

Protective Effects of Antiretroviral Therapy against SARS-CoV-2 Infections and COVID-19 Severity among PWH in Kenya

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ABSTRACT

People living with HIV (PLWH) are believed to be vulnerable to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections due to their lowered immune system. Although antiretroviral therapy (ART) strengthens the body's ability to fight infections, it has been hypothesised to reduce the severity of SARS-CoV-2. However, evidence remains inconsistent and limited in sub-Saharan Africa. We aimed to evaluate the potential protective effects of ART against SARS-CoV-2 infection and Coronavirus Disease 2019 (COVID-19) severity among PLWH in Kenya. To achieve these, we designed a retrospective research study among 303 PLWH receiving medical care at three selected HIV treatment facilities in Kenya. Medical records and Demographic information were mined from patient records and questionnaires. Descriptive statistics summarised participant characteristics, and associations between ART related variables obtained, immune markers, vaccination, and COVID-19 outcomes were analysed for statistical significance. From the analysis, SARS-CoV-2 prevalence was detected in 9.2% (28/303) of the participants. Majority of the infected cases were mild (89.3%; 25/28), while 10.7% (3/28) were moderate, and severe case. SARS-CoV-2 status was less associated with ART regimen ($p=0.492$), nor viral suppression ($p=0.484$). However, missed ART doses showed a significant relationship with SARS-CoV-2 infection, which was relatively higher among infected participants (35.7%), compared to non-infected individuals (18.5%; $p=0.031$). Interestingly all infected participants were vaccinated. In our Conclusion, ART regimen did not show measurable protection against SARS-CoV-2 infection; however, non-adherence to ART increased infection risk, while COVID-19 vaccination showed reduced progression to severe disease. Ensuring ART adherence remains crucial for improving immune stability and strengthening pandemic resilience among PLWH.

Keywords

Antiretroviral therapy, COVID-19, SARS-CoV-2, People living with HIV, Kenya, Adherence, Vaccination, Viral suppression.

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Literature review

People living with HIV (PLWH) are at a higher risk of severe Coronavirus Disease 2019 (COVID-19) despite access to ART. Meta-analyses review show a higher COVID-19 mortality among HIV-infected than non-infected persons [1,2]. Studies in sub-Saharan Africa have indicated, PWH experience elevated disease severity than non HIV infected persons [2].

Pandemic-related disruptions further compounded risks, including reduced HIV testing, delayed ART initiation, and hospital services interruptions [3,4]. In Kenya, where prevalence of HIV is high, with disparities in healthcare and comorbidity burden make regional data crucial in guiding interventions [4] among the stakeholders. The lockdown disruptions experienced led to reduced access to scheduled routine clinic appointments, interruptions in supply and refills for ART medication, delays in laboratory services, a shortage of healthcare personnel due to illness or quarantine, and the diversion of routine healthcare resources to the COVID-19 response [5].

Increased immunosuppression heightens susceptibility with adverse outcomes. A review study pointed that HIV-infected persons with a CD4 counts below 200 cells/ μ L shed SARS-CoV-2 for longer durations than HIV-non-infected individuals [6,7]. Prolonged infection in immunocompromised individuals may facilitate viral replication and the emergence of variants with immune evasion potential [8]. Observational studies also reviewed that ART, particularly tenofovir disoproxil fumarate/emtricitabine (TDF/FTC), may increase COVID-19 severity compared with other regimens [9,10]. However, randomised trials reported mixed findings on its prophylactic effects and its impact on viral clearance [11,12].

The entry of COVID-19 vaccination transformed the disease risk for PWH. Those with compromised immunity showed reduced antibody responses after the second vaccine dose, yet nearly all gained sero-conversion following a third dose, without adverse HIV viral load effects [12]. Integrating COVID-19 vaccination into routine HIV care through “one-stop-shop” programs increased its uptake in Kenya [13]. Apart from biological risks, the pandemic has also affected psychosocial well-being, with adolescence and female living with HIV reporting ART adherence challenges, disrupted clinic visits, and negative mental health outcomes [14].

We therefore highlight the urgent need for niche specific findings to clarify how ART regimens, immune status, and vaccine mediated protection collectively influence COVID-19 outcomes among PWH, particularly in resource limited places, with high HIV burden in Kenya.

Objective

The study aimed at evaluating the potential protective effects of antiretroviral therapy (ART) on SARS-CoV-2 infection risk and COVID-19 disease severity among people living with HIV in Kenya.

