ORIGINAL ARTICLE

The validation and inter-rater reliability of the Serbian translation of the Richmond agitation and sedation scale in post anesthesia care unit patients

Stasevic Karlicic I[1], Stasevic M[1], Jankovic S[2], Djukic Dejanovic S[1,3], Dutina A[1], Grbic I[1]

[1]Clinic for Psychiatric Disorders "Dr Laza Lazarevic", Emergency Department, Belgrade
[2]University Clinic for Pharmacology, Toxicology and Clinical Pharmacology, Faculty of Medical Sciences
[3]Faculty of Medical Sciences, University of Kragujevac, Kragujevac
Serbia

Abstract

Background: Targeted light sedation is recommended because it shortens the time of mechanical ventilation and the length of stay in an intensive care unit (ICU). However, there is no validated scale for sedation and agitation in ICU in the Serbian speaking area. The aim of the current study was to validate, verify the reliability and enable the application of the Richmond Agitation and Sedation Scale (RASS) in the Serbian speaking area.

Methods: In this prospective cohort study, RASS was applied to 301 adult patients hospitalized in surgical ICUs by two different research team members. We tested RASS for inter-rater reliability by the correlation between them. The scale was validated by comparison to Glasgow Coma Scale (GCS) scores which was applied by the third investigator. Inter-rater agreement was measured using weighted kappa (k) and for correlation Spearman's test was used.

Results: The inter-rater reliability of the scale was high (k >0.7). The degree of correlation between the RASS and the GCS during all five days of observation was high (>0.7 for both investigators, the fifth day). In all the cases, Spearman's correlation coefficient was highly significant ($p < 0.01$).

Conclusions: The Serbian translation of the RASS is a reliable and valid instrument for the assessment of the levels of sedation and agitation with patients in ICU. Hippokratia 2016, 20(1): 50-54

Keywords: Richmond Agitation and Sedation Scale, intensive care unit, inter-rater reliability, validity

Corresponding Author: Ivana Stašević, Clinic for Psychiatric Disorders "Dr Laza Lazarević", 26 Višegradska street, Belgrade, tel: +38163222832, e-mail: ivanastasevic73@gmail.com

Introduction

Sedation is an integral part of treatment in an intensive care unit (ICU)[1,2]. The protocols of targeted light sedation shorten the time of mechanical ventilation and the length of stay in ICU, and they are significant for preventing and treating delirium[3-7]. In order to improve the outcome of the patients' treatment, it is recommended that a standardized protocol of analgesia and sedation should be introduced, which also includes the application of validated scales for the assessment of sedation[8-12].

The Richmond Agitation-Sedation Scale (RASS) is a suitable staff-scored instrument for application by the hospital bed for the purpose of monitoring the levels of sedation and possible changes in the behavior of critically ill patients in ICU[13-15].

The aim of this study was to validate, verify the reliability and enable the application of the RASS in the Serbian speaking area and cultural milieu.

Material and Method

Instrument description

The RASS is a ten-level scale developed by a multidisciplinary team at Virginia Commonwealth University in Richmond (Table 1)[13]. Four levels denote the levels of anxiety or agitation [from +1 to +4 (combative)], one level denotes calm and alert state (0), and five levels denote the levels of sedation [from -1 to -5 (unarousable)][13,16]. The Serbian translation of the values and definitions for each level of agitation and sedation, as well as the instructions for assessment, are displayed in Table 2. Excellent inter-rater reliability has been demonstrated for the RASS on a large sample of adult patients in three surgical ICUs, as well as excellent validity in comparison to selected scales for the assessment of sedation[13,14,16,17].

Translation

Translation and cultural adaptation of the RASS were made according to the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guide-

Table 1: The Richmond Agitation and Sedation Scale (RASS) [authors have permission from Delirium Group from Vanderbilt University for CAM-ICU, which is RASS an integral part of, and it can be found on the their site www.icudelirium.org – section CAM-ICU Resources in Additional Languages (Serbian)].

