Original Article

Microalbuminuria and its Associated Risk Factors among Human Immunodeficiency Virus-Infected Patients Attending a Tertiary Care Facility in Kano, Northwest Nigeria

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Abstract

Background: Human immunodeficiency virus (HIV) infection affects multiple organs and the kidney is a common target, thereby making renal disease one of the recognised complications of HIV infection. Microalbuminuria represents an early, important marker of kidney damage in several disease conditions including HIV-infected highly active antiretroviral therapy (HAART)-naïve patients. Early detection of microalbuminuria is critical to slowing down the progression of kidney dysfunction to chronic kidney disease in HIV-infected patients. Determination of predictive factors for microalbuminuria in these group of patients may serve as avenues for intervention to prevent HIV-associated renal diseases. **Aim:** The aim of the study was to determine the prevalence and risk factors of microalbuminuria in HIV/AIDS-infected adults on HAART at Aminu Kano Teaching Hospital, Kano, Nigeria. **Patients, Materials and Methods:** A descriptive cross-sectional study was carried out among 500 subjects including 250 HAART-treated and 250 HAART-naïve HIV/AIDS participants. An interviewer-administered structured questionnaire was used to collect relevant demographic and clinical information. Blood and urine samples were collected for serum creatinine and urinary albumin and creatinine measurements, respectively, and the results were collated and analysed. Comparison of categorical variables was done using Chi-square/Fisher's exact test, where applicable with level of significance set at $P < 0.05$. **Results:** The prevalence of microalbuminuria among the two groups studied was found to be high (22.8% for HAART naïve versus 18.4% for HAART treated, respectively) while the risk factors identified were estimated glomerular filtration rate, low CD4 count, and duration of HIV treatment. **Conclusion:** The major predictors of microalbuminuria include low CD4 count, duration of HIV infection (<30 months), and duration of HAART treatment (<30 months).

Keywords: Risk factors, human immunodeficiency virus, microalbuminuria, highly active antiretroviral therapy

Introduction

Advances in the treatment of human immunodeficiency virus (HIV) infection have led to the widespread use of highly active antiretroviral therapy (HAART) in mid to late 1990s and the effort has resulted in improvement in quality of life, increase in life expectancy, and reduction on the incidence of opportunistic infections.[1,2] Thus, the prolonged use of HAART by HIV/AIDS patients is associated with complications such as renal impairement.[1,2] Some of the drugs that have been implicated to be nephrotoxic include both first- and second-line drugs such as tenofovir, stavudine, didanosine, ritonavir, and saquinavir. Additionally, some medications used in the management of opportunistic infections such as some anti-tuberculous drugs, antifungals, and some antibiotics have also been implicated in nephrotoxicity.[1,2]

Among the early laboratory findings of renal involvement in HIV-infected patients is the presence of microalbuminuria.[3-6] It is defined as a urinary albumin excretion of between 30 and

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300 mg/day or 20 and 200 μg/min.[5,6] Microalbuminuria is also defined as albumin creatinine ratio (ACR) ≥2.5 mg/mmol in males and ≥3.5 mg/mmol in females or, with both albumin and creatinine measured by mass, as an ACR between 30 and 300 mg/g creatinine, using spot urine sample.[5-7]

Microalbuminuria is widely accepted as a measurable biomarker of early kidney damage in HIV-infected patients.[3,4,8] Therefore, early detection of microalbuminuria provides an opportunity for identification of individuals at risk of developing chronic kidney disease (CKD). This may create a platform for the implementation of preventive measures aimed at curtailing the risk factors, such as withdrawal of nephrotoxic drugs, that will help to retard CKD progression and treatment optimisation of other comorbid conditions such as diabetes mellitus, hypertension, and some infections.[1,8,9]

A cross-sectional study was conducted in the USA in HIV/AIDS HAART-naïve patients to evaluate HIV/AIDS as an independent risk factor for microalbuminuria. Prevalence of microalbuminuria was reported to be 11% in the HIV/AIDS-infected patients while control participants, consisting of healthy young men and women aged 18–30 years, had a prevalence of 2%.[10]

For most of the studies conducted at global, regional, and local levels, predictors of microalbuminuria implicated in HIV/AIDS include Afro-American origin, low CD_4 count (<200 cell/mm^2), estimated glomerular filtration rate (eGFR) of <60 mL/min/1.72 m^3, increasing age, duration of HIV/AIDS infection, viral Load as well as duration on HAART and HAART regimen.[10-14]

The aim of the study was to determine the prevalence and risk factors for the development of microalbuminuria in HIV/AIDS adult patients on HAART in Aminu Kano Teaching Hospital (AKTH), Kano, Nigeria.

