Neuropsychiatric Disease and Treatment

Dovepress
Taylor & Francis Group

Open Access Full Text Article

CLINICAL TRIAL REPORT

Reliability and Validity of the Chinese Version of the Frequency, Intensity, and Burden of Side Effects Rating (FIBSER) in Patients with Major Depressive Disorder—a Cross-Cultural Adaptation Study

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Background: Assessing adverse medication reactions can play a vital role in maximizing therapeutic outcomes by promoting the adherence and minimizing the cost of medication therapy in patients with major depressive disorder (MDD). Selecting a simple clinical tool that helps physicians assess and treat patients more effectively is necessary. The Frequency, Intensity, and Burden of Side Effects Rating (FIBSER) scale has already been proven to be an effective measurement. This study aimed to identify the reliability and validity of the Chinese version of the FIBSER in MDD.

Methods: Patients who had been diagnosed with MDD according to the Diagnostic and Statistical Manual for Mental Disorders – Fifth Edition (DSM-5) were enrolled (n=105). The depressive symptoms and adverse medication reactions were assessed by using the Hamilton Depression Scale (HAMD), the Treatment Emergent Symptom Scale (TESS), and the Frequency, Intensity, and Burden of Side Effects Rating Scale (FIBSER). The psychometric analysis was conducted on the FIBSER.

Results: The Cronbach's α coefficient for the FIBSER in patients with MDD ranged from 0.872 to 0.942. After four weeks, the test-retest reliability was evaluated with the intraclass correlation coefficient (ICC) ranging from 0.335 to 0.456. The parallel validity of the FIBSER was examined using Pearson's correlation analysis, and r values ranged from 0.694 to 0.776 (P<0.001), which indicated significantly moderate to high correlations between FIBSER and TESS.

Conclusion: The Chinese Version of the FIBSER demonstrates acceptable validity and internal consistency reliability, though test-retest reliability was low in this sample of major depressive disorder patients.

Keywords: major depressive disorder, reliability, validity, FIBSER, side effect

Introduction

According to the survey of the World Health Organization (WHO), the prevalence of major depressive disorder (MDD) is rapidly increasing. There are approximately 270 million patients with MDD worldwide, and the lifetime prevalence rate is 10–20%.[1] Depression has thus become one of the top 10 leading causes of the global burden of disease in the last two

Received: 1 April 2025
Accepted: 1 September 2025
Published: 5 September 2025

decades years.[1] The treatment of depressive disorders mainly covers pharmacotherapy, physical therapy, and psychotherapy. At present, methods such as the transcranial magnetic stimulation (TMS) therapy, ketamine, and electroconvulsive therapy (ECT) have shown certain efficacy in the clinical intervention of treatment-resistant depressive disorders.[2–4] Without early diagnosis and effective treatment, patients with MDD are likely to experience decreased quality of life, suicidal ideation, or suicide attempts.[5] Lifetime MDD may also be associated with an increased risk of all-cause mortality.[6] Therefore, as a part of the comprehensive management of depression, long-term administration of antidepressants is often necessary, which can improve clinical symptoms and reduce the risk of relapse effectively. However, less than half of patients with MDD receiving healthcare are treated adequately.[7] One of the main causes is the high discontinuation rate (up to 20–40%) that is caused by adverse effects of antidepressants.[8] Adverse reactions not only diminish patient adherence to antidepressive therapy[9,10] but also impede the maintenance phases of treatment, consequently impacting long-term prognosis.

To manage adverse reactions and enhance the cost-efficiency of treatment appropriately, assessing the adverse effects associated with the treatment is necessary. Moreover, measurement-based care on adverse drug reactions helps to identify the adverse reactions that occur during the drug treatment of depressive disorders at an early stage, enabling doctors to make rapid decisions and carry out early interventions, so as to improve the quality of life of patients. Commonly used clinical scales for adverse drug reactions, such as the patient self-rating scale, the Glasgow Antipsychotic Side-effects Scale(GASS), and the clinician-rated scale, the Treatment Emergent Symptom Scale (TESS), although these scales evaluate from different types and cover a comprehensive range of assessment contents, they are time-consuming. However, the measurement-based care (MBC) requires simple and easy-to-use scales. Therefore, selecting a suitable scale for evaluating the adverse effects is particularly important.

