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Clinical and Anthropometric Evolution of People Living with Human Immunodeficiency Virus during 6 Months of Dolutegravir Treatment in Kinshasa, Democratic Republic of Congo

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Abstract

Background: AntiRetroViral Treatment (ART) remains an important tool for reducing morbidity and mortality and improving the quality of life of people living with the Human Immunodeficiency Virus (PLHIV). Under the pressure of ART, several parameters of PLHIV change and are the subject of different evaluations. **Objective:** The objective of this work was to study the clinical and anthropometric evolution of PLHIV after 6 months of ART based on Dolutegravir (DTG). **Methods:** The present study was a non-interventional prospective cohort to assess the clinical and anthropometric evolution of PLHIV after 6 months of ART in the Ambulatory Treatment Center (CTA) for HIV in Kinshasa. The patients included were followed for 6 months in compliance with the schedule promulgated by the National Program. The parameters of interest were: Age, Sex, Marital Status, Weight, Height, Body Mass Index and Clinical Status. **Results:** On inclusion, 119 patients (56.3% women; 43.7% men) were selected. During the consultation appointments, 42 patients (66.7% women; 33.3% men) were present at M1, 37 patients (70.3% women; 29.7% men) at M3, and 67 patients (61.3% women and 38.7% men) in M6. On inclusion, 41.5% of patients were at Stage 3 and 47.0% had a normal clinical condition.

In M1, 48.7% of patients were at Stage 1 and 65.8% had a normal clinical condition. At M3, 41.7% of patients were at Stage 3 and 67.6% had a normal clinical condition. At M6, 61.8% of patients were at Stage 3 and 67.9% had a normal clinical condition. On D0, 45.5% of patients were in the 45 to 55 kg range and 56.5% had a normal Body Mass Index (BMI). At M1, 45.7% were in the 45 to 55 kg range and 50.0% had a normal BMI. At M3, 34.4% were in the 45 to 55 kg range and 64.3% had a normal BMI. At M6, 31.8% were in the range of 45 to 55 kg and, respectively, 37.5% of patients were lean and had a normal BMI. **Conclusion:** The clinical and anthropometric parameters evolve in saw tooth. Improvements are easily visible up to the third month of Anti-RetroViral Treatment (ART). At the sixth month, with the pressure of the infection by the Human Immunodeficiency Virus (HIV), the evolution of the patients is compromised.

Keywords

Evolution, Clinical, Anthropometric, PLHIV, ART

1. Introduction

Human Immunodeficiency Virus (HIV) infection and Acquired Immunodeficiency Syndrome (AIDS) are major public health problems. The United Nations Organization for the Fight against HIV/AIDS (UNAIDS) estimated that at the end of June 2021, 28.2 million people had access to Anti-Retroviral Treatment (ART), an increase of 7.8 million [6.9 million - 7.9 million] compared to 2010, with a global coverage rate of 74% in 2020 [1]. Indeed, the Democratic Republic of Congo (DRC) has made progress in access to ART for People Living with HIV/AIDS (PLHIV) with an average coverage of 82%, the highest in Central Africa in 2020 [2].

ART remains an important intervention for reducing morbidity and mortality and improving the quality of life of PLHIV [2]. But in clinical practice, treatment including AntiRetrovirals (ARVs) remains lifelong treatment, having both beneficial therapeutic effects and side effects, including major metabolic disorders, in particular lipodystrophy, insulin resistance and the change in plasma concentrations of lipids and lipoproteins [3] [4]. The consequences of the viral presence in the blood on the increase in energy expenditure, thus causing muscle proteolysis with an exaggerated loss of lean tissue in PLHIV have been mentioned by several authors [5].

Weight gain in PLHIV would also be linked to ART, but also to excessive consumption of bad foods not associated with physical exercise. This considerably modifies their Body Mass Index (BMI) over time [6] [7]. The clinical and anthropometric evolution of PLHIV on ART is the subject of the current issue of several publications [8]. However, no studies have associated the two to date. Hence the objective of this study was to determine the clinical and anthropometric evolution of PLHIV in 6 months of treatment in the era of Dolutegravir (DTG) in Kinshasa, DRC.

