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Immunogenicity and effectiveness of the Sinopharm BIBP COVID-19 inactivated vaccine in people living with HIV: A case-control study in Omicron era

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ABSTRACT

There is limited information about COVID-19 vaccines in people living with HIV (PLWH). We aimed to compare the immunogenicity and effectiveness of the Sinopharm BIBP COVID-19 inactivated vaccine between PLWH and non-HIV individuals in the Omicron era. We evaluated the production of receptor-binding domain (RBD), spike, SARS-CoV-2 IgG, and neutralizing antibodies in both PLWH (case) and individuals without HIV (control) groups three months after they received the second dose of the vaccine. All participants were also followed during three months after the second dose for the COVID-19 infection and its outcomes (hospital admission, need to intensive care unit, and mortality). A total of 250 individuals comprising 150 PLWH and 100 people without HIV were recruited. The mean age was 42.2 years. The infection rate was significantly higher in non-HIV individuals than in PLWH (63% vs. 21.3%, $p < 0.001$). The hospitalization rate in the PLWH group was significantly hig1her than that in the non-HIV group (5.3% vs. 1%, $p = 0.009$). There were no significant differences in the mean levels of Spike antibody (84.4 ± 34.4 vs. 95 ± 109.5 RU/mL), RBD antibody (65.6 ± 42 vs. 69 ± 42.3 RU/mL), and SARS-CoV-2 IgG (2.9 ± 2.5 vs. 3 ± 2.3 Index) between the groups. The mean value of neutralizing antibodies was significantly higher in non-HIV individuals (34 ± 23.3 vs. 26.2 ± 20 µg/mL, $p = 0.005$). The Sinopharm BIBP COVID-19 inactivated vaccine can be as immunogenic in PLWH as in non-HIV individuals. This vaccine is likely more effective in preventing Omicron-associated hospitalization in non-HIV individuals.

Keywords: HIV; AIDS; COVID-19; Immunization; Sinopharm BIBP COVID-19; inactivated vaccine

1. Introduction

The coronavirus disease 2019, caused by SARS-CoV-2, was first identified in China. It spread rapidly throughout the world, causing more than 6.6 million deaths worldwide by 15 December 2022 [1]. A significant reduction in the disease burden was observed following the administration of COVID-19 vaccines, particularly among those at high risk of developing severe COVID-19, Such as people living with HIV (PLWH) [2,3].

The HIV-1 infection profoundly suppresses the immune system. Specifically, the progressive loss of CD4+ T helper cells (Th) renders individuals susceptible to various infections [4]. These infections can be prevented by vaccines. However, lapses in vaccination are reported among these individuals, likely due to concerns about vaccine safety and efficacy [5].

Developing a COVID-19 vaccine requires an understanding of the virus's biological and epidemiological properties [6,7]. However, vaccine efficacy depends on the immune system' ability to recognize SARS-CoV-2 cell binding and produce sufficient neutralizing antibody (NA) titers [8]. The association between antibody titers and the immune response to COVID-19 has been demonstrated in a clinical efficacy study [9].

Many vaccines with diverse platforms, from nucleic acid-based technologies to traditional inactivated virus, have been designed and developed for COVID-19 immunization. However, only a few of them have been approved for the general population as safe and effective COVID-19 vaccines [10,11]. In clinical trials, the efficacy of COVID-19 vaccines has been reported to range from 50% for inactive vaccines to over 90% for mRNA vaccines [12,13].

Studies show that inactivated viral vaccines can effectively stimulate the immune system without causing clinical diseases [14]. The Sinopharm BIBP COVID-19 vaccine is a fully inactivated form of SARS-CoV-2. It was developed by the Chinese state-owned pharmaceutical company Sinopharm and was first released and accepted for the general population vaccination in the United Arab Emirates (UAE) [15]. When the vaccine is introduced into the body via the intramuscular injection, antigens from the inactivated virus stimulate and develop the immune system responses, preparing the vaccinated person to defend against attacks by the original virus [16]. According to the phase 3 clinical trial data, the UAE announced that the Sinopharm BIBP COVID-19 vaccine demonstrated an efficacy of 86% [16]. The World Health Organization (WHO) has reported that the side effects of Sinopharm COVID-19 vaccine, as assessed in three clinical trials, were mild to moderate [17].

