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Original Article

Obstetrics and Gynaecology Section

Maternal and Perinatal Outcomes in Pregnancies Associated with HIV Infection: A Prospective Cohort Study

HASIBUL HASAN SHIRAZEE[1], MADHURIMA KAR[2], FARUK HASSAN[3], SUVASMITA SAHA[4], RUPKAMAL DAS[5]

ABSTRACT

Introduction: Human Immunodeficiency Virus (HIV) has persisted as the world's leading infectious killer disease. Globally, around 19.3 million women in the reproductive age group are suffering from HIV, and most of these women are capable of transmitting this infection to their babies. Although pregnancy does not have an adverse effect on the natural history of HIV infection in women, Acquired Immunodeficiency Syndrome (AIDS) has become a leading cause of maternal and perinatal morbidity and mortality in some areas as the epidemic progresses.

Aim: To assess the impact of HIV infection on maternal health, the risk of vertical transmission, and neonatal complications.

Materials and Methods: This prospective cohort study was conducted at the Department of Obstetrics and Gynaecology, RG Kar Medical College and Hospital, Kolkata, West Bengal, India between March 1, 2021, and August 31, 2022. The study population comprised all pregnant patients with a known positive HIV status or those diagnosed newly during routine antenatal screening at the antenatal Outpatient Department (OPD) and Prevention of Parent to Child Transmission of HIV (PPTCT) clinic, or attending obstetric emergency. After registering in the antenatal clinic, they underwent all routine investigations, including baseline CD4 count, husband's HIV status, screening for other sexually transmitted diseases, and initiation of Antiretroviral Therapy (ART). Maternal and perinatal outcomes, such as maternal complications, risk of vertical transmission, gestational age at birth, and birth weight of the baby, were assessed throughout the antenatal period and up to six weeks post-delivery. Data were entered into a Microsoft Excel datasheet and analysed using Statistical Packages for Social Sciences (SPSS) version 22.0 software. Categorical data were represented in the form of frequencies and proportions. Chi-square test was used for significance testing, with a p-value <0.05 considered statistically significant.

Results: Out of a total of 15,087 deliveries during the study period, 55 were HIV-positive cases, with a prevalence of 0.36%. Both vaginal delivery and cesarean section showed almost similar vertical transmission rates in the newborns, i.e., 4 (14%) and 4 (17%), respectively. Opportunistic infection rates were significantly higher in mothers with lower CD4 counts (<200). Mothers receiving regular ART treatment showed a lower incidence of perinatal complications, such as neonatal sepsis, perinatal asphyxia, convulsions, or perinatal death, i.e., 6 (13.63%), compared to those not on treatment, 8 (72.72%) (p-value=0.005475). Higher rates of vertical transmission were observed in patients with significantly lower Cluster of Differentiation 4 (CD4) counts, 5 (71%) versus 3 (6.8%) (p-value=0.00001).

Conclusion: Pregnancy outcomes in terms of maternal risks of infection, risk of vertical transmission, preterm births, foetal deaths, and neonatal complications can be significantly improved by early diagnosis and treatment of HIV infection. Proper antenatal care, early detection, initiation of antiretroviral drugs, and patient compliance with the multidrug regimen are the mainstay of feto-maternal well-being.

Keywords: Foetal deaths, Human immunodeficiency virus, Neonatal complications, Pregnancy, Preterm births, Vertical transmission

INTRODUCTION

Human Immunodeficiency Virus (HIV) has persisted as the world's leading infectious killer disease. According to UNAIDS (Joint United Nations Programme on HIV/AIDS), globally, 37.7 million people are living with HIV, among which around 19.3 million are women in the reproductive age group [1]. Most women infected with HIV in the reproductive age group are capable of transmitting this infection to their babies. The disease is usually transmitted in three ways: through unprotected sexual intercourse (heterosexual or homosexual), through blood or blood products, donated semen, or organs; or from an infected mother to her child (vertical transmission). Approximately 70% of infections in the general population are due to heterosexual transmission, and about 90% of infections in children are due to vertical transmission [2]. In 2021, at the national level, there were an estimated 2.401 million (1.992-2.907 million) People Living with HIV (PLHIV), with an adult (15-49 years) HIV prevalence of 0.21% [3]. West Bengal constitutes 0.69 million of the population with HIV infection [3]. According to the India HIV estimates 2021, around 20.61 thousand pregnant women were estimated to be in need of Prevention of Mother-To-Child Transmission (PMTCT) [3]. The prevalence of HIV infection among pregnant women in India is decreasing, and the current prevalence is around 0.7%. However, India still ranks among the top 10 countries with a high prevalence of HIV among pregnant women and is the third largest country in the HIV epidemic [3].

