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Psychometric Properties of the "Diabetes Quality of Life – Brief Clinical Inventory" in Greek Diabetic Patients

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ABSTRACT

Indroduction: Diabetes has a deleterious effect on patients' clinical, social, and economic status as well as their quality of life (QoL).

Aim: The purpose of the present study was to investigate the psychometric properties of the Diabetes Quality of Life Brief Clinical Inventory (DQL -Brief Clinical Inventory) in a Greek diabetic population

Material & Methods: The DQL-BCI and the SF-36 questionnaire were filled in by 150 type 2 diabetic patients. Construct and concurrent validity, along with test-retest and internal reliability were examined.

Results: After principal component analysis of the DQL-BCI, three factors emerged: treatment satisfaction, psychosocial influence and somatic impact. Intraclass correlation and pearson r correlation indicated high repeatability. Cronbach's a coefficient

Key Words: *Questionnaire, Validity, Reliability, Type 2 diabetic population*

for all items was equal to 0.79, showing high internal reliability. All three subscales tested exhibited high correlation with SF-36 general physical and mental state. Mean item value was ranged between 1.3-3, showing a modest patient burden.

Conclusion: The DQL-BCI (Greek version) is a valid and reliable tool for measuring QoL in type 2 diabetic patients. This instrument will further help improve the patient-health communication and detect the factors that affect QoL.

INTRODUCTION

It is estimated that 382 million people have diabetes worldwide, type 2 accounting for 90% of these cases. [6, 7, 13] As diabetes is a principal cause of death worldwide, with considerable expenditure on its treatment and its complications, research on self care is necessary to prevent further patient deterioration.[3, 6] Diabetes has a deleterious effect on patients' clinical, social, and economic status as well as their quality of life (QoL) and a vicious circle precipitating disease worsening and undermining survival is possible [4, 13]. In that context, it is necessary to seek and apply interventions that facilitate and promote self-care including treatment compliance and Quality of Life (QoL) improvement to address these issues. A great number of variables including the type of diabetes (DM), use of insulin, age, race, social status, level of education, disease complications, psychological factors, knowledge about the disease, and type of health care may influence the QoL of patients with diabetes [2, 3, 11].

Many survey instruments on diabetic patients QoL have been implemented.[16] Nevertheless, cultural differences in disease and QoL perception often demand adaptation at national level. These differences reflect different socioeconomic influence on disease management and the subjective disease and health assessment. [19] A thorough QoL assessment with appropriate scales provides valuable information on treatment efficacy and care improvement. DQL-BCI is a short (15 closed type questions) and specialized instrument for QoL measurement in routine medical assessment. It comprises specific and actionable questions, facilitating health care worker and patient communication, therapy scheduling and treatment satisfaction. [1] It is the short version of Diabetes Quality of Life (DQOL) question, originally designed for Diabetes 1 & 2 patients, with 46 questions.[11] DQL-BCI exhibited high internal (Cronbach's a ≈0.75-0.85 and excellent test-retest (r≈0.95) reliability, in Iran [10], Poland [5] and Malaysia.[12]

The purpose of the present study was to investigate the psychometric properties of the Diabetes Quality of Life Brief Clinical Inventory (DQL -Brief Clinical Inventory) in a Greek diabetic population. We assumed that the aforementioned instrument is a valid and reliable instrument for QoL assessment in diabetic patients.

MATERIAL AND METHODS

Research tool

DQL-BCI answers in the Greek version are rated on a 5-point Likert scale the highest score indicating worse QoL. This rating was preferred, as questions assess the impact of diabetes on Quality of life and researchers tried to depict this burden. Patients provide answers by selecting from "very satisfied" to "very dissatisfied". Answers to each question correspond to a score of 1–5: 1 is the lowest score of a given parameter (which means the highest level of satisfaction or the lowest frequency of occurring problems) and 5 is the highest (which means the highest level of dissatisfaction or the highest frequency of occurring problems). The total score is the sum of scores of individual questions. The scoring ranges from 15 (the best assessment of QoL) to 75 points (the worst assessment of QoL) [1]. The SF-36 questionnaire, comprises 36 questions on the last month's QoL assessment and it was used for comparison (concurrent validity).

Translation and adaptation in Greek

The DQL-BCI, originally created and available in English, has not been used in Greece so far. The author of the questionnaire permitted its application and translation into Greek. Translation was performed in accordance with generally accepted international principles of translation and cultural adaptation of measurement tools. Translation from English into Greek was performed by 2 independent translators, English graduates, native Greeks (foreword translation). Then, an analysis and comparison of the translations was made, after which an agreed version of the questionnaire in Greek was developed. The next step was for three other independent translators to re-translate the agreed version of the tool from Greek into the source language (backward translation).The obtained translations were compared with the original version, and linguistic matters were discussed with the research team. Some alterations in how a question was asked (without changing the meaning) have been made in the Greek version by two endocrinologists using the probing technique via face-to-face interview**.** Afterwards, within the pilot study, 10 patients with diabetes completed the questionnaire, submitting their comments about the understanding and design of the questions. By taking the patients' opinion into account the final Greek version of the questionnaire was created. The final version of the questionnaire was assessed positively by a group of experts involved in the treatment of diabetes. The scoring system of the translated version of questionnaire is identical to the original version of the DQL-BCI.

