

THE DEVELOPMENT AND VALIDATION OF THE MALAYSIAN MEDICATION ADHERENCE SCALE (MALMAS) ON PATIENTS WITH TYPE 2 DIABETES IN MALAYSIA

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ABSTRACT

Objective: Thus far, there is no gold standard for assessing medication adherence although various methods and assessment tools have been used. Therefore, the present study aimed to evaluate the reliability and validity of an assessment tool, the Malaysian Medication Adherence Scale (MALMAS).

Methods: The MALMAS consists of one domain with 8 items. The face and content validity of the MALMAS was established via an expert panel. The MALMAS was compared to the 8-item Morisky Medication Adherence Scale (MMAS-8). A total of 84 patients with type 2 diabetes were recruited from a teaching hospital and randomly allocated to answer either the MALMAS (43 respondents) or the MMAS-8 (41 respondents). A retest was conducted 4 weeks later on each group.

Results: Demographic and medical characteristics of participants who answered the MALMAS and MMAS-8 were similar. Reliability analysis of MALMAS produced a Cronbach's alpha value of 0.689 whereas that of the MMAS-8 was 0.504. All items in the MALMAS showed no significant difference in the test-retest analysis, indicating that the MALMAS has achieved stable reliability. There was no difference in psychometric properties of the MALMAS and the MMAS-8. In addition, MALMAS produced similar non-adherence rate as the MMAS-8 (34.9% and 36.6%, respectively; $p=0.871$). The MALMAS also produced similar results to that obtained from two questions posed via face-to-face interview on medication adherence and the reason(s) for non-adherence ($p=0.625$ and 0.486 , respectively).

Conclusion: The 8-item MALMAS developed in this study is a reliable and valid instrument for assessing medication adherence.

Keywords: Medication adherence, Reliability, Validation, MALMAS, MMAS.

INTRODUCTION

According to the World Health Organization (WHO), medication adherence is defined as: "The extent to which a person's behaviour - taking medication, following a diet and/ or executing lifestyle changes, corresponds with agreed recommendations from a health care provider" [1]. Generally, only 50% of patients on long term therapy for chronic diseases adhere to their medications in developed countries, and this could be lower in developing countries [1].

Two systematic reviews on medication adherence of patients with type 2 diabetes reported adherence rates of 30% to 93% to oral hypoglycemic agents, depending on the definitions used, methods of assessment, duration of assessment, treatment regimens and number of medications [2, 3]. In developed countries such as the United States, approximately 50% of patients treated for hypertension adhered to their prescribed regimens [4]. Adherence to antihypertensive regimens has been reported to be lower in countries such as China (46%) and Gambia (27%) [1]. Poor adherence to medications not only limits treatment efficacy and increases healthcare costs [5-8], it also increases morbidity and mortality rates [9].

Non-adherence to medications remains an unresolved healthcare problem especially among patients with chronic diseases. Studies have implicated that medication non-adherence is a persistent concern for all health professionals [10, 11]. Chronic diseases, such as diabetes are associated with complex medication regimens which are necessary for the effective management of the disease [12]. Barriers to optimal medication adherence include costs [13], complexity of regimens [14], unclear physician instructions [15-17] and adverse effects [18].

Potential predictors of medication adherence may be classified into three main categories: (1) patient factors, (2) medication factors and (3) health care system factors [3]. Demographic and behavioral

characteristics of patients, patients' awareness and knowledge regarding their medications and diseases, complexity of treatment regimens and side effects of medications as well as convenience and cost of healthcare system are examples of multiple factors which may affect patients' medication adherence [6, 19-24]

Various methods and assessment tools have been used to evaluate medication adherence. Nonetheless, each method has its advantages and disadvantages [25]. To date, no gold standards have been set for assessing medication adherence [1, 26]. Methods available for assessing medication adherence can be categorized into direct methods (which include directly observed therapy or measurement of blood levels of medicine / metabolite / biomarker) and indirect methods (which include patient self-reports, patient diaries, pill counts, rate of prescription refills, assessment of patient's clinical response and electronic medication monitors). A review of current literature revealed that one of the most commonly used tool for assessing medication adherence is the Morisky, Green and Levine Scale [27]. This tool was originally developed as a 4-item scale [27, 28]. Following further development, the scale was improved to its present 8-item measure, MMAS-8 [22, 29].

