

# Immuno-Virological Follow-Up in HIV Patients under Antiretroviral Treatment in Medical Biology Laboratory of Point G University Hospital, Bamako, Mali

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## Abstract

**Purpose:** Our study consisted in monitoring the viral load and CD4 count of people living with HIV/AIDS under antiretroviral treatment (ART) who came for biological follow-up at the Point G Hospital biomedical laboratory, then to describe the sociodemographic and clinical characteristics of these patients, and finally to establish a correlation between the viral load and the sociodemographic and clinical characteristics of these cases. **Methods:** It was a cross-sectional study with prospective recruitment from January to December 2024, conducted at the Point G Hospital biomedical laboratory. The study population included people living with HIV/AIDS who presented to the laboratory for a biological follow-up testing for ART. In particular, measurement of HIV viral load and CD4 count. Data were collected using individual patient data collection designed for the needs of the study. **Results:** The study involved 82 patients. The survey revealed that 69.5% of the patients were women. The average age of the participants was 40.55 years, and 81.7% of them lived in Bamako. Housewives represented 46.3% of the participant. HIV-1 was the most common type of virus (98.8%), and 60.9% of the patients were

classified as stage 1 according to the WHO. The patients (96.3%) were on first-line treatment, primarily the TDF-3TC-DTG regimen (62.2%). Regarding viral load, 56.1% of patients had a viral load greater than 1000 copies/ml at inclusion, but at 6 months, 63.4% of patients had returned to a viral load below 40 copies/ml, and at 12 months, this number had risen to 86.6%. At inclusion, 24.4% of patients had a CD4 count below 500 cells/mm<sup>3</sup>. There was no significant link between the duration of ART and viral load at 6 months, but a significant link was observed at 12 months. Additionally, 81.7% of patients had good adherence to treatment, with medication errors and illnesses being the main causes of non-adherence (40% each). **Conclusion:** This study showed that the majority of our patients responded favourably to ART.

## Keywords

HIV, Treatment, Viral Load, CD4, Point G University Hospital

## 1. Introduction

Human Immunodeficiency Virus (HIV) is a retrovirus belonging to *Retroviridae* family, *Orthoretrovirinae* subfamily and *Lentivirus* genus. Two types are distinguished on the antigenicity basis: HIV-1 and HIV-2 [1] [2]. HIV-1 is widespread on all continents and is responsible for the global pandemic, while HIV-2 is found mainly in West Africa [3]. HIV-1, because of its transmissibility and pathogenicity, is more important in inducing severe immune deficiency than HIV-2 [4] [5]. HIV infection primarily targets immune system cells, weakening them against infections and certain types of cancer. In this way, reduced immune cell function leads to a progressive immune deficiency in infected patients, whose immune function is then measured by CD4 cell count [3]. Acquired immunodeficiency syndrome (AIDS) is defined as a group of infectious and/or tumoral manifestations caused by the human immunodeficiency virus (HIV). To date, there are three (03) main transmission modes: sexual transmission; transmission by exposure to blood; vertical transmission (mother-to-child transmission) [6]-[8].

HIV remains a global public health problem, resulting in 40.4 million deaths to date. At the end of December 2022, the number of people living with HIV was estimated at 39 million, and 29.8 million people had access to antiretroviral therapy. In 2022, 630,000 people died of HIV-related causes and 1.3 million were infected with HIV [9].

According to estimates, 7.7 million deaths will be added to the heavy toll of HIV infection if nothing is done in the next ten (10) years. This is why the Joint United Nations Programme on HIV/AIDS (UNAIDS) has set the new global targets 95 - 95 - 95 (increase the percentage of persons who know their HIV status, receive antiretroviral therapy, and have achieved viral suppression) to avoid the worst-case scenario [9]. At the same time, in West and Central Africa, there were 4 5.1 million [4.5 million - 5.9 million] people living with HIV, of whom 79% [61%

- 96%] had access to antiretroviral treatment, and around 190,000 [130,000 - 280,000] new HIV infections [9].

