Comparison of the Prognostic Accuracy of Full Outline of Unresponsiveness (FOUR) Score with Glasgow Coma Scale (GCS) Score among Patients with Traumatic Brain Injury in a Tertiary Care Center

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Abstract

Objectives The Glasgow Coma Scale (GCS) is widely used and considered the gold standard in assessing the consciousness of patients with traumatic brain injury. However, some significant limitations, like the considerable variations in interobserver reliability and predictive validity, were the reason for developing the Full Outline of Unresponsiveness (FOUR) score. The current study aims to compare the prognostic accuracy of the FOUR score with the GCS score for in-hospital mortality and morbidity among patients with traumatic brain injury.

Materials and Methods A prospective cohort study was conducted, where 237 participants were selected by consecutive sampling from a tertiary care center. These patients were assessed with the help of GCS and FOUR scores within 6 hours of admission, and other clinical parameters were also noted. The level of consciousness was checked every day with the help of GCS and FOUR scores until their last hospitalization day. Glasgow Outcome Scale was used to assess their outcome on the last day of hospitalization. The GCS and FOUR scores were compared, and data were analyzed by descriptive and inferential statistics. The chi-square test, independent Student's *t*-test, and receiver operating characteristic analysis were used for inferential analysis.

Results The area under the curve (AUC) for the GCS score at the 6th hour for predicting mortality was 0.865 with a cutoff value of 5.5, and it yields a sensitivity of 87% and a specificity of 64%. The AUC for FOUR scores at the 6th hour for predicting the

Keywords
- traumatic brain injury
- Glasgow Coma Scale
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mortality was 0.893, with a cutoff value of 5.5, and it yields a sensitivity of 87% and a specificity of 73%.

Conclusion The current study shows that, as per the AUC of GCS and FOUR scores, their sensitivity was equal, but specificity was higher in the FOUR score. So, the FOUR score has higher accuracy than the GCS score in the prediction of mortality among traumatic brain injury patients.

Introduction

Many patients get admitted with head trauma in neurocritical care units or emergency care settings. Sixty-nine million individuals around the world sustain a head injury each year.[1] Younger people (15–44 years) have a higher incidence of traumatic brain injury (TBI), although peaks are noted in infants, children, and older people. In-hospital treatment and outcomes of these patients have been highly variable, especially in developing countries like India.[2] These patients need aggressive management based on their baseline data, in which consciousness is one of the most important criteria.[1]

The severity of TBI is classified according to an index called the Glasgow Coma Scale (GCS). This level of consciousness assessment should be done very carefully to avoid errors.[2] Numerous scales have been proposed to rule out the level of consciousness in patients admitted with TBI. However, the GCS scale is considered a standard method and universally accepted for assessing a patient's consciousness level.[3] Teasdale and Jennett in 1974 developed the GCS score and revised it in 1976.[4] The GCS score is used to predict a patient's functional outcome, but this scale has several limitations. GCS cannot be used for assessing a major component, which is a verbal response in intubated patients or patients with tracheostomy.[5]

To overcome the existing limitations in GCS, a new scale called the FOUR scale or Full Outline of Unresponsiveness score coma scale was introduced.[6] This scale consists of four components: eye response, motor response, brainstem reflexes, and respiration.[5] The only common component for both GCS and FOUR scales is eye response. As this new scale can be used in patients who are intubated or have a tracheostomy, this scale will give more accurate value to assess the consciousness level of the patients.[7]

Although the FOUR scale has been validated by comparing it with GCS in various settings, there are still several disagreements, which make it difficult to conclude between these two scales, which can give proper data on prognostic accuracy. Hence, the current study was conducted to compare the prognostic accuracy of the FOUR score with the GCS score for in-hospital mortality and morbidity among patients with TBI.

Materials and Methods

A prospective cohort study was carried out among 237 participants who were admitted to trauma care units of a public tertiary care center in South India from September 2022 to April 2023.

Sample size and sampling: The sample size was estimated to be 237 with a minimum expected difference in area under the curve (AUC) between GCS and FOUR as 0.1 (0.6 vs. 0.7) at a 5% level of significance and 80% power with an expected event rate of 50%.[8] Patients above 18 years and with moderate to severe brain injury were enrolled in the study using a consecutive sampling technique. Patients who were shifted to another hospital or expired within 24 hours of admission were excluded.

