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Virological Follow-up of Adults Living with HIV on Dolutegravir in an Approved Treatment Center in Douala (Cameroon)

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Authors' contributions

This work was carried out in collaboration among all authors. Authors NDG and OEC coordinated the study, Authors BBLV, NDG and OEC drafted the manuscript. Authors NDG, BBLV, NAG, MSC and EJ collected the data and performed the laboratory analyses. Authors NMJP and PIC participated in study design. Authors OEC and NNLS performed the statistical analysis. All authors read and approved the final manuscript.

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ABSTRACT

Background: Human immunodeficiency virus infection constitutes one of the greatest contemporary human pandemics, lethal in the absence of treatment. WHO 2018 recommendations have placed Dolutegravir-based treatment as first-line treatment, particularly in resource-limited countries. The aim of this work was to study the evolution of virological parameters in people undergoing treatment with this molecule.
Methodology: This was an analytical cross-sectional study of people aged 25 and over, received since January 2015 at the Approved Treatment center of Laquintinie Hospital in Douala (Cameroon). After plasma collection and centrifugation, viral load was determined on the Abbott m2000^{TM} platform, targeting the *Pol* gene. The detection threshold was greater than or equal to 40 copies/mL. Data analysis was performed using Excel and SPSS version 20 softwares.
Results: A total of 504 people were selected, with an average age of 48±11 years and a predominance of women (70.8%). Antiretroviral treatment had been initiated at clinical stage 1 in over 80% of participants. The TDF/3TC/EFV regimen prior to initiation of Dolutegravir was used in 93.5% of cases. Mean weight after initiation of treatment was 75.9 kg. People with a viral load <40 copies/ml before starting Dolutegravir therapy accounted for 332 (65.9%) of cases, compared with 91.1% six months after starting treatment. Weight (>75kg) (95% CI, OR=1.112-2.381, p=0.012) and non-adherence (95% CI, OR=2.790-25.613, p=0.001) were considered factors associated with viral load variation.
Conclusion: The ARV protocol comprising two nucleoside reverse transcriptase inhibitors and Dolutegravir improves virological response in people living with HIV at all clinical stages.

Keywords: HIV viral load; dolutegravir; Douala.

1. INTRODUCTION

The Human Immunodeficiency Virus (HIV) is the etiological agent of acquired immunodeficiency syndrome (AIDS) [1]. It is an RNA virus of the Lentivirus subgroup and *Retroviridae* family that can be transmitted by sexual contact, exposure to contaminated blood products or by an infected mother to her fetus [2]. Since the late 1990s, HIV infection has become a chronic, persistent disease, due to the use of antiretroviral drugs, which are molecules that control the replication of the virus [3]. Despite the strong commitment of healthcare systems, this pathology remains a major public health challenge, with over 38 million people infected and around 29 million on tritherapy by 2021 [4,5].

Significant progress has been made in the therapy of people living with HIV (PLHIV), with the development of increasingly effective antiretrovirals (ARVs) drugs [6]. Since 2018, the first-line antiretroviral recommended treatment by the World Health Organization (WHO) for type 1 HIV infection consists of two nucleoside inhibitors combined with a non-nucleoside reverse transcriptase inhibitor (NRTI and NNRTI), namely Efavirenz at a dose of 600 mg per day [7]. For years, treatment with Efavirenz has been favoured, reflecting incomparable performance in clinical trials [8]. With the worldwide prevalence of resistance to NNRTIs (Nevirapine, Efavirenz) reaching levels of over 10% in the population starting first-line treatment, new molecules such as integrase inhibitors are now the best choice in recommended preferential combinations, due to their virological potency and excellent clinical and metabolic tolerability [9].

