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Original Research

The 8-item Morisky Medication Adherence Scale: Validation of a Brazilian–Portuguese version in hypertensive adults

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Abstract

Background: The Morisky Medication Adherence Scale (MMAS-8) remains one of the most widely used mechanisms to assess patient adherence. Its translation and testing on languages in addition to English would be very useful in research and in practice.
Objective: To translate and examine the psychometric properties of the Portuguese version of the structured self-report eight-item Morisky Medication Adherence Scale among patients with hypertension.
Methods: The study was designed as a cross-sectional survey conducted in six Family Health Units of the Brazilian Unified Health System, in Maceió, between March 2011 and April 2012. After a standard "forward–backward" procedure to translate MMAS-8 into Portuguese, the questionnaire was applied to 937 patients with hypertension. Reliability was tested using a measure of internal consistency (Cronbach's alpha), and test–retest reliability. Validity was confirmed using known groups validity. Three levels of adherence were considered based on the following scores: 0 to <6 (low); 6 to <8 (medium); 8 (high).
Results: The mean age of respondents was 57.1 years (SD = 12.7 years), and 71.5% were female. The mean number of prescribed antihypertensives per patient was 1.62 (SD = 0.67). The mean score for the medication adherence scale was 5.78 (SD = 1.88). Moderate internal consistency was found (Cronbach's alpha = 0.682), and test–retest reliability was satisfactory (Spearman's $r = 0.928$; $P < 0.001$). A significant relationship between MMAS-8 levels of adherence and BP control (chi-square, 8.281; $P = 0.016$) was found. 46.0%, 33.6%, and 20.4% of patients had low, medium, and high adherence, respectively. The

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self-report measure sensitivity, specificity, positive and negative predictive values were 86.1%, 31.2%, 57.4% and 68.3% respectively.
Conclusions: Psychometric evaluation of the Portuguese version of the MMAS-8 indicates that it is a reliable and valid measure to detect patients at risk of non-adherence. The MMAS-8 could still be used in routine care to support communication about the medication-taking behavior in hypertensive patients.

Keywords: Hypertension; Medication adherence; Self-reported adherence; Validation; Cross-cultural adaptation; Morisky scale

Introduction

Hypertension is a major risk factor in the development of cardiovascular disease and one of the most important public health problems in developed countries, affecting >25% of adults.[1] In Brazil, the prevalence of hypertension seems to have diminished 6% in the last three decades, but it still is approximately 30%, while cardiovascular disease represents the most frequent cause of death, at 32%.[2,3] Given the linear relationship between level of blood pressure (BP) and risk for cardiovascular events,[4] it becomes clear why hypertension control to systolic BP (less than 140 mm Hg) and diastolic BP (less than 90 mm Hg) approximates only 20% among treated and untreated Brazilian adults.[5,6] Even among treated patients (67.3%), hypertension control rates remain suboptimal at about 26%.[7]

A significant but often unrecognized cardiovascular risk factor universal to all patient populations is medication nonadherence,[8] which can be defined as the extent to which a person's behavior – taking medication, following a diet, and/or executing lifestyle changes – corresponds with agreed recommendations from a healthcare provider.[9] According to the World Health Organization, in developed countries, such as the United States, only 51% of the patients treated for hypertension adhere to the prescribed treatment, while in China only 43% of patients with hypertension adhere to their antihypertensive medication regimen.[10] In Brazil, previous studies have shown a prevalence of medication adherence varying from 22% to 40%.[11,12] This is a growing concern to clinicians and healthcare systems because of mounting evidence that non-adherence is prevalent and associated with adverse outcomes and higher costs of care.[13–15] Thus, poor medication adherence must be addressed in any intervention aimed to improve BP control.[16,17]

