

Statistical Analysis and Evaluation of CD4 Count after 6 Months on ART

Sir,

Human immunodeficiency virus (HIV) attacks CD4 T cells primarily. In HIV infection, the CD4 count decreases. Current CD4 count is a strong predictor of the immediate risk of acquired immunodeficiency syndrome (AIDS) or death than HIV RNA level. Antiretroviral therapy (ART) has dramatically reduced the morbidity and mortality associated with HIV infection and has improved the prognosis for people living with HIV AIDS (PLHA). The free ART initiative was launched by the Government of India on 1 April 2004 with a view to improve access to ART for the estimated 2.5 million PLHA in India.⁽¹⁾

ART is started in HIV-infected individuals having CD4 count below 250/ μL . The current study was undertaken to evaluate the response to ART after 6 months on therapy in a government hospital. CD4 counts of the patients on ART, before starting the treatment and after 6 months on ART, were performed and analyzed statistically. The present study is a retrospective cohort study. It was conducted in the Department of Microbiology in collaboration with ART centre, Shri Bhausaheb Hire Govt. Medical College, Dhule, Maharashtra.

In this study, 57 consecutive patients attending the ART centre in the month of February, 2010 for CD4 count follow-up were included. The CD4 counts of these 57 patients performed in September 2009 were noted. ART was given as a combination of Zidovudine, Lamivudine and Nevirapine. Of these 57 patients, 38 were ART-naïve. Nineteen patients were already on ART for more than 6 months. Pregnant ladies and children were excluded from the study.

Five milliliters of sterile blood sample was collected in an diamminetetraacetic acid vacutainer and transported to the microbiology laboratory within 1 hour. The sample was processed within 24 h according to the Maharashtra State AIDS Control Society (MSACS) guidelines based on Clinical laboratory standard institute (CLSI). CD4 count was estimated by PARTEC Cyflow machine using flow cytometry with single platform technology as the principle.

The 6 months prior CD4 counts and CD4 counts after ART intervention of all the 57 patients were analyzed by calculating standard error of mean, standard deviation and paired *t* tests.

The ethical committee of research society of this institute

provided the ethical clearance.

In this study, the mean CD4 count in 57 patients before ART was 222, with standard deviation ± 149 of mean value. After 6 months of ART, the mean value of CD4 count increased to 306 with ± 178 standard deviation of mean value. This shows that when we study 57 patients as a group after ART intervention for 6 months, their mean CD4 count has increased from 222 to 306, a picture that all of them are being benefited from the ART.

But, in our study, it was seen that in 44 patients, the CD4 count actually increased. One patient had constant CD4 count while in 12 patients the count decreased. We have analyzed and interpreted our findings as follows. When we analyzed the results, it was seen that in 44 patients, the mean CD4 count increased from 192 to 332 after 6 months of ART. These 44 patients included 34 ART-naïve patients and 10 patients on ART for more than 6 months.

The mean difference of the CD4 count increase in patients obtained was of 139, and is statistically highly significant ($P < 0.01$) by the paired *t* test. The confidence limit in 95% of the patients having ART treatment for 6 months will have a mean increase of CD4 count in between 104 and 174.

Mocroft *et al.* have reported the greatest mean increase in CD4 count of 100 cells/ μL after the first year of ART.⁽²⁾ CASCADE Collaboration have reported that the median CD4 count increase at 6 months on ART was 119 cells/ μL .⁽³⁾

In 12 patients, even after giving ART, the mean CD4 count reduced from 336 to 226. These 12 patients were on ART for more than 6 months. The mean difference in fall of CD4 count was 109. It was statistically significant when compared using the paired *t* test ($P < 0.05$). The fall in between 30 and 188 CD4 count gives the 95% confidence limit by the study.

CASCADE Collaboration has also pointed that CD4 response was strongly associated with the CD4 level at which HAART was initiated. Delaying HAART initiation until a CD4 count of 200 cells/ μL or lower reduced the chance of short-term immunologic response.⁽³⁾ Badri *et al.* have reported that the negative CD4 count slope in patients on ART was associated with virological failure. They have concluded that the CD4 count changes

correlated significantly with viral load at a group level. But, this has limited utility in identifying virological failure in individual patients.⁽⁴⁾ Highleyman⁽⁵⁾ has also reported poor CD4 cell recovery or no increase in CD4 count in a few patients on ART in their studies.

We correlated these studies with the findings in our study. It was observed that if we consider all patients together, it appears that CD4 count of the cohort has increased, but this is not the actual case. We have to separately evaluate the patients who showed rise and those who showed fall in CD4 count after ART to get the true picture.

Patients showing decrease in CD4 count should be investigated for viral load and drug resistance studies. Reasons for lowering count may be non-adherence, lack of support from families, shortage of drugs and toxicity of drugs.

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