Advances in Research on COVID-19 Vaccination for People Living with HIV

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Introduction

In December 2019, multiple cases of aggravated pneumonia of unidentified origin were reported in Wuhan, China. These were confirmed to be caused by a novel coronavirus. The World Health Organization (WHO) named the disease coronavirus disease 2019 (COVID-19). The International Committee on Taxonomy of Viruses officially identified the novel virus severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[1] Although China is now a low endemic area with a downward trend in the number of confirmed and suspected cases,[2] the threat of the COVID-19 pandemic remains critical. By mid-March 2022, the cumulative number of reported confirmed cases of COVID-19 worldwide exceeded 450 million, with more than 6 million deaths.[3] Since there is no specific therapeutic drug for the treatment of COVID-19, it is important to control the epidemic by actively promoting SARS-CoV-2 vaccination globally, reducing the risk of viral transmission and the incidence of severe COVID-19, thus improving prognoses.[4]

The human immunodeficiency virus (HIV) pandemic has resulted in nearly 37.7 million people being infected with HIV worldwide. People living with HIV (PLWH) are classified by the WHO as imposing a higher peril for SARS-CoV-2 infection. Although HIV infection is not a risk factor for COVID-19, several studies have shown that the clinical course of PLWH, especially for those with low CD4+ T cell counts and untreated HIV infection, may be more severe than that in HIV-negative populations.[5-9] PLWH are typically excluded from randomized clinical trials of antiviral drugs, immunomodulators, and vaccines, resulting in the lack of large-scale safety and efficacy data to support COVID-19 vaccination strategies in this population.[10] This study reviewed the current data and challenges of COVID-19 vaccination among PLWH, summarizing their willingness to receive the vaccination and the factors that influence this decision to receive the COVID-19 vaccine and providing a reference for subsequent studies.

Intentions and factors influencing the decision for COVID-19 vaccination in PLWH

There are few data on the willingness of PLWH to receive COVID-19 vaccination. A single-center online survey among PLWH who had been vaccinated against SARS-CoV-2 in France showed that 28.7% (68/237) of participants expressed hesitation.[11] Another online survey study, including 1942 healthy individuals on their inclination on receiving the COVID-19 vaccine, demonstrated that approximately 28.8% of the participants outright refused to be vaccinated.[12] However, a study analyzed the uptake of the COVID-19 vaccine in 44,260 individuals, with 15 survey samples from 10 low-and middle-income countries in Asia, Africa, South America, Russia (an upper-middle-income country), and the United States, and found that the intention to receive the COVID-19 vaccine was high, with a mean of up to 80.3%.[13] Another US online survey of PLWH regarding COVID-19 vaccination showed that 319 of the 496 individuals had received at least one dose of the COVID-19 vaccine, and 66.3% of those who had not received at least one dose of the COVID-19 vaccine at the time of the survey said they would receive the vaccine when it became available to them.[14] A Chinese study, using an online questionnaire that recruited 527 PLWH who had received the COVID-19 vaccine and 1091 unvaccinated PLWH, showed high rates of inclination to receive the COVID-19 vaccine among individuals with higher levels of education and those with occupations with a higher risk of novel coronavirus infection, such as essential urban security workers, international transport workers, quarantine entry point workers, and cold chain logistics workers.[15] According to this study, fear of adverse effects was the most common concern for hesitation.[13] Adverse reactions to COVID-19 vaccination in PLWH include negative impacts on HIV/AIDS disease progression or antiretroviral therapy (ART), disclosure of HIV infection status, or underlying comorbidities.[14-16] The percentage of PLWH undergoing COVID-19 vaccination also varies by sex, race, sexual orientation, CD4+ T cell count, viral load, and education, with one study showing that men infected with COVID-19 were five times more likely than women to receive the vaccine.[17] A study including 6441 PLWH showed that individuals with CD4+ T cell counts >200 cells/μL were more likely to be vaccinated with the COVID-19 vaccine than those with CD4+ T cell counts <200 cells/μL.[18] Another study showed a higher intention to vaccinate
for COVID-19 in PLWH with an undetectable viral load. There is a need to further understand the possible reasons for hesitation or rejection of the COVID-19 vaccination in PLWH to better address these concerns.

