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ORIGINAL RESEARCH

Prevalence of Weight Gain and Associated Factors Among People Living with HIV 6- and 12-Months Post Dolutegravir-Based Anti-Retroviral Regimen Initiation in Gulu, Uganda; A Hospital-Based Retrospective Cohort Study

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Background: Dolutegravir (DTG), an integrase-strand transfer inhibitor approved by WHO in 2019 as part of first-line HIV treatment, has been linked to weight gain; however, data on this and its associated factors remain limited.

Objective: This study aimed to determine the prevalence of weight gain and associated factors among people living with HIV (PLHIV) on DTG-based antiretroviral therapy (ART) regimens.

Methods: We conducted a retrospective cohort study of PLHIV at St. Mary's Hospital Lacor between January 2020 and December 2021. Charts were reviewed for demographic and clinical data at baseline, at 6 months and at 12 months. Weight gain was defined as a ≥5% increase in weight from baseline at 6 months. Bivariate analysis followed by stepwise multivariable logistic regression was used to identify independent predictors of weight gain. Data were analyzed using STATA 17.

Results: A total of 432 participants were included, 83.8% of whom were female. The median age was 44 years (IQR: 37.0–49.5). Most (97.0%) programmatically switched to DTG-based regimens. The prevalence of weight gain (defined as ≥5% increase from baseline) at 6 months was 7.4% (n=32/432) and 16.5% (n=31/187) at 12 months. Mean weight at baseline and 6 months was comparable (61.0 kg vs 60.0 kg, p=0.108), but a statistically significant increase in weight (p<0.001) and BMI (p<0.001) was observed from baseline to 12 months. On bivariate analysis, lower baseline WHO stage (p=0.048) and viral load <1000 copies/mL (p=0.009) were associated with weight gain; however, no factor remained significantly associated in multivariable analysis.

Conclusion: Weight gain occured in approximately **1 in 14 participants at 6 months** and **1 in 6 participants at 12 months** post-DTG initiation. WHO stage I and lower viral load were associated with weight gain on bivariate analysis, though not independently on multivariable analysis. Routine weight and cardiovascular risk monitoring is recommended. A prospective study is warranted.

Keywords: prevalence, weight gain, Uganda, people living with HIV, Dolutegravir, anti-retroviral regimens

Introduction

In 2020, 37.6 million people were living with HIV (PLHIV) globally; 35.9 million adults and 1.7million children (0–14years), while 1.5 million of the sum were newly infected and 20.6 million (55%) resided in Sub-Saharan Africa.[1] In Uganda, the prevalence of HIV amongst adults (15–49 years) was 5.4%, (1.4million) higher amongst females at 6.8% as compared to 3.9% males while, at the Ugandan district level, the HIV prevalence is highest in Kalangala District, 18%, least in Nabilatuk, 0.2%, however, Uganda noted an improvement in the fight against HIV and AIDs and is among 8 countries in the world to have achieved the 90-90-90 goal by 2020.[1]

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Worldwide, combination Anti-Retroviral Therapy (ART) has significantly increased survival among HIV-positive adults, approximating that of the general population.[2] Dolutegravir (DTG) is not only a new integrase strand transfer inhibitor (INSTI) approved for Anti-Retroviral Therapy but also a highly effective antiretroviral drug whose efficacy is evidenced by its greater virologic suppression, high resistance barrier, good tolerability, infrequent drug-to-drug interactions and once-daily administration.[3] Therefore, in 2018, the World Health Organization (WHO) HIV management guidelines standardized switching from non-nucleoside reverse transcriptase inhibitors (efavirenz and nevirapine) to DTG-based ART regimens (DBRs)[4] and Uganda adopted DTG into its first-line HIV treatment regimen within the same year.[5] However, several studies from USA,[6] Botswana[7] and Canada[8] have demonstrated significant weight gain in PLHIV on DBRs coupled with.[9] Further reports identifying several factors associated, including being on Tenofovir/Emtricitabine-based regimens in individuals aged 60 years and above,[10] treatment-naïve status at initiation of DBR,[11] a lower baseline CD4 count[12] and elevated baseline viral load (> 1000 copies/mL).[13] Notably, a lower WHO staging has been related to weight gain irrespective of the ART regimen. This staging spans from stages 1–4 defined as: Stage 1—asymptomatic or persistent generalized lymphadenopathy; Stage 2—mild symptoms like recurrent respiratory infections; Stage 3—advanced symptoms like weight loss >10% or chronic diarrhea; Stage 4—severe conditions like AIDS-defining illnesses),[14] reflecting the progression from clinically silent infection to advanced immunosuppression.

