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Factors Associated with Antiretroviral Treatments Failure among HIV-Positive Patients in Congo: A Retrospective Cohort Study

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Abstract

Background: Viral load is the key indicator of the effectiveness of antiretroviral treatment in HIV patients. Study aimed to determine antiretroviral treatments failure rates and associated risk factors among HIV-infected adult patients in Congo. **Methods:** Data from the Congolese AIDS and Epidemics Control Council were combined to create a historical cohort. Patients were followed up between 2003 to 2017. Mixed logistic regression was used to identify treatment failure associated-factors. Intercooled Stata 10 (StataCorp LP, College Station, Texas, USA) software packages was used for analysis. **Results:** Over 14 years of follow-up, a total of 25,500 visits for 6391 adult patients were reported. Among them, 88% *i.e.* 22,328 visits (for a total of 6127 patients) were visits with treatment failure. In the multivariate analysis, being aged >26 years, having primary education level, being student, others nationality, unspecifiedmarital status and being worker in informal sector were found associated with a higher risk of treatment failure. Conversely, being pensioners, receiving second line therapeutic protocols and having good adherence to treatment were found significantly associated with a lower risk of treatment failure. **Conclusion:** Antiretroviral treatments failure among HIV-treated patients is common in Congo. Developing treatment adherence-centered interventions with focus in patients who have low socio-economic status needed to reduced treatments failure. As treatment failure is not only determined by individual factors, psychosocial supports and availability of antiretroviral drugs needs to be taken into account.

Keywords

Congo, HIV, Antiretroviral Therapy, Treatment Failure, Risk Factors

1. Introduction

The human immunodeficiency virus (HIV) epidemic has affected populations around the world. In 2019, 38 million people globally were living with HIV, 1.7 million people became newly infected with HIV and 690,000 died from acquired immunodeficiency syndrome (AIDS)-related illnesses and Africa remains the continent with the highest number of cases, new infections and deaths [1].

Since the introduction of highly active antiretroviral therapy in 1996, there has been a significant reduction in HIV-related mortality rates [2] and effective treatment leads to better clinical and virological outcomes [3]. But, many patients on treatment experienced Virological and immunological failure in developing countries. For example, in Brazil, in a historical cohort study of 76,950 HIV patients aged 34 years on average, 85.2% achieved viral load suppression after 6 months of treatment [4] while in Uganda this proportion was 11% in a sample of 100,678 patients [5]. Factors associated with non-suppression of viral load vary from country to country and include co-morbidity, CD4 count , injection drug use, age, late diagnosis, type of treatment, drug pharmacokinetics, resistance to treatment and adherence [6]-[11].

Among people living with HIV, viral load suppression is one of the 10 global indicators for World Health Organization (WHO) guidelines on HIV infection information. This indicator is used to assess the United Nations Programme on HIV/AIDS (UNAIDS) latest "goal 90": to ensure that 90% of people on antiretroviral treatment have permanently suppressed viral load by 2020 [12]. Viral load suppression is therefore becoming a key indicator in HIV surveillance, not only improving the quality of life of People Living with HIV but is also an effective means of preventing sexual [13].

In Congo, VIH seroprevalence was estimated at 3.2% in 2009 among people aged 15 and 49 years [14]. Based in this prevalence, in 2020 approximately 128 000 adults are living with HIV/AIDS in Congoand 16% are receiving antiretroviral treatment. For care, to date, there are 83 care centres. Antiretroviral treatment is offered to all people living with HIV after confirmation of diagnosis and clinical evaluation according national therapeutic guidelines. Antiretrovirals treatment (ART) initiation is offered on the same day to people who are ready to start. The efficacy of ART is defined as the maintenance of a viral load <50 copies/ml after 6 months of continuous treatment and failure determined by a viral load >1000 copies/ml confirmed for at least 6 months after correcting adherence problems in a patient.

However, studies on virological response to ART in Congo are sparse, available studies have found that the proportions of patients with incomplete virologi-

cal suppression at 6 months and 12 months were 70% and 89.4% [15] [16], respectively after initiation of treatment. To our knowledge, no study has been carried out to date on the effectiveness and failure of long-term treatment of antiretroviral treatments used in the care units for HIV-infected patients in the Congo. In this context, this study aimed to determine antiretroviral treatments failure rates and associated risk factors among HIV-infected adult patients in Congo.

