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Translation and reliability of the Richmond Agitation-Sedation Scale in an Italian neurological intensive care unit: a pilot study

Mattia Martina, Elisabetta Rollo, Francesca Trevisi, Emilia Tricarico, Giulio Verrienti

Department of Neurorehabilitation, Casa di Cura Villa Verde, Lecce, Italy

Traduzione ed affidabilità inter valutatore della Richmond Agitation-Sedation Scale (RASS) in un reparto di terapia intensiva neurologica italiana: uno studio pilota

ABSTRACT

Introduction: among patients with acquired brain injuries, agitation is a frequent behavioral problem, which often requires the use of sedation. The Richmond Agitation-Sedation Scale (RASS) is commonly used to assess the level of alertness and agitated behavior in critically ill patients. The aims of this study were to translate the RASS into Italian and to test its inter-rater reliability among sedated patients in an Italian neurological Intensive Care Unit (nICU).
Materials and Methods: a translation (I-RASS) of the RASS from English into Italian was carried out. The inter-rater reliability testing was conducted in an Italian nICU. From May 2022 to October 2024, 21 sedated patients were included and evaluated using the I-RASS by four investigators; the inter-rater reliability was tested using intraclass correlation coefficient (ICC) and Fleiss' kappa statistics.
Results: the I-RASS was found to be satisfactory and well applicable in a nICU. When tested for inter-rater reliability, ICC and Fleiss' kappa were compatible with a substantial agreement among investigators (ICCs = 0.9786; ICCa = 0.9946; k=0.769). In addition, a post-hoc analysis on traumatic brain injury (TBI) patients was performed.
Conclusions: the I-RASS, showing excellent inter-rater reliability values, can be useful for sedation and agitation assessment purposes in Italian nICUs.

Key words: Richmond agitation sedation scale, neurological intensive care unit; traumatic brain injury; weaning from mechanical ventilation; acquired brain injuries, neurological assessment.

RIASSUNTO

Introduzione: tra i pazienti con lesioni cerebrali acquisite, l' agitazione è un problema comportamentale frequente, il cui trattamento richiede spesso l'uso di sedativi. La Richmond Agitation-Sedation Scale (RASS) è una scala comunemente utilizzata per valutare il livello di vigilanza e di agitazione in pazienti in condizioni critiche. Gli obiettivi del presente studio comprendono la traduzione della scala RASS in lingua italiana e la successiva valutazione della sua affidabilità inter-valutatore in pazienti sedati ricoverati all'interno di un'unità di terapia intensiva neurologica italiana (nICU).
Materiali e Metodi: è stata effettuata una traduzione (I-RASS) della RASS dalla lingua inglese a quella italiana. Il test di affidabilità inter-valutatore è stato condotto in una nICU italiana. Da maggio 2022 a ottobre 2024, 21 pazienti sedati sono stati arruolati e valutati attraverso la somministrazione della scala I-RASS da quattro ricercatori diversi; l'affidabilità inter-valutatore è stata testata utilizzando il coefficiente di correlazione intraclasse (ICC) e il kappa di Fleiss.
Risultati: l'utilizzo della scala I-RASS è risultato soddisfacente e ben applicabile in una nICU. Quando è stata testata l'affidabilità inter-valutatore, l'ICC e il kappa di Fleiss sono risultati compatibili con una sostanziale concordanza tra i diversi ricercatori (ICC = 0,9786; ICCa = 0,9946; k = 0,769). Inoltre, è stata eseguita un'analisi post hoc su pazienti con trauma cranico (TBI).
Conclusioni: essendo caratterizzata da valori eccellenti di affidabilità inter-valutatore, la scala I-RASS può essere utile per la valutazione del livello di sedazione e di agitazione nelle nICUs italiane.

Key words: scala di sedazione e agitazione di Richmond, unità di terapia intensiva neurologica; trauma cranico; svezzamento dalla ventilazione meccanica; lesioni cerebrali acquisite, valutazione neurologica.

Correspondence: Giulio Verrienti, Department of Neurorehabilitation, Casa di Cura Villa Verde, 73100 Lecce, Italy.
E-mail: gverrienti@villaverde.lecce.it

Introduction

Agitation is a frequent behavioral problem in neurological Intensive Care Units (nICU), especially among patients with Traumatic Brain Injuries (TBI) and/or postanoxic encephalopathies. In such settings, the administration of sedation is one of the most adopted strategies to control excessive behaviors.

