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Seroconversion after anti-SARS-CoV-2 mRNA vaccinations among moderate-to-severe psoriatic patients receiving systemic biologicals—Prospective observational cohort study

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Abstract

It is unclear whether biological antipsoriatic therapies affect seroconversion after messenger ribonucleic acid (mRNA)-based antisevere acute respiratory syndrome coronavirus 2 (anti-SARS-CoV-2) vaccinations. To assess antibody formation and the incidence of side effects after anti-SARS-CoV-2 mRNA vaccinations in psoriatic patients receiving different biologicals compared to healthy controls. 102 moderate-to-severe psoriatic patients (56.2 [±13.5] years) and 55 age-matched healthy (56.4 ± 13.6 years) volunteers were included in our study. Ten to 21 days after the administration of the second dosage of BNT162b2 or mRNA-1273 vaccine, antibody levels specific to the SARS-CoV-2 spike (S) protein receptor binding domain were monitored. The incidence of postvaccination side effects was recorded and compared to real-life data in the literature. Of the 102 patients, 57 (55.88%) received tumor necrosis factor (TNF), 28 (27.45%) received interleukin (IL)-12/23, 16 (15.68%) received IL-17, and 1 (0.99%) received IL-23 inhibitors. No significant differences in the median serum level of anti-SARS-CoV-2S antibody were observed between the study population and the control group (median IQR range: 1681.0 U/mL (600.0–4844.0) versus 1984.0 U/mL (1000.0–3136.0; $p = 0.82$). The most frequent side effects of the mRNA vaccines within 7 days after the administration of both dosages were arm pain on the side of injection (23.53% and 23.53%), fatigue (9.80% and 13.72%), headache (4.9% and 5.88%), and chills or shivering (4.9% and 8.82%). Detectable antibodies against SARS-CoV-2S protein appear 10–21 days after the administration of the

ABBREVIATIONS: ACE-2, angiotenzin converting enzyme-2; COVID-19, coronavirus disease-19; DLQI, dermatology life quality of index; EMA, European Medicines Agency; Ig, immunoglobulin; IL, interleukin; IQR, interquartile range; MERS, Middles East respiratory syndrome; mRNA, messenger ribonucleic acid; MTX, methotrexate; PASI, psoriasis area severity index; PCR, polymerase chain reaction; PsoProtect, Psoriasis Patient Registry for Outcomes, Therapy and Epidemiology of COVID-19 Infection; RBD, receptor binding domain; REDCap, Research Electronic Data Capture; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SARS, severe acute respiratory syndrome; S, Spike; ssRNA, single-strand ribonucleic acid; TNF, tumor necrosis factor.

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second dosage of BNT162b2 or mRNA-1273 vaccines in moderate-to-severe psoriatic patients receiving biologicals, similar to those of healthy controls.

KEYWORDS
biologic therapy, mRNA vaccine, psoriasis, SARS-CoV-2, seroconversion

1 | INTRODUCTION

Coronavirus diseases, such as severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS), have appeared in the last decade, mainly in East Asia and the Middle East. In December 2019, a novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), emerged in Wuhan, China, causing coronavirus disease 19 (COVID-19), and it has steadily progressed into a global pandemic.[1]

A large amount of data is already available about comorbidities, which lead to a poor outcome of COVID-19.[2–4] Compared to the general population, psoriasis does not increase the risk of SARS-CoV-2 infection.[5,6] However, psoriasis is often accompanied by several other comorbidities, such as metabolic syndrome and cardiovascular diseases, which on their own result in a poor COVID-19 outcome in the general population.[7] Data from 374 clinician-reported patients with psoriatic disease who were diagnosed with confirmed or suspected COVID-19 from 25 countries were registered in an international registry called Psoriasis Patient Registry for Outcomes, Therapy and Epidemiology of COVID-19 Infection (PsoProtect). Seventy-one percent of the population received biological therapy, 18% received traditional systemic therapy, and 10% did not receive any systemic treatment. A total of 83.4% of the patients treated with biologicals were not hospitalized, and 95.1% showed full recovery. This patient group showed the lowest rate of hospitalization and the highest rate of full recovery.[8]

Vaccination programme is an effective way to reduce the pandemic and subsequently eradicate the virus. A number of vaccine developments has been launched worldwide. Due to the emergency, the registration of vaccines was conducted under an accelerated procedure by the European Medicines Agency (EMA). Elderly adults and individuals with several comorbidities were among the first to receive vaccinations because these proportions of the population are at a greater risk of acquiring SARS-CoV-2 infection and associated death.

