

Patient Characteristics and Current Management of Systemic Lupus Erythematosus Patients in a Large, Representative US-based Real World Cohort

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Background

- Systemic lupus erythematosus (SLE) is a heterogeneous, multifactorial disease with a debilitating and highly variable clinical course.
- Real world data are critical to better understanding these patients and their unmet clinical needs, particularly as inclusion and exclusion criteria for clinical studies are by design highly restrictive and typically not representative of the overall SLE population.
- Disease activity scores, such as the self-reported Multidimensional Health Assessment Questionnaire (MDHAQ, score range: 0-3) and the Health Assessment Questionnaire (HAQ, score range: 0-3) collect information on disability not captured by more commonly used clinical assessments.
- 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.

Objectives

- To identify the occurrence of clinical manifestations and lupus treatments within a cohort of patients with lupus.
- To describe disease activity score levels using the MDHAQ and HAQ scores.
- To characterize levels and changes in the 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 U.S. who are followed prospectively, was used to assess clinical, laboratory, symptomatic and disease activity information. The combined electronic medical record data (EMR) 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.
- ICD and SNOMED diagnosis codes were used to identify patients with key clinical manifestations. NDC and CPT procedure coded medication orders and prescription fills were used to identify disease-modifying and other treatments (DMTs) for lupus.
- MDHAQ, HAQ and SLEDAI scores were obtained from structured EMR data documented during clinical care.
- SLEDAI scores were categorized by disease severity (no disease, mild, moderate, high, very high) and transitions between first and last observed categories were described.

Abbreviations: ICD, International Statistical Classification of Diseases and Related Health Problems ;SNOMED, Systematized Nomenclature of Medicine; NDC, National Drug Codes; CPT, Current Procedural Terminology

Results

- The cohort included 36,603 SLE patients with deep clinical rheumatology data ranging from January 2013 to May 2019. The mean age was 51.5 years [standard deviation (SD) 15.0] and 92% were female.
- The percent of patients with lupus nephritis or proteinuria was 18.5% and 2.2% had lupus endocarditis or pericarditis. While only 5% of patients were treated with the DMT belimumab, 73.7% were treated with antimalarial medications.
- Among the 10,597 patients with at least one MDHAQ score, the average number scores was 4.38 (SD: 4.78). The distribution of the categories is presented in Table 1.
- Among the 1,952 patients with at least one HAQ score, the mean was number of scores was 4.56 (SD: 5.82). The distribution of the categories is presented in Table 1.
- The distribution of the first observed SLEDAI score and changes in category over time are presented in Table 2.

Table 1: Distribution of First Observed MDHAQ and HAQ scores

	MDHAQ		HAQ		
	N	%	N	%	
0 to < 1	4,787	45%	0 to < 1	1,119	58%
1 to < 3	3,245	31%	1 to < 2	624	32%
3 to < 5	2,804	26%	2 to < 3	193	10%
5+	933	9%	3	10	1%

Table 2: Distribution of SLEDAI Scores and Changes from First to Last Observed Scores

	First observed score (N)	No change compared to last score		Decreased categories by last score		Increased category by last score	
		N	%	N	%	N	%
No disease 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 treatment patterns and outcomes.
- This registry includes patients with a range of disease activity
- Chronic treatment options are currently limited to a single marketed DMT and variety of immunomodulators and antimalarials.
- The MDHAQ is easier to use than the HAQ. It is self-administered and more commonly used in clinical practice.
- A substantial number of patients showed improvement in SLEDAI scores over time.

Conference

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