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ORIGINAL ARTICLE

# Psychometric properties of Persian Diabetes-Mellitus Specific Quality of Life (DMQoL) questionnaire in a population-based sample of Iranians

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## Abstract

Health-related quality of life (HRQoL) among patients with diabetes mellitus is often poorer than in those with other chronic medical conditions. Appropriate disease specific measures are needed to measure HRQoL in these patients. This study sought to validate a culturally adapted version of the Diabetes-Mellitus Specific Quality of Life (DMQoL) questionnaire module in Persian. Concurrent validity of the scale was assessed by the Diabetes Quality of Life (DQOL) questionnaire. Convergent and discriminative validity of the DMQoL was determined using a brief version of World Health Organization's Quality of Life Scale Brief version (WHOQOL-BREF), Hospital Anxiety and Depression Scales (HADS), and Medication Adherence Report Scale (MARS). Construct validity was examined using confirmatory factor analysis. Rasch analysis was also performed to examine the unidimensionality of the DMQoL. Known-group method was used to examine the ability of the scale to differentiate between different categories of patients. A sample of 824 patients (512 females) with diabetes mellitus was recruited from diabetic care centers located in Qazvin, Iran. The mean age of participants was 54.1 (SD 6.3) and 27% were smokers. All items loaded on a single factor (factor loadings $\geq 0.6$) and internal consistency of the scale was acceptable ($\alpha = 0.89$). Significant associations were found between the scale and DQOL, indicating concurrent validity ($p < 0.001$). The DMQoL was able to differentiate subgroups of patients with hypertension, HbA1c, cholesterol, and diabetic diet. All items were appropriate with regard to difficulty level and confirmatory factor analysis verified the scale's single dimension (CFI = 0.927; RMSEA = 0.067). Persian DMQoL is a reliable and valid measure of HRQoL in a Persian-speaking population with type II diabetes. Further assessment is needed to confirm the psychometric properties of the scale in other cultures and languages. Future studies are needed to determine the sensitivity of the scale to change over time in response to treatment.

**Keywords** Diabetes mellitus · Health-related quality of life · Psychometrics · Validity · Reliability

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## Introduction

Diabetes mellitus (DM) is a global health problem that threatens the lives of many people, particularly those who pursue a sedentary lifestyle, are overweight or obese, and those with a familial history of diabetes [1]. The prevalence of DM is increasing worldwide and is estimated by 2035 to affect 592 million people (i.e., 7% of world population) [2]. The mortality rate attributed to DM is also considerable and those with this disease experience an age-adjusted death rate that is nearly twice that of healthy people [3]. DM is not limited to a particular region, ethnicity, culture, or country, and those in both developed and developing countries are at risk. In the UK, 6–9% of people over age 65 years suffer from DM [4] and the prevalence is even higher in the US population with more than one fourth of older adults affected [5]. Among Asian countries, the prevalence is also high, particularly in countries such as China, Malaysia, Taiwan, and Turkey that reported a DM prevalence of 8–15% [6–8]. The prevalence of the disease in Iran has increased substantially over the past two decades and is now estimated to be about 5% in general population and nearly 14% in older adults [9, 10].

Chronic diseases such as diabetes include various physical, psychological, social, and cultural dimensions that may affect the development and progression of the disease. Consequently, monitoring diabetics only by laboratory assessments such as fasting blood sugar, hemoglobin A1C, lipid profile, and blood pressure does not provide a holistic approach to this disease [1]. Health-related quality of life (HRQOL) is a patient-centered measure of health that informs health care providers about patients' perceptions of how the disease is affecting them. This construct describes the individual's perception of their health in the context of their social, cultural, and value systems and in light of their goals, standards, and life concerns [11]. Utilizing HRQOL as a measure of subjective health is a common practice for chronic diseases such as diabetes particularly since many studies have shown that people with DM have poorer HRQOL than those with other chronic diseases or those who are healthy [12–14]. This construct is also useful for describing the overall effectiveness of all interventions implemented to improve health [11].

There are two primary categories of HRQOL instruments, those that assess this construct more generally and disease-specific measures. Although both types of measure may provide valuable information regarding patients perceptions of their health, disease-specific measures have been recognized as more efficient in assessing different aspects of a disease that may not be captured by more general measures [15]. Measures assessing disease-specific HRQOL also have higher sensitivity to change in response to therapeutic interventions because the items are adapted to the particular disease. Thus, disease-specific measures are more likely to capture the effects that a specific disease has on an individual's performance and functioning [16].

