Original Article

Clinical Profile of Patients on Highly Active Antiretroviral Therapy (HAART) Seen in a Tertiary Eye Clinic

Abstract

Background: Highly active antiretroviral therapy (HAART) is the medication regimen for the management of human immunodeficiency virus. Over time, it has been dubbed to have revolutionised the clinical course and outcomes of HIV/AIDS. **Objective:** The objective of this study is to determine the clinical factors associated with the ocular manifestation of HIV/AIDS among patients on HAART. **Materials and Methods:** This was a descriptive cross-sectional study conducted at the ophthalmology department of the University of Nigeria Teaching Hospital (UNTH) in 2017 among adult patients (≥18 years) attending the hospital's antiretroviral therapy (ART) clinic and selected using systematic random sampling technique. Statistical Package for Social Sciences (SPSS) version 21 was used for data analysis, with variables being summarised using frequencies and proportions. Inferential statistics (*t* test, Chi-square test, and Fisher's exact test) was used to test associations between variables. A level of significance was set at a *P* value of less than 0.05 corresponding to a 95% confidence interval. **Results:** A majority of patients were in WHO stages 1 and 2 of HIV and the mean CD4+ cell count of the whole population was 575.0 ± 512.56 cells/μL, while that of those with ocular manifestations was 315.2 ± 290.76 and 633.7 ± 533.54 cells/μL for those who do not have ocular manifestation. There was a significant association between CD4+ cell count and ocular manifestations such as conjunctival microvasculopathy, anterior uveitis, and cytomegalovirus retinitis. **Conclusion:** Our results suggest that HAART has some positive effect on the clinical profile of people with HIV/AIDS with CD4+ count being a major determinant of ocular manifestations.

Keywords: *Clinical profile, Enugu, HAART, tertiary eye clinic*

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Introduction

The Human Immunodeficiency Virus (HIV) is the causative agent for the Acquired Immune Deficiency Syndrome (AIDS). AIDS is the last clinical stage of the HIV spectrum where the "white soldiers of the body" become anergic antigens, which ordinarily would have caused no harm to the body's immune response. In other words, the body becomes susceptible to opportunistic infections (OIs) such as cytomegalovirus (CMV) infections, candidiasis, coccidioidomycosis, cryptococcosis, cryptosporidiosis, cystoisosporiasis, herpes simplex infection, herpes zoster infection, and tumours, kaposi sarcoma, cervical cancer, etc.[1] This is due to a decline in the person's $CD4^+$ cells to a count less than or equal to 200μL cells. HAART is a combination medication regimen used for the management of human immunodeficiency virus.[2] The advent of highly active antiretroviral therapy (HAART) and its ability to restore some immune function by increasing the CD4+ cell count thus reducing the viral load of the body gives some hope. It has been shown to improve the quality of life of people with HIV/AIDS (PLWHA).[3-5] This improvement in immune function has been shown to reduce the OIs and change the clinical course of patients.[6] However, it has also been shown to be associated with a special type of inflammatory response called immune recovery uveitis.

It is expected that the widespread availability of HAART will alter the epidemiology of ocular manifestation of HIV, which were quite prevalent prior to the advent of HAART.[7,8] Ocular manifestation could be the presenting feature of HIV/AIDS.[9,10] They include the OIs (CMV infections, herpes zoster ophthalmicus, molluscum contagiosum, keratitis, orbital cellulitis), tumours (Kaposi, lymphomas),

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microangiopathies (example the conjunctival vessels), neuro-ophthalmic lesions and drug-induced reactions (immune recovery uveitis [IRU], a component of immune recovery inflammatory syndrome [IRIS]).[7] There is a positive correlation between CD4+ count of lymphocytes and the ocular manifestations of HIV/AIDS.[11,12] Other clinical factors that still relate to the CD4+ count include clinical stage of disease, duration of infection, use/compliance of HAART, duration on HAART and viral load.[13-15] There is evidence of decline in these ocular changes with HARRT,[16,17] unlike in the pre-HAART era where OIs like CMV retinitis were the most prevalent ocular manifestation and occurring in up to 80% of patients.[7] OI used to be an important cause of ocular morbidity in that era. A study in Croatia reported a reduced incidence of CMV retinitis and better visual acuity in patients on HAART compared with naïve patients.[18]

