

Interobserver Variability of Both Glasgow Coma Scale and Full Outline of Unresponsiveness Scores in Forecasting the Results of Critically Ill Patients with Altered Sensorium



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ABSTRACT

Background: Altered mental status (AMS) refers to changes in cognitive function or consciousness, encompassing cognitive, attention, arousal, and consciousness disorders. The Glasgow Coma Scale (GCS) and full outline of unresponsiveness (FOUR) score are tools used to evaluate patients with altered consciousness. Few studies have compared the interobserver reliability of these scales. This study aimed to assess interobserver variability between GCS and FOUR scores in predicting outcomes of critically ill patients with altered sensorium.

Methodology: This hospital-based forecasting experimental study included 200 patients who were admitted to the critical care unit at King Edward Memorial (KEM) Hospital, Pune. Patients were randomly selected and scored once within 24 hours of admission using both GCS and FOUR scores by two independent observers, a critical care resident (CCR) and a critical care consultant (CCC), with a 5-minute interval between assessments. Interrater reliability was measured using kappa values, with outcomes focused on agreement within ± 1 score point for both scales. Statistical analysis was conducted using Epi Info.

Results: Demographics showed males (62%) outnumbered females (38%). The largest age-group was 51–70 years (38%). GCS and FOUR scores showed no significant differences between CCR and CCC in mean GCS (CCR: 8.2 ± 2.9 ; CCC: 8.5 ± 3.0 ; $p = 0.249$) or FOUR score (CCR: 10.74 ± 3.2 ; CCC: 10.9 ± 3.1 ; $p = 0.6118$). A close to borderline difference was observed in GCS for females ($p = 0.0423$). Interrater agreement showed kappa values for GCS components eye-openings (0.78291), verbal responses (0.64858), and motor responses (0.38867). For FOUR scores, kappa values were eye-openings (0.81014), motor responses (0.77721), brainstem reflexes (0.89801), and respirations (0.91623).

Conclusion: The study found very good interobserver reliability for GCS eye and verbal components but poor agreement for motor responses due to confusion with localization and abnormal movements. The FOUR score demonstrated good to excellent reliability across all components and provided more detailed neurologic assessments, especially in intubated patients and those with brainstem dysfunction. It is more efficient in predicting outcomes, making it a preferred tool in intensive care units (ICUs). Larger studies are recommended to incorporate the FOUR score as a standard neuromonitoring tool in the intensive care unit.

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INTRODUCTION

Altered sensorium or altered mental status (AMS) refers to changes in cognitive function or self-consciousness, and undifferentiated AMS is a common reason for emergency visits and hospitalizations, especially in the elderly. It includes symptoms like coma, drowsiness, confusion, irritability, and abnormal behavior. Causes of AMS vary by age, with cerebrovascular disorders, systemic failure, and infections being primary causes in the elderly, while drugs, toxic factors, and metabolic issues are more common in younger patients.¹

The reported causes of altered sensorium include vascular events such as ischemic stroke, intracerebral hemorrhage, and subarachnoid hemorrhage. Infectious causes include urinary tract infections,

pneumonia, septic conditions, viral encephalitis, and meningitis. Toxic effects include intoxication and overdose, with withdrawal of substances like alcohol, barbiturates, heroin, benzodiazepines, and drug use (prescribed, herbal preparations, or over-the-counter). Traumatic causes include concussion and subdural hematoma. Autoimmune causes are neuropsychiatric lupus, Behcet syndrome, vasculitis, and disseminated acute encephalomyelitis. Neoplastic causes include large brain tumors and carcinomatous meningitis. Seizure-related causes include postictal states, nonconvulsive status epilepticus, and epilepticus. Degenerative causes include dementia with Lewy bodies and prion disease.² Risk factors for altered sensorium include age over 65, anesthesia, preexisting cognitive impairment, environmental

