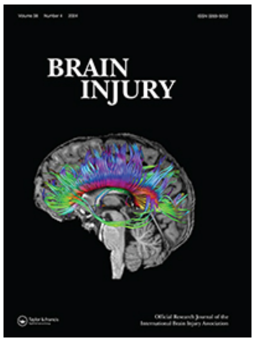

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Reliability and validation of the Japanese version of the coma recovery scale-revised (CRS-R)

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ABSTRACT

Primary objective: This study aimed to verify the reliability and validity of the Japanese version of the Coma Recovery Scale-Revised (CRS-R).

Methods: Subjects included 59 patients with disorders of consciousness (DOC) due to acquired brain injury. To validate test-retest reliability, Evaluator A assessed the CRS-R twice on the same day (A1, A2). To examine inter-rater reliability, Evaluators A (A2) and B (B) assessed the CRS-R without a time interval. To test concurrent validity, Evaluator A (A1) assessed the CRS-R, Japan Coma Scale (JCS), and the Glasgow Coma Scale (GCS) consecutively. To validate diagnostic accuracy, we evaluated the degree of agreement between A1 and A2 and between A2 and B in their diagnosis of DOC by CRS-R.

Results: The test-retest ($\rho = 0.92$) and inter- ($\rho = 0.98$) reliability of CRS-R were excellent" and Concurrent validity of CRS-R with JCS ($\rho = -0.82$) and GCS ($\rho = 0.92$) were high. Results of DOC diagnosis were consistent for 48/59 cases ($\kappa = 0.82$) for A1 and A2 and for 54/59 cases ($\kappa = 0.92$) for A2 and B.

Conlcusion: The Japanese version of the CRS-R may be as reliable and valid as the original English and other language versions.

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KEYWORDS
Coma recovery scale-revised; disorders of consciousness; unresponsive wakefulness syndrome; minimally conscious state; emergence from minimally conscious state

Background

In Japan, the Glasgow Coma Scale (GCS) and the Japan Coma Scale (JCS) are employed to evaluate disorders of consciousness (DOC) (1). Although the GCS was originally developed to triage and predict head trauma patients' prognosis in the emergency department, it is also used in rehabilitation (2). The motor items (M) of the GCS are scored from M1 to M6, and if the patient follows the examiner's instructions, they are scored as 'M6'. Nonetheless, because the GCS scale scores motor items as 'M6' regardless of whether the patient follows simple or complex instructions, the scale may not accurately detect patients' small changes over time (3). The JCS, commonly used in Japan, can present similar issues. The JCS classifies patients into three major states of consciousness: I (eyes open without stimulation), II (eyes open upon stimulation), and III (eyes not open upon stimulation) (4). Each state is further divided into three more detailed stages. For example, patients with JCS I are classified into one of the following: I-1 (not fully conscious), I-2 (unable to answer date or location), or I-3 (unable to state their name or birthdate). However, among JCS I patients, those who cannot answer their name or birthdate but can follow simple instructions and those who are unresponsive to verbal instructions are both scored as I-3. These examples illustrate how the GCS and JCS may assign the same score to patients with different levels of consciousness.

Developed by Giacino in 1991, the Coma Recovery Scale (CRS) was created to capture minor consciousness changes difficult to assess with the traditional GCS (3). A revised version of the CRS, the Coma Recovery Scale-Revised (CRS-R), was subsequently published in 2004 (5). DOC is classified in order of severity to mildness as Unresponsive Wakefulness Syndrome (UWS), Minimally Conscious State (MCS), and Emergence from Minimally Conscious State (EMCS) (6). UWS was formerly known as the Vegetative State (VS). The distinguishing feature of the VS is an irregular but cyclic state of circadian sleeping and waking unaccompanied by any behaviorally detectable expression of self-awareness, specific recognition of external stimuli, or consistent evidence of attention, intention, or learned responses (7). Since Laureys et al. proposed 'UWS' as an alternative to the pejorative 'VS' in 2010, 'UWS' has become more commonly used (8). In 2002, the Aspen Work Group proposed definitions of MCS and EMCS (9). MCS is a condition of severely altered consciousness in which minimal but definite behavioral evidence of self or environmental awareness is demonstrated (9). EMCS is characterized by reliable and consistent demonstration of one or both of the following: 1) functional interactive communication; 2) functional use of two different objects (9).

In many studies, changing from UWS to MCS or from MCS to EMCS has been considered an outcome for improving DOC (10–13). Currently, the CRS-R is the only assessment that can

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categorize DOC according to criteria proposed by the Aspen Workgroup to distinguish among UWS, MCS, and EMCS (14). A systematic review of the CRS-R's psychometric properties was reported in 2010 (14) when it was found to have clearly defined standardized assessment instruments and scoring procedures, excellent content validity, good internal consistency, good inter-rater reliability, and good intra-rater reliability but showed no evidence of criterion validity, diagnostic validity, or predictive validity. Concurrent validity has been reported as highly correlated between CRS-R and GCS (15–19). Additionally, reports of studies on predictive validity have increased in recent years. For example, the CRS-R's total score at admission after severe brain injury affects improvement in impaired consciousness 6 or 12 months after admission (10,20), and the CRS-R's total score at discharge is an independent predictor of death 1 year after discharge (21). Among psychometric properties, no prior investigations regarding standard error (SEM), limit of agreement (LOA), and smallest detectable change (SDC) have been discovered in the author's literature search. These properties are indices of measurement error, and LOA and SDC are especially important because they provide information to determine if the change in CRS-R surpasses random error (22).

