Characteristics and Outcomes of COVID-19-Related Hospitalization among PLWH

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Abstract: Background: There is conflicting evidence for how HIV influences COVID-19 infection. The aim of this study was to compare characteristics at presentation and the clinical outcomes of people living with HIV (PLWH) versus HIV-negative patients (non-PLWH) hospitalized with COVID-19. Methods: Primary endpoint: time until invasive ventilation/death. Secondary endpoints: time until ventilation/death, time until symptoms resolution. Results: A total of 1647 hospitalized patients were included (43 (2.6%) PLWH, 1604 non-PLWH). PLWH were younger (55 vs. 61 years) and less likely to be with PaO₂/FiO₂ = 0.926). Conclusion: A less-severe presentation of COVID-19 at hospitalization was observed in PLWH compared to non-PLWH; no difference in clinical outcomes could be detected.

Keywords: HIV; COVID-19; SARS-CoV-2

1. Introduction

COVID-19 disease, related to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), emerged as the greatest health issue of 2020. To date, no conclusive evidence about the relationship between COVID-19 and HIV infection is available. In fact, many small cohort studies failed to demonstrate a higher risk of COVID-19 or more aggressive course of disease in people living with HIV (PLWH) compared to those without HIV (non-PLWH) [1-9].

However, larger and more recent studies reported a higher risk of poor outcomes of COVID-19 in PLWH, in particular a higher mortality rate [10-14], higher rate of hospitalization due to COVID-19 [15] or higher rate of in-hospital intubation [11].
The WHO Global Clinical Platform for COVID-19 affirmed that HIV appeared to be a significant independent risk factor for severe or critical illness at hospital admission and in-hospital mortality. In this analysis, including more than 15,000 PLWH, data were predominantly from South Africa, and this may limit the generalizability of the results [16].

Two small studies from the UK and France suggested a substantial morbidity or mortality from COVID-19 among Black PLWH [16,17]. Moreover, PLWH might have high prevalence of risk factors for severe SARS-CoV-2 infection, including hypertension, diabetes, cardiovascular disease, lung disease, smoking, and the male sex [17]. Uncontrolled HIV infection or advanced immunodeficiency, in the context of additional co-morbidities, might have a higher risk of COVID-19-related death [18].

Moreover, limited information about the difference in levels of inflammatory and immune markers among people hospitalized with COVID-19 by HIV serostatus is available [10,15].

Thus, continued data collections that explores the coinfection between PLWH and COVID-19 are warranted to clarify their mutual relationship and the role of traditional risk factors for COVID-19 outcomes in PLWH.

The aim of this study was to compare characteristics at presentation and clinical outcomes of PLWH versus HIV-negative patients hospitalized with COVID-19.

2. Materials and Methods

We conducted a retrospective cohort study in the INMI COVID-19 Database of L. Spallanzani Institute in Rome (Italy), which contains data from patients who had a diagnosis of COVID-19 from January 2020 and were hospitalized in L. Spallanzani Institute in Rome. INMI COVID-19 Database was approved by the local INMI, Rome Ethical Committee, and patients provided written informed consent. The study was performed in accordance with the Declaration of Helsinki. INMI COVID-19 Database retrieves epidemiological, demographic, clinical and laboratory data of patients, as well therapy prescribed for COVID-19 patients.

Patients were included in this study if the following inclusion criteria were satisfied: ≥18 years of age, a diagnosis of SARS-CoV-2 infection, defined as positive RT-PCR from nasal/oropharyngeal (NP/OP) swab; admitted at INMI L. Spallanzani Institute in Rome (Italy).

Pneumonia was evaluated by CT scan. All patients had PaO2/FiO2 ratio measured at admission by arterial blood gas analysis.

The start of follow-up (baseline) for each patient was the time of admission to the hospital. All patients were followed up from baseline until death, discharge, last available visit or the administrative censored date of 1 June 2021, whichever occurred first.

Primary endpoint of this study was the evaluation of time from baseline to invasive ventilation or death (whichever occurred first).

Secondary endpoints were: (i) the evaluation of time from start of therapy to non-invasive or invasive ventilation or death (whichever occurred first), (ii) time until symptoms resolution, defined as resolution of fever (first day without fever) or weaning from oxygen (first day without oxygen supplementation). Non-invasive ventilation includes CPAP and NIV.

Baseline demographic characteristics, symptoms, immune and inflammatory marker levels were compared by HIV serostatus.

Use of therapy with immuno-modulants (e.g., anti-IL6, anti-JAK), corticosteroids, heparin, hydroxychloroquine or lopinavir/ritonavir was based on local medical consensus, guidelines and the clinicians’ own opinions.