To date, many disease-specific measures have been developed for people living with DM. Examples of these are the Diabetes Quality of Life (DQOL) Scale [17], health-related quality of life measure in older African American women with type II diabetes [18], Audit of Diabetes-Dependent Quality of Life (ADDQoL) Scale [19], and Diabetes Quality of Life Clinical Trial Questionnaire (DQLCTQ) [20]. However, these measures are usually available only in English and are specifically developed for those who live in Western countries. The cultural and contextual factors that may influence the use of these measures in different regions or countries have not yet been determined. Recently, a new disease-specific measure of the HRQOL in diabetics has been translated and culturally adapted for use among Persian speaking people (i.e., DQOL) [21]. Adapting an instrument such as this one (originally developed in one particular region) for those in other regions of the world will enrich the measure's use more globally.

The Diabetes-Mellitus Specific Quality of Life (DMQoL) scale was initially developed to assess HRQOL among Taiwanese patients with DM. This is a short disease-specific measure with only 10 items derived from recommended guidelines for the disease. The authors used objective measures such as HbA1c, lipid profile, and glomerular filtration rate, along with the World Health Organization Quality of Life Scale Brief version (WHOQOL-BREF) to develop the scale. The DMQoL has been used for two purposes, both individually as a stand-alone disease-specific measure and as a module of the WHOQOL-BREF [22]. Thus, this measure allows for the determination of both general and specific profiles of HRQol for a target population. Assessment of the DMQoL's psychometric properties has shown it to be a reliable valid measure for use in other languages and populations. The limited number of items allows researchers to determine the quality of life of participants in a brief manner.

Given the relatively few scales available to measure HRQOL in Iranian patients, we decided to conduct a linguistic and cultural validation of the DMQoL in Persian-speaking diabetics in Iran.

## Methods

### Design

The study was conducted in two phases. In the first phase, the DMQoL was translated into Persian and culturally adapted. The second phase involved evaluating the psychometric properties of the DMQoL in Iranian patients with diabetes mellitus. The study was approved by the Ethic Committee at Qazvin University of Medical Sciences, and all patients gave written informed consent prior to participation.

### Participants

Participants were selected based on consecutive sampling technique. The patients with type II diabetes being seen at specialty outpatient clinics of the Qazvin University of Medical Sciences in Qazvin (a city near to Tehran, Iran) were selected from August until September 2017. Patients were eligible if they were 18 years of age or older with a diagnosis of diabetes mellitus type II determined by a physician, spoke Persian, and were willing to participate in the study. Patients were excluded if they had significant cognitive impairment (Mini-Mental State Examination [MMSE] less than 26), major psychiatric disorders (psychotic and bipolar disorders), or were pregnant.

### Translation procedure

The translation procedure was performed based on international guidelines for cross-cultural adaptation of measures [23]. The following steps were taken to adapt the English version of the DMQoL into Persian/Farsi. First, two bilingual translators translated the DMQoL into Persian independently (forward translation). The translators had different academic backgrounds and training (in medicine and in history) as recommended. The two translated versions were then compared and synthesized into one Persian version by consensus of the translators. The resulting Persian version was then translated back into English by two different translators whose native language was English (backward translation). The translators worked independently and were blinded to the original English version of the DMQoL. An expert committee (endocrinologist, nurse, psychologist, epidemiologist, and the translators) was then convened to construct the semi-final version of the Persian DMQoL. This version was then piloted in 37 diabetic patients (21 women and 16 men, mean age 51.2 years). Patients were interviewed to determine their views regarding how easy the items were to understand in terms of phrasing, response options, and initial instructions. Additional revisions were performed on the Persian DMQoL based on the pilot testing, and the final version was then administered to 824 patients with DM to assess its psychometric properties.

## Measures

### Socio-demographic factors

Data on age, gender, education, living situation, duration of diabetes, type of treatment, and smoking status were collected.

### Anthropometric measures

Participants' height (cm) and weight (kg) were measured in the standard fashion to calculate body mass index (BMI).

