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Abstract

Background: Assessment of consciousness level is a basic ability that medical personnel, especially doctors and nurses should master. There are various types of scales to measure consciousness level of patient. One of the most famous and most widely applied scale is Glasgow Coma Scale (GCS). The GCS presents several weaknesses, such as limited utility in intubated patients as well as an inability to estimate brainstem reflexes. The objective is to determine predictive accuracy of FOUR score against GCS. To assess the neurological outcome based on modified Rankin scale. Materials and Methods: Children, who are admitted in the PICU with altered level of consciousness, recruited in this study based on inclusion and exclusion criteria after obtaining written informed consent from the parents or caregivers. Detailed clinical and neurological examination done in all study subjects. Full Outline of Un Responsiveness Score (FOUR score) and Glasgow Coma Scale (GCS) collected for each patient separately and simultaneously after admissions in the intensive care unit. Result: The area under ROC showed FOUR score and GCS were good at discriminating survivors and no survivors (P < 0.05 and P < 0.05, respectively). The Area Under Curve (AUC) = 0.968 for FOUR score and the AUC = 1 for GCS, pointed out that the discrimination power of GCS score was better than FOUR. Among admitted children 7.8% children had no evident disability despite symptoms and 1.3% of children had slight disability, with an inability to carry out all previous activities at the time of discharge. Conclusion: FOUR score provides no significant advantage over GCS in predicting morbidity and mortality in children in PICU with impaired neurological status.

INTRODUCTION

Altered level of consciousness (ALC) is a spectrum of disease that presents a diagnostic and therapeutic challenge to the practitioner caring for infants, children and adolescents.

The western studies have shown that the annual incidence of hospital admission due to non-traumatic causes of depressed level of consciousness is 30 per 100,000 children.^[1] Estimated rates of severe traumatic brain injury from accidental and non-accidental causes are similar and accidental injury remaining the leading cause of pediatric mortality in developed countries.^[2,3]

The encephalopathy patient may have a non-specific presentation, whereas agitation secondary to

ingestion may be associated with classic signs and symptoms suggesting intoxication with a particular substance.^[4]

Impaired consciousness is invariably associated with generalized seizure activity and is a distinguishing feature in the classification of focal seizures.^[5] Status epilepticus may present as continuous clinical and / or electrographic seizure activity that lasts duration of 5 minutes or more, or as recurrent seizure activity without return to baseline between seizures.^[6]

Despite advances in technology and monitoring devices, clinical assessment is still the key to identifying subtle changes in a patient"s neurological status and is crucial for the management of neuroscience patients. The need for intubation and mechanical ventilation might suggest brainstem involvement and can be an important component in the assessment of coma severity.^[7]

MATERIALS AND METHODS

It was a Cross Sectional Prospective Study done at Pediatric Intensive Care Unit (PICU), Institute of Child Health Kottayam for a period of One year after obtaining IRB approval among Children admitted with altered level of consciousness in the Pediatric Intensive Care Unit, Institute of Child Health, Kottayam.

Sample size was calculated using n Master software with sample agreement, Single group- dichotomous outcome- Kappa (Testing against population). From the study, by Khajeh B et al8 showed PICU mortality of children admitted with impaired neurological status is 28.5% and 71.5% got discharged. So P is taken as 28%.

Formula used for sample percentage calculation: $N=21[Z\alpha + Z1-\beta]^2$

21 $[(1 - \pi)(\rho 1 - \rho 0)]$ $[\pi 2 + (1 - \pi)0 + \pi(1 - \pi)(1 - \rho 0) + (1 - \pi)2 + \pi(1 - \pi)]$ π) ρ 0]

Population agreement = 0.5 Sample agreement = 0.7Prevalence = 0.28

Power (%) = 90 Alpha Error (%) = 5 Sided = 1 Z -1.96 Z1- -0.84 P1-0.7 P0-0.5

II-0.28(Prevalence)

Sample Size = 192

Consecutive sampling technique was used.

Methodology

Children, who are admitted in the PICU with altered level of consciousness, recruited in this study based on inclusion and exclusion criteria after obtaining written informed consent from the parents or caregivers. Basic information regarding child"s age, gender, address with phone number for follow up, intubation status, and administration of any premedication during intubation were obtained and entered in patient data entry form. Detailed clinical and neurological examination done in all study subjects. Full Outline of UnResponsiveness Score (FOUR score) and Glasgow Coma Scale (GCS) collected for each patient separately and simultaneously after admissions in the intensive care unit.

Inclusion Criteria

Case Definition: Altered level of consciousness defined as conscious level is below or equal to "V "in abbreviated coma scale. (AVPU Scale).^[9]

A- ALERT -child can follow commands.

V - VOICE - the child responds only when the parents or examiner/physician call the child"s name or speak loudly.

P – PAINFUL – the child responds only to a painful stimulus, such as pinching the nail bed.

