The Coma Recovery Scale-Revised: Evidentiary Support for Hierarchical Grading of Level of Consciousness.

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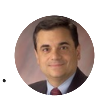
3 authors:


Paul B Gerrard
New England Rehabilitation Hospital of Po…


Ross Zafonte
Spaulding Rehabilitation Hospital


Joseph Giacino
Harvard Medical School

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ORIGINAL ARTICLE

Coma Recovery Scale—Revised: Evidentiary Support for Hierarchical Grading of Level of Consciousness

Paul Gerrard, MD, Ross Zafonte, DO, Joseph T. Giacino, PhD

From Spaulding Rehabilitation Hospital and Harvard Medical School, Boston, MA.

Abstract

Objective: To investigate the neurobehavioral pattern of recovery of consciousness as reflected by performance on the subscales of the Coma Recovery Scale—Revised (CRS-R).

Design: Retrospective item response theory (IRT) and factor analysis.

Setting: Inpatient rehabilitation facilities.

Participants: Rehabilitation inpatients (N=180) with posttraumatic disturbance in consciousness who participated in a double-blinded, randomized, controlled drug trial.

Interventions: Not applicable.

Main Outcome Measures: Scores on CRS-R subscales.

Results: The CRS-R was found to fit factor analytic models adhering to the assumptions of unidimensionality and monotonicity. In addition, subscales were mutually independent based on residual correlations. Nonparametric IRT reaffirmed the finding of monotonicity. A highly constrained confirmatory factor analysis model, which imposed equal factor loadings on all items, was found to fit the data well and was used to estimate a 1-parameter IRT model.

Conclusions: This study provides evidence of the unidimensionality of the CRS-R and supports the hierarchical structure of the CRS-R subscales, suggesting that it is an effective tool for establishing diagnosis and monitoring recovery of consciousness after severe traumatic brain injury.

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The measurement of level of consciousness is a difficult but crucial aspect of diagnostic and prognostic assessment of persons with disorders of consciousness (DOC). Estimates of misdiagnosis in this population consistently fall within the 30% to 45% range.[1-3] Diagnostic error may result from biases contributed by the examiner, patient, and environment.[1] Examiner error may arise when the range of behaviors sampled is too narrow, response-time windows are over- or underinclusive, criteria for judging purposeful responses are poorly defined or not adhered to, and examinations are conducted too infrequently to capture the full range of behavioral fluctuation. The second source of variance concerns the patient. Fluctuations in arousal level, fatigue, subclinical seizure activity, occult illness, pain, cortical sensory deficits (eg, cortical blindness/deafness), motor impairment (eg, generalized hypotonus, spasticity, or paralysis), or cognitive (eg, aphasia, apraxia, agnosia) disturbance can conspire to confound accurate diagnostic assessment, constitute a bias to the behavioral assessment, and therefore decrease the probability to observe signs of consciousness. Finally, the environment in which the patient is evaluated may bias assessment findings. Paralytic and sedating medications, restricted range of movement stemming from restraints and immobilization techniques, poor positioning, and excessive ambient noise, heat, or light can decrease or distort voluntary behavioral responses.

Accurate evaluation requires well-validated and reliable measurement tools. Since consciousness itself is a nebulous concept, efforts to develop effective assessment methods typically begin with an a priori operational definition of the construct of consciousness. Frameworks for describing consciousness have been previously proposed based on neuroanatomic, philosophical, and even computational criteria.[4-10] However, such explanations have

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Disclosures: Giacino has served as an expert witness/consultant on 4 legal cases over the last 36 months involving patients with disorders of consciousness concerning diagnosis, prognosis, pain and suffering, and adequacy of treatment. The other authors have nothing to disclose.

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limited practical use in clinical assessment. An alternative approach to characterizing the construct of consciousness involves empirically identifying a set of behaviors that represent levels of neurologic function along the continuum of consciousness. While this strategy does not have the theoretical rigor that may be seen in computational or philosophical criteria, it has the advantage of providing a clinically useful approach that can guide diagnostic decision-making.