The European Society of Neurology's 2020 guidelines recommend using the CRS-R for diagnosing DOC levels in patients suffering from DOC (23). While the CRS-R has been translated into numerous languages (15–19,24,25), it had not been translated into Japanese. Translating the CRS-R into Japanese would prove advantageous for evaluating the efficacy of rehabilitation and various treatments for improving DOC. Such translation is also vital for promoting Japan's development of clinical research on DOC.

The purpose of this study was to translate the CRS-R into Japanese and elucidate its reliability and validity.

Methods

Participants

The subjects were 59 patients with DOC due to acquired brain injury. The 'COSMIN Study Design checklist for Patient-reported outcome measurement instruments' provides recommendations for designing a study to assess the scale characteristics of patient-reported outcome measures. This document includes a section on measurement error and reliability, which states that the appropriate number of samples is 'adequate' for 50–99 persons and 'very good' for 100 or more persons (26). The inclusion criteria were as follows (1): age of 20 years or above (2), determination by the attending physician of impaired consciousness based on GCS and medical examination, and (3) native speaker of Japanese. The exclusion criteria were (1): visual impairment and (2) hearing impairment. Table 1 depicts the characteristics of this study's subjects.

This study was conducted in accordance with the Declaration of Helsinki and approved by the Medical Ethics Committee of Hamamatsu Medical Center (Approval No.: 2020-3-059). Informed consent was provided on an opt-out basis according to the Japanese ethical guidelines for medical research, 'Guidance on Ethical Guidelines for Life Sciences and Medical Research Involving Human Subjects' (27). A document outlining the study was posted on the Hamamatsu Medical Center website to allow patients and their families to refuse participation in the study.

Translation

With permission of the original author, Joseph T. Giacino of the Harvard Medical School, the following process was conducted to translate the CRS-R into Japanese. The CRS-R's original English version includes the comprehensive evaluation manual 'Coma Recovery Scale-Revised Administration and Scoring Guidelines 2004' (28), which was first translated from English-to-Japanese by a native Japanese speaker. Next, the provisional Japanese version was back-translated from Japanese-to-English by a professional translator. This back-translation version underwent review by the original author's team, and after two rounds of revisions, the final version of the 'Guidelines for Implementation and Scoring of the Japanese Version of the CRS-R' was approved. All back-translation versions (https://zenodo.org/record/8300303) and the Japanese translation (https://zenodo.org/record/8300427) have been registered in the Zenodo repository and are freely accessible to anyone.

Procedure

The raters for the current study were two physical therapists (Raters A and B), both new users of the CRS-R. Prior to data collection, Raters A and B were trained in the administration

Table 1. Subjects' characteristics.

Item	Value	Range
Age	83(72–87) *	42–100
Sex	Male 30, Female 29	-
Days since onset	7 (3–20)*	2–151
CRS-R	4(0–17)*	0–23
GCS	7(0–13)*	15
JCS	I-3(I-3–II-30)*	I-1–III-300
Classification of disorders of consciousness	UWS 16/MCS 25/EMCS 18	-
Type of disease	Infarction 30 Hemorrhage14 Head trauma 8 Other 7	-
Damaged side	Right 24/Left 25/Both 4/Other 6	-

*Median (Quartile range).

of the CRS-R using published CRS-R training materials (29). First, Evaluator A administered the CRS-R, JCS, and GCS consecutively (A1). The order in which the three assessments were performed was not specified. In A1, all patients were diagnosed with UWS, MCS, or EMCS based on CRS-R results according to the Aspen Workgroup criteria. To determine whether the CRS-R is helpful in detecting more signs of consciousness than the GCS, we created preliminary definitions for classifying levels of consciousness into UWS, MCS, and EMCS based on the Aspen Workgroup criteria and previous research (Table 2). On the other hand, creating a definition for the diagnosis of DoC using the JCS was challenging. This is because JCS scores are based on the presence or absence of eye-opening responses to spontaneous eye opening or stimulation, which is not relevant to the current diagnostic criteria for DoC. On the same day as A1, a secondary CRS-R assessment was administered by Evaluator A (A2), and Evaluator B (B) conducted the primary CRS-R evaluation. A2 and B used the same diagnostic criteria as A1 to classify all patients' level of consciousness impairment as UWS, MCS, or EMCS. The order of assessment for A2 and B was random. Although A2 and B visited the patient's room at the same time, while one was evaluating, the other waited outside and did not observe the other's CRS-R evaluation. A2 and B were not aware of each other's results and submitted their assessments separately. A1, A2, and B were all performed on the same day, but the time was not specified (Figure 1).

Statistical analysis

The normality of each parameter's results was assessed using the Shapiro-Wilk test. Test-retest and inter-rater reliability of the CRS-R total score was evaluated by computing Pearson's product-moment correlation coefficient in the presence of normality and Spearman's rank correlation coefficient in its absence. Interpretation of correlation coefficients was based on existing literature: $|r| \leq 0.2$ (indicating almost no correlation), $|r| = 0.2–0.4$ (suggesting a somewhat correlated relationship), $|r| = 0.4–0.7$ (indicating a fairly correlated relationship), and $|r| = 0.7–1.0$ (indicating a fairly strong correlation) (30).

