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ORIGINAL ARTICLE

Characteristics of emerging new autoimmune diseases after COVID-19 vaccination: A sub-study by the COVAD group

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Abstract

Background: Despite the overall safety and efficacy of COVID-19 vaccinations, rare cases of systemic autoimmune diseases (SAIDs) have been reported post-vaccination. This study used a global survey to analyze SAIDs in susceptible individuals' post-vaccination.

Methods: A cross-sectional study was conducted among participants with self-reported new-onset SAIDs using the COVID-19 Vaccination in Autoimmune Diseases (COVAD) 2 study dataset—a validated, patient-reported e-survey—to analyze the long-term safety of COVID-19 vaccines. Baseline characteristics of patients with new-onset SAIDs and vaccinated healthy controls (HCs) were compared after propensity score matching based on age and sex in a 1:4 ratio.

Results: Of 16 750 individuals, 74 (median age 52 years, 79.9% females, and 76.7% Caucasians) had new-onset SAID post-vaccination, mainly idiopathic inflammatory myopathies (IIMs) ($n = 23$, 31.51%), arthritis ($n = 15$; 20.53%), and polymyalgia rheumatica (PMR) ($n = 12$, 16.40%). Higher odds of new-onset SAIDs were noted

Russka Shumnalieva and Jennifer Hannah contributed equally to this study.

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For affiliations refer to page 8.

among Caucasians (OR = 5.3; 95% CI = 2.9–9.7; $p < .001$) and Moderna vaccine recipients (OR = 2.7; 95% CI = 1.3–5.3; $p = .004$). New-onset SAIDs were associated with AID multimorbidity (OR = 1.4; 95% CI = 1.1–1.7; $p < .001$), mental health disorders (OR = 1.6; 95% CI = 1.3–1.9; $p < .001$), and mixed race (OR = 2.2; 95% CI = 1.2–4.2; $p = .010$), where those aged >60 years (OR = 0.6; 95% CI = 0.4–0.8; $p = .007$) and from high/medium human development index (HDI) countries (compared to very high HDI) reported fewer events than HCs.

Conclusion: This study reports a low occurrence of new-onset SAIDs following COVID-19 vaccination, primarily IIMs, PMR, and inflammatory arthritis. Identified risk factors included pre-existing AID multimorbidity, mental health diseases, and mixed race. Revaccination was well tolerated by most patients; therefore, we recommend continuing COVID-19 vaccination in the general population. However, long-term studies are needed to understand the autoimmune phenomena arising post-vaccination.

KEYWORDS
autoimmune diseases, COVID-19, idiopathic inflammatory myopathies, SAIDs, vaccination

1 | INTRODUCTION

The introduction of COVID-19 vaccines has resulted in a significant reduction in both morbidity and mortality associated with COVID-19 infection among individuals affected by rheumatic and musculoskeletal diseases, a population at higher risk for severe outcomes than the general population. Although these vaccines have demonstrated a favorable safety profile,[1] there have been documented instances of new-onset systemic autoimmune diseases (SAIDs) following vaccination, which has given rise to apprehension and the potential to contribute to vaccine hesitancy.[2]

A range of postvaccination new-onset SAIDs have been reported, including autoimmune rheumatic diseases, immune-mediated nephropathies, and autoimmune hematological diseases.[3] While the underlying pathogenic mechanism is not well established, hypotheses include molecular mimicry and immune cross-reactivity, bystander activation, and the role of vaccine adjuvants.[4] These emerging reports warrant careful consideration to better understand the potential association between COVID-19 vaccination and the development of autoimmune conditions. A comprehensive analysis of such cases has the potential to advance our knowledge of vaccine-related adverse events and aid in the formulation of appropriate management strategies.

Thus, the principal aim of this study was to address existing knowledge gaps by investigating self-reported instances of new-onset SAID subsequent to COVID-19 vaccination within a large and diverse population encompassing various ethnicities and geographic regions. Additionally, this study endeavors to identify plausible links between specific COVID-19 vaccines and the exacerbation of symptoms post-revaccination and seeks to comprehensively characterize the determinants, duration of symptoms, and treatment requirements among individuals afflicted by new-onset SAID post-vaccination.

Through the accomplishment of these objectives, we aimed to enable early intervention in the anticipation of new-onset SAIDs and facilitate informed decision-making regarding vaccination for high-risk patients. Moreover, we also aimed to bolster public health endeavors geared towards the optimization of future vaccination strategies.

