

Adherence to Insulin Therapy Among Children with Type I Diabetes: Reliability and Validity of the Arabic Version of the 4-Item Morisky Medication Adherence Scale

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Background: Inadequate adherence to insulin is a major concern, necessitating the use of reliable and valid metrics for assessing adherence. Up to date, there are no Arabic validated tools assessing adherence to insulin therapy among children with type 1 diabetes (T1DM). Thus, the aim of this study is to evaluate the psychometric properties of an Arabic version of the four-item Morisky Green Levine Medication Adherence Scale (MGLS-4) as a self-reported measure of adherence to insulin among a cohort of Egyptian children with T1DM.

Methods: The MGLS-4 was translated using forward and backward translation. The Cronbach's alpha was used to assess reliability. Criterion validity of the scale was tested by examining the correlation coefficients between the compliance score (level of adherence) and the HbA1c levels.

Results: A total of 400 patients completed the Arabic version of MGLS-4. 26.25% of the studied cohort was found to be non-adherent to insulin therapy; non-adherent patients were significantly older ($P=0.001$). Decreased maternal education level, decreased frequency of blood glucose monitoring and prolonged disease duration best predicted the occurrence of non-adherence among the studied cohort. The internal consistency of the current version showed good reliability (Cronbach's alpha = 0.857). The adherence score and adherence level showed very strong correlation with HbA1c level ($\rho = 0.830$, $P < 0.001$ and $\rho = 0.808$, $P < 0.001$, respectively).

Conclusion: The Arabic version of MGLS-4 showed good reliability and validity as a self-administered tool for assessing adherence to insulin in pediatric patients with T1DM.

Keywords: adherence to insulin, Morisky–Green–Levine Medication Adherence Scale, type 1 diabetes

Introduction

Adherence to long-term therapy is defined by the World Health Organization as 'the amount to which a person's behavior—taking drugs, following a diet, and/or implementing lifestyle modifications, matches with approved recommendations from a healthcare professional'.¹ Management of diabetes possess a real challenge, making adherence to treatment more problematic and worse than adherence to treatment for other chronic disorders.^{2,3}

Low adherence is a frequent symptom among children and adolescents with type 1 diabetes.⁴ As a result, achieving glycemic control remains a difficult task for patients. Endothelial dysfunction and microvascular consequences, as well as macrovascular problems and atherosclerotic hazard, are all risks associated with poor glycemic management.⁵

Furthermore, in countries with high prevalence of diabetes, such as many Arab countries, inadequate adherence to therapy, especially insulin is a major concern, necessitating the use of reliable and valid metrics assessing adherence to treatment. Among these measures, patient questionnaires are often employed since they are simple, inexpensive, and easy

to administer.⁶ Simple, reliable, and valid self-reported tools are needed to assess medication adherence levels that could lead to a better consideration of low-adherence and settle the basis for interventions aimed at improving health consequences and decreasing the global healthcare costs.⁷

The four-item Morisky Green Levine Medication Adherence Scale (MGLS) questionnaire is one of the most widely used self-reported measures of pharmaceutical non-adherence. The scale's psychometric qualities have been proven.⁸ The scale is simple to use and understand, and may be easily incorporated into routine care of patients. It has been used to assess drug adherence in different chronic conditions.^{9–11}

Several studies evaluated the validity and reliability of different versions of MGLS-4 among patients with type 2 diabetes.^{11–14} However, to the best of our knowledge, data evaluating adherence to insulin among children and adolescents with type 1 diabetes is limited. Thus, the aim of the current study is to evaluate the psychometric properties of an Arabic version of the four-item Morisky Green Levine Medication Adherence Scale (MGLS-4) as a self-reported measure of adherence to insulin among a cohort of Egyptian children and adolescents with type 1 diabetes.

