Validation of the Polish version of Diabetes Quality of Life – Brief Clinical Inventory (DQL-BCI) among patients with type 2 diabetes

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Abstract

Introduction: The aim of the study was to develop a Polish version of the Diabetes Quality of Life Brief Clinical Inventory (DQL-BCI) and to perform validating evaluation of selected psychometric aspects.

Material and methods: The translation process was performed in accordance with generally accepted international principles of translation and cultural adaptation of measurement tools. Two hundred and seventy-four subjects with type 2 diabetes completed the Polish version of DQL-BCI, the generic EQ-5D questionnaire and the diabetes-specific DSC-R. The examination provides information about the reliability (internal consistency, test-retest) and the construct validity of the studied tool (the relationship between the DQL-BCI score and EQ-5D and DSC-R scales, as well as selected clinical patient characteristics).

Results: Cronbach’s α (internal consistency) for the translated version of DQL-BCI was 0.76. Test-retest Pearson correlation coefficient was 0.96. Spearman’s coefficient correlation between DQL-BCI score and EQ-5D index and EQ-VAS were 0.6 (p = 0.0000001) and 0.61 (p = 0.0000001) respectively. The correlation between scores of the examined tool and DSC-R total score was −0.6 (p = 0.0000001). Quality of life was lower among patients with microvascular as well as macrovascular complications and with occurring hypoglycemic episodes.

Conclusions: The result of this study is the Polish scale used to test the quality of life of patients with diabetes, which includes the range of problems faced by patients while maintaining a patient-friendly form. High reliability of the scale and good construct validity qualify the Polish version of DQL-BCI as a reliable tool in both research and individual diagnostics.

Key words: quality of life, type 2 diabetes, psychometric evaluation, reliability, validity.

Introduction

In the course of treatment of the patient, physicians should take into account both objective factors (clinical and socio-demographic) and
subjective factors, such as a sense of satisfaction with various aspects of bio-psycho-social development. It is an embodiment of the idea of holism in medicine [1]. A survey of quality of life (QoL) enables widening of the perspective from which we look at a patient. There are many definitions of quality of life. Frequently cited is the definition of WHO, which defines QoL as perceived by the person’s own life situation within the context of the cultural, value system and in relation to its objectives, standards and interests [2]. This aspect is particularly important in the case of chronic diseases such as diabetes, where treatment requires the patient’s major commitment, often with adjustments of the current lifestyle to requirements of the treatment.

A number of diabetes-specific quality of life measures have been developed [3–5], but the majority of them were originally developed for use among English-speaking patients. The process of creating measurement tools to assess health-related quality of life (HRQoL) is dynamic; for many questionnaires the process of translation into other languages and cultural adaptation (validation) is in progress [3, 4, 6]. Extensive questionnaires are of limited use in clinical practice because of the time required for their completion, which is inversely proportional to the level of patient cooperation. Therefore, shortened versions of the questionnaires are especially useful when working with patients.

The Diabetes Quality of Life Brief Clinical Inventory (DQL-BCI) was developed as a brief, diabetes-specific tool to measure QoL, especially useful in routine clinical practice [7]. Despite the availability of several diabetes-specific questionnaires in Polish language version, there was a lack of a short, patient-friendly form including the wide range of clinically significant problems faced by patients.

The aim of the present study was to develop a Polish version of the questionnaire to assess quality of life DQL-BCI and to perform validating evaluation of selected psychometric aspects: reliability and construct validity among patients with type 2 diabetes.

Material and methods

Two hundred and seventy-four patients diagnosed with type 2 diabetes were included in the study (153 female; 121 male). They were chosen at random out of all patients with type 2 diabetes treated (from January 2007 to December 2008) at the Department of Endocrinology at the Medical University of Lublin, the Diabetes Outpatient Clinic in Lublin and at the District Diabetes Outpatient Clinic in Lublin. 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 ≥ 6 months, patient’s agreement and physical and psychological health condition allowing independent completion of questionnaires, age greater than 18 years. No upper age limit was assumed in the criteria for participation in the study. Exclusion criteria: lack of patient’s agreement, treatment with incretin mimetics, presence of acute or advanced complications of diabetes or other illness which could significantly interfere with self-assessment of health and quality of life (ketoadiabetes, 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).

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 three QoL questionnaires: EQ-SD, DQL-BCI and DSC-R. In addition, the study used data on selected clinical characteristics (the presence of chronic complications of diabetes) and glycemic control (measured by glycated hemoglobin (HbA1c); the immunochromic method ADIVA 1650 Chemistry Systems, Siemens, was applied) obtained through the analysis of medical records.

