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Quality of life assessment in behçet's disease: an observational case control single center study

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Article History:	ABSTRACT (Deck for updates
Received on: 05.06.2019 Revised on: 25.07.2019 Accepted on: 29.07.2019 <i>Keywords:</i>	Behçet's disease (BD) is a multisystemic inflammatory disorder character- ized by recurrent exacerbations. Limited studies have shown it has a negative impact on patients quality of life(QoL). This study aimed to evaluate Quality of Life in Patients with Behçet's disease compared with healthy controls. A case-
Behcets disease, Vasculitis, Quality of life, Short form 36	control study involved 71 patients with BD compared with 71 healthy controls matched in age and sex. Health-related quality-of-life was evaluated using the Short Form-36 (SF-36). All the components of Short Form-36 (SF-36), its sum- mary scores, and Total Short Form-36 (Total SF-36) score was significantly lower (p-value <0.001) in patients compared to controls. Each organ involve- ment studied may affect independently specific SF-36 subscores. Central ner- vous system involvement in BD had a strong impact since it affects most of the SF-36 subscores. Health-related Quality of life was significantly impaired in Iraqi patients with Behçet's disease compared to healthy controls. Each organ involvement studied may affect independently specific SF-36 subscores.

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INTRODUCTION

Behçet's disease (BD) is a multi system inflammatory disorder characterized by recurrent exacerbations affecting mucocutaneous tissues, eyes, blood vessels, and several other tissues (Gül, 2014; Hisamatsu and Hayashida, 2017). Among them, vascular and nervous system involvement are the most common causes of mortality in BD (Saadoun *et al.*, 2010). Behçet's disease is more frequent in the countries along the 'Silk Road', an ancient trad-

ing route, where the prevalence of HLAB51 is relatively high compared with the other parts of the globe. Turkey has the highest prevalence of Behçet's disease in the range of 20–421/100000 population (Yurdakul and Yazıcı, 2010).

The estimated prevalence of 1.7 BD patients for 10,000 Iraqi population is more or less similar to the prevalence in other Mediterranean and Far East countries, excluding Turkey (Al-Rawi and Neda, 2006).

The pathogenesis of BD appears very complex; however, the main factors are represented by the genetic background (HLA-B*51 and non-HLA (Emmi *et al.*, 2014). The frequency of HLA-B51 in the Silk Road area is 20-25% among the general population and 50-80% among patients. In Northeastern Europe and the United States, this frequency is 2-8% and 15%, respectively (Scherrer *et al.*, 2017).

The World Health Organization (WHO) put forward a definition of Health-Related Quality of Life (HRQOL) In 1993 : the perception by the individual regarding their position in life, in the context of their culture and value systems, and in relation to their goals, expectations, standards, and concerns (Onal, 2010). The Short Form-36 (SF-36), the most widely used generic HR-QOL measure, was administered (Stewart *et al.*, 1989). Any systemic disease, having considerable morbidity and mortality may readily affect the quality of life of the patients (Başaran *et al.*, 2005; Canpolat and Yurtsever, 2011). Chronic rheumatologic problems in patients with Behçet's disease are reported to limit their daily activities and have a negative impact on their self-esteem and relationships with others (Bodur *et al.*, 2006).

Most of the previous studies viewed the relationship between disease activity and Quality of Life (QoL) compared the QoL of patients with other patients group or assessed the specific impact of the type and number of symptoms on the QoL of BD patients (Mumcu et al., 2006; Alder et al., 2008; for diagnosis of Behcet's disease, 1990). The previous studies have shown that QoL in patients with BD was negatively affected by the disease. However, Behcet's disease may negatively affect patients physically, mentally and socially and may decrease their QoL significantly (Bodur et al., 2006). Up to our knowledge, there is no previous study assessed QoL in BD among a sample of Iraqi patients. This study was designed to evaluate QoL in patients with BD compared with healthy controls and to assess the correlation of QoL with organ involvement of BD.

PATIENTS AND METHODS

Study Design and Setting

This case-control study was conducted at the Rheumatology Unit of Baghdad Teaching Hospital in Medical City from July 2017 to January 2018. Informed consent was obtained from each participant included in this study, according to the declaration of Helsinki. Ethical approval was obtained from the Ethics Committee in Medical Department, College of Medicine, University of Baghdad.

Sample selection

A total of 71 consecutive patients (45 male: 26 female) were classified as Behçet's disease by fulfilling the International Study Group criteria 1990 for Behçet's disease (for diagnosis of Behcet's disease, 1990) and compared with 71 healthy controls (45 male: 26 female) matched for age and sex. Patients were excluded from the study if they had any of the following: Patient suspected to have BD clinically but did not fulfil the inclusion criteria; Pregnancy, chronic diseases, psychiatric disorders, cancer, and dependence on alcohol or other substances.

