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Estimating risk of acquiring SARS-COV2 infection in treatment-experienced PLWH: A case-control study

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ABSTRACT

Background: Risk factors for acquiring SARS-CoV-2 infection in people living with HIV (PLWH) and the true relationship between HIV and SARS CoV-2, are still not fully understood.
Objectives: The aim of this study was to identify the independent risk factors for SARS-CoV-2 acquisition in treatment experienced PLWH, shedding light on potential risk factors associated with SARS CoV-2 infection in PLWH undergoing treatment.
Study design: PLWH were recruited from the Infectious Diseases Outpatient Clinic of Fondazione Policlinico Universitario A.Gemelli IRCCS in Italy and randomly interviewed via a questionnaire during their follow-up visits to determine if they had experienced a SARS-CoV-2 infection between March 2020 and June 2022.
For each participant with reported history of SARS-CoV-2 (cases), two PLWH with no declared COVID-19 infection were selected (controls); PLWH had a similar potential exposure time to SARS-CoV-2. A total 220 PLWH were selected: 72 cases and 148 controls. None developed severe Covid-19 disease and only one participant required hospitalization.
Results: Overall, 220 PLWH were enrolled: 72 cases and 148 controls. Characteristics of cases and controls were similar, except for the ART regimen used and the last HIV-RNA concentration before the enrollment date. By an adjusted multivariable logistic regression, the estimated odds of SARS-CoV-2 infection was higher in more recent years (2022 versus 2020 aOR 20.74, 95 % CI 5.26–81.8) and in PLWH with last HIV-RNA >50 cp/mL before enrollment date (versus <50 aOR 4.56, 95 % CI 1.01–20.46). A reduced odds was correlated with >3 vaccine doses (versus <3 or not vaccinated aOR 0.08, 95 % CI 0.02–0.24).
Conclusion: In this cohort, the odds of SARS-CoV-2 acquisition increased over time, probably due to change in lock-down measures and in SARS-CoV-2 circulating variants.Detectable viral load was associated with increased risk of infection, highlighting the importance of HIV-RNA monitoring during pandemics.

Background

The global spread of COVID-19 led to a pandemic, prompting extensive investigations into its impacts on various population groups, particularly those identified as being at higher risk of severe disease, such as people with HIV (PLWH) [1–4]. HIV infection leads to immune activation resulting in a proinflammatory state [4], which may persist even with antiretroviral therapy (ART). This chronic immune dysregulation exposes PLWH to a higher risk of developing various chronic comorbid conditions, including postviral syndromes [5]. In addition, PLWH tend to present multiple chronic comorbidities more frequently than their HIV-negative counterparts, which could represent a

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predisposing factor for both SARS-CoV-2 acquisition and worse COVID-19 outcomes. Long-term exposure to HIV infection, low-grade inflammation and immune dysregulation, further increase the risk of severe COVID-19 manifestations, despite ART and immune reconstitution [6]. A systematic review and meta-analysis showed an increased risk of COVID-19-related mortality among PLWH, highlighting the importance of prioritizing this population in prevention programs [7]. A detectable HIV viral-load (HIV-RNA > 50 copies/mL) and certain sociodemographic factors, such as older age, have been associated with more severe COVID-19 outcomes [8] highlighting the need for tailored vaccination programs. In addition, viral pneumonia, such as SARS CoV-2-related pneumonia in immunocompromised patients, can lead to persistent infection and an increased mortality rate [9]. These clinical concerns were further amplified by strict initial lockdown measures, which generated challenges in accessing healthcare facilities and medication refills.

Objectives

The purpose of this study was to identify potential risk factors associated with SARS CoV-2 infection within the population of PLWH on effective antiretroviral therapy (treatment experienced PLWH), while also elucidating the true impact of SARS-CoV-2 infection in this population and the role of viral load monitoring during pandemic.

Study design

We conducted a case-control study involving a cohort of treatment experienced PLWH who attended the Infectious Diseases Outpatient Clinic at Fondazione Policlinico Universitario Agostino Gemelli IRCCS in Rome, Italy, from January 2022 to July 2022. Adults PLWH (> 18 years old) were consecutively and randomly enrolled during their routine follow-up visits and invited to complete a questionnaire investigating a known history of SARS CoV-2 infection (dependent variable), occurring between March 2020 to June 2022, along with associated symptoms, vaccination status (number of doses), and antiviral and symptomatic therapies administered for COVID-19. Each participant with a reported history of SARS-CoV-2 infection was considered a case and was matched with at least two participants without a reported SARS-CoV-2 infection (controls), based on a similar potential exposure period to SARS-CoV-2. Demographics variables (age, gender at birth, nationality), clinical history, immune-virological characteristics (TCD4 cell/count, TCD4/TCD8 ratio, and Viral Load [VL]) and antiretroviral therapy regimen before the enrollment date, were collected for all participants from electronic medical records. Participants' characteristics were described using percentages for categorical variables and means (±SD) for continuous variables. Univariate analyses were performed using the Chi-square test for categorical variables and the Student's *t*-test or Mann-Whitney *U* test for continuous variables, as appropriate.

