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Reliability and Validity of the Japanese Version of BEMIB Modified for Patients With Bipolar Disorder: a Self-rating Scale for Medication Adherence

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ABSTRACT

Purpose: Accurate evaluation of medication adherence is important; however, no simple evaluation scale that is applicable to patients with bipolar disorder has been established in Japan. In this study, we prepared a modified Japanese version of a self-rating scale for medication adherence in the field of psychiatry, the Brief Evaluation of Medication Influences and Beliefs (BEMIB), and investigated its reliability and validity.
Methods: Forty-one patients with bipolar disorder who visited several facilities, including Nagoya University Hospital, from April 2006 to August 2006 and from April 2009 to July 2009 underwent medication adherence evaluations using the Japanese versions of BEMIB and the Drug Attitude Inventory-10 Questionnaire (DAI-10).
Results: The Cronbach α coefficient of the Japanese version of BEMIB was 0.73. Four-week test-retest reliability coefficients of each item and the BEMIB total score were 0.39-0.68 ($p < 0.05$) and the intra-class correlation coefficient was 0.63 (95% CI = 0.33-0.75, $p < 0.001$). In addition, a significant positive correlation was observed between the BEMIB and DAI-10 total scores (Pearson's correlation coefficient = 0.39, $p < 0.001$), showing that the concurrent validity was sufficient.
Discussion: The Japanese version of BEMIB modified for patients with bipolar disorder is sufficiently reliable and valid. We suggest that this simple evaluation scale of medication adherence in patients with bipolar disorder is applicable in routine medical practice.

Keywords: BEMIB, modified Japanese version, medication adherence, reliability, validity

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INTRODUCTION

Adherence requires a positive attitude on the part of the patients – accepting one's own disease and actively participating in deciding on a therapeutic policy. In a study in which physicians evaluated the adherence of patients by disease, adherence was worse in patients with chronic diseases, such as hypertension, diabetes and schizophrenia, than in people with headache or acute infections [1]. Specifically, adherence in mental disorders was lower than in patients with other chronic diseases. In psychiatric patients, medication adherence

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was associated with prognosis, indicating the importance of adherence for treatment success [2].

Medication adherence in the field of psychiatry has been investigated in many studies, including studies in schizophrenic patients [3,4]. In addition, the importance of medication adherence in improving prognosis in bipolar disorder has been attracting an increasing amount of attention [5,6]. Specifically, it has been reported that medication adherence in bipolar disorder patients is low (54-66%) [7-9], and that the recurrence rate is increased [10] and the incidence of suicidal behavior is increased five-fold [11] when medication adherence is poor.

To improve medication adherence, it first needs to be accurately evaluated. There are various evaluation methods, such as pill counting, measurement of the blood drug concentration, interview-based evaluations by physicians and self-rating scales. All of these methods have advantages and disadvantages [12]. Pill counting lacks reliability because the ingestion of drugs cannot be confirmed [13]. Measurement of the drug concentration in blood is a direct and objective method, but it has disadvantages, such as interindividual pharmacokinetic variability, interactions with food or other drugs, and favorable findings resulting from the re-initiation of medication for only a few days. Moreover, only a few drugs can be readily measured at clinical sites. Physician use of a structured interview that includes an evaluation scale, the Rating of Medication Influence (ROMI), has been reported [14]; however, this rating instrument is not used in routine clinical practice because of the training required for the person performing the interview, and because of the total amount of time needed to complete the interview. In a study in which the adherence of schizophrenic outpatients was evaluated by various methods, the proportion of patients considered nonadherent was 3% in self-reports, but 24% and 25% in physician evaluation and pill counting, respectively, and 52% in an evaluation method in which an electronic device, the Electronic Medication Monitor (EMM), was used. These results clearly show that there was extreme inconsistency among the methods [15].

Of the adherence evaluation methods, self-rating scales are simple and have been shown to be useful, although overestimation and recall bias are likely to occur in self-evaluation [11]. In a study mostly in bipolar disorder and schizophrenia, the adherence level estimated from the blood drug level was significantly correlated with the results obtained using self-evaluation [16]. In another study, the consistency with objective data (e.g., pill counting, plasma drug concentration, electronic measures) was higher than that of interview-based evaluation performed by physicians [17]. Although self-rating scales are useful, as described above, there are few instruments that have been translated into Japanese. Typical evaluation scales generally used in Western countries include the Brief Evaluation of Medication Influences and Beliefs (BEMIB) [18] and the Drug Attitude Inventory-10 Questionnaire (DAI-10) [19]. A Japanese version of DAI-10 [20] exists, and its application and rating system are simple; however, it also has the disadvantage that medication behavior is not evaluated. In other words, DAI-10 may evaluate compliance rather than adherence. BEMIB is another useful self-rating scale, prepared by Dolder and coauthors in 2004 (see reference 18, Fig. 1); its reliability and validity have been demonstrated in a study in sixty-three psychiatric outpatients in which adherence was investigated for six months based on refills. BEMIB is shorter than DAI-10, avoids the above disadvantages of DAI-10 and does not require training; however, a Japanese version is not yet available.

