VIROLOGICAL RESPONSE AND TOLERABILITY OF DOLUTEGRAVIR BASED REGIME FOR CHILDREN LIVING With HIV AND ITS ASSOCIATED FACTORS.

In order to partially fulfill the requirements for the Specialty Certificate Program in Pediatrics and Child Health, the research thesis must be submitted to Addis Ababa University's College of Health Science and Pediatrics Department.

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Acronym

NNRTI……Non -nucleoside reverse inhibitor
HAART……Highly active anti retroviral therapy
DTG…….Tenofovir disoproxil fumarate
HIV…….Human immunodeficiency virus
PMTCT…….prevetion mother to child transmission
ABC…….Abacavir
ART……Antiretroviral therapy
WHO…….World health organization

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Acknowledgment

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Abstract

Background: The World Health Organization advised using integrase strand transfer inhibitors and strong ART medications, particularly HAART, as soon as the diagnosis was established. Due to its low side effects, excellent viral suppression, and superior gentic barrier against ART medication resistance, DTG is preferred over other ART drug regimens. Weight loss, hepatotoxicity, elevated blood sugar, and sleep disturbance are some of the side effects associated with DTG-based regimens, but other benefits include low side effects, high viral suppression, and a better genetic barrier against ART medication resistance. DTG is used as first- and second-line ART regimens, and early initiative HAART plays a significant role in lowering morbidity and mortality.

Objectives: To evaluate children with HIV's virological response and side effects related to a DTG-based regimen

Methods: This study was conducted in the pediatric infectious disease specialty hospital Tikur Anbessa using a retrospective cross-sectional study methodology. SPSS 26 was used to enter the data for any ensuing descriptive and analytical statistics. In terms of statistics, a p-value of less than 0.05 was considered to indicate a significant..

Result

We included 218 children living with HIV on a DTG-based regimen, and after 6–12 months, the prevalence of viral suppression was 92.7%. However, only 6.4% of study participants started a DTG-based regimen with reported side effects, such as gastrointestinal symptoms like nausea 11 (5%), and sleep disturbance 3 (1.3%), after taking it within 24 hours. There were no serious side effects, and the side effects were insufficient to cause them to change their ART regimen. In this study, the viral suppression rate was 71% (95% CI;.316,26.2, AOR 1.593), p-value<.0.016. ART can reduce viral load as soon as it is started, and the adherence to the regimen was 96% (95% CI;.678,51, AOR 1.912), p-value <.025. Poor adherence was linked to high viral load.

***c**onclusion*

According to this study, children with HIV who are on a DTG-based regimen have good viral suppression, good tolerability, and a low incidence of side events.

1. introduction

Background According to WHO estimates, 90% of children under the age of nine live in sub-Saharan Africa, and there are 2.6 million children living with HIV/AIDS, with 270,000 new infections occurring each year. According to estimates from 2022, 13.9 million people are HIV/AIDS orphans. The majority of infections worldwide are vertically transmitted from mother to kid. About 11,700 children with HIV were infected during pregnancy in the United States. In the United States, adolescents aged 13 to 24 years had a prevalence of about 21% in 2018; 50% of these adolescents were HIV positive, and they were the group most unaware of the disease of any age.

Since the introduction of HIV/AIDS in Ethiopia in 1984, thousands have reportedly become orphans, prompting the Ethiopian government to take various steps to stop the disease's spread and improve access to HIV care and treatment. According to the 2016 EDHS, the country's adult HIV prevalence is 0.96%, while the urban prevalence is 2.9%. Free ART services were introduced in 2005, providing more than 1500 health facilities with ART coverage of 40.03% in children.

The ART guidelines indicated to use HAART as soon as diagnosis confirmed whatever the clinical stages and CD4 count with powerful medications notably with integrase strand transfer inhibitors which are with low side effects and greater safety. DTG is second generation INSI that operates by blocking integrase enzyme . As an early initiative and first- and second-line regimen approved by the WHO in 2013, HAART significantly reduces morbidity and mortality.

1.2 statement of the problem

Since there is no cure for HIV/AIDS, patients must be managed with HAART for the rest of their lives in order to lower morbidity and mortality. However, long-term use of ARV medication can result in drug-associated toxicity and intolerance, which can lower adherence, decrease viral suppression, and increase resistance to HAART. Additionally, treating children with HIV infection can be difficult because of social and clinical factors This led to the creation of new antiretroviral medications with less side effects. The DTG-based regimen mentioned gastrointestinal side effects, such as nausea and diarrhea, as well as neuropsychiatric symptoms, such as headache, insomnia, and suicidal thoughts.