2. Methods

2.1. Study Design and Procedures

Data used in this study are from the survey on the Evaluation of Therapeutic Management of HIV Patients in CongoEVAL-CO. Eval-Co is a historical Cohort study in which 18,000 patients were follow-up in all care centres between 2003 to 2017. Main objective of EVAL-CO was to assess the survival of HIV patients after treatment initiation in Congo. The secondary objectives were: 1) assess retention of patients on antiretroviral therapy, 2) measure the proportions of patients with CD4 cell counts below <350 cells/mm^3 among those with initial CD4 cell counts, 3) assess the virological efficacy of treatment regimens, and 4) measure the incidence of tuberculosis and hepatitis B in people living with HIV in Congo. The Eval-Co database were compiled from the fragmented databases of the various health facilities in congo including data in first (Visit 0) and follow-up visits. Patient records were eligible if the patient was registered as HIV-infected. The other inclusion criteria were to have started ART between 2003 and 2017, to be at least 18 years old at treatment initiation, to have at least one follow-up visit after treatment initiation. At inclusion, following data were collected: sociodemographic data (Date of birth, sex, nationality, education level, marital status), clinical data (HIV status, weight, height, WHO stage), standard biological data (ASAT, ALAT, blood glucose, amylase, creatinine, blood cholesterol and triglyceride levels), virological data (Plasma viral load, CD4 T cell count). During follow-up, in the first two years, data were collected according to the following schedule: Day 15, Months 1 (M1), M3, M6, M9, M12, M15, M18, M21 and M24; then every 6 months until the 13th year after starting treatment. For these different dates the following data were collected: clinical data (therapeutic protocols, weight, WHO stage and information on therapeutic adherence), comorbidities (tuberculosis, viral hepatitis, malaria at each visit), vital status (death or loss of follow-up), virological data (viral load, CD4 T cell count from the 6th month of treatment then every 6 months until the 14th year). Therapeutic regimens for providing care to HIV patients in the Congo are classified in two periods: Before (Lines published in 2014) and after (Lines published in 2018). Details are in **Table 1**.

2.2. Variables

Variables retained for the analyses were classified into the following categories:

Table 1. Overview of therapeutic regimens for providing care to HIV patients, Republic of Congo.

Before (Lines published in 2014)	After (Lines published in 2018)
1st line treatment regimens	1st line treatment regimens
Main regimen: TDF+ FTC (or FTC) + EFV in fixed-dose combinations Alternative: – TDF + 3TC (or FTC) + NVP – AZT + 3TC + NVP (or EFV) – ABC + 3TC + NVP (or EFV) – AZT (or ABC) + 3TC + LPVr (or ATVr)	Main regimen: TDF+3TC (or FTC) +EFV Alternative: – TDF + 3TC + DTG – AZT + 3TC + EFV – ABC + 3TC + DTG – AZT + 3TC + NVP
2nd line treatment regimens	2nd line treatment regimens
If 1st line Protocol with TDF give in 2nd line this: AZT + 3TC + LPV/r (1^{st} intention) AZT + 3TC + ATV/r (2^{nd} intention) If 1st line Protocol with AZT, give in 2nd line this: TDF + 3TC (ou FTC) + LPV/r TDF + 3TC (ou FTC) + ATV/r	– If 1st line received is: TDF + 3TC (or FTC) +EFV, the 2nd line will be: AZT + 3TC + LPV/R – If 1st line received is: TDF + 3TC + DTG, the 2nd line will be: AZT + 3TC + EFV
3rd line treatment regimens	3rd line treatment regimens
Darunavir (DRV) + Etravirine (ETV) + Raltegravir (RAL)	The 3rd line treatment must be initiated according to the genotyping results. In the absence of genotyping: – 2 INRT + RAL (or DTG or DRV + RTV) – DRV + RTV + RAL or DTG± 1 or 2 INRT

- Socio-demographic characteristics: Gender (Male/Female), age (years), marital status (not in union, in union, divorced/widowed, nospecified), level of education (none, primary; secondary, university; unspecified), nationality (Congolese, other nationalities, unspecified), occupation in six modalities (none, student, formal sector, informal sector, retired, unspecified), care site (Centre for Health Care in Brazzaville, Centre for Health Care in Pointe Noire);
- HIV-related variables: CD4 count at initiation of treatment (<200 cell/mm^3; 200 - 350 cell/mm^3; >350 = cell/mm^3), plasma viral load per visit (Copies/ml), therapeutic protocols (1^{st} line, 2^{nd} line, 3^{rd} line).
- Psychosocial variable *i.e.*, adherence to therapy.

