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Research Article

Evaluation of the Virological Efficacy of Switching to a Dolutegravir-Based Tritherapy in Patients Followed Under Real-Life Conditions in Abidjan (Côte d'Ivoire)

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Abstract

In Côte d'Ivoire, the initiation or transition to dolutegravir (DTG)-based triple therapy often occurs without prior assessment of viral replication or resistance mutations to nucleoside reverse transcriptase inhibitors (NRTIs), which possess a lower genetic barrier. This cross-sectional study, conducted at the Integrated Centre for Bioclinical Research in Abidjan (CIRBA) between February 2019 and January 2022, aimed to evaluate the virological impact of switching to TDF+3TC+DTG (TLD) under real-world conditions. The study included two groups of people living with HIV-1 (PLHIV-1), each having undergone two plasma viral load measurements. One group remained on TLD throughout, while the other transitioned from TLE or TLL to TLD. Plasma HIV-1 RNA quantification was performed using Roche Cobas AmpliPrep/Cobas TaqMan or Cobas 4800 platforms (Roche Diagnostics, Mannheim, Germany), with a detection threshold of 20 copies/mL. Viral load categories were defined as: virological failure (≥1,000 copies/mL), detectable viraemia (20-999 copies/mL), and undetectable viraemia (< 20 copies/mL). Among 6,275 samples analysed, 198 patients met the inclusion criteria. The median age was 39 years, with a female predominance (sex ratio: 1.5). Following transition to TLD, the proportion of patients with undetectable viraemia increased from 62% to 73%, and virological failure decreased from 17% to 4%. These findings confirm the efficacy of DTG-based therapy, while underscoring the need for systematic virological monitoring, including plasma RNA quantification and genotypic resistance testing, to guide therapeutic transitions.

Keywords: *HIV-1; Viral Load; Dolutegravir (DTG); Antiretroviral Regimen; Therapeutic Switch; Côte d'Ivoire*

Abbreviations

AIDS: Acquired Immunodeficiency Syndrome; HIV: Human Immunodeficiency Virus; HAART: Highly Active Antiretroviral Therapy; ARV: Antiretroviral Drugs; NRTI: Nucleoside Reverse Transcriptase Inhibitors; NNRTI: Non-Nucleoside Reverse Transcriptase Inhibitors; PLHIV: People Living with HIV; MSHP: Ministry of Health and Public Hygiene; INI: Integrase Inhibitor; DTG: Dolutegravir; WHO: World Health Organization; PI: Protease Inhibitors; PLHIV-1: People Living with HIV-1; CIRBA: Bioclinical Research in Abidjan; PCR: Polymerase Chain Reaction; TLD: TDF+3TC+DTG; TLE: TDF + 3TC + EFV; TLL: TDF + 3TC + LPV/r

Introduction

Acquired Immunodeficiency Syndrome (AIDS) is a life-threatening infectious disease caused by the Human Immunodeficiency Virus (HIV) [1]. It remains a major global health concern due to the absence of an effective vaccine and curative therapy [2].

The standard therapeutic approach is Highly Active Antiretroviral Therapy (HAART), typically comprising a combination of three or more antiretroviral drugs (ARVs) that inhibit viral replication at various stages of its lifecycle [3,4]. These regimens primarily target reverse transcriptase through the use of nucleoside reverse transcriptase inhibitors (NRTIs) and non-nucleoside reverse transcriptase inhibitors (NNRTIs) [3]. However, ARVs targeting other mechanisms such as viral entry, fusion, and key viral enzymes including protease and integrase have also been developed [3]. This therapeutic strategy has yielded favourable outcomes, including sustained viral suppression, reduced incidence of opportunistic infections, and partial restoration of immune function [5].

In Côte d'Ivoire, the "Test and Treat All" strategy has been adopted as a national policy for the management of people living with HIV (PLHIV). This approach entails initiating treatment for all individuals who test positive for HIV, irrespective of clinical or immunological eligibility criteria [6].

Historically, the first-line regimen consisted of two NRTIs and one NNRTI [7]. However, as of 1 March 2019, the Ministry of Health and Public Hygiene (MSHP) replaced the NNRTI component with an integrase inhibitor (INI), Dolutegravir (DTG), in accordance with World Health Organization (WHO) recommendations [8,9]. The superior efficacy of INI-based regimens compared to those based on protease inhibitors (PIs) or NNRTIs has been well documented [10,11].