**Overview of SARS-CoV-2 vaccination in PLWH**

Since the outbreak of COVID-19, nations worldwide have accelerated the development of vaccines against the new coronavirus. Currently, there are three main types of COVID-19 vaccines: inactivated, adenovirus vector, and mRNA. In addition, subunit vaccines, live attenuated vaccines, and DNA vaccines are under development. Most data on vaccine safety and efficacy come from healthy populations. For several other vaccines, including the ones against yellow fever, influenza, and hepatitis B, PLWH have been shown to display lower or delayed immune responses than healthy controls. According to the currently available data on the safety and efficacy of COVID-19 vaccines in PLWH, the recommendation from the Chinese national guidelines, WHO, and UNAIDS is to prioritize early and complete vaccination in this high-risk population in all immunization status, except for those with contraindications (such as allergy to similar vaccine components, uncontrolled epilepsy, or other serious neurological diseases).

**mRNA vaccination in PLWH**

There are two main mRNA vaccines used worldwide: the BNT162b2 mRNA vaccine, which was jointly developed by Pfizer/BioNTech in the United States, and Moderna mRNA-1273. To date, limited studies have included PLWH in approved phase II/III vaccine trials, in Moderna and Pfizer’s mRNA-1273 and BNT162b2 mRNA vaccine trials, the proportion of PLWH was <1%. Although the original SARS-CoV-2 mRNA vaccine trials found near-universal robust immune responses in the general population, the response to SARS-CoV-2 vaccines has not been fully characterized in PLWH. The entry of SARS-CoV-2 into its target cells depends on binding between the receptor-binding domain (RBD) of the viral spike protein and its cellular receptor angiotensin-converting enzyme 2 (ACE2). Antibodies competing with this entry step should effectively block SARS-CoV-2 entry into the host cells. A meta-analysis showed that the seroconversion rate to SARS-CoV-2 was comparable in PLWH and immunocompetent controls. In several small studies analyzing the humoral response induced after mRNA SARS-CoV-2 vaccination, all PLWH developed anti-RBD antibodies after each dose of the SARS-CoV-2 mRNA vaccination, and the anti-RBD antibody titers increased over time. Moreover, adverse effects were generally mild. In a study testing RBD-IgG and neutralizing antibodies after two doses of the BNT162b2 mRNA vaccine in PLWH, a similar immunological response was observed in PLWH and healthy individuals. In other trials conducted with PLWH displaying high CD4+ T cell counts, no difference in immune response was observed after BNT162b2 vaccination compared with healthy controls. However, a more recent study reported decreased IgG titers after vaccination with BNT162b2 in PLWH compared with healthy controls, although the neutralizing capacity was comparable in the two groups. Interestingly, several studies have shown that high CD4+ T cell counts in PLWH may be associated with robust humoral and cell-mediated immune responses, whereas serological responses in PLWH with low CD4+ T cell counts cannot be detected. Multiple studies showed similar antibody responses triggered in PLWH with a well-controlled disease on ART and in HIV-negative individuals and correlated with CD4+ T cell counts and CD4+/CD8+ ratios. The BNT162b2 vaccine demonstrated immunogenicity and safety in 143 PLWH; among them, three individuals experienced an increase in HIV-1 viral load from undetectable (<40 copies/mL) to low-level viremia (<100 copies/mL) after vaccination, which may be associated with low CD4+ T cell count levels (<200 cells/μL). In contrast, a recent study did not confirm an HIV viral load increase, as all PLWH inoculated mRNA vaccinations had a minor impact on HIV-1 viral RNA levels after two doses of vaccination and over 6 months.

Current research indicates that, in HIV-negative individuals, the immune response is stronger when applying the mRNA-1273 vaccine (Moderna) compared with BNT162b2 (Pfizer/BioNTech). This may be due to the higher mRNA content in the Moderna vaccine and the longer interval (4 vs. 3 weeks) between priming and boosting. However, there is currently no randomized study comparing the effectiveness of BNT162b2 and mRNA-1273 in PLWH. In a study of 100 PLWH vaccinated with two doses of mRNA-1273 and BNT162b2, all participants successfully generated anti-spike IgG antibodies, but the study lacked sufficient power to compare the efficacy of the vaccines as only 10 PLWH received the BNT162b2 vaccine. However, several studies have shown that PLWH receiving two doses of mRNA-1273 have a greater neutralizing humoral response than PLWH receiving two doses of BNT162b2. Moreover, a recent study described a higher risk of SARS-CoV-2 breakthrough in PLWH with BNT162b2 (Pfizer/BioNTech), with an increased risk of breakthroughs of 2.6% and 1.7% for mRNA BNT162b2 and mRNA-1273 vaccines, respectively, in PLWH than in HIV-uninfected individuals. Among PLWH, the cumulative incidence and relative risks of breakthroughs were not significantly different based on CD4+ T cell count or HIV viral load suppression. Most studies on COVID-19-vaccinated PLWH have focused on patients with suppressed plasma HIV viral load and CD4+ T cell counts in the healthy range. Therefore, further studies are needed to focus on PLWH who did not receive ART or who still had low CD4+ T cell counts for clinical management and guidelines.

