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Comparison of Pregnancy Outcomes in HIV-Infected Women and Non-Infected Women: A Case Control Study from Central India

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Abstract: HIV infection has compounded the obstetric problems. There is conflicting data on the effect of HIV infection as well as antiretroviral therapy (ART) on pregnancy outcome. To assess maternal and neonatal outcome in HIV positive pregnant women whether or not on antiretroviral therapy (ART).2. To study HIV prevalence of pregnant women delivering in tertiary care center and 3. To study pregnancy outcome in HIV infected women as compared to uninfected women. This case control was carried out in tertiary care teaching institute in central India for period of three years which included both retrospective and prospective data. We studied the pregnancy outcome of HIV positive patients (Group-A) and compared it with healthy uninfected controls (Group-B). Further analysis of HIV positive patients was done by subdividing it into two groups as on ART (Group-A1) and not on ART (Group-A2). A detailed clinical examination was carried out in each patient as per proforma at the time of admission and relevant information was recorded. Patients monitored throughout the pregnancy and delivered according to hospital protocols. Maternal and neonatal outcomes were studied in details. Statistical analysis: For descriptive statistics mean, standard deviation, proportions and percentages were used. Unpaired t test and Fisher exact test were used as test of significane. Total 108 patients were found to be HIV infected and controls were 222 non-infected patients. Prevalence of HIV infected patients delivering in our institute was 0.35%.Preterm deliveries were observed significantly more in infected patients (14.8%) than uninfected controls (7.6%) (p=0.042). Whereas no significant difference was observed whether on ART or not (p=0.834).ICCU admissions were observed significantly more in infected patients (2.7%) than uninfected controls (0%) (p=0.034). Whereas no significant difference was observed whether on ART or not (p=1.000).Mean birth weight was 2.38±0.56 kg in cases and 2.59±0.42kg in controls. Birth weight >2500grams was observed significantly more in babies born in uninfected group mothers (72%) as compare to infected group mothers (57.9%) (p=0.010). Whereas no significant difference was observed whether on ART or not (p=0.315).Live births were observed more in controls (100%) than cases (93.4%) (p=0.001). Low birth weight was found significantly more in babies of infected group (43%) as compared to uninfected group (27.9%) (p=0.006). Whereas no significant difference was observed whether on ART or not (p=0.204). Early prenatal or pre-pregnancy identification of HIV infected women remains an essential goal in the prevention of risky conception and adverse pregnancy outcome. It should be emphasized for all pregnant HIV-infected women, to maximize early and regular ANC visits.

Keywords: Prgnancy Outcomes, HIV Infected Women, HIV Non Infected Women, Comparision, Central India.

INTRODUCTION

The Human Immunodeficiency Virus (HIV) infection continues to be a major global public health issue, having claimed more than 35 million lives so far. In 2016, 1.0 million people died from HIV-related causes globally. There were approximately 36.7 million people living with HIV at the end of 2016 with 1.8 million people becoming newly infected in 2016 globally. 54% of adults and 43% of children living with HIV are currently receiving lifelong antiretroviral therapy (ART). Global ART coverage for pregnant and breastfeeding women living with HIV is high at 76% [1].

India continues to portray a concentrated epidemic. As per the recently released, India HIV Estimation 2015 report, National adult (15–49 years) HIV prevalence in India is estimated at 0.26% (0.22% – 0.32%) in 2015. In 2015, adult HIV prevalence is estimated at 0.30% among males and at 0.22% among Females. The adult HIV prevalence at national level has continued its steady decline from an estimated peak of 0.38% in 2001-03 through 0.34% in 2007 and 0.28% in 2012 to 0.26% in 2015. Similar consistent declines are noted both in males and females at the national level. According to HSS 2014-15, the overall HIV prevalence among ANC clinic attendees, considered a proxy for prevalence among the general population, continues to be low at 0.29% (90% CI:0.28-0.31) in the country, with an overall declining trend at the national level[2].

HIV infection has compounded the obstetric problems of many overstretched and under resourced health care systems. Many pregnant women with unknown HIV status present late in gestation for antenatal care. This obstetric scenario possibly accounts for the increasing burden of maternal as well as fetal morbidity, especially among those who could have benefitted from perinatal prophylaxis or treatment with antiretroviral drugs. Adverse pregnancy outcomes are seen in both early and late pregnancy. HIV may be the direct cause or a marker of a complex interaction of related medical and social conditions that affect pregnancy.Pregnancy itself does not appear to accelerate HIV progression or increase maternal mortality when appropriate prenatal care is given and women have access to antiretroviral medication. However, there is some data on the effect of HIV and related therapies on pregnancy outcome as it relates to prematurity, low birth weight and still birth, although the results are mixed and more study and follow-up is needed. [3] Other observational studies have shown that HIV infection is associated with varying rates of adverse pregnancy outcomes, such as increased spontaneous abortions, intrauterine growth restriction, low birth weight, stillbirths, chorioamnionitis and perinatal and infant mortality [4].

