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Antiretroviral Therapeutic Profile in Patients Living with HIV with Chronic Kidney Disease

Yawovi Mawufemo Tsevi[1*], Lidaw Déassoua Bawe[2], Komi Dzidzonu Nemi[3], Abdou Razak Moukaila[2], Akessiwe Akouda Patassi[2], Majesté Ihou Wateba[2]

[1]Department of Nephrology and Hemodialysis, University Hospital Sylvanus Olympio of Lomé, University of Lome-Togo
[2]Departement of Infectious and Tropical Diseases, University Hospital Sylvanus Olympio of Lomé, University of Lome-Togo
[3]Department of Internal Medicine, University Hospital Sylvanus Olympio Lomé, University of Lome-Togo
Email: *tseviclaude@gmail.com

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Abstract

Chronic Kidney disease (CKD) is one of the important complications during HIV infection. The advent of Highly Active Antiretroviral Therapy (HAART) has significantly improved the prognosis of these patients. This was a descriptive and analytical cross-sectional study of people living with HIV received at the Ambulatory Treatment Center (ATC) of the Department of Infectious Diseases of Sylvanus Olympio University Hospital (CHU-SO). The study period was 6 months from January 1, 2018 to June 30, 2018. A total of 234 patients were enrolled during the study period. The mean age of patients at initiation of treatment was 42.07 ± 9.49 years with an average duration of follow-up under antiretroviral treatment of 5.61 ± 3.22 years. The female sex was predominant (70.09%) and a sex ratio (M/F) of 0.43. Most people living with HIV were mostly classified at clinical stage 2 (30.77) and 3 (31.62%) of WHO at initiation of HAART. The mean CD4 rate was 223.30 ± 143.764 at initiation of HAART and 462.58 ± 202.723 at the time of study. The frequency of CKD was 11.11%. The majority of patients were placed in a fixed combination of Tenofovir/Lamivudine/Efavirenz in a proportion of 81.20% of cases. In univariate analysis shows that age greater than 45 years ($p = 0.017$). Pathological proteinuria ($p = 0.021$) were associated with CKD. In multivariate analysis, only age ($p = 0.045$) and pathological proteinuria ($p = 0.035$) were significantly associated with CKD.

Keywords

Therapeutic Profile, CKD, HIV, HAART, Togo

1. Introduction

The prevalence of Human Immunodeficiency Virus (HIV) infection is high in the African region, with more than 25.7 million people living with HIV [1]. In 2017, Africa alone accounted for 25.7 million people living with HIV (PLHIV) [1]. In 2017, in Togo, the average prevalence in the general population aged 15 to 45 increased from 2.5% to 2.1% [2]. The survival of people living with HIV depends on several factors: early diagnosis of HIV infection, early antiretroviral therapy and especially adherence to treatment [3] [4] [5]. In 2019, in Togo, the incidence of kidney disease is high (41.8%) in HIV-infected ART naive patients [6].

Since the advent of Highly Active Antiretroviral Therapy (HAART), the prognosis of patients has been greatly improved. There has been a decrease in the frequency of opportunistic infections and mortality [7]. Opportunistic infections accounted for more than 40% in the early 2000s, and only 15% - 20% in the most recent series [8] [9].

The increase in the life expectancy of patients treated with HAART is accompanied by an increase in the incidence of age-related diseases (diabetes and high blood pressure in particular), possible co-infections with hepatitis B and C viruses and late complications of HIV infection, including arteriosclerosis and cancers other than those defining AIDS [10] [11] [12]. These different factors contribute to the increase in the prevalence of chronic kidney disease in HIV-infected patients [13]. In Togo, this is the first ever study conducted to determine the therapeutic profile of HIV-infected patients with Chronic Kidney disease (CKD).

