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Treatment Outcomes for HIV Patients on Three HAART Regimens in South East Nigeria: A Comparative Study

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Abstract Human Immunodeficiency Virus (HIV) attacks the body's immune system and is responsible for a major public health problem. Highly Active Anti-Retroviral Therapy (HAART) is key to its management. This study aimed at evaluating and comparing the clinical and virological outcomes of three HAART regimens - TLD, TLE and TL/LPV/r. Number of participants was 330 patients (110 in each group). Data were analysed and compared between groups. A 5-parameter scoring system was used to compare the performance of the regimens. Overall mean age was 44.7 (±10.7) years. Normal BMI 138 (41.8%), overweight (33.3%), obese (20.9%) and underweight (3.9%). Normal hemoglobin level, 194 (58.8%). Mean baseline CD4 count was 389.9 ± 293.7. Adherence to TLD (90.0%), TLE (89.1%), TL/LPVr (62.7%). TLD group showed the most clinical improvement with the most patients in stage 1 after one year, 108 (99.1%). Viral suppression at 6 months for TLD (86.4%), TLE (86.4%), TL/LPVr (50.0%) and at 12 months, TLD (90.0%), TLE (91.8%), TL/LPVr (88.2%). The difference in viral suppression between the TLD/TLE and TL/LPVr groups was statistically significant ($p < 0.001$). Factors associated with WHO clinical stage 1 at 6 months were age ≥35 years with TLD and female sex for TLE; and with viral suppression at 6 months were good adherence with TLD and TL/LPVr and female sex with TLE. For all patients collectively, good adherence was significantly associated with viral suppression at 6 months and 1 year. Predictor of WHO stage 1 at 6 months was female sex, OR 0.483 (95% CI 0.238 – 0.980). For predictors of viral suppression at 6 months, good adherence had the highest odds ratio, OR 6.911 (95% CI 3.768 – 12.676), being currently married OR 1.826 (95% CI 1.036 – 3.217). TLD performed best with a score of 14, TLE 13, TL/LPVr 5, out of a maximum score of 15.

Keywords: *HIV, treatment, clinical, virological, outcomes, HAART, dolutegravir*

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1. Introduction

Adherence to an effective HIV treatment regimen allows persons who have HIV infection to live healthy lives and also reduces the chances to transmission of the infections to others. [1] This reduction of HIV transmission to others is an important goal of Highly Active Anti-Retroviral Therapy (HAART). Good adherence to HAART has an association with a reduction of viral load levels and the reduction of the risk of sexual transmission to partners to almost zero. [2]

Human Immunodeficiency Virus (HIV) is responsible for an ongoing global public health problem that has led to about 33 million lives as at 2019. [3] Following improved access to effective HIV prevention, diagnosis, treatment for opportunistic infections, treatment with HAART and care, HIV infection has become a manageable chronic health condition like many other diseases like hypertension and diabetes. At the end of the year 2019, there were about 38.0 million people living with HIV. [3] By 2019 ending, it was estimated that about 81% of persons who were living with HIV were aware of their status, while 67% were placed on antiretroviral therapy and 59 percent had attained viral suppression where the

risk of transmission to others is said to be zero. [3] Viral load measurement using Polymerase Chain Reaction (PCR) serves as a marker and is the gold-standard for monitoring the HIV progression and the efficacy of anti-retroviral therapy in persons infected with HIV. [4]

The term HAART is an abbreviation for "highly active anti-retroviral therapy," which has been used since the later end of the 1990s to describe how effective the combination therapies for the treatment of HIV are. HAART is a huge achievement in the treatment of HIV and it changed the course of the pandemic. [5] Before the discovery of HAART, using one or two of these drugs gave limited control over the virus, which resulted in rapid treatment failure and the development of multi-drug resistance. [6] HAART is a regimen consisting of co-administration of three, four or more anti-retroviral drugs. The principle of HAART lies in the concurrent administration of different classes of medicines that stop the replication of the virus by different mechanisms so that the virus cannot develop resistance to a single drug as they are inhibited by the activities of the other two drugs. [7] The goals of HAART in patients with HIV infections are to reduce disease and death (AIDS and non-AIDS associated causes), improve the quality of life, reduce plasma viral RNA load, prevent transmission to others (sex partners, mother to child, needle-sharing partners), improve immune function and prevent drug resistance. [8] HAART intensely suppresses the replication of HIV, which appreciably increases CD4(+) T cells, with partial reconstitution of the immune system. [9]