Post-TBI agitation has been defined as a state of confusion that follows the initial brain injury during the period of impaired consciousness. It is characterized by excessive behaviors such as tension, anxiety, irritability, emotional unrest, impulsivity, disinhibition, and aggression.[1] Agitation may affect all stages of recovery, from the acute hospital to the community setting; specifically, agitation is reported in 20-41% of patients during the early stage of recovery in ICU and in up to 70% of patients in rehabilitation units.[2] In the TBI context - but also in other Acquired Brain Injuries (ABI) scenarios - the administration of sedative drugs finds both 'general' rationales (control of anxiety, pain, discomfort, agitation, facilitation of mechanical ventilation), as well 'neuro-specific' reasonings (reduction of cerebral metabolic demand, improved brain tolerance to ischemia).[3]

Given the fact that the administration of sedation is mostly appropriate and - in some clinical scenarios - mandatory, the definition of "adequate sedation" may be challenging. In this context, the use of an excessive sedation may lead to prolonged mechanical ventilation and increased ICU length of stay. Anyway, only limited evidence is available to guide the sedation management in ABI patients. A recent, international survey[4] revealed that there is great variability in the choice of sedative agents, duration of sedation, performance and frequency of wake-up testing and depth of sedation in neurological patients. In this context, the routinary assessment of the sedation level is essential to determine whether patient-specific outcomes (*e.g.* need of mechanical ventilation) might be improved.

In the last decades, several sedation scales have been proposed and used in different ICU protocols. Examples of sedation scales include the Ramsay Sedation scale (RSS),[5] the Riker Sedation-Agitation Scale (SAS),[6] and the Richmond Agitation-Sedation Scale (RASS)[7] (for a review on these scales see Sessler *et al.*).[8]

The RSS,[5] developed in 1974, was the first tool designed to assess sedation depth in ICU patients. Even though this scale was sometimes criticized because of insufficient reliability,[9] the RSS remains one of the most commonly used measures of sedation. The SAS, introduced by Riker *et al.*,[6] classifies sedation and agitation across seven levels: from level 7 (dangerously agitated state) to level 1 (unresponsive state). Unlike RSS, which emphasizes stimulus response time, SAS focuses on a broader range of behaviors at each level to measure both sedation and agitation. The RASS[7] is a clinical instrument, commonly used to assess the level of alertness and agitated behaviour in critically ill patients. This 10-point scale, ranging from -5 to +4, includes four levels to describe agitation (from +1 to +4), one level for calm and alert state (0), and 5 levels to describe sedation (from −1 to −5). Since its inception, the use of RASS has exponentially increased. The reasons behind its success and diffusion are different. The strong validity and inter-rater reliability across a range of critical care populations represent two key factors of this scale. In addition, the ease, with which this assessment can be administered, is another strenght of the scale. Moreover, the RASS does not require equipment, and it can be administered in less than a minute. In contrast to many other sedation scales, the use of the RASS improves discrimination between different levels of mild to moderate sedation (-1 to -4). Evidence-based research supports the use of the RASS to assess sedation in critically ill patients. Even though the RASS is broadly used in the United States, only few studies[10-14] assessing validity and reliability in languages other than English were published. Moreover, the knowledge about the RASS use in nICU is limited [4]. Aims of this study were therefore to translate the RASS into Italian and to validate the inter-rater reliability of the scale in an Italian nICU.

