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Original article

Concurrent validity of the Arabic version of General Medication Adherence Scale using two validated indirect adherences measures in Saudi patients with non-communicable diseases

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ABSTRACT

Purpose: This study aimed to evaluate the concurrent validity of the Arabic version of the General Medication Adherence Scale (GMAS) using two validated scales namely Adherence to Refills and Medications Scale (ARMS) and Medication Adherence Rating Scale (MARS) in Saudi patients with non-communicable diseases.

Methods: A cross sectional study was conducted for 2 months in out-patient departments at a tertiary care hospital in Khobar, Saudi Arabia. The study collected data from patients with chronic illnesses through convenience sampling. Pearson correlation (ρ) was conducted to report concurrent validity of GMAS. A correlation coefficient value ≥ 0.5 with p-value < 0.01 was considered threshold for establishing concurrent validity. The study was approved by an ethics committee (IRB-2019–05-002).

Results: A total of 406 patients responded to the study. The average age was 42.4 ± 5.94 years, and most patients were females (53.7%), married (70%), graduates (65.3%), employed (39.9%) and, had a monthly family income > SAR 10,000, i.e., USD 2666.2 (56.4%). The mean adherence scores obtained from MARS, ARMS and GMAS were 7.09, 19.9, and 27.4. The correlation (ρ) between GMAS and MARS scores was 0.65, and between GMAS and ARMS scores was −0.79, $p < 0.01$ for both comparisons.

Conclusion: The concurrent validity of GMAS-AR was established in this study that would further substantiate psychometric properties of the scale in this population.

1. Introduction

Adherence to medications forms the cornerstone of any successful treatment and is considered as one of the determinants of treatment success (Forbes et al., 2018; Naqvi et al., 2018). Adherence could be defined as the degree to which patients' medicine taking behavior, dietary and lifestyle changes correspond to agreed recommendations (WHO, 2003). However, studies have reported that non-adherence to medications is a common occurrence

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among different patient populations (Nguyen, La Caze & Cottrell, 2014; AlQarni et al., 2019). Poor adherence may lead to negative outcomes that may further debilitate a patient's health, quality of life and may result in additional healthcare costs (Gehi et al., 2007; Nguyen et al., 2014; Sokol et al., 2005).

Assessment of medication adherence could be done by several direct and indirect methods. Direct methods include observation of therapy and estimation of serum levels while indirect methods include myriad measures such as patient diaries, pill counters, self-reported questionnaires, etc. (Forbes et al., 2018; Naqvi et al., 2019a,b). Each method has pros and cons; however, none could be considered as a standardized adherence evaluating technique. Studies recommend using a combination of direct and indirect methods to assess adherence however, direct methods are tedious and may require careful supervision which at times, is not possible (Forbes et al., 2018). Alternatively, indirect methods are less expensive, require self-reporting, and have proven to be easier to follow. Though, issues of sensitivity and specificity may be considered for such tools (Forbes et al., 2018).

Several indirect adherence measures have been developed and validated in different populations. In a systematic review by Nguyen and colleagues, 43 adherence scales were available in English language (Nguyen, La Caze & Cottrell, 2014). The Morisky, Green and Levine Scale (MGLS), Adherence to Refills and Medications Scale (ARMS) and Medication Adherence Rating Scale (MARS) are commonly used assessments for evaluating medication adherence (Morisky et al., 1986; Thompson et al., 2000, Kripalani et al., 2009; Chan et al., 2019). However, an important aspect to consider is that each scale has its own limitations (Forbes et al., 2018; Naqvi & Hassali, 2019).

The English and Arabic versions of the General Medication Adherence Scale (GMAS) were recently validated in Saudi patients (Naqvi et al., 2019a; 2020a). The scale has been validated successfully using a number of statistical techniques in different populations. In a systematic review by Kwan and colleagues, the GMAS was considered having at least a moderate level of evidence according to the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) guidelines and was the only scale to possess sufficient positive rating in at least four measuring properties (Kwan et al., 2020). Further, the scale has been translated in different languages namely Urdu, English, Arabic and Chinese, etc., and translated versions have been validated in different populations (Naqvi et al., 2018; 2019b; 2020a; Wang et al., 2021).

