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Background: Published data suggest no increased rate of flare of autoimmune inflammatory rheumatic diseases (AIIRD) after COVID-19 mRNA vaccination; however, the studies are limited by small sample size, short follow up or at risk of selection bias (voluntary physician reports or patient surveys).
Objectives: To study flares of AIIRD within three months of the first dose of an anti-SARS-COV2 mRNA vaccine.
Methods: A retrospective cohort study of consecutive AIIRD patients ≥ 12 years old, across six public hospitals in Singapore who received at least one dose of an mRNA (Pfizer/BioNTech or Moderna) vaccine. Data were censored at the first post-vaccine clinic visit when the patient had flared or if ≥ three months had elapsed since the first dose of the vaccine, whichever came first. Predictors of flare were determined by Cox proportional hazards analysis and time to flare was examined using a Nelson Aalen cumulative hazard estimate (Figure 1).
Results: 2339 patients (74% Chinese, 72% female) of median (IQR) age 64 (53, 71) years were included in the interim analysis (Table 1). 2112 (90%) had the Pfizer/BioNTech vaccine and 195 (8%) had Moderna, with a median (IQR) interval of 21 (21, 23) days between the two doses. The most common AIIRD diagnoses were Rheumatoid arthritis (1063, 45%), Psoriatic arthritis (296, 12.6%) and Systemic lupus erythematosus (SLE) (288, 12.3%). 186 (8%) were treated with biologics/ targeted disease modifying agents. 2125 (91%) patients were in low disease activity or remission. Treatment was interrupted for vaccination in only 18 (0.8%) patients. Seven (0.3%) patients had previous COVID-19 infection.

Table 1. Patient characteristics

Baseline characteristics	No flares (n = 1887, %)	Flares within 0—3 months of 1st vaccine dose (n= 272, %)	Flares outside of 0 – 3 months after 1st vaccine dose (n = 180, %)
Age (median years, IQR)	64 (53, 71)	61 (50, 69)	65 (55, 71)
Race			
Chinese	1386 (73)	206 (76)	129 (72)
Malay	193 (10)	28 (10)	20 (11)
Indian	195 (10)	27 (10)	26 (14)
Gender	1367 (72)	200 (74)	117 (65)
Female			
Vaccine type			
Pfizer/BioNTech	1713 (92)	239 (90)	160 (90)
Moderna	149 (8)	28 (10)	18 (10)
Diagnosis			
Rheumatoid Arthritis	831 (44)	139 (51)	93 (52)
Systemic Lupus Erythematosus	269 (14)	20 (7)	9 (5)
Psoriatic Arthritis	225 (12)	42 (15)	29 (16)
Spondyloarthropathies	141 (7)	21 (7)	17 (9)
Sjogren's Syndrome	114 (6)	15 (6)	8 (4)
Systemic sclerosis	94 (5)	4 (1)	6 (3)
Baseline Physician Disease Activity			
Remission	1007 (53)	99 (36)	63 (35)
Low Disease Activity	731 (39)	128 (47)	97 (54)
Moderate Disease Activity	134 (7)	40 (15)	20 (11)
High Disease Activity	15 (1)	5 (2)	0

452 (19%) flares were recorded during 9798.8 patient-months [4.6/100 patient-months, median (IQR) follow up duration 4.2 (3.3, 5.3) months], of which 272 (11.6%) patients flared within the 3-month period of interest and 180 (7.7%) flared outside of the 3-month period (Table 1). Median (IQR) time-to-flare was 40.5 (18, 56.6) days. 60 (22.1%) were mild and self-limiting, 170 (62.5%) were mild-moderate and 42 (15.4%) were severe. 190 (69.8%) of those who flared required escalation of treatment and 15 (5.5%) required hospital admission. 239 (10.2%) had improved disease activity after the vaccine.
On multivariate Cox regression analysis, patients in the oldest age tertile [median (IQR) 74 (71, 79) years] were less likely to flare [HR 0.80 (95% CI 0.63, 1.00), p = 0.05] Patients with inflammatory arthritis (compared with connective tissue disease, vasculitis and others) and patients with baseline active disease were more likely to flare [HR 1.72 (95% CI 1.35, 2.20), p < 0.001 and 1.82 (95% CI 1.39, 2.39), p < 0.001 respectively]
Conclusion: There was a moderately high rate of AIIRD flares after mRNA vaccination; however, there was no clustering of flares in the immediate post-vaccine period to suggest causality. Older patients were less likely to flare, while those with inflammatory arthritis and active disease at baseline were more likely to flare.
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POS0201 COVID-19 SEVERITY AND VACCINE BREAKTHROUGH INFECTIONS IN IDIOPATHIC INFLAMMATORY MYOPATHIES, OTHER SYSTEMIC AUTOIMMUNE AND INFLAMMATORY DISEASES, AND HEALTHY INDIVIDUALS: RESULTS FROM THE COVID-19 VACCINATION IN AUTOIMMUNE DISEASES (COVAD) STUDY.