Ethical considerations: The study was approved by the institute's Research Monitoring Committee (CON/NRMC/M.Sc/2021/MSN/6) and the Ethical Committee for Human Studies (CON/IEC/M.Sc./2021/MSN/5). The procedures followed were by the institution's ethical standards, as well as the Declaration of Helsinki, revised in 2013. All the participants were enrolled after obtaining informed consent from legally authorized representatives of the patients. Data confidentiality, the anonymity of the subjects, and the right to withdraw from the study were explained to participants before data collection.

Data Collection

Following hospital admission, within 6 hours, the GCS and FOUR scores were assessed by two independent observers and recorded. Daily assessment was also done by two independent observers when the patient was free of any sedation in the morning hours until the last hospitalization day. The GCS includes three key categories, including eye-opening (1–4), verbal response (1–5), and motor response (1–6), which sums up to a total score ranging from 3 to 15. The four components of the FOUR score are eye tracking, motor response, brainstem function, and respiratory drive. Each category is given 0 to 4 points, 0 being the worst and 4 being the best. The lower scores denote an increasing deviation from normal for both the FOUR scores and GCS.[4,5] Participants' characteristics, including severity of TBI, total intensive care unit (ICU) days, total hospital stay, Acute Physiology and Chronic Health Evaluation (APACHE) II, radiological profile, admission hemodynamic parameters, comorbidities, duration of mechanical ventilation, and surgical treatment history were also collected.

Statistical Analysis

Data were analyzed using the IBM Statistical Package for the Social Sciences (Version 25.0). Data normality was assessed

using the Kolmogorov–Smirnov test. The chi-square test was used for the association of the categorical variables with in-hospital mortality and morbidity. Comparison of GCS and FOUR scores at the 6th hour between survival groups was done using an independent Student's *t*-test. The prognostic accuracy of the FOUR score and GCS score for in-hospital mortality and morbidity was assessed by using receiver operating characteristics (ROC) curve analysis, and the AUC was used to compare the prognostic accuracy. An optimum value of FOUR and GCS which maximizes the sensitivity and specificity was identified. All statistical analyses were carried out at a 5% level of significance.

Results

The median age of the 237 study participants was 44 (18, 84) years, and male preponderance was noted (81.9%). Seventy-four (31.2%) participants were diagnosed with moderate TBI, while 163 (68.8%) were diagnosed with severe TBI. The median APACHE II score was 12 (1, 37), and the median duration of mechanical ventilation was 3 (0, 30) days. The median duration of hospitalization for the participants was 4 (0, 30) days; the median duration of ICU stay was 5 (1, 35) days (►**Table 1**).

Among 43 women, 14 (32.6%) died in the hospital, whereas 63 (32.5%) out of 194 males died in the hospital. It shows that the hospital mortality rate was almost the same in both males and females. The in-hospital mortality rate was significantly higher ($p < 0.05$) in patients with severe TBI (44.8%) than those who had moderate TBI (5.4%). The in-hospital mortality was also found to be significantly lower ($p < 0.05$) among the patients undergoing surgery (21.7%) as compared to the participants who did not undergo any surgical interventions (39.3%) (►**Table 2**).

The mean GCS versus FOUR scores at the 6th hour among the survivors was 8.22 ± 2.45 versus 9.53 ± 3.42, while it was 4.83 ± 1.93 versus 3.88 ± 3.05 among the dead participants ($p < 0.001$). It shows that the mean GCS and FOUR scores at the 6th hour were both significantly lower among the patients who died when compared to the survivors (►**Table 3**).

The AUC for the GCS score at the 6th hour for predicting mortality was 0.865 with a cutoff value of 5.5 and it yields a sensitivity of 87% and a specificity of 64%. The prognostic accuracy of the FOUR score at the 6th hour for mortality among moderate and severe TBI patients was also described in ►**Table 4**. The AUC for FOUR score at the 6th hour for predicting the mortality was 0.893, with a cutoff value of 5.5 and it yields a sensitivity of 87% and specificity of 73%. This shows that the prognostic accuracy was higher for the FOUR score than the GCS score at the 6th hour (►**Table 4** and ►**Fig. 1**).

