Weight/BMI Change Following Initiation of Darunavir- or Bictegravir-Based Single-Tablet Regimens among Treatment-Naïve Female, Black, or Hispanic People Living with HIV-1 Who Are Overweight/Obese

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BACKGROUND

- Integrase strand transfer inhibitor (INSTI)-based combinations, including bictegravir (BIC)/emtricitabine (FTC)/tenofovir alafenamide (TAF), are recommended as an initial regimen for most people living with HIV-1 (PLWH)[1]
- Guidelines from the United States (US) Department of Health and Human Services (DHHS) underline a greater risk of weight gain associated with INSTI-based regimens versus other approved ART regimens, including darunavir (DRV)/cobicistat (c)/FTC/TAF, a protease inhibitor (PI)-based regimen[1-3]
- ART-associated weight gain or body mass index (BMI) increase does not affect all PLWH equally. Certain demographic groups, including female, Black, or Hispanic PLWH are generally at greater risk of ART-associated weight gain,[4-6] particularly following initiation of INSTI-based regimens[7]
- A previous retrospective study among female, Black, or Hispanic PLWH has shown that ART-associated weight gain within 6 months of treatment initiation was associated with a higher risk of developing incident type II diabetes mellitus[8]
- The Centers for Disease Control and Prevention considers adults with BMI between ≥25 kg/m^2 and <30 kg/m^2 to be overweight and adults with BMI ≥30 kg/m^2 to be obese, with obesity being further subdivided into the following categories: Class 1 (BMI of 30 to <35 kg/m^2), Class 2 (BMI of 35 to <40 kg/m^2), and Class 3 (BMI ≥40 kg/m^2)[9]
- When assessing the real-world impact of ART on weight change among PLWH, it can be challenging to separate return-to-health weight gain (occurring following viral suppression for PLWH who initially lost weight) from clinically undesirable weight gain[10]

OBJECTIVE

- To describe and compare real-world weight and BMI changes among female, Black (male or female), or Hispanic (male or female) treatment-naïve PLWH who are overweight/obese (i.e., BMI ≥25 kg/m^2; thus excluding weight/BMI changes occurring due to the return-to-health phenomenon) who initiated either DRV/c/FTC/TAF or BIC/FTC/TAF in the US

METHODS

Data Source

- Electronic medical records (EMR) data from Symphony Health, an ICON plc company, IDV® database (from 07/17/2017 to 12/31/2021) were used to identify the study population and conduct the analysis
- This provider-based EMR database comprises historical clinical information such as medications prescribed and administered, lab results, vital signs including weight and BMI measurements, and clinical diagnoses
- The data were de-identified and compliant with the requirements of the Health Insurance Portability and Accountability Act (HIPAA)

Study Design

- A retrospective longitudinal cohort study design was used for this study
- Adult (≥18 years old) females, Black, or Hispanic PLWH with BMI ≥25 kg/m^2 initiated on DRV/c/FTC/TAF or BIC/FTC/TAF between 07/17/2018 and 08/31/2021 were included
- PLWH were assigned to mutually exclusive DRV/c/FTC/TAF or BIC/FTC/TAF cohorts based on the first observed prescription for either medication (index date), with no previous ART prescriptions observed in the 12-month period prior to the index date, to ascertain that these were treatment-naïve cohorts
- The baseline period was defined as the 12-month period before the index date
- For patients without a weight/BMI measurement in the baseline period, weight/BMI was further assessed up until 30-days post-index, given weight/BMI change during this period is likely unrelated to the index ART[11]
- An on-treatment approach was used to define the follow-up period that spanned from 30 days after the index date until earliest of initiation of a new ART regimen, end of continuous clinical activity, or end of data availability (i.e., 12/31/2021)

Study Population

- The sample selection criteria are presented in **Figure 1**

Figure 1. Identification of the study population

≥1 diagnosis code for HIV-1
N= 196,892

≥1 characteristic associated with higher risk of BMI/weight gain: female, Black, or Hispanic
N= 104,991 (53.3%)

