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PERIPARTUM VERTICAL TRANSMISSION OF HIV: A COMPARATIVE STUDY OF WOMEN WITH PRIOR ARV EXPOSURE AND ARV-NAÏVE WOMEN

By

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Abstract:

Background: The prevention of mother-to-child transmission (PMTCT) of HIV remains a public health challenge, particularly in resource-limited settings. This study aimed to compare the rates of vertical transmission among HIV-positive pregnant women with prior antiretroviral (ARV) exposure and those who were ARV-naïve. **Methods:** This prospective cohort study was conducted in four hospitals in Jos, Nigeria. A total of 131 HIV-positive pregnant women were recruited, categorized into an exposed group (prior ARV exposure) and an unexposed group (ARV-naïve). Data were collected on demographic characteristics, ARV regimen, maternal viral load and infant outcomes. Polymerase chain reaction (PCR) testing was utilized to determine HIV status in infants. The data was analysed using SPSS version 17. Descriptive statistics was used; continuous variables were summarized with mean, while discrete variables were summarized with numbers and percentages. **Results:** The study found a maternal-to-child transmission rate of 3.23%, significantly lower than the national average. The exposed group exhibited a transmission rate of 1.6%, compared to 4.9% in the unexposed group. The majority of subjects in both groups were of low parity and below 30 years of age. Furthermore, 98.38% of subjects in the index pregnancy received combined triple ARV therapy.

Conclusion: The findings underscore the effectiveness of HAART in reducing vertical transmission rates. While the study highlights the importance of ARV adherence, further research is necessary to address limitations related to sample size and population representation, ensuring broader applicability of the results. Enhanced access to PMTCT programs is essential for improving maternal and infant health outcomes in Nigeria.

Keywords:

Peripartum vertical transmission, HIV, Prior ARV exposure, ARV-naïve

Introduction

Peripartum vertical transmission of HIV(Human Immunodeficiency Virus) is a critical public health issue, especially in sub-Saharan Africa, where HIV prevalence is the highest (Cardenas *et al.*, 2023; Karunarathna *et al.*, 2024). The transmission of HIV from mother to child during pregnancy, labour, delivery or breastfeeding is a major concern, as it accounts for most paediatric HIV infections(Thorne and Newell, 2003). Despite significant advances in the prevention of mother-to-child transmission (PMTCT), barriers to accessing antiretroviral (ARV) therapy and inconsistent clinical practices still affect outcomes, particularly in resource-limited settings like Nigerian communities(Deya, 2022).

In 2021, an estimated 1.3 million pregnant women were living with HIV worldwide, with 90% of them residing in sub-Saharan Africa (Fassinou *et al.*, 2024). In Nigeria alone, approximately 150,000 pregnant women are infected with HIV each year(ENIOLA, 2017). While the introduction of ARV regimens for PMTCT (prevention of mother -to- child transmission of HIV) has dramatically reduced vertical transmission rates from 20-45% without treatment to less than 5% with effective intervention, significant challenges persist (Amin *et al.*, 2021). These include limited ARV coverage and delays in starting treatment, which are particularly pronounced in Nigeria due to gaps in healthcare infrastructure and limited access to maternal care (Olakunde *et al.*, 2019).What is known so far is that ARV therapy, when properly administered, significantly reduces the risk of peripartum vertical transmission of HIV(Money *et al.*, 2014). Numerous studies have demonstrated the effectiveness of PMTCT programs, showing that women who receive ARVs during pregnancy have a markedly lower risk of transmitting the virus to their infants compared to those who are ARV-naïve(Aziz *et al.*, 2013; Aulicino *et al.*, 2019).

This study aims to explore the rates of peripartum vertical transmission among two groups of women: those with prior ARV exposure and those who are ARV-naïve. Despite being conducted in 2011, the findings of this study on peripartum vertical transmission of HIV remain highly relevant today due to several enduring and evolving challenges. First, gaps in access to and adherence to antiretroviral (ARV) therapy, particularly in resource-limited settings like Nigeria, continue to affect maternal and child health outcomes (Vreeman and Scanlon, 2013; Haberer *et al.*, 2017). The dynamics of ARV availability, HIV treatment protocols and healthcare infrastructure remain pressing issues, and historical data can provide valuable insights into current trends and treatment efficacy. Furthermore, with the ongoing global efforts to eliminate mother-to-child transmission (MTCT) of HIV, understanding the long-term impact of various ARV regimens on reducing transmission is essential for refining PMTCT strategies. This study offers a comparative analysis of women with prior ARV exposure and those who are ARV-naïve, providing invaluable data to inform policy, particularly in settings where universal ARV coverage is still not fully achieved.

