Original article

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QUALITY OF LIFE AND SEVERITY OF FATIGUE IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS

Valentina Živković[1,2], Bojana Stamenković[1,2], Sonja Stojanović[1,2], Tatjana Cvetković[1,3], Biljana Radovanović-Dinić[1,4]

In order to assess adequately the success of treatment in patients with systemic lupus erythematosus (SLE), it is necessary to evaluate their quality of life and severity of fatigue. This study aimed to investigate the quality of life of SLE patients, severity of fatigue they experience, and correlations between disease activity, organ damage and quality of life. The study involved 85 patients with SLE in whom the diagnosis was made based on the revised 1997 ACR criteria and 30 healthy examinees. The disease activity was assessed using the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI), organ damage was evaluated using the SLICC/ACR damage index (SDI), quality of life using the Medical Outcome Survey Short Form 36 (SF-36), and severity of fatigue using the Fatigue Severity Scale. The quality of life of SLE patients measured with SF-36 was significantly lower than that in healthy individuals ($p < 0.001$) and in most of the surveyed domains was not correlated with disease activity. The domain of physical functions in SLE patients demonstrated poorer results compared to mental functions, and the average results were below 52% in all SF-36 domains. Poorer quality of life was associated with a higher organ damage index (SDI), with the exception of emotional status domain. There was a significant difference in the severity of fatigue between SLE patients and controls ($p < 0.001$). Fatigue was positively correlated with organ damage ($p < 0.01$), and was not correlated with disease activity. Quality of life and severity of fatigue are associated more with organ damage than with disease activity in SLE patients.

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Key words: *systemic lupus erythematosus, quality of life, severity of fatigue*

[1]University of Niš, Faculty of Medicine, Niš, Serbia
[2]Institute for Treatment and Rehabilitation „Niška Banja", Niš, Serbia
[3]Clinic of Nephrology Niš, Clinical Centre Niš, Serbia
[4]Clinic of Gastroenterology and Hepatology, Clinical Centre Niš, Serbia

Contact: Valentina Živković
Vidoja Jovanovića 28, Niška Banja, Serbia
E-mail: ljubisa.nina@gmail.com

Introduction

SLE is a chronic inflammatory autoimmune disease characterized by multisystem clinical manifestations and serological finding of a multitude of antibodies (1). In order to assess adequately the success of treatment in SLE patients, in addition to the measurement of disease activity and degree of organ damage, the patient perception of one's own physical and mental health and degree of integration into the socity is necessary as well (2). The most commonly used standardized questionnaire for health-related quality of life (HRQoL) assessment, involving physical, psychological, mental and social domains, is the Medical Outcome Survey Short Form 36 (SF-36) (3, 4). The results obtained so far have been conflicting regarding the correlation of disease activity index, degree of organ damage in SLE patients and quality of life (4-8). Since fatigue is one of the primary symptoms in SLE patients, the severity of fatigue should be adequately assessed as well.

Aim of the paper

The aim of this paper was to assess the quality of life in individuals with SLE using the SF-36 questionnaire, as well as the severity of fatigue using the Fatigue Severity Scale (FSS). We also examined the correlation between disease activity index (Systemic Lupus Erythematosus Disease Activity Index – SLEDAI), organ damage index (Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index for SLE – SLICC /ACR Damage Index – SDI) and quality of life.

Material and methods

Our cross-sectional study involved 85 patients with SLE aged over 18 years, hospitalized in the Institute „Niška Banja", in whom the definitive diagnosis of SLE had been made in accordance with the revised 1997 ACR criteria, with the presence of at least 4 out of the total of 11 criteria for the disease (9). Thirty healthy examinees constituted our control group. In all patients, the degree of disease activity was assessed using the SLEDAI activity index (10); the degree of organ damage was assessed using the SDI organ damage index (11); quality of life was assessed using the SF-36 questionnaire (12); and severity of fatigue was assessed using the FSS scale (13) (all standardized questionnaires). The SLEDAI index estimated disease activity in 9 organ systems based on the presence or absence of 24 variables during the examination. The values ranged from 0 to 105. The SDI index estimated organ damage in 9 organ systems and 3 disease complications. Each component was precisely defined in the glossary for SLICC/ACR damage index and was assigned a number of points. The SF-36 questionnaire consisted of 36 questions grouped in 8 domains, as well as the question about status changes. These domains were as follows: physical functioning, limitations related to physical difficulties, limitations related to emotional difficulties, vitality and energy, emotional status, social functioning, pain and general health. It also included three general, summative domains originating from the mentioned eight particular domains: physical health, mental health and general health. All the responses were assigned from 0 to 100 points, in accordance with the supplemented key, with more points indicating better quality of life. The fatigue scale contained 9 statements with possible answers graded from 1 to 7 (with 1 indicating „I completely disagree" and 7 indicating „I completely agree"). The average value was calculated from the sum of the values obtained for each question, i.e. statement, related to the severity of fatigue and degree of its impact on physical activity and motivation. Fatigue was considered serious if the average FSS scale value was over 4.

