

## Background

Efavirenz (EFV) is a non-nucleoside reverse transcriptase inhibitor used in South Africa's first-line Highly Active Anti-Retroviral Therapy (HAART) regimen. It is classified as FDA Pregnancy Category D amidst first-trimester teratogenicity fears. Despite this, HIV-positive women in South Africa conceive while on EFV. A report from Brazil suggested increased risk of miscarriage for women receiving EFV. South African public sector surveillance reports spontaneous miscarriage rate of 6.3% (2001), stillbirth rate of 2.4% (2006-07), and elective termination of pregnancy (TOP) rate of 13.6% (2001).

## Study design and Methods

We performed a retrospective review of 886 HIV-infected women who received HAART at the Perinatal HIV Research Unit, South Africa between August 2004 and March 2008. Details of HAART regimens, pregnancy, gestational age and outcomes were recorded. Miscarriage, stillborn and TOP rates were compared between EFV-exposed and EFV-unexposed pregnancies. Chi-square test was used to calculate proportional differences between EFV exposed and non-EFV exposed pregnancies.



## Findings

117 pregnancies were recorded in 886 women taking HAART between August 2004 and March 2008. Total pregnancy outcomes were: 73 live births (1 set of twins), 8 spontaneous miscarriages, 2 stillbirths, 30 TOP, and 5 without recorded outcomes. 83/117 (70.9%) conceptions were efavirenz-exposed for mean duration 97.05 days (range 12-343 days) and of these 3/83 (2.6%) miscarried, 1/83 (1.2%) were stillbirths, and 28/83 (33.7%) were electively terminated. 34/117 (29.1%) conceptions were efavirenz-unexposed, and of these 5/34 (14.7%) miscarried, 1/34 (2.9%) were stillbirths, and 2/34 (5.9%) were electively terminated. Compared to live births, TOP rates were significantly greater ( $\alpha=0.05$ ) among EFV-exposed than non-EFV exposed (Chi Square = 8.206,  $p=0.00418$ ).

Regimen	N	Miscarriage (%)	Stillborn (%)	TOP (%)
Unexposed to HAART at time of conception	10	0	0	2 (20%)
Exposed to EFV-containing HAART regimen during pregnancy	83	3 (3.6%)	1 (1.2%)	28 (33.7%)
Exposure to non-EFV-containing HAART regimen during pregnancy	34	5 (14.7%)	1 (2.9%)	2 (5.9%)

## Conclusions

provider teratogenicity counselling and indicate provider choice to initiate EFV-containing regimens for women

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