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COMPARATIVE ANALYSIS OF DIAGNOSTIC ACCURACY OF GLASGOW COMA SCALE WITH FULL OUTLINE OF UNRESPONSIVENESS (FOUR) SCALE IN PEDIATRIC NON-TRAUMATIC COMA CASES.

Paediatrics

Anand Wani Ankura Hospital Senior Paediatric Consultant

Mohammad Khan

Rohankumar Hire* Department Of Pharmacology, Rajiv Gandhi Medical College, Thane Associate Professor
*Corresponding Author

ABSTRACT

Coma is a neurological emergency in children, with possibly unpleasant consequences. Non-Traumatic Coma (NTC) in children is an important paediatric emergency. Despite its widespread use, the GCS has many limitations, including the impossibility to assess the verbal score in intubated or aphasic patients, and an inconsistent inter-rater reliability. The full outline of unresponsiveness (FOUR) score is a new coma scale that was recently developed and validated in adults as a proposed replacement for the GCS, and it is not reliant on the verbal response. Hence we aimed to compare the diagnostic accuracy for prediction of mortality (in terms of sensitivity and specificity) of Glasgow coma scale and Full Outline of Unresponsiveness Scale for paediatric non-traumatic coma cases. This was an observational, hospital-based screening test study. This study was conducted in Department of Paediatrics of a tertiary care centre. Sample size was calculated using formulae: n = Zα2 (5%) p (1-p) / E2 and found to be 38. Children aged <18 years who presented with impaired consciousness were subjected to inclusion and exclusion criteria. Severity of coma was calculated at the time of admission by using modified Glasgow coma scale [19] and FOUR score [20]. Most common aetiology for paediatric non-traumatic coma was meningoencephalitis (27.5%) followed by TBME (20.5%), bacterial meningitis and cerebral malaria (12.5% each). Sensitivity and specificity of FOUR score at the cut-off of 7 was 88.9% and 83.9% while its positive and negative predictive value was 61.5% and 96.3% with overall diagnostic accuracy of 85%. Sensitivity and specificity of GCS score at the cut-off of 8 was 88.9% and 77.4% while its positive and negative predictive value was 53.3% and 96% with overall diagnostic accuracy of 80%. The results of our study showed that, GCS and FOUR score both have good value in predicting the mortality of paediatric non-traumatic coma case. We also concluded there is high correlation between GCS and FOUR score in predicting in-hospital mortality. However, FOUR score has slightly better diagnostic accuracy than GCS scale. With further clinical research, this tool can supersede GCS as the monitoring tool of choice in such cases.

KEYWORDS

Nontraumatic Coma, GCS, FOUR

INTRODUCTION

Coma is a neurological emergency in children, with possibly unpleasant consequences [1]. There are multiple aetiologies of coma, but they are usually divided into two major groups, namely traumatic and non-traumatic [1]. Non-Traumatic Coma (NTC) in children is an important paediatric emergency. Etiologically it can be divided into three broad categories [2]: 1) Those without focal neurologic signs (e.g., metabolic encephalopathies); 2) Meningitis syndromes, characterized by fever or stiff neck and an excess of cells in the spinal fluid (e.g., bacterial meningitis, subarachnoid haemorrhage); and 3) Conditions associated with prominent focal signs (e.g., stroke, cerebral haemorrhage). In most instances coma is part of an obvious medical problem such as drug ingestion, hypoxia, stroke, trauma, or liver or kidney failure. Conditions that cause sudden coma include drug ingestion, cerebral haemorrhage, trauma, cardiac arrest, epilepsy, or basilar artery embolism. Coma that appears sub-acutely is usually related to a preceding medical or neurologic problem, including the secondary brain swelling of a mass lesion such as tumour or cerebral infarction [2].

NTC in children is a non-specific sign with a wide potential of differential diagnosis [3]. CNS infections are the most common cause [3-6]. Toxic-metabolic, status epilepticus, hypoxic-ischemic, intracranial bleed etc. are other main causes. Neurological outcome is often the foremost concern of parents and physicians [4]. Aetiology of coma and clinical status at the time of presentation are the most likely predictors of outcome [7]. Coma carries a high risk for morbidity and mortality and many studies have indicated that the longer the duration of coma, poorer is the outcome. Also, prediction of outcome of coma is difficult early in the course of the illness, especially in children. Hence prompt assessment of severity and early institution of appropriate therapy is essential for better outcome.