The entry and tabular representation of data was done using the MS Office Excel software package. Statistical calculations were performed using the SigmaStat 3.5 software. Attributive parameters were expressed as percentages, and continual (measurable) parameters were espressed as mean values (X) and standard deviations (SD), median (Md), coefficient of variation (CV) and 95% confidence interval (95% CI). Coefficient of variation was determined as the measure of homogeneity of the studied examinee samples related to the studied parameters. A homogenous sample was considered the one in which CV was 30 as a maximum. The correlation of continuous variables was established using the Pearson's coefficient of linear correlation (r).

Results

The study included 85 patients with SLE and 30 healthy controls. The average age of SLE patients at the time of the study was 45.3 ± 9.7 years (range, 22 to 64 years). The average age of control group subjects was 44.7 ± 9.5 years. In SLE group, there were 78 women (91.8%) and 7 men (8.2%), with female-to-male disease ratio of 11.1:1. Both groups were homogenous as to the age and gender distribution. The average disease duration in the studied group was 10.4 ± 8.0, and average age at the disease onset was 34.9 ± 9.4 years. The average period from the onset of symptoms of SLE to diagnosis was 13.1 ± 15.3 months (Table 1). At diagnosis, most of the patients fulfilled 4 and 5 criteria for the disease; 5 criteria (min 4; max 9) was the median, and the mean value of the number of criteria was 5.2 ± 1.2.

General disease manifestations, such as weakness, exhaustion and fatigue, were most common and present in 83 patients (97.6%). Arthritis and arthralgias were present in 80 patients (94.1%), skin changes in 76 (89.4%), photosensitivity in 61 (71.7%), serositis in 40 (47.1%), and hematological manifestations in 50 patients (58.5%). Lupus nephritis was found in 32 patients (37.6%), and neuropsychic manifestations in 16 (18.8%). The mean value of SLEDAI was 11.4 ± 7.5, with median value of 8 (min 0, max 36). The mean value of SDI was 1.8 ± 1.9, and median was 1 (min 0, max 9).

In 58 patients (68.2%) SDI was ≥1, and 27 patients (31.8%) had no organ damage. In 21 patients (24.7%) SDI value was 1; 20 patients had SDI of 2 or 3 (23.5%); and 17 patients (20.0%) had SDI ≥ 4. As for organ damage, neuropsychic and musculoskeletal changes were the most common and present in 23 patients (27.1%). In 21 patients (24.7%) cardiovascular changes were found, and eye lesions were present in 14 patients (16.5%). Renal and pulmonary changes were present in 13 patients (15.3%), skin changes in 3 patients (3.5%), and gastrointestinal changes in 2 patients (2.4%). Malignancies were present in 5 patients (5.9%), and diabetes mellitus in 2 patients (2.4%).

In all the domains of the SF-36, quality of life was significantly worse in the group of SLE patients compared to controls ($p < 0.001$). The domain of physical functions in SLE patients had poorer results compared to mental functions (36.7 vs. 49.1), and average results were below 52% in all the SF-36 domains (Table 2). Examining the correlation between the SLEDAI and quality of life as expressed in the SF-36, a negative correlation was found only between the limitations due to physical difficulties and SLEDAI ($r = -0.216$; $p < 0.05$). There was a negative correlation between all the SF-36 domains and SDI damage index ($p < 0.001$ for most of the domains), with the exception of emotional status and SDI, where no correlation was found (Table 3).

