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COMPARISON STUDY ON IMMUNOVIROLOGICAL AND CLINICAL RESPONSE OF DOLUTEGRAVIR BASED REGIMEN WITH OTHER ANTIRETROVIRAL THERAPY BASED REGIMENS IN PEOPLE LIVING WITH HIV/AIDS: A LONGITUDINAL STUDY.

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Abstract

Background: Antiretroviral therapy (ART) has transformed HIV infection into a chronic manageable disease. Dolutegravir (DTG), an integrase strand transfer inhibitor, has emerged as a preferred first-line ART because of its high antiviral potency, favourable safety profile, and high genetic barrier to resistance. However, comparative data between DTG-based and non-DTG-based regimens remain limited in the Indian setting. ***Methods:*** A longitudinal comparative study was conducted at the Centre of Excellence ART Centre, Regional Institute of Medical Sciences (RIMS), Imphal, from March 2023 to March 2025. Ninety-six HIV-positive adults were enrolled, including 48 participants receiving DTG-based regimens and 48 receiving non-DTG regimens. Clinical response, CD4 count, viral load, metabolic profile, liver function parameters, adherence, and adverse events were evaluated at enrolment, 6 months, and 12 months. Statistical analysis was performed using SPSS version 26, with $p < 0.05$ considered significant. ***Results:*** At 12 months, virological suppression with target-not-detected viral load was achieved in 97.9% of participants in the DTG group and 95.8% in the non-DTG group. Mean CD4 count at 12 months was significantly higher in the DTG group (454.5 ± 212.5 cells/μL) compared with the non-DTG group (371.8 ± 183.4 cells/μL; $p=0.04$). Significant CD4 improvement from baseline was observed in both groups, though greater in the DTG cohort. BMI increased significantly in the DTG group over one year ($p=0.03$). Random blood sugar levels increased modestly in both groups. Liver function parameters remained stable throughout follow-up. Insomnia was the most common adverse event but decreased over time in both groups. ***Conclusion:*** DTG-based ART demonstrated superior immunological recovery with excellent virological suppression and acceptable tolerability compared with non-DTG regimens. These findings support the continued use of DTG as a preferred first-line ART regimen while highlighting the importance of metabolic monitoring during long-term therapy.

Keywords: Dolutegravir, HIV, Antiretroviral therapy, CD4 count, Viral suppression, Immunological response.

INTRODUCTION

Human immunodeficiency virus (HIV) infection continues to remain a major global public health challenge despite remarkable advances in diagnosis, treatment, and prevention strategies. According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), approximately 39 million people were living with HIV globally in recent years, with substantial disease burden persisting in low- and middle-income countries. The introduction and widespread availability of antiretroviral therapy (ART) have significantly reduced HIV-associated morbidity and mortality, transforming HIV infection from a fatal disease into a chronic manageable condition.1,2

Modern ART regimens consist of combinations of drugs acting at different stages of the HIV replication cycle. Current standard therapy generally includes two nucleoside reverse transcriptase inhibitors (NRTIs) combined with either a non-

nucleoside reverse transcriptase inhibitor (NNRTI), protease inhibitor (PI), or integrase strand transfer inhibitor (INSTI).3 Among these classes, INSTIs have emerged as highly effective agents due to their potent antiviral activity, rapid viral suppression, favourable safety profile, fewer drug-drug interactions, and improved tolerability.4

Dolutegravir (DTG), a second-generation integrase strand transfer inhibitor, has become one of the most preferred first-line ART agents worldwide. DTG inhibits the integration of viral DNA into the host genome by binding to the integrase enzyme, thereby preventing viral replication.5 Several randomized controlled trials have demonstrated superior virological suppression and robust immunological recovery with DTG-based regimens compared with efavirenz-based or protease inhibitor-based regimens.6,7 Additionally, DTG possesses a high genetic barrier to resistance, making it particularly useful in treatment-naïve individuals as well as in treatment-experienced patients.8

The World Health Organization (WHO) currently recommends DTG-based ART as the preferred first-line regimen for adults and adolescents living with HIV.9 Similarly, the National AIDS Control Organization (NACO) in India has incorporated Tenofovir + Lamivudine + Dolutegravir (TLD) as the preferred first-line regimen under the national ART programme.10 The rapid adoption of DTG has largely been driven by its efficacy, simplified dosing schedule, low pill burden, and excellent long-term treatment outcomes.

