**Development and validation of a local trauma severity score for adult trauma patients in urban India**

**Background**

Trauma is global public health challenge, accounting for one-tenth of all deaths and disability-adjusted life-years (DALYs) (1–3). Nearly 90% of trauma-related deaths occur in low-and-middle-income countries (LMICs), and improving trauma care in these settings can save nearly 2 million lives each year (4,5). Standardized quantification of variables is important to assess patient prognosis and can improve the quality of trauma care (6,7). These variables can be used as predictors to develop prognostic models to estimate the probability of defined outcomes (8,9). This can play a crucial role in over-burdened settings with limited pre-hospital care or triage (10,11).

Prognostic models should be objective, replicable in different settings, less resource-intensive, and revised over time (12–14). There are multiple variables that affect trauma outcomes but trauma severity is the most important variable for predicting trauma outcomes (15,16). It informs clinical practice at different stages such as pre-hospital triage, in-hospital decision-making, and patient outcomes (12,17). There are several trauma scoring systems based on quantifying trauma severity using different physiological, anatomical parameters, injury features, and patient characteristics to predict patient prognosis, specifically patient mortality (18–28).

The most widely used trauma severity scoring system is the Trauma and Injury Severity Score (TRISS) (29). Developed using a large population sample from the United States and Canada, it predicts patient survival using age, physiological status, anatomical severity of the injury, and the nature of the injury (21,30). Despite subsequent revisions and additions (31,32), TRISS continues to have considerable limitations. There are methodological issues such as the nature of the variables, high propensity for misclassification, and limited validation (12,33–39). TRISS has also been criticized for its poor predictions in different settings, especially in LMICs (6,40–50). Therefore, the aim of this study is to develop a local trauma severity model using an ensemble machine learning algorithm and to compare this model with TRISS.

**Methodology**

*Study Design*

This is a retrospective study of prospectively collected multi-center observational cohort in three public hospitals in urban India between August 2016 to December 2019. The study will be reported using the model derived by Labarère et al (51).

*Setting*

The three hospitals participating in this study are Maulana Azad Medical College (MAMC), New Delhi; KB Bhabha Hospital (KBBH), Mumbai; and the Institute of Post-Graduate Medical Education and Seth Sukhlal Karnani Memorial Hospital (IPGMER & SSKM), Kolkata. They are part of on-going study Trauma Triage Study (TTRIS) funded by the Swedish National Board of Health and Welfare. Each of the three hospitals have trauma units that receive patients from across the city. These are public hospital with free or nominal fees, providing access to low socio-economic groups.

*Eligibility Criteria*

All adult patients (≥ 18 years of age) who were admitted to participating centers with a history of trauma—Chapter XX, block V01-Y36, in the International Classification of Disease 10th-revision (ICD 10) (52). Patients who were dead on arrival were excluded.

*Variables*

The primary outcome will be all-cause mortality within 30-days of arrival (Not 6 months?) at the participating center. Additionally, for each participant demographic factors such as age and sex as well injury-related details transfer status, time of injury, mode of transport, mechanism of injury, number of severe injuries and triage category were collected. Physiological measures including systolic blood pressure (SBP), respiratory rate (RR), heart rate (HR), oxygen saturation, and Glasgow Coma Scale (GCS) were recorded.

*Data*

Each participating center has a dedicated project officer collecting data in 8-hour shifts per day by prospectively enrolling patients. On-arrival of the patients the project officer would also measure SBP, HR, RR, and oxygen saturation independently but would not be part of patient care. The project officer would follow-up with the patients in the hospital and if discharged telephonically to record the mortality at 24-hours, 30-days and 6-months. The shifts would alternate between morning, evening, and night in rotation. The project officers are funded through the TTRIS Project and have continuous training and supervision throughout the study period. The collected data is uploaded to a central database and each week reviewed by a team of trauma clinicians. Based on injury details, Injury Severity Score (ISS) was computed for each participant by trained researchers.

*Developing Trauma Severity Models*

For the local model, based on existing literature, recommendations from trauma clinicians, and feasibility we constructed a priori consisting of the parameters age, SBP, RR, HR, ISS and GCS. (Not clear how we describe the rationale?). For the TRISS model, we calculated the Revised Trauma Score (RTS) based on GCS, SBP and RR. Age, type of injury (blunt or penetrating) RTS and ISS were used to calculate the probability of survival (P) ranging from 0 to 1, where 0 corresponds to 0% and 1 to 100% probability of survival (30,53).

The TTRIS dataset of has xxx participant. Both the local model and the TRISS model will be developed from a random sample of the TTRIS dataset (50% of the TTRIS dataset). We will then use an out-of-sample validation set (remaining 50% of the TTRIS dataset) to assess the validity of each model’s predictive performance.

*Sample Size*

Based on previous studies we will use 10 events per parameter to calculate the sample size. The event was defined as a participant who died within 30-days of admission. As we will use xxx parameters and the overall mortality in the TTRIS data set was xx%, the sample size required for developing the local model is xxx. The validation will require an additional xx participants.

*Statistical Methods*

*Missing Data*

In case of missing data, we will compare differences of means of continuous variables (students t-test) and if not normally distributed we will use non-parametric tests. We will perform X-square test to compare mortality between complete cases and those with missing -variables. Based on this we will use established norms on multiple imputation norms to handle the missing data (54).

*Model Assessment*

We will assess the Local Model and TRISS model for overall performance (R2 ?), discrimination (ROC curve?) and calibration (calibration slope?) (55).

The sensitivity and specificity associated with ability of both the Local Model and TRISS Model to predict 30-day mortality was assessed by analyzing area under the ROC curve. The discrimination of each model was compared using these ROC curve. Really unsure about this section.

**Ethical Considerations**

The institutional ethics committee of each participating center has individually approved the collation and analysis of the TTRIS dataset. The reference numbers are: Maulana Azad Medical College, New Delhi (F.1/IEC/MAMC/(53/2/2016/No.97); KB Bhabha Hospital, Mumbai (HO/4882/KBBH of 3/8/2016); and Institute of Post-Graduate Medical Education and Seth Sukhlal Karnani Memorial Hospital (IPGMER & SSKM), Kolkata (Inst/IEC/2016/328).

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