Systemic Treatment Patterns in Systemic Lupus Erythematosus (SLE): Associations with Disease Severity and Organ-Specific Activity Across 5 Registries in the Lupus Federated Data Network (LupusNet)

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Key Takeaways

- **Treatment use varied substantially by SLE disease activity severity and features**
- **Glucocorticoids were the most commonly used medication, with the majority of patients using glucocorticoids regardless of disease activity severity or SLEDAI-2K manifestations**
- **Hydroxychloroquine was the second most commonly used medication, which is consistent with the current ACR guidelines**
- **Most treatments were more frequently used in patients with severe disease activity**
- **Use of biologics approved for SLE was low during the examined period**
- **Use of symptom-specific therapies was largely consistent with ACR guidelines, with high rates of mycophenolate mofetil use in patients with renal involvement and methotrexate use in patients with musculoskeletal involvement**
- **Limitations of this analysis include incomplete visibility into longitudinal treatment trajectories as well as limited data on comorbidities, dosing, and treatment discontinuation due to intolerance and contraindications that may restrict use of specific therapies**

Background

- Systemic lupus erythematosus (SLE) is a chronic autoimmune disease characterised by a heterogeneous clinical presentation and recurring patterns of relapse and remission[1,2]
- Per the 2025 American College of Rheumatology (ACR) guidelines, SLE treatment aims to achieve remission or low disease activity[3,4]
- Hydroxychloroquine is recommended for most patients with SLE, short-term glucocorticoids for flares, immunosuppressants for moderate-to-severe or organ-threatening disease (eg, use of mycophenolate mofetil for renal manifestations and methotrexate for musculoskeletal manifestations), and biologics primarily for moderate-to-severe or refractory cases[3,4]
- A better understanding of real-world treatment patterns, especially for organ-specific manifestations, is essential for more effective realization of treatment goals

Objective

To describe treatment patterns associated with SLE disease severity and organ-specific manifestations using data from the Lupus Federated Data Network (LupusNet)

Methods

Data Source

- LupusNet is the largest existing federated SLE data network, with data (2012–2024) in these analyses from 4 longitudinal observational registries across Latin America, Europe, and Asia Pacific: Grupo Latino Americano De Estudio del Lupus (GLADEL 2.0) and Rheumatology Department of the Hospital Guillermo Almenara Irigoyen (Almenara), Lupus Register of the Spanish Society of Rheumatology (RELESSER), and Asia Pacific Lupus Collaboration (APLC), respectively[5]
  - Registries included both prevalent and incident patients
  - Registry datasets were harmonized using the Observational Medical Outcomes Partnership Common Data Model v5.4, a standard representation of healthcare experiences and common vocabularies for coding clinical concepts, which enables consistent analyses across data sources

Study Assessments

- Collected data included treatments, disease activity, and damage accrual at registration (during a 30-day window before and after enrolment into the registry) and follow-up visits over the following 3 years
- Disease activity and organ-specific manifestations were evaluated using the Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) total score and features

Data Analyses

- Patients were classified by their maximum recorded SLEDAI-2K total score (mild: ≤4; moderate: >4 to <10; or severe: ≥10) within the first 3 years of follow-up and further classified by organ-specific manifestations based on SLEDAI-2K features recorded at registration
  - Patients with a SLEDAI-2K total score of 0 at registration were excluded from the analysis of SLEDAI-2K features as they did not have SLE activity
- The proportion of patients in each SLEDAI-2K severity group with any exposure to the specified SLE treatment by Year 3 following registration was evaluated

Results

Study population

- A total of 3734 patients with sufficient 3 year follow-up data were included (**Table 1**)
  - Patients were predominantly female across all severity groups, and mean age and time from SLE diagnosis to registration were lowest in the severe group followed by the moderate and mild groups

