

# A Study of Compliance to Antiretroviral Therapy among HIV Infected Patients at a Tertiary Care Hospital in North Karnataka

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## ABSTRACT

**Introduction:** Compliance to Antiretroviral Therapy (ART) is a primary determinant of treatment success of HIV-AIDS. Many studies have shown inadequate compliance to ART in the Indian population.

**Aim:** To assess the compliance to ART among HIV infected patients, to explore the factors affecting compliance and impact of compliance on CD4 count.

**Materials and Methods:** A cross-sectional study was conducted with 200 adult patients attending ART center, KIMS, Hubli. The patients were randomly selected and compliance to ART over preceding 3 months was assessed. Reasons for non-compliance were assessed among those with inadequate compliance.

**Results:** Mean age of the study population was 40.07±9.99 years. The sex ratio was 1.02:1 (M:F). Majority of patients were in WHO stage 1 with treatment, with CD4 count above 500/μl.

Pulmonary tuberculosis was the most common opportunistic infection.

Most of the patients were on long term ART, more than 5 years {81 (40.5%)}. Most of the patients were on ZLN regimen {97 (48.5%)}. Compliance over the preceding 3 months was 94.84±14.93% for ART and 88.97±23.75% for opportunistic infection prophylaxis. There was no significant difference in compliance in relation to age group, sex, educational status, residence, religion, habits, HIV status of spouse or child, the regimen of ART and frequency of dosing. The compliance was better among those on long term treatment, i.e., those on treatment for more than 5 years compared to those who started ART in last 1 year (p=0.06). The most common reasons given by patients for non-compliance were going away from home, busy with other work and simply forgot. Better compliance was associated with higher CD4 count.

**Conclusion:** Compliance to ART was inadequate in the studied population, which is a major obstacle to success of ART.

**Keywords:** CD4 count, Compliance to medication, HIV-AIDS

## INTRODUCTION

India is the second largely populated country in the world with a diverse set of social demographics. An estimated 34.0 million people were living with HIV as of 2011; 3.3 million of them were children under 15 years [1].

Four high prevalence states of South India (Andhra Pradesh, Karnataka, Tamil Nadu, Maharashtra) account for 53% of all HIV infections in our country [2].

Compliance to therapies is a primary determinant of treatment success of HIV-AIDS. Poor compliance attenuates optimum clinical benefits and therefore reduces the overall effectiveness of health systems [3].

Compliance to medication also known as 'adherence with medications' is the extent to which patient follows medical instructions [4]. In the treatment of patients with HIV infection it is essential to achieve more than 95% compliance to ART (Antiretroviral Therapy) in order to suppress viral replication and avoid the emergence of resistance. Many of the studies have shown that optimal compliance is 95% and compliance less than 95% is associated with virological failure rate of more than 50% [5]. Achieving such high rates of compliance is often difficult because the regimens include multiple and expensive medicines with complex dosing schedule which may cause multiple food interactions and adverse effects resulting in poor tolerability. In addition, lifestyle factors and patient-provider relationship has a significant impact on compliance. Considering these issues, a practical definition of compliance in the context of ART has been

defined as 'the extent to which a person's behaviour in taking medication, following dietary specifications and/or executing lifestyle changes corresponds to the advised recommendations from a doctor/ healthcare provider' [5-7].

Compliance to ART is the second strongest predictor of progression to AIDS and death, after CD4 count [8,9]. Inadequate compliance to ART, however, is common in all groups of treated individuals. The average rate of compliance to ART is approximately 70%, but long-term viral suppression requires near-perfect compliance [8].

A 10% improvement in compliance results in a 21% reduction in disease progression [10,11]. The various factors affecting compliance are social aspects like motivation to begin and adhere to therapy, socioeconomic status, educational status, financial status, family support, lifestyle pattern, advantages and disadvantages of starting therapy like tolerability of regimen, availability of drugs, regimens-pill burden, frequency of dosing, food requirements, convenience, toxicity and drug availability [10].

This study was undertaken to assess compliance of the patients to therapy among those registered at ART center, Karnataka Institute of Medical Sciences (KIMS), a government run tertiary hospital at Hubli, Karnataka.