Publishing this work now adds to the limited longitudinal data on the subject, offering historical perspectives that can shape current interventions. Additionally, reflecting on past challenges and successes is crucial for adapting existing programs to meet evolving healthcare demands in HIV prevention.

Materials and methods

This multi-centred, hospital-based study was conducted in Jos, the capital city of Plateau State in north-central Nigeria. The study was conducted between 1st of January, 2011 and 31st of December, 2011. Jos is located on a pear-shaped upland known as the Jos Plateau, covering approximately 8,600

km² and rising to an average height of 1,200 meters above sea level. The city is metropolitan, encompassing the Jos and Bukuru areas, with residents ranging from low to high income earners.

This study was conducted among HIV-positive pregnant women and their infants attending the PMTCT units of the APIN Plus/PEPFAR program at four hospitals: Jos University Teaching Hospital (JUTH), Solat Specialist Women Hospital, Our Lady of Apostles (OLA) Hospital, and Comprehensive Health Centre, Dadinkowa. Solat Specialist, OLA and Comprehensive Health Centre serve as PMTCT satellite centres to JUTH.

JUTH, a federal government-owned teaching hospital, functions as a referral center for neighbouring states, including Bauchi, Gombe, Benue, Kogi, Taraba, Adamawa and parts of Kaduna. Solat Specialist Women Hospital is a private facility focused on women and neonatal care, while Our Lady of Apostles (OLA) is a Catholic Missionary hospital. Comprehensive Health Centre, Dadinkowa, owned by the Plateau State Government, is a secondary health facility also linked to the APIN/PEPFAR program of JUTH for PMTCT services.

This study was designed as a prospective cohort study, focusing on HIV-positive pregnant women and their infants attending the PMTCT units of the APIN/PEPFAR Plus program in four hospitals. Participants were recruited from Jos University Teaching Hospital (JUTH), Solat Specialist Women Hospital, Our Lady of Apostles (OLA) Hospital and Comprehensive Health Centre, Dadinkowa. These women were grouped into two categories based on their prior exposure to antiretroviral (ARV) drugs for PMTCT during a previous pregnancy. The "Exposed" group consisted of women who had previously used ARVs in a prior pregnancy, while the "Unexposed" group included women who were ARV-naïve.

The study included HIV-positive pregnant women who were diagnosed during their current pregnancy, those who had previous exposure to ARVs for PMTCT in an earlier pregnancy, and women diagnosed with HIV while in labor. However, women who were on HAART for their own health before the current pregnancy were excluded from participation in the study.

Ethical approval for the research was obtained from the Institutional Health Research Ethics Committee of JUTH. Additionally, permission was granted by the heads of the Obstetrics and Gynaecology Department and the PMTCT units at JUTH, as well as from the leadership of the satellite centres. Informed consent was sought and obtained from all participants before their enrolment in the study, ensuring that ethical standards were upheld throughout the research process.

All eligible and consenting HIV-positive pregnant women were recruited for the study. Each subject was fully informed about the study's purpose and procedures and written informed consent was obtained individually. Data collection was conducted using a well-designed questionnaire administered by the researchers. The information gathered included details such as age, parity, gestational age at the start of ARV therapy, ARV regimen, CD4 count, maternal viral load and fetal birth weight. For women in the exposed group, additional information regarding prior ARV usage, including the specific regimen and duration of use, was recorded.

To determine HIV positivity among infants, the study utilized amplification of target DNA by Polymerase Chain Reaction (PCR) and Nucleic Acid Hybridization. Two millilitres of whole blood were collected from the infants at birth (within 48 hours) and again at six weeks of age. Blood samples were drawn via venepuncture and stored in vacutainer EDTA screw tubes, which were

labelled with the patient's name, identification number and the date of collection. The Roche AMPICLOR HIV-DNA Test version 1.5 was employed to detect HIV DNA in the samples, using PCR and nucleic acid hybridization techniques. All testing was carried out in the APIN Plus laboratory at Jos University Teaching Hospital.