### Biochemical measures

Overnight fasting (12 h) blood samples were taken from patients to determine blood sugar (FBS) and were assessed by a HbA1cbya glucometer (YSI 2700 Select, YSI, Inc., Yellow Springs, OH) and by ion exchange chromatography (DS5 Analyzer, Drew Scientific Limited, Cumbria, UK). In addition, triglyceride (TG), total cholesterol, high-density lipoprotein (HDL), low-density lipoprotein (LDL), creatinine (Cr), and blood urea nitrogen (BUN) were assessed using an auto analyzer (Liasys, AMS, Italy). Glomerular filtration rate (eGFR) was then calculated based on age, gender, blood creatinine, and body size using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation. An eGFR < 60 ml/min is defined as chronic kidney disease.

### Blood pressure and related complications

Systolic and diastolic blood pressures were measured using the left arm (mmHg) by a mercury sphygmomanometer after 15 min of rest in the seated position.

The presence of diabetes-related complications (e.g., retinopathy, coronary heart disease (CHD), and neuropathy) was determined based on the International Classification of Diseases, ninth version (ICD-9), using patients' medical records.

### WHOQOL-BREF

The WHOQOL-BREF is a brief version of WHOQOL-100 that is used to assess quality of life. The WHOQOL-BREF consists of 26 items that cover four domains: physical health, psychological health, social relationships, and environment. Higher scores on each domain and on the overall measure indicate better quality of life. The WHOQOL-BREF has been translated into several languages including Persian [24].

### DQOL

The DQOL is a diabetes-specific measure of quality of life used in diabetic patients. It contains 46 items with four subscales that assess satisfaction with treatment, impact of treatment, worry about the future effects of diabetes, and worry about social/vocational issues. All items are rated on a five-point Likert scale, with higher scores indicating more complications or greater dissatisfaction. In addition, a total score is computed. The Persian version of the DQOL has been shown to have acceptable psychometric properties for use in adult Iranian diabetics [21].

### Hospital Anxiety and Depression Scale

Psychological distress was assessed using the Hospital Anxiety and Depression Scale (HADS), a 14-item self-report measure that assesses symptoms of depression and anxiety. All items are scored on a four-point Likert scale (range 0–3) with higher scores indicating higher distress. The psychometric properties of the Persian version of the HADS have been examined and found to be acceptable in Iranian patients [25].

### Medication Adherence Report Scale

The Medication Adherence Report Scale (MARS) is a self-report measure of medication adherence. It contains five items, each rated on a five-point Likert scale with an overall score ranging from 5 to 25, where higher scores indicate better adherence. The psychometric properties of the Persian version of the MARS have been examined among Iranian patients and found to be acceptable [26].

### DMQoL

The DMQoL was recently developed to assess quality of life among patients with DM. The DMQoL consists of 10 items scored on a five-point Likert scale with higher scores indicating better quality of life [22].

### Statistical analysis

Two categories of measurement properties were examined: classical test theory (CTT) and the Rasch model. The CTT is a traditional quantitative approach for assessing the reliability and validity of a measure (e.g., corrected item-total correlation, factor analysis). However, the CTT uses an inappropriate scoring system (e.g., means and standard deviations) and does not assess item difficulty and person ability (influence of respondent's abilities, attitudes, or personality traits). The Rasch model is a modern psychometric model that can estimate item difficulty and person ability. Therefore, both CTT and Rasch analyses were performed. CTT analyses were conducted using MPLUS version 7 (Muthén and Muthén 2012), and Rasch analysis was performed using WINSTEPS version 4.0.1. The Persian version of the DMQoL was examined for response rate, floor and ceiling effects, construct validity, internal consistency, concurrent validity, test-retest reliability, known-group validity, item difficulty, and item and person separation reliability.

Floor effects (percentage of the sample achieving the lowest possible scores) and ceiling effects (percentage of the sample achieving the highest possible scores) were computed. Floor and ceiling effects are present if 20% of the participants provide minimum or maximum possible scores.

Internal consistency was assessed by the Cronbach's alpha coefficient and corrected item-total correlation. A Cronbach's alpha > 0.70 is considered satisfactory, as are corrected item-total correlations > 0.40. Test-retest reliability was evaluated in 783 patients who completed the Persian DMQoL on two occasions (baseline and 3 weeks later). The intra-class correlation coefficient (ICC) between the scores at baseline and 3 weeks later was used to assess reliability across time.

