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Evaluation of SARS-CoV-2 antibody titres following Covid vaccination in HIV patients on Antiretroviral therapy: An Observational study

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ABSTRACT

Background: COVID-19 vaccine emergency approvals were primarily based on immunogenicity studies in healthy individuals, with limited representation of immunocompromised populations such as people living with HIV. Since vaccine responses may differ in these groups, this cross-sectional observational study assessed IgG antibody responses to COVID-19 vaccines in HIV patients on antiretroviral therapy (ART).

Methods: The study was conducted from November 2021 to April 2022. Adult HIV patients on ART who had received two doses of COVISHIELD™ or COVAXIN™ within 8–24weeks were recruited. SARS-CoV-2 IgG antibodies were qualitatively assessed using a commercially available Microwell ELISA kit.

Results: Among the 42 enrolled subjects (mean age 42.17±9.04 years; 73.8% male), 35 received COVISHIELD™ and 7 received COVAXIN™. Most (90.5%) were on a tenofovir, lamivudine, and dolutegravir regimen. Only 4 participants had CD4 counts <300 cells/mm³. A majority (97.6%) showed a positive IgG antibody response to the SARS-CoV-2 spike protein.

Conclusions: HIV patients on ART mounted a strong humoral immune response following two doses ofCOVID-19 vaccines commonly used in India. Despite a small sample size and lack of neutralizing antibody testing, the study offers important data on vaccine response in this underrepresented population.

Keywords: Antibody response, ART, COVID vaccine, HIV, India.

BACKGROUND

Emergency use authorization of Covid vaccines were based on evaluation of the products in healthy human volunteers. It is suggested that immune response to vaccines may be different in individuals with compromised immune state as various factors including nature of the vaccine, extent of immune compromise play a role. Conventionally, most pre-licensure approval studies exclude such population. However, immunocompromised patients were considered to be equally or even more susceptible to COVID-19. HIV positive patients especially those with low CD4 count may have a higher chance of getting infected with COVID-19. The Centre for Disease Control and Prevention (CDC) had advised that People Living with HIV (PLWH) can choose to be vaccinated against COVID-19, but may have reduced immune responses to the vaccine, while the World Health Organization recommended that PLWH are to be immunized with COVID-19 vaccines.[1] A meta-analysis published in 2022 showed that the mortality rate among COVID-19 patients with HIV was significantly higher than those without HIV.[2]

There was paucity of data on COVID-19 vaccine immunogenicity in HIV patients when this study was planned. Accordingly, this cross-sectional observational study was designed. The primary objective was to evaluate the immune response in a cohort of HIV patients who are on ART who were fully immunized i.e. those who had received two doses of Covid-19 vaccine by estimating the SARS-CoV-2 antibody titres while the secondary objective was to correlate their antibody titres with the HIV disease activity state.

In India, two vaccines received EUA in 2021 – *Covaxin™*, a whole virion inactivated vaccine, developed in India by Bharat Biotech. [3]The second being the ChAdOx1 nCoV-19, a viral vector vaccine developed by Oxford University and marketed by AstraZeneca in India under the brand *Covishield™*.[4]

However, most of the published studies of COVID vaccines that were conducted for emergency use authorization globally, had excluded immunocompromised participants.

Thus, the objective of this study was to evaluate the humoral immune response following two doses of Covid vaccines in adult HIV patients who were on antiretroviral therapy (ART). In the study the humoral immune response was evaluated by estimation of total IgG antibody level.

MATERIALS AND METHODS

This cross-sectional observational study was initiated with prior approval from the Institutional Ethics Committee [IPGME&R/IEC/2021/551]. The study was conducted from November 2021 to May 2022. Subject recruitment was done from ICTC (Integrated Counseling & Testing Center) of the host institute. Adult registered patients of the center were screened for the following study selection criteria for recruitment.

Subject selection criteria Adult HIV patients (18 to 60 yr) of any gender on ART irrespective of their HIV disease stage, antiretroviral treatment regimen / CD4 count/ viral load status fulfilling the following.

