Original article

Translation and validation of the Arabic version of the General Medication Adherence Scale (GMAS) in Saudi patients with chronic illnesses

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Abstract

Purpose: The study aimed to translate and validate the Arabic version of General Medication Adherence Scale (GMAS) in Saudi patients with chronic diseases.

Methods: A multi-center cross sectional study was conducted for a month in out-patient wards of hospitals in Khobar, Dammam, Makkah, and Madinah, Saudi Arabia. Patients were randomly selected from a registered patient pools at hospitals and the item-subject ratio was kept at 1:20. The tool was assessed for factorial, construct, convergent, known group and predictive validities as well as, reliability and internal consistency of scale were also evaluated. Sensitivity, specificity, and accuracy were also evaluated. Data were analyzed using SPSS v24 and MedCalc v19.2. The study was approved by concerned ethics committees (IRB-129-25/6/1439) and (IRB-2019-05-002).

Results: A total of 282 responses were received. The values for normed fit index (NFI), comparative fit index (CFI), Tucker Lewis index (TLI) and incremental fit index (IFI) were 0.960, 0.979, 0.954 and 0.980. All values were >0.95. The value for root mean square error of approximation (RMSEA) was 0.059, i.e., <0.06. Hence, factorial validity was established. The average factor loading of the scale was 0.725, i.e., >0.7, that established convergent validity. Known group validity was established by obtaining significant p-value <0.05, for the associations based on hypotheses. Cronbach’s α was 0.865, i.e., >0.7. Predictive validity was established by evaluating odds ratios (OR) of demographic factors with adherence score using logistic regression. Sensitivity was 78.16%, specificity was 76.85% and, accuracy of the tool was 77.66%, i.e., >70%.

Conclusion: The Arabic version of GMAS achieved all required statistical parameters and was validated in Saudi patients with chronic diseases.

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1. Introduction

Chronic diseases are physical or mental illnesses that limit patients’ daily activities and last for a year or more requiring continuous medical treatment (Center for Disease Control and Prevention, 2019; Naqvi et al., 2018). In the United States (US), 60% of the adults suffered from chronic diseases such as heart disease, cancer, and diabetes, and 42% had multiple chronic diseases.
in 2014 (Raghupathi and Raghupathi, 2018). Chronic diseases have significant mortality and economic burden that increases healthcare expenditure globally. Evidence highlighted that yearly healthcare expenditure on heart disease and stroke amounted to USD 199 billion (Benjamin et al., 2018). Besides, healthcare cost attributed to diabetes was USD 237 billion (American Diabetes Association, 2018).

In Saudi Arabia, there were about 114,000 premature deaths in 2016 that were attributed to chronic diseases (World Health Organization (WHO), 2018). Data from Institute of Health Metrics and Evaluation (IHME) mentions non-communicable diseases as the most common cause of deaths, premature deaths, disabilities as well as, death and disability combined. Seven out of top ten causes of deaths were non-communicable illnesses. Of total deaths reported in the country, 67.21% were attributed to chronic diseases. 85.57% of years lived with disabilities (YLDs) and 72.2% of disease adjusted life years (DALYs) were attributed to such illnesses. All figures were reported per 100,000 (IHME, 2017).

Adherence could be described as the degree to which a person’s medicine taking behavior, dietary habits and/or implementation of lifestyle changes relate to agreed recommendations from his/her health care provider (WHO, 2003). Non-adherence to prescribed medication remains a major problem and has negative impact on patients’ treatment goals, especially among those suffering from chronic diseases (Haynes et al., 2008), where, the rate of non-adherence to medication among patients with chronic diseases in the Middle East was estimated to be between 1.4–88% (Al-Qasem et al., 2011). Within Saudi Arabia, a study conducted among a large patient cohort in Riyadh reported that 42.8% had poor adherence to oral antidiabetic medications (Balkhi et al., 2019). In two studies conducted in Khobar, unsatisfactory adherence in over 40% of out-patients with type 2 diabetes was reported (AlQarni et al., 2019; AlShayban et al., 2020). Poor adherence was also reported among hypertensive patients (55%) (Shaik et al., 2016).