Based on the most recent literature, systemic biological treatments for psoriasis and psoriatic arthritis do not increase the risk of SARS-CoV-2 infection and COVID-19 complications.[9–11] The majority of the literature includes case reports; however, an analysis was performed involving 1400 patients from different fields of medicine (gastroenterology, rheumatology, and dermatology) and concluded that biologicals and disease-modifying antirheumatic drugs do not affect the severity of COVID-19 outcomes.[4]

Published data on the efficacy of the different vaccines against SARS-CoV-2 infection among patients with psoriatic disease undergoing systemic biological treatments are limited.[12–14] It is not clear whether systemic biological therapy alters antibody formation (seroconversion) after anti-SARS-CoV-2 vaccination. Methotrexate (MTX) therapy significantly reduces the response rate to pneumococcal vaccine compared to placebo or etanercept treatments in patients with psoriatic arthritis.[15] In a cohort study, the authors observed seroconversion 28 days after the administration of the first dose of BNT162b2 vaccination among 84 patients with psoriatic disease treated with anti-tumor necrosis factor (anti-TNF), anti-interleukin (anti-IL)-17, anti-IL-23 therapy or MTX. Lower rates of seroconversion were observed in patients receiving systemic treatments than in controls, with the lowest rate observed in patients receiving methotrexate. Cellular immune responses were induced in all groups.[16]

In this study, the authors' aim was to investigate anti-SARS-CoV-2S antibody levels after the administration of the second dose of the anti-SARS-CoV-2 messenger ribonucleic acid (mRNA) [BioNTech/Pfizer Comirnaty® (BNT162b2) or Moderna COVID-19 Spikevax® (mRNA-1273)] vaccinations among patients with moderate-to-severe psoriatic disease who were treated with systemic biological antipsoriatic therapies. Both mRNA vaccines trigger the immune system, which results in temporary expression of the SARS-CoV-2 spike protein in human cells. The Pfizer vaccine conferred 95% protection and the Moderna vaccine conferred 94.5% protection against COVID-19.[17,18]

Data on the development and maintenance of antibody formation after anti-SARS-CoV-2 vaccination are limited to a large number of patients with psoriatic disease receiving systemic biological therapies. Here, the authors publish the interim analysis of their results obtained in 102 psoriatic patients.

2 | MATERIALS AND METHODS

This paper provides the first preliminary analysis of our multicenter prospective observational cohort study. The enrollment of patients started in February 2021 at the Department of Dermatology, Venereology and Dermatooncology of Semmelweis University, Budapest, Hungary. All enrolled patients were informed about the specific study procedures and signed the patient consent forms. The study was funded by the grant Investing in the Future Fund: "National level adjustments to the challenges of the SARS-CoV2 pandemic on blood banking operations", ID No: 2020–1.1.6-JÖVŐ-2021-00010.

2.1 | Ethics

This study protocol was reviewed and approved by the Medical Research Council Scientific and Research Ethics Committees,

Budapest, Hungary (approval number: IV/861–1/2021/EKU, date of approval: January 27, 2021) and meets all requirements of the Declaration of Helsinki. Patients provided written informed consent to participate and donate blood for the purpose of our study.

2.2 | Study design

This multicenter study investigated a prospective cohort of immunocompromised patients to assess the characteristics of the seroconversion rate and follow the permanence of antispike protein levels in patients receiving different systemic immunosuppressive therapies after anti-SARS-CoV-2 vaccination according to the national protocol. The following departments/clinics of Semmelweis University are participated in this study: Department of Dermatology, Venereology and Dermatooncology, Department of Surgery, Transplantation and Gastroenterology, 1st Department of Surgery and Interventional Gastroenterology, Heart and Vascular Centre, Department of Rheumatology and Clinical Immunology, Department of Pulmonology as well as the Rheumatology Centre of Buda Hospital of the Hospitaller Order of Saint John of God.

Here, a preliminary analysis of patients with psoriatic disease, who were treated with different systemic biological therapies and vaccinated with anti-SARS-CoV-2 mRNA vaccines, was reported from the Department of Dermatology, Venereology and Dermatooncology.

