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**Original Research Article**

# Factors for nonadherence to first line art therapy in a cohort of Human Immunodeficiency Virus positive adult patients

**Sivaranjani H., Harsha V. Patel*, Meghana B. S.**

Department of Internal Medicine, Bangalore Medical College and Research Institute, Karnataka, India

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***Correspondence:**
Dr. Harsha V. Patel,
E-mail: hvpatel18@gmail.com



## ABSTRACT

**Background:** Antiretroviral therapy is one of the reasons for falling trend of HIV epidemic at present. The clinical efficacy, toxicity and reasons for failure of first line ART is understudied. This study aimed to determine the frequency rates and reasons for discontinuation of first line ART in a cohort of HIV positive adult patients.
**Methods:** Cross sectional study was conducted on 11,968 patients of HIV registered at Victoria Hospital ART centre from 2011 to 2017. Using a structured proforma, relevant information was collected from patients taking first line ART. Descriptive statistics was used for analysing the results obtained.
**Results:** Total 11,968 HIV patients were registered at ART centre during our study period of which only 4,008 patients were taking ART among them, 167 patients were referred for initiation of 2nd line ART. After evaluation 28 were continued on First line,1 opted out, 20 were transferred out,1 discontinued treatment, 17 died, 14 were lost to follow up, 5 were excluded from the study and only 81 patients were started on second line ART. Failure rate of first line ART in our study was 2.02%. Immunological failure followed by clinical failure were the most common reasons for changeover in this study. Tuberculosis was the most common comorbid disease in this study.
**Conclusions:** First line ART is very effective and well tolerated and has a low failure rate. Low CD4 count, anaemia, raised ALP, low albumin were among the factors associated with treatment failure. WHO staging did not correlate with the treatment failure, recommended routine viral load monitoring for assessing treatment failure.

**Keywords:** Alkaline phosphatase, Anti-retroviral therapy, Human immunodeficiency virus, Karnataka state acquired immunodeficiency syndrome prevention society

## INTRODUCTION

Human Immunodeficiency Virus is a retrovirus which is the causative agent of AIDS it was first diagnosed in 1981. India has the third largest HIV epidemic in the world. In 2017, the prevalence of HIV among adults (aged 15-49) was estimated to be 0.2%. Although it appears to be a small figure this equates to about 2.1 million people having HIV due to large population of our country.[1,2] As observed between 2010 and 2017 new infections declined by 27% and AIDS-related deaths more than halved, falling by 56% indicating HIV epidemic in India was slowing down.[1]

In the year 2017, 79% of people affected with HIV were aware of their status and 56% of them were on antiretroviral therapy.[1] Females are more likely to be diagnosed, compared to Males (87% Vs 68%), simply because they were screened for HIV during pregnancy.[1]

The most important reason for the decline of the epidemic was introduction of Highly active antiretroviral

therapy. In the year 2013 only 36% of people living with HIV were receiving the treatment which increased to 56% in the year 2017,which was due to adoption of policy of "Test and Treat" by India since 2017 according to WHO guidelines, which means regardless of the CD4 count all patients tested positive for HIV were treated.[3]

The viral load of patients who were on treatment reflecting their health status and infectiousness of the patient were not routinely done ,although NACO had included viral load testing in its treatment strategy, in reality it was offered to a few whose treatment was failing.[3] One of the most important factor to be considered before labelling as treatment failure is adherence to the therapy, in 2017 as per statistics adherence level for first line ART was 71% among adults.[4]

HAART reduces the viral burden, improves the immune functions leading to reduction of morbidity and mortality due to HIV.[5] A certain number of patients fail to achieve the response and lead to failure of the therapy.[6] Treatment failure can be assessed clinically, immunologically or virologically.[7]

WHO endorses monitoring of the viral load for assessment of success of HAART as well as for assessment of the treatment failure since 2010.[8,9] If the viral load testing is not feasible or possible then clinical monitoring alone or both clinical and immunological monitoring can be used for assessment of the response to HAART and also determine the treatment failure.[10]

First line ART failure can predict roughly the percentage of patients likely to fail on second line ART as observed which could be as high as 46% which could be attributable to various factors.[11]

