PB2236 HUMORAL RESPONSE TO SARS-COV-2 VACCINATION WITH BNT162B2 COVID-19 MRNA IN PATIENTS WITH HAEMOGLOBINOPATHIES

**Topic:** 27. Thalassemias

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**Background:**

Thalassemia and sickle cell disease are globally amongst the most common inherited hemoglobin disorders, both resulting in defective hemoglobin production and chronic hemolytic anemia. Patients with sickle cell disease and transfusion-dependent thalassemia (TDT) are considered in high risk of developing severe SARS-CoV-2 infection, due to the several co-morbidities related to the underlying disease, as well as complications of chronic transfusions. These include cirrhosis, diabetes, nephropathy, coagulopathy, anatomic and functional asplenia.

**Aims:**

Even though vaccination is encouraged for these patients, data on the efficacy of anti-Sars-CoV-2 vaccines in this specific population remain limited, due to its exclusion from clinical trials.

**Methods:**

In the following prospective observational study, serum antibody titers for SARS-CoV-2 after vaccination were measured in a total of 63 TDT and SCD patients and 63 healthy controls matched for age and sex. Informed consent was obtained from all participating individuals. Both groups received two doses of Pfizer-BioNTech mRNA COVID-19 vaccine (BNT162b2). Serum samples were collected from both groups 15 to 30 days after the second dose of the vaccine and tested for the quantitative determination of anti-spike IgG antibodies to SARS-CoV-2. Antibody titers were measured by Abbott SARS-CoV-2 IgG II (Semy-Quant) immunoassay with the Alinity i system. Results are reported as Arbitrary Units (AU)/ml and the cut-off defining non-response, as set by the manufacturer, is <50 AU/ml.

Fifty-three patients suffered from TDT and 10 patients had SCD. None reported COVID-19 infection before the vaccination. Patients’ mean age was 46 years (range 28-75), 41% of them were male and 59% were female.

**Results:**

All patients achieved a serological response to vaccination (>50AU/ml). Antibody titers were significantly higher in the patients’ group (p<0.001) (mean 17.676,63 AU/ml ± 13286,01, median 14.536,60, range 489.4-40.000) compared to the control group (mean 13.244,69 ± 9837,91, median 11.304,40, range 451,3-40.0000). In particular patients with TDT had a significantly elevated mean antibody titer (18.848,4 AU/ml) compared to the healthy population, while those with SCD had a slightly lower one (11.466,3 AU/ml). Age wise the youngest subjects in both groups (<30 years old) had the poorest serological response in terms of antibody titers. Among the TDT patients those who developed the highest titers (>30.000 AU/ml) had particularly low serum ferritin levels (<500ng/ml). In the patients’ group the ferritin levels above 1000ng/ml were related with lower but not statistically significant antibody titers (18.931,93 vs 14213,41 p=0,652). Response to vaccination was not affected by the spleen status (anatomic and functional asplenia vs spleen presence) or the immunoglobulins’ serum levels. With a median follow-up of 6 months, only one patient with TDT and Common Variable Immunodeficiency (CVID) developed a COVID-19 infection.

**Summary/Conclusion:**

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In conclusion, the BNT162b2 anti-SARS-Cov-2 mRNA vaccine demonstrated efficacy in our cohort of TDT and SCD patients. Antibody titers in TDT patients without hemosiderosis were significantly higher than in the control group. The immunological stimulation as a result of multiple blood transfusions could increase nonspecifically the antibody producing cells in TDT without iron overload. Further observations are needed to assess the humoral response, efficacy and possible factors influencing this finding in TDT patients.