Despite the substantial advantages of DTG-based regimens, emerging evidence has raised concerns regarding metabolic complications including weight gain, hyperglycaemia, obesity, and cardiovascular risk.11,12 Neuropsychiatric adverse effects such as insomnia, anxiety, and depression have also been reported in some observational studies, although the incidence remains relatively low.13 Furthermore, data regarding the safety and efficacy of DTG-based regimens among Indian populations, especially in the North-Eastern region of India, remain limited.

Immunological recovery following ART initiation is primarily assessed using CD4+ T lymphocyte counts, while virological response is evaluated through plasma viral load suppression. Effective ART is expected to achieve sustained viral suppression with gradual restoration of immune function.14 Studies have consistently shown that earlier initiation of ART and stronger viral suppression correlate with better long-term clinical outcomes.15 However, differences in treatment response may occur because of demographic factors, baseline disease severity, adherence, comorbidities, and treatment-related toxicities.

Several international studies including the SINGLE, GEMINI, and FLAMINGO trials have demonstrated favourable outcomes with DTG-based regimens in terms of virological suppression and CD4 recovery.16–18 However, comparative evidence from real-world clinical settings in India remains scarce. Moreover, there is limited information regarding the long-term metabolic and clinical effects of DTG among people living with HIV/AIDS (PLHIV) in resource-limited settings.

The present study was therefore conducted to compare the immunovirological and clinical response of Dolutegravir-based regimens with other non-DTG antiretroviral regimens among PLHIV attending the Centre of Excellence ART Centre at Regional Institute of Medical Sciences (RIMS), Imphal, Manipur. The study also aimed to assess adverse events, metabolic outcomes, and safety profiles associated with these regimens.

MATERIALS AND METHODS

Study Design and Study Setting- This longitudinal comparative study was conducted in the Department of Medicine and Centre of Excellence (CoE) ART Centre, Regional Institute of Medical Sciences (RIMS), Imphal, Manipur, over a period of two years from March 2023 to March 2025. The CoE ART Centre caters to a large number of HIV-positive patients from different districts of Manipur and neighbouring states.

Study Population- The study population included adult HIV-positive patients who were initiated on either Dolutegravir-based antiretroviral therapy or non-Dolutegravir-based ART regimens and were attending the CoE ART Centre or admitted to the Medicine wards during the study period.

Inclusion Criteria

1. HIV-positive patients aged 18 years or older.
2. Patients receiving DTG-based ART regimens.
3. Patients receiving non-DTG-based ART regimens.
4. Patients willing to provide informed written consent.

Exclusion Criteria

1. Patients without baseline viral load reports.

2. Terminally ill patients.
3. Patients with established psychiatric illness.
4. Patients likely to migrate during follow-up resulting in attrition.

Sample Size- The sample size was calculated using standard statistical formulae based on expected virological suppression rates among DTG and non-DTG groups. The calculated minimum sample size was 48 participants in each group. Therefore, a total of 96 participants were enrolled in the study, including 48 participants in the DTG group and 48 participants in the non-DTG group.

Sampling Technique- Convenience sampling method was employed. Eligible patients fulfilling the inclusion and exclusion criteria were consecutively enrolled until the desired sample size was achieved.