The prevalence of OIs has reduced with HAART, with appreciable increase in life expectancy of PLWHA. However, new ocular and potentially sight-threatening morbidities have emerged such as IRU, macular oedema, neovascularization and retinal detachment.[8,17] The purpose of this study is to determine the clinical factors associated with the ocular manifestation of HIV/AIDS among patients on HAART in Enugu, Nigeria.

Materials and Methods

Study area, design and period

This was a quantitative cross-sectional study conducted in the ophthalmology department of the University of Nigeria Teaching Hospital (UNTH), from June to September, 2017. The hospital runs an Antiretroviral Therapy (ART) clinic supported by the President's Emergency Plan for AIDS Relief (PEPFAR) project. The outpatient clinic where about 120–150 patients are seen daily (Mondays–Fridays) with free services and drugs also has an adjoining laboratory where patients' CD4+ cell count and viral load are analysed every 3 months and 6 months, respectively.

Ethical consideration

Following ethical clearance by the UNTH Health Research Ethics Committee, the study was conducted in accordance with the tenets of the Declaration of Helsinki and the National Code of Health Research Ethics in Nigeria. Written informed consent was obtained with signature or thumb prints. Participants were at liberty to withdraw at any point in the study. Confidentiality was ensured by masking each patient's identity and use of a serial number, which was known to only the researcher and the patient, for identification purposes.

Sampling and recruitment

A total of 331 consenting patients ≥ 18 years on HAART were recruited using systematic random sampling. The corresponding serial numbers in the daily clinic attendance list of the patients were used.

Numbers were written on pieces of paper and mixed thoroughly in a container. A number was then randomly picked and the patient on the attendance list whose name corresponded with the number was selected. This was repeated until the required daily sample was obtained. This was done for two days every week at an average of 12 patients a day. This was repeated until the desired sample size was reached. Patients with systemic comorbidities like hypertension, diabetes, psychiatric illness were excluded from the study. A pre-tested interviewer-administered semi-structured questionnaire was distributed and variables of interest such as bio data, use of HAART, duration, CD4+ count, viral load were obtained from the consenting respondents.

Ophthalmic examination

Ocular examinations done included distance visual acuity, external eye examination with flash light for corneal reflex, and ocular motility, slit lamp examination to examine the anterior segment and dilated slit lamp fundus examination with +78 D Volks lens. Dilation was done with tropicamide 1% eye drop.

General examination was also done to enable clinical staging of the patients. WHO clinical staging was used.[19,20]

All the information obtained were recorded in the questionnaire.

After the ocular examinations, the patients whose CD4+ and viral load results were more than one month old or who are yet to be investigated routinely in the ART clinic were directed to the PEPFAR laboratory, where blood samples were collected for analyses of CD4+ cells and viral load at no cost to the patients.

Patients with no ocular complaints were not given any treatment, those with minor ocular pathologies such as allergic conjunctivitis and dry eyes were treated at the ART clinic, while those with significant ocular pathologies including HIV-related ocular manifestations were referred to and managed at the eye clinic.

Data management

Statistical Package for Social Sciences (SPSS) version 21 was used for data analysis, and variables were summarised using frequencies and proportions. Inferential statistics was used to test associations between the CD4+ count and ocular manifestations and was determined using *t* test; clinical factors and ocular manifestations were done using Chi-square and Fisher's exact test. A *P* value of less than 0.05 was used to define statistical significance corresponding to a 95% confidence interval.

