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Validation of BDI-II response and remission cut-points for assessment of seasonal affective disorder patients

Gloria M. Reeves, MD¹, Kelly J. Rohan, Ph.D², Patricia Langenberg, Ph.D³, Soren Snitker, MD, Ph.D.⁴, and Teodor T. Postolache, MD⁵

¹Division of Child and Adolescent Psychiatry, University of Maryland School of Medicine, Baltimore, MD, USA

²Psychology Department, University of Vermont, Burlington, Vermont, USA

³Department of Epidemiology and Preventive Medicine, University of Maryland School of Medicine, Baltimore, MD, USA

⁴Division of Endocrinology, Diabetes, and Nutrition, Department of Medicine, University of Maryland School of Medicine, Baltimore, MD, USA

⁵Mood and Anxiety Program, Department of Psychiatry, University of Maryland School of Medicine, Baltimore, MD, USA

Abstract

Background—The purpose of this study is to define treatment response and remission cut-point scores for the Beck Depression Inventory-Second Edition (BDI-II) when used to monitor a seasonal affective disorder (SAD) episode.

Methods—Data from two published randomized clinical trials for SAD were utilized to complete a ROC analysis to define response and remission thresholds for the BDI-II. The Structured Interview Guide for the Hamilton Rating Scale for Depression-Seasonal Affective Disorder Version (SIGH-SAD) was used as a reference standard. Data from the two trials included BDI-II and SIGH-SAD scores for patients at baseline, 6 weeks (post-treatment), and 1 year (next winter).

Results—BDI-II score of 9 was the derived criterion for remission of SAD, and BDI-II score decrease of 50% from baseline was the criterion for treatment response.

Limitations—Study participants were primarily female (94%) and Caucasian (80%) so demographic diversity of the sample was limited.

Corresponding author: Gloria M. Reeves MD, Division of Child and Adolescent Psychiatry, University of Maryland School of Medicine, 701 W Pratt Street, Baltimore, MD 21201, greeves@psych.umaryland.edu, Fax: 410-328-0202, Phone: 410-328-9087.

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Conclusion—This study validated BDI-II scores compared to the SIGH-SAD reference standard. The BDI-II has greater potential for widespread use by clinicians than the SIGH-SAD to monitor SAD patients because it is a brief self-report instrument that can be conveniently administered in the waiting room.

Keywords

BDI-II; SIGH-SAD; Seasonal Affective Disorder

Introduction

Standardized outcome tools help the practicing clinician distinguish *response* (partial symptom reduction) from *remission* (full return to healthy functioning). This distinction is important in depression treatment, since patients often fail to achieve remission after an adequate treatment trial (Trivedi et al. 2006). A prospective, naturalistic study of individuals with a first lifetime major depressive episode found that patients with incomplete remission of depression experienced more rapid depression recurrence and had more chronic major depressive episodes (>2 years) compared to patients with full remission (Judd et al. 2000). Patients with residual depression symptoms have also demonstrated worse social/relationship and occupational outcomes compared to patients who achieved remission (Kennedy and Paykel 2004).

A challenge, however, in using outcome measures to determine treatment response and remission is that scores may not be validated for specific depression subgroups. One subtype of major depressive disorder is seasonal affective disorder (SAD). Patients with SAD experience marked changes in mood and activity over the fall/winter months and spontaneous remission of symptoms in the spring/summer. These patients often present with significant atypical depressive symptoms, including low energy, increased appetite/weight gain, hypersomnia, and carbohydrate craving (Rosenthal et al. 1984). Individuals with SAD often require ongoing monitoring because of the highly recurrent nature of this disorder (Sakamoto et al. 1995; Schwartz et al. 1996), and the seasonal pattern of symptoms allows for a more predictable time frame to assess for recurrence of symptoms. Prevention of subsequent mood episodes and early intervention is a major public health concern in SAD management (Rohan et al. 2009). In one study of over 1000 SAD patients, individuals reported an average of 13 previous seasonal depression episodes (Modell et al. 2005).

A standard clinical research tool to assess SAD symptom severity and treatment response is the Structured Interview Guide for the Hamilton Rating Scale for Depression-Seasonal Affective Disorder Version (SIGH-SAD; Williams et al. 1992). This semi-structured interview tool is not useful for widespread use in community treatment because of lengthy administration time and required training.

The Beck Depression Inventory-Second Edition (BDI-II; Beck et al. 1996b) is a commonly used treatment outcome measure for non-seasonal depression. The BDI-II can be used in both primary and specialty care settings because it is a self-report measure and takes only 5-10 minutes to complete.

