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BRIEF REPORT

Evaluating the Use of Glucocorticoids Among Belimumab-Treated Patients With Systemic Lupus Erythematosus in Real-World Settings Using the Rheumatology Informatics System for Effectiveness Registry

Nevin Hammam,[1] Michael Evans,[1] Christopher F. Bell,[2] Kerry Gairy,[3] Jinoos Yazdany,[1] and Gabriela Schmajuk[4]

Objective. Glucocorticoids are part of standard therapy for systemic lupus erythematosus (SLE), despite adverse effects associated with long-term treatment. Belimumab improved clinical manifestations of SLE and reduced glucocorticoid doses in clinical trials and clinical practice; however, associations have not been examined using multi-institutional electronic health record (EHR) data. Using the Rheumatology Informatics System for Effectiveness registry, we examined glucocorticoid use patterns among belimumab-treated adults with SLE.

Methods. This retrospective analysis (GSK Study 209267) used EHR prescription records of patients with SLE managed by rheumatologists. Eligible patients had an index date (first belimumab prescription) between January 2014 and June 2018. The primary analysis compared patients' mean daily oral glucocorticoid (prednisone equivalent) dose over the 6 months preindex versus 6 months post index. An exploratory analysis assessed glucocorticoid doses at 12 and 24 months post index for patients with extended follow-up.

Results. Of the 1987 patients receiving their first belimumab prescription, 767 had available glucocorticoid prescribing data, whereas 204 (primary analysis population) had glucocorticoids prescribed in the 6 months preindex and received belimumab according to the prescribing information for the first 8 weeks post index. The mean (SD) glucocorticoid dose was 12.5 (13.5) mg/day 3 months preindex, reducing to 10.3 (10.6) mg/day over the 6 months post index, and 8.7 (9.4) and 9.0 (9.3) mg/day at 12 and 24 months post index.

Conclusion. This study showed reductions in mean daily glucocorticoid dose after belimumab initiation. Several limitations of EHRs for real-world effectiveness research were identified, which limited interpretation of results and may inform future study designs.

INTRODUCTION

Glucocorticoids are part of the standard therapy for systemic lupus erythematosus (SLE), helping to rapidly control disease activity (1). However, long-term treatment with glucocorticoids can have significant adverse effects, especially at high cumulative doses (2). Thus, reducing glucocorticoid doses is an important treatment goal in SLE management (1). For patients who do not adequately respond to standard therapy, belimumab is considered.

Belimumab is a disease-modifying human monoclonal antibody therapy that inhibits soluble B lymphocyte stimulator and is an approved treatment for active, autoantibody-positive SLE in patients 5 years of age and older and for adults with

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active lupus nephritis (3–5). Results from a large pooled post hoc analysis of clinical trial data demonstrated the role of belimumab as a glucocorticoid-sparing treatment in SLE management (6). Similarly, a pooled analysis of OBSErve (evaluation Of use of Belimumab in clinical practice SEttings) studies from several countries provided real-world evidence for improved clinical manifestations of SLE and a 50.3% reduction in mean glucocorticoid use (prednisone equivalent) from 16.7 mg/day at date of belimumab initiation to 8.3 mg/day after 6 months of continued treatment (7). Furthermore, a recent retrospective claims database analysis showed reduced glucocorticoid doses following belimumab initiation (8). However, interpretation of prescription data should take into consideration the data source. For example, although administrative claims databases provide large-scale data, prescription data typically lack detailed physician administration guidance, including prescription reasoning, dosing, and tapering instructions. In contrast, electronic health records (EHRs) provide detailed physician notes on prescribed doses and records of pharmacy-dispensed prescriptions. Additionally, previous retrospective studies relied on the mean glucocorticoid dose at different time points, limiting the detail available on treatment tapering and treatment of flares (7,9,10).

The Rheumatology Informatics System for Effectiveness (RISE; NCT02230943) is a rheumatology registry with more than 1000 participating rheumatology clinicians in the USA. Unlike other registries, RISE passively extracts data from EHRs of patients from participating practices, avoiding separate data entry by clinical staff (11). As it relates to prescription records, this data extraction allows for the collection of detailed pharmacy data, including glucocorticoid administration instructions from the physician.

