

COVID-19 vaccination in adults with congenital heart disease: results of 1-year prospective study

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Background: Adults with congenital heart disease (ACHD) are a vulnerable population. Routine vaccination is the only strategy to prevent a life-threatening infection. However, concerns on the cardiac safety and efficacy of COVID-19 vaccines have been raised.

Aim: To assess safety and efficacy of available COVID-19 vaccines in ACHD patients.

Methods: Data on COVID-19 infection and vaccines including booster doses and any suspected or confirmed adverse events were prospectively collected for all ACHD patients attending our tertiary centre from the beginning of the vaccination campaign (March 2021). A group of 75 healthy volunteers, matched per age and sex, was included for comparison. Anti-spike IgG titre was routinely obtained at the ACHD clinic. Patients' attitude towards COVID-19 was explored with a questionnaire.

Results: As of February 2022, 498 ACHD patients (36.7±16 years, 54% male, 69% with moderate-complex defects, 48% with advanced physiological stage) were enrolled. Four hundred and sixty-one (92%) were fully vaccinated: the type of vaccine was Pfizer-BioNTech for 399 (86%) patients, Moderna for 20 (4%) and AstraZeneca for 26 (6%), 9 received a mixed vaccine regimen (2%). Forty-two (9%) had a history of previous COVID-19 infection and therefore received only one dose. Two-hundred and sixty-nine (58%) patients received a booster dose. Adverse events were mainly mild and transient. One patient complaining of chest pain

following administration of mRNA-based vaccination was diagnosed with acute pericarditis, which made full remission after appropriate therapy. Two patients reported a non-specific increment of inflammatory markers. No other severe adverse events were reported. Thirty-seven (7%) refused COVID-19 vaccination being scared of potential cardiac/extra-cardiac adverse events. Among those not-vaccinated, 9 (24%) had a history of previous mild COVID-19 infection. IgG titre was measured in 243 patients at 1915 [835–5934] BAU/ml, which was significantly higher compared to controls (1196 [827–2048] BAU/ml, $p=0.002$). Three ACHD patients contracted COVID-19 infection after the first dose, while 65 (14%) fully vaccinated patients tested positive for COVID-19, all with mild to moderate symptoms. COVID-19 symptoms duration was significantly longer in case of infection before vaccination (10 [2.7–15] vs 3 [1.2–7], $p=0.03$). One Fontan patient was tested positive for COVID-19 twice, before and after COVID-19 vaccination, requiring hospitalization in both cases. Four hundred and seven patients completed the questionnaire: 128 (31%) declared to be scared of potential cardiac effects of the vaccine and that the discussion with the ACHD cardiologist was crucial to decide to undergo COVID-19 vaccination. **Conclusions:** Our data provide real-world evidence on COVID-19 vaccines safety and efficacy in ACHD patients. Patients' education from the ACHD team may play a key role in vaccine acceptance in this vulnerable population.