HIV DRUG THERAPY GLASGOW 2024 P 301

Dolutegravir/lamivudine versus bictegravir/emtricitabine/tenofovir alafenamide fumarate: Real-world Assessment of weight Gain in naïve people living with HIV of Asian OrigiN (DRAGON study)

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Background

Studies have shown an increase in weight among people living with HIV (PLWH) who have taken integrase strand-transfer inhibitor (INSTI)-containing antiretroviral therapy (ART). However, limited data are available among treatment-naïve PLWH in Asia. The aim was to assess the effectiveness and weight change after initiating bictegravir/emtricitabine/tenofovir alafenamide fumarate (BIC/FTC/TAF) or dolutegravir and lamivudine (DTG/3TC).

Methods

This was a retrospective, multi-center, observational cohort study conducted at 11 HIV-care-designated hospitals from October 2019 to January 2024. Information on demographics, body weight, clinical characteristics, laboratory tests, HIV viral loads, and lipid profiles was collected and analyzed. The proportion of participants with HIV-1 RNA levels less than 50 copies/mL and 200 copies/mL (Snapshot) at weeks 24 (W24), 48 (W48), 72 (W72), and 96 (W96) were analyzed.

The first weight measurement after the initiation of DTG/3TC or BIC/FTC/TAF, both pre- and 30 days post-index, was defined as baseline weight. The follow-up measurements taken every 6 months, both pre- and 30 days post, were defined as post-weight. Weight change was reported as the absolute change, along with the proportion of patients with increased weight.

Results

A total of 617 patients were included, with 226 in the DTG/3TC group and 391 in the BIC/FTC/TAF group. The CD4+ cell count was 302 (186-439) cells/µL and 243 (95-403) cells/µL in the DTG/3TC and BIC/FTC/TAF groups, respectively (p=0.08), and HIV RNA was 4.68 (4.03-5.23) log10 copies/mL and 4.79 (4.20-5.34) log10 copies/mL (p<0.01), respectively (Table 1). Figure 1 showed that the effectiveness was not significantly different from week 24 to week 96 between DTG/3TC and BIC/FTC/TAF. The interval change in CD4+ cell count was not significantly different in the DTG/3TC and BIC/FTC/TAF groups (adjusted difference: 2 cells/µL; 95% CI, -54 – 58; p=0.94) at week 48.

The absolute body weight and body mass index (BMI) at baseline were 67.5 (60-75) kg and 23 (20.8-25.7) kg/m² in the DTG/3TC group and 67 (60-74) kg and 22.4 (20.3-25) kg/m² in the BIC/FTC/TAF group, respectively. The adjusted mean weight change from baseline to week 48 was 2.9 kg in the DTG/3TC group and 5.1 kg in the BIC/FTC/TAF group (adjusted difference: 2.2 kg; 95% CI, 0.5 – 3.9; p<0.01). Additionally, 22 patients (16.5%) in the DTG/3TC group and 62 patients (30.2%) in the BIC/FTC/TAF group exhibited ≥10% weight gain (p<0.01; Figure 2).

Statistical analysis revealed no significant differences in total cholesterol (CHOL), HDL, LDL, and CHOL/HDL ratio between the two groups at week 96, though the triglyceride change was significantly different (adjusted difference: 28 mg/dL; 95% CI, 1.3 – 54.7; p=0.04; Figure 3).

Table 1. Baseline characteristics of naïve PLWH in the study cohort

	DTG/3TC (n=226)	BIC/FTC/TAF (n=391)	*p*
age, y/o, median (IQR)	36 (29-45)	35 (28-45)	0.34
male, n (%)	207 (92)	374 (96)	0.04
route of transmission			0.11
Men who have sex with men, n (%)	182 (81)	319 (82)	
Injection drug user, n (%)	9 (4)	9 (2)	
Heterosexual, n (%)	35 (15)	55 (14)	
other, n (%)	0 (0)	8 (2)	
CD4 counts at baseline, median (IQR)	302 (186-439)	243 (95-403)	0.08
CD4 counts < 200 cells/uL, n (%)	63 (28)	169 (43)	<0.01
HIV-1 RNA at baseline, copies/mL, median (IQR)	4.68 (4.03-5.23)	4.79 (4.20-5.34)	<0.01
HIV-1 RNA >100,000 copies/mL, n (%)	76 (34)	153 (39)	0.17
HIV-1 RNA >500,000 copies/mL, n (%)	19 (8)	59 (15)	0.02
Body weight at baseline, kg, median (IQR) (n=535)	67.5 (60-75)	67.0 (60-74)	0.61
BMI (body mass index), kg/m², median (IQR) (n=530)	23.0 (20.8-25.7)	22.4 (20.3-25.0)	0.19

Figure 1. Effectiveness of viral suppression was demonstrated among ART-naïve PLWH in the DTG/3TC and BIC/FTC/TAF groups from week 24 to week 96.

