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# *Vaccine Hesitancy Decreases in Rheumatic Diseases, Long-term Concerns Remain in Myositis: A comparative analysis of the COVAD surveys*

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**Running title-**

COVID-19 vaccine hesitancy in IIMs between 2021-2022

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***Vaccine Hesitancy Decreases in Rheumatic Diseases, Long-term Concerns Remain in Myositis: A comparative analysis of the COVAD surveys***


**Abstract**

**Background**

COVID-19 vaccines have a favorable safety profile in patients with autoimmune rheumatic diseases (AIRDs) such as idiopathic inflammatory myopathies (IIMs), however hesitancy continues to persist among these patients.

Therefore, we studied the prevalence, predictors, and reasons for hesitancy in patients with IIMs, other AIRDs, non-rheumatic autoimmune diseases (nrAIDs) and healthy controls (HCs), using data from the two international COVID-19 Vaccination in Autoimmune Diseases (COVAD) e-surveys

**Methods**

The 1st and 2nd COVAD patient self-reported e-surveys were circulated from March to December 2021, and Feb-June 2022 (ongoing). We collected data on demographics, comorbidities, COVID-19 infection and vaccination history, reasons for hesitancy, and patient reported outcomes. Predictors of hesitancy were analyzed using regression models in different groups.

**Results**

We analyzed data from 18,882 (COVAD-1) and 7666 (COVAD-2) respondents. Reassuringly, hesitancy decreased from 2021 (16.5%) to 2022 (5.1%) [OR 0.26; 95%CI: 0.24-0.30, p<0.001]. However, concerns/fear over long-term safety had increased [OR 3.6;95% CI:2.9-4.6, p<0.01].

We noted with concern greater skepticism over vaccine science among patients with IIMs than AIRDs [OR:1.8; 95%CI: 1.08-3.2, p=0.023] and HCs [OR: 4; 95%CI: 1.9-8.1, p<0.001], as well as more long-term safety concerns/fear [IIMs vs AIRDs; OR: 1.9; 95%CI: 1.2-2.9, p=0.001; IIMs vs HCs; OR: 5.4 95%CI: 3-9.6), p<0.001]

Caucasians [OR 4.2 (1.7-10.3)] were likely to be more hesitant, while those with better PROMIS physical health score were less hesitant [OR 0.9 (0.8-0.97)].

**Conclusion**

Vaccine hesitancy has decreased from 2021 to 2022, long-term safety concerns remain among patients with IIMs, particularly in Caucasians and those with poor physical function.



**Key words**: COVID-19 vaccines, vaccine hesitancy, autoimmune disease, Idiopathic Inflammatory Myopathies, registries


**Key messages**

1. Vaccine hesitancy has decreased among patients with autoimmune diseases from 2021-2022, though long term safety remains an important concern
2. Patients with IIMs have more long-term safety concerns than other AIRDs, HCs, with Caucasians and those with poor physical function particularly hesitant

***Vaccine Hesitancy Decreases in Rheumatic Diseases, Long-term Concerns Remain in Myositis: A comparative analysis of the COVAD surveys***

## Introduction

The ongoing COVID-19 pandemic has been a significant cause of morbidity and mortality in patients with autoimmune rheumatic diseases (AIRDs) [1]. Data on safety profiles of COVID-19 vaccines in patients with AIRDs, especially rare rheumatic diseases such as idiopathic inflammatory myopathies (IIMs), was scarce in the early stages of the pandemic. However, recent evidence has shown that the benefits of vaccination in reducing the severe outcomes of COVID-19 in this high-risk patient group for severe COVID-19, outweigh the risk of potential vaccine-related adverse effects [2–5]

Nevertheless, vaccine hesitancy continues to be a significant impediment to achieving optimum COVID-19 vaccination in patients with AIRDs, and the reasons for this are poorly understood, especially in rare AIRDs such as idiopathic inflammatory myopathies (IIMs) [6–9].