Currently, there are several side effect scales for patients with depressive disorders. For instance, the antidepressant side effect scale (SERS)[11] is characterized by limited items and options, and simplicity in scoring, which makes it convenient in clinical practice. However, the SERS has a narrow range of applications because it primarily focuses on the side effects of tricyclic antidepressants. The Treatment Emergent Symptom Scale (TESS)[12] is one of the most commonly used tools for assessing drug side effects in psychiatric clinical practice and research in China. It is a clinician-rated scale that encompasses comprehensive items of side effects, including symptoms and laboratory indexes. The severity, the strength of the relationship with medications, and the treatment measures of existing side effects are evaluated in detail. However, the content of TESS is too complex for MBC and lacks specificity for depression. Besides, it requires training and is challenging to assess column B (the strength of the relationship with medications) due to the subjectivity. Likewise, the Patient-Rated Inventory of Side Effects (PRICE) scale,[13] the Toronto Side Effects Scale,[14] and the UKU Side Effects Rating Scale[15] are too time-consuming to use for the MBC. In addition, some of these are physician-administered rating scales that do not provide the patients' perspective, and some of them neglect to assess the frequency and severity of side effects. Consequently, for better managing long-term medication therapy for patients with depressive disorders, there is a pressing need for an efficient and reliable scale to assess adverse drug reactions.

The Frequency, Intensity, and Burden of Side Effects Rating (FIBSER)[16] scale was developed for clinical use to provide a quick and easy way to self-evaluate the side effects of antidepressant treatment. The FIBSER scale consists of three questions which assess the frequency, intensity, and burden of drug side effects over the past week. Notably, the greatest advantage of the FIBSER lies in its simplicity, rendering it a reliable and valid self-assessment tool.

The FIBSER has been widely used to assess adverse reactions of drugs among individuals with depressive disorders. It was first used in the seminal Sequenced Treatment Alternatives to Relieve Depression (STAR*D) trial program.[17,18] For instance, Bryan et al[17] demonstrated that there was no significant difference in the side effects of antidepressants assessed by the FIBSER scale between depressed patients with and without diabetes mellitus. Han et al[19] used FIBSER to assess the changes in adverse reactions to antidepressants throughout the course of treatment; their findings indicated that pharmacogenomic-based antidepressant therapy could offer more precise guidance in drug treatment. Mantani et al[20] used FIBSER to evaluate the combination of smartphone cognitive behavioral therapy and antidepressants, which was found to reduce the overall burden of side effects of treatment. In a longitudinal study, the FIBSER was applied to reveal the association of the greater burden of side effects with poorer treatment outcomes.[21]

Given the clinical utility of the FIBSER, the present study aims to examine the psychometric properties of a Chinese version of the FIBSER scale and to evaluate its reliability and validity in patients with MDD.

Method

Subjects

All participants in this study were recruited from the outpatient department of Shanghai Mental Health Center between January 2021 and December 2021. This study was a part of our former clinical trial (Clinical Trial Registry ID: NCT04500379) which was approved by the Institutional Review Board of Shanghai Mental Health Center, and the data used here were collected simultaneously. The study was conducted according to the Helsinki Declaration. All subjects voluntarily signed a written informed consent before enrollment.

These patients were Han Chinese, aged between 18 and 65 years old. They were diagnosed with MDD according to the DSM-5 and prescribed stable antidepressive medication treatment regimens, such as the Selective Serotonin Reuptake Inhibitor (SSRI) and the Selective Serotonin-Norepinephrine Reuptake Inhibitor (SNRI) antidepressants, for at least eight weeks before the enrollment. Patients also met criteria for clinical remission, ie, the total scores of the 17-item Hamilton Depression Rating Scale (HAMD)≤7.

