Feasibility and Validity of the Coma Recovery Scale-Revised for Accelerated Standardized Testing: A Practical Assessment Tool for Detecting Consciousness in the Intensive Care Unit

Yelena G. Bodien, PhD [1,2]
Isha Vora, PhD,[3] Alice Barra, PhD,[1,4]
Kevin Chiang, MD,[5]
Camille Chatelle, PhD,[1,4]
Kelsey Goostrey, MPH,[1]
Geraldine Martens, PhD,[1,4,6]
Christopher Malone, PhD,[1]
Jennifer Mello, MS, CCC-SLP,[7]
Kristin Parlman, DPT, PT,[8]
Jessica Ranford, MS, OT,[9]
Ally Sterling, ScM, MBE,[1]
Abigail B. Waters, PhD,[1,10]
Ronald Hirschberg, MD,[1,11]
Douglas I. Katz, MD,[12,13]
Nicole Mazwi, MD,[1,11,14]
Pengsheng Ni, PhD,[15]
George Velmahos, MD, PhD,[5]
Karen Waak, DPT, PT,[8]
Brian L. Edlow, MD [2,16] and
Joseph T. Giacino, PhD[1,17]

We developed and validated an abbreviated version of the Coma Recovery Scale-Revised (CRS-R), the CRS-R For Accelerated Standardized Testing (CRSR-FAST), to detect conscious awareness in patients with severe traumatic brain injury in the intensive care unit. In 45 consecutively enrolled patients, CRSR-FAST administration time was approximately one-third of the full-length CRS-R (mean [SD] 6.5 [3.3] vs 20.1 [7.2] minutes, $p < 0.0001$). Concurrent validity (simple kappa 0.68), test–retest (Mak's $\rho = 0.76$), and inter-rater (Mak's $\rho = 0.91$) reliability were substantial. Sensitivity, specificity, and accuracy for detecting consciousness were 81%, 89%, and 84%, respectively. The CRSR-FAST facilitates serial assessment of consciousness, which is essential for diagnostic and prognostic accuracy.

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Introduction

Bedside examination plays a key role in clinical management of patients with disorders of consciousness (DoC) in the intensive care unit (ICU) and, in addition to serving as the gold standard for diagnostic assessment, is the primary means of determining intensity of care, detecting complications, monitoring rate of recovery, establishing prognosis, and planning discharge disposition.[1] However, studies of diagnostic accuracy in patients with DoC conducted in both acute and post-acute settings consistently indicate that 30–40% of those judged to be unconscious on bedside examination actually retain some degree of conscious awareness.[2] Failure to detect signs of conscious awareness may inappropriately influence clinical decision-making, lead to premature withdrawal of life-sustaining therapy, and limit access to medical and rehabilitation services.

The Glasgow Coma Scale[3] and the Full Outline of UnResponsiveness[4] score are brief and widely used assessment scales developed to detect changes in level of consciousness in acutely injured patients. However, neither scale was designed to quantify level of consciousness or differentiate the minimally conscious state (MCS) from

From the [1]Department of Physical Medicine and Rehabilitation, Spaulding Rehabilitation Hospital, Harvard Medical School, Charlestown, MA, USA; [2]Center for Neurotechnology and Neurorecovery, Department of Neurology, Massachusetts General Hospital and Harvard Medical School, Boston, MA, USA; [3]Department of Rehabilitation Sciences, MGH Institute of Health Professions, Boston, MA, USA; [4]Coma GIGA Science Group, University of Liege, Liege, Belgium; [5]Department of Surgery, Massachusetts General Hospital, Boston, MA, USA; [6]Department of Surgery, University of Montréal, Montréal, QC, Canada; [7]Department of Speech-language and Swallowing, Massachusetts General Hospital, Boston, MA, USA; [8]Department of Physical Therapy, Massachusetts General Hospital, Boston, MA, USA; [9]Department of Occupational Therapy, Massachusetts General Hospital Boston, Boston, MA, USA; [10]Department of Clinical and Health Psychology, University of Florida, Gainesville, FL, USA; [11]Department of Physical Medicine and Rehabilitation, Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA; [12]Department of Neurology, Boston University Chobanian & Avedisian School of Medicine, Boston, MA, USA; [13]Encompass Health Braintree Rehabilitation, Braintree, MA, USA; [14]Department of Rehabilitation Medicine, University of Washington, Seattle, WA, USA; [15]Biostatistics & Epidemiology Data Analytic Center, Department of Health Law, Policy, and Management, Boston University School of Public Health, Boston, MA, USA; [16]Athinoula A. Martinos Center for Biomedical Imaging, Massachusetts General Hospital, Charlestown, MA, USA; and [17]Department of Psychiatry, Massachusetts General Hospital, Boston, MA, USA

