

ORIGINAL RESEARCH

Early experience of COVID-19 vaccination in adults with systemic rheumatic diseases: results from the COVID-19 Global Rheumatology Alliance Vaccine Survey

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ABSTRACT

Background We describe the early experiences of adults with systemic rheumatic disease who received the COVID-19 vaccine.

Methods From 2 April to 30 April 2021, we conducted an online, international survey of adults with systemic rheumatic disease who received COVID-19 vaccination. We collected patient-reported data on clinician communication, beliefs and intent about discontinuing disease-modifying antirheumatic drugs (DMARDs) around the time of vaccination, and patient-reported adverse events after vaccination.

Results We analysed 2860 adults with systemic rheumatic diseases who received COVID-19 vaccination (mean age 55.3 years, 86.7% female, 86.3% white). Types of COVID-19 vaccines were Pfizer-BioNTech (53.2%), Oxford/AstraZeneca (22.6%), Moderna (21.3%), Janssen/Johnson & Johnson (1.7%) and others (1.2%). The most common rheumatic disease was rheumatoid arthritis (42.3%), and 81.2% of respondents were on a DMARD. The majority (81.9%) reported communicating with clinicians about vaccination. Most (66.9%) were willing to temporarily discontinue DMARDs to improve vaccine efficacy, although many (44.3%) were concerned about rheumatic disease flares. After vaccination, the most reported patient-reported adverse events were fatigue/somnolence (33.4%), headache (27.7%), muscle/joint

Key messages

What is already known about this subject?

- People with systemic rheumatic diseases, who were largely excluded from COVID-19 vaccine clinical trials, may have additional concerns about the impact of their underlying disease or antirheumatic medications on COVID-19 vaccine response.
- Studies of rheumatic disease flares following vaccination for other infections were previously reassuring, and studies from a physician-based registry and a prospective cohort have shown a low frequency of flares following COVID-19 vaccination.

What does this study add?

- In this international online survey of adults with systemic rheumatic disease who received COVID-19 vaccination, patient-reported adverse events were typical of those reported in the general population, with rheumatic disease flare requiring medication changes occurring in <5%.
- Most patients were willing to temporarily discontinue disease-modifying antirheumatic drugs in order to improve vaccine efficacy.

Key messages

How might this impact on clinical practice or further developments?

- ▶ Clinicians should maintain awareness of changing guidelines as further data become available in order to provide continued communication and patient counselling regarding risks and benefits of vaccination.

pains (22.8%) and fever/chills (19.9%). Rheumatic disease flares that required medication changes occurred in 4.6%.

Conclusion Among adults with systemic rheumatic disease who received COVID-19 vaccination, patient-reported adverse events were typical of those reported in the general population. Most patients were willing to temporarily discontinue DMARDs to improve vaccine efficacy. The relatively low frequency of rheumatic disease flare requiring medications was reassuring.

INTRODUCTION

Multiple COVID-19 vaccines have become available, with established safety and efficacy in the general population.¹ However, people with systemic rheumatic diseases, who may have a unique risk and benefit profile, were largely excluded from the initial vaccine clinical trials. People with systemic rheumatic diseases may have specific concerns on how their underlying disease or their immunomodulatory therapies affect the benefit and safety of receiving COVID-19 vaccination.^{2,3} These concerns have been further complicated by heterogenous vaccine roll-outs and access, and conflicting advice from clinicians in response to major organisation recommendations.⁴⁻⁶ There is a paucity of data regarding vaccinated patients with rheumatic diseases, and better information could inform decision making and guidance for clinicians and patients. This study describes a large, international survey of adults with systemic rheumatic disease who received a COVID-19 vaccine, focusing on their experiences communicating with clinicians, their beliefs about and management of medications for their rheumatic disease around the time of vaccination, and their experience with adverse events after vaccination.

METHODS

Survey design and inclusion

The COVID-19 Global Rheumatology Alliance (C19-GRA) Vaccine Survey was developed and refined based on feedback from relevant stakeholders (clinicians, researchers and patient partners) and collaborators from December 2020 through March 2021. The survey collected information from both COVID-19 vaccinated and unvaccinated adults with systemic rheumatic diseases.

