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Validation of CRASH Model in Prediction of 14-Day Mortality and 6-Month Unfavourable Outcome of Pediatric Traumatic Brain Injury

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Abstract

Background: Value of Corticosteroid Randomisation after Significant Head Injury (CRASH) prognostic model has not been assessed in children with traumatic brain injury (TBI). This study is designed to examine the value of CRASH model in prediction of 14-day mortality and 6-month unfavourable outcome of pediatric TBI.

Materials and Methods: In a cross-sectional study, 738 children with TBI brought to the emergency ward of four hospitals were studied. For assessing the predictive value of the CRASH model discrimination power and calibration of CRASH basic model and CRASH CT model were examined.

Results: The areas under the curve (AUC) of CRASH basic and CRASH CT models in prediction of 14-day mortality were 0.89 and 0.91, respectively. AUCs of the CRASH basic and CRASH CT models in predicting unfavourable outcome were 0.93 and 0.94. The value of two models in prediction of 14-day mortality (p=0.20), and 6-month unfavourable outcome (p=0.22) were equal. Both models had proper calibrations in predicting 14-day mortality and 6-month unfavourable outcome.

Conclusion: As calculations of the basic model are easier than those of the CT model and it does not necessitate CT scanning, the CRASH basic model is suggested in the field of pediatrics.

Key Words: Clinical, Emergency Service, Sensitivity and Specificity, Pediatrics.

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1- INTRODUCTION

Traumatic brain injury (TBI) is one of the most important causes of mortality and severe disability across the world, especially in low and medium income countries. The burden of TBI is high and is responsible for almost 33% of mortality in individuals under 25 years of age. The incidence of traumatic brain injuries in individuals between 0-20 years of age is 691 children in 100,000 population with 20% of them leaving the hospital with a disability (1). Most of these children are taken care of in the emergency wards and are discharged with the final diagnosis of mild TBI (2, 3). Although studies show that prevalence of mortality and persistent disability among TBI children is considerably high (4, 5), a reliable method for predicting the mortality and persistent disability in children with TBI is still lacking and physicians take measures when confronted with these children based on their self-assessment of the prognosis of the children (6, 7). Moreover, while there are many models in predicting mortality and disability in adults with TBI, these models are lacking for children.

One of the most known models of scoring in children with TBI is the Pediatric Emergency Care Applied Research Network (PECARN) which is designed to identify high risk children with mild TBI for clinically important traumatic brain injury (8), but this scoring system is not recommended for children with moderate or severe TBI. Another model is the Canadian Assessment of Tomography for Childhood Head Injury (CATCH), which is also designed for children with mild TBI, and its external validation in middle and low-income countries has not been evaluated yet. Both models have only one rule-out criteria for reducing unnecessary CT scanning and are not direct predictors of the patients' outcome (8). One of the main problems with scoring systems in TBI patients is the lack of their external validation in developing countries. For example, both models of CATCH and PECARN are designed based on data from developed countries, but most head traumas and injuries occur in developing countries (9, 10). Therefore, a model needs to be designed to assess data gathered from developing countries. Prognostic model of corticosteroid randomisation after significant head injury (CRASH) is one of the best models designed in recent years and consists of two models for low-income countries and medium or high income countries. This model was designed by Medical Research Council (MRC) CRASH and predicts 14-day mortality and unfavourable outcome (death or severe disability) (11). Although its discrimination and external validation are assessed in several studies (12-16), the results are confounding. In addition, the predictive value of this model has not been assessed in children yet. Therefore, this study was designed to assess the value of CRASH prognostic system in predicting 14-day mortality and 6-month unfavourable outcome of pediatric traumatic brain injury.

2- MATERIALS AND METHODS

2-1. Study design and setting

Children with head trauma brought to the emergency ward of four hospitals in Tehran, Tabriz, and Urmia in Iran were studied during the period 2017 to 2018. Ethics Committee of Tehran University of Medical Sciences approved the study protocol: (IR.TUMS.CHMC.REC.1398.041).

