

Availability of Disease Activity Measures from Systemic Lupus Erythematosus Patients in a Large, Representative US-based Real World Registry Cohort

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Background

- Systemic lupus erythematosus (SLE) is a heterogeneous, multifactorial disease with a debilitating and highly variable clinical course.
- Measurement of disease activity is resource intensive but essential to the monitoring of disease status. These scores can be used for diagnosis and prognosis as well as evaluation of changes over long periods in routine clinical practice.
- Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) scores are not widely used in standard clinical practice but may be useful to assess changes in disease activity.
- Additional non-SLE specific disease activity scores such as the self-reported Health Assessment Question Disability Index (HAQ-DI), Multidimensional Health Assessment Questionnaires (MDHAQ) patient global assessment, physician global assessment, fatigue visual analogue scale (VAS), and SLEDAI scores collect information on disability not captured by more commonly used clinical assessments.

Objectives

- To assess the availability of disease activity information in a cohort of patients with SLE.
- To characterize levels and changes in disease activity using the SLEDAI score.

Methods

- The OM1 SLE Registry (OM1, Boston), an ongoing, continually enrolling, representative sample of patients with SLE in the United States who are followed prospectively, was used to assess clinical, symptomatic, and disease activity information. The combined electronic medical record (EMR) data and administrative claims dataset provided additional insights into the complete patient journey, including specialty data from rheumatologists, with deep clinical data within both structured and unstructured fields.
- National Drug Code (NDC) and Current Procedural Terminology (CPT) coded prescription fills and medication orders were used to identify disease-modifying therapy (DMT) for lupus.
- HAQ-DI, MDHAQ patient global assessment, physician global assessment, fatigue VAS, and SLEDAI scores were obtained from structured EMR data documented during clinical care.
- SLEDAI scores were categorized by disease severity (no disease activity [0], mild [1-5], moderate [6-10], high [11-19], very high [≥ 20]), and transitions between first and last observed categories were described.

Results

- The cohort included 36,603 SLE patients with deep clinical rheumatology data from January 2013 to May 2019. The mean age was 51.5 years (standard deviation: 15.0), and 92% were female.
- SLEDAI scores were reported for 1,451 patients (4%). Among those with ≥ 1 SLEDAI score, 23% were treated with the DMT, belimumab (Benlysta®).
- Among those with ≥ 2 SLEDAI scores (n=801), the median time between first and last score was 11.9 months (interquartile range: 6.1, 24.1).
- Based on the first observed score for patients with ≥ 2 SLEDAI scores, 21% had no disease activity, 32% were classified as mild, 28% were classified as moderate, 12% were classified as high, and 6% were classified as very high.
- Changes in SLEDAI score category over time are presented in **Table 1**. Thirty percent of patients showed improvement (i.e., decreased score), 15% worsened (i.e., increased score), and 55% showed no change.
- The proportion of patients with non-specific to SLE health-related scores included: HAQ-DI (29%), MDHAQ patient global assessment score (30%), MDHAQ physician global assessment score (18%), and fatigue VAS (8%).

Table 1: Distribution of SLEDAI Scores and Changes from First to Last Observed Scores

	First observed score	No change compared to last score		Decreased category by last score		Increased category by last score	
		N	%	N	%	N	%
No activity (0)	169	123	73%	--	--	46	27%
Mild (1-5)	259	142	55%	73	28%	44	17%
Moderate (6-10)	225	111	49%	98	44%	16	7%
High (11-19)	100	33	33%	54	54%	13	13%
Very high (≥ 20)	48	30	63%	18	38%	--	--

Conclusions

- Use of a representative, real world cohort of SLE patients followed by rheumatologists provides unique information on availability of disease activity measures.
- This registry included patients with a range of disease activity, and a substantial number of patients showed improvement in SLEDAI scores over time.
- Although a variety of non-specific scores are recorded for patients with SLE, capturing changes in diseases status over time remains challenging in the absence of repeated measurements of disease-specific scores in routine practice.