Original

Transition to Pediatric Dolutegravir: A Before and After Study of Virologic Suppression Rate Among Pediatric Treatment Cohort in Rivers State, Nigeria

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ABSTRACT

Background: Dolutegravir (DTG) is known for its high genetic resistance barrier and reduced occurrence of adverse drug reactions. It has demonstrated superiority over protease inhibitor-based regimens, showing a lower risk of treatment failure in infants and young children compared to lopinavir/ritonavir (LPV/r) formulations. This study compared the rates of viral suppression in children living with HIV (CLHIV) weighing less than 20kg who transitioned from Lopinavir-Ritonavir (LPV/r) regimen to peadiatric dolutegravir (pDTG)-based regimen.

Methods: A descriptive study conducted in Rivers State to compare the virologic suppression among CLHIV on LPV/r and pDTG treatment. Descriptive statistics using counts and proportions for categorical variables and means and standard deviations for continuous variables. Test of association using McNamar Chi-square. P-value 0.05.

Results: The mean age before and after the transition to pDTG was 4 years and 5 years, respectively. Before the transition to pDTG, 88.2% (656) of children were virally suppressed. After the cohort was transitioned to pDTG, viral suppression increased to 90.2% (671). The disaggregated percentage of viral load suppression after transition to pDTG showed that the undetectable viral load among the suppressed cohort was 99.7%. However, before transition to pDTG, it was 84%; these proportions were also not statistically significant (p-value = 0.167)

Conclusion: The introduction of dolutegravir-based anti-retroviral therapy in the peadiatric cohort of the study improved viral load suppression by 2% but this was not statistically significant. Further studies may be necessary to explore other essential factors that may be operational in achieving viral suppression in CLHIV.

Keywords: Viral suppression**,** HIV**,** dolutegravir, lopinavir/ritonavir, regimen, children

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INTRODUCTION

Globally, virologic suppression rate among children living with HIV have been suboptimal[1,2] and falls below the Joint United Nations Programme on AIDS (UNAIDS) treatment target of having at least 95% of people living with HIV/AIDS on Antiretroviral therapy (ART) with a viral load of fewer than 1,000 copies/ ml.[3] Sustained viral suppression is necessary to prevent the development of antiretroviral (ARV) drug resistance, reduce morbidity from opportunistic infections, and improve the quality of life of HIV-infected individuals.[4] In children, it will also promote and restore normal growth and development.[5,6] Moreover, progression to Acquired Immunodeficiency Syndrome (AIDS) is faster and death can occur in over 80% of children within five years of birth without effective treatment.[6] The goal of ART is to achieve viral suppression in PLHIV.[7] However, adults living with HIV who are on appropriate and effective regimens are more likely to achieve viral load suppression.[8,9] In order to accurately follow up the progress towards viral suppression, and sustaining the same, CLHIV on the State and National treatment programme routinely have viral load assays (count) done six-monthly for monitoring in care.[7] Yet, achieving virologic suppression among children below 15 years of age remains a challenge for several reasons, including suboptimal dosing, poor drug literacy, socio-cultural beliefs, as well as convenient oral delivery of the ARV drug.[10,11] The introduction of dolutegravir, an integrase Inhibitor with numerous pharmacological advantages, has proven to be effective over earlier combinations of ART in achieving rapid viral suppression.[12–14] DTG is known to have a high genetic barrier to resistance and fewer adverse drug reactions.[15] It has also been found to be superior to a protease inhibitor-based regimen with a lower risk of treatment failure in infants and young children.[14]

In addition to the above advantages, the pediatric DTG (pDTG) formulation comes in a once-daily dispersible tablet administered alongside dispersible formulations of abacavir/lamivudine (ABC/3TC).[14] It is more convenient than the twice-daily lopinavir/ritonavir (LPV/r) tablets; hence reducing the pill burden.[16] This also overcomes other disadvantages of the poorly palatable LPV/r formulations; the LPV/r granules/pellets require additional counseling and guidance to ensure appropriate administration.[17] The LPV/r tablet on the other hand is recommended to be swallowed whole for better potency[16]. Overall, these challenges limit adherence and consequentially limit the comparative effectiveness of LPV/r formulation [17]. The pDTG formulation became available for use in Nigeria in late 2021 and is preferred over the LPV/r as the recommended first-line regimen for the treatment of children less than 20kg living with HIV.[18]

In Rivers State, Children Living with HIV (CLHIV) on LPV/r based-regimen were transitioned to pDTG-based regimen between October 2021 and February 2022 for better treatment outcomes in line with global standards and the recommendation of the Federal Ministry of Health.[7] The study aimed to compare viral suppression rates among CLHIV (< 20kg) transitioned from LPV/r based-regimen to pDTG-based regimen in Rivers State.

