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Full Outline of UnResponsiveness (FOUR) Scale: a Multicenter Validation Study of the Psychometric Properties of the Approved Russian Version

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Summary

Assessment of the individual level of consciousness on admission of a patient with brain injury to the intensive care unit (ICU) is a priority task and a mandatory step in the overall assessment of neurological status. The Full Outline of UnResponsiveness (FOUR) scale, developed at the Mayo Clinic (USA) in 2005, is a widely used tool for comprehensive assessment of patients with altered state of consciousness. The lack of a validated Russian-language version of the FOUR scale has hindered its widespread use in clinical practice. Therefore, the official Russian version of the FOUR scale was developed and adapted for use in Russia after the first stage of the validation study (linguistic and cultural adaptation).

Aim. To evaluate the psychometric properties of the Russian version of the FOUR scale for comprehensive assessment of patients in altered state of consciousness.

Materials and Methods. As part of a prospective multicenter validation study, the psychometric properties of the scale (reliability, validity, and sensitivity) were evaluated in a group of 171 adult patients with altered conscious state of various etiologies, such as ischemic and hemorrhagic stroke, neuroinflammatory conditions, and traumatic brain injury. Patients' responses were assessed on the first day of ICU stay and 2–3 days later by two ICU neurologists with at least three years of experience.

Results. High levels of validity and reliability were obtained for the Russian version of the FOUR scale for comprehensive assessment of unresponsive patients, including Spearman's rank correlation coefficient R=0.99 (P<0.0001), Cohen's κ=0.77 (P<0.001), Cronbach's α=0.87 (P<0.0001). Regarding the sensitivity of the FOUR scale, no significant changes were found after comprehensive assessment of unresponsive patients on day 1 in the ICU and 2–3 days later (Wilcoxon test, p=0.906). There was a good correlation between the FOUR and Glasgow Coma Scale scores used to assess patients with altered state of consciousness, confirming the validity of the test with R=0.91 (P<0.0001).

Conclusion. The Russian version of the FOUR scale for comprehensive assessment of unresponsive patients is a valid, reliable, and sensitive clinical tool. Sufficiently verified level of psychometric properties allows its authorized use in Russia and other Russian-speaking countries. The scale is available for download via QR code and at the website of the International Scales and Questionnaires Validation Group at the Research Center for Neurology.

Keywords: FOUR scale; Full Outline of UnResponsiveness; coma; altered state of consciousness; validation; resuscitation

Conflict of interest. The authors declare no conflict of interest.

Introduction

Clinical assessment of coma patients is an important diagnostic skill for medical professionals. The scales used to assess neurological patients in critical illness have been developed to standardize the examination, objectively evaluate the results and, obviously, facilitate communication between specialists. The most commonly used scale is the Glasgow Coma Scale (GCS) [1]. The GCS is a classic scale developed in 1974 to assess the severity of impaired consciousness in patients with brain injury admitted to intensive care. It is an algorithm consisting of a series of tests, including eye opening, verbal response, and motor response [2]. Although the authors of the GCS reported evidence of the practical reliability of the scale, later difficulties in its application emerged, and the arsenal of equipment available to maintain vital functions in the ICU necessitated the expansion of the diagnostic items to address the severity of impaired wakefulness [3–4].

Thus the verbal component of the GCS assessment cannot be tested during tracheal intubation. Some clinicians use the lowest possible score, while others extrapolate other neurological findings to the verbal response [5]. Second, changes in respiratory pattern and the need for ventilatory support may reflect the depth of coma, but GCS does not include these clinical parameters [6]. Third, the GCS may not reflect minor changes on neurological examination [7].

Due to the need for a new tool, an improved scale to assess the status of a coma patient, the Full Outline of UnResponsiveness (FOUR) detailed assessment scale for unresponsive patients was developed [8].

The score consists of 4 components to be tested: eye response, motor response, brainstem reflexes, and respiration [9]. The introduction of this scale into clinical practice has shown a high degree of consistency in the interpretation of scores by practitioners of different specialties, including emergency department nurses [10].

This scale has been linguistically and culturally adapted and validated in many countries [11–12]. The lack of a validated version of the scale complicates its use in Russia. For successful standardized clinical and relevant use of the scale, the adapted Russian-language version must undergo all necessary validation stages.

