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COVID-19 Vaccine Uptake Among Patients With Systemic Lupus Erythematosus in the American Midwest: The Lupus Midwest Network (LUMEN)

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ABSTRACT. ***Objective.*** Patients with systemic lupus erythematosus (SLE) are at higher risk of poor outcomes from coronavirus disease 2019 (COVID-19). The vaccination rate among such patients is unknown. We aimed to assess COVID-19 vaccine uptake among patients with SLE.

Methods. We included 342 patients with SLE from the Lupus Midwest Network (LUMEN) and 350 age-, sex-, race-, and county-matched comparators. Vaccination uptake for influenza, pneumococcal, and zoster vaccines before pandemic restrictions began (up to February 29, 2020) was assessed. First-dose COVID-19 vaccine uptake was electronically retrieved and manually ascertained (December 15, 2020, to July 31, 2021). Time to COVID-19 vaccination, demographics, SLE manifestations, medications, Charlson Comorbidity Index, Area Deprivation Index, and Rural-Urban Commuting Area codes were compared.

Results. On July 31, 2021, 83.3% of patients with SLE and 85.5% of comparators were vaccinated against COVID-19. The COVID-19 vaccination rates were similar among SLE and comparators (hazard ratio 0.93, 95% CI 0.79-1.10). Unvaccinated patients with SLE were more likely than vaccinated patients to be men (27.3% vs 14.1%), younger (mean age 54.1 vs 58.8 yrs), have a shorter SLE duration (median 7.3 vs 10.7 yrs), and be less frequently vaccinated with influenza and pneumococcal vaccines.

Conclusion. Patients with SLE in the Lupus Midwest Network had similar COVID-19 vaccination uptake as matched comparators, most of whom were vaccinated early when the vaccine became available. One in 6 patients with SLE remain unvaccinated.

Key Indexing Terms: COVID-19, hesitancy, immunization, systemic lupus erythematosus, vaccine, vaccination

Patients with autoimmune and inflammatory rheumatic diseases (AIIRDs), including those with systemic lupus erythematosus (SLE), are at higher risk of poor outcomes from coronavirus disease 2019 (COVID-19).[1] Vaccinations against COVID-19 have been shown to be safe and effective[2-4] and first became available for use in the United States on December 14, 2020. However, surveys of patients with SLE and other AIIRDs have identified vaccine hesitancy in up to 50% of patients, which may be related to concerns about side effects, potential disease flares, or lack of data among patients with SLE.[5,6] As of February 13, 2022, the vaccination coverage with at least 1 dose in the US among those aged 12 years and older was > 85%.[7] A case-control

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study among US veterans reported an mRNA COVID-19 vaccination coverage (≥ 1 dose) of 43% among immunocompromised patients during the first 3 months of vaccine availability,[8] but the rate of vaccination and the factors associated with vaccination of patients with SLE are unknown. We aimed to assess the rate of COVID-19 vaccine uptake among patients with SLE as compared to a matched cohort of comparators.

METHODS

Study population. The US-based Lupus Midwest Network (LUMEN) is a population-based registry of 27 counties in southeast Minnesota and southwest Wisconsin. It is part of the Rochester Epidemiology Project (REP),[9] a record-linkage system that allows access to medical records from healthcare providers in the 27 counties.[10,11] All patients with SLE who fulfilled the 2019 European Alliance of Associations for Rheumatology/American College of Rheumatology classification criteria for SLE[12] on January 1, 2015, in the 27-county area were included (see details of patient identification methods in the Supplemental Material, available with the online version of this article). Patients with SLE were matched by age, sex, race, and county of residence to non-SLE comparators from the REP in a 1:1 ratio. Both groups were followed until July 31, 2021, last medical encounter, or death. Exclusion criteria were those patients without medical encounters on or after December 15, 2020, and any identified subjects who did not provide consent for use of their medical records for research purposes. This study was approved by the institutional review boards of the Mayo Clinic (20-006485) and Olmsted Medical Center (036-OMC-20).