In order to confirm the factor structure of the Persian DMQoL, a confirmatory factor analysis (CFA) was performed to assess construct validity and confirm the factor structure reported in the original study. Due to the ordinal nature of the data, weighted least squares estimation (WLS) with poly choric correlations and an asymptotic covariance matrix were computed. Goodness of fit was assessed using the following fit indices: chi-squared test ($\chi^2$), comparative fit index (CFI), Tucker-Lewis index (TLI), root-mean-square error of approximation (RMSEA), and standardized root-mean-square residual (SRMR). A nonsignificant $\chi^2$, CFI, TLI > 0.90, RMSEA, and SRMR < 0.80 support the construct validity of a measure. Additionally, a series of multigroup CFA's were conducted to examine structural invariance across subgroups of the patients based on gender and living situation. These models were examined for factorial invariance, configural invariance (pattern of factor loadings), metric invariance (the magnitude of factor loadings), and scalar invariance (the magnitude of item intercepts). According to Chen, factorial invariance is confirmed if $\Delta$CFI > − 0.01, $\Delta$SRMR < 0.01, and $\Delta$RMSEA < 0.015 [27].

Pearson correlation coefficients were computed between the DMQoL and other instruments (WHOQOL-BREF, HADS, DQOL, and MARS) to measure concurrent validity. These correlations were controlled for age and gender.

To examine known-group validity, an independent *t* test was performed to determine whether the DMQoL total score differed among subgroup of patients based on specific characteristics of diabetic patients. It was hypothesized that patients with higher HbA1c, higher cholesterol, and the presence of diabetic complications (e.g., hypertension, diabetic foot, neuropathy, and retinopathy) would show differences in quality of life.

Rasch rating scale models were used to examine item difficulty and person separation reliability. Information-weighted fit statistic (in fit) mean square (MnSq) and outlier-sensitive fit statistic (outfit) MnSq were used to determine item fit. Item fit is supported if in fit or outfit MnSq are between 0.5 and 1.5. Differential item functioning (DIF) was also examined for DMQoL in terms of gender and situation to further investigate the measurement variance of the DMQoL at the item level. A DIF contrast (the difficulty for group 1 minus the difficulty for group 2) < 0.5 logits is considered small or absent.

## Results

The mean (SD) age of participants was 54.1 (6.3) years, and the majority were female. More than half of participants were illiterate or had only an elementary school education. Nearly 70% of subjects were from rural areas. Hypertension (37%), ischemic heart disease (35%), and nephropathy (31%) were the most prevalent health problems. The mean (SD) for laboratory parameters were HbA1c = 7.9 (2.1%), triglyceride = 161.6 (11.0 mg/dl), and cholesterol = 183.4 (30.2), all of which exceeded international normal ranges. Details of other clinical and demographic characteristics are presented in Table 1.

There was no floor (ranged from 0.7 to 3.1%) or ceiling effects (ranged from 0.4 to 10.4%) for any of the items or for the total score.

As shown in Table 2, all items of the DMQoL loaded on a single factor with high factor loadings (≥ 0.6) and corrected item-total correlations (≥ 0.64). Test-retest reliability was excellent for all items (ICC ≥ 0.78). Rasch analysis revealed that participants in different genders or in different living situations (rural vs. urban) interpreted the ten-item descriptions in a similar fashion (DIF < 0.5). Multigroup CFA further confirmed that participants in different gender (ΔCFI = − 0.005 and − 0.001; ΔRMSEA = 0.002 and 0.005) or in different living situations (ΔCFI = − 0.001 and − 0.004; ΔRMSEA = − 0.004 and 0.005) interpreted the DMQoL similarly (Table 3).

Internal consistency was high (α = 0.89), as was separation reliability based on the Rasch analysis (person separation = 0.88; item separation = 0.95). Measures for the CFA were in all in acceptable ranges ($\chi^2$ = 159.2; CFI = 0.927; TLI = 0.916; RMSEA = 0.067; SRMR = 0.049) (Table 4). In addition, the DMQoL total score demonstrated acceptable average variance extracted (0.51), satisfactory composite reliability (0.91), and low standard error of measurement (0.202).

Associations between the DMQoL and the DQOL (total score and subscale scores) were robust (*r* = − 0.398 to − 0.512), indicating concurrent validity for the DMQoL. Associations between the DMQoL and other instruments were likewise significant (*r* = 0.241 to 0.467 for WHOQOL-BREF; − 0.301 and − 0.382 for HADS; 0.341 for MARS), again supporting the concurrent validity of the DMQoL (Tables 5 and 6).

Similar to the DQOL, the DMQoL differentiated patients with and without hypertension, those having high HbA1c and low HbA1c, those having high and low cholesterol, and those consuming diabetic foods and those not ($p < 0.05$). However, the DMQoL could not differentiate those with and without nephropathy (Table 7).