After the development of the official Russian version of the Full Outline of UnResponsiveness scale [13–15], the second and final stage of the validation study was conducted.

The aim of this study was to evaluate the psychometric properties of the Russian version of the FOUR scale.

Materials and Methods

Patients were prospectively recruited at the Research Center for Neurology (Moscow), S. P. Botkin City Clinical Hospital (Moscow), N. V. Sklifosovsky Research Institute of Emergency Medicine (Moscow), V. A. Almazov National Medical Research Center of the Ministry of Health of Russia (St. Petersburg), and Clinical Institute of Brain (Yekaterinburg) in the period from June 2018 to July 2021.

According to the inclusion and exclusion criteria (Table 1), 176 neurological patients over 18 years of age with different levels of impaired consciousness (coma, stupor, obtundation), as well as patients in full consciousness participated in the study.

During the inter-evaluation period, 5 patients were excluded from the study: three due to death, one due to sedation specifics, and one patient was transferred to a multidisciplinary hospital due to bleeding.

The final group consisted of 171 patients (87 males and 84 females). Severity of altered consciousness was clinically assessed on the first day of hospitalization (concurrent with the first GCS assessment) by two ICU neurologists with at least 3 years of experience.

Validation procedure. The second stage of validation of international scales involves the study of psychometric parameters such as reliability, validity, and sensitivity. These parameters of the FOUR scale were evaluated with the participation of two experienced neurologists. The scores of the questionnaire at the first, second and third examination by the first physician were designated as «A1», «A2» and «A3», and at the examination by the second physician as «B1», respectively.

Psychometric parameters. Based on the principles of validation of tests, questionnaires, and

Table 1. Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
• Age ≥ 18 years. • Hospitalization in the intensive care unit with the following types of altered consciousness: stupor, obtundation, coma, as well as those in full consciousness. • Signed informed consent from patient or patient's representative. • Documented neurological conditions such as ischemic/hemorrhagic acute cerebrovascular accident (including subarachnoid hemorrhage), traumatic brain injury, infectious diseases of the central nervous system (meningitis, encephalitis, etc.), acute neuromuscular diseases (Guillain-Barré syndrome, myasthenic crisis, etc.), and others.	The effect of sedatives or neuromuscular blockers at the time of assessment using the specified scales. In this case, it was necessary to wait one maximum half-life (during the baseline and repeated assessment over the next 3 days after establishing the fact of taking these medications).

scales, the following psychometric parameters were evaluated: test-retest and inter-rater reliability, internal consistency, criteria-related and content validity, and sensitivity [16].

The content validity study was conducted by interviewing five experts (neurologists with at least 8 years of experience) to determine how well the content of the scale matches the tasks for which it is used. The assessment was made on a 10-point scale.

The study of the sensitivity of the scale included a comparison of the results of the initial and final examinations of the patients (A1–A3). The hypothesis about the effectiveness of the scale in detecting changes in clinical parameters was tested.

Statistical analysis of data. An adequate sample size was calculated according to generally accepted recommendations [17]. The sample size, which amounted to 171 people, provided the necessary level of its representativeness.

The following methods of statistical data analysis were used to study the psychometric parameters of the scale: retest reliability and criterion-related validity (with GCS scores) were assessed using the Spearman correlation test, inter-rater reliability was assessed using Cohen's kappa, internal consistency was assessed using Cronbach's alpha coefficient and intraclass correlation coefficient, and sensitivity was assessed using the Wilcoxon test. The attainment of a threshold level of inter-rater consistency, Cohen's kappa, was used as the endpoint. The size of the differences was chosen at the level of 0.4 points on the scale under study. The power level was 0.8. In all cases of statistical hypothesis testing, $P \leqslant 0.05$ was considered significant. Statistical analysis of data was performed using SPSS Statistics 22 software (IBM Corp., Chicago, USA).

Results

Patient characteristics. Based on the neurological profile, the studied patients (N=171, mean age 63.0±16.8 years) were divided into the group with brain injury (N=164) and the group with peripheral nervous system injury (N=7). The etiology of brain injury is shown in Figure.

