

Comparative efficacy and safety of dolutegravir/lamivudine versus ainoovirine-based triple therapy in people living with HIV: a real-world cohort study

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Research Article

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Abstract

Background

Optimizing antiretroviral therapy (ART) requires balancing virological efficacy with long-term safety. Evidence comparing two-drug regimens with emerging non-nucleoside reverse transcriptase inhibitor (NNRTI)-based triple regimens in real-world settings remains limited.

Methods

We conducted a retrospective cohort study including 216 people living with HIV (PLWH) who received either dolutegravir/lamivudine (DTG/3TC) or abacavir/lamivudine/tenofovir disoproxil fumarate (ANV/3TC/TDF) at Zhenjiang Third People's Hospital between January 2019 and January 2026. Participants were followed for at least 12 months. Virological suppression, immunological recovery ($CD4^+$ T-cell count and $CD4^+ / CD8^+$ ratio), and safety outcomes including hepatic, renal, metabolic parameters, body weight, and body mass index (BMI) were assessed.

Results

At 12 months, virological suppression rates were comparable between the DTG/3TC and ANV/3TC/TDF groups (94.45% vs. 84.45%, $P = 0.24$). Both regimens resulted in significant immunological improvement, with no between-group differences at study endpoint. The DTG/3TC group showed higher levels of serum creatinine and lipid parameters, including low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), and non-high-density lipoprotein Cholesterol (non-HDL-C), whereas high-density lipoprotein cholesterol (HDL-C) was also significantly elevated. No significant differences were observed in liver function, body weight, or BMI.

Conclusions

DTG/3TC and ANV/3TC/TDF demonstrated comparable virological efficacy and similar hepatic safety profiles. However, differences in renal biomarkers and lipid metabolism were observed. These findings highlight the importance of individualized ART selection based on metabolic and renal risk profiles.

Introduction

Despite substantial advances in antiretroviral therapy (ART), HIV infection remains a major global public health concern[1]. With increasing life expectancy among people living with HIV (PLWH), the clinical focus has shifted from short-term viral suppression to long-term health outcomes, including the management of non-acquired immunodeficiency syndrome (AIDS)-related comorbidities such as cardiovascular disease and metabolic disorders[2, 3].

Modern ART strategies emphasize regimen simplification, improved tolerability, and reduced drug–drug interactions[4]. Integrase strand transfer inhibitor INSTI-based regimens, particularly DTG, are widely recommended as first-line therapy due to their high efficacy and favorable resistance profile[5]. The two-drug regimen DTG/3TC has been validated in randomized clinical trials as a viable simplification strategy[6, 7].

However, INSTI-based regimens have been associated with metabolic alterations, including weight gain and dyslipidemia, which may influence long-term cardiovascular risk[8]. In parallel, elvitegravir (ANV), a novel NNRTI, has emerged as a promising alternative due to its improved tolerability and activity against common resistance mutations[9, 10].

To date, real-world comparative data between DTG-based dual therapy and ANV-based triple therapy remain scarce. This study aimed to evaluate and compare their virological efficacy, immunological outcomes, and safety profiles in a real-world clinical setting.

Methods

1. Study design and participants

This retrospective cohort study included HIV-1-infected adults treated at the Department of Infectious Diseases, Zhenjiang Third People's Hospital between January 1, 2019 and January 31, 2026.

Inclusion criteria: Age ≥ 18 years; Receiving DTG/3TC or ANV/3TC/TDF; Continuous treatment without regimen switch; Follow-up duration ≥ 12 months. Exclusion criteria: Hepatitis B virus co-infection; Baseline drug resistance; Missing key clinical data; Pregnancy or breastfeeding

2. Data collection

Baseline demographic and clinical characteristics were collected, including age, sex, body weight, BMI, HIV RNA levels, CD4⁺ T-cell count, liver function, renal function, and lipid profile.

Outcomes

1. Primary outcome: Virological suppression (HIV RNA below detection threshold)

2. Secondary outcomes: CD4⁺ and CD8⁺ T-cell counts; CD4⁺ /CD8⁺ ratio; Liver function (alanine aminotransferase(ALT), aspartate aminotransferase(AST)); Renal function (serum creatinine(Cr), blood urea nitrogen(BUN)); Lipid profile (LDL-C, HDL-C, TC, triglycerides(TG)); Body weight and BMI changes

Statistical analysis

Statistical analyses were performed using Python (version 3.9.13). Continuous variables were expressed as mean $\pm$ standard deviation or median (interquartile range), depending on distribution. Between-group comparisons were conducted using Student's t-test or Mann–Whitney U test. Categorical variables were analyzed using the chi-square test. A two-sided P-value < 0.05 was considered statistically significant.

