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ORIGINAL RESEARCH

Impact of Systemic Lupus Erythematosus on Health-Related Quality of Life in Colombian Patients: A Cross-Sectional Analytical Study

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Objective: To describe the impact of systematic lupus erythematosus (SLE) on health-related quality of life (HRQL) compared with healthy subjects.

Methods: This was an analytical cross-sectional study of 50 patients with SLE and 50 healthy controls. Sociodemographic, clinical and treatment variables were included. The diagnosis of SLE was made according to the classification criteria of the American College of Rheumatology/European League Against Rheumatism, and the activity of the disease was evaluated with the SLEDAI-2K. The reliability, internal consistency and discriminant power of the SF-36 were evaluated. The information analysis included summary measures, Pearson's chi-square test, Mann–Whitney's *U*-test, Kruskal–Wallis's *H*-test and linear regression.

Results: Forty-eight percent of the patients were women with an average age of 43.4 ± 14.8 years, 74% presented with comorbidities, and 22% were hospitalized in the last six months due to their illness. Seventy percent of the patients received corticosteroids, 62% with immunomodulators and 10% with biological treatments. SLE significantly impacts the domains of HRQL related to physical function, body pain, social function, emotional role, and general health. The factors that explain this impact on HRQL are having comorbidity with fibromyalgia, receiving treatment with DNA synthesis inhibitors and receiving corticosteroid treatments. The SF-36 presents good psychometric performance in the study group.

Conclusion: SLE results in a deterioration in the HRQL of patients, as reflected in the domains of body pain and the perception of general health. This effect is more pronounced in patients who also have fibromyalgia. The mental health domain was more affected in those who received corticosteroid treatment.

Keywords: health-related quality of life, systematic lupus erythematosus, comorbidity, psychometry

Introduction

Systemic lupus erythematosus (SLE) is an autoimmune connective tissue disease characterized by dysregulation of the immune response. This pathology manifests itself with a wide variety of clinical symptoms that range from mild manifestations to catastrophic manifestations, involving multiple organs and presenting a risk of organ failure with a high probability of mortality.[1] The incidence of SLE varies according to the region studied; for example, a low incidence of 1.18 per 100,000 inhabitants is reported in Asia, whereas the incidence in Europe is 13.74 per 100,000 inhabitants.[2]

For Colombia, a total of 37,498 patients diagnosed with SLE were reported, with an estimated prevalence of 91.9 per 100,000 persons and an adjusted gender prevalences of 204.3 and 20.2 per 100,000 for women and men, respectively.[3]

In addition to affecting many people, SLE has important consequences for not only physical health but also mental health. At the physical level and secondary to the persistent inflammatory state,[4] signs and symptoms such as weight loss, arthritis, serositis, lupus nephritis, malar erythema, alopecia, photosensitivity, pleurisy, pulmonary interstitial disease, pulmonary hypertension, anemia, leukopenia and thrombocytopenia[5] can occur. In the mental sphere, some studies have

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shown that symptoms such as anxiety, alterations in the pattern and quality of sleep, fatigue and the perception of pain are strongly related to the development of depression in this population. It has been estimated that 80 to 100% of people who suffer from SLE experience some degree of depression, between 15 and 68.7% present serious depressive episodes, and 14% present some suicidal ideation.[6] Similarly, some studies and meta-analyses have revealed that depression increases the perception of pain, functional disability and even disease activity.[6,7] This bidirectional relationship between the physical and psychological dimensions in people with SLE impacts their health-related quality of life.

Health-related quality of life (HRQOL) is a construct that measures the subjective perception of an individual about the value assigned to his life due to the functional status and social opportunities that are affected by diseases, injuries, treatments or disabilities.[8] HRQoL has gained relevance in recent years, and its use in routine clinical practice has been recommended as part of patient-centered outcomes.[9] The reason is that it is a non-invasive and cost-effective measure to monitor the progression of the disease, the response to treatments and even the prognosis of patients. HRQL is independently related to indicators of hospitalization and death, the fulfillment of goals and pharmacological adherence.[10,11]