Many studies have been conducted to assess medication adherence among Saudi patients (Balkhi et al., 2019; AlQarni et al., 2019; AlShayban et al., 2020). A novel scale termed as the General Medication Adherence Scale (GMAS) was developed and validated in Urdu and English languages in Pakistan; a country with similar culture as Saudi Arabia (Naqvi et al., 2018, 2019a). The English version of the scale has already been validated in Saudi patients (Naqvi et al., 2019b). However, an Arabic version of the scale is needed to document adherence to medications from a representative population. Moreover, this would be beneficial to other countries in the Middle East and North Africa (MENA) region where Arabic is spoken as first language. The aim of this study was to translate and validate the Arabic version of GMAS among Saudi patients with chronic diseases.

2. Methods

2.1. Study participants and eligibility

Adult male and female Saudi out-patients above age of 18 years who had a confirmed diagnosis of a chronic disease, with or without co-morbidities, on long-term therapy during implementation phase of adherence, for at least a month before study, were invited to participate in the study. The implementation phase of adherence is the stage in which the patient continues to take medications from the time of the first dose until the last one (Dowrick et al., 2005; Vrijens, 2012; Naqvi et al., 2020).

Patients with acute illnesses, planned surgery and pregnancy were excluded. Besides, patients who met the criteria but had a disease resulted complication that required immediate medical attention were also not included. In addition, patients not meeting the above criteria and/or those who did not consent to participate were left out. Patients who were excluded from study were provided with normal hospital care.

2.2. Randomization and patient recruitment

The study was conducted in OPD during hospital timings and randomization was conducted from the pool of registered patients who were scheduled for appointment. Simple randomization was conducted based on patients’ medical record number (MRN) via computer generated list. The patients selected for invitation through randomization were directly approached and were invited to participate in the study.

2.3. Sampling size calculation

Since the study was based on statistical validation, the sample size was calculated based on item-subject ratio. Based on available literature, a ratio of 1:5 up to 1:20 could be used for such studies (Osborne and Costello, 2004). We selected the maximum ratio of 1:20 based on methodology of study that validated the English version of GMAS in this population (Naqvi et al., 2019b). Henceforth, a ratio of 1:20 implied that a sample of 220 patients was needed. In addition, a drop-out rate of 25% was considered that resulted in a final required sample of 275 patients.

2.4. Research instrument and its Arabic translation

The GMAS is an 11-item self-reporting adherence measure. Each item has 4 outcomes and awards an adherence score. The total score that could be achieved is 33. Sum of all items yields a final score that is interpreted in various levels of adherence; high (30–33), good (27–29), partial (17–26), low (11–16), and poor (≤10) (Naqvi et al., 2018, 2019a). The scale was originally developed in Urdu language and validated (Naqvi et al., 2018). Recently, the English version of the scale was validated in English speaking Saudi patients (Naqvi et al., 2019b). However, an Arabic version would be required to document adherence from a representative Saudi population.

The translation of the scale was conducted according to the standard process for translation and cross-culture adaptation of questionnaires (Beaton et al., 2000; Wild et al., 2005). At first, the tool was forward translated by two health experts with knowledge of the field and familiarity with the topic. The experts were native Arabic speakers who spoke English as a second language. Both were not aware of each other. Thus, two Arabic versions of GMAS were prepared at this point. An expert panel was formed at this point consisting of two pharmacists, two academicians, a physician, and an Arabic linguist. All were native Arabic speakers who spoke English as second language. The two versions were presented to the panel and were reviewed for conceptual and cultural equivalence, language, and ease of understanding of questions for patients. The two versions were reconciled, and a single final Arabic version of scale was formulated at this stage.

An independent reviewer was appointed by the expert panel who was a native English speaker with Arabic language competence to carry out back-translation of the instrument. A back-translated instrument was prepared and subsequently reviewed by expert panel. Any disagreements in both forward and back
translated versions were resolved at this stage. The final Arabic version of the scale was piloted in 8 patients to check for any difficulty in understanding of language and concepts. No difficulty was reported and the Arabic version of GMAS was deemed satisfactory at this point.