One hundred and two adult patients were enrolled consecutively in the study. The inclusion criteria were as follows: psoriatic disease for more than 6 months and moderate-to-severe psoriasis (PASI ≥ 10 and DLQI ≥ 10) with stable disease activity and maintenance period of the applied antipsoriatic systemic biological therapy (TNF or IL-12/23 or IL-17 or IL-23 inhibitors), and age older than 18 years. None of the patients received concomitant MTX therapy.

Patients were excluded if they had a polymerase chain reaction (PCR) proven current or previous SARS-CoV-2 infection, previous severe vaccination reaction (anaphylaxis), known primary immunodeficiency that affects adaptive immunity, status of splenectomy or functional asplenia, solid organ transplantation within 3 months, treatment targeting B-cell clones (anti-CD20), neutropenia (neutrophil granulocyte < 0.5 G/L), lymphopenia (lymphocyte count < 0.5 G/L), pregnancy or breast-feeding, or were planning to conceive a child within 2 months.

Patients were also excluded if any of the following conditions were present: psoriatic disease for less than 6 months, induction period of the applied antipsoriatic systemic biological therapy, concomitant MTX therapy, or younger than 18 years.

Fourteen to 21 days (median value of 16 days) after the administration of the second dose of the anti-SARS-CoV-2 mRNA [BioNTech/Pfizer (BNT162b2) or Moderna COVID-19 (mRNA-1273)] vaccination, 5 mL of blood samples were collected. Side effects were registered after both vaccinations. We examined the effects of these two vaccines together because the mechanism and efficacy are approximately the same.[18,19] We did not stratify the patients according to the type of mRNA vaccinations.

Control group consisted of 55 volunteers who were, healthy age-matched health care workers (45 women, 10 men) were enrolled in the study (age: 56.4 ± 13.6 years). The exclusion criteria were an autoimmune disease or positive SARS-CoV-2 antibody test results with the Roche test before vaccination. Specific antibody tests (Roche anti-SARS-CoV-2 S immunoassay) were used to examine the presence of antibodies 10–14 days after the administration of the second dose of mRNA vaccine.

2.3 | Laboratory analyses

Antibody detection:

SARS-CoV-2 specific antibodies were analyzed using Elecsys. Anti-SARS-CoV-2 S immunoassay (Roche Diagnostics International Ltd., Switzerland) on a Cobas e6000 instrument. The test detects antibodies specific for the SARS-CoV-2 spike (S) protein receptor binding domain (RBD) (total RBD-specific antibodies: immunoglobulin [Ig]G/IgA/IgM) in human serum and plasma. The method is based on the double-antigen sandwich principle using electrochemiluminescence for the quantitative determination of antibodies. The limit of quantification is 0.4 U/mL. Results less than 0.8 U/mL are considered negative, and results equal to or greater than 0.8 are considered positive according to the test description.

2.4 | Evaluation of data

Research Electronic Data Capture (REDCap) 8.10.1 software was used for prospective data capture and storage. Data analysis was performed using Stata/SE 13.0 (StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP.) After data cleansing, sorting, and data property examination, a descriptive analysis was performed. Means and standard deviations were calculated unless indicated otherwise. Nonparametric data with skewed distributions are displayed as medians and interquartile ranges (IQRs). Shapiro–Wilk tests were used to assess normality. Variance analyses were performed using ANOVA and the Krsukal–Wallis test. A linear multivariate regression analysis was performed to assess individual effectors associated with dependent variables. A p-value of <0.05 was considered statistically significant.[20,21]

3 | RESULTS

3.1 | Patients' characteristics

Patients' characteristics are presented in Table 1. One hundred and two adult (age ≥ 18 years) patients [41 women (40.20%) and 61 men (59.80%); mean age of 56.2 (±13.5) years] with moderate-to-severe plaque-type psoriasis were enrolled in the study. All enrolled patients received one of the currently used systemic biological therapies for

TABLE 1 Characteristics of moderate-to-severe psoriatic patients receiving different biological therapies