Very few research studies are available from central India showing the current trend in HIV prevalence in the antenatal population; which led us to carry out this study at a tertiary care hospital in central India with following objectives,

- To assess maternal and neonatal outcome in HIV positive pregnant women whether or not on antiretroviral therapy (ART).
- To study HIV prevalence of pregnant women delivering in tertiary care center.
- To study pregnancy outcome in HIV infected women as compared to uninfected women.

MATERIALS & METHODS

This Hospital based case control study was carried out in tertiary care teaching institute run by the state government for the period of three years from 2011-2013. Study Subjects: All patients diagnosed as HIV seropositive admitted to labour ward and delivered at tertiary care institute.

Sample size

Sample size was estimated on the assumption that prevalence of preterm birth in HIV infected mothers in P1= 23.3% and in uninfected mothers P2= 8.5%, with power (1-β)%=80 and level of significance α%=5% the sample size required in each group is 90[5]. Assuming numbers of HIV positive women delivering in the institute as 35-40 patients per year, we decided to include cases retrospectively of one year to fulfill the sample size.

Inclusion Criteria

All HIV positive pregnant women either screened positive during current pregnancy or before pregnancy, both booked and emergency delivering in our institute.

Exclusion criteria: Nil

We studied the pregnancy outcome of HIV positive patients (Group-A) and compared it with healthy uninfected controls (Group-B). Further analysis of HIV positive patients was done by subdividing it into two groups as on ART (Group-A1) and not on ART (Group-A2).

Study protocol

A detailed clinical examination was carried out in each patient as per proforma at the time of admission and relevant information was recorded. Patients monitored throughout the pregnancy and delivered according to hospital protocols. Maternal outcome was studied in terms of distribution according to CD4 count, maternal complication, gestational age at the time of delivery, mode of delivery – vaginal or caesarean section (CS), elective or emergency CS. Outcome of neonate was studied in terms of live birth, still birth, birth weight, Apgar score at 1 and 5 minutes. HIV status of baby was done at one and half month, 6 months, 12 months and 18 months of birth as per guidelines lay down by NACO [6].

All patients received intrapartum Nevirapine 200 mg stat dose. All babies after delivery have received Nevirapine syrup 2mg/kg stat dose within 48 hours of birth and syrup Zidovudine 2mg/kg/dose 6 hourly till one and half month of age. All babies received top feeding. Maternal and neonatal complications and their correlation with gestational age at which ART started were studied.

Statistical Analysis

Continuous variables (age, parity, gestational age) were presented as mean and standard deviation. Categorical variables (CD4 count, complications, mode of delivery, type of C.S.) were expressed in actual number and percentages. Continuous variables were compared between infected and uninfected HIV mothers by performing un-paired t-test. Categorical variables were compared by applying chi-square test. Fisher exact test was applied for small numbers wherever it is applicable. All the tests were two sided. $p<0.05$ was considered as statistically significant.

Ethical considerations

The study was conducted according to the Declaration of Helsinki; the protocol was reviewed and approved by the institutional ethics committee of the institute. Due permission is also taken from National AIDS Control program (NACO). Written informed consent was obtained from the study subject.

RESULTS

Total 108 patients were found to be HIV infected and controls were 222 uninfected patients. In one year duration from January 2011 till December 2011 total 11,127 patients were delivered from which HIV infected patients were 39. So prevalence of HIV infected patients in our institute was 0.35% in year 2011. Majority (48.1%) of patients were belonging to age group of 25-29 years. The mean age of the patients was 25.29±3.39 years among cases and 25.34±3.42 years among controls. Hence both the groups were comparable (p=0.9115). In group A 46.3% patients and in group B 45% patients were Nulliparous. Whereas 42.6% in group A and 44.1% in group B was primipara. Mean parity was found 1.67± 0.72 among cases and 1.66±0.69 among controls. Median CD4 count was found to be 441.5 cells/mm^3 (mean 460.97 cells/mm^3, SD 210.0; range 32-1251). Initially 36 patients had CD4 count ≤350 at diagnosis and 72 patients had CD4 count >350 at diagnosis but in subsequent follow up period CD4 count in 2 patients decreased and they were started on ART. Also, due to regular ART treatment 6 patients on ART showed increment in the counts to >350 and ART was continued in them during pregnancy. So ultimately in this study 38 patients were on ART. Out of 108 cases 38 patients (35.2%) received ART and remaining 70 patients did not receive ART. Mean duration of ART use was 12.64months with SD 12.29months. All patients received Nevirapin in labour. ART was started before pregnancy in 20 patients, in 2nd trimester to 10 patients and in 3rd trimester to 8 patients. No patient was newly started on ART in 1st trimester. The patients who were started on ART before pregnancy were continued ART throughout the pregnancy and thereafter in post-partum period.

