ORIGINAL ARTICLE

FOUR SCORE FOR PREDICTING EARLY MORTALITY IN PATIENTS WITH CLOSED TRAUMATIC BRAIN INJURY IN THE EMERGENCY DEPARTMENT OF ANTIOQUIA-COLOMBIA

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ABSTRACT

OBJECTIVE: To evaluate the predictive performance of the Full Outline of UnResponsiveness (FOUR) score for in-hospital mortality in patients with moderate and severe traumatic brain injury (TBI) treated in emergency departments in Antioquia-Colombia.

METHODS: Prospective cohort study in subjects with moderate and severe TBI treated at the emergency departments of three hospitals between June 2021 and February 2022. The discrimination performance of the FOUR score and the Glasgow Coma Scale (GCS) was determined by calculating the C index and the AUC-ROC, and the calibration using a likelihood test. The association between the different values of the scales and in-hospital mortality was estimated through a multivariate logistic regression model.

RESULTS: 101 cases were analyzed, 61.3% were classified as severe and 38.7% as moderate. Overall mortality was 28.71%, 14.50%, and 38.70% for moderate and severe TBI respectively. The AUC-ROC for mortality of the FOUR score was 0.70 (95% CI 0.58-0.81), and 0.75 (95% CI 0.64-0.85) for the GCS. When adjusting for variables of interest, AUC-ROC for FOUR of 0.916 (95% CI 0.84-0.98) and 0.916 (0.843-0.989) for GCS. Calibration for the FOUR score was adequate (likelihood test with a p-value of 0.0003). The OR for in-hospital death was 3.4; (95% CI 1.40-8.75) and 4.7 (95% CI 1.05-20.93) in the crude and multivariate analysis, respectively, when the score was 8 or less.

CONCLUSIONS: The FOUR score predicts in-hospital mortality in a similar way to the GCS in patients with moderate and severe TBI.

KEYWORDS: Emergency Medical Services, Coma, FOUR (Full Outline of UnResponsiveness), Craniocerebral Injuries, Mortality, Predictive value of tests.

INTRODUCTION

Background.

Traumatic brain injury (TBI) is frequent in the emergency department (ED)(1). Its incidence is estimated at 200 cases per 100,000 inhabitants, but the limited availability of epidemiological databases, especially in low- and middle-income countries, makes these estimates inaccurate. (1). In Colombia, the death rate ranges from 7 to 14 per 100,000 inhabitants, being an important cause of mortality and disability in the working population (2).

The determination of the level of consciousness is critical for the acute treatment of patients with TBI since it guides therapeutic decisions and prognosis. Several scales have been proposed but perhaps the most commonly used is the Glasgow Coma Scale (GCS)(3). According to some studies, the usefulness of the GCS is poor in scenarios where language cannot be assessed, as in intubated patients. Furthermore, t does not assess important such as brainstem reflexes and the respiratory pattern in patients with spontaneous breathing or mechanical ventilation. (4)

Importance.

Two decades ago, The Full Outline of UnResponsiveness (FOUR) scale was developed and validated, which includes the assessment of stem reflexes, respiratory patterns, and voluntary, involuntary, reflex, and automated motor activity. (5) Many patients with TBI in the ED require intubation, which makes neurological assessment difficult but the FOUR score assesses other elements of consciousness, so it can be used in intubated patients.

The current evidence about the FOUR score indicates that it has a similar prognostic performance to the GCS, with no differences in mortality prediction. (5–8) However, two studies suggest that this scale is superior as a predictor of mortality in neurocritical and neurosurgical care populations with lower levels of consciousness (9,10).

Goals of this investigation

This study aims to evaluate the prognostic capacity of the FOUR score in patients with moderate and severe closed TBI, admitted in three EDs from high complexity hospitals in Medellín and Rionegro, Colombia as well as the association between the different scores of the FOUR score and in-hospital or 28-day mortality.

METHODS

Study design and setting: A prospective cohort study including subjects with moderate and severe TBI who were treated in the EDs of three high-complexity hospitals in Medellín and Rionegro, between June 2021 and February 2022.