During the study period, all researchers adhered to the principles of the Helsinki declaration and a consent form was obtained from parents of the children before entering the study. A physician in each hospital did data gathering prospectively. All head trauma children under 19 years who were brought to the emergency wards with a pediatric Glasgow coma scale (pGCS) of 14 or below within the first 8 hours of trauma were included. Patients with isolated head trauma and patients with multiple trauma were also included. Inability to access patients during the follow-up period was considered an exclusion criterion.

2-2. Data gathering

The physicians gathered the clinical and radiological data in each hospital. The emergency medicine physicians were trained before starting the study for 60 min on how to fill the data gathering checklist and assessing the prognostic factors of CRASH model. Factors under assessment were demographic factors (age and sex), mechanism of trauma, comorbidity, presence of external cranial injury, consciousness level based on pGCS, pupil reactivity to light, data from brain of computed tomography (CT) scans and at the end, the patients' outcome.

2-3. Prognostic model

In this study, the CRASH prognostic model was assessed. This scoring system predicts 14-day mortality and 6-month unfavourable outcome. Based on available equipment (access to CT scans) two models of "Basic" and "CT" were defined. The basic model is calculated based on age, level of consciousness, pupil reactivity to light and major extra-cranial injury and is reported in percentage. In the CT model, in addition to previous factors the following factors in the brain CT scans of the patients are also included in calculations: petechial haemorrhages, obliteration of the third ventricle or basal cisterns, subarachnoid bleeding, midline shift and non-evacuated haematoma. 14-day mortality and 6-month unfavourable outcome of patients were calculated using the web-based program designed by CRASH trial (11).

2-4. End-points

End-points were 14-day mortality and 6-month unfavourable outcome of patients. The 6-month outcome was assessed based on pediatric Glasgow outcome scale-extended (pGOS-E). In this scale, 6-month outcome of patients is divided into two groups of 6-month favourable outcome (upper and lower good recovery and moderate disability), and 6-month unfavourable outcome (upper and lower severe disability, vegetative state, and death).

2-4. Statistical analysis

For calculating the sample size, instructions in Hajian-Tilaki's study were used (17). Based on table 5 of the mentioned study and considering an area under the curve of 0.80 for CRASH basic model (18), and an accuracy of 3% (d=0.03), 510 samples are sufficient for this study. Data were analysed by STATA version 11.0. Area under the receiving operating characteristics (ROC) curve (AUC), sensitivity, specificity, positive predictive value, negative predictive value, positive and negative likelihood ratio were calculated with a confidence interval of 95% (Cl: 95%) in order to assess the predictive value of the CRASH model.

The Cleves and Rock's suggested method was used to compare the value of CRASH basic model and CRASH CT model in predicting the 14-day mortality and 6-month unfavourable outcome of patients (19). General calibration was assessed by drawing calibration plot. For this purpose, theoretically perfect line was fitted which had slope of 1 and an intercept of 0.

A perfect scoring model in predicting mortality and unfavourable outcome should have the closest slope to 1 and closest intercept to 0. Then calibration plot of CRASH basic model and CRASH CT model were drawn and compared to the theoretically perfect line. Additionally, overall performance was assessed by measurement of Brier score, scaled reliability and Nagelkerke's R^2. In all analyses p<0.05 was considered significant.

