Antiretroviral Drug Regimens and Pregnancy Outcomes

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Panel's Recommendations
• Given the clear and proven benefits of HIV treatment in pregnancy, antiretroviral therapy (ART) should not be withheld due to concern for possible associations with adverse neonatal and pregnancy outcomes **(AII).** • ART use should not be avoided or withheld before conception or in early pregnancy for the purpose of preventing preterm birth **(AII).** • ART should not be avoided or withheld to prevent hypertensive disorders of pregnancy (HDP) or stopped if HDP develop **(AIII).** • Enhanced antenatal surveillance of fetal growth in the third trimester may be considered for pregnancy in the setting of HIV, especially those who are prescribed ART with boosted protease inhibitors, due to the increased risk for low birth weight or small-for-gestational-age infants **(CIII).**
Rating of Recommendations: *A = Strong; B = Moderate; C = Optional* ***Rating of Evidence:*** *I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion*

In this section, the Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission (the Panel) provides a summary of data published in the preceding 10 years on antiretroviral therapy (ART) and adverse pregnancy outcomes. Regardless of antiretroviral (ARV) drug use, there may be increased risk for adverse neonatal outcomes for pregnancy with HIV. These outcomes may include preterm birth (PTB) (delivery before 37 weeks of gestation), low birth weight (LBW) infants (those weighing <2,500 g), small-for-gestational-age (SGA) infants (those with a birth weight <10th percentile expected for gestational age and sex), and stillbirth (delivery of a nonviable infant after 20 weeks). The gestational age cutoff used to define stillbirth in the studies described varies between ≥20 weeks and ≥28 weeks. Limited data suggest a potential association between HIV infection and hypertensive disorders of pregnancy (HDP) (i.e., chronic hypertension, gestational hypertension, preeclampsia, and eclampsia). As a result of variable study periods, some of the data described in this section involve historical ARV drugs that are no longer commonly prescribed. For additional historical data related to this topic, please refer to the archived versions of this section. For information related to ARV drug use and teratogenicity (i.e., their relation to birth defects), please refer to Teratogenicity and the individual drug sections in Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy and Table 14. Antiretroviral Drug Use in Pregnancy: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy.

Interpretation of Adverse Pregnancy Outcomes Data

Multiple studies have evaluated the potential association between ARV drug use and PTB, LBW, SGA, and stillbirth with conflicting results. These adverse outcomes often occur without an identifiable cause, and it can be difficult to establish a causal link with medication exposure. Adverse pregnancy outcomes are relatively common, so a small increase in risk can have substantial public health impact.

Much of the conflicting data in earlier studies about ARV drugs and adverse pregnancy outcomes can be ascribed to the use of inappropriate comparison groups and failure to stratify the data by timing of ARV drug initiation (before or after conception). Pregnancies impacted by HIV during which ART is not used are not an appropriate comparator for pregnancies during which ART is used because of an increased risk of adverse outcomes due to immunocompromised status. Comparing ART use during pregnancy to pregnancies that are not impacted by HIV is confounded by HIV status. In the setting of limited data, the Panel may reference studies with these comparators.

Some evidence suggests that the risk of adverse outcomes varies by ARV drug—even within ARV drug classes—and the timing of ART initiation. A suggested approach to evaluate ART and pregnancy outcomes is to use a comparative safety approach in which ARV drug regimens or ARV drug classes are compared with each other. Studies evaluating the safety of newer ART, specifically integrase strand transfer inhibitors (INSTIs), on pregnancy outcomes are reassuring.[1] More studies are needed to fully evaluate the association between the risk of adverse pregnancy outcomes and the use of specific ARV drugs, classes of ARV drugs, and ART.