Patients, Materials and Methods

This cross-sectional study was conducted at the Professor Wali treatment Centre of AKTH, Kano. The centre adopts the National Guidelines on HIV/AIDS treatment of adults and children in Nigeria, hence HAART eligibility is based on WHO recommendations.[15]

The sample size was determined using the Fisher's formula and adopting a prevalence rate of 17.5% from a previous study conducted in Kano.[14] A total of 500 participants were studied. They were made up of 250 HIV sero-positive patients on HAART (Group I) and 250 HAART-naïve HIV sero-positive patients (Group II).

Groups I and II participants were clinically stable HIV seropositive patients between the ages of 18 and 45 years that were either on HAART or were HAART naïve. Both groups of participants were age- and sex-matched. Patients with hematuria or overt proteinuria, and those with a history of hypertension, diabetes mellitus, renal disease, and previous diagnosis of microalbuminuria were excluded from the study. Pregnant women, lactating mothers, patients with signs and symptoms of urinary tract infection (UTI), and those on treatment for UTI as well as individuals above 45 years were also excluded from the study.

Approval to conduct the study was obtained from the Ethical Research Committee of AKTH, Kano. Informed written consent was also obtained from each of the participants after verbal explanation on the objectives of the study to them in a language well understood by them. All data collected from the participants were treated with utmost confidentiality.

About 5 mm each, of urine and whole blood were collected from the study participants. A total of 5 mm of urine was required. Urine samples collected was stored refrigerated at temperature between 0°C and 4°C until analysis (3–5 days).

Relevant demographic data were collected; blood pressure and anthropometric measurements were also documented. Visual inspection and dipstick examination of urine samples were carried out to exclude evidence of UTI, hematuria, or overt proteinuria. The levels of urinary creatinine as well as serum creatinine concentrations for all participants were measured using Architect c4000 automated clinical chemistry analyser (Abbott diagnostics®; serial number: C461238; IL, USA) which uses the principle of Jaffe reaction.[16,17] Urine albumin was measured using Hemocue Albumin analyser (Hemocue America, USA) that utilise the principle of turbidimetric immunoassay.[18]

Primary outcome measures

The urine ACR was computed. Results were interpreted using American Diabetes Association (ADA)-recommended reference values for urine ACR as follows: [9]

- Normal <30 mg/g creatinine
- Microalbuminuria 30 – 300 mg/g creatinine
- Macroalbuminuria 300 mg/g creatinine

The eGFR was calculated using Cockcroft and Gault formula.[19] Results were interpreted using Kidney Disease Improving Global Outcome criteria.[19]

Statistical analysis of results

All data generated from both laboratory analysis and questionnaire were entered into an excel spread sheet and subsequently exported into Statistical Package for Social Sciences (SPSS) version 20.0 (IBM SPSS Armonk, NY: IBM Corp) for processing and analysis. Frequencies and percentages were used to describe categorical variables. Comparison of categorical variables for associations was conducted in most cases using Chi-Square test, with $P < 0.05$ being statistically significant.[20] In situations where the tables contained empty cell numbers, Fisher's exact test was used for the comparison.[21]

Continuous variables were tested for normality to determine their distribution. Data that were normally distributed were reported using means and standard deviations, while those that were not normally distributed were described using median and inter-quartile ranges. The prevalence of microalbuminuria was presented as percentages.[21]

Results

Socio-demographic characteristics of the study participants

Table 1 shows the age distribution of the study participants. The mean age of the study participants was 35.34 ± 5.64 years while the corresponding mean age for groups I and II was 33.46 ± 7.2 years, and 31.70 ± 6.74 years, respectively. The observed difference in the mean age was not statistically significant ($P = 0.4224$).

The sex distribution of the study participants is shown in Table 2. This study shows a slight female preponderance in both Groups I and II (male-to-female ratios of 1:2.3 and 1:1.4, respectively).