Several methods are available for the assessment of adherence, however accurate measurement continues to be difficult, and each available method has its own advantages and disadvantages.[18,19] Methods for assessing adherence to medications are categorized as either direct or indirect.[3] Direct methods include measurement of the level of target drug or metabolite in blood, measurement of a biological marker in blood and directly observed therapy. Although direct methods are considered to be more robust than indirect methods, they also have limitations, once knowledge of the "true" adherence of a patient is ultimately based on assumptions that depend on the health professional's empathy and intuition and the patient's beliefs and frankness.[10] Indirect methods of adherence assessment – which are prone to underestimation of non-adherence – include patient self-reports, pill counts, rate of prescription refills, electronic medication monitors, assessment of the patient's clinical response, measurement of physiological markers and patient diaries.[11,12] The most commonly used indirect methods include patient self-report, pill counts, and pharmacy refills. One of the most widely used patient self-report instruments is the validated four-item Morisky, Green, and Levine Self-Reported Medication Taking Scale,[15] later revised as Morisky Medication Adherence Scale (MMAS-4),[16,17] which measures non-adherence using 4 items and identifies 2 types of non-adherence behavior – unintentional and intentional.[14,18,19,23–25] The Morisky Medication Adherence Scale (MMAS-8) is an 8-item self-report scale for measuring medication-taking behavior developed from the previously validated 4-item scale[20–22] and supplemented with additional items to better capture barriers surrounding adherence behavior. To date, a validated Portuguese version of the MMAS-8 has not been available. The aims of our study were to translate the MMAS-8, to analyze psychometric properties

and to identify whether the MMAS-8 is a suitable instrument for assessing medication adherence in hypertensive patients.

Method

The study was designed as a cross-sectional survey conducted in six Family Health Units of the Brazilian Unified Health System, in Maceió, between March 2011 and April 2012. Participating units recruited patients who were taking at least one medication to control hypertension, and were 18 years old or older. Participants were randomly recruited during regularly scheduled appointments at the health units from lists of patients registered with general practitioners. All patients were informed of the objective of the study and gave written consent before inclusion in the study, which was approved by the Ethics Committee of Federal University of Alagoas.

Data collection

Data were collected through home interviews and blood pressure measure. The interviews were carried out in the patients' houses, by previously trained students of pharmaceutical sciences who were members of the Health Tutorial Education Program team and who were monitored during the home visit by a health agent of the Family Health Unit. The values of systolic (SBP) and diastolic (DBP) blood pressure were obtained by the mean of two blood pressure measurements, carried out by the research team during the visit, according to the guidelines established in the VI Brazilian Guidelines for the Treatment of Hypertension,[8] using a mercury sphygmomanometers calibrated with a minimum interval of 5 min between each measurement.

A target sample size of 246 was estimated based on a previous study,[26] however, a larger sample size of 700 patients was estimated to increase the reliability of the conclusion.[27]

Instrument translation

To obtain a Portuguese version of MMAS-8, conceptual equivalence needs to be achieved with the original version to ensure that the instrument is comprehensible and practical in the target population. The MMAS-8 was translated into Portuguese according to the guidelines for translation and cultural adaptation of patient-reported outcome measures.[28–30] First, the English original version was translated into Portuguese by authors A.D.O.F. (Pharmacist) and F.A.C. (Cardiologist Physician), both native speakers of Portuguese and proficient in English. Each translator produced a forward translation without any mutual consultation. Both versions were discussed and a final reconciled Portuguese version was agreed on. A back translation was then performed by two English first-language lay translators, who had no information about the original version. This ensured that the quality of the Portuguese version was also comprehensible for lay people.[28,30] The developer of the MMAS-8 approved the back translation. The first draft of the MMAS-8 was then piloted among twenty hypertensive patients to ensure that the items were understood as having a meaning equivalent to the meaning of the source item. These patients were not included in the main study data. The items themselves were understood similarly by all. As a second method to verify the quality of the translation, the original and the translated versions were given to bilingual lay people to detect differences in meaning. Additionally, 2 postgraduate pharmacy students and 1 postgraduate medicine student judged the face and content validity of the final version of the questionnaire. Adaptations were not regarded as necessary.