2 | METHODS

2.1 | Study design

2.1.1 | Population selection

The COVID-19 Vaccine in Autoimmune Diseases (COVAD)2 e-survey was developed with the primary objective of gathering patient-reported data on the long-term safety and tolerability of COVID-19 vaccines among individuals with existing SAIDs. The survey was collaboratively disseminated by the COVAD study group, which was composed of researchers spanning multiple countries through diverse channels, including medical clinics, patient support organizations, and social media platforms. The data collection phase for the survey spanned months, with a comprehensive protocol delineating the particulars of the COVAD-2 survey published separately.[5]

To confirm eligibility for participation in the study, individuals were required to provide an affirmative response to specific questions in the e-survey that inquired about the development of symptoms and formal diagnosis confirming a new-onset autoimmune condition or rheumatic disease after receiving any dosage of the COVID-19 vaccine. Participants lacking a physician- or rheumatologist-confirmed diagnosis of SAID were tagged as non-confirmed cases and deemed ineligible for inclusion. These

respondents who reported new-onset SAID could be healthy previously or with pre-existing different SAID.

A follow-up questionnaire was distributed to eligible participants who provided consent for further contact. The survey link included a cover letter outlining the purpose, content, data handling, and study investigators. No incentives were offered to the participants to complete the survey. (Figure 1) provides a detailed flowchart illustrating the participant selection process for the study.

2.1.2 | Survey design

The validated follow-up questionnaire included 32 questions covering several areas, including diagnosis and current symptom status of new SAIDs ($n=12$), COVID-19 vaccination status ($n=4$), current treatment status ($n=2$), details of other vaccines and illnesses ($n=5$), COVID-19 antibody status ($n=5$), evidence of new autoimmune disease in the family ($n=2$), quality of life (QoL) ($n=1$), and long-term safety of vaccines ($n=1$). The survey is enclosed in Appendix S1.

Autoimmune disease (AID) multimorbidity was defined as the presence of two or more coexisting SAIDs in a patient prior to vaccination. Hybrid vaccination refers to respondents who received different vaccines as part of their primary or booster vaccination.

2.2 | Survey regulatory approvals

An exemption from review was obtained from the local institutional ethics review committee as per local guidelines.[6] We adhered to the Checklist for Reporting Results of Internet E-surveys (CHERRIES) to report the data.[7,8]

2.3 | Statistical analysis

Descriptive statistics were used, and data were expressed as median (range: 25th–75th), or numbers (%). A 1:4 propensity score (PS) matched analysis between new-onset SAIDs and vaccinated HCs without new-onset SAIDs was performed with age and sex variables and a tolerance of 0.2, with an emphasis on exact matches. Chi-Square/Fisher's Exact and Mann–Whitney *U* were used to compare categorical and continuous variables, respectively. Predictors of new-onset SAIDs were assessed using binary logistic regression adjusted for age, sex, ethnicity, and country using the Human Development Index (HDI).[9] Statistical analyses were performed using SPSS version 28.

3 | RESULTS

Of 16 570 vaccinated individuals who participated in the COVAD-2 survey, 628 reported a diagnosis of new-onset SAID after receiving any dose of the COVID-19 vaccine. Of those, 365 consented to a follow-up survey, and 115 completed the survey. After excluding participants with a non-confirmed SAID diagnosis, 74 were included in the final sample. The median age of the respondents was 58 years (46.5–67.0); more than three-quarters were female and most commonly of Caucasian ethnicity (Table 1).

The most commonly reported SAIDs following COVID-19 vaccination were idiopathic inflammatory myopathies (IIMs) ($n=23$, 31.5%), followed by arthritis (unspecified type, $n=15$, 20.5%), and polymyalgia rheumatica (PMR) ($n=12$, 16.4%). Other reported diagnoses were systemic lupus erythematosus (SLE) ($n=7$, 9.5%), vasculitis ($n=7$, 9.5%), Crohn's disease ($n=3$, 4.1%), hyper/hypothyroidism ($n=2$, 2.7%), sarcoidosis ($n=1$, 1.3%), interstitial pneumonia ($n=1$, 1.3%), morphea ($n=1$, 1.3%), and pyoderma gangrenosum ($n=1$, 1.3%).

Pfizer ($n=37$, 37.4%), followed by Moderna ($n=32$, 32.3%), and Oxford/AstraZeneca ($n=26$, 26.3%) were the most common vaccines among individuals with postvaccination new-onset SAID. Most individuals received two doses before symptom onset, and the median duration from vaccination to symptom onset was 14 (5–30) days.