Table 2 shows the occupation of the participants in the various study groups. Most of the study participants in Groups I and II were self-employed. Majority of the participants in both groups were married and constituted 58.4% and 37.6% in Groups I and II, respectively, as shown in Table 2. Most of the participants in Groups I and II had secondary level of education [Table 2].

Anthropometric variables and body mass index of the study participants

The mean body mass index (BMI) of Groups I and II was 24.81 ± 4.61 and 22.01 ± 3.80, respectively [Table 3]. The differences were statistically significant, ($P < 0.001$).

Frequency distribution of the body mass index of the study participants

Majority of the participants in all the three groups had normal BMI. However, participants in Group I had the highest proportion of those with overweight (25.2%), obesity (11.2%), and morbid obesity (1.2%). In contrast, participants in Group II had the highest proportion of underweight (17.2%). The difference in BMI among the two groups was statistically significant ($P < 0.001$) [Table 4].

CD4 count status of the study participants

The CD4 status of study participants are as shown in [Table 5].

Estimated glomerular filtration rate status and prevalence of microalbuminuria of the study participants

The eGFR of study participants are as shown in [Table 6]. The prevalence of microalbuminuria among both sets of study participants is shown in [Table 7].

Correlation between estimated glomerular filtration rate, duration of human immunodeficiency virus/AIDS infection, and duration of highly active antiretroviral therapy among Group I study participants

eGFR showed a negative correlation with both duration of HIV/AIDS (r =-0.405, $P < 0.001$) and duration of HAART therapy ($r = -0.406$, $P < 0.001$).

Correlation between CD4 count, serum creatinine, and estimated glomerular filtration rate among Groups I and II study participants

CD4 count showed a negative correlation with serum creatinine among both Groups I ($r = -0.297$, $P < 0.001$) and II ($r = -0.337$, $P < 0.001$), while a positive correlation was found between CD4 count and eGFR among Groups I ($r = 0.447$, $P < 0.001$) and II ($r = 0.603$, $P < 0.001$) study subjects.

Relationship between duration of human immunodeficiency virus/AIDS and microalbuminuria of the study participants

The proportion of study participants with microalbuminuria in Group I was significantly higher among those with HIV/AIDS duration of ≤30 months as compared to HIV/AIDS duration of >30 months (60.3% vs. 12.7%; $P < 0.001$) [Table 8].

Table 1: Age distribution of study participants

	Participants	
	Group I, *n* (%)	Group II, *n* (%)
Age group (years)		
18-22	5 (2.0)	23 (9.2)
23-27	16 (6.4)	51 (20.4)
28-32	60 (24.0)	60 (24)
33-37	60 (24.0)	53 (21.2)
38-42	93 (37.2)	51 (20.4)
43-45	16 (6.4)	12 (4.8)
Total	250 (100)	250 (100)
Mean age	33.46±7.2	31.70±6.74

n: Number of participants

Table 2: Sociodemographic characteristics of the study participants

Sociodemographic Variables	Characteristics	Participants	
		Group I, *n* (%)	Group II, *n* (%)
Sex	Male	75 (30.0)	103 (41.2)
	Female	175 (70.0)	147 (58.8)
Marital status	Single	40 (16.0)	90 (36.0)
	Married	146 (58.4)	94 (37.6)
	Divorced	16 (6.4)	28 (11.2)
	Widowed	48 (19.2)	38 (15.2)
Occupation	Civil servant	35 (14.0)	37 (14.8)
	Self employed	157 (62.8)	129 (52.6)
	Others	58 (23.2)	84 (33.6)
Educational status	Nonformal	64 (25.6)	70 (28.0)
	Primary	39 (15.6)	25 (10.0)
	Secondary	80 (32.0)	85 (34.0)
	Tertiary	67 (26.8)	70 (28.0)

Table 3: Anthropometric variables and body mass index of the study participants

Category	Participants, mean±SD		*P*
	Group I	Group II	
Height (m^2)	1.65±0.07	1.64±0.72	0.002
Weight (kg)	67.22±13.21	59.17±10.19	<0.001
BMI (kg/m^2)	24.81±4.61	22.01±3.80	<0.001

