Pharmacoepidemiology

1603 RACIAL DIFFERENCES IN PERSISTENT GLUCOCORTICOID USE PATTERNS AMONG MEDICAID BENEFICIARIES WITH INCIDENT SYSTEMIC LUPUS ERYTHEMATOSUS

[1,2]Mia T Chandler, [2]Leah M Santacroce, [2]Karen H Costenbader, [2,3]Seoyoung C Kim, [2,3]Candace H Feldman*. [1]*Division of Immunology, Boston Children's Hospital, Boston, MA, U.S*; [2]*Division of Rheumatology, Inflammation, and Immunity, Department of Medicine, Brigham and Women's Hospital, and Harvard Medical School, Boston, MA, U.S*; [3]*Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital, Boston, MA, U.S*

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Background Glucocorticoids ("steroids") are frequently used in systemic lupus erythematosus (SLE) to treat active disease. While effective, steroid use has been associated with increased risk of potentially avoidable adverse events including serious infections, osteoporosis, avascular necrosis, and cardiovascular disease. Prolonged use may contribute to racial/ethnic disparities in these avoidable outcomes and in acute care use. We therefore examined racial/ethnic differences in longitudinal patterns of steroid use and dose in a cohort of beneficiaries of Medicaid, the largest public insurance serving lower income individuals in the U.S.

Methods We identified Medicaid beneficiaries from the 29 most populous U.S. states 2000- 2010 who were 18-65 years, had incident SLE (≥3 ICD-9 codes for SLE separated by ≥30 days with no SLE codes in the prior 24 months) and who received steroids for 12 months following the date of the third ICD-9 code (index date). We used group-based trajectory modeling to identify patterns of daily prednisone-equivalent steroid doses over the 12-month follow-up period beginning at the index date. We examined demographic, clinical and healthcare utilization factors, as well has SLE severity markers, during the baseline period and used multinomial logistic regression to estimate the odds of belonging to the higher vs. lowest steroid dose trajectories (Odds Ratio [OR], 95% CI).

Results We identified 6,323 individuals with SLE with ≥1 dispensed steroid prescription. The mean (SD) prednisone-equivalent dose was 7 (23) mg/day for Black, 7 (26) Hispanic, 7 (13) Asian, and 4 (10) for White individuals. We identified four trajectories of steroid dose and use (figure 1). Multinomial models adjusted for demographics, comorbidities, other medication use, healthcare utilization and SLE disease severity demonstrated higher odds of belonging to the highest vs. lowest steroid trajectory for Black (OR 2.06, 95% CI 1.64-2.60), Hispanic (OR 1.82, 95% CI 1.38-2.40), and Asian (OR 2.40, 95% CI 1.52-3.80) vs. White individuals. Having >5 outpatient visits during the baseline period was associated with lower odds of being in the persistently high-dose steroid trajectory (OR 0.78; 95% CI 0.61-1.00).

Conclusion Black, Hispanic, and Asian (vs. White individuals) had higher odds of persistently high-dose steroid use that remained after adjusting for SLE disease severity markers. Sustained access to outpatient care and the development of standardized steroid-tapering regimens from clinical trials with diverse populations may be targets for intervention to mitigate disparities in steroid-related avoidable adverse outcomes.

1604 COMPARATIVE RISKS OF INFECTION WITH BELIMUMAB VERSUS ORAL IMMUNOSUPPRESSANTS IN PATIENTS WITH NON-RENAL SYSTEMIC LUPUS ERYTHEMATOSUS

[1,2]April Jorge, [3]Emma Materne, [1,2]Hyon Choi, [1]Baijun Zhou, [2,4]Karen Costenbader, [1,2]Yuqing Zhang, [1,2]Hyon Choi. [1]*Division of Rheumatology, Allergy, and Immunology, Department of Medicine, Massachusetts General Hospital*; [2]*Harvard Medical School*; [3]*Department of Medicine, Massachusetts General Hospital*; [4]*Division of Rheumatology, Inflammation, and Immunity, Brigham and Women's Hospital*

