

## ORIGINAL CONTRIBUTIONS

# Treatment of psoriasis with biologics in the early COVID-19 pandemic: A study examining patient attitudes toward the treatment and disease course

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## Abstract

**Background:** Since March 2020, the coronavirus disease 2019 (COVID-19) pandemic has been ongoing all around the world with a wide range of clinical course including asymptomatic cases to severe and fatal respiratory tract disease. Patients on immunosuppressive treatments were predicted to be more susceptible to COVID-19.

**Aims:** It was aimed to assess treatment continuity, the course of psoriasis and the course and clinical features of COVID-19 in patients treated with biological agents for psoriasis at the early initial period of COVID-19 pandemic.

**Patients/Methods:** Patients treated with biological agents for psoriasis at our institute were contacted by phone between 1 and 10 July 2020 and fulfilled a questionnaire about their continuity to psoriasis treatments, clinical course of psoriasis, and any suspicion/diagnosis of COVID-19.

**Results:** A total of 106 patients, 41 females and 65 males, were enrolled. Mean age of the patients was  $46.1 \pm 12.1$  years (range: 19–77). Median duration of psoriasis was 18 years (min–max: 1 month–51 years). Twenty-four patients (22.6%) were using tumor necrosis alpha inhibitors (ETA:1, IFX:19, ADA:4), whereas 82 patients (77.4%) were using interleukin (IL) 12/23 or IL-17 inhibitors (UST:48, SECU:30, IXE:4). Seventy-six patients (71.7%) continued the treatment, whereas 30 patients (28.3%) interrupted the treatment voluntarily. Twenty out of 30 patients (66.6%) who interrupted the treatment had an exacerbation of psoriasis. None of the patients were diagnosed with COVID-19 in the study period.

**Conclusion:** Patients with psoriasis who received biological therapy continued their treatment at a high rate during the early period of the COVID-19 pandemic. No COVID-19 diagnosis was made among patients whether they continued or discontinued treatment. Recurrence and exacerbation of psoriasis in a significant proportion of patients who interrupted treatment and absence of COVID-19 diagnosis in each group support the importance and safety of continuity of biological treatments for psoriasis in COVID-19 era.

## KEYWORDS

biologics, COVID-19, drug continuity, pandemic, psoriasis, safety

## 1 | INTRODUCTION

COVID-19 is a viral respiratory tract infection caused by a new coronavirus, named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).<sup>1</sup> The disease, which emerged in Wuhan, China at the end of 2019, spread around the world in a short time and the World Health Organization (WHO) declared the COVID-19 pandemic in March 2020.<sup>2</sup> The disease has a fairly wide clinical spectrum, including asymptomatic infection, mild upper respiratory disease, respiratory failure from severe viral pneumonia, hyperinflammatory syndrome, and even death.<sup>3,4</sup> The presence of conditions such as advanced age, male gender, smoking, obesity, hypertension, diabetes mellitus, cardiovascular diseases, cerebrovascular diseases, chronic obstructive pulmonary disease (COPD), malignancy, and HIV infection are indicated as risk factors for severe disease.<sup>3,5,6</sup>

Psoriasis is a chronic and systemic inflammatory disease that affects approximately 2–3% of the general population.<sup>7</sup> Management of psoriasis is a complicated process; since it has been frequently associated with systemic inflammatory comorbidities including arthritis, metabolic syndrome, cardiovascular diseases, diabetes mellitus, obesity, and inflammatory bowel disease.<sup>8,9</sup> Biological immunomodulatory agents targeting the inhibition of cytokines such as tumor necrosis factor alpha (TNF- $\alpha$ ), interleukin (IL) 17, IL 12/23, and IL 23 are also used successfully in selected moderate-to-severe psoriasis.<sup>10</sup> Although biological agents do not have cumulative organ-specific toxicities, they are known to predispose various infections, especially upper respiratory tract infections just as older conventional agents including methotrexate (MTX) and cyclosporine.<sup>11</sup> Therefore, COVID-19 pandemic has raised significant concern on severe psoriasis management due to presence of common inflammatory comorbidities as well as the immunosuppressive and immunomodulatory agents used in its treatment. Lack of clinical evidence and outcome reports especially during the initial period of the pandemic led both physicians and patients to experience the dilemma of potentially fatal SARS-CoV-2 infection risk to psoriasis exacerbation and/or secondary ineffectiveness to treatment which may occur as a result of interruption of treatment. In the light of observational studies during the pandemic period, discontinuation/withdrawal or dose reduction of biological agents is not recommended in the management of patients with psoriasis unless a COVID-19 documentation is made.<sup>12</sup> In this study, it was aimed to assess treatment continuity, the course of psoriasis and the course and clinical features of COVID-19 in patients treated with biological agents for psoriasis at the early initial period of COVID-19 pandemic.

