

Quality of Life Assessment in Patients with Behçet's Disease using the Persian Version of the Leeds BD-QoL Questionnaire

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What's Known

- Behçet's disease (BD) is a chronic rheumatologic disorder that negatively impacts the quality of life of the affected patients.
- The Leeds Behçet's disease-quality of life (BD-QoL) questionnaire is a validated and specific tool for measuring the quality of life of patients with Behçet's disease patients. It has been shown to have a good correlation with the SF-36 questionnaire.

What's New

- The QoL of BD patients was assessed using the Persian version of the Leeds BD-QoL questionnaire.
- The questionnaire can be used as an alternative instrument to the WHOQOL-BREF questionnaire to assess the impact of BD on the QoL of the affected patients.

Abstract

Background: Behçet's disease (BD) can negatively impact the quality of life (QoL) of the affected patients. The present study aimed to assess the QoL of BD patients using the Leeds BD-QoL and compare its results with the WHOQOL-BREF questionnaire.

Methods: In the present cross-sectional study, 179 BD patients and 304 healthy individuals (the control group) were recruited in Shiraz, 2017. The Persian version of the Leeds BD-QoL and WHOQOL-BREF questionnaires were used to assess the QoL of patients with BD. The QoL in the patient and control groups was compared after controlling the effect of some variables (age, sex, marital status, and educational level) using the multiple linear regression analysis. Spearman's correlation coefficient was calculated for the Leeds BD-QoL and WHOQOL-BREF scores. Disease activity was measured using the Behçet's Disease Current Activity Form. All the statistical analysis was performed using SPSS software (version 21.0). $P < 0.05$ was considered statistically significant.

Results: The mean of the Leeds BD-QoL total score in the patient group was 12.3 ± 8.7 . The control group had significantly higher scores in the WHOQOL-BREF total score and the physical health and psychological health domains compared with the patient group; mean difference of 10.24, 10.8, and 4.62, respectively ($P < 0.001$). The Spearman's correlation coefficient for the Leeds BD-QoL score and WHOQOL-BREF total score and its domains (physical health, psychological health, social relationships, and environment) was -0.669, -0.713, -0.714, -0.536, and -0.550, respectively. The disease activity score was correlated with the Leeds BD-QoL score ($r = 0.361$, $P < 0.001$).

Conclusion: BD patients had a lower QoL than healthy individuals, specifically in the physical health and psychological health domains. An increase in disease activity and severity was associated with a reduced QoL. The Persian version of the Leeds BD-QoL questionnaire had an acceptable correlation with the WHOQOL-BREF questionnaire.

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Keywords • Behçet's disease • Quality of life • Leeds BD-QoL

Introduction

Behçet's disease (BD) is a serious chronic and multisystem inflammatory disorder that can involve multiple organs of the human body; leading to some degree of functional disability.¹ BD

is prevalent worldwide but it is more common in the areas such as the Mediterranean Sea (Turkey and Greece), the Middle East, and the Far East.² After Turkey, Iran has the highest prevalence of BD with a rate of 80 per 100,000 people.³ Like any other chronic disorder, the severity of the disease and number of symptoms negatively affects mental health, life satisfaction, and quality of life (QoL) of the affected patients.⁴⁻¹⁰ Most studies on the QoL of patients with BD have focused on assessing the impact of specific symptoms such as mouth ulcers,^{11, 12} arthritis,¹³ and ocular involvement.^{14, 15} A few studies have measured the QoL of patients using general questionnaires such as the Short Form 36 (SF-36) or The World Health Organization Quality of Life Instrument Short Form (WHOQOL-BREF).^{4-6, 8} The latter is a generally accepted and widely used instrument to measure QoL. However, the Leeds BD-QoL questionnaire has been specifically developed to assess the QoL of patients with BD.¹⁶ This questionnaire has been translated in different languages (e.g., Persian, Arabic, and Korean) and the validity and reliability of these local versions have been confirmed.¹⁷⁻¹⁹

To the best of our knowledge, no other studies have compared the results of the Leeds BD-QoL with the WHOQOL-BREF questionnaire. Besides, since the validation of the Persian version of the Leeds BD-QoL, we are not aware of any studies in Iran that have measured the QoL of BD patients using this questionnaire. Considering the relatively high prevalence of BD in Iran and the adverse effect of this disease, the present study aimed to assess the QoL of BD patients using the Persian version of the Leeds BD-QoL and correlate its results with those from the WHOQOL-BREF questionnaire.

