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Evolution of Viral Load Under First-Line Antiretroviral Treatment (Art) Based on Dolutegravir in N'djamena, Chad

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Abstract

The objective of this study was to assess the evolution of viral load on Tenofovir (TDF)+Lamivudine (3TC) +Dolutegravir (DTG) (TLD) in PLVAs newly initiated on ART. The study took place at the Psycho Medico-Social Support Center (APMS) in N'Djamena over a period of 12 months. Sociodemographic data and viral load (VL) data were collected using a pre-established form. The VC examination was performed using the BIOCENTRIC molecular biology platform. A total of 120 patients were included in this study. Analyses showed a highly significant decrease in CVs during TLD follow-up ($p < 0.0001$). The proportion of patients with a suppressed viral load (CV <1000 copies/m) was 20,8% at M0, 98.3% at M3, 93.3% at M6 and 95% at M12. These results show that the Dolutegravir-based therapeutic line is remains an essential pillar in HIV ART.

Keywords: Viral load, antiretroviral treatment, Dolutegravir.

INTRODUCTION

Since the introduction of triple antiretroviral therapy, which is increasingly effective and well tolerated, HIV infection has evolved from a constant fatality to a chronic disease, with a remarkable improvement in the quality of life of people living with HIV (PLHA). Antiretrovirals (ARVs) effectively inhibit viral replication and thus promote immune restoration that protects infected people from major opportunistic infections **(**Day k et *al*., 2017). The ambitious UNAIDS 95-95-95 targets for the elimination of AIDS by 2030 were achieved in 2024 in the following proportions: 87% of infected people knew their HIV status, among those who knew their status, 89% have access to antiretroviral treatment (ART), and among those who have access to ART, 94% have a suppressed viral load **(**ANAIDS, 2025).

Chad has a generalized epidemic with a prevalence of 1.6% (INSEED, 2015) but it has been estimated at 1.2% (Spectrum, 2020). It is 1.3% among women and 0.8% among men in the same age group. Chad reacted very early to the outbreak of the HIV epidemic, setting up its first control Program in 1987. In 2007, HIV treatment, including screening tests and follow-up of PLV, was instituted free of charge. The implementation of the WHO's "test, treat" strategy has enabled the country to significantly increase the number of PLVs on ART. It was estimated that 69188 PLVs were on ART at the end of 2023 **(**PSLSH/IST, 2023).

Given the benefits of early initiation of ART, namely the rapid control of viral replication on HIV-related morbidity and mortality and on the major reduction in the risk of HIV transmission **(**Morlat P et *al*., 2018**;** Hocqueloux L et *al*., 2013 **),** the WHO (2015) recommends the use of antiretrovirals in all HIV-

infected people regardless of the number of TCD4 lymphocytes, even if it is > 500 cells/mm3 **(**WHO, 2015**).** To achieve its goal, ART must render and maintain undetectable viral load (CV < 50 Cp/ml) **(**Morlat P et *al*., 2018**).** If the spread of ART is associated with treatment failures and does not suppress viral loads, HIV drug resistance is likely to increase. This in turn could jeopardize ARV regimens and increase the cost of effective treatments, increasing the number of deaths and threatening the sustainability of treatment program **(**Ayele G et *al.*, 2018**;** WHO, 2016).

