



Validation Study of the Persian Translation of the Treatment Satisfaction Questionnaire for Medication in Patients Living with Type 2 Diabetes

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Abstract

Introduction: Diabetes is rapidly increasing in Iran, necessitating the improvement of treatment satisfaction to boost patients' adherence and health outcomes. This research investigated the psychometric of the Persian version of the 9-item Treatment Satisfaction Questionnaire for Medication (TSQM-9) in patients diagnosed with type 2 diabetes mellitus (T2DM) in Iran.

Methods: This cross-sectional study, including 126 males and 274 females with T2DM recruited via convenience sampling, was conducted in Kerman, Iran, from January to February 2021. Internal consistency of the TSQM-9 was assessed using Cronbach's alpha and item-total correlations, while construct validity was determined through structural equation modeling (SEM), known-groups comparison, and convergent validity assessment.

Results: Cronbach's alpha for the TSQM-9 total scale and subscales (effectiveness, convenience, and global satisfaction) ranged from 0.91 to 0.98. Item-total correlation coefficients also ranged from 0.57 to 0.87, all exceeding the 0.30 threshold. Moreover, SEM fit indices indicated an adequate model fit ($\chi^2 = 71.5$, $DF = 25$, $P \leq 0.001$, $CFI = 0.99$, $RMSEA = 0.06$, $TLI = 0.98$, $NFI = 0.98$). The mean TSQM-9 scores for both hemoglobin A1C and fasting blood glucose significantly decreased across the first to third tertile groups, demonstrating good known group validity. For convergent validity, the Spearman correlation between the Morisky Medication Adherence Scale and the TSQM-9 total score was 0.33 ($P < 0.001$), indicating a weak but significant relationship.

Conclusion: Our findings revealed that the Persian TSQM-9 possesses adequate validity and reliability, making it suitable for assessing treatment satisfaction in Iranian patients with T2DM by clinicians and investigators.

Keywords: Patient satisfaction, Surveys and questionnaires, Psychometrics, Diabetes mellitus, Iran

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Introduction

Over the past few decades, the global prevalence of diabetes has risen steadily, transforming it into one of the most pressing public health challenges faced by both developed and developing nations.¹ According to the International Diabetes Federation's Diabetes Atlas, more than 536 million adults aged 20–79 years (10.5%) were living with diabetes in 2021, a number expected to exceed 783 million (12.2%) by 2045.² In Iran, the prevalence of diabetes was reported to be 9.3% among individuals aged 30 years and above in 2011, with forecasts indicating an increase to 13.1% by 2030.³ Lifestyle changes and the use of oral medications or insulin to control blood glucose are the basis of diabetes treatment, and patients must undergo lifelong treatment. Furthermore, higher levels of treatment satisfaction are closely associated with better compliance, reduced risk of acute and chronic complications, decreased premature mortality, and lower overall healthcare expenditures.^{4,5}

The World Health Organization seeks to measure and improve patient satisfaction with healthcare services.⁶ Patient satisfaction with treatment is a cognitive and emotional concept through which patients express how their needs are met. This concept is of great importance in measuring the quality of treatment and health services. Treatment satisfaction may also influence patients' adherence to prescribed medications, which is an important factor in achieving optimal treatment outcomes. Medication non-adherence in patients leads to substantial exacerbation of the disease, death, and increased healthcare costs. On the other hand, treatment satisfaction raises the quality of life for individuals with diabetes.⁷ Conversely, dissatisfaction can cause medication non-adherence in patients, thereby increasing death and healthcare costs and worsening the disease.⁸

Numerous studies have employed various instruments to assess treatment satisfaction among patients with diabetes worldwide.^{9–11} The 9-item Treatment Satisfaction

Questionnaire for Medication (TSQM-9) is a common and valid instrument for evaluating patient treatment satisfaction. The TSQM-9 has been designed to measure the three main aspects of treatment satisfaction, namely, effectiveness, convenience, and global satisfaction.¹² It has been translated and validated across multiple languages and disease contexts.¹²⁻¹⁵ In Iran, one study examined the validity and reliability of this instrument among individuals with opium dependence and reported favorable psychometric properties.¹⁵ However, to the best of our knowledge, no prior research has validated the Persian version of the TSQM-9 for diabetic populations. Therefore, the present study aims to evaluate the psychometric properties of the Persian version of the TSQM-9 among individuals diagnosed with type 2 diabetes mellitus (T2DM) in Kerman, southeastern Iran.

