

The association between dolutegravir-based antiretrovirals and high blood pressure among adults with HIV in southern Ethiopia: a cross-sectional study

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Abstract

Background: Dolutegravir (DTG), a novel antiretroviral therapy (ART) for HIV, is increasingly adopted across sub-Saharan Africa. However, its impact on blood pressure in Ethiopia remains unclear, highlighting a need for further studies.

Objective: This study aimed to investigate the association between DTG-based first-line regimens and other covariates of high blood pressure (HBP) among adults living with HIV receiving care at health facilities in Hawassa City, southern Ethiopia.

Design: A cross-sectional study.

Methods: Data were collected between January 2023 and May 2024 among 444 systematically selected adults, complemented with a review of their medical records. HBP was defined according to the seventh report of the Joint National Committee (JNC7) guidelines, with a threshold of systolic or diastolic blood pressure of $\geq 120/80$ mmHg. Multivariable logistic regression analysis was performed to identify predictors of HBP. Adjusted odds ratios (AORs) with 95% confidence intervals (CIs) were computed to determine statistically significant associations.

Results: Of the study participants, 58.3% were women and 41.7% were men, resulting in a response rate of 95.5%. The mean [standard deviation (SD)] age of the participants was 38.4 (± 8.9) years. The prevalence of HBP was 57.9% (95% CI: 52.5–62.4), with 40.5% classified as prehypertension and 17.3% as hypertension. Among participants with hypertension, 84.4% were newly diagnosed. Initiating ART with DTG-based regimens was associated with higher odds of HBP (AOR 5.9; 95% CI: 1.5–22.7) and switching to DTG-based regimens also increased the odds of HBP (AOR 3.8; 95% CI: 1.1–13.9). Other significant covariates associated with HBP included being male (AOR 2.6; 95% CI: 1.4–4.9), age >45 years (AOR 2.0; 95% CI: 1.2–3.4), high waist-to-height ratio (AOR 2.4; 95% CI: 1.1–4.9), inadequate vegetable intake (AOR 1.7; 95% CI: 1.0–2.7), low physical activity (AOR 2.4; 95% CI: 1.1–5.4), and LDL-cholesterol (AOR 1.1; 95% CI: 1.0–1.2).

Conclusion: Proactive blood pressure screening and management are important for individuals on DTG-based regimens. In addition, early identification and intervention of modifiable risk factors through comprehensive strategies and regular screenings are pivotal for improving cardiovascular health among individuals on ART.

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Plain language summary

The association between dolutegravir based antiretroviral therapy and high blood pressure among adults with HIV in southern Ethiopia

This study in southern Ethiopia evaluated blood pressure in adults with HIV on first-line antiretroviral treatment (ART). The rate of high blood pressure (HBP) was 57.9%, with

40.5% classified as prehypertension and 17.3% as hypertension. Among participants with hypertension, 84.4% were newly diagnosed in this study. ART initiating or switching to DTG-based first-line regimens was significantly associated with HBP compared to efavirenz-based regimens. Additionally, factors such as male sex, advanced age, waist-height ratio, low vegetable intake, inadequate physical activity, and low density lipoprotein cholesterol levels were significantly associated with the prevalence of HBP. Therefore, addressing post-treatment HBP in individuals on DTG based regimens is essential for enhancing cardiovascular health. In addition timely identification and management of modifiable risk factors, supported by comprehensive strategies and routine screenings are vital for this population.

Keywords: antiretroviral therapy, blood pressure, dolutegravir, Ethiopia, HIV, hypertension

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Introduction

The improved accessibility of and adherence to combination antiretroviral treatment (cART) have resulted in a remarkable increase in the life expectancy of people living with HIV (PLWH).¹ However, the increased burden of noncommunicable diseases (NCDs) in this population, particularly in low- and middle-income countries (LMICs), has posed new challenges.² NCDs such as cardiovascular diseases (CVDs), diabetes, hypertension (HTN), and certain cancers² are becoming increasingly prevalent among PLWH in LMICs.^{3,4} Globally, an estimated 1.28 billion adults aged 30–79 have HTN, with two-thirds residing in LMICs. Notably, approximately 46% of adults with HTN are unaware of their condition.⁵ This issue is particularly concerning as it affects not only the general population but also PLWH. Compared to individuals without HIV, PLWH are more susceptible to CVD risk factors and experience higher rates of cardiovascular morbidity and mortality.⁶ In addition, a significant proportion (35%) of adult PLWH who receive cART globally have HTN.⁷

The rise in HTN is largely attributed to factors such as long-term exposure to cART and underlying inflammation related to HIV infection itself.^{3,4} In addition khat (*Catha edulis*) chewing,⁸ age, male sex, obesity, history of alcohol consumption,^{9,10} smoking,¹¹ family history of hypertension and a sedentary lifestyle¹² were risk factors of elevated blood pressure. Studies have also

shown an association between anxiety and/or depression¹³ and central adiposity¹⁴ with HTN. Moreover, various mechanisms such as adipogenesis and lipodystrophy, activation of the adipocyte, the renin–angiotensin system (RAAS), immune reconstitution, dyslipidemia, chronic systemic and vascular inflammation and renal insufficiency¹⁵ can potentially impact the development of HTN among PLWH.

The adoption of integrase strand transfer inhibitors (INSTIs), especially regimens based on dolutegravir (DTG), has become increasingly preferred as first- and second-line treatment options in LMICs, particularly following approval by the World Health Organization (WHO).¹⁶ This is because the effectiveness and low risk of drug resistance make them ideal for treating HIV. In addition, the safety profile, with fewer interactions and side effects than older medications also enhanced their approval.¹⁶

Despite their efficacy, DTG-based regimens have been associated with cardiometabolic risks,¹⁷ including a possible association with higher rates of HTN compared to non-nucleoside reverse transcriptase inhibitors (NNRTIs) regimens.¹⁸ The mechanisms behind the association between DTG and weight gain are not fully understood, but increased adipose tissue activation and RAAS modulation may play a role, potentially raising the risk of blood pressure.¹⁹ In addition, studies indicated that individuals starting or switching to

DTG-based regimens often experienced excess weight gain^{20,21} and the association between obesity and HTN is well established.^{22,23}

DTG-based cART is now widely used across Africa, including in countries like Ethiopia following endorsement by the WHO.¹⁶ However, despite the growing adoption of DTG, there is still a lack of data on its association with NCDs, particularly in East African settings.^{10,23} To the best of our knowledge, there is currently no published data on the association between high blood pressure (HBP) and DTG-based regimens, especially in the context of treatment initiation following the implementation of a universal test-and-treat strategy in Ethiopia. Consequently, this study aimed to determine DTG-based first-line regimens and other covariates of HBP among adults living with HIV in southern Ethiopia.

