Original Article

The Validity and Reliability Study of the Self-reported Measure of Medication Adherence Scale in Patients Taking Oral Antidiabetic Treatment

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Abstract

Background: Diabetes has become an important public health problem; an appropriate and timely use of medication is known to be a key factor in regulating blood glucose and minimizing potential complications of diabetes. Adherence to the medication that is used in the management of type-2 diabetes is vital for increasing the effectiveness of the treatment and providing effective disease control.
Objective: The aim of this study was to determine the validity and reliability of the Self-reported Measure of Medication Adherence Scale, which was developed by Morisky, Green, and Levine in 1986, for individuals with type-2 diabetes and taking oral antidiabetic therapy.
Methods: The sample of this methodological study consisted of 182 patients with type-2 diabetes who were followed-up in the Department of Internal Medicine and the Diabetes Education and Monitoring Unit at Bolu İzzet Baysal Public Hospital between May 2018 and August 2018 and met the inclusion criteria. The participant information form and the Self-reported Measure of Medication Adherence were used as data collection tools in face-to-face interviews.
Results: The language equivalence of the scale was achieved, followed by the calculation of Davis's content validity index, which was found to be 1. For construct validity, the Kaiser-Meyer-Olkin value was 0.615; Bartlett's test result was χ^2=173.9 and statistically significant ($p<0.001$). The factor loadings for the items were as follows: 0.955 for item 1, 0.955 for item 2, 0.757 for item 3, 0.788 for item 4. The eigenvalue was 3.053, and the total variance explained was 76.33%. The Cronbach alpha coefficient was 0.701, and the correlation coefficient for each item ranged from 0.63 to 0.73 in the test-retest analysis.
Conclusions: The Turkish version of the Self-reported Measure of Medication Adherence Scale was found to be a valid and reliable measurement tool for measuring drug compliance in individuals with type-2 diabetes taking oral antidiabetic therapy.

Keywords: diabetes mellitus, type-2 diabetes, drug compliance, validity and reliability

Introduction

Diabetes is a metabolic disease characterized by an increased blood glucose level due to a deficiency in the secretion and/or utilization of insulin (American Diabetes Association, 2007). Diabetes is one of the most common non-communicable diseases, and the increasing prevalence of diabetes has made diabetes one of the most significant public health problems facing the entire world (World Health Organization, 2006). The data from the International Diabetes Federation indicate that the number of diabetic individuals is expected to increase from 424.9 million in 2017 to 628.6 million in 2045 (International Diabetes Federation, 2017). With a prevalence of 12.1%, Turkey was reported to rank third, following Germany and Russia, among European countries in the number of people with diabetes (International Diabetes Federation, 2017). The

Diabetes Epidemiology Study of Turkey (TURDEP-II), which involved 26,499 people aged 20 years and above, indicated that the prevalence of diabetes had increased 90% in 12 years, from 7.2% to 13.7% (Satman et al., 2002, 2013). Effective and successful glucose control in diabetes typically necessitates appropriate and timely use of medications throughout the, usually life-long, treatment period (Abebe, Berhane and Worku, 2014). Lifestyle modifications and compliance with the drug regimen are important factors in improving the course of diabetes (Inamdar et al., 2013). It is well known that the adherence of diabetic individuals to the treatment is of great importance for the effectiveness of the treatment and is considered to be the main link between the purpose and outcome of the medical treatment (Fenerty et al., 2012). Although medication adherence had been defined as the extent to which the patients implement the instructions given for the treatment (Haynes et al., 2002), World Health Organization (WHO) defined treatment adherence as the extent to which a patient maintains the treatment process - including taking medication, following the diet, and/or executing lifestyle modifications - in line with the agreed recommendations from a health care provider (World Health Organization, 2003). Although type-2 diabetes is a common condition, it is easily treatable; however, diabetes is difficult to control due to medication non-adherence in society (Aruna et al., 2015). The key factors in diabetes management are medication adherence, lifestyle changes, and the coordination of the multidisciplinary medical care team (El-hadiyah et al., 2016).