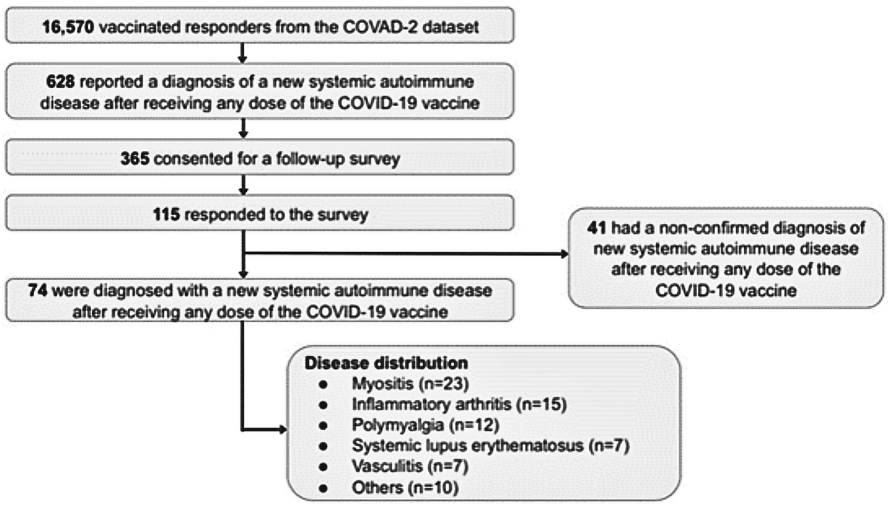

FIGURE 1 Flowchart showing the process of study participant selection.

TABLE 1 Propensity score-matched analysis (1:4) between emergent SAIDs and vaccinated HCs without new SAIDs.

	Unmatched			Matched			
	Emergent SAIDs ($n=74$)	Vaccinated HC ($n=3558$)	p[a]	Emergent SAIDs ($n=73$)	Vaccinated HC ($n=277$)	OR (95% CI)	p[a]
Age in years, median (IQR)	58.0 (46.5–67.0)	38.0 (30.0–49.0)		58.0 (46.5–67.0)	51.0 (38.5–66.0)		.085
Sex			<.001				
Male	13 (17.8)	1355 (38.1)		13 (17.8)	74 (26.7)	0.6 (0.3–1.1)	.133
Female	59 (80.8)	2144 (60.2)		59 (80.0)	203 (73.3)		
Ethnicity			<.001				<.001
African American	1 (1.4)	134 (3.8)		1 (1.4)	23 (8.3)		NS
Asian	4 (5.5)	903 (25.4)		4 (5.5)	51 (18.4)	0.2 (0.1–0.7)	.011
Caucasian	56 (76.7)	1028 (28.9)		56 (76.7)	105 (37.9)	5.3 (2.9–9.7)	<.001
Hispanic	8 (11.0)	903 (25.4)		8 (11.0)	41 (14.8)		NS
Mixed	3 (4.1)	244 (6.9)		3 (4.1)	12 (4.3)		NS
Native American	0 (0)	31 (0.9)		0 (0)	4 (1.4)		NS
Others	1 (1.4)	124 (3.5)		1 (1.4)	22 (7.9)		NS
Do not wish to disclose	0 (0)	158 (4.4)		0 (0)	19 (6.9)		NS
Number of vaccine doses			<.001				<.001
1	2 (2.7)	112 (3.1)		2 (2.7)	6 (2.2)		NS
2	17 (23.3)	1174 (33.0)		17 (23.3)	92 (33.2)		NS
3	28 (38.4)	2006 (56.4)		28 (38.4)	143 (51.6)	0.5 (0.3–0.9)	.039
4	9 (12.3)	267 (7.5)		9 (12.3)	36 (13.0)		NS
5	6 (8.2)	0 (0)		6 (8.2)	0 (0)		NS
Hybrid vaccination	26 (35.6)	1349 (37.9)	.081	26 (35.6)	108 (39.0)	1.0 (0.5–1.7)	.909
First dose vaccine			<.001				<.001
Covaxin	0 (0)	44 (1.2)		0 (0)	1 (0.4)		NS
Covishield	1 (1.4)	321 (9.0)		1 (1.4)	24 (8.7)		NS
Janssen	1 (1.4)	53 (1.5)		1 (1.4)	3 (1.1)		NS
Moderna	16 (21.9)	188 (5.3)		16 (21.9)	26 (9.4)	2.7 (1.3–5.3)	.004
Oxford	23 (31.5)	682 (19.2)		23 (31.5)	77 (27.8)		NS
Pfizer	13 (17.8)	1168 (32.8)		13 (17.8)	101 (36.5)	0.3 (0.2–0.7)	.003
Sinopharm	1 (1.4)	332 (9.3)		1 (1.4)	11 (4.0)		NS
Sinovac	1 (1.4)	311 (8.7)		1 (1.4)	10 (3.6)		NS
Sputnik	0 (0)	154 (4.3)		0 (0)	7 (2.5)		NS
Unsure	0 (0)	37 (1.0)		0 (0)	5 (1.8)		NS