To study a more homogenous group and to obtain a better understanding of characteristics and factors associated with vaccination, this analysis was restricted to adults with systemic rheumatic diseases who received COVID-19 vaccination. Respondents were included if

they completed the survey in English, Italian or Hebrew (first translations made available) between 2 April and 30 April 2021 and reported having received at least one dose of any COVID-19 vaccine. Respondents were excluded if they did not provide information on the following characteristics: age, sex, country of residence, race/ethnicity, rheumatic disease diagnosis and use of antirheumatic medications. Respondents reporting only diagnoses of osteoarthritis and/or only fibromyalgia without other systemic rheumatic diseases were also excluded.

The survey was administered online using the Qualtrics platform, an online survey software that allows for the creation and distribution of surveys and other measurement tools. After providing initial consent to participate, respondents were required to enter their year of birth and only received additional questions if they were over the age of 18 years. Where possible, participants were required to enter a response to questions before proceeding in order to minimise missing responses. Also, Internet Protocol address gating, restricting only one survey entry per individual (or source), was employed in order to secure integrity of responses and data.

Measures and data collection

Demographics

Self-reported demographics including year of birth (from which age was calculated), sex assigned at birth, highest level of education, current employment and country of residence were collected. Country of residence was grouped by the WHO region.⁷ Race/Ethnicity was grouped into mutually exclusive categories: black, Asian (including East Asian, South Asian and West Asian), Hispanic, Latinx or Latin American, white, American Indian/Alaska Natives/Aboriginal/Indigenous/First Nations, Arab, Pacific Islander and multiple identities (ie, participants reporting more than one race/ethnicity).

Systemic rheumatic disease diagnosis and clinical information

Participants could report multiple systemic rheumatic disease diagnoses. Comorbidities were also collected and included over 30 possible selections. Patient global assessment of current rheumatic disease activity was self-reported using a patient global assessment of disease activity visual analogue scale from 0 (remission/very low disease activity) to 10 (very high disease activity).⁸

Disease-modifying antirheumatic drug, glucocorticoid and non-steroidal anti-inflammatory drug use

Participants reported the disease-modifying antirheumatic drugs (DMARDs), glucocorticoids and non-steroidal anti-inflammatory drugs (NSAIDs) that they were taking at the time of the survey. Medications were grouped into different classes according to mechanism of action, with a free text option to report additional medications. Free text was categorised into appropriate medication classes after translation.

DMARDs were categorised using the most recent American College of Rheumatology (ACR) COVID-19 Vaccine Clinical Guidance Summary.⁶ Medications, where holding or altered dosage timing around time of vaccination was recommended (methotrexate, abatacept, rituximab, Janus kinase (JAK) inhibitors) were grouped independently.

Communication with clinicians and medication changes

Participants were asked about vaccine-related communication and counselling by their clinicians. All survey respondents were asked about their general willingness to temporarily discontinue medications based on a 5-point Likert scale. In addition, for each specific medication that participants reported taking, they were asked if they would be willing to discontinue those medications (yes/no/unsure), to improve the effectiveness of a COVID-19 vaccine. They were also asked about their greatest concern(s) about temporarily discontinuing those medications. Finally, participants were asked if they held any medications before or after vaccination (yes/no/unsure).

Adverse events after vaccination

In addition to self-reported anaphylaxis, participants were asked about the occurrence of postvaccination adverse events, lasting >2 days and within 2 months of vaccination, such as headaches, fever or chills, widespread muscle/joint pain and rash, among others. Respondents also reported whether they experienced postvaccine flares of existing systemic rheumatic disease (lasting >2 days) and if these flares required treatment modifications.

Survey dissemination

The English language version of the survey was launched globally on 2 April 2021. Translations in Italian and Hebrew were added on 5 April 2021. We employed a convenience sampling strategy with patient partners leading survey dissemination. International patient organisations received images, text and survey links designed to explain the survey's purpose, and disseminated the survey to their members. Additionally, the survey was publicly accessible from the C19-GRAs website (www.rheum-covid.org) and disseminated via social media by GRA members and patient organisations. The full survey is included in the online supplemental materials.

Statistical analysis

Descriptive statistics, including means and SD, proportions and 95% CIs, were reported. All analyses were performed using R V.4.1.0.

