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Clinical and Paraclinical Profile of People Living with Human Immunodeficiency Virus on Second Line Treatment in Kinshasa, Democratic Republic of Congo

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Abstract

Context: For the year 2018, the Provincial Division of the National Program for the Fight against HIV/AIDS and Sexually Transmitted Diseases published for the city of Kinshasa a total of 58,327 People Living with HIV (PLHIV) on Antiretroviral Treatment (ART) of which 5789 (9.9%) were on second-line ART. **Objective:** The objective of this study was to determine the clinical and paraclinical profile of people living with HIV on second-line treatment followed in Kinshasa. **Methods:** The present study was an exploratory cohort study to evaluate the profile of PLHIV on second-line of treatment in Kinshasa. All PLHIV confirmed on first-line treatment failure and second-line ART were selected for this study. The clinical and paraclinical parameters were recorded from the individual files of the patients selected on inclusion (D0) and after 6 months of treatment (M6). Viral Load (VL) determination was done by PCR on Abbott m2000rt and CD4 cell count was determined using BD Facs Count. The clinical and paraclinical parameters of M6 were compared with those taken on D0. **Results:** 50 patients were selected for this study based on the inclusion criteria. 27 patients (54%) were women. The age of the patients was between 18 and 82 years with an average of 50.5 ± 11.75 years. The dominant age group was of 46 to 55 years with 18 patients (36%). At inclusion, the mean duration of treatment under the 1st line was 35 ± 8 months of ART. Thirty-eight patients (76%) were on clinical stage 3 for HIV infection according to the World Health Organization (WHO) classification. The average patient weight on D0 was 54.36 ± 13.70 kg; the median value of CD4 was 217 cells/µl. At M6, 32 patients (64%) were in clinical stage 3; the

average patient weight was 60.34 ± 13.07 kg. The median CD4 value on M6 was 371 cells/µl. The median value of the Viral Loads (VL) of the patients was 0 RNA copies/ml. After 6 months of ART, 36 patients (72%) experienced significant weight gain; 7 patients (14%) showed an improvement in their clinical status. 41 patients (82%) had an increase in baseline CD4 count and 31 patients (62%) had a VL less than 200 RNA copies/ml. **Conclusion:** Patients on second-line ART start treatment with a significantly higher average age. Biological parameters are systematically higher in general. After 6 months of ART, the second-line ART failure rate was estimated at 38% with a population with a visible weight gain.

Subject Areas

HIV

Keywords

Antiretroviral Treatment, Second Line, HIV, Kinshasa

1. Introduction

More than thirty years after its discovery, the Human Immunodeficiency Virus (HIV) remains a public health problem throughout the world. In its 2016 annual report, the United Nations AIDS Service (UNAIDS) reports an average of 35.3 million [32.2 - 38.8 million] HIV-infected people worldwide the year and an average of 2.3 million [1.9 - 2.7 million] new cases for the same year. Sub-Saharan Africa still bears the greatest burden of the global epidemic. More than 60% of all adults and children living with HIV in the world were in sub-Saharan Africa. More than 30% of all people living with HIV (PLHIV) in the world were in Southern Africa and nearly 34% of all deaths from Acquired Immune Depression Syndrome (AIDS) were found there [1].

The Democratic Republic of Congo (DRC) is one of the countries with stable seroprevalence for HIV infection. The prevalence of infection was 1.2% for the country and 1.6% for Kinshasa according to the report of the Demographic Study of Health in 2014 (EDS-2014) [2]. According to the calibrations made on the basis of Spectrum 5.41 software for 2016, the number of PLHIV, for the year 2016, was estimated at 381,187 PLHIV, of whom 121,762 (28.76%) were on Antiretroviral Treatment (ART) within that period [3] [4]. For the year 2018, the Provincial Division of the National Program for the Fight against HIV/AIDS and Sexually Transmitted Diseases (PNLS) published for Kinshasa in its programmatic report a total of 58,327 PLHIV on ART of which 5789 (9.9%) were on second-line ART [5].