Out of 108 cases that are infected with HIV, preterm labor was found to be the most common (14.8%) complication with statistically significant. difference with controls when compared (p=0.042). But no statistically significant difference noted in ART and Non ART groups. Incidence of ICCU admission and maternal mortality was found significantly higher in HIV infected patients than non-infected controls with p values of 0.034 and 0.012 respectively. But no statistically significant difference noted in ART and Non ART groups. Preeclampsia was seen in 10.2% cases and 10.8% controls with no statistically significant difference. When further studied, it was found that preeclampsia is more common in ART group (20.1%) as compared to Non-ART group (4.1%). This difference was statistically significant (p=0.006).

Out of total 4 maternal mortalities, one patient died during pregnancy. So further analysis of pregnancy outcome was done in remaining 107 cases.

Table-1: Maternal complications

Complications	A (%) n=108	B (%) n=222	p value for A and B	A1 (%) n=38	A2 (%) n=70	p value (A1vs A2)
Preterm delivery	16(14.8)	17(7.6)	0.042 ,S	6 (15.8)	10(14.3)	0.834,NS
Oligohydramios	6(5.5)	6(2.7)	0.194,NS	4(10.5)	2(2.8)	0.097,NS
PROM	7(6.5)	20(9.0)	0.432,NS	3(7.9)	4(5.6)	0.660,NS
Preeclampsia	11(10.2)	24(10.8)	0.863,NS	8(20.1)	3(4.1)	0.006, HS
Eclampsia	2(1.8)	1(0.5)	0.251,NS	-	2(2.8)	0.540,NS
Placenta previa	1(0.9)	1(0.5)	0.548,NS	-	1(1.4)	1.000,NS
Abruptio placentae	1(0.9)	-	0.327,NS	-	1(1.4)	1.000,NS
PPH	1(0.9)	1(0.5)	0.548,NS	-	1(1.4)	1.000 ,NS
ICCU admissions	3(2.7)	-	0.034 S	1(2.6)	2(2.8)	1.00,NS
Maternal Mortality	4(3.7)	-	0.012 S	1(2.6)	3(4.1)	0.664,NS

Out of 38 patients who were on ART, 20 patients were receiving ART before pregnancy, 10 were started on ART in second trimester and 8 in third trimester. Those patients who received ART in second and third trimester were first time diagnosed as HIV positive and immediately started on ART. All maternal complications were commonly seen in those cases in which ART was started in second trimester. But we found no statistically significant difference whether ART was started before pregnancy or during pregnancy

in relation with maternal complications.

Mean gestational age was 37.86±3.72 weeks and median was 39weeks. Majority (85%) of cases had term delivery. Preterm labor (<37 weeks) was found in 16 (15%) patients in cases and 17 patients (7.7%) in controls. When HIV infected cases were compared with uninfected controls the difference was statistically significant and showed that deliveries less than 34 weeks was more in infected group than uninfected group (p=0.025) and term deliveries were more in controls than in cases (p=0.039). But when comparison among cases was done we found no statistically significant difference in ART and Non ART group.Out of 107 cases, 67 patients (62.6%) delivered vaginally and 40 (37.4%) cases delivered by C.S. In controls 82% delivered vaginally and 18% required C.S. The difference was statistically significant (p =0.000).

The mean birth weight among cases was 2.38±0.56kg and 2.59±0.42kg in controls. Birth weight less than 1500 grams was seen in 10.2% (11/107) cases from HIV infected group and 0.9% (2/222) in uninfected controls. This difference was found to be significant (p=0.000). But no difference was found in ART and Non ART group. Babies weighing more than 2500 grams were found more in controls (72%) as compared to cases (57.9%) with statistically significant difference (p=0.010). Mean birth weight in ART group was found to be 2.31±0.67kg and that of non-ART group was 2.42±0.49kg. There was no statistically significant difference seen in group A1 and A2.

