Research Article

https://doi.org/10.23934/2223-9022-2023-12-2-202-209

The Comorbidities Coma Scale (CoCoS): Assessment of Psychometric Properties

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INTRODUCTION An increase in the survival rate of patients with severe brain injuries of various origins determines the relevance of the search for approaches to assessing the prognosis of changes in the state of patients with chronic disorders of consciousness (CDC). Concomitant diseases are predictors of the recovery of consciousness and functional independence of patients with CDC. To assess the impact of the level of comorbidity on the prognosis of the patient state, the Comorbidities Coma Scale (CoCoS) is used abroad. However, the lack of a Russian-language version of this scale limits the practical and scientific areas of work with this category of patients.

THE AIM of the study was to evaluate the psychometric properties of the developed Russian version of the Comorbidities Coma Scale (CoCoS).

MATERIALS AND METHODS As part of the validation study, an assessment of psychometric properties (reliability, validity, sensitivity) was performed on a group of 52 adult patients with traumatic (18/52) and non-traumatic (34/52) brain damage.

RESULTS High levels of validity and reliability were obtained (the Spearman's Rank Correlation Coefficient r=0.98 ($p<0.0001$), Cronbach's alpha α=0.73 ($p<0.001$), Cohen's kappa κ=0.72 ($p<0.0001$)). However, when evaluating the CoCoS sensitivity, there were no statistically significant changes in the parameters ($p=0.316$).

CONCLUSION In the present study, a sufficient level of psychometric properties of the Russian-language version of the CoCoS was obtained, which opens up the possibility of a quantitative assessment of comorbidities in unresponsive patients both in scientific research and clinical practice. The scale is available for download on the website of the Group for Validation of International Scales and Questionnaires of the Research Center of Neurology.

Keywords: CoCoS, chronic disorders of consciousness, comorbidity, validation

For citation Suponeva NA, Kirichenko OA, Yatsko KA, Zimin AA, Legostayeva LA, Sergeev DV, et al. The Comorbidities Coma Scale (CoCoS): Assessment of Psychometric Properties. *Russian Sklifosovsky Journal of Emergency Medical Care*. 2023;12(2):202–209. https://doi.org/10.23934/2223-9022-2023-12-2-202-209 (in Russ.)

Conflict of interest Author declare lack of the conflicts of interests

Acknowledgments, sponsorship The study has no sponsorship

The authors would like to express their deepest gratitude to the staff of the Department of Anesthesiology and Intensive Care with Resuscitation and Intensive Care Units of the Research Center of Neurology for assistance in data collection and analysis

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CDC – chronic disorder of consciousness
CNS – central nervous system
CoCoS – Comorbidities Coma Scale
MCS – minimally conscious state
UWS/ VS – unresponsive wakefulness syndrome/ vegetative state

INTRODUCTION

In clinical practice, the presence of consciousness in a patient is determined by the preservation of its two main components: wakefulness and awareness of self and the surrounding reality [1]. A condition in which a patient recovers from a coma due to severe brain damage in the absence of complete or partial contact with the environment is referred to as a chronic disorder of consciousness (CDC) [2, 3]. Chronic disorders of consciousness are represented by unresponsive wakefulness syndrome/vegetative state (UWS/VS), in which there is no reaction to surrounding events [4], and minimally conscious states (MCS) "minus" and "plus" with partial restoration of awareness [5, 6].

The use of improved methods of intensive care in the treatment of patients with severe traumatic and non-traumatic brain injuries has led to a significant increase in the survival rate of this category of patients. In this regard, it has become relevant at present to predict prognosis in patients with CDC. In addition to the clinical picture and a number of neurophysiological and neuroimaging signs [7–9], the main factors influencing the prognosis for both survival and recovery of cognitive functions include comorbidities and the degree of their compensation, as well as the presence of complications [10, 11], which emphasizes the importance of providing proper care (caring for a tracheostomy, if any, timely sanitation of the tracheobronchial tree, turning every two hours, preventing the formation of contractures, etc.), and carrying out rehabilitation treatment in a volume accessible to the patient (physiotherapy exercises, passive gymnastics, massage, verticalization). Taking into account the complexity of organizing follow-up of patients with CDC for a long time, investigating the contribution of specific factors to the prognosis of the outcome of these conditions is not an easy task. Until

recently, there has been no validated tool specifically designed to assess the impact of complications and comorbidities on prognosis in patients with CDC. To solve this problem, in 2019, the staff of the Department of Biotechnological and Applied Clinical Sciences, Neurological Institute, University of L'Aquila (Italy) developed an evaluation tool – the Comorbidities Coma Scale (CoCoS) [12, 13].

The developers of the scale conducted a study of the reliability and validity of the CoCoS in patients in coma, UWS/ VS and MCS due to traumatic and non-traumatic brain damage [13]. At the moment, according to information from the available databases (PubMed, Best Evidence), this validation study has been the only one.