Recently, the American Congress of Rehabilitation Medicine conducted an evidence-based review[11] of assessment scales designed specifically for use in persons with DOC. The authors concluded that among the 13 assessment scales reviewed, only the Coma Recovery Scale−Revised (CRS-R) had sufficient psychometric properties to be recommended for use in clinical practice with minor reservations. The CRS-R is a standardized measure of neurobehavioral function that has been widely used for diagnostic assessment and outcome measurement in studies involving persons with DOC.[3,12-15] It consists of 23 hierarchically arranged items that comprise 6 subscales designed to assess arousal level, audition and language comprehension, expressive speech, visuoperceptual abilities, motor functions, and communication ability. Scoring is based on the presence or absence of behavioral responses to stimuli presented in a standardized manner. The lowest item on each subscale represents reflexive behavior, while the highest item reflects cognitively mediated activity.

The examiner presents a stimulus according to standardized instructions and scores the response against predefined criteria. If an item is "failed," the examiner progresses to the next item down, continuing this process until a scorable response is obtained. For example, in an awake and fully conscious patient, only the first (ie, highest level) item on each subscale would be administered, as the corresponding behavioral response would be expected to reflect cognitively mediated activity. In contrast, in a patient with impaired brainstem function, the examiner would likely administer all items within a particular subscale, because the corresponding higher-level neurobehavioral responses would not occur. A score is assigned for each subscale based on the highest-level behavior observed. The lowest score on all subscales is 0, and the maximum ranges from 2 (communication subscale) to 6 (motor subscale). Higher scores are intended to indicate higher levels of neurologic function. Notably, some subscales include pathologic behaviors (eg, abnormal posturing) that are expected to be extinguished at higher levels of consciousness. The term *subscale* as it is used in the CRS-R refers to the item response theory (IRT) notion of an item. Thus, we refer to the subscales of the CRS-R as "items" and the individual stimulus-response pairs as "response categories." The 6 items of the CRS-R and the behavioral response categories for each item are provided in figure 1.

Identification of the underlying construct represented by the CRS-R would yield not only a quantitative measure of consciousness but also possible operational definitions for discrete levels of consciousness. The manner in which the CRS-R is administered relies on a theoretical hierarchy of neurobehavioral responses, which is in part derived from analysis of the original CRS-R.[13,16] This hierarchy rests on the assumption that behaviors considered higher level by the test do indeed correspond to a higher level of neurologic functioning and that if persons are able to demonstrate higher-level behaviors, they also either are able to demonstrate the lower-level behaviors or have progressed to a level of consciousness where such behaviors have extinguished (as is the case with pathologic behaviors). In general, evidence of construct validity is sought by determining whether the outcome measure of interest has a construct that behaves in the expected manner. Psychometricians have described 2 types of construct validity: weak validity and strong validity. Weak validity is established by a correlation with some external criterion, whereas strong validity is established by testing a well-formulated hypothesis that should explain the observed scores on the instrument.[17] To provide evidence for strong construct validity on a unidimensional assessment scale, the constituent items should demonstrate unidimensionality, monotonicity, mutual independence, and invariant item ordering.[18-20] Unidimensionality refers to the fact that a scale represents a single latent construct. Monotonicity asserts that as a respondent's score on the test increases, the expected score on any single item should increase or at least remain stable. Mutual independence holds that the only source of correlation in scores between any 2 (or more) items on a given scale should be the underlying construct that is being measured by the scale as a whole. Invariant item ordering, sometimes also referred to as the "nonintersection of the item response curves," refers to the notion that for any given ability level, the order of difficulty of items should remain the same.

To test these properties of the CRS-R individually, we applied a series of psychometric models to the CRS-R in a graded fashion from least to most restrictive as follows. We first applied kernel density smoothing IRT[21] (KSIRT) to ensure that the assumption of monotonicity was met, providing evidence of the hierarchical structure of the scale. If this assumption was not met, further analysis would not have been appropriate. Once monotonicity was established, we obtained polychoric correlations to explicitly model the ordinal CRS-R data as monotonic continuous data. We then used these polychoric correlations as input to factor analyses, further exploring construct validity and the hierarchical composition of the CRS-R items. First, exploratory factor analysis (EFA) was performed to test the adequacy of a single dimension to explain the observed data and look for evidence of local independence. Once unidimensionality and local independence were established, we tested the assumption of invariant item ordering. This was accomplished using confirmatory factor analysis, constraining item loadings to be equal.

