Research Article

Assessment of health-related quality of life using the EQ-5D-3L in individuals with type 2 diabetes mellitus

Abstract

The daily experience with type 2 diabetes mellitus (T2DM) has significant adverse effects on health-related quality of life (HRQoL). HRQoL assessment is essential for measuring the impact of the disease on the patient and selecting individualized strategies. Generic measures for assessing HRQoL are very useful because, unlike specific measurement instruments, they allow for the comparison with other instruments. The EQ-5D-3L is a generic measure and it describes HRQoL in five dimensions; mobility, self-care, usual activities, pain/discomfort and anxiety/depression, with three levels each. In Portugal, studies using the EQ-5D-3L as a generic measure to assess HRQoL in diabetic patients are scarce.

Objective: To assess HRQoL in individuals with T2DM using the Portuguese version of the EQ-5D-3L.

Methodology: An accidental sample of patients with T2DM (n=437) was selected at Family Health Units and healthcare centers in Coimbra, Portugal, between January 2013 and January 2014. The EQ-5D-3L was applied in interviews. The EQ-5D-3L score was calculated based on the answers to the five dimensions and the value system for the Portuguese population.

Results: In this sample, 100% of the participants answered the EQ-5D-3L. The HRQoL score was 0.6772 in the EQ-5D-3L and 64.85 in the EQ-VAS. The most frequent answers to the five dimensions were *no problems* or *some problems*. The mean score of the EQ-5D-3L was significantly associated with age, male gender, high level of education, having an occupation, practicing physical activity, being single and having been diagnosed with T2DM for less time. The Cronbach alpha's value was 0.674, confirming an acceptable internal consistency.

Conclusion: HRQoL levels in individuals with T2DM are lower than the national average and vary depending on sociodemographic and clinical characteristics. The EQ-5D-3L is a reliable instrument that can be used to assess the quality of life of diabetic patients and contribute to assess the patients' overall health status, adding data from the subjective dimension of self-care management.

Keywords: type 2 diabetes mellitus, EQ-5D-3l, health-related quality of life, diabetes mellitus, anxiety, depression, chronic disease, macrovascular complications, asthma, chronic obstructive pulmonary disease, rheumatoid arthritis

Ana Filipa Cardoso,[1] Rui Cruz,[2] Paulo Queirós,[3] Luiz Santiago,[4] Carlos Fontes Ribeiro,[5] Pedro Lopes Ferreira[6]

[1]Nursing School of Coimbra, Health Sciences Research Unit: Nursing. Portugal
[2]Polytechnic Institute of Coimbra, Coimbra Health School, Pharmacy, Portugal
[3]Department of Nursing, Health Sciences Research Unit: Nursing, Portugal
[4]Invited Associate Professor, University of Beira Interior, Portugal
[5]Department of Pharmacology and Experimental Therapeutics, University of Coimbra, Portugal
[6]Center of Study and Research in Health, University of Coimbra, Portugal

Correspondence: Ana Filipa Cardoso, Nursing School of Coimbra, Health Sciences Research Unit: Nursing, Portugal, Tel +351 239 802 850/239 487 200, Fax +351 239 442 648, Email cardoso.anafilipa@gmail.com

Introduction

Diabetes mellitus (DM) is a silent chronic disease, with slow evolution to chronicity, and a high prevalence worldwide.[1] It is estimated that 387million people have diabetes worldwide.[2] In 2013, the estimated prevalence of diabetes among Portuguese adults aged 20-79years was 13.0%.[3] Portugal ranks among the European countries with the highest prevalence of diabetes, and whose incidence has been exponentially increasing, particularly among younger people.[3] Diabetes affects mainly individuals aged 40-59years, and its prevalence is different between men (15.6%) and women (10.7%).[3] As a chronic disease, diabetes can lead to long-term microvascular and macrovascular complications.[4–6] It has a negative impact on individuals, affecting all spheres of life and reducing their quality of life.[7,8] The psychosocial[9] and psychological[10,11] problems associated with diabetes, as well as the burden of disease and the lifestyle restrictions of diabetic patients are widely addressed in the literature.[12]

For these reasons, individuals with DM need ongoing professional support and specific training to minimize complications and improve their well-being.[13–15]