The study was approved by the Bioethics Committee of the Faculty of Medicine of the University of Antioquia registered in Act No. 003 of March 4th, 2021. The waiver of informed consent was authorized because the research was non-interventional, with minimal risk. The research committee of each hospital individually authorized the study. One hospital requested informed consent for which deferred informed consent was obtained.

The participating institutions are part of the group of highly complex hospitals and clinics that provide health services to the population of the Valle de Aburrá, Antioquia, and other surrounding regions.

The demographic and clinical data were extracted from the medical records provided by the hospitals.

Selection of Participants: Patients with closed TBI who were treated in the EDs of the aforementioned hospitals were selected. We include patients with closed TBI, older than 16 years, with an indication for neuroimaging and GCS $\leq$ 12 points at admission to the ED. The exclusion criteria were: pre-existent hearing, speech, or psychomotor disability impeding the assessment of the FOUR or GCS, death in the first hour after admission to the ED, omission of the assessment within 12 hours from admission, acute decompensation of chronic conditions that may alter the evaluation of the neurological status, and withdraw or withhold of the informed consent in the institution that requested it.

Interventions: Comparison groups were divided depending on the GCS score at ED admission in severe TBI (GCS between 3 and 8), and moderate TBI (GCS between 9 and12).

Each patient was assessed sequentially by two evaluators, at least one of them was an expert (emergency physician or emergency medicine resident) and in some cases was assessed too by non-expert personnel (general practitioners or final-year medical students). All evaluations included the GCS and the FOUR score and were registered using Google Forms™ . The data registered by expert personnel were analyzed for prognostic capacity of the scales and compared with non-expert personnel registers to find the degree of agreement between both groups with different levels of training. The two evaluations were independent and blind.

The clinical decisions and interventions were made according to the medical criteria of the attending group following institutional and international guidelines for the management of TBI patients.

Outcomes and predictive variables: The primary outcome was mortality within the first 28 days after admission to the ED. Patients with hospital discharge were contacted by phone on day 28th and inquired through a semi-structured survey to establish the outcome.

The other variables measured were the Injury Severity Score (ISS), Charlson index, intubation before evaluation, and sedation before evaluation.

Analysis: A sample size was calculated based on the mortality reported in the literature in patients with moderate and severe TBI according to the GCS, 7% and 26%, respectively,(3,11) with a 1:1 ratio, a confidence level of 95% and a power of 80% with an increase of 10% for potential losses and correction of Yates. The sample size was 140 participants, half of them for moderate and the other half for severe TBI.

Univariate analysis of the demographic and clinical characteristics of the patients was performed as absolute values and percentages for the categorical variables, and the quantitative variables as mean and standard deviation, or median and interquartile range (IQR), depending on the distribution of the data. The differences between the scores of the FOUR and GCS scales were analyzed with the t-test for two samples.

The calibration of the scale and the final model were made by calculating the significance of the residual difference between the model with predictors and the null model using a likelihood test. To assess the discrimination performance of the FOUR score to predict mortality in patients with moderate or severe TBI, the concordance index (C index) and the

Areas Under the Receiver Operating Characteristics Curve (AUC-ROC) were calculated with a 95% of CI. The same process was made to determine the discrimination performance of the GCS for the same outcome.

The association between the different scores of the FOUR score and GCS with in-hospital mortality was estimated through a binary logistic regression model to estimate crude odds ratios with their respective 95% of CI. A multivariate logistics regression analysis was performed using variables selected from the bivariate model. The selection of the variables was made using the Hosmer Lemeshow criteria (p-value <0.25) and those variables of clinical relevance(12). The model was adjusted by Injury Severity Score [ISS], Charlson index, intubation before evaluation, and sedation before evaluation. We used a significance level of 0.05. All data were available for this analysis.

All statistical analyzes were performed using R (version 4.1.0, R Foundation for Statistical Computing, Vienna, Austria) and R Studio (version 1.4.1717, R Studio Inc., Boston, United States) software.

RESULTS

Characteristics of study subjects: 133 cases with TBI were assessed for inclusion, and 32 were excluded. The reasons for exclusion are detailed in Figure 1. 101 cases were analyzed. 61.3% had severe TBI and 38.7% had moderate TBI. 39 patients required a phone call to apply the survey about the outcome.