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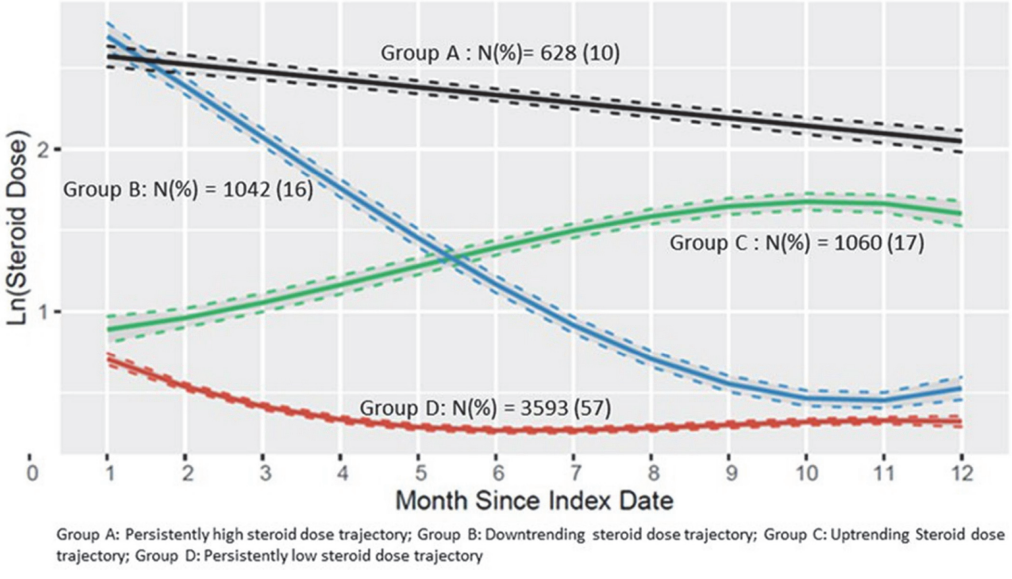
Background/Purpose Belimumab, a biologic B-Lymphocyte stimulator (BLyS) inhibitor, was FDA-approved in 2011 for the treatment of active systemic lupus erythematosus (SLE). Initial phase 3 placebo-controlled trials found no increased risk of infection in patients initiated on belimumab in addition



Abstract 1603 Figure 1 Group-based trajectory model of 12-month steroid dose and use patterns among Medicaid beneficiaries with incident SLE (N=6,323)

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to standard therapy. However, the comparative risk of infection associated with initiating belimumab versus an oral immunosuppressant in non-renal SLE is unknown.

Methods Using observational data from TriNetX, a multi-center electronic health record database including 46 health care organizations across the United States, we identified patients aged ≥18 with SLE (≥2 ICD codes ≥2 months and ≤2 years apart) who initiated belimumab, azathioprine, methotrexate, or mycophenolate between 2011-2021 and who did not have lupus nephritis (defined by ≥1 LN code (ICD-10 M32.14/15) or ≥2 nephritis codes (Chibnik 2010) prior to the index date. We designed and emulated three hypothetical target trials to estimate the cumulative incidence and hazard ratios (HRs) of severe infection and of hospitalization for severe infection comparing initiation of belimumab vs. azathioprine, belimumab vs. methotrexate, and belimumab vs. mycophenolate. In each comparison, patients had never used the comparators but could use other immunosuppressants (e.g., in belimumab vs. azathioprine comparison, methotrexate or mycophenolate could be used). In each analysis, we emulated randomization using propensity score overlap weighting to balance covariates, including age, sex, race/ethnicity, geographic region, year of initiation, use of concomitant SLE medications (other oral immunosuppressants, glucocorticoids, hydroxychloroquine, rituximab, cyclophosphamide), Charlson comorbidity index, SLE severity index (Garris 2013), chronic kidney disease, healthcare utilization, and prior infection history. Patients were followed until the outcome, death, or end of the study period, and we adjusted for adherence to treatment group using inverse probability of treatment weighting. We repeated the analysis with the negative control outcome of injury/trauma.