Score	Level	Description
+4	Combative	Overtly combative or violent; immediate danger to staff
+3	Very agitated	Pulls on or removes tube(s) or catheter(s) or has aggressive behavior toward staff
+2	Agitated	Frequent non-purposeful movement or patient-ventilator dyssynchrony
+1	Restless	Anxious or apprehensive but movements not aggressive or vigorous
0	Alert and calm	
-1	Drowsy	Not fully alert, but has sustained (more than 10 seconds) awakening, with eye contact, to voice
-2	Light sedation	Briefly (less than 10 seconds) awakens with eye contact to voice
-3	Moderate sedation	Any movement (but no eye contact) to voice
-4	Deep sedation	No response to voice, but any movement to physical stimulation
-5	Unarousable	No response to voice or physical stimulation

Procedure

1. Observe patient. Is patient alert and calm (score 0)?
   Does the patient have behavior that is consistent with restlessness or agitation score +1 to +4 using the criteria listed above, under Description)?
2. If the patient is not alert, in a loud speaking voice state patient's name and direct patient to open eyes and look at speaker. Repeat once if necessary. Can prompt patient to continue looking at speaker.
   Patient has eye opening and eye contact, which is sustained for more than 10 seconds (score -1).
   Patient has eye opening and eye contact, but this is not sustained for 10 seconds (score -2).
   Patient has any movement in response to voice, excluding eye contact (score -3).
3. If the patient does not respond to voice, physically stimulate patient by shaking shoulder and then rubbing sternum if there is no response to shaking shoulder.
   Patient has any movement to physical stimulation (score -4).
   Patient has no response to voice or physical stimulation (score -5).

lines[18]. 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 version at the meeting of the study investigators and the translators. The harmonized Serbian version was then translated back into English by a native English speaker who was not aware of the original English version of the RASS. 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 version of the RASS was agreed on. The final translation of RASS into Serbian was then tested on five physicians for clarity and comprehension.

Table 2: Serbian translation of the Richmond Agitation-Sedation Scale (RASS) and procedure for its assessment.

Skor	Nivo	Opis
+4	Ratoboran	Ratoboran, nasilan, neposredno opasan po osoblje
+3	Vrlo agitiran	Čupa tubuse ili katetere; agresivan prema osoblju
+2	Agitiran	Česti nesvrsishodni pokreti, udara ventilator
+1	Uznemiren	Napet ili preplašen, pokreti nisu agresivni
0	Budan i miran	
- 1	Pospan	Nije potpuno budan, ali ga je moguće probuditi glasom (otvaranje očiju i kontakt očima duži od 10 sekundi)
-2	Lako sediran	Nakratko se budi na glas (otvorene oči i kontakt očima kraći od 10 sekundi)
-3	Srednje sediran	Pokretanje ili otvaranje očiju na glas (bez kontakta očima)
-4	Duboko sediran	Ne reaguje na glas, ali se pokreće ili otvara oči na fizičku stimulaciju
-5	Bez svesti	Ne reaguje na glas, niti na fizičku stimulaciju

Instrukcije za procenu

1. Opserviraj pacijenta. Da li je pacijent budan i miran (skor 0)?
   Da li se pacijent ponaša na način koji ukazuje na uznemirenost ili agitaciju (skoruj od +1 do +4 korišćenjem kriterijuma nabrojanih u opisu)?
2. Ako pacijent nije budan glasno pozovi pacijenta po imenu i naloži mu da otvori oči i pogleda u ispitivača. Ponovi još jednom ako je neophodno. Dozvoljeno je podsticanje pacijenta da nastavi da gleda u ispitivača.
   Pacijent otvara oči i održava kontakt očima duže od 10 sekundi (skor -1).
   Pacijent otvara oči i održava kontakt očima, ali kraće od 10 sekundi (skor -2).
   Pacijent ima neki pokret kao odgovor na glas, ali ne uspostavlja kontakt očima (skor -3).
3. Ako pacijent ne reaguje na glas, fizički stimuliši pacijenta drmusanjem za ramena, a ako nema odgovora primeni pritisak na sternum.
   Pacijent ima neki pokret na fizičku stimulaciju (skor -4).
   Pacijent ne reaguje na glas, niti na fizičku stimulaciju (skor -5).

Table 3: Baseline characteristic of the 301 adult patients hospitalized in surgical intensive care units that the Richmond Agitation-Sedation Scale was applied to.

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)
RASS, mean (SD)	-0.01 (0.68)
GCS, mean (SD)	14.54 (1.33)

n: number of patients, RASS: Richmond Agitation-Sedation Scale, GCS: Glasgow Coma Scale, SD: standard deviation.

After the pilot, a few minor changes were made, and then the final Serbian version of RASS was copied and prepared for inter-rater reliability and validity testing.

