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COVID-19 vaccination in people living with HIV: current data and perspectives

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Abstract

There is no correlation between HIV per se and other risk factors for severe COVID-19 disease. Pivotal studies have shown that vaccination is one of the effective ways to prevent severe COVID-19 illness in the general population. Studies on people living with HIV (PLWH) are scarce. The majority of these studies with mRNA (BNT126b2 and mRNA-1273) and adenovirus vector (Ad26.COV2.2 and ChAdOx1) vaccines with a low number of patients included shows that PLWH on antiretroviral treatment and with CD4 count > 200/mm³ has a robust immune response. These vaccines are thus effective in preventing severe infection caused by severe acute respiratory syndrome coronavirus 2 in PLWH. However, PLWH with a CD4 count of < 200/mm³ and uncontrolled viral load (VL) seems to have a lower immune response. COVID-19 vaccines are safe in PLWH; adverse effects are mild or moderate, and their incidence is similar to non-HIV people (NHP). The CD4 count decreased significantly and transiently, and the VL rebounded insignificantly in a few patients. A complete vaccination including a third dose is, therefore, recommended. A booster dose with an mRNA vaccine is recommended in PLWH with an advanced stage of their disease.

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Keywords

Severe acute respiratory syndrome coronavirus 2. COVID-19. Vaccine. HIV.

Introduction

COVID-19 has caused unprecedented disruption to all health systems and, until now, more than 6 million deaths worldwide[1]. Vaccination is one of the effective ways to prevent severe infections (hospitalizations and deaths) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It is unknown whether the COVID-19 vaccine works well in people living with human immunodeficiency virus (PLWH), especially those whose CD4+ count is < 200/mm^3, since these individuals were not included in randomized clinical trials (RCTs)[2-5]. The immunological and vaccine response mechanisms are not yet completely understood.

This article summarized the available data concerning COVID-19 vaccination in PLWH, emphasizing efficacy and tolerance.

Risk factors for severe infection IN PLWH

Preliminary data qualifying human immunodeficiency virus (HIV) as a risk factor for severe SARS-CoV-2 infection or mortality have evolved considerably. However, it appears that HIV infection is an independent risk factor for severe infection and increased mortality[6,7],

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particularly in those who do not have a controlled viral replication and a CD4+ count below 200/mm^3. Nevertheless, HIV *per se* is a risk factor independent of other risk factors for severe COVID-19 (such as aging, obesity, diabetes, hypertension, cardiovascular disease, and chronic renal failure)[8] in PLWH. Considering these data, the World Health Organization (WHO) has considered that PLWH should be among the priority patients eligible for the COVID-19 vaccination[9].

Efficacity

The efficacy of COVID-19 vaccination has been demonstrated in significant Phase III randomized clinical trials in the general population[2-5]. These RCTs included a limited number of PLWH. The Janssen's RCT for Ad26.COV2.2 enrolled the highest number of PLWH, comparing the BNT126b2 (Pfizer) and mRNA-1273 (Moderna) trials; despite this fact, this population represents only 2.8% of the total study sample; therefore, it's not possible to extrapolate the efficacy of the vaccine to the specific group of PLWH[5]. The most prominent clinical study until now about COVID-19 vaccination in PLWH was conducted with Ad26.COV2.S (Janssen), in a study performed on health care workers in South Africa, showed similar efficacy between PLWH and non-HIV people (NHP) for protection against severe COVID- 19, hospitalizations and deaths[10].

In table 1, we summarized recent data concerning vaccination in PLWH. The majority of studies compare PLWH and HNP and report the levels of anti-S (Spike) IgG, anti-RBD (receptor-binding domain) IgG, and the neutralization capacity of these antibodies after complete vaccination with BNT126b2 (Pfizer), mRNA-1273 (Moderna), or ChAdOx1 (Astra-Zeneca) vaccines. Some studies compare the vaccine's clinical efficacy[2-5,10], cellular response[11,12], and difference in neutralization capacity[13]. Most studies confirm that PLWH on antiretroviral treatment (ART) and with CD4 count > 200/mm^3 has a robust immune response similar to the control group.

