Scientific Research Publishing

Advances in Infectious Diseases, 2026, 16(1), 192-203
https://www.scirp.org/journal/aid
ISSN Online: 2164-2656
ISSN Print: 2164-2648

# Weight Gain Following Dolutegravir Based Antiretroviral Therapy in HIV-Naive Patients: A Comparative Study at the Ambulatory Treatment Center of the Regional Hospital of Kaolack (Senegal)

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**How to cite this paper:** Massaly, A., Badiane, A.S., Fall, N.M., Mbaye, K.D., Lakhe, N.A., Thioub, D., Diouf, A., Cisse, V.M.P., Ka, D., Fortes, L., Ndour, C.T. and Seydi, M. (2026) Weight Gain Following Dolutegravir Based Antiretroviral Therapy in HIV-Naive Patients: A Comparative Study at the Ambulatory Treatment Center of the Regional Hospital of Kaolack (Senegal). *Advances in Infectious Diseases*, **16**, 192-203.
https://doi.org/10.4236/aid.2026.161014

**Received:** February 3, 2026
**Accepted:** March 10, 2026
**Published:** March 13, 2026



## Abstract

**Introduction**: Initiation of antiretroviral therapy is often associated with weight gain. The objective of this study is to compare weight gain at 12 and 24 months after initiation of dolutegravir-based ART with other regimens and to determine the factors associated with weight gain of more than 10% at 24 months. **Methods:** We conducted an observational, longitudinal and retrospective study of a cohort of people living with HIV followed at Kaolack Regional Hospital between January 2015, and July 2023. Patients were divided into two groups: one group of patients receiving TLD and a second group receiving a regimen based on non-nucleoside inhibitors or protease inhibitors. In multivariate analysis, logistic regression was performed to determine the factors associated with weight gain greater than or equal to 10%. **Results**: Among the 203 patients who met the inclusion criteria, 70 were on a Dolutegravir-based regimen and 133 were on a non-nucleoside inhibitor or protease inhibitor-based regimen. The average age was 45 years ± 11.5 years, and women accounted for 73.5% of the population. More than half of the patients were classified as stage 3 or 4 according to the WHO clinical classification. The average weight change at 24 months was +8.51 kg for patients on dolutegravir versus +7.24 kg for patients on other regimens. A weight gain greater than or equal to 10% at 24 months was observed in 58.1% of patients, and the factors associated with this gain were female gender (OR: 1.98 (95% CI: 1.01 - 3.90);

p = 0.04) and WHO clinical stage 3 and 4 (OR: 4.03 (95% CI: 1.30 - 7.04); p < 0.001). **Conclusion**: We report greater weight gain in patients on Dolutegravir-based regimens compared to other non-nucleoside and protease inhibitor-based regimens. However, DTG is not significantly associated with excessive weight gain in this cohort of HIV-positive patients.

## Keywords

Weight Gain, Antiretrovirals, Dolutegravir, Kaolack, Senegal

## 1. Introduction

The initiation of antiretroviral therapy is often associated with weight gain in people living with HIV [1]. This weight gain is accompanied by therapeutic success with restored immunity, improved nutritional status, and survival. However, being overweight or obese is associated with a risk of cardiovascular and metabolic diseases and excess mortality [2] [3]. Several factors have been identified in the occurrence of excessive weight gain in patients living with HIV, including low CD4 counts at inclusion, low initial body mass index (BMI), and antiretroviral therapy [4] [5]. This antiretroviral therapy has significantly changed the course of HIV infection, which has become a chronic disease. There are now antiretroviral drugs capable of rapidly suppressing viral load and over time eliminating the virus from the body. Regimens based on integrase inhibitors are the preferred treatment regimen for HIV due to their efficacy, better tolerance, limited drug interactions, and high genetic barrier [6] [7]. Some studies have shown an association between integrase inhibitors and excessive weight gain compared to other ARV regimens [8] [9]. A meta-analysis showed that DTG is the integrase inhibitor most associated with excessive weight gain [9].