Type 2 Diabetes Mellitus (T2DM) has significant adverse effects on health-related quality of life (HRQoL). HRQoL is a multidimensional concept that assesses the individuals' perception of their health, thus being a useful indicator for the burden of disease.[16] Diabetic patients perceive themselves as having less HRQoL than non-diabetics, and the quality of life decreases with the progression of the disease and its complications.[13,17,18] In short, the impact of its treatment, complications and comorbidities substantially affect HRQoL.[17] Therefore, given the evolution of the disease to chronicity, its continuous monitoring in clinical practice is essential. HRQoL assessment helps to identify needs for new or revised health policies, the allocation of health resources, and strategic planning, while guiding and helping to improve the monitoring of the outcomes from community health interventions.[19]

Specific and generic instruments have been developed for measuring HRQoL, making it difficult to compare results and select research instruments.[12] Thus, greater attention has been given to the development of generic instruments to measure HRQoL since, unlike specific measure, they have the advantage of enabling comparisons across different diseases.[16] The EQ-5D-3L is a generic instrument for measuring HRQoL that allows creating a health status index[20] and, for this reason, its use has an advantage over other instruments. It also allows combining two key components of any HRQoL measure to be used in cost-utility economic evaluations: a profile describing the health status in terms of domains or dimensions, and a numeric value associated with the health status previously described.[20]

On the other hand, this instrument can be applied to a wide range of health conditions and treatments, because it allows creating not only a health profile, but also an index value for the individuals' health status.[12,20] The EQ-5D-3L has been widely used at an international level, however, there are only a few studies in Portugal using the EQ-5D-3L to assess HRQoL in individuals with T2DM. We selected the EQ-5D-3L because it has the advantage of being able to calculate an index that can be compared among diseases and used for economic evaluation.

This instrument has been used by some researchers in Portugal,[21] but the validation process was conducted by Ferreira, Ferreira & Pereira (2013) using three samples, including one composed of individuals with chronic diseases (cataracts, asthma, chronic obstructive pulmonary disease, and rheumatoid arthritis).[21] More recently, the value system and the normative data of the EQ-5D-3L were established for the Portuguese population.[22,23]

This study has the following objectives:

a. To assess HRQoL using the EQ-5D-3L in patients with T2DM;

b. To analyze the impact of T2DM on HRQoL using the EQ-5D-3L Portuguese population norms;

c. To assess the psychometric properties of the EQ-5D-3L by calculating its reliability and validity in patients with T2DM.

Methods

This cross-sectional study included a sample of 437 patients with T2DM attending six Health Care Centers/Family Health Units (FHU) of the central region of Portugal. For data collection, the principal investigators conducted interviews using an instrument developed for this study. The data collection instrument consisted of two parts. The first part was composed of sociodemographic variables (age, gender, education, marital status, and professional situation) and clinical variables (time elapsed since diabetes diagnosis, glycated hemoglobin, and physical activity). The participants were divided into three groups according to their level of education: "Low" (below 9th grade), "Medium" (completed 9th grade) and "High" (completed 12th grade). As regards the professional situation, two groups were created: active (with professional activity) and non-active (pensioners, unemployed and students).

The second part consisted of the HRQoL questionnaire: the EQ-5D-3L. The EQ-5D-3L is a descriptive system of the HRQoL that includes five dimensions: Mobility (MO), Self-Care (SC), Usual activities (UA), Pain/discomfort (PD) and Anxiety/depression (AD). The answers predict three levels of severity: no problems, some problems, and extreme problems. It also comprises a visual analogue scale (VAS) in which respondents classify their general health status

from 0 (worst health state imaginable) to 100 (best health state imaginable). The global index is generated by an algorithm, based on the preferences of the answers obtained for the five dimensions. The EQ-5D uses a scale from 1 (perfect health) to 0 (death), admitting, however, negative values corresponding to health states considered worse than death.[1,20,22] Data were collected between January 2013 and January 2014. The participants were selected based on pre-established inclusion criteria: having been diagnosed with T2DM for no less than six months, being 18 years old or above, having preserved cognitive skills, and accepting to voluntarily participate in the study. The following exclusion criteria were used: existence of previous history of degenerative, neurological or psychiatric disorders that could prevent a correct self-administration.

This study was approved by the Ethics Committee of the Faculty of Medicine of the University of Coimbra and of the Central Regional Health Administration (ARSC). Participants were asked to participate on a voluntary basis. They were informed about the study objectives, procedures, risks, benefits, alternatives, their rights, and data anonymity and confidentiality.[24] This information was included in the informed consent form signed by the participants. Permission to use the instrument was also requested from and granted by the Center of Study and Research in Health of the University of Coimbra (CEISUC).

