# Effectiveness of Antiretroviral Therapy In HIV Positive Patients by Monitoring CD4+ T Lymphocytes Count

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Abstract: India stands third with respect to Human Immunodeficiency Virus (HIV) epidemic in the world. About 2.1 million people are estimated to be living with HIV in India. The natural history of infection with the human immunodeficiency virus is characterized by a progressive decline of T helper lymphocytes, cluster of differentiation 4 i. e., CD4+ lymphocytes. Measurement of CD4+ lymphocytes is essential for assessing disease course, clinical staging epidemiological studies, and decisions regarding prophylactic therapies against opportunistic infections. Antiretroviral therapy (ART) has drastically improved the survival of patients who suffer from HIV/AIDS. ART's primary goals are maximal and durable suppression of viral replication, restoration of immunologic function, reduction of HIV - related morbidity and mortality, improvement of quality of life, and prolonging survival.

Keywords: HIV, AIDS, CD4+Lymphocytes, Antiretroviral Therapy, Mortality

#### 1. Introduction

AIDS was initially identified in 1981, clustering among male homosexuals, intravenous drug users, and hemophiliacs in the United States and among sexually active heterosexuals in various nations of equatorial Africa<sup>[1]</sup>. HIV infection has reached pandemic levels in several nations all over the world since the first instance of an HIV - infected high - risk male individual was identified in 1981. In 2003, more than five million people contracted HIV, raising the total number of people living with the virus to almost 42 million<sup>[2]</sup>, according to a World Health Organisation (WHO) report.

The majority of those affected reside in Sub - Saharan Africa and Asia <sup>[3]</sup>. Without treatment, 3 million people are predicted to pass away from HIV/AIDS each year. The problem is expected to worsen over the next ten years, with estimates putting the number of infected individuals at 100 million worldwide <sup>[4]</sup>. This condition symbolizes a terrible human catastrophe and significantly negatively influences the social, economic, and health systems of nations with a high HIV prevalence <sup>[5]</sup>. The lowering of viral load by effective antiretroviral therapy has been regarded as a powerful instrument among all intervention options used to stop the HIV pandemic. National AIDS Control Organisation (NACO) has started introducing affordable and generic antiretroviral medication (ART) in India.

Affordable laboratory monitoring is necessary for a successful treatment that is cheap. To monitor HIV - infected patients' disease progression and evaluate the effectiveness of antiretroviral therapy, it is crucial to count CD4+ T - lymphocytes in peripheral blood. T helper cells (CD4+ T - cells), also known as CD4+ T lymphocytes, are coordinators of the body's immunological response <sup>[6]</sup>. HIV's main target population is these CD4+ T - cells. The host's immune system is weakened as a result of the loss of these cells in HIV infection, both qualitatively and quantitatively,

which impairs the host's ability to respond to foreign antigens, making them more vulnerable to infections and ultimately resulting in AIDS.

To evaluate immunological suppression and disease progression in HIV - infected individuals, the CD4+ T - cell counts are often checked <sup>[7]</sup>. HIV treatment has significantly advanced over the last 20 years because of ART. The prior ten years <sup>[8]</sup>have seen a dearth of antiretroviral medications. When antiviral medications were first used, they were given as monotherapy; however, later on, the idea of combination therapy, which involves giving at least three medications together, was adopted. The highly active antiretroviral therapy (HAART) that was used as part of this treatment program has the potential to lower HIV - related mortality and morbidity <sup>[9]</sup>. By suppressing viral replication and lowering the viral burden below the threshold of detection, this medication significantly contributes to the remodeling of the immune system and lengthens patient lives, but it is unable to completely eradicate HIV - 1 infection<sup>[10]</sup>. Over 30 antiretroviral drugs have received licenses for the treatment of HIV infection. Drug classes with FBA approval include protease inhibitors (PIs), entry inhibitors, and integrase inhibitors <sup>[11]</sup>, as well as nucleoside reverse transcriptase inhibitors (NRTIS) and non - nucleoside reverse transcriptase inhibitors (NNRTIS). Current HIV treatment guidelines advise ART for all patients, regardless of CD4 cell count, to help delay the disease's progression to AIDS [12].

One of the major challenges that patients and physicians face with ART is the incidence of adverse drug reactions (ADR)<sup>[13]</sup>. CD4 count is a laboratory test that measures CD4 T Lymphocytes via flow cytometry. CD4 count is a reliable indicator of a patient's immunologic status and is used to determine the necessity for the commencement of prophylactic treatment against opportunistic infection<sup>[14]</sup>.

#### 2. Materials and Methods

Type of Study: Hospital - based, Retrospective study

**Sample size:** 60samples data were examined retrospectively.

#### Method of collection of data

- 1) Inclusion criteria:
  - HIV positive patients above 15 years of age.
  - CD4 lymphocyte count below 500.
- 2) Exclusion criteria:
  - Pregnant Women and children (under 15).
  - CD4 lymphocyte count above 500.

