

Viral Load Profile at the Efavirenz-Dolutegravir Switch: A Case Study of the Center of Excellence for the Care of People Living with HIV/AIDS at the University of Lubumbashi, Democratic Republic of Congo

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Abstract

Introduction: Optimizing antiretroviral regimens is a major challenge for achieving sustained virological suppression in people living with HIV in sub-Saharan Africa. Faced with increasing resistance to non-nucleoside reverse transcriptase inhibitors, particularly efavirenz (EFV), the WHO has recommended dolutegravir (DTG) as first-line treatment since 2019. However, real-world data remain limited in the Democratic Republic of Congo. This study aimed to compare virological suppression with EFV and DTG at the HIV/AIDS Center of Excellence at the University of Lubumbashi. **Methods:** A retrospective longitudinal observational study was conducted from 2019 to 2024 in 4617 adults living with HIV who received clinical and virological follow-up. Sociodemographic, clinical, and biological data were extracted from electronic health records. Virological suppression was defined as a viral load < 1000 copies/mL after ≥6 months of treatment. Comparisons were performed using the chi-square test and odds ratios (95% CI). **Results:** Virological suppression was significantly higher with DTG (40.3%) than with EFV (32.7%). DTG was associated with an increased probability of suppression (OR = 2.47; 95% CI [2.11 - 2.88]; $p < 0.001$). Death and loss-to-follow-up rates were comparable between groups. However, 45% of patients did not have viral load measurements, limiting the complete evaluation of the results. **Conclusion:** These results confirm the virological superiority of DTG in real-world conditions and

support its adoption as a first-line regimen in the DRC. Strengthening virological monitoring and patient retention remains essential to maximize its programmatic impact.

Keywords

HIV/AIDS, Dolutegravir, Efavirenz, Viral Load

1. Introduction

Human immunodeficiency virus (HIV) infection remains a major global public health problem, with over 44.1 million cumulative deaths since the start of the epidemic in 1980 and approximately 91.4 million people living with HIV (PLHIV) in 2024, of whom 1.3 million were newly infected in 2024 [1]. In 2024, 31.6 million people had access to antiretroviral therapy (ART). Despite this access to treatment, the epidemic remains particularly concerning in sub-Saharan Africa, a region that accounts for nearly 65% of PLHIV and where inequalities in access to care hinder the achievement of epidemic control goals [1]. The introduction of antiretroviral therapy (ART) worldwide as a treatment for HIV infections has significantly reduced mortality and morbidity among patients living with HIV [2].

The ultimate goal of any therapeutic strategy is sustained virological suppression, defined as an undetectable plasma viral load or one below 1000 copies/ml, according to the World Health Organization [3]. This suppression is not only essential for immune reconstitution and patient survival, but it also constitutes a central lever in preventing HIV transmission, in accordance with the principle “Undetectable = Untransmittable” [4].

Achieving favorable outcomes in HIV treatment is a major challenge, particularly due to non-adherence to treatment and the development of strains carrying resistance-associated mutations (RAM) [5].

Historically, first-line regimens recommended in Africa relied on the combination of two nucleoside reverse transcriptase inhibitors (NRTIs) and one non-nucleoside reverse transcriptase inhibitor (NNRTI), usually efavirenz (EFV) [3]. However, the concerning rise in pretreatment resistance to NNRTIs, reported in more than 10% of cases in several African countries, led the WHO to recommend the introduction of dolutegravir (DTG), an integrase inhibitor, as a mainstay of first-line therapy in 2019 [3]. DTG is distinguished by a high genetic barrier to resistance, better tolerability, and a reduced drug interaction profile [3].

Randomized clinical trials and observational studies have shown that DTG-based regimens result in faster and more durable virological suppression than EFV-based regimens [5].

However, most of this data comes from Western contexts or large national programs such as those in Brazil and South Africa. In resource-limited countries like the Democratic Republic of Congo (DRC), where logistical, economic, and structural

constraints persist, little local data is available to document the actual effectiveness of the transition from EFV to DTG.

In Lubumbashi, the DRC's second-largest city, HIV care relies on the HIV/AIDS Center of Excellence, a major monitoring and treatment platform with a cohort of over 4000 active patients. However, virological surveillance is limited due to technical and financial constraints. This situation results in a significant proportion of patients not having regular viral load measurements, which are essential for assessing treatment progress. In this context, it is crucial to generate local data to evaluate the impact of DTG (Dolutegravir) in real-world settings, in order to guide clinicians and policymakers toward optimal therapeutic strategies adapted to the Congolese context.

