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Original Research Article

Determinants of virological failure in HIV1 infected patients followed in a third-level hospital Abidjan, Cote d'Ivoire

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ABSTRACT

Introduction: Côte d'Ivoire has been committed to achieving the UNAIDS 90-90-90 targets of People Living with HIV (PLHIV) follow-up since 2015. The proportion of patients on antiretroviral therapy (ART) was below the desired rates for 2020. The laboratory of the University Hospital Center (CHU) of Yopougon has been equipped with instruments capable of quantifying the plasma viral load (VL) of PLHIV on ART. This quantification allowed for early detection of virological failure in PLHIV. The objective of this study was to determine the rate of virological failure and the epidemiological, immunological and virological determinants of virological failure in patients followed at the Yopougon University Hospital in Abidjan.
Materials and Methods: This was a retrospective study covering the period from January 1, 2015 to October 31, 2019. It was carried out on data related to blood samples (plasma) of PLHIV (infected with HIV-1) under ART for at least 6 months and who had quantified their viral load.
Results: A total of 52356 PLHIV were included in this study. The age group 40-50 years comprised the majority of the patients (46.7%) with a median age of 40 +/- 0.3 years. The female sex predominated with 72% and a sex ratio of (M/F) = 0.38. The TCD4 cell were between 500 and 350 cells/μL in 57.0% of patients at treatment initiation. The TDF+3TC+EFV treatment regimen was prescribed in the majority of patients (88.62%). The population of patients with virological failure (defined as VL $\geq$ 1000 copies/ml) was 12924 or a prevalence of 24.7%. The determinants of virological failure were age $\leq$ 15 years, male sex and CD4+ LT rate below 250 cells/μL ($p < 0.05$).
Conclusion: The virological failure rate was high especially in children and male subjects at the Yopougon University Hospital. It appears therefore important to act on these determinants, by additional efforts through concrete actions such as regular and systematic measurement of CV at the time of rapid change of treatments with effective combinations for this type of PLHIV. The goal is to achieve the objectives of the UNAIDS to eradicate HIV by 2030.

1. Introduction

Human Immunodeficiency Virus (HIV) infection remains a serious public health problem worldwide and particularly in Sub-Saharan Africa. The pandemic continues with 38.4 million people living with HIV (PLHIV) and 650,000 deaths worldwide in 2020.[1] The link between plasma viral load (VL) and HIV transmission has been demonstrated in several studies.[2–4] Prevention and antiretroviral treatment (ART) will contribute to a reduction in HIV transmission. As a result, strategies to improve access to testing, antiretroviral treatment and virological monitoring are being

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developed. In 2015 this lead UNAIDS to define its 90-90-90 triple target for 2020, which specify that 90% of PLHIV should know their HIV status, 90% of those diagnosed with HIV should be on ART and 90% of those on ART should be virally suppressed.[5] The World Health Organization (WHO) recommends VL quantification as the preferred approach to ART monitoring over clinical or immunological criteria.[6] It has been shown that routine monitoring of VL leads to earlier detection of treatment failure compared to immunological and clinical criteria.[7] However, the lack of molecular tools for the quantification of the VL is a barrier to large-scale testing of patients under ART in sub-Saharan Africa.

Côte d'Ivoire, with approximately 430,000 PLHIV and 230,000 PLHIV on ART in 2020, is committed to achieving this UNAIDS goal. Since 2015, with the support of partners in the fight against HIV/AIDS including PEPEFAR, the Central Laboratory of the Yopougon University Hospital has been equipped with a molecular biology platform for the quantification of the VL of patients who have been on ART for at least 6 months. This quantification allowed for the early detection of poor adherence and virological failures in HIV1 positive patients. The objective of this study was to determine the rate of virological failure and the epidemiological, immunological and virological determinants of virological failure in patients followed at the Yopougon University Hospital in Abidjan.

2. Materials and Methods

2.1. Materials

This is a retrospective study covering the period from January 01, 2015 to October 31, 2019. It was conducted on blood samples (plasma) of PLHIV. The study included patients with type 1 HIV infection, on ART for at least 6 months, who received a VL test. The viral load measurement was performed in the molecular biology unit of the central laboratory of the Yopougon University Hospital. Data was collected from the patients using a standardized collection form. The surveyed parameters of the study were sociodemographic data on age, sex, reason for requesting the VL (for control under ART, for virological or immunological failure), therapeutic data (the line and the therapeutic regime), immunological data (CD4 count) and virological data (type of HIV, CV RNA HIV-1).