The objective of this study was to determine the clinical and paraclinical profile of people living with HIV on second-line treatment followed in Kinshasa.

2. Methods

2.1. Frame

The present study was an exploratory cohort study to evaluate the profile of PLHIV on second line of treatment followed in an Ambulatory Treatment Center (ATC) in Kinshasa from June to December 2015. The second-line treatment used for all patients was a combination of Lamivudine (3TC), Tenofovir (TDF) and Lopinavir boosted with Ritonavir (LPV/r) which was the recommended combination for second-line ART by the national program for the country [3].

2.2. Study Population

PLHIV confirmed on first-line treatment failure and second-line ART treatment were selected for this study. The failure of first-line treatment was recorded based on the virological, immunological and clinical facts. A total of 50 randomly selected patients were included in the study. All the included patients were starting the second-line ART after treatment failure, they were older than 18 years, and signed a consent form. The treatment failure was based on CD4 cells count, on Viral Load results and on clinical appreciation from the medical team.

2.3. Clinical and Biological Monitoring

The clinical and paraclinical parameters were recorded from the individual patient files of the selected patients available in the ATC as well as from the survey forms previously tested. The Viral Load (VL) determination was done by PCR using the Abbott Real Time HIV-1 assay on the Abbott m2000rt. The CD4 lymphocyte count was done using the BD Facs Count.

Patient data and blood samples were collected at the inclusion (D0) and after 6 months (M6) of second-line ART.

2.4. Comparison of Variables

The clinical and paraclinical parameters (CD4 count, Viral Load and Clinical stage) on the 6thmonth of treatment were compared with those recorded at the beginning of the cohort at baseline to determine the evolution of patients on second-line ART. For compliance, the clinical parameters were evaluated according to the World Health Organization (WHO) classification; paraclinical examinations were performed in the same laboratories and under the same conditions.

2.5. Statistics

The collected data were entered on Excel sheets and interpreted with the SPSS 20.0 software. The qualitative values were described by calculating the numbers while the quantitative variables by calculating the medians because the distributions of the data were not Gaussian. The probability threshold of $p < 0.05$ was considered significant.

2.6. Ethical Clearance

The present study had received the consent of the ethical comity. The center where the study was conducted also gave its consent. Each patient had signed a consent form prior to being included in the study.

2.7. Operational Definitions [6] [7] [8]

ART Clinical failure is based on the reappearance of opportunistic infections and/or progression to a higher clinical stage after 6 months of ART, as well as on the patient's weight loss in a stress and syndrome-free setting reconstitution.

ART Immunological failure is defined by the absence of an increase in CD4 lymphocyte counts despite effective ART after 6 months. In general, a CD4 count of less than 200 cells/µl or a non-elevated CD4 count is considered indicators of immunological failure.

ART Virologic failure is defined as a VL persistence greater than 200 RNA copies/ml (2.3 $\log_{10}$ RNA copies/ml) 6 months after the start of treatment.

3. Results

Fifty (50) patients were selected for this study based on the inclusion criteria. Twenty-seven patients (54%) were women, giving a sex ratio H/F of 1. The age of patients was between 18 and 82 years with an average of 50.5 ± 11.75 years. The dominant age group was 46 to 55 years with 18 patients (36%), followed by those of 36 to 45 years (26%), 56 to 65 years (22%) and over 65 years (10%). Table 1 shows the characteristics of the patients.

3.1. Clinical and Biological Data at Baseline (D0)

At the inclusion of the second-line treatment, the mean duration of treatment

Table 1. Characteristic data of patients.

