



Follow-up of the biological assessment in people living with HIV and AIDS under treatment with Dolutegravir at the Reference Health Center of Commune V of Bamako in Mali.

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Summary :

Introduction/aims: Combination therapy with at least three different antiretroviral drugs is now the standard treatment for all people newly diagnosed with HIV. Combination antiretroviral therapy stops HIV from multiplying and can suppress HIV to undetectable levels in the blood. This allows a person's immune system to recover, overcome infections, and prevent the development of AIDS and other long-term effects of HIV infection. The aim of our study was to assess the state of health of patients on dolutegravir and followed up over 12 months at the CSRéf of commune V. **Method:** We followed up the evolution of clinical and biological parameters in patients on antiretroviral triple therapy. The variables concerned were the blood count, the viral load and the assays

(hemoglobin level, glycaemia, creatinaemia, ALAT), at M0, at M6 and at M12.

Results: The female gender was the most represented, i.e. 63.2% of patients, The age group (45 years and over) represents the majority of our sample, i.e. 49.1%. Only 29.8% of our patients weighed less than or equal to 60 kg at the start of treatment. Patients infected with HIV1 were in the majority, i.e. 85.1%. The rate of patients weighing ≥ 60 kg did not statistically increase from inclusion (35.1%) to M12 (36.80%) $p=0.416$. The rate of non-compliant patients did not experience any statistically significant change: 46.5% at M1; 36.8% at M6; 41.2 to M12. $p=1.101$, $KHI2=138.105$. The rate of patients who switched treatment regimens did not experience a statistically significant change from M1 (3.5%) to M6 (4.4%) and M12 (0.9%). $P=0.890$, $KHI2 90.408$. In total, only 4.4% of our patients underwent a therapeutic change, ie 2.6% for side effects and 1.8% for stock-out reasons. The difference was statistically significant. $p=0.0066$, $KHI2=94.312$. The majority of patients had mild anemia at the start of treatment, ie 86% of our patients. The rate of patients with high ALAT was 20.2% against 79.8% for those with normal ALAT. Serum creatinine for the majority of our patients was normal at 92.1%. The rate of patients with normal blood sugar levels was the majority at the start of treatment, ie 81.6%. The rate of patients with an undetectable VL experienced a statistically significant increase: from 15.8% at M6 and 21.9% at M12. $P=0.0000142$, $KHI2 2.299$. **Conclusion:** This study shows that the biological disorders observed before the initiation of ARV treatment gradually regressed, thus demonstrating the effectiveness of antiretroviral triple therapy based on dolutegravir on HIV infection.

Keywords: HIV- Dolutegravir- biological parameters.

Introduction :

Since the discovery of AIDS in 1981 and its cause, the retrovirus HIV, in 1983, dozens of new antiretroviral drugs to treat HIV have been developed. Different classes of antiretroviral drugs work against HIV in different ways, and when combined are much more effective at controlling the virus and less likely to promote drug resistance than when given alone. Combination treatment with at least three different antiretroviral drugs is now the standard treatment for all people newly diagnosed with HIV. Combination antiretroviral therapy stops HIV from multiplying and can suppress HIV to undetectable levels in the blood. This allows a person's immune system to recover, overcome infections, and prevent the development of AIDS and other long-term effects of HIV infection. This study would like to contribute to the achievement of SDG3 which is to promote health and well-being for all.

Objective :

Main objective:

Evaluate the state of health of patients on dolutegravir and follow-up over 12 months at the CSRéf of the commune V.

Specific objectives:

- Describe the evolution of the parameters of the biological assessment during treatment with dolutegravir.
- To determine the efficacy and biological tolerance of dolutegravir.
- Determine the impact of compliance on the evolution of biological assessment parameters.

METHODOLOGY

1. Location of the study:

Our study was carried out in the USAC department of the CSRéf of the commune V of Bamako.

Presentation of the USAC:

The care, animation and advice unit (USAC) for people living with HIV and AIDS was created in September 1996 in order to provide a medical and psychosocial response adapted to the problems of the care of people facing the burden of HIV infection and AIDS.

This center was created thanks to the financial support of the French Cooperation in collaboration with the Ministry of Health, the Elderly, Solidarity and ARCAD SIDA (association for research, communication and home support for people living with HIV and AIDS). The USAC is located in the heart of the CSRéf of the commune V of Bamako

2. Type of study

This is a prospective study from July 2021 to June 2022.

3. Study population:

Adult patients living with HIV and AIDS on antiretroviral treatment based on dolutegravir, initiated and followed up at the USAC of the CSRéf in commune V of Bamako.

3.1. Inclusion criteria:

Any patient who initiated antiretroviral treatment at the USAC of the CSRéf in the commune of V de Bamako during the period from July 2021 to June 2022, who agreed to participate in the study.