In Senegal, national guidelines have recommended integrase inhibitor-based regimens such as Dolutegravir such as Tenofovir + lamivudine + Dolutégravir (TLD) as first-line treatment for adults and adolescents since 2020, following recommendations from the World Health Organization (WHO). As a result, the country has opted to transition older and treatment-naive patients to DTG-based regimens. However, there is very little current data on weight gain in our patients taking these DTG-based regimens. The objective of this study is to evaluate, 24 months after initiation of ART, the differences in weigt evolution between TLD to other regimens (based on non-nucleoside inhibitors or protease inhibitors) and to identify the factors associated with greater weight gain in these patients.

## 2. Methods

This was an observational, longitudinal and retrospective study conducted in a cohort of patients living with HIV who were being treated at Kaolack Regional Hospital. This cohort has been in place since 2002 in the hospital's infectious dis-

eases department. The medical records of patients who started treatment between January 2015 and July 2023 were collected.

### 2.1. Participants

We included all HIV patients over the age of 18 who were treatment-naive and regularly monitored for at least two years after starting antiretroviral therapy.

Patients were divided into two groups: the first group consisted of patients who started with a treatment regimen containing dolutegravr (TLD). The second group consisted of patients who were on a regimen based on non-nucleoside reverse transcriptase inhibitors (TDF + 3TC + EFV) or a regimen based on protease inhibitors (TDF + 3TC + LPV/r). In each group, patients were regularly monitored for at least two years, with data on height and weight collected at M0, M12, and M24. We did not include patients who were transferred from another site with ART, patients who had been off treatment for more than 1 month, women who were pregnant or patients who had been on substitution therapy for more than 1 month due to a break of the ARV protocol.

### 2.2. Data Collection

Data collection is based on individual medical records and an Excel tracking template set up by the National Council for the Fight against HIV (CNLS) at treatment sites. The data collected were sociodemographic (age, gender, marital status, level of education, origin) and clinical (year of inclusion, presence of tuberculosis, occurrence of opportunistic infections other than tuberculosis, comorbidities, WHO clinical stage of HIV, height, weight, ARV protocol) biological data (hepatitis B serology, fasting blood glucose, hemoglobin level, creatinine level at inclusion). Body mass index (BMI) was calculated based on weight at the start of ART, at 12 months, and at 24 months of treatment. We defined clinically significant weight gain as an increase in body weight of ≥10% compared to initial body weight.

### 2.3. Statistical Analysis

Data were entered using Excel software and analyzed using Jamovi software version 4.3.3. Qualitative variables were expressed as frequencies and percentages, and quantitative variables as means and standard deviations or medians with interquartile ranges. In bivariate analysis, demographic, clinical, and biological characteristics in the two treatment groups were evaluated using a Student's t-test or a chi-square test, depending on the nature of the variable. To determine the difference in weight at month 12 and 24 in the entire population, we performed a paired t-test if normality was respected, otherwise a Wilcoxon test was used. However, to compare weight gain between the two groups, an independent t-test or Mann-Whitney test was performed. In multivariate analysis, to identify the factors associated with weight gain of more than 10%, a stepwise logistic regression method was used. All variables with a p-value ≤ 0.25 in the bivariate analysis were included in the multivariable model, and variables such as baseline BMI and sex

were systematically included. The variables for determining ORa with 95% confidence intervals. An alpha threshold of 5% was set for statistical significance of the tests. The presence of collinearity between the explanatory variables included in the regression model was assessed using the variance inflation factor, and a value of this factor > 5 was considered to indicate significant collinearity. A Hosmer Lemeshow test was used to assess the goodness of fit of the logistic regression model, and a p-value > 0.05 indicated a satisfactory fit to the data.

Regarding ethical considérations, authorization was obtained from the authorities of the Ambulatory Treatment Center of the regional hospital of Kaolack. Confidentiality and anonymity were strictly maintained and personal infomation was numerically coded.

