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Flares Of Autoimmune Rheumatic Disease following COVID-19 Infection: Observations From The COVAD Study

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Flares Of Autoimmune Rheumatic Disease Following COVID-19 Infection: Observations From The COVAD Study

Dear Editor,

The COVID-19 pandemic has significantly impacted the health of individuals with Autoimmune Rheumatic Diseases (AIRDs), who being immunologically vulnerable, are at an increased risk of complications following a COVID-19 infection[1,2]. This can be attributed to the derangement of the interferon axis in both autoimmune diseases and COVID-19 infection. Particularly, type I interferons have been indicated in the pathogenesis of autoimmune diseases[3] and in the generation of an immune response to a COVID-19 infection[4,5]. The similar pathogenesis puts patients with AIRDs at an increased risk for disease exacerbations. Although there is a wealth of data concerning new onset phenomena following a COVID-19 infection, there remains a scarcity of information regarding the characteristics and risk factors associated with disease flares in patients with AIRDs subsequent to a COVID-19 infection. [6]

The COVID-19 Vaccination in Autoimmune Diseases (COVAD) study is an international collaborative study involving 167 collaborators in 110 countries designed to explore the different facets of COVID-19 infection, vaccination, and disease activity in individuals with AIRDs[7–9]. The COVAD database is an ideal cohort for this study due to its extensive geographical coverage including under-represented regions, and its use of validated tools. Using a

standardized and validated self-reported questionnaire, the COVAD study collected data regarding demographics, vaccine types, medications, and comorbid conditions in patients with AIRDs and healthy controls. Binary logistic regression (BLR) analyses were performed with adjustment for age, gender, ethnicity, vaccine type, immunosuppressive medications, comorbidities, COVID-19 antibody status, and clinical features during previous COVID-19 infection, stratified by country of residence (detailed methods in Supplementary file). Medians and interquartile ranges (IQR) were used to summarize continuous data and Chi-squared ($\chi 2$) and Mann-Whitney U tests were used to compare AIRDs patients with flares to those without flares for categorical and continuous variables, respectively. Finally, physical and mental health, fatigue, and pain were assessed using the PROMIS PF10 scores.

Of the 15,165 study participants enrolled in the study between March 2021[9] and June 18, 2022, 824 had AIRDs and had at least one episode of COVID-19 infection (Supplementary Figure 1). Most respondents were Caucasian (53.8%), female (86.5%), and had received the Pfizer-BioNTech vaccine (42.8%). Methotrexate was the most commonly used immunosuppressant drug (29.9%). A significant proportion had associated comorbidities (n=361, 43.8%), with over one quarter (n=218, 26.5%) reporting an additional non-rheumatic autoimmune (AID) comorbidity (Table 1).

Notably, 304 (36.9%) experienced at least one flare of the underlying AIRD following COVID-19 infection over a 127-day period (IQR: 62-308 days) from the date of infection to the date of the survey. Females (OR:1.6; 95%CI: 1.04-2.5; p=0.032) and patients with comorbidities such as asthma (1.6; 1.09-2.5; 0.017), chronic obstructive pulmonary disease (3.5; 1.3-9.4; 0.008), diabetes mellitus (1.9; 1.04-3.6; 0.03), mental health disorders (1.5; 1.3-1.8; 0.001), and non-rheumatic AID comorbidities (1.5; 1.1-2.1; 0.004) had higher odds of flaring of their disease (Table 1). Patients who reported flares had worse (higher) PROMIS PF10 physical health scores (median=14; p=0.038), pain VAS (median=5.0, p<0.001), fatigue VAS (median=3.0, p=0.003), and

lower mental health scores (median=12.0, p<0.001) compared to those who did not report flares (Table 1).

Certain features of COVID-19 disease, such as joint pain (3.5; 2.2-5.6; <0.001), cough (1.5; 1.0-2.3; 0.032), headache (1.5; 1.0-2.3; 0.030) and abdominal pain (2.3; 1.1-4.8; 0.027) were associated with an increased risk of flares (Supplementary Table 1). In contrast, the vaccine type, number of vaccine doses and COVID-19 autoantibody status showed no association. Individuals who experienced flares demonstrated a higher need for advanced treatment with monoclonal antibodies (1.7; 1.1-2.8; 0.020).