The exclusion criteria included: (a) patients who were diagnosed with bipolar disorder or had a total score on the Hypomania Checklist-32 (HCL-32)>12 at baseline; (b) patients who suffered from severe physical diseases that adversely affect the performance of neuropsychological tests; and (c) patients who were treated with modified electro-convulsive therapy within the past six months before enrollment.

Clinical Assessment

A self-designed case report form was used to collect the demographic and clinical information. We used the HAMD to evaluate the severity of depression, the TESS, and FIBSER to assess adverse drug reactions. In our study, the TESS was used as the comparator scale to assess side effects. The TESS[22] is an interviewer-administrated instrument to evaluate the tolerability of psychotropics and to reflect the symptoms of adverse drug reactions and laboratory changes from multiple perspectives. The 34 items of this scale were grouped into 6 groups: adverse behavioral reactions, laboratory tests, neurological reactions, autonomic symptoms, cardiovascular reactions, and others. The TESS can be used to assess the "relationship between adverse reactions and medications"; management of side effects was classified into seven grades ranging from (0) no need for treatment to (6) termination of treatment.

The FIBSER was originally developed and authorized by Dr. Stephen R Wisniewskiand et al;[16] the adapted FIBSER by Dr. Raymond W. Lam was used for this study. The 3-item self-reported scale was utilized to evaluate three domains of drug side effects corresponding to the FIBSER1, FIBSER2, and FIBSER3, namely frequency, intensity, and burden, respectively. Frequency pertained to the number of adverse reactions caused by antidepressive treatments experienced in the past week. Intensity refers to the severity of these adverse reactions during the same time frame. Lastly, the burden encompassed the impact of these adverse reactions on patients' daily activities. The Likert type 7-level point system was adopted in these three domains, ie, Frequency from 0 points (no side effects) to 6 points (all the time), Intensity from 0 points (no side effects) to 6 points (intolerable severity), Burden from 0 points (no interference with activities) to 6 points (unable to function). The score from FIBSER3 (Burden) is used to aid clinical decisions, eg, a score from 0 (no interference with activities) to 2 (mild interference) is deemed acceptable, suggesting that ongoing treatment can be sustained unless safety or symptom severity concerns arise. A score of 3 (moderate interference) or 4 (marked interference) necessitates attention towards potential side effects, such as potential dose reduction, while a score of 5 (severe interference) or 6 (unable to function) signifies that the current treatment is deemed unsatisfactory and necessitates alteration, such as dose reduction or substitution of the medication.

The adapted FIBSER was translated to Chinese and back-translated by Dr. Tao Yang, Dr. Lu Yang, and Dr. Jun Chen using strict adherence to the evaluation criteria[23] of conceptual equivalence, semantic equivalence, and content equivalence. During the process of scale translation, they engaged in the exchange and iterative correction of their respective translations. They meticulously deliberated and considered the translation of phrases and sentences for each item of the

scale, and made item-by-item modifications based on the specific language environment and cultural background. Three domestic clinical psychiatry experts were invited for expert consultation to evaluate the scale and provide revision suggestions, leading to the development of the preliminary Chinese version of the FIBSER scale. Before conducting the reliability and validity study of the scale, a pre-survey was administered using the preliminary Chinese FIBSER scale to identify items that were ambiguous or difficult to understand from the patients' perspective. The results were then reported to the research team for joint discussion and revision, ensuring that each item in the scale is clearly expressed and adheres to Chinese linguistic habits, thus completing the Chinese adaptation process.

To ensure the quality of assessments, all assessors were psychiatrists and graduate students from the research team. Prior to data collection, they underwent standardized training to achieve inter-rater consistency and were required to pass a qualification exam before participating in formal assessments. At baseline, demographic and clinical data were collected, and the Hamilton Rating Scale for Depression (HAMD), FIBSER, and Treatment Emergent Symptom Scale (TESS) were administered. To evaluate test-retest reliability and temporal stability, participants were reassessed using the HAMD and FIBSER scales 4 weeks later.