Although the GMAS underwent validation previously and its concurrent validity was established with direct adherence measures, the concurrent validity with commonly used validated indirect adherence measures has never been established. Henceforth, this study aimed to further characterize its psychometric properties by evaluating concurrent validity of GMAS-AR using Arabic versions of ARMS and MARS in Saudi patients with non-communicable illnesses (NCDs).

2. Methods

A cross sectional study was conducted for two months (July-August 2020) in out-patient clinics at a tertiary care hospital in Khobar, Saudi Arabia.

2.1. Participants and eligibility criteria

The study invited all adult male and female Saudi patients aged 18 years or above, with non-communicable illness/es and, with or without comorbidity, and prescribed medications for at least a month before study. The eligibility criteria further included patients prescribed medications on long-term therapy and, in implementation phase of adherence. 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 (Vrijens et al., 2012; Khan & Aslani, 2020). Patients with acute illnesses, planned surgery and pregnancy were excluded.

2.2. Sampling

The patients were approached at an out-patient department of a tertiary care hospital in Khobar, Saudi Arabia. Convenience sampling was used and patients who fulfilled the eligibility criteria were invited. The sample size was calculated using an online sample size calculator for correlation studies (Kohn & Senyak, 2021). A two-tailed alpha error rate of 0.01 was considered while type II (β) error rate was set at 0.1. A value of 0.2 for expected correlation coefficient (r) was considered. The total sample size required was 365 using this approach (Hulley et al., 2013).

2.3. Data collection process

The patients were approached in the clinics and were invited. Those interested were briefed about the study and were asked to sign an electronic informed consent form after which they were asked to fill in their response on an electronic data collection form available on a tablet. The data collection was facilitated by research assistants when needed. The adherence was measured once during data collection. All protocols for social distancing and disinfection were followed during data collection. The patients were asked to sanitize their hands before handing them the tablet. The screen of the tablet was disinfected after data collection from each patient. The trained staff assisting data collection also followed all protocols during this process.

3. Research instruments

The GMAS, MARS and ARMS were used. The GMAS is an 11 – item scale and each item has 4 choices. Each choice awards a score and sum of all items indicates adherence to medicines. The range of the scoring is from 0 to 33. A score $\geq$ 27 indicates adherence while score $\leq$ 26 indicates non-adherence (Naqvi, et al., 2020a). The MARS is a product of two psychometric scales and has been used in European countries (Hogan et al., 1983; Thompson et al., 2000; Fialko et al., 2008). It is comprised of 10 items in dichotomous (yes/no) format. The scoring criteria is provided with the scale. The range of the scoring is from 0 to 10. Scores are treated as a continuous measure and a higher score indicates a greater compliance. The MARS demonstrated fair psychometric properties in a previous study (Owie et al., 2018). Therefore, it was selected as one of the standards in this study.

Kriplani and colleagues have reported good psychometric properties of ARMS scale in patients with chronic disease who had low literacy (Kripalani et al., 2009). The scale is comprised of 12 items and each item has four options. The range of the scoring is from 0 to 48. A lower score indicates better adherence. This scale provides the options to treat adherence scores either as continuous or categorical. A score >12 indicates non-adherence in case latter is considered. Besides, the scale has been validated in patients of countries located in the Middle Eastern region (Alsous et al., 2017; Barati et al., 2018). Such patient populations may have similar characteristics to our participants. Hence, the ARMS was also considered as one of the standards. An Arabic version for all three scales was used. Apart from the scales, a demographic data collection form was also added to document patients' information.

3.1. Concurrent validity of GMAS

The concurrent validity of GMAS was assessed through Pearson correlation coefficient (ρ). The adherence scores obtained from GMAS were evaluated for correlation with those obtained from ARMS and MARS. All assumptions of bivariate correlation were checked and justified before conducting the correlation. Concurrent validity was established if the correlation coefficient value was ≥ 0.5 with p-value < 0.01 (Hinkle et al., 2003; Mukaka, 2012).

3.2. Data analysis

The data were analyzed through IBM SPSS version 23. The categorical data were expressed as sample (N) and frequency (%) while continuous data were reported at mean (X), standard deviation (SD) and Range. We interpreted the correlation as moderate if the coefficient was $\geq 0.5 \leq 0.7$ and, strong if it was ≥ 0.7.