**Table 1** Participant characteristics (*n* = 824)

| | Mean (SD) | *n* (%) |
|---|---|---|
| Age (year) | 54.1 (6.3) | |
| Gender (female) | | 512 (62.1) |
| Educational year | 6.9 (4.1) | |
| Body mass index (kg/m $^2$) | 28.2 (4.5) | |
| Currently smoker (yes) | | 223 (27.1) |
| Living situation | | |
| Rural | | 585 (71.0) |
| Urban | | 239 (29.0) |
| Diabetes-related complications | | |
| Hypertension | | 304 (36.9) |
| Neuropathy | | 255 (30.9) |
| Nephropathy | | 171 (20.8) |
| Retinopathy | | 102 (12.4) |
| Diabetic foot | | 181 (22.0) |
| Ischemic heart disease | | 288 (35.0) |
| Systolic blood pressure (mmHg) | 135.4 (19.1) | |
| Diastolic blood pressure (mmHg) | 87.8 (15.2) | |
| Fasting blood sugar (mg/dl) | 162.8 (85.2) | |
| HbA1c, percentage, | 7.9 (2.1) | |
| Creatinine (mg/dl) | 0.9 (0.3) | |
| Blood urea nitrogen (mg/dl) | 18.1 (7.6) | |
| Triglyceride (mg/dl) | 161.60 (11.0) | |
| Total cholesterol (mg/dl) | 183.4 (30.2) | |
| LDL- cholesterol (mg/dl) | 118.1 (61.6) | |
| HDL- cholesterol (mg/dl) | 56.4 (41.2) | |
| Duration of diabetes (years) | 13.1 (5.7) | |
| eGFR | 89.2 (3.2) | |
| Oral agent, n (%) | | 596 (72.3) |
| Insulin | | 98 (11.9) |

## Discussion

The present study examined the psychometric properties of the Persian version of the DMQoL among a sample of Iranian patients with DM. We found that this measure had acceptable concurrent and construct validity as well as high internal consistency and test-retest reliability. In addition, known-group validity revealed its value in differentiating between patients with different diabetic characteristics indicating high sensitivity of the DMQoL across various conditions. Measurement invariance analyses confirmed the scale's ability to assess HRQOL among different groups of patients. Finally, the unidimensional nature for the DMQoL was confirmed using CFA and Rasch analyses.

Although not an epidemiological study designed to determine prevalence rates, the sex distribution of the sample was consistent with current rates of type II diabetes in women more generally [28, 29]. Furthermore, females usually access health services at a higher rate than males, which may explain the higher number of women in this sample (62%). CFA in a sample of 200 subjects (5–10 persons per item) would have been sufficient for the

**Table 2** Psychometric properties of DMQoL at the item level

| Item no. | Analyses from classical test theory | | | Analyses from Rasch | | | | |
|---|---|---|---|---|---|---|---|---|
| | Factor loading[a] | Item-total correlation | Test-retest reliability[b] | InfitMnSq | Outfit MnSq | Difficulty | DIF contrast across gender[c, d] | DIF contrast across living situation[c, e] |
| DMQoL-1 | 0.70 | 0.73 | 0.92 | 0.96 | 0.94 | − 0.51 | 0.02 | − 0.08 |
| DMQoL-2 | 0.60 | 0.64 | 0.81 | 1.30 | 1.35 | 0.38 | − 0.43 | − 0.03 |
| DMQoL-3 | 0.78 | 0.79 | 0.84 | 0.81 | 0.74 | 0.03 | − 0.03 | − 0.05 |
| DMQoL-4 | 0.77 | 0.77 | 0.86 | 0.90 | 0.88 | − 0.06 | 0.02 | − 0.36 |
| DMQoL-5 | 0.73 | 0.74 | 0.85 | 0.87 | 0.93 | 0.34 | − 0.38 | − 0.15 |
| DMQoL-6 | 0.69 | 0.73 | 0.82 | 1.16 | 1.06 | − 0.28 | 0.28 | − 0.04 |
| DMQoL-7 | 0.63 | 0.66 | 0.81 | 1.06 | 1.06 | 0.05 | 0.07 | 0.20 |
| DMQoL-8 | 0.80 | 0.77 | 0.78 | 0.68 | 0.70 | − 0.37 | − 0.02 | 0.01 |
| DMQoL-9 | 0.74 | 0.80 | 0.87 | 1.11 | 1.09 | 0.05 | 0.37 | 0.07 |
| DMQoL-10 | 0.67 | 0.69 | 0.79 | 1.12 | 1.13 | 0.38 | 0.15 | 0.08 |