Characteristics of research tools

Diabetes Quality of Life Brief Clinical Inventory (DQL-BCI)

DQL-BCI is a standardized questionnaire developed by Burroughs’ et al. in 2004 in the USA [7]. The starting point for the development of this tool was a 46-question Diabetes Quality of Life Measure (DQOL) questionnaire by Jacobson et al. used, among others, in the DCCT study [8]. Gradual analysis, including the multiple linear regression method of analysis, made it possible to select 15 questions, which explained the maximum amount of variance in diabetes-related quality of life assessment, especially in diabetes-control satisfaction and reported self-care. A reliable (Cronbach’s α = 0.85) and a relevant tool was obtained
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The disease-specific Diabetes Symptom Checklist-Revised (DSC-R)

The DQL-BCI, originally created and available in English, has not been used in Poland so far. The author of the questionnaire permitted its application and translation into Polish. Translation was performed in accordance with generally accepted international principles of translation and cultural adaptation of measurement tools [3, 11]. Translation from English into Polish was performed by two independent translators, English graduates, native Poles (forward translation). Then, an analysis and comparison of the translations was made, after which an agreed version of the questionnaire was developed. The next step was for two other independent translators to re-translate the agreed version of the tool from Polish into the source language (backward translation).

The obtained translations were compared with the original version, and no significant differences were reported. Afterwards, within the pilot study, 39 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 Polish version of the questionnaire was created. Some alterations in how a question was asked (without changing the meaning) have been made in the Polish version. These modifications were dictated by the language differences and better understanding of the modified version of questions as reported by patients, which derives from the need for cultural adaptation of the research tool.

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. The Polish version was given a layout as graphically close as possible to the original version. According to the authors’ best knowledge, this is the first psychometric evaluation of DQL-BCI in Europe.

The procedure of translating the DQL-BCI

The EQ-5D

The generic EQ-5D questionnaire consists of two parts: an EQ-5D descriptive system and an EQ visual analog scale (EQ-VAS) [12, 13]. The EQ-5D descriptive system is presented as a single summary index (EQ-5D index) by use of data from Polish population research presented by Golicki et al. [14]. EQ-VAS is a standard, vertical scale, designed to resemble a thermometer, with values from 0 to 100. On the scale 0 stands for “the worst imaginable health state” and 100 for the best; thus the higher the score, the better is the reported health condition [13].

EQ-5D

The disease-specific Diabetes Symptom Checklist-Revised (DSC-R)

The disease-specific Diabetes Symptom Checklist-Revised (DSC-R) is used for evaluation of QoL, especially from the point of view of occurrence and burden of diabetes-related symptoms [15, 16]. The DSC-R questionnaire consists of 34 items grouped into 8 symptom subdomains: psychological cognitive, psychological fatigue, neuropathic pain, neuropathic-sensory, cardiovascular distress, ophthalmologic function, hypoglycemia and hyperglycemia. Total score of DSC-R as well as certain subscale scores range from 0 to 100. A higher score means worse QoL as an effect of the greater burden of symptoms.

Statistical analysis

The values of the considered parameters were measured in the nominal scale, characterised by means of multiplicity and percentages, as well as in the quotient scale, which referred to mean values and standard deviation with its variance. Reliability of the DQL-BCI was analyzed by examining internal consistency using Cronbach’s \( \alpha \) coefficient and test-retest reliability. The test-retest reliability was obtained by comparison (Pearson’s correlation coefficient) of scores of the form repeated for the 32 patients within a period of 4–6 weeks. Construct validity was assessed using the method of correlation analysis (Spearman’s correlation coefficient) of the results obtained by a questionnaire.

The obtained results were compared with the original version, and no significant differences were reported. Afterwards, within the pilot study, 39 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 Polish version of the questionnaire was created. Some alterations in how a question was asked (without changing the meaning) have been made in the Polish version. These modifications were dictated by the language differences and better understanding of the modified version of questions as reported by patients, which derives from the need for cultural adaptation of the research tool.

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tested and the EQ-5D and DSC-R used concomitantly (convergent validity) and glycemic control measured by HbA1c. 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. Additional analysis of the results of the DQL-BCI scale with clinical data was performed as well (Mann-Whitney U test; the U and Z statistics were used for subgroups of < 20 or \geq 20 people, respectively). Factor analysis via the varimax-rotation method was performed. A 5% error of inference was accepted along with the, associated with it, level of significance \( p < 0.05 \), indicating the existence of statistically significant differences or relationships. Statistical analysis was performed based on the computer software Statistica v. 8.0 (StatSoft, Poland).

