*IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*
*e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 19, Issue 9 Ser.2 (September. 2020), PP 13-19*
*www.iosrjournals.org*

# Ophthalmic manifestations and their correlation with CD4 count in adult HIV patients on HAART (Tenofovir, Lamivudine and Efavirenz)

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***Abstract***
***Introduction:*** *HIV virus may cause adnexal, anterior segment, posterior segment or neuro ophthalmic manifestations. Prevalence of these manifestations shows an inverse relationship with CD4 count. This study depictsthat Indian population showsophthalmic manifestations similar to western studies in relation to HAART era.*
***AIM:*** *The aim of this study is to report the ophthalmic manifestations in Human Immune deficiency Virus (HIV) patients on Highly Active Anti-Retroviral Therapy (HAART) and their association with CD4 count.*
***METHODS:*** *Hundred diagnosed,adult patients of HIV, all on HAART, were included in the study. These patients were divided in two groups on the basis of their CD4 count.* ***Group 1*** *included 50 patients with CD4 count ≥ 200 cells/µl and* ***Group 2*** *included 50 patients with CD4 count < 200 cells/ µl. All patients underwent complete ophthalmic examination.*
***RESULTS:*** *In group 1, 16 patients (32%) showed ocular lesions and in group 2, 28 patients (56%) showed ocular lesions. This difference in prevalence was statistically significant (p value=0.016). In group 1, five patients (10%) showed posterior segment lesions and in group 2, 18 patients (36%) showed posterior segment lesions. This difference was statistically significant (p value <0.05). 29 patients (47%) out of 62 patients showed ocular findings with HAART duration less than 5 yearand 15 patients (39%) out of 38 patients showed ocular findings with HAART duration more than 5 year (p value 0.09).*
***CONCLUSION:*** *As CD4 count decreases ophthalmic manifestations increases, so all patients with CD4 count below 200 cells/ µl should be screened for ocular lesions. HAART has reduced incidence of ocular opportunistic infections in HIV patients with emergence of new lesions.As the duration of HAART increases incidence of ophthalmic manifestation decreases.*
***Keywords****: Human Immune deficiency Virus (HIV), Highly Active Anti-Retroviral Therapy (HAART), Cytomegalo Virus retinitis (CMV retinitis)*

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Date of Submission: 20-08-2020 Date of Acceptance: 06-09-2020

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## I. Introduction

Human Immunodeficiency virus (HIV) belongs to genus Lentivirus within family of Retroviridae.[1,2] As per WHO total HIV burden in the world is 36.9 million[3] and according to National AIDS Control Organization (NACO) India has an estimate of 2.1 million HIV patients.[4]

As per various studies life time cumulative rate of developing any ocular lesion in HIV patients is 50-75%,[5] with post-mortem studies showing rates closer to 90%.[6] Ocular lesions can involve any part of the eye from the adnexa and anterior segment to posterior segment, including orbital and optic nerve. Amongst them anterior segment lesions aloneaff ectsmore than 50% of all HIV patients.[5]As the immunocompetency decreases, which is measured by CD4 count, severity of ophthalmic sequelae increases along with their prevalence. CD4 count is a reliable predictor of immune status of patients for the risk of various infections.[7] There has been a dramatic change in the pattern and prevalence of HIV related ophthalmic manifestation between the pre- and post-HAART (highly active anti-retro viral therapy) era. Patients on HAART shows lesser incidence of severe posterior segment lesions along with emergence of new immune reconstitution inflammatory problems. The purpose of the present study is to evaluate various ocular manifestations and their correlation with CD4 count in adult HIV patients on HAART with Tenofovir, Lamivudine and Efavirenz as first line drugs. Literature on such correlation with entire study population on HAART in Indian population is scarce. Similar study was done by Shah SU et al.[8] in 2009 but it included only patients with CD4 count less than 200 which could have

confounded the results. Another relevant study was done by Agarwal et al.[9] in 2017 comparing the ocular manifestation in HAART and pre-HAART era but for HAART era it included patients from 2009 to 2010 and duration of HAART was not accounted. Newer guidelines for prescribing HAART to all HIV patients irrespective of CD4 count were started in 2015. The present study takes into consideration of these limitation and aims at depictingany change in the pattern since then, supporting the novelty of the study.

