

Confounding variable



**ASSIGN
BUSTER**

Mitochondrial dysfunction following perinatal exposure to nucleoside analogues

Abstract: We conducted a study to estimate the association of in utero NA exposure and potential confounders and MD in the International Maternal Pediatric Adolescent AIDS Clinical Trials Group protocol P1025, a multisite US cohort of HIV-infected women and their infants. The study population included HIV-uninfected or indeterminate infants born on or before November 1, 2006. This date restriction was used to allow 6 months of follow-up to evaluate the persistence or resolution of possible signs of MD at the time data were frozen for review.

P1025 visits were conducted during routine prenatal and pediatric visits. Infant visits were scheduled at birth, 2, and 6 weeks of age, and at 4, 6, 9, and 12 months of age. Data were primarily abstracted from medical records of routine clinical care, and were supplemented by certain focused assessments including infant physical and neurological examinations, and Bayley neuropsychological testing. To identify possible or established cases of early MD according to the Enquete Perinatale Francaise (EPF) screening definition, a retrospective review of clinical data recorded on protocol case report forms were performed by clinicians blinded to in utero exposures. Possible and established cases (N = 3) were significantly more likely to be born in earlier years (all born in 2003) than noncases (N = 979, born in 2002-2006), P = 0.02. Among infants with maternal HIV viral loads recorded, the log median maternal HIV viral load during the first trimester was significantly higher among cases [N = 2, 5.2 (IQR: 4.6, 5.7)] than noncases [N = 355, 3.2 (IQR: 2.6, 4.1), P = 0.

01]. The maternal HIV viral load of the established case was 187 copies/mL at the time of the maternal HIV diagnosis early in the second trimester]. No significant difference in the distribution of other potential confounders was detected. Overall, peak maternal HIV viral loads in the first and second trimesters significantly decreased with increasing year of delivery. No significant difference was observed in peak maternal HIV viral load in the third trimester by year of delivery: half of all women were below the limit of detection of 400 copies/mL in 2003 through 2006.

We did not detect any significant differences in the in utero NA exposure of possible cases and noncases. Summary: Discussion section mentioned in study, confounding from year of birth was evident, and possible confounding from maternal drug use and HIV viral loads was suggested. To identify possible or established cases of early MD according to the Enquete Perinatale Francaise (EPF) screening maternal drug use should be assessed. I chose the confounding variable maternal drug use because infants??™ physical and neurological growth will be greatly affected if mothers used drugs while pregnant. The study did not evaluate cases and controls for characteristics of in utero alcohol, tobacco, cocaine, heroin, and prescription methadone exposure.

The Study did not detect any significant differences in the in utero NA exposure of possible cases and noncases. Incidence-prevalence bias was avoided because retrospective review of clinical data recorded on protocol case report forms were performed by clinicians blinded to in utero exposures.