RESULTS

Demographics and clinical characteristics

Between 2 April and 30 April 2021, 2860 adults with systemic rheumatic disease who received at least one dose of a COVID-19 vaccine participated in the survey (see [figure 1](#) for flow diagram of analysed sample). The

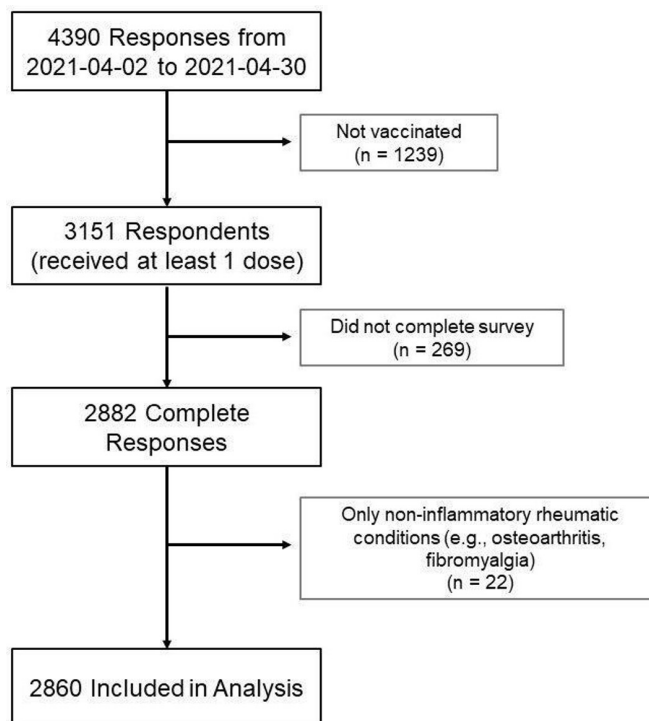


Figure 1 Flow diagram illustrating the analysed sample.

mean (SD) age of participants was 55.3 (14.3) years, 2480 (86.7%) were female and 2469 (86.3%) self-identified as white. Most participants (1603, 56.1%) were from the Americas (USA $n=1366$, Canada $n=200$ and Latin America $n=37$), followed by respondents from the European region (UK $n=935$, and rest of Europe $n=252$). Demographics and clinical characteristics of respondents are shown in [table 1](#).

Rheumatoid arthritis (RA) (1209, 42.3%) was the most common systemic rheumatic disease reported among participants, followed by inflammatory myositis (487, 17.0%), Sjögren's syndrome (438, 15.3%), systemic lupus erythematosus (391, 13.7%) and spondyloarthritis (256, 9.0%). Use of systemic glucocorticoids and NSAIDs was reported by 762 (26.6%) and 740 (25.9%), respectively. The most used DMARDs were methotrexate (855, 29.9%), antimalarials (733, 25.6%) and other conventional synthetic DMARDs (510, 17.8%). Tumour necrosis factor (TNF) inhibitors were the most used biologic DMARD (bDMARD) (493, 17.2%), and 520 (18.2%) of patients reported not taking any DMARD.

The most reported comorbidities were hypertension (912, 31.9%), lung disease (736, 25.7%) and obesity (673, 23.5%). The most received COVID-19 vaccine was the Pfizer-BioNTech vaccine (1522, 53.2%), followed by Oxford-AstraZeneca (645, 22.6%), Moderna (610, 21.3%) and Janssen/Johnson & Johnson (50, 1.7%). Few respondents received other vaccines (33, 1.2%).

Communication with healthcare providers regarding COVID-19 vaccination

Most participants (2341, 81.9%) had discussed COVID-19 vaccination with their healthcare provider. Participants

Table 1 Demographics and clinical characteristics of the COVID-19 Global Rheumatology Vaccine Survey respondents who received COVID-19 vaccination (n=2860)

	Number of respondents N (%)
Age (years), mean (SD)	55.3 (14.3)
Age (years) categories	
18–29	139 (4.9)
30–49	788 (27.6)
50–69	1336 (46.7)
70+	469 (16.4)
Sex at birth	
Female	2480 (86.7)
Male	373 (13.0)
Other/Prefer not to say	7 (0.2)
Race/Ethnicity	
White	2469 (86.3)
Hispanic, Latinx or Latin American	77 (2.7)
Asian (South, East Asian)	46 (1.6)
Black	37 (1.3)
Middle Eastern or North African	21 (0.7)
American Indian/Alaska Natives/Aboriginal/Indigenous/First Nations	7 (0.2)
Other*	203 (7.1)
WHO region	
Region of the Americas	1603 (56.1)
European region	1187 (41.5)
Western Pacific/South-East Asian/African/Eastern Mediterranean regions	70 (2.4)
Educational level	
High school (secondary level)/General Educational Development (GED) or less	314 (11.0)
Some college	553 (19.3)
Bachelor's degree (graduated college)	776 (27.1)
Graduate or professional degree	1217 (42.6)
Systemic rheumatic disease diagnosis†	
Rheumatoid arthritis	1209 (42.3)
Inflammatory myositis	487 (17.0)
Sjögren's syndrome	438 (15.3)
Systemic lupus erythematosus	391 (13.7)
Spondyloarthritis, other than psoriatic arthritis	256 (9.0)
Psoriatic arthritis	206 (7.2)
Other connective tissue disease‡	196 (6.9)
Systemic vasculitis	167 (5.8)
Systemic sclerosis	126 (4.4)
Antiphospholipid syndrome	68 (2.4)
Autoinflammatory disease	31 (1.1)
Sarcoidosis	21 (0.7)
Medications†	
Systemic glucocorticoids	762 (26.6)
NSAIDs	740 (25.9)
DMARDs	

