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Validation of the Italian version of a new coma scale: the FOUR score

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Abstract The Glasgow Coma Scale (GCS) is the most widely accepted tool for the evaluation of consciousness, despite several reported shortcomings. A new coma scale, named Full Outline of UnResponsiveness (FOUR) score, is now available. The aim of the present study is to provide and validate the Italian version of the FOUR score. The Italian version of the FOUR score was developed according to a standardized protocol, and thereafter validated in a series of patients with acute neurological illness. For each patient, the FOUR and the GCS scores were recorded by two physicians randomly selected. The inter-rater agreement for the FOUR and the GCS scores was evaluated using the weighted kappa (κ_w). The receiving operating characteristic curve was also calculated to determine the ability of the scales to predict outcome. Eighty-seven consecutive patients with an acute brain injury were enrolled. The inter-rater agreement was excellent both for the FOUR ($\kappa_w = 0.953$; $P < 0.0001$) and the GCS ($\kappa_w = 0.943$; $P < 0.01$). The area under the curve for mortality was 0.935 for the FOUR and 0.953 for the GCS. The FOUR score provides greater neurological details than the GCS. Our data indicate that the Italian version of the FOUR score is a valid predictor of outcome, yielding reproducible findings across raters independent of their expertise.

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Introduction

The Glasgow Coma Scale (GCS) is the most used scoring system for the evaluation of patients with impaired consciousness [1]. However, a few but important limitations of the GCS have been recognized. The verbal component cannot be properly assessed in intubated patients; in this case, some physicians use the lowest possible score and others extrapolate the verbal response score from other neurological findings [2]. Moreover, the GCS does not detect subtle clinical changes in comatose patients [3]. For those reasons, over the past few decades, many scales were developed with the aim of integrating with or replacement of the GCS. Most of them were complex or not reliable, and thus were not widely accepted [4–8].

The Full Outline of UnResponsiveness (FOUR) score, has been recently proposed as a new coma scale [2]. It explores four components: eye response, motor response, brainstem reflexes, and respiration pattern (including mechanical ventilation); at variance with the GCS, the FOUR score does not evaluate the verbal response. Globally, the scale provides more neurological details than the GCS since it also includes items to assess respiration and brainstem reflexes. The maximum score for the four items is 4. In subjects in whom all categories are graded as 0, brain death should be considered [2, 9]. Moreover, the FOUR score can detect a locked-in syndrome as the presence of a vegetative state where the patient can spontaneously open the eyes, but is unable to track the examiner's finger [2]. Nevertheless, the FOUR score does not

Risposta oculare (O)	Risposta motoria (M)
4 palpebre aperte o apertura, inseguimento oculare o ammiccamento su comando	**4** segno del pollice, del pugno, della vittoria
3 palpebre aperte in assenza di inseguimento oculare	**3** localizzazione dello stimolo doloroso
2 palpebre chiuse che si aprono su comando vocale forte	**2** risposta in flessione allo stimolo doloroso
1 palpebre chiuse che si aprono in risposta allo stimolo doloroso	**1** risposta in estensione allo stimolo doloroso
0 palpebre che restano chiuse in risposta allo stimolo doloroso	**0** nessuna risposta allo stimolo doloroso o stato di male mioclonico generalizzato
Riflessi del tronco encefalico (T)	**Respiro (R)**
4 riflessi pupillari e corneali presenti	**4** non intubato, respiro normale
3 midriasi fissa unilaterale	**3** non intubato, respiro di Cheyne-Stokes
2 riflessi pupillari o corneali assenti	**2** non intubato, respiro irregolare
1 riflessi pupillari e corneali assenti	**1** respira ad una frequenza superiore al ventilatore
0 assenza dei riflessi pupillari, corneali e della tosse	**0** respira alla stessa frequenza del ventilatore o apnea