Data from the COVID-19 Vaccination in Autoimmune Diseases (COVAD) study in 2021 indicated the prevalence of COVID-19 vaccine hesitancy was 15%, and two major associated factors identified were limited data on the long-term safety of vaccines, and fear of vaccine-induced disease flares [7], largely consistent with findings from other studies at that time [8,10,11]. However, since then, data on vaccine safety in AIRDs and their impact on disease flares has increased, mostly indicating a favorable safety profile [2,3,12]. However, there is still a paucity of recent data on the prevalence and reasons for hesitancy in patients with AIRDs.

Understanding the factors contributing to vaccine hesitancy is essential. It would help guide interventions to help mitigate this hesitancy and advance vaccine uptake and protection against severe COVID-19 outcomes in vulnerable groups such as patients with AIRDs, in general, and patients with IIMs, in particular.

Therefore, this study explored the prevalence, reasons, and predictors of vaccine hesitancy among patients with IIMs, other AIRDs, non-rheumatic autoimmune diseases (nrAIDs), and healthy controls (HCs), and compare the differences between the current and the early pandemic period using data from the two global patient COVAD surveys [13,14]

## Methods

### *Study Design*

The COVAD survey is an ongoing international, cross-sectional, multi-center, patient self-reported electronic survey [13]. Participated consented electronically to the online survey after being informed about the survey via a cover letter, in lieu of written consent, as per updated IRB guidelines for health research during the COVID-19 pandemic [15]. We obtained approval from the local institutional ethics committee, and adhered to the Checklist for Reporting Results of the Internet E-Surveys (CHERRIES) when reporting results [16,17]

***Data Collection***

The 36-question baseline validated survey was hosted on the online platform surveymonkey.com and circulated by the international COVAD study group (110 physicians, 94 countries), resulting in the collection of over 19,200 responses from March to December 2021. Data collected included baseline characteristics, COVID-19 infection history and course, AIRD/nrAID details, COVID-19 vaccination details and reasons for hesitancy, as well as patient-reported outcome measures according to the Patient Reported Outcomes Measurement Information System (PROMIS) tool [18]

A more comprehensive and extensive second survey was launched in February 2022 and is ongoing. Additional questions on comorbidities, antibody status, quality of life, and other aspects were included along with the original question set. Survey questions and methods have been detailed in the previously published protocols [13,14]

***Data Extraction***

After excluding respondents with incomplete responses, data were extracted from the second survey on 23rd May 2022. Relevant parameters extracted included demographics, AIRD/nrAID details, patient-reported outcomes, COVID-19 infection history and vaccination details, and reasons for hesitancy.

***Reasons for hesitancy***

All respondents reporting not having received even a single dose of a COVID-19 vaccine received a follow-up question via electronic protocols, asking for the reason for not taking the vaccine.

This was a single-choice question with multiple options, including “My doctor has advised against it”, “Not available to me so far but I plan to take the vaccine as soon as possible”, “I don’t believe in the science behind the vaccine”, “Will not have the vaccine due to long term safety concerns or fear”, “Planning to wait for more time/data regarding safety before I have the vaccine”, “I have scheduled my vaccine but have not received yet”, “Not recommended as I had COVID-19 infection recently”, and “Unsure”. An open-ended option, “Others” was also included in the survey [7,13,14].

***Statistical Methods***

The percentage of vaccine recipients and non-recipients was calculated. Data were presented as numbers (frequencies) and median (inter-quartile range) for categorical and scale variables respectively. Vaccine recipients and non-recipients were compared, using Chi-squared and Mann-Whitney U tests for categorical and scale variables respectively.