Results Among 21,481 patients with non-renal SLE, we compared 2841 and 6343 initiators of belimumab and azathioprine (table 1), 2642 and 8242 initiators of belimumab and methotrexate, and 2813 and 8407 initiators of belimumab and mycophenolate, respectively. After propensity score overlap

Abstract 1604 Table 1 Renal Systemic Lupus Erythematosus

	Before overlap weighting			After overlap weighting		
	Belimumab (n=2841)	Azathioprine (n=6343)	Standardized difference	Belimumab	Azathioprine	Standardized difference
Age, years, mean (SD)	44.6 (13.1)	44.8 (15.6)	0.0126	44.7	44.7	<0.001
Female, n (%)	2700 (95.0)	5820 (91.8)	0.1324	94.3	94.3	<0.001
Race/Ethnicity, n (%)			0.3034			<0.001
White	1673 (58.9)	2880 (45.4)		54.0	54.0	
Black	695 (24.5)	2128 (33.5)		27.7	27.7	
Asian	55 (1.9)	143 (2.3)		2.1	2.1	
Hispanic	204 (7.2)	675 (10.6)		8.5	8.5	
Other	214 (7.5)	517 (8.2)		7.8	7.8	
Geographic Region, n (%)			0.4224			<0.001
East	974 (34.3)	1116 (17.6)		26.1	26.1	
Midwest	322 (11.3)	1144 (18)		13.8	13.8	
South	1084 (38.2)	3142 (49.5)		43.3	43.3	
West	461 (16.2)	941 (14.8)		16.9	16.9	
Treatment initiation year, median	2018	2016	0.5439	2018	2018	
CKD stage ≥3, n (%)	355 (12.5)	999 (15.7)	0.0935	13.0	13.0	<0.001
Charlson Comorbidity Index, mean (SD)	0.88 (0.86)	0.99 (1.05)	0.1142	0.91	0.91	<0.001
SLE Severity Index, n (%)			0.0988			<0.001
Mild	1852 (65.2)	3945 (62.2)		64.6	64.6	
Moderate	869 (30.6)	2035 (32.1)		30.8	30.8	
Severe	120 (4.2)	363 (5.7)		4.6	4.6	
Medication Use, n (%)						
Glucocorticoids	1639 (57.7)	3463 (54.6)	0.0624	56.0	56.0	<0.001
Hydroxychloroquine	1511 (53.2)	2842 (44.8)	0.1682	48.9	48.9	<0.001
Methotrexate	595 (20.9)	641 (10.1)	0.3027	15.7	15.7	<0.001
Mycophenolate	437 (15.4)	570 (9)	0.1965	12.8	12.8	<0.001
Other oral immunosuppressant	266 (9.4)	343 (5.4)	0.1517	7.5	7.5	<0.001
Rituximab	53 (1.9)	98 (1.5)	0.0248	1.8	1.8	<0.001
Cyclophosphamide	17 (0.6)	62 (1.0)	0.0429	0.7	0.7	<0.001
Healthcare Utilization						
Outpatient visits, median (IQR)	3 (5)	3 (7)	0.0408	3	3	<0.001
ER/Inpatient visits, n (%)	520 (18.3)	1659 (26.2)	0.1897	21.0	21.0	<0.001
Prior hospitalized infection, n (%)	43 (1.5)	200 (3.2)	0.1088	1.9	1.9	<0.001