U- UNRESPONSIVE- child does not respond to any stimulus.

All children admitted in Pediatric intensive care unit with altered level of consciousness as per the case definition above during the study period were enrolled in this study.

Exclusion Criteria

- Children with preexisting neurological illness, cerebral palsy, developmental delay.
- Children on continuous neuromuscular blockade drugs.
- Less than two years.

Statistical Analysis

The data were entered in MS Excel and Statistical Package for Social Sciences (SPSS) version 25. The statistical analysis was done by applying descriptive statistics i.e., mean ± S.D. Comparison of blood pressure indices between patients was done by using Student's t test. 'p' value of less than 0.05 was considered significant.

RESULTS

As per [Table 1] mean FOUR score for less than 5 years is 12.39 and for 5-10 year 12.65, for more than 10 years it was 12.10 in this study. There was no statistically significant difference in the mean FOUR score among the different age groups. In present study out of 77 children, 41 were male and 36 children were female. Male to female ratio was 1.1:1. As per [Table 2] in male children, mean four score was 12.76(SD 1.445). Similarly in female children were 12(SD 2.402). There was no statistically significant difference in the mean FOUR score between two groups.

As per [Table 3] in present study only one child had hospital stay less than 2 days and the child expired. Forty five children had hospital stay of 2-7 days among which 40 survived (88.9%) and 5(11.1%) expired. In cases of more than 7 days hospital stay it was 14.40 (SD 0.527). This study showed statistically significant correlation between the mean FOUR of duration of hospital stay and outcome

As per [Table 4] present study showed 100% children requiring intubation expired and statistically significant association noted between intubation and outcome (p value <0.05).

As per [Table 5] in this study mean FOUR score of children requiring mechanical ventilation was significantly lower (6.67) compared to those who not requiring mechanical ventilation (12.89). Since the p value was <0.05 there was statistically significant correlation between mean FOUR score of intubated and non-intubated children with the outcome.

As per [Table 6] discharged patients had and mean eye opening score of 2.65 and mean score of mortality was 2. Seventy one discharged patients had mean mean verbal response of 3.61 and mortality patients had mean of one which was the lowest among all four components since all of them were intubated. Motor response had mean of 4.73 and 2.67

for discharged and mortality cases respectively. Mean GCS of discharged patients was 10.99 and mortality cases were 5.67. In this study individual components of GCS and total score had statistically significant association with the outcome (p<0.05).

As per [Table 7] Mean eye response of discharged patients was 2.23 and expired patients was one. Mean motor response of discharged and expired patients was 2.66 and 1.17 respectively. Brainstem reflex had mean score of 4 for survived patients and 3.17 for mortality cases. Out of 77 cases 71 survived cases had a mean respiration score of 4 and mortality cases had 1.33. Mean FOUR score for discharged patients was 12.89 and mortality cases had mean score of 6.67. In this study individual components of FOUR score and total score had statistically significant association with the outcome (p<0.05).



The ROC curve is a graphical representation of the discriminating power of a test. Area under the ROC curve is an effective way to summarize the overall

diagnostic accuracy of the test. If one cut off point is chosen to differentiate from death to survival, at the extremes of the range there are bound to be false positives and false negatives. In present study Cut off point for GCS 6.5 and for FOUR score it is 7.5. Calculating the area under the ROC curve, distinguishing between survivors and non survivors (discrimination) was assessed. An AUC of 0.5 is equivalent to random chance (a diagonal line), AUC >0.7 indicates a moderate prognostic model, and AUC value >0.8 (a bulbous curve) indicates a good prognostic model.63



The area under ROC showed FOUR score and GCS were good at discriminating survivors and non survivors (P < 0.05 and P < 0.05, respectively). However the AUC = 0.968 for FOUR score and the AUC = 1 for GCS, pointed out that the discrimination power of GCS score was better than FOUR.

	Ν	Mean	Std. Deviation	F	P value
<5 Years	31	12.39	2.539	.439	.646
5 to 10 Years	26	12.65	1.129		
>10Yeras	20	12.10	1.889		
Total	77	12.40	1.975		

Table 2: Mean FOUR Score for Sex

	Sex	Ν	Mean	Std. Deviation	t	p value
Total FOUR Score	Male	41	12.76	1.445	1.64	.094
	Female	36	12.00	2.402		

Table 3: Mean FOUR Score and Duration of Hospital Stay

	Ν	Mean	Std. Deviation	F	p value
< 2 days	1	7.00		4.12	.020
2 to 7 days	45	12.51	2.427		
> 7 days	31	12.42	.502		
Total	77	12.40	1.975		

Table 4: Intubatio	n Status a	and Outcom	e				
			Outcome		Total	Chi-square	p value
			Discharge	Death			
Intubated	Yes	Count	0	6	6	42.144	.000
		%	0.0%	100.0%	100.0%		