Psychometric properties of the EQ-5D-3L

To assess the respondents' level of acceptability of the questionnaire, we used the nonresponse pattern (missing values). The analysis of the distribution of the participants' answers revealed floor and ceiling effects, i.e. the percentage of individuals in the upper or lower end of the scale.[25] As a measure of reliability, internal consistency was analyzed through the calculation of Cronbach's alpha values. Cronbach's alpha values greater than 0.70 were considered acceptable.[25] The construct validity of the EQ-5D-3L was measured based on the correlations between the EQ-5D-3L dimensions and the sociodemographic and clinical characteristics. The correlations were classified according to the criteria proposed by Cohen and Holliday:[26] very high correlation for values above 0.90, high correlation for values between 0.70 and 0.89, moderate correlation for values between 0.40 and 0.69, low correlation for values between 0.20 and 0.39, and very low correlation for values below 0.19.

Statistical analysis

Descriptive statistics were used to calculate the mean, median, standard deviation, minimum and maximum values, and floor and ceiling effects in each dimension. Both floor and ceiling effects were considered significant if >15%.[25] The mean scores were compared through the two-tailed Student's t-test for continuous variables. Categorical variables were compared using the chi-square test ($\chi 2$). Reliability was assessed through the Cronbach's alpha, whereas the normality of the distribution of the EQ-5D-3L and the EQ-VAS was assessed using the Kolmogorov-Smirnov-Lilliefors test for normality. The significance level was set at 0.05. Data were analyzed using SPSS, version 21.0 for Windows.

Results

In this study, the sample was composed of 437 individuals with T2DM. The EQ-5D-3L was well accepted by the diabetic patients, simple and easy to apply. Table 1 shows the sociodemographic and clinical characteristics of the sample. Most participants were women (52.4%). The mean age was 66.28±9.67 years, ranging from a

minimum of 35 years to a maximum of 94 years. Most respondents were aged 50-69 years (57.7%). With regard to marital status, 73.5% of the participants were married or cohabiting, 4.6% were single, 5.9% were separated, and 16% were widowed. Most of the participants had a low level of education (62%), i.e. they had not completed compulsory education (9th grade) and 29.5% had a medium level of education. In relation to the professional situation, the great majority of participants (66.4%) were non-active (pensioners, unemployed and students). Concerning the practice of physical activity, our sample was divided: 50.1% practiced physical activity on a regular basis and 49.9% did not practice any physical activity. On average, the mean time elapsed since T2DM diagnosis was 8.8±7.26 years, ranging from 1 to 42 years.

Table 1 Sociodemographic and clinical characteristics of the sample

Variable	N	%
Gender		
Female	229	52.4
Male	208	47.6
Total	**437**	**100**
Age		
Min: 35 – Max: 94	437	100
Mean: 66.28±9.678		
30-49	27	6.2
50-69	252	57.7
≥70	158	36.2
Total	**437**	**100**
Marital status		
Single	20	4.6
Married/Cohabiting	321	73.5
Divorced/separated	26	5.9
Widowed	70	16
Total	**437**	**100**
Level of education		
Low	271	62
Medium	129	29.5
High	37	8.5
Total	**437**	**100**
Professional Situation		
Active	67	15.3
Non-active	290	66.4
Total	**357**	**81.7**
Physical Activity		
Yes	219	50.1
No	218	49.9
Total	**437**	**100**
Time elapsed since T2DM diagnosis (years)		
Min: 0 – Max: 42	435	99.5
Mean: 8.88±7.260		

Table Continued.....