Studies have suggested that COVID-19 infection can trigger a strong type I interferon mediated antiviral response[10] which exacerbates the sustained interferon production already present in patients with AIRDs[11]. This sustained type I interferon response could potentially explain the flares experienced by AIRDs patients following a COVID-19 infection. The findings of the study above are corroborated by other studies such as the one that predicted a four-fold odds of disease flare in 178 Latinos with AIRDs[7.] Prior literature suggests medication non-adherence as a possible reason for disease flares in patients with AIRDs[12].Such observations may be accounted for my perceived flares due to disparity in physician patient reporting, or accentuated immune responses in individuals with associated autoimmune comorbidities, as identified by the COVAD group in previous publications, both being avenues for further research[13],[14].

One limitation of our study is the self-reported nature of the disease flares without verification by a physician which could be impacted by patients' perceptions of flares and their inability to distinguish flares from ongoing symptoms of long-COVID syndrome or secondary fibromyalgia. Other limitation include selection bias in survey distribution and survivorship bias inherent to the self-reported nature of the survey.

In conclusion, our study affirms the importance of monitoring for disease flares post-COVID-19 infection in vulnerable AIRD patients. In addition, vaccine safety should no longer be considered a risk factor for causing significant disease flares in these patients and hence, should be encouraged. With very limited data available, further research addressing the predictors of flares, post COVID syndrome and the long-term sequelae in AIRDs in needed.

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Table 1. Patient-reported flares following COVID-19 infection among AIRD patients.

Table 1. Patient-reported flares following COVID-19 infection among AIRD patients who contracted COVID-19					
	Total AIRDs (n=824) N (%)	AIRDs with flare following infection (n=304) N (%)	AIRDs without flare following infection (n=520) N (%)	OR (95%CI)	p
Age (median, IQR) years	46.0 (36.0-55.0)	45.0 (37.0-55.0)	46.0 (36.0-57.0)	-	0.121
Gender					**0.032**
Male	105 (12.7)	**29 (9.5)**	**76 (14.6)**		
Female	713 (86.5)	**274 (90.1)**	**439 (84.4)**	**1.6 (1.04-2.5)**	
Ethnicity					<0.001
Caucasian	443 (53.8)	175 (57.6)	268 (51.5)	-	
Asian	122 (14.8)	32 (10.5)	90 (17.3)	-	
Native American	4 (0.5)	1 (0.3)	3 (0.6)	-	
African American or African origin	42 (5.1)	25 (8.2)	17 (3.3)	-	
Hispanic		30 (9.9)	79 (15.2)	-	
Mixed		17 (5.6)	17 (3.3)	-	
Others	109 (13.2)	17 (5.6)	26 (5.0)	-	
I do not want to disclose	34 (4.1)	7 (2.3)	20 (3.8)	-	
	43 (5.2)				
	27 (3.3)				
Type of vaccine taken (after 1st dose)				-	0.788
Pfizer	353 (42.8)	124 (35.1)	229 (44.0)	-	
Moderna	42 (5.1)	14 (4.6)	28 (5.4)	-	
Oxford	219 (26.6)	84 (27.6)	135 (26.0)	-	
Sinopharm	43 (5.2)	21 (6.9)	22 (4.2)	-	
Covishield	17 (2.1)	3 (1.0)	14 (2.7)	-	
Covaxin	7 (0.8)	2 (0.7)	5 (1.0)	-	
Sputnik	16 (1.9)	4 (1.3)	12 (2.3)	-	
Johnson and Johnson	7 (0.8)	5 (1.6)	2 (0.4)	-	
Sinovac	62 (7.5)	23 (7.6)	39 (7.5)	-	
Immunosuppression received prior to vaccination					
Methotrexate	246 (29.9)	103 (33.9)	143 (27.5)	1.3 (0.9-1.8)	0.053
Mycophenolate mofetil	57 (6.9)	15 (4.9)	42 (8.1)	0.5 (0.3-1.0)	0.056
Azathioprine	54 (6.6)	**9 (3.0)**	**45 (8.7)**	**0.3 (0.1-0.6)**	**0.001**
Hydroxychloroquine	242 (29.4)	81 (26.6)	161 (31.0)	0.8 (0.5-1.1)	0.189
Sulfasalazine	73 (8.9)	33 (10.9)	40 (7.7)	1.4 (0.9-2.3)	0.123
Leflunomide	39 (4.7)	20 (6.6)	19 (3.7)		0.056
Oral tacrolimus	4 (0.5)	1 (0.3)	3 (0.6)		0.621
Cyclosporine	12 (1.5)	6 (2.0)	6 (1.2)		0.343
Iv immunoglobulins		1 (0.3)	1 (0.2)		0.706
		1 (0.3)	6 (1.2)		0.213

