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CORONAVIRUS VACCINATION IN PATIENTS WITH PSORIASIS VULGARIS UNDER IMMUNOSUPPRESSIVE THERAPY

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The COVID-19 disease brought numerous hospitalizations and deaths worldwide, which exerted implications not only for health care professionals of different specialties, but also for the general population in need of medical attention - and psoriasis patients make no exception. The COVID-19 pandemic raised multiple issues of concern such as whether immunosuppressant, including biologic therapy may increase the risk of patients with psoriasis to develop the viral infection or to progress more severely; the possibility of a disease flare-up after discontinuation of immunosuppressive therapy; the safety of COVID-19 vaccination in immunocompromised patients including those on immunosuppressive medications. In this review, we aim to bring attention to the coronavirus vaccination among psoriasis population, a fundamental point of interest for dermatologists, rheumatologists and general practitioners, according to the available guidelines and recommendations. Patient education with respect to SARS-CoV-2 vaccination is of great importance and proper counseling by healthcare professionals is essential for a better understanding of the use of vaccines while on immunosuppressive or biologic therapy.

Key-words: psoriasis; immunosuppressive therapy; biologic therapy; COVID-19 vaccination; SARS-CoV-2 vaccine.

INTRODUCTION

The coronavirus disease 2019 (COVID-19) brought numerous hospitalizations and deaths worldwide, with a reported fatality of approximately 6.9%, healthcare systems having to adjust to the nowadays reality.[1] As expected, this exerted implications not only for health care professionals of different specialties, but also for the general population in need of medical attention – and psoriasis patients make no exception.

Psoriasis is a chronic inflammatory skin disease with a prevalence of 2% in Europe and North America.[2,3] Five types of psoriasis have been described: plaque psoriasis, inverse psoriasis, guttate psoriasis, pustular psoriasis, and erythrodermic psoriasis – a rare, but serious complication of the disease.[3] Systemic therapeutic options available for psoriasis encompass immunosuppressants (such as methotrexate, cyclosporine – mainstays of therapy for moderate to severe psoriasis) and also biologic therapies with targeted molecules, that have changed the traditional approach of the disease, having proven to be highly efficient.[4]

MANAGEMENT OF PSORIASIS IN TIMES OF COVID-19 PANDEMIC

Among the first issues of concern regarding the management of psoriasis in times of pandemic was whether immunosuppressant and biologic therapy may render patients with psoriasis more susceptible to COVID-19 infection and, therefore, interruption of treatment should be taken into consideration.[5]

Advances in understanding the complex pathophysiology of the COVID-19 showed that the host's T cells activate in response to the infection

and massive production and release of cytokines occur leading to organ damage, particularly, lungs, a process also known as the cytokine storm.[6] Interleukin 23 (IL-23), tumor necrosis factor alpha (TNF-α) and interleukin 17 (IL-17) are examples of cytokines involved in the exacerbated immune response to COVID-19 infection[6], molecules also involved in the pathogenesis of psoriasis.

From the available data, Ebrahimi A *et al.* (2020) concluded on the absence of an increased susceptibility to COVID-19 infection in psoriasis patients on biologic therapy.[7] It was also stated that the severity of the disease and overall outcome of the infection are not influenced by the targeted therapies. Moreover, it was suggested that patients under Il-12/23, Il-23, TNF- α, Il-17 inhibitors may benefit from the immunomodulatory effects of these new molecules since they may prevent the cytokine storm in severely affected patients with COVID-19.[7] Discontinuation of biologic therapies with some agents may lead to resistance to therapy in patients affected by severe psoriasis.[7] Altogether, the decision of whether to discontinue or not a biologic agent in patients with psoriasis should be made based on the severity of the COVID-19 disease, on the severity of psoriasis and on the presence of comorbidities in these patients.[7]

A review from September 2020 by Ricardo JW and Lipner SR suggested that conventional immunosuppressive medications such as corticosteroids, methotrexate, azathioprine and cyclosporine were associated with an increased risk of COVID-19 infection and, consequently, patients might need strict measures in order to minimize exposure as much as possible.[8] Tofacitinib and TNF-α inhibitors were also believed to increase the risk of infection.[8] IL 17, IL 23 and IL-12/23 inhibitors appeared to be among the safer biologic therapies, while apremilast and acitretin seemed to have, as well, favorable safety profiles.[8]

In addition to the above-mentioned increased risk of infection in psoriasis patients under immunosuppressive therapy, another point of interest may need to be taken into account: the possibility of a disease flare-up after discontinuation of treatment. A case report from May 2020 by Nasiri S *et al.* described the case of a 73-year-old male treated with cyclosporine 100 mg daily and methotrexate 7.5 mg weekly who, after discontinuation of immunosuppressive therapy due to COVID-19 infection, experienced disease flare-up.[9]