## 3. Results

### 3.1. Baseline Characteristics of the Study Participants

Between January 2015 and July 2023, a total of 435 patients were included in the cohort, of whom 203 met the study inclusion criteria. Seventy patients (34.5%) were receiving TLD treatment. Meanwhile, 133 (65.5%) were receiving treatment based on either non-nucleoside reverse transcriptase inhibitors or protease inhibitors. The average age of the patients was 45 ± 11.5 years, with no significant difference between the two groups. There was a clear predominance of women, at 73.4%, and among them 22.2% were on DTG-based therapy. Among men, only 12.3% were on DTG-based therapy (Table 1).

Table 1. Socio-demographic and anthropometric characteristics of the study population.

| Variables | Total N = 203 | ART protocol | | p-value |
|---|---|---|---|---|
| | | TLD N = 70 | Other protocol N = 133 | |
| Age in years means (±DS) | 45.4 ± 11.5 | 45.8 ± 13.2 | 45.2 ± 10.6 | **0.743** |
| **Gender** | | | | |
| Female | 149 (73.4) | 45 (22.2) | 104 (51.2) | **0.03** |
| Male | 54 (26.6) | 25 (12.3) | 29 (14.3) | |
| **Marital status** | | | | |
| Single | 18 (8.9) | 08 (3.9%) | 10 (4.9) | **0.368** |
| Maried (Monogamous) | 76 (37.4) | 20 (9.9) | 56 (27.6) | |
| Maried (polygamous) | 50 (24.6) | 21 (10.3) | 29 (14.3) | |
| Separed | 20 (9.9) | 06 (3) | 14 (6.9) | |
| Widowed | 38 (18.7) | 15 (7.4) | 23 (11.3) | |
| Not specified | 01 (0.5) | 0(0) | 01 (0.5) | |
| **Residence** | | | | |
| Urban | 136 (67) | 48 (23.6) | 88 (43.3) | **0.729** |
| Rural | 67 (33) | 22 (10.8) | 45 (22.2) | |

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| | | | | |
|---|---|---|---|---|
| **Occupation** | | | | |
| Housewife | 92 (45.3) | 29 (14.3) | 63 (31) | **0.447** |
| Self employed | 77 (37.9) | 26 (12.8) | 51 (25.1) | |
| Employed | 25 (12.3) | 10 (4.9) | 15 (7.4) | |
| No job | 7 (3.4) | 03 (1.5) | 04 (2) | |
| Retired | 1 (0.5) | 1(0.5) | 0 (0) | |
| Students | 1 (0.5) | 1 (0.5) | 0 (0) | |
| **Weight (Kg) means (Kg) (DS)** | | | | |
| M0 | 56 ± 14.5 | 56.1 (±12.2) | 56.1 (±15.3) | **0.373** |
| M12 | 62.3 ± 13.8 | 63 (±11.8) | 61.9 (±14.9) | **0.215** |
| M24 | 63.7 ± 14.3 | 64.6 (±11.6) | 63.3 (±15.5) | **0.237** |
| **BMI (kg /m²) means (DS)** | | | | |
| BMI M0 | 19.7 ± 4.58 | 19.7 ± 4.49 | 19.7± 4.64 | **0.715** |
| BMI M12 | 21.9 ± 4.40 | 22.1 ± 4.41 | 21.7 ± 4.41 | **0.431** |
| BMI M24 | 22.4 ± 4.65 | 22.7 ± 4.51 | 22.2 ± 4.73 | **0.387** |

Opportunistic infections were found in 147 (72%) patients. More than half of the patients were classified as stage 3 or 4 according to the WHO classification at inclusion. Hbs antigen testing was performed in 178 patients, with a positivity rate of 11.8%. Chemoprophylaxis with cotrimoxazole was administered to 121 (59.6%) patients with no significant difference between the protocols (p = 0.393). However, isoniazid chemoprophylaxis was administered to 48.3% of patients, with a statistically significant difference between the two groups (p < 0.001) (Table 2).