Newly initiated DRV/c/FTC/TAF or BIC/FTC/TAF between 17 July 2018 and 31 August 2021, with the date of the first prescription defined as the index date
N= 4,716 (4.5%)

≥12 months of continuous clinical activity before the index date (baseline period)
N= 3,006 (63.7%)

≥1 diagnosis code for HIV-1 on or before the index date
N= 2,966 (98.7%)

≥18 years old as of the index date
N= 2,952 (99.5%)

Exclusion criteria:

≥1 written prescription for an ART during the baseline period	**N= 1,381 (46.8%)**
≥1 diagnosis HIV-2 during the baseline period	**N= 2 (0.1%)**
≥1 diagnosis for liver cirrhosis or hepatitis during the baseline period	**N= 151 (5.1%)**
≥1 diagnosis for stage V CKD or ESRD, or creatinine clearance <15 ml/minute during the baseline period	**N= 18 (0.6%)**
≥1 diagnosis for pregnancy during the baseline period or on the index date	**N= 33 (1.1%)**
≥1 diagnosis for cancer, excluding cutaneous Kaposi's sarcoma, basal cell carcinoma, or resected, non-invasive cutaneous squamous carcinoma during the baseline period	**N= 89 (3.0%)**
≥1 written prescription for DRV/c/FTC/TAF and BIC/FTC/TAF on the index date	**N= 8 (0.3%)**

PLWH eligible for the study
N= 1,471 (49.8%)

PLWH in the DRV/c/FTC/TAF cohort
N= 116 (7.9%)

PLWH with ≥1 BMI/weight measurement in both the baseline and the follow-up
N= 55 (47.4%)

PLWH with baseline BMI ≥25 kg/m^2
N= 35 (63.6%)

PLWH in the BIC/FTC/TAF cohort
N= 1,355 (92.1%)

PLWH with ≥1 BMI/weight measurement in both the baseline and the follow-up
N= 741 (54.7%)

PLWH with baseline BMI ≥25 kg/m^2
N= 549 (74.1%)

Abbreviations: ART = antiretroviral therapy; BIC = bictegravir; BMI = body mass index; c = cobicistat; CKD = chronic kidney disease; DRV = darunavir; ESRD = end-stage renal disease; FTC = emtricitabine; PLWH = people living with HIV-1; TAF = tenofovir alafenamide.

Study Measures

- Demographic and clinical characteristics were evaluated during the baseline period
- For each patient, the baseline weight/BMI measurement was the measurement closest to the index date in the baseline period, or within 30 days post-index if no baseline measurements were available
- Mean differences in weight and BMI between the baseline and follow-up periods were assessed at 3-, 6-, 9-, 12-, 18-, and 24-month time points starting 30 days post-index and compared between the DRV/c/FTC/TAF and BIC/FTC/TAF cohorts
  - Mean follow-up weight/BMI measurements were based on all weight/BMI measurements available 45 days before and after each of the study time points

Statistical Analysis

- Baseline characteristics were balanced between PLWH in the DRV/c/FTC/TAF and BIC/FTC/TAF cohorts using inverse probability treatment weighting (IPTW)
  - Weights were calculated based on propensity scores obtained from a logistic regression model adjusting for the following variables: age, sex at birth, race, geographic region, insurance plan type, year of the index date, Quan-Charlson Comorbidity index (Quan-CCI; excluding HIV-1 symptoms), and baseline BMI
  - Comparison of baseline characteristics after applying IPTW were made using standardized differences, with differences of <10% being considered balanced[12]
- The mean change in weight and BMI between each follow-up time point and the baseline period was compared between the DRV/c/FTC/TAF and BIC/FTC/TAF cohorts using mean differences obtained from weighted ordinary least squares regression models
- All weighted models were further adjusted for the following additional baseline variables that remained imbalanced after IPTW, to obtain doubly robust estimates: age, race, insurance plan type, year of the index date, dyslipidemia/hyperlipidemia, type II diabetes mellitus, use of medication leading to weight loss, use of medication leading to weight gain, use of any antihypertension, antihyperlipidemic, or antidiabetic medications, and BMI
- Non-parametric bootstrap procedures with 500 iterations were used to calculate 95% confidence intervals (CIs) and p-values

