



Validity of a claim-based algorithm for classifying disease activity levels using Systemic Lupus Erythematosus Disease Activity Index 2000 in Korean patients with systemic lupus erythematosus

Yoon-Kyoung Sung, M.D., Ph.D., M.P.H.¹, Ha-Rim Park, Ph.D.¹, Eunwoo Nam, Ph.D.¹,
Hyoungyoung Kim, M.D., Ph.D.¹, Sun-Young Jung, Ph.D.², Eun Jin Jang, Ph.D.³, Soo-Kyung Cho, M.D., Ph.D.¹

¹Department of Rheumatology, Hanyang University Hospital for Rheumatic Diseases, ²College of Pharmacy, Chung-Ang University, Seoul, ³Department of Information Statistics, Andong National University, Andong, Korea

Objective: To validate algorithms for classifying disease activity in patients with systemic lupus erythematosus (SLE) using Korean claims data.

Methods: We used data from a prospective cohort of SLE patients enrolled at a single academic center between October 2014 and August 2020. Disease activity was assessed at each visit using the Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K), with the annual average score serving as the gold standard. Three claims-based algorithms incorporating diagnostic codes for comorbidities and medication use were evaluated: (1) a previously established model including SLE-related comorbidities, immunosuppressants, and oral glucocorticoids, (2) a modified version incorporating intravenous glucocorticoids, and (3) a version with adjusted glucocorticoid dosage criteria (5 mg) to better identify mild to moderate disease. The performance of each algorithm in classifying mild disease activity—defined as SLEDAI-2K <3—was assessed by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value, and the area under the curve.

Results: A total of 151 patients were included. The mean age was 34.5±8.7 years, and 94.7% were female. The mean initial SLEDAI-2K score was 3.6±2.6. The PPV for identifying mild disease activity ranged from 75.9% to 77.2%, with Algorithm 3 demonstrating the highest PPV. However, incorporating intravenous glucocorticoids or adjusting dosage thresholds did not result in further improvement.

Conclusion: A claims-based algorithm using diagnostic and medication codes demonstrated a PPV of 77.2% for classifying mild disease activity in SLE. This approach may offer a practical method for disease activity assessment in Korean claims-based research.

Keywords: Systemic lupus erythematosus, Disease severity, Algorithms, Claims data

INTRODUCTION

Systemic lupus erythematosus (SLE) is a chronic autoimmune disorder with diverse clinical manifestations involving multiple

organ systems, including the mucocutaneous, hematologic, renal, musculoskeletal, neurologic, and cardiovascular systems [1]. These manifestations may fluctuate over time, necessitating reliable assessment of disease activity. Disease activity at the time of

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Corresponding author: Soo-Kyung Cho, https://orcid.org/0000-0003-4493-8837

Department of Rheumatology, Hanyang University Hospital for Rheumatic Diseases, 222-1 Wangsimni-ro, Seongdong-gu, Seoul 04763, Korea. **E-mail:** skchomd@hanyang.ac.kr

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diagnosis is a significant prognostic indicator for future organ damage [2], and frequent disease flares may result in irreversible organ impairment [3]. Moreover, patients experiencing SLE flares demonstrate poorer patient-reported outcomes and increased healthcare resource utilization compared to those without flares, emphasizing the need for more effective interventions to mitigate or prevent disease flares [4]. Accordingly, achieving low disease activity or remission is a critical goal within the treat-to-target framework [5]. Furthermore, genetic and ethnic diversity plays an important role in the clinical expression and severity of SLE, influencing both disease activity and response to treatment [6].

Given the relatively low prevalence of SLE, clinical research using claims data is of considerable value. However, accurately measuring disease activity using claims data remains challenging due to the limited availability of detailed clinical and laboratory information. Disease activity in SLE is typically assessed using indices that integrate clinical signs and laboratory parameters. A previous study in the United States introduced an operational definition for assessing disease activity in SLE using a combination of International Classification of Diseases (ICD)-9 codes, medication data, and procedure codes extracted from claims data [7]. This algorithm was later validated [8] and has been widely employed in clinical research using claims data in multiple countries, including the United States, Germany [9], the United Kingdom [10], and Thailand [11]. Nonetheless, it is essential to assess the applicability of this U.S.-based algorithm in the context of Korean claims data, given potential differences in treatment practices and drug approval status that may influence clinical care.

