Assessment of medication-related burden among a sample of Iraqi patients with systemic lupus erythematosus and its relationship with disease activity: a cross-sectional study

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Abstract

Background: Systemic lupus erythematosus (SLE) is a chronic autoimmune disease with high morbidity and disability. The routines involved in taking medications, side effects, the nature of medicines, difficulties with the healthcare system, and disruptions to social activities all contribute to patients frequently experiencing medication-related burdens (MRB). The current study aimed to assess the perceived MRB among a sample of SLE patients from Iraq and to look for any possible relationship between MRB and disease activity.

Methods: The current study was cross-sectional on diagnosed SLE patients who arrived at Baghdad Teaching Hospital/Medical City/Rheumatology department from September 2021 to January 2022. MRB was measured using the Living with Medicines Questionnaire (LMQ).

Results: The study recruited 156 SLE patients. The patients were 35.8 ±11.7 years old on average. Great majority of them were women (96.8 %). The average LMQ score was 117.30±18.37. The results showed that most patients (69.87%) experienced a moderate level of burden, followed by a low level (19.87%), high level (7.69%), and no burden at all (2.56%). No patients experienced an extremely high level of burden (0.0%). The mean burden scores for two LMQ domains—relationships with health care professionals (HCPs) and effectiveness of prescription medications—were the lowest (below average).

Conclusions: Many of the SLE patients in this study reported experiencing MRB. Healthcare professionals should implement strategies to reduce this burden, particularly for low-income patients.
Keywords
Systemic lupus erythematosus, medication-related burden, Living with Medicines Questionnaire, SELENA-SLEDAI, Iraq.

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**Introduction**

Systemic lupus erythematosus (SLE) is a chronic, heterogeneous autoimmune disease associated with complex and varied immunological dysregulation. Regardless of age or race, women of childbearing age are 10 times more likely than men to be affected by SLE. Globally, SLE prevalence and incidence vary considerably with sex, age, ethnicity, and time. In Iraq, the prevalence of SLE is about 1/1867 of the general population, and the first case of SLE was reported in 1971. Genetic factors, environmental factors, and hormonal factors are believed to contribute to the occurrence of SLE. Systemic lupus erythematosus is an autoimmune disease with a chronic-relapsing course in which periods of remission alternate with periods of activity of the disease. Multiple organ systems, including the musculoskeletal, mucocutaneous, cardiopulmonary, renal, and hematologic systems, are clinically involved in SLE. The short-term goals of SLE treatment are to reduce or control disease activity, alleviate clinical symptoms, and achieve clinical remission. The long-term objectives are to achieve long-term sustained remission of the disease, lower mortality, enhance the quality of life, avoid and reduce recurrence, reduce adverse drug responses, prevent and control organ damage carried on by the disease, and prevent and control certain organ damage events. The US Food and Drug Administration currently approved corticosteroids, antimalarials like hydroxychloroquine, and belimumab for treating SLE. Nonsteroidal anti-inflammatory drugs (NSAIDs), immunosuppressive and immunomodulatory drugs and rituximab are further treatments for the management of SLE. The idea of “medication-related burden” (MRB) or “treatment burden” succinctly describes the entire workload that patients are subject to as a result of using healthcare, with several harmful effects on their lives. Because medications are the primary method of managing most disorders, MRB is a significant portion of the overall treatment burden and is commonly mentioned in qualitative studies. The treatment burden includes financial, temporal, physical, and psychosocial time demands on patients to adhere to the recommended treatment plan. Adherence to the prescribed regimen may be difficult for patients who experience high MRB. As a result, patients stop taking their medications as prescribed, which raises morbidity and mortality, the frequency of hospital admissions, and the expenditure on healthcare. Systemic lupus erythematosus is associated with high unmet needs and a considerable patient burden. The current study aimed to measure MRB among a sample of Iraqi patients with SLE and to determine the possible association between MRB and disease activity.

**Methods**

**Ethical approval**

The scientific and ethical committee examined and gave its approval to the research proposal that was submitted to the College of Pharmacy, the University of Baghdad, which describes the goals of the current study as well as the expected methods for data collection (ethics board approval code: 2014 on 15th February 2021). Additionally, approval was obtained from the Iraqi Ministry of Health (ethics board approval code: 6325) on 25th February 2021. The investigator explained the purpose of the study to each participant and obtained verbal consent. Written informed consent was then gained before administering the questionnaire. No incentives were offered to the patients.

**Study design**

The current study was an observational, cross-sectional study on already diagnosed SLE patients.

**Setting**

This research was conducted in a single center and recruited patients who attended Baghdad Teaching Hospital/Medical City/Rheumatology Department from September 2021 to January 2022.