Methods

Study design, setting, and period

This institution-based cross-sectional study was conducted between January 2023 and May 2024, at health facilities in the Hawassa City administration. Hawassa is the capital city of Sidama Regional State and is located approximately 275 km to the south of Addis Ababa, the capital city of Ethiopia. The city administration encompasses 157.2 sq km and is divided into eight sub-cities and 32 kebeles. According to the 2022 population profile report from the Hawassa City Health Department office, the city administration has a total population of 402,903 with a nearly equal distribution of 201,371 females and 201,532 males.

Population

The study included adult PLWH aged 18–65 years who were receiving cART. Currently, eight health facilities offer ART services in Hawassa City administration for more than 6300 PLWH. However, the study did not include participants from two health facilities based on their personal preferences.

Inclusion and exclusion criteria

The study enrolled individuals who regularly attended the health facilities of the city administration and commenced their cART after

Ethiopia adopted the test-and-treat strategy in February 2017. In addition, those who met the following specific criteria were included: they had been on first-line cART for at least 12 months, had HIV ribonucleic acid (HIV-1 RNA) viral load of <1000 copies/mL and demonstrated adequate adherence to cART as per National consolidated guidelines for comprehensive HIV prevention, care, and treatment.²⁴ Concerning ART regimens, individuals who initially started ART with two nucleos(t)ide reverse transcriptase inhibitors (*N(t)*RTIs) and one NNRTI, either remained on this regimen or subsequently switched to DTG-based first-line therapies. In addition, individuals who initiated treatment with a DTG-based first-line regimens and remained on these regimens throughout the study were included in the study. However, participants who had switched to other first line regimens more than once, had severe illnesses or physical disabilities or were pregnant were excluded from the study.

Sample size and sampling techniques

The required sample size for this study was calculated using Centers for Disease control and Prevention (CDC) Epi Info version 7.2 software using a single population proportion formula, assuming a 95% confidence interval (CI), a significance level (α) of 0.05 and a margin of error of 0.05. Using an 18.5% prevalence rate of HTN among PLWH on ART in Ethiopia,¹² an initial sample size of 258 was calculated accounting for a 10% nonresponse rate. Again we determined the sample size using risk factors for HTN at a 95% CI, power of 80 and a 1:1 ratio of unexposed to exposed participants. The HTN prevalence among individuals who were not exposed to DTG-based regimens was 39.1% and exposure to DTG was associated with an increased risk of HTN (adjusted odds ratio (AOR) = 2.4).²⁵ Considering a 10% nonresponse rate, the sample size was calculated to be 207. However, this study was conducted as part of a larger NCD project with multiple objectives. The sample size of 279 was calculated based on a 23.9% prevalence rate for one of the NCDs,²⁶ which was larger than the sample size calculated for blood pressure. To maximize representativeness, a total sample size of 279 was accepted for the evaluation of all NCDs including blood pressure. Accounting for a 10% nonresponse rate and a design effect of 1.5, the final sample size was adjusted to 465. A sample size of 465 was then proportionally

allocated to each health facility based on the number of PLWH on first-line ART at each study site. Sampling intervals were determined by dividing the number of PLWH on first-line regimens by the allocated sample size for each facility. Following this, a systematic random sampling technique was then applied to select participants at each facility.

Data collection tools and procedures

The data collection questionnaire was first developed by adapting the WHO stepwise approach²⁷ and reviewing different literatures. This structured questionnaire covered sociodemographic, economic, anthropometric, lifestyle, and behavioral and clinical variables. The questionnaire was then translated into Amharic by a proficient bilingual language expert. After obtaining signed informed consent, trained nurses administered data collection questionnaires to participants at the ART clinics of the study health facilities. In addition, patients' medical records were reviewed to extract information such as HIV-related factors, ART medications, comorbid conditions, and other relevant data.

Variables and measurement

Variables such as physical measurements that include systolic blood pressure (SBP) and diastolic blood pressure (DBP); and anthropometric measurements such as height, body weight, waist circumference (WC), and hip circumference (HC) were collected from study participants. The data collectors followed the standard techniques to measure each variable. Participants rested comfortably for 10 min before measurement, seated with uncrossed legs and ankles in the isolated data collection room. A digital blood pressure monitor (Heuer, model number: 16-200) was used to measure SBP, DBP, and heart rate. This device has a measurement range of 0–300 mmHg for blood pressure and 30–180 beats per minute for pulse. It also offers a diagnostic accuracy of ± 3 mmHg for blood pressure and 5% for pulse rate. Two readings were taken within a 5-min interval and the average of these two was recorded. If the measurements differed by more than 5 mmHg, a third reading was taken and the average of the last two readings was recorded to determine the participants' blood pressure.^{28,29}

The primary outcome of this study was HBP (prehypertension and HTN) defined according to

the seventh report of the Joint National Committee (JNC7),³⁰ as Ethiopia has incorporated the JNC7 definition of blood pressure into the National Clinical and Programmatic Management of Major NCDs Guideline.³¹ Based on this, HBP was classified as SBP and/or DBP equal $\geq 120/80$ mmHg, which includes both pre-hypertension and HTN. HTN was defined as SBP/DBP of $\geq 140/90$ mmHg, or confirmed by a physician, or the individual was taking antihypertensive medications. Pre-HTN was defined as a SBP of 120–139 mmHg and/or a DBP of 80–89 mmHg.³² Newly diagnosed HTN refers to participants who had a SBP/DBP of $\geq 140/90$ mmHg and were unaware of their condition prior to this study.