Address correspondence to Dr Bodien, Department of Physical Medicine and Rehabilitation, Spaulding Rehabilitation Hospital, Charlestown, MA 02114, USA. E-mail: ybodien@mgh.harvard.edu

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the vegetative state/unresponsiveness wakefulness syndrome (VS/UWS), a critical diagnostic distinction for predicting subsequent outcome.[1] The Coma Recovery Scale-Revised (CRS-R)[5,6] enables this distinction, has the best performance characteristics among 13 DoC assessment scales,[7] is recommended by current American[8] and European[9] clinical practice guidelines, and is a National Institute of Neurological Disorders and Stroke Common Data Element.[10] CRS-R administration time, however, can extend up to 30 minutes, limiting its use in the ICU, as patients often cannot tolerate being unsedated for extended periods, and clinicians face significant time pressure. The Simplified Evaluation of CONsciousness DisorderS[11] is a brief instrument developed to assess level of consciousness, but is not validated in the ICU. To address these limitations, we developed the CRS-R For Accelerated Standardized Testing (CRSR-FAST; clinicaltrials.gov NCT03549572), an abbreviated version of the full-length CRS-R. We tested the feasibility, concurrent validity, reliability, diagnostic sensitivity, and specificity of the CRSR-FAST in the ICU.

Methods

Participants

We consecutively enrolled patients with acute traumatic brain injury (TBI) admitted to an ICU at a level 1 trauma center between August 2018 and December 2022. Patients were aged at least 18 years, English-speaking, had a total Glasgow Coma Scale score ≤8 on at least 1 assessment within the first 48 h of injury, were not consistently following commands (per clinical chart review conducted by a study team member not involved with data acquisition), and were ≤3 weeks post-injury. Of 776 patients screened, 127 met the inclusion criteria and 56 were enrolled (see Supplementary Figure S1, Table 1). A total of 11 patients did not complete at least two study assessments, excluding them from further analyses. Legally-authorized representatives provided informed consent, consistent with the protcol approved by the local institutional review board.

Measures

The CRS-R consists of six subscales that are designed to detect behaviors associated with different levels of consciousness. Further details are available online.[12] The CRSR-FAST assesses only those CRS-R behaviors that differentiate conscious (MCS or emerged from MCS [eMCS]) from unconscious (coma or VS/UWS) patients. Multidisciplinary ICU clinicians, representing physicians, therapists, and nurses involved in neurocriticial care and rehabilitation, participated in focus groups and surveys to establish a maximum acceptable duration of 10 min for an ICU assessment, and to reach at least 80% consensus on the final core behaviors included in the CRSR-FAST: command-following, automatic motor responses, visual pursuit/fixation, localization to noxious stimulation, and intelligible speech (Figure and Supplementary Materials provide the scale and administration manual).

Medical complications and other factors confounding the examination are documented to convey the

TABLE 1. Patient Demographics and Clinical Characteristics

	Included in analysis ($n = 45$)	Eligible, but not enrolled or did not complete at least 2 assessments ($n = 71$)
Mean age, years (SD)	44 (20)	55 (21)*
Sex (M), *n* (%)	30 (67%)	46 (72%)
Mechanism of injury, *n*		
Motor vehicle collision	26	29
Fall	16	32
Gunshot	3	1
Unknown	0	9
Total GCS score in the ED		
Min range	3/3 T - 10	3/3 T - 15
Max range	3/3 T - 14	3/3 T - 15
Mean days from injury to first study assessment, *n* (SD)	8.3 (5.1)	NA
CRS-R diagnosis (*n*)		
Coma/VS-UWS	18	
MCS−	17	
MCS+	9	
eMCS	1	
Mean CRS-R total score (SD)	6.9 (5.2)	

Note: In addition to the 45 patients included in the analysis, 71 patients with traumatic brain injury met all inclusion criteria at the time of screening but became ineligible prior to consent ($n = 24$), refused participation ($n = 21$), were positive for coronavirus disease 2019 ($n = 6$), did not have a surrogate who could be reached ($n = 9$), or consented, but did not complete at least 2 assessments ($n = 11$). Patients in the cohort that were eligible, but not included in the study, were older (*t test $p < 0.005$), but otherwise similar to the patients who were included. The minimum GCS values includes patients with (i.e., 3T) and without intumation.