Inclusion criteria:

a. Subjects who have documented evidence (full vaccination certificate) of having received two doses of either *COVAXIN*™ or *COVISHIELD ™*vaccine.
b. Study subjects who have received second dose of the vaccine, 8 to 24 weeks prior to the study enrolment date
c. Subjects willing to give written informed consent
d. Subjects willing to comply with all study related activities

Exclusion criteria:

a. Subjects who have received only one dose of the vaccine
b. Subjects who have received any other COVID 19 vaccines other than *COVAXIN™* or *COVISHIELD™*
c. HIV subjects who are not on ART drug therapy at enrolment visit

Study visits and activity: After taking written informed consent from all participants, their socio-demographic, disease and ongoing ART related data were collected. Information included the latest CD4 count, viral load and past history of documented COVID 19 disease and its treatment. Detailed history of covid vaccination (date/ name of vaccine) was verified from the vaccination card. Confidentiality was maintained and subject's identity was kept anonymous in all study related documents.

Estimation of antibody: 3 ml of blood was collected aseptically by venipuncture for SARS CoV2 IgG antibody estimation. The *Covid Kawach IgG Microelisa*™ (J Mitra& Co.Pvt Ltd. New Delhi, India) kit was used for qualitative detection of SARS CoV2 IgG antibody. The kit was validated by ICMR National Institute of Virology (NIV), Pune and had a sensitivity of 96.33 % and a specificity of 100%. The samples were processed as per the manufacturer's instructions.[5]

As per the kit, a test sample was considered "seropositive" if the P/N ratio i.e.
OD value of the test sample ÷ OD of negative control (provided in kit) was ≥1.5.

RESULTS

We recruited 42 subjects during the study period from November 2021 to May 2022. The baseline characteristics of the study population are summarized in **Table 1**. The mean age of participants was 42 yrs and they were mainly urban residents. Majority (83.3%) had no known co-morbidities like hypertension, diabetes, dyslipidemia or hypothyroidism. Analysis of the Antiretroviral therapy (ART) regimens showed that 90.4% were on TLD (Tenofovir + Lamivudine + Dolutegravir) while rest were on alternate therapies like TL ATV/r (Tenofovir + Lamivudine + Atazanavir/Ritonavir)

4.8%; ZLN (zidovudine+lamivudine+nevirapine) (2.4%) and DTG + LPV/r (Dolutegravir+Lopinavir/Ritonavir) (2.4%) regimens.

With regard to their Covid vaccination status all subjects had received both doses of vaccine as per our national schedule. Out of 42 subjects enrolled, 35 (83.3%) received *COVISHIELD ™* and 7 (16.66%) had received *COVAXIN ™*.As mentioned in the inclusion criteria, recruited subjects had received their 2nd dose of COVID vaccine 8-24 weeks from the study recruitment date. 11 (26.8%) participants were in 8-12 weeks, 14 (34.1%) within 12-16 weeks, 9 (21.9%) within 16-20 weeks and 7 (17.1%) within 20-24 weeks. The CD4 and CD8 count in the study population comprised on two cohorts. For 26 subjects, CD4 counts were done at recruitment, however for 16 subjects, CD4 count reports were taken from their records as the reports were relatively recent (< 6 months).

SARS-CoV-2 antibody response

Table 2 shows that out of 42 subjects, 41 (97.6%) showed a positive IgG antibody response (i.e P/N ratio ≥ 1.5) after two doses of COVID vaccination indicating that the subjects had mounted a good humoral antibody response. The subject who did not have a positive antibody response (P/N ratio<1.5) was 31 years old and had received two doses of *Covisheild*. When he was vaccinated, he was not on ART and his CD4 count was 420cells/ mm^3. After two doses of vaccination, he was initiated on antiretroviral therapy (TLD) and the time lag between vaccination and study enrolment was 97 days.

Table 2 is the representation of the seropositivity profile of the study participants. As described previously, a P/N ratio ≥ 1.5 is considered as seropositive. We analysed the type of Covid 19 vaccine received, CD4 count and gender amongst the seropositive versus the seronegative individuals. However, statistical analysis could not be performed as we had only one individual who was seronegative.

Table 1: Baseline characteristics of study population

Characteristic (n=42)	**Value**
Age in yrs(Mean ± SD)	42.17 ± 9.04
Gender n (%) • Male • Female	 31 (73.8) 11 (26.2)
Residence n (%) • Urban • Semi-urban • Rural	 39 (92.8) 1 (2.4) 2 (4.8)
Education n (%) • Primary school • High school • Graduate and above	 21 (50) 10 (23.8) 11 (26.2)
Estimated monthly income(₹)category n (%) • <10,000 • 10,000-20,000 • >20,000	 15 (35.7) 21 (50) 6 (14.3)
Associated Comorbidities • None • Hypertension • Dyslipidaemia • Hypothyroidism	 35 (83.3) 3 (7.1) 4 (9.5) 1 (2.4)
CD4 count (cells/mm^3) category n (%) • < 300 • 300-600 • > 600	 4 (9.52%) 26 (61.90%) 12 (28.57%)
ART regimen n (%) • TLD (Tenofovir + Lamivudine + Dolutegravir) • TL ATV/r (Tenofovir + Lamivudine + Atazanavir/Ritonavir) • ZLN (zidovudine + lamivudine + nevirapine) • DTG + LPV/r (Dolutegravir + Lopinavir/Ritonavir)	 38(90.47%) 2(4.76%) 1(2.38%) 1(2.38%)

