

Role of Triple Drug Antiretroviral Prophylaxis in Reducing Mother-to-Child Transmission of Human Immunodeficiency Virus

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ABSTRACT

Aim: To study the efficacy of the triple drug (Antiretroviral [ARV] prophylaxis i.e., Tenofovir, Lamivudine and Efavirenz as a single tablet) in reducing the parent to child transmission of human immunodeficiency virus [HIV] virus in the antenatal period, labor and postpartum period. **Materials and Methods:** This study was done at Government Maternity Hospital, Hanamkonda in the Department of obstetrics and gynecology, Kakatiya Medical College between November 15, 2012 and October 15, 2014. This was a prospective case study. Number of patients eligible for ARV prophylaxis was 60 and percentage of seroprevalence was 0.75%. **Results:** 85% of the subjects are attending the antenatal clinic before 25 weeks of gestation. In our study, 83.32% of the subjects started receiving ARV/antiretroviral therapy (ART) prophylaxis between 14 and 25 weeks gestation. 96.66% (58) of the subjects took the drug regularly and were compliant to the drug and only 3.33% (2) have not taken the drug due to side effects, such as vomiting, giddiness, and nausea. 66.6% subjects were delivered by vaginal delivery and cesarean section rate was over all 33.3% which were done for obstetric indication. The delivery and the cesarean section were done as per universal precautions. 84.8% of the neonates were born with weight ranging from 2.5 to 3.9 kg and 13.2% of the neonates were born with weight ranging from 1.5 to 2.4 kg and only 1.6% with <1.5 kg. Out of total subjects of 60, the total number of adverse fetal outcome were 8 (13.3%). Of which, IUD constituted 3 (5%), Still birth constituted 3 (5%) and early neonatal deaths constituted 2 (3.3%). As recommended by e National acquired immunodeficiency syndrome Control Organisation this study has initiated exclusive breast feeding in 95% (57 of 60) of the neonates. The 5% (3 of 60) of the neonates have received artificial feeding on request. 28.3% are followed up to 18 months, 31.6%, up to 12 months, 26.6%, up to 6 months and 13.3% infants have not followed due to IUD, Still born and early neonatal deaths. **Conclusion:** Triple drug ARV prophylaxis/ART is more efficacious when compared to single drug Nevirapine/Zidovudine in all aspects and is having few side effects and drug compliance is also better. The triple drug ARV prophylaxis/ART allows the spontaneous vaginal delivery because of the significant reduction in viral loads <50 HIV RNA copies per mL.

Keywords: Antiretroviral prophylaxis, Lamivudine and Efavirenz, Tenofovir

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INTRODUCTION

Pediatric human immunodeficiency virus (HIV) is a problem for the Obstetricians and the Pediatricians in the developing Countries. 90% of all Pediatric HIVs patients would have got infections from their parents (mother-to-child transmission [MTCT] of HIV virus). The patient-to-child transmission of HIV virus, especially from the infected mother to the fetus is a well-known evidence based method of transmission of virus. As per National acquired immunodeficiency syndrome (AIDS) Control Organisation (NACO) statistics 2009 and 2010, 5.4% is the parent to child transmission in India. Breastfeeding by an infected mother adds an additional 5–20% risk for an overall transmission rate of 20–45%.^[1]

There are an estimated 2.1 million (2011) people living with HIV in India, with National adult HIV prevalence of 0.27% (2011). Up to 2009 single drug Zidovudine was widely used as the Antiretroviral (ARV) prophylaxis during pregnancy and during labor, with un booked cases getting single dose Nevirapine (NVP) during labor. In 2010, the World Health Organization (WHO) and NACO 2010 noted that the single dose NVP was giving rise to drug resistance^[3-5] during ART administration to the patient when indicated. This drug resistance was phenotypic and genotypic in nature. It leads to a plateau in the parent to child transmission.