Early identification of treatment failure is crucial as late detection may lead to increased toxicity of the drug, emergence of drug resistance, economic burden, increased opportunistic infections and increased morbidity and mortality. Some of the risk factors for treatment failure are demographic factors, baseline clinical characteristics, (e.g. high pre-treatment viral load, low pre-treatment CD4 count, prior WHO stage), drug interactions, side effects, drug toxicity or poor adherence to treatment, few drug regimens, primary infection with drug-resistant strains of HIV.[12-16]

Study aimed at identifying the reasons for switch over of first line ART regimen to second line and to determine the reasons for discontinuation of 1st line ART in a cohort of HIV positive adult patients enrolled at ART Centre, Victoria Hospital, Bengaluru, Karnataka, India.

## METHODS

A cross sectional study was conducted at Victoria hospital ART center between the time period of November 2011 to October 2017. All adult HIV infected/AIDS patients registered at Victoria hospital ART center who had first line ART failure.

### *Inclusion criteria*

Cases of HIV patients aged above 18 years who were on first line ART referred for initiation of second line ART were included in the study.

### *Exclusion criteria*

- Subjects with age less than 18 years.
- Established cases of chronic liver disease
- Patients with chronic kidney disease
- Alcoholics
- Diabetic patients and
- Patients on statins.

The following definitions were used to identify treatment failure

*Virological failure*

Viral load above 1000 copies/ml at or after six months of ART, with patient being treatment adherent by >95%.

*Immunological failure*

CD4 count fall to baseline (or below) OR Persistent CD4 levels below 100 cells/mm$^3$ OR 50% fall from "on treatment "peak value.

*Clinical failure*

New or recurrent clinical event indicating sever immunodeficiency (WHO clinical stage 4 condition) after six months of effective treatment.

### *Methodology for data collection*

Patients aged above 18 years who were on first line ART were included in the study after obtaining institutional ethical committee clearance and KASCEP permission. During this study period 11,968 patients of HIV were registered at Victoria hospital ART center among which 167 patients who were referred to Center of Excellence Bowring and Lady Curzon Hospital for initiation of second line ART were included in the study. Data was collected using data collection format. The data collection format consisted of the socio demographic data (i.e. age, gender, weight (during initiation and switching HAART), risk factors and antiretroviral treatment related data (i.e. date of starting and changing regimen, CD4 count, reasons for regimen change, duration of initial regimen, WHO stage of HIV/AIDS and viral load). Other relevant laboratory parameters were also obtained from all these patients at the time of referral.

***Statistical analysis***

Descriptive statistics were used for analyzing the results obtained. Mean and Standard deviation was used for describing normally distributed data. Median and interquartile range were used to describe non normally distributed data. Numbers and proportions were used to describe discrete variables.

## RESULTS

A total of 11,968 patients of HIV were registered at Victoria hospital ART center during the study period of which 3,252 patients were in pre ART stage. Among 3,252 patients in Pre ART stage 1,962 patients were lost to follow up, 514 patients died before starting ART ,680 patients were transferred out and 82 patients opted out of therapy, 8,717 patients were initiated on ART among them 1,122 were lost to follow up 1,378 patients died on ART, 48 patients opted out of ART,14 patients stopped taking ART for unknown reasons, 2,147 patients were transferred out to other ART center, 4,008 patients were actually on ART among them 167 patients were referred to Center of Excellence for initiation of 2nd line. After detailed evaluation including adherence and other factors, 28 of them were continued on First line ART, one patient opted out of therapy, 20 patients were transferred out, one patient discontinued the therapy and 17 patients died before initiation of second line ART and 14 patients were lost to follow up, based on study exclusion criteria 5 patients were excluded from the study and 81 patients were actually started on second line ART. Among the above 81 patients 51 were males and 30 females. Failure rate of first line ART in the study was 2.02%. Of the 81 patients one patient was homosexual (MSM) and the rest were heterosexual.

