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Case Report

Exploring the Efficacy and Safety of Dolutegravir Plus Lamivudine as a Two-Drug Regimen in Pregnancy: A Case Series of ART-Naïve Women living with HIV

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Abstract

Introduction: The two-drug regimen (2DR) comprising dolutegravir (DTG) and lamivudine (3TC) has been shown to be effective and tolerable in non-pregnant populations, but evidence regarding its safety and efficacy in pregnant women, particularly those newly diagnosed with HIV, remains scarce. This case series describes the maternal virological and immunological outcomes, pregnancy management, and neonatal health in five ART-naïve pregnant women treated with DTG/3TC.

Methods: We retrospectively evaluated five pregnant women diagnosed with HIV, ART-naïve who initiated treatment with DTG/3TC during the second or third trimester. Data collected included baseline HIV-RNA levels, CD4 counts, timing of ART initiation, maternal virological suppression at delivery, mode of delivery, and neonatal HIV and health status. Additional variables included maternal obstetric history, adherence to treatment, and the use of intrapartum antiretroviral prophylaxis.

Results: ART was initiated during the second trimester in four women and the third trimester in one. Four achieved undetectable HIV-RNA levels (<20 copies/mL) by delivery, while one had low-level viremia (HIV-RNA 53 copies/mL). Maternal CD4 counts improved across all cases, with no adverse drug reactions reported. Obstetric management included caesarean delivery for

three women due to prior surgical history or detectable viremia and vaginal delivery for two women. Neonatal outcomes were universally favourable, with all infants testing HIV-negative during follow-up and no congenital anomalies observed. Three neonates were classified as high-risk for perinatal transmission due to maternal viremia or late diagnosis and received enhanced post-exposure prophylaxis with three antiretrovirals, while two received zidovudine monotherapy.

Conclusions: This case series demonstrates that the DTG/3TC regimen can achieve rapid virological suppression and favourable pregnancy outcomes in ART-naïve pregnant women. Its use may be particularly relevant in situations where traditional three-drug regimens are contraindicated or not tolerated. While the findings support its potential as a viable therapeutic option, further prospective studies are needed to confirm its safety and efficacy in this population.

Keywords: Dolutegravir; Lamivudine; Two-drug regimen; HIV; Pregnancy; Antiretroviral therapy; Maternal outcomes; ART-naïve women.

Keyword Abbreviations: NA: Non-applicable; TDN: Target Not Detected (<20 cp/ml); RV: Residual Viraemia (>20 cp/ml); 2DR: Two-Drug Regimen; DTG: Dolutegravir; NRTI: Nucleoside Reverse Transcriptase Inhibitor; INSTI: Integrase Strand Transfer Inhibitor; LMP: Last Menstrual Period.

Introduction

Globally, approximately 1.3 million women and adolescent girls living with HIV become pregnant annually, highlighting the importance of effective interventions to prevent perinatal transmission. Without antiretroviral therapy (ART), the risk of mother-to-child transmission (MTCT) of HIV during pregnancy, labour, delivery, or breastfeeding ranges between 15% and 45% [1]. However, in women achieving virological suppression (HIV-RNA <1000 copies/mL) through ART, the perinatal transmission rate decreases significantly to approximately 1% [2]. Achieving and maintaining virological suppression remains the cornerstone of preventing vertical transmission, with antiretroviral prophylaxis playing a pivotal role [3].

Zidovudine (ZDV) monotherapy was the first attempt to control HIV replication. Soon after, two-drug combinations became the preferred strategy, as ZDV effects lasted only for the short term due to the selection of resistance mutations. Unfortunately, the dual strategy also failed to achieve long-lasting virologic control. Combination antiretroviral therapy (ART), containing three active drugs from at least two different classes, has been the standard of care for HIV treatment worldwide since 1996, based on findings from seminal studies [4-5].

