P3-K10

Exposure to PrEP and Safety Monitoring in Pregnancy: Importance of Objective Exposure Measurement

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Objective measurements of oral PrEP use during pregnancy suggest it is ***safe to use in pregnancy*.**

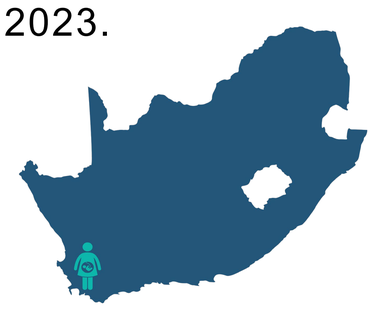
Discordance in self-reported versus objective exposure data highlights the ***imperative for objective exposure monitoring of PrEP in future pregnancy safety research.***

BACKGROUND

- In South Africa, ~1/3 of infant HIV infections are attributed to maternal HIV acquisition during pregnancy or postpartum periods.
- Safety evaluations of oral pre-exposure prophylaxis (TDF/FTC) during pregnancy have been based on self-reported adherence or study allocation with no safety studies using objective exposure measures.

METHODS

- The PrEP in pregnancy and postpartum (PrEP-PP) study in Cape Town enrolled pregnant women ≥16 years without HIV at their first antenatal care visit and followed-up through 12-months postpartum between Aug 2019- Feb 2023.



- All women were counselled quarterly on HIV risk including counseling on safety and effectiveness of oral PrEP (TDF/FTC).

- In women who reported taking PrEP in the last month, we quantified tenofovir diphosphate (TFV-DP) levels in dried blood spots (DBS).
- Using multivariable logistic regression, adjusting for maternal age and gestational age at baseline, we **compared pregnancy outcomes among women using the following exposures:**
    1. Self-reporting PrEP use in pregnancy (any)
    2. Objective levels of PrEP use (any TFV-DP detected)
    3. Missing PrEP exposure data (received prescription at baseline but never confirmed PrEP use

RESULTS

- In 826 women who reported PrEP use during pregnancy with pregnancy outcome data, the median age was 27 years (IQR:23-31), baseline gestation age (GA) was 22 weeks (IQR:14-30) at baseline; 32% were primigravid.
- Among pregnant women reporting PrEP use in the last 30 days, 181 of 471 (39%) had objective levels of PrEP use (any TFV-DP in DBS).
- Women with TFV-DP present were older age, >20 weeks GA (vs <20 weeks) at PrEP start, had a partner with unknown serostatus or living with HIV, and had higher sex frequency in past month (>5 times vs. <5 times or no sex) ($p<0.05$).

RESULTS CONTINUED

Table 1. Comparison of pregnancy outcomes by PrEP exposure: (1) self-report, (2) objective measures of TFV-DP in DBS, (3) missing PrEP exposure (received prescription but did not return to confirm PrEP use) in PrEP-PP study, Cape Town, South Africa, August 2019-February 2023

	1. Self-reported PrEP use in pregnancy	**2. Objective levels of TFV-DP in pregnancy (subset of #1)**	**3. Missed PrEP exposure (never returned for follow-up)**
Total	**826**	**181**	**141**
Pregnancy loss (miscarriage or stillbirth)	27 (3.3)	7 (3.9)	26 (18.4)
Preterm Delivery	68 (8.5)	12 (6.6)	12 (10.4)
SGA	74 (9.3)	12 (6.6)	10 (8.7)
Composite Adverse Outcome	**169 (20.5)**	**31 (17.1)**	**46 (32.6)**

* Composite outcome includes: pregnancy loss, neonatal death, infant born SGA, preterm birth or low birthweight infant

- Women with missing PrEP exposures had the highest rates of adverse pregnancy outcomes during the study period at 32.6% (18.4% pregnancy loss, 10.4% preterm delivery, 8.7% infant born SGA).
- In women with TFV-DP in their DBS (n=181), had lower adverse outcomes including composite outcome at 17%, 3.9% had pregnancy loss, 6.6% had preterm delivery, 6.6% had an infant born SGA.
- Correlation between self-reported PrEP use and objective TFV-DP levels was low (–0.07 in pregnancy).

CONCLUSIONS

- The proportion of "PrEP-exposed" pregnant women with **adverse pregnancy outcomes differed significantly based on how PrEP exposure was defined**, highlighting the <u>importance of objective monitoring in pregnancy safety studies as self-reported PrEP use</u> did not correlate with objective levels.
- Pregnant women who discontinued PrEP had worst pregnancy outcomes and may require additional interventions for PrEP and pregnancy health.
- Rapid, cost-effective methods for measuring objective PrEP use are urgently needed.

ADDITIONAL KEY INFORMATION

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