Journal of the International AIDS Society

Oral presentation

O223 Antiretroviral Pregnancy Registry (APR) at 10,000 prospective reports

KP Beckerman*[1], D Covington[2], K Dominguez[3], A Scheuerle[4], VX Vannappagari[5], DH Watts[6] and H Tilson[7]

Address: [1]Albert Einstein College of Medicine, Bronx, New York, USA, [2]Kendle International Inc, Wilmington, North Carolina, USA, [3]Centers for Disease Control, Atlanta, Georgia, USA, [4]Tesserae Genetics, Dallas, Texas, [5]Glaxo Smith Kline, New Jersey, USA, [6]National Institute of Child Health and Human Development, Bethesda, Maryland, USA and [7]University of North Carolina School of Public Health, Chapel Hill, North Carolina, USA

* Corresponding author

from Ninth International Congress on Drug Therapy in HIV Infection
Glasgow, UK. 9–13 November 2008

Published: 10 November 2008

Journal of the International AIDS Society 2008, **11**(Suppl 1):O22 doi:10.1186/1758-2652-11-S1-O22

This abstract is available from: http://www.jiasociety.org/content/11/S1/O22

Background

Prospective data on neonatal outcome following in utero exposure to antirerovirals (ARVs) are essential components of safety monitoring of these life-saving therapies. Toward this end, APR was created in 1989 and is now one of the largest ongoing pregnancy registries in the world.

Methods

APR is an international registry that uses a prospective exposure-registration cohort design to monitor potential birth defects following in utero ARV exposure. Health care providers voluntarily enroll exposed pregnant women, then provide follow-up neonatal data. We analyzed APR data for their ability to detect, at 80% power with Type I error rate of 5%, potential increases in birth defect prevalence following fetal 1st trimester (TRI) exposure (when organogenesis occurs), vs. 2nd and 3rd TRI exposures.

Summary of results

By January 2008, APR received 11,209 prospective reports. Of these, 9,400 live birth (LB) outcomes were available, including 3,951 LB following 1st TRI exposures. These reports allow detection of a potential 1.5-fold increase in overall anomalies following 1st TRI exposure to any ARV compared to 2nd/3rd TRI exposures. We found no such increase. Birth defect prevalence after any 1st TRI ARV exposure was 3.0% vs. 2.6% following any 2nd/3rd TRI ARV exposure (1.13 relative risk, 95% CI = 0.89, 1.43). Twelve individual drugs have >200 1st TRI reports and allow us to detect a potential 1.5–2-fold increase in all defects for each agent (Table 1). Such an increase has not been found.

Two drugs met the threshold for evaluation and further monitoring: zidovudine was associated with an increased risk of hypospadius [1], and a higher than expected defect prevalence following didanosine exposure that has no apparent pattern and is not statistically significant [2].

Conclusion

In summary, prospectively collected APR data have not detected an overall increase in birth defects following in utero ARV exposure during organogenesis. We continue to follow two trends that do not reach statistical significance.

References

1. Watts DH, *et al.*: **Assessment of birth defects according to maternal therapy among infants in the Women and Infants Transmission Study.** *Journal of Acquired Immune Deficiency Syndromes: JAIDS* 2007, **44(3):**299-305.
2. **Antiretroviral Pregnancy Registry International Interim Report for 1 January 1989 through 31 January 2008** 2008 [http://www.APRegistry.com]. *Wilmington, NC: Registry Coordinating Center*

Table 1:

	Defects	LB Prevalence (95%CI)
Zidovudine	87/2808	3.1% (2.5%,3.8%)
Lamivudine	85/2784	3.1% (2.4%,3.8%)
Nelfinavir	33/972	3.4% (2.3%,4.7%)
Nevirapine	18/737	2.4% (1.5%,3.8%)
Stavudine	19/651	2.9% (1.8%,4.5%)
Ritonavir	16/628	2.5% (1.5%,4.1%)
Abacavir	17/512	3.3% (1.9%,5.3%)
Tenofovir	11/491	2.2% (1.1%,4.0%)
Efavirenz	10/364	2.7% (1.3%,5.0%)
Didanosine	16/353	4.5% (2.6%,7.3%)
Lopinavir	6/328	1.8% (0.7%,3.9%)
Indinavir	6/272	2.2% (0.8%,4.7%)