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PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV – A COMPARISON OF SINGLE-DOSE NEVIRAPINE VERSUS MULTI-DRUG ANTIRETROVIRAL REGIMEN.

Paediatrics

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ABSTRACT

Introduction: The Prevention of Parent to Child Transmission (PPTCT) of HIV/AIDS program was started in the country in the year 2002 with the aim to offer HIV testing to all pregnant women. During the initial years, single-dose Nevirapine was the drug of choice to prevent mother to child transmission and was offered to the HIV-infected pregnant woman during labour and to her new born infant. This has now been replaced with the World Health Organization's(WHO) 2015 Consolidated guidelines that all pregnant and breastfeeding women with HIV initiate anti-retroviral therapy(ART) and continue ART as lifelong treatment. This study compares two PPTCT interventions - single-dose nevirapine (sd-nvp) to multi-drug ART regimen in a PPTCT centre in coastal Andhra Pradesh, where there is a high prevalence of HI**V.**

METHODS: This is a retrospective and prospective cohort study carried out during different periods, i.e., between February 2004 to August 2008 (single dose nevirapine group) and April 2015 to March 2018(multi-drug regimen group).

RESULTS: The present study showed a statistically significant reduction (Fisher exact test 0.046, $p<0.05$) in incidence of HIV in babies born to mothers who used multi-drug ART. No significant reduction has been noted in incidence with respect to the mode of delivery or the type of feed given to the baby

CONCLUSION: Triple-drug ART regimen is more effective as compared to the earlier regimen of single-dose nevirapine prophylaxis for the PPTCT programme. ART reduces the risk of transmission in such a way that the contribution of other factors remains significantly low.

KEYWORDS

PPTCT, multi-drug ART, breastfeeding, HIV

INTRODUCTION:

There are an estimated 21.17 lakh People Living with HIV (PLHIV) in India, with National adult HIV prevalence of 0.26% (2015). Of these, women constitute 40.5% of all PLHIV while children less than 15 years of age constitute 6.54% of all infections.1 The PPTCT of HIV/AIDS program was started in the country in the year 2002 with the aim to offer HIV testing to all pregnant women.2 As on 31st August 2016, in India there are 20,756 Integrated Counselling and Testing Centres (ICTC), most of these in government hospitals, which offer PPTCT services to pregnant women. The PPTCT programme aims to prevent the perinatal transmission of HIV from an HIV infected pregnant mother to her newborn baby. Without any intervention, the risk of transmission of HIV from infected pregnant women to her children is estimated to be around 20-45%. The PPTCT services cover about 47 percent annual estimated pregnancies in the country.3

During the initial years, single-dose Nevirapine was the drug of choice for prophylaxis to prevent mother to child transmission(MTCT) and was offered to the HIV-infected pregnant woman during labour and to her new born infant. WHO in 2010 had recommended two more efficacious regimens, option A & option B, to further reduce the chances of HIV transmission from mother-to-child. Further in 2015, WHO has recommended moving away from the previous terms "Options A, B and B+". Instead, the WHO new guidelines (2015) recommend providing lifelong ART to all the pregnant and breastfeeding women living with HIV regardless of CD4 count or clinical stage.4 With effect from 1st January 2014, pregnant women who are found to be HIV positive are initiated on lifelong ART irrespective of CD4 count and WHO clinical Staging; their newborn (HIV exposed) babies are initiated on 6 weeks of syrup Nevirapine immediately after birth so as to prevent transmission of HIV from mother to child and is extended to 12 weeks of syrup Nevirapine if the duration of the ART of mother is less than 24 weeks. Under the Essential Package of Services of the PPTCT Programme, NACO provides ART to all HIV infected pregnant women regardless of WHO staging and CD4 count results. Preferred regimen is a three-drug combination of Tenofovir, Lamivudine and Efavirenz. The launch of the multi-drug regimen in the PPTCT Programme in Andhra Pradesh called the "MAMATHA" Programme (in September 2012 and continued under the same banner until December 2013) rapidly scaled – up due to the wide dissemination of IEC messages in the programme developed by the State AIDS Control Society. When the Department of AIDS Control decided to roll-out Option-B +, country-wide from January 1st 2014 onwards, these IEC materials also underwent a quick modification to match the programme's needs. Option-B+ was then re-named as the "MAMATHA PLUS" Programme which entailed life-long ART.5

METHODS:

This is a retrospective and prospective cohort study carried out during two different time periods, when two different regimens(single dose vs multi dose regimen) were advised by National AIDS Control Organisation (NACO) i.e., between February 2004 to August 2008(single dose nevirapine group) and March 2015 to March 2018 (multi-drug regimen group). The data during both the time periods was collected from records in the PPTCT centre.

Their modes of delivery, type of feeding, anti-retroviral (ARV) prophylaxis given to the mother and infant, rapid antibody test results at 18 months of age were assessed. As per the Obstetric unit policy, lower segment caesarean section was performed for obstetric indications alone. No other invasive delivery technique was done. Both the mother and baby received ARV prophylaxis as mentioned above. The benefits and risks involved in replacement feeding as well as breast feeding were discussed with the parents and infant feeding was practiced accordingly.

EXCLUSION CRITERIA:

1. Women who had an abortion or a still birth.
2. Women who were lost to follow up during the antenatal period and post partum.
3. Women who delivered outside our institution (where no facilities for ARV were available)
4. Women who were registered at a PPTCT centre elsewhere, whose babies were followed up elsewhere.

Statistical analysis: Analysis is done using SPSS software. Odds ratio, confidence intervals, Chi square testing and Fisher's exact test were employed to assess the predictors of outcome.