Continued

Table 1 Continued

	Number of respondents N (%)
Antimalarials	733 (25.6)
Methotrexate	855 (29.9)
Other csDMARDs§	513 (17.8)
Mycophenolate mofetil	228 (8.0)
Other antimetabolites¶	21 (0.7)
Abatacept	71 (2.5)
Rituximab	162 (5.7)
TNF inhibitors	498 (17.2)
Other bDMARDs**	206 (7.2)
JAK inhibitors	121 (4.2)
IVIG	102 (3.6)
Number of DMARDs	
0	520 (18.2)
1	1271 (44.4)
2	839 (29.3)
3 or more	230 (8.0)
Patient global assessment of disease activity (0=very low; 10=very high)	
Mean (SD)	4.2 (2.4)
Comorbidities	
Hypertension	912 (31.9)
Lung disease††	736 (25.7)
Obesity	672 (23.5)
Diabetes	164 (5.7)
Cardiovascular disease	163 (5.7)
None	832 (29.1)
COVID-19 vaccine received	
Pfizer-BioNTech	1522 (53.2)
Oxford-AstraZeneca	645 (22.6)
Moderna	610 (21.3)
Janssen/Johnson & Johnson	50 (1.7)
Other vaccines‡‡	33 (1.2)

*Other participants include Pacific Islander, other, prefer not to say and do not know/unsure.

†Participants may indicate more than one rheumatic disease and more than one antirheumatic medication.

‡Other connective tissue disease include mixed connective tissue disease and undifferentiated connective tissue disease.

§Includes apremilast, azathioprine, 6-mercaptopurine, leflunomide, sulfasalazine.

¶Includes calcineurin inhibitors (cyclosporin, tacrolimus), cyclophosphamide, thalidomide and lenalidomide.

**Includes asthma, emphysema, chronic bronchitis, chronic obstructive pulmonary disease, pulmonary hypertension, interstitial lung disease, idiopathic pulmonary fibrosis, other lung diseases.

††Includes belimumab, IL-1 inhibitors (anakinra, canakinumab, rilonacept), IL-6 inhibitors (tocilizumab, sarilumab, siltuximab), IL-12/IL-23 inhibitors (ustekinumab, guselkumab), IL-17 inhibitors (secukinumab, ixekizumab), eculizumab, mepolizumab and vedolizumab.

‡‡Includes Novavax, Sinovac/Sinopharm, Sputnik V, Cansino, 'not sure' and 'other'.

bDMARDs, biologic DMARDs; csDMARDs, conventional synthetic DMARDs; DMARDs, drug-modifying antirheumatic drugs; IL, interleukin; IVIG, intravenous immunoglobulin; JAK, Janus kinase inhibitors; NSAIDs, non-steroidal anti-inflammatory drugs; TNF, tumour necrosis factor.

Table 2 Communication with healthcare providers regarding COVID-19 vaccination

	Number of respondents N (%)
Contacted healthcare provider to discuss vaccine	N=2860
Yes	1775 (62.1)
No	965 (33.7)
Not sure/Not applicable	120 (4.2)
Contact from healthcare provider to discuss vaccine	N=2860
Yes	1349 (47.2)
No	1383 (48.4)
Not sure/Not applicable	128 (4.5)
Discussed vaccine with healthcare provider during a visit	N=2860
Yes	1817 (63.5)
No	932 (32.6)
Not sure/Not applicable	111 (3.9)
Advice from healthcare provider about receiving COVID-19 vaccine	N=2341
Strongly endorsed	1938 (82.8)
Suggested it	300 (12.8)
Provider was unsure	42 (1.8)
Advised against it	6 (0.3)
Strongly discouraged	4 (0.2)
Respondent unsure/Missing	51 (2.2)
Satisfaction about COVID-19 vaccine conversation with healthcare provider	N=2341
Very satisfied	1491 (63.7)
Satisfied	574 (24.5)
Neither satisfied nor dissatisfied	210 (9.0)
Dissatisfied	52 (2.2)
Very dissatisfied	14 (0.6)