2. Methods

2.1. Study Design, Setting, Patients and Samples

The present study is a non-interventional prospective cohort with a descriptive aim to determine the clinical and anthropometric evolution of PLHIV after 6 months of ART in the Outpatient Treatment Centers (OTC) for HIV selected in Kinshasa, DRC. The inclusion period was from October 4, 2021 to April 4, 2022. Sixteen (16) OTCs were selected because of their accessibility and their expertise in the care of PLHIV on a random basis [9].

The patients included were followed for 6 months in compliance with the schedule promulgated by the National Program for the Fight against HIV/AIDS and Sexually Transmitted Infections (PNLS) [10].

2.2. Study Population

The population was made of adults aged over 18 years at inclusion, infected with HIV and initiating ART in the OTCs selected during the inclusion period (October 04, 2021 to February 15, 2022). Patients were included on the following criteria: to be diagnosed as PLHIV at the OTC, to be at least 18 years old at inclusion and naïve to ART. PLHIV were followed in the respective OTCs for 6 months.

2.3. Parameters of Interest

The parameters of interest followed for the present study were: Age, Sex, Marital Status, Weight, Height, Body Mass Index and Clinical Status.

2.4. Ethical Consideration

This study was approved by the research ethics committee of the School of Public Health, Faculty of Medicine, University of Kinshasa (ESP-UNIKIN). Authorization to access the OTCs was obtained from each authority respectively from the various institutions selected. Prior to inclusion, fully informed consent was obtained from each patient.

2.5. Statistical Analyzes

Analyzes were performed using SPSS version 26 software. Only available data were analyzed, missing data were considered completely random. Continuous variables were presented as mean ± standard deviation and compared using Student's t-test. The proportions and their respective 95% confidence intervals were calculated for each of the categorical labor data.

2.6. Operational Definitions

The definitions used in this study are as follows:

- Clinical State: the Clinical State was considered.
- Normal if the patient's vital functions are normal, he is able to do everything without assistance.

- Good if the patient's vital functions are almost normal, he is still able to walk, eat and take care of himself without assistance.
- Bad if the patient's vital functions are impaired, he is only able to walk, eat and take care of himself when assisted.
- Pre-moribund if the patient is in very bad condition, he is totally bedridden and has a clouded conscience, but he is able to eat when he is assisted.
- Moribund if the patient is in very poor general condition, he is completely bedridden and is in a vigil or deep coma.

- Clinical stage of patients: According to the WHO, HIV infection is divided into 4 clinical stages.

- Stage 1: Asymptomatic patient, generalized persistent lymphadenopathy.
- Stage 2: Weight loss < 10% of body weight, Shingles, Minor mucocutaneous manifestations, Recurrent infections of the upper airways.
- Stage 3: Weight loss greater than 10% of body weight, Unexplained chronic diarrhea > 1 month, Unexplained prolonged fever > 1 month, Persistent oral candidiasis (thrush), Oral hairy leukoplakia, Pulmonary tuberculosis within the previous year, Severe bacterial infection, Acute necrotizing ulcerated stomatitis, Persistent anemia (hb < 8 g/dL)/Chronic neutropenia < 500/mm^3/ Chronic thrombocytopenia < 50,000/mm^3.
- Stage 4: HIV wasting syndrome (>10% of body weight, associated with unexplained chronic diarrhea or unexplained chronic asthenia or prolonged fever), various and multiple opportunistic infections.

- Body Mass Index (BMI): It is used to assess the weight status of an individual. It is calculated from the height and weight of the individual according to the formula BMI = weight in kg/height^2 in meter (kg/m^2).

