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Evaluation of post-vaccination humoral immune response against SARS-CoV-2

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Abstract:

Background: The new variant of Coronavirus SARS-CoV-2 is responsible for the COVID-19 pandemic. Currently, there is no curative treatment available for this virus. Therefore, researchers have developed several types of vaccinations.The evaluation of the post-vaccination humoral response is essential in determining vaccine efficiency and formulating an efficient vaccination plan .Algeria has adopted a vaccine strategy involving inactivated vaccines (SINOVAC and SINOPHARM) and vector vaccines (SPUTNIK V, ASTRAZENECA, and JENSSEN).

Objective: The main objective of this study is to investigate the humoral immune responses after administering two doses of the same available COVID-19 vaccine (Sputnik V, Sinopharm, or Sinovac) among workers at Mustapha Bacha Hospital. Additionally, the impact of key factors related to immunity, including a person's age, sex, previous COVID-19 infection, neutralizing capacity according to the type of vaccine and the interval following the second dose, was also explored.

Results: The seroprevalence of IgG anti-S1 RBD was found to be approximately 93.4%, 93.6%, and 90.7% for SINOVAC, SINOPHARM, and SPUTNIK V, respectively. The average rates of IgG anti-S1 RBD were higher in the SPUTNIK V group. Different factors such as age and prior SARS-CoV-2 infection influenced the humoral response to some vaccines separately. The neutralizing capacity of IgG anti-S1 RBD was positive in 72% of participants vaccinated with SINOVAC and SPUTNIK V.

Conclusion: It is crucial to focus on the longevity of the vaccines immune response at this time. The findings from various studies may help make decisions about the efficiency of vaccines, introduction of a booster dose, and prioritizing the high-risk population.

Key words

SARS-COV 2, COVID 19, Vaccins, SINOVAC, SINOPHARM, SPUTNIK V, ASTRAZENECA, JANSSEN.

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Introduction:

In December 2019, researchers identified a new coronavirus in the Chinese population, causing severe atypical and unexplained pneumonia (1). The genome of SARS-CoV-2 is a single-stranded positive-sense RNA. The nucleocapsid protein (N) forms the capsid outside the genome, which is further enveloped by three structural proteins: membrane protein (M), spike protein (S), and envelope protein (E)(2). Transmission of SARS-CoV-2 can occur through direct, indirect, or close contact with infected individuals via infected secretions such as saliva and respiratory droplets(3).

The viral particles infect respiratory tract cells using the spike protein (S)(4). This protein can bind to ACE2 receptors expressed on respiratory cells, leading to cellular fusion and penetration of the nucleocapsid into the cytosol of host cells. Consequently, the cycle of viral replication is triggered, and neighboring cells become contaminated. This results in an increased viral load and triggers a cellular immune response, followed by the production of specific antibodies against various components of the virus, particularly the spike protein. The spike protein has two subunits, S1 and S2, and contains the Receptor binding domain (RBD), which interacts with ACE2 receptors (5)(6)(7).The COVID-19 pandemic has been ongoing for more than two years, during which prevention has been the most effective strategy to control the virus spread. Researchers from different countries have developed several types of vaccines (Russia, America, China, and England) (8)(9)(10).In Algeria, since February 2021, health authorities have adopted a vaccination strategy involving five vaccines: two inactivated vaccines (Sinovac and Sinopharm) and three vector vaccines (Sputnik v, AstraZeneca, and Janssen) (11)(12).As the vaccination campaign commenced, scientists published works evaluating the kinetics of the immune response against the vaccines, using methodologies such as tests for cellular immune response and estimation of antibody levels and their neutralizing capacity(13)(14)(15)(16)(17). These studies provided information about individual and epidemiological seroprevalence (18).

The main objective of this study is to investigate the humoral immune responses after administering two doses of the same available COVID-19 vaccine (Sputnik V, SINOPHARM, or SINOVAC) among workers at Mustapha Bacha Hospital. Additionally, the impact of key factors related to immunity, including a person's age, sex, previous COVID-19 infection, neutralizing capacity according to the type of vaccine and the interval following the second dose, was also explored**.**

Patients and methods:

Our Study is a monocentric prospective observational one, conducted by the Immunology Department in collaboration with the Occupational Medicine Department at Mustapha Pacha Hospital in Algiers over a period of 17 months (March 2021 to July 2022). The study participants included health and administrative workers who were fully vaccinated with two doses of one of the three COVID-19 vaccines: SINOVAC, SINOPHARM, and SPUTNIK V. Prior to commencing the study, it was approved by the hospital's ethics committee.