In this study, we aimed to develop an algorithm-based definition for assessing SLE disease activity among Korean patients and to evaluate its validity using medical records from a single

academic hospital.

MATERIALS AND METHODS

Study population and study design

We utilized a prospective cohort of patients with SLE from a single academic institution, HUMAN-LI (Hanyang University Medical Center Arthritis Network-Lupus Initiatives). Participants had been followed for a minimum of 1 year post-enrollment, with clinical data collected on an annual basis. Eligible individuals were adults aged 18 years or older who were enrolled between October 2014 and August 2020. Patients with less than 1 year of follow-up were excluded from the analysis (Figure 1).

Among the overall cohort, 151 patients were included. For these patients, we retrospectively assessed the Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) at each visit using medical records over the course of 1 year per individual. Chart review was manually conducted by a rheumatologist and a healthcare professional. The SLEDAI-2K provides a continuous measure of disease severity and has also been validated for categorical classification: scores <3 indicate mild disease, 3~6 indicate moderate disease, and >6 indicate severe disease [12]. The average SLEDAI-2K over the 1-year period was designated as the reference standard for identifying moderate to severe SLE.

Diagnostic, procedural, and medication codes were obtained from Hanyang University Hospital database, which integrates both billing claims and electronic health record data. This study was approved by the Institutional Review Board (IRB) of Hanyang University Hospital (IRB no. HYUH 2022-03-002). The requirement for informed consent was waived due to the retrospective nature of the study.

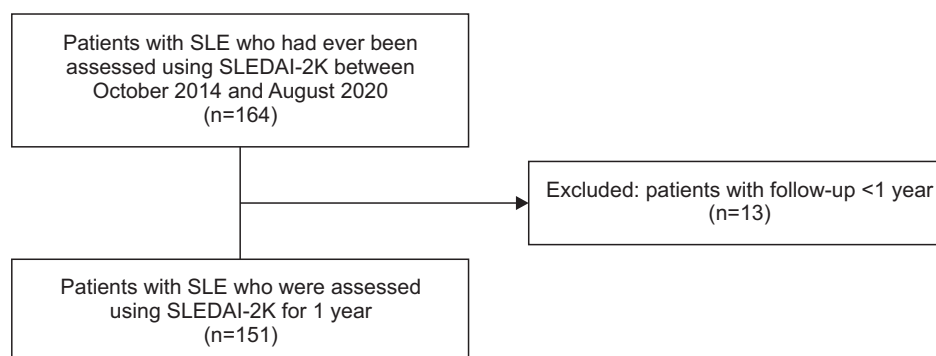


Figure 1. Flow chart of patient selection. SLE: systemic lupus erythematosus, SLEDAI-2K: Systemic Lupus Erythematosus Disease Activity Index 2000.

Table 1. Various algorithms to classify disease activity in patients with SLE

Algorithm	Definition
1 [7]	Mild disease • Did not meet the criteria for moderate or severe disease. • Patients who died and had less than 1 month (30 days) of enrollment in the time period (follow-up, year 1, or year 2) were classified as having died with short enrollment rather than being assigned an SLE disease severity level. Moderate disease • Had no filled prescriptions for cyclophosphamide or rituximab or oral glucocorticoid with ≥ 60 mg/day of prednisone equivalent dose and no claims with a diagnosis of a “severe” condition; AND • Met one or both of the following at any time during the follow-up period: - Had ≥ 1 non-laboratory claim with a diagnosis of a condition listed as “moderate,” where the diagnosis occurs in any position on the claim; OR - Had ≥ 1 filled prescription for an oral glucocorticoid with a prednisone equivalent dose of ≥ 7.5 mg/day and < 60 mg/day or for an immunosuppressive agent (other than cyclophosphamide). Severe disease • Had ≥ 1 filled prescription for cyclophosphamide or rituximab or oral glucocorticoid with a prednisone equivalent dose of ≥ 60 mg/day; OR • Had ≥ 1 non-laboratory claim with a diagnosis listed as “severe,” where the diagnosis occurs in any position on the claim.
2	Modify Algorithm 1 by adding the use of intravenous glucocorticoids.
3	Modify Algorithm 1 by lowering the criteria for glucocorticoid dose with 5 mg/day to differentiate between mild and moderate SLE.