Statistical Analysis

According to Kendall's brief estimation, the sample size should be at least 5~l0 times the number of variables. The SPSS 22.0 was used for statistical analysis. Descriptive analysis, correlation analysis, factor analysis, and Spearman correlation analysis, were used to evaluate the reliability and validity of the FIBSER scale. The internal consistency was evaluated using Cronbach α coefficient, while the external consistency was analyzed using Pearson correlation analysis. Additionally, the correlation between FIBSER and TESS was examined using Pearson correlation analysis to establish concurrent validity. P-value<0.05 (two sides) was considered statistically significant.

Results

Demographic and Clinical Characteristics

A total of 105 patients with MDD were included, of whom 30 were males (28.57%) and 75 were females (71.43%). The average age of patients was 29.53± 6.34 years old. Among them, 93 patients (88.57%) completed a 4-week follow-up, and 12 patients (11.43%) withdrew for various reasons (refusing to visit, could not attend the follow-up, etc). (see Table 1).

Internal Consistency

The Cronbach's α coefficient of the FIBSER scale was calculated to be 0.942 at baseline and 0.872 after four weeks. Additionally, the Cronbach's α coefficient of the TESS scale was 0.984 (see Table 2).

Table 1 The Demographic and Clinical Information of All Subjects

Item	MDD (baseline) (n=105)	MDD (4-week) (n=93)
Age, (years, mean ± SD)	29.53±6.34	29.69±6.48
Gender (n, %)		
Male	30 (28.57)	26 (27.96)
Female	75 (71.43)	67 (72.04)
Years of education (years, mean±SD)	15.81±2.08	15.75±2.05
Age at onset (years, mean ± SD)	20.33±7.94	23.46±7.99
Scale scores		
HAMD scores (mean ± SD)	3.42±2.26	n/a
FIBSER scores (mean ± SD)	2.25±2.81	1.76±2.76

Abbreviations: MDD, Major depressive disorder, HAMD-Hamilton Depression Scale; FIBSER, Frequency, Intensity, and Burden of Side Effects Rating; SD, standard deviation; n/a, not available.

Table 2 Internal Consistency of the FIBSER and Standard Test

	Cronbach's α	Items
FIBSER (baseline)	0.942	3
FIBSER (4 weeks)	0.872	3
TESS	0.984	2

Abbreviations: FIBSER, Frequency, Intensity, and Burden of Side Effects Rating; TESS, Treatment Emergent Symptom Scale.

Table 3 Test-Retest Reliability of the FIBSER Scale (n=93)

Item	ICC	95% CI	P
FIBSER1	0.335	0.43–1.07	<0.01
FIBSER2	0.456	0.42–0.99	<0.001
FIBSER3	0.407	0.30–0.84	<0.001
FIBSER total scores	0.443	1.19–2.80	<0.001

Note: P<0.05 was statistically significant.
Abbreviations: FIBSER, Frequency, Intensity, and Burden of Side Effects Rating; ICC, Intra-group Correlation Coefficient; CI, Confidence Interval.

Table 4 Parallel Validity Analysis of the FIBSER and Standard Test (n=105)

Item	Standard Test	Pearson(r)	P
FIBSER1	TESS total A, B	0.694	<0.001
FIBSER2	TESS total A, B	0.728–0.736	<0.001
FIBSER3	TESS total A, B	0.763–0.776	<0.001
FIBSER total scores	TESS treatment measure	0.751	<0.001

Note: P<0.05 was statistically significant.
Abbreviations: FIBSER, Frequency, Intensity, and Burden of Side Effects Rating; TESS, Treatment Emergent Symptom Scale.

Test-Retest Reliability

The test-retest reliability was assessed using the intraclass correlation coefficient (ICC) at the end of 4 weeks. A total of 93 patients were followed up for retesting the FIBSER scale. The results indicated that the ICC values ranged from 0.335 to 0.456 (p<0.001) (see Table 3).