The sample size for this study was determined using Fisher's formula(Persons, 1921). The calculation was based on a 95% confidence level, with the standard normal deviate (z) set at 1.96. The national HIV prevalence among antenatal care attendees, estimated at 4.1%, was used as the proportion (p), while the degree of accuracy (d) was set at 0.05. After substituting these values, the calculated sample size for each group was 61 participants. Ultimately, a total of 131 subjects were recruited, with 65 in the exposed group (those with prior ARV exposure) and 66 in the unexposed group (ARV-naïve).

The data was analysed using SPSS version 17. Descriptive statistics was used; continuous variables were summarized with mean, while discrete variables were summarized with numbers and percentages.

Results

A total of 131 subjects were enrolled in the study, consisting of 65 participants in the Exposed group (those with prior ARV exposure) and 66 in the Unexposed group (ARV-naïve). There were two fresh stillbirths, one in each group. Additionally, five participants were lost to follow-up (1 from the Exposed group and 4 from the Unexposed group). Ultimately, 124 mother-baby pairs were fully analyse, comprising 63 from the Exposed group and 61 from the Unexposed group.

Table 1: Age profile of the subjects

Mothers Age Groups (Years)	UNEXPOSED SUBJECTS		EXPOSED SUBJECTS		TOTAL	
	Frequency	Percent (%)	Frequency	Percent (%)	Frequency	Percent (%)
≤ 20	5	8.2	3	4.76	8	6.45
21 - 25	14	23.0	13	20.63	27	21.77
26 – 30	17	27.9	20	31.75	37	29.84
31 – 35	18	29.5	19	30.16	37	29.84
36 and above	7	11.5	8	12.70	15	12.10
Total	61	100.0	63	100	124	100

Table 1 illustrates the distribution of mothers by age group. In the Unexposed group, 11.5% (7 out of 61) of the subjects were aged 35 years and older, while in the Exposed group, this figure was 12.7% (8 out of 63). The majority of the patients were in the younger age bracket.

Table 2: Parity of the subjects

Parity	UNEXPOSED SUBJECTS		EXPOSED SUBJECTS		TOTAL	
	Frequency	Percent (%)	Frequency	Percent (%)	Frequency	Percent (%)
0	20	32.8	0	0	20	16.13
1	16	26.2	12	19.0	28	22.58
2	14	23.0	18	28.6	32	25.81
3	10	16.4	16	25.4	26	20.97
4	1	1.6	13	20.6	14	11.29
5	0	0	3	4.8	3	2.42
6	0	0	1	1.6	1	0.81
Total	61	100	63	100	124	100

In Table 2, the parity distribution of Unexposed subjects reveals that most participants had a parity of 0, accounting for 32.8% (20 out of 61). In contrast, among the Exposed group, the majority had a parity of 2, comprising 28.6% (16 out of 63). Overall, parities 0 to 3 represented approximately 85.4% (106 out of 124) of both groups combined.

Table 3: ARV/ART regimen used during index pregnancy by Unexposed and Exposed subjects

Index ARV/ART Regime	UNEXPOSED SUBJECTS		EXPOSED SUBJECTS		TOTAL	
	Frequency	Percent (%)	Frequency	Percent (%)	Frequency	Percent (%)
HAART (AZT + 3TC + EFV)	32	52.5	34	54.0	66	53.23
HAART(AZT + 3TC + NVP)	9	14.8	21	33.3	30	24.19
HAART(AZT + 3TC + LPV/r^3)	18	29.5	8	12.7	26	20.97
AZT	1	1.6	0	0	1	0.81
AZT + 3TC	1	1.6	0	0	1	0.81
Total	61	100.0	63	100.0	124	100

Key: AZT: Zidovudine; 3TC: Lamivudine; NVP: Nevirapine; EFV: Efavirenz; LPV/r^3: Lopinavir/ritonavir

Table 3 displays the ARV/ART regimens used during the index pregnancy by both Unexposed and Exposed subjects. The predominant regimen in both groups was HAART. Specifically, the HAART combination of AZT, 3TCand EFV was used by 52.5% (32 out of 61) of the Unexposed group and 54.0% (34 out of 63) of the Exposed groups.