Istruzioni per la valutazione delle singole categorie del punteggio FOUR (Full Outline of UnResponsiveness)*. ***Per la risposta oculare (O)***: graduare la miglior risposta possibile dopo almeno tre prove per ottenere il miglior livello di vigilanza. Un punteggio O4 indica almeno tre escursioni volontarie. Se le palpebre sono chiuse l'esaminatore deve aprirle e esaminare l'inseguimento oculare di un dito o di un oggetto. L'inseguimento oculare con l'apertura di una sola palpebra è sufficiente in caso di edema palpebrale o trauma facciale. Se l'inseguimento oculare è assente orizzontalmente, si deve esaminare l'inseguimento oculare verticale. In alternativa devono ottenersi due ammiccamenti volontari palpebrali su comando. Questo permette di riconoscere eventualmente una sindrome locked-in (il paziente è completamente cosciente). Un punteggio O3 indica l'assenza di inseguimento volontario ad occhi aperti. Un punteggio O2 indica l'apertura palpebrale su comando vocale forte. Un punteggio O1 indica l'apertura palpebrale in risposta allo stimolo doloroso. Un punteggio O0 indica l'assenza di apertura palpebrale in risposta allo stimolo doloroso. ***Per la risposta motoria (M)***: graduare la migliore risposta possibile degli arti superiori. Un punteggio M4 indica che il paziente riproduce almeno uno dei tre segni (pollice in alto, pugno chiuso, segno di vittoria) con l'una o l'altra mano. Un punteggio M3 (localizzazione) indica che il paziente tocca la mano dell'esaminatore dopo uno stimolo doloroso di compressione dell'articolazione temporo-mandibolare o del nervo sovraorbitario. Un punteggio M2 indica la risposta in flessione degli arti superiori allo stimolo doloroso. Un punteggio M1 indica la risposta in estensione allo stimolo doloroso. Un punteggio M0 indica l'assenza di risposta motoria allo stimolo doloroso o uno stato di male mioclonico generalizzato. ***Per i riflessi del tronco encefalico (T)***: graduare la migliore risposta possibile. Esaminare i riflessi pupillari e corneali. E' preferibile valutare i riflessi corneali instillando due-tre gocce di soluzione fisiologica sulla cornea, da una distanza di 10-14 cm (questo minimizza il trauma corneale conseguente a ripetute valutazioni). In alternativa si possono utilizzare batuffoli di cotone sterile. Il riflesso della tosse, mediante l'aspirazione tracheale, si valuta quando i riflessi corneali e pupillari sono entrambi assenti. Un punteggio T4 indica che i riflessi pupillari e corneali sono presenti. Un punteggio T3 indica la presenza di midriasi fissa unilaterale. Un punteggio T2 indica l'assenza del riflesso pupillare o corneale. Un punteggio T1 indica l'assenza di entrambi i riflessi pupillari e corneali. Un punteggio T0 indica l'assenza dei riflessi pupillari, corneali e della tosse (usando l'aspirazione tracheale). ***Per il respiro (R)***: valutare il respiro spontaneo in un paziente non intubato e graduare semplicemente come respiro regolare (R4), irregolare (R2) o di Cheyne-Stokes (R3). In pazienti intubati, valutare la forma dell'onda pressoria del comportamento respiratorio normale o l'innesco del ventilatore da parte del paziente (R1). Si confronta il ritmo respiratorio misurato con quello del ventilatore meccanico: una frequenza superiore a quella del ventilatore indica l'integrità del centro respiratorio. Non si attuano modifiche al ventilatore quando il paziente è valutato, ma la valutazione è effettuata preferibilmente con una $PaCO_2$ entro i limiti della norma. Un test standard per l'apnea (diffusione di ossigeno) può essere necessario quando il paziente respira alla frequenza del ventilatore (R0).

