

## Gradations of clinical severity and sensitivity to change assessed with the Beck Depression Inventory-II in Japanese patients with depression

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### Abstract

Knowledge of what constitutes a minimal clinically important difference and change on a psychiatric rating scale is essential in interpreting its scores. The present study examines the Beck Depression Inventory-II (BDI-II), a recently revised successor to the world's most popular self-rating instrument for depression. BDI-II was administered to 85 patients with major depression, diagnosed with DSM-IV along with its severity specifiers. It was again administered to 40 first-visit patients from the original sample when they returned 14 or more days later. The Clinical Global Impression-Change Scale was rated at the same time. All the ratings were done independent of each other. The BDI-II was able to distinguish between all grades of depression severity. An approximate 10-point difference existed between each severity specifier. The BDI-II was also sensitive to change in depression: a 5-point difference corresponded to a minimally important clinical difference, 10–19 points to a moderate difference, and 20 or more points to a large difference. Given the already established high reliability, content validity, construct validity and factorial validity, and the high sensitivity to between-subject differences and within-subject changes demonstrated in the present study, the BDI-II promises to continue to be a leading self-rating instrument to assess depression severity worldwide.

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## 1. Introduction

The increasing use of psychometric scales within psychiatry and related disciplines necessitates a clear understanding of how to appraise the importance of differences in severity (assessed cross-sectionally and between subjects) and changes over time (assessed longitudinally and within subjects) recorded with these scales. The knowledge of what constitutes a minimal clinically important difference and change is, however, often wanting with regard to many widely used psychiatric instruments.

The Beck Depression Inventory-Second Edition (BDI-II) appears to be one such instrument. The Beck Depression Inventory (BDI) has been one of the most widely used self-report instruments for measuring the severity of depression. In the years since its original development in 1961 (Beck et al., 1961), the BDI was once slightly revised with minimal modification in wording in 1979 (Beck et al., 1979). With the advent of operationalized diagnostic criteria for depression, the original developers of the scale deemed it necessary and appropriate to modernize the instrument and developed the second edition of the BDI in 1996 (Beck et al., 1996). All but three of the 21 items were reworded: four old items (weight loss, body image change, somatic preoccupation, and work difficulty) were replaced by new items (agitation, worthlessness, concentration difficulty, and loss of energy) to harmonize with DSM-IV diagnostic criteria for major depression (American Psychiatric Association, 1994); two items were changed to allow for increases as well as decreases in appetite and sleep; many of the statements used in the ratings were revised. The BDI-II has found a rapid and widespread acceptance on the international scene, with Spanish, Portuguese (Coelho et al., 2002), Arabic (Al-Musawi, 2001) and Japanese (Kojima et al., 2002) versions now available.

Although the BDI has been shown to be an excellent screener for depression in the general and medical populations, the manual for the BDI-II states that it is primarily an assessment tool to rate the severity of depression in patients whose diagnosis has already been established, and proposes guidelines to interpret total scores (Beck et

al., 1996). Whether the guidelines apply to patients outside Western cultures is not known. Moreover, no study to date has examined the scale's sensitivity to change and set out clear guidelines to interpret changes in scores. After developing the Japanese version of the BDI-II and ascertaining its excellent internal consistency reliability, criterion validity and factor validity (Kojima et al., 2002), we therefore realized that there was an urgent need to standardize this instrument by establishing minimal clinically important difference and change scores. Without such knowledge, clinicians and patients would find it extremely difficult, and probably impossible, to interpret scores obtained with the BDI-II.

## 2. Methods

### 2.1. Subjects and procedures

Eighty-five patients with major depressive disorder, single episode or recurrent, according to DSM-IV participated in this study at the Departments of Psychiatry of Nagoya City University Hospital and Toyokawa Municipal Hospital, Japan. The patients were asked to complete the BDI-II. The treating psychiatrist rated the severity of their depressive episode according to DSM-IV as severe, moderate, mild, partially remitted or remitted without knowledge of the patients' (subsequently obtained) BDI-II scores.

Forty subjects of the original cohort, all of whom consented to the baseline evaluation at the time of their first visit to our hospitals, were re-administered the BDI-II when they returned 14 or more days later. This time period was chosen because the time frame of evaluation for the BDI-II is 2 weeks, unlike the BDI-I, which set the time frame at 1 week. Using the Clinical Global Impression-Change (CGI-Change) (Guy, 1976) Scale, the treating physician rated the patient as much worse, moderately worse, slightly worse, no change, slightly improved, moderately improved or much improved, again before having access to the patients' BDI-II scores. The patients consented to allow their data to be used for research purposes after receiving an explanation of the study.

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