TABLE 1: Baseline characteristics by the maximum SLEDAI-2K score over follow-up

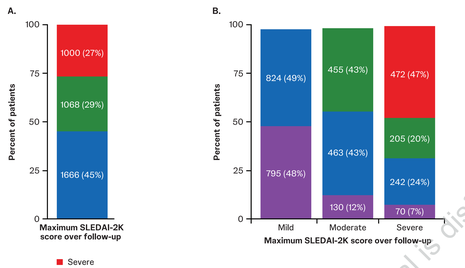
Characteristic	Mild (n=1666)	Moderate (n=1068)	Severe (n=1000)	Overall (N=3734)
Female, n (%)	1532 (92)	977 (91)	921 (92)	3430 (92)
Mean (SD) age at registration, years	45.8 (13.1)	42.2 (12.5)	37.0 (11.8)	42.4 (12.9)
Mean (SD) duration from SLE diagnosis to registration, years	11.9 (8.4)	10.6 (8.0)	8.8 (7.5)	10.7 (8.1)

Mild: SLEDAI-2K score ≤4; moderate: SLEDAI-2K score >4 to <10; severe: SLEDAI-2K score ≥10.
***SD**=standard deviation, **SLE**=systemic lupus erythematosus, **SLEDAI-2K**=Systemic Lupus Erythematosus Disease Activity Index 2000.*

SLEDAI-2K severity through 3 years of follow-up

- Based on the maximum SLEDAI-2K total score from baseline through Year 3, 1666 (45%) patients were classified as mild, 1068 (29%) as moderate, and 1000 (27%) as severe (**Figure 1A**)
  - For approximately 50% of patients with mild (49%), moderate (43%), or severe (47%) disease, their maximum SLEDAI-2K score occurred after registration (**Figure 1B**)

FIGURE 1: Distribution of SLEDAI-2K severity by (A) the maximum SLEDAI-2K score over follow-up and (B) SLEDAI-2K score at baseline and over follow-up

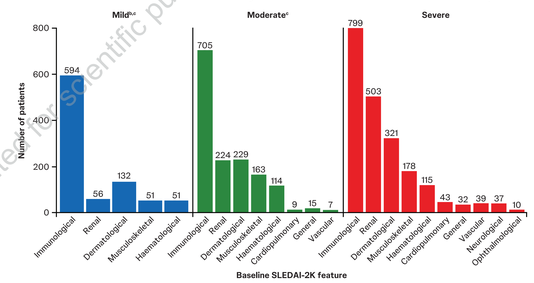


No disease activity: SLEDAI-2K score = 0; mild: SLEDAI-2K score ≤4; moderate: SLEDAI-2K score >4 to <10; severe: SLEDAI-2K score ≥10.
***SLEDAI-2K**=Systemic Lupus Erythematosus Disease Activity Index 2000.*

SLEDAI-2K features by maximum SLEDAI-2K score over follow-up

- Immunological activity (ie, positive for the SLEDAI-2K components "low complement" and/or "high DNA binding") was the most common SLE activity feature for all groups (mild: 594/871 [68%]; moderate: 705/938 [75%]; severe: 799/930 [86%]; **Figure 2**)
- Other common SLE activity features included renal, dermatological, musculoskeletal, and haematological
  - In patients with mild disease activity, dermatological symptoms were more common, whereas renal symptoms were more common in patients with severe disease activity

FIGURE 2: Baseline SLEDAI-2K features by maximum SLEDAI-2K score over follow-up[a]