The introduction and widespread use of ART have dramatically improved the life expectancy and quality of life for women living with HIV, enabling many to make informed decisions about pregnancy [6-10]. Routine HIV screening during pregnancy facilitates early detection and timely initiation of therapy. Despite these advancements, managing HIV in pregnancy faces critical gaps, particularly concerning the safety and efficacy of newer ART regimens. Pregnant women are frequently excluded from phase 1, 2, and some phase 3 clinical trials, resulting in significant knowledge gaps [11-14]. This exclusion poses potential risks, including insufficient safety data for new therapies that may lead to unacceptable fetal or maternal risks, and a lack of pregnancy-specific pharmacokinetic data that can result in toxicity or suboptimal dosing. Furthermore, delayed evidence generation restricts access to next-generation antiretrovirals for this population [15,16].

For ART-naïve patients, guidelines strongly recommend initiating treatment early to reduce maternal viral load and prevent transmission [17-19]. Pregnant women should be closely monitored throughout gestation, with more frequent evaluations during the third trimester and near delivery. For women with HIV-RNA >50 copies/mL at 34–36 weeks, elective caesarean delivery at 38 weeks is advised to minimize transmission risk [20-23]. Intrapartum intravenous zidovudine (2 mg/kg as a loading dose followed by a 1 mg/kg/hour infusion) is recommended to further reduce transmission risk. All new-borns should receive post-exposure prophylaxis (PEP) according to local protocols, and exclusive formula feeding is advocated to prevent postnatal transmission in settings where safe alternatives to breastfeeding are available [24,25].

Preferred ART regimens during pregnancy include dolutegravir (DTG) combined with two nucleoside reverse transcriptase inhibitors (NRTIs), such as abacavir/lamivudine (ABC/3TC), tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) or tenofovir alafenamide/emtricitabine (TAF/FTC). Alternative regimens include two NRTIs combined with either a protease inhibitor boosted with ritonavir (PI/r) or a non-nucleoside reverse transcriptase inhibitor (NNRTI) [26,27].

Dolutegravir (DTG) is a potent integrase strand transfer inhibitor (INSTI), exhibiting rapid reduction in viral load (VL) and a high barrier to resistance. DTG is a once-daily (QD) drug that is well tolerated, can be taken with or without food, has a low potential for drug–drug interactions, and exhibits a high genetic barrier

to resistance [28]. Lamivudine (3TC) is a cytidine nucleoside analogue with minimal side effects and a well-established safety profile. Like DTG, 3TC is a QD drug that can be administered with or without food, with no significant drug–drug interactions [29].

The DolPHIN-1 and DolPHIN-2 studies, along with the IMPAACT 2010/VESTED trial, have demonstrated superior virological suppression at delivery with dolutegravir-based regimens compared to efavirenz-containing regimens. These studies report no significant differences or a lower incidence of adverse birth outcomes when dolutegravir is initiated in early or late pregnancy [29].

Previous studies, such as those reported in The Lancet, have demonstrated that dolutegravir plus lamivudine (DTG/3TC) achieves virological suppression (<50 copies/mL) rates comparable to triple ART regimens, with suppression observed in 93% of patients at 48 weeks [30]. These findings underscore the potential of DTG/3TC as an effective two-drug regimen in ART-naïve patients.

Although combination ART (3-drug regimens, 3DRs) remains the preferred therapy during pregnancy, this case series aims to explore whether the two-drug regimen (2DR) of dolutegravir and lamivudine offers a viable alternative for ART-naïve pregnant women diagnosed with HIV.

Case Descriptions

Each case is presented with details on the patient's demographic information, clinical history, diagnostic findings, antiretroviral therapy initiation, pregnancy management, and outcomes.

Case 1

A 26-year-old woman from the Ivory Coast was diagnosed with HIV during routine prenatal screening at 20 weeks of gestation. Initial laboratory investigations revealed an HIV-RNA viral load of 296 copies/mL and a CD4 count of 388 cells/mm³. Hepatitis B serology indicated a prior infection with positive hepatitis B core antibodies (HBcAb) and protective hepatitis B surface antibody (HBsAb) titers. HLA-B*5701 testing was positive, guiding the selection of antiretroviral therapy (ART). Dolutegravir/lamivudine (DTG/3TC) was initiated at 23 weeks of gestation. Two weeks after the initiation of ART, the patient achieved undetectable HIV-RNA levels (<20 copies/mL). At term, the patient delivered vaginally a healthy female infant without complications. The infant received post-exposure prophylaxis (PEP) with zidovudine for four weeks and tested HIV-negative during follow-up assessments.