Methodology

Study Design

This retrospective-observational study evaluated people living with HIV to determine the correlation between ART, immune status, vaccination, and COVID-19 outcomes.

Study Population and Data Collection

Data were mined from patient medical records and participant questionnaires. Variables included ART regimen, HIV viral load, CD4/CD8 T-cell counts, COVID-19 vaccination status, SARS-CoV-2 infection, and COVID-19 disease severity.

Study variables

Categorical variables included ART regimen, vaccination status, and SARS-CoV-2 infection. Continuous variables included age, CD4/CD8 counts, and viral load. COVID-19 severity was classified according to standard clinical criteria.

Data Analysis

Statistical inference were done using SPSS version 22.0 (IBM Corp., 2013). Exploratory data analysis (EDA) examined distributions, missing data, and outliers. Descriptive statistics summarized variables: Descriptive statistics and proportions for categorical data, and mean \pm SD or median interquartile range (IQR) for numerical data, depending on distribution. Associations between ART, HIV immune status, and vaccination with SARS-CoV-2 infection and COVID-19 severity were assessed using Chi-square or Fisher's exact tests, as appropriate. All tests were two-sided, with p-values <0.05 considered statistically significant.

Results

Sociodemographic data of participants

Data from 303 participants from Kisumu County RH (48.5%), Nakuru PGH (29.7%), and Malindi/Mariakani SCH, Kilifi (21.8%) was reviewed. 214 were females (70.6%) and 89 males (29.4%), aged 19–82 years (median 40; IQR 33–49). Most of them (77.2%) were aged 25–54 years. Married participants accounted for 46.8%, while 24.1% were single and 17.5% widowed. About half (51.8%) had primary education or below, while the leading occupations were business (28.1%) and employed (26.1%). Most participants (69.6%) lived with immediate family, 14.5% lived alone, and the remainder with spouses or others. Demographic findings are detailed in Table 1.

Antiretroviral therapy (ART)

All the participants were on ART, predominantly first-line regimens (90.8%), with TDF/3TC/DTG or TLD/TDL being the most common (72.9%). Nearly half of them had been on ART for over 10 years (median duration of 10 years (IQR: 6–14)). Most participants (83.5%) reported a change in ART regimen, mainly due to government-directed optimization (73.1%). ART was primarily taken once daily (94.1%), and about one-fifth (20.1%) reported missing at least one dose, mostly due to forgetfulness, travel, or work-related reasons (Table 2).

Table 1: Socio-Demographic characteristics (N=303).

Characteristic		Frequency [N(%)]
Health facility	Kisumu County Referral Hospital	147(48.5)
	Malindi/Mariakani SCH - Kilifi County	66(21.8)
	Nakuru County PGH	90(29.7)
Gender	Females	214(70.6)
	Males	89(29.4)
Age group in years	15-24	24(7.9)
	25-54	234(77.2)
	55-64	35(11.6)
	≥65	10(3.3)
Marital Status	Single	73(24.1)
	Married (monogamous)	121(39.9)
	Married (polygamous)	21(6.9)
	Separated	28(9.2)
	Divorced	7(2.3)
Education	Widowed	53(17.5)
	No education	32(10.6)
	Primary school incomplete	51(16.8)
	Primary school complete	74(24.4)
	High school incomplete	43(14.2)
	High school complete	57(18.8)
	Tertiary institution	46(15.2)
Occupation in last 12 months	Unemployed/Student	61(20.1)
	Retired	4(1.3)
	Farmer	8(2.6)
	Employed	79(26.1)
	Self-employed	66(21.8)
Who live with	Business	85(21.8)
	Alone	44(14.5)
	Spouse	28(9.2)
	Immediate family	211(69.6)
Who live with	Other (Aunt, Friend, Gurdian, Employer)	6(2.0)
	Not indicated	14(4.6)

Table 2: Antiretroviral therapy (N=303).

