

Virological Discordance in Patients on Antiretroviral Therapy (ART) with Immunological Failure in Government Hospital of Thoracic Medicine (GHTM), Tambaram: First time experience in Indian Government Programme

**Ganesh Anusuya¹ Rajasekaren Shikamani¹ Manoharan Gurusamy²
Jyoti Somani² Raja Krishnaraj³ Ezhil Radhakrishnan⁴ Patrick Nadol³**

Background:

Patients who fail ART via immunologic (i.e. CD4 cell count) criteria may have a discordant indication when tested with a viral load assay. Such patients may be incorrectly initiated on an alternative or second-line ART (SLA). The prevalence and factors associated with this discordance have not been studied in the Indian HIV treatment context. We studied the prevalence and factors for this discordance in patients enrolled in an HIV treatment program in a large tertiary care hospital (GHTM) in India

Methodology:

A cross-sectional study of HIV patients on First Line ART (FLA) in GHTM with immunological failure (IF) and who were eligible for viral load testing as determined by the State AIDS Clinical Expert Panel (SACEP). SACEP is a pilot program in India to evaluate and initiate patients on second-line ART (SLA). Eligibility criteria for SLA include: received FLA for at least 6 months with adherence > 95% and has failed ART immunologically or clinically (WHO) with a subsequent failed virologic response. Concordant response was defined as IF and VL > 10,000 copies/ml, discordant response as IF and a VL < 400 copies/ml; intermediate response was defined as IF and VL between 400 and 10,000 copies/ml. Various clinical and demographic factors were analyzed between discordant and concordant groups using Chi-Square and Fisher's exact test.

Results:

From January to August 2008, 106 patients were referred for SACEP. Of these, 76 (71.6%) were eligible for evaluation. In those evaluated 69.7%, 21.1%, and 9.2% had a concordant, discordant and an intermediate response. The respective baseline characteristics for discordant and concordant groups were: mean age in years 35 and 39 (p-value < 0.05), 81.3% and 96.2% males (p-value >0.05), median CD4 count of 51 and 56 cells/cubic millimeter (p-value > 0.05). Other characteristics of the discordant and concordant groups respectively were: median CD4 count at IF (68 vs. 96 cells/cubic millimeter; p-value > 0.05), median time to IF (12 vs. 15 months; p-value >0.05), previous history of ART (6.3% vs. 37.7%; p-value <0.05), ART substitution (50% vs. 71.7%; p-value >0.05), previous history of anti-tuberculosis therapy (68.8% vs. 84.9%; p-value > 0.05), clinical failure (CF) in addition to IF (12.5% vs. 37.7%; p-value < 0.05).

Conclusion:

In this population, 21.1% of HIV treatment patients indicated discordant results in their immunologic and virologic responses to ART. Such patients may be inappropriately initiated on more costly and potentially toxic SLA. Further studies are required to determine the various other risk factors and outcomes that are associated with such discordance. In addition, such data should be evaluated by the National AIDS Control Organization (NACO) in India to inform guidelines for the initiation of SLA.