**Sample size**

G*Power (RRID:SCR_013726) version 3.1.9.7 software was used to figure out the number of participants. With a 95% confidence interval, 90% power, a two-tailed alpha of 0.05, and an effect size of 0.30, and the output parameters were as the following: noncentrally parameter $\delta=3.6404323$, critical $t=1.9780988$, Df=132 the sample size had to be at least 134 patients ($f$).

**Eligibility criteria**

The inclusion criteria of the study were: (1) SLE patients who were eligible to participate in the study and were $\geq 18$ years of age and either sex, (2) Had the disease for $\geq 6$ months.

**Exclusion criteria**

The exclusion criteria of the study were: (1) Patients didn’t consent to participate, (2) Patients with hearing, speech, or cognitive deficits (physical or mental state) impairing understanding of the questions.

**Bias**

During sample selection, selection bias may occur. This is particularly apparent in retrospective cohort studies when exposure and outcome have already happened. As a matter of fact, in this study, sampling error is less probable. The ideal
study population is well-defined, accessible, highly dependable, and reasonable in order to get the intended outcome. To remove prejudice, participants were chosen in such a manner that individuals with hearing, speech, or cognitive issues that limit subject understanding were not given included. We also utilized common terms to prevent misinterpretation.

The questionnaires
The Arabic version8 of the living with medicine questionnaire (LMQ) was used to assess MRB in SLE patients. The LMQ consisted of 41 items to which participants responded on a five-point Likert-type scale (from strongly disagree to agree strongly). Furthermore, a free text (open-ended) question permitted the participant to add any additional topics not addressed in the questionnaire. Relationships with health professionals, Practicalities, Information, Efficacy, Side effects, Attitudes, Impact, and Control were the 8 domains covered by the questionnaire. The total LMQ score is the sum of all 41 questionnaire questions and ranges from 41 to 205, with higher scores suggesting more MRB.8 In addition, SLE disease activity was evaluated using the Systemic Lupus Erythematosus Disease Activity Index score with the Safety of Estrogens in Lupus Erythematosus National Assessment (SELENA-SLEDAI).12

Administration of questionnaires
When the patients presented at the Rheumatology Department, they were asked whether they would accept to participate in the study. If they would, each patient was explained the questionnaire and given 20 to 30 minutes to complete it.

Statistical analysis
IBM SPSS Statistics (RRID: SCR_016479) version 27 software for Microsoft Windows was used throughout the statistical analysis process. The participants and disease were calculated by descriptive statistics (means, standards deviations, frequencies and percentages). Because the continuous variables were not normally distributed, non-parametric tests were used for the differential analyses. Spearman correlation was used to measure the correlations of LMQ domains with the SELENA-SLEDAI Score. The impact of a patient’s demographic on MRB was evaluated using the Mann-Whitney and Kruskal-Wallis tests. P-values below 0.05 were regarded as statistically significant.

Results
The study recruited 156 SLE patients Figure 1.62 95.5% of the study participants living in urban cities. The patient’s age was 35.8 ± 11.7 years old on average. 96.8% of the population were women, and 71.8% of them were married. More than two-thirds (68%) had primary or secondary school degrees, and 66.7% had a middle income, as shown in Table 1.

The mean SELENA-SLEDAI value was 15.26 ± 10.199, the mean disease duration was 6.248 ± 5.44 years, no. of chronic medications was 4.6 ± 2.23, no. of other chronic diseases was 0.62 ± 0.85 as shown in (Table 2).

The mean LMQ score was 117.30 ± 18.37 (Range: 52-163). The findings showed that the majority of the SLE patients experienced a moderate degree of medication burden (69.87%), followed by minimum burden (19.87%) and high burden (7.69%). Finally, no burden at all (2.56%), with no patient experiencing an extremely high burden (0.0 %), as illustrated in Table 3.

Two LMQ domains had the lowest mean of burden scores (below the average): domain-1 [relationships with health care professionals (HCPs)] and domain-5 (effectiveness of prescribed medications). In other words, the patients had good relationships with their HCPs and reasonable belief in their medication effectiveness, reducing their MRB in these two domains. On the other hand, three domains had the highest mean of burden scores: Domain-2 (practical difficulties in using medicines), Domain-6 (concerns about medicine use), and Domain-7 (impact of using medications on daily life). In other words, the patients had relatively great difficulties in using medicines and had concerns about medicine use and their prescriptions impact their everyday life, as illustrated in Table 4.