RESULTS

Patient Characteristics

- A total of 35 PLWH who were overweight/obese were eligible for inclusion in the DRV/c/FTC/TAF cohort and 549 PLWH who were overweight/obese were eligible for inclusion in the BIC/FTC/TAF cohort (**Figure 1**)
- After IPTW, the weighted sample size yielded 260 PLWH in the DRV/c/FTC/TAF cohort and 324 PLWH in the BIC/FTC/TAF cohort
- Among the DRV/c/FTC/TAF cohort, the mean age was 51.9 years, 56.6% were female, 60.2% were Black, 15.9% were Hispanic, and 82.1% resided in the South (**Table 1**)
- Among the BIC/FTC/TAF cohort, the mean age was 50.6 years, 59.6% were female, 56.3% were Black, 14.6% were Hispanic, and 79.1% resided in the South
- The mean (standard deviation [SD]) baseline BMI was 32.8 (6.7) kg/m^2 in the DRV/c/FTC/TAF cohort and 33.3 (6.2) kg/m^2 in the BIC/FTC/TAF cohort
- The mean (SD) follow-up period was 13.8 (8.7) months in the DRV/c/FTC/TAF cohort and 16.3 (9.8) months in the BIC/FTC/TAF cohort

Table 1. Baseline Demographics and Clinical Characteristics

	Weighted population[a]		
	DRV/c/FTC/TAF cohort N=260	**BIC/FTC/TAF cohort N=324**	**Standardized difference[b]**
Demographic characteristics			
Age at the index date (years), mean ± SD [median]	51.9 ± 11.0 [51.0]	50.6 ± 12.4 [52.0]	11.0%
Female, n (%)	147 (56.6)	193 (59.6)	5.9%
Race, n (%)			
Black	156 (60.2)	183 (56.3)	7.8%
Hispanic	41 (15.9)	47 (14.6)	3.6%
White	24 (9.2)	47 (14.6)	16.7%
Unknown	38 (14.7)	44 (13.6)	3.4%
Other	0 (0.0)	3 (0.9)	13.6%
US geographic region, n (%)			
South	213 (82.1)	256 (79.1)	7.5%
Northeast	28 (10.7)	28 (8.6)	7.3%
West	19 (7.2)	25 (7.6)	1.4%
Midwest	0 (0.0)	15 (4.6)	31.0%
Unknown	0 (0.0)	1 (0.2)	6.0%
Insurance plan type, n (%)			
Insurance plan information available (in claims)	260 (100.0)	314 (97.0)	24.8%
Commercial	202 (77.8)	226 (69.7)	18.4%
Medicaid	34 (13.1)	42 (12.8)	0.7%
Medicare	24 (9.2)	43 (13.3)	13.0%
Other/Unknown	0 (0.0)	4 (1.2)	15.8%
Year of the index date, n (%)			
2018-2019	142 (54.8)	175 (54.0)	1.7%
2020-2021	117 (45.2)	149 (46.0)	1.7%
Clinical characteristics			
Quan-CCI (excluding HIV-1 symptoms), mean ± SD [median]	0.4 ± 0.8 [0.0]	0.4 ± 1.0 [0.0]	0.5%
Other physical comorbidities, n (%)			
Hypertension	47 (18.2)	67 (20.5)	5.9%
Obesity	27 (10.5)	42 (13.0)	7.9%
Dyslipidemia/hyperlipidemia	17 (6.5)	40 (12.4)	20.5%
Type II diabetes mellitus	12 (4.6)	30 (9.4)	18.9%
Prediabetes	10 (3.8)	16 (5.1)	6.0%
BMI (kg/m^2), mean ± SD [median]	32.8 ± 6.7 [31.9]	33.3 ± 6.2 [32.1]	7.8%
BMI categories (kg/m^2), n (%)			
25-29	104 (40.1)	119 (36.6)	7.2%
30-34	83 (32.1)	100 (30.9)	2.6%
≥35	72 (27.8)	105 (32.5)	10.2%
Weight (kg), mean ± SD [median]	95.9 ± 19.3 [90.7]	94.9 ± 18.9 [92.5]	5.3%
Antihypertensives or antihyperlipidemics or antidiabetics, n (%)	87 (33.5)	83 (25.6)	17.4%
Medications associated with weight gain, n (%)	41 (16.0)	79 (24.4)	21.2%
Medications associated with weight loss, n (%)	3 (1.2)	19 (6.0)	25.6%