Preterm Birth

Multiple meta-analyses and systematic reviews have evaluated the potential association of ARV drug use and PTB, and most have not demonstrated a significant association between ARV use and PTB. The sample sizes pooled for these meta-analyses ranged from 13 to 90 studies and included 11,224 to 37,877 women and/or infants. Most of the studies that were included were observational studies, and most were older studies that do not include ARV drugs currently used.[2-7] A large meta-analysis of 61 observational studies (n = 409,781) compared the risk of PTB in ART-naive women and women with HIV who were prescribed zidovudine (ZDV) single-drug therapy or ART. Although the risk of any PTB in women with HIV who were prescribed ART compared with ART-naive women with HIV was not significantly different, women who were prescribed ART were less likely to experience spontaneous PTB (relative risk 0.46; 95% confidence interval [CI], 0.32–0.67).[5] Another meta-analysis compared pregnancy outcomes between women with HIV who received tenofovir disoproxil fumarate (TDF)–based regimens and women who received regimens that did not contain TDF. This study found no difference in the risk of PTB between these two groups.[2]

Multiple observational studies describe an association between the use of ARV drugs during pregnancy and an increased risk of PTB.[4,8-19] In general, the observational studies reviewed in this section have not comprehensively controlled for all factors that may be associated with PTB. An observational study that evaluated ARV drug use among women with HIV in British Columbia reduced confounding variables by excluding multiple gestation pregnancies and antiquated ARV drug regimens (i.e., single-drug therapy, two-drug therapy, and triple nucleoside reverse transcriptase inhibitor [NRTI] regimens). The authors concluded that women with HIV were twice as likely to experience PTB as the general population. Women with HIV on any ART were less likely than women with HIV not on ART to have spontaneous PTB (hazard ratio [HR] 0.54; 95% CI, 0.29–1.04), and the protective effect for each week of ART was cumulative (HR 0.98; 95% CI, 0.96–0.99). Neither preconception nor first-trimester ARV use was associated with PTB.[20]

Antiretroviral Therapy and Preterm Birth

Integrase Strand Transfer Inhibitor–Based Regimens

INSTIs are a preferred class of ARV drug for HIV treatment in pregnancy. Compared to other ARV drug classes, INSTI use does not appear to be associated with an increased risk of PTB. In the VESTED International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) randomized controlled trial (RCT) comparing pregnant participants receiving efavirenz (EFV)/TDF/

emtricitabine (FTC) (n = 207), dolutegravir (DTG)/TDF/FTC (n = 202), and DTG/tenofovir alafenamide (TAF)/FTC (n = 208), women taking ART with EFV were more likely to experience PTB than women taking ART with DTG/TAF/FTC (12% vs. 6%; 95% CI, -11.8% to -0.9%; *P* = 0.02). The percentage of PTB was similar between DTG ART groups.[21]

Observational studies of INSTI use during pregnancy have not reported an association with an increased risk of PTB when compared with non-INSTI ART. Additionally, when compared with one another, individual INSTIs have not been associated with an increased risk of PTB.[16] Very limited data suggest no association between the use of long-acting injectable cabotegravir in combination with rilpivirine during pregnancy and PTB.[22] However, this dataset was too small to make definitive conclusions regarding adverse neonatal and pregnancy outcomes. In conclusion, INSTI use in pregnancy has not been associated with an increased risk of PTB compared to other ARVs.

Nucleoside Reverse Transcriptase Inhibitor–Based Regimens and Non-nucleoside Reverse Transcriptase Inhibitor–Based Regimens

Data regarding an association between NRTI and non-nucleoside reverse transcriptase inhibitor (NNRTI)–based ART and PTB are inconclusive. A meta-analysis of 17 studies of women with HIV who were on ART (n = 37,877) compared those on TDF regimens with women who were on regimens that did not include TDF. TDF-based ART was associated with a modest reduction in the rate of PTB (relative risk 0.9; 95% CI, 0.81–0.99; I^2 = 59%).[2] Some observational studies have shown an association between the use of NRTI-based regimens and PTB, but there are conflicting reports.[23]

Protease Inhibitor–Based Regimens

The association between the use of protease inhibitor (PI)–based ART and PTB has been investigated in multiple studies across Europe, North America, and Africa.[8,10,12,13,15,24-28] Not all the studies reviewed for this section have identified an association between PI use and an increased risk of PTB.[10,20,24,29,30]