Participants' height was measured using a Seca stadiometer (SECA GmbH and Co, Germany) to the nearest 0.1 centimeter (cm). Body weight and body mass index (BMI) were assessed with an Omron Body Composition Monitor and Scale (Omron HBF-514C: manufactured for Omron Healthcare Co., Ltd, China), which uses bioelectrical impedance analysis (BIA)³³ and measurements were performed according to the manufacturer's protocol. For the assessment, each participant's age, height (in cm), and sex were input into the device. Participants then stood barefoot on the scale, dressed in light clothing, held the display unit with both hands and kept their arms parallel to the floor. The device measures body weight directly and calculates the BMI based on the entered height value of each participant. Then, the BMI was classified according to the WHO category as underweight (< 18.5 kg/m²), normal (18.5–24.9 kg/m²), overweight (25–29.9 kg/m²), or obese (≥ 30 kg/m²).³⁴

WC was measured at the level of the umbilicus while the participants were standing and wearing light clothing with measurements taken after exhalation. HC was measured around the widest part of the buttocks. Both the WC and HC measurements were performed using a non-stretchable tape measure following the WHO stepwise approach and recorded to the nearest 0.1 cm. In addition, the waist-to-hip ratio (WHR) and waist-to-height ratio (WHtR) were computed by dividing WC by HC and WC by height, respectively. Abdominal obesity was defined as a WC ≥ 94 cm for males and ≥ 80 cm for females.³⁵ Moreover, a WHR > 0.90 in men and > 0.85 in women as well as a WHtR ≥ 0.5 indicate the presence of abdominal obesity.³⁵

Participants' physical activity (PA) was measured using the International Physical Activity Questionnaire Short Form (IPAQ-SF).³⁶ To calculate the metabolic equivalents of task in minutes per week (METs-min/wk) for each specific activity, the METs value of the activity (3.3 for walking (low intensity); 4.0 for moderate PA; and 8.0 for vigorous PA) was multiplied by the minutes spent engaging in that activity. Finally, PA was classified as low activity (<600 METs-min/week), moderate activity (600 to <3000 METs-min/week), or high activity (≥ 3000 METs-min/week).³⁶

Current alcohol consumption, smoking, and khat use refer to individuals who used each of these at least once in the month preceding the study. Ever alcohol drinking, smoking, and khat use denote respondents who have used each of these substances at any point in their lifetime.³⁷ The participants' mental health conditions were evaluated using a validated Amharic version of the Hospital Anxiety and Depression Scale (HADS) that includes anxiety and depression, as well as their respective severity categories.³⁸

Regarding fruit and vegetable (FAV) consumption, participants were asked about their weekly FAV intake in terms of frequency and portion sizes. The WHO recommends five portions of FAV daily, with each portion weighing 80 g.³⁹ However, none of the participants in this study met the recommended frequency or portion sizes, and the proportion of those consuming FAV daily was also small. As a result, participants were classified based on the frequency of FAV intake per week rather than the recommended portion sizes.

An overnight fasting blood sample was collected from each participant for lipid profile analysis. The samples were then processed and analyzed following standard operating procedures using the Cobas c 501, a module of the Cobas 6000 analyzer series (Roche Diagnostics GmbH, Sandhofer Strasse 116 D-68305 Mannheim, Germany).

Data quality management

Before actual data collection, the Amharic questionnaire underwent pretesting and improvements were made based on participants' feedback. Nurses working in the ART clinics received training on data collection, variable measurement, and ethical principles. In addition, the precision of the

blood pressure and weight scale instruments was checked daily using a mercury sphygmomanometer and standard calibration equipment, respectively. Each participant underwent at least two measurements and the average was considered to ensure accuracy in physical, anthropometric, and body composition assessments. The study information was collected using the same equipment and procedures under daily supervision by the principal investigator.

Data processing and statistical analysis

Categorical variables were summarized using frequency, whereas continuous variables were summarized using means with standard deviations (SDs) or medians with interquartile ranges (IQRs) as appropriate. A skewed continuous variable underwent logarithmic or square root transformation prior to logistic regression analysis. The variation between health facilities was minimal, as indicated by an intraclass correlation coefficient, which was 0.039 and reflecting an insignificant facility-level effect. This finding led us to use a standard logistic regression model for analysis. To identify predictors of HBP, we applied a binary logistic regression model. Independent variables with a p -value <0.2 in bivariable analysis were included in the multivariable analysis. In addition, based on findings from previous literature, factors such as fruit consumption, TB infection, anxiety/depression, time since ART initiation, and treatment regimens were included in the multivariable analysis, regardless of their significance level. Moreover, we assessed the interaction effects between ART regimens and selected variables such as sex, treatment duration, age, PA, and BMI on blood pressure. Multicollinearity was assessed through multiple regression analysis by sequentially removing variables with high variance inflation factor (VIF). Tolerance values >0.1 and VIF of <10 were used as cutoffs to determine the candidate variables for the final model. Furthermore, the Hosmer-Lemeshow test was used to determine the model's goodness of fit, with a p -value >0.05 indicating a well-fit model. The association between outcome and explanatory variables was determined using AORs with a 95% CI. Finally, variables with a p -value <0.05 were considered to have a significant association. Data entry and statistical analysis were managed using EpiData 3.1 and IBM SPSS 27.0 (IBM Corp., Armonk, NY, USA), respectively.

Results

Sociodemographic and economic features of the study participants

Among the 465 eligible adult PLWH, 444 participants were enrolled in the study, resulting in a response rate of 95.5%. Table 1 summarizes the sociodemographic and economic characteristics of the study participants. Among the participants, 58.3% were women ($n=259$) and 41.7% were men ($n=185$). The mean (\pm SD) age of the participants was 38.4 (8.9) years, with the majority (67.8%) falling within the 30–49 years age range. Over 90% of the participants were living in urban areas, half were married, 31.1% had completed primary-level education, 43% were employed, and 41.2% reported their monthly income of \leq 2000 Ethiopian birr (ETB).

