Paediatrics Section

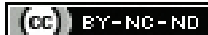# Comparison of Full Outline of UnResponsiveness Score and Glasgow Coma Scale in Predicting the Outcome of Children aged 3 to12 Years with Altered Level of Consciousness Admitted to the Paediatric Intensive Care Unit

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ABSTRACT

Introduction: The commonly used Glasgow Coma Scale (GCS) score for assessing consciousness has several shortcomings, especially in intubated patients. Recently, the Full Outline UnResponsive Score (FOUR) has been validated as an alternative to the GCS due to its additional benefits in evaluating brainstem reflexes and respiratory patterns. The use of the FOUR score can overcome the shortcomings of the GCS and aid in prognosticating patients with altered sensorium.

Aim: To compare the FOUR score with GCS score to find a better scoring system for predicting outcomes among children aged 3-12 years with non-traumatic causes of Altered Level Of Consciousness (ALOC) in the hospital.

Materials and Methods: A prospective cohort study was conducted on a total of 100 children with ALOC in the Paediatric Intensive Care Unit (PICU) of Gandhi Medical College and Hospital, Telangana, from December 2020 to November 2021. FOUR and GCS assessments were performed simultaneously within two hours of admission. For statistical analysis, continuous variables are expressed as mean±standard deviations. The predictive values of the GCS score and FOUR score were established using the Receiver Operating Characteristic (ROC) curve, by calculating the Area Under the Curve (AUC) with a 95% Confidence Interval (CI).

Results: The mean age of the study population was 7.3±5.2 years, and the mean duration of hospital stay was 7.5±6.74 days. In-hospital mortality was 34%, and the survival rate was 66%. The mean FOUR score for in-hospital mortality and survival was 8.47±3.01 and 12.24±1.46, respectively (p-value <0.001). The mean GCS scores were 11.35±1.64 in survivors and 7.45 ±2.63 in non-survivors (p-value <0.001). A FOUR score of <10 was associated with higher mortality than a FOUR score of >10 (p<00.05). The Area Under Curve (AUC) for the FOUR score was 0.862 with a 95% CI (0.774 to 0.95) in the ROC curve (p-value <0.001), and for the GCS score, the AUC was 0.822 with a 95% CI (0.723 to 0.92) and p-value <0.001. The FOUR Score has a higher AUC than the GCS in the ROC curve, indicating that the FOUR Score has better discrimination than the GCS in outcome assessment.

Conclusion: FOUR score and GCS score were comparable for predicting outcomes in children with ALOC. However, the FOUR score showed better discrimination than the GCS; hence, the FOUR score can be used as an alternative tool to the GCS for prognosis.

INTRODUCTION

The ALOC in children is characterised by the failure to respond to verbal or physical stimulation in a manner appropriate to the child's developmental level [1]. The spectrum of ALOC ranges from confusion or delirium to lethargy, stupor, and coma. Comatose patients are unresponsive and cannot be aroused by verbal or physical stimulation [2]. ALOC is caused by abnormalities of the ascending reticular activating system, located deep within the upper part of the brainstem or cerebral cortex. There are many non-traumatic conditions that can cause dysfunction of the reticular activating system, including inadequate substrate availability, impaired blood supply, the presence of toxins or metabolic waste substances, alterations in body temperature, infections, and systemic illness [3-5]. ALOC resulting from these conditions can be fatal if not recognised quickly and treated sufficiently [6].

ALOC is an emergency condition requiring admission to the PICU. It is challenging for clinicians to initiate appropriate treatment in a timely fashion and to provide accurate prognostication regarding survival and functional outcome. Although advances in brain imaging, biochemical markers, and electrophysiological studies have aided in accurate prognostication, clinical scoring systems should be used in conjunction with neurophysiological techniques to predict outcomes and manage children with altered sensorium [7-10].

