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Comparison of lung involvement related to COVID-19 infection in patients using sulfasalazine and biological agents diagnosed with ankylosing spondylitis

Ankilozan spondilit tanılı sulfasalazin ve biyolojik ajan kullanan hastaların COVID-19 enfeksiyonuna bağlı akciğer tutulumlarının karşılaştırılması

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ABSTRACT

Objectives: The aim of this study is to examine the lung involvement caused by the SARS CoV-2 factor in patients diagnosed with ankylosing spondylitis using sulfasalazine and biological drugs.

Material and Method: File systems of patients with RT-PCR positive AS diagnosis who have undergone COVID-19 were retrospectively reviewed. Patients with a diagnosis of AS were divided into two groups as those using sulfasalazine and biological agents. Thoracic computed tomography (CT) results of the patients were divided into mild, moderate, severe, bilateral or unilateral. The data were also compared between the patient and control groups.

Results: Of the 58 patients included in the study, 26 were receiving biological agent and 32 were receiving sulfsalazine. Of the patients using DMARD, 17 were receiving adalimumab, 4 etanercept, 2 golimumab, 2 certolizumab, and 1 patient infliximab. Thirteen patients in the AS group had lung involvement due to SARS CoV-2 on thorax computed tomography. It was seen that patients, 9 men and 4 women, were hospitalized due to COVID-19. In 10 patients, involvement due to COVID-19 was found in both lungs.

Conclusion: It is not yet known whether immunomodulatory treatments used in autoimmune and inflammatory rheumatic diseases will affect the course of COVID-19 positively or negatively. In this study, COVID-19 progressed with mild symptoms in patients diagnosed with AS using sulfasalazine and biological agents.

Keywords: Ankylosing spondylitis, COVID-19, sulfasalazine, DMARDs

ÖZ

Amaç: Bu çalışmanın amacı, ankilozan spondilit tanılı sülfasalazin ve biyolojik ilaç kullanan hastalarda SARS CoV-2 faktörünün neden olduğu akciğer tutulumunu incelemek.

Gereç ve Yöntem: COVID-19 geçirmiş RT-PCR pozitif AS tanısı olan ve en az bir yıldır hastanemizde takibi olan hastaların dosya sistemleri retrospektif olarak gözden geçirildi. AS tanısı alan hastalar sülfasalazin ve biyolojik ajan kullananlar olarak iki gruba ayrıldı. Hastaların toraks bilgisayarlı tomografi (BT) sonuçları hafif, orta, şiddetli, iki taraflı ve tek taraflı olarak ayrıldı. Veriler ayrıca hasta ve kontrol grupları arasında karşılaştırıldı.

Bulgular: Çalışmaya alınan 58 hastanın 26'sı biyolojik ajan, 32'si sülfasalazin alıyordu. DMARD kullanan hastalardan 17'si adalimumab, 4'ü etanercept, 2'si golimumab, 2'si sertolizumab ve 1'i infliximab kullanıyordu. AS grubundaki 13 hastada toraks bilgisayarlı tomografisinde SARS CoV-2 nedeniyle akciğer tutulumu vardı. 9'u erkek, 4'ü kadın olan hastaların COVID-19 nedeniyle hastaneye yatırıldığı görüldü. 10 hastada her iki akciğerde de COVID-19'a bağlı tutulum saptandı.

Sonuç: otoimmün ve inflamatuar romatizmal hastalıklarda kullanılan immünomodülatör tedavilerin COVID-19 seyrini olumlu ya da olumsuz etkileyeceği henüz bilinmemektedir. Bizim çalışmamızda sulfasalazin ve biyolojik ajan kullanan AS tanılı hastalarda COVID-19 hafif semptomlarla seyretmiştir.