Case 2

A 29-year-old Italian woman with an otherwise uncomplicated pregnancy initially tested HIV-negative during routine first-trimester screening. At the beginning of the third trimester, she presented with a history of flu-like symptoms and was found to be HIV-positive at 32 weeks of gestation. Laboratory evaluations revealed an HIV-RNA viral load of 36,500 copies/mL and a CD4 count of 381 cells/mm³. The patient had received prior hepatitis B vaccination. ART with DTG/3TC was initiated immediately while awaiting HLA-B*5701 results. Therapeutic drug monitoring (TDM) confirmed optimal dolutegravir levels. After 15 days of therapy, HIV-RNA levels became undetectable. Due to the late diagnosis and high viremia at presentation, the patient was classified as high risk. She underwent a caesarean section at term, and intrapartum intravenous zidovudine was administered. The infant was started on enhanced PEP with a three-drug regimen (zidovudine, lamivudine, and nevirapine) for six weeks and tested HIV-negative during follow-up. No congenital anomalies were noted.

Case 3

A 34-year-old Romanian woman presented at 23 weeks of gestation and was diagnosed with HIV during prenatal screening. She had not undergone first-trimester screening and reported a history of a prior pregnancy two years earlier with a documented HIV-negative status. Additionally, she had undergone emergency surgery for an ectopic pregnancy the year before, during which HIV testing had not been performed. At the time of diagnosis, laboratory investigations revealed an HIV-RNA viral load of 9,554 copies/mL and a CD4 count of 397 cells/mm³. Hepatitis B serology was negative. The patient was immediately started on ART with DTG/3TC. Two weeks after initiating therapy, her HIV-RNA levels became undetectable. Given her obstetric history, she underwent a caesarean section at term and delivered a healthy infant. The infant received PEP with zidovudine for four weeks and tested HIV-negative during follow-up evaluations.

Case 4

A 36-year-old Italian woman, aware of her HIV diagnosis for two years, was referred for antenatal care at 15 weeks of gestation. She reported a prior attempt at ART with dolutegravir plus tenofovir alafenamide/emtricitabine (DTG + TAF/FTC) but had discontinued therapy after a few days due to gastrointestinal side effects. At the time of referral, her HIV-RNA viral load was 1,050 copies/mL, and her CD4 count was 759 cells/mm³. She had been vaccinated against hepatitis B. Based on her history of intolerance to other regimens, ART with DTG/3TC was initiated. Within two weeks of treatment initiation, her HIV-RNA levels became undetectable. The patient delivered at term without complications, and her infant, who received PEP with zidovudine for four weeks, tested HIV-negative during follow-up.

Case 5

A 23-year-old Nigerian woman presented to care after being newly

diagnosed with HIV during pregnancy. Laboratory tests at the time of diagnosis showed an HIV-RNA viral load of 209,577 copies/mL and a CD4 count of 101 cells/mm³. Hepatitis B serology was negative. The patient reported menstrual irregularities and did not initially associate her amenorrhea with pregnancy. An ultrasound revealed a gestational age of 22 weeks. ART with DTG/3TC was initiated immediately and continued after the pregnancy was confirmed. Following treatment, HIV-RNA levels decreased rapidly, but at delivery, residual viremia of 53 copies/mL was detected. Given her detectable viremia, a caesarean section was performed at term. The infant was classified as high risk and was started on enhanced PEP with a three-drug regimen (zidovudine, lamivudine, and nevirapine) for six weeks. Follow-up testing confirmed the infant was HIV-negative, and no congenital anomalies were reported.

