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Original Research Article

Safety, acceptability, and adherence to a dolutegravir-based regimen among adults living with HIV at Kenyatta National Hospital

Caroline Kaeni Mwanthi[1]*, Julius Oyugi[2], Gloria Omosa-Manyonyi[2], George A. Mugendi[3]

[1]Institute of Tropical and Infectious Diseases, [2]Department of Medical Microbiology, [3]Department of Pharmacology, Clinical Pharmacy and Pharmacy Practice, University of Nairobi, Kenya

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***Correspondence:**
Dr. Caroline Kaeni Mwanthi,
E-mail: karolkaeni@gmail.com

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ABSTRACT

Background: Dolutegravir-based therapy was rolled-out in Kenya in 2017 with limited safety studies in the country and Africa. This study sought to assess and profile the adverse drug reactions, acceptability, and adherence to the newly rolled out dolutegravir-based regimens among HIV patients attending Kenyatta National Hospital.
Methods: This was a cross-sectional study conducted between November and December 2019 at Kenyatta national hospital comprehensive care clinic. Through systematic random sampling, a sample of 219 adult HIV patients on a dolutegravir-based antiretroviral regimen were recruited and interviewed for the experience of adverse drug reactions, adherence, and acceptance of the dolutegravir-based regimen using a researcher-administered questionnaire. Descriptive analysis was conducted using IBM SPSS V 21 software. The alpha was set at $p \leq 0.005$.
Results: A-quarter of the patients (24.7%, n=54) reported experiencing drug-related adverse drug reactions. The most frequent adverse reaction was insomnia (24.1%, n=19), followed by headaches (19.0%, n=15) and skin reactions (13.9%, n=11). The least cited was vomiting (2.5%. n=2). Most (87.3%, n=69) of the adverse reactions were mild (grade 1 reactions), with very few (7.6%, n=6) of them being severe (toxicity grade 3). Only 2 (0.9%) of the reactions resulted in the dolutegravir-based regimen switch. Adherence was high (97.3%, n=213), and 90.4% (n=198) of patients reported to accept the new dolutegravir-based regimen.
Conclusions: Adult patients living with HIV on a dolutegravir-based regimen experienced some adverse drug reactions; mostly mild and resolved without medical intervention. Generally, the regimen had an acceptable safety profile, and a high adherence rate was reported.

Keywords: Acceptance, Adherence, Adverse drug reactions, Dolutegravir, HIV

INTRODUCTION

Dolutegravir (DTG), a second-generation integrase strand transfer inhibitor (INSTI), is an antiretroviral (ARV) drug that was approved by the U.S. Food and Drug Administration as a first-line drug for HIV management in 2013. It is effective in suppressing HIV, is well tolerated, and has a low resistance profile.[1,2] In October 2017, the Kenyan Ministry of Health rolled out a DTG-based antiretroviral therapy (ART) fixed-dose combination as a first-line treatment regimen composed of tenofovir, lamivudine, and dolutegravir (TDF+3TC+DTG) for both ART treatment-naive and experienced.[3]

Lifelong therapy with ARVs increases the chance of drug-related toxicities and intolerance, which directly contribute to reduced adherence, lower rates of viral

suppression, and increased risk of emergence of drug-resistant mutations.[4] Therefore, continuous monitoring for adverse drug effects and toxicities among HIV patients is required.[5] The most commonly reported side effects associated with DTG include nausea, diarrhea, hypoglycemia, central nervous system side effects, and headache. In Africa, apart from the Tsepamo birth surveillance, which reported neural tube defects in children born of women on DTG-based ART regimen in Botswana, among pregnant women, there has been no comprehensive study of the safety profile of DTG-based regimens.[6]

This creates a need for continual safety surveillance and enhanced monitoring for unexpected or long-term adverse effects as DTG use is scaled up.[2,7] According to the World Health Organization (WHO), adverse drug reactions are harmful and unintended response to drugs at normal dosages. Clinical trial data on drug toxicities and adverse effects are usually inconclusive because of the limited number and characteristics of study populations, limited duration of follow-up, and exclusion of individuals with some comorbidities and those using some concomitant medication, all of which limit the ability to obtain a comprehensive safety profile from clinical trials. Therefore, these drug-related toxicities do not always present acutely and may only become apparent during long-term use.