*DMQoL* diabetes-specific quality of life questionnaire, *MnSq* mean square error, *DIF* differential item functioning

[a] Based on the first-order confirmatory factor analysis

[b] Using intraclass correlation coefficient (ICC)

[c] DIF contrast > 0.5 indicates substantial DIF

[d] DIF contrast across gender = difficulty for females − difficulty for males

[e] DIF contrast across accommodation = difficulty for participants living in rural − difficulty for participants living in urban

present study [11]. Therefore, including a large number of participants here may be considered as strength because it increases the study's power. In the initial study that developed the DMQoL, only 117 participants were included due to limitations involving the costs of laboratory tests [22]. In other studies which have done psychometric assessment of new instruments for disease-specific measures of HRQOL among patients with DM, the sample size has ranged between 100 and 500 subjects [18–20, 30].

Obesity, hyperlipidemia, hypertension, and poor health behavior such as smoking are modifiable risk factors in DM [1]. These conditions were also prevalent in our

**Table 3** Measurement invariance across gender and across living situation (rural vs. urban) by confirmatory factor analysis

| Model and comparisons | Fit statistics | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | $\chi^2$ (*df*) | $\Delta\chi^2$ ($\Delta$*df*) | CFI | ΔCFI | SRMR | ΔSRMR | RMSEA | ΔRMSEA |
| Gender (male vs. female) | | | | | | | | |
| M1: configural | 280.03 (70)* | | 0.925 | | 0.051 | | 0.063 | |
| M2: plus all loadings constrained | 295.35 (80)* | | 0.920 | | 0.060 | | 0.065 | |
| M3: plus all intercepts constrained | 310.58 (90)* | | 0.919 | | 0.064 | | 0.070 | |
| M1 vs. M2 | | 15.35 (10) | | − 0.005 | | 0.009 | | 0.002 |
| M1 vs. M3 | | 15.23 (10) | | − 0.001 | | 0.004 | | 0.005 |
| Accommodation (rural vs. urban) | | | | | | | | |
| M1: configural | 341.99 (70)* | | 0.915 | | 0.039 | | 0.075 | |
| M2: plus all loadings constrained | 352.72 (80)* | | 0.914 | | 0.048 | | 0.071 | |
| M3: plus all intercepts constrained | 366.62 (90)* | | 0.910 | | 0.057 | | 0.076 | |
| M1 vs. M2 | | 10.81 (10) | | − 0.001 | | 0.009 | | − 0.004 |
| M1 vs. M3 | | 13.9 (10) | | − 0.004 | | 0.009 | | 0.005 |

*M1* model 1, a configural model; *M2* model 2, a model based on M1 with all factor loadings constrained being equal across groups; *M3* model 3, a model based on M2 or M2P with all item intercepts constrained being equal across groups; *CFI* comparative fit index; *SRMR* standardized root-mean-square residual; *RMSEA* root-mean-square error of approximation

*$p < 0.05$

**Table 4** Psychometric properties of the DMQoLat the scale level

| Psychometric testing | Value | Suggested cutoff |
|---|---|---|
| Ceiling effects (%) | 5.8 | < 20 |
| Floor effects (%) | 0.3 | < 20 |
| Internal consistency (Cronbach's α) | 0.89 | > 0.7 |
| Person separation reliability from Rasch | 0.88 | > 0.7 |
| Item separation reliability from Rasch | 0.95 | 0.7 |
| Confirmatory factor analysis | | |
| $\chi^2$ (*df*) | 159.19 (35)* | Nonsignificant |
| Comparative fit index | 0.927 | > 0.9 |
| Tucker-Lewis index | 0.916 | > 0.9 |
| Root-mean-square error of approximation | 0.067 | < 0.08 |
| Standardized root-mean-square residual | 0.049 | < 0.08 |
| Average variance extracted | 0.51 | > 0.5 |
| Composite reliability | 0.91 | > 0.6 |
| Standard error of measurement | 0.202 | The smaller the better |

*$p < 0.001$

sample and indicate poor disease control. We also found in our test of known-group validity that those with hypertension or hyperlipidemia experienced poorer HRQoL than did other participants. This finding suggests that the scale is sensitive enough to differentiate between patients with various health conditions and DM-related risk factors.