Cyclophosphamide Rituximab Anti TNF agents JAK inhibitors Glucocorticoids Steroids None <10 mg a day 10-20 mg a day >20 mg a day	2 (0.2) 7 (0.8) 36 (4.4) 91 (11.0) 19 (2.3) 486 (59.0) 217 (26.3) 50 (6.1) 16 (1.9)	10 (3.3) **47 (15.5)** 11 (3.6) 175 (57.6) 76 (25.0) 26 (8.6) 12 (1.3)	26 (5.0) **44 (8.5)** 8 (1.5) 311 (59.8) 141 (65.0) 24 (4.6) 4 (2.3)	1.8 (0.9-3.5) 0.5 (0.06-5.4) 1.7 (0.5-5.4) 1.7 (0.1-27.4) 0.2 (0.03-2.3) 0.6 (0.3-1.3) **1.9 (1.2-3.0)** 2.4 (0.9-6.0) -	0.246 **0.002** 0.049 0.139
Comorbidities **Any comorbidity** **Asthma** Chromic kidney disease Chronic liver disease **Chronic obstructive lung disease** Interstitial lung disease Coronary artery disease **Diabetes Mellitus** Epilepsy Dyslipidaemia HIV-AIDS Hypertension Stroke Tuberculosis Organ transplant **Mental health disorders** Anxiety Bipolar disorder **Depression** Eating disorder **Insomnia** Schizophrenia Substance use disorders	 361 (43.8) 96 (11.7) 35 (4.2) 6 (0.7) 18 (2.2) 16 (1.9) 19 (2.3) 42 (5.1) 11 (1.3) 107 (13.0) 1 (0.1) 138 (16.7) 12 (1.5) 10 (1.2) 4 (0.5) 258 (31.3) 162 (19.7) 6 (0.7) 151 (18.3) 13 (1.6) 58 (7.0) 2 (0.2) 5 (0.6)	 **151 (49.7)** **46 (15.1)** 10 (3.3) 0 (0.0) **12 (3.9)** 9 (3.0) 8 (2.6) **22 (7.2)** 7 (2.3) 42 (13.8) 0 (0.0) 56 (18.4) 4 (1.3) 5 (1.6) 1 (0.3) **126 (41.4)** 69 (22.7) 1 (0.3) **82 (27.0)** 6 (2.0) **29 (9.5)** 0 (0.0) 3 (0.6)	 **210 (40.4)** **50 (9.6)** 25 (4.8) 6 (1.2) **6 (1.2)** 7 (1.3) 11 (2.1) **20 (3.8)** 4 (0.8) 65 (12.5) 1 (0.2) 82 (15.8) 8 (1.5) 5 (1.0) 3 (0.6) **132 (25.4)** 93 (17.0) 5 (1.0) **69 (13.3)** 7 (1.3) **29 (5.6)** 2 (0.4) 2 (0.7)	 **1.2 (1.06-1.5)** **1.6 (1.09-2.5)** 0.6 (0.3-1.4) 0.6 (0.5-0.6) **3.5 (1.3-9.4)** 2.2 (0.8-6.0) 1.2 (0.4-3.1) **1.9 (1.04-3.6)** 3.0 (0.8-10.4) 1.1 (0.7-1.7) 0.6 (0.6-0.6) 1.2 (0.8-1.7) 0.8 (0.2-2.8) 1.7 (0.4-5.9) 0.5 (0.5-5.4) **1.5 (1.3-1.8)** 1.3 (0.9-1.9) 0.3 (0.0-2.9)	 **0.010** **0.017** 0.297 0.060 **0.008** 0.105 0.634 **0.033** 0.064 0.588 0.444 0.325 0.797 0.387 0.621 **<0.001** 0.093 0.303 **<0.001** 0.485 **0.032** 0.279 0.885