Results

1. Baseline characteristics

A total of 216 participants were included, with 126 in the DTG/3TC group and 90 in the ANV/3TC/TDF group. Baseline characteristics were well balanced between groups, including age, sex distribution, immunological status, and biochemical parameters. Further details were displayed in Table 1. In the DTG/3TC group, there were 47 treatment-naïve patients (37.30%), while in the ANV/3TC/TDF group, there were 81 treatment-naïve patients (90.00%).

Table 1
Comparison of baseline characteristics between the two groups

Variable	DTG/3TC (n = 126)	ANV/3TC/TDF (n = 90)	t value	P value
Male, n (%)	112 (88.89)	78 (86.67)	—	—
Age (years)	41.17 ± 14.93	49.07 ± 15.05	-4.82	< 0.005
Weight (kg)	67.34 ± 9.76	69.10 ± 13.58	-0.88	0.38
BMI (kg/m ²)	23.02 ± 3.34	23.68 ± 4.41	-0.95	0.35
CD4 ⁺ (/μL)	406.01 ± 233.06	455.82 ± 299.16	-1.44	0.15
CD4 ⁺ /CD8 ⁺ ratio	0.63 ± 0.46	0.69 ± 0.45	-0.93	0.35
ALT (U/L)	29.94 ± 30.79	31.94 ± 22.14	-0.55	0.58
AST (U/L)	24.81 ± 21.38	25.27 ± 11.57	-0.20	0.84
Cr (μmol/L)	78.37 ± 17.52	77.02 ± 18.82	0.57	0.57
BUN (mmol/L)	5.08 ± 1.53	5.22 ± 1.64	-0.71	0.48
UA (μmol/L)	347.63 ± 84.26	332.01 ± 97.05	1.31	0.19
LDL-C (mmol/L)	2.57 ± 0.78	2.63 ± 0.81	-0.58	0.56
HDL-C (mmol/L)	1.11 ± 0.31	1.08 ± 0.35	0.63	0.53
TC (mmol/L)	4.36 ± 1.26	4.42 ± 1.00	-0.34	0.73
TG (mmol/L)	2.19 ± 1.91	2.36 ± 2.46	-0.58	0.56
non-HDL-C (mmol/L)	3.28 ± 1.29	3.36 ± 1.00	-0.46	0.64
Note. Data are presented as mean ± SD or n (%). DTG, dolutegravir; 3TC, lamivudine; ANV, ainoovirine; TDF, tenofovir disoproxil fumarate; BMI, body mass index; ALT, alanine aminotransferase; AST, aspartate aminotransferase; Cr, creatinine; BUN, blood urea nitrogen; UA, uric acid; LDL-C, low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; TC, total cholesterol; TG, triglyceride; non-HDL-C, non-high-density lipoprotein cholesterol. P values were calculated using independent-samples t-test for continuous variables.				

Table.1 Baseline characteristics of patients in the DTG/3TC group versus the ANV/3TC/TDF group.

2.Virological outcomes

After 12 months of ART, both regimens achieved high rates of virological suppression, with no statistically significant difference between groups(Fig. 1).

Figure 1.Virological suppression status after one year of antiviral therapy.

3. Immunological outcomes

Both treatment groups demonstrated significant increases in CD4⁺ and CD8⁺ T-cell counts (Table 2&3). The CD4⁺ /CD8⁺ ratio improved significantly within the DTG/3TC group. However, no significant differences were observed between groups at study endpoint (Table 4).

Table 2
Changes in immunological indicators at baseline and study endpoint in the DTG/3TC group

Immune indicator	Baseline	Study endpoint	t value	P value
CD4 ⁺ (/μL)	406.01 ± 233.06	593.03 ± 269.70	-6.01	< 0.005
CD8 ⁺ (/μL)	764.24 ± 419.92	889.73 ± 446.93	-2.32	0.02
CD4 ⁺ /CD8 ⁺ ratio	0.63 ± 0.46	0.79 ± 0.44	-2.71	0.01
Note. Data are presented as mean ± SD. CD4 ⁺ , CD4-positive T lymphocyte count; CD8 ⁺ , CD8-positive T lymphocyte count. P values were calculated using paired-samples t-test.				

