The Effect of Antiretroviral Therapy (ART) on Obstetric Complications Risk in Pregnant Women with HIV: A Scoping Review

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Abstract

Antiretroviral therapy (ART) is a cornerstone in the management of HIV among pregnant women due to its ability to suppress viral load and prevent vertical transmission. However, its effectiveness on pregnancy outcomes remains a challenge because of the potential risk of obstetric complications. This scoping review aimed to map and summarize existing evidence on the association between ART use and obstetric complications among pregnant women living with HIV. The review was conducted using the Arksey and O'Malley framework and reported in accordance with the PRISMA-ScR guidelines. A comprehensive literature search was performed across Scopus, EBSCOhost, PubMed, and ScienceDirect to identify full-text English-language original studies published between 2020 and 2025. Study selection was guided by the Population–Intervention–Outcome framework, focusing on pregnant women with HIV receiving ART and associated obstetric complications. Out of 11,669 identified articles, ten met the inclusion criteria. The findings revealed that initiating ART before pregnancy reduced the risk of small-for-gestational-age (SGA) infants, while regimens based on non-nucleoside reverse transcriptase inhibitors (NNRTIs) and protease inhibitors (PIs) were associated with a higher risk of preterm birth compared to integrase strand transfer inhibitor (INSTI)–based regimens. Low birth weight (LBW) was more frequently observed when ART initiation occurred during the second trimester. Immunological, placental, metabolic, and psychosocial factors were also found to influence pregnancy outcomes. In conclusion, ART management should consider drug type, timing of initiation, and maternal condition to minimize obstetric risks. Future research is recommended to examine the longitudinal effects of ART regimens using a multidimensional approach to achieve more precise and context-specific therapeutic management.

Keywords: antiretroviral therapy, HIV, obstetric labor complications, pregnancy

Introduction

Antiretroviral therapy (ART) is a cornerstone in the management of human immunodeficiency virus (HIV) (Lathifah et al., 2022). This therapy including during pregnancy, due to its effectiveness in suppressing viral load and preventing mother-to-child transmission, which has led to a substantial reduction in vertical HIV transmission rates. However, despite its clear benefits, ART use during pregnancy is not without potential risks. Growing evidence suggests that ART exposure may be associated with short- and long-term adverse pregnancy outcomes, including small-for-gestational-age (SGA) infants, preterm birth, miscarriage, stillbirth, low birth weight, and congenital anomalies (Delicio et al., 2018; Serunjogi et al., 2022; Theron et al., 2021; Tukei et al., 2021; Uthman et al., 2017). In particular, initiation of ART before conception or in early pregnancy and the use of protease inhibitor–based regimens have been linked to a modestly increased risk of preterm birth compared to non-nucleoside reverse transcriptase inhibitor–based regimens (Lary et al., 2023; Williams et al., 2021). These findings highlight a persistent risk–benefit tension in the use of ART during pregnancy, as its life-saving role in preventing vertical transmission must be balanced against potentially increased obstetric risks, which remain inconsistently reported across studies due to variations in ART regimens, timing of initiation, maternal characteristics, and study designs.

The results of studies on the effect of ART on obstetric complications show considerable variability, such as variations in the control group, population characteristics, the mother's immunological status, the type of ART regimen used, and inconsistent outcome definitions (Dube et al., 2023). The heterogeneity of these findings underscores the importance of systematic literature mapping to evaluate the consistency of evidence, identify potential methodological biases, and formulate relevant research agendas, particularly regarding the use of ART regimens. Therefore, this scoping review aims to map and synthesize existing evidence on the association between antiretroviral therapy (ART) use and obstetric complications among pregnant women living with HIV. Given the inconsistent and heterogeneous findings across studies regarding ART regimens, timing of initiation, and reported pregnancy outcomes, this review seeks to clarify the scope of available evidence and highlight key research gaps. The findings are expected to inform future research directions and support evidence-based decision-making in maternal HIV care.