Discussion

There are various scoring systems that are established as useful for the prediction of patient outcomes based on their consciousness evaluation, but GCS remains a common tool in clinical settings. However, the parameters such as respiratory pattern, brainstem reflex, and verbal response, in the case of the patients who are intubated, cannot be assessed using GCS which may lead to an erroneous decision in evaluating the clinical outcome of the patients.[4] This led to the discovery of the FOUR scale, which is a simple tool that can assess the level of consciousness in a very detailed manner as compared to GCS. This prospective cohort study was carried out to find out in comparison to GCS whether the FOUR score is also a reliable tool for assessing consciousness in head injury patients.

In the current study, the maximum number of participants was victims of road traffic accidents, especially motor vehicle injury, which can explain the reason for the male preponderance (81.9%) in the gender, with a middle-aged population (44 years). Male dominance among TBI patients was also seen in other similar studies, and the young male group was victim of road traffic accidents.[8–10] Most of the studies did not report any patient comorbidities, as the maximum study participants were in the younger age group.[11]

The median duration of mechanical ventilation, length of ICU stay, and length of hospital stay for the current study were 3 (0, 30), 5 (1, 35), and 4 (0, 30) days, respectively. However, related studies report a higher mean length of hospitalization (8.41 ± 3.76) and longer ICU days among patients. Note that 38.8% of the study participants had surgical intervention, and among them, 78.3% of them survived which was in line with other studies.[6,12–14] The higher mortality (21.7%) could be due to the inclusion of more emergency neurosurgical cases in our study.

The mean GCS and FOUR scores at the 6th hour were higher among survivors than nonsurvivors (8.22 and 9.53 vs. 4.83 and 3.88), which was significant at $p < 0.05$. This result was consistent with the Saika et al[15] study, where the mean GCS score was 9.5 ± 2.4 and the mean FOUR score was 11 ± 3. This signified that the patients who survived had higher FOUR and GCS scores than those who died. Similarly, in a study by Babu et al, the mean GCS score was 9.46 ± 3.82 among patients who were alive and 5.36 ± 2.42 among dead patients. The FOUR score among survivors was 9.18 ± 3.42 and 4.98 ± 3.21 among dead patients.[16,17]

The Glasgow Outcome scale (GOS), discovered by Jennet and Bond, is also widely used for measuring the outcome of patients who suffered head injuries.[18] The scale consists of the following criteria: dead, vegetative state, severe disability (able to follow commands/unable to live independently), moderate disability (able to live independently: unable to return to work or school), and good recovery, scored as 1, 2, 3, 4, and 5, respectively. In the current study, GOS was assessed on the last day of hospitalization similar to the Mahmoud et al study. From the GOS score, we can conclude that 77 patients (32.5%) died in hospital. A similar mortality rate, that is, 32%, was noted in a study by Mishra et al,[7] but the Mahmoud et al study showed one-fifth of total patients (25.2%) died, which was less than the current study's mortality.[19]

Discrimination for GCS and FOUR at the 6th hour for predicting mortality was assessed using AUC, which shows that the prognostic accuracy was marginally higher for the FOUR score (AUC 0.893) than the GCS score (AUC 0.865) at the

Table 1 Distribution of participants' characteristics

Variables	Groups	Frequency (percentage) or median (min, max)
Age		44 (18, 84)
Gender	Female	43 (18.1)
	Male	194 (81.9)
Severity of traumatic brain injury	Moderate	74 (31.2)
	Severe	163 (68.8)
APACHE II score		12 (1, 37)
Comorbidities	Diabetes mellitus	6 (2.5)
	Hypertension	1 (0.4)
	Lower motor neuron paralysis	1 (0.4)
	Inferior wall myocardial infarction	1 (0.4)
Radiological profile	Epidural hemorrhage (EDH)	10 (4.2)
	Subdural hemorrhage (SDH)	43 (18.1)
	Contusion	34 (14.3)
	Diffuse axonal injury	19 (8)
	Subarachnoid hemorrhage	16 (6.8)
	Fracture with pneumocephalus	20 (8.4)
	Multiple injury with fracture, EDH, SDH	86 (36.3)
	Polytrauma	9 (3.8)
Hospital mortality	Yes	77 (32.5)
	No	160 (67.5)
GOS score	Death	77 (32.5)
	Survived	160 (67.5)
Surgery of traumatic brain injury	Yes	92 (38.8)
	No	145 (61.2)
Mechanical ventilation	Yes	183 (77.2)
	No	54 (22.8)
Duration of mechanical ventilation		3 (0, 30)
Duration of hospitalization		4 (0, 30)
Duration of intensive care unit stay		5 (1, 35)
GCS score at the last day of hospitalization or time of death	Same	73 (30.8)
	Improved	112 (47.3)
	Deteriorated	52 (21.9)
FOUR score at the last day of hospitalization or time of death	Same	69 (29.1)
	Improved	129 (54.4)
	Deteriorated	39 (16.5)