Other causes included inflammatory diseases of the brain and meninges (encephalitis and meningitis) (3/164), closed traumatic brain injury (3/164), demyelinating diseases (3/164), cerebrovascular disease (2/164), epilepsy (2/164), brain tumors (2/164), consequences of cardiac arrest (1/164), consequences of aorto-coronary bypass surgery (1/164), opportunistic infection with human immunodeficiency virus (1/164), toxic encephalopathy with heroin addiction (1/164).

The peripheral nerve injury group consisted of patients with Guillain–Barré syndrome (6/7) and myasthenic crisis (1/7).

The median and interquartile range *(Me [IQR])* of the FOUR score at the first visit was 16.0 [11.25–16.0] points. Full consciousness was noted in 94 patients (55.0%), mild obtundation in 6 patients (3.5%), severe obtundation in 14 patients (8.2%), stupor in 26 patients (15.2%), and coma in 31 patients (18.1%).

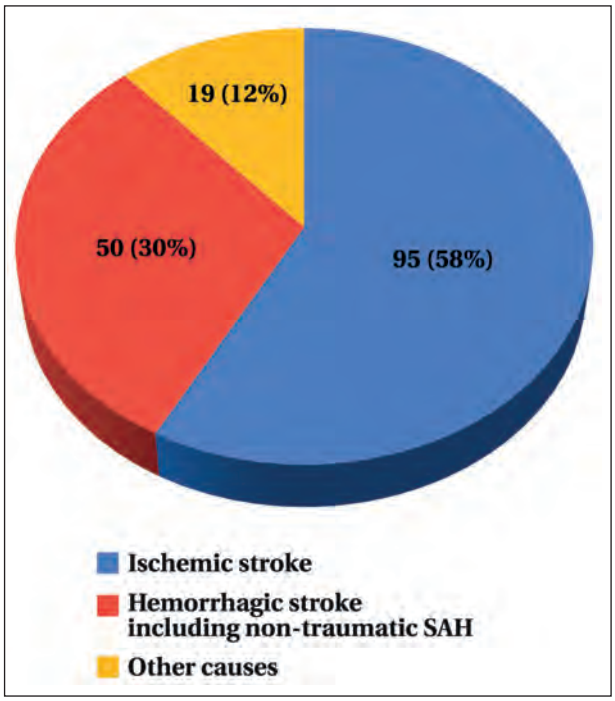

Fig. Distribution of patients in the CNS injury group (N=164) by ethology.

Psychometric properties of the Russian version of the FOUR scale.

Reliability. The Spearman correlation coefficient between the results of repeated examinations in the study of retest reliability was R=0.99 (P<0.0001), which corresponds to a high level of stability of the scale to time-related errors.

Cohen's kappa coefficient was κ=0.77 (P<0.0001), which supports significant inter-rater agreement in independent assessment of the FOUR scale. When examining the discrepancy between the scores of each of the E, M, B, and R score components, significant and balanced scores were obtained (Table 2).

The internal consistency study of the FOUR scale showed that the Cronbach's alpha coefficient was α=0.87 (P<0.0001) with an intraclass correlation coefficient (ICC) of 0.87 (P<0.0001), indicating a strong balance of scale items.

When examining the criterion validity between the FOUR and GCS scores, a significant correlation of R=0.912 (P<0.0001) was found.

Based on expert evaluation, the content validity was high, scoring 8.8 out of 10.

Sensitivity of the Russian version of the FOUR scale. Comparing the score of the FOUR scale at the first examination (16.0 [11.2–16.0] points) and

Table 2. Inter-rater agreement on the components of the Full Outline of UnResponsiveness (FOUR) score.

Inter-rater agreement	The components of Full Outline of UnResponsiveness (FOUR) score				
	Eye response (E)	Motor response (M)	Brainstem reflexes (B)	Respiration (R)	Total
Cohen's kappa (threshold value ⩾0.7)	0.847	0.875	0.807	0.92	0.770
P-value			<0.0001		

Table 3. Psychometric parameters of the Russian version of the Full Outline of UnResponsiveness (FOUR) scale.