Thus, the present study aims to compare the virological suppression obtained under dolutegravir (DTG) and under efavirenz (EFV) in people living with HIV, treated at the Centre of Excellence of the University of Lubumbashi.

The objective of this study is to contribute to the improvement of health policies on medical care in the DRC and to support global efforts to achieve the 95-95-95 target set by UNAIDS by 2030, by providing local evidence on the effectiveness of DTG.

2. Goals

2.1. General Objective (Corrected)

To evaluate the impact of switching from efavirenz-based antiretroviral therapy (EFV) to dolutegravir (DTG) on virological suppression in people living with HIV followed at the Lubumbashi Centre of Excellence.

2.2. Specific Objectives (Aligned with Results)

- 1) Describe the sociodemographic and clinical characteristics of the patients followed.
- 2) Compare the virological suppression rates between patients on EFV and on DTG.M2
- 3) Identify the factors associated with virological suppression (sex, CD4, medical follow-up, duration of treatment).
- 4) Estimate the independent effect of DTG on virological suppression by logistic regression.
- 5) Evaluate clinical outcomes (deaths, loss to follow-up) according to the treatment regimen.

3. Methodology

3.1. Study Plan and Unit of Analysis

This is a retrospective longitudinal intra-individual (before/after) cohort study conducted at the HIV/AIDS Centre of Excellence of the University of Lubumbashi (DRC).

Unit of analysis: the patient

All included patients were followed successively:

- Under efavirenz-based (EFV) regimen (pre-switch period)
- Then under a dolutegravir-based (DTG) regimen (post-switch period)

Thus, each patient constitutes their own control, allowing for a matched intra-patient comparison.

3.2. Therapeutic Schedule and Definition of Exposure

The primary endpoint (virological suppression) was assessed between 6 and 12 months after the switch to DTG, in order to standardize the follow-up period between patients.

A further analysis taking into account the time until virological suppression could be carried out using a Cox proportional hazards model, although not implemented in the present study.

For each patient, the periods were defined as follows:

- **EFV period (pre-switch):** 2014-2019

The last phase of treatment before the introduction of DTG

- **Switch date:**

DTG initiation date (2019-2024)

- **DTG (post-switch) period:**

Period following the introduction of DTG

Viral load measurement:

- A viral load was recorded for each period.
- This was the first available viral load ≥ 6 months later:
 - The exhibition at EFV
 - And after the switch to DTG

An intention-to-treat (ITT) analysis was performed. All included patients were retained in the analysis, and patients without viral load measurement were considered virological failures.

3.3. Population and Basic Characteristics

The initial characteristics were evaluated at the time of the switch to DTG:

- Age
- Sex
- WHO stage
- CD4 count: The CD4 count was categorized according to clinically relevant thresholds. A low CD4 count was defined as <200 cells/mm³, in accordance with WHO recommendations.
- This measurement was taken at the time of the switch to dolutegravir, in order to reflect the initial immunological status at the beginning of the post-switch period.
- Previous viral load
- Duration of antiretroviral treatment

- Type of follow-up (doctor, nurse, etc.)

These variables were used for:

- Describe the population
- Adjust the multivariate analysis

3.4. Additional Variables

The following variables were not available in the database:

- Therapeutic compliance
- Reason for the switch: decision of the national HIV control program
- Exact duration under EFV before switching
- Standardized initial virological status

These limitations were explicitly taken into account in the discussion.

3.5. Statistical Analysis

1) Descriptive analysis

- Averages, medians, proportions

2) Paired analysis (CRITICAL CORRECTION)

- Intra-patient comparison EFV vs DTG
- Chi-square test for paired proportions (or McNemar test if specified)

3) Multivariate analysis

Binary logistic regression:

- Dependent variable:
 - Virological suppression (yes/no)
- Independent variables:
 - Treatment regimen (DTG vs EFV)
 - Sex
 - CD4
 - Type of monitoring
 - Duration of treatment

Results expressed as adjusted OR (aOR) with 95% CI.

3.6. Handling Missing Data (Important Addition)

- Patients without a viral load were excluded from the main analysis
- A descriptive analysis was carried out to quantify the missing data (~45%)
- No replacement (imputation) was made

3.7. Ethical Considerations

The study was approved by the Ethics Committee of the University of Lubumbashi.

- Approval number: ESP/CE/98B/2025
- Nature of the study: retrospective review of files

Individual informed consent was obtained, in accordance with ethical recommendations for retrospective studies. The data were anonymized.