## II. Material and methods

This cross sectional,comparative study was conducted at a tertiary care hospital of western Maharashtra betweenOct 2018 to December 2019. This study included 100 diagnosed cases of HIV, attending ART centre of the hospital. All patients were on HAART with Tenofovir, Lamivudine and Efavirenz as their primary first line drugs. Patients were randomly divided in twogroups on the basis of CD4 count. **Group 1** included patients with CD4 count more than 200 cells/µl and **Group 2** included patients with CD4 count less than 200 cells/ µl.Informed written consent was taken from all the patients.

**Inclusion criteria**

1. Diagnosed cases of HIV on HAART with Tenofovir, Lamivudine and Efavirenz as first line drugs
2. Age > 18 years

**Exclusion criteria**

1. Any preexisting ocular morbidity before the diagnosis of HIV
2. Patients who refused to give consent
3. Age < 18 years

**Study parameters**

A complete history including patient's demographic characteristics includingage and gender, duration of disease, duration since commencement of HAART, last CD4 count (as per endorsed in documents) were documented. All patients underwent thorough ophthalmic examination and the following parameters of each patient were studied. BCVA, IOP, Anterior segment examination using slit lamp biomicroscopy, Schirmer test, general fundus examination using Direct ophthalmoscope, Indirect Ophthalmoscope, +90D examination etc, visual fields were done using Humphrey visual field analyser (30-2). OCT and FFA were done only if required.

**Statistical analysis**

The statistical analysis was performed on SPSS statistical software version 25;0. Chi-square test/ Fischer's exact were used to find the association between ocular manifestations with various variables. P-value less than 0.05 was considered statistically significant.

## III. Results

This cross- sectional observational study included 100 diagnosed HIV patients on HAART. These 100 patients were then divided into two groups on the basis of CD4 count. **Group 1** included 50 patients with CD4 count less than 200 cells/µl and **Group 2** included 50 patients with CD4 count equal or more than 200 cells/ µl.

Amongst total 100 HIV patients 63 (55%) were males and 37 (45%) were females. Their age group varied from 21 years to 70 years. In group 1 mean age was 47.14 years, there were 30 (60%) males and 20 (40%) females.In group 2 mean age was 41.68 years, there were 33 (66%) males and 17 (34%) females.

Duration of HIV infection in study population varied from 11 months to 120 months. Mean duration of HIV infection in 100 patients was 54.99 months. Mean duration of HIV infection in group 1 was 50.84 months and mean duration of HIV infection in group 2 was 59.80 months.

Out of total 100 patients, ocular lesions were seen in 44 patients (44%). In group 1, 28 patients (56%) showed ocular lesions and in group 2, 16 patients (32%) showed ocular lesions. Total 33 patients were symptomatic, in group 1, 21(42%) patients were symptomatic and in group 2, 12 (24%) patients were symptomatic.Many asymptomatic patients also showed ocular lesion hence number of patients with ocular lesions is more than number symptomatic patients.

**Table no. 1**: Distribution of Ocular lesions (p-value is 0.016 (< 0.05) **significant**; Chi-square test used) in the study population in two groups.

| **Ocular lesions** | CD4 (cells/µl) | | Total | p-value |
|---|---|---|---|---|
| | < 200 (group1) | ≥ 200 (group2) | | |
| Present | 28 | 16 | 44 | **0.016** |
| Absent | 22 | 34 | 56 | |
| Total | 50 | 50 | 100 | |

**Table no. 2**: Distribution of ocular symptoms (p-value is 0.056 (> 0.05) not Significant; Chi-square test used) in the study population in two groups.

| **Ocular Symptoms** | CD4 (cells/µl) | | Total | p-value |
|---|---|---|---|---|
| | < 200 (group1) | ≥ 200 (group2) | | |
| Present | 21 | 12 | 33 | 0.056 |
| Absent | 29 | 38 | 67 | |
| Total | 50 | 50 | 100 | |

**Anterior segment and adnexal lesions**- Dry eye was most common anterior segment finding in both the groups, with 8 patients (16%) in group 1 and 6 patients (12%) in group 2.

