

Diagnostic tools for evaluating the effectiveness of COVID 19 vaccines: Challenges and solution

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ABSTRACT

Evaluation of potential immunity due to SARS-CoV-2 (Severe acute respiratory syndrome coronavirus 2) infection or vaccination is essential for health as well as social and economic recovery. Two vaccines (Covishield and Covaxin) produced in India have been authorized for emergency use in India. Which vaccine to prefer if the choices given to the recipients is a matter of general curiosity and public health interest. Different types of testing methodologies are being carried out in various laboratories around the world. There is no standardized measurement process and definitive set of values to know the protective immune response. A suitable antibody test which can be used as a tool to check whether the vaccine has triggered a sufficient immune response is required. The method needs to have the ability to measure the true quantity of antibody generated and it should be traceable to the international unit.

Keywords: COVID-19, neutralizing antibody, quantitative measurement, SARS-CoV-2

COVID-19 Pandemic and the Vaccination Drive

The unprecedented global crisis arising due to the ongoing COVID-19 pandemic has led to the call for reliable diagnostic tools to monitor and understand the effectiveness of vaccinations and the epidemiology of SARS-CoV-2. The pandemic is surging again and accounts for more than 126 million confirmed cases and over 2.7 million related deaths at the time of manuscript preparation. The authorities have initiated phase-wise vaccinations to cover and protect the entire population. The main purpose of the mass vaccination is to produce neutralizing antibodies against SARS-CoV-2 and help the community to achieve immunity against this deadly disease. Two vaccines (Covishield and Covaxin) produced in India have been authorized for emergency use

in India. Which vaccine to prefer if the choice is given to the recipients is a matter of general curiosity and public health interest.

The Two Vaccines in India: Covishield and Covaxin

The evaluation of potential immunity due to SARS-CoV-2 infection or vaccination is essential for health as well as social and economic recovery. Generation of antibodies (seroconversion) may inform on acquired immunity from prior exposure, and antibodies against the SARS-CoV-2 spike protein receptor-binding domain (S-RBD) are speculated to neutralize the virus infection post-vaccination.

Covishield is an adenovirus (ChAdO × 1) vector-based vaccine which carries genetic material of the spike protein of SARS-CoV-2 into human cells. This vaccine produces antibodies against only a specific region of the virus. Covaxin is based on an old conventional platform and contains an inactivated whole SARS-CoV-2 virus with all its 29 proteins intact. The immunity

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provoked by it will be more comprehensive and closer to natural immunity due to infection.

Structure of Coronavirus and Serology Tests

Coronavirus has four main structural proteins: Nucleocapsid (N), spike (S), membrane (M), and envelope (E). The N protein is abundantly expressed during infections and also has high immunogenic activity. The S protein is highly immunogenic since it is located on the surface of the virus. It consists of the S1 and S2 subunits. The S1 subunit contains immunologically crucial RBD, which is the key target of neutralizing antibodies.

Because of the urgency and demand, many serological tests have been developed rapidly and made commercially available with only limited validation on clinical samples. Some detect the presence of antibodies against the nucleocapsid antigen (anti-N), while others detect antibodies against the spike protein (anti-S) to identify exposure to natural infection and convalescent individuals that have developed immunity. These tests have provided important information to those who have not been able to test for COVID-19 while unwell or tested with PCR (Polymerase chain reaction) too late or early. It has helped people confirm that the illness they experienced was indeed COVID-19. It was useful for clinicians in segregation and appropriate treatment of those patients who had COVID-19-like symptoms but their repeated RT PCR (Reverse transcription polymerase chain reaction) tests were negative to confirm active infection. The antibody tests for a few of them were positive which confirmed their prior exposure. Such post-COVID-19 hyper-inflammatory conditions were observed usually in children.

Evaluation of Effectiveness of COVID-19 Vaccines: Key Considerations

Now the vaccination has started all over and it is important to evaluate the effectiveness of the vaccination. Different types of testing methodologies are being carried out in various laboratories around the world. There is no standardized measurement process and definitive set values to know the protective immune response.

Quantitative Method of Estimation

The challenge is the selection of a quantitative method of estimation which can determine the true amount of antibody traceable to an international unit like anti-HBs for Hepatitis B vaccination. So, it can be reliably used for the assessment of effective immunization post-vaccination. The minimum level of antibodies required for protection against this disease is yet to

be established. This is a time-taking procedure and based on a statistical analysis of significant amount of data from measured quantitative antibody level post-vaccination. Providing relevant data to health authorities might be crucial for controlling the spread of COVID-19 and reopening the societies.

Duration of Protection

Duration of protection after COVID-19 and post-vaccination is not known. It is possible that the number of antibodies may decrease with time but memory B cells and memory T cells of the immune system may retain information about the virus for years to provide optimal protection.

To Differentiate Previous Infection or Effect of the Vaccine

Another interesting aspect is to know whether the present antibodies are because of a previous infection or because of vaccination. Serological tests targeting spike (S) protein cannot differentiate between the antibodies produced due to the past infection or any of the vaccination. But serological test targeting nucleocapsid (N) protein can differentiate between the antibodies due to natural infection and Covishield vaccination.

Validation of a New Testing Tool

In the process to find out a suitable antibody test which can be used as a tool to check whether the vaccine has triggered a sufficient immune response a standardized method of estimation for detection of antibodies with the ability to measure the true quantity in the international unit of measurement will help define the minimum level of protection.

A new test has become available that not only gives a positive or negative result but also provides a quantitative result traceable to this international unit. We are validating this method along with a few other methods for the estimation of antibodies in randomly selected post-vaccinated people to find out a method which can be reliably used as a COVID-19 vaccine antibody test.

Conclusion: Key Message

Diverse and non-uniform antibody testing methodologies are in use around the world to measure a single aspect of immune response. Standardization of assay will occur with time to provide a method for better understanding of immune response to the SARS-CoV-2 infection and vaccination. A quantitative method in a true sense with traceability to the international unit will help define the threshold for successful immune response.