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Posted Date: 3 January 2024

doi: 10.20944/preprints202401.0131.v1

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Article

Effect of Dolutegravir-Based First-Line Antiretroviral Therapy on Mother-to-Child Transmission of HIV among HIV-Exposed Infants in Southern Ethiopia: A Retrospective before-after Study

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Abstract: Background: Currently, a Dolutegravir (DTG)-based regimen is administered to women on option B plus to prevent mother-to-child transmission (MTCT) of the virus. However, its effect on reducing MTCT of human immunodeficiency virus (HIV) among exposed infants over the previously used Efavirenz (EFV)-based regimen is unknown. **Objective:** This study aimed to compare the effects of DTG-based and EFV-based regimens on the MTCT of HIV among exposed infants in southern Ethiopia. **Methods:** A retrospective before-after study design was employed from March to May 2023 among 958 mother-infant pairs (479 on EFV-based and 479 on DTG-based regimens) enrolled in the prevent mother-to-child transmission (PMTCT) care from September 2015 to February 2023. The outcome variable was the HIV infection status among the exposed infants. A log-binomial model was employed and the proportion was computed to compare the incidence of MTCT of HIV in both groups. The risk ratio (RR) with 95% confidence interval (CI) was calculated to assess the predictor variables. **Results:** Mothers on a DTG-based regimen were approximately 44% (adjusted risk ratio (aRR): 0.56; 95% CI: 0.44, 0.70) less likely to transmit HIV to their infants than those on an EFV-based regimen. In addition, poor/fair adherence to antiretroviral therapy (ART) (aRR: 5.82; 95% CI: 3.41, 9.93), home delivery (aRR: 3.61; 95% CI: 2.32, 5.62), mixed feeding practice (aRR: 1.83; 95% CI: 1.45, 2.3), and not receiving antiretroviral prophylaxis (aRR: 3.26; 95% CI: 1.6, 6.64) were found to increase the risk of MTCT of HIV infection, whereas older maternal age (aRR: 0.93; 95% CI: 0.9, 0.96) was a protective factor. **Conclusion:** The Dolutegravir-based regimen significantly reduced MTCT of HIV among exposed infants compared to the EFV-based regimen. Thus, DTG-based first-line ART regimen supplementation should be sustained to achieve global and national targets for zero new infections in HIV-exposed infants.

Keywords: mother-to-child transmission; ART; Dolutegravir; HIV-exposed infants; Ethiopia

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Article summary

Article focus

- The study compares the effect of DTG-based first-line ART versus EFV-based regimen on MTCT of HIV.
- The study also assesses the incidence of HIV infection among infants born to HIV-positive mothers.

Key messages

- The DTG-based regimen significantly reduced the risk of MTCT of HIV than the Efavirenz-based regimen.

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- The overall incidence of HIV infection among infants born from HIV-positive mothers was lower than the national and WHO targets of 5% in breastfed infants.

Strengths and limitations of this study

- This study is the first study that compares the effect of the DTG-based first-line ART over the EFV-based regimen on MTCT of HIV in Ethiopia.
- The present study included a larger sample size and covered a wider geographic area than the EFV-based studies conducted on MTCT of HIV in Ethiopia.
- There might be measurement and recording errors due to the nature of secondary data. Those mother-infant pairs who were transferred out and lost to follow-up were excluded from the analysis due to incomplete data which may have been underestimated the incidence of MTCT of HIV.

Introduction

Human immunodeficiency virus (HIV) infection continues to be a global public health problem.[1] Globally, approximately 1.5 million children (0–14 years) are living with HIV, and 130,000 acquire the virus by the end of 2022.[2] Most of which are due to mother-to-child transmission (MTCT), which accounts for approximately 90% of all new infections.[3] Without any intervention, approximately 20-45% of infants acquire HIV infection from their mothers during pregnancy, labor, delivery, and the breastfeeding period.[3,4]