SLE: systemic lupus erythematosus.

Algorithms for assessment of disease severity in patients with SLE

We developed three algorithms to estimate SLE disease activity based on ICD-10 codes for SLE-related comorbidities and prescriptions for SLE therapies (Table 1). The first algorithm was adapted from the Garris et al. [7]’s severity classification, incorporating SLE-related comorbidities, immunosuppressants (including rituximab and cyclophosphamide), and oral glucocorticoids (Algorithm 1). The second algorithm was a modification of Algorithm 1, with the addition of intravenous glucocorticoids as one of the criteria indicating moderate or severe disease activity (Algorithm 2). The third algorithm modified Algorithm 1 by lowering the oral glucocorticoid threshold to 5 mg/day to differentiate mild from moderate disease (Algorithm 3). Algorithm components were extracted for each individual for the corresponding calendar year. Detailed definitions of the algorithms used to classify SLE disease activity are provided in Supplementary Table 1.

Statistical analysis

We compared the classification of SLE activity generated by each algorithm with the average SLEDAI-2K score for the corresponding year. For the primary analysis, algorithm-derived binary disease activity status was compared with SLEDAI-2K categories using a threshold of ≥ 3 to define moderate to severe SLE and < 3 to define mild SLE. Identifying patients with very

mild disease is clinically meaningful, as therapeutic approaches and outcomes differ markedly from those in patients with higher disease activity. Using a SLEDAI-2K score < 3 as the threshold for mild disease, we calculated the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and area under the curve (AUC) for each algorithm. As a sensitivity analysis, we also compared algorithm-based disease activity to both the lowest and highest SLEDAI-2K scores recorded during the corresponding year.

RESULTS

Baseline characteristics of the patients

A total of 151 patients with SLE were included in the analysis. The mean age was 34.5 ± 8.7 years, and 94.7% were female. The mean disease duration was 5.8 ± 5.7 years, and the baseline SLEDAI-2K score was 3.6 ± 2.6 . The average number of outpatient clinic visits per year was 7.7 ± 2.2 . Most patients (95.4%) received hydroxychloroquine, and 82.8% were treated with oral glucocorticoids, with a mean prednisolone-equivalent dose of 6.1 mg/day (Table 2). Based on the annual average SLEDAI-2K score, 85 patients were classified as having mild disease activity, and 66 as having moderate to severe disease activity.

Validity of claims-based algorithms of SLE activity

The diagnostic performance of three claims-based algorithms

for identifying patients with mild disease activity, defined as an average SLEDAI-2K score <3, is presented in Table 3 and Figure 2. Algorithm 1 exhibited the highest sensitivity (0.553) and a PPV of 0.770, with an AUC of 0.670. Algorithm 2, which incorporated intravenous glucocorticoid prescriptions, did not

enhance overall performance and demonstrated slightly lower PPV (0.759) and AUC (0.653) relative to Algorithm 1. Algorithm 3, which applied a modified glucocorticoid dose criterion, achieved the highest specificity (0.803) and PPV (0.772), reflecting the best performance in accurately identifying patients with mild disease activity. However, the NPV values were modest across all algorithms, ranging from 0.559 to 0.578, suggesting that a substantial proportion of patients not identified as having mild disease activity may, in fact, have mild disease. AUC values ranged from 0.653 to 0.670, indicating moderate discriminative performance overall.