Population and settings of the study

This prospective cohort study included 301 patients from the surgical intensive care units of the Clinical Centre of Serbia in Belgrade; Post-Anesthesia Intensive Care Unit (PAICU) of the Abdominal Surgery clinic, PAICU of the Orthopedic clinic and PAICU of the Abdominal Surgery department of the Emergency centre. All of these ICUs had 12, 9 and 39 beds respectively. The study was approved by the local Ethical Committees of the clinics where the research was conducted (respectively; No 215/ 28.1.15. No 01- 446/ 6.2.15. No 695/ 19.2.15). We obtained written informed consent from all patients or their relatives. The respondents were recruited by the method of successive sampling. The sample included all ventilated and non-ventilated patients that had spent more than 24 hours in the PAICU and that were treated during the period from 2 February 2015 to 12 March 2015. Hearing-impaired and vision-impaired patients, as well as patients not speaking Serbian, were excluded from the study. The following variables were observed: age, gender, diagnosis, type of surgery (elective or emergency) and the presence of mechanical ventilation.

Rating

Two investigators, after three days' training time, independently of each other, applied the Serbian translation of RASS in an ICU. The rating was conducted during five days at the most, always in the same period of the day (from 03.00 p.m. to 05.00 p.m.), in agreement with the instructions defined by the same team that had developed and validated the scale in the English speaking area, already displayed in Table 1. There was no other formal training recommended by the author[13,14,16].

As gold standard the investigators evaluated the respondents in the same period, independently of other participants in the study. As well as in the studies of other validators[13,14,17], the Glasgow Coma Scale (GCS) has been used[19] as gold standard. It was applied by the anesthesiologists in ICUs where RASS was validated.

Validation and inter-rater reliability

The validation of the Serbian translation of the RASS was performed based on the comparison of the results obtained by applying this scale with the results obtained by applying the scale used as the gold standard.

The inter-rater reliability of the instrument was obtained as a result of comparing the scores of the Serbian translation of the RASS obtained by the two investigators.

Statistics

The inter-rater variability between the two raters was determined with the use of Cohen's kappa coefficient (k). The reliability of the questionnaire was assessed through the calculation of the coefficient of correlation between the score of the RASS scale and the score of the GCS; Spearman's correlation coefficient was used because the data were not normally distributed. For the statistical analysis, the Statistical Package for the Social Sciences (SPSS) software (IBM Corp., Armonk, NY, USA) version 18, with the level of statistical significance p =0.05, was used.

Results

The study included a total number of 301 respondents. The baseline characteristics of the respondents are shown in Table 3. The inter-rater reliability of the scale was high (k >0.7) (Table 4). The degree of correlation between the RASS and the GCS during all five days of observation was high (>0.7 for both raters, the fifth day). In all the cases, Spearman's correlation coefficient was highly significant (p <0.001) (Table 5).

Discussion

The only scale that measures the quantitative decrease in the level of consciousness, translated for the Serbian speaking areas is the GCS[20]. It is designed primarily for the needs of the clinical neurosurgical practice, for quantifying decreases in the level of consciousness in the patients who have experienced head traumas[19]. Due to a lack of other instruments, the GCS is widely used in neurological, psychiatric, surgical and general medical intensive care units. The introduction of the RASS in clinical practice enables the measurement of both quantitative level of consciousness and agitation level of patients hospitalized in ICU.

This is the first study of reliability and transcultural validation of the RASS in the Serbian speaking areas. Our study has shown a high degree of inter-rater reliability (r >0.7), which corresponds to the results of other similar studies (r =0.64-0.91)[11,13,14]. Furthermore, there has been a high degree of compliance with the "gold standard", i.e. the scores of the RASS from -5 to 0 are highly correlated with the scores of the GCS (r >0.7; p <0.001). Similar results have been obtained by other authors as well; Nassar et al (r =0.7; p < 0.001) and Elly (r =0.91; p <0.01)[14,17].

Table 4: Richmond Agitation-Sedation Scale (RASS) scores and inter-rater reliability testing after RASS implementation in an intensive care unit.

Population	RASS		Inter-rater reliability	
	Number	Mean ± SD	ICC (95% CI)	k*
All	301	0.01 ± 0.68	0.976 (0.970-0.981)	0.799
Age, yr				
≤60	128	-0.09 ± 0.58	0.989 (0.984-0.992)	0.855
>60	173	0.07 ± 0.71	0.958 (0.943-0.969)	0.664
Sex				
Male	153	0.03 ± 0.61	0.983 (0.977-0.988)	0.821
Female	148	-0.01 ± 0.74	0.961 (0.946-0.972)	0.727
Mechanical ventilation				
Present	86	0.06 ± 0.93	0.981 (0.971-0.987)	0.875
Absent	215	0.00 ± 0.55	0.970 (0.961-0.977)	0.762
Surgery				
Emergency	118	0.10 ± 0.63	0.974 (0.962-0.982)	0.862
Elective	183	-0.04 ± 0.70	0.976 (0.968-0.982)	0.840

SD: standard deviation, k: kappa coefficient, *: p <0.001, ICC: intraclass correlation coefficient, 95% CI: 95% confidence interval.