In Mali, HIV prevalence stands at 1.1%, with 110,000 people living with HIV, according to the demographic and health survey conducted by the Mali *Cellule Sectorielle de Lutte Contre le SIDA* (Coordinating Committee for HIV/AIDS) [10] [11]. The city of Bamako remains the most affected, with 1.7%. The same survey reports that women are more infected than men, with a prevalence of 1.3% versus 0.8% [10].

However, to prevent this infection progressing to AIDS, the use of ART is an indispensable tool. To achieve this, ART must render the plasma viral load undetectable. Since ART is a lifelong process, its effectiveness depends on good compliance, which is the key factor in the success or failure of treatment. Poor compliance can lead to treatment failure, worsening of the disease and recurrence of opportunistic infections. The most serious consequence of non-adherence is the emergence of ART-resistant strains, making treatment more difficult and potentially fatal for the patient [12]. Biological monitoring plays an essential role in the management of HIV infection. In untreated patients, it helps determine the right time to start antiretroviral treatment, or to begin prevention of certain infectious diseases. The follow-up of treated patients enables the efficacy and tolerance of treatment to be verified.

The complexity of HIV management with continuous multitherapy motivated us to undertake this study to determine the outcome of ART in People Living With HIV/AIDS (PLHIV) under care.

The aim was to study the monitoring of viral load and CD4 T lymphocyte count in PLHIV under ART at the medical biology laboratory in Point G Hospital in Mali.

## 2. Methods

### 2.1. Ethical Approval

The study was reviewed and approved by the ethics committee and Medical Establishment Commission (CME) of Point G University Hospital.

### 2.2. Study Design

This was a cohort study running from January to December 2024, that involved PLHIV whose samples have been received at the laboratory for ARV monitoring.

### 2.3. Study Setting and Population

Our study included people living with HIV undergoing ART whatever the therapeutic line: 1) who had undergone biological monitoring in medical biology laboratory in Point G Hospital during our study period, and 2) who had given their consent.

The following were not included in our study: 1) HIV-2-positive patients; 2) HIV-positive patients not initiated on ART; 3) all people living with HIV on ARV treatment who had not completed their biological follow-up at the biomedical

analysis laboratory of the Point G University Hospital; 4) all PLHIV on ARV treatment who had completed their biological follow-up in Point G Hospital medical biology laboratory without consent.

## 2.4. Pre-Analysis

Sampling was exhaustive and included all PLWH who met the inclusion criteria. A total volume of 4 ml of blood sample was collected from patients using EDTA tubes. Blood samples were then transported by container to the lab from the PLHIV care department within two hours of collection. Once in the lab, plasma was recovered from each sample and stored at  $-20^{\circ}\text{C}$  before processing.

## 2.5. CD4 Count Analysis

Blood part was used for CD4 count analysis, before plasma collected for viral load testing.

Samples were tested using the BD FACSCalibur<sup>TM</sup> instrument with BD Tritest<sup>TM</sup> CD3/CD4/CD45 reagent, BD Trucount<sup>TM</sup> tubes and BD Multiset<sup>TM</sup> software for AbsCD4 and %CD4 [13] [14].

## 2.6. HIV RNA Extraction

RNA was extracted and purified from 200 $\mu\text{L}$  of frozen plasma using the Abbott mSample preparation system kit (Promega corporation 2800 Woods Hollow Rd. Madison, WI 53711 USA) according to the Manufacturer's instructions. After incubating the plasma with lysis buffer (mLysis) in a  $50^{\circ}\text{C}$  water bath for 20 minutes, viral RNA is first captured in microparticles (mMicroparticles) contained in 1.5 ml tubes placed on magnetic rack, then washed four times with mWash 1 and mWash 2 buffers to obtain pure RNA. After removing the wash buffers, 1.5 ml tubes are transferred to a non-magnetic rack and then 25  $\mu\text{L}$  of mElution buffer was added and resuspend the magnetic particles. Placed the lysis tubes in the  $75^{\circ}\text{C}$  heating bath for incubation for 20 min. Tubes transferred to a non-magnetic rack, then added 63  $\mu\text{L}$  of mWash 2 solution and resuspend magnetic particles by aspiration. The tubes were placed in a magnetic rack for 1 minute and the eluate removed and transferred to a new 1.5 ml tube.

