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Renal Function Evaluation of HAART and HAART-Naïve HIV/AIDS Patients in Makurdi, Nigeria

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ABSTRACT

Background and Objective: Antiretroviral (ART) drugs have been suspected to impair renal function and there appears to be a paucity of data on renal function amongst Human Immunodeficiency Virus (HIV) positive patients in Nigeria/West Africa. Therefore, this study was to assess the effect of HAART on renal function in HIV-positive patients and to determine the prevalence of the renal disease among these patients in Makurdi, North-Central, Nigeria. **Materials and Methods:** This cross-sectional study conducted between May, 2017 and July, 2018 assessed the renal function of patients distributed into four groups, group 1 (HIV positive HAART naïve patients = 60 subjects), group 2 (HIV positive patients on HAART for 0-2 years = 60 subjects), group 3 (HIV positive patients on HAART for >2 years = 60 subjects) and group 4 (HIV negative patients (control group) = 60 subjects). Data were analyzed using IBM SPSS Version 21. Values of $p<0.05$ were considered significant. **Results:** Out of the 240 participants in the study sub-divided into 4 groups, 60 were HIV negative and 180 were HIV positive. Of the 180 HIV positive patients, 75.8% were females and 24.2% were males. The findings revealed a significant decrease in body weight and CD4 counts of HIV positive patients in comparison with the control group. There was no significant difference between the Creatinine Clearance (eCrCl) of the HIV positive HAART naïve patients (106.40±36.97 mL min^{-1}), HIV positive patients on HAART for 0-2 years (104.70±34.09 mL min^{-1}) and HIV positive patients on HAART for >2 years (99.97±36.26 mL min^{-1}) and the control (HIV negative = 108±22.13 mL min^{-1}). Prevalence of renal impairment for HIV/AIDS-HAART naïve patients was 5% and 7.5% for HIV/AIDS on HAART for 0-2 years and >2 years. **Conclusion:** The prevalence of renal impairment among HIV-positive study participants was minimal and may not be linked to the HAART regimen.

KEYWORDS

HIV/AIDS, HAART, renal function, renal impairment, prevalence, Makurdi

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INTRODUCTION

Acquired Immunodeficiency Syndrome (AIDS) is a spectrum of disease states characterized by progressive immunosuppression, it results from infection with the Human Immunodeficiency Virus (HIV). Since the beginning of the epidemic, over 75 million people have been infected with HIV, about over 36 million people have died of HIV and more than 35 million are living with HIV globally[1]. Sub-Saharan Africa remains most severely affected, with about two-thirds of recent global HIV infections and accounting for nearly 70% of HIV mortality worldwide[2].

Nigeria is third in ranking among nations with the highest HIV prevalence in the world[3]. Although HIV prevalence among adults is remarkably small (1.4%) compared to other Sub-Saharan African Countries: Such as South Africa (19.2%) and Zambia (12.9%), the size of Nigeria's population connotes about 1.7 million people were living with HIV in 2020[4,5]. Globally, approximately 1 million people died from AIDS-related illnesses in 2017[4,5]. An estimated 60% of new HIV infections in Western and Central Africa in 2015 occurred in Nigeria, together with South Africa and Uganda, Nigeria accounts for almost half of all new HIV infections in Sub-Saharan Africa every year. This is despite achieving a 35% reduction in new infections between 2005 and 2013. Unprotected heterosexual sex accounts for 80% of new HIV infections in Nigeria, with the majority of remaining HIV infections occurring in key affected populations such as Female Sex Workers (FSW), People Who Inject Drugs (PWID) and men who have sex with men (MSM)[4]. HIV prevalence is higher among females (1.9) than males (0.9), regionally, it is highest in Nigeria's South-South zone and stands at 3.1%. It is also high in the North-Central zone (2.0%) and lowest in the Northwest zone where there is a prevalence of 0.6%. There are higher rates of HIV in rural areas (4%) than in urban ones (3%)[4,5]. Presently the new national prevalence rate of HIV in Nigeria is 1.4%, Benue State is the 2nd with a prevalence of 4.9%.