The aim of this study was to explore the use of the RISE registry to examine patterns of oral glucocorticoid use among belimumab-treated adults with SLE.

MATERIALS AND METHODS

Study design and outcomes. This is a retrospective analysis of the RISE registry (GSK Study 209267). The registry contains patient-level data collected in EHR systems, reflecting patients' ambulatory clinical care within participating

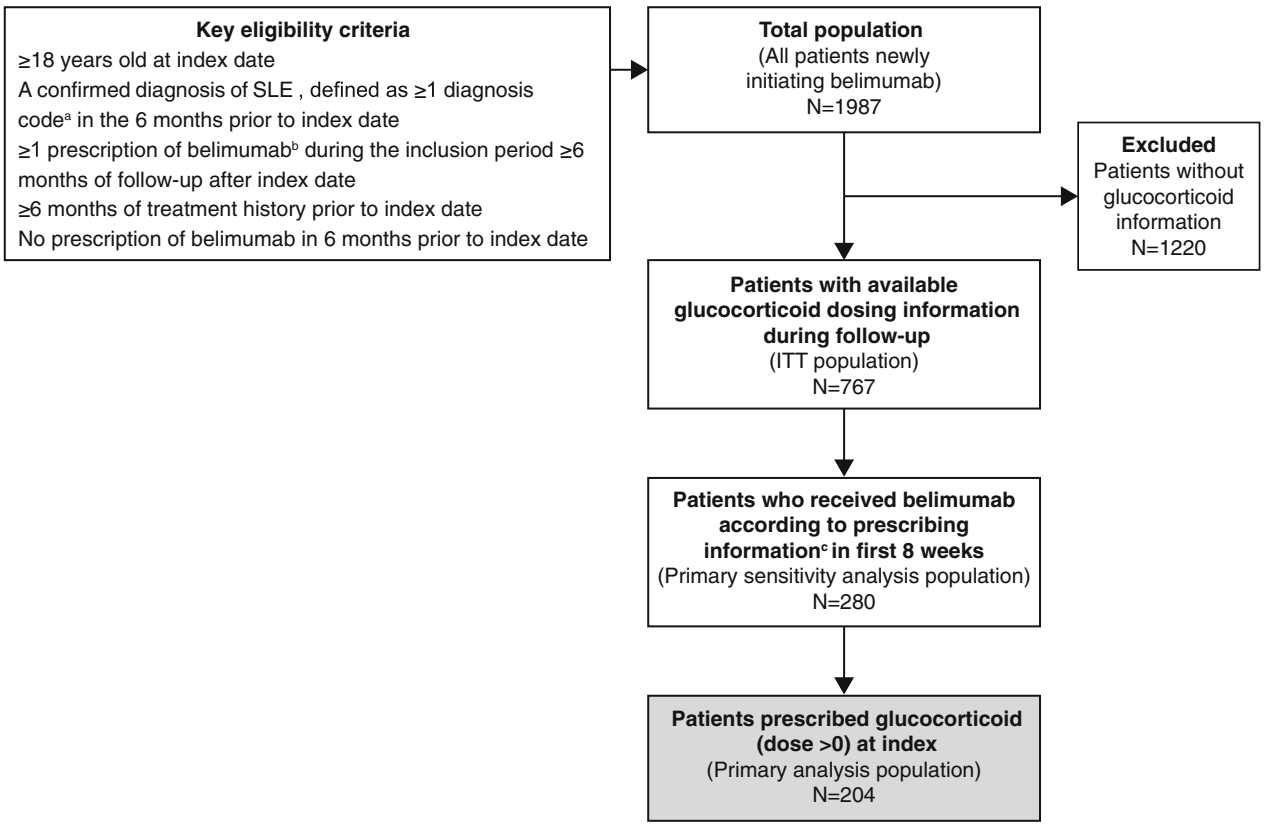

Figure 1. Flowchart of patient selection. [a]Diagnosis codes included, from the *International Classification of Diseases, Ninth Revision* (ICD-9), 710.0 and, from the *International Classification of Diseases, Tenth Revision* (ICD-10), M32 (excluding M32.0). [b]Patients who received their first belimumab prescription (defined as the index date) from January 1, 2014, to June 30, 2018, were included in the analysis. [c]Defined as three or more intravenous administrations or two or more subcutaneous orders where one order was assumed to reflect four subcutaneous doses. ITT, intention-to-treat; SLE, systemic lupus erythematosus.