There are, however, a few nuances to consider.

On the one hand, studies show lower levels of anti-S IgG in PLWH, which may indicate a lower immune response[14,15]. On the other hand, other studies have shown lower levels of anti-RBD IgG and a lower rate of neutralization in PLWH[13,16]. Likewise, we observe a lower response with Pfizer than with Moderna, probably due to the higher concentration of messenger RNA (mRNA) in this vaccine (30 g vs. 100 g) and the greater interval between doses (3 vs. 4 weeks)[17-19]. Finally, age, sex, and comorbidities are not uniformly distributed in several studies[11,14,20].

Data concerning PLWH with CD4 count < 200/mm^3 are listed in table 2 and are scarce[21-24]. Anti-RBD IgG levels are lower in this subgroup of patients, as neutralization capacity data. Therefore, the immune response seems to correlate with the CD4 count. Patients in this subgroup, considered immunocompromised, are consequently eligible for a third and a booster dose, in the same way that patients who are not on ART (except for elite controllers) or those who are not undetectable under ART[25-27].

Others vaccinations

The NVX-CoV2373 study (Novavax) includes 201 PLWH (6% of all participants). Vaccine efficacy appears to be higher when PLWH is not counted in the survey (49.4% vs. 60.1%)[28]. These data need some confirmation on larger samples.

A Russian study by Gushchin et al.[29] with 2543 PLWH fully vaccinated with Sputnik V shows that the vaccine effectiveness is not different from the general population (for peoples witch CD4+ count ≥ 350/mm^3). For PLWH with CD4+ count < 350/mm^3, the vaccine effectiveness was lower but was still present.

PLWH and HNP suffer similar levels of anti-RBD antibodies, neutralization capacity, and a similar T-cell response in a small study in China involving 42 PLWH (all with a CD4 count > 200/mm^3)[30]. Another Chinese study showed lower levels of total antibodies, anti-S IgG, and T-cell response in PLWH than in HIV-negative people[31].

Tolerability

Adverse effects (AEs) after COVID-19 vaccination were also studied and compared between PLWH and HNP: these are summarized in table 3. Most local and systemic AE was mild or moderate with mRNA vaccines[24].

With BNT162b2, the local AEs were more frequent following the first vaccine, and systemic AEs were more common following the second dose. The most common local reaction was pain at the injection site. The most common systemic impact after the first dose were fatigue and headache, whereas fatigue and fever (< 38°C) were the most common AEs after the second dose[20].

With an mRNA-1273 vaccine, AEs are more frequent after the second dose. Locally, the most common side effects were pain, swelling, and redness. We mainly

Table 1. Available evidence in the literature about COVID-19 vaccine post complete prime vaccination scheme in PLWH

Authors	Type of study	Type of vaccine	PLWH (n)	Control	CD4+/mm^3 (median)	Lab test	Result	Follow -up	Comments
Polak et al.[2]	Placebo-controlled, observer-blinded, pivotal efficacy trial	BNT162b2	82	NHP*	NA	Vaccine efficacity	NA*	120 d*	Sub-analysis NA
Jedike et al.[14]	Observational	BNT162b2	88 (1 dose) 52 (2 doses)	NHP (HCW*)	716 All on ART*	Anti-S IgG Neutralization	– 12% have lower neutralizing activity – Anti-S IgG: lower and more variable	35 d	Differences in age, sex, and comorbidities between the two groups
Levy et al.[17,20]	Prospective open	BNT162b2	143	NHP (HCW)	700 All on ART	Anti-RBD IgG Neutralization	97% PLWH developed RBD-IgG antibodies versus 98.9% – 97% PLWH developed neutralization activity	26 d	95.8% Caucasians differences in age and sex between the two groups
Rahav et al.[39]	Prospective cohort study	BNT162b2	156	NHP (HCW)	700 All on ART	Anti-RBD IgG Neutralization	Similar immunological response in PLWH Anti-RBD IgG are detected in 98.7% of PLWH versus 98.9% in NHP	28 d	
Woldemesekel et al.[12]	Observational	BNT162b2	12	NHP	913 All on ART	Anti-S IgG T-cell response	No significant difference between PLWH and NHP	NA	Small number of participants
Xu et al.[15]	Randomized controlled trial	BNT162b2	90	NHP	565 49% < 200 All on ART 86% VL < 50 copies/ml	Anti-S IgG	Lower anti-S IgG levels in PLWH Seroconversion: 98.7% in PLWH versus 100% NHP	35 d	People with baseline viral load more than 50 copies/ml had lower levels of spike IgG