**Table no.3**: Distribution of anterior segment and adnexal lesions in the study population in two groups. P-value > 0.05 (not significant); Chi-square test used.

| **Anterior segment and adnexal lesions** | CD4 count(cells/µl) | | p-value |
|---|---|---|---|
| | < 200 (n=50) | ≥ 200 (n=50) | |
| Dry eye | 8(16%) | 6(12%) | 0.564 |
| Conjunctival Vasculopathy/ Ciliary congestion | 6(12%) | 6(12%) | 0.999 |
| Acute Uveitis / Drug induced uveitis | 4(8%) | 2(4%) | 0.999 |
| Cataract | 3(6%) | 1(2%) | 0.617 |
| Herpes Zoster Ophthalmicus | 2(4%) | 1(2%) | 0.617 |
| Keratitis | 1(2%) | 2(4%) | 0.999 |
| molluscum contagiosum | 2(4%) | 0 | 0.495 |
| immune recovery uveitis | 1(2%) | 1(2%) | 0.999 |
| Blepharitis | 0 | 1(2%) | 0.999 |
| Chalazion | 0 | 1(2%) | 0.999 |
| Squamous cell ca | 1(2%) | 0 | 0.999 |
| Kaposi | 1(2%) | 0 | 0.999 |
| corneal opacity | 0 | 1(2%) | 0.999 |

**Posterior segment lesions**–HIV vasculopathy was seen in 30 patients (30%) out of total 100 patients. CMV retinitis was seen as the most common opportunistic infection with 04 affected patients (8%) in group 1.

**Table no.4**: Distribution of posterior segment lesions in the study population in two groups. ***Significant (p-value < 0.05)** Chi-square test used.

| **Posterior segment lesions** | CD4 count(cells/µl) | | P-value |
|---|---|---|---|
| | < 200 (n=50) | ≥ 200(n=50) | |
| HIV Vasculopathy / Cotton wool spots | 11(22%) | 4(8%) | **0.049*** |
| CMV retinitis | 4(8%) | 0 | **0.041*** |
| Acute Retinal Necrosis (ARN)/Progressive outer retinal necrosis (PORN/viral retinitis) | 2(4%) | 1(2%) | 0.558 |
| Toxoplasmosis | 2(4%) | 0 | 0.153 |
| Tuberculoma | 0 | 0 | - |

**Neuro-ophthalmic manifestations**- Out of total 100 patients, neuro-ophthalmic manifestations were seen in 7 patients (14%). It includes Visual field defect, abnormal ocular movement and disc pathologies.

**Table no.5**: Distribution of Neuro-ophthalmic lesions in the study population in two groups. P-values are > 0.05 (not significant); Fisher's exact test used.

| **Neuro-ophthalmic lesions** | CD4 count(cells/µl) | | P-value |
|---|---|---|---|
| | < 200 (n=50) | ≥ 200 (n=50) | |
| Visual field defect | 2 (4%) | 0 | 0.495 |
| Abnormal ocular movement | 1 (2%) | 2(4%) | 0.999 |
| Disc oedema | 1(2%) | 1(2%) | 0.999 |

**Association of CD4 count with ocular manifestations**

As CD4 count decrease,prevalence of ophthalmic manifestations increases. All patients with CD4 count < 50 cells/µlshowed ocular lesions. Both anterior and posterior segment lesions showed strong correlation with CD4 count.

**Table no.6**: Association of ocular manifestation with CD4 count in the study population. P value > 0.05 (not significant); Chi square test used.

| **CD4 Count (cells/µl)** | Ocular Manifestation | | Total | p-value |
|---|---|---|---|---|
| | Present | Absent | | |
| < 50 | 2 (100%) | 0 | 2 | 0.027 |
| 50 – 199 | 26 (54%) | 22 | 48 | |
| 200 – 500 | 3 (18%) | 13 | 16 | |
| > 500 | 13(38%) | 21 | 34 | |
| Total | 44 | 56 | 100 | |