## AIM

To assess the compliance to ART among HIV infected patients, to identify the factors affecting compliance and impact of compliance on CD4 count.

## MATERIALS AND METHOD

This was a hospital based observational cross-sectional study conducted at government run Tertiary hospital, Karnataka, over a period of 2 month from June 2015 to July 2015. Two hundred patients were randomly selected, among those who fulfill the inclusion criteria and agree to participate in the study, after having explained the procedure in detail and obtaining a written informed consent.

**Inclusion criteria:** HIV Infected adults  $\geq 18$  years on treatment for atleast 3 months from ART center, KIMS, Hubli and willing to participate in the study.

**Exclusion criteria:** Those not giving willing to participate in the study.

Clearance from the Ethical committee of KIMS, Hubli was obtained. Pretested and structured proforma was used to assess the details of the patients, family history, duration since HIV is diagnosed, duration of ART initiation, type of regimen and frequency of dosing. The recent CD4 counts of all the patients were noted from register.

The compliance of the patient in each month for previous 3 months was assessed based on number of missed doses and number of pills remaining unconsumed. The number of pills remaining unused was noted for each patient. The compliance, expressed as percentage compliance in each month was calculated by dividing total number of pills taken in the month divided by total number of drugs expected to be taken, multiplied by 100. The average of percentage compliance of preceding 3 months was calculated and considered for analysis

The ART register was used for the patients who were unable to recall details of previous months. Among the patients with non-compliance, the reasons for it were enquired.

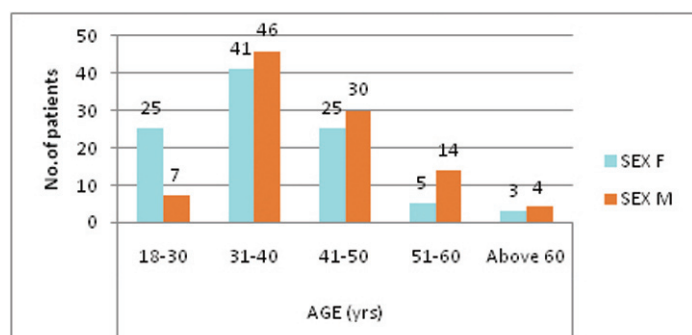
Similarly compliance to opportunistic infection prophylaxis was assessed by enquiring the patient about number of doses/tablets they had missed and expressed as percentage compliance.

## STATISTICAL ANALYSIS

Values were expressed in mean  $\pm$  S.D. and percentage. Statistical analysis was done using Chi-square test, Fisher-Exact test, unpaired t-test, ANOVA test in SPSS version 20. The  $p \leq 0.05$  was considered statistically significant.

## RESULTS

Mean age of our study population was  $40.07 \pm 9.99$  years. For males, it was  $42.01 \pm 9.47$  years and for females, it was  $38.12 \pm 10.17$  years. Both among males and females, HIV prevalence was highest among 31-40 years [Table/Fig-1]. The sex ratio was 1.02:1 (M:F) (101 male, 99 female). The distribution of the residence was 1.45: 1 (Urban: Rural). Majority of the patients were in WHO stage 1 with treatment [Table/Fig-2]. Majority had CD4 count above 500 cell/ $\mu$ l [Table/Fig-3]. Tuberculosis was the commonest opportunistic infection among them (18.5%), predominantly in the form of pulmonary tuberculosis (14%) [Table/Fig-4].



[Table/Fig-1]: Age and sex distribution of patients.

The HIV positive status was found in 97 (48.5%) of spouse and 6 (3%) of children.

## Interpretation of compliance to ART

Most of the patients were on long term ART, greater than 5 years {81 (40.5%)} [Table/Fig-5]. Most of the patients were on ZLN regimen {97 (48.5%)}. But, the patients who were recently started ART were commonly on TLE regimen [Table/Fig-6,7].