Numerous variables, including adherence level, ART duration, ART beginning timing, and clinical staging, are linked to viral suppression. The patient's good adherence resulted in a high reduction of the viral load; nevertheless, poor adherence may have led to treatment failure. Given that the viral load exceeds 1000 copies/ml, it is preferable to rotate between the second and third line regimens and repeat the viral load and drug resistance tests after three months. One of the world's health issues is HIV/AIDS. Over 37.7 million individuals were living with HIV in 2020. Nearly 45% of newly infected individuals reside in sub-Saharan Africa. Children living with HIV are significantly impacted by the mortality and morbidity caused by HIV/AIDS. Those under 20 years old accounted for 15% of the 770,000–1500,000 AIDS-related fatalities worldwide in 2018.

1.3 significance of study

The study's objectives are to evaluate the virological response following the start of antiretroviral therapy linked to a DTG-based regimen, evaluate the factors linked to a virological response with a DTG-based regimen, and outline the adverse effects of the initial DTG regimen in children with HIV/AIDS.The combination of TDF+3TC+DTG in the medication regimen according to the WHO protocol is crucial for proper use. Thus, in addition to two nucleoside reverse transcriptases, the combination also includes NNRTIS, PIs, and INSTIs. The best ART medication combination lowers HIV/AIDS transmission and enhances people's quality of life.

2. Review of the literature

One study conducted in Nigeria revealed that 106 children between the ages of 10 and 18 participated in the study, with a mean age of 14. Of these, 59% came from a low socioeconomic background, and 56.6% were men. Even though the prevalence of viral suppression was 97 (91.5%) after six months of DTG-based treatment, the baseline viral load was 48 (45.3%), which was less than 1000 copies/ml.

A statistically significant difference in the proportional viral suppression rate was observed (X2=53.77, p=.0001). Before beginning a DTG-based regimen, 23.6% of the children had an undetectable viral load < 20 copies/ml; however, following six DTG-based regimens, the viral load was significantly reduced in 61 (57.5%) of the children, and in 80.6% of the children who failed treatment, the viral load was suppressed. According to this study, there was no correlation (p>.05) between the suppression of viral load and age, sex, or social status (4).

According to a prospective cohort research conducted in Tanzania, the majority of children had normal BMI during the start of the DTG-based regimen, and the mean age of children living with HIV was 13 years. Additionally, 103 (51.5%) of the patients were found to be between the ages of 10 and 15. Only57 (28.5%) of the children with HIV who were born to an HIV-positive mother had been exposed to ARV prophylaxis, whereas the majority (75%) of the infants had been perinatally infected. Of the 200 children living with HIV, the majority (85.5%) had experience with ART, and 69.5% had been on HAART for more than five years. Patients self-reported their adherence levels as good (48%), fair (40.5%), and low (11.5%). Self-reported adherence was higher among ART-naïve patients (69%) compared to those who had previously used ART (44.4%), with a p-value of 0.015.Only 51.4% of children living with HIV who had good adherence based on pharmacy refills also had good adherence based on self-reporting, compared to 71% of those children who were refilling on a DTG-based regimen. among the kids who failed to achieve a virological response. After initiating a HAART regimen, the mean CD4 count was immunologic improved in those whose CD4 count was less than 200 cells/mm3 after starting a DTG-based regimen after 6 months, while those with a viral load greater than 1000 copies/ml experienced treatment failure due to poor adherence (7).