Despite these advances, virological monitoring remains a challenge in Côte d'Ivoire. Moreover, the initiation or systematic transition to DTG-based regimens is not always guided by viral load measurements or resistance profiling, which are often unavailable. Consequently, assessing the severity of infection, evaluating treatment efficacy, and selecting appropriate therapeutic agents are critical steps in optimising patient outcomes.

Objective of the Study

The objective of this study was to evaluate the virological impact of switching to DTG-based triple therapy in people living with HIV-1 (PLHIV-1), monitored under real-world conditions at the Integrated Centre for Bioclinical Research in Abidjan (CIRBA), Côte d'Ivoire.

Materials and Methods

Study population

This cross-sectional study was conducted between February 2019 and January 2022 at the CIRBA, a national reference facility for the clinical management of PLHIV. The study population comprised two groups of HIV-1-positive individuals receiving antiretroviral therapy and monitored at CIRBA, each of whom had undergone two separate viral load measurements for the assessment of virological control. The first group underwent both measurements while maintained on a DTG-based regimen, whereas the second group had their initial measurement while on a non-DTG regimen and their subsequent measurement following a switch to a DTG-based regimen.

Ethical considerations and biological analyses

The study was conducted within the molecular biology laboratory of the CIRBA, a national reference institution for HIV virological monitoring in Côte d'Ivoire. It received internal approval from CIRBA in accordance with prevailing ethical principles and recognised standards of biomedical research practice. All analyses were performed in full compliance with confidentiality protocols, biological data integrity, and the protection of individuals living with HIV, in line with both national guidelines and international recommendations. Biological analyses consisted of quantifying HIV-1 viral RNA in plasma using real-time polymerase chain reaction (PCR). Quantification was performed with Roche-developed assays on the Cobas AmpliPrep/Cobas TaqMan platform (Roche Diagnostics, Mannheim, Germany) and the Cobas 4800 system (Roche Diagnostics, Mannheim, Germany), with a lower detection threshold of 20 copies/mL. Viraemia was categorised as virological failure (viral load ≥ 1,000 copies/mL), detectable viraemia (viral load between 20 and 1,000 copies/mL), or undetectable viraemia (viral load < 20 copies/mL).

Data processing and statistical analyses

Data processing was performed using Microsoft Excel 2013, and statistical analyses were conducted with IBM SPSS Statistics, version 25.

Results

Sociodemographic characteristics of the study population

A total of 6,275 plasma samples were received for the quantification of HIV 1 viral RNA. Patients for whom quantification was performed at two distinct time points accounted for 3.5% (n = 220/6,275) of all samples. Of these, 90% (n = 198/220) of individuals who either switched to or remained on the TDF+3TC+DTG (TLD) regimen constituted the study population. The sex ratio was 1.5 (118 women to 80 men) in favour of women. The median age was 39 years (range: 10 - 78 years), and the median duration of ARV treatment was 14 years (range: 2 - 23 years). At the time of the first plasma viral RNA quantification, the distribution of ARV regimens was as follows: 73% (145/198) on TLD, 20% (40/198) on TDF + 3TC + EFV (TLE), and 7% (13/198) on TDF + 3TC + LPV/r (TLL). The median interval between the two plasma viral RNA measurements was 11 months (range: 1 - 24 months). At the time of the second quantification, all patients were receiving TLD (Table 1). Among the 73% (145/198) of patients who underwent both plasma viral RNA quantifications while on TLD, the sex ratio was 1.3 (82 women to 63 men) in favour of women. The median age was 22 years (range: 10 - 78 years), the median interval between measurements was 8 months (range: 1 - 17 months), and the median duration of ARV treatment was 13 years (range: 2 - 23 years) (Table 2). In the 20% (40/198) of patients who had their first plasma viral RNA quantification on TLE and their second on TLD, the sex ratio was 1.85 (26 women to 14 men) in favour of women. The median age was 50 years (range: 12 - 70 years), the median interval between measurements was 12 months (range: 3 - 24 months), and the median duration of ARV treatment was 13 years (range: 4 - 22 years) (Table 3). In the 7% (13/198) of patients who had their first plasma viral RNA quantification on TLL and their second on TLD, the sex ratio was 3.33 (10 women to 3 men) in favour of women. The median age was 42 years (range: 20 - 55 years), the median interval between measurements was 10 months (range: 3 - 13 months), and the median duration of ARV treatment was 15 years (range: 9 - 21 years) (Table 4).