In 2015, Dolutegravir, a new integrase inhibitor, was introduced to the HIV therapeutic arsenal [10]. Recent data have demonstrated the superiority of Dolutegravir-based regimens over Efavirenz, regardless of viral load [11-13]. In the face of NNRTI drug resistance, the WHO has called for an accelerated transition to newer Dolutegravir-based protocols, and the 2019 recommendations for the management of HIV-1 have placed this molecule among first-line treatments, particularly in resource-limited countries [9,14]. This new molecule was introduced at the the Approved Treatment Center of Laquintinie Hospital in Douala in 2020. It was in this context that this study on the virological follow-up of patients on dolutegravir at this hospital was initiated.

2. METHODOLOGY

This was an analytical cross-sectional study conducted from january to june 2023, jointly at

the laboratory of the approved treatment center and the virology laboratory of Laquintinie Hospital in Douala (Cameroon), where HIV plasma viral load samples were collected and analyzed respectively. The study included adults aged 25 and over, followed up since 2015, switched to Dolutegravir from January 2020 and having at least one plasma viral load measurement before and after being put on Dolutegravir.

2.1 Data Collection

Data were collected on the basis of a pre-established, standardized and anonymous questionnaire, after a consecutive non probabilistic sampling. For each patient who gave informed consent, the data collection form included sociodemographic (gender, age, occupationnal status), clinical and biological data (weight, type of HIV, WHO clinical stage, date of screening, date and protocol of initiation of ARV treatment, date and protocol of starting Dolutegravir, viremia before and after starting Dolutegravir) and associated factors such as interruption of treatment since starting Dolutegravir. Non-compliant patients were those who had not taken their treatment at least once. Clinical stages were determined according to the WHO classification into 4 groups from 1 to 4 [15]. HIV plasma viral load after at least six months of treatment was the variable of interest.

2.2 Sample Collection, Transport and Processing

After collecting the patient's blood in a tube containing EDTA, the sample was transported to the virology laboratory in triple packaging for analysis.

Once received at the molecular biology unit, the sample was centrifuged at 2500 rpm for 10 min. A minimum of 600 µl of plasma was then aliquoted into ependorf tubes for analysis.

2.3 Determination of Viral Load

The Abbott m2000^{TM} platform was used for RNA extraction and viral genome amplification; with the Abbott m Sample preparation and Real Time HIV-1 Amplification reagent kits respectively and according to the manufacturer's recommendations. The amplified target was the *Pol* gene. All manipulations were carried out in compliance with good laboratory practice. The PCR plate was validated at the end of amplification when the strong and weak positive controls had the expected Ct (Cycle Treshold) values, and the negative and internal controls were present in each sample ; the detection threshold was greater than or equal to 40 copies /ml [16].

2.4 Data Analysis

Data analysis was performed using Excel and SPSS version 20 softwares. Categorical variables were expressed as percentages and numbers, and comparisons were made using the chi-square test^2. Quantitative variables were expressed as means plus or minus standard deviation, and comparisons were made using Student's t test. All tests were significant at the 5% risk (α).

3. RESULTS

3.1 Socio-Demographic Data

A total of 504 people living with HIV were included in this study, with women predominating at 70.8%.
The 35-45 and 45-55 age groups were the most represented, with 29.6% and 33.1% respectively.

According to marital status, the population comprised 258 single people (51% of all genders) and 167 couples (33.1%). The most represented socio-professional category was salaried employees (329 or 65.3%) (Table 1).

3.2 Clinical and Biological Data

ARV treatment had been initiated at clinical stage 1 in over 80% of participants. Prior to initiation of Dolutegravir, 93% of the study population was on a TDF-3TC-EFV-based regimen, with an average weight of 75.9 kg (±16.5).

After starting Dolutegravir, the percentage of patients with a viral load of less than 40 copies/ml rose from 65.9 to 91.1%, representing a reduction in viremia with a statistically significant difference when comparing means before and after starting Dolutegravir.

3.3 Factors Associated with Viral Load Variation

Age was not a factor associated with virological response, with a significant static difference (p=0.382). Gender, weight and adherence to treatment were considered to be factors significantly associated with variation in viremia (p=0.026; 0.012 and 0.001 respectively).