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; FOUR, Full Outline of Unresponsiveness; GCS, Glasgow Coma Scale; GOS, Glasgow Outcome Scale.

6th hour. Similarly, In the Nair et al study, there was a good correlation between GCS and the FOUR scores, and the FOUR score gave better neurological details than the GCS score.[20] Some studies showed that there is a significant difference in the FOUR score and GCS score while predicting the outcome of patients. The Mishra et al study concluded that researchers found higher FOUR score efficiency than GCS, in terms of outcome prediction of TBI patients (86.27% vs. 72.55%).[5] From a systematic review of Ahmadi et al and Foo et al, it can be concluded that the FOUR score has a better ability to predict outcomes and give wide neurological information regarding patient conditions.[21,22] Gorji et al showed that, while

Table 2 Association of participants' characteristics with hospital mortality among patients with traumatic brain injury

Variables	Groups	In-hospital mortality		*p*-Value
		Died ($n = 77$)	Survived ($n = 160$)	
Gender	Female ($n = 43$)	14 (32.6%)	29 (67.4%)	0.593
	Male ($n = 194$)	63 (32.5%)	131 (67.5%)	
Severity of TBI	Moderate ($n = 74$)	4 (5.4%)	70 (94.6%)	< 0.001[a]
	Severe ($n = 163$)	73 (44.8%)	90 (55.2%)	
Surgery	Yes ($n = 92$)	20 (21.7%)	72 (78.3%)	0.005[a]
	No ($n = 145$)	57 (39.3%)	88 (60.7%)	
Radiological profile	Epidural hemorrhage ($n = 10$)	2 (20%)	8 (80%)	0.097
	Subdural hemorrhage ($n = 43$)	9 (20.9%)	34 (79.1%)	
	Contusion ($n = 34$)	10 (29.4%)	24 (70.6%)	
	Diffuse axonal injury ($n = 19$)	9 (47.4%)	10 (52.6%)	
	Subarachnoid hemorrhage ($n = 16$)	4 (25%)	12 (75%)	
	Fracture with pneumocephalus ($n = 20$)	4 (20%)	16 (80%)	
	Multiple injury with fracture, EDH, SDH ($n = 86$)	34 (39.5%)	52 (60.5%)	
	Polytrauma ($n = 9$)	5 (55.6%)	4 (44.4%)	
Mechanical ventilation	Yes ($n = 183$)	76 (41.5%)	107 (58.5%)	< 0.001[a]
	No ($n = 54$)	1 (1.9%)	53 (98.1%)	

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; EDH, epidural hemorrhage; SDH, subdural hemorrhage; TBI, traumatic brain injury.
[a]Chi-square test $p \leq 0.05$.

Table 3 Comparison of GCS and FOUR score at 6th hour with mortality among the patients with traumatic brain injury

Variables	Outcome	Mean ± SD	*p*-Value
Glasgow Coma Scale at 6th hour	Survived ($n = 160$)	8.22 ± 2.45	< 0.001[a]
	Death ($n = 77$)	4.83 ± 1.94	
Full Outline of Unresponsiveness score at 6th hour	Survived ($n = 160$)	9.53 ± 3.43	< 0.001[a]
	Death ($n = 77$)	3.88 ± 3.06	

Abbreviations: FOUR, Full Outline of Unresponsiveness; GCS, Glasgow Coma Scale; SD, standard deviation.
[a]Independent Student's *t*-test $p \leq 0.05$.