First-generation non-nucleoside reverse transcriptase inhibitors (NNRTIs), namely efavirenz (EFV) and nevirapine (NVP), were the recommended first-line regimens, in combination with nucleoside reverse transcriptase inhibitors (NRTIs) such as lamivudine (3TC) and tenofovir (TDF) **(**Dinesha T et *al*., 2016**).** However, given the low genetic barrier of NNRTIs to HIV drug resistance and the emergence of resistance to NNRTIs/NPV pre-treatment drugs above the 10% threshold in several resource-limited settings, the use of NNRTI-free regimens has become a top priority **(**Rusine J et al., 2013**;** Scidev, 2019**).** Since 2017, WHO has recommended ART containing Dolutegravir (DTG) as a first-line treatment regimen in HIV regimens **(**WHO, 2019**).** According to WHO, DTG is associated with better tolerability, higher antiretroviral efficacy, lower treatment discontinuation rates, a higher genetic barrier to resistance and fewer drug interactions, compared to other ARVs (WHO, 2019). As a result, many low- and middle-income countries (LMICs) have since adopted TLD as a new first-line treatment. Chad's sectoral program to combat AIDS, viral hepatitis and sexually transmitted infections (PSLSH/STI) adopted dolutegravir-based antiretroviral therapy (ART) as its first-line treatment in 2019. The fixed-dose combination of TDF-3TC-DTG (TLD) was gradually introduced in 2020 with the new patients, and at the same time, replaced the old combinations gradually **(**Abderrezzack A, 2021**).** Today, the majority of PLV in Chad, in the first line, are on DTG-based treatment. Several studies in Africa highlight that the TLD combination seems to make the viral load undetectable much faster than with the old first-line ARV combinations.

To strengthen clinical and biological management, the objective of our study is to evaluate the evolution of viral load under TLD in PLVs newly initiated to ART.

METHODS

Data Collection Sites

It is a longitudinal analytical study carried out from August 2023 to August 2024 at the Psycho Medico-Social Support Center (APMS) located in the 6th district of the city of N'Djamena.

Study Population

The study population consisted of HIV-1 infected elderly people followed at the APMS. Individuals 18 years of age or older, HIV-infected, initiating ART-containing Dolutegravir, and with verbal or written consent were included in this study. Individuals who did not meet the inclusion criteria were excluded from the study.

Data Collection Method

The sampling method was consecutive and allowed the recruitment of 120 PLV. Sociodemographic data (age, sex, marital status, occupation and level of education) were collected from HIV test requisition forms and by individual interview using the pre-established collection sheets at ART initialization (M0). Viral load (VL) data were collected from the load examination requisition forms at M0, month 3 (M3), month 6 (M6) and month 12 (M12). Three categories of CV results were considered: undetectable CV (CV< 50 Cp/ml), deleted CV (CV ≥ 1000 Cp/ml) and unsuppressed CV (CV< 1000 Cp/ml).

Venous blood (5 ml) was collected in the EDTA tube, centrifuged at 1500 rpm for 20 min. Aliquot plasma was either immediately used or stored at 2 to 8°C for 24 hours for VC examination.

Viral Load Measurement

The examination of the CV was performed by the Generic HIV viral load tests, a real-time *in vitro* RT-PCR test that allows the quantification of HIV-1 virus RNA in human plasma. The principle of the test is based on the extraction of HIV-1 RNA from plasma samples with the automated extractor GenoXtract®, followed by reverse transcription, amplification and detection with the FluoroCycler® XT.

❖ RNA Extraction

The GXT NA extraction device comes in the form of a 12-well cartridge and allows complete automation by the GenoXtract automated system of the extraction of retroviral RNA from plasma samples (EDTA, citrate). The GXT NA extraction and RNA purification technique uses the principle of magnetic beads for RNA capture. After lysis and precipitation, the immobilized RNA is washed several times by deactivating magnetic capture between each washing step. The bead/RNA complex is finally taken back into the elution buffer. After activation of magnetic capture, the supernatant containing the RNA is transferred to the elution tube; it is ready to be quantified with the GENERIC HIV VIRAL LOAD test (BIOCENTRIC, 2021).

❖ Mix Preparation

For a test, the reaction mixture was composed of the following elements: (3 µL of H2O without nuclease, 5µL of the enzyme mix, 0.5 µL of the sense

primer A, 0.5 µL of the anti-sense primer B, 0.5 µL of probe C) with the "reporter" the FAMTM fluorophore at 5' and the nonfluorescent MGB "quencher" at 3' and 0.5 µL of IC primers/Cy5-probes (BIOCENTRIC, 2021).