Patients' Characteristics	Whole study population	TNF inhibitor	IL-17 and IL-23 inhibitors	IL-12/23 inhibitor
Total sample (N/%)	102 (100%)	57 (100%)	17 (100%)	28 (100%)
Gender (N/%)				
Men	61 (59.80%)	36 (63.16%)	9 (52.94%)	16 (57.14%)
Women	41 (40.20%)	21 (36.84%)	8 (47.06%)	12 (42.86%)
Age (years, mean, SD)	56.2 (±13.5)	56.7 (±12.1)	57.6 (±14.9)	54.4 (±15.5)
Psoriatic arthritis (N/%)	57 (55.88%)	40 (70.17%)	9 (52.94%)	8 (28.57%)
PASI, median (IQR)	0.0 (0.0–1.8)	0.0 (0.0–1.0)	1.0 (0.0–2.0)	0.7 (0.0–2.5)
DLQI, median (IQR)	0.0 (0.0–2.0)	0.0 (0.0–1.0)	0.0 (0.0–2.0)	0.0 (0.0–2.5)
Hypertension (N/%)	52 (50.98%)	29 (50.87%)	10 (58.82%)	13 (46.43%)
Diabetes Mellitus (N/%)	23 (22.55%)	15 (26.31%)	4 (23.53%)	4 (14.28%)
Obesity (N/%)	42 (41.17%)	19 (33.33%)	9 (52.94%)	14 (50%)

Abbreviations: DLQI, Dermatology Life Quality of Index; IL, interleukin; IQR, interquartile range; PASI, Psoriasis Area Severity Index; *SD*, standard deviation; TNF, tumor necrosis factor.

TABLE 2 The incidence rate of side effects after the first and the second dosage of anti-SARS-CoV-2 mRNA vaccines among moderate-to-severe psoriatic patients receiving different biological therapies

Side effects	Incidence rate after the first dosage of mRNA vaccines (N/%)	Incidence rate after the second dosage of mRNA vaccines (N/%)
Total sample	102 (100%)	102 (100%)
Disease relapse	1 (0.99%)	0 (0.00%)
Local reaction	24 (23.53%)	24 (23.53%)
Hyperemia	1 (0.99%)	0 (0.00%)
Tumor	1 (0.99%)	2 (1.96%)
Fatigue	10 (9.90%)	14 (13.72%)
Headache	5 (4.90%)	6 (5.88%)
Muscle pain	1 (0.98%)	4 (3.92%)
Joint pain	1 (0.99%)	5 (4.90%)
Chills or shivering	5 (4.90%)	9 (8.82%)
Fever	1 (0.99%)	4 (3.92%)
Vomiting/diarrhea	3 (2.94%)	3 (2.94%)
New symptom	1 (0.99%)	1 (0.99%)

Abbreviation: anti-SARS-CoV-2 mRNA vaccines, antisevere acute respiratory syndrome coronavirus 2 messenger ribonucleic acid vaccines.

the treatment of psoriatic disease in a maintenance dosage regimen. The allocation of the applied therapies was based on the S3 European and the relevant national guidelines and access to the current medicinal product. Fifty-seven patients (55.88%) received anti-TNF, 28 patients (27.45%) received anti-IL-12/23, 16 patients (15.68%) received anti-IL-17, and 1 patient (0.99%) received anti-IL-23 therapies. Considering the small sample size of the anti-IL-23 group and the fact that anti-IL-23 therapy acts at a different level but inhibits the same T-cell activation pathway as anti-IL-17 therapy, the results of these two groups were merged. None of the patients received concomitant MTX therapy. The disease activity at the time of vaccination was low. The median values of the patients' skin symptoms and quality of life scales [Psoriasis Area Severity Index (PASI) and Dermatology Life Quality of Index (DLQI] were both 0.0. Fifty-seven patients from the study population had clinically proven psoriatic arthritis. In the study population, 86 patients (84.31%) received the BNT162b2 vaccine, and 16 patients (15.69%) received the mRNA-1273 vaccine. Thirty-five days elapsed between the administration of the two dosages of one vaccine, and 16 days elapsed between the administration of the second dosage of the vaccine and blood sample collection (median values). Registration of side effects was also performed. The most common side effects observed after the administration of both dosages of injections in the whole study group were arm pain on the side of the injection (23.53% and 23.53%), fatigue (9.80% and 13.72%), headache (4.9% and 5.88%), and chills or shivering (4.9% and 8.82%).

The incidence rates of side effects after the administration of both dosages of mRNA vaccines are shown in Table 2.

3.2 | Laboratory findings

The results of the laboratory examinations are shown in Tables 3 and 4 and Figure 1.