To tackle the problem, Ethiopia adopted the World Health Organization (WHO) option B plus recommendations as the preferred strategy for the prevention of mother-to-child transmission (PMTCT) of HIV in 2013.[5] Option B plus consists of lifelong antiretroviral (ART) for all HIV-infected pregnant and breastfeeding women, irrespective of their CD4 count and WHO clinical staging.[4] Since the implementation of the Option B plus program, there have been various guideline changes for treatment protocol.[4,6] As per WHO recommendation, the previous Efavirenz (EFV)-based regimen was changed to a Dolutegravir (DTG)-based regimen as the preferred first-line regimen for people living with HIV initiating ART as of the end of 2018[7] and for pregnant and breastfeeding women as of July 2019.[8,9] The EFV-based regimen consists of Tenofovir (TDF), Lamivudine(3TC), and Efavirenz (EFV) while the DTG-based regimen consists of TDF, 3TC, and DTG.[4,8,10] The change in regimen was a result of a rapid and sustained viral suppression by the DTG-based regimen than did the EFV-based regimen.[7,11]

Previous studies have focused on the incidence and risk factors of MTCT of HIV among infants exposed to EFV-based regimens.[12–27] Despite its preference due to rapid viral suppression, the high genetic barrier to resistance, and availability at a low cost[4,28], the effectiveness of DTG-based therapy in reducing MTCT of HIV over the previously used EFV-based therapy is not known. Therefore, this study aimed to compare the effect of DTG-based first-line antiretroviral therapy versus EFV-based regimen on MTCT of HIV among HIV-exposed infants in Southern Ethiopia.

Material and Methods

Study design and period

This retrospective before-after study was conducted between March and May 2023. The study included seven-year retrospective data of mother-infant pairs who received PMTCT care

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from September 2015 to February 2023(September 2015 to August 2019 for the EFV-based group and September 2019 to February 2023 for the DTG-based group).

Study setting

This study was conducted in two regions of Southern Ethiopia: central Ethiopia, and south Ethiopia. South Ethiopia is administratively divided into 12 zones, whereas Central Ethiopia is divided into 7 zones and 3 special districts. In these regions, 140 health facilities (49 hospitals and 91 health centers) currently provide PMTCT and ART services to 28,885 patients, of which 1,236 are pregnant and breastfeeding women (675 in South Ethiopia and 561 in Central Ethiopia). Thirty-four facilities (20 hospitals and 14 health centers) providing services to approximately 86% of the patients were randomly selected for inclusion in our study. Twenty-one facilities (11 hospitals and 10 health centers) were from the south Ethiopia region and 13 facilities (nine hospitals and four health centers) were selected from central Ethiopia.

Source and study population

The source population for the unexposed (before) group was all mother-infant pairs on EFV-based first-line ART, and for the exposed (after) group, all mother-infant pairs on DTG-based first-line ART in Southern Ethiopia. However, the study participants in the unexposed group were mother-infant pairs on an EFV-based regimen, and for the exposed group, mother-infant pairs on a DTG-based regimen were enrolled in PMTCT care from September 2015 to February 2023 in the selected facilities. This period was selected to obtain a comparable sample size for the DTG-based regimen that was implemented in 2019. An infant whose mother was taking only EFV-based first-line ART until discharge from the PMTCT program was considered 'unexposed' whereas an infant whose mother was taking only DTG-based first-line ART until discharge from the PMTCT program was considered 'exposed'.

Inclusion and exclusion criteria

Mother-infant pairs enrolled in PMTCT care from September 2015 onwards who took only an EFV-based regimen until discharge were recruited for the unexposed (before) group, whereas mother-infant pairs who took only a DTG-based regimen during the entire PMTCT period until discharge were recruited for the exposed (after) group. However, mother-infant pairs whose outcomes (HIV infection status) were not determined or unknown were excluded from both the groups. Mother-infant pairs who started the EFV-based regimen and then shifted to the DTG-based regimen were also excluded from the study.

Sample size determination and sampling technique

The sample size was calculated using the double population proportion formula using G power 3.1.9.7 statistical software. A significance level (alpha) of 5%, power of 80%, incidence of MTCT of HIV of 8.87% among infants born to mothers exposed to an EFV-based regimen based on a study conducted in the Sidama region [12], and a ratio of unexposed to exposed of 1. We used 3.87% MTCT of HIV among infants born to mothers exposed to a DTG-based first-line ART regimen to detect a 5% reduction in the viral transmission status. After adding 20% for missing data, the total sample size was 958 (479 for EFV-based regimens and 479 for DTG-based regimens). The final sample size was allocated proportionally to the number of mother-infant pairs enrolled in the PMTCT care in the two regions and different health facilities. A consecutive sampling technique was employed to include eligible study participants (mother-infant pairs) enrolled in all 34 health facilities for the exposed and unexposed groups.