The emergence of SARS-CoV-2 strains with complex spike protein mutations has affected various epidemiological and clinical aspects of COVID-19 [18]. Some variants spread widely and showed evidence of greater transmissibility, severe clinical forms, and reduced neutralization by antibodies produced during previous COVID-19 infections or vaccinations. These variants were recognized as variants of concern (VOC) by the WHO [19]. The emergence of new variants raised concerns about the generation and durability of immune system responses induced by vaccines designed against previous variants [20], with reduced vaccine efficacy reported against the Beta and Delta variants [21,22].The Omicron (B.1.1.529) variant, announced on November 26, 2021, caused serious restrictions and ultimately accelerated booster vaccination programs [23]. However, vaccine effectiveness against this variant was reported to be significantly lower than that against previous variants, limiting the antibody-mediated neutralization [6,24-26]. The production of neutralizing antibodies is a crucial component of humoral immunity, which plays a strong role in limiting COVID-19 infection and preventing reinfection [27]. Evidence shows that neutralizing antibodies against Omicron increased following a booster dose of COVID-19 vaccination, although this increase was lower than what observed with the ancestral type or the Delta variant [6,24-26,28,29].

Protective and persistent immune responses to viral infections or vaccines usually arise from the coordinated action of B lymphocytes (mediating humoral immunity) and T lymphocytes (mediating cellular immunity) [30]. While humoral immunity is a fundamental criterion for evaluating the immune response to vaccines, a low antiviral antibody titer and/or reduced neutralizing activity do not necessarily rule out the vaccine effectiveness in immunocompromised individuals.

COVID-19 vaccination in immunocompromised patients showed lower immunogenicity based on a systematic review [31]. While some studies indicate reduced immunogenicity in PLWH, the efficacy results remain a topic of debate [32]. The COVID-19 vaccination in immunocompromised patients can initially be assessed by determining the titer of different antibodies against SARS-CoV-2 and performing the neutralizing test. While PLWH have been included in some studies of COVID-19 vaccines, limited information has been published about this population [33,34]. In this study, we aimed to compare the immunogenicity and effectiveness of the Sinopharm BIBP COVID-19 inactivated vaccine between PLWH and non-HIV individuals.

2. Materials and Methods

2.1 STUDY DESIGN AND PARTICIPANTS

A case-control study was conducted on PLWH whose infections were confirmed by the fourth-generation ELISA, based on the WHO guidelines, and individuals without HIV to evaluate the Sinopharm BIBP COVID-19 inactivated vaccine immunogenicity and antibody production between the two groups. The study was performed from February 10, 2022, to May 10, 2022, when Omicron was the dominant variant circulating in Iran, at the Iranian Research Center for HIV/AIDS (IRCHA) at Imam Khomeini Hospital Complex (IKHC), Tehran, Iran. The IRCHA care for and monitor more than 3000 PLWH in Tehran.

In this study, a number of non-pregnant adults living with and without HIV were enrolled. The participants who met the inclusion criteria i.e., age ≥ 18 years and receiving only two doses of Sinopharm BIBP COVID-19 inactivated vaccine (with a three-month interval between the

immunizations) were included in the study. After receiving the second dose of COVID-19 vaccine in our center and signing the consent form, participants were categorized into two groups of PLWH and people without HIV.

2.2 DATA COLLECTION

A questionnaire was designed to collect study population data. All participants were interviewed, and the questionnaires were filled out by trained healthcare providers. The collected data were demographic characteristics (age, gender, and marital status) and clinical features (comorbidities and HIV viral load, $CD4^+$ T cell count, and anti-retroviral treatments (ART) in PLWH). During the three months following the second dose of vaccine, people were contacted monthly by phone and were followed up for the COVID-19 infection and its outcomes (hospital admission, need to intensive care unit, and mortality). Individuals who exhibited COVID-19-related symptoms during the three-month follow-up, and subsequently tested positive for SARS-CoV-2 infection via reverse transcription polymerase chain reaction (RT-PCR) were considered positive for COVID-19 infection.