The parameters of measurement error SEM, LOA, and SDC were determined for total CRS-R scores within and between examiners. SEM was calculated using the standard deviation (SD) of the difference between the two assessments (d), according to the following formula:

$$SEM = SD(d)/\sqrt{2}$$

The Bland – Altman method was used to calculate the LOA. The difference between the two measurements (d) was plotted on the y-axis, and their mean (m) was plotted on the x-axis for the total CRS-R scores within (A1 and A2) and between (A2 and B) examiners, respectively (Bland – Altman plot) (Figure 2). The LOA was calculated by using the mean value of d (Mean (d)) and the SD of d (SD(d)), according to the following equation (22):

$$LOA = Mean(d) \pm 1.96 \times SD(d)$$

Systematic error was interpreted as Mean (d), and random error as $1.96 \times SD(d)$ (22). Systematic errors were classified as fixed and proportional. If the confidence interval of the difference between the two CRS-R values (d) encompassed zero at the 95% level, we inferred the absence of a fixed error. Proportional errors were estimated using

Table 2. Diagnostic criteria for disorders of consciousness by CRS-R and GCS.

Scale	UWS	MCS	EMCS
CRS-R	Auditory ≦ 2 AND Visual ≦ 1 AND Motor ≦ 2 AND Oromotor/Verbal ≦ 2 AND Communication = 0 AND Arousal ≦ 2	Auditory = 3–4 OR Visual = 2–5 OR Motor = 3–5 OR Oromotor/Verbal = 3 OR Communication = 1	Motor = 6 Communication = 2
GCS	Eyes opening = 2–4 AND Verbal = 1–2 AND Motor = 1–4	Verbal = 3–4 OR Motor = 5–6	Verbal = 5

CRS-R: Coma Recovery Scale-Revised; GCS: Glasgow Coma Scale; UWS: Unresponsive Wakefulness Syndrome; MCS minimally conscious state; EMCS: emergence from minimally conscious state.

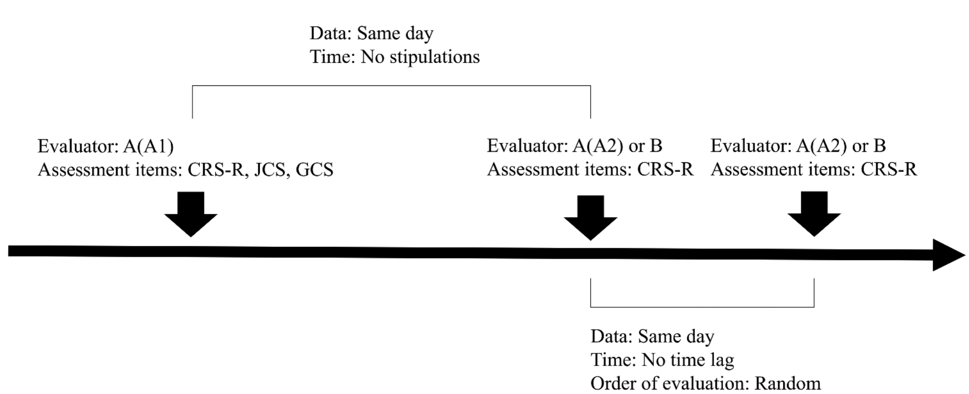

Figure 1. Research procedure.

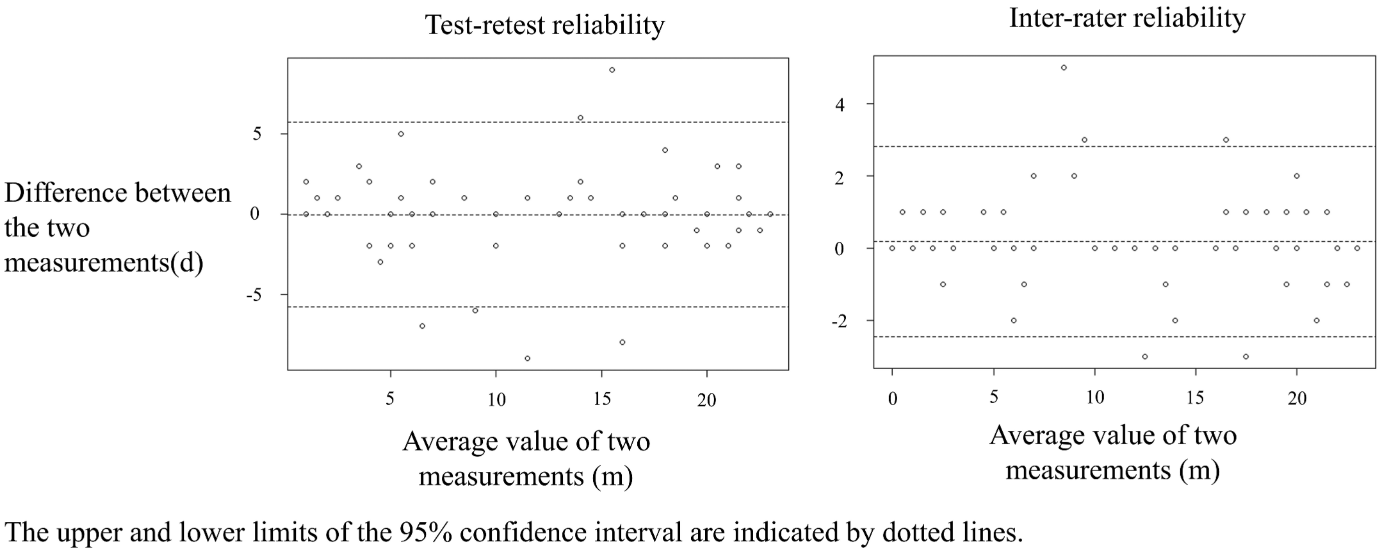

Figure 2. Bland – Altman plot of CRS-R test-retest and inter-rater reliability.

d and m regression analysis. SDC is defined as a change beyond the measurement error, that is, a change outside the limits of agreement (LOA) in the Bland-Altman method. SDC in the absence of systematic error was $1.96 \times SD$ (d). If the change in score was less than SDC, it was attributed to measurement error (22).