For the statistical analysis, chi-square or Wilcoxon rank sum (Mann–Whitney) tests were used to compare categorical or continuous variables in descriptive analyses, respectively.

Kaplan–Meier survival method was used to estimate the cumulative proportion of patients experiencing study endpoints, with a corresponding 95% confidence interval (CI);
differences between PLWH versus HIV-negative patients (non-PLWH) were evaluated by the log-rank test.

In order to control for measured confounders, a Cox regression model was used, adjusted for the following variables: age, gender, comorbidities, ratio of arterial oxygen partial pressure to fractional inspired oxygen (PaO$_2$/FiO$_2$) and pneumonia at admission to the hospital.

A sensitivity analysis including only patients with COVID-19 pneumonia was performed. All statistical analyses were performed with STATA.

3. Results
3.1. Population Characteristics

A total of 1647 patients hospitalized with a diagnosis of COVID-19 were evaluated in this analysis, of whom 43 were PLWH and 1604 were non-PLWH. Of 1647 patients, 33.4% were female, the median age was 61 years (IQR 50–74), 82.8% were of Italian nationality, and 72.4% had at least one comorbidity. At hospitalization, 90% had a diagnosis of pneumonia, median baseline PaO$_2$/FiO$_2$ 321 (IQR 230–386) mmHg, days from onset of symptoms to hospitalization 7 (IQR 4–10). Demographic characteristics, signs, symptoms and biomarkers are shown in Table 1.

| Characteristics                                      | Total Population N = 1647 | Non-PLWH N = 1604 | PLWH N = 43 | p-Value   |
|------------------------------------------------------|---------------------------|-------------------|-------------|-----------|
| Gender                                               |                           |                   |             |           |
| Male, n(%)                                           | 1097 (66.6)               | 1065 (66.4)       | 32 (74.4)   | 0.271     |
| Age, years, median (IQR)                             | 61 (50–74)                | 61 (50–74)        | 55 (47–62)  | 0.003     |
| Not Italian, n (%)                                   | 283 (17.2)                | 268 (16.7)        | 15 (34.9)   | 0.002     |
| BMI, median (IQR)                                    | 25.9 (24.0–29.4)          | 26.0 (24.0–29.4)  | 24.7 (22.0–28.4) | 0.062 |
| At least 1 comorbidity, n (%)                        | 1192 (72.4)               | 1165 (72.6)       | 27 (62.8)   | 0.154     |
| Obesity, n (%)                                       | 226 (20.9)                | 223 (21.1)        | 3 (10.3)    | 0.255     |
| Diabetes, n (%)                                      | 273 (16.6)                | 270 (16.8)        | 3 (7.0)     | 0.086     |
| Heart diseases, n (%)                                | 422 (25.6)                | 419 (26.1)        | 3 (7.0)     | 0.005     |
| Hypertension, n (%)                                   | 644 (39.1)                | 638 (39.8)        | 6 (14.0)    | 0.001     |
| Chronic lung diseases, n (%)                          | 241 (14.6)                | 237 (14.8)        | 4 (9.3)     | 0.316     |
| CNS diseases, n (%)                                   | 178 (10.8)                | 174 (10.9)        | 4 (9.3)     | 0.723     |
| Therapies                                            |                           |                   |             |           |
| HCQ, n (%)                                           | 403 (24.5)                | 398 (24.8)        | 5 (11.6)    | 0.047     |
| PI/b, n (%)                                          | 455 (27.6)                | 438 (27.3)        | 17 (39.5)   | 0.077     |
| Remdesivir, n (%)                                    | 454 (27.6)                | 438 (27.3)        | 16 (37.2)   | 0.152     |
| Immune therapy, n (%)                                | 158 (9.6)                 | 156 (9.7)         | 2 (4.7)     | 0.265     |
| LMWH, n (%)                                          | 1316 (79.9)               | 1284 (80.1)       | 32 (74.4)   | 0.363     |
| Steroids, n (%)                                      | 956 (58.0)                | 937 (58.4)        | 19 (44.2)   | 0.062     |
| PaO$_2$/FiO$_2$ ratio <300 at admission, n (%)       | 627 (38.1)                | 619 (38.6)        | 8 (18.6)    | 0.011     |
| PaO$_2$/FiO$_2$ ratio at admission, median (IQR)     | 321 (230–386)             | 319 (229–386)     | 376 (314–438) | 0.007 |
| Worst PaO$_2$/FiO$_2$ ratio during FL, median (IQR)  | 234 (138–350)             | 232 (138–348)     | 338 (232–414) | 0.001 |
| Pneumonia, n (%)                                     | 1494 (90.7)               | 1463 (91.2)       | 31 (72.1)   | <0.001    |
| Oxygen supplementation, n (%)                        | 1244 (75.6)               | 1217 (75.9)       | 27 (62.8)   | 0.048     |
| Venturi Mask, n (%)                                  | 1077 (65.4)               | 1053 (65.7)       | 24 (55.8)   | 0.181     |
| NIV, n (%)                                           | 475 (28.8)                | 467 (29.1)        | 8 (16.6)    | 0.133     |
| OTL, n (%)                                           | 234 (14.2)                | 232 (14.5)        | 2 (4.7)     | 0.069     |
| Time from symptoms to admission, days, median (IQR)  | 7 (4–10)                  | 7 (4–10)          | 8 (5–10)    | 0.148     |
| Time until viral clearance from symptoms, median (IQR)| 19 (13–27)                | 19 (13–27)        | 21 (14–32)  | 0.252     |
| Headache, n (%)                                      | 136 (8.3)                 | 127 (7.9)         | 9 (20.9)    | 0.001     |
| Flu-like symptoms, n (%)                             | 31 (2.9%)                 | 28 (2.7%)         | 3 (9.7%)    | 0.022     |
| Cough, n (%)                                         | 534 (49.7%)               | 523 (50.1%)       | 11 (35.5%)  | 0.109     |
Table 1. Cont.