2.3 ANTIBODY DETERMINATION

Three months after the second dose and before receiving the booster dose, the participants' serum samples were collected for the humoral response assessment. Geometric mean titers (GMT) and geometric mean ratios (GMR) of antibodies against SARS-CoV-2, i.e., SARS-CoV-2 IgG, anti-receptor binding domain (RBD) of the spike protein antibody, anti-spike glycoprotein antibody, and anti-SARS-CoV-2 neutralizing antibody were measured using Anti-SARS-CoV-2 IgG, anti-RBD IgG, anti-spike IgG, and neutralizing antibodies (sVNT) (Pishtazteb ELISA kit, Tehran, Iran), respectively. The characteristics of the ELISA kits used in this study were as follows (according to the data sheets of the kits):

The SARS-CoV-2 (IgG) Pishtazteb ELISA kit was used for the semi-quantitative detection of IgG Abs against the nucleocapsid (N) antigen of the COVID-19 virus. As one of the most abundant antigens in the COVID-19 virus, antigen N is the best antigen used in immunological diagnostic assays. The Cut-Off index of this kit was 0.9–1.1. Values greater than 1.1 were considered positive, and values less than 0.9 were considered negative. Samples with index values between 0.9 and 1.1 were tested again using fresh serum or plasma. The sensitivity and specificity of this kit were 94.1% and 98.3%, respectively.

The SARS-CoV-2 Anti-RBD IgG Pishtazteb ELISA kit was used for the quantitative detection of IgG Abs against the RBD antigen of the COVID-19 virus. The RBD domain of the spike antigen is the most immunogenic antigen for inducing the protective antibodies with neutralizing ability, which prevent the COVID-19 virus from binding the angiotensin-converting enzyme 2 (ACE-2) receptor and, therefore, inhibit the virus replication. The Cut-Off value of this kit was 5 RU/ml. Values greater than or equal to 5 RU/ml were considered positive, and values less than 5 RU/ml were considered negative. The sensitivity and specificity of this kit were 97.1% and 100%, respectively.

The SARS-CoV-2 Anti-spike IgG Pishtazteb ELISA kit was used for the quantitative detection of IgG Abs against the spike antigen of the COVID-19 virus. The spike antigen contains the RBD domain and, therefore, is the most immunogenic antigen for inducing the protective antibodies with neutralizing ability, which prevent the COVID-19 virus from binding the ACE-2 receptor and, therefore, inhibit the virus replication. The Cut-Off value of this kit was 8 RU/ml. Values greater than or equal to 8 RU/ml were considered positive, and values less than 8 RU/ml were reported as negative. The sensitivity and specificity of this kit were 98.2% and 99.0%, respectively.

Not all COVID-19 infection-induced antibodies have the ability to inhibit and neutralize the virus. The SARS-CoV-2 Neutralizing Ab Pishtazteb ELISA kit was used for the quantitative detection of neutralizing Abs. The Cut-Off value of this kit was 2.5 µg/ml. Values greater than or equal to 2.5 µg/ml were considered positive, and values less than 2.5 µg/ml were considered negative.

All the kits used in this study were for research use only, and their accuracy had been confirmed by validated kits or WHO reference materials.

The virological and cellular immunity parameters were also evaluated in PLWH. Specifically, the viral load was measured using the RT-PCR method with the Qiagen HIV kit (USA), and the CD4 cell count was determined using the FACSPresto CD4 counter (BD, USA). An undetectable threshold for the HIV viral load in the Qiagen HIV kit was considered as less than 76 IU/ml or 38 copy/ml.

2.4 SAMPLE SIZE CALCULATION

The sample size was calculated by G*Power 3.1 software as below:

T-tests - Means: Difference between two independent means (two groups)

Analysis:	A priori: Compute required sample size		
Input:	Tail(s)	=	Two
Effect size d	=	0.364	
	α err prob	=	0.05
	Power (1-β err prob)	=	0.80
	Allocation ratio N2/N1	=	1.5
Output:	Noncentrality parameter δ	=	2.8195319
Critical t	=		1.9695757
	Df	=	248
	Sample size control group	=	100
	Sample size case group	=	150
	Total sample size	=	250
	Actual power	=	0.8019582