changes, constipation or urinary retention, dehydration, depression, alcohol abuse history, previous delirium episodes, intensive care unit stays, malnutrition, medical conditions (such as heart, lung, liver, or kidney disease), polypharmacy, sleep deprivation, social isolation, visual or hearing impairments, and the presence of medical devices like urinary catheters or intravenous cannulae.³ Definitive care involves supportive measures, patient monitoring, and transfer to the emergency department (ED) for further evaluation. Treatment options for altered sensorium include intubation, external pacing, volume resuscitation, glucose administration, neurological interventions, antibiotics, psychological support, noise reduction, and patient mobilization.⁴ Clinical assessment of neurological condition is essential for decision-making, outcome prediction, and communication among healthcare providers. The Glasgow Coma Scale (GCS) is mostly used to measure the level of consciousness but presents challenges, particularly in intubated patients; to reduce these limitations, the full outline of unresponsiveness (FOUR) score was introduced in 2005.^{5,6} The FOUR score assesses responsiveness of eyes, sensory motor responses, brainstem reflexes, and respiratory patterns, providing a more comprehensive evaluation. Although the GCS remains popular, the FOUR score is considered more effective for assessing

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intubated patients and offers better insights into brainstem function.⁷⁻⁹ While several studies have compared the precision of the GCS and FOUR scores, the FOUR score has shown advantages in certain aspects. However, few studies have focused on comparing the interobserver reliability of these two scoring systems. The objective of this study is to evaluate and compare the interobserver variability of both the GCS and FOUR scores in evaluating outcomes for severely ill patients with altered sensorium.

RESOURCES AND TOOLS

Study Map

It was a forecasting experimental study undertaken in which the GCS and FOUR scores were compared.

Study Site

The study was executed in the Department of Critical Care Medicine, King Edward Memorial (KEM) Hospital, Pune, India, 550+ bed multispecialty tertiary care center.

Study Duration

The study period was from June 2022 to March 2023.

Study Population

All cases who were admitted to the Department of Critical Care Medicine, KEM Hospital, Pune, with altered sensorium and assessed upon arrival to the Critical Care Unit during the period of study, fulfilling the study criteria below.

Inclusion Criteria

All patients who were admitted with altered sensorium and were above 18 years of age.

Exclusion Criteria

Patient relatives refusing consent for this study. Patients receiving neuromuscular blocking agents or heavy sedation were excluded.

The number of samples was estimated with the software Epi Info™, created by the Centers for Disease Control and Prevention (CDC). Based on the study by Suresh et al., the agreement for the eye-opening component of the GCS was 65.8%, thus $p = 0.658$ was used for this study. The required sample size was determined to be approximately 200 subjects, with a power of 89.8% (~90%). The formula used for sample size estimation was $n = 4pq/(L^2)$, where n = required number of samples, $p = 0.658$ (based on Suresh et al.'s study), $q = 1 - p = 0.342$, L = information loss = 10.2%.

The total sample size was 200. Patients were randomly selected from critically ill cases

admitted to the intensive care unit (ICU) with altered sensorium, using random numbers for selection.

Sampling Technique

Patients were chosen at random using random numbers generated from the "Kevin Conroy: 5120 Random Numbers" (a JavaScript pseudorandom number generator).

Definition

Consciousness is stated as the condition of being aware of oneself and the environment. Altered sensorium refers to a disturbance in this awareness, covering a spectrum of brain dysfunctions such as confusion, clouded consciousness, disorientation, inattention, behavioral changes, and drowsiness.

The ethical committee's approval was obtained from the Board of Institutional Ethics and Research Committee.

Subject Confidentiality and Informed Consent

Data collection was conducted on paper. Patients were screened for eligibility, and those who qualified for the inclusion criteria were enrolled in the study. Only study personnel contacted the enrolled patients. All patient-related data was handled with strict confidentiality. Informed consent was obtained from all participants, with the consent form providing detailed information to ensure patients understood their role in the study. The form was written in a language accessible to the study population.

Data Collection

A self-administered and predesigned pro forma was prepared to keep the objectives of the study at the center point. The motive of this study was briefed to the patient, and informed consent was obtained. Patients were chosen for the study as per inclusion criteria. In the preparation of the pro forma, every aspect desired to be studied was incorporated. Scoring was done at the first possible occasion within 24 hours of hospital admission, and each patient was scored only once. The patient was scored by two independent observers [critical care resident (CCR) and critical care consultant (CCC)] within a time interval of 5 minutes. Each patient was scored using GCS and FOUR score separately. The observers remained constant throughout the study. GCS scoring was recorded on a one-sided form having written instructions. In the case of intubated patients, the score of the speech response of the GCS was considered to be 1, whereas in the case of FOUR scoring, the observers utilized a form with both written

as well as visual instructions. The written instructions were from the original guidelines to follow from the Mayo Clinic, while the visual instructions were a color reproduction of the 2005 published version, resized to fit the scoring form.

