

## Comparison of Quality of Life in Patients with Systemic Lupus Erythematosus and Healthy Controls in North-East of Iran

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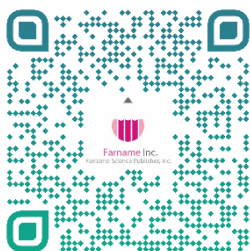
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### ABSTRACT

**Background & Objective:** Systemic Lupus Erythematosus (SLE) is a multi-system autoimmune disorder that its symptoms could affect all aspects of a patient's quality of life (QoL). This study aimed to assess the quality of life of SLE patients and compare them with those of healthy individuals. It also attempted to compare the QoL of SLE patients suffering from minor and major organ involvement to that of healthy individuals.

**Materials & Methods:** This cross-sectional study was conducted at the Rheumatic Diseases Research Center, Mashhad, Iran, from 2018 to 2019. A total of 280 participants were selected and divided into two groups of patients with SLE (n=139, one of whom was excluded from the case group due to the lack of information.) and healthy controls (n=140). After obtaining the demographic characteristics of the general health, the groups were compared using the 36-Item Short Form Survey (SF-36) and the World Health Organization Quality of Life-BREF (WHOQOL-BREF) questionnaire.

**Results:** The mean QoL score was significantly lower in SLE patients, compared to the healthy controls (P<0.001). The total score of QoL was also lower in patients with lung involvement, compared to the healthy controls (P<0.05). Moreover, according to the WHOQOL-BREF, environmental health was lower in patients with lung and skin involvement, compared to the healthy controls (P=0.01). According to the results obtained from the SF-36 questionnaire, the total QoL status was lower in patients with both minor and major organ involvement, compared to the healthy controls (P<0.05). There was also a significant difference between patients with joint involvement and the healthy controls regarding QoL (P=0.02).

**Conclusion:** According to the obtained results, SLE can negatively alter QoL. The severity and activity of the disease in some major organs, including the lung and joints, were associated with reduced QoL.

**Keywords:** Health Status, Quality of Life, SF-36 Questionnaire, Systemic Lupus Erythematosus



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## Introduction

Systemic Lupus Erythematosus (SLE) is a multi-system autoimmune disorder in which the immune system attacks its tissues and organs (1). Inflammation caused by SLE is a major symptom that dysregulates the activity of the skin, joints, kidneys, heart, and lungs (2). The onset of various symptoms of lupus is different between males and females. Studies have shown that males are more probable to have lupus nephritis and cardiovascular comorbidities, whereas the inflammatory rash, including butterfly facial rash across both cheeks and arthritis, was reported more in females (3-5).

SLE is a relatively common disorder in Iran with a prevalence of 40 per 100,000 population (6).

Approximately 85% of the early-diagnosed patients have a survival rate of 10 years, and a delay in diagnosis will decrease the survival rate (7, 8). Symptoms of SLE, which can appear slowly or quickly, could affect all aspects of a patient's quality of life (QoL). In addition, aggravation and spread onto the vital organs could be followed by a complete disability of some organs, leading to the impairment of QoL (9). The QoL is described by the World Health Organization (WHO) as individuals' perceptions of their positions in a culture or the way their needs are fulfilled regardless of their physical state of health or socioeconomic status (10). Current treatment strategies with glucocorticoids and disease-modifying anti-rheumatic drugs aim to decrease symptoms, induce

remission, or at least alleviate the activity of the disease and prevent the potential flares and subsequent harms.

Due to the lack of appropriate treatment procedures and investigations into new medications, SLE patients suffer from an inadequately controlled disease. These factors lead to substantial increases in morbidity and poor health-related QoL, both of which are more pronounced in developing countries (11).

To reduce the unwanted physical and mental difficulties imposed by SLE and improve QoL, there is a need for more studies about the impact of SLE on QoL (12). In this regard, more assessments are needed to unravel the risks among the different affected populations. Several studies have been conducted in various regions of Iran to investigate the condition of QoL or mental status in SLE patients (13-17). In this study, we aimed to investigate the impact of SLE on the QoL of patients and compare it to that of healthy individuals. We also attempted to evaluate the association of QoL with disease severity, the type of organ involved, the duration of the disease, as well as the dose and type of medications.