2.5 STATISTICAL ANALYSIS

Data analyses were performed using SPSS version 26. Quantitative variables with normal distribution were reported using mean and standard deviation, and the quantitative variables with non-normal distribution were reported using median and interquartile range (IQR). The categorical variables were reported using frequency (percentage). A bivariate analysis was used to compare the demographic features and outcomes between the two groups. Since the two groups were different in some variables, a multivariate analysis was used for adjusting significant variables in the bivariate analysis between the

two groups. A p-value of < 0.05 was considered statistically significant for the multivariate logistic analysis. We further adjusted all the variables utilized in our analysis because we had numerous independent variables, and we also needed to control other significant variables in our multivariate regression analysis. In the final analysis, associated factors, after adjustment in the HIV and non-HIV groups, were considered with their respective adjusted odds ratios (AORs) and 95%CI (confidence interval). In addition, the Pearson correlation coefficient was used for evaluating the correlation of CD4+ T cell count with different antibody titers.

3. Results

3.1. STUDY POPULATION

Three hundred and twenty-five adults living with and without HIV, who referred to our center for receiving the second dose of the COVID-19 vaccine, were enrolled. Based on the inclusion criteria, a total of two-hundred and fifty individuals, comprising 150 PLWH (case group) and 100 people without HIV (control group), were recruited in the study. The study population consisted of 142 men (56.8%) and 108 women (43.2%). The percentage of males was significantly higher in the case group than in the control group (66% vs. 43%, $p < 0.001$). The mean age of the study population was 42.2 ± 11.9 years; PLWH were significantly older than people without HIV (44.7 ± 10.2 vs. 38.5 ± 13.3, $p = < 0.001$). Regarding medical history, PLWH were diagnosed more commonly with hypertension ($p = 0.002$) and chronic kidney dysfunction ($p = 0.03$). Details of each groups' demographic and clinical data are summarized in Table 1.

Table 1. Demographic features of HIV & non-HIV participants

Characteristics		Total (N= 250)	HIV Status		P-value
			Positive n=150	Negative n=100	
Age (year)		42.2±11.9	44.7±10.2	38.5±13.3	<0.001
Gender	Male	142(56.8%)	99(66%)	43(43%)	<0.001
	Female	108(43.2%)	51(34%)	57(57%)	
Marital status	Single	116(47%)	66(44%)	50(51.5%)	0.25
	Married	131(57%)	84(56%)	47(48.5%)	
Comorbidity	Hypertension	18(7.2%)	17(11.3%)	1(1%)	0.002
	Diabetes mellitus	9(3.6%)	6(4%)	3(3%)	0.75
	Liver disease	5(2%)	5(3.3%)	0(0%)	0.16
	Kidney dysfunction	12(4.8%)	11(7.3%)	1(1%)	0.03

3.2. FOLLOW-UP OUTCOMES

During the three-month follow-up, a total of 95 participants (38%) had a positive SARS-CoV-2 PCR from nasopharyngeal swabs. The number of infected patients was higher in the non-HIV group than in the PLWH group (63 (63%) vs. 32 (21.3%), $p < 0.001$). The rate of hospital admissions in the PLWH group infected with COVID was significantly higher than in the non-HIV group (5.3% vs. 1%, $p = 0.009$) (Figure 1). Furthermore, no case of ICU admission or mortality was observed during the follow-up period.