Table 2. Clinical and biological characteristics of the study population.

| Variables | Total N = 203 | ART protocol | | p-value |
|---|---|---|---|---|
| | | TLD N = 70 | Other protocols N = 133 | |
| **Opportunistic infection** | | | | |
| Yes | 147 (72.4) | 46 (22.7) | 101 (49.8) | **0.121** |
| No | 56 (27.6) | 24 (11.8) | 32 (15.8) | |
| **HBV co-infection** | | | | |
| Non | 164 (80.8) | 52 (25.6) | 112 (55.2) | **0.134** |
| Oui | 24 (11.8) | 09 (4.4) | 15 (7.4) | |
| Missing | 15 (7.4) | 9 (4.4) | 6 (3) | |
| **Comorbidites** | | | | |
| Hypertension | 24 (11.9) | 07 (3.5) | 17 (8.4) | **0.736** |
| Heart diseases | 2 (1) | 01 (0.5) | 01 (0.5) | |
| Diabetes | 3 (1.5) | 01 (0.5) | 02 (1) | |
| Dyslipidemia | 1 (0.5) | 01(0.5) | 0 (0) | |
| Asthma | 2 (1) | 0 (0) | 02 (01) | |
| Not specified | 175 (86.2) | 61 (30) | 114 (56.2) | |

Continued

| | | | | |
|---|---|---|---|---|
| **WHO clinical stage** | | | | |
| Stage 1 | 49 (24.1) | 19 (9.4) | 30 (14.8) | **0.393** |
| Stage 2 | 40 (19.7) | 17 (8.4) | 23 (11.3) | |
| Stage 3 | 76 (37.4) | 21 (10.3) | 55 (27.1) | |
| Stage 4 | 38 (18.7) | 13 (6.4) | 25 (12.3) | |
| **Receipt of cotrimoxazole** | | | | |
| Yes | 121 (59.6) | 37 (18.2) | 84 (41.4) | **0.155** |
| No | 82 (40.4) | 33 (16.3) | 49 (24.1) | |
| **Receipt of INH** | | | | |
| Yes | 98 (48.3) | 52 (25.6) | 46 (22.7) | **<0.001** |
| No | 105 (51.7) | 18 (8.9) | 87 (42.9) | |
| **Median hemoglobine level (g/dl) DS** | 11 [4.9 - 16] | 11.6 [7 - 15.6] | 10.8 [4.9 - 16] | **0.05** |
| **Median glucose level (g/l) DS** | 0.85 [0.56-1.94 | 0.95 [0.65 - 1.94] | 0.87 [0.56 - 1.81] | **0.41** |

### 3.2. Weight Gain According to Treatment Protocols

In both groups, the average initial weight was identical at 56.1 kg. After 12 months of treatment, an increase in average weight was observed in both groups: the average weight reached 63 kg ± 11.8 in the DTG group compared to 61.9 kg ± 14.9 in the group of patients on other protocols, with no statistically significant difference ($p = 0.215$). This trend continued at 24 months of treatment, with an average weight of 64.6 kg ± 11.6 in the DTG group compared to 63.3 kg ± 15.5 in the other protocol group (Table 3).

Considering the entire cohort, weight gain was +6 kg (95% CI: 5 - 7.5) at 12 months and +8 kg (95% CI: 6.5 - 9.5) at 24 months of treatment, with a significant difference ($p < 0.001$). In the DTG group, weight gain was +6.9 kg (95% CI: 5 - 7.5) at 12 months and +8.51 kg (95% CI: 6.4 - 10.6) at 24 months, also with a statistically significant difference ($p < 0.001$). Similarly patients on other protocols had a gain of +6 kg (95% CI: 4.5 - 7.5) at 12 months and 7.2 kg (95% CI: 5.6 - 8.6) at 24 months of treatment. The comparison between the two groups showed no statistically significant difference in weight gain at either 12 or 24 months ($p = 0.21$) (Table 3).