For internal consistency, Cronbach's alpha was computed for each of the three measurements of A1, A2, and B. A Cronbach's alpha value between 0.70 and 0.90 is considered good (22). In addition, the appropriate correlation coefficient between subscales of the scale is typically considered to be between 0.2 and 0.5. In other words, items with a correlation coefficient less than 0.2 indicate problems with internal consistency, whereas items with a correlation coefficient greater than 0.7 suggest that they assess the same content, and it is worth considering removing one of the items (22).

Weighted Kappa coefficients were used to examine CRS-R subscales' intra- and inter-examiner agreement. Thresholds for the Kappa coefficient have been defined as follows: slight agreement (Kappa: 0–0.2), fair agreement (Kappa: 0.21–0.40), moderate agreement (Kappa: 0.41–0.60), substantial agreement (Kappa: 0.61–0.80), and near-perfect or complete agreement (Kappa: 0.81–1.0) (31). The agreement between the diagnosis of DOC by CRS-R of A2 and B was examined with weighted Kappa coefficients. In the context of evaluating the test-retest reliability of CRS-R, should alterations manifest within the arousal subscale when transitioning from A1 to A2, there exists the potentiality for consequential influence upon the aggregate score. In order to explore the correlation between variances within the arousal subscale as it pertains to A1 and A2, subjects were categorized into distinct cohorts: those exhibiting consistent arousal subscale scores for both A1 and A2, those exhibiting a 1-point deviation, those demonstrating a 2-point variance, and those manifesting a 3-point discrepancy. Subsequently, the mean alteration in CRS-R total score was computed for each respective group. The CRS-R's concurrent validity was examined using Spearman's rank correlation coefficient to determine the relationship between the CRS-R, a new assessment, and the traditionally used assessments of GCS and JCS. The level of statistical significance was set at $p < 0.05$. All analyses were performed using R (version 4.0.5).

Results

Test-retest reliability

The total CRS-R scores obtained by A1 and A2 on the same day displayed high correlation ($\rho = 0.92$, $p < 0.01$), indicating excellent test-retest reliability (Table 3). Bland – Altman analysis revealed no fixed or proportional errors in CRS-R scores for A1 and A2. Measurement errors were 2.08 for SEM, −5.79–5.72 for LOA and 5.75 for SDC (Table 3, Figure 2). Weighted Kappa coefficients for CRS-R subscales were 0.87 for auditory ($p < 0.01$), 0.81 for visual ($p < 0.01$), 0.89 for motor ($p < 0.01$), 0.89 for oromotor/verbal ($p < 0.01$), 0.83 for communication ($p < 0.01$), and 0.75 for arousal ($p < 0.01$). Except for the arousal item, all subscales showed excellent agreement. Forty of the 59 (67.8%) had the same score on the arousal subscale for A1 and A2. The mean difference in

Table 3. Test-retest reliability.

	Bland – Altman Analysis							
	Fixed error		Proportional error			Measurement error		
Correlation coefficient	95% confidence interval of (d)	Yes or No	Correlation coefficient between (d) and (m)	p	Yes or No	SEM	LOA	SDC
ρ = 0.92	−0.47–0.43	No	0.04	0.98	No	2.08	−5.79–5.72	5.75

Table 4. Test-retest and inter-rater reliability of DOC classification.

Test-retest reliability						Inter-rater reliability					
		Evaluator A (A1)						Evaluator A (A2)			
		UWS	MCS	EMCS	Total			UWS	MCS	EMCS	Total
Evaluator A (A2)	UWS	13	1	0	14	Evaluator B (B)	UWS	14	1	0	15
	MCS	2	21	4	27		MCS	0	24	2	26
	EMCS	0	4	14	18		EMCS	0	2	16	18
	Total	15	26	18	59		Total	14	27	18	59

total CRS-R scores was 1.1 points, and only one of the 40 (2.5%) had a change that exceeded the SDC (5.75 points). Those with a one-point change on the arousal subscale were 12 of 59 (20.3%). The mean difference in total CRS-R scores was 2.5 points, with only one of the 12 individuals (8.3%) showing a change greater than the SDC. Within the group of 59 individuals, 7 (11.9%) experienced a two-point change on the Arousal subscale. The mean difference in total CRS-R scores for this subgroup was 5.0 points, and 4 of the 7 individuals (57.1%) had changes that exceeded the SDC. There were no individuals who experienced a three-point change on the arousal subscale. The diagnosis of DOC by A1 and A2 on the same day coincided in 48 of 59 (81%) cases (κ = 0.82, $p < 0.01$, excellent agreement) (Table 4).