Data collection. Through medical record review, we abstracted demographics, weight, height, and clinical SLE characteristics. Education level was electronically retrieved for patients with and without SLE. Immunosuppressant and immunomodulation therapy was retrieved for patients with SLE. Smoking status was electronically retrieved in August 2021. Charlson Comorbidity Index (CCI),[13] excluding the rheumatological domain, was estimated using diagnostic codes for 5 years prior to December 15, 2020. Area Deprivation Index (ADI)[14] at the census block group level was obtained using patient addresses. Rurality was assessed using the rural-urban commuting area (RUCA) codes.[15] History of COVID-19 diagnosis or a positive test prior to December 15, 2020, was electronically retrieved. Vaccination uptake for seasonal influenza (at least once), pneumococcal, recombinant zoster (at least once) and COVID-19 vaccines was obtained from electronic medical records, which were complemented by information from the immunization information systems of Minnesota and Wisconsin.[16] Vaccine administration data were abstracted for the 3 COVID-19 vaccines authorized in the US: BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), and Ad26.CoV2.S (Janssen). Receipt of the first dose was ascertained from December 15, 2020, to July 31, 2021. For the rest of vaccines, the uptake was evaluated from January 1, 2015, to February 29, 2020, just before the beginning of pandemic restrictions.

Statistical analysis. Descriptive statistics (eg, means, percentages) were used to summarize the data. Chi-square and Wilcoxon rank-sum tests were performed to compare the baseline characteristics between patients with SLE and comparators, and between vaccinated and unvaccinated patients with SLE. The cumulative incidence of vaccination was estimated for patients with SLE and comparators using Kaplan-Meier methods. Cox proportional hazards models with adjustment for age, sex, and race were used to compare vaccination rates between the 2 groups, and Poisson regression models were used to compare vaccination rates in the first 4 months to those after 4 months. Given the potential differences between groups following the exclusion of patients after matching, we performed a sensitivity analysis for COVID-19 vaccine uptake among those patients with SLE who kept their matched comparators. A P value of < 0.05 was considered statistically significant for all analyses. Analyses were performed using SAS version 9.4 (SAS Institute) and R 4.0.3 (R Foundation for Statistical Computing).

RESULTS

The LUMEN registry included 465 patients with prevalent SLE and 465 non-SLE comparators matched on January 1, 2015. One hundred twenty SLE and 109 non-SLE did not have a medical encounter after December 15, 2020, when the COVID-19 vaccines became available, and were not included in the analysis. In addition, 3 SLE and 6 non-SLE cases were excluded from the analysis since their vaccination data was not available. The study population included 342 patients with SLE and 350 non-SLE comparators (Table 1). Patients with SLE and comparators had a similar age, sex, racial/ethnic, and education level distribution. The ADI score was also similar in SLE and non-SLE comparators (mean 93.3 vs 93.6, respectively), and we did not observe differences in rurality with similar proportions of patients and comparators living in urban and rural areas (P = 0.18) Patients with SLE had more comorbidities than comparators based on CCI scores (2.4 [SD 2.7] vs 1.6 [SD 2.3]; P < 0.001). The mean BMI (calculated as weight in kilograms divided by height in meters squared; kg/m^2) was similar between patients with SLE and comparators (29.6 [SD 7.8] vs 30.0 [SD 7.1], respectively), as well as the proportion of individuals with BMI > 30 and > 40. Smoking status was also similar, 18.8% of SLE patients and 26.4% of comparators were current smokers (P = 0.06). The history of COVID-19 diagnosis or having a positive test prior to the availability of COVID-19 vaccine was similar between patients with and without SLE (5.0% vs 6.3%, respectively; P = 0.45). Previous vaccination for influenza and pneumococcus were significantly more frequent among patients with SLE than non-SLE comparators (Table 1).

COVID-19 vaccine uptake. On July 31, 2021, the percentages of patients with SLE and non-SLE comparators with at least 1 dose of COVID-19 vaccine were 83.3% (95% CI 78.6-86.9) and 85.5% (95% CI 80.7-89.1), respectively, and this difference was not significant after adjustment for age, sex, and race (hazard ratio 0.93, 95% CI 0.79-1.1; P = 0.40; Figure). By the fourth month of vaccine availability, > 70% of the patients with SLE and the non-SLE comparators were vaccinated. In the sensitivity analysis, the vaccine uptake rates were similar among those patients with SLE who kept their matched comparators (83.6% [95% CI 78.3-87.7] and 85.3% [95% CI 79.6-89.5], respectively; Supplementary Table S1, available with the online version of this article).

