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Evaluation of the Impact of Antiretroviral Therapy (ART) on Renal Function in HIV Positive Patients Receiving HIV treatment at Federal Medical Centre, Makurdi, Nigeria

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Abstract

Introduction: The management of HIV involves the lifelong administration of Antiretroviral Therapy (ART), which includes drugs with a known history of nephrotoxicity. Despite the widespread use of ART, there remains a significant gap in understanding its long-term effects on kidney function. This study seeks to address this knowledge gap by examining how prolonged use of ART regimens impacts renal indices in HIV-infected patients attending the APIN clinic at the Federal Medical Centre, Makurdi.

Method: This was a hospital-based case-control study that included both HIV positive and negative patients who attended the APIN clinic, Federal Medical Centre Makurdi during the study period. Sociodemographic characteristics and some clinical variables were collected using self-administered structured questionnaires. Blood samples were collected from respondents using standard phlebotomy protocol. Renal impairment was classified in accordance with the National Kidney Foundation clinical practice guideline. Glomerular Filtration Rate was calculated using the 24-hour creatinine clearance method. Blood urea nitrogen was calculated from serum urea concentrations. Values were compared between the two groups using chi-square and independent sample T-test at 95% Confidence level using SPSS version 26.0

Result: Prevalence of renal impairment was 25.6% in HIV positive patients. creatinine clearance (Crcl) and estimated Glomerular Filtration Rate (eGFR) were significantly decreased in HIV respondents on ART compared to the control group (baseline) with values of (62.0ml/min/1.73m^2) and (66.09ml/min) respectively, while the BUN was elevated in the HIV-positive respondents compared to the control group (15.71mg/dl). Proteinuria was 8% in the HIV group. Creatinine (99.0umol/L), Urea (5.6mmol/L) HCO3 (26.9mmol/L), Cl^- (105.2mmol/L) were all significantly elevated in the HIV positive group, but fell within normal range ($P<0.05$). While Na^+ and K^+ had same levels in both group ($p>0.05$) and were within normal reference range for study population.

Conclusion: Respondents on ART for at least two years or more had decreased renal function, renal indices showed a significant decrease in Crcl and eGFR indicating an association of renal function with prolonged use of ART in HIV-positive respondents. Further study is required to ascertain specific ART combinations associated with these findings.

Keywords: HIV; ART; Baseline; Renal function; Renal dysfunction; Renal impairment

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1. Introduction

Nigeria is one of the countries with the highest HIV prevalence in Africa, with approximately 1.9 million people living with HIV and an adult prevalence rate of 1.4% among those aged 15-49 according to the 2018 Nigeria AIDS Indicator and Impact Survey (NAIIS). [1] However, recent studies suggest that this prevalence might be higher, with estimates ranging up to 2.1%.[2] As of the recent data, about 1.7 million people of the 1.9 million PLWHIV are on antiretroviral therapy (ART) which is 90% of those diagnosed and placed on treatment conforming closely to the UNAIDS 95–95–95 targets. [3] ART has been instrumental in reducing the morbidity and mortality associated with HIV/AIDS by suppressing viral loads and restoring immune function. [1,2] However, there is growing concern about the potential nephrotoxic effects of certain antiretroviral drugs. Some ART regimens, particularly those involving tenofovir, have been suspected to impair renal function, although recent studies suggest that this impact may be minimal or not directly associated with HAART use. [4] The mechanism of renal toxicity involves the potential for certain drugs to cause damage to the renal tubules or affect kidney function through other pathways. [5] ART over different durations of time has an effect on the nephron by inducing toxicity.[6] Renal dysfunction by ART has been associated primarily with tenofovir disoproxil fumarate(TDF), which is actively accumulated in the proximal renal tubule. [7] According to the National guidelines for HIV prevention, treatment and care under the national AIDS and STIs control programme, Federal Ministry of Health Nigeria, 2020, [8] document TDF, combined with two other ART's as part of the preferred first-line ART regimen in Nigeria for HIV patients. In Nigeria, assessing the impact of ART on renal function is crucial, especially given the high prevalence of HIV and the increasing number of patients on treatment. Studies conducted in Nigeria have shown varying results regarding the prevalence of renal dysfunction among HIV-positive patients on ART, a study by Agbaji et al. [9] shows a prevalence 10% to 45% of renal dysfunction over a period of 24 to 144 weeks of TDF use highlighting the need for more comprehensive data for involvement of other ART's. Several methods have been employed to assess ART induced renal dysfunction, but widely reported is the use of Serum creatinine levels to estimate the glomerular filtration rate (eGFR), [10,11] creatinine clearance. [12] and proteinuria. [11] The risk of undiagnosed HIV associated renal dysfunction is worrisome in resource limited settings like Nigeria where routine laboratory testing is often not available. Early diagnosis and monitoring is key for efficient management of patients. [11] Despite the several reports for renal dysfunction among HIV infected patients in Nigeria, it has been studied relatively rarely in this population. This study aims to evaluate the renal function of HIV-positive patients receiving ART at Federal Medical Centre, Makurdi, Nigeria.