Oral antidiabetic therapy plays an important role in the management of type-2 diabetes. It has been suggested that better results in pharmacological methods are associated with adherence to pharmacological treatment (Brincat, 2012). Patient's adherence to the treatment is an important factor for glycemic control and compliance with oral hypoglycemic agents is generally low (Peeters et al., 2015). Low medication adherence is considered an important obstacle in achieving successful clinical outcomes (Brincat, 2012), and the good treatment adherence is associated with a decrease in diabetes-related complications and mortality rate (McGovern et al., 2016).

The adherence rates for oral antidiabetic drugs have been reported to vary between 30% and 80% in type-2 diabetes, and drug non-adherence may cause serious complications in diabetes due to failure in the treatment (Winkler et al., 2002; Abebe, Berhane and Worku, 2014).

Drug non-adherence is a serious problem that reduces the benefit of treatment, decreases the patient's satisfaction from medical care, and results in more physician appointments, unnecessary hospitalizations, and prescription of additional drugs. These, in turn, affect not only the individuals but also the whole healthcare system and lead to an increase in costs (Clark, 2004, Krepia et al., 2011).

An individual's level of adherence to the medication/treatment can be measured using different tools although there is no gold standard for such an evaluation. The use of these tools may help determine and improve individuals' medication adherence. Various methods such as self-reports, urine and serum levels, number of pills, electronic monitoring devices and patient interviews can be used to evaluate medication adherence (Chandrashekar et al., 2013). The use of scales is also important in evaluating medication adherence.

This study aimed to determine the validity and reliability of the Turkish version of the Self-reported Measure of Medication Adherence Scale, which has demonstrated validity and reliability for various conditions, in individuals undergoing antidiabetic treatment for type-2 diabetes (Morisky and Green, 1986; Wang et al., 2012, 2017; Bahar et al., 2014).

Methods

Study Design

This study has the methodological design.

Study Sample

In the validity and reliability studies, the sample size should be at least 10 times the total number of items in the scale (Capık, 2014). The SMMA has four items in total; the study sample included 182 individuals who presented to the Department of Internal Medicine or the Diabetes Education and Monitoring Unit at Bolu İzzet Baysal State Hospital and had been taking oral antidiabetic therapy for type-2 diabetes.

Inclusion Criteria

The study included individuals who were 18 years or older, had been diagnosed with type-2 diabetes at least 6 months before the time of the study, had been taking oral antidiabetic therapy,

had no problems with reading, writing, speaking, understanding, or vision, and volunteered to participate in the study.

Exclusion Criteria

The individuals who were illiterate, had visual or hearing loss, or had other types of diabetes were excluded from the study.

Data Collection Tools

The data were collected by using the Participant Information Form and the Self-reported Measure of Medication Adherence Scale.

Participant Information Form consisted of 23 questions addressing the socio-demographic and diabetes-related variables such as age, gender, marital status, education, employment status, occupation, social security, income status, smoking, alcohol consumption, time of diagnosis with diabetes, treatment methods used for diabetes, family history of diabetes, presence of chronic comorbid diseases, diabetes education, use of non-prescription medication, blood glucose monitoring at home, and frequency of diabetes monitoring.

The Self-reported Measure of Medication Adherence Scale was developed by Morisky et al. in 1986 and includes 4 closed-ended questions. The answer "yes" was scored as "0" point and "no" as "1". Total scale score ranges from 0 to 4. A score of 4 means high adherence, 2-3 means moderate adherence, and 0-1 means low adherence. The Cronbach alpha value of the scale was 0.61 (Morisky and Green, 1986).

Data Collection

The individuals who met the inclusion criteria were informed about the study and their verbal consent was obtained before the data collection. The data were collected between May-August 2018 through face-to-face interviews. For the test-retest method to determine the reliability of the scale, the data were collected through phone interviews.

Ethical Disclosures

The approval for the study was obtained from the local ethics committee (Approval No. 18-2/15). Written permission was obtained from the institution where the study was conducted. The participants were informed that the participation was voluntary and that their personal information would be kept confidential and their consent was obtained in writing before administering data collections tools. The permission for using the Self-reported Measure of Medication Adherence Scale was obtained from Dr. Morisky via e-mail.

