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ORIGINAL ARTICLE

Translation to Serbian, Transcultural Adaptation and Validation of the Confusion Assessment Method for the Intensive Care Unit (CAM- ICU)

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ABSTRACT

Aim: CAM- ICU is instrument for brief delirium screening in the intensive care unit (ICU) for ventilated and non-ventilated patients. The aim of this study was to translate, validate and evaluate the applicability of this instrument in the Serbian speaking area.
Methods: Translation of the CAM-ICU was made according to International Society for Pharmacoeconomics and Outcomes Research guidelines. In this prospective cohort study, CAM-ICU was applied to 301 adult surgical ICUs by two different raters. We tested CAM-ICU for interrater reliability by correlation between them. The scale was validated by comparison with the reference evaluation, wich was done by a psychiatrist using the Diagnostic and Statistical Manual of Mental Disorders V (DSM-V). Interrater agreement was measured using weighted kappa (k) and correlation used Spearman´s test.
Results: The Spearman correlation coefficient was highly significant for rater 1 (r=0.672, p<0.001) and for rater 2 (r=0.625, p<0.001). The inter-rater reliability expressed by the kappa coefficient between rater 1 and rater 2 was highly significant (k= 0.859, 95% CI, 0.910-0.99, p<0.001).
Conclusion: CAM- ICU, the first validated instrument for early detection of delirium in the Serbian speaking area, is reliable, valid and easily applied in daily clinical practice.

INTRODUCTION

Delirium is an acute or sub acute, mostly reversible syndrome of damage of higher cortical functions which manifests itself as a generalized disorder.[1] It is most frequent in surgical patients, especially in intensive care units (ICU), and also in intensive care units in general hospitals, hospices and retirement homes.[2] During hospitalization, between 11% and 25% of elderly patients suffer from delirium, while 29-31% of hospitalized elderly patients admitted without delirium develop delirium during their hospital stay.[2] Ely and others report a delirium frequency of over 80% among ICU patients.[3-5] General frequency was estimated to be between 11 and 42%, with a rough clinical estimate that one in 5 hospitalized patients will suffer from delirium in one hospitalization period.[1] Patients with delirium have higher mortality rate, they stay longer in hospitals, their treatment is significantly more expensive, and they have high institutionalization rates after the end of hospital treatment.[5-7] Despite its great clinical significance, a delirium diagnosis is frequently overlooked if valid instruments are not used as a part of the routine patient evaluation.[8,9]

CAM ICU is a valid instrument for brief delirium screening in the ICU for ventilated and non-ventilated patients.[3] It is easily applied by non-psychiatric staff after not-so-demanding training and it requires only several minutes to implement.[10] These particularities classify it as the most used and most translated delirium detection instrument which has been validated in many languages and cultural milieus.[11]

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The aim of our study was to translate, validate and assess the applicability of this instrument in the Serbian speaking area and cultural milieu.

MATERIALS AND METHODS

Translation and Cultural Adaptation

We have translated CAM ICU and adapted it culturally according to International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines.[12] Permission for translation of CAM ICU (version wit) from English into Serbian was granted by the author of the original scale. The original scale was first translated into Serbian by two independent translators, who were not members of the study team. They translated the scale independently of each other, and then the translations were harmonized into one Serbian translation at the meeting of the study investigators and the translators. The harmonized Serbian translation was then translated back into English by a native English speaker. When translated back into English, the translator was not aware of the original English version of the CAM ICU. The back-translation into English was then compared with the original English version by the study investigators, and at the new meeting of investigators the final Serbian translation of the CAM ICU was agreed on. The final translation of CAM ICU into Serbian was then tested on 5 physicians for clarity and comprehension. After the pilot, a few minor changes were made, and then the final Serbian translation of CAM- ICU was copied and prepared for inter-rater reliability and validity testing (www.icudelirium.org).

Population

In this prospective study we made cohort which included 301 ICUs patients of the Clinical Center of Serbia in Belgrade – Post-anesthesia intensive care (PAIC) of the Clinic for abdominal surgery, PAIC Orthopedic clinic and PAIC Abdominal surgery department of the Emergency Center. Subjects were recruited by using a successive sampling method, in such a way that the sample included all artificial ventilated and non-ventilated patients, whose stay in the PAICU was longer than 24 hours, and which were treated in the period from 02/02 – 12/03/2015. The study excluded comatose and soporose patients, as well as patients who had previously been diagnosed as delirious and were already taking anti-psychotic therapy.

Validation and Inter-rater Reliability

Two examiners applied the Serbian translation of the Confusion Evaluation Method in the ICU, independently from one another. The diagnosis of a psychiatric specialist based on diagnostic criteria of the currently valid disease classification system Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM V) was the golden standard.[13] All examiners performed patient evaluation in the same time interval (from 8 to 11h) in order to avoid the influence of the time of day on the fluctuation of the mental status of patients. The results of the Serbian translation of CAM-ICU were compared with the delirium diagnosis given by a psychiatric specialist based on DSM V criteria as the golden standard. Inter-rater variability of the instrument was examined by comparing scores of the Serbian translation of CAM ICU obtained by the two examiners.

Before and during the study period, all examiners completed training for the application of the CAM-ICU scale.