Materials and Methods

This study was carried out from May 2022 to October 2024 and was designed with two phases: the translation process of the scale from English into Italian and the reliability testing of the scale in a nICU. The study was performed in the 15-bed nICU of a secondary hospita (Casa di Cura "Villa Verde" - Lecce) in the southeast of Italy and was conceived and designed according to the SQUIRE 2.0 guidelines.[15]

RASS translation process

During the entire RASS translation process, we followed the principles of the guidelines suggested by the Translation and Cultural Adaptation Group.[16] A translation from English into Italian was carried out; the translation process was as follows: i) Preparation: permission to translate the RASS was requested by the original author Curtis Sessler; ii) Forward translation: two of the authors translated the scale from English into Italian independently and compared their translations. The two translations were very similar and minor adjustments were made to create a final version (Italian RASS, I-RASS); iii) Back-translation: the final version of the RASS was given to a native English-speaking intensive care nurse from the ICU for back-translation to English. The back translation was carried out without having seen the original RASS version. The back-translated version was definitively consistent with the original RASS; iv) Back-translation review: the two authors met with the English-speaking nurse and critically back-reviewed both the English and the Italian version. Another evaluation of the I-RASS was performed and reviewed by a third author (G.V.), who assessed the good quality of the new created I-RASS. The final version used in this study is available on request from the corresponding author.

Inter-rater reliability testing

Sedated, adult (age>18) ABI-patients were included during the inter-rater reliability testing. Between May 2022 and October 2024, the included patients were rated by four investigators (one neurologist and three nurses) during the first week of ICU stay. The day of the week for the assessment was intentionally varied, but the evaluations of each investigator was performed on the same day with a time lapse of ten minutes. Patients with the following characteristics were excluded: i) concurrent neuromuscular blockade, ii) contact or airborne isolation precautions, iii) non-Italian speaking, iv) impaired visual and/or hearing acuity such as blindness or facial or eye trauma, v) history of severe dementia and vi) absence of sedation. The investigators independently performed the RASS ratings, as well they were blinded to each other's' ratings. 2 of 9 In addition, patient characteristics such as age, gender, type of ABI, Glasgow Coma Score- (GCS),[17] Disability Rating Scale- (DRS),[18] Levels of Cognitive Functions - (LCF)[19] and Acute Physiologic Assessment and Chronic Health Evaluation II (APACHE II)[20] were collected. GCS-, DRS-, LCF-, APACHE II initial score and the sedative drugs were noted in a protocol during the testing phase. Similarly to Sessler *et al.*,[7] we calculated the inter-rater reliability using both kappa statistics (Fleiss' kappa) and Intraclass Correlation Coefficient (ICC). Fleiss' kappa is a statisti-

cal test used to measure the inter-rater agreement between two or more observers when patients are being assigned a categorical rating. Fleiss' kappa can range from -1 to +1, whereas a negative value indicates that agreement between the two or more raters was less than the agreement expected by chance; kappa values increasingly greater than zero represent increasingly better-than-chance agreement for the two or more raters; a value of +1 indicates perfect agreement between investigators.[21] ICC is a widely used reliability index in test-retest, intra-rater, and inter-rater reliability analyses. Based on the 95% confidence interval, ICC values less than 0.5 are indicative of poor reliability, values between 0.5 and 0.75 indicate moderate reliability, values between 0.75 and 0.9 indicate good reliability, and values greater than 0.90 indicate excellent reliability. In our study, we report two coefficients (single and average measures) with their respective 95% confidence Interval. The single-measure ICC (ICCSM) is an index for the reliability of ratings by a single rater, while the average-measures ICC (ICCAM) is an index for the reliability of ratings averaged across different raters. The ICCAM is always higher than ICCSM, while ICC values are generally higher than the kappa values.[22] Associations between RASS and GCS, LCF, DRS and APACHE II were investigated using Spearman's correlation.[23] A p=0.05 was accepted as statistically significant. Data were computerized and analyzed using Medcalc (MedCalc Software Ltd, version 23.0.8, Ostend, Belgium). The rBiostatistics software available online[24] was used for the calculation of Fleiss' kappa.

Ethics statement

Approval for the project was granted by the local health directorate and the ICU medical staff. Awake patients and relatives, if present, were informed before each RASS rating of the patient. Since the ratings were similar to those performed continually in our ICU using other assessments and considering that this non-intervention study posed no added risk to subjects, the requirement for obtaining written informed consent was waived.

