

SAFETY OF COVID-19 VACCINE IN CONNECTIVE TISSUE DISEASES AND SYSTEMIC VASCULITIS – A PRELIMINARY ANALYSIS FROM SAFER STUDY

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BACKGROUND

Vaccination is the main strategy to prevent severe illness of the COVID-19 pandemic. This is especially important in vulnerable population groups such as patients with systemic autoimmune rheumatic diseases (AIRDs). The evidence about the safety of COVID-19 vaccines in AIRD patients has gradually become available, mainly for rheumatoid arthritis and systemic lupus erythematosus. To date, there are no data about the safety of COVID-19 vaccination in Brazilian patients with primary systemic vasculitides (PSVs) or other AIRDs including systemic sclerosis (SSc), mixed connective tissue disease (MCTD), autoimmune inflammatory myopathies (Myo) and overlap syndromes (OS).

METHODS

SAFER is a prospective, multicenter, Brazilian cohort study to assess the safety of vaccines against SARS-CoV-2 in patients with AIRD and PSV (n = 1,089). This preliminary analysis of the SAFER study aims to evaluate the safety, related to the occurrence of adverse events (AEs) following the primary vaccination, with two doses, of COVID-19 vaccination in patients with PSVs and AIRDs (i.e., SSc, MCTD, Myo, and OS).

RESULTS

The mean age at baseline was 40.1 years, 79.1% of patients were female and 62.4% nonwhite. This preliminary analysis included 192 patients with PSVs (n = 74) and other AIRDs (n = 118). The main PSVs were small and medium vessel vasculitides (n = 30, 40%), Behçet's disease (n = 28, 37.8%) and large vessel vasculitides (n = 17, 22.9%). AIRDs included SSc (n = 49, 41.5%), OS (n = 35, 29.6%), Myo (n = 20, 16.9%) and MCTD (n = 14, 11.8%). COVID-19 vaccines applied on PSVs and AIRDs were respectively: CoronaVac (39.1% and 40.2%), Oxford-AstraZeneca (56.5% and 53.6%), and Pfizer-BioNTech (4.3% and 6.1%). Adverse effects of SARS-CoV-2 vaccines were local pain (52.0–68.8%), headache (40.8–44.2%), fatigue (29.5–42.6%) and arthralgia (29.5–45.9%). Fever was reported in 22.4–24.5% and dizziness in 25.5–27.8%. Nor severe adverse events nether flares were reported in the study

period postvaccination. AstraZeneca and Pfizer vaccines were associated with more frequent local pain than CoronaVac on PSV and AIRD patients, with a p value = 0.038 and < 0.001, respectively. No other statistically significant difference of adverse effect was observed between the vaccines. Generally, the second shot had a lower frequency of adverse events, whilst local pain presented a similar frequency in both shots.

CONCLUSION

Different types of COVID-19 vaccines seem to be safe in PSVs and in AIRDs, such as SSc, MCTD, Myo, and OS as patients presented only mild-to-moderate AEs. The profile of AEs resembles that reported for the general population and seems to be more intense on the first dose of the vaccine.

KEYWORDS: COVID-19 vaccine, Systemic vasculitis, Connective tissue disease, Systemic sclerosis, Myositis.