Abbreviations: BIC = bictegravir; BMI = body mass index; c = cobicistat; CCI = Charlson comorbidity index; DRV = darunavir; FTC = emtricitabine; PLWH = people living with HIV-1; SD = standard deviation; TAF = tenofovir alafenamide; US = United States.

[a] Of note, the number of PLWH reported in this weighted population represents the sum of weights for the corresponding PLWH, rounded to the nearest integer. The proportions displayed were calculated prior to the rounding and may be slightly different than if they were calculated based on rounded numbers.

[b] For continuous variables, the standardized difference is calculated by dividing the absolute difference in means of the DRV/c/FTC/TAF cohort and the BIC/FTC/TAF cohort by the pooled standard deviation of both groups. The pooled standard deviation is the square root of the average of the squared standard deviations. For categorical variables with two levels, the standardized difference is calculated using the following equation where P is the respective proportion of participants in each group: $(P_{BIC/FTC/TAF}-P_{DRV/c/FTC/TAF})/\sqrt{([p1+p2]/2)}$, where $p1=P_{BIC/FTC/TAF}(1-P_{BIC/FTC/TAF})$ and $p2=P_{DRV/c/FTC/TAF}(1-P_{DRV/c/FTC/TAF})$.

Changes in BMI Categories

- During follow-up, among the BIC/FTC/TAF cohort, 13.6% (44/324) increased one BMI category, relative to 8.1% (21/260) of the DRV/c/FTC/TAF cohort (**Table 2**)
- A higher proportion of DRV/c/FTC/TAF PLWH who were overweight became normal/underweight (14.8%) than BIC/FTC/TAF PLWH who were overweight (7.4%); a higher proportion of DRV/c/FTC/TAF PLWH with Class 3 obesity moved to Class 2 (36.9%) than BIC/FTC/TAF PLWH with Class 3 obesity (11.7%)
- A higher proportion of BIC/FTC/TAF PLWH with Class 1 obesity progressed to Class 2 (14.1%) than DRV/c/FTC/TAF PLWH with Class 1 obesity (6.8%); a higher proportion of BIC/FTC/TAF PLWH with Class 2 obesity also progressed to Class 3 (16.4%) than DRV/c/FTC/TAF PLWH with Class 2 obesity (0.0%)

Table 2. Index BMI Category and Proportion of PLWH with BMI Category Shifts During Follow-up

	DRV/c/FTC/TAF (N=260)[a]					
	Post-index BMI category (kg/m^2)[b]					
	BMI <25	BMI 25-29	BMI 30-34	BMI 35-39	BMI ≥40	Total
Index BMI category (kg/m^2)	n (%)	n (%)	n (%)	n (%)	n (%)	n
BMI 25-29 (overweight)	15 (14.8)	74 (70.6)	15 (14.6)	0 (0.0)	0 (0.0)	104
BMI 30-34 (Class 1 obesity)	0 (0.0)	7 (8.8)	70 (84.4)	6 (6.8)	0 (0.0)	83
BMI 35-39 (Class 2 obesity)	0 (0.0)	0 (0.0)	0 (0.0)	12 (100.0)	0 (0.0)	12
BMI ≥40 (Class 3 obesity)	0 (0.0)	0 (0.0)	0 (0.0)	22 (36.9)	38 (63.1)	61