(continues)

Table 1. Available evidence in the literature about COVID-19 vaccine post complete prime vaccination scheme in PLWH *(continued)*

Authors	Type of study	Type of vaccine	PLWH (n)	Control	CD4+/mm^3 (median)	Lab test	Result	Follow -up	Comments
Baden et al.[3]	Phase 3 randomized, observer-blinded, placebo-controlled trial	mRNA-1273	92	HNP	NA	Vaccine efficacity	NA	120 d	Sub-analysis NA
Spinelli et al.[16]	Randomized, observational, controlled study	BNT162b2 mRNA-1273	100	NHP	511	Anti-RBD IgG Neutralization	IgG antibody non-response was seen in 12% PLWH compared with 5% of HNP	35 d	Unsuppressed HIV had an 86% Lower IgG antibody level and an 89% lower surrogate neutralization response. Lower CD4 Count was also a risk factor. All seven people with a CD4 count below 200/mm^3 were non-responders.
Ruddy et al.[24]	Prospective observational cohort	BNT162b2 mRNA-1273	14	None	2/14 < 200/ mm^3 All on ART	Anti-RBD Neutralization	High titers of anti-RBD IgG, similar to NHP	7 d	Small, non-randomized sample
Brumme et al.[40]	Preprint, unclear	ChAdOx1 mRNA-1273	100	NHP	710 All on ART	Anti-RBD IgG Neutralization	No statistically significant difference between PLWH and controls	28 d	Differences in terms of sex and ethnicity ChAdOx1 versus mRNA
Frater et al.[11]	Single arm substudy of a phase 2/3 clinical trial	ChAdOx1	54	NHP, group from the same study	694 All on ART	Anti-S IgG T-cell proliferative response Neutralization	No difference in magnitude or persistence of SARS-CoV-2 spike-specific humoral or cellular responses	56 d	Imbalance in the sex distribution in the PLWH group

(continues)

Table 1. Available evidence in the literature about COVID-19 vaccine post complete prime vaccination scheme in PLWH *(continued)*

Authors	Type of study	Type of vaccine	PLWH (n)	Control	CD4+/mm^3 (median)	Lab test	Result	Follow -up	Comments
Voysey et al.[4]	Within Phase 2/3	ChAdOx1	103	NHP	NA	Vaccine efficacity	NA	NA	NA
Madhi et al.[41]	Randomized, double-blind, placebo-controlled, Phase 1B/2A trial	ChAdOx1	103 (vaccine group: 52)	NHP	742 All on ART	Anti-FLS and Anti-RBD IgG Neutralization	Similar FLS-binding and RBD-binding IgG and SARS-CoV-2 neutralizing in PLWH and NHP	14 d after 2nd dose	Neutralization retained against beta
Bekker et al.[10]	Single-arm, open-label, phase 3B, implementation study	Ad26.COV2.S	39383	NHP (HCW)	Sub analysis non available	Vaccine efficacity	No difference between PLWH and NHP	28 d	
Sadoff et al.[5]	Randomized, double-blind, placebo-controlled, phase 3 trial	Ad26.COV2.S	601	NHP	NA	Vaccine efficacity	NA	28 d	Small proportion of the participants
Khan et al.[13]	Randomized control trial	Ad26.COV2.S	26	NHP (HCW)	735 (only vaccinated) 852 (infected and vaccinated)	Neutralization	No difference neutralization between PLWH and NHP	74 d (only vaccinated) 51 d (infected and vaccinated)	
Guschin et al.[29]	Retrospective cohort study	Sputnik V	2543	NHP	89.5% > 350 All on ART	Vaccine efficacity	Vaccine effectiveness with CD4+ ≥ 350/mm^3 was not different from the general population	3-6 months	In patients with CD4+counts < 350/mm^3, vaccine effectiveness was lower but was still present.
Shinde et al.[28]	Randomized, double-blind, controlled Phase 2A-B trial	NVX-CoV2373	80	NHP	NA	Vaccine efficacity Anti-S IgG (for seronegative participants)	49.4% versus 60% efficacity when PLWH are excluded	60 d	PLWH represent 6% of the study population

