

Metabolic Health Consequences of Switching to the Bictegravir/Emtricitabine/Tenofovir Alafenamide and Dolutegravir Plus Lamivudine Regimens in Virologically Suppressed People Living with HIV Aged > 40 Years: A Retrospective Real-World Study

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Objective: Both B/F/TAF and DTG/3TC are recommended in treatment guidelines for switch therapy in PLWH. This study aimed to evaluate the safety and metabolic health consequences of two switched regimens in a real-world setting among virologically suppressed PLWH previously treated with EFV/TDF/3TC.

Methods: This retrospective real-world study in Hangzhou included 220 virologically suppressed PLWH who switched from EFV/TDF/3TC to DTG/3TC or B/F/TAF between January 1, 2020 and October 30, 2023. All participants were examined the changes in weight, BMI, GLU levels, lipid parameters (TC, LDL-C, HDL-C, and TG), and eGFR at post-12-month.

Results: The mean age of included participants was 50.8 years (SD: 11.3). After 12 months of switching, the HIV RNA level was below the limit of detection (< 20 copies/mL) among all participants. The switch to DTG/3TC or B/F/TAF therapy was associated with significant improvement in LDL-C, GLU levels, and eGFR values (all $P < 0.05$), while other metabolic indexes did not change significantly. Furthermore, there was a significant difference in the incidence of hyperglycemia (5.7% vs 19.35%; $P = 0.004$) between the B/F/TAF and DTG/3TC groups, but not included the mean changes of weight, BMI, lipid profiles, GLU levels, and eGFR and incidence of high TC and high TG. For the aged 40–59 years and aged ≥ 60 years PLWH, the differences in metabolic indicators were minimal between DTG/3TC and B/F/TAF groups post-12-month, with no significant differences between the arms in mean change from baseline in TC, TG, HDL-C, LDL-C, GLU, BMI, weight, and eGFR.

Conclusion: In this study, the B/F/TAF or DTG/3TC regimens are safe for virologically suppressed PLWH aged > 40 years. The transition to B/F/TAF demonstrated dual clinical benefits, significantly reducing hyperglycemia incidence while preserving renal function.

Keywords: people living with HIV, virological suppression, antiretroviral therapy, metabolic indices

Introduction

Acquired immunodeficiency syndrome (AIDS), caused by the human immunodeficiency virus (HIV), is a great threat to public health. Currently, antiretroviral therapy (ART) is the most effective treatment for HIV infection; ART efficiently blocks viral replication and achieves immune reconstitution, thus providing substantial benefits to people living with HIV (PLWH).^{1–3} Standard ART comprises two nucleoside reverse transcriptase inhibitors (NRTI) with a core drug that may

include a non-nucleoside reverse transcriptase inhibitor (NNRTI), boosted protease inhibitor (PI), or integrase strand transfer inhibitor (INSTI).⁴ With extended lifespans, PLWH require drug treatment for decades and face chronic age-related diseases (such as incomplete immune reconstitution, metabolic abnormalities, reproductive dysfunction, and AIDS-related cancers) and damage from long-term drug treatment.^{4,5} Therefore, optimized ART regimens are needed to avoid drug side effects (including dyslipidaemia and poorly controlled glucose) and improve tolerance while maintaining antiviral efficacy.

Currently, dolutegravir (DTG) and bictegravir (BIC) are the most commonly used integrase inhibitors for PLWH, with high resistance barrier, better efficacy and safety profiles, and fewer drug-drug interactions.^{6,7} Thus, DTG- or BIC-based regimens are recommended for initial and switch therapy in PLWH.^{8,9} In comparison to other 2-drug or 3-drug INSTI-based treatments, regimens of BIC/emtricitabine/tenofovir alafenamide (B/F/TAF) and DTG plus lamivudine (DTG/3TC) are currently more often prescribed clinically (including trials) for ART-naïve and virologically suppressed individuals.^{10–12} In Chinese cohort, Wei et al found that ART-naïve PLWH who adopted B/F/TAF regimens experienced a faster viral decline and fewer drug-related adverse effects (DRAEs) compared to those adopting DTG/3TC regimens.⁷ Gan et al proved that DTG/3TC and B/F/TAF regimens are well tolerated and effective for ART-naïve PLWH.¹³ Currently, research in China mainly focuses on comparing DTG/3TC and B/F/TAF as initial treatment regimens, with fewer comparative studies on switching to DTG/3TC and B/F/TAF after treatment. Although Gan et al reported favorable efficacy and tolerability when switching to these two regimens in PLWH with diverse ART histories,⁹ the heterogeneity in prior treatment exposure may introduce confounding factors. On the other hand, while multiple non-mainland clinical trials have demonstrated sustained virologic suppression after switching to either B/F/TAF or DTG/3TC in treatment-experienced individuals,^{14–17} the pharmacokinetic and pharmacodynamic profiles may differ across racial groups.¹⁸ Therefore, comparative studies evaluating switches to DTG/3TC versus B/F/TAF in Chinese patients with identical baseline ART regimens are warranted.

