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The prevalence of COVID-19 in patients with rheumatoid arthritis, multiple sclerosis, or systemic lupus erythematosus receiving biologic disease-modifying antirheumatic drugs

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Abstract

Introduction: The coronavirus disease (COVID-19) became a global pandemic in 2019. Some studies have shown that the virus can cause a higher mortality in people with weakened immune systems, such as the elderly, those taking immunosuppressive drugs, and those with underlying disorders, than in the general population.
Objectives: The aim of this study was to evaluate the prevalence of COVID-19 in patients with rheumatic disorders who received biologic disease-modifying antirheumatic drugs (DMARDs). The effect of precautionary self-isolation in these patients was also determined.
Patients and Methods: This descriptive study involved 200 patients with rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), and multiple sclerosis (MS) who were treated with biologic DMARDs. Patients with symptoms of the coronavirus infection were invited to have a COVID-19 test that involved a COVID-19 IgG antibody test or a polymerase chain reaction (PCR) test (i.e., nasal swab). Additionally, patients were asked about their precautionary self-isolation status during this period.
Results: The mean age of the patients was 51.29 years ± 13.38 years. The ratio of males to females was 27 to 173. Of the 200 patients included in the study, 156 (78%) had RA, 10 (5%) had SLE, and 34 (17%) had MS. Seventy-five percent of the patients used rituximab. Ten patients (5%) were symptomatic of COVID-19, although only four patients had a definitive diagnosis of the disease. All patients who were symptomatic of COVID-19 took rituximab. Ten percent of patients who did not observe the precautionary self-isolation period were diagnosed with COVID-19.
Conclusion: Patients who receive biologic DMARDs have a lower risk of developing COVID-19 and a lower risk of mortality from the disease than the general population.

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Introduction

In December 2019, an outbreak of a novel pneumonia was seen in Wuhan province, China. The disease was caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a new member of the Coronaviridae family, which spread around the world (1). Approximately 15%-20%of patients had severe cases of the coronavirus disease 2019 (COVID-19), which was characterized by a dry cough, headache, dyspnea, fatigue, fever, and lymphopenia. COVID-19 can initiate interstitial pneumonia with alveolar injury, leading to acute respiratory distress syndrome (ARDS) and even death (2–6). Elderly people, people with comorbidities, and those with a deficient immune system have the highest risk of mortality from COVID-19. Patients with autoimmune disorders, such as systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA), not only have a deficient immune system, but also take prescription immunosuppressive medicines

Key point

The prevalence of coronavirus disease 2019 (COVID-19) in patients with rheumatic disorders who received biologic disease-modifying antirheumatic drugs (DMARDs) was studied. The effects of precautionary self-isolation for COVID-19 were also investigated in these patients. Our study showed that the prevalence of COVID-19 in these patients was the same as the prevalence in the normal population.

that render them more vulnerable to infections (7). It is important to establish the association between the risk of COVID-19 and patients with rheumatic diseases in this setting. The rapid and uncontrolled transmission of an infectious disease in patients with rheumatic diseases is concerning because the risk of infection is high in these patients. The immunosuppressive effects of agents, such as corticosteroids or biologic medications, can also increase the risk of infection with COVID-19 due to underlying rheumatic diseases (8).

Another important factor associated with the risk of mortality from COVID-19 is the cytokine storm, which is caused by infection. The use of interleukin-6 (IL-6) blockers tends to be effective in controlling cytokine storms that are associated with pulmonary injury and can result in acute respiratory distress syndrome (ARDS) in SARS-CoV-2 infection patterns (9). According to the National Health Service (NHS), patients receiving biologic therapy are in a high-risk group for acquiring COVID-19; these drugs include rituximab, especially if given in the last 12 months, all anti-TNF medications, Janus kinase (JAK) inhibitors, and tocilizumab, which can suppress the C-reactive protein (CRP) reaction (10). It has not yet been established if there is any correlation between rituximab and the possibility of COVID-19 infection (11). However, immune-suppressive drugs reduce the potency of the immune system, and people with weak immune systems are more likely to develop severe forms of COVID-19. Although these drugs have an anti-inflammatory effect on the body, one of the main pathogenesis of the coronavirus is the inflammatory involvement.

The present study investigated the vulnerability of immune-suppressed patients to severe forms of COVID 19 infection considering the immunosuppressive effect of disease-modifying antirheumatic drugs (DMARDs). Although we might expect an increased prevalence of this infection among patients with rheumatic diseases who are receiving biologic treatments, few DMARDs seem to be effective in controlling the cytokine storm caused by the coronavirus. Thus, the aim of this study was to investigate the prevalence of COVID 19 in three groups of patients with RA, SLE, and multiple sclerosis (MS) who were receiving biologic drugs.