The demographic and viro-immunological characteristics potentially associated with SARS-CoV-2 infection (namely age, gender at birth, ethnicity, antiretroviral therapy regimen, zenith HIV RNA, detectable serum HIV RNA, current and nadir CD4 count, number of vaccination doses administered, and the year of the initial positive SARS-CoV-2 test) were evaluated through univariable regression analysis [2,3] Variables associated with SARS-CoV-2 infection at a *p*-value <0.100 were retained in a multivariable logistic regression model to assess the adjusted odds ratios (aOR) of developing SARS-CoV-2 infection.

The multivariable model fit was evaluated through Hosmer-Lemeshow goodness-of-fit test.

All statistical analyses were performed in SPSS version 22.0 (IBM, Chicago, IL, USA).

The study protocol was reviewed and approved by our local Ethics Committee. Written informed consent was obtained from all participants (Approval number 7768/16).

Results

Among the 356 PLWH who filled out the questionnaire, based on the inclusion criteria. Of the total 356 PLWH, 302 had complete data, while 54 were excluded due to missing essential information (e.g number of vaccination doses). Additionally, 15 participants moved to other clinical centers for personal reasons and were lost to follow-up. Ultimately, 220 participants were selected based on an exact case-control matching process: 72 cases and 148 controls. The study population selection process is detailed in Fig. 1.

The characteristics of both cases and controls are presented in Table 1.

Among the total number of participants, 41 out of 220 (18.6 %) reported hypertension (13/72 cases, 18.1 %; 28/148 controls, 18.9 %), 12/220 (5.5 %) reported dyslipidemia (3/72 cases, 4.2 %; 9/148 controls, 6.1 %) and 69/220 (31.4 %) participants declare a smoking habit (19/72 cases, 26.4 %; 50/128 controls, 39.1 %). Additionally, 31/220 (14.1 %) where in psychiatric follow up (12/72 cases, 16.7 %, 19/148 controls 12.8 %). The characteristics of cases and controls were largely similar, except for differences in the antiretroviral regimen and the last recorded HIV-RNA concentration before the enrollment date. Among 72 cases, 51 (70.8 %) reported symptoms: 36 (50.0 %) reported fever, 13 (18.1 %) reported cough, 14 (19.4 %) reported sore throat, 9 (12.5 %) reported coryza, 8 (11.1 %) reported headaches, 10 (13.9 %) reported arthralgia, 3 (4.2 %) participants reported anosmia and 2 (2.8 %) reported diarrhea. Notably, no participant developed severe COVID-19 and only one case (1.39 %) required hospitalization for the administration of early antiviral therapy.

In the multivariable analysis, after adjusting for age, sex, antiretroviral therapy and zenith HIV-RNA, the likelihood of a previous SARS-CoV-2 infection was higher in more recent years (2022 versus 2020 aOR 20.7, 95 % confidence interval (CI) 5.3–81.8) and in PLWH with a last recorded HIV- RNA >50 cp/mL (versus HIV-RNA < 50, aOR 4.6, 95 % CI 1.0–20.5). A reduced risk of infection was observed among participants who received the full 3 doses of the COVID-19 vaccination in comparison to those with fewer than three doses or those who remained unvaccinated (aOR 0.1, 95 % CI 0.0–0.2). Gender, age, type of antiretroviral regimen and zenith HIV-RNA were associated with the outcome in the univariable analysis but lost their significance in the multivariable analysis. Table 2 summarizes the results of the multivariable analysis.

The Hosmer-Lemeshow test indicated good calibration of the multivariable model (goodness-of-fit test-$p = 0.382$).