**Table 1: Clinical characteristics of study subjects.**

| Characteristic | No. of study subjects | Percent |
|---|---|---|
| Duration of initial regimen (months) | | |
| < 30 | 31 | 38.27 |
| 30-60 | 23 | 28.40 |
| >60 | 27 | 33.33 |
| Baseline who staging | | |
| Stage I | 29 | 35.80 |
| Stage II | 15 | 18.52 |
| Stage III | 15 | 18.52 |
| Stage IV | 10 | 12.35 |
| Stage T1 | 12 | 14.81 |
| Who staging before switching regimen | | |
| Stage I | 19 | 23.46 |
| Stage II | 1 | 1.23 |
| Stage T1 | 60 | 74.07 |
| Stage T4 | 1 | 1.23 |
| Non anti-HIV therapies | 7 | 8.61 |
| Anti-TB | 6 | 7.41 |
| Other antibiotics | 1 | 1.20 |

As can be seen from Table 1, the median time for which the initial regimen was continued was 36 months (3 years) ranging from a minimum of 9 months to a maximum of 99 months. Majority of the patients were between the age group of 20-50 years as seen in (Figure 1). All 81 patients had immunological failure and 6 patients also had clinical failure in addition. Viral load was done on patients referred for initiation of second line ART. Interestingly study did not show drug toxicity as a cause of switch over to second line ART. All patients were on 2NRTI+1NNRTI as initial regimen.

As it is evident from the (Table 1) majority of the patients were in WHO clinical stage 1 while on 1st line ART (35.80%), but during the switching over of the regimen majority of the patients were in WHO stage T1 (74.07%) and there was no correlation to WHO staging and treatment failure in the study, 6 out of 81 patients at the time of referral for initiation of 2nd line ART were on treatment for pulmonary tuberculosis.

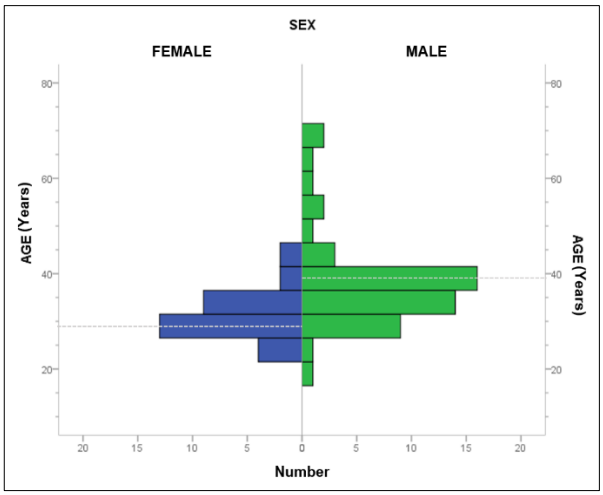


**Figure 1: A population pyramid showing the distribution of study subjects according to age and sex (n=81).**

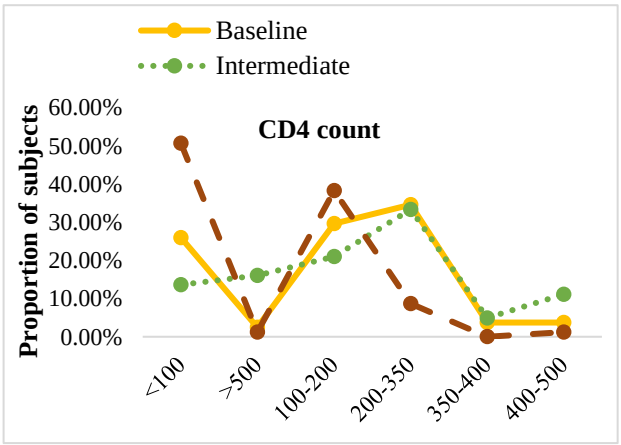


**Figure 2: Immunological (CD4 levels) picture at various time points.**

In this study as evident from (Table 2) at the time of diagnosis of HIV 25.93% (21) of the patients had CD4 count less than 100 and 29.63% (24) had CD4 count between 100-200 and 34.57 % (28) of the patients had CD4 count between 200-350. However during switching over of the regimen 50.62% (41) of the patients had CD4 count of less than 100 and 38.27% (31) had CD4 count of 100-200 indicating positive correlation of falling CD4 count as a marker of treatment failure.