Concurrent Validity

Pearson correlation analysis was used to analyze the concurrent validity. The correlation coefficient (r-value) between FIBSER and TESS scale ranged from 0.694 to 0.776 (all P <0.001) (see Table 4).

Discussion

Psychotropics can induce various adverse reactions. These side effects have been frequently reported, resulting in numerous issues concerning treatment compliance and efficacy.[24] Trivedi[25] emphasized that precise evaluation with appropriate scales, such as FIBSER, was beneficial for formulating treatment plans. In the present study, we translated the FIBSER scale to the Chinese version and assessed its reliability and validity in Chinese patients with MDD. Our findings show that the scale demonstrates good internal consistency and concurrent validity, along with user-friendly

characteristics that make it suitable for clinical settings. However, it exhibits low test-retest reliability-a limitation that warrants attention in future refinements of the instrument.

In this study, Cronbach's coefficient was used to evaluate the internal reliability of the scale. The scale was considered to have ideal reliability if the reliability coefficient of the total scale was >0.80.[26] The results showed that the FIBSER Chinese version had Cronbach's α coefficients of 0.942 at baseline and 0.872 at the end of 4 weeks. The standard scale, ie TESS scale, displayed a Cronbach's α coefficient of 0.984. These aligned with Wisniewski's study,[16] which reported Cronbach's α values of the FIBSER scale ranging from 0.91 to 0.93. The high Cronbach's α coefficients showed good internal consistency for the FIBSER and TESS scale.

The test-retest reliability of a measurement refers to the completion of the same measurement on two separate time points within a reasonably short timeframe to determine if the measured characteristics undergo any changes. In our study, a total of 93 patients with MDD were retested after four weeks to assess the test-retest reliability. If the correlation coefficient between the two measurement results is >0.7, it indicates good test-retest reliability of the scale and high cross-time stability.[26] The findings of this study revealed that the intraclass correlation coefficient (ICC) of each item ranged from 0.335 to 0.456, indicating that test-retest reliability is low. One of the primary reasons for the relatively low test-retest reliability scores is the long time interval between the two testing sessions. Patients may experience fluctuations in psychological state or physiological indicators, or exhibit response bias due to environmental changes, which significantly reduces test-retest reliability coefficients (such as ICC values). However, the FIBSER scale contains only three items, and the short follow-up period may be more susceptible to influences from memory and practice effects. Additionally, considering the typical patient follow-up cycle (usually once a month), this study chose to conduct the retest at the fourth week. Wisniewski et al[16] conducted a 14-week study to examine the temporal reliability of FIBSER, and the result indicated that a shorter measurement interval corresponded to a higher correlation. Furthermore, the FIBSER scale exhibited strong test-retest reliability, with an ICC range of 0.68–0.89 between items at each bi-weekly follow-up assessment. Therefore, the test-retest reliability of the FIBSER scale still requires additional research to validate its time stability.

This study examined the parallel validity of the FIBSER Chinese version by establishing significant correlations between FIBSER and standard items from the TESS scale. Our results showed good correlations between each item of the FIBSER and TESS, indicating that there is a high consistency between the FIBSER scale and the TESS in evaluating drug side effects. Wisniewski et al study[16] investigated the parallel validity of the modified scale by examining the correlation between FIBSER items and two other measures: one was a side effect scale called PRICE, and another one was a scale of depression symptom severity known as the Quick Inventory of Depressive Symptoms-Clinician Rated version (QIDS-C16). The Spearman Correlation Coefficient was also used to determine the correlation between each item of the FIBSER scale and the PRISE and the QIDS-C16. As one might expect, the findings of the study indicated that the FIBSER was significantly correlated with the PRISE, but less so with the QIDS-C16. It is indicated that there is a high consistency between the FIBSER scale and the PRISE in measuring drug side effects. This aligned with the overall conclusion of the study. Therefore, The Chinese version of the FIBSER was found to be a reliable prediction tool in assessing drug-related side reactions in clinical practice. It could be more responsive to the side effects experienced by individuals with depressive disorder. Additionally, multiple studies by scholars such as Braund,[21] Han,[19] and Nierenberg[18] have preliminarily confirmed that the FIBSER scale demonstrates favorable applicability in depression disorders, particularly showing high application value in follow-up treatment scenarios.