We assessed the psychometric properties of the DMQoL at both the item and the scale level. At the item level, all 10 items loaded on a single factor, confirming that the measure is assessing a single dimension. According to Stevens, when the number of items is 10 or lower, finding more than one dimension is difficult because related items tend to concentrate around a single concept [31]. Finding a single dimension in the DMQoL also suggests that disease-specific quality of life in diabetic patients may be a relatively simple and does not require developing long and complex instruments. However, longer scales with more items may identify different dimensions of HRQoL providing further insight with regard to this construct in diabetic patients.

The strong associations between the DMQoL and DQOL, along with relatively weak correlations with other measures (HADS and MARS), supported the convergent and divergent validity of the scale. Rasch model analyses also supported the construct validity of the scale. When comparing our assessment of the DMQoL with studies of other diabetes-specific measures of HRQoL, many of these other scales were validated using a less comprehensive package of validation tools than were employed in

**Table 5** Concurrent validity of the DMQoL using Pearson correlation and partial correlation adjusted for age and gender

| Criterion | Pearson correlation *r* (*p* value) | Partial correlation *r* (*p* value) |
|---|---|---|
| WHOQOL-BREF overall QoL | 0.375 (< 0.001) | 0.360 (< 0.001) |
| WHOQOL-BREF general health | 0.241 (< 0.001) | 0.234 (< 0.001) |
| WHOQOL-BREF physical domain | 0.398 (< 0.001) | 0.382 (< 0.001) |
| WHOQOL-BREF psychological domain | 0.467 (< 0.001) | 0.460 (< 0.001) |
| WHOQOL-BREF social domain | 0.410 (< 0.001) | 0.392 (< 0.001) |
| WHOQOL-BREF environment domain | 0.333 (< 0.001) | 0.281 (< 0.001) |
| WHOQOL-BREF total score | 0.290 (< 0.001) | 0.269 (< 0.001) |
| HADS anxiety | − 0.301 (< 0.001) | − 0.274 (< 0.001) |
| HADS depression | − 0.382 (< 0.001) | − 0.368 (< 0.001) |
| MARS | 0.341 (< 0.001) | 0.327 (< 0.001) |

*HADS* Hospital Anxiety and Depression Scale, *MARS* Medication Adherence Report Scale, *WHOQOL-BREF* World Health Organization Quality of Life scale brief version

**Table 6** Construct validity of the DMQoL using Pearson correlation and partial correlation adjusted for age and gender

| Diabetes Quality of Life (DQOL) | Pearson correlation *r* (*p* value) | Partial correlation *r* (*p* value) |
|---|---|---|
| Satisfaction | − 0.483 (< 0.001) | − 0.451 (< 0.001) |
| Impact | − 0.512 (< 0.001) | − 0.493 (< 0.001) |
| Diabetes-related worry | − 0.398 (< 0.001) | − 0.337 (< 0.001) |
| Social/vocational worry | − 0.402 (< 0.001) | − 0.374 (< 0.001) |
| Total DQOL | − 0.436 (< 0.001) | − 0.401 (< 0.001) |

the present study. For example, in a recent assessment of the Appraisal of Diabetes Scale, Hara and colleagues examined only concurrent validity and internal consistency when validating the Japanese version [32]. Similarly, Chin et al. in their evaluation of the English version of the Diabetes Distress Scale examined only convergent and discriminant validity along with internal consistency [33].

Also measured here were a variety of objective measures of health status such as HbA1c, eGFR, BUN, creatinine, and lipid profile. Because of the poor HRQoL reported by participants, it was expected that these parameters might also indicate poor health status and diabetic control (as an indicator of criterion validity of the DMQoL). HbA1c and lipid profile values were indeed out of range among those with low HRQoL (normal range for HbA1c is defined as less than 5.6% and less than 6.5% indicates good diabetic control; likewise, the normal range for total cholesterol is less than 100 mg/dl). However, the other laboratory values were surprisingly within the normal range. The relationship between poor HRQoL and increased HbA1c has been demonstrated in prior studies [34, 35].

The findings from this study also underscore the need for education to improve self-care behaviors among those with low education. The majority of our sample was illiterate or had only an elementary school education. Lack of education can negatively impact lifestyle choices, resulting in poorer disease prognosis and increased diabetic complications [36].