Plasma samples were collected from the participants for the analyses, and a clinical

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summary sheet named 'COVID-19 post-vaccination serology' was used for recording relevant data.

Patients:

The patients included in the analysis were health and administrative workers; fully vaccinated (Two doses of the same COVID-19 vaccine; namely, SINOVAC. SPUTNICK and SINOPHARM)

The non-inclusion criteria were:

- Subjects who had not been vaccinated against COVID 19
- Patients who had not received a second / booster dose
- Those who had received two different types of COVID-19 vaccines
- Those with an antibody response delay of less than 14 days after Covid-19 vaccination

Clinical and laboratory data were summarized in an Excel Sheet. The clinical parameters collected included: sociodemographic status (age in years and gender), prior Sars-Cov2 infection (Y/N), and the type of vaccine received. We collected 381 plasma specimens randomly from fully vaccinated participants over a period of 17 months. The plasma samples were divided into three groups based on the type of vaccination received (SINOVAC, SINOPHARM, and SPUTNIK V). (Table 1).

Table 1: Demographic characteristics of the studied population.

		DEMOGRAPHIC CHARACTERISTICS
Number of participants vaccinated		**381**
Meanage (years)		**49,9 (21-87)**
Sex ratio W/M		**2**
Men (N,%)		**127 (33,3%)**
Women(N,%)		**254 (66,6%)**
COVID 19 history (N,%)		**168 (44,1%)**
Type of vaccine	**SINOVAC (N,%)**	**226 (59,3%)**
	SPUTNIK V (N,%)	**108 (28,3%)**
	SINOPHARM (N,%)	**47 (12,3%)**

It should be noted that the average time between the day of the second dose and the day of test analyze is 138.5 days for SPUTNIK V and 118.6 95.8, 92.3, 90.3 days for ASTREAZENCA, SINOPHARM, JANSSEN and SINOVAC respectively. The results of both JANSSEN and ASTRAZENECA vaccines are not included in this study (n< 30).

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Methods:

To evaluate the post-vaccination humoral response, we measured the levels of IgG anti S1 RBD using ELISA (Quantivac EUROIMMUN®, Lübeck Germany) (19). The units of measurement used are Relative Units per milliliter (RU/ml) or International Binding Antibody Units per milliliter (BAU/ml = RU*2.4/ml). The interpretation intervals for the results are as follows: Negative <11 RU/ml, Low Positive 11-60 RU/ml, Medium to High Positive 61-120 RU/ml, and High Positive >120 RU/ml.

In addition to measuring IgG anti S1 RBD levels, we also evaluated the neutralizing capacity of these antibodies using an immune enzymatic technique called competition (Neutralisa EUROIMMUN®, Lübeck Germany) (20). This technique assesses the percentage of inhibition of IgG anti S1 RBD neutralizers. The interpretation intervals for the results are as follows: Negative <20%, Doubtful 20-35%, Positive >35%.

Statistical analysis:

The statistical analyses were conducted using Prism 7.05 software (GraphPad).To assess the normality of data distribution, the Kolmogorov-Smirnov test was utilized. For comparisons of numbers and frequencies, the chi-square test was employed, while the T-test was used to compare average values. In all statistical tests, a p-value less than 0.05 was considered statistically significant.

Results:

Percentage of anti S1 RBD IgG seropositivity

The seroprevalence of IgG anti S1 RBD was approximately 93.4%, 93.6%, and 90.7% for SINOVAC, SINOPHARM, and SPUTNIK V, respectively (Figure 1). The age, sex, and clinical history of COVID-19 did not significantly impact the percentage of IgG anti S1 RBD seropositivity in the different study groups. However, it was observed that seropositivity was higher in subjects under 60 years old who received the SINOVAC vaccine (p=0.01).