Sampling and procedure

The questionnaire was originally administered to 328 patients and 152 of them

responded. Fully completed questionnaires were 150. As a result one hundred and fifty patients diagnosed with type 2 diabetes were included in the study (92 males and 59 females). They were chosen at random out of all patients with type 2 diabetes treated (from April 2016 to September 2016) at the General hospital "Laiko" (Athens) and the general hospitals of Kalamata and Lakonia (Sparta). All studied patients underwent physical examination and, in order to exclude advanced dementia changes, they completed a Mini Mental State Examination, scoring > 27 points. All patients gave written consent before participating in the study in compliance with principles of the Declaration of Helsinki. General inclusion criteria: duration of type 2 diabetes ≥ 12 months, patient's agreement and physical and psychological health condition allowing independent completion of questionnaires, age greater than 18 and less than 85 years. Exclusion criteria: lack of patient's agreement, presence of acute or advanced complications of diabetes or other illness which could significantly interfere with self-assessment of health and quality of life (ketoacidosis, lactic acidosis, diabetic retinopathy with impairment of sight, hindering the process of reading the questionnaire, chronic obstructive pulmonary disease in stage III and IV according to Global Initiative for Chronic Obstructive Lung Disease (GOLD), partly controlled and uncontrolled asthma according to Global Initiative for Asthma (GINA), heart failure in stage NYHA III and IV, chronic kidney disease in stage 4 and 5 according to Kidney Disease Outcomes Quality Initiative (KDOQI), cancer, multiple sclerosis, damaged spinal cord, amputation).

The method of diagnostic survey used the research techniques of survey questionnaire, including an author's questionnaire assessing socio-demographic aspects and the frequency of self-reported hypoglycemic episodes, and the SF- 36 QoL questionnaire. In addition, the study used data on selected clinical characteristics (the presence of chronic complications of diabetes) and glycemic control (measured by glycated hemoglobin (HbA_{1c}); obtained through the analysis of medical records.

Test-retest reliability was examined repeating questionnaire competion by 53 randomized patients, 4 weeks after first completion. Answers were received by phone. Patients were instructed to follow their ordinary therapy schedule. No QoL affecting factor (i.e hospital admission) occurred for any patients during this time period.

Permission was obtained from SF36v2 and DQL-BCI questionnaire manufacturers (Quality Metric and Dr. Thomas Burroughs respectively) and the research was approved by bioethics committee of the local hospital medical councils.

Statistics

The values of the considered parameters were measured in the nominal scale, described by mean values and standard deviation. Reliability of the DQL-BCI was

analyzed by examining internal consistency using Cronbach's α coefficient and test-retest reliability. Construct validity was assessed by principal component analysis (PCA) via the varimax-rotation and the results obtained by the questionnaire tested and the SF-36 were used concomitantly (concurrent validity).

Item loadings above 0.30 were used to retain items under one pre hypothesized factor and testing the dimensionality of the scale. Eigen value above 1.00 (Kaiser's criterion), the scree plot and percentage of explained variability criteria were used to specify the retained factor. Bartlett Test of Sphericity showed statistical significance ($p<0,0005$), while Kaiser-Meyer-Olkin Measure of Sampling Adequacy was > 0,60 (0,736). Items loading on more than one factor were classified to the conceptually closer factor.

For testing the concurrent validity hypothesis, Pearson r correlation coefficients were used to examine the relationship between the scores with SF-36 quality of life scores. A correlation at moderate ($0.3 \leq R < 0.5$) or higher levels (high $0.5 \leq R < 0.7$, very high $0.7 \leq R < 0.9$) in expected directions was assumed. The 0.05 level of significance was selected to test the above statistical hypotheses. Finally, the Cronbach alpha and intraclass reliability coefficients reported the internal consistency and stability of the scale. Statistical analysis was performed based on the computer software SPSS v. 22.0 (IBM, Chicago, USA).

