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FULL PAPER

SARS-CoV-2 infection clinical picture and outcomes in adults living with HIV: a cohort analysis

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SUMMARY

Existing evidence about HIV and SARS-CoV-2 co-infection has, so far, yield conflicting results.
Methods: This is a cohort, single center, clinical study aimed at identifying possible characteristics of PLWH that could correlate with the risk of acquiring SARS-CoV-2 and would influence the outcome. 155 cases of SARS-CoV-2 infection were compared with 307 PLWH who tested negative. No variable was associated with an increased risk of infection. SARS-CoV-2 PLWH were completely asymptomatic in 20.6% of cases. Factors associated with severe COVID-19 were age (P=0.001), diabetes (P=0.009) hypertension (P=0.004), cardiovascular disease (P=0.001) or an increasing number of chronic co-morbidities (P=0.002); only the first two variables retained statistical significance in a multivariable model. Only older age and a lower CD4 count were statistically associated with death in the multivariate model. Sixteen PLWH not included in the analysis were infected by SARS-Cov-2 after vaccination. In 4 cases the infection was completely asymptomatic, while in the remaining 12 cases the infection was mild and resembled a flu-like syndrome.
Conclusions: No baseline characteristic defines patients at greater risk of SARS-CoV-2 infection. Older age and the presence of multi-comorbidities are risk factors for a severe clinical course. Lower CD4 counts correlate with a fatal outcome.

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INTRODUCTION

Older people, subjects with multiple co-morbidities (Wu, 2020; Zhou, 2020; Richardson, 2020) or with immune-compromising conditions such as solid organ transplant or malignant diseases are at greater risk of SARS-CoV-2 infection and have overall poorer COVID-19 outcomes (Chams, 2020; Osibogun, 2021; Cho, 2021; Wu, 2020). Evidence is less clear for people with other types of immune-compromising conditions, including people living with HIV (PLWH) (Geretti, 2020; Tesoriero, 2021; Dandachi, 2020).
Existing evidence about HIV and SARS-CoV-2 co-infection has largely been limited, consisting mostly of case reports or case series (Blanco, 2020; Gervasoni, 2020), large population-based studies where PLWH were a small minority and that yield conflicting results (Geretti, 2021; Bhaskaran, 2021; Waters, 2021) and meta-analysis based on heterogeneous studies (Wang, 2021).
Because PLWH are living longer with ART, many will also have chronic conditions associated with severe COVID-19 disease (Weiser, 2021). However, observational studies specifically measuring symptoms, disease severity, complications, multi-morbidity, and the proportion of death in SARS-CoV-2 infected PLWH offer contrasting results (Del Amo, 2020, Braunstein, 2021). We focused our attention on whether virologically controlled PLWH who are clinically stable will have any distinctive characteristic that could put them at greater risk for SARS-CoV-2 infection and, in this case, which variables would indicate a greater risk of severe COVID-19 and negative outcomes. This would help clinicians caring for HIV/AIDS to identify subjects at greater risk.

Key words:
HIV, SARS-CoV-2, COVID-19, asymptomatic, mortality, CD4.

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METHODS

This is a cohort, single center, clinical study performed in a Province of Northern Italy severely hit by the SARS-CoV-2 pandemic. The aim of the study

was to identify possible characteristics of PLWH that could correlate with the risk of acquiring SARS-CoV-2 infection and, in case of infection, would influence the outcome.

From the beginning of the epidemic to the end of 2021, data of all suspected or confirmed COVID-19 cases were recorded in a specific database linked to a common research project authorized by the local Ethical Committee. The present study was authorized by the such Committee (authorization number 1588, 18/08/2021). All patients gave their written informed consent. Data for the present cohort study were extracted from the original database and were cross-linked with information from the outpatient clinic's electronic health records. Data of patients not admitted to the hospital were obtained from each patient during a regular visit performed after August 2021. All of these patients also signed an informed consent.

Recorded variables were age, gender, comorbidities, HIV-specific variables such as year of HIV infection diagnosis, nadir and most recent (e.g., within 3 months from visit and/or infection) CD4 cell counts, CD8 cell counts, CD4/CD8 ratios, HIV-RNA plasma levels, current antiretroviral therapy (ART). Clinical characteristics of COVID-19, and outcomes were recorded for SARS-CoV-2 positive patients.

During the first wave of the epidemics, laboratory diagnosis of SARS-CoV-2 infection was done by RT-PCR with primer and probes targeting E, RdRp and N genes. Nasopharyngeal swabs or lower respiratory tract aspirates were tested only in individuals admitted to the hospital, as public health authorities' regulations did not recommend tests in individuals with mild symptoms not admitted to hospitals. Later on, for specific categories (e.g., health-care workers) nasopharyngeal swabs were permitted. In all other cases, the diagnosis was achieved by means of serological tests.

