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The psychometric validation of the Sheehan Disability Scale (SDS) in patients with bipolar disorder

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Abstract

Bipolar disorder (BD) adversely affects daily activities/functioning. The Sheehan Disability Scale (SDS) assesses disability in work/school activities, family relationships, and social functioning, and it evaluates the functional impact of psychiatric disorders. BD outpatients from 21 U.S. sites completed a battery of validated instruments (including the SDS) three times over 8–12 weeks. Instrument reliability (internal consistency, test–retest), validity (construct, convergent validity, known groups) and responsiveness were measured. There were missing data for the SDS in 2% of the 225 subjects with BD. One factor explained 82% of the variance. All SDS items had rotated factor loadings on the first factor >0.90, confirming the appropriateness of the SDS total score. Item-scale correlations surpassed 0.40. There was excellent internal consistency reliability for the SDS total score (Cronbach's alpha = 0.89). Test–retest reliability was acceptable for the SDS total score (intraclass correlation coefficient = 0.73). Correlations with other instruments demonstrate convergent and divergent validity. The SDS total and item scores significantly discriminated between (self-rated) overall health status, clinician-rated functional status, and clinician-rated depression, evidencing known group validity. The SDS demonstrated ability to detect change over time. The SDS is a valid, reliable measure of disability and is responsive to change over time when used in subjects with BD.

Keywords: Bipolar disorder; Functioning; Patient-reported outcome; Sheehan Disability Scale; Validation; Disability

1. Introduction

Bipolar disorder (BD) is a mood disorder characterized by recurrent episodes of mania and depression. Six different types of BD have been classified in

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DSM-IV (American Psychiatric Association, 1994), each varying in relation to the intensity and duration of manic and depressive episodes. Most common are the subtypes BD I (mania and major depression) and BD II (hypomania and major depression). The prevalence of BD is reported to be 3.7% (Hirschfeld, 2003).

The symptoms of BD have been shown to adversely affect daily activities, performance at work or school, and involvement in social activities (Calabrese et al., 2003). Disability or functional impairment is a concept that reflects the impact of the symptoms of a disease on a person's ability to conduct daily activities and fulfill social and familial roles (Hambrick et al., 2004). Disability is incorporated into the diagnostic criteria of most psychiatric disorders (American Psychiatric Association, 1994). In 1990, the World Health Organization identified BD as the sixth leading cause of disability-adjusted life years among individuals aged 15–44 years (Calabrese et al., 2003).

Systematic assessment of the patient's perspective can provide valuable information that can be lost when that perspective is filtered through a clinician's evaluation of the patient's response to clinical interview questions (US Food and Drug Administration, 2006). The Sheehan Disability Scale (SDS) is commonly used as a brief self-report measure of symptom-related disability (Sheehan, 1983).

The SDS was developed as a global measure of the impact of mental illness on functioning (Sheehan, 1983). The SDS is a composite of three self-rated, 10-point Likert scale response items that aim to assess the level of the subjects' impairment with regard to their work/school activities, family relationships, and social functioning. In addition, the numbers of lost and unproductive days due to symptoms are reported in two single items not included in the total score.

The SDS has been used in numerous psychiatric disorders including panic disorder, general anxiety disorder (GAD), major depressive disorder, BD, obsessive–compulsive disorder, and drug and alcohol dependence (Leon et al., 1992; Olfson et al., 1996; Sheehan et al., 1996). The validity and reliability of the SDS has been demonstrated in subjects with panic disorder (Leon et al., 1992) and social anxiety disorder (SAD) (Hambrick et al., 2004). The scale has been demonstrated to be discriminative of primary care subjects differing in impairment for depression, BD, specific phobias, GAD, substance abuse, and SAD (Olfson et al., 1996; Olfson et al., 1997; Hambrick et al., 2004).

An elevated Sheehan score (≥ 5) has been shown to be associated with an increased risk of psychiatric impairment (Leon et al., 1997). There is also evidence that the SDS is sensitive to change due to treatment, with 39.6% to 43.9% improvements in item scores for panic disorder subjects, and 28.9% to 35.2% improvements in scores for social phobia (Sheehan et al., 1996).

Despite its widespread use, the psychometric properties (including validity, reliability, and ability to detect change) of the SDS have not been assessed in subjects with BD. Neither has the performance of the instrument in different BD mood states been examined. The current study was undertaken with the intention of documenting the psychometric properties of the SDS as a measure of functional impairment in subjects with BD, and to provide information to assist researchers and practitioners in interpreting SDS scores in this population.

2. Materials and methods

2.1. Subjects

All subjects gave written, informed consent before entering the study, which was conducted according to the principles of the 1996 amendment of the Declaration of Helsinki and approved by Copernicus (a centralized ethics committee in the United States). Subjects were eligible for participation if they were at least 18 years of age; met the DSM-IV criteria for bipolar disorder I or II; were currently undergoing treatment for bipolar disorder as an outpatient; had no change in treatment in the past 4 weeks; were fluent in English; and were willing and able to provide written informed consent and comply with the study requirements.

Subjects were excluded from the study if they had a clinically significant or unstable medical condition other than bipolar disorder; if they were newly diagnosed with bipolar disorder; or if they were dependent on alcohol and/or drugs (other than caffeine or nicotine) at enrollment, as defined by DSM-IV criteria. It was planned to recruit sufficient numbers of subjects experiencing mania/hypo-mania, depression, and euthymia (maintenance) to allow scaling tests to be assessed within these subgroups. Subjects were categorized into these mood state subgroups based on their clinician rating of their mood state.

2.2. Study design and data collection procedures

Subjects were recruited from 21 clinical sites across the US. All study assessments were completed between June 2005 and May 2006. All subjects were asked to complete questionnaires at three study visits: the baseline visit, a