Characteristics of unvaccinated patients with SLE. Unvaccinated patients with SLE were more likely than vaccinated patients with SLE to be men (27.3% vs 14.1%, P = 0.01), younger (mean 54.1 [SD 14.6] vs 58.8 [SD 15.4] yrs, P = 0.02), and have a shorter course of the disease (median duration 7.3 [IQR 2.6-13.4] vs 10.7 [IQR 4.7-20.3] yrs, P = 0.008; Table 2). There were no differences in racial distribution, education level, BMI, smoking status, CCI, ADI, RUCA codes, medications, or history of COVID-19 (Table 2). Unvaccinated patients were also more likely to have a history of class II or V lupus nephritis (16.7% vs 8.0% in vaccinated patients, P = 0.03), and were less frequently vaccinated with influenza and pneumococcal vaccine. No other SLE involvement was significantly different in relation to vaccine uptake.

Table 1. Characteristics of patients with systemic lupus erythematosus (SLE) and non-SLE matched comparators, in the LUMEN registry on December 15, 2020.

	SLE, n = 342	Non-SLE, n = 350	*P**
Age, yrs, mean (SD)	57.9 (15.3)	60.3 (15.3)	0.05
Sex, n (%)			0.79
Women	285 (83.3)	289 (82.6)	
Men	57 (16.7)	61 (17.4)	
Race/ethnicity, n (%)			0.94
Non-Hispanic White	297 (86.8)	312 (89.1)	
Hispanic	15 (4.4)	14 (4.0)	
Non-Hispanic Black	13 (3.8)	9 (2.6)	
Non-Hispanic Asian	12 (3.5)	10 (2.9)	
Other/mixed	5 (1.5)	5 (1.4)	
Education level, n (%)			0.29
Graduate school[c]	69 (21.3)	71 (25.7)	
Technical school/college/university[c]	172 (53.1)	137 (49.6)	
High school[c]	75 (23.1)	56 (20.3)	
< High school[c]	8 (2.5)	12 (4.3)	
Missing, n	18	74	
Area Deprivation Index, mean (SD)	93.3 (12.5)	93.6 (12.1)	0.63
Primary RUCA code, n (%)			0.18
Metropolitan area core	135 (39.5)	120 (34.3)	
Metropolitan area high commuting	79 (23.1)	80 (22.9)	
Micropolitan area core	61 (17.8)	53 (15.1)	
Micropolitan area high commuting	15 (4.4)	33 (9.4)	
Micropolitan area low commuting	1 (0.3)	2 (0.6)	
Small town core	25 (7.3)	26 (7.4)	
Small town high commuting	4 (1.2)	5 (1.4)	
Rural areas	22 (6.4)	31 (8.9)	
Charlson Comorbidity Index[a], mean (SD)	2.4 (2.7)	1.6 (2.3)	< 0.001
BMI[b], kg/m^2, mean (SD)	29.6 (7.8)	30.0 (7.1)	0.17
BMI > 30[c], n (%)	132 (40.1)	128 (40.9)	0.84
BMI > 40[c], n (%)	35 (10.6)	31 (9.9)	0.76
Missing, n	13	37	
Smoking[b], n (%)			0.06
Current[c]	57 (18.8)	74 (26.4)	
Former[c]	119 (39.1)	92 (32.9)	
Never[c]	128 (42.1)	114 (40.7)	
Missing, n	38	70	
History of COVID-19 diagnosis or positive test, n (%)	17 (5.0)	22 (6.3)	0.45
Previous vaccination[d], n (%)			
Influenza (at least once)	271 (79.2)	253 (72.3)	0.03
Pneumococcal vaccine	167 (48.8)	125 (35.7)	< 0.001
Recombinant zoster vaccine (at least once)	60 (17.5)	61 (17.4)	0.97

* Wilcoxon rank-sum or chi-square test. [a] From December 15, 2015, to December 14, 2020, excluding rheumatologic category. [b] Upon entry to LUMEN cohort, January 1, 2015. [c] The denominator excludes missing. [d] Vaccine uptake from January 1, 2015, to February 29, 2020, for influenza and pneumococcal vaccine, and from January 1, 2018, to February 29, 2020, for zoster vaccine. COVID-19: coronavirus disease 2019; LUMEN: Lupus Midwest Network; RUCA: rural-urban commuting area.