*Prior to switching to a DTG-based regimen, 63.2% of the 171 children living with HIV who experienced it had viral load suppression below 50 copies/ml. Children who had reached undetectable viral loads were more likely to have viral loads below 50 copies/ml prior to starting a DTG-based regimen than those with viral loads over 50 copies/ml (81.7% vs. 49%, p<.01)**.** Of the 52 patients who received treatment and did not demonstrate viral load suppression at 6 months, 33 (63.5%) had baseline viral loads more than 50 copies/ml. There were 4.04 (95% CI copies/ml of p =.026) virologic differences between treatment-experienced patients. Six months later, 66.7% of the children had a viral load < 50 copies/ml. After a 6-month DTG-based therapy, 4.5% experienced persistent suppression (p=.023). After a year, the virological suppression was substantially correlated with baseline (p=.008) and six months (p=.023). 60.6% and 57.9% of the 38 patients who did not achieve viral load suppression after a year of follow-up had viral loads greater than 50 copies/ml (6).*

Following a DTG-based regimen, 16.5% of children experienced side symptoms, with the majority reporting 18.1%. Additionally, 33 patients experienced sleep disturbance (18.2%), with nausea/vomiting (15.2%) being the most common adverse effects. All of the adverse effects were categorized as light, moderate, and severe; the mild and moderate ones went away on their own in a matter of weeks without any medical intervention. The hematological parameters are impacted by the DTG-based regimen. 200 patients' CBC results revealed a wide range of erythrocytes, including 13.5%, 8% ALAT, 6% lymphocytes, 4.5% eosinophils, 4.5% monocytes, and 2.5% platelet count (5).

The Naples Center conducted a retrospective study on children with HIV/AIDS who were treated with a DTG-based regimen. All children under the age of 18 were evaluated prior to starting the medication regimen and were then evaluated every three months after the new regimen was introduced to determine its virological and immunologic efficacy as well as any possible side effects. The PCR diagnosis modality with a sensitivity of 40 copies/ml was used to measure the viral load, and thcaretakers were evaluated on the results of the medication regimen at the ART center with regard to the adherence level of the children living with HIV and the side drug effects (8).
One study, a retrospective cohort, was conducted in Tanzania between 2019 and 2021 among children with HIV who were receiving DTG-based treatment. A study of 63453 children on a new medication regimen based on DTG revealed that the prevalence of viral suppression was 91.6%, that 66.2% of the children with prior treatment-unsuppressed viral loads became suppressed, and that 88% of the children who were suppressed again remained suppressed at a significant level. Children living with WHO clinical stage 1 (aRR:1.03;95% CI:1.01-1.04) had significant viral suppression with the eary stage, and those factors that affect lowering the viral load to become suppressed with age range of below 20 years took the drug regimen more than 2 years (aRR:.77;95% CI:.91-.93) with eary initiatives potent ART with DTG-based regimen (7).

3.objective

General objectives

To evaluate the virological response and tolerance of a DTG-based regimen for children with HIV at the TASH pediatric infectious clinic between December 2017 and December 2010 E.C.

specific objectives

To characterize the adverse effects of the initial DTG regimen in children with HIV/AIDS

To evaluate the virological response following the initiation of antiretroviral treatment associated with DTG based regimen;

To evaluate the factors related with virological response with DTG based regimen

4. Methodology

4.1 studyArea

The study was done in the Department of Pediatrics and Child Health, TASH-PIDC, College of Health Sciences, Addis Ababa University. TASH was established in early 1964 and is the largest and most renowned public hospital. The study was carried out at the Referral Center for Pediatric HIV at a referral hospital where HIV infection was treated with DTG.

4.2 study design
Children living with HIV who were on an ART-initiated DTG-based regimen in TASH participated in this retrospective cross-sectional study.
4.3 Population under study
HIV-positive children under the age of 20 who were receiving ART for six months throughout the research period

***4.4** study participants*
Children under the age of 20 who were receiving treatment and care in clinics during the research period and on a dolutegravir-based regimen.

***4.5** inclusion criteria*

All children with HIV who have been on ART for fewer than six months are receiving care and therapy.

Criteria for exclusion
children living with HIV lost viral load results after initiation with DTG

4.6. study variables

4.6.1 Independent factors in the study

Age, ART duration and sex , length; adherence to ART

4.6.2 Dependent variables:

side effects and reduction of viral load

***4.7** sample size*

Relative precision was set at 5%, the prevalence of viral suppression on dolutegravir was 84% of those the previous research Tanzania who achieved viral load <50 copies/mL at 6 months, and the sample size was determined using a single population proportion formula with a 95% confidence level.

*The study period was chosen until the sample size was reached using the formula: n=z confidence level.Formula: n=za/22 *p (1-p)/d2*

Where: n = the desired sample size

P= 84%.

d =5% (maximum margin of error the researcher is willing to allow)

Z =1.96 (standard normal deviation value corresponding to 95% confidence level)

n= (1.96)2*0.84(1-0.84) =207

(0.05)2

10% n=227

Adding 10% non-response rate, the final sample size was become 227 but we use 218 patients on follow up

All Children who were on a dolutegravir based regimen during the study period was selected until the sample size achieved.