Statistical analysis was performed using the software Epi Info™, developed by the CDC. The interrater accuracy of both the GCS and FOUR scores was determined using the kappa statistics. A kappa value of 0.4 or below indicated low agreement, values between 0.4 and 0.6 represented medium agreement, values between 0.6 and 0.8 indicated high agreement, and values above 0.8 were considered excellent.

The primary outcome measured was interrater agreement within ± 1 point for both the GCS and FOUR scores. Another outcome included exact interrater agreement and an assessment of the individual subcomponents of both scoring systems.

The kappa statistic (k) was utilized to assess agreement, while internal consistency for both the GCS and FOUR scores was evaluated with the help of Cronbach's α and Spearman's correlation coefficient. Internal consistency values of 0.5 or below were regarded as unacceptable, values between 0.5 and 0.6 as poor, values between 0.6 and 0.7 as questionable, values between 0.7 and 0.8 as acceptable, values between 0.8 and 0.9 as good, and values above 0.9 as excellent. A p -value of <0.05 was considered statistically significant.

Key Outcome

Around 200 patients took part in this experiment from the Department of Critical Care Medicine, KEM Hospital, Pune, India, a 550+ bedded multispecialty tertiary care hospital, between June 2022 and March 2023. Age and gender distribution is shown in Table 1 and Table 2.

The GCS parameters included were explained along with the scoring pattern in Table 3. The levels of responses in the components of the GCS are scored from 1 for no response up to normal values of 4 (eye-opening response), 5 (verbal response), and 6 (motor response). Further, GCS and FOUR scores recorded by CCRs and CCCs with gender distribution were depicted in Table 4 and Table 5.

The mean GCS score evaluated by CCRs was 8.2 ± 2.9 and by CCCs was 8.5 ± 3.0 , with no statistically notable difference between the two groups ($p = 0.249$). There was no statistically significant difference in the mean FOUR score assessed by residents (10.74 ± 3.2) and consultants (10.9 ± 3.1) ($p = 0.6118$).

The mean GCS assessed by residents and consultants in males was 8.42 ± 3.1

Table 1: Gender allocation for subjects enrolled

Gender	N	%
Men	124	62
Women	76	38
Total	200	100

As the above table depicts that, males (62%) outnumbered the female population (38%)

Table 2: Age-group distribution of the subjects enrolled

Age (years)	N	%
10–30	19	9.5
31–50	51	25.5
51–70	76	38
>70	54	27
Total	200	100

The majority 38% of the study population belonged to the age-group 51–70 years; followed by beyond >70 years (27%); 31–50 years (25.5%) and 10–30 years (9.5%)

Table 4: GCS and FOUR scores recorded by CCR and CCC

Scores	Group	Mean \pm SD	p-value
GCS	CCR	8.2 \pm 2.9	p = 0.3099
	CCC	8.5 \pm 3.0	
FOUR	CCR	10.7 \pm 3.2	p = 0.5259
	CCC	10.9 \pm 3.1	

Table 5: GCS scores recorded by CCRs and CCCs

Gender	GCS–CCR Mean \pm SD	GCS–CCS Mean \pm SD	p-value
Men	8.42 \pm 3.1	8.59 \pm 3.2	0.5898
Women	7.78 \pm 2.7	8.31 \pm 2.5	0.0423

Table 6: FOUR scores recorded by CCR and CCC

Gender	FOUR score–CCR Mean \pm SD	FOUR score–CCS Mean \pm SD	p-value
Men	10.86 \pm 3.3	10.87 \pm 3.4	0.9762
Women	10.55 \pm 2.9	10.93 \pm 2.6	0.1684