Since the roll out of dolutegravir-based therapy in Kenya in late 2017, there have been limited prior safety studies in the country and Africa. This study, therefore, sought to determine the safety, acceptability, and adherence to the dolutegravir-based regimen among adults living with HIV at Kenyatta National Hospital.

METHODS

This descriptive cross-sectional investigation was conducted among adult HIV patients on a DTG-based regimen attending the comprehensive care clinic at Kenyatta National Hospital between November 2019 and December 2019. The target population was adult patients living with HIV on a DTG-based regimen (tenofovir disoproxil fumarate/lamivudine/dolutegravir) as first-line for at least two weeks and were either ART treatment-naive or experienced.

Inclusion criteria

Patients with other chronic conditions and also on concomitant medications were considered eligible for the study.

Exclusion criteria

Adult patients who were on other regimens for HIV rather than DTG were excluded from the study. Acutely ill patients, those who had less than a week on medication, and those with documented mental health disorders were also excluded from the study.

Approval for this study was sought from the Kenyatta National Hospital/University of Nairobi Ethics and Research Committee (KNH/UoN-ERC-P716/08/2019).

Using Cochran's formulae for sample size estimation, a sample size of 350 participants was obtained and sampled systematically with a skip/sampling interval of 11.[8] The sampling frame was derived from a list of pre-booked eligible adult patients living with HIV and on TDF/3TC/DTG attending KNH CCC clinic, obtained from the clinic's records department a day prior to the data collection day. Each patient was then assigned a random number and every 11th patient number was selected for recruitment into the study. A secondary random list was generated to fill up patients who failed to turn up for clinic or for some reason could not participate in the study. To avoid repeat recruitment of the same patient, the file number of those that had participated were marked with the letter x.

Data was collected from patients who had signed informed consent forms through interviews and a review of medical records. The information was recorded in a structured questionnaire adapted from HIV i-Base: HIV treatment information for healthcare professionals and HIV-positive people.[9] The principal investigator, a trained pharmacist, relied on clinical trial studies and peer reviewed published studies on DTG-based ART regimens to identify adverse drug reactions that could be associated with the DTG-based regimen and trained two nurses to help with data collection.

Data on patient-reported adverse drug reactions were graded using the United States Division of AIDS grading system.[9] Adherence was assessed using an adherence tool adapted from the International Network for the rational use of drugs initiative on adherence to antiretroviral (INRUD-IAA).[10] The tool collected information on the frequency of attendance of clinical appointments, percentage of days covered by dispensed medicines (from pill counts), and self-reported adherence to all instructions provided by the health care provider. Patients' acceptability of the DTG-based ART regimen for more than two weeks was assessed by enquiring if they were bothered by the regimen. Data was entered and saved in a Microsoft Excel sheet (MS Office 97-2003) and then imported to IBM SPSS Statistics version 21. The data in SPSS was cleaned and analysed. To handle missing data, mean imputation was used for continuous variables, while mode imputation was used for categorical variables. Imputation was only performed on variables with ≤20% missingness to avoid bias. Descriptive analysis for continuous variables included n (number of respondents), mean, standard deviation (SD), median, minimum and maximum values, while descriptive analysis for categorical data included establishing frequencies and percentages.

Univariate analysis using Chi-square or Fisher's exact tests (when chi-square rules were violated) was done to test the association between the dependent and independent categorical variables. All statistical tests were significant at $\alpha \leq 0.05$). Data were presented and summarized in tables, figures, and prose.

RESULTS

Background characteristics of respondents

The study enrolled 219 participants between November and December 2019, representing a response rate of 62.5%.

As shown in Table 1, slightly over half of those recruited (57.8, n=127) were male. The mean age of the respondents was 47.6 years (SD±10.7), of whom most (44.3%) were aged between 35 and 49 years. Their mean weight was 73.8 kilograms (SD±15.6), and the mean body mass index of 111 participants was 27.1 (SD±4.9). Most (47.9%, n=105) respondents had attained secondary education and were married (72.6%, n=159). The respondents' average duration on the DTG-based ART regimen at the time of the study was 10.4 months (SD±9.5).

Table 1: Sociodemographic information of adult HIV patients on TLD/3TC/DTG regimen at Kenyatta National Hospital.

