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BACKGROUND

- Bictegravir (BIC), co-formulated in a tablet with tenofovir alafenamide and emtricitabine, is being increasingly prescribed to pregnant persons with HIV (PWH)
- Limited birth outcome data have been reported in PWH who have taken BIC

METHODS

Study Population

- PWH 18-45 years of age enrolled in at least one PHACS-affiliated protocol:
  - SMARTT
  - AMP Up
  - AMP Up Lite
  - HOPE
- Received BIC for at least 7 days during pregnancy
- Completed follow-up through delivery

Statistical Methods

- Prevalence with Clopper-Pearson 95% CIs was calculated among infants exposed to BIC
  - For anomalies, only exposure to BIC in the first trimester was considered
- Maternal CD4 count and HIV viral load (VL) nearest and prior to delivery were reported (if available)

**Table 1. Reported Birth Outcomes Among Infants Exposed to ≥7 days of Bictegravir during Gestation**

| Gestational age at birth                                                   | Birth weight Z-score (adjusted for gestational age): BWZ |
|----------------------------------------------------------------------------|----------------------------------------------------------|
| Preterm birth (<37 weeks gestation)                                        | Birth length Z-score (adjusted for gestational age): BLZ |
| Small for gestational age (birth weight <10 <sup>th</sup> percentile): SGA | Neonatal death in first 28 days of life                  |
| Any major congenital anomaly                                               | Infant HIV status                                        |

In this US cohort, the use of *bictegravir* during pregnancy appears to be common. Findings *do not suggest early safety signals* for adverse birth outcomes with bictegravir use in pregnancy.

RESULTS

- 144 infants** were born between September 2018 and October 2023 to **134 unique PWH** (including 2 twin sets) who received BIC for at least 7 days during pregnancy
- Summary of demographic characteristics:**
  - Median PWH age at delivery was 29.7 years (IQR: 26.1, 33.9)
  - 71% of PWH reported their race/ethnicity as Black or African American
  - 52% had annual household income <\$20,000
  - All US census regions were represented
- HIV disease status nearest to delivery:**
  - 82% had maternal VL <50 copies/mL
  - Median CD4 count was 466.5 (IQR: 309, 744) cells/mm<sup>3</sup>
- Timing of BIC use:**
  - 53% of PWH initiated BIC prior to conception
  - 99 infants (69%) were exposed to BIC in the first trimester
- Birth outcomes:**
  - Summarized in Table 2**
  - No neonatal deaths or perinatal HIV transmissions were reported

**Table 2: Birth Outcomes of Infants Exposed to ≥ 7 Days of Bictegravir during Gestation**

| Infant Outcome                                                                                       | Pre-Conception Initiation (N=76) | Post-Conception Initiation (N=68) | Total (N=144)                   |
|------------------------------------------------------------------------------------------------------|----------------------------------|-----------------------------------|---------------------------------|
| <b>Gestational age</b>                                                                               | N=76*<br>37.9 (1.5)              | N=67*<br>38.4 (1.4)               | N=143*<br>38.2 (1.5)            |
| <b>Preterm birth</b>                                                                                 | 15/76,<br>19.7% (11.5%, 30.5%)   | 5/67*,<br>7.5% (2.5%, 16.6%)      | 20/143*,<br>14.0% (8.8%, 20.8%) |
| <b>Small for gestational age</b>                                                                     | 3/76*,<br>3.9% (0.8%, 11.1%)     | 12/66*,<br>18.2% (9.8%, 29.6%)    | 15/142*,<br>10.6% (6.0%, 16.8%) |
| <b>Congenital anomalies (among pregnancies with 1<sup>st</sup> trimester bictegravir exposure)**</b> | 4/76,<br>5.3% (1.5%, 12.9%)      | 1/23,<br>4.3% (0.1%, 21.9%)       | 5/99,<br>5.1% (1.7%, 11.4%)     |
| <b>Birth weight Z-Score (adjusted for gestational age)</b>                                           | N=76*<br>-0.50 (0.84)            | N=66*<br>-0.47 (1.03)             | N=142*<br>-0.49 (0.93)          |
| <b>Birth length Z-Score (adjusted for gestational age)</b>                                           | N=53*<br>0.04 (1.08)             | N=50*<br>0.12 (1.19)              | N=103*<br>0.08 (1.13)           |

Data shown as % (with 95% CI) or mean (SD). \*Differences between N in top row and column are due to incomplete data  
\*\*Anomalies included ventricular septal defect, Turner syndrome, Dandy-Walker malformation, polydactyly, and Jacob's syndrome

CONCLUSIONS

- In this US cohort, BIC use during pregnancy was frequent
- BIC initiation prior to conception was common, but 30% initiated during pregnancy
- These findings provide initial reassuring observations about the potential safety of BIC use during pregnancy
- Comparative data and continued surveillance of outcomes of antiretroviral therapy among pregnant PWH is warranted

REFERENCES

- Rough K, Seage GR III, Williams PL, Hernandez-Diaz S, et al for the Pediatric HIV/AIDS Cohort Study (PHACS) and International Maternal Pediatric Adolescent AIDS Clinical Trial (IMPAACT) P1025 Study Teams. **Birth outcomes for pregnant women with HIV using tenofovir-emtricitabine.** N Engl J Med **2018**; 378:1593-1603.
- Jao J, Kacanek D, Williams PL, Geffner ME, et al for the Pediatric HIV/AIDS Cohort Study and International Maternal Pediatric Adolescent AIDS Clinical Trials Network. **Birth weight and preterm delivery outcomes of perinatally vs. non-perinatally HIV-infected pregnant women in the U.S.: results from the PHACS SMARTT study and IMPAACT P1025 protocol.** Clin Infect Dis **2017**; 65(6):982-989.
- Williams PL, Hazra R, Van Dyke RB, Yildirim C, et al for the Pediatric HIV/AIDS Cohort Study. **Antiretroviral exposure during pregnancy and adverse outcomes in HIV-exposed uninfected infants and children using a trigger-based design: The SMARTT Study.** AIDS **2016**; 30(1):133-44.
- Caniglia EC, Patel K, Huo Y, Williams PL, Kapetanovic S, Rich K, Sirois PA, Jacobson DA, Hernandez-Diaz S, Hernan MA, Seage GR III for the Pediatric HIV/AIDS Cohort Study. **Atazanavir exposure in utero and neurodevelopment in infants: A comparative safety study.** AIDS **2016**; 30(8):1267-78.

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