Parameter	Elements	Assessment method	Threshold value	*Result*	
				Value	P-value
Reliability	Internal consistency (A1)	Cronbach's alpha	0.8 and more	0.87	<0.0001
		Intraclass correlation coefficient	0.8 and more	0.87	<0.0001
	Inter-expert agreement	Cohen's kappa	0.7 and more	0.77	<0.0001
	Test-retest reliability (A1–A2)	Spearman correlation coefficient	0.7 and more	0.73	<0.0001
Validity	Criterion-related validity	Spearman correlation coefficient	0.7 and more	0.91	<0.0001
	Content validity	Expert evaluation	7/10 and more	8.8/10	—
Sensitivity	Sensitivity (A1–A3)	Wilcoxon test	*P*<0.05	0.118	0.906

at the final examination (16.0 [11.0–16.0] points), no significant change in the scores was found (Wilcoxon criterion, *P*=0.906), which may indicate that the patients' condition remained stable during this period between assessments (2–3 days).

Discussion

The FOUR scale is an effective tool for rapid and standardized assessment of acute impairment of consciousness. It can be used to assess the degree of altered state of consciousness [18]. The modalities presented in this scale can be used for assessment not only by subspecialists such as neurologists and intensivists, but also by trainees and nurses [19]. The Full Outline of Unresponsiveness scale is easy to use and remember, quick to implement, reliable in different settings, and provides physicians with sufficient information about the patient's condition to determine management strategies [20]. Unfortunately, the lack of a Russian version limited the use of the scale, necessitating its development and validation.

Previously, at the first stage of validation, we conducted forward and backward translations of the scale, then approved the final text of the scale, taking into account all cultural and linguistic peculiarities of Russian medical terminology. The official Russian version of the FOUR scale was published in 2019 in the journal Annals of Clinical and Experimental Neurology [13].

However, the first step is not sufficient for the reliable use of the developed version of the scale in clinical and research practice. Only the evaluation of psychometric parameters with the use of statistical methods of analysis will allow to ensure that the use of this assessment tool will provide objective clinical data and the same result as the use of the original version. In addition, the comparison of the obtained results with those of international researchers, as well as the global acceptance of the results obtained in Russia and in the Russian population, will be possible only after the examination of psychometric parameters.

In the second step of validation we conducted a multicenter study, which included 171 patients with various levels of altered consciousness (coma, obtundation, stupor), as well as patients in full consciousness. After data collection, significant psychometric parameters of the Russian version of the scale were obtained (Table 3).

The examination using the FOUR scale was performed by two experienced neurologists, which made it possible to assess the inter-expert reliability of the scale in a heterogeneous population.

The inter-rater reliability for the total score of the FOUR scale was significant (κ=0.77, *P*<0.0001), which is a positive result compared to previous studies [21]. This could be because the current study involved two experienced neurologists working with patients in the neurological intensive care unit, which significantly improved the examination's accuracy.

This also confirms the importance of practical training of physicians in the use of the scale to reduce bias.

The scale showed a high resistance to time-related errors (Spearman correlation coefficient *R*=0.99, *P*<0.0001), which indicates the short time required for assessment and is one of the advantages of the scale, along with its accessibility and simplicity. Thus, the tool can be used not only in scientific research but also in routine clinical practice.

The elements of the scale were found to be highly balanced with α=0.87 (*P*<0.0001) and ICC=0.87 (*P*<0.0001), which also emphasizes the reliability of the scale.

The scores of the Russian version of the FOUR scale were highly consistent. All of this confirms the primary goal of the developed FOUR scale, which is to meet the need for simple and rapid assessment of all major neurological signs in patients with acute disorders of consciousness. The scale does not assess the verbal modality, but it provides a good assessment of eye movements, brainstem reflexes and respiratory pattern in ventilated patients.

The Russian version of the FOUR scale is available in the appendix and on the website of the International Scale and Questionnaire Validation Group of the Research Center for Neurology https://neurology.ru/o-centre/struktura/institut-neyroreabilitatsii-i-vosstanovitelnykh-tekhnologiy/gruppa-validatsii-mezhdunarodnykh-shkal-i-oprosnikov/?ysclid=lo46dsgpr9826437705.

Conclusion

We completed all necessary validation steps for the Russian version of the FOUR (Full Outline of Unresponsiveness) scale. The scale psychometric properties of the scale were evaluated and found to be highly reliable and valid. This version is recommended for use in research and clinical settings.

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