## Materials and Methods

This cross-sectional study was conducted on SLE patients referred to the Clinic and Rheumatology Department of Ghaem Hospital, Mashhad, Iran, between 2018 and 2019.

The present study was extracted from a thesis to obtain the doctorate in rheumatology (Code: 950837). This study protocol was approved by the Research Ethics Committee of Mashhad University of Medical Sciences, Mashhad, Iran (IR.MUMS.fm.REC.1395.485). Before the study, research objectives and procedures were explained to the patients, and informed consent was obtained from them. They were also assured that their information would remain confidential.

### Inclusion and Exclusion Criteria

The study population included all patients diagnosed with SLE referred to the Rheumatic Diseases Research Center, Iran. It should be mentioned that they were at least 18 years old, and the diagnosis was made based on the criteria of Systemic Lupus International Collaborating Clinics (SLICC) (2012) (18). On the other hand, patients with underlying diseases were excluded from this study.

### Research Tools

The WHO Quality of Life (WHOQOL)-BREF is a shorter variant of the WHOQOL-100 that comprises 26 questions and was developed and published in 1995 by the WHO. The WHOQOL-BREF determines individuals' perceptions of four major domains, including physical health, psychological health, social relationships, and environmental health (19). The Iranian version of the WHOQOL-BREF was approved by Nejat *et al.* (20). The Cronbach's alpha values of physical health, psychological health, social communication, and environmental health were estimated at 0.81, 0.79, 0.82, and 0.8, respectively.

Additionally, the 36-Item Short Form Survey (SF-36) was used as a general questionnaire (21) to assess health. Following that, specific questionnaires, including the SLICC American College of Rheumatology Damage Index, were utilized in this study to collect data. Specific questionnaires were developed by specialists to cover all factors that can affect the QoL of SLE patients (22-24). Another index used in this study was the Systemic Lupus Erythematosus Disease Activity Index 2000, which is regarded as a global clinical index to survey the lupus disease activity in 10 days. Furthermore, it provides information for the basis of clinical global judgment by assessing variants of nine organ systems (25).

### Study Design

The sample was selected through available sampling. A total of 139 patients with SLE were included in this study, and 140 healthy individuals were selected as the healthy controls. Lupus patients referred to the Clinic and Rheumatology Department of Ghaem Hospital, Mashhad, Iran, were selected for the case group, and the controls were selected from the companions of patients referred to blood transfusion centers and orthopedic clinics. Companions of patients with chronic diseases were not selected because their QoL may have been affected by the illness of their loved ones.

The case group included patients suffering from SLE with and without vital organ involvement. This group was subsequently divided into two subgroups based on the need for hospitalization or outpatient treatment. On the other hand, the control group included healthy individuals with no reports of chronic diseases. The controls were not part of the hospital staff.

After obtaining approval from the local Ethical Committee, the demographic characteristics of the patients, including age, gender, level of education, income, and marital status, were recorded on a checklist. Moreover, a history of the disease, including the age of onset and duration, major symptoms, disease severity, and medications, was gathered by a nurse and a clinical psychologist. The information was taken from both medical records and study interviews.

The QoL questionnaires were filled out by the patients themselves (in the case of illiteracy, they were completed by a trained nurse). Finally, the data were gathered, and the groups were compared in terms of various variables.

### Statistical Analysis

The obtained data were analyzed in the SPSS software (version 16) through the Kolmogorov-Smirnov test to assess the normality of data distribution. Moreover, the quantitative and qualitative variables were described through mean±SD and frequency, as well as percentage, respectively. Following that, the independent t-test, Chi-squared test, and regression were used to analyze the data. A P-value of less than 0.05 was considered statistically significant.

