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The Impact of Sputnik SARS-CoV-2 Vaccines on Antibody Response in the Egyptian Population

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Abstract

BACKGROUND: The coronavirus disease 2019 (COVID-2019) causes the severe contagious acute respiratory syndrome. Therefore, massive vaccination campaign is mandatory to control the spread. Sputnik COVID-19 vaccines induce immunity through different mechanisms involving antibody response that bind to the spike protein to neutralize the viral entry into the cells.

AIM: This study aims to compare the titers of specific antibodies in the pre- and post-vaccination sera in the vaccinated Egyptian population to evaluate the efficacy of the sputnik vaccine.

METHODS: Samples were collected from 205 adult volunteers receiving the Sputnik vaccine in the Reference Laboratory of Egyptian University Hospitals. Samples were collected before vaccination and within 1, 2, or 3 months after receiving two doses of Sputnik SARS-CoV-2 vaccines from August to October 2021, serum samples collected were tested by quantitative chemiluminescent immunoassay using (Mindray CL-960i chemiluminescence analyzer, India) at the Reference laboratory of Egyptian University Hospitals for neutralizing antibodies, anti-spike antibodies, and total antibody levels before and after vaccination.

RESULTS: The results of the 205 paired samples illustrated that there was a statistically significant difference between pre- and post-vaccination antibody levels with a p-value of (< 0.001) indicating that the vaccine produced significantly high levels of antibodies.

CONCLUSION: COVID-19 Sputnik vaccines induce immunity through an antibody response that binds to the virus to neutralize its entry into cells. Our study showed a significant increase in the measured post-vaccination levels of the three antibodies among the enrolled volunteers compared to the basal pre-vaccination level and thus sputnik vaccine protects against SARS-CoV-2 infections.

Introduction

The coronavirus disease 2019 (COVID-19) causes the severe acute respiratory syndrome. COVID-19 was declared by the World Health Organization as a pandemic on 11 March 2020 [1]. This pandemic was confirmed to have reached Egypt by February 2020. Egypt's Health Ministry announced the first case in the country at Cairo International Airport involving a Chinese national on February 14 [2]. Thereafter, the number has increased proportionally due to non-compliance with curfew precautions [3].

Therefore, it became evident that a massive vaccination campaign is mandatory to control the spread, and many unprecedented efforts were directed at vaccine development.

COVID-19 vaccines induce both innate and adaptive immunity through different mechanisms. Adaptive immunity, our point of concern, involves an antibody response caused by B cells, which expand and multiply proportionally, leading to the production of specific antibodies that bind to the spike protein to neutralize viral entry into cells [4].

These antibodies are the principle of vaccination effectiveness and responsible of forming the immunological memory [5]. There are two types of antibodies: N or neutralizing antibodies and the other against the spike or S protein found on the virus's surface. The virus uses the later protein to enter the host body cells. Consequently, measurement of the pre- and post-level should be of benefit in investigating the efficacy of different vaccines [6].

Since the COVID-19 pandemic, many coronavirus vaccines have been developed to be used widely among the population; the vaccine should be equally safe and effective.

Various genetically engineered vaccines have been created based on RNA encoding including the

SARS-CoV-2 S-antigen (Pfizer, Moderna, USA) and DNA-based vector vaccines encoding the SARS-CoV-2 S-antigen: "Gam-COVID Vac" ("Sputnik V") (N.F. Gamaleya National Epidemiology and Microbiology Research Center, Moscow, Russia). Moreover, Ad 26 CoVS (Johnson and Johnson/Janssen-Cilag, Belgium/USA), Sinopharm (BBIBP-CorV (Vero Cells) vaccine type: inactivated virus; China) and AZD 1222 (AstraZeneca, UK/Sweden) had also been developed [7].

Sputnik V also known as Gam-COVID-Vac. was the first COVID-19 vaccine to be registered for use in any nation and has since been approved in 67 countries [8]. The peculiar characteristic of Sputnik V is being consisting of two various vectors. For the first injection, a vector based on the serotype 26 recombinant adenovirus (A d26) of a human, and for the second injection a vector based on a recombinant adenovirus of the fifth serotype (Ad 5) of a human [9].

The purpose of this study is to evaluate the Sputnik vaccine effect by measuring the level of the pre- and post-vaccination antibodies level against the SARS-CoV-2 in the vaccinated person's blood: Neutralizing (N) and spike (S) and total antibodies for SARS-CoV-2 in the vaccinated person's blood.

Objectives

This study aimed to compare the difference between the pre- and post-vaccination level of the neutralizing (N) and spike (S) and total antibodies for SARS-CoV-2 after the Sputnik vaccine to evaluate its efficacy.

Study design

This was a retrospective study.