4.8 The sampling method

Until the target sample size was reached, children who were following a dolutegravir-based regimen during the trial period were included in the study using the ART registration logbook.

4.9. Information gathering

Data collectors and the primary investigator created and completed a standardized questioner in English for the ART follow-up patients who had been on a DTG-based regimen for at least six months in order to harvest data.

4.9.1. Management of Data

Hard copies were converted to soft copies for analysis while the principal analyzer verified and cleaned the data

4.9.2 Assurance of Data Quality

The primary investigatort was cross-checking the hard copies for neatness;completeness and consistency before carrying out analysis.

4.9.3 Analysis of Data

SPSS26 was used for data entry, cleaning, and analysis. The association and statistical significance were evaluated using the odd ratio with 95% CI, with a p-value of less than 0.05. and tables, graphs, and figures were used to display the outcome.

4.9.4 Ethical consideration

Confidentiality was maintained throughout the data analysis and results distribution, and ethical approval was acquired from Addis Ababa University's pediatric departments and research and ethical council.

4.9.5 Definition of an operation

Viral suppression is the undetectable viral load, which is less than 50 copies/ml. Viral load is greater than 50 but less than 1000 copies/ml, indicating low viremia. A viral load of more than 1000 copies/ml, as determined by two consecutive viral load assays taken three months apart with improved adherence assistance, is considered virological failure.Adherence ;the patients behavior is in agreement with the health care giver suggestions Good adherence is when a patient misses only one dosage out of thirty, or when their adherence level greatethan95%.

Equitable adherence 85–94% adherence, meaning the patient misses two–four doses out of thirty Poor adherence: when a patient misses more than five doses out of thirty, their adherence level is below 85%.

5 .Result

5.1 socio-demographic characteristics of respondant

Of the 218 patients who participated and were included in the trial, 215 were on a first-line ART regimen based on DTG, two were on a second-line regimen, and one was on a third-line regimen. The results indicated that the majority of study participants, 100 (45.9%), were between the ages of 16 and 20. Of these, 128 (58.7%) were male and 90 (41.3%) were female.

Clinical features of HIV patients at TASH on a DTG-based regimen The majority of research participants—126, or 57.8%—were on AZT+3TC+EFregimen prior to starting a dolutegravir-based regimen.

Table 1 of the present ART regimen revealed that 48 (22%), and the majority 164 (75.2%), were on ABC+3TC+DTG and TDF+3TC+DTG.

The majority of study participants—210, or 96.3%—had begun with WHO clinical stage one, and the majority—174, or 79.8%—had begun as soon as an HIV-positive test, such as a DNA PCR or antibody test, was verified. Of the study subjects, 198 (91%) had been on antiretroviral medication for more than 24 months, 209 (96%) had high adherence, and 2 (.9%) had poor adherence.

Table 1 HIV/AIDS attendants' sociodemographic and clinical characteristics at TASH{ N=218}

Variable	*Category*	*Frequency{n}*	*Percent {%}*
sex	*male*	*128*	*58.7*
	female	*90*	*41.3*
Age	*<10 years*	*37*	*17*
	11-15 years	*81*	*37.1*
	16-21 years	*100*	*45.9*
WHO baseline clinical stage	*Stage1*	*210*	*96.3*
	Stage 2	*3*	*1.3*
	Stage 3	*5*	*2.4*
ART time started	*As soon as HIV positive*	*174*	*79.8*
	6-12 months	*25*	*11.5*
	>12 months	*19*	*8.7*
ART duration	*> 24 months*	*198*	*91*
	13months-24 months	*18*	*8.1*
	6-12 months	*2*	*.87*
Previous ART before DTG based regimen	*AZT+3TC+EFV*	*126*	*57.8*
	AZT+3TC+NVP	*27*	*12.4*
	ABC+3TC+EFV	*65*	*29.8*
Perinatal infection	*yes*	*206*	*95*
	No	*3*	*1*
	I don't know	*9*	*4*