Discussion

The immunodeficiency resulting from HIV infection primarily affects CD4+ T cells, which are critical components of the immune system responsible for coordinating a multifaceted defense against a wide range of pathogens. It is plausible to hypothesize that an impairment of the immune system may render PLWH more susceptible to severe manifestations of COVID-19 [10]. Concerns arose mostly at the onset of the pandemic due to evidence showing a higher frequency of superinfections and pneumonia in immunocompromised patients [9]. In addition, low-grade inflammation and immune dysregulation could expose this "vulnerable" population to a higher risk of developing severe manifestations of COVID-19, despite having an undetectable viral load and immune reconstitution [6]. However, in contrast to these theoretical concerns, this study did not reveal a correlation between CD4+ T cell depletion and the development of severe COVID-19. While theoretical considerations suggest an increased risk of severe outcomes in PLWH co-infected with SARS-CoV-2 [9], empirical evidence are, at times, conflicting [11,12] 0. Several cofactors, including ART adherence, "uncontrolled" viral-load, and sociodemographic factors [6–8], may further complicate the relationship between these two viral infections. A recent study analyzing 5700 COVID-19 patients with underlying medical conditions in the New York City area found that the hospitalization rate

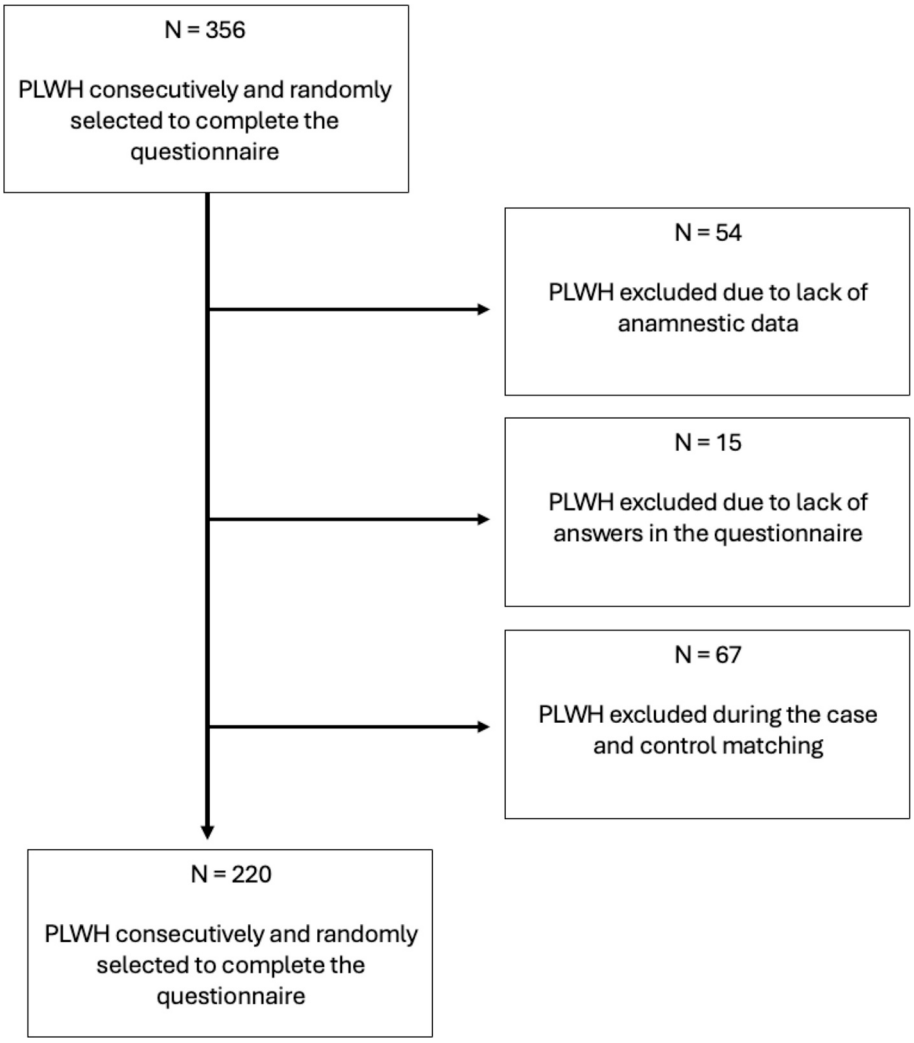

Fig. 1. Flow diagram of study population selection process.