Variable	N	%
Glycated Hemoglobin		
Normal	237	69.5
High	104	30.5
Total	**341**	

Acceptability and distribution

The acceptability rate, which was measured through the participants' non response rate, was 100%. In the dimensions of mobility, self-care and usual activities, more than 70% of the sample scored at level 1 (no problems). In the dimensions of pain/discomfort and anxiety/depression, more than 50% of the participants scored at level 2 (some problems) (Table 2). A ceiling effect was found in all dimensions, i.e. few individuals were positioned in level 3 of the five dimensions, but particularly in the dimensions of mobility and self-care. A higher response rate and a less pronounced ceiling effect were found in the dimensions of pain/discomfort and anxiety/depression. The results showed total mean scores for the population of T2DM patients of 0.677 in the EQ-5D-3L and 64.85 in the EQ-VAS. Men scored higher (0.744) than women (0.617) in the EQ-5D-3L and in the EQ-VAS (68.44 and 61.58, respectively) (Table 3). As expected, the EQ-5D-3L and the EQ-VAS scores decreased with age. Widowed individuals had the lowest score in the EQ-5D-3L. Divorced/separated individuals had substantially lower EQ-VAS scores than the others. In this sample, the individuals with a higher level of education had higher EQ-5D-3L and EQ-VAS scores than individuals with a lower level of education.

Active individuals and those who practice physical activity had the highest scores in the EQ-5D-3L (0.737/0.728) and in the EQ-VAS (68.58/68.69), respectively. As regards the time elapsed since T2DM diagnosis, the EQ-5D-3L scores increased with the number of years since diagnosis (from 0.682 to 0.731). However, in the EQ-VAS analogue scale, these scores are not uniform, as the individuals who were diagnosed with T2DM for 21 to 30 years had the lowest scores (59.29) and the individuals who were diagnosed for 31 to 30 years had the highest scores (67.50).

Reliability

The standardized Cronbach's alpha for the total questionnaire was 0.674, which suggests an acceptable internal consistency.[25,27]

Criterion validity

The analysis of the distribution of the EQ-5D-3L and the EQ-VAS, using the Kolmogorov-Smirnov (K-S) Test and the Shapiro-Wilk Test, showed that it differs from a normal distribution ($\rho=0.000$). Thus, we continued analyzing the data through a non-parametric statistical analysis.[28] We found that the mean rank of the total EQ-5D-3L was higher in men than in women (265.26 and 176.98, respectively), and that this difference was statistically significant ($\rho<0.01$). The same applied to the EQ-VAS, with men scoring higher (mean=244.25) than women (mean=196.06). This difference was statistically significant ($\rho<0.01$) (Table 4).

We observed that individuals who practiced physical activity had higher mean scores in the EQ-5D-3L and in the EQ-VAS than those who practiced no physical activity, and this difference was statistically significant ($\rho<0.01$). Individuals with an active professional situation also scored higher in the EQ-5D-3L and in the EQ-VAS ($\rho<0.01$) (Table 4).

In both the EQ-5D-3L and the EQ-VAS, we observed higher mean scores in the age group of 30-49years than in the other age groups, with these differences being statistically significant ($\rho<0.01$). Divorced/ separated individuals had the highest mean score in the EQ-5D-3L and this difference was statistically significant ($\rho<0.01$). However, in the EQ-VAS, single individuals had the highest scores, but without statistical significance ($\rho>0.01$). As regards education, individuals with a high level of education had higher mean scores in the EQ-5D-3L and in the EQ-VAS than individuals with a medium and low level of education, with this difference being statistically significant ($\rho <0.01$) (Table 5). Spearman's correlation was used to investigate the association between the EQ-5D-3L and the EQ-VAS (Table 6).

Table 2 Distribution of the answers to the EQ-5D-3L dimensions and the EQ-VAS

EQ-5D-3L		N	%
	I have no problems in walking about	315	72.1
Mobility(MO)	I have some problems in walking about	122	27.9
	I am confined to bed	0	0
	I have no problems with self-care	384	87.9
Self-Care(SC)	I have some problems washing or dressing myself	53	12.1
	I am unable to wash or dress myself	0	0
	I have no problems with performing my usual activities	374	85.6
Usual activities(UA)	I have some problems with performing my usual activities	62	14.2
	I am unable to perform my usual activities	1	0.2
	I have no pain or discomfort	146	33.4
Pain/discomfort(PD)	I have moderate pain or discomfort	288	65.9
	I have extreme pain or discomfort	3	0.7
	I am not anxious or depressed	206	47.1
Anxiety/depression(AD)	I am moderately anxious or depressed	225	51.5
	I am extremely anxious or depressed	6	1.4
	Total	437	100
	5th Percentile	40	
	10th Percentile	50	
	25th Percentile	50	
	50th Percentile	60	
	75th Percentile	80	
	90th Percentile	90	
EQ_VAS	95th Percentile	95	
	100th Percentile	100	
	Minimum	0	
	Maximum	100	
	Mean	64.85	
	Standard deviation	18.18	
	Total	437	100