As outlined in the 2011 China National Guidelines for HIV/AIDS Diagnosis and Treatment, the efavirenz + lamivudine + tenofovir (EFV/TDF/3TC) regimen has been recommended as first-line therapy for Chinese populations and remains widely used in clinical practice.¹⁹ In 2019, dolutegravir (DTG) superseded EFV in first-line regimens due to its superior efficacy, higher genetic barrier to resistance, favorable safety profile, and cost-effectiveness.²⁰ While tenofovir alafenamide (TAF) is the preferred alternative to tenofovir disoproxil fumarate (TDF) for patients with renal impairment, clinicians must carefully balance its renal protective effects against potential metabolic adverse effects, including dyslipidemia and weight gain.²¹ To date, robust clinical evidence remains insufficient to fully characterize the safety and metabolic profiles of switching ART-experienced PLWH to either bictegravir/emtricitabine/TAF (B/F/TAF) or dolutegravir/lamivudine (DTG/3TC) regimens, with limited data available from both controlled trials and real-world studies. Thus, differences in safety and metabolic health consequences among DTG/3TC and B/F/TAF groups must be investigated in the context of the same naïve regimen EFV/TDF/3TC.

Previous studies have highlighted the significant incidence of metabolic syndrome in ART-naïve PLWH in China, and showed that older age (40 years and over) had significant associations with metabolic diseases, including diabetes, hyperglycemia and others.^{22–24} In addition, there are significant associations between age (> 40 years) and metabolic diseases among PLWH.²⁵ ART-naïve or ART-experienced PLWH of age \geq 60 years have more frequent comorbidities, including metabolic diseases.²⁶ Though some studies have focused on elderly PLWH switching to B/F/TAF or DTG/3TC, there have been limited data regarding changes of biochemical indicators of aged 40–59 years or aged \geq 60 years groups after switching to B/F/TAF or DTG/3TC.

To address this knowledge gap, we conducted a single-center study to investigate and compare the safety and metabolic health consequences among virologically suppressed adult (> 40 years) PLWH who switching from EFV/TDF/3TC to DTG/3TC and B/F/TAF regimens. Notably, this study included the incidence of ART-related metabolic disorders at baseline and after switch 12-month for the Chinese populations.

Methods

Study Population and Design

This retrospective real-world study included 220 virologically suppressed PLWH who switched from EFV/TDF/3TC to DTG/3TC or B/F/TAF between January 1, 2020 and October 30, 2023 at Hangzhou Xixi Hospital, the largest dedicated AIDS

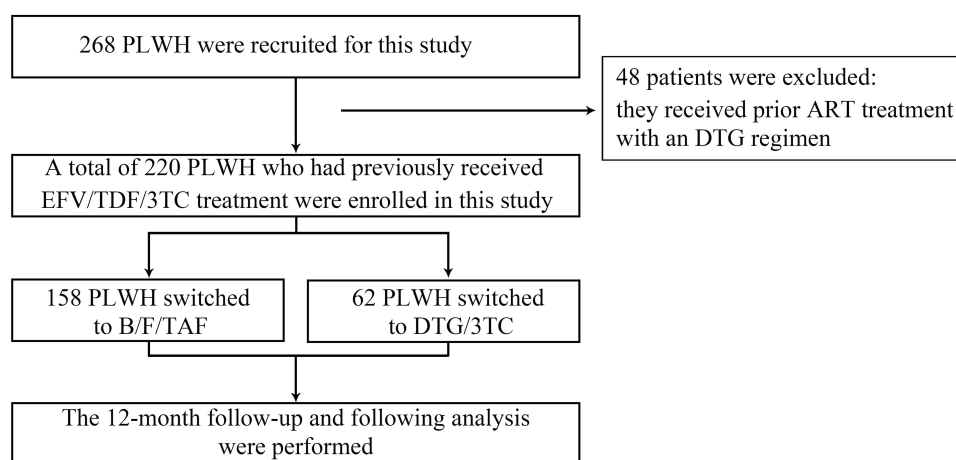


Figure 1 Study flow diagram. A total of 220 PLWH were included in the study.

Abbreviations: PLWH, people living with HIV; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; DTG/3TC, dolutegravir/lamivudine.

hospital in Zhejiang Province, China. The inclusion criteria were: (1) receiving ART treatment with an EFV/TDF/3TC regimen for at least 6 months, (2) plasma HIV RNA < 50 copies/mL for at least 6 months, (3) age ≥ 40 years, (4) followed over the period 2020–2023. The exclusion criteria were: (1) pregnancy, (2) allergic history or high degree of sensitivity to any component or auxiliary material of the research drug, (3) with history of virologic failure (2 consecutive measurements ≥ 200 copies/mL), (4) receiving prior ART treatment with an DTG regimen. By these criteria, 48 PLWH were excluded because of prior DTG treatment. The remaining 220 PLWH received prior ART treatment with an EFV/TDF/3TC regimen for at least 6 months after HIV diagnosis. Among them, according to the different reasons and recommended usage guidelines for regimen switch, 62 and 158 PLWH switched to DTG/3TC or B/F/TAF regimens, respectively.

Baseline demographic data and clinical variables were collected from the Electronic Medical Records (EMR) management system; data included age, sex, weight, body mass index (BMI), smoking status, drinking status, hepatitis B virus (HBV) status, high blood pressure (HBP) status, diabetes status, and ART therapy time. A study flowchart is shown in Figure 1.

Outcomes of Interest

The primary outcome was the differences in weight, BMI, lipid profiles, glucose (GLU) levels, and eGFR between 12-month and baseline among virologically suppressed PLWH who switched from EFV/TDF/3TC to DTG/3TC or B/F/TAF. The secondary outcome were differences in the mean changes of the above metabolic indicators from baseline to post-12-month between DTG/3TC and B/F/TAF regimens.