of PLWH with COVID-19 was 0.8 %, significantly lower than that observed for hypertension and diabetes (56.6 % and 33.8 %, respectively) [13]. In this study, we observed a hospitalization rate of 0.5 %, but no increased risk of severe infection was found among diabetic and hypertensive participants. In line with existing literature, no severe cases of COVID-19 were reported in our cohort of PLWH [14]. In addition, the difficulties experienced by individuals during the pandemic in maintaining an adequate refill of medications are particularly noteworthy considering our results that suggest a correlation between HIV-RNA values >50 cp/mL and an increased risk of acquiring SARS-CoV-2 infection, as emerged in literature [8]. Overcoming barriers to ART adherence and ensuring regular monitoring of HIV-RNA levels is crucial to mitigating this risk. [8] Susceptibility to SARS-CoV-2 in PLWH was found to be more pronounced in a large cohort in San Francisco, particularly in people living with social disparities and homelessness during the first six months of the COVID-19 pandemic [14]. Another interesting finding comes from a smaller American cohort, where a higher percentage of PLWH tested positive to SARS-CoV-2 compared to HIV-negative individuals undergoing the same testing rate [15].

The observed increased risk of SARS- CoV-2 acquisition over time within study period may be attributed to the evolving pandemic measures, including variations in lockdown stringency and the circulation of different SARS-CoV-2 variants during various phases of the pandemic [14,15]. Importantly, the administration of three doses of the COVID-19 vaccine seemed highly protective against SARS-CoV-2 acquisition in this population.

Some important limitations should also be acknowledged. Due to the retrospective nature of this study, there is a potential for recall and misclassification bias. Participants might have reported more recent SARS-CoV-2 infections more accurately than older ones, potentially leading to differential misclassification. If recall bias has occurred, it may have resulted in an underestimation of infections in earlier years, thereby inflating the observed association between more recent time periods and infection risk. Additionally, indications for nasopharyngeal swab testing varied throughout the study period. In 2020, diagnostic tests were primarily performed on symptomatic individuals, whereas in 2021 and 2022, testing was more widespread. This shift in testing criteria may have contributed to a stronger association between later time periods and infection risk. Moreover, the easing of government lockdown measures and the widespread availability of vaccination in 2021 and 2022 may have led to risk compensation behaviors, increasing SARS-CoV-2 exposure and potentially attenuating the protective effect of vaccination in the later periods. Finally, some potential confounders in the association between vaccination and infection risk, such as cultural and socioeconomic factors, were not assessed in this study. This limitation may have affected the accuracy of the estimated effect size of vaccination, as well as the impact of other covariates.

Table 1
Full population' characteristic of cases and controls.

VARIABLES	Cases (n = 72)	Controls (n = 148)	P value
Male gender n (%)	40 (55.5 %)	91 (61.5 %)	0.400
Age, (mean ± SD)	54 (±12)	56 (±12)	0.127
Risk Factor HIV n (%)			0.966
-Heterosexual	39 (54.2 %)	79 (53.4 %)	
-MSM	21 (29.2 %)	44 (29.7 %)	
-IDUs	10 (13.9 %)	19 (12.9 %)	
-Other/Unknown	2 (2.7 %)	6 (4 %)	
Previous diagnosis of AIDS, n (%)	17 (23.6 %)	28 (18.9 %)	0.418
Diabetes n (%)	26 (17.6 %)	9 (12.5 %)	0.335
CVD risk n (%)	9 (12.5 %)	15 (10.1 %)	0.598
Solid tumor n (%)	7 (9.7 %)	8 (5.4 %)	0.233
ARV before enrolment date			0.042
3DR *INI based.*	27 (37.5 %)	45 (30.4 %)	
3DR NNRTIs based	5 (6.9 %)	31 (20.9 %)	
3DR PI-based	1 (1.4 %)	12 (8.1 %)	
2DR *DTG based*	32 (44.4 %)	48 (32.4 %)	
Other dual	4 (5.6 %)	10 (6.8 %)	
Others	3 (4.2 %)	2 (1.35 %)	
Last HIV-RNA > 50 cp/mL, n (%)	7 (9.7 %)	5 (3.4 %)	0.052
Duration of HIV infection, years (mean ± SD)	18.6 (± 8.9)	17.54 (± 9.0)	0.394
Cumulative time of antiretroviral exposure, years (mean ± SD)	16.9 (± 9.0)	16.7 (± 8.2)	0.869
Nadir CD4+ cell/μL (mean ± SD)	213 (± 184)	198 (± 162)	0.554
Zenith log cp/ml (mean ± SD)	4.39 (± 1.33)	4.73 (± 1.10)	
Last CD4+ cell/μL (mean ± SD)	629 (±255)	688 (± 281)	0.14
Dyslipidemia, n (%)	3 (4.2 %)	9 (6.1 %)	0.55
Hypertension, n (%)	13 (18 %)	28 (18 %)	0.87
Smoking habit, n (%)	19 (26.4 %)	50 (33.8 %)	0.26
Psychiatric disorders, n (%)	12 (16.7 %)	19 (12.9 %)	0.44

