doi:10.22100/ijhs.v8i1.882
Original Article

IJHS 2022;8(1):11-17
ijhs.shmu.ac.ir
IJHS
International Journal of Health Studies

Determining a National Trauma Prognostic Scale (TPS) to Predict Preventable Trauma Death in Iran: The Research Protocol

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Received: 23 June 2021
Accepted: 1 September 2021

Abstract

Background: *Despite available trauma scoring (TS) models, considering the setting characteristics and feasibility issues, there may be a need to select, develop or adapt a trauma prognostic model to ensure higher efficacy and system compliance. Upon a national demand, this study aimed to develop a trauma prognostic scale (TPS) in compliance with the Iranian health care system.*

Methods: *A 7-phases methodology will be applied to conduct this study as following; 1- Identification of trauma severity parameters and scales predicting mortality from literature, 2- Developing a data collection tool for research data collection), 3- Data collection in selected clinical settings, 4- Statistical modeling, 5- Model adaptation with three levels of trauma care settings including pre-hospitals, general hospitals and trauma specialty hospitals, 6- Scale-up and extrapolation, and 7- Comparison with international models and selection of Iranian national model.*

Results: *The content validity of the tool was confirmed with a total scale-level content validity (S-CVI)=0.93. The reliability of the final instrument was calculated using the Pearson correlation coefficient and the Spearman correlation was evaluated above 0.7 for all cases. Up to date April 2020, From the hospital of the study, 210 patients participated in the study. The mean and standard age deviation of patients was 35.18±18.44 and 165 (78.57 %) of these patients were male. The most important cause of trauma in patients was a motorcycle accident (27.62 %).*

Conclusions: *We expect this methodology is satisfied with developing TPS prototypes appropriate for implementation in the Iranian trauma care system.*

Keywords: Trauma, Modeling, Injury severity assessment, Mortality predictor, Trauma scale.

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Please cite this paper as: Jalilvand H, Sadeghi-Bazargani H, Nouri Sari H, Meshkini M, Kolivand PH, Ala A, et al. Determining a national trauma prognostic scale (TPS) to predict preventable trauma death in Iran: the research protocol. Int J Health Stud 2022;8(1):11-17

Introduction

Trauma is one of the main problems for the healthcare system worldwide.[1,2] In medicine, any type of wound or penetrating injury due to the intentional or unintentional external factors in the human body is called trauma.[3-5] Traumatic injuries are a threat to health worldwide and are responsible for 9% of deaths worldwide.[6] Trauma is the most common cause of death in the first 30 years of life[5,7] and a major cause of death especially in children between age 1 and 14 years.[5] According to the Korean medical emergency organization, the proportion of trauma patients and their mortality rate is steadily increasing.[8] From 2000 to 2010 trauma in the United States population has been increased by 9.70% and the number of deaths caused by trauma increased by 22.8%, the biggest increase in mortality due to the trauma was in the fifth and sixth decades of life, and in 54 year-olds they saw the highest relative increase in mortality due to trauma (118%). In the United States, trauma is now the most important cause of death in people with 46 years old and younger.[9] In low-income countries, 11% of all years of life lost is due to trauma-related disability.[8] Trauma is the first cause of death and one of the main causes of disability of the active population in the developing countries,[10,11] but these countries have low attention to this subject.[12] Also, blunt trauma is the leading cause of death in the industry.[13] Iran has the highest frequency of trauma among Middle Eastern countries. The prevalence of trauma in Iran is 58 per 100,000 people and the most important factor is traffic accidents.[14] In Iran the direct and indirect cost of trauma is high, for example, the average cost of a death case caused by traffic accidents is about 45000 USD and the average cost of a permanent disability is about 70000 USD.[15] There are three types of scales for assessing trauma which are physiological scales, anatomical scales, and combined scales.[16,17]