3.3. Ethics approval and patient consent

The eligible patients were asked to participate and given a briefing. The participation was voluntary, and patients were informed that their decision regarding participation would not affect their hospital care. An ethics approval was granted by the Institutional Review Board of Imam Abdulrahman Bin Faisal University, Dammam, Saudi Arabia (IRB-2019–05-002).

4. Results

4.1. Demographic information

A total of 406 patients responded to the study. The average age was 42.4 years (X = 42.4, SD = 5.94). Most patients (N = 204, 50.2%) were 45 years and above, females (N = 218, 53.7%) and married (N = 284, 70%). Patients were most graduates (N = 265, 65.3%), employed (N = 162, 39.9%) and had a monthly family income more than SAR 10,000 (N = 229, 56.4%). The majority of patients (N = 204, 50.2%) obtained their medicines through the government coverage (Table 1).

Table 1
Participants' demographic information.

Demographic data	N	%
Age group		
Below 45 years	202	49.8
45 years and above	204	50.2
Gender		
Male	188	46.3
Female	218	53.7
Marital status		
Married	284	70
Single	122	30
Level of Education		
No formal education	6	1.5
Primary education	31	7.6
High school	104	25.6
Graduate	265	65.3
Occupation		
Employed	162	39.9
Retired	101	24.9
Unemployed	71	17.5
Home maker	72	17.7
Monthly income (USD)*		
Less than SAR 5,000 (USD < 1333.2)	65	16
Between SAR 5,000–10,000 (USD 1333.2 – 2666.2)	112	27.6
More than SAR 10,000 (USD > 2666.2)	229	56.4
Medication obtaining method		
Government coverage	204	50.2
Private insurance	96	23.6
Out-of-pocket	70	17.2
More than one source	36	8.9

*1 USD equals SAR 3.75

4.2. Medication adherence scores and scale reliability

The mean score obtained from MARS was 7.09, SD 2.07. The range was 1 – 10 and Cronbach's α was 0.53. Besides, the mean score obtained from ARMS was 19.9, SD 5.80. The range 12 – 44 and α = 0.82. Furthermore, the mean score obtained from GMAS was 27.4, SD 5.47. The range was 3 – 33 and α = 0.85.

4.3. Concurrent validity of GMAS

The correlation (ρ) between GMAS score and MARS score was 0.65 (p < 0.01). The correlation (ρ) between GMAS score and ARMS score was −0.79 (p < 0.01) (Fig. 1).

5. Discussion

This study was conducted in a large sample of patients visiting a tertiary care healthcare setting in Khobar, Saudi Arabia. Furthermore, the indirect measures selected in this study were MARS and ARMS. Both scales have demonstrated good psychometric properties in different populations. At the same time, MARS and ARMS have been validated in countries of the Middle Eastern region (Alsous et al., 2017; Barati et al., 2018). Further to this, both scales were available in native Arabic language that provided an excellent opportunity to consider these two as standard indirect measures to evaluate the concurrent validity of the Arabic version of GMAS. All three scales demonstrated acceptable internal consistency as the Cronbach's α value reported in the study was > 0.5 (Bowling, 2009; Chung et al., 2015).

Most patients aged 45 and above, however the average age of was reported at 42 years. The majority was married, educated, and had a high monthly family income. The demographic profile reported in this study was similar to those reported by two previous studies at this venue (AlQarni et al., 2019; AlShayban et al., 2020). The patients had an average adherence score of 7.09 out of 10 obtained from MARS while they had an average score of 27 out of 33 from GMAS. For both of these scales, a higher score indicated better adherence. Conversely, lower score obtained using ARMS indicated a better adherence. The patients had an average adherence score of 19.9 out of 48.

The approach of comparing adherence scores obtained from a population using different adherence measures has been utilized in past. Cabral and colleagues carried out a study to establish concurrent validity of the 8 – item Morisky's Medication Adherence Scale (MMAS – 8) by comparing the adherence scores obtained from MMAS-8 with scores obtained from another adherence measure, i.e., (MAT) (Treatment Adherence Measure) in a sample of Portuguese patients and reported a value of 0.67 (p < 0.001) (Cabral et al., 2018). Since all three scales had continuous variables therefore correlation was conducted. The correlation was 0.65 with p < 0.01, which indicated moderate correlation. This was similar to the value obtained by Cabral and colleagues (Cabral et al., 2018).