Objectives

This study investigated the effects of precautionary self-isolation in reducing both the prevalence and incidence of COVID-19.

Patients and Methods

Study design

This cross-sectional study involved 200 patients with RA, MS, or SLE who were treated with biologic drugs at the infusion ward of Loghman Hakim hospital, Tehran, Iran (from October 2019 to May 2020). The information on whether patients received rituximab or infliximab since October 2019was extracted from their files. Participants in the study were selected by random sampling from patient lists in the clinic and inpatient ward. Telephone contact was made with the selected patients and a questionnaire was completed. After obtaining informed consent, participants were asked questions about their demographics, medications, comorbidities, the date of their last dose of biologic drug, and their symptoms of COVID-19, including dry cough, shortness of breath, fever, headache, chest pain, sore throat, loss of sense of smell and taste, muscle pain, bruising, fatigue, diarrhea, nausea and vomiting, and abdominal pain. Patients were also asked about their precautionary self-isolation period when they had symptoms of COVID-19. Patients with symptoms were invited to have a COVID-19 antibody test using the GenePro detection kit and\or a lung CT scan. The test results determined whether the patient had COVID-19. The principles of protecting the patient's information and the patient's rights were considered.

Ethical issues

The research followed the tenets of the Declaration of Helsinki. The Ethics Committee of Shahid Beheshti University of Medical Sciences approved the study and all study protocols (IR.SBMU.MSP.REC.1399.307). Written informed consent was obtained from all participants before any intervention. This study was extracted from the rheumatology fellowship/subspecialty thesis of Samaneh Hatami at the university.

Statistical analysis

Quantitative data were presented as the mean and standard deviation. Qualitative data were given as a frequency and percentage. The UpSet plot diagram was used to display information about the patients. Fisher's exact test was used to compare the features and symptoms of the disease among patients with Covid-19 and patients with a negative antibody test and/or lung CT scan. A P value of 0.05 was considered to be significant for the statistical test. Data analysis was performed using software R version 3.6.1 for statistical computing.

Results

Two hundred patients participated in this study: 156 patients (78%) had RA, 10 patients (5%) had SLE, and 34 patients (17%) had MS. The mean age of the patients was 51.29 ± 13.38 years; the youngest patient was 23 years old, while the oldest patient was 80 years old. There were 27 males and 173 females. Most patients were housewives (79.5%). About 7% of patients were smokers. The demographic information of the patients is shown in Table 1.

In terms of treatment, 150 patients (75%) used rituximab, while 50 patients took infliximab; 67% of patients received

Table 1. Demographic features of patients

Demographic features	
Age, mean ± SD	51.29 ± 12.38
Gender, No. (%)	
Women	173 (86.5)
Men	27 (13.5)
Job, No. (%)	
Housewife	159 (79.5)
Freelance	19 (9.5)
Employee	22 (11)
Smoking, No. (%)	13 (6.5)

their last infusion of the biologic drug in 2019. Prednisolone was taken by 75.5% of patients; the prednisolone dose was 10 mg in 1.32% of patients, 5 mg in 79.47% of patients, and 2.5 mg in 18.54% of the patients. Other drugs included hydroxychloroquine, which was taken by 73 patients (36.5%), methotrexate (47.5%), azathioprine (18.5%), tacrolimus (0.5%), and mycophenolate mofetil (1%). Table 2 presents the distribution of patients in terms of treatment.

Table 3 shows the distribution of patients in terms of their underlying disorders. Sixty-three patients (31.5%) had at least one underlying disorder. The most common underlying disorders in patients were as follows; hypertension in 32 patients (16%), diabetes mellitus in 19 patients (9.5%), coronary vascular disease in 12 patients (6%), anemia in 8 patients (4%), hypothyroidism in 7 patients (3.5%), hyperlipidemia in 6 patients (3%), psychological disorders in 6 patients (3%), and pulmonary diseases in 4 patients (2%). Three percent of patients had other disorders: one person had psoriasis, one person had IBD, two people had epilepsy, and two people had cancer.

Four of 10 patients had symptoms of COVID-19. Two patients had a CT scan that showed a typical manifestation of COVID-19 at the first screening, one patient had a polymerase chain reaction (PCR) test (i.e., a nasal swab) that confirmed COVID-19, and another had a serological blood test that confirmed COVID-19. A serological blood test (IgG) was used to confirm COVID-19 in all four patients. Six other patients who exhibited COVID-19 symptoms received a blood serology test, but were negative for COVID-19.

