Research Article

Effectiveness of dolutegravir-based regimens in treating children and adolescents living with HIV at Al-Sabbah Children's Hospital, Juba, South Sudan

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ABSTRACT

Introduction: South Sudan has an HIV epidemic with a prevalence of 2.3% and an estimated 180,000 adults and children living with HIV. The country transitioned from lopinavir/ritonavir (LPV/r)-based regimens to optimized dolutegravir (DTG)-based regimens for the treatment of HIV in children and adolescents in 2022. This study aimed to assess the effectiveness and efficacy of DTG in children and adolescents living with HIV, measured by a 6-month follow-up of HIV-RNA viral load, at Al-Sabbah Children's Hospital, among those aged 6 weeks to 19 years who were transitioned to a DTG-based regimen from October 2022 to April 2023.

Method: This retrospective observational cohort study was conducted from September 2024 to February 2025 using a structured questionnaire with 28 questions. We analyzed the data using the Statistical Package for the Social Sciences (SPSS).

Results: One hundred medical records of children and adolescents living with HIV were reviewed for both clinical and laboratory outcomes after transition to the DTG regimen. The study population comprised 62% males and 38% females. The most frequent age group was 5-9 years (62%). Six months after transition, 86% of clients achieved HIV viral suppression; 14% had high viral load. Dolutegravir was more effective than lopinavir/ritonavir in achieving HIV viral load suppression in the study population (p-value 0.045). Common DTG side effects reported were increased appetite and weight gain (58%), gastrointestinal and psychiatric symptoms (12.8%), and musculoskeletal symptoms (7%).

Conclusion: DTG-based regimens show greater effectiveness than LPV/r-based regimens in our study population, all children and adolescents living with HIV, with good adherence, achieving HIV viral load suppression within six months after transition to DTG, with minimal side effects.

Keywords: HIV, children, adolescents, dolutegravir side effects, treatment outcome, South Sudan

Introduction

Human Immunodeficiency Virus (HIV) infection remains a major international public health concern. There were an estimated 39.9 million people living with HIV at the end of 2023, and approximately 1.7 million children aged 0-14 years living with HIV worldwide.[1,2] The Republic of South Sudan is considered a low HIV burden country, with a prevalence of 2.3%.[2] Antiretroviral Therapy (ART) for people living with HIV was introduced in 2008.[3] South Sudan transitioned from a lopinavir/ritonavir-based regimen to an optimized dolutegravir (DTG) based regimen for the treatment of HIV in children and adolescents in 2022.[3]

DTG is a second-generation potent integrase strand transfer inhibitor (INSTI). It inhibits DNA strand transfer into the host cell genome and thus prevents HIV viral integration[4,5] without conferringresistance to other ART classes.[6,7,8]

DTG is a preferred first- and second-line regimen in children aged over four weeks or weighing more than four kilograms, and adolescents living with HIV.[9,10] Since treatment is life-long, optimizing therapeutic regimens to maximize effectiveness and tolerability is important. [4,11,12]

Since the transition, no single study has been done to assess the effectiveness and safety of the DTG-based regimens on HIV viral load suppression in children and adolescents living with HIV in South Sudan. The study aims to assess the effectiveness and efficacy of DTG in children and adolescents living with HIV, aged six weeks to 19 years, measured through a six-month follow-up of HIV-RNA viral load, at Al-Sabbah Children's Hospital.

Method

This observational retrospective cohort study used secondary data from medical records of children and adolescents living with HIV aged six weeks to 19 years and who were transitioned to the DTG-based regimens from the period of October 2022 through April 2023.

The sample size was calculated using Slovin's formula (https://statcalc.net/slovins-formula-calculator/)

n = N / (1 + Ne2)

n= Sample size N= total population

e= sampling error (5% assumed)

Confidence interval =95%

n= 134 / (1 + 134 * 0.05 2) = 100.37

The study used a structured questionnaire to collect data, consisting of 28 questions and divided into three parts. The first part covered demographic information, the second covered health and past medical history, and the third covered DTG adherence and side effects.

After data collection, we checked the data for completeness, consistency, and accuracy. We analyzed the data using the Statistical Package for the Social Sciences (SPSS).

The study obtained ethical approval from the National Ministry of Health Research Ethics and Review Board.

Results

The study population comprised 62% males and 38% females. The most frequent age group was 5-9 years (62%).

Table 1 shows the age-group breakdown.

Table 2 shows the last ART regimen before transition to DTG, which was lopinavir-based.