2. Patients and Methods

This was a descriptive and analytical cross-sectional study of people living with HIV received at the Ambulatory Treatment Center (ATC) of the Infectious Diseases Department of the Sylvanus Olympio University Hospital (CHU-SO) for their follow-up consultation. The study period was 6 months from January 2018 to June 30, 2018. The infectious and tropical diseases department of the CHU-SO is the reference service for the care of patients infected with HIV. The patients included in this study were known PLHIV over 15 years of age, who have been regularly monitored at ATC for at least 3 months on ART (Antiretroviral treatment). Each patient had two creatinines (at initiation of treatment and at 3 months) and a urine test for proteinuria. It is in this population of patients included that we have identified those with chronic kidney disease.

Proteinuria was said to be pathological with a urinary strip if it was positive at one or more crosses. Treatment initiation information such as WHO (World Health Organization) clinical course, CD4 count, serum creatinine and antiretroviral therapy molecules were collected in the medical management record. Not included were children, pregnant women or naive patients with HAART during the study period and those without a minimum baseline nephrological checkup (at least one three-month-old serum creatinine, urinary tape proteinuria).

The variables studied were sociodemographic parameters (age, sex and level of education); anthropometric parameters (weight, height and Body Mass Index (BMI)); clinical and biological parameters (WHO clinical stage of HIV (**Table 3**) at initiation of HAART, CD4 count) and antiretroviral therapy lines. Patients' creatinine clearance was estimated by the simplified MDRD formula [14]. CKD was defined as a clearance less than 60 ml/min/1.73 m^2 for at least 3 months. CKD was classified into 5 stages according to K-DIGO [15]. Age was divided into two categories: higher or lower than 45 years old. This age was randomly selected.

Definition of operational terms:

- High Blood Pressure (HBP) was defined as a systolic blood pressure above 140 mmHg and a diastolic blood pressure as above 90 mmHg.
- Diabetes is defined as fasting blood sugar levels above 1.21 g/l.
- BMI is classified according to WHO in 4 stages [16].
- The CD4 count is divided into two categories: low if less than 200 cells/microliter and not low if greater than 200 cells/microliter.

Data collection was performed using Epidata 3.1 software; analysis was performed using SPSS software version 13.0 and R software. A univariate and multivariate comparative analysis with a logistic regression of socio-demographic, clinical and therapeutic data of CKD versus non-CKD patients was performed with statistical tests (Pearson's Chi-square test and Fisher's test). One variable was considered significantly associated with CKD if $p < 0.05$.

3. Results

3.1. Descriptive Aspect

A total of 1300 patients were followed at the CTA during the study period, but only 234 patients met the inclusion criteria. Of the 234 patients, 26 had CKD. The prevalence of CKD was 11.11%. The average age of patients at initiation of treatment was 42.07 ± 9.49 and at the time of the study was 47.68 ± 9.88 with an average follow-up time on HAART of 5.61 ± 3.22 years. The female sex was predominant (70.09%) and a sex ratio (M/F) of 0.43. Of these PLHIV on HAART, 87.6% did not have a first cycle patent (**Table 1**). High blood pressure was found in 13.68% of enrolled patients and diabetes in 1.71% of cases. The average body mass index (BMI) was 23.80 kg/m^2. Overweight and obesity were

Table 1. Level of education of HIV-infected patients with CKD.

Level of education	Effective (n)	Percentage (%)
None	65	27.8
Primary	65	27.8
Middle School	75	32
Secondary school	19	8.1
High	10	4.3
Total	234	**100.00**

found in 26.50% and 8.54% of cases respectively (Table 2). Pathological proteinuria was present in 25.64% of patients. The average creatinine clearance was 58.25 ± 10.48 ml/min/1.73 m^2.

The majority of PLHIV were classified as WHO clinical stage 2 (30.77%) and 3 (31.62%) when initiating HAART (Table 3). The average CD4 count was 223.30 ± 143.764 at initiation of HAART and 462.58 ± 202.723 at the time of study. At the therapeutic level, the majority of patients were placed on a fixed combination of Tenofovir/Lamivudine/Efavirenz in 81.20% of cases. The remaining data on HAART are summarized in Tables 4-6.

3.2. Comparative Analysis

Univariate analysis shows that age greater than 45 years is associated (RR = 4.71,

Table 2. Patient distribution according to weight class.