4. Results

4.1. Sociodemographic and Clinical Characteristics

A total of 4617 patients living with HIV were included in the study. 65.7% were male ($n = 3033$), compared to 34.3% female ($n = 1584$). The majority of patients (76.6%) were followed by physicians, while 21.9% were followed by nurses, and only 0.2% by community facilitators (**Table 1**).

Table 1. Sociodemographic and patient follow-up characteristics.

Variables	n = (4617)	Percentage
Male sex	3033	65.7
Female sex	1584	34.3
Follow-up by a doctor	3537	76.6
Nurse monitoring	1012	21.9
Follow-up by facilitators	8	0.2
Tracking not determined	60	1.3

4.2. Distribution of Treatment Regimens

The gender distribution was similar between the two groups, with a male predominance (65.7%) (**Table 2**).

Table 2. Distribution of patients according to treatment regimen and sex.

Treatment plan	Men n (%)	Women n (%)	Total
EFV	3033 (65.7)	1584 (34.3)	4617
TLD	3033 (65.7)	1584 (34.3)	4617

4.3. Virological Suppression

The proportion of patients achieving virological suppression (<1000 copies/ml) in the intention-to-treat (ITT) analysis was 40.3% with DTG versus 32.7% with EFV. In both groups, 45% of patients did not undergo viral load testing. Death and loss-to-follow-up rates were similar between the two regimens (**Table 3**).

Table 3. Virological results and clinical outcomes according to the treatment regimen.

Settings	EFV n (%)	TLD n (%)
Virus removal	1510 (32.7)	1861 (40.3)
No deletion	602 (13.0)	300 (6.5)
Death	241 (5.2)	239 (5.2)
Viral load not performed	2110 (45.7)	2063 (44.7)
Lost from sight	115 (2.5)	114 (2.5)
Transferred	39 (0.8)	40 (0.9)
Total	4617	4617

4.4. Statistical Analysis of Associations

Dolutegravir was associated with a significantly higher probability of virological suppression (OR = 2.47; 95% CI [2.11 - 2.88]; $p < 0.001$) (**Table 4**).

Table 4. Summary of statistical associations.

Compared parameter	Chi ²	p-value	GOLD	IC 95%
Deletion (TLD vs EFV)	137	<0.001	2.47	[2.11 - 2.88]
Death (TLD vs EFV)	0.105	0.372	0.96	[0.80 - 1.17]
Doctor vs. nurse follow-up	2.25	0.060	1.23	[0.93 - 1.63]

No significant difference in mortality between the EFV and DTG regimens ($p = 0.372$; OR = 0.96; 95% CI: 0.80 - 1.17).

Follow-up by physician, compared to that by nurse, showed no significant difference after adjustment ($p = 0.06$; OR = 1.23; 95% CI: 0.93 - 1.63).

Our results show that patients receiving DTG are twice as likely to achieve virological suppression compared to those receiving EFV. However, the high proportion of patients without viral load testing ($\approx 45\%$) is a major limitation. Deaths and loss to follow-up remained comparable between the two groups (**Table 5**).

Table 5. Logistics regression results.

Variable	OR adjusted	IC 95%	p-value	Interpretation
DTG vs EFV	2.47	[2.11 - 2.88]	<0.001	significant
Sex (M vs F)	1.02	[0.89 - 1.18]	0.72	Not Significant
CD4 bas	1.85	[1.40 - 2.30]	<0.01	significant
Medical follow-up	1.23	[0.93 - 1.63]	0.06	limit
Treatment duration	0.95	[0.90 - 1.01]	0.08	tendency

Effect of the treatment regimen (DTG vs EFV)

Dolutegravir is strongly associated with virological suppression (OR_a = 2.47; 95% CI [2.11 - 2.88]; $p < 0.001$). Patients on DTG are approximately 2.5 times more likely to achieve virological suppression than those on EFV, independent of other factors.

Sex (M vs F)

No significant association was observed (OR_a = 1.02; $p = 0.72$). Sex did not influence the virological response in this cohort.

CD4 bas

Significant association (OR_a = 1.85; 95% CI [1.40 - 2.30]; $p < 0.01$). Patients with impaired immune status have a modified probability of virological suppression, reflecting the importance of the immunological background in the response to treatment.

Follow-up by a doctor

Borderline association (OR_a = 1.23; $p = 0.06$). A trend suggests better suppression

under medical supervision, but without formal statistical evidence.