In the present study, we prepared a modified Japanese version of BEMIB, with the aim of establishing a self-rating scale in Japanese for the simple evaluation of medication adherence in patients with bipolar disorder, in whom medication adherence markedly influences the prognosis. We also investigated the reliability and validity of this scale.

SUBJECTS AND METHODS

Subjects

The subjects were 47 patients who were treated as outpatients at Nagoya University Hospital or its affiliated sites, Yagoto Hospital and Hinaga General Center for Mental Health, from April 2006 to August 2006 and from April 2009 to July 2009. The patients had received diagnoses of bipolar disorder type I or II using the bipolar disorder section of the Structured Clinical Interview for DSM-IV Axis I disorders (SCID-I) [21], administered by expert psychiatrists. Patients with concurrent Axis I or II disorders (e.g., anxiety disorder, dementia and personality disorder) were excluded. Written informed consent was obtained from each participant after a full explanation of the study. This study was approved by the Ethics Committee of Nagoya University.

Methods

Preparation of Japanese version of BEMIB

After obtaining the consent of the author, the original BEMIB was carefully translated into Japanese by Japanese researchers including a bilingual psychiatrist whose first language is English. In order to apply BEMIB to patients with bipolar disorder, we translated the term "antipsychotic medication" to "psychotropic medication" in Japanese, with the permission of the original author. BEMIB is based on the modified health belief model [22], and its questions encompass all domains considered to influence medication adherence: benefits of treatment, risk of illness, costs of treatment, barriers to treatment and cues to act. BEMIB is composed of eight statements, each of which is evaluated using a 5-point Likert-type scale from 1 (completely disagree) to 5 (completely agree). A high score means favorable medication adherence, except for in statements 3 and 5, for which a low score represents high-level adherence.

Reliability

Evaluation of the modified Japanese version of BEMIB was repeated within four weeks to investigate test-retest reliability. To investigate the internal consistency reliability, the Cronbach α coefficient was determined. To avoid performance bias, the subjects were only told that this was a "study of an evaluation scale": there was no specific mention of "medication adherence."

Validity

To investigate the concurrent validity, the patients were simultaneously evaluated with the Japanese version of DAI-10 and with the modified Japanese version of BEMIB. The Japanese versions of the Beck Depression Inventory (BDI) [23] and the Altman Self-Rating Mania Scale (ASRM) [24] were used to evaluate depressive and manic symptoms, respectively. Since the clinical condition of a patient can change, the assessments performed using the Japanese versions of BEMIB, DAI-10, BDI and ASRM were repeated after twelve weeks. Pearson's correlation coefficients between the total scores of the modified Japanese version of BEMIB and the other scales were calculated. The scores at 0 and 12 weeks were used to analyze the correlation between the scales.

Data analysis

Statistical data are expressed as mean ± SD. Statistical analysis was performed using SPSS for Windows Version 20.0J. Significance was determined at the 0.05 level in all tests.

RESULTS

Characteristics of subjects

Of the 47 participants, one patient with major depressive disorder and five patients who could not complete one of the evaluation scales were excluded, leaving 41 patients who were ultimately included in the analysis. No patients dropped out during the study period. There were 22 males (54%) and 19 females (46%), and the mean age was 50.0 ± 12.3 years (27-73 years). The diagnosis was bipolar I disorder in 24 patients (59%) and bipolar II disorder in 17 patients (41%) (Tables 1, 2).

Table 1. Patient characteristics

Diagnosis	Bipolar I Disorder	23 (57%)
	Bipolar II Disorder	18 (43%)
Gender	Male	22 (54%)
	Female	19 (46%)
Age (years)		50.0 ± 12.4
Duration of illness (years)		16.1 ± 13.8
Mood stabilizers	Lithium	28 (68%)
	Valproate	18 (44%)
	Carbamazepine	1 (2%)
Dose of mood stabilizers (mg/day)	Lithium	596 ± 199
	Valproate	705 ± 280
	Carbamazepine	1000 ± 0