BMI: Body mass index, SD: Standard deviation

Table 4: Frequency distribution of the body mass index of the study participants

BMI category (kg/m²)	Participants	
	Group I, *n* (%)	Group II, *n* (%)
Underweight (<18.5)	7 (2.8)	43 (17.2)
Normal (18.5-24.9)	149 (59.6)	159 (63.6)
Overweight (25.0-29.9)	63 (25.2)	40 (16.0)
Obesity (30.0-39.9)	28 (11.2)	7 (2.8)
Morbid obesity>40.0	3 (1.2)	1 (0.4)
Mean BMI	24.81±4.61	22.01±3.80

n: Number of participants, BMI: Body mass index

Table 5: CD4 count status of the study participants

CD4 count (cell/mm³)	Participants	
	Group I, *n* (%)	Group II, *n* (%)
>500	90 (36.0)	71 (28.4)
200-499	129 (51.6)	103 (41.2)
<200	31 (12.4)	76 (30.4)

n: Number of participants

Table 6: Estimated glomerular filtration rate status of the study participants

eGFR category (mL/min/1.73 m²)	Participants	
	Group I, *n* (%)	Group II, *n* (%)
G1≥90	193 (77.2)	185 (74.0)
G2 (60-89)	46 (18.4)	53 (21.2)
G3a (45-59)	10 (4.0)	8 (3.2)
G3b (30-44)	1 (0.4%)	3 (1.2)
G4 (15-29)	0	1 (0.4)
G5<15	0	0

eGFR: Estimated glomerular filtration rate

Table 7: Prevalence of microalbuminuria among the study participants in Groups I and II

Category (mg/g)	Participants	
	Group I, *n* (%)	Group II, *n* (%)
Normal (0-<30)	204 (81.6)	193 (77.2)
MA (30-300)	46 (18.4)	57 (22.8)

n=Number of participants, MA: Microalbuminuria

Relationship between duration on highly active antiretroviral therapy and microalbuminuria of the participants

Similar to duration of diagnosis of HIV/AIDS, microalbuminuria was significantly associated with duration of treatment of HIV/AIDS (HAART) of ≤30 months [Table 9].

Relationship between types of highly active antiretroviral therapy regimen and microalbuminuria of the study participants

Majority of the study subjects in Group I with microalbuminuria were on first-line HAART regimen (40 [87.0%]) while the remaining subjects 6 (13.0%) were on second-line HAART. However, no statistical significance exists between the type of HAART regimen and the development of microalbuminuria among Group I participants ($P = 0.151$).

Logistic regression for significant predictors of microalbuminuria among participants on highly active antiretroviral therapy

Multivariate sub-analysis of variables (using logistic regression) was conducted to determine the significant predictors of microalbuminuria among adult patients on HAART. It was found that age greater than 28 years, adjusted odd ratio (AOR) 9.8 (95% confidence interval [CI]: 1.3–76.6), duration of HIV of <30 months, AOR 26.9 (95% CI: 9.3–78.4); duration on HAART of 30 months and below, AOR 12.0 (95% CI: 1.9–73.4); CD4 count <200 AOR, 11.8 (95% CI: (3.0–46.9) were significant predictors of microalbuminuria with $P = 0.030$, <0.001, 0.007, and < 0.001, respectively [Table 10]. However, eGFR <60 mL/min/1.73 m² that was found to be significantly associated with microalbuminuria lost significance on multivariate analysis.

Logistic regression for significant predictors of microalbuminuria among highly active antiretroviral therapy-naive study participants

Multivariate sub-analysis of variables (using logistic regression) was conducted to determine the significant predictors of microalbuminuria among HAART-naive adult patients. It was found that CD4 count of <200 cell/mm³, AOR 14.4 (95% CI: 6.7–30.9) was an independent predictor of microalbuminuria with $P < 0.001$. On the contrary, eGFR <60 mL/min/1.73 m² was significantly associated with microalbuminuria at bivariate analysis, logistic regression could not be computed due to the fact that, all those with eGFR <60 mL/min/1.73 m² had microalbuminuria.

Discussion

The slightly older participants with HIV/AIDS on HAART found in this study when compared to the HIV/AIDS HAART-naïve group (mean age 33.46 years vs. 31.70 years, respectively) may be due to the effect of HAART in improving the life expectancy of individuals with HIV/AIDS, thus enabling them to live longer.[1,2] However, the difference in the mean age of the groups was not statistically significant.