2.5. Factorial validity

Factorial validity was assessed by partial confirmatory factor analysis (PCFA) resultant calculation of fit indices namely, normed fit index (NFI), comparative fit index (CFI), Tucker Lewis index (TLI), incremental fit index (IFI) and root mean square error of approximation (RMSEA). A value > 0.95 for NFI, CFI, TLI and IFI were considered acceptable whereas a value <0.06 for RMSEA was considered acceptable (Zwick and Velicer, 1986; Pett et al., 2003). Attainment of acceptable values for all indices established the factorial validity of scale (Shima et al., 2015).

2.6. Convergent validity

The convergent validity was established if the value for average factor loadings was ≥0.7 (Cronbach and Meehl, 1955).

2.7. Construct validity

The construct validity of the scale was assessed by correlating the adherence score with pill burden, i.e., number of medicines prescribed. Spearman’s rank correlation (\(\rho\)) was used to assess the relationship. The construct validity was established if there was a correlation, i.e., \(\rho \geq 0.3\) with p-value < 0.05 (De Vellis, 1991; Strauss and Smith, 2009; Salt et al., 2012).

2.8. Known group validity

Based on previous findings, it was hypothesized that patients with better employment status and monthly family income were more likely to be adherent (AlShayban et al., 2020; Alqarni, 2019). This hypothesis was tested as a proxy for known group validity. This was assessed through cross-tabulation of dichotomous adherence categories obtained from adherence scores, with demographic variables of monthly family income and employment status. The dichotomous categories were adherent, i.e., GMAS score ≥27, and non-adherent, i.e., GMAS score <26. A significant chi square (\(\chi^2\)) test with p-value < 0.05 established known group validity (Cohen, 1988; De Vellis, 1991; Kurlander et al., 2009; Iuga and McGuire, 2014).

2.9. Reliability and internal consistency

The reliability of the scale was assessed by Cronbach’s alpha (\(\alpha\)) value. A value of \(\alpha \geq 0.7\) was considered acceptable reliability. Further to this, internal consistency was estimated through item-total correlation (ITC) and intra-class correlation (ICC). ITC and ICC were acceptable if their values were > 0.2 (Cohen, 1988; De Vellis, 1991).

2.10. Predictive validity

It was assessed through a multivariate logistic regression model to evaluate determinants of medication adherence. The model was adjusted for patients’ demographic variables. Available evidence highlighted that monthly family income and comorbidity status were linked to adherence (Alqarni et al., 2019; AlShayban et al., 2020). In addition, we tested other demographic and related variables in the model. Predictive validity was established if there was a significant association (p < 0.05) between a variable and adherence, with a meaningful odds ratio (Morisky et al., 2008).

2.11. Sensitivity, specificity, and accuracy

The Arabic version of GMAS was evaluated for its sensitivity, specificity and accuracy in screening patients based on self-reported adherence.

2.12. Data analyses

The data were analyzed through SPSS version 24 (Armonk, NY). Analyses for evaluating sensitivity, specificity, and accuracy were conducted using MedCalc version 19.2. Descriptive statistics such as mean, median and standard deviation (SD) were used to report continuous data while categorical data were reported in sample count (N) and frequency (%). Statistical significance was considered at p-value < 0.05. Data pertaining to sensitivity, specificity, accuracy and regression analysis were also expressed in 95% confidence intervals.

2.13. Ethics approval and patient consent

The study was approved by Institutional Review Board, General Directorate of Health Affairs, Ministry of Health, Saudi Arabia (IRB-129-25/6/1439) and Institutional Review Board of Imam Abdulrahman Bin Faisal University, Dammam, Saudi Arabia (IRB-2019-05-002). All patients were invited and were provided a briefing about the study and its objectives. The participation was voluntary, and patients were informed that their decision would not affect the standard of hospital care they are entitled to receive. Those who agreed to participate were asked to sign a written informed consent.

3. Results

3.1. Demographic information

A total of 282 patients provided their response and the mean age of participants was 43.1 ± 15.8 years. Most patients were females (N = 156, 55.3%), married (N = 210, 74.5%) and graduates (N = 162, 57.4%). The majority of patients were employed (N = 106, 37.6), had a monthly family income above SAR 10,000 (N = 160, 56.7%) and, obtained medicines through governmental coverage (N = 128, 45.4%) (Table 1). Most patients had no comorbidity (N = 180, 63.8%). Hypertension (HTN) was most common illness (N = 42, 14.9%) followed by diabetes mellitus (DM) (N = 34, 12.1%). Half of patients had 1 medicine prescribed (Table 2).