HAART regimens are important in improving patient outcomes and reducing the infection of others with HIV. Good adherence to a HAART regimen and proper utilization of HIV care and treatment services and are critical to achieving adequate therapeutic response and preventing viral resistance. [8,10,11] Before now, boosted protease inhibitor (PI) combinations were the standard second-line ART in low and middle-income settings. However, the DAWNING study showed that patients who fail first-line non-nucleoside reverse transcriptase inhibitor (NNRTI)-based regimens, will benefit from dolutegravir which had superior efficacy and was more tolerable when compared to a lopinavir-ritonavir regimen. [12]

WHO has recommended dolutegravir to be a part of first-line, second-line, and third-line ART combinations due to high prevalence of pre-treatment drug resistance to NNRTI. Dolutegravir is an integrase inhibitor that has a high barrier against resistance and is usually combined with lamivudine and tenofovir. [12] Following newer evidence weighing risks and benefits, WHO approves dolutegravir as the preferred first, second and third line treatment for all age groups, including women of childbearing age and pregnant ones. [13] Dolutegravir has been found to be more effective, easier to adhere to having less side effects than other drugs that are presently in use. These qualities improve adherence to dolutegravir. Dolutegravir has the ability to withstand resistance in the face of rising incidence of these with efavirenz and nevirapine-based combinations. It is based on these findings that the 2019 guidelines were updated. [13]

A multi-centre study done in Spain found that the outcome of patients on a long term was associated with immunologic response by the end of one year of therapy and age at the time of HAART initiation, but not with the first antiretroviral combination selected. [14] A study in South Korea showed that fewer new medicines in HAART, advanced clinical stage, and poor adherence to clinic appointment for 1 year after HAART were important risk factors for developing new AIDS-defining illnesses or death. The study concluded that adherence to clinic visits early after starting HAART is an independent predictor of long-term clinical advancement in HIV patients. [15]

At the end of 6 months on HAART, the clinical outcome of patients with HIV infection in France showed that patients with good immunologic response show good clinical outcome regardless of virological response. This connotes that both immunological and virological indicators should be used in clinical practice in assessing treatment response. [16] Impact of HAART on incidence and treatment of HIV related opportunistic infections in Taiwan was studied. It was found that opportunistic infections due to HIV continued to occur in patients who are newly diagnosed with HIV infection, those in the early course of HAART or non-adherent to HIV care and HAART, and those in whom non-HIV-related infections have emerged as a significant cause of disease and death in the post-HAART era. [17]

A study was conducted in India the most common presenting complaints were weight loss (74.4%), cough (72.1%) and diarrhoea (67.4%). During follow-up, as many as 80.8% patients showed clinical improvement. [18] The performance of HAART in advanced AIDS patients in China showed a significant positive correlation was shown between the change of CD4(+) count and plasma viral load. The study concluded that immune reconstitution as well as the significantly improved clinical outcomes was observed in advanced AIDS patients after HAART. [9]

A multi-centre pilot study was done in Nigeria to evaluate the clinical outcomes of adult patients who were started on ART within 2 weeks of HIV diagnosis in the Test and Treat strategy. Among Test and Treat patients, 79% of those whose viral loads were known were virally suppressed (≤400 copies/ml) after six months and 78% were virally suppressed after 12 months. While randomized controlled trials have identified Test and Treat strategies as a tool which can increase patient retention in care and increase the proportion of those who are virally suppressed when compared to the usual standard care, however other findings show that the effectiveness of Test and Treat strategies in some other settings may be much lower than that demonstrated in randomized controlled trials. The mode of implementation of Test and Treat strategies can help improve access to HAART. [19]

This research aimed at determining and comparing the clinical and virological outcomes of patients on the three most commonly used HAART regimens at the hospital.