Characteristics	Patients (n = 50)
Sex	
Male	23 (46%)
Female	27 (54%)
Age Interval (years)	
18 - 25	1 (2%)
26 - 35	2 (4%)
36 - 45	13 (26%)
46 - 55	18 (36%)
56 - 65	11 (22%)
+65	5 (10%)
Mean age (years)	50.5 ± 11.75

under the first-line ART was 35 ± 8 months. Thirty-eight patients (76%) were on clinical stage 3, nine (18%) on clinical stage 2 and three (6%) on clinical stage 4 for HIV infection according to the WHO classification. The average patient weight was 54.36 ± 13.70 kg. The levels of CD4 T cells were between 7 and 554 cells/µl, respectively for the minimal and maximal values. The median CD4 value at the beginning of second-line ART was 217 cells/µl (Table 2).

3.2. Clinical and Biological Data after 6 Months of ART (M6)

After 6 months second-line ART, thirty-two patients (64%) were on clinical stage 3, ten (20%) on clinical stage 2 and eight (16%) on clinical stage 4 according to the classification of WHO. The average patient weight after 6 months of ART was 60.34 ± 13.07 kg. The levels of CD4 T cells ranged from 31 to 1035 cells/µl, respectively for the minimal and maximal values. The median value of CD4 T cells was 371 cells/µl. The median value of the VLs of the patients was 0 RNA copies/ml. The minimal and maximal values were respectively of 0 and 1,978,470 RNA copies/ml with 19 patients (38%) having a VL greater than 200 RNA copies/ml or 2.3 $\log_{10}$ RNA copies/ml (Table 3).

3.3. Comparative Data D0 and M6

After 6 months of second-line ART, 14 patients (28%) lost weight; 36 patients (72%) showed a weight gain of which 36% showed a gain of more than 10 kilograms. Ten patients (20%) experienced a deterioration of their clinical status, 7 patients (14%) showed an improvement in their clinical status and 33 patients (66%) remained stationary in their clinical state. Nine patients (18%) had a reduction in baseline CD4 count, 41 patients (82%) had an increase in baseline CD4 count, of whom 29 (58%) had a CD4 increase of more than 100 cells/µl in 6 months. Thirty-one patients (62%) had a VL less than 200 RNA copies/ml versus 19 (38%) with a VL greater than 200 RNA copies/ml thus giving a failure rate of ART of second-line of 38%. Table 4 presents the comparative data of D0 and M6.

Table 2. Patient data on D0.

Parameters on D0	Patients (n = 50)
Clinical Stage	
Stage 1	0
Stage 2	9 (18%)
Stage 3	38 (76%)
Stage 4	3 (6%)
Initial average weight (Kg)	54.36 ± 13.70
Biological Parameters	
Initial CD4 median (cells/µl)	217 [7 - 554]

Table 3. Patients data on M6.

Parameters on M6	Patients (n = 50)
Clinical Stage	
Stage 1	0
Stage 2	10 (20%)
Stage 3	32 (64%)
Stage 4	8 (16%)
Average weight after ART (Kg)	60.34 ± 13.07
Biological Parameters	
Median CD4 after 2nd line ART (cells/µl)	371 [31 - 1035]
Median VL after 2nd line ART (RNA copies/ml)	0 [0 - 1,978,470]

Table 4. Comparative data of patients.

Parameters	Patients (n = 50)
Patients weight	
Loss of weight	14 (28%)
Gain of weight	36 (72%)
Gain of weight for more than 10 Kg	18 (36%)
Clinical State	
Stationary clinical state	33 (66%)
Improvement of clinical state	7 (14%)
Clinical state deterioration	10 (20%)
Level of CD4 T cells count	
Decrease of CD4	9 (18%)
Increase of CD4	41 (82%)
Increase of CD4 of more than 100 cells/µl	29 (58%)
Viral Load	
Virologic failure*	19 (38%)
Virologic success	31 (62%)

*Virologic failure is defined as a viral load greater than 1000 copies of RNA/ml.

4. Discussion

The purpose of this study was to determine the profile of people living with HIV (PLHIV) on second-line antiretroviral therapy (ART) followed in Ambulatory Treatment Centers (ACT) in Kinshasa, DRC.