The Glasgow Coma Scale (GCS) is the most widely used, studied, and universally accepted coma scale to date. In children, no other scale replaces the GCS in clinical practice or for research. It is still the recommended coma scale for the assessment and monitoring of children with ALOC. For children older than five years, the response in GCS is similar to that of adult patients. Infants and children younger than five years are not able to provide the necessary verbal and motor responses to assess their orientation or obey commands. The Child's Glasgow Coma Scale (GCS score) has evolved from the adaptation of Jennett B and Teasdale's G GCS by James and Trauner for use in paediatric patients. It is recommended by the British Paediatric Neurology Association for use in the United Kingdom [11-13].

Wijdicks EF et al., published a new scoring system in 2005, the FOUR score [14]. The newer FOUR score coma scale can be an attractive replacement for all children with an alteration in the state of consciousness and is gradually gaining wide acceptance. The FOUR score coma scale is superior to GCS in that it can account

for the intubated patient without substitute scores, may provide a more complete assessment of brain stem functions, identify a locked-in state, and detect the presence of a vegetative state [3]. The FOUR score has been shown to have good inter-rater reliability as well [15].

The FOUR score has been validated with reference to the GCS score in several studies; however, the results were conflicting in stating which scoring system has the best predictive value [16-19]. Several studies [20-22] have been validated in adults, but very limited studies [23,24] are available in the paediatric population. Hence, the present study was conducted to compare the FOUR score with GCS to find the better scoring system for predicting the outcome among children aged 3-12 years with altered level of consciousness due to non-traumatic causes in the hospital.

MATERIALS AND METHODS

A prospective cohort study was conducted in the PICU of the Gandhi Medical College and Hospital in Telangana state after obtaining approval from the Institutional Ethical Committee (approval no: IEC/GMC/2020/01/38). The study was conducted over a period of one year from December 2020 to November 2021 after obtaining written informed consent from the parents/caregivers.

Inclusion criteria: All children aged between 3-12 years, admitted to the PICU with an ALOC of <7 days duration due to non-traumatic causes within the study duration, were included. ALOC is defined as a conscious level below or equal to "V" in the abbreviated AVPU coma scale ('Alert'-child is alert, 'Verbal'-child responds only when parents/physicians call the child's name or speak loudly, 'Pain'-child responds only to painful stimuli, 'Unresponsive'-child does not respond to any stimulus) [Annexure-1] [25].

Exclusion criteria: Children with ALOC of more than seven days, with underlying neurological conditions like cerebral palsy and developmental delay, with head trauma, children referred with an endotracheal tube on sedatives or neuromuscular blockade drugs, and those who died within six hours of hospital admission were excluded from the study.

Procedure

Data collection: Basic information regarding the child's age, gender, address with phone number, place of referral, intubation status, if intubated, the reason for intubation, and administration of any premedication during intubation was collected from the study population. Detailed clinical history was obtained from the parents/caregivers of all children with ALOC about the onset of symptoms and their duration before admission to our hospital to identify the medical or traumatic cause of ALOC. A complete neurological examination was performed for all included children.

The FOUR coma scale and CGCS [Annexure-1,2] were applied simultaneously in children within two hours of admission to the PICU by paediatric residents after the stabilisation of their vital status. Demographic, clinical data, and both coma scale scores were entered into a pre-designed proforma.

The FOUR coma scale assesses four variables: eye response, motor response, brainstem reflexes, and respiration pattern. Each item is scored on a 5-point scale, ranging from 0 to 4, with a total FOUR score ranging from 0 to 16, where 16 indicates the highest level of consciousness [14]. The scores in each component can be added together to obtain the total FOUR score. All patients were categorised into four groups as 0-4, 5-8, 9-10, and >10 based on their FOUR score for the purpose of this particular study.

The ALOC is assessed with CGCS coma scale in children <5 years and GCS coma scale is used in children 0f >5 years with three components of responsiveness [12,13]. These components include best Eye (E) response, best Motor (M) response, and best Verbal (V)

response, with the minimum score for each component as one and the maximum score as four for eye response, five for verbal response, and six for motor response. Hence, the GCS score ranges from a minimum of three to a maximum of 15. The three components of CGCS were recorded individually. The scores in each component can be added together to obtain the total CGCS score. For the purpose of the study, the verbal GCS score of intubated patients was taken as one. All the patients were categorised into three groups based on GCS score ranges: severe [3-8], moderate [9-12], and mild [13-15] for the analysis of results.