Variables

To assess the study endpoint, we collected the data of the primary variables including weight, BMI, Tg, TC, LDL-C, HDL-C, GLU, creatinine, and estimated glomerular filtration rate (eGFR) at the time of switching (baseline measurement) and after 12 months. Changes in weight, BMI, and metabolic variables were calculated as the difference between post-12-month value with respect to the baseline measurement. The eGFR was calculated from serum creatinine using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula.²⁷

Diagnostic Standards

The diagnosis of dyslipidaemia (high TG or High TC) is an abnormally elevation of TG (TG level > 1.7 mmol/L) or TC (TC level > 5.2 mmol/L); the diagnosis of dysglycemia is an abnormally elevation of GLU (fasting glucose level ≥ 5.6 mmol/L) in the blood.²⁸

Statistical Analysis

All statistical analyses were performed using SPSS (v.25.0). Normally distributed continuous variables were described and compared using the means with standard deviations (SD) and *t*-test, respectively. Variables with non-normal distributions were described and compared using the median (M) and interquartile range (IQR, 1st quartile, 3rd quartile) and nonparametric Wilcoxon signed-rank tests (paired or unpaired), respectively. Categorical variables were reported with numbers and percentages. Proportions were compared using Pearson's Chi-square test. All graphs were created using GraphPad Prism 8 software (GraphPad Software Inc., San Diego, CA, USA).²⁹ All reported levels of statistical significance were two-sided, and *p*-value < 0.05 or lower were considered statistically significant.

Results

Baseline Characteristics of the Study Population

A total of 220 PLWH were enrolled in this study. As shown in Table 1, the primary reasons for regimen switch among 220 PLWH were the side effects (*n* = 57; 25.9%) and regimen simplification (*n* = 93; 42.3%). The mean participant age was 50.8 years (SD: 11.3). The cohort was 88.6% male and 11.4% female, with a mean BMI of 23.0 (SD: 2.7). The mean ART therapy time was 5.3 years (SD: 2.7). The CD4⁺ T cells count < 200 cells/μL, 200–499 cells/μL and ≥ 500 accounted for 6.4%, 43.2% and 50%, respectively. At baseline and post-12-month, the HIV RNA level was below the lower limit of detection (< 20 copies/mL) among all participants.

Table 1 Baseline Characteristics of All Participants (*n* = 220)

Characteristics	Values
Age, years (before switching), (Mean ± SD)	50.8 ± 11.3
Sex, <i>n</i> (%)	
Male	195 (88.6)
Female	25 (11.4)
Smoking, <i>n</i> (%)	
Yes	40 (18.2)
No	179 (81.4)
Unkown	1 (0.4)
Drinking, <i>n</i> (%)	
Yes	69 (31.4)
No	150 (68.2)
Unkown	1 (0.4)
BMI, (Mean ± SD)	23.0 ± 2.7
Weight, (Mean ± SD)	66.8 ± 9.2
HBP, <i>n</i> (%)	
Yes	24 (10.9)
No	196 (89.1)
Diabetes, <i>n</i> (%)	
Yes	14 (6.4)
No	206 (93.6)
HBV status, <i>n</i> (%)	
Positive	17 (7.7)
Negative	203 (92.3)
ART therapy time, years (before switching), (Mean ± SD)	5.3 ± 2.7
HIV viral load < 20 copies/mL (before switching), <i>n</i> (%)	220 (100)
CD4 ⁺ T (cells/μL), <i>n</i> (%)	
< 200	14 (6.4)
200–499	95 (43.2)
≥ 500	110 (50)
Unkown	1 (0.4)

(Continued)

Table 1 (Continued).

Characteristics	Values
Reasons for switching ART, n (%)	
Patient's request	22 (10.0)
Side effects	57 (25.9)
Regimen simplification	93 (42.3)
Economic reasons	6 (2.7)
Reason not specified	42 (19.1)

Abbreviations: BMI, body mass index; HBP, high blood pressure; HBV, hepatitis B virus; ART, antiretroviral therapy; HIV, human immunodeficiency virus; CD4⁺ T, CD4-positive T cells; SD, standard deviation.

Changes in the Levels of Clinical Indicators Among PLWH at 12-month After Switching to B/F/TAF or DTG/3TC Regimens

We compared the BMI, weight, and metabolic indices of PLWH after switching from EFV/TDF/3TC to DTG/3TC or B/F/TAF regimens between baseline and post-12-month. The metabolic changes are shown in [Figure 2](#) and [Table S1](#). Regarding blood lipid parameters, the levels of low-density lipoprotein cholesterol (LDL-C) at 12-month were significantly higher than at baseline (2.72 vs 2.43, $P = 0.001$, [Figure 2D](#)). There were significant decreases in glucose (GLU) level (5.58 vs 5.41, $P = 0.005$, [Figure 2E](#)) between two time points. Regarding renal function parameter, the change of estimated glomerular filtration rate (eGFR) was also markedly decreased at post-12-month (98.7 vs 89.2, $P < 0.001$, [Figure 2H](#)). However, another three metabolic parameters including total cholesterol (TC), triglyceride (TG), high-density lipoprotein cholesterol (HDL-C) did not change markedly from baseline to post-12-month (all $P > 0.05$, [Figure 2A–C](#) and [Table S1](#)). In addition, the absolute mean BMI at baseline vs at 12-month was 23.02 vs 23.35 kg/m² ([Figure 2F](#)), and the adjusted mean weight gain from baseline to 12-month