Operational definitions

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HIV-infected infant: Infants whose DNA/PCR test result is positive at the age of 6 weeks and later, or whose antibody test result is positive at the age of 18 months or later after breastfeeding has been discontinued for more than six weeks.[6]

Infant: A child aged 0–24 months or older until a serologic test determines his/her final HIV status.[4]

Maternal duration on ART until delivery: The period found by subtracting the date of delivery from the ART initiation date for known positive women. However, this is the period from the PMTCT enrolment date to the date of delivery for newly diagnosed women.

Mother-to-child transmission of HIV: Transmission of HIV from mother to baby at any time during pregnancy, labor and delivery, and breastfeeding period.

Study variables

The outcome variable was the HIV infection status among infants born to HIV-positive mothers on ART. HIV positivity for exposed infants was determined either by virological test (DNA/PCR test at the age of 6 weeks and then after), or by serological test (antibody test at the age of 18 months or later after breastfeeding has been discontinued for more than six weeks).[6] The exposure variable was the ART regimen the mother was receiving. The covariates in the present study were maternal socio-demographic, obstetric, drug and clinical-related and infant-related variables. Maternal socio-demographic variables included age, residence, marital status, educational status, and occupation. Obstetric-related variables included gestational age at enrolment, antenatal care, syphilis test results, and delivery conditions (place and delivery outcome). Drug- and clinical-related variables included enrolment type, World Health Organization clinical stage, viral load status, adherence status, disclosure status, partner HIV status, duration of treatment, timing of ART initiation, and type of health facility.

Mothers' ART adherence was categorized as *poor*, *fair*, or *good*. Women with poor adherence status at any time during the follow-up period were classified as having *poor adherence*. It is considered poor if a woman missed >5 out of 30 doses or > 10 out of 60 doses at any time during the follow-up period. A woman whose adherence status was recorded as fair (but not poor at any time during the follow-up period) was classified as having *fair adherence*. This means that a woman missed 2–4 of 30 doses or 4–9 of 60 doses. On the other hand, a woman whose adherence status was recorded as good (but not poor or fair at any time during the follow-up period) was classified as having *good adherence*. It was recorded as good if a woman missed only one of 30 doses or two of 60 doses.[10]

A viral load measurement that was not detected or below 50 copies/ml throughout the follow-up period was considered as a suppressed viral load status, whereas a viral load measurement above 50 copies/ml at any time during the follow-up period was indicated as an unsuppressed viral load status.[10]

Infant-related variables were sex, ARV prophylaxis (type and duration), feeding practice, and HIV test results. The delay in starting ARV prophylaxis was defined as the time passed to initiate prophylaxis after delivery. Antiretroviral prophylaxis is the short-term use of ARV drugs (6–12 weeks) in HIV-exposed infants to prevent MTCT.[6]

Data collection tools and procedures

Data were gathered by reviewing the records of mother-infant pairs in the exposed and unexposed groups. After obtaining permission from the administrative officials of the respective facilities, mother-infant pair data were retrieved from the PMTCT registration book, Smart Care (a computer-based data registry found at the ART unit of the respective facilities), and individual folders of the mothers and their infants. Maternal obstetric, drug, and clinical-related data were extracted from the PMTCT registration book, mothers' follow-up cards, and Smart Care, while socio-demographic data were extracted from their folders. Infant data were retrieved from the PMTCT registration books and their folders. This helped us obtain all available data from different sources and validate the existing data. An Open Data Kit (ODK) version 2.4 was used to collect data using a smartphone. Four data collectors and one supervisor participated in the data collection process. Two

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days of training were provided to the supervisor and data collectors. A pre-test was conducted at the Sodo Health Center and Wolaita Sodo University Teaching and Referral Hospital on 5% of the sample, which was excluded from the final analysis. Based on the pre-test findings, the necessary arrangements and corrections of tools were performed before data collection. All data collectors and supervisor had a Master's degree in health-related fields and a bachelor's degree in midwifery or public health. They were previously trained on basic PMTCT (to easily understand the nature of the data) and had data collection experience using ODK, which eased the data collection process.