Despite the weight outcomes, Ugandan data on weight gain in PLHIV taking DTG remain scanty - with few surveys similarly investigating its prevalence. Consequently, the contribution of DTG-associated weight gain to cardio-metabolic illness is also not well established. This study therefore aimed to determine the prevalence and factors associated with weight gain among PLHIV on DBRs attending the ART clinic of St. Mary's Hospital, Lacor, Gulu, Uganda.

Methods

Study Design & Setting

We conducted a retrospective cohort study between 2020 and 2021 among PLHIV attending St. Mary`s Hospital, Lacor - ART clinic, Gulu, Uganda. The hospital serves as a general referral hospital for a significant percentage of the population within the Acholi sub-region, while its ART clinic has approximately 5000 registered clients on ART and commenced DTG usage in 2018.

Study Population

The study population consisted of adults living with HIV attending the ART clinic at St. Mary's Hospital Lacor, who were switched to or initiated on DTG-based first-line ART regimens.

Inclusion & Exclusion Criteria

PLHIV aged ≥18 years who had been on a DTG-based first-line ART regimen for at least 6 months, enrolled between January 2020 and December 2021. Exclusion criteria: (1) ART-naïve individuals initiated on DTG as salvage therapy; (2) records missing ≥75% of predefined essential data points (a priori defined as weight, BMI, CD4 count, viral load, WHO stage, and sex at baseline and follow-up; threshold operationalized by excluding charts with >3/6 missing variables per time point, such as a chart missing weight, CD4, and viral load would be excluded).

Study Procedures

At the time of data collection, no studies in Uganda had examined DBR-associated weight gain. A standardized electronic abstraction tool generated on the kobo-collect servers was used to collect socio-demographic and clinical characteristics data at baseline, 6 months and 12 months post DTG initiation; this data encompassing age, sex, and WHO HIV stage, CD4 count, Viral Load, Weight, mode of DTG therapy, DTG regimen switched/substituted to, reason for the switch/substitution, duration for which one has been on a DTG based ART regimen, and any other prevailing comorbidities or chronic medications. All eligible participant records within the study period were considered for the study. Confidentiality was observed by using participant identifying numbers instead of names.

Data Analysis

We calculated the summary statistics for the socio-demographics and the clinical data (WHO HIV staging, CD4 count, Viral Load and Body Mass Index) were stratified by WHO standards. Consequently, clinical characteristics' statistics at baseline (pre-DTG initiation), 6 months and 12 months post-DTG initiation were calculated basing on this stratification. Furthermore, frequencies and percentages were used to summarize the discrete variables (gender, WHO Staging, stratified CD4 counts and viral loads, mode of DTG therapy, reason for switch/substitution, comorbidities, and other medication) while medians and interquartile ranges were applied for continuous variables (age, un-stratified CD4 counts and viral loads, weight, and duration of DTG therapy).

Subsequently, weight gain was calculated as the difference between participants' weight at 6 months and 12-month intervals post DTG initiation versus baseline (pre-DTG initiation) weight and a 5% prevalence of weight gain in the initial 6 months (post switch/substitution to DTG) was determined as significant at a 95% confidence interval (CI). Bivariate analysis was first used to identify potential predictors of weight gain. Variables with a p-value < 0.2 were then entered into a multivariable logistic regression model. A backward stepwise method was used to select the final independent predictors, with a p-value < 0.05 considered statistically significant. Results were reported as adjusted odds ratios (aOR) with 95% confidence intervals (CI). All analyses were conducted using STATA version 17, and graphs were generated with GraphPad Prism 8.4 software.