Considering the importance of this topic, different studies have evaluated HRQL in patients with SLE with specific and generic measures. Among the specific instruments, the Lupus QoL, SLEQoL, LupusPro, and L-QoL stand out,[12] these specific instruments are highly sensitive for detecting changes and characteristics associated with each disease, making them particularly recommended for use in intervention studies or clinical trials. However, they have notable limitations, including a reduced ability to detect unforeseen effects, their inapplicability to individuals or populations without the disease, and the lack of comparability of results with those from individuals with other clinical conditions or healthy populations. Consequently, it is common to find studies in the literature involving diseased populations that utilize generic scales. These scales have the advantage of enabling the evaluation and comparison of populations with different diagnoses while revealing the impact of the disease using the healthy population as a reference. Among generic instruments, the most commonly used is the Short Form-36 health Survey (SF-36), a generic HRQL scale that captures the patient's subjective perception across eight domains: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health.[13] One of the studies carried out in Sweden, highlighted that symptoms such as fatigue and pain decrease the perception of health and are linked to the development of depression, cognitive disorders, memory disorders and even social relationships.[14] Another study carried out in the United Kingdom revealed that patients with SLE have a negative perception of their quality of life and conception of health. Study patients reported enormous physical, social and emotional consequences.[15] Specifically, in Colombia, a study from 2013 demonstrated the relationship between organic damage in patients with lupus and quality of life. In addition, physical affect is more marked than mental health is, but patients report feeling less vital and having the worst social function.[16]

Despite the available evidence, few recent studies have compared the HRQL profiles of patients with SLE with those of healthy controls and revealed the impact of different comorbidities and treatments on patients' perceptions of their HRQL. Therefore, this study was designed to describe the HRQL profile in a group of people with SLE from Medellín, Colombia, from 2023 to 2024.

Methods

Type of Study

An analytical cross-sectional study was conducted.

Study Subjects

Two groups were formed. The first group comprises patients with systematic lupus erythematosus who consecutively attended a rheumatology service in the city of Medellín between December 2022 and January 2024. The inclusion criteria were as follows: i) were over 18 years of age, ii) met four or more American College of Rheumatology/European League Against Rheumatism (ACR/EUL) classification criteria,[17] and iii) were ambulatory. Patients i) without demographic and clinical information and ii) for whom it was impossible to use the HRQL instrument were excluded. In addition, a second

group was formed, composed of the general population (control donors) from the same geographic area, and they were matched with the patients according to age, sex and education.Those who had any chronic disease or were pregnant or lactating were excluded.

Two rheumatologists collected the following information in an instrument that contained questions on sociodemographic aspects (age, sex, education, economic level, and marital status), clinical factors (family history of the disease, comorbidities, hospitalization, treatments, smoking, sedentary lifestyle, alcoholism, and antinuclear antibodies), an index for disease activity and HRQL. The disease activity index was evaluated with the *Systemic Lupus Erythematosus Disease Activity Index* (SLEDAI) in its 2000 version (SLEDAI-2K),[18] which is a global index and a clinical tool designed, validated and introduced in clinical practice between 1985 and 1986 to evaluate disease activity in patients with SLE. It consists of 24 items based on the presence of signs and symptoms and their severity level. Nine systems (cutaneous, mucocutaneous, articular, neurological, renal, hematological, immunological, and pleuropericardial) are evaluated. The fever parameter is added when the exclusion of an infectious cause is confirmed), with a score of 0 when the manifestations are absent and 105 when the manifestations are very serious (maximum score).[19] A score of 0 to 1 was considered inactivity, a score from 2 to 5 was considered mild activity, and a score greater than 5 was considered moderate to severe activity.

HRQL Assessment

The HRQL assessment was performed with the Short Form-36 health Survey (SF-36), a generic HRQL scale that accounts for the subjective perception of the patient on 8 dimensions of their daily life: physical functioning (the degree to which the disease limits physical activity), role physical (the degree to which health interferes with work), bodily pain (intensity of pain and its effect), general health (personal assessment of current and future health), vitality (energy, vitality, fatigue and burnout), social functioning (the degree to which health interferes with social relationships), role emotional (the degree to which emotional problems interfere with work) and mental health.[13] The instrument comprises 36 items that generate a score ranging from 0 to 100, with higher scores indicating better HRQoL. The instrument has been used in a wide variety of diseases and has shown good reliability in Colombian adults.[18]

Information Analysis Plan

The demographic and clinical characteristics of the patients are described with absolute and relative frequencies. The groups were verified to be well-matched with Pearson's chi-square test. The assumption of normality was evaluated with the Shapiro–Wilk test. To identify the magnitude of the difference in HRQoL between patients with SLE and the general population, the medians were calculated, together with the interquartile range of the scores for each dimension. Comparisons between groups were made with the Mann–Whitney *U*-test.