The rationale for this approach is that each psychometric method has different constraints. For example, in the recent IRT analysis of the CRS-R by La Porta et al,[22] the Rasch model was applied. This particular psychometric approach imposes that all items have the same discrimination parameter, and the estimation algorithms are typically based on a maximum likelihood approach. This is in contrast to other methods for handling ordinal data such as nonparametric IRT models, IRT models that allow discrimination parameters to vary between items, and factor analytic methods. Because it is not possible to know for certain which psychometric model best represents any given construct,

List of abbreviations:

CFA	**confirmatory factor analysis**
CRS-R	**Coma Recovery Scale−Revised**
DOC	**disorders of consciousness**
EFA	**exploratory factor analysis**
IRT	**item response theory**
KSIRT	**kernel density smoothing item response theory**
SRMR	**standardized root mean square of the residuals**
TLI	**Tucker-Lewis Index**

JFK COMA RECOVERY SCALE - REVISED ©2004

Record Form

This form should only be used in association with the "CRS-R ADMINISTRATION AND SCORING GUIDELINES" which provide instructions for standardized administration of the scale.

Patient:	**Diagnosis:**	**Etiology:**
Date of Onset:	**Date of Admission:**	

Date																
Week	**ADM**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
AUDITORY FUNCTION SCALE																
4 - Consistent Movement to Command *																
3 - Reproducible Movement to Command *																
2 - Localization to Sound																
1 - Auditory Startle																
0 - None																
VISUAL FUNCTION SCALE																
5 - Object Recognition *																
4 - Object Localization: Reaching *																
3 - Visual Pursuit *																
2 - Fixation *																
1 - Visual Startle																
0 - None																
MOTOR FUNCTION SCALE																
6 - Functional Object Use †																
5 - Automatic Motor Response *																
4 - Object Manipulation *																
3 - Localization to Noxious Stimulation *																
2 - Flexion Withdrawal																
1 - Abnormal Posturing																
0 - None/Flaccid																
OROMOTOR/VERBAL FUNCTION SCALE																
3 - Intelligible Verbalization *																
2 - Vocalization/Oral Movement																
1 - Oral Reflexive Movement																
0 - None																
COMMUNICATION SCALE																
2 - Functional: Accurate †																
1 - Non-Functional: Intentional *																
0 - None																
AROUSAL SCALE																
3 - Attention																
2 - Eye Opening w/o Stimulation																
1 - Eye Opening with Stimulation																
0 - Unarousable																
TOTAL SCORE																

Denotes emergence from MCS †

Denotes MCS *

Fig 1 Face sheet for CRS-R. The CRS-R is composed of 6 hierarchically ordered subscales reflecting increasingly complex neurobehavioral function. Abbreviation: MCS, minimally conscious state. Copyright © 2004 Joseph T. Giacino, PhD. Used with permission.

applying different psychometric approaches provides an opportunity to test a scale under different sets of assumptions.

The purpose of this study, therefore, was to examine the construct validity of the CRS-R using IRT and factor analytic approaches to affirm the theoretical hierarchy of the neurobehavioral responses represented on the CRS-R subscales. Specifically, we hypothesized that the CRS-R would meet criteria for unidimensionality, monotonicity, mutual independence, and potentially invariant item ordering. Demonstration that the CRS-R possesses the monotonicity property would provide empirical support for the hierarchical conceptual framework of the CRS-R which assumes that subscale scores reflect increasing levels of consciousness. Adequate performance of the scale across the other 3 properties would strengthen this assertion.

Methods

Participants

Data were obtained from a recently published prospective, multicenter, randomized controlled trial[23] of the drug amantadine hydrochloride that followed patients with DOC on the CRS-R. The original sample was composed of adults who were admitted for inpatient rehabilitation between 4 and 16 weeks postinjury and met existing diagnostic criteria for posttraumatic vegetative or minimally conscious state at the time of enrollment. Patients who emerged from the minimally conscious state (including those with posttraumatic confusion) were excluded. CRS-R scores were obtained by pretrained raters from the 11 sites that participated in the study. CRS-R scores were available for 180 of the 184 patients enrolled in the study. Descriptive data for the study sample are shown in table 1.