Results

Between May 1st, 2022, and October 31st, 2024, one hundred seventy-eight persons were admitted to our nICU. Among these, 21 (11,8%) patients were deemed eligible for the study. The patients included in the study were administered sedative drugs, including benzodiazepines (diazepam, midazolam; n=6, 28%), alpha-2 adrenoreceptor agonists (dexmedetomidine; n=9, 43%), antipsychotics (chlorpromazine; n=1, 5%), hypnotic agent (propofol; n=3, 14%) or analgesic agents (fentanyl n=4, 19%) with sedative effects, either by a continuous intravenous infusion or by repetitive administrations. The ages of the included subjects ranged from 18 to 62 years (40.8 ± 17.7) and the median APACHE II score was 12.4 points (± 4.8). A total of 84 I-RASS records were generated (four investigators rating 21 patients). The subjects' main characteristics are summarized in Table 1. On the whole, the RASS scores documented in our study ranged from -5 to 3 points. Specifically, 37 (44%) RASS scores were in the agitation range (RASS≥1); 11 (13%) RASS scores were in the calm state, while 36

Table 1. Main clinical features of enrolled patients.

	Min-max	Mean ± SD
Age (years)	18-62	40.8 ± 17.7
Latency from acute event (days)	11-92	37.5±23.1
Initial Apache	4-23	12.4±4.8
Initial GCS (points)	4-15	8.9±3.3
Discharge GCS (points)	5-15	12.2±3.6
Initial DRS (points)	17-28	22.5±3.3
Discharge DRS (points)	9-26	18.3±4.3
Initial LCF (points)	2-5	2.9±1.1
Discharge LCF (points)	2-7	4.5±1.8

Table 2. Inter-rater reliability testing of the I-RASS across patient subgroups.

Population	N	RASS		Inter-rater reliability		
		Mean	±SD	ICC		K
				Single	Average	
All	21	-0.31	2.80	0.9786 (0.9589)	0.9946 (0.9894)	0.769
Age, yy						
< 40	9	-1.75	2.53	0.9498 (0.8693)	0.9870 (0.9638)	0.651
> 40	12	0.77	3.00	0.9924 (0.9818)	0.9981 (0.9954)	0.837
Gender						
Male	17	-0.07	2.78	0.9895 (0.9782)	0.9974 (0.9945)	0.803
Female	4	1.31	2.75	0.9453 (0.7621)	0.9857 (0.9276)	0.536
Initial APACHE II						
< 15	13	0.21	2.57	0.9731 (0.9389)	0.9931 (0.9840)	0.745
≥ 15	8	-2.50	2.78	0.9683(0.9101)	0.9919 (0.9759)	0.756
Initial GCS						
> 8	12	0.77	1.85	0.9749 (0.9409)	0.9936 (0.9846)	0.778
≤ 8	9	-1.75	3.21	0.9741 (0.9304)	0.9934 (0.9816)	0.717
Mechanical ventilation						
Present	16	-0.91	2.92	0.9797 (0.9572)	0.9948 (0.9890)	0.816
Absent	5	1.60	0.99	0.8478 (0.5376)	0.9571 (0.8230)	0.499
Sedative/analgesic infusion						
Present	14	0.04	2.71	0.9891 (0.9758)	0.9973 (0.9938)	0.802
Absent	7	-1.00	2.91	0.9626 (0.8867)	0.9690 (0.9690)	0.685

RASS, Richmond agitation sedation score; SD, standard deviation; ICC, intraclass coefficient; k, Fleiss' kappa.

(43%) RASS scores indicated a sedation level (RASS≤-1). All investigators selected the same score in 14/21 (66%) patients. A substantial agreement among the entire nICU population could be demonstrated (ICCs=0.9786; ICCa=0.9946; k=0.769). In addition, inter-rater reliability was high (ICCs=0.8478-0.9924; k=0.499-0.816), as reported in Table 2. A moderate strength monotonic relation between RASS and entry GCS- (r=0.45, p<0.05), DRS- (r=-0.51, p;<p<0.05), LCF- (r=0.47, p<0.05) and APACHE II scores (r=-0.43; p<0.05) could be demonstrated.