A meta-analysis of 10 studies (8 prospective cohort studies, 1 RCT, and 1 surveillance study) demonstrated that the use of PI-based ART is associated with an increased risk of PTB, with an adjusted odds ratio of 1.32 (95% CI, 1.04–1.6) and I^2 = 47% (moderate heterogeneity). When evaluating the effects of initiating PI-based ART during the first and third trimesters of pregnancy, the pooled effect was not significant.[31] A network meta-analysis of seven RCTs evaluated seven different ART regimens and their associations with PTB, including spontaneous PTB in three trials. When compared with women prescribed ZDV/lamivudine (3TC)/abacavir, women prescribed ZDV/3TC/lopinavir/ritonavir (LPV/r) had an increased risk of spontaneous PTB (n = 991; relative risk 1.81; 95% CI, 1.21–2.71).[26] Another meta-analysis using data from 34 observational studies (n = 57,546) evaluated differences in infant outcomes between pregnant women with HIV prescribed PI-based and non-PI-based ART.[32] PI-based ART was not associated with an increased risk of PTB. In subanalyses, the authors compared individual PI ARV drugs and determined that women prescribed LPV/r were more likely to experience PTB than women prescribed nelfinavir (relative risk 1.33; 95% CI, 1.03–1.72; I^2=0%; four studies; n = 1,937 women). Compared with women prescribed non-boosted PI-based ART, women prescribed boosted PIs were more likely to experience PTB (relative risk 1.36; 95% CI, 1.12–1.65; I^2=0%; five studies; n = 3,333).[32] These authors performed a subsequent systematic review and meta-analysis of 18 studies (n = 32,883) and reported that PI-based ART was not more likely to be associated with PTB when compared to NNRTI-based ART (relative risk 1.08; 95% CI, 0.93–1.25). In a subanalysis of these data, LPV/r-based ART was associated with an increased risk of PTB before 32 weeks of gestation compared to EFV (relative risk 1.66; 95% CI, 1.1–2.5).[7]

ART that includes PIs boosted with ritonavir may be associated with an increased risk of PTB compared with non-boosted PI regimens.[33] Despite this potential association between the use of PI-based ART and PTB, PI-based regimens may be required during some pregnancies. In these cases, the Panel recommends the use of darunavir/ritonavir over LPV/r.[34]

Preterm Birth and Antiretroviral Therapy Exposure Before Pregnancy

A meta-analysis of 24 observational studies (n = 38,293 pregnancies) in 15 countries reported that women initiating ART before pregnancy were at increased risk of PTB compared with women initiating ART during pregnancy (relative risk 1.16; 95% CI, 1.03–1.31; I^2 = 81%).[6] Additional studies have described an association between initiating ART before pregnancy and an increased risk of PTB.[13-15,18,23,27,28,35,36] These studies were conducted in Asia, Europe, Latin America, Africa, and North America and included various ART regimens (including no ART and single-drug, two-drug, and multidrug regimens). The association between PTB and ARV drug use prior to conception is attenuated in some multivariate analyses.[9,13,27,37-39] ART should not be withheld prior to conception or in the first trimester for the prevention of PTB.

Birth Weight

For the purpose of this section, abnormalities of birth weight related to ARV drug use are commonly reported as LBW infants or SGA infants. LBW may reflect constitutionally small infants, growth restriction, and/or preterm birth; SGA may reflect growth restriction or constitutionally small infants. Given that LBW and SGA may be caused by different mechanisms, this section discusses studies that have reported LBW and SGA separately.

Low Birth Weight

In a meta-analysis of 12 studies (n = 40,495), women with HIV on ART were not more likely to birth LBW infants than women with HIV not on ART.[5] A secondary analysis of the MOTIVATE study reported that women prescribed ART before conception and after conception birthed a similar percentage of LBW infants (3.3% and 4.4%, respectively).[39] Although multiple observational studies have reported associations between ARV drug exposure and LBW, these studies are heterogeneous in population, design, and comparison groups.[3,9,11,13,14,16,24,25,28,30,37,40-45] Given this potential association between ARV drug use and LBW, providers may consider additional monitoring for fetal growth abnormalities during pregnancy.