Note: Hybrid vaccination—Those who received more than one type of COVID-19 vaccine. NS not significant p-value, $p<.05$ is significant. Age and gender are matched in PS matched analysis with 1:4 patients and healthy controls.

Abbreviations: CI, confidence interval; OR, odd's ratio.

[a]Chi-square test/Fisher's exact for categorical variables and Mann–Whitney U-test for continuous variables.

Fatigue/lethargy was the most commonly reported symptom ($n=38$, 50.7%), and was also the most common initial symptom ($n=15$, 20.0%). Other common symptoms included joint pain ($n=35$, 46.7%), joint stiffness ($n=27$, 36.0%), inability to get up from sitting posture or do overhead work ($n=24$, 32.0%), early morning stiffness lasting more than 30 min ($n=24$, 32.0%), low back pain ($n=16$, 21.3%), rash ($n=16$, 21.3%), difficulty in eating or drinking ($n=19$, 25.3%), and shortness of breath on exertion/rest ($n=10$, 13.3%).

Concerningly, nearly half of the respondents ($n=31$, 45.6%) rated their quality of life as less than 5 out of 10 after the development of a new SAID, though the other half did better.

3.1 | Autoimmune disease subgroups

IIMs were the most commonly reported SAID, with dermatomyositis (DM) being the most common subtype ($n=13$, 56.5%) (Table S1), followed by necrotizing myopathy ($n=4$; 17.4%), anti-synthetase syndrome (ASyS) ($n=3$, 13.04%), juvenile DM (JDM) ($n=2$, 8.7%), and inclusion body myositis (IBM) ($n=1$, 4.4%). Nearly half ($n=12$, 52%) of those who developed IIM received the Moderna vaccine, followed by Pfizer ($n=4$, 17.4%), and the majority ($n=3/4$, 75.0%) experienced no worsening of their symptoms on receiving subsequent COVID-19 vaccines.

Arthritis was the second most common rheumatic disease reported after the COVID-19 vaccination (Table S2). Within this category, rheumatoid arthritis (RA) was the most prevalent subtype ($n=8$, 53.3%), followed by psoriatic arthritis ($n=4$, 26.7%), and ankylosing spondylitis ($n=3$, 20.0%). The most commonly administered COVID-19 vaccines were Pfizer ($n=10$, 66.7%) and Moderna ($n=7$, 46.7%). Notably, over half ($n=7/12$, 58.3%) of the individuals who received subsequent COVID-19 vaccinations in this group experienced worsening of their arthritis symptoms.

PMR was ranked as the third most frequently reported disease following COVID-19 vaccination (Table S3). Within this group, both Pfizer ($n=9$, 75.0%) and Moderna ($n=8$, 66.7%) vaccines were the most commonly used types. In contrast to the inflammatory arthritis group, the majority of the respondents in the PMR group ($n=6/9$, 66.7%) did not experience worsening of their symptoms after receiving subsequent COVID-19 vaccine doses. This suggests a relatively favorable response to vaccination in individuals with PMR.

SLE was reported in seven patients (10.0%), associated with Pfizer ($n=4$, 57.1%) and Oxford/Astra Zeneca ($n=4$, 57.1%) vaccines (one patient with hybrid vaccination), with subsequent worsening with revaccination in half of the group ($n=3/7$, 42.9%) (Table S4).

Among the seven cases of vasculitis, four cases of giant cell arteritis (GCA) ($n=4$, 57.1%) and a further three cases of ANCA-associated vasculitis, including microscopic polyangiitis, and granulomatosis with polyangiitis were reported. These were in relation to Oxford/Astra Zeneca ($n=4$, 57.1%), followed by Pfizer ($n=3$, 42.9%). None of the seven individuals with vasculitis chose to revaccinate (Table S5).