PREVENTIVE APPROACH OF COVID-19 THROUGH VACCINATION AND ITS APPLICABILITY TO PSORIASIS PATIENTS

The actual unprecedented global crisis with an accelerated spread of the coronavirus infection led to a collective effort aimed at a better understanding of the SARS-CoV-2 virus and its complex interaction with the human host in order to develop prophylactic and curative therapies.[10,11] Advances in genomic technologies and computational infrastructure has led to significant scientific breakthroughs during the past year. On January 10th 2020, the genome sequence of the virus was made public and, soon enough, the structure of different viral proteins was determined, which represented a starting point in the development of coronavirus vaccines.[12]

Immunization through vaccination is the preferred protection method in public health and in order to achieve herd immunity against the COVID-19 infection, at least 70% of the general population would need to be vaccinated.[13] The development of a vaccine is an elaborate process, requiring a long period of time for production and clinical trials towards establishing the vaccine's capability, purity and efficacy.[14] At the moment, launches of effective vaccines is possible by means of biotechnological approaches and advanced molecular biology.[12] On November 16th 2020, Moderna reported an efficacy of 94.5% of the mRNA-1273 vaccine during phase III clinical trials.[15] Pfizer and BioNTech reported that the BNT162b2 vaccine efficacy was 95% in high-risk groups with no serious adverse effects.[16] On November 18th 2020, the University of Oxford and Astrazeneca reported that the AZD1222 clinical trials showed a mean efficacy of 70% in preventing the COVID-19 disease.[17]

A serious issue which needs to be addressed is the safety of COVID-19 vaccination in immunocompromised patients, such as psoriasis patients on immunosuppressive medications. In January 2021, Sonani B *et al.* mentioned that the group of immunocompromised patients has been excluded from the Pfizer, BioNTech and Moderna vaccine trials, thereby, the efficacy of vaccination in this population is yet to be established.[18]

It is considered that suppression of humoral immunity by systemic agents such as methrotrexate may also inhibit the production of neutralizing antibodies to neoantigens.[19] Methotrexate has been shown to reduce antibody formation to seasonal influenza and pneumococcal vaccines.[20] A review fom December 2020 by

Chiricozzi A *et al.* on the immune response to vaccines in patients with moderate to severe psoriasis treated with systemic agents shows that the use of conventional systemic compounds (methotrexate and cyclosporine) is associated with an impairment of the humoral response to vaccines, since they reduce antibody production, lowering protective antibody titers.[21] Biologic agents, on the other hand, preserve the humoral response to vaccines, since they exert selective immunomodulation.[21] Despite the fact that non-live vaccines may be safely administered during treatment, vaccination programs are apparently unsuccessful among patients with psoriasis, even if these patients are meant as a risk population because of their immunocompromised status and psoriasis-related comorbidities.[21]

The influence of methotrexate and other immunosuppressant agents on a SARS-CoV-2 vaccine may need evaluation especially considering their impact on other types of vaccines. It is suggested that a thorough planning of vaccination should be made, with the possibility of holding methotrexate for two weeks after vaccination.[18]

COVID-19 VACCINE RECOMMENDATIONS FOR PATIENTS AFFECTED BY PSORIASIS

Several dermatologic associations announced official recommendations regarding COVID-19 vaccination in psoriasis patients (some resumed in Table 1). However, there are no universal guidelines on the subject. The International Psoriasis Council advises healthcare professionals to take into account the following considerations[22]:

- Avoidance of live attenuated vaccines in patients receiving immunosuppressive/ immunomodulatory therapies and understanding that the effectiveness of vaccination may be reduced in patients on medication affecting the immune system.[22]
- The currently available vaccines (RNA-based-Pfizer/BioNTech, Moderna and based on replication deficient virus encoding the S glycoprotein of SARS-CoV-2- Astra Zeneca) are safe to use, since they are not live attenuated vaccines.[22]
- Most patients with psoriasis who do not suffer from a known allergy to a vaccine component or do not have a particular contraindication will be advised to receive one of the SARS-CoV-2 vaccines as soon as possible, based on guidance from local public health bodies and local availability.[22]
- The exact effects of SARS-CoV-2 vaccines on population taking medication that affects the immune system is yet to be clearly established through clinical trials.[22]
- Until the present moment, there is no evidence that the coronavirus vaccines may influence the onset or severity of psoriasis.[22]
- It is important that psoriasis patients benefit from proper healthcare, including access to coronavirus vaccines.[22]

On January 7th 2021, the National Psoriasis Foundation COVID-19 Task Force Guidance for management of psoriatic disease during the pandemic updated their statements regarding the approach of the disease, the COVID-19 vaccination and COVID-19 treatments. The Task Force included 18 physicians with expertise in dermatology, rheumatology, epidemiology, infectious diseases, and critical care.[23] With respect to the SARS-CoV-2 vaccines in psoriasis patients, there are a few high-level consensus recommendations:

- Patients with no contraindication to vaccination should receive an mRNA-based SARS-CoV-2 vaccine, as soon as available.[23]
- In most cases, patients who are to receive an mRNA-based COVID-19 vaccines should continue their oral or biologic therapy for either psoriasis or psoriatic arthritis.[23]

For patients deciding whether or not to participate in a COVID-19 therapeutic or vaccine clinical trial, the Task Force advises that the decision should be made on a case-by-case basis and should involve the patient, the researcher and the provider.[23]

According to the Risk Stratification Grid of The British Association of Dermatology from November 2020, high risk patients which are strongly advised to shield are the ones with at least two agents within immunosuppressive, biologic/monoclonals or novel small molecule immunosuppressants[24]; patients with minimal disease and at least one comorbidity of the following: diabetes mellitus, adults on dialysis or chronic kidney disease (with stage 5), any history of ischemic heart disease or hypertension on treatment, age > 70[24]; corticosteroid dose of ≥ 20 mg prednisolone (or equivalent) per day for more than four weeks[24]; corticosteroid dose of ≥ 5 mg prednisolone (or equivalent) per day for more than 4 weeks plus at least one other immunosuppressive

medication, biologic/monoclonal or novel small molecule immunosuppressants (*e.g.* Janus kinase inhibitors)[24]; cyclophosphamide at any dose orally or if received intravenously dose within last 6 months[24]; rituximab or infliximab when prescribed mainly for dermatologic diseases (e.g. psoriasis or pemphigus).[24]

The American Academy of Dermatology is another medical society which provides guidance regarding the administration of the COVID-19 vaccine. It states that patients on immunomodulatory agents may receive COVID-19 vaccination if they have no contraindications to vaccination.[25] However, there are no data to establish the safety and efficacy of mRNA based COVID vaccines in patients taking immunosuppressive agents, including systemic drugs and biologic therapies used in dermatology.[25] This is in accordance with the recommendations of The International Psoriasis Council and the National Psoriasis Foundation COVID-19 Task Force Guidance.

The Centers for Disease Control and Prevention states that immunocompromised patients, including those on immunosuppressive therapy, may receive COVID-19 vaccines.[26] Ideally COVID-19 vaccination should be completed at least two weeks before initiation of immunosuppressive therapies.[26] This is in agreement with the General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP).[27] Decisions to delay immunosuppressive therapy to complete COVID-19 vaccination should consider the person's risks related to their underlying condition.[26]

On February 2021, the American College of Rheumatology published a COVID-19 Vaccine Clinical Guidance for patients with Rheumatic and Musculoskeletal Diseases, which was later updated on March 4th 2021. Its principles were established by The North American Task Force panel, consisting of 9 rheumatologist, 2 public health experts, 2 infectious disease specialists with current or past employment at the Centers for Disease Control (CDC).[28] This guideline recommends that patients under methotrexate or Janus kinase inhibitors should hold these agents for 1 week after each vaccine dose, with no particular modification in timing for those with stable disease.[28] Patients under biologic therapy TNF alpha; IL-17; IL-12/23; IL-23 inhibitors, as well as apremilast; glucocorticoids, prednisone-equivalent dose ≥ 20mg/day; mycophenolate; azathioprine; cyclophosphamide (oral) need no modification to either immunomodulatory therapy nor vaccination timing.[28]

The Psoriasis Group of the Spanish Academy of Dermatology and Venerology advises that patients under methotrexate and cyclosporin A should be temporarily held before and after vaccination due to their immunosuppressant effect which may interfere with the host's immune response after vaccination.[29] Also, anti-TNF alpha therapy is considered to reduce the production of antibodies, but without minimizing the vaccine's overall protection and efficacy.[29] Moreover, ustekinumab, secukinumab, ixekizumab seem to not interfere with the immunogenicity of the vaccines.[29] This is in accordance with recommendations of other medical societies.[22, 30]

The Romanian Society of Dermatology made the following recommendations:

- Patients with stable psoriatic disease with no other contraindications to COVID-19 vaccination may be immunized.[31]
- The initiation of immunosuppressive/ immunomodulatory therapies at least one week after the second dose of vaccine.[31]
- Cessation of immunosuppressive/ immunomodulatory therapies (if possible) before the first dose (ideally according to its half-life) and resuming treatment at least one week after the second dose of vaccine.[31]
- In cases diagnosed with severe clinical forms of psoriasis (erythrodermic, generalized pustular disease, extensive psoriasis vulgaris), vaccination should be postponed until the disease stabilizes.[31]
- Initiation ot resumption of therapy after vaccination should be done under close monitoring.[31]
- Patients who suffered from COVID-19 can be vaccinated after at least 28 days from infection.[31]

