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Internal Validation of Two Models Developed for Prognostication of Patients with Isolated Traumatic Brain Injury

Ahmet Tolgay AKINCI[1], Osman SIMSEK[1], Murat KOCATURK[2]

[1]Trakya University, School of Medicine, Department of Neurosurgery, Edirne, Turkey
[2]Cigli Regional Education Hospital, Department of Neurosurgery, Izmir, Turkey

Corresponding author: Ahmet Tolgay AKINCI ✉ ahmettolgayakinci@gmail.com

ABSTRACT

AIM: To evaluate the efficiency of two models for prognostication of patients with isolated traumatic brain injury.

MATERIAL and METHODS: The models developed with the data of the patients who applied within ten years were subjected to internal validation with the data of the patients who applied within the following five years. The records of 204 patients with traumatic brain injury admitted into Neurosurgery Department and Intensive Care Units were reviewed. Models were applied to procure estimates of prognosis. The estimates were statistically compared with the actual clinical outcome of patients using discriminant analysis.

RESULTS: For Model 1, the correct classification rate was calculated as 87.9%, the specificity as 66.7%, the sensitivity as 94.2%, the positive predictive value as 68.8%, and the negative predictive value as 93.6%. For Model 2 the correct classification rate was evaluated as 90.2%, the specificity as 57.6%, the sensitivity as 96.5%, the positive predictive value as 76%, and the negative predictive value as 92.2%.

CONCLUSION: Both of the models had decent correct classification rates and may be efficient estimation tools for the prognostication of unfavourable outcome in patients with isolated traumatic brain injury. These models are good candidates to be used widely following the evaluation of their validity with national and international multicentric studies.

KEYWORDS: Computer model, Patient outcome assessment, Prognosis, Traumatic brain injury

ABBREVIATIONS: CE: Cerebral oedema, **CDF:** Closed depression fracture, **CT:** Computed tomography, **GOS:** Glasgow outcome scale, **GCS:** Glasgow coma scale, **ICH:** Intracerebral hematoma, **OP:** Operation, **PR:** Pupil reaction, **SDH:** Subdural hematoma, **TBI:** Traumatic brain injury, **TG:** Trauma groups, **tSAH:** Traumatic subarachnoid haemorrhage

INTRODUCTION

Traumatic brain injury (TBI) is one of the leading causes of mortality and disability (6,8,11,19,30,34). The estimated TBI frequency in developed countries is 150–250 per 100,000 people annually, with a mortality incidence of 20–30 per 100,000 people each year (3). The incidence in Europe is approximately 235 per 100,000 people annually, with an estimated prevalence of 7,775,000 people (32). Approximately 1,700,000–1,900,000 American people have TBI each year; of these, 1,100,000 people are discharged from the emergency room; 235,000 people are hospitalised; 50,000 die and more than 5,300,000 people continue living with a disability as its result (3,6,26).

Predicting the prognosis for TBI has always been a goal for physicians, especially for neurosurgeons. However, a survey conducted among physicians who routinely treated patients

Ahmet Tolgay AKINCI : 0000-0002-9937-076X Osman SIMSEK : 0000-0002-8716-5187 Murat KOCATURK : 0000-0002-3305-4158

with TBI revealed that only 37% thought they assessed prognosis accurately (25).

Despite the advances in science and more accurate application of evidence-based medicine in the past decades, gaps in the evidence for severe TBI management persists (4,14). In addition, long-term outcomes are unique and differ with the types and severities of TBI (6). Furthermore, the most evident benefit of assessing outcome prognosis is in facilitating realistic counselling of relatives (17,18).

Establishing an accurate and easy-to-use predictive tool for TBI outcomes is not an easy task. Many parameters are well known to aid prediction, such as Glasgow Coma Scale (GCS), pupil reactivity, CT findings and blood tests (7,19,21). Although numerous models have been developed for prognostication, none have become standard till date (12,13,18,21–24,27,29,31,33).

Simsek et al. developed two models to estimate the prognosis of patients with isolated TBI. They used data from 919 patients with isolated TBI admitted into Trakya University Hospital Neurosurgery Department and Intensive Care Units between January 1996 and December 2006 (28). In this study, we aimed to evaluate the efficiency of these models by investigating data of 204 patients with isolated TBI who were hospitalised in the same departments in Trakya University Hospital between December 2006 and July 2011. The Ethics Committee of Trakya University approved the study (Decision number: TUTF-GOKAEK 2012/171), and written informed consent was waived.