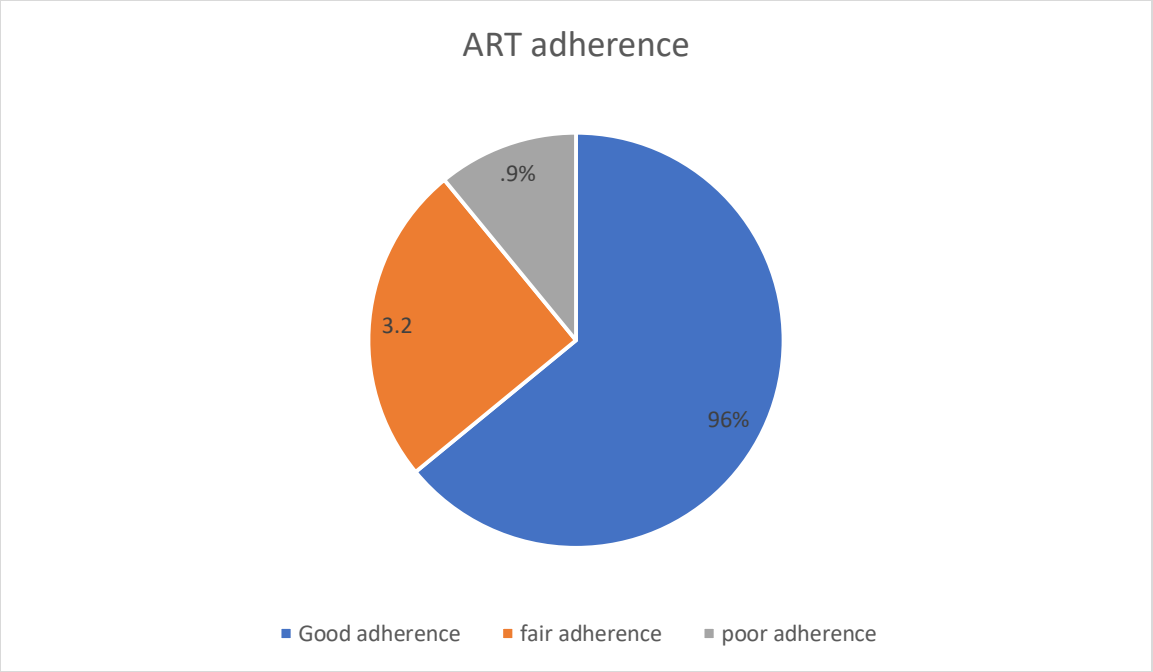


Figure 1 pie chart ART adhernce

The number of children on ART regimen

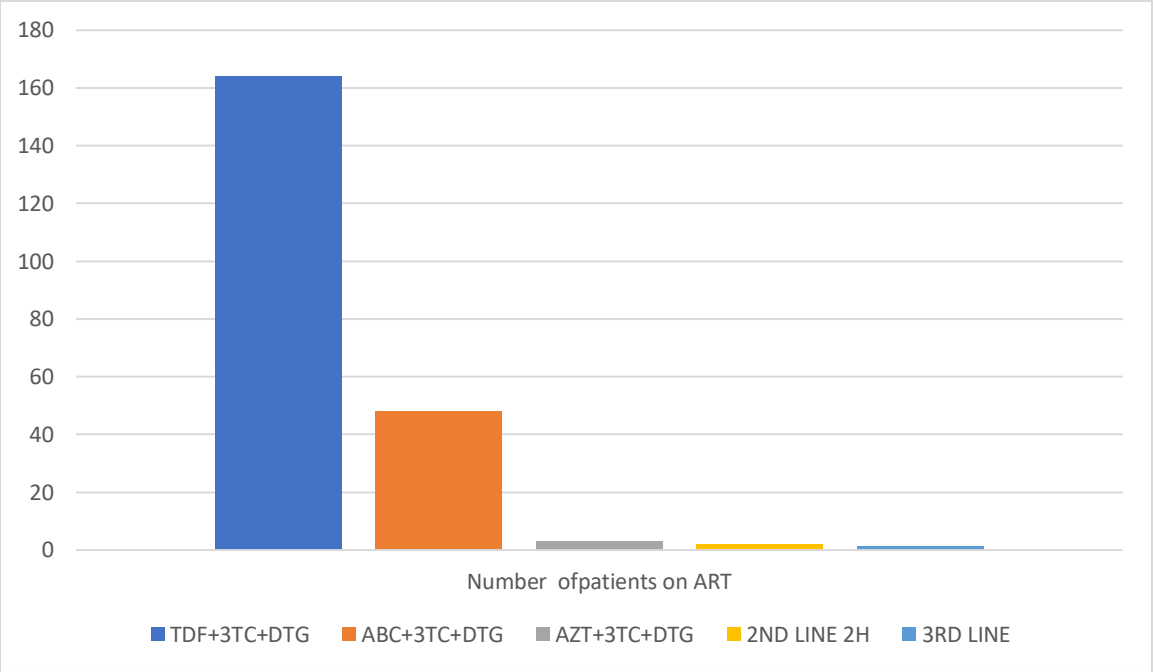


FIGURE 2

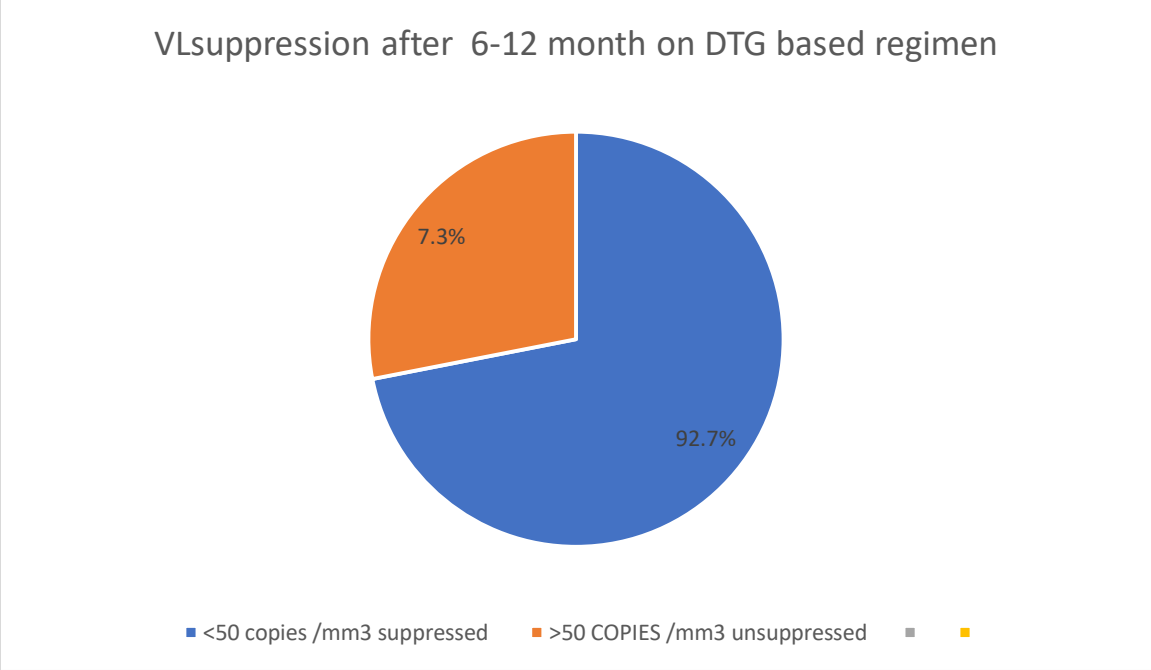
5.2 side effects on DTG based regimen

According to this study, gastrointestinal issues account for 6.4% of side effects in children living with HIV. After taking it for 24 hours, there were 11 (5%), mild cases of nausea, and 3 (1.3%), sleep disturbances. There were no more severe side effects, and the adverse effects were insufficient to warrant changing the HAART regimen.

Table 2 side effecton DTG based regimen

Variable	*Category*	*Frequency*	*Percent*
side effect after taking DTG based regimen within 24 hrs	*yes*	*14*	*6.4*
	NO	*204*	*93.6*
GI symptoms	*Nausea*	*11*	*5*
psychiatric symptoms and CNS	*sleep distrbance*	*3*	*1.3*

5.4 virological suppression after 6-12 months DTG based regimen in children



***F**igure 3 viral load among patient on ART unsuppressed and suppressed on DTG based regimen*

From pie chart among the 218 study participates of children on living with HIVon DTG based regimen after taking 6-12 months the prevalence viral suppression was 92.7%.