Covid vaccine taken n (%) • *Covishield*™ • *Covaxin* ™	 35 (83.3%) 7 (16.66%)

Table 2: Analysis of profile of seropositive and seronegative individuals in the study population

Variable	Seropositive n=41	Seronegative n=1
P/ N ratio (range)	2.7 to 28.5	1.31
Vaccinereceived n (%) *Covishield* *Covaxin*	 34 (97.14%) 7 (100%)	 1(2.86%) 0
CD4 count cells/mm^3 (range)	142- 895	420*
Male gender n (%) Female gender n (%)	30 11	1 0

P/N ratio ≥ 1.5 was considered "seropositive" as per manufacturer's kit information

*Only one subject belonged to this category, so range was not applicable

DISCUSSION

We compared the results of our study with other studies which had been conducted on populations with varying types of immune suppression. Few studies have evaluated the immunogenicity of various Covid vaccines on patients who were on anticancer chemotherapy or post organ transplant and few on PLWH. However, the results were varied and at times contradictory. This prompted us to undertake this observational study wherein adult HIV positive participants(age group of 18-60 yrs) on ART therapy, irrespective of their disease state, antiretroviral treatment regimen/CD4 counts/ viral load, who had received 2 doses of the Covid vaccine widely used vaccines in India namely *Covishield*™ or *Covaxin*™ were enrolled. This study was initiated about 6 months after the second wave of the pandemic. The total IgG Covid 19 antibody titer was estimated using an ICMR approved commercially available ELISA kit. Our study results showed that 41 out of 42 subjects showed a positive antibody response. We can thus infer that the study population were seropositive 8 to 24 weeks after receiving the second dose of the *Covishield*™ or *Covaxin*™ vaccine. However, since majority of the study participants were seropositive and had CD4 counts> 300/µL at enrolment we cannot comment whether seronegativity was associated with low CD4 count as the only subject who was seronegative had a CD4 count of 420 cells/µL.

Only 1 out of 42 subjects had documented Covid infection while the rest denied any history of Covid. The subject who gave history of Covid infection had a time gap of 104 days between positivity for SARCoV2 and receipt of the first dose of the covid vaccine and an interval of 296 days between testing and study enrolment. Since majority of the study participants had denied prior SARCoV2 infection, we may infer that the Covid 19 IgG antibody response in our population is most likely to be indicative of vaccine immune response rather than prior infection.

We compared our study results with a single-arm open-label vaccination sub-study within a larger phase 2/3 trial COV002, with ChAdOx1 nCoV-19 vaccine which was conducted in adult HIV patients from London, UK.[6]The participants had either undetectable or low HIV viral load (<50 copies/ml) and had CD4 counts > 350/µL. The study assessed both the humoral and cellular immune responses to 2 doses of the test vaccine. There were about 50 participants and the results demonstrated that the test vaccine given 4–6 weeks apart was well tolerated and produced equivalent immune responses in PLHIV who are well controlled on ART compared with a similar adult population without HIV. Our study was a real-world pragmatic study so we did not have strict study selection criteria and subjects irrespective of their HIV viral load or CD4 counts were enrolled. In our study cohort also, majority of the participants had CD4 counts above 300/ µL.The humoral antibody response was comparable with our study indicating that possibly HIV viral load or CD4 count has either minimal or no impact on the immunogenic response in those who had CD4 counts above 300/ µL.

Another early phase regulatory clinical trial was conducted in South Africa where the immunogenicity and safety of two doses of the ChAdOx1 nCoV-19 vaccine was compared in participants who were HIV positive versus those who were negative.[7]The trial results demonstrated that HIV positive patients generated good humoral response i.e IgG antibody titers against the wild-type Wuhan-1 Asp614Gly. Additionally, they showed a heightened response in participants who were SARS Vov2 seropositive at baseline versus those who were seronegative. Several HIV positive individuals also had cross reactive binding antibodies. Our results too were in agreement with this regulatory trial data.