2. Material and methods

2.1. Study Site

The study was conducted at the out-patient department, APIN, Federal medical Centre Makurdi (FMC). Makurdi is the state capital of Benue state Nigeria. FMC, Makurdi is one of the leading tertiary hospitals in the state that provide healthcare to over 5000 PLWHIV in North central, Nigeria.

2.2. Study design

A comparative hospital based case-control study involving both HIV positive and negative adults within the age group of 18 to 80 years. Study participants were recruited at the APIN Antiretroviral therapy clinic, FMC, Makurdi. Recruitment of participants took a span of 5 months from August to December 2022.

2.3. Study population

Participants were recruited from HIV-infected patients who came to the center for drug refill or routine check-up or healthy individuals who came to the clinic for voluntary HIV counselling and testing (VCT). The study population was recruited under two study categories: participants who were HIV negative (Baseline), and HIV infected participants on ART (for two years or more)

2.4. Inclusion and Exclusion Criteria

Participants included those whose HIV/AIDS status have been confirmed (Western blot), whether symptomatic or asymptomatic and were receiving ART (≥ 2 years). Excluded from the study were patients with kidney disease, family history of kidney disease, participants that were diabetic, hypertensive or have any other conditions that may interfere with the result were also excluded.

2.5. Sample Size Determination

For a case-control study, the following statistical formula was used to determine the sample size.

$$n = \frac{(Z\alpha/2 + Z\beta)^2 \times (P1(1-P1) + P2(1-P1))}{(p1-p2)^2}$$

Where:

n = minimum sample size per group (cases or controls)
p1= prevalence of renal dysfunction in cases=13.8% (0.138) [13]
p2= prevalence of renal dysfunction in controls = 3.6 %(0.036) [36]
(p1−p2) = the difference in proportions between cases and controls
Zα/2=Standard Z value at 5% significance level =1.96
Z_β=standard normal power at 80% =0.84
n= 116
However, for convenience, a minimum sample size of 250 per group was adopted for this study.

2.6. Sample Collection

Two hundred and fifty (250) HIV/AIDS positive and 250 healthy HIV negative participants aged 18 - 80 years without any underlining renal impairment drawn from patients attending the medical out-patient department of Federal Medical Centre Makurdi, Nigeria, were recruited for participation in the study, with baseline renal function from the healthy HIV negative participants taken at the clinic.

2.7. Sample and Sample Collection Technique

2.7.1. Administration of Questionnaires

Socio-demographic characteristics, medical history and some anthropometry measurements (height and weight) were collected using a structured self-administered questionnaire. A simple random consecutive sampling technique was used.

2.7.2. Sample Collection

About 2 mls of venous blood sample was collected from each participant into a labelled dry tube using a vacutainer needle. These blood samples were allowed to clot at room temperature and centrifuged at 3000rpm for 5mins to obtain sera. The sera were aliquoted into labelled Eppendorf tubes and stored at -20^{o}C and were later analysed in batches for Urea and Creatinine, Sodium, potassium and Bicarbonate and chloride concentrations. The participants were requested to provide about 50 ml on-spot urine in a small, leak-proof container which was used for urinalysis for the screening of proteinuria.

2.8. Determination of Plasma Electrolytes

Serum urea and Creatinine levels were analyzed spectrophotometrically with an ERMA BIOCHEMICAL ANALYZER (ERMA INC. Tokyo Japan, Model AE-600N) following the manufacturer's instructions. urine protein was estimated using a urinalysis dip stick following the manufacturer's instructions with ≥ two pluses (++) considered significant. Serum creatinine concentrations were then used to calculate Creatinine clearance (Crcl) while serum urea and creatinine were used to calculate blood urea nitrogen (BUN) as described by Tietz, N.W. (1987). [35] Serum sodium, potassium and chloride levels were determined by ion selective electrode method using Humalyte machine (Human, Germany), while bicarbonate was assayed by back titration. [35]

Renal impairment was classified according to the National Kidney Foundation clinical practice guideline based on the GFR determined by the Crcl method. Accordingly, [14]. Renal impairment was defined as Crcl <60ml/min/1.73m^2. Reference ranges for renal function tests were set as follows; Crcl >90ml/min/1.73m2, BUN 10-20mg/dl, and urine protein < (++).

