**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 prediction 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).

Prediction 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). Severity 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 designed to quantify trauma severity. They predict mortality 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 prediction model is the Trauma and Injury Severity Score (TRISS) (29). This model was developed using a large population sample from the United States and Canada, and it predicts mortality 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 external validation (12,33–41). TRISS has also been criticized for its poor predictions in different settings, especially in LMICs which have limited resources to capture advanced or accurate data (6,42–52).

Machine learning algorithms are increasingly being used in medicine, including trauma medicine, to accurately predict complex outcomes across different settings (53–55). Ensemble machine learning algorithms combine several different statistical techniques to build an optimal prediction model rather than relying on a single technique (56). Thus, they are flexible and can be used to capture the complex relationships in trauma data. 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 analysis 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 Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis (TRIPOD) guidelines (9).

*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 an on-going study Trauma Triage Study (TTRIS). 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) (57). Patients who were dead on arrival were excluded.

*Variables*

The primary outcome will be all-cause mortality within 30-days of arrival 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, type of injury, and mechanism of injury are collected. Physiological parameters including systolic blood pressure (SBP), respiratory rate (RR), heart rate (HR), oxygen saturation, and Glasgow Coma Scale (GCS) are also 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 have continuous training and supervision throughout the study period. The collected data is uploaded to a central database and each week reviewed by the research team. Based on injury details, Injury Severity Score (ISS) was computed for each participant by accredited coders.

*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. 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 (30,58).

*Sample Size*

To develop a prediction model with a binary outcome, the current recommendation, is to include at least ten events, i.e. participants with the outcome, and at least as many non-events per free parameter in the model (59). Depending on the data structure as many as 25 events and non-events or more per free parameter may be required to obtain stable estimates (60). These recommendations are however mainly for logistic regression, whereas no recommendations exist for ensemble learners except that more data is likely needed (61). We will therefore include at least 25 events and non-events per free parameter in the training sample, and let the training sample constitute 80% of the total sample. The remaining 20% of the cohort will be used as the test sample.

*Analyses and Statistical Methods*

The ensemble machine learning procedure SuperLearner will be used in the study (62). It will combine different techniques such as linear regression for linear associations, restricted cubic splines for non-linear associations, generalized linear models, etc to create a local model that best fits with the data. The complete TTRIS cohort will be randomly split into a training and a test set, with 80% of the observations in the training set and 20% of the observations in the test set. We will use the training set to build the ensemble learner and to update TRISS. We will use the test set to estimate the performance of each of the ensemble learner, the original TRISS, and the updated TRISS. We will then compare the performance of all models in a pair-wise fashion. Performance and differences in performance will be estimated as medians across imputations and 95% confidence intervals will be estimated using bootstrapping.

*Missing Data*

In case of missing data we will use established norms on multiple imputation norms to handle the missing data (63).

*Model Assessment*

We will assess the local model and TRISS model for overall performance, discrimination, and calibration (64). Discrimination, if the higher scores correspond to higher mortality, will be measured using the cross-validated area under the receiver-operating characteristic curve (AUROC), reported with corresponding 95% confidence interval (95% CI). Calibration, if the predicted mortality coincides well with the observed mortality, and will be assessed by either Hosmer-Lemeshow statistic or Cox calibration test. 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.

**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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