E-ISSN 2250-0944
ISSN 2250-1150
doi: 10.48047/ijprt/16.01.02

Research Article

A CLINICAL STUDY OF TRAUMATIC BRAIN INJURY COMPARING FULL OUTLINE UNRESPONSIVE SCORE (FOUR SCORE) AND GLASGOW COMA SCALE SCORE (GCS SCORE) IN PREDICTING THE IN-HOSPITAL MORTALITY IN EMERGENCY DEPARTMENT OF TERTIARY CARE HOSPITAL

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Received date: 20-12-2025, Accepted date: 27-12-2025, Date of Publication: 05-01-2026.

Abstract

Objective: To compare and predict the mortality in patients with TBI, by using Full Outline of Unresponsiveness (FOUR) score and the Glasgow Coma Scale (GCS) in Emergency department.

Study design: The study was a prospective, descriptive and single center study.

Methodology: All Patients admitted to the Emergency Room between December 2015 to June 2017 with the history of trauma and satisfying the inclusion criteria of TBI were included as per proforma defined designed for the purpose. Necessary investigations helping the surgical management for those patients outcome were documented for analysis.

Results: The study sample contained 50 patients with predominantly males are involved. The most common age groups were 18 -39 years, followed by 50-59 years. The most common mode of injury is road traffic accident (RTA) followed by self fall from height. Most patients with GCS <7 on initial presentation have high mortality and similarly patients with initial FOUR score of <9 have higher mortality, when compared to higher GCS and FOUR score values. The Specificity of GCS <6 is 98.65% and Specificity of FOUR Score of <9 is 98.68% in predicting mortality.

Conclusion: Motor vehicle accident is leading cause of TBI. In this study comparing the FOUR, GCS scores in patients who are severely brain damaged shows that the FOUR is a valid tool with prognostic value comparable to GCS. The FOUR score may offer the additional advantage to be performable in intubated patients and to identify non-verbal signs of consciousness by assessing visual pursuit.

Key words: Traumatic Brain Injury (TBI), Glasgow Coma Scale (GCS), Full Outline Unresponsiveness Scale (FOUR).

INTRODUCTION

Teasdale and Jennet first presented the Glasgow Coma Scale in 1974 as an aid in the clinical assessment of unconsciousness[1]. The GCS is an objective measurement of clinical status, as it correlates with outcome, it is a reliable tool for inter observer measurements and also effective for measuring patient recovery or ongoing response to treatment. It was devised as a formal scheme to overcome the ambiguities and misunderstandings that arose when information about comatose patients was presented and groups of patients were compared. Since then, the Glasgow Coma Scale has been used extensively, being used to grade individual patient, compare effectiveness of treatments, and as a prognostic indicator in all such cases. It has been incorporated into numerous trauma and critical illness classification systems. However, a number of competing scales have also been developed to overcome its perceived deficiencies. These scales have generally been more complex.[2]

One of the expressed reservations regarding the Glasgow Coma Scale has been its failure to incorporate brainstem reflexes. The scale also includes a numerical bias toward the motor response and also an important concern of issue is appropriate application in intubated patients. A number of approaches have been used to assign the verbal score to such patients. Despite its drawbacks, the Glasgow Coma Scale is popular universally for management of consciousness score.[3]

In this study, based on GCS deficiencies, we hypothesized that GCS might be ineffective for initial assessment of traumatic brain injury and a simple scoring system such as the FOUR scale might demonstrate similar test performance. Therefore we took up investigating test performance of both scales in the prediction of outcomes noted in the present study patients presenting to Emergency Department (ED).[4]

Many comatose patients are intubated, the verbal component cannot be tested and abnormal brainstem reflexes, changing breathing patterns, and the need for mechanical ventilation could reflect severity of coma, but GCS does not include those clinical indicators; lastly GCS doesn't signify subtle changes in neurological examination[2]. Mayo Clinic, which evaluates 4 components, developed a new scale: eye, motor responses, brainstem reflexes, and respiration, this is called The Full Outline of Unresponsiveness (FOUR) score.[5]

AIMS AND OBJECTIVES

To use widely acknowledged GCS score and The FOUR score to assess TBI patients on arrival to the hospital.

To compare the prognostic values of GCS, and the FOUR scores in Patients with Traumatic brain injury admitted to Emergency Department**.**

MATERIALS AND METHODS

STUDY DESIGN: A Prospective observational study.