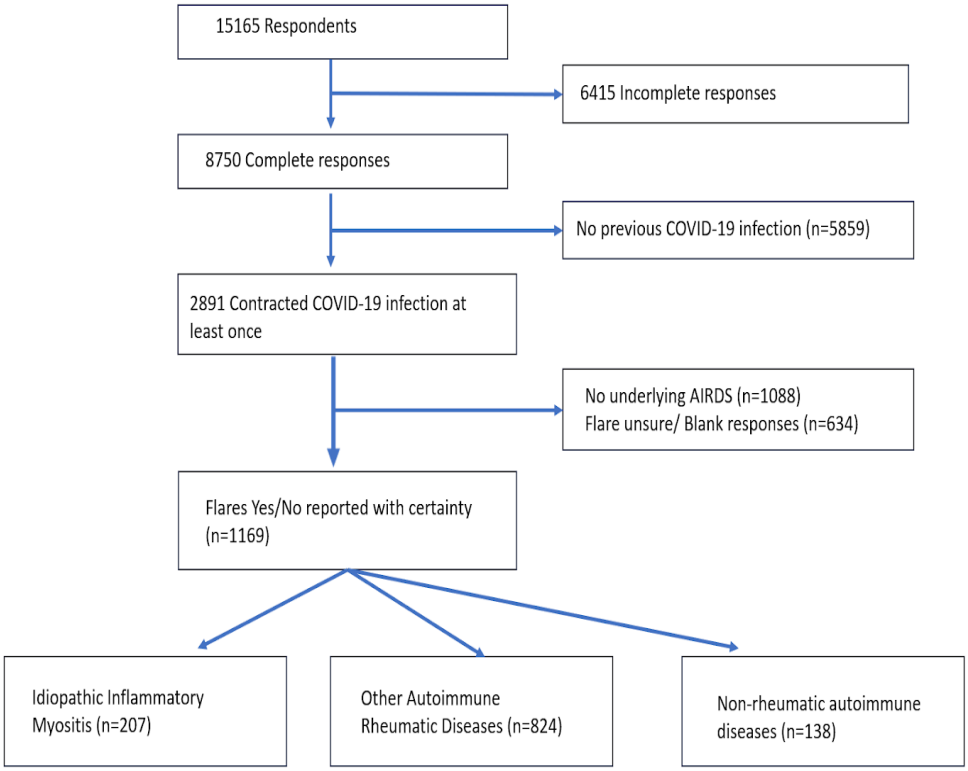
				2.4 (1.6-3.4) 1.4 (0.4-4.4) **1.7 (1.04-3.0)** 0.6 (0.6-0.6) 1.1 (0.1-6.8)	
Non-rheumatic AID comorbidities Yes	218 (26.5)	**98 (32.2)**	**120 (23.1)**	**1.5 (1.1-2.1)**	**0.004**
COVID-19 antibody status Antibodies present	124/150 (82.6)	48/58 (82.7)	76/92 (82.6)	1.0 (0.4-2.4)	0.981
PROMIS PF Global 10a (median, IQR) Global physical health score Global mental health score Fatigue VAS Pain VAS	 13.0 (12.0-15.0) 13.0 (10.0-15.0) 3.0 (3.0-4.0) 4.0 (2.0-6.0)	 **14.0 (12.0-15.0)** **12.0 (9.0-14.0)** **3.0 (2.0-3.0)** **5.0 (3.2-7.0)**	 **13.0 (12.0-15.0)** **13.5 (11.0-16.0)** **4.0 (3.0-4.0)** **2.0 (1.0-5.0)**	 - - - -	 **0.038** **<0.001** **0.003** **<0.001**
Clinical features during previous COVID-19 infection Any symptom Fever Fatigue Muscle aches Joint pains Cough Difficulty in breathing Loss of smell Loss of taste Running nose Congestion Throat pain/scratchiness Chest pain Diarrhoea Headache Oral ulcers Nausea/vomiting Abdominal pain Skin rashes Hospitalisation ICU/High dependence unit Oxygen supplementation Need for advanced biologics treatment	 783 (95.0) 439 (53.3) 532 (64.6) 415 (50.4) 347 (42.1) 479 (58.1) 218 (26.5) 278 (33.7) 252 (30.6) 330 (40.0) 284 (34.5) 381 (46.2) 130 (15.8) 147 (17.8)	 **301 (99.0)** **194 (63.8)** **245 (80.6)** **205 (67.4)** **205 (67.4)** **212 (69.7)** **126 (41.4)** **118 (38.8)** **109 (35.9)** 133 (43.8) **129 (42.4)** **165 (54.3)** **84 (27.6)** **89 (29.3)** **189 (62.2)** **24 (7.9)** **69 (22.7)** **58 (19.1)** **21 (6.9)** **30 (9.9)** 6 (2.0) **18 (5.9)** **42 (13.8)**	 482 (92.7) 245 (47.1) 287 (55.2) **210 (40.4)** **142 (27.3)** **267 (51.3)** **92 (17.7)** **160 (30.8)** **143 (27.5)** 197 (37.9) **155 (29.8)** **216 (41.5)** **46 (8.8)** **58 (11.2)** **187 (36.0)** **11 (2.1)** **38 (7.3)** **18 (3.5)** **9 (1.7)** **18 (3.5)** **3 (0.6)** **8 (30.8)** **23 (4.4)**	 **7.9 (2.4-25.8)** **1.9 (1.4-2.6)** **3.3 (2.4-4.7)** **3.0 (2.2-4.1)** **5.5 (4.0-7.5)** **2.1 (1.6-2.9)** **3.2 (2.3-4.5)** **1.4 (1.0-1.9)** **1.4 (1.0-1.9)** 1.2 (0.9-1.7) **1.7 (1.2-2.3)** **1.6 (1.2-2.2)** **3.9 (2.6-5.8)** **3.2 (2.2-4.7)**	 **<0.001** **<0.001** **<0.001** **<0.001** **<0.001** **<0.001** **0.018** **0.012** 0.097 **<0.001** **<0.001** **<0.001** **<0.001** **<0.001** **<0.001** **<0.001** **<0.001** **<0.001** 0.063 **<0.001** **<0.001**