(continues)

Table 1. Available evidence in the literature about COVID-19 vaccine post complete prime vaccination scheme in PLWH *(continued)*

Authors	Type of study	Type of vaccine	PLWH (n)	Control	CD4+/mm^3 (median)	Lab test	Result	Follow -up	Comments
Huang et al. [31]	Cross-sectional study	Inactivated vaccine	129	NHP	630 All on ART	SARS-CoV-2 total IgG Anti-S IgG Neutralization T-cell response	Lower total IgG, anti-S IgG, and T-cell response y in PLWH but same neutralization between PLWH and HIV-negative people	15-84 d	Higher response when higher interval between 2 doses (< 21 d versus > 28 d) and longer time since HIV diagnosis
Feng et al. [30]	Non-randomized cohort study	Inactivated vaccine	42	NHP	659 All on ART	Anti-S IgG Neutralization T-cell response	Similar response between the two groups	28 d	CD4+ count and viral load decrease significantly after vaccination

NHP: non-HIV people, HCW: health care worker, ART: asntiretroviral treatment, NA: non-available, d: days, PLWH: people living with HIV.

observed asthenia, arthromyalgia, fever, chills, and headache regarding systemic effects. Young women with uncontrolled viral load (VL) are at higher risk of AEs. Failure to control the HIV infection would have a pro-inflammatory effect[32].

With the ChAdOx1 vaccine, local reactions, fatigue, and headaches are the most reported effects, usually after the first dose. AEs are mild or moderate. There was no difference between the two groups, and also, a lower rate of AE was reported by PLWH[11].

About NVX-Cov2373 (Novavax), the side effects and the reactogenicity were similar and mild in PLWH and HNP. The most frequent local adverse event was pain at the injection site. The most frequent systemic effects were headache, muscle pain, and fatigue. The mean duration was generally < 3 days[28].

Impact of COVID vaccine on CD4 count and VL

A significant and transient decline in CD4 count was observed from 700/mm^3 to 531/mm^3 and 634/mm^3, respectively, for a median duration of 4 months with no clinical consequences. Insignificant rebounds in VL were also observed in a few patients[17,20].

With inactivated vaccines, unexpectedly, the VL decreased after vaccination, and the total peripheral T-cell count, decreased significantly, but with the CD4+/CD8+, which remained stable[30].

Breakthrough infections after COVID-19 vaccination in PLWH

According to a recent US study by Coburn et al.,[33] the rate of breakthrough infection 9 months after a complete vaccination is low but 28% higher in PLWH (3.8%) than non-HIV people (NHP) (4.4%). The younger age (< 44 years) and non-receipt of a booster dose are linked to a higher rate of post-vaccination infection. The rate of post-vaccination infection was highest in Janssen prime vaccination recipients (5.7%) followed by Pfizer (4.4%) and Moderna (2.8%). PLWH had a higher rate of breakthrough infection regardless of CD4 count or VL suppression. The risk of breakthrough infection was higher during the delta surge than during earlier waves with previous variant. The population of the study is not representative of the general population because the great proportion of men (92%).