Fifty (50) patients were included for this study based on the inclusion criteria. Twenty-seven patients (54%) were women giving a sex ratio H/F of 1. The age of the patients was between 18 and 82 years with an average of 50.5 ± 11.75 years. Patients on second-line ART were older than those in the first-line whose aver-

age age was between 35 and 40 years [9]. The difference in population mean ages was statistically significant ($p < 0.01$). The dominant age group was of 46 to 55 years with 18 patients (36%), followed by those of 36 to 45 years (26%), 56 to 65 years (22%) and those over 65 (10%). The sociodemographic data of patients on second-line ART were different from those of patients starting first-line ART.

At the inclusion of second-line treatment, the average duration of treatment of patients under the first-line was 35 ± 8 months. In a cohort in Senegal, the average length of passage in the second-line was 38.5 months [10]. Treatment times of treatment are approaching in different cohorts in Sub-Saharan Africa.

Thirty-eight patients (76%) were on clinical stage 3, nine (18%) on clinical stage 2 and three (6%) on clinical stage 4 for HIV infection according to the WHO classification. The average patient weight was 54.36 ± 13.70 kg. The CD4 T cell levels were between 7 and 554 cells/µl, respectively minimal and maximal values. The median value of CD4 at the beginning of second-line ART was 217 cells/µl. Patients who started second-line ART had failed both clinically and immunologically. According to the experts' recommendations, a CD4 count below 200 cells/µl after 6 months of ART is an index of treatment failure [6] [7] [8]. For the clinical data, low mean weight, and high clinical stages justify the collapsed CD4 count in patients starting second-line ART.

After 6 months (M6) of second-line ART, thirty-two patients (64%) were on clinical stage 3, ten (20%) on clinical stage 2 and eight (16%) on clinical stage 4 according to the classification of the WHO. The average weight of patients after 6 months of ART had increased to an average of 60.34 ± 13.07 kg, an average improvement of more than 5 kg. The median CD4 level after 6 months of second-line ART increased to 371 cells/µl, an improvement of more than 150 cells/µl. Fourteen patients (28%) lost weight; 36 patients (72%) showed a weight gain of which 36% showed a gain of more than 10 kilograms. Ten patients (20%) experienced a deterioration of their clinical status, 7 patients (14%) showed an improvement in their clinical status and 33 patients (66%) remained stationary in their clinical state. In clinical terms, the second-line ART failure rate was greater than 20%; 20% according to clinical stage and 28% according to the evaluation of the initial weight change. Nevertheless, weight loss (28%) is better considered for classifying clinical failure because of the suggestive factor of WHO stage classification [6] [7] [8].

At M6, nine patients (18%) had a reduction in baseline CD4 count, 41 patients (82%) had an increase in baseline CD4 count, of which 29 (58%) had a CD4 increase of more than 100 cells/µl in 6 months. According to the experts' recommendations, the immunological failure of ART is defined by the absence of an increase in the level of CD4 lymphocytes despite effective ART after 6 months [6] [7] [8]. After 6 months of second-line ART, 18% of patients are considered to be in immunological failure.

Thirty-one patients (62%) had a VL less than 200 RNA copies/ml versus 19 (38%) with a VL greater than 200 RNA copies/ml giving a virologic failure rate of second-line of 38%.

5. Conclusion

Patients on second-line ART start treatment with a significantly higher average age compared to those starting first-line ART. Biological parameters are systematically higher in general. After 6 months of ART, the second-line treatment failure rate was estimated at 38% with a population having a visible weight gain.

Conflicts of Interest

The authors declare that they have no conflict of interest in publishing this work.

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Abbreviation

AIDS: Acquired Immuno Deficiency Syndrome,
ART: Anti Retro Viral Treatment,
ARV: Anti Retro Viral,
ATC: Ambulatory Treatment Center,
DRC: Democratic Republic of Congo,
HIV: Human Immunodeficiency Virus,
LMIC: Low and Middle Income Country,
PLHIV: People Living with the Human Immunodeficiency Virus,
RNA: Ribonucleic Acid,
VL: Viral Load,
WHO: World Health Organization.