Table 3. Differences in weight by treatment regimens at 12 and 24 months relative to baseline.

| Différence moyenne de poids (kg) IC 95% | M12 | M24 |
|---|---|---|
| Total | 6 [5 - 7.5] | 8 [6.5 - 9.5] |
| DTG based protocol | 6.9 [5 - 7.5] | 8.51 [6.43 - 10.6] |
| Other protocols | 6 [4.5 - 7.5] | 7.24 [5.6 - 8.6] |
| DTG vs other protocoles | 2 [−1; 6] p = 0.21 | 2 [−1; 6] p = 0.23 |

### 3.3. Factors Associated with Weight Gain ≥ 10%

Two years after initiation of antiretroviral therapy, weight gain of ≥10% was observed in 118 patients, representing 58.1% of the study participants. In multivariate analysis, the Dolutegravir-based treatment regimen was not significantly associated with weight gain ≥ 10% (OR: 1.40 [0.68 - 2.49], p = 0.35). Although a risk was observed with DTG compared to other regimens, it did not reach the threshold of significance. On the other hand, female gender emerged as an independent risk factor for weight gain. Women had an almost twofold increased risk of major weight gain [OR: 1.98 (95% CI: 1.01 - 3.90); p = 0.04] compared to men. In addition, the presence of advanced HIV infection (stages 3 and 4 of the WHO clinical classification) had a major influence on weight gain. These patients were four times more likely to have weight gain ≥ 10% (OR: 4.03 (95% CI: 1.30 - 7.04); p < 0.001) compared to those in the early stages of HIV infection (Table 4).

Table 4. Factors associated with weight gain according to treatment regimens: results from multivariate analysis.

| Variables | ORa | IC 95% | p |
|---|---|---|---|
| **Gender** | | | |
| F | 1.98 | 1.01 - 3.90 | **0.04** |
| M | - | | |
| **Age ≥ 45 years** | | | |
| Oui | 0.65 | 0.32 - 1.33 | 0.27 |
| Non | - | | |
| **WHO clinical stage** | | | |
| 1 et 2 | - | 1.30 - 7.04 | **< 0.001** |
| 3 et 4 | 4.03 | | |
| **DTG based protocol** | | | |
| **Oui** | 1.40 | 0.68 - 2.49 | 0.35 |
| **Non** | - | | |
| **Receipt of cotrimoxazole** | | | |
| Oui | 1.04 | 0.48 - 2.25 | 0.91 |
| Non | - | | |
| **Receipt of INH** | | | |
| Oui | 1.23 | 0.64 - 2.38 | 0.52 |
| Non | - | | |

## 4. Discussion

In our study, patients who started antiretroviral therapy with a dolutegravir-based regimen had a greater average weight gain at 12 and 24 months compared to those on non-nucleoside inhibitor or protease inhibitor-based regimens. Weight gain

after initiation of antiretroviral therapy was greater during the first 12 months. However, when comparing weight gain in patients on TLD versus other regimens, no significant difference was found. Our study also shows that in this population of HIV-naive patients, significant weight gain two years after initiation of antiretroviral therapy is more influenced by female gender and advanced clinical stage of the disease than by the use of DTG-based regimens.

The weight gain observed in our antiretroviral treatment-naive patients has been widely found in most cohorts of patients living with HIV. In a multicenter, prospective study, the authors noted a 2.6 kg increase in median weight in treatment-naive patients after 2 years of antiretroviral treatment [10]. Several other studies confirm our findings on weight gain regardless of the treatment protocol [4] [11]-[13]. Weight gain during antiretroviral treatment can be explained by several mechanisms. HIV infection is associated with an increase in basal metabolism linked to viral replication and the resulting generalized inflammatory response. Inflammation markers have an effect on the hypothalamus, causing anorexia and promoting weight loss. Another factor is inflammation of the intestinal mucosa linked to the local immune response, which causes enteropathy and changes in the microbiota. This enteropathy is accompanied by increased digestive permeability and decreased intestinal absorption, contributing to the weight loss observed in patients [14]. The reversal of this phenomenon of hypermetabolism under antiretroviral treatment, with the return of appetite and improved intestinal absorption, contributes to weight gain [15]. However, greater weight gain during the first 12 months of antiretroviral treatment could suggest an improvement in clinical condition under treatment.