	376 (45.6) 35 (4.2) 107 (13.0) 76 (9.2) 30 (3.6) 48 (5.8) 9 (1.1) 26 (3.2) 65 (7.9)			**2.9 (2.1-3.9)** **3.9 (1.9-8.2)** **3.7 (2.4-5.7)** **6.5 (3.8-11.4)** **4.2 (1.9-9.3)** **3.0 (1.6-5.5)** **3.4 (0.8-13.9)** **4.0 (1.7-9.3)** **1.8 (1.5-2.2)**	

Bold are significant (P<0.05). Chi-square for categorical variables, Mann Whitney U for scale variable comparisons.

AIRDs: Autoimmune rheumatic diseases, IQR: Interquartile range, OR: Odd's ratio, ICU: Intensive care unit

Flares Of Autoimmune Rheumatic Disease Following COVID-19 Infection: Findings From The COVAD Study
Supplement



Supplementary Figure 1. Flowchart depicting inclusion and exclusion criteria for the study

Methods

COVAD Study: The COVID-19 Vaccination in Autoimmune Diseases (COVAD) study is a global research project involving 157 investigators across 106 countries. The study was designed to collect information related to COVID-19 infection, vaccination uptake, adverse events, patient reported outcomes and comorbidities among individuals with various autoimmune diseases. The study involves the use of a standardized and validated questionnaire administered online in 18 languages. It recruited participants >18 years of age who were either healthy or had some type of autoimmune disease. A detailed description of the study protocol has been published online and is available for review [5].

Inclusion criteria: Among the 2891 patients who had COVID-19 infection at least once, 1169 respondents who answered the question 'Did your autoimmune disease flare following COVID-19 infection?' with a "Yes" or "No" response were included in the study. Among them, 824 respondents had AIRDs.