Post hoc analysis of TBI Patients

Of the one hundred seventy-eight persons included in our study, 50 (28%) subjects suffered from TBI; after excluding 33 patients (because they did not met the inclusion criteria), we included the rest of the TBI patients and performed a post hoc analysis on their data; in terms of Glasgow Coma Scale, 8 (47%) subjects were classified as having a severe TBI (GCS≤8). 7(41%) subjects were classified as moderate TBI patients (9≤GCS≤12), while 2 (12%) patients were rated as minor TBI patients (GCS≥13). The distribution of the I-RASS scores in the TBI cohort is displayed in Figure 1. Also in this subgroup, a moderate strength monotonic relation between RASS- and admission GCS-, DRS- and APACHE II scores could be demonstrated; however, after excluding non-TBI patients, these correlations are slightly stronger, as showed in Table 3.

Discussion

The RASS is a clinical tool that allows for the assessment of sedation and agitation states in ICU patients. Because of its excellent properties, it has been validated in other languages than English, such as Spanish,[10] French,[11] Swedish,[12] Portuguese[13] and Serbian.[14] Even though some versions of the RASS in the Italian language [*e.g.*, 25] have already been carried out, none of these have undergone an official validation process. After receiving permission from the author of the scale, Curtis Sessler, we translated the RASS into Italian without major difficulties. The resulting version (I-RASS) is consistent with the work of Mistraletti *et al.*;[25] therefore, we tested the inter-rater reliability and the validity of the I-RASS in the context of a pilot study. Between May 2022 and October 2024, 21 sedated patients were enrolled. A total of 84 assessments was calculated. Very high Fleiss' kappa- and ICC values (0.76 and 0.97, respectively) were found, indicating a substantial level of inter-rater reliability. In addition, a moderate strength relation between I-RASS and admission GCS- (r = 0.45, p<0.05), DRS- (r = - 0.51, p<0.05), LCF- (r=0.47, p<0.05) and APACHE II scores (r = - 0.43; p<0.05) could be demonstrated.

The high degree of inter-rater reliability of the I-RASS measured with Fleiss' kappa (k= 0.76) in our study is in line with the results of other similar studies (k = 0.64-0.91).[10-14,26-28] Also in our study, similarly to other published studies, a correlation between the RASS and both GCS and APACHE II on the admission time point could be demonstrated. In addition, our study reveals correlations between RASS with other clinical scales (LCF and DRS, measured at the admission time point).

Even though we tried to hold the general protocol and structure of the original study of Sessler *et al.*,[7] our work shows some peculiar issues. The first evident difference concerns the main characteristics of the included population. Unlike to Sessler *et al.*,[7] we included only sedated patients. Demonstrating a very high inter-rater reliability in this selected population, our study suggests a wide usefulness of the RASS as a clinical assessment tool in such a typology of patients; this consideration assumes more relevance in clinical contexts in which the RASS may be used to reduce over-sedation (and the subsequent length of stay in the ICU). Furthermore, only neurological patients, including TBI patients, were enrolled. This population type was frequently excluded from past research[7,22] because of the presumptive influence of the neurological impairment on the RASS assessment. However, it should be noted that the monitoring of both levels of sedation and agitation were included among the original aims of the RASS. In the nICU context, it is widely recognized that TBI patients are more prone to present agitation in comparison to patients with other diagnoses. Therefore, more than 80% of the enrolled patients in our thirty-month-long study showed TBI as first diagnosis. In this sense, the a priori exclusion of TBI patients should be re-evaluated. Furthermore, the use of the RASS in TBI patients has already been practiced in other studies (e.g. Robinson *et al.*, and Wang *et al.*),[29,30] but its adaptation in this type of pathology has never been validated nor explicited in the literature we reviewed. Thus, we performed a post hoc analysis, including only TBI patients. The available data on this patient category reveal a comparable Fleiss' kappa value, indicating a substantial agreement among investigators; however, the correlations between RASS and admission

Table 3. Comparison of Spearman's rho of the relation of RASS scores with Admission GCS, DRS and Apache II before ("Entire population") and after ("TBI population") excluding non TBI population: the reported comparison reflects the moderate strength monotonic relation between RASS scores and admission GCS-, DRS- and APACHE II scores. In comparison with data emerging from the entire population, this relation appears to be slightly stronger in the TBI population.