Methods

Participants

A total of 400 patients, ages 6 to 18 years, were randomly recruited from the Pediatric and adolescent Diabetes Unit (PADU), at Ain Shams University. If a participant's cognitive disability interfered with the study, they were ruled out. The study was approved by the Research Ethical Committee at the Faculty of Medicine, Ain Shams University (Ethical Committee No. FMASU R 64) and was conducted in accordance with the Helsinki Declaration of 1975. Written consent was taken from the participants and/or their caregivers before enrolment in the study after being informed about the purpose of the study.

Procedure

A cross-sectional study using face-to-face interview, the participants fulfilled a self-administered questionnaire that contained three parts: sociodemographic data (age and gender of the child, marital status, education level, and employment status of the parents); disease profile (duration of diabetes, current diabetes medications, frequency of glucose monitoring, and last HbA1c result); and the Arabic version of the four-item Morisky Green Levine Medication Adherence Scale (MGLS-4).

HbA1c was measured by HPLC based on the charge of the glycated molecule by cation exchange high performance liquid chromatography (CE-HPLC) and the value of the last 3 months prior to enrolment in the study was reported.

Measures

The MGLS-4 scale is a four questions questionnaire with yes/no answers. The MGLS-4 score ranged from 0 to 4. Based on the score, adherence is categorized into high, medium, and low adherence. A score of 4 denotes high adherence, a score of 2 or 3 denotes medium adherence and a score of 0 or 1 denotes low adherence.⁸

Translation

The MGLS-4 was translated from English to Arabic with the agreement of the scale's owner, Professor Morisky.⁸ This version was created utilising a forward and backward translation process, in which two pairs of linguistic specialists worked separately to complete the translation. Researchers looked through the two primary copies and decided on an Arabic draft copy. The draft was re-translated into English by a bilingual specialist. In terms of conceptual comparability, translators compared the backward-translated English draft to the initial. The translated questionnaire was then distributed to 30 Egyptian patients with type 1 diabetes mellitus, who finished it and provided feedback on the questions. The researchers took care of the patients' feedback, and a final Arabic version was developed and prepared for reliability and validity testing.

Statistical Analysis

IBM SPSS Statistics version 23 (IBM Corp., Armonk, NY) was used to analyse the data. To describe sample characteristics, descriptive statistics and frequencies were used. Means and SDs were used to represent continuous

demographic data such as age, diabetes duration, HbA1c, and insulin dose, which were then compared using Tukey's post hoc test. Percentage was used to describe category qualities, followed by Dunn test for multiple comparisons.

The four questions of the scale were subjected to maximum likelihood principal component analysis (PCA). To determine the adequacy of data for component analysis, the Kaiser-Meyer-Olkin (KMO) Measure of Sampling Adequacy and Bartlett's Test of Sphericity were utilized. As criteria for sample adequacy and practicality, a KMO value of at least .6 and a P-value of at least .05 for Bartlett's Test were identified.

Reliability Assessment

The Cronbach's alpha coefficient was used to assess internal consistency reliability. Cronbach's alpha of >0.5 can be acceptable for newly created measures; otherwise, 0.7 should be the cut-off.¹⁵

Criterion Validity

Criterion validity of the scale was tested by examining the correlation coefficients between the compliance score (level of adherence) and the HbA1c levels (or adequacy of glycemic control). Inadequate glycemic control was defined as HbA1c level $> 7\%$ (53 mmol/mol). P-value < 0.05 is considered statistically significant.

Diagnostic Accuracy (Sensitivity and Specificity)

Sensitivity and specificity were assessed to identify the efficacy of MGLS-4 to identify patients with inadequate glycemic control. Only two sets of adherence scores were included in the sensitivity and specificity analysis: low adherence patients as one group, and medium and high adherence patients as the second group.