Table 2. Baseline characteristics of patients with SLE

Variable	SLE patient (n=151)
Sex, female	143 (94.7)
Age (yr)	34.5±8.7
Body mass index (kg/m ²)	21.7±3.7
Weight (kg)	57.7±12.1
Disease duration of SLE (yr)	5.8±5.7
Number of 2019 EULAR/ACR classification items met*	5.2±1.3
SLEDAI-2K at enrollment	3.6±2.6
Number of visits per year	
Outpatient department	7.7±2.2
Hospitalization	0.2±0.6
Concomitant medication†	
Hydroxychloroquine	144 (95.4)
Methotrexate	17 (11.3)
Mycophenolate mofetil	24 (15.9)
Azathioprine	17 (11.3)
Tacrolimus	14 (9.3)
Cyclosporine	3 (2.0)
Cyclophosphamide	2 (1.3)
Oral glucocorticoid‡	125 (82.8)
Prednisolone-equivalent dose‡ (mg/day, n=125)	6.1±11.0

Values are presented as number (%) or mean±standard deviation. SLE: systemic lupus erythematosus, EULAR: European Alliance of Associations for Rheumatology, ACR: American College of Rheumatology, SLEDAI-2K: Systemic Lupus Erythematosus Disease Activity Index 2000. *The number of 2019 SLE EULAR/ACR classification items met at the time of SLE diagnosis or thereafter. †Concomitant medications were assessed at baseline enrollment. ‡Regular prescriptions of oral glucocorticoids indicated continuous use and excluded PRN (as-needed) prescriptions.

Sensitivity analysis of claims-based algorithms of SLE severity

A sensitivity analysis was performed using the lowest and highest annual SLEDAI-2K scores as alternative reference standards to assess the robustness of the algorithms. When using the lowest SLEDAI-2K definition, all algorithms showed reduced sensitivity (41.9%~44.2%) but improved specificity (79.2%~81.8%) and notably high PPV (91.5%~93.4%). Among these, Algorithm 1 yielded the highest PPV (93.4%) and specificity (81.8%), whereas Algorithm 3 demonstrated the highest AUC (0.641), although the difference was marginal.

Conversely, applying the highest SLEDAI-2K definition increased sensitivity across all algorithms (64.0%~68.0%) and resulted in substantially higher NPV (90.4%~94.1%), indicating an improved ability to exclude mild disease activity. In this setting, Algorithm 2 exhibited the highest NPV (94.1%) and PPV (29.3%), while Algorithm 3 again achieved the highest AUC (0.677) (Supplementary Table 2 and Supplementary Figure 1).

DISCUSSION

In this study, we validated a claims-based algorithm originally developed by Garris et al. [7] in the United States for classifying SLE disease activity and proposed modifications to enhance its

Table 3. Validity of algorithms to predict disease activity in patients with moderate to severe SLE

Algorithm	Sensitivity	Specificity	PPV	NPV	AUC
1	0.553	0.788	0.770	0.578	0.670
2	0.518	0.788	0.759	0.559	0.653
3	0.518	0.803	0.772	0.564	0.660

SLE: systemic lupus erythematosus, PPV: positive predictive value, NPV: negative predictive value, ROC: receiver operating characteristic, AUC: area under the ROC curve.

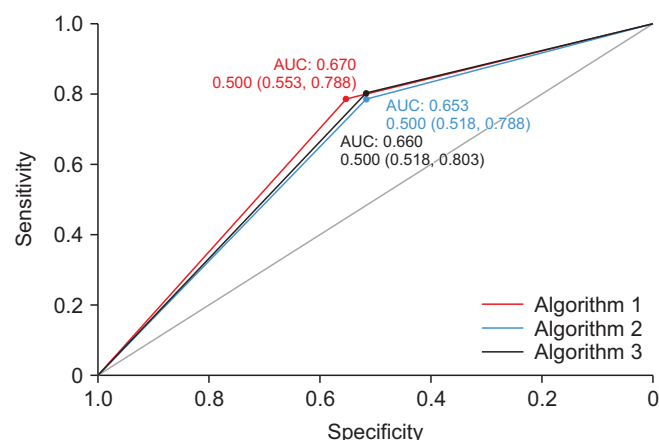


Figure 2. Performance of algorithms to predict moderate to severe SLE: ROC curves and AUCs. ROC: receiver operating characteristic, AUC: area under the ROC curve, SLE: systemic lupus erythematosus.