The HIV infection may predispose to adverse pregnancy and perinatal outcomes, although the evidence for this is still conflicting [4-8]. Transmission rates from mother to child range from 15% to 40% and vary among different countries [1]. Transmission may occur either in utero, during labour, or in the postpartum period through breast milk. The primary objective was to assess the impact of HIV infection on maternal health, vertical transmission risks, and perinatal outcomes. The secondary objective was to study the beneficial effect of Antiretroviral Theraphy (ART) on pregnancy outcomes and feto-maternal health.

MATERIALS AND METHODS

This was a prospective cohort study conducted at the Department of Obstetrics and Gynaecology, RG Kar Medical College and Hospital, a tertiary care hospital in Kolkata, West Bengal, India, between March 1, 2021, and August 31, 2022. Ethical clearance was obtained through proper channels from the review and Ethics Committee of the Institution (RKC/323 dated February 11, 2021).

Inclusion and Exclusion criteria: All pregnant patients with a known positive HIV status or those newly diagnosed during routine antenatal screening at the antenatal OPD and PPTCT clinic, or attending obstetric emergency, were included. Women with an uncertain HIV status, those who terminated the pregnancy at an early stage, were lost to follow-up, or denied informed consent, were excluded from the study.

Study Procedure

The prevalence of HIV among pregnant females attending the tertiary healthcare centers was found to be 1.4% (p). Using a formula, a minimum sample size of 25 was estimated. Additionally, 10% was included for dropouts/technical failures, etc. For the purpose of this study, a final sample size of 55 was taken for a 95% Confidence Interval (CI) and an alpha error of 0.05. A record-based sampling technique was used.

After obtaining proper written consent, cases were registered for the study. After recruitment, they underwent all routine investigations, including baseline CD4 count, husband's HIV status, screening for other sexually transmitted diseases, and initiation of ART prescribed by the ART center. Patients were admitted through the OPD or gynaecology emergency department when they presented in labour or at term gestation for safe delivery. On admission, all patients underwent general, systemic, and obstetric examinations, and the mode of delivery was determined based on obstetric indications. Delivery was conducted with proper aseptic universal precaution techniques to minimise exposure, followed by standard waste disposal methods. The newborns were sent to the Special Newborn Care Unit (SNCU) for Nevirapine prophylaxis. Patient counseling was provided for contraception and family planning, breastfeeding practices, and regular follow-up at the ART center. The patients were followed-up until six weeks post-delivery for any postpartum complications, such as puerperal sepsis, pyrexia, wound infections, other opportunistic infections, and neonatal assessment was done for vertical transmission, foetal growth restriction, other neonatal complications like sepsis, convulsion, asphyxia, jaundice, and perinatal deaths. HIV transmission in newborns was assessed by foetal whole blood Deoxyribonucleic Acid Polymerase Chain Reaction (DNA PCR).

STATISTICAL ANALYSIS

The data were entered into a Microsoft Excel datasheet and analysed using Statistical Packages for Social Sciences (SPSS) version 22.0 software. Categorical data were represented in the form of frequencies and proportions. Chi-square test was used as a test of significance. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 15,087 deliveries were documented during present study period, out of which 55 were HIV positive cases, resulting in a prevalence of 0.36%. The maximum number of patients belonged to the age group of 25-30 years, with a mean age of 26.53±8.42 years. Among them, 31 (57%) were nulliparous, and 1 (1.8%) was grand multipara. Based on the Modified Kuppuswamy scale for socioeconomic status, the majority of them belonged to the lower-middle class (20, 37%) or upper-lower class (17, 31%) [Table/Fig-1] [9]. In the present study, 31 (56%) mothers had vaginal delivery, and 24 (44%) had a caesarean section. Both vaginal delivery and caesarean section delivery showed almost similar vertical transmission rates in newborns, i.e., 4 (14%) and 4 (17%), respectively (p-value=0.703) [Table/Fig-2].