| Characteristics          | Total Population | Non-PLWH | PLWH         | p-Value |
|--------------------------|------------------|----------|--------------|---------|
| White blood cells, ×109/L, median (IQR) | 6.2 (4.8–8.5) | 6.2 (4.8–8.6) | 6.4 (3.0–8.0) | 0.881   |
| Neutrophils, ×109/L, median (IQR) | 4.3 (2.8–6.5) | 4.3 (2.8–6.5) | 4.0 (2.7–5.7) | 0.542   |
| Lymphocytes, ×109/L, median (IQR) | 1130 (780–1630) | 1120 (770–1630) | 1290 (990–1780) | 0.063   |
| Hemoglobin, g/dL, median (IQR) | 13.5 (12.1–14.7) | 13.5 (12.1–14.7) | 13.5 (12.1–14.6) | 0.976   |
| Platelets, ×106/L, median (IQR) | 219 (172–282) | 219 (172–282) | 206 (153–288) | 0.604   |
| Potassium, mEq/L, median (IQR) | 3.6 (3.4–3.9) | 3.6 (3.4–3.9) | 3.5 (3.3–3.9) | 0.532   |
| C-reactive protein, mg/L, median (IQR) | 2.9 (1.0–8.2) | 2.9 (1.0–8.2) | 3.1 (1.3–6.6) | 0.910   |
| D-dimer, mg/L, median (IQR) | 659 (400–1266) | 666 (403–1274) | 479 (324–746) | 0.014   |
| Ferritin, mg/L, median (IQR) | 380 (176–833) | 389 (177–838) | 243 (159–313) | 0.033   |

Notes: PLWH, people living with HIV; IQR, interquartile range; BMI, body mass index; HCV-Ab, hepatitis C virus antibodies; HBsAg, Hepatitis B surface antigen; PaO2/FiO2, ratio of arterial oxygen partial pressure to fractional inspired oxygen; NIV, non-invasive ventilation; OTI, oro-tracheal intubation.

PLWH were significantly younger and less likely to be with PaO2/FiO2 below 300 mmHg at admission, with less alterations in D-dimer, ferritin and slight alternations in lymphocytes compared with non-PLWH (Table 1).

Symptoms at presentation were similar in the two groups, apart from headache, which was more frequent in PLWH (Table 1).

Viro-immunological characteristics of the PLWH group were the following: median CD4+ cells count at COVID-19 diagnosis: 272 cells/µL (IQR127–468); median CD4+ cells count at lowest point: 185 cells/µL (IQR75–322); 32% with a previous diagnosis of AIDS, all had antiretroviral therapy; and 77% had HIV-1 RNA < 50 copies/mL at COVID-19 diagnosis. Characteristics of PLWH who were not virologically suppressed are shown in detail in Table 2, but a sub-analysis of the above-specified endpoints was not performed in this population due to the small dimension of this subgroup.

3.2. Invasive Ventilation or Death

Overall, 306 patients over 1647 (18.6%) underwent to invasive ventilation or death, two in PLWH group.