❖ **RNA Amplification**

The amplification technique of the Generic HIV CV kit is based on the principle of real-time RT-PCR, with: (1) reverse transcription of viral RNA into complementary DNA (cDNA); and (2) PCR amplification of the target cDNA and simultaneous fluorescence measurement resulting from the hydrolysis of an HIV-1-specific oligonucleotide detection probe labeled in 5' with an emitting fluorochrome ("reporter") and in 3' with a non-fluorescent suppressor group ("quencher"). This results in detectable fluorescence which is proportional to the amount of PCR products accumulated (BIOCENTRIC, 2021).
The assay was performed in accordance with the manufacturer's recommendation.

Statistical Analysis

The collected data was entered and processed using Microsoft Excel 2021 and analyzed using SPSS version 25.0 The statistical significance level was set at 0.05.

Ethical Consideration

Our study has benefited from the authorization of the coordination of the Sectoral Program for the Fight against AIDS, Viral Hepatitis and Sexually Transmitted Infections (PSLSH/IST) N°: 174 /PT/PMT/MSPP/SE/SG/PSLSH_IST/2023. Free and informed consent, verbal or written, was obtained from participants before their recruitment for the study. The necessary arrangements were made to guarantee the anonymity of participants, and the confidentiality of the data was ensured by individual patient codes.

RESULTS

A total of 120 ART-naïve PLPV were enrolled in this study. The study population consisted of 59.2% women, with an F/M sex ratio of 1.45; the mean age was 32 years and the median age was 32 years, with a dispersion ranging from the extreme youth of 18 years to a maximum of 50 years. Nearly half of the patients were married (44.2%), the uneducated represented 41.7% of the participants, and housewives were the most represented professional category (25.8%). All subjects in the sample (n=120) were on the TLD regimen (Tenofovir (TDF)+Lamivudine (3TC) +Dolutegravir (DTG)).

The cross-analysis of Table 1 shows that all the majority categories (married, uneducated, housewives) dominate the population under TLDs.

Table I: Cross-Breeding of Patients by Marital Status, Occupation, Level and of Education

Variable	Category	Workforce (n)	%	Chi²	bill	P-value
Gender	Female	71	59,2			
	Men's	49	40,8			
Ages	< 25 years	20	16,6			
	25 – 34 years old	53	44,1			
	35 – 44 years old	40	33,3			
	≥ 45 years	7	6,0			
Marital status	Single	25	20,8	24,53	3	<0.001
	Divorced	30	25,0			
	Married	53	44,2			
	Widower	12	10,0			
Level of education	Uneducated	50	41,7	16,27	2	<0.001
	Secondary	47	39,2			
	Superior	23	19,1			
Profession	Other	23	19,2	66,17	9	<0.001
	Driver	3	2,5			
	Merchant	19	15,9			
	Student	6	5,0			
	Student	8	6,7			
	Military	7	5,8			
	Housewife	31	25,8			
	Employee	13	10,8			
	Unemployed	10	8,3 %			

Statistical analysis showed a highly significant decrease in viral loads during TLD follow-up (p <0.0001, Friedman test). Pairwise comparisons indicate that median viral load decreased significantly between M0 and M6 (p <0.0001), as well as between M0 and M12 (p <0.0001). The difference between M6 and M12 also remains significant (p = 0.03). All analyses show p-

values well below 0.05, which confirms that the change in viral load under TLD is highly significant.

Regarding virologic suppression, the proportion of patients with a viral load <1000 copies/mL increased from 20.8% (25/120) at M0, 98.3% at M3 (118/120), 93.3% (112/120) at M6, and then to 95% (114/120) at M12, with a highly significant difference ($p < 0.0001$, Cochran's Q test).

Spearman's correlations between the different steps confirm these results: M0 and M6 ($\rho \approx 0.50$, $p < 0.0001$), M0 and M12 ($\rho \approx 0.45$, $p < 0.0001$), and M6 and M12 ($\rho \approx 0.80$, $p < 0.0001$). These results suggest a gradual control and then a stabilization of the viral load in most patients. Similarly, the proportion of patients with a viral load <50 copies/mL increased significantly during follow-up, from 0% at M0, 89% at M3 to 98.3% at M6, and finally to 94.2% at M12 ($p < 0.0001$, Cochran's Q test).