To identify the factors associated with HRQL in patients with SLE, associations between demographic and clinical characteristics and each dimension of HRQL with medians, the interquartile range, the Mann–Whitney *U*-test and the Kruskal–Wallis *H*-test were explored. Additionally, a multivariate analysis with linear regression was performed to identify possible confounders.

Because the psychometric properties of the scales are not intrinsic characteristics but may vary with the study group, the internal consistency, discriminant power and reliability of the SF-36 were evaluated.

For internal consistency, Spearman correlations were calculated for each item with the dimension to which it belongs. They were considered favorable when values greater than 0.4 were obtained because a Spearman correlation above 0.4 indicates a moderate level of correlation, while values over 0.8 represent a strong correlation. For the discriminant power, Spearman correlations were calculated for each item with the dimensions to which they do not belong. They were considered favorable when the correlation coefficient was lower than that found in the item domain relationship to which it belongs. Cronbach's alpha was calculated for reliability, and values greater than 0.7 were considered satisfactory. The analyses were performed in SPSS version 29, and p values <0.05 were considered statistically significant.

Results

Sociodemographic and Clinical Characteristics of the Patients

The average age of the patients with lupus was 43.4 ± 14.8 years, with a minimum of 23 years and a maximum of 83 years; 96.1% were women, 50% had university or postgraduate training, 6% consumed tobacco, and 66% were sedentary. Forty-two percent of the patients with lupus had a family history of the disease; 74% presented with comorbidities, and the most common comorbidities were arterial hypertension (35%), hypothyroidism (27%), osteoporosis (19%), and fibromyalgia (8%). Three patients presented with fibromyalgia simultaneously. For the SLEDAI-2K, almost half of the patients had an active SLE (≥ 4). Twenty-two percent of the patients were hospitalized in the last six months due to lupus; 70% received treatment with corticosteroids (with prednisolone doses ranging from 5 to 25 mg/day and methylprednisolone doses from 4 to 24 mg/day), 62% with immunomodulators and 10% with biological treatments (Table 1).

Table 1 Description of the Demographic and Clinical Characteristics of Patients with Lupus and Their Comparison with Healthy Controls

		Patients with SLE		Healthy Controls		p-value
		n	%	n	%	
Sex	Female	48	96.0	48	96.0	1.000
	Male	2	4.0	2	4.0	
Marital status	Married/Cohabiting	32	64.0	20	40.0	
	Separated/Widowed	4	8.0	5	10.0	
	Single	14	28.0	25	50.0	0.050
Level of education	Primary/Secondary	17	34.0	19	38.0	
	Technical	8	16.0	10	20.0	
	University	15	30.0	12	24.0	0.869
	Postgraduate	10	20.0	9	18.0	
Economic level	Low	12	24.0	13	26.0	
	Medium	19	38.0	34	68.0	<0.001*
	High	19	38.0	3	6.0	
Smoking		3	6.0	5	10	0.715
Alcohol consumption		2	4.0	2	4.0	1.000
Sedentary lifestyle		33	66.0	34	68.0	0.832
Owning pets		21	42.0	21	42.0	1.000
Family history of lupus		21	42.0	-	-	
Treatment with corticosteroids		35	70.0	-	-	
Treatment with immunomodulators **		31	62.0	-	-	
Treatment with cyclosporine		3	6.0	-	-	
Treatment with hydroxychloroquine		31	62.0	-	-	
Treatment with biologicals		5	10.0	-	-	
Comorbidities		37	74.0	-	-	
Hospitalization in the previous 6 months due to lupus		11	22.0	-	-	
Positive anti-DNA antibodies		13	26.0	-	-	

Notes: *P-value <0,05 indicates statistically significant differences. ** Methotrexate, azathioprine, mycophenolate mofetil, cyclophosphamide.

Impact of SLE on HRQL

When the HRQoL of patients with lupus was compared with that of healthy controls, patients had significantly lower scores in the domains of physical function, physical role, body pain, general health, social function and emotional role. The vitality domain had the lowest scores in patients with lupus; however, no significant differences were found, since this domain also presented low scores in healthy controls (Table 2). When the psychometric properties of the quality of life scale used were evaluated, excellent reliability, internal consistency and discriminating power were found in all the evaluated domains (Table 3).