Material & Methods

This case series included five pregnant women living with HIV, ART-naïve, who started an antiretroviral treatment during gestation with a once-daily, two-drug antiretroviral regimen (dolutegravir/lamivudine [DTG/3TC]). All patients provided informed consent for the use of their anonymized clinical data in this study.

Study Variables

The primary variables investigated included maternal HIV-RNA levels and CD4 cell counts at three time points: at diagnosis, during the second and third trimesters, and at delivery. Additional parameters included the timing of antiretroviral therapy (ART) initiation, mode of delivery, and neonatal HIV-1 status.

Data Collection

Clinical data were retrospectively collected from patient medical records. Information gathered included maternal sociodemographic characteristics (age, nationality, and obstetric history), clinical parameters (HIV-RNA levels, CD4 counts, and hepatitis B status), laboratory findings, and treatment details. Obstetric variables, including gestational age at ART initiation, timing of first prenatal care, and mode of delivery, were also documented. Neonatal outcomes were assessed through HIV testing results, post-exposure prophylaxis regimens, and evaluations for congenital anomalies.

Gestational Age Determination

Gestational age was calculated using the date of the last menstrual period (LMP) and confirmed via first-trimester or early second-trimester ultrasound assessments, where available.

Ethical Considerations

This study was conducted in accordance with institutional guidelines and ethical standards. Ethical approval was not required for this retrospective analysis as it involved anonymized patient data, and all participants had provided prior consent for their data to be used in research.

Results

This case series evaluated five antiretroviral therapy (ART)-naïve pregnant women diagnosed with HIV during gestation and treated with dolutegravir/lamivudine (DTG/3TC).

Baseline Characteristics

The baseline demographic, clinical, and laboratory characteristics of the cohort are summarized in Table 1. The patients ranged in age from 23 to 36 years and were ethnically diverse, including two Italian, one Romanian, one Ivorian, and one Nigerian woman. All patients were diagnosed with HIV during the second or third trimester. CD4 counts at diagnosis ranged from 101 to 759 cells/mm³, and HIV-RNA levels ranged from 296 to 209,577 copies/mL. One patient had prior ART exposure, which was discontinued due to intolerance.

Maternal ART

The decision to initiate DTG/3TC was guided by individual clinical circumstances, including the absence of HLA-B5701 data, presence of HLA-B5701 positivity, intolerance to abacavir or tenofovir-based regimens, and patient preference. The regimen was well-tolerated in all cases, with no reported adverse effects.

Maternal Virological Outcomes

Four of the five patients achieved complete virological suppression (HIV-RNA <20 copies/mL) by delivery. One patient exhibited low-level detectable viremia (HIV-RNA 53 copies/mL) at delivery despite a rapid decline in viral load following ART initiation in the third trimester. CD4 counts improved across all patients during pregnancy.

Pregnancy Outcomes

Details of delivery modes are summarized in Table 2. Two patients had spontaneous vaginal deliveries, while three underwent caesarean sections due to obstetric indications or elevated risk of vertical transmission. The patient with residual viremia received intrapartum intravenous zidovudine to further mitigate transmission risk.

Neonatal Outcomes

All five infants were born at term with appropriate birth weights and no reported neonatal malformations. Postpartum lactation suppression with cabergoline was implemented in all cases, and exclusive formula feeding was used.

Infants born to mothers with virological suppression (HIV-RNA <50 copies/mL) and good adherence to ART in the four weeks

preceding delivery were categorized as "low risk" for perinatal HIV transmission. These infants received zidovudine monotherapy for four weeks. Two infants were classified as "high risk" and received enhanced post-exposure prophylaxis (PEP) with a three-drug regimen (zidovudine, lamivudine, and nevirapine) for six weeks. High-risk classifications were based on:

1. Detectable maternal viremia at delivery (HIV-RNA 53 copies/mL).
2. Late maternal HIV diagnosis during the second trimester.
3. Maternal seroconversion in the third trimester.

Follow-Up

All infants tested HIV-negative on follow-up evaluations. No significant adverse neonatal outcomes or congenital anomalies were reported in this cohort.