All the patients were followed-up until the time of discharge (survivors) or death in the hospital (non-survivors) to determine the outcome. Admission CGCS and FOUR scores were analysed to predict the outcome.

STATISTICAL ANALYSIS

The statistical analysis was performed using SPSS for Windows version 22.0 software (also available for Mac and Linux). Descriptive statistics were expressed as frequencies and mean±standard deviation. The chi-squared test was used to find associations among variables. The predictive values of GCS score and FOUR score were established with an ROC curve by calculating the AUC curve with a 95% confidence interval. The critical value of P, indicating the probability of a significant difference, was considered as <0.05.

RESULTS

A total of 100 children were enrolled in the present study. The mean age of the total study population was 7.3±5.2 years, and the mean duration of hospital stay was 7.5±6.74 days. The in-hospital mortality rate was 34%, and the survival rate was 66%. The mean GCS and FOUR scores of all children were 9.84±2.47 and 10.96±2.77, respectively. The mean GCS scores and FOUR scores were higher in children who survived than those of children who did not. The mean GCS scores were 11.35±1.64 in survivors and 7.45±2.63 in non-survivors, and the difference was statistically significant (p-value=0.001). The mean FOUR scores were 12.24±1.46 and 8.47±3.01 in survivors and non-survivors, respectively (p-value <0.001). These scores were higher than the GCS score in survivors and non-survivors [Table/Fig-1].

Study group	Total number of children (n=100)	Number of children died (%) (n=34)	Number of children alive (%) (n=66)	p-value
Age mean (SD) (Years)	7.3±5.2	7.1±5.1	7.2±5	0.11
Mean (SD) duration of hospital stay (in days)	7.5±6.74	6.5±9.65	7.4±3.77	0.13
Intubation status	100	34	66	
Yes		27 (73)	10 (27)	0.16
No		7 (11.1)	56 (88.9)	
GCS score Mean (SD)	9.84±2.47	7.45±2.63	11.35±1.64	**0.001***
FOUR score Mean (SD)	10.96±2.77	8.47±3.01	12.24±1.46	**<0.001***

[Table/Fig-1]: Baseline characteristics of the study population.
*p-value: Significant

FOUR score of <10 was associated with higher mortality than FOUR score of >10, which was statistically significant (p<0.001). In GCS score range of 3-8, mortality rate was 68.96% and survival rate was 31.3% which was statistically significant (p<0.001) [Table/Fig-2].

The sensitivity of FOUR score was very low which suggest it is not accurate for diagnosing true positive cases (p<0.05). Specificity of FOUR score decreased as the score increases and it was significant at 95% CI with chi-square value of 90.4038 and a p-value <0.001 [Table/Fig-3].

Variable	Total number of children	Outcome	
		No. of children died (%)	No. of children alive (%)
FOUR score range			
0-4	3	3 (100.0)	0
5-8	13	13 (100.0)	0
9-10	17	9 (52.9)	8 (47.1)
>10	67	9 (13.4)	58 (86.6)
p-value		<0.001*	
GCS score range			
3-8	29	20 (68.96)	9 (31.03)
9-12	59	11 (18.64)	48 (81.35)
13-15	12	3 (25)	9 (75)
p-value		<0.001	

[Table/Fig-2]: Range wise FOUR Score and GCS score in study population and their outcome (N=100).
*p-value: Significant

| Score	Sensitivity	Specificity	Positive Predictive Value (PPV)	Negative Predictive Value (NPV)
Four score				
0-4	9.7	100.0	100.0	68.0
5-8	38.2	100.0	100.0	75.9
9-10	26.5	67.4	52.9	69.9
>10	26.5	12.1	52.9	9.6
p-value		<0.001*		