Factors Associated with HRQL in Patients

To identify the factors associated with the HRQL profile, associations between the clinical and demographic characteristics and each of the domains were explored. In this sense, patients who, in addition to having lupus, have fibromyalgia have a greater impact on their physical role, body pain, general health and vitality. Patients receiving corticosteroid treatments have greater impacts on physical function, vitality, and mental health. Patients receiving immunomodulatory treatments have more affected physical health, and patients with moderate or severe disease activity have greater alterations in body pain and general health. (Table 4).

Table 2 Comparison of the Health-Related Quality of Life Profiles of Patients with Lupus and Healthy Controls

	Healthy Controls Me (RIQ)	Patients with SLE Me ** (IQR) ***	p-value
Physical functioning	100 (100–100)	85.0 (60.0–100)	<0.001*
Role physical	100 (100–100)	75.0 (0.0–100)	<0.001*
Bodily pain	100 (100–100)	74.0 (41.0–100)	<0.001*
General health	67.0 (62.0–70.0)	57.0 (45.0–62.0)	<0.001*
Vitality	55.0 (40.0–85.0)	50.0 (35.0–70.0)	0.129
Social functioning	100 (100–100)	100 (50.0–100)	<0.001*
Role emotional	100 (100–100)	100 (66.7–100)	0.028*
Mental health	86.0 (60.0–88.0)	66.0 (48.0–88.0)	0.188

Notes: *P-value <0,05 indicates statistically significant differences. **Me: Median; ***IQR: Interquartile range.

Table 3 Psychometric Properties of the Health-Related Quality of Life Instrument in Patients with Lupus

Domain	Internal Consistency	% Success Internal Consistency	Discriminating Power	% Success Discriminating Power	Reliability (Cronbach's Alpha)
Physical functioning	0.346–0.804	90% (9/10)	0.003–0.640	100% (70/70)	0.878
Role physical	0.803–0.872	100% (4/4)	0.012–0.705	100% (28/28)	0.892
Bodily pain	0.969–0.977	100% (2/2)	0.269–0.656	100% (14/14)	0.936
General health	0.445–0.764	100% (4/4)	0.029–0.467	100% (28/28)	0.753
Vitality	0.580–0.772	100% (4/4)	0.155–0.598	100% (28/28)	0.653
Social functioning	0.931–0.997	100% (2/2)	0.018–0.685	100% (14/14)	0.973
Role emotional	0.797–0.958	100% (3/3)	0.025–0.554	100% (21/21)	0.892
Mental health	0.530–0.721	100% (5/5)	0.010–0.593	96.6% (29/30)	0.647

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Table 4 Factors Associated with Health-Related Quality of Life in Patients with Lupus

Bivariate Analysis						
Associated Factor	**Physical Functioning**	**Role Physical**	**Bodily Pain**	**General Health**	**Vitality**	**Mental Health**
	Me ** (RIQ) * **	**Me (IQR)**	**Me (IQR)**	**Me (IQR)**	**Me (IQR)**	**Me (IQR)**
Patients with fibromyalgia	55 (40–65)	0 (0–0)	22 (10–41)	45 (35–45)	0 (0–25)	36 (16–100)
Patients without fibromyalgia	90 (60–100)	100 (25–100)	74 (41–100)	57 (47–62)	50 (40–70)	68 (48–100)
p value	0.051	0.015*	0.027*	0.036*	0.012*	0.283
Treatment with corticosteroids	80 (60–95)	75 (0–100)	62 (32–84)	52 (45–62)	45 (20–60)	64 (44–88)
Without corticosteroids	100 (75–100)	100 (75–100)	84 (52–100)	62 (47–67)	70 (50–85)	100 (68–100)
p value	0.040*	0.208	0.242	0.132	0.021*	0.004*
Treatment with immunomodulators	75 (50–100)	75 (0–100)	62 (32–100)	57 (45–62)	50 (35–75)	68 (44–88)
Without immunomodulators	95 (80–100)	75 (25–100)	84 (42–84)	57 (45–62)	50 (35–75)	88 (52–100)
p value	0.029*	0.563	0.605	0.717	0.763	0.122
Inactive disease	90 (60–100)	75 (0–100)	52 (32–84)	47 (45–57)	50 (25–70)	88 (40–100)
Mild activity	85 (60–100)	100 (50–100)	84 (62–100)	62 (57–67)	50 (40–70)	68 (48–88)
Moderate to severe activity	80 (62–97)	50 (0–87)	41 (26–68)	54 (46–62)	42 (10–55)	60 (50–66)
p value	0.974	0.223	0.039*	0.041*	0.435	0.339
Multivariate Analysis with Linear Regression Model						
Associated Factor	**Physical Functioning**	**Role Physical**	**Bodily Pain**	**General Health**	**Vitality**	**Mental Health**
	p- value	**p- value**	**p- value**	**p- value**	**p- value**	**p- value**
Fibromyalgia comorbidity	-	0.009*	0,020*	0.046*	0.004*	-
Treatment with corticosteroids	0.323	-	-	-	0.009*	0.005*
Treatment with immunomodulators	0.044*	-	-	-	-	-
Disease activity	-	-	0.784	0.269	-	-