METHODS

Study Area: The study was conducted in Rivers State, Nigeria. Rivers State is in the South-South geo-political region of Nigeria. It is made up of three senatorial zones and 23 Local Government Areas, with the capital as Port-Harcourt. The 6th most populous state with a population estimate of about 7,303,924 as of 2016 (from the 2006 Census).[19] According to the National AIDS Impact and Indicator survey, Rivers State has an HIV prevalence of 3.6% (95% CI 2.9–4.3)[20] and the UNAIDS Spectrum 2019 model projected the total number of People living with HIV (PLHIV) in the state in 2020 to be 184 551.[18]

Study design: **A** quasi-experimental study conducted among Children Living with HIV on treatment in Rivers State.

Study Population: The study population were ALL Children Living with HIV (CLHIV), less than 20kg and enrolled in the treatment programme of the Rivers State AIDS/STI & Hepatitis Control Programme (SASCP) who were on LPV/r regimen at the time of study as documented in the Electronic Medical Record (EMR) and enlisted in the study.

Sample selection:*Inclusion criteria:* These CLHIV on the LPV/r-based regimen

- On the treatment programme of the SASCP for at least six months before the period of transition to pDTG (October 2021 and February 2022)
- Less than 20kg at time of study
- Who had a documented (routine) viral load assay result of not more than six months before the transition

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- Who also had a documented (routine) viral load assay result at six months after transition to pDTG.

Exclusion Criteria: CLHIV within the cohort were excluded if they were classified as treatment mortality, and losses ((TX__ML): IIT (Interruption in Treatment), died, transferred out, and stopped treatment). CLHIV with no clinical contact or ARV pick-up for greater than 28 days since their last expected clinical contact or ARV pick-up was excluded either during transition or after transition to pDTG.

Intervention: Following the introduction of pDTG into the national treatment guidelines in Nigeria, as a better treatment choice in line with global standards, a decision was reached in the SASCP, Rivers State, to transition all eligible Children Living with HIV (CLHIV) on LPV/r-based regimen to pDTG regimen (remove and replace). In the cohort of study, CLHIV on LPV/r regimen under 20kg with documented routine viral load (pre-transition viral load assay) result, formed the eligible cohort of study. The transition intervention was implemented over a period of five months (between October 2021 and February 2022) in the cohort of study. This was to enable all scheduled clinic visits to have a clinical transition interphase which includes replacement of the LPV/r-based regimen with the new pDTG regimen, pharmacy dispensing of the same to the cohort, caregiver notification, adherence counselling, pharmacovigilance plans and feedback systems in line with standard care practices of the State AIDS/STI & Hepatitis Control Programme. At completion of the process, the cohort became eligible for a six-month viral load assay for treatment monitoring. The results of the viral load assay were used for treatment monitoring and became the post-transition comparative indicator of the study.

Data Analysis: Data from the SASCP records were exported to SPSS and cleaned. For analysis, descriptive statistics were done using counts and proportions for categorical variables; means and standard deviations for continuous variables. The Test of Association was done using McNemar's Chi-square to test the difference in the proportion. All analysis was done using the SPSS v25 software at a 95% confidence interval, and a p-value less than 0.05 was considered statistically significant

Indicators for assessment: The following key indicators were assessed comparatively before and after the intervention (transition to pDTG) in both the before- and after-treatment cohorts.

- Percentage viral load suppression (PVLS) before the transition to pDTG
- PVLS after transition to pDTG

Where Viral Load Suppression (VLS) is a viral load assay result in PLHIVs measuring ≤1000 copies/ml, Low-level Viraemia is the viral load assay in PLHIVs measuring 50 – 999 copies/ml, and Undetectable viraemia is a viral load assay result in PLHIVs < 50 copies/ml.[7]

Ethical Approval: Ethical approval was obtained from the State AIDS/STI & Hepatitis Control Program (SASCP) and the Ethics unit of the Rivers State Ministry of Health. (Communicated via RSHMB/RSHREC/2023/ of 22nd March, 2023) and Secondary patient-level data were utilized, as such, researchers had no direct contact with PLHIVs for this study. Strict confidentiality and anonymity were maintained, and the outcome of the analysis was shared with the SASCP team as feedback.

RESULTS

Sociodemographic variables of the cohort of study

Table 1: Sex distribution

Sex	Frequency	Percentage (%)
Male	368	49.5
Female	376	50.5
Total	744	100

Table 1A show that there was a total of 744 CLHIV in the cohort of study; out of which 377 (50.7%) were females while 367 (49.3%) were males.

