Estimated rates of treatment failure in first-line antiretroviral treatment in Kinshasa: Case of the ACS AMO-Congo

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ABSTRACT

Introduction: In the Democratic Republic of Congo (DRC), the first line of treatment for HIV adopted since 2008 for the PLHIV is a combination of single-dose Azydothimidine (AZT), Lamivudine (3TC) and Nevirapine (NVP). In 2009, 34 947 PLHIV were on the first line HAART in the DRC, of which 28,918 or 82.75% were adults.

Objective: Estimate the rate of treatment failure in first-line antiretroviral therapy in treatment centers in Kinshasa.

Method: This study is a cross-sectional study in three outpatient treatment centers of the NGO ACS AMO-Congo in the city of Kinshasa in the Democratic Republic of Congo in January 2009. Any patient on antiretroviral therapy in first intension followed regularly in one of three centers of study for more than six months in January 2009 was considered. Blood sampling was done in a tube with EDTA anticoagulant, from a venous puncture. The numbering of CD4 has been made in the laboratory of ACS / AMO-Congo Kasa Vubu on FACSCount^{TM} and viral load at the National Reference Laboratory AIDS / STI (LNRS) by NucliSens Easy Q - HIV1, Version 1, 2. Data were entered using Excel and SPSS software. The Student test was used for quantitative variables and Chi-square (X^2) for categorical variables. The significance (p) was chosen for the probability of p <0.05. Results are expressed as mean ± standard deviation. The tables have been reformatted in Excel. Respect for the individual and the confidentiality of records were found.

Result: A total of 102 patients were included in this work with a female predominance (66.7%) and a mean age of 41.4 ± 9.4 years. The mean CD4 count of third control (395.5 ± 145.2 cells / l) were significantly higher than those of CD4 at baseline (252.1 ± 128.7 cells / l). Controls were performed CD4 at 1 month (control 1), 3 months (control 2) and ± 6 months (control 3). The viral load (VL) average of 20,258.3 ± 10,209.0 RNA copies / ml. Eighteen patients (17.6%) had a CD4 count lower than the third control values before treatment, 16 patients (15.7%) had a viral load above 1000 RNA copies / ml and 7 patients (6.9%) evolved at the AIDS stage.

Conclusion: The estimated rate of treatment failure of patients on ARV first line in Kinshasa conducted in 3 treatment centers for AMO-Congo gave a rate of 17.6%.

Keywords: HIV treatment failure, viral load, CD4

Introduction

In 2009, 5.25 million people living with HIV (PLHIV) are under Highly Active AntiRetroviral Treatment (HAART) in low-and middle-income as reported in 2010 the World Health Organization (WHO)[1]. The goal of HAART is to slow the progression to AIDS by reducing viral load to undetectable value and restoring immunity to a CD4 count above 500 cells/mm3 for patients infected with HIV[2].

In the Democratic Republic of Congo (DRC), the first line of treatment for HIV adopted since 2008 for the PLHIV is a combination of single-dose Azydothimidine (AZT), Lamivudine (3TC) and Nevirapine (NVP)[3]. In 2009, 34 947 PLHIV were on the first line HAART in the DRC, of which 28,918 or 82.75% were adults[4].

The failure of HAART is considered as an increase in Viral Load (VL) of more than 0.7 log and/or a decrease in CD4 evaluated after 6 months from start of HAART[5]. It includes a variety of situations, it is based on immunological criteria, virological and/or clinical[5-9]. Immunological Failure is based on a return of CD4 to the value before treatment, a decrease of 50% at the maximum rate achieved on HAART CD4, a persistent CD4 count <100 cells/mm3 despite treatment and not a rise in CD4 count despite treatment[5-9]. Virological Failure is based on viral load (VL) greater than 1000 RNA copies/ml[5-9]. Clinical failure is based on the reappearance of opportunistic infections and/or progression to a higher stage after starting treatment, as well as the fall of the patient's weight in the context where we excluded all (problem, stress syndrome recovery)[5-9].

The biological failure is defined as a substantial impairment of immunity with a lack of control of viral load. Hence it includes the standard immunological and virological criterion[5]. However, the VL is not generally available in settings with limited resources, it is recommended to apply the clinical criteria and, if possible, to use the numbering of CD4 to define failure[7].

The aim of this study is to estimate the rate of treatment failure to antiretroviral therapy in primary care treatment centres in Kinshasa.

Material and Method

Framework

This study is a cross-sectional study, experimental and retrospective carried out in 3 outpatient treatment centres of the NGO ACS AMO-Congo (Binza Ozone, Kasa Vubu and Ndjili) in the city of Kinshasa in the Democratic Republic of Congo in January 2009.

Patients

Any patient on Highly Active AntiRetroviral Therapy (HAART) in the first line followed regularly in one of three centres of study for over six months in January 2009 was considered. A sampling interval was applied to draw the number volunteers from lists made up. As we had 15 patients Binza Ozone (BO), 78 patients Kasa Vubu (KV) and 27 patients Ndjili (Nd), a total of 120 patients on first line treatment in January 2009 included in the work.