Fig. 1 Italian version of the FOUR score, of the items' instructions and drawings

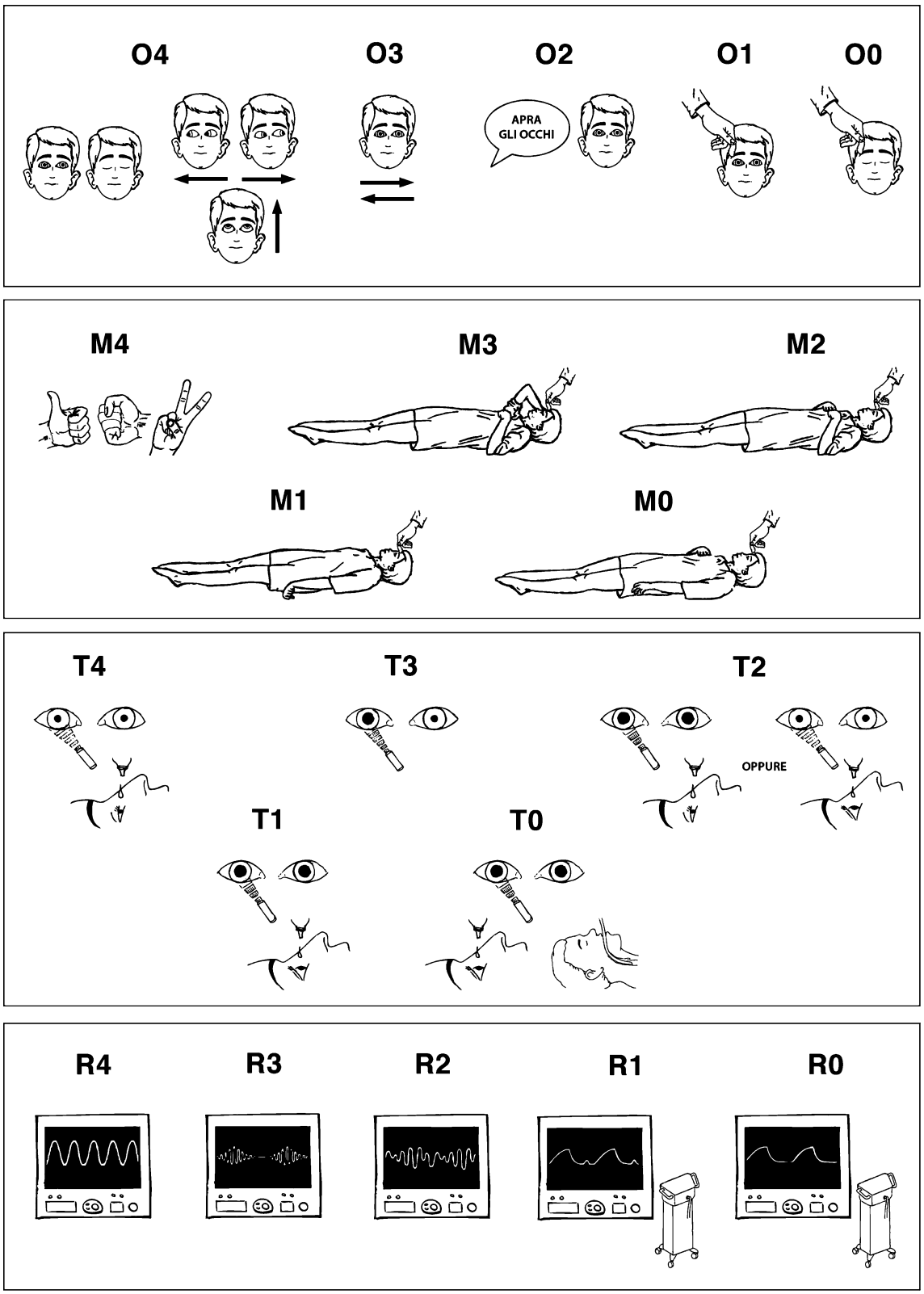

Fig. 1 continued

distinguish patients in the vegetative state from those in the minimally conscious state [10, 11]. The scale has been considered valid, reliable, and a good prognostic predictor in critically ill patients [2, 12–15], and has already been translated into French [16] and Spanish [17, 18] while an Italian version is not yet available. The aim of this study was to provide and validate the Italian version of the FOUR score.

