REVIEW ARTICLE

COVID-19 Vaccination in Autoimmune Patients: A Literature Review

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ABSTRACT

Patients with autoimmune diseases, especially rheumatic diseases, have their own concerns regarding the coronavirus disease 2019 (COVID-19) vaccination. Their concerns are specifically related to the physicological response, side effects, and effectiveness of the COVID-19 vaccination. COVID-19 and autoimmune diseases share some similarities in their clinical manifestations, immune responses, and pathogenic mechanisms. The correlation between COVID-19 vaccination and autoimmune diseases can be attributed to epitope mimicry, where the antigen contained in the vaccine has a structural similarity to self-antigen. The purpose of this literature review was to discuss the various types of vaccines, the side effects of the COVID-19 vaccination, and the effect of autoimmune patients' medication on the administration of the COVID-19 vaccination. According to several articles obtained in this study, most autoimmune patients typically experienced mild to moderate side effects. It was not advised for these patients to stop treatment before receiving the COVID-19 vaccination, as doing so was unlikely to affect the vaccine's effectiveness or the patients' immune response. The condition of the autoimmune patients was what influenced the immune response mediated by antibodies. Therefore, the COVID-19 vaccination must be administered when the patients are in a stable condition. In conclusion, it was determined that there is no restriction preventing autoimmune patients from receiving the COVID-19 vaccination. However, it should be noted that autoimmune patients are not recommended to receive live vaccines.

Keywords: Coronavirus disease 2019 (COVID-19) vaccine; autoimmune disease; non-communicable disease; illness

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Highlights:
1. This study reviewed the concerns of autoimmune patients over the side effects of the COVID-19 vaccination on their prescribed medication.
2. It is advisable for autoimmune patients to refrain from obtaining live-attenuated vaccines because of their potential effect on the immune response.

Article history: •Received 21 December 2023 •Revised 27 February 2024 •Accepted 11 March 2024 •Published 31 August 2024

INTRODUCTION

The virus newly discovered in the city of Wuhan, China, on December 31, 2019, belongs to the Coronaviridae family and constitutes a new strain of the novel coronavirus (nCoV). This particular strain has been confirmed to infect humans. The transmission or spread of this virus can occur from human to human through droplets (Kaswa & Govender, 2020). This virus has the potential to cause severe pneumonia, with a death rate of approximately 36% (Ciotti et al., 2020). Furthermore, uncontrolled immune responses can lead to an increase in pro-inflammatory cytokines due to the coronavirus disease 2019 (COVID-19) virus (Liu et al., 2021).

Patients infected with the COVID-19 virus or severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) may exhibit mild to severe symptoms, but a significant number of patients may be asymptomatic. The most commonly observed symptoms are fever (83%), cough (82%), and shortness of breath (31%). Additionally, other symptoms such as vomiting, diarrhea, and abdominal pain are reported in 2-10% of COVID-19 patients (Ciotti et al., 2020).

By July 2021, COVID-19 vaccines had been successfully distributed worldwide with the hope of ending the COVID-19 pandemic (Ndwandwe & Wiysonge, 2021). However, patients with autoimmune diseases, particularly rheumatic diseases, express concerns regarding the physicological response, side effects, and effectiveness of

Available at https://e-journal.unair.ac.id/CIMRJ ; DOI: 10.20473/cimrj.v5i2.53033

the COVID-19 vaccination (Velikova & Georgiev, 2021). Various types of COVID-19 vaccines have been developed and are currently in use. These include whole virus vaccines, protein-based vaccines, viral vector vaccines, and nucleic acid vaccines that utilize deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) (Ndwandwe & Wiysonge, 2021).