Trauma scoring systems are used for various purposes including; 1- Predicting the outcome of trauma which is a function of its intensity. By determining the severity of trauma in valid and reliable ways, it is possible to determine the probable outcome in injured persons. 2- Supporting the pre-hospital triage: The severity of trauma determines the level of medical care that the injured person needs. A proper assessment of the severity of the injury will be useful in identifying those who need immediate transfer to advanced centers, and in determining the priority of the transfer (like air transportation). 3- For Care quality assurance: Determining the severity of trauma contributes to compare the effectiveness of caring from patients with similar severity of the injury. This also makes it possible to monitor the effectiveness of care and to identify any changes in care outcomes. 4- To identify appropriate death audit cases. 5- Trauma scores/scales indicators are used for resource allocation, end-of-life decisions, trauma care assessment with and between trauma centers, trauma care researches, strengthening trauma registration system.[17]

Having a trauma management system is necessary because numerous studies have shown that the survival of traumatized patients increases after the establishment of the trauma care system. Trauma scoring indexes can be used at the trauma scene, through the transfer to a hospital and in the hospital.[18] The pattern and incidence of injuries may highly vary according to geographical regions, environmental situations, and population variants. Despite the astonishing number of up to 258 trauma scoring models presented worldwide, there is no specific trauma system developed or adopted or approved for use in Iran.[17,19,20] Accordingly, the big question is on deciding which indicator to use at the national level and what tool to be used. There is also no unanimously acceptable national indicator for predicting the preventable death in Iran.[17] Therefore, this study aimed to design a tool for measuring injury severity parameters for building a national model of traumatic death predictors to be most appropriate for use at various referral levels.

Materials and Methods

This is a national multicenter prospective study in Iran. TPS score is looking for developing a model that can be used in Iran or in countries with similar settings most appropriate to be used at trauma settings of different referral namely trauma specialty hospitals; general hospitals; and pre-hospital situations.

Participants of this study are in two categories of hospital wards (traumatic patients admitted to the emergency department or transferred patients from other hospitals) and pre-hospital ward (traumatic patients who transferred with emergency medical service to hospitals).

Study eligibility: Previous studies on trauma scoring indices assessed patients in physiologic, anatomic, and combined categories (Table 1).

Measurement and development of the model have been done in three phases.

Phase 0: In this phase, we will run a systemic review about trauma scoring indices and we will define any parameter which they used in their studies. We will compare them and find their advantages and disadvantages.

Phase 1: The view of expert members will commonly be evaluated by using well-known scoring indicators i.e. level of consciousness as well as some other modifiable factors affecting trauma mortality. After identifying related indicators and modifying parameters according to feasibility and cost of conditions in trauma specialty hospitals in Iran, they will be evaluated by field experts using the Delphi technique.

Phase 2: To make a model for the main three hospitals having trauma service centers across Iran, based on the level of facilities of those hospitals, the opinion of the Iranian ministry of health and medical education, the opinion of the emergency medical services in Iran, and the willingness to cooperate are selected. These three centers were Imam Reza medical research & training hospital located in Tabriz, Shohaday Haft-e-Tir hospital, and Imam Khomeini hospital both located in Tehran, Iran. 300 trauma patients (sample 1) were selected based on the ATLS guideline and the information collected in the tool. Then using multiple regression model specification and assessing study sample 1, the predictive power of the different models were finally examined, and the model that had the best predictive power was chosen as the full model, herein referred to as M1.

In the same three trauma specialty hospitals, 300 new trauma patients (sample 2) will be selected, and the data collection instrument we are administered for these new patients. Then the mortality predictive power of the first model (model M1) on data these patients will be evaluated using the receiver operating characteristic (ROC) Curve and versus the predictive power of the model in the previous patients (sample1). If it gives rise to an acceptable predictive power through step 1 external validation, the study enters the next phase of external validity assessment, otherwise, the remodeling using data from sample 1 and /or sample 2 will be done until an acceptable predictive power is reached. Model external validity assessment in trauma specialty hospitals: three other trauma Special centers were selected in Iran including Sina university hospital Tehran, Fatemi university hospital Ardabil and Imam Khomeini university hospital Urmia. Thereafter, the final instrument information was completed for the 300 new trauma patients (sample 3), and the data were collected using the final tools made in phase II for this sample. After data collection and model assessment, the performance of the M1 model on sample 3 data was tested. There were two possible modes: 1) acceptable predictive power on external validation step 3, in which the narration enters the next stage. 2) not acceptable predictive power on external validation step 2 (section 1): in this case remodeling iteration until the appropriate model is reached and after reaching the appropriate model, the model enters the next step of external validation.

