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ORIGINAL ARTICLE

Effects of Covid-19 Infection on Rheumatological Patients Treated with Biological Agents During the Pandemic Process

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Abstract

Introduction: This study aims to assess the progression of infection and vaccine response in patients with rheumatic diseases monitored during the COVID-19 pandemic and compare the findings with data from a control group.

Methods: A total of 106 patients with rheumatic diseases were enrolled, including 63 with ankylosing spondylitis (AS), 42 with rheumatoid arthritis (RA), and 1 with psoriatic arthritis (PsA). The control group comprised 56 participants. We evaluated the participants' demographic characteristics, diagnosis, disease duration, additional systemic diseases, history of COVID-19 infection, the course and severity of infection for those affected, presence of prolonged symptoms, vaccination status, and vaccine side effects.

Results: There were no differences between the patient and control groups in terms of demographic data, vaccination status, COVID-19 experience, and disease duration among those with COVID-19. When compared based on medication use, no significant differences were found in demographic data, vaccination status, and disease duration.

Discussion and Conclusion: When comparing the patient and control groups based on medication use, no significant differences were observed between the groups regarding the frequency of COVID-19, vaccination status before COVID-19 infection, symptoms caused by COVID-19, hospitalization, lung involvement, intubation frequency, need for intensive care, and prolonged post-COVID complaints. The data collected indicate that patients with rheumatic diseases should continue their treatment as usual when they do not have an active infection. The medications they are taking do not pose an increased risk in terms of infection or vaccine-induced immunity.

Keywords: Biological therapies; COVID-19; immunosuppressive therapy; rheumatological diseases; vaccine response.

Since the outbreak in Wuhan, China, in December 2019, the COVID-19 pandemic has resulted in approximately 684 million confirmed cases and 6.8 million reported deaths globally. Considering potential complications and undiagnosed cases, the death toll could be as high as 13.4 to 22.7 million.[1,2] While the main symptoms of COVID-19 include fever, cough, and difficulty breathing, severe cases can progress to pneumonia and heightened inflammatory responses. The disease's immune late complications and long-term COVID syndrome are also increasingly recognized.[3]

During the COVID-19 pandemic, managing rheumatic diseases presented unique challenges. There were concerns about the effects of immunosuppressive therapies on viral immunity and vaccine effectiveness in patients with rheumatic diseases. Both national and international rheumatology research societies suggested limiting or stopping immunosuppressive medications during active COVID-19 infection while recommending the continuation

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of these drugs and disease control for non-infected patients.[4,5] It was believed that the increased inflammation and inappropriate immune response linked to rheumatic/autoimmune diseases, as well as immunosuppressive drug treatments, could pose a risk for severe illness. Therefore, it is important to manage active rheumatic disease as effectively as possible.[6]

It is well established that rheumatic diseases, particularly when treated with biological agents, increase the risk of severe infections. Another well-known fact is that immunosuppressive treatments can alter vaccine responses.[7]

The aim of this study is to evaluate the progression of infection and the effectiveness of the vaccine in patients with rheumatic diseases during the COVID-19 pandemic. Additionally, the study seeks to compare the experiences of patients using biological drugs with those who are not and to compare these observations with data from a control group.

Materials and Methods

In this study, we assessed the vaccine response and COVID-19 exposure among patients with rheumatic diseases under our clinic's care. The outcomes of COVID-19 infection in patients treated with b-DMARDs (biological disease-modifying antirheumatic drugs) for inflammatory rheumatic diseases in our Physical Therapy and Rehabilitation outpatient clinics were examined. These outcomes were compared with those of patients with rheumatic diseases on non-biological treatments (corticosteroids [CS], non-steroidal anti-inflammatory drugs [NSAIDs], and s-DMARDs [synthetic disease-modifying antirheumatic drugs]) and individuals without inflammatory rheumatic diseases.

This study was designed as a cross-sectional survey study. Ethical committee approval was obtained from our hospital's local ethics committee with decision number 2022/246, and written consent was obtained from all participants. The study was conducted in accordance with the Helsinki Declaration.