**Table no.7** – Association of anterior and posterior segment manifestation with CD4 count in the study population.

| **Anterior Segment and adnexal Manifestations** | CD4 count (cells/µl) | | | Total (n) |
|---|---|---|---|---|
| | < 100 | 100 – 199 | ≥ 200 | |
| Dry eye | 3(21%) | 5(36%) | 6(43%) | 14 |
| Conjunctival Vasculopathy/ Ciliary congestion | 1(8%) | 5(42%) | 6(50%) | 12 |
| Acute Uveitis / Drug induced uveitis | 2(33%) | 2(33% | 2(33% | 6 |
| Cataract | 0 | 3(75%) | 1(25%) | 4 |
| Herpes Zoster Ophthalmicus | 0 | 2(67%) | 1(33%) | 3 |
| Keratitis | 0 | 1(33%) | 2(67%) | 3 |
| molluscum contagiosum | 0 | 2(100%) | 0 | 2 |
| immune recovery uveitis | 1(50%) | 0 | 1(50%) | 2 |
| Blepharitis | 0 | 0 | 1(100%) | 1 |
| Chalazion | 0 | 0 | 1(100%) | 1 |
| Squamous cell ca | 0 | 1(100%) | 0 | 1 |
| Kaposi | 0 | 1(100%) | 0 | 1 |
| corneal opacity | 0 | 0 | 1(100%) | 1 |
| **Posterior Segment Manifestations** | CD4 count (cells/µl) | | | Total (n) |
| | < 100 | 100 – 199 | ≥ 200 | |
| HIV Vasculopathy / Cotton wool spots | 0 | 11(73%) | 4(27%) | 15 |
| CMV retinitis | 4(100%) | 0 | 0 | 4 |
| Acute Retinal Necrosis (ARN)/Progressive outer retinal necrosis (PORN/viral retinitis) | 0 | 2(67%) | 1(33%) | 3 |
| Toxoplasmosis | 0 | 2(100%) | 0 | 2 |
| Tuberculoma | 0 | 0 | 0 | 0 |

**Duration of HAART-**

Duration of HAART varied from 11 months to 96 months. Mean duration of HAART in 100 patients was 51.55 months. Mean duration of HAART in group 1 was 45.51 months and mean duration of HAART in group 2 was 58.36 months. As duration of HAART increases incidence of ophthalmic manifestation decreases.

**Table no.8**: Mean duration of HAART of study population in two groups. P-value is 0.008 (< 0.05) significant; Mann-Whitney U test used.

| Group | **Duration of HAART** (months) | |
|---|---|---|
| | Mean | SD |
| CD4 < 200cells/µl (Group 1) | 57.84 | 26.84 |
| CD4 ≥ 200cells/µl (Group 2) | 44.74 | 27.76 |

**Association of HAART duration with ocular manifestations**

**Table no.9**: Association of ocular manifestation with HAART duration in the study population. P-value > 0.05 (not significant) Chi-square test used.

| **HAART Duration** | Overall Ocular Manifestations | | Total | p-value |
|---|---|---|---|---|
| | Present | Absent | | |
| ≤ 5 years | 30 | 33 | 63 | 0.341 |
| > 5 years | 14 | 23 | 37 | |
| Total | 44 | 56 | 100 | |

## IV. Discussion

In this study,ocular manifestations in 100 HIV patients attending an ART center of a tertiary care hospital, all being on HAART, were studied with main emphasis on comparison of proportion of these manifestation in two pre- formed groups on the basis of CD4 count.

No significant difference between two groups was seen in respect of age, gender and duration of HIV infection.

**Prevalence of Ocular lesions**

Out of total 100 patients, ocular lesions were seen in 44 patients (44%). Prevalence of ocular manifestation varies from 73% as per Douglas A et al.[10] to 100% as per Shah et al.[8] Decreased prevalence in our study may be attributed to the fact that all patients were on HAART. In group 1, 28 patients (56%) showed ocular lesions and in group 2, 16 patients (32%) showed ocular lesions. Difference of prevalence in two group is **statistically significant** and support a strong inverse relationship of ophthalmic lesions with CD4 count.[11]Total 33 patients (66%) were symptomatic, out if which, group 1 had 21 (42%) symptomatic patients and group 2 had 12 (24%) symptomatic patients. Many asymptomatic patients also showed ocular lesion hence number of patients with ocular lesions is more than number symptomatic patients.