Variables	Frequency	Percentage
Maternal age (years)		
<20	2	3.63%
20-25	16	29.09%
25-30	22	40%
30-35	15	27.28%
Parity		
Nulliparous	31	56.36%
P1	20	36.38%
P2	2	3.64%
P3	1	1.81%
P4	1	1.81%
Maternal education status		
Illiterate	8	14.5%
Literate	47	85.5%
Socioeconomic status (Modified Kuppuswamy Scale)		
Upper	3	5.46%
Upper middle	9	16.36%
Lower middle	20	36.37%
Upper lower	17	30.91%
Lower	6	10.90%
Serodiscordancy		
Husband HIV +ve	15	27.28%
Husband HIV -ve	37	67.27%
Status unknown	3	5.45%

[Table/Fig-1]: Socio-demographic characteristics.

HIV transmission	Mode of delivery		p-value
	(n_1=28)* Vaginal delivery n (%)	(n_2=20)* Caesarean delivery n (%)	
Yes	4 (14.28)	4 (17.39)	0.7031
No	24 (85.71)	16 (69.56)	

[Table/Fig-2]: Risk of transmission to foetus in respect to mode of delivery.
*lost to follow-up=3, 4 IUFD excluded

In present study, 47% of the HIV-infected mothers had postpartum complications. Among them, postpartum haemorrhage, wound site infections, and puerperal sepsis were seen in 11%, 10%, and 8% of mothers, respectively [Table/Fig-3].

Postpartum complications	n (%)
Postpartum haemorrhage	7 (11.4)
Puerperal sepsis	5 (8)
Postpartum convulsions	2 (3.6)
Wound infections	6 (10.2)
Postpartum fever	2 (3.3)
Urinary tract infections	4 (7.27)
Lower respiratory tract infections	3 (5.45)
NIL	33 (53)

[Table/Fig-3]: Postpartum complications in HIV infected mothers (N=55).

Opportunistic infection rates were significantly higher in mothers with a lower Cluster of Differentiation (CD4) count (<200) compared to mothers with CD4 counts ≥200 (100% vs. 25%, respectively, p-value=0.00001) [Table/Fig-4].

The majority of the patients (44 out of 55 cases) were on regular ART treatment, and the remaining 11 (20%) were non compliant with ART therapy. Based on the ART intake among the study subjects, compliant mothers had 59% term healthy newborns, which was statistically significant. However, in non compliant mothers or those not on any treatment, there were only 9% term babies, 55% preterm

births, and 37% intrauterine foetal deaths (p-value=0.618952, 0.049752, and 0.000389) [Table/Fig-5].

Maternal complications	CD4 count <200 (n=11)	CD4 count ≥200 (n =44)	p-value
Postpartum pyrexia	2	0	0.00001
Urinary tract infections	1	3	
Lower respiratory tract infections	1	2	
Wound infections	3	3	
Puerperal sepsis	2	3	
Other sexually transmitted infections	2	0	
Total	11 (100%)	11 (25%)	

[Table/Fig-4]: Maternal complications in study population in respect of CD4 count.

Treatment to mother	Preterm live births n (%)	Term live births n (%)	IUFD n (%)
On ART (n=44)	18 (40.91)	26 (59.09)	--
Not on ART and non compliant (n=11)	6 (54.54)	1 (9.09)	4 (36.36)
p-value	0.618952	0.049752	0.000389

[Table/Fig-5]: Foetal outcomes in terms of preterm, term live births or IUFD with respect to ART intake (n=55).
IUFD: Intrauterine foetal demise

Mothers on regular ART treatment had 37% normal birth weight babies at delivery. However, those not on ART or non compliant with ART had 90% low birth weight infants and only 9% normal birth weight babies [Table/Fig-6].

Category	Birth weight <2.5 kg	Birth weight >2.5 kg
Mother on ART (n=44)	28	16
Not on ART/Non compliant (n=11)	10	1
p-value	0.473937	0.172218

[Table/Fig-6]: Birth Weight in respect of ART treatment in the study population (n=55).

Also, the study subjects who were on regular ART treatment showed a lesser incidence of adverse perinatal outcomes like early neonatal sepsis, convulsions, hyperbilirubinemia, Foetal Growth Restriction (FGR), and perinatal asphyxia (13.63%) compared to those who were not on ART treatment (72.72%) (p-value=0.005475) [Table/Fig-7].