3.2. Medication adherence information

The median score for medication adherence was 28. Most patients had high adherence (N = 120, 42.6%) while 19.1% (N = 54) had good adherence. Slightly more than a third (N = 92, 32.6%) were partially adherent. Some patients (N = 12, 4.3%) had low adherence and few (N = 4, 1.4%) had poor adherence. The responses of patients for each item of the scale is tabulated in Table 3.

3.3. Factorial validity

PCFA with Maximum Likelihood Analysis (MLA) using Varimax rotation was conducted and factor number was fixed at 3 based on previous validation results of the scale (Naqvi et al., 2018, 2019a, 2019b). The Kaiser-Mayer Ollkin (KMO) measure of sampling adequacy was 0.870, i.e., >0.7 with significant Bartlett’s test of sphericity, i.e., p < 0.01. The null model \(\chi^2\) value was reported at 1237.888.
and df was 55. The implied model $\chi^2$ value was reported at 49.651 and df was 25. Based on these values fit indices were calculated. The values for NFI, CFI, TLI and IFI were 0.960, 0.979, 0.954 and 0.980. All values were > 0.95. The value for RMSEA was 0.059, i.e., <0.06. A satisfactory attainment of all these values in recommended range established factorial validity of GMAS-AR.

3.4. Convergent validity

The average factor loading of the scale was 0.725, i.e., >0.7. Hence, convergent validity was established.

3.5. Construct validity

The correlation coefficient $r$ was 0.388 with p < 0.001. Hence, construct validity was established.

3.6. Known group validity

A significant association ($\chi^2 = 17.108$, p < 0.01) existed between adherence status and employment status. The Cramer’s V value of 0.25 indicated moderate association and no cell had expected count < 5. Therefore, the results were reliable. It implied that patients who were unemployed tended to be non-adherent. Furthermore, there was a significant association ($\chi^2 = 38.824$, p < 0.01) between adherence category and monthly family income. The Cramer’s V value of 0.34 indicated moderate association and no cell had expected count < 5. Therefore, the results were reliable. It implied that patients with a higher monthly family income tended to be adherent. Thus, the hypothesis was true and known group validity was established (Table 4).

3.7. Reliability and internal consistency

The value for Cronbach’s $\alpha$ was 0.865 for all 3 constructs containing 11 items, i.e., >0.7. All items were positively correlated with minimum correlation coefficient value >0.062 while ICC was reported at 0.862 (95% CI: 0.837–0.885). The Cronbach’s $\alpha$ values were 0.773, 0.723 and 0.641 for all three individual constructs, respectively. The data pertaining to reliability and internal consistency of all three constructs of the scale are tabulated in Table 5.

3.8. Predictive validity

A multivariate logistic regression model was developed while adjusting for variables namely age, gender, marital status, education, occupation, monthly family income, medical insurance and comorbidity, to evaluate determinants of medication adherence. All variables were first evaluated using univariate analysis and the significant ones i.e., all except variables of gender and educa-

### Table 1
Participants’ information.

| Demographic information | N  | %   |
|-------------------------|----|-----|
| Gender                  |    |     |
| Male                    | 126| 44.7|
| Female                  | 156| 55.3|
| Marital status          |    |     |
| Married                 | 210| 74.5|
| Single                  | 72 | 25.5|
| Level of education      |    |     |
| Primary education       | 28 | 9.9 |
| High school             | 92 | 32.6|
| Graduate                | 162| 57.4|
| Employment status       |    |     |
| Employed                | 106| 37.6|
| Retired                 | 74 | 26.2|
| Unemployed              | 42 | 14.9|
| Household               | 60 | 21.3|
| Monthly family income   |    |     |
| Less than SAR 5000      | 44 | 15.6|
| 10,000–2660.88         | 78 | 27.7|
| More than SAR 10,000    | 160| 56.7|
| Mode of obtaining medicines |     |
| Governmental coverage   | 128| 45.4|
| Private insurance       | 102| 36.2|
| Out of pocket           | 24 | 8.5 |
| More than one mode      | 28 | 9.9 |

SAR = Saudi Arabian Riyal, USD = United States Dollar.