Abbreviations: CRS-R = Coma Recovery Scale-Revised; ED = emergency department; eMCS = emergence from the minimally conscious state; GCS = Glasgow Coma Scale; MCS = minimally conscious state without (MCS−) or with (MCS+) evidence of language function; SD = standard deviation; T = intubateion; VS-UWS = vegetative state/unresponsive wakefulness syndrome.

CRSR-FAST Record Form

Patient:_____ Date: _____

Administer each item per guidelines until a scoreable response is obtained									
Present (1=yes, 0=no)	**Signs of Consciousness**	**Responses**							
	Reproducible command following ▪								
	Fixation/Visual pursuit*								
	Automatic motor response*								
	Localization to noxious stimulation*								
	Intelligible expression ▪								
Supplementary Items									
	Functional object use[t]								
	Functional: accurate communication[t]								
	Non-Functional: intentional communication ▪								

* MCS-; ▪ MCS+; [t] eMCS

Trial scoring: 0 =no response; - =incorrect response; + =correct

Resting Posture	
RUE:	RLE:
LUE:	LLE:

Spontaneous Behaviors
Eye Opening:
Visual Tracking:
Active Movements:

Psychoactive Medications/Paralytics (use Notes section for additional medications)			
Name	1.	2.	3.
Dose			
Time admin. hh:mm			
Time lifted			

	Check all potential confounders to exam findings
	Psychoactive agents not lifted for exam
	General anesthesia within 24 hrs
	Ictal event within 24 hrs
	Intubation
	Fever >99 within 2 hrs of exam
	Underarousal (i.e., sustained eye closure >3 seconds)
	No confounding factors

Notes: Record observations or concerns that may influence or ambiguate scoring of any items

____**#** Arousal Facilitation Protocol administrations

Test Completion Codes - circle one			
1	test completed in full, in person- results valid		
Test attempted, not completed due to:		**Test not attempted** due to:	
2.1	impaired sensory function (cortical or peripheral)	3.1	impaired sensory function (cortical or peripheral)
2.2	aphasia	3.2	aphasia
2.3	physical limitation restricting movement (e.g., fracture, hemiparesis)	3.3	physical limitation restricting movement (e.g., fracture, hemiparesis)
2.4	primary language barrier	3.4	primary language barrier
2.5	illness/medical instability	3.5	illness/medical instability
2.6	examiner error	3.6	examiner error
2.7	logistical problem	3.7	logistical problem
2.8	other (specify):	3.8	other (specify):

FIGURE: The five core items of the Coma Recovery Scale-Revised For Accelerated Standardized Testing (CRSR-FAST) are administered in order until a scoreable response is elicited or, for specified items, observed to occur spontaneously and meet the scoring criteria. The final rating is "conscious" if at least one of the core items is observed, or "not conscious" if none of these items are observed. There are three supplementary items, two of which can be used by the examiner to detect emergence from the minimally conscious state. Resting posture is recorded as the position of the extremities at rest, which can influence motor responses to noxious stimulation. Contextual factors that may confound assessment findings such as psychoactive medications, recent anesthesia, and intubation are recorded. Test completion codes are entered to establish the validity of the assessment and to record reasons for confounding or failure to complete the examination. The CRSR-FAST Administration and Scoring Manual is provided in the Supplementary Materials.

TABLE 2. Psychometric Properties of the Coma Recovery Scale-Revised For Accelerated Standardized Testing

Concurrent validity			
	CRS-R		Simple kappa (SE)
CRSR-FAST	Conscious	Not conscious	0.68 (0.10)
Conscious	22	2	
Not conscious	5	16	
Test–retest reliability			
	CRSR-FAST		Mak's ρ (SE)
CRSR-FAST	Conscious	Not conscious	0.76 (0.10)
Conscious	21	1	
Not conscious	4	16	
Inter-rater reliability			
	CRSR-FAST		Mak's ρ (SE)
CRSR-FAST	Conscious	Not conscious	0.91 (0.06)
Conscious	23	1	
Not conscious	1	20	

Abbreviations: CRS-R = Coma Recovery Scale-Revised; CRSR-FAST = Coma Recovery Scale-Revised For Accelerated Standardized Testing; SE = Standard Error.