Model adaptation for general hospitals and pre-hospital trauma cares: At this point, the parameters were initially measured from three aspects: Feasibility, cost, and parameter contribution effect size. The feasibility of this study is to determine which of the parameters in model M in public hospitals and pre-hospital settings can be measured based on the facilities available in these centers. In terms of cost, it also means that we consider each of the parameters in model M in terms of the cost of the collection at these centers. After specifying the parameters as described above, formatting model M1 into prognostic scales, the three proprietary models can be built including TPS-TH (for trauma specialty hospitals), TPS-GH (for general hospital (non-trauma specialty hospitals)), and TPS-PH (for pre-hospital). There are two steps at this stage: 1) Assessing the prognostic value of scales based on the reduced model (TPS-GH and TPS-PH) applied on accumulated samples (sample 1, sample 2, sample 3), and 2) Comparing our three prognostic scales (TPS-TH, TPS-GH, and TPS-PH) with previously presented trauma severity scales regarding their overall standardized score agreement and predictive power.

The external validity of TPS-GH: 1) data collection: Initially, five general hospitals (non-trauma specialty hospitals) across the country were selected based on inclusion criteria, then 1000 trauma patients with an equal proportion of these hospitals were chosen. 2) Subsequently, the parameters of the model TPS-GH for these 1000 trauma patients were collected and the predictive power of this model was again evaluated.

The external validity of TPS-PH: 1) data collection: Initially, five EMS services across the country were selected based on inclusion criteria. Then thousands of trauma patients with an equal proportion of these EMS services were selected. 2) The parameters of the model TPS-PH for these 1000 trauma patients were collected and the predictive power of this model was again evaluated.

Table 1. The most important scores/scales that have been considered in the design of the tools of this study

Indices	Year of development	Description	What it assess	Type
Abbreviated injury scale[21, 22,23]	1971	Hospital patients	Type of injury, place of injury, severity of injury	Anatomic
Glasgow Coma scale [24,25,26]	1974	Pre-hospital-traumatic brain patients, awareness test	Eye response, verbal response, motor response	Physiologic
Injury severity score[23,27,28]	1974	Hospital, traumatic patients	The sum of the squares of the three regions of the AIS that have the most damage	Anatomic
Circulation, respiration, abdomen, motor, and speech[29,30,31]	1982	Pre-hospital, traumatic patients	Circulation, respiration, abdominal, motor, speech	Anatomic
Acute physiology, age, chronic health evaluation II[32,33,34,35]	1985	Hospital, traumatic patients	Temperature, mean arterial blood pressure, heart rate, the respiratory rate per minute, pH, arterial blood PaO2, sodium and potassium levels, serum creatinine, hematocrit, and white blood cell count, age, Chronic diseases	Physiologic
Pre-hospital index[36,37,38]	1986	Pre-hospital, traumatic patients	Blood pressure, pulse, respirations, consciousness	Physiologic
Trauma injury severity score[39-42]	1987	Hospital, traumatic patients	ISS and RTS	Combined
Pediatric trauma score[43-46]	1987	Hospital patients, child traumatic patients	Wight, airway, systolic, central nervous system, fractures, wounds	Combined
Modified ISS[47,48]	1987	Hospital, traumatic patients	Total squares of 3 physical areas of abbreviated injury scale	Anatomic
Revised trauma score[49-52]	1989	Hospital, traumatic patients	Glasgow Coma scale, systolic blood pressure, respiratory rate	Physiologic
Triage revised trauma score[49,53]	1989	Pre-hospital, traumatic patients	Revised trauma score used in Triassic	Physiologic
A severity characterization of trauma[54-57]	1990	Pre-hospital, traumatic patients	Abbreviated injury scale, age, revised trauma score, Glasgow coma scale, systolic blood pressure, respiratory rate	Anatomic
New injury severity score[58,59,60]	1997	Hospital, traumatic patients	Based on 3 severe abbreviated injury scale -based body injuries, no matter the area	Anatomic
Rapid emergency medicine score[61,62,63]	2003	Pre-hospital, Traumatic patients	Glasgow Coma scale, respiratory rate, oxygen saturation, mean arterial pressure, heart rate, and age.	Physiologic
ICD-derived injury severity score[64]	2008	Hospital, traumatic patients	Survival score is based on ICD-9 classification	Anatomic
Emergency trauma score[65]	2009	Pre-hospital, traumatic patients	Prothrombin time, base excess, Glasgow Coma scale, age	Physiologic
The mechanism, Glasgow Coma scale, age, and arterial pressure[66]	2009	Pre-hospital, traumatic patients	Glasgow Coma scale, age, mechanism of injury, and blood pressure systolic	Physiologic
Glasgow coma scale, Age and arterial Pressure[53]	2010	Pre-hospital, traumatic patients	Glasgow Coma scale, age, blood pressure Systolic	Physiologic