A recent single centre observational study published from Switzerland evaluated the immunogenicity and safety of two doses of mRNA vaccines (*Moderna*™) and BNT162b2 (Pfizer BioNTech) in people living with HIV (PLWH) on ART.[8] Immunogenicity was assessed by serial estimation of anti-receptor binding domain antibodies (RBD) at 0, 1 and 6 months following vaccination. The vaccines elicited satisfactory immunogenicity as revealed by good anti-RBD antibodies titers up to 6 months with no major safety concerns. No statistically significant differences in antibody response in subjects with HIV 1 RNA viral load < 20 copies versus those with >20 copies/ml were observed. Similarly, another study reported that PLWH who had received 2 doses of the SARSCoV2 mRNA vaccines had elicited satisfactory anti-RBD antibodies up to 4 months post vaccination. [9] Their study findings corroborate with ours although our vaccines were not mRNA vaccines.

A study from Canada observed that that the anti-RBD antibody response in HIV positive participants was not significantly different from those who were HIV negative. [10] But the immune response in HIV positive subjects with CD4 <250 cells/mm^3 was significantly lower than those having higher CD4 counts.

There were a few published studies which have evaluated immunogenicity of covid vaccines in different categories of immunocompromised patients, like those on immunosuppressants or on dialysis.

A retrospective observational study published from Vienna evaluated the immunogenicity and safety of RNA-1273 Moderna® vaccine on a cohort of patients who were undergoing peritoneal dialysis.[11]After full vaccination, there was high seroconversion rate (97.4%) and no serious adverse events were observed. Our study also reflected similar results of robust seroconversion in immunocompromised population though the patient cohort was not PLWH.

A study from Spain evaluated the effects of messenger RNA (mRNA) vaccines against SARS-CoV-2 in a subset of immunocompromised population of multiple sclerosis.[12] They found that mRNA vaccines against SARS-CoV-2 are as safe in these patients as in other individuals. Immunosuppressive therapies like fingolimod, cladribine, alemtuzumab, ocrelizumab and rituximab, might reduce the effectiveness of these vaccines and require the scheduling of their vaccination, preferably before the start of treatment if possible.

A recently published meta-analysis of 82 studies including 77 with mRNA vaccines, 16 with viral vector vaccines, and 4 with inactivated whole virus vaccines showed a different picture albeit for a total subset of immunocompromised population.[13] It showed that seroconversion rates after covid-19 vaccination were significantly lower in immunocompromised patients, especially organ transplant recipients following single dose of vaccine, however the response was shown to improve following subsequent doses. The major limitation with this meta-analysis however was that though this was a meta-analysis of immunocompromised subjects, even here the HIV population was underrepresented as not many studies had HIV patients as participants.

Our study has its strength and limitations. To the best of our knowledge, when we initiated our study there was no published academic study from India on this patient cohort. Perhaps this is the first single center cross sectional pragmatic study that evaluated the humoral antibody response on HIV patients on ART and has generated clinical and immunological data on the humoral immune response following two doses of the commonly used covid vaccines in India.

Our study has its share of limitations. We evaluated the total IgG COVID 19 antibody, and could not evaluate anti-RBD IgG responses and neutralizing antibodies as there was no commercially available ICMR approved and validated kits for these antibodies and we had very limited funds for this academic study. Secondly, our study results may have limited external generalisability for HIV positive individuals who have received other types of covid 19 vaccines like mRNA vaccines.

Our study was not a comparative one hence we cannot comment on the immunogenic response of HIV subjects who are not on ART. Finally, we cannot ensure whether all study subjects provided us with a correct history of past covid infection, but being a real-world pragmatic study this issue cannot be avoided and the study results need to be interpreted taking into consideration the above fact.

CONCLUSION

The antibody response to Covid vaccination has been varied across different vaccines and population subsets. The HIV positive populations have been under-represented in different immunogenic studies conducted for the Covid vaccines. This study was the first of its kind in Eastern India that evaluated this aspect. The study showed that HIV patients on ART have developed good antibody response to the two most commonly used vaccines in India, i.e.*Covishield* ™ and *Covaxin* ™. The antibody response following vaccination had no correlation with the CD4 counts of the subjects.

However further studies in other subgroups of immunocompromised population and with other vaccines can provide more information regarding the immunogenic response to vaccines in immunocompromised population.

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