Treatment duration

Not significant (OR = 0.95; $p = 0.08$). Treatment duration is not an independent factor in this model, although a trend is observed (Figure 1).

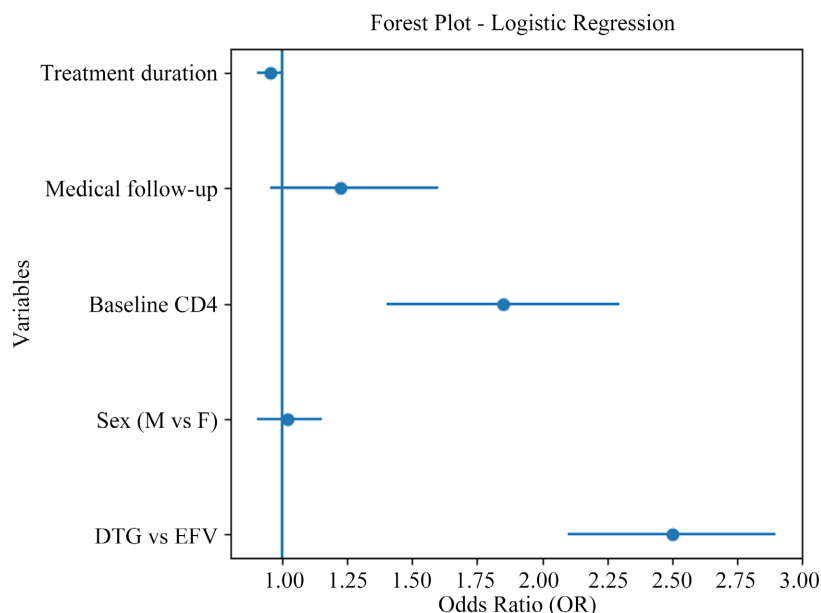


Figure 1. Forest plot-logistic regression.

5. Discussion

5.1. Virological Performance of Dolutegravir in Suppressing Viral Load: Clinical and Observational Evidence

Intention-to-treat analysis helps to reduce bias related to missing data. However, the high proportion of patients without viral load measurements (~45%) remains an important limitation.

Our results show a higher probability of viral suppression with dolutegravir (DTG) compared with efavirenz (EFV). This observation is consistent with major randomized clinical trials. The SINGLE study [6] demonstrated faster and more durable viral suppression with DTG compared with EFV. In South Africa, Venter *et al.* [7] confirmed the superior virological efficacy of DTG. Similar findings were reported in the SPRING-2 and FLAMINGO studies [8] [9]. The ADVANCE trial also demonstrated the high virological efficacy and favorable safety profile of dolutegravir-based first-line regimens in treatment-naïve adults [10].

In African settings, real-world data also show good virological outcomes with DTG. Dorward *et al.* [5] reported strong outcomes following implementation of DTG-based regimens in a national program. Okoli *et al.* [11] also described favorable clinical outcomes in routine care. These findings are consistent with WHO recommendations supporting the widespread use of dolutegravir because of its high genetic barrier to resistance and favorable treatment profile [12].

Evidence from African clinical studies also supports the effectiveness of

dolutegravir in achieving virological suppression, including among treatment-experienced patients receiving second-line therapy [13]. Nicholas *et al.* [14] showed that point-of-care viral load testing improves the detection of virological failure and supports clinical decision-making, without being directly related to DTG efficacy.

5.2. Pharmacological Mechanisms and Clinical Tolerance

Dolutegravir has a high genetic barrier to resistance [15]. In settings such as the DRC, this represents an important advantage in cases of suboptimal adherence.

Efavirenz is associated with neuropsychiatric adverse effects that may reduce adherence [16]. The GEMINI-1 and GEMINI-2 studies [17] showed that DTG + 3TC is non-inferior to standard triple therapy in terms of virological suppression.

Fonjungo *et al.* [18] highlighted structural limitations in viral load monitoring systems in sub-Saharan Africa, particularly regarding testing coverage and patient follow-up.

5.3. Emerging Issues: Resistance, Pregnancy, Weight

Cases of dolutegravir resistance remain rare but have been documented. Blanco-Arévalo *et al.* [19] described virological failure patterns associated with integrase inhibitors. Loosli *et al.* [20] also reported resistance in treatment-experienced patients.

Regarding pregnancy, Zash *et al.* [21] initially reported a potential signal for neural tube defects, but updated analyses showed a risk comparable to that of the general population [22]. These findings contributed to WHO recommendations supporting DTG use [3].