From February 1, 2023, to August 1, 2023, we conducted a survey among patients with rheumatic diseases who visited our outpatient clinics. The survey collected information on age, diagnosis, disease duration, other existing health conditions, history of COVID-19, severity of COVID-19 if contracted, presence of prolonged symptoms, vaccination status, and vaccine side effects.

The study included patients aged 18 and older, excluding those with conditions causing immunosuppression unrelated to rheumatic diseases (e.g., cancer, organ transplantation, chronic viral diseases) and those with cognitive dysfunction (e.g., dementia). The patients were diagnosed with ankylosing spondylitis (AS) based on the Assessment of Spondyloarthritis International Society (ASAS) criteria,[8-10] rheumatoid arthritis (RA) based on the American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) 2010 Classification Criteria,[11] and psoriatic arthritis (PsA) based on the Classification Criteria for Psoriatic Arthritis (CASPAR).[12]

Statistical Analysis

Quantitative variables were assessed using measures of central tendency and variance: mean±SD (standard deviation). Fisher's exact test and the chi-square test were used for smaller sample sizes to determine differences between ratios or relationships among categorical variables.

For comparisons of group means:

- ANOVA T-test (for groups >2) and Student's T-test (for groups =2) were used when normality and homogeneity of variance assumptions were met.
- Kruskal-Wallis H-test (for groups >2) and Mann-Whitney U-test (for groups =2) were used when these assumptions were not met.

The Bonferroni post-hoc correction method was applied for multiple comparisons between groups. Statistical significance was set at p=0.05. The analyses were conducted using IBM SPSS software package (Statistical Package for the Social Sciences, Version 21.0, Armonk, NY, IBM Corp).

Results

In the study, a total of 106 patients with rheumatic diseases were included, comprising 63 with AS, 42 with RA, and 1 with PsA. Additionally, a control group of 56 participants was included. Among the patients, 53 were using b-DMARDs, 39 were using s-DMARDs, and 14 were undergoing non-DMARD treatments (Table 1).

Table 1. Distribution of Rheumatologic Patients within Groups

Parameter	Condition	n (%) n=106
Medication	b-DMARD	53 (50.0)
	s-DMARD	39 (36.8)
	non-DMARD	14 (13.2)
Diagnosis	AS	63 (59.4)
	RA	42 (39.6)
	PsA	1 (0.9)

b-DMARD: biological disease-modifying antirheumatic drug, s-DMARD: synthetic disease-modifying; antirheumatic drug, DMARD: disease-modifying antirheumatic drug, AS: ankylosing spondylitis, RA: rheumatoid arthritis, PsA: psoriatic arthritis.

There were no significant differences between the patient and control groups in terms of demographic variables, including age, gender, height, weight, body mass index, vaccination status, and disease duration among those who were infected with COVID-19 (Table 2). After analyzing the COVID-19 infection rates, it was found that 27 (51%) patients using b-DMARDs, 9 (23%) patients using s-DMARDs, 3 (22%) patients on non-DMARD treatments, and 22 (39%) individuals in the control group were infected with COVID-19. No statistically significant difference was found between the groups regarding COVID-19 infection (p=0.064).

When evaluated by diagnosis, 28 out of 63 AS patients (44%), 10 out of 42 RA patients (24%), and 22 out of 56 control subjects (39%) were infected with COVID-19. There was no significant difference between the groups in terms of COVID-19 infection rate (p=0.112). When comparing the patient groups based on medication use, there were no significant differences in vaccination status before COVID-19 infection, number of vaccine doses, vaccine side effects, COVID-19 disease duration, COVID-19-related symptoms, hospitalization, lung involvement, intubation frequency, need for intensive care, and post-COVID prolonged complaints (Table 3).

Table 2. Variables Between Groups

	Patient (n=106)	Control (n=56)	p
Age*	51.62±12.1	54.66±16.32	0.16
Gender (Female:Male)	65:41	36:20	0.711
Body Mass Index*	28.37±4.95	27.49±3.61	0.383
Number of Vaccine Doses*	3.17±0.94	3.35±1.02	0.191
Covid-19 Disease Duration*	12.0±11.01	19.85±30.26	0.443

*Mean±Standard Deviation; Mann-Whitney U Test.