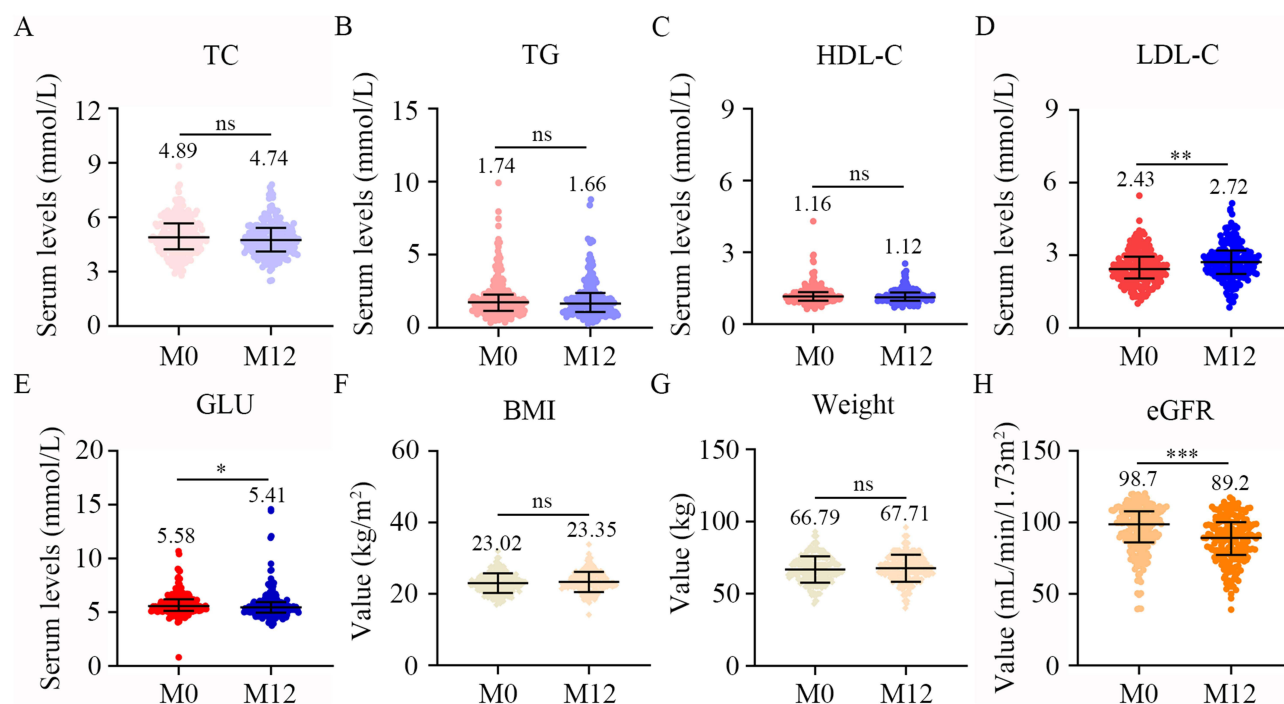


Figure 2 Changes in metabolic indicators from baseline to 12-month. The levels of TC (**A**), TG (**B**), HDL-C (**C**), LDL-C (**D**), and GLU (**E**) at baseline and 12-month. The values of BMI (**F**), weight (**G**), and eGFR (**H**) at baseline and 12-month. ns $P > 0.05$, * $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$.

Abbreviations: TC, total cholesterol; TG, triglyceride; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; GLU, glucose; BMI, body mass index; eGFR, estimated glomerular filtration rate.

(66.79 vs 67.71) was 0.92 kg among PLWH who switching to B/F/TAF or DTG/3TC regimens (Figure 2G), but there was no statistical significance (Both $P > 0.05$, Figure 2 and Table S1).

For PLWH cohort who switched to B/F/TAF, Table 2 summarizes the changes in metabolic indicators of PLWH at post-12-month. Comparing to the baseline, the LDL-C level (2.45 vs 2.73, $P < 0.001$) was clearly higher, and GLU level (5.59 vs 5.4, $P = 0.009$) and eGFR value (99.4 vs 90.47, $P < 0.001$) were significantly lower at post-12-month (Table 2). Nevertheless, other metabolic indices (including TC, TG, HDL-C levels, and BMI, and weight) and the incidence of hyperglycemia, high TC and high TG were comparable (All $P > 0.05$) (Table 2).

For PLWH cohort who switched to DTG/3TC, Table 3 summarizes the changes in metabolic indicators of PLWH at post-12-month. As shown in Table 3, comparing to the baseline, the eGFR value was dramatically reduced (92.7 vs 81.33, $P = 0.014$), but the incidence of hyperglycemia was higher at post-12-month (6.45% vs 19.35%, $P = 0.030$).

Table 2 Comparison of the Metabolic Indexes Between Baseline and Post-12-month Among B/F/TAF Group (n = 158)

Variables	M0	M12	P value
Metabolic indexes			
TC (mmol/L)	4.82 (4.19, 5.58)	4.69 (4.08, 5.31)	0.138
TG (mmol/L)	1.62 (1.07, 2.15)	1.6 (1.05, 2.18)	0.751
HDL-C (mmol/L)	1.17 (1.01, 1.39)	1.13 (0.99, 1.31)	0.146
LDL-C (mmol/L)	2.45 (2.05, 2.91)	2.73 (2.35, 3.2)	< 0.001***
GLU (mmol/L)	5.59 (5.16, 6.15)	5.4 (4.96, 5.86)	0.009**
BMI	22.88 ± 2.62	23.22 ± 2.76	0.191
Weight (kg)	66.53 ± 8.77	67.48 ± 9.01	0.262
eGFR	99.4 (86.9, 108.2)	90.47 (78.66, 100.4)	< 0.001***
Incidence of abnormal metabolic			
Hyperglycemia, n (%)			
Yes	16 (10.12)	9 (5.70)	0.297
No	142 (89.87)	133 (84.17)	
Unknown	0 (0)	16 (10.13)	
High TC			
Yes	58 (36.71)	40 (25.32)	0.729
No	100 (63.29)	102 (64.55)	
Unknown	0 (0)	16 (10.13)	
High TG			
Yes	76 (48.10)	65 (41.14)	0.139
No	82 (51.90)	77 (48.73)	
Unknown	0 (0)	16 (10.13)	

Note: ** $P < 0.01$, *** $P < 0.001$.