	BIC/FTC/TAF (N=324)[a]					
	Post-index BMI category (kg/m^2)[b]					
	BMI <25	BMI 25-29	BMI 30-34	BMI 35-39	BMI ≥40	Total
Index BMI category (kg/m^2)	n (%)	n (%)	n (%)	n (%)	n (%)	n
BMI 25-29 (overweight)	9 (7.4)	90 (76.0)	17 (14.6)	2 (1.5)	1 (0.5)	119
BMI 30-34 (Class 1 obesity)	1 (0.6)	17 (16.6)	66 (66.3)	14 (14.1)	2 (2.3)	100
BMI 35-39 (Class 2 obesity)	0 (0.0)	1 (1.2)	6 (11.9)	35 (70.5)	8 (16.4)	50
BMI ≥40 (Class 3 obesity)	0 (0.0)	1 (1.1)	2 (3.2)	6 (11.7)	46 (84.0)	55

🟦 Patients who had a decrease between index and post-index BMI categories
🟩 Patients who had no change between index and post-index BMI categories
🟧 Patients who had an increase between index and post-index BMI categories

Abbreviations: BIC = bictegravir; BMI = body mass index; c = cobicistat; DRV = darunavir; FTC = emtricitabine; PLWH = people living with HIV-1; TAF = tenofovir alafenamide.

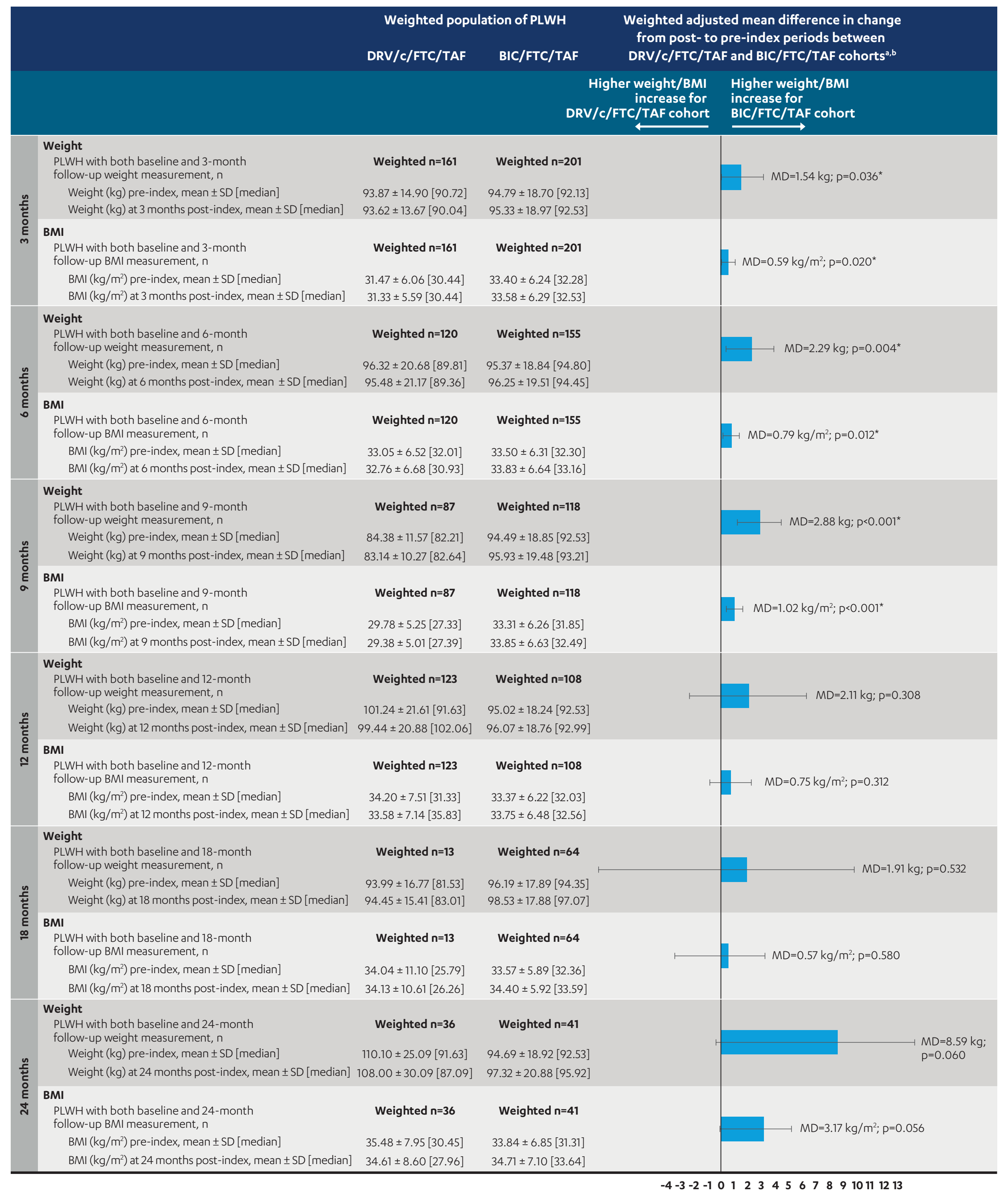
[a] Of note, the number of PLWH reported in this weighted population represents the sum of weights for the corresponding PLWH, rounded to the nearest integer. The proportions displayed were calculated prior to the rounding and may be slightly different than if they were calculated based on rounded numbers.