Materials and Methods

The present cross-sectional study was conducted during August-December 2017 at the Behçet's Disease Clinic of Shahid Motahari Hospital affiliated to Shiraz University of Medical

Sciences, Shiraz, Iran. Behçet's Disease Clinic is the main referral center in southern Iran.

Based on a pilot study involving 65 participants, the required sample size was estimated using the two-sample comparison of means formula (significance level of 0.05 and statistical power of 80%). The estimated required number of patients and healthy individuals was 152 and 304, respectively. However, the number of patients was increased to 179 to ensure adequate participation. The patients were recruited using the convenient sampling method. The inclusion criteria were confirmed diagnosis of BD by a rheumatologist (according to the International Criteria for Behçet's Disease), being a patient at our clinic, and willingness to participate in the study.²⁰ The exclusion criteria were the presence of any other diagnosed chronic disease and/or psychiatric disorder, and unwillingness to participate. The healthy participants (control group) were selected from the medical records of family physicians using the simple randomization method. The term "healthy" was defined as the absence of any diagnosed disease affecting the QoL. In the course of the study, 7.2% of the recruited healthy individuals did not complete the questionnaire and therefore were substituted by the next eligible person on the list. The demographic characteristics included sex, marital status, and education level (table 1).

The validated Persian versions of the Leeds BD-QoL and WHOQOL-BREF questionnaires were used to assess the QoL of BD patients. The QoL in the control group was only assessed with the WHOQOL-BREF questionnaire. The 30-item Leeds BD-QoL questionnaire has been specifically developed to assess the QoL of BD patients. The test-retest reliability of the questionnaire was 0.84 and the validity of its Persian version was confirmed ($\alpha=0.949$).^{16, 17} The questions are answered in a true (1) or false (0) response format with a maximum score of 30. Higher scores indicate a lower QoL. The 26-item WHOQOL-BREF consists of four domains,

Table 1: Demographic characteristics of the participants with Behçet's disease

Variables		Patient group	Control group	P value
Age (mean±SD)		42.3±11.1	32.7±8.8	0.001
Sex (n, %)	Male	56 (31.3%)	108 (37.5%)	0.44
	Female	123 (68.7%)	193 (63.5%)	
Marital status (n, %)	Single	24 (13.4%)	96 (31.8%)	0.05
	Married	150 (83.8%)	196 (64.9%)	
	Widowed	5 (2.8%)	3 (1%)	
	Divorced	0	7 (2.3%)	
Education level (n, %)	Illiterate or primary school	62 (34.6%)	14 (4.6%)	0.001
	Middle or high school	84 (46.9%)	102 (33.8%)	
	University	33 (18.4%)	188 (61.6%)	

namely physical health, psychological health, social relationships, and environment, and an overall QoL and general health score.²¹ Each question is scored from 1 to 5 on a response scale. Raw scores for each domain are the sum of respective item scores, and then transformed linearly to a 0-100 scale. Higher scores indicate a better QoL. WHOQOL-BREF has been standardized and validated for use in the Iranian population. The Cronbach's alpha values of the four domains ranged from 0.7 to 0.84.²²

The disease activity in patients with BD was assessed by a rheumatologist researcher using the Behçet's Disease Current Activity Form (BDCAF) questionnaire. The overall perceived QoL of patients and clinicians was measured using a visual analog scale (VAS). The scores ranged from 1 to 7; higher scores indicated the worst impression of the disease activity. The patient's index score (from 0 to 12) and the transformed index score (from 0 to 20) were then calculated; higher scores indicated severer symptoms.²³

Statistical Analysis

The data were analyzed using SPSS software, version 21.0. Descriptive statistics of the data were described as mean and frequency. The independent *t* test, Chi-squared test, Spearman's correlation test, and multiple linear regression analysis were also used to analyze the data. $P < 0.05$ was considered statistically significant.

Ethical Considerations

The present study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Shiraz University of Medical Sciences, Shiraz, Iran (code: IR.SUMS.REC.1396.s59). Prior to the study, the research goals and methods were explained to the participants, the confidentiality of any disclosed information was guaranteed,

and voluntary participation was emphasized. A member of the research team assisted illiterate participants ($n=15$) with filling in the questionnaires. To help participants with low vision, they were interviewed by a researcher who subsequently completed the questionnaire on their behalf. Written informed consent was obtained from all the participants.