Reasons for hesitancy between patients with IIMs, AIRDs, nrAIDs, and HCs were compared. We also compared the reasons for hesitancy in the COVAD-1 and 2 surveys to identify trends over time. Binary Logistic Regression with vaccine uptake as the outcome variable, and adjustment for age, gender, ethnicity, and stratified by country of origin was performed using the backward wald method for factors found significant in the univariate analysis as covariates. The odds ratio (OR) and confidence interval were calculated, P-value was set at $p<0.05$ for statistical significance for univariate analysis. Bonferroni corrected p value$<0.0625$ was considered significant for multivariate regression analysis. Statistical analysis was performed using IBM SPSS version 26.

## Results

### *Baseline demographics and vaccine uptake*

Data from 18,882 respondents from the 1st survey (2021) and 7666 respondents from the 2nd survey (2022), with complete responses, were included in the analysis. In the first survey, 16.5% (n=3109) had not received even a single dose of a COVID-19 vaccine while this had decreased to 5.1% (n=387) in the 2nd survey. (Supplementary Figure 1)

Among the 7666 respondents of the 2nd survey, 7229 (94.9%) had received at least one dose of a COVID-19 vaccine. The median age of both vaccine recipients and non-recipients was similar (45 years) and both groups were similarly female (male: female= 1:2.9, and 1:4.5) and Caucasian (48.6% vs 55.8%) predominant. Comorbidities were common, with chronic liver disease (CLD) [OR 2.7 (1.3-5.3)], and chronic obstructive pulmonary disorder (COPD) [OR 1.9 (1.1-3.3)] being more prevalent among non-recipients. Other population characteristics have been detailed in Table 1.

Of the 387 vaccine non-recipients of the 2nd survey, 69 (17%) were patients with IIM, 179 (46%) were with other AIRDs, 80 (20.6%) with other AIDs, and the rest 59 (15%) were HCs

### *Reasons for hesitancy, and comparison between the two surveys*

It is noteworthy that the proportion of respondents hesitant to take the vaccine significantly decreased from 16.5% (n=3109) in the 1st survey (2021) to 5.1% (n=387) in the 2nd survey [OR 0.26 (0.24-0.3), p< 0.001].

In the first survey, the major reasons for hesitancy included vaccine non-availability (25.6%) and patients planning to wait for more time, and data regarding vaccine safety (23.5%). Reassuringly, vaccine non-availability was far less common a reason in the 2nd survey compared to the 1st survey a year prior [1.8%, OR 0.05 (0.02-0.11)]. Similarly, there was a lower proportion of respondents who had scheduled vaccination but not received it yet [OR 0.1 (0.06-0.3)] (Table 2)

It was concerning to note, however, that the proportion of patients who reported having been advised not to get vaccinated at the time of survey completion by their physician [OR 2.5 (1.8-3.6)] and those reporting long-term safety concerns or fear [OR 3.6 (2.9-4.6)] had increased in the 2nd survey compared to the 1st one (Table 2). Moreover, the patient group advised not to get vaccinated represented a higher percentage of comorbidities than the entire cohort (68.1% vs 43.3%) (Table 3). Other reasons for hesitancy have been detailed in Table 2 Figure 1.

### *Reasons for hesitancy in different groups*

After multivariable regression analysis with baseline adjustment, the reasons for not taking the COVID-19 vaccine hesitancy were largely consistent across patients with IIMs, other AIRDs, nrAIDs, and HCs. The reasons and their proportions in the different sub-groups are detailed in Table 4 and Figure 1.

Patients with IIMs were more likely to be skeptical of the science behind the vaccine compared to other AIRDs [OR:1.8 (1.08-3.2), p=0.023] and HCs [OR: 4 (1.9-8.1), p<0.001], as well as have concerns/fear of long term effects more frequently than both these groups [IIMs vs AIRDs; OR: 1.9 (1.2-2.9), p=0.001; IIMs vs HCs; OR: 5.4 (3-9.6)]. At the time of survey completion, patients with IIMs were

also more likely to be advised not to get vaccinated for COVID-19 by their physician compared to HCs [OR: 12.9 (2.8-5.9), p<0.001] (Table 4 Figure 1)