- Underweight/Thinness: 15 < 18.5 kg/m^2.
- Normal build: 18.5 < 24.9 kg/m^2.
- Overweight: 25 < 29.9 kg/m^2.
- Moderate obesity: 30 < 34.9 kg/m^2.
- Severe obesity: 35 < 39.9 kg/m^2.
- Morbid or massive obesity: >40 kg/m^2.

3. Results

3.1. Sociodemographic Data

One hundred and nineteen (119) patients were included in accordance with the inclusion criteria; 67 (56.3%) were female while 52 (43.7%) were male, giving a sex ratio of 1.29 in favor of women. In the first month (M1) of ART, forty-two patients (66.7% women and 33.3% men; sex ratio of 2.00) were present during the consultation. At the third month (M3), thirty-seven patients (70.3% women and 29.7% men; sex ratio of 2.36) attended the follow-up appointment. At the sixth month (M6) of ART, sixty-two patients (61.3% women and 38.7% men; sex ratio of 1.58) were present at the medical follow-up appointment. The loss rate of patients from D0 to M6 is 47.9% in the centers of Kinshasa.

3.2. Clinical Data

At inclusion, 41.5% of patients were at WHO Stage 3 for HIV, followed by 33.9% at Stage 1, 15.3% at Stage 2 and 9.3% at Stage 4. Forty-seven percent (47.0%) had normal clinical status, 33.3% had good clinical status, 18.8% had poor clinical status and 0.9% were pre-moribund.

At M1, 48.7% of patients were at WHO Stage 1 for HIV, followed by 45.9% at Stage 3, 2.7% at Stage 2 and 4 respectively. Nearly sixty-six percent (65.8%) had a normal clinical condition and 34.2% had a good clinical condition.

At M3, 41.7% of patients were at WHO Stage 3 for HIV, followed by 38.9% at Stage 1 and 19.43% at Stage 2. Nearly sixty-eight percent (67.6%) had normal clinical status and 32.4% had good clinical status.

At M6, 61.8% of patients were at WHO Stage 3 for HIV, followed by 29.1% at Stage 1 and 9.1% at Stage 2. Nearly sixty-eight percent (67.9%) had normal clinical status, 28.3% had good clinical status and 3.8% had poor clinical status.

Table 1 and Figure 1 and Figure 2 present the data mentioned above.

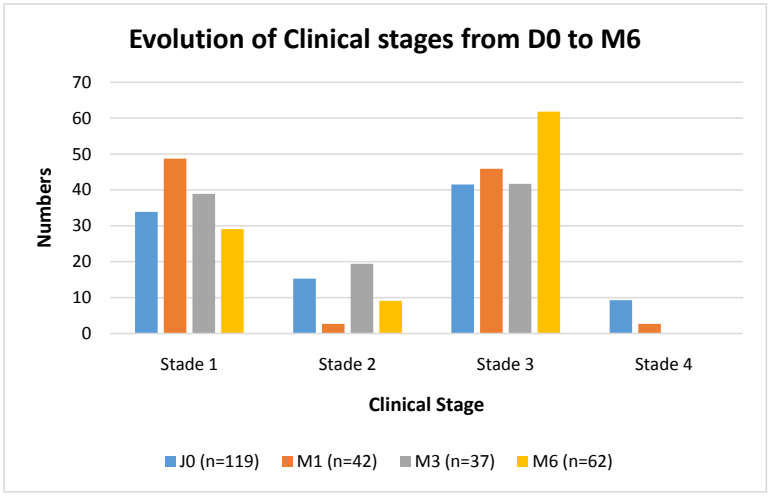

Figure 1. Evolution of clinical stages from D0 to M6.