Statistical analysis

The data collectors submitted the data to a server administered by the principal investigator daily. Data were downloaded and edited using Excel program (MS Office 2010) and then exported to Stata 14.0 (StataCorp, College Station, Texas, U.S.A.) for analysis. Descriptive statistics (median and interquartile range) were calculated for continuous data and frequencies and percentages were calculated for categorical data. Baseline demographic, obstetric, clinical, and infant characteristics across the ART treatment groups were evaluated using Pearson's chi-squared test. A multivariable log-binomial model was fitted to determine the effect of the DTG-based regimen on the MTCT of HIV. Bivariate analysis using generalized linear models for the binomial family was employed to select covariates for entry into the multivariable model. Covariates associated with the outcome variable $P < 0.25$ in the unadjusted analyses were included in the multivariate analysis. The adjusted risk ratio (aRR) with 95% confidence interval (CI) was used to measure the presence and magnitude of significant effects. Multicollinearity was assessed using the variance inflation factor (VIF) among predictor variables. A VIF greater than 10 indicated a high possibility of multicollinearity.

Results

Socio-demographic characteristics of the study participants

This study included 958 mother-infant pairs (479 exposed and 479 unexposed) enrolled in PMTCT care at 34 selected facilities (20 hospitals and 14 health centers) in Southern Ethiopia. The median (interquartile range [IQR]) maternal age at enrolment to PMTCT care was 29(25-32) years: 29 (25-32) years in the EFV-based regimen group and 29 (25-33) years in the DTG-based regimen group. One hundred seventy-eight (18.6%) mothers (17.9% in the EFV-based group and 19.2% in the DTG-based group) had a higher occupational risk of acquiring HIV infection. By contrast, 346(36.1%) mothers (38% in the EFV-based group and 34.2% in the DTG-based group) did not attend formal education. Overall, the EFV-based and DTG-based regimen groups appeared to be balanced in terms of basic socio-demographic characteristics (Table 1).

Table 1. Socio-demographic characteristics of the mothers.

Variables	Total (n=958)	EFV-based regimen arm (n=479)	DTG-based regimen arm (n=479)	P-value†
Age (in years)				
Median(IQR)	29(25-32)	29(25-32)	29(25-33)	0.149
Residence				
Rural	238(24.8)	126(26.3)	112(23.4)	0.295
Urban	720(75.2)	353(73.7)	367(76.6)	
Occupation				
High risk*	178(18.6)	86 (17.9)	92(19.2)	0.618
Low risk**	780(81.4)	393 (82.1)	387 (80.8)	
Educational status				

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Formal	612(63.9)	297 (62.0)	315 (65.8)	0.226
Not formal	346(36.1)	182 (38.0)	164 (34.2)	
Marital status				
Divorced/widowed	130(13.6)	65(13.6)	65(13.6)	1.000
Married	828(86.4)	414(86.4)	414(86.4)	

*High risk: commercial sex workers & daily labourers; **Low risk: housewife, employee, merchant, student † Pearson chi-square test.

Obstetric characteristics

A total of 900 (93.9%) women (94.2% in the EFV-based group and 93.7% in the DTG-based group) attended antenatal care during pregnancy. In addition, 45(4.7%) women (3.8% in the EFV-based group and 5.6% in the DTG-based group) delivered their infants at home (Table 2).

Table 2. Obstetric characteristics of the mothers.

Variables	Total (n=958)	EFV-based regimen arm (n=479)	DTG-based regimen arm (n=479)	P-value†
Attended ANC*				
Yes	900(93.9)	451(94.2)	449(93.7)	0.786
No	58 (6.1)	28(5.8)	30(6.3)	
Tested for syphilis				
Yes	818(85.4)	401(83.7)	417(87.1)	0.143
No	140(14.6)	78(16.3)	62(12.9)	
Place of delivery				
HF**	913(95.3)	461(96.2)	452(94.4)	0.169
Home	45(4.7)	18(3.8)	27(5.6)	

*ANC: antenatal care; **HF: health facility; † Pearson chi-square test.

Drug and clinical-related characteristics

Our study revealed that 75(7.8%) women (8.8% in the EFV-based group and 6.9% in the DTG-based group) showed poor/fair adherence to ART during the PMTCT period. In addition, 145(15.1%) women (15.4% in the EFV-based group and 14.8% in the DTG-based group) did not disclose their HIV status to their partners and 93(9.7%) women (11.9% in the EFV-based group and 7.5% in the DTG-based group) did not achieve successful viral load suppression (not detected or below 50 copies/ml). The study also showed that 298(31.1%) women (32.2% in the EFV-based group and 30.1% in the DTG-based group) were enrolled in PMTCT care newly, and 60(6.3%) of them (5.4% in the EFV-based group and 7.1% in the DTG-based group) started ART during the delivery or breastfeeding period. The median (IQR) maternal ART duration until delivery was 32 (4-60) months in the EFV-based group and 45 (5-90) months in the DTG-based group (Table 3).

