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Adherence and Clinical Outcomes among People Living with HIV on First-Line Antiretroviral Therapy: A Prospective Observational Study

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Abstract

Background:
Acquired Immunodeficiency Syndrome (AIDS) results from chronic Human Immunodeficiency Virus (HIV) infection, characterized by CD4 cell depletion or AIDS-defining illnesses. Antiretroviral therapy (ART) restores immune function, with recent WHO guidelines favoring Tenofovir + Lamivudine + Dolutegravir (TLD) over Tenofovir + Lamivudine + Efavirenz (TLE) due to better efficacy and tolerability. Adherence plays a key role in treatment success.

Methods:
A prospective observational study was conducted over 18 months at a tertiary care center in Bhilai, including 55 adults with HIV on first-line ART. Data were collected through interviews, questionnaires, and outpatient records. ART failure was assessed biannually using CD4 counts and viral load. Adherence was evaluated using patient recall and records. Drug substitutions were done only for adverse effects.

Results:
Most patients were middle-aged males. Initially, 83.6% were on TLE, and 92.72% were later switched to TLD. Adherence improved from 54.55% to 65.45%, with a reduction in poor Adherence. Major causes of non-adherence included forgetfulness, gastrointestinal intolerance, and alcohol use. Clinical (34.55%), immunological (18.18%), and virological (16.36%) failures were significantly associated with poor adherence. Patients with adherence >95% had better outcomes.

Conclusion:
Switching to TLD was associated with improved adherence and treatment outcomes. Poor adherence was strongly associated with treatment failure, highlighting the importance of adherence and updated ART regimens

Keywords: Adherence, Antiretroviral Therapy, Dolutegravir, HIV, Treatment Failure

Introduction

Acquired Immunodeficiency Syndrome (AIDS) is a clinical condition resulting from chronic Human Immunodeficiency Virus (HIV) infection, characterized by progressive depletion of CD4+ T lymphocytes. It is defined by a CD4 count <200 cells/µL or the presence of AIDS-defining illnesses, irrespective of CD4 count. Advanced HIV disease is marked by CD4 counts <50 cells/µL. With effective antiretroviral therapy (ART), immune restoration can occur, and patients may no longer meet criteria for AIDS if CD4 counts rise above 200 cells/µL in the absence of defining conditions.

Standard ART regimens typically consist of two nucleoside reverse transcriptase inhibitors (NRTIs), such as Tenofovir disoproxil fumarate (TDF) and Lamivudine (3TC), combined with a third agent from either non-nucleoside reverse transcriptase inhibitors

(NNRTIs) like Efavirenz (EFV) or integrase strand transfer inhibitors (INSTIs) such as Dolutegravir (DTG). The TDF + 3TC + EFV (TLE) regimen has been widely used as first-line therapy. However, due to increasing NNRTI resistance and suboptimal outcomes, the World Health Organization (WHO) now recommends transitioning to Dolutegravir-based regimens (TLD: TDF + 3TC + DTG), which offer improved efficacy, tolerability, and a higher barrier to resistance[1–4].

Adherence to ART is a critical determinant of treatment success and is the second strongest predictor of disease progression after CD4 count[5, 6]. Poor adherence is associated with virological failure, emergence of drug resistance, increased morbidity, and mortality. Factors influencing adherence include socioeconomic status, patient motivation, family support, pill burden, adverse drug effects, and accessibility to healthcare services[7–9].

Highly Active Antiretroviral Therapy (HAART) has significantly improved survival and quality of life among people living with HIV (PLHIV) by suppressing viral replication and restoring immune function. Monitoring of treatment response is primarily done through CD4 counts and plasma viral load estimation. However, in resource-limited settings, viral load testing may not be readily available, making CD4 monitoring essential despite its lower sensitivity for early detection of virological failure[10–12].

According to WHO guidelines, treatment failure is classified as clinical, immunological, or virological. Clinical failure is defined as the occurrence of new or recurrent WHO stage 4 conditions after at least 6 months of ART. Immunological failure includes a fall in CD4 count to baseline or persistently low CD4 levels (<100 cells/mm³), while virological failure is defined as a viral load >1000 copies/mL after 6 months of therapy[13].

Given the limited data from Central India, particularly Chhattisgarh, this prospective observational study was undertaken to evaluate adherence and clinical outcomes among PLHIV receiving first-line ART at a tertiary care centre in Bhilai.

Materials And Methods

Study Design and Setting

This was a hospital-based prospective observational study conducted in the Department of General Medicine at Jawaharlal Nehru Hospital and Research Centre, Bhilai, Chhattisgarh, over a period of 18 months (January 2023 to June 2024).