Fatigue was the predominant symptom in SLE patients, present in 97.6% of the cases. There was a significant difference in the severity of fatigue be-

tween SLE patients and controls (30 healthy examinees). The mean value of fatigue calculated using the FSS scale in SLE group was 5.8 ± 1.6 versus 3.1 ± 0.8 in controls ($p < 0.001$) (Table 4). Serious fatigue, expressed as the mean value of > 4 on the fatigue scale, was present in 70 patients with SLE (82.4%) and in only 5 controls (16.7%). There was not any correlation between the SLEDAI activity index and severity of fatigue assessed based on the FSS fatigue scale. We found a positive correlation between the SDI damage index and FSS scale value ($r = 0.324$; $p < 0.01$).

Table 1. Demographic characteristics of the subject

	Controls (n = 30)	SLE (n = 85)
Gender (M/F)	3/27	7/78
Age (years)	44.7 ± 9.5	45.3 ± 9.7
Disease duration (years)		10.4 ± 8.0
Age at diagnosis (years)		35.9 ± 9.7
Time to diagnosis (months)		13.1 ± 15.3

Table 2. Quality of life calculated using the SF-36

SF-36	Controls (n = 30)	SLE (n = 85)
Physical functioning	85.8 ± 13.1	38.9 ± 31.6*
Limitations related to physical difficulties	81.2 ± 19.3	42.4 ± 32.9*
Limitations related to emotional difficulties	75.5 ± 16.1	51.4 ± 29.6*
Vitality and energy	64.9 ± 19.3	31.7 ± 27.5*
Emotional status	70.1 ± 15.3	44.6 ± 27.9*
Social functioning	81.7 ± 14.2	51.3 ± 32.8*
Pain	77.4 ± 17.1	40.8 ± 30.0*
General health	74.2 ± 15.4	29.9 ± 22.3*
Physical health	76.7 ± 14.7	36.7 ± 26.7*
Mental health	75.7 ± 13.4	49.1 ± 26.9*
Total health	76.4 ± 13.8	41.0 ± 25.2*

* - $p<0.001$ vs. controls

Table 3. Correlation between all the SF-36 domains and SDI

SF36	SDI
Physical functioning	$r = -0.418$ $p < 0.001$
Limitations related to physical difficulties	$r = -0.411$ $p < 0.001$
Limitations related to emotional difficulties	$r = -0.384$ $p < 0.001$
Vitality and energy	$r = -0.313$ $p < 0.01$
Social functioning	$r = -0.341$ $p < 0.01$
Pain	$r = -0.382$ $p < 0.001$
General health	$r = -0.352$ $p < 0.001$
Physical health	$r = -0.410$ $p < 0.001$
Mental health	$r = -0.336$ $p < 0.01$
Total health	$r = -0.407$ $p < 0.001$

Table 4. The mean value of fatigue calculated using the FSS scale

FSS	Controls (n = 30)	SLE (n = 85)
FSS total score	27.8 ± 7.4	51.8 ± 14.3*
FSS mean value	3.1 ± 0.8	5.8 ± 1.6*

* - p<0.001 vs. controls

Discussion

SLE is a chronic disease which affects physical, social and psychological status of the affected. Although the survival rate of SLE patients has been dramatically improving over the last 50 years, quality of life of the affected is still relatively poor. Fatigue, fibromyalgia, depression and cognitive dysfunction significantly contribute to their poor quality of life. HRQoL, as it appears, is not so much associated with disease activity or organ damage, but the issue has still been debated in the literature (4-8, 14, 15). Various questionnaires have been used in quality of life assessments. Some of them are SLE-specific, but the one most widely used (and not only in SLE patients) is the SF-36 questionnaire (4, 16). Touma et al. have reported their results which sug-gest that SF-36 and LupusQoL are of similar value in the assessment of quality of life in SLE patients and that they represent sensitive enough quality of life measures for SLE patients with disease progression and exacerbations (17).