Results

The study involved 274 patients with type 2 diabetes: 153 women (55.8%) and 121 men (44.2%), aged from 37 to 84 years (mean: 62.2 ±9.8 years). Duration of diabetes since diagnosis ranged from 1 to 25 years and averaged 10.5 ±7.2 years. Socio-demographic characteristics of the studied population are presented in Table I. Among the surveyed patients 179 people (65.3%) were treated with oral drugs, and 95 patients (34.7%) with insulin, combined with oral agents (\( n = 55, 20.1\% \)) or alone (\( n = 40, 14.6\% \)). The incidence of chronic complications of diabetes and the frequency of incidence of hypoglycemia reported by the patients are shown in Table I. Quality of life results, obtained with the DQL-BCI, are shown in Table II. Factor analysis via the varimax rotation method was performed. A 4-factor solution was considered to be optimal. The 4-factor structure of the questionnaire explained 54% of the variance. Table III contains detailed information on the factor loadings of 15 questions of the DQL-BCI questionnaire.

Table I. Characteristics of subjects

| Variable                                      | Result                        |
|----------------------------------------------|-------------------------------|
| Age, mean ± SD [years]                       | 62.2 ±9.8                     |
| Number of cases, n (%):                       | 274                           |
| Women                                        | 153 (55.8)                    |
| Men                                          | 121 (44.2)                    |
| Domicile, n (%):                             |                               |
| Country                                      | 77 (28.1)                     |
| Town < 100 000                                | 57 (20.8)                     |
| Town > 100 000                                | 140 (51.1)                    |
| Working, n (%)                               | 49 (17.9)                     |
| Education, n (%):                            |                               |
| Elementary                                   | 55 (20.1)                     |
| Vocational                                   | 77 (28.1)                     |
| Secondary                                    | 99 (36.1)                     |
| Higher                                       | 43 (15.7)                     |
| Marital status, n (%):                       |                               |
| Single                                       | 13 (4.7)                      |
| Married                                      | 204 (74.5)                    |
| Widowed                                      | 45 (16.4)                     |
| Divorced                                     | 12 (4.4)                      |
| Diabetes complications, n (%):               |                               |
| Coronary heart disease                       | 107 (39.1)                    |
| Diabetic retinopathy                         | 39 (14.2)                     |
| Diabetic neuropathy                          | 20 (7.3)                      |
| Diabetic nephropathy                         | 15 (5.5)                      |
| Previously acute myocardial infarction       | 44 (16.1)                     |
| Previous PCI/CABG procedures                 | 39 (14.2)                     |
| Peripheral artery disease                    | 13 (4.7)                      |
| Previous cerebral stroke                     | 12 (4.4)                      |
| Self-reported hypoglycemia, n (%):           |                               |
| Never                                        | 133 (48.5)                    |
| Seldom                                       | 116 (42.4)                    |
| Often                                        | 25 (9.1)                      |
| Duration of diabetes, mean ± SD [years]      | 10.5 ±7.2                     |
| HbA1c, mean ± SD [%]                         | 7.5 ±1.5 (58 ±16.4)          |

PCI – percutaneous coronary intervention, CABG – coronary artery bypass graft, HbA1c – glycated hemoglobin

Reliability of the DQL-BCI

While examining the psychometric properties of the tool, the example of the author of the original scale was followed. The assessment of reliability was based on an analysis of internal consistency, Cronbach’s \( \alpha \) coefficient for the scale was 0.76. Table IV shows the results of internal consistency analysis for the translated version as well as the original version of DQL-BCI and DQOL.

Thirty-two patients of the sample population participated in the re-administration of the tool in the period of 4–6 weeks. Test-retest reliability was evaluated; Pearson’s correlation coefficient was \( 0.96 (p < 0.00001) \) (Table IV). This results indicates high reliability of the form.

Construct validity of the DQL-BCI

The construct validity of the discussed scale was determined by calculating the Spearman’s rank correlation coefficient between the results of the DQL-BCI and other tools applied to assess quality of life – the general EQ-5D and the diabe-
It was found that there is a statistically significant correlation between the analyzed parameters. The results of the DQL-BCI scale correlate to a similar extent with the results of the EQ-5D questionnaire as well as with the overall result of the DSC-R – strong magnitude of correlation (absolute values $r \geq 6$). The degree of correlation varied between the result of the DQL-BCI and the individual DSC-R subdomains. There was a high correlation magnitude in the symptom domain psychology-cognitive ($r = -0.54$), and psychology-fatigue ($r = -0.53$), while in the domain of symptoms associated with hypoglycemia the magnitude of correlation was weak ($r = -0.22$). Other parameters analyzed were characterized by a moderate degree of correlation.