Table 3. Drug and clinical-related characteristics of the mothers.

Variables	Total (n=958)	EFV-based regimen arm (n=479)	DTG-based regimen arm (n=479)	P-value†
Adherence status				
Good	883(92.2)	437(91.2)	446(93.1)	0.279

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Poor/fair	75(7.8)	42(8.8)	33(6.9)	
Partner HIV status				
Negative/unknown	430(44.9)	200(41.8)	230(48.0)	0.051
Positive	528(55.1)	279(58.2)	249(52.0)	
Disclosure status				
Yes	813(84.9)	405(84.6)	408(85.2)	0.787
No	145(15.1)	74(15.4)	71(14.8)	
Viral load status				
Suppressed	865(90.3)	422(88.1)	443(92.5)	0.022
Unsuppressed	93(9.7)	57(11.9)	36(7.5)	
WHO stage				
Stage 1	918(95.8)	470(98.1)	448(93.5)	0.001
Stage >=2	40(4.2)	9(1.9)	31(6.5)	
Enrolment type				
Known	660(68.9)	325(67.8)	335(69.9)	0.485
New	298(31.1)	154(32.2)	144(30.1)	
When ART started				
Before delivery	898(93.7)	453(94.6)	445(92.9)	0.286
During delivery/ breastfeeding	60(6.3)	26(5.4)	34(7.1)	
Types of facility				
Health centre	327(34.1)	152(31.7)	175(36.5)	0.117
Hospital	631(65.9)	327(68.3)	304(63.5)	
Maternal duration on ART until delivery (in months)				
Median (IQR)	36(4-73)	32(4-60)	45(5-90)	0.152

†Pearson's chi-squared test.

Infant-related characteristics

In this study, 60(6.3%) infants (4.4% in the EFV-based group and 8.1% in the DTG-based group) had mixed-feeding practices in the first six months of life, and 75(7.8%) infants (5.0% in the EFV-based group and 10.6% in the DTG-based group) did not receive ARV prophylaxis. The median (IQR) duration to start ARV prophylaxis for infants in this study showed no delay in either group (Table 4).

Table 4. Infant-related characteristics.

Variables	Total (n=958)	EFV-based regimen arm (n=479)	DTG-based regimen arm (n=479)	P-value†
Sex				
Female	425(44.4)	208(43.4)	217(45.3)	0.558
Male	533(55.6)	271(56.6)	262(54.7)	

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Feeding practice				
EBF*	898(93.7)	458(95.6)	440(91.9)	0.016
Mixed feeding	60(6.3)	21(4.4)	39(8.1)	
Received antiretroviral prophylaxis				
Yes	883(92.2)	455(95.0)	428(89.4)	0.001
No	75(7.8)	24(5.0)	51(10.6)	
How long infant delayed to start ARV prophylaxis in days? (n=883)**				
Median (IQR***)	0(0)	0(0)	0(0)	0.452

***EBF:** Exclusive breastfeeding**; ****ARV:** antiretroviral; *****IQR**: Interquartile range; †Pearson chi-square test.

MTCT of HIV

The incidence of MTCT of HIV infection was 4.59% (95% CI: 3.04, 6.89%) in the EFV-based regimen group and 2.3% (95% CI: 1.27, 4.11%) in the DTG-based regimen group, with an overall incidence rate of 3.44% (95% CI: 2.46, 4.81%).

Effect of DTG-based regimen on MTCT of HIV

In multivariable analysis, mothers who were on a DTG-based regimen were approximately 44%(aRR: 0.56; 95% CI: 0.44, 0.70) less likely to transmit HIV to their infants than mothers on an EFV-based regimen. In addition, a one-year increase in maternal stay on PMTCT care led to a 7% (aRR: 0.93; 95% CI: 0.9, 0.96) reduction in the risk of transmitting the virus to their infants. On the other hand, those mothers who had poor/fair adherence to ART drugs were about 5.82 times (aRR: 5.82; 95% CI: 3.41, 9.93) more likely to transmit HIV to their infants than those who had good adherence. This study also showed that infants who delivered at home were 3.61 times (aRR: 3.61; 95% CI: 2.32, 5.62); had mixed feeding practice in the first six months of age were 1.83 times (aRR: 1.83; 95% CI: 1.45, 2.3)**;** and had not received ARV prophylaxis were 3.26 times (aRR: 3.26; 95% CI: 1.6, 6.64) more likely to acquire HIV infection than their counterparts (Table 5).