Sampling

PLHIVs selected by our survey were contacted by telephone for appointment in their respective centres where they were followed for blood sampling after an informed consent written down in the questionnaire work.

Blood sampling was done in a tube with EDTA, from a venepuncture. The samples were shipped to various laboratories for analysis.

Laboratory Work

The numbering CD4 was made in the laboratory of ACS/AMO-Congo in the Kasa Vubu with the FACSCount[TM] and Viral Load at the National Reference Laboratory for AIDS/STI (LNRS) by NucliSens Easy Q - HIV1, Version 1, 2.

Statistical analysis

Data were entered using Excel and SPSS software. Student's T test was used for quantitative variables and Chi-square (X^2) for categorical variables. The significance (p) was chosen for the probability of $p < 0.05$. Results are expressed as mean ± standard deviation. The tables have been reformatted in Excel.

Ethics

This study was approved by the ethics committee of the School of Public Health, University of Kinshasa and the centre managers. Respect for the individual and the confidentiality of records were implemented.

Results

A total of 102 patients were included in this study with a female predominance (66.7%) and a mean age of 41.4 ± 9.4 years (minimum limit of 17 years and maximum 64 years). The mean values of CD4 third control (395.5 ± 145.2 cells/µl) were significantly higher than those of CD4 at baseline (252.1 ± 128.7 cells/µl). Controls were performed in CD4 1 month (control 1), at 3 months (control 2) and ± 6 months (control = 3 during the study). The viral load (VL) average was of 20,258.3 ± 10,209.0 RNA copies/ml (lower limit of 25 RNA copies/ml and a maximum of 85,000 RNA copies/ml). Eighteen patients (17.6%) had a CD4 count lower than the third control values before treatment, 16 patients (15.7%) had a viral load above 1000 RNA copies/ml and 7 patients (6.9%) progressed to AIDS stage. Table 1 shows the frequencies depending on the age and sex. Table 2 shows the values of CD4 and viral load. Table 3 presents the assessment of various parameters in relation to patient outcomes.

Discussion

The aim of this study was to estimate the rate of treatment failure patients on first-line ARVs in the city of Kinshasa in the context of free health care program in medical management.

 Women (66.7%) visit more the treatment centres than men (33.3%). This corroborates with the literature that says that the feminization of the epidemic is nowhere more apparent than in sub-Saharan Africa, where women represent over 57% of HIV infections in adults and where 75% of infections affecting young women and girls[10].

Immunologically, 17.6% of patients are to be considered in Treatment Failure because the CD4 count at 6 months which is lower than before treatment initiation. For the treatment to be considered successful, the CD4 count should be maintained and constantly increasing above the initial value[5-9].

Virologically, 16% of patients are to be considered in Treatment Failure because their VL that is still greater than 1000 viral RNA copies/ml. The goal of HAART is to achieve a VL undetectable after 6 months of treatment[5-9].

Clinically, 7% of patients could be considered in Treatment Failure because they have gone up on a higher clinical staging, according to WHO, despite starting treatment[5-9].

To the extent that the failure of treatment is considered the decrease in CD4 count, higher viral load viral load of more than 0.7 log and/or progression of clinical stage evaluated after 6 months the start of HAART[5-9], 17.6% of patients should be considered in treatment failure of first line from the rate of CD4.

 The difference between the virological and immunological failure was not statistically significant. However, 7% failure compared with clinical criteria is an underestimation of failure rate (p = 0.001). It is therefore necessary to require follow-up examinations in all patients in order to make informed decisions. This is a problem in several African countries where treatment

failure is often underestimated by lack adequate diagnosis and mismanagement of data[11, 12]. The VL is not available for all patients, the CD4 count properly instructed on the evolution of patients' conditions.

Conclusion

The estimated failure rate of patients on ARV therapy in the first line in Kinshasa conducted in three treatment centres AMO-Congo gave a rate of 17.6%.

 This result confirms that in these patients, there is a failure rate that is beyond the clinician based on several parameters. Biological monitoring tests are important to determine the status of treatment failure.

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Conflict of Interest: None declared.

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Table 1: Sex and age of the population

	Males	Females
n = 102	34 (33,3%)	68 (66,7%)
Age (years)	45,4 ± 10,11	39,3 ± 8,4

Table 2: Values of CD4 and Viral Load

	CD4 (cells/µl)				Viral Load (copies of RNA/ml)
	Initial	**Control 1**	**Control 2**	**Control 3**	
Mean	252,1 ± 128,7	359,4 ± 141,8	393,3 ± 116,8	395,5 ± 145,2	20258,3 ± 10209,0
n	73	60	35	83	102

Table 3: Evaluation of parameters

	Variables	Frequencies (%)
Evaluation of CD4	Lower than the Initial Value	**18 (17,6%)**
	Higher than the Initial Value	73 (71,6%)
Viral Load	Lower than 1000 copies RNA/ml	86 (84,3%)
	Higher than 1000 copies of RNA/ml	**16 (15,7%)**
Clinic	Evolution Toward AIDS	**7 (6,9%)**
	No Evolution of Stage	95 (93,1%)