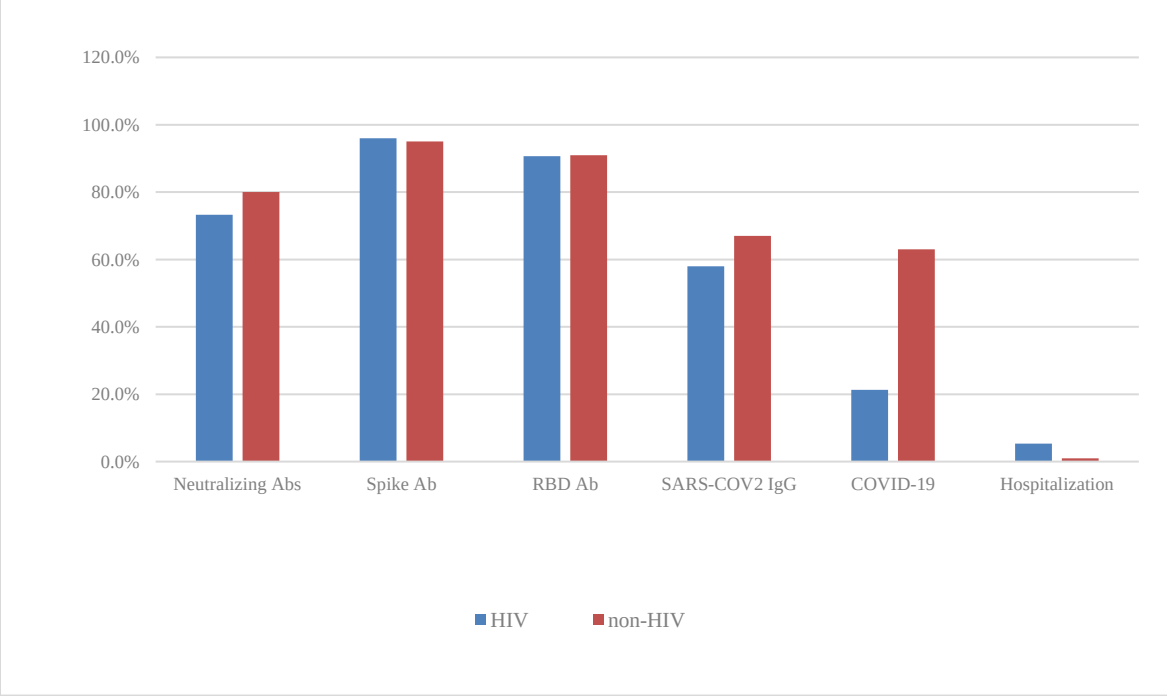

Figure 1. Comparison of the percentage of individuals that developed antibody responses to SARS-CoV-2 and the effectiveness (infection and hospitalization rates) following immunization of PLWH and non-HIV individuals with the Sinopharm BIBP COVID-19

3.3. IMMUNOGENICITY

The results of antibody titer measurement showed no difference between the case and control group in the mean levels of Spike Ab (84.4 ± 34.4 vs. 95 ±109.5 RU/mL, p = 0.29), RBD Ab (65.6 ± 42 vs. 69 ± 42.3 RU/mL, p = 0.53), and SARS-COV2 IgG (2.9 ± 2.5 vs. 3 ± 2.3 Index, p = 0.74). A total of 190 participant (76%) could maintain NAs (after 3 months) with a positive threshold titer of 2.5 µg/mL, and there were no significant differences between the two groups. However, the mean level of NAs was significantly higher in non-HIV cases than in HIV patients (34 ± 23.3 vs. 26.2 ± 20 µg/mL, p = 0.005). Details of the immunological tests of the two groups are summarized in Table 2. The comparison of immunogenicity and the effectiveness of the vaccine in PLWH and non-HIV groups are shown in Figure 1.

Table 2. The outcomes of COVID-19 vaccination in HIV & non-HIV people

Variables		HIV Status		P-value
		positive	negative	
Antibodies Positive rate (%)	Neutralizing Abs	110(73.3%)	80(80%)	0.227
	Spike Ab	144(96%)	95(95%)	0.759
	RBD Ab	136(90.7%)	91(91%)	0.929
	SARS-COV2 IgG	87(58%)	67(67%)	0.152
Antibodies titer/mean	Neutralizing Abs	26.2±20	34±23.3	0.005
	Spike Ab	84.8±34.4	95.0±109.5	0.29
	RBD Ab	65.6±42	69.0±42.3	0.53
	SARS-COV2 IgG	2.9±2.5	3.0±2.3	0.74
COVID-19	Infection	32(21.3%)	63(63%)	<0.001
	Hospital admission	8(5.3%)	1(1%)	0.009
	ICU admission	0	0	----
	Death	0	0	----

3.4 MULTIVARIATE AND REGRESSION ANALYSES

In the multivariate analysis, after adjusting for the significant variables in the bivariate analysis (p < 0.05), age and hypertension were significantly higher in the PLWH group than in the non-HIV group. Moreover, neutralizing antibodies and the female/male ratio were significantly lower in the PLWH group than in the non-HIV group (Table 3).