In the last three decades various scores have been used to assess the severity of coma and to predict its outcome. These includes [8]: the Glasgow Coma Scale (GCS), James Adaptation of Glasgow Coma Scale, the Simpson and Reilly Scale, Children's Coma Scale, the Children's Orthopaedic Hospital and Medical Centre Scale, the Jacobi's Scale, etc. Through the years, the GCS has become the gold standard for describing the level of consciousness. Paediatric Glasgow coma scale (GCS) used to assess the mental state of child patients. It is considered coma when the score is less than 12 for more than 6 hours [9,10]. Despite its widespread use, the GCS has many limitations, including the impossibility to assess the verbal score in intubated or aphasic patients, and an inconsistent inter-rater reliability that are well documented in the literature [11].

The full outline of unresponsiveness (FOUR) score is a new coma scale that was recently developed and validated in adults as a proposed replacement for the GCS, and it is not reliant on the verbal response. Decreasing in GCS and FOUR score is associated with worsening level of consciousness [12,13]. Although the FOUR score has been validated with reference to the GCS in several clinical contexts [14-17], there are still conflicting data concerning that which of these two scoring systems has the best predictive value.

In present study, we thus aimed to compare the diagnostic accuracy for prediction of mortality (in terms of sensitivity and specificity) of Glasgow coma scale and Full Outline of Unresponsiveness Scale for paediatric non-traumatic coma cases.

Aim And Objectives

1. To compare the diagnostic accuracy for prediction of mortality (in terms of sensitivity and specificity) of Glasgow coma scale and Full Outline of Unresponsiveness Scale for paediatric non-traumatic coma cases.
2. To study the clinical spectrum of paediatric non-traumatic coma cases presenting to a tertiary care hospital.

MATERIAL AND METHODS

This was an observational, hospital-based screening test study. This study was conducted in Department of Paediatrics of a tertiary care centre. Paediatric cases admitted in PICU with impaired consciousness over a period of one year were the study population of our study. Based on the previous literature, mortality rate in Non-traumatic Coma in children was approx. 34% [18]. Sample size was calculated using formulae: $n = Z_{\alpha}^2$ (5%) p (1-p) / E^2 where n=sample size, Z = Level of significance (at 95% confidence level, its value is 1.96), P = probability (0.34), Q = 1-P (1-0.34=0.66), E= Absolute Error (15%). Thus, $n = (1.96)^2 * (0.34) * (0.66) / (0.15)^2$ Thus, n =38 (approx.) So, by rounding off, final sample size was taken as 40 pediatric patients fulfilling eligibility criteria. Children aged <18 years who presented with impaired consciousness were subjected to inclusion and exclusion criteria. Patients with traumatic brain injury patients already

on sedatives or neuromuscular blockade children with cerebral palsy, severe mental retardation, degenerative brain disease, children with vision/Hearing impairment children with ongoing seizures or seizure within last 1 hour were excluded from our study. A written informed consent was obtained from the primary caregivers or parents of the participating children. Details of demographic data, history and examination findings was recorded in a predesigned interview schedule. The clinical variables recorded were heart rate, respiratory rate and pattern, blood pressure (average of three recordings using mercury sphygmomanometer, by auscultatory method), temperature, pupillary size and response to light, extra ocular movements and fundus picture. Severity of coma was calculated at the time of admission by using modified Glasgow coma scale [19] and FOUR score [20]. The details of the score is given below. Outcome of the cases in terms of survived or died was noted at the time of discharge. Aetiology of coma was determined on the basis of history, clinical examination and relevant laboratory investigations. The investigations such as lumbar puncture, CT scan and metabolic work up was determined by clinical presentation and decided by the consultant in-charge. Aetiology was classified into infections, toxic-metabolic, hypoxic-ischemic, post-status epilepticus, intracranial bleeding and miscellaneous.

Bacterial meningitis was defined as acute febrile encephalopathy with identification of microorganisms from the CSF culture or presence of 3 or more of the following abnormalities in CSF: a) Polymorphonuclear leucocytosis ≥100 cells/mm^3, b) Glucose ~40 mg/dl or 50% of blood sugar, c) Elevated proteins >40 mg/dl, d) Micro-organisms seen by Gram staining. Diagnosis of tuberculous meningitis was made when there was family history of tuberculosis, positive tuberculin skin test, CSF analysis showing pleocytosis with leukocyte count 10-250/mm3 (rarely >500/mm^3) with lymphocyte predominance and protein concentration 100-3000 mg/dl with decreased glucose usually <50 mg/dl and/or CT/MRI showing basilar enhancement or communicating hydrocephalus with signs of cerebral oedema or early focal ischemia [21]. Encephalitis was defined as acute febrile encephalopathy with CSF pleocytosis with lymphocyte predominance (>5 cells/mm^3), slightly elevated protein (usually 50-200 mg/dl) and absence of bacteria on direct microscopy or culture and where no other alternative diagnosis is identifiable [22, 23]. Focal seizures or focal findings on CT/MRI scans suggested HSV encephalitis [21]. Hypertensive encephalopathy was diagnosed when coma of acute onset is associated with blood pressure more than 95th percentile for age and sex, with or without retinal changes [22, 23]. When there is metabolic derangement commensurate with the clinical picture or toxic ingestion is confirmed, a label of toxic-metabolic coma was used [22]. Coma following hypoxic cerebral injury such as after cardio-respiratory compromise, shock, near-drowning or accidental or homicidal hangings is considered to be hypoxic-ischemic [22, 23]. Children with coma with evidence of bleed on radio imaging of head will be labelled as having intracranial bleed [22].