The mean age was 42.2 (SD 18.70), being more frequent in men of both groups. The included population had a low burden of diseases according to the Charlson comorbidity index, however, it was higher in patients who died. Sedation before the assessment occurred in 37% of the subjects, and it was more frequent in the survivors; in contrast, orotracheal intubation before the evaluation was more common in patients who died. Other sociodemographic characteristics are summarized in Table 1. 8 subjects were assessed by a single evaluator; 93 subjects were assessed by two evaluators, distributed as follows: emergency residents (32.9%), emergency physicians (29.8%), general practitioners (29.3%) and interns (7.7%).

28.7% (n = 29) of the total cases died before day 28th, in the moderate TBI group 12.8% (n = 5) and in the severe TBI group 38.7% (n = 24). The estimated time from admission to the ED until death for those who presented the outcome was 5.4 days (SD 4.7). The average hospital stay was 11.4 days (SD 10.3), 69.3% were transferred to the Intensive Care Unit (ICU) or the Special Care Unit (SCU) and the average length of stay was 12.2 days (SD 9). The average ISS was 16.5 points (SD 10.8), and the most frequent finding identified in the skull tomography was hemorrhagic contusions in both survivors and non-survivors, followed by traumatic subarachnoid hemorrhage, subdural hemorrhage, cerebral edema, and epidural hematoma in order of frequency. The percentage of traumas in other body regions was 47%, more frequent the multiple trauma in patients who died (55.17% vs. 43.05%) See Table 1.

Main results

Performance of the model: The brainstem assessment component had the highest scores (66/101 observations; 65.3%) compared to the other components of the FOUR. The distribution of ocular and motor response scores was similar for both scales. The distribution of all the evaluations of the FOUR score and the GCS are shown in the Figures. 2a-2b.

The median of the FOUR was 10 points [IQR 7-12]. For survivors it was 10.5 [IQR 8-12], and non-survivors it was 7 [IQR 3-7], p-value: 0.0003. The median of the GCS was 7 [IQR 6-10]; 8 points [IQR 7-11] for survivors and 6 points [IQR 3, 8] for non-survivors, p-value <0.0001. (see Figure 3).

The calibration of the scales was evaluated through the analysis of the difference of the residuals with a likelihood test, finding an adequate calibration for both the FOUR score and the GCS, with statistically significant findings (p values 0.0003 and <0.0001, respectively). The AUC-ROC curves were plotted to compare the discrimination capacity of the two scales for mortality at 28 days, with the models that only contemplate the scales without adjustment variables. The discrimination for the GCS was 0.7502 (95% CI 0.644-0.856), and for the FOUR score 0.7004 (95% CI 0.585-0.815) (Figures 4a, 4b).

The association between the FOUR score scores with the variable death at 28 days in the study population was determined, finding an increased risk of death for each 1-point decrease in the total FOUR score (OR 1.23; 95% CI 1.10 - 1.41). In the case of the GCS, for every 1-point decrease in the total score, there was also an increased risk of in-hospital death at 28 days (OR 1.48; 95% CI 1.23-1.84).

The interobserver reliability between expert and non-expert evaluations of the scales was high for both scales, Spearman-Rho 0.923 (95% CI, 0.88–0.94) for the FOUR score and 0.930 (95%, 0. 89-0.95) for the GCS.

Adjustment of the model

The model was adjusted for the variables of interest (ISS, Charlson index, intubation before assessment, and sedation before assessment), and an adequate model calibration was evidenced for both scales (p-value 0.0003 for the FOUR score and p-value < 0.0001 for GCS), statistically significant for both cases. The change in discrimination was evaluated with the adjusted model, finding an AUC-ROC of 0.916 (0.846-0.987) in the FOUR score and 0.916 (0.843-0.989) for the GCS (See Figures 4c and 4d).

When adjusting the model, we found an increasing association with 28-day mortality for each decreasing point in the FOUR score (OR 1.35 CI95% 1.09 - 1.71) and in the GCS (OR 1.51; CI95% 1.14-2.10). The association of each variable of interest with the result of mortality is described in Table 2.