Covariates assessed within the six months prior to the index date. Non-renal lupus defined by meeting SLE definition (≥2 SLE ICD codes ≥2 months and ≤2 years apart) and not meeting lupus nephritis definition (defined by ≥1 LN code (ICD-10 M32.14) or ≥2 nephritis codes (e.g., ICD-9 580-586, 791.0 or ICD-10 N00, N04-5, N17-18, R80.9; Chibnik 2010) prior to the index date.
MTX, methotrexate. CKD, chronic kidney disease, defined by ≥1 ICD codes or GFR <60 on ≥2 occasions. ER, emergency room. SLE Severity Index is adapted from Garrison algorithm for administrative data, based on ICD codes and not including medication dosing.
Other oral immunosuppressant use includes leflunomide, sulfasalazine, cyclosporine, tacrolimus, abatacept, tocilizumab, TNF inhibitors, IL17 inhibitors, IL12/23 inhibitors, and JAK inhibitors

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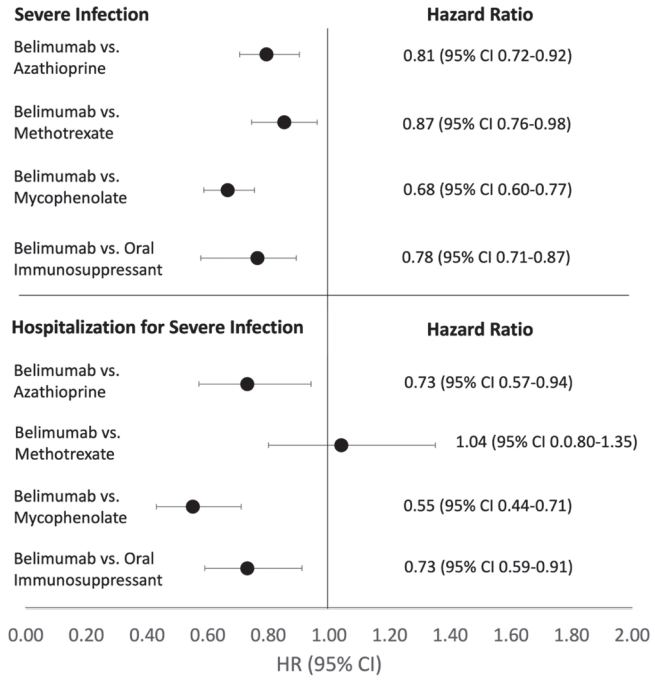
Abstract 1604 Table 2 Comparative Risk of Severe Infection and Hospitalizations for Severe Infections with Belimumab versus Azathioprine use in Non-Renal Systemic Lupus Erythematosus and Comparative Risk of the Control Outcome of Injury/Trauma (Per-protocol analysis)

Treatment arms	Number of Events	Cumulative Incidence (%)	Adherence-Adjusted Hazard Ratio (95% CI)
Severe Infection			
1 Year			
Azathioprine	1040	16.1	1.00 (ref)
Belimumab	282	12.8	0.75 (0.65-0.87)
2 years			
Azathioprine	1475	23.7	1.00 (ref)
Belimumab	427	20.4	0.82 (0.73-0.94)
5 years			
Azathioprine	1986	34.8	1.00 (ref)
Belimumab	542	30.0	0.81 (0.72-0.92)
Hospitalization for Severe Infection			
1 Year			
Azathioprine	291	4.5	1.00 (ref)
Belimumab	56	3.1	0.65 (0.48-0.89)
2 years			
Azathioprine	412	7.1	1.00 (ref)
Belimumab	92	5.5	0.75 (0.58-0.98)
5 years			
Azathioprine	544	10.4	1.00 (ref)
Belimumab	117	8.0	0.73 (0.57-0.94)
Injury/Trauma			
1 Year			
Azathioprine	830	13.2	1.00 (ref)
Belimumab	317	13.2	1.00 (0.87-1.15)
2 years			
Azathioprine	1253	21.5	1.00 (ref)
Belimumab	468	21.4	0.99 (0.87-1.12)
5 years			
Azathioprine	1844	39.5	1.00 (ref)
Belimumab	633	39.5	1.00 (0.89-1.12)