These results support that the TLD regimen is highly effective and well tolerated in the study population, inducing rapid and sustained viral load suppression in patients living with HIV.

Table II: Suppression of patient CV as a function of follow-up time

Follow-up time	CV ≤ 1000 copies/mL)	%	CV ≥1000 copies/mL	%
M0	25	20,8	95	79,1
M3	118	98,3	2	1,6
M6	112	93,3	8	6,6
M12	114	95	6	5

Legend: M = Month, Suppressed viral load = CV ≤ 1000 copies/mL, Unsuppressed viral load = CV ≥1000 copies/ml.
The analyses in Table II show that viral suppression is significant as a function of the duration of ART from M3.

Table III: Patients and Viral Suppression

Variable	Category	Not deleted	%	deleted	%	Chi²	P-value
Gender	Female	1	0,8	70	58,3	**3,05**	**0,080**
	Men's	5	4,1	44	36,6		
Ages	< 25 years	1	0,8	19	15,8	**1,06**	**0,78**
	25 – 34 years old	2	1,6	51	42,5		
	35 – 44 years old	3	2,5	37	30,8		
	≥ 45 years	0	00	7	5,8		
Marital status	Single	2	1,6	23	19,1	3,40	0,33
	Divorced	0	00	30	25		
	Married	4	3,3	49	40,8		
	Widower	0	00	12	10		
Level of education	Uneducated	4	3,3	46	38,3	1,78	0,40
	Secondary	1	0,8	46	38,3		
	Superior	1	0,8	22	18,3		
Profession	Other	2	1,6	23	19,1	5,35	0,80
	Driver	0	00	3	2,5		
	Merchant	2	1,6	17	14,1		
	Student	0	00	6	5		
	Student	0	00	8	6,6		
	Military	0	00	7	5,8		
	Housewife	1	0,8	31	25,8		
	Employee	1	0,8	12	10		
	Unemployed	0	00	10	8,3		

The analyses in Table III reveal that no sociodemographic factors are associated with virological success (p> 0.05).

DISCUSSION

Rapid and effective suppression of HIV CV depends on the potency and efficacy of the ARV regimen, the patient's adherence to treatment, and the sensitivity of the virus to the ARVs administered. Regimens using Dolutegravir are reported to result in faster CV suppression, with fewer side effects and a stronger barrier to drug resistance (USAID, 2017**).** The objective of our study was to assess the evolution of CV on the TLD combination therapy during the 12 months of ART.

During our study, we observed that 59.2% of the participants were female. This observation agrees with the literature data which indicate that women are more affected by HIV infection than men. This situation can be explained by the anatomical vulnerability of women in terms of their genital tract with a larger surface

area and a longer contact time during heterosexual intercourse and by the socioeconomic precariousness to which women are exposed. They would also be willing to attend health care facilities more than men in case of illness. Our results are close to those obtained by Bruce et *al* (62.9%) **(**Bruce S et *al*., 2024**);** however, they are lower than those of Nouhoum et *al* in Bamako (69.9%) **(**Nouhoum T et *al*., 2022**)**, F. Koné et *al* (69%) **(**Kone F et *al*., 2019**)** and Mariam et *al* (86.4%) **(**Bakay M et *al*., 2025**),** but different from those of Gado et *al* and Coulibaly et *al* **(**Gado A et *al*., 2022**;** Coulibaly Y et *al*., 2023**)** who had obtained a male predominance of 89.5% and 54.7% respectively.

An average age of 32 years was observed in our study. It is mainly young adults, who are naturally very sexually active, who are infected with HIV. Our result is slightly lower than those of Gado et *al* in Niamey (37.5 years) **(**Gado A *et al.*, 2022**)** and Nouhoum et *al* (44.6 years) **(**Nouhoum T et *al*., 2022**)**. Married couples represented 44.2% of the population studied. Our result is higher than that of Mariam et *al* (25.5%) **(**Bakay M *et al*., 2025**)** and lower than that of Nouhoum *et al* (60.9%) **(**Nouhoum T et *al*., 2022**)**. Housewives were the most represented professional profile in our study (25.8%); this result is lower than that of Mariam et *al* (35.5%) and different from that of Nouhoum *et al* in Bamako, which found 27.3% of traders. Non-literate people accounted for 41.7% of the study population. It is recognized that low literacy limits access to HIV information and is believed to be an obstacle to effective HIV control **(**Kadiané-Oussou N *et al.*, 2023).