INCLUSION CRITERIA:

- Patients >18 years age admitted with traumatic brain injury during the study period to ED of KIMS hospital.
- Patients of TBI with grade 2 and above Severity.

EXCLUSION CRITERIA:

- Patients with no history of change in consciousness. who were intubated before admission in KIMS hospital
- Those administered with sedative or paralytic agents before admission,
- Those with history of intoxication.
- Those with known speech, vision, hearing, or motor impairments were excluded from the study.

METHODOLOGY:

Sample: 50 patients attending the Emergency Medicine Department after assessing for inclusion and exclusion criteria

STUDY PROTOCOL:

- Each patient presenting to our ED is evaluated at admission and re-evaluated within 24 hours of admission.
- The patients will be followed-up until discharge or death.
- The information regarding discharge from the ED, referral to regular ward, ICU admission, and mortality will also be recorded

STATISTICAL METHODS: Descriptive analysis: Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was also represented using appropriate diagrams like bar diagram, pie diagram and box plots.

Inferential statistics:

Quantitative outcome;

The association between categorical explanatory variables and quantitative outcome was assessed by comparing the mean values. The mean differences along with their 95% CI were presented. Independent sample t-test/ ANOVA/Paired t- test was used to assess statistical significance. Association between quantitative explanatory and outcome variables was assessed by calculating person correlation coefficient and the data was represented in a scatter diagram.

Categorical outcome The association between explanatory variables and categorical outcomes was assessed by cross tabulation and comparison of percentages. Odds ratio along with 95% CI is presented. Chi square test was used to test statistical significance.

P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.

RESULTS

A total of 50 subjects were included in the final study. The mean age of study population was 40.44 years with minimum 4 years and maximum 90 years. (Table 1)

Table 1: Descriptive analysis for Age in study population (N= 50)

Parameter	Mean ± STD	Median	Min	Max	95% C.I. for EXP(B)	
					Lower	Upper
Age	40.44±17.31	36.50	4.00	90.00	35.52	45.36

Table 2: Descriptive analysis of Age group in study population (N=50)

Age group	Frequency	Percentages
18-29	16	32.00%
30-39	11	22.00%
40-49	4	8.00%
50-59	12	24.00%
60-69	5	10.00%
70 and above	2	4.00%

Majority of the study population (32%) were between 18-29 years, the proportion of 30-39 years age group was (22%) the proportion of 40-49 years age group and 50-59 years age group was 8% and 24% respectively. Whereas 60-69 years age group population were 10% and the proportion of 70 years above people was only 4% (Table 2)

Fig 1: Bar chart of Age group distribution in study population (N=50)

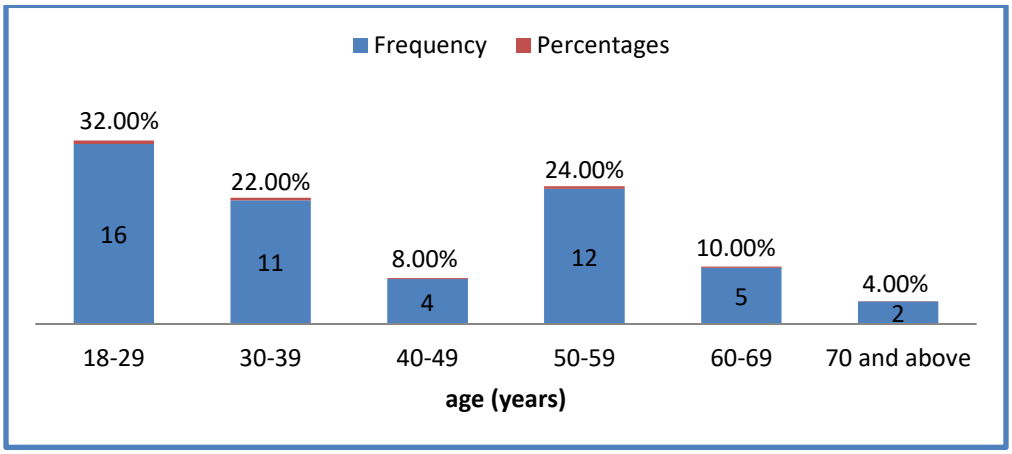

Table 3: Descriptive analysis of Gender in study population (N=50)

Gender	Frequency	Percentage
Female	12	24.00%
Male	38	76.00%

The majority of the study population (76%) were Male where as the proportion of females was only 24%.