Table 3
Changes in immunological indicators at baseline and study endpoint in the ANV/3TC/TDF group

Immune indicator	Baseline	Study endpoint	t value	P value
CD4 ⁺ (/μL)	455.82 ± 299.16	607.34 ± 306.80	-3.4	< 0.005
CD8 ⁺ (/μL)	764.80 ± 423.54	904.74 ± 506.52	-2	0.05
CD4 ⁺ /CD8 ⁺ ratio	0.69 ± 0.45	0.80 ± 0.47	-1.6	0.11
Note. Data are presented as mean ± SD. CD4 ⁺ , CD4-positive T lymphocyte count; CD8 ⁺ , CD8-positive T lymphocyte count. P values were calculated using paired-samples t-test.				

Table 4
Comparison of immunological indicators at study endpoint between the two groups

Immune indicator	DTG/3TC group	ANV/3TC/TDF group	t value	P value
CD4 ⁺ (/μL)	593.03 ± 269.70	607.34 ± 306.80	-0.36	0.72
CD8 ⁺ (/μL)	889.73 ± 446.93	904.74 ± 506.52	-0.23	0.82
CD4 ⁺ /CD8 ⁺ ratio	0.79 ± 0.44	0.80 ± 0.47	-0.23	0.82
Note. Data are presented as mean ± SD. CD4 ⁺ , CD4-positive T lymphocyte count; CD8 ⁺ , CD8-positive T lymphocyte count. P values were calculated using independent-samples t-test.				

4. Safety outcomes

4.1Hepatic and Renal safety

No significant differences in liver enzyme levels were observed between the two groups, and no cases of clinically significant hepatotoxicity were identified. Serum creatinine levels were significantly higher in the DTG/3TC group, whereas blood urea nitrogen levels were comparable between groups (Table 5).

Table 5
Comparison of liver and kidney function at study endpoint between the two groups

Variable	DTG/3TC group	ANV/3TC/TDF group	t value	P value
ALT (U/L)	27.94 ± 19.16	27.35 ± 15.60	0.25	0.8
AST (U/L)	21.88 ± 8.36	22.34 ± 7.78	-0.42	0.67
Cr (µmol/L)	83.83 ± 20.99	70.81 ± 19.03	4.80	< 0.005
BUN (mmol/L)	5.54 ± 1.53	5.49 ± 1.70	0.27	0.79
Note. Data are presented as mean ± SD. ALT, alanine aminotransferase; AST, aspartate aminotransferase; Cr, creatinine; BUN, blood urea nitrogen. P values were calculated using independent-samples t-test.				

4.2Metabolic outcomes

The DTG/3TC group exhibited significantly higher levels of LDL-C, TC, and non-HDL-C. Notably, HDL-C levels were also higher in this group (Table 6).

Table 6
Comparison of lipid profiles at study endpoint between the two groups

Variable	DTG/3TC group	ANV/3TC/TDF group	t value	P value
LDL-C (mmol/L)	2.74 ± 0.71	2.51 ± 0.69	2.48	0.01
HDL-C (mmol/L)	1.05 ± 0.25	0.94 ± 0.23	3.38	< 0.005
TC (mmol/L)	4.74 ± 0.92	4.35 ± 0.98	3.03	< 0.005
TG (mmol/L)	2.05 ± 1.36	1.99 ± 1.53	0.33	0.74
non-HDL-C (mmol/L)	3.69 ± 0.91	3.42 ± 0.96	2.21	0.03
Note. Data are presented as mean ± SD. LDL-C, low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; TC, total cholesterol; TG, triglyceride; non-HDL-C, non-high-density lipoprotein cholesterol. P values were calculated using independent-samples t-test.				

4.3Body weight and BMI

No significant differences were observed between groups in body weight, BMI, or their changes over the 12-month follow-up period (Table 7).

Table 7
Changes in body weight and BMI between the two groups

Variable	DTG/3TC group	ANV/3TC/TDF group	t value	P value
Weight (kg)	68.44 ± 11.48	68.38 ± 13.44	0.04	0.97
BMI (kg/m ²)	23.55 ± 3.46	23.49 ± 4.06	0.11	0.91
ΔWeight (kg)	1.08 ± 5.14	0.25 ± 3.29	1.03	0.31
ΔBMI (kg/m ²)	0.35 ± 1.88	-0.03 ± 1.18	1.67	0.10

Note. Data are presented as mean ± SD. BMI, body mass index; ΔWeight, change in body weight from baseline to study endpoint; ΔBMI, change in BMI from baseline to study endpoint. P values were calculated using independent-samples t-test.