Abbreviations: M0, baseline; M12, post-12-month; GLU, glucose; TC, total cholesterol; TG, triglyceride.

Table 3 Comparison of the Metabolic Indexes Between Baseline and Post-12-month Among DTG/3TC Group (n = 62)

Variables	M0	M12	P value
Metabolic indexes			
TC (mmol/L)	4.97 (4.41, 5.74)	5.01 (4.26, 5.55)	0.544
TG (mmol/L)	1.93 (1.21, 3.19)	1.83 (1.24, 3.29)	0.900
HDL-C (mmol/L)	1.09 (0.95, 1.29)	1.08 (0.95, 1.35)	0.850
LDL-C (mmol/L)	2.42 (2.03, 3.1)	2.65 (1.92, 3.19)	0.755
GLU (mmol/L)	5.55 (5.06, 6.32)	5.53 (4.93, 6.5)	0.763
BMI	23.37 ± 3.03	23.67 ± 2.91	0.543

(Continued)

Table 3 (Continued).

Variables	M0	M12	P value
Weight (kg)	67.44 ± 10.01	68.29 ± 10.28	0.561
eGFR	92.7 (80.9, 105.9)	81.33 (69.8, 98.89)	0.014*
Incidence of abnormal metabolic			
Hyperglycemia, n (%)			
Yes	4 (6.45)	12 (19.35)	0.030*
No	56 (90.32)	44 (70.97)	
Unknown	2 (3.23)	6 (9.68)	
High TC			
Yes	27 (43.55)	23 (37.10)	0.851
No	33 (53.22)	33 (53.22)	
Unknown	2 (3.23)	6 (9.68)	
High TG			
Yes	35 (56.45)	31 (50.00)	0.710
No	25 (40.32)	25 (40.32)	
Unknown	2 (3.23)	6 (9.68)	

Note: * $P < 0.05$.

Abbreviations: M0, baseline; M12, post-12-month; GLU, glucose; TC, total cholesterol; TG, triglyceride.

However, eight metabolic indices (including TC, TG, HDL-C, LDL-C, GLU levels, and BMI, and weight, and eGFR) and the incidence of high TC and high TG were comparable (All $P > 0.05$) (Table 3).

Comparison of Metabolic Indicators in DTG/3TC and B/F/TAF Groups

Among 220 PLWH, there were 62 PLWH in the DTG/3TC cohort and 158 PLWH in the B/F/TAF cohort. With the exceptions of HBP and TG ($P < 0.05$), other baseline characteristics were largely similar between the DTG/3TC and B/F/TAF groups (All $P > 0.05$), including age, sex, BMI, smoking status, drinking status, HBV status, diabetes status, ART therapy time, CD4, CD8, CD4/CD8 ratio, GLU, TC, HDL, LDL, ALT, AST, AST/ALT ratio, eGFR (Table S2). First, no adverse reactions and discontinuation were observed among all participants after switching to DTG/3TC or B/F/TAF regimens (Table S3). In addition, Figure 3 and Table S3 demonstrated the differences in metabolic indicators were minimal between DTG/3TC and B/F/TAF groups at post-12-month, with no significant differences between the arms in mean change from baseline in TC, TG, HDL-C, LDL-C and GLU (All $P > 0.05$, Figure 3A–E).

Mean BMI change from baseline to 12-month was +0.332 kg/m² in the B/F/TAF group and +0.231 kg/m² in the DTG/3TC group ($P = 0.688$, Figure 3F and Table S3). Similarly, mean weight change from baseline to 12-month was +0.968 kg in the B/F/TAF group and +0.759 kg in the DTG/3TC group ($P = 0.767$, Figure 3G and Table S3). And so beyond that, mean change from baseline to 12-month in eGFR were comparable between the B/F/TAF and DTG/3TC groups (−6.26 vs −6.99 mL/min/1.73m², $P = 0.721$, Figure 3H and Table S3).

In addition, we compared the differences in the occurrence of abnormal metabolic indexes between B/F/TAF and DTG/3TC groups. At the baseline, there were no significant statistical differences in the occurrence of hyperglycemia (10.12% vs 6.45%), high TC (36.71% vs 43.55%) and high TG (48.1% vs 56.45%) between two groups (All $P > 0.05$) (Table 4). However, at post-12-month, the occurrence of hyperglycemia in DTG/3TC group was significantly higher than those in B/F/TAF group (19.35% vs 5.70%, $P = 0.004$, Table 4). But beyond that, there was no significant difference in the occurrence of high TC (37.1% vs 25.32%) and high TG (50% vs 41.14%) between B/F/TAF and DTG/3TC groups (Both $P > 0.05$, Table 4).

