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involved in a patient's intoxication, which is why the use of confirmatory techniques is required.

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Efficacy and safety of SARS-CoV-2 vaccine in patients with giant cell arteritis[☆]



Eficacia y seguridad de la vacuna frente a SARS-CoV-2 en pacientes con arteritis de células gigantes

Dear Editor:

The efficacy and safety of the messenger ribonucleic acid (mRNA) vaccine against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in patients with systemic autoimmune diseases (SADs) and receiving immunosuppressive treatment is unknown. The American Rheumatology Society has recently published their guidelines for these patients.¹ In a publication regarding 325 patients with a SAD who had been vaccinated with either the Pfizer/BioNTech (51%) or Moderna (49%) vaccine, mild local and generalized reactions were described, with no evidence of outbreak of the disease being reported, but no antibody response against the virus being described either.² Giant cell arteritis (GCA) is the most common type of vasculitis among the elderly,³ mostly among patients over 80 years, age at which the vaccine was initially administered in Spain. The influence of the 2019 coronavirus disease (COVID-19) pandemic on the diagnosis and treatment of GCA has recently been reviewed.⁴ However, the efficacy and safety of the vaccine against the SARS-CoV-2 in patients with GCA has been unknown to date, which is why we set out to analyze them.

To this end, we reviewed the medical records of patients with GCA who had received this vaccine and were being followed at our unit. We determined the presence and concentration of immunoglobulin G (IgG) antibodies in these patients through an enzyme-linked immunosorbent assay (ELISA) starting one week after they had received the second dose. In this context, safety was defined by the absence of recurrence of the disease according to the GiACTA criteria,⁵ including reappearance of the signs and symptoms of GCA and/or increased C-reactive protein levels >0.5 mg/dl,

in relation to the GCA, after completing the vaccination. Both local and generalized effects were collected through telephone calls.

A total of 17 patients, 12 of whom were women and five men, with a pooled mean age of 85.1 (80–95) years, were included in the study. The time elapsed between the GCA diagnosis and the vaccination was 6.6 (1–14) years. Two patients had previously overcome the infection with a positive (+) polymerase chain reaction (PCR) test performed on a nasopharyngeal exudate sample. All patients had received two doses of the Pfizer/BioNTech vaccine separated by a 21-day interval. At the time of vaccination, five patients were not receiving specific treatment, four were only receiving prednisone at a dose of 5 mg/day, five were receiving prednisone at a dose of 5 mg/day together with methotrexate 7.5 mg/week, and three were receiving subcutaneous tocilizumab 162 mg/week. None exhibited signs of clinical activity. None had symptoms of GCA other than low-grade fever, asthenia, and headache in five patients (29.4%), all of which resolved within less than 48 h with symptomatic treatment and were more attributable to the vaccine itself rather than to GCA. Fourteen out of the 17 patients (82.35%) described localized symptoms. Two patients had increased CRP levels without other signs of disease activity. All but one developed antibodies at a mean concentration of 1025.7 (57–2080) binding antibody units (BAU) per milliliter. The only patient who did not develop them was an 88-year-old woman who was untreated at the time of vaccination and had received only glucocorticoid therapy.

In this paper we present the first efficacy and safety data of the vaccine against SARS-CoV-2 in patients with GCA, with no vasculitis relapses being detected and with a very good immune response being achieved, reflected by the significant concentrations of IgG antibodies developed in all but one patient. Local reactions occurred in most patients (87%) and mild systemic reactions were only reported by a minority of them.

There have been, and still are, many doubts regarding the safety and efficacy of the different vaccines marketed against SARS-CoV-2 in patients with SADs, mainly in relation to the occurrence of outbreaks/disease activity and the capacity to generate an antibody response. Guidelines recently published by the American Rheumatology Society highlight some of them.² In this case, GCA is included in the group of SADs for which vaccination is recommended, and it is advised that the vaccine be administered once the disease activity is well controlled. It is completely unknown whether the

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mRNA vaccine against SARS-CoV-2 is capable of inducing the onset of vasculitis, in general, and of GCA, in particular.

The main limitation of our study is its sample size and the lack of a control group. Even so, we believe that our results are interesting with a view to promoting vaccination in patients with SADs, in general, and with GCA, in particular.

Thus, we conclude that the Pfizer/BioNTech mRNA vaccine against SARS-CoV-2 is safe and effective in patients with GCA.

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