## 2 | MATERIALS AND METHODS

Patients treated with biological agents for psoriasis at our institute were contacted by phone between 1 and 10 July 2020 and fulfilled a questionnaire about their continuity to psoriasis treatments, clinical course of psoriasis, and any suspicion/diagnosis of COVID-19. Demographical data, systemic comorbidities, clinical course of

psoriasis during the first 4 months of the pandemic, the type and continuity of biological agents and the suspicion or the diagnosis of COVID-19 including the clinical course were recorded for each patient.

During the early initial period of COVID-19 pandemic, patients who reached our department were advised to strictly comply with the COVID-19 protection measures recommended by WHO and Turkish Ministry of Health, and if necessary rest reports were written. With the first data from the observational studies, as there was no evidence of an increased risk of serious infection with SARS-CoV-2 who received biological treatment, our patients were informed and advised to continue to the treatment if there were no signs of SARS-CoV-2 infection.

### 2.1 | Statistical Analysis and Ethics

Statistical analyses were performed using the SPSS software version 22. The variables were investigated using visual (histograms, probability plots) and analytical methods (Kolmogorov-Smirnov/Shapiro-Wilk test) to determine whether or not they are normally distributed. Descriptive analyzes were presented using means and standard deviation for normally distributed variables, and median and interquartile range (IQR) for non-parametric variables. Categorical variables were summarized as frequencies and percentages. The chi-square test was used to compare the exacerbation ratio of psoriasis between the groups that discontinued and continued treatment. A *p*-value of less than 0.05 was considered to show statistically significant results.

All procedures were performed in accordance with the ethical principles of the Helsinki Declaration. After having received a complete description of the study, patients provided recorded verbal consent.

## 3 | RESULTS

A total of 106 patients, 41 females (38.6%) and 65 males (61.3%), were included in the study. The mean age of the patients was  $46.1 \pm 12.1$  (range 19–77 years), and the median duration of disease was 18 years (IQR 10–25.5 years). Five patients were 65 years or older. The demographic characteristics of the patients, the treatments they used and the continuation of treatment are summarized in Table 1. *N* = 24 (22.6%) patients were using TNF- $\alpha$  inhibitors [infliximab (IFX): 19, adalimumab (ADA): 4, etanercept (ETA): 1] whereas *N* = 82 (77.4%) were using IL12/23 or IL-17 inhibitors [ustekinumab (UST): 48, secukinumab (SECU): 30, ixekizumab (IXE): 4]. Fourteen patients (13.2%) were receiving MTX treatment in addition to biological therapy.

### 3.1 | Risk factors for COVID-19

Nine patients (8.4%) stated that they did not comply with the recommendations for protection from COVID-19 because of their

**TABLE 1** Demographic characteristics, treatment continuation, and disease activation status of patients

Demographic characteristics	All patients (n = 106)
Female, n (%)	41 (38.6)
Male, n (%)	65 (61.3)
Smoking, n (%)	
None	33 (31.1)
Ex-smoker	27 (25.5)
Smoker	46 (43.4)
Age, year, mean $\pm$ SD (range)	46.1 $\pm$ 12.1 (19–77)
Disease duration, year, median (IQR)	18 (10–25.5)
BMI, mean $\pm$ SD, (range)	28.4 $\pm$ 5.2 (19.5–49.5)
BMI <18.5, n (%)	0 (0)
BMI 18.5–24.9, n (%)	27 (25.4)
BMI 25–29.9, n (%)	45 (42.4)
BMI $\geq$ 30, n (%)	34 (32.1)
Any comorbidity <sup>a</sup> , n (%)	89 (83.9)
<b>Treatments</b>	
Anti-TNF, n (%)	24 (22.6)
INF, n (%)	19 (17.9)
ADA, n (%)	4 (3.7)
ETA, n (%)	1 (0.9)
Other biologic agent, n (%)	82 (77.4)
UST, n (%)	48 (45.2)
SEKU, n (%)	30 (28.3)
IXE, n (%)	4 (3.7)
Additional MTX, n (%)	14 (13.2)
<b>Treatment continuation and disease activation</b>	
Treatment continuation, n (%)	76 (71.7)
Disease activation, n (%)	25 (23.5)
In patients who discontinue treatment	20 (18.8)
In patients continuing treatment	5 (4.7)