Methods

Development of the Italian version of the scale

Two participants in the study (E.M. and S.S.) independently translated into Italian the original version of the FOUR score, of the associated instructions, and of the drawings' text. Thereafter, a consensus meeting was held to agree on a fully comprehensible and accurate Italian translation consistent with the original English text. The draft was back translated into English, and compared with the original to develop the final Italian translation (Fig. 1). Thereafter, the Italian version of the FOUR score was validated.

Participants

Patients admitted to the Neurology, Neurosurgery, and Intensive Care Units in the L'Aquila Hospital and to the Emergency Department Stroke Unit and Intensive Care Unit of the Policlinico Umberto I in Rome, were consecutively enrolled and evaluated within 7 days from symptom onset, from August to October 2010. In detail, 13 (14.9%) patients were evaluated on hospital arrival (day 0), 22 (25.3%) patients on day 1 and 52 (59.8%) from day 2 to day 7. Inclusion criteria were an age ≥18 years, and a diagnosis of acute brain injury. Exclusion criteria were treatment with neuromuscular junction blockers and sedatives less than 30 min prior and within the evaluation period. The study was performed in accordance with the Helsinki Declaration. Consent was obtained from the patient or from the legal surrogate.

Procedure

A pair of raters, randomly chosen, independently assessed all patients using the Italian version of the FOUR score and the GCS. Two raters were neurologists (N1–N2) and two were residents in neurology (R1–R2) with at least 4 years in clinical practice (N1: S.S.; N2: A.C.; R1: Alf.C.; R2: S.R.). Raters were provided with written instructions to ensure adequate understanding of the administration procedure and scoring of the scales. A trial session on two patients was also performed. The pairs of raters were N1/R1, N1/R2, N2/R1, N2/R2, N1/N2, and R1/R2; each patient was assessed by the two raters within a time interval of 1 h. The order of the evaluations was randomly set.