Severe infection defined by ICD codes for bacteremia, pneumonia, skin/soft tissue infection, osteomyelitis, meningitis, and gastrointestinal infection. Hospitalization for severe infection defined as hospitalization with ICD code for one of the above infections. Injury/trauma defined by ICD-9 codes 800-804, 810-819, 822-828, 830-959 and ICD-10 codes S00-S99 but excluding S72, T07-T32.

weighting, all covariates were balanced in each comparison, with mean age 45 and 94% female; glucocorticoids were used by 56% of patients. Belimumab was associated with a lower incidence of severe infection (HR 0.81 [95% CI 0.72-0.92]) and hospitalization for infection (HR 0.73 [95% CI 0.57-0.94]) than was azathioprine through 5 years of use (table 2). Findings were similar for the other medication comparisons (figure 1). There was no difference in the risk of injury/trauma.

Conclusions In this large cohort of patients with non-renal SLE, after rigorous propensity score overlap weighting to balance multiple covariates, belimumab was associated with a lower risk of severe infection and hospitalizations due to severe infection compared to several comparative oral immunosuppressants. This finding should inform risk/benefit considerations for SLE treatment.



Abstract 1604 Figure 1 Comparative Risk of Severe Infection and Hospitalizations for Severe Infections with Belimumab versus Oral Immunosuppressants.
Figure Legend. Hazard ratios and 95% confidence intervals shown for the three separate target trial analyses comparing belimumab vs. azathioprine, belimumab vs. methotrexate, and belimumab vs. mycophenolate. Datasets for weighted populations (with overlap weights and inverse probability of treatment weights) from three separate target trial analyses were combined to obtain the hazard ratios for belimumab vs. oral immunosuppressant using generalized estimating equations, which addressed the correlation within subject and obtain a valid standard error since the same subject may be in more than one analyses (especially for the belimumab initiators).

1701 IMPROVING COMPLETION RATES OF ROUTINE MENTAL HEALTH SCREENING FOR DEPRESSION AND ANXIETY IN PAEDIATRIC LUPUS OUTPATIENT CLINIC TO ENHANCE PATIENT MENTAL HEALTH CARE

[1]Tala El Tal, [2]Avery Longmore, [1]Abdulaziz Al Mutairi, [1]Audrea Chen, [1]Holly Convery[2]Dinah Finkelstein, [1]Linda Hiraki, [3]Chetana Kulkarni, [4]Justine Ledochowski, [1]Neely Lerman, [5]Karen Leslie, [1]Deborah Levy, [6]Sharon Lorber, [1]Jayne MacMahon, [1]Jeanine McColl, [4]Sarah Mossad, [1]Oscar Mwizerwa, [1]Lawrence Ng, [6]Luana F Pereira, [5]Vandana Rawal, [1]Alaa Shehab, [1]Amani Al Bijadi, [7]Evelyn Smith, [5]Alene Toulany, [1]Andrea Knight. *[1]The Hospital for Sick Children, Division of Rheumatology, Department of Paediatrics, University of Toronto,ON, Canada; [2]The Hospital for Sick Children, Department of Paediatrics, University of Toronto, ON, Canada; [3]The Hospital for Sick Children, Division of Child and Youth Mental Health, Department of Psychiatry, University of Toronto,ON, Canada; [4]The Hospital for Sick Children, Department of Psychology, University of Toronto, ON, Canada; [5]The Hospital for Sick Children, Division of Adolescent Medicine, Department of Paediatrics, University of Toronto, ON, Canada; [6]The Hospital for Sick Children, Factor Inwentash Faculty of Social Work, University of Toronto, ON, Canada; [7]The Hospital for Sick Children, Division of Psychiatry, Department of Paediatrics, University of Toronto, ON, Canada*

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Background/Purpose Mental health (MH) problems are prevalent in adolescents with childhood-onset lupus (cSLE), with cross-sectional studies estimating prevalences of 20-60% for depression symptoms and 20-40% for anxiety symptoms.

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