3.2. Non-inclusion criteria:

Patients who have not been initiated to antiretroviral treatment at the USAC of the CSRéf of commune V of Bamako during the period from July 2021 to July 2022 or who do not consent to participate in the study.

-Children under 15 years old.

3.3. Exclusion criteria:

-Any patient transferred or lost to follow-up (patient who has stopped treatment and does not have a contact).

3.4. Sampling:

The size of our sample was 114 patients, referring to the inclusion criteria of our study among the 160 patients initiated on ARV treatment from July 1, 2021 to July 30, 2022.

4. Variables measured:

4.1. Qualitative variables:

Sex, residence, type of HIV, treatment regimen used, adherence to treatment.

4.2. Quantitative variables:

Age, weight, CD4 count, viral load, hemoglobin count, ALT, blood sugar, creatinine.

5. Course of the study:

5.1. Ethical aspects:

The survey took place in the greatest confidentiality after informed consent without any influence from the patients. The Bambara language was our main means of communication.

5.2. Collection of data :

Data were collected from patient medical records and Logone data entry software from the medical consultation room.

6. Data entry and analysis:

The texts were entered on Windows in the Word software and the data were analyzed with the SPSS software version 21.fr.

The statistical test used was the Chi² test to compare the proportions.

A value of $p < 0.05$ was considered statistically significant.

RESULT

We conducted a prospective study on the evolution of biological assessment parameters in 114 patients on antiretroviral treatment from July 2021 to June 2022 at the USAC of CSRéf in commune V of Bamako.

The female sex was the most represented, 63.2% of patients with a sex ratio of 0.70. Only 9.6% of our patients lived outside Bamako.

The age group (45 years and over) represents the majority of our sample, i.e. 49.1%. Only 29.8% of our patients weighed less than or equal to 60 kg at the start of treatment. Patients infected with HIV1 were in the majority, i.e. 85.1%. The rate of patients weighing ≥ 60 kg did not statistically increase from inclusion (35.1%) to M12 (36.80%) $P=0.416$ (fig1).

The rate of non-compliant patients did not experience any statistically significant change: 46.5% at M1; 36.8% at M6; 41.2 to M12. $P=1.101$, $KHI2=138.105$. The rate of patients who switched treatment regimens did not experience a statistically significant change from M1 (3.5%) to M6 (4.4%) and M12 (0.9%). $P=0.890$, $KHI2 90.408$. In total, only 4.4% of our patients underwent a therapeutic change, ie 2.6% for side effects and 1.8% for stock-out reasons. The difference was statistically significant. $p=0.0066$, $KHI2=94.312$. The majority of patients had mild anemia at the start of treatment, ie 86% of our patients. The rate of patients

with high ALAT was: 20.2% against 79.8% for those with normal ALAT. Serum creatinine for the majority of our patients was normal at 92.1%.

The rate of patients with normal blood sugar levels was the majority at the start of treatment, ie 81.6%.The rate of patients with an undetectable VL experienced a statistically significant increase: from 15.8% at M6 and 21.9% at M12. P=0.0000142, KHI2 2.299 (Table I).