Table 1 Characteristics of study sample

Variable	n	%	Mean ± SD
Age (y)			36.6±15.4
Male sex	130	72	
Race			
Asian	2	1	
Black	16	9	
White	156	87	
Other	6	3	
Hispanic			
Yes	16	9	
No	164	91	
Education			
Less than high school	31	17	
High school/GED	82	46	
Some college	52	29	
College degree	8	4	
Graduate work	6	3	
Time from injury to CRS-R administration (d)			82.1±22.3
CRS-R score			15±6.4
Injury location			
Mesial frontal	115	65.0	
Lateral frontal	134	75.7	
Orbital	82	46.3	
Temporal	105	59.3	
Parietal	75	42.4	
Insula	78	44.1	
Basal ganglia	43	24.3	
Internal capsule	51	28.8	
Thalamus	34	19.2	
Brainstem	43	24.3	

Abbreviation: GED, General Education Development.

Procedures

Before enrolling patients in the original study, approval from each site's institutional review board was obtained. The current study represents a post hoc analysis of the CRS-R data that were obtained during week 4 of the prior study's treatment window. This time point was selected because it provided the widest range of CRS-R scores.

Data analysis

The internal aspects of the construct of the CRS-R were examined using KSIRT, EFA using minimum residual factor extraction on the polychoric correlation matrix, and CFA based on polychoric correlations. We started by using the 2 relatively unrestrictive psychometric models (KSIRT, EFA) to establish some basic properties of the CRS-R. The reason for starting with unrestrictive models is that restrictive models may cause a bias in observed item behavior if the model is misspecified. After demonstrating that the CRS-R conformed to the assumptions of unidimensionality, monotonicity, and local independence with these less restrictive models, a highly restricted CFA model was applied. Polychoric correlations explicitly assume that the raw data are an ordinal representation of some continuous underlying distribution. To compute these correlations, a discretizing threshold is estimated for each ordinal response. These correlations were used in the exploratory and confirmatory factor analyses. Notably, factor analysis completed using polychoric correlations can be used to estimate IRT parameters.[24,25]

Less restrictive models

KSIRT makes no assumption about the algebraic form of the function relating the response on an item to the construct; rather, curves are created empirically. This method was used in particular to look for evidence of monotonicity. The rationale for the use of this method is that it does not constrain an item to have monotonicity, but rather provides a visual representation of whether any violations to monotonicity exist. Thus, this was a test of monotonicity, which does not impose any a priori model on the data, but rather shows the behavior of the items with minimal assumptions.

EFA using a minimum residual estimation method was applied specifically to examine the properties of unidimensionality, monotonicity, and local independence (which is highly related to unidimensionality). The factor analytic model itself adhered to the unidimensionality and monotonicity assumptions, so the assumptions were tested by assessing the fit of the model to the data. Since the EFA model only constrains the number of dimensions and ordering of item thresholds, it is not as restrictive as the CFA model that was subsequently used. Model fit was assessed with the Tucker-Lewis index (TLI). Local independence was tested using a residual correlation method, with a residual correlation >0.2 between any 2 items indicating a violation.[26,27]

Confirmatory factor analysis

If the 2 less restrictive models, EFA and KSIRT, were to yield supportive evidence of unidimensionality, monotonicity, and local independence, the next step was to apply a highly restrictive CFA model. As in the EFA, polychoric correlations were used. However, unlike the EFA, item loadings were constrained to be equivalent across all items. Two different constraint paradigms were used: (1) a less restrictive model in which factor loadings were constrained to produce the same discrimination parameter across all items; and (2) a more restrictive model in which all factor loadings were constrained such that the item discrimination parameters would not only be equal to each other, but would be equal to 1, the a priori−specified discrimination parameter of the Rasch model. The intended outcome is to create a factor analysis model analogous to a cumulative response, 1-parameter IRT model. Model fit was assessed with the TLI and the standardized root mean square of the residuals (SRMR). The polychoric correlations and factor loadings were used to estimate location and discrimination parameters of a 1-parameter logistic IRT model based on prior psychometrics literature exploring the relationship between factor analysis and IRT.[24,25]

All data analysis was performed using R Statistical Environment.[a] KSIRT[21] was used to allow visual examination of item response functions with the KernSmoothIRT[b] package. Factor analysis was performed with the Psych,[b] Lavaan,[28,b] and Polycor[b] packages.