To assess therapeutic adherence, we used the following procedure:

a) assessment of the treatment period with the following formula:

1) Date of last dispensation - Date of first dispensation

b) Estimate the number of days in which patient has taken his pills, using the following formula:

2) Number pills received for all dispensation/ Expected number of pills per day

c) Measure the proportion of tablets consumed by the patient during the selected period, using the following formula:

3) Number of days in which patient has taken his pills/Number of consumption days expected ×100

Finally, two modalities of the compliance variable: patients who had a proportion of pills use of <95% [17] [18] in the time between the study visits were considered as have "poor adherence". On the other hand, patients with a proportion of drug use of at least 95% were considered as have "good adherence".

2.3. Definition of the Treatment Failure

Virological response to treatment was assessed in patients with viral load (VL) data over the follow-up visit. Patients who had a least one a viral load count >1000 copies/ml during the previous 6 months over the first 14 years were considered as patients having treatment failure. On the other hand, Patients who had a least one a viral load count <1000 copies/ml during the previous 6 months over the first 14 years were considered as patients with not having treatment failure.

2.4. Statistical Analysis

We first described the socio-demographic characteristics of the patients at baseline and estimated the proportion of follow-up visits with unsuppressed viral load. Mixed-effect logistic regression which enable the correlation between repeated measures to be taken into account [34] were used to identify the predictors of treatment failure among HIV patients. Variables with a p-value lower than 0.20 in univariate analyses were considered eligible to enter the initial multivariate model (*i.e.*, age, marital status, level of education, professional sector, follow-up centre, adherence to treatment). The final multivariate model was obtained using a backward stepwise selection procedure based on the log-likelihood ratio test to eliminate non-significant variables ($p > 0.05$) from the initial model. Statistical analyses were performed using Intercooled Stata 10 (StataCorp LP, College Station, Texas, USA) software packages.

2.5. Ethical Considerations

The study protocol was approved by institutional ethics committee of the health sciences faculty (Brazzaville, Congo). We used data collected for routine patient care at all health facilities in Congo and submitted to the *Conseil National de Lutte contre le Sida et les Epidémies* (CLNSE) which is mandated to conduct centralized HIV data in Congo. All data did not carry personal identifiers. The data were not accessible by any other third parties other than the study team. Permission to use the data was sought from the Congo Ministry of Health.

3. Results

3.1. Baseline Characteristics of the Study Population (n = 6924)

The main characteristics of the study population are presented in the **Table 2**. From 2003 to 2019, 19306 patients started ART, of whom 6924 (36%) had information available and were included in the study. At initiation of antiretroviral

Table 2. Main characteristics of study population (N = 6924 patients VIH).

Variables	Frequency	%
Gender		
Female	4902	71
Male	2022	29
Age (years)		
18 - 25	464	7
26 - 45	5463	79
>45	990	14
Matrimonial status		
Not in union	111	2
In union	132	2
Divorced/widowed	76	1
No specified	6605	95
Education level		
None	104	1
Primary	1260	18
Secondary	5041	73
University	526	8
Nationality		
Congolese	346	5
Others	14	0
No specified	6564	95
Professional activity		
Professionally inactive	1863	27
Students	305	4
Formal sector	755	11
Informal sector	3164	46
Pensioners	90	1
No specified	741	11
Baseline VIH-related characteristics		
With CD4 measures		
Yes	3717	54
No	3207	46
With viral load measures		0
Yes	3717	54
No	3207	46

therapy, the most represented age group was 26 - 45 years (79%), 4902 (71%) were women and the marital status for 6605 (95%) patients was not indicated. The socioeconomic status of the study population was low with 6931 (92%) pa-

tients having level education do not exceed grammar school and 3164 (46%) were unemployed or worked in the informal sector. In addition, 3717 (54%) had their CD4 count and viral load measured. Among them, 2114 (57%) had a CD4 count below 200 cells/mm^3 and 2127 (57%) had a viral load above 1000 copies/ml.