Table 5: Correlation of Richmond Agitation-Sedation Scale (RASS) and Glasgow Comma Scale (GCS).

	1st day	2nd day	3rd day	4th day	5th day
Rater 1	0.323	0.647	0.410	0.512	0.755
Rater 2	0.301	0.607	0.403	0.499	0.748

In the all cases the Spearman correlation coefficient is p <0.001.

In addition to being reliable and valid, the scale can be easily applied by the hospital bed, i.e. it can be applied by a large team of professionals (physicians and nurses) for a time shorter than 20 seconds, after simple training, through three steps: observation, verbal and physical stimulation[13,14]. In this way, the RASS scores the levels of sedation or agitation that are determined by the patient's response to physical/verbal stimulation. Apart from its extreme significance for determining the levels of sedation in patients for the purpose of finely titrating analgosedation therapy, the scale can also be used for the early detection of delirium in ICU patients[21,22]. It is known that there is a high degree of association between the presence of delirium and poor outcomes, including death in ICU patients[20,23,24]. In addition, the oversedation of patients in ICU correlates with adverse outcomes such as longer stay for treatment, delirium, and death[25]. The use of valid instruments, such as the RASS, contributes to easier and faster determination of the levels of sedation and thus to a more precise dosage of analgosedation[12,13,17,19,25]. Furthermore, as it easily detects and quantifies changes in behavior (from the calm state to extreme agitation), it can have wide application and significance in the early detection of delirium whose prevention contributes to better prognosis and treatment of critically ill patients[23,24,26]. It is especially practical for application in intubated patients because we can detect delirium even without a clinical psychiatric examination by using the RASS. A shortcoming of the instrument is that it cannot be applied to hearing impaired and vision impaired patients.

There are several potential limitations of our study. First, the investigators were only trained for a short period of time before applying the scale. Perhaps if our training had been longer, the inter-rater agreement could have been greater. Second, in the statistical analysis, we did not take into account the total number of observations, but we only compared the daily scores. Last, our team consisted of only three investigators.

In conclusion, the Serbian translation of the RASS has proved to be a reliable and valid instrument for the assessment of the levels of sedation and agitation of patients in ICU. Also, there has been a high degree of correspondence between the investigators. As such, it can be valuable in clinical practice, for the titration of the dose of analgosedation within the protocols and interventions aimed at reducing the adverse effects of oversedation and agitation on the further course of treatment and prognosis for seriously ill patients.

Conflict of Interest

Authors report no conflict of interest

References

1. Shehabi Y, Chan L, Kadiman S, Alias A, Ismail WN, Tan MA, et al; Sedation Practice in Intensive Care Evaluation (SPICE) Study Group investigators. Sedation depth and long- term mortality in mechanically ventilated critically ill adults: a prospective longitudinal multicentre cohort study. Intensive Care Med. 2013; 39: 910-918.
2. Yousefi H, Toghyani F, Yazdannik AR, Fazel K. Effect of using Richmond Agitation Sedation Scale on duration of mechanical ventilation, type and dosage of sedation on hospitalized patients in intensive care units. Iran J Nurs Midwifery Res. 2015; 20: 700-704.
3. Gommers D, Bakker J. Medications for analgesia and sedation in the intensive care unit: an overview. Crit Care. 2008; 12 Suppl 3: S4.
4. Skrobik Y, Ahern S, Leblanc M, Marquis F, Awissi DK, Ka-