reported contacting their healthcare provider to discuss COVID-19 vaccination (1775, 62.1%), having the healthcare provider contact them (1349, 47.2%) and/or having a discussion regarding vaccines during a clinical visit (1817, 63.5%) (table 2). Of all respondents who discussed vaccination with their healthcare provider, 2238/2341 (95.6%) reported that vaccination was recommended, while 42 (1.8%) answered that their provider was unsure, and 10 (0.4%) reported a provider recommendation against vaccination. Most patients (2065, 88.2%) were satisfied with the conversation with their clinician, while only a minority were dissatisfied (66, 2.8%) or neither satisfied nor dissatisfied (210, 9.0%).

Medications and COVID-19 vaccination

Most participants (1911, 66.8%) agreed with temporarily discontinuing their medications to improve

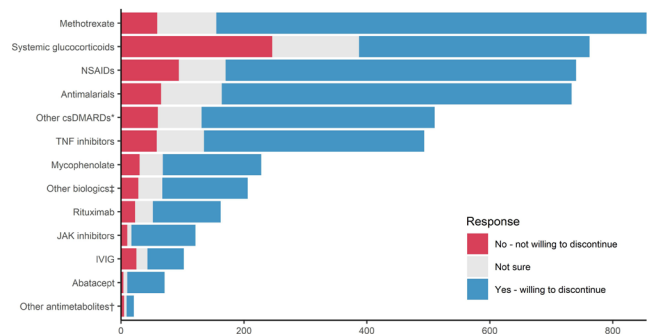
Figure 2 Willingness to temporarily or permanently discontinue medications when receiving the COVID-19 vaccine


Figure 2 Willingness to temporarily or permanently discontinue medications when receiving the COVID-19 vaccine. IL, interleukin; NSAIDs, non-steroidal anti-inflammatory drugs; csDMARDs, conventional synthetic drug modifying antirheumatic drugs; JAK, Janus kinase inhibitors; TNF, tumour necrosis factor; IVIG, intravenous immunoglobulin. *Includes apremilast, azathioprine, 6-mercaptopurine, leflunomide and sulfasalazine. †Includes calcineurin inhibitors (cyclosporin, tacrolimus), cyclophosphamide, thalidomide and lenalidomide. ‡Includes belimumab, IL-1 inhibitors (anakinra, canakinumab, rilonacept), IL-6 inhibitors (tocilizumab, sarilumab, siltuximab), IL-12/IL-23 inhibitors (ustekinumab, guselkumab), IL-17 inhibitors (secukinumab, ixekizumab), eculizumab, mepolizumab and vedolizumab.

vaccine effectiveness, while 472 (16.5%) disagreed and 477 (16.7%) reported being unsure. Concern for flare of systemic rheumatic disease after receiving the vaccine was reported in 1267 (44.3%) respondents, while 1009 (35.3%) were not concerned, and 584 (20.4%) were unsure.

When asked about the specific medications that participants reported taking for the treatment of their systemic rheumatic disease, the majority were willing to discontinue these medications due to COVID-19 vaccination (figure 2; online supplemental table). For participants taking methotrexate, 700/855 (81.9%) were willing to stop, with only 59 (6.9%) not willing to stop. For other medications recommended by the ACR to be modified around COVID-19 vaccination (eg, NSAIDs, mycophenolate, abatacept, rituximab, JAK inhibitors), the majority of respondents were willing to discontinue temporarily. Among participants taking systemic glucocorticoids, fewer (375/762, 49.2%) were willing to stop, 246 (32.3%) were not willing to stop and 141 (18.5%) were unsure.

Finally, when asked about actual medication discontinuation, most patients who reported taking any prescription medication (1875/2644, 70.9%) answered that they did not temporarily stop or discontinue any of their rheumatic medications before or after receiving the COVID-19 vaccine, while a minority decided to change their medication use (764, 28.9%). Only five (0.2%) patients were not sure if they had made any changes to their medication use.