Serological diagnosis was made with VivaDiagTM COVID-19 IgM/IgG immune-chromatographic assay from VivaChekTM Biotech (China), performed according to the manufacturer's instructions. All PLWH in the control negative group were tested serologically.

Since the beginning of 2022, after the vaccination program was largely implemented we collected data only of those patients who tested positive to RT-PCR despite having been vaccinated.

Confirmed COVID-19 was defined by positive RT-PCR for SARS-CoV-2 in respiratory samples or a positive serological test. The severity of disease was scored according to NIH classification (NIH 2021). Confirmed SARS-CoV-2 negative patients were asymptomatic, with negative serology tests.

No sample size was calculated, given that all known individuals with a diagnosis of COVID-19 were included. Continuous variables are presented as means and 95% confidence interval. Categorical variables are expressed as number of patients (percentage). Comparisons were assessed by using the Mann-Whitney *U* test for continuous variables, whereas categorical variables were assessed by chi-square test. We used a logistic regression model to explore factors associated with COVID-19 severity and risk of death. Statistical significance was defined as a two-sided P-value <0.05. All statistics were done with SPSS Statistics for Windows, version 17.0.

The study was partially founded by Ministry of Health finalized research fund COVID-2020-12371675 and Gilead Fellowship program 2021.

RESULTS

At our center, 2834 PLWH are currently on active follow-up. Among these, we identified 155 cases of SARS-CoV-2 infection and compared them with 307 PLWH who tested negative for SARS-CoV-2.

Baseline characteristics are reported in *table 1*. No significant difference was observed between SARS-CoV-2 positive and negative patients for age distribution, gender, time with HIV infection, nadir CD4 cell counts, type and number of co-morbidities, current CD4 and CD8 counts and type of anti-HIV therapy. The only difference was the country of origin, with more frequent cases among native Italians than among foreigners. SARS-CoV-2 positive PLWH were completely asymptomatic in 20.6% of cases, while mild, moderate, or severe disease presented in 50.3%, 18.1% and 11%, respectively. The most common symptoms were fever (69.7% of cases), dyspnea (29.1%), ageusia (28.4%), anosmia and non-productive cough (24.5%), and fatigue (20.6%). Amongst positive cases only 33 (18.7%) were admitted to the hospital and 6 subjects (3.9%) died from COVID-19.

Factors associated with a severe form of COVID-19 were more advanced age (P=0.001), concomitant diabetes (P=0.009), hypertension (P=0.004), cardiovascular disease (P=0.001), or an increasing number of chronic co-morbidities (P=0.002). However, only the first two variables retained statistical significance when entered in a multivariable model (*Table 2*). COVID-19 had a fatal outcome in 6 subjects with a severe disease. They were all males and, according to univariate analysis, factors significantly associated with death included age, a previous diagnosis of AIDS, current CD4 count, the number of chronic co-morbidities and some specific co-pathologies (*Table 3*). However, only older age and a lower current CD4 count were statistically associated with the outcome in the multivariate model. In 2022, 16 further PLWH age 50 years (mean), 12 males and 4 females, not included in the above description were infected by SARS-CoV-2 despite being vaccinated. In three

cases the infection occurred after a single dose of vaccine, in 12 after 2 and in 3 after a full 3 doses of vaccine. In 4 cases the infection was completely asymptomatic and was detected because a nasal swab was performed for other reasons (e.g., contact with a case); in the remaining 12 cases the infection was mild and resembled a flu-like syndrome. Most patients (13 cases) had 2 or fewer symptoms, mostly fever (6) rhinitis/pharyngitis (7) and headache (4), usually lasting 3 days or less.

Table 1 - *Baseline characteristics of PLWH (data are expressed as means and 95%CI or numbers and percentages).*