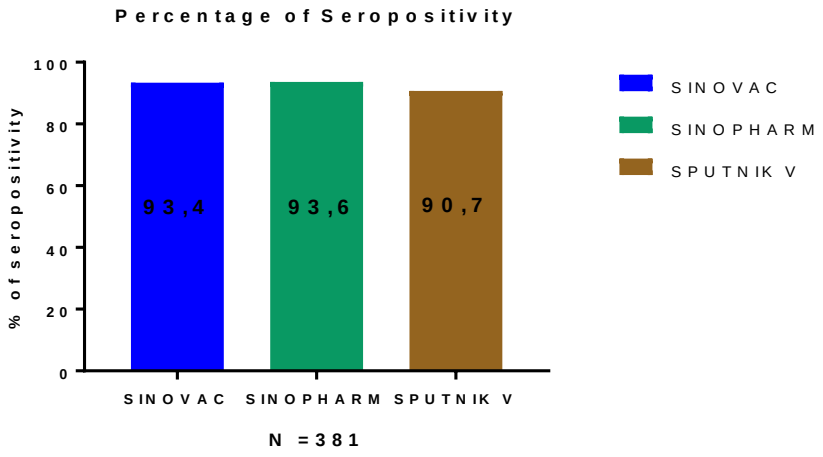

Figure 1: Percentage of seropositivity of anti-S1 RBD antibodies

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IgG anti S1 RBD levels:

We assessed the levels of IgG anti S1 RBD in the different vaccine groups at five time periods after the second vaccine dose. These time periods were established with reference to the day of test analysis for each specimen. The average rates of IgG anti S1 RBD were as follows: 255 RU/ml for the SPUTNIK V group, 166 RU/ml for SINOVAC, and 112 RU/ml for SINOPHARM. The differences in IgG anti S1 RBD levels were statistically significant between SINOVAC and SPUTNIK V (p=0.001) and between SINOPHARM and SPUTNIK V (p=0.003) (Figure 2.A).

We observed a lower level of IgG anti S1 RBD in two time periods, specifically 91-120 days and >120 days, compared to the under 30 days period in the SPUTNIK V group (p<0.005) (Figure 2D). However, for the SINOVAC and SINOPHARM groups, the levels were relatively similar (p=NS) (Figure 2B, 2C).

Next, we evaluated the influence of three factors - sex, age (<60 years old vs >60), and prior history of COVID-19 - on the IgG anti S1 RBD levels. The results showed that a prior SARS-CoV-2 infection had a positive impact on the level of IgG anti S1 RBD (p=0.001) only in the SINOVAC and SINOPHARM groups (Figure 3A.3, 3B.3). Additionally, in participants over 60 years old vaccinated with SINOPHARM, the IgG anti S1 RBD levels were statistically significant (p=0.007) (Figure 3B.2). However, the sex of the subjects had no significant influence on the IgG anti S1 RBD level in all vaccination groups (p=NS).