Systemic rheumatic disease flare was the most frequently reported concern regarding holding or stopping

Table 3 Concerns about medication discontinuation around COVID-19 vaccination

	N	Disease flare	Withdrawal effects	Side effects when previously stopped	Unsuccessful when previously stopped	Medication may no longer work as well	No concerns
Systemic glucocorticoids	762	443 (58.1)	188 (24.7)	26 (3.4)	28 (3.7)	15 (2.0)	62 (8.1)
NSAIDs	740	412 (55.7)	18 (2.4)	29 (3.9)	13 (1.8)	14 (1.9)	254 (34.3)
Antimalarials	733	518 (70.7)	24 (3.3)	8 (1.1)	8 (1.1)	18 (2.5)	157 (21.4)
Methotrexate	855	616 (72.0)	13 (1.5)	10 (1.2)	3 (0.4)	39 (4.6)	174 (20.4)
Other csDMARDs*	513	372 (72.5)	13 (2.5)	6 (1.2)	8 (1.6)	19 (3.7)	95 (18.5)
Mycophenolate	228	169 (74.8)	8 (3.5)	9 (4.0)	2 (0.9)	7 (3.1)	33 (14.6)
Other antimetabolites†	21	11 (52.4)	1 (4.8)	1 (4.8)	0 (0)	1 (4.8)	7 (33.3)
Abatacept	71	53 (74.6)	3 (4.2)	1 (1.4)	0 (0)	5 (7.0)	9 (12.7)
Rituximab	162	131 (81.9)	1 (0.6)	3 (1.9)	2 (1.3)	7 (4.4)	18 (11.3)
TNF inhibitors	493	369 (75.5)	6 (1.2)	5 (1.0)	4 (0.8)	73 (14.8)	36 (7.4)
Other biologics‡	206	157 (77.3)	4 (2.0)	2 (1.0)	3 (1.5)	21 (10.2)	19 (9.4)
JAK inhibitors	121	104 (86.0)	2 (1.7)	1 (0.8)	0 (0)	7 (5.8)	7 (5.8)
IVIG	102	80 (79.2)	2 (2.0)	1 (1.0)	1 (1.0)	1 (1.0)	17 (16.8)

*Includes apremilast, azathioprine, 6-mercaptopurine, leflunomide, sulfasalazine.

†Includes calcineurin inhibitors (cyclosporin, tacrolimus), cyclophosphamide, thalidomide and lenalidomide.

‡Includes belimumab, IL-1 inhibitors (anakinra, canakinumab, rilonacept), IL-6 inhibitors (tocilizumab, sarilumab, siltuximab), IL-12/IL-23 inhibitors (ustekinumab, guselkumab), IL-17 inhibitors (secukinumab, ixekizumab), eculizumab, mepolizumab and vedolizumab. csDMARDs, conventional synthetic DMARDs; DMARDs, drug-modifying antirheumatic drugs; IL, interleukin; IVIG, intravenous immunoglobulin; JAK, Janus kinase inhibitors; NSAIDs, non-steroidal anti-inflammatory drugs; TNF, tumour necrosis factor.

antirheumatic medications (table 3). In participants taking systemic glucocorticoids, disease flares were the most frequently reported concern (443/762, 58.1%) followed by withdrawal effects (188, 24.7%). Disease flare was the most common concern among patients on all other medications. 'No concerns' was the second most frequent response for people receiving all other medications, except for TNF inhibitors and other bDMARDs where 'concern for rheumatic medication may not work as well' (73/494, 14.8% and 21/206, 10.2%, respectively) was reported.

COVID-19 vaccination-associated adverse events

Among all participants, 1371/2860 (47.9%) participants reported at least one adverse event lasting for at least 2 days post-COVID-19 vaccine (table 4). Fatigue or sleepiness (955, 33.4%) was the most common reported adverse event, followed by headache (792, 27.7%), and widespread muscle/joint pains (653, 22.8%). There were only six (0.2%) episodes of self-reported anaphylaxis. Flares of existing systemic rheumatic disease, lasting at least 2 days post-COVID-19 vaccine, were reported by 382 (13.4%) of participants, with 132 (4.6%) requiring a new or increased dose of medication to treat the flare. The frequency of adverse events and flares of disease were similar across vaccine types.