Table 1. Baseline characteristics of the primary analysis and total populations

Characteristics	Primary analysis patients (n = 204)	Total population (N = 1987)
Sociodemographic and treatment characteristics		
Age, mean (SD) y	49.3 (13.5)	50.2 (13.3)
Female, n (%)	194 (95.1)	1871 (94.2)
Race and ethnicity, n (%)		
White	109 (53.4)	1025 (51.6)
Hispanic or Latino	13 (6.4)	183 (9.2)
Black African ancestry/African American	45 (22.1)	437 (22.0)
Asian	2 (1.0)	36 (1.8)
Native Hawaiian or Other Pacific Islander	0	2 (0.1)
American Indian or Alaska Native	0	6 (0.3)
Multiracial	2 (1.0)	1 (0.1)
No determinate office of management and budget race classification	0	64 (3.2)
Missing	16 (7.8)	233 (11.7)
Insurance, n (%)		
Medicare	32 (15.7)	410 (20.6)
Medicaid	8 (3.9)	121 (6.1)
Private	98 (48.0)	985 (49.6)
Other	5 (2.5)	113 (5.7)
Missing	61 (29.9)	358 (18.0)
US geographic region, n (%)		
East North Central	2 (1.0)	37 (1.9)
West North Central	30 (14.7)	323 (16.3)
Mid-Atlantic	18 (8.8)	135 (6.8)
Mountain	9 (4.4)	69 (3.5)
New England	89 (43.6)	807 (40.6)
Pacific	27 (13.2)	237 (11.9)
South Atlantic	16 (7.8)	158 (8)
East South Central	2 (1.0)	113 (5.7)
West South Central	11 (5.4)	108 (5.4)
Concomitant medications during belimumab treatment, n (%)		
Immunosuppressants[a]	55 (27.0)	719 (36.2)
Antimalarials	99 (48.5)	1040 (52.3)
Rituximab	1 (0.5)	27 (1.4)
Belimumab formulation use, n (%)		
Intravenous	173 (84.8)	1535 (77.3)
Subcutaneous	3 (1.5)	138 (6.9)
Switched	20 (9.8)	185 (9.3)
Unknown	8 (3.9)	129 (6.5)
Months of follow-up, mean (SD)	61.9 (31.8)	62.6 (33.1)
Patients with 24 mos post index, n (%)	117 (57.4)	1084 (54.6)
Number of visits in 2018, mean (SD) per patient	5.4 (5.2)	4.9 (4.1)
SLE immunological tests		
ANA, n (%)		
Patients with test results	98 (48.0)	1004 (50.5)
Patients with >40 IU/ml	78 (79.6)	744 (74.1)
Complement component 3, n (%)		
Patients with test results	152 (74.5)	1351 (68.0)
Patients with <80 mg/dl	42 (27.6)	370 (27.4)
Complement component 4, n (%)		
Patients with test results	152 (74.5)	1314 (66.1)
Patients with <16 mg/dl	57 (37.5)	499 (38.0)
Complement component 3 or 4, n (%)		
Patients with test results	152 (74.5)	1353 (68.4)
Patients with abnormal results[b]	69 (45.3)	583 (43.1)
Anti–double-stranded DNA, n (%)		
Patients with test results	147 (72.1)	1240 (62.4)
Patients with >30 IU/ml	53 (36.1)	395 (31.9)

Abbreviations: ANA, antinuclear antibody; SLE, systemic lupus erythematosus.
[a]Including azathioprine, chlorambucil, cyclophosphamide, cyclosporine, methotrexate, mycophenolate mofetil, and tacrolimus.
[b]Patients with component 3 less than 80 mg/dl or with component 4 less than 16 mg/dl.

rheumatology practices. Contributors to the RISE registry consist of approximately 2.4 million patients and more than 1000 rheumatology clinicians across the USA, collected from January 2014 onward (11,12). Data were collected during routine clinical care and include patients' demographics, diagnoses, procedures, medications, laboratory test results, and vital signs. Oral glucocorticoid doses were obtained from patients' medication information (reflecting ambulatory medication reconciliation of self-reported drugs) and, when available, medication order information (e-prescriptions). These data were converted to oral prednisone-equivalent doses for analyses.