Our results show a highly significant decrease in viral load over the duration of treatment ($p< 0.0001$). The median viral load decreased significantly. This high-speed decrease in CV is explained by the fact that Dolutegravir-based regimens are known to have potent and rapid antiretroviral activity (USAID, 2017**).** The proportion of patients with a suppressed viral load (CV <1000 copies/mL) increased sharply during the duration of ART (93.3% at M6 and 95% at M12), with a highly significant difference ($p < 0.0001$). In a study done in India, the authors observed a virologic suppression rate of 94.6% at 24 weeks and 100% at 48 weeks **(**Sumit A *et al.*, 2025**),** and the study by Ferdinand et al showed a viral suppression of 98% was observed at 6 months and 12 months in PLV on DTG-based ART **(**Mynthlu F et *al.*, 2024**).** With the same DTG-based ARV combination, Ezechiel Ngoufack *et al.,* Cameroon, and Adella G et al, Ethiopia, found a viral suppression rate of 97.08% and 91.3%, respectively, after 14 months and 6 months of ART **(**Ezechiel Ngoufack *et al.,* 2023; Adella G et al., 2023**).** The difference in results could be explained by differences in study populations, the types and methods of studies used by the authors, ART monitoring methods, HIV resistance to ARVs, and ART adherence.

The proportion of patients with an undetectable viral load (<50 copies/ml) increased significantly during follow-up ($p < 0.0001$). Several comparative studies show that the ARV combination containing DTG has a better virological undetectability rate compared to other ARV combinations. The NAMSAL study, conducted in Cameroon, showed that 74.5% of participants submitted TDF+3TC+DTG had an undetectable CV (CV > 50 Cp/ml) compared to 69.0% for those submitted TDF+3TC+ EFV 400 **(**Kouanfack C et *al.*, 2019**).** A comparative study in Brazil showed that viral suppression after 12 months of treatment was 84.0% with TDF+3TC+EFV, 90% with TDF+3TC+DGT, and less than 80% for other protease inhibitor-based combinations **(**Mariana V et *al.*, 2023**).** Another study in Brazil, in first-line ART, achieved a viral suppression rate of 58.1% with the EFV-containing combination and 76.7% with the DTG-based combination **(**Gabriella J *et al.*, 2023**).** These results demonstrate the superiority of DGT over Efavirenz and protease inhibitors over viral suppression **(**Mariana V et *al.*, 2023). Even in dual therapy, the ARV combination containing DTG has demonstrated superiority over other ARV combinations. The PADDLE pilot study, where PLHIV were on ART consisting of DTG 50 mg/day + 3TC 300 mg/day, showed that 90% achieved a CV < 50 Cp/ml in 48 weeks **(**Pedro C et *al.*, 2017**).** PLAs who are on first-line ART with TLD have a higher rate of viral suppression than those who remain on other regimens (Allahna E et *al.*,2022**).** These results obtained in these different studies demonstrate that PLHIV on ARV treatment with a DTG-containing combination achieve viral suppression of HIV more quickly and effectively. DTG is an essential pillar in HIV ART.

CONCLUSION

In accordance with the WHO recommendation, Chad has adopted, as a first-line treatment for ART, a combination therapy containing DTG, namely TLD. We then evaluated the evolution of plasma viral load in PLVs starting ART with this new first-line ARV regimen for 12 months of treatment. The results obtained show a very significant good viral suppression over the treatment time. As mentioned in several studies, our results confirm the hypothesis that dolutegravir can rapidly suppress the HIV viral load and render it undetectable. It would be wise to consider the evaluation of treatment adherence and the possible appearance of HIV resistance to ARVs in PLHIV on ART containing DTG.

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Conflict of interest:

The authors declare that they have no potential conflicts of interest with the research, writing, and publication of this article.

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