Table 3. Differences in COVID-19 Course and Vaccination Status Among Medication Groups

	b-DMARD (n=27)	s-DMARD (n=9)	non-DMARD (n=3)	Control (n=22)	p
Symptom*, n (%)					
Asymptomatic	3 (11)	0 (0)	0 (0)	2 (9)	0.812
Fever	3 (11)	2 (22)	0 (0)	1 (5)	
Headache	2 (7)	2 (22)	0 (0)	3 (14)	
Joint Pain	6 (22)	2 (22)	2 (67)	6 (27)	
Cough	5 (19)	2 (22)	1 (33)	7 (32)	
Loss of Taste/Smell	6 (22)	1 (11)	1 (33)	2 (9)	
Hospitalization*, n (%)					
Yes	3 (11)	1 (11)	0 (0)	3 (14)	1.000
No	24 (89)	8 (89)	3 (100)	19 (86)	
Intensive care admission*, n (%)					
No	27 (100)	9 (100)	3 (100)	21 (95)	1.000
Lung involvement*, n (%)					
Yes	4 (15)	2 (22)	1 (33)	3 (14)	0.782
No	23 (85)	7 (78)	2 (67)	19 (86)	
Intubation*, n (%)					
No	27 (100)	9 (100)	3 (100)	21 (95)	1.000
Prolonged complaints*, n (%)					
Longer than 1 month	6 (22)	1 (11)	1 (33)	1 (5)	0.125
Longer than 3 months	2 (7)	1 (11)	0 (0)	7 (32)	
None	19 (70)	7 (78)	3 (100)	14 (64)	
Vaccination before Covid-19*, n (%)					
Yes	20 (74)	5 (56)	2 (67)	11 (50)	0.247
No	7 (26)	4 (44)	1 (33)	11 (50)	
Number of Doses**					
Mean±SD	3.3±0.91	3.15±0.99	2.71±0.91	3.35±1.02	0.121
Vaccination side effects*, n (%)					
Yes	6 (22)	2 (22)	1 (33)	5 (23)	0.658
No	21 (78)	7 (78)	1 (33)	18 (82)	
Covid-19 disease duration**					
Days	10.88±10.59	13.0±7.45	18.33±23.09	19.85±30.26	0.475

* n (%), Pearson Chi-Squared Test; Fisher Exact Test; **Mean±standart deviation; Kruskal Wallis Test; SD: standart deviation; b-DMARD: biological disease-modifying antirheumatic drug; s-DMARD: synthetic disease-modifying; antirheumatic drug, DMARD: disease-modifying antirheumatic drug.

Table 4. Differences in COVID-19 Course and Vaccination Status Among Diagnostic Groups

	AS (n=28)	RA (n=10)	Control (n=22)	p
Symptom*, n (%)				
Asymptomatic	3 (11)	0 (0)	2 (9)	0.346
Fever	3 (11)	2 (20)	1 (5)	
Headache	1 (4)	3 (30)	3 (14)	
Joint Pain	8 (29)	1 (10)	6 (27)	
Cough	5 (18)	2 (20)	7 (32)	
Loss of Taste/Smell	7 (25)	1 (10)	2 (9)	
Hospitalization*, n (%)				
Yes	2 (7)	2 (20)	3 (14)	0.496
No	26 (93)	8 (80)	19 (86)	
Intensive care admission*, n (%)				
No	28 (100)	10 (100)	21 (95)	1.000
Lung involvement*, n (%)				
Yes	4 (14)	2 (20)	3 (14)	0.803
No	24 (86)	8 (80)	19 (86)	
Intubation*, n (%)				
No	28 (100)	10 (100)	21 (95)	1.000
Prolonged complaints*, n (%)				
Longer than 1 month	5 (18)	2 (20)	1 (5)	0.244
Longer than 3 months	3 (11)	1 (10)	7 (32)	
None	20 (71)	7 (70)	14 (64)	
Vaccination before Covid-19*				
Yes	3.08±0.98	3.31±0.89	3.35±1.02	0.185
No, n (%)	8 (40)	2 (33)	4 (36)	0.883
Number of Doses**, n (%)				
Mean±SD	12 (60)	4 (67)	7 (64)	
Vaccination side effects*				
Yes	9.35±8.6	15.6±10.9	19.85±30.2	0.052

* n (%), Pearson Chi-Squared Test; Fisher Exact Test; **Mean±standart deviation; Kruskal Wallis Test; SD: standart deviation; AS: ankylosing spondylitis; RA: rheumatoid arthritis.