[b] Evaluated based on the on-treatment measurement furthest from the index date.

Comparison of Weight and BMI Change at Specific Time Points

- PLWH who were overweight/obese in the BIC/FTC/TAF cohort experienced greater absolute weight or BMI increases than PLWH in the DRV/c/FTC/TAF cohort who were overweight/obese at all time points, with results reaching statistical significance at 3-, 6-, and 9-month time points (**Figure 2**)
- Significant weighted doubly robust mean differences in weight ranged from 1.54 kg [3.40 lbs] at 3 months (increase for BIC/FTC/TAF cohort: $\Delta_{3\ months}$= +0.54 kg [+1.19 lbs]; decrease for DRV/c/FTC/TAF cohort: $\Delta_{3\ months}$= -0.25 kg [-0.55 lbs]; p=0.036) to 2.88 kg [6.35 lbs] at 9 months (increase for BIC/FTC/TAF cohort: $\Delta_{9\ months}$= +1.44 kg [+3.17 lbs]; decrease for DRV/c/FTC/TAF cohort: $\Delta_{9\ months}$= -1.24 kg [-2.73 lbs]; p<0.001)
- The largest weighted doubly robust mean difference in weight, which was 8.59 kg [18.94 lbs], was observed at 24 months (increase for BIC/FTC/TAF cohort: $\Delta_{24\ months}$= +2.63 kg [+5.80 lbs]; decrease for DRV/c/FTC/TAF cohort: $\Delta_{24\ months}$= -2.10 kg [-4.63 lbs]; p=0.060), although a small sample of patients was evaluated at this time point (n=77)
  - Descriptively, at each time point, PLWH in the DRV/c/FTC/TAF cohort experienced an overall mean decrease in weight post-index, while PLWH in the BIC/FTC/TAF cohort experienced an overall mean increase in weight post-index
- Results were consistent for BMI increases observed between the DRV/c/FTC/TAF and BIC/FTC/TAF cohorts

Figure 2. Comparison of mean weight or BMI change between the pre- and post-index periods