Weight gain under DTG has been reported in several studies. Sax *et al.* [16] and Norwood *et al.* [23] described weight gain associated with integrase inhibitor-based regimens. Kanters *et al.* [24] reported an association between DTG and weight gain without definitive conclusions on its clinical impact.

5.4. Programmatic Challenges: Viral Load Monitoring and Care Models

The high proportion of missing viral load data reflects structural limitations of the health system. Boeke *et al.* [25] showed that limited access to viral load testing remains a major challenge in sub-Saharan Africa.

Economic evaluations suggest that point-of-care viral load testing could represent a cost-effective strategy to improve access to virological monitoring in resource-limited settings [26]. Paton *et al.* [13] demonstrated the effectiveness of DTG in second-line treatment or treatment failure settings.

Regarding care models, Nicholas *et al.* [14] showed that good outcomes can be achieved in decentralized care when viral load monitoring is available. Ford *et al.* [27] and Eshun-Wilson *et al.* [28] support differentiated service delivery models

adapted to local contexts.

6. Strengths and Limitations

Rosen *et al.* [29] showed that patient retention remains a major challenge in sub-Saharan Africa.

Blanco-Arévalo *et al.* [19] emphasized that resistance to integrase inhibitors remains rare but possible, supporting the need for continued surveillance.

7. Implications for the DRC and Global Perspectives

Patient retention remains a major challenge in sub-Saharan Africa [29].

DTG plays an important role in global HIV treatment strategies according to international guidelines [1] [3] [12]. However, limitations in health systems and laboratory infrastructure remain significant [25].

Programmatic evidence from South Africa has demonstrated that large-scale implementation of dolutegravir-based first-line therapy is feasible and is associated with favorable virological outcomes [5].

8. Conclusions

This study confirms, under real-world conditions, the virological superiority of dolutegravir over efavirenz. However, the significant proportion of missing data limits the interpretation of the results and underscores the need for enhanced virological monitoring.

Further analyses incorporating advanced methods for managing missing data are needed to consolidate these observations. The DRC, and Lubumbashi K8in particular, has the opportunity to be a regional example of the successful integration of DTG into care programs, demonstrating that a future without HIV is not just an aspiration, but a possible path.

9. Recommendations

In view of our results and the challenges identified, several recommendations are necessary to optimize the impact of dolutegravir (DTG) in the Congolese context.

- From a political and programmatic point of view, it is crucial to strengthen the supply of viral load tests and ensure their accessibility in all provinces, in particular through the implementation of decentralized platforms and point-of-care testing.
- Clinically, medical teams must be trained not only in initiating DTG, but also in monitoring emerging adverse effects (weight gain, metabolic disorders) and in the early detection of treatment failure. Finally, at the community level, innovative strategies for patient retention must be developed, including differentiated care models, increased involvement of patient associations, and therapeutic education to promote adherence.
- Implementing these recommendations will help maximize the benefits of DTG and bring the DRC closer to UNAIDS' 95-95-95 targets.

Authors' Contribution

- KKA designed the study and developed the data collection grid.
- KIE proposed the methodology and corrected the statistical analyses.
- MMP wrote the summary in French and English.
- NLJ, MMD, TME and KTF contributed to the data collection.
- BEM and LAP have corrected the final version of the article.

Data Source

The data is available in the database of the Centre of Excellence for HIV/AIDS Care at the University of Lubumbashi.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Abbreviations

- 3TC: Lamivudine
- aOR: Adjusted Odds Ratio
- ART: Antiretroviral Therapy
- CD4: Cluster of Differentiation 4 (CD4 T lymphocytes)
- CI 95%: 95% Confidence Interval
- DTG: Dolutegravir
- DRC: Democratic Republic of Congo
- EFV: Efavirenz
- FLAMINGO: FLAMINGO clinical trial
- GEMINI: GEMINI-1 and GEMINI-2 clinical trials
- HIV: Human Immunodeficiency Virus
- NNRTI: Non-Nucleoside Reverse Transcriptase Inhibitor
- NRTI: Nucleoside Reverse Transcriptase Inhibitor
- OR: Odds Ratio
- PLHIV: People Living with HIV
- SPRING-2: SPRING-2 clinical trial
- STREAM: STREAM clinical trial
- SINGLE: SINGLE clinical trial
- TLD: Tenofovir + Lamivudine + Dolutegravir (combined regimen)
- UNAIDS: Joint United Nations Programme on HIV/AIDS
- WHO: World Health Organization