COVID-19 and autoimmune diseases share several similarities in terms of clinical manifestations, immune responses, and pathogenic mechanisms. Autoantibodies, which are characteristic of autoimmune diseases, can also be detected in patients infected with the COVID-19 virus (Liu et al., 2021). Generally, autoimmune diseases are characterized by the activation of the adaptive immune system (involving T and B cells) and the innate immune system (involving macrophages and dendritic cells) (Liu & Perl, 2019). In cases of COVID-19 infection, signs of a hyper-responsive phase in the immune system are often found. This phase can result in the development of secondary autoimmune diseases, such as immune thrombocytopenic purpura, autoimmune hemolytic anemia, Guillain-Barré syndrome, Miller Fisher syndrome, antiphospholipids, and Kawasaki-like disease (Olivieri et al., 2021). Elevated angiotensin-converting enzyme 2 (ACE2) levels in systemic lupus erythematosus and rheumatoid arthritis patients may heighten susceptibility to COVID-19 and may exacerbate COVID-19 outcomes (Najafi et al., 2020; Kocivnik & Velnar, 2022).

Viruses are among the agents that transmit and cause the pathogenesis of autoimmune diseases. The relationship between COVID-19 vaccination and autoimmune diseases is represented by epitope mimicry, as the antigen present in the vaccine shares structural similarities with the self-antigen (Olivieri et al., 2021). A spike in the glycoprotein of the COVID-19 virus can cause a cross-reaction between the immune response and antigens in human body tissues, which can cause autoimmunity. The development of autoimmunity is also triggered by molecular mimicry, which occurs within the human body (Chen et al., 2022). This study aimed to discuss the COVID-19 vaccination options that can be administered to autoimmune patients, as well as the potential adverse effects of different types of COVID-19 vaccines on autoimmune patients.

OBJECTIVE

COVID-19 and Autoimmune Diseases

Systemic lupus erythematosus is a chronic autoimmune disorder affecting various organs, with infections being a leading cause of mortality among patients with this condition. The pathogenic parallels between systemic lupus erythematosus and COVID-19 involve heightened activity of T helper 17 (Th17) and T follicular helper (Tfh) cells, potentially contributing to the production of autoantibodies. Key factors such as interleukin 17 (IL-17) and interleukin 21 (IL-21), which are crucial in systemic lupus erythematosus, also play several roles in the incidence of COVID-19. Their roles may have an impact on kidney tissues and prompt procoagulant changes. Systemic lupus erythematosus patients with increased ACE2 levels may have a heightened susceptibility to COVID-19. The presence of dysregulated apoptosis and cytokine storms in both conditions suggests potential therapeutic strategies targeting cytokine receptors (Najafi et al., 2020).

Patients with rheumatoid arthritis face an elevated risk of COVID-19 infection due to their immune system disorder and immunosuppressive treatments. The migration of white blood cells in rheumatoid arthritis causes joint issues. Genetic, environmental, and hormonal factors contribute to immune dysfunction in rheumatoid arthritis, impacting the severity of viral infections. Shared pathways involving angiotensin II suggest overlapping pathogenic mechanisms. This highlights the need for further genetic research to understand their biological roles in the pathogenesis of COVID-19. The presence of ACE2 gene polymorphisms in rheumatoid arthritis patients may exacerbate the outcomes of COVID-19 (Kocivnik & Velnar, 2022).

Both multiple sclerosis and COVID-19 exhibit elevated levels of inflammatory cytokines, particularly Th17-related cytokines such as interleukin 6 (IL-6) and interleukin 23 (IL-23). Immune reactions in multiple sclerosis cause damage in the central nervous system, which involves T helper 1 (Th1) and T helper 17 (Th17) cells. COVID-19 patients experience a similar cytokine surge, contributing to respiratory symptoms. Th17 cells play a crucial role in both conditions, emphasizing their involvement in the development of cytokine storms (Najafi et al., 2020)

Types of Vaccines in General

In general, vaccines are categorized into several types, including live-attenuated viruses, recombinant viral vector vaccines, inactivated viruses, protein subunit vaccines, virus-like particles (VLP), and nucleic acid vaccines that utilize deoxyribonucleic acid (DNA) or ribonucleic acid (RNA). Essentially, vaccines require antigenic components and infection signals to activate the host's immune system (Jeyanathan et al., 2020).