NB: this was part of a larger study on the ocular manifestations of HIV/AIDS in Enugu State, South-

Eastern Nigeria. The prevalence of HIV-associated ocular manifestation was 18.4%.[21]

Results

A total of 331 participants were interviewed and examined, comprising 252 (76.1%) females and a M:F = 1:3.2 The mean age of participants was 43.6 ± 9.9 years and an age range of 22–81 years [Table 1]. Of 331 respondents, 61 (18.4%) have ocular manifestations.

Table 2 shows the HIV serotypes, CD4+ cell counts and WHO clinical stages of participants. Most of the participants (74.9%) were infected with HIV serotype I. About 85.5% of those studied were at WHO stages I and II while 83.6% of those with ocular manifestations were also at WHO stages I and II. More than half of the participants (62.5%) were at CDC stage A, only 4.8% were at stage C. Of those with ocular manifestations 62.3% were at CDC stage A and only 3.3% of them were at stage C.

The mean CD4+ cell count of the study participants was 575.0 ± 512.56 cells/μL, while that of those with ocular manifestations was 315.2 ± 290.76 cells/μL. More than half of the study population (52.3%) had CD4+ cell count of 500 cells/μL or more and all (100%) of those with CD4+ cell count of less than 100 cells/μL had HIV-related ocular manifestations. More than half of those with ocular manifestations (80.3%) had CD4+ cell count of less than 500 cells/μL and about half of those with ocular manifestation (50.8%) had CD4+ cell count of less than 200 cells/μL.

All the participants were on HAART and 63.1% of them had been on HAART for 60 months (5 years) or more.

Table 1: Socio-demographic characteristics of participants (*n* = 331)

Characteristics	Frequencies	Percentage (%)	Mean (SD)
Age (Years)			
<25	2	0.6	43.6 (9.9)
25–34	44	13.3	
35–44	149	45.0	
45–54	96	29.0	
55–64	24	7.3	
≥65	16	4.8	
Total	331	100.0	
Gender			
Male	79	23.9	
Female	252	76.1	
Total	331	100	
Marital Status			
Single	63	19.0	
Married	152	45.9	
Divorced	10	3.0	
Separated	3	0.9	
Widowed	103	31.1	
Total	331	100.0	
Education level			
Primary school	89	26.9	
Secondary school	126	38.1	
Tertiary	102	30.8	
None	14	4.2	
Total	331	100	
Occupation			
Civil servant	76	23.0	
Trading	115	34.7	
Farming	37	11.2	
Artisan	49	14.8	
Unemployed	35	10.6	
Driver/cyclist	4	1.2	
Military/Paramilitary	2	0.6	
Health worker	3	0.9	
Self-employed	8	2.4	
Clergy	1	0.3	
Student	1	0.3	
Total	331	100.0	

The mean duration on HAART of the participants was 92.13 ± 54.56 months with a range of 1–324 months as shown in Figure 1.

Ocular manifestations of HIV found to be statistically significantly associated with CD4+ count level were conjunctival microvasculopathy, anterior uveitis and cytomegalovirus retinitis.

Table 3 shows the relationship between ocular manifestations and CD4+ count level.

Table 2: HIV Serotype, CD4+ cell counts and WHO clinical stages of participants

Characteristics	Frequencies	Percentage (%)
Serotype (*n* = 331)		
Type 1	248	74.9
Type 2	82	24.8
Both types 1 and 2	1	0.3
Total	331	100
CD4+ cell counts (*n* = 331)		
<100	9	2.7
100–199	27	8.2
200–299	25	7.6
300–399	40	12.1
400–499	57	17.2
≥500	173	52.3
Total	331	100
WHO clinical stages (*n* = 331)		
Stage 1	200	60.4
Stage 2	83	25.1
Stage 3	41	12.4
Stage 4	7	2.1
Total	331	100

Boxes and whiskers plot in Figure 2 shows the distribution of the various ocular manifestations of HIV in relation to the CD4+ cells. All the participants with SCC, molluscum contagiosum, anterior uveitis, keratitis, CMVR and gaze palsy had CD4+ less than 500 cells/μL while more than half of those with conjunctival microvasculopathy, HZO, keratoconjunctivitis sicca, optic atrophy and had CD4+ cell count of less than 500 cells/μL. About half of those with HIV microangiopathy and pupillary abnormality (post-uveitic posterior synechiae, relative afferent pupillary defect) had CD4+ cell count of 500 cells/μL, while CD4+ cell count was more than 500 cells/μL in more than half of those with toxoplasma retinitis and immune recovery uveitis.