LIMITATIONS

The initially calculated sample size could not be reached. This is explained by the decrease in the number of TBIs during the health emergency due to COVID19 thanks to the restrictive measures. However, the power was recalculated, because in-hospital and 28-day mortality was higher than expected, obtaining a statistical power of 83% for 101 cases. This sample was higher or at least similar to the studies reported in the literature. (10,13–15) The observational nature of the study and the non-exclusion of patients under the effect of legal or illegal central nervous system depressant substances, muscle relaxants for intubation, and sedation before evaluation could induce bias and overestimate the severity of TBI in the initial evaluation of the patients.

DISCUSSION

In this study, we show that the FOUR score predicts 28-day mortality in patients with moderate and severe TBI who are admitted to high-complexity hospitals in a similar way to the GCS.

The FOUR score calibrates and discriminates, in a similar way to the GCS, the population with moderate and severe TBI who are more likely to die within 28 days from admission to the EDs of high-complexity hospital centers for their care. Our findings are similar to those reported by the original study by Wijdicks et al. where they show that the FOUR score has a similar performance as a predictor of in-hospital mortality to the GCS (AUC-ROC 0.81 for both scales)(5). Another investigation based on secondary data developed by Foo, Loan, and Brennan in a systematic review, reported performance for mortality between reasonable and excellent (AUC-ROC 0.70 -1.0), but the majority between reasonable and good (AUC-ROC 0.7 - 0.89), but with high heterogeneity in patient characteristics(16). The studies by Kocak et al, and Surabenjawong et al, found significant differences between the FOUR and GCS scales, in populations with acute ischemic stroke, finding that AUC-ROC for the mortality outcome of 0.62 for the first and 0.99 for the second. Although these last two were made in a different context, these diseases are associated with disabling neurological damage. (17,18) Our study showed that there are no significant differences in calibration or discrimination between the scales evaluated.

Previous studies found some grades of the superiority of the FOUR score in predicting mortality in patients with a greater level of consciousness compromise. In our results, the median of the GCS was 7 points, similar to that found by Chen et al, who evaluated only patients with a GCS of less than 8, finding an AUC of 0.768 for the FOUR and 0.699 for the GCS (9); in another study, Okasha et al, found an AUC of 0.85 and 0.80 for FOUR and GCS, respectively. In this study, the median GCS was 8 points (10), lower than previously reported by Sadaka (14) and McNett(6) among others, but similar to the median reported in our results (median of 7 for GCS).

It is important to highlight the usefulness of prognostic models that incorporate data and variables of interest beyond the simple evaluation of the scale, which is consistent with the findings of Kasprowicz et al, who obtained an AUC > 0.90 when incorporating into the prediction model variables such as age, presence of hypotension and the need for mechanical ventilation among others(19). Recently, Almojuela et al published a systematic review that included 49 studies in adults, most of them prospective, like ours, about the prognostic value of the FOUR score. In 32 of these, the FOUR score was found to be equivalent or superior to GCS in predicting mortality and functional outcomes. Of these investigations, 4 were carried out in the ED and 10 included patients with TBI, in which mortality was evaluated as one of its outcomes in variable observation times (8). As evidenced in our study, incorporating new variables of interest can improve discrimination performance.

The mortality found in patients with moderate and severe TBI was higher than that reported in the previous series (11). This can be explained by multiple factors. On the one hand, some of the studies recruited fewer patients with severe TBI (11,20); when comparing mortality rates with publications with a similar proportion of severe TBI, it is evident that mortality is similar, an example of this is the studies by Scheiber and Rosenfeld in which mortality was 38% and 39% % respectively(21,22). On the other hand, the emergency medical systems in our region are probably insufficient to meet the demand for care according to the protected population, so the time of arrival in the field and transport of the patient to an appropriate hospital unit may be delayed. Therefore, there are limited resources, and a logistics system still growing (23). This problem is common in other developing countries around the globe, where simple interventions in trained hands can significantly reduce adverse outcomes (24,25).