We noted that even in the 2nd survey, patients with IIM who did not get vaccinated against COVID-19 were more likely to wait for more data regarding the vaccine safety profile compared to HCs [p=0.006] (Table 4 Figure 2)

***Predictors of hesitancy***

Caucasians [OR 4.2 (1.7-10.3)] were more likely to be hesitant to take the COVID-19 vaccine, while those having a lower PROMIS physical health score i.e. better physical health were less likely to be hesitant [OR 0.9 (0.8-0.97)] (Supplementary Table 1**).**

**Discussion**

Studies have shown that patients with AIRDs, such as IIMs, are a high-risk group for severe outcomes of COVID-19, and suggested that the benefits of vaccination in reducing these severe outcomes, outweigh the potential risks of vaccine-related adverse events [2,3,19–24]. Reassuringly, our study found that vaccine hesitancy had reduced more than two-fold between 2021 and 2022, a finding consistent with other similar studies [25]. This may be attributed to greater vaccine availability due to vaccination campaigns, more data on vaccine safety and efficacy profiles, as well as a greater awareness of the possible severe outcomes of COVID-19 and the benefits of vaccines, specifically targeting vulnerable groups. [26–28].

However, tackling residual hesitancy is nonetheless imperative to achieve acceptable levels of global vaccination and herd immunity, especially in light of the emerging strains of the virus and serial waves of recurrence. Current understanding of the factors for hesitancy, especially in the current phase of the pandemic, is still limited, which consequently impairs targeted approaches to encourage vaccine uptake. Patients with IIMs and other AIRDs often require immunosuppressive treatment, including glucocorticoids, for their underlying disease [29]. This is likely to result in fears of disease flares following vaccination [30], in addition to concerns about vaccine adverse effects, the use of new mRNA vaccine technologies, and teratogenicity, among others, in this patient group [11,30,31]. This may explain the cause of long-term safety concerns among most vaccine-non recipients with IIMs revealed by our study findings.

Though the data is still preliminary, the safety profile of mRNA COVID-19 vaccines and COVID-19 vaccination in pregnancy appear to have a favorable risk-to-benefit ratio [32,33]. A study by Rider et al. [12] involving 5,619 patients with systemic rheumatic diseases found that the risk of vaccine-induced disease flares in patients with AIRDs is small, with 4.9% of patients reporting a flare requiring a change of treatment following COVID-19 vaccination. They also found patients with IIMs at a lower risk of flares than other disease groups. However, more long-term, extensive studies are needed to form any firm conclusions.

Consisting with previous studies reporting ethnicity as one of the predictors for COVID-19 vaccine acceptance, our study found that vaccine non-recipients were more likely to be Caucasians [34,35]. Contrasting our findings, a study from Ohio, USA, found that blacks were less likely to accept the COVID-

19 vaccine than whites [35]. This also supports Jacobi and Vaidyanathan [36] found that blacks and Hispanics are less likely to accept COVID-19 vaccines mainly due to mistrust and religiosity than American whites. In Hong Kong, it was found that Filipinos were the most likely to accept COVID-19 vaccines [34]. The contrasting ethnic distribution of vaccine-hesitant patients in our study may be attributed to the growing knowledge of vaccine science and dissemination of information of its adverse effects.

Our study found that patients with better physical function were less likely to be hesitant to be vaccinated against COVID-19. Patients with AIRDs, such IIMs have poorer physical function compared to healthy controls and suffer from worse outcomes following COVID-19 infection, worsened by the comorbidities frequently experienced by these patients [37,38]. This may have prompted fears of adverse effects and disease flares associated with COVID-19 vaccination in these IIMs and other AIRDs patients with poorer physical function, leading to a higher observed hesitancy [39].