2.9. Statistical Analysis

Independent sample T-test was used to compare the mean levels of kidney function parameters between baseline values and ≥ 2years ART use at 95% confidence level. Chi-square analysis was used to compare the distribution of socio demographic characteristics and some clinical variables of respondents in the two groups, using Statistical Package for Social Sciences version 26.0, Result was presented using tables and charts. Continuous values were given as mean ± standard error of mean.

2.10. Ethical clearance

The study was approved by the Health Research Ethical Committee (HREC) of Federal Medical Center, Makurdi Benue State with Ref. No: FMH/FMC/HREC/108/VL.1. Study participation was preceded by written informed consent of each participant; after a thorough explanation and clarification of study aims. Participation in the study was voluntary; with confidentiality and anonymity of study participants assured.

3. Results

Table 1 Socio demographic characteristics of respondents in the two study group at Federal Medical Centre Makurdi

Variables	**Response**	**Baseline (HIV Negative)**	**≥ 2 years ART use**	**TOTAL**	**χ2**	**p-value**
		n=250	**n=250**	**N=500**		
Sex	Male	135(54.0)	64(25.6)	199(39.8)	42.079	<0.001
	Female	115(46.0)	186(74.4)	301(60.2)		
	Sex ratio (M: F)	1:1	1:3			
Age (years)	≤20	15(6.0)	2(0.8)	17(3.4)	36.257	<0.001
	21-40	145(58.0)	95(38.0)	240(48.0)		
	41-60	70(28.0)	132(52.8)	202(40.4)		
	61-80	20(8.0)	21(8.4)	41(8.2)		
	Mean age	38.4±13.3	44.9±11.7		33.420	<0.001
Religion	Christianity	238(95.2)	247(98.8)		6.167	0.046
	Islam	9(3.6)	3(1.2)			
	Others	3(1.2)	-			
Marital Status	Single	98(39.2)	31(12.4)	129(25.8)	87.197	<0.001
	Married	141(56.4)	139(55.6)	280(56.0)		
	Widowed	9(3.6)	69(27.6)	78(15.6)		
	Divorced	2(0.8)	11(4.4)	13(2.6)		
Level of education	NFE	27(10.8)	31(12.4)	58(11.6)	44.695	<0.001
	Primary	88(35.2)	71(28.4)	159(31.8)		
	Secondary	129(51.6)	95(38.0)	224(44.8)		
	Tertiary	6(2.4)	53(21.2)	59(11.8)		