DISCUSSION

This is the largest international survey of patient perceptions and outcomes related to COVID-19 vaccines among

vaccinated people with systemic rheumatic diseases. Almost all participants who discussed vaccination with a provider were recommended to receive a COVID-19 vaccination and respondents were overall satisfied with COVID-19 vaccine-related conversations with their clinicians. The majority were willing to discontinue their medications to improve vaccine response, although many remained concerned about systemic rheumatic disease flares. Although 1 in 8 reported a flare of disease after vaccination, fewer than 1 in 20 required a change in treatment. While these findings have been reassuring regarding communication with physicians regarding vaccination recommendations, individuals with systemic rheumatic disease remain concerned about the side effects of vaccines, and the risk of flares associated with vaccination, particularly around holding antirheumatic medications.

People with systemic rheumatic disease represent a subgroup for whom general population data may not apply. Potential concerns include reduced immunogenicity of vaccines related to either the underlying condition or the use of antirheumatic medications; and vaccines causing worsened adverse events or flares of their underlying rheumatic diseases.² In an international survey of 1531 individuals with rheumatic disease conducted in December 2020, for instance, 32% reported uncertainty around vaccination,³ which may in part be driven by these concerns.

Table 4 Adverse events and disease flares after COVID-19 vaccination, reported by patients to be severe and lasting at least 2 days

	All n=2860	Pfizer-BioNTech n=1522	Oxford/AstraZeneca n=645	Moderna n=610	Janssen/Johnson & Johnson n=50	Others* n=33
Any adverse events	1350 (47.2)	648 (42.6)	335 (51.9)	327 (53.6)	30 (60.0)	10 (30.3)
Fatigue or sleepiness	955 (33.4)	455 (29.9)	229 (35.5)	245 (40.2)	22 (44.0)	4 (12.1)
Headache	792 (27.7)	350 (23.0)	218 (33.8)	196 (32.1)	23 (46.0)	5 (15.2)
Widespread muscle/Joint pain	653 (22.8)	294 (19.3)	166 (25.7)	176 (28.9)	17 (34.0)	0 (0)
Fever or chills	568 (19.9)	214 (14.1)	167 (25.9)	170 (27.9)	16 (32.0)	1 (3.0)
Anaphylaxis†	6 (0.2)	2 (0.1)	1 (0.2)	1 (0.2)	1 (2.0)	1 (3.0)
Other‡	204 (7.1)	86 (5.7)	49 (7.6)	64 (10.5)	4 (8.0)	1 (3.0)
Nausea or vomiting	364 (12.7)	167 (11.0)	90 (14.0)	101 (16.6)	6 (12.0)	0 (0)
Any flare of rheumatic disease§	382 (13.4)	184 (12.1)	93 (14.4)	96 (15.7)	7 (14.0)	2 (6.1)
Flare requiring new or increased dose of medication§	132 (4.6)	58 (3.8)	40 (6.2)	32 (5.2)	2 (4.0)	0 (0)

*Includes Novavax, Sinovac/Sinopharm, Sputnik V, Cansino, not sure and others.

†Anaphylaxis was not required to last 2 days.

‡Including chest pain/palpitations, other allergic reactions and rash.

§Exacerbation of symptoms or new symptoms attributed to underlying systemic rheumatic disease.

Rheumatologists have a prominent role in communicating risks and benefits of vaccination. Prior surveys of people with systemic rheumatic diseases have highlighted limited communication with rheumatologists or other healthcare providers, especially about medication changes.^{9–11} Other studies have cited lack of a recommendation from a treating physician for vaccination hesitancy.^{12–15} Among the vaccinated population in our study, there was a high frequency of communication with clinicians about the COVID-19 vaccines, and respondents were generally very satisfied. A key factor is the timing of our survey during global vaccination efforts versus other surveys that were completed prior to the availability of the COVID-19 vaccine. Another factor is that our study sample was limited to those who were vaccinated, so good communication with healthcare providers over vaccine recommendations is unsurprising.