applicability to Korean patients. The original algorithm, which incorporated diagnostic codes for SLE-related comorbidities, immunosuppressants, and oral glucocorticoids, demonstrated moderate performance in identifying mild SLE. In adapting the original U.S.-based claims algorithm to Korean real-world data, we lowered the glucocorticoid dosage threshold from 7.5 mg/day to 5.0 mg/day to reflect local treatment patterns. In our cohort, the mean daily prednisolone-equivalent dose was 6.1 ± 11.0 mg/day among glucocorticoid users, which is notably lower than the 16.8–19.4 mg/day reported in recent U.S. claims-based studies [13]. This difference may reflect variations in treatment strategies, prescribing behaviors, and ethnic or genetic factors. The adjustment enhances the algorithm's contextual validity and alignment with Korean clinical practice. After adjusting the glucocorticoid criteria, the modified algorithm exhibited improved performance, with a PPV of 77.2%, indicating that most patients classified as having mild SLE were correctly identified.

This algorithm may serve as a useful tool for classifying SLE activity in Korean claims database studies, thereby facilitating further research on SLE management and outcomes in this population. However, sensitivity remained moderate, suggesting that some cases of mild disease may not be captured. The NPV remained relatively low (55.9%–57.8%), reflecting a limited ability to exclude mild disease based solely on claims data. Nonetheless, the high PPV suggests that these algorithms can reliably identify patients with mild SLE, supporting their potential utility in guiding tailored treatment strategies and informing resource allocation in real-world clinical settings. Overall, these findings

highlight Algorithm 3 as the most practical approach for identifying mild SLE in claims data when the average SLEDAI-2K is used as the reference standard, offering a balanced performance compared to definitions based on extreme values.

Sensitivity analyses using the lowest and highest SLEDAI-2K scores further illustrated the variability in algorithm performance based on how disease activity is defined. When the lowest score was used, all algorithms showed reduced sensitivity but maintained high PPV, with Algorithm 1 exhibiting the most favorable performance on these metrics. Conversely, under the highest score definition, sensitivity and NPV improved, whereas PPV declined substantially. Across both sensitivity analyses, Algorithm 3 consistently demonstrated the highest AUC, suggesting superior and more stable discriminative ability.

Misclassification of patients by the claims-based algorithm may have resulted from its partial alignment with clinical manifestations captured by the SLEDAI-2K, which served as the reference standard in this study. Because the algorithm is based on claims data, it may not fully account for manifestations that influence the SLEDAI-2K score. This limitation was examined through detailed medical chart review of patients with discrepancies between algorithm-based and SLEDAI-2K-based classifications. Among the 41 patients assessed as having mild disease activity by SLEDAI-2K but classified as moderate to severe by the algorithm, 14 had a history of lupus nephritis, one had vasculitis, and one had epilepsy diagnosed more than 30 days prior. This discordance likely reflects the difference in the timeframes captured by each method, as SLEDAI-2K assesses disease activity within the previous 30 days, whereas the algorithm includes events from the past year. Additionally, some patients had manifestations such as arterial or venous thrombosis ($n=2$) and ischemic necrosis of bone ($n=2$), which are not included in the SLEDAI-2K but are detected through diagnostic or procedural codes in claims data. Moreover, transient conditions such as episcleritis or scleritis may not be consistently recorded in claims data, particularly if they were treated externally or resolved before documentation.