In 2010, the WHO has recommended the use of multi drug, that is, triple drug prophylaxis (Tenofovir, Lamivudine and Efavirenz) as ARV prophylaxis and ART treatment from the 14th week of pregnancy until the cessation of breast feeding.^[6] The NACO held

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a meeting in month of February 2010 at New Delhi which was attended by UNAIDS, WHO and UNICEF wherein the single drug Zidovudine option A and the triple drug option B, were discussed in detail.^[7] Later on subsequently after a series of meetings the NACO and the government of India opted for a pilot project of triple drug ARV prophylaxis (Tenofovir, Lamivudine and Efavirenz) starting early in pregnancy until the cessation of breast feeding in high prevalence states, such as Andhra Pradesh, Maharashtra, Karnataka, Manipur, Tamil Nadu since October 2012. Recommendations have the potential to reduce the risk of mother-to-child transmission to <5% in breastfeeding populations.^[8] Based on these guidelines,

the NACO in January 2014 has come out with revised prevention of parent-to-child transmission (PPTCT) guidelines.^[2] There is a necessity and need to change over to more evidence based protocols, such as the triple drug prophylaxis in all tertiary Hospitals to reach the goal of zero transmission of HIV transmission from parent to child and in the process eliminate the pediatric HIV infection totally which is a long term goal.

MATERIALS AND METHODS

This study was done at Government Maternity Hospital, Hanamkonda in the Department of obstetrics and gynecology, Kakatiya Medical College between November 15, 2012 and October 15, 2014. This was a prospective case study.

Inclusion criteria were all antenatal Women who have been counseled and tested positive for HIV as per the standard NACO guidelines. All antenatal Women who have been tested positive and are willing to continue the pregnancy with ARV prophylaxis during the antenatal period, labor, up to cessation of breast feeding. Positively tested antenatal subjects, with their spouse, should agree for testing the polymerase chain reaction (PCR) DNA with early infant diagnosis at 6 weeks postpartum with informed consent.

Exclusion criteria were all antenatal women who were counseled about the Universal screening but tested negative for HIV.

All antenatal women counseled tested positive willing for medical termination of pregnancy. All antenatal women counseled and tested positive but not willing for the triple drug ARV prophylaxis. All antenatal women who were already on ART before pregnancy and continuing ART during pregnancy. All antenatal women who have reported for screening to the antenatal O.P will undergo pre-test counseling in groups of 10–15, by the qualified counselor.

The antibody testing are done by three rapid tests (three test kits) alternatively and any antenatal women who is tested positive through all the three methods is declared as seropositive by a proper post-test counseling done by the medical officer concerned. The implications of the testing are explained to the patient and husband, the spouse is also requested to come for testing. The patient is sent to the ART clinic for baseline CD4 testing, and the triple drug Tenofovir 300 mg, Lamivudine 150 mg, Efavirenz 600 mg in a single tablet is started irrespective of CD4 count report as early as 14 weeks of gestation or whenever the patient report to antenatal O.P with the eligibility criteria.

If the CD4 count is <350 cells/mm³, the patient will be on ART lifelong with the same drug. If the CD4 count is more than 350 cells/mm³ she will be counseled to use the drug in antenatal period, during labor and in the postpartum period up to the cessation of breast feeding. The antenatal women are followed throughout pregnancy by regular antenatal check-ups and other investigations, such as Hepatitis B and Hepatitis C screening, venereal disease research laboratory screen, complete blood picture and serum creatinine periodically (because Tenofovir is Nephrotoxic) the patient were counseled regarding the drug adherence and also Co-trimoxazole double strength tablet was given if the CD4 count is <250 cells/mm³. The subjects in the study were screened for opportunistic infections (by sputum acid-fast bacillus study) and also screened for sexually transmitted diseases and reproductive tract infections and appropriately treated. The

patients were delivered by Universal precautions and cesarean section was done only for Obstetric indication only (because the viral load is undetectable). Triple drug ARV prophylaxis is continued during labor and the infant was administered NVP for 6 weeks (extended NVP prophylaxis) as per the dose based on the body weight of the infant. Exclusive breast feeding was recommended up to 6 months as per the NACO guidelines and the infant is tested at 45 days in the PPTCT center taking a dry blood spot test and sent for PCR DNA analysis at MGR University Chennai. The end point of the study is the percentage of perinatal transmission which would be recorded by the PCR DNA. If the PCR DNA is positive a repeat sample of fresh blood was sent.

RESULTS

Incidence of Sero-prevalance of HIV status in Antenatal population in our study was total number of subjects counseled were 12000. Number of patients tested were 11850, number of patients tested positive for HIV was 88, number of patients eligible for ARV prophylaxis was 60 and percentage of seroprevalence was 0.75%.