Results

Characteristics of Study Participants at Baseline to 6 Months Post-DTG Initiation

Data from 432 participants' were reviewed. The majority (83.8%) were female (n=362) while 16.2% where male (n=70). The median age was 44 years (IQR: 37–49.5years), Tables 1 and 2: Summarizes the participants' characteristics from baseline to 6 months post-DTG initiation, including BMI at 12 months post DTG initiation for those with recorded follow-up data.

Table 1 Baseline Socio-Demographic and Clinical Characteristics of Participants (N=432)

Variable	Frequency (n)	Percentage (%)
Age, median (IQR), years	44	37–49.5
Sex		
Female	362	83.8
Male	70	16.2
WHO Staging at DTG initiation		
1	355	92
2	27	7
3	3	0.8
4	1	0.3
CD4 count at DTG initiation		
<200	146	34
≥200	283	66

(*Continued*)

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Table 1 (Continued).

Variable	Frequency (n)	Percentage (%)
Viral load at DTG initiation		
<1000	137	92
≥1000	12	8.1
Weight, median (IQR), kg	60	53–69
BMI at DTG initiation		
<18.5	47	12.2
18.5–24.9	249	64.5
25–29.9	67	17.4
≥30	23	6
Mode of DTG		
As initial regimen	419	97
Switch	13	3
Reason for switch		
New drug available	363	98.1
Toxicity	4	1.1
Unsuppressed	3	0.8
Duration of therapy, median (IQR), months	12	10–15
Comorbidity		
No	378	96.2
Yes	15	3.8
Other medication		
No	314	79.7
Yes	80	20.3

Table 2 Longitudinal Comparisons of Key Variables

Variable	Baseline	6 Months Post DTG Initiation	12 Months Post DTG Initiation
WHO Staging			
1	355 (92%)	367 (97.4%)	
2	27 (7%)	7 (1.9%)	
3	3 (0.8%)	2 (0.5%)	
4	1 (0.3%)	1 (0.3%)	

(*Continued*)

Table 2 (Continued).

Variable	Baseline	6 Months Post DTG Initiation	12 Months Post DTG Initiation
CD4 count			
<200	146 (34%)		
≥200	283 (66%)		
Viral load			
<1000	137 (92%)	129 (97.7%)	
≥1000	12 (8.1%)	3 (2.3%)	
Weight, median (IQR), kg	60 (53–69)	61 (55–70)	
BMI			
<18.5	47 (12.2%)	40 (10.5%)	17 (9.2%)
18.5–24.9	249 (64.5%)	232 (60.7%)	103 (56%)
25–29.9	67 (17.4%)	80 (20.9%)	45 (24.5%)
≥30	23 (6%)	30 (7.9%)	19 (10.3%)

At baseline, 92% were at WHO stage 1, and more than half (66%) had CD4 counts ≥200 cells/μL, with a median CD4 count of 274 cells/μL (IQR 155–378; n=429). At 6 months, median CD4 was 312 cells/μL (IQR 210–450; n=285), showing a non-significant increase (p=0.12). At 12 months, median CD4 was 345 cells/μL (IQR 220–480; n=187), also non-significant from baseline (p=0.08). Viral loads were <1000 copies/mL in 92% (n=137/149). Median baseline weight was 60 kg (IQR 53–69), and 64.5% (n=249) had BMI 18.5–24.9, with median BMI 22.1 (IQR 19.7–24.8).

At 6 months post-DTG initiation, 97.4% (n=367) remained at WHO stage 1 and 97.7% (n=129) had viral loads <1000 copies/mL. The median weight slightly increased to 61kg (IQR=55-70) and 60.7% (n=232) maintained a BMI within the normal range, however the median BMI was raised to 22.6 (IQR=19.9–25.9). CD4 count data at 6 and 12 months were grossly missing on collection.

Furthermore, most participants (97.0%) had switched to DTG due to new drug availability, the median duration on therapy was 12 months (IQR: 10–15), nearly many participants (96.2%) had no other recorded comorbidities (96.2%, n=378), and most (79.7%) were not on any other medication.

Prevalence of Weight Gain Among the Participants 6 Months Post-DTG Initiation

Overall, 7.4% of participants (n=32) experienced weight gain.

A statistically significant increase in weight was observed at 6 months post-DTG initiation compared to baseline (p<0.001) (Figure 1). Similarly, BMI increased significantly at 6 months compared to baseline (p<0.001) (Figure 2).