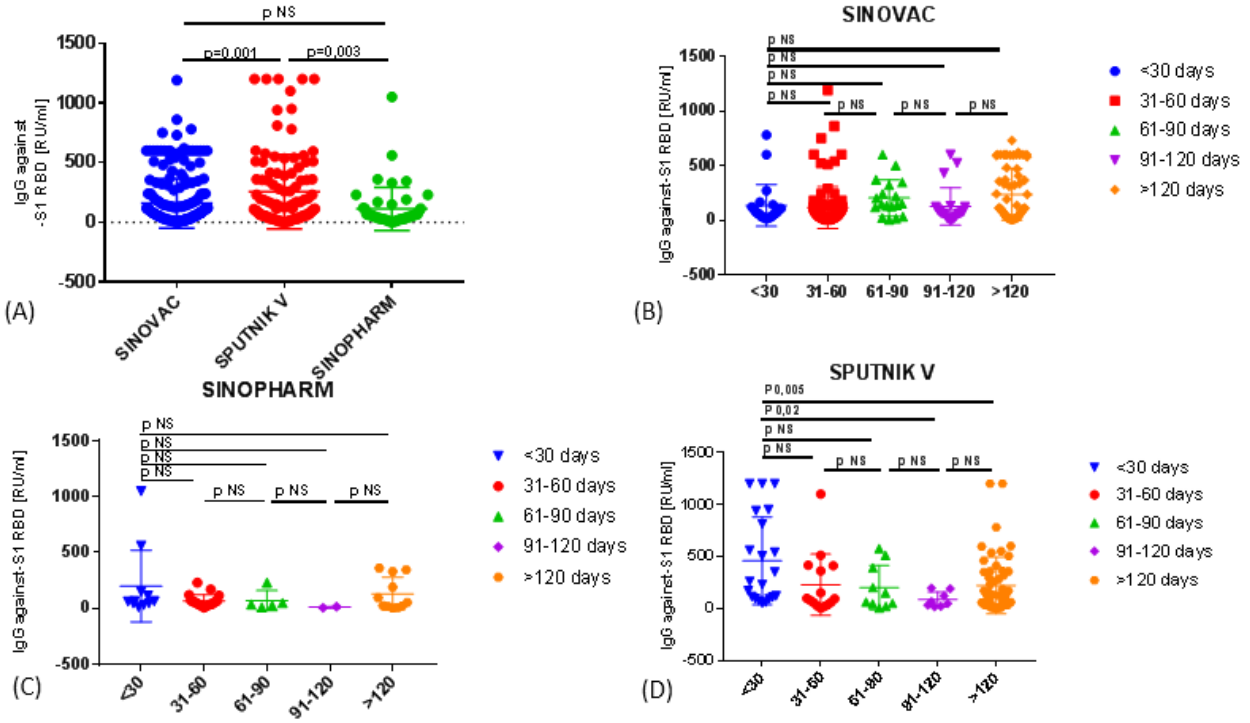

Figure 2: Rate of IgG against S1 RBD antibodies according to the differentvaccines (SINOVAC, SINOPHARM, SPUTNIKV)(A), according to the post-vaccination serological delay of SINOVAC(B),SINOPHARM(C)andSPUTNIK V(D).

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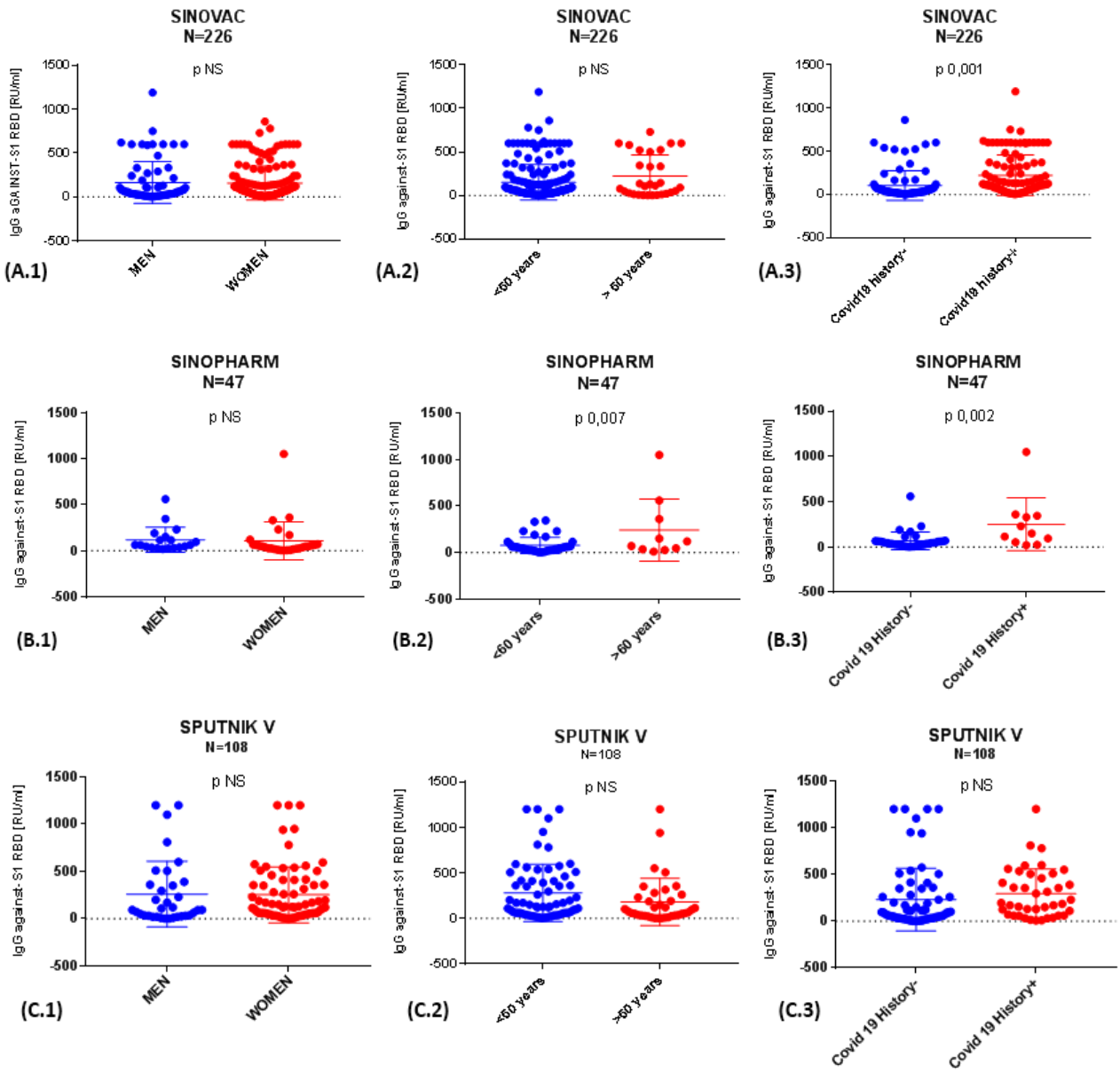

