

# Estimation of Clinical and Immunological Failure of First Line Antiretroviral Treatment in King Koti ART Centre, Hyderabad, Telangana

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## ABSTRACT

**Introduction:** The treatment outcomes under national antiretroviral therapy (ART) programme are being evaluated in ART centers in the country. We carried out this study to analyze the impact of first line antiretroviral therapy in HIV infected patients attending free ART. The main objective of this work is to determine the clinical and immunological failure rate at first-line treatment.

**Methods:** We have conducted a prospective, observational cohort study of patients living with HIV who had suspected failure of first line ART using data collected under programmatic condition. Four hundred and three patients from ART center King Koti, Hyderabad from January 1, 2017 to December 2018 was taken in the study.

**Results:** Between January 2017 to December 2018, 403 patients were registered in the ART clinic. Of these, 318 (52.6%) were on ART. Females accounted for 48% and males constitute 51%. Patients had a mean age of  $37 \pm 12$  yr, Median CD4 count was 560 cells/ $\mu$ l (IQR: 289-734). 13 patients (4.2%) were in clinical stage 3 and 10 (8.24%) in clinical stage 4 for HIV infection according to the WHO classification. CD4 T-cells counts were between 4 and 1591 cells/mm<sup>3</sup> with 174 patients (56%) with CD4 count below 500 cells/mm<sup>3</sup>.

**Conclusion:** The rate of immunological failure rate of first-line antiretroviral treatment of patients under treatment in King Koti, Hyderabad is 7.5% for the year 2017 and 18.

**Key Words:** Antiretroviral therapy, Clinical failure, Immunological failure

## INTRODUCTION

Total number of individuals living with HIV (PLHIV) in India was evaluated at 21.17 lakhs (17.11 lakhs- 26.49 lakhs) in 2015 contrasted and 22.26 lakhs (18.00 lakhs-27.85 lakhs) in 2007. Children (< 15 years) represented 6.54%, while women contributed around two fifth (40.5%) of absolute HIV diseases. Unified Andhra Pradesh and Telangana have the most elevated evaluated number of PLHIV (3.95

lakhs) trailed by Maharashtra (3.01 lakhs), Karnataka (1.99 lakhs), Gujarat (1.66 lakhs), Bihar (1.51 lakhs) and Uttar Pradesh (1.50 lakhs). These seven States together record for 66% (64.4%) of all out evaluated PLHIV. Rajasthan (1.03 lakhs), Tamil Nadu (1.43 lakhs) and West Bengal (1.29 lakhs) are different States with assessed PLHIV quantities of 1 lakh or more. In India, the assessed number of new HIV infections in 2015 were around 86 (56-129) thousand.

Manipur has shown the highest estimated adult HIV prevalence (1.15%), trailed by Mizoram (0.80%), Nagaland (0.78%), Andhra Pradesh and Telangana (0.66%), Karnataka (0.45%), Gujarat (0.42%) and Goa (0.40%). Other than these States, Maharashtra, Chandigarh, Tripura and Tamil Nadu have shown an estimated adult HIV predominance more noteworthy than the national pervasiveness (0.26%), while Odisha, Bihar, Sikkim, Delhi, Rajasthan and West Bengal have demonstrated an expected grown-up HIV commonness in the scope of 0.21– 0.25%. Every other State/UTs have adult HIV pervasiveness underneath 0.20%.<sup>[1]</sup>

The basic principle for first-line ART for treatment naïve adult and adolescent patients is to use a triple drug combination from two different classes of ARVs. The first-line ART essentially comprises of a NRTI backbone, preferably Non-Thymidine (Tenofovir plus Lamivudine) and one NNRTI, preferably EFV. Based on the evidence supporting better efficacy and fewer side effects, it is now recommended that all PLHIV with HIV-1 infection be initiated on a regimen consisting of TLE

The objective of this work is to determine the clinical and immunological failure rate at first-line treatment in King Koti Hospital secundrabad, Telangana.

## METHODS

### Study design and population

We have conducted a prospective, observational cohort study of patients living with HIV who had suspected failure of first line ART using data collected under programmatic condition. Four hundred and three patients from ART center King Koti, Hyderabad from January 1, 2017 to December 2018 was taken in the study. At 6th month of antiretroviral treatment, 318 patients were received for the as-assessments and analyzes of the parameters remaining patients were left out from the treatment. The first-line treatment used for all patients was a combination of

Zidovudine (ZDV), Lamivudine (3TC) and Nevi-rapine (NVP) and Tenofovir Lamivudine (3TC) and Nevi-rapine (NVP) which is the most available combination in the ART centers India.

### Data collection and analysis

Statistic and clinical data of all patients living with HIV was recorded in patient documents. The clinical information that was routinely gathered for every patient, including treatment and investigation reports, was entered into an excel database. A full-time data manager routinely administered information section for precision and culmination. Information from all patients associated with first -line failure between January 1, 2017 to December 2018 were incorporated into the investigations. Descriptive statistics for measurements were utilized to investigate the information of these patients utilizing SPSS.