3- RESULTS

During the study, 759 children between 1-18 years of age were included among whom 21 families were missed in the 6-month follow-up period. Finally, data from 738 children were assessed. Their average age was 11.70±4.09 years and 627 of them (84.96%) were boys. Accident with motorcycle (51.495) was the most common mechanism of trauma. During the first 14 days of admission, 18 (2.44%) children died and during the 6-month follow up period 47 (6.37%) children had unfavourable outcome (death or severe disability). **Table.1** shows the associations between baseline characteristics and children's 6-month outcome. Unfavourable outcome in children under 3 (p<0.0001), and in boys (p=0.01) was significantly higher. All factors in the CRASH scoring system had significant associations with patient's outcome. Unfavourable outcome had a significant association with decreased level of consciousness (p<0.0001), abnormal pupil reactivity to light (p<0.0001), and the presence of abnormal findings in CT scan (p=0.001). AUC of CRASH basic and CRASH CT models in predicting 14-day mortality and 6-month unfavourable outcome are depicted in **Figure.1**. Both models had proper values in predicting mortality and unfavourable outcome. AUCs of CRASH basic and CRASH CT models in predicting 14-day mortality are 0.89 (95% CI: 0.77-1.0), and 0.91 (95% CI: 0.82-1.0), respectively. AUCs of these models in predicting 6-month unfavourable outcome are 0.93 (95% CI: 0.87-0.98), and 0.94 (95% CI: 0.91-0.98), respectively. The value of both models in predicting 14-day mortality (p=0.20) and 6-month unfavourable outcome (p=0.22) were similar.

Table-1: Baseline characteristics of included children.

Variables	Good outcome (n=691)	Unfavourable outcome (n=47)	Total (n=738)	P-value
Age				
1-3	17 (2.80)	6 (13.33)	23 (3.53)	<0.001
4-6	43 (7.07)	4 (8.89)	47 (7.20)	
7-12	254 (41.78)	22 (48.89)	276 (42.27)	
13-18	377 (54.56)	15 (31.91)	392 (31.91)	
Gender				
Boy	593 (85.82)	34 (72.34)	627 (84.96)	0.01
Girl	98 (14.18)	13 (27.66)	111 (15.04)	
Mechanism				
Pedestrian	196 (28.36)	13 (27.66)	209 (28.32)	0.42
Motorcycle	360 (52.10)	20 (42.55)	380 (51.49)	
Fall	56 (8.11)	5 (10.64)	61 (8.27)	
Car accident	73 (10.56)	9 (19.15)	82 (11.11)	
Bicycle	6 (0.87)	0 (0.0)	6 (0.81)	
Comorbidity				
Diabetes	3 (0.44)	0 (0.0)	3 (0.41)	0.99
Hypertension	1 (0.15)	0 (0.0)	1 (0.15)	
Asthma	2 (0.29)	0 (0.0)	2 (0.27)	
Seizure	5 (0.72)	0 (0.0)	5 (0.68)	
Cancer	1 (0.14)	0 (0.0)	1 (0.14)	
Extra cranial injury				
No	195 (28.22)	13 (27.66)	208 (28.18)	0.93
Yes	496 (71.78)	34 (72.34)	530 (71.82)	
Pediatric Glasgow coma scale				

14	632 (92.46)	5 (10.64)	637 (86.31)	<0.001
9-13	45 (6.51)	19 (40.43)	64 (8.67)	
3-8	14 (2.03)	23 (48.94)	37 (5.01)	
Pupil response				
Both	687 (99.42)	32 (68.09)	719 (97.43)	<0.001
One	2 (0.29)	3 (6.38)	64 (8.67)	
None	2 (0.29)	12 (25.53)	14 (1.90)	
CT scan findings				
Non	632 (91.42)	35 (74.47)	667 (90.38)	0.001
Petechial haemorrhages	29 (4.20)	3 (6.38)	32 (4.34)	
Obliteration of the third ventricle or basal cisterns	5 (0.72)	1 (2.13)	6 (0.81)	
Subarachnoid bleeding	12 (1.74)	3 (6.38)	15 (2.03)	
Midline shift	1 (0.14)	1 (2.13)	2 (0.27)	
Non-evacuated haematoma	12 (1.74)	4 (8.51)	16 (2.17)	

CT: Computed tomography.