Discussion

With the iterative development of antiretroviral therapy (ART) and advances in clinical research, the life expectancy of people living with HIV (PLWH) has increased substantially. The current goals of HIV treatment extend beyond viral suppression to include treatment safety and comprehensive management of comorbidities[11]. In this context, simplification and optimization of ART regimens have become a key clinical focus. This study compared the efficacy and safety of a dolutegravir (DTG)-based dual therapy (DTG/3TC) with a traditional anenovirine (ANV)-based triple therapy (ANV/3TC/TDF). The results demonstrated comparable virological suppression rates, with differences in metabolic and renal safety, providing useful guidance for individualized regimen selection.

1) Virological efficacy

Our findings are consistent with previous large-scale trials. Both treatment-naïve and treatment-experienced patients showed no statistically significant differences between DTG/3TC and ANV/3TC/TDF regimens, supporting conclusions from the GEMINI-1/2 and TANGO studies that DTG-based dual therapy achieves virological suppression comparable to traditional triple therapy without evidence of resistance enrichment[12, 13].

CD4⁺ /CD8⁺ ratio: While baseline CD4⁺ /CD8⁺ ratios were similar between groups, post-treatment ratios in the DTG/3TC group increased significantly compared to baseline. This suggests that DTG/3TC may provide a greater advantage in immune reconstitution. The effect may be attributed to the potent and rapid viral suppression of integrase inhibitors like dolutegravir, which effectively reduce chronic immune activation and systemic inflammation associated with HIV[14, 15]. Improvements in the CD4⁺ /CD8⁺ ratio may indicate enhanced immune restoration and have been associated with a reduced risk of non-AIDS-related morbidity in virally suppressed PLWH [16].

2) Drug safety

Hepatic and renal function:

No significant differences in hepatic safety were observed between groups. Regarding renal safety, serum creatinine was higher in the DTG/3TC group. Data from phase III GEMINI trials suggest a 10–15% increase in serum creatinine in some patients during the first 1–4 weeks of therapy, which stabilizes thereafter[12]. This phenomenon results from reversible inhibition of renal organic cation transporter 2 (OCT2) and multidrug and toxin extrusion (MATE) transporters by DTG, leading to reduced tubular secretion of creatinine rather than true glomerular filtration impairment[17]. Monitoring cystatin C and calculating eGFR using cystatin C–based CKD-EPI formulas are recommended. Tubular function can also be evaluated using urinary N-acetyl-β-D-glucosaminidase (NAG) and urinary β2-microglobulin.

TDF is hydrolyzed to tenofovir (TFV), primarily excreted via the kidneys. Intracellular accumulation of TFV in renal tubular epithelial cells can induce mitochondrial dysfunction and impaired reabsorption, potentially manifesting as Fanconi syndrome or other tubular injuries[18]. Given the 12-month follow-up of this study, long-term TDF-associated nephrotoxicity may not have been fully captured. Continuous monitoring of creatinine, BUN, urinary β2-microglobulin, and NAG is warranted.

Lipid profile and body weight:

Dyslipidemia is an important parameter for assessing long-term ART safety and is closely linked to cardiovascular risk. LDL-C is recognized as an independent risk factor for atherosclerotic cardiovascular disease (ASCVD)[19]. In this study, the DTG/3TC group had significantly higher LDL-C, total cholesterol, and non-HDL-C levels compared to the ANV/3TC/TDF group (non-HDL-C: 3.69 ± 0.91 mmol/L vs 3.42 ± 0.96 mmol/L, $t = 2.21$, $p = 0.03$), suggesting a potential increase in long-term cardiovascular risk. These findings are consistent with reports of integrase inhibitor–associated dyslipidemia[20, 21]. HDL-C was also elevated in the DTG/3TC group, partially offsetting adverse effects, while triglycerides did not differ significantly. Overall, the ANV/3TC/TDF regimen demonstrated a more stable lipid profile, indicating a possible advantage in lipid management.

Body weight:

Weight gain has been observed in patients receiving INSTI-based regimens, particularly DTG, which may increase the risk of metabolic syndrome [8, 22]. Although the present study did not show statistically significant differences in weight change over 12 months, longer follow-up is needed to evaluate potential metabolic complications.

Clinical implications:

Our findings suggest that DTG/3TC dual therapy provides virological efficacy comparable to conventional ANV/3TC/TDF triple therapy while offering potential advantages in immune reconstitution. However, differences in lipid and renal safety profiles highlight the need for individualized regimen selection based

on patient comorbidities and risk factors. Close monitoring of renal function, lipid metabolism, and body weight is recommended during long-term treatment.