Anahtar Kelimeler: Ankilozan spondilit, COVID-19, sulfasalazin, DMARDs

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INTRODUCTION

In the epidemic that occurred in Wuhan, China in December 2019, pneumonia developed due to the newly defined SARS CoV-2 factor was defined as Coronavirus disease 2019 (COVID-19) (1). The World Health Organization, the disease in many countries to spread, and many due to lead to the death of people on March 11, 2020 COVIDien-19 has been declared a pandemic on the same date in Turkey have also been reported by the health ministry first COVIDien-19 cases (2,3). The disease-causing SARS CoV-2 is an enveloped RNA virus from the corona virus family. Although it has been shown that the infection is mainly transmitted by droplets and by touching the mucous membranes of the mouth, nose or eyes of the sick people who have touched the floors contaminated with the droplets they emit, the virus has also been found in whole blood, serum, urine and fecal samples (1). The incubation time for virus after exposure is thought to be 2-14 days, and most cases have been found to be symptomatic about 4 to 5 days after exposure. SARS CoV-2 attaches to angiotensin converting enzyme II (ACE2) via the receptor-binding region (RBB) of spike proteins and initiates membrane fusion and thus reaches host cells in humans (4). Clinical findings mostly include gastrointestinal symptoms such as fatigue, fever, cough, myalgia, shortness of breath, nasal congestion, headache, runny nose, sore throat, vomiting and diarrhea (5). The gold standard in the diagnosis of SARS CoV-2 is to show the presence of viral RNA in appropriate clinical samples by real-time reverse transcriptase-polymerase chain reaction (RT-PCR) (6). The World Health Organization (WHO) recommends taking nasopharyngeal and oropharyngeal swab or washing samples together in possible cases, since the virus has more replication in the upper respiratory tract. Identification of COVID-19 infected people who do not have a definitive treatment and vaccine, laboratory diagnosis, treatment, isolation and patient management, including contact surveillance, slowing the spread of the virus, determining infection control strategies and slowing down the pandemic are of great importance (7). Among the causes that negatively affect the course of COVID-19, advanced age, male gender, diabetes mellitus, hypertension and coronary artery disease are among the most common causes (8). Although it is known that inflammatory rheumatic diseases with a rate of 2-3.5% increase the risk of infection, especially in the respiratory system, due to both the relationship with the immune system and the drugs used in their treatment, the course of COVID-19 in individuals with rheumatological diseases has not been clearly determined (9,10). The existence of publications and suggestions supporting the use of some immunomodulators and biological treatments used in the treatment of rheumatological patients in COVID-19 indicates that more studies should be done on these patients (11).

In this study, we aimed to compare the pulmonary involvement of patients with ankylosing spondylitis (AS) diagnosed with sulfasalazine and biological drugs from the inflammatory type rheumatic disease group with COVID-19 individuals who do not have any additional disease.

MATERIAL AND METHOD

This study was approved by Hitit University Clinical Research Ethics Committee (Date: 10.03.2021, Decision No:422). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

The file systems of patients who applied to our hospital between March 2020 and December 2020 and had a diagnosis of RT-PCR positive AS with COVID-19 and had been followed up in our hospital for at least one year were retrospectively reviewed. Permission was obtained from the chief physician of our hospital to enter the hospital automation system. Patients' age, gender, height, weight, additional disease history, medication used for AS, medications used for COVID-19, hospitalization history, thorax tomography results taken in COVID-19 and medical treatments were recorded. In addition, all patients were called by phone and questioned whether they continued their AS treatment before COVID-19 and whether there was postCOVID-19 AS disease activation. Patients with a diagnosis of AS were divided into two groups as those using sulfasalazine and biological agents. Thoracic computed tomography (CT) results of the patients were divided into mild, moderate, severe, bilateral or unilateral. Patients without thoracic CT were not included in the study. The data obtained were compared between both groups. In addition, a control group consisting of 27 age- and gender-matched persons who applied to our hospital on the same date using the hospital automation system, had no chronic disease, had undergone COVID-19, had RT-PCR positive and thorax CT was formed by random assignment method. The data were also compared between the patient and control groups.