Pattern of blood pressure among the study participants

The median (IQR) SBP was 117 (107–128) mmHg with a range of 77–249 mmHg, while the median (IQR) DBP was 77 (70–84) mmHg with a range of 45–148 mmHg. The prevalence of HBP was 57.9% (95% CI: 52.5–62.4). The sex-specific rate of HBP was 68.1% (95% CI: 60.5–74.1) for men and 50.6% (95% CI: 44.4–56.8) for women. The prevalence of pre-hypertension was 40.5% (95% CI: 35.4–45) and HTN was 17.3% (95% CI: 13.7–20.9). Among participants with HTN, 84.4% (65/77) were newly diagnosed in this study and were previously unaware of their condition. In addition, 48% (37/77) were identified as having systolic–diastolic HTN (SDH), and 29.9% (23/77) were diagnosed with isolated diastolic HTN (IDH) (Figure 1). The sex-specific rate of pre-HTN and HTN was 44.9% (95% CI: 37.8–51.9) and 23.2% (95% CI: 17.3–29.2) for men and 37.5% (95% CI: 31.7–43.6) and 13.1 (95% CI: 9.3–17.8) for women, respectively.

Among participants with HTN, 20.8% (16/77) were aged 30–49 years, 44.2% (34/77) were aged 40–49 years, and 45.5% (35/77) were married. The rate of HTN was significantly higher in men (55.8%) compared to women (44.2%) (Table S1). More than 44% of the participants were overweight-obese, 37.6% had a history of khat chewing, 5.2% had comorbid health problems, and 32.7% were sedentary to less active in PA. About 14.5% had a history of smoking and 57.8%

reported alcohol consumption, with 38.7% being former drinkers and 19.1% current drinkers (Table S2).

Behavioral, clinical, and nutritional characteristics of the study participants

The median (IQR) time since HIV diagnosis was 4.2 (2.3–6.1) years. All participants received cART following the implementation of the universal test-and-treat strategy in Ethiopia and had been on cART for a mean (\pm SD) of 3.8 (1.9) years, with nearly half (48.9%) having been on treatment for at least 4 years. Only 12 participants (2.7%) and 14 participants (3.2%) reported consuming fruits and vegetables daily, respectively, regardless of the recommended portion sizes. Over 75% of the participants mentioned economic constraints as the main reason for inadequate intake of FAV, while others described factors such as access limitations, lack of desire, the belief that their intake was sufficient, and discomfort while eating (Table 2).

At the time of ART initiation, the majority of participants (62.4%) were classified as having WHO clinical stages I and II disease. In addition, most participants (85.8%) began ART while in a working functional status. Among them, 106 individuals (23.9%) had a history of tuberculosis (TB) infection, with 57.5% (61/106) diagnosed with pulmonary TB and 42.5% (45/106) with extrapulmonary TB.

Predictors of HBP among the study participants

In the bivariable regression model, several factors were significantly associated with high HBP such as sex, age, BMI, family history of HTN, WC, WHR, WHtR, occupational status, vegetable intake, meat intake, alcohol consumption, physical activity, monthly income level, low density lipoprotein cholesterol, and triglycerides.

After adjustment for potential confounding factors using multivariable logistic regression, ART regimens and the other seven variables were found to be significantly associated with HBP. Initiating ART with DTG-based first-line regimens as well as switching to these regimens were significantly associated with higher odds of HBP compared to NNRTI-based first-line regimens. Adults who initiated and remained on DTG-based first-line ART had 5.9 times higher odds of

Table 1. Sociodemographic and economic characteristics of people with HIV on antiretroviral treatment.

Variables	Category	Overall <i>n</i> = 444 (%)	Blood pressure status		<i>p</i> Value
			High <i>n</i> = 257 (%)	Normal <i>n</i> = 187 (%)	
Sex	Female	259 (58.3)	131 (51)	128 (31.6)	<0.001
	Male	185 (41.7)	126 (49)	59 (31.9)	
Age, years	Mean (\pm SD)	38.4 (8.9)	42.9 (9.9)	38.4 (8.8)	<0.001*
	20–29	51 (11.5)	24 (9.3)	27 (14.4)	<0.001
	30–39	153 (34.5)	70 (27.2)	83 (44.4)	
	40–49	148 (33.3)	96 (37.4)	52 (27.8)	
	\geq 50	92 (20.7)	67 (26.1)	25 (13.4)	
Residence	Rural	41 (9.2)	22 (8.6)	19 (10.2)	0.565
	Urban	403 (90.8)	235 (91.4)	168 (89.8)	
Marital status	Single	47 (10.6)	27 (10.5)	20 (10.7)	0.99
	Married	222 (50.0)	129 (50.2)	93 (49.7)	
	Divorced	102 (23.0)	59 (23)	43 (23)	
	Widow/widower	73 (16.4)	42 (16.3)	31 (16.6)	
Education	Unable to read and write	50 (11.3)	27 (10.5)	23 (12.3)	0.727
	Informal	1 (0.2)	1 (0.4)	0 (0.0)	
	Primary level	138 (31.1)	76 (29.6)	62 (33.2)	
	Secondary level	132 (29.9)	78 (30.4)	54 (28.9)	
	At least college	123 (27.7)	75 (29.2)	48 (25.7)	
Occupation	Students	8 (1.8)	5 (1.9)	3 (1.6)	0.005
	Employed	191 (43.0)	120 (46.7)	71 (38)	
	Merchants	89 (20.0)	58 (22.6)	31 (16.6)	
	No job	35 (7.9)	19 (7.4)	16 (8.6)	
	Daily laborers	51 (11.5)	17 (6.6)	34 (18.2)	
	Housewife	48 (10.8)	25 (9.7)	23 (12.3)	
	Farmers	10 (2.3)	4 (1.6)	6 (3.2)	
	Retired and others	12 (2.7)	9 (3.5)	3 (1.6)	
Income in ETB	\leq 2000 birr	183 (41.2)	87 (33.9)	96 (51.3)	<0.001
	2001–4000 birr	89 (20.0)	52 (20.2)	37 (19.8)	
	4001–6000 birr	78 (17.6)	51 (19.8)	27 (14.4)	
	6000+ birr	94 (21.2)	67 (26.1)	27 (14.4)	

ETB, Ethiopian birr (1 Ethiopian birr = 0.0173 USD during the study); SD, standard deviation; significance level (by chi-square test; *, by independent *t*-test).