Variable	*SARS-CoV-2 negative (307)*	*SARS-CoV-2 positive (155)*	*Total*	*P value*
Age, years	51 (50-53)	53 (51-55)	53 (52-54)	0.146
Gender Male	231 (75.2%)	114 (73.5%)	345 (74.7%)	0.734
Female	76 (24.8%)	41 (26.5%)	117 (25.3%)	
Risk factor for HIV Heterosexual contacts	136 (44.3%)	66 (42.6%)	202 (43.7%)	0.883
MSM	96 (31.3%)	52 (33.5%)	148 (32.0%)	
IVDU	75 (24.4%)	37 (23.9%)	112 (24.3%)	
Origin Italy	281 (91.5%)	151 (97.4%)	432 (93.5%)	0.016
Other	26 (8.5)	4 (2.6%)	30 (6.5%)	
Years since HIV infection	13 (12-14)	14 (12-15)	13 (12-14)	0.353
Nadir CD4 count, cells per µL	349 (312-386)	355 (301-408)	351 (321-381)	0.863
Antiretroviral drugs NRTIs	243 (79.2%)	126 (81.3%)	369 (79.9%)	0.340
NNRTIs	122 (39.7%)	55 (35.5%)	177 (38.3%)	0.418
PIs	88 (28.7%)	44 (28.4%)	132 (28.6%)	1.000
INIs	159 (51.8%)	82 (52.9%)	241 (52.2%)	0.844
Number of co-morbidities	1.1 (1.0-1.3)	1.3 (1.0-1.6)	1.2 (1.0-1.3)	0.337
Major co-morbidities Cardiovascular diseases	42 (13.7%)	21 (13.5%)	63 (13.6%)	1.000
Hypertension	45 (14.7%)	34 (21.9%)	79 (17.1%)	0.066
Gastro-enteric	55 (17.9%)	29 (18.7%)	84 (18.2%)	0.898
Malignancies	25 (8.1%)	18 (11.6%)	43 (9.3%)	0.238
Neurological	31 (10.1%)	16 (10.3%)	47 (10.2%)	1.000
Diabetes	14 (4.6%)	14 (9.0%)	28 (6.1%)	0.065
HBV co-infection	19 (6.2%)	10 (6.5%)	29 (6.3%)	1.000
HCV co-infection Negative	217 (70.7%)	110 (71.0%)	327 (70.8%)	0.874
Cured	84 (27.4%)	43 (27.7%)	127 (27.5%)	
HCV-RNA positive	6 (2.0%)	2 (1.3%)	8 (1.7%)	
Last CD4 count, cells per µL	803 (757-850)	1000 (893-1107)	816 (777-855)	0.472
Last CD8 count, cells per µL	989 (927-1051)	994 (902-1086)	993 (938-1047)	0.803
Last CD4/CD8 ratio	0.43 (0.36-0.50)	0.54 (0.38-0.71)	0.47 (0.40-0.54)	0.265
Last HIV-RNA < 50 copies/mL	295 (96.1%)	149 (96.1%)	444 (96.1%)	1.000

Table 2 - *Factors associated with the severity of the clinical picture of SARS-CoV-2 infection.*

Variable	*NIH Classification*				*P*	*P*
	Asymptomatic	*Mild*	*Moderate*	*Severe*	*univariate*	*multivariate*
Number	32 (20.6%)	78 (50.3%)	28 (18.1%)	17 (11.0%)	–	–
Age (years)	56 (52-59)	52 (50-54)	54 (51-57)	62 (58-67)	0.001	0.002
Diabetes					0.009	0.019
No	28 (87.5%)	74 (94.9%)	27 (96.4%)	12 (70.6%)		
Yes	4 (12.5%)	4 (5.1%)	1 (3.6%)	5 (29.4%)		
Hypertension					0.004	0.175
No	26 (81.3%)	67 (85.9%)	20 (71.4%)	8 (47.1%)		
Yes	6 (18.8%)	11 (14.1%)	8 (28.6%)	9 (52.9%)		
CV diseases					0.001	0.240
No	24 (75.0%)	76 (97.4%)	23 (82.1%)	11 (64.7%)		
Yes	8 (25.0%)	2 (2.6%)	5 (17.9%)	6 (35.3%)		
Number of co-morbidities	1.59 (1.0-2.1)	1.01 (0.7-1.3)	1.32 (0.8-1.8)	2.47 (1.3-3.6)	0.002	0.690

Data are expressed as means and 95%CI or numbers and percentages.

Table 3 - *Factors associated with a fatal outcome of COVID-19.*

Variable	*Alive*	*Deceased*	*P univariate*	*P multivariate*
Number	149 (96.1%)	6 (3.9%)	–	–
Number of CD4/ml (last count)	852 (791-915)	502 (421-584)	0.027	0.024
Number of co-morbidities	1.26 (1.0-1.5)	3.50 (1.5-5.5)	< 0.0001	0.002
Age (years)	54 (52-55)	67 (61-74)	< 0.0001	0.206
Diabetes				
No	138 (92.6%)	3 (50.0%)	0.010	0.120
Yes	11 (7.4%)	3 (50.0%)		
Hypertension				
No	119 (79.9%)	2 (33.3%)	0.021	0.557
Yes	30 (20.1%)	4 (66.7%)		
Cardiovascular diseases				
No	131 (87.9%)	3 (50.0%)	0.033	0.644
Yes	18 (12.1%)	3 (50.0%)		
Dyslipidemia				
No	130 (87.2%)	3 (50.0%)	0.038	0.427
Yes	19 (12.8%)	3 (50.0%)		
Renal				
No	141 (94.6%)	4 (66.7%)	0.049	0.948
Yes	8 (5.4%)	2 (33.3%)		
CDC A3:B3:C3	41 (27.5%)	4 (66.0%)	0.001	0.127

Data are expressed as means and 95%CI or numbers and percentages.