Research Method

This study employed a scoping review design following the Arksey and O'Malley framework and was reported in accordance with the PRISMA-ScR guidelines. The literature search strategy was conducted thru four major databases: Scopus, EBSCOhost, PubMed, and ScienceDirect, using a combination of keywords adapted to Medical Subject Headings (MeSH) and Boolean operators (AND and OR), including "antiretroviral therapy" OR "ART", "HIV", "pregnancy" OR "pregnant women", and "obstetric complications". Inclusion criteria were established using the PIO framework: Population is pregnant women with HIV, Intervention is ART therapy, and Outcome is obstetric complications such as preeclampsia, preterm labor, premature rupture of membranes, hemorrhage, and low birth weight. Studies were included if they were original research articles, reported primary or secondary data on the association between ART exposure and obstetric labor complications, and met the defined PIO criteria. Articles were excluded if they were review papers, case reports, case series, editorials, commentaries, conference abstracts, or opinion articles, or if they did not specifically examine obstetric outcomes related to ART use in pregnant women with HIV. The analyzed articles are full-text articles in English with full access and published within 2020 – 2025.

Results

The selection process was conducted following the PRISMA flowchart, including identification, screening, and eligibility

(Figure 1). Out of a total of 11,669 articles found (324 from Scopus, 3,486 from EBSCOhost, 208 from PubMed, and 7,651 from ScienceDirect), after screening based on publication year, language, and full-text availability, 1,074 articles remained. Further screening based on title and abstract relevance yielded 61 articles, and after excluding studies not focused on obstetric complications due to ART, ten articles were obtained that met the criter

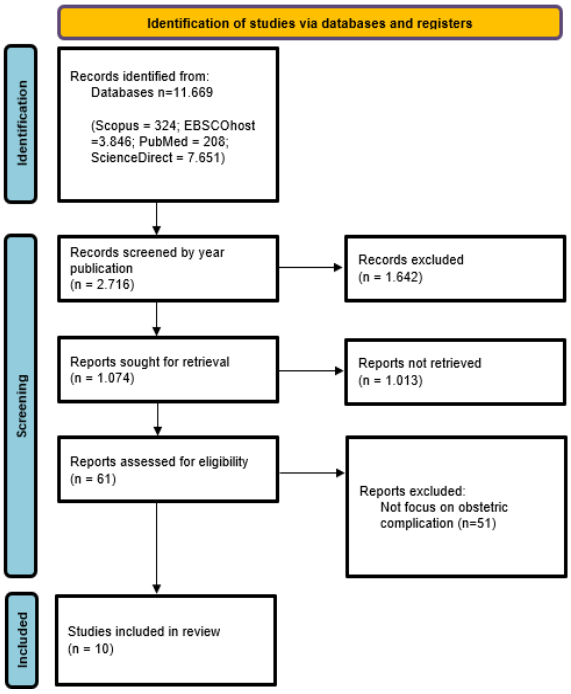

Figure 1. Article selection flow using PRISMA

In Table 1, the general characteristics of ten articles can be seen based on study design, geographical location of the research, and research focus. The majority used a prospective cohort study design (30%), followed by a retrospective cohort study and an observational laboratory/in vitro study (20% each). The majority of the research originated from Canada (30%), followed by South Africa, Malawi, and Tanzania, each contributing 20%, as well as several other countries including Denmark, Kenya, and Botswana. The primary focus of most studies is on pregnancy outcomes such as preterm birth, small for gestational age (SGA), and low birth weight (70%), while others address maternal immunological, metabolic, and mortality status in the ART era.

Table 1. Characteristics of the article findings (n=10)

Article characteristics	Frequency
Study design	
Prospective cohort study	**3 (30%)**
Retrospective cohort study	**2 (20%)**
Observational laboratory/in vitro study	**2 (20%)**
Secondary analysis of cohort/RCT	**1 (10%)**
Longitudinal cohort	**1 (10%)**
Population-based cohort	**1 (10%)**
Country	