Whole-virus vaccines are produced using weakened or inactivated forms of the virus, for which the genetic material has already been destroyed but can still trigger an immune response. Currently, live-attenuated vaccines that are widely used include the measles vaccine, the oral polio vaccine, and the yellow fever vaccine. Protein-based vaccines are made from virus subunits and particles that resemble the virus. These vaccines consist of virus fragments derived from recombinant proteins. Widely distributed and used protein-based vaccines encompass those designed for whooping cough, Streptococcus pneumoniae infection, and Haemophilus influenzae type B infection. Several forms of viral vector vaccines that are currently in use include adenovirus-vectored influenza vaccines and measles virus vaccines. Nucleic acid vaccines use genetic instructions, either DNA or RNA, as exemplified by the COVID-19 vaccines (Ndwandwe & Wiysonge, 2021).

Different Types of COVID-19 Vaccines

Vaccines against COVID-19 come in several types and can be categorized based on their composition or manufacturing basis. These include live-attenuated vaccines, recombinant protein vaccines that use messenger ribonucleic acid (mRNA), adenovirus vector-based vaccines, and chemically inactive vaccines. Live-attenuated vaccines have the ability to induce a mild infection that resembles a real infection. These vaccines are considered safe and can result in a strong immune response (Soy et al., 2021).

Messenger ribonucleic acid (mRNA)-based vaccines require repeated doses and supplementary materials during their production process. DNA-based vaccines are weaker compared to mRNA-based vaccines. Furthermore, the immune response induced by DNA-based vaccines is not as robust as certain viral vector vaccines. Live-attenuated

vaccines generate a strong immune response and may require only a single dose. However, they necessitate more extensive safety testing. Inactivated vaccines elicit a strong induction of the immune response, but their effectiveness depends on the specific adjuvant used. Both live-attenuated and protein subunit vaccines require repeated doses and have weak immunogenicity. Virus-like particle vaccines, similar to protein subunit vaccines, have greater immunogenicity (Jeyanathan et al., 2020).

The effectiveness of a COVID-19 vaccine is defined by measuring the proportion of individuals who remain uninfected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) after completing the whole vaccination regimen. The documented rates of COVID-19 vaccine effectiveness are as follows: 95% for Pfizer/BioNTech, 94.1% for Moderna, 91.6% for Gamaleya, 70.4% for Oxford/AstraZeneca, and varying efficacy rates of 50%, 65%, 78%, and 91% for Sinovac depending on the country of the studies (Cairoli & Espinosa, 2021). The adverse effects of different types of COVID-19 vaccines will be further discussed.

COVID-19 Vaccination in Autoimmune Patients

Currently, numerous studies have been conducted on COVID-19 vaccines in patients with autoimmune rheumatic and autoinflammatory diseases (Esquivel-Valerio et al., 2021). The expected benefits of COVID-19 vaccination include providing long-term protection against the COVID-19 virus to both the general population and rheumatic patients while avoiding the onset of new diseases or complications. Besides the autoimmune conditions of the patients, each vaccine contains different components that are added during its production, resulting in varying levels of immunity against COVID-19 (Velikova & Georgiev, 2021).

Vaccine adjuvants, such as aluminum salt (alum), have the ability to activate the nucleotide oligomerization domain-like receptor family, pyrin domain containing 3 (NLRP3) inflammasome and release pro-inflammatory cytokines. The activation of the NLRP3 inflammasome can potentially trigger autoimmunity. Meanwhile, the release of pro-inflammatory cytokines can affect monocytes, dendritic cells (DC), and cluster of differentiation 4+ (CD4+) T cells. Therefore, it is necessary to pay attention and observe the acceptance of the COVID-19 vaccination that incorporates adjuvants. mRNA molecules possess intrinsic immunogenicity, and some of them can induce a type I interferon response that can influence inflammation and autoimmunity (Soy et al., 2021).

In a study conducted by Tharwat et al. (2022), the most widely used vaccines in autoimmune rheumatic patients at a rheumatology and immunology unit in Lower Egypt were Sinopharm (29.7%) and AstraZeneca (24.3%), both of which belong to the type of inactivated vaccines. The reported side effects ranged from mild to moderate in severity. Widespread muscle or joint pain was the most common side effect, followed by fatigue and fever or chills. Apart from that, there were also reports regarding other side effects experienced by autoimmune patients, including rashes, diarrhea, and dry mouth (Boekel et al., 2021). A multivariable logistic regression analysis discovered similarities between autoimmune patients and healthy people in terms of side effects caused by the COVID-19 vaccination. The perceived side effects consist of local or systemic side effects that are temporary or can resolve on their own (Boekel et al., 2021; Sen et al., 2022b).

