

Study to Evaluate the Impact of Haart on Cd4 Cell Count in S.V.R.R.G.G.H, Tirupati.

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Abstract

Introduction

HIV/AIDS is a global pandemic, with cases reported from virtually every country. Human immunodeficiency virus, the cause of AIDS, continues to spread being described as a global health emergency by WHO. Recent reductions in global HIV incidence likely reflect natural trends in the pandemic as well as the result of prevention programmes resulting in behaviour change. A rapid expansion of access to antiretroviral therapy likely has helped lower AIDS related death rates in recent years.

Objective: To monitor the laboratory and clinical markers of disease progression and to analyse the impact of HAART on CD4 cell count

Methods: The data for the study was collected from the patients who attended the ART centre at S.V.R.R.G.G.H, Tirupati, from January 2015 to December 2015, who are HIV positive as confirmed by NACO guidelines with CD4 count <350/ μ L. A total of 100 patients are included in the study.

Results: Total of 100 patient's initial CD4 count and CD4 count after 6 months of HAART were obtained and statistically analysed by using paired t- test. From this T value was calculated which is 3.6697. S (standard deviation) is 2.764. Degree of freedom is 6. 'P' value is 0.0105, which is statistically significant.

Conclusion: CD4 count is an effective laboratory tool to monitor disease progression in HIV infected persons and analysing the impact of HAART on CD4 count during the 6 months period.

I. Introduction

Human Immunodeficiency Virus, the cause of AIDS, continues to spread, being described as a global health emergency by the world health organization. HIV type¹ is the etiologic agent of most cases of AIDS². The epidemic of HIV-1 infection continues to expand globally, with more than 40 million humans currently infected by the virus³ HIV disease has claimed more than 20 million lives worldwide⁴. The recent estimate done by National AIDS Control organization reports 5.1 million HIV infected people in India. India has the second highest HIV / AIDS burden in the world next to South Africa⁵. It is a disease that is acquired, for which no permanent cure has been found till date, and consequently has a great impact on the quality of life of a patient. HIV/AIDS infection results in a wide range of clinical consequences from asymptomatic carriage to life threatening opportunistic diseases. In persons infected with HIV, ongoing viral replication produces a sequential decline in and ablation of cell mediated immunity, giving rise to diverse manifestations of opportunistic diseases. The acquired immune deficiency syndrome is the most advanced stage of this illness, in which the infected host can no longer control opportunistic organisms or malignancies that rarely cause illness in immune competent individuals. The interactions between the human immunodeficiency virus and the human immune system are, extraordinarily complex, as evidenced by the highly variable rates of disease progression observed in HIV infected individuals⁶.

HIV subverts the immune system by infecting CD4+ T cells that normally orchestrate immune responses and by activating the immune system and inducing a cytokine milieu that the virus uses to its own replicative advantage. The discovery that certain chemokine receptors function as HIV Co-receptors of HIV entry into target cells has expanded the scope of host factors that play a role in the pathogenesis of HIV-induced disease. The lack of recognizable correlates of protective immunity in HIV infection continues to hamper vaccine development and immunotherapeutic approaches. It remains unclear why the vast majority of HIV infected patients experience inexorable immunodeficiency and disease progression despite the presence of these robust antiviral immune responses. The progress that has been made to date in understanding the pathogenesis of HIV infection is unparalleled. The recent availability of effective combination anti retroviral therapy has had

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extraordinary clinical benefits for patients and has also provided important insights into the immunologic and virologic factors associated with control of HIV infection and disease progression. It is clear that HIV induces dysfunction of nearly all elements of the immune system and that the pathogenesis of HIV disease is multifactorial, causing CD4+ T cell depletion and dysfunction. The prevalence and morbidity due to opportunistic infections can be controlled by improving the general condition and immune status of the individual. In this study the impact of antiretroviral therapy on CD4+ cell count is evaluated in patients suffering from HIV / AIDS at S.V.R.R.G.G.H. Tirupati.