3.2 | Treatment outcomes

Sixty-seven participants (89.3%) required pharmaceutical treatment for their new-onset SAID that developed post-vaccination. The most commonly prescribed treatment regime included oral glucocorticoids ($n=46$, 68.6%) followed by methotrexate ($n=30$, 44.8%) and NSAIDs/analgesics ($n=15$, 22.3%).

3.3 | Revaccination in patients of new-onset SAIDs

More than half of the participants ($n=40$) chose to receive additional doses of the COVID-19 vaccine despite experiencing symptoms of their new-onset SAID. In this subgroup, 23 participants (56.1%) reported no worsening of symptoms in their autoimmune condition post COVID-19 revaccination, whereas 18 participants (43.9%) experienced worsening of symptoms.

3.4 | Comparison of new-onset SAIDs and vaccinated HCs (PS-matched analysis)

Comparisons of the reported SAIDs with HCs suggest potential variations in the risk of developing new-onset SAIDs based on ethnicity and the type of COVID-19 vaccine administered (Table 2). Specifically, among Caucasians, the odds of developing new-onset SAIDs were higher (OR = 5.3; 95% CI = 2.9–9.7; $p<.001$), whereas among Asians, the odds were lower (OR = 0.2; 95% CI = 0.1–0.7; $p=.011$). Furthermore, individuals who received the mRNA-1273 vaccine (Moderna) reported higher odds of new-onset SAIDs (OR = 2.7; 95% CI = 1.3–5.3; $p=.004$), while those who received the BNT162b2 vaccine (Pfizer-BioNTech) reported lower odds of new-onset SAIDs (OR = 0.3; 95% CI = 0.2–0.7; $p=.003$).

3.5 | Associations of new-onset SAIDs

The associations of new-onset SAIDs included the presence of AID multimorbidity (33.5% vs. 24.5%; OR = 1.4; 95% CI = 11–1.7; $p<.001$), mental health disorders (41.7% vs. 28.2%; OR = 1.6; 95% CI = 1.3–1.9; $p<.001$), and mixed race (5.5% vs. 3.4%; OR = 2.2; 95% CI = 1.2–4.2; $p=.010$).

On the other hand, those aged greater than 60 years (23.5% vs. 28.8%; OR = 0.6; 95% CI = 0.4–0.8; $p=.007$), receiving a higher number (>2 doses) of vaccine doses (16.8% vs. 20.6%; OR = 0.3; 95% CI = 0.2–0.5; $p<.001$), and belonging to high/medium HDI countries (compared to very high HDI) (24.9% vs. 29.2%; OR = 0.6; 95% CI = 0.4–0.8; $p=.002$) seemed to have protection against new-onset SAIDs. It is noteworthy that sex, non-autoimmune comorbidities, and type of vaccine did not predict the development of new-onset SAIDs in binary logistic regression.

4 | DISCUSSION

Concerns have previously been raised about the increased occurrence of SAIDs following the COVID-19 infection,[10] thereby, also raising concerns about the safety and efficacy of COVID-19 vaccination since their advent. Our study reported a low occurrence of new-onset SAIDs, with 74 of 16 750 vaccinated respondents reporting a confirmed diagnosis. Among these, certain diseases were overrepresented, including IIM, arthritis, PMR, and SLE. While most patients improved with medications, including glucocorticoids, and tolerated revaccination well, a notable proportion of those with arthritis and SLE experienced a worsening of symptoms following revaccination, warranting caution. In addition, pre-existing autoimmunity, mixed

TABLE 2 Associations of new-onset SAIDs compared to vaccinated healthy controls by binary logistic regression.

