the content validity and inter-rater reliability of a data collection tool used to develop a national TPS. The composition of patients participating in this study was close to the composition

of trauma patients in the Iranian trauma registry system. In the national trauma registry of Iran, road traffic accidents, falls, and penetrating injuries are the three main causes of trauma with 57.78 %, 17.78 %, and 20.00 % proportions, respectively, and in the study of road traffic accidents, falls, and penetrating injuries are three main causes of trauma with 53.20 %, 21.10 % and 18.70 % proportions.³⁴ This led us to believe that our developed tool can be used to create a national predictive scale/score for predictable deaths in trauma patients. As our data collection tool uses a combination of scores/scales from both pre-hospital and hospital levels, we believe that this tool can be used to construct prediction models for trauma-related death at all levels. One of the limitations of this study is the use of a selected number of trauma-scoring indicators and not all of these trauma-scoring indicators. We suggest that more studies be conducted in the future to use this tool in the development of trauma scoring indices on patients with varying degrees of trauma at different levels of service, to determine the effectiveness of this tool.

The content validity and inter-rater test-retest reliability of the data collection tool for the developed TPS was confirmed.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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