Inter-rater reliability

The total CRS-R scores assessed by A2 and B on the same day without any time interval exhibited high correlation (ρ = 0.98, $p < 0.01$) and good inter-rater reliability (Table 5). Additionally, Bland – Altman analysis revealed no fixed or proportional errors in their inter-rater reliability. Measurement error was determined to be 0.95 for SEM, −2.45–2.82 for LOA, and 2.62 for SDC (Table 5, Figure 2). The CRS-R subscale-weighted Kappa coefficients were 0.97 for auditory ($p < 0.01$), 0.98 for visual ($p < 0.01$), 0.92 for motor ($p < 0.01$), 0.91 for oromotor/verbal ($p < 0.01$), 0.92 for communication ($p < 0.01$), and 0.94 for arousal ($p < 0.01$), with excellent agreement for all items. The diagnosis of DOC by A2 and B on the same day without any time interval coincided in 54 of 59 (92%) cases (κ = 0.92, $p < 0.01$, excellent agreement) (Table 4).

Internal consistency

Results of Cronbach's alpha for the CRS-R were 0.91 for each A1, A2, and B, indicating good internal consistency. Spearman's rank correlation coefficients between subscales ranged from 0.53 to 0.91, demonstrating good correlation (Table 6). Strong correlations were observed in some of the subscales, with correlation coefficients of 0.7 or higher,

Table 5. Inter-rater reliability.

	Bland – Altman Analysis								
	Fixed error		Proportional error			Measurement error			
Correlation coefficient	95% confidence interval of (d)	Yes or No	Correlation coefficient between (d) and (m)	p	Yes or No	SEM	LOA	SDC
ρ = 0.98	−0.32–0.10	No	0.02	0.87	No	0.95	−2.45–2.82	2.62

Table 6. Intercorrelation of CRS-R subscales.

	Auditory	Visual	Motor	Oromotor/Verbal	Communcation	Arousal
Evaluator A(A1)						
Auditory	1					
Visual	0.91	1				
Motor	0.69	0.74	1			
Oromotor/verbal	0.7	0.72	0.7	1		
Communication	0.75	0.77	0.6	0.72	1	
Arousal	0.68	0.74	0.64	0.58	0.57	1
Evaluator A(A2)						
Auditory	1					
Visual	0.87	1				
Motor	0.7	0.64	1			
Oromotor/Verbal	0.74	0.72	0.65	1		
Communication	0.76	0.73	0.56	0.68	1	
Arousal	0.69	0.71	0.64	0.69	0.66	1
Evaluator B						
Auditory	1					
Visual	0.88	1				
Motor	0.67	0.66	1			
Oromotor/verbal	0.76	0.73	0.65	1		
Communication	0.76	0.7	0.53	0.63	1	
Arousal	0.7	0.72	0.6	0.63	0.63	1

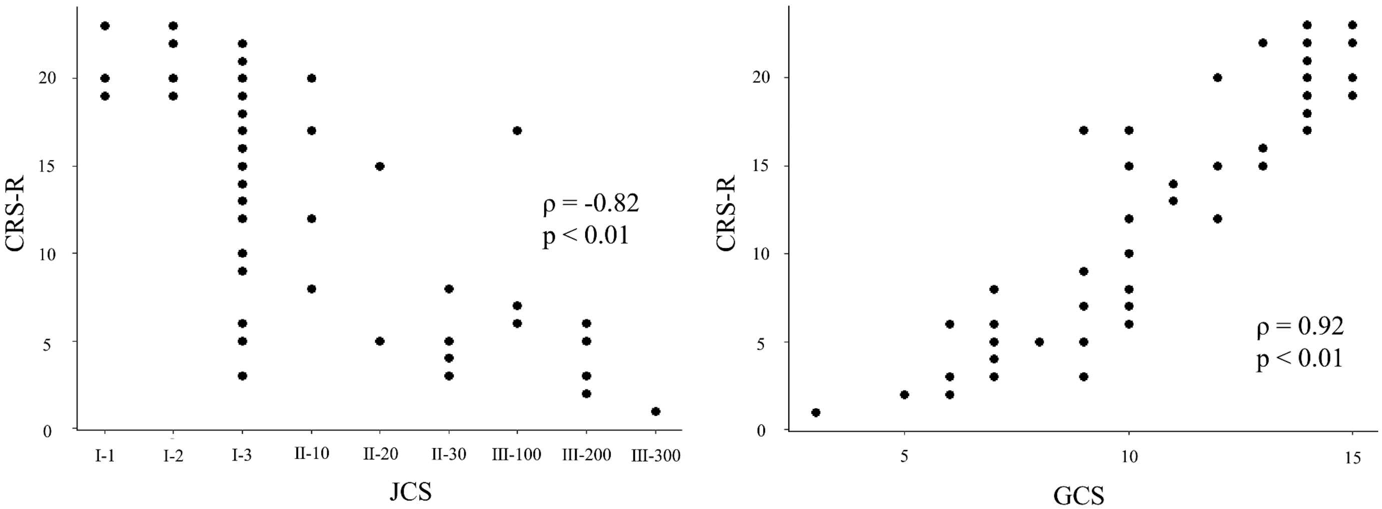

Figure 3. Correlation between CRS-R, JCS and GCS.

Table 7. Concordance in DoC diagnosis between CRS-R and GCS.