**Table 2: Distribution of study subjects according to their immunological picture(n=81).**

| Parameter (cells/cu mm) | Baseline | Intermediate | Before switching regimen |
|---|---|---|---|
| CD4+Count | | | |
| <100 | 21 | 11 | 41 |
| | (25.93%) | (13.58%) | (50.62%) |
| >500 | 2 | 13 | 1 |
| | (2.47%) | (16.05%) | (1.23%) |
| 100-200 | 24 | 17 | 31 |
| | (29.63%) | (20.99%) | (38.27%) |
| 200-350 | 28 | 27 | 7 |
| | (34.57%) | (33.33%) | (8.64%) |
| 350-400 | 3 | 4 | 0 |
| | (3.70%) | (4.94%) | (.00%) |
| 400-500 | 3 | 9 | 1 |
| | (3.70%) | (11.11%) | (1.23%) |
| Median CD4+ Count (Q1-Q3) | 171(97-278) | 263(158.5-436) | 96(49.5-148) |

*Q1=First Quartile, Q3=Third Quartile (Since the data does not follow normal distribution, median and quartiles describe the characteristics of data better than mean and SD and hence have been used here.)

**Table 3: Hematological profile of the study subjects (n=81).**

| Parameter | No. of study subjects | Percent |
|---|---|---|
| Anemia (g/dl) | | |
| 11-12.9 | 27 | 33.33% |
| 8-10.9 | 25 | 30.86% |
| <8 | 1 | 1.23% |
| Absent | 28 | 34.57% |
| Total Leucocyte Count (per cu mm) | | |
| <4000 | 28 | 34.57% |
| 4000-11,000 | 53 | 65.43% |
| Differential Count (%) | | |
| Neutrophils | | |
| <40 | 3 | 3.70% |
| 40-80 | 76 | 93.83% |
| >80 | 2 | 2.47% |
| Lymphocytes | | |
| <20 | 16 | 19.75% |
| 20-40 | 49 | 60.49% |
| >40 | 16 | 19.75% |

**Table 4: Biochemical profile of the study subjects (n=81).**

| Parameter | No.of study subject | percent |
|---|---|---|
| Liver Function Test- ALP(IU/L)) | | |
| 30-120 | 34 | 41.98% |
| >120 | 47 | 58.02% |
| Lipid profile | | |
| Total Cholesterol (mg/dl) | | |
| <200 | 75 | 92.59% |
| 200-239 | 4 | 4.94% |
| >239 | 2 | 2.47% |
| LDL Cholesterol (mg/dl) | | |
| <130 | 78 | 96.30% |
| 130-159 | 3 | 3.70% |
| HDL Cholesterol(mg/dl) | | |
| >55 | 3 | 3.70% |
| 35-55 | 40 | 49.38% |
| <35 | 38 | 46.91% |
| Triglycerides (mg/dl) | | |
| <150 | 53 | 65.43% |
| 150-199 | 8 | 9.88% |
| >199 | 20 | 24.69% |

The number of subjects who showed an improvement in the CD4+ counts from baseline after start of therapy was 21 of 81 (25.93%). However, they showed a fall in the counts at subsequent testing as depicted pictorially in (Figure 2) and hence the switch of regimen was deemed necessary.

The viral load at the time of referral for switching of regimen was documented for 73 of 81 (90.12%) patients on first line ART. The median viral load at the time of referral for the 73 patients was 70057 copies/ml (Q1-Q3: 12375-170130).

However, the viral load measured 6 months after starting Second line ART were documented for the above 73 patients majority of them had viral suppression but 4 patients had their viral load more than 1000 copies/ml and 7 of them between 100-1000 copies/ml indicating second line faliure.

It can be seen from (Table) 3 that 52 of 81 patients had anemia at the time of referral for switch over of regimen and 28 of them had total counts less than 4000. Six of them had Pancytopenia. As seen in (Table 4) significant Liver function abnormality observed in this study was hypoalbuminemia in 39 of the patients (≤3.5g/dl) and raised ALP in 47 patients(>120 IU/L).

Lipid profile revealed 38 of 81 patients had HDL <35 mg/dl and 20 of them had triglyceride levels more than 199 mg/dl and 2 had total cholesterol levels more than 239mg/dl.