Fig 2: Bar chart of Gender distribution in study population (N=50)

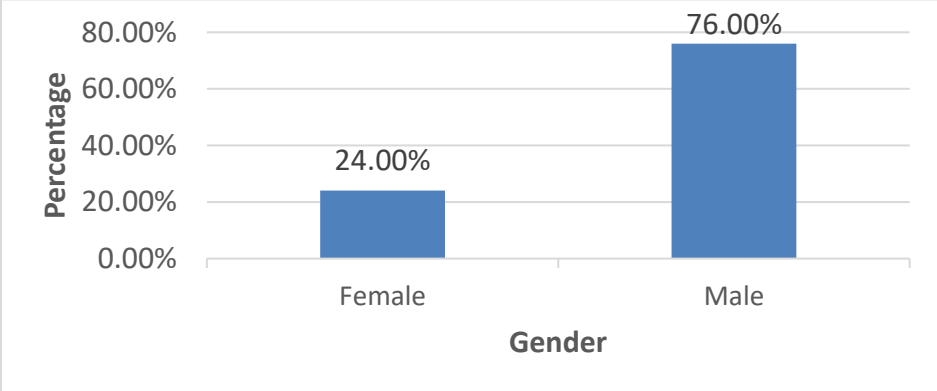

Table 4: Descriptive analysis for Total Hospital_Stay in study population (N=50)

Parameter	Mean ±STD	Median	Min	Max	95% C.I. for EXP(B)	
					Lower	Upper

Total Hospital Stay	9.26 ± 7.021	6.00	1.00	35.00	7.26	11.26

The mean Total hospital stay in study population was 9.26 days with minimum 1 day and maximum 35 days. (Table 4)

Table 5: Descriptive analysis of Place of Admission in study population (N=50)

Place of Admission	Frequency	Percentages
Both	9	18.00%
ICU	17	34.00%
Ward	24	48.00%

There were majority of the patients (48%) in study population admitted to ward alone whereas the proportion of patients admitted in ICU alone and in both ICU & Ward was 34% and 18% respectively.

Table 6: Descriptive analysis of Diagnosis in study population (N=50)

Diagnosis	Frequency	Percentages
SUBDURAL HAEMATOMA	17	34.00%
DIFFISE AXONAL INJURY	7	14.00%
SUBARACHNOID HAEMORRHAGE	7	14.00%
EXTRADURAL HAEMATOMA	5	10.00%
PARENCHYMATOUS INJURY	14	28.00%

Majority of the study population (34%) were diagnosed with Subdural hematoma and there were 28% of the patients diagnosed with parenchymatous injury. Whereas the proportion of Diffise axonal injury, extra Dural hematoma and subarachnoid hemorrhage was 14%, 10% and 14% respectively. (Table 6)

Table 7: Descriptive analysis of Family History in study population (N=50)

Family History	Frequency	Percentage
Diabetes	50	100.00%

Hypertension	50	100.00%
Chronic Liver Disease	50	100.00%
Tuberculosis	50	100.00%
Neoplasm	50	100.00%

Table 8: Descriptive analysis for Systolic BP, Diastolic BP, Pulse, Respiratory Rate, Temperature, Oxygen Saturation in study population (N=50)

Parameter	Mean ±STD	Median	Min	Max	95% C.I. for EXP(B)	
					Lower	Upper
Systolic BP in mm of hg	127.8 ± 9.688	130.00	100.00	150.00	125.07	130.57
Diastolic BP in mm of hg	86.3 ± 7.746	90.00	70.00	110.00	84.10	88.50
Pulse bpm	90.82 ± 11.53	89.50	65.00	130.00	87.54	94.10
Respiratory Rate cycles per min	21.68 ± 3.322	22.00	13.00	36.00	20.74	22.62
Temperature	98 ± 0.202	98.00	97.00	99.00	97.94	98.06
Oxygen Saturation	97.78 ± 0.887	98.00	96.00	99.00	97.53	98.03

The mean systolic BP of the study population was 127.8 with minimum 100 and maximum 150. The mean diastolic BP of the study population was 86.3 with minimum and maximum values as 70 and 110. The mean pulse rate was 90.82 in study population with minimum 65 and maximum 130. The mean respiratory rate of the study population 21.68 with minimum and maximum values as 13 and 36. The mean temperature was 98 with minimum 97 and maximum 99 in study population. The mean oxygen saturation was 97.78 with minimum and maximum values as 96 and 99. (Table 8)