Study Population and Sample Size

A total of 55 people living with HIV (PLHIV) attending the outpatient department (OPD) and admitted to the wards were included in the study. The sample size was calculated using Cochran's formula, taking a reference adherence rate of 73%, with a 95% confidence level (Z = 1.96) and an allowable error of 12%, yielding a minimum sample size of 53. Therefore, 55 patients were enrolled.

Inclusion Criteria

1) Patients aged ≥18 years (both males and females)
2) Patients willing to participate and providing written informed consent
3) PLHIV receiving first-line ART regimen
4) Patients undergoing transition from TLE to TLD regimen
5) Newly diagnosed HIV patients initiated on TLD regimen

Exclusion Criteria

1) Patients aged <18 years
2) Patients or relatives not providing informed consent
3) Patients already on second-line ART

Data Collection Procedure

Data were collected using patient interviews, structured questionnaires, and review of outpatient department (OPD) records.

Treatment Regimen

Patients received first-line antiretroviral therapy (ART) consisting of Tenofovir disoproxil fumarate (TDF), Lamivudine (3TC), and Efavirenz (EFV) (TLE regimen). As per updated guidelines, patients were transitioned to Tenofovir, Lamivudine, and Dolutegravir (TLD regimen). In addition, adherence-focused interventions including patient counselling, identification and management of causes of non-adherence, and optimization of ART regimen

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(switching to dolutegravir-based therapy and drug substitution where required) were carried out during follow-up

Assessment of Treatment Failure

Treatment failure was classified as clinical, immunological, or virological according to standard WHO criteria. Patients were followed up at 6-month intervals, and CD4 counts and viral load measurements were used to assess treatment response.

Assessment of Adherence

Adherence was assessed using patient recall and OPD records. Adherence was calculated as:

Adherence (%) = (Number of pills actually taken / Number of pills prescribed) × 100

Adherence ≥95% was considered well, while <95% was considered poor.

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 20.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were analyzed using the Chi-square test, and a p-value of <0.05 was considered statistically significant.

Ethical Considerations

Ethical approval was obtained from the Institutional Ethics Committee (IEC) of Jawaharlal Nehru Hospital and Research Centre, Bhilai *(JLNHRC/IEC/2023/248)*. Written informed consent was obtained from all participants prior to inclusion in the study.

Results

Baseline Characteristics

A total of **55 patients** were included in the study. The age ranged from 23 to 73 years, with a mean of **46.62 ± 12.33** years and a median of 49 years. The majority belonged to the 41–60 years age group (63.64%). There was a male predominance (70.9%). Most patients were initiated on **Tenofovir disoproxil fumarate (TDF), Lamivudine (3TC),** and **Efavirenz (EFV)** regimen (83.6%), while 16.4% received **Tenofovir disoproxil fumarate (TDF), Lamivudine (3TC),** and **Dolutegravir (DTG).**

Table 1: Baseline Characteristics of Study Population (n = 55)

Variable	Category	N (%)
Age group (years)	21–30	8 (14.55)
	31–40	8 (14.55)
	41–50	16 (29.09)
	51–60	19 (34.55)
	>60	4 (7.27)
Gender	Male	39 (70.9)
	Female	16 (29.1)
Initial ART regimen	TDF+3TC+EFV	46 (83.6)
	TDF+3TC+DTG	9 (16.4)

Adherence Before and After Intervention

Table 2: Adherence Before and After Intervention

Adherence (%)	Before Intervention N (%)	After Intervention N (%)

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<80	14 (25.45)	3 (5.45)
80–95	11 (20.0)	16 (29.09)
>95	30 (54.55)	36 (65.45)
Total	55 (100)	55 (100)

p = 0.013 (Significant)

A statistically significant improvement in treatment Adherence was observed following the intervention **(p = 0.013)**. The proportion of patients with poor Adherence (<80%) decreased markedly from 25.45% to 5.45%, whereas those demonstrating high Adherence (>95%) increased from 54.55% to 65.45%.

Opportunistic Infections

The most common opportunistic infection was **pulmonary tuberculosis (14.55%)**, followed by **oral candidiasis (5.45%)**. Other infections were less frequent (1.82–3.64%).

Table 3: Opportunistic Infections in Study Population

Infection	N (%)
Pulmonary TB	8 (14.55)
Oral candidiasis	3 (5.45)
TB lymphadenitis	2 (3.64)
Abdominal TB	1 (1.82)
CMV retinitis	1 (1.82)
Herpes genitalis	1 (1.82)
Pneumonia	1 (1.82)
TB abscess	1 (1.82)
TB effusion	1 (1.82)

A strong association was observed between **poor Adherence and higher incidence of opportunistic infections** (**p < 0.001**). Patients with **>95% Adherence predominantly had no infections**.