The compliance over the period of preceding three months was studied and it was  $94.84 \pm 14.93\%$  for ART drugs [Table/Fig-6]. 100% compliance all through the 3 months was found in 124 patients (62%). Compliance was optimal ( $\geq 95\%$  as per national ART guidelines) in 162 patients (81%) and suboptimal in 38 (19%). Highest compliance was found in younger age group, i.e. 18-30 years ( $96.82 \pm 7.27\%$ ) and least among those more

| Stage of HIV | Male | Female | Total |
|--------------|------|--------|-------|
| T1           | 93   | 96     | 189   |
| T2           | 4    | 3      | 7     |
| T3           | 3    | 0      | 3     |
| T4           | 1    | 0      | 1     |
| TOTAL        | 101  | 99     | 200   |

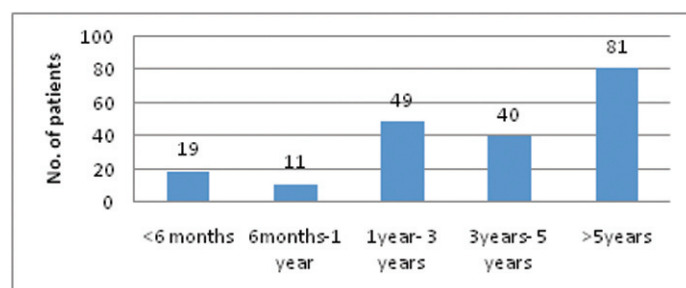
[Table/Fig-2]: Presentation in different stages of HIV.

| CD4 count(cells per $\mu$ l) | No. of pt. | Percentage (%) |
|------------------------------|------------|----------------|
| < 50                         | 6          | 3.0            |
| 51-100                       | 6          | 3.0            |
| 101-200                      | 32         | 16             |
| 201-300                      | 23         | 11.5           |
| 301-400                      | 43         | 21.5           |
| 401-500                      | 37         | 18.5           |
| >500                         | 53         | 26.5           |
| TOTAL                        | 200        | 100.0          |

[Table/Fig-3]: CD4 count among patients studied.

|   | Opportunistic infection               | No. of patients | Percentage (%) |
|---|---------------------------------------|-----------------|----------------|
| 1 | Tuberculosis                          | 37              | 18.5           |
| A | Pulmonary tuberculosis                | 28              | 14.0           |
| B | Tuberculous pleural effusion          | 3               | 1.5            |
| C | Tuberculous lymphadenitis             | 4               | 2.0            |
| D | Tuberculous meningitis                | 1               | 0.5            |
| E | Abdominal tuberculosis                | 1               | 0.5            |
| 2 | Pneumocystis Jiroveci Pneumonia (PJP) | 4               | 2.0            |
| 3 | Oral candidiasis                      | 5               | 2.5            |
| 4 | Tinea                                 | 1               | 0.5            |
| 5 | Cryptococcal meningitis               | 1               | 0.5            |
| 6 | Herpes zoster                         | 1               | 0.5            |
| 7 | Chronic diarrhoea                     | 2               | 1.0            |
|   | TOTAL                                 | 51              | 25.5           |

[Table/Fig-4]: Opportunistic infections (present and past) among patients



[Table/Fig-5]: Duration of ART initiation among patients studied.

than 50 years (90.67±24.17). Compliance was better among female (95.79±11.38), compared to male (93.88±17.80%), but insignificant (p=0.3679). It was better among literates (95.47±15.54%) compared to illiterates (93.72±15.64%), but insignificant (p=0.779). Urban people had better compliance than to rural people. (95.16±14.97% v/s 94.37±14.95%, p= 0.7154).

**Association between compliance and CD4 count:** Mean CD4 count was very significantly lower among the patients with suboptimal compliance (75.12±26.45%) compared to those with optimal compliance (99.46±1.21%) p<0.0001). Better compliance was associated with higher CD4 count and those with lower compliance had lower CD4 count as shown in table. This indicates that compliance plays vital role in improving CD4 count. (p= 0.0036) [Table/Fig-8,9].