The study has a few limitations, as it utilized convenient sampling methodology to gather responses from patients. Besides, only the Arabic version of the GMAS scale was evaluated for concurrent validity despite availability of a validated English version of GMAS for this population. Hence, the findings of this study are limited to the Arabic version of the scale and do not extend the benefits of the English version in Saudi patients. Documentation of the type of non-communicable illnesses would have provided better

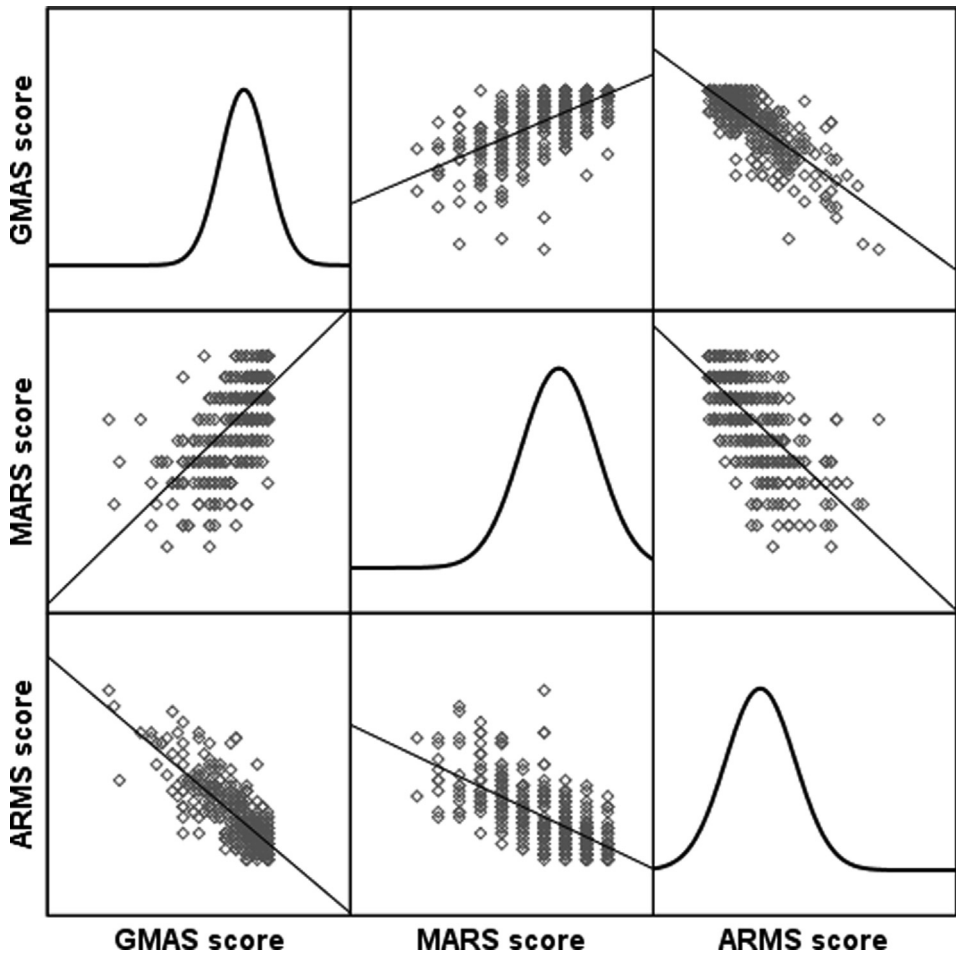

Fig. 1. Correlation of adherence scores.

understanding of the sample make-up. Nonetheless, the findings of this study would further strengthen the psychometric property of GMAS as the scale has never been validated against another indirect measure. Further validation of the English version of the scale in this population is recommended.

6. Conclusion

The GMAS adherence scores correlated significantly and with moderate strength, with the adherence scores obtained by MARS and ARMS. These findings highlight that Arabic version of GMAS established concurrent validity in Saudi patients with non-communicable illnesses.

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.

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