Table 1. Socio-demographic profile of PLHIV on ART according to clinical stage and treatment regimen prior to initiation of Dolutegravir

Variables		Clinical stage n (%)				Treatment regimen before Dolutegrvir n (%)				
		1 N= 428	2 N=20	3 N=43	4 N=13	A N=469	B N=8	C N=13	D N=10	E N=4
Gender	**Female**	310 (61.5)	9 (1.8)	29 (5.8)	9 (1.8)	332 (65.9)	4 (0.8)	9 (1.8)	8 (1.6)	4 (0.8)
	Male	118 (23.4)	11 (2.2)	14 (2.8)	4 (0.8)	137 (27.2)	4 (0.8)	4 (0.8)	2 (0.4)	0
Age range (years)	**[25-35]**	43 (8.5)	0	2 (0.4)	1(0.2)	43 (8.5)	0	1 (0.2)	2 (0.4)	0
M= 48 ±11	**[35-45]**	128 (25.4)	5 (1)	13 (2.6)	3 (0.6)	139 (27.6)	0	5 (1)	3 (0.6)	2 (0.4)
	[45-55]	146 (29)	5 (1)	12 (2.4)	4 (0.8)	155 (30.8)	2 (0.4)	5 (1)	4 (0.8)	1 (0.2)
	[55-65]	73 (14.5)	8 (1.6)	13 (2.6)	4 (0.8)	90 (17.9)	5 (1)	1 (0.2)	1 (0.2)	1 (0.2)
	≥ 65	38 (7.5)	2 (0.4)	3 (0.6)	1 (0.2)	42 (8.3)	1 (0.2)	1 (0.2)	0	0
Weight (in kg)	**[43-53]**	10 (2)	0	2 (0.4)	1 (0.2)	12 (2.4)	0	0	1 (0.2)	0
M = 75.9 Kg	**[53-63]**	60 (11.9)	2 (0.4)	11 (2.2)	0	71 (14.1)	0	1 (0.2)	0	1 (0.2)
(±16.5)	**[63-73]**	139 (27.6)	8 (1.6)	12 (2.4)	2 (0.4)	149 (29.6)	3 (0.6)	3 (0.6)	4 (0.8)	2 (0.4)
	[73-83]	97 (19.2)	7 (1.4)	11 (2.2)	3 (0.6)	107 (21.2)	2 (0.4)	4 (0.8)	5 (1)	0
	[83-93]	67 (13.3)	2 (0.4)	3 (0.6)	3 (0.6)	73 (14.5)	1 (0.2)	0	0	1 (0.2)
	≥ 93	55 (10.9)	1 (0.2)	4 (0.8)	4 (0.8)	57 (11.3)	2 (0.4)	5 (1)	0	0
Marital status	**Single**	214 (42.5)	10 (2)	26 (5.2)	8 (1.6)	242 (48)	2 (0.4)	8 (1.6)	4 (0.8)	2 (0.4)
	Divorced	17 (3.4)	4 (0.8)	2 (0.4)	1 (0.2)	22 (4.4)	2 (0.4)	0	0	0
	Married	149 (29.6)	4 (0.8)	12 (2.4)	2 (0.4)	151 (30)	4 (0.8)	5 (1)	5 (1)	2 (0.4)
	Widower	48 (9.5)	2 (0.4)	3 (0.6)	2 (0.4)	54 (10.7)	0	0	1 (0.2)	0
Socio-	**Student**	16 (3.2)	0	0	0	14 (2.8)	0	0	2 (0.4)	0
professional	**Non-employee**	125 (24.8)	7 (1.4)	21 (4.2)	6 (1.2)	145 (28.8)	2 (0.4)	8 (1.6)	3 (0.6)	1 (0.2)
status	**Employee**	287 (56.9)	13 (2.6)	22 (4.4)	7 (1.4)	310 (61.5)	6 (1.2)	5 (1)	5 (1)	3 (0.6)