Conversely, 13 patients were classified as having mild disease by the algorithm but as moderate to severe by SLEDAI-2K. Among these, three patients presented with arthritis, a manifestation captured by SLEDAI-2K but not included in the algorithm. Other cases included patients with abnormal urinalysis findings without a definitive diagnosis of lupus nephritis, mucocutaneous manifestations such as alopecia, mucosal

ulcers, and new rash, or laboratory abnormalities including low complement levels and rising anti-dsDNA antibody titers. These factors contribute to the SLEDAI-2K score but may not be consistently recorded in claims data, leading to an underestimation of disease activity by the algorithm. These observations underscore the need for cautious interpretation when using claims-based algorithms to classify SLE disease activity. While claims data represent a valuable resource for large-scale epidemiologic research, particularly in settings with limited access to clinical data, the use of algorithm-based classifications requires careful consideration of their inherent limitations.

The strengths of this study lie in its comprehensive evaluation and contextual adaptation of claims-based algorithms for assessing SLE disease activity. Using detailed medical chart reviews, we validated an algorithm originally developed in the United States and other countries by applying it to Korean claims data. Furthermore, we proposed a modified version of the algorithm tailored to the Korean healthcare system, thereby improving its applicability and accuracy in both clinical research and practice.

Several limitations of this study should be acknowledged. First, the analysis was based on data from a single academic hospital, which may not be fully representative of the broader SLE patient population in Korea. Second, the study employed the average SLEDAI-2K score as the reference standard for disease activity. While SLEDAI-2K is widely used, it has recognized limitations and may fail to capture transient or clinically meaningful manifestations not included in its scoring criteria. Third, our algorithm did not include belimumab because it had not been approved during the study period, and there were no belimumab users in our dataset. However, as new therapeutic agents such as belimumab become more widely available and are incorporated into clinical practice, future updates to the algorithm will be necessary to ensure its continued applicability and relevance. Fourth, the relatively small sample size may have reduced the statistical power to detect significant associations. Moreover, the possibility of selection bias exists, as patients presenting with severe disease activity at the time of enrollment may have been less likely to participate in the study. Broader validation across different populations will further reinforce its generalizability and support wider implementation in clinical and policy settings.

CONCLUSION

This study highlights the critical importance of adapting and validating disease activity measurement algorithms for specific populations. The successful validation of a claims-based algorithm for assessing SLE disease activity in Korean patients offers new avenues for the utilization of claims data in SLE research, enabling large-scale studies that can deepen our understanding of disease dynamics and inform patient care strategies. Further research is warranted to refine and generalize these algorithms across diverse healthcare settings and populations, thereby advancing both scientific knowledge and clinical management in SLE.

SUPPLEMENTARY DATA

Supplementary data can be found with this article online at <https://doi.org/10.4078/jrd.2025.0053>

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CONFLICT OF INTEREST

S.K.C. has served as an editorial board member of the Journal of Rheumatic Diseases since June 2020 but had no role in the decision to publish this article. The other authors declare no conflicts of interest.

AUTHOR CONTRIBUTIONS

Conceptualization: YKS, HK, SKC. Data curation: HRP, EN, HK. Formal analysis: HK, EN. Funding acquisition: HK. Investigation: YKS, SYJ, EJJ, SKC. Methodology: YKS, SYJ, EJJ, EN, SKC. Writing – original draft: YKS, HK. Writing – review & editing: HRP, EN, SYJ, EJJ, SKC. Approval of the final manuscript: all authors.

ORCID

Yoon-Kyoung Sung, <https://orcid.org/0000-0001-6691-8939>
 Ha-Rim Park, <https://orcid.org/0000-0001-7782-6052>
 Eunwoo Nam, <https://orcid.org/0000-0001-5175-7095>
 Hyoungyoung Kim, <https://orcid.org/0000-0003-1415-461X>
 Sun-Young Jung, <https://orcid.org/0000-0003-2032-112X>
 Eun Jin Jang, <https://orcid.org/0000-0002-9137-9815>
 Soo-Kyung Cho, <https://orcid.org/0000-0003-4493-8837>

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