Table 5. Effect of DTG-based first-line ART regimen and other covariates on MTCT of HIV.

Variables	Infant's HIV status		cRR(95% CI)	aRR(95% CI)
	Positive (n=33)	Negative (n=925)		
PMTCT drug regimen				
Dolutegravir- based	11(2.3)	468(97.7)	0.5(0.25, 1.02)	**0.56(0.44, 0.70)†**
Efavirenz-based	22(4.6)	457(95.4)	1	1
Maternal age (in years)				
Median (IQR)	28(23-30)	29(25-33)	**0.93(0.87, 0.99) †**	**0.93(0.9, 0.96)†**
Occupation				
High risk®	12(6.7)	166(93.3)	**2.5(1.26, 4.99) †**	0.89(0.49, 1.62)
Low risk®®	21(2.7)	759(97.3)	1	1
Educational status				
No formal	19(5.5)	327(94.5)	**2.4(1.22, 4.73) †**	1.15(0.72, 1.82)
Formal	14(2.3)	598(97.7)	1	1

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Attended ANC*				
No	15(25.9)	43(74.1)	**12.93(6.88,24.32)** ǂ	0.43(0.07, 2.74)
Yes	18(2.0)	882(98.0)	1	
Delivery place				
Home	18(40.0)	27(60.0)	**24.35(13.14, 45.1)** ǂ	**3.61(2.32, 5.62)**ǂ
Health facility	15(1.6)	898(98.4)	1	1
Adherence status				
Poor/Fair	19(25.3)	56(74.7)	**15.98(8.35, 30.57)** ǂ	**5.82(3.41, 9.93)**ǂ
Good	14(1.6)	869(98.4)	1	1
Disclosure status				
No	15(10.3)	130(89.7)	**4.67(2.41, 9.06)** ǂ	1.55(0.95, 2.52)
Yes	18(2.2)	795(97.8)	1	1
Viral load status				
Unsuppressed	21(22.6)	72(77.4)	**16.28(8.28, 32.01)** ǂ	2.1(0.91, 4.77)
Suppressed	12(1.4)	853(98.6)	1	1
WHO stage				
Stage >=2	4(10.0)	36(90.0)	**3.17(1.17, 8.57)** ǂ	0.84(0.51, 1.39)
Stage 1	29(3.2)	889(96.8)	1	1
Enrolment type				
New	22(7.4)	276(92.6)	**4.43(2.18, 9.02)** ǂ	1.23(0.41, 3.66)
Known	11(1.7)	649(98.3)	1	1
When started ART**				
During delivery/ breastfeeding	15(25.0)	45(75.0)	**12.47(6.62, 23.5)** ǂ	2.47(0.35, 17.43)
Before delivery	18(2.0)	880(98.0)	1	1
Maternal duration on ART until delivery (in months)				
Median (IQR)	0(0-26)	37(5-74)	**0.98(0.97, 0.99)** ǂ	1.0(0.99, 1.01)
Infant's feeding practice				
Mixed feeding	13(21.7)	47(78.3)	**9.73(5.1, 18.59)** ǂ	**1.83(1.45, 2.3)**ǂ
EBF***	20(2.2)	878(97.8)	1	1
Infant received ARV prophylaxis				
No	20(26.7)	55(73.3)	**18.11(9.39, 34.95)** ǂ	**3.26(1.6, 6.64)**ǂ
Yes	13(1.5)	870(98.5)	1	1

®High risk: commercial sex workers and daily laborers; ®®Low risk: housewife, employee, merchant, student; *ANC: antenatal care; **ART: antiretroviral therapy; ***EBF: Exclusive breastfeeding; ǂP-value < 0.05.

Discussion

In this study, the DTG-based regimen significantly reduced the risk of MTCT of HIV. Conversely, younger age and poor adherence to ART were maternal risk factors for transmitting the

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virus to infants, whereas home delivery, mixed feeding practices, and lack of ARV prophylaxis were infant-related risk factors for MTCT of HIV.