MATERIAL and METHODS

We retrospectively reviewed all consecutive patients admitted into the Trakya University Hospital Neurosurgery Department and Intensive Care Units for TBI between December 2006 and July 2011. Patients with multi-system trauma such as trauma to the respiratory, circulatory, urinary or digestive systems as well as orbital region trauma affecting the pupillary reflex were excluded from the study. After excluding 448 patients with multi-system trauma, 204 patients with isolated TBI were included.

We recorded patient age, GCSscores at the initial neurological examination as well as trauma aetiology, neurological examination findings, neuro-radiological findings, surgical need and Glasgow Outcome Scale (GOS) grades of patients. Trauma aetiology was classified into four groups according to the occurrence mechanism, energy amount to be exposed and trauma severity. The first group included low-energy traumas, such as bicycle accidents and object hits. The second group had low-to-middle-energy traumas, such as simple falls and poundings. The third group included middle-to-high-energy traumas such as falls from high ground, motor vehicle accidents and similar traumas. The fourth group had penetrating and high-energy traumas including gunshot injuries. Trauma groups (TGs) were coded as 1, 2, 3 and 4, respectively (Table I).

We evaluated pupil diameter and pupillary light reflex during the first neurological examination. A difference of more than 1 mm between two pupil diameters was noted as anisocoria. The pupillary light reflex was also assessed.

Neuro-radiological evaluation was conducted using cranial computed tomography (CT) at admission. In addition, neuro-radiological findings such as depression fracture, traumatic subarachnoid haemorrhage, cerebral oedema, epidural haemorrhage, subdural haemorrhage and intracerebral hematoma were recorded.

Patients were classified into three groups: not operated, operated without a mass effect and operated for a mass effect.

The outcome was evaluated using GOS. Patients were coded as 1 when their GOS grades were 1 (death) and 2 (permanent vegetative state), indicating an unfavourable outcome; patients were coded as 0 when their GOS grades were 3 (partial healing, sequels, permanent need for help with daily living), 4 (partial healing, sequels, no need for assistance in daily activities) and 5 (complete healing without sequels), indicating a favourable outcome.

Simsek et al. developed two models. Model 1 included age, TG, GCS, pupil reaction (PR), closed depression fracture (CDF), traumatic subarachnoid haemorrhage (tSAH) and cerebral oedema (CE) as parameters. Model 2 was developed for patients for whom GCS could not be evaluated and included age, TG, PR, CDF, subdural haematoma (SDH), tSAH, intracerebral hematoma (ICH), CE and operation (OP) parameters. The weighted values for each parameter were as follows: TG1=0, TG2=4, TG3=8, TG4=55, PA0=9, PA1=43, PR0=5, PR1=26, PR2=92, DUEMR0=9, DUEMR1=40, SDH0=8, SDH1=42, CLF0=12, CLF1=13, CBF0=6, CBF1=15, CDF0=11, CDF1=28, ODF0=11, ODF1=25, EDH0=12, EDH1=13, SDH0=8, SDH1=42, tSAH0=7, tSAH1=34, CC0=9, CC1=24, ICH0=11, ICH1=56, CE0=5, CE1=32, AI0=15, AI1=0, OP0=8, OP1=2, OP2=39 (28).

The coded data were inputted into the models to calculate predictive values of the models for each patient. Finally, these predictive values were statistically compared with the actual clinical outcome.

Statistical Analysis

The results were expressed as means ± standard deviations or as numbers (percentages). Descriptive statistics were calculated for all continuous variables. Additionally, the frequencies and percentages for categorical variables were assessed. Finally, the prognostic estimates of both the

Table I: Trauma Groups

	Energy Amount	Trauma Cause
TG 1	Low	Bicycle accidents, simple hits
TG 2	Low - Middle	Simple falls and poundings
TG 3	Middle - High	Falls from an elevation, motor vehicle accidents
TG 4	High	Gunshot injuries, penetrating injuries

TG: *Trauma group.*

models were statistically compared with the actual clinical outcome of patients via discriminant analysis. For statistical analyses, Statistica 7.0 software package (Licence number: 31N6YUCV38) was used.

RESULTS

Overall, 204 patients were hospitalised for isolated TBI between December 2016 and July 2011. The mean age of these patients was 45.6 ± 25.7 years, and the age range was 0–88 years. The frequencies of GCS scores have been summarised in Table II.

Analyses demonstrated that 15 patients were within TG1 (7.4%), 89 were within TG2 (43.6%) and 100 were within TG3 (49%). No patients were within TG4. The frequencies of TGs are summarised in Table III.