DISCUSSION

To our knowledge, this is the first population-based study to document COVID-19 vaccine uptake among patients with SLE compared to a matched non-SLE population sample. In this study, 17% of patients with SLE were not vaccinated 7 months after vaccines became available. Vaccine uptake with at least 1 dose was not higher among patients with SLE compared to the non-SLE comparators and was similar to the current US vaccination coverage. Among patients with SLE, COVID-19 vaccine uptake was lower in men, younger patients, and those with a shorter disease duration.

Patients with SLE are at a higher risk of severe COVID-19 as compared to the general population.[1] Despite this elevated risk, in a prior international survey of 1266 patients with AIIRD performed before the COVID-19 vaccines were available, only 54% were willing to get vaccinated and 32% of the respondents were uncertain about getting a COVID-19 vaccine, but opinions may have evolved since then.[5] In an Italian survey of patients

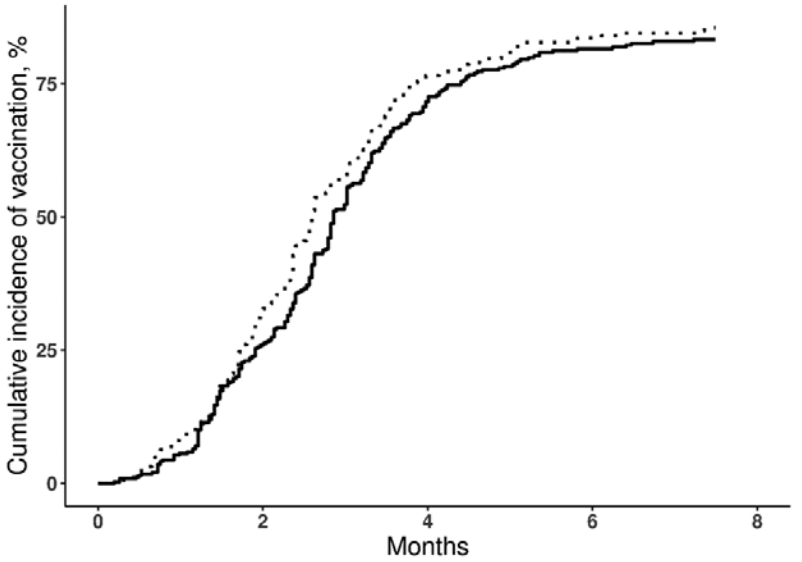

Figure. Kaplan-Meier curve showing the cumulative incidence of COVID-19 vaccination in patients with SLE (solid line) and non-SLE comparators (dashed line), from December 15, 2020, to July 31, 2021 (hazard ratio 0.93; 95% CI 0.79-1.1). COVID-19: coronavirus disease 2019; SLE: systemic lupus erythematosus.

Table 2. Characteristics of patients with systemic lupus erythematosus (SLE) according to COVID-19 vaccination status (≥ 1 dose) in the LUMEN registry on December 15, 2020.

	Vaccinated, n = 276	Not Vaccinated, n = 66	*P**
Age, yrs, mean (SD)	58.8 (15.4)	54.1 (14.6)	0.02
Sex, n (%)			0.01
Women	237 (85.9)	48 (72.7)	
Men	39 (14.1)	18 (27.3)	
Race/Ethnicity, n (%)			0.98
Non-Hispanic White	240 (87.0)	57 (86.4)	
Hispanic	12 (4.3)	3 (4.5)	
Non-Hispanic Black	11 (4.0)	2 (3.0)	
Non-Hispanic Asian	9 (3.3)	3 (4.5)	
Other/mixed	4 (1.5)	1 (1.5)	
Education level, n (%)			0.05
Graduate school[c]	62 (23.7)	7 (11.3)	
Technical school/college/university[c]	132 (50.4)	40 (64.5)	
High school[c]	63 (24.0)	12 (19.4)	
< High school[c]	5 (1.9)	3 (4.8)	
Missing, n	14	4	
Area Deprivation Index, mean (SD)	93.2 (12.8)	94.0 (11.4)	0.75
Primary RUCA code, n (%)			0.67
Metropolitan area core	115 (41.7)	20 (30.3)	
Metropolitan area high commuting	59 (21.4)	20 (30.3)	
Micropolitan area core	47 (17.0)	14 (21.2)	
Micropolitan area high commuting	12 (4.3)	3 (4.5)	
Micropolitan area low commuting	1 (0.4)	0 (0.0)	
Small town core	20 (7.2)	5 (7.6)	
Small town high commuting	3 (1.1)	1 (1.5)	
Rural areas	19 (6.9)	3 (4.5)	
Charlson Comorbidity Index[a], mean (SD)	2.4 (2.7)	2.5 (2.5)	0.43
BMI[b], kg/m^2, mean (SD)	29.4 (7.9)	30.0 (7.3)	0.40
BMI > 30[c], n (%)	104 (39.5)	28 (42.4)	0.67
BMI > 40[c], n (%)	27 (10.3)	8 (12.1)	0.66
Missing, n	13	0	