This study revealed that the DTG-based regimen significantly reduced MTCT of HIV compared to the EFV-based regimen. Women receiving DTG-based first-line ART were 44% less likely to transmit the virus to their infants than those receiving EFV-based regimens during PMTCT. This could be because of the significantly higher and rapid viral suppression among women on the DTG-based regimen than the EFV-based regimen.[8,11,29] Contrary to this finding, the study conducted in Botswana showed that there were no significant differences in MTCT of HIV among infants exposed to DTG-based and EFV-based regimens.[30] The difference could be due to the timing of HIV testing, such that the previous study determined an infant's HIV status at less than 96 hours of life, while our study determined the infant's HIV status at the age of 6 weeks using the DNA/PCR test, or at the age of 18 months using the antibody test.[6] The overall incidence of MTCT of HIV among HIV-exposed infants in Southern Ethiopia was 3.44% (95% CI, 2.46-4.81%). The findings of our study are comparable to those of studies conducted in the Amhara region [24,26,31] West Guji Zone [32], and Mekelie City [33]. The similarities might be due to similar treatment protocols (WHO option B plus PMTCT guidelines).[5] However, the incidence is higher than that in studies conducted in different parts of Ethiopia,[25,34] and the WHO's zero new HIV infection target by 2020.[35] This might be related to the study area, such that the present study included mother-infant pairs residing in both rural and urban areas compared to previous studies conducted in urban areas. However, the overall incidence of MTCT of HIV in our study was lower than that in the study conducted in Sidama zone,[12] South Omo,[14] Bahir Dar,[27] Gondar,[36] West Gojam,[37] University of Gondar,[38] Jimma,[39] and Addis Ababa.[40] The variation might be due to the difference in drug regimens, such that the present study included mothers on a DTG-based regimen, which rapidly lowered the viral load status[8,29] and decreased the chance of MTCT of HIV compared to other studies that included mothers on an EFV-based regimen. Thus, DTG-based first-line ART regimen supplementation should be sustained to achieve global and national targets for zero new infections in HIV-exposed infants.

In this study, the place of delivery was a risk factor for MTCT in patients with HIV. In this regard, the risk of acquiring the virus from mothers was 3.61 times higher among infants born at home than among those born at a health facility. This finding is consistent with a study conducted in the Amhara region,[13,18,22,24] Addis Ababa,[15] Dire Dawa,[17] and Southern Ethiopia.[21] This might be because mothers who gave birth at home could not receive PMTCT services available at health facilities, such as active management of labor with partographs, infection prevention practices, safe delivery practices, and lack of ARV prophylaxis for their infants.[4,41] This could increase the chance of transmitting the virus to their infants compared to those delivered at a health facility. In addition, mothers who practiced home delivery are unlikely to have attended ANC during their pregnancy, and thus might have missed the opportunity to take PMTCT drugs during ANC.[42] The concerned body should focus on activities to mobilize and create awareness among pregnant women to attend institutional delivery.

In our study, the lack of ARV prophylaxis at birth was another risk factor for MTCT in patients with HIV. Infants who did not start ARV prophylaxis at birth were 3.26 times at higher risk of acquiring HIV than those who received prophylaxis. This finding is in line with studies conducted in South Omo,[14] Dire Dawa,[17] Oromia region,[20] Dessie,[24] Bahir Dar,[27] Tigray,[43] and eight regions of Ethiopia[44] where ARV prophylaxis for infants was a determinant factor for MTCT in HIV. Lack of ARV prophylaxis makes infants unprotected from exposure during pregnancy, labor, and delivery, which increases the risk of HIV acquisition.[4] Thus, early identification of maternal HIV status and provision of ARV prophylaxis for exposed infants should be augmented to decrease the risk of HIV infection.

This study also revealed that mixed-feeding practices are predictors of HIV infection among HIV-exposed infants. Our study showed that infants who had mixed feeding practices before the age of six months were 1.83 times more likely to acquire the virus than those who practiced exclusive breastfeeding. This finding is similar to those of studies conducted in different parts of Ethiopia: Addis Ababa,[15] Oromia region,[20] Bahr Dar,[27] West Gojam,[37] and Gondar.[18,38] The gut micro-biome of exclusively breastfed infants has dominant protective gut bacteria that utilize the complex sugars in

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human milk.[45] Lack of a gut protective barrier among infants with mixed feeding practices causes irritation and laceration of the immature gastrointestinal tract.[10] This may cause microscopic cuts in the mucosal tissues and subsequent promotion of viral entry into the infant's bloodstream and progression of HIV infection among infants with mixed feeding practices compared to exclusive breastfeeding practices.