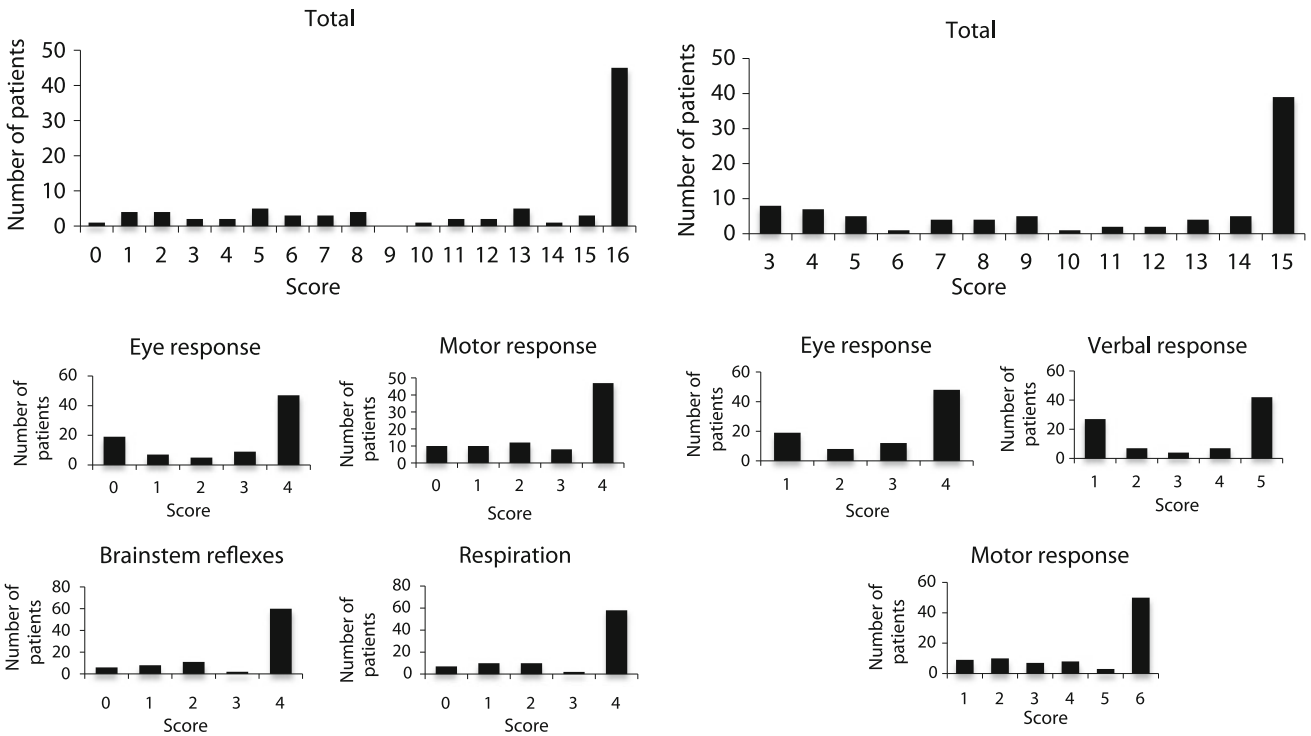

Fig. 2 Distribution of the FOUR scores (*left panel*) and GCS (*right panel*) in our cohort

Table 1 Inter-rater agreement (κ_w) for the FOUR score and the Glasgow Coma Scale

Pair of raters	Number of patients	FOUR score					GCS			
		Eye response	Motor response	Brainstem reflexes	Respiration	Total	Eye response	Verbal response	Motor response	Total
N1/N2	14	0.804	0.857	0.865	1.000	0.837	0.872	0.817	0.844	0.810
N1/R1	14	0.896	1.000	1.000	1.000	0.965	0.929	1.000	0.940	0.928
N1/R2	14	1.000	0.776	1.000	1.000	0.841	1.000	0.894	0.842	0.876
R1/R2	15	0.948	0.893	0.819	1.000	0.897	1.000	1.000	0.965	0.983
N2/R1	15	0.963	0.766	0.928	1.000	0.906	0.909	1.000	0.768	0.833
N2/R2	15	1.000	1.000	0.897	1.000	0.945	1.000	0.947	0.942	0.965
Overall	87	0.960	0.915	0.918	1.000	0.953	0.954	0.964	0.923	0.943