The common HIV comorbidities are cardiovascular diseases, Chronic Kidney Disease (CKD), diabetes, cancer, dyslipidemia, hepatitis B and hepatitis C[6]. However, with the increased life expectancy of the affected individuals due to drug therapy, kidney diseases have emerged as the possible cause of morbidity and mortality. Chronic Kidney Disease (CKD) constitutes a serious health concern globally and it is a rising challenge in low-and-middle-income countries with approximately 17 million Nigerians having various stages of CKD[7]. Infection with HIV has been associated with many types of renal diseases including acute renal failure, acute tubular necrosis and HIV-Associated Nephropathy (HIVAN) which may progress to End-Stage Renal Disease (ESRD)[6,8-10]. In addition to HIV infections, black race, older age, HAART use, hypertension, diabetes, low CD4 cell count and high viral load remained important risk factors for kidney disease[11]. Some antiretroviral agents (e.g., nucleotide reverse-transcriptase inhibitors such as tenofovir, protease inhibitors such as indinavir) can cause serious side effects that affect multiple systems, including the kidneys[10]. Approximately about 1,500,000 people living with HIV in Nigeria are on ART[4] and it is imperative to evaluate the effect of its use on patients.

Because of these, this study was designed to assess the effect of HIV/AIDS and HAART regimen on renal function and also stress the importance of determination of renal function before and after initiation of HAART.

MATERIALS AND METHODS

Study site: The study was conducted in Bishop Murray Medical Centre Makurdi, Nigeria. It is a secondary hospital that treats HIV-positive patients from Benue State and its neighbouring states such as Nasarawa and Taraba States.

Study design: The study adopted a cross-sectional design.

Study population: Patients attending the ART/HIV Clinic at Bishop Murray Medical Centre Makurdi, Benue State is the State with the second highest prevalence (4.9%) of HIV/AIDS in Nigeria[5]. There are about 5000 adult patients in the ART/HIV Clinic at Bishop Murray Medical Centre Makurdi in 2016/17 and about 200 HIV patients are seen daily at the ART outpatient clinic. HIV-infected individuals seen for routine clinical visits were enrolled within 0-2 years, more than 2 years and newly diagnosed HAART naïve patients.

Study duration: The study was conducted between 2nd May, 2017 and 31st July, 2018.

Eligibility criteria: The study eligibility criteria included newly diagnosed ART patients that have not commenced HAART and those who are already on ART treatment (between 20 and 49 years). Age and sex match HIV-negative participants were recruited from the same centre to serve as the control.

Patients known to have acute or chronic kidney disease, taking nephrotoxic drugs, pregnant, or known to have diabetes mellitus, known to be hypertensive, HBsAg +ve, HCV Ab +ve, were excluded from the study.

Outcome measures: Serum creatinine and creatinine clearance were the primary outcome measures. Other outcome measures included the CD4 count, duration of HAART intake, lifestyle and race.

Sample size estimation: To estimate the sample size, the formula[12]:

$$N = \frac{(Z)^2 Pq}{d^2}$$

Where:
N = Sample size
Z = 1.96 critical value at 95% level of confidence
P = Proportion of renal insufficiency
P = 3.5%[13]
q = 1-P
d = Precision = 0.05

$$N = \frac{1.96 \times 1.96 \times 0.035 \times (1\text{-}0.35)}{0.05 \times 0.05}, N = 52$$

Attrition = 10% of the sample size[13]= 5.2

Therefore, N = 52+5.2 = 57.2, N = Approximately 60

Total number of subjects = 60×4 = 240

Group 1 = HIV +ve HAART naïve patients = 60 subjects
Group 2 = HIV +ve patients on HAART for 0 to 2 years = 60 subjects
Group 3 = HIV +ve patients on HAART for >2 years = 60 subjects
Group 4 = HIV –ve patients (control group) = 60 subjects

Study procedure

Clinical, social demographic and anthropometric measurements: Clinical and Social Demographic characteristics were obtained from the 4 groups. Anthropometric measurements such as weight were measured. Data of special interest such as, medical records of kidney disease and factors known to

contribute to kidney disease, known systemic complications, as well as, treatment regimen status were collected using a standardized questionnaire or data sheet format. Analog scale with kg reading was used to measure the weight of study subjects. Blood pressure of the subjects was measured according to the WHO recommendation using a sphygmomanometer. Both systolic and diastolic blood pressure measurements were taken in units of millimetre mercury (mm Hg).