### Operational Definitions

Clinical failure to treatment is based on the reoccurrence of opportunistic infections and/or progression to a higher clinical stage after the start of treatment, as well as the lost of weight of patient in a context without stress problem and reconstruction syndrome.

Immunological failure to treatment is defined by the absence of increased CD4 T-cells count despite effective ARV therapy for at least 6 months. This is seen more frequently in patients with initially low CD4 cell counts. As a general rule, a CD4 count below 200 cells/mm<sup>3</sup> is an indicator of immunological failure.

Virological failure to treatment is defined as a persistence VL greater than 1000 copies of RNA/ml 6 months after the start of treatment.<sup>[2-4]</sup>

## RESULTS

Between January 2017 to December 2018, 403 patients were registered in the ART clinic. Of these, 318 (52.6%) were on ART. The baseline characteristics of these patients are shown in the Table 1. Females

accounted for 48% and males constitute 51%. Patients had a mean age of  $37 \pm 12$  yr, Median CD4 count was 560 cells/ $\mu$ l (IQR: 289-734). 13 patients (4.2%) were in clinical stage 3 and 10 (8.24%) in clinical stage 4 for HIV infection according to the WHO classification. [5] CD4 T-cells counts were between 4 and 1591 cells/mm<sup>3</sup> with 174 patients (56%) with CD4 count below 500 cells/mm<sup>3</sup>. [6]

**Table 1. Characteristics of patients**

Characteristics	Patients
Male	164(51.5)
Female	151(48.5)
Age (years) (n = 318)	
Interval	18-65
Mean	37 $\pm$ 12
18-25	22(6.9%)
26-35	129(40.6%)
36-45	107(33.6%)
46-55	48(15.1%)
56-65	12(3.8%)
Cd4 range	4-1591
Median cd4	560 cells/mm <sup>3</sup>
WHO Clinical stages	
Stage I & II	295(92.5%)
Stage III & IV	23(7.5%)

## DISCUSSION

The aim of this work was to determine the clinical and immunological failure rate at treatment in ART center King Koti, Hyderabad. The data collected from ART programme clinic provided evidence supporting that the first line therapy was effective in HIV infected patients attending the clinic. In India CD4 testing is available in all ART sites therefore immunological criteria are widely used to determine treatment failure. The survival analysis was carried out using CD4 counts stratification and the results showed that patients with advanced disease had probability of less survival as compared to those with ART initiation at CD4 counts of  $>100$  cells/ $\mu$ l.

The optimal response to ART therapy is indicated by a median rise of CD4 count of 50 cells/ $\mu$ l at the end of 6 months or 100 cells/ $\mu$ l at one year of treatment. The studies conducted in different countries have documented different levels of rise in CD4 counts after the treatment. Our results on rise in CD4 counts are similar to that

observed in other studies in India as well as in other countries. [7-10]

Though overall immunological response was satisfactory, three patients did not show increase in CD4 cell count at 6 months and one year follow up. Viral load assays were not performed at scheduled follow up visits. So it was not clear whether the patients had suboptimal response to antiretroviral therapy or virological failure. In another study in Kenyan [11] also found that immunological and clinical failure had poor prediction of virological failure. The study showed the sensitivity of immunological and clinical failure to detect viral failure was 36.4%, specificity was 83.5% and the positive-predictive value was 12.3%. In this study the sensitivity was studied for each individual criteria which varied between 20 to 91%, specificity was between 29 to 87% and positive predictive value was 46 to 59% which was higher. In a study Natarajan Kandasamy [12,13] CD4 falling more than 50% criteria can alone be used to screen viral load for treatment failure. Stress on adherence for the whole duration of HAART rather than last 6 months may improve the immunological criteria sensitivity.

In another study in Mbeya Region, Tanzania Prevalence of immunological treatment failure was high (48.2%) among HIV-infected patients attending Care and Treatment Clinics (CTCs) in two hospitals. Increased age, being patient from District hospital, baseline CD4 cell values of  $\geq 350$  cells/ $\mu$ l, severe anemia (hemoglobin count  $<8$ g/dL), longer duration from HIV infection diagnosis to ART initiation and AZT-based regimen were the significant predictors of immunological failure. [14]

Patients with IF were more likely to be early age adults, females, late presenters for HIV care, and have a low ( $<200$  cells/mm<sup>3</sup>) baseline CD4 count and history of HIV testing before diagnosis. Very few patients were shifted to second-line ART drugs despite the high prevalence of CF and/or IF. [15]

## CONCLUSION

The immunological failure rate of first-line antiretroviral treatment of patients on treatment in ART center King Koti is estimated at 7.5% for the year 2017 and 18.

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