### Table 2
Participant’s medical information.

| Participants’ medical information | N  | %   |
|-----------------------------------|----|-----|
| Comorbidity                       |    |     |
| Yes                               | 102| 36.2|
| No                                | 180| 63.8|
| Illness                           |    |     |
| Hypertension (HTN)                | 42 | 14.9|
| Diabetes mellitus (DM)            | 34 | 12.1|
| Dyslipidemia                      | 10 | 3.5 |
| Thyroid disorders (Hypo/Hyperthyroidism) | 12 | 4.3 |
| Pulmonary diseases (COPD, Asthma) | 44 | 15.6|
| Various forms of arthritis (Rheumatoid, osteo, gouty, psoriatic) | 22 | 7.8 |
| HTN, DM and dyslipidemia          | 20 | 7.1 |
| DM and HTN                        | 26 | 9.2 |
| HTN, dyslipidemia and arthrythmia | 4  | 1.4 |
| HTN, dyslipidemia and asthma      | 2  | 0.7 |
| Other illnesses (IBS, IBD, arthrythmia, IHD, SCA, IDA, etc.) | 66 | 23.4 |
| Number of medicines prescribed    |    |     |
| 1                                 | 142| 50.4|
| 2                                 | 70 | 24.8|
| 3                                 | 38 | 13.5|
| 4 or more                         | 32 | 11.3|

### Table 3
Medication adherence information.

| GMAS items Brief item description | Participants’ response (%) |
|-----------------------------------|---------------------------|
|                                  | Always | Mostly | Sometimes | Never |
| 1 Difficult to remember taking medications | 2.8  | 8.5  | 27.7  | 61  |
| 2 Forgetfulness in taking medicines due to events, schedules, and travel | 5  | 9.2  | 41.8  | 44  |
| 3 Discontinuation of medicines when patient feels well | 12.1 | 11.3 | 19.9  | 56.7|
| 4 Stops medicines when experiences an adverse effect | 12.8 | 11.3 | 29.8  | 46.1|
| 5 Stops medicines without prior intimation to the doctor | 9.9  | 8.5  | 24.1  | 57.4|
| 6 Discontinuation of medication therapy due to medicines for additional disease | 4.3  | 5.7  | 22.7  | 67.4|
| 7 Hassle to remember medicines due to regime complexity | 6.4  | 8.5  | 25.5  | 59.6|
| 8 Missing medicines due to disease progression and/or addition of new medicines | 2.1  | 2.8  | 15.6  | 79.4|
| 9 Altering medication regimen in any sense | 3.5  | 6.4  | 22   | 68.1|
| 10 Medicines deemed as unworthy of money spent and discontinued | 2.8  | 3.5  | 9.9   | 83.7|
| 11 Difficult to buy costly medicines | 2.1  | 7.1  | 15.6  | 75.2|
Cross-tabulation of adherence status and demographic variables.

| Demographic variables | Adherence status | Non-adherent (≥26) |
|-----------------------|------------------|-------------------|
| **Employment status** |                  |                   |
| Employed              | Count (Expected count) | 62 (65.4) | 44 (40.6) |
|                       | % within Occupation   | 58.5% | 41.5% |
|                       | % within Adherence status | 35.6% | 40.7% |
| Retired               | Count (Expected count) | 56 (45.7) | 18 (28.3) |
|                       | % within Occupation   | 75.7% | 24.3% |
|                       | % within Adherence status | 32.2% | 16.7% |
| Unemployed            | Count (Expected count) | 16 (25.9) | 26 (16.1) |
|                       | % within Occupation   | 38.1% | 61.9% |
|                       | % within Adherence status | 9.2% | 24.1% |
| Household             | Count (Expected count) | 40 (37) | 20 (23) |
|                       | % within Occupation   | 66.7% | 33.3% |
|                       | % within Adherence status | 23.0% | 18.5% |
| **Monthly income**    |                  |                   |
| Less than SAR 5000, i.e., USD < 1330.44 | Count (Expected count) | 12 (27.1) | 32 (16.9) |
|                       | % within income       | 27.3% | 72.7% |
|                       | % within Adherence status | 6.9% | 93.1% |
| SAR 5000 – 10000, i.e., USD 1330.44 – 2660.88 | Count (Expected count) | 44 (48.1) | 34 (29.9) |
|                       | % within income       | 56.4% | 43.6% |
|                       | % within Adherence status | 25.3% | 31.5% |
| More than SAR 10000, i.e., USD > 2660.88 | Count (Expected count) | 118 (98.7) | 42 (61.3) |
|                       | % within income       | 73.8% | 26.3% |
|                       | % within Adherence status | 67.8% | 32.2% |