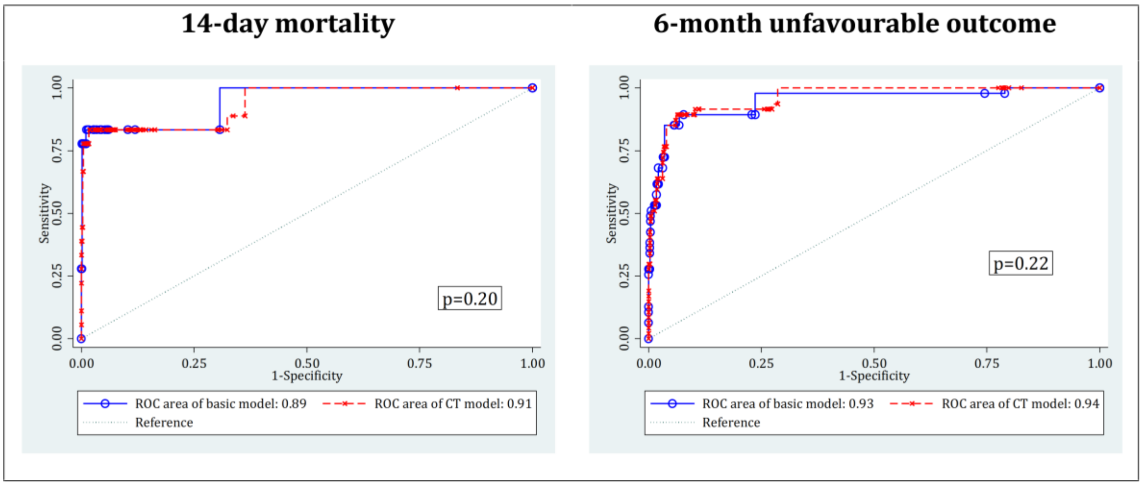

Fig.1: Area under the receiver operating characteristics (ROC) curve of CRASH prognostic model in prediction of 14-day mortality and 6-month unfavourable outcome of traumatic brain injured children. CT: Computed tomography.

Calibration plots of CRASH basic and CASH CT models are depicted in **Figure.2**. As shown, both models have proper calibrations in predicting 14-day mortality and 6-month unfavourable outcome. However, it seems that both models underestimate 14-day mortality in high-risk patients and overestimate 6-month unfavourable outcome in high-risk children. Slopes and intercepts of calibration plots of CRASH basic and CASH CT models were similar. Overall performance of CRASH basic and CASH CT models were appropriate. Brier score of CRASH basic and CASH CT models in predicting 14-day mortality were 1.12 and 1.09. These amounts were 0.96 and 0.94, respectively for predicting 6-month unfavourable outcome. In Nagelkerke's R^2, CRASH basic and CASH CT models had proper levels in predicting 14-day mortality (R2 for basic model=0.68 and R2 for CT model=0.64) and 6-month unfavourable outcome (R2 for basic model=0.50 and R2 for CT model=0.50). All these findings are indicative of proper reliability and predictive accuracy of the CRASH scoring system (**Figure.2**).