The lack of a validated version of the scale for the Russian-speaking population limits its use within the framework of a single approach and does not allow comparing the results obtained with the assessment data of other researchers. The development of the official Russian-language version of the scale will provide an opportunity to use this tool to assess the impact of complications and comorbidities on the prognosis of patients with CDC. Previously, the first stage of validation was carried out - linguocultural adaptation of the scale for the Russian-speaking population [14]. Forward and backward translations of the scale were performed, followed by assessment of the developed version by an expert panel with the participation of an expert translator who had not previously participated in the work on the scale's translation. This article describes the results of the second stage of validation - evaluation of the psychometric properties of the Russian version.

The aim of the study was to assess the psychometric properties of the Russian version of the Comorbidities Coma Scale which had previously undergone linguocultural adaptation [14] – the first stage of the validation study.

MATERIAL AND METHODS

The second stage of the validation of international scales consists of assessing their psychometric properties: reliability, validity and sensitivity. Experienced neurologists who were trained to use CoCoS participated in the examination of patients with CDC and filling out the CoCoS evaluation protocol. The results of the first neurologist were designated as "A", the second - as "B". The data obtained, according to chronological order, were designated as follows: "A1" - the first assessment by the first neurologist, "B1" - the first assessment by the second neurologist, "A2" - the second assessment by the first neurologist, and "A3" - the third assessment by the first neurologist.

The reliability of the scale reflects its resistance to various measurement errors and includes a number of parameters [15, 16], among which the following were evaluated in this study: the reproducibility of the CoCoS, as well as its internal and interrater consistency.

The reproducibility of the scale, that is, its resistance to errors associated with the time factor, was assessed by the test-retest method (A1–A2). This method is based on the correlation between scores obtained from two examinations of the same patient with an interval of two hours in the absence of changes in the patient's condition. The internal consistency of the scale shows the degree of correlation of assessments between all points on the scale. To assess this characteristic of the scale, the generally accepted criterion - the Cronbach's alpha coefficient - was used, and it was taken into account that the acceptable value of the criterion was 0.7 or more. Interrater consistency characterizes the degree of divergence in the assessments of two different researchers during examination of the same patient, carried out at intervals of one day with unchanged symptoms (A1-B1). To assess the agreement between the two raters, the Cohen's kappa coefficient was used, a sufficient level of which was considered to be from 0.7 and above.

Validity is the capability of a scale to evaluate exactly those characteristics for which the scale was created. The study of the CoCoS validity included an assessment of content validity which reflects how the points of the scale correspond to the semantic component embedded in it. This parameter was investigated by peer review.

Another important psychometric property of the scale is **sensitivity**, that is, the ability to detect dynamics in the patient's condition. To assess sensitivity, we compared CoCoS values (A1–A3) at the time of the first and subsequent examinations after 2 weeks (Fig. 1).

Fig. 1. Scheme of the second stage of the validation study of the CoCoS (assessment of psychometric properties)

STATISTICAL DATA ANALYSIS

The size of a representative sample was determined in accordance with generally accepted recommendations [17]. The size of the CoCoS group consisting of 52 people was sufficient, assuming a deviation of the sample mean from the theoretically true one by 3.2%, which, taking into account the range of possible scores on this scale from 0 to 100% points, suggests a sufficient number of subjects.

The study involved 52 patients with CDC (31 men, 21 women), the causative factors were traumatic (n=18) and non-traumatic (n=34) injuries of the central nervous system (CNS).

The results obtained during the study did not correspond to a normal distribution, which required the use of nonparametric methods of statistical analysis. When studying the psychometric properties of the scale, the following statistical methods were used: the reproducibility and criterion-related validity of the scale were evaluated using the Spearman's rank correlation coefficient; internal and interrater consistency, as mentioned above, by means of Cronbach's alpha and Cohen's kappa coefficients, respectively; sensitivity - using the Wilcoxon signed rank test. The Kruskal-Wallis test was used to compare the parameters of the groups. When evaluating the ratio of patient distribution by sex, Fisher's exact test was used. In all cases of testing hypotheses, $p<0.05$ was considered a statistically significant level of difference. Statistical data processing was carried out using the IBM SPSS Statistics 22.

RESULTS

Characteristics of patients participating in the study. The sample is represented by patients with UWS/ VS (24/52) and MCS (28/52) older than 18 years. The median age in the whole group was 32 (25.0–48.5) years, in the group with traumatic CNS injury – 25.5 (22.8–32.8) years, with non-traumatic CNS injury – 32.0 [25– 48.5] years, respectively (hereinafter, the data are presented as the median and interquartile interval — Me [IQR]). The median duration of the injury was 32.5 (20.0–71.3) weeks in the total sample: 56 (32.8–98.8) weeks for traumatic CNS injury and 25 (12.0–52.0) weeks for non-traumatic CNS injury. A more frequent causative factor of the CDC development in the study sample was non-traumatic CNS damage (34/52). All scores (A1, B1, A2, A3) were performed in all the patients. The characteristics of the patients participating in the study are presented in Table 1.