Figure 3: Level of anti-S1 RBD antibodies of the different vaccines: SINOVAC (A), SINOPHARM (B), SPUTNIKV(C)according to SEX(1), age (2) and COVID19 History (3)

Neutralization

A functional neutralization test was conducted for 128 participants vaccinated with either SINOVAC (N=68) or SPUTNIK V (N=60) (Table 2). It was found that 72% of the participants vaccinated with either SINOVAC or SPUTNIK V developed neutralizing antibodies (Figure 4).

In this group of participants, we observed that the presence of a prior history of COVID-19 significantly impacted the neutralizing capacity in the SINOVAC group (p=0.01) (Figure 4 A.2). Additionally, age was found to be a factor influencing the neutralizing capacity in the SPUTNIK V group (p=0.03) (Figure 4 B.1).

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Furthermore, a correlation test was performed between the IgG anti S1 RBD levels and the percentage of inhibition of antibodies for both SINOVAC and SPUTNIK V. The association was moderately positive for SINOVAC and strongly positive for SPUTNIK V (p<0.0001) (Figure 4 A.3) (Figure 4 B.3).

Table 2: Demographic characteristics of the participants with Neutralization test.

	DEMOGRAPHIC CHARACTERISTICS	
Number of participants vaccinated	**128**	
Meanage (years)	**50,3(21-82)**	
Sex ratio W/M	**2,2**	
Men (N,%)	**40 (31,25%)**	
Women(N,%)	**88 (68,75%)**	
COVID 19 history (N,%)	**46 (36%)**	
Type of vaccine	**SINOVAC (N,%)**	**68 (53%)**
	SPUTNIK V (N,%)	**60 (47%)**