Exclusion criteria: Incomplete responses, those who were vaccinated prior to June 2020 (probably trial participants), and those with wrong dates (n=6415). Those who had not reported contracting COVID-19 infections were excluded (n=5859). IIM patients were excluded from other AIRDs (as they form a disproportionately large group, they were overrepresented in the study cohort as compared with normal prevalence and are analyzed for a separate manuscript to avoid confounding and sampling bias) (n=207, 17.7%). HCs and nrAIDs were also excluded. Those who responded to the question 'Did your autoimmune disease flare following COVID-19 infection?' with "I am not sure" or "I do not have autoimmune disease" were excluded (n=1722).

Definitions: Flare of AIRDs were patient self-reported. AIRDs were self-reported as assessed by their treating physician. Patient global physical health and mental health were assessed using the standard tool Patient-Reported Outcome Measurement Information System (PROMIS) global health score.

Statistical analysis: We compared the characteristics of patients with AIRDs who did and did not experience flares following COVID-19 infection using Chi-square tests for categorical variables. The Mann-Whitney U tests were used for comparing continuous variables. Multivariable regression analyses were performed to assess factors associated with flare, with adjustment for age, gender, ethnicity, vaccine type, type of immunosuppression, comorbidities, COVID-19 antibody status, and clinical features during previous COVID-19 infection (covariates with p-value<0.2 in univariate analysis were added in the regression model) and stratified by country of residence. The vaccine groups were clubbed together into three categories: adenoviral vector, mRNA, and others. SPSS version 28.0 was used to perform all the statistical analyses.

Supplementary Table 1: Associations of flare of AIRDs following COVID-19 infection

	p	Exp(B)	95% C.I. for EXP(B)	
			Lower	Upper
Age	0.226	0.9	0.9	1.01
Male gender (ref female)	0.065	0.5	0.3	1.04
Ethnicity (ref Caucasians)	0.173			
Asian	0.280	0.7	0.3	1.3
Hispanic	0.111	0.6	0.3	1.1
Mixed	0.197	1.8	0.7	4.3
African American	0.829	1.1	0.4	2.9
Native American	0.675	0.5	0.04	7.6
Others	0.280	0.7	0.3	1.3
First dose Vaccine (ref adenoviral vector vaccine)	0.184			
mRNA	0.391	0.8	0.5	1.2
Others	0.180	1.5	0.8	3.0

Comorbidities				
AID multimorbidity	0.690	1.1	0.7	1.6
Any comorbidity	0.119	0.7	0.5	1.1
Mental health disorder	0.371	1.2	0.8	1.7
Number of COVID-19 vaccines received (ref 2 doses)	0.840			
3 doses	0.681	1.1	0.6	1.7
4 doses	0.558	1.2	0.6	2.1
COVID-19 infection symptoms				
Fever	0.292	0.8	0.5	1.2
Fatigue	0.098	1.4	0.9	2.3
Muscle aches	0.816	1.1	0.6	1.7
Joint pains	**<.001**	**3.5**	**2.2**	**5.6**
Cough	**0.032**	**1.5**	**1.0**	**2.3**
Difficulty in breathing or Shortness of breath	0.312	1.2	0.8	2.0
Loss of smell	0.592	0.8	0.4	1.5
Loss of taste	0.753	0.9	0.4	1.6
Running nose	0.793	0.9	0.6	1.4
Congestion	0.841	0.9	0.6	1.4
Throat pain/scratchiness	0.661	0.9	0.6	1.3
Chest pain	0.794	1.1	0.6	1.8
Diarrhoea	0.286	1.3	0.7	2.2
Headache	**0.030**	**1.5**	**1.0**	**2.3**
Oral ulcers	0.332	1.6	0.6	4.3
Nausea/vomiting	0.604	1.1	0.6	2.1
Abdominal/Belly pain	**0.027**	**2.3**	**1.1**	**4.8**
Skin rashes	0.099	2.5	0.8	7.8
Need for hospitalization	0.057	2.3	0.9	5.4
Intensive Care Unit (ICU) or Other High Dependence Unit	0.169	4.1	0.5	31.2
Oxygen supplementation	0.436	1.5	0.5	4.7
Need for advanced treatment	**0.020**	**1.7**	**1.1**	**2.8**

Binary logistic regression using Enter method adjusted for age, gender, ethnicity, vaccine doses and other covariates with $p<0.2$ in univariate analysis was used in the analysis

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