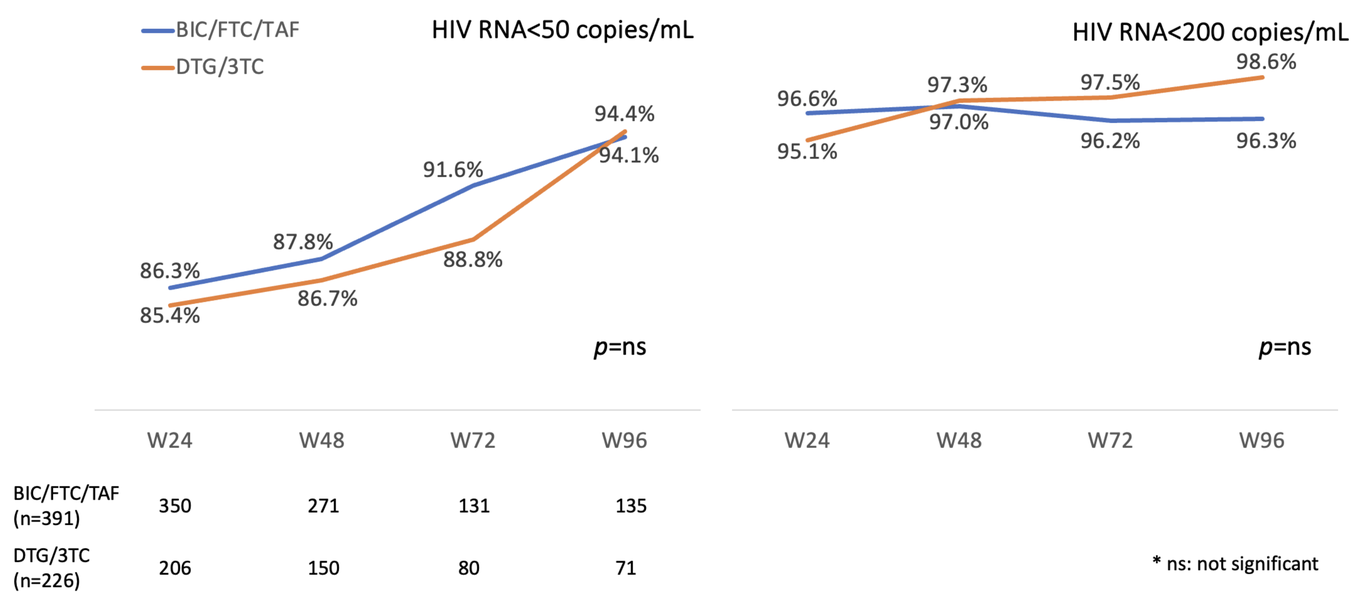


Figure 2. Weight change was demonstrated among ART-naïve PLWH in the DTG/3TC and BIC/FTC/TAF groups from week 24 to week 96.

