MODERATE IMMUNOGENICITY AND EXCELLENT SAFETY OF AN INACTIVATED VIRUS VACCINE AGAINST SARS-COV-2 IN PRIMARY SJÖGREN'S SYNDROME: A PROSPECTIVE PHASE 4 CONTROLLED TRIAL

Sandra Gofinet Pasoto^{1,*}, Nadia Emi Aikawa¹, Ari Stiel Radu Halpern¹, Lissiane Karine Noronha Guedes¹, Lorena Elizabeth Betancourt Villamarín¹, Victor Adriano de Oliveira Martins¹, Giordano Bruno Henriques Deveza¹, Carolina C.M.F. Martins¹, Emily Figueiredo Neves Yuki¹, Carla Gonçalves Schahin Saad¹, Ana C. M. Ribeiro¹, Tatiana do Nascimento Pedrosa¹, Léonard de Vinci Kanda Kupa¹, Elaine Pires Leon¹, Margarete Borges Galhardo Vendramini¹, Clovis Artur Almeida da Silva¹, Renata Soares¹, Eloisa Silva Dutra de Oliveira Bonfá¹

1. Universidade de São Paulo, São Paulo (SP), Brazil.

*Corresponding author: sandra.pasoto@hc.fm.usp.br

BACKGROUND

There are scarce data regarding antibody response for SARS-CoV-2 vaccine in primary Sjögren's syndrome (pSS), and an additional concern in these patients is older age of onset compared to other autoimmune diseases, a known deleterious factor for vaccine response. We therefore assessed immunogenicity and safety of an inactivated SARS-CoV-2 vaccine (Sinovac-CoronaVac), and the possible effect of therapy in this antibody response.

METHODS

Fifty-one pSS patients and 102 sex- and age-matched control individuals without autoimmune diseases were included in a prospective phase 4 controlled trial of the Sinovac-CoronaVac vaccine (2 doses with a 28-day interval). Immunogenicity was assessed by anti-SARS-CoV-2 S1/S2 IgG seroconversion (SC), anti-S1/S2 IgG geometric mean titer (GMT), factor increase GMT (FI-GMT), neutralizing antibodies (NAb) positivity, and median neutralizing activity on each vaccine dose (D0 and D28) and 6 weeks after the second dose (D69). Patients/controls with prevaccination positive IgG serology and/or NAb and those with RT-PCR confirmed COVID-19 during the protocol were excluded of immunogenicity analysis.

RESULTS

Patients and controls were similar one female sex (98.0% vs. 98.0%, $p = 1.000$) and age (53.5 ± 11.7 vs. 53.4 ± 11.4 years, $p = 0.924$), respectively. Forty pSS patients and 86 controls were included in the immunogenicity analysis. At D69, pSS patients had significantly lower SC (67.5% vs. 93.0%, $p < 0.001$), GMT (22.5 [95% CI = 14.6–34.5] vs. 59.6 [95% CI 51.1–69.4] AU/mL, $p < 0.001$), FI-GMT (8.9 [5.6–14.0] vs. 27.4 [22.9–32.7], $p < 0.001$), and frequency of NAb (52.5% vs. 73.3%, $p < 0.05$) than controls. Median neutralizing activity at D69 was comparable in both groups (58.6% [IQR = 43.7–63.6] vs. 64% [46.4–81.1], $p > 0.05$). Importantly, methotrexate use was associated with a reduced SC in pSS ($p = 0.029$). Vaccine-related adverse events were mild, with higher frequencies of vomiting, muscle weakness, arthralgia, and back pain in pSS patients ($p < 0.05$).

CONCLUSION

Sinovac-CoronaVac has an excellent safety profile and despite an older mean age, a moderate short-term immunogenicity in pSS was observed, although lower than CTRL. Methotrexate was identified as the only drug to have a negative impact in antibody response. Clinical trial registration: #NCT04754698.

KEYWORD

Sjögren's syndrome, SARS-CoV-2, Vaccine, COVID-19.