Study Variables

Independent Variables

1. Age
2. Sex
3. Weight and BMI
4. Duration of HIV diagnosis
5. Adherence to ART
6. Presence of comorbidities
7. Opportunistic infections
8. ART regimen

Dependent Variables

1. CD4 count
2. Viral load
3. Clinical symptoms and adverse events
4. Blood sugar levels
5. Liver function parameters

Data Collection Procedure- After obtaining informed written consent, detailed demographic and clinical information was collected using a structured proforma. Baseline investigations including CD4 count, viral load, blood sugar levels, liver function tests, and anthropometric measurements were recorded. Follow-up assessments were performed at 6 months and 12 months after enrolment.

Clinical assessment included evaluation of WHO clinical staging, opportunistic infections, adherence, and treatment-related adverse effects. ART adherence was assessed according to NACO guidelines, with adherence greater than 95% considered optimal.

Laboratory Investigations

CD4 Count: CD4+ T lymphocyte count was estimated using Fluorescence Activated Cell Sorter (FACS) methodology at baseline, 6 months, and 12 months.

Viral Load: Plasma viral load estimation was performed using Abbott RealTime HIV-1 assay with a lower detection limit of 150 copies/mL.

Liver Function Tests: Serum SGOT and SGPT levels were estimated using standard biochemical methods.

Blood Sugar Estimation: Random blood sugar (RBS) levels were measured at baseline and follow-up visits.

Outcome Definitions- Immunological Response: Improvement in CD4 count from baseline following ART initiation.

Virological Suppression: Plasma viral load less than detectable limits (<150 copies/mL).

Virological Failure: Plasma viral load ≥1000 copies/mL after at least 6 months of ART with adequate adherence.

Adverse Events: Any undesirable clinical or laboratory abnormality occurring during ART treatment.

Ethical Considerations- Ethical approval for the study was obtained from the Research Ethics Board, RIMS, Imphal. Written informed consent was obtained from all participants prior to enrolment. Confidentiality of patient data was strictly maintained throughout the study.

Statistical Analysis- Collected data were entered into Microsoft Excel and analysed using Statistical Package for Social Sciences (SPSS) version 26. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Paired t-test and appropriate statistical tests were used to compare outcomes within and between groups. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 96 HIV-positive participants were included in the study, comprising 48 participants receiving Dolutegravir-based regimens (DTG group) and 48 participants receiving non-Dolutegravir-based regimens (non-DTG group). Participants were followed for 12 months with assessment at enrolment, 6 months, and 12 months.

Table 1. Baseline demographic and clinical characteristics of study participants (N=96)

Variable	DTG Group (n=48)	Non-DTG Group (n=48)
Age 21–40 years	23 (47.9%)	20 (41.7%)
Age ≥41 years	18 (37.5%)	20 (41.7%)
Male sex	29 (60.4%)	32 (66.7%)
WHO Stage I	44 (91.6%)	43 (89.6%)
Diabetes Mellitus	3 (6.2%)	2 (4.2%)
Hypertension	4 (8.4%)	6 (12.5%)
Pulmonary Tuberculosis	5 (10.4%)	4 (8.4%)
HCV Coinfection	6 (12.5%)	4 (8.4%)
Adherence >95%	46 (95.8%)	45 (93.7%)

Most participants in both groups belonged to the 21–40 years age category. Male predominance was observed in both groups. The majority of participants were classified as WHO clinical stage I at enrolment. Common comorbidities included hypertension, diabetes mellitus, pulmonary tuberculosis, and hepatitis C virus coinfection. Treatment adherence was excellent in both groups, with more than 95% adherence observed among the majority of participants.

Table 2. Comparison of BMI between DTG and non-DTG groups during follow-up

Time Period	DTG Mean ± SD	Non-DTG Mean ± SD	p-value
At enrolment	23.5 ± 3.0	22.6 ± 1.5	0.05
At 6 months	23.6 ± 2.9	22.3 ± 1.2	0.006
At 12 months	23.8 ± 2.8	22.5 ± 1.2	0.007

At baseline, BMI was comparable between the two groups. However, participants receiving DTG-based regimens demonstrated significantly greater BMI increase during follow-up compared with the non-DTG group. Significant weight gain was observed within the DTG group at 12 months (p=0.03), whereas no significant BMI change was observed in the non-DTG group.