According to the European Alliance of Associations for Rheumatology, formerly known as the European League Against Rheumatism (EULAR), autoimmune patients experienced a 5% recurrence of the disease after receiving the COVID-19 vaccination. Furthermore, a 1.2% recurrence rate of severe disease was observed among these patients after the administration of the COVID-19 vaccination. The Global Rheumatology Alliance COVID-19 Vaccination Survey also confirmed these statements through the finding of a 13.4% recurrence rate in autoimmune patients. In prior research carried out at Johns Hopkins University in the United States, autoimmune patients who received the COVID-19 vaccination reported side effects. Among these patients, 89% exhibited local symptoms such as pain, swelling, and erythema, while 69% suffered from systemic symptoms. No instances of allergic reactions requiring the use of epinephrine were observed in the study. However, 3% of the patients reported the occurrence of new infections (Sen et al., 2022a).

According to the Centers for Disease Control (CDC), patients with autoimmune diseases are more likely to receive mRNA vaccines than other types of vaccines. However, the CDC also recommends close monitoring following vaccination. Antirheumatic immunosuppressive agents, such as corticosteroids, methotrexate, and leflunomide, may cause low-grade immunosuppression. The outcomes are dependent on the administered dose. The CDC advises that the COVID-19 vaccination can still be administered to patients who consume low doses of immunosuppressive drugs. However, it is noteworthy that the EULAR does not advocate administering live vaccines to patients who are immunosuppressed (Soy et al., 2021). Nucleic acid vaccines, specifically mRNA vaccines such as those developed by Pfizer-BioNTech and Moderna, are highlighted for their mild side effects and reduced risk of complications in autoimmune individuals.

Individuals who have comorbidities experience a weakened immune system, making it more challenging for their bodies to fight COVID-19 infections. This is particularly challenging for patients with autoimmune and autoinflammatory diseases. The administration of the COVID-19 vaccination is an effective preventive measure against COVID-19. Patients diagnosed with autoimmune diseases may be eligible for the COVID-19 vaccination after obtaining approval from their treating physicians. However, this is contingent upon the patients being in a stable condition, as it allows the efficacy of the vaccine while minimizing the risk of adverse effects that can potentially endanger the patients' health (Koesnoe & Maria, 2021). The administration of the COVID-19 vaccination for autoimmune patients must consider several factors, including routinely consumed medications such as immunosuppressants. Nevertheless, some immunosuppressive drugs, such as prednisone, methotrexate, and azathioprine, are not expected to affect vaccine effectiveness. According to the American College of Rheumatology, the Canadian Rheumatology Association, and the British Society of Rheumatology, special attention or adjustments are necessary for certain drugs, such as rituximab (Koesnoe & Maria, 2021).

Vaccine adjuvants can trigger autoimmunity by activating the NLRP3 inflammasome and releasing pro-inflammatory cytokines. The release of cytokines can potentially affect monocytes, dendritic cells (DC), and CD4+ T cells. Therefore, it is necessary to observe and evaluate the acceptance of the COVID-19 vaccination that

incorporates adjuvants. mRNA molecules have intrinsic immunogenicity, and some of them have the ability to induce a type I interferon response, which can influence the occurrence of inflammation and autoimmunity (Soy et al., 2021; Pisetsky, 2023).

Adverse Effects of COVID-19 Vaccination on Autoimmune Patients

According to a previous study conducted by Esquivel-Valerio et al. (2021), the side effect of local pain was reported most frequently, with 158 cases (70.2%) of the total patients. The most common systemic symptoms reported by the patients were fatigue with 78 cases (34.7%), headache with 69 cases (30.6%), and muscle pain with 66 cases (29.3%). Additionally, 52 (23.1%) patients did not experience any side effects. Out of the patients who had been vaccinated against COVID-19, 42 (18.5%) individuals contracted the disease. Among these COVID-19 patients, 29 individuals (69%) experienced mild symptoms, while 12 individuals (28.6%) experienced moderate symptoms. Only one patient (2.4%) exhibited severe symptoms.