Materials and Methods

Sample collection

All data were collected from the reference laboratory of the Egyptian University Hospitals (RLEUH) database. Two hundred and five adult volunteers were enrolled in this study. All participants provided their informed consent before collecting data and samples. Blood samples were drawn from volunteers within 1, 2, or 3 months before and after receiving two doses of Sputnik SARS-CoV-2 vaccines in Egypt from the period between August and October 2021.

Sample processing

All serum samples were subjected to quantitative chemiluminescent immunoassay using (Mindray CL-960i chemiluminescence analyzer, India) at the Reference laboratory of Egyptian University Hospitals for:

1. SARS-CoV-2 Spike Receptor Binding Domain (S-RBD) IgG (CLIA), (Mindray).
2. SARS-CoV-2 Neutralizing antibody (CLIA) (Mindray).
3. SARS-CoV-2 Total antibody (CLIA) (Mindray).

Serological assays for the detection of antibodies against SARS-CoV-2 (CLIA):

All serum samples were tested to detect pre- and post-vaccination antibodies against SARS-CoV-2 IgG/IgM and total antibodies by Mindray fully automated analyzer (Mindray CL-960i chemiluminescence analyzer, India) according to the manufacturer's instructions. CLIA has been considered the reference method for the evaluation of immunochromatography strip assays. Mindray SARS-CoV-2S-RBDIgGassay is a chemiluminescent immunoassay for the quantitative determination of SARS-CoV-2RBD IgG in human serum or plasma from suspected patients with COVID-19. While the MindraySARS-CoV-2 neutralizing antibody assay is a chemiluminescent immunoassay for the quantitative determination of SARS-CoV-2 neutralizing antibodies that block the interaction between the viral spike glycoprotein with the angiotensin-converting enzyme (ACE2) cell surface receptor in human serum or plasma. The procedure was performed according to the manufacturer's protocol for the device. The interpretation of the test results was done according to the manufacturer's instructions. Specimens with results <10.0AU/mL are considered negative for S-RBD IgG antibodies to SARS-CoV-2 while specimens with results ≥10.0 AU/mL are considered positive for S-RBD IgG antibodies to SARS-COV-2, suggesting recent or prior infection. Similarly, samples with results <10.0 AU/mL are considered non-reactive for neutralizing antibodies to SARS-CoV-2 in Mindray neutralizing antibody assay and samples with results ≥10.0 AU/mL are considered reactive for neutralizing antibodies to SARS-CoV-2.

Statistical analysis

Data will be analyzed using the statistical package for the Social Sciences software version 25. Frequency (count) and relative frequency (percentage) are used for the categorical data. The sensitivity, specificity, positive predictive value, and negative predictive value will be calculated, along with the 95% confidence interval. The measurement agreements between tests are to be evaluated with Cohen's kappa (κ) statistics. The comparison between the categorical data will be done using the Chi-square (χ^2) test. Fisher's exact

test will be used instead when the expected frequency is <5. p ≤ 0.05 is considered statistically significant.

Results

Demographic data

As per the demographic data in the present study, 121/205 (59%) of the participants were males, while 84/205 (41%) were females. The age of the enrolled volunteers ranged from 18 to 82 years with a mean age of 47.3 + 16.95 years.

Pre- and post-vaccination antibodies levels

The levels of the three antibodies measured before and after vaccination among the enrolled volunteers in the present study are summarized in Table 1.

Table 1: The levels of different antibodies in the pre- and post-vaccination samples in the current study

SARS-Cov-2 measured Antibodies	n	Mean	
		Mean	SE
Neutralizing antibodies (before vaccination)	205	52.0660	7.53321
Antispike antibodies (before vaccination)	205	131.1270	19.02190
Total antibodies (before vaccination)	205	304.0874	41.37004
Neutralizing antibodies (after vaccination)	205	250.3207	20.36967
Antispike antibodies (after vaccination)	205	553.8206	30.23964
Total antibodies (after vaccination)	205	1290.5737	96.99382

SE: Standard error.

To assess the ability of the vaccination given to our volunteers to induce a significant boost in antibodies, paired samples test was done for the difference of each antibody before and after vaccination. Pair 1 was the difference between the levels of neutralizing antibodies after and before vaccination, Pair 2 was the difference between anti-spike antibodies, and Pair 3 was the difference between the levels of total antibodies. Table 2 illustrates that there was a statistically significant difference levels before and after vaccination with p-value of (< 0.001). That indicates that the vaccine produced significantly high levels of antibodies.

Discussion

Sputnik is a recombinant vaccine developed by the Gamaleya Research Institute, Russia, using human adenovirus vectors as a delivery mechanism for inserting the genetic code for the SARS-CoV-2 spike protein into human cells. Sputnik V is different from other vaccines as Oxford–AstraZeneca and Johnson and Johnson vaccines as it uses two different engineered adenoviruses, called rAd26 and rAd5, for the first and second doses, respectively, instead of using one vector [9].