Table 3. Clinical complaints among participants during follow-up

Complaint	DTG Enrolment	DTG 12 Months	Non-DTG Enrolment	Non-DTG 12 Months
Fatigue	7 (14.6%)	5 (10.4%)	6 (12.5%)	4 (8.3%)
Fever	10 (20.8%)	0	11 (22.9%)	0
No Complaints	31 (64.6%)	43 (89.6%)	31 (64.6%)	44 (91.7%)

Fever and fatigue were common symptoms at enrolment in both groups. Fever resolved completely by 12 months in all participants. The proportion of asymptomatic individuals progressively increased during follow-up, with more than 89% of participants in both groups reporting no complaints at 12 months.

Table 4. Comparison of CD4 count between DTG and non-DTG groups during follow-up

Time Period	DTG Mean ± SD (cells/µL)	Non-DTG Mean ± SD (cells/µL)	p-value
At enrolment	225.1 ± 187.4	252.8 ± 189.7	0.47
At 6 months	285.5 ± 163.7	260.9 ± 151.5	0.46
At 12 months	454.5 ± 212.5	371.8 ± 183.4	0.04

Baseline CD4 counts were comparable between groups. Both groups demonstrated progressive improvement in CD4 count during follow-up; however, immunological recovery was significantly greater in the DTG group at 12 months. Within-group analysis showed significant increase in CD4 count from baseline to 12 months in both groups, with greater magnitude of improvement among DTG recipients.

Table 5. Distribution of viral load suppression during follow-up

Viral Load Status	DTG Enrolment	DTG 12 Months	Non-DTG Enrolment	Non-DTG 12 Months
Target Not Detected	42 (87.5%)	47 (97.9%)	41 (85.4%)	47 (95.8%)
150–999 copies/mL	1 (2.1%)	1 (2.1%)	2 (4.2%)	2 (4.2%)
≥1000 copies/mL	5 (10.4%)	0	5 (10.4%)	0

Substantial virological improvement was observed in both groups during follow-up. By 12 months, nearly all participants achieved target-not-detected viral load levels, with slightly higher suppression rates in the DTG group. Significant reductions in viral load were observed within both groups during follow-up.

Table 6. Distribution of adverse events during follow-up

Adverse Event	DTG 6 Months	DTG 12 Months	Non-DTG 6 Months	Non-DTG 12 Months
Insomnia	8 (16.6%)	4 (8.3%)	7 (14.5%)	3 (6.2%)
Depression	0	0	0	0

Insomnia was the most frequently reported adverse event in both groups, although its incidence decreased over time. No participant developed depression or severe neuropsychiatric adverse events during the study period.

Table 7. Comparison of random blood sugar levels during follow-up

Time Period	DTG Mean ± SD (mg/dL)	Non-DTG Mean ± SD (mg/dL)	p-value
At enrolment	102.2 ± 24.8	101.2 ± 23.9	0.50
At 6 months	106.4 ± 21.2	107.2 ± 22.2	0.04
At 12 months	114.3 ± 37.8	115.1 ± 36.1	0.04

Random blood sugar levels increased modestly during follow-up in both groups. Significant increases from baseline were observed within both DTG and non-DTG groups over one year of therapy.

Table 8. Comparison of liver function parameters during follow-up

Parameter	DTG Group at 12 Months Mean ± SD	Non-DTG Group at 12 Months Mean ± SD	p-value
SGOT (IU/mL)	45 ± 29.1	44 ± 23.2	0.05
SGPT (IU/mL)	52 ± 22.4	50 ± 23.5	0.05

Liver function parameters remained stable throughout the study period in both treatment groups. No statistically significant differences in SGOT or SGPT levels were observed between the DTG and non-DTG groups, indicating good hepatic safety profile of both ART regimens.