Data Analysis

Statistical data analyses were performed with Mplus (version 7.31), R Studio, IBM SPSS (version 22), and FACTOR (version 10.3.01) developed by Urbano Lorenzo Seva and Pere Joan Ferrando. All evaluations were performed at 95% confidence interval ($p<0.05$). The language validity, content validity, and construct validity were examined for the evaluation of validity. Davis's content validity index was used for content validity (Davis 1992). Confirmatory Factor Analysis (CFA) and Exploratory Factor Analysis (EFA) were performed to test the construct validity (REF). Applicability of factor analysis was determined with Bartlett's sphericity test and Kaiser-Meyer-Olkin (KMO) value. The unweighted least squares (ULS) method based on the tetrachoric correlation was used for EFA. The test-retest method was used for the reliability of the scale; Kuder-Richardson Formula 20 (KR-20) and Cronbach alpha value were for internal consistency. Spearman correlation analysis was used to determine the relationship between the scores obtained from the test and retest. Number and percentage were used to present socio-demographic data. Descriptive statistics (frequency distribution, mean, standard deviation) were used for socio-demographic characteristics and descriptive information about the participants.

The Methods for the Validity and Reliability of the Scale

Validity Analyses

Language Validation aimed to obtain the equivalents of scale items in the Turkish language. The scale items were translated from English to Turkish by five individuals independently.

The scale was translated back to English by an expert translator who had never seen the original version of the scale. Finally, the scale items were compared to the original version items and the Turkish version of the scale was finalized.

Content Validity indicates the extent to which the scale and each item in the scale serve the purpose (Karakoc and Donmez, 2014). Content validity was implemented based on the relevant literature (Gozum and Aksayan, 2003). Each scale item

was scored 1 to 4 by a panel of seven researchers based on Davis technique to measure the item's relevance to the purpose of the scale (Davis 1992). Davis technique grades the items as (a) "Item is representative (relevant)", (b) "Item needs a minor revision to be representative", (c) "Item needs major revision to be representative", or (d) "Item is not representative" based on expert opinion. The content validity index (CVI) for an item was calculated by dividing the number of experts checking the choices (a) or (b) to the total number of expert reviewers; a CVI of 0.80 is considered a benchmark instead of a comparison to a statistical criterion (Rubio et al., 2003). The CVIs for items and for the whole measure were calculated based on the reviews by seven experts according to Davis technique.

Construct Validity was tested with factor analysis. Prior to factor analysis, the Kaiser-Meyer-Olkin (KMO) measure of sample adequacy and Bartlett's sphericity test were performed to assess whether the sampling was adequate and the factor correlation matrix was appropriate. In CFA, the goodness of fit index (GIF) was examined.

Reliability Analyses: Cronbach's alpha coefficient was calculated to evaluate the internal consistency of the scale. Higher the Cronbach's alpha reliability coefficient (close to 1) indicates that the scale contains items that are consistent and measuring the equivalent features (Gozum and Aksayan 2003). Cronbach's alpha coefficients are generally categorized as follows: substantial internal consistency ($0.81<\alpha<1.00$), moderate ($0.61<\alpha<0.80$), fair ($0.41<\alpha<0.60$), and slight ($0.0<\alpha<0.40$) (Peirce 1995). Test-retest method was used for the reliability analysis. Spearman correlation technique was used to evaluate the relationship between the test and re-test scores of the subjects.

Limitations of the Study: The fact that the data were collected in a single center is one of the limitations of the study.

Results

Socio-demographic Characteristics of the Participants: Mean age of the participants was 60.41 ± 10.76 (min: 36 max: 86); mean duration of diabetes was 7.81 ± 6.05 years (min: 1 year, max: 33 years) (Table 1). Of the participants, 63.7% were female, 86.3% were married, 28.0 % were literate, 56.6% were elementary school graduates, and 63.2% were not employed. The majority of the individuals did not smoke (80.8%) or consume alcohol (98%) (Table 1).