2.2. Operational definitions

The criteria for clinical, immunological and virological failure were defined according to WHO recommendations.[8]

1. Clinical failure was defined as a WHO clinical stage III or IV;
2. Virological failure was defined as a detectable plasma viral load ≥1000 copies/mL 6 months after initiation of initial ART;
3. Immunological failure was defined as a

CD4count at 250 cells/μL following clinical failure or persistent CD4 cell count below 100 cells/μL (adults and adolescents).

Persistent CD4 cell count below 200 cells/μL (Children younger than five years).

Persistent CD4 cell count below 100 cells/μL (Children Older than five years).

2.3. Method for viral load quantification

2.3.1. Pretreatment of whole blood

Whole blood on EDTA collected from each PLHIV was transported to the laboratory at low temperature and centrifuged at 8000 rpm for 10 minutes to obtain plasma.

2.3.2. Extraction, RNA quantification and CD4 count

In our study the Cobas TaqMan® method for human immunodeficiency virus type 1 (HIV-1) (Roche Molecular Systems, Branchburg, NJ) was used. First, total nucleic acid extraction was performed on Cobas AmpliPrep® (CAP) using magnetic bead nucleic acid capture technology. A volume of 850 μL of plasma according to the manufacturer's instructions was used for the extraction. Nucleic acid amplification was performed by real-time PCR (RT-PCR) on the Cobas TaqMan® analyzer (CTM).[9] The primers used in this technique targeted the long terminal repeat (LTR) regions of the HIV genome (Biosentric ®).[10] The sequence is sufficiently conserved to allow amplification of the vast majority of group M HIV-1 subtypes.[10] The CD4 count of each PLHIV was determined by flow cytometry FacsCalibur® (Becton Dickinson, Californie, US).

2.4. Statistical analysis

Data entry and analysis were done with Epi info version 6.0 and graphs with Excel®. Qualitative variables were expressed as a percentage and comparisons were made using the chi-square test (X2). Quantitative variables were expressed as mean ± standard deviation, median, minimum and maximum and comparisons were made using Student's t test. The alpha (α) statistical significance level was set at 5% ($p<0.050$).

2.5. Ethical considerations

Respect for anonymity was taken into consideration during data collection. No names or coordinates that could identify a patient were used in our study. Each patient is encrypted by a unique code. The data from this study will only be used for scientific purposes.

3. Results

During the study period, 52356 PLHIV were included. Epidemiologically, the 40-50 year age group accounted for the majority of patients (46.7%) with a median age of 40 +/- 0.3 years. Females predominated, (72.0%) with a sex ratio of (M/F) = 0.38. Routine monitoring during ART (99.3%) and virological failures (0.6%) were the main reasons for requesting a VL test among the PLHIV followed in our study (Table 1). The TDF+3TC+EFV treatment regimen was prescribed in 88.62% of cases, compared to 0.64% for the second line regimen TDF + 3TC + LPV/r. The CD4 cell count was greater than 350 cells/μL in 57.0% of patients at treatment initiation (Figure 1). The mean CD4 count was 507.7 cells/μL. And the mean VL was 81,996 copies/ml. The absolute number of PLHIV with virological failure (as defined by VL ≥ 1000 copies/mL) was 12,924 or a prevalence of 24.7% as shown in Table 2. Regarding the determinants of virological failure to treatment presented in Table 3, age (less than 15 years), sex (male) and CD4 cell count (<250 cells/μL) were related to the occurrence of virological failure (p=0.0001) regardless of the line of the patients' the rapeutic regimen (2INTI +1INNTI= 1 st line, 2INTI+1IP/r= 2nd line).

Table 1: Epidemiological characteristics of the PLHIV population studied

Epidemiological characteristics	Frequency (N=52356)	%
Age (Years)		
[0 ; 15]	4737	9,0
[16 ; 40]	23185	44,3
[41 ; 65]	24434	46,7
Gender		
Male	14621	27,9
Woman	37735	72,9
Reasons for requesting a CV		
Control on ARVs	52 014	99,34
Clinical Failure	16	0,03
Immunological Failure	21	0,04
Virological Failure	305	0,6

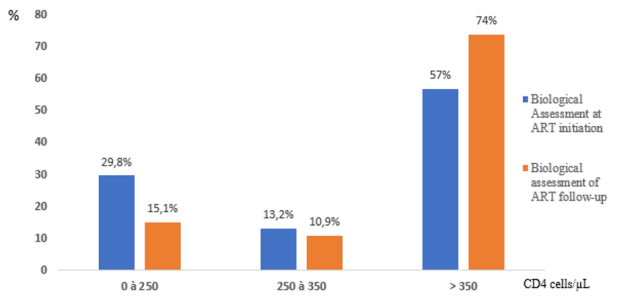

Fig. 1: CD4 count distribution in the population at ART initiation and follow-up

Table 2: Virological characteristics of the PLHIV population studied

Virological Characteristics	Frequency (N=52356)	%
CV (copies/mL)		
Undetectable	29756	56,8
[0;1000[	9676	18,5
[1000; 10000[	3610	6,9
[10000; 100000[	6119	11,7
[100000; –>[	3195	6,1
Therapeutic efficacy threshold		
Failure (CV ≥ 1000 copies/ mL)	12924	24,7
Successful (CV < 1000 copies/mL)	39432	75,3