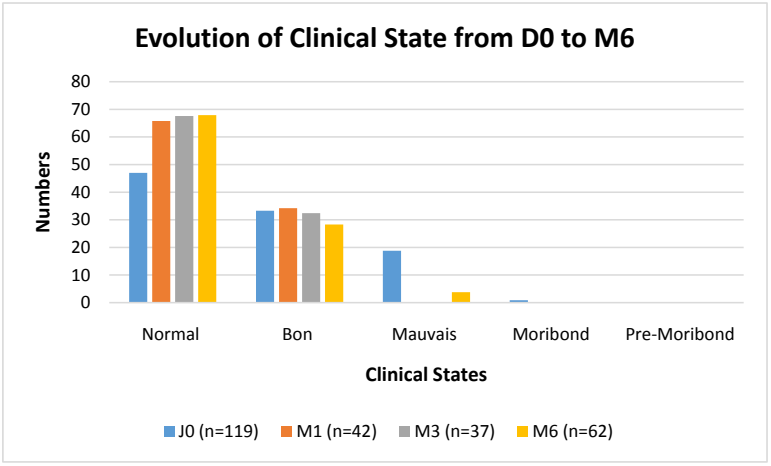

Figure 2. Evolution of clinical state from D0 to M6.

Table 1. Clinical parameters of PLHIV from D0 to M6.

Parameters	D0 (n = 119) %	M1 (n = 42) %	M3 (n = 37) %	M6 (n = 62) %
		Clinical Stage		
Stage 1	33.9	48.7	38.9	29.1
Stage 2	15.3	2.7	19.4	9.1
Stage 3	41.5	45.9	41.7	61.8
Stage 4	9.3	2.7	0	0
		Clinical State		
Normal	47	65.8	67.6	67.9
Bon	33.3	34.2	32.4	28.3
Bad	18.8	0	0	3.8
Moribund	0.9	0	0	0
Pre-Moribund	0	0	0	0

3.3. Anthropometric Data

The PLHIV included had an average height of 1.66 ± 0.08 meters with extremities of 1.50 to 1.75 meters.

On D0, the mean weight of the patients was 56.41 ± 13.30 kg with extremities of 30 to 106 kg. Almost half of the patients (45.5%) were in the 45 - 55 kg range, followed by 21.8% in the 56 - 66 kg range, 18.2% were under 45 kg. More than half of the patients (56.5%) had a normal Body Mass Index (BMI), followed by 26.1% who were lean and 17.4% who were overweight.

At M1, almost half of the patients (45.7%) were in the 45 - 55 kg range, followed by 25.7% in the 56 - 66 kg range, 14.3% were under 45 kg. Half of the patients (50.0%) had a normal BMI, followed by 33.3% who were lean and 16.7% who were overweight.

At M3, 34.4% were in the 45 - 55 kg range, followed by 28.1% in the 56 - 66 kg range, 15.7% in the 67 - 77 kg range. More than half of the patients (64.3%) had a normal BMI, followed by 14.3% who were lean, 14.3% who were severely obese and 7.1% who were overweight.

At M6, 31.8% were in the 45 - 55 kg range, followed by 26.8% in the 56 - 66 kg range, 14.6% respectively were under 45 kg and are in the range from 67 to 77 kg. Respectively, 37.5% of the patients were lean and had a normal BMI, followed by 18.7% who were overweight and 6.3% who were severely obese.

All the anthropometric data mentioned above are presented in Table 2 and Figure 3 and Figure 4.

3.4. Evolutionary Data

At M6, 9 patients (21.43%) lost weight compared to D0, 4 patients (9.52%) kept the same weight, 20 patients (47.62%) gained weight, while 9 patients (21.43%) gained more than 10 kg in 6 months of ART. The clinical stage was deteriorated in 9 patients (16.07%), stationary in 38 patients (67.86%) and improved in 9 patients (16.07%). These evolutionary data are presented in Table 3.