vanagh BP. Protocolized intensive care unit management of analgesia, sedation, and delirium improves analgesia and subsyndromal delirium rates. Anesth Analg. 2010; 111: 451-463.
5. Strøm T, Martinussen T, Toft P. A protocol of no sedation for critically ill patients receiving mechanical ventilation: a randomised trial. Lancet. 2010; 375: 475-480.
6. Patel SB, Kress JP. Sedation and analgesia in the mechanically ventilated patients. Am J Respir Crit Care Med. 2012; 185: 486-497.
7. Ashkenazy S, DeKeyser-Ganz F. Assessment of the reliability and validity of the Comfort Scale for adult intensive care patients. Hear Lung. 2011; 40: e44-e51.
8. Sneyers B, Laterre PF, Perreault MM, Wouters D, Spinewine A. Current practices and barriers impairing physicians' and nurses' adherence to analgo-sedation recommendations in the intensive care unit-a national survey. Crit Care. 2014; 18: 655.
9. Barr J, Fraser GL, Puntillo K, Ely EW, Gélinas C, Dasta JF, et al; American College of Critical Care Medicine. Clinical practice guidelines for the management of pain, agitation, and delirium in adult patients in the intensive care unit. Crit Care Med. 2013; 41: 263-306.
10. Jacobi J, Fraser GL, Coursin DB, Riker RR, Fontaine D, Wittbrodt ET, et al; Task Force of the American College of Critical Care Medicine (ACCM) of the Society of Critical Care Medicine (SCCM), American Society of Health-System Pharmacists (ASHP), American College of Chest Physicians. Clinical practice guidelines for the sustained use of sedatives and analgesics in the critically ill adult. Crit Care Med. 2002; 30: 119-141.
11. Martin J, Heymann A, Bäsell K, Baron R, Biniek R, Bürkle H, et al. Evidence and consensus-based German guidelines for the management of analgesia, sedation and delirium in intensive care-short version. Ger Med Sci. 2010; 8: Doc02.
12. Mehta S, McCullagh I, Burry L. Current sedation practices: lessons learned from international surveys. Crit Care Clin. 2009; 25: 471- 488. vii-viii.
13. Sessler CN, Gosnell SM, Grap MJ, Brophy GM, O'Neal PV, Keane AK, et al; The Richmond Agitation-Sedation Scale: validity and reliability in adult intensive care unit patients. Am J Respir Crit Care Med. 2002; 166: 1338-1344.
14. Ely EW, Truman B, Shintani A, Thomason JW, Wheeler AP, Gordon S, et al. Monitoring sedation status over time in ICU patients: reliability and validity of the Richmond Agitation-Sedation Scale (RASS). JAMA. 2003; 289: 2983-2991.
15. Prottengeier J, Moritz A, Heinrich S, Gall C, Schmidt J. Sedation assessment in a mobile intensive care unit: a prospective pilot-study on the relation of clinical sedation scales and the bispectral index. Crit Care. 2014; 18: 615.
16. Sessler CN, Grap MJ, Brophy GM. Multidisciplinary management of sedation and analgesia in critical care. Semin Respir Crit Care Med. 2001; 22: 211-226.
17. Nassar Junior PA, Pires Neto RC, de Figueiredo WB, Park M. Validity, reliability and applicability of Portuguese versions of sedation-agitation scales among critically ill patients. Sao Paulo Med J. 2008; 126: 215-219.
18. Wild D, Grove A, Martin M, Eremenco S, McElroy S, Verjee-Lorenz A, et al; ISPOR Task Force for Translation and Cultural Adaptation. Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. Value Health. 2005; 8: 94-104.
19. Teasdale G, Jennett B. Assessment of coma and impaired consciousness. A practical scale. Lancet. 1974; 2: 81-84.
20. Republička stručna komisija za izradu i implementaciju vodiča u kliničkoj praksi. Akutni ishemijski moždani udar, Nacionalni vodič. Medicinski fakultet Univerziteta, Beograd. 2004; 1:10.
21. Bush SH, Grassau PA, Yarmo MN, Zhang T, Zinkie SJ, Pereira JL. The Richmond Agitation-Sedation Scale modified for palliative care inpatients (RASS-PAL): a pilot study exploring validity and feasibility in clinical practice. BMC Palliat Care. 2014; 13: 17.
22. Benitez-Rosario MA, Castillo-Padrós M, Garrido-Bernet B, Gonzáles-Guillermo T, Martinez-Castillo LP, Gonzáles A; Members of the Asocación Canaria de Cuidados Paliativos (CANPAL) Research Network. Appropriateness and reliability testing of the modified Richmond Agitation-Sedation Scale in Spanish patients with advanced cancer. J Pain Symptom Manage. 2013; 45: 1112-1119.
23. Eeles EM, Hubbard RE, White SV, O'Mahony MS, Savva GM, et al. Hospital use, institutionalisation and mortality associated with delirium. Age Ageing. 2010; 39: 470-475.
24. Mariz J, Santos NC, Afonso H, Rodrigues P, Faria A, Sousa N, et al. Risk and clinical-outcome indicators of delirium in an emergency department intermediate care unit (EDIMCU): an observational prospective study. BMC Emerg Med. 2013; 13: 2.
25. Brinkkemper T, van Norel AM, Szadek KM, Loer SA, Zuurmond WW, Perez RS. The use of observational scales to monitor symptom control and depth of sedation in patients requiring palliative sedation: a systematic review. Palliat Med. 2013; 27: 54-67.
26. Whittamore HK, Goldberg SE, Gladman JR, Bradshaw LE, Jones RG, Harwood RH. The diagnosis, prevalence and outcome of delirium in a cohort of older people with mental health problems on general hospital wards. Int J Geriatr Psychiatry. 2014; 29: 32-40.