2. Materials and Methods

2.1. Study Area

This study was carried out in Chukwuemeka Odumegwu Ojukwu University Teaching Hospital (COOUTH), located in Awka South Local Government Area of Anambra State, Nigeria. It provides tertiary medical care to the immediate

community and beyond. This includes comprehensive care for HIV positive patients in the Anti-Retroviral Therapy (ART) clinic. The clinic was established in February 2007. Since inception, 11,974 HIV positive patients have been enrolled for care. The number of patients on treatment at the time of the study was 3,678.

2.2. Study Population

HIV positive clients accessing care at the Anti-Retroviral Therapy (ART) clinic in COOUTH, Awka.

2.3. Study Design

A comparative analytical study for patients on three HAART combinations.

2.4. Sample Size Determination

The sample size was calculated using the formula for comparing two independent groups. [20] Since there are 3 groups, the two most commonly used HAART combination in the clinic will be used to calculate N for each of the three groups. [21]

$$N = \frac{2(Z\alpha + Z\beta)^2 P0(1- P0)}{d^2}$$

where N = minimum sample size
P0 = mean proportion of patients that are virally suppressed in the 2 comparison groups i.e. (P1 + P2) /2

$$\frac{P1+P2}{2} = \frac{0.95+0.83}{2} = 0.89$$

P1= 0.95. Proportion of patients on TDF/3TC/DTG in Minna, Nigeria who were virally suppressed.(63)
P2= 0.83. Proportion of patents on TDF/3TC/EFV in Cameroon who were virally suppressed.(83)
d = Difference between P1 and P2 = 0.12
Zα = Standard normal deviate corresponding to the probability α, i.e. the probability of making a type 1 error at 5% = 1.96.
Zβ = the standard normal deviate at 80% statistical power, corresponding to the probability of making a type 2 error = 0.84

$$N = \frac{2(1.98 + 0.84)^2 0.89(1-0.89)}{0.12^2}$$

$$N = 108$$

A total of 110 respondents in each of the 3 groups were studied giving a sample size of 330.

2.5. Ethical Consideration

Permission for the study was obtained from the COOUTH Ethical Review Committee.

2.6. Sampling Procedure

Three commonly used HAART combinations were compared. These were:

- Tenofovir/lamivudine/dolutegravir (TLD)
- Tenofovir/lamivudine/efavirenz (TLE)
- Tenofovir/lamivudine/lopinavir (TL/LPV/r)

Patients that were included in the study were those who have been on HAART for at least one year. Sociodemographic characteristics, baseline and follow-up clinical information and laboratory investigations were collected. Patient's adherence to HAART is determined based on adherence to clinic appointments and self-reported adherence to HAART as determined by clinician's interaction with the patient. Viral load was determined using Polymerase Chain Reaction (PCR). Data was collected between August 2021 and April 2022.

2.7. Instrument Design

A proforma was used to collect data.

2.8. Data Management

Data were entered into the computer, cleaned and analyzed using SPSS version 26.0. Frequencies, proportions, and means were compared between the three HAART groups. Chi square test was used to test associations between categorical variables at 5% level of significance. Multivariate analysis was done with binary logistics regression. Variables included in the enter method were those that were found to be significant from bivariate analysis at $p \leq 0.2$, as well as factors that has been shown by other literature to be associated with WHO clinical staging and viral suppression. The enter method was used in running the logistic model. Predictors were those significant at p = 0.05.

A scoring system was used to assess the performance of the 3 HAART regimens against 5 parameters:

- Proportion of patients on WHO stage 1 at 6 months
- Proportion of patients on WHO stage 1 at 1 year
- Proportion of patients with viral load suppression at 6 months
- Proportion of patients with viral load suppression at 1 year
- Proportion of patients with good adherence

The scores of 3 – 1 were assigned for best to least performance.