		Weighted population of PLWH		Weighted adjusted mean difference in change from post- to pre-index periods between DRV/c/FTC/TAF and BIC/FTC/TAF cohorts[a,b]
		DRV/c/FTC/TAF	BIC/FTC/TAF	← Higher weight/BMI increase for DRV/c/FTC/TAF cohort · Higher weight/BMI increase for BIC/FTC/TAF cohort →
3 months	**Weight**			
	PLWH with both baseline and 3-month follow-up weight measurement, n	**Weighted n=161**	**Weighted n=201**	MD=1.54 kg; p=0.036*
	Weight (kg) pre-index, mean ± SD [median]	93.87 ± 14.90 [90.72]	94.79 ± 18.70 [92.13]	
	Weight (kg) at 3 months post-index, mean ± SD [median]	93.62 ± 13.67 [90.04]	95.33 ± 18.97 [92.53]	
	BMI			
	PLWH with both baseline and 3-month follow-up BMI measurement, n	**Weighted n=161**	**Weighted n=201**	MD=0.59 kg/m^2; p=0.020*
	BMI (kg/m^2) pre-index, mean ± SD [median]	31.47 ± 6.06 [30.44]	33.40 ± 6.24 [32.28]	
	BMI (kg/m^2) at 3 months post-index, mean ± SD [median]	31.33 ± 5.59 [30.44]	33.58 ± 6.29 [32.53]	
6 months	**Weight**			
	PLWH with both baseline and 6-month follow-up weight measurement, n	**Weighted n=120**	**Weighted n=155**	MD=2.29 kg; p=0.004*
	Weight (kg) pre-index, mean ± SD [median]	96.32 ± 20.68 [89.81]	95.37 ± 18.84 [94.80]	
	Weight (kg) at 6 months post-index, mean ± SD [median]	95.48 ± 21.17 [89.36]	96.25 ± 19.51 [94.45]	
	BMI			
	PLWH with both baseline and 6-month follow-up BMI measurement, n	**Weighted n=120**	**Weighted n=155**	MD=0.79 kg/m^2; p=0.012*
	BMI (kg/m^2) pre-index, mean ± SD [median]	33.05 ± 6.52 [32.01]	33.50 ± 6.31 [32.30]	
	BMI (kg/m^2) at 6 months post-index, mean ± SD [median]	32.76 ± 6.68 [30.93]	33.83 ± 6.64 [33.16]	
9 months	**Weight**			
	PLWH with both baseline and 9-month follow-up weight measurement, n	**Weighted n=87**	**Weighted n=118**	MD=2.88 kg; p<0.001*
	Weight (kg) pre-index, mean ± SD [median]	84.38 ± 11.57 [82.21]	94.49 ± 18.85 [92.53]	
	Weight (kg) at 9 months post-index, mean ± SD [median]	83.14 ± 10.27 [82.64]	95.93 ± 19.48 [93.21]	
	BMI			
	PLWH with both baseline and 9-month follow-up BMI measurement, n	**Weighted n=87**	**Weighted n=118**	MD=1.02 kg/m^2; p<0.001*
	BMI (kg/m^2) pre-index, mean ± SD [median]	29.78 ± 5.25 [27.33]	33.31 ± 6.26 [31.85]	
	BMI (kg/m^2) at 9 months post-index, mean ± SD [median]	29.38 ± 5.01 [27.39]	33.85 ± 6.63 [32.49]	
12 months	**Weight**			
	PLWH with both baseline and 12-month follow-up weight measurement, n	**Weighted n=123**	**Weighted n=108**	MD=2.11 kg; p=0.308
	Weight (kg) pre-index, mean ± SD [median]	101.24 ± 21.61 [91.63]	95.02 ± 18.24 [92.53]	
	Weight (kg) at 12 months post-index, mean ± SD [median]	99.44 ± 20.88 [102.06]	96.07 ± 18.76 [92.99]	
	BMI			
	PLWH with both baseline and 12-month follow-up BMI measurement, n	**Weighted n=123**	**Weighted n=108**	MD=0.75 kg/m^2; p=0.312
	BMI (kg/m^2) pre-index, mean ± SD [median]	34.20 ± 7.51 [31.33]	33.37 ± 6.22 [32.03]	
	BMI (kg/m^2) at 12 months post-index, mean ± SD [median]	33.58 ± 7.14 [35.83]	33.75 ± 6.48 [32.56]	
18 months	**Weight**			
	PLWH with both baseline and 18-month follow-up weight measurement, n	**Weighted n=13**	**Weighted n=64**	MD=1.91 kg; p=0.532
	Weight (kg) pre-index, mean ± SD [median]	93.99 ± 16.77 [81.53]	96.19 ± 17.89 [94.35]	
	Weight (kg) at 18 months post-index, mean ± SD [median]	94.45 ± 15.41 [83.01]	98.53 ± 17.88 [97.07]	
	BMI			
	PLWH with both baseline and 18-month follow-up BMI measurement, n	**Weighted n=13**	**Weighted n=64**	MD=0.57 kg/m^2; p=0.580
	BMI (kg/m^2) pre-index, mean ± SD [median]	34.04 ± 11.10 [25.79]	33.57 ± 5.89 [32.36]	
	BMI (kg/m^2) at 18 months post-index, mean ± SD [median]	34.13 ± 10.61 [26.26]	34.40 ± 5.92 [33.59]	
24 months	**Weight**			
	PLWH with both baseline and 24-month follow-up weight measurement, n	**Weighted n=36**	**Weighted n=41**	MD=8.59 kg; p=0.060
	Weight (kg) pre-index, mean ± SD [median]	110.10 ± 25.09 [91.63]	94.69 ± 18.92 [92.53]	
	Weight (kg) at 24 months post-index, mean ± SD [median]	108.00 ± 30.09 [87.09]	97.32 ± 20.88 [95.92]	
	BMI			
	PLWH with both baseline and 24-month follow-up BMI measurement, n	**Weighted n=36**	**Weighted n=41**	MD=3.17 kg/m^2; p=0.056
	BMI (kg/m^2) pre-index, mean ± SD [median]	35.48 ± 7.95 [30.45]	33.84 ± 6.85 [31.31]	
	BMI (kg/m^2) at 24 months post-index, mean ± SD [median]	34.61 ± 8.60 [27.96]	34.71 ± 7.10 [33.64]	