No significant differences in the median serum level of anti-SARS-CoV-2S antibody were observed between the study population and the control group (1681.0 U/mL (600.0–4844.0) versus 1984.0 U/mL (1000.0–3136.0; $p = 0.82$). Comparing the different biologicals, the highest serum level of anti-SARS-CoV-2S antibody was measured in the IL-12/23 inhibitor group, with a median value of 3779.0 U/mL, followed by the IL-17 and IL-23 inhibitor group, with a median value of 2074.0 U/mL. In the TNF inhibitor group, the median value was 1126.0 U/mL. No significant differences were observed when comparing the patients receiving different biological therapies to the control group ($p = 0.552$ for the anti-TNF group, $p = 0.992$ for

TABLE 3 Levels of serum Roche Spike immunoglobulins (Ig) in moderate-to-severe psoriatic patients treated with different biological therapies versus controls

Factor	Whole study population	Controls	*p*-Value (Wilcoxon signed-rank test)
Total Sample (*N*/%)	102 (100%)	55 (100%)	
Gender (N/%)			
Men	61 (59.80%)	10 (18.18%)	
Women	41 (40.20%)	45 (81.82%)	
Age (years, mean [*SD*])	56.2 (±13.5)	56.4 (±13.6)	
Roche serum Ig (U/ml), median (IQR),	1681.0 (600.0–4844.0)	1984.0 (1000.0–3136.0)	0.82
log Roche, mean (*SD*)	3.2 (±0.7)	3.2 (±0.4)	0.88

Abbreviations: *SD*, standard deviation; IQR, interquartile range.

TABLE 4 Levels of serum Roche Spike immunoglobulins (Ig) in different biological therapies

Factor	Whole study population	TNF-inhibitor	IL-17and IL-23 inhibitors	IL-12/23 inhibitor
Total sample (*N*)	102	57	17	28
Delta vaccination (days), median (IQR)	35.0 (29.0–35.0)	35.0 (28.0–35.0)	34.0 (29.0–35.0)	35.0 (31.0–35.0)
Delta serology (days), median (IQR)	16.0 (14.0–21.0)	16.0 (14.0–20.0)	18.0 (15.0–21.0)	15.5 (14.0–22.5)
Roche serum Ig (U/ml), median (IQR)	1681.0 (600.0–4844.0)	1126.0 (425.5–3115.0)	2074.0 (1297.0–2860.0)	3779.0 (1036.0–8347.0)

Abbreviations: Delta serology, time elapsed between the second dosage of mRNA vaccinations and blood sample collection; Delta vaccination, time elapsed between the two dosages of mRNA vaccinations; IQR, interquartile range.

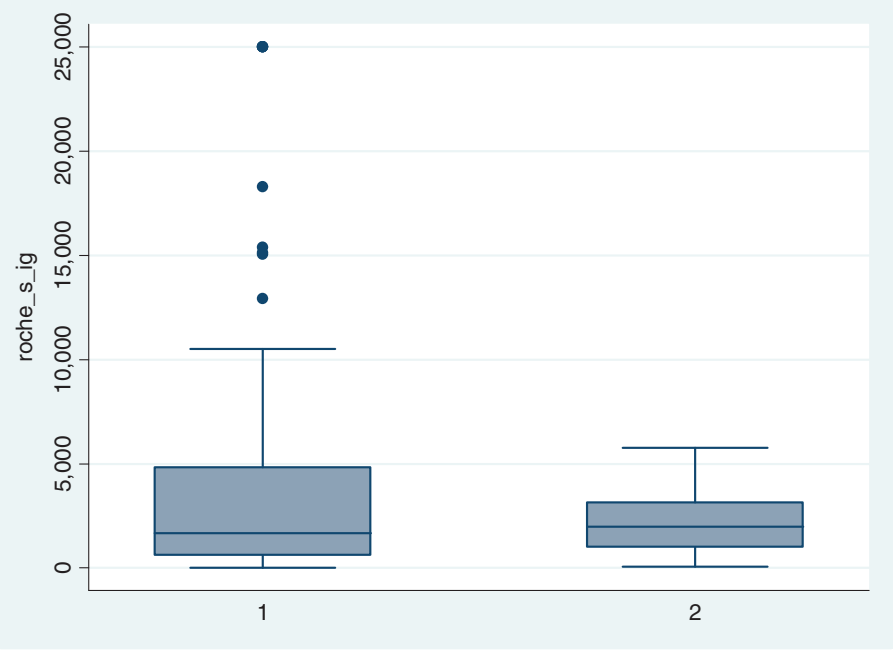

FIGURE 1 Box plot for Serum Roche Spike immunoglobulins (Ig) of the moderate-to-severe psoriatic patients receiving different biological therapies (1) versus controls (2)

the anti-IL17 and anti-IL-23 group and $p = 0.453$ for the anti-IL-12/23 group).