Limitations

This study has several limitations, including its retrospective design, single-center setting, and relatively small sample size. Additionally, heterogeneity between treatment-naïve and treatment-experienced patients was not fully stratified. Residual confounding factors, such as concomitant lipid-lowering therapy, may also have influenced the results.

Conclusions

DTG/3TC and ANV/3TC/TDF provide comparable virological efficacy and similar hepatic safety in PLWH. However, differences in renal biomarkers and lipid metabolism highlight the need for individualized treatment selection based on patient-specific risk factors.

Abbreviations

3TC
lamivudine
AIDS
acquired immunodeficiency syndrome
ALT
alanine aminotransferase
ANV
ainuovirine
ART
antiretroviral therapy
AST
aspartate aminotransferase
BMI
body mass index
BUN
blood urea nitrogen
Cr
serum creatinine
DTG
dolutegravir
HDL-C
high-density lipoprotein cholesterol

LDL-C
low-density lipoprotein cholesterol
NNRTI
non-nucleoside reverse transcriptase inhibitor
non-HDL-C
non-high-Density lipoprotein cholesterol
PLWH
people living with HIV
TC
total cholesterol
TDF
tenofovir disoproxil fumarate
TG
triglycerides
UA
uric acid

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of Zhenjiang Third People's Hospital (approval number: AF01-SOP-G-14-04.2) Written informed consent was obtained from all participants prior to inclusion in the study.

Consent for publication

Not applicable.

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Author Contribution

L.W. and H.H. conceived and designed the study. L.W., Y.B. and J.W. collected the clinical data. Y.B. performed the data curation. L. W. is the first author and led the study design and data collection, statistical analysis and drafted the original manuscript. H.H. supervised the study, acquired funding, and

revised the manuscript critically for important intellectual content. All authors reviewed, edited and approved the final manuscript. H.H. is the guarantor of this work.

Data Availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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Figures

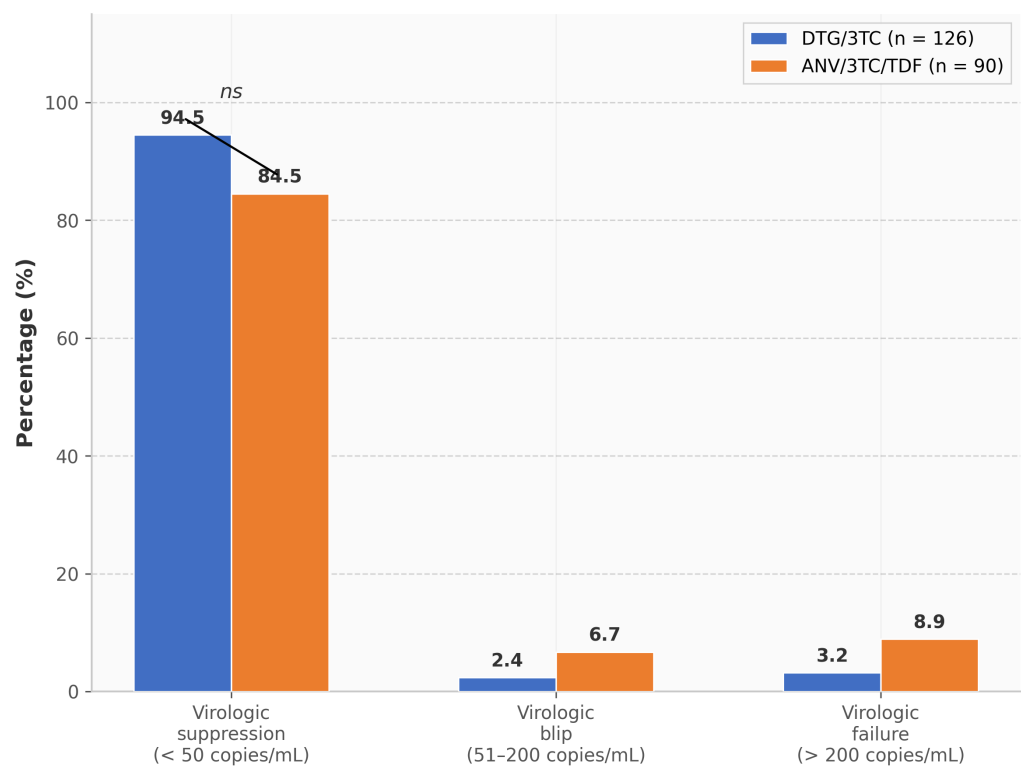


Figure 1

Virologic outcomes at 1 year after antiviral therapy.

No statistically significant difference was observed between the two groups in virologic suppression rate (P = 0.24).