Notes: *P-value <0,05 indicates statistically significant differences. **Me: Median; ***RIQ: Interquartile range.

In the multivariate adjustment model used to identify confounders, the association between treatment with immunomodulators and physical function impairment remained. The associations between fibromyalgia as a comorbidity and impairments in physical role, general pain and body health also remain. Vitality remains associated with the comorbidity of fibromyalgia and corticosteroid treatment; ultimately, the association between corticosteroid treatment and deterioration in the mental health domain remains. (Table 4)

Discussion

Health-related quality of life constitutes a central outcome in the care of patients with SLE within the framework of the assessment of disease activity and response to treatment from a multidimensional perspective. In this sense, SLE was found to affect all HRQOL domains, particularly physical function, body pain, social function, emotional role, general health, and mental health. However, HRQL results in studies on patients with SLE are heterogeneous. Some studies have revealed a significant physical and mental condition.[20–22] In contrast, other studies do not show a significant alteration in HRQoL and even favorable results.[23,24] Therefore, it is necessary to delve into the clinical and therapeutic aspects that influence the HRQL of these patients.

One of those clinical aspects to consider is musculoskeletal symptoms, which manifest in up to 6.1% of patients with SLE[25] and affect mainly the wrists, knees, lumbar region and shoulders. Although different studies have shown that pain in general is intermittent, its negative impact on quality of life is significant and limits not only one's physical health but also one's mental health.[25]

Another important result of this study is that patients with the comorbidity of fibromyalgia have greater body pain, deterioration of physical role and deterioration of general health, independent of the activity of the LES. This finding is consistent with the literature, which indicates that patients with this comorbidity have greater deterioration in HRQoL. Studies that have compared the HRQL of patients with SLE and patients whose SLE and fibromyalgia converge have shown that patients with comorbidities have worse performance in the dimensions of physical function, general health and vitality, although fibromyalgia does not affect disease activity.[26,27] This finding has important repercussions when considering the number of affected individuals, since it is estimated that the prevalence of fibromyalgia among patients with SLE is as high as 12%.[26]

In terms of treatment, the primary strategy is to achieve a state of remission or low disease activity. The widespread use of corticosteroids and immunomodulators in the present study reflects the conventional therapeutic strategies for SLE, as they are widely used. However, it is essential to consider the long-term adverse effects of these drugs, as well as the need to explore alternative therapies that can improve HRQL without compromising clinical efficacy.[28]

In this study, the degree to which SLE limits physical activity was more pronounced in those who received immunomodulatory treatments than in those who did not. This association was independent of disease activity, age, and comorbidities. However, several studies have indicated that using immunomodulators such as mycophenolate mofetil (MMF) positively affects the scores of the SF-36 quality of life questionnaire. Significant improvements have been reported in the domains of general health, physical health and role limitations secondary to emotional problems. In addition, a lower incidence of serious adverse events, such as infections, has been reported than with other drugs, such as cyclophosphamide (CTX).[29] This finding could be explained by the widespread use of MMF and its adverse effects. In this context, MMF was initially restricted to treating lupus nephritis; however, it is now widely used in SLE patients with other organic manifestations. This drug can have adverse effects, including flu, gastrointestinal symptoms (nausea, emesis and diarrhea) and hematological effects such as anemia due to deficient erythropoiesis and leukopenia.[30,31] Despite the above findings, it is important to note that our study did not discriminate between the different immunomodulatory drugs, so it is possible that the use of CTX influences this result. An additional study is needed to specifically examine each of the drugs belonging to this pharmacological group and evaluate whether the greatest deterioration in physical health persists in those treated with MMF.