Interpretation of BMI	Frequency	Percentage	Cumulative Percentage
Underweight	28	11.97	11.97
Normal BMI	124	52.99	64.96
Overweight	62	26.50	91.45
Moderate obesity	14	5.98	97.44
Morbid obesity	6	2.56	100.00
Total	234	**100.00**	

BMI: Body Mass Index.

Table 3. Distribution of HIV-infected patients according to WHO clinical stage.

Initiation stages	Effective (n)	Percentage (%)
Stage 1	48	20.51
Stage 2	72	30.77
Stage 3	74	31.62
Stage 4	40	17.1
Total	234	**100.00**

Table 4. Distribution of antiretrovirals used in patients.

Prescribed molecules	Yes	No	Total
Tenofovir (TDF)	222 (94.87)	12 (5.13)	234 (100)
Efavirenz (EFV)	196 (83.76)	38 (16.24)	234 (100)
Atazanavir (ATV)	30 (12.82)	204 (87.18)	234 (100)
Zidovudine (AZT)	6 (2.56)	228 (97.44)	234 (100)
Abacavir (ABC)	6 (2.56)	228 (97.44)	234 (100)
Lopinavir (LOP)	6 (2.56)	228 (97.44)	234 (100)
Nevirapine (NEV)	2 (0.85)	232 (99.15)	234 (100)

Table 5. Distribution according to HAART therapeutic diagrams.

Type of triple therapy	Effective (n)	Percentage (n)
TDF/3TC/EFV	190	81.20
TDF/3TC/ATV	26	11.11
TDF/3TC/LOP	6	2.56
ABC/3TC/EFV	6	2.56
AZT/3TC/ATV	4	1.71
AZT/3TC/NEV	2	0.85
Total	234	**100.00**

HAART: Highly Active Antireviral Therapy.

Table 6. Distribution of patients according to different treatment lines.

Current treatment line	Effective (n)	Percentage (%)
Line 1	198	84.62
Line 2	36	15.38
Total	234	**100.00**

Line 1: TDF/3TC/EFV; ABC/3TC/EFV; AZT/3TC/NEV. Line 2: TDF/3TC/ATV; TDF/3TC/LOP; AZT/3TC/AT.

95% IC = [1.09, 20.34]) with CKD p = 0.017 (Table 7). Sex (p = 0.339), body mass index (BMI) RR = 0.82; 95% IC = [0.27; 2.51], clinical stage of HIV, history of hypertension (HBP) RR = 2.81; 95% IC = [0.98; 8.04] or diabetes RR = 4.79; 95% IC = [1.08; 21.17] were not associated with CKD. The existence of pathological proteinuria was associated with CKD (RR = 3.38; 95% IC = [1.23; 9.27] (p = 0.0021)). With respect to anti-retroviral drugs administered to patients, none was associated with the occurrence of CKD (Table 8).

In multivariate analysis, only age and pathological proteinuria were significantly associated with CKD (OR of 5.50 (p = 0.045)) and (OR 4.11 (p = 0.045)), respectively (Table 9).

4. Discussion

To our knowledge, this is the very first study conducted in our country to determine the antiretroviral therapeutic profile of PLHIV with CKD. The limitations of our study lie in the small size of the sample because the infectious diseases department of our center is not the only care center; however, the results found make it possible to document the African literature in the sense that it is the reference center for HIV care in Togo. Attolou *et al.* reported in their series a population of 92 patients with similar results [17]. The prevalence of CKD in our sample was 11.11%. This prevalence varies according to the studies and depends on the population studied and the method used to estimate the eGFR [18]. Zannou *et al.* found 18.7% in a Beninese population of 480 HIV-infected people using the Cockcroft and Gault formula; the median age was 41.4 ± 9.16 years old [19]. The elevation of creatinine levels (≥15 mg/l) was used in another study; it

Table 7. Univariate analysis of sociodemographic and clinical data.

