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Virological Profile of People Living with HIV after 12 Months of Treatment with Dolutegravir in Kinshasa

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Abstract

Context: The evaluation of plasma Viral Load constitutes an indicator of the progression of the infection, the effectiveness and the tolerance of the treatment. Objective: The objective of this study is to present the virological profile of Patients Living with HIV (PLHIV) after 12 months of AntiRetro Viral Treatment (ART) based on Dolutegravir (DTG) in Kinshasa. Method: The present study is a cross-sectional view of the virological profile of the twelfth month of a prospective cohort of PLHIV at M12 of DTG-based ART in Kinshasa. During the M12 appointment, a blood sample was taken for Molecular Biology analyses from all PLHIV included. Result: During the M12 appointment, 28 patients were registered, including 16 (57.1%) women. Nine (9) patients (45.0%) had an undetectable Viral Load (VL). The median VL value was 3.18 log₁₀ RNA copies/mL (1530 RNA copies/mL). The mutations K65R, T69P/N, K70R and M184V have been listed as mutations conferring resistance to Nucleotide Reverse Transcriptase Inhibitors. No mutations associated with Dolutegravir were observed at M12. Conclusion: After 12 months of AntiRetroViral Treatment based on Dolutegravir, half of the Patients on first-line ART are in a state of virological failure.

Keywords

Viral Load, PLHIV, 12 Months of ART, Dolutegravir, Kinshasa

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1. Introduction

The evaluation of the plasma Viral Load (VL) of the Human Immunodeficiency Virus (HIV) in People Living with HIV (PLHIV) constitutes an indicator of the evolution of the infection, the effectiveness and the tolerance of the treatment. The biological assessment in general and virological in particular from the initiation and during the follow-up of HIV infection is an important contribution to the clinical assessment of infected patients. Among other things, it makes it possible to determine the right moment when it becomes necessary to start or modify a treatment [1].

However, with the "Test and Treat" strategy, the care of PLHIV has been distorted to simplify patient monitoring. The different patient monitoring parameters are no longer considered to put patients on AntiRetro Viral Treatment (ART) for Countries with Limited Resources (CLR) [1] [2] [3]. It is therefore difficult to correctly understand patients at the start of ART. It is important to specify that the assessment of VL remains an essential tool for good guidance in patient care. Since the introduction of Dolutegravir (DTG) in 2019 as first-line ART in the Democratic Republic of Congo (DRC), no data is available on the virological and even molecular profile of PLHIV after one year of ART.

Hence the objective of this study is to present the virological profile of Patients Living with HIV after 12 months of AntiRetroViral Treatment based on Dolutegravir in Kinshasa, Democratic Republic of Congo.

2. Methods

2.1. Study Design, Setting, Patients and Samples

The present study is a cross-sectional view of the virological profile of the twelfth month of a prospective cohort of PLHIV on first-line ART based on DTG in the Outpatient Treatment Centers (OTC) of Kinshasa, DRC.

A 5 mL blood sample was taken during the appointment for Molecular Biology analyzes from all PLHIV who responded to the appointment.

2.2. Study Population

The source population of the present study was the patients included in the cohort who responded to their M12 appointment in the period from October 2022 to February 2023, all having been previously seen during the inclusion period. The inclusion criteria for the cohort were: being at least 18 years old at inclusion, confirmed HIV positive by RDT, naïve to ART, consenting and having signed an informed consent.

2.3. Parameters of Interest

The parameters recorded were: age, sex as well as molecular assessment (Viral Load and Resistance).

2.4. Biological Analyzes

After collection, the samples were taken to the Molecular Biology laboratory of the Department of Basic Sciences at the Faculty of Medicine of the University of Kinshasa (UNIKIN) where the molecular biology analyses were carried out under the conditions previously described [4] [5].

2.5. Ethical Consideration

The present study was approved in its entirety by the research ethics committee of the School of Public Health, Faculty of Medicine, University of Kinshasa (ESP/CE/115/2021). Permission to access the centers was obtained from each competent authority. The samples in the centers were taken by the technical teams of the centers.

3. Results

During the M12 appointment, 28 patients were registered, 16 (57.1%) women versus 12 (42.9%) men. The attached **Figure 1** shows the gender distribution in the population.

The average age of the patients included was 43 ± 14.28 years with a range of 18 to 69 years. The most common age group is 46 to 55 years old (28.6%), followed by the age group 36 to 45 years old (25%), those from 18 to 25 years old and 56 to 65 years old (17.9%), and that of 26 to 35 years old (10.7%). **Figure 2** attached shows the distribution of age groups in the population.

Nine (9) patients (45.0%) presented an undetectable Viral Load (VL), less than 50 RNA copies/mL. The median VL value was 3.18 \log_{10} RNA copies/mL (1530 RNA copies/mL) with the lower and upper ends equal to $0.0 \log_{10}$ and $5.14 \log_{10}$ RNA copies/mL, respectively. The virological failure rate of first-line treatment was 50%, with 10.0% of patients experiencing major failure. The results of the VLs mentioned above are presented exhaustively in **Table 1**.