The studied group of 85 patients with SLE hospitalized for treatment in the Institute „Niška Banja" was a representative patient sample, similar by their demographic characteristics to other reported patient cohorts (18). The results of this study showed a significantly worse quality of life in all the SF-36 surveyed domains in SLE patients compared to control examinees ($p < 0.001$), which agreed with the literature data (5, 6, 14, 15, 19). We were also able to show that the average quality of life result was below 52% in all 8 examined domains, and that physical function domains yielded worse results compared to mental function domains, which was in accordance with the results obtained by a group of Portuguese authors (14). They also reported that there was no correlation between the SLEDAI clinical activity index and cumulative damage (SDI) with quality of life measured by the SF-36 questionnaire.

In the present study, examining the correlation between the SLEDAI disease activity index and quality of life assessed by SF-36, a negative correlation was found only between limitations due to physical activity and SLEDAI ($p < 0.05$), which was similar to the results of other studies, being mostly unable to find any correlation between quality of life and disease activity (5, 14, 15, 20).

The present study showed a significant negative correlation between all the SF-36 domains and SDI damage index ($p < 0.001$), except for the emotional status and SDI values, where there was no correlation, meaning that organ damage was associated with poorer quality of life. Some of the studies have reported the association of organ damage with quality of life in SLE patients (21). A study which investigated quality of life, degree of disease activity, organ damage, depression and fatigue in SLE patients, showed an association of quality of life, depression and fatigue, as well as daily glucocorticoid dose, and there was not any association of quality of life with the degree of disease activity and organ damage. SLE patients had stronger depression compared to control subjects. Similar to the results of this study, quality of life was markedly worse compared to the control group of healthy individuals (15).

Similar to this study, the study of 125 patients with SLE by Moldovan et al. in California (PATROL study) showed that the SLEDAI disease activity index was not correlated with quality of life measured using the SF-36, either among Latin Americans or among caucasians. Depression was significantly correlated with most of the SF-36 domains, except with general health, and age was significantly correlated only with the domain of physical function. Their conclusion was that depression had a considerable impact on quality of life in SLE patients, and disease activity did not have such an impact (20). The results of a cross-sectional study of prevalence and predictors of depression in 61 SLE patients have shown that depression and anxiety were common in SLE patients. Moreover, a high degree of anxiety and younger age may increase the risk of depression (22). There have been reports suggesting the loss of working ability in SLE patients, which is directly related to disease activity, more advanced age, incidence of thromboses and musculoskeletal manifestations, as well as with a greater number of clinical manifestations (23). Preservation of physical and mental functions in SLE patients or their better quality of life may help them to regain their working and general productivity, as the recommendations suggest (24). Furthermore, some more recent reports have indicated the importance of physical activity and physical exercise in people affected by SLE (25, 26). It is thought that one of the principal causes of morbidity in SLE patients is chronic, debilitating fatigue which reduces their quality of life, makes them unable to work and raises health care costs. The factors associated with fatigue include lack of physical activity, obesity, sleep disturbances, depression, anxiety, mood disorders, cognitive dysfunction, vitamin D deficiency or insufficiency, pain, effects of drugs, fibromyalgias, and other comorbid conditions. The results of a study showed that fatigue in SLE patients was similar to that in Lyme disease or multiple scle-rosis, and was significantly more severe than that in general population (27).

Some studies have reported a beneficial effect of aerobic or strength training on the improvement of health outcomes, including fatigue and quality of life parameters (27, 28).

The results of the present study showed that the severity of fatigue assessed using the FSS was significantly higher in the group of SLE patients compared to healthy controls ($p < 0.001$), which agreed with other studies' results (27). Serious fatigue, expressed as the mean value > 4 on the fatigue scale, was present in 82.35% patients with SLE and in only 16.67% healthy control group subjects. A significant correlation was also demonstrated between the SDI damage index and fatigue scale ($r = 0.324$; $p < 0.01$) (29), and there was no correlation between the SLEDAI disease activity index and fatigue. Fatigue was the predominant and most commonly encountered symptom in the studied group of patients, present in 83/85 (97.6%) patients. In other reported studies as well, the percentage of patients with SLE experiencing fatigue was rather high, and the impact of fatigue on numerous aspects of life (emotions, cognitive functioning, occupation, everyday social and family interactions and activities) has been stressed (29). Petterson et al., in their cross-sectional study of 324 patients with SLE, demonstrated that fatigue, pain, and musculoskeletal distress were the predomi-nant symptoms in about half of their patients. Only the patients reporting fatigue as the predominant symptom had lower mental and physical aspects of quality of life, which led to the conclusion about the importance of therapeutic interventions regarding these symptoms in order to improve the quality of life in SLE. Further, the same authors reported that the patients without these symptoms had better quality of life, lower grade depression and anxiety and lower activity of their disease (30).