Table 3 Distribution of the EQ-5D-3L and the EQ-VAS according to the sociodemographic and clinical characteristics of T2DM patients

Characteristics		N	EQ-5D-3L		EQ-VAS	
			Mean	sd	Mean	sd
	Total	437	0.677	0.193	64.85	18.188
Gender	Male	208	0.744	0.18	68.44	16.029
	Female	229	0.617	0.184	61.58	19.411
Age	30-49	27	0.802	0.163	78.22	10.649
	50-69	252	0.695	0.181	65.54	18.162
	≥70	158	0.628	0.202	61.46	18.149
Marital status	Single	20	0.69	0.213	72	18.595
	Married/Cohabiting	321	0.695	0.186	65.41	17.369
	Divorced/separated	26	0.691	0.187	56.92	23.583
	Widowed	70	0.587	0.202	63.14	18.75
Level of education	Low	271	0.639	0.191	61.96	18.732
	Medium	129	0.73	0.179	69.29	16.753
	High	37	0.774	0.181	70.46	14.521
Professional situation	Active	67	0.737	0.16	68.58	16.039
	Non-active	290	0.662	0.198	63.89	18.599
Physical activity	Yes	219	0.728	0.176	68.69	17.912
	No	218	0.627	0.197	60.98	17.674
Time elapsed since T2DM diagnosis (years)	0-10	315	0.682	0.187	64.9	19.042
	20-Nov	95	0.674	0.216	65.63	15.475
	21-30	21	0.625	0.194	59.29	17.556
	31-40	2	0.604	0.076	67.5	17.678
	>40	2	0.731	0.052	62.5	17.678

Table 4 Association between the EQ-5D-3L and the EQ-VAS and the variables gender, physical activity and professional situation

Characteristics		N	EQ-5D-3L			EQ-VAS		
			Mean rank	Z	ρ	Mean rank	Z	ρ
Gender	Male	208	**265.26**	-7.384	0	**244.25**	-4.05	0
	Female	229	176.98			196.06		
Physical Activity	Yes	219	**255.91**	-4.154	0	**243.63**	-6.195	0
	No	218	181.92			194.26		
Professional Situation	Active	89	**266.74**	-4.043	0	**244.44**	-2.165	0.03
	Non-active	348	206.79			212.49		
	Total	437						

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Table 5 Association between the EQ-5D-3L and the EQ-VAS and the variables age, marital status and level of education

Characteristics		N	EQ-5D-3L			EQ-VAS		
			Mean order	KW	ρ	Mean order	KW	ρ
Age	30-49	27	**297.89**		0	**318.65**		
	50-69	252	230.52	23.221		223.38	23.586	0
	≥70	158	187.15			194.99		
Marital Status	Single	20	235.15			**264.43**		
	Married/Cohabiting	321	229.36			221.9		
	Divorced/separated	26	**235.42**	18.221	0	182.04	5.865	0.118
	Widowed	70	160.79			206.45		
Level of Education	Low	271	191.78			198.02		
	Medium	129	258.79	34.718	0	252.02	20.407	0
	High	37	**279.62**			**257.54**		
	Total	437						

Table 6 Association between the EQ-5D-3L and the EQ-VAS

		EQ-5D-3L	EQ-VAS
EQ-VAS	rho	0.370**	1
	ρ	0	.
	N	437	437
EQ-5D-3L	rho	1	0.370**
	ρ	.	0
	N	437	437

Discussion

Most participants were women (52.4%), which contradict the higher prevalence of diabetes in men observed in Portugal.[8] This situation was also described and analyzed by Morais and colleagues (2015), who concluded that this may be, to some extent, associated with gender-related cultural issues, i.e. women are more likely to adhere to vigilance than men.[1] The mean age of participants was 66.28 years. This data contradicts the results found in the literature which indicate that the prevalence of diabetes in the Portuguese population increases with age and that more than one-fourth of the individuals aged 60-79 years have diabetes.[3] The participants had a low level of education, as most of them did not complete compulsory education (9th grade) (62%). This result contributes to asserting the need for increased support to individuals with lower levels of education, which is an obstacle to the fight against diabetes.[1]

