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The Induction of *De Novo* Autoimmune Biomarkers Production in Healthcare Professionals Vaccinated with BNT162b2

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ABSTRACT

Introduction: The vaccine BNT162b2 was the first one to be approved and the first mRNA-based vaccine ever. Some vaccines are known to induce autoinflammatory mechanisms, most of those are mild and transient and only a minor part is pathogenic.To date, the literature has reported the existence of a link between autoimmunity and COVID-19. The aim of this study was to evaluate whether subjects vaccinated with BNT162b2, initially negative to autoimmune biomarkers, will show at 3 months after the second dose of vaccine, a *de novo* production of autoantibodies.

Methods: Blood samples of 155 healthcare professionals (HCPs) of our hospital (114 females and 41 males, age range 20-66 years, median age 46) vaccinated with COVID-19 mRNA BNT162b2 (Pfizer) were collected before (T0) and 3 months after the administration of the two doses of the vaccine (T1). All samples were analyzed for the presence of a) antinuclear antibodies (ANA) and anti-smooth muscle antibodies (ASMA) (Indirect Immunofluorescence [IIF], Euroimmun); b) anti-myeloperoxidase (anti-MPO), anti-proteinase 3 (anti-PR3) and anti-citrullinated peptide antibodies (anti-CCP) ([FEIA], Thermo Fisher Scientific); c) anti-phospholipid antibodies (anticardiolipin [aCL], anti-beta-2- glycoprotein I [anti-ß-2GPI] (Chemiluminescence, Werfen). Clinical data were collected using the REDCap software (REDCap version 10.2.3©2020 Vanderbilt University).

Results: Fifty (32,3%) out of 155 HCPs, presented ANA and 15 (9,7%) ASMA at T0. In contrast at T1, 53/137 HCPs, were positive for ANA (38,7%) and 21 (15,3%) for ASMA at T1. Most importantly, 9 HCPs that were negative at T0 for ANA and 10 negatives for ASMA, display a newly generated positivity at T1. Nine HCPs had high positive levels of ß-2GPI IgG and aCL at all time points and the values did not significantly change after vaccination.

Conclusions: Our preliminary results regarding the BNT162b2 vaccine effects on the development of potential autoimmune events in healthy individuals revealed an induction of autoinflammatory mechanisms in a small percentage of HCPs, developing a *de novo* autoantibodies production after vaccination.

Keywords: Vaccine, Autoimmunity, Autoimmune biomarkers, Covid-19

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