Blood sample collection and handling: Blood samples were obtained from newly diagnosed ART patients that have not commenced HAART and from those who are already on ART treatment. The HIV negative individuals (control groups) were also enrolled. Non-fasting venous blood (5.0 mL) was collected by research assistants (trained professionals) from each participant. The blood sample was dispensed into jell coated serum separatory test tube and centrifuged at 3500 revolutions per minute (rpm) for 10 min for the separation of the serum. Serum creatinine was gotten (using Roche/Hitachi 902 analyser, Germany). In addition, creatinine clearance and eGFR were calculated from serum creatinine, age, sex and weight of the study participants.

Determination of creatinine clearance: Creatinine clearance was calculated from the patient's sex, age and serum creatinine using Cockcroft and Gault formula[14]:

Calculation: Cockcroft and Gault normalized

$$\text{Male CrCl} = \frac{(140 - \text{age}) \times (\text{weight})}{(\text{SCr} \times 72)}$$

$$\text{Female CrCl} = \frac{(140 - \text{age}) \times (\text{weight}) \times 0.85}{(\text{SCr} \times 72)}$$

Where:
CrCl = Creatinine clearance in mL min^{-1}

Age is in years, weight is in kilograms and SCr is serum creatinine in mg dL^{-1}

$CD4^+$ T cell count tests: The $CD4^+$ T cell count tests were determined by BD Fluorescence-Activated Cell Sorting (FACS) count version 1.0 01/08 machine.

Statistical analysis: Data were presented as Mean±Standard deviation and differences between groups were compared using Analysis of Variance (ANOVA). All statistical analysis was performed using IBM SPSS Version 21.0. Values of $p<0.05$ were considered significant.

Ethical consideration: Ethical clearance for the study was obtained from the Bishop Murray Medical Centre Ethical Committee with Approval Reference number: 062/07/17.

RESULTS

Demographic classification of patients: A total of 240 patients attending the ART/HIV Clinic at Bishop Murray Medical Centre Makurdi who met the eligibility criteria participated in the study. The 240 participants were sub-divided into four study groups, 60 (25%) were HIV negative, 60 (25%) were newly diagnosed HIV positive HAART naïve patients, 60 (25%) were HIV positive patients on HAART for 0-2 years and 60 (25%) were HIV positive patients on HAART for >2 yearrs. About 24.2% (58) of the study population were males while 75.8% (182) were females representing a higher proportion of females, females represented 75.6% of HIV-infected patients and males represented 24.4% of HIV-infected patients.

Table 1: Clinical characteristics of the study subjects (= 240)

Characteristics Numbers	HIV -ve (n = 60)	HIV +ve (newly diagnosed, HAART naïve) (n = 60)	HIV +ve (on HAART for 0-2 years) (n = 60)	HIV +ve (on HAART for >2 years) (n = 60)	Total (n = 240)
Sex					
Male	14 (23.3%)	17 (28.3%)	9 (15.0%)	18 (30.0%)	58 (24.2%)
Female	46 (76.7%)	43 (71.7%)	51 (85.0%)	42 (70.0%)	182 (75.8%)
Age category (years)					
20-29	32 (53.3%)	17 (28.3%)	18 (30.0%)	28 (46.7%)	95 (39.6%)
30-39	12 (20.0%)	30 (50.0%)	29 (48.3%)	18 (30.0%)	89 (37.1%)
40-49	16 (26.7%)	13 (21.7%)	13 (2.7%)	14 (23.3%)	56 (23.3%)

Table 2: Anthropometric measurements and CD4 count (Mean±SD) in the study population

	HIV -ve	HIV +ve (newly diagnosed, HAART naïve)	HIV +ve (on HAART for 0-2 years)	HIV +ve (on HAART for >2 years)
Age (years)	32.33±7.22	33.45±7.24	33.80±7.18	31.93±8.25
Body weight (kg)	72.03±7.52	60.72±12.79*	60.70±12.18*	59.87±14.15*
CD4 count (cells/mm^3)	888.10±217.30	293.92±205.44*	490.85±295.64*	499.43±264.02*

CD4: T helper cells, -ve: Negative and +ve: Positive

Table 3: Serum creatinine and creatinine clearance of different study groups and control