		GCS (A1)			
		UWS	MCS	EMCS	Total
CRS-R (A1)	UWS	15	0	0	15
	MCS	5	20	1	26
	EMCS	0	11	7	18
	Total	20	31	8	59

while there were no items with weak correlations below 0.2 (Table 6).

Concurrent validity

The CRS-R showed excellent correlation with the JCS ($\rho = -0.82$, $p < 0.01$) and the GCS ($\rho = 0.92$, $p < 0.01$), confirming its concurrent validity (Figure 3).

Agreement in diagnosis of DOC

In this study, the level of consciousness of 59 participants was assessed using the CRS-R, resulting in a diagnosis of EMCS in 18, MCS in 26, and UWS in 15 (Table 7). CRS-R and GCS diagnoses were in agreement in 42 of 59 cases (71.2%), with a weighted kappa coefficient of 0.63 ($p < 0.01$). Among patients diagnosed with EMCS by the CRS-R, the GCS was able to diagnose 7 of 18 cases (38.9%). Among patients diagnosed with MCS by CRS-R, GCS was able to diagnose 20 of 26 cases (76.9%). Among patients diagnosed with UWS by CRS-R, GCS was able to diagnose all 15 cases (100%). There were 17 of 59 cases (28.8%) in which the diagnoses from CRS-R and GCS did not agree. Of these cases, 16 of 17 individuals (94.1%) were aided by CRS-R in detecting higher level signs of consciousness compared to GCS. Signs of consciousness detected by the CRS-R but not the GCS included 'Functional object use' from the Motor scale in 10 cases, 'Functional: Accurate' from the Communication scale in 5 cases, 'Fixation' from the Visual Function scale in 1 case, and 'Automatic Motor Response' from the Motor Function scale in 4 cases.

Discussion

This investigation's findings indicate that the Japanese CRS-R version exhibited sound test-retest reliability, inter-rater reliability, internal consistency, and concurrent validity.

Table 8 compares the Japanese version's psychometric attributes with its counterparts in other languages. Perhaps significantly, this study's test subjects were distinguished by their older age and shorter duration from onset to evaluation compared with those in previous research on the CRS-R's psychometric properties in other languages.

The inter-rater reliability correlation coefficient for the Japanese version was $\rho = 0.98$, approximately equal to that of the Russian ($\kappa = 0.99$) (18) and Korean ($\kappa = 0.93$) versions (17). However, the correlation coefficient of the Japanese version was marginally higher than those of English ($\rho = 0.84$) (5), French ($\kappa = 0.80$) (15), Italian ($\rho = 0.81$) (24), Polish ($\rho = 0.76$) (25), and Chinese (ICC = 0.72) versions (19). The Japanese and Russian versions exhibited higher correlation coefficients, possibly owing to the absence of a time lag between the two raters' evaluations. However, with the exception of the Russian version, no detailed explanation was found for the time interval between the two raters' administering the test in other languages. Because there is diurnal variation in the level of consciousness (33), the measurement error could be large if there is a large time lag between the two raters' assessments.

When examining test-retest reliability, the concordance observed within the arousal subscales of A1 and A2 ($\kappa = 0.75$) showed a somewhat lower level compared to the other five subscales. In the previous study, both the Chinese (ICC = 0.66) (19) and Polish (ICC = 0.73) (25) versions showed slightly

Table 8. Comparison of CRS-R psychometric results between Japanese and other language versions.

Language	Year	n	Disease	Characteristics	Test-retest reliability	Inter-rater reliability	Internal consistency	Measurement error	Concurrent validity	Diagnostic agreement with DOC
Japanese	2024	59	TBI($n = 8$) NTBI ($n = 51$)	Age:83(72–87)* Time post injury: 7 (3–20)days*	ρ = 0.92 Date: Same day Time: No stipulations	ρ = 0.98 Date: Same day Time: No time lag	Cronbach α = 0.91	Test-retest SEM: 2.08 LOA: −5.79–5.72 SDC: 5.75 Inter-rater SEM: 0.95 LOA: −2.45–2.82 SDC: 2.62	CRS-R and GCS: ρ = 0.92 CRS-R and JCS: ρ = −0.82	Test-retest agreement rate = 81%(48/59) κ = 0.82 Inter-rater agreement rate = 92%(54/59) κ = 0.92
English (original)	2004	80	TBI($n = 37$) NTBI($n = 43$)	Age:38 ± 13** Time post injury: 58 ± 31 days**	ρ = 0.94 Date: Two consecutive days Time: No stipulations	ρ = 0.84 Date: Same day Time: No stipulations	Cronbach α = 0.83	No data	CRS-R and CRS: ρ = 0.97 CRS-R and DRS: ρ = 0.90	Test-retest κ = 0.82 Inter-rater κ = 0.60
French	2008	77	TBI($n = 26$) NTBI($n = 51$)	Age:[19–86] *** Time post injury: No data	No data	κ = 0.80 Date: No stipulations Time: No stipulations	No data	No data	CRS-R and GCS: r = 0.59 CRS-R and FOUR: r = 0.63	No data
Italian	2011	38	TBI($n = 8$) NTBI($n = 30$)	Age:59 ± 14** Time post injury: 88 (32–147)days*	ρ = 0.97 Date: Two consecutive days Time: No stipulations	ρ = 0.81 Date: Same day Time: No stipulations	Cronbach α = 0.80–0.81	No data	No data	Test-retest κ = 0.92 Inter-rater κ = 0.75
Spanish	2014	35	TBI($n = 24$) NTBI($n = 11$)	Age:30[18–62] **** Time post injury: 146[28–1154] days****	No data	Cronbach α = 0.97 Date: No stipulations Time: No stipulations	No data	No data	CRS-R and GCS: r = 0.74 CRS-R and DRS: r = −0.54	Test-retest No data Inter-rater κ = 0.79
Korean	2018	39	TBI($n = 10$) NTBI($n = 29$)	Age:57 ± 17** Time post injury: 126 ± 129 days**	κ = 0.94 Date: Two days later Time: No stipulations	κ = 0.93 Date: Same day Time: No stipulations	Cronbach α = 0.90	No data	CRS-R and GCS: r = 0.89	Test-retest agreement rate = 97% (38/39) Inter-rater agreement rate = 95% (37/39)
Polish	2018	20	TBI($n = 10$) NTBI($n = 10$)	Age:38[21–71] **** Time post injury: 383[49–1178] days****	ρ = 0.92 Date: Two consecutive days Time: No stipulations	ρ = 0.76 Date: Same day Time: No stipulations	Cronbach α = 0.85–0.86	No data	None	Test-retest κ = 0.90 Inter-rater κ = 0.72
Russian	2018	60	TBI($n = 8$) NTBI($n = 52$)	Age:46 ± 18** Time post injury: 2.5 (1–7)months*	r = 1 Date: same day Time: No stipulations	κ = 0.99 Date: Same day Time: No time lag	Cronbach α = 0.87	No data	CRS-R and GCS: r = −0.90 CRS-R and FOUR: r = −0.60	No data
Chinese	2019	169	TBI($n = 73$) NTBI($n = 96$)	Age:58[18–86] **** Time post injury: No data	ICC = 0.87 Date: Two consecutive days Time: No stipulations	ICC = 0.72 Date: Same day Time: No stipulations	Cronbach α = 0.84	No data	CRS-R and GCS: r = 0.78	No data