The seroprevalence of HIV in our study was 0.75%, and 60 subjects were recruited for this study. 28 of them needed ART based on their CD4 count and they are referred to ART center.

There are 48.33% of Primi Gravida, 43.33% of 2nd Gravida and 8.3% of 3rd Gravida. 65% of women who are tested seropositive presented with stage II as per WHO staging and 35 presented with stage I. the recent NACO guidelines recommend that irrespective of the clinical WHO staging and the CD4 count ART should be started and continued lifelong. The mean distribution of CD4 count in our study is 534.36.

85% of the subjects are attending the antenatal clinic before 25 weeks of gestation. In our study, 83.32% of the subjects started receiving ARV/ART prophylaxis between 14–25 weeks gestation. NACO 2014 guidelines recommend that the ART should be started as early as 14 weeks of gestation to prevent maternal to child transmission of HIV [Table 1].

96.66% (58) of the subjects took the drug regularly and were compliant to the drug and only 3.33% (2) have not taken the drug due to side effects, such as vomiting, giddiness, and nausea. The triple ARV prophylaxis in a single tablet of Tenofovir + Lamivudine + Efavirenz has very few side effects, which are documented like vomiting noted with all. Raised creatinine noted with Tenofovir. With Efavirenz some patient can complain of nightmares and altered sleep pattern. The result of our study shows that the triple drug prophylaxis is safe and effective and has got few side effects.

In our study, 66.6% subjects were delivered by vaginal delivery and cesarean section rate was over all 33.3% which were done for obstetric indication [Figure 1].

84.8% of the neonates were born with weight ranging from 2.5 to 3.9 kg, 13.2% of the neonates were born with weight ranging from 1.5 to 2.4 kg, and only 1.6% with <1.5 kg. This proves that there is no evidence of intrauterine growth restriction (IUGR) or reduction in fetal weight (small for dates) for the neonates [Table 2].

As recommended by NACO we have initiated exclusive breast feeding in 95% of the neonates. The 5% of the neonates have received artificial feeding on request.

Total number of subjects delivered = 60

Total number of IUD and still birth = 6

Total number of live births = 54

Number of early neonatal deaths = 2

Number of NVP prophylaxis given to the infants = 52

Percentage of the live neonates given NVP prophylaxis for 6 weeks = 100% [Figure 2].

In our study, there was 100% follow-up of live infants. The follow-up is very important because the PCR DNA testing should be done around 6 weeks of infancy, which reveals the status of the infant regarding HIV infection and also show the efficacy of ARV prophylaxis/ART.

The transmission rate was calculated as 1.9% which is extremely acceptable. The goal of NACO is to completely eliminate parent to child transmission of HIV and the goal is almost achieved by the triple drug ARV prophylaxis/ART. It is to be noted here that with single-drug AZT or single-drug NVP given as single dose the prenatal transmission was around 10–12%. Therefore, we have achieved a significant breakthrough in preventing parent to child transmission of HIV and arriving at zero transmission.

28–3% are followed up to 18 months, 31.6%, up to 12 months, 26.6%, up to 6 months and 13.3% infants have not followed due to IUD, Still born and early neonatal deaths [Table 3].

All the infants who came for follow-up are 18 months were healthy, immunized and also tested negative by standard ELISA method. It should be noted that NACO recommends that the final proof of Serological status of the infant for HIV infection is to test at 18 months by rapid testing; where all three tests are done to prove Seronegativity.

DISCUSSION

The discussion is based on the results obtained in the study and the review of literature from 2006 to 2014. The concept of Universal counseling was followed in this study and has counseled almost 99% of all the new antenatal women per day. Out of which 98–99% were tested and out of which 0.75% were found to be positive for HIV- AIDS. The most important and initial step toward reducing parent to child transmission for HIV virus is to counsel as many antenatal women as possible and then perform HIV testing and followed by post-test counseling for ARV prophylaxis/ART initiation, including drug compliance and delivery options, infant feeding immunization and early infant diagnosis. The "SOUTH AFRICAN NATIONAL AIDS COUNCIL" has also concluded that it is important to do universal screening, testing and identification of women who are HIV positive for early initiation of ART. The NICE guidelines in 2012 has recommended that repeat antenatal testing would be offered to any women who was thought to be having and continue to have risk of infection and those who requested a subsequent test. The NACO guidelines presently don't recommend the routine repetition of the HIV testing as of now. In our study, we had two subjects of second gravida and one subject of third gravida who were already HIV positive and were on ART treatment in the ART clinic. In all the three subjects they were administered single dose NVP at the onset of labor preceded by AZT which was given from 28 weeks of pregnancy. As per the NACO guidelines 2013, we have substituted Efavirenz with Lopinavir and Ritonavir combination boosted PI's to avoid NVP and NNRTI'S cross resistance in the future. In our study, 15% of the spouses (husband) were found negative. This assumes importance because the NACO has changed the terminology from maternal to child transmission of HIV to parent to child transmission because both the partners contribute to the perinatal transmission of HIV. Routine use of condoms is advocated even though both the parents are tested positive because of the fact that the viral load is exchanged