On the other hand, in this study, vitality and mental health were diminished in patients receiving corticosteroid treatment. Glucocorticoids rapidly control SLE activity through different mechanisms that include a wide spectrum of effects on different components of the immune system, such as decreased cytokine production and expression of adhesion molecules in mononuclear and neutrophilic phagocytes, regulation of leukocyte chemotaxis and access to the endothelium at sites of inflammation.[32] In addition, glucocorticoids can also functionally modulate fibroblasts, endothelial cells, and leukocytes.[33]

However, previous studies have shown that these medications can lead to adverse psychiatric events, such as depression, manic episodes, delirium, anxiety, panic disorder and psychosis.[31,34,35] The manifestation of these psychiatric adverse events seems to be influenced by the duration and doses of treatment.[36] Euphoria and hypomania have been observed with short-term use, whereas depressive symptoms are more common with long-term use.[37] Similarly, the risk of developing neuropsychiatric symptoms depends on the dose of the drug, although neuropsychiatric effects have been reported up to low doses of 2.5 mg.[32] The precise mechanism behind these adverse events has not been fully described. Still, it has been hypothesized that the permanent release of the hormones arginine and vasopressin could trigger persistent activation of the hypothalamic–pituitary–adrenal axis. Memory alterations seem to be related to the effects of corticosteroids in the hippocampus, causing genomic effects such as alterations in the transcription of genes and neurotransmitters at the neuronal level.[38–40] Taking into account the above, permanent caution and monitoring of the mental sphere is recommended in patients who receive this therapeutic agents until studies are developed that confirm this result.

Concerning the instrument for the evaluation of HRQL, the SF-36 presented excellent reliability, consistency and discriminating power. Although this scale was not created exclusively for patients with SLE, it has become the most widely used tool to assess the quality of life in patients with this disease because of its multiple validations and sensitivity to change over time. A strong correlation has also been shown between physical health/physical function, mental and

emotional health, body pain/fatigue and vitality.[41] This scale has been applied in studies carried out in the American continent, with findings indicating that it is a reliable, coherent instrument capable of distinguishing between different levels of perceived health, supporting its usefulness as a tool for assessing HRQOL in clinical and epidemiological research.[42,43] Furthermore, it is important to note that this instrument is often used as a comparator in studies validating lupus-specific questionnaires in various languages.

Limitations

The main limitation of this study is the size of the sample. Although patients were collected over a period of two years, a more robust size was not achieved. In addition, since the study was performed at a single rheumatology center, the results may affect the generalizability of the results. Similarly, the study was conducted only in an outpatient setting, so the results cannot be extrapolated to hospitalized patients. In addition, the measurements used in this study were cross-sectional, so establishing causal relationships was not possible. It would be beneficial to complement the cross-sectional data with longitudinal multicenter studies that allow us to follow patients over time and evaluate how symptoms change, the development of new comorbidities and the quality of life in response to treatment and other factors. Finally, we did not explore changes in HRQoL in patients with different corticosteroid doses because the small sample size could lead to a type II error. Future studies could investigate this topic.

Conclusion

Systemic lupus erythematosus results in a deterioration in the health-related quality of life of patients, as reflected in the domains of body pain and the perception of general health. This impact is more pronounced in subjects who also have fibromyalgia. The mental health domain was more affected in those who received corticosteroid treatment. While this study is cross-sectional in nature, the finding is consistent with the literature, possibly suggesting the need to weigh corticosteroid risks more carefully or explore alternative treatments. The design of longitudinal studies to confirm these findings is highly recommended, as such data are essential for capturing changes in health-related quality of life over time and for understanding the progression of SLE and comorbidities such as fibromyalgia.

Data Sharing Statement

All data generated or analyzed during this study are included in this published article.

Ethics Approval and Informed Consent

According to ethical guidelines, all subjects signed a written informed consent form, which was previously reviewed and approved by the research ethics committees of the *Universidad Cooperativa de Colombia* (Act BIO272, may/2022) and *Universidad Pontificia Bolivariana* (Act 19, October/2022). The protocols were carried out following the principles of the Declaration of Helsinki.

Patients were involved in the conduct of this research. During the feasibility stage, recruitment methods were informed by discussions with patients through a focus group session. Once the trial has been published, participants will be informed of the results through a study newsletter suitable for a non-specialist audience.

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Disclosure

The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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