However, the MMAS-8 does not specify the duration of adherence that the patient is expected to recall since it is an integral scale conceptualized as a behavioral measure of medication adherence. Only items 2 and 5 of the MMAS-8 specify a recall period of "2 weeks" and "yesterday", respectively. Lu and colleagues [30] stated that self-reported medication adherence varied with regards to the recall period, and that the optimal recall period was one month [30]. It was therefore hypothesized that it would be easier for patients to comprehend if a recall period was specified in the medication adherence questionnaire. This led to the development of the Malaysian Medication Adherence Scale (MALMAS), where 6 out of the 8 items specify a recall period (5 items investigate the "past one month" and one item investigates "yesterday"). Therefore, this study

aimed to evaluate the reliability and validity of the English version of the MALMAS on patients with type 2 diabetes in Malaysia

METHODS

The MALMAS was developed with reference to the 9-item Morisky Medication Adherence Scale, MMAS-9 [31]. The MALMAS consists of one domain with 8 items. The first item has 5 answers: (1) All the time, (2) Often (> 15 but less than 1 month), (3) Sometimes (6 - 15 times), (4) Rarely (1 - 5 times) and (5) Never. These responses were scored according to that used by the MMAS-8 [22]. The other seven items were given a dichotomous response of "Yes" or "No".

To assess convergent validity, the MALMAS was compared with the previously validated MMAS-8 [22] as MMAS-9 had not been subjected to psychometric assessment. The total score of the MALMAS and the MMAS-8 ranged from 0 to 8. Medication adherence of both instruments was trichotomised into three levels of adherence: high adherence (total score=8), medium adherence (6 to < 8) and low adherence (<6) [22, 29].

Participants

Patients with type 2 diabetes who were on at least one anti-diabetic medication and able to communicate in English were recruited. Excluded were those less than 21 years of age, not taking any medication for diabetes, had severe health problems or cognitive impairments. Patients were randomly allocated using a random table [32] to answer either the MALMAS or the MMAS-8 twice: at baseline and at 4 weeks later.

In addition, all participants were asked the following two questions via a face-to-face interview by a researcher: (1) "During the past one month, was there any time that you were not able to take your medicines according to the instructions given?" and (2) "During the past one month, what were the reasons(s) that you could not take your medicines according to the instructions given?". The answer to question (1) was either a "yes" or a "no" whereas any participant who provided a reason for not following the instructions given in question (2) was considered as non-adherent. Vik and colleagues also used similar questions on the reason(s) for non-adherence to assess the construct validity of the MMAS-8 [25].

Sample size

Most validation studies used the number of items multiplied by 5 to calculate the sample size needed [33]. Therefore, for this study, a total of at least 40 (8 x 5) participants were required.

Procedure

The face and content validity of the MALMAS instrument was established by a team of 12 experienced pharmacists and researchers. This instrument was then piloted on five patients in a teaching hospital to obtain their feedback on the clarity of the instrument.

Patients were recruited from the diabetes and primary care clinics of a teaching hospital in Kuala Lumpur, Malaysia. A researcher explained the aim and study procedure to potential participants. Written informed consent was obtained and baseline information such as demographic data, medical and medication history were gathered. Participants completed either the MALMAS or MMAS-8 by themselves, which took approximately 5-10 minutes. The completed instrument was checked by the researcher to ensure that all questions were answered. The instrument was administered again to the same group of participants 4 weeks later. This study was approved by the Medical Ethics Committee of the teaching hospital under study.