To our knowledge, the BDI-II has never been calibrated to the SIGH-SAD, the reference standard in SAD research, in order to establish appropriate cut-point scores for SAD treatment response and remission. The purpose of this study was to identify appropriate BDI-II threshold scores to define “response” and “remission” in SAD treatment. We did so by comparing BDI-II and SIGH-SAD scores of SAD patients treated in a randomized clinical trial. Patient assessments using both instruments were completed at baseline, after the 6-weeks treatment phase, and at a 1-year naturalistic follow-up the next winter.

Methods

Participants

Participants were treated in one of two published randomized clinical trials for SAD (Rohan et al. 2004; Rohan et al. 2007). The first study (Rohan et al. 2004) was a 6-week randomized clinical trial of light therapy, group cognitive-behavioral therapy, or combination treatment for SAD. The second study (Rohan et al. 2007) was a 6-week randomized clinical trial with the same interventions plus a wait-list control group. Follow-up data were obtained for participants in both studies during January or February of the next winter season (Rohan et al. 2009).

Recruitment and full inclusion/exclusion criteria are detailed in Rohan et al. 2004 and Rohan et al. 2007. Diagnosis of recurrent major depressive disorder with seasonal pattern was confirmed by both Structured Clinical Interview for DSM-IV Axis I Disorders – Clinician Version (SCID-CV; First et al. 1995) and SIGH-SAD interview using published guidelines on criteria for current SAD episode (Terman et al. 1990). Research was conducted with approval by the Uniformed Services University of the Health Sciences Institutional Review Board.

Structured Interview Guide for the Hamilton Rating Scale for Depression (SIGH-SAD)

The SIGH-SAD consists of the 21-item Structured Interview Guide for the Hamilton Rating Scale for Depression (HAM-D) plus an 8-item subscale to assess atypical depressive symptoms associated with SAD. Inter-rater reliability for total SIGH-SAD scores was high, $r_s = .93-.96$ at pre-treatment, $.98-.99$ at post-treatment (Rohan et al. 2004; Rohan et al. 2007) and $r = .99$ at 1-year (Rohan et al. 2009).

Beck Depression Inventory-Second Edition (BDI-II)

The Beck Depression Inventory-Second Edition (BDI-II) is an updated version of the amended Beck Depression Inventory (BDI-IA; Beck et al. 1993) that includes atypical depressive symptoms (i.e., fatigue, hypersomnia, hyperphagia), consistent with the DSM-IV criteria for major depression. Participants rate 21 items on a scale of 0 to 3 based on how they have been feeling over the last two weeks, and the total score is the sum of these items. The BDI-II has a high level of internal consistency (Coefficient $\alpha = .91$) (Beck et al. 1996a), and has been shown to yield reliable, internally consistent, and valid scores in a primary care setting (Arnau et al. 2001).

Statistical Methods

We conducted a calibration analysis comparing SIGH-SAD and BDI-II scores pooled across the two studies at treatment endpoint (after 6 weeks of treatment) and at 1-year follow-up. The SIGH-SAD score was considered the reference standard for “response” (at least 50% reduction in SIGH-SAD score) and “remission” (SIGH-SAD score of ≤ 8) criteria. Remission criteria are consistent with prior SAD clinical trials (Terman et al. 1998; Koorengel et al. 2001; Lavoie et al. 2009).

The BDI-II cut-points for treatment response and remission were determined using the 6-week outcome data. First, BDI-II scores were regressed against SIGH-SAD scores in separate models for the baseline and 6 weeks time points. Figure 1 displays BDI-II scores as a function of SIGH-SAD scores at baseline and at 6 weeks. For remission, a logistic regression model was developed with SIGH-SAD remission status (yes/no) at 6 weeks as the dependent variable, and BDI-II score at 6 weeks as the independent variable, providing data (potential cutpoints) for a receiver operating characteristic (ROC) curve analysis. The c -statistic (area under the curve, perfect calibration = 1) was calculated as a measure of goodness of fit.

For response, defined as 50% or more reduction in SIGH-SAD score from baseline, a similar procedure was used. In this case, the % reduction in BDI-II score at 6 weeks was first calculated for each observation. Next, the logistic model was developed with SIGH-SAD response status (yes or no) as the dependent variable and percent reduction in BDI-II score at 6 weeks as the predictor variable. The ROC curve was plotted, and the c -statistic recorded.

The BDI-II cut-points for remission and response derived from the 6 week data were then used to determine the proportion of remitters and responders at 1-year follow up compared to the SIGH-SAD reference standard.