<sup>a</sup>Any comorbidity described as presence of at least one of the following: diabetes mellitus, hypertension, obesity, smoking, or being an ex-smoker.

profession. Of whom 2 were chefs, 2 were police officers, 2 were engineers, 1 was sales consultant, 1 was painter, and 1 was a shopkeeper. One patient had contact with another person with COVID-19 and 2 patients had suspected COVID-19 due to their complaints, but no patient was diagnosed with COVID-19 during this time. Thirty-three patients were non-smokers (31.1%), 27 patients were ex-smokers (25.5%), and 46 patients (43.4%) were smokers. The mean body mass index (BMI) of the patients was 28.4  $\pm$  5.2 (range 19.5–49.5). Thirty-four patients (32.1%) had obesity (BMI  $\geq$ 30). A total of 89 patients (83.9%) had diabetes mellitus, hypertension, obesity, and/or being smoker or ex-smoker.

### 3.2 | Treatment attitudes

Seventy-six patients (71.7%) continued the treatment they were using, while 30 patients (28.3%) interrupted the treatment voluntarily. Of the patients who interrupted the treatment, 14 were female (46.6%) and 16 were male (53.3%). Of the 25 patients (23.5%) who stated an exacerbation of psoriasis during the pandemic period, 20 (18.8%) had interrupted the biological therapy, and 5 (4.7%) experienced an exacerbation while continuing the treatment. Twenty (66.6%) of the 30 patients who interrupted the treatment had exacerbation. The rate of exacerbation was significantly higher in patients who interrupted treatment than those who continued their treatments ( $p < 0.0001$ ).

## 4 | DISCUSSION

The COVID-19 pandemic caused by the new SARS-CoV-2 virus has led to numerous infections and deaths worldwide.<sup>13</sup> Patients on immunosuppressive therapies are generally more prone to infections. In a meta-analysis of 62 studies involving 319,025 patients using conventional disease-modifying agents (csDMARDs), biologics or targeted synthetic DMARDs (b/tsDMARDs); prevalence of COVID-19 was found to be increased in patients with autoimmune diseases. Risk and severity of COVID-19 were increased with glucocorticoids, csDMARDs and b/tsDMARDs–csDMARDs combination therapy whereas the risk of severe COVID-19 reduced with b/tsDMARDs monotherapy and particularly with anti-TNF therapy.<sup>14</sup> Currently, biological and non-biological systemic treatments of psoriasis are accepted to not pose an increased risk of SARS-CoV-2 infection and /or an increased risk of hospitalization and death compared to the normal population.<sup>15–17</sup> Moreover, rate of hospitalization due to COVID-19 in psoriasis patients receiving biological therapy was lower than those receiving conventional systemic therapies.<sup>18</sup> Thus, even when there was not enough evidence in the earlier period of the pandemic, the majority of patients who informed by phone calls decided to continue to the treatment and did not experience an increased COVID-19 rate compared to those who stopped treatment.

The risk-mitigating behaviors of patients with psoriasis who use biological agents are reported to be greater than those who use non-biological systemic therapy and those who do not use systemic therapy.<sup>18,19</sup> In a study including 1626 patients with psoriasis by Mahil et al., compliance with social or individual isolation measures was reported as 72% in patients with psoriasis using biological agents, and 63% in patients using non-biological systemic therapy and not using systemic therapy.<sup>18</sup> In the same study, the rate of those who did not comply with general virus protection measures was reported as 0.4% in patients with psoriasis using biological agents whereas 0.8% using non-biological systemic therapy and 0.9% in patients not using systemic therapy. In our study, 8.4% ( $N = 9$ ) of our patients stated that they could not comply

with general SARS-CoV-2 protection measures. According to the Ministry of Health COVID-19 Situation Report at 30 June 2020, there were 186.8 COVID-19 cases per 100,000 population in the Western of Central Anatolia region, which includes Ankara, Konya, and Karaman provinces.<sup>20</sup> In the same time period, COVID-19 was not observed in any of 106 patients who used biological therapy for psoriasis in our study. This finding may be related to the biological treatment of psoriasis that does not pose an increased risk of COVID-19 and/or the increased preventive behavior of the patients.

