**0792 - EXTENDED PROPHYLAXIS WITH NEVIRAPINE DOES NOT AFFECT GROWTH IN HIV-EXPOSED INFANTS**

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**Background:** The effect of anti-retroviral prophylaxis (ART) on growth in HIV-exposed uninfected (HEU) children is of interest, especially in settings where growth is already limited, as in sub-Saharan Africa. The potential benefit of ART against perinatal HIV transmission must be balanced against the potential harm of ART on growth. The HPTN 046 trial examined the growth effects of prophylaxis with Nevirapine (NVP) in HIV-exposed, uninfected infants. The primary outcome was the incidence of adverse growth outcomes in infants through 18 months of age. The secondary outcomes were the incidence of stunting, wasting and overweight in infants through 18 months of age. The study was a randomized, placebo-controlled, single-blinded trial conducted in six sites in South Africa. The infants were randomized between 1 and 30 days of life and received postpartum ART or placebo. The infants were followed for 18 months after randomization. The authors report on their assessment of growth as a result of the trial and discuss the implications of their findings.

**Methods:** The trial enrolled HIV-exposed, uninfected infants aged less than 30 days at the time of randomization. Infants were randomized to receive either NVP (N=751) or placebo (N=750) within 1-30 days of life. Those infants who were randomized to NVP received NVP 2.5 mg/kg once daily for 28 days. The primary endpoint was the incidence of adverse growth outcomes in infants through 18 months of age. The secondary endpoints were the incidence of stunting, wasting and overweight in infants through 18 months of age. The trial was powered to detect a 22% reduction in the incidence of adverse growth outcomes using a Cox proportional hazard regression model with an alpha of 0.05. The main analyses were based on the intention-to-treat principle. The authors performed sensitivity analyses to assess the effect of selection bias.

**Results:** The incidence of adverse growth outcomes increased substantially over the study period from 6 weeks to 18 months. The authors observed a significant increase in the incidence of adverse growth outcomes in the first 6 weeks of life compared to the second 6 weeks of life (p<0.01). The authors found that male sex, short duration of breastfeeding, lack of maternal ART exposure may increase risk for growth compromise in HEU infants. The authors also noted that the incidence of adverse growth outcomes was higher in infants who were breastfed for less than 6 months compared to those who were breastfed for 6-12 months. The authors concluded that the incidence of adverse growth outcomes was lower in infants who received NVP compared to those who received placebo. The authors recommended further research to determine the long-term effects of NVP prophylaxis on growth in HIV-exposed, uninfected infants.