The inverse association between older age and breakthrough infection risk may be because of behavioral modifications by older patients (including adop-

Table 2. Available literature about COVID-19 vaccine for PLWH with low CD4 (< 250/mm^3)

Authors	Type of article journal	n PLWH	Control	CD4+/mm^3	Type of vaccine, number of doses	Results	Comments
Nault et al.[21]	Preprint	6	Health care worker and higher CD4	< 250	BNT162b2 1 dose	Lower anti-RBD IgG than in HCW and others CD4 strates	Only anti-RBD IgG Age effect
Touizer et al.[22]	Case report	1	No	20 Uncontrolled HIV replication	BNT162b2 2 doses	No neutralization No anti-S IgG No cellular immunity	
Antinori et al.[23]	EACS 2021 Abstract OS4/3	32	Health care worker and higher CD4	< 200	BNT162b2 mRNA-1273 2 doses	Compared to HCWs a detectable anti-RBD response was elicited in 87% and neutralization activity in 69% of PLWHs with CD4 ≤ 200. Strong correlation between CD4 count and magnitude of humoral and cell-mediated immune response to vaccine.	
Ruddy et al.[24]	Prospective observational cohort	2	No	< 200	mRNA vaccine 2 doses	Low titers in anti-RBD-IgG than others CD4 strates	

PLWH: people living with HIV, HCW: health care worker.

tion of masking and social distancing). The higher risk of breakthrough infection regardless of CD4 count suggests residual immune function abnormalities (despite CD4 count recovery) and means that the risk is for all PLWH and not only those an advanced HIV disease or unsuppressed VL[33].

Guidelines for COVID-19 vaccination in PLWH

PLWH is considered at risk of severe COVID-19[9] and should be prioritized for vaccination. According to the British HIV Organization[26], a third dose has to be administered to all people aged 18 or older, including all PLWH. This dose is recommended 3 months after the end of the prime vaccination[26].

It is recommended to offer a booster dose 3 months after the third dose under the following conditions: CD4 count below 200/mm^3, HIV-related symptoms or active tuberculosis (regardless of CD4 count), a detectable VL after being on HIV treatment for at least a year, no current antiretroviral therapy according to Center for Diseases Control (CDC), and British HIV Organization[26,27]. The indication of these booster doses is confirmed by the higher risk of breakthrough infection after vaccination in PLWH.

Table 3. Most frequent adverse effects (AE) after COVID-19 vaccination in PLWH

Vaccine	Local AE	Systemic AE	Comments
BNT162b2[20]	Injection site pain. Mean duration: 24h.	After 1st dose: fatigue and headache After 2nd dose: fatigue and fever < 38°C	Local AE: most common after 1st dose Systemic AE: most common after 2nd dose
mRNA-1273[32]	Pain, swelling, redness, and itch	Asthenia, arthromyalgia, headache, chills, and fever	Local AE: most frequent after 1st dose Systemic AE is mild or moderate: and more frequent after 2nd dose
ChAdOx1[11]	Pain at injection site	Headache and fatigue. Reported more frequently after the 1st dose	No serious AE Similar incidence of AE between PLWH and HIV-negative peoples
NVX-CoV2373[28]	Injection site pain	Headache, muscle pain, and fatigue	Mean duration < 3 days Moderate and transient AE Severe and serious AE infrequent but more frequent in the vaccine group No difference between PLWH and HIV-negative peoples
Inactivated vaccines[31]	Pain at injection site	Fatigue, headache, and muscle pain	Most of AE were very mild or mild Similar between PLWH and HIV-negative peoples

PLWH: people living with HIV, AE: adverse effect.

The third and booster doses have to be an mRNA vaccine even if the prime vaccination was made with ChAdOx1 or Ad26.COV2.S[26,27].