Statistical Analysis

Statistical analyzes were made using a package program called SPSS (IBM SPSS Statistics 24). Frequency tables and descriptive statistics were used in the interpretation of the findings. Nonparametric methods were used for measurement values that are not suitable for normal distribution. In accordance with non-parametric methods, the "Kruskal-Wallis H" test (χ2-table value) method was used to compare the measurement values of three or more independent groups. The expected Pearson-χ2 cross tables were used to examine the relationships between two qualitative variables. Binary Logistic Regression: Backward LR model was used to determine risk factors.

RESULTS

Among the patients who had COVID-19, who applied to our hospital between March 2020 and December 2020, 109 patients with a diagnosis of AS were reached. 39 patients were excluded from the study because they did not use any medication for AS and they did not have thorax CT, and 12 patients only used nonsteroidal anti-inflammatory drugs.

Of the 58 patients included in the study, 26 were receiving biological agent and 32 were receiving sulfsalazine. In the group receiving sulfasalazine, 5 patients were taking acemetacin, 2 patients indomethacin, and 3 patients diclofenac sodium, in addition to the treatment. Seventeen patients using DMARD were receiving adalimumab, 4 etanercept, 2 golimumab, 2 certolizumab, and 1 patient infliximab.

It was determined that the mean age of the sulfasalazine group was 44.25±11.21 (years) and the mean BMI was 24.36±3.02 (kg / m²). It was determined that the mean age of the biological agent group was 43.69±11.68 (year) and the mean BMI was 25.00±3.61 (kg / m²).

In terms of comorbidity, the group receiving sulfasalazine included 3 patients with hypertension (HT), 2 patients with diabetes mellitus (DM), 3 patients with familial Mediterranean fever (FMF), 1 patient with Behçet's disease, 2 patients with hypothyroidism, 1 patient with asthma and 1 patient with thyroid papillary cancer.

It was observed that 2 of the 58 patients in the AS group died. One of these patients was in the group receiving sulfasalazine and the other was in the group using biological agents (adalimumab). Both patients were male and the patient who used sulfasalazine had a diagnosis of HT and DM as an additional disease, and the patient who used adalimumab had a diagnosis of DM (**Table 1**).

Thirteen patients in the AS group had lung involvement due to SARS CoV-2 on chest CT. It was seen that patients, 9 men and 4 women, were hospitalized due to COVID-19. Involvement due to COVID-19 was found in both lungs in 10 patients (**Table 2**). Tomography involvements of the patients are shown in **Table 2**.

There was no statistically significant difference between the groups in terms of age, gender, BMI classes, lung involvement and treatment type (p> 0.05). The groups were determined to be homogeneous and independent from each other in terms of the specified characteristics (**Table 3**).

The optimal model is given in **Table 4** as a result of the Backward LR logistic regression analysis made on the basis of the involvement risk using predictive parameters that may have all effects. In the current model; Age (years) was found to be a significant factor affecting the risk of involvement (p <0.05). When age (year) increases by 1 unit, the risk of involvement will increase by 9.1%.

Table 1: Demographic data of patients diagnosed with ankylosing spondylitis with COVID-19 infection

	AS group using sulfasalazine (n=32)	AS group using biological agents (n=26)
Age (years)	44.25±11.21	43.69±11.68
BMI		
Normal	21 (65.6%)	16 (61.5%)
Overweight	10 (31.3%)	7 (26.9%)
Obese	1 (3.1%)	3 (11.6%)
Treatments taken with sulfasalazine		
Acemetacine	5	-
Indomethacin	2	-
Diclofenac sodium	3	-
Biological agent		
Adalimumab		17
Etanercept		4
Golimumab		2
Infliximab		1
Certolizumab		2
Comorbidity		
HT	3	3
DM	2	3
FMF	3	2
Behçet Disease	2	-
Thyroid papillary cancer	1	-
Hypothyroidism	2	2
Asthma	1	
Number of patients who died	1 (Male patient)	1 (Male patient)
Those who stopped AS treatment before COVID-19	-	1 (adalimumab)
PostCOVID AS activation	-	1