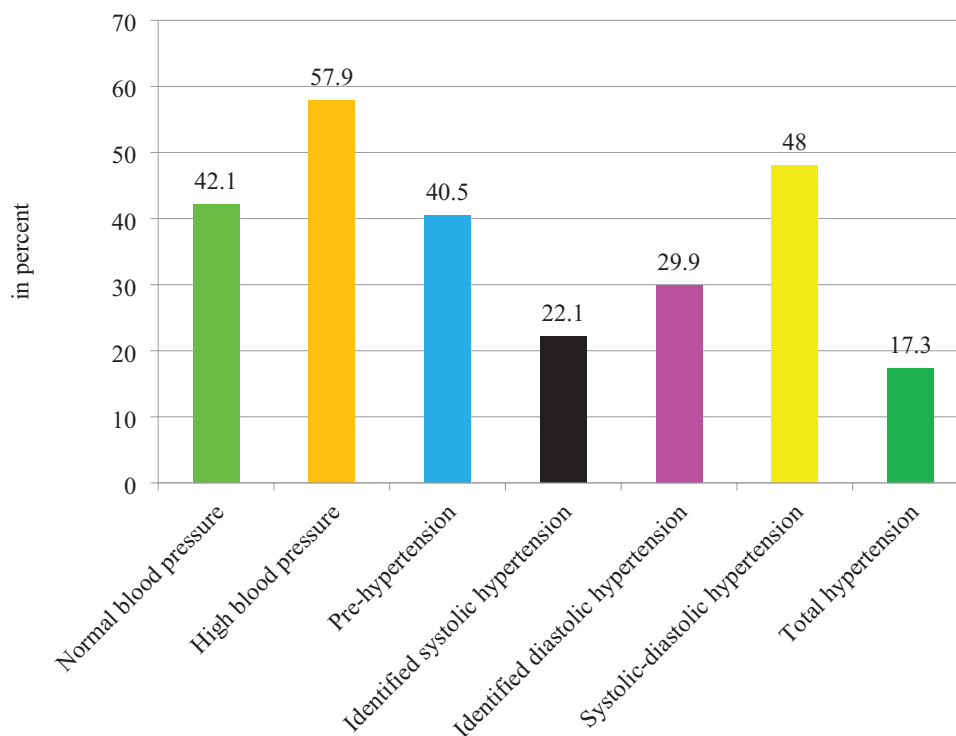


Figure 1. The pattern of blood pressure among the study participants.

developing HBP compared to those on NNRTI-based regimens (AOR: 5.9; 95% CI: 1.5–22.7). While those who switched from NNRTI-based regimens to DTG-based regimens had 3.8 times higher odds of developing HBP compared to those who remained on NNRTI-based regimens (AOR: 3.8; 95% CI: 1.1–13.9). Men had 2.6 times greater odds of developing HBP compared to women (AOR: 2.6; 95% CI: 1.4–4.9). In addition, participants who were older than 45 years had twofold higher odds of developing HBP compared to their younger counterparts (AOR: 2.0; 95% CI: 1.2–3.4). Moreover, participants who consumed vegetables for less than 4 days a week had nearly twofold greater odds of developing HBP compared to those who consumed at least 4 days a week (AOR: 1.7; 95% CI: 1.01–2.7) (Table 3).

Statistically significant interaction effects were found between treatment regimens and independent variables such as male sex, adequate physical activity, and BMI in the prediction of HBP and HTN (Table 4). Sex-stratified analysis indicated that switching to DTG-based regimens, being over 45 years, and having a BMI ≥ 25 kg/m² were significantly influenced blood pressure with

remarkably significant effects observed in women (Table S3).

Discussion

In this study, 57.9% of participants had HBP, with 40.5% classified as pre-hypertensive and 17.3% as hypertensive. Among the 17.3% of participants with HTN, 84.4% (14.6% of the total participants) were newly diagnosed during this study. In addition, initiating treatment with or switching to DTG-based first-line regimens had higher odds of HBP compared to efavirenz-based first-line regimens. Non-modifiable risk factors such as older age and male sex were associated with higher odds of HBP. In addition, inadequate vegetable intake along with other modifiable risk factors such as HC, WHtR, lipid profiles, and inadequate PA were also associated with increased odds of HBP.

More than 96% of participants were on DTG-based first-line regimens, either initiated directly or switched from NNRTI-based therapy and 57.9% of participants had HBP in this study. This result is consistent with a study from Ghana, which reported a prevalence of HBP of 54.6%.⁴⁰

Table 2. Behavioral, clinical, and nutritional characteristics of the study participants.

Variables		Category	Total (n=444)	Blood pressure status	
				High n= 257 (%)	Normal n= 187 (%)
Body mass index, kg/m ²		Mean (standard deviation)	24.8 (4.8)	26 (4.7)	23.1 (4.5)
Underweight		≤18.4 kg/m ²	27 (6.1)	8 (3.1)	19 (10.2)
Normal weight		18.5–24.9 kg/m ²	220 (49.5)	105 (40.9)	115 (61.5)
Overweight		25–29.9 kg/m ²	138 (31.1)	100 (38.9)	38 (20.3)
Obese		≥30 kg/m ²	59 (13.3)	44 (17.1)	15 (8)
Duration of HIV, years		Median (interquartile range)	4.2 (2.3–6.1)	4.0 (2.4–6.0)	4.3 (2.3–6.2)
Duration on antiretrovirals, years		Mean (standard deviation)	3.8 (1.9)	3.8 (1.8)	3.9 (1.9)
Treatment regimens	AZT/TDF+3TC+EFV	Maintained	17 (3.8)	8 (3.1)	9 (4.8)
	TDF/ABC+3TC+DTG	Switched	205 (46.2)	118 (45.9)	87 (46.5)
	TDF/ABC+3TC+DTG	Maintained	222 (50.0)	131 (51)	91 (48.7)
Smoking		Never smoked	380 (85.6)	222 (86.4)	158 (84.5)
		Former	54 (12.2)	30 (11.7)	24 (12.8)
		Current	10 (2.3)	5 (1.9)	5 (2.7)
Alcohol intake		Never	187 (42.1)	93 (36.2)	94 (50.3)
		Former	172 (38.7)	105 (40.9)	67 (35.8)
		Current	85 (19.1)	59 (23)	26 (13.9)
Comorbidity state		No	421 (94.8)	240 (93.4)	181 (96.8)
		Yes	23 (5.2)	17 (6.6)	6 (3.2)
Fruit intake/week		≤2 days	322 (72.5)	187 (72.8)	135 (72.2)
		3–4 days	89 (20.0)	55 (21.4)	34 (18.2)
		≥5 days	33 (7.4)	15 (5.8)	18 (9.6)
Vegetables intake/week		≤2 days	197 (44.4)	119 (46.3)	78 (41.7)
		3–4 days	160 (36.0)	90 (35)	70 (37.4)
		≥5 days	87 (19.6)	48 (18)	39 (20.9)
Physical activity		≤Less active	145 (32.7)	107 (41.6)	38 (20.3)
		Moderate	243 (54.)	131 (51)	112 (59.9)
		Highly active	56 (12.6)	19 (7.4)	37 (19.8)