RESULTS:

A total of 120 mothers were taken in to study group based on the criteria in to sd-nvp group and 73 in to multi-drug ART regimen group.

Out of the 120 babies, only 7 were found to be retroviral positive at the end of 18 months were as in multi-drug group none of the babies were affected (Table 1) and the difference between both the groups is statistically significant.(P<0.05)

Table 2 depicts the impact of mode of delivery on the outcome at 18 months. Among the 120, in sd-nvp group, 31 mothers underwent Caesarean section while the others were delivered by vaginal delivery without instrumentation. Only 2 babies were retroviral positive among those delivered by Caesarean section while 5 babies were positive in the vaginal delivery group, but this difference is not statistically significant. Among the 73 in multi-drug group, 43 mothers underwent vaginal delivery ant the remaining 30 Caesarean section

Table 1 Comparison between single vs multi drug regimens

	No. of Mother-infant pairs	No. of infants with HIV at the end of 18 months	Incidence of HIV Infection (%)
Single drug group (sd-nvp)	120	7	5.8%
Multi drug regimen group	73	0	0%

The Fisher exact test statistic value is 0.046. The result is significant at $p < 0.05$.

Table 2 : Effect of mode of delivery on HIV status of baby

	Normal vaginal delivery	No. of infants with HIV(%)	Caesarean section	No. of infants with HIV(%)	P value
Single drug group (sd-nvp)	89	5 (5.6%)	31	2 (6%)	0.865 (insignificant)
Multidrug regimen group	43	0 (0%)	30	0 (0%)	Fisher exact t test :1 P > 0.05 (insignificant)

Table 3 Effect of feeding on HIV status of baby

	Breastfed	No. of infants with HIV(%)	Top fed	No. of infants with HIV(%)	p value
Single drug group (sd-nvp)	6	2 (4.38%)	114	5 (33.3%)	0.791 (insignificant)
Multi-drug regimen group	32	0 (0%)	41	0 (0%)	Fisher exact t test :1 P >0.05 (insignificant)

The effect of feeding on the HIV status of the baby is depicted in Table 3. Majority of the babies in the single drug group were top fed(n=114). Only 6 were given breastfeed, out of whom 2 are retroviral positive. Among the top fed group only 5 were positive, but this has no statistical significance.

DISCUSSION:

India has witnessed a major upscaling of PPTCT services from the year 2012. Andhra Pradesh is one of the 4 states in South India with high incidence of HIV. We have undertaken this study to find out the efficacy of multi drug ARV regimen on PPTCT. We have also compared the previously followed single drug Nevirapine regimen to the presently followed multi drug regimen to underline the importance of multi drug regimen in eliminating MTCT, which was possible in the developed world.

The transmission of HIV from mother to child during the sd-NVP era in our study was 5.8%. Majority of women and infants received ARV in the form of single dose Nevirapine, which had a significant protective effect. Replacement feeding lowered the transmission as compared to exclusive breast feeding, however this effect is not statistically significant. In contrast, during the multi drug regimen period, the transmission rate is 0 %, which points out the fact that multi drug regimen given to the mother from 24 weeks of gestation or during the first check-up, given lifelong, along with syrup Nevirapine to the baby for a minimum period of 6 weeks is highly efficacious, paving the way for elimination of HIV in India.

Efficacy of multidrug ART prophylaxis has been tested across the world in different regions with huge success rate. One sub-Saharan Africa based study also demonstrated that the regimen was very effective in reducing mother-to-child HIV transmission.6 India-based studies were limited and one such study from South India was conducted with 92 positive pregnant women only which study showed a transmission rate of 3.3% with ARV prophylaxis.7 One Cameroon-based study used three different types of multidrug regimens and it was found that all these regimens brought down the mother-to-child transmission rate to 6.6% without any difference in efficacies across the regimens.8 One review in 2008 emphasized that the use of fully suppressive ART initiated during pregnancy and the breastfeeding period, even in women with no indication of treatment, was a potentially effective PPTCT strategy and this might constitute a very relevant alternative when formula feeding was not judged to be safe or well accepted.9 Another Kenya-based study reiterated the same fact that lack of maternal use of highly active antiretroviral therapy was associated with increased risk of HIV transmission to the child.[10]

Our study observed that the infant feeding option did not result in any significant difference in PPTCT outcome when the HIV-infected mothers were already put on ART but one study conducted in Southeast Nigeria demonstrated that breastfeeding reduced the efficacy achieved by the use of ARV drugs.11 In India exclusive breast feeding until the six month of the HIV-exposed infant is a nationally recommended practice and replacement feeding is only recommended if it is affordable, acceptable, feasible, accessible, sustainable and safe. A risk reduction effect of caesarean section was also observed in one randomized clinical trial.12 Our study did not show any significant difference in HIV transmission rate with respect to modes of delivery.

CONCLUSION:

In a state like Andhra Pradesh ,where the prevalence of HIV is high, the early detections of antenatal mothers with HIV, early initiation of multi drug ARV before 24 weeks, institutional delivery, Syrup Nevirapine prophylaxis for baby along with Early Infant Diagnosis are all pivotal for elimination of MTCT of HIV. The type of feeding and mode of delivery do not have a significant impact on the transmission of HIV. The decision to breastfeed still lies with the mother, however, the World Health Organisation recommends exclusive breastfeeding for the first 6 months to all infants exposed to HIV as the risk of transmission of HIV to the infant is quite low with the advent of the newer ARV regimens for both the mother and the baby.

The NACO along with Government of India should be applauded for their efforts in elimination of HIV especially by offering free diagnosis for baby and mother, highly efficacious ARV regimens free of cost.

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