HT: Hypertension DM: Diabetes mellitus FMF: Familial Mediterranean Fever

Table 2: History of pulmonary involvement and hospitalization of Ankylosing Spondylitis patients

	n	%
Lung Involvement		
No	45	77.6
Unilateral mild involvement	3	5.2
Bilateral mild involvement	2	3.4
Bilateral middle involvement	4	6.9
Double sided heavy involvement	4	6.9
	Female (n=24)	**Male (n=34)**
No	n.%	n.%
Unilateral mild involvement	20 (83.4%)	25 (73.5%)
Bilateral mild involvement	-	2 (5.9%)
Bilateral middle involvement	2 (8.3%)	1 (2.9%)
Double sided heavy involvement	2 (8.3%)	2 (5.9%)
	-	4 (11.8%)
Home isolation	45	77.6

Hospitalization	13	22.4	

Table 3: Examining the relationships between groups and parameters

	AS group using sulfasalazine (n=32)	AS group using biological agents (n=26)	Control group (n=27)	Statistical analysis* Possibility
Age (years)				
≤40	14 (43.8%)	11 (42.3%)	11 (40.7%)	χ^2=2.553
>40	18 (56.2%)	15 (57.7%)	16 (59.3%)	p=0.862
Sex				
Female	17 (53.1%)	7 (26.9%)	11 (40.7%)	χ^2=4.069
Male	15 (46.9%)	19 (73.1%)	16 (59.3%)	p=0.131
BMI (kg/m²)				
Normal	21 (65.6%)	16 (61.5%)	10 (37.0%)	χ2=6.316
Overweight	10 (31.3%)	7 (26.9%)	15 (55.6%)	p=0.120
Obese	1 (3.1%)	3 (11.6%)	2 (7.4%)	
Thoracic Involvement				
Yes	27 (84.4%)	18 (69.2%)	18 (66.7%)	χ^2=2.860
No	5 (15.6%)	8 (30.8%)	9 (33.3%)	p=0.239
Treatment				
Home isolation	25 (78.1%)	20 (76.9%)	20 (74.1%)	χ^2=0.138
Hospitalization	7 (21.9%)	6 (23.1%)	7 (25.9%)	p=0.933
Hospital stay (days)	11.6	12.8	13.7	χ2=0.168 p=0.853

*χ^2cross tables were used to examine the relationship between two qualitative variables.

Table 4: Logistic Regression model established on the basis of lung involvement risk status

Variable	B	S.H.	Wald	sd	p	OR	95% Confidence Interval (OR)	
Group-Control*			1.849	2	0.397			
Sulfasalazine	-0.982	0.857	1.313	1	0.252	0.375	0.070	2.009
Biological agents	0.057	0.799	0.005	1	0.943	1.059	0.221	5.065
Age	0.087	0.031	7.869	1	0.005	1.091	1.026	1.159
Sex A	-0.352	0.738	0.228	1	0.633	0.703	0.166	2.985
BMI (kg/m²)	0.125	0.098	1.644	1	0.200	1.133	0.936	1.372
Constant	-8.779	3.079	8.132	1	0.004	0.000		

* Reference category + A: Male, B: No, CCR=83,5%χ2 (8)=10,427; p=0,166

DISCUSSION

AS is an inflammatory rheumatic disease and is included in the spondyloarthropathy (SpA) group with similar clinical, radiological, epidemiological and genetic characteristics. While inflammatory back pain, axial skeleton, enthesal and peripheral joint involvement is predominant, lung involvement is rare and apical fibrosis is the most common pulmonary finding (12,13).

Sulfasalazine and anti TNF-α inhibitors (infliximab, etanercept, adalimumab, certolizumab, golimumab) used in the treatment of ankylosing spondylitis are disease modifying drugs (DMARDs), and anti TNF-α inhibitors are the most commonly used biological agents (14,15).