Table 3. Coma Recovery Scale-Revised For Accelerated Standardized Testing Accuracy and Precision

Measure	Formula	Value	SE*
True positive rate (*TPR*), sensitivity	$\frac{TP}{TP+FN}$	0.81	0.07
True negative rate (*TNR*), specificity	$\frac{TN}{TN+FP}$	0.89	0.08
Accuracy	$\frac{TP+TN}{TP+TN+FP+FN}$	0.84	0.05
Positive predictive value (*PPV*)	$\frac{TP}{TP+FP}$	0.92	0.06
Negative predictive value (*NPV*)	$\frac{TN}{TN+FN}$	0.76	0.09
False positive rate (*FPR*)	$\frac{FP}{FP+TN}$	0.11	0.08
False discovery rate (*FDR*)	$\frac{FP}{FP+TP}$	0.08	0.06

Abbreviations: FN = false negative: number of times Coma Recovery Scale-Revised full rating is "conscious" and Coma Recovery Scale-Revised For Accelerated Standardized Testing rating is "not conscious." FP = false positive: number of times Coma Recovery Scale-Revised full rating is "not conscious" and Coma Recovery Scale-Revised For Accelerated Standardized Testing rating is "conscious"; SE = standard error; TN = true negative: number of times both Coma Recovery Scale-Revised full and Coma Recovery Scale-Revised For Accelerated Standardized Testing ratings indicate "not conscious"; TP = true positive: number of times both Coma Recovery Scale-Revised full and Coma Recovery Scale-Revised For Accelerated Standardized Testing ratings indicate "conscious".
*Bootstrap method, 1,000 samples.

conditions under which the CRSR-FAST is administered, and Test Completion Codes are used to establish the validity of the assessment. To minimize administration time, the CRSR-FAST includes stop rules that are triggered when a behavior indicating consciousness is observed or elicited. CRSR-FAST results provide a binary diagnostic rating (i.e., conscious vs not conscious).

Procedure

Three trained examiners completed 4 study examinations (1 CRS-R and 3 CRSR-FAST assessments) over a maximum period of 48 hours. Examiners were masked to the clinical diagnosis of the patient and to the results of the other examinations (except for test–retest assessment). Test administration order and the assignment of raters to test condition (ie, reliability or validity) was pseudo-randomized to prevent order effects. To optimize examination, all assessments were performed during periods when continuous infusion of sedative agents were held. Examiners recorded data on case report forms that were transcribed into a REDCap[13] database. Methodological details, the CRSR-FAST Administration Manual, and the CRSR-FAST scoring form are provided in Supplementary Materials.

Data Analysis

Examiners documented the start and end time of each assessment to determine the feasibility of the CRSR-FAST (goal: mean ≤10 minutes). We tested concurrent validity by comparing CRS-R and CRSR-FAST diagnostic ratings (conscious [MCS or eMCS] vs unconscious [coma or VS/UWS]), using the simple kappa coefficient,[14] and CRSR-FAST test–retest and interrater reliability using Mak's ρ (Statistical Analysis System [SAS v9.4; SAS

Institute, Cary, NC, USA]).[15] We established an a priori threshold of ≥0.60 to indicate substantial validity and reliability.[16]

Results

The 45 participants had the following characteristics: mean age 44 years (SD 20.1 years), 67% male, mean full-length CRS-R total score 6.9 (SD 5.2), and CRS-R range 1–22 (see Table 1 for sample characteristics and Supplementary Figure S2 for CRS-R score distributions). Participants completing the study protocol were younger than those who were eligible, but not enrolled, or enrolled, but did not complete the protocol (Table 1, Supplementary Figure S1). The administration time for the CRSR-FAST was on average 32% of the time required for the full-length CRS-R (CRSR-FAST mean [SD] 6.5 [3.3] minutes, CRS-R 20.1 [7.2] minutes; including the 1-minute observation period, $p < 0.0001$). Of 134 CRSR-FAST administrations, 81% required <10 minutes. All full-length CRS-R administrations required ≥10 minutes (see Supplementary Figure S3). Simple kappa for concurrent validity, Mak's ρ for test–retest reliability, and interrater reliability were 0.68, 0.76, and 0.91, respectively (Table 2), indicating substantial agreement in ratings. The sensitivity, specificity, and accuracy of the CRSR-FAST for detecting consciousness were 81%, 89%, and 84%, respectively (Table 3). Diagnostic disagreements between the CRS-R and CRSR-FAST, test validity, and the results of alternate methods for calculating validity are detailed in Supplementary Materials.