Results

The EFA model constraining the scale to meet the criteria of unidimensionality and monotonicity fit the data well, with a SRMR of .02 and a TLI of .97 indicating good model fit. The single factor explained 77% of the total variance in the 6 items. Additionally, local independence was supported with residual correlations between items ranging in magnitude from .0018 to .142, below the threshold of 0.2 prespecified as the maximum acceptable value. As displayed in figure 2, KSIRT showed monotonically increasing item characteristic curves for all 6 items, further supporting the presence of monotonicity.

Two CFA models were fit to the data, which constrained the scale to be unidimensional with monotonically increasing item thresholds and, unlike the EFA, required an item response function based on normal ogive. The less restrictive model that constrained item loadings to be equal, but did not prespecify what those loadings should be, had excellent model fit with a TLI of .99 and an SRMR of .039. The more constrained model in which the loadings were constrained to give item discrimination parameters of 1 showed substantially less good fit with a TLI of .903 and an

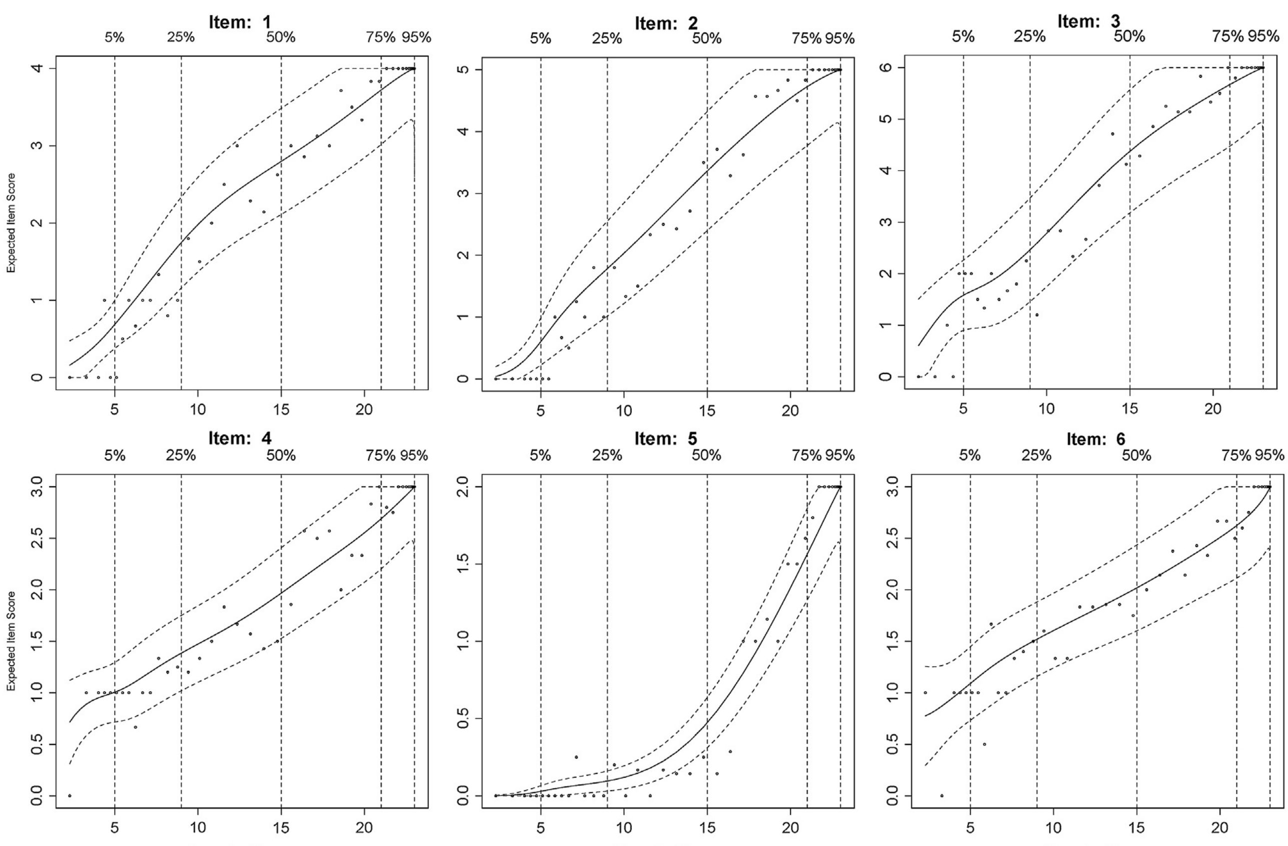

Fig 2 Item characteristic curves for the CRS-R. The item characteristic curves for each of the 6 CRS-R items are shown. The same item numbering convention is used here as is used in table 2. The horizontal axis represents the expected score on the test as a whole, while the vertical axis represents the expected score on the item. The dark black lines in each plot are the item characteristic curves, and the dotted lines running on either side are the 95% confidence intervals for the curves. As depicted, both the item characteristic curves and each curve's 95% confidence interval are monotonically increasing. Dots represent the individual data points. The vertical dotted lines represent the percentiles of total scores obtained by subjects in the study sample.

Table 2 Logistic IRT parameters estimated from the constrained CFA

CRS-R Subscale	Discrimination Parameter	Thresholds Between Response Options					
		0–1	1–2	2–3	3–4	4–5	5–6
Auditory	1.621	−5.327	−2.299	−1.151*	1.199*	NA	NA
Visual	1.621	−4.364	−2.072*	−1.495*	−0.316*	0.961*	NA
Motor	1.621	−6.509	−3.953	−1.545*	−1.395*	−0.820*	1.346†
Verbal/oromotor	1.621	−5.939	−1.698	1.151*	NA	NA	NA
Communication	1.621	0.045*	1.803†	NA	NA	NA	NA
Arousal	1.621	−7.405	−2.241	1.495	NA	NA	NA

NOTE. The discrimination parameter was constrained to be the same for all items.
Abbreviation: NA, not applicable.