## DISCUSSION

There are many factors which lead to non-adherence of ART. Immunological failure, virological failure, drug toxicity, noncompliance and others. Treatment option following development of either drug toxicity or virological failure are often limited due to high costs of alternative medications. The median duration of treatment in the study was 3 years whereas in UK they reported median duration of treatment before switch over of first line ART regimen was 17 months and 38% of patients changed or discontinued regimen within 2-5 years of commencing therapy.[17] The majority of the patients who were changed to second line ART were on TLE based regimen in this study in comparison to a study done by Lima et al where majority of patients were on ZLE based regimen, (44%).[18]

In a study from Treat Asia HIV Observational Database(TAHOD)19 there was a treatment failure rate of 2.43% i.e. 45 out of 1846 patients with a median duration of treatment being 1.2 years. This study had a treatment failure of 2.02% i.e. 81 out of 4008 patients with a median duration of treatment of three years.

Co morbidities in patients with advanced disease and concurrent treatments for opportunistic diseases could affect antiretroviral tolerance and thereby increase the risk of toxicities.[20] In this study, 6 patients were on anti TB drugs which is in agreement with Coited'lvoire in 2010 where TB was the only comorbid condition found in the study.[21]

Cok Istriet al, in their study found HIV clinical stage IV as an important factor predicting treatment failure ,however in this study there was no correlation with HIV clinical staging as majority of patients were in stage T1 at the time of first line failure.[22] Same study revealed immunological failure followed by virological failure as the most common reasons for treatment failure. The present study of authors showed all 81 patients had immunological failure and six of them also had clinical failure, virological failure was not a reason for treatment failure in this study as routine viral load monitoring were not done in ART center during the study period. NACO has started routine viral load monitoring at ART centers recently.

Anup Singh et al, in their study found low baseline CD4 count ,lower levels of plateau CD4 counts as an important predictors of treatment failure. Older age ,male gender and TB co-infection were other factors for first line ART failure in their study.[23] Authors study also showed Low baseline CD4 count, persistently low CD4 count or CD4 plateau as an important predictors of treatment failure, treatment failure was also high among males (51) as compared to females (30) in study but majority of them belonged to age group of 20 to 50 years in this study.

In a study by Kumaraswamy et al, concluded that 20 % of the patients modified their first line ART regimen and most common reason for modification was adverse drug effects and treatment failure less common.[24,25] Patients not tolerating first line drugs were initially switched to other first line drugs and only patients failing on first line ART were changed over to second line .

In study by Ntshebo Mirriam Morketsi et al, 46.4% reported toxicities( peripheral neuropathy, lactic acidosis, lipodystrophy), 5.4% changed due to pregnancy, 1.3% changed because of resistance and 0.7% changed because of TB.[26] In this study 3 patients experienced lactic acidosis, two of them had peripheral neuropathy however they were excluded from study as two of lactic acidosis patients were lost to follow up, one was transferred out and all the patients who developed peripheral neuropathy were diabetics who were on oral hypoglycemic agents . None of the patients in the given study were pregnant and drug resistance was not assessed. Unlike several other studies in various countries patients tolerated the first line ART drugs well and the adverse reactions to them were much less than expected.

It was also found that 4 patients started on second line ART had no viral suppression indicating 2nd line ART failure Assessment of factors associated and reasons for the same was not a part of this present study.

Limitations of this particular study was as follows

- The retrospective nature of the study does not assure the cause-effect relationship as some of the variables could be measured after the occurrence of the outcome;
- Monitoring of routine viral load was not done for assessment of treatment failure.

## CONCLUSION

Majority of patients had no problem with adherence to first line ART and first line ART failure rate was only 2.02%. First line ART is very effective and well tolerated and has a low failure rates. Treatment failure was mostly due to immunological failure. Low baseline CD4 count ,male gender, anemia, raised ALP levels, hypoalbuminemia were among the important predictors of treatment failure. WHO staging did not correlate with the treatment failure. Authors recommend routine viralload monitoring for assessing treatment failure. Adverse effects or drug toxicity were not a major factor for non-adherence of first line ART as they were shifted to alternate first line drugs when they experienced adverse effects.

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