Canada	**3 (30%)**
South Africa	**1 (20%)**
Malawi	**1 (20%)**
Tanzania	**1 (20%)**
Denmark	**1 (10%)**
Kenya	**1 (10%)**
Botswana	**1 (10%)**
Multiple countries (Tanzania, Malawi, South Africa)	**1 (10%)**
Research focus	
Neonatal outcomes (premature, SGA, LBW)	**7 (70%)**
Mother's immunological and metabolic status	**2 (20%)**
Maternal mortality	**1 (10%)**

A variety of ART regimens were used in the ten studies reviewed. The most commonly reported combination is Tenofovir Disoproxil Fumarate (TDF) with Lamivudine (3TC) or Emtricitabine (FTC) and Efavirenz (EFV), which is the first-line regimen in HIV prevention of mother-to-child transmission (PMTCT) programs in various countries. Some studies also report the use of protease inhibitor (PI)-based regimens such as Lopinavir/ritonavir (LPV/r) and Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs). Meanwhile, new-generation regimens based on Integrase Strand Transfer Inhibitors (INSTIs), particularly Dolutegravir (DTG) and Tenofovir Alafenamide (TAF), are beginning to emerge in recent studies from Botswana and Canada. Additionally, some studies also list a combination of Nucleoside Reverse Transcriptase Inhibitors (NRTIs) as the basis of treatment, with variations in regimens tailored to national policies and drug availability in each region. Some studies also highlight the timing of ART initiation, both before and during pregnancy, which has been reported to influence variations in birth and perinatal outcomes.

Table 2 below presents a summary of the main findings from the ten articles that met the inclusion criteria for this scoping review. Each study examines the relationship between antiretroviral therapy (ART) use and pregnancy outcomes and maternal conditions, including the risk of preterm birth, small for gestational age (SGA), low birth weight (LBW) infants, as well as immunological and metabolic changes in the mother. The information presented includes the type of ART regimen, the time of therapy initiation, and the main reported outcomes, providing a comprehensive overview of the patterns of findings across studies.

Table 2. Summary of key findings

No	Authors, Year	Country	Study design	Regimen ART	Initiation Time	Findings
1.	**Quinn et al., 2022**	**Tanzania**	**Prospective cohort**	**TDF + 3TC + EFV (combined ART)**	**Before & after 20 weeks**	**Initiation <20 weeks increases the risk of prematurity (30%) but decreases the risk of SGA (29%). There is no significant relationship with stillbirth.**
2.	**Chagomerana et al., 2023**	**Malawi**	**Prospective cohort (Option B+)**	**TDF + 3TC + EFV**	**Since the HIV diagnosis**	**There were 14 stillbirths, 5 miscarriages, and 6 HIV-positive babies; no new HIV transmissions occurred in subsequent pregnancies.**

3.	Schneidman et al., 2023	Canada	Retrospective cohort	INSTI, NNRTI, PI (TDF, 3TC, EFV)	Before fertilization, trimesters 1–2	NNRTIs/PIs increase the risk of prematurity, while INSTIs are safer; initiating ART before pregnancy reduces the risk of SGA.
4.	Moseholm et al., 2022	Denmark	Retrospective cohort	NRTI + PI; NNRTI; INSTI (TDF, 3TC, EFV, LPV/r, DTG)	Before or during pregnancy	Incidence: 12% preterm, 9% SGA, 12% LBW; viral load <50 copies/mL in 86% of mothers.
5.	Yampolsky et al., 2021	Canada	Prospective matched cohort	PI ± NNRTI/ INSTI + NRTI backbone (TDF/ FTC, AZT/3TC)	Before pregnancy	Placental abnormalities (reduced weight, asymmetrical shape) were found, associated with a risk of preeclampsia, SGA, LBW, and fetal growth disorders.
6.	Siqithi et al., 2024	South Africa	Secondary analysis (prospective cohort)	TDF/FTC/EFV; PI (LPV/r); kombinasi NRTI+NNRTI	Before & each trimester	ART in the second trimester increases the risk of LBW; high viral load and CD4 <200 increase the risk of prematurity and LBW.
7.	Kojovic et al., 2020	Canada	Observational + in vitro	2 RTI + 1 PI/ NNRTI/INSTI	20 before pregnancy, 5 during pregnancy	The PI regimen alters placental transporters (↑PGP/ BCRP, ↓OAT4), potentially leading to impaired fetal growth and prematurity.
8.	Jiang et al., 2022	Kenya	Longitudinal cohort	TDF + 3TC/ FTV/WFV	Before & during pregnancy	There was no significant relationship between the type/timing of ART and stillbirth, prematurity, or neonatal death; the effect depended on treatment adherence.
9.	Zash et al., 2021	Botswana	Prospective observational	DTG + TAF	Since fertilization	Maternal weight gain due to ART increases the risk of macrosomia.
10.	Calvert et al., 2020	Malawi, Tanzania, South Africa	Population-based cohort	ART (various regimens)	Not mentioned	HIV continues to increase the risk of maternal death by 4.5–5.9 times, even though ART is widely available.