Small for Gestational Age

Infants born to women with HIV may be at risk for SGA.[9,11,14-17,21,23,29,30,37,44,46,47] In a meta-analysis of five studies (n = 6,818), women prescribed ART were more likely to birth SGA infants than women with HIV not on ART (relative risk 1.38; 95% CI, 1.09–1.75).[5] Another meta-analysis (34 studies) reported that women with HIV prescribed PI-based ART are more likely to birth SGA infants than women with HIV prescribed non-PI ART (relative risk 1.24; 95% CI, 1.08–1.43; I^2 = 67%; 11 studies; n = 25,893).[32] A subsequent meta-analysis of 11 studies (n = 24,255) by these authors reported that PI-based ART was associated with SGA when compared to NNRTI-based ART (relative risk 1.28; 95% CI, 1.09–1.51).[7]A systematic review and meta-analysis of 28 studies from 1997 to 2020 reported that PI-based ART was not significantly associated with an increased risk of SGA (pooled odds ratio 1.09; 95% CI, 0.76–1.55).[48] In an RCT, the percentage of SGA infants was similar among women with HIV who were randomized to DTG-based ART (TAF/FTC or TDF/FTC) or EFV-based ART (16%, 23%, and 21%, respectively).[21] In a subsequent analysis of these data, women prescribed DTG/TAF/FTC were more likely to gain weight in accordance with the National Academy of Medicine—formerly the Institute of Medicine—recommendations for pregnancy and were less likely to experience PTB or birth SGA infants.[49] Observational data are mixed regarding an

association with SGA infants and ARV exposure.[28,50,51] Data on the risk of SGA in infants exposed to HIV and/or ARVs, even when considering PI-boosted ART, are mixed.

In summary, data are mixed regarding the effect of ARV drug use on birth weight. Given the potential for LBW or SGA infants, especially in cases where ART was initiated preconception, providers may consider additional monitoring for fetal growth abnormalities during pregnancy.

Stillbirth

Stillbirth is a relatively rare outcome in resource-rich settings, and data related to stillbirth and ARV drug use are limited. In a meta-analysis of 17 studies that included 37,877 women with HIV who were on ART, 3 studies included stillbirth outcomes. Women with HIV who were on TDF-based ART had a lower risk of stillbirth than those who were on other regimens (pooled relative risk 0.6; 95% CI, 0.43–0.84; I^2 = 72%).[2] In another meta-analysis evaluating the difference in stillbirth between PI-based and non-PI-based ART, data from a single study (n = 6,952) reported that PI-based ART was not associated with an increased risk of stillbirth (relative risk 1.04; 95% CI, 0.06–1.79).[32] In a single RCT, the percentage of stillborn infants was not significantly higher among pregnant women randomized to DTG-based ART (3.7% DTG/TAF and 5.2% DTG/TDF) than to EFV-based ART (1.9%).[21]

Some studies have reported an association between HIV infection and stillbirth,[9,16,24,28,35,36,40,42,44,52,53] and other studies do not report an association.[54] Data regarding the timing of ART initiation and stillbirth are mixed, but timing of ART initiation is likely not a factor associated with an increased risk of stillbirth.[53]

Outcomes During Pregnancy

Hypertensive Disorders of Pregnancy

Limited data suggest that women with HIV may have an increased risk of HDP. A single meta-analysis did not reveal a clear association between HIV and HDP.[55] Observational data evaluating an association with HDP and HIV infection, ART use during pregnancy, and timing of ART initiation reported conflicting findings.[56]

Two observational studies have reported a potential association between INSTIs and HDP.[57] Pregestational diabetes has been associated with an increased risk of HDP in two observational studies of women with HIV who were prescribed INSTIs.[58] Although these limited data may suggest an association between HDP and HIV, no known interventions reduce this risk of developing HDP. Providers should not withhold ART in the setting of HDP. Low-dose aspirin to prevent or delay the onset of HDP may be of benefit during some pregnancies with HIV. For more information, please refer to U.S. Preventive Services Task Force recommendations.[59]

Summary

Given that ART has clear benefits for health during pregnancy and reduces the risk of perinatal HIV transmission, ART or specific ARVs should not be withheld due to concern for increased risk of adverse outcomes. Clinicians should monitor for potential pregnancy complications, including PTB, LBW and SGA infants, and HDP.

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