Discussion

The reemergence of behaviors signaling consciousness marks a pivotal milestone in the early phase of recovery from severe TBI. An accurate and efficient method of detecting recovery of consciousness during the acute phase is essential, as this milestone is a strong predictor of outcome and often influences decisions regarding intensity of treatment.[1] The results of this study indicate that the CRSR-FAST is a feasible, valid, reliable, and accurate method of detecting consciousness in patients with acute TBI in the ICU. The CRSR-FAST offers clinicians a standardized assessment tool that can be used in the ICU setting to capture subtle, but clinically important, behavioral signs of consciousness that might otherwise be missed on routine bedside examination. The short duration of the CRSR-FAST facilitates serial assessment, which is more likely to capture fluctuating consciousness. These features may also improve diagnostic precision, and patient selection and classification procedures in TBI clinical trials.

Five participants were deemed conscious on the full CRS-R, but not conscious on the CRSR-FAST examination that was conducted to determine concurrent validity (see Supplementary Tables S6 and S12). In 4 of these 5 participants, behavioral evidence of consciousness was detected on one or both of the other two CRSR-FAST assessments. For the 5th participant, the full-length CRS-R detected only one subtle sign of consciousness (i.e., visual fixation) not observed on the CRSR-FAST, likely reflecting the difficulty of capturing optimal performance in a single assessment. These findings, coupled with evidence supporting the need for serial assessment to detect consciousness when it is present,[17] reinforce the notion that behavioral fluctuation is a hallmark feature of patients with severe brain injury,[8,17–21] and a likely contributor to the scoring discrepancies between the CRS-R and CRSR-FAST.

The CRSR-FAST is set apart from other behavioral measures used in the ICU by its ability to differentiate between MCS and VS/UWS, systematic approach to documenting factors that may confound the examination (e.g., sedation, peripheral pathologies), and comprehensive administration and scoring manual. CRSR-FAST administration requires ∼6.5 minutes, which includes the 1-minute baseline observation. A scale of this duration can be administered repeatedly over the course of the day and, for patients receiving continuous sedation, provides an opportunity to acquire a standardized behavioral assessment during periods of sedation weaning. In the ICU setting, where patients are critically ill and multiple procedures may need to be carried out during short windows of opportunity, a rapid, repeatable, and reliable determination of consciousness may inform clinical decisions that result from an unexpected decline, improvement, or a response to treatment, and provide prognostic information. In contrast, an assessment that requires ≥20 minutes is infeasible to administer during short sedation lifts and cannot be conducted serially. However, it is important to acknowledge that despite these advantages, given the significant level of prognostic uncertainty associated with recovery from TBI, the absence of early behavioral signs of consciousness during the acute period should not drive decisions regarding withdrawal of life-sustaining therapy.

Optimal clinical management and disposition planning across the continuum of recovery require a common frame of reference for clinical data sharing. The CRSR-FAST provides a standardized metric for longitudinal assessment that bridges the communication divide between acute care and rehabilitation clinicians, and may facilitate caregiver education across the recovery continuum. The diagnostic and prognostic accuracy of the CRSR-FAST relative to other brief assessment measures, generalizability to non-TBI etiologies, potential application in low-resource environments, and scaling properties (i.e., ordinal vs interval) should be assessed in future studies.

Author Contributions

Y.B., C.C., J.M., K.P., J.R., R.H., D.K., N.M., K.W., B.E., and J.G. contributed to the conception and design of the study. Y.B., I.V., A.B., K.C., C.C., C.M., A.S., A.W., R.H., N.P., G.V., K.W., B.E., and J.G. contributed to the acquisition and analysis of data. Y.B., I.V., A.B., C.C., K.G., G.M., J.M., K.P., J.R., A.S., R.H., D.K., N.M., N.P., G.V., B.E., and J.G. contributed to drafting the text or preparing the figures.

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