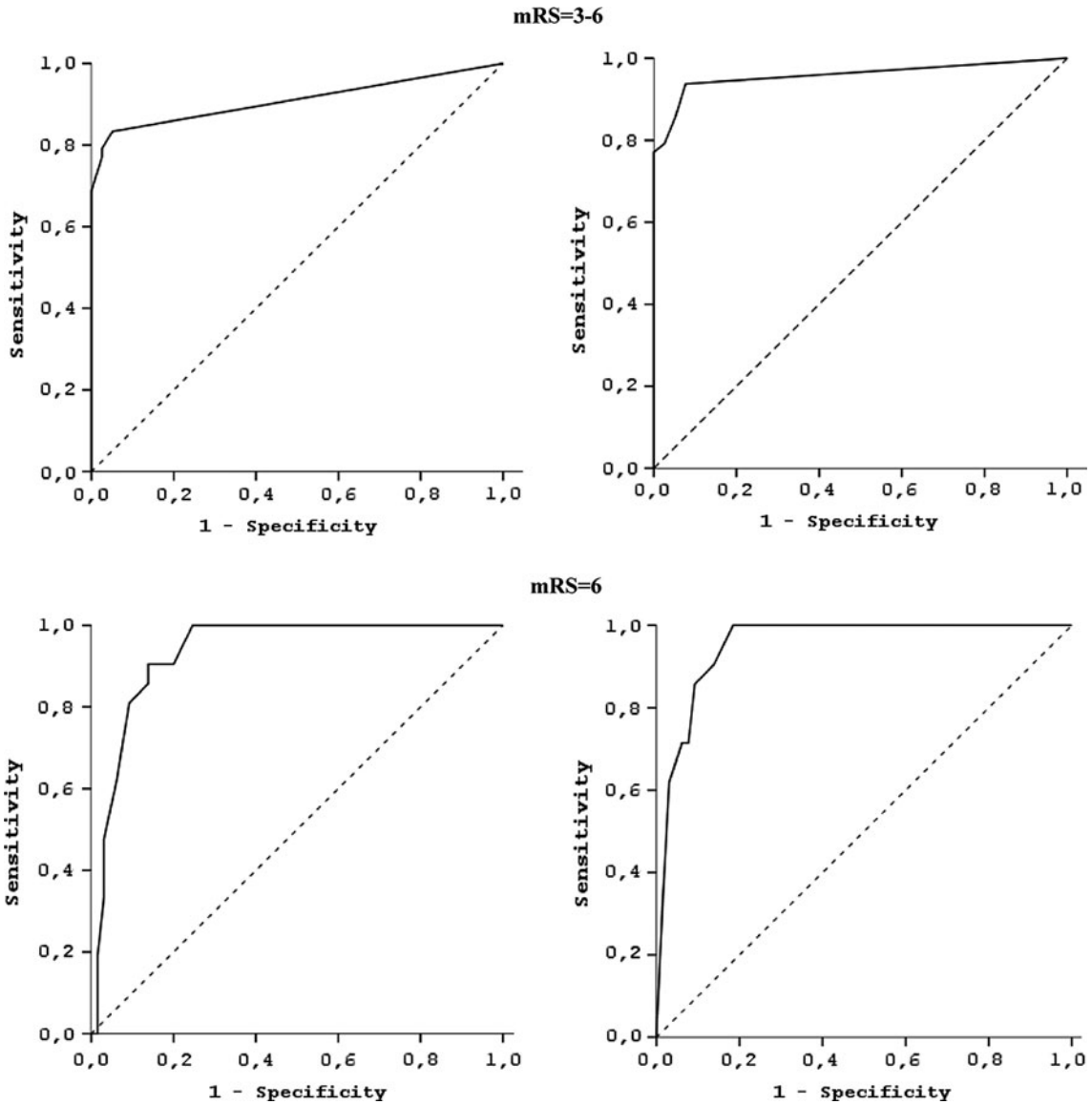

Fig. 3 Area under the curve (AUC) values for the FOUR score (*left*) and the GCS (*right*) for poor outcome (mRS = 3–6) and mortality (mRS = 6)

Table 2 Area under the curve (AUC) values for the items of the FOUR score according to the modified Rankin Scale

Item	AUC (95% CI)
Modified Rankin Scale = 3–6	
Eye response	0.898 (0.828–0.968)
Motor response	0.887 (0.814–0.961)
Brainstem reflexes	0.781 (0.684–0.879)
Respiration	0.802 (0.708–0.896)
Modified Rankin Scale = 6	
Eye response	0.949 (0.904–0.994)
Motor response	0.936 (0.887–0.985)
Brainstem reflexes	0.820 (0.702–0.938)
Respiration	0.842 (0.741–0.944)

For each patient age, gender, medical history, diagnosis on admission, day of evaluation, intubation, neuroimaging data, and degree of consciousness (awake, drowsy, stuporous, or comatose) according to established criteria were recorded [19]. During the assessment, vital functions (heart rate, breath rate, blood pressure, oxygen saturation) were monitored.

Outcome at discharge was assessed by the modified Rankin Scale (mRS) by the same rater randomly selected from each pair. The mRS is a 7-point scale that assesses overall function and mortality, in which patients who die are scored 6, the worst possible score of the scale. In our study, patients were regarded as having a good recovery when the mRS score was between 0 and 2 and a poor outcome when the score was between 3 and 6.