Table 2: Age and Weight Distribution

Variables	n	Range	Min	Max	Mean	SD
Pre-transition Age (years)	744	9.25	.75	10.0	4.10	1.90
Post-transition Age(years)	744	10.00	1.00	11.00	5.12	2.00
Pre-transition weight (kg)	744	12.00	7.00	19.0	14.60	2.70
Post-transition weight(kg)	744	19.00	10.0	29.0	17.23	3.61

Table 2 shows that the mean age before (pre) and after (post) the transition to pDTG was 4 years and 5 years, respectively.

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2. Analysis of Viral load result

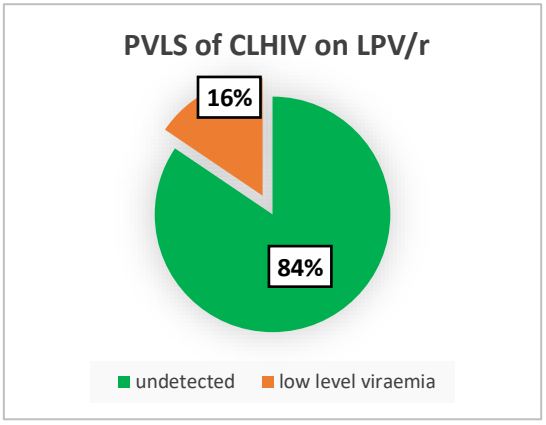
Table 3: Viral Load assay result before and after the transition

Viral load assay result	Pre-transition (LPV/r regimen)		Post-transition (pDTG regimen)		% change
	Freq	%	Freq	%	
Unsuppressed viral load	88	11.8	73	9.8	- 2.0
Suppressed viral load	656	88.2	671	90.2	+ 2.0%
Total	**744**	**100**	**744**	**100**	

Before the transition to pDTG, 88.2% (656) of children were virally suppressed. After the cohort was transitioned to pDTG, viral suppression increased to 90.2% (671). Though not statistically significant it represented a 2.0% change in the viral load suppression in the cohort of the study (Table 3).

Table 4: Disaggregation of Percentage Viral Load Suppression (PVLS) by regimen

The disaggregated PVLS after the transition to pDTG showed that the undetectable viral load among the suppressed cohort was 99.7%, while on LPV/r regimen (before the transition to pDTG), it was 84% (p-value = 0.00). A further test of significance using an exact McNemar's test determined that 52 of the total CLHIV that were suppressed before the transition to pDTG became unsuppressed after the transition to pDTG while 67 of the total CLHIV that were unsuppressed before transitioning to pDTG became suppressed after transitioning to pDTG but these proportions were not statistically significant (p-value = 0.167)



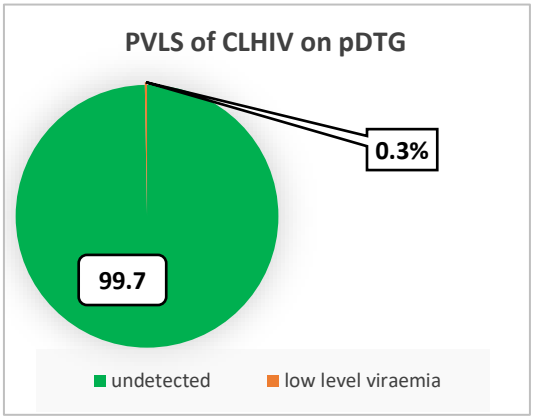


***Figure 1**: Disaggregation of PVLS*

Table 4: Disaggregation of PVLS by sex

Sex	LPV/r		p-value	pDTG		p-value
	Unsuppressed	Suppressed		unsuppressed	suppressed	
Male	45	323		34	334	
Female	43	333	0.738	39	337	0.603
Total	88	656		73	671	

Before the transition to pDTG, more males had unsuppressed viral load compared to females (p-value = 0.738) but after the transition to pDTG more females had unsuppressed viral load compared to males (p-value = 0.603), but these were not statistically significant – Table 4.

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DISCUSSION

Achieving good adherence to treatment and viral suppression has remained a challenge in children and adolescents perinatally infected with HIV.[10,11] In the cohort of study, there were 50.7% were females 49.3% were males. Before the transition to pDTG, 88.2% of the CLHIV cohort were virally suppressed; however, after the cohort was transitioned to pDTG, the viral suppression increased to 90.2%. Though this is not statistically significant it represents a 2.0% change in viral load suppression within the cohort shortly after transition. This improvement in viral suppression resonates with the study by Bruzzese et al, which also shows that a dolutegravir-based regimen is very effective in adolescents.[12] However, very few studies exist beyond the clinical trials on viral suppression rate among young children weighing less than 20kg on DTG-based regimens in Africa. Also, older children (greater than 20kg in weight), adolescents, and adults on DTG-based regimens have shown better viral suppression when compared to regimes like Efavirenz and Ritonavir-boosted Lopinavir.[21–25]