A = TDF-3TC-EFV; B = ABC-3TC-EFV; C = TDF-3TC-ATVr; D = TDF-3TC-NVP; E = AZT-3TC-ATVr;
TDF = Tenofovir; 3TC = Lamuvidine; EFV = Efavirinz; ABC = Abacavir; ATVr = Atazanavir-ritonavir;
NVP = Nevirapine; AZT = Zidovidine

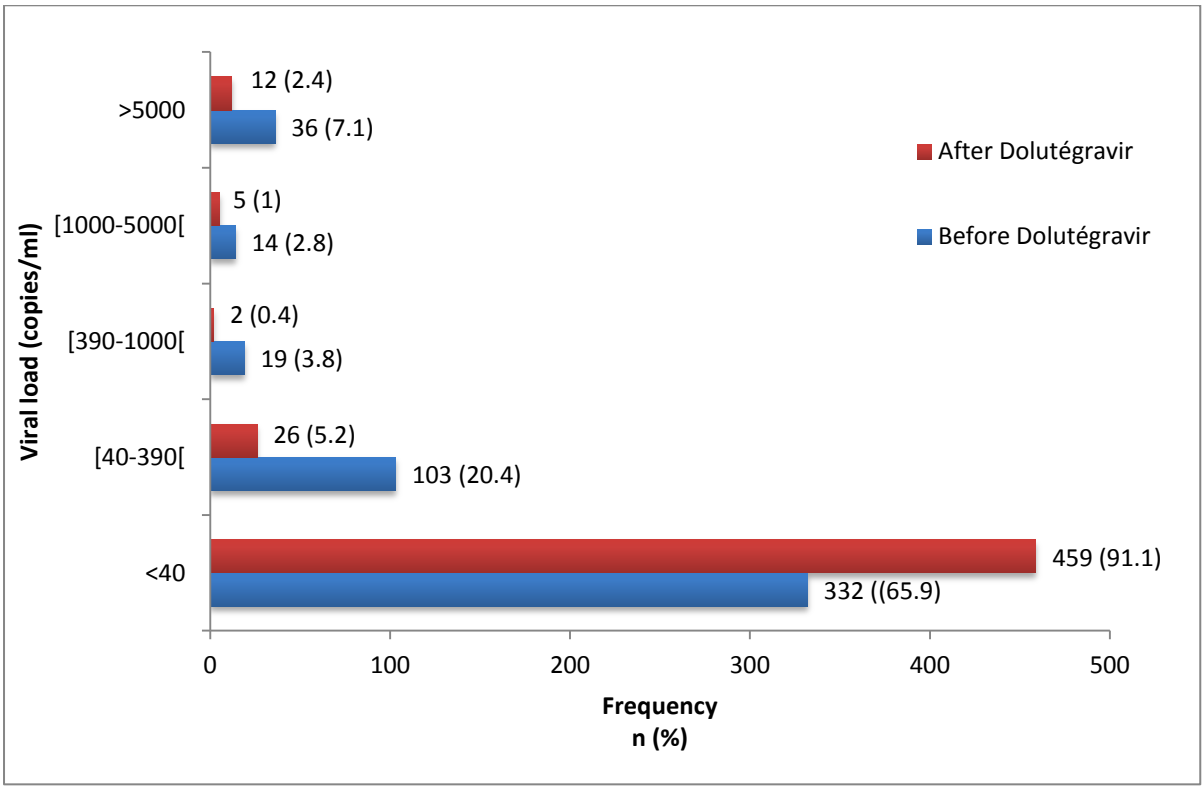

Fig. 1. Viremia before and after starting Dolutegravir

Table 2. Comparison of viremia averages before and after treatment with Dolutegravir

Variables	Workforce	Average	standard deviation	CI (95%)	P-value
Viremia before	504	19 201.47	193617,120	[6461,12-36523,20]	**0.0001**
Viremia after	504	1 950.19	16173,036	[1103,63-2818,99]	