Table 1

Characteristics of patients with chronic disorders of consciousness included in the study

Injury type	Duration of injury, weeks	Age, years	Coma Recovery Scale-Revised (CRS-R), points
Traumatic (n=18)	56.0 (32.8–98.8)	25.5 (22.8–32.8)	10.5 (6.5–14.8)
Non-traumatic (n=34)	25.0 (12.0–52.0)	43.0 (27.8–55.0)	7.0 (6.0–12.0)
Whole sample (n=52)	32.5 (20.0–71.3)	32.0 (25.0–48.5)	9.0 (6.0–13.0)
p-value	0.003*	0.002*	0.126

Notes: * — statistically significant. The data are presented as Me (IQR) — median and interquartile range. To compare the parameters of the groups (traumatic, non-traumatic injuries of the central nervous system and the entire sample), the Kruskal–Wallis test was used

PSYCHOMETRIC PROPERTIES OF THE RUSSIAN VERSION OF THE COCOS

Reliability. Spearman's rank correlation coefficient reflecting retest reliability (A1–A2) was r=0.98 (p<0.0001, statistically significant), which indicates a very strong correlation between the results of repeated assessments (Fig. 2). This confirms the resistance of the Russian version of the CoCoS to errors associated with the time factor, since after the control time interval (120-180 minutes) the corresponding estimates did not change statistically significantly.

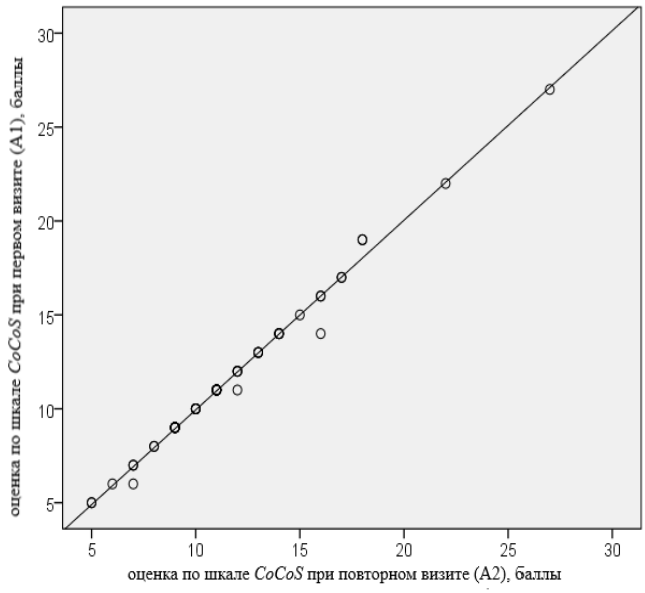

Fig. 2. Test-retest reliability — correlation between the first researcher's scores (A1) and (A2)

The calculation of the **internal consistency** of the CoCoS showed that the Cronbach's alpha value was α=0.73 (p<0.001, statistically significant), which satisfies the requirements for this indicator [18]. The analysis of **interrater reliability** (A1-B1) revealed that the Cohen's kappa coefficient was at the level of 0.72 (p<0.0001, statistically significant), which meets the requirements for this indicator (Fig. 3).

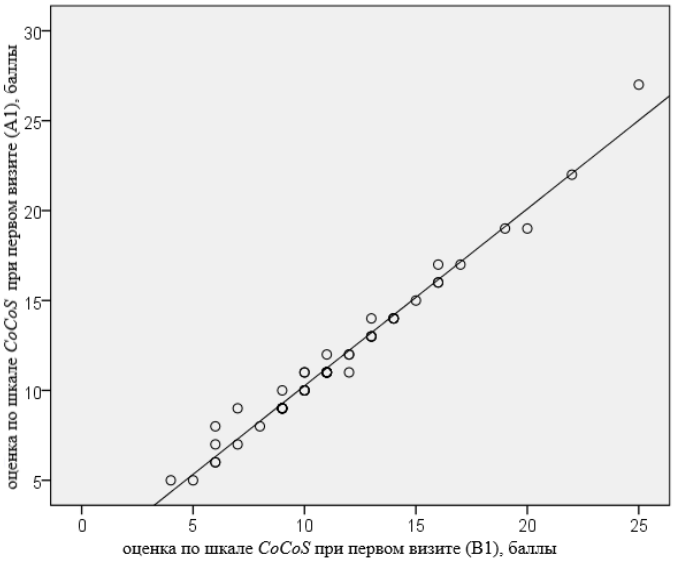

Fig. 3. Inter-rater reliability — the correlation between the scores of the first and second researchers (A1) and (B1)

Validity. According to the results of the expert assessment of the content of the scale by specialists (researchers A and B, directly involved in the study), a high degree of representativeness of the test tasks' content with the psychometric properties' measured area was revealed.