Results

The mean age of the participants in the patient and control groups was 42.3 ± 11.1 and 32.7 ± 8.8 years, respectively. There was no significant difference between the sex of the patients ($P=0.25$), different educational levels ($P=0.14$), and types of marital status ($P=0.66$). The mean of the Leeds BD-QoL score in the patient group was 12.3 ± 8.7 .

The mean duration of the disease in patients with BD was 11.1 ± 8.3 years, which had no significant positive correlation with the Leeds BD-QoL score ($r=0.155$, $P=0.047$). The scores obtained from the BDCAF questionnaire had a significant positive correlation with the Leeds BD-QoL score (table 2). The mean of the WHOQOL-BREF total score in the patient and control groups was 54.5 ± 19.4 and 67.6 ± 15.6 , respectively. The corresponding values for the domains of the WHOQOL-BREF questionnaire are shown in table 3.

The results of multiple linear regression analysis are shown in table 4. Overall, the participants in the control group obtained significantly higher scores in the WHOQOL-BREF total score and its physical health and psychological health domains compared with the patient group; mean difference of 10.24, 10.8, and 4.62, respectively. Female participants scored lower in the psychological health and social relationships domains than the male participants; mean difference of -4.96 and -4.07, respectively. Any increase in age by 5 years

Table 2: The mean of the Behçet's disease current activity form variables and their correlation with the Leeds BD-QoL score

Variables		Leeds BD-QoL total score	Mean \pm SD	P value
Patients' VAS*	Correlation coefficient	0.294	3.2 \pm 1.6	<0.001
Clinician's VAS	Correlation coefficient	0.299	2.8 \pm 1.4	<0.001
Patient index score**	Correlation coefficient	0.337	1.80 \pm 2.03	<0.001
Transformed index score**	Correlation coefficient	0.361	3.89 \pm 3.31	<0.001

*Visual analog scale; **Behçet's disease current activity form

Table 3: The mean score of the WHOQOL-BREF questionnaire and its dimensions for the patient and control groups. Data presented as mean \pm SD

Groups	Total score	Physical health	Psychological health	Social relationships	Environment
Patient	54.5 \pm 19.4	52.2 \pm 19.1	52.9 \pm 17.4	57.7 \pm 22.1	55.6 \pm 15.7
Control	67.6 \pm 15.6	65.04 \pm 15.9	58.1 \pm 15.9	59.5 \pm 21.2	56.8 \pm 15.3

Table 4: The results of multiple linear regression analysis after comparing the QoL of patients with BD and healthy individuals after controlling the effect of demographic variables

Variables	WHOQOL-BREF total score			Physical health			Psychological health			Social relationships			Environment		
	Beta	P value	95% CI	Beta	P value	95% CI	Beta	P value	95% CI	Beta	P value	95% CI	Beta	P value	95% CI
Constant	52.97	<0.001	43.77 to 62.16	59.40	<0.001	49.74 to 69.1	58.86	<0.001	51.54 to 66.17	68.39	<0.001	58.91 to 77.87	49.8	<0.001	41.62 to 57.98
BD patient/control	10.24	<0.001	6.41 to 14.6	10.8	<0.001	7.12 to 14.48	4.62	0.008	1.23 to 8.05	-0.622	0.78	-5.02 to 3.77	0.18	0.917	-3.23 to 3.59
Sex (male/female)	-2.84	0.093	-6.16 to 0.47	-2.68	0.119	-6.05 to 0.69	-4.96	0.002	-8.09 to -1.84	-4.07	0.05	-8.13 to -0.007	2.60	0.085	-0.36 to 5.56
Age (per 5 years)	-0.113	0.805	-1.01 to 0.78	-0.968	0.022	-1.94 to 0.14	-0.29	0.45	-1.06 to 0.47	-1.85	0.001	-2.92 to -0.78	0.22	0.57	-0.54 to 0.98
Marital status	1.38	0.405	-1.88 to 4.65							8.63	<0.001	4.68 to 12.58			
Education level	3.79	0.006	1.09 to 6.48										2.50	0.037	0.15 to 4.86

BD: Behçet's Disease

was associated with a significant decrease in the scores of the physical health and social relationships domains; mean difference of -0.968 and -1.85, respectively.

The Leeds BD-QoL score had a significant negative correlation with the WHOQOL-BREF total score and its domains (P<0.001). The Pearson correlation coefficient for the Leeds BD-QoL score and WHOQOL-BREF total score and its domains (physical health, psychological health, social relationships, and environment) was -0.669, -0.713, -0.714, -0.536, and -0.550, respectively.