Table 9: Descriptive analysis of loss of consciousness in study population (N=50)

Loss of consciousness	Frequency	Percentage
conscious	1	2.00%
Un conscious	49	98.00%

There were majority of the patients (98%) with loss of consciousness in study population. (Table 9)

Table 10: Descriptive analysis for CBC parameters in study population (N=50)

CBC parameter	Mean ±STD	Median	Min	Max	95% C.I. for EXP(B)	
					Lower	Upper
HB in gm per dl	12.34 ± 0.894	13.00	10.00	14.00	12.09	12.59
TC	9865 ± 2853.	10000.00	4000.00	15000.00	9053.97	10676.03
Platelet count	166608 ± 36513	150000.00	120000.00	270000.00	155703.05	176456.95
RBC	4.73 ± 0.341	4.60	4.00	5.60	4.63	4.83
ESR	10.02 ± 3.819	9.50	5.00	21.00	8.93	11.11

The mean HB of the study population was 12.34 with minimum 10 and maximum 14. The mean TC of the study population was 9865 with minimum and maximum values as 4000 and 15000. The mean platelet count was 16608 in study population with minimum 120000 and maximum 270000. The mean RBC of the study population 4.73 with minimum and maximum values as 4 and 5.6. The mean ESR was 10.02 with minimum 5 and maximum 21 in study population. (Table 10)

Table 11: Descriptive analysis for Bleeding test in study population (N= 50)

Parameter	Mean ±STD	Median	Min	Max	95% C.I. for EXP(B)	
					Lower	Upper
PT Control	16.64 ± 1.271	16.95	14.00	21.00	16.29	17.01
PT Test	14.66 ± 1.136	15.00	13.00	17.50	14.35	14.99
INR	1.026 ± 0.105	1.00	0.70	1.30	1.00	1.06
APPT Control	35.60 ± 2.500	35.30	29.00	46.00	34.90	36.32
APPT Test	28.48 ± 1.476	29.00	25.00	30.80	28.06	28.90

The mean PT control was 16.64 in study population with minimum 14 and maximum 21. The mean PT test of the study population was 14.66 with minimum and maximum values as 13 and 17.5. The mean INR of the study population was 1.03 with minimum 0.70 and maximum 1.3. The mean APPT control of the study population was 35.60 with minimum 29 and maximum 46.The mean APPT test of the study population was 28.48 with minimum 25 and maximum 30.8.

Table 12: Descriptive analysis for Electrolytes in study population (N=50)

Electrolytes	Mean ±STD	Median	Min	Max	95% C.I. for EXP(B)	
					Lower	Upper
Blood Sugar	143.9 ± 15.29	143.00	120.00	187.00	139.59	148.29
Sodium	133.8 ±	134.00	123.00	143.00	132.88	134.76

	3.293					
Potassium	4.276 ± 0.573	4.00	3.00	5.60	4.11	4.44
Chloride	92.64 ± 7.782	98.00	65.00	103.00	90.43	94.85

All patients in the study group are normo-glycemic and no electrolyte abnormalities are noted.(Table 12)

Table 13: Descriptive analysis of Outcome in Hospital in study population (N=50)

Outcome in Hospital	Frequency	Percentage
Non-survivors	14	28.00%
Survivors	36	72.00%

The majority of the study population (72%) survived and got discharged where as 28% of the study population were died. (Table 13)

Table 14: Descriptive analysis of Grade of injury in study population (N=50)

Grade of injury	Frequency	Percentage
moderate	9	18.00%
severe	41	82.00%

There were majority of the study population (82%) with severe grade of injury and only 18% with moderate grade of injury. (Table 14)

The area under the curve for the predictive validity of the GCS at admission in predicting mortality was 0.132 (95% CI 0.00 -0.29, P value <0.01)

The area under the curve for the predictive validity of the GCS at 24 hrs in predicting mortality was 0.049 (95% CI 0.00 -0.11, P value <0.01)

The area under the curve for the predictive validity of the GCS at admission and FOUR score at admission in predicting survival of the study population was 0.868 (95% CI 0.72 -1.00, P value <0.01) and 1.00 (95% CI 1.00 -1.00, P value <0.01) respectively.

Table 15: Comparison of median values of the GCS with the mortality

Two-sample Wilcoxon rank-sum (Mann-Whitney) test

Variable	Observed value	Median (75%, 25%)	P value
Recovered	36	11 (13,7)	P value <0.001
Not recovered	14	3 (4,3)	

By comparing the Median value of the GCS with the Survivors by using the Mann-Whitney test it showed a significant p value <0.001.