Characteristic		Frequency [n(%)]
Regimen	First line AF2E	48(15.8)
	TDF/3TC/DTG or TLD/TDL	221(72.9)
	TLD/CPT	3(1.0)
	TDF/3TC/EFV or TLE	2(0.7)
	ABC/3TC/DTG	1(0.3)
	Second line [TDF/3TC/ATV/r]	8(2.6)
	TDF/3TC/LPV/r	4(1.3)
	ABC/3TC/ATV/r	3(1.0)
	AZT/3TC/ATV/r	13(4.3)
Regimen	First line	275(90.8)
	Second line	28(9.2)
Duration of ARV use	Short term (<=3 years)	38(12.5)
	Medium term (>3-5 years)	29(9.6)
	Long term >5-10 years	99(32.7)
	Long term >10 years	137(45.2)

Ever changed ARVs?	Yes	253(83.5)
	No	50(16.5)
Reasons for changing ARVs (N=253)	Government directive/Optimization	185(73.1)
	New drug available/Substitution/Switch	28(11.1)
	Treatment failure	15(5.9)
	Virological failure	4(1.6)
	Out of stock	7(2.8)
	Others #1	4(1.6)
Times have changed ARVs (N=253)	1	216(85.4)
	2	22(8.7)
	3 plus	15(5.9)
How often take ARVs	Once	285(94.1)
	Twice	18(5.9)
Times missed ARV doses	None	242(79.9)
	1	31(10.2)
	2	16(5.3)
	3 plus	14(4.6)
Reasons for missing daily ARV dose (N=61)	None/No reason given	9(14.8)
	Forgot to take ARVs	15(24.6)
	Travelled and forgot ARVs	10(16.4)
	Busy with work	9(14.8)
	Stigmatization	4(6.6)
	Stress/Family stress	3(4.9)
	Domestic issues/Violence	3(4.9)
	Sick/Unwell	3(4.9)
	Others #2	5(8.2)

Others#1: Toxicity (1 case), Restart after lost to follow up (1), Anemia & neuropathy (1), Enlargement of breasts (1). Others#2: Missing appointment, forgetting appointments dates, Ran out of drugs, Pill burden, Time inconvenience (1 each).

Association of ART with SARS-CoV-2 infections or COVID-19 severity

A higher proportion of those infected had missed ARV doses (35.7% vs. 18.5%, $p=0.031$). ART regimen and viral load showed no statistical significant correlation with COVID-19 infection ($p>0.05$). The prevalence of infection was disproportionately higher among the vaccinated (100% vs. 85.1%, $p=0.014$). Duration of ARV use could not be reliably assessed due to invalid Chi-square assumptions (Table 3a).

Association of ART with COVID-19 severity

COVID-19 severity was based on signs & symptoms with the following classification: 1. Mild (Asymptomatic & tested positive, experiencing fever, cough, and fatigue); 2. Moderate (difficulty breathing or mild pneumonia); and 3. Severe (severe pneumonia, other organ failure). Association of Covid-19 severity with ART, Viral load and Covid-19 vaccination could not be established due to violation of conditions for Chi-square validity, Table 3b.

Table 3a: Association of ART with Sars-cov-2 infections (N=303).

Characteristic		Total N=303 %	Covid-19 infections		P- value
			Yes (N=28) %	No (N=275) %	
ART regimen	First line	90.8	89.3	90.9	0.492
	Second line	9.2	10.7	9.1	
		8	2.6		
Ever missed dosage	Yes	20.1	35.7	18.5	0.031
	No	79.9	64.3	81.5	
Duration of ARV use	Short term (<=3 years)	12.5	14.3	12.4	N.V.#
	Medium term (>3-5 years)	9.6	10.7	9.5	
	Long term >5-10 years	32.7	17.9	34.2	
	Long term >10 years	45.2	57.1	44.0	
Viral load		N=114	N=7	N=107	
	<200 copies/LDL*	91.2	85.7	91.6	0.484
	≥ 200 copies	8.8	14.3	8.4	
Covid-19 vaccination		N=303	N=28	N=275	
	Yes	86.5	100	85.1	0.014
	No	13.5	0	14.9	

*LDL = Less than detectable limit; *N.V. = Chi-square not valid.

Table 3b: Association of ART with Covid-19 severity (N=303).

Characteristic	Total N=303 %	Covid-19 severity			P- value
		No infection (N=275) %	Mild (N=25) %	Moderate (N=3) %	
ART regimen					
First line	90.8	90.9	88.0	100	N.V.#
Second line	9.2	9.1	12.0	0	
Ever missed dosage					
Yes	20.1	18.5	32.0	66.7	N.V.
No	79.9	81.5	68.0	33.3	
Duration of ARV use					
Short term (<=3 years)	12.5	12.4	12.0	33.3	N.V.
Medium term (>3-5 years)	9.6	9.5	12.0	0	
Long term >5-10 years	32.7	34.2	16.0	33.3	
Long term >10 years	45.2	44.0	66.0	33.3	
Viral load					
<200 copies/LDL*	N=114	N=107	N=5	N=2	
≥ 200 copies	91.2	91.6	100	50.0	N.V.
	8.8	8.4	0	50.0	
Covid-19 vaccination					
Yes	N=303	N=275	N=25	N=3	N.V.
No	86.5	85.1	100	100	
	13.5	14.9	0	0	

*LDL = Less than detectable limit; *N.V. = Chi-square not valid.