Table 7: Interrater agreement between CCR and CCC about GCS score

GCS	Kappa value	95% CI
Eye opening	0.78291	0.71421–0.85162
Verbal response	0.64858	0.56631–0.73084
Motor response	0.38867	0.30114–0.47620

Table 8: Interrater agreement between CCR and CCC in regard to FOUR score

FOUR scale	Kappa value	95% CI
Eye response	0.81014	0.74653–0.87375
Motor response	0.77721	0.70472–0.84970
Brainstem reflexes	0.89801	0.81153–0.98449
Respiration	0.91623	0.86631–0.96615

and 8.59 \pm 3.2, respectively, without any significant difference (p = 0.5898). There exists

Table 3: GCS parameters and their scoring pattern

Best eye reaction (4)	<ul style="list-style-type: none"> Do not open eyes Does open eyes to pain stimuli Does open eyes to sounds Spontaneous eyes-opening
Best verbal reaction (5)	<ul style="list-style-type: none"> Zero verbal response Mumbling sounds Not suitable words Perplexed Familiarized
Best motor reaction (6)	<ul style="list-style-type: none"> No motor response Abnormal extension to pain Abnormal flexion to pain Withdrawal from pain Localizing pain

and consultants (8.31 \pm 2.5) in females (p = 0.0423).

The mean FOUR score assessed by residents and consultants in males was almost similar, with a value of 10.86 \pm 3.3. The mean FOUR score in females assessed by consultants and residents was 10.55 \pm 2.9 and 10.93 \pm 2.6, respectively. There was no significant difference in the FOUR scores assessed by residents and consultants, as shown in Table 6.

With regard to interrater agreement between CCR and CCC in individual parameters of GCS scoring, the kappa value for eye-opening, verbal responses, and motor response was 0.78291, 0.64858, and 0.38867, respectively, as shown in Table 7. Distribution of the interrater agreement between CCR and CCC regarding FOUR score is shown in Table 8. With regard to interrater agreement between CCR and CCC in individual parameters of FOUR scoring, the kappa value for eye-opening, motor response, brainstem reflexes, and respiration was 0.81014, 0.77721, 0.89801, and 0.91623, respectively.

DISCUSSION

Altered sensorium, or AMS, is a collection of clinical symptoms involving reduced consciousness, impaired attention, and cognitive dysfunction.^{10,11} Patients with undifferentiated AMS, where the exact cause is not known, frequently present in departments of emergency and ICU. These patients often exhibit vague symptoms, making their evaluation and management particularly challenging for ICU physicians.^{12–14} The GCS is the preferred tool to assess consciousness, while the FOUR score is a newer, validated alternative to the GCS.^{15–18} Few studies in India have compared the interobserver variability in GCS and FOUR score assessments by resident doctors to predict outcomes in AMS patients. This study aimed to assess the interobserver agreement and variability within CCR and CCC in predicting outcomes for critically ill patients with altered sensorium.

This prospective observational study included 200 patients, with a male-to-female ratio of 1.6:1, consistent with other studies by Suresh et al., Haldar et al., and Iyer et al., which reported male-to-female ratios of 2.5:1, 1.6:1, and 1.2:1, respectively. The mean age of participants was 56.22 \pm 18.2 years, higher than the 40.1 \pm 17.6 years in Suresh et al.'s study, but comparable to the 58-year median in Haldar et al.'s study¹⁹ and the 63.0 \pm 18.4 years in Iyer et al.'s study.

An ideal scale for a coma must be reliable, valid, linear, and easy to refer. The GCS evaluates three components—eye-opening, motor response, and verbal response, which assess

the cerebral cortex, reticular activating system, and upper brainstem.^{20,21} However, it has several limitations. Its verbal component is often questioned for its usefulness in assessing consciousness, and the GCS does not account for brainstem reflexes, rapid eye movements, or complex sensory-motor responses. Additionally, it tends to be skewed toward motor responses. While many other scales have been developed to address these shortcomings, none have gained widespread acceptance as a replacement for the GCS.¹⁸ The FOUR score, however, aims to overcome such limitations by incorporating four equally weighted components—rapid eye response, sensory and motor response, brainstem reflexes, and respiration pattern. This scale is easy to remember and provides a comprehensive neurological assessment, particularly useful for patients with metabolic derangements, septic shock, or nonstructural brain injuries.