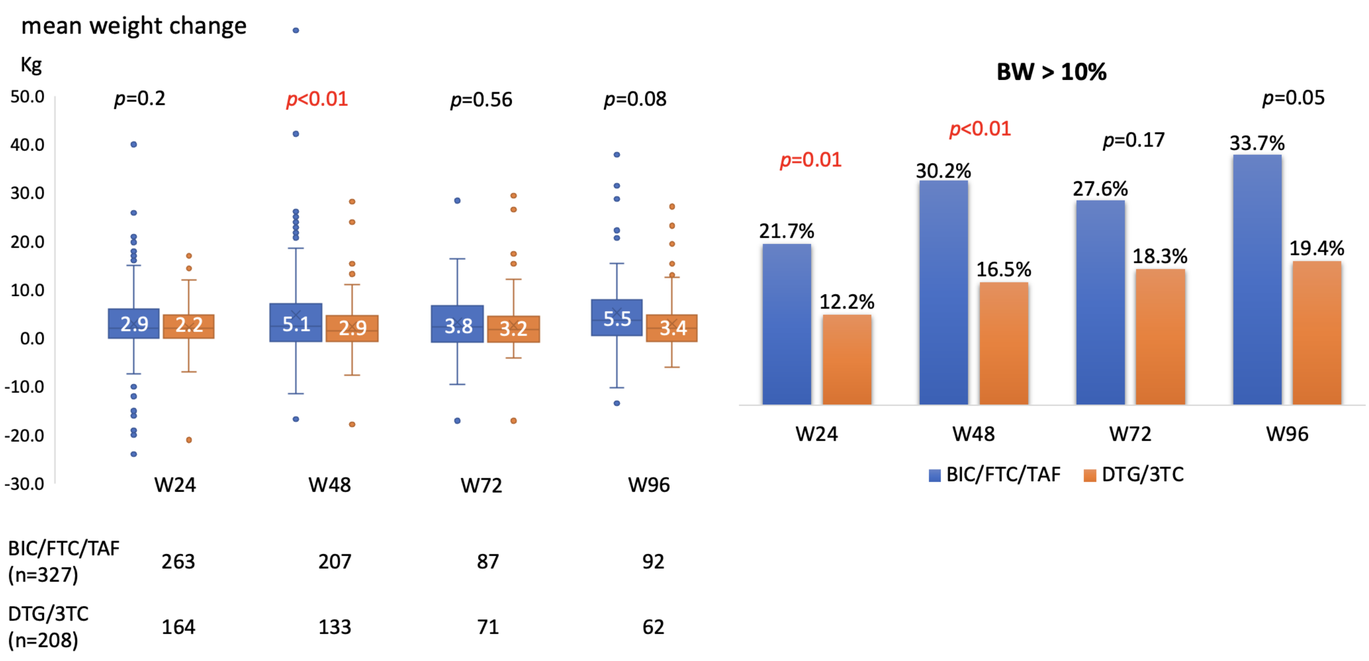
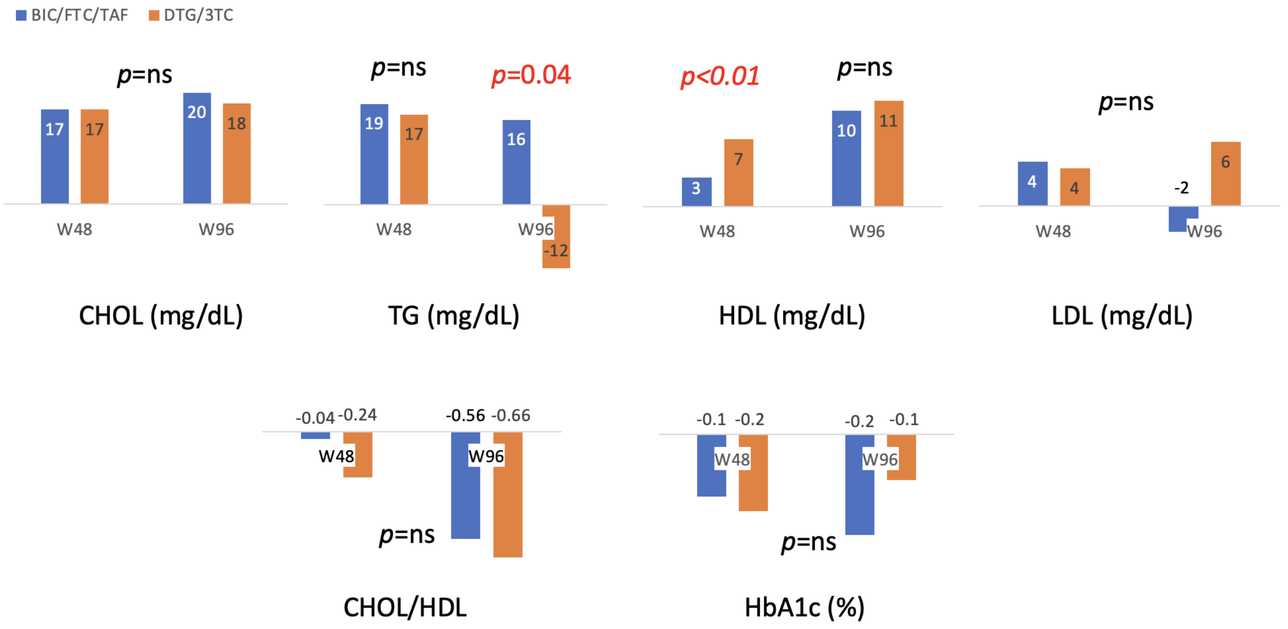


Figure 3. Metabolic profiles were demonstrated among ART-naïve PLWH in the DTG/3TC and BIC/FTC/TAF groups at weeks 48 and 96.



Conclusions

In a real-world setting, statistical analysis showed that DTG/3TC was comparable to BIC/FTC/TAF in achieving virologic suppression during follow-up. Furthermore, BIC/FTC/TAF was associated with greater weight gain compared to DTG/3TC among treatment-naïve PLWH in Asia.

The strength of the study lies in the diverse population, which demonstrated the effectiveness of second-generation integrase inhibitors in individuals of Asian origin. However, the limitations include incomplete data due to the retrospective nature of the study, making it difficult to assess dynamic weight changes across different regimens. Therefore, a prospective, matched study is warranted. Additionally, resistance testing was not performed for people living with HIV who experienced virological failure during the study.