Materials and Methods

Participants and Setting

This cross-sectional study was performed on patients with T2DM who attended the Diabetes Center of Kerman University of Medical Sciences in Kerman, southeastern Iran, between January and February 2021. This center is located in a teaching hospital (the third level of the healthcare delivery system in Iran), which delivers healthcare to diabetes patients who were referred from primary healthcare centers. The study included 400 patients with T2DM (126 males and 274 females), selected using a convenience sampling approach, all of whom had been treated with medication for at least one year. Patients with severe and acute physical or mental health problems were excluded from the investigation.

Instruments

A three-section questionnaire was employed for data collection. The first part contained items on demographic factors such as age, gender, occupation, and education, as well as clinical details, such as fasting blood glucose (FBG), hemoglobin A1C levels, and diabetes complications. Further, the second section included the 8-item Morisky Medication Adherence Scale (MMAS-8). This scale encompasses eight items designed to evaluate different dimensions of medication adherence behavior. Items 1–7 use a dichotomous (yes/no) response format, while item 8 is rated on a five-point Likert-type scale. Scores for the first seven items range from 0 to 7, with each item scored as 0 or 1, and responses to item 8 are scored as 0, 0.25, 0.5, 0.75, or 1.^{16,17}

The original version of TSQM was developed and introduced by Atkinson et al.¹⁸ This instrument consists of 14 items across four subscales: effectiveness, convenience, side effects, and global satisfaction. Subsequently, Bharmal et al introduced a revised nine-item version, the TSQM-9, in which the items related to side effects were removed to create a shorter and more focused measure of treatment satisfaction.¹² Therefore, the TSQM-9 includes three subscales: effectiveness (3 items), convenience (3 items), and global satisfaction (3 items). The items of TSQM-

9 are designed on a 5-point Likert-type scale, ranging from strongly disagree to strongly agree. Accordingly, the total TSQM-9 score ranges from 9 to 45. The specific items of the TSQM-9 questionnaire are presented in [Supplementary File 1](#).

Two qualified translators translated the English versions of TSQM-9 into Persian. Following the comparison of two initial translations, one of the researchers performed a back-translation into English. The finalized version was then reviewed and approved by an expert committee comprising three physicians, the research team, and the translators.

Statistical Analysis

Descriptive statistics were calculated for all demographic variables. Cronbach's alpha, Cronbach's alpha if item deleted, inter-item correlations, and item-total correlations were also employed to check internal consistency reliability. Likewise, structural equation modeling (SEM) was used to evaluate the construct validity. Additionally, comparative fit index (CFI) cutoff ≥ 0.90 , root mean square error of approximation (RMSEA) cutoff < 0.08 , Tucker-Lewis index (TLI) cutoff ≥ 0.90 , normed fit index (NFI) cutoff ≥ 0.90 , and chi-square test were reported to assess the fit of the model, and the standardized parameter estimates had to be statistically significant.¹⁹

In addition, known-groups validity was utilized to confirm construct validity. The subjects were categorized based on A1C into 3 groups: the first tertile $\leq 6.7\%$, the second tertile $> 6.7\%$ and $\leq 7.9\%$, and the third tertile $> 7.9\%$. Further, the FBG level was divided into 3 groups: the first tertile ≤ 132.5 , the second tertile > 132.5 and ≤ 180 , and the third tertile > 180 . One-way analysis of variance was also applied to compare A1C and FBG levels for the sum scale and the subscales in terms of these tertile groups. Furthermore, the correlation between the TSQM-9 and MMAS-8 was calculated using Spearman correlation analysis in order to evaluate convergent validity. Data analyses were performed using SPSS (version 20) and AMOS (version 23; IBM Corporation, Armonk, NY, USA), with statistical significance set at a P -value < 0.05 .