through the genital secretions and may lead to increased viral load in one of the partners. To prevent this condom usage is advocated. Pre-exposure prophylaxis in the form of ARV prophylaxis is now recommended by the NACO to uninfected partner. In our study, all the subjects were in stage I or II and we could not get any subjects of WHO stage III or IV. The NACO guidelines of 2012 recommendations are based on the baseline CD4 testing and WHO clinical staging for initiation of ARV prophylaxis/ART. Antenatal subjects who tested positive, a CD4 count of 350 cells/mm³ was kept as cut off for deciding whether to initiate ARV prophylaxis/ART. Subjects <350 cells/mm³ or WHO stage III and IV were started on ART lifelong with three drugs Tenofovir, Lamivudine and Efavirenz. In subjects >350 cells/mm³ or WHO stage I and II ARV prophylaxis with the three drug regimen should be given throughout the antenatal period upto 1 week after cessation of breast feeding. NACO 2014 guidelines have clearly mentioned that ART should be initiated in antenatal women tested positive for HIV at the earliest in the second trimester irrespective of WHO staging and CD4 count. This was done to ensure the drug compliance and prevent drug resistance. In this study baseline CD4 testing was done for all the subjects and the mean CD4 count is recorded as 534.36. In this study there were no subjects reported with CD4 count of <350 cells/mm³. It has to be noted that pregnancy being an immuno-compromised condition there is a marginal drop of CD4 count because of impaired T-cell immunity. The CD4 counts are useful for monitoring the response of treatment to ART which is done for every 6 months.

In this study ART was initiated in majority of subjects between 15 and 20 weeks which is as per the NACO guidelines. Early initiation of ART will reduce the viral load and prevent parent to child transmission. The NACO 2014 guidelines had also recommended for an early initiation of ARV at 14 weeks of gestation for preventing maternal to child transmission. The "South African National AIDS Council" also recommended early initiation of ART from 14 weeks of pregnancy. In this study, 96% of the subjects took the drug regularly as per NACO guidelines. More than 85% of the drug compliance is required to reduce the viral load. There was no major side effect due to the triple drug ARV prophylaxis. It is the safe and effective drug combination with minimum side effects. In this study we have strictly followed the NACO guidelines regarding the mode of delivery which recommends that unless there is an obstetric indication on women who are on ARV prophylaxis/ART should be delivered vaginally. The NICE guidelines 2012 also recommends that vaginal delivery should be performed because the viral load at 36 weeks is <50 HIV RNA copies/mL. The morbidity and mortality associated with cesarean section also precludes that particular option. In the study 33.3% of our subjects underwent elective or emergency cesarean section for obstetric indication. The delivery was conducted with the universal precautions in our study. The "South African National AIDS Council" 2010 also recommends vaginal delivery is the safe delivery technique and it also recommends that cesarean section should only be done for obstetric indication. In this study the fetal outcome as measured by the birth weight shows that majority of the newborns, 84.8% were found with birth weight in the range of 2.5–3.9 kg and the infants weighing around 1.5 to 2.4 kg were 13.2%. These figures prove that the triple drug prophylaxis has a good fetal outcome as measured by the birth weight adjusted to the gestational age. It should be noted that the incidence of preterm delivery was roughly 5.5%. There were no cases of low