Anisocoria was absent in 189 patients (92.6%) and was present in 15 patients (7.4%). Pupillary light reflex was positive on both sides in 181 patients (88.7%), was positive only on one side in 5 patients (2.5%) and was negative on both sides in 18 patients (8.8%).

The neuro-radiological findings observed were depression fractures in 8 patients (3.9%), traumatic subarachnoid haemorrhage in 59 patients (28.9%), cerebral oedema in 30 patients (14.7%), epidural haemorrhage in 32 patients (15.7%), subdural haemorrhage in 88 patients (43.1%) and intracerebral hematoma in 1 patient (0.5%).

Overall, 130 patients were not operated on (63.7%), while 13 patients were operated on without a mass effect (6.4%) and 61 patients for a mass effect (29.9%). The descriptive statistics for predictive parameters have been summarised in Table IV.

Classification of patients by GOS revealed that 29 were dead (14.2%) and four were in the permanent vegetative state (2%). Therefore, these 33 patients (16.2%) were considered to have an unfavourable outcome. In contrast, the number of patients with GOS grades 3, 4 and 5 were 8 (3.9%), 41 (20.1%) and 122 (59.8%), respectively, and these 171 patients (83.8%) were considered to have a favourable outcome. The descriptive statistics for GOS are summarised in Table V.

The estimates of prognosis of Model 1 were compared with the actual clinical outcomes of patients using discriminant analyses. According to these estimates, an unfavourable outcome was expected in 32 patients (15.7%) and a favourable outcome in 172 patients (84.3%). The correct classification rate of Model 1 was 87.9%, specificity was 66.7%, sensitivity was 94.2%, positive predictive value was 68.8% and negative predictive value was 93.6%.

In Model 2, an unfavourable outcome was expected in 25 patients (12.2%) and a favourable outcome in 179 patients (87.8%). The correct classification rate of Model 2 was 90.2%, specificity was 57.6%, sensitivity was 96.5%, positive predictive value was 76% and negative predictive value was 92.2%.

Statistical results regarding the evaluation of models are summarised in Table VI.

Table II: Frequencies of GCS

Scores	Counts	% of Total	Cumulative %
3	6	2.9	2.9
4	9	4.4	7.4
5	4	2.0	9.3
6	6	2.9	12.3
7	5	2.5	14.7
8	7	3.4	18.1
9	6	2.9	21.1
10	12	5.9	27.0
11	7	3.4	30.4
12	7	3.4	33.8
13	24	11.8	45.6
14	33	16.2	61.8
15	78	38.2	100.0

GCS: *Glasgow coma scale.*

Table III: Frequencies of Trauma Groups

	Counts	% of Total	Cumulative %
TG 1	15	7.4	7.4
TG 2	89	43.6	51.0
TG 3	100	49.0	100.0
TG 4	0	0	100.0

TG: *Trauma group.*

DISCUSSION

Trakya University Training - Research and Implementation Hospital is one of the biggest health centres that intensively admits traumatic patients in the Trakya Region (1,2). A significant number of predictive criteria have been developed for determining the prognosis of TBI particularly in high-income countries (5,13,22,23). In contrast, TBI frequently occurs in low-middle-income countries. Still, most studies have been conducted in high-income countries; thus, an internationally accepted model has not yet been developed (23,24).

Simsek et al. developed two predictive models based on simple parameters using the data of 919 patients between 1996 and 2006 (28). Our study evaluated the validity of these models using data of 204 patients in the following 5 years (2006–2011).

We determined that both the models had decent correct classification rates. Alterations in the profile of patients hospitalised for TBI owing to the changes in health politics allowed the evaluation of model validity in a much more

Table IV: Descriptive Statistics for Predictive Parameters

	Counts	% of Total	Cumulative %
Anisocoria (-)	189	92.6	92.6
Anisocoria (+)	15	7.4	100.0
Pupil Reaction (+/+)	181	88.7	88.7
Pupil Reaction (+/-) or (-/+)	5	2.5	91.2
Pupil Reaction (-/-)	18	8.8	100.0
Depression Fracture (-)	196	96.1	96.1
Depression Fracture (+)	8	3.9	100.0
Traumatic SAH (-)	145	71.1	71.1
Traumatic SAH (+)	59	28.9	100.0
Brain Oedema (-)	174	85.3	85.3
Brain Oedema (+)	30	14.7	100.0
Epidural Haemorrhage (-)	172	84.3	84.3
Epidural Haemorrhage (+)	32	15.7	100.0
Subdural Haemorrhage (-)	116	56.9	56.9
Subdural Haemorrhage (+)	88	43.1	100.0
Intracerebral Haemorrhage (-)	203	99.5	99.5
Intracerebral Haemorrhage (+)	1	0.5	100.0
Not operated	130	63.7	63.7
Operated without a mass effect	13	6.4	70.1
Operated for a mass effect	61	29.9	100.0