Results

Baseline Characteristics

The mean $\pm$ standard deviation (SD) age of the 400 patients was 59.3 (12.3) years, and the median duration of the disease was 11 years (mean = 13.3, SD = 8.5). In addition, 80% ($n = 320$) of the patients were married, and 68.5% ($n = 274$) were female. Only 12% ($n = 48$) of the participants were employed, and the rest were unemployed, retired, or homemakers. Further, a quarter of the participants ($n = 100$) were illiterate, and over 41% ($n = 166$) of them had high school or university education. Moreover, more than half of the patients (52%, $n = 208$) had at least one diabetes-related complication. Furthermore, the median A1C and FBG were 7% (mean = 7.5%, SD = 1.6%) and 155.5 mg/dL (mean = 172.7, SD = 84.0), respectively.

Item Analysis and Internal Consistency

The mean and SD of the total scores of the TSQM-9 were 34.9 and 9.8, respectively. Likewise, the sum scale Cronbach's alpha of the TSQM-9 was 0.93. Cronbach's alpha values for effectiveness, convenience, and global satisfaction subscales were also 0.98, 0.98, and 0.91, respectively. If each of the 9 items was deleted, the Cronbach's alpha values did not increase more than 0.02. The mean item-total correlation of the TSQM-9 was 0.85 (SD=0.01), 0.57 (SD=0.01), and 0.80 (SD=0.08) for the effectiveness, convenience, and global satisfaction subscales, respectively. Additionally, item-total correlation coefficients ranged from 0.57 to 0.87, and all of them were higher than 0.30. Finally, the mean item-subscale correlation coefficients were 0.98 (SD=0.01) for the effectiveness subscale, 0.97 (SD=0.01) for the convenience subscale, and 0.92 (SD=0.05) for the global satisfaction subscale (Table 1).

Construct Validity

The SEM showed that the individual standardized parameters for all the items in the model were higher than 0.3, and all these standardized parameters were statistically significant (Table 2). Moreover, all the indices were acceptable ($\chi^2=71.5$, $DF=25$, $P\leq 0.001$, $CFI=0.99$, $RMSEA=0.06$, $TLI=0.98$, and $NFI=0.98$; Figure 1).

Known-Groups Validity

The TSQM-9 sum scale means for the first, second, and third tertile groups of A1C were 40.0, 35.2, and 29.7, respectively ($P<0.001$). In addition, the mean of the TSQM-9 sum scale decreased from the first (38.5) to the third (31.5) FBG tertile ($P<0.001$). Similarly, there were significant decreasing values from the first to the third tertile for A1C and FBG levels (Table 3).

Convergent Validity

The Spearman correlation between the MMAS-8 and the sum-scale of TSQM-9 was 0.33 ($P<0.001$). Additionally, a weak but positive relationship was found between the TSQM-9 subscales and the MMAS-8 scores, which equaled 0.23 ($P<0.001$), 0.32 ($P<0.001$), and 0.26 ($P<0.001$) for convenience, effectiveness, and global satisfaction subscales, respectively.