In this study, the interobserver variability between CCR and CCC in GCS and FOUR scores was compared. The kappa score for eye-opening in GCS showed good agreement between CCR and CCC ($k = 0.7829$), while the FOUR score showed very good agreement ($k = 0.8101$). Most eye responses in GCS were on the lower end (E1/E2: no eye-opening or response of eye to pain), while in the FOUR score, responses ranged from E0 to E3 (eyes closed with pain, eyes open but not tracking). The additional subscore in the rapid eye responses component of the FOUR score, which enhanced the total responses to 5, improved interobserver agreement and added clinical value. Heron et al. also found high interrater reliability for eye response in GCS.

For the motor component, GCS showed only fair agreement ($k = 0.38867$), while the FOUR score demonstrated good agreement ($k = 0.7772$). Most motor responses in GCS were withdrawal from or localization to pain (M4/M5), while the FOUR score ranged from M2 to M3 (flexion response to pain and localization to pain). The addition of specific motor responses, such as "thumbs-up" or "peace sign," to the FOUR score's M4 subscore was well-received by observers. The GCS motor component had the lowest interobserver reliability, a finding supported by Heron et al., who also noted significant interrater disagreement for motor responses in GCS.²¹

The verbal components of the GCS, often difficult to assess in intubated patients, showed good agreement between CCR and CCC ($k = 0.64858$). Most verbal responses fell on the lower end of the scale (V1/V2/V3: no verbal response, incomprehensible sounds, and inappropriate words). Holdgate et al.²² reported excellent interrater agreement

for GCS verbal scores between nurses and senior physicians in the ED, with intermediate reliability for motor and eye scores.

In this study, brainstem reflexes in the FOUR score were well distributed, with most patients displaying pupil and corneal reflexes. The kappa score for brainstem reflexes showed very good agreement between CCR and CCC ($k = 0.89801$), suggesting these components should be incorporated in future coma evaluations. The respiratory component also showed very good agreement ($k = 0.91623$), though it should be interpreted cautiously due to the limited evaluation of breathing patterns. Most patients in this study were not intubated and had regular breathing patterns, making assessment straightforward.

Previous studies, such as those by Wijdicks et al. and Wolfe and Brown, found excellent reliability for both the GCS ($k = 0.82$) and FOUR score. Similarly, Stead et al. reported excellent interrater reliability for both scales ($k = 0.88$ for FOUR and $k = 0.86$ for GCS).^{6,8}

This study has several limitations. The raters were not blinded to the case diagnoses, which may have introduced bias into clinical assessments. A fundamental limitation in validating coma scales is the lack of an objective measure for the level of coma. Therefore, better interrater accuracy does not necessarily equate to greater accuracy. A follow-up study to evaluate patient outcomes using the FOUR score was not conducted. The study may lack external validation for surgical patients, as the sample primarily consisted of medical patients with fewer surgical cases. Since the raters assessed both the GCS and FOUR score simultaneously, any real-time changes in consciousness levels cannot account for the noted contrasts in interrater agreement of the two scoring systems.

CONCLUSION

This study found that the interobserver reliability for the eye and verbal components of the GCS was very good, but the motor component had the lowest reliability. Raters experienced confusion due to differences in localization, abnormal flexion, and extension responses, which were major sources of disagreement. In contrast, the FOUR score demonstrated good to excellent interobserver reliability across all components. Since the verbal component of the GCS cannot be used in intubated patients, it may be more appropriate for nonintubated, less critical patients without brainstem dysfunction.

The FOUR score has several key advantages, as it includes detailed assessments of brainstem

reflexes and eye movements, which the GCS does not provide. It can further distinguish a GCS score of 3 and is more accurate in assessing a patient's consciousness level and predicting disease outcomes. This makes the FOUR score a more dependable score for patients in medical ICUs. Given the level of disagreement observed in GCS scoring, it should not be solely relied upon for clinical decisions and must be interpreted alongside other clinical data. Additionally, this research should encourage larger studies to consider using the FOUR score as a valuable neuromonitoring tool in all ICU.

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