Discussion

The Influence of Type, Initiation Time, and Supporting Factors of ART on Obstetric Complications

One significant contribution to this literature comes from the study by Schneidman et al., (2023) in Canada, which evaluated the influence of ART type and initiation time on the risk of preterm delivery (PTD) and SGA infants. This study found that initiating ART before pregnancy was associated with a decreased risk of SGA, while the use of NNRTI- and PI-based regimens was associated with an increased risk of preterm birth compared to INSTI-based regimens. These findings highlight the

importance of selecting the type and timing of ART administration to minimize the risk of obstetric complications.

In line with this, findings by Moseholm et al. (2022) in Denmark provide additional perspective thru a population-based national cohort study. Although the general administration of the combination of NRTIs and PIs and the timing of initiation did not significantly increase the risk of PTD, SGA, or LBW, this study found that initiating ART in the first trimester was more associated with an increased risk of intrauterine growth restriction (IUGR). In this finding, it can be stated that the timing of ART initiation also plays an important role in determining pregnancy outcomes.

Regarding the timing of initiation, another study by Chagomerana et al. (2023) in Malawi evaluated pregnancy outcomes and maternal health over three years in women who initiated ART with the TDF/3TC/EFV regimen during pregnancy thru the Option B+ program. The results showed that the risks of preterm birth and low birth weight were not significantly different between the first pregnancy (when ART was newly initiated) and subsequent pregnancies (which were initiated while ART was already ongoing). This indicates that initiating ART during pregnancy can still result in births comparable to using ART that was already started beforehand, at least within the context of the regimens and populations studied.

Research by Quinn et al. (2022) in Tanzania provides additional insight into the timing of ART initiation. The results show that pregnant women who start cART before 20 weeks of gestation have a lower risk of SGA but a higher risk of preterm birth compared to those who start therapy after 20 weeks. This suggests that earlier initiation of cART can support better fetal growth in utero, but on the other hand, it could increase the risk of preterm birth.

Regarding previous research, another finding was the presence of complications in mothers who initiated ART when already pregnant, specifically in the second trimester, as reported by Siqithi et al. (2024). The results found indicate an increased risk of low birth weight, meaning that ART administered after the first trimester can have a negative impact on fetal growth. Additionally, high or low viral load and CD4 < 200 cells/mm3 are also associated with an increased risk of prematurity and LBW. This confirms that the timing of ART initiation, immunity, and viral control influences the risk of obstetric complications.

Physiological Changes due to ART Exposure

Unlike previous studies, recent findings indicate that in addition to the timing of ART initiation, placental morphology also plays a significant role as an indicator in detecting pathological conditions or injuries (Yampolsky et al., 2021). This is evidenced by the findings of Yampolsky et al., (2021) which showed that exposure to ART regimens, particularly NNRTI and PI types, is correlated with significant morphological changes in the placenta. The placenta in the NNRTI group showed a decrease in weight and surface area, while in the PI group, the weight loss was accompanied by an asymmetrical shape, as evidenced by the high RSD value. These findings are associated with placental perfusion disorders and an increased risk of preeclampsia and LBW. Additionally, abnormal umbilical cord insertion was found in all ART groups, which can increase the risk of fetal vascular rupture and invasive obstetric interventions. This finding is supported by research revealing that exposure to PI affects the expression of placental transporters, with increased PGP and BCRP (ABCG2) found, which can limit the transfer of drugs and hormones from mother to fetus (Kojovic et al., 2020). As for the decrease in OAT4 and OATP4A1, this has implications for the disruption of placental steroid transport and metabolism, including estrogen. The consequences of this transport dysfunction can lead to subtherapeutic antiretroviral exposure, HIV resistance, and obstetric complications such as intrauterine growth restriction, prematurity, and small for gestational age.