SAH: *Subarachnoid haemorrhage.*

Table V: Descriptive Statistics for GOS

Levels	Counts	% of Total	Cumulative %
1	29	14.2	14.2
2	4	2.0	16.2
3	8	3.9	20.1
4	41	20.1	40.2
5	122	59.8	100.0

GOS: *Glasgow outcome scale.*

Table VI: Statistical Data of the Models

	Model 1	Model 2
Correct Classification Rate	87.9	90.2
Specificity	66.7	57.6
Sensitivity	94.2	96.5
Positive Predictive Value	68.8	76
Negative Predictive Value	93.6	92.2

heterogeneous population. Thus, the classification rates of 87.9% for Model 1 and 90.2% for Model 2 showed that both models can be efficiently used in various populations. Recalling the determination of 80% correct classification rate of the model derived from the study named 'Medical Research Council Corticosteroid Randomisation after Significant Head Injury' as 'perfect', the efficiency of these two models would be better understood (23).

Moreover, Model 2 has the advantage of not including GCS. GCS is a well known definite determiner for the outcome; even its motor component alone is reported to correlate highly (19,21). However, assessing GCS at admission is not always feasible, especially when patients are sedated and curarised. Consequently, Model 2 proves to be a valuable tool by efficiently predicting outcomes without including GCS.

Even patients hospitalised for only isolated TBI were included, and multi-traumatic patients were excluded. Thus, TBI intrinsically comprises a vast and various clinical spectrum. In our study, specificity of 66.7% and 57.6% and positive predictive values of 68.8% and 76%, respectively, indicated that the models estimated the unfavourable prognosis very well.

In addition, the sensitivity of Model 1 and 2 was 94.2% and 96.5%, with negative predictive values of 93.6% and 92.2%, respectively; these values indicated that the models estimated the favourable prognosis very well.

The models are found to be successful for unfavourable prognosis estimates as well as very successful for classification and favourable prognosis estimates. Thus, their validity was proved in a different and more heterogeneous population.

Li et al. established and internally validated a prediction model titled 'BISCPM', using the data of 1156 patients admitted between July 2006 and June 2012 (16). Muisyo et al. proposed that the BIG Score was an accurate tool for predicting trauma mortality in paediatric population (20). Ghorbani et al. assessed two Norwegian survival prediction models for trauma (NORMIT 1 and 2) in Swedish population and found them to be excellent for discriminating survivors from non-survivors (9). Lamparello et al. proposed a stratification scheme based on periods following the trauma, focusing on biomarkers, clinical parameters and gene markers (15). Finally, Graaf et al. developed and internally validated a PRO-Trauma model using 246 patients and reported acceptable calibration and discrimination (10). This study aimed to internally evaluate the models developed using the data of 919 patients with TBI between 1996 and 2006 and using data of 204 patients between 2006 and 2011.

Many models based on similar parameters and with various classifications and prognosis capacities can be found in the literature (5,9,10,13,15,16,20,23,24,27,31). However, these models are primarily developed in high-income countries, and their populations are demographically, socio-economically and clinically different from patients in Turkey. Both models are good candidates for wide use following their validity in national and international multicentric studies.

CONCLUSION

This study has been designed to evaluate the efficiency of the models developed for prognostication of isolated TBI in hospitalised patients, compare the results with the current academic knowledge and use the knowledge gained to form a resource for further research. There are many benefits of predicting prognosis early and accurately, including clinical decision making, delineating mechanisms and informing patients' relatives.

We believe that these models may be efficient estimation tools, and their usage would offer benefits for the prognostication of patients with isolated TBI. Furthermore, by evaluating their validity in national and international multicentric studies, these models can be good candidates for used widely.

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AUTHORSHIP CONTRIBUTION

Study conception and design: ATA, OS, MK
Data collection: ATA, MK
Analysis and interpretation of results: ATA, OS, MK
Draft manuscript preparation: ATA, OS, MK
Critical revision of the article: ATA, OS, MK
Other (study supervision, fundings, materials, etc...): OS
All authors (ATA, OS, MK) reviewed the results and approved the final version of the manuscript.

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