DTG versus EFV initiation in pregnancy is not associated with postpartum blood pressure

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BACKGROUND

- Numerous studies conducted in non-pregnant adults have indicated potential associations between dolutegravir (DTG) use and increases in blood pressure (BP), although findings are inconsistent.
- However, there is a notable lack of data on this topic from two key populations: (i) individuals residing in sub-Saharan Africa and (ii) pregnant and postpartum women living with HIV (PPHIV).
- Understanding the effects of DTG on BP in these populations is crucial for optimising HIV treatment strategies and ensuring the well-being of pregnant and postpartum women.
- Therefore, there is a pressing need for further research to explore the relationship between DTG use and BP changes specifically in sub-Saharan African populations and among pregnant and postpartum women.

Despite concerns about BP increases associated with DTG use, we found no evidence of postpartum association; however ongoing vigilance for long-term cardiometabolic effects of DTG use remains crucial.

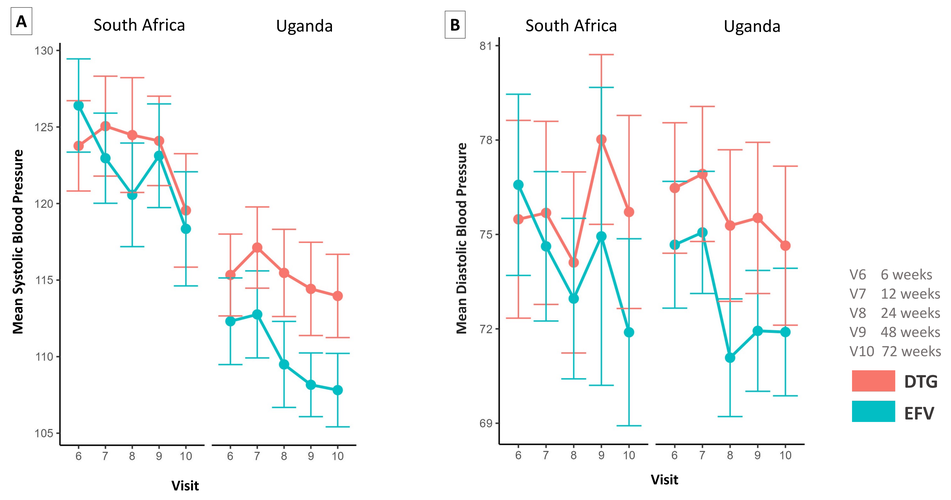
METHODS

- We compared BP in PPHIV initiating DTG versus EFV regimens in the DolPHIN-2 trial (NCT03249181).
- Pregnant women initiating ART ≥28 weeks gestation were randomly assigned tenofovir+lamivudine/emtricitabine and either DTG or EFV as first-line therapy in South Africa and Uganda.
- Follow-up included 8 study visits through 72 weeks postpartum, with standardised anthropometric and BP assessments using sized cuffs.
- Given perinatal physiologic changes, analyses focused on systolic (sBP) and diastolic BP (dBP) at 24 (visit 8), 48 (visit 9), and 72(visit 10) weeks postpartum in PPHIV assigned to DTG vs EFV, utilising mixed effects linear models adjusted for age, BMI, site, and enrolment BP.
- Temporal changes were evaluated using time interactions in separate models.
- Additionally, the risk of incident hypertension (BP>140/>90mm/Hg) was examined at the 3 time points among those with BP<140/<90mm/Hg at enrolment and 6 weeks postpartum.

RESULTS

- Overall 268 women were enrolled in Dolphin-2 (231 included in BP analysis postpartum)
  - median age 28 years; median gestation 31 weeks; median BMI 28kg/m^2.
- Participants in South Africa had consistently higher BMI, sBP (Figure 1A) and dBP (Figure 1B) compared to those in Uganda at enrolment and throughout follow-up.

Figure 1: Mean blood pressure by visit and site (A) systolic (B) diastolic



RESULTS Cont.

- After accounting for site and baseline values there was no evidence of associations observed through 72w postpartum between DTG use and
  - Systolic BP: beta=2.2 mmHg; 95% CI -0.6 to 5.0
  - Diastolic BP: beta=1.54 mmHg; 95% CI: -0.9 to 4.0
  - Weight: beta=0.7kg; 95% CI -0.9 to 2.3
- Four participants had hypertension detected at enrolment, and 23 at 6 weeks postpartum; during follow-up 8 participants switched treatment assignment, none related to blood pressure or weight gain.
- There was no evidence of difference in the occurrence of hypertension at any time point between DTG and EFV.

CONCLUSIONS

- Reassuring RCT data indicate no association between DTG versus EFV initiation late in pregnancy and BP through 72 weeks postpartum, following adjustment for critical pre-treatment covariates.
- While the immediate impact on BP appears negligible, ongoing attention is warranted to evaluate potential cardiometabolic risks associated with DTG treatment in pregnant and postpartum women living with HIV.

ADDITIONAL KEY INFORMATION

- Funded by UNITAID
- DTG donation from ViiV Healthcare
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