DQL-BCI scores in the study population also correlated with the occurrence of complications and hypoglycemia. In the interview microvascular complications were considered together as diabetic retinopathy, diabetic nephropathy and diabetic neuropathy, and macrovascular complications were also considered together as ischemic heart disease, post-myocardial infarction state, post-PTCA/CABG state, peripheral artery disease,
and stroke. Patients with microvascular complications assessed their QoL significantly lower when compared to those without complications (score 51.3 and 55.3, respectively, $Z = –3.53$, $p = 0.0004$).

Similarly, people with macrovascular complications reported decreased QoL when compared to patients without this diagnosis (score 52.5 and 55.9, respectively, $Z = –3.69$, $p = 0.0002$). Patients who reported experiencing hypoglycemia assessed their QoL lower when compared to patients not experiencing hypoglycemia (score 53.2 and 55.8 respectively, $Z = 3.06$, $p = 0.002$).

DQL-BCI scores also correlated with HbA1c (Spearman $r = –0.26$, $p = 0.00002$), which is connected with lower QoL among patients showing a lower level of glycemic control.

The obtained parameters indicate good psychometric properties of the translated version of the questionnaire.

**Discussion**

The Polish-language DQL-BCI questionnaire was developed to test the quality of life in diabetes. Psychometric properties of the scale have been tested on a group of 274 patients with type 2 diabetes.

The accuracy of the scale was based on an analysis of internal consistency as in the case of the creators of the original scale. The coefficient of internal consistency for the tested tool (Cronbach’s $\alpha$) was 0.76. Cronbach’s $\alpha$ value for the original version of DQL-BCI was 0.85 [7], in another analysis of the tool $\alpha = 0.75$ [10], while this value for the DQOL questionnaire which makes a starting scale for the construct of the analyzed tool was in the range of 0.47–0.87 [8]. It is assumed that a Cronbach’s $\alpha$ value above 0.7 indicates high reliability of the form [17]. As described in the literature, the favored way of reliability assessment of the tool is conducting and comparing two independent measurements [17]. DQL-BCI has an excellent test-retest reliability, as was proven in this study and described by other researchers [10].

Test-retest parameters of DQOL ranged from 0.78 to 0.92 in Jacobson’s study [18], and 0.83–0.94 in another analysis [19].

The authors of the English version of the questionnaire assessed the validity based on determining the correlation of results with the output tool, treating DQOL as a gold standard (criterion validity) [7, 18]. In this study we compared the results of the DQL-BCI with the results of other scales

**Table IV. Reliability of Polish version of DQL-BCI in comparison to original version of DQL-BCI and DQOL**

|                     | Polish version of DQL-BCI | Original version of DQL-BCI | DQOL |
|---------------------|---------------------------|----------------------------|------|
| Cronbach’s $\alpha$| 0.76                      | 0.85$^{[6]}$               | 0.47–0.87$^{[7]}$ |
| Test-retest         | 0.96                      | –                          | 0.78–0.92$^{[7]}$ |

$^{[6]}$ – Diabetes Quality of Life-Brief Clinical Inventory, $^{[7]}$ – Diabetes Quality of Life

**Table V. Spearman’s correlation coefficient between DQL-BCI and EQ-SD, DSC-R**

| DQL-BCI score     | Spearman $r$ | Value of $p$ |
|-------------------|--------------|--------------|
| EQ-SD index       | 0.6          | < 0.0001     |
| EQ-VAS            | 0.61         | < 0.0001     |
| DSC-R total score$^1$ | –0.6        | < 0.0001     |

$^1$Because of the direction of scoring, the negative correlation signifies a positive relationship between DSC-R and DQL-BCI scores. DQL-BCI – Diabetes Quality of Life-Brief Clinical Inventory, DSC-R – Diabetes Symptoms Checklist-Revised
assessing QoL (convergent/discriminant validity) [3, 4], similarly to other authors [8, 18–20]. In this study, we found the existence of a significant, positive correlation of high power between the tested scale and the overall EQ-SD questionnaire for both variables (EQ-5D index, EQ-VAS), which confirms that the person who assesses their overall quality of life as better also assesses as better the quality of life dependent on diabetes.