Discussion

The present study assessed the validity and reliability of the Persian version of the TSQM-9 among individuals with T2DM in Iran. The results revealed that the internal consistency of the TSQM-9 was acceptable, so the questionnaire was reliable. Moreover, SEM was used to assess the construct validity. The SEM results demonstrated that the questionnaire consisted of three

Table 1. Distribution of Items, Internal Consistency, and Item-Total Correlation

Subscale	Item	Mean	Standard Deviation	Item-Total Correlation	Item-Subscale correlation	Cronbach's Alpha if Item Deleted
Effectiveness	Q1	3.77	1.43	0.84	0.98	0.91
	Q2	3.82	1.38	0.84	0.98	0.91
	Q3	3.79	1.39	0.87	0.99	0.91
Convenience	Q4	3.96	1.34	0.57	0.97	0.93
	Q5	3.97	1.333	0.57	0.98	0.93
	Q6	4.01	1.30	0.58	0.98	0.93
Global satisfaction	Q7	3.93	1.35	0.83	0.95	0.91
	Q8	3.87	1.28	0.70	0.87	0.92
	Q9	3.82	1.38	0.86	0.95	0.91

Table 2. Structural Path Estimates for the TSQM-9 Questionnaire in Iranian Patients With Diabetes

Construct/Path	Item/Predictor	Standardized Loading	Unstandardized Estimate	SE	CR	P-Value
Structural Model						
Effectiveness	Global satisfaction	0.97	0.99	0.018	56.14	<0.001
Convenience	Global satisfaction	0.34	0.32	0.046	6.97	<0.001
Measurement Model						
Effectiveness	Q3	0.99	1.00	--	--	--
	Q2	0.98	0.97	0.012	78.14	<0.001
	Q1	0.97	0.99	0.015	66.47	<0.001
Convenience	Q6	0.98	1.00	--	--	--
	Q5	0.97	1.01	0.016	62.79	<0.001
	Q4	0.96	1.01	0.017	57.70	<0.001
Global satisfaction	Q9	0.98	1.00	--	--	--
	Q8	0.72	0.68	0.034	20.15	<0.001
	Q7	0.94	0.94	0.020	45.89	<0.001

Note. TSQM-9: 9-item Treatment Satisfaction Questionnaire for Medication. Fixed parameter for scale identification (--). SE: Standard error; CR: critical ratio.

Table 3. Known-Groups Validity for A1C and FBG Using One-Way ANOVA

Subscale	A1C				FBG			
	First Tertile (n=137)	Second Tertile (n=123)	Third Tertile (n=140)	P-Value	First Tertile (n=133)	Second Tertile (n=116)	Third Tertile (n=51)	P-Value
Effectiveness	13.7 (2.4)*	11.4 (3.8)	9.1(4.5)	<0.001	13.0 (3.1)	11.3 (3.9)	10.0 (4.6)	<0.001
Convenience	12.8 (3.5)	12.2 (3.6)	10.8 (4.1)	<0.001	12.5 (3.6)	12.2 (3.8)	11.2 (4.1)	0.01
Global satisfaction	13.5 (2.1)	11.6 (3.5)	9.7 (4.1)	<0.001	13.0 (2.6)	11.7 (3.6)	10.3 (4.2)	<0.001
Sum-scale	40.0 (6.5)	35.2 (9.0)	29.7 (10.4)	<0.001	38.5 (7.7)	35.3 (9.2)	31.5 (10.6)	<0.001

Note. ANOVA: One-way analysis of variance; SD: Standard deviation. *Values are presented as means $\pm$ standard deviation; A1C: Hemoglobin A1c; FBG: Fasting blood glucose.