Weight and BMI Changes Among the Participants Were Followed Up at 12 months

At 12 months post-DTG initiation, participants showed a statistically significant increase in weight compared to baseline (p<0.001) (Figure 3). However, the change in BMI over the same period was not statistically significant (p=0.076) (Figure 4).

Factors Associated with Weight Gain at 6 Months Post DTG Initiation at Bivariate Analysis

Table 3 summarizes the bivariate analysis of factors associated with weight gain at 6 months post-DTG initiation.

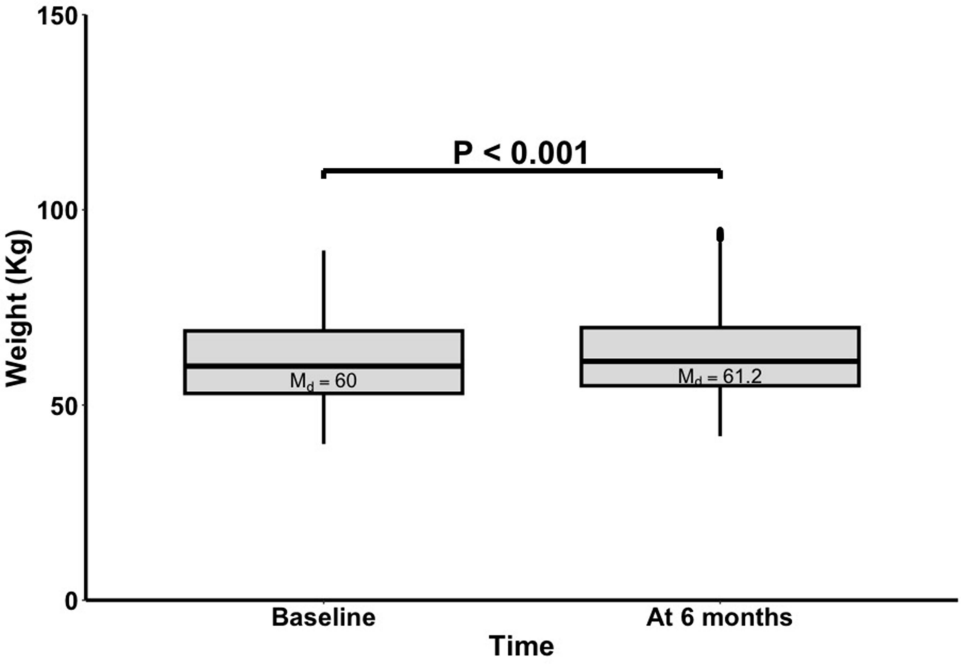

Figure 1 Comparison of participant weight at baseline and 6 months. Data are presented as box-and-whisker plots showing the median and interquartile range. The statistical comparison was performed using a Wilcoxon signed-rank test. (n=432).