Data Collection

For each participant, findings were gathered using a pre-constructed data collection sheet for patients and controls that evaluate age, sex, smoking status, disease duration, age at disease onset, and BD organ involvements were reported. Height in centimetres and weight in kilograms were measured for all patients and controls, body mass index (BMI) was calculated according to the equation BMI=weight / height ², disease activity and medications were recorded for all patients.

A full history was taken, and a medical examination was performed for all included subjects, and the data were obtained by interviewing the patients on a one- on- one basis in a private room to make the patients feel more comfortable while answering the questions.

Measurements

The Short Form-36 (SF-36) was used to measure health-related QoL. There are currently two sources for the SF-36 and scoring instructions: licensing them from Optum, Inc., or obtaining them from publicly available documentation from the Research And Development (RAND) Corporation (Laucis *et al.*, 2015).

The RAND 36-Item Health Survey 1.0 (distributed by RAND) includes the same items as those in the SF-36 that are distributed by Medical Outcomes Study (MOS) Trust, Inc. but the recommended scoring algorithm is somewhat different (Hays *et al.*, 1993). The RAND-36 and it's scoring instructions are publicly available on the RAND Corporation website (Health, 2017).

RAND-36 assesses eight health concepts with multi-item scales (35 items): physical functioning (10 items), role limitations caused by physical health problems (4 items), role limitations caused by emotional problems (3 items), social functioning (2 items), emotional wellbeing (5 items), energy/fatigue (4 items), pain (2 items), and general health perceptions (5 items). An additional single item assesses change in perceived health during the last 12 months. Physical and mental health summary scores are also derived from the eight RAND-36 scales. The most common scoring approach for the RAND36 items boils down to transforming every item linearly to a 0-100 possible range (percent of total possible score) and then averaging all items in the same scale together (Hays and Morales, 2001). Total SF-36 score made by averaging all items in all scales collectively.

Statistical Analysis

Anderson darling test was done to asses if continuous variables follow a normal distribution if follow normal distribution then mean and standard deviation used. Discrete variables presented using their number and percentage. Chi-Square test used to analyze the discrete variable. Two samples t-test used to analyze the differences in means between two groups (if both follow a normal distribution with no significant outlier). Microsoft excel 2010 used to draw radar plot, SPSS 20.0.0, Minitab 17.1.0 software package used to make the statistical analysis, p-value considered to be significant if less than 0.05.

RESULTS AND DISCUSSION

A total of 71 patients (45 males, 26 females) with Behcet's disease were enrolled in this study. Demographic manifestations and BD Current Activity Form (BDCAF) scores of patients and healthy controls are summarized in Table 1. There was no statistically significant difference between patients and healthy controls in their age, gender, BMI, and smoking. There was statistical significant difference in the education level between patients and healthy controls (p-value <0.001), in which 36 (50.7%) of the patients had primary education level while 7(9.9%) of the healthy controls had primary education level, 21(29.6%) of the healthy controls group had college education level in contrast to 11(15.5%) in the patients group, and 18(25.4%) of the healthy controls had a Post-graduate education level in contrast to 1(1.4%) in the patients group, as illustrated in Table 1.

The mean values of SF-36 scores and its subscores were significantly lower in BD patients compared with healthy controls (p<0.001). Physical functioning (75.9 \pm 24.3), role-physical (22.9 \pm 41.6), bodily pain (56.0 \pm 35.3), general health (36.2 \pm 21.0), vitality (44.7 \pm 20.7), social functioning (75.9 \pm 36.9), role-emotional (48.4 \pm 48.7), mental health (52.7 ± 17.3) , Physical components summary (48.0 \pm 24.5), Mental components summary (55.4 \pm 23.8) and Total SF-36 score (51.8 \pm 22.0) and the mean values of SF-36 scores its subscores for healthy controls were : physical functioning (99.9 \pm 0.6), rolephysical (100.0 \pm 0.0), bodily pain (89.2 \pm 12.7), general health (83.5 \pm 7.6), vitality (80.1 \pm 8.4), social functioning (100.0 \pm 0.0), role-emotional (100.0 ± 0.0) , mental health (80.6 \pm 5.7), Physical components summary(93.2 \pm 3.7), Mental components summary (90.2 \pm 2.8) and total SF-36 score (91.7 ± 2.6) as illustrated in Table 2 and Figure 1.

This Figure 1 showed that the mean values of all SF-36 subscores were significantly lower (p-value <0.001) in patients compared to healthy controls.