3.2. Treatment Failure among HIV Patients

Over the whole follow-up, a total of 25,500 visits for 6391 patients was reported. Among them, 88% *i.e.*, 22,328 visits (for a total of 6127 patients), were visits with treatment failure (*i.e.*, viral load count >1000 copies/ml) and for 12% *i.e.*, 3172 visits (for a total of 364 patients), the viral load was controlled.

3.3. Factors Associated with Treatment Failure

As shown in Table 3, variables significantly associated in univariate analysis with a higher risk of treatment failure included the following: being aged 26 - 35 years (OR [95%CI]: 2.207; [1.238 - 3.933], p = 0.007), being aged 36 - 45 years (OR [95%CI]: 2.159 [1.298 - 3.593], p = 0.003), having unspecified marital status (OR [95%CI]: 5.109 [3.801 - 6.866], p < 0.001), having primary education level (OR [95%CI]: 3.073 [1.812 - 5.213], p < 0.001), having secondary education level (OR [95%CI]: 1.815 [1.168 - 2.820], p = 0.008), having university education level (OR [95%CI]: 1.665 [1.010 - 2.745], p = 0.046), Being student (OR [95%CI]: 1.819 [1.127 - 2.936], p = 0.014), being worker in the informal sector (OR [95%CI]: 2.031 [1.596 - 2.585], p < 0.001), living in Pointe Noire (OR [95%CI]: 3.548 [2.843 - 4.428]) and having initiating treatment from 2014 onwards (OR [95%CI]: 2.454 [1.832 - 3.288], p < 0.001). Conversely, being widowed/divorced (OR [95%CI]: 0.752 [0.576 - 0.983], p = 0.037), being pensioners (OR [95%CI]: 0.329 [0.228 - 0.475], p < 0.001) and having good adherence to treatment (OR [95%CI]: 0.006 [0.002 - 0.025], p < 0.001) were significantly associated with less risk of treatment failure.

Most of these results were confirmed in multivariate analysis (Table 3). After adjustment, being aged 26 to 35 years (OR [95%CI]: 2.690 [1.419 - 5.100], p = 0.004), being aged 26 to 45 years (OR [95%CI]: 3.665 [2.086 - 6.440], p < 0.001), being aged > 45 years (OR [95%CI]: 1.720 [1.001 - 2.954], p < 0.001), having unspecified marital status (OR [95%CI]: 2.032 [1.108 - 3.727], p = 0.022), having primary education level(OR [95%CI]: 2.002 [1.124 - 3.564], p = 0.018), having unspecified nationality (OR [95%CI]: 2.439[1.288 - 4.620], p = 0.006), being a student (OR [95%CI]: 1.820 [1.076 – 3.079], p = 0.025) and being a worker in the informal sector (OR [95%CI]: 1.782 [1.386 - 2.291], p < 0.001) were all associated with a higher risk of having treatment failure. Conversely, being pensioners (OR [95%CI]: 0.467 [0.316 - 0.690], p < 0.001), receiving second line therapeutic protocols (OR [95%CI]: 0.674 [0.505 - 0.899], p = 0.007) and having good adherence to treatment (OR [95%CI]: 0.008 [0.001 - 0.032] p < 0.001,) were significantly associated with a lower risk of treatment failure.

Table 3. Factors associated with antiretroviral treatments failure among HIV patients in Congo: univariate and multivariate analysis using mixed effects logistic regression (Eval-Co cohort, 25,500 visits for 6391 patients, 14 years of follow-up: 2003-2017).