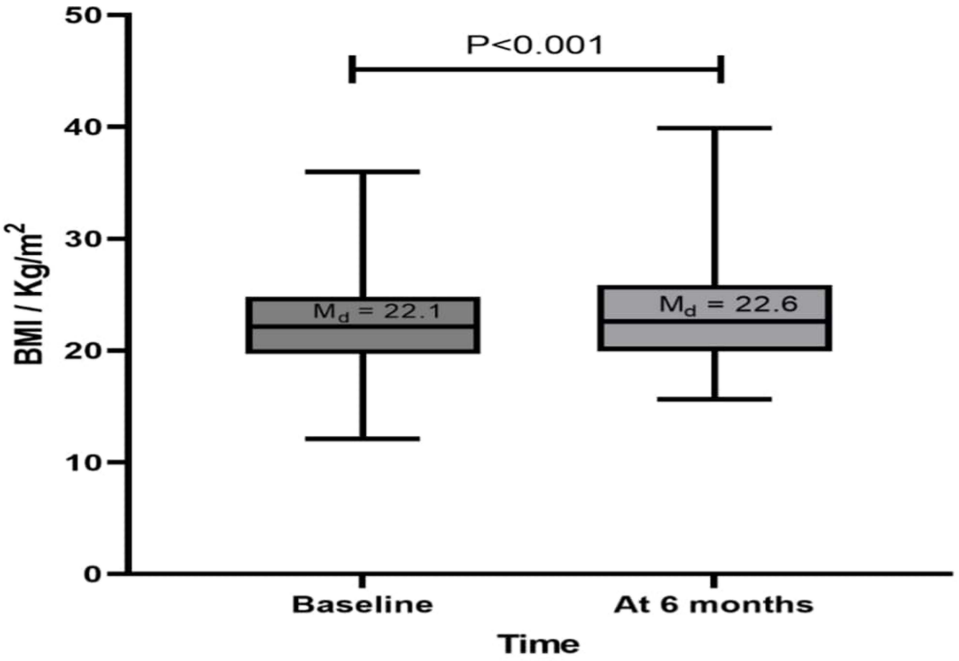

Figure 2 Comparison of participant BMI at baseline and at 6 months. Data are presented as box-and-whisker plots showing the median and interquartile range. The statistical comparison was performed using a Wilcoxon signed-rank test. (n=432).

Of the 32 participants (7.4%) who experienced weight gain, the median age was 42.5 years, and most were female (n=28). More than half (n=23) had baseline CD4 counts ≥200 cells/μL, and most (n=28) were still at WHO Stage 1 at 6 months post-DTG initiation however majority had only switched to DTG (n=30). Furthermore, most had no comorbidities (n=31) and were not on other medications (n=22). Therefore, weight gain at 6 months post-DTG initiation was significantly associated with baseline WHO Stage 1 (p=0.048).

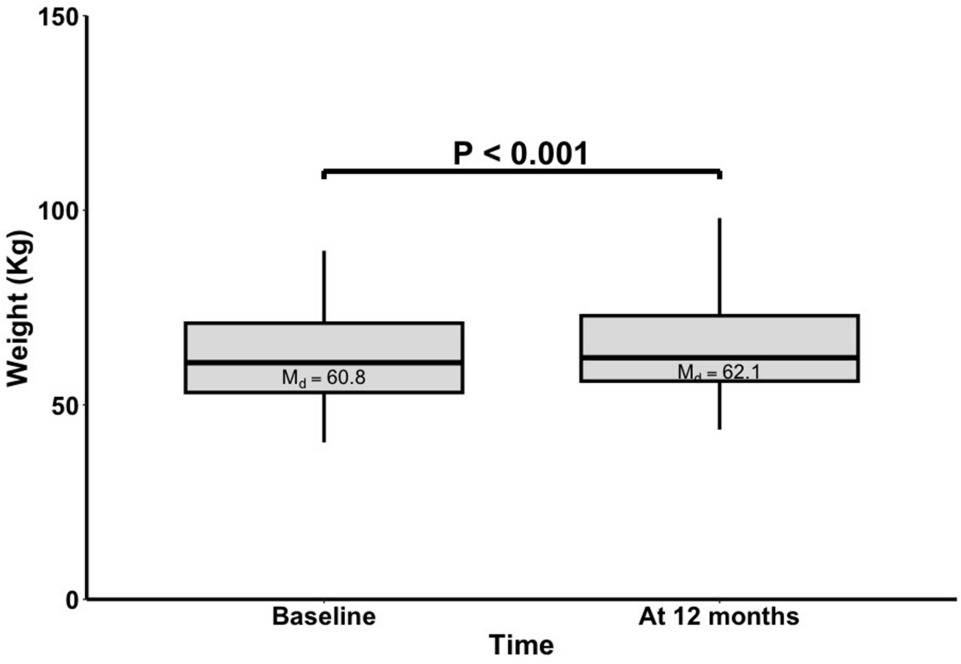

Figure 3 Comparison of participant weight at baseline and 12 months. Data are presented as box-and-whisker plots showing the median and interquartile range. The statistical comparison was performed using a Wilcoxon signed-rank test. (n=187).