Statistical analysis

Descriptive statistics for the study was presented as mean ± SD or median. Inter-rater agreement for the total score and the single items' scores was evaluated by the weighted Cohen's kappa (κ_w). A κ_w of 0.40 or less was considered poor, between 0.41 and 0.60 fair to moderate, between 0.61 and 0.80 good; values above 0.81 were considered to show an excellent agreement [20]. Internal consistency of the scale was evaluated by Cronbach's α and intercorrelations of the items' scores by the ρ Spearman's correlation coefficient. The receiving operating characteristic (ROC) curve analyses adjusted for age, gender, consciousness, and clinical diagnosis were also calculated to determine the ability of the FOUR score and the GCS to predict mortality or poor outcome at discharge. Sensitivity, specificity, and likelihood ratio of those scales were also computed. Internal consistency, construct validity, intraclass correlation coefficients (ICC) and ROC curves were performed with SPSS 17.0 using the same rater score from each pair of raters and κ_w was performed with MedCalc 11.4. Statistical significance was set at $P < 0.05$.

Results

Eighty-seven patients (62% men; mean age ± SD 70.2 ± 13.9 years) were assessed. Median time from the acute event to evaluation was 2.78 days. Forty-three (49.4%) patients were alert, 12 (13.8%) drowsy, 6 (6.9%) stuporous, and 26 (29.9%) comatose; 15 (17.3%) patients were intubated and mechanically ventilated. Fifty-six (64.3%) patients had an ischemic stroke, 11 (12.6%) a traumatic head injury, 7 (8.0%) an intracerebral hemorrhage, 6 (6.9%) a subarachnoid hemorrhage, 3 (3.5%) an acute encephalitis, 1 (1.2%) a meningitis, 1 a right fronto-temporo-parietal meningioma, 1 a cerebral cysticercosis, and 1 a metabolic coma.

In the 87 enrolled patients, a total of 174 ratings were performed by the FOUR score and by the GCS. Distributions of overall and single items scores are reported in Fig. 2.

The inter-rater agreement for all raters was excellent, both for the total FOUR score (κ_w 0.953, 95% CI 0.928–0.978; ICC 0.991, 95% CI 0.986–0.994) and the total GCS score (κ_w 0.943, 95% CI 0.917–0.972; ICC 0.988, 95% CI 0.981–0.992) (Table 1). The inter-rater agreement for each pair of raters ranged from good to excellent, independent of the level of expertise; the agreement for the items included in the FOUR score and in the GCS was good for the motor response and excellent for the others. The inter-rater agreement for the FOUR score was excellent in alert (κ_w 1.000, 95% CI 1.000–1.000) and

Table 3 Cross-tabulation of the FOUR score and the GCS in patients with the most severe brain injuries

GCS	FOUR score									
	0	1	2	3	4	5	6	7	8	Total
3	1	4	1	0	0	1	1	0	0	8
4	0	0	3	1	1	1	1	0	0	7
5	0	0	0	1	1	2	0	0	1	5
Total	1	4	4	2	2	4	2	0	1	20

stuporous patients (κ_w 0.920, 95% CI 0.810–1.000) and good in drowsy (κ_w 0.749, 95% CI 0.581–0.917) and comatose (κ_w 0.782, 95% CI 0.645–0.920) patients. The inter-rater agreement for the GCS was excellent in alert (κ_w 0.944, 95% CI 0.834–1.000) patients and good in drowsy (κ_w 0.791, 95% CI 0.587–0.996), stuporous (κ_w 0.781, 95% CI 0.540–1.000), and comatose patients (κ_w 0.711, 95% CI 0.520–0.901). The Cronbach's α showed a high internal consistency both for the FOUR score (0.995) and the GCS (0.994). Spearman's ρ between the items of the scales was 0.953 ($P < 0.01$) both for the FOUR score and the GCS.

Thirty-nine patients (44.8%) had a favorable outcome at discharge and 48 (55.2%) a poor outcome, including 22 (25.3%) patients who died. When considering mortality (Fig. 3), the area under the curve (AUC) in the ROC curve analyses was comparable for the FOUR score (AUC = 0.935; 95% CI 0.884–0.985) and the GCS (AUC = 0.953; 95% CI 0.913–0.994). The optimal score to predict mortality at discharge was 10 for the FOUR score (sensitivity 91%; specificity 86%) and 9 for the GCS (sensitivity 100%; specificity 81%). Similarly, as shown in Fig. 3, referring to poor outcome, the AUC values were 0.909 for the FOUR score and 0.958 for the GCS. At the FOUR score, items assessing brainstem reflexes and respiration had lower AUC values with respect to items that assessed eye and motor response (Table 2). These findings remained statistically significant after adjusting the analyses for age, gender, consciousness, and clinical diagnosis.