Similarly, when comparing the different diagnostic groups in terms of pre-COVID-19 vaccination status, number of vaccine doses, vaccine side effects, COVID-19 disease duration, symptoms, hospitalization, lung involvement, frequency of intubation, need for intensive care, and prolonged post-COVID complaints, no significant differences were found between the groups (Table 4).

In the comparison of comorbidities and vaccination status

Table 5. Differences in Comorbidity and Vaccination Status Between Diagnosis Groups

	AS (n=63)	RA (n=42)	Control (n=56)	p
Comorbidity*				
Multiple systemic disease	12 (19)	6 (14)	19 (34)	0.001
Hypertension	7 (11)	10 (24)	3 (5)	
Cardiovasculary disease	4 (6)	3 (7)	3 (5)	
None	33 (52)	13 (31)	17 (30)	
Vaccination status*				
Biontech	31 (49)	8 (19)	17 (30)	0.031
Biontech+Sinovac	19 (30)	22 (52)	26 (46)	
Sinovac	12 (19)	9 (21)	12 (21)	
Vaccination side effects *				
Yes	15 (24)	10 (24)	12 (21)	0.883
No	47 (75)	29 (69)	44 (79)	

*n (%) Pearson Chi-Squared Test; Fisher Exact Test; AS: ankylosing spondylitis; RA: rheumatoid arthritis.

between the AS and RA groups and the control group, the comorbidity rate was statistically lower in the AS group compared to the RA and control groups. Regarding vaccination status, the rate of receiving the Biontech vaccine was statistically higher in the AS group compared to the other groups (Table 5).

Among the volunteers in our study, vaccination status was high in both the group of patients with rheumatic diseases (96.2%) and the control group (98.2%). In the rheumatic disease group, 102 out of 106 participants were vaccinated, while in the control group, 55 out of 56 participants were vaccinated.

Discussion

Our controlled cross-sectional survey study included 162 patients who visited our outpatient clinics between February 1, 2023, and August 1, 2023. The control group comprised 56 patients, while the patient group comprised 106 patients. Among the patients with rheumatic diseases, 63 had AS, 42 had RA, and 1 had PsA. The b-DMARD usage rate in the group of patients with rheumatic diseases was 50%, and our medication usage rates were similar to those of other clinics.[13]

In our study, no significant differences were observed between the patient and control groups regarding vaccination status or disease duration among those infected with COVID-19. Similarly, Emmi et al.,[14] in a study involving 458 patients with systemic autoimmune diseases undergoing immunosuppressive therapy, reported no increased risk related to the progression of COVID-19, consistent with our findings.

In a cohort study conducted by Figueroa-Parra et al.,[15] which examined risk factors for severe COVID-19 infection in phenotypic subgroups of RA patients diagnosed with COVID-19, involving 582 RA patients and a control group of 2,875 non-RA patients, the most significant risk factor identified was RA-associated interstitial lung disease. Furthermore, erosive disease and seropositivity were also identified as risk factors for severe COVID-19 infection. The study found a higher incidence of severe COVID-19 among RA patients compared to the control group, which contrasts with our findings. However, the methodology of this study, which included only patients diagnosed with COVID-19, differs from ours, and we attribute the discrepancies in the results to this methodological difference. In our study, we did not observe an increased risk of severe disease in patients with rheumatologic conditions. On the contrary, although not statistically significant, the duration of illness was shorter in the group of patients with rheumatic diseases, with the shortest duration observed in those receiving b-DMARD treatment. Similarly, regarding indicators of severe illness such as lung involvement, hospitalization, and the need for intubation, no differences were found between the rheumatic disease group, including drug subgroups, and the control group.