Eligible patients were greater than or equal to 18 years of age, had at least one *International Classification of Disease, Ninth Revision* (ICD-9) 710.0 or *International Classification of Disease, Tenth Revision* (ICD-10) M32 (excluding M32.0) diagnosis code in the 6 months prior to the date of the first belimumab prescription (the index date). The first belimumab prescription was between January 2014 and June 2018 (the inclusion period). Patients must have had at least 6 months of observation preindex, with no prescription of belimumab, and at least 6 months of observation post index (Figure 1). In the primary analysis, the patients' mean daily glucocorticoid dose over the 6 months preindex was compared with that over the 6 months post index. In an exploratory analysis, the glucocorticoid dose 12 and 24 months post index was investigated for patients for whom data were available.

This study complied with all applicable laws regarding patient privacy. No direct patient contact or primary collection of individual human patient data occurred. This study was approved by a central institutional review board (Western IRB) and the University of California at San Francisco IRB.

Data analysis. To calculate glucocorticoid dose, the "sig" (*signetur*) for the prescription had to be available in the form of e-prescription data. The sig, pill size, and start and stop dates were used to calculate average daily dose of glucocorticoids. For cases in which the stop date was not available (35% of included patients), prescriptions were considered to be continued to the end of the study period or until a newer prescription with the same size pill was recorded. Patients were assumed to take one prescription per pill dose at a time and could be taking a combination of prescriptions for different pill doses. If a patient had overlapping prescriptions for different pill doses (eg, 5-mg tablets and 1-mg tablets), their daily dose was calculated as the combined dose of their active prescriptions. For patients without an active prescription, the daily dose was considered to be zero.

Data were summarized with descriptive statistics using mean and standard deviations (SDs). Variables were analyzed as observed, with no imputation of missing data.

RESULTS

Of the patients with SLE who were identified in the RISE registry, 1987 received a first prescription of belimumab during the inclusion period and met all other eligibility criteria. Among these patients, 38.6% (767 of 1987) had necessary data on glucocorticoid doses available in their EHR during the study period, whereas 10.3% (204 of 1987) had been prescribed glucocorticoids (ie, a nonzero dose could be estimated) in the 6 months preindex and received belimumab according to the prescribing information (3) for the first 8 weeks post index. These patients were included in the primary analysis population (Figure 1). Follow-up data for the primary analysis population were available at 12 and 24 months for 84.3% (172 of 204) and 57.4% (117 of 204) of patients, respectively. Characteristics of the primary analysis population and total population who initiated belimumab are listed in Table 1.

Most patients (84.8%; 173 of 204) received intravenous belimumab compared with 1.5% (3 of 204) receiving subcutaneous belimumab. The remaining patients were either those who switched belimumab formulations (9.8%; 20 of 204) or whose formulation was unknown (3.9%; 8 of 204). Approximately half (48.5%; 99 of 204) of all patients included in the primary analysis population received concomitant antimalarials at baseline (ie, 0–6 months post index), whereas nearly a third (27%; 55 of 204) were concomitantly treated with immunosuppressants. The mean daily glucocorticoid dose and the number of patients with a dose of greater than or equal to 7.5 mg/day did not change over 6 months of follow-up; however, both gradually decreased in the extended follow-up period of up to 24 months (Table 2). For the 3 months preindex and 6 months post index, the daily mean (SD) glucocorticoid dose was 11.5 (13.1) and 10.3 (10.6) mg/day, respectively. The mean (SD) daily glucocorticoid dose (not including days prior to the first glucocorticoid prescription) was 11.1 (13.5) mg/day from 6 to 3 months preindex, 12.5 (13.5) mg/day over the 3 months preindex, and 10.3 (10.6) mg/day over 6 months post index (Table 2).

