

Effect of Highly Active Antiretroviral Treatment (HAART) during Pregnancy on Pregnancy Outcomes: Experiences from a PMTCT Program in Western India

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Background

- While the benefits of highly active antiretroviral treatment (HAART) for prevention of mother to child transmission of HIV (PMTCT) are undisputed, there have been some concerns regarding its possible adverse effects on pregnancy outcomes.
- While there is an increasing number of studies suggesting higher risk of preterm birth (PB) (<37 weeks) and low birth weight (LBW) among babies of women receiving HAART during pregnancy, there are also some studies that did not observe this association.
- Most of the studies are from developed regions and only recently research findings are emerging from developing regions.
- HAART is being rapidly scaled-up in developing countries for PMTCT following conclusive studies demonstrating its efficacy in reducing mother to child transmission of HIV (MTCT).

Method

This study compared adverse pregnancy outcomes among HIV infected women (N=516) who received either HAART (N=192) - mostly without protease inhibitor - or antepartum azidothymidine (AZT) with intrapartum nevirapine (N=324) from January 2008 to March 2012 through a PMTCT program in western India.

- The differences among women who received HAART and those who received AZT in terms of pregnancy outcomes (PB, LBW and non-live births), HIV related factors, obstetric factors and demographic factors were assessed using chi-square tests.
- The effect of ARV protocol on pregnancy outcomes was analysed using independent univariate and multivariate logistic regression models for all three outcome variables, the latter by including all other background HIV related, obstetric and demographic variables.
- Data were analysed using SPSS (version 20).

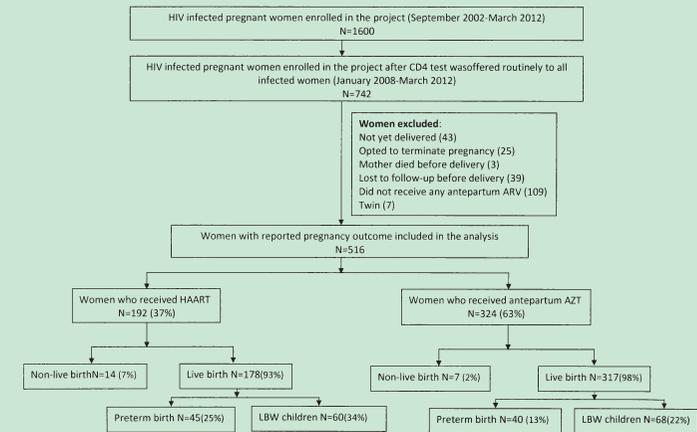


Figure 1 : Pregnancy outcomes among women enrolled in the project

Setting

- The data used in this study were collected prospectively in a PMTCT program implemented by PRAYAS, a non-government organization located in the city of Pune, in Maharashtra State of India.
- The PRAYAS PMTCT program was initiated in 2002 with the support from Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) and is primarily being implemented in the private health sector
- The program currently reaches to approximately 36000 pregnant women annually through 50 hospitals in 10 districts of Maharashtra.
- 1600 HIV infected women were provided PMTCT services through the program as per the then contemporary WHO recommended protocols



Conclusion

- This study has demonstrated a high risk of adverse pregnancy outcomes - particularly preterm birth - among HIV infected Indian women receiving HAART not containing PI through a private sector PMTCT program in Maharashtra.
- The Indian national program for prevention of mother to child transmission is likely to rollout HAART (option B). While the benefits of HAART must be provided to pregnant women, there is a need to address certain knowledge gaps associated with rolling out HAART for PMTCT.
- Prospective studies assessing the impact of HAART on MTCT as measured in terms of HIV-free survival among children are needed.

Results

- Women on HAART had 48% adverse pregnancy outcomes, 25% preterm births, and 34% low birth weight children compared to respectively 32%, 13%, and 22% among women on AZT.
- Women receiving HAART were more likely to have adverse pregnancy outcomes and preterm births compared to women receiving AZT.
- Preconception HAART was significantly related to low birth weight children
- This study demonstrated increased risk of adverse pregnancy outcomes with protease inhibitor excluded HAART.

Table 3 : Crude and adjusted risk ratios (RR) for preterm birth, low birth weight and all adverse pregnancy outcomes

Protocol	Preterm Birth (PB) RR (95% CI)		Low Birth Weight (LBW) RR (95% CI)		All Adverse Pregnancy Outcomes RR (95% CI)	
	Crude	Adjusted	Crude	Adjusted	Crude	Adjusted
HAART	2.343 (1.459-3.762)	3.350 (1.520-7.383)	1.826 (1.209-2.758)	1.463 (0.746-2.871)	2.029 (1.400-2.941)	1.949 (1.099-3.454)
AZT	Ref	Ref	Ref	Ref	Ref	Ref
CD4	2.320 (1.095-4.917)	1.211 (0.422-3.471)	2.092 (1.050-4.168)	0.976 (0.370-2.578)	2.417 (1.290-4.526)	1.192 (0.519-2.742)
0-200	1.353 (0.716-2.559)	0.882 (0.375-2.071)	1.307 (0.749-2.281)	1.061 (0.510-2.209)	1.371 (0.844-2.229)	1.127 (0.609-2.084)
201-350	0.806 (0.405-1.601)	0.917 (0.441-1.909)	1.313 (0.760-2.267)	1.291 (0.705-2.365)	1.013 (0.617-1.662)	1.047 (0.617-1.778)
351-500	Ref	Ref	Ref	Ref	Ref	Ref
>500	Ref	Ref	Ref	Ref	Ref	Ref
Age						
16-20	2.167 (0.851-5.519)	3.370 (1.031-11.012)				
21-25	1.232 (0.540-2.811)	1.192 (0.449-3.161)				
26-30	1.354 (0.573-3.200)	1.598 (0.592-4.312)				
≥31	Ref	Ref				
Preterm delivery						
Yes	-	-	3.850 (2.357-6.287)	3.795 (2.149-6.704)	-	-
No	-	-	Ref	Ref	-	-