Six domains of LMQ (domains 2, 3, 4, 5, 6, and 7) had significant (P-value <0.05) positive correlations with the SELENA-SLEDAI score. In other words, when the scores of these six LMQ domains increase, the scores of SELENA-SLEDAI increase. In contrast, Domain-1 (relationships with HCPs) and Domain-8 (autonomy to vary regimen) had non-significant (P-value >0.05) correlations with the SELENA-SLEDAI score as illustrated in (Table 5).

According to Mann-Whitney test, there were no significant differences in MRB (total LMQ score) according to eight demographic and clinical characteristics (Table 6A). However, according to Kruskal-Wallis test, there was a significant difference in the total LMQ score according to the patient’s income. The higher-income patient had significantly lower MRB (total LMQ score) compared to low-income patients (Table 6B).
Discussion
Systemic lupus erythematosus is a chronic, prototypic autoimmune disorder that may affect almost any organ or system.\textsuperscript{13} SLE continues to carry an unacceptably high morbidity burden.\textsuperscript{14} However, over the past 50 years, patient survival has drastically increased, probably due to earlier diagnosis and more effective treatment plans.\textsuperscript{15} This study measured MRB and assessed any associations between the MRB and various patient-related factors. As shown in sociodemographic data of the patients, about (96.8\%) of patients were female. Nearly 80\% of autoimmune disease patients are female, which brings attention to the gender disparity.\textsuperscript{16}

According to our study, a significant number of the participants (97.44\%) had varying degrees of MRB. For patients and their families, chronic rheumatic diseases such as rheumatoid arthritis (RA), ankylosing spondylitis (AS), and SLE are very burdensome.\textsuperscript{17–21} In addition, patients who had organ failure (such as lupus nephritis), disease flare-ups, high disease activity, and chronic disease are more burdened.\textsuperscript{22}

The current study showed that the mean LMQ score was 117.30 ± 18.37 with the majority of the participants reporting experiencing minimum (19.87\%) to moderate (69.87\%) MRB. According to the recent increase of interest in understanding and quantifying MRB, there is currently no study measuring MRB among SLE patients to compare our results. Most of the available studies included patients with chronic diseases in general. The results of the current study differ from
### Table 1. The sociodemographic characteristics of the patients.

| Subcategory               | Frequency (N) | %  |
|---------------------------|---------------|----|
| **Gender**                |               |    |
| Male                      | 5             | 3.2|
| Female                    | 151           | 96.8|
| **Education level**       |               |    |
| Illiterate                | 31            | 19.9|
| Primary school            | 53            | 34 |
| Secondary school          | 53            | 34 |
| College degree            | 19            | 12.2|
| **Social status**         |               |    |
| Single                    | 32            | 20.5|
| Married                   | 112           | 71.8|
| Divorced                  | 9             | 5.8 |
| Widowed                   | 3             | 1.9 |
| **Living Place**          |               |    |
| Urban                     | 149           | 95.5|
| Rural                     | 7             | 4.5 |
| **Monthly income (Iraqi dinars)** |           |    |
| < 0.5 million             | 49            | 31.4|
| 0.5-1.0 million           | 104           | 66.7|
| > 1.0 million             | 3             | 1.9 |
| **Cigarette smokers**     |               |    |
| Yes                       | 6             | 3.8 |
| No                        | 150           | 96.2|
| **Alcohol drinker**       |               |    |
| Yes                       | -----         | -----|
| No                        | 156           | 100.0|
| **Age (years)**           |               |    |
| Minimum                   | 18            |    |
| Maximum                   | 69            |    |
| Mean                      | 35.76         |    |
| Std. Dev.                 | 11.66         |    |

### Table 2. Disease characteristics of the patients.

| Variables                                                | Mean (SD)  |
|---------------------------------------------------------|------------|
| Disease duration (years) (mean ± SD)                    | 6.248 (5.44)|
| Number of chronic medications (mean ± SD)              | 4.6 (2.23) |
| Number of other chronic diseases (mean ± SD)           | 0.62 (0.85)|
| SELENA-SLEDAI value (mean ± SD)                         | 15.26 (10.199)|

**SELENA-SLEDAI**: Systemic Lupus Erythematosus Disease Activity Index score with the Safety of Estrogens in Lupus Erythematosus National Assessment; **SD**: standard deviation.