This study also showed that maternal age at enrolment in PMTCT care was a determining factor for MTCT of HIV. Thus, for every one-year increase in maternal stay on PMTCT care, the incidence of HIV transmission to infants was reduced by 7%. This finding is inconsistent with studies conducted in Gojam[16] and Kinshasa[46], where infants born from younger mothers were less likely to acquire HIV infection than older mothers. This discrepancy might be due to the study period in which the previous studies were conducted at an early period of PMTCT intervention, when mothers had no earlier experience with infants' outcomes. Thus, older mothers might be motivated by their experience of having an uninfected infant and, therefore, adhere to providers' recommendations more than younger mothers do.

According to the current study, mothers who poorly adhered to ART were approximately six times more likely to transmit the virus to their infants than those with good ART adherence. This finding is consistent with those of studies conducted in Sidama[12], West Amhara[13], Addis Ababa,[15] and Southern Ethiopia.[21] This could be because poor ART adherence can cause treatment failure, which may increase the viral load status, leading to an increased risk of MTCT.[47–49] Therefore, healthcare workers in the PMTCT unit should strengthen adherence counselling to achieve the required adherence status of 95% and above by their clients to prevent MTCT of HIV in the study area.[4,10]

This study included a larger sample size and covered a wider geographic area than those previous studies in Ethiopia. However, certain methodological limitations should be considered when applying these results. First, there may be measurement and recording errors owing to the nature of secondary data. Second, mother-infant pairs who were transferred out and lost to follow-up were excluded from the analysis due to incomplete data. The results of this study may have been underestimated because those excluded from the analysis were at a higher risk of transmitting the virus than those included in the study.

Conclusion

The DTG-based regimen was more effective in preventing MTCT of HIV infection than the EFV-based regimen. Moreover, the overall incidence of HIV infection among infants born to HIV-positive mothers was lower than the national and WHO targets of 5% in breastfed infants. Thus, DTG-based first-line ART regimen supplementation should be sustained to achieve global and national targets for zero new infections among HIV-exposed infants.

Author Contributions: WF was involved in conception, study design, execution, statistical analysis, and interpretation, and drafted the manuscript. TT and EW were involved in the project concept, guidance, analysis, validation, interpretation of data, and critical review. AA was involved in the project concept, guidance, analysis, data curation and validation, interpretation of data, and critical review. All the authors have read and approved the final manuscript.

Funding: This research received no specific grants from any funding agency in the public, commercial, or not-for-profit sector.

Ethics approval and informed consent: Ethical approval and clearance were obtained from the Institutional Review Board (IRB) of the College of Health Sciences and Medicine, Wolaita Sodo University (ethical approval number WSU41/32/223). Since the data were retrieved from records of mother-infant pairs, informed consent for study participants was waived by IRB ethical clearance.

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The confidentiality of patient-related data was maintained by avoiding possible identifiers, such as the names of the mothers and their infants; only numerical identification was used as a reference.

Consent for publication: Not applicable

Data availability: All data generated or analyzed during this study are included in this article and are available whenever requested.

Acknowledgments: The authors acknowledge the staff of the South and Central Ethiopia Regional Health Bureau for their technical and logistical support. Moreover, the authors sincerely thank all the data collectors and staff working in the PMTCT and ART units at the surveyed health facilities for their patience and cooperation during the entire data collection period.

Competing interests: The authors declare that they have no competing interests.

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Abbreviations

ART: Antiretroviral Therapy; ARV: Antiretroviral; aRR: adjusted risk ratio; CI: confidence interval; CRR: crude risk ratio; DNA-PCR: Di-ribonucleic acid polymerase chain reaction; 3TC: Lamivudine; DTG: Dolutegravir; EFV: Efavirenz; HIV: Human Immunodeficiency Virus; IQR: Interquartile Range; MTCT: Mother to Child Transmission; PMTCT: Prevention of Mother to Child Transmission; TDF: Tenofovir; WHO: World Health Organization

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