Characteristics	CKD+ (N = 26)		CKD− (N = 208)		OR IC 95%	P
	N	(%)	N	(%)		
Sexe					1.21 [0.90; 3.60]	0.339
Male	4	15.38	66	31.73		
Female	22	84.62	142	68.27		
Age (years)					4.17 [1.09; 20.34]	0.017
≤45	43	15.38	104	50.00		
>45	22	84.62	104	50.00		
HBP					2.81 [0.98; 8.04]	0.078
Yes	8	30.77	24	11.54		
No	18	69.23	184	88.46		
Diabetes					4.79 [1.08; 21.17]	0.21
Yes	2	7.69	2	0.96		
No	24	92.31	206	99.04		
BMI (kg/m^2)					0.82 [0.27; 2.51]	0.49
<25	8	30.77	74	35.58		
≥25	18	69.23	134	64.42		
WHO Clinical Stage					-	0.857
Stage 1	6	23.08	42	20.20		
Stage 2	10	38.46	62	29.82		
Stage 3	8	30.77	68	32.69		
Stage 4	2	7.69	36	17.29		
Pathological proteinuria					3.38 [1.23; 9.27]	0.021
Yes	14	53.85	46	22.12		
No	12	46.15	162	77.88		
CD4 rate					8.58 [0.31; 4.51]	0.51
<200	14	53.85	104	50		
≥200	12	46.15	104	50		

BMI: Body Mass Index; HBP: High Blood Pressure; WHO: World Health Oragnization.

Table 8. Univariate analysis of antiretroviral related characteristics.

Characteristics	CKD+ (N = 26)		CKD− (N = 208)		OR IC 95 %	P
	N	(%)	N	(%)		
TDF					0.65 [0.1; 4.2]	0.515
Yes	24	92.31	198	95.19		
No	2	7.69	10	4.81		
EFV					0.44 [0.15; 1.27]	0.22
Yes	18	69.23	178	85.58		

Continued

No	8	30.77	30	14.42		
ATV					3.02 [1.06; 8.60]	0.063
Yes	8	30.77	22	10.58		
No	18	69.23	186	89.42%		
Treatment lines					0.35 [0.99; 1.21]	0.114
Line 1	18	69.23	180	86.54		
Line 2	8	30.77	28	13.46		

Table 9. Multivariate analysis of characteristics associated with CKD.

Characteristics	Adjusted OR	IC95% adjusted	P
Age	5.50	[1.16; 26.03]	0.045
HBP	2.36	[0.51; 10.82]	0.266
Diabetes	3.87	[0.20; 73.76]	0.368
Proteinuria	4.11	[1.26; 13.43]	0.035
HAART	-	-	0.999
HAART Line	-	-	0.999

HBP: High Blood Pressure; HAART: Highly Active Antireviral Therapy.

gave a prevalence of 31.1% with a mean age of 34.6 ± 9.4 years [20]. In contrast, Umeizudike *et al.* [21] found 23.5% with an average age of 35 ± 8.3 years. It was generally accepted in Sub-Saharan Africa that CKD prevalence ranged from 6 to 48.5% in HIV-infected patients [22]. Contrary to this observation, studies conducted in Europe in caucasian subjects showed a prevalence around 4%; in France for example, it was only 4.7% in a population of 7378 patients using the MDRD formula [23]. The analysis of Hsieh M.-H. *et al.* [24] in Taiwan after finding a prevalence of 7.9% in its population unlike other Asian studies (15.4% in Japan and 16.8% in Hong Kong), showed that age had an impact on CKD prevalence in the HIV-infected population. It should be noted that the prevalence of CKD increased after the age of 40 [22]. Consistent with this observation, the average age of 42.07 ± 9.49 years in our study, would partly explain the superiority of our prevalence to other studies such as Umeizudike *et al.* [21]. In addition, the genetic susceptibility of the black subject to develop CKD must be added [25]. Nevertheless, our prevalence may be considered underestimated because of the small size of our sample.