For the subgroups of patients with extended follow-up, the mean daily glucocorticoid dose was 8.7 (9.4) mg/day and 9.0 (9.3) mg/day for index to 12 and 24 months post index, respectively (Table 2).

DISCUSSION

This study describes the use of an EHR registry to determine the prescribing patterns of glucocorticoids by rheumatology clinicians among belimumab-treated adult patients with SLE. The RISE registry provided glucocorticoid dose data for a large sample of patients with SLE in a predominantly community setting, who were newly treated with belimumab and included detailed prescribing notes from which daily fluctuations in prescribed dose can be derived.

Table 2. Changes in oral glucocorticoid dosage during treatment with belimumab

Variables	All patients (N = 204)			Subgroup of patients with extended visit history	
	6-3 mos preindex	3 mos to index	Index to 6 mos post index	Index to 12 mos post index (n = 172)	Index to 24 mos post index (n = 117)
Daily dose from start of glucocorticoid,[a] mean (SD) mg/d	11.1 (13.5)	12.5 (13.5)	10.3 (10.6)	8.7 (9.4)	9.0 (9.3)
Patients with glucocorticoid dose ≥7.5 mg/d, n (%)	111 (54)	121 (59)	110 (54)	78 (45)	53 (45)
Patients with a change in glucocorticoid dose, n (%)					
Newly initiated	—	—	3 (1.5)	6 (3.5)	1 (0.9)
Increase	—	—	26 (12.7)	21 (12.1)	9 (7.7)
No change	—	—	107 (52.7)	106 (61.9)	80 (68.4)
Decrease	—	—	47 (22.9)	25 (14.5)	14 (12)
Discontinued	—	—	21 (10.2)	14 (8.1)	13 (11.1)

Note: The prescribed doses for all oral glucocorticoids were converted to oral prednisone-equivalent doses.
[a]Not including days prior to first glucocorticoid prescription in the preindex period.

The results of this analysis show a modest change in mean daily glucocorticoid dose after belimumab initiation. Similar trends were observed in a claims database study evaluating belimumab use in a US-managed care setting (10), but they are contrary to findings from clinical trials and other real-world studies that have reported a greater glucocorticoid-sparing effect (7,9,13–17). This discrepancy may be explained by differences in study design, data collection period, and length of follow-up period combined with differences in prior glucocorticoid dosage before belimumab treatment and in patient characteristics and/or adherence to the recommended belimumab dosing regimen.

The primary end point of this study was the glucocorticoid dose at 6 months after belimumab initiation. This time period was selected because this is the minimal recommended duration of belimumab treatment before treatment effect is assessed (4). Also, this time period minimizes the impact of patient loss during follow-up in retrospective analysis, which increased over time in the current study. However, because belimumab modifies the underlying course of the disease, full efficacy occurs over longer treatment periods (13,14). Thus, an assessment at 6 months after initiation may not accurately reflect the glucocorticoid-sparing effect of belimumab. Indeed, the decrease in average daily glucocorticoid dose from index was larger at 12 and 24 months; however, owing to the concomitant decrease in patient numbers over time, the incomplete adherence to monthly belimumab infusions, and the exploratory nature of this analysis, these results should be interpreted with caution.

In the OBSErve US study, the mean (SD) glucocorticoid dose at baseline was higher than that in the current study (19.9 [14.4] mg/day) and subsequently decreased to 8.4 (7.4) mg/day at 6 months and 6.1 (9.3) mg/day after 24 months of belimumab treatment (15). Previous retrospective claims database analyses reported an average daily dose of 19.4 and 17.6 mg prior to initiating belimumab, with more than half of patients receiving an average dose of greater than or equal to 15 mg/day (9,10). In contrast, the mean (SD) glucocorticoid dose was lower in the multicenter Belimumab in Real Life Setting Study (BeRLiSS) at baseline than in the current study (10.6 [8.6] mg/day); and it subsequently decreased to 5.3 (4.7) mg/day at 12 months and 3.8 (3.8) mg/day after 24 months of belimumab treatment (16). The differences in starting glucocorticoid doses suggest there may be differences in disease activity in patient populations between the current and previously published studies and likely reflect significant variations in glucocorticoid use among patients with SLE more generally.