Table-2: Neonatal outcome

	A (n=107)	B (n=222)	P value	A1 (n=37)	A2 (n=70)	p value for A1 and A2
Live birth	100 (93.4)	222 (100)	0.001 HS	32 (86.5)	68 (97.2)	0.034 S
Fresh Still birth	7(6.6)	-	0.001 HS	5(13.5)	2 (2.8)	0.034 S
Neonatal deaths	6(5.6)	1(0.4)	0.002 HS	3 (9.4)	3 (1.5)	0.414,NS

In infected group 93.4% (100/107) babies were born live as compared to 100% live births in uninfected group with statistically significant difference (p=0.001). Analysis among cases showed that live birth was more in non-ART group than in ART group (p=0.034). Fresh still birth occurred only in infected group (7/107). Out of these 7 cases, 5 (13.5%) from ART group and 2 (2.8%) from Non ART group had fresh still births. The difference was significant (p=0.034). In HIV infected group, out of 100 live births, 6 babies had neonatal death. In our study, all neonatal deaths were within 7 days of birth (Early Neonatal Death). 9.4% from ART group (3/32) and 1.5% from non-ART group (3/68). Only one baby (0.4%) died in control group. The difference was statistically significant (p=0.002).

One minute Apgar <5 was seen in one baby (1%) from HIV infected group who was on ART versus one baby (0.5%) in uninfected group and the difference was statistically not significant (p=0.525). 5 minute Apgar <7 was seen in 3% babies from infected group versus 0.5% babies in uninfected group with no significant difference (p=0.094). When comparison is done in ART and Non-ART group, we found no association of low Apgar with use or non-use of ART.

Table-3: Neonatal complications

Complications	A n=107	B n=222	p value	A1 n=37	A2 n=70	p value for A1 and A2
LBW	46 (43)	62(27.9)	0.006 S	19(51.3)	27(38.6)	0.204,NS
SGA/ IUGR	28(26.2)	33(14.9)	0.013 S	12(32.4)	16(22.8)	0.628,NS
Birth asphyxia	3(2.8)	1(0.4)	0.068,NS	3(8.1)	-	0.016,S
Jaundice	4(3.7)	-	0.011 S	2(5.4)	2(2.8)	0.608,NS
Septicemia	4(2.8)	-	0.011 S	2(5.4)	2(2.8)	0.608,NS
Cephalhematoma	1(0.9)	-	0.325,NS	1(2.7)	-	0.352,NS
Anomalies	2(1.8)	-	0.105 ,NS	1(2.7)	1(1.4)	0.540,NS
NICU admission	11(10.2)	4(1.8)	0.033 S	5(13.5)	7(10)	0.584,NS
Perinatal mortality	13(12.1)	1(0.4)	0.000 S	8(21.6)	5(7.1)	0.029 S

In our study the incidence of LBW and SGA was commonly found in HIV infected cases 43% and 26.9% respectively. Whereas in uninfected group LBW was in 27.9% and SGA in 14.9% cases. The difference was statically significant with p value 0.006 and 0.013 respectively. When comparison among cases was done for LBW and SGA, we found no significant difference in ART and Non ART group. Jaundice and septicemia was found in 3.7% and 2.8% babies in infected group and no baby in uninfected group with statistically significant difference with p value 0.011 each respectively. When comparison among cases was done

for Jaundice and septicemia, we found no significant difference in ART and Non ART group. Birth asphyxia was seen in 2.8% babies from infected group versus 0.4% babies from uninfected group. Difference is statistically not significant. But when compared among cases, it was found to be significantly more in mothers on ART (p=0.016). In HIV infected group 10.2% babies required NICU admission whereas only 1.8% babies in uninfected group required NICU admission. The difference was significant (p=0.033). When further divided in ART and Non-ART group, no significant difference was seen. Perinatal mortality was found in 12.1% in HIV infected group and 0.4% in uninfected group with statistically significant difference (p=0.000). Neonatal complication that occurred in ART group was not related with duration of ART whether started before or during pregnancy except birth asphyxia and NICU admission which were seen more in those babies with mother diagnosed HIV positive and immediately started on ART in second trimester. The difference was statistically significant (p=0.018 and 0.023 respectively).

DISCUSSION

There is conflicting data on the effect of HIV infection as well as antiretroviral therapy (ART) on pregnancy outcome [7]. Perinatal transmission of human immunodeficiency virus (HIV) infection occurs in the absence of any interventions. The benefits of antiretroviral treatment (ART) in decreasing mother to child transmission (MTCT) of HIV infection are largely undisputed [8].