The mean age of the four patients with COVID-19 was 48.25 ± 10.05 years. None of the patients were older than 65 years; one man was 59 years old, and 3 women were 54 years old, 37 years old, and 43 years old. Three patients had RA, and one patient had SLE. Three patients were using rituximab, while one patient was using infliximab. The ratio of the use of rituximab and infliximab was not statistically significant between patients (25% versus 75%, respectively, $P = 0.480$). Of the 50 people who took infliximab, 49 (98%) were not infected with COVID-19. Of 150 people who took rituximab, 147 (98%) were not infected with COVID-19. There was no statistically

Table 2. Distribution of patients in terms of consumption of biologic and other drugs

	Number (%)
Biologic drug	
Rituximab	150 (75)
Infliximab	50 (25)
Last use of biologic drug	
2019	134 (67)
2020	66 (33)
Other drugs	
Prednisolone	151 (75.5)
Hydroxychloroquine	73 (36.5)
Methotrexate	95 (47.5)
Azathioprine	37 (18.5)
Tacrolimus	1 (0.5)
CellCept	2 (1)

Table 3. Distribution of patients by underlying disorders

Type of disorder	Number (%)
Hypertension	32 (16)
Diabetes mellitus	19 (9.5)
Hyperlipidemia	6 (3)
Cardiac disorders	12 (6)
Psychological disorders	6 (3)
Anemia	8 (4)
Pulmonary disorders	4 (2)
Hypothyroidism	7 (3.5)
Psoriasis	1 (0.5)
IBD	1 (0.5)
Epilepsy	2 (1)
Cancer	2 (1)
Other	6 (3)

significant difference between using these drugs and becoming infected with COVID-19 ($P = 0.999$). Regarding other drugs, one patient was taking azathioprine, three patients were taking hydroxychloroquine, three patients were taking methotrexate, and three patients were taking prednisolone. One patient had diabetes mellitus and hyperlipidemia, while another patient had anemia. Figure 1 shows the type of disease, drugs taken, and underlying disorders for the four patients diagnosed with COVID-19.

The mean age of the six symptomatic patients who had a negative antibody test for COVID-19 was 46.33 years ± 18.04 years. The youngest patient was 28 years old, while the oldest patient was 65 years old. There were four females and two males; three patients had RA, two had SLE, and one had MS. All patients took rituximab. In addition, five patients were taking prednisolone, two were taking hydroxychloroquine, two were on methotrexate, two were taking azathioprine, and one was on mycophenolate mofetil. One patient had cancer and one patient had hypertension and diabetes mellitus. Figure 2 shows the type of disease, drugs taken, and underlying disorders for the patients who tested negative for COVID-19, but

exhibited symptoms of the disease.

Figure 3 shows the UpSet plot for the distribution of symptoms in each symptomatic patient, their precautionary self-isolation status, and the result of their antibody test. The four patients who had a positive test for COVID-19 antibodies all had muscle pain, sore throat, dyspnea, and a cough. In addition, one patient had a headache, three patients had chest pain, and two had a fever. A nasal discharge was not observed in any of these patients. Two of the patients were placed in precautionary self-isolation at home; one patient had a family member with COVID-19.

All six symptomatic patients who had a negative test for COVID-19 antibodies were placed in precautionary self-isolation. One patient had a family member with COVID-19. Among these six patients, one had a fever, one had a cough, one experienced dyspnea, one displayed a runny nose, and two had sore throats. None of the patients experienced pain or headaches (Figure 3).

Of 200 patients enrolled in the study, 20 patients (10%) did not observe precautionary self-isolation at home. Among those who did not observe precautionary self-isolation, 2 patients (10%) had symptoms of COVID-19 and had a positive antibody test. Of 180 patients who observed precautionary self-isolation, 8 (4.4%) had symptoms of COVID-19. In other words, 10% of the patients who did not observe precautionary self-isolation tested positive for COVID-19, while the incidence of COVID-19 was 4.4% among patients who complied with precautionary self-isolation. There was no statistically significant difference between the proportion of patients infected with COVID-19 who did not observe precautionary self-isolation and those infected with the disease who observed precautionary self-isolation (10% versus 1%, $P = 0.064$; Figure 4).