Despite being a high-risk group for serious COVID-19 outcomes, our findings showed that higher vaccine hesitancy prevalence was noted in patients with COPD and CLD, aligning with some previous studies [39,40]. It is feasible that individuals with the highest background risk for COVID-19 are also more hesitant to receive vaccination due to the frequent need for healthcare and anxiety around the potential risks. Recent evidence indicated that individuals with autoimmune multimorbidity are at higher risk for vaccine adverse events, though more robust data from long-term studies are needed to provide more information [41]. Therefore, allaying patient concerns in complex scenarios, the elderly, and those with poor physical function and multimorbidity, involving multidisciplinary efforts and counseling support should be a priority of all healthcare systems.

Facing the persisting fear of disease flares, it is challenging for physicians to confidently recommend vaccination to patients with AIRDs, especially in the absence of robust and consistent guidelines that change as new data emerges, conflicting with previous reports. Additionally, in this new age of modern health journalism, as well as rampant misinformation on the often exaggerated, sometimes fictitious risk of adverse effects of COVID-19 vaccines circulating on social media, it's becoming increasingly difficult for physicians and patients to reach a consensus on COVID-19 vaccination decision-making and implementation [43–45]. This might explain our findings that the proportion of patients advised against vaccination had increased in the previous year, and more patients were waiting for more data on vaccine safety than the HCs. This could be attributed to a high number of comorbidities in this group, which reduces the risk-benefit ratio of vaccination and makes it less appealing by treating physicians. Supporting this, we discovered that non-vaccinated respondents had the highest co-morbidity percentage. A proportion of these patients may also represent patients in whom vaccination was contraindicated, such as those with a history of anaphylaxis to a previous vaccine dose or component, or deferred at the time of survey completion and later recommended, such as in patients with AIRDs receiving Rituximab (RTX), in whom the vaccine needs to be held off prior to the next cycle of RTX as per recent guidelines [46–49].

With the emergence of guidelines for relative contraindications of vaccination, there is greater clarity on the approach to individual vaccination risk. It is imperative that physicians and GPs be educated on the absolute and relative contraindications for vaccination, to allow them to take evidence-based informed decisions with the patient in complex scenarios, with specialist support as appropriate.

This also highlights the need to communicate updated, clear, and verified evidence-based quality data on the safety profile of vaccines in AIRDs patients with medical practitioners at all levels, who may

better educate their patients after being informed. Numerous studies have indicated an increase in the willingness of patients to get vaccinated against COVID-19 after their physicians recommended it [6,10,11,48]. Thus, physicians can play a crucial role to curb vaccine hesitancy in patients with AIRDs, and thus, in the long term, cuts the loop of unvaccinated individuals, which is essential to attain herd immunity.

Our study has limitations, including those associated with self-reported surveys, such as the possibility of recall and reporting bias. Dissemination of the survey was not systematic and represents a convenience sample. We targeted our survey to patients with autoimmune diseases in general, and there were no steps taken to make any subgroup of autoimmune disease representative. Considering the inherent profile of patients who can respond to an online survey, low-income patients without internet access, the severely disabled, and the deceased are not represented. Non-recipients who were unable to receive the vaccine due to administrative roadblocks, socioeconomic constraints, and/or religious hesitancy, who may have been included under “Others” in our study, are a priority for future research to enable appropriate and focused interventions to promote vaccine uptake in these patients.

Nevertheless, our study is one of the few in terms of size, ethnic diversity, and global reach to study vaccine hesitancy and its factors in a group of patients with a diverse group of autoimmune disorders, including large numbers of patients with rare disorders, many of which are underrepresented in the current literature, as well as healthy individuals. Another important strength of our study is the anonymized, patient self-reported nature of the questionnaire, with a high rate of completion by respondents, minimizing bias and providing a unique insight into the changing reasons and determinants of vaccine hesitancy for patients with AIRDs. Thus, our study findings and other previous and future studies can help formulate targeted approaches toward combating vaccine hesitancy in this vulnerable patient group. It is important to have a growing and evolving data bank on vaccine hesitancy as future waves of COVID-19 will necessitate health authorities to neutralize the hesitancy points and such studies shall further help in achieving the same.

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