Variables	Category	Frequency (n, %)
Gender	Male	127 (58)
	Female	92 (42)
Age group (years)	18-34 (young adults)	26 (11.9)
	35-49 (middle-aged adults)	97 (44.3)
	≥50 (elderly)	96 (43.8)
BMI group	Underweight	0
	Normal/healthy	29 (26.1)
	Overweight	34 (30.6)
	Obese	48 (43.3)
Education	Primary	55 (25.1)
	Secondary	105 (47.9)
	Tertiary	56 (25.6)
	Informal	3 (1.4)
Marital status	Married	159 (72.6)
	Not married	40 (18.3)
	Divorced	8 (3.7)
	Other	12 (5.5)
Cigarette smoking	Yes	6 (2.7)
	No	213 (97.3)
Alcohol intake	Yes	33 (15.1)
	No	186 (84.9)
Duration of DTG regimen		Mean=10.4±9.5

NB: BMI: underweight (<18.5), normal/healthy (≥18.5 to <25), overweight (≥25 to <30), obese (≥30).

Clinical characteristics of adult patients living with HIV on TLD/3TC/DTG at Kenyatta National Hospital

Regarding adverse drug reactions (ADRs), 54 out of 219 patients reported at least one side effect since commencing the DTG regimen. Overall, ART-related drug effects were mentioned 79 times by adults living with HIV on the TDF/3TC/DTG regimen at KNH CCC (Figure 1 and Table 2). As illustrated in Figure 1, the most frequent ADRs were related to the central nervous system (62%, n=49), followed by the gastrointestinal infections at 24% (19), and skin hypersensitivity reactions at 14% (11).

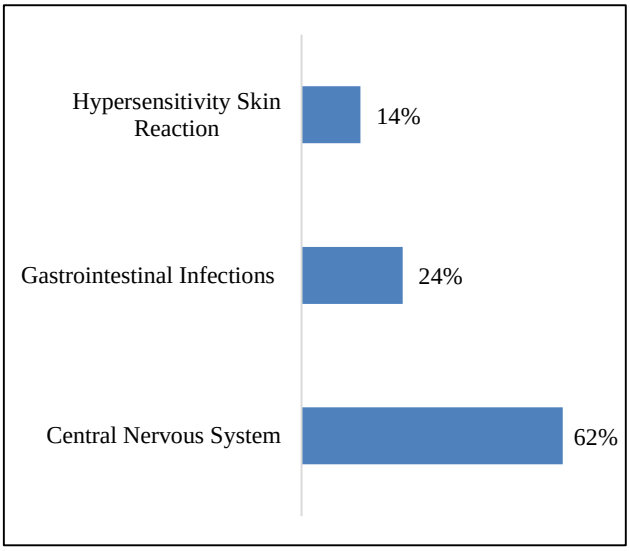

Figure 1: Frequency of reported DTG-based ART adverse drug effects.

As shown in Table 2, 69 (87.3%) of the drug effects were grade one (were mild and were not a hindrance to daily activities), 3 (3.8%) of the drug effects were grade two (moderate and posed some bother to the patients, requiring them to seek medical attention), 6 (7.6%) of the drug effects were grade 3 (severe, i.e., though not life-threatening to the patients, they required further intervention by their primary caregivers. Only 1 (1.3%) of the drug effects were grade 4 (potentially life-threatening).

Table 3 shows the DTG-based ART regimen adherence and acceptability levels among adult HIV patients on TLD/3TC/DTG at Kenyatta National Hospital. To measure adherence, patients were asked to recall if they followed all the clinic instructions given about treatment in the last 30 days. The majority (97.3%, n=213) of the patients followed all the instructions their healthcare providers gave concerning taking their ARV medicine. On acceptance of the regimen, 90.4% (n=198) were comfortable with the regimen. All those that reported not to accept the regimen (9.6%, n=21) attributed adverse effects as the reason of unacceptance.

Table 2: Toxicity grading of reported adverse drug effects by adult patients living with HIV on TLD/3TC/DTG regimen at Kenyatta National Hospital.

Grouping	Drug effects	Grade 1 (%)	Grade 2 (%)	Grade 3 (%)	Grade 4 (%)
Overall		69 (87.3%)	3 (3.8%)	6 (7.6%)	1 (1.3%)
Central nervous system	Headaches	13 (16.5%)	0	2 (2.5%)	0
	Insomnia	18 (22.8%)	1 (1.3%)	0	0
	Psychiatric disorders (depression/ psychosis)	5 (6.3%)	1 (1.3%)	0	0
	Suicidal ideation or attempt	9 (11.4%)	0	0	0
Gastro-intestinal tract	Diarrhea	8 (10.1%)	0	0	0
	Nausea	6 (7.6%)	1 (1.3%)	1 (1.3%)	0
	Other	1 (1.3%)	0	0	0
	Vomiting	2 (2.5%)	0	0	0
Hypersensitivity skin reactions	Pruritus	6 (7.6%)	0	2 (2.5%)	1 (1.3%)
	Rash	1 (1.3%)	0	1 (1.3%)	0

NB: n=79: Percentages are based on the frequency of reported drug effects.
Grading of adverse drug effects was adopted from the United States Division of AIDS in the order of increasing severity.