DISCUSSION

Current evidence indicates that people living with HIV represent around 1% (95% CI 0.0-3.0) of total hospitalized COVID-19 cases (Blanco, 2020; Bhaskaran, 2021), whereas SARS-CoV-2 infection prevalence in PLWH is 0.68-1.8%, similar to the SARS-CoV-2 prevalence reported in the general population (Cooper, 2020; Mirzaei, 2021). However, all studies deal with symptomatic patients, mostly admitted to hospitals, and therefore may present an imprecise picture of SARS-CoV-2 epidemics in PLWH. As a matter of fact, in our casuistry we observed 20.6% of cases that were completely asymptomatic. This value is lower than previously reported in a Spanish cohort of PLWH (Rial-Crestelo, 2021) but is nevertheless a relevant proportion of SARS-CoV-2-infected individuals.

The proportions of PLWH with severe COVID-19 (11.0%) and who died (3.9%) that we observed are lower than proportions of PLWH with COVID-19 reported early in the pandemic in a Spanish national cohort (Del Amo, 2020), and in New York City (Braunstein, 2021) which may in part reflect the overwhelmed healthcare capacity during the first wave of the pandemic. In contrast, PLWH in a Spanish (PISCIS) registry (Nomah, 2021) and in the US national registry of COVID-19 patients (N3C Cohort) (Yang, 2021) through mid-2021 had similar, slightly lower rates of severe outcomes compared to our cohort.

We found that cardiovascular and/or metabolic co-morbidities and the association of multiple chronic pathologies is linked with increased COVID-19 disease severity, and these results are consistent with those seen in other cohorts of PLWH and in the general population affected by COVID 19 (Ko, 2021; Dandachi, 2020; Ambrosioni, 2021).

A recent large cohort analysis found a consistent and significant increased risk of hospitalization and severity of COVID-19 outcomes in PLWH with lower CD4 counts (Shapiro, 2022). This contrasts with results from early studies of PLWH with COVID-19 that did not detect any association between classical variables used to characterize HIV infection and the severity of COVID-19 outcomes (Inciarte, 2020). Our results seem to confirm a role of current CD4 counts in increasing the risk of a fatal outcome. Although all on antiretroviral therapy, with suppressed HIV-RNA levels and with a fairly good immune status, subjects included in our cohort who died of COVID-19 had significantly lower CD4 counts than PLWH who did not. Along with baseline characteristics already described for the general population, such as older age, multi-morbidity, and selected chronic co-pathologies, a relatively immunosuppressed condition therefore seems to increase the risk of death in PLWH. These results are in line with previous analyses showing how a CD4 count <200 cells/mcL would increase the risk of severe COVID-19 and death in PLWH (Kanwugu, 2021).

We are aware that our study has some limitations. First, the low prevalence of PLWH with severe immunosuppression, the absence of elevated HIV-RNA levels and the generalized use of antiretroviral drugs may prevent generalizing the results. Second, the ob-

servational design did not allow us to evaluate other factors that could potentially influence the clinical course of the disease. Finally, there could be some selection bias as only PLWH with laboratory-confirmed infection were included. It is highly probable that, especially during the first pandemic wave, the number of infected subjects with no or mild symptoms may have been higher, but confirmatory tests were not performed at that time because of the critical epidemiological situation and the collapse of the health infrastructure.

A distinctive aspect of our cohort is having prolonged the observation beyond the introduction of vaccination programs. Although not included in the main analysis so as not to introduce selection biases, we identified 13 PLWH with SARS-CoV-2 infection acquired after the beginning of the vaccination schedule. Most of these cases did not complete (at the time of infection) the recommended three-dose schedule, but, interestingly, all of them had an asymptomatic or mild disease resembling a self-limiting flu-like infection.

CONCLUSIONS

In conclusion, no baseline characteristic of PLWH define a subgroup of patients at greater risk of SARS-CoV-2 infection. The infection is completely asymptomatic in one case out of five, and this should be considered when epidemiological programs are defined. Older age and the presence of multi-comorbidities, as in the general population, are risk factors for a more severe clinical course. Lower CD4 counts do correlate with a fatal outcome of COVID-19 in PLWH despite active antiretroviral treatment and control of HIV replication.

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