Table 3. Factors associated with virological response

Variables		Viremia variation		OR [IC(95%)]	ORa [IC(95%)]	P-value
		Yes N=191	No N=313			
Gender	Female	124	233	1,574 [1,064-2,326]	0,629 [0,419-0,947]	**0.026***
	Male	67	80			
Age	≥48	105	158	1,198 [0,835-1,719]	1,182 [0,812-1,720]	0.382
	<48	86	155			
Weight	≥75	121	166	1,531 [1,059-2,213]	1,627 [1,112-2,381]	**0.012***
	< 75	70	147			
Compliance	Yes	19	4	8,533 [2,857-25,488]	8,454 [2,790-25,613]	**0.001***
	No	172	309			

** Significative results*

4. DISCUSSION

The study involved 504 HIV-infected adult patients followed up at the Centre de Traitement Agrée of Laquintinie Hospital, Douala. The mean age of participants was 48.4 years, with a large female predominance at 70.8%. Kone et al. in 2019 in Côte d'Ivoire, Kouanfack et al. in 2020 in Cameroon and Nicholas et al. in 2022 had found similar results [6,11,12]. The predominance of women may be explained by their greater vulnerability to HIV than men in developing countries [17]. In the West and in developed countries, several studies have shown a

predominance of males [8]. The mean weight of patients was 75.9 kg, close to that of the study by Kouanfack et al in 2021 in Cameroon, who found 75 kg [11]. Dake et al found a marked weight gain in patients, with a mean weight of 67 kg after initiation of Dolutegravir [19]. Single people were in the majority; this status is conducive to multi-partnering at the origin of sexually transmitted infections, in comparison with single, married or cohabiting people [20]. Wage-earners were in the majority, contrary to the work of Ouedraogo et al, and Pitroipa et al, who found in Burkina Faso, 55.6% and 44% of cases of unemployed people respectively, with the majority being housewives [21,22]. No link was found between occupation and variation in viremia, and more than 80% of patients were started on ARV treatment at clinical stage 1; the evolution of the time required to start ARV treatment and the test-and-treat policy have favoured universal access to ARV treatment [23]. Before starting Dolutegravir, the TDF+3TC+EFV regimen was the most common, accounting for 93.5% of cases, in line with the previous recommended national regimen. Of the 504 patients, 65.9% had an undetectable viral load (less than 40 copies). After initiation of Dolutegravir, this percentage rose to 91.1%. Dake et al in Mali found an undetectable viral load in 56.4% and 92.3% of patients before and after initiation of Dolutegravir respectively [24]. Keene et al reported similar results, with an undetectable viral load in 85% of patients started on DTG after six months of treatment [25]. The majority of patients were non-adherent (95%). Essomba et al found 49% of patients to be compliant; the variation in this rate may be linked to the criteria evaluated to define compliance: either forgetting to take more than one dose of medication in the last 7 days for three-dose protocols; or not taking the drug for a week or more in the month preceding or since initiation of therapy [26,27]. Age was not considered a factor associated with virological response, with a significant statistical difference (p=0.382). Gender, weight and adherence were found to be factors associated with variation in viremia. Coulibaly et al found age and first-line treatment to be associated factors in a study of adolescents in Mali [28]. Kone et al in Côte d'Ivoire reported gender as a factor associated with success in maintaining viremia below the detection threshold [6].

5. CONCLUSION

The results show that dolutegravir-based regimens offer efficacy that is not inferior or superior to other treatment regimens. They therefore support the introduction of dolutegravir as a first-line treatment to overcome drug resistance to non-nucleoside reverse transcriptase inhibitors.

6. STUDY LIMITATIONS

This study concerns only the Laquintinie hospital in Douala. It is by no means exhaustive for all public or associative care structures for PLWHA in Cameroon.

ETHICAL APPROVAL

The study was conducted in accordance with the ethical guidelines for research in Cameroon. We obtained research authorization from the director of the hospital concerned, and ethical approval from the Institutional Human Health Research Ethics Committee of the University of Douala (N° 3690 CEI-UDo/05/2023/M).

CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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