[Table/Fig-3]: Diagnostic accuracy of FOUR score in study population.
*p-value: Significant

Variables	Youden Index J and cut-off	Sensitivity	Specificity	Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% CI	
							Lower bound	Upper bound
GCS score	0.5820 and ≤9	79.41	78.79	0.822	0.050	<0.001*	0.723	0.920
FOUR score	0.6141 and <10	73.53	87.88	0.862	0.045	<0.001*	0.774	0.950

[Table/Fig-4]: AUC (Area Under Curve) comparison between GCS score and FOUR Score.
a-Standard error, b-Asymptotic significance, *p-value: Significant
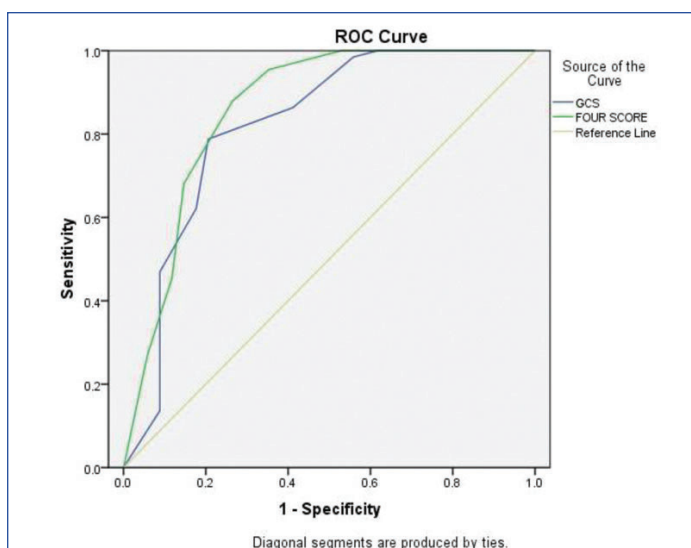
[Table/Fig-5]: Receiver Operating Characteristic (ROC) curve of Glasgow Coma Scale (GCS) and Full Outline Unresponsive (FOUR) score.

The AUC for FOUR score was 0.862 with 95% CI (0.774 to 0.950) and for GCS score was 0.822 with 95% CI (0.723 to 0.92) in ROC curve, which was significantly higher for FOUR score than for GCS

score. The cut-off values obtained for FOUR score was 10 and for the GCS score was 9 based on the ROC analysis [Table/Fig-4].

FOUR Score has higher AUC than AUC of GCS in ROC curve, which indicate that the FOUR score has better discrimination than the GCS in outcome assessment [Table/Fig-5].

DISCUSSION

Patients with a higher FOUR score are fully conscious. In-hospital mortality risk decreased with an increasing score. The cut-off point of the FOUR score varies in the literature to predict the outcome as per various studies. A cut-off point of 10 in the study by Akavipat P et al., a cut-off point of 9 in the study by Wijdicks EF et al., and a cut-off point of 8 in the study by Khajeh A et al., correlated with a worse outcome [15,21].

In the present study, the authors prospectively examined 100 children in the age group of three years to 12 years. This is slightly different from a study done on 150 children between the age group of 1 to 14 years in a tertiary care teaching hospital in India, where the mean age group was found to be 6.64±4.13 years [26]. In the present study, the authors observed that there was no statistically significant difference in the mean FOUR score among the age groups. The in-hospital mortality (34%) and survival (66%) outcomes, as well as the lower mean GCS than FOUR score at admission for children who expired in the present study findings, are consistent with Mittal K et al., study [27].