Medication adherence

Responses of the items of the MMAS-8 were coded analogous to the English version. A total score of all items was calculated with a sum score ranging from 0 to 8 for adherence. Frequencies, mean, median and standard deviation were calculated for the sum scores. MMAS-8 score was calculated if the respondent answered at least 6 of 8 items. The MMAS scores were trichotomized previously into the following 3 levels of adherence: high adherence (score, 8), medium adherence (score, 6 to <8), and low adherence (score, <6).[31]

Internal consistency

The internal consistency was assessed using Cronbach's α which indicates whether each item of a scale is appropriate for assessing the underlying concept of its scale. Values above 0.6 are generally considered to indicate satisfactory internal consistency, with values >0.8 indicating high internal consistency[32]; however, opinions differ for acceptable cut-off points. In this study, Cronbach's alpha values below 0.5 were considered unacceptable.[33]

Test–retest reliability

Retest reliability was measured to determine scale stability. This test examines the probability of a measure yield the same description of a given phenomenon if that measure is repeated.[34] Pearson's correlation coefficient r scores range between −1 and +1: magnitudes of +1 showing highest correspondence and 0 demonstrating no correspondence. Instruments showing r values larger than 0.80 are considered to be very reliable; however, the reliability also depends on the expected stability of the construct being measured. Test–retest reliability was assessed through the administration of a second questionnaire to 101 patients who were re-visited 2 weeks after their initial interview.

Known-groups validity

Known-groups validity can be assessed by testing the ability of a measure to distinguish between groups of people that differ according to some known factor. This study assessed known-groups validity through the association of BP control (systolic BP < 140 mm Hg, and diastolic < 90 mm Hg) and MMAS-8 categories using Chi square and t tests, assuming that patients with poor lower adherence scores also report poor BP control.[17,22,35] The significance level was set at $P < 0.05$.

Sensitivity and specificity analysis

To determine how well the Portuguese version of MMAS-8 would serve as a screening tool for identifying patients with poor blood pressure control, sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were estimated through a dichotomous low/medium versus high measure of adherence.

Statistical analysis

Data analysis was performed using SPSS software, release 12. Statistical analyzes involved: descriptive analyzes, the Kolmogorov–Smirnov test to check the normality of continuous variables, chi-square and Kruskal–Wallis test to test the relationship between adherence and other independent variables (age, sex, educational level, number of antihypertensive medications and blood pressure control, characterized by systolic BP values <140 and diastolic BP < 90 mm Hg), and binary logistic regression. All variables with $P < 0.25$ in the bivariate analysis were included in the initial model of the multivariate analysis. The variables that showed a higher value of P were removed, one by one, until only variables with statistical significance remained in at least one of the categories of therapeutic adherence. The level significance was set at $\alpha < 0.05$. Medication adherence, frequencies, mean, median and standard deviation were calculated for the sum scores of medication adherence scale.

Results

Socio-demographic data and medication adherence

The MMAS-8 was responded by 937 hypertensive outpatients. The mean age of respondents was 57.1 years (SD = 12.7 years), with 73.9% older than 50 years, 71.5% female, 52.1% had incomplete basic school education or were functionally illiterate. Mean number of prescribed antihypertensives per patient was 1.62 (SD = 0.7).

The study population had 46.0% low adherers, 33.6% medium adherers, and 20.4% high adherers. The mean score for the medication adherence scale was 5.78 (SD = 1.88). Table 1 displays characteristics of the total and adherent groups.

Internal consistency

Cronbach's alpha test of internal consistency was calculated at alpha = 0.682 for the eight items in MMAS. Its item-to-total correlation coefficient ranged from 0.160 to 0.566 (Table 2). The corrected item–total correlation showed a value less than 0.20 for item 7, considered a low value, although significantly different from zero. However, the Cronbach's alpha values if item deleted were lower than the resulting coefficient ($\alpha = 0.682$), indicating that the inclusion of item 7 does not affect the reliability of the instrument (Table 2).

Test–retest reliability

The test–retest reliability of MMAS-8 indicates satisfactory reliability and stability of the instrument with Spearman's rank correlation coefficient of 0.928 ($P < 0.001$).

