Systemic lupus erythematosus and associated organ damage in real-world settings: estimating damage scores using administrative claims data

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Abstract

Objective

The Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index (SDI) captures organ damage (OD) in patients with systemic lupus erythematosus (SLE). However, SDI is not always documented in the clinic or medical claims data. This non-interventional retrospective cohort study (GSK Study 209523) used a claims-based algorithm to estimate annual damage scores and associated economic burden in patients with SLE in Germany.

Methods

Patients were identified from the Betriebskrankenkassen German Sickness Fund Database based on the first recorded SLE diagnosis code (index). A claims-based algorithm incorporating conditions listed in the SDI was used to identify OD and estimate damage scores for each follow-up year. Annual costs were estimated from inpatient and outpatient resources and stratified by a damage score point increase.

Results

Patients with SLE (n=2121; pre-existing: n=1037; newly diagnosed: n=1084) and without SLE (n=6308) were included. At baseline, 60.5% (n=1283) of patients with SLE had OD, including 55.3% (n=599) newly diagnosed patients. In Year 1, the mean damage score was 1.82 among all patients with SLE; it was similar between patients with baseline OD and pre-existing (2.76) and newly diagnosed SLE (2.89). Among patients with SLE, during years with a 1-, 2- and ≥3-point increase in damage score, median annual costs were 1.94, 3.75 and 7.84 times those in years without damage score increase.

Conclusion

Our findings suggest that real-world administrative claims data can effectively estimate damage scores in patients with SLE, and that the increase in scores correlates with a higher economic burden.

Key words

autoimmune diseases, cost of illness, epidemiology, systemic lupus erythematosus, health care outcome assessment

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Data availability: All data required for interpretation of these results are included in this article. Details regarding the claims-based algorithm can be obtained from the corresponding author upon request.

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Competing interests: M. Schultze and M. Pignot were employees of Kantar Health at the time of the study, which was contracted by GSK to conduct this study, and they now work for ZEG - Berlin Center for Epidemiology and Health Research GmbH. E. Garal-Pantaler is an employee of Team Gesundheit GmbH, which was subcontracted by ZEG Berlin for the execution of this study. R.A. Levy and H. Carnarius are employed by GSK and hold financial equities in GSK. K. Gairy was an employee of GSK at the time of the study and holds financial equities in the company. M. Schneider received consulting and lecture fees from AbbVie, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, GSK, Roche, and UCB.

Introduction

Up to 50% of patients with systemic lupus erythematosus (SLE) develop organ damage (OD) within 5 years of diagnosis (1). OD is defined for multiple organs by the Systemic Lupus International Collaborating Clinics / American College of Rheumatology Damage Index (SDI), as cumulative and irreversible (2). In SLE, OD is associated with increased morbidity (3), and substantial economic burden (4). The 10-year cumulative costs among patients with OD are up to nine times that of patients without OD (4). Risk factors for OD progression include age, sex, steroid dose, and disease activity and duration (5, 6).

In clinical settings, OD is assessed in SLE using the SDI, a clinically validated tool developed in 1996 to estimate morbidity over 10 years (2, 7). The SDI, completed by physicians, captures 42 clinical conditions present for ≥6 months post-SLE diagnosis, regardless of cause (2). Despite annual measurement recommendations, SDI is rarely used in clinical practice (8-10); only 12% of Canadian rheumatologists routinely performed the SDI due to its complexity and time demands (11). This may lead to underestimation of OD, which may exist pre-diagnosis but is only captured post-diagnosis (2, 11, 12). Standardised approaches that take the individual's multimorbidity and frailty into account, and organ-specific measures adapted for use in SLE, would also facilitate more effective SLE assessments (13).

Real-world data on economic burden of OD in patients with SLE are limited, including in Germany. Our previous non-interventional retrospective analysis (GSK Study 209523) used a claims-based algorithm to identify conditions included in SDI and demonstrated that many German patients with SLE had OD at diagnosis, leading to significant economic burden (14).

This brief paper expands on the above analysis (14), and aims to estimate damage scores in patients with SLE using the administrative claims-based algorithm and to determine any association between these scores and economic burden.

Materials and methods

Study design

The full study design was published previously (14). Briefly, patients with SLE were identified between 1 January 2009 and 31 December 2014 (identification period) from the Betriebskrankenkassen (BKK) German Sickness Fund Database. The BKK database is representative of approximately 72 million individuals covered by statutory health insurance (Gesetzliche Krankenversicherung) in Germany, and in 2017 it included over 5 million people who were included in this analysis. The index date was the first day of the first quarter with the first recorded SLE diagnosis.