## Results

### Demographic Characteristics and Health History

In total, 280 patients were included in this study, one of whom was excluded from the case group due to a lack of information. Therefore, 139 patients with SLE (hospitalized [n=19] and outpatient [n=114]) and 140 healthy controls were included in this study. The mean ages at presentation were determined at 38.46±11.37 and

36.92±11.27 years in the case and control groups, respectively, without any significant difference ( $Z=-1.303$ ,  $P=0.192$ ). The mean ages at disease onset and duration of illness were estimated at 32.92±12.9 and 6.54±5.61 years, respectively. Furthermore, the mean number of hospitalizations was determined at 2.68±3.63 years. There was also no significant difference between the two groups in terms of gender or marital status ( $P>0.005$ ). The demographic characteristics of the case group and the healthy controls are presented in [Table 1](#).

**Table 1. Demographic characteristics of the case group and the healthy controls**

Variables	SLE group (n=139)		Control group (n=140)		P-value	
	N	%	N	%		
Gender	Female	124	89.2	125	89.3	0.983
	Male	15	10.8	15	10.7	
Education	Illiterate	13	9.4	3	2.1	0.012
	Middle school	42	30.2	30	21.4	
	Diploma	43	30.9	38	27.1	
Marital status	Academic	41	29.5	69	9.3	0.303
	Married	112	82.4	106	75.7	
Income	Single	24	18	33	23.6	0.012
	Low	60	43.2	52	37.1	
	Middle	69	49.6	61	43.6	
	High	10	7.2	27	19.3	

As can be seen in [Table 2](#), of 139 patients who suffered from SLE, 85 (61.2%) had minor organ involvement (skin and joints), and 74 (53.2%) had major organ involvement (heart, lungs, kidneys, eyes, and blood).

The mean length of the disease was less than 3 years in 9.1% of inpatients. It was between 3-10 years in 72.7% and more than 10 years in 18.2% of them.

Moreover, the mean length of the disease was lower than 3 years in 41.1% of outpatients. It was between 3-10 years in 42.1% and more than 10 years in 16.8% of them ( $P=0.093$ ). The frequencies of minor and major organ involvement among inpatients and outpatients were obtained at 10 (52.6%) and 73 (64%), respectively. [Table 2](#) presents the distribution of minor and major organ involvement in the two subgroups of SLE, including outpatients and inpatients.

**Table 2. Distribution of minor and major organ involvement in the two subgroups of systemic lupus erythematosus, including outpatients and inpatients**

Organ type	Outpatient (n=114)		Inpatient (n=19)		Total		
	N	%	N	%	N	%	
Minor organs	Skin	41	36	7	36.8	50	36
	Joint	49	43.0	7	36.8	57	41
	Kidney	32	27.8	9	47.4	42	30.2
Major organs	Lung	15	13.2	0	0	16	11.5
	Heart	5	4.4	1	0.7	6	4.3

Blood	24	21.1	2	1.4	28	20.1
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### WHOQOL-BREF and SF-36 Findings

[Table 3](#) tabulates the results of the WHOQOL-BREF questionnaire in the SLE and healthy control groups. As can be seen, there was a significant difference between the two groups in physical, psychological, social, and environmental health, as well as the total score of QoL ( $P < 0.005$ ). Based on the obtained results, there was also a significant difference between the SLE and healthy control groups in physical functioning, emotional role functioning (limitations in usual role activities because of emotional problems), body pain, vitality (energy and fatigue), social role functioning

(limitations in social activities because of physical or emotional problems), and general mental health (psychological distress and well-being) ( $P < 0.005$ ). However, no significant difference was observed between the two groups regarding physical role functioning (limitations in usual role activities because of physical health problems) or general health perceptions ( $P > 0.005$ ). The total score of SF-36 was higher in patients with SLE than in the healthy controls ( $P < 0.005$ ). The comparison of WHOQOL-BREF and SF-36 questionnaires in outpatients and inpatients with healthy individuals is presented in [Table 4](#).