#### Materials required

- Capillary/Venous blood
- Sterile needle and syringe
- Tourniquet
- Potassium EDTA vacutainer tubes
- Lancet (If finger prick blood collection is used)
- ALEREPIMA<sup>TM</sup> CD4 Analyser

#### Methodology

After the collection of the venous sample,  $25\mu L$  of blood was immediately added to the Pima CD4 cartridge. In the

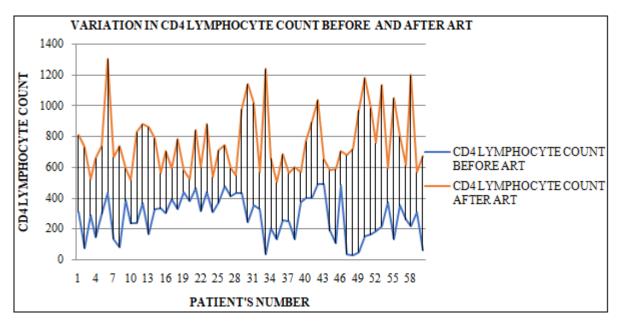
case of the finger prick sample, the sample was directly collected on the cartridge. The cartridge was capped and inserted immediately into the Pima Analyzer. The Pima analyzer works on the volumetric principle. Hence every time  $5\mu$ L of blood was drawn into the detection channel of the Pima cartridge from the blood added into the receptacle.

During the incubation, freeze - dried fluorescently labeled antibodies (anti - Cd3 and anti - CD4) get mixed with the blood, and the images of the CD3+ and CD4+ cells are captured by the camera and the results are then expressed as cells/ $\mu$ L within 20minutes.

# 3. Observation and Result

Retrospective data collection from a hospital was done on 60 HIV - positive patients. Patients' ages ranged from 22 to 85 years, with a mean age of 42, and 53% of them were male. According to the current study, the CD4 T cell count significantly rises after receiving antiretroviral medication for six months.

The graph shows how much variation there was six months after starting treatment, and it depends on a variety of circumstances.



# 4. Discussion

At the Government Hospital in Kannur over the course of a month, a total of 60 samples were retrospectively examined as part of our study.

Our data lend credence to the idea that HAART improves immunological recovery, which was partially reflected in a rise in absolute CD4 T lymphocyte count.

Participants in this trial were started on a HAART regimen that included lamivudine, efavirenz, and either tenofovir or zidovudine. Compared to the baseline CD4 T lymphocyte count before starting HAART, participants' overall CD4 T lymphocyte counts significantly increased after 6 months of treatment.

This study's findings support the findings of numerous earlier research that indicated HAART speeds up immunological recovery.

The findings are significant since they are in line with a recent WHO recommendation that increased the CD4 cell threshold for starting ART from 350 to 500 cells/mm3. This will boost the number of HIV - positive people who are qualified to receive ART. For the study to be completed, there were a number of restrictions. The minimal number of HIV - infected people with complete data available for retrospective analysis was a significant constraint. The lack

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of information on clinical patient presentations, distribution of CD4 counts, the percentage of patients needing therapy annually, HIV risk factors, place of residence, family income, and marital status are only a few more restrictions. Additionally, children and pregnant women were not evaluated in our study. These organizations offer distinct recommendations for starting ART that does not rely on CD4 numbers.

According to the Kaplan study <sup>[15]</sup>, there was a significantly higher risk of mortality and AIDS in the 350–500 cells/mm3 group compared to the 500 cells/mm3 referent group; in fact, the risk of a bad outcome was three times higher in those starting therapy at 350–500 cells/mm3 compared to starting therapy at more than 500 cells/mm3. This backs with the conclusions of Garcia et al <sup>[16]</sup>, VanGriensven and Thai <sup>[17]</sup>, and Van Lelyveld et al <sup>[18]</sup> that starting medication at a higher CD4 level will lower the chance of a bad outcome. In order to avoid death and morbidity from AIDS progression, the medication should be started as soon as the CD4 counts are at or above 500 cells/mm3, rather than waiting for the CD4 counts to drop to lower numbers or the previously recommended criteria (350 cells/mm3).

Similarly, to this, M. A. Brockman et al. and S. M. Keating et al. have conducted two separate studies and found that antiretroviral medication is related to an improvement in patients' immune health.

# 5. Conclusion

The study we conducted focused on measuring the CD4 cell count to determine how effective antiretroviral therapy was in HIV patients. Therefore, we came to the conclusion that CD4 lymphocyte count had been a reliable marker to assess the efficacy of antiretroviral therapy and a common laboratory indicator of immunological recovery and disease progression in HIV - infected patients. We were able to accurately determine the HIV disease stage by measuring CD4 lymphocytes on the basis of the study. It was also clear that starting treatment when the CD4 lymphocyte count was below 500 cells/mm3 would reduce the probability of a negative outcome

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