Results

Demographic Characteristics

The demographic data and disease characteristics of studied cohort are highlighted in [Table 1](#). The mean age of the studied cohort was 8.1 ± 2.07 years with female predominance (66%), most of the patients were having diabetes for at least one year with average duration of 1.21 ± 0.94 years. All the patients were on multiple daily injections with the majority receiving 3 daily injections of insulin. The educational levels were diverse among the caregivers. The MGLS-4 scale was used to categorize the respondents' adherence to insulin medication into low, medium, and high adherence levels. 26.25% of the studied cohort was found to be non-adherent to insulin therapy; non-adherent patients were significantly older. Following the completion of the multiple regression analysis, decreased maternal education level, decreased frequency of self-monitoring of blood glucose and prolonged disease duration best predicted the occurrence of non-adherence to insulin therapy among the studied cohort ([Table 2](#)).

Reliability

The internal consistency of the 4 items comprising the scale indicated good reliability (Cronbach's alpha = 0.857). The reliability index dropped, when any item was removed, as a result, all four objects were kept. The overall correlation coefficient for items 1 to 4 varied from 0.63 to 0.73 ([Table 3](#)).

Validity

The criterion validity of MGLS-4 is illustrated in [Table 4](#). The adherence score and adherence level showed very strong correlation with HbA1c level (Spearman's $\rho = 0.830$, P-value < 0.001 and 0.808 , P-value < 0.001 , respectively). Similarly, the adherence score and adherence level showed strong correlation with inadequacy of glycemic control (rank biserial correlation coefficient = 0.740, P-value < 0.001 and 0.697 , P-value < 0.001 , respectively).

Sensitivity and Specificity

The sensitivity and specificity of MGLS were 75% and 27%, respectively. Positive and negative predictive values were 25% and 73%, respectively.

Table 1 Socio-Demographic Data and Disease Characteristics Based on Patients' Level of Adherence

Characteristics	Total Sample N=400	Low Adherence N=105 (26.25%)	Medium Adherence N=161 (40.25%)	High Adherence N=134 (33.5%)	P-value
Age (mean $\pm$ SD)	8.10 $\pm$ 2.07	8.66 $\pm$ 2.57	8.06 $\pm$ 2.01	7.66 $\pm$ 1.37	0.001*
Gender (%)					
Male	136 (34%)	29 (27.6%)	52 (32.3%)	55 (41.0%)	0.079
Female	264 (66%)	76 (72.4%)	109 (67.7%)	79 (59.0%)	
Diabetes duration N (%)					0.014
Less than 6 months	78 (19.5%)	16 (15.2%)	30 (18.6%)	32 (23.9%)	
6–12 months	160 (40.0%)	32 (30.5%)	71 (44.1%)	57 (42.5%)	
>1 year	162 (40.5%)	57 (54.3%)	60 (37.3%)	45 (33.6%)	
HbA1c% (mean $\pm$ SD) IFCC (mmol/mol)	8.18 $\pm$ 1.93 66	10.69 $\pm$ 1.6 93	8.05 $\pm$ 0.76 65	6.38 $\pm$ 0.45 46	0.001**
Mother education					0.001
Illiterate /Literate Certificate	107 (26.8%)	50 (47.6%)	34 (21.1%)	23 (17.2%)	
Primary/Preparatory	48 (12.0%)	18 (17.1%)	16 (9.9%)	14 (10.4%)	
Secondary	85 (21.2%)	13 (12.4%)	45 (28.0%)	27 (20.2%)	
University	160 (40.0%)	24 (22.9%)	66 (41.0%)	70 (52.2%)	
Father education					0.001
Illiterate/ Literate Certificate	80 (20.0%)	28 (26.7%)	34 (21.1%)	18 (13.4%)	
Primary/Preparatory	60 (15.0%)	25 (23.8%)	16 (9.9%)	19 (14.2%)	
Secondary	88 (22.0%)	21 (20.0%)	40 (24.8%)	27 (20.1%)	
University	172 (43.0%)	31 (29.5%)	71 (44.1%)	70 (52.2%)	
Employment status of mother N (%)					0.001
Employed	204 (51.0%)	32 (30.5%)	86 (53.4%)	86 (64.2%)	
Unemployed	196 (49.0%)	73 (69.5%)	75 (46.6%)	48 (35.8%)	
Employment status of father N(%)					0.348
Employed	383 (95.8%)	100 (95.2%)	152 (94.4%)	131 (97.8%)	
Unemployed	17 (4.3%)	5 (4.8%)	9 (5.6%)	3 (2.2%)	
Frequency of glucose monitoring					0.02
1–2 times/day	68 (17%)	27 (25.7%)	22 (13.7%)	19 (14.2%)	
3–4 times/day	240 (60%)	57 (54.3%)	107 (66.5%)	76 (56.7%)	
More than 4 times/day	92 (23%)	21 (20.0%)	32 (19.8%)	39 (29.1%)	