**Anterior segment and adnexal manifestations**

In our study there was no statistically significant difference in anterior segment and adnexal lesions among the two groups. Most common lesion seen in both groups was dry eye, with 08 patients (16%) in group 1 and 06 patients (12%) in group 2, which is similar to findings of the study by Sisay Bekele et al.[12]Singalavanija et al.[13]Conjunctival vasculopathy/ ciliary congestion was seen in 6 patients (12%) in both the groups. Patients with acute uveitis and keratitisshowed ciliary congestion as part of inflammation. 04 patients (08%) showed acute uveitis in group 1 and 2 patients (04%) showed acute uveitisin group 2. One patient amongst uveitis patients had drug induced uveitis due to Nevirapine. Although all patients were started on Tenofovir, Lamivudine and Efavirenz but this patient was not responding properly, so was changed to Nevirapine.Two patients (04%) ofherpes zoster ophthalmicus was seen in group 1 and one patient (02%) herpes zoster ophthalmicus were seen in group 2 respectively. Keratitis was seen in one patient (02%) in group 1 and two patients (04%) in group 2. Molluscum contagiosum was seen in two patients (4%)in group 1 with no patient in group 2. One patient (2%) of immune recovery uveitis was seen in each group.One patient (2%) of blepharitis and one patient (2%) of chalazion were seen in group 2 with zero case of each in group 1. One patient (2%) of Kaposi sarcoma and one patient (2%) of squamous cell carcinomawere seen in group 1 with zero patient of each in group 2.One case (1%) of corneal opacity was seen in group 2. Four patient showed cataract as incidental finding and has no relation with HIV infection per se.

**Posterior segment manifestations**

Posterior segment lesions were seen in total24 patients (48%). In group 1, 18 patients (36%) showed posterior segment lesions and in group 2, 05 patients (10%)showed posterior segment lesions. The difference in prevalence of posterior segment lesions in two group was **statistically significant**. Most common posterior segment lesion in our study was HIV vasculopathy and cotton wool spots with 11 patients (22%) in group 1 and 4 patients (08%) in group 2. As per a study of India done by Ram Sharma et al[14]prevalence of HIV vasculopathy was 50%, lower prevalence in our study may be attributed to HAART. All opportunistic infection in HIV like Cytomegalovirus, Varicella zoster virus, Herpes simplex virus, Toxoplasma Gondi, Pneumocystis

carinii, Mycobacterium tuberculosis and Histoplasmosis shows specific posterior segment involvement.[15]Most common opportunistic infection seen in our study was CMV retinitis, with four patients (8%) in group 1 and zero patient in group 2, which was similar to frequency of CMV retinitis seen in study by Ram Sharma et al[14] and Pathai et al. [16] All cases of CMV retinitis were confirmed with PCR. Incidence of CMV retinitis has decreased after the invent of HAART. However, after the commencement of HAART, a relapse of CMV retinitis as vitritis has been reported. Group 1 showed two patients (04%) of ARN and viral chorioretinitis and group 2 showed one patient (2%) of ARN. Diagnosis was made on the basis of clinical presentation. Two patients(4%) of ocular toxoplasmosis, another opportunistic infection, were seen in group 1, which correlates with its frequency of 4.1%found in study by Sudharshan et al. [17] All cases of toxoplasmosis were confirmed by serology.None of our patient showed tuberculoma although 04 Patient of systemic Tuberculosis were reported.

**Neuro-ophthalmic manifestations**

Out of 100 patients, neuro-ophthalmic manifestations were seen in 07 patients (14%) in our study with no significant difference of prevalence in two groups. Study by Aseefa et al.[18]and Sudharshan et al.[17] showed statistically similar frequency of 9.6% and 8.9% respectively. In group 1, visual defects were seen in two patients (04%) with zero patient in group 2. Each group showed one patient (2%) of disc oedema. Group 1 showed one patient (02%) with abnormal ocular movements and group 2 showed two patients (04%) of abnormal ocular movements.