DISCUSSION

The present longitudinal comparative study evaluated the immunological, virological, clinical, and metabolic outcomes among people living with HIV/AIDS receiving Dolutegravir-based antiretroviral therapy compared with non-Dolutegravir-based regimens. The findings of the present study demonstrated that DTG-based regimens were associated with superior immunological recovery, excellent virological suppression, acceptable tolerability, and favourable overall clinical outcomes over a follow-up period of 12 months.

In the present study, the majority of participants belonged to the 21–40 years age group, with male predominance in both treatment arms. These findings are comparable to previous HIV epidemiological studies conducted in India and other developing countries, where HIV infection is more common among economically productive young adults [16,17]. The predominance of male participants observed in the present study may reflect gender-related differences in healthcare utilization, exposure risk factors, and HIV testing patterns.

The majority of participants in both groups were classified under WHO clinical stage I at enrolment, indicating relatively early diagnosis and initiation of therapy. Early ART initiation has been consistently associated with improved long-term outcomes, better immune restoration, and reduced HIV-related morbidity and mortality [18]. Similar observations were reported in the GEMINI and SINGLE trials, where most participants initiating DTG-based therapy were in early stages of HIV infection [16,19]. The comparable distribution of WHO clinical stages between the two groups in the present study minimized the possibility of baseline disease severity influencing treatment outcomes.

One of the most important findings of this study was the superior immunological recovery observed among participants receiving DTG-based regimens. At 12 months, the mean CD4 count in the DTG group was significantly higher compared

with the non-DTG group. Furthermore, within-group analysis showed significant increases in CD4 counts from baseline to both 6 months and 12 months among DTG recipients. These findings are consistent with studies conducted by Cahn et al., Sax et al., and Cruciani et al., which demonstrated superior immune restoration with DTG-based therapy compared with efavirenz-based and protease inhibitor-based regimens [16,17,20].

The enhanced immunological response observed with DTG may be attributed to its potent antiviral activity, rapid viral suppression, and high genetic barrier to resistance. Improved immune recovery is clinically important because higher CD4 counts are associated with lower incidence of opportunistic infections, improved quality of life, and reduced mortality among people living with HIV/AIDS [21]. The present findings therefore support the role of DTG as an effective first-line ART regimen capable of achieving robust immune restoration.

Virological suppression rates in the present study were excellent in both groups, although slightly higher in the DTG group. By 12 months, target-not-detected viral load was achieved in 97.9% of participants in the DTG group compared with 95.8% in the non-DTG group. Significant reductions in viral load were observed within both treatment groups during follow-up. Similar findings have been reported in international clinical trials and meta-analyses evaluating DTG-based ART regimens [20,22]. Kanters et al. and Bagella et al. reported consistently high rates of virological suppression with DTG-based therapy among treatment-naïve individuals [22,23].

The superior virological efficacy of DTG may be explained by its favourable pharmacokinetic profile, rapid onset of action, and reduced likelihood of resistance development. The high rates of viral suppression observed in the present study also indicate good adherence to therapy among participants, which is essential for sustained treatment success and prevention of drug resistance.

Another important finding of the present study was the significant increase in BMI observed among participants receiving DTG-based regimens. At 12 months, the DTG group demonstrated significantly greater BMI values compared with the non-DTG group. Significant weight gain within the DTG group was also observed during follow-up. These findings are consistent with studies by Taramasso et al. and Hickey et al., who reported increased weight gain among patients receiving DTG-containing regimens [24,25].

The mechanism of DTG-associated weight gain remains incompletely understood. Proposed mechanisms include improved appetite following viral suppression, reduced resting energy expenditure, direct metabolic effects of integrase inhibitors, and alterations in adipocyte differentiation. Although moderate weight gain after ART initiation may reflect clinical improvement and recovery from chronic illness, excessive weight gain may predispose patients to obesity, diabetes mellitus, metabolic syndrome, and cardiovascular disease [26]. Therefore, regular monitoring of body weight and metabolic parameters is essential among patients receiving long-term DTG-based therapy.