**Association between compliance and duration of ART:** The compliance was significantly better among those on treatment for

|                       | Compliance at present month | Compliance in last month | Compliance 2 months back | Overall compliance of preceding 3 months | Compliance with opportunistic infection prophylaxis/ treatment |
|-----------------------|-----------------------------|--------------------------|--------------------------|--|--|
| Mean                  | 96.02                       | 93.89                    | 93.46                    | 94.84                                    | 88.97  |
| Std. Deviation (S.D.) | 14.54                       | 18.66                    | 20.53                    | 14.93                                    | 23.75  |

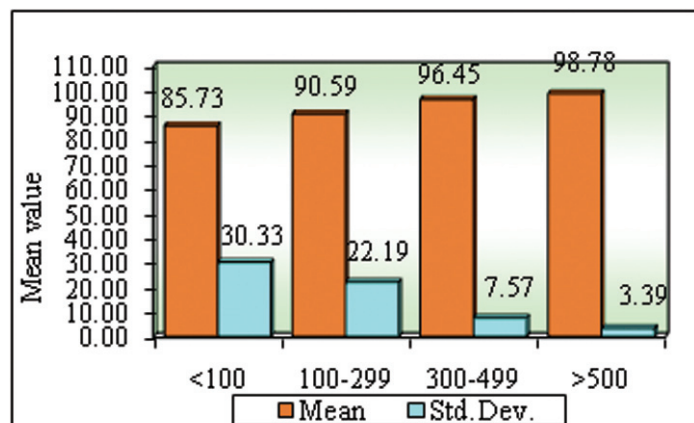
[Table/Fig-6]: Compliance to ART.

| Regimen. | No. of patients (%) | Overall compliance |       |      |
|----------|---------------------|--------------------|-------|------|
|          |                     | Mean               | S.D.  | S.E. |
| TLE      | 83 (41.5%)          | 95.21              | 11.45 | 1.27 |
| ZLN      | 97(48.5%)           | 93.93              | 18.46 | 1.87 |
| ZLE      | 15(7.5%)            | 96.98              | 5.10  | 1.32 |
| TL.AZ    | 5(2.5%)             | 98.80              | 0.45  | 0.20 |
| TOTAL    | 200                 | 94.84              | 14.93 | 1.05 |
| p- value |                     | 0.74               |       |      |

[Table/Fig-7]: ART regimens of patients. (TLE- Tenofovir, Lamivudine and Elavirenz, ZLN-Zidovudine, Lamivudine and Nevirapine, ZLE- Zidovudine, Lamivudine and Elavirenz, TL.AZ- Tenofovir, Lamivudine and Atazanavir)

| CD4     | N   | Mean    | S.D   | SE   |
|---------|-----|---------|-------|------|
| <100    | 11  | 85.73   | 30.33 | 9.15 |
| 100-299 | 56  | 90.59   | 22.19 | 2.96 |
| 300-499 | 80  | 96.45   | 7.57  | 0.85 |
| >500    | 53  | 98.78   | 3.39  | 0.47 |
| Total   | 200 | 94.84   | 14.93 | 1.06 |
| p-value |     | 0.0036* |       |      |

[Table/Fig-8]: Comparison of groups with different CD4 counts with overall compliance by one-way ANOVA. \* Significant



[Table/Fig-9]: Comparison of groups with different CD<sub>4</sub> counts with overall compliance.

more than 5 years compared to those on treatment for less than 5 years (p=0.021) [Table/Fig-10,11].

There was no significant difference in compliance in relation to age group, sex, educational status, residence, religion, habits, HIV status of spouse and child, the regimen of ART and frequency of dosing.

**Compliance with opportunistic infection prophylaxis/ treatment:** Compliance to opportunistic infection prophylaxis/ treatment was 88.97 ±23.75%, which is lower compared to that of ART [Table/Fig-12].

Opportunistic infection prophylaxis was received by 63 patients for PJP 1 for cryptococcal meningitis. 3 were on treatment for tuberculosis, 3 for oropharyngeal candidiasis.