* Mean ± SD **Median (interquartile range) *** [Range] ****Mean [Range].

lower concordance within the arousal subscales, making them comparable to the Japanese version. Regarding the subject characteristics of the previous study, the Chinese version included a mixed population of 70 acute phase patients within 28 days of onset and 99 non-acute phase patients after 28 days. In contrast, the Polish version included chronic-phase patients with an average of 383 days from onset. The Japanese version may have been more susceptible to fluctuations in arousal levels for A1 and A2 due to the shorter interval from onset to assessment compared to the Chinese and Polish versions. Regarding the relationship between changes in the arousal subscales of A1 and A2 and the CRS-R total score, when the change in the arousal subscale was equal to 0 or 1 point, the disparity in the CRS-R total score exceeded the SDC in a limited number of cases. Conversely, when the change in the arousal subscale was 2 points, the change in CRS-R total score exceeded the SDC in 57.1% of patients, indicating that the change exceeded the margin of measurement error. Thus, if the change in the arousal subscale is greater than 2 points, it is imperative to determine whether the patient's level of consciousness has actually changed substantially or whether the patient was not sufficiently aroused prior to assessment. In the latter scenario, reassessment may be warranted after administration of an arousal-promoting protocol.

Next, the SDC between evaluators A1 and A2 was 5.75, while that between A2 and B was 2.62. The former value (5.75) represents the sum of random error and diurnal variation, whereas the latter (2.62) is considered less affected by diurnal variation. In general, however, the CRS-R is not administered continuously, and the impact of diurnal variation cannot be ignored. Therefore, when evaluating changes in CRS-R over time, verifying a change of 5.75 points or greater is imperative.

To accurately assess the CRS-R, it is essential to conduct evaluations following the 'Coma Recovery Scale-Revised Administration and Scoring Guidelines' (28). However, these guidelines span 17 pages, and due to the numerous considerations involved in CRS-R evaluations, it is considered challenging for individuals evaluating CRS-R for the first time to conduct accurate assessments. Previous studies have reported that the inter-rater reliability of CRS-R evaluations improves with higher levels of experience in assessing CRS-R (34). In this study, two evaluators underwent training using the CRS-R training module recommended by the original authors' group prior to the evaluations, resulting in favorable test-retest reliability and inter-rater reliability. While there are no mandatory training or certifications specifically designed for evaluating CRS-R, the training module utilized in this study is freely accessible (29). It may prove useful for individuals about to conduct their initial CRS-R evaluations, potentially enhancing the reliability of their assessments.

Regarding the internal consistency of the Japanese version, the highest correlation coefficients between subscales were observed in the auditory and visual domains (0.87–0.91). This trend was similar to that of the English (0.700) (5), Korean (0.899) (17), and Chinese (0.874) (19) versions. As a guideline for internal consistency, Cronbach's α is often used, with a range of 0.7–0.9 considered acceptable (22). If Cronbach's α is high, there may be an opportunity to remove items to make the scale more efficient. In this study, Cronbach's α was 0.91, slightly above the guideline of 0.9. This result suggests that there may be room to remove some assessment items from the CRS-R.

The Japanese version of the CRS-R demonstrated outstanding correlations with the JCS ($\rho = -0.82$) and the GCS ($\rho = 0.92$), validating its comorbid validity. The relationship between the CRS-R and GCS in the English version was reported as $\rho = 0.97$ (5), in the Korean version as $\rho = 0.89$ (17), in the Chinese version as $\rho = 0.78$ (19), in the Spanish version as $\rho = 0.74$ (16), and in the Russian version as $\rho = 0.90$ (18). Outcomes of the Japanese version aligned with those of previous investigations.