In present study majority (48.1%) of patients were belonging to age group of 25-29 years with mean maternal age 25.2 years and 25.3 years among cases and controls respectively which is similar to Philippe L. *et al*. [9] Study who also reported the highest prevalence in age group 20-25 years with mean maternal age was 25.1 years in cases and 26.4 years in control group. The results of other studies done by Nigel C Rollins *et al*. [42], Jennifer Vincent-T. *et al.* [10] and Jenny L.Coley *et al.* [11] are also similar.

In the present study the preterm delivery occurred in 14.8% and 7.6% in cases and controls respectively which is comparable with study by K Boer *et al*.[12] who found that preterm delivery is significantly higher in HIV infected patients than in controls (p=0.042). Similar results were seen by Valeriene Leroy *et al*.[13] and Sandeh Patil *et al*.[14] with significant difference.

In our study we found oligohydramnios in 5.5% cases, PROM in 6.5% cases, preeclampsia in 10.2% cases, eclampsia in 1.8%, placenta previa and abruptio placenta in one case (0.9%) each, postpartum haemorrhage in one patient (0.9%) and ICCU admission in 2.7% cases who are HIV infected. Similar results were observed in a randomised clinical trial conducted on 212 HIV infected patients by Sandeh Patil *et al*.[14] in which incidence of oligohydramnios in 4.7% cases, preeclampsia in 9.4%, antepartum haemorrhage in 0.48% cases, postpartum haemorrhage in 0.94% cases. All these maternal complication had not shown any significant difference with controls in our study. This is in consistence with the observations by Sandeh Patil *et al*.[14] who found no differences between HIV-infected and uninfected pregnant women with respect to the proportion with elevated intrapartum blood pressure, eclampsia, oligohydramnios, (p>0.05)

Median birth weight was 2.5kg in our study whereas Karoline Aebi-Popp *et al*. [15] noted median birth weight 2810g. Low birth weight was observed in 43% HIV infected cases versus 27.9% in uninfected controls which was significantly higher in HIV infected cases (p=0.006). Similar result was noted by Valeriene Leroy *et al*. [13]. That low birth weight (< 2500 g) was observed in 25.5% of infants born to HIV-positive women versus 14.8% of those born to HIV-negative women and it was significantly more frequent in infants born to HIV-positive mothers than to HIV-negative mothers. Philippe L. *et al*. [9] also found that children born to HIV positive mothers had mean birth weight 130g lower than the children born to HIV negative mothers (2840 versus 2970g; p=<0.01) Biodun O. *et al*. [16] also found Low birth weight was significantly more in the HIV positive women [*p*<0.0001, odds ratio (95% CI) 5.43 (2.4–12.0)].

In the present study IUGR/SGA (43% vs.27.9%, p=0.006) was significantly more in HIV infected patients than in controls, but no association with use or non-use of ART [ART 32.4% vs. Non-ART 22.8%, p=0.628]. Joseph O. *et al.* [17]. Observed that Intrauterine growth restriction (IUGR) (20.5% vs. 6.3%, p = 0.003) was significantly higher among women with untreated-HIV infection in pregnancy compared with women who received HAART from early pregnancy. Like our study, NA Habib et al[5] also observed that IUGR was found significantly more in HIV infected patients (30.1%) as compared to HIV uninfected patients (11.2%). But the incidence of SGA was found to be more in untreated patients (18.1%) as compared to treated patients (12.0%).

We observed that babies of HIV infected mothers had more NICU admissions (11.2% vs.1.8%, p=0.000). Whereas no significant association was found in treated and untreated patients [13.5% vs. 10%, p=0.584]. Similarly, Joseph O. *et al*. [17] reported that untreated maternal HIV-infection was associated with higher frequency of admission into neonatal unit (p < 0.05). On the other hand, Elie Azaria *et al*. [18] reported that NICU admissions were seen in 8% cases and in 9% controls with no significant difference.

CONCLUSION

This study concluded that adverse outcomes of pregnancy attributable to ART are low and likely outweighed by the known benefits of such therapy during pregnancy. However, it cannot replace good antenatal care. Our results emphasized the importance of recommending an HIV test before conception and routinely performing the test in the first trimester in order to avoid missing the diagnosis during pregnancy or delayed diagnosis during pregnancy. It is further emphasized that early prenatal or pre-pregnancy identification of HIV infected women remains an essential goal in the prevention of risky conception and adverse pregnancy outcome. It should be emphasized for all pregnant HIV-infected women, to maximize early and regular ANC visits.

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