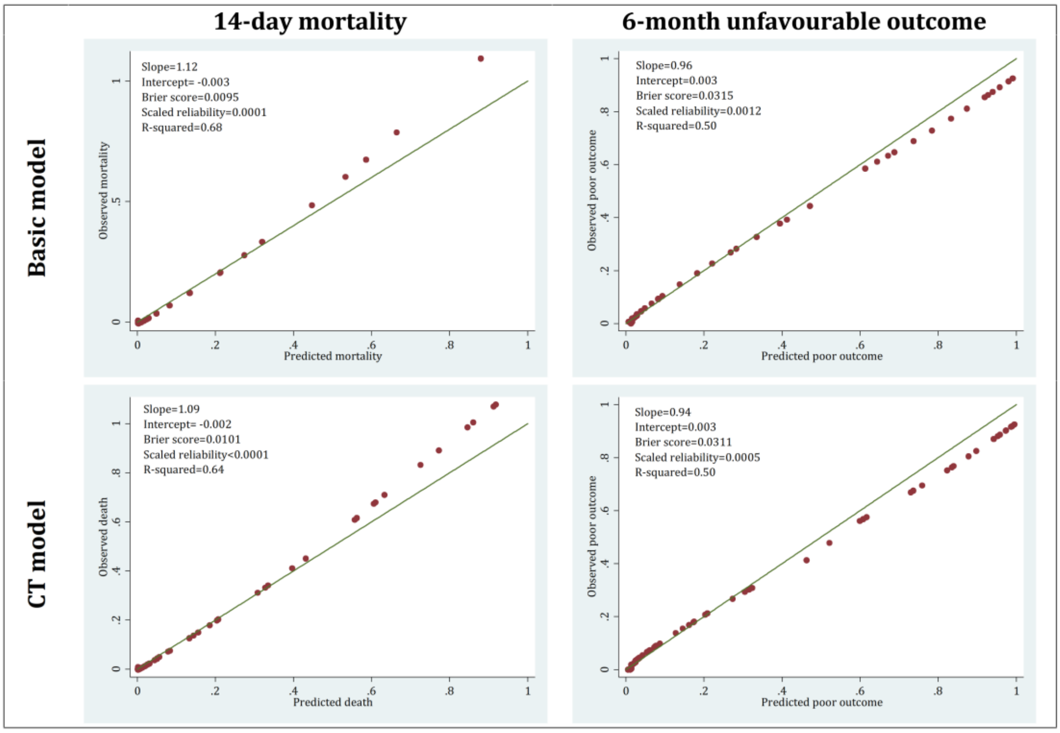

Fig.2: Calibration plots of basic and computed tomography (CT) models of CRASH scoring system in prediction of 14-day mortality and 6-month unfavourable outcome in pediatric traumatic brain injury.

The best cut-off points in Basic and CT models for predicting 14-day mortality were 46 and 30, respectively. In these cut-off points, the sensitivity and specificity of CRASH basic model in predicting 14-day mortality were 83.33 and 98.89, respectively and these amounts were 83.33 and 95.56, respectively for CRASH CT model. The best cut-off points of CRASH basic and CASH CT models for predicting 6-month unfavourable outcome were 17 and 13, respectively. The sensitivities of these models in prediction of 6-month unfavourable outcome were 85.10 and 89.36, respectively and their specificities were 94.36 and 93.63, respectively (**Table.2**).

Table-2: Screening performance characteristics of CRASH scoring system in prediction of 14-day mortality and 6-month unfavourable outcome in pediatric traumatic brain injury.

Characteristics*	14-day mortality		6-month unfavourable outcome	
	CRASH Basic model	CRASH CT model	CRASH Basic model	CRASH CT model
Cut off	46	30	17	13
True positive	15	15	40	42
True negative	712	688	652	647
False positive	8	32	39	44
False negative	3	3	7	5
Sensitivity	83.33 (57.73-95.59)	83.33 (57.73-95.59)	85.10 (71.08-93.31)	89.36 (76.11-96.02)
Specificity	98.89 (95.29-97.97)	95.56 (93.71-96.89)	94.36 (92.29-95.91)	93.63 (91.47-95.28)

Positive predictive value	65.21 (42.82-82.81)	31.91 (19.52-47.25)	50.63 (39.23-61.97)	48.84 (38.00-59.78)
Negative predictive value	99.58 (98.67-99.89)	99.57 (98.63-99.89)	98.94 (97.72-99.53)	99.23 (98.11-99.72)
Positive likelihood ratio	75.0 (36.53-153.99)	18.75 (12.61-27.88)	15.08 (10.87-20.92)	14.03 (10.37-18.99)
Negative likelihood ratio	0.19 (0.06-0.47)	0.17 (0.06-0.49)	0.16 (0.08-0.31)	0.11 (0.04-0.26)

*, Data are presented as value (95% confidence interval); CT: Computed tomography; CRASH: Corticosteroid Randomisation after Significant Head Injury.