Table 1. Socio-demographic characteristics of the participants (N=182).

Variables	N	%
Age 60.41 ± 10.76 (min-max= 36-86)		
Duration of diabetes 7.81 ± 6.05 years (min -max: 1-33 years)		
Gender		
Male	66	36.3
Woman	116	63.7
Marital Status		
Married	157	86.3
Single	25	13.7
Education		
Literate	51	28.0
Elementary School	103	56.6
Middle School	10	5.5
High School	15	8.2
University	3	1.6
Employment Status		
Employed	27	14.8
Not Employed	115	63.2
Retired	40	22.0
Occupation		
Worker	54	29.7
Civil Servant	20	11.0
Housewife	108	59.3
Smoking		
Yes	35	19.2
No	147	80.8
Alcohol		
Yes	2	1.1
No	180	98.9
Total	**182**	**100**

Results of the Validity Analyses

Language Validity: The scale was translated from English to Turkish by five individuals independently. The scale was translated back to English by a language expert who had never seen the scale in the English language. The Turkish version of the scale was finalized by comparing the expressions in the back-translated and original versions.

Content Validity: In content validity, it is aimed to create a complete scale with relevant items by allowing a panel of experts to examine how well the items in the scale represent the subject to be measured. The scale is reconstructed based on the recommendations and comments of the

experts (Gozum and Aksayan, 2003). Each scale item in the Self-reported Measure of Medication Adherence Scale was scored 1 to 4 by a panel of seven researchers based on Davis technique to measure the item's relevance to the purpose of the scale. Davis technique grades the items as (a) "Item is representative (relevant)", (b) "Item needs a minor revision to be representative", (c) "Item needs major revision to be representative", or (d) "Item is not representative" based on expert opinion. The CVI for an item was calculated by dividing the number of experts checking the choices (a) or (b) to the total number of expert reviewers; a CVI of 0.80 is considered a benchmark instead of a comparison to a statistical criterion (Rubio et al., 2003). Based on the reviews by seven experts according to Davis technique, the CVIs for items and the CVI for the whole measure were found to be 1.

Preliminary Study: It is recommended that the scale is implemented in a group of 10-20 subjects who have similar characteristics with the individuals to be measured but will not be included in the sample (Gozum and Aksayan, 2003). After the language equivalency and content validity studies of the scale, the approved version of the scale was applied to 10 individuals with type-2 diabetes who have been taking oral antidiabetic therapy. Since there was no negative feedback from the participants, the scale was plemented in a sufficiently large sample for the reliability studies.

Construct Validity: Prior to factor analysis, the Kaiser-Meyer-Olkin (KMO) measure of sample adequacy and Bartlett's sphericity test were performed to assess whether the sample was adequate and the factor correlation matrix was appropriate. The KMO was 0.615 (>0.50), which indicated that the sampling was adequate for factor analysis (Sonmez et al, 2017). Bartlett's test result was χ^2=173.9 and statistically significant (p<0.001), which indicated that the correlation matrix of the items was applicable.

Exploratory Factor Analysis (EFA): The unweighted least squares (ULS) method based on the tetrachoric correlation was used for EFA. Total variance explained by four items were found %76.3 (Table 2).

Table 2. The results of factor analysis for scale items.

Items	Factor Load
Item 1	0.955
Item 2	0.955
Item 3	0.757
Item 4	0.788
Eigenvalue	3.053
Total Variance Explained	76.33

Confirmatory Factor Analysis (CFA): The GIFs and standard values in CFA were shown in Table 3.

Table 3. The goodness of fit indexes for the scale.

Compliance Indexes	Value	Normal	Acceptable
X^2/sd	1.568	<2	<5
RMSEA	0.057	<0.05	<0.08
GFI	0.991	>0.95	>0.90
CFI	0.991	>0.95	>0.90

References: (Hooper et al, 2008; Schumacker and Lomax, 2010)

Results of the Reliability Analyses

Internal Consistency: The Cronbach alpha coefficient, which determines the level of equity and the variation between the items were examined. The internal consistency/reliability coefficient was found to be α=0.701 for four items.