Definitions of study variables were as follows:

- **Coma:** A state of unresponsiveness without evidence of awareness of self or environment, a state from which the patient cannot be aroused by vocal or sensory stimuli.
- **Tachycardia:** Heart rate above upper limit for that age.
- **Bradycardia:** Heart rate less than sixty per minute.
- **Hypertension:** Blood pressure more than 95th centile for age and sex.
- **Hypotension:** Blood pressure below 5th centile for the age and sex.
- **Hyperthermia:** Axillary temperature above 38°C.3
- **Hypothermia:** Temperature below 35°C.3
- **Coma severity:** Based on score obtained on the modified Glasgow coma scale and FOUR score [19].
- **Pupils:** (i) normal - both pupils equal in size, 2-3 mm in diameter and reactive to light, (ii) abnormal-pupils small (= 1 mm), or dilated (= 4 mm), unequal or non-reactive to light.3
- **Extra Ocular Movements (EOM):** (i) normal - no impairment of movement in any direction, (ii) abnormal - if lateral, medial, upward, downward or all movements of eyeballs were absent [22].
- **Corneal reflex:** Absent or present.
- Motor patterns were recorded as normal pattern or abnormal if there was diffuse decrease in tone (flaccidity), increase in tone (hypertonia) or decerbrate or decorticate posture [22]. Respiratory pattern was said to be abnormal if the breathing was central neurogenic hyperventilation, apneustic, ataxic or apnoeic [22].

Outcome Variables

1. **Glasgow coma scale** - Glasgow Coma Scale (GCS) was recorded on admission for every child. The score ranges from 3 to 15. ROC curve analysis was used for identifying its optimal cut-off for prediction of mortality.
2. **FOUR Scale** – FOUR scale was also recorded on admission for every child. The score ranges from 0 to 16. ROC curve analysis was used for identifying its optimal cut-off for prediction of mortality
3. **Modified Rankin Scale -** Outcome was recorded as survived and died. Among those who survived it was further graded according to **Modified Rankin Scale (mRS)** [83]. The categories in mRS are as follows:

- 0 - No symptoms.
- 1 - No significant disability. Able to carry out all usual activities, despite some symptoms.
- 2 - Slight disability. Able to look after own affairs without assistance, but unable to carry out all previous activities.
- 3 - Moderate disability. Requires some help, but able to walk unassisted.
- 4 - Moderately severe disability. Unable to attend to own bodily needs without assistance, and unable to walk unassisted.
- 5 - Severe disability. Requires constant nursing care and attention, bedridden, incontinent.
- 6 - Dead

Statistical Analysis

All the data was noted down in a pre-designed proforma (case report form). Qualitative data was represented in the form of frequency and percentage. Quantitative data was represented using Mean ± SD. Analysis of Quantitative data between the two groups was done using unpaired t-test. Correlation between the scores was computed using Pearson's correlation coefficient. ROC curve analysis was performed to evaluate the diagnostic accuracy and finding optimal cut-off of GCS and FOUR score for predicting survival. Standard formulae were applied to calculate screening parameters like sensitivity, specificity, PPV and NPV (described below). A p-value < 0.05 was taken as level of significance. Results were graphically represented where deemed necessary. SPSS Version 21.0 was used for analysis.

RESULTS

Present observational hospital-based screening study was conducted on 40 children of Non-traumatic Coma admitted in PICU of our hospital. Mean age of the study cases with non-traumatic coma was 8.32 years with over half of them (57.5%) were less than 10 years of age. Female predominance was observed among study cases with 65% females to 35% males. Most common aetiology for paediatric non-traumatic coma was meningoencephalitis (27.5%) followed by TBME (20.5%), bacterial meningitis and cerebral malaria (12.5% each) (Figure 1). Mortality rate among cases of paediatric non-traumatic coma was 22.5%.

