Nearly one third of lupus patients in one study had low responses to COVID-19 vaccines

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New research presented this week at ACR Convergence, the American College of Rheumatology's annual meeting, shows that nearly 30% of patients with lupus in a multi-ethnic and multi-racial study had a low response to the new COVID-19 vaccines.

Systemic lupus erythematosus (SLE or lupus), is a chronic (long-term) disease that causes systemic inflammation which affects multiple organs. In addition to affecting the skin and joints, SLE can affect other organs in the body such as the kidneys, the tissue lining the lungs (pleura), heart (pericardium), and brain. Many patients experience fatigue, weight loss and fever.

Since Phase III clinical trials of COVID-19 vaccines excluded people who took immunosuppressant or immune-modifying drugs within the last six months before enrollment, there is little data on how the new shots work in people with SLE. Because they fear a disease flare, some people with rheumatic diseases like lupus have been hesitant about getting vaccinated. This new study looked at seroreactivity (the ability of the vaccine to cause the immune system to generate antibodies against COVID-19) and SLE disease flares after COVID-19 vaccination in a broad group of 90 lupus patients compared to 20 healthy controls.

"Many of us in the rheumatology community have been working on addressing the question of whether certain immunosuppressive medications affect the response to the new COVID-19 vaccines," says Peter M. Izmirly, MD, a rheumatologist at NYU Langone Health in New York City and the study's co-author. "Our group has previously shown that after natural infection with SARS-CoV-2 (coronavirus), most lupus patients did develop and maintain a serologic response to the virus. We decided to limit our study to only patients with SLE to assess both the medications and disease effect on the response to the vaccine, and to assess any change in disease activity post-vaccination."

All patients in the study received a complete COVID-19 vaccine schedule. Their IgG seroreactivity to the SARS-CoV-2 Spike receptor binding domain was measured by two different tests to evaluate B-cell response to the vaccine, and their IFN-gamma production was measured to determine their T-cell response. Their SLE disease activity and any

lupus disease flares were also measured.

Overall, patients with SLE had a lower mean titer of post-vaccine antibodies compared to healthy patients. Researchers found that 26 SLE patients generated IgG antibody responses to the SARS-CoV-2 Spike receptor binding domain that fell below the lowest response levels for healthy patients.

Researchers found that the patients medications mattered: Lower vaccine response was associated with use of prednisone in combination with at least one immunosuppressant drug, use of prednisone alone, use of a combination of two immunosuppressants, or use of mycophenolate mofetil or mycophenolic acid. People with SLE who had a normal anti-dsDNA antibody level before vaccination had a lower response, as well as those who received the Jansen/Johnson & Johnson brand vaccine.However, taking an antimalarial drug was associated with a more positive response to the vaccine. Taking an antimalarial or no medication or having an elevated anti-dsDNA before vaccination independently predicted a positive response to the shots.

People with SLE who had poor antibody responses to the vaccine also had lower IFN-gamma production. There was no change in post-vaccination lupus disease activity scores compared to pre-vaccination. Only 11% of patients had SLE flares after vaccination, with 1% being a severe flare. The low incidence of severe disease flares after vaccination is a reassuring finding.

This study's findings suggest that many people with SLE could have a low response to standard COVID-19 vaccine protocols. Researchers would like to see immediate studies to determine the efficacy of a booster shot for these patients.

"The data from our group and others have shown that overall disease

activity did not change after vaccination. Our study also showed that severe flares were rare. Most flares were mild to moderate and manageable. Our data and that of other groups suggest that certain medications or combinations of medications could affect the efficacy of the vaccines. While minimal protective levels remain unknown, these data suggest protocol development is needed to assess efficacy of booster vaccination," says Dr. Izmirly.

To learn more, Dr. Izmirly's laboratory at NYU is participating in a new study the National Institute of Allergy and Infectious Diseases (NIAID) is funding to evaluate booster vaccines in patients taking certain medications with a poor serologic response to the vaccine.

"This study aims to address the efficacy of booster vaccines on patients taking certain immunosuppressing medications. If patients are concerned about side effects or efficacy of a COVID-19 booster vaccine, I encourage them to participate in the NIAID trial to help get answers."

More information: Peter M. Izmirly et al, Evaluation of Immune Response and Disease Status in SLE Patients Following SARS-CoV-2 Vaccination, *Arthritis & Rheumatology* (2021). DOI: 10.1002/ART.41937

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