In a separate study carried out by Sen et al. (2022a), the most prevalent systemic autoinflammatory diseases (SAID) were found to be rheumatoid arthritis (13%), idiopathic inflammatory myopathy (11%), and hyper/hypothyroidism (9%). The study included SAID patients who had received at least one dose of the COVID-19 vaccination. Among these patients, the Pfizer-BioNTech vaccine was the most commonly administered (39.8%, n = 4,333), followed by the Sinopharm vaccine (17%, n = 1,821) and Oxford/AstraZeneca (13.4%, n = 1,456). The SAID patients reported that they experienced minor systemic side effects, such as pain at the injection site, myalgia, body aches, fever, chills, headaches, and fatigue. In comparison to normal patients, the SAID patients indeed had a significantly higher likelihood of experiencing side effects from the COVID-19 vaccination. However, the difference was not substantial and somewhat comparable, with rates of 65% vs. 62%. Additionally, there were major side effects that were more significant compared to healthy individuals, i.e., anaphylaxis (11% vs. 5%), difficulty breathing (36% vs. 27%), throat closure (27% vs. 4%), and rash (41% vs. 15%).

Messenger ribonucleic acid (mRNA) vaccines enhance immune responses by activating additional cytoplasmic pathways. There is a possibility for immune mechanisms to be triggered, which may lead to abnormal activation of innate or acquired immune responses. Hypothetically, this can induce systemic autoimmune diseases (SAD). In particular, an analysis of a serious adverse reaction to the Moderna vaccine revealed that one out of 30,000 participants developed rheumatoid arthritis (Cairoli & Espinosa, 2021).

Muthu et al. (2023) argue that the majority of autoimmune patients throughout India who participated in their study experienced mild and manageable side effects post-vaccination. The commonly reported side effects included localized pain at the injection site, fatigue, and headaches. The study emphasized the importance of monitoring and understanding the impact of the vaccination on autoimmune patients, as they represent a vulnerable population with unique immune responses. The survey, which involved 842 autoimmune patients, revealed that COVID-19 vaccines demonstrated a favorable safety profile with mild and transient side effects. This data contributes to the growing body of evidence supporting the vaccination of autoimmune patients, underscoring its importance in protecting this vulnerable population against the severe outcomes associated with COVID-19.

In a recent study conducted by Mahroum et al. (2022), the researchers explored the relationship between COVID-19 vaccination and immune or autoimmune adverse events. It was found that different vaccine types had varying effects. The study demonstrated that mRNA vaccines (e.g., Pfizer and Moderna) carry a low risk of autoimmune reactions, mainly limited to local reactions. Adenovirus vector vaccines (e.g., AstraZeneca and Johnson & Johnson) might pose a higher risk of autoimmune reactions, as evidenced by cases of thrombosis and autoimmune thrombocytopenia. While the study acknowledges the overall safety of COVID-19 vaccines, it also highlights potential adverse effects, particularly in individuals with autoimmune conditions. The documented adverse events included local reactions, systemic symptoms, and rare instances of autoimmune phenomena. Notably, mRNA vaccines have been associated with a higher incidence of myocarditis and pericarditis, particularly in younger men. Viral vector vaccines may pose a minimal risk of thrombosis, whereas inactivated vaccines have been linked to rare instances of Guillain-Barré syndrome.

Prior research has reported new cases of secondary autoimmune diseases due to the SARS-CoV-2 infection. These diseases include immune thrombocytopenic purpura, autoimmune hemolytic anemia, Guillain-Barré syndrome, Miller Fisher syndrome, antiphospholipid syndrome, and Kawasaki-like disease (Olivieri et al., 2021). Autoimmune patients who receive the Moderna and AstraZeneca vaccines are at a higher risk of experiencing minor vaccine side effects compared to those who receive the Pfizer and Sinopharm vaccines (Sen et al., 2022b).

DISCUSSION

Vaccines work by stimulating the human immune system to elicit an immune response against potential viral or bacterial invaders, such as the COVID-19 virus. However, the administration of COVID-19 vaccines necessitates careful consideration of factors such as age and the presence of comorbidities, particularly autoimmune and autoinflammatory diseases (Sadarangani et al., 2021). It is important to recognize that all vaccines, including COVID-19 vaccines, trigger an immune response that may result in varying degrees of adverse effects. Therefore, it becomes crucial to acknowledge certain factors, such as age and underlying health conditions.