Treatment Failure

Table 4: Types of Treatment Failure

Type of Failure	N (%)
Clinical	19 (34.55)
Immunological	10 (18.18)
Virological	9 (16.36)

The prevalence of treatment failure was notable, with clinical failure observed in 34.55% of patients, immunological failure in 18.18%, and virological failure in 16.36%, indicating a substantial burden across multiple parameters of treatment response.

Association between Adherence and Treatment Failure

Table 5: Association between Adherence and Treatment Failure

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Adherence	Clinical Failure (%)	Immunological Failure (%)	Virological Failure (%)
<80	57.89	90	66.67
80–95	31.58	10	33.33
>95	10.53	0	0

P < 0.01 (Highly significant for all)

A statistically significant association was observed between baseline Adherence and all forms of treatment failure ($p < 0.01$). A majority of patients with clinical failure (57.89%), immunological failure (90%), and virological failure (66.67%) had baseline Adherence of less than 80%, indicating a strong correlation between poor adherence and adverse treatment outcomes.

Causes of Poor Adherence

Table 6: Causes of Poor Adherence

Cause	N (%)
Forgetfulness	6 (10.91)
GI intolerance	6 (10.91)
Alcoholism	5 (9.09)
Renal toxicity	3 (5.45)
Insomnia	2 (3.64)
Osteoporosis	1 (1.82)
Social stigma	1 (1.82)

The most common causes of poor Adherence were forgetfulness (10.91%), gastrointestinal intolerance (10.91%), and alcoholism (9.09%). Forgetfulness demonstrated a highly significant association with Adherence ($p < 0.001$), while alcoholism was also found to be significantly associated ($p = 0.035$).

Drug Substitution

Table 7: Drug Substitution due to Adverse Effects

Cause	Substitute Drug	N (%)
Renal toxicity	Tenofovir Alafenamide	3 (5.45)
Osteoporosis	Abacavir	1 (1.81)
Total	—	4 (7.26)

Total of 7.26% of patients required substitution of Tenofovir Disoproxil Fumarate (TDF) due to adverse effects, of which renal toxicity accounted for 5.45% and osteoporosis for 1.81% of cases.

Discussion

In the present study, the majority of HIV patients belonged to the 51–60 years age group (34.55%), with a mean age of 46.62 ± 12.33 years. In contrast, Ajith Sivadasan et al.[15], Teshome W et al.[16], and Ayalew MB et al.[17] reported lower mean ages of 38.9 ± 8.4 years, 36.9 ± 9.2 years, and 34.4 years, respectively. The higher mean age observed in the present study may reflect improved survival with antiretroviral therapy and a shift toward older age groups.

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In the present study, males constituted 70.9% of cases, indicating a clear male predominance. Similar findings were reported by Ajith Sivadasan et al.[15] (74.8% males) and Sandeep Rai et al.[18] (76% males). However, Ayalew MB et al.[17] reported female predominance (60.3%). These differences may be attributed to sociocultural factors and variations in healthcare access and utilization.

Regarding treatment patterns, in the present study, TDF+3TC+EFV was the most commonly initiated first-line regimen (83.6%), followed by TDF+3TC+DTG (16.4%). In contrast, Ajith Sivadasan et al.[15] reported the use of d4T+3TC+NVP and AZT+3TC+NVP regimens, while Ayalew MB et al.[17] reported zidovudine- and tenofovir-based regimens. This reflects a shift in current practice toward safer and more effective tenofovir-based therapies.

In the present study, 76.36% of patients were switched from TDF+3TC+EFV to TDF+3TC+DTG in accordance with updated guidelines[14], indicating increasing adoption of dolutegravir-based regimens. Drug substitution due to toxicity was observed in 7.26% of patients, most commonly due to tenofovir-related renal toxicity and osteoporosis. In contrast, Ajith Sivadasan et al.[15] reported higher rates of toxicity-related regimen changes (27%), and Kumarasamy N et al.[19] reported adverse effects such as rash, hepatotoxicity, and anemia. The lower rate of toxicity observed in the present study may be attributed to improved regimen safety and better monitoring.

Overall, the findings of the present study highlight evolving treatment practices and an aging HIV population, while also emphasizing the importance of adherence-focused interventions, including counselling and regimen optimization, to improve treatment outcomes.

Limitations Of The Study

The study is limited by its small sample size and single-center design, which may affect generalizability. Its observational nature precludes causal inference. Adherence assessment relied partly on self-reporting and may be subject to bias, and the short follow-up limits evaluation of long-term outcomes.

