

COVID-19 Update for the GRAPPA 2021 Annual Meeting: Focus on COVID-19 Vaccination

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ABSTRACT. The efficacy and safety of coronavirus disease 2019 (COVID-19) vaccination in patients with autoimmune inflammatory diseases (AIRDs) who are treated with immunomodulatory therapies was the focus of a symposium at the 2021 virtual annual meeting of the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA). The keynote address was delivered by Dr. Jeffrey Curtis, chair of the American College of Rheumatology COVID-19 Vaccine Clinical Guidance task force, detailing what we do and do not know about vaccine efficacy and safety in patients with AIRDs and providing guidance about the need for modification of dosing in some immunomodulatory medications for optimal vaccine response. A consensus of the task force was that all patients with AIRDs should be vaccinated as soon as it is allowed in their respective locations, since the benefits of increased protection against COVID-19 infection outweigh the potential for vaccination reactions, including flares of underlying disease, or for reduced efficacy of vaccination because of disease state or medications. Key issues among patient research partners with psoriatic disease expressed in the premeeting survey and panel discussion/question-and-answer period included: vaccine efficacy and safety, the need to continue safe social habits and masking, how to assess efficacy of vaccination, how to deal with vaccine hesitancy among social contacts, medication management relative to vaccination, and concerns about the adequacy of ongoing telehealth visits vs the convenience of that technology.

Key Indexing Terms: GRAPPA, psoriasis, psoriatic arthritis

Introduction

Dr. Philip Mease, Chair and Moderator. The coronavirus disease 2019 (COVID-19) pandemic has had an immense effect on each of our lives. In keeping with the magnitude of the pandemic,

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a special session on COVID-19 was held at the 2020 annual Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) meeting and again during the 2021 annual meeting. Last year we hosted expert lectures by rheumatologists and infectious disease specialists on topics relating to patients with COVID including changes of medications, impact of immune-mediated inflammatory diseases (IMIDs), and the effect of these factors on infection severity.¹ We also discussed the conversion of health care from in-person visits to telehealth appointments. A survey was conducted among GRAPPA patient research partners (PRPs) on these subjects and their overall concerns during the pandemic, then discussed in panel format. Now that vaccination against the virus and its variants has become available, our focus turned to the vaccines, their efficacy and safety, recommendations for use, and questions about vaccinations from the PRP group. The keynote speaker was Dr. Jeffrey Curtis, rheumatologist and epidemiologist from the University of Alabama in Birmingham, and chair of the American College of Rheumatology (ACR) COVID-19 Vaccine Clinical Guidance Task Force. Panel discussants included Drs. Philip Mease and Kevin Winthrop, and Wendy Olsder (PRP).

Presentation

Vaccination against SARS-CoV-2 in patients with psoriasis, psoriatic arthritis, and other IMIDs, by Dr. Jeffrey Curtis, Keynote Speaker. The ACR guidance for COVID-19 vaccination in patients with rheumatic and musculoskeletal diseases, version 3, was published in March 2021.² The charge of the task force was to develop clinical guidance for rheumatology patient management on how to best use COVID-19 vaccines and facilitate implementation of

vaccination strategies for at-risk patients with rheumatic and musculoskeletal disease. It was acknowledged that the guidance was based on scant but rapidly evolving evidence and was not meant to replace clinical judgment and shared decision making with the patient. The literature search for version 3 was carried out through early January 2021. The task force formed 3 groups focused on the following topics: (1) vaccine efficacy and safety of the 2 mRNA vaccines developed by Pfizer and Moderna, as well as other vaccines such as the Johnson & Johnson and Oxford/AstraZeneca viral vector vaccines; (2) COVID-19 epidemiology and vaccine effectiveness in patients with IMiDs and their immunomodulatory therapies, based on past experience with influenza and pneumococcal vaccines in such patients; and (3) safety concerns such as IMiD flare/worsening related to vaccination. A 70-page evidence summary was developed, then the task force completed a 2-step Delphi exercise to determine level of agreement on summary recommendations. Nine vaccines were described, with either mRNA, viral vector, or inactivated virus mechanisms.³

General principles and considerations agreed to by the task force were described.² The rheumatology clinician is responsible for engaging the patient with autoimmune inflammatory rheumatic disease (AIRd) in shared decision making about the COVID-19 vaccine. Taking into account contextual factors such as disease severity and treatment, demographic factors, and comorbidities, patients with AIRd are at greater risk for hospitalization and worse outcomes than the general population if infected with COVID-19 and thus should be prioritized for vaccination.⁴ There are no known contraindications for COVID-19 vaccination for patients with AIRd, and vaccination response may be blunted. There is the potential for flare of AIRd symptoms and signs post vaccination, but the benefit outweighs the risk. Supportive data for these points were presented, as well as the point that flares of AIRd symptoms and signs, new-onset AIRd, and increased autoantibody production could occur as a result of COVID-19 infection.

Recommendations for use of COVID-19 vaccines in patients with AIRd were reviewed.² All patients should receive vaccination according to U.S. Food and Drug Administration and European guidelines, regardless of disease activity, with no preference for a specific vaccine. Measurement of spike antibody post vaccination to assess response was not recommended, partly based on uncertainty of reliability, interpretation, and meaningfulness of various tests. Regardless of vaccination status, patients with AIRd should continue to follow the public health guidelines of masking and social distancing. Household members and other close contacts of patients with AIRd should be vaccinated as soon as allowable.