We identified that elderly, the number of comorbidities, and the severity of other associated traumas is related to the presentation of the outcome, as in other studies that propose them as part of mortality prediction models in TBI(26–30). The use of sedation before the evaluation of the scales was a protective factor according to our findings, which can be explained by the effect of sedation on the decrease in intracranial pressure, an independent variable associated with mortality and poor outcomes(31).

The length of hospital stay was shorter than the length of stay in the ICU, which was probably because some patients with moderate TBI did not require admission to high dependency units, due to the rapid recovery of alertness or because the neurological deterioration was due to the use of depressant substances of the central nervous system (alcohol, psychoactive substances), and death of the patients in the ED before transfer to other services.

Despite the compromise of the level of consciousness, most of those evaluated presented minimal or no involvement of the brainstem reflexes, but about two-thirds of those who died had alterations in this item of the FOUR score, which affirms that the score provides greater neurological detail than the GCS. In the original study, Wijdicks et al. mention the advantage, over GCS, of assessing respiratory components and brainstem reflexes. This reaffirms their clinical importance and encourages the systematic incorporation of these components in the evaluation of coma.

Another element evaluated was the inter-observer agreement between expert and non-expert personnel working in the EDs, finding a high degree of concordance between the assessments made by the two groups, which suggests that the scale can be implemented by staff with a lower level of training with short-term educational modules. This finding is similar to those reported by Wijdicks(5), Kevric(32), and others(15,33,34).

Regarding the strengths of the research, we highlight the nature of the multicenter study, with a prospective design and in highly complex institutions, which suggests that the level of care and management strategies were similar for all study subjects. Methodological aspects such as the development of a univariate and multivariate logistic regression model, the complete follow-up of the patients, the analysis of an important outcome, and the similarity of our findings to previous investigations add validity to our results. This is the first study in Colombia that has evaluated the performance of the FOUR score in EDs. The results showed a behavior comparable to that of the GCS as a predictor of 28-day mortality when adjusted for variables of interest included in a multivariate model. This finding is an addition to the evidence of possible equivalence between both scales and revalidates its usefulness in EDs.

In summary, the FOUR score predicts 28-day mortality in the population with moderate or severe TBI in a similar way to the GCS. The findings regarding calibration and discrimination allow us to establish that the FOUR score is a valid tool that can be used in the population studied.

The prediction improves when it is adjusted for variables of clinical interest, becoming in this context a valuable instrument that provides important elements in the neurological assessment of this population in the ED.

DISCLOSURES

The study was financed with our own resources, the authors declare that they have no conflicts of interest for this study.

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TABLES AND FIGURES

Table 1: Baseline Demographic and Clinical Characteristics of Moderate to Severe Closed TBI Patients at Enrollment

Characteristics	Total	Alive	Dead
Sample, n (%)	101 (100)	72 (%)	29 (%)
Baseline characteristics			
Age (Mean [SD])	42.2 [18.70]	36.92 [15.01]	56.00 [20.44]
Male sex, n (%)	87 (86.13)	62 (86.11)	25 (86.20)
Insurance, contributive system n (%)	55 (58.51)	40 (58.82)	15 (57.69)
Urban procedence, n (%)	88 (87.12)	60 (83.33)	28 (96.55)
Charlson index (Median, IQR)	0 (0, 2)	0 (0, 0)	2 (0, 3)
Clinical features			
Sedation before evaluation, n (%)	34 (33.66)	29 (40.27)	5 (17.24)
Intubation before evaluation (%)	38 (37.62)	26 (36.11)	12 (41.37)
SAP, Mean (SD)	133.7 (28.43)	129.5 (21.32)	144.1 (39.73)
Heart rate, bpm; Mean (SD)	85.22 (19.85)	88.6 (17.02)	76.83 (23.88)
Respiratory rate, rpm; (Median, IQR)	18 (16, 20)	18 (16, 20)	18 (16, 18)
Trauma features			
Severe TBI, n (%)	62 (61.38)	38 (52.77)	24 (82.75)
Trauma in Other regions, n (%)	47 (46.53)	31 (43.05)	16 (55.17)
ISS, Mean (SD)	16.52 (10.76)	13.32 (9.5)	24.48 (9.35)
Trauma mechanism (MVA), n (%)	65 (64.35)	49 (66.66)	16 (55.17)
CT findings			
Subarachnoid hemorrhage, n (%)	40(40.40)	25 (35.21)	15 (53.57)
Subdural hematoma, n (%)	39(39)	22 (30.98)	17 (58.62)
Epidural hematoma, n (%)	21 (21.42)	17 (24.28)	4 (14.28)
Haemorragic contusions, n (%)	51 (50.49)	28 (39.43)	23 (79.31)
Cerebral edema, n (%)	28 (28)	13 (18.30)	15 (51.72)