Test-retest Reliability: In the test-retest reliability, the scale was administered to 56 participants approximately two weeks apart. The time interval between the two tests is recommended to be long enough not to affect the test scores in the retest since there is a possibility that the respondents may recall the test content. On the other hand, the interval should be short enough not to change the measured characteristics of individuals (Sonmez et al., 2017). Spearman correlation analysis was used to determine

the relationship between the scores obtained from the test and retest. The correlation coefficients for each scale item ranged from 0.63 to 0.73. The analysis indicated a strong positive correlation between the items ($p<0.001$); thus, the scale was found to be reliable over time (Table 4).

Table 4. Test-retest correlations of the scale items.

	Test-retest (n=56)	
Scale Items	**r**	**p**
Item 1.	0.73	<0.001
Item 2.	0.70	<0.001
Item 3.	0.63	<0.001
Item 4.	0.68	<0.001
Cronbach's alpha		0.701

Discussion

In this study, the Turkish version of the Self-reported Measure of Medication Adherence Scale was found to have sufficient validity and reliability to measure medication adherence in individuals with type-2 diabetes who have been taking oral antidiabetic therapy.

The findings related to the reliability of the Turkish version of the Self-reported Measure of Medication Adherence Scale for individuals with type-2 diabetes taking oral antidiabetics were obtained by calculating the Cronbach's alpha internal consistency/reliability coefficient and test-retest reliability coefficients. The Cronbach alpha coefficient is important for determining the internal consistency of the items in the scale and whether the scale is homogeneous. Higher the Cronbach's alpha coefficient (close to 1) indicates that the scale contains items that are consistent and measuring the equivalent features (Gozum and Aksayan 2003). The Cronbach's alpha coefficient was found to be $\alpha=0.701$ for a total of four items. The validity and reliability study of the original scale was performed by Morisky and Green who reported a Cronbach alpha coefficient of 0.61 (Morisky and Green, 1986). In a study evaluating the medication adherence and the side effects among patients using antipsychotic drugs, Cronbach alpha coefficient of the scale was found to be 0.52 (Yılmaz, 2004). Cronbach alpha coefficient was found to be 0.62 in the validity reliability study of the same scale for the bipolar affective disorder (Bahar et al., 2014). The Cronbach alpha coefficient of the Turkish version of the scale in this study was higher than that of the original scale (Morisky and Green, 1986) and other studies (Wang et al., 2012; Bahar et al., 2014; Beyhaghi et al., 2016).

In the test-retest reliability, another reliability analysis, the correlation coefficients of the scale items ranged between 0.63 and 0.73. A strong positive correlation was found between the items ($p<0.001$). In the study by Bahar et al., the correlation coefficients were found to range from 0.64 to 0.96 (Bahar et al., 2014). The results of the test-retest studies indicate that this scale is stable across time.

The factor analysis method was used to examine the construct validity of the scale. The KMO was 0.615 (>0.50); Bartlett's test result was $\chi^2=173.9$ and statistically significant ($p<0.001$). The KMO value indicated that the sampling was adequate for analysis; Bartlett's test result indicated that items correlated well with each other. These analyses suggested that the data were suitable for factor analysis.

Factor analysis revealed that the factor loadings for the scale items ranged from 0.955 and 0.757. It was suggested that the cutoff values of 0.30-0.40 might be chosen to consider an item as an important contributor to the factor (Bahar et al., 2014). The factor loadings of all items were above 0.40 and meet the requirements.

This study found that the scale items could be grouped in one factor, which explained 76.33% of the total variance; higher total variance explained indicates better factor structure.

Conclusion

This study demonstrated that the Turkish version of the Self-reported Measure of Medication Adherence Scale is a valid and reliable self-reported assessment tool for measuring the medication adherence of individuals with type-2 diabetes who use oral antidiabetics. The fact that the scale is composed of clear, understandable, and short expressions facilitates the applicability of the scale and it is considered suitable for clinical use.

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