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Background: Significant gaps are present in the evidence of the spectrum and severity of COVID-19 infection in idiopathic inflammatory myopathies (IIM). IIM patients typically require immunosuppressive therapy, may have multiple disease sequelae, and frequent comorbidities, and thus may be more susceptible to severe COVID-19 infection and complications (1). The possibility of attenuated immunogenicity and reduced efficacy of COVID-19 vaccines due to concomitant immunosuppressive medication is a major concern in these patients, and there is little data available on COVID-19 vaccine breakthrough infections (BI) in IIM (2).

Objectives: This study aimed to compare disease spectrum and severity and COVID-19 BI in patients with IIM, other systemic autoimmune and inflammatory diseases (SAIDs) and healthy controls (HCs).

Methods: We developed an extensive self-reporting electronic-survey (COVAD survey) featuring 36 questions to collect respondent demographics, SAID details, COVID-19 infection history, COVID-19 vaccination details, 7-day post vaccination adverse events and patient reported outcome measures using the PROMIS tool. After pilot testing, validation, translation into 18 languages on the online platform surveymonkey.com, and vetting by international experts, the COVAD survey was circulated in early 2021 by a multicenter study group of >110 collaborators in 94 countries. BI was defined as COVID-19 infection occurring more than 2 weeks after receiving 1st or 2nd dose of a COVID-19 vaccine. We analyzed data from the baseline survey for descriptive and intergroup comparative statistics based on data distribution and variable type.

Results: 10900 respondents [mean age 42 (30-55) years, 74% females and 45% Caucasians] were analyzed. 1,227 (11.2%) had IIM, 4,640 (42.6%) had other SAIDs, and 5,033 (46.2%) were HC. All respondents included in the final analysis had received a single dose of the vaccine and 69% had received 2 primary doses. Pfizer (39.8%) was the most common vaccine received, followed by Oxford/AstraZeneca (13.4%), and Covishield (10.9%). IIM patients were older, had a higher Caucasian representation and higher Pfizer uptake than other SAIDs, and HC. A higher proportion of IIM patients received immunosuppressants than other SAIDs.

IIMs were at a lower risk of symptomatic pre-vaccination COVID-19 infection compared to SAIDs [multivariate OR 0.6 (0.4-0.8)] and HCs [multivariate OR 0.39 (0.28-0.54)], yet at a higher risk of hospitalization due to COVID-19 compared to SAIDs [univariate OR 2.3 (1.2-3.5)] and HCs [multivariate OR 2.5 (1.1-5.8)]. BIs were very uncommon in IIM patients, with only 17 (1.4%) reporting BI. IIM patients were at a higher risk of contracting COVID-19 prior to vaccination than ≤2 weeks of vaccination [univariate OR 8 (4.1-15)] or BI [univariate OR 4.6 (2.7-8.0)]. BIs were equally severe compared to when they occurred prior to vaccination in IIMs, and were comparable between IIM, SAIDs, and HC (Figure 1), though BI disease duration was shorter in IIMs than SAIDs (7 vs 11 days, p 0.027). 13/17 IIM patients with BI were on immunosuppressants.

Conclusion: IIM patients experienced COVID-19 infection less frequently prior to vaccination but were at a higher risk of hospitalization and requirement for oxygen therapy compared with patients with HC. Breakthrough COVID-19 infections were rare (1.4%) in vaccinated IIM patients, and were similar to HC and SAIDs, except for shorter disease duration in IIM.

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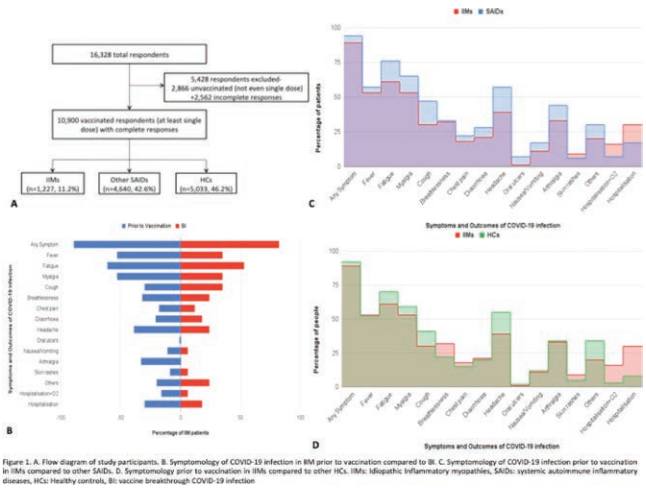


Figure 1. A. Flow diagram of study participants. B. Symptomology of COVID-19 infection in IIM prior to vaccination compared to BI. C. Symptomology of COVID-19 infection prior to vaccination in IIMs compared to other SAIDs. D. Symptomology prior to vaccination in IIMs compared to other HCs. IIMs: Idiopathic Inflammatory myopathies, SAIDs: systemic autoimmune inflammatory diseases, HCs: Healthy controls, BI: vaccine breakthrough COVID-19 infection