4. Discussion

4.1. Epidemiological characteristics

In our study 46.7% of the patients were between 40 and 50 years old, almost half 44.3% were between 16 and 40 years old with a median age of 40 +/- 0.3 years. Many studies have noted the same age ranges in the PLHIV population in sub-Saharan Africa.[7,11] These findings suggest that patients are disproportionately affected by HIV infection. The proportion of women living with HIV was high (72.1%) in the study population. Our results are similar to the percentage of women living with HIV in South Africa 61% and Cameroon 81.9%.[12,13] However, other studies have reported a high proportion of HIV-infected men.[14–16] The anatomy of the female genital system, the diminished economic power of women, and early sexuality have contributed to the gender vulnerability gap. Failure occurred more often in men than in women (p=0.0001). Our finding was corroborated by Nouhoum Telly et al. 2022 who stated that men were 6 times more likely to experience treatment failure in Mali (OR= 6.4 95% CI:1.5-27.2).[17] In addition, African studies on ART adherence have shown that although the rate of HIV-infected women is high, they were more adherent to treatment than men, for various reasons.[12] The majority of patients in this study were treated with combinations containing 2 NRTIs plus an NNRTI or PI. The fixed dose combination (TDF+3TC+EFV) was prescribed as first line treatment in 88.62% of patients. As for the second line treatment regimens, the regimen (TDF + 3TC + LPV/r) with 0.64% was followed in a minority. The low prescription of second-line regimens was also reported by Minata Dembele et al. in Bamako.[18] These the combinations of 2 NRTIs with an NNRTI or PI were in agreement with the recommendations of the Côte d'Ivoire national policy of July 2010 and those of the WHO of November 2010. At the time of our data collection, the majority of our patients were not yet on the new TDF+3TC +DTG regimens recommended for all men and women.

Table 3: Determinants of virological failure in PLHIV

Variables	Workforce (N=52356)	Virological failure		P- value
		No	Yes	
Gender				
Male	14621	10640(72,77%)	3981(27,22%)	0,0001
Woman	37735	28792(76,30%)	8943 (23,67%)	
Age (years)				
<15	4737	1970(41,58%)	2767(58,4%)	10-6
>15	47619	28792(60,40%)	8943(39,5%)	
Art				
TDF+3TC+EFV	46402	35363(76,21%)	11039(23,37%)	0,642
AZT+3TC+LPV/r	5610	3806(67,84%)	1804(32,15%)	
CD4 (cells/μL.)				
< 250	7 893	4 666 (59,11%)	3 227 (40,88%)	0,0001
>250	44 463	34766(78,19%)	9697(21,80%)	

4.2. Immunological and virological data

Regular CD4 count in HIV-positive patients on ART remains an important and critical factor in disease progression. For patients with a CD4 count below 350, the average time for the CD4 count to fall from 350 to 250 cells/μL is 3 to 5 years. It is during this time that a number of stage II symptoms may develop. It is advisable to start treatment at screening to avoid the development of stage II symptoms. However, the discussion remains open, as long-term exposure to antiretroviral drugs is known to have toxic consequences, so some argue for starting at 250 cells/μL CD4.[19] In our study the CD4 count was between 0 and 250 cells/μL in 29.8% patients, between 250 and 350 cells/μL in 13.2% and above 350 cells/μL in 57.0%. Although a quarter of patients have a CD4 count of less than 250, efforts are being made to raise awareness of early detection of AIDS patients. The admission of ARV treatment as soon as patients are screened in the consultation room is a strategy to be encouraged in PLHIV care centers. In fact, according to the recommendations in force in Côte d'Ivoire, ART is started in asymptomatic patients as soon as the patient is tested positive for HIV. The mean CD4 count in our study of 507.7 cells/μL was close to that reported by Cisse Diallo et al. in Senegal and differed from those of Dokékias et al. in Congo and Sozio et al. in Italy, who reported 255 cells/μL, and 133 cells/μL, respectively.[7,20,21]

Regarding the measurement of the patient's HIV RNA, at least two annual determinations are required for patients treated with antiretroviral drugs. VL is an essential marker for monitoring treatment effectiveness. It allows virological evaluation of efficacy and indirectly of adherence after initiation of ART in naive patients. The mean VL was 81,996 copies/ml. High mean VL values were also found in Cameroon with more than 95,740 copies/ml in HIV positive patients.[22] A viremia of more than 100,000 copies/ml indicates a patient in a very advanced stage of the disease, a proportion of patients (6.1%) exceeded 100,000 copies/ml. This is mainly due to the very late management of the disease in developing countries.