Groups	Serum creatinine (mg dL^{-1})	Creatinine clearance (mL min^{-1})
HIV -ve	0.92±0.23	108.43±22.13
HIV +ve (newly diagnosed)	0.96±1.17	106.40±36.97
HIV +ve on HAART (0-2 years)	1.23±2.57	104.70±34.09
HIV +ve on HAART (>2 years)	1.23±2.28	099.97±36.26
F-ratio	0.638	001.558
p-value	0.592	000.200

-ve: Negative and +ve: Positive

39.6% (95) of the study population were in the age category of 20-29 years, 37.1% (89) were between 30-39 years and 23.3% (56) were between 40-49 years, respectively. From the study population, HIV-infected patients were 42.8%, 35% and 22.2% for age categories 30-39 years, 20-29 years and 40-49 years, respectively. The distribution is shown in Table 1.

Anthropometric measurements and CD4 count in the study population: Table 2 summarizes the anthropometric measurements and CD4 count of the study population. The average age of the newly diagnosed HIV positive HAART naïve patients is 33, 34 years for HIV positive patients on HAART for 0-2 years and 32 years for HIV positive patients on HAART for more than 2 years. The CD4 counts of the subjects in the 4 groups are also represented.

Serum creatinine and creatinine clearance of study population: Table 3 demonstrated the differences in renal function among the different study groups and control. The results for both serum creatinine and creatinine clearance for the HIV positive newly diagnosed/HAART naive patients were 0.96 mg dL^{-1} and 106.4 mL min^{-1}, patients on HAART for 0-2 years were 1.23 mg dL^{-1} and 104.7 mL min^{-1} and patients on HAART for more than 2 years were 1.23 mg dL^{-1} and 99.97 mL min^{-1}, respectively, which are however not significantly different in comparison to the control group (HIV negative).

Distribution of CKD in study population: Table 4 displays the distribution of the five stages of Chronic Kidney Disease (CKD) in the study population. The findings revealed that for the HIV positive HAART naïve patients, 15 (25%), 2 (3.3%) and 1 (1.7%) were in stages II, III and V of CKD while 42 (70%) patients were normal, the HIV positive patients on HAART for 0-2 years, 14 (2.3%), 3 (5%) and 2 (3.3%) were on stages II, II and V of CKD while 41 (68.3%) were normal and the HIV positive patients on HAART for >2 years, 28 (46.7%), 2 (3.3%) and 2 (3.3%) were on CKD stages II, III and V, respectively while 28 (46.7%) were normal. The prevalence of CKD among HIV positive HAART naïve patients was 5%, for HIV positive patients on HAART for 0-2 years was 8.3% and for HIV positive patients on HAART for more than 2 years was to 6.7%, respectively bringing the prevalence for 120 HIV positive patients on HAART to 7.5%.

Table 4: Distribution of CKD in study population

	Stages of CKD					
Groups (n)	I	II	III	IV	V	Normal
Control (n = 60)	-	2 (3.3%)	2 (3.3%)	-	-	56 (93.3%)
Group 2 (HIV +VE HAART (naïve) (n = 60)	-	15 (25.0%)	2 (3.3%)	-	1 (1.7%)	42 (70.0%)
Group 3 (HIV +VE on HAART 0-2 years) (n = 60)	-	14 (2.3%)	3 (5.0%)	-	2 (3.3%)	41 (68.3%)
Group 4 (HIV +VE on HAART >2 years) (n = 60)	-	28 (46.7%)	2 (3.3%)	-	2 (3.3%)	28 (46.7%)

n: Sample size, CKO: Chronic kidney disease, stages of CKD eCrCl (mL min^{-1}), I: >90, II: 60-89, III: 30-59, IV: 15-29 and V: <15

DISCUSSION

The assessment of renal function in HIV patients on HAART can be beneficial to the improvement of renal function in HIV patients. Assessment of renal dysfunction due to HAART associated with an adverse effect on the renal system such as acute renal failure, tubular necrosis, kidney stones, or chronic renal disease is important, as it could potentially detect kidney impairment at an early stage before manifest kidney disease has occurred.

From the study, out of the 240 patients that participated, 60 patients were HIV negative and 180 patients were HIV positive. About 75.6% of the 180 HIV positive patients were females and the remaining 24.4% were males. Participants within the age category of 30-39 years make up 42.8% of the total infected, age category 20-29 years make up 35% and age category 40-49 years make up 22.2% of the total infected patients studied.