The French Psoriasis Association states that the currently available mRNA vaccines are „inert" vaccines, since they do not contain neither live virus nor inactivated virus.[32] Consequently, they do not present an infectious risk for patients affected by psoriasis, those on immunomodulatory therapies included. Moreover, up until the present moment, there is no evidence that vaccination may influence the severity of psoriasis or promote the occurrence of relapse.[32] Since there is no evidence that COVID-19 vaccines exert the same effectiveness in immunosuppressed patients, it is advisable to consider vaccination before initiating the immunomodulatory therapy.[32]

Table 1

COVID-19 Vaccine recommendations for patients affected by psoriasis

Medical society	**Proper health care in psoriasis includes access to COVID-19 vaccination**		**Unless there are contraindications, vaccination is recommended**		**Delay of initiation of immunosupperesive/ immunomodulatory therapy after vaccination**		**Modification of therapy or vaccination timing for Methotrexate, cyclosporin A and Janus kinase inhibitors**		**Modification of therapy or vaccination timing for: glucocorticoids, azathioprine, cyclophosphamide**		**Modification of therapy or vaccination timing for biologic therapies***	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
International Psoriasis Council[22]	Yes	-	Yes	-	-	-	-	-	-	-	-	-
National Psoriasis Foundation[23]	Yes	-	Yes	-	-	-	-	No	-	Nu	-	No
American Academy of Dermatology[25]	Yes	-	Yes	-	-	-	-	-	-	-	-	No
Centers for Disease Control and Prevention[26]	Yes	-	Yes	-	The initiation of immunosuppressive therapies at least 2 weeks after COVID-19 vaccination (ideally).	-	Delay considering the person's risks related to their underlying condition	-	Delay considering the person's risks related to their underlying condition	-	Delay considering the person's risks related to their underlying condition	-
American College of Rheumatology[28]	Yes	-	Yes	-	-	-	Yes, held 1 week after each vaccine dose	-	-	No	-	No
Academia Española de Dermatología y Venereología[29]	Yes	-	Yes	-	-	-	Yes, held 1 week after each vaccine dose	-	-	No	-	No
Association France Psoriasis[32]	Yes	-	Yes	-	-	-	-	No	-	No	-	No
Romanian Society of Dermatology[31]	Yes	-	Yes	-	The initiation of immunosuppressive/ immunomodulatory therapies at least 1 week after the second dose of vaccine.	-	Yes, held before the first dose (!half-life) and resume treatment at least 1 week after the second dose of vaccine	-	Yes, held before the first dose (!half-life) and resume treatment at least 1 week after the second dose of vaccine	-	Yes, held before the first dose (!half-life) and resume treatment at least 1 week after the second dose of vaccine	-

The Arthritis Foundation states that the new COVID-19 vaccines should also be addressed to people suffering from autoimmune diseases, since experts believe that there is no reason to think they may be unsafe for this particular population.[33]

The New England Journal of Medicine states that COVID-19 vaccines should be administered to immunocompromised patients, but whether the antigens in the vaccines may trigger an autoimmune disease (for those with an underlying rheumatologic or autoimmune disorders) is still unknown.[34] When deciding to immunize an immunosuppressed patient, physicians should counsel them about a potential reduction in the vaccine effectiveness.[34]

Another matter of concern is represented by patient education regarding vaccination. In January 2021, Le H and Vender RB published a psoriatic patient-based survey on 661 subjects which aimed to collect information about the understanding of the use of vaccines while on biologic therapy during COVID-19 pandemic showed the following results: the mean percent of patients who understand the difference between live and inactivated vaccines was of 36.6%; 36.6% did not know the difference between the two type of vaccines and 26.6% responded with "unsure".[35] Patients were also asked whether it was possible or not to receive inactivated vaccine while on biologic therapy and 66.9% from both the control and study group responded with "unsure".[35] Consequently, there is an obvious need for additional education of psoriasis patients regarding vaccines and physicians should be encouraged to counsel their patients on the use of SARS-CoV-2 available vaccines while on biologic therapy.[35]

CONCLUSIONS

The COVID-19 pandemic is an unprecedented event which led to a collective action aimed at understanding the complex pathophysiology of coronavirus infection in order to develop highly efficient vaccines. The safety of these vaccines in patients with psoriasis under immunosuppressive or biologic therapy is a matter of great concern, thereby this particular issue is addressed in the above-mentioned available guidelines and recommendations. Dermatologists, rheumatologists and general practitioners should be encouraged to counsel psoriasis patients about coronavirus vaccines, in order to assure that patients fully understand their use, safety and efficacy.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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