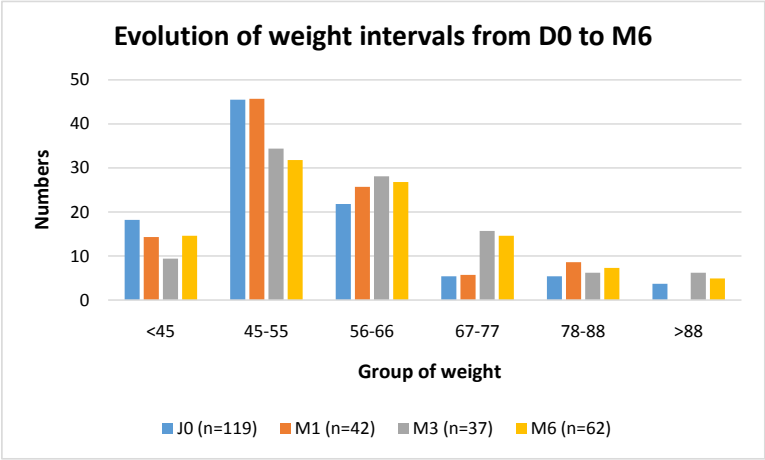

Figure 3. Evolution of weight intervals from D0 to M6.

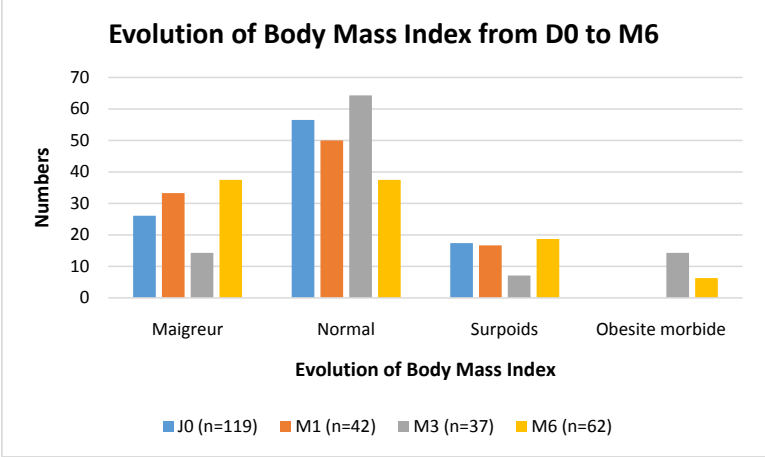

Figure 4. Evolution of BMI from D0 to M6.

Table 2. Anthropometric parameters of PLHIV from D0 to M6.

Parameters	J0 (n = 119) %	M1 (n = 42) %	M3 (n = 37) %	M6 (n = 62) %
		Patients weight (kg)		
<45	18.2	14.3	9.4	14.6
45 - 55	45.5	45.7	34.4	31.8
56 - 66	21.8	25.7	28.1	26.8
67 - 77	5.4	5.7	15.7	14.6
78 - 88	5.4	8.6	6.2	7.3
>88	3.7	0	6.2	4.9
		Body Mass Index (Kg/m²)		
Thinness	26.1	33.3	14.3	37.5
Normal	56.5	50	64.3	37.5
Overweight	17.4	16.7	7.1	18.7
Obesity	0	0	14.3	6.3

Table 3. Comparative patient data.

Parameters	Patients
Patients weight	
Loss of weight	9 (21.43%)
Stationary weight	4 (9.52%)
Gain of weight	20 (47.62%)
Gain of weight of more than 10 kg	9 (21.43%)
Clinical Stage	
Deterioration of stage	9 (16.07%)
Stationary stage	38 (67.86%)
Amelioration de stage	9 (16.07%)

4. Discussion

The objective of this study was to determine the clinical (stage and clinical state) and anthropometric evolution of People Living with HIV (PLHIV) followed in the Outpatients Treatment Centers (OTC) disseminated in the four districts of Kinshasa, Democratic Republic of Congo. The follow-up schedule for PLHIV promulgated by the National Program for the Fight against HIV/AIDS and Sexually Transmitted Infections (PNLS) includes, after the consultation on D0, the first consultation appointment which is retained for the first month (M1) after ART initiation, the second appointment is scheduled for the third month (M3) on ART, the third for the sixth month (M6) on ART, the fourth for the ninth month (M9) on ART, the fifth for the twelfth month (M12) on ART; after the first year of ART, appointments are every six months [10].