The boxes and whiskers plot shown in Figure 3 represents the distribution of the classes of ocular manifestations in relation to CD4+cell count. More than half of those with adnexal, anterior segment and neuro-ophthalmic manifestations had CD4+ cell count of less than 500 cells/μL, while about 50% of those with posterior segment ocular manifestations had CD4+ cell count of less than 500 cells/μL.

Discussion

From this study, 330 (99.7%) respondents had HIV-1, with 74.9% and 24.8% with type 1 alone and both serotypes respectively. HIV-1 remains the most prevalent type in Nigeria and sub-Saharan Africa but second globally,[22] as demonstrated by this study. Also, over 80% of the respondents have CD4+ cell count >300 cells/μL with 52.3% above 500. This is most likely due to the effect of HAART, which has altered the clinical course of HIV/AID globally.[3-6]

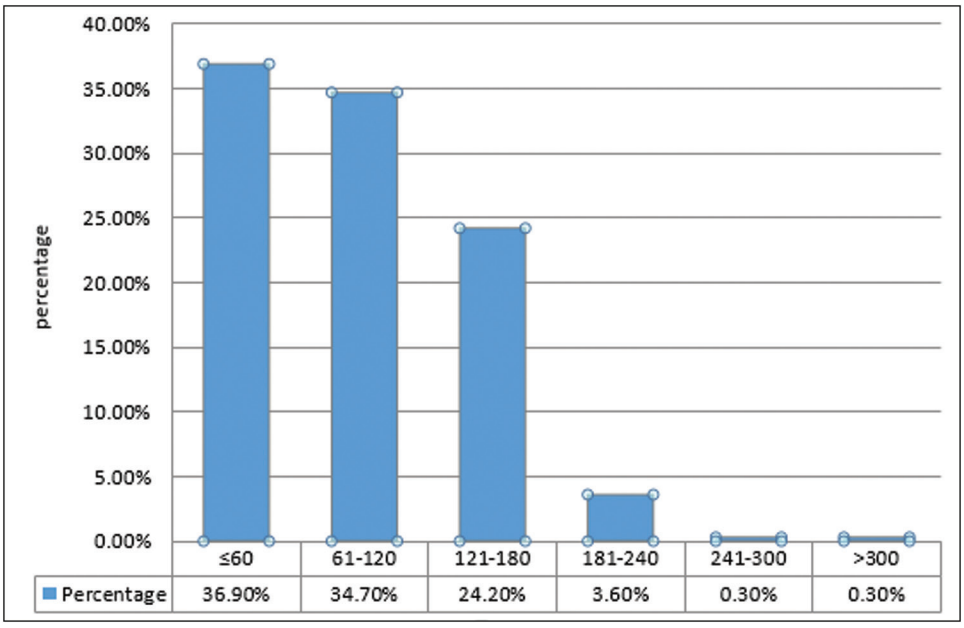

Figure 1: Duration on HAART in months among participants

Table 3: Association between CD4+ cell level and ocular manifestations of HIV among participants