## 2.7. Master Mix Preparation

A 271  $\mu\text{L}$  volume of HIV-1 activation reagent was added to a vial of thermostable rTth DNA polymerase enzyme, followed by 949  $\mu\text{L}$  of HIV-1 oligonucleotide reagent added. The resulting master mix was transferred to a disposable tube and vortexed to homogenize. A 50  $\mu\text{L}$  volume of amplification master mix was then dispensed on to 96-well plates before adding 50  $\mu\text{L}$  of extracted samples.

## 2.8. Viral Load Analysis

Plasma specimens were prospectively tested on m2000rt RealTime systems, according to manufacturers' instructions [15].

## 2.9. Statistical Analysis

Statistical analyses were performed using SPSS version 25.0 for demographic and clinical characteristics. Relationships between categorical variables were determined using Pearson's Chi2 test; Fisher's test for theoretical numbers less than 5. To compare the means of quantitative variables across several groups, we used the Kruskal-Wallis test. The significance threshold is  $p < 0.05$ .

Odds ratios (OR) and their 95% confidence intervals (95% CI) were calculated using the Wald method, which relies on the normal approximation of the log-OR. For each  $2 \times 2$  contingency table, the OR was estimated by the cross-product ratio, and the standard error of the log-OR was calculated from the counts in the four cells. The 95% CI was then obtained by exponentiating the lower and upper bounds of the log-OR.

When a cell in the table contained a zero count, making the OR impossible or infinite to calculate, a Haldane correction was applied by adding 0.5 to each of the four cells. This correction allows a finite estimate of the OR and its CI to be obtained, while remaining interpretable in the context of small sample sizes.

## 3. Results

### 3.1. Demographic and Clinical Characteristics

Our study included 82 PLHIV who met our inclusion criteria. Demographic and clinical characteristics of study participants are summarized in **Table 1**. Females were more represented in our study (69.5%), with a sex ratio 0.4. The age group [39 - 48] was the most represented, at 32.9%. The average age was  $40.55 \pm 10.7$  years, with extremes of 19- and 67-years (**Figures 1-2**). Majority of patients (81.7%) lived in Bamako. Regarding participant's occupation, we found that housewife (46.3%) were the most represented followed workmen (17.1%) and trader (17.1%). According to clinical characteristics, HIV-1 was found in 98.8% of cases and over half the patients (60.9%) were classified as WHO stage 1. Almost all patients (96.3%) were on first-line therapy. Tenofovir disoproxil fumarate-Lamivudine-Dolutegravir (TDF-3TC-DTG) regimen was the most widely used, at 62.2%. The majority of patients (46.3%) had completed 12 months (M12) of ARV treatment. we found that 84.1% of patients had no previous hospitalization. More than half the patients (64.6%) had no associated pathologies at the time of the survey. Most patients (81.7%) had good compliance with ART. Medication errors and illness were the most common causes of non-compliance (40%).

**Table 1.** Sociodemographic and clinical characteristics of PLHIV.

| Parameters N = 82 | Values | Frequency (%) |
|-------------------|--------|---------------|
| <b>Residence</b>  |        |               |
| Bamako            | 67     | 81.7          |
| Outside Bamako    | 15     | 18.3          |
| <b>Occupation</b> |        |               |