Perinatal complications	Mother on ART (n=44)	Mother not on ART/Non compliant (n=11)	p-value
Early neonatal sepsis	1	2	0.005475
Convulsions	2	4	
Hyperbilirubinemia	5	4	
Perinatal asphyxia	1	2	
Foetal growth restrictions	1	3	
Perinatal death	0	1	
Total babies with complications	6 (13.63%)	8 (72.72%)	

[Table/Fig-7]: Perinatal outcomes with respect to ART treatment.

Higher rates of vertical transmission were observed in patients with significantly lower CD4 counts. When CD4 counts were lower (<200), almost 71% of the newborns from such cases had HIV transmission detected by foetal whole blood DNA PCR at six weeks of age. With higher CD4 counts (≥200), the rates of transmission were only 6.8%, and it was statistically significant (p-value=0.00001) [Table/Fig-8].

In present study, 45.45% of newborns were found to be HIV positive at six weeks of age, and history revealed that mixed feeding techniques were practiced by all of those mothers. With Exclusive Breastfeeding (EBF) techniques, HIV transmission was significantly less (10.34% newborns, p-value=0.013184) [Table/Fig-9].

Values	HIV transmission		p-value
CD4 count	Yes	No	
≥200 (n_1=44)	3 (6.82%)	39 (88.63%)	0.00001
<200 (n=7)	5 (71.42%)	1 (14.28%)	
Total (51#)	8*	40*	

[Table/Fig-8]: Risk of transmission of HIV among newborns with respect to maternal CD4 counts (n=55).
*lost to follow-up=3, #IUFD=4

Feeding practice	HIV transmission		p-value
	Yes n (%)	No n (%)	
Exclusive Breast Feeding (EBF) (n_1=29)	3 (10.34)	26 (89.66)	0.013184
Mixed feeding (n_2=11)	5 (45.45)	6 (54.54)	

[Table/Fig-9]: Risk of transmission of HIV to newborns with respect to different feeding practices.

DISCUSSION

Early detection of the disease, along with integrated counseling and management, can help reduce the disease burden. HIV itself does not cause a change in the natural outcome of pregnancy in affected mothers; however, Mother-to-Child Transmission (MTCT) remains a major concern. The risk of HIV transmission in newborns is influenced by the mode of delivery to some extent. However, in present study, the rates of transmission through vaginal delivery and C-section were found to be similar (15% and 17%, respectively). Mittal M et al., also showed similar transmission rates in vaginal delivery and C-section (16% vs. 9%, respectively) [10]. According to American College of Obstetricians and Gynaecologists (ACOG) recommendations, vaginal delivery is appropriate for HIV-infected pregnant women who have been on combination ART (cART) and have viral loads of 1,000 copies/mL or less at or near delivery. These women can be managed similarly to HIV-uninfected women [11].

According to National AIDS Control Organisation (NACO) National guidelines for (PPTCT), caesarean section is not recommended for PMTCT and is only performed if there is an obstetric indication for it [12]. Townsend CL et al., and Thorne C et al., concluded that the vertical transmission rate is consistently lower than 0.5% in women with viral loads of <50 HIV RNA copies/mL who are taking cART, regardless of the mode of delivery [13,14]. Timely diagnosis and early intervention with ART as soon as the diagnosis is confirmed helps improve both foetal and maternal outcomes. In present study, 80% of the mothers were on ART, and 59% of them had full-term deliveries, while 40% had preterm births. However, in untreated mothers, the occurrence of preterm births was 54%. The incidence of low birth weight was also significantly higher in HIV-infected mothers who were not on ART (90%).

A study by Dadhwal V et al., concluded that HIV-infected women were more likely to have a Preterm Birth Rate (PTB), Intrauterine Growth Restriction (IUGR), and anaemia (9.4%, 9.9%, and 5.2%, respectively) compared to uninfected women (7.6%, 5%, and 3.8%, respectively) [15]. A study by Ikpim EM et al., showed that preterm births were higher in HIV cohorts who did not take ART: 13 (16.9%) vs. 7 (3.9%) [16]. Premature birth (<37 completed weeks of gestation) was observed in 22.7% of infants born to HIV-positive women versus 14.1% of those born to HIV-negative women. Low birth weight (<2500 g) was observed in 25.5% of infants born to HIV-positive women vs. 14.8% of those born to HIV-negative women. Low birth weight was significantly more frequent in full-term infants born to HIV-positive mothers than in HIV-negative mothers [17]. Shankar P et al., concluded that the introduction of Highly Active Antiretroviral Therapy (HAART) significantly reduced

the incidence of Premature Rupture of Membranes (PROM) and IUGR [18].