* Indicates thresholds corresponding to the transition from vegetative to minimally conscious state.
† Indicates thresholds corresponding to transitions from minimally conscious to emergence from minimally conscious state.

SRMR of .164. Based on these findings and previously published CFA fit criteria,[29] the less restrictive model better fit the data produced by the scale than the more restrictive model.

The less restrictive CFA model estimated that the standardized factor loading of each item on the latent trait was .851, which can be transformed to a discrimination parameter of 1.621. The item threshold location parameters are shown in table 2. Additionally, the residual correlations of the less restrictive model had magnitudes of .079 or less, consistent with the criteria for local independence that were established a priori.

Discussion

We subjected the CRS-R to 3 different psychometric approaches—KSIRT, EFA, and CFA—to determine whether its key underlying construct, the level of consciousness, behaved in the desired and expected manner. We found that the CRS-R adhered to the 4 critical scaling criteria of unidimensionality, monotonicity, mutual independence, and equivalent loadings of all items.

The demonstration of monotonicity provides empiric support for the theoretical hierarchy of the neurobehavioral tasks included in the CRS-R—as one's level of consciousness improves, performance on the CRS-R increases accordingly. Even though some CRS-R subscales include pathologic behaviors within the hierarchy of tasks, the relationship between ability and performance holds. On the motor subscale, for example, automatic motor behavior, a pathologic frontal release sign, is assigned a higher score than object manipulation, a normal but developmentally less complex behavior. Thus, as the level of consciousness and inhibitory motor control improve, the abnormal release of automatic motor behaviors should resolve. The demonstration of higher-level behaviors does not necessarily mean that lower-level behaviors would be expected, and in some instances, they would even be unexpected. IRT analysis reconciles this seeming imbalance by testing the strength of the relationship between specific behaviors and the putative underlying construct they represent. The adherence to the assumptions of unidimensionality and local independence indicates that a single underlying trait accounts for measured scores, and fit of the scale to a model of equivalent discriminations further strengthens the support for measurement properties of the scale.