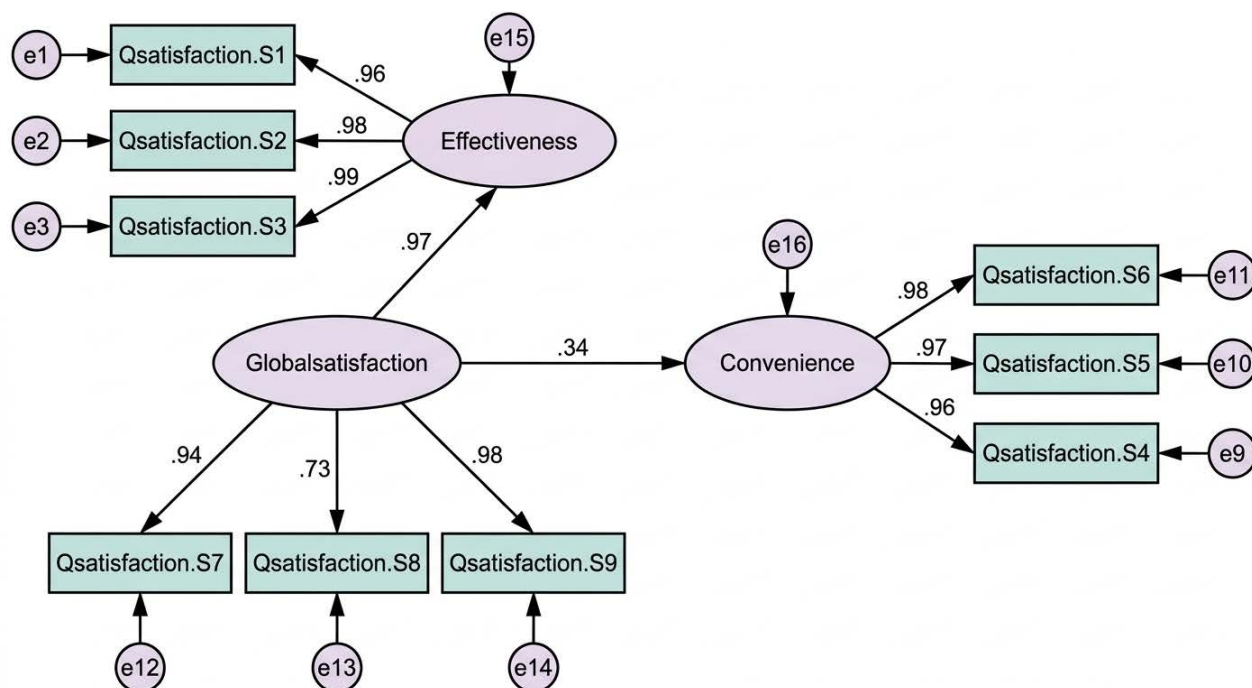


Figure 1. Structural Equation Modeling Analysis for TSQM-9
Note. TSQM-9: 9-item Treatment Satisfaction Questionnaire for Medication

dimensions, including convenience, effectiveness, and global satisfaction. In addition, TSQM-9 scores for the subscales and the sum scale significantly decreased from the first to the third A1C and FBG tertile. Convergent validity was also evaluated between the MMAS-8 and the sum scale and subscales of the TSQM-9 using Spearman correlation, and there was a weak positive significant correlation.

Further, the Cronbach's alpha coefficients for the total scale and all subscales of the TSQM-9 exceeded 0.90, indicating excellent internal consistency. Consistent with this result, previous studies reported Cronbach's alpha values for the total scale ranging from 0.70 to 0.94 across different disease populations.^{12-15,19,20} According to the findings of the original validation study, the Cronbach's alpha coefficients for the effectiveness, convenience, and global satisfaction subscales were 0.90, 0.88, and 0.86, respectively, which corroborates our results.¹⁹ Similarly, a study conducted among hypertensive patients reported Cronbach's alpha values of 0.94 for effectiveness, 0.91 for convenience, and 0.84 for global satisfaction.¹²

Overall, the findings confirmed that the Persian version of the TSQM-9 demonstrates excellent internal

consistency among patients with diabetes, which conforms to psychometric results obtained in studies of other diseases and languages.

Based on the findings, item total correlation coefficients ranged from 0.57 to 0.87, with all values exceeding 0.30, suggesting a strong relationship between each item and the total score. Likewise, the results of a study performed among warfarin users in Saudi Arabia represented that item-total correlations ranged from 0.439 to 0.747, and another study in the United States involving patients receiving antihypertensive therapy found all correlations above 0.65.^{12,13} Therefore, these findings highlight that the Persian version of the TSQM-9 exhibits satisfactory internal consistency, aligning well with the results reported for other disease populations in both Saudi Arabia and the United States.