Table 2. Continued.

	Vaccinated, n = 276	Not Vaccinated, n = 66	*P**
Smoking[b], n (%)			0.73
Current[c]	46 (19.0)	11 (17.7)	
Former[c]	92 (38.0)	27 (43.5)	
Never[c]	104 (43.0)	24 (38.7)	
Missing, n	34	4	
History of COVID-19 diagnosis or positive test, n (%)	12 (4.3)	5 (7.6)	0.28
Previous vaccination[d], n (%)			
Influenza (at least once)	229 (83.0)	42 (63.6)	< 0.001
Pneumococcal vaccine	147 (53.3)	20 (30.3)	< 0.001
Recombinant zoster vaccine (at least once)	52 (18.8)	8 (12.1)	0.20
SLE duration, yrs, median (IQR)	10.7 (4.7-20.3)	7.3 (2.6-13.4)	0.008
2019 EULAR/ACR criteria[b]			
Constitutional, n (%)			
Fever	17 (6.2)	5 (7.6)	0.67
Hematologic domain, n (%)			
Leukopenia	123 (44.6)	26 (39.4)	0.45
Thrombocytopenia	44 (15.9)	10 (15.2)	0.87
Autoimmune hemolysis	12 (4.3)	2 (3.0)	0.63
Neuropsychiatric domain, n (%)			
Delirium	2 (0.7)	0 (0.0)	0.49
Psychosis	1 (0.4)	0 (0.0)	0.62
Seizures	5 (1.8)	1 (1.5)	0.87
Mucocutaneous domain, n (%)			
Nonscarring alopecia	13 (4.7)	2 (3.0)	0.55
Oral ulcers	25 (9.1)	5 (7.6)	0.70
Subacute cutaneous or discoid lupus	45 (16.3)	10 (15.1)	0.82
Acute cutaneous lupus	68 (24.6)	20 (30.3)	0.34
Serosal domain, n (%)			
Pleural or pericardial effusion	40 (14.5)	13 (19.7)	0.29
Acute pericarditis	26 (9.4)	5 (7.6)	0.64
Musculoskeletal domain, n (%)			
Arthritis	186 (67.4)	44 (66.7)	0.91
Renal domain, n (%)			
Proteinuria > 0.5g/24h	64 (23.2)	17 (25.8)	0.66
Class II or V LN	22 (8.0)	11 (16.7)	0.03
Class III or IV LN	43 (15.6)	13 (19.7)	0.42
Immunology domain, n (%)			
aPL	65 (23.6)	19 (28.8)	0.38
Low C3 or C4	105 (38.0)	22 (33.3)	0.48
Low C3 and C4	89 (32.2)	18 (27.3)	0.43
Anti-dsDNA	203 (73.6)	49 (74.2)	0.91
Anti-Sm	57 (20.7)	16 (24.2)	0.52
Immunosuppressant and immunomodulator drugs[e], n (%)	239 (86.6)	57 (86.4)	0.96
Hydroxychloroquine	208 (75.4)	47 (71.2)	0.49
Mycophenolate mofetil	76 (27.5)	17 (25.8)	0.77
Methotrexate	47 (17.0)	11 (16.7)	0.94
Azathioprine	35 (12.7)	8 (12.1)	0.90
Tacrolimus	16 (5.8)	4 (6.1)	0.94
Leflunomide	10 (3.6)	3 (4.5)	0.73
Chloroquine	6 (2.2)	3 (4.5)	0.28
Rituximab	6 (2.2)	1 (1.5)	0.73
Belimumab	5 (1.8)	2 (3.0)	0.53
Cyclophosphamide	1 (0.4)	1 (1.5)	0.27