Table 2. Detailed patient characteristics

No.	Diagnosis	Gender	Age (y)	Duration of illness (m)	Mood stabilizers (mg/day)	Antipsychotics (mg/day)	Occupational Status
1	BP-I	m	32	14	Li 800		white-collar worker
2	BP-II	m	59	200	VPA 600		white-collar worker
3	BP-II	f	45	188	Li 400		housewife
4	BP-II	m	36	57	Li 600		blue-collar worker
5	BP-I	m	58	68	Li 800		retired
6	BP-II	f	42	75	VPA 600		housewife
7	BP-I	f	65	600	Li 400, VPA 400		housewife
8	BP-I	f	33	63	Li 600		white-collar worker
9	BP-I	f	59	79	Li 400	APZ 6	housewife
10	BP-I	m	51	21	Li 500		white-collar worker
11	BP-II	f	62	313	Li 400		housewife
12	BP-I	m	65	444	Li 400		white-collar worker
13	BP-I	f	37	210	Li 300, VPA 100	RIS 2	salesperson
14	BP-I	f	73	308	Li 400, VPA 600		housewife
15	BP-I	f	57	358	Li 600	RIS 1	housewife
16	BP-II	m	64	39	Li 300, VPA 600		farmer
17	BP-II	f	42	100	VPA 800		housewife
18	BP-II	f	48	220	Li 800		housewife
19	BP-I	m	42	136	Li 1000	QTP 400	retired
20	BP-I	m	61	103	Li 600	RIS 1	retired
21	BP-II	f	38	80	VPA 600		housewife
22	BP-II	f	71	43	VPA 400	QTP 50	housewife
23	BP-I	f	51	384	Li 800, VPA 1200		housewife
24	BP-II	m	35	156	VPA 600		care worker
25	BP-I	m	29	87	Li 600, VPA 1000		rehabilitation helper
26	BP-I	m	36	28	VPA 1000		blue-collar worker
27	BP-I	m	66	468	VPA 1200	QTP 750	retired
28	BP-I	m	37	21	VPA 600		blue-collar worker
29	BP-II	m	55	444	Li 400		blue-collar worker
30	BP-II	m	48	72	VPA 800		white-collar worker
31	BP-I	f	69	591	Li 400		retired
32	BP-I	m	54	312	Li 800	QTP 500	blue-collar worker
33	BP-I	f	58	366	Li 600		housewife
34	BP-I	m	45	197	CBZ 1000		unemployed
35	BP-II	f	27	43	VPA 1000	QTP 200	blue-collar worker
36	BP-II	m	43	147	Li 1000	QTP 200	white-collar worker
37	BP-II	m	53	75	Li 800	QTP 50	teacher
38	BP-I	f	51	67	VPA 600		housewife
39	BP-I	m	52	192	Li 800	OLZ 20	unemployed
40	BP-I	f	63	488	Li 600	RIS 2	housewife
41	BP-I	m	39	84	Li 600	QTP 200	unemployed

BP: Bipolar Disorder Li: Lithium VPA: Valproic Acid CBZ: Carbamazepine
APZ: Aripiprazole RIS: Risperidone QTP: Quetiapine

Results for each evaluation scale

A negative correlation was confirmed between the scores of statements 3 and 5 of the modified Japanese version of BEMIB and the total scores of the Japanese version of DAI-10. In contrast, we detected a positive correlation between the scores of all other statements of the modified Japanese version of BEMIB and the total scores of the Japanese version of DAI-10. As with the original version of BEMIB, it was considered adequate to invert the scores of two statements.

The mean total score of the modified Japanese version of BEMIB was 28.7 ± 4.6, and the mean total score of the Japanese version of DAI-10 was 4.89 ± 4.03.

The mean total scores of the modified Japanese ver-

sion of BDI on the first and second evaluations were 15.3 ± 12.1 and 14.0 ± 12.5, respectively, showing no significant difference between the two evaluations by paired t-test ($p = 0.47$). The mean total scores of the Japanese version of ASRM were 4.36 ± 3.26 and 3.95 ± 2.91, again showing no significant difference between the two evaluations by paired t-test ($p = 0.48$).

Reliability

The four-week test-retest reliability coefficients of each item and total score of BEMIB ranged from 0.39 to 0.68 ($p < 0.05$, Table 3) and the intra-class correlation coefficient (ANOVA-ICC) was 0.63 (95% confidence interval [CI] = 0.33-0.75, $p < 0.001$). The Cronbach α coefficient was 0.73. In the analysis of test-retest reliability, we surveyed the medical records of all the patients and confirmed that their moods were stable and they did not experience any mood episodes, and that they were treated on an outpatient basis during the four weeks.

Validity

Regarding the concurrent validity, the correlation level was determined by calculating Pearson's correlation coefficient. The total score of the modified Japanese version of BEMIB correlated significantly with the DAI-10 total score (correlation coefficient: 0.39; $p < 0.001$). However, no significant correlation was observed between the total scores of the modified Japanese version of BEMIB and BDI (correlation coefficient: -0.14; $p = 0.24$). In addition, there was no significant correlation between the total score of the modified Japanese version of BEMIB and the ASRM total score (correlation coefficient: 0.01, $p = 0.91$).