Discussion

Sociodemographic characteristics

The study population consisted predominantly of women (70.6%). This gender pattern is consistent with HIV treatment programs

in Sub-Saharan Africa, where uptake among men is low in HIV care and prevention services, while women are highly likely to obtain the services due to increased health-seeking behaviour and linkage through prenatal and Prevention of Mother-To-Child Transmission (PMTCT) services [15]. This reviews the need for gender responsive interventions that focus on male engagement in HIV programs, including tailored health messaging, male-friendly clinic models, and community outreach through community social workers (CSW) [16]. Most Participants (77.2%) were aged 25–54 years, which aligns with national age distribution among PLA in Kenya; according to Kenya Population-based HIV Impact Assessment (KENPHIA), the prevalence of HIV was shown increases with age up to 45–49 years, with significant prevalence persisting in the 50–54-year age band [17,18]. John J, found higher COVID-19 infection odds showed an inverse relationship with younger age, specific racial groups, and geographic location, rather than viral load [19]. H. Noureldine, similarly found young age were a predictor of COVID-19 infection among people living with HIV [20]. Age can also influence vaccine response and comorbidity profiles, which are critical considerations for COVID-19 outcomes. Approximately half participants were married (46.8%), and 17.5% were widowed. Evidence in literature review show that marital status influences ART adherence through social support, where partnered individuals tend to have better adherence and improved treatment [21]. Widowhood in PLWH may reflect HIV-related spousal mortality coupled with psychological effects, stigma, including reduced support and health-seeking behaviour [22].

ART History and Adherence

Most participants (90.8%) were on first-line ART, and the majority were on DTG-based regimens (72.9%), consistent with Kenyan Ministry of Health and WHO recommendations prioritising Dolutegravir [23]. This drug is preferred due to its high genetic barrier to resistance, tolerability, and favourable immune reconstitution profiles [19]. Earlier studies suggested a potential protective effect of Tenofovir disoproxil fumarate (TDF) against SARS-CoV-2 due to its antiviral properties, but newer evidence shows no meaningful reduction in COVID-19 acquisition solely due to ART regimen type [24,25]. Our study supports this updated evidence since no significant statistical association was found between regimen type and COVID-19 infection.

Prolonged ART use was common among 45.2% of participants on treatment for >10 years. Prolonged ART exposure is correlated with elevated risk of comorbidities that influence COVID-19 outcomes, including metabolic diseases and cardiovascular complications [26]. Sustained ART use is reported to improve viral suppression, immune recovery and survival [25]. Although our data suggested an increased proportion of COVID-19 cases among those with over 10 years on ART, this association could not be statistically confirmed due to test validity limitations. Limited information is available correlating the duration on ART and COVID-19 infection. However, growing literature suggests that HIV status does not increase COVID-19 risk. Rowena Johnston found no difference between hospitalization or death in people with HIV

and from the general population [27]. Sandeep Prabhu specifically noted no evidence of higher COVID-19 prevalence among HIV patients [28], and J. Del Amo concluded that HIV infection is not associated with SARS-CoV-2 infection when socioeconomic factors are considered [29]. A robust sample size could showcase whether chronic comorbidity related to long-term ART has a modifying effect on COVID-19 risk.

We established that adherence played a critical role: 35.7% of COVID-19-infected participants reported missed doses, compared to 18.5% in the uninfected ($p=0.031$). ART interruptions increase immune dysregulation and raise vulnerability to infections, including respiratory viral diseases [30]. Recent empirical data indicates that even short-term adherence lapses during the COVID-19 pandemic resulted in poorer immune markers and increased symptomatic disease among PLWH [31]. Strategies to strengthen adherence—including reminder systems and integrated psychosocial support—remain critical in pandemic contexts.

Viral Load and Immune Status

Although viral load burden was not significantly associated with COVID-19 infection ($p=0.484$), the direction of effect (higher infection among those with ≥ 200 copies/mL) suggests immune status remains relevant. This concurs with global findings that PLWH with unsuppressed viral loads or low CD4 counts have poorer COVID-19 outcomes than those with stable suppression [30]. The lack of significant association in this study likely reflects the small subsample with viral load data and the suppression rate (91.2%), limiting statistical power. However, comparable findings have been documented in earlier studies, by M. Folayan supporting the possibility that the observed lack of association may reflect a true underlying trend rather than a methodological limitation [32]. Xueying Yang noted that while viral suppression was statistically associated with reduced hospitalization, the relationship was complex [33].