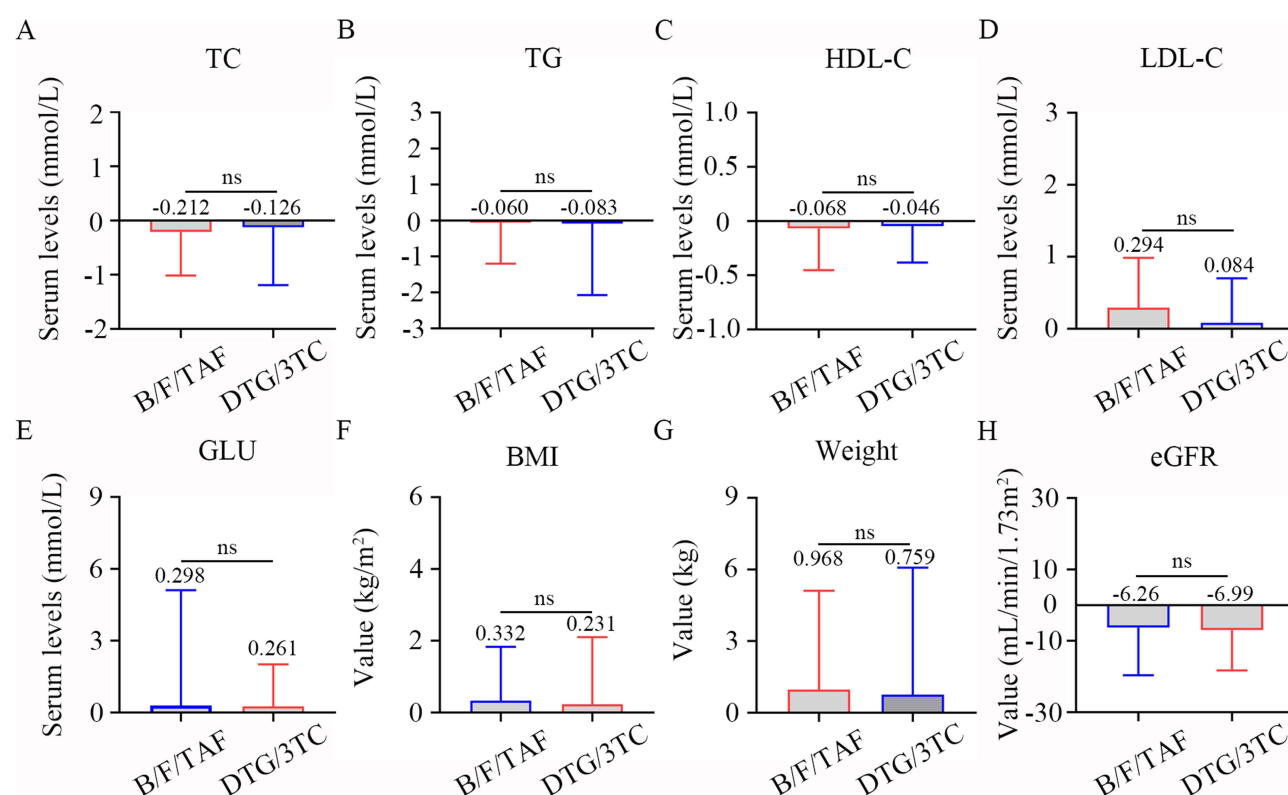


Figure 3 Differences of the mean changes from baseline in metabolic indicators between B/F/TAF and DTG/3TC PLWH. Comparisons of the mean changes in TC (A), TG (B), HDL-C (C), LDL-C (D), and GLU (E), BMI (F), weight (G), and eGFR (H) between two groups. ns $P > 0.05$.

Abbreviations: TC, total cholesterol; TG, triglyceride; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; GLU, glucose; BMI, body mass index; eGFR, estimated glomerular filtration rate.

Changes of Clinical Indicators from Baseline to 12-month for the Middle-Aged (40–59 Years) PLWH or Old-Aged (≥ 60 Years) PLWH

Among middle-aged (40–59 years) PLWH, there were 118 PLWH in B/F/TAF group and 41 PLWH in DTG/3TC group. With the exceptions of ART therapy time, TC, TG and BMI ($P < 0.05$), other baseline characteristics were largely similar

Table 4 Comparison of the Abnormal Metabolic Indexes Between B/F/TAF and DTG/3TC Groups

Variables	B/F/TAF (n = 158)	DTG/3TC (n = 62)	P value
Baseline			
Hyperglycemia, n (%)			
Yes	16 (10.12)	4 (6.45)	0.601
No	142 (89.87)	56 (90.32)	
Unknown	0 (0)	2 (3.23)	
High TC, n (%)			
Yes	58 (36.71)	27 (43.55)	0.279
No	100 (63.29)	33 (53.22)	
Unknown	0 (0)	2 (3.23)	
High TG, n (%)			
Yes	76 (48.10)	35 (56.45)	0.225
No	82 (51.90)	25 (40.32)	
Unknown	0 (0)	2 (3.23)	

(Continued)

Table 4 (Continued).

Variables	B/F/TAF (n = 158)	DTG/3TC (n = 62)	P value
Post-12-month Hyperglycemia, n (%)			
Yes	9 (5.70)	12 (19.35)	0.004**
No	133 (84.17)	44 (70.97)	
Unknown	16 (10.13)	6 (9.68)	
High TC, n (%)			
Yes	40 (25.32)	23 (37.10)	0.091
No	102 (64.55)	33 (53.22)	
Unknown	16 (10.13)	6 (9.68)	
High TG, n (%)			
Yes	65 (41.14)	31 (50.00)	0.270
No	77 (48.73)	25 (40.32)	
Unknown	16 (10.13)	6 (9.68)	

Note: ** $P < 0.01$.