*Wilcoxon rank-sum or chi-square test. [a] From December 15, 2015, to December 14, 2020, excluding rheumatologic category. [b] Upon entry to LUMEN cohort, January 1, 2015. [c] The denominator excludes missing. [d] Vaccine uptake from January 1, 2015, to February 29, 2020, for influenza and pneumococcal vaccine, and from January 1, 2018, to February 29, 2020, for zoster vaccine. [e] Medications which were used during a 5-year lookback prior to December 15, 2020. ACR: American College of Rheumatology; aPL: antiphospholipid antibody; COVID-19: coronavirus disease 2019; EULAR: European Alliance of Associations for Rheumatology; LN: lupus nephritis; LUMEN: Lupus Midwest Network; RUCA: rural-urban commuting area.

with rheumatic diseases (RDs) made during the first weeks of vaccine availability, 48% of patients with SLE who completed the survey declared willingness to receive COVID-19 vaccine.[17] This low willingness may be related to concerns specific to this population, including RD flares or a reduced effectiveness of vaccines due to concomitant immunosuppressive drugs.[6,18] Additionally, high-quality data for the safety and efficacy of all 3 vaccines are available for the general population, but patients with RDs were underrepresented in these studies and may be waiting for data specific to people like them.[2-4]

While a vaccination rate of 83% as of July 31, 2021, may be viewed as encouraging, the vaccination curve plateaued after a few months of vaccine availability. This trend was similar to comparators in the present study and reflects broader observations of vaccine uptake in the US.[7] In a prior report about vaccine hesitancy among patients with AIIRD, unvaccinated patients with SLE were more likely to be younger,[6] but unlike in our present study, they did not find differences by sex or disease duration. Both men and younger patients appear to be less likely to be vaccinated in the general population as well, suggesting that vaccination campaigns targeting these groups may be important, both for SLE and the general population.[19] We assessed social determinants of health with the ADI score and did not find any difference between vaccinated and unvaccinated patients with SLE. We did not find differences in the education level or the medications used by vaccinated and unvaccinated patients with SLE, nor with the previous diagnosis of COVID-19 infection, suggesting it was not a factor that affected the willingness to get vaccinated. However, we did find a significant difference in the uptake for other vaccines, suggesting that vaccination hesitancy might be general and not exclusive to COVID-19 vaccine.

Strengths of this study include that the population-based data was retrieved up to July 31, 2021, a time when vaccines were widely available and most of the patients who wanted to get vaccinated would have had the opportunity to do so. In addition, access to medical records through the REP allowed us to confirm the SLE diagnosis and verify vaccination status regardless of where vaccinations were received. There are also limitations to our approach. LUMEN is based in the American upper Midwest and may not be generalizable to other regions of the US. We did not observe differences among vaccinated and unvaccinated patients with SLE based on race or ethnicity, but differences have been observed in the general population.[19] Additional SLE-specific data (eg, disease activity, damage), which might have an important role in the decision to receive COVID-19 vaccination, was not available at the time of the analysis. However, we did not find any difference in the CCI score (as a proxy of damage),[20] between vaccinated and unvaccinated patients with SLE. Our study included patients with SLE who were diagnosed on or before January 1, 2015, and matching with comparators was performed on January 1, 2015; this may have led to some differences between groups at the time they received the vaccine. However, our sensitivity analysis demonstrated the robustness of our results. We focused on coverage with at least 1 dose of the COVID-19 vaccines, so we did not know the completeness of the recommended vaccination series or additional doses. It is possible (but unlikely) that some patients could have been vaccinated in other states. Conceivably, those patients with SLE at earlier stages of their disease might have different vaccination rates. Finally, reasons for vaccination and nonvaccination were unknown.

In conclusion, most patients with SLE were vaccinated in the first 4 months after vaccinations became available. However, many patients with SLE remain unvaccinated despite a higher risk of severe COVID-19 outcomes. More studies are needed to evaluate how other factors like disease activity or damage may influence the decision to get vaccinated or not against COVID-19 in patients with SLE. Our findings suggest that the COVID-19 vaccination uptake among patients with SLE is not different to the general population and that there is an opportunity to reduce vaccine hesitancy among those patients with SLE who are newly diagnosed, among men, and younger patients.

ONLINE SUPPLEMENT

Supplementary material accompanies the online version of this article.

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