Known-groups validity

As hypothesized, patients who reported poor blood pressure control also reported lower levels of adherence to medications. Mean (SD) scores of MMAS-8 for patients with poor BP control vs. good BP control were 5.67 (SD = 1.87) and 6.00 (SD = 1.88), respectively ($P = 0.003$, Kruskal Wallis test). Median scores were 6.0 and 6.5 respectively. Although these values could be considered

Table 1
Characteristics of study population according to the groups of adherence

Patient characteristics	Total sample $n = 937$	Low adherers (score: <6) 438 (46.7%)	Medium adherers (score: 6 to <8) 309 (33.0%)	High adherers (score: 8) 190 (20.3%)	P
Sex (%)					
Male	268 (28.6)	123 (28.1)	88 (28.5)	57 (30.0)	0.886
Female	669 (71.4)	315 (71.9)	221 (71.5)	133 (70.0)	
No. of prescribed medications, mean (SD)	1.62 (0.67)	1.54 (0.65)	1.71 (0.68)	1.59 (0.67)	0.067
Educational level N (%)					
Illiteracy or incomplete basic school	474 (52.1)	230 (55.2)	148 (48.4)	96 (51.3)	0.348
Complete basic school	267 (29.3)	119 (28.5)	91 (29.7)	57 (30.5)	
Complete high school	159 (17.5)	63 (15.1)	65 (21.2)	31 (16.6)	
Complete college	10 (0.6)	5 (1.2)	2 (0.7)	3 (1.6)	

Pearson chi-square.

as non-clinically significant, the strong association observed in a large sample indicates a potential in distinguishing between poor and good BP control. While the mean score related to BP control is identical to the cut point (=6) previously suggested by the developer of the MMAS-8, the median score related to uncontrolled blood pressure was also 6.0. The chi-square test showed a significant relationship between MMAS-8 categories and BP control ($\chi 2 = 8.281$; $P = 0.016$), as 57.4% of the high adherence patients had BP controlled to recommended levels, while 34.3% and 29.7 of those in the medium and low adherence groups had their BP controlled, respectively (Table 3).

Sensitivity and specificity

Using a cut point of less than 8, the sensitivity of the measure for identifying patients with poor blood pressure control through medication adherence assessment was estimated to be 86.1%, the specificity was only 31.2%. PPV and NPV were 57.4% and 68.3%, respectively (Table 3).

Table 2
Reliability test

	Corrected item–total correlation	Cronbach's alpha if item deleted
Question 1	0.566	0.555
Question 2	0.469	0.578
Question 3	0.223	0.632
Question 4	0.353	0.607
Question 5	0.327	0.617
Question 6	0.410	0.599
Question 7	0.160	0.645
Question 8	0.501	0.623

Alpha reliability = 0.682.

Discussion

The Portuguese version of the MMAS-8 demonstrated satisfactory psychometric properties, as present results provide evidence of the reliability and validity in patients with hypertension. The population in which the instrument was tested is representative of the Portuguese-speaking part of the Brazilian population with known hypertension, once they share similar patterns (e.g. age, gender and number of prescribed antihypertensives per patient). On the other hand, our study focused on low income patients and thus the high levels of illiteracy among our sample of hypertensive patients, although their answers should not be attributed to a lack of understanding of the questions, since the retest reliability was remarkably satisfactory and non-adherence behavior was related to poor BP control.

The assessment of medication non-adherence in clinical practice is essential but still challenging, and patients' self-reports on medication-taking behavior – the most simple and inexpensive method to receive information on this issue – are often the only means available in routine practice settings, however, their accuracy and agreement with other data sources remain problematic, leading to a need for validity investigation. The original MMAS-8 was originally tested by Morisky et al,[22] and it was found that the scale was reliable with good concurrent and predictive validity in primarily low income patients with hypertension and

Table 3
Relationship between level of adherence and blood pressure control

Patient characteristics	Low adherers (<6)	Medium adherers (6 to <8)	High adherers (8)	*P*
Controlled blood pressure	127 (29.7)	107 (34.3)	109 (57.4)	0.003
Uncontrolled blood pressure	300 (70.3)	205 (65.7)	81 (42.6)	
Total	427	312	190	