In this study, it was observed that there was a statistically significant difference in the body weight measurements, in which the body weights of the study groups (Groups II, III, IV) were significantly lower ($p<0.05$) when compared with the weights of the control group (Group I). This can be attributed to a result of acyclic nucleoside phosphonates contained in HAART treatment such as tenofovir, adefovir and cidofovir, whose risk factors include weight loss[15,16].

The present study also showed a significant difference in the CD4 count. In which the CD4 count in the study groups (Groups II, III, IV) was significantly decreased in comparison with the control group (Group I). However, this decrease is in line with the normal range of values. This can be attributed to the immunosuppression caused by HIV in its early stages, whilst the initiation of HAART interrupts the virus life cycle causing an increase in the CD4 cells, as it was observed that CD4 count improved in the vast majority of patients undergoing HAART therapy.

Increasing serum creatinine level is a decisive indicator of poor glomerular filtration and a significant clinical marker for renal impairment[17]. In this study, no significant differences were observed in serum creatinine and creatinine clearance in the study groups (II, III and IV), as compared to the control group (I) and the prevalence of Chronic Kidney Disease (CKD) was described as CrCl<60 mL min^{-1} amongst HIV positive HAART naïve patients was 5%, for HIV positive patients on HAART for 0-2 years was 8.3% and for HIV positive patients on HAART for more than 2 years was 6.7%, respectively bringing the prevalence for 120 HIV positive patients on HAART to 7.5%. This finding may be attributed to our exclusion criteria which excluded traditional risk factors known to be associated with a renal impairment such as diabetes and high blood pressure. It may also be attributed to the effect HAART has on the improvement of renal function of patients as suggested by Kamkuemah *et al.*[18] and Deckert *et al.*[9]. The prevalence obtained from our finding is consistent with similar studies carried out in Uganda (2.52%)[10] and Northeast Ethiopia (6.7%)[19] comparatively lower than the findings of previous studies carried out in South-South Nigeria (53.3%), Northwest Cameroon (26.5%), Southeast Nigeria (24.3%), Southwest Nigeria (23.7%), Southwest Ethiopia (20.7%) and Northeast Ethiopia (16.1%)[6,19-23]. However, these other studies recording high prevalence had not excluded HIV-infected patients that had known traditional risk factors

associated with renal impairment. Specifically, Nforbugwe *et al.*[21] in their study had similarly reported that there was no statistically significant difference in mean creatinine clearance of HAART-naïve and HAART-experienced groups, they also noted that there was no association between HAART regimen and renal dysfunction and linked decreased renal function to the detrimental effect of HIV. Other studies that have assessed renal dysfunction among HIV patients were not classified or differentiated into groups to obtain data on renal function and understand the differences in renal function of HIV patients that were HAART naïve, on HAART for 0-2 years and greater than 2 years. Current study had few limitations, no baseline renal function was done to evaluate the change in renal function over time thereby allowing for short-term impairment that may be reversible. Also, microalbuminuria was not evaluated, as it has been demonstrated to be a vital indicator for renal dysfunction identification in HIV-infected individuals[24,25].

CONCLUSION

This study has revealed that concentrations of serum creatinine were not statistically different in HIV positive HAART naïve patients and HIV/AIDS patients on HAART. It also revealed that the prevalence of renal function impairment amongst HIV-infected patients on and off HAART attending the ART/HIV Clinic at Makurdi, Nigeria was minimal and not associated with HAART regimen and may be linked to traditional risk factors for renal impairment. Hence, proper history of HIV/AIDS patients should be taken and investigations should be done to detect patients with co-morbidities (diabetic or hypertensive) to manage them early and HIV/AIDS positive patients should be properly assessed and evaluated for kidney disease using a sensitive marker (eCrCl) to establish a baseline before the commencement of any antiretroviral therapy.

SIGNIFICANCE STATEMENT

This study identified that the use of HAART is not significantly related to renal dysfunction in HIV/AIDS patients and this has particularly corrected the misconception that had related HAART use to renal dysfunction in HIV-infected patients. This study may help researchers to uncover other confounding factors that may be associated with renal dysfunction in HIV/AIDS patients and explore ways of mitigating them.

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