3. Results

3.1. Sociodemographic Characteristics

A total of 330 patients were studied, 110 from each of the three study groups. The mean age was 44.7 (±10.7) years. The 35-44 years age group has the highest proportion of patients of HAART, 122 (37.0%). There were more female patients than males in all study groups, 218 (66.1%) as shown in Table 1.

3.2. WHO Clinical Staging

Table 2 shows WHO clinical staging pre-treatment/baseline, at 6 months and at 1 year. No patient commenced treatment on stage 4. There were more patients on stage 3 within the TL/LPVr group than in the others at baseline, 6 months and 1 year ($p < 0.05$). There was an improvement

in staging in all groups over the one-year treatment period with the TLD group having the highest proportion of patients in stage 1 after one year of treatment 108 (99.1%). Despite this improvement, 8 (2.4%) of patients deteriorated clinically either at 6 months or at 1 year. This include TLD 1 (0.9%), TLE 3 (2.7%) and TL/LPVr 4 (3.6%).

3.3. Adherence to HAART

Figure 1 shows the proportion of patients in each study group that adhered to therapy. The TLD group had the highest level of adherence, 99 (90.0%), closely followed by TLE group, 98 (89.1%). TL/LPVr group had the least, 69 (62.7%) (p <0.001).

Table 1. Sociodemographic characteristics

Socio-demographic characteristics	TLD N=110 n (%)	TLE N=110 n (%)	TL/LPVr N=110 n (%)	Total N=330 n (%)	Statistics χ^2	p-value
Age group (yrs)						
≤ 24	3 (2.7)	1 (0.9)	1 (0.9)	5 (1.5)		
25-34	12 (10.9)	27 (24.5)	11 (10.0)	50 (15.2)		
35-44	25 (22.7)	48 (43.6)	49 (44.5)	122 (37.0)		
45-54	39 (35.5)	22 (20.0)	26 (23.6)	87 (26.4)		
≥ 55	31 (28.2)	12 (10.9)	23 (20.9)	66 (20.0)	34.027	<0.001*
Mean age (±SD)	47.6 (±11.0)	41.5 (±10.3)	45.1 (±10.0)	44.7 (±10.7)	2109.861**	<0.001*
Sex						
Male	46 (41.8)	24 (21.8)	42 (38.2)	112 (33.9)		
Female	64 (58.2)	86 (78.2)	68 (61.8)	218 (66.1)	11.137	0.004*
Religion						
Christianity	109 (99.1)	110 (100.0)	110 (100.0)	329 (99.7)		
Islam	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.3)	1.823	1.000
Marital status						
Single	24 (21.8)	15 (13.6)	34 (30.9)	73 (22.1)		
Married	76 (69.1)	83 (75.5)	63 (57.3)	222 (67.3)		
Separated	0 (0.0)	1 (0.9)	1 (0.9)	2 (0.6)		
Widowed	8 (7.3)	10 (9.1)	12 (10.9)	30 (9.1)		
Divorced	2 (1.8)	1 (0.9)	0 (0.0)	3 (0.9)	14.008	0.034*
Residence						
Anambra	105 (95.5)	104 (94.5)	103 (93.6)	312 (94.5)		
Others	5 (4.5)	6 (5.5)	7 (6.4)	18 (5.5)	0.402	0.658

*Statistically significant
**ANOVA.

Table 2. WHO clinical staging of participants

WHO Clinical Staging	TLD N=110 n (%)	TLE N=110 n (%)	TL/LPVr N=110 n (%)	Total N=330 n (%)	Statistics Fisher's Exact	p-value
Baseline						
Stage 1	98 (89.1)	95 (86.4)	94 (85.5)	287 (87.0)		
2	11 (10.0)	14 (12.7)	7 (6.4)	32 (9.7)		
3	1 (0.9)	1 (0.9)	9 (8.2)	11 (3.3)		
4	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12.005	0.013*
6 months						
Stage 1	101 (91.8)	101 (91.8)	92 (83.6)	294 (89.1)		
2	7 (6.4)	9 (8.2)	11 (10.0)	27 (8.2)		
3	2 (1.8)	0 (0.0)	7 (6.4)	9 (2.7)		
4	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9.285	0.043*
1 year						
Stage 1	108 (99.1)	101(91.8)	100 (90.9)	309 (93.9)		
2	1 (0.9)	9 (8.2)	6 (5.5)	16 (4.9)		
3	0 (0.0)	0 (0.0)	4 (3.6)	4 (1.2)		
4	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12.644	0.005*

*Statistically significant.