By Kaplan–Meier analysis, the estimated probability of invasive ventilation or death was 4.7% (95% CI 1.2–17.3) in PLWH and 18.9% (95% CI 16.1–21.1) in non-PLWH 15 days after hospitalization (log-rank test = 0.023).

Following the adjustment for age, gender, comorbidities, PaO2/FiO2 and pneumonia at admission, the adjusted hazard ratio (aHR) of mechanical ventilation/death of PLWH was 0.49 (95% CI 0.12–1.96, p = 0.310) versus non-PLWH.

3.3. Non-Invasive or Invasive Ventilation or Death

The cumulative probability of non-invasive or invasive ventilation/death at day 15 was 20.9% (11.5–36.4) in PLWH versus 37.6% (35.1–40.2) in non-PLWH (log-rank test = 0.044).

Following the adjustment for the aforementioned variables, the aHR of non-invasive or invasive ventilation/death of PLWH was 1.03 (95% CI 0.53–2.00, p = 0.926).

3.4. Symptoms Resolution

The cumulative probability of symptoms resolution at day 15 was 65.3% (48.4–81.7) in PLWH versus 50.5% (47.6–53.4) in non-PLWH (log-rank test = 0.041).

In the adjusted model, the probability of symptoms resolution at day 15 PLWH was similar in the two groups (aHR 0.92; 0.63–1.36; p = 0.691).
Table 2. Characteristics of PLWH who were not virologically suppressed.

| Ethnicity     | Gender | Age | HIV RNA, Copies/mL | CD4 Count at Admission, Cells/mm³ | AIDS Defining Disease at Admission | COVID-19 Pneumonia | Comorbidities                        | PaO₂/FiO₂ at Admission, mmHg | Worst PaO₂/FiO₂ during FU, mmHg | Oxygen Therapy | Invasiv Ventilation | Death |
|---------------|--------|-----|-------------------|----------------------------------|-----------------------------------|-------------------|-------------------------------|-------------------------------|-------------------------------|----------------|---------------------|--------|
| Patient 1     | Black  | F   | 28                | 222,713                          | 4                                 | Yes               | No                           | 357                           | 263                           | yes             | IOT                 | Yes    |
| Patient 2     | White  | M   | 53                | 289                              | 53                                | No                | COPD                        | 495                           | 495                           | No              | NO                  | No     |
| Patient 3     | White  | F   | 56                | 4070,603                         | 53                                | No                | COPD, HCV chronic hepatitis | 462                           | 462                           | No              | No                  | No     |
| Patient 4     | Afro-American | M | 48                | 125                              | 792                               | No                | Hypertension, OSAS         | 386                           | 386                           | No              | No                  | No     |
| Patient 5     | White  | F   | 71                | 573,680                          | 271                               | No                | Yes                         | 338                           | 338                           | No              | No                  | no     |
| Patient 6     | White  | M   | 63                | 671,810                          | 272                               | No                | Hypertension, dyslipidemia, CKD | 248                           | 195                           | Yes             | No                  | No     |
| Patient 7     | Afro-American | M | 48                | 792                              | 184                               | No                | Squamous cell carcinoma of rectum | NA                           | NA                           | No              | No                  | no     |

Abbreviations: COPD, chronic obstructive pulmonary disease; OSAS, obstructive sleep apnea syndrome; CKD, chronic kidney disease; FU, follow up; NA, not available.
3.5. Sensitivity Analysis

A total of 1494 patients hospitalized with diagnoses of COVID-19 pneumonia were evaluated in this sensitivity analysis. By Kaplan–Meyer analysis, the estimated probabilities of invasive ventilation or death was 6.5% (95% CI 1.7–23.4) in PLWH and 20.5% (95% CI 18.4–23.4) in non-PLWH after 15 days of hospitalization (log-rank test = 0.073).

Following adjustment for age, gender, comorbidities, PaO$_2$/FiO$_2$, aHR of mechanical ventilation/death of PLWH was 0.46 (95% CI 0.11–1.85, $p = 0.272$) versus non-PLWH.

The cumulative probability of non-invasive or invasive ventilation/death at day 15 was 29.0% (16.3–48.4) in PLWH versus 40.69% (38.3–43.7) in non-PLWH (log-rank test = 0.276). Following adjustment for the same variables, aHR of non-invasive or invasive ventilation/death of PLWH was 1.02 (95% CI 0.53–1.98, $p = 0.954$).

The cumulative probability of symptoms resolution at day 15 was 58.2% (39.8–77.7) in PLWH versus 49.9% (39.8–77.7) in non-PLWH (log-rank test = 0.162).