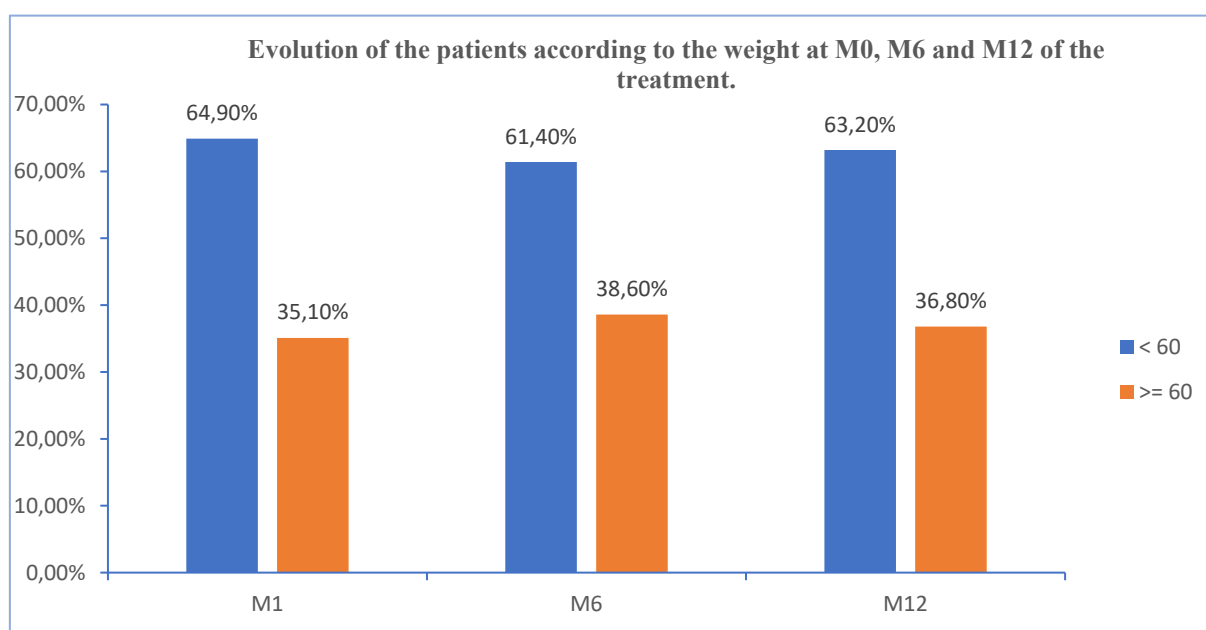


Figure 1: Evolution of the patients according to the weight at M0, M6 and M12 of the treatment.

Table I: Evolution of the viral load of patients from M6 to M12 of treatment

viral load	M6		M12	
	Number	Percentage	Number	Percentage
1033 copies/ml	5	4,4	2	1,8
839 copies/ml	1	,9	2	1,8

Undetectable	18	15,8	25	21,9
Moderate	0	0,0%	1	,9
Detectable with 2165 copies/ml	1	0,9%	0	0,0%
Nothing	90	78,90%	84	73,7
Total	5	4,4	114	100,0

DISCUSSION

The aim of our study was to follow the evolution of the biological parameters in patients under antiretroviral treatment at M0, M1, M6 and M12 at the USAC of the CSRéf of the commune V of Bamako. For this we proceeded to count platelets and assay hemoglobin levels and biochemical parameters (glycemia, creatinine, and ALAT) and viral load.

A. Sociodemographic characteristics:

Gender

The sex ratio was 0.70 in favor of women. This result is comparable to that obtained by EDSM-IV which reported a sex ratio of 1.70 in favor of women [1]. It could be explained by their vulnerability, socio-cultural constraints and their physiological constitution exposing them more easily to HIV infection [2].

Age

The average age was 36 years with extremes of 18 and 68 years. The age groups (35-44) and (45 and over) were in the majority with 35.1% and 49.1% respectively. This result is comparable to that of KIBANGOU in Congo [3], who obtained in his study on the clinical and biological evolution of

patients on ARVs, a majority age group of 29 to 51 years with extremes of 15 to 67 years.

These age groups correspond to the most sexually active sections of the population [4].

Residence:

Almost all of our patients reside in Bamako (90.4%). This can be explained by the presence of the USAC in the city of Bamako.

B. Regularity in the biological assessment:

The regularity in the biological assessment statistically regressed at the end of our study ($p=0.0000004$). This state of affairs is due on the one hand to a lack of knowledge of the importance of the biological assessment and on the other hand to a lack of financial means for patients to come to the center.

C. Parameters studied:

Weight

On inclusion, the majority of our patients weighed less than 60 kg with a frequency of 70.2%, this result is comparable to those of Sanogo M [3] and Maiga OI [5] who respectively found 57.8% and 83%. This rate could be explained by an altered general condition of the patients on arrival.

At the end of our study, we noticed a statistically significant increase in patients weighing ≥ 60 kg ($p=0.0416$), which shows a beneficial effect of triple antiretroviral therapy in weight gain, which is one of the parameters of the effectiveness of treatment.

Viral load

The rate of patients with undetectable VL increased significantly ($p=0.00142$).

Laurent et al found an undetectable viral load in 80% of patients after 6 months of treatment. [5]

This shows the effectiveness of ARV treatment from a virological point of view, especially since the rise in CD4 counts is correlated with the drop in viral load (mirror evolution).

Hemoglobin level

A slight anemia was observed in the majority of our patients on inclusion with a frequency of 86%, this would be explained by an altered general condition of the patients on arrival [6].

At the end of our study, the hemoglobin level did not change significantly $p=0.336$.

However, at the Leopold-Franzens University in Australia, Sarcletti et al obtained in January 2003 an increase in the hemoglobin level after 6 months of triple therapy ($p=0.0001$) [7].

Biochemical results (blood sugar, creatinine, ALAT). On inclusion, 79.8% of our patients had a normal ALAT, 92.1% had a normal creatinine level and the majority of these patients also had a normal blood sugar level, i.e. 81.6%. At M6 and M12 these different examinations were not honored by the patients.

Our results are comparable to those of Coulibaly and col [8] who found ($p>0.05$) in a similar study conducted at the CHU de point G in 2007 where the 102 patients followed did not experience a significant increase in these biochemical parameters after six months of triple therapy, which shows the good biological tolerance of the treatment based on dolutegravir.

CONCLUSION :

It appears from this study that the biological disorders observed before the initiation of ARV treatment have gradually regressed, thus demonstrating the effectiveness of antiretroviral triple therapy based on dolutegravir on the infection, which leads to an improvement in the quality of life of people living with HIV.

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