Statistical analysis

All data were entered and analysed using the Statistical Package for Social Sciences (SPSS) version 16 (SPSS Inc., Chicago, IL). Descriptive statistics were presented as percentage and frequencies, while means and standard deviations were calculated for continuous variables. Associations between categorical variables were analysed using chi square (χ^2) tests while t-tests were used for continuous variables.

Internal consistency of the MALMAS and MMAS-8 was determined using Cronbach's alpha values. A Cronbach's alpha value of more than 0.5 is considered as acceptable [34]. Cronbach's alpha values of 0.70 - 0.90 are considered as having strong internal consistency [35] while Cronbach's alpha values >0.90 indicate a high level of item redundancy [34, 36]. If deleting an item increases Cronbach's alpha significantly, then excluding the item will increase the homogeneity of the scale [34]. Corrected item-total correlations refer to the extent to which each item in the instrument is correlated to the total score. Corrected item-total correlations should exceed 0.2 to be considered as acceptable [36]. Lower values of item-total correlations indicate that the item is measuring some different construct from that of the whole instrument [34, 37].

The Shapiro-Wilk test was used to determine if data were normally distributed. Test-retest reliability was assessed using Wilcoxon Signed Ranks test, McNemar test and Spearman's rho. Correlations were interpreted as followed: little or no correlation (0 - 0.25), fair correlation (0.25 - 0.5), moderate to good correlation (0.5 - 0.75) and very good to excellent correlation (> 0.75) [38]. Construct validity was assessed using chi-square test (for proportions of participants who were adherent to their medications) and Mann-Whitney U test (for the total adherence scores), when the results of the MALMAS were compared with that of the MMAS-8. In addition, the MALMAS was compared with the two questions via a face-to-face interview on medication adherence and also the reason(s) for non-adherence using the McNemar test. A p value of < 0.05 was considered as statistically significant.

RESULTS

A total of 84 participants were recruited in this study: MALMAS group = 43, MMAS-8 group = 41. No significant difference in demographic and medical data was observed between the two groups (Table 1).

Psychometric properties of the MALMAS

Reliability analysis

The Cronbach's alpha coefficients for the MALMAS and MMAS-8 were 0.689 and 0.504, respectively; which are considered as acceptable, indicating that these instruments have good internal consistency. However, if item 7 in the MALMAS was excluded, the Cronbach's alpha increased to 0.711 (Table 2). The exclusion of item 5 in the MMAS-8 also increased its Cronbach's alpha to 0.613 (Table 2). The item-total correlations for most items in the MALMAS except for item 7 exceeded 0.2 [22] while 3 out of 7 items in the MMAS-8 (items no. 3, 5 and 7) have item-total correlations of less than 0.2 (Table 2).

Using the McNemar's test for dichotomous variables and Wilcoxon Signed Ranks test for Likert-like responses in the MALMAS and the MMAS-8, all the 8 items showed stable reliability ($p > 0.05$) [Table 2]. In addition, the total scores between the test-retest for both the MALMAS and the MMAS-8 were also not significantly different (Table 2).

The total scores of the test-retest were compared using Spearman's correlation coefficient. The Spearman's rho for MALMAS was 0.713 ($p < 0.001$), indicating moderate to good correlation. For the MMAS-8, the Spearman's rho was 0.465 ($p = 0.007$), indicating fair correlation between the first and second tests.

Construct validity

The MALMAS was compared with the MMAS-8 (Table 3). Since the adherence scores did not fulfill normal distribution requirements using the Shapiro-Wilk test (MALMAS: $p < 0.001$ and MMAS-8: $p = 0.003$), the median scores of the MALMAS and the MMAS-8 were compared using the Mann-Whitney U test.

The results obtained with the MALMAS were grouped as high/moderate adherence and low adherence. Using the McNemar test, no significant difference was found between the results obtained with the MALMAS and that with questions (1) and (2) [Table 4].