**Table 3.** Items of the World Health Organization Quality of Life-BREF and 36-Item Short Form Survey questionnaires in the case group and the healthy controls

Variables	Healthy group (n=140)		SLE group (n=139)		Total (n=280)		T**	P-value	
	Mean	SD	Mean	SD	Mean	SD	Z*		
WHOQOL-BREF	Physical health	63.77	22.27	47.82	25.1	56	24.96	26.97*	<0.001
	Psychological health	61.79	17.22	55.88	20.41	58.88	19.05	5.94*	0.013
	Social relationships	60.68	21.39	53.2	23.32	57.02	22.62	6.95*	0.008
	Environmental health	64.87	17.35	58.16	19.4	61.61	18.64	8.59*	0.003
	Total score	15.91	63	17.55	53.75	17.31	58.57	-4.48**	<0.001
SF-36	Physical functioning	70.87	29.18	34.16	29.16	52.45	34.43	77.31	<0.005
	Physical role functioning	99.81	2.15	98.91	5.94	99.35	4.51	2.608	0.106
	Emotional role functioning	96.54	14.26	99.5	4.042	98.02	10.57	3.83	0.050
	Vitality (energy and fatigue)	39.17	18.85	51.03	23.49	44.79	21.95	17.63	<0.005
	Social role functioning	37.65	19.91	42.36	23.61	39.9	21.84	2.03	0.154
	General health perceptions	68.96	25.17	61.91	29.96	65.23	27.97	2.71	0.100
	Bodily pain	70.31	24.57	59.44	28.36	64.73	27.08	9.11	0.003
	General mental health	40.27	16.54	46.14	20.02	43.25	18.58	6.02	0.014
Total score	60.82	11.7	54.09	11.86	57.48	12.23	28.55	<0.005	

\*Kruskal-Wallis test

\*\*T-test

**Table 4.** Comparison of the subscales of World Health Organization Quality of Life-BREF and 36-Item Short Form Survey questionnaires in outpatients and inpatients to the healthy controls

Variables	Outpatients		Inpatients		Z	P-value
	Mean	SD	Mean	SD		
Physical health	49.57	25.06	38.36	23.07	2.79	0.091

	Variables	Outpatients		Inpatients		Z	P-value
		Mean	SD	Mean	SD		
WHOQOL-BREF	Psychological health	56.41	20.42	52.36	21.77	0.67	0.413
	Social relationships	53.08	23.88	53.52	21.40	0.05	0.824
	Environmental health	58.38	18.6	56.78	21.23	0.74	0.387
	Total score	54.37	17.79	50.26	16.3	-0.93	0.354
SF-36	Physical functioning	33.84	28.65	39.47	32.44	0.56	0.451
	Physical role functioning	98.67	6.54	100	0	0.86	0.352
	Emotional role functioning	99.39	4.47	100	0	0.34	0.555
	Vitality (energy and fatigue)	50.38	21.86	56.47	27.88	0.88	0.348
	Social role functioning	41.8	22.61	43.27	24.51	0.25	0.802
	General health perceptions	64.66	28	47.91	34.63	4.15	0.041
	Bodily pain	62.63	25.76	38.88	31.52	8.79	0.003
	General mental health	44.61	19.56	56.66	19.17	5.87	0.015
Total score	53.91	11.4	55.07	13.52	0.39	0.691	

#### Quality of Life Based on Minor and Major Organ Involvement

The comparison of patients with minor and major organ involvement in terms of the subscales of WHOQOL-BREF and SF-36 scores is shown in [Table 5](#).

**Table 5.** Comparison of patients with minor and major organ involvement in terms of the subscales of WHOQOL-BREF and SF-36 scores

Questionnaires	Minor Organs				Major organs				
	Skin	Joint	Total	Renal	Lung	Heart	Blood	Total	
WHOQOL-BREF	Physical health	0.2	0.33	0.73	0.107	0.06	0.69	0.71	0.19
	Psychological health	0.07	0.84	0.07	0.44	0.58	0.46	0.51	0.42
	Social relationships	0.87	0.41	0.74	0.93	0.09	0.89	0.06	0.97
	Environmental health	0.01	0.41	0.32	0.09	0.01	0.82	0.19	0.49
	Total score*	0.051	0.35	0.51	0.09	0.02	0.79	0.99	0.49
SF-36	Physical functioning	0.37	0.003	0.007	0.051	0.16	0.62	0.53	0.02
	Physical role functioning	0.87	0.4	0.406	0.2	0.41	0.62	0.25	0.12
	Emotional role functioning	0.68	0.806	0.73	0.86	0.603	0.75	0.28	0.908
	Vitality (energy and fatigue)	0.12	0.63	0.14	0.31	0.04	0.95	0.49	0.58
	Social role functioning	0.28	0.98	0.26	0.008	0.008	0.33	0.44	0.05
	General health perceptions*	0.29	0.73	0.41	0.58	0.19	0.85	0.21	0.99
	Bodily pain	0.104	0.12	0.003	0.56	0.02	0.38	0.77	0.056
	General mental health	0.91	0.59	0.74	0.02	0.12	0.96	0.36	0.01