Table 4: CD4 of the subjects during index pregnancy

CD4 Cells/mm^3	UNEXPOSED SUBJECTS		EXPOSED SUBJECTS		TOTAL	
	Frequency	Percent (%)	Frequency	Percent (%)	Frequency	Percent (%)
≤350	18	29.5	21	33.3	39	31.45
> 350	43	70.5	42	66.7	85	68.55
TOTAL	61	100.0	63	100.0	124	100.00

Table 4 illustrates the CD4 cell counts of the subjects. In the Unexposed group, a majority of 70.5% (43 out of 61) had CD4 counts exceeding 350 cells/mm³. Similarly, in the Exposed group, 66.7% (42 out of 63) had CD4 counts above 350 cells/mm³. The distribution of CD4 counts was comparable in both groups.

Table 5: Viral load of the subjects during index pregnancy

Viral Load Copies/mm^3	UNEXPOSED SUBJECTS		EXPOSED SUBJECTS		TOTAL	
	Frequency	Percent	Frequency	Percent	Frequency	Percent
<1000	37	60.7	40	63.5	77	62.1
≥ 1000	24	39.3	23	36.5	47	37.9
TOTAL	61	100.0	63	100.0	124	100.0

Table 5 shows the viral load of the subjects. A majority, comprising 60.7% of the Unexposed group and 63.5% of the Exposed group, had viral load counts below 1000 copies/mm³.

Table 6: Infant PCR results (at birth) in Unexposed and Exposed Subjects

Infant PCR Result	UNEXPOSED SUBJECTS		EXPOSED SUBJECTS		BOTH SUBJECTS	
	Frequency	Percent (%)	Frequency	Percent (%)	Frequency	Percent (%)
HIV Negative	56	91.80	60	95.24	116	93.55
HIV Positive	2	3.28	1	1.59	3	2.42
Indeterminate	3	4.92	2	3.17	5	4.03
Total	61	100	63	100	124	100

Table 6 presents the infant PCR results at birth. Among the Unexposed subjects, 91.8% (56 out of 61) tested HIV negative, while 3.28% (2 out of 61) were HIV positive and 4.92% (3 out of 61) were classified as indeterminate at birth. In contrast, the Exposed group showed that 95.24% (60 out of 63) were HIV negative, 1.59% (1 out of 63) were HIV positive and 3.17% (2 out of 63) were indeterminate at birth.

Table 7: Infant PCR results (at 6 weeks) in Unexposed and Exposed Subjects

Infant PCR Result	UNEXPOSED SUBJECTS		EXPOSED SUBJECTS		BOTH SUBJECTS	
	Frequency	Percent (%)	Frequency	Percent (%)	Frequency	Percent (%)
HIV Negative	58	95.1	62	98.4	120	96.77
HIV Positive	3	4.9	1	1.6	4	3.23
Total	61	100.0	63	100.0	124	100

Table 7 shows the infant PCR results. In the Unexposed group, 95.1% (58 out of 61) tested HIV negative, while 4.9% (3 out of 61) were HIV positive. Conversely, in the Exposed group, 98.4% (62 out of 63) were HIV negative, and 1.6% (1 out of 63) was HIV positive. The relative risk (RR) was 0.33, indicating that infants born to mothers who received ARV treatment were three times less likely to be HIV positive compared to those born to Unexposed mothers.

Discussion

Findings from the study indicate that a significant majority of the women in both groups, 85.48% (106 out of 124), had parities ranging from 0 to 3. This prevalence of low parity aligns with the prevailing trends in our environment, where high parity is often the norm (Adebowale, 2019; Solanke, 2021). Therefore, this demographic insight suggests that many of these women may be likely to enrol in future Prevention of Mother-to-Child Transmission (PMTCT) programs. Furthermore, approximately 59.2% (72 out of 124) of the participants were aged 30 years or younger. This young age, combined with the low parity, implies a considerable potential for re-enrollment in PMTCT initiatives as these women continue to have children (Solanke, 2021).

In terms of perinatal outcomes, the stillbirth rate observed in this study was 1.61% (2 out of 124), which is notably lower than the 3.2% stillbirth rate reported in another Nigerian study (Sambo *et al.*, 2023). An earlier investigation conducted in Jos revealed an even higher stillbirth rate of 4.05% (Mutihir and Eka, 2011). The stillbirths recorded in this study were attributed to complications arising from pregnancy and labor, rather than directly related to HIV infection or the effects of PMTCT interventions. These findings highlight the need for ongoing monitoring and support for pregnant women, particularly in the context of HIV management, to mitigate risks associated with childbirth and improve overall maternal and neonatal health outcomes.