Comparison with international models and selection of the best models for Iran: at this stage, the predictive power of the TPS-TH, TPS-GH, and TPS-PH models will be compared in terms of the feasibility of assessment at the aforementioned three levels concerning the conditions of Iran with the international models. Finally, the best model for the three sections of trauma specialty hospitals, general hospitals, and pre-hospital settings was chosen. After extracting previous models' indicators of assessment we will use the Delphi method to construct the final TS Model and I-CVI, S-CVI, CVR, modified Kapa, and Alpha Cronbach will be run for validity and reliability. Also, PLS-DA will be used for the dimension reduction method. We will use Logistic regression for the two-way consequence of death and multiple linear regression for the survival time variable. Stata 14 and SPSS are the main analysis programs that will be used in this research. We will share our funding with shareholders, the ministry of health, and the national emergency department, and at last, we will publish articles for public access. This study will: 1. Help to the grading of hospitals for giving services to traumatic patients 2. Affect general policies 3. Help to the prediction of trauma outcome 4. Help in assessing proper death audit 5. Help to the comparison of hospitals services for traumatic patients.

Results

In the first phase of this study, the data collection tools of this study were designed and their validity and reliability were investigated. The initial questionnaire included 63 items in six sections including demographics (part A with 15 items), patient's previous medical history (part B with 17 items), type of patient transfer to the hospital (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). The final data collection tool had a total of 51 items. To evaluate the reliability of the study, 45 patients from the three hospitals participated. 32 (71.10%) patients were male and the mean age of patients was 34.06±16.9. The content validity of the tool was confirmed with a total scale-level content validity (S-CVI)=0.93. The reliability of the final instrument was calculated using the Pearson correlation coefficient and Spearman correlation was evaluated above 0.7 for all cases. Out of 300 case-patients who were to be evaluated in the first stage (sample one) according to this protocol, Up to date April 2020, From the hospital of the study, 210 patients participated in the study in equal proportions (70 patients in each hospital). The mean and standard age deviation of patients was 35.18±18.44 and 165 (78.57 %) of these patients were male. Among the patients, 159 patients (75.71 %) were transferred directly from the accident site and 51 patients (24.29 %) were transferred from other medical centers to the studied hospitals. Out of the total number of patients, 135 patients (64.29 %) were transported by emergency medical ambulance (115 ambulances), 28 patients (13.33 %) by personal ambulance, and 47 patients (22.38 %) by ambulance to medical centers. The most important cause of trauma in patients was a motorcycle accident. The most important injured limbs of the patients were head and face injuries. Finally, until one-month follow-up, 25 patients (11.90 %) died and 140 patients (66.67 %) survived. Out of 210 patients, 45 patients (21.43 %) were alive until the 24-hour follow-up but did not participate in the one-month follow-up. (Table 2).