(Continued)

Table 2. (Continued)

Variables	Category	Total (n=444)	Blood pressure status	
			High n=257 (%)	Normal n=187 (%)
Intake of meat	≤3 days/month	296 (66.7)	164 (63.8)	132 (70.6)
	1–3 days/week	124 (27.9)	75 (29.2)	49 (26.2)
	≥4 days/week	24 (5.4)	18 (7)	6 (3.2)
Family history of hypertension	No/don't know	294 (66.2)	160 (62.3)	134 (71.7)
	Yes	150 (33.8)	97 (37.7)	53 (28.3)
Waist circumference, centimeter	Median (interquartile range)	85 (76–94)	90 (81–98)	78 (72–88)
Hip circumference, centimeter	Median (interquartile range)	95 (89–102)	98 (91–103)	91 (85–100)
Waist-to-hip ratio	Median (interquartile range)	0.9 (0.83–0.96)	0.92 (0.86–0.98)	0.87 (0.81–0.92)
Waist-to-height ratio	Median (interquartile range)	0.52 (0.47–0.6)	0.54 (0.5–0.6)	0.48 (0.44–0.54)
Triglycerides, milligram/deciliter	Median (interquartile range)	119 (87.9–102)	131 (95–197)	105 (81.9–150)
High density lipoprotein cholesterol, milligram/deciliter	Mean (standard deviation)	36.7 (9.6)	36.8 (9.8)	36.5 (9.4)
Low density lipoprotein cholesterol, milligram/deciliter	Mean (standard deviation)	91 (30.9)	96.1 (31.9)	84 (28.2)
Waist to sitting height ratio	Median (interquartile range)	1.07 (0.96–1.2)	1.1 (1.0–1.2)	0.99 (0.91–1.1)

ABC, abacavir; AZT, zidovudine; DTG, dolutegravir; EFV, efavirenz; 3TC, lamivudine; TDF, tenofovir disoproxil fumarate.

Table 3. Factors associated with high blood pressure among the study participants.

Variables	Category	Total 444 (%)	Blood pressure status		COR (95% CI)	AOR (95% CI)
			High 257 (%)	Normal 187 (%)		
Sex	Male	185 (41.7)	126 (49)	59 (31.6)	2.1 (1.4–3.1)***	2.6 (1.4–4.9)**
Age	>45 years	156 (35.1)	113 (44)	43 (23)	2.6 (1.7–4.0)***	2.0 (1.2–3.4)**
Duration on antiretrovirals	≥6 years	83 (18.7)	48 (18.7)	35 (18.7)	1.0 (0.61–1.6)	1.1 (0.56–2.1)
Body mass index	≥25 kg/m ²	197 (44.4)	144 (56)	53 (28.3)	3.2 (2.1–4.8)***	0.95 (0.48–2.0)
Family history of hypertension	Yes	150 (33.8)	97 (37.7)	53 (28.3)	1.5 (1.02–2.3)*	1.2 (0.75–2.0)
High waist circumference	Yes	131 (29.5)	94 (36.6)	37 (19.8)	2.3 (1.5–3.6)***	0.93 (0.46–1.9)

(Continued)

Table 3. (Continued)

Variables	Category	Total 444 (%)	Blood pressure status		COR (95% CI)	AOR (95% CI)
			High 257 (%)	Normal 187 (%)		
High waist-to-hip ratio	Yes	270 (60.8)	179 (69.6)	91 (48.7)	2.4 (1.6–3.6)***	1.1 (0.58–2.1)
High waist-to-height ratio	Yes	287 (64.6)	200 (77.8)	87 (46.5)	4.0 (2.7–6.1)***	2.4 (1.1–4.9)*
Occupation	Working	280 (63.1)	178 (69.3)	102 (54.5)	1.9 (1.3–2.8)**	1.2 (0.69–2.0)
Fruits intake	≤2 days/week	223 (50.2)	123 (47.9)	100 (53.5)	0.8 (0.55–1.2)	1.0 (0.62–1.7)
Vegetables intake	<4 days/week	302 (68)	185 (72)	117 (62.6)	1.5 (1.02–2.3)*	1.7 (1.01–2.7)*
Tuberculosis infection	Yes	106 (23.9)	66 (25.7)	40 (21.4)	1.3 (0.81–2.0)	1.2 (0.68–2.3)
Intake of meat	≥2 days/week	163 (36.7)	115 (44.7)	48 (25.7)	2.3 (1.6–3.5)***	1.4 (0.81–2.3)
Alcohol use	Ever consumed	257 (57.9)	164 (63.8)	93 (47.9)	1.8 (1.2–2.6)**	0.89 (0.53–1.5)
World Health Organization	stage-II	88 (19.8)	57 (22.2)	31 (16.6)	1.6 (0.97–2.7)	1.7 (0.90–3.2)
Clinical stage	stage-III	118 (26.6)	70 (27.2)	48 (25.7)	1.3 (0.81–2.1)	0.99 (0.54–1.8)
	stage-IV	49 (11.0)	30 (11.7)	19 (10.2)	1.4 (0.74–2.7)	0.94 (0.40–2.2)
Physical activity	≤Less active	145 (32.7)	107 (41.6)	38 (20.3)	4.5 (2.8–10.7)***	2.4 (1.1–5.4)*
	Moderate	243 (54.7)	131 (51)	112 (59.9)	2.3 (1.2–4.2)***	1.6 (0.8–3.3)
Comorbidity	Yes	23 (5.2)	17 (6.6)	6 (3.2)	2.1 (0.83–5.5)	1.5 (0.49–4.7)
Treatment switched to TDF/ABC + 3TC + DTG		205 (46.2)	118 (45.9)	87 (46.5)	1.5 (0.57–4.1)	3.8 (1.1–13.9)*
Regimens maintained on TDF/ABC + 3TC + DTG		222 (50)	131 (51)	91 (48.7)	1.6 (0.6–4.3)	5.9 (1.5–22.7)*
Monthly income	≥3500 ETB	198 (44.6)	135 (52.5)	63 (33.7)	2.2 (1.5–3.2)***	0.93 (0.52–1.6)
Anxiety/depression	Yes	18 (4.1)	9 (3.5)	9 (4.8)	0.72 (0.28–1.8)	0.92 (0.30–2.8)
Hip circumference (SqrtT), mg/dl	Mean (SD)	9.7 (0.53)	9.9 (0.49)	9.6 (0.54)	2.9 (1.9–4.3)***	2.4 (1.2–4.8)*
Triglycerides (LogT), mg/dl	Mean (SD)	2.1 (0.22)	2.1 (0.23)	2 (0.2)	7.1 (2.8–17.7)***	2.1 (0.69–6.7)
Low density lipoprotein cholesterol, mg/dl	Mean (SD)	91 (30.9)	96 (31.9)	84 (28.2)	1.01 (1.01–1.02)***	1.1 (1.0–1.02)*