## Continued

|                                 |    |      |
|---------------------------------|----|------|
| Housework                       | 38 | 46.3 |
| Worker                          | 14 | 17.1 |
| Shopkeeper                      | 14 | 17.1 |
| Government employee             | 13 | 15.9 |
| Student                         | 2  | 2.4  |
| Driver                          | 1  | 1.2  |
| <b>HIV type</b>                 |    | 3.34 |
| HIV-1                           | 81 | 98.8 |
| HIV-1+2                         | 1  | 1.2  |
| <b>WHO stage</b>                |    | 0.92 |
| Stage 1                         | 50 | 60.9 |
| Stage 2                         | 9  | 11.0 |
| Stage 3                         | 14 | 17.1 |
| Stage 4                         | 9  | 11.0 |
| <b>Therapeutic line</b>         |    |      |
| First line                      | 79 | 96.3 |
| Second line                     | 3  | 3.6  |
| <b>Treatment plan</b>           |    | 8.35 |
| TDF-3TC-DTG                     | 51 | 62.2 |
| TDF-3TC-EFV                     | 27 | 32.9 |
| ZDV-3TC-ATV/r                   | 2  | 2.5  |
| TDF-3TC+ATV/r                   | 1  | 1.2  |
| -3TC-LPV/r                      | 1  | 1.2  |
| <b>Duration of treatment</b>    |    | 4.33 |
| 12-Months                       | 38 | 46.3 |
| Between 1 and 5 years old       | 23 | 28.0 |
| >5 years                        | 21 | 25.7 |
| <b>Previous hospitalization</b> |    |      |
| Yes                             | 13 | 15.9 |
| No                              | 69 | 84.1 |
| <b>Related conditions</b>       |    | 0.03 |
| Yes                             | 29 | 35.4 |
| No                              | 53 | 64.6 |
| <b>Adherence</b>                |    | 0.19 |
| Good                            | 67 | 81.7 |
| Bad                             | 15 | 18.3 |
| <b>Non-compliance Reasons</b>   |    |      |

**Continued**

|                       |   |      |
|-----------------------|---|------|
| Medication error      | 6 | 40   |
| Disease               | 6 | 40   |
| Side effects          | 2 | 13.3 |
| Geographical location | 1 | 6.7  |

**TDF:** Ténofovir Disoproxil Fumarate; **DTG:** Dolutégravir; **LPV/r:** Lopinavir/ritonavir; **ATV:** Atazanavir; **ATV/r:** Atazanavir/ritonavir; **3TC:** Lamivudine; **EFV:** Efavirenz; **ZDV/AZT:** Zidovudine.