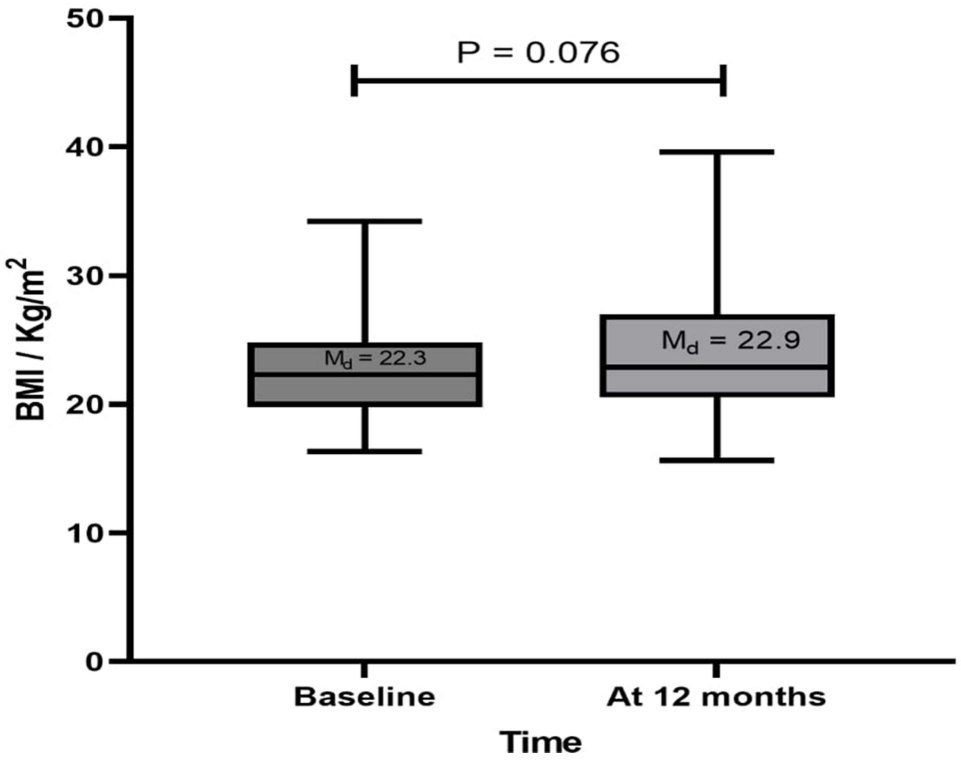

Figure 4 Comparison of participant BMI at baseline and 12 months. Data are presented as box-and-whisker plots showing the median and interquartile range. The statistical comparison was performed using a Wilcoxon signed-rank test. (n=187).

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Table 3 Bivariate Analysis of Factors Associated with Weight Gain Among the Participants at 6 Months

Variable	All N=432 (Freq (%)) [Median (IQR)]	Weight Gain		P Value
		No n=400 (Freq (%)) [Median (IQR)]	Yes n=32 (Freq (%)) [Median (IQR)]	
Age,	[44(37–49.5)]	[44(37–50)]	[42.5(36–47)]	0.561
Sex				
Female Male	362(83.8) 70(16.2)	334(83.5) 66(16.5)	28(87.5) 4(12.5)	0.803
Baseline WHO staging				
1 2 3 4	355(92) 27(7) 3(0.8) 1(0.3)	325(91.6) 27(7.6) 3(0.8) 0(0)	30(96.8) 0(0) 0(0) 1(3.2)	0.048
CD4 at baseline	[274(155–378)]	[265(154–382)]	[294.5(166–351)]	0.667
<200 ≥200	146(34) 283(66)	137(34.5) 260(65.5)	9(28.1) 23(71.9)	0.563
Viral load at baseline, n=149	[231(59–231)]	[231(58–638)]	[67(61–312)]	0.159
<1000 ≥1000	137(92) 12(8.1)	124(91.2) 12(8.8)	13(100) 0(0)	0.601
WHO staging after 6 months, n=377				
1 2 3 4	367(97.4) 7(1.9) 2(0.5) 1(0.3)	339(97.4) 7(2) 2(0.6) 0(0)	28(96.6) 0(0) 0(0) 1(3.5)	0.103
Viral load at 6 months	[115(50–231)]	[60(55–70)]	[61(56.5–75.5)]	0.359
<1000 ≥1000	129(97.7) 3(2.3)	121(97.6) 3(2.4)	8(100) 0(0)	0.999
Mode of DTG				
As initial regimen Switch	13(3) 419(97)	11(2.8) 389(97.3)	2(6.2) 30(93.8)	0.249
Reason for switch				
New drug available Toxicity Unsuppressed	363(98.1) 4(1.1) 3(0.8)	334(98) 4(1.2) 3(0.9)	29(100) 0(0) 0(00	0.738
Duration of therapy in months	[12(10–15)]	[12(10–15)]	[11.5(10–15)]	0.773
Comorbidity				
No Yes	378(96.2) 15(3.8)	347(96.1) 14(3.9)	31(96.9) 1(3.1)	0.831
Other medication				
No Yes	314(79.7) 80(20.3)	292(80.7) 70(19.3)	22(68.8) 10(31.3)	0.113