ABC, abacavir; AOR, adjusted odds ratio; COR, crude odds ratio; CI, confidence interval; DTG, dolutegravir; ETB, Ethiopian birr (1ETB=0.0173USD during the study); EFV, efavirenz; 3TC, lamivudine; LogT, log10 transformed; SD, standard deviation; Sqrt, square root transformed; TDF, tenofovir disoproxil fumarate; Reference category: female-sex; age ≤45 years; ART duration <6 years; BMI <25 kg/m²; family history of HTN no; WC normal; WHR normal; WHtR normal; occupation-currently not working; fruit use ≥2 days/week; vegetable use ≥4 days/week; tuberculosis no; meat use <2 days/week; alcohol use-never; smoking-never; WHO clinical stage I; exercise moderate-high; comorbidity no; ART regimen arm: EFV-based; monthly income <3500 ETB; anxiety/depression no; [significance level: **p* < 0.05; ***p* < 0.01; ****p* < 0.001].

Table 4. The interaction effect between antiretroviral regimens and other covariates on blood pressure using a multivariable logistic regression model.

Interaction and variables	Treatment category	High blood pressure		Hypertension	
		AOR (95% CI)	p Value	AOR (95% CI)	p Value
ART regimens × sex	Efavirenz based	Reference		Reference	
	Switched to dolutegravir	2.1 (1.1–4.2)	0.028	2.8 (1.3–6.0)	0.008
	Maintained on dolutegravir	2.0 (1.1–3.5)	0.017	1.2 (0.59–2.5)	0.582
ART regimens × treatment duration, years	Efavirenz based	Reference		Reference	
	Switched to dolutegravir	0.67 (0.52–0.87)	0.002	0.75 (0.55–1.02)	0.70
	Maintained on dolutegravir	0.84 (0.65–1.1)	0.217	1.3 (0.9–1.8)	0.182
ART regimens × age >45years	Efavirenz based	Reference		Reference	
	Switched to dolutegravir	2.6 (1.3–5.0)	0.007	2.1 (0.98–4.6)	0.056
	Maintained on dolutegravir	1.8 (0.95–3.6)	0.072	0.99 (0.45–2.2)	0.977
ART regimens × low Physical activity	Efavirenz based	Reference		Reference	
	Switched to dolutegravir	2.0 (0.998–5.0)	0.051	0.66 (0.30–1.5)	0.322
	Maintained on dolutegravir	2.3 (1.1–4.6)	0.017	2.3 (1.04–5.0)	0.039
ART regimens × body mass Index, kg/m ²	Efavirenz based	Reference		Reference	
	Switched to dolutegravir	1.1 (1.06–1.2)	<0.001	1.1 (1.03–1.16)	0.006
	Maintained on dolutegravir	1.06 (1.01–1.1)	0.008	1.01 (0.95–1.06)	0.787

AOR, adjusted odds ratio; ART, antiretroviral therapy; COR, crude odds ratio; CI, confidence interval; Reference category: female sex, age ≤45years, moderate to high physical activity.

In addition, a longitudinal study from Zimbabwe reported a significant increase in blood pressure among PLWH on DTG-based regimens over 2years, while the rate remained stable for those using NNRTIs and protease inhibitors (PIs).⁴¹ However, the findings of the present study were remarkably higher than the 35% prevalence of

HBP reported in Zambia.⁴² The differences in blood pressure rates within this population may be factors such as genetic diversity, variations in data collection methods (e.g., the use of national electronic records in Zambia versus direct participant contact in our study), treatment initiation criteria, and differences in participant selection criteria.

The prevalence of HTN in this study was 17.3%, which is consistent with several other studies conducted in African settings such as 17.4% in Burundi,⁴³ 17.4% in Ghana,⁴⁴ 14.7% in Zambia,⁴² 18.5% in south Ethiopia,¹² 14.2% in South Africa,²¹ and 18.4% in Zambia.²⁵ However, the rate observed in this study was lower than the rates reported in several other studies such as 24.7% in Rwanda,⁴⁵ 27.2% in Uganda,¹⁰ and 23% in Europe and Australia.¹⁸ Variations in HTN prevalence across these studies may be attributed to differences in HIV clinical stages at treatment initiation, the effects of different ART regimens on cardiovascular health, ethnic factors, and geographic factors.

Over 44% of participants in this study had a BMI of ≥ 25 kg/m² and 73.1% of those individuals had HBP, representing 56% of all HBP cases. Similar studies have reported high rates of HTN among individuals who have a BMI ≥ 25 kg/m².^{10,42} The exact mechanisms behind weight gain associated with DTG remain unclear; however, weight gain may increase blood pressure through pathways involving adipose tissue activation and the RAAS system.¹⁹

In this study, both treatment initiation with DTG-based first-line regimens and switching to these regimens were significantly associated with HBP compared to NNRTI-based regimens. These findings are consistent with prior studies showing a significant association between increased blood pressure and INSTI-based regimens, particularly those containing DTG, leading to a higher rate of elevated blood pressure compared to NNRTI or PI-based regimens.^{10,21,41} This may be influenced by the fact that individuals who initiated or switched to DTG-based regimens experienced greater weight gain^{20,21,41}, which could contribute to increased blood pressure compared to those on NNRTI-based regimens.^{21,41} In addition, efavirenz is associated with reduced body weight, which could explain the people taking efavirenz based regimens tend to have lower blood pressure compared to those taking DTG based regimens.⁴¹ The mechanism of DTG's ability to bind and chelate magnesium (Mg²⁺)^{46,47} may interfere with magnesium's regulatory role in blood pressure, extending beyond its primary role in integrase inhibition.