Study populations

Adults with SLE were identified using inpatient or outpatient claims with an SLE International Classification of Diseases 10th Revision (ICD-10) diagnosis code. Outpatient-based claims met additional criteria (see the online Supplementary file). All patients required continuous enrolment for ≥2 years pre-index and ≥3 years post-index (follow-up period; except in the case of death during follow-up).

Patients were subcategorised as having pre-existing or newly diagnosed SLE (*i.e.* presence or absence of a pre-index SLE diagnosis). A comparator cohort was propensity score matched (3:1) and had continuous enrolment and no SLE diagnosis during the study period (1 January 2007 to 31 December 2017). The propensity score included the following confounders: age, sex and comorbidities in the Charlson Comorbidity Index (15).

Patients with or without OD pre-index and during follow-up were identified using a claims-based algorithm (described below) based on the presence of clinical conditions outlined in the SDI, using ICD-10 diagnosis codes and/or healthcare procedures or treatment codes (Suppl. file).

Variables and endpoints

Baseline characteristics were collected at index. Mean annual damage score was reported pre-index and for the follow-up period, and mean time to first

increase in damage score was reported for the follow-up period. Unlike the clinical SDI, which only includes conditions that develop after an SLE diagnosis, this claims-based damage score included pre-index OD. The SDI was selected here as it is a validated tool for measuring OD and is used in observational studies (4, 5). The damage score was calculated as the sum of OD condition weights as reported by Gladman *et al*. 1996 (2). The damage score was applied to both cohorts to estimate the incremental burden of OD associated with SLE.

Annual costs, stratified by absolute damage score point increase (0, 1, 2 or ≥3) in the corresponding year, were estimated in 2017 Euros based on the sum of fees retrieved from major inpatient and outpatient resources (hospital admissions, ambulant hospital services and outpatient care).

Statistical analysis

Study measures were summarised descriptively. Time to damage score increase is presented using Kaplan-Meier curves; differences in time to worsening between the SLE and comparator cohorts were assessed using a log-rank test. Hazard ratios (HR) for time to increase in damage score were calculated using a Cox regression; HRs were used to compare the risk of increase in damage score between cohorts.

Patient and public involvement

Patients or the public were not involved in the design or implementation of the study, or the dissemination of its results.

Ethical approval

This study complied with European and German data protection regulations. All patient-level data in the database are anonymised. No direct patient contact or primary collection of individual human patient data occurred. Study results are in tabular form and aggregate analyses that omit patient identification; therefore, informed consent was not required. Institutional Review Board / ethical approval was not needed. Any reports do not include patient identifiers. The study conformed with the Helsinki Declaration of 1964, and its later amendments, concerning human and animal rights.

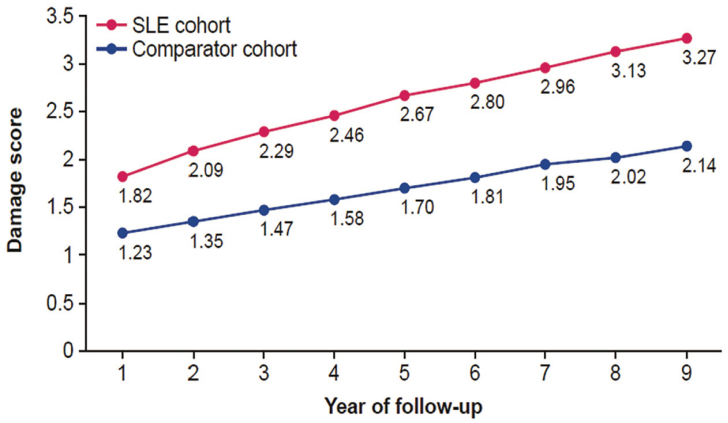


Fig. 1. Mean cumulative damage scores during each year of follow-up among patients with SLE (n=2121) *vs*. comparators (n=6308)[a]
[a]Damage scores were not zero as the SLE population includes patients with pre-existing SLE.
OD: organ damage; SLE: systemic lupus erythematosus.

Results

Patient population

Overall, 2121 patients with SLE were identified, with a mean (standard deviation [SD]) follow-up of 6.37 (2.05) years. The mean (SD) age was 50.86 (16.18) years, and 1770 (83.5%) patients were female. In total, 6308 propensity score-matched comparator patients without SLE were included, and their characteristics were well matched. Full demographic and baseline characteristics are reported elsewhere (14). At baseline, 1283 (60.5%) patients in the SLE cohort and 2990 (47.4%) in the comparator cohort had OD. The most common types of OD at baseline in the SLE and comparator cohorts, respectively, were ocular (26.9% and 22.3%), neuropsychiatric (18.9% and 15.4%) and cardiovascular (14.5% and 10.6%); findings were similar during follow-up, but OD was higher overall versus baseline (Suppl. Table S1). A total of 1037 (48.9%) patients had pre-existing SLE and 1084 (51.1%) had newly diagnosed SLE, of which 684 (66.0%) and 599 (55.3%) had OD at baseline, respectively.