4. Discussion

The impact of HIV coinfection on the clinical course of patients with COVID-19 has yet to be fully clarified.

Our findings suggest that HIV status did not significantly impact clinical outcomes in patients with SARS-CoV-2 coinfection and are in line with other large studies conducted in the US, which evaluated clinical evolution and mortality among PLWH and COVID-19 [19,20]. This study was conducted on a cohort of 7576 veterans (Veterans Aging Cohort Study, VACS) and states that people with HIV are more likely to be assessed for COVID-19, but there is no difference in the risk of hospitalization, ICU admission, intubation or death between HIV-positive and HIV-negative patients [19].

A previous study investigating clinical outcomes in a small case series of patients admitted to our institute, did not find an increased risk and severity of COVID-19 in PLWH despite a significant T-cell activation and inflammatory profile, suggesting a potential role of HIV-driven immunological dysregulation in avoiding immune-pathogenetic processes [21].

Moreover, lymphopenia in COVID-19 infection seems to be a relevant factor for the progression of severity of illness [22].

CD4 lymphopenia was reported with variable severity of COVID-19 infection. It was hypothesized that a low CD4 count might protect PLWH from the development of the cytokine storm, which is part of the COVID-19 clinical syndrome, and potentially reduce some of the severe manifestations of COVID-19 infection [23] resulting in a protective feature in preventing severe clinical manifestations of COVID-19 infection [6,7,24,25]. In our cohort, PLWH had quite low CD4+ levels at COVID-19 diagnosis (272 CD4+ cells/µL [IQR 127–468]).

A study derived from a large US database included more than 50,000 patients with COVID-19, of whom about 49,000 were HIV-negative and 400 were HIV-positive, mostly of African American ethnicity, obese, hypertensive, with diabetes, renal failure and other concomitant diseases. This demonstrated that the severity of COVID-19 in PLWH might be dependent on the presence of comorbidities [9]. Subsequent to this study, Boulle and colleagues showed an approximately 2.7-fold increased risk of death from COVID-19 in the HIV-positive population compared to the HIV-negative population, after adjustment for confounding factors such as age, the presence of other concomitant infectious and non-infectious diseases [26]. Both studies emphasize that the severity of COVID-19 in HIV-positive patients was not due to the presence of HIV itself, but to the ageing and comorbidities of these individuals [9,26].

Moreover, a systematic review by Cooper T. et al. on 70 PLWH from 8 studies did show that well-controlled HIV patients were not associated with poorer outcomes of COVID-19 infection than the general population, which was similar to our observation [27].

According to the WHO Global Clinical Platform for COVID-19, HIV infection is an independent risk factor of worse COVID-19 outcomes, but these data were predominantly
from South Africa, mainly without information on antiretroviral therapy. Moreover, not all potentially relevant risk factors, such as body mass index, were evaluated [16].

In our cohort, HIV-positive patients were significantly younger than the HIV-negative comparator, mostly virologically suppressed before COVID-19 and with a median CD4 count of 272 cells/µL; hence, these findings may not be applicable to a population with poorly controlled HIV or AIDS. The two groups did not differ in terms of COVID-19 symptoms (only headache was more frequent in PLWH) and comorbidities, with the exception of hypertension and cardiovascular diseases found in a significantly higher proportion of HIV-negative patients.

At time of admission to hospital, hypoxemia, the need for oxygen supplementation, and pneumonia were significantly more frequent in those without HIV; these differences could be explained by the older age of those without HIV and/or increased prevalence of cardiovascular diseases.

Among the seven PLWH not virologically suppressed, only two PLWH had an AIDS diagnosis at admission; the other patients had more than one comorbidity. All of them were discharged alive with no COVID-related complications, except one patient who required invasive mechanical ventilation and died for reasons not related to COVID-19.

The main limitation of this study is the retrospective analysis, performed in a single medical center; therefore, results may not be generalizable to other centers and may also be limited by a small sample size. Larger prospective studies from multiple centers will be needed to verify findings from this study and to examine the impact of poorly controlled HIV on the clinical course of SARS-CoV-2. Additionally, given the lack of immunological data on all study subjects, we are unable to report on the immunological response of PLWH to SARS-CoV-2 infection as compared with patients with COVID-19 but not with HIV infection. Taken together, our findings are reassuring in that HIV-positive patients on antiretroviral therapy may not experience significantly worse outcomes in SARS-CoV-2, even though these data should be considered with caution. This urges us not to rush to conclusions about a reversal of previous data on large cohorts telling us that HIV still remains a risk factor for COVID-19.

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