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Evidence of the Presence of Antinuclear Antibodies (ANA) in Healthcare Workers after BioNtech/Pfizer BNT162b2 mRNA Vaccination

Maria Cristina Sacchi[1,2*], Stefania Tamiazzo[1], Marinella Bertolotti[3], Carolina Pelazza[3], Antonella Cassinari[3], Daniele Ielo[4], Lisa Agatea[5], Piera De Gaspari[5], Paolo Stobbione[6], Maria Matilde Ciriello[1], Marisa Grappiolo[1], Tatiana Bolgeo[3] and Antonio Maconi[2]

[1]SC Laboratorio Analisi, Azienda Ospedaliera SS. "Antonio e Biagio e Cesare Arrigo", Alessandria, Italy

[2]SSD Laboratori di Ricerca, Dipartimento Attività Integrate Ricerca Innovazione,Azienda Ospedaliera SS. Antonio e Biagio e Cesare Arrigo, Alessandria, Italy

[3]SC Infrastruttura Ricerca, Formazione e Innovazione, Dipartimento Attività Integrate Ricerca Innovazione, Azienda Ospedaliera SS. "Antonio e Biagio e Cesare Arrigo", Alessandria, Italy

[4]Werfen, Italy

[5]Laboratory department, Affiliated to Euroimmun, Padova, Italy

[6]SSD Reumatologia, Azienda Ospedaliera SS. "Antonio e Biagio e Cesare Arrigo", Alessandria, Italy.

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ABSTRACT

Background and Aim: Evidence from clinical trials strongly supports the safety and efficacy of the different COVID-19 vaccines. Indeed, the risk to develop a severe form of the disease, possibly leading to death, it is highly decreased in fully vaccinated individuals. The BioNtech/Pfizer BNT162b2 mRNA vaccine was the first to receive FDA and EMA approval. Nowadays, its effects and possible ability to stimulate an autoimmune reaction are still poorly understood. The aim of this study was to check the development and /or persistence of antinuclear antibodies (ANA) in healthcare workers (HCPs) after BioNtech/Pfizer BNT162b2 mRNA vaccination.

Methods: Blood samples from 108 HCPs (83 females and 25 males, age range 26-67 years, median age 46) vaccinated with 3 doses of BioNtech/Pfizer BNT162b2 mRNA were considered. Samples were collected before the inoculation of the vaccine (T0), at 3 (T1) and 12 months (T2) after the first dose. ANA were evaluated using indirect immunofluorescence on Hep-2 cell (dilutions: 1:80; 1:160; 1:320; 1:640).

Results: Among 108 subjects enrolled, 34 were positive for ANA at T0 and they maintained this positivity also at T1 and T2. Differently, 43 subjects were ANA negative during all the 12 months. However, 25 subjects ANA negative at T0, they became positive over time. In particular, 5 of them presented ANA positivity at T1, whereas 20 at T2. Furthermore, the 90,7% of individuals positive at T1 were positive at T2 too, showing a definite increased in the antibody titer. The predominant ANA pattern was homogeneous one.

Conclusion: Our results suggest that BioNtech/Pfizer BNT162b2 mRNA vaccination seems to induce the onset of de novo ANA in 23,15% of individuals and that the percentage of positivity seems to directly correlate to the number of vaccine expositions (5.5% after 2 doses vs 17.59% after 3 doses).

Keywords: Autoantibodies, ANA, SARS-CoV-2, BNT162b2 vaccine, Healthcare workers

Corresponding author: Maria Cristina Sacchi, SC Laboratorio Analisi, Azienda Ospedaliera SS. "Antonio e Biagio e Cesare Arrigo", Alessandria, Italy, E-mail: csacchi@ospedale.al.it

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