Table 3. Multivariate logistic regression analysis.

This study's duration of more than 24 months and viral suppression rate of 71% (95% CI:.316,26.2,AOR 1.593), p-value<.0.016, can be explained by the fact that HAART can reduce viral load over an extended period of time and that ART can reduce viral load as soon as it is started. The study participants on ART who adhere to their ART regimen have a viral suppression rate of 96% (95% CI:.678,51,AOR 1.912), p-value <.025, while poor adherence is linked to a high viral load and may result in the development of HAART resistance.

***Ta**ble 3. Multivariate logistic regression analysis of viral outcome*

variable	*category*	*Viral load*				*p-value*	*AOR*
		Suppressed <50 copies /mm3		*Unsuppressed >50 copies /mm3*			
		n{%}	*95%CI{%,%}*	*n{%}*	*CI{%,%}*	*0.363*	*1.472*
Age	*<10 years*	*31{14}*	*(.411, 7.6.)*	*2(.9)*	*(.021, .429)*		
	11-15 years	*81{37.2}*	*(.261,. 16)*	*4(1.8)*	*(.041,.532)*		
	16-21 years	*90{42}*	*(.248, 39)*	*10(4.5)*	*(.263, 39.8)*		
Duration of ART	*6-12 months*	*6(2.7)*	*(.026, 5.3)*	*3(1.3)*	*(.053,.944)*	*.016*	*1.593*
	13-24 months	*42(19.3)*	*(.064, 12.7)*	*9 (4.1)*	*(.602,.732)*		
	>24 months	*154(71)*	*(.316,26.2)*	*4(1.8)*	*(.067,.803)*		
ART adherence	*Good*	*209(96)*	*(.678,51)*	*12(5.5)*	*(.327 .675)*	*.029*	*1.912*
	fair	*7(3.2)*	*(324 .618)*	*4(1.8)*	*(.031 .212)*		
	poor	*2(.09)*	*(.0317 .104)*	*3(1.3)*	*(.012 .314)*		
ART time initiated	*assoon as HIV positive confirmed*	*158((74)*	*(.421 ,52.8)*	*2(.09)*	*(.012 .216)*	*.004*	*1.955*
	6-12 months	*25(1.2)*	*(.234,3.37)*	*5(2.2)*	*(.032,.231)*		
	>12 months	*19(8.7)*	*(.0211,2.76)*	*11(5)*	*(.234 ,1.49)*		
Baseline clinical stage	*Stage1*	*196(90)*	*(.983, ,82)*	*14(6.4)*	*(.236, 2.54)*	*.021*	*4.885*
	Stage2	*1(0.04)*	*(.101, .1.3)*	*2(.09)*	*(.014 ,.213)*		
	Stage3	*2(.09)*	*(.201, .213)*	*1(.04)*	*(.010, .131)*		

6.Discussion

The purpose of this study was to evaluate the virological suppression and adverse effects of a DTG-based regimen in children with HIV who were receiving treatment at TASH. After 6–12 months, the prevalence of viral suppression among the 218 study participants who were HIV-positive children on a DTG-based regimen was 92.7% (N=215 95%CI;.638-67.5, AOR 3.962), with a P-value <.0.037. This percentage of viral suppression was comparable to the 91.64% percentage of viral suppression found in a study conducted in Tanzania's mainland between 2019 and 2021.

The percentage of children living with HIV who had HIV viral suppression on a DTG-based regimen was 92.7% in this trial, which was lower than the 97% percentage in a study conducted in Nigeria. This may be the result of differing guidelines and a lack of resources.

The duration >24 months with a viral suppression rate of 71% (95% CI:.316,26.2 AOR 1.593), p-value<.0.016, which can be explained by prolonged use can reduce viral load, and as soon as ART is started, it can reduce viral load; the adherence to ART regimen with good adherence has a viral suppression rate of 96% (95% CI:.678,51AOR1.912), p-value<.025 according to this study.
but the poor adherence associated with high viral load and the study done in Tanzania mainland between 2019 and 2021.
This study discovered that the age group of 16–20 years had the highest percentage of viral suppression (42%; 95% CI:.248, 39), followed by the age group of 11–15 years (37%;.261,16) and the age group of less than 10 years (14%;.411,7.6). Males were more likely to have viral suppression (59%; 95% CI:.298,27) than females (34%; 95% CI:.213,5.9).
In this study DTG based regimen has similar result which the study done in Nigeria. but the study conducted in Tanzania's mainland between 2019 and 2021, and the poor adherence linked to a high viral load. Age group, sex, and prenatal infection were not statistically significantly linked with DTG-based regimen of virologic response, according to this study's findings, which had p-values >0.05.
In this study DTG based regimen has similar result which the study done in Nigeria. However, a study carried out on Tanzania's mainland between 2019 and 2021 found that a high viral load was associated with low adherence.