In the present study, random blood sugar levels increased modestly but significantly in both treatment groups during follow-up. Slightly greater increases were observed among participants receiving DTG-based regimens. Similar findings have been reported by Odenyo et al. and Ankunda et al., who observed elevated blood glucose levels among HIV-positive patients receiving DTG therapy [27,28]. Although the increases observed in the present study were not clinically severe, they highlight the importance of regular metabolic monitoring, particularly among patients with pre-existing risk factors for diabetes mellitus.

Clinical symptoms improved progressively during follow-up in both groups. Fever, which was commonly reported at enrolment, resolved completely during follow-up. The proportion of participants without complaints increased substantially by 12 months, indicating overall clinical improvement with ART. Similar observations have been reported in previous studies evaluating the effectiveness of modern ART regimens, where successful viral suppression and immune restoration resulted in reduction of HIV-related symptoms and opportunistic infections [29].

Insomnia was the most commonly reported adverse event in both treatment groups, although the frequency decreased over time. No cases of depression or severe neuropsychiatric adverse events were reported during the study period. Neuropsychiatric side effects associated with DTG have been reported in previous observational studies. Rossetti et al. documented insomnia and sleep disturbances among DTG recipients, particularly during the early months of therapy [30]. However, the relatively low incidence and gradual improvement of insomnia observed in the present study suggest that DTG remains generally well tolerated.

Liver function parameters including SGOT and SGPT remained stable throughout the study period in both treatment groups, with no evidence of clinically significant hepatotoxicity. Similar findings have been reported in studies by Fenta et al. and Jemal et al., where DTG-based regimens demonstrated favourable hepatic safety profiles [31,32]. Preservation

of liver function is particularly important among HIV-positive individuals because of the high prevalence of coinfections such as hepatitis B and hepatitis C, as well as exposure to potentially hepatotoxic medications.

Adherence to ART was excellent in both groups, with more than 95% adherence observed among the majority of participants. High adherence rates likely contributed to the favourable virological outcomes observed in the study. The once-daily dosing schedule, low pill burden, and good tolerability associated with DTG-based therapy may improve adherence and long-term treatment satisfaction among patients [33].

The present study has several strengths, including prospective follow-up, direct comparison between DTG and non-DTG regimens, and comprehensive evaluation of immunological, virological, clinical, and metabolic outcomes. However, certain limitations should also be acknowledged. The study was conducted at a single tertiary care centre with relatively small sample size, which may limit generalizability of findings. Additionally, the follow-up duration of 12 months may not be sufficient to fully evaluate long-term metabolic and cardiovascular complications associated with DTG therapy. Larger multicentric studies with longer follow-up duration are therefore warranted.

Overall, the findings of the present study support the continued use of DTG-based ART regimens as preferred first-line therapy among people living with HIV/AIDS because of their superior immunological recovery, excellent virological suppression, and favourable safety profile.

CONCLUSION

The present study demonstrated that Dolutegravir-based antiretroviral therapy provided superior immunological recovery with excellent virological suppression compared with non-Dolutegravir-based regimens among people living with HIV/AIDS. Participants receiving DTG-based therapy showed significantly greater improvement in CD4 count over 12 months while maintaining high rates of viral suppression and good treatment adherence.

Both treatment regimens were generally well tolerated, with insomnia being the most commonly reported adverse event. Significant weight gain and modest increases in blood sugar levels were observed among participants receiving DTG-based therapy, highlighting the importance of long-term metabolic monitoring. Liver function parameters remained stable in both groups, indicating favourable hepatic safety profiles.

Overall, the findings of the present study support the continued use of Dolutegravir-based regimens as preferred first-line ART because of their superior efficacy, strong immunological response, and acceptable safety profile. Further multicentric studies with larger sample sizes and longer follow-up duration are recommended to evaluate the long-term metabolic and cardiovascular effects associated with DTG therapy.

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