A significant portion of the exposed subjects, specifically 58.7% (37 out of 63), reported having used only a single dose of Nevirapine as their antiretroviral (ARV) treatment for Prevention of Mother-to-Child Transmission (PMTCT) interventions in their previous pregnancies. This finding is consistent with the findings of earlier earlier studies conducted (Tukur, Galadanci and Adeleke, 2007; Martinson *et al.*, 2009; Arora, Gupta and Kochar, 2014). These statistics highlight a concerning trend regarding the reliance on single-dose Nevirapine within PMTCT programs, suggesting that while it remains a common practice, there is a pressing need to explore more comprehensive ARV regimens to enhance maternal and infant health outcomes in the region.

In the index pregnancy, an overwhelming majority of the subjects, accounting for 98.38% (122 out of 124), utilized combined triple antiretroviral (ARV) drugs for the prevention of mother-to-child transmission (MTCT) of HIV. This marks a significant shift from the previously prevalent practice of using a single dose of Nevirapine as an ARV for MTCT prevention. This trend contrasts with findings from various studies conducted in the region, which reported lower rates of combined ARV use (Lehman *et al.*, 2009). However, the extensive use of HAART in the current pregnancy aligns with the recent World Health Organization (WHO) "rapid advice guideline," which promotes the use of triple antiretroviral drugs during pregnancy to optimize maternal and infant health outcomes (Organization, 2016).

Findings from the study also indicate a comparable CD4 count distribution in both the Exposed and Unexposed groups, with the majority in each group having CD4 counts exceeding 350 cells/mm³ (66.7% and 70.5%, respectively). This is consistent with similar studies, which report that early

treatment initiation helps maintain higher CD4 counts, regardless of exposure status (Lima *et al.*, 2015; Eholié *et al.*, 2016).

The maternal-to-child transmission rate of 3.23% observed in this study for both groups is significantly lower than the 13.1% reported for Nigeria in 2009 (van Dijk, 2013; Ogbo, 2016). This reduction may be attributed to the adoption of the World Health Organization's (WHO) rapid guidelines promoting highly active antiretroviral therapy (HAART) for the prevention of mother-to-child transmission (PMTCT). Interestingly, contrary to the expectation that prior exposure to single-dose Nevirapine might adversely affect the efficacy of HAART when used for PMTCT, the vertical transmission rate was actually lower in the exposed group compared to the unexposed group. Specifically, the transmission rate was 1.6% (1 out of 63) for the exposed group, whereas it was 4.9% (3 out of 61) for the unexposed group. This lower rate of vertical transmission in the exposed group may be attributed to factors such as the duration of treatment and the specific regimen employed.

The study exhibits several strengths that contribute to its significance in understanding maternal-to-child transmission (MTCT) of HIV. Its multi-centre design, involving multiple hospitals, enhances the generalizability of findings across diverse populations in Nigeria. Rigorous data collection methods, including well-designed questionnaires and Polymerase Chain Reaction (PCR) testing, ensure accurate determination of HIV status in infants. Furthermore, the prospective nature of the study allows for real-time data collection, minimizing recall bias and ensuring precise documentation of antiretroviral therapy (ART) exposure. The findings reveal a notable reduction in MTCT rates among the exposed group, underscoring the effectiveness of HAART in preventing vertical transmission.

However, the study is not without limitations. The relatively small sample size, particularly in the exposed group, may limit statistical power and the ability to detect subtle differences. Additionally, the reliance on specific hospitals may not fully represent the experiences of HIV-positive pregnant women in more rural or underserved areas of Nigeria, raising questions about the broader applicability of the findings. Overall, while the study contributes valuable insights, its limitations highlight the need for further research to comprehensively understand the impact of ART on MTCT across various settings.

Conclusion

This study underscores the critical importance of effective antiretroviral therapy (ART) in reducing maternal-to-child transmission (MTCT) of HIV in pregnant women. The findings demonstrate a significant decrease in transmission rates among women exposed to highly active antiretroviral therapy (HAART) compared to those who were ARV-naïve. This highlights the efficacy of modern treatment regimens in preventing vertical transmission, aligning with global health recommendations. Continued efforts to improve access to ART and expand PMTCT programs are vital for achieving the goal of eliminating HIV transmission from mother to child, ultimately advancing public health outcomes in Nigeria and beyond.

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