Viral suppression was highest among those aged 16–20 years (42%; 95% CI:.248, 39), followed by those aged 11–15 years (37%;.261,16) and those under 10 years (14%;.411,7.6), according to this study. Compared to women (34%; 95% CI:.213,5.9), men were more likely to have viral suppression (59%; 95% CI:.298,27). Age group, sex, and prenatal infection were not statistically significantly linked with DTG-based regimen of virologic response, according to this study's findings, which had p-values >0.05. The results of this study's DTG-based regimen are comparable to those of a study conducted in Nigeria.

According to this study, 6.4% of study participants started a DTG-based regimen with reported side effects such gastrointestinal issues, indicating the incidence and outcome of side effects among

adolescents living with HIV. There are no more severe side effects, and the adverse effects were insufficient to warrant changing the ART regimen. After taking the medication for 24 hours, there were 11 (5%), nausea, and 3 (1.3%), sleep disturbances. Compared to a research conducted at a pediatric HIV clinic in Mbeya, Tanzania, where 16.5% of patients reported adverse events on a DTG-based regimen, along with symptoms of nausea (15.2%) and insomnia (18.2%), the number of reported adverse events in this study was reduced. Recall bias and ignorance about adverse effects could be the cause of this.

7. limitation of the studyThe study's cross-sectional design predisposes it to biases due to unmeasured cofounders and prevents it from establishing a cause-and-effect link between dependent and independent variables. effects of DTG on lipid profiles, liver function tests, hematologic parameters, and renal function that are not routinely performed. Not being able to perform drug resistance testing

8 .conclusion

The current study provides clinically relevant data on DTG in first line regimen. DTG has proven to be a drug with high virological response and good tolerability with low frequency 6.4% of adverse events. This study demonstrated that the prevalence of viral suppression among children living with HIV on DTG-based regimen was 92.7%. Good adherence, beginning as soon as HIV positive was confirmed, and duration of ART were significantly associated with viral suppression.

9. Recommendation

These suggestions were provided in light of the noteworthy findings from the study.
1. This study is a first step in educating medical professionals about the safety and efficacy of DTG-based regimens.
2. DTG impacts should be performed on a regular basis to determine the hematologic parameters, liver function test, lipid profiles, and renal function.
3. It is necessary to conduct drug resistance testing.

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1o. Annex

11. Social demographic information from the Annex Questionnaire

1. Age ……. (Years)

2. Gender 1. Male 2. Female

. B. Clinical information

1. A child who has been exposed to PMCT 1. Certainly 2. No 3. I'm not sure

2. 2. Did the infant or patient get ARV for PMCT?
1. YES 2 .NO 3 I don't know

3. WHO clinical stage at base line. Stage 1 . Stage 2 Stage 3 . Stage 4

4 Viral load after 6-12 months of Post- DTG based regimen 1. < 50 2 .>50

5. Time between HIV diagnosis and initiating ART 1. As soon as HIV positive confirmed 2.6-12 months 3. more than 12 months

6. Duration on ART 1. 6-12 months 2. 13- 24 months 3.> 24 months

7 . Previous HAART before DTG based regime ----------1. TDF-3TC-EFV 2.AZT-3TC-NVP 3 AZT-3 TC-EFV

8. New ART regimen DTG based 1. TDF+3TC+DTG 2. ABC+3TC+DTG 3. AZT+3TC+D

9 ART adherence 1. Good 2. Fair 3. Poor

10. side effects after introducing the first antiretroviral regimen containing Dolutegravir 1. Yes 2. NO

11..If Yes No.

12 1.GI symptoms 1. Vomiting 2. Nausea 3. Diarrhea

2. Psychiatric symptoms 1. Anxiety 2. Sleep disturbnce 3. Headaches 4. Visual changes 5. Others……