The viral suppression rate of study participants on LPV/r-based regimen before transition to DTG-based regimen was 88.2%, though this is above the suppression rate for CLHIV on ART in the region and globally;[2,26,27] it falls short of the expected 95% PVLS of UNAIDS Fast track target to End AIDS by 2030.[3] After the transition to a DTG-based regimen, there was an increase in viral suppression to 90.2%, though this was not statistically significant suggesting a better treatment intervention. Our finding therefore suggests that though there may be other possible factors contributing to improvement in viral suppression, beyond ART regimen, type, and ease of administration which was not explored in this study, pDTG is likely to have contributed to the observed improvement in the proportion of virally suppressed children in the cohort of study which is in keeping with the pharmacologic characteristics of pDTG achieving sustained and better virologic suppression.[7,18] Notably younger children are dependent on their caregivers for ART management; hence, caregiver-related factors can pose a significant barrier to adherence in children and subsequently virologic suppression rate.[28,29] Other factors also include co-morbidities such as Tuberculosis, nutrition, the child's age, socio-economic environment, the mental health status of children, and site-level factors.[6,29–31]. Notwithstanding, the proportion of virally suppressed CLHIV who had an undetectable viral load (<50c/ml) increased remarkably from 75.3% pre-transition to 99.5% post-transition and this was significant. On the contrary, a study in Northern Nigeria found DTG-based regimen did not increase the likelihood of undetectable viral load among children even though there was an increase in adherence as compared to those on protease inhibitor (PI)-based regimen.[31] Though some CLHIV who were suppressed on LPV/r became unsuppressed after transition, more unsuppressed children on LPV/r became suppressed after transition but this was not statistically significant. While the overall effect of pDTG on PVLS is beneficial on the overall[7,12-15], this study did not explore factors that could have contributed to a higher viraemia, post transition in these few CLHIV who became unsuppressed. Yet, it is of critical interest to consider targeted adherence counselling for the CLHIV who lapse into unsuppression post transition to pDTG, in compliance with the national guidelines and the need to meet End AIDS targets of 95-95-95.

Strengths and limitations of the study

The study offers real-world field data on the effectiveness of achieving viral suppression using pDTG in CLHIV on treatment. It is an asset for program entities and program managers, especially having utilized a large cohort of >700 samples for the study. This study is set in actual implementation conditions with each child serving as a component of the similar cohort for comparison and minimizing variability; yet the age at transition varied slightly in months as the transition stretched over months, and the challenges of using secondary data equally apply as expected.

Implications of the findings of the study

The high burden of CLHIV and new infections among children in Africa holds strong global and local implications for treatment. The need for an effective and convenient regime for secondary level intervention cannot be underestimated. Dolutegravir promises holds strong evidence of treatment potential in literature. This study provides context to that in Africa and Nigeria and indeed in comparison with the previous LPV/r regimen. Moreso, this study lends filed credence to the World Health Organisation guidelines for use of DTG in children under 20kg, as offering a no less convenient option for viral suppression in children, further strengthening the adopted practices in Nigeria and the transition plans implemented for CLHIV in Rivers State. Perhaps it represents in the paucity data an early

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observational analysis of the treatment outcome in the State HIV control programme for CLHIV on treatment. In the approach to 2030, the study provides a key framework for the expectation of reaching 95-95-95, as well as a basis for further studies in that quest. The study suggests that optimization of regimen alone may be insufficient in reaching the targets and the need to consider other factors such as nutrition, adherence support, DSMD models and complementary interventions is of necessity.

CONCLUSION

The introduction of dolutegravir-based ART in the peadiatric cohort of the study improved the viral load suppression rate by a percentage change of 2%, but this was not statistically significant. The total number of children on ART with undetectable viral load increased significantly post transition (to DTG-based ART). Though the DTG-based regimen seems to have some advantage over LPV/r in achieving undetectable viral load in suppressed CLHIV, further studies may be necessary to explore other essential factors that may be operational in achieving the PVLS in CLHIV in order to reach the population targets of 95-95-95.

Declarations

Availability of data and materials: The datasets analyzed in this study were obtained from the State AIDS/STI and Hepatitis Control Program (SASCP), Rivers State, and are available from the corresponding author upon reasonable request.

Competing interests: The authors declare that they have no conflicts of interest.

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Authors' contribution: GO, CD, and ST conceptualised the study. SI, CD and UE organised the data and reviewed the tables. IAW, CE and UK conducted the statistical analysis. NA, GO, MO and OC were involved in the introduction and discussion. MO and OC interpreted the results and edited the discussion. ST and AO designed the methods and provided insight into the conclusion. All authors reviewed and approved the final manuscript. GO supervised the research implementation.

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