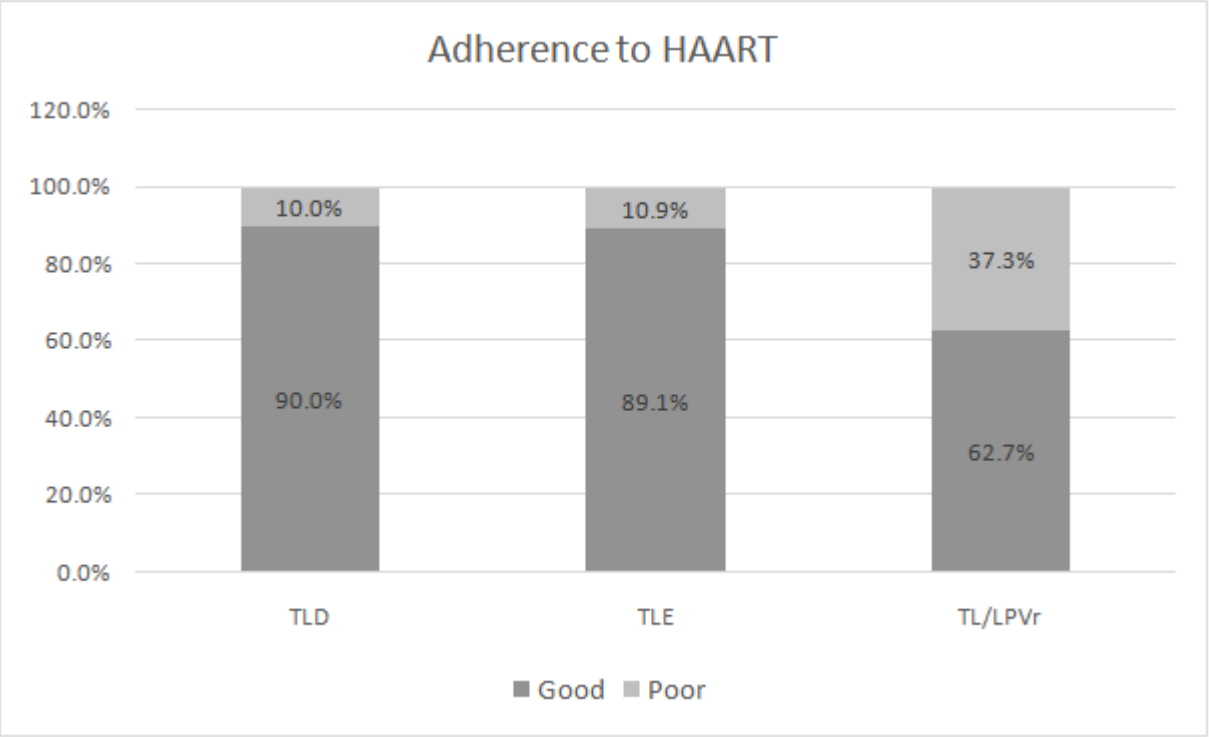

Figure 1. Adherence to HAART by patients on different regimen

Table 3. Viral load classification based on viral suppression

Viral Load (VL)	TLD N=110 n (%)	TLE N=110 n (%)	TL/LPVr N=110 N (%)	Total N=330 n (%)	Statistics χ^2	p-value
6 months VL (copies/ml)						
Virally suppressed (<1,000)	95 (86.4)	95 (86.4)	55 (50.0)	245 (74.2)		
Not-virally suppressed (≥1,000)	15 (13.6)	15 (13.6)	55 (50.0)	85 (25.8)	50.708	<0.001*
1 year VL (copies/ml)						
Virally suppressed (<1,000)	99 (90.0)	101(91.8)	91 (82.7)	291 (88.2)		
Not-virally suppressed (≥1,000)	11 (10.0)	9 (8.2)	19 (17.3)	39 (11.8)	4.885	0.098

*Statistically significant.