Patients And Methods

This study is conducted on the patients who attended the ART center at Sri Venkateswara Ram Narain Ruia Government General Hospital (S.V.R.R.G.G.H) Tirupati between the period January 2015 to December 2015. A total of 100 patients are included in the study.

Inclusion Criteria

1. All the patients with confirmed adult HIV /AIDS and with CD4 counts <350/microliter (according to WHO guidelines 2010).
2. Patients irrespective of the CD4 count in clinical stage III&IV.
3. Patients above the age of 12 yrs.

Exclusion Criteria

1. All the patients with confirmed adult HIV /AIDS and with CD4 counts >350/microliter.
2. Patients who lost for follow up.
3. Patients below the age of 12 yrs.

A chart was prepared with details pre and posts therapy CD4 counts, opportunistic infections at the time of presentation, type of HAART therapy and the pre and post therapy body weight.

Confirmation Of Hiv/Aids

All patients who attended the ART center at SVRRGGH between January 2015 and December 2015 were screened for HIV, and the HIV positive status was confirmed according to NACO guidelines. The blood sample collected at one time is tested with the first kit (coomb-AIDS). If it is reactive, it is then retested sequentially with the second (ASPEN) and third kits. (SIGNAL HIV).

Cd4 Count Assay

Blood was collected in heparinised bottles for flow cytometry analysis. The heparinised blood of about 100 pl of whole blood is stained and analysed for CD4 by FACS Count Cytometry using LASER. CD4 count was repeated after 6 months.

Investigations Considered

1. Measurement of weight/BMI
2. HB%, TC, DC, ESR
3. Blood urea
4. Serum creatinine
5. Urine analysis
6. Chest X ray
7. Other relevant investigation wherever necessary
8. Liver function tests

After obtaining the consent from the patient he/she was included in the study.

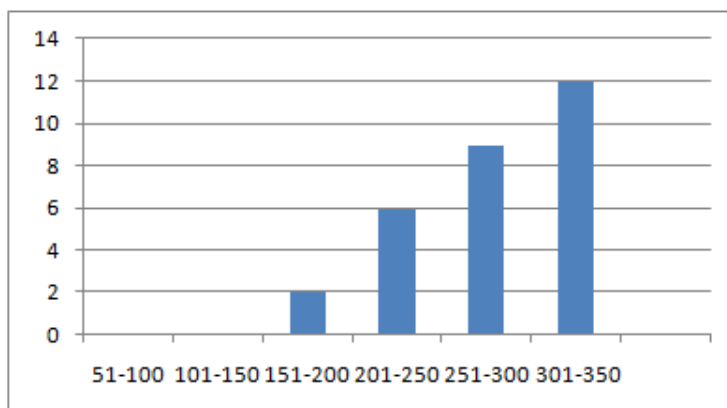
Results

Total numbers of 100 patients were analysed. Both the initial CD4 count and CD4 count after 6 months of highly active antiretroviral therapy were obtained as follows

Cd4 Count Analysis (Pre Art)

CD4 Count	No. of Patients
<50	15
51-100	19
101-150	17
151-200	12

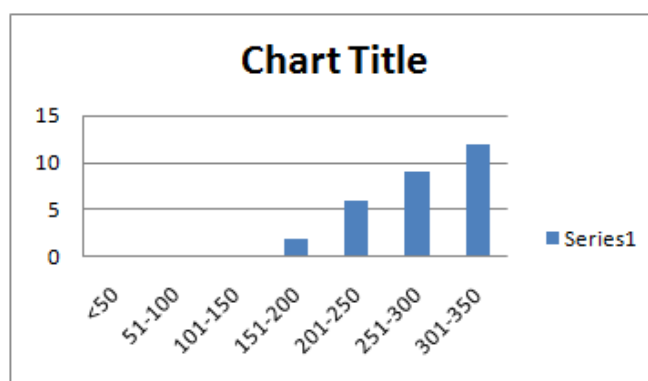
201-250	13
251-300	13
301-350	12



Among the 100 patients, the maximum no. of patients who were started on HAART had a CD4 count between 51-100 (19%) followed by 17 patients in having CD4 count between 101-150 (17%) followed by 15 patients having CD4 count between less than 50 (15%). 13 patients had CD4 count between 201-250, 12 patients had CD4 count between 151-200, and 11 patients having CD4 count between 301-350.

