The Minimal Clinically Important Difference for the Rasch Neuropsychiatric Inventory Irritability and Aggression Scale for Traumatic Brain Injury

James F. Malec, PhD, ABPP-Cn, Rp (Corresponding Author)
Professor and Research Director,
Department of Physical Medicine and Rehabilitation, Indiana University School of Medicine and Rehabilitation Hospital of Indiana
Emeritus Professor of Psychology, Mayo Clinic
4141 Shore Drive
Indianapolis, IN 46254
Tel: 317-329-2352
Fax: 317-329-2600
jfmalec@iupui.edu

Flora M. Hammond, MD
Professor and Chair,
Department of Physical Medicine and Rehabilitation, Indiana University School of Medicine
Chief Medical Officer, Rehabilitation Hospital of Indiana
Goodman Hall 4700
355 W. 16th St.
Indianapolis, IN 46202
Tel: 317-963-7077
Fax: 317-963-7075
Flora.hammond@rhin.com

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Running Head: Rasch NPI-TBI-IA MCID

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Abstract

Objective: To determine the Minimal Clinically Important Difference (MCID) for a Rasch measure derived from the Irritability/Lability and Agitation/Aggression subscales of the Neuropsychiatric Inventory (NPI-TBI-IA) **Design:** Distribution-based statistical methods were applied to retrospective data to determine candidates for the MCID. These candidates were evaluated by anchoring the NPI-TBI-IA to Global Impression of Change (GIC) ratings by participants, significant others, and a supervising physician. **Main Outcome Measure:** NPI-TBI-IA. **Setting:** Postacute rehabilitation outpatient clinic. **Participants:** 274 cases with observer ratings; 232 cases with self-ratings by participants with moderate-severe TBI at least 6 months post-injury. **Results:** For observer ratings on the NPI-TBI-IA, anchored comparisons found an improvement of ½ SD was associated with at least minimal general improvement on GIC by a significant majority (69-80%); ½ SD improvement on participant NPI-TBI-IA self-ratings was also associated with at least minimal improvement on the GIC by a substantial majority (77-83%). The percent indicating significant global improvement did not increase markedly on most ratings at higher levels of improvement on the NPI-TBI-IA. **Conclusions:** A ½ SD improvement on the NPI-TBI-IA indicates the MCID for both observer and participant ratings on this measure.

Abbreviations

GIC	Global Impression of Change scale
MCID	Minimal Clinically Important Difference
NPI	Neuropsychiatric Inventory

NPI-TBI-IA	Rasch Neuropsychiatric Inventory Irritability/Aggression Scale for Traumatic Brain Injury
RCID	Robust Clinically Important Difference
TBI	Traumatic brain injury

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The Minimal Clinically Important Difference (MCID) is the smallest change on a clinical measure that is associated with a meaningful perceived difference in an individual's condition, function, or quality of life. Meaningful change may be evaluated from the perspective of the person served, that of a close other, or a clinician involved in their care.

A number of values for the MCID based on distribution-based statistical methods (i.e.,methods that compare change scores to a measure of variability)[1] have been proposed including the standard error of measurement (SEM), standard deviation, reliable change index (RCI) and derivatives of these values.[2] For example, 1.96SEM describes the 95% confidence interval for the SEM and the 95% confidence interval for the RCI is equal to 2.77SEM.[3] Anchored methods (i.e., those that compare change scores to change in another measure considered to be an external criterion)[1] in which a hypothetical MCID value is evaluated in relationship to another measure that reflects meaningful change have also been recommended.[1,4] A Global Impression of Change (GIC) scale has been frequently used as the anchor for MCID estimates. Current recommendations are to use both statistical and anchored methods to triangulate on the best supported value of the MCID.[3,5]

In this paper, we estimate— from multiple perspectives using both statistical and anchored methods—the value of the MCID for a measure based on the Neuropsychiatric Inventory (NPI) subscales for irritability and aggression among individuals with traumatic brain injury (TBI). The NPI was originally designed for administration as a structured interview for assessing neuropsychiatric syndromes with scoring based on the most problematic item on each subscale.[6] We have developed a measure, the Rasch Neuropsychiatric Inventory Irritability and

Aggression Scale for TBI (NPI-TBI-IA), for use with individuals with TBI that combines the Irritability/Lability and Agitation/Aggression subscales and is based on scoring all specific items in these subscales. The development and structural validation of this measureis described in detail in a prior publication.[7]