In a cohort study involving 1,266 patients with systemic rheumatic diseases, Rubbert-Roth et al.[16] reported that 13.6% of patients were unwilling to receive the COVID-19 vaccine, while 32.2% were undecided about vaccination. In a separate study on vaccination, 54% of patients with rheumatic diseases accepted the vaccine, whereas those who declined expressed concerns about potential side effects and disease flare-ups.[17]

In a cohort study conducted between June and November 2021, involving 1,307 patients with RA and systemic lupus erythematosus (SLE), hydroxychloroquine and prednisone were the most frequently used medications, while hypertension and hyperlipidemia were the most common comorbidities. Among this population, none had been infected with COVID-19, and the vaccination rate among individuals with rheumatic diseases was 30.2%, compared to 60.6% in the general population.[18] Of the rheumatic patients, 64.0% were vaccinated with Biontech and 36.0% with Sinovac. The vaccinated cohort tended to be younger, predominantly male, more educated, more likely to be healthcare workers, had fewer comorbidities, and used fewer medications.

Vaccination rates were higher among patients with spondyloarthritis compared to those with SLE. The top three reasons for choosing to be vaccinated were self-protection against COVID-19, protecting others, and contributing to ending the pandemic. Among the 69.8% of participants who were not vaccinated, the primary reasons were fear of side effects, fear of disease flare-ups, and concerns about additional side effects due to the underlying rheumatic disease. In the study, no association was found between the presence of a rheumatic disease or the use of immunosuppressive drugs and the occurrence of vaccine-related side effects in the vaccinated group.

It was therefore concluded that the potential benefits of COVID-19 vaccination in individuals with rheumatic diseases outweighed the possible risks, and vaccination was recommended for this population.

In our study, there was no difference in vaccination status or the number of doses administered between individuals with and without rheumatic diseases. However,

the preference for Biontech was higher in the AS group. Furthermore, the vaccination rate among patients with rheumatic diseases in our study was 96.2%, compared to 98.2% in the control group, which is notably higher than the figures reported in the earlier study.

We attribute this difference primarily to the time gap between the periods of volunteer recruitment in the two studies. By the time our study was conducted, significant advances had been made globally in both vaccine availability and the management of the pandemic, resulting in fewer uncertainties regarding the benefit-risk ratio of vaccines. A secondary explanation could be the absence of more severe and widespread systemic rheumatic diseases, such as SLE and vasculitis, among our patient population.

In our study, 56% of patients using b-DMARDs and 31% of the control group were vaccinated prior to contracting COVID-19. Although this difference was not statistically significant, another study assessing vaccine protection rates in patients using b-DMARDs reported a seroconversion rate of 69.9%, with concerns specifically raised regarding rituximab.[19]

A review examining mRNA vaccine responses in autoimmune rheumatic diseases, which included 60 prognostic studies, 69 case series, and 8 international clinical guidelines, concluded that the use of rituximab, methotrexate, mycophenolate mofetil, systemic glucocorticoids at doses exceeding 10 mg/day, and abatacept, as well as factors such as advanced age and comorbid lung disease, could adversely affect vaccine response after two doses of the mRNA vaccine.[20] The review emphasized that vaccine protection remained relatively high in these special patient groups, and the consideration of additional doses could be beneficial for enhancing protection.

Conclusion

When comparing the patient and control groups concerning the medications used, no significant differences were observed in the frequency of contracting COVID-19, pre-COVID-19 vaccination status, COVID-19-related symptoms, hospitalization rates, lung involvement, frequency of intubation, need for intensive care, or duration of post-COVID complaints.

A comparison of comorbidities, vaccination status, and COVID-19 infection status between the AS and RA groups and the control group revealed a significant difference only in the AS cohort, which showed a greater preference for the Biontech vaccine and a lower prevalence of comorbidities. No other statistically significant differences were noted.

These findings suggest that, in the absence of active infection, the ongoing treatment of patients with rheumatic diseases should continue as per standard protocols, and the medications used do not present an additional risk regarding infection or vaccine efficacy.

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