Table 21: Comparison of median values of FOUR score with the mortality

Two-sample Wilcoxon rank-sum (Mann-Whitney) test

Variable	Observed value	Median (75%, 25%)	P value
Recovered	36	13.0(15,9.0)	P value < 0.001
Not recovered	14	0.5 (1.00,0.00)	

By comparing the median value of FOUR score with the Mortality by using the Mann-Whitney test it showed a significant P value of <0.001.

FOUR SCORE is comparable with the GCS.

DISCUSSION

According to Kamal et.,al males were at a higher risk with a male: female ratio of 6.5:1 and there were 86.64% were male where the mean age was 32.15 years. According to Shekhar C et al., among 791 cases 72% males and only 28% were females. According to Agarwal A et al., The median age of the study population was 31 years but the TBI occurrence was high in 21-30 years age group with proportion of 27.7%. The proportion of males in the study population was 70.76%. According to Gorji MA, The female and male proportion was 20% and 80% respectively. The average age of the sample was 33.80 years. There were 26.2% people died during the treatment. According to sepahvand et al., out of 198 patients with mean age 40.88±17.7 years, and age range from 16 years to 80 years were assessed. The results of our study more or less similar to the previous studies with the mean age of study population was 40.44 years with minimum 4 years and maximum 90 years. Majority of the study population (54%) were below 39 years, the proportion of 40-49 years age group and 50- 59 years age group was 8% and 24% respectively. Whereas 60-69 years age group population were 10% and the proportion of 70 years above people was only 4%. The majority of the study population (76%) were Male where as the proportion of females was only 24%.

Khajeh A et al., provided the information as out of 200 children who admitted to pediatric ICU 71.5% were discharged and the remaining 28.5% were died. There were almost similar results described in the present study also as the majority of the study population (72%) were discharged where as 28% of the study population were died. [6]

According to Idrovo et al., The TBI related complication distributed as among 60 patients, 41 were cerebral infractions, 15

were cerebral hemorrhage and only 4 were transient ischemic attacks. There were 55% in alert condition but 28.3% were drowsy and 16.7% were comatose. In the present study the consciousness of the patients was little away from the previous studies because of majority of the patients (98%) with loss of consciousness in study population.[7]

Orient-Lopez F et al., discussed about epidemiological and clinical characteristics of TBI as follows. Out of 174 patients 88.52% were Severe TBI cases. Coming to the causes of TBI Road accidents occupies major proportion with 78%. The Clinical characteristics of TBI as the neurological injuries were parenchymatous (68.05%), with the 40.58% subarachnoid haemorrhages in second place where as 87.58% of the study population experiencing TBI-related complications. According to sepahvand et al., All patients with traumatic brain injuries, 80 (40%) had epidural hematoma, 40 (20%) had subdural hematoma, 5 (2%) had subarachnoid hematoma, and 73 (36%) had hematoma in brain tissue. The diagnosis of the TBI explained in present study was more or less similar to previous studies with the facts as Majority of the study population (34%) were diagnosed with Subdural hematoma and there were 28% of the patients diagnosed with RTA. Whereas the proportion of Diffise axonal injury, extra Dural hematoma and subarachnoid hemorrhage was 14%, 10% and 14% respectively. There were majority of the study population (82%) with severe grade of injury and only 18% with moderate grade of injury.[8]