In both the HAART-treated and HAART-naïve groups, majority of the subjects were between 23 and 37 years of age. This suggests that HIV/AIDS affects individuals in their prime, as obtained in most developing nations, with consequent loss of productivity and resultant socio-economic effects. A possible explanation to this finding is the fact that, participants in this age group are likely to be more sexually active with increased tendency of unprotected sexual intercourse, drug abuse, and other negative acts associated with increase sexual drive. This observation is in agreement with United Nation progress report on Nigeria, 2019, which stated that drug abuse and unprotected

Table 8: Relationship between duration of human immunodeficiency virus/AIDS and microalbuminuria in Group I study participants

Duration of HIV/AIDS (months)	MA		*P*
	Present (*n*=46)	Absent (*n*=204)	
1-30	38 (60.3)	25 (39.7)	<0.001
31-60	4 (4.3)	90 (95.7)	
61-90	1 (2.3)	43 (97.7)	
>90	3 (6.1)	46 (93.9)	
Median (IQR)	14.5 (10.0-26.8)	58.0 (39.0-84.0)	

IQR: Interquartile range, HIV: Human immunodeficiency virus, MA: Microalbuminuria

Table 9: Relationship between duration on highly active antiretroviral therapy and microalbuminuria of the study participants

Duration on HAART (months)	MA		*P*
	Present, *n* (%)	Absent, *n* (%)	
1-30	41 (51.3)	39 (48.8)	<0.001
31-60	1 (1.2)	82 (98.8)	
61-90	3 (5.4)	53 (94.6)	
>90	1 (3.2)	30 (96.8)	
Median (IQR)	14.0 (10.0-24.0)	50.0 (35.3-80.0)	

IQR: Interquartile range, HAART: Highly active antiretroviral therapy, MA: Microalbuminuria

Table 10: Logistic regression for significant predictors of microalbuminuria among patients on highly active antiretroviral therapy

Variables	AOR (95% CI)	*P*
Age (28+years)	9.8 (1.3-76.6)	0.030*
Duration of HIV (1-30 months)	26.9 (9.3-78.4)	<0.001*
Duration on HAART (1-30 months)	12.0 (1.9-73.4)	0.007*
CD4 (<200 cell/mm^3)	11.8 (3.0-46.9)	<0.001*
eGFR (<60 mL/min/1.73 m^2)	2.6 (0.1-87.2)	0.597

*Statistically significant. AOR: Adjusted odds ratio, CI: Confidence interval, HIV: Human immunodeficiency virus, eGFR: Estimated glomerular filtration rate, HAART: Highly active antiretroviral therapy

sexual intercourse are among the leading causes of HIV in this age group.[20]

While the slight female preponderance in Groups I and II study subjects suggest that HIV/AIDS appear to be more common among females than males in the area of the study, this may just be a reflection of better health-seeking behavior among females. Findings by Laah and Ayiwulu in Nasarawa (North-Central Nigeria) and that reported by Nwozor and Nwankwo in Awka (South-East Nigeria) showed female preponderance of 51.5% and 68.9%, respectively.[22,23] Similar female preponderance was reported in other studies conducted outside Nigeria by Owusu Adobea in the Eastern Region of Ghana as well as Pettifor *et al*. in South Africa.[24,25] This finding may be related to the increased risk of acquiring HIV infection among females compared to their male counterparts as a result of cultural and religious values that permit polygamy, low socioeconomic status of females when compared to males, and favoritism of male education within our communities.

Although majority of the study participants in both groups had a normal BMI, HIV/AIDS HAART-naïve subjects had a statistically significant higher proportion of underweights. This may be attributed to inadequate oral intake, malabsorption, endocrine dysfunction, and cytokine dysregulation, which may contribute to wasting syndromes that is commonly associated with the disease, particularly, if untreated, as in the case of this group. Inadequate intake may result from oropharyngeal and esophageal diseases or systemic illnesses.[14] Endocrine disorders, such as adrenal and thyroid dysfunctions and low testosterone levels, have been found to cause malnutrition among HIV/AIDS patients.[14] On the contrary, HIV/AIDS HAART-treated group had significant proportions of those with overweight, obesity, and morbid obesity compared to HIV/HAART-naïve group. This observation suggests that HIV/AIDS patients taking HAART may have better nutritional status than HIV/AIDS HAART-naïve subjects. This pattern was reported by Sakajiki *et al*. and Yusuf *et al*. from Kano and Zaria, North west Nigeria, respectively.[13,14] More so, Baekken *et al*. from Oslo, Norway, reported similar findings.[26]

The mean CD4 count was observed to be higher among HIV/AIDS HAART-treated group than the HAART-naïve group. This finding may not be unconnected to the fact that HAART is known to improve the immune status of HIV-positive patients, thus increasing the CD4 count levels.[27,28] Low CD4 count has been established as a major risk factor for the development of microalbuminuria. This inverse relationship was similarly observed in this study whereby, low CD4 count of <200 cell/mm^3 was significantly associated with microalbuminuria and serves as an independent predictor.