	OR	95% CI for OR		p
		Lower	Upper	
Age_tertiles (ref <30 years)				.022
30–60 years	**0.793**	**0.598**	**1.051**	.107
>60 years	**0.627**	**0.447**	**0.879**	**.007**
Sex (ref female)	**1.099**	**0.866**	**1.394**	.437
Ethnicity (ref African American)				.070
Asian	1.120	0.656	1.912	.677
Caucasian	1.330	0.796	2.222	.276
Do not want to disclose	0.905	0.421	1.942	.797
Hispanic	1.603	0.921	2.790	.095
Mixed	2.259	1.212	4.212	**.010**
Native American	0.981	0.271	3.556	.977
Others	1.480	0.786	2.785	.224
Country by HDI (ref very high HDI)				.001
High HDI	0.647	0.492	0.85	**.002**
Low HDI	0.544	0.218	1.359	.193
Medium HDI	0.471	0.286	0.774	**.003**
Comorbidities				
Any comorbidity	**1.104**	**0.912**	**1.338**	.309
Mental health disorders	**1.614**	**1.334**	**1.953**	**<.001**
AID multimorbidity	1.414	1.161	1.722	**<.001**
Vaccine type				
Pfizer	**1.124**	**0.795**	**1.589**	.510
Oxford	**1.357**	**0.941**	**1.956**	.102
Jansen	**0.599**	**0.237**	**1.511**	.277
Moderna	**1.289**	**0.869**	**1.913**	.207
Covishield	**1.456**	**0.764**	**2.775**	.254
Covaxin	**0.902**	**0.248**	**3.283**	.876
Sputnik	**0.475**	**0.155**	**1.457**	.193
Sinopharm	**1.300**	**0.669**	**2.527**	.439
Sinovac	**1.122**	**0.654**	**1.924**	.675
Vaccine doses (ref 2 doses)				
3 doses	**0.466**	**0.371**	**0.587**	**<.001**
4 doses	**0.366**	**0.268**	**0.500**	**<.001**

Note: By binary logistic regression. $p < .05$ is significant. Bold are significant.
Abbreviations: CI, confidence interval; OR, odd's ratio.

race, and underlying mental health disorders are potential risk factors for new-onset postvaccination SAIDs. Although the study design was not appropriate to assess incidence, it provides preliminary insights into revaccination, which was tolerated well for more than half of the respondents, except those with arthritis and SLE. Long-term studies are needed to ascertain the persistence of autoimmune diseases.

In our sample, the majority of respondents were female, with a mean age of over 50 years and an average duration of symptom onset of more than 3 weeks. This is consistent with a systematic review that reported a higher incidence of new-onset SAIDs in female patients of a similar age and duration of onset (64.3% female, and 51.1 years and 23.7 days, respectively).[11] Another systematic review reported similar findings (62.5% female, and 56 years and 11 days, respectively).[12]

A study in The Lancet reported a 4.4% incidence of SAIDs across the 22 million individuals in the United Kingdom from 2000 to 2019, in the pre-COVID era.[13] The difference in percentages can be attributed to a much larger sample size and duration when compared to our study. This implies that the incidence of SAIDs following COVID-19 vaccination may be regarded as a co-incidence rather than a consequence of the vaccination.

Our study reported IIM to be the most commonly self-reported new-onset SAID following COVID-19 vaccination, which is otherwise a rare disease. This is similar to the disease distribution found in a systematic review, with IIM being the most common connective tissue disease (CTD) disorder after COVID-19 vaccination.[11] The fact that IIM is the most reported SAID likely reflects our sampling strategy/bias. Many investigators who disseminated this survey have a particular interest in IIM, which means their patient populations would be enriched for this disease. Additionally, the survey was circulated among IIM patient groups. IIM was followed by arthritis and PMR. Our study did not assess causality, making it difficult to determine whether the distribution of diseases was due to reporting bias, thus warranting the need for further population-based studies to confirm causality.

Vaccination-associated myositis has also been described in the literature following the use of other vaccines, such as BCG[14] and HBV.[15] Seventy percent of vaccine-associated IIM occurred following an mRNA vaccine, according to one systematic review. This could be attributed to higher vaccination rates with mRNA vaccines globally.[16–19] Although the exact mechanism underlying vaccine-induced IIM is not clear, it is noteworthy that COVID-19 vaccination and infection have been associated with the development of myositis-specific autoantibodies, particularly anti-melanoma differentiation-associated gene 5 (MDA-5) antibodies.[20] However, these links remain tenuous and further warrant extensive research.

New-onset arthritis and SLE after COVID-19 vaccination have been previously documented.[21–23] We additionally observed that such individuals may experience an exacerbation of symptoms following revaccination, a phenomenon not observed in other COVID-19 vaccine-induced SAIDs. The recurrence of symptoms with subsequent vaccination may strengthen the possibility of causality in these individuals. This underscores the importance for future studies to document the long-term prognosis and evolution of vaccine-induced SAID. No patients with vasculitis chose to be revaccinated, so response to revaccination within this group remains completely unknown.

Immunomodulatory pharmacological treatment for new-onset SAIDs was required in nine out of every 10 patients, of whom over two-thirds experienced alleviation of symptoms following treatment. Oral glucocorticoids were the most common treatment modality for, administered more than half of the patients, followed by methotrexate, and NSAIDs/analgesics. Our study did not collect data on the duration of glucocorticoid use, which should be addressed in future studies.