Prevalence of virological failure among study population

Among the 90% (n = 198/220) of patients who either transitioned to or remained on the TLD regimen, 62% (n = 124/198) exhibited undetectable viraemia (viral load (VL) < 20 copies/mL), 21% (n = 41/198) presented with detectable viraemia (VL between 20 - 1000 copies/mL), and 17% (n = 33/198) experienced virological failure (VL ≥ 1000 copies/mL) at the time of the first plasma viral RNA quantification. At the second plasma viral RNA quantification, 73% (n = 144/198) had undetectable viraemia an increase of 10% (n

Characteristics (N= 198)		
Sex Male (n, %) Female (n, %)	 80 118	 40 60
Age (years) Median; Range	 39	 [10-78]
ARV regimen at first plasma viral RNA quantification TDF+3TC+DTG (TLD) (n, %) TDF+3TC+EFV (TLE) (n, %) TDF+3TC+LPV/r (TLL) (n, %)	 145 40 13	 73 20 7
ARV regimen at second plasma viral RNA quantification TDF+3TC+DTG (TLD) (n, %)	 198	 100
Time between 2 plasma viral RNA quantifications (months) Median; Range	11	[1-24]
Time on ARVs (years) Median; Range	 14	 [02-23]

Table 1: *Sociodemographic characteristics of all study patients.*

Characteristics (N=145)		
Sex Male (n, %) Female (n, %)	 63 82	 43 57
Age (years) Median; Range	 22	 [10-78]
ARV regimen at first and second plasma viral RNA quantifications TDF+3TC+DTG (TLD) (n, %)	145	100
Time between 2 plasma viral RNA quantifications (months) Median; Range	8	[1-17]
Time on ARVs (years) Median; Range	 13	 [2-23]

Table 2: *Sociodemographic characteristics of patients in continuous treatment with TLD.*

Characteristics (N= 40)		
Sex Male (n, %) Female (n, %)	 14 26	 35 65
Age (years) Median; Range	 50	 [12-70]
ARV regimen at first plasma viral RNA quantification TDF+3TC+EFV (TLE) (n, %)	40	100

ARV regimen at second plasma viral RNA quantification TDF+3TC+DTG (TLD) (n, %)	40	100
Time between 2 plasma viral RNA quantifications (months) Median; Range	12	[03-24]
Time on ARVs (years) Median; Range	13	[04-22]

Table 3: *Sociodemographic characteristics of TLE patients who switched to TLD.*

Characteristics (N = 13)		
Sex Male (n, %) Female (n, %)	 3 10	 23 77
Age (years) Median, Range	42	[20-55]
ARV regimen at first plasma viral RNA quantification TDF+3TC+EFV (TLE) (n, %)	13	100
ARV regimen at second plasma viral RNA quantification TDF+3TC+DTG (TLD) (n, %)	13	100
Time between 2 plasma viral RNA quantifications (months) Median; Range	10	[3-13]
Time on ARVs (years) Median; Range	15	[9-21]

Table 4: *Sociodemographic characteristics of patients on TLL who switched to TLD.*

= 20/198); 23% (n = 45/198) had detectable viraemia an increase of 2% (n = 4/198); and 4% (n = 9/198) showed virological failure a decrease of 12% (n = 24/198) (Table 5 and figure 1). Of the 73% (n = 145/198) of patients who underwent two plasma viral RNA quantifications under TLD, 64% (n = 93/145) had undetectable viraemia, 21% (n = 30/145) had detectable viraemia, and 15% (n = 22/145) had virological failure at the first quantification. At the second quantification, 73% (n = 106/145) had undetectable viraemia an increase of 9% (n = 13/145); 22% (n = 32/145) had detectable viraemia an increase of 1% (n = 2/145); and 5% (n = 7/145) had virological failure a decrease of 10% (n = 15/145) (Table 6). Among the 20% (n = 40/198) of patients who had a first plasma viral RNA quantification under TLE and a second under TLD, 65% (n = 26/40) had undetectable viraemia, 20% (n = 8/40) had detectable viraemia, and 15% (n = 6/40) had virological failure at the first quantification. At the second quantification, 80% (n = 32/40) had undetectable viraemia an increase of 15% (n = 6/40); 15% (n = 6/40) had detectable viraemia a decrease of 5% (n = 2/40); and 5% (n = 2/40) had virological failure a decrease of 10% (n = 4/40) (Table 7). Among the 7% (n = 13/198) of patients who had a first plasma viral RNA quantification under TLL and a second under TLD, 46% (n = 6/13) had undetectable viraemia, 8% (n = 1/13) had detectable viraemia, and 46% (n = 6/13) had virological failure at the first quantification. At the second quantification, 46% (n = 6/13) maintained undetectable viraemia an increase of 8% (n = 1/13); 46% (n = 6/13) had detectable viraemia an increase of 38% (n = 5/13); and no cases of virological failure were observed in this group (Table 8).