The NEAT022 trial found no difference in HTN rates after 48 weeks between individuals who

switched from boosted PI-based to DTG-based regimens compared to those who remained on PI-based regimens, in contrast to our findings.⁴⁸ A study has reported a strong association between PIs and the pathophysiology of HTN through mechanisms such as RAAS activation, endothelial dysfunction, arterial stiffness, lipodystrophy, insulin resistance, and oxidative stress.⁴⁹ This supports the notion that DTG-based regimens may not show significant variability in HTN outcomes compared to PI-based regimens, as both have been found to potentiate increased blood pressure. The observed differences in blood pressure in these studies may reflect variability between study groups, as our participants switched from NNRTI-based to DTG-based regimens, compared to those who remained on NNRTI-based regimens. Another factor that may be attributed to the difference is that participants in the NEAT022 study were on DTG for only 48 weeks after switching, while our participants had been on DTG for a mean duration of 38 months (ranging from 12 to 60 months).

Men showed a higher rate of elevated blood pressure compared to women in this study, indicating significantly greater odds of developing HBP.^{9,10,23} Various factors such as hormones and RAAS activation are suggested to contribute to sex-related disparities in blood pressure levels.⁵⁰ In support, estrogen, the primary female sex hormone, has been implicated in protecting females from HTN by exerting cardiovascular effects such as vasodilation, anti-inflammatory actions, and modulation of the RAAS, which contribute to blood pressure regulation.⁵¹

The proportion of HBP and HTN varied significantly with age in this study, with those over 45 years old showing significantly higher odds of HBP compared to their younger counterparts. This finding aligns with previous studies that indicated the association between advanced age and increased blood pressure.^{9,10,12,42} Physiological factors such as changes in blood flow, arterial stiffness, neurohormonal imbalances, autonomic system changes, and age-related effects on kidney function possibly contribute to the association between age and HTN among older individuals.⁵² Furthermore, the aging process may lead to various structural and functional changes in the arterial vasculature, contributing to the development of HTN and other cardiovascular conditions.⁵³

A significant association between PA and blood pressure was observed in the present study, revealing that individuals who engaged in low PA had notably higher odds of developing HBP compared to those who maintained moderate to high levels of PA. This aligns with other studies conducted in Ethiopia.^{12,54} In addition, PA contributes to maintaining a healthy weight, improving endothelial function for better blood flow regulation, reducing sympathetic nervous system activity, enhancing insulin sensitivity, and mitigating inflammation and oxidative stress, which are all central factors in lowering blood pressure and promoting cardiovascular health.⁵⁵

Several studies have shown a strong association between HTN and factors such as increased weight.^{10,12,44} By contrast, our study found no association between BMI and HBP; however, a significant interaction effect between switching to DTG-based first-line regimens and BMI was observed in predicting increased odds of HBP and HTN in this study. This aligns with previous studies that indicated increased blood pressure among those who switched to DTG was associated with weight gain.^{21,22,41,56} Furthermore, we found a significant association between HBP and factors such as lipid profile, low vegetable intake, and high WHtR. The findings are consistent with previous studies highlighting the association between elevated blood pressure and inadequate vegetable intake,⁵⁷ lipid profiles,⁴⁴ and high WHtR.⁵⁸

This study has several limitations. As a cross-sectional study, it is limited in its ability to establish causality and can only identify associations. The high odds ratio of HBP associated with DTG-based regimens may reflect systematic differences in participant characteristics between the comparison groups. In addition, the limited representation of individuals on efavirenz-based regimens (the reference group), due to the national rollout of DTG-based regimens, may introduce socioeconomic or clinical factors that influence blood pressure. Furthermore, the use of single-phase blood pressure measurements may not capture the dynamic variability of blood pressure throughout the day or in different environments.

Conclusion

The prevalence of HBP among adult PLWH is alarmingly high. HBP was significantly associated with DTG-based first-line regimens compared to

NNRTI-based regimens. In addition, a significant interaction effect was observed between treatment regimens and several covariates in predicting increased blood pressure. The study also identified associations between elevated blood pressure and both non-modifiable and modifiable risk factors.

Therefore, proactive blood pressure screening and management are crucial for individuals on DTG based regimens, especially considering the increasing trends in post-treatment blood pressure. In addition, identifying and addressing modifiable risk factors early through comprehensive strategies and regular screenings are also key steps for enhancing cardiovascular health in this population.

Declarations

Ethics approval and consent to participate

The study was approved by the Institutional Review Board (IRB) of the College of Natural and Computational Sciences (CNS-IRB) at Addis Ababa University on September 19, 2022 with reference of IRB/07/14/2022. Before initiating the study, a support letter from the Hawassa City Administration Health Department was obtained and submitted to each study health facility. Permission was also secured from the medical director's office or the head of each health facility. Participants were informed on the study's objectives, potential effects, and the significance of the data collected. Written informed consent was obtained from all participants, as well as from legally authorized representatives for participants unable to read or write, prior to the study's commencement. Participation was entirely voluntary, and participants were made aware of their right to withdraw or decline at any stage. To ensure confidentiality, all information remained anonymous.

Consent for publication

Not applicable.

Author contributions

Agete Tadewos Hirigo: Conceptualization; Data curation; Formal analysis; Funding acquisition; Investigation; Methodology; Project administration; Resources; Software; Writing – original draft; Writing – review & editing.

Daniel Yilma: Conceptualization; Data curation; Formal analysis; Investigation; Methodology;

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Competing interests

The authors declare that there is no conflict of interest.

Availability of data and materials

The data are not publicly accessible and it can be accessible with reasonable request from the corresponding author.

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Supplemental material

Supplemental material for this article is available online.

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