Conclusion

In conclusion, treatment adherence remains a key determinant of therapeutic success among PLHIV. Targeted interventions such as counselling and regimen optimization significantly improve Adherence and reduce treatment failure. Strengthening adherence strategies is essential to enhance long-term treatment outcomes.

References

1. National Institutes of Health. Treatment goals [Internet]. Available from: https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adultand-adolescent-arv/treatment-goals
2. Saravanan S, Kausalya B, Dinesha T, Boobalan J, Sivamalar S, Gomathi S, et al. Immune activation is associated with poor CD4 reconstitution: A study from South India. J Virus Erad. 2019;5:6–7.
3. The Pharmaceutical Journal. The World Health Organization warns of increasing HIV drug resistance and issues new guidelines to address threat. Pharm J. 2017.
4. Llibre JM. Time to get serious with HIV-1 resistance in sub-Saharan Africa. Lancet Infect Dis. 2017;17(3):241–3.
5. Charles K, Mireille ME, Pierrette OB, Sabrina EDD, Sandrine L, Sylvie B, et al. Dolutegravir-based or low-dose efavirenz–based regimen for the treatment of HIV-1. N Engl J Med. 2019;381:816–26.
6. Calmy A, Pascual F, Ford N. First-line and second-line antiretroviral therapy. Lancet. 2004;364(9431):329.
7. Wainberg MA, Han YS, Mesplède T. Might dolutegravir be part of a functional cure for HIV? Can J Microbiol. 2016;62(5):375–82.
8. Inzaule SC, Hamers RL, Doherty M, Shafer RW, Bertagnolio S, Rinke de Wit TF. Curbing the rise of HIV drug resistance in low-income and middle-income countries: The role of dolutegravir-containing regimens. Lancet Infect Dis. 2019;19(7):e246–52.
9. Vitoria M, Hill A, Ford N, Doherty M, Clayden P, Venter F, et al. The transition to dolutegravir and other new antiretrovirals in low- and middle-income countries: What are the issues? AIDS.

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2018;32(12):1551–61. Available from: https://pubmed.ncbi.nlm.nih.gov/29746295/

10. Lal V, Kant S, Dewan R, Rai S, Biswas A. A two-site hospital-based study on factors associated with nonadherence to highly active antiretroviral therapy. Indian J Public Health. 2010;54(4):179.
11. Osterberg L, Blaschke T. Adherence to medication. N Engl J Med. 2005;353(5):487–97.
12. Stone VE, Hogan JW, Schuman P, Rompalo AM, Howard AA, Korkontzelou C, et al. Antiretroviral regimen complexity, self-reported adherence, and HIV patients' understanding of their regimens. J Acquir Immune Defic Syndr. 2001;28(2):124–31.
13. Ajithkumar K, Neera P, Rajani P. Relationship between social factors and treatment adherence: A study from South India. East J Med. 2011;16:147–52. Available from: https://dergipark.org.tr/en/download/article-file/62090
14. National AIDS Control Organization. National guidelines for HIV: care and treatment 2021. New Delhi: NACO, Ministry of Health and Family Welfare; 2021. Available from: https://naco.gov.in/sites/default/files/National_Guidelines_for_HIV_Care_and_Treatment_2021.pdf
15. Teshome W, Asefa A, et al. Predictors of immunological failure of antiretroviral therapy among HIV-infected patients in Ethiopia: a matched case-control study. PLoS One. 2015;10(5):e0128393. doi:10.1371/journal.pone.0128393
16. Ajith S, Abraham OC, Rupali P, Pulimood SA, Rajan J, Rajkumar S, et al. High rates of regimen change due to drug toxicity among a cohort of South Indian adults with HIV infection initiated on generic first-line antiretroviral treatment. J Assoc Physicians India. 2009;57:384–8.
17. Ayalew MB, Kumilachew D, Belay A, et al. First-line antiretroviral treatment failure and associated factors in HIV patients at the University of Gondar Teaching Hospital, Northwest Ethiopia. HIV AIDS (Auckl). 2016;8:141–6. doi:10.2147/HIV.S112048
18. Rai S, Mahapatra B, Sircar S, Raj PY, Venkatesh S, et al. Adherence to antiretroviral therapy and its effect on survival of HIV-infected individuals in Jharkhand, India. PLoS One. 2013;8(6):e66860. doi:10.1371/journal.pone.0066860
19. Kumarasamy N, Vallabhaneni S, Cecelia AJ, Yepthomi T, Balakrishnan P, et al. Reasons for modification of generic highly active antiretroviral therapeutic regimens among patients in southern India. J Acquir Immune Defic Syndr. 2006;41(1):53–8.

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