Table 1: Demographic and medical data of participants

| Demographic and medical data | MALMAS [Frequency (%)] (N=43) | MMAS-8 ^c [Frequency (%)] (N=41) | χ^2 / z value ^b | p-value |
|---|-------------------------------------|--|---------------------------------|---------|
| Age | 61.9 (9.1) | 64.7 (9.6) | -1.446 ^b | 0.148 |
| Mean age in years (SD) ^a [Median] | [62.0] | [65.0] | | |
| Gender | 24 (55.8) | 22 (53.7) | 0.039 | 0.843 |
| Male | 19 (44.2) | 19 (46.3) | | |
| Female | | | | |
| Ethnic group | 8 (19.5) | 4 (9.8) | 2.283 | 0.319 |
| Malay | 13 (31.7) | 11 (26.8) | | |
| Chinese | 20 (19.5) | 26 (63.4) | | |
| Indian | | | | |
| Working status | 13 (30.2) | 9 (22.0) | 0.745 | 0.388 |
| Working | 30 (69.8) | 32 (78.0) | | |
| Not working | | | | |
| Education level | 21 (48.8) | 20 (48.8) | 2.865 | 0.239 |
| Primary and secondary | 13 (30.2) | 7 (17.1) | | |
| Diploma / Technical | 9 (20.9) | 14 (34.1) | | |
| Tertiary | | | | |
| Duration of diabetes | 15.8 (9.4) | 17.4 (10.8) | -0.481 ^b | 0.630 |
| Mean duration in years (SD) [Median] | [13.5] | [16.0] | | |

^aSD = Standard deviation

^bz value obtained using the Mann-Whitney U test

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Table 2: Reliability analysis of the MALMAS and the MMAS-8

| Item number | Corrected item - Total correlations | | Cronbach's alpha if item deleted | | Test Retest reliability McNemar test / Wilcoxon Signed Ranks test ^a P value | |
|-------------------------------|-------------------------------------|---------------------|----------------------------------|--------------------|---|---------------------------------|
| | MALMAS (n=43) | MMAS-8 (N=41) | MALMAS (N=43) | MMAS-8 (N=41) | MALMAS (N=37) | MMAS-8 (N=32) |
| 1 for MALMAS and 8 for MMAS-8 | 0.657 | 0.291 | 0.650 | 0.445 | 0.763 (-0.302 ^a) | 0.059 (-1.890 ^a) |
| 2 | 0.618 | 0.537 | 0.586 | 0.304 | 1.000 | 1.000 |
| 3 | 0.404 | 0.127 ^b | 0.655 | 0.504 | 0.727 | 1.000 |
| 4 | 0.331 | 0.427 | 0.673 | 0.381 | 1.000 | 1.000 |
| 5 | 0.209 | -0.162 ^b | 0.690 | 0.613 ^c | 1.000 | 1.000 |
| 6 | 0.420 | NA | 0.656 | NA | 0.500 | NA |
| 7 | 0.041 ^b | 0.186 ^b | 0.711 ^c | 0.495 | 1.000 | 0.453 |
| 8 for MALMAS and 1 for MMAS-8 | 0.544 | 0.475 | 0.613 | 0.423 | 0.453 | 0.227 |
| Total Score | | | | | 0.701 (-0.384 ^a) | 0.404 (-0.835 ^a) |

^az value obtained from Wilcoxon Signed Ranks test

^bCorrected item-total correlations < 0.2

^cIncrease in Cronbach's alpha value if item was deleted

Table 3: Comparison between MALMAS and MMAS-8

| Adherence status | MALMAS [Frequency (%)] | MMAS-8 [Frequency (%)] | χ^2 / z value | P value |
|---|---------------------------|------------------------------|---------------------|---------|
| High adherence (scores = 8) | 15 (34.9) | 8 (19.5) | 2.891 | 0.236 |
| Medium adherence (6 to < 8) | 13 (30.2) | 18 (43.4) | | |
| Low adherence (0 to < 6) | 15 (34.9) | 15 (36.6) | | |
| Absolute adherence (scores = 8) | 15 (34.9) | 8 (19.5) | 2.494 | 0.114 |
| Non adherence (scores < 8) | 28 (65.1) | 33 (80.5) | | |
| High and moderate adherence (scores = 6 - 8) | 28 (65.1) | 26 (63.4) | 0.026 | 0.871 |
| Low adherence (scores < 6) | 15 (34.9) | 15 (36.6) | | |
| Mean total scores (SD) ^a [Median] | 6.5 (1.6) [6.7] | 6.4 (1.3) [7.0] | -0.581 ^b | 0.561 |