Areas under the curve (AUC) for mortality were 0.834 (95 % CI, 0.740-0.928) and 0.815 (95 % CI, 0.723-0.908) for the FOUR score and GCS, respectively. The area under curve (AUC) of FOUR score in early mortality was 0.90 (C1 = 0.95, 0.88-0.90). The amount AUC for GCS was 0.80 (C1 = 0.95, 0.78-0.84), which in delayed mortality it was ordered as 0.86 (C1 = 0.95, 0.84-0.90) and 0.89 (C1 = 0.95, 0.78-0.88). In terms of predictive power for in-hospital mortality, the area under the receiver operating characteristic (ROC) curve was 0/92 (95% CI. 0/81-0/97) for FOUR score and 0/96 (95% CI. 0/87-0/99) for GCS. In terms of predictive power of poor neurologic outcome, the area under the ROC curve was 0/95 (95% CI. 0/86-0/99) for FOUR score and 0/90 (95% CI.0/79-0/96) for GCS as evidenced by GOS 1-3. AUC for in-hospital mortality for GCS was 0.83 (CI 0.7 to 0.9) and FOUR score was 0.8 (CI 0.7 to 0.9) [difference between areas -0.0250 (95%CI 0.0192 to 0.0692), The areas under the curves was significantly higher with the FOUR score than with GCS (respectively 0.867 confidence interval [CI]: 95% [0790-0.944] and 0.832 CI: 95% [0.741-0.923]; P = 0.014). Discrimination for GCS and FOUR score was fair with the area under the receiver operating characteristic curve of 0.79 and 0.82, respectively. At a cut-off score of 7 for FOUR score, the AUC was 0.97, with sensitivity of 97.5 and specificity of 88.2 % ($p < 0.0001$). For GCS score, AUC was 0.95, with sensitivity of 98.3 % and specificity of 82.4 % with cut-off score of 6 ($p < 0.0001$).(134) The result of present study were more or less similar with old studies as The area under the curve for the predictive validity of the GCS at admission in predicting mortality was 0.132 (95% CI 0.00 -0.29, P value <0.01) The area under the curve for the predictive validity of the GCS at 24 hrs in predicting mortality was 0.049 (95% CI 0.00 -0.11, P value <0.01).[10]

According to Khanal, K., et al., GCS and FOUR score were measured within 24 h of Intensive Care Unit admission. The mean GCS and the FOUR scores were lower among nonsurvivors than among the

survivors and were statistically significant (P < 0.001).11 Discrimination for GCS and FOUR score was fair with the area under the receiver operating characteristic curve of 0.79 and 0.82, respectively.[13] The cutoff point with best Youden index for GCS and FOUR score was 6.5 each.(133)The present study results also showed almost similar facts about GCS and FOUR scores as the area under the curve for the predictive validity of the GCS at admission and FOUR score at admission in predicting survival of the study population was 0.868 (95% CI 0.72 -1.00, P value <0.01) and 1.00 (95% CI 1.00 -1.00, P value <0.01) respectively.[14] The area under the curve for the predictive validity of the GCS at admission and FOUR score at admission in predicting survival of the study population was 0.951 (95% CI 0.89 -1.00, P value <0.01) and 1.00 (95% CI 1.00 -1.00, P value <0.01) respectively.[15]

OUTCOME

1. In this study patients with low GCS and Low FOUR score on initial presentation are more prone for prolonged length of stay in the hospital. Initial score of < 6 of GCS and < 8 of FOUR score are showing high incidence of mortality.
2. The area under the curve for the predictive validity of the GCS at admission and FOUR score at admission in predicting survival of the study population was 0.868 (95% CI 0.72 -1.00, P value <0.01) and 1.00 (95% CI 1.00 -1.00, P value <0.01) respectively. Hence the predictive validity of FOUR score at admission is better than the GCS at admission in predicting survival
3. The area under the curve for the predictive validity of the GCS at 24 hours and FOUR score at 24 hours in predicting survival of the study population was 0.951 (95% CI 0.89 -1.00, P value <0.01) and 1.00 (95% CI 1.00 -1.00, P value <0.01) respectively. Hence the predictive validity of FOUR score at 24 hours is better than the GCS at 24 hours in predicting survival.

CONCLUSION

The present study found that Four score is reliable, easy to use, reproducible gives more clinical information and takes less time to perform and can be useful alternative to GCS in the ER settings.

The study findings point that the Four score can replace the GCS scale It is also suggested that the health care team can be trained and made proficient in using the FOUR score. A similar study can be undertaken with large sample size under reproducible environment for meta analytical approach.

In conclusion, our prospective study comparing the FOUR, GCS scores in patients with history of severe brain injury shows that the FOUR is a valid tool with prognostic value comparable to GCS. The FOUR score may offer the additional advantage to be performable in intubated patients and to identify non-verbal signs of consciousness by assessing visual pursuit**.**

LIMITATIONS

1. Considering the relatively smaller sample size, the effect of various confounding factors like age, gender, presence of other co-morbidities on survival/ mortality could not be analyzed
2. Considering the limited follow up time, the predictive validity of the scores in long term mortality could not be evaluated

RECOMMENDATIONS

1. There is a need to conduct further large scale studies on the subject to evaluate the performance of these scores in different population subgroups, so evidence based clinical recommendations can be evolved

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