IMMUNOGENICITY AND SAFETY AFTER SARS-COV-2 VACCINE IN PRIMARY ANTIPHOSPHOLIPID SYNDROME (PAPS)

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BACKGROUND

Immunogenicity data of COVID-19 vaccines for primary antiphospholipid syndrome (PAPS) is lacking. Recent reports of thrombosis with adenovirus-based vaccines raise concern in this predisposed population. Our aim was to evaluate the efficacy and safety of CoronaVac in PAPS patients.

METHODS

In this phase 4 prospective controlled trial, thrombotic PAPS patients were balanced by age ($p = 0.982$) and sex ($p = 1.000$) to a control group (CTRL) without autoimmune rheumatic disease or under immunosuppressive therapy. Participants positive to COVID-19 serology and/or neutralizing antibody (Nab) at baseline or those who tested positive for RT-PCR COVID-19 were excluded. Patients received a two-dose vaccine (D0 and D28) and blood samples were obtained at D0, D28 and D69 (6 weeks after second dose). Immunogenicity was evaluated by SARS-CoV-2 IgG seroconversion (SC), geometric mean titer (GMT), factor increase-GMT (FI-GMT), presence of Nab and its neutralizing activity (Nab-activity) at all time-points. Adverse events and incident cases of COVID-19 were registered.

RESULTS

Forty-four PAPS and 132 controls received the vaccine first dose. They were mostly women (86.4%), median age of 46 years. Thirty-one PAPS and 108 controls were included in the immunogenicity analysis. At D28, a low and analogous seroconversion was observed for PAPS and CTRL (25.8% vs. 30.6%, $p = 0.609$). A significant increase was observed at D69 with comparable SC (83.9% vs. 93.5%, $p = 0.092$), GMT (50.2 [95%CI = 34.5–73.2] vs. 61.7 [95%CI = 52.8–72.3], $p = 0.249$) and FI-GMT (21.4 [95%CI = 14.5–31.6] vs. 26.5 [95%CI = 22.3–31.4], $p = 0.586$) in both groups. The frequency of Nab at D28 was lower in PAPS than CTRL (16.1% vs. 35.2%, $p < 0.05$), with a robust rise and comparable rates at D69 (77.4% vs. 78.7%, $p = 0.440$). Nab-activity was similar between PAPS patients vs. CTRL (38.1% [32.0–55.5] vs. 43.7% [34.2–66.4], $p = 0.275$) at D28 and (64.3 [49.0–77.0%] vs. 60.9 [45.6–81.3%], $p = 0.689$) at D69. Four patients (1 PAPS and 3 CTRL) became mildly symptomatic and tested positive for RT-PCR COVID-19, until 4 days after second dose. Regarding safety, no moderate/severe adverse events occurred.

CONCLUSION

We demonstrated for the first time that CoronaVac two-dose vaccine elicits a very good antibody response with rates comparable to CTRL group. The excellent safety profile reinforces its recommendation for all PAPS patients.

KEYWORDS

Antiphospholipid syndrome, SARS-CoV-2, CoronaVac, COVID-19.