In this study, both duration of HIV/AIDS and duration of treatment with HAART were found to be significantly associated with microalbuminuria. In the two scenarios, duration of 30 months or less was significantly associated with microalbuminuria. This perhaps could be due to the inverse relationship between antiretroviral therapy and development of kidney disease, whereby long term treatment with HAART has been shown to decrease microalbuminuria in HIV/AIDS patients.[10,13,29] While it may appear that prolonged duration of HAART treatment is protective against HIV/AIDS-related kidney diseases, this observation may be complicated by the possible nephrotoxic effects that may occur with HAART and may require more large-scale studies for validation. Yusuf *et al*. in Zaria, North west Nigeria, and Schwartz *et al*. (USA) have also reported similar findings in their studies.[10,13,29] Multivariate analysis have shown that both duration of HIV/AIDS and duration of HAART treatment were independent predictors of microalbuminuria among Group I participants of this study. This observation was difficult to assess among Group II participants who generally had a few days between

diagnosis of HIV/AIDS and commencement of HAART, in line with the current guidelines for HIV/AIDS management.[15,30]

Conclusion

This study has shown that microalbuminuria is common among both HIV/AIDS HAART-treated and HAART-naïve patients with a prevalence of 18.4% and 22.8%, respectively, while the overall pooled prevalence of microalbuminuria among HIV/AIDS participants in this study, irrespective of HAART status was 20.6%. There was a statistically significant association between microalbuminuria and shorter duration of HIV/AIDS (≤30 months), as well as shorter duration of HAART treatment. HIV/AIDS and HAART treatment duration were independent predictors of microalbuminuria in our study subjects. In addition, age 28 years and above as well as low CD4 count (<200 cell/mm^3) were found to be independent predictors of microalbuminuria in HIV/AIDS participants.

Recommendations

1. Physicians managing HIV/AIDS patients should routinely screen these patients for microalbuminuria. This will help in the identification and risk stratification of those susceptible to renal disease, so that appropriate measures can be instituted early to retard the progression of the disease
2. Regular monitoring of BMI among HIV/AIDS patients on HAART should be done to prevent overweight/obesity and its complications. This can be achieved through therapeutic life style modifications
3. Duration of HIV/AIDS and duration of HAART treatment were found to be independent predictors of microalbuminuria among the study participants. HIV/AIDS patients on HAART treatment may need periodic evaluation to facilitate early detection of patients at risk of HIV-associated renal disease
4. eGFR and CD4 counts were found to be significantly associated with microalbuminuria. These should be measured to detect those at risk as such patients may need closer monitoring and evaluation for early onset of CKD.

Scope and limitations of the study

This research work determined the prevalence of microalbuminuria in HIV/AIDS adult patients on HAART between the ages of 18 and 45 years at AKTH, Kano, Nigeria. Single measurement of serum creatinine and UACR in this study is not sensitive enough in detecting microalbuminuria, as compared to sequential measurements of UACR, ideally done on at least 3 occasions in a period of three to six months.[31] Therefore, the prevalence found in this study may not be a true prevalence of microalbuminuria among the study participants. Although majority of the study participants had normal BMI, the proportion of those with high BMI (overweight, obesity, and morbid obesity) and underweight may affect the true value of eGFR, given the effect of body mass and nutritional status on serum and urine creatinine levels.[32] Some of our findings may not be applicable to hypertensives, diabetics, children, the elderly, pregnant women and lactating mothers, and who are HIV/AIDS positive. Similarly, our study was a single centre and hospital based, hence the prevalence of microalbuminuria among HIV/AIDS patients found in this study may not be directly applicable to the general population.

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Conflicts of interest

There are no conflicts of interest.

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