	No	Count	71	0	71	
		%	100.0%	0.0%	100.0%	
Total		Count	71	6	77	
		%	92.2%	7.8%	100.0%	

Table 5: Intubation and Mean FOUR Score						
	Intubated	Ν	Mean	Std. Deviation	t	p value
Total FOUR Score	Yes	6	6.67	1.633	13.95	.000
	No	71	12.89	.994		

Table 6: Componen	its of GCS and Outco	ome		
	Outcome	Ν	Mean	Std. Deviation
Eye opening	Discharge	71	2.65	.510

Eye opening	Discharge	71	2.65	.510	3.094	.003
	Death	6	2.00	.000		
Verbal Response	Discharge	71	3.61	.801	7.916	.000
	Death	6	1.00	.000		
Motor Response	Discharge	71	4.73	.792	6.255	.000
	Death	6	2.67	.516		
Total GCS	Discharge	71	10.99	1.545	8.352	.000
	Death	6	5.67	.516		

Table 7: Components of FOUR Score and Outcome

	Outcome	Ν	Mean	Std. Deviation	t	p value
Eye Response	Discharge	71	2.23	.453	6.579	.000
	Death	6	1.00	.000		
Motor Response	Discharge	71	2.66	.755	4.773	.000
	Death	6	1.17	.408		
Brain Stem reflux	Discharge	71	4.00	.000	7.721	.000
	Death	6	3.17	.983		
Respiration	Discharge	71	4.00	.000	29.752	.000
*	Death	6	1.33	.816		
Total Four Score	Discharge	71	12.89	.994	13.957	.000
	Death	6	6.67	1.633		

DISCUSSION

The age group of study was between 2-12 years similar to study done by Khajehet et al:^[8]. Jennifer Cohen et al10 done study in children between 2 to 18 years of age at CHOC Children"s hospital in PICU setting. Overall mortality observed in our study was 7.7%, which was 28.5% in Khajeh et al.^[8] study, 34.8% in Sepahvand et al study.^[10,11] The different mortality rate in studies may be due to different inclusion criteria and severity of illness of patients who were involved in those investigations. Children with support mechanically ventilation had an mean FOUR score of 6.67(SD-1.633) which was significantly lower compared to non-intubated children and statistically significant correlation was seen between mean FOUR score of intubated children and outcome.

There was a significant statistical difference in mean FOUR score between the mortality group and survival groups irrespective of etiology. In this study individual components of both GCS and FOUR score had significant association with the outcome. Best cut of point was calculated using ROC in our study was 6.5 for GCS and 7.5 for FOUR score. However, this is not compatible with Wijdicks et al,^[12] where the best cutoff point was 7 and 9 for GCS and FOUR score, respectively. The present study showed the area under ROC showed FOUR score and GCS were good at discriminating survivors and no survivors (P < 0.05 and P < 0.05, respectively). The AUC = 0.968

for FOUR score and the AUC = 1 for GCS, pointed out that the discrimination power of GCS score was better than FOUR. Similar results were seen study done by Büyükcam et al,^[13] where Area under the curve (AUC) values in predicting inhospital mortality, poor GOS (score of 1-3) at discharge, and poor GOS after three months were similar for GCS and FOUR score. FOUR score provides no significant advantage over GCS in predicting morbidity and mortality in children with head trauma. The study done by Kochar et al,^[14] Seventy children aged 5 to 18 years admitted with impaired consciousness the area under the curves for Glasgow Coma Scale and Full Outline of Unresponsiveness scores were 0.916 and 0.940, respectively. However, the difference between the areas under curve for the 2 scores was not statistically significant (0.023; 95% confidence interval: -0.0115 to 0.058). Both the scores are good predictors for in-hospital mortality and functional outcome. However, no significant difference was observed between the ability of the 2 scores to predict the outcomes.

p value

t

Jamal Atahar et al,^[15] Done observational study in children (5–12 years) with impaired consciousness. 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) AUC for mortality at 3 months for GCS was 0.78 (CI 0.67 to 0.90) and FOUR score was 0.74 (CI 0.62 to 0.87) (P=0.1102) and AUC for poor functional outcome for GCS was 0.82 (CI 0.72 to 0.93) and FOUR score was 0.79 (CI 0.68 to 0.9) (P=0.2377),

which were also comparable. Inter-rater reliability for GCS was 0.96 and for FOUR score 0.98. The FOUR score does had good inter rater reliability but not superior to GCS in predicting outcome.

CONCLUSION

The FOUR score was developed to overcome the limitations of the GCS, but it does not appear to provide any significant advantage over GCS in predicting morbidity and mortality in children in PICU with impaired neurological status. The GCS has been most commonly used scale for longer period, so it would be difficult to employ another coma scale in its place, unless an alternative scale shown to have significant advantage in predicting outcome.

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