Whether to hold antirheumatic medications for vaccination, and for how long, remains unclear for many medication classes. Hypothetical concerns about reduced immunogenicity have recently been corroborated by antibody titre studies.^{16–17} Recommendations from the ACR, for instance, have reflected these concerns. Initial guidance in February of 2021 recommended holding methotrexate, JAK inhibitors, abatacept and rituximab in certain patients with controlled disease⁶; an April 2021 update also included mycophenolate mofetil.¹⁸ These guidelines were based on limited data, including one randomised controlled trial of methotrexate holding for influenza vaccination in patients with RA,¹⁹ and two studies of holding tofacitinib in patients with RA.²⁰ Our survey found that most patients would be willing to temporarily discontinue their medications but had

concerns about a flare of their systemic rheumatic disease. As expected, current glucocorticoid users had an especially high frequency of respondents who were less willing to hold these medications. This may be explained by prior experience of flares when stopping or lowering dose of glucocorticoids, concerns about adrenal insufficiency or a relationship between glucocorticoid use and active disease. However, despite reported willingness, only a minority of participants discontinued any medication around COVID-19 vaccination. Future studies are needed to firmly establish an evidence base for temporarily holding specific antirheumatic therapies to enhance vaccine efficacy while balancing risk for disease flare.

The degree to which vaccination in general and the COVID-19 vaccinations in particular cause flares of rheumatic diseases has been a principal concern.²¹ Prior to the COVID-19 pandemic, a study in the UK Clinical Practice Research Database found no increased risk of flare after influenza vaccination among people with autoimmune inflammatory rheumatic disease.²² In a small study, RA disease activity remained stable following hepatitis B vaccination.²³ Conversely, an internet-based case-crossover study of patients with confirmed gout found twofold higher odds for gout flares after any patient-reported vaccination.²⁴ Similar to the rates reported in trials in the general population, a minority of patients in our study reported systemic reactions to vaccination, which included fatigue, fever and pain. Systemic rheumatic disease flares requiring a change in medication, however, were uncommon. These data align with a large, physician-reported registry supported by EULAR COVID-19 database.²⁵ Between 5 February and 27 April 2021, clinicians

reported 1519 patients with rheumatic disease who had received COVID-19 vaccination, the majority (83%) of whom received an mRNA-based vaccine. Overall, 31% had potential vaccine-related side effects; 5% had flares of their underlying systemic rheumatic disease, 1.2% of which were reported as severe. In two prospective cohorts of patients with systemic rheumatic disease followed after COVID-19 vaccination, disease activity remained stable.^{26 27} The complementary findings from these two studies provide reassuring evidence regarding safety and reactogenicity of COVID-19 vaccination among a systemic rheumatic disease population.

Strengths of our study include rapid dissemination, global reach and questions specifically addressing concerns and willingness to hold specific antirheumatic medications. Several important limitations should be acknowledged. First, selection bias may have resulted from respondents with adverse events being more likely to fill out the survey. Despite this, the frequency of systemic rheumatic disease flares requiring medication changes remained low and was overall consistent with similar registries. Second, although participants were asked “Has a doctor ever told you had any of the following rheumatologic diseases?”, report of self-diagnosis or misdiagnosis is a possibility. However, the reports of treatment with systemic immunomodulators prescribed by clinicians and the fact that the distribution of the survey through patient organisations potentially minimises this making it unlikely that this could substantially affect the results. Third, this study was limited to English, Hebrew and Italian translations of the survey and may not be generalisable to those who speak other languages or reside in other regions. Translations into other languages are ongoing and will be reported in the future. Fourth, respondents were mostly white and reported high levels of education. These results may not be applicable to addressing barriers among other racial or ethnic groups or among other socioeconomic groups.^{28–30} Fifth, at the time of the survey, geographic variation in vaccine availability and access resulted in a preponderance of UK and US respondents. Sixth, the timing of our survey coincided with the Centers for Disease Control and Food and Drug Administration pause on the Janssen/Johnson & Johnson vaccine,^{31–33} which limited the number of responses from those who had received this vaccine. Seventh, some conditions such as inflammatory myositis may be over-represented in our cohort, due to the registries and patient advocacy groups to which our survey was disseminated most easily. Finally, this was a descriptive analysis and inferential statistics were intentionally not performed.

CONCLUSION

This study presents encouraging data regarding communication between people with systemic rheumatic diseases and their physicians and to the overall safety of COVID-19 vaccination in this patient population. Reassuringly,

significant flares requiring changes in medications were relatively infrequent. Clinicians should maintain awareness of changing guidelines as further data become available to provide continued communication and patient counselling regarding risks and benefits of vaccination. Future studies should assess the degree to which vaccine immunogenicity and reactogenicity among individuals with systemic rheumatic disease differ compared with the general population. Further knowledge about barriers to vaccination in different racial and ethnic groups among patients living with systemic rheumatic diseases is needed.

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