HIV-related ocular manifestations	CD4+ cell count level		Chi-square/Fisher's exact	*P* value
	<300	≥300		
Adnaxal manifestations				
Conjunctival microvasculopathy	6 (60.0)	4 (40.0)	7.04	0.016*
Herpes zoster ophthalmicus	0 (0.0)	4 (100.0)	1.31	0.576
Squamous cell carcinoma	2 (66.7)	1 (33.3)	2.92	0.149
Molluscum contagiosum	1 (100.0)	0 (0.0)	3.09	0.245
Anterior segment manifestations				
Keratoconjunctivitis sicca	3 (30.0)	7 (70.0)	0.17	0.711
Anterior uveitis	6 (100.0)	0 (0.0)	18.86	0.001*
Keratitis	0 (0.0)	2 (100.0)	0.65	1.000
Posterior segment manifestations				
HIV microangiopathy	3 (23.1)	10 (76.9)	0.01	1.000
Immune recovery uveitis	0 (0.0)	6 (100.0)	1.98	0.342
Toxoplasma retinitis	1 (25.0)	3 (75.0)	0.001	1.000
Cytomegalovirus retinitis	3 (100.0)	0 (0.0)	9.34	0.014*
Neuro-ophthalmic manifestations				
Optic atrophy	0 (0.0)	3 (100.0)	0.98	0.430
Gaze palsy	0 (0.0)	2 (100.0)	0.65	1.000
Pupillary abnormality	0 (0.0)	2 (100.0)	0.65	1.000

*statistically significant

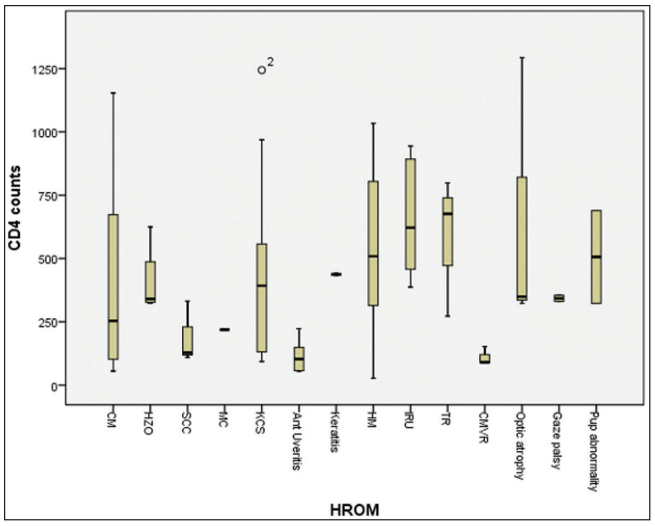

Figure 2: Boxes and whiskers plot showing the relationship between HROM and CD4+ cell among participants

Approximately 1 in 5 patients had HIV-related ocular manifestations (HROM) unlike the report in Ethiopia that had 1 in 7.[5] The mean CD4+ cell count of those with HROM (315.2 ± 290.76 cells/μL) was lower than that of the study population (575.0 ± 512.56 cells/μL) and much lower than that of those without HROM (633.7 ± 533.54). This is similar to the observation by Bekele *et al.*[11] observed that the mean CD4+ cell of those with HROM (308.74 cells/μL) was lower than that of those without HROM (386.56 cells/μL). Although Abdollahi *et al.*[23] observed the same pattern with the mean CD4+ cell count as in this study, the mean CD4+ cell of those with HROM in this study was higher than that reported in their study (204 ± 123.8 cells/μL). This may be explained by the fact that all the participants with HROM in this study were on HAART, while only 50% of those with HROM in their study were on HAART.

Evidence from this study demonstrated CD4+ and viral load as determinants of HROM [Figure 3] as seen in subsequent discussions. Most participants with adnexal manifestations in this study had CD4+ cell count of less than 500 cells/μL. All the patients with SCC and molluscum contagiosum had CD4+ cell count of less than 500 cells/μL. This is similar to the report by Bekele *et al.*[11] where 100% of the participants with SCC had CD4+ cell count of less than 500 cells/μL. Emina *et al.*[24] also reported that 100% of those with molluscum contagiosum had CD4+ cell count of 200 cells/μL to 500 cells/μL. More than half of those with conjunctival microvasculopathy and HZO in this study had CD4+ cell count of less than 500 cells/μL. Other researchers have reported that all those with HZO had CD4+ cell count of less than 500 cells/μL.[11,24]