**Viral vector vaccination in PLWH**

The main adenovirus vector vaccines currently available for PLWH are the ChAdOx1-S vaccine (AZD 1222) developed by Oxford/AstraZeneca (UK) and the Ad26.COV2.S vaccine developed by Johnson & Johnson (United States). A randomized, double-blind, placebo-controlled trial with 102 PLWH in South Africa showed that the ChAdOx1 COVID-19 vaccine had good safety and immunogenicity in PLWH and that vaccination may consolidate the immune response, drive long-term immune memory, and provide some protective efficacy in this population regardless of prior exposure to SARS-CoV-2.

For the PLWH population, the vaccine ChAdOx1 COVID-19 showed a strong induction of serum IgG response against full-length spike protein and RBD, which increased with the booster dose. These studies found no significant differences in SARS-CoV-2-specific humoral or cellular immune responses between PLWH and HIV-negative cohorts. The Ad26.COV2.S adenovirus vector vaccine (Janssen/Johnson & Johnson COVID-19 vaccine) trial enrolled 467 participants, the largest number of PLWH with well-controlled disease enrolled to date (with viral suppression, CD4+ T cell count ≥300 cells/μL), with no significant difference in safety compared with HIV-negative individuals. However, another study found an increased risk of breakthrough infection, with the highest increase
(3.3%) observed for the Janssen/Johnson & Johnson COVID-19 vaccine. Notably, there are important concerns regarding the potential use of adenoviral vector vaccines in PLWH. Various studies have shown that adenovirus type 5 (Ad5) immune complexes activate the dendritic cell-T cell axis, which may enhance HIV-1 replication in CD4+ T cells. In addition, Ad5-specific CD4+ T cells may be more susceptible to HIV infection. More studies are needed to determine whether adenoviral vector vaccination of PLWH patients develops long-term protective properties without adverse effects. Despite these potential concerns, it is important to note that, in a pandemic setting, the benefits of all licensed COVID-19 vaccines outweigh the potential risks associated with SARS-CoV-2 infection in PLWH.

**Vaccination with inactivated vaccines in PLWH**

At present, the use of inactivated vaccines among HIV-infected patients mainly includes the BBIBP-CorV vaccine developed by China’s Sinopharm and inactivated SINOVAC CoronaVac vaccine of Sinovac Biological Products Co, Ltd. Phase I/II clinical trials with healthy individuals have shown good immunogenicity and safety. A robust humoral immune response was observed in 100% of the vaccine recipients. Other phase III clinical trials of this vaccine are currently under evaluation worldwide. To date, only a few studies have been conducted on inactivated novel coronavirus vaccines for individuals with HIV. In China, a cross-sectional study comparing the immune response of HIV-infected and HIV-negative individuals to an inactivated vaccine showed that the immunogenicity of inactivated SARS-CoV-2 vaccination was lower in the PLWH population, although the incidence and severity of adverse events were similar. Another study including 48 HIV-infected patients who received an inactivated COVID-19 vaccine also showed a weaker and delayed early humoral immune response in PLWH than in healthy individuals, regardless of ART status, CD4+ T cells, and HIV viral load. Interestingly, a study including 42 PLWH vaccinated with an inactivated vaccine found comparable RBD-binding antibodies, neutralizing antibodies, and 5 protein-specific T cell responses between PLWH and HIV-negative populations in PLWH with high baseline CD4+/CD8+ T cell ratios, whereas PLWH with low baseline CD4+/CD8+ T cell ratios showed weaker antibody responses. Several studies have shown that inactivated booster vaccination (BBIBP-CorV or CoronaVac) is negatively affected by low CD4+ T cell counts. Recently, a new study evaluated the immune response to the CoronaVac vaccine in immunocompromised patients, and the proportion of PLWH who achieved neutralizing antibody positivity and total anti-SARS-CoV-2 IgG antibodies was significantly lower than that in the control group. PLWH with CD4+ T cell counts >500 cells/μL had higher seroconversion rates, neutralizing antibody positivity, and functional activity. These results suggest that vaccine-induced antibody responses are dependent on CD4+ T cells. Development of humoral and cellular immune responses to inactivated SARS-CoV-2 vaccines may take longer in PLWH. Further follow-up of the immune response is needed to determine how inactivated SARS-CoV-2 vaccines respond to PLWH.