The examination of the CD4 cell count and HIV RNA viral load in PLWH, who were stable on ART regimens and had suppressed HIV RNA viral load, showed that 88% of PLWH had a complete HIV virologic suppression, and the rest had a serum viral load of less than 1000 IU/ml (Table 3). The mean number of CD4 count was 676, ranging from 81 to 1568. Analysis also showed no correlation between the CD4 count and the titers of spike Ab, SARS-CoV-2 IgG, and neutralizing Abs. A poor correlation was observed between the CD4 cell count and the RBD Ab titer of the hospitalized patients (p = 0.025, r = 0.183) (Table 4).

Table 3. Final associated variables after adjustment in HIV & non-HIV groups

Variable	AOR	95%CI	P-value
Age (year)	1.04	1.01-1.07	0.002
Hypertension Yes	10.34	1.30-81.98	0.027
No	Referent	Referent	Referent
Neutralizing Abs	0.99	0.97-1.00	0.022
Gender Female	0.42	0.24-0.73	0.002
Male	Referent	Referent	Referent

Table 4. HIV-related variables (N=150)

Variables					n (%)
ART* regimens		Emtricitabine/tenofovir disoproxil fumarate/Dolutegravir			72(48)
		Emtricitabine/tenofovir disoproxil fumarate / Efavirenz			78(52)
Viral load		Detectable			18(12)
		Undetectable			132(88)
CD4 count (cells/mm3)		<200			9(6)
		200-500			34(22.6)
		>500			107(81.4)
CD4		Spike	RBD	Neutralizing	IgG
	r**	0.093	0.183	0.126	0.062
	p-value	0.256	0.025	0.125	0.449

*ART, anti-retroviral treatment; **r, Pearson correlation coefficient

4. Discussion

In this study, we investigated the effectiveness and immunogenicity of the Sinopharm BIBP COVID-19 inactivated vaccine in PLWH and compared it with people without HIV during the Omicron pandemic. In the three-month follow-up, the rate of SARS-COV-2 infection was higher in individuals without HIV. Some studies have also reported a lower incidence of COVID-19 infection among PLWH compared with the general population [35,36]. Evidence shows that PLWH are less susceptible to SARS-CoV-2 infection than people without HIV [37,38]. Adherence to COVID-19 prevention protocols and using anti-retroviral therapy by PLWH could be associated with the reduced rate of SARS-COV2 infection in these patients in our center [39]. Studies on PLWH with high COVID-19 test rate suggest that the HIV infection does not significantly alter the clinical picture and mortality rate of COVID-19 [35,40,41]. Additionally, it seems that HIV status does not increase the severity of COVID-19, although a lower CD4 count may be associated with an increased mortality rate [42,43].

Our study on vaccinated PLWH infected with Omicron showed that the hospitalization rate was as low as 5.3%, and no patient required ICU admission. In a study on unvaccinated PLWH infected with previous COVID-19 variants in the United States in 2020, the rate of hospitalization was more than 50%, with 16.5% of patients requiring ICU [43].

Studies have shown that inactivated COVID-19 vaccines can produce acceptable immunogenicity against different variants in fully immunocompetent individuals [44-46]. In PLWH, immune responses to most vaccines can be impaired [47], and vaccine-induced antibodies may decline faster. However, the immune response to COVID-19 immunization in PLWH remains understudied due to the limited inclusion of PLWH in clinical trials [48]. The evaluation of the humoral immune response three months after the second dose of the Sinopharm BIBP COVID-19 inactivated vaccine revealed that the immune response was comparable between PLWH and individuals without HIV.

Antibody response is only one way to evaluate the immune system response to vaccines [49]. The CD4 cell count can also predict the level of immunodeficiency in PLWH. The insufficient CD4+ T cells can interfere with the functioning of CD8+ T cells and B cells. Consequently, the cellular immunity and antibody production may be compromised [50]. The minimum CD4+ cell count required for an appropriate immune response in PLWH varies between 150 and 500 cells/mm^3. The level of functional antibody response is significantly lower in patients with CD4 count below 150 cells/mm^3 [51]. In the present study, more than 80% of PLWH had CD4+ cell count above 500 cells/mm^3. Our results showed that receiving two doses of the Sinopharm BIBP COVID-19 inactivated vaccine in PLWH could be as immunogenic as in individuals without HIV because it produced comparable levels of Spike Ab, RBD Ab, and SARS-CoV-2 IgG in both groups. In a study on the immunogenicity of the BNT162b2 mRNA COVID-19 vaccine, the SARS-COV2 IgG, NAs, and RBD-IgG antibody levels were lower in PLWH than in the control group, two to three weeks after the second dose [52].