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POS0202

CONTROL OF RHEUMATIC DISEASE AND COVID-19: RESULTS FROM THE INTERNATIONAL COVID-19 EUROPEAN PATIENT REGISTRY

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Background: A major concern across rheumatology in recent years is how contracting COVID-19 may impact the control of rheumatic diseases.
Objectives: To quantify any difference in rheumatic disease control between those who did and did not contract COVID-19 between March and December 2020 and whether rheumatic disease control changed after COVID-19 was contracted.
Methods: Adults with rheumatic diseases recruited to the COVID-19 European Patient Registry, a patient-led, online, self-referred prospective cohort recruiting participants from around the globe, were included if enrolled between March and December 2020. Rheumatic disease control was self-reported weekly on a scale of 0 (very poor) to 10 (very well). Dates of contracting COVID-19 were self-reported.
Differences in rheumatic disease control trends between those who did and did not contract COVID-19 over the study period were tested via multilevel linear regression. Within those who contracted COVID-19, differences in rheumatic disease control trends were tested via segmented multilevel, multivariable linear regression, adjusting for month of COVID-19 contraction and with the interruption point set at the point of COVID-19 contraction.
Results: Of 3646 adults with rheumatic diseases, the majority were female (89%), most commonly from the UK (82%) and the most common rheumatic disease diagnosis was RA (63%). Between March and December 2020, 3% of the cohort contracted COVID-19 (n=103).
Over the study period, rheumatic disease control for adults who did not contract COVID-19 decreased weekly by 0.01 points (95% CI 0.01, 0.02, p<0.001). In those who contracted COVID-19, rheumatic disease control decreased weekly by 0.03 points (95% CI 0.2, 0.05, p<0.001), with a significant weekly difference of 0.86 points between groups (95% CI 0.28, 1.44, p=0.004) (Figure 1a).
Within those that contracted COVID-19, there were significant differences in rheumatic disease control trends before and after contracting COVID-19 (p=0.001). In the run up to contracting COVID-19, rheumatic disease control significantly decreased weekly by 0.03 points (95% CI 0.02, 0.04, p<0.001), dropped significantly by 0.53 points (95% CI 0.23, 0.83, p=0.001) at the point of COVID contraction and then stabilised with no further reductions or improvement in rheumatic disease control for the remainder of follow-up (p=0.831) (Figure 1b).
Conclusion: People who contracted COVID-19 had initial decreases in rheumatic disease control before contracting the virus, after which their disease control stabilised at a lower level. Those with disease flares should consider increased screening for COVID-19 and COVID-19 mitigation measures. The stabilising lower disease control post-COVID is concerning and should prompt further work into restoring disease control pre-COVID-19 levels.
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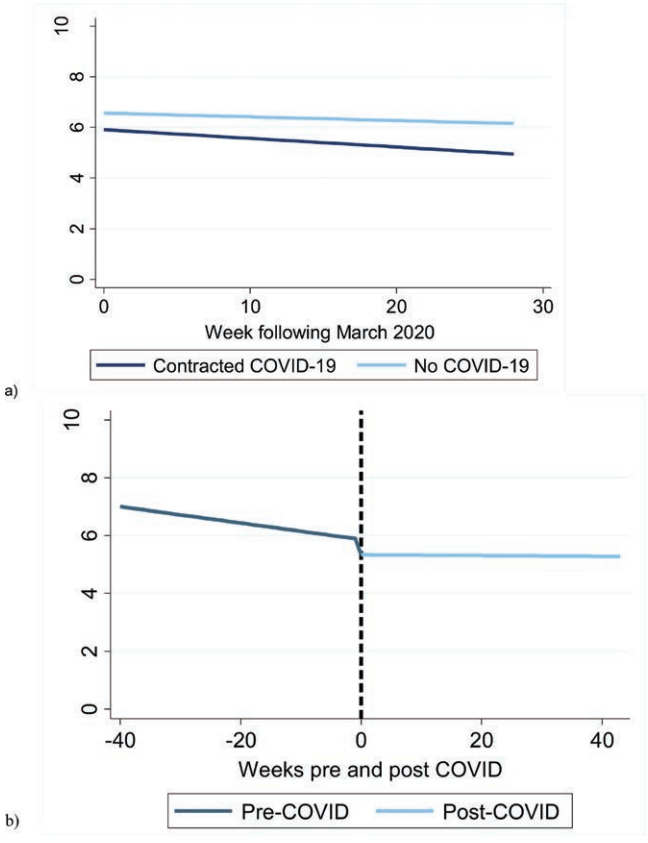


Figure 1. Trends in rheumatic disease control in those who did and did not contract COVID-19 between March and December 2020 a) overall and b) before and after contracting COVID-19

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