The **sensitivity** of the scale included comparing the results of assessments at the first and repeated examinations and testing the hypothesis that this scale can detect changes in the degree of comorbidity in this category of patients. Calculations using the Wilcoxon signed rank test (Fig. 4) showed that by the time of the third evaluation by the first researcher (A3), there were no statistically significant changes in the CoCoS scores (p=0.316).

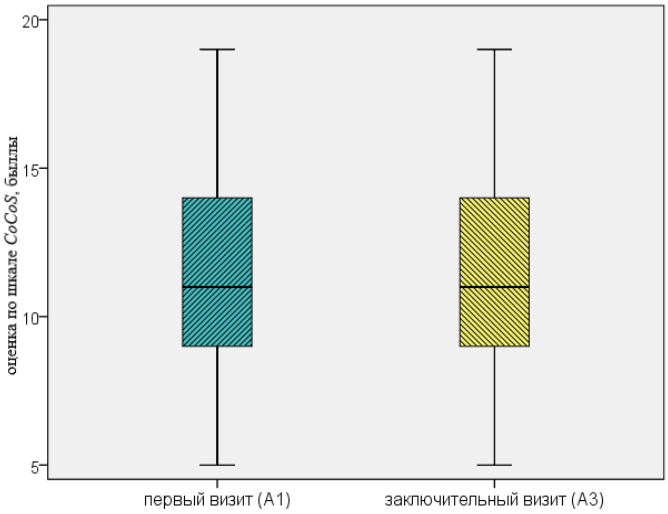

Fig. 4. Dynamics of indicators on the CoCoS during repeated examinations

DISCUSSION

One of the key problems in the management of patients with CDC is comorbidities, which play an important role in determining the prognosis and potential outcome [19, 20]. Until now, there has been no special tool available in Russian that would allow assessing the degree of comorbidity in patients with chronic impairment of consciousness.

As part of the previously carried out linguocultural adaptation of the CoCoS, no significant difficulties were identified when filling out the scale, and the high quality of the text translation and the expediency of its application in clinical practice were also shown.

At the second stage of validation, psychometric properties - reliability, validity and sensitivity - were assessed (Table 2). Spearman's rank correlation coefficient was 0.98, which indicates high reliability. Cronbach's alpha was 0.73. The Cohen's kappa coefficient for interrater reliability was 0.72, indicating a good degree of consistency. The expert assessment of validity demonstrated a high degree of compliance of the criteria used with the measured indicators.

Table 2

Psychometric properties of the Russian version of CoCoS

Parameter	Parameter elements	Assessment Method	Criteria threshold/p	Result	
				criterion	p-value
Reliability	Reproducibility (A1–A2)	The Spearman correlation	Over 0.8	0.98	<0.0001
	Internal consistency (A1)	Cronbach's alpha	Over 0.7	0.73	<0.001
	Interrater reliability (A1–B1)	Cohen's kappa	Over 0.7	0.72	<0.0001
Validity	Content validity	Expert examination	No		
Sensitivity (A1–A3)		The Wilcoxon signed-rank test	p-value under 0.05	1.24	0.316

Notes: * — statistically significant

When assessing sensitivity, the p-value was 0.316, which indicated the absence of statistically significant changes in the condition of patients during the observation period of 2 weeks. It can be assumed that this is a consequence of the stable patient condition, as well as the absence of decompensation of concomitant diseases. Therefore, the use of the CoCoS is possible in clinical practice to assess objective changes in comorbidity indicators.

The obtained results confirm that the Comorbidities Coma Scale is a reliable and sensitive tool for assessing the influence of a large number of factors on the course of the disease, controlling over the decompensation of concomitant diseases, as well as identifying complications, which is necessary in tracking the dynamics and predicting outcomes in patients with CDC.

The Russian version of the Comorbidities Coma Scale can be found via the QR code and on the website of the Group for Validation of International Scales and Questionnaires of the Research Center of Neurology https://www.neurology.ru/reabilitaciya/centr-validacii-mezhdunarodnyh-shkal-i-oprosnikov.

CONCLUSION

The Russian version of the CoCoS is characterized by a high level of psychometric properties, high retest reliability, and good interrater reliability. The Comorbidities Coma Scale can be used in both research and clinical assessment of comorbidity in patients with chronic impairment of consciousness.

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Received on 16.02.2023

Review completed on 13.04.2023

Accepted on 28.03.2023