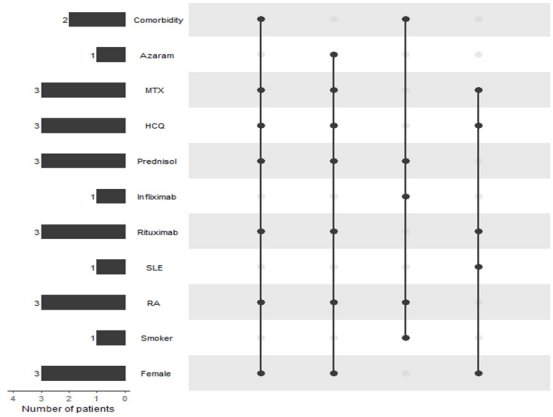

Figure 1. Description of demographic characteristics, type of disease, drugs, and underlying disease of each IgG positive patient. Each vertical bar in the chart represents a patient and the points on the bar represent the presence of a measured variable for that patient. (MTX: methotrexate, HCQ: hydroxychloroquine, SLE: systemic lupus erythematosus, RA: rheumatoid arthritis).

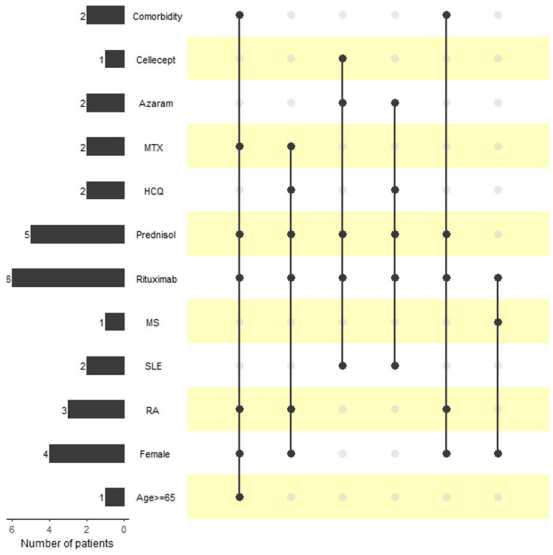

Figure 2. Description of demographic characteristics, type of disease, drugs, and underlying disease of each symptomatic patient with the negative IgG test result. Each vertical bar in the chart represents a patient and the points on the bar represent the presence of a measured variable for that patient. Symptomatic patients had no statistically significant difference with the results of negative and positive antibody tests in any of the factors of age, sex, type of disease, biologic drug and use of other drugs, smoking status, and underlying diseases (all *P* values Were greater than 0.05).

Discussion

The present study found that the most common comorbidities among patients with RA, SLE, and MS

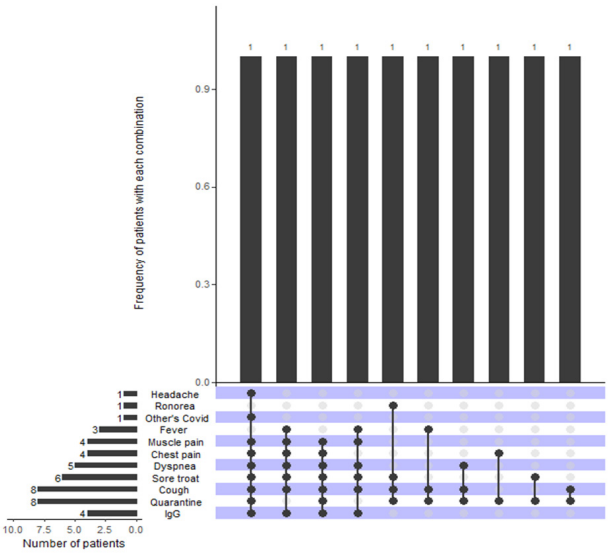

Figure 3. The upset chart show precautionary self-isolation status and symptoms in symptomatic patients based on their antibody test results. Each vertical line at the end of the graph corresponds to one person (4 with a positive antibody test and 6 with a negative antibody test). The frequency distribution of symptoms among patients is shown in the left corner. Each of the circles on the vertical lines indicates the presence of that feature in the person.

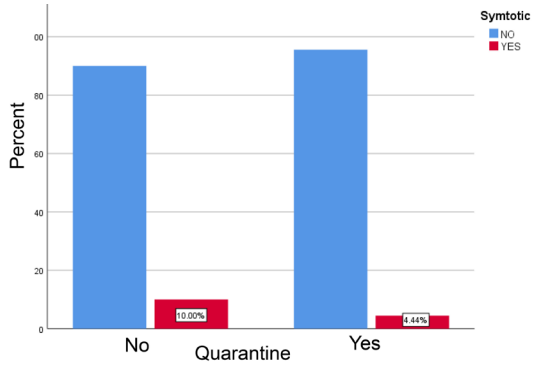

Figure 4. Distribution of symptomatic patients in terms of precautionary home self-isolation.

were hypertension, diabetes mellitus, and coronary vascular disease. Nune et al found that the most prevalent comorbidities in patients with SLE were diabetes and kidney diseases. In their study, Nune et al found that diabetes was the second most common comorbidity, which was similar to the results of the current study in terms of underlying disorders (10).

