ADVERSE EVENTS POST FIRST COVID-19 VACCINATION IN PATIENTS WITH AUTOIMMUNE DISEASES AND HEALTHY CONTROLS: FIRST DATA FROM SAFER STUDY

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BACKGROUND

In the setting of the pandemic scenario caused by COVID-19, several studies were published in search of an effective vaccine. However, there are few studies in the literature that assess the safety of the COVID-19 vaccine in patients with autoimmune diseases (AID). In this context, the present study aims to evaluate the safety during 28 days after the first dose of the vaccine against COVID-19 in patients with AID.

METHODS

These data are from Safety and Efficacy on Covid-19 Vaccine in Rheumatic Disease (SAFER) study, a Brazilian multicentric prospective phase IV study to evaluate COVID-19 vaccine in AID, in the real life, in Brazil. Adverse events (AE) from a single center were assessed, after the first COVID-19 vaccination (Oxford/AstraZeneca) in patients with AID and healthy controls (HC). Inclusion criteria were ≥ 18 years and fulfilling criteria according international classification for AID. Exclusion criteria were pregnancy, previous severe AE to any vaccine, other immunosuppression causes. Stratification of postvaccination AE was performed using a diary, filled out daily and returned at the end of 28 days.

RESULTS

A total of 377 volunteers with AID and 50 HC were included. Groups were similar for age (43.5 vs. 41.7, $p = 0.308$) and sex, with female predominance (73.5% vs. 74.0%, $p = 0.937$). Patients with spondyloarthritis ($n = 64$), systemic lupus erythematosus ($n = 63$), rheumatoid arthritis ($n = 61$), primary Sjögren's syndrome ($n = 61$), vasculitis ($n = 31$), systemic sclerosis ($n = 14$), inflammatory myopathy ($n = 9$), Crohn's disease ($n = 49$), ulcerative colitis ($n = 11$) and other systemics AID ($n = 12$) were evaluated. Both HC and AID showed high prevalence (92% vs. 89.9%, $p = 0.647$) but only mild AE. Pain at the injection (85.7% vs. 78.4%, $p = 0.239$), headache (67.3% vs. 53.8%, $p = 0.074$) and fatigue (59.2% vs. 46.2%, $p = 0.089$) were common in both groups. Overall, reactions like arthralgia (52.6% vs. 22.4%, $p < 0.001$), hematoma (14.1% vs. 4.1%, $p = 0.05$), cutaneous rash (9.5% vs. 0%, $p = 0.024$) were more frequent in AID. Most participants related that they felt safer after receiving a COVID-19 vaccination, and 52.4% did not worse patient global assessment (PGA) index.

CONCLUSION

Our data indicated that Oxford/AstraZeneca vaccine is safe for patients with AID. High prevalence of mild AE was found and similar in both groups. Arthralgia, hematoma and cutaneous rash were more frequent in AID. Next analysis from SAFER and other phase IV studies are necessary to confirm these findings.

KEYWORDS

COVID-19, Vaccine, Autoimmune disease, Adverse events.