Total score*	0.14	0.02	0.02	0.06	0.03	0.7	0.17	0.04
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Based on both WHOQOL-BREF and SF-36, the total score of QoL was lower in patients with lung involvement than in the healthy controls ( $P < 0.005$ ). Moreover, according to the WHOQOL-BREF, environmental health was lower in patients with lung and skin involvement than in the healthy controls ( $P = 0.013$ ). Based on the SF-36 questionnaire, the total QoL score was lower in patients with both minor and major organ involvement than in the healthy controls ( $P < 0.005$ ). Furthermore, the findings revealed that physical functioning ( $P = 0.022$ ), social role functioning ( $P = 0.050$ ), and general mental health ( $P = 0.012$ ) were lower in patients with major organ involvement, compared to the healthy controls. Moreover, a significant difference was reported between the patients with lung and renal involvement and the healthy control in terms of social role functioning ( $P = 0.008$ ). The total score of SF-36 was significantly different between the patients with joint involvement and the healthy controls ( $P = 0.02$ ).

#### Univariate Regression Test of QoL

The results of the univariate regression test of the subjects' QoL and their demographic characteristics showed a significant correlation of QoL with age, the number of children, level of education, income, and marital status ( $P < 0.005$ ). The relationship between QoL and the health status of the studied patients with the type of medications used was also evaluated, which was not significant ( $P > 0.005$ ).

## Discussion

The evaluation of QoL in SLE patients continues to attract studies to unravel the challenges of living with SLE. Moreover, it leads to the development of supportive plans and ensures the proper relationship between physicians and patients (26). Several previous cross-sectional studies have shown varying degrees of correlation between SLE and QoL (13-17). However, based on our knowledge, this is the first cross-sectional study comparing SLE patients with minor and major organ involvement in the Iranian community.

The results of the WHOQOL-BREF and SF-36 questionnaires showed that the QoL of the SLE group was significantly lower than that of the healthy group, indicating the non-negligible impact of SLE and health on individuals' understanding of their QoL. It means that SLE can affect most aspects of life, as some studies have recorded that QoL is exacerbated by disease activity in SLE patients (27, 28).

The current study showed that SLE patients with more disease activity had lower QoL scores, which was consistent with the results of other studies (13, 14).

Moreover, the results of the two questionnaires confirmed a lower QoL in SLE patients with lung involvement, compared to the healthy controls. Based

on the WHOQOL-BREF, environmental health was lower in patients with lung and skin involvement than in the healthy controls. Based on SF-36, the QoL of patients with both minor and major organ involvement was lower, compared to that of the healthy controls. Patients with lung and renal involvement showed lower ability in the subscale of social role functioning. Moreover, physical functioning, social role functioning, and general mental health were lower in patients with major organ involvement, compared to the healthy controls. Additionally, physical functioning was lower in patients with joint involvement than in the healthy controls.

Another cross-sectional study conducted on 252 patients also reported the disturbed function of major organs, including the kidneys, leading to physical limitations and emotional problems (28). However, it was not confirmed in the present study, which may be due to sample differences. Moreover, our findings faced limitations because of the lack of patients' awareness of the status of major organs, which might have affected the responses to the questionnaires. In the current study, major organ involvement (lungs) and minor organ involvement (skin) were associated with decreased environmental health status. However, other major organ involvements were not related to decreased environmental health status, which can be attributed to the dysregulation in function and involvement of minor organs, such as skin and joints, since they are apparent and occur earlier, while the involvement of vital organs can be silent (29). According to the results of recent studies, skin manifestations will not directly affect daily activities; nonetheless, they can reduce the score of QoL (29). The SF-36 showed that both minor and major organ involvement were related to the total score of QoL.