TBI: Traumatic brain injury; CT: Computed tomography; SD: Standard deviation; IQR: Interquartile range, bpm: beats per minute; rpm: respirations per minute; ISS: Injury Severity Score; MVA: Motor vehicle accidents.

Table 2: Association of the variables included in the multivariate model with the result of mortality at 28 days.

Scales and adjusted variables	OR	95 % IC	
FOUR score	1,35	1,09	1,71
ISS	1,13	1,05	1,23
Charlson's index	2,01	1,36	3,21
Intubation before evaluation	1,66	0,19	36,8
Sedation before evaluation	0,06	0	0,43
GCS	1.51	1.14	2.10
ISS	1.12	1.05	1.22
Charlson's index	1.91	1.29	3.06
Intubation before evaluation	2.39	0.34	50.71
Sedation before evaluation	0.06	0.07	0.42

ISS: Injury severity score;

Figure 1: Flowchart showing the number of patients screened, enrolled, and excluded

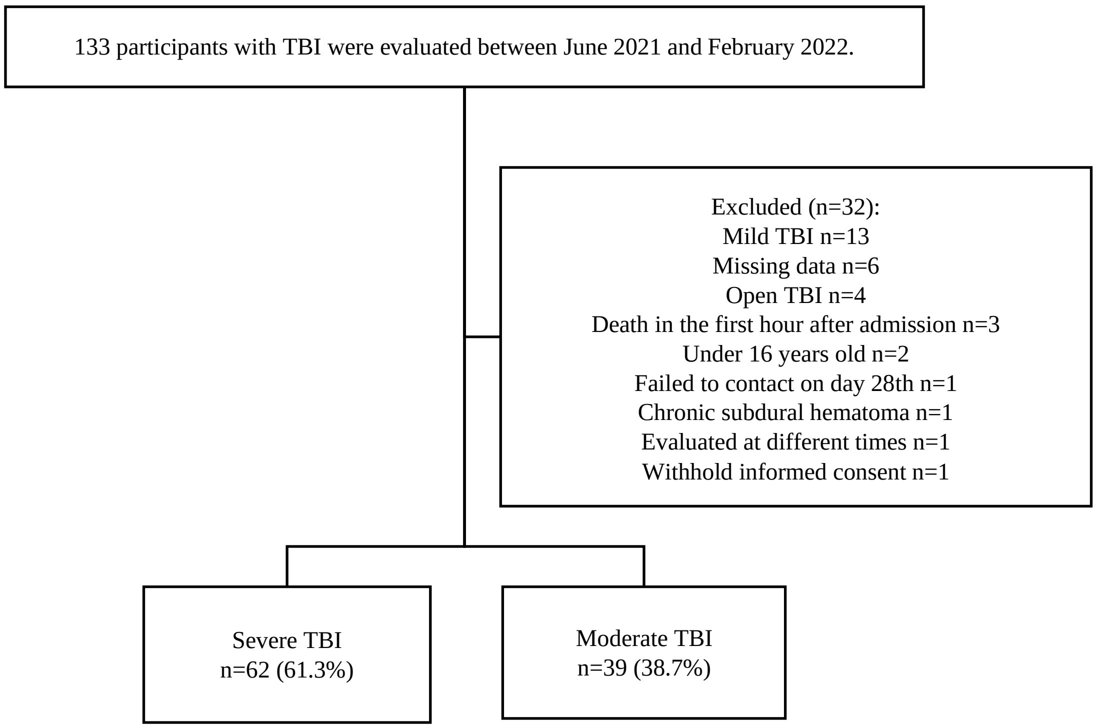


Figure 2a: Frequency of the categories of the FOUR score in 101 patients evaluated.