We found an association between new-onset SAIDs and AID multimorbidity, but no such association with non-autoimmune comorbidities. This could potentially be linked to overactivity of the interferon axis or activation of other immune pathways, predisposing individuals with pre-existing SAIDs or a family history of SAIDs to other SAIDs.[24] Similarly, mental health disorders were associated with an increased risk of developing SAIDs. This can possibly be attributed to an altered perception of pain and fatigue, which may lead patients to consider these symptoms as SAID. In addition, dysregulation of immunological pathways has been shown to underlie certain mental health disorders, potentially leading to autoimmune dysfunction that manifests as new-onset SAID.[25,26]

Pfizer and Moderna, both mRNA vaccines, were the most commonly used vaccines in our sample size compared to the DNA vaccines, Oxford/AstraZeneca, and Johnson & Johnson. This does not necessarily suggest a stronger association between mRNA vaccines and SAIDs. The increased usage of mRNA vaccines may be due to their higher efficacy compared to DNA vaccines (94.1% and 91.6%, respectively)[27,28] or more effective marketing and distribution. Limited literature is available on the comparison of COVID-19 vaccines with regard to the incidence of SAIDs following administration.

Data on the background incidence of SAIDs in the general population are critical to establishing an association between vaccination and SAIDs. Clinical trials and postmarketing surveillance studies conducted during the COVID-19 vaccination drive have not demonstrated substantially increased rates of SAID diagnoses in the population since the onset of the pandemic. Further, the intra-pandemic incidence of rheumatological SAIDs was shown to be reduced compared to pre-pandemic levels in a case series.[29] They found a reduction in the intra-pandemic levels of the disease compared to its pre-pandemic levels, potentially due to modifications during the pandemic. This illustrates how unmeasured confounders cause difficulty in drawing associations from case series or biased retrospective cohort studies on SAIDs and COVID-19 vaccinations.

Treatment of SAIDs can have implications for the future health outcomes of patients who undergo vaccination, including their risk of severe COVID-19, the very condition the vaccination aims to prevent. A limitation of this study is the lack of long-term follow-up or assessment of the severity, outcome of autoimmune diseases, the efficacy of vaccination, or antibody associations.

Our study was a self-reported survey that was prone to selection, non-responder, and recall biases. The circulation of surveys across social media could lead to an "echo chamber" effect where the survey is more likely to be shared among individuals who have developed certain subtypes of autoimmune disease following vaccination or by clinicians with a particular sub-specialist interest. This may explain the higher frequency of IIM reports, despite being a rare SAID. Social media behavior has also been linked to vaccine hesitancy due to the spread of misinformation and conspiracy theories.[30] This is a patient self-reported survey. Although the patients report that their physician confirmed the diagnosis of new-onset SAID following the COVID vaccination, cross-checking the same individually proves challenging. Also, in such a scenario, temporality alone is not enough to prove causation.

It is critical to remember that within a relatively short timeframe, enormous numbers of individuals have been vaccinated worldwide. According to the WHO, as of June 29, 2023, over 13.2 billion doses of COVID-19 vaccine have been administered

globally.[31] Simultaneously, many new patients are being diagnosed globally on a daily basis, irrespective of their SAIDs. While COVID-19 vaccination cannot be excluded as a contributory factor, its association with newly reported SAIDs may be coincidental. Causality cannot be proven using temporal association alone. Several systematic reviews have reported SAIDs after a native COVID-19 infection; hence, it is possible that susceptible individuals who developed postvaccination SAIDs would have developed them following a native COVID-19 infection. Thus, studies comparing unvaccinated and vaccinated groups are needed to ascertain how vaccination affects the risk of developing SAIDs after a native COVID-19 infection.

Although the benefits of COVID-19 vaccination in preventing a COVID-19 infection outweigh associated risks that come with its use, further research is needed to identify vulnerable groups in population-based studies. Attention should be paid to the potential risk of triggering SAID post-vaccination in patients with known genetic susceptibility, a family history of autoimmune diseases, or pre-existing autoimmune diseases. Further research is needed into the mechanisms underlying these autoimmune phenomena to allow the possibility of preventing them by altering the vaccine type, dose, or schedule.