	Entire population	TBI population
RASS – Admission GCS	0.45	0.52
RASS – Admission DRS	- 0.51	-0.51
RASS – APACHE II	- 0.43	-0.58

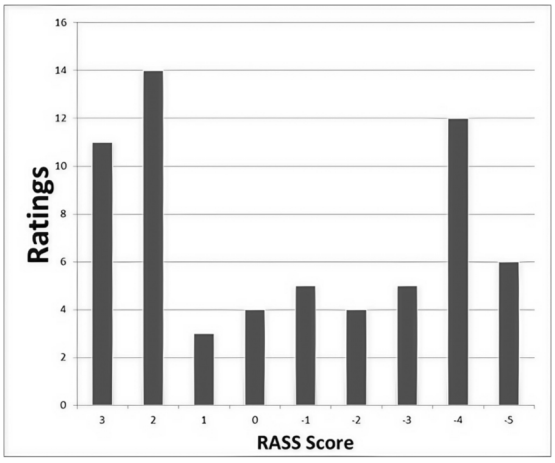

Figure 1. Number of performed Italian-Richmond Agitation-Sedation Scale (I-RASS) ratings for each score in our traumatic brain injury patients. In our TBI patient-cohort, we globally performed 64 RASS scores, ranging from −5 to +3 points; n=32 (50%) performed RASS scores were in the sedation range (RASS≤−1),while n=28 (44%) were in the agitation range (+1 ≤ RASS ≤ +3). Only in n=4 (6%) cases, the calm state (RASS=0) was recorded.

GCS-, DRS-, and APACHE II scores appear to be slightly stronger in comparison with those of the general ABI population.

Our study shows some limitations. The small sample size represents one major limitation and our results should be confirmed by larger trials. Furthermore, if we consider the RASS as an instrument to guide the clinician to manage the optimal sedation, the choice to exclude non-sedated patients (which is in contrast with the study of Sessler *et al.*)[7] represents only a theoretical limit. In this sense, we set the six exclusion criteria (absence of sedation) as pertinent for the aim of this study. However, we believe that future research should also include such type of patients (non-sedated patients). Finally, considering the internal socio-cultural variability between the different regions of our country, the monocentric design of our study might represent another limitation, restricting the possibility to generalize the results to broader clinical settings. Our study also reveals several significant strengths; the validation and adaptation process for the scale's use in Italian nICUs was overall successful. The meticulous translation process, which involved forward/backward translation and critical review, ensured linguistic and conceptual consistency, making the scale both accessible and applicable to the Italian ICU environment. In addition, the study design was created on the basis of past research experience. Similarly to previously published RASS validations in English, we conducted our validation study with four individuals applying a scale. In all other validation studies, sedation scales were evaluated with fewer than four investigators. Finally, the time lapse of approximately ten minutes between each assessment was intentionally chosen to reduce the possible "wake-up" effect; this latter was suspected by Almgren *et al.*[12] in their validation study, in which a time lapse of one minute between each assessment was set. Ultimately, it should be emphasized that the use of the I-RASS in the daily practice resulted helpful in terms of communication among rehabilitation staff units (in particular, between nurses and clinicians); this additive benefit facilitated its implementation in the routinary patients assessment in our nICU.

Conclusions

In this study, we translated the RASS into Italian language. The resulting version (I-RASS) is conceptually equivalent to the original, is reproducible, and comprehensible to Italian-speaking physicians. The findings of our study demonstrate a substantial I-RASS inter-rater reliability. Notably, while previous studies excluded TBI patients due to the complexity of their neurological conditions, this study successfully validated the use of the RASS in such cases, further supporting its applicability in this selected field. Therefore, the I-RASS can play a pivotal role in advancing sedation practices, ensuring better outcomes for critically ill patients in Italian intensive care settings. Further research with larger, multi-center samples is needed to extend the tool's validation across a broader range of clinical scenarios.

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Conflict of interest: the authors declare no potential conflict of interest, and all authors confirm accuracy.

Ethics approval: the local Ethics Committee approved this study. The study is conformed with the Helsinki Declaration of 1964, as revised in 2013, concerning human and animal rights.

Informed consent: since this non-intervention study posed no added risk to subjects, the requirement for obtaining written informed consent was waived. However, awake patients and relatives, if present, were informed before each clinical rating.

Patient consent for publication: written informed consent was obtained from a legally authorized representative(s) for anonymized patient information to be published in this article.

Availability of data and materials: all data generated or analyzed during this study are included in this published article.

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