Abstract View

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OP363 11.12-11.24 **TIME SINCE LAST DRUG EXPOSURE IN PREGNANCY DETERMINES ADALIMUMAB AND INFLIXIMAB LEVELS IN NEONATES (ERA STUDY)**

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INTRODUCTION/OBJECTIVES:

Recent studies suggest no adverse pregnancy outcomes in babies exposed to anti TNF antibodies (ATA). However, the long term implications are unknown. This study aimed to examine drug levels of ATA in cord blood of newborns exposed to ATA in pregnancy, and to correlate these with maternal levels, the duration of therapy during pregnancy, and time to clearance of ATA in infants.

AIMS & METHODS:

Women with IBD exposed to infliximab (IFX) or adalimumab (ADA) during pregnancy were included from 2012-present at 14 hospitals in Denmark, Australia and New Zealand. ATA levels were measured using an ELISA in cord and maternal blood at delivery (Matriks Biotek). If positive at birth, the infants were tested every third month until ATA were undetectable. Demographics, disease phenotype, disease activity in pregnancy, duration of ATA use in pregnancy, medication and pregnancy outcomes were prospectively collected by questionnaire and from the treating doctor.

RESULTS:

53 mother-baby pairs have been tested (27 IFX and 26 ADA). An inverse correlation between duration since last exposure and cord ATA levels at birth was found (IFX: $r = -0.58$, $p = 0.002$; ADA: $r = -0.42$, $p = 0.047$). This was also the case for maternal levels at birth (IFX: $r = -0.59$, $p = 0.002$; ADA: $r = -0.52$, $p = 0.01$). There was a strong correlation between cord blood and maternal levels at delivery (IFX: Pearson's $r = 0.80$, $p < 0.0001$; ADA: $r = 0.80$, $p < 0.0001$). Drug was ceased prior to gestational week (GW) 30 in 15 (28%) women. In them, mean serum concentrations were 0.81 µg/ml (IFX) and 0.08 µg/ml (ADA), and the cord blood level at delivery was <3 µg/ml in 11/15 (73%). So far 30 babies have completed testing for detectable ATA levels, and testing is ongoing in the remaining 23 babies. Complete clearance of ATA was seen in 7, 5, 12 and 6 babies at birth, by 3, 6 and 9 months, respectively. To date there has been one detectable ATA level at 9 months. Three women (5.7%) gave birth preterm (GW 33-35). No congenital malformations were detected and all babies are developing normally.

CONCLUSION:

Maternal and neonatal ATA levels were inversely correlated with the duration since last exposure. Cord blood ATA levels were strongly correlated with maternal level at delivery. Maternal cessation of ATA prior to week 30 successfully reduced fetal exposure to drug in the vast majority of cases. Follow up will determine whether high neonatal levels have any negative consequences.