**Reasons for non-compliance:**

The most common reason given by patients for non-compliance was 'going away from home'. The other common causes were, 'being busy with other work' and 'simply forgot'. Some of the patients had multiple reasons [Table/Fig-13].

| Duration of ART | N   | Means  | S.D   | SE   |
|-----------------|-----|--------|-------|------|
| <6 months       | 19  | 91.88  | 20.02 | 4.59 |
| 6 months-1years | 11  | 84.61  | 27.66 | 8.34 |
| 1years- 3years  | 49  | 95.22  | 8.48  | 1.21 |
| 3years- 5 years | 40  | 93.21  | 18.18 | 2.87 |
| >5years         | 81  | 97.49  | 11.81 | 1.31 |
| Total           | 200 | 94.84  | 14.93 | 1.06 |
| p-value         |     | 0.0600 |       |      |

[Table/Fig-10]: Comparison of duration of ART with COM-OV scores by one-way ANOVA.

| Duration of ART initiation | Mean  | S.D.  |
|----------------------------|-------|-------|
| < 5 years                  | 97.49 | 11.81 |
| ≥5 years                   | 93.03 | 16.53 |
| p-value                    | 0.021 |       |

[Table/Fig-11]: Comparison of compliance to ART between the patients on treatment for more than 5 years and those less than 5 years.

| Opportunistic infection   | Drugs            | No. of patients | Compliance (mean±S.D) |
|---------------------------|------------------|-----------------|-----------------------|
| PJP prophylaxis           | Cotrimoxazole-DS | 63              | 88.97± 23.75          |
| PJP treatment             | Cotrimoxazole-DS | 4               | 84.12±14.21           |
| Tuberculosis treatment    | ATT under DOTS   | 3               | 100                   |
| Oropharyngeal candidiasis | Fluconazole      | 3               | 100                   |

[Table/Fig-12]: Compliance with opportunistic infection prophylaxis/ treatment.

|    | Reasons  | No. of patients giving the reason |
|----|--|-----------------------------------|
| 1  | Went away from home                            | 23                                |
| 2  | Were busy with other work                      | 13                                |
| 3  | Simply forgot                                  | 12                                |
| 4  | Had a change in daily routine                  | 7                                 |
| 5  | Fell sick/ ill                                 | 7                                 |
| 6  | Did not have knowledge/ was not told of dosing | 6                                 |
| 7  | Did not want others to notice taking drugs     | 4                                 |
| 8  | Felt that the drug was toxic                   | 4                                 |
| 9  | Slept through dose timing                      | 3                                 |
| 10 | Ran out of pills                               | 3                                 |
| 11 | Felt good                                      | 3                                 |
| 12 | Felt depression/ worthless                     | 2                                 |
| 13 | Problem taking pills as specified              | 1                                 |

[Table/Fig-13]: Reasons for non-compliance to ART\* (\*some of the patients had multiple reasons)

The compliance to PJP prophylaxis was lower than that for ART, reason being difficulty in taking Tab. Cotrimoxazole-DS at afternoon as they are busy with their work.

### Adverse effects to ART

They were found in 19 patients, the common being hyperpigmentation due to Zidovudine and drowsiness due to Efavirenz [Table/Fig-14].

## DISCUSSION

Several studies have been conducted to assess compliance to ART and the factor affecting it at various geographical regions. Our study assessed the compliance over previous 3 months and it was 94.84±14.93%. This is consistent with the study by Vivek Lal et al., conducted at Lok Nayak Hospital, New Delhi, in which 90% compliance was found over the previous four-day period [3]. The common reasons cited by patients for non-compliance in our study were 'away from home', busy with other work' and 'simply forgot.' This is in consistent with the reasons in the above mentioned study. Several other studies like by Bangsberg DR et al., and Chesney MA et al., have also reported the commonest barriers to compliance were absent-mindedness/forgetfulness and being away from home [11-13].