In this study, 10 patients (5%) reported having one family member with COVID-19. Four patients tested positive for COVID-19. The diagnostic methods used to confirm COVID-19 were a CT scan for two patients, a PCR test for one patient, and a serological test for another patient. Ten patients (5%) were symptomatic; the antibody test for COVID-19 was negative for six patients and positive for four patients, which indicated that they had a definite diagnosis of COVID-19. In their study of 320 patients, Monti et al found that 13 patients were symptomatic of COVID-19. Of these 13 patients, five had contact with people known to have COVID-19, 4 had a positive swab, and four had symptoms of COVID-19. The findings by Monti et al differed from the current study in terms of the diagnostic methods used to detect COVID-19 (12).

Fan et al studied 882 patients with MS who did not receive biologic drugs, and found that only 2 patients developed COVID-19 (13). The researchers concluded that patients with MS were less likely to develop COVID-19 if they did not take biologic drugs. In the present study, we found that the incidence of COVID-19 in patients with MS was low even if they took biologic drugs, such as rituximab. Berger et al also reported that the incidence of COVID-19 in patients with MS who took disease-modifying drugs was low, which agreed with the present study (14).

Tang et al found that dyspnea, headache, and diarrhea were the most common symptoms in patients with SLE who had COVID-19. This result contradicted the result of the present study, which found that muscle pain, sore throat, dyspnea, and a cough were the most common symptoms (15).

In this study, 20 patients (10%) did not observe precautionary self-isolation at home; two of those patients (10%) had COVID-19 symptoms. Among the patients who did observe precautionary self-isolation, 8 (4.4%) had COVID-19 symptoms (P = 0.064). This observation was similar to the results reported by Tang et al who found that precautionary self-isolation reduced the COVID-19 incidence in a normal population (15).

In a study by Gianfrancesco et al, the use of biologic DMARDs was not associated with higher rates of hospitalization for patients with SLE and RA who were diagnosed with COVID-19. The researchers also found that patients who took biologic DMARDs did not have severe symptoms, and only 2% were infected with the coronavirus. There were similarities in terms of the relationship between biologic DMARDs and severe symptoms (i.e., the need for hospitalization) between the study by Gianfrancesco et al and the present study (16).

A study by Gartshteyn et al, mentioned in Columbia, found that the prevalence of COVID-19 in patients with SLE was 2%, and that the hospitalization of these patients was not associated with the use of immunosuppressant drugs. The present study found that the prevalence of COVID-19 in patients with SLE was 1%. In addition, patients who took immunosuppressant drugs had no higher risk for severe COVID-19 symptoms than patients who did not receive this type of treatment. Thus, the study by Gartshteyn et al and the present study had similar results (17).

The current study revealed that the incidence of COVID-19 in patients who had autoimmune disorders, such as RA, SLE, or MS, and who took biologic DMARDs was 2%. This prevalence was identical to the incidence of a positive test for COVID-19 in the general population of New York City, USA. This study showed that patients with RA, SLE, or MS who took biologic DMARDs did not have an increased risk of developing severe COVID-19 (18).

Conclusion

In this study, we found that, of the 200 patients with RA, SLE, and MS who took rituximab or infliximab, only 2% developed COVID-19. These patients also took immunosuppressive and anti-inflammatory drugs, such as hydroxychloroquine and prednisolone. Although some researchers believe that these patients have a higher risk for COVID-19, this study showed that this belief was not true for various reasons, including an adherence to precautionary self-isolation by patients and the use of drugs that reduce inflammation. Other studies have shown that inflammation is a major cause of mortality in patients with COVID-19. This study also showed that the observance of precautionary self-isolation and the drug effect had a significant effect on reducing the incidence of COVID-19 in patients with rheumatic diseases.

Limitations of the study

This study was limited by a lack of cooperation by the

patients. In addition, some patients provided incomplete information about the drugs used. The lack of correct information used to communicate with patients was another limitation.

Acknowledgement

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Authors' contribution

AA and SH were the principal investigators of the study. AA and SH were involved in preparing the concept and design. AA, MME, and FF revisited the manuscript and critically evaluated the intellectual contents. All authors participated in preparing the final draft of the manuscript, revising the manuscript, and critically evaluating the intellectual contents. All authors have read and approved the content of the manuscript, and confirmed the accuracy or integrity of any part of the work.

Conflicts of interest

The authors declare that they have no competing interests.

Ethical considerations

Ethical issues, which include plagiarism, data fabrication, and double publication, have been completely observed by the authors.

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