Results of a vaccination against COVID-19 by a vector based vaccine Sputnik V in patients with chronic myeloid leukemia

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Background

Data on the efficacy and safety of vaccination in oncohematological diseases are extremely relevant during the COVID 19 pandemic. This information was collected in patients with chronic myeloid leukemia (CML) at the National Medical Research Center for Hematology of the Russian Ministry of Health.

Objective

To assess the tolerability of vaccination with the adenovirus vector-based vaccine GamCovidVac (Sputnik V) and the humoral response in CML patients.

Materials & Methods

The data on adverse events (AEs), level of IgG antibodies (AB) to SARS-CoV-2 and about COVID 19 disease after vaccination were prospectively collected in CML patients who referred to outpatient consultations. Within 11 months (from 12/18/20 to 11/13/21), 95 patients with chronic phase CML were vaccinated by GamCovidVac vaccine (Sputnik V)

At least 3 weeks after the 2nd vaccination, the patients were advised to perform an IgG AB test. The SARS-CoV-2-IgG-ELISA reagent kit was used. It allowed to detect IgG to the SARS-CoV-2 S1 subunit (RBD) by enzyme immunoassay (ELISA). The results were considered positive when the positivity ratio (PR)>1.1 (semi-quantitative test). The results of the other certified tests for the detection of the AB to S protein of SARS-CoV-2 were also taken into account.

Table 1. Characteristics of 95 patients with chronic phase CML at the time of vaccination against COVID 19

Characteristic, n(%)	Parameters
Age, median (range), years	54 (29-89)
Gender: male / female, n (%)	40(42) / 54 (58)
CML duration, median (range), years	8 (0-20)
▪ on TKI therapy, n(%)	75 (79)
▪ without TKI therapy, n (%)	20 (21)
- at the time of diagnosis, n (%)	3 (3)
- in a treatment-free remission, n (%)	17 (18)
Molecular response (MR)	
deep MR (BCR-ABL<0.01%), n (%)	57 (60)
major MR (BCR-ABL<0.1%), n (%)	17 (18)
MR2 (BCR-ABL≤1%), n (%)	7 (7)
No MR2 (BCR-ABL>1%), n (%)	14 (15)
COVID 19 after the vaccination, n(%)	**17 (18)**

Results

Adverse events

After the vaccination, 53 (56%) patients had the following AEs (including a combination of several):

- pain/discomfort at the injection site - 30 (31.5%),
- weakness/drowsiness - 29 (30.5%),
- fever and/or chills - 28(29%),
- other AEs - 10 (12%) including headache, palpitations, myalgia, rash, transient visual impairment, herpes infection).

All general reactions stopped within 1-2 days. No severe or life-threatening AEs were noted.

Analysis of the level of IgG AB to SARS-CoV-2

The study of the level of antiviral AB was carried out in 71 (75%) patients. The median time of the analysis after the 2nd injection of the vaccine was 31 days (range 5 -179). Using various tests, the AB were detected in 66 (93%) patients.

The ELISA test was performed in 55 (58%) patients and was positive in 48 (94%), Median PR was 6.9 (from 1.106 to 12).

A very weak inverse correlation of the level of AB with the period after vaccination (corr. coefficient -0.32,) and age (corr. coefficient -0.28) was noted (Figure 1.2). The median age of 7 patients with the PR less than 1 was 58 years (from 40 to 70). Inn 3 of those 7 patients the AB were detected by other test systems, with the levels only slightly above the detection threshold.

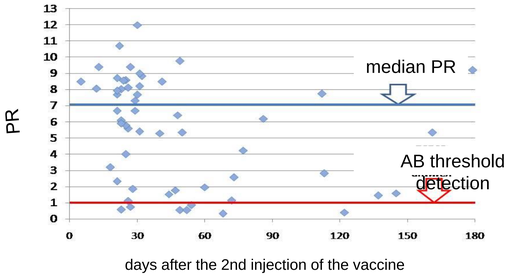


Figure 1. IgG AB to SARS-CoV-2 levels in accordance with the time after the vaccination

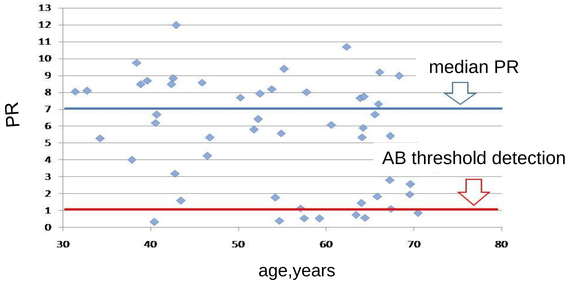


Figure 2. IgG AB to SARS-CoV-2 levels in accordance with the age of CML patients

COVID-19 after vaccination.

Seven (7%) patients got COVID 19 after the vaccination, in a period of the "delta" strain, before appearance of the Omicron strain. Two of these patients, age 66 and 67 years, were after booster vaccination.Two episodes of COVID 19 were observed in 1 patient, 47 years old. The disease course was mild and moderate in 6 and 1 patient (67 years, PR 1.106), accordingly.

Summary

Sputnik V (GamCovidVac) has shown a safety and efficacy in CML patients, comparable with clinical trial phase III data in the general population and it can be recommended for CML patients during the ongoing pandemic of COVID 19. Humoral response after vaccination was observed in 93% of patients. The older age group (>60 y) could have lower AB levels although the correlation was week. This age category requires a special attention and additional non-specific protective measures.