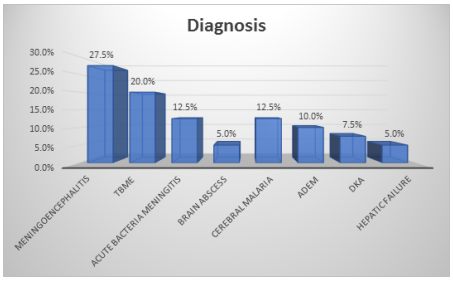


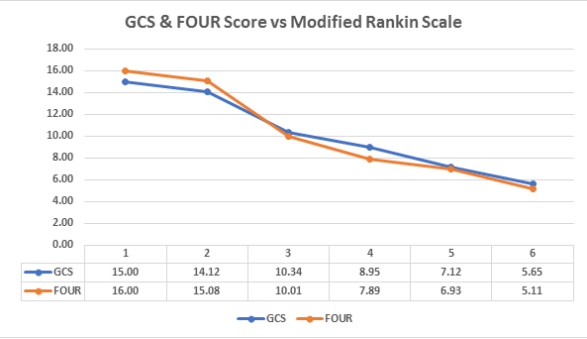
Figure 1: Aetiology of NTC

Modified Rankin scale (MRS) of </= 2 was observed in 22.5% cases while 32.5% has value more than 4. Mean GCS score (5.65 vs 9.93) and FOUR score (5.11 vs 10.23) both were significantly lower among non-survivors as compared to survivors (p<0.01) (Table 1).

Table 1. Mean comparison of GCS and FOUR Scores among survivors and non-survivors

Scores	Outcome	N	Mean	SD	p- value
GCS	Dead	9	5.65	3.21	<0.01
	Alive	31	9.93	3.42	
FOUR	Dead	9	5.11	3.19	<0.01
	Alive	31	10.23	3.42	

Mean GCS and FOUR scores were significantly associated with modified Rankin scale. Both scores decreased linearly when the MRS increased from 1 (perfectly active) to 6 (death).



A significant correlation was observed between GCS and FOUR score in present study (r-0.89; p<0.01).

Diagnostic accuracy of FOUR Score for prediction of Mortality: Sensitivity and specificity of FOUR score at the cut-off of 7 was 88.9% and 83.9% while its positive and negative predictive value was 61.5% and 96.3% with overall diagnostic accuracy of 85%.

Diagnostic accuracy of GCS Score for prediction of Mortality: Sensitivity and specificity of GCS score at the cut-off of 8 was 88.9% and 77.4% while its positive and negative predictive value was 53.3% and 96% with overall diagnostic accuracy of 80%.

DISCUSSION

GCS has been validated as a useful tool for outcome prediction post intracranial haemorrhage, subarachnoid haemorrhage (SAH), poisonings, neurodegenerative diseases, drowning, cardiac arrest, prediction of death in palliative care and tuberculous meningitis. GCS has also been incorporated into many other scoring systems such as Revised Trauma Score (RTS), the APACHE II, the Simplified Acute Physiology Score (SAPS), SAPSII, the Circulation, Respiration, Abdomen, Motor, Speech scale (CRAMS), the Traumatic Injury Scoring System (TRISS), and A Severity Characterization of Trauma (ASCOT) scale which provides ample testimony to the wide acceptance and ease of use of GCS [24].

The FOUR score was developed in the context of multiple demerits of GCS. Sub-optimal degrees of inter-rater agreement among inexperienced staff, especially in patients with moderate scores, ('intermediate' levels of consciousness) is widely reported with GCS. The verbal sub-score assessment in intubated and aphasic patients remains a constrain in GCS. GCS has limited efficacy in children prior to the acquisition of language (age <3 years). Withdrawal from pain, which can be wrongly interpreted as a flexion response, can confound GCS [24].

Suganthi V et al. [25] observed 10% children in the age group of 2- 12 months; 30% in 1 to 5 years and 60% in 5 to 12 years. Mean age of the group was 8.73 years with 56% females to 44% males. Rajesh S et al. [25] observed 20% children below the age of 1 year, 48% between 1-5 years and 32% above 5 years. Maximum children 24 (48%) were in 1-to-5-year age group with mean age of 4.2 years. Study included 54% girls to 46% boys. Sixty-one patients were included in the study by Ahmad I et al. [18], 34 (55.7%) were male and 27 (44.3%) were female. A total of 33 (54.1%) were of age ≤3 years and 28 (45.9%) were >3 years of age with mean age 5.2 years.