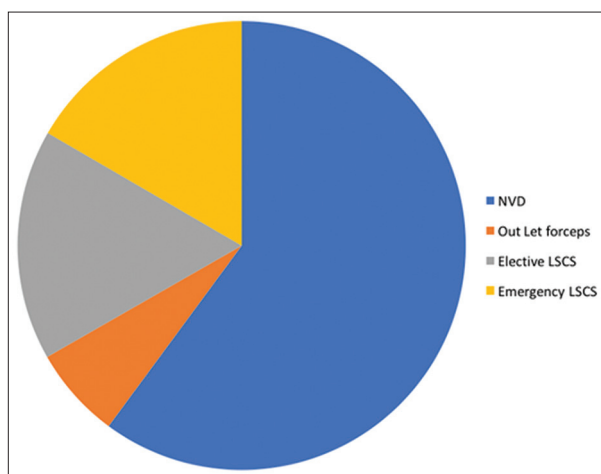


Figure 1: Mode of delivery in the subjects

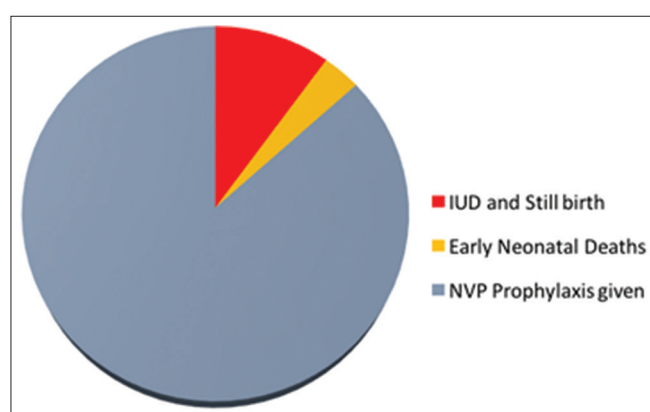


Figure 2: Nevirapine prophylaxis given to the neonates

Table 1: Distribution as per gestational age at first visit to the antenatal clinic and initiation of ARV prophylaxis

Distribution of cases as per gestational age at first visit to the antenatal clinic				
8–13 weeks	14–19 weeks	20–25 weeks	26–31 weeks	32–37 weeks
12	21	18	8	1
20%	35%	30%	13.3%	1.66%
Distribution of cases as per gestational age in initiation of ARV prophylaxis				
0	22	28	9	1
0%	36.6%	46.66%	15%	1.66%

ARV: Antiretroviral

Table 2: Fetal outcome as per the birth weight

Fetal outcome as per the birth weight (kgs)					
<1.5	1.5–1.9	2–2.4	2.5–2.9	3–3.4	3.5–3.9
1	4	4	25	22	4
1.6%	6.6%	6.6%	41.66%	36.66%	6.6%

Table 3: Follow-up details of the infants

18 months	12 months	6 months	Not followed
17	19	16	8
28.3%	31.6%	26.6%	13.3%

birth weight or IUGR. In our study, we had two neonates who were born with IUGR of the fetus and were because of pre-eclampsia