Statistical Analysis

Descriptive statistics was used to describe the basic features of data in the study (mean, range for continuous variables; number, percentage for categorical variables). To validate the Serbian translation of CAM-ICU sensitivity (true positive/[true-positive + false-negative]), specificity (true-negative/[false-positive + true-negative]), positive predictive value (true-positive/[true-positive+ false-positive]), and negative predictive value (true-negative/[false-negative + true-negative]) were calculated. We assessed inter-rater reliability using Cohen's kappa coefficient and intra class correlation coefficient. Correlation of CAM-ICU and DSM-V was estimated by Spearman correlation coefficient. SPSS 20.0 software package was used to analyze all the data.

RESULTS

Throughout the study period, all 301 patients, included in the study, were rated, and 522 observations were performed.

Basic characteristics of subjects are shown in Table 1. Out of the total number of subjects, 153 (50.8%) were male. The average age of subjects was 61, 183 (60.8%) subjects were electively operated, and 86 (28.6%) of them were in mechanical ventilation. According to DSM-V criteria, 38 (12.5%) subjects developed delirium.

Patients were evaluated only during their stay in the PAIC unit. The number of paired observations performed by the two raters was 522. The sensitivity of the used CAM- ICU in comparison with the golden standard was 72.5% for rater 1 and 70.5% for rater 2. Specificity of the instrument was 96.4% for rater 1 and 95.7% for rater 2. Positive predictable value for both raters was 79.5%, i.e. 75.3%, while the negative predictive value of the instrument was 94.9% for rater 1 and 94.6% for rater 2 (Table 2).

The degree of concurrence of the clinical diagnosis with the diagnosis detected by the instrument, expressed by the Spearman correlation coefficient was highly significant for rater 1 ($r=0.672$, $p<0.001$) and for rater 2 ($r=0.625$, $p<0.001$) (Table 3).

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The inter-rater reliability expressed by the kappa coefficient between rater 1 and rater 2 was highly significant (k= 0.859, 95% CI, 0.910-0.99, p<0.001) (Table 4).

DISCUSSION

Our study has shown that the Serbian translation of the CAM- ICU is reliable, has a high inter-rater reliability, it is valid, sensitive and highly specific. Similar results were published by foreign authors as well. Results of meta- analysis from 2012[14] report high sensitivity of 80% (77.1-82.6%) and specificity of CAM -ICU of 95.9% (94.8-96.8%), which is in accordance with our findings. Similar results, confirming that CAM - ICU is a valid, sensitive and specific instrument, were published later by Japanese, Thai and American authors.[15-17]

The degree of concurrence of diagnosis between the two raters in our study, expressed with the k coefficients, was 0.859. Similar findings were obtained during validation of other language versions (original English version, Spanish, Korean, Greek, Italian, Thai, and Japanese).[3,11,15,16,18-20]

Table 1: Baseline characteristic of patients

Characteristic	Number
Age, mean (range) years	61 (19-93)
Sex	
Male, n (%)	153 (50.8)
Female, n (%)	148 (49.2)
Mechanical ventilation	
Present, n (%)	86 (28.6)
Absent, n (%)	215 (71.4)
Surgery	
Emergency, n (%)	118 (39.2)
Elective, n (%)	183 (60.8)
DSM-IV, n (%)	38 (12.5)

Table 2: Validity of Serbian CAM-ICU (sensitivity, specificity, positive and negative predictive value of CAM-ICU)

	Rater 1	Rater 2
Sensitivity (95% CI)	72.5 (61.4-81.9)	70.5 (59.1-80.3)
Specificity (95% CI)	96.4 (94.2-98.0)	95.7 (93.3-97.4)
Positive predictive value (95% CI)	79.5 (68.4-88.0)	75.3 (63.9-84.7)
Negative predictive value (95% CI)	94.9 (92.3-96.7)	94.6 (92.0-98.5)

Table 3: Correlation of CAM-ICU and DSM-IV

	Spearman correlation coefficient (p-value)
Rater 1	0.672 (p<0.001)
Rater 2	0.625 (p<0.001)

Table 4: Inter-rater reliability of Serbian CAM-ICU

Patients	ICC (95% CI)	k (p-value)
All	0.924 (0.910-0.936)	0.859 P<0.001

k – Kappa coeffcient, ICC – intraclass correlation coeffcient

LIMITATIONS OF THE STUDY

Our study has several potential limitations. First, our team consisted of only three members. Second, it seems that the degree of concurrence between raters was getting increasingly better as examination progressed, which indicates that their training could have been longer. Third, a small number of observations when compared to the total number of rated examiners were the consequence of short-term admittance in the PAICU due to death or transfers to other departments.

CONCLUSION

CAM- ICU, the first validated instrument for early detection of delirium in the Serbian speaking area, is reliable, valid and easily applied in daily clinical practice. Apart from the fact that it is applied in a very short time, it can be used by members of the intensive care staff who are not doctors or psychiatrists. As such, it is suitable for quick diagnosis and monitoring of delirious critically ill patients. Its use may result in rapid beginning of causal treatment of delirious patients, which is a prerequisite for reducing the number of bad outcomes, including patient death.

ETHICS

The study has been approved by the local Ethics Committee. Written informed consent was obtained from patients or proxies.

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