4- DISCUSSION

Rapid assessment of trama patients has a significant effect on reducing mortality and disabilities caused by TBI, especially in children (20). Considering the growing interest in a reliable, simple and accurate scoring system, designing a proper model for this purpose is of significant priority in researches. For the first time, the present study assessed the predictive value of the CRASH model in predicting 14-day mortality and 6-month unfavourable outcome in children with TBI. Our results showed that both CRASH basic model and CRASH CT model have a high accuracy in predicting mortality and unfavourable outcome.

One of the interesting findings in the present study was that CRASH basic model and CRASH CT model did not differ in predicting the outcome in patients with TBI. Therefore, using basic model might prevent performing unnecessary CT scanning. In addition, CT scanning in children, especially in ones with younger age, comes with problems such as children's anxiety and lack of cooperation and sometimes sedation is needed (20-22).

Giving sedation in patients with TBI is challenging for physicians because it can lead to reduction in the level of consciousness of children and worsen their outcome. Therefore, it seems that using the CRASH basic model is more reasonable in children with TBI. As said, there are no studies assessing the accuracy of the CRASH model in prediction of outcomes in children with TBI. However, results from the present study are in accordance with results of studies on adults. For example, in the derivation study of the CRASH model it revealed that this model has a proper value in predicting the outcome of patients with TBI (11). In another study by Han et al., it was stated that the CRASH model has a good discrimination and calibration in prediction of TBI (18). In another study by Hashemi et al., it was claimed that both CRASH basic and CRASH CT models have similar values in predicting the outcome of patients with TBI (23). In the study of Hashemi et al., area under the curve of basic and CT models in predicting 14-day mortality were 0.95 and 0.96, respectively and 0.96 (for both models) in predicting 6-month mortality. Although this subsidiary analysis was performed on a small number of children, it was consistent with the findings of present study.

Assessing the calibration of CRASH model showed that CRASH basic model and CRASH CT model underestimate 14-day mortality and overestimate 6-month unfavourable outcome in high risk patients. This might be a consequence of giving the score of zero to age in these models for children and therefore age does not have any effect on the value of these models' predicting value. However, findings in Table.1 show that prevalence of unfavourable outcome is higher in age group of 1-3 years than other age groups.

Therefore, it might be needed to re-evaluate the effect of children's age on CRASH model in another study with a sufficient sample size. However, revising the CRASH model should be done with caution as modifying every scoring system comes with problems. The difference between mortality and disability caused by head trauma in different healthcare centres across the world (24-26) is indicative of difference in the quality of the care given to patients, difference in the individual characteristics of patients and differences in the severity and kind of trauma in diverse societies. Incompatibilities or errors in scoring systems make patient assessment imperfect and considering these diversities, developing a single protocol for all situations is a time-consuming and complicated task. Therefore, attention must be paid to diversities among individual and clinical predictive variables in constructing a model (27-31).

One of the most important limitations to the present study is the different definitions of extra cranial injury. However, in the derivation study of the CRASH model these injuries were defined as injuries which caused the individual to be admitted to the hospital (11). This broad definition causes different interpretations and might cause bias in the findings as type of extra cranial injury differs from one society to the other. Other limitation to the present study is that age has no effect as factor on the CRASH-scoring model. As all individuals who were entered in the derivation study were over 16 years, age of individuals under 40 years (16 to 40 years old) had a weight of zero in the model while age group of 1-3 years was considered an effective factor on unfavourable outcome in the present study.

5- CONCLUSION

For the first time, the present study assessed the predictive value of the CRASH model in predicting 14-day mortality and 6-month unfavourable outcome in children with TBI. The result of present study showed that both CRASH basic model and CRASH CT model have a high accuracy in prediction of mortality and unfavourable outcome in children with TBI. As CRASH basic model is easier than CRASH CT model and CT scanning is not necessary in it, the CRASH basic model is suggested in the field of paediatrics.

6- AUTHORS CONTRIBUTION

All authors passed four criteria for authorship contribution based on recommendations of the International Committee of Medical Journal Editors.

7- CONFLICT OF INTEREST: None.

8- ACKNOWLEDGMENT

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