In addition to affecting fetal growth and placental morphology, the effects of ART are also linked to the mother's nutritional status, which also influences pregnancy outcomes. Research by Zash et al. (2021) in

Botswana provides a different perspective by highlighting the mother's weight as an important determinant of pregnancy outcomes in women with HIV who have been using ART since before conception. This study found that mothers with a pre-pregnancy weight <50 kg had a higher risk of preterm birth (<32 weeks) and SGA. Conversely, mothers with a pre-pregnancy weight >90 kg were more likely to have a higher risk of macrosomia and gestational hypertension. An interesting aspect of this study is its connection to the type of ART used, specifically dolutegravir (DTG), which is known to cause weight gain. Long-term use of DTG is associated with a decrease in the number of mothers in the low weight category, but simultaneously increases the proportion of overweight mothers who are at risk of maternal complications such as hypertension and delivering macrosomic babies. This finding suggests that while ART can improve fetal outcomes, such as reducing the risk of growth disorders, it can also lead to metabolic consequences that require close monitoring during pregnancy.

Non-Pharmacological Factors Influencing Pregnancy Outcomes

Consistent with previous findings, research by Jiang et al. (2022) in Kenya showed that the use of ART, particularly the TDF+3TC/FTC+EFV regimen, was generally not directly associated with an increased risk of obstetric complications such as stillbirth, preterm birth (PTB), and neonatal death (NND), regardless of whether it was initiated before or during pregnancy. Although these results appear to differ from some other studies highlighting the role of ART type and initiation time on pregnancy outcomes, it is important to understand that the study population in this research had largely undergone ART before the third trimester and used a relatively uniform regimen. The findings of Jiang et al. (2022) actually confirm that the effectiveness of ART is highly dependent on the successful suppression of viral load, as women with an unsuppressed viral load at their initial pregnancy visit have a 28% higher risk of preterm birth. Additionally, non-pharmacological factors such as depression, domestic violence, and a history of sexually transmitted infections (STIs) have been shown to contribute to the risk of obstetric complications. Therefore, although the type and timing of ART are important, optimal pregnancy outcomes can be achieved thru a comprehensive approach that includes psychosocial support, management of co-infections, and intensive monitoring of maternal virology during pregnancy.

Limitations

This scoping review has several limitations. The included studies varied widely in their study design, study populations, ART regimens, timing of ART initiation, and definitions of obstetric outcomes, which made it difficult to directly compare findings and draw causal conclusions. In addition, as a scoping review, this study did not evaluate the quality or risk of bias of the included studies, which may influence the strength of the evidence presented. Lastly, important contextual factors such as differences in healthcare systems, ART adherence, and socioeconomic conditions were not consistently reported, which may limit the applicability of the findings to different settings.

Conclusion

This scoping review highlights the heterogeneous evidence regarding the association between antiretroviral therapy (ART) use and obstetric outcomes among pregnant women living with HIV. The findings indicate that pregnancy outcomes are influenced by multiple interacting factors, particularly ART regimen type and timing of initiation, rather than ART exposure alone. While early ART initiation may reduce the risk of small-for-gestational-age infants, certain regimens have been associated with increased risks of preterm birth, underscoring the need for individualized treatment strategies. The primary contribution of this review lies in mapping the complexity of existing evidence and identifying key gaps related to regimen-specific effects, timing of ART initiation, and the limited consideration of maternal biological and psychosocial factors in current

studies. These insights support the need for more integrative clinical approaches and future research that systematically accounts for these factors to optimize maternal and neonatal outcomes in women living with HIV.

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