Factors Associated with Weight Gain at 12 Months Post-DTG Initiation at Bivariate Analysis

Table 4 summarizes the bivariate analysis of factors associated with weight gain at 12 months post-DTG initiation as compared to the baseline values. Weight gain was significantly associated with a baseline viral load <1000 copies/mL (n=13, p=0.009).

Table 4 Bivariate Analysis of Factors Associated with Weight Gain Among the Participants at 12 Months Compared to Baseline Values

Variable	All N=187 (Freq (%)) [Median (IQR)]	Weight Gain at 12 Months		P Value
		No n=156 (Freq (%)) [Median (IQR)]	Yes n=31 (Freq (%)) [Median (IQR)]	
Age,	[45(37–52)]	[45.5(37.5–51.5)]	[44(27–55)]	0.952
Sex				
Female Male	145(77.5) 42(22.5)	122(78.2) 34(21.8)	23(74.2) 8(25.8)	0.640
Baseline WHO staging, n=183				
1 2 3 4	166(90.7) 14(7.7) 2(1.1) 1(0.5)	138(90.2) 14(9.2) 1(0.7) 0(0)	28(93.3) 0(0) 1(3.3) 1(3.3)	0.021
CD4 at baseline				
<200 ≥200	60(32.4) 125(67.6)	48(31) 107(69)	12(40) 18(60)	0.395
Viral load at baseline, n=76				
<1000 ≥1000	72(94.7) 4(5.3)	59(93.7) 4(6.3)	13(100) 0(0)	0.009
Mode of DTG				
As initial regimen Switch	6(3.2) 181(96.8)	5(3.2) 151(96.8)	1(1.2) 30(96.8)	0.999
Reason for switch				
New drug available Toxicity	176(98.9) 2(1.1)	147(98.7) 2(1.3)	29(100) 0(0)	0.999
Duration of therapy in months	[15(13–21)]	[15(13–20.5)]	[15(14–22)]	0.216
Comorbidity				
No Yes	175(94.1) 11(5.9)	146(94.2) 9(5.8)	29(93.6) 2(6.4)	0.999
Other medication				
No Yes	141(75.8) 45(24.2)	120(77.4) 35(22.6)	21(67.7) 10(32.3)	0.257

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Table 5 Summarizes Factors Associated with Weight Gain at Multivariable Logistic Regression Analysis

Variable	Adjusted Odds Ratio	95% CI	P value
Other medication			
No	1.0		
Yes	1.9	0.86–4.18	0.113

Of the 187 participants with follow-up data at 12 months post-DTG initiation, 31 (16.5%) experienced weight gain. Their median age was 44 years, and most were female (n=23). Nearly all (n=28) were at WHO Stage 1, and more than half (n=18) had baseline CD4 counts ≥200 cells/μL. Most participants with weight gain had switched to DTG (n=30); majority had no comorbidities (n=29) and were not on other medications (n=21).

Factors Associated with Weight Gain at Multivariable Logistic Regression Analysis

At multivariable logistic analysis, no factor had a statistically significant association with weight gain (Table 5).