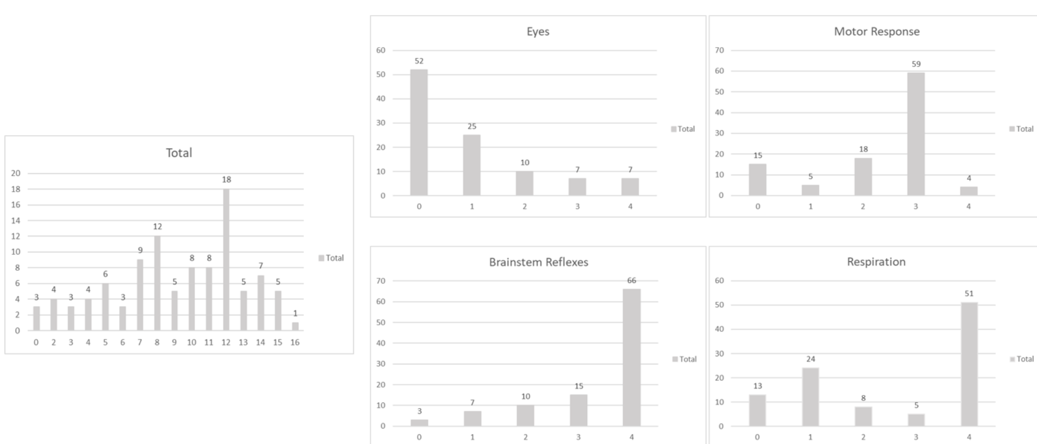


Figure 2b: Frequency of the categories of the GCS in 101 patients evaluated.

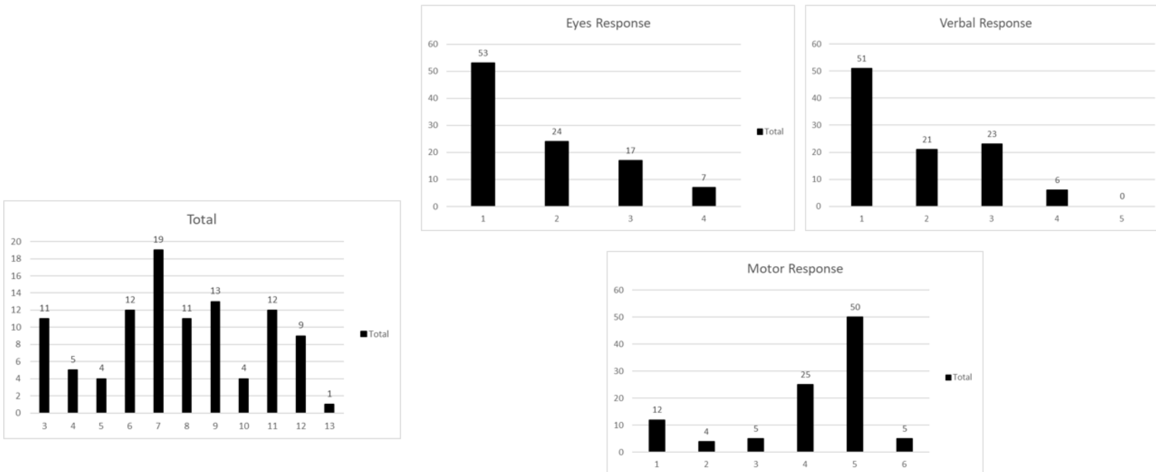


Figure 3: Distribution of the scores for the FOUR and the GCS (median, IQR).