In HIV infection, the immune response to influenza vaccination is weakened due to factors such as reduced CD4+ T cell activity and impaired B cell function [53]. Although in this study, the CD4 cell count of the HIV group was moderately high, no correlation between the level of antibodies and the CD4 cell levels was observed.

The ART regimen inhibits the replication of the HIV virus and eventually results in the restoration of memory T cell subpopulations and CD4+ lymphocytes in the blood [54]. In some studies, patients on ART who have received vaccines have demonstrated robust protective immunity [55]. Similarly, serum HIV viral load at the time of vaccination can serve as an important predictor of the development and persistence of immunogenicity induced by various vaccines [56-58]. In a study on nearly 200 HIV-infected people undergoing hepatitis B vaccination, it was shown that an HIV viral load of less than 400 copy/mL was associated with a complete immune system response [59]. Our results found that 88% of PLWH had an undetectable HIV viral load, and the rest had a serum viral load of less than 1000 IU/ml. These findings may explain the acceptable levels of immunological indicators observed in the PLWH group in our study.

Neutralizing antibodies play a crucial role in acquired immunity against SARS-CoV-2 infection by primarily blocking the virus from binding to cellular receptors [60,61]. The NAs seroconversion rate in COVID-19 patients reaches 100% by day 14 of the disease, making these antibodies detectable [62,63]. The primary method for measuring the level of NAs is the virus neutralization test, which requires an expensive biosafety level 3 laboratory for work with live microorganisms. An acceptable alternative method to this test is the SARS-CoV-2 surrogate virus neutralization test (sVNT) [64-66], which was used in the present study. Virus neutralization remains the primary approach for assessing the effectiveness of antibodies [67]. Therefore, to evaluate the immunogenicity of COVID-19 vaccines, an accurate measurement of the level of SARS-CoV-2 neutralizing antibodies is essential [68,69]. Although most of our participants, including 73.3% of PLWH, had NAs titers in the positive range three months after receiving the second dose of the Sinopharm BIBP COVID-19 inactivated vaccine, the mean value of NAs was significantly higher in the non-HIV group. This difference led to a lower COVID-19 hospitalization rate in the non-HIV group. The NAs values remained significantly different between the two groups after adjustment. Assessing neutralizing antibody levels for COVID-19 vaccines in different high-risk populations can guide health policymakers in allocating resources effectively and determining the preferred vaccine [68,69].
The main limitations of this study include the absence of a suitable control group (a matched case-control study was not feasible due to the different age distribution and imbalanced sex ratio in the PLWH group compared with individuals without HIV), the limited follow-up times, and the lack of information regarding participants' previous history of SARS-COV2 infection. Additionally, the study did not evaluate cellular immunity induced by

the Sinopharm BIBP COVID-19 inactivated vaccine in recipients.

5. Conclusion

In the Omicron era, the rate of COVID-19 hospitalization and severe cases were infrequent in both the vaccinated groups of PLWH and non-HIV individuals, and there were no reported deaths. The Sinopharm BIBP COVID-19 inactivated vaccine in PLWH can be as immunogenic as in non-HIV individuals. In terms of effectiveness, although PLWH experienced a lower rate of SARS-COV2 infection, they had a higher hospitalization rate. Therefore, this vaccine likely provides better admission prevention in non-HIV individuals.

Authors' contributions

Conceptualization: MS, methodology: SADM, software: SASA, validation: AZD and CM, formal analysis: SADM, investigation: BA and FR, resources: MS, data curation: ATT, writing original draft: MS and AZD, review and editing: MS, HK, and AZD, visualization: MFA: supervision: MS, project administration: SADM and AZD, funding acquisition: MS

All authors have read and agreed to the published version of the manuscript.

Availability of data and materials

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Declarations

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by the ethical committee of Tehran University of Medical Sciences (TUMS) under the ethical number of IR.TUMS.MEDICINE.REC.1400.1364. Informed written consent was obtained from all participants.

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DISCLOSURE STATEMENT

The authors declare to have no conflict of interest.

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