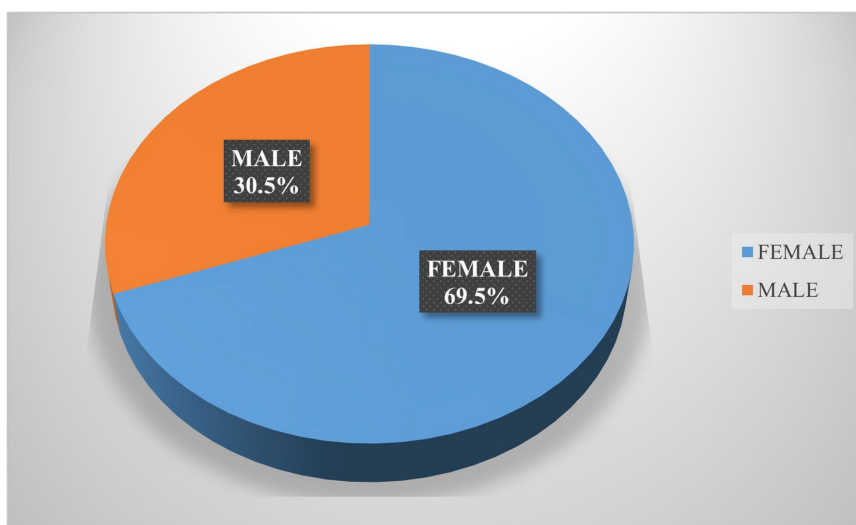


**Figure 1.** Distribution of patients by gender.

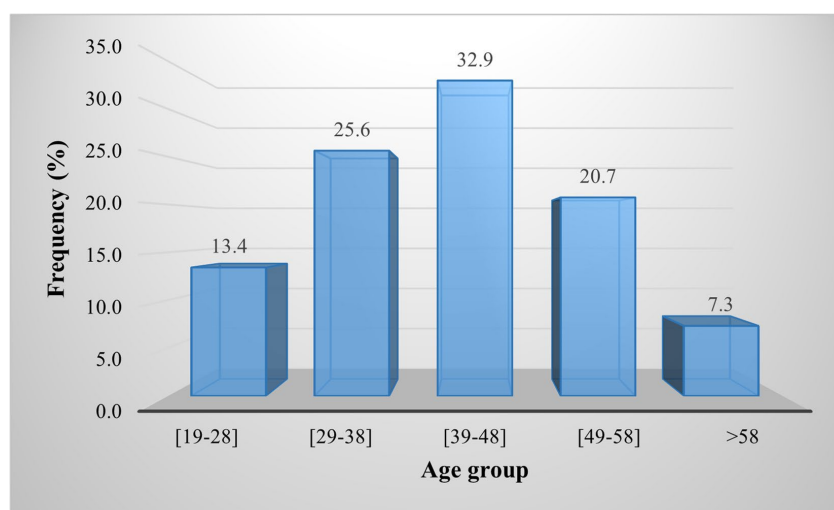


**Figure 2.** Distribution of patients by age group.

### 3.2. Immunological-Virological Characteristics

At inclusion (M0), 56.1% of patients had a viral load >1000 copies/ml. After 6 months (M6) of ARV treatment, 63.4% of patients had a viral load <40 copies/ml. However, at M12 treatment, 86.6% of patients had a viral load <40 copies/ml.

Regarding CD4 count, 24.4% of patients had a CD4 count < 500 Cell/mm<sup>3</sup> at treatment inclusion. At M6 of treatment, 9.7% of patients had a CD4 count >500 Cell/mm<sup>3</sup>. Moreover, at M12 of treatment, 7.3% of patients had a CD4 count >500 Cell/mm<sup>3</sup> (**Table 2**).

**Table 2.** Immunological-virological characteristics of PLHIV.

| Parameters N = 82                              | Values | Frequency (%) |
|------------------------------------------------|--------|---------------|
| <b>Viral load at M0 (copies/mL)</b>            |        |               |
| <40                                            | -      | -             |
| 40 - 1,000                                     | 36     | 43.9          |
| >1,000                                         | 46     | 56.1          |
| <b>Viral load at M6 (copies/mL)</b>            |        |               |
| <40                                            | 52     | 63.4          |
| 40 - 1,000                                     | 10     | 12.2          |
| >1,000                                         | 20     | 24.4          |
| <b>Viral load at M12 (copies/mL)</b>           |        |               |
| <40                                            | 71     | 86.6          |
| 40 - 1,000                                     | 4      | 4.9           |
| >1,000                                         | 7      | 8.5           |
| <b>CD4 count at M0 (cells/mm<sup>3</sup>)</b>  |        |               |
| <500                                           | 20     | 24.4          |
| >500                                           | 9      | 11.0          |
| Not completed                                  | 53     | 64.6          |
| <b>CD4 count at M6 (cells/mm<sup>3</sup>)</b>  |        |               |
| <500                                           | 5      | 6.1           |
| >500                                           | 8      | 9.8           |
| Not completed                                  | 69     | 84.1          |
| <b>CD4 count at M12 (cells/mm<sup>3</sup>)</b> |        |               |
| <500                                           | 3      | 3.6           |
| >500                                           | 6      | 7.3           |
| Not completed                                  | 73     | 89.0          |

M0 = 0-Months; M6 = 6-Months; M12 = 12-Months.

### 3.3. Relationship between Sex, Treatment Duration, and Viral Load

According to the distribution of viral load based on treatment duration, no statistics were calculated because viremia was constantly detectable at M0. We found no statistically significant association between sex, treatment duration, and viral load at M0 and M6 of treatment ( $p = 1$ ;  $p = 0.6$ ;  $p = 0.7$ ) (**Tables 3-4**). Furthermore, no significant association was found between sex, treatment regimen, and viral load at M12 of treatment ( $p = 1$ ). However, treatment duration was found to be significantly associated with viral load at M12 of treatment ( $p = 0.03$ ) (**Table 5**).