The negative correlation between the analyzed scale and the DSC-R scale and its domains means that along with the increase of one parameter the second parameter decreases, which is understandable and arises from the way the results of both questionnaires are interpreted. The highest correlations with psychological issues were observed. This result is similar to those obtained in other studies concerning DQOL [8, 18, 19]. However, in another study higher correlations between physical than psychological aspects were found [20]. In the study mentioned above, different tools in convergent validity assessment were used, but there is a need of further analysis. The low degree of correlation in combination with the DSC-R individual domains (especially hypoglycemia) can be explained by a narrow scope of the discussed aspects within each domain. A high strength of correlation characterized the results of the DQL-BCI with DSC-R total score, which is a result of individual subscales, therefore giving a fuller assessment of QoL.

Correlations with clinical parameters, complications and frequency of hypoglycemia incidence confirm other authors’ reports. Hypoglycemia is a widely recognized independent factor worsening the QoL and satisfaction with diabetes treatment [21–23]. In this study, patients undergoing hypoglycemia episodes also described their QoL as lower than those without such episodes. The authors, studying a connection between the presence of complications and the QoL of patients with diabetes, agree that their presence, especially the presence of two or more complications, microvascular as well as macrovascular, is associated with impaired QoL [24–26]. Similar results concerning complications were obtained in this study, as well as during previous psychometric evaluation of DQOL [8, 20]. Correlation between DQL-BCI results and HbA1c was relatively low. When analyzing the correlation of QoL and glycemic control it is often said that glycated hemoglobin is not a perfect point of reference and does not give unequivocal results [16, 27, 28]. Many authors emphasize above all the importance of the impact of states of hyperglycemia on quality of life [27, 28], which confirms the high correlation of DQL-BCI with symptoms of hyperglycemia (DSC-R subdomain) in our study.

The obtained results confirm the good psychometric properties (reliability and construct validity) of the Polish version of the DQL-BCI. Similarly, in another recently published study good psychometric properties of this tool were proved [10]. Moreover, in this research [10], 3 subdomains of the scale were distinguished: complications, diagnosis/therapy and psycho-social issues. This subdivision is consistent with the original 46-item DQOL (subscales: satisfaction, impact, social/vocational worry, diabetes worry) [8, 18]. In the factor analysis of the original version of DQL-BCI a similar distribution of items of individual factors as in the present study was observed. The brief, 15-item DQL-BCI does not allow one to evaluate particular subdimensions with equal precision as DQOL, but is more useful in practice. As a consequence, in our study, similarly as in the original version of DQL-BCI [7], the questionnaire is assessed as a whole without dividing it into subscales, but further considerations are needed.

This study, as well as the questionnaire itself, also has several limitations. The DQL-BCI is designed to assess QoL among patients with type 2 and type 1 diabetes. This study was conducted only among patients with type 2 diabetes. Therefore, conducting a survey among Polish patients with type 1 diabetes requires further research, which is the authors’ target for the near future.

Additionally, this questionnaire addresses selected aspects of QoL in diabetes. The wide scope of the concept of quality of life and the many variables that affect it imply the possibility of testing a large number of aspects with respect to the disease and everyday life. The American authors, when creating the DQL-BCI, reached a compromise between the scope of the aspects addressed and the length of the questionnaire. A brief, clear questionnaire was obtained, which patients can complete in about 10 min. These features are particularly useful in the conditions of everyday clinical practice (inpatients and outpatients), where the questionnaire can be helpful in identifying problems of QoL, which may not be detected during normal doctor-patient conversations. For studies that aim to explore wider the problem of QoL in diabetes (mainly scientific research), therefore, there remains a need to consider the use of DQL-BCI as a component of a research tool, along with other scales, both generic and disease-specific.

Despite some limitations, the DQL-BCI, as demonstrated previously [7, 10], can be used successfully among patients with type 2 diabetes. This fact is confirmed by the present study.

The analysis of construct validity and reliability of the Polish version of the DQL-BCI showed that it is a valuable tool for assessing the quality of life of patients with diabetes. The study extends the
posibility to evaluate a patient and extends the range of tests to assess the QoL in type 2 diabetes in the conditions of our country. However, there is a need to continue the research, expanding it to other aspects of psychometric analysis, also among patients with type 1 diabetes.

In conclusion, the result of this study is the Polish scale used to test the QoL of patients with diabetes, which includes the range of problems faced by patients while maintaining a patient-friendly form. High reliability of the Polish version of DQL-BCI and good construct validity qualify the questionnaire as a reliable tool in both research and individual diagnostics.

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