Abbreviations: BIC = bictegravir; BMI = body mass index; c = cobicistat; CI = confidence interval; DRV = darunavir; FTC = emtricitabine; MD = mean difference; PLWH = people living with HIV-1; SD = standard deviation; TAF = tenofovir alafenamide.

[a] A mean difference >0 indicates that the BIC/FTC/TAF cohort had a larger weight or BMI gain than the DRV/c/FTC/TAF cohort.

[b] Non-parametric 95% bootstrap CIs and p-values were obtained from 500 bootstrap resamples. At each bootstrap resample, the inverse probability of treatment weights were re-estimated.

* Significant at the 5% level.

LIMITATIONS

- Claims and EMR data may contain inaccuracies or omissions in diagnoses, billing, and other variables
- Furthermore, as with all EMR databases, the prescription of an ART medication was assumed to indicate its use and that it was taken as indicated
- This provider-based data source does not capture the services PLWH received from a provider that is outside of the network
- Since the validity of IPTW rests on the untestable assumption that all confounders are accounted for, the possibility of unmeasured confounding may exist even though many variables were included in this analysis
- Information that may have an impact on weight outcomes such as waist circumference, lifestyle measures, socioeconomic status, family/social history were not available in the EMR and laboratory testing data such as CD4+/CD8+ cell counts, HIV-1 viral load, cholesterol/lipid panel data were sparse and thus could not be included in the propensity score model for balancing
- Given the small sample size available at later time points, additional studies with larger sample sizes of patients who initiate DRV/c/FTC/TAF and BIC/FTC/TAF and longer follow-up may be warranted to confirm the study findings

CONCLUSIONS

- **Female, Black, or Hispanic PLWH who were overweight/obese and initiated BIC/FTC/TAF experienced a trend towards greater weight/BMI increase over 24 months compared to similar PLWH who initiated DRV/c/FTC/TAF**
- **Mean differences in pre- versus post-index weight/BMI gain between the study cohorts were driven by weight/BMI increases among the BIC/FTC/TAF cohort and a weight/BMI decreases among the DRV/c/FTC/TAF cohort**
- **Although larger sample size and longer follow-up is warranted, BIC/FTC/TAF-treated PLWH experienced continued and clinically relevant weight/BMI gain over time, suggesting a need for additional monitoring to reduce the risk of weight gain-related cardiometabolic disease**

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