On inclusion, one hundred and nineteen (119) patients were included in accordance with the inclusion criteria; 67 (56.3%) were female while 52 (43.7%) were male, giving a sex ratio of 1.29 in favor of women. In the first month (M1) of ART, forty-two patients (66.7% women and 33.3% men; sex ratio of 2.00) were present during the consultation. At the third month (M3), thirty-seven patients (70.3% women and 29.7% men; sex ratio of 2.36) attended the follow-up appointment. At the sixth month (M6) of ART, sixty-two patients (61.3% women and 38.7% men; sex ratio of 1.58) were present at the medical follow-up appointment. These data show that despite the loss of patients during the treatment period, the predominance of the female gender is still present. This predominance is found in several studies carried out in Kinshasa and even in Central Africa [7]-[15]. It has been explained by the social and economic characteristics of African society, the biological vulnerability of women as well as the occurrence of vaginal lesions during sexual intercourse [13] [14].

In this cohort, the loss rate of the population from D0 to M6 is 47.9% in the centers of Kinshasa. This loss rate is also found in various studies published for Kinshasa [16]. This reinforces the problem of the difficulty of retaining PLHIV in the various CTAs in Kinshasa.

At inclusion, 41.5% of patients were at WHO Stage 3 for HIV, followed by 33.9% at Stage 1, 15.3% at Stage 2 and 9.3% at Stage 4. Forty-seven percent (47.0%) had normal clinical status, 33.3% had good clinical status, 18.8% had poor clinical status and 0.9% were pre-moribund. More than half (50.8%) of patients start ART late at higher stages, stage 3 (41.5%) and stage 4 (9.3%) [17]. This same observation is presented by several authors at the start of ART when the clinic begins to deteriorate [8] [11] [12] [18]. The majority of patients (80.3%) have non-incapacitating clinical signs, they are able to manage themselves without difficulty [17].

At M1, 48.7% of patients were at WHO Stage 1 for HIV, followed by 45.9% at Stage 3, 2.7% at Stage 2 and 4 respectively. Nearly sixty-six percent (65.8%) had a normal clinical condition and 34.2% had a good clinical condition. Compared to D0, the rate of patients in the lower clinical stage (stages 1 and 2) went from 49.2% on D0 to 51.4% in M1. Although not significant, this change ($\Delta = 2.2$) demonstrates the improvement in the condition of patients on ART.

At M3, 41.7% of patients were at WHO Stage 3 for HIV, followed by 38.9% at Stage 1 and 19.43% at Stage 2. Nearly sixty-eight percent (67.6%) had normal clinical status and 32.4% had good clinical status. Compared to M1, the rate of patients in the lower clinical stage (stage 1 and 2) went from 51.4% in M1 to 58.3% in M3. Although not significant, this change ($\Delta = 6.9$) demonstrates the effectiveness of ART at this point.

At M6, 61.8% of patients were at WHO Stage 3 for HIV, followed by 29.1% at Stage 1 and 9.1% at Stage 2. Nearly sixty-eight percent (67.9%) had normal clinical status, 28.3% had good clinical status and 3.8% had poor clinical status. In M6, the HIV infection settles comfortably in the patient despite the therapeutic management [19]. A large number of patients (61.8%) end up in clinical stage 3 despite the duration and effectiveness of ART. Similar data, prevalence of high stage 3 patients in M6, are also presented in the literature for Kinshasa [20].

On D0, the mean weight of the patients was 56.41 ± 13.30 kg with extremities of 30 to 106 kg. Almost half of the patients (45.5%) were in the 45 - 55 kg range, followed by 21.8% in the 56 - 66 kg range, 18.2% were under 45 kg. More than half of the patients (56.5%) had a normal Body Mass Index (BMI), followed by 26.1% who were lean and 17.4% who were overweight. The average weight of PLHIV on D0 is quite low [9]. It is lower than that presented for the general population of the city of Kinshasa [21]. This low average is explained by the advanced infectious state of patients at the start of ART. The dominance of normal BMI (56.5%) is explained by the clinical condition of the patients.