4 | DISCUSSION

Several studies observed seroconversion (antibody formation) after different types of vaccination among patients with psoriasis receiving systemic antipsoriatic treatments. The majority of serological control studies reported the increase in the titer 4–6 weeks after vaccination. Overall, seroconversion developed among patients with psoriatic disease treated with TNF and IL-12/23 inhibitors, and in some cases, the increase in the titer exceeded the median titer of the healthy control group. A significantly lower increase in the titer was observed in the MTX group than in the group treated with other biological therapies and healthy control group.[15,22–24] Secukinumab treatment was proven

to not affect the humoral response against influenza vaccine among patients with psoriatic arthritis.[25,26]

SARS-CoV-2 is a positive sense single-stranded RNA (ssRNA) β-coronavirus. It enters the host cell by interacting with the angiotensin converting enzyme-2 (ACE-2) receptor. The severity of SARS-CoV-2 infection ranges from a mild infection to multiorgan failure associated with bleeding and thrombotic complications.[27] Data are limited and controversial, but psoriasis does not increase the risk of SARS-CoV-2 infection compared to the general population.[4,5] Patients with moderate-to-severe psoriatic disease who are receiving systemic traditional or systemic biological treatments do not have an increased risk of SARS-CoV-2 infection or death related to COVID-19 compared to the general population; therefore, patients who are not infected with SARS-CoV-2 should not stop ongoing antipsoriatic treatment.[28] Yousaf et al. analyzed a database with 53 million patient records and identified no evidence of an increased risk of COVID-19-related hospitalization or mortality among patients treated with TNF inhibitors, methotrexate, or their combination compared to patients who did not receive systemic therapies.[29]

One hundred and two patients with moderate-to-severe psoriatic disease receiving different systemic biological therapies were enrolled in the present study to evaluate the development of the anti-SARS-CoV-2S antibody after the administration of two dosages of anti-SARS-CoV-2 mRNA vaccinations. Based on a nationwide study conducted in the United Kingdom with 45,965 adults from the general population, high anti-spike protein antibody levels were measured 28 days after the administration of the second dose of the BNT162b2 vaccine.[30] In another study, the antibody level was measured 24 days after the administration of the second dosage of the BNT162b2 vaccine.[31] In our study, 14–21 days after the administration of the second dosage of BNT162b2 or mRNA-1273 mRNA vaccines, patients with moderate-to-severe psoriatic disease treated with biologicals developed immunity equal to that of healthy control patients. No significant differences in the median serum level of anti-SARS-CoV-2S antibodies were observed between the whole study population and the control group or between each biological therapy group and the control group.

In the literature, systemic events after the administration of the second dosage of the BNT162b2 vaccine were reported in 64.2% of recipients; 47.8% reported fatigue, 22.7% reported chills or shivering, and 40.4% reported headache. Arm pain on the injection side occurred in 66.5% of the recipients. After the administration of the second dosage of the mRNA-1273 vaccine, systemic events occurred in 74.8% of the recipients; fatigue in 60%, chills and shivering in 40%, headache in 53.2%, and arm pain on the injection side in 78.3%.[32] Comparing our results to the literature data, side effects occurred at a lower incidence. After the administration of the second dosage of mRNA vaccines, arm pain on the injection side appeared in 23.53%, fatigue in 13.72%, headache in 5.88%, and chills or shivering in 8.82%. The reduction in generalized inflammation with systemic antipsoriatic treatments may have affected the incidence rate of vaccination-related side effects.

5 | CONCLUSION

In December 2019, a novel coronavirus emerged, and the COVID-19 pandemic developed worldwide. Vaccines are our only chance to reduce the pandemic and develop adequate immunity against the virus. Our study revealed adequate antibody formation at a median value of 16 days after the administration of the second dosage of mRNA vaccines in 100% of patients with psoriatic disease who were receiving different types of biological antipsoriatic treatments compared to healthy controls. No significant differences in the specific antibody levels were observed between patients and healthy controls after vaccination. Based on these data, we conclude that this group of patients present with the same levels of antibody formation as healthy controls. The most commonly reported adverse events were arm pain on the injection side, fatigue, headache, and chilling or shivering. Comparing our results to the published data, side effects occurred at a lower incidence. Further examinations are needed to assess the maintenance of antibodies produced in response to the currently used vaccines.