^aSD = Standard deviation

^bz value obtained using the Mann-Whitney U test

Table 4: Comparison of the MALMAS with two questions asked by the researcher

| Assessment method | Frequency (%) | McNemar Test P value |
|---|---------------|----------------------|
| MALMAS (N = 43) | 28 (65.1) | |
| High/moderate adherence | 15 (34.9) | |
| Low adherence | | |
| (1) "During the past one month, was there any time that you were not able to take your medicines according to the instructions given?" (N = 37) | 23 (62.2) | 0.625 |
| No (Adherence) | 14 (37.8) | |
| Yes (Non-adherence) | | |
| (2) "During the past one month, what were the reasons(s) that you could not take your medicines according to the instructions given?" (N = 43) | 20 (46.5) | 0.486 |
| No reasons provided (Adherence) | 23 (53.5) | |
| Reasons for non-adherence provided (Non-adherence) | | |

DISCUSSION

The study showed that the MALMAS is a reliable and valid instrument for assessing medication adherence. The psychometric properties of the MALMAS were similar to that of the validated MMAS-8. Both the MALMAS and the MMAS-8 produced Cronbach's alpha coefficients of above 0.5 but below 0.7 which are considered as acceptable [34]. The Cronbach's alpha value for the MMAS-8 in this study was lower than that reported by other studies [22]. This may be due to the smaller sample size in this study, which tends to affect the Cronbach's alpha [34, 39]. In addition, the value of Cronbach's alpha is affected by the small number of items and the use of binary response options (yes/no) [34, 39].

The Cronbach's alpha coefficient of the MALMAS was increased to 0.711 if item 7 was excluded from the instrument. However, this item was retained in the MALMAS as the total number of items in this instrument was small to begin with and a Cronbach's alpha coefficient of 0.689 is still acceptable.

Both the MALMAS and the MMAS-8 showed stable reliability. MMAS-8 is an established validated instrument commonly used for assessing medication adherence. The prevalence of medication non-adherence obtained using the MALMAS was very similar to that using the MMAS-8 (34.6% and 36.6%, respectively, $p = 0.871$). These results are comparable to that of other studies which used the MMAS-8 [22, 39]. In addition, the MALMAS produced similar overall results to that obtained via a question posed by an experienced researcher to assess medication adherence (non-adherence rate of 37.8% with the latter). However, when the participants were questioned about the reason(s) for non-adherence, a higher rate of non-adherence (53.5%) was obtained. This implies that the use of self-filled questionnaire may underestimate the prevalence of non-adherence to medications.

One of the limitations of the study was the small sample size. In addition, the recall period in MALMAS was set at one-month and hence inaccuracy in recall could not be ruled out. Another limitation of the MALMAS was that it was only developed and validated in English hence, only patients who understand this language could be included in the study. However, Malaysia is a multiracial society with three main ethnic groups: Malays, Chinese and Indians. Therefore, further studies to translate and validate the Malay, Mandarin and Tamil versions of the MALMAS should be conducted so that medication adherence studies in Malaysia will be more representative of its multiethnic population.

CONCLUSIONS

The study demonstrates that the MALMAS possesses internal consistency and stable reliability. The psychometric properties of the MALMAS are also similar to the validated MMAS-8. Therefore, the MALMAS is a reliable and valid instrument and can be used for assessing medication adherence of type 2 diabetes patients in Malaysia.

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