Blood pressure in control: Systolic BP < 140 mm Hg, and Diastolic < 90 mm Hg.
Sensitivity = [(300 + 205)/(300 + 205+81)] × 100.
Specificity = [109/(127 + 107 + 109)] × 100.
PPV = [(300 + 205)/(300 + 205 + 127 + 107)] × 100.
PNV = [109/(109 + 81)] × 100.

significantly associated with blood pressure control. Other studies evaluated MMAS-8 translated versions in Thailand[36] and Malaysia.[37] The Malaysian and the Thai studies showed that MMAS-8 translated versions had acceptable internal consistency, good test–retest reliability and good convergent validity (with high correlations between the two Morisky scales). Validity among known groups was also confirmed in both studies. In the same way, the French MMAS-8 has shown acceptable psychometric effects to measure medication adherence in hypertensive patients.[38]

The overall Cronbach's alpha for the Portuguese MMAS-8 was found to be the same as those reported about the above mentioned versions whereas the original validation study reported a Cronbach's alpha 0.83. The value of alpha is based on the correlation between items and the number of items in a scale, with scales with fewer items tending to have lower alpha values,[39] but it is not believed that the smaller number of items and dichotomous answers explain our lower alpha value, in face of Morisky et al[22] results. Although it is recognized that some scales can have high alpha values, it may also make the scale more unstable. Moreover, as Moss et al[40] suggest, a low alpha value does not necessarily mean that the scale will not work well as a screening tool, where the aim is to assess nonadherent behavior, not to give a specific diagnosis. Additionally, retest reliability was high, confirming both the reliability of the test and the stability of the construct being measured.[41] This notably high value ($r = 0.928$) may be a consequence of the time slot for applying the second questionnaire. There is less chance that adherence rates be changed during a 2-week interval.

Validity among known groups was equally satisfactory. The Portuguese version of MMAS-8 was able to differentiate significantly between patients with controlled and uncontrolled blood pressure. Al-Qazaz et al[37] state that a valid instrument for measuring medication adherence must be able to differentiate between patients who are clinically different. In our study, patients who scored high on the adherence scale were more likely to have their blood pressure under control and a significant relationship between MMAS-8 levels of adherence and BP control was observed, as in the original study.[22]

Otherwise, the sensitivity and specificity were different from other studies. Despite relatively high sensitivity, specificity was very low, which would result in a high proportion of false-positives for non-adherence. One possible cause may be the different cultural and social aspects on reporting non-adherence to medication. Furthermore, in clinical practice, it may be more worthwhile to identify patients with non-adherent behavior (with both poor or high blood pressure control, since a sustained non-adherent behavior may lead to uncontrolled blood pressure) than adherent patients with controlled BP. Also, considering the potentially high proportion of false-non-adherers as a consequence of low specificity, the efforts to improve medication adherence usually do not lead to expensive or risk-related measures. To perform sensitivity and specificity analysis of the experimental data, all possible cut points were examined. Final cut points were chosen based on the relationship of MMAS-8 to blood pressure control, so that the medication adherence scale could provide useful information in a clinical setting (Table 3).

Potential confounding factors (e.g. age, sex, number of prescribed medications, educational level) did not influence medication adherence, in common with evidences which suggest that reported adherence is not strongly influenced by some patient characteristics.[19,42]

Limitations

In the absence of a definite gold-standard medication adherence scale,[43] the investigators did not perform convergent validity tests, although

convergent validity could have been accomplished with the translation of another valid and reliable adherence scale. Another possible limitation could be the Hawthorne Effect biasing patient answers, even patients were assured anonymity.

Conclusion

Psychometric evaluation confirmed the validity of the Portuguese version of the MMAS-8 in identifying hypertensive patients at risk of non-adherence, even among populations with high levels of illiteracy. The MMAS-8 still could be used in routine care to support communication about the medication-taking behavior.

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