6 | STUDY LIMITATIONS

One of the limitations of the study is that the control group only received the BioNTech/Pfizer (BNT162b2) vaccine, and no controls were available for the Moderna (mRNA-1273) vaccination. We examined the effects of these two vaccines together because the mechanism and efficacy are approximately the same.[18,19] We did not stratify the patients according to the mRNA vaccinations. Considering the small sample size of the anti-IL-23 group and the fact that anti-IL-23 therapy acts at a different level but inhibits the same T-cell activation pathway as anti-IL-17 therapy, the two groups were merged. In our study group, a median value of 16 days elapsed between the administration of the second dosage of the vaccine and blood sample collection, while the interval was 10–14 days in the control group. However, no significant differences in the serum levels of anti-SARS-CoV-2 antibodies were observed between groups.

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CONFLICT OF INTERESTS

The authors have no conflict of interest to declare.

ETHICS STATEMENT

This study protocol was reviewed and approved by the Medical Research Council Scientific and Research Ethics Committees, Budapest, Hungary (approval number: IV/861–1/2021/EKU, date of approval: 2021.01.27) and meets all requirements of the Declaration of Helsinki.

INFORMED CONSENT

Patients provided written informed consent to participate and donate blood for the purpose of our study.

CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

The article has not been presented prior. Manuscript has not been previously published and is not currently submitted elsewhere.

AUTHOR CONTRIBUTIONS

All the authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.

DATA AVAILABILITY STATEMENT

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request for non-commercial purposes.