Discussion

Current data confirm that the BNT162b2 (Pfizer), mRNA-1273 (Moderna), ChAdOx1 (AstraZeneca), and Ad26.COV2.2 (Janssen) vaccines, administered according to a complete schedule, are effective in PLWH in preventing severe forms of SARS-CoV-2 infection. Regarding that HIV infection *per se* is an independent risk factor for severe infection and mortality, vaccination in these patients is, therefore, recommended. COVID-19 vaccines are safe in PLWH; AEs are mild or moderate, and their incidence is similar to NHP. There is no current evidence of interference with ART or viral rebound with clinical repercussions following COVID-19 vaccination. However, PLWH with CD4 counts below 200/mm^3 has a poorer vaccine response with lower IgG levels that persist for a shorter time; these patients are, therefore, prioritized for a fourth dose as a booster dose.

About immunology, cellular immunity, and neutralizing antibodies jointly contribute to protection against SARS-CoV-2 infections, although these two types of immunities are not always correlated and may even be discordant[34]. After an infection with SARS-CoV-2, the memory T-cell compartment alteration is observed, characterized by a decrease in the absolute number of CD4+ and CD8+ for 6 months[35-37].

In PLWH, the humoral and T-cell response mechanism is similar to NHP (as the vaccine response) and persists for 5-7 months. Due to the naive CD4 reservoir and the CD4+/CD8+ ratio, immune reconstitution plays a significant role in the immunological response (34) and vaccine response. Therefore, the total CD4 count is critical, independent of the ART administration, although it retains all its importance in controlling HIV infection. However, a small study by Xu et al.[15] highlights the link between an uncontrolled VL and a lower humoral response to the vaccine.

In PLWH, the T-cell memory compartment is more impaired than in NHP; a relative immunosenescence can alter the immune response to a new pathogen[36] or the vaccine response. Viral control under ART and good immune reconstitution allows a similar response as NHP.

Despite these data, some elements still need to be confirmed. Given the limited duration of follow-up (28-56 days on average), long-term efficacy should be

demonstrated by other studies or by long-term follow-up; the humoral response being more variable and less critical[14,16], there is shorter duration. The correlate of protection between the antibody level and the neutralization rate is currently recognized[35] but should be confirmed with more extensive studies of clinical efficacy in PLWH. The impact of vaccination on the sequelae of COVID-19 and long COVID seems to be encouraging[38] but some data are contradictory and should be confirmed for PLWH. Finally, the emergence of new variants of concern (delta and omicron) with an immune escape and a loss of clinical efficacy of vaccines should be evaluated in PLWH[39]. The risk of breakthrough infection is higher with omicron and particularly with the BA.4 and BA.5 omicron variants[40]. We need additional data for PLWH. All PLWHs have a higher risk of breakthrough infection, regardless of CD4 count or VL suppression. The younger age (< 44 years) and non-receipt of a booster dose are linked to a higher rate of post-vaccination infection. The risk is lower with a prime vaccination with Moderna than Pfizer[33]. Heterologous vaccination schedules show a better B and T immune response in the general population[19], which deserves confirmation in PLWH.

Given these data and in this context of the evolution of the pandemic, the effectiveness of particular vaccination regimens or new generation vaccines will undoubtedly have to be confirmed by recent studies, including a sufficient number of PLWH.

Conclusions

HIV *per se* is a risk factor independent of other risk factors for severe COVID-19 disease. The majority of these studies with mRNA (BNT126b2 and mRNA-1273) and adenovirus vector (Ad26.COV2.2 and ChAdOx1) vaccines with a low number of patients included shows that PLWH on ART and with CD4 count > 200/mm^3 has a robust immune response. Thus, these vaccines effectively prevent severe infection caused by SARS-CoV-2 in PLWH as in the general population. However, PLWH with a CD4 count < 200/mm^3 and uncontrolled VL seems to have a lower immune response. COVID-19 vaccines are safe in PLWH; AEs are mild or moderate, and their incidence is similar to NHP.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that no patient data appear in this article.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

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