The results of the present study showed that damage to the cardiovascular system is rather common and present in a quarter (24.7%) of the studied SLE patients. This agreed with other studies' results, suggesting that the list of potential consequences of severe fatigue and low-level physical activity in SLE was extended to involve an increased risk of cardiovascular diseases as well, among other factors due to an elevated proinflammatory biomarker-proinflammatory high density lipoprotein (HDL)-together with increased presence of carotid plaques (31, 32).

Conclusion

The quality of life of SLE patients measured by the SF-36 index was significantly lower compared to healthy individuals, and in most of the examined domains it was not correlated with disease activity. Lower quality of life was associated with a higher organ damage index (SDI) (with the exception of the domain of emotional status). Fatigue is a predominant symptom in patients with SLE. Quality of life and severity of fatigue were associated more with organ damage than with disease activity in SLE patients.

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KVALITET ŽIVOTA I INTENZITET ZAMORA KOD BOLESNIKA SA SISTEMSKIM ERITEMSKIM LUPUSOM

Valentina Živković[1,2], Bojana Stamenković[1,2], Sonja Stojanović[1,2], Tatjana Cvetković[1,3], Biljana Radovanović-Dinić[1,4]

[1]Univerzitet u Nišu, Medicinski fakultet, Niš, Srbija
[2]Institut za lečenje i rehabilitaciju „Niška Banja", Niš, Srbija
[3]Klinika za nefrologiju i hemodijalizu, Klinički centar Niš, Srbija
[4]Klinika za gastroenterologiju i hepatologiju, Klinički centar Niš, Srbija

Kontakt: Valentina Živković
Vidoja Jovanovića 28, Niška Banja, Srbija
E-mail: ljubisa.nina@gmail.com

U cilju adekvatne procene uspešnosti lečenja obolelih od sistemskog eritemskog lupusa (SLE) neophodna je procena kvaliteta života i intenziteta zamora. Cilj ove studije bio je ispitati kvalitet života kod obolelih od SLE, intenzitet zamora, kao i korelaciju između aktivnosti bolesti, oštećenja organa i kvaliteta života. Istraživanje je obuhvatilo 85 bolesnika sa SLE, kod kojih je dijagnoza postavljena na osnovu revidiranih ACR kriterijuma iz 1997. godine, kao i 30 zdravih ispitanika. Aktivnost bolesti ispitana je pomoću upitnika Systemic Lupus Erythematosus Disease Activity Index (SLEDAI), oštećenje organa pomoću indeksa SLICC/ACR damage index (SDI), kvalitet života pomoću upitnika The Medical Outcome Survey Short Form 36 (SF-36), a intenzitet zamora korišćenjem Skale zamora (Fatigue Severity Scale). Kvalitet života bolesnika sa SLE meren indeksom SF-36 je značajno lošiji u odnosu na zdrave osobe ($p < 0,001$) i u većini domena nije u korelaciji sa aktivnošću bolesti. Domen fizičkih funkcija kod bolesnika sa SLE je pokazao niže rezultate u odnosu na mentalne funkcije, a prosečni rezultati su bili ispod 52% u svim domenima upitnika SF-36. Lošiji kvalitet života udružen je sa većim indeksom oštećenja organa SDI, izuzev u domenu emotivnog statusa. Postoji značajna razlika u intenzitetu zamora između SLE bolesnika i kontrolne grupe ($p < 0,001$). Zamor je u korelaciji sa oštećenjem organa ($p < 0,01$), a nije u korelaciji sa aktivnošću bolesti. Kvalitet života i intenzitet zamora povezani su više sa oštećenjem organa nego sa aktivnošću bolesti kod bolesnika sa SLE.

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Ključne reči: *sistemski eritemski lupus, kvalitet života, intenzitet zamora*