SARS-CoV-2, the agent of COVID-19, first appeared in Wuhan, China and caused pneumonia epidemic worldwide.1 Since inflammatory rheumatic diseases are at high risk for many infectious diseases, including viral infections, SARS-CoV-2 infection has become a concern for these diseases (16).

Due to the fact that SARS-CoV-2 is a new and recently identified virus, information about the risk and clinical course of individuals with inflammatory rheumatic diseases is still insufficient (8,17).

In COVID-19, male gender, diabetes mellitus, hypertension and coronary artery disease are among the most common causes that negatively affect the clinical course (18). In our study, 9 out of 13 patients with pulmonary involvement were men. While severe lung involvement was not detected in female patients, severe lung involvement was found in 4 male patients. In addition, the fact that 2 patients who lost their lives are men, and a history of hypertension and diabetes mellitus support the studies.

In the telephone questionnaire study conducted by Emmi et al. (19) on 458 patients with rheumatological disease, it was reported that 40 patients were diagnosed with spondyloarthropathy and 41% of the patients had a history of using biological drugs. In 7 of 13 patients with suspected COVID-19, the swab test was found to be positive. Symptoms requiring hospitalization were encountered in only one patient with a diagnosis of COVID-19. In general, the prevalence of SARS-CoV-2 infection among patients with systemic autoimmune diseases was reported to be 0.22%, and this rate was reported to be similar to the general population prevalence (0.20%) in the same region. In another study, it was reported that 43% of 320 chronic arthritis cases who received DMARD treatment had spondyloarthropathy, spondyloarthropathy was detected in only one of 4 patients diagnosed with COVID-19, and one was hospitalized. In addition, it was found that none of the 700 patients admitted to the hospital with a diagnosis of severe COVID-19 on the same date did not receive DMARDs (20). In another cohort study conducted by Favelli et al. (21), it was observed that 36.8% of 530 patients with a history of inflammatory disease followed up due to COVID-19 had spondyloarthropathy, and 2 patients, one using infliximab and the other using secukinumab, died with the diagnosis of COVID-19. In this study, it was reported that most individuals with inflammatory diseases had COVID-19 asymptomatic.

There are case reports in the literature reporting that patients who used etanercept and golimumab for the diagnosis of AS had a mild course of COVID-19 (22-24). In our study, there were 4 patients using etanercept and 2

golimumab. A patient using etanercept was hospitalized, but lung involvement was found to be mild.

Studies show that the course of COVID-19 in individuals with inflammatory diseases is similar to the general population. In our study, it was observed that most of the AS cases had a mild course of COVID-19 and were followed up on an outpatient basis. Approximately 22.4% of our patients needed hospitalization. The mortality rate in this patient group was 3.4%. Pulmonary involvement was not found to be more severe than the general patient population. The duration of treatment in the hospital was similar to the control group.

Another important issue in patients with inflammatory rheumatic disease is the decision of whether or not the biological therapy of the patients should be stopped. Considering the data to date, pre-discontinuation of biological therapy is not recommended in patients without signs of SARS-CoV-2 infection (25,26). In patients with a definite diagnosis or a history of SARS-CoV-2 contact, stopping immunosuppressant therapy should be considered (27,28). In our study, it was found that the treatment of a patient using adalimumab before COVID-19 was stopped by the doctor and the same patient had an exacerbation after COVID-19.

CONCLUSION

As a result, it is not yet known whether immunomodulatory treatments used in autoimmune and inflammatory rheumatic diseases will affect the course of COVID-19 positively or negatively. In our study, COVID-19 progressed with mild symptoms in patients diagnosed with AS using sulfasalazine and biological agents.

ETHICAL DECLARATIONS

Ethics Committee Approval: This study was approved by Hitit University Clinical Research Ethics Committee (Date:10.03.2021, Decision No:422).

Informed Consent: All patients signed the free and informed consent form.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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