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REFERENCES

1. Rodriguez-Morales AJ, Bonilla-Aldana DK, Balbin-Ramon GJ, et al. History is repeating itself: probable zoonotic spillover as the cause of the 2019 novel coronavirus epidemic. *Infez Med*. 2020;28(1):3-5.
2. Cummings MJ, Baldwin MR, Abrams D, et al. Epidemiology, clinical course, and outcomes of critically ill adults with COVID-19 in new York City: a prospective cohort study. *Lancet*. 2020;395(10239):1763-1770.
3. Li J, Huang DQ, Zou B, et al. Epidemiology of COVID-19: a systematic review and meta-analysis of clinical characteristics, risk factors, and outcomes. *J Med Virol*. 2021;93(3):1449-1458.
4. Gianfrancesco M, Yazdany J, Robinson PC. Epidemiology and outcomes of novel coronavirus 2019 in patients with immune-mediated inflammatory diseases. *Curr Opin Rheumatol*. 2020;32(5):434-440.
5. Haberman R, Axelrad J, Chen A, et al. Covid-19 in immune-mediated inflammatory diseases — case series from New York. *New Engl J Med*. 2020;383(1):85-88.
6. Vispi M, Corradin T, Peccianti C, et al. Psoriasis, biological drugs and coronavirus disease 2019: real life experience of two Italian provinces. *Dermatol Reports*. 2020;12(1):8642.
7. Deng G, Yin M, Chen X, Zeng F. Clinical determinants for fatality of 44,672 patients with COVID-19. *Crit Care*. 2020;24(1):179.
8. Mahil SK, Dand N, Mason KJ, et al. Factors associated with adverse COVID-19 outcomes in patients with psoriasis—insights from a global registry-based study. *J Allergy Clin Immunol*. 2021;147(1):60-71.
9. Valenti M, Facheris P, Pavia G, et al. Non-complicated evolution of COVID-19 infection in a patient with psoriasis and psoriatic arthritis during treatment with adalimumab. *Dermatol Ther*. 2020;33(4):e13708.
10. Conti A, Lasagni C, Bigi L, Pellacani G. Evolution of COVID-19 infection in four psoriatic patients treated with biological drugs. *J Eur Acad Dermatol Venereol*. 2020;34(8):e360-e361.
11. Facheris P, Valenti M, Pavia G, et al. Complicated coronavirus disease 2019 (COVID-19) in a psoriatic patient treated with ixekizumab. *Int J Dermatol*. 2020;59(8):e267-e268.
12. Geisen UM, Berner DK, Tran F, et al. Immunogenicity and safety of anti-SARS-CoV-2 mRNA vaccines in patients with chronic inflammatory conditions and immunosuppressive therapy in a monocentric cohort. *Ann Rheum Dis*. 2021;80(10):1306-1311.
13. Damiani G, Allocco F, Network YDI, Malagoli P. COVID-19 vaccination and patients with psoriasis under biologics: real-life evidence on safety and effectiveness from Italian vaccinated healthcare workers. *Clin Exp Dermatol*. 2021;46(6):1106-1108.
14. Al-Janabi A, Littlewood Z, Griffiths CEM, et al. Antibody responses to single-dose SARS-CoV-2 vaccination in patients receiving immunomodulators for immune-mediated inflammatory disease. *Br J Dermatol*. 2021;185(3):646-648.
15. Mease PJ, Ritchlin CT, Martin RW, et al. Pneumococcal vaccine response in psoriatic arthritis patients during treatment with etanercept. *J Rheumatol*. 2004;31(7):1356-1361.
16. Mahil SK, Bechman K, Raharja A, et al. The effect of methotrexate and targeted immunosuppression on humoral and cellular immune responses to the COVID-19 vaccine BNT162b2: a cohort study. Lancet. *Rheumatology*. 2021;3(9):E627-E637.
17. Polack FP, Thomas SJ, Kitchin N, et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. *N Engl J Med*. 2020;383(27):2603-2615.
18. Gelfand JM, Armstrong AW, Bell S, et al. National Psoriasis Foundation COVID-19 task force guidance for management of psoriatic disease during the pandemic: version 2-advances in psoriatic disease management, COVID-19 vaccines, and COVID-19 treatments. *J Am Acad Dermatol*. 2021;84(5):1254-1268.
19. Pushparajah D, Jimenez S, Wong S, Alattas H, Nafissi N, Slavcev RA. Advances in gene-based vaccine platforms to address the COVID-19 pandemic. *Adv Drug Deliv Rev*. 2021;170:113-141.
20. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009;42(2):377-381.
21. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: building an international community of software platform partners. *J Biomed Inform*. 2019;95:103208.
22. Polachek A, Korobko U, Mader-Balakirski N, et al. Immunogenicity and safety of vaccination against seasonal 2012 influenza virus among patients with psoriatic arthritis and psoriasis. *Clin Exp Rheumatol*. 2015;33(2):181-186.
23. Brodmerkel C, Wadman E, Langley RG, et al. Immune response to pneumococcus and tetanus toxoid in patients with moderate-to-severe psoriasis following long-term ustekinumab use. *J Drugs Dermatol*. 2013;12(10):1122-1129.
24. Kaine JL, Kivitz AJ, Birbara C, Luo AY. Immune responses following administration of influenza and pneumococcal vaccines to patients with rheumatoid arthritis receiving adalimumab. *J Rheumatol*. 2007;34(2):272-279.
25. Furer V, Zisman D, Kaufman I, et al. Immunogenicity and safety of vaccination against seasonal influenza vaccine in patients with psoriatic arthritis treated with secukinumab. *Vaccine*. 2020;38(4):847-851.
26. Richi P, Martín MD, de Ory F, et al. Secukinumab does not impair the immunogenic response to the influenza vaccine in patients. *RMD Open*. 2019;5(2):e001018.
27. Nappi F, Iervolino A, Avtaar Singh SS. Thromboembolic complications of SARS-CoV-2 and metabolic derangements: suggestions from clinical practice evidence to causative agents. *Metabolites*. 2021;11(6):341.
28. Gisondi P, Bellinato F, Chiricozzi A, Girolomoni G. The risk of COVID-19 pandemic in patients with moderate to severe plaque psoriasis receiving systemic treatments. *Vaccines (Basel)*. 2020;8(4):728.
29. Yousaf A, Gayam S, Feldman S, Zinn Z, Kolodney M. Clinical outcomes of COVID-19 in patients taking tumor necrosis factor inhibitors or methotrexate: a multicenter research network study. *J Am Acad Dermatol*. 2021;84(1):70-75.

30. Wei J, Stoesser N, Matthews PC, et al. Antibody responses to SARS-CoV-2 vaccines in 45,965 adults from the general population of the United Kingdom. *Nat Microbiol*. 2021;6(9):1140-1149.
31. Kontou E, Ranellou K, Zoulas D, et al. Antibody response following a two-dose mRNA vaccination regimen, in Health Care Workers of a Tertiary Hospital in Athens, Greece. *J Pers Med*. 2021;11(6):576.
32. Chapin-Bardales J, Gee J, Myers T. Reactogenicity following receipt of mRNA-based COVID-19 vaccines. *JAMA*. 2021;325(21):2201-2202.

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