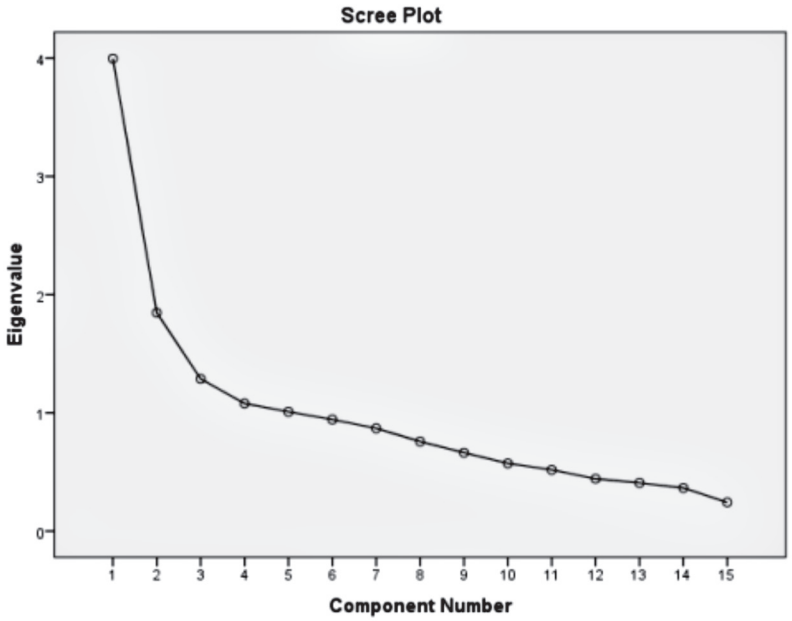

Fig. 1. *Scree plot diagram*

RESULTS

The main demographic characteristics of the diabetic patient sample analyzed are presented in Table 1. In our sample, 61.3% were men, 72.7% were married, 44,7% were elementary education graduates, while 30.7% were university graduates. Mean patient age was 65.91±10.73 years, while mean disease duration was 13.74±8.99 years old.

Table 1

Demographic characteristics of the sample

	N	**%**
Gender		
Maen	92	61,3
Womaen	58	38,7
Total	150	100,0
Family status		
Married	109	72,7
Unmarried	15	10,0
Divorced	10	6,7
Widowed	16	10,7
Total	150	100,0
Educational level		
Elementary	45	30,0
Junior High school	22	14,7
High school	37	24,7
University	46	30,7
Total	150	100,0
	MT	**TA**
Age	65,91	10,73
Disease duration	13,74	8,99
HbA1c (%) (N=118)	7.16	1.40

Principal component analysis

Five factors were initially retrieved, explaining the 61.46% of variance. Based on conceptual consistency, these factors were further classified and reducted to 3, a resolution supported by the eigenvalue plot (screeplot). The factor “treatment satisfaction” comprised items 1, 2, 5, 14, 15, (5 items), the factor «somatic impact» items 10, 12, 13 (3 items) and the factor «psychosocial influences» items 3, 4, 6, 7, 8, 9, 11 (7 items).

Table 2
PCA

	Rotated Component Matrix				
	1	**2**	**3**	**4**	**5**
Item 1	.723				
Item 2	.752				
Item 3					.632
Item 4			.826		
Item 5	.705			-.343	
Item 6				.368	-.393
Item 7				.701	
Item 8		.736			
Item 9			.802		
Item 10		.443	.556		.336
Item 11	.313	.357	.367		
Item 12		.608			
Item 13		.786			
Item 14	.589				.480
Item 15	.336				

Table 3
The final 3 factor solution loadings

	Factors		
Items	**Satisfaction**	**Impact**	**Psychosocial influence**
Item 1	.688		
Item 2	.786		
Item 3			.369
Item 4			.652
Item 5	.622		
Item 6			.531
Item 7			.374
Item 8			.669
Item 9			.840
Item 10		.325	
Item 11			.426
Item 12		.674	
Item 13		.698	
Item 14	.722		
Item 15	.394		

Cronbach's a coefficient for the three factors were as follows: satisfaction 0.68, psychosocial influence 0.63, (somatic) impact 0.68. Cronbach's a coefficient for all items was equal to 0.79, showing high internal reliability. Factor loadings after varimax rotation are presented in table 2, while in table 3 the three factor loading are showed. All loadings exceed the critical cut off point (0.30), while the smallest number of questions appears in factor 3 "somatic impact".

Test-retest reliability results are presented in table 4, along with intra-class correlation coefficient (ICC)].Mean ICC was high for the total sample: ICC =0,867 (0,808-0,914), p<0,001.