3.4. Viral Load

This classification is used in determining treatment efficacy in the clinic. The proportions of patients who were virally suppressed at 6 months were TLD (86.4%), TLE (86.4%), TL/LPVr (50.0%) and at 1 year, TLD (90.0%), TLE (91.8%), TL/LPVr (82.7%). This is shown in Table 3.

3.5. Factors Associated with Clinical and Virological Outcomes

Age ≥35 years was associated with patients on TLD being on WHO stage 1 at 6 months ($p < 0.05$). Female sex was associated with patients on TLE being on WHO stage 1 at 6 months ($p < 0.05$). Neither sociodemographic characteristic, nor level of adherence had significant association for patients on TL/LPVr stage 1 at 6 months.

There was no association between sociodemographic characteristic and level of adherence for patients overall with clinical outcome (being on WHO stage 1) at 6 months as shown in Table 4 (and also at 1 year, table not shown).

For all patients, good adherence was associated with viral suppression at 6 months ($p < 0.05$) as shown in Table 5 (and at 1 year, table not shown).

3.6. Predictors of Clinical and Virological Outcomes

Table 6 shows odds ratio for the sociodemographic predictors of being on WHO stage 1 at 6 months. Female sex had more likelihood than male with the odds of WHO stage 1, OR 0.483 (95% CI 0.238 – 0.980).

Good adherence to medication has the highest odds ratio for sociodemographic predictors of viral suppression at 6 months OR 6.911 (95% CI 3.768 – 12.676). Another predictor was being currently married OR 1.826 (95% CI 1.036 – 3.217). This is shown in Table 7.

3.7. Performance Score for HAART Regimens

Table 8 presents the scores of the performance of the three HAART regimens against some criteria. The scores ranged from 3 – 1 for best to least performance. The total scored showed that TLD had the highest score of 14 being marginally better than TLE with a score of 13. TL/LPVr performed least with a score of 5.

Table 4. Characteristics of all patients associated with WHO clinical stage 1 at 6 months

Factors	WHO clinical stage N=330			
	Stage 1 n (%)	Stages 2,3,4 n (%)	χ^2	p-value
Age				
≤ 34	48 (87.3)	7 (12.7)		
≥35	246 (89.5)	29 (10.5)	0.224	0.814
Sex				
Male	94 (83.9)	18 (16.1)		
Female	200 (91.7)	18 (8.3)	4.649	0.040
BMI (kg/m^2)				
≥ 18	286 (89.4)	34 (10.6)		
< 18	8 (80.0)	2 (20.0)	Fisher's exact	0.299
Marital status				
Currently married	197 (88.7)	25 (11.3)		
Not currently married	97 (89.8)	11 (10.2)	0.087	0.852
Residence				
Anambra	276 (88.5)	36 (11.5)		
Others	18 (100.0)	0 (0.0)	2.331	0.127
Adherence				
Good	240 (90.2)	26 (9.8)		
Poor	54 (84.4)	10 (15.6)	1.817	0.178

Table 5. Characteristics of all patients associated with viral suppression at 6 months

Factors	Virally suppressed (VL <1,000 copies/ml) N=330			
	VL <1,000 n (%)	VL ≥ 1,000 n (%)	χ^2	p-value
Age				
≤ 34	43 (78.2)	12 (21.8)		
≥35	202 (73.5)	73 (26.5)	0.536	0.505
Sex				
Male	80 (71.4)	32 (28.6)		
Female	165 (75.7)	53 (24.3)	0.702	0.427
BMI (kg/m^2)				
≥ 18	240 (75.0)	80 (25.0)	Fisher's exact	
< 18	5 (50.0)	5 (50.0)		0.133
Marital status				
Currently married	171 (77.0)	51 (23.0)		
Not currently married	74 (68.5)	34 (31.5)	2.751	0.097
Residence				
Anambra	232 (74.4)	80 (25.6)	Fisher's exact	
Others	13 (72.2)	5 (27.8)		0.787
Adherence				
Good	219 (82.3)	47 (17.7)		
Poor	26 (40.6)	38 (59.4)	46.923	<0.001*

*Statistically significant.