In our study, patients who started treatment with Dolutegravir based regimens had greater weight gain at 12 months and 24 months compared to other patients taking either NNRTI- or PI-based regimens, but without a significant difference. Several recent studies confirm our findings. A meta-analysis involving 5680 patients found that patients on integrase inhibitor-based regimens had greater weight gain after 24 months of treatment (+3.34 kg) compared to patients on non-nucleoside inhibitor-based and protease inhibitor-based regimens, with +1.96 kg and +1.72 kg, respectively [16]. In sub-Saharan Africa, similar results were observed in studies on weight gain under integrase inhibitors. In Ethiopia, in a retrospective cohort study, patients who started Dolutegravir-based regimens gained an average of +8.6 kg at 24 months compared to +4.95 kg in the INNTI-based treatment group [17]. Other studies in Cameroon, South Africa, and a multicenter study (Nigeria, Uganda, Kenya, and Tanzania) confirm these data on weight gain with integrase inhibitors compared to other protocols, particularly NNRTI or PI [18]-[20]. Among integrase inhibitors, dolutegravir and bictegravir appear to be most associated with weight gain [20] [21].

The mechanisms explaining weight gain under integrase inhibitors are not fully understood. Some studies suggest that integrase inhibitors are associated *in vitro* with the inhibition of melanocortin 4 receptors (MC4R). The latter is involved in

the regulation of appetite and metabolic energy homeostasis by modulating leptin and insulin signaling [22]. However, McMahon *et al.* have shown that in order to have an effect on MC4R receptor inhibition, plasma concentrations of integrase inhibitors would need to be much higher than those achieved with the recommended doses. This makes this explanation highly unlikely [23]. According to other studies, dolutegravir has an effect on adipogenesis and lipogenesis, which would therefore be the cause of weight gain. In a French study to investigate the effects of integrase inhibitors on adipose tissue, human and simian models were used. The authors showed that treatment with integrase inhibitors, in this case DTG, was associated with adipose tissue fibrosis with a profibrotic profile of adipocytes that exhibited oxidative stress promoting lipid accumulation and insulin resistance [24].

Weight gain is therefore frequently observed after the initiation of antiretroviral treatment. However, excessive weight gain increases the risk of obesity, cardiovascular disease, dyslipidemia, diabetes, chronic kidney disease, and cancer [25]. When combined with HIV, these comorbidities are a major risk factor for morbidity and mortality [3] [26]-[28].

In our study population, multivariate analysis showed that the factors associated with excessive weight gain (>10%) were female gender and advanced disease stage. Previous studies have demonstrated the association between female gender, advanced HIV infection, and weight gain during antiretroviral therapy [18] [19] [29] [30]. Contrary to our results, several recent studies have reported a significant association between excessive weight gain and integrase inhibitor-based regimens in both treatment-naive patients and patients switching regimens [8] [16] [17] [31] [32].

The absence of an association noted in our study could be explained by characteristics specific to our population, the limited size of our sample, and the limited follow-up period for observing this association. It should also be noted that DTG was combined with tenofovir disoproxil fumarate (TDF) and lamivudine (TLD). Thus, the mitigating effect of TDF on weight gain described in some studies could also partly explain our results [33]. In this study, we did not take into account certain factors such as socioeconomic conditions, eating habits or lifestyle, which may have an impact on weight gain.

Furthermore, our results are reassuring in the context of the widespread use of integrase inhibitor-based protocols as first-line treatment in adults and adolescents, as well as in children. However, careful monitoring of weight gain is necessary, as is active screening for cardiovascular and metabolic risk factors in our patients receiving these protocols.

## 5. Conclusion

In our study, patients on DTG-based regimens (TLD) gained more weight than patients on non-nucleoside inhibitor or protease inhibitor regimens. Excessive weight gain was more common in women and in patients with advanced HIV

infection. Thus, the weight gain observed suggests an improvement in clinical condition rather than the direct effects of the drugs. However, long-term studies on larger cohorts, incorporating anthropometric, nutritional, metabolic, and cardiovascular parameters, are needed to better understand the determinants of excessive weight gain in our African populations.

## Conflicts of Interest

There are no conflicts of interest.

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