EVALUATION OF COVID-19 VACCINATIONS' SAFETY

Abstract

The SARS-CoV-2 infection causing COVID-19 disease was first reported in China in late 2019. Due to its rapid spread worldwide, high infectivity and frequent occurrence of severe multisystem symptoms leading to death, a pandemic was declared by the World Health Organization (WHO) in March 2020. The urgent need to develop an effective vaccine against this disease has led to the implementation of not only traditional vaccinees but also technologically novel ones such as the mRNA vaccine. This mRNA vaccines has been used in most European countries. Their accelerated development required an increased need to monitor their safety. Therefore, the main objective of our prospective cohort study was the safety of the mRNA vaccines.

The study, conducted from April 2021 to May 2022, enrolled 83 professional soldiers. During the 10 study visits, participants were interviewed about adverse events, had blood samples drawn for hematologic examination, and serum was obtained for the determination of IgG antibodies specific for SARS-CoV-2 S protein and antinuclear antibodies (ANA), antineutrophil cytoplasmic antibodies (ANCA), and apolipoprotein A-1 (AAA1) antibodies. The results were evaluated by statistical and analytical methods with respect to the nature of the variable. They were performed at a significance level of 0.05 with two-sided confidence intervals.

Any adverse event documented within 7 days occurred in 71.1% of participants after the first dose and in 85.5% of participants after the second dose of vaccination. After the booster dose, the occurrence of adverse events was registered in only 21% of participants because they were not interviewed immediately or within 7 days after vaccination. The most commonly reported local reaction was shoulder pain after vaccine administration. Fatigue, headache and chills were predominant among general reactions. Haematological results showed a decrease in leukocytes, lymphocytes, neutrophils and platelets within 1-4 days after vaccine administration, usually irrespective of the number of administered doses. Conversely, a significant increase in monocyte levels was found immediately after vaccination.

However, the changes found in the number of blood elements were only transient in nature, as they showed no differences from baseline up to seven days after vaccination, and their numbers remained unchanged for the remainder of the study follow-up period. The numbers of erythrocytes, basophils and eosinophils were not significantly affected by vaccination. Vaccination with the mRNA vaccine did not show an increased risk of ANA and ANCA autoantibody positivity. The incidence rate of AAA1 autoantibodies in vaccinated individuals did not show an association with mRNA vaccine vaccination. However, the rate of transient AAA1 positivity appeared to be 24.1% among study participants. Moreover, it was associated with higher BMI and was as high as 47% in obese individuals.

Post-vaccination anti-S IgG antibodies were significantly higher after the first dose in primoinfected subjects and after the second dose, antibody concentrations of 20,300 BAU/mL were not significantly different between primoinfected and immune naive subjects. Within 10 months, antibody concentrations decreased to a level of 4,600 BAU/mL. However, anti-S IgG concentrations did not return to their maximum values after the booster dose. During the study, 22 breakthrough infections were recorded, mostly in individuals who were immune naive before vaccination.

Based on the results obtained during this study, the acceptable safety of mRNA vaccines can be confirmed. Given the relatively short duration of use of mRNA vaccines, long-term monitoring not only of the aforementioned safety parameters but also, if necessary, of other parameters not yet used is certainly advisable.