In this study, we measured the HRQoL of T2DM patients using the EQ-5D-3L. The EQ-5D-3L score was calculated based on the value set for Portugal.[22] We found that the acceptability of the EQ-5D-3L was 100%, both in the descriptive system and in the EQ-VAS, and that participants had no difficulties understanding or completing it, which is similar to results found in other studies.[20] The assessment of the health status of the participants in our study allowed us to conclude that the ceiling effect overlaps/as been observed in all dimensions, i.e. few individuals were placed on level 3 of the five dimensions. The ceiling effect was more marked in the dimensions of mobility and self-care than in the others, which is consistent with other studies.[20,29] In this study, individuals with T2DM perceive themselves more often to be at the "*no problems*" level in the five dimensions, but particularly in the dimensions related to mobility, self-care and usual activities. However, the percentage of individuals who answered "*some problems*" is higher in the dimensions of pain/discomfort and anxiety/depression (65.9% and 51.5%, respectively). "Extreme problems" were also found in these dimensions. This group of individuals with T2DM clearly valued the psychological dimensions over the physical dimensions,[12,23] as these possibly have a greater impact on their lives.

In this study, the mean score of the EQ-5D-3L was 0.6772 and the mean score of the EQ-VAS was 64.85. As expected, these values are lower than those found for the general Portuguese population[20] (EQ-5D-3L: 0.758; EQ-VAS: 74.9). However, we found that the EQ-5D-3L score is higher than the one found by Ferreira, Ferreira & Pereira[20] in a group of patients with other chronic conditions (rheumatoid arthritis, asthma, cataracts and chronic obstructive pulmonary disease),[20] similar to the score found in a Portuguese study with patients with multiple sclerosis,[21] and lower than the score found for Portuguese asthma patients.[30]

We found that the score is lower than the one found in samples of diabetic patients in other cultural contexts.[12,17,30] The EQ-5D-3L measures HRQoL indirectly based on the five dimensions, whereas the EQ-VAS measures it directly through the patients' subjective feelings. For this reason, the EQ-VAS shows the severity of the disease which the patient himself/herself experiences.[12] The same trend was observed in the EQ-VAS score, which is higher than the one found in patients with other chronic conditions (rheumatoid arthritis, asthma, cataracts and chronic obstructive pulmonary disease) in the study of Ferreira, Ferreira & Pereira (2013),[20] but lower than the one found in samples of diabetic patients in different cultural contexts.[12,17,31,32] Although the association between HRQoL and diabetes complications was not analyzed in our study, we noticed that the EQ-5D-3L score obtained in our sample is still much lower than the one found in studies with diabetic patients without complications[17,32] and similar to the one found with diabetic patients with more than two diabetes complications.

The psychometric characteristics tested in this study indicate a reasonable internal consistency (0.674),[27] although lower than the one found in the previous Portuguese study.[20] The dimensions of mobility, self-care and usual activities of the physical component of HRQoL are more clearly interrelated than the dimensions of pain/discomfort and anxiety/depression of the psychological component, which seems to indicate that the EQ-5D-3L is more sensitive in the physical dimension of HRQoL. However, this is not a diabetes-specific instrument and, for this reason, it may reflect problems related to other conditions.[17] Although our sample did not include individuals aged 18-29 years, we observed that HRQoL decreases with age, reflecting the same trend observed in other studies. Our results indicate that men,[1,12,17,23] younger people,[1,23,30] people with a higher level of education,[1,19,30] single people,[30] people who practice physical activity and people with less time elapsed since T2DM diagnosis scored higher in the EQ-5D-3L and in the EQ-VAS.

Conclusion

In this sample of diabetic patients, the mean score of the EQ-5D-3L and the EQ-VAS was 0.677 and 64.85, respectively. These scores are lower than those observed in the general Portuguese population, and also than those found in other groups of diabetic patients in other cultural contexts. Men, younger people, people with a higher level of education, single people, people who practice physical activity and people with less time elapsed since T2DM diagnosis scored higher both EQ-5D-3L and EQ-VAS. Women reported more problems than men. HRQoL is affected by age, regardless of sex.

These results emphasize the impact of diabetes on the patients' quality of life and highlight the subjective experience of diabetic patients. Given its metric characteristics (Cronbach's α: 0.674), acceptability, ease and short time of administration (mean completion time of 10minutes), this instrument is extremely useful and valuable in clinical practice and research for valuing the subjective dimension of T2DM patients.

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Conflict of interest

Author declares that there is no conflict of interest.

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