The present study had a number of limitations that should be considered when interpreting the results reported here. First, we recruited only clinic patients that may influence the generalizability of the findings. However, use of a large sample and comprehensive assessment of psychometric properties may help to diminish this concern. Second, we only included patients with type II diabetes because the scale was initially developed for such patients. However, the prevalence of individuals with type I diabetes is growing and developing similar scales appropriate for this population is also necessary. Future studies should focus on developing measures of HRQoL that may be relevant for those with both types of disorders. Finally, the DMQoL's sensitivity to change over time was not examined in the present study. Therefore, future studies will need to address this issue in order to demonstrate the usefulness of this scale for both clinical and research purposes.

**Table 7** Known-group validity for DMQoL compared with that of DQOL

| | | Satisfaction, *M* (SD) | Impact, *M* (SD) | Diabetes-related worry, *M* (SD) | Social/vocational worry, *M* (SD) | Total DQOL, *M* (SD) | DMQoL, *M* (SD) |
|---|---|---|---|---|---|---|---|
| Hypertension | Yes | 2.37 (0.61) | 2.46 (0.71)* | 2.79 (0.65)* | 2.47 (0.58)* | 2.42 (0.77)* | 3.51 (0.70)* |
| | No | 2.21 (0.55) | 2.10 (0.45)* | 2.31 (0.62)* | 2.13 (0.76)* | 2.11 (0.59)* | 3.81 (0.87)* |
| Retinopathy | Yes | 2.54 (0.51) | 2.35 (0.42) | 2.63 (0.38) | 2.58 (0.56)* | 2.48 (0.60) | 3.27 (0.41) |
| | No | 2.22 (0.57) | 2.21 (0.52) | 2.40 (0.44) | 2.39 (0.62)* | 2.22 (0.47) | 3.44 (0.44) |
| Nephropathy | Yes | 2.42 (0.75)* | 2.50 (0.78) | 2.31 (0.34) | 2.39 (0.58) | 2.36 (0.62 | 3.19 (0.51) |
| | No | 2.04 (0.50)* | 2.32 (0.37) | 2.23 (0.42) | 2.21 (0.42) | 2.25 (0.44 | 3.30 (0.53) |
| Neuropathy | Yes | 2.67 (0.59)* | 2.59 (0.47)* | 2.62 (0.60) | 2.71 (0.61)* | 2.54 (0.51* | 3.42 (0.52) |
| | No | 2.29 (0.50)* | 2.23 (0.45)* | 2.22 (0.49) | 2.43 (0.55)* | 2.27 (0.48* | 3.57 (0.49) |
| HbA1c | > 8% | 2.63 (0.37)* | 2.61 (0.51)* | 2.57 (0.64)* | 2.78 (0.51)* | 2.61 (0.49* | 3.40 (0.49)* |
| | ≤ 7% | 2.11 (0.59)* | 2.03 (0.42)* | 2.09 (0.55)* | 2.15 (0.44)* | 2.01 (0.52* | 3.71 (0.55)* |
| Cholesterol | > 200 mg/dl | 2.74 (0.43)* | 2.49 (0.39)* | 2.72 (0.59)* | 2.79 (0.67)* | 2.61 (0.47* | 3.37 (0.46)* |
| | ≤ 200 mg/dl | 2.19 (0.68)* | 2.01 (0.29)* | 2.19 (0.58)* | 2.12 (0.25)* | 2.07 (0.33* | 3.78 (0.53)* |
| Diabetic food | Yes | 2.69 (0.42)* | 2.63 (0.34)* | 2.59 (0.55)* | 2.48 (0.38)* | 2.55 (0.41* | 3.19 (0.41)* |
| | No | 2.28 (0.36)* | 2.12 (0.31)* | 2.19 (0.47)* | 2.18 (0.33)* | 2.19 (0.30* | 3.64 (0.48)* |

*$p < 0.05$

## Conclusion

The DMQoL is a brief, reliable, and valid measure of disease-specific HRQoL among Persian-speaking patients with type II diabetes. Use of this measure along with other more general measures of HRQoL may deepen our understanding of the perceptions of diabetic patients in Iran regarding their health state. Further evaluation of this scale in diabetic patients from different cultures, regions of the world, and those speaking other languages will help to determine whether the DMQoL may be useful more generally. Finally, we recommend that the DMQoL be examined over time and in response to medical and psychological treatments to determine whether it is sensitive in detecting clinically relevant changes in HRQoL among diabetic patients.

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## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical approval** The study was approved by the Ethic Committee at Qazvin University of Medical Sciences, and all patients gave written informed consent prior to participation.

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