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Validation of Chinese version of the Morisky Medication Adherence Scale in patients with epilepsy

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ABSTRACT

Purpose: This study aimed to validate a Chinese version of the Morisky Medication Adherence Scale (MMAS-8) in patients with epilepsy. The relationships between adherence, seizure frequency, and adverse effects were assessed using this method.
Methods: Data from patients diagnosed with epilepsy at the Department of Neurology of Huashan Hospital were collected between January and June 2013. To validate the MMAS-8, internal consistency, test–retest reliability, and factor analysis were calculated. Relationships between adherence, seizure frequency, and adverse effects were assessed using Pearson's correlation.
Results: One hundred and eleven patients were recruited. The MMAS-8 had moderate internal consistency (Cronbach's $\alpha = 0.556$) and good test–retest reliability (intraclass correlation coefficient = 0.729). The MMAS-8 adherence rate was 79.2%. MMAS-8 adherence was negatively correlated with seizure frequency and adverse effects ($r = -0.708$, $p < 0.001$; $r = -0.484$, $p < 0.001$).
Conclusion: The MMAS-8 scale can be used as a tool to assess medication adherence in Chinese patients with epilepsy. Better seizure control and lower rates of adverse effects were significantly correlated with higher adherence scores.

1. Introduction

Epilepsy is a common neurological problem affecting approximately 65 million people globally.[1] In China, the lifetime prevalence of epilepsy is approximately nine million people (7 per 1000), whereas currently six million people (4.6 per 1000) have active epilepsy.[2]

Antiepileptic drug (AED) regimens can dramatically control seizure occurrence and improve the prognosis for patients with epilepsy. However, it can be difficult to achieve ideal efficacy in practice. One main reason for this is the non-adherence to AED regimens. Cramer and colleagues have defined adherence to "the extent to which a patient acts in accordance with the prescribed interval and dose of a dosing regimen."[3] Non-adherence to AEDs is common, with an average range from 30% to 60% and dose omission of approximately 70%.[4,5] Non-adherence to AEDs, co-medications, seizure type, and factors such as gender and co-morbidity[6,7] may influence seizure risk. Furthermore, non-adherence to AEDs may be associated with more serious outcomes (increased hospitalization, inpatient days, and emergency department visits) and increases in the cost of treatment.[8,9] Thus, it is important to assess medication adherence and discuss it with patients when treatment appears to fail.[10]

Despite the lack of a gold standard for measuring adherence to medication, both direct and indirect measures are currently used in clinical practice. Direct methods, the most common measures of adherence, involve monitoring metabolite concentration through body fluid (plasma and saliva) and therapeutic drug monitoring. However, in clinical settings, it is often unreliable to measure adherence through plasma concentration because a number of factors can influence the results such as drug interaction and physiological changes.[11] In addition, assessing plasma concentration is expensive and time intensive. Thus, health care researchers have begun developing indirect instruments (pill counts, medication event monitoring systems [MEMS], and self-reporting),[12,13] which are non-invasive. Each of these has different advantages and disadvantages.[14] One self-reported questionnaire, the 8-item Morisky Medication Adherence Scale (MMAS-8),[15] is used to assess adherence in outpatients with chronic disease. It is widely used because it is free to administer, simple, and has a good relationships with other measures of adherence.[16] Because some studies have

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been conducted in Chinese populations[17,18] and the scale has not been validated in China, we were interested in translating the scale and validating some of its psychometric properties in Chinese patients with epilepsy. The utility of this scale in different languages aids international studies,[19] and it can meet the requirements of non-English speaking people in China.

In addition, three main factors were revealed to be associated with medication adherence: patient-related factors (e.g., beliefs about AEDs),[20] illness-related factors (e.g., seizure frequency),[10,21] and medication-related factors (e.g., adverse effects).[22] Currently, studies have focused on assessing the relationship between adherence and seizure frequency, suggesting patients experience a lower seizure frequency when they are more adherent to their AEDs.[10,21] It is also important for health care providers to not only understand how adherence is associated with seizure frequency, but also potential factors related to adherence, such as adverse effects. There have been a few studies conducted, and they found that adherence is related to adverse effects.[23] Because of the lack of relevant research among Chinese patients with epilepsy, an investigation of the relationships between adherence, seizure frequency, and side effects is needed.