**Table 3.** Viral load at M0 by treatment duration, sex, and treatment regimen of PLHIV.

| Parameters                       | Viral load detected at M0 (copies/mL) (%) | Viral load not detected at M0 (copies/mL) (%) | P value | OR (95% CI)        |
|----------------------------------|-------------------------------------------|-----------------------------------------------|---------|--------------------|
| <b>Duration of ARV Treatment</b> |                                           |                                               | -       | NA                 |
| 12-Months                        | 38 (46.3)                                 | -                                             |         |                    |
| 1 - 5 years                      | 23 (28)                                   | -                                             |         |                    |
| >5 years                         | 21 (25.7)                                 | -                                             |         |                    |
| <b>Sex</b>                       |                                           |                                               | 1       | 1.01 (0.39 - 2.59) |
| Male                             | 14 (30.4)                                 | 11 (30.6)                                     |         |                    |
| Female                           | 32 (69.6)                                 | 25 (69.4)                                     |         |                    |
| <b>Therapeutic line</b>          |                                           |                                               | 0.6     | 0.38 (0.03 - 4.35) |
| First line                       | 45 (97.8)                                 | 34 (94.4)                                     |         |                    |
| Second line                      | 1 (2.2)                                   | 2 (5.6)                                       |         |                    |

Viral load detection at M0 according to ARV treatment duration, sex, and therapeutic line. At M0, all patients (100%) had detectable viral load, so no OR could be calculated for treatment duration. Sex was not associated with viral load detection at M0 (OR = 1.01; 95% CI: 0.39 - 2.59;  $p = 1$ ). Similarly, therapeutic line was not significantly associated with viral load detection (OR = 0.38; 95% CI: 0.03 - 4.35;  $p = 0.6$ ), although the very small number of patients on second-line therapy ( $n = 3$ ) limits interpretation.

**Table 4.** Viral load at M6 by treatment duration, sex, and treatment regimen of PLHIV.

| Parameters                       | Viral load detected at M6 (copies/mL) (%) | Viral load not detected at M6 (copies/mL) (%) | P value | OR (95% CI)         |
|----------------------------------|-------------------------------------------|-----------------------------------------------|---------|---------------------|
| <b>Duration of ARV Treatment</b> |                                           |                                               | 0.6     | 0.95 (0.32 - 2.72)  |
| 12-Months                        | 14 (50.0)                                 | 24 (44.5)                                     |         |                     |
| 1 - 5 years                      | 6 (21.4)                                  | 17 (31.5)                                     |         |                     |
| >5 years                         | 8 (28.6)                                  | 13 (24)                                       |         |                     |
| <b>Sex</b>                       |                                           |                                               | 0.5     | 0.57 (0.20 - 1.63)  |
| Male                             | 8 (32)                                    | 17 (68)                                       |         |                     |
| Female                           | 12 (21)                                   | 45 (79)                                       |         |                     |
| <b>Therapeutic line</b>          |                                           |                                               | 0.7     | 0.41 (0.01 - 15.16) |
| First line                       | 20 (25)                                   | 59 (75)                                       |         |                     |
| Second line                      | 0 (0.0)                                   | 3 (100)                                       |         |                     |

None of the variables were significantly associated with viral load detection at M6. Women had a non-significant lower odds of detectable viral load compared to men (OR = 0.57; 95% CI: 0.20 - 1.63;  $p = 0.5$ ). Similarly, treatment duration was not significantly associated with viral load detection (12 months vs > 5 years: OR = 0.95; 95% CI: 0.32 - 2.72;  $p = 0.6$ ). No patient on second-line therapy had detectable viral load, but the very small sample size ( $n = 3$ ) precludes any conclusion (OR = 0.41; 95% CI: 0.01 - 15.16;  $p = 0.7$ ).

**Table 5.** Viral load at M12 by treatment duration, sex, and treatment regimen of PLHIV.

| Parameters                       | Viral load detected at M12 (copies/mL) (%) | Viral load not detected at M12 (copies/mL) (%) | p value | OR (95% CI)         |
|----------------------------------|--------------------------------------------|------------------------------------------------|---------|---------------------|
| <b>Duration of ARV Treatment</b> |                                            |                                                | 0.03    | 8.60 (0.46 - 160.8) |
| 12-Months                        | 6 (75)                                     | 32 (43.2)                                      |         |                     |
| 1 - 5 years                      | 2 (25)                                     | 0 (00.0)                                       |         |                     |
| >5 years                         | 0 (00.0)                                   | 21 (28.4)                                      |         |                     |
| <b>Sex</b>                       |                                            |                                                | 1       | 1.11 (0.20 - 6.12)  |
| Male                             | 2 (8)                                      | 23 (92)                                        |         |                     |
| Female                           | 5 (9)                                      | 52 (91)                                        |         |                     |
| <b>Therapeutic line</b>          |                                            |                                                | 1       | 1.38 (0.07 - 29.4)  |
| First line                       | 7 (9)                                      | 72 (91)                                        |         |                     |
| Second line                      | 0 (00.0)                                   | 3 (100)                                        |         |                     |