Variables	Number of visits (%)	Number of Patients	OR_{brute}	IC 95%	P	$OR_{adusted}$	IC à 95%	P
Gender								
Male (*Ref.*)	7967 (31.24)	2103	1					
Female	17,533 (68.7)	4861	1.029	[0.850 - 1.247]	0.763			
Age (years) at ART initiation								
18 - 25 (*Ref.*)	1028 (4.03)	329	1					
26 - 35	3910 (15.33)	1141	2.207	[1.238 - 3.933]	0.007	2.690	[1.419 - 5.100]	0.004
36 - 45	8388 (32.89)	2494	2.159	[1.298 - 3.593]	0.003	3.665	[2.086 - 6.440]	<0.001
>45	12,174 (47.74)	3056	0.690	[0.432 - 1.102]	0.121	1.720	[1.001 - 2.954]	<0.001
Marital status								
Not in union (*Ref.*)	3069 (1.04)	839	1					
In union	3784 (14.84)	1239	0.912	[0.706 - 1.178]	0.482	1.069	[0.814 - 1.404]	0.628
Divorced/widowed	2673 (10.8)	819	0.752	[0.576 -0.983]	0.037	0.875	[0.657 - 1.165]	0.362
No specified	15,974 (62.64)	3972	5.109	[3.801 - 6.866]	<0.001	2.032	[1.108 - 3.727]	0.022
Education level								
None (*Ref.*)	569 (2.23)	149	1					
Primary	3750 (14.71)	1110	3.073	[1.812 - 5.213]	<0.001	2.002	[1.124 - 3.564]	0.018
secondary	18,615 (73.00)	5000	1.815	[1.168 - 2.820]	0.008	1.020	[0.638 - 1.644]	0.935
University	2566 (10.06)	797	1.665	[1.010 - 2.745]	0.046	1.220	[0.710 - 2.095]	0.471
Nationality								
Congolese (*Ref.*)	9813 (38.48)	3049	1					
Others	384 (1.51)	171	2.384	[1.118 - 5.084]	0.024	2.068	[0.962 - 4.442]	0.063
No specified	15,303 (60.01)	3666	6.162	[4.776 - 7.950]	<0.001	2.439	[1.288 - 4.620]	0.006
Professional activity								
Professionally Inactive (Ref.)	7184 (28.17)	2007	1					
Students	1388 (5.44)	451	1.819	[1.127 - 2.936]	0.014	1.820	[1.076 - 3.079]	0.025
Formal sector	3504 (13.74)	1081	1.027	[0.787 - 1.339]	0.842	1.215	[0.914 - 1.615]	0.179
Informal sector	10,133 (39.74)	3007	2.031	[1.596 - 2.585]	<0.001	1.782	[1.386 - 2.291]	<0.001
Pensioners	497 (1.95)	107	0.329	[0.228 - 0.475]	<0.001	0.467	[0.316 - 0.690]	<0.001
No specified	2794 (10.96)	1173	1.046	[0.782 - 1.399]	0.758	1.120	[0.824 - 1.521]	0.467
Locality								
Brazzaville (*Ref.*)	8970 (40.17)	2573	1					
Pointe Noire	13,358 (59.83)	3606	3.548	[2.843 - 4.428]	<0.001			
Guideline on ART eligibility								
Before 2014 (*Ref.*)	16,972 (76.01)	4584	1					
From 2014 onwards	5356 (23.99)	1595	2.454	[1.832 - 3.288]	<0.001			

Continued

Therapeutic protocols								
1st line (*Ref.*)	21,470 (89.37)	5555	1					
2nd line	2490 (10.36)	545	0.909	[0.690 - 1.197]	0.498	0.674	[0.505 - 0.899]	0.007
3rd line	64 (0.27)	13	1.520	[0.209 - 11.020]	0.678	0.245	[0.0281 - 2.131]	0.203
Adherence								
***Poor adherence* (*Ref.*)**	10,604 (41.58)	3351	1					
Good adherence	14,896 (58.42)	4407	0.006	[0.002 - 0.025]	<0.001	0.008	[0.001 - 0.032]	<0.001

4. Discussion

In this study carried out among patients initiating antiretroviral treatments and a follow-up in a long period of 14 years, patients experienced frequently episodes of treatment failure, despite an improvement in access to treatment over the last decade in the Congo, which is consistent with previous studies in AR-treated patients in sub-Saharan African countries [19] [20] [21]. The fact that most of HIV patients treated in Congo having difficulties to achieve undetectable viral load over follow-up can lead to high mortality and limits the effect of treatment as prevention (TasP), thus leading to the persistence of the epidemic. Our results highlight also factors associated with treatment failure. key factors contributing to the high proportion of treatment failure in this study included both individual situations and related to the quality of care provided. Our results also highlight factors associated with treatment failure. The main factors that explain the high proportion of treatment failure in this study are both individual situations and healthcare supply-related. These factors underline difficulties in the management of HIV-infected patients in monitoring units in the Congo. Our study is the first to provide data on long-term treatment failure based on usual treatment regimens in the Congo. This means that our results are of major interest for decision making to improve the quality of care offered to HIV patients within the framework of the national AIDS programme.