The mutations K65R (2 cases), T69P/N (3 cases), K70R (5 cases) and M184V

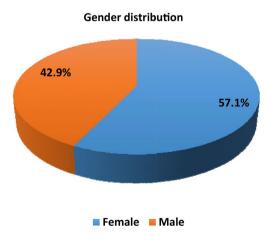


Figure 1. Population distribution by gender.

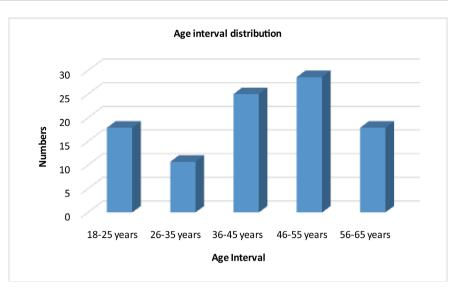


Figure 2. Distribution of the population by age intervals.

Table 1. Patient Viral Load Values at M12.

	Viral Load (RNA copies/mL)	
	Values	Log_{10}
Median	1530	3.18
Lower Limit	1	0.00
Upper Limit	137 861	5.14

	Viral Load Intervals		
	Values	Percentage	
Undetectable VL	9	45.00	
$\mathrm{VL} < 3.0 \; log_{10}$	1	5.00	
$3.0 \log_{10} < \text{VL} < 5.0 \log_{10}$	8	40.00	
$VL > 5.0 \log_{10}$	2	10.00	

Table 2. Molecular data from M12 patients.

Prevalence of Mutations in M12	Numbers		
NRTI			
K65R	2		
T69P	3		
K70E/R	5		
M184V	5		

(5 cases) were listed in patients as mutations that confer resistance to Nucleotide Reverse Transcriptase Inhibitors (INTR). No mutations associated with Dolutegravir were observed at M12. **Table 2** presents the molecular data mentioned above.

4. Discussion

The objective of the present work was to describe the virological profile of Patients Living with HIV after 12 months of AntiRetroViral Treatment based on Dolutegravir in Kinshasa, Democratic Republic of Congo (DRC). During the M12 appointment, 28 patients responded and were registered; 16 (57.1%) women versus 12 (42.9%) men. The sex ratio favoring the female gender is usual in the populations of PLHIV monitored in Kinshasa in particular, in the country and even the Central African region in general [6] [7] [8] [9]. It can also be explained by the participation of adult women in prenatal consultation programs where HIV testing is compulsory [10] [11]. It can also be explained by the social and economic characteristics of African society in particular, the biological vulnerability of women as well as the occurrence of vaginal lesions during sexual intercourse [6] [7] [8] [9].

The age group most found is between 46 to 55 years old (28.6%), followed by the age group of 36 to 45 years old (25%). The age group of 36 to 45 years remains among the most dominant in the literature found in Kinshasa on HIV [7] [8] [12] [13] [14]. This can be explained by the fact that HIV infection affects the productive and active segment of populations, which is at the origin of enormous socio-economic implications, but also by the fact that this age group is where sexual activity is the most intense and by awareness of certain responsibilities [7] [15].

Nine (9) patients (45.0%) presented a Viral Load of less than 50 RNA copies/mL. The median CV value was 3.18 log₁₀ RNA copies/mL (1530 RNA copies/mL) with the lower and upper ends equal to 0.0 log₁₀ and 5.14 log₁₀ RNA copies/mL, respectively. The virological success rate is 50.0%. Hence, the virological failure rate of first-line treatment according to the recommendations of the World Health Organization (WHO) is 50.0%, with 10.0% of patients experiencing major failure (greater than 5 .0 log₁₀ RNA copies/mL). These data are justifiable by the high rate of patients with a poor virological prognosis at the start of ART [4] [16]. Different studies had shown that there is a strong correlation between VL at the inclusion and at M12 [4] [16]. This demonstrates the need for virological and molecular monitoring of patients on ART, and that this monitoring should continue to appear in treatment recommendations even for countries with limited resources.

After 12 months of ART, no mutation was found for DTG. However, the mutations K65R (2 cases), T69P/N (3 cases), K70R (5 cases) and M184V (5 cases) were listed as existing mutations for Nucleotide Reverse Transcriptase Inhibitors. This confirms the strong genetic barrier attributed to DTG in the different literature in the field [17]. However, the mutations found are generally associated with resistance to Lamivudine-3TC (K65, T69, M184) and Tenofovir-TDF (K70) [17]. As a result, more than 14.52% of patients on ART, or 36% of patients with virological failure, are in a situation of failure because of the mutation which confers resistance to TDF. This calls for a revision of the first-line formula based on scientific evidence from local studies.

5. Conclusion

After 12 months of first-line ART based on Dolutegravir, half of the Patients on first-line ART are in a state of virological failure with a high rate of Mutations conferring resistance to Nucleotide Reverse Transcriptase Inhibitors without any Mutation against the Dolutegravir.

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Conflicts of Interest

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

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