predicting outcomes, the GCS score AUC was 0.92 and the FOUR score AUC was 0.96, so the FOUR score AUC was also marginally higher than the GCS score.[23] As per the study of Ansari and Rai, the sensitivity of GCS and FOUR scores were 64.2 and 65.6, respectively. The specificity of the GCS and FOUR scores were 66.4 and 71.5, respectively, showing that the FOUR score gives a more accurate prediction of outcomes in TBI patients.[24]

In contrast to our findings, the AUC for GCS and FOUR were 0.87 and 0.88, respectively, as calculated at the 6th hour of patient admission to the hospital from a study by Temiz et al, which was not significantly different in terms of patient outcome prediction.[13] Similarly, Ghelichkhani et al, Bayraktar et al, and Mcnett et al reported that there is no difference between the FOUR score and GCS score in terms of prediction of outcome in patients.[3,6,10]

Table 4 Comparison of the prognostic accuracy of GCS and FOUR score at 6th hour for mortality among patients with traumatic brain injury

Prognostic test	AUC value	Cutoff value	Sensitivity	Specificity
Glasgow Coma Scale at 6th hour	0.865	5.5	87%	64%
Full Outline of Unresponsiveness score at 6th hour	0.893	5.5	87%	73%

Abbreviations: AUC, area under the receiver operating characteristic curve; FOUR, Full Outline of Unresponsiveness; GCS, Glasgow Coma Scale.

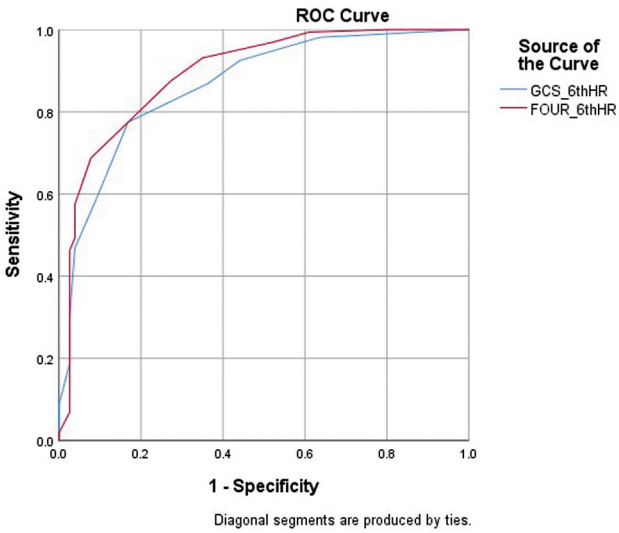

Fig. 1 Receiver operating characteristics (ROC) curves for Glasgow Coma Scale (GCS) and Full Outline of Unresponsiveness (FOUR) scores.

Limitations of the study: This study has certain limitations as the study was conducted in the emergency care unit and trauma care unit of a single tertiary care center with a limited sample size. Further, the subgroups had different locations of brain injury which could affect the patient's level of consciousness. The patients can be followed up for longer period to get favorable outcome and can be conducted in patients with different neurological disorders.

Conclusion

Even though the FOUR score and GCS score are both excellent in ruling out consciousness in patients, as well as prediction of outcome, the current study suggests the use of FOUR score in trauma care units for TBI patients, in view of higher specificity and higher accuracy than GCS score in the prediction of mortality among TBI patients.

Ethical Approval

Institutional Ethics Committee (JIP/CON/IEC/M.Sc./2020/MSN/5) for human studies and Nursing Research Monitoring Committee (JIP/CON/NRMC/M.Sc./2020/MSN/6) approved the study. The procedures followed were by the ethical standards of the institution as well as the Declaration of Helsinki revised in 2013. All the participants were enrolled after obtaining informed consent from legally authorized representatives of the patients. Data confidentiality, the anonymity of the subjects, and the right to withdraw from the study were explained to participants before data collection.

Data Availability Statement

The data set used in the current study is available on request from College of Nursing, JIPMER, through the corresponding author. L.R., I.C., M.K., K.T.H., H.T.L., and R,S. reported support for the present manuscript from JIPMER Intramural Research Fund (payment to primary investigator).

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Conflict of Interest

None declared.

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