In our study, we reported that age greater than 45 years with an OR of 5.5 ($p = 0.045$) was associated with the occurrence of CKD. Zannou *et al.* [19] in Cotonou found that age ≥ 47 years with an OR = 3.79 and IC = [1.92 - 7.50] ($p < 0.001$) was associated with CKD; in New York Wyatt *et al.* [26] had found an age slightly older than 50 ($p < 0.0001$). The age of occurrence of CKD in HIV-infected patients is early in the majority of studies involving black subjects [20] [25] [27]. This precocity could be explained on one hand by the genetic predisposition of

black subjects to develop CKD characterized histologically by HIVAN (HIV Associated Nephropathy). On the other hand, the late diagnosis of the disease in our environments, most often at the complication stage, could be an element in favor. In addition, low CD4 levels are a risk factor for CKD in patients infected in some studies [20] [23]. Flandre *et al.* [23] found that having a TCD4 ≥ 200 cells/microliter with a RR of 0.63 (0.48 to 0.81) and p = 0.03 was associated with the occurrence of CKD. This correlation was not found in our study and also in others [19] [28]. HBP, diabetes and dyslipidemia are traditional risk factors for CKD in the general population and in HIV-infected patients. In our study 13.36% of patients were hypertensive. There was no correlation found between hypertension and CKD in our study. In Cotonou, Zannou *et al.* [19] found 12.3% of cases of hypertension and 3.1% of diabetes with ORs of 1.57 [0.83 - 2.97] (p = 0.17) and 0.30 IC = [0.03 - 2.32] (p = 0.17) respectively. In contrast, in France, Flandre *et al.* [23] found that 48% of patients with HIV were hypertensive and 9.8% were diabetic. They also observed that HBP was statically related to the occurrence of CKD with OR = 2.39 and p < 0.0001. Min-Han Hsieh *et al.* [24] found a risk of developing CKD in HIV-infected patients with hypertension (OR = 23.06, IC = 4.67 - 113.87 and p < 0.001) and diabetes (OR = 9.822, IC = 1.862 - 51.08, p = 0.007) and high cholesterol levels (OR = 5.52 and IC = 1.23 - 4.68, p = 0.025). In the USA, Schwartz al [20] had shown that the presence of hypertension is a marker of high-risk of developing CKD. This observed difference can be explained by the sample sizes of the different studies. Indeed, studies that found hypertension and diabetes as a risk factor had a relatively large sample size. Moreover, the fact that the presence of hypertension and diabetes in HIV patients under treatment is not statically related to the occurrence of CKD in our study may be explained by the fact that hypertension and diabetes although traditional risk factors for CKD, were probably not the main causes of kidney disease in Black HIV-infected patients.

In our study, pathological proteinuria was a risk factor for CKD. Zannou *et al.* [19] did not reach the same conclusion in their study in Benin. Nevertheless, the association of proteinuria with CKD in HIV-infected patients is an indicator of the importance of managing these patients. Because in the absence of treatment, it progresses on average in two years in CKD and it is responsible for 50% of cases of ESRD (End-Stage Renal Disease) [29]. The fixed-combination therapy based on Tenofovir/Lamivudine/Efavirenz was the most commonly found in our series; and no antiretroviral therapy line was associated with the occurrence of CKD. CKD involves pathophysiological changes that will influence not only the renal excretion of endogenous substances, but also the excretion of drugs and in particular HAART. The management of HAART in a patient with renal failure requires close collaboration between nephrologists and infectiologists because of the diversity of situations encountered, the multiple potential drug interactions, the variability of absorption after enteral administration and the frequency of associated acute or CKD [30]. The problem often encountered in our developing

countries is the administration of doses that are sometimes not commercially available on the market. The majority of our patients were on Tenofovir. Tenofovir, a nucleotide inhibitor of HIV reverse transcriptase, is the main HAART involved and causes up to 70% of the drug tubulopathies observed in these patients [31]. This molecule may be responsible for proximal tubular lesions. Tenofovir treatment should be permanently interrupted in the event of Fanconi syndrome or acute renal failure due to this drug [32].

5. Conclusion

CKD is common in HIV-infected patients. The frequency of chronic kidney disease remains high with an increase related to age, comorbidities and chronic toxicity some HAART molecules. The dramatic improvement in the long-term survival of patients treated with HAART encourages better collaboration between nephrologists and infectiologists.

Conflicts of Interest

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

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