The sensitivity of GMAS-AR was 78.16% (95% CI: 71.28–84.06%) while its specificity was 76.85% (95% CI: 67.75–84.43%). The accuracy of the tool was 77.66% (95% CI: 72.34–82.38%).

4. Discussion

Previous study by Naqvi and colleagues have validated the English version of GMAS in Saudi patients with chronic illnesses (Naqvi et al., 2019b). Notwithstanding the importance of availability of an English version for this population, an Arabic version of the scale was a pre-requisite to measuring adherence to medications from a representative population of Saudi patients. This representative population may not be able to read and understand English thereby limiting the benefits of the scale. Henceforth, there was a need to translate the scale in Arabic and validate it in this population.

An important feature of validation is to sample the scale in an adequate number of participants sampled in a randomized manner. We used the item-response theory to calculate the sample size and opted for the highest item-subject ratio of 1:20. Moreover, we added a 25% drop-out rate and utilized simple randomization technique based on patients’ MRN. This strategy helped gather adequate responses that were representative of the population. This was evident from value obtained for KMO measure of sampling adequacy, i.e., 0.870 that implied that sampling was adequate. It is worthwhile mentioning that the KMO value obtained in this study was higher than that those for English version of GMAS in this population (Naqvi et al., 2019b).

Previous studies have reported a 3-factor structure of GMAS scale in patients with chronic diseases. We confirmed the 3-factor model and calculated the fit indices (Naqvi et al., 2018, 2019a, 2020). The fit indices were in the acceptable range that indicated that the 3-factor model was fit. This established the factorial validity of the scale. Following the methodology used for English version of the scale, the convergent validity was evaluated using a cut-off value of 0.7 for average factor loading (Cohen, 1988; De Vellis, 1991). The average factor loading was >0.7, that established it convergent validity. This highlighted the strength of the scale items to relate to their intended purpose, i.e., measurement of adherence. Besides, the construct validity of the scale was evaluated by correlating the adherence score with pill burden, i.e., number of medicines prescribed. Construct validity indicates that the measure is associated with a variable that it was supposed to associate in theory and/or in practice (Westen and Rosenthal, 2003). Available evidence highlights that adherence has been reported to be associated with pill burden (Scott Sutton et al., 2016). It was reported that Saudi patients who were prescribed with ≤2 medicines had better adherence (AlShayban et al., 2020). In this study the correlation between adherence score and pill burden was weak-to-moderate and significant, that was enough to establish construct validity of the tool.

Reliability of Arabic version of GMAS was high. It was higher than those reported from English version of GMAS in this population and the 8-item Morisky’s Medication Adherence Scale (MMAS-8) (Ashur et al., 2015; AlShayban et al., 2020). This signifies the consistency and dependability of the scale. The known group validity was also evaluated by testing the hypothesis derived from previous studies in this population (Naqvi et al., 2019b; AlShayban et al., 2020). Known group validity of a measure indicates that the scale has the ability to differentiate among groups hypothesized to demonstrate a certain type of trait (Rodrigues et al., 2019). The study hypothesized that adherence is associated with occupation and monthly family income as previous studies in Saudi patients highlighted that an employment that serves as a
The GMAS scale has been developed after reviewing the shortcomings in previous adherence measures (Naqvi and Hassali, 2019). The availability of a validated Arabic version of the scale would foster better documentation of adherence to medications in Arabic speaking Saudi patients with chronic diseases. The scale would be more beneficial as Arabic is the national language for other countries of the Middle East and North African Region. Furthermore, validation of this version in specific disease state is recommended.

### Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. No funding was obtained for this study.

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