Cd4 Count Analysis (Post Art)

CD4 Count	No. of Patients
<50	0
51-100	0
101-150	0
151-200	2
201-250	6
251-300	9
301-350	12



Results

The above results were statistically analysed by using paired T-test. Confidence interval of 95% was taken. From this T value calculated which is 3.6697. Degree of freedom is 6. 'S' (Standard Deviation) is 2.764. 'P' value is 0.0105 which is statistically significant.

II. Discussion

HIV /AIDS is a global pandemic where once infected the person remains infected for life time . The clinical scenario ranges from an asymptomatic carrier to fulminant opportunistic infection resulting in AIDS.HIV targets the host's immune system mainly the CD4 cells resulting in the qualitative and quantitative sequential decline and ablation of the cell mediated immunity . Because of the decreased cell mediated immunity the host becomes susceptible to opportunistic infection and malignancies that rarely cause illness in immune competent individuals. The interactions between the HIV and human immune system are extraordinarily complex as evidenced by highly variable rates of disease progression observed in HIV infected

individuals. The progress that has been made till date in combating HIV/AIDS is unparalleled. The number of new HIV infection is in decline and the life expectancy of the HIV infected person is almost reaching to that of a normal individual. Success achieved by ART has now transformed the HIV infection from being a virtual death sentence to a chronic manageable illness.

The current study is primarily aimed at observing the effect of ART (HAART) on the CD4 counts. A total of 100 patients were confirmed HIV positive between Jan 2015 to Dec 2015 in ART center at SVRRGGH, Tirupati and Anti Retroviral Therapy was initiated in them. Among 100 patients confirmed HIV positive from January 2015 to December 2015, 100 patients who had CD4 counts <350 OR WHO STAGE III & IV irrespective of CD4 Count were included in the study and followed up to for the next six months. These patients CD4 counts are analysed and represented in the study. Patients in stage III and IV are included in the study irrespective of their initial CD4 count.

Revised Who Clinical Staging Of Hiv/Aids⁶ For Adults And Adolescents

(Interim African Region version for persons aged 15 years or more with positive HIV antibody test or other laboratory evidence of HIV infection)⁶

Table 1. Revised Who Clinical Staging Of Hiv/Aids For Adults And Adolescents

Primary HIV infection

Asymptomatic

Acute retroviral syndrome

Clinical stage 1

Asymptomatic

Persistent generalized lymphadenopathy (PGL)

Clinical stage 2

Moderate unexplained weight loss (<10% of presumed or measured body weight) Recurrent respiratory tract infections (RTIs, sinusitis, bronchitis, otitis media, pharyngitis) Herpes zoster

Angular cheilitis Recurrent oral ulcerations Papular

pruritic eruptions Seborrhoeic dermatitis

Fungal nail infections of fingers

Clinical stage 3

Conditions where a presumptive diagnosis can be made on the basis of clinical signs or simple investigations

Severe weight loss (>10% of presumed or measured body weight) Unexplained chronic diarrhoea for longer than one month

Unexplained persistent fever (intermittent or constant for longer than one month) Oral candidiasis

Oral hairy leukoplakia

Pulmonary tuberculosis (TB) diagnosed in last two years

Severe presumed bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia)

Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis

Conditions where confirmatory diagnostic testing is necessary

Unexplained anaemia (<8 g/dl), and or neutropenia (<500/mm³) and or thrombocytopenia (<50 000/mm³) for more than one month

All clinical events or conditions referred to are described in the Annexes. The UN defines adolescents as persons aged 10–19 years but, in the present document, the category of adults and adolescents comprises people aged 15 years and over for

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