Results

The current calibration analysis included data only from subjects who completed both the SIGH-SAD and the BDI-II at a given time point. Across both studies, of the 72 individuals who were randomized to CBT, light therapy, or combination treatment (24 CBT, 25 LT, 23 CBT+LT), 55 provided data at the 1-year followup (18 CBT, 20 LT, 17 CBT+LT). The BDI-II cut-point for remission was determined as the value that provided the percentage of participants in remission closest to the SIGH-SAD percentage of remitters, in addition to optimal values of sensitivity, specificity, and correct classification. A similar procedure was followed for determination of the BDI-II cut-point for response.

For SAD treatment response, the BDI-II derived cut-point was 50% improvement (i.e., 50% reduction in BDI-II score from baseline). This cut-point correctly identified 76.3% of treatment responders at 6 weeks and 70.9% of responders at one year follow-up per the reference SIGH-SAD measure. Figure 2 illustrates the correct/incorrect classification of response at 6 weeks by the BDI-II cut-point (50% improvement) compared to the reference SIGH-SAD response score.

Regarding the primary clinical goal of remission, 36.8% of participants ($N=76$) achieved SAD remission by 6 weeks and 36.4% were in remission at one year follow up ($N=55$) by SIGH-SAD score. Table 1 indicates the sensitivity/specificity and positive predictive value/negative predictive value associated with four possible remission cut-points on BDI-II, and calibration with the SIGH-SAD score (8). Table 2 indicates the c -statistic (area under the ROC curve) as well as the sensitivity and specificity for the BDI-II remission and response cut-points compared to the reference SIGH-SAD.

Discussion

Based on our calibration analysis, BDI-II score of 9 was the derived criterion for remission of SAD, and BDI-II score decrease of 50% or more was the criterion for treatment response. The BDI-II may be a practical and useful tool for monitoring treatment response and remission in SAD patients. Assessing for remission is important because there are several treatment options available to optimize response, including light therapy, antidepressant medication, and cognitive-behavioral therapy. Of note, SIGH-SAD scores indicate that less than half of patients in the included studies achieved full remission after six weeks of carefully administered treatment by SAD experts, suggesting that most patients will require a longer duration of treatment or optimization of their current regimen.

The area under the curve (c -statistic) was .84 for remission and .87 for response. When ROC analysis is used for validating screening tools, a c -statistic of .80 indicates a scale is a good screening instrument and .90 indicates an excellent screening tool (DeSouza et al. 2009). Treatment response in non-seasonal depression intervention trials is often defined as 50% improvement on standardized rating scales (Keller 2003; Israel 2006). Because treatment response is defined as percentage improvement, there is considerable variability in the actual scores that denote response.

This study has the limitation that participants in the two SAD studies were mainly female (94%) and Caucasian (80%). It is possible that our derived calibration of the BDI-II does not extend to other demographic samples. The BDI-II can be a useful tool to monitor seasonal depression treatment response and has the advantages of short administration time, self report, and widespread use by both primary care and mental health clinicians compared to the semi-structured interview SIGH-SAD scale. Further research is needed to test use of this scale to monitor SAD treatment response for different demographic groups and use in different types of treatment settings. Although individuals with SAD typically experience spontaneous remission in spring/summer months, the recurrent nature of this subtype of depression indicates the need for careful, ongoing monitoring.

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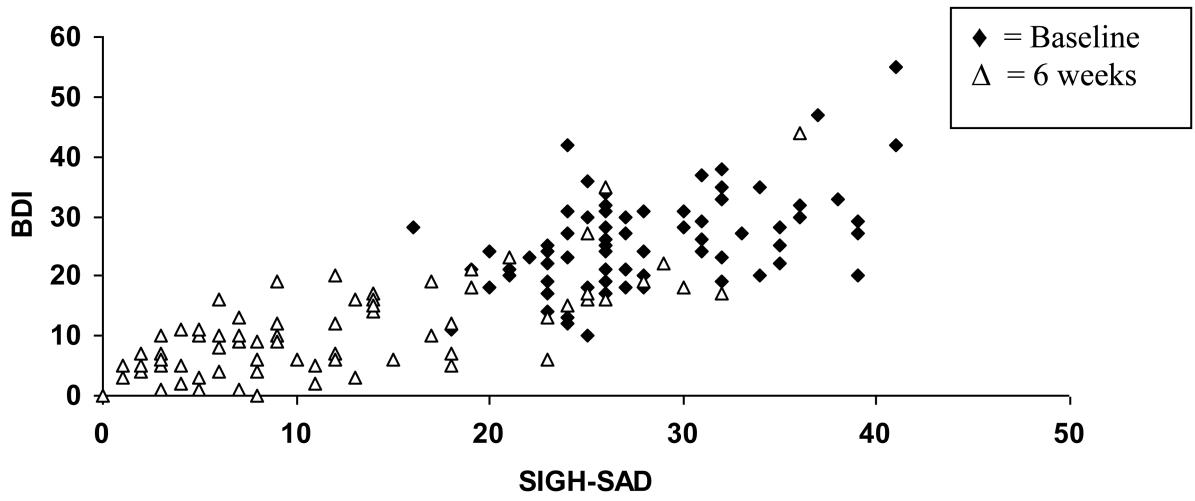