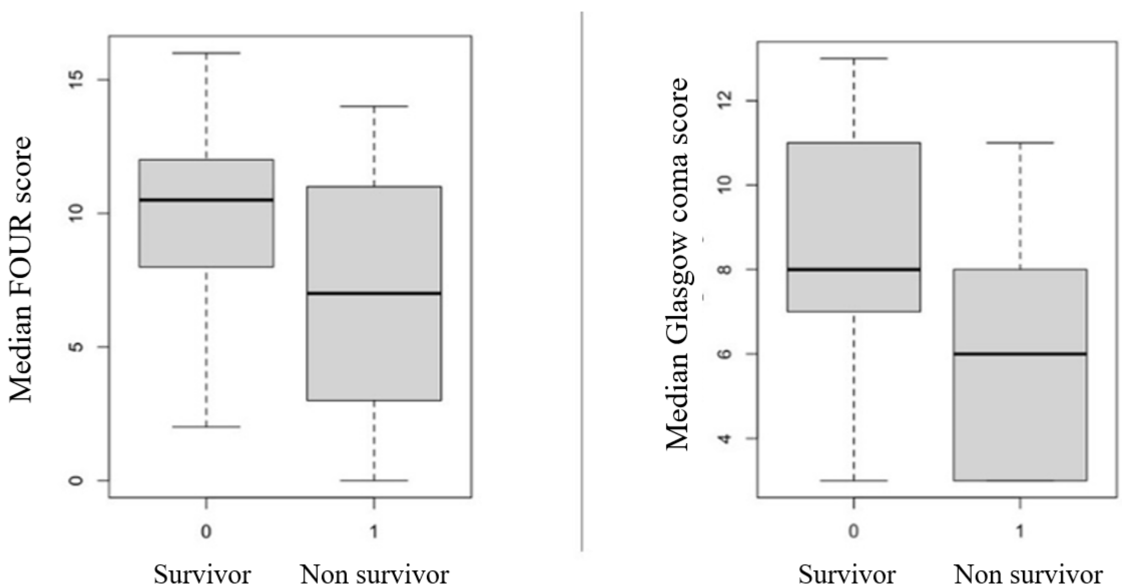
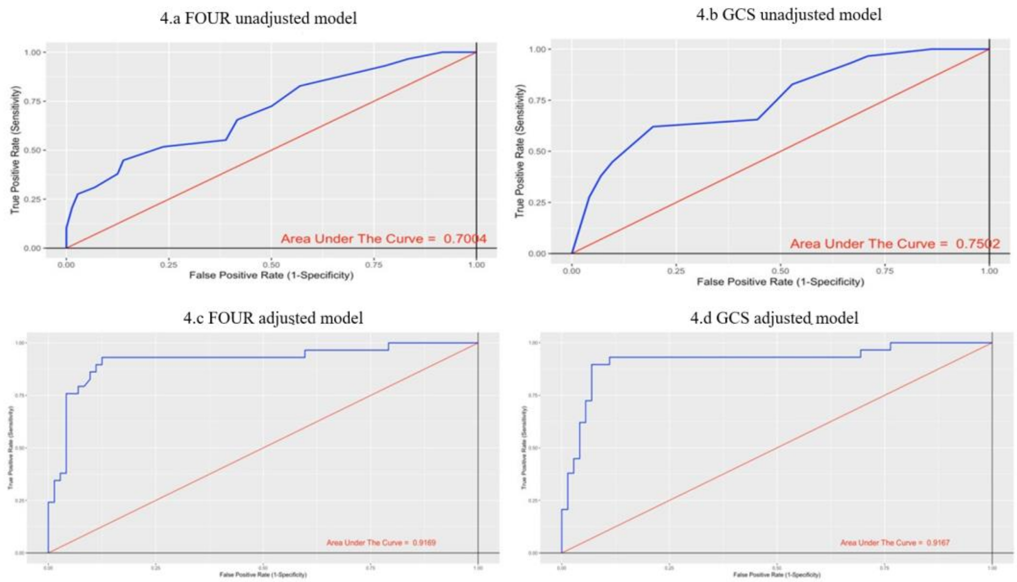


Figure 4: Receiver operating characteristics (ROC) of the FOUR and GCS scales as predictors of 28-day mortality in univariate and multivariate models.



Receiver operating characteristic curves for prediction of 28-day mortality: **4a**: FOUR unadjusted model, **4b**: FOUR adjusted model, **4c**: GCS unadjusted model, **4d**: GCS adjusted model. Variables included in the adjusted model: Injury Severity Score (ISS), Charlson index, intubation before evaluation, and sedation before evaluation.