Annual damage score

The mean damage score was 1.82 in the first year of follow-up and increased by approximately 0.20 each year in all patients with SLE; in the comparator cohort, mean score was 1.23 in the first year of follow-up and increased by approximately 0.12 each year (Fig. 1). In the first year of follow-up, among patients with pre-existing SLE, the mean damage score for those with and without pre-index OD was 2.76 and 0.25, respectively, and 2.89 and 0.33 among patients with newly diagnosed SLE.

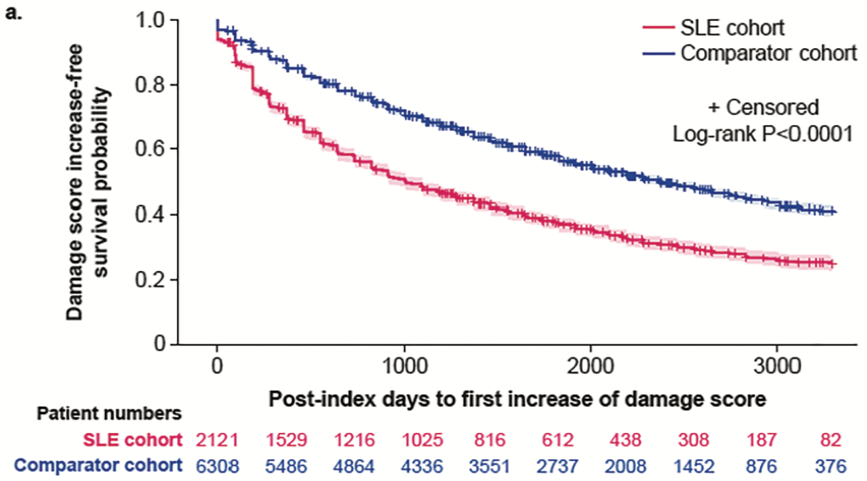
Mean time to first increase of damage score was significantly shorter among patients with SLE than among comparators (HR [95% confidence interval] 1.81 [1.70, 1.93]; p<0.0001; Fig. 2a-b). The mean change in damage score per year was higher among newly diagnosed patients with pre-index OD than those without (0.19 and 0.16, respectively; Fig. 2c).

Association between damage score and economic burden

Among patients with SLE with OD during follow-up, during years with a 1-, 2- and ≥3-point damage score increase, median total annual costs were 1.94, 3.75 and 7.84 times those of the years with a 0-point increase, respectively (Fig. 3a). Excess median cost of OD in patients with SLE versus comparators was approximately €6000/year for patients with a damage score increase of ≥3 points (Fig. 3b).

Discussion

This real-world study showed that a claims-based algorithm based on the SDI could reliably estimate damage scores among patients with SLE, and that patients with higher scores incur



b.

Parameter	Parameter estimate	Standard error	Chi-square	Pr > Chi-square	Hazard ratio	95% CI
SLE	0.30	0.02	333.89	<0.0001	1.81	1.70 1.93
Age 50–64 years at index	0.32	0.02	274.70	<0.0001	1.90	1.76 2.04
Age 65–79 years at index	0.48	0.02	456.42	<0.0001	2.63	2.40 2.87
Age 80+ years at index	0.64	0.04	254.83	<0.0001	3.60	3.08 4.22
Female	−0.01	0.02	0.29	0.5882	0.98	0.91 1.06
Multimorbidity[c]	0.08	0.03	8.14	0.0043	1.18	1.05 1.32
Pre-index OD	0.13	0.04	11.21	0.0008	1.14	1.05 1.23

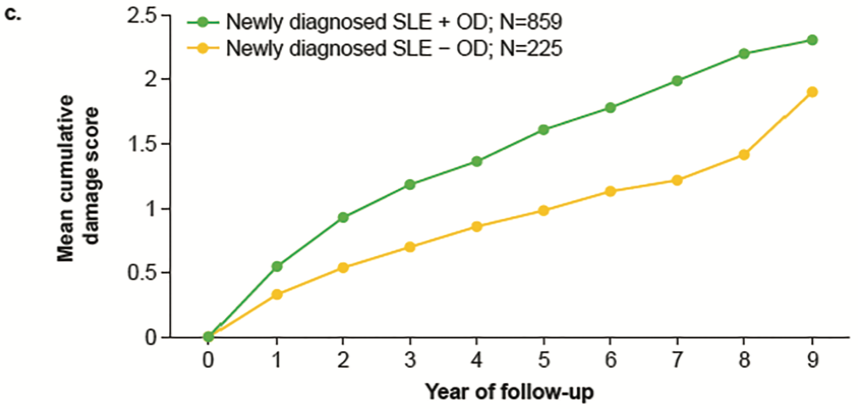


Fig. 2. (**a**) Kaplan-Meier curve and (**b**) Cox regression analyses[a] for the first increase of damage score among patients with SLE *vs*. comparators; (**c**) mean cumulative damage score among patients with newly diagnosed SLE with (n=859) or without OD (n=225) pre-index[b]

[a]Cox regression analyses were adjusted for sex, age, baseline CCI comorbidities and baseline OD; [b]The damage scores for patients with pre-index OD have been rescaled by subtracting the cumulative damage score reached at index from their yearly cumulative damage score values; [c]Defined as presence of multiple pre-index comorbidities.