Table 4
Test-retest reliability

Items	Pearson r	ICC	p
Item 1	0.441	0.611	0.001
Item 2	0.596	0.747	<0.001
Item 3	0.783	0.878	<0.001
Item 4	0.676	0.803	<0.001
Item 5	0.600	0.749	<0.001
Item 6	0.706	0.827	<0.001
Item 7	0.700	0.809	<0.001
Item 8	0.704	0.829	<0.001
Item 9	0.313	0.544	0.005
Item 10	0.614	0.738	<0.001
Item 11	0.637	0.778	<0.001
Item 12	0.743	0.852	<0.001
Item 13	0.376	0.613	0.006
Item 14	0.727	0.842	<0.001
Item 15	0.746	0.854	<0.001

Table 5
Concurrent validity

N=150		PSC (SF-36)	MSC (SF-36)
Impact	r	-.577	-.599
	p	<0.001	<0.001
Treatment	r	-.307	-.336
	p	<0.001	<0.001
Psychosocial influence	r	-.439	-.506
	p	<0.001	<0.001

All three subscales tested exhibited high correlation with SF-36 general physical and mental state. A lower score in the tested questionnaire (lower impact, higher satisfaction and lower psychosocial impact) was correlated with higher SF score ($p<0.001$ for all correlations) (Table 5). Mean item value was ranged between 1.3-3, showing a modest patient burden.

Descriptive statistics

After validity and reliability testing, descriptive statistics per item is depicted in table 6. The greater burden (dissatisfaction) appeared in items 7,9,13.

Table 6
Descriptive statistics

N=150	Minimum	Maximum	Mean value	Standard deviation
Item 1	**1.00**	**5.00**	1.65	0.83
Item 2	1.00	5.00	1.90	1.04
Item 3	1.00	5.00	2.42	1.21
Item 5	**1.00**	**5.00**	1.27	0.68
Item 6	1.00	5.00	1.54	0.86
Item 7	1.00	5.00	3.01	1.45
Item 8	1.00	5.00	2.17	1.25
Item 9	1.00	5.00	2.67	1.11
Item 10	1.00	5.00	1.50	0.95
Item 11	1.00	5.00	1.50	1.05
Item 12	1.00	5.00	2.24	1.33
Item 13	1.00	5.00	2.57	1.08
Item 15	1.00	5.00	1.83	0.96
Subscales				
Satisfaction	5,00	22,00	8,95	3,31
Impact	3,00	14,00	5,89	2,41
Psychosocial influence	7,00	29,00	15,31	4,53

DISCUSSION

This study was the first to translate the 15-DQoL-BCI into Greek and investigate its psychometric properties. In addition, it is the first specific questionnaire to measure the quality of life of patients with diabetes in the Greek population. In addition, recruitment of 150 patients with type 2 diabetes mellitus met the sample size needs to be weighed (5-10 volunteers for each Eagle's Question).[15] The findings of the analysis suggest that the Greek DQoL-BCI is a valid instrument for the evaluation of the QoL of type 2 diabetes patients. However, unlike the Polish version of DQoL-BCI [5] and Malaysia's one [12], with 4 suggested factors, the Greek version, as well as the Iranian one, [10] exhibited 3 domains. This decision to use three factors is supported by the eigenvalue graph. The factors were defined as: satisfaction, psychosocial influence and (physical) impact.

While the factor analysis of the authentic DQoL-BCI had a similar ranking of the results with that of Poland [1, 5] it was not divided into subscales but it was evaluated in total. It is possible to possess a limited ability to evaluate specific fields as opposed to the full DqoL scale of the 46 items [16], which used 4 domains for 46 Questions (treatment satisfaction, treatment impact, social anxiety and concern about labor factors).

Based on the factor loadings, it is concluded that items 7, 10 and 15 show relatively low loadings. Perhaps the 7th is responsible for the fact that sleep quality is multifactorial and may not be related to diabetes. For the 10th, the sample includes patients receiving antidiabetic tablets instead of insulin, which excludes the risk of pain suffering from diabetes. Finally, the 15th "How satisfied you are with your knowledge of diabetes?", belonging to satisfaction domain, differs from the other items that reflect the satisfaction with treatment. Question 9 shows the low Pearson coefficient and low average intracorrelation, probably due to the high mean age of the sample since many retirees were involved or did not care about the career issue. In the Greek population, it may have required adaptation to increase its usefulness for the elderly, probably asking for past time career development.

This study has its own limitations. First, in contrast to the English QoL-BCI, the Greek, as well as the Iranian, Polish and Malaysian version, was weighted only in a population of type 2 diabetes. This fact restricts the capacity of the QoL evaluation in patients with type I diabetes. The present study, like the other three, did not evaluate the responsiveness of the translated DQoL-BCI to various direct approaches to diabetes and the predictive validity for the clinical outcome as well as the outcome of QoL.

CONCLUSIONS

The findings of the present study showed that the Greek version of DQoL- BCI is valid and reliable and can be used in its proposed form for QoL assessment of patients with type 2 diabetes mellitus. Measuring the quality of life with DQoL- BCI showed a small-moderate burden on patients. This instrument will further help improve the patient-health communication and detect the factors that affect QoL of patients with diabetes and thus improve the quality of the patient's care and patient compliance with treatment regimes.

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