Guidance regarding holding (or not) medications used to treat AIRds was provided.² Methotrexate (MTX), Janus kinase inhibitors, and mycophenolate mofetil (MMF) should be held for 1 week after each mRNA vaccine dose. If a single-dose vaccine (such as Johnson & Johnson) is given, MTX should be held for 2 weeks after the vaccine. Abatacept (ABA; subcutaneous) should be held for 1 week before and 1 week after first vaccine administration. The COVID-19 vaccine can be administered 4 weeks

after previous dose of intravenous ABA and can be resumed 1 week after. Intravenous cyclophosphamide (CYC) should be timed so that it is given 1 week after vaccine administration. Regarding rituximab (RTX), vaccination should be scheduled 4 weeks prior to the next RTX cycle, and RTX should be delayed until 2–4 weeks after the second vaccine dose. No modifications were advised regarding all other medications. Some of these recommendations were influenced by studies of antibody responses seen after influenza vaccination⁵ or COVID-19 vaccinations.⁶

The ACR guidance statements are considered conditional/provisional, given the weakness of supportive data, and should not override the values and perspectives of the patient or judgment of the clinician. It is acknowledged that there is a high degree of variability from 1 patient with AIRd to another in terms of disease severity, comorbidities, treatments, and relationships with their providers—all of which should be considered when individualizing care. The evolution of COVID-19, including variants, as well as societal behavior regarding vaccination, remains volatile and thus will require nimble adjustment depending on the circumstances. Even if vaccine response is blunted due to disease or treatment, the risk of not being vaccinated is greater. It is anticipated that vaccine boosters will be necessary and advisable.²

PRP Survey

Nine PRPs completed an online survey conducted in the month prior to the annual meeting. One patient had been infected with COVID-19, and all had received at least 1 dose of a COVID-19 vaccine. Approximately half were concerned about potential side effects and efficacy. One-third had been tested for antibody response to the vaccine. One-third were not concerned about contracting the virus after vaccination; thus, two-thirds had concerns and remained cautious about potential exposure. Half felt they had been adequately informed about risk of viral infection in relation to their underlying disease and its treatment, but half felt either inadequately educated or only moderately so. The same percentage felt adequately informed about the risk that their medications conveyed. Only a quarter felt adequately informed about the potential for severe illness should they acquire viral infection, either due to their disease or its treatment. One-quarter of the PRPs had experienced a change in medication, either in relation to COVID-19 risk or vaccination. Between 10% and 25% had concerns about their mental health, frustration with the persistence of the pandemic, new viral strains emerging, and potential issues with vaccination. One of the 9 PRPs had experience with a telehealth appointment prior to the pandemic and 6 had experience with telehealth during the pandemic. For those experienced with telehealth visits, all noted that their physician's practice had pivoted quickly to providing telehealth service. Two-thirds did not feel that the visits were as thorough or comprehensive. All felt that their medical privacy was respected. Questions generated by PRPs in the survey centered around how to test for adequate response to vaccination, including assessing T cell-mediated immunity and how psoriatic disease and its treatment might influence acquisition

of infection, its severity, and vaccination effectiveness. Concern was expressed about the number of unvaccinated persons around them and how they might deal with such vaccine reluctance. Others wondered if this experiment with telehealth will allow for a paradigm shift in the way care is delivered, with the option of being seen occasionally in person but utilizing telehealth for routine visits.

Virtual Discussion Session

Panel discussion: Drs. Philip Mease, Jeffrey Curtis, and Kevin Winthrop, and PRP Wendy Olsder. A key question that recurred, both in the panel and in the online chat, had to do with concern about whether a vaccinated individual had developed an adequate antibody response to the vaccine, particularly given lack of full understanding about whether a patient with an AIRD undergoing immunomodulatory therapy might have some blunting of response. There was general optimism that patients with psoriatic arthritis (PsA), psoriasis (PsO), or axial spondyloarthritis would likely not have a blunted response since, as a whole, this patient group is not using B cell–depleting therapies such as RTX, high-dose steroid therapy, or drugs like MMF, azathioprine, or CYC. Thus, the ACR recommendation is for patients not to have quantitative spike antibody testing to test for humoral antibody response, especially for patients with PsA or PsO, since it is not clear whether a low or negative test result is correlated with poor immunity to the virus, in part because T cell–mediated immunity may be present. Physicians may want to order this test for their patients if COVID symptoms seem severe, but should consider the possibility of false negatives in immune-suppressed patients. At the time of the meeting, there was no clear guidance from health agencies such as the Centers for Disease Control and Prevention about whether patients with low immune response to the vaccine could be eligible for a booster or repeat vaccination series. At the time of writing, however, elderly subjects and immunocompromised patients are being allowed to receive booster shots, based on evidence of ebbing viral immunity over time as well as new viral strains emerging.

Although the initial observations from the Global Rheumatology Alliance registry suggested that patients with autoimmune diseases may not have more risk for acquiring COVID-19 or more severe disease, Dr. Curtis pointed out that

without a control group of subjects without these conditions and treatments, it is difficult to make such an observation with confidence. He pointed to general population studies where this comparison could more reliably be made and noted that patients with AIRDs who are on immunomodulatory therapy do appear to have a slightly higher risk for viral acquisition and more severe disease. This will depend on a number of contextual factors, including AIRD disease severity, immunosuppressive potency of therapy being used, demographic features, and comorbidities.

There was a general acknowledgment that the pandemic has upended our lives profoundly, with significant consequences on our personal relations, work, and life trajectory. Although the rapid introduction of vaccines for global use provides a ray of hope that we will eventually see the pandemic in our rearview mirror, there remain huge challenges to overcome, including the provision of vaccines to underdeveloped segments of the global population, working against vaccine hesitancy, confronting variants of the virus as they arise, and dealing with economic hardship and political strife engendered by the pandemic.

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