Table 6. Predictors of WHO stage 1 at 6 months

Model	OR	95% CI	p-value
Age (yrs)			
≤ 35	1		
≤ 35	0.735	0.299 – 1.810	0.503
Sex			
Male	1		
Female	0.483	0.238 – 0.980	0.044*
Marital status			
Currently married	1		
Not currently married	0.876	0.406 – 1.890	0.736
Residence			
Anambra	1		
Others	0.000	0.000	0.998
Adherence			
Good	1.537	0.682 – 3.460	0.300
Poor	1		
BMI (kg/m^2)			
< 18	1.563	0.303 – 8.054	0.593
≥ 18	1		
Constant	48331484.35		0.998

*Statistically significant.

Table 7. Predictors of viral suppression at 6 months

Model	OR	95% CI	p-value
Age (yrs)			
≤ 35	1.377	0.650 – 2.916	0.404
≤ 35	1		
Sex			
Male	1		
Female	0.901	0.512 – 1.584	0.717
Marital status			
Currently married	1.826	1.036 – 3.217	0.037*
Not currently married	1		
Residence			
Anambra	1.261	0.387 – 4.102	0.700
Others	1		
Adherence			
Good	6.911	3.768 – 12.676	<0.001*
Poor	1		
BMI (kg/m^2)			
< 18	2.254	0.506 – 10.045	0.287
≥ 18	1		
Constant	0.006		<0.001

*Statistically significant.

Table 8. Overall performance of the three HAART combination

Parameters	TLD		TLE		TL/LPVr	
	Value	Score	Value	Score	Value	Score
WHO stage 1 at 6 months	91.8%	3	91.8%	3	83.6%	1
WHO stage 1 at 1 year	99.1%	3	91.8%	2	90.9%	1
Viral load suppression at 6 months	86.4%	3	86.4%	3	74.2%	1
Viral load suppression 1 year	90.0%	2	91.8%	3	82.7%	1
Good adherence	90.0%	3	89.1%	2	62.7%	1
TOTAL SCORE		**14**		**13**		**5**

4. Discussion

This study showed that 2.4% of patients developed new diseases evidence by deterioration in WHO clinical staging at 6 months or 1 year. This is similar to 5.3% of patients in a study in Spain who developed a new AIDS-defining event while on HAART. [14] This similarity may be due to similarities in HAART regimen which were protease inhibitor-based and non-nucleoside reverse-transcriptase inhibitor-based. Similarly in Taiwan, it was found that HIV-related opportunistic infections continue to occur in patients who are newly diagnosed with HIV infection, those in the early course of HAART or non-adherent to HIV care and HAART, and those in whom non-HIV-related infections have emerged as a significant cause of disease and death in the post-HAART era. [17] These may be related to poor adherence as identified in both studies and other non-HIV related co-morbidities.

A study in South Korea found that attending clinics as scheduled after commencement on HAART is an important predictor for clinical progression among HIV patients. [15] However, our study did not find adherence an independent predictor for clinical staging, but for viral suppression. Viral load is a better indicator of drug efficacy because HIV patients can have co-morbidities which can influence clinical picture. Also, a study in Italy has shown differences in virologic and immunologic response. It was also found that patients who responded only virologically or only immunologically had a significantly reduced risk for clinical progression than non-responders. [20]

During follow-up, a study done in India found that 80.8% patients showed clinical improvement. [18] This is similar to our findings as the proportion of patients with WHO clinical stage 1 at baseline, at 6 months and at 12 months increased from 87.0% to 89.1% to 93.9%. Another study among Chinese advanced AIDS patients observed significantly improved clinical outcomes after HAART. [9]