In Traumatic Brain Injury (TBI) patients, Nyam TTE et al., examined which score is superior, FOUR score, APACHE II, or GCS score in predicting ICU mortality and found that the FOUR score was similar to the GCS and APACHE II [28]. Said T et al., compared the usefulness of the FOUR score in predicting extubation failure in critically ill patients and concluded that the FOUR has a better ability

to predict successful extubation than GCS [17]. A prospective study in patients >16 years of age compared the outcome prediction by measuring both the FOUR score and GCS score within 24 hours of admission. They found that the mean scores of non-survivors were lower than survivors (p<0.001). The AUCs of GCS and FOUR were 0.79 and 0.82, respectively, indicating fair discrimination power for both [29]. The findings of the present study are in agreement with a previous study in terms of higher FOUR score and GCS score being significantly associated with a lower mortality rate [19].

The authors observed in the present study that no children survived at discharge with a sum FOUR score of 4 or less, yielding a specificity of 100%. The authors also found that the vast majority of children with a sum FOUR score of more than 8 survived to hospital discharge [30-32]. The present study has 0.862 (86.2%) accurate prediction for the outcome, as per the ROC curve, and high specificity in lower sum FOUR scores, which means that more than 97% of children will die if the sum FOUR score is 4 or less. Similarly, more than 99% of children may survive if the sum FOUR score is >10, in contrast to the GCS score, which has an accuracy of 0.822 (82.2%). In agreement with these findings, most of the studies have pointed out acceptable or excellent discrimination power of the FOUR coma scale and GCS in predicting the outcome [Table/Fig-6] [19,22,33-38].

Author, year of publication	Place/year of the study	Number and population	Variable	Cut-off score	Sensitivity (%)	Specificity (%)	AUC
Present study		100 children	FOUR score	10	73.53	87.88	0.862
			GCS score	9	79.41	78.79	0.822

Study	Place Year	Sample	Score	Cut-off	Sensitivity	Specificity	AUC
Zahid S et al., [33]	Pakistan 2022	170 children	FOUR score		63.46	86.44	-
			GCS score		55.76	83.39	-
Sofia F et al., [34]	Sen Francisco 2017	27 children	FOUR score		71.4	95	0.939
			GCS score		100	60	0.925
Jamal A et al., [22]	Chandigarh 2017	63 children	FOUR score		-	-	0.8
			GCS score		-	-	0.83
Sri K and Doshi A [35]	Pune 2023	125 adults	FOUR score	10.50	96.2	6.7	0.984
			GCS score	6.5	98.1	33.3	0.974
Fahad A and Arvind R [36]	Madhya Pradesh 2021	100 adults	FOUR score		65.6	71.5	
			GCS score		64.2	66.4	
Ramazani J and Hosseini M [19]	Iran 2019	300 adults	FOUR score	6.5	78.31	78.24	0.873
			GCS score	7.5	79.76	68.98	0.823
Silvitasari I et al., [37]	Indonesia 2017	74 adults	FOUR score	6	0.861	0.816	0.893
			GCS score	5	0.722	0.737	0.859
Saika A et al, [38]	Banglore 2015	138 adults	FOUR score	7	97.5	88.2	0.97
			GCS score	6	98.3	82.4	0.95

[Table/Fig-6]: Characteristics of various studies in children and adult showing sensitivity, specificity and AUC to predict outcome [19,22,33-38].

Limitation(s)

This study was conducted in the intensive care unit among children with ALOC due to a wide range of non-traumatic aetiology. Admission FOUR scores and GCS scores were the only ones taken to predict the outcome. Subsequent scores until death or discharge were not taken into account.

CONCLUSION(S)

The FOUR score and GCS score were comparable for predicting outcomes in patients admitted to the PICU. The possibility of using the FOUR coma scale as an alternative to GCS in children with ALOC for prognostication is promising, as it showed better discrimination than the GCS score. ALOC in children can be due to various non-traumatic and traumatic causes. The present study was done in children with altered sensorium of diverse aetiology. To use it as a better alternative outcome predictor, the authors need further studies with a large sample size and homogeneous aetiology to observe the discrimination power of the FOUR score and GCS score.

Acknowledgement

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• For any images presented appropriate consent has been obtained from the subjects.   NA

[Annexure-1]: Full outline of UnResponsiveness score.

[Annexure-2]: Child Glasgow Coma Scale (CGCS).