At M1, the mean weight of the patients was 54.74 ± 11.8 kg with extremities of 34 to 85 kg. Almost half of the patients (45.7%) were in the 45 - 55 kg range, followed by 25.7% in the 56 - 66 kg range, 14.3% were under 45 kg. Half of the patients (50.0%) had a normal BMI, followed by 33.3% who were lean and 16.7% who were overweight. Compared to the inclusion data, there is no significant improvement with the masses of the patients in M1.

At M3, the mean weight of the patients was 61.20 ± 15.2 kg with extremities of 40 to 103 kg; 34.4% were in the 45 - 55 kg range, followed by 28.1% in the 56 - 66 kg range, 15.7% in the 67 - 77 kg range. More than half of the patients (64.3%) had a normal BMI, followed by 14.3% who were lean, 14.3% who were obese and 7.1% who were overweight. After 3 months of ART, weight improvement is clearly visible in patients, but not statistically significant. This weight improvement has been increasing since D0.

At M6, the mean weight of the patients was 60.44 ± 15.7 kg with extremities of 40 to 108 kg; 31.8% were in the 45 - 55 kg range, followed by 26.8% in the 56 - 66 kg range, 14.6% respectively were under 45 kg and are in the 67 - 67 kg range. 77 kg. Respectively, 37.5% of the patients were lean and had a normal BMI, followed by 18.7% who were overweight and 6.3% who were obese.

After 6 months of ART, 9 patients (21.43%) lost weight compared to D0, 4 patients (9.52%) kept the same weight, 20 patients (47.62%) gained weight, while 9 patients (21.43%) gained more than 10 kg in 6 months of ART. The majority of patients followed, 69.05%, gained weight on ART; this demonstrates the effectiveness of ART in our environment. Previous studies have presented similar data with over 60% of patients gaining weight on ART [11] [19] [20]. The clinical stage was deteriorated in 9 patients (16.07%), stationary in 38 patients (67.86%) and improved in 9 patients (16.07%). These data showing an improvement in clinical stages are documented in the literature [11] [19] [20].

Limitation of the Study

This present study was limited to some centers of Kinshasa. Therefore, generalization of the results should be done carefully. However, being the first study in the new conditions, this does not take any value out of the findings.

5. Conclusion

The clinical and anthropometric parameters evolve in saw tooth. Improvements are easily visible up to the third month of AntiRetroViral Treatment (ART). At the sixth month, with the pressure of the infection by the Human Immunodeficiency Virus (HIV), the evolution of the patients is compromised. For the lower clinical stages (stage 1 and 2), the rates were 49.2% in D0, 51.4% in M1, 58.3% in M3 and 38.2% in M6. For clinical states, rates were normal at 47.0% on D0, 65.8% on M1, 67.6% on M3, and 67.9% on M6. The mean progressive weight values were 56.4 kg, 61.2 kg and 60.5 kg respectively for D0, M3 and M6. The Body Mass Indexes (BMI) were normal at 56.5% on D0, 50.0% in M1, 64.3% in M3 and 37.5% in M6; with 18.7% of patients overweight and 6.3% moderately obese in M6.

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Conflicts of Interest

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

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List of Abbreviations and Acronyms

ARV: AntiRetroViral; **ART:** AntiRetroViral Treatment; **DRC:** Democratic Republic of Congo; **DTG:** Dolutegravir; **HIV:** Human Immunodeficiency Virus; **OTC:** Outpatient Treatment Center; **PLHIV:** Person Living with Human Immunodeficiency Virus; **RDT:** Rapid Screening Test; **SSA:** Sub-Saharan Africa.