Viral load detection at M12 according to ARV treatment duration, sex, and therapeutic line. Treatment duration was significantly associated with viral load detection ( $p = 0.03$ ): no patient treated for > 5 years had detectable viral load at M12, compared with 6/38 (75%) at 12 months and 2/2 (100%) at 1 - 5 years. However, the very small sample size in the 1 - 5 year group ( $n = 2$ ) makes the OR estimate highly unstable (OR = 215; 95% CI: 3.45 - 13,400). Sex and therapeutic line were not significantly associated with viral load detection at M12.

#### 4. Discussion

The large-scale establishment of care centers for people living with HIV/AIDS through antiretroviral therapy has contributed to one of the greatest successes of Mali's HIV response program in recent years. It has been consistently reported that ART suppresses HIV RNA to levels below the detection threshold and reduces clinical progression risk [16] [17]. Despite these advances, treatment failures due to HIV drug resistance, compounded by poor adherence, pose a major challenge for the ART program. That is why the WHO recommends regular monitoring of viral load and CD4 T-cell counts as part of antiretroviral therapy.

In this study, we conducted a longitudinal study to assess viral load and CD4 T-cell counts in people living with HIV who are on antiretroviral therapy.

This study found that 69.5% of the patients were female, with a male-to-female sex ratio of 0.4. These results are consistent with those reported by Zenash *et al.* in Ethiopia [18] and Zoungrana *et al.* in Burkina Faso [19], who also observed an overrepresentation of women in their cohorts 69.9% and 65.1%, respectively with sex ratios of 0.4 and 0.5. These results could be explained by the particular vulnerability of women especially to sexually transmitted infections such as HIV/AIDS in the African region, which, according to the WHO, is the hardest-hit region. Furthermore, women seek medical care more often than men, whether for

gynecological issues or reproductive health concerns, which makes them more likely to undergo HIV testing. However, other studies, such as the one by Jacomet *et al.* [20], conducted in France, show a predominance of males (68%), which may be explained by cultural differences between the two populations studied.

The [39 - 48] age group was the most represented, accounting for 32.9% of the sample. The mean age was  $40.55 \pm 10.7$  years, with ages ranging from 19 to 67 years. Mean ages vary across studies but tend to fall within a similar range, reflecting the working-age population most affected by the epidemic. Mouhari Touré *et al.* found similar results in their study in Togo, with a median age of 35 but a female prevalence of 68.6% [21]. Another study conducted in Togo by Potchoo *et al.*, which aimed to assess adherence to antiretroviral therapy among PLHIV, showed a median age similar to ours (36.8%) and the same age group most affected by the infection, but with a higher percentage: 83.7% compared to 32.9% in our study [22]. The majority of patients lived in Bamako (81.7%). The predominance of urban residents in our study likely reflects better access to care in urban areas compared to rural areas, where medical infrastructure may be inadequate. These results are similar to those reported by Sissoko in Mali in 2024 [23], where nearly all of these patients lived in Bamako (97.03%).

Although HIV infection is often diagnosed at advanced clinical stages 3 and 4, according to some authors, as reported by Lewden *et al.* [24] and Willy S. David *et al.* [25], the majority of patients included in the study were in clinical stage 1 of the WHO classification (60.9%). The diagnosis and management of HIV infection are reportedly occurring at an increasingly early stage, thanks to the nationwide adoption of the WHO's "test and treat" recommendations, which are included in the document outlining national standards and protocols for the management of HIV infection. The implementation of this protocol in Mali could also explain why the majority of our patients received therapy based on the tenofovir-lamivudine-dolutegravir combination in 62.2% of cases, followed by the Tenofovir-Lamivudine-Efavirenz combination (32.9%). These results are consistent with those reported by Sall *et al.* in 2023 in Mali, where a combination of Tenofovir-Lamivudine-Dolutegravir is used in 80.3% of cases, which constitutes the first-line treatment in Mali [26]. Nearly all of the subjects in the studies were HIV-1-positive (98.8%); HIV-1+2 was present in 1.2% of cases. This distribution is consistent with the findings reported by Sall in 2023 [26]. This finding is consistent with data from the literature, which indicate that HIV-1 is more prevalent worldwide than HIV-2, particularly in sub-Saharan Africa [27].