The results of a study performed by Goreshti et al. showed that 62% of patients with dermatomycosis had poor QoL based on questionnaire findings (30). The present study also indicated the joints as the most affected organ among SLE patients, which had a direct relationship with environmental health status. One of the factors that help achieve this result in many studies is probably a sign of self-reported measures being closely related to rheumatic symptoms. It means that irreversible organ damage and the presence of pain and inflammation in joints can strongly limit the daily activity of patients and exacerbate their QoL (31-33).

Only a few studies have addressed the impact of minor or major organ involvement in SLE on QoL. According to the results of the SF-36, QoL significantly correlated with minor and major organ involvement; however, lung involvement was related to QoL based on both WHOQOL-BREF and the SF-36. The reasons for this discrepancy between these questionnaires regarding the QoL score of joint involvement are not clear. Accordingly, further studies

are recommended in this regard. In our study, joints obtained the highest rate of involvement (41%), and kidney involvement was reported in 30% of the patients, which was lower, compared to that in other studies (34). The association between joint damage and reduced QoL in SLE patients should be considered by rheumatologists. As mentioned before, one of the factors that can limit our results is the lack of patients' awareness of the major organs' status, which affects the responses to questionnaires. However, if the focus is on the results obtained from the inpatients, kidney damage can strongly reduce QoL, which does not seem far-fetched. This result is in line with the international and cross-sectional data from 1,259 SLE patients, demonstrating poor QoL in patients with active lupus nephritis (35-37). It is worth mentioning that patients with active lupus nephritis need more comprehensive QoL assessments.

Furthermore, our results showed that the overall SLE-related QoL was significantly associated with the level of education and income. A higher level of education and income improved SLE patients' QoL. This outcome was consistent with a previous finding that stated the level of education and income affect SLE patients' QoL (38, 39). Furthermore, according to the results of a recently conducted narrative review by Phuti et al. on the relationship between QoL and SLE, poor socio-economic status can reduce access to healthcare, as well as mental, social, and emotional support services. This increases the harmful effects of the disease on SLE patients' QoL. Therefore, there is a need for more studies (11).

However, the positive correlation between the level of education and SLE patients' QoL contradicts the results of a study conducted by Gaballah and El-Najjar on Egyptian patients with SLE (40). This discrepancy could be attributed to the lack of a healthy group in their study. The findings also revealed a significant relationship of QoL scores with age, marital status, and the number of children (41). Most of the participants in both the healthy and SLE groups were female and married. However, the mothers who had more children had more difficulties playing games, shopping, and doing household chores, which reduced their self-satisfaction levels and QoL (42).

Based on the total score of the WHOQOL-BREF and SF-36 questionnaires, no significant difference was found between outpatients and inpatients in their QoL. However, the outpatients outperformed the inpatients in some domains of the questionnaires, including general health, health limitations, physical pain, and social role functioning. This result can be interpreted by the disease activity and severity, which are the results of the lupus-specific questionnaire. Approximately, the disease activity in the inpatients was 2.5 greater than that in the outpatients. In addition, most of the outpatients (95.9%) had low illness severity. More disease activity and severity in inpatients resulted in poor health status, fatigue, and

pain, which could worsen the score of the special domains of the WHOQOL-BREF and SF-36 questionnaires. The correlation between disease activity and QoL was also proven by two recently conducted meta-analyses and systematic studies (43, 44).

## Conclusion

According to the obtained results, SLE can negatively alter QoL. This study provided the first comprehensive assessment of the relationship of QoL with disease activity and organ damage in SLE outpatients and inpatients. We found that the severity and activity of the disease in some major organs, including the lung and joints, were associated with reduced QoL. Another important point that should be considered by specialists in this regard is the significant effect of some major and minor organ involvements on a person's view of their health status.

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## Authors' Contributions

This study was carried out in collaboration by all authors. ZRY designed the study and performed the statistical analysis. MKH wrote the protocol and the first draft of the manuscript. MS and ZF managed the analysis of the study. RKH managed the literature searches. All authors approved the final manuscript submitted and agreed to be accountable for all aspects of the work.

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## Conflict of Interest

The authors declare that there was no conflict of interest.

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