The safety of adenoviral vector vaccines has been extensively studied, and therapeutic drugs based on adenoviral vectors are used in clinical practice. Adenovirus vector-delivered antigens are effective in inducing cellular and humoral immunity after a single immunization, allowing their use as an emergency prophylaxis tool in a pandemic. Furthermore, the use of two immunizations gives a durable and long-lasting immune response. These characteristics that stimulate the rapid onset of protective immunity make recombinant replication-deficient adenovirus (rAd)-based vaccines efficient for the long-term protection of people at high risk for COVID-19 in outbreak settings [10].

A promising aspect of Sputnik V is that it is a heterologous prime-boost vaccine, which means the first and second doses differ. Each dose uses a different adenovirus vector to get the coronavirus spike protein DNA into human cells. Heterologous prime-boost immunization is seen as a possible way to squeeze an even bigger response from existing vaccines.

To achieve a similar effect, a team at the University of Oxford is leading a trial of various combinations of the vaccines from Oxford/AstraZeneca, Pfizer/BioNTech, Moderna and Novavax vaccines in people over the age of 50 years [11].

In our study, we measured the pre- and post-vaccination levels of three antibodies among the enrolled volunteers to evaluate the vaccine effect; the antibodies include neutralizing (N) and spike (S) antigens of and total antibodies of SARS-CoV-2. We found that the antibodies level increased significantly with a p-value of (<0.001) and consequently it protects against SARS-CoV-2 infections.

González *et al*. agreed with our results that the Sputnik V vaccine confers high protection against laboratory-confirmed SARS-CoV-2 infections, and decreased COVID-19 hospitalizations and mortality rates [1].

Table 2: The paired difference between different antibodies in the pre- and post-vaccination samples in the present study

Paired differences (pre and post vaccination)	Mean	SEM	95% CI of the difference		p (significance)
			Lower	Upper	
Pair 1	198.25478	18.19901	162.37251	234.13705	<0.001
Neutralizing antibodies (after vaccination) - neutralizing antibodies (before vaccination)					Significant
Pair 2	422.69366	28.11154	367.26723	478.12009	<0.001
Antispike antibodies (after vaccination) - antispike antibodies (before vaccination)					Significant
Pair 3	986.48635	88.28991	812.40859	1160.56410	<0.001
Total antibodies (after vaccination) - total antibodies (before vaccination)					Significant

CI: Confidence ınterval, SEM: Standard error of mean.

Furthermore, Doroftei *et al*. concluded that the efficacy of Sputnik V was greater than 92% while the efficacy of Oxford–AstraZeneca was only 81% [12].

Another study conducted by Sapkal *et al*. showed that the robust neutralizing antibody response induced by the sputnik V vaccine among all groups may help limit the severity of disease and mortality in the vaccinated individuals. They stated that the recovered individuals who took the vaccine have higher antibody titers, which may ensure long-term protection from reinfections [13].

However, Jeewandara *et al*. stated that after the first dose of the Sputnik Vaccine, 88.7% of the population was seroconverted, with significantly lower seroconversion than that previously proved with AstraZeneca. Furthermore, 82.6% of the study sample developed receptor-blocking antibodies with significantly lower levels than after natural infection and a single AstraZeneca dose. Moreover, they stated that although the single dose of the Sputnik Vaccine was highly immunogenic, administration of a second dose is likely to be beneficial [14].

Since permanent immunity is less likely to develop after COVID-19 vaccines, a regular vaccination policy is recommended, especially since the minimal neutralizing antibody titer that provides a protective effect against SARS-CoV-2 infection is still unclear. It is well known that the higher neutralizing antibody vaccination induces a better protective effect it will be [15], [16]. Therefore, it is of great importance to conduct further studies characterizing the correlation between neutralizing antibodies and protective effects to guide COVID-19 vaccine development.

Conclusion

Sputnik is a recombinant vaccine developed by the Gamaleya Research Institute; Russia uses human adenovirus vectors as a delivery mechanism for inserting the genetic code for the SARS-CoV-2 spike protein into human cells. The Sputnik vaccine uses two different engineered adenoviruses, for the first and second doses, called rAd26 and rAd5, respectively. The Sputnik vaccine induces immunity through an antibody response that binds to the virus and neutralizes its entry into cells. Our study showed a significant increase in the measured post-vaccination levels of the three antibodies: neutralizing (N) antibodies,anti-spike (S) antibodies and total antibodies of SARS-CoV-2among the enrolled volunteers compared to the basal pre-vaccination level with a p-value of (< 0.001) and consequently Sputnik vaccine protects against SARS-CoV-2 infections and decreased COVID-19 hospitalizations and mortality rates.

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