COVID-19 Vaccination and Infection

Contrary to expectations, all individuals who reported COVID-19 infection were vaccinated, compared to 85.1% among those not infected ($p=0.014$). This paradox is supported by real-world evidence showing that COVID-19 vaccination prevents severe disease, not necessarily infection, especially with circulating variants that escape immune protection [34]. Vaccinated individuals may also be more likely to seek testing and report symptoms. Moreover, increased vaccine uptake in Kenya coincided with waves of variant-driven transmission, increasing exposure despite immunisation [35]. Importantly, the non-existence of severe cases in this study population suggests that vaccination likely reduced disease severity, despite infection [36,37].

COVID-19 Severity and ART

Most infections reported in our study were mild (89.3%) with no severe disease outcome. Statistical assessment the associations between severity, ART, viral load, and vaccination was limited due to small numbers. However, literature review, consistently

shows that PLWH with suppressed viral loads and effective ART are favourably likely to experience mild COVID-19, particularly when vaccinated [38,39]. These findings show the importance of maintaining viral suppression and integrating vaccination into routine HIV care, especially in routine clinic check-ups [40,41].

Conclusion

This study provides specific evidence on the relationship between ART use, immune status, and COVID-19 outcomes among PLWA in Kenya. While ART regimen type was not protective against SARS-CoV-2 infection, adherence emerged as a critical determinant. Higher infection rates were significantly associated with missed doses. This study re-emphasizes the importance of consistent ART use for effective immune resilience and reducing susceptibility to respiratory viral infections. Despite a low rate of breakthrough infections, it was confirmed that the COVID-19 vaccination prevented illness, with all infected subjects experiencing mild symptoms and no severe cases. More mild clinical courses were seen when viral suppression, long-term access to ART, and increased vaccination coverage within the HIV care program were combined. Strong adherence support, ongoing access to ART, and complete integration of COVID-19 vaccination into routine HIV services are still crucial for preparing PWH for future respiratory epidemics.

Organizations should focus on enhancing ART adherence support through the use of digital adherence interventions, peer-led counseling, education, and counseling for care or treatment supporters, and reminder tools. To boost SARS-CoV-2 vaccine uptake and prevent severe disease onset, COVID-19 vaccination (e.g., “one-stop-shop” models) should be expanded in the routine HIV care setting. Maintaining services during public health emergencies is crucial, such as multi-month ART, home-based drug delivery, and the use of emergency treatment refills to avoid disruptions in care. Increased availability of immunologic monitoring (CD4 count and viral load) can be used to identify high-risk individuals and for focused management. Increasing male participation in HIV care requires gender-responsive strategies.

Implications

To find out how long-term ART exposure, comorbidities, and changing SARS-CoV-2 variants affect clinical outcomes in HIV-affected populations, particularly in low-income settings, larger prospective studies are needed. The results of the study demonstrate the ongoing significance of strong HIV care systems in safeguarding PWH during concurrent medical crises. SARS-CoV-2 infection risk was found to be primarily determined by adherence rather than the type of ART regimen, highlighting the need for continuous ART access and focused adherence support. The fact that the majority of vaccinated individuals had mild COVID-19 illness highlights the protective value of including regular immunization services in HIV initiatives. These results are especially pertinent to health systems in high-HIV-burden, resource-constrained areas where service interruptions can rapidly reverse HIV control gains and increase vulnerability to new infections.

Strengths and Limitations

Strengths

The study sites that cut across three Kenyan counties where targeted, this increased generalizability to diverse HIV care settings in Kenya. Another strength is the inclusion of ART history, adherence, viral load, CD4 markers, and vaccination which enabled a comprehensive analysis of determinants of COVID-19 outcomes among PWH. In addition real-world clinic data from the study, generates actionable insights that enhance the relevance and effectiveness of policy and program implementation

Limitations

The retrospective design used in the study limits causal inference and depends on accuracy of clinical records. An example is the viral load data which were only available for a subset of participants, reducing power to evaluate immune status associations. The small number of COVID-19 cases restricted statistical assessment of disease severity and subtype specific outcomes. We relied on self-reported adherence and vaccination histories, which may be subject to recall or may have led to reporting biasness.

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