**Adverse reactions to vaccination in PLWH**

Current studies have shown that most COVID-19 vaccines are safe and well-tolerated in PLWH. The adverse reactions to COVID-19 vaccination are mild in PLWH, with injection site pain being the most common adverse reaction, followed by fatigue, headache, dizziness, or drowsiness. In the evaluation of the efficacy and safety of the BNT162b2 mRNA vaccine in immunodeficient populations, including HIV-infected individuals, the rates of reported adverse events between immunodeficient populations and healthy controls were not significantly different. Interestingly, the incidence of systemic reactions (fever, chills, headache, tiredness/fatigue, diarrhea, vomiting, new/worsened muscle pain, or joint pain) was slightly lower in PLWH than in healthy controls after two doses of the mRNA vaccine. These decreased adverse effects may be related to the immunosuppressed state of the PLWH. For vaccination with inactivated virus, the overall incidence of adverse events within 7 days was similar between PLWH and healthy controls. Currently, inactivated vaccines do not induce serious adverse events in PLWH. Indeed, the proportion of adverse reactions in PLWH inoculated with inactivated vaccines was significantly lower than that in PLWH that received mRNA vaccines. However, more targeted studies with larger sample sizes are required.

**Conclusion and outlook**

The COVID-19 pandemic continues to ravage the world, and different types of vaccines have been designed and developed in several countries worldwide. The design of COVID-19 vaccines requires eliciting broad humoral, cellular, and mucosal immune responses to effectively reduce transmission and severe disease. Several studies have shown that mRNA vaccines have superior immunogenicity compared with vector and inactivated vaccines in healthy controls. Moreover, studies have demonstrated that the immune response is stronger in HIV-negative individuals when applying the mRNA-1273 vaccine (Moderna) compared with BNT162b2 (Pfizer-BioNTech) because of its higher mRNA content and longer interval (4 vs. 3 weeks) in healthy controls as well as in PLWH. Vaccine effectiveness (VE) against COVID-19 hospitalizations was higher for the Moderna vaccine than for the Pfizer-BioNTech vaccine, and VE for both mRNA vaccines was higher than that for the Janssen vaccine. However, it is still not clear which COVID-19 vaccine produces the best safety and protection. COVID-19 mRNA vaccines represent a new class of vaccines. Therefore, it is difficult to directly compare the seroconversion rates of COVID-19 mRNA vaccines with those of traditional and frequently used vaccines.

Owing to their compromised immune status, vaccine-induced immune responses might be impaired in PLWH, which affects various immunological pathways causing immune activation, impaired cellular and humoral responses, and their clinical outcomes. However, a systematic review and meta-analysis evaluating the safety and efficacy of COVID-19 vaccination in immunocompromised populations showed that mRNA vaccines appeared to be the most effective after two doses compared with non-replicating viral vector vaccines and inactivated vaccines. This is similar to recent results comparing the safety and efficacy of different types of vaccines in immunocompetent populations. Additional vaccination studies involving PLWH with COVID-19 are necessary for the future to gain further insight into the persistence of humoral and cellular immunity to SARS-CoV-2.

If SARS-CoV-2 undergoes a large degree of mutation, the vaccines under development may no longer work for the mutated virus. It is yet to discover what level of immunity is required to prevent hospitalization and death, but real-world data suggest that vaccination is successful in preventing these even in the presence of transmissible and virulent variants of concern (VOCs). In the future, repeated boosting might be necessary to maintain long-term immunological memory of SARS-CoV-2 and VOCs, especially for immunocompromised populations such as PLWH.
Therefore, there is a need to increase the surveillance of the virus so that effective measures can be taken promptly. Moreover, to improve the immune efficacy and duration of SARS-CoV-2 vaccination, different vaccine types should be tested in combination. A heterologous mRNA booster after two doses of inactivated vaccine elicited higher levels of neutralizing antibodies than the inactivated vaccine alone.\[7\] A recent study showed that the mRNA BNT162b2 and inactivated CoronaVac vaccines had higher VE over, further vaccine efficacy studies in PLWH should be performed to elucidate the potential impact of various immunization strategies, according to their disease status and outcome. More-
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