Characteristics (N = 198)	Frequency	Percentage (%)
First quantification of plasma viral RNA (Copies/mL)		
VL < 20 (n, %)	124	62
VL between [20-1000[(n, %)	41	21
VL ≥ 1000 (n, %)	33	17
Second quantification of plasma viral RNA (Copies/mL)		
VL < 20 (n, %)	144	73
VL between [20-1000[(n, %)	45	23
VL ≥ 1000 (n, %)	9	4

Table 5: *Prevalence of virological failure among all patients in the study.*

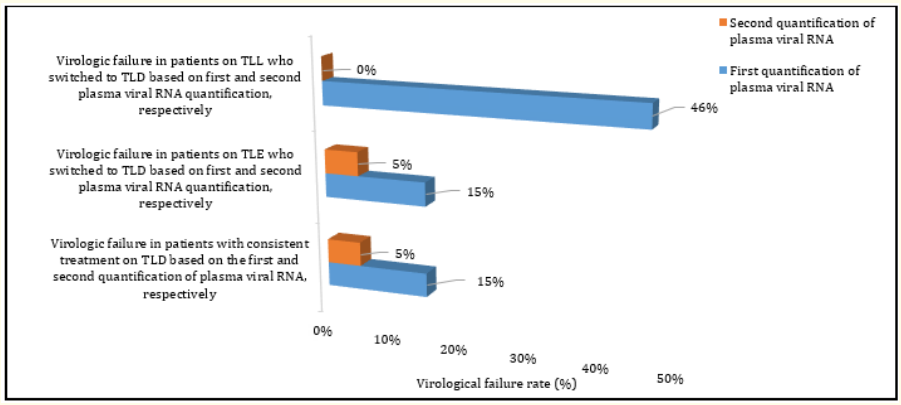

Figure 1*: Warts in the back.*

Characteristics (N = 145)	Frequency	Percentage
First quantification of plasma viral RNA (Copies/mL)		
VL < 20 (n, %)	93	64
VL between [20-1000[(n, %)	30	21
VL ≥ 1000 (n, %)	22	15
Second quantification of plasma viral RNA (Copies/mL)		
VL < 20 (n, %)	106	73
VL between [20-1000[(n, %)	32	22
VL ≥ 1000 (n, %)	7	5

Table 6: *Prevalence of virologic failure in patients with consistent treatment on TLD.*

Characteristics (N = 40)	Frequency	Percentage
First quantification of plasma viral RNA (Copies/mL)	26	65
VL < 20 (n, %)	8	20
VL between [20-1000[(n, %)	6	15
VL ≥ 1000 (n, %)		
Second quantification of plasma viral RNA (Copies/mL)	32	80
VL < 20 (n, %)	6	15
VL between [20-1000[(n, %)	2	5
VL ≥ 1000 (n, %)		

Table 7: *Prevalence of virologic failure in patients on TLE who switched to TLD.*

Characteristics (N = 13)	Frequency	Percentage
First quantification of plasma viral RNA (Copies/mL)	6	46
VL < 20 (n, %)	1	8
VL between [20-1000[(n, %)	6	46
VL ≥ 1000 (n, %)		
Second quantification of plasma viral RNA (Copies/mL)	7	54
VL < 20 (n, %)	6	46
VL between [20-1000[(n, %)	0	0
VL ≥ 1000 (n, %)		

Table 8: *Prevalence of virologic failure in patients on TLL who switched to TLD.*

Discussion

As part of the present study, an evaluation of the virological efficacy of switching to a DTG-based triple therapy was conducted among patients monitored under real-life conditions in Abidjan, Côte d'Ivoire.