**Association of CD4 count and Ophthalmic manifestations**

As CD4 count decreases ocular lesions increases.[10]All patients with CD4 count < 50 cells/µlshowed ocular lesions. In patients with CD4 count 50 to 199 cells/µl, 26 patients (54%) out of 48 patients showed ocular lesion. In patients with CD4 count 200 to 500 cells/µl, 6 patients (18%) out of 16 patients showed ocular lesions. In patients with CD4 count more than 500 cells/µl, 13 patients (38%) out of 34 patients showed ocular lesions. Anterior segment and adnexal lesions did not show any correlation with CD4 count. Posterior segment lesions were more commonly seen in HIV patients with CD4 count <200cells/µl, as opportunistic infections increase when CD4 counts is below 200 cells/µl. All patients with CMV retinitis had CD4 count < 100 cells/µl. Toxoplasma chorioretinitis was seen in 02 patients, both of them had CD4 count <200 cells/µl. HIV vasculopathy also showed higher prevalence in group 2 with CD4 count <200 cells/µl. Neuro-ophthalmic lesions were almost same in both groups and shoed no specific correlation with CD4 count. This study clearly showed CD4 count can be used as a prognosticator for ocular examination.

**Association between duration of HAART therapy and Ophthalmic manifestations**

HAART causes rise in CD4 count by reducing HIV RNA to low level, which in turn boosts the immunity and decreases the incidence of opportunistic infections. [19] In the pre-HAART era, the most common HIV associated ocular manifestation was CMV retinitis, occurring in 80% of patients. Whereas in HAART era, the incidence of CMV retinitis declined to less than 40%,[20] with appearance of new variants of classic clinical lesions. Our study supports this finding even in Indian population which was not depicted in the study by Agarwal et al.[9]Clinically HAART- related immune recovery is a boon for the patient but some 10- 25% patient experiences immune reconstitution inflammatory problems, which are different frompre-HAART era. Immune reconstitution inflammatory syndrome (IRIS) refers to acute immune mediated inflammatory response to antigens in response to raised CD4 count post treatment with HAART.[21,22]In this study30 patients (48%) out of 63 patients showed ocular findings with HAART duration less than 5 yearand 14 patients (38%) out of 37 patients showed ocular findings with HAART duration more than 5 year.Though not statistically significant this study supports that patients with longer duration of HAART has lesser ocular manifestation as compared to lesser duration of HAART.This is in support witha recent study done byAnteneh Amsalu et al.[23]

## V. Conclusion

The ophthalmic manifestations in HIV patients involvesanterior segment with adnexa, posterior segment and neuro-ophthalmic lesions. A vigilant ophthalmic evaluation can help in diagnosing HIV, as on many instances ocular manifestations are the primary reason for seeking medical consultation.

As CD4 count decreases, immunity of HIV patients decreases making them more susceptible to opportunistic infections. These opportunistic infections are most common cause of severe ocular morbidity and frequently involves posterior segment. It is recommended that guidelines for screening of ophthalmic lesions in HIV patient should be more evolved as many asymptomatic patients also shows ocular lesions. If these ocular manifestations are diagnosed at early stage and treated promptly there will be a substantialreduction in visual loss due to HIV. This study has shown that CD4 count can be used as a strong predictor as well indicator for ophthalmic evaluation. All patients with CD4 count < 200 cells/µl should be screened and followed up more intensely as prevalence of ophthalmic manifestations surges once the CD4 count is below 200cells/µl. This early

screening is of enormoussignificance in developing countries where burden of ocular morbidity is extensive and effective treatment is deficient.

This study has clearly documented how HAART use has changed the pattern of posterior segment lesions in HIV patients as compared topre-HAART era even in India which was not shown in earlier studies.Considering the evolving patterns of ophthalmic manifestations due to HAART,well-acquainted ophthalmologists are required for early diagnosis and treatment even in non-classical lesions of HIV.

**Limitations-** Limited sample size and non-inclusion of viral load are major drawbacks.

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Anju Pannu, et. al. "Ophthalmic manifestations and their correlation with CD4 count in adult HIV patients on HAART (Tenofovir, Lamivudine and Efavirenz)." *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, 19(9), 2020, pp. 13-19.