Table 3: Adherence and acceptability measures among adult patients living with HIV on TLD/3TC/DTG at Kenyatta National Hospital.

Variables	Characteristic	Response (N, %)
Follows all instructions	Yes	213 (97.3%)
	No	6 (2.7%)
Forgets to take ARV medicine	Never	172 (78.5)
	Once in a while	35 (16.0%)
	Often	12 (5.5%)
Attendance of clinic appointments	Timely	159 (72.6%)
	Not-timely	60 (27.4%)
Percentage of days covered by medicine (Determined by pill count balances)	<50%	30 (13.4%)
	50%-80%	183 (83.6%)
	>80%	6 (2.7%)
Acceptance of TDF/3TC/DTG regimen	Yes	198 (90.4%)
	No	21 (9.6%)
Reason for lack of acceptance	Adverse drug effects	21 (100%)
	Other	0

NB: n=219 (Representing number of respondents).

Table 4: Relationship between sociodemographic information and experience of adverse drug reactions among adult patients living with HIV on TDF/3TC/DTG regimen at Kenyatta National Hospital.

Socio-economic factor		Experience of ADR				P value
		Yes		No		
		N	%	N	%	
Sex	Male	26	11.9	101	46.1	0.1123
	Female	28	12.8	64	29.2	
Alcohol intake	Yes	7	3.2	26	11.9	0.8267
	No	47	21.5	139	63.5	
Age (years)	18-34 (young adults)	6	2.7	20	9.1	0.5508
	35-49 (middle-aged adults)	20	9.1	77	35.2	
	≥50 (elderly)	28	12.8	3	60	
Smokes cigarettes	Yes	1	0.05	5	2.3	1.000
	No	53	24.2	160	73.1	

NB: n=219.

Table 5: Relationship between clinical information and experiencing of adverse drug reactions among adult patients living with HIV on TDF/3TC/DTG regimen at Kenyatta National Hospital.

Clinical characteristic		Experience of ADR				P value
		Yes		No		
		N	%	N	%	
Duration on TDF/3TC/DTG regimen (months)	<6	15	6.8	38	17.4	0.6689
	6-12	32	14.6	98	44.7	
	>12	7	3.2	29	13.2	
Number of tablets/drugs taken in a day	1	42	19.2	120	54.8	1.000
	2	2	0.9	5	2.3	
	≥3	10	4.6	40	18.3	
Time of taking the drug	Morning	28	12.8	97	44.3	0.4291
	Evening	26	11.9	68	31.1	
Drug taking (timing) with meals	Before	15	6.8	42	19.2	0.7243
	After	39	17.8	123	56.2	

NB: n=219.

Cross-tabulation of background characteristics, clinical information and drug effects

A chi-square test or Fisher's exact test was used to assess the relationship between the occurrence of side effects and the patient's sociodemographic or clinical characteristics. All findings were considered significant at $p \leq 0.05$. Tables 4 and 5 show no significant relationship between the occurrence of adverse drug reactions and the patients' most sociodemographic and clinical characteristics ($p > 0.05$).

DISCUSSION

In this cross-sectional study recruiting people living with HIV on treatment with a DTG based regimen in a tertiary referral hospital in Kenya, there was more male than female participants. This is because, at the time of the study, the Kenyan government had withdrawn and restricted the use of DTG-based regimens amongst women of reproductive age. This was after a WHO communication on the regimen to potentially cause neural tube birth defects in babies born of mothers using DTG-based as reported in the Tsepamo study in Botswana.[6] However, following rigorous quality data checks and birth defect surveillance studies, WHO has since withdrawn the restriction on the use of DTG-based regimens in women of childbearing potential, albeit cautiously, as more research is being conducted.[6] Majority of the participants were middle-aged, and this concurs with local literature about HIV being most prevalent within this population.[3]