Figure 1. BDI-II scores as a function of SIGH-SAD scores at baseline and 6 weeks
Legend: BDI, Beck Depression Inventory-II
SIGH-SAD – Structured Interview guide for the Hamilton Rating Scale for Depression –
Seasonal Affective Disorder Version

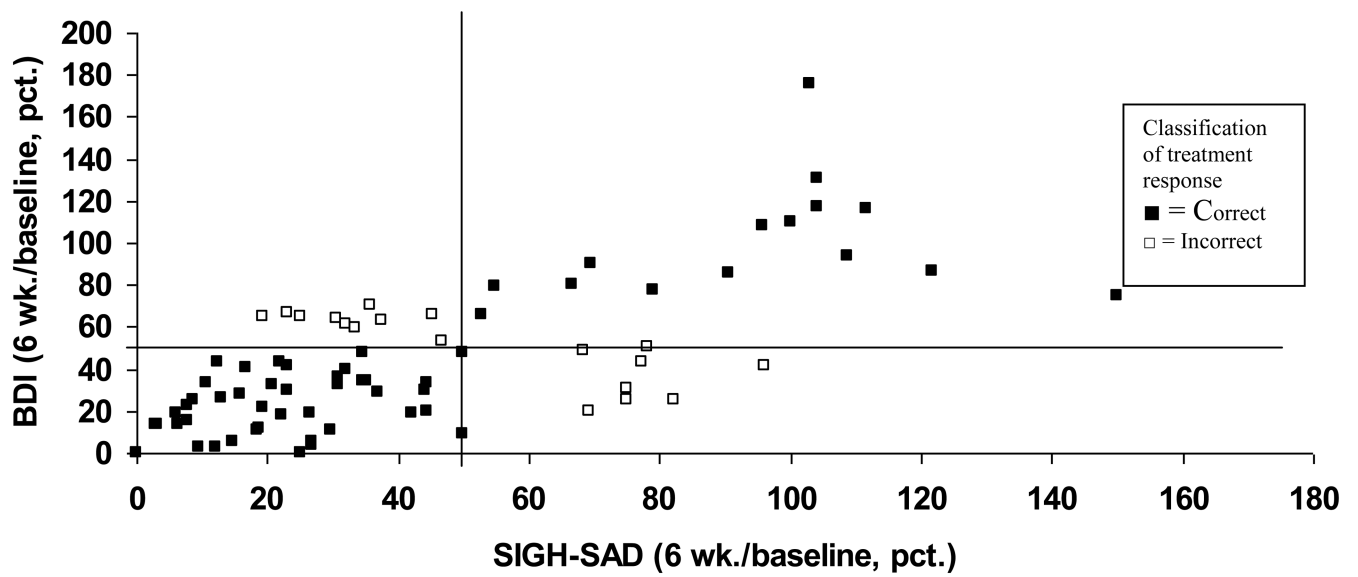


Figure 2. BDI-II scores at 6 weeks (percentage of baseline) as a function of SIGH-SAD scores at 6 weeks (percentage of baseline)
 Treatment response is defined as 50% reduction in BDI-II
 Reference standard is 50% reduction in SIGH-SAD
 Additional lines indicate 50% baseline BDI-II and 50% baseline SIGH-SAD scores
 Correct classification (n=58); Incorrect classification (n=11)

Sensitivity and specificity associated with four cut-points for BDI-II, and calibration with the SIGH-SAD score 8.

Table 1

BDI cut-point	6 weeks post treatment		One year post treatment		One year post treatment	
	Sensitivity N=34	Specificity N=42	Sensitivity N=20	Specificity N=35	Positive Predictive Value	Negative Predictive Value
<= 8	67.7	73.8	85.0	71.4	63.0	89.3
<= 9	76.5	71.4	90.0	60.0	56.3	91.3
<= 10	88.2	66.7	90.0	45.7	48.7	88.9
<= 11	94.1	66.7	95.0	42.9	48.7	93.8

Table 2

Sensitivity and specificity of BDI II cut-point scores in designating SAD “response” and “remission” compared to SIGH SAD:

		c-statistic	Sensitivity	Specificity
Remission	6 weeks	0.84	76.5	71.4
	1 year		90.0	60.0
Response	6 weeks	0.87	80.8	66.7
	1 year		87.5	47.8

c-statistic is area under the ROC curve

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