While this is not the first study to examine the validity of the CRS-R, it is the first study to explicitly examine the validity of the hierarchical structure of the 6 subscales, and the first to use IRT data drawn from an international sample. Additionally, it subjected the CRS-R to a number of different psychometric models in a graded fashion progressing from least to most restrictive. Since restrictions on a parameter can introduce bias in observations about the scale's behavior, we tested the most important assumptions of the scale before applying highly restrictive models.

We used psychometric methods that were both less than and as restrictive as Rasch analysis. The KSIRT was the least restrictive of all models used, enforcing almost no constraints on the scale, and was able to show violations to the desired hierarchical ordering of the scale. EFA was more restrictive than KSIRT, but it imposed no constraints on the item parameters. The less restrictive CFA model was slightly less restrictive than the Rasch model, forcing all item loadings (and therefore discrimination parameters) to be equivalent. The more restrictive CFA was the most restrictive of all models, as it constrained the item discrimination parameters to be 1 (in line with the Rasch model.)

This study differs from a recently published Italian study by La Porta[22] that examined the construct validity of the CRS-R by using Rasch analysis in patients undergoing rehabilitation in an Italian network of hospitals. In that study, the validity of the hierarchical ordering of behaviors within each subscale (ie, the lowest item represents a primitive brainstem reflex, while the highest item reflects cognitively mediated behavior[13]) was not explicitly tested. In addition, La Porta's study specifically examined the fit of the CRS-R to a single model, the Rasch model, and showed a lack of model rejection as assessed with statistical significance testing using a chi-square statistic. La Porta's study did not compare whether other models provide better fit, and the statistical significance testing did not actually assess model fit, but rather was a test for rejecting (or failing to reject) the Rasch model. In contrast, our study used 3 different psychometric models and compared 2 restrictive CFA models for better fit by using measures of fit rather than relying on statistical significance tests for misfit. Our approach is not only mathematically distinct from LaPorta's Rasch-based approach, but also philosophically distinct. Rasch analysis is not simply a mathematical model but rather a prescribed approach to scale development, characterized by fitting a scale to a selected rigid model. We set out instead to find the model that best fits the scale. In general, the validity of a scale is not a binary property but exists on a continuum.[17] Testing the hypothesized construct of a scale in different ways strengthens the evidence supporting that scale on the continuum of validity. To that end, our study is complementary to La Porta's study precisely because it tests the hypothesized underlying construct of the CRS-R using a different set of assumptions.

Study limitations

The present study has some important limitations. Analyses were conducted post hoc using data from a prior randomized controlled trial in which a study of the construct of consciousness was not the primary aim. Additionally, this study included only patients with traumatic brain injury, so we are unable to determine whether the results are generalizable to patients who have DOC from non-traumatic injuries. Lastly, this study relies on data from a single time point, establishing relative item difficulties in a between-subjects fashion. While we would assume that changes within a subject would reflect the same pattern of results, this has not been demonstrated.

Conclusions

This study examined the CRS-R using nonparametric IRT and provides evidence of construct validity and empiric support for the theoretical hierarchy of behaviors assessed within each subscale. The strong support for the latent construct of the CRS-R suggests that the scale represents a useful quantitative tool for clinical assessment, monitoring outcome, and gauging recovery within specific neural networks in patients with posttraumatic DOC.

Suppliers

a. R-The R Core Team; R Foundation for Statistical Computing, Vienna, Austria, Available at: http://www.R-project.org/.
b. Cran-R project. Available at: http://cran.r-project.org/web/packages.

Keywords

Traumatic brain injury; Disorders of consciousness; Psychometrics; Rehabilitation

Corresponding author

Joseph T. Giacino, PhD, Spaulding Rehabilitation Hospital, 300 First Avenue, Charlestown, MA 02129. *E-mail address:* jgiacino@partners.org.

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