Firstly, our study reports that seven out of ten HIV patients are women. The feminisation of the HIV epidemic has already been reported by previous studies in Congo [15] and elsewhere in Africa [5]. In Congo, more HIV patients were recruited in Pointe Noire than compared to Brazzaville ($P < 0.001$), which consolidates the estimates of the Seroprevalence and AIDS Indicators Survey in Congo (ESISC-I) 2009 survey, which established HIV prevalence at 6.2% in Pointe Noire and 3.5% in Brazzaville [14].

Consistent with previous cohort study conducted at University Hospital in Brazzaville [15] or elsewhere in African region [22], low level of education was among most important predictors of treatment failure . It is well reported that low level of education which like poverty is an important systemic determinant of health in low-income countries and calls for major structural changes [23].

Results show also that compared to first-line treatment, patients receiving second-line treatment were less likely to have treatment failure viral load, something already shown by previous studies among HIV-patients [24]. In our cohort, only 8% of patients received second-line protocol drugs. Therefore, there is an urgent need to improve second-line treatment coverage for support the global treatment strategy as a means of prevention [25] [26].

Finally, as reported previously, non-adherence to ART was a major risk factor of treatment failure [5] [6] [7]. To ensure continuous and complete viral suppression, adherence of at least 95% *(i.e.* consumed at least 95% of the prescribed drugs) is required [27] [28] [29] [30]. Or, in this our study, approximately 57% of patients taking at least 95% of the tablets. The current result shows that patients with poor adherence is a problem that will in turn affect the UNAIDS global targets of 90% viral suppression by 2020 [31]. This may indicate the need for more investment and commitment to improving patient adherence in the study area. We reported above that the majority of patients in our study population have economic difficulties. However, adherence to treatment depends on several factors, including the regular acquisition of meals. Indeed, patients who do not have regular meals tend not to take their medication regularly [32] [33]. Thus, strategies to increase adherence to treatment must take into account the fact that it is urgent to provide regular meals to patients who are in financial need. Lack of adherence to treatment is of particular concern here, as poor adherence in HIV patients is associated with higher risk of engaging in unprotected sexual behaviours [34], and thus increasing the spread of HIV.

Despite these interesting results, some study limitations need to be recognized. Firstly, social behavioural factors such as stigmatization and discrimination are major factors associated with viral load as previously reported by several studies [35]-[40]. The major limitation of this study is that these socio-behavioural variables were did not assess because the design of study (*i.e.*, a historical study), so researchers did not have any contact with patients. In addition, using a tablet count for assessing adherence may under or overestimate the proportion of patients with adherence to AR treatment [41]. Even so, we were able to adjust adherence according to VL and were able to show that the higher the VL the lower the adherence.

5. Conclusion

Antiretroviral treatments failure among HIV-treated patients is common in Congo. Developing treatment adherence-centred interventions with focus in patients who have low socio-economic status needed to reduced treatments failure. As treatment failure is not only determined by individual factors, psychosocial supports and availability of antiretroviral drugs needs to be taken into account. The high rate of treatment failure indicates the low quality of care. The development of a vast psychological support programme including advice on adherence to treatment, new technologies such as SMS reminders by phone to take the

prescribed doses and the provision of meals to destitute patients is becoming an essential part of the national AIDS programme.

Author Contributions

NG had the idea for and designed the study and had full access to all data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. AN, MFG, MNBU, AA DM and MED contributed to writing of the report. AA contributed to critical revision of the report. GN, MFG and MNBU contributed to the statistical analysis. All authors contributed to data acquisition, data interpretation, reviewed and approved the final version.

Declaration of Interests

All authors declare no competing interests.

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