CCI: Charlson Comorbidity Index; CI: confidence interval; OD: organ damage; SLE: systemic lupus erythematosus.

greater annual healthcare costs *versus* patients with lower scores. We found that the algorithm-derived damage scores steadily increased over 5 years, and that the presence of OD before diagnosis is associated with a greater cumulative damage score, and therefore, economic burden. A diagnosis of SLE was associated with a 1.8-times higher risk of developing OD compared with no SLE diagnosis. This was a higher risk than multimorbidity and pre-index OD, suggesting these characteristics potentially reflect general mechanisms of disease progression and inflammation rather than being specific to SLE. This may be due to shared baseline risks, overlapping comorbidities in the comparator group, steroid use for non-SLE conditions, and limitations related to follow-up duration and claims data.

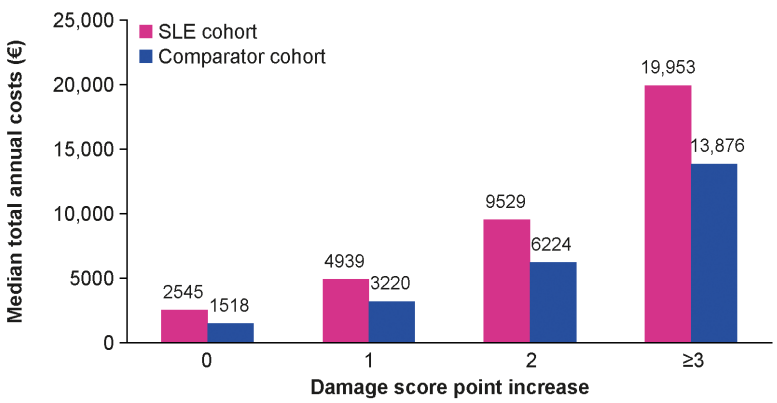
The damage score values estimated here are consistent with changes in SDI scores derived from clinical cohorts. Specifically, two studies showed that SDI scores increased by 0.72–1.01 points over 5 years among different cohorts of patients with SLE (1, 16). This suggests that the claims-based algorithm is a reliable substitute to clinical SDI data.

In this study, median total annual costs increased with an increase in damage score, similar to the change in predicted annual healthcare costs reported elsewhere (increase by a factor of 2.1 for 1-point and 5.2 for 3-point SDI increases) (4). These data provide evidence that disease-modifying interventions that delay the progression of OD could offer substantial cost offsets, especially if prescribed early and before the onset of OD.

Limitations of this study are inherent to retrospective analyses. Misclassification bias may have occurred due to inaccurate coding of diagnoses. OD proxies were based on the presence of clinical conditions, which are not always reported in healthcare administrative datasets where there is no associated treatment; therefore, the prevalence of OD may be underestimated. As the comparator cohorts were comorbidity matched, the difference in OD progression in the SLE cohort may be conservative. As patients with newly diagnosed SLE had no SLE diagnosis pre-index, the pre-index period of 2 years may have been insufficient to robustly differentiate newly diagnosed patients from those with pre-existing SLE. Furthermore, due to inclusion of pre-index OD, the high proportion of newly diagnosed patients with SLE and OD at baseline may have been misattributed to SLE rather than comorbidities.

In summary, we have shown that the damage score can be estimated among a large real-world SLE cohort in Germany, and increases in damage score are associated with substantial economic burden. This study also shows how a clinical tool could be adapted for claims-based data, which could be applied to other diseases.

a.



b.

	Damage score point increase	Patient-years	Total annual costs (€)		
			Median	25th percentile	75th percentile
SLE cohort	0	9145	2545	1203	5896
	1	1998	4939	2172	11,730
	2	409	9529	4376	18,397
	≥3	226	19,953	8967	36,610
Comparator cohort	0	23,167	1518	666	3952
	1	4026	3220	1264	8013
	2	628	6224	2350	13,920
	≥3	235	13,876	5619	31,509

Fig. 3. Total annual costs stratified by damage score increase among patients with SLE with OD (n=1760) *vs*. comparators with OD (n=4197).
OD: organ damage; SLE: systemic lupus erythematosus.

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