which is not related to HIV. Therefore, it can reasonably assumed that, anti-retroviral therapy in subjects who are on ART per se will not cause fetal growth restriction. Regarding the adverse fetal outcome in our study we have three still births, three IUDs and two early neonatal deaths. In all these cases the adverse fetal outcome were attributed to pre-eclampsia, abruptio placenta and preterm labor which are not attributed to HIV. HIV can give rise to preterm labor because in the pregnancy it can cause chorioamnionitis which may activate prostaglandin cascade. Furthermore, a pre-term baby is less likely to be immunologically competent and may die of sepsis. In this study, in 95% of the live births; the mother resorted to exclusive breast feeding and artificial feeding was given to 5% of neonates on demand. The NACO policy has initiated exclusive breast feeding because of the rise of diarrheal and respiratory diseases and the seropositivity is not known. NACO recommends extended NVP prophylaxis up to 6 weeks and continuation of ART lifelong, exclusive breast feeding up to 6 months and followed by abrupt weaning. The ART triple drug reduces the viral load in the breast milk and significantly reduces the perinatal transmission. In our study, 100% of the live infants were administered NVP as per the birth weight depending on their body weight from birth up to 6 weeks irrespective of whether they are breast fed or artificially fed. This extended NVP prophylaxis significantly reduces viral load in the neonate. NVP is the safe drug given in the doses recommended by the NACO and we did not encounter any side effects or adverse effects. The objectively measured outcome of the parent to child transmission of HIV virus is performed by doing a PCR DNA testing after 6 weeks of infancy as recommended by Centers for Disease Control and Prevention and NACO. In this study, there was 100% compliance and out of 54 live births 2 infants died in the neonatal period. Out of the 52 living infants 51 tested negative for PCR DNA and 1 tested positive giving a percentage of 1.9 as parent to child transmission. If we analyze the evolution of PPTCT from single drug NVP 10 to 12%, single drug AZT 8 to 10% and dual drug combination of AZT plus NVP 6 to 8% to triple drug ARV prophylaxis/ART 1.9%. It is very obvious that we have significantly reduced the parent to child transmission of HIV by the evidence based protocol using three drugs (2 NRTI's + NNRTI) initiated early in the second trimester. One more important advantage of the triple drug ARV prophylaxis/ART is that it prevents drug resistance to the single dose NVP or single drug AZT and also there is a synergistic action of all the three drugs. There has been a change since January 2014, from the existing three drug ARV prophylaxis used up to 1 week beyond the cessation of breast feeding to ART life long, to ensure drug compliance and prevent multi drug resistance. Chukwuemeka *et al.*, This study evaluated the effectiveness of prevention of mother-to-child transmission (PMTCT) activities in reducing the incidence of HIV infection among exposed babies at the National Hospital Abuja, Nigeria and in this study early infant diagnosis laboratory records of 515 exposed babies aged below 18 months who had PCR test between January 1st 2011 and December 31st 2012 were reviewed. The details of ARV therapy commencement for mother and baby, infant feeding choices, mode of delivery and HIV test results were analyzed and out of the 515 samples tested, 36 (7.0%) were found to be positive. The mean age of exposed children tested was 4 months. Highest prevalence was among children in the age group 6–18 months (16.1%). There was statistically significant association between HIV positive results and age. If the mother and child pairs received ARVs, the prevalence

was 1.3%, whereas if the mother only received ARV, then the prevalence was 4.6%, and when only the child received ARV the prevalence was 20.0%. When neither the mother nor the child received ARVs, the prevalence was 66.7% and the authors concluded that there was a high prevalence of HIV among exposed children in our setting, especially if the mother and child pairs did not receive any form of ARV prophylaxis. This further emphasizes the usefulness of ARVs as the single most important intervention in PMTCT. Therefore, there is need to expand ARV coverage, ensure access of the PMTCT program, and provide effective services to support infected children.^[9] Van Schalkway *et al.* This study was done in HIV infected pregnant women who were initiated ART for their own health. The main outcome measure was HIV transmission. 250 antenatal women with HIV were studied over that period and the PCR results were available for 212 of infants. The average pre-natal transmission was 5%. The study also noted that infant had significantly higher odds of being tested if their mothers had been on ART for <8 weeks before delivery. There was no significant association between HIV transmission and maternal age, maternal parity, baseline CD4 count, WHO staging, or delivery method. The author conclude that following the release of 2010 PMTCT guidelines, HIV infected pregnant women began ART earlier in their pregnancies. This longer period on ART before delivery is associated with reduced risk of MTCT and suggested that women should be educated about the benefits of entering care early and staying in care.^[10] In 2007, Thorne and Newell published an extensive literature review of the evidence for short-term to medium-term potential adverse effects and toxicities of exposure to ARV drugs in utero and in the neonate (including hematological, mitochondrial, teratogenic and carcinogenic effects). They concluded that the immense benefits of ARV prophylaxis in PMTCT far outweighed the potential for adverse effects. However, they also noted that these adverse effects required further and longer-term monitoring, because some adverse effects might occur later in childhood.^[11]

CONCLUSION

Universal screening by counseling and testing HIV is mandatory for all antenatal women in the antenatal clinics after proper pre-test counseling. Proper interpretation of HIV tested lab reports is important in the post-test counseling by the counselor or treating obstetrician. All antenatal women tested positive by the NACO protocol for HIV should be counseled with their partner for ART with triple drug single dose drug from 14 weeks of gestation,

irrespective of CD4 count or WHO clinical staging. Triple drug ARV prophylaxis/ART is more efficacious when compared to single drug NVP/AZT in all aspects and is having few side effects and drug compliance is also better. The triple drug ARV prophylaxis/ART allows the spontaneous vaginal delivery because of the significant reduction in viral loads <50 HIV RNA copies per mL.

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