Bhattacharya M et al., studied compliance to ART and its correlates among HIV infected children at New Delhi and the mean compliance was 91.4% and range was 75-100% [14]. Long duration since ART initiation, low caregiver educational state, efavirenz-based ART regimens and female gender were associated with lower compliance. The rise in CD4 count after ART initiation was more marked in the high compliance group, with the difference in the two groups becoming statistically significant after 6 months of ART [14]. Although the mean compliance to ART in our study was similar to this study results, we did not find statistically significant difference in compliance in relation to gender, education status and ART regimens. Arunkumar De et al., assessed the factors affecting compliance to ART among HIV positive mothers and their infected children at Kolkota [15]. 56% of mothers and 65.8% of children showed good compliance to ART. The compliance to ART was lesser compared to western countries. The study showed that different socio- demographic factors, health system related factors, drug related factors and psychological factors influence the compliance. This study also shows that maternal compliance has a great influence on pediatric compliance [15].

N Joglekar et al., have done research on barriers to ART compliance in Maharashtra and have reported multiple barriers such as: (1) financial barriers, such as unemployment and economic dependence; (2) social barriers of attending family cultures, functions and rituals; (3) patient related barriers, such as their attitude towards medications and their social stigma; and (4) health- care related barriers long waiting period, poor doctor-patient relationship and inadequate counselling at ART centers [16].

|    | Adverse effects         | No. of patients | Percentage |
|----|-------------------------|-----------------|------------|
| 1. | Anemia                  | 3               | 1.5        |
| 2. | Drowsiness              | 5               | 2.5        |
| 3. | Fatigue                 | 1               | 0.5        |
| 4. | Gastritis               | 2               | 1          |
| 5. | Hyperpigmentation       | 5               | 2.5        |
| 6. | Lip discoloration       | 1               | 0.5        |
| 7. | Nevirapine reaction     | 2               | 1          |
| 8. | Pruritis                | 1               | 0.5        |
| 9. | Swelling of face & legs | 1               | 0.5        |

**[Table/Fig-14]:** Adverse effects to ART among patients studied (some of the patients had multiple adverse effects).

Mamta Sharma et al., conducted a study at SMS hospital, Jaipur and found that 13% of patients were non-compliant to ART [17]. Elderly age, lower education status, unemployment and presence of co-infections were significantly associated with non-compliance. Sex of patients, their marital status, area of residence, family size, distance from ART center and type of ART regimen were not associated with non-compliance, similar to findings in our study. Common reasons stated by patients for non-compliance were moving out of station, forgetfulness, lack of accompanying person, not feeling well and busy in occupation or other day to day activities [17]. Same reasons were cited by non-compliant patients even in our study.

A multi-centric-prospective observational study conducted by ART adherence study group across 30 ART centres in India revealed suboptimal compliance in 24.5% of patients [18] and the determinants of suboptimal compliance were illiteracy, on ART for less than 6 months, male gender, tribals, those on efavirenz based regimen, anxiety, non-disclosure of HIV status to family members, neglect from friends, inadequate motivation for treatment, frequent change of residence, travel expenses, inadequate counselling. In our study 19% had suboptimal compliance, which is lesser compared to above multi-centric study [18]. In consistent with above study even in our study, suboptimal compliance was common among male, rural residence, those on lesser duration of treatment, but it was not statistically significant. In contrast to the above study, our study demonstrated compliance to be better with TLE regimen, compared to ZLN regimen, but not statistically significant.

A meta-analysis on compliance to ART in sub-Saharan Africa and North America reported the optimal compliance of 77% among African population and 55% among North American population [19].

A cross-sectional study by Visanou Hansana et al., in Lao People's Democratic Republic (PDR) showed 60% of patients to have more than 95% compliance to ART. Reasons for non-compliance were being busy (97.0%), and being forgetful (62.2%). The reasons are similar to those in our study [20].

## CONCLUSION

Compliance to ART was inadequate in the studied population, which is a major obstacle to success of ART. Similarly it is inadequate at many ART centers in India. Although compliance to ART in our study was better than that in other studies in India and abroad, it is still inadequate. HIV/AIDS control, being an important national health programme, it is by the health education and counselling on the importance of compliance to ART, that this major obstacle can be overcome. Adequate pre-ART counseling of patients and also their family members on drugs, their importance and consequences of inadequate compliance is needed. Major reasons for non-compliance being moving out of station, measures are to be taken to make drugs available to these patients at other ART centers on emergency basis. Better compliance is associated with better survival and effective outcome.

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