Among Test and Treat patients in a multi-centre study in Nigeria, 79% were virally suppressed at 6 months and 78% were suppressed at 12 months. [19] This is similar to our findings as 79.1% of our study participants were virally suppressed at 6 months. However, 91.2% were virally suppressed at 12 months which is an improvement on the multi-centre finding. [21]

In a study in Latin America, the majority of HAART initiators were male (66%) and the median age at HAART initiation was 35 years. The frequency of viral suppression was higher in treatment-naïve patients in care (VL<400 copies/mL in 78.0% at year 1) than in treatment-experienced patients (52.3% at 1 year). [22] In our study, the majority of HAART initiators were female (66.1%) and the median age at HAART initiation was 44 years. The frequency of viral suppression was higher in treatment-naïve patients in care (VL<400 copies/mL in 90.0% and 90.9% at year 1 for TLD and TLE respectively) than in treatment-experienced patients on TL/LPVr (76.4% at 1 year).

A Swiss study found 90·7% of treatment-naïve patients had viral load <400 copies/mL by 12 months. [23]

Similarly our study found that 85.8% of the patients had viral load <400 copies/mL at 12 months.

About a quarter of our patients (25.8%) had virological failure at 6 months and 11.8% at 1 year. This is comparable with 17.6% of patients attending a national reference clinic in Yaoundé - Cameroon who experienced virological failure (VL ≥1000 copies/ml) at 36 months. [24] Nigeria and Cameroon are neighbouring countries and patients' characteristics are likely to be similar.

A multi-centre study in three hospitals in Nigeria on immune-virologic outcome of adults on anti-retroviral therapy showed that virologic suppression rate (<400 copies/ml) was 76.7%. In multivariate logistic regression, virologic failure was associated with age <30 years (OR 1.79; 95% CI: 1.17-2.67, p=0.03) and poor adherence (OR 3.82; 95% CI: 2.17-5.97, p=0.001). (62) Our study showed that virologic suppression rate (<400 copies/ml) was higher at 85.8%. Using multivariate logistic regression, virologic failure was found to be associated with being currently married (OR 1.826; 95% CI: 1.036-3.217, p=0.037), and similarly, poor adherence (OR 6.911; 95% CI: 3.768-12.676, p<0.001).

Our study showed that dolutegravir and efavirenz based combination regimen showed statistically significant effect in supressing viral load when compared with lopinavir-ritonavir combination. A study done in Minna, Nigeria revealed that dolutegravir based combination regimen showed a statistically significant effect in suppressing viral load. The majority of respondents, 398 (95.2%), had viral load suppression (VL<1000 copies/ml) after 6 months of intervention compared to 302 (72.3%) of respondents' who had viral load suppression (VL<1000 copies/ml) before intervention. [26] This similarity is not surprising as the participants has similar characteristics.

The DAWNING study showed that in patients who fail first-line non-nucleoside reverse transcriptase inhibitor (NNRTI)-based regimens, dolutegravir had better efficacy and tolerability compared with lopinavir-ritonavir regimen. [12] This was similar with our results where dolutegravir-based regimen performed better than lopinavir-ritonavir regimen on all parameters.

5. Conclusion

There was an improvement in clinical staging in all groups over the one-year follow-up period, with patients on TLD faring better. Viral suppression was similar and better with TLD and TLE than with TL/LPVr. Our study concluded that tenofovir/lamivudine/dolutegravir (TLD) is the preferred regimen based on its performance on the scoring system.

Further studies can determine the factors that are associated with poor adherence to TLD.

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Statement of Competing Interests

The authors have no competing interests.

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List of Abbreviations

HAART -	Highly active antiretroviral therapy
HIV -	Human Immunodeficiency Virus
NNRTI -	Non-nucleoside reverse transcriptase inhibitors
PCR -	Polymerase Chain Reaction
TLD -	Tenofovir/lamivudine/dolutegravir
TLE -	Tenofovir/lamivudine/efavirenz
TL/LPVr -	Tenofovir/lamivudine/ritonavir boosted lopinavir (TL/LPV/r)
WHO -	World Health Organization
VL -	Viral load

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