Abbreviations: B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; DTG/3TC, dolutegravir /lamivudine; GLU, glucose; TC, total cholesterol; TG, triglyceride.

between the DTG/3TC and B/F/TAF groups (All $P > 0.05$), including sex, smoking status, drinking status, HBP status, diabetes status, HBV status, CD4, CD8, CD4/CD8 ratio, GLU, HDL, LDL, ALT, AST, AST/ALT ratio, weight, and eGFR (Table S4). We further compared the mean changes in metabolic indicators at post-12-month between B/F/TAF and DTG/3TC groups among middle-aged PLWH. As shown in Table 5, there were no significant differences between B/F/TAF and DTG/3TC groups in mean change from baseline in TC, TG, HDL-C, LDL-C, GLU, BMI, weight, and eGFR (All $P > 0.05$).

For old-aged (≥ 60 years) PLWH, there were 40 B/F/TAF group and 21 DTG/3TC group. With the exceptions of drinking status, HBP status, diabetes status, and ART therapy time ($P < 0.05$), other baseline characteristics were largely similar between the DTG/3TC and B/F/TAF groups (All $P > 0.05$), including sex, smoking status, drinking status, HBP status, diabetes status, HBV status, CD4, CD8, CD4/CD8 ratio, GLU, TC, TG, HDL-C, LDL-C, ALT, AST, AST/ALT

Table 5 Comparison of the Levels of Metabolic Indicators Between B/F/TAF and DTG/3TC Groups Among Aged 40–59 years PLWH

Parameters	B/F/TAF (n = 118)	DTG/3TC (n = 41)	P value
Lipid metabolism markers			
TC (mmol/L)	-0.25 ± 1.01	-0.09 ± 1.02	0.419
TG (mmol/L)	-0.11 ± 1.13	-0.13 ± 2.35	0.840
HDL-C (mmol/L)	-0.43 ± 4.0	-0.04 ± 0.32	0.607
LDL-C (mmol/L)	0.09 ± 2.3	-0.02 ± 0.7	0.795
Other metabolism markers			
GLU (mmol/L)	0.38 ± 5.41	0.20 ± 1.51	0.837
BMI	0.57 ± 2.55	0.24 ± 2.08	0.476
Weight (kg)	1.70 ± 7.78	0.79 ± 5.82	0.507
eGFR	-7.31 ± 17.67	-6.55 ± 11.96	0.810

Abbreviations: TC, total cholesterol; TG, triglyceride; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; BMI, body mass index; GLU, glucose; eGFR, estimated glomerular filtration rate.

Table 6 Comparison of the Levels of Metabolic Indicators Between B/F/TAF and DTG/3TC Groups Among Aged ≥ 60 years PLWH

Parameters	B/F/TAF (n = 40)	DTG/3TC (n = 21)	P value
Lipid metabolism markers			
TC (mmol/L)	-0.27 ± 0.65	-0.19 ± 1.17	0.554
TG (mmol/L)	0.07 ± 1.17	0.01 ± 0.98	0.850
HDL-C (mmol/L)	0.07 ± 0.49	-0.11 ± 0.45	0.203
LDL-C (mmol/L)	0.40 ± 0.94	0.13 ± 0.67	0.288
Other metabolism markers			
GLU (mmol/L)	-0.18 ± 1.53	0.37 ± 2.13	0.287
BMI	0.25 ± 1.93	0.21 ± 1.43	0.939
Weight (kg)	0.69 ± 5.43	0.69 ± 4.31	0.998
eGFR	-5.86 ± 7.57	-7.95 ± 9.97	0.396

Abbreviations: TC, total cholesterol; TG, triglyceride; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; BMI, body mass index; GLU, glucose; eGFR, estimated glomerular filtration rate.

ratio, BMI, weight, and eGFR (Table S5). In addition, Table 6 summarizes the differences in metabolic indicators. The minimal differences between DTG/3TC and B/F/TAF groups were observed at post-12-month, with no significant differences between the arms in mean change from baseline in TC, TG, HDL-C, LDL-C, GLU BMI, weight, and eGFR (All $P > 0.05$).

Discussion

Both B/F/TAF and DTG/3TC are recommended in worldwide treatment guidelines for switch therapy in PLWH.^{30–32} In this study, the switch to B/F/TAF or DTG/3TC regimens was safe and conducive to the decrease of GLU at post-12-month among virologically suppressed adult PLWH who aged > 40 years. While no significant differences in metabolic indices were observed between B/F/TAF and DTG/3TC groups over 12 months. Our data demonstrate that switching to B/F/TAF was associated with a statistically significant reduction in hyperglycemia incidence compared to DTG/3TC.

Prior work has evaluated the safety and efficacy of B/F/TAF and DTG/3TC switch therapy regimens for virologically suppressed adult PLWH (≥ 18 years).³⁰ The current study focused on the switching to B/F/TAF or DTG/3TC in virologically suppressed middle-aged (40–59 years) and old-aged (≥ 60 years) PLWH. We found no significant changes in the majority of biochemical indices among PLWH who switching to B/F/TAF or DTG/3TC regimens; only the levels of LDL-C, GLU and eGFR value varied significantly at post-12-month. The alterations in certain lipid profiles are a typical occurrence following therapeutic regimen changes, a phenomenon that has also been noted in prior clinical research.^{33–35} For example, increases in LDL-C were also observed in Hsu's study.³⁶ One interesting study revealed that higher LDL-C levels in PLWH were associated with a reduced risk of poor immune reconstitution,³⁷ which supports a switch to B/F/TAF or DTG/3TC in virologically suppressed PLWH. These evidence underpins the switch to B/F/TAF or DTG/3TC regimens was safe for middle-aged and elderly PLWH.