Discussion

For the first time in Iran, since the validation of the Persian version of the Leeds BD-QoL, we assessed the QoL of patients with BD using this questionnaire. In addition, the results of the Leeds BD-QoL and WHOQOL-BREF questionnaires were compared and the correlation between the Leeds BD-QoL score and the disease activity was assessed using the BDCAF questionnaire.

Overall, the mean QoL score from the Leeds BD-QoL and WHOQOL-BREF questionnaires in the patient group was 12.3 and 54.5, respectively; significantly lower than the QoL scores in the control group. In line with our findings, a similar study in Iran reported a mean QoL score of 10.3 and found no significant difference due to the demographic variables (sex, education level, and marital status).¹⁷ Therefore, it can be concluded that the QoL of BD patients as measured by the Leeds BD-QoL questionnaire was comparable in different regions of Iran. However, another study reported a better QoL score (9.12) in their patient group while indicating no significant effect due to the demographic variables.¹⁸ The inconsistency between the above-mentioned QoL scores could be due to the different number of participants (sample size).

We found a moderate positive correlation between the Leeds BD-QoL score, BDCAF overall perceived QoL by patients and clinicians (VAS), the patient's index score, and transformed the index score. One may infer from these findings that the perception of patients of the disease activity and severity can negatively influence their QoL. Additionally, it was shown that the overall higher disease activity can be associated with a lower QoL in BD patients. Similar findings were reported by Choi and colleagues.²⁴ The mean WHOQOL-BREF total score in our patient group was 54.5±19.4; lower than of the control group. This was also the case for the domains of the WHOQOL-BREF. Another study reported higher scores (up to 15) in all

domains of the WHOQOL-BREF, which could be due to the small sample size and shorter disease duration in their patients.⁸

We found that by controlling the effect of some variables (sex, age, education level, and marital status), the control group had a higher QoL in the WHOQOL-BREF total score, and physical health, and psychological health domains. BD had a negative physical impact on the patient group due to the articular, ocular, and other organ involvement. These may cause some degree of disability and detrimentally affect the patients' psychological and overall QoL. Furthermore, age is a factor that can influence the physical aspect of QoL. In comparison with the control group, it appeared that BD did not affect the QoL score of the social relationships and environment domains in our patients. However, the education level was an influential factor in the environment domain. This could be due to the fact that people with better education interact more efficiently with their living environment. Similarly, other studies reported a significant difference in physical and psychological QoL between the patients with BD and healthy individuals.^{5, 8} A previous study, using Beck's questionnaire, reported a difference in psychological status between BD patients and healthy individuals, which can be related to the difference in the psychological QoL.¹⁰

Ertam and colleagues did not find any significant difference in the environment domain between their patient and control groups.⁵ However, based on other instruments than WHOQOL-BREF, several studies have reported a lower QoL in patients with BD than healthy individuals.^{4, 9}

The results showed that the Leeds BD-QoL score had a moderate negative correlation with the scores of all domains of the WHOQOL-BREF questionnaire; particularly with the physical health and psychological health domains. The negative correlation could be due to the interpretation of the scores; higher scores in the Leeds BD-QoL indicate lower QoL, whereas it indicates a better QoL in the WHOQOL-BREF. In our study, it could be due to the effect of the disease on the physical and psychological aspects of the QoL of our patients in relation to their disease duration. While we compared the results of the Leeds BD-QoL with WHOQOL-BREF scores, another study assessed the correlation between the Persian version of the Leeds BD-QoL with SF-36 questionnaire; reporting non-significant and weak negative correlations.¹⁷

The main strength of the present study was the inclusion of a large number of both patients and

healthy individuals. The novelty of our research was in comparing the Persian version of the Leeds BD-QoL questionnaire with the previously validated WHOQOL-BREF questionnaire. In addition, we used a questionnaire that has been specifically developed to assess the QoL in patients with BD. The main limitation of the study was the inability to match the age, sex, and education level of the patients with that of healthy individuals. However, the negative effect of these variables was reduced by using appropriate statistical analysis. Based on our findings and considering the moderate correlation obtained between the specific and general questionnaires, further studies with more diverse samples are recommended.

Conclusion

Patients with BD had a lower QoL than healthy individuals, specifically in the physical and psychological aspects of their lives. An increase in disease activity and severity was associated with a reduced QoL. The Persian version of the Leeds BD-QoL had a good correlation with the WHOQOL-BREF questionnaire. It can be used as an alternative instrument to assess the impact of BD on the QoL of the affected patients.

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