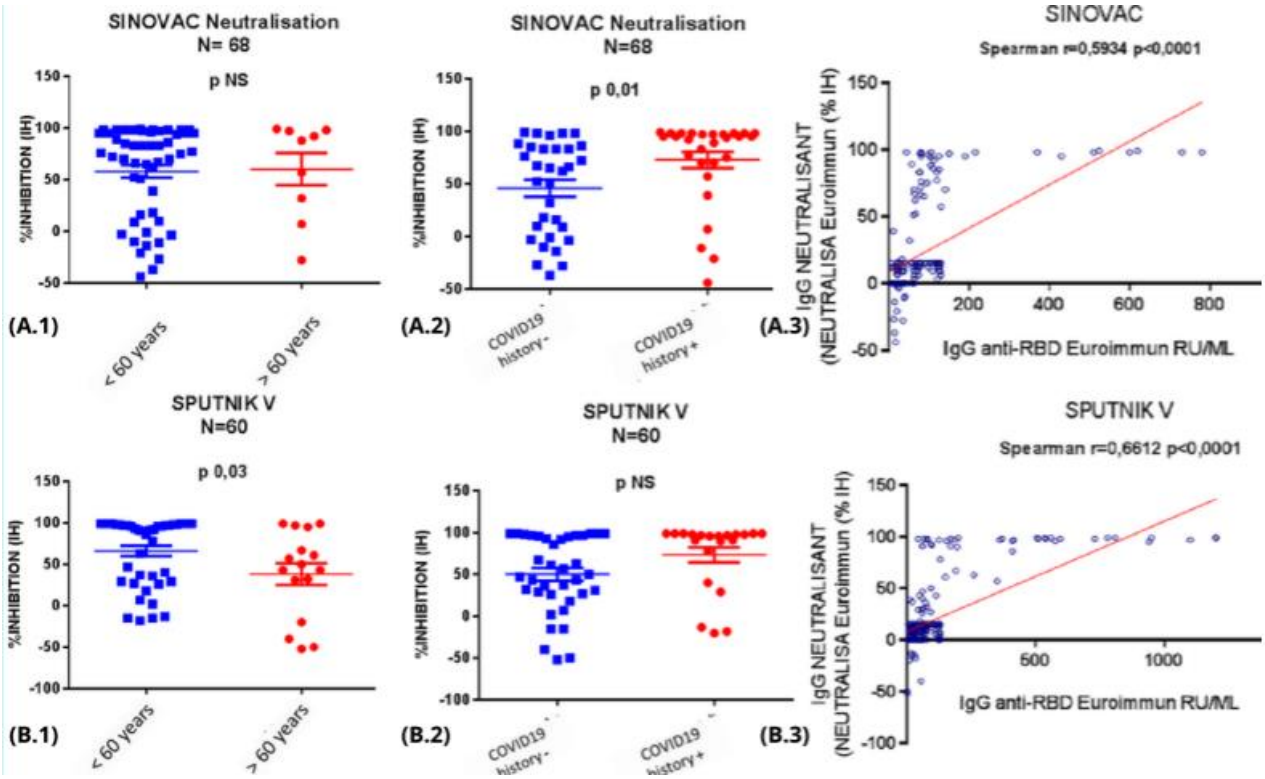

Figure 4: Percentage de Neutralisation IH% des anticorps anti-S1 RBD des differentesvaccins :SINOVAC (A), SPUTNIK V(B) according to age(1) , COVID19 history(3) and the correlation (3) between te IH% and the levels of IgG against-S1 RBD RU/Ml.

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Discussion:

During the COVID-19 pandemic, prevention was the only effective strategy to control the spread of the virus. The vaccination program strengthened this strategy. Like many countries, Algerian health authorities adopted an extensive vaccination plan. Initially, the primary targets of this plan were patients with weak immunity and healthcare workers.

At Mustapha Pacha Hospital, three vaccines (SINOVAC, SPUTNIK, and SINOPHARM) were used to vaccinate healthcare and administrative workers. These vaccines were not available simultaneously. To assess the post-vaccination humoral response against SARS-COV2 in this population, we conducted serological and functional tests on 381 randomly selected fully vaccinated volunteers over a 17-month period. We also analyzed the humoral response based on the type of vaccine used and various factors. The seroprevalence of IgG anti-S1RBD was over 90% for all three vaccine groups, with an average time of 90.5 days for SINOVAC, 95.8 days for SINOPHARM, and 138.5 days for SPUTNIK V, between the day of the second dose and the day of the test analysis. Similar results have been reported in Algeria (21; 22) and other countries (23, 24, 25), suggesting a strong post-vaccination response.