Psoriasis is a common chronic and systemic inflammatory disease with both physical and psychosocial burden.<sup>21,22</sup> It has been shown that the quality of life in psoriasis patients is affected as much as other principal chronic diseases such as cancer and diabetes including physical and psychological evaluations.<sup>10</sup> Indeed, this is reflected in patients' risk tolerance behavior for better treatment responses.<sup>23</sup> In the study by Fairchild et al., including 927 patients with psoriasis; it was reported that 72% of the patients were willing to accept the higher risks of infection-related mortality associated with treatment in order to completely remove the plaques covering only 1% of the body.<sup>24</sup> In another study of Mahil SK et al, the rate of discontinuation of treatment due to pandemic was reported as 17% in patients with psoriasis using biological agents, and 20% in patients using non-biological systemic agents.<sup>18</sup> In a study from Turkey, 61% of 133 patients with psoriasis and receiving biological therapy were reported to continue to their treatment.<sup>25</sup> Similarly, in our study, approximately 72% of the patients who received biological therapy for psoriasis continued to the treatment at the initial period of the COVID-19 pandemic which represents the most uncertain period in terms of biological treatment risks. This suggests that psoriasis is an important disease for patients to take some risks including a fatal infection. In addition, we believe that being easily accessible by all our patients and being informed with self-sacrifice contributes to the treatment compliance of our patients in this period.

The treatment duration is predicted to be long-term due to the chronic repetitive nature of psoriasis. Although research on discontinuation or dose reduction of biological therapies after disease remission continues, the optimal duration of use for biological therapies is currently not specified.<sup>26</sup> In real-life data, discontinuation of biological therapies is often reported to be due to ineffectiveness or loss of efficacy over time.<sup>27</sup> In addition, low-dose and intermittent use of biological therapies are not recommended because of the risk of secondary ineffectiveness due to the development of neutralizing antibodies.<sup>28</sup> In a study by Huang et al, 86.1% of the patients required systemic treatment and 41.9% required re-biological treatment within the first 12 months following the discontinuation of biological therapy.<sup>29</sup> In our study, approximately 67% of the patients who interrupted biologics reported an exacerbation. Considering the lower psoriasis exacerbation rate with adherence to biological therapy and the reported finding of not increasing risk of SARS-CoV-2 infection and/or hospitalization

and death with biological agents, we also consider to continue biological treatments unless presence of COVID-19 symptoms and signs. Psychological stress is known to be a major risk factor for psoriasis exacerbation and is thought to be the major impact in our small group of patients with exacerbations who were still continuing treatment.<sup>30</sup>

Psoriasis is associated with systemic inflammatory comorbidities such as diabetes, obesity, hypertension, chronic heart disease, and COPD, which are thought to increase the mortality and morbidity of COVID-19.<sup>31,32</sup> In the meta-analysis performed by Zhang et al., severe COVID-19 was more common in patients with diabetes mellitus, hypertension, cardiovascular diseases, malignancy, cerebrovascular diseases, COPD, HIV infection and especially in ex-smokers.<sup>5</sup> The fact that an important group of our patients have at least one of the conditions (89%) associated with severe COVID-19 warrants severe COVID-19 risk. Fortunately, none of the patients developed COVID-19 during the study period thus we cannot make an evaluation between these comorbidities and the severity of infection.

Continuation of biological treatments in more than 70% of the patients with moderate-to-severe psoriasis even during the onset of the pandemic indicates that psoriasis is a serious debilitating disease affecting the risk tolerance behavior of the patients. Precise orientation, consultation, and guidance of patients by physicians contribute to major treatment compliance. Adherence to biological therapy is associated with a significant lower exacerbation rate thus supporting patients for continuing their treatments with prevention measures is mandatory.

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None

#### CONFLICT OF INTEREST

We declare that there is no conflict of interest of all authors in this work.

#### AUTHOR CONTRIBUTIONS

Basak Yalici-Armagan, Sibel Dogan Gunaydin, Duygu Gulseren, Neslihan Akdogan, Nilgun Atakan contributed to the study conception, design and critically revision of the manuscript. Gulsun-Hazan Tabak acquired the patient data and Basak Yalici-Armagan drafted the manuscript; she is the study guarantor.

#### ETHICAL APPROVAL

The study was approved by Hacettepe University Non-interventional Clinical Researches Ethics Board (06/23/2020 - GO 20/612) and Turkish Ministry of Health (06/12/2020 - 2020-06-08T15\_36\_57).

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