The results of this study show that at enrollment, 56.1% of patients had a viral load  $> 1,000$  copies/mL, compared with 24.4% after 6 months of treatment. Indeed, 63.4% of patients had a viral load  $< 40$  copies/mL at M6, and nearly all (86.6%) patients had a viral load  $< 40$  copies/mL which means, undetectable at M12 of treatment. This gradual decrease in viral load leading to virologic suppression demonstrates the effectiveness of the treatment protocols implemented in Mali since 2019 in accordance with WHO recommendations [12]. A significant

correlation was observed between treatment duration and viral load at M12 ( $p = 0.03$ ). Virologic suppression was greater with longer treatment duration. This is consistent with the study by Calmy *et al.* [28], which reported virologic suppression in 88% of patients on the TDF-3TC-DTG regimen after 93 months of treatment. A study conducted in Mali initially included patients with a viral load  $> 1,000$  copies/mL, who accounted for 64.36% of cases. At M6 and M12, this rate had decreased by 8.91% and 5.94%, respectively [23]. However, a Kenyan study reported a viral suppression rate (72%) even with lower adherence. However, a Kenyan study reported a viral suppression rate (72%) even with lower adherence [29]. The differences could be attributed to the quality of follow-up, adherence strategies, and the prevalence of pre-existing ART resistance. The predominant use of the TDF-3TC-DTG regimen (62.2% in our study) is a strength, as this treatment is associated with high rates of virologic suppression, as has also been reported [30].

With regard to CD4 counts, only 7.3% of patients had a count  $> 500/\text{mm}^3$  after M12 of treatment. This result is lower than that reported by Sarıgül Yıldırım *et al.*, [31], who found a significant increase in CD4 counts to  $> 500/\text{mm}^3$  in 90% of patients after one year. As reported by E. Lozès *et al.* [32] in their study, approximately 9 out of 10 HIV-positive patients were immunocompromised at the start of ART; 87.7% of these, including (20.3%), were severely immunocompromised. These differences may be due to the high proportion of tests not performed in our study (at M6 and M12), which could limit the interpretation of the results. Local factors such as the quality of follow-up due to patients missing appointments or the lack of centralized data on patients living with HIV who are followed at Point G University Hospital.

## 5. Conclusion

Overall, our study found a low level of achievement of CD4 counts. At the conclusion of our study, 86.6% of our patients responded favorably to ART. Nevertheless, efforts to improve comprehensive care could enhance these results. Good treatment adherence remains a key factor in the success of ART and, consequently, prevents treatment failure and the emergence of strains that are multidrug-resistant to antiretrovirals.

## Abbreviations

**AIDS:** Acquired Immunodeficiency Syndrome, **ART:** Antiretroviral therapy, **ARV:** Antiretroviral, **CD:** Cluster of Differentiation, **DTG:** Dolutégravir, **EDTA:** Ethylenediaminetetraacetic acid, **HIV:** Human Immunodeficiency Virus, **PLHIV:** People living with HIV, **RNA:** Ribonucleic acid, **3TC:** Lamivudine, **TDF:** Ténofovir Disoproxil Fumarate, **WHO:** World Health Organization.

## Author Contributions

All authors read and approved the final manuscript. Study concept and design:

MTD, AM, BS, DK, Clinical and pathological data: YC, Data analysis and interpretation: MTD, BS, DK, Writing of the manuscript: MTD, AM, BS, DK Critical review of the manuscript for significant intellectual content: YK, DMC, MAB, MM, AIM, OAD, FC.

## Ethics Approval

We obtained prior approval from the department head, the ethics committee, and the Medical Institution Committee (CME) of Point-G University Hospital, Bamako. This study was conducted while ensuring the complete anonymity of the participants. Under no circumstances may the study data be used to formally identify a study participant.

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## Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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