Therefore, the two main objectives in this study were: (a) to validate a Chinese version of the MMAS-8 in patients with epilepsy and (b) to evaluate the relationships between adherence, seizure frequency, and adverse effects. In addition, the study hypothesized MMAS-8 is moderately reliable in Chinese patients with epilepsy, and adherence is negatively correlated with seizure frequency and adverse effects. There have been: (a) studies validating MMAS-8 with moderate psychometric properties in patients with hypertension,[24] diabetes mellitus,[25,26] osteoporosis,[27] and those taking warfarin[28] and (b) two studies revealed that the relationship between adherence and seizure frequency was negative.[10,21]

2. Methods

2.1. Study Design

This was a prospective, cross-sectional study. It was approved by the Ethics Committee of Huashan Hospital (2013-006) before data collection. Outpatients with epilepsy were recruited from January to June 2013. To be eligible for participation, patients had to: (a) be patients with epilepsy, (b) have been taking AEDs for at least 3 months, and (c) provide written informed consent.

Patients with epilepsy were asked to complete a self-designed questionnaire that contained three parts: history information form (socio-demographic, age, education background, etc.; clinical: etiology, age of onset of epilepsy, seizure frequency, etc.; and medication data), the MMAS-8 scale, and the Liverpool Adverse Event Profile (LAEP). In addition, to assess the test-retest reliability of the MMAS-8 scale, a random sample of 10% of the patients with epilepsy was asked to complete the scale again 2-4 weeks later. Finally, the relationships between adherence, seizure frequency, and adverse effects were accessed by statistical methods.

2.2. Measures

2.2.1. MMAS-8

First, the scale was translated into Chinese by the author (see Appendix A). To ensure consistency between the original and translated versions, an expert clinician and an experienced clinical pharmacist translated the initial translation back to English to ensure that the content was the same (see Appendix B). The scale is composed of eight items.[15] Seven items (item 1 to item 7) are yes/no questions, in which a "no" answer received a score of 1, and a "yes" answer received a score of 0, except for item 5, which was reverse scored. Item 8 is measured on a five-point Likert scale. Responses of "never," "once in a while," "sometimes," "usually," and "all the time" were scored 1, 0.75, 0.50, 0.25, and 0, respectively, whereas for item were scored "1" for "never" and "0" for other responses. The total scores ranged from 0 to 8. Scores of 8, 6-8, and < 6 indicate high, medium, and low adherence, respectively. Patients with scores of 8 and 6-8 were considered adherent, and a score < 6 was considered as non-adherent in our study.

2.2.2. LAEP

The adverse effects to AEDs were assessed using the Chinese version of the LAEP.[29] The LAEP is a validated 22-item questionnaire consisting of two factors: central nervous system (CNS) dose-related (unsteadiness, tiredness, headache, double/blurred vision, difficulty in concentration, shaky hands, dizziness, sleepiness, memory problems and disturbed sleep), non-CNS dose-related and psychiatric adverse effects (restlessness, feelings of aggression, nervousness/agitation, hair loss, skin problems, upset stomach, trouble with mouth, trouble with gums, weight gain, weight loss, depression, and paresthesia).[29] All items were scored using a four-point Likert scale in which 1 = never, 2 = rarely, 3 = sometimes, and 4 = always. The scores for the LAEP range from 22 to 88, with higher scores indicating greater adverse effects in these patients. Based on a prior study,[29] the mean score is 34.77 on the LEAP for Chinese patients, and thus, patients with a score > 34.77 were considered to be suffering severe adverse effects.

2.2.3. Seizure Frequency

The seizure frequency during the preceding month was self-reported.

2.3. Statistical Analysis

Internal consistency reliability was assessed by calculating the Cronbach's α coefficient. A Cronbach's $\alpha \geq 0.5$ is considered acceptable.[26] To assess test-retest reliability, a random sample of 10% of the patients with epilepsy was readministered the MMAS-8 after 2–4 weeks. Based on the results, we calculated an intraclass correlation coefficient (ICC). An ICC over 0.60 indicates good test-retest reliability.[30] Finally, factor analysis was conducted to assess construct validity when the p value of Bartlett's test of sphericity was less than 0.001 and the value of Kaiser-Meyer-Olkin measure of sampling adequacy (KMO) was more than 0.5.[31] Eigenvalues > 1 were used to assess the number of factors, and items with loading on each ≥ 0.4 were viewed as the corresponding factors.[32]

The relationships between MMAS-8 scores and continuous variables were calculated using Pearson's correlation, and associations with MMAS-8 scores and categorical variables were examined by univariate analysis.

The significance threshold was set as 0.05. Statistical analysis was conducted by SPSS 16.0 for Windows.

3. Results

3.1. Patient and Clinical Data

A total of 111 patients with epilepsy were recruited for our study (56 women and 55 men). The patients' mean age (SD) was 32.9 (14.9) years. Approximately 91.9% were educated above the elementary school (36.9% middle school, 21.6% high school, 32.4% university, 0.9% Masters degree). The mean time (SD) since the first seizure was 22.3 (17.0) years. Around half of the patients (47.7%) reported that they had less than one seizure in the previous month. One type of AED (55.9%) was administered by patients, followed by two types of AEDs (36.0%) and three types of AEDs (7.2%). The mean