5 | CONCLUSION

Overall, new-onset, postvaccination SAIDs were rarely reported despite sampling and recall bias with survey-based research, where an adverse event is more likely to be remembered, with the most common being IIMs, PMR, arthritis, CTDs, and vasculitis. Most of these patients were treated with oral glucocorticoids and tolerated the revaccination well, though postvaccination exacerbation was more widely reported in those with inflammatory arthritis and SLE. Pre-existing AID multimorbidity, mental health diseases, and mixed race were identified as potential risk factors for new-onset SAID. However, long-term studies are needed to fully understand the autoimmune phenomena that arise post-vaccination, including their causality, prevention, and management. Overall, COVID-19 vaccination remains one of the most efficacious ways of preventing severe COVID-19 and death, and should be positively encouraged, even in patients with underlying SAID who remain at a higher risk. Further case-controlled studies and epidemiological studies are required to identify vulnerable groups in population-level studies and to establish how risk compares to that of the unvaccinated population.

AUTHOR CONTRIBUTIONS

Conceptualization: RS, JH, NR, and LG. Data curation: all authors. Formal analysis: NR. Funding acquisition: N/A. Investigation: RS, JH, and NR. Methodology: LG, VA, NR, and RA. Software: LG. Validation: VA, RA, and HC. Visualization: RA, VA, and LG. Writing-original draft: RS, JH, NR, and LG. Writing—review and editing: all authors.

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CONFLICT OF INTEREST STATEMENT

MK has received speaker honoraria/participated in advisory boards for Asahi-Kasei, AstraZeneca, Boehringer Ingelheim, Chugai, GSK, Kissei, MBL, Mochida, Nippon Shinyaku, and Ono Pharmaceuticals. ALT has received honoraria for advisory boards and speaking for Abbvie, Gilead, Janssen, Lilly, Novartis, Pfizer, and UCB. EN has received speaker honoraria/participated in advisory boards for Celltrion, Pfizer, Sanofi, Gilead, Galapagos, AbbVie, and Lilly, and holds research grants from Pfizer and Lilly. HC has received grant support from Eli Lilly and UCB, consulting fees from Novartis, Eli Lilly, Orphazyme, Astra Zeneca, speakers for UCB, and Biogen. IP has received research funding and/or honoraria from Amgen, AstraZeneca, Aurinia Pharmaceuticals, Elli Lilly and Company, Gilead Sciences, GlaxoSmithKline, Janssen Pharmaceuticals, Novartis, and F. Hoffmann-La Roche AG. JD has received research funding from CSL Limited. NZ has received speaker fees, advisory board fees, and research grants from Pfizer, Roche, Abbvie, Eli Lilly, NewBridge, Sanofi-Aventis, Boehringer Ingelheim, Janssen, and Pierre Fabre; none are related to this manuscript. OD has/had consultancy relationship with and/or has received research funding from and/or has served as a speaker for the following companies in the area of potential treatments for systemic sclerosis and its complications in the last three calendar years: 4P-Pharma, Abbvie, Acceleron, Alcimed, Altavant, Amgen, AnaMar, Arxx, AstraZeneca, Baecon, Blade, Bayer, Boehringer Ingelheim, Corbus, CSL Behring, Galderma, Galapagos, Glenmark, Gossamer, iQvia, Horizon, Inventiva, Janssen, Kymera, Lupin, Medscape, Merck, Miltenyi Biotec, Mitsubishi Tanabe, Novartis, Prometheus, Redxpharma, Roivant, Sanofi, and Topadur. Patent issued "mir-29 for the treatment of systemic sclerosis" (US8247389, EP2331143). RA has a consultancy relationship with and/or has received research funding from the following companies: Bristol Myers-Squibb, Pfizer, Genentech, Octapharma, CSL Behring, Mallinckrodt, AstraZeneca, Corbus, Kezar, Abbvie, Janssen, Kyverna Alexion, Argenx, Q32, EMD-Serono, Boehringer Ingelheim, Roivant, Merck, Galapagos, Actigraph, Scipher, Horizon Therepeutics, Teva, Beigene, ANI Pharmaceuticals, Biogen, Nuvig, Capella Bioscience, and CabalettaBio. TV has received speaker honoraria from Pfizer and AstraZeneca, non-related to the current manuscript. The rest of the authors have no conflict of interest relevant to this manuscript.

DATA AVAILABILITY STATEMENT

The datasets generated and/or analyzed during the current study are not publicly available but are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

Ethical approval was obtained from the Institutional Ethics Committee of the Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, 226014.

DECLARATIONS

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DISCLAIMER

Part of this study has been accepted for a poster presentation at ACR Convergence 2023 (Session: Epidemiology and Public Health).

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX

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