Our study revealed the prevalence of adverse drug reactions among HIV patients on a DTG-based regimen to be 24.7%. In comparison, a country-wide prospective pharmacovigilance study carried out among 79,742 adult HIV patients on the TDF/3TC/DTG regimen in Brazil between April and December 2017 revealed the prevalence of DTG-based regimen drug reactions to be lower at 2.24%.[11] Similarly, participants in a south Indian year-long prospective study reported no adverse drug reactions among 564 adult HIV patients on the TDF/3TC/DTG regimen.[12] The differences in the prevalence of adverse drug reactions between this study and these two studies, albeit some similarities in data collection, can be explained by the different genetic and clinical characteristics of the study populations, both of which affect drug pharmacodynamics and pharmacokinetics.[13]

This study revealed that CNS adverse reactions were the most frequently reported (n=49, 62%), while the Brazilian pharmacovigilance study reported GIT reactions more regularly than CNS. Similar to this study, skin reactions were the least reported ADR in clinical trial studies and the Brazilian pharmacovigilance study. A 2016 follow-up study in the Netherlands, which followed 556 adults living with HIV on DTG-containing ART regimens for 225 days, like the current study, revealed CNS (insomnia and neuropsychiatric effects) to be the most frequent.[14] The study findings also revealed some similarities with local pharmacovigilance reporting primarily insomnia, GIT side effects, and skin hypersensitivity reactions. However, environmental and genetic factors, which play a role in racial and ethnic differences in health and disease, may cause disparities in the reported rates of ADRs in these studies.

Similar to these findings, in the 2016 follow-up study in the Netherlands, participants reported having experienced adverse psychiatric reactions such as unexpected depression and suicidal ideation.[14] Clinical trial studies and some post-market surveillance studies on DTG-based ART regimens have also reported depression in patients, especially among HIV patients with underlying psychosocial issues.[15,16] This points to the need for increased mental health assessment and monitoring among people living with HIV on DTG regimens. It is worth noting that people living with HIV are two to three

times more likely than the general population to be depressed.[17]

Further, on toxicity grading of reported adverse drug reactions by adult HIV patients on TLD/3TC/DTG regimen at Kenyatta National Hospital, the majority of the reported ADRs (n=69, 87.3%) were grade one, which was mild and not a hindrance to daily activities compared with only grade 4 (n=1, 1.3%), which can be potentially life-threatening. These findings align with clinical trial studies on DTG-based regimens and the Brazilian and South Indian studies, all of which reported that ADRs among patients on DTG-based ART regimens are primarily mild and resolve without medical intervention. However, this study revealed that severe (grade 3 and 4) hypersensitivity skin reactions, although the least experienced, were the only ADRs resulting in DTG-regimen switch in two patients.

Adherence and acceptability to the TDF/3TC/DTG regimen were very high (≥90% in all aspects). Lack of compliance was related to the unacceptability of the DTG-based regimen in patients experiencing severe and potentially life-threatening adverse drug reactions. This is concurrent with literature on the effect of ARV adverse drug reactions being the primary reason for intolerance and non-adherence among people living with HIV.[18] Consequently, this can result in treatment failure and rapid clinical deterioration in the affected patients. Therefore, routine and close monitoring for adverse drug reactions in all people living with HIV is paramount.

The investigation did not show any significant association between all the sociodemographic/clinical information and the reported adverse drug reactions among the study participants. These results differ from earlier local undocumented pharmacovigilance information that DTG-based regimens are significantly associated with ADRs such as insomnia, especially among patients taking the DTG regimens at bedtime. Nevertheless, additional evidence is required to conclusively determine whether there is an association between clinical information and the occurrence of ADRs among patients on DTG-based ART regimens.

CONCLUSION

In conclusion, this study's prevalence of DTG-associated adverse drug reactions was higher than most reported studies globally. Further, the study established that a greater percentage of adult patients living with HIV on a DTG-based regimen reported having experienced adverse drug reactions mainly related to CNS, GIT, and skin reactions. Most of these ADRs were mild and resolved without medical intervention, and none of the studied clinical information was significant to the occurrence of ADRs. The study participants had high acceptance and adherence to the DTG-based ART regimen. Nevertheless, our study could have benefited from thorough clinical and laboratory assessments of patients who reported to have experienced the adverse effects to determine possible causalities and to rule-out confounding factors. We, therefore, recommend that a cohort event monitoring study is most appropriate to investigate and provide better insight into the experience of ADRs by patients on the most recently rolled out DTG-based regimen.

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