Legend of table: SD: standard deviation; MSM: Men who have sex with men; PWID: Persons who inject drugs; CVD: cardiovascular disease; ARV: Antiretroviral therapy; 2DR: Two-drug-regimen; 3DR: three-drug-regimen. IDUs: individuals drug users; INI: Integrase inhibitor; NNRTI: Non-Nucleoside Reverse Transcriptase Inhibitor; PI: Protease inhibitors; DTG: Dolutegravir.

Table 2
Logistic regression results, adjusted for age, gender at birth, antiretroviral therapy regimen, HIV RNA zenith, HIV RNA detectable (study participants with detectable viremia, VL >50 cp/ml), number of vaccination doses administered, and year of initial positive SARS-CoV-2 test result.

Variables	Multivariable aOR	95 % CI
Age > 60 years (versus ≤60)	1.2	0.5–2.5
Gender (male vs female)	0.7	0.3–1.5
Antiretroviral Therapy		
2NRTI + INSTI	Ref	
2NRTI + NNRTI	4.1	0.4–39.5
2NRTI + PI	1.6	0.1–17.5
DTG-based 2DR (3TC/DTG, RPV/DTG)	5.1	0.5–48.0
Other 2DR	2.1	0.2–28.3
Other ARV regimen	16.5	0.8–321.9
Zenith HIV-RNA (per 1 log cp/mL higher)	0.8	0.6–1.0
Detectable HIV-RNA detectable (≥ 50 cp/ml versus <50)	4.6	1.0–20.5
Full 3 doses of the vaccine against COVID-19 (versus <3)	0.1	0.0–0.2
Year of SARS CoV-2 acquisition		
2020	Ref.	
2021	5.5	1.5–23.9
2022	0.7	5.3–81.8

Conclusions

Our study provides valuable insights from clinical practice regarding the interplay between HIV infection and susceptibility to SARS-CoV-2 in this frail population, focusing on potential predictors of coinfection. Vaccination status and effective long-term control of HIV-RNA levels appear to be of utmost importance in mitigating the risk of SARS-CoV-2 acquisition among PLWH. These findings support the need for enhanced healthcare strategies aimed at protecting vulnerable populations during pandemics.

Further research is needed to deepen our understanding of the dynamic relationship between HIV and SARS-CoV-2, which could ultimately lead to the development of a "risk score" for predicting severe disease progression. The creation of a risk score would help identify individuals at higher risk of developing severe disease, allowing for early intervention and personalized management strategies. Such a tool could aid clinicians in prioritizing high-risk patients for closer monitoring, timely antiviral treatment, or intensified preventive measures. Additionally, a validated risk score could inform public health policies by helping allocate healthcare resources more efficiently, ensuring that those most vulnerable receive appropriate care. Finally, incorporating key clinical, immunological, and sociodemographic factors into a risk assessment model could improve prognostic accuracy and contribute to optimizing patient outcomes.

Data statement

The data presented in this study are not publicly available due to ethical restrictions. The data are available on reasonable request from the corresponding author.

CRediT authorship contribution statement

Pierluigi Francesco Salvo: Writing – review & editing, Writing – original draft, Visualization, Validation, Resources, Investigation, Data curation, Conceptualization. **Valentina Iannone:** Writing – review & editing, Writing – original draft, Visualization, Validation, Resources, Investigation, Data curation, Conceptualization. **Francesca Lombardi:** Writing – review & editing, Visualization, Validation, Software, Resources, Methodology, Data curation. **Arturo Ciccullo:** Validation, Methodology, Data curation. **Francesco Lamanna:** Investigation, Data curation. **Rosa Anna Passerotto:** Methodology, Investigation, Data curation. **Gianmaria Baldin:** Writing – review & editing, Methodology, Investigation, Data curation. **Rebecca Jo Steiner:** Validation, Investigation, Data curation. **Andrea Carbone:** Validation, Resources, Data curation. **Valentina Massaroni:** Investigation, Data curation. **Simona Di Giambenedetto:** Writing – review & editing, Validation, Supervision, Project administration, Methodology. **Alberto Borghetti:** Writing – review & editing, Visualization, Supervision, Software, Methodology, Formal analysis.

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Declaration of competing interest

S.D.G. was a paid consultant or member of advisory boards for Gilead

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