Method

Participants

Distribution-based indicators were derived from de-identified archival data obtained at baseline assessment in three studies of pharmacologic interventions for irritability and aggression after TBI conducted in rehabilitation outpatient settings in the United States: (1) single site amantadine trial,[8] (2) amantadine multi-site intervention study (AIMS),[9] and (3) a carbamazepine trial.[10] These data were used in the development of the NPI-IA-TBI in English.[7] Observer ratings included a sample of the 274 cases used in the final Rasch calibration of the NPI-TBI-IA (mean age=38.78 yrs; SD=13.09; 41% women). Participant self-ratings included the 232 cases used in the final Rasch calibration of these data (mean age=39.12; SD=12.65; 38% women). For anchor-based estimates, change scores from baseline to Day-28 and Day-60 follow-up were computed from de-identified data for the NPI-TBI-IA for 161 cases from the AIMS trial (mean age= 39.42; SD=12.56; 22% women). These change scores were compared or "anchored" to Global Impression of Change scores provided by the participant, an observer, and a physician. Participants in all studies had a history of moderate-severe TBI and were at least 6 months post-injury. Additional details regarding these studies are available in prior reports.[7-10] Analyses of the de-identified data sets used in this study was approved as exempt by the Indiana University IRB.

Measures

Rasch NPI TBI Irritability/Aggression Scale (NPI-TBI-IA). The psychometric qualities of this measure were found acceptable in its initial development and evaluation.[7] Using tables provided as supplemental material in that report, raw scores were converted to a Rasch metric on a 0-100 scale.

Global Impression of Change scale (GIC). As part of the AIMS trial, GIC were independently completed by participants with TBI, an observer, and the physician conducting evaluations at 28-day and 60-day follow-ups. Overall change in irritability and aggression was rated on a 7-point scale: (1) very much improved, (2) much improved, (3) minimally improved, (4) no change, (5) minimally worse, (6) much worse, and (7) very much worse.

Statistical analyses

Observer and participant ratings on the NPI-TBI-IA were converted to a Rasch 0-100 metric. Distribution-based indicators were computed from baseline values. The mean for observer baseline ratings=45.17 (SD=6.96) with no extreme scores; mean baseline participant ratings=40.68 (SD=10.56) with 8 zero scores and no maximum scores. The Rasch person reliability coefficient of .89 for observer ratings and .85 for participant self-ratings were used to compute SEMs. The reliability coefficient that is required in the computation of the SEM is the proportion of a measure that represents true variance; the Rasch person reliability coefficient provides a conservative estimate of this value.[11] Missing item data were rare (<1%), and consequently imputation of missing values was not attempted.

In anchored comparisons, change scores were computed by subtracting 28-day and 60-day Rasch metric values from baseline values. Specified cut-points (1 SEM, ½ SD, 1.96 SEM, 2.77 SEM or RCI, and 1 SD), representing hypothetical MCID, were selected as distribution-

based benchmarks. For ease of use and to avoid exaggerating the precision of this measure, cut-points were rounded to the nearest ½ point. The sample was then divided into those whose change scores indicated improvement greater or less than the selected cut-points. Finally, percent agreement between classification based on the selected cut-point and minimal to very much improvement on GIC completed by participants with TBI, an observer, and the physician were examined. At Day 28, no participant or observer NP-TBI-IA scores were missing; 1 participant GIC and 3 physician GIC were missing. At Day 60, 6 observer and 1 participant NPI-TBI-IA scores were missing; GIC data were also missing for these cases. Because of the small number of missing data, imputation was not attempted.

Results

Values for distribution-based indicators for both participant and observer ratings are reported in the far left column of Table 1. In order to anchor these indicators to improvement on the GIC, we computed the ratio of cases in which NPI-TBI-IA scores at 28- and 60-day follow-up reflect a positive change from baseline greater than or equal to the amount of change specified by each distribution-based indicator to the total number of cases with minimal to very much improvement on the GIC.

Examination of Table 1 reveals that the percent of individuals achieving either a SEM or ½ SD level of improvement on the NPI-TBI-IA with at least a minimal level of improvement recorded on the GIC is substantial (69-83%), suggesting that either of these levels might serve as the MCID. Table 2 describes agreement between GIC and NPI-TBI-IA change scores at 60-day evaluations in greater detail at the ½ SD and 1 SD level of improvement. There is only slight shift toward greater endorsement of “much” and “very much” general improvement at the 1 SD

improvement level. A similar slight shift toward the perception of greater improvement was also apparent at 28-day evaluations (see Supplemental Table 1).

