Study finds COVID-19 vaccine not associated with severe disease flare in patients with rheumatic diseases

November 1 2021

Credit: Unsplash/CC0 Public Domain

New research presented this week at ACR Convergence, the American College of Rheumatology's annual meeting, shows that the COVID-19

vaccine was not associated with severe disease flares in patients with rheumatic diseases. Medications to treat rheumatic diseases were associated with a reduction in vaccine-induced antibody responses.

During the clinical trials for the COVID-19 vaccines, individuals with an immunocompromised condition and/or a history of autoimmune disease were excluded. This left patients concerned about the safety and immunogenicity of the vaccines once they were widely available. Researchers set to find out how safe the vaccines were for patients with rheumatic diseases.

"This study was proposed a year ago when there was essentially no information about the safety and immunogenicity of COVID-19 vaccines in people living with rheumatic diseases. We presented the study proposal to our provincial Government as a 'priority,'" said Dr. Inés Colmegna, MD, Associate Professor at McGill University's Department of Medicine-Rheumatology in Montreal, QC and the study's co-author. "Historically, some groups of patients with rheumatic diseases had reduced immunogenicity to other vaccines. In addition, case reports indicated a risk of viral mutations in severely immunosuppressed hosts."

To find out more about the safety and immunogenicity of the vaccines in patients with rheumatic diseases, researchers conducted a prospective, non-randomized, open label, comparative clinical trial at two academic centers in Quebec, Canada. Trial participants were adults with one of the following diagnoses: Seropositive rheumatoid arthritis (RA) on stable treatment for more than three months, systemic lupus erythematosus (SLE) on stable treatment with mycophenolate mofetil (MMF), patients with another rheumatic disease receiving greater than 10 mg of prednisone per day, or age/sex matched adults without rheumatic diseases (the control group).

Two hundred twenty participants were enrolled in the study. One

hundred thirty-one patients with RA, 23 with SLE, 8 with another rheumatic diseases, and 58 controls. The average age was 60.4 and 72% of the participants were female.

The primary outcomes of the study were the frequency of pre-specified (i.e., solicited) local and systemic adverse events in the seven days after each vaccine dose and any other (i.e., unsolicited) adverse events (including disease flares) in the 28 days following each dose. The study sought to determine the safety profile of the mRNA-COVID-19 vaccine from Moderna in young and elderly patients with RA on different treatments, SLE patients on MMF, and people with any rheumatic disease requiring high doses of steroids. In addition, it evaluated the proportion of those patients that developed vaccine-induced antibodies compared to a control group without rheumatic diseases.

Local and systemic solicited adverse events were more frequently reported after the second dose of the vaccine with pain in the injection site being the most common. Swollen joints (a solicited adverse event) following both doses of the vaccine were more frequently reported by the RA patients than the control group. There was no increase in disease activity post-vaccination. No serious adverse events were attributed to the vaccine.

After the first dose, positivity for the SARS-CoV-2 spike protein and its receptor binding domain was 100% in the control group, but only 67.7% in the patients with RA, 34.8% in the patients with SLE, and 87.5% in the patients with other rheumatic diseases. After the second dose, positivity for the SARS-CoV-2 spike protein and its' receptor binding domain remained at 100% in the control group, but only 88.5% in the patients with RA, 78.3% in the patients with SLE, and 87.5% in the patients with other rheumatic diseases. Positivity after the second doses in RA patients who were 65 years or older versus patients who were younger was similar. After the two vaccine doses, people taking

rituximab or mycophenolate mofetil (MMF) had lower humoral responses than patients who are not taking those drugs. These results indicate that most rheumatology patients included in this study had good vaccine responses following two doses of a mRNA-vaccine with the exception of two groups: RA patients on rituximab and SLE patients on MMF. In these two groups, additional strategies to enhance vaccine responses need to be tested.

This study, entirely funded by the Government of Quebec, is still ongoing. The study's authors say antibody responses will be assessed at 6 months post vaccination as well as after a third dose of a vaccine. In addition, cellular responses will be evaluated.

"These findings help to reassure patients with rheumatic diseases and their providers who are concerned that COVID-19 vaccines could lead to an increase in disease activity," said Dr. Colmegna. "It highlights the importance of having a complete vaccine scheme in order to enhance vaccine responses. It confirms reduced immunogenicity in patients on drugs that affect B cell function, emphasizing the importance of the Cocoon Strategy (vaccinating those in close contact with these vulnerable patients) and other measures to prevent infection."

More information: Inés Colmegna et al, COVID-19 Vaccine in Immunosuppressed Adults with Autoimmune Diseases [abstract]. *Arthritis Rheumatology* (2021). Available at acrabstracts.org/abstract/covi … autoimmune-diseases/

Provided by American College of Rheumatology