Discussion

Since the construction of the tools used in this protocol, we have a complete search to find the scoring indicators widely used in scoring and predicting the outcome of trauma in patients with trauma in various databases such as PubMed, ProQuest, Ovid, EBSCO, EMBASE, science direct, web of science, Wiley and eth. We will do and use the expert panel, including various experts in the field of providing services to patients with trauma, so we hope that the tools created as a result of this protocol work properly to develop a national model at different levels. Provide services were including pre-hospital, public hospitals, and dedicated trauma centers. The presence of specialists from different fields (such as emergency medicine, orthopedics, neurology, and surgery) involved in providing services to patients with trauma makes the acceptance of the models that are developed more acceptable.[17] Since in this protocol, the components of the indicators used in the construction of data collection tools are examined in terms of feasibility, so the usability of the tool is higher and the scores/scales developed as a result of this study will be more usable. Each of the different scores/scales used to assess trauma patients uses different physiological or anatomical items.[17,19,20] The anatomical and physiological features of a wide range of international trauma scoring scales in trauma patients have been used to construct the tools of this protocol. This compares the models developed in the continuation of this protocol with a wide range of international prediction models for patients with trauma. As a result, the best scoring models, predicting trauma outcomes, and determining the services required for trauma patients are further developed in this protocol. The PTS study is the first national study in Iran to develop a model for predicting predictable trauma-related deaths in Iran and countries such as Iran. In this study, we will find indices of trauma prediction scoring and it will be based on the facilities of Iran. We will develop specific methods at three levels of specialized trauma centers, general hospitals, and pre-hospital. Thus, it can be used more appropriately for Iran and countries like Iran than the worldwide indices.

There are various models in the world for predicting death due to trauma in the world. Each of these models is developed based on the capabilities of their countries of manufacture. There is no national model for predicting trauma deaths in Iran. In this study, we have considered a significant number of indicators and variables predicting death from trauma. We have also considered measuring patients at different levels of service to trauma patients. Therefore, we hope to finally be able to develop national indicators for predicting death from trauma in Iran.

Table 2. Distribution of the patient's vital signs, the cause of trauma, and the location of injury in patients

Part A: Distribution of patient's vital signs			
Variable name		Mean (Standard Error)	Median
Glasgow coma scale (GCS)		12.12(4.86)	15.00
Systolic blood pressure (SBP)		125.17(22.05)	122.00
Diastolic blood pressure (DBP)		78.05(14.98)	79.00
Pulse rate (PR)		89.58(20.77)	85.00
capillary oxygen saturation (SpO2)		95.90(5.16)	97.00
Number of breaths per minute (RR)		18.62(6.89)	17.00
Part B: Distribution of cause of trauma			
Cause of trauma		absolute frequency	Absolute frequency percentage
Pedestrian accident		42	20.00
Bicycle accident		2	0.95
motorcycle accident		58	27.62
Lightweight car crash		44	20.95
Cargo pickup accident		3	1.43
Accident of other vehicles		1	0.48
Fall and slip		31	14.76
Exposure to static mechanical force		1	0.48
Exposure to moving mechanical force		6	2.85
Intentional self-harm/suicide		1	0.48
Injury from rape or assault		16	7.62
Unintentional and unintentional incidents		5	2.38
Total		210	100.00
Part C: Location of injury			
Location of injury	Injury status	Absolute frequency	Absolute frequency percentage
	Yes	88	41.90
Head and face injury	No	122	58.10
	Total	210	100.00
	Yes	42	20.00
Thoracic injury	No	168	80.00
	Total	210	100.00
	Yes	34	16.19
Abdominal, pelvic and spine injuries	No	176	83.81
	Total	210	100.00
	Yes	14	6.67
Shoulder and arm injury	No	196	93.33
	Total	210	100.00
	Yes	29	13.81
Elbow and forearm injury	No	181	86.19
	Total	210	100.00
	Yes	27	12.86
Wrist and hand injuries	No	183	87.14
	Total	210	100.00
	Yes	15	7.14
Thigh and hip joint injury	No	195	92.86
	Total	210	100.00
	Yes	39	18.57
Knee and leg injuries	No	171	81.43
	Total	210	100.00
	Yes	13	6.19
Ankle and foot injury	No	197	93.81
	Total	210	100.00
	Yes	36	17.14
Injuries involving different parts of the body	No	174	82.86
	Total	210	100.00

Acknowledgement

We would like to thank all the people who helped us with this study.

Conflict of Interest

The authors declare that they have no conflict of interest.

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