Discussion

Anchoring potential statistically-based MCID values to GIC ratings suggests that either the SEM or ½ SD level of improvement is considered by a large majority of participants, observers, or supervising physicians to represent meaningful improvement on the GIC. Since the SEM is the smallest amount of change that is statistically reliable, we suggest adopting the slightly more conservative value of ½ SD improvement as the MCID (3.5 for observer ratings; 5.5 for participant self-ratings). As would be expected, the percentage of cases with a positive GIC rating increases as the value of the required improvement on the NPI-TBI-IA increases. However, except for physician ratings at Day 28, the difference between percent agreement based at ½ SD level of improvement is not dramatically different from percent agreement based on 2.77 SEM (RCI) or 1 SD (see Table 1), reinforcing the ½ SD level as a reasonable value for the MCID. The level of improvement indicated by the RCI or 1 SD might be considered what we have previously termed a "robust clinically important difference" (RCID).[12] Because it is the traditional value for a large effect size, the 1 SD improvement is proposed as the RCID for the NPI-TBI-IA (7.0 for observer ratings; 10.5 for participant self-ratings). On the other hand, the perception of greater improvement on the GIC at the 1 SD level compared to the ½ SD level is not marked. For the NPI-TBI-IA, once the MCID threshold of ½ SD is crossed, further improvement is not strongly associated the perception of overall improvement.

Limitations. These analyses were based on retrospective data and may not be generalizable to all individuals with TBI.

Conclusions. The MCID for the NPI-TBI-IA is represented by a ½ SD improvement for both participant and observer ratings; a 1 SD change represents a robust clinically important difference (RCID).

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Table 1. Percent with improvement on GIC showing positive change at or above distribution-based indicators for 28- and 60-day NPI-TBI-IA ratings						
Distribution-based indicators (rounded cut point)	**Participant**		**Observer**		**Physician**	
	28-day	**60-day**	**28-day**	**60-day**	**28-day**	**60-day**
Observer ratings						
1 SEM=2.31 (2.5)	68%	70%	72%	79%	71%	77%
½ SD=3.48 (3.5)	69%	71%	74%	80%	73%	77%
1.96SEM=4.53 (4.5)	70%	74%	77%	82%	76%	79%
2.77SEM=6.40 (6.5)	76%	76%	78%	87%	80%	82%
1 SD=6.96 (7.0)	78%	76%	80%	87%	83%	82%
Participant self- ratings						
1 SEM=4.09 (4.0)	72%	76%	76%	80%	75%	78%
½ SD=5.28 (5.5)	77%	80%	77%	83%	75%	81%
1.96SEM=8.02 (8.0)	81%	84%	80%	87%	82%	84%
2.77SEM=11.33 (11.5)	89%	83%	86%	88%	96%	86%
1 SD=10.56 (10.5)	88%	82%	84%	87%	94%	87%

Table 2. Percent indicating various levels of change on GIC with ½ SD or greater and 1 SD or greater change on 60-day NPI-TBI-IA ratings						
NPI-TBI-IA change score:	**Participant**		**Observer**		**Physician**	
	½ SD	**1 SD**	**½ SD**	**1 SD**	**½ SD**	**1 SD**
Observer GIC ratings						
Very much improved	9%	11%	19%	21%	15%	16%
Much improved	38%	41%	35%	39%	37%	37%
Minimally improved	24%	24%	26%	27%	25%	29%
No change	24%	21%	18%	13%	22%	18%
Minimally worse	2%	2%	1%	0%	1%	0%
Much worse	2%	1%	1%	0%	0%	0%
Very much worse	1%	0%	0%	0%	0%	0%
Participant GIC self- ratings						
Very much improved	10%	12%	21%	26%	16%	21%
Much improved	39%	43%	32%	31%	38%	45%
Minimally improved	31%	27%	30%	30%	27%	21%
No change	18%	18%	16%	13%	19%	13%
Minimally worse	1%	0%	0%	0%	0%	0%
Much worse	1%	0%	1%	0%	0%	0%
Very much worse	0%	0%	0%	0%	0%	0%

Highlights

- A measure combining the Irritability/Lability and Agitation/Aggression subscales of the Neuropsychiatric Inventory (NPI-TBI-IA) has been developed for use with individuals with traumatic brain injury (TBI).
- The new measure (the Rasch Neuropsychiatric Inventory Irritability and Aggression Scale for TBI; NPI-TBI-IA) was developed with Rasch analysis and includes responses to all specific items on these subscales.
- The Minimal Clinically Important Difference (MCID) is the smallest change on a clinical measure that is associated with a meaningful perceived difference in an individual's condition, function, or quality of life.
- We determined the MCID for this measure using distribution-based and by anchoring the measure to Global Impression of Change scales completed by individuals with TBI, their observers, and their physicians.
- Our analysis suggests that the MCID for the NPI-TBI-IA is ½ standard deviation and that a standard deviation change indicates a Robust Clinically Important Difference for both observer ratings and participant self-ratings.