Results is significant were $p<0.05$ at $p<0.05$; NFE=No formal education

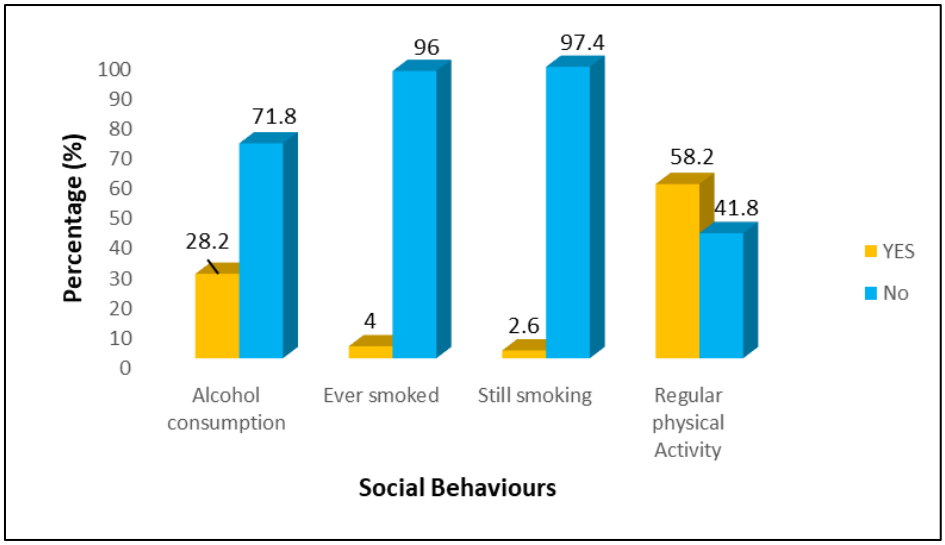

Figure 1 Distribution of some social behaviours of respondents

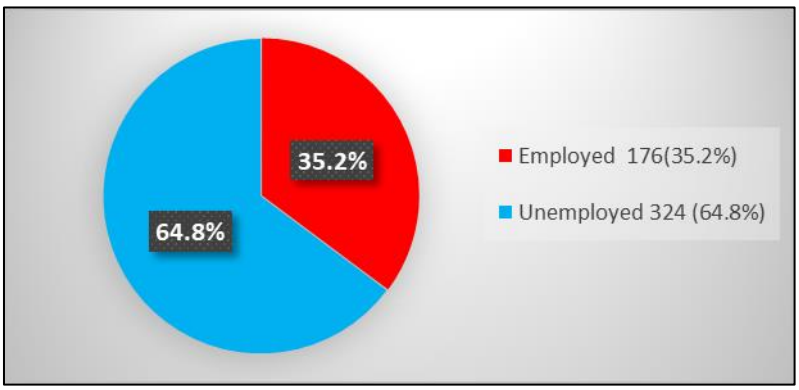

Figure 2 Distribution of employment status of respondents

Table 2 Renal function parameters of respondents in the two study group at FMC, Makurdi, Nigeria

Variables	Cr (umol/L)	Urea (mmol/L)	Na^+ (mmol/L)	K^+ (mmol/L)	HCo_3^- (mmol/L)	Cl^- (mmol/L)
Reference range	72-126	2.5±6.6	134-145	3.5-5.5	21-31	96-106
Baseline(Control)	78.6±30.2	3.76±1.3	141.7±4.6	4.1±0.5	26.0±2.9	101.5±5.6
≥ 2 years Post ART	99.0±35.5	5.6±1.2	146.8±63.2	5.8±23.4	26.9±3.2	105.2±10.1
t	6.916	15.867	1.265	1.154	3.302	5.090
p-value	<0.001	<0.001	0.206	0.249	0.001	<0.001

Result is significant where p<0.05; Values are Mean ± SD

Table 3 Prevalence of renal dysfunction in the study group at FMC, Makurdi, Nigeria

Variables	Frequency	CrCl <90 ml/mim/1.73mm² (%)	χ2	p-value
Baseline (Control)	250	21(8.4)	18.039	0.002
≥ 2 years post ART	250	64(25.6)		
TOTAL	500	85(17.0)		

Result is significant where p<0.05;

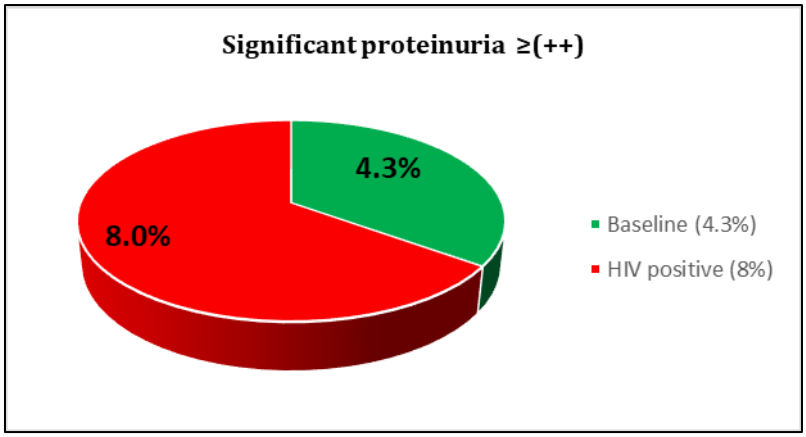

Figure 3 Level of proteinuria among respondents

Table 4 Assessment of renal dysfunction among respondents in the two study group at FMC, Makurdi, Nigeria

Variables	eGFR (ml/min)	CrCl(ml/mim/1.73mm²)	BUN (mg/dl)
Reference range	>90	>90	10-20
Baseline (Control)	113.0±15.6	106.25	10.55
≥ 2 years post ART	62.0±7.2	66.09	15.71
t	-25.621	32.101	9.381
p-value	0.001	0.010	0.023

Result is significant where p<0.05; Values are Mean ± SD

4. Discussion

This study shows that the mean creatinine clearance (Crcl) decreased significantly in respondents who were HIV positive and were on ART for at least two years compared to the HIV negative control respondents. This decreased may indicate a renal involvement with prolonged use of ART. Our study is in keeping with a similar report in Cameroon, [15] another study by Nforbugwe et al. [16] has also linked renal dysfunction with respondents on HAART with a decrease in mean Crcl. Another study also found impaired renal function to be common in HIV-infected patients using ART for at least 3 years in Ethiopia. [17] The mean estimated glomerular filtration rate (eGFR) was significantly decreased in HIV patients compared to respondents in the HIV negative (control) group, but was not below (60 ml/min/1.73m²) cut off. This is in keeping with a study in Chaina by Zhao et al. [18] Other studies have also shown a varying degree of renal impairment with decrease in eGFR in HIV patients on ART in Burkina Faso, [19] Cameroon, [16] Spain [20] and Nigeria. [21]The decline in eGFR may be due to the nephrotoxic effects of ART and the duration of use, as many respondents were on ART as long as 20 years. Gallant and associates in their study reported that participants on HAART had a significant decline in eGFR especially those on tenofovir and protease inhibitors. [22]