The RISE registry was designed to support practice-based evidence to be used to inform health care quality and to facilitate rheumatology clinical practice improvement. As such, neither SLE-specific disease activity measures nor structured descriptions of organ damage manifestations were available in the RISE registry; therefore, disease severity could not be fully assessed. Indeed, there may be underreporting of comorbidities by ICD diagnosis codes in that, for example, chronic renal disease was not a code that was used for many patients identified with having nephritis (data not shown). Similarly, patients' test results appeared to be missing from the EHR in many cases; only half of the included patients had available antinuclear antibody levels, although this is now part of the 2019 European Alliance of Associations for Rheumatology/American College of Rheumatology classification criterion for SLE (18). Although the prevalence of patients with antinuclear antibody test results was about 50%, almost 80% of patients with results had levels greater than 40 IU/ml. Low prevalence of antinuclear antibody test results may be explained from the method of data collection used through the course of routine clinical care; positive tests conducted prior to the rheumatologist visit in an external laboratory

were unlikely to be repeated and therefore not be recorded in the EHR. As such, comparisons with patient populations in other studies were not possible beyond patient demographics. Although the RISE registry collates data from multiple practices, these were almost exclusively from community-based rheumatology practices. Thus, a differing emphasis on the need for glucocorticoid tapering may have been reflected between community and academic settings.

One advantage of using EHR-based registries, such as the RISE registry, is that the mean glucocorticoid dose over the entire study period could be used rather than the dose at the end of follow-up. However, estimations of mean daily dose for all patients were not always feasible owing to the stated requirements (glucocorticoid prescription preindex and glucocorticoid use in the 6 months preindex) and the unavailability of complete e-prescription data, including days supplied and/or number of refills; glucocorticoid dosing information during the 6-month postindex period was available for only 38.6% of the original population that had available glucocorticoid information. When focusing further on those patients with glucocorticoid use preindex and belimumab use according to prescribing information in the first 8 weeks post index, only 10.3% of the total patients with SLE were included in the primary analysis. Because most studies report that the majority of patients initiating belimumab are also prescribed glucocorticoids (6,7), missing data for a large proportion of our cohort are an important limitation.

A second advantage of using EHR registries is the large number of patients available for inclusion; 1987 patients were found to have newly initiated belimumab in this study. Repeated ICD diagnosis codes were not required for inclusion because belimumab prescription was also an inclusion criterion for this study.

Medication data in the RISE registry EHRs are derived from patient-reported medication lists, which are variably reconciled and may not include detailed prescribing information; a minority of practices have e-prescribing information available. Our analysis showed that there is a need for more information from e-prescriptions or pharmacy claims to elucidate use treatments in the real world; for example, subcutaneous belimumab prescription data from medication lists were often unclear and did not include all administration dates, refill information, or number of days supplied per prescription. These findings raise two important points. First, when e-prescription data are available, they provide critical detail for studying drug use patterns for pharmacy-administered drugs. Second, linking EHR data, which include more detailed prescribing information and tapering schedules, with pharmacy claims, which reflect whether a patient also filled a prescription, would help to accurately elucidate medication use. The current finding that approximately half of all patients with SLE received concomitant antimalarials at baseline is consistent with a previous report (19); however, it is less than that reported in the overall RISE data set (71.5%) (20). This difference could be explained by fewer patients who receive belimumab taking concomitant antimalarials because of previous adverse events or drug intolerance reported with use of these treatments (21). This would be an interesting area for future research.

In conclusion, this study revealed challenges related to using EHRs that limited the interpretation of the observed reduction in mean daily glucocorticoid dose after belimumab initiation. A formal review of the literature is ongoing to gain further understanding of the impact of belimumab on glucocorticoid use and other outcomes in the real-world clinical setting.

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AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article and revising it critically for important intellectual content, and all authors approved the final version to be published. Hammam, Evans, Yazdany, Schmajuk had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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ROLE OF THE STUDY SPONSOR

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