The EULAR advises against administering live vaccines to immunosuppressed patients. COVID-19 vaccines can be administered to autoimmune patients who consume low-dose antirheumatic immunosuppressants, corticosteroids, and disease-modifying antirheumatic drugs (DMARDs) such as methotrexate. However, the antibody response to the COVID-19 vaccination in autoimmune patients may change if they receive a higher dose of the medications. Hence, autoimmune patients are advised to receive the COVID-19 vaccination when their condition is stable and requires only low doses of medication. Temporary discontinuation of methotrexate and leflunomide does not affect disease activity. These medications also do not affect the effectiveness of the COVID-19 vaccination. Therefore, there is no requirement for autoimmune patients to temporarily stop treatment prior to getting vaccinated against COVID-19. As per the recommendation of the American College of Rheumatology, autoimmune patients

should wait for one week after receiving the vaccination to see the antibody and immune response in their bodies (Soy et al., 2021).

Individuals with autoimmune diseases are advised against receiving live attenuated vaccines due to potential impacts on immunity, ongoing treatments, and the likelihood of severe side effects. Notably, these COVID-19 vaccines contain aluminum hydroxide adjuvants aimed at enhancing the immune response. In the case of subunit protein vaccines necessitating adjuvants, the administration should be approached cautiously in autoimmune patients to ensure optimal vaccine efficacy (Soy et al., 2021).

The AstraZeneca vaccine, a vector adenovirus vaccine, is commonly used for autoimmune patients and rarely causes severe side effects. The Pfizer COVID-19 vaccine, which is an mRNA vaccine, is also considered safe for administration to autoimmune patients as it does not cause serious side effects. However, there have been reports of new instances or flares of autoimmune conditions in patients who have received mRNA vaccines, leading to advanced episodes such as multiple sclerosis. Additionally, there were cases of systemic lupus erythematosus patients who developed flares after receiving the COVID-19 vaccination. This might be attributed to the spike-binding ACE2 receptor, which became a target for autoantibodies in the COVID-19 virus (Frasca et al., 2023). The COVID-19 vaccination and autoimmune agents share a similar immunopathogenicity, which can induce flares and new cases in individuals with autoimmune conditions. Molecular mimicry of the SARS-CoV-2 virus has the potential to trigger autoimmune diseases (Rodríguez et al., 2022).

CONCLUSION

The COVID-19 vaccination can be administered to autoimmune patients with careful evaluation by the attending doctor. The vaccination is considered safe when the medical condition of the patient is stable. It is crucial to meticulously evaluate the specific type of COVID-19 vaccination administered to autoimmune patients in order to avoid severe adverse reactions, flares, and the onset of new diseases. Patients diagnosed with autoimmune diseases are preferably recommended to receive mRNA vaccines, as they are associated with mild adverse effects. Autoimmune patients are advised to avoid receiving live attenuated vaccines due to their potential impact on the immune response. Additionally, advanced age and other comorbidities should be taken into account when administering a specific type of COVID-19 vaccine. Despite the nuanced considerations associated with each vaccine, there is no outright prohibition against autoimmune patients receiving the COVID-19 vaccination. Autoimmune patients should consult their treating physician to determine whether they will benefit from the COVID-19 vaccination. The decision should prioritize the stability of the patients and involve careful consideration of the specific type of COVID-19 vaccine to be administered.

ACKNOWLEDGEMENT

None to declare.

CONFLICT OF INTEREST

The authors declare there is no conflict of interest.

FUNDING DISCLOSURE

None to declare.

AUTHOR CONTRIBUTION

ANW contributed to the conception and design, analysis and interpretation of the data, drafting of the article, provision of administrative, technical, and logistic support, as well as the collection and assembly of the data. A contributed to the conception and design, drafting of the article, critical revision of the article for important intellectual content, and final approval of the article. RJS contributed to the conception and design, critical revision of the article for important intellectual content, final approval of the article, and statistical expertise.

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