Notes: *Post hoc test: low adherence vs high adherence: $P<0.01$, low adherence vs medium adherence: $P=0.045$, medium adherence vs high adherence: $P=0.2$. **Post hoc test: low adherence vs high adherence: $P<0.01$, low adherence vs medium adherence: $P<0.01$, medium adherence vs high adherence: $P<0.01$.

Discussion

Despite the importance of adherence to treatment regimens, assessment of adherence is not easy to measure in clinical practice.¹⁶ Several studies successfully assessed adherence to insulin therapy among a cohort of patients with diabetes using the 4-item Morisky–Green–Levine Medication Adherence Scale.^{16,17} To date, there is no Arabic validated measure assessing adherence to insulin in patients with diabetes. This is the first study to assess the Arabic version of MGLS-4 among a cohort of children and adolescents with type 1 diabetes.

Data from the current study showed that almost 26% of the studied cohort was not adherent to insulin therapy. These findings are in agreement with studies showing that non-adherence is common among pediatric patients with T1DM, with

Table 2 Multivariate Regression Analysis for Determinants Predicting Non- Adherence to Insulin Among Studied Cohort

	B	S.E.	Wald	P-value	Odds Ratio (OR)	95% C.I. for OR	
						Lower	Upper
Age	0.053	0.101	0.280	0.597	1.055	0.866	1.285
Disease duration >1 year	1.333	0.654	4.154	0.042	3.791	1.052	13.655
Frequency of glucose monitoring ≤ 3 times/day	1.736	0.506	11.751	0.001	5.673	2.103	15.305
Mother education Illiterate/Literate Certificate	1.217	0.569	4.579	0.032	3.377	1.108	10.296
Father education Illiterate/Literate Certificate	-0.336	0.620	0.293	0.588	0.715	0.212	2.412
Employment status of mother Unemployed	0.296	0.468	0.400	0.527	1.344	0.538	3.361

Table 3 The Cronbach's Alpha Coefficient Assessing Internal Consistency Reliability of the Arabic Version of MGLS-4

Item	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted	Cronbach's Alpha for Whole Scale
Item 1	0.63	0.85	0.857
Item 2	0.72	0.84	
Item 3	0.73	0.84	
Item 4	0.65	0.85	

Table 4 Criterion Validity of MGLS-4

Variable	Correlation Coefficient	Adherence Score	Adherence Level
HbA1c level	Spearman's rho	0.830	0.808
	P-value	<0.001	<0.001
Inadequate glycemic control *	Rank biserial	0.740	0.697
	P-value	<0.001	<0.001

Note: *Inadequate glycemic control was defined as HbA1c level > 7%.