Six months after transition to the DTG-based regimen,

Table 1. HIV client age group

Age group	n (%)
Less than 5 Years	16 (16.0)
5 - 9 years	62 (62.0)
10 - 15 Years	17 (17.0)
16 Years above	5 (5.0)
Total	**100 (100.0)**

Table 2. Last ART regimen before transition to DTG-based regimen: Current Viral Load Status Cross-tabulation

Count		Current Viral Load Status		Total n (%)
		BDL	HVL	
Last ART regimen before transition to DTG-based regimen	4c	7	4	11 (11.0)
	4i	79	10	89 (89.0)
Total		**86**	**14**	**100 (100.0)**

BDL (Below Detection Level) HVL (High Viral Load)

Table 3. DTG side effects

DTG side effects	Responses n (%)
Signs of Renal System Diseases	2 (2.3)
Signs and Symptoms of Musculo-skeletal Diseases	6 (7.0)
Signs and Symptoms of Central Nervous System Diseases	2 (2.3)
Signs and Symptoms of GIT Diseases	11(12.8)
Signs and Symptoms of Haematologic Diseases	4 (4.7)
Signs and Symptoms of Psychiatric diseases	11 (12.8)
Others (weight gain, increased appetite)	50 (58.1)
Total	**86 (100)**

Table 4. Chi-Square Test - The effectiveness of DTG

Chi-Square Tests			
	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	8.834[a]	2	.012
Likelihood Ratio	6.223	2	.045
No of Valid Cases	100		

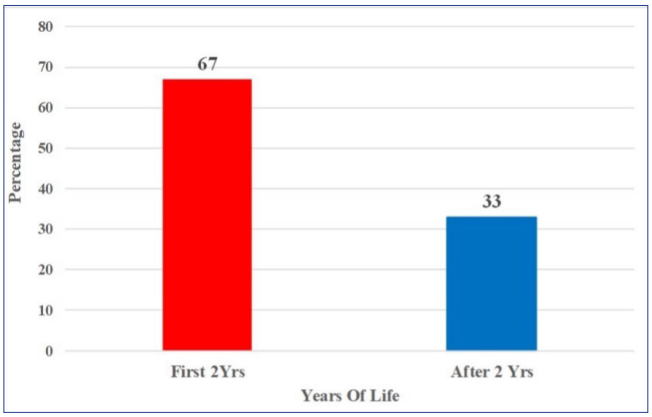

Figure 1. Time of acquiring HIV infection

86% of children and adolescents achieved HIV viral suppression, and 14% had high viral load.

Common DTG side effects reported were increased appetite and weight gain (58.1%) and gastrointestinal and psychiatric symptoms 12.8% each (Table 3).

Table 4 shows the DTG Chi-Square Test results, and Figure 1 shows the age at which HIV is acquired.

Discussion

DTG is more effective than LPV/r in achieving HIV viral load suppression in our study population (p-value 0.045; Table 4).

The findings were similar to those of the study done by Townsend et al.,[9] where the DTG-based regimen showed effectiveness in treating children and adolescents living with HIV.

Common DTG side effects reported were increased appetite and weight gain (58.1%) and gastrointestinal and psychiatric symptoms (12.8% each) (Table 4). Moreover, Failla reported similar findings on DTG's neuropsychiatric effects.[13]

Findings on the effectiveness of the DTG-based regimen as a preferred first-line treatment were consistent with those of a randomized clinical trial conducted by White et al.;[14] the only difference was the study duration which was almost two years

Most of our study population acquired HIV infection during the first twenty-four months of life. Out of 100 children and adolescents, 67% acquired HIV during the birth and breastfeeding period, and 33% acquired HIV infection after that period (Figure 1). The findings were similar to those reported by Giorgi et al.,[15] where most HIV infections occurred early and during the breastfeeding period, while Prendergast et al., [16] linked the high rate of HIV vertical transmission to the duration of breastfeeding. Moreover, Webb et al.[17] reported similar findings on timely early infant diagnosis (EID) in HIV-exposed Infants (HEI) in preventing new HIV infection.

Conclusion

DTG-based regimens show effectiveness over LPV/r-based regimens in our study population, with good adherence, achieving HIV viral load suppression within six months after transition to DTG, with minimal side effects. These results align with the World Health Organization recommendation for the use of dolutegravir-based

regimens as first-line treatment in children and adolescents living with HIV.

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Conflict of interest: None.

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