A formal test of accuracy was conducted using the positive likelihood ratio (+LR); we found higher +LR values for the FOUR score (6.6 for mortality and 16.3 for poor outcome) as compared to the GCS, still representing the gold standard in clinical practice (5.4 for mortality and 12.2 for poor outcome).

In patients with the most severe brain injury (GCS 3–5), the FOUR score provided greater neurological details than the GCS. In 8 (9.2%) patients with a GCS of 3 the FOUR score ranged from 0 to 6, in 7 (8%) patients with a GCS of 4 the FOUR score ranged from 2 to 6, and in 5 (5.8%) patients with a GCS of 5 the FOUR score ranged from 3 to 8 (Table 3).

Discussion

Our study shows that the Italian version of the FOUR score is a valid predictor of outcome providing greater details than the GCS, and can be reliably used in patients with acute brain injury. Inter-rater agreement for the overall FOUR score is excellent ($\kappa_w = 0.953$) and comparable to that of the GCS ($\kappa_w = 0.943$), and is similar to that reported by the developers of the scale ($\kappa_w = 0.82$ for both scales) [2], by the authors of the French version ($\kappa_w = 0.86$ for the FOUR score and $\kappa_w = 0.85$ for the GCS) [16], and by those of the Spanish version of the scale ($\kappa_w = 0.93$ for the FOUR score and $\kappa_w = 0.96$ for the GCS) [17]. Inter-rater agreement ranges from good to excellent in all categories of patients showing a greater agreement than the GCS in stuporous and comatose patients.

Our evaluations were performed by neurologists and neurology residents with clinical expertise, and show that the scale is reliable and independent of the expertise of the raters. The study did not include nurses and fellows as raters because in Italy only evaluations performed by physicians hold legal value. The validation of the French version of the scale involved highly, moderately, and less-experienced raters; performances are comparable only among the highly and moderately experienced raters [11]. At variance with other studies, this different finding may have depended on the higher level of expertise of our residents who were chosen among those with at least 4 years of clinical practice.

Scores of the single items can be used reliably as suggested by all available data, including ours [12, 20]. The inter-rater agreement shows values from good to excellent for all the items of the FOUR score with lower κ_w values for motor response at the FOUR score and the GCS, as already reported [13]. The chance of inter-rater agreement at both scales increases in alert patients, according to Wolf et al. [15] and at variance with Idrovo et al. [17].

Our ROC curves show that the AUC values of the FOUR score and the GCS are comparable; accordingly, both scoring systems are excellent outcome predictors of in-hospital mortality. However, prediction was less accurate in patients with a poor outcome (mRS $\geq$ 3) both with the FOUR score and the GCS. At variance with the developers of the scale and according to Eken et al. [2, 12], we find that brainstem reflexes and respiration do not provide the expected benefit in predicting prognosis, since the evaluation of eye and motor responses as included in the FOUR score shows a greater variability. The positive likelihood ratio is higher for the FOUR score than the GCS suggesting that the former scale is better able to identify the outcome.

Moreover, patients with the lowest GCS (3–5) had values between 0 and 8 at the FOUR score, emphasizing that the FOUR score is more useful in tracking the clinical status of patients with acute brain injuries.

In conclusion, we found that the Italian version of the FOUR score can be used to reliably assess patients with impaired consciousness. The scale is easily taught and administered, allows accurate tracking of the neurological status in patients with severe brain injury, and is useful to predict poor outcome. For all the above reported reasons, in our opinion, the FOUR score is worthy of a greater knowledge and application in clinical practice.

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Conflict of interest None.

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