4.3. Determinants of virological failure

At the inclusion of our study, 75.7% of stable patients had a VL less than or equal to 1000 copies/ml and 24.7% of patients with a VL greater than 1000 copies/ml were considered to be in virological failure. This level of PLHIV with virological failure was also observed in the capital cities and rural areas of Guinea-Conakry 24% (n=136), Senegal 26% (n=119).[23] Lower rates, with an overall prevalence of patients with virological failure between 6 and 16% have been reported in several other African and Asian countries.[24–27] We were not able to demonstrate the development of mutations associated with possible resistance to ART to address this situation.[28] In this study, virological failure in PLHIV was strongly associated with age. We observed 27.2% of children under 15 years of age in failure (p=0.0000001). A higher proportion of HIV-infected children, 64%, was reported by Abdoul-Magib Cissé et al. among whom there was resistance to at least one drug in 86.5% of cases in Senegal.[23] Furthermore, authors in sub-Saharan Africa such as Moise K Nyongesa et al in Kenya and Arne Kroidl et al. in Tanzania,stated that one of the adjusted risk factors for virological failure was age < 30 years (RR 5.2 [95% CI: 2.5-10.8]) combined with years on ART ≥ 3 years (RR 3.0 [1.0-8.9]) and poor self-reported adherence (RR 2.0 [1.2-3.4]).[25,29] This supported our findings for Côte d'Ivoire. In the Tanzanian study, VL>1000 copies/ml at first screening was detected in 16.3% of patients while the Kenyan study described an overall prevalence of 32.0% [95% CI: 27.5-36.9]. The strategy of early initiation of ART for PLHIV is very commendable, but the youth of our populations in virological failure could be explained by the difficulties of following the advice on adherence to ART according to a study carried out in Togo in 2012.[30] Adherence to treatment and its determinants were not the subject of our study, but many authors have looked at the causes of adherence or non-adherence in

Africa. Identifying Forgetfulness, cost of treatment, distance from the treatment center or side effects as the main determinants of non-adherence.[31,32] In a population of 37735 women living with HIV-1, the proportion of patients with virological failure was 23,7% (8943), compared with 27,2% for 14621 men (3981). A predominance of virological failure in the female population infected with HIV has been reported in some studies.[10,33] Koné et al. reported a higher virological success in women (74%) compared to 1479 (26%) virological failures in a population of 5709 women, but the difference was not statistically significant. The reasons for this failure in women were not specified in these studies. In our study, virological failure to treatment was detected in 21.8% (n= 9697/44463) of patients with CD4 cell counts >250 cells/μL. Patients in immuno-virological failure represented 21.8% versus 78.2% in success. These results are different from those reported in a study of PLHIV (n= 8410) followed up in care centers in Abidjan.[10] In this study the rate of immuno-virological failure was 20.5% against 29.3% success. The cases of virological failure associated with immunological success (21.8%) were a sign of early detection of virological failure despite immunological success, which could be confirmed by genotyping to detect antiretroviral drug resistance mutations.[28,34]

5. Conclusion

The rate of virological failure was high especially among children and male HIV subjects followed in Yopougon Abidjan. The measurement of viral load (VL) is beneficial for the early detection of virological failure, detection of non-adherence to ART and prevention of resistance accumulation. It therefore appears important to act on the identified determinants, by additional efforts through concrete actions such as regular and systematic measurement of CV at the time of rapid change of treatments with effective combinations for this type of PLHIV. The goal is to achieve the objectives of the UNAIDS in order to reach the objectives of the UNO AIDS to eradicate HIV by 2030.

6. Source of Funding

None.

7. Conflict of Interest

None.

8. Authors' Contributions

Meité S. and Monemo P. wrote the first draft of this article. Yapi AJC, Diallo C, Monney B, Abounou J, Dao I participated in the data collection. Mlan A, Zaba F, Meité S, Monemo P participated in the molecular diagnosis of HIV and the follow-up of PLHIV. Faye-Kette H and Dosso M reviewed the manuscript.

All the authors contributed to the proofreading and correction and gave their agreement for the publication of this manuscript.

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