### Table 3. Perceived MRB using LMQ in patients with SLE (N = 156).

| LMQ overall Score (mean ± SD) | 117.30 ± 18.37 |
| Degree of burden              | Frequency (%)  |
| No burden at all (41–73)      | 4 (2.56%)      |
| Minimum burden (74 – 106)     | 31 (19.87%)    |
| A moderate degree of burden (107–139) | 109 (69.87%) |
| High burden (140–172)         | 12 (7.69%)     |
| Extremely high burden (173–205) | --          |

**LMQ**: Living with Medicine Questionnaire; **MRB**: Medication-Related Burden; **SD**: standard deviation.
those in Qatar, where the MRB ranged from minimal (66.8%) to moderate (24.1%) degrees of burden while being comparable to those in England: minimal (33.1%) to moderate (54.6%); and in Kuwait that ranged from minimal (35.4%) to moderate (62.0%) degrees of burden.

The three domains with the highest mean burden scores were (practical difficulties in using medications), (concerns about the use of drugs), and (the impact of using medicines on daily life). The results are consistent with recent qualitative research that examined patient perceptions on treatment and MRB and showed that medication use could impair relationships, work, and social relationships and have adverse physiological effects. In addition, patients are burdened more by dealing with their drugs’ harmful effects and adjusting their daily routines to meet the requirements of their therapeutic regimens.

In the current study, two LMQ domains had the lowest mean of burden scores: (relationships with HCPs) and (the effectiveness of prescribed medications). In other words, the patients had good relationships with their HCPs and reasonable belief in their medication effectiveness, reducing their MRB in these two domains. To make appropriate

| LMQ domain                          | Min. | Max. | Mean  | S. D |
|-------------------------------------|------|------|-------|------|
| Domain 1: Relationships with HCPs   | 5.00 | 17.00| 7.03  | 2.51 |
| Domain 2: Practical Difficulties in Using Medicines | 9.00 | 32.00| 22.07 | 4.17 |
| Domain 3: Cost-Related Burden       | 4.00 | 15.00| 10.49 | 2.05 |
| Domain 4: Side Effects of Medicines | 4.00 | 20.00| 13.77 | 3.78 |
| Domain 5: Effectiveness of prescribed medications | 6.00 | 25.00| 10.90 | 4.64 |
| Domain 6: Concerns about Medicines Use | 11.00 | 34.00| 24.40 | 4.51 |
| Domain 7: Impact of Using Medicines on Daily Life | 8.00 | 28.00| 19.65 | 3.79 |
| Domain 8: Autonomy to Vary Regimen  | 3.00 | 14.00| 8.99  | 3.00 |

HCPs: Health Care Professionals; LMQ: Living with Medicine Questionnaire; SD: standard deviation.

| LMQ Domains                          | SELENA-SLEDAI |
|--------------------------------------|--------------|
| Domain 1: Relationships with HCPs    | Correlation Coefficient 0.077 |
|                                      | P-value 0.337 |
| Domain 2: Practical difficulties in using medicines | Correlation Coefficient 0.487 |
|                                      | P-value 0.002* |
| Domain 3: Cost-related burden       | Correlation Coefficient 0.251 |
|                                      | P-value 0.002* |
| Domain 4: Side effects of medicines  | Correlation Coefficient 0.517 |
|                                      | P-value 0.000* |
| Domain 5: Effectiveness of prescribed medications | Correlation Coefficient 0.330 |
|                                      | P-value 0.000* |
| Domain 6: Concerns about medicine use | Correlation Coefficient 0.381 |
|                                      | P-value 0.000* |
| Domain 7: Impact of using medicines on daily life | Correlation Coefficient 0.491 |
|                                      | P-value 0.000* |
| Domain 8: Autonomy to vary regimen   | Correlation Coefficient 0.082 |
|                                      | P-value 0.311 |

HCPs: Health Care Professionals; LMQ: Living with Medicine Questionnaire; SELENA-SLEDAI: Systemic Lupus Erythematosus Disease Activity Index score with the Safety of Estrogens in Lupus Erythematosus National Assessment.
therapy decisions, developing a connection between the patient and the HCP can allow collaborative discussions to assist practitioners in identifying the specific MRB observed and understanding the actual lived experiences of the patient. Improvements in patient knowledge, satisfaction, and therapeutic and health outcomes were made possible by the value of two-way patient-provider interactions where patients’ experiences are discussed and shared decisions.

Across studies, people’s good attitude toward medications could be seen. Positive attitudes were primarily associated with trust in healthcare professionals, positive drug experiences, and achieving anticipated therapeutic goals.