According to the Centres for Disease Control and Prevention (CDC), one of the indications for the diagnosis of AIDS is when the CD4 cell count drops below 200 cells/mm^3 [19].

A study conducted by Dadhwal V et al., found that out of 212 HIV-infected women, 26 (12.26%) were co-infected with another sexually transmitted disease (Genital herpes- 7, Pulmonary tuberculosis-4, Warts-1, HbsAg-9, HCV-3, Syphilis-2) [15]. A study by Chilaka VN and Konje JC, concluded that due to immunosuppression, HIV can adversely affect the frequency and course of many infections in pregnancy [20]. A study conducted by Calvert C and Ronsmans C, observed that HIV-infected women had over three times the risk of puerperal sepsis compared to HIV-uninfected women (pooled OR: 3.43, 95% CI: 2.00-5.85) [21]. The present study showed that higher rates of transmission occur in patients with lower CD4 counts. When CD4 counts are lower (<200), almost 72% of the newborns had HIV transmission. A study by Mittal M et al., showed that when the standard triple ART regimen (Tenofovir, Lamivudine, Efavirenz) is given for at least three months before delivery, the chances of MTCT are low (11.7%) compared to when standard ART is started late in pregnancy or at the time of delivery (16.6%) [10].

MTCT risk was significantly higher for all modes of delivery in women with a viral load of 50-399 copies/mL (1.0%, 14/1349) compared to a viral load of less than 50 copies/mL (0.09%, 6 of 6437, p<0.001) [13]. According to the study results, there is some risk of transmission (10%) when exclusively breastfeeding. However, in developing countries like India, where exclusive breastfeeding practice is important for proper nutrition of the baby, the benefits outweigh the risk of HIV transmission. However, mixed feeding should not be practiced. In present study, 45.45% of newborns were found positive at six weeks of age, and the history revealed that mixed feeding techniques were practiced by these mothers. According to the NACO guidelines 2013, mixed feeding should not be done during the first six months. Feeding a baby with both breastfeeds and replacement feeds is known as mixed feeding, which leads to mucosal abrasions in the gut of the baby, facilitating HIV virus entry through these abrasions [12].

CONCLUSION(S)

The maternal health and foetal prognosis are affected by undetected underlying HIV infection. Early detection of the disease and initiation of ART significantly reduce the risk of vertical transmission to the foetus. The duration of ART and suppression of the viral load are essential factors in preventing MTCT. Proper compliance with multidrug therapy improves maternal immune function and prevents opportunistic infections. When the viral load is well suppressed, the mode of delivery should not be different from that of uninfected women unless obstetrically indicated. The incidence of preterm births, stillbirths, foetal death, and foetal growth restriction is lower with viral load suppression. All pregnant women should be offered an HIV test (Opt-in-technique), and opting out should be managed as infected. Regardless of viral load and CD4 cell count, all pregnant women with HIV infection should receive ART during pregnancy. The social stigma associated with the disease needs to be addressed. Integrated counseling and testing centers provide comprehensive clinical and psychological support services that empower pregnant women to make their own decisions and prevent HIV transmission to their infants through continuous information, education, and counseling.

Limitation(s)

A few study subjects were lost to follow-up midway through the study, which may have affected the final results and study was conducted at a single center. A multicentric trial would provide more conclusive results.

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PARTICULARS OF CONTRIBUTORS:
1. Associate Professor, Department of Obstetrics and Gynaecology, RG Kar Medical College and Hospital, Kolkata, India.
2. Junior Resident, Department of Obstetrics and Gynaecology, RG Kar Medical College and Hospital, Kolkata, India.
3. RMO cum Clinical Tutor, Department of Obstetrics and Gynaecology, RG Kar Medical College and Hospital, Kolkata, India.
4. Resident Medical Officer cum Clinical Tutor, Department of Obstetrics and Gynaecology, College of Medicine and JNM Hospital, Kalyani, India.
5. Professor, Department of Obstetrics and Gynaecology, RG Kar Medical College and Hospital, Kolkata, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Suvasmita Saha,
c/o Dr. Hasibul Hasan Shirazee, North Kolkata Infertility and IVF Centre,
15/1C/1G, Raja Manindra Road, Paikpara-700037, Kolkata, India.
E-mail: shirazeehasan@rediffmail.com; saha.suvasmita@gmail.com

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