Behcets disease is systemic vasculitis with signifi-



Figure 1: Graphical representation of mean values of SF-36 subscores with a radar chart in healthy controls and all BD patients

cant morbidity and mortality. This study showed the total SF-36 score and all subscores of SF-36, the two summary subscores were significantly lower in BD patients compared to healthy controls. This significant difference shown in all subscores of SF-36 in the current study may be affected in part by the higher educational level in the healthy controls compared to BD patients, This observation may be explained by the fact that Level of education determines how reasonable one is in one's reactions to the events that happen around them. People with a higher level of education could also have a higher income and better social status. Because of all these factors, one could say that people with a higher level of education might have higher QoL (Canpolat and Yurtsever, 2011).

Similar findings were reported by a recent study which showed that BD patients had significantly lower mean scores in all the SF-36 QoL subscores except for mental health and role-emotional for which the results was not significantly lower (Fabiani *et al.*, 2017).

Another study showed lower levels of Total SF-36 (p<0.001) in BD patients than healthy controls, The predominant contributors to this low Total SF-36 were general health, vitality and role-emotional domains (Bernabe *et al.*, 2010).

Previous studies showed that QoL in patients with BD was negatively affected by the disease itself or by the impact of the symptoms (Canpolat and Yurtsever, 2011; Bodur *et al.*, 2006; Mumcu *et al.*, 2006; Santos-Faria *et al.*, 2017; Tanriverdi, 2003) as shown in this study also.

Limitations of this study are the small sample size and short duration of the study that led to an inability to evaluate QoL in patients with the large vessel and several systemic involvements. However, this is the first study in Iraq that assessed health-related QoL in Behçet's disease in comparison to healthy

Variables	BD	Control	p-value
Number	71	71	-
Age (years), mean \pm SD	36.0 ± 10.8	35.9 ± 10.8	0.969 [NS]
Gender, No. (%)			
Female	26 (36.6%)	26 (36.6%)	1.0 [NS]
Male	45 (63.4%)	45 (63.4%)	
BMI (kg/m 2), mean \pm SD	28.7 ± 6.1	28.3 ± 5.7	0.691 [NS]
Education level, no. (%)			
Primary	36 (50.7%)	7 (9.9%)	<0.001 [S.]
Intermediate	12 (16.9%)	8 (11.3%)	
Secondary	11 (15.5%)	17 (23.9%)	
College	11 (15.5%)	21 (29.6%)	
Post-graduate	1 (1.4%)	18 (25.4%)	
Smoking, no. (%)	20 (28.2%)	15 (21.1%)	0.330 [NS]

BD: Behcet's disease, BDCAF: Behcet's Disease CurrentActivity Form, KG: kilogram, M²: square meter, No: number, NS:nonsignificant, P-value: Probability Value (<0.05), %: percent, S: significant, SD: standard deviation

Variables	BD	Control	p-value
Number	71	71	-
Physical function, mean \pm SD	$\textbf{75.9} \pm \textbf{24.3}$	99.9 ± 0.6	< 0.001
Role physical, mean \pm SD	22.9 ± 41.6	100.0 ± 0.0	< 0.001
Bodily pain, mean \pm SD	56.0 ± 35.3	89.2 ± 12.7	< 0.001
General health, mean \pm SD	36.2 ± 21.0	83.5 ± 7.6	< 0.001
Vitality, mean \pm SD	44.7 ± 20.7	80.1 ± 8.4	< 0.001
Social functioning, mean \pm SD	75.9 ± 36.9	100.0 ± 0.0	< 0.001
Role emotional, mean \pm SD	48.4 ± 48.7	100.0 ± 0.0	< 0.001
Mental health, mean \pm SD	52.7 ± 17.3	80.6 ± 5.7	< 0.001
Physical components summary, mean \pm SD	48.0 ± 24.5	93.2 ± 3.7	<0.001
Mental components summary, mean \pm SD	55.4 ± 23.8	90.2 ± 2.8	<0.001
The total score, mean \pm SD	51.8 ± 22.0	91.7 ± 2.6	< 0.001

Fable 2: Mean and standard devi	ation values of SF-36 subsc	ores in BD patients and controls
		F

Abbreviations:BD: Behçet's disease, SD:standard deviation, SF-36: Short form -36; P-value, Probability Value(<0.05); Independent t-test compares the means of two groups

controls group with strict inclusion and exclusion **REFERENCES** criteria.

CONCLUSION

In Conclusion, Health-related QoL was significantly impaired in Iraqi patients with BD compared to their age- and gender-matched healthy controls. Further, studies with larger sample size and longer duration are highly recommended. Proper management of manifestations of Behcet's disease and controlling disease activity is crucial to improving the quality of life of Behçet's disease as part of clinical management.

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