### Table 6A. Influence of patients’ demographic and clinical characteristics on medication burden.

| Medication Burden         | Gender  | N  | Mean Rank | P-value |
|---------------------------|---------|----|-----------|---------|
| Total LMQ score           | Male    | 5  | 77.60     | 0.964   |
|                           | Female  | 151| 78.53     |         |
| Social status             | N       |    | Mean Rank |         |
|                           | Without spouse | 44 | 79.10     | 0.917   |
|                           | Married  | 112| 78.26     |         |
| Address                   | N       |    | Mean Rank |         |
| Total LMQ score           | Urban   | 149| 77.90     | 0.443   |
|                           | Rural   | 7  | 91.29     |         |
| Smoker                    | N       |    | Mean Rank |         |
| Total LMQ score           | Yes     | 6  | 101.25    | 0.208   |
|                           | No      | 150| 77.59     |         |
| Chronic disease           | N       |    | Mean Rank |         |
| Total LMQ score           | No      | 85 | 78.40     | 0.976   |
|                           | Yes     | 71 | 78.62     |         |
| Chronic medications       | N       |    | Mean Rank |         |
| Total LMQ score           | ≤ 5     | 116| 76.41     | 0.582   |
|                           | > 5     | 40 | 84.56     |         |
| Disease duration          | N       |    | Mean Rank |         |
| Total LMQ score           | ≤ 5 years | 91 | 77.49     | 0.741   |
|                           | > 5 years | 65 | 79.92     |         |
| Age category              | N       |    | Mean Rank |         |
| Total LMQ score           | ≤ 40 years | 97 | 82.02     | 0.212   |
|                           | 40 > years | 59 | 72.71     |         |

Mann-Whitney Test; LMQ: Living with Medicine Questionnaire.

### Table 6B. Influence of Patient’s Demographic on Medication Burden.

| Monthly income (ID)        | N   | Mean Rank | P-value |
|----------------------------|-----|-----------|---------|
| Total LMQ score            |     |           |         |
| < 0.5 million ID           | 49  | 92.90     | 0.015*  |
| 0.5-1.0 million ID         | 104 | 72.69     |         |
| >1.0 million ID            | 3   | 44.67     |         |
| Education level            |     |           |         |
| Total LMQ score            |     |           |         |
| Illiterate                 | 31  | 71.60     | 0.262   |
| Primary school             | 53  | 88.13     |         |
| Secondary school           | 53  | 76.00     |         |
| University                 | 19  | 69.87     |         |

*Significant (P-value <0.05) according to Kruskal-Wallis Test.
LMQ: Living with Medicine Questionnaire.
Six domains of LMQ (practical difficulties, cost, side effects, effectiveness of prescribed medications, concerns regarding medication use, and the effect of medication use on daily life) correlated positively with the SELENA-SLEDAI score. In addition, treatment burden was associated with several adverse health outcomes, including specific symptoms, recurrence of disease, decline in health, reduced survival, decreased treatment satisfaction and reduced quality of life.

Age, gender, marital status, place of residence, smoking, the number of drugs one takes, comorbidities, the length of the disease, and level of education were unrelated to MRB (P > 0.05 for all comparisons). The results of the current study do not match the results of many previous studies. Age and treatment burden showed a significant relationship. Given the likelihood of illness and various disorders, older persons appeared to have a higher treatment burden than younger people. Chronic conditions such as diabetes were associated with a more significant treatment burden. Longer illness duration in diabetic patients was linked to lower burden. Using many medications emerged as the most common predictor of commitment. In addition, the low education level was associated with a higher medication burden.

Patients with higher income had significantly lower MRB (total LMQ score) compared to low-income patients. Rheumatic diseases are frequently treated with many drug combinations, contributing to the patient’s burden of high medical costs. As a result, patients on the border of poverty are more likely to stop taking their drugs due to financial difficulties.

Limitations
When interpreting the findings of this study, a few potential limitations should be considered. The first thing to remember was the limited patient population, partially due to rheumatic disorders’ rarity. Second, self-selection and recall bias was probably present in the results obtained from self-report questionnaires. Third, all participants were recruited from one center. Finally, it is crucial to replicate this study with a larger sample size because our patients might not be representative of Iraqi patients overall. Another limitation is the cross-sectional nature of the data, which was presented at a specific time and does not account for changes in participants’ lived experiences regarding medication usage and adherence over time.

Conclusions
A significant number of the SLE patients in this research had MRB, with the majority of participants reporting a medium level of burden. According to the present research results, HCPs should be aware of the influence of treatment strategies on the lives of SLE patients. Furthermore, healthcare professionals must develop initiatives to reduce this burden, particularly amongst low-income populations.

Data availability
Underlying data
Zenodo: Demographic data along with questionnaires responses. https://doi.org/10.5281/zenodo.6941308.

This project contains the following underlying data:
- Article’s data.xlsx (Demographic data along with questionnaires responses)

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

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12. Immunology Pathways Weight Descriptor SLEDAI-2K Definition SELENA-SLEDAI Definition SELENA-SLEDAI Score* 

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