16–49% being non-adherent to insulin therapy.^{4,18} Additionally, Chu et al similarly observed that non-adherent patients were significantly older.¹⁸

The current study explored various factors that could affect and predict adherence to insulin therapy. Similar to findings by Chua et al,¹⁸ duration of diabetes was an important and significant predictor of non-adherence among the studied cohort. This finding could be attributed to treatment fatigue occurring with longer diabetes durations, which requires more frequent assessment of adherence among patients with longer duration of diabetes.¹⁹ Maternal education with better knowledge of diabetes was another significant predictor of adherence. Mariye et al, reported that better understanding of diabetes could positively impact adherence to treatment.¹⁷

In this study, the reliability of the Arabic version of the 4-item Morisky– Green–Levine Medication Adherence Scale was good and was found to be higher than the reliability reported by Morisky et al (Cronbach's alpha = 0.61).⁸

Compared with other translated versions of MGLS evaluating medication adherence in patients with diabetes, the reported alpha coefficient reported in this study was higher than those reported for the Singaporean (0.62),¹² Thai (0.61)¹³ and Korean (0.66)²⁰ versions.

Earlier Ashur et al evaluated the reliability and validity of the Arabic version of the 8-item Morisky Medication Adherence among a cohort of patients with type 2 diabetes on oral hypoglycemic. They postulated that the Arabic version of MGLS - 8 is a reliable and valid tool for assessing adherence to oral hypoglycemic among patients with type 2 diabetes.¹⁴

Insulin therapy is the cornerstone in the management of T1DM. Insulin non-adherence was found to be associated with increased risk of complications and increasing costs and expenses by the health-care system.¹⁸ Therefore, this signifies the importance of validating simple tool for assessing adherence to insulin therapy and incorporating it as a part of the standard of care offered to pediatric patients with type 1 diabetes.¹⁸

In spite of different versions validating the usage of MGLS among patients with type 2 diabetes,^{12–14,20} data about versions evaluating adherence to insulin in patients with type 1 diabetes is scarce. To the best of our knowledge this is the first study in Egypt to validate a patient-reported measure in patients with type 1 diabetes addressing adherence to insulin therapy.

In concordance with previous findings,^{12,14,21–24} higher scale scores were associated with better glycemic control, as evidenced by better HbA1c levels. Hood et al in their meta-analysis supported the adherence-glycemic control link in pediatric type 1 diabetes.²⁵ Patients with higher medication adherence are more likely to be concerned with their disease and more aware of the importance of achieving a target glycemic control.¹²

The current version of MGLS -4 successfully differentiated between pediatric patients with poor and adequate glycemic control, supporting the criterion validity of the Arabic version of MGLS -4.

Although the sensitivity of the current Arabic version is lower than that reported with the original MGLS (93%),¹⁴ however the sensitivity is comparable to that reported among other versions of the MGLS.^{12–14,20} The current reported sensitivity highlights the efficacy of the Arabic version of MGLS-4 to identify patients with type 1 diabetes non-adherent to their insulin therapy. Although the sensitivity of the Arabic version of MGLS-4 was comparable to that reported among other versions of the MGLS, the specificity of Arabic version of MGLS-4 among patients with type 1 diabetes was lower than that reported among other versions of the MGLS^{12–14} and this is an important limitation of the current study.

Insulin adherence is an important pillar in diabetes care and it is essential to have simple and reliable tools aiming to assess adherence in patients with type 1 diabetes.¹² This study represents a comprehensive insight for the validation of the Arabic version of MGLS-4 as a measure of adherence to insulin in pediatric patient with type 1 diabetes, providing sufficient psychometric properties of the Arabic version of MGLS-4.

The convenience sampling method may have subjected the study to a sort of selection bias which may impose a limitation on the generalizability of the findings. An important limitation of the current study is the low reported specificity of the Arabic version of MGLS-4. Absence of assessing the ceiling effect and confirmatory factor analysis of the Arabic version of MGLS-4 is another important limitation. The sample size in the current study is an important strength factor of this study.

Conclusion

The Arabic version of MGLS-4 showed good reliability and validity as a self-administered tool for assessing adherence to insulin in pediatric patients with type 1 diabetes. Arabic version of MGLS-4 could be a simple and feasible screening tool for assessing insulin adherence paving the way for implementing intervention strategies, which could positively impact both glycemic control and economic outcomes.

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Disclosure

The authors report no conflicts of interest in this work.

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