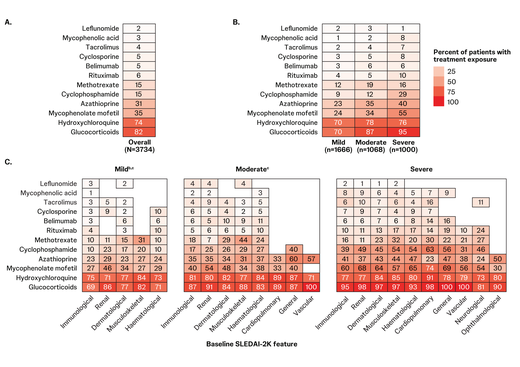


Mild: SLEDAI-2K score ≤4; moderate: SLEDAI-2K score >4 to <10; severe: SLEDAI-2K score ≥10.
[a]Of the patients with a SLEDAI-2K score available, 795/1666 (48%) patients in the mild group, 130/1068 (12%) in the moderate group, and 70/1000 (7%) in the severe group had a SLEDAI-2K score of 0 at registration and were excluded from the SLEDAI-2K feature analysis. [c]Categories "cardiopulmonary," "general," and "vascular" were not included in the mild subgroup; patients with these symptoms had SLEDAI-2K scores ≥4. "Categories "neurological" and "ophthalmological" were not included in the mild or moderate subgroups; patients with these symptoms had SLEDAI-2K scores ≥10. ***SLEDAI-2K**=Systemic Lupus Erythematosus Disease Activity Index 2000.*

Treatment exposure through 3 years of follow-up

- Glucocorticoids were the most common treatments across SLEDAI-2K severity groups and features (82% of overall patients; **Figure 3A**)
  - Glucocorticoid usage increased with severity of disease activity, with 95% of patients with severe disease activity having any recorded usage versus 70% of patients with mild disease activity (**Figure 3B**)
  - There was limited variability in glucocorticoid usage by baseline SLEDAI-2K features (**Figure 3C**)
- Hydroxychloroquine was used in 74% of patients across cohorts (**Figure 3A**)
  - No clear trend was observed in hydroxychloroquine usage by severity of disease activity, with 76% of patients with severe disease activity having any recorded usage versus 70% of patients with mild disease activity (**Figure 3B**)
- Mycophenolate mofetil was used in 35% of the overall patients followed by azathioprine, cyclophosphamide, and methotrexate (**Figure 3A**)
  - Most treatments were used more frequently among patients with severe disease activity than patients with mild disease activity, but this trend was particularly pronounced for cyclophosphamide, azathioprine, and mycophenolate mofetil, with use in 29% to 55% of patients with severe disease activity versus 9% to 24% of patients with mild disease activity (**Figure 3B**)
  - Mycophenolate mofetil use was more common for patients with renal involvement at registration (mild: 46%; moderate: 54%; severe: 68%; **Figure 3C**)
  - Methotrexate use was similar across severity groups and more common for patients with musculoskeletal involvement at registration (mild: 31%; moderate: 44%; severe: 32%)
- Rituximab was used in 6% of the overall patients; off-label rituximab was more commonly used overall than the approved novel biological belimumab during the examined period (2012–2024; **Figure 3A**)
  - Rituximab use was similar across activity features within each severity group (**Figure 3C**)

FIGURE 3: Percent of patients with treatment exposure for (A) the overall group over 3 years of follow-up, (B) by maximum SLEDAI-2K score over 3 years of follow-up, and (C) by maximum SLEDAI-2K score over 3 years of follow-up and baseline SLEDAI-2K feature[a]



Mild: SLEDAI-2K score ≤4; moderate: SLEDAI-2K score >4 to <10; severe: SLEDAI-2K score ≥10.
[a]Of the patients with a SLEDAI-2K score available, 795/1666 (48%) patients in the mild group, 130/1068 (12%) in the moderate group, and 70/1000 (7%) in the severe group had a SLEDAI-2K score of 0 at registration and were excluded from the SLEDAI-2K activity feature analysis. [c]Categories "cardiopulmonary," "general," and "vascular" were not included in the mild subgroup; patients with these symptoms had SLEDAI-2K scores ≥4. "Categories "neurological" and "ophthalmological" were not included in the mild and moderate subgroups; patients with these symptoms had SLEDAI-2K scores ≥10. ***SLEDAI-2K**=Systemic Lupus Erythematosus Disease Activity Index 2000.*

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