Table 3. Four-week test-retest reliability coefficients for the modified Japanese version of BEMIB

Item	r	p value
1	0.42	0.006
2	0.53	0.000
3	0.64	0.000
4	0.57	0.000
5	0.61	0.000
6	0.39	0.012
7	0.45	0.003
8	0.68	0.000
TOTAL	0.58	0.000

r: Pearson's correlation coefficient

DISCUSSION

Our study suggested that the modified Japanese version of BEMIB is sufficiently reliable. Using a four-week test-retest method, the score for each item and the total score of the modified Japanese version of BEMIB were significantly correlated; the intra-class correlation coefficient (ANOVA-ICC) was 0.63. According to a report describing the criteria of ANOVA-ICC in psychiatric clinical research [25], a value of 0.6 or higher is "satisfactory," suggesting that the Japanese version of BEMIB has satisfactory test-retest reliability. Moreover, the Cronbach α coefficient (0.73) was also acceptable, showing sufficient internal reliability.

According to our data, the modified Japanese version of BEMIB has satisfactory internal reliability and validity. Regarding the concurrent validity, the total scores of DAI-10 and the original BEMIB were significantly correlated (correlation coefficient: 0.55, $p < 0.001$) [18]. A significant positive correlation was also noted between the total scores of the Japanese version of DAI-10 and the modified Japanese version of BEMIB, suggesting that the concurrent validity was also sufficient. However, the correlation coefficient shown in our study is not as high as that shown by the original BEMIB. The DAI-10 lacks evaluation of medication behavior, and the Japanese version of BEMIB used in this study was modified for patients with bipolar disorder; these factors may account for the difference between the correlation coefficient shown in our study and that for the original BEMIB.

Only a few studies have focused on the association between changes in mood and medication adherence in patients with bipolar disorder [26]. The modified Japanese version of BEMIB was not significantly correlated with the Japanese version of BDI or ASRM. Depressive symptoms and manic symptoms may occur in patients with bipolar disorder, even though their medication adherence is good. If good adherence

becomes a habit, mood symptoms may not directly compromise adherence. Therefore, the scores of BDI and ASRM could change even when the BEMIB score remains stable. Moreover, higher adherence may lead to lower correlation between the scores of the modified Japanese version of BEMIB and BDI or ASRM. Actually, many previous studies have described poor insight as a factor influencing medication adherence, rather than symptom severity [27-29].

The modified Japanese version of BEMIB is advantageous in several respects compared with other scales designed for the evaluation of medication adherence. First, BEMIB does not require training and can be readily carried out in routine medical practice. Increases in total score indicate improved adherence. It is possible for patients to complete the scale by themselves while waiting for outpatient consultation; in our study, all patients could complete the scale within three minutes. Second, it can be combined with an education plan. Factors reducing medication adherence can be identified, facilitating investigation of a psychoeducational approach to improving adherence. It may also be possible to investigate changes in medication adherence caused by therapeutic interventions. Third, the modified Japanese version of BEMIB overcomes the problems of one of the few self-rating scales available in the Japanese language, DAI-10. The validity of DAI-10 is based on judgments made by physicians, and is disadvantageous in that medication behavior is not evaluated, but the modified Japanese version of BEMIB resolves this issue. For example, statement 4 of the modified Japanese version of BEMIB is: "I have a system (e.g., pill box, medication calendar, someone giving me my medication) that helps me remember to take my psychotropic medication." Finally, the statements are applicable to various treatment methods, and the scale is not limited only to pharmacological therapy.

Several limitations must be considered when interpreting the study findings. First, the sample size was relatively small. The sample size of the article describing the original study focused on BEMIB was also relatively small, with only 63 patients. As our study had only 41 patients, the statistical power may have been reduced, and consequently the possibility of a type 2 error cannot be completely ruled out. Second, since we investigated the reliability and validity only for bipolar disorder in this study, it was impossible to determine if the same results could be obtained in other psychiatric disorders. However, the statements in the modified Japanese version of BEMIB are not limited to bipolar disorder, and could potentially be applied to other psychiatric disorders. In this study, the original BEMIB was modified in translation from English to Japanese in order to evaluate medication adherence in patients with bipolar disorder. Back translation was not performed because the original BEMIB and its modified Japanese version are not identical in content. This means that the BEMIB modified for patients with bipolar disorder is available only in Japanese, not in English.

This study showed the usefulness of the modified Japanese version of BEMIB as an evaluation scale of medication adherence in the field of psychiatry using a sample that consisted of patients suffering from bipolar disorder.

CONCLUSIONS

This study demonstrated the sufficient reliability and validity of the modified Japanese version of BEMIB for patients with bipolar disorder. This is a useful tool well suited for the evaluation of medication adherence in patients with bipolar disorder, without training in routine medical practice.

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CONFLICTS OF INTEREST

All authors declare that they have no conflicts of interest.

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