Variable	Frequency (n)	Percentage (%)
Timing of ART Initiation		
- Before conception	0	0%
- First trimester	0	0%
- Second trimester	4	80%
- Third trimester	1	20%
Nationality		
- Italian	2	40%
- Other	3	60%
Age at Conception		
- < 25 years	1	20%
- 25–34 years	3	60%
- ≥ 35 years	1	20%
Timing of First Prenatal Care		
- First trimester	1	20%
- Second trimester	4	80%
- Third trimester	0	0%
- Labor or delivery	0	0%
Education Level		
- At least high school graduation	2	40%
Lifestyle Factors		
- Tobacco use during pregnancy	1	20%
- Alcohol use during pregnancy	1	20%
- Other substance use during pregnancy	0	0%
STI or Vaginitis Diagnosed During Pregnancy	1	20%

Table 1: The baseline demographic, clinical, and laboratory characteristics of the cohort.

PT	HIV-RNA cp/ml I Trim	HIV-RNA cp/ml III Trim	HIV-RNA cp/ml III Trim	HIV-RNA cp/ml at delivery	Delivery	Neonatal post-exposure prophylaxis
1	NA	296	TDN	TDN	Vaginal	AZT
2	NA	NA	36500	TDN	Elective cesarian	AZT + 3TC + NVP
3	NA	9554	20	TDN	Elective cesarian	AZT
4	NA	1050	TDN	TDN	Vaginal	AZT
5	NA	209,577	775	53	Elective cesarian	AZT + 3TC + NVP

NA: not applicable; TDN: target not detected.

Table 2: Details of delivery modes.

Discussion

Our findings are consistent with previous studies that demonstrated demonstrates the long-term virologic efficacy of the 2DR DTG/3TC in naïve patients. These data strengthen the case for DTG/3TC as a viable alternative to traditional triple therapy in women living with HIV ART- naïve, particularly for patients with adherence or tolerance challenges.

Conclusion

This case series demonstrates that the two-drug regimen (2DR) of dolutegravir and lamivudine (DTG/3TC) may serve as a viable and effective therapeutic option for ART-naïve pregnant women living with HIV. The regimen was well-tolerated, achieved rapid virological suppression in most patients, and was associated with favourable maternal and neonatal outcomes. These findings highlight its potential utility, particularly in cases where traditional three-drug regimens (DTG + 2NRTIs) are contraindicated or poorly tolerated.

The primary limitation of this study is its small sample size, which restricts generalizability and necessitates caution in extrapolating these results to broader populations. Additionally, the retrospective nature of the study precludes prospective evaluation of adherence and long-term outcomes.

The selection of DTG/3TC as a therapeutic option during pregnancy should be made on a case-by-case basis, with careful consideration of individual clinical circumstances, patient preferences, and adherence monitoring. Close maternal and fetal surveillance remains essential to ensure optimal outcomes.

Further large-scale, prospective studies are urgently needed to establish the safety, efficacy, and long-term impact of DTG/3TC in pregnant populations. These studies will provide critical insights into its role as part of standard care for HIV-infected pregnant women, particularly those presenting late in pregnancy or with contraindications to traditional regimens.

Disclosure

Competing Interests: LP is in the advisory board for Gilead Science, ViiV Healthcare, and Johnson & Johnson. She's in the speaker's bureau for ViiV-Healthcare, Gilead Science, MDS, Johnson & Johnson., Abbvie. RG is in the advisory board for Gilead Science, ViiV Healthcare, and Merck Sharp & Dohme (MDS). He is in the speaker's bureau for ViiV-Healthcare, Gilead Science, MDS, Johnson & Johnson., Abbvie. He receives educational/research founding from ViiV-Healthcare, Gilead Science. The other authors declare no competing interests or conflicts of interest relevant to this study.

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Ethical Approval: This study adhered to the ethical principles

outlined in the Declaration of Helsinki. Ethical approval was not required as this study involved a retrospective analysis of anonymized data. Informed consent was obtained from all participants for the use of their data in research.

Data Availability Statement: The data supporting this study are available from the corresponding author upon reasonable request.

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