We studied the influence of three factors: age, sex, and a history of COVID-19 on the immune vaccine response. Our results showed that age had an impact on the production of IgG anti-S1RBD in the SINOVAC group, with higher seropositivity in subjects under 60 years old compared to older participants ($p=0.01$) (Figure 1B). However, in a Algerian (21) and Indonesian (23) studies, the percentage of seropositivity was influenced by natural SARS-CoV-2 infection for SINOVAC and SPUTNIK V vaccines. We also compared the average IgG anti-S1RBD levels in the three groups vaccinated with SINOVAC, SINOPHARM, and SPUTNIK V. The SPUTNIK V group had a higher average rate of IgG anti-S1RBD (255 RU/ml) than the SINOVAC (160 RU/ml) and SINOPHARM (112 RU/ml) groups ($p<0.05$) (Figure 2A). Dashdorj NJ and al (26) also reported this observation.

The primary objective of vaccination is to ensure the persistence of a significant level of antibodies to prevent potential SARS-CoV-2 re-infection. For this reason, the comparison groups were divided into subgroups based on five time periods (<30 days, 31-60 days, 61-90 days, 91-120 days, >120 days). The time periods were established based on the day of the test analysis for each specimen, after the second vaccine dose. We noticed a lower level of anti-S1RBD in two time periods: 91-120 days and > 120 days, compared to the under 30 days period, in the SPUTNIK V group ($p<0.005$) (Figure 2D). However, the antibody levels were almost similar for SINOVAC and SINOPHARM subgroups ($p=NS$) (Figure 2B, 2C). Unlike our study, Cucunawangsih C and al (23) and Chahla RE and al (24) monitored antibody levels in the same group of individuals at different points in time after receiving vaccines. They observed a decrease in IgG anti-S1RBD levels for SINOVAC and SPUTNIK V vaccines. This difference in results may be related to the type of participant recruitment and the way we decided to analyze the specimens (monitoring the same vaccinated participants versus groups of time after the second dose for randomly vaccinated participants).

In this study, we also demonstrated that age, sex, and prior SARS-CoV-2 infection did not influence the rate of anti-S1RBD production in the SPUTNIK V group ($p=NS$) (Figure 3C). However, prior SARS-CoV-2 infection

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did have an impact on the capacity of IgG anti-S1RBD production in SINOVAC and SINOPHARM groups ($p<0.05$) (Figure 3 A.3, B.3), and in fact, people over 60 years old vaccinated with SINOPHARM had a higher level of IgG anti-S1RBD compared to younger people ($p=0.007$) (Figure 3 B.2). It is impossible to draw any overall conclusions from these results due to the small effective sample size; therefore, further studies with more participants are needed to confirm these hypotheses.

Finally, a functional neutralization test was performed on 128 participants vaccinated with SINOVAC (N=68) or SPUTNIK V (N=60). Seventy-two percent of the participants vaccinated with SINOVAC or SPUTNIK V developed neutralizing antibodies. A correlation test between IgG anti-S1RBD levels and the percentage of inhibition of antibodies for SINOVAC and SPUTNIK V was also conducted. The association was moderately positive for SINOVAC and strongly positive for SPUTNIK V ($p<0.0001$) (Figure 4 A.3) (Figure 4 B.3), indicating a greater neutralizing capacity of antibodies against the virus in people with high levels of IgG anti-S1RBD. Three other studies (25)(26)(27) confirmed this correlation. In this group of participants, we noticed that the neutralizing capacity was impacted by the presence of a clinical history of COVID-19 in the SINOVAC group ($p=0.01$) (Figure 4 A.2). We also observed that age influenced this neutralizing capacity in the SPUTNIK V group ($p=0.03$) (Figure 4 B.1). Similar results were found by Chahla RE and al (24), Bueno SM and al (25), and Dashdorj Nj and al (26).

Conclusion:

Throughout the COVID-19 pandemic, numerous studies have been conducted to estimate and evaluate the post-vaccination seroconversion against the virus. These studies play a vital role in informing decisions regarding the efficiency of vaccines, the potential need for booster doses, and prioritizing vaccination for high-risk populations.

Looking ahead, we recommend further investigations to evaluate the humoral immune response after receiving three vaccine doses. Additionally, it would be beneficial to assess the cellular immune response against SARS-CoV-2. By understanding both aspects of the immune response, we can gain a comprehensive understanding of the effectiveness and longevity of vaccine-induced immunity, which will aid in developing more effective vaccination strategies and public health measures in the fight against COVID-19.

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