The results of our study revealed a significant improvement in virological suppression following the introduction or continuation of TLD, with an increase in undetectable viraemia from 62% to 73% and a decrease in virological failure from 17% to 4% between two measurements. The hypothesis of an overall signal is confirmed in the subgroup of patients who initiated treatment with TLD (undetectable: 64% to 73%; failure: 15% to 5%). This trend is even more pronounced in the subgroup of patients who switched from TLE to TLD (undetectable: 65% to 80%; failure: 15% to 5%). These observations suggest a rapid and clinically relevant benefit of DTG, both as a first-line regimen and as a switch strategy. The findings of our research are strongly supported by the conclusions of several studies [12-14], which have demonstrated the superiority of DTG over EFV in sub-Saharan Africa. The response observed in patients already on TLD at the first measurement may be interpreted, in real-life settings, as an expression of the pharmacological robustness and tolerability of this class of integrase inhibitors.

The subgroup of patients who switched from TLE to TLD had the highest median age (50 years) and a historical exposure to EFV. This subgroup illustrates the expected "switch gain". Indeed, the increase in the proportion of undetectable patients and the reduction in the virological failure rate to one-third of its initial value are consistent with the benefits observed when switching to a DTG-based triple

therapy in several African countries [15,16]. Conversely, some studies have reported that this benefit may be attenuated in individuals with significant comorbidity and poor adherence [17-19]. It is therefore essential to emphasise the importance of adherence and differentiated support to maximise the effectiveness of the drug switch.

The subgroup of patients who switched from TLL to TLD reveals a more complex dynamic. We observed the disappearance of virological failure (46% to 0%) but a rise in detectable viraemia without failure (8% to 46%). Two complementary interpretations are warranted. Firstly, many failures under boosted protease inhibitors (here LPV/r) are, in practice, more often due to poor adherence than to genuine resistance to PIs [20]. Switching to DTG, which is better tolerated and simpler to use, can therefore improve adherence and rapidly resolve failure, without guaranteeing immediate undetectability. Secondly, after long treatment durations (median: 15 years), archived resistance to NRTIs (M184V for 3TC, K65R for TDF) may reduce the activity of the "backbone", leaving DTG to provide the main control. The clinical outcome may thus be a persistently low or moderate viraemia before complete suppression. These hypotheses are consistent with the findings of Aboud and colleagues, who established the superiority of DTG over LPV/r in second-line therapy, provided that at least one active NRTI is retained [21]. Similarly, Paton and colleagues, as well as Loosli and colleagues, have shown that the use of DTG with partially compromised NRTIs can still achieve high levels of suppression, albeit at the cost of a risk of persistent viraemia and, in a minority of poorly adherent patients, the potential emergence of DTG resistance [22,23].

Conclusion

This study, conducted under real-life conditions in Abidjan, confirms the virological efficacy of DTG-based triple therapy, both at initiation and upon switching. However, it also highlights that some patients who have undergone this transition still present with detectable viraemia and virological failure. These observations underscore the importance of rigorously supporting the systematic transition to a DTG-based regimen with appropriate virological tools, notably plasma HIV RNA quantification and genotypic resistance testing. Such an approach would optimise therapeutic monitoring and ensure sustained virological suppression, in line with the requirements of the Ivorian context and international standards.

Author Contributions

Toni Thomas d'Aquin: Conceptualization, performed the experiments and processed the data, analyzed the data and wrote the manuscript.

Dechi Jean-Jacques Renaud: Conceptualization, performed the experiments and processed the data, analyzed the data and wrote the manuscript.

N'din Jean-Louis Philippe: Performed the experiments

Ake Aya Jeanne Armande: Provided critical input and feedback

Gogbe Leto Olivier: Performed the experiments

Kouabla Liliane Siransy: Provided critical input and feedback

Kabore Saydou: Provided critical input and feedback

Brou Emmanuel: Provided critical input and feedback

Fieni Flore: Performed the experiments

Aby Roland: Performed the experiments

Chenal Henri: Performed the experiments

Massara Camara-Cisse: Performed the experiments

Sekongo Yassongui Mamadou: Performed the experiments

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Conflicts of Interest

We declare that we have no conflict of interest.

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