Overall, some limitations remain in the present study. Firstly, the demographic characteristics of participants in this study were relatively limited. For example, the male-to-female ratio exhibited an imbalance. The subjects predominantly consisted of young and middle-aged individuals (average age of 29.53 years) with a relatively high level of education (average of 15.81 years of schooling with a majority holding a college degree). Consequently, the representativeness of the enrolled population may be inadequate. Secondly, our study featured a relatively extended time interval, specifically a four-week follow-up period, which could potentially affect the assessment of test-retest reliability. Thirdly, some of the patients had combination therapies of antidepressants and other adjuvant medications, which might interfere with the assessment of side effects. Fourthly, a notable limitation of this study is the lack of exploration into subgroup differences (eg, gender, age) and cross-cultural applicability (eg, different linguistic and cultural contexts) in the performance of the FIBSER. Future research should systematically assess the scale's measurement invariance across diverse subgroups and validate its psychometric properties in various linguistic and cultural contexts. Additionally, the small sample size in this study may adversely affect the reliability, validity, and statistical significance of the research. In future research, the reliability and generalizability of conclusions can be enhanced by increasing the

sample size, adopting stratified sampling, and incorporating more diverse characteristics of research subjects. Finally, a limitation of the FIBSER scale cannot discern the impact of specific side effects, nor can it determine whether the impact reported across visits is attributed to the same side effects. However, we contend that the absence of specificity is an acceptable trade-off for the benefits of expeditious and simple assessment of side effect burden.

In summary, the present study demonstrated that the Chinese Version of the FIBSER exhibited good internal consistency and concurrent validity among individuals with MDD. The FIBSER provides a concise and informative assessment of side effects, thereby facilitating time-saving evaluations in routine clinical practice. This simple rating scale for side effects will help clinicians better implement MBC for depression, thereby enhancing medication adherence, reducing the social burden of side effects, and improving the long-term prognosis. Additionally, the FIBSER scale offers advantages of conciseness and operational convenience, making it promising for broader application in populations beyond depression (such as those with anxiety or chronic pain). However, its applicability requires further validation in non-depression samples.

Data Sharing Statement

All data generated or analyzed during this study are included in this published article.

Consent for Publication

All authors reviewed and agreed to publish the manuscript.

Acknowledgments

The authors would like to thank all the participants of this study.

Funding

This study was funded by Pudong New Area Science and Technology Development Fund public institutions livelihood research project(PKJ2023-Y20), National Natural Science Foundation of China (81761128032, 81930033, 81771465), the Clinical Research Plan of SHDC (SHDC12020126), Key Area Research and Development Program of Guangdong Province (2018B030334001), Clinical Research Center of Shanghai Mental Health Center Key Project (CRC2021ZD01, CRC2021DX01), Shanghai Key Clinical Specialties Construction Project (Psychiatry and Mental Health), Shanghai Clinical Research Center for Mental Health (19MC1911100).

Disclosure

Dr Raymond Lam reports grants administered through UBC from BC Leading Edge Endowment Fund, Brain Canada, Canadian Institutes of Health Research, Canadian Network for Mood and Anxiety Treatments, Grand Challenges Canada, Healthy Minds Canada, Janssen, Michael Smith Foundation for Health Research, MITACS, Ontario Brain Institute, Unity Health, Vancouver Coastal Health Research Institute, VGH-UBCH Foundation, personal fees from Carnot, Canadian Medical Protective Association, Lundbeck, Neurotorium, Otsuka, Shanghai Mental Health Center; non-financial support from Asia-Pacific Economic Cooperation, Canadian Network for Mood and Anxiety Treatments, CB Solutions, and Genome BC, outside the submitted work. The authors declare no other conflicts of interest in this work.

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