The standardized estimates for all items exceeded 0.30 and were statistically significant, showing adequate model fit. In a validation study of the TSQM-14 in patients with cystic fibrosis, the standardized factor loadings for the effectiveness, convenience, and global satisfaction subscales ranged from 0.67 to 0.93, reflecting a satisfactory model fit.¹⁴ Furthermore, the finding of a

study conducted among hypertensive patients using the TSQM-9, the standardized parameter estimates for all items were above 0.67, with CFI and NFI values greater than 0.95.¹² In line with these findings, the Persian version of the TSQM-9 among diabetes patients displayed good construct validity.

The results indicated that the mean scores for the overall scale and its subscales substantially decreased from the first to the third tertile of A1C and FBG levels, supporting acceptable known-groups validity. Similarly, some previous studies conducted in Saudi Arabia and the United States demonstrated acceptable known-groups validity for the TSQM-9.^{12,13}

The findings of this study revealed significant but weak positive correlation coefficients ranging from 0.23 to 0.33 between the TSQM-9 score and its subscales and the MMAS-8. Moreover, studies conducted in the United States and Saudi Arabia reported comparable weak correlations, ranging from 0.34 to 0.46 and 0.29 to 0.32, respectively.^{12,13} Overall, these findings consistently demonstrate a low degree of association between the TSQM-9 and MMAS-8 in assessing convergent validity. This modest relationship may stem from the conceptual differences between the two instruments, as they measure distinct constructs: treatment satisfaction and medication adherence. Therefore, the MMAS-8 may not be an ideal comparative measure for evaluating treatment satisfaction. Instead, employing an instrument that captures a similar construct, such as the Diabetes Treatment Satisfaction Questionnaire, would be more appropriate.^{21,22}

Although this was the first study to investigate the psychometric properties of the TSQM-9 among individuals with T2DM, it had several limitations. First, the study did not include repeated measurements over time to assess test-retest reliability, which could have provided additional evidence of instrument stability. In addition, the participants were recruited from a tertiary care diabetes clinic, where most patients exhibited poor disease control and multiple complications, potentially limiting the representativeness of the sample. While the process of translation and back-translation was rigorously followed, no formal quantitative assessment of content validity (e.g., calculating the content validity ratio and content validity index) was performed in this study. Additionally, although the face validity and qualitative content were confirmed by a panel of experts, the absence of quantitative indices remains a methodological limitation that should be considered when interpreting the developmental phase of the instrument. Moreover, reliance on convenience sampling has introduced selection bias, potentially compromising the external validity of the results. Considering that the study was conducted within a single tertiary care institution, the findings may not be entirely generalizable to the wider Iranian diabetic population, especially those in rural or primary care settings. Thus, the extrapolation of these findings to different socioeconomic or clinical strata should be approached conservatively.

Conclusion

The Persian version of the TSQM-9 has acceptable reliability and good construct validity. Therefore, it can be applied to measure satisfaction with medication among Iranian diabetic patients by health-care providers and researchers. However, it seems that the MMAS-8 is not a suitable scale for assessing the convergent validity of the TSQM-9; hence, it is recommended that future studies use a proper instrument to achieve this goal.

The study was performed according to the ethical principles in medical science research. Moreover, the study proposal was approved by the Ethics Committee of Kerman University of Medical Sciences (ethical code: IR.KMU.REC.1399.522).

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Artificial Intelligence Disclosure

AI-based tools were used solely for editing the language and improving the clarity of the manuscript. However, no AI tools were employed to generate scientific content, data, analyses, interpretations, results, or conclusions. The authors take full responsibility for the accuracy and integrity of the work.

Authors' Contribution

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Competing Interests

All authors declare that they have no conflict of interests.

Ethical Approval

Patients were enrolled with informed consent and were assured of personal data confidentiality. In addition, the questionnaire was anonymously completed, and all stages of the study were.

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Supplementary File

Supplementary File contains Table S1.

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