Most common aetiology for paediatric non-traumatic coma in our study was meningoencephalitis (27.5%) followed by TBME (20.5%), bacterial meningitis and cerebral malaria (12.5% each). Suganthi V et al. [26] observed Infections as the predominant cause of non-traumatic coma, accounting for 58% of cases. Acute bacterial meningitis (22%) was the most common cause followed by tuberculous meningitis (16%), viral encephalitis (14%), septicaemia (4%) and cerebral malaria (2%). Rajesh S et al. [80] in their study observed that Central nervous system (CNS) infections accounted for (n=32) 64% of cases. Amongst non-infectious causes (n=18) hepatic coma constituted five (27.8%) leads followed by Diabetes ketoacidosis (2) and intracranial bleed (2) each (11.1%). Ahmad I et al. [18] in their study observed that etiologically out of 61 patients, 25 (41.0%) were caused by infection. Toxic-metabolic causes were found in 16 (26.2%), status-epilepticus was causative in 10 (16.4%) and structural CNS lesions in 5 (8.2%). In infections, encephalitis was the largest sub-group responsible for 10 (16.4%) cases. Rest of the cases were caused by pyogenic meningitis 7 (11.5%), tubercular meningitis 4 (6.6%), herpes encephalitis 2 (3.3%) and septic shock and HIV encephalopathy 1 (1.6%) each. Ahmed S et al. [27] in another similar study observed that most common aetiology for paediatric non-traumatic coma was infective (65%). Among infective causes, ABME was 31%, viral encephalitis was 18%, TBME was 12% and cerebral malaria was 29% respectively. Amon non-infective causes (35%), metabolic derangements were most common (26%) followed by poisoning and epilepsy (15% each).

Mortality rate among cases of paediatric non-traumatic coma was 22.5% which is discordant to Rajesh S et al. [25] who observed mortality rate as 38% and Ahmad I et al. [18] observed mortality rate as 33.9% in their study.

Mean GCS score (5.65 vs 9.93) and FOUR score (5.11 vs 10.23) both were significantly lower among non-survivors as compared to survivors (p<0.01). A significant correlation was observed between GCS and FOUR score in present study (r-0.89; p<0.01). Both GCS and FOUR scores were significantly associated with Modified Rankin scale. Means of both scores decreased linearly when the mRS increased from 1 (perfectly active) to 6 (death). On evaluation the diagnostic accuracy and optimal cut-offs for FOUR and GCS score for prediction of mortality, we observed AUC that both scores had a good accuracy for the prediction of the same. AUC for FOUR was 0.889 (95% CI: 0.69-0.98; p<0.01) and optimal cut-off was 7 while AUC for GCS was 0.831 (95% CI: 0.58-0.94; p<0.01) and optimal cut-off was 8. Sensitivity and specificity of FOUR score at the cut-off of 7 was 88.9% and 83.9% while its positive and negative predictive value was 61.5% and 96.3% with overall diagnostic accuracy of 85%. Sensitivity and specificity of GCS score at the cut-off of 8 was 88.9% and 77.4% while its positive and negative predictive value was 53.3% and 96% with overall diagnostic accuracy of 80%.

Kochar GS et al. (2014) [28] compared GCS and FOUR scores in children with impairment of consciousness. The area under the curves for Glasgow Coma Scale and FOUR scores were 0.916 and 0.940, respectively. Study data indicate that both the scores are good predictors for in-hospital mortality and functional outcome. Jamal A et al. [29] observed that 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), Z statistic 1.109, P=0.2674]. 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. Study concluded that FOUR score was as good as GCS in prediction of in-hospital and 3-month mortality and functional outcome at 3 months. Sidra I et al. [30] in a similar study observed the AUC for FOUR as 0.89 and optimal cut-off was 12 while AUC for GCS was 0.87 and optimal cut-off was 9. Logistic regression analysis showed that FOUR score is better than GCS in predicting in-hospital mortality in children with non-traumatic coma.

To summarize, present study observed that GCS and FOUR score both have good value in predicting the mortality of paediatric non-traumatic coma case. We also concluded that there is high correlation between GCS and FOUR score in predicting in-hospital mortality. However, FOUR score has slightly better diagnostic accuracy than GCS scale. With further multicentric clinical research with larger sample size (our limitations) , this tool can supersede GCS as the monitoring tool of choice in such cases.

CONCLUSION

The results of our study showed that, GCS and FOUR score both have good value in predicting the mortality of paediatric non-traumatic coma case. We also concluded there is high correlation between GCS and FOUR score in predicting in-hospital mortality. However, FOUR score has slightly better diagnostic accuracy than GCS scale. With further clinical research, this tool can supersede GCS as the monitoring tool of choice in such cases.

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