Regarding the relationship between the CRS-R and the JCS, the CRS-R showed greater variability when the JCS was scored from I-3 to III-100. Concerning the relationship between the CRS-R and GCS, the CRS-R showed greater variability when the total GCS score was 9–10. A total GCS score of 3–8 is deemed severe, 9–12 moderate, and 13–15 mild (35). These findings suggest that JCS and GCS are challenging for evaluating patients with moderate DOC with the same accuracy as CRS-R.

This study demonstrated good agreement for the diagnosis of impaired consciousness, with $\kappa = 0.82$ within examiners and $\kappa = 0.92$ between examiners. It has been posited that patients with an MCS level of consciousness upon admission exhibit better Glasgow Outcome Scale scores after 1 year compared with those with UWS (36). Hence, accurately diagnosing UWS and MCS is crucial to predicting a patient's physical function prognosis. However, a previous investigation noted that 41% of patients diagnosed with VS based on the medical team's clinical consensus were diagnosed with MCS by CRS-R (32). These findings underscore the importance of employing CRS-R to evaluate consciousness disorders precisely. The degree of diagnostic concordance of DOC through the CRS-R's Japanese version was comparable to or slightly superior to that reported in previous studies (Table 4), so it is deemed satisfactory for clinical applications.

Limitations

Several limitations are present in this study. First, the outcomes are based on a small sample size ($n = 59$), so they require cautious interpretation. According to the 'COSMIN Study Design Checklist for Patient-reported Outcome Measurement Instruments,' a sample size of 100 or more is defined as excellent for reliability studies. Therefore, a sample size greater than 100 is deemed necessary for future studies (26). Second, the study encompassed a mixed sample of diseases, so it did not distinguish between traumatic brain injury (TBI) and non-traumatic brain injury (NTBI). Since the prognosis for impaired consciousness has been reported to be better for TBI than for NTBI (37), they should be investigated separately in future studies. Third, this study did not specify the number of days between disease onset and evaluation. In this study, the median time for CRS-R evaluation was 7 days, which is considered a period of high variability in consciousness level. The CRS-R's psychometric characteristics might differ depending on the specific number of days, such as 7 or 30 days after disease onset, so additional research is required. Fourth, CRS-R was administered three times in a single day (A1, A2, and B), but the assessments' timing could not be kept constant. Hence, if the time interval between the A1 and A2 assessments was short, evaluator A may have recalled the first one's results. This could potentially lead to intra-examiner reliability results better than actual results. Fifth, the test-retest reliability of the CRS-R was lower within the arousal subscale compared with the other five subscales. The American Academy of Neurology (AAN) guidelines recommend that efforts should be made to increase arousal, such as using arousal-enhancing protocols within the CRS-R, before assessing level of consciousness in patients with arousal fluctuations (38). In this study, we followed the guidelines and implemented arousal-promoting protocols as needed. However, of the 59 participants, 17 individuals (32.2%) had inconsistent arousal subscale scores between the first (A1) and second (A2) measurement. The measurement period for the CRS-R in this study had a median duration of 7 days, with a interquartile range of 3 to 20 days. It is important to note that the acute phase of disorders of consciousness (DoC) is defined as within 28 days of onset. The majority of subjects in this study were in the acute phase of DoC. The acute phase is characterized by a potential decrease in response consistency and behavioral responsiveness due to systemic medical problems, secondary neurological complications, and other adverse events (e.g., medication side effects) compared to the chronic phase. Therefore, to mitigate these issues, future investigations should consider targeting patients in the chronic phase with stable overall conditions.

Sixth, this study focuses on adults; therefore, it cannot demonstrate whether the CRS-R has equivalent reliability and validity for children as it does for adults. In particular, the assessment of DoC in very young children may be limited because the types of behaviors expected in their developmental stage are limited, and it is possible that the CRS-R may not adequately detect signs of consciousness. To assess DoC in children under 5 years of age, the Coma Recovery Scale for Pediatrics (CRS-P) is a pediatric version of the CRS-R with some modifications to its subitems, proposed for use in children 12 months of age and older (39). To assess disorders of consciousness in very young children, it may be necessary to translate the CRS-P into Japanese in the future. On the other hand, in a study investigating the utility of using the CRS-R to assess patients aged 5–18 years with DoC due to acquired brain injury, it was reported that the CRS-R can track changes in DoC in children as young as 5 years (40). However, when applying the Japanese version of the CRS-R to children, it is considered necessary to conduct additional validation of its reliability and validity for the pediatric population.

Finally, the CRS-R's Japanese translation was not ideally conducted. An appropriate translation process would entail having the English version translated into Japanese by two or three experts in DOC and then having the Japanese translation back-translated by three professional translators. In this case, however, the English-to-Japanese translation was performed by one native Japanese-speaking disorientation specialist. The back-translation to English was also conducted by one professional translator. Possibly, both the English-to-Japanese and Japanese-to-English translations might have been biased because they were each performed by a single translator.

Conclusions

The Japanese version of the CRS-R seems likely to have the same level of reliability and validity as the English original and other language versions. To increase this study's generalizability, future research is needed to establish the number of days from admission to assessment and the timing of assessment for each disease with a larger sample size of 100 or more patients.

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