The prevalence of renal malfunction in the HIV patients in this study was 25.6%, the prevalence is in keeping with a similar study by Nforbugwe et al. [16] who reported 26.5% among HAART experienced patients. Similarly, in Uganda, Odongo et al. [23] showed a 14.4% prevalence; however, Kahsu et al. [24] in Ethiopia reported a greater prevalence of 30.1% among patients who were not on HAART. In Nigeria, renal impairment among HIV patients on ART was reported to be 13.8% in Bayelsa state South east Nigeria by Egbi et al. [13] Umeizudike et al found a prevalence of 23.5% in their cross-sectional case-control study in Lagos, South-West Nigeria. [25] Another study by Emem-Chioma described even a higher prevalence rate of 38% in Port Harcourt, South-South, Nigeria. [26] A study in Jos, North Central Nigeria, a state close to Makurdi where this study is carried out revealed higher prevalence rates of 30.8%, [27] and 51% [28] in serial studies. The discrepancies in prevalence rate may be due to the different criteria used in defining renal dysfunction. In the studies by Umeizudike [25] and Emem-Chioma [26] renal dysfunction was defined as the presence of albuminuria and/or reduced kidney function unlike in our study where we used Crcl and eGFR. The mean BUN of the ART-using respondents was higher than that of the negative group. This outcome differed from the study by Kahsu et al. [24] which showed that those who had not taken HAART had higher mean BUNs. Our study showed presence of significant proteinuria (≥++) on urine dipstick to be 8.0% among HIV positive respondents, this prevalence is low compared to a

report by Nforbugwe et al. [16] a similar study by Anyabolu et al. [29] reported 32.5%. The disparity could be due to the method of screening used. Nforbugwe et al and Anyabolu et al employed the 24 hours urine protein estimation while, dipstick urinalysis was used in this study which may be less sensitive. Comparative mean values of creatinine and urea levels were significantly higher in HIV respondents on ART compared to the control group, despite this elevation, values were within the normal reference range for study population. This is in contrast with a study in Enugu which found that there was no significant difference in creatinine and urea levels between HIV-positive individuals on HAART and HIV-negative individuals. [30] The present study found that there was no significant changes in the level of measured electrolytes. The level of sodium (Na^+) and potassium (K^+) were similar between the two groups. A study from Owerri Metropolis, South Eastern Nigeria, found that potassium levels were within the normal range for HIV patients on HAART. However, sodium levels were observed to be decreased compared to the normal range. [31] Another study from University of Port Harcourt Teaching Hospital found significantly lower sodium levels in HIV patients on HAART compared to controls. [32] This study found bicarbonate (HCO_3) and chloride (Cl^-) to be slightly increased In the HIV positive respondents on ART compared to negative control group. This is in keeping with a study elsewhere, [33] however, contrast to these, a study reported no significant difference in bicarbonate and chloride levels between HIV-positive subjects and normal subjects. [34]

It is worth noting that this study can be considered limited in some aspects because ART regimen combination and duration of use was not assessed, which could have help estimate the relationship between (combination, type and duration of ART use) with renal function. Similarly, CD4 and viral load was not assessed because of cost associated with investigating these parameters. The difference in renal function observed in this study between the HIV positive and the negative control group is indicative that these changes could have been a result of the devastating effect of ART use.

5. Conclusion

Respondents on ART for 2 years or more had changes in renal function, significant decrease in creatinine clearance (Crcl), estimated glomerular filtration rate (eGFR) and a substantial rate of proteinuria is indicative of an association of changes in renal function with prolonged use of ART.

Compliance with ethical standards

AUTHORS' CONTRIBUTIONS

Data was collected and analyzed as well as manuscript writing by Akpagher Shawon Fredrick, Funding and manuscript review was carried out by Yanmeer Simeone Tyotswam, Daniel Joseph Ajii , Victor Amaachi Ohanu , Oladayo Timothy Abimbola, Clement Egba Ejim and Daniels Obadiah Dauda.

Disclosure of conflict of interest

All authors declared that there is no conflicting interest.

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