Growing evidence supports the use of B/F/TAF as the preferred ART regimens because of their high barrier to resistance.^{11,36,38–40} However, several studies have demonstrated the efficacy of the two-drug DTG/3TC regimen, which is not inferior to the three-drug regimens.^{13,41–43} Thus, we further compared the metabolic health consequences of B/F/TAF and DTG/3TC in real-world settings. Given that the mean age in the DTG/3TC group was slightly higher than in the B/F/TAF group, this age disparity may account for the observed baseline differences in HBP and TG between the two treatment groups. Previous studies showed that HBP was associated with older age among PLWH,⁴⁴ TG levels were higher in the older PLWH.⁴⁵ Except for HBP and TG, other baseline characteristics were largely similar between the DTG/3TC and B/F/TAF groups. We did not detect significant differences between B/F/TAF and DTG/3TC group in the adjusted mean change of weight, BMI, lipid parameters (TC, TG, HDL-C, and LDL-C), and fasting GLU. Furthermore,

our findings are similar to others.^{9,43} A long-term study favored that the changes in weight, fasting GLU and lipid parameters through Week 144 are similar between B/F/TAF and DTG-containing regimens.⁴⁶ Our data showed that there was not significant differences in eGFR value between two groups. Van Wyk J et al' data also favored that the changes in renal biomarkers were similar between DTG/3TC and TAF-based regimens.⁴⁷ On the other hand, although both regimens showed statistically significant eGFR declines after 12 months, these changes may reflect the limited observation period rather than clinically meaningful renal impairment. Importantly, the B/F/TAF group maintained mean eGFR levels within the normal range ($> 90 \text{ mL/min/1.73m}^2$), suggesting preserved renal function. This result may imply that the impact of B/F/TAF regimen on renal function was relative minimal. Longer-term data from our cohort are planned to determine the significance of changes in these parameters.

Interestingly, at post-12-month, the incidence of dysglycemia in the DTG/3TC group was significantly increased, and higher than those in the B/F/TAF group. In addition, we also found that the switch to B/F/TAF treatment lowered GLU level and incidence of hyperglycemia among the virologically suppressed PLWH at post-12-month. A newest findings provide important information regarding the effect of B/F/TAF on the low incidence of treatment-emergent diabetes (dysglycemia) in PLWH.⁴⁶ These data illustrated that the switched B/F/TAF regimens could bring more benefits for virologically suppressed PLWH with hyperglycemia problem.

Another shining point of the article is the comparison of the safety and metabolic health consequences of switching to B/F/TAF or DTG/3TC in old-aged (≥ 60 years) PLWH. Generally, elderly patients with weakened immune systems, especially those over age 60, were more likely to experience comorbidities.²⁶ Previous studies primarily revealed the efficacy and safety of switching to B/F/TAF in older PLWH,^{35,48} which was also observed in our study. In addition, our data also reveals that there were no significant differences between B/F/TAF and DTG/3TC groups in eight metabolic indices among old-aged (≥ 60 years) PLWH. These results highlights either DTG/3TC or B/F/TAF regimens could be considered in virologically suppressed older PLWH.

Our study is not without limitations. First, all safety incidents were self-reported and may be under-reported. Another study limitation is the smaller size of the old-aged (≥ 60 years) group. However, the two groups were well balanced for all variables, thus potentially limiting the confounders. Additionally, the external validity of these results may be constrained when applied to patients with uncontrolled comorbid non-communicable conditions. Finally, this was a single-center study that lasted for only 12 months, limiting the ability to extrapolate.

Conclusions

This study confirmed the safety of both regimens while revealing B/F/TAF's metabolic advantages over DTG/3TC, most notably in glucose metabolism where it significantly lowered dysglycemia incidence among the virologically suppressed PLWH aged > 40 years at post-12-month. This study provides theoretical support for PLWH who are considering changing their treatment regimens. Future studies would focus on the B/F/TAF- and DTG/3TC-associated long-term metabolic health consequences of weight gain, lipid and glucose parameter changes.

Ethical Approval

This retrospective study was reviewed and approved by the Clinical Research Ethics Committee of the Hangzhou Xixi Hospital (No. 2023-Research ethics-97) in accordance with the tenets of the Declaration of Helsinki. This study met requirements for consent waived by the Ethics Committee. This study was a retrospective study, where researchers only conducted retrospective analysis on the medical records and data from laboratory examinations, not involving personal privacy or commercial interests. Meanwhile, strict confidentiality was maintained for all patient information, and no any intervention was performed on patients. Hence, the patient consent was waived by the Ethics Committee.

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Author Contributions

All authors made a significant contribution to the work reported, including its conception, study design, execution, acquisition of data, analysis, and/or interpretation. The authors took part in drafting, revising, or critically reviewing the article, gave final approval of the version to be published, agreed on the journal to which the article has been submitted, and agreed to be accountable for all aspects of the work.

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Disclosure

Regarding the publication of this paper, the authors declare that they have no conflicts of interest.

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