Anterior segment manifestations were associated with CD4+ cell count of less than 500 cells/μL in more than half of those with the manifestations in this study. All those with anterior uveitis and keratitis had CD4+ cell count of less than 500 cells/μL and more than 50% of those with KCS had CD4+ cell count of less than 500 cells/μL. The study by Emina and Odjimogho[24] showed that all those with anterior uveitis had CD4+ cell count below 500 cells/μL. In another study,[11] about 76% of those with KCS had CD4+ cell count below 500 cells/μL, while 50% of those with keratitis also had CD4+ cell count below 500 cells/μL.

CD4+ cell count of less than 500 cells/μL was noted in about half of those with posterior segment ocular manifestations

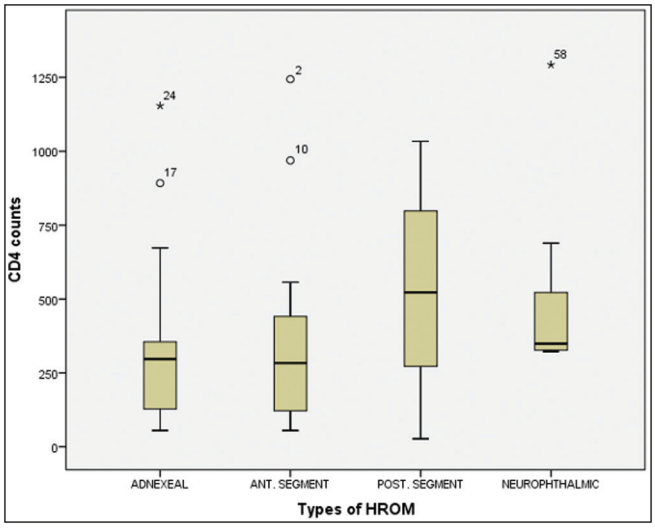

Figure 3: Boxes and whiskers plot showing the relationship between types (classes) of HROM and CD4+ cell among participants

in this study. All the participants with CMVR had CD4+ cell count of less than 100 cells/μL. CMVR has been noted to be associated with immunosuppression and even much lower CD4+ cell level has been reported by other researchers.[24] About half of those with HIV microangiopathy in this study had CD4+ cell count of 500 cells/μL and less. The report by Bekele *et al*[11] varies with this finding; all the participants with HIV microangiopathy in their study had CD4+ cell count of 200 cells/μL and less. This may be due to the fact that about half of their study participants were not on HAART. Immune recovery uveitis in this study was associated with CD4+ cell count of more than 500 cells/μL in more than half of those affected. This may be expected as IRU usually occurs following immune reconstitution.

Most of the participants with neuro-ophthalmic manifestations had CD4+ cell count below 500 cells/μL but above 250 cells/μL. Bekele *et al.*[11] noted neuro-ophthalmic manifestations to occur in those with CD4+ cell count above 200 cells/μL. All the participants with gaze palsy in this study had CD4+ cell count of less than 500 cells/μL unlike in the study by Bekele *et al.*[11] where only 60% of them had CD4+ cell count below 500 cells/μL. Optic atrophy was associated with CD4+ cell count of less than 500 cells/μL in most of those with the condition just like the report by other researchers.[11]

The design of this study did not allow for possible comparison of the clinical profile and ocular manifestations of HIV in patients on HAART and HAART naïve patients. This would have provided more interesting results and allowed for more robust discussion.

Conclusion

This study set out to determine the clinical factors associated with the ocular manifestation of HIV/AIDS among patients on HAART in the study population. A majority of respondents in WHO clinical stage I and II, and higher CD4+ cell count. It could be adduced that use of HAART improved the clinical course in HIV/AIDS. However, it would be difficult to conclude on this since no comparison was made with patients who are not on HAART. Future studies comparing the clinical profile and HROM in patients on HAART and naïve patients in our environment.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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