Discussion

This study investigated the prevalence of weight gain and associated factors among PLHIV attending the ART clinic at St Mary's Hospital, Lacor, at 6 and 12months post DTG initiation (PDN). Primary data on the prevalence of weight gain among patients on DTG-based regimen (DBRs) in sub-Saharan Africa and Uganda remain scarce. However, we found a 7.4% overall weight gain prevalence after 6 months whilst on DTG and a significant ($p<0.001$) weight and BMI difference between baseline and 6 months PDN. Also, the weight difference between baseline and 12 months PDN was significant ($P<0.001$). These findings are consistent with similar studies; in a lower-income sub-Saharan African population; higher weight gain with DBRs compared with traditional ART for treatment-naïve patients has been reported.[15] Furthermore, a Korean cohort also denoted weight gain from 6months through a 24-month follow-up in PLHIV on DBRs.[16] However, results from an Italian cohort rejected any significant weight gain association with the switch to DTG in PLHIV at 65 years of age,[17] albeit denoting a low intake of female participants as a study limitation when compared to other supporting studies. Furthermore, the discrepancies could also be due to differences in study populations, methodologies, or the presence of confounding factors not accounted for in retrospective study designs.

In our study, Lower baseline WHO clinical staging (Stage I, n=30/32 at baseline, p=0.048) and Viral loads <1000copies (p>0.009) were significantly associated with weight gain at 6 and 12 months PDN, respectively. At bivariate analysis, baseline WHO Stage I (n=28, 93.3%, p=0.021) also predicted weight gain at 12 months. These findings are consistent with an Ethiopian study where PLHIV initiating TDF/3TC/DTG at lower WHO HIV stages were more likely to gain weight than those on non-DTG regimens (mean 12-month weight gain: 3.88 ± 2.02 kg vs 2.26 ± 2.39 kg on EFV-based ART). The similarity may reflect comparable African populations and the better baseline health status represented by lower WHO stages.[13] Females on DBRs were more likely to gain weight (n=28, 87.5% at 6 months; and n=23, 74.2% at 12 months) than males (n=4, 12.5% at 6 months; and n=8, 25.8% at 12 months), therefore echoing Kenyan findings where male sex appeared protective.[15] This may partly reflect the predominance of female participants, though sex-related effects on weight warrant further investigation. Notably, no factor remained statistically significant in multi-variable logistic regression.

To our knowledge, this is among the first studies in Uganda, and specifically the Acholi sub-region, to examine the association between DBRs and weight gain, associated factors, and post-initiation weight and BMI differences in PLHIV. In addition, the study did not assess key metabolic markers and potential confounders such as waist circumference, waist–hip ratio, blood pressure, blood glucose, lipid profile, nutrition, and physical activity. Incorporating serial reviews of these factors during DTG treatment is recommended. Despite these limitations, our findings are instructive and lay a foundation for future research and policy review aimed at preventing non-communicable diseases in PLHIV on DBRs.

Conclusions

Our study found a substantial prevalence of weight gain among people living with HIV on DBRs at 6 months post-DTG initiation and a significant baseline to 6months weight and BMI difference was uncovered. Also, the Baseline to 12 months post-DTG initiation weight difference was significant. Lower baseline WHO clinical staging and viral loads <1000copies were the only factors significantly associated with weight gain at 6 (primary endpoint) and 12 months (secondary endpoint) post-DTG initiation, respectively. However, a larger prospective-type study is recommended to substantiate this finding, resolve the role of the female status and uncover the significance of other potential confounders. We recommend routine weight monitoring at 6 months intervals (especially in females, and WHO stage 1), or per 3 months in case of co-morbid confounders, and this - coupled with the integration of active Non-communicable diseases' screening into ART clinic care for PLHIV on DBRs.

Abbreviations

DTG, Dolutegravir; EFV, Efavirenz; TDF/3TC/DTG, Tenofovir/Lamivudine/Dolutegravir; AIDS, Advanced Immune Deficiency Syndrome; ART, Antiretroviral therapy; DBRs, Dolutegravir-Based ART Regimens; PDN, Post-DTG initiation; HIV, Human immunodeficiency syndrome; PLHIV, People living with HIV; WHO- World Health Organisation.

Data Sharing Statement

Data and materials are available upon reasonable request from the corresponding author (Ivaan Pitua) with institutional approval.

Ethical Considerations

The study protocol and informed consent waiver were approved by the Gulu University Research Ethics Committee (GUREC), approval number GUREC 2022-375. The study complied with the Declaration of Helsinki at all stages.

Author Contributions

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

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Disclosure

The authors report no conflicts of interest in this work.

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