Postpartum weight changes in women initiating DTG vs EFV in pregnancy: DolPHIN-2

0771

Thokozile R. Malaba[1], Tao Chen[2], Kenneth Kintu[3], Christiana Papamichael[2], Helen Reynolds[4], Jesca Nakibuka[3], Catriona Waitt[3,4], Eva Maria Hodel[4], Angela Colbers[5], Catherine Orrell[6], Duolao Wang[2], Mohamed Lamorde[3], Saye Khoo[4], Landon Myer[1], for the DolPHIN-2 trial team

[1]Division of Epidemiology & Biostatistics, University of Cape Town, Cape Town, South Africa, [2]Tropical Clinical Trials Unit, Liverpool School of Tropical Medicine, Liverpool, United Kingdom, [3]Infectious Diseases Institute, Makerere University, Kampala, Uganda , [4]University of Liverpool, Liverpool, United Kingdom, [5]Radboud Institute for Health Sciences, Radboud University Medical Centre, Nijmegen, The Netherlands, [6]Desmond Tutu HIV Centre, Department of Medicine, Institute of Infectious Diseases & Molecular Medicine, University of Cape Town, Cape Town, South Africa

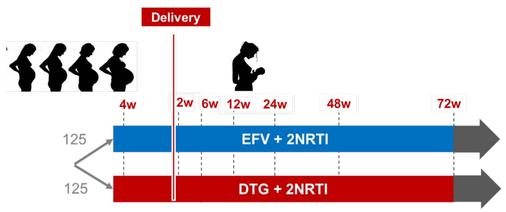
BACKGROUND

- Weight gain and body mass index (BMI) increase are central issues in HIV-infected individuals on antiretroviral therapy
- There are growing concerns about weight gain with dolutegravir (DTG) use, with some suggestion of heterogeneity of effects across populations especially among women
- However despite it's importance in shaping women's heath over time, there are limited data on weight gain/loss during pregnancy and the postpartum (PP) period

METHODS

- DolPHIN-2 (NCT03249181) - open label trial randomizing (1:1) pregnant women from Uganda and South Africa (SA) initiating ART from 28w gestation to DTG vs efavirenz (EFV) plus 2 NRTIs (Figure 1)

Figure 1: DolPHIN-2 Study Design



- Maternal weights measured using standardized procedures at enrolment, <14 days of delivery and at 6, 12, 24 and 48 weeks PP
- For this secondary analysis changes in PP weight and BMI examined between study arms between 6w ⟶ 72w
- Mixed effects linear regression models: random intercept for variable individual enrolment weights
  - Adjusted for duration of ART use over time

Increased postpartum weight in women receiving DTG vs EFV, with heterogeneity across population groups

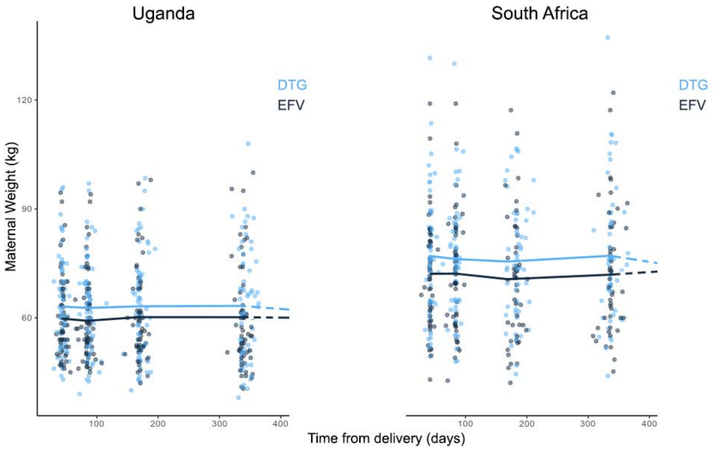
RESULTS

- Enrolment took place between Jan - Aug 2018, and follow-up data were censored Sept. 2019
- 232 women (mean age, 28y) included with median follow-up of 60 months
- At enrolment (median gestation, 31w): mean weight 73 kg and mean BMI 30 kg/m^2
  - Higher 3rd trimester mean weight in SA (80 kg) vs Uganda (67 kg)
- Across arms and sites, mean change in weight from enrolment to 6w PP was -6.1 kg
- Mean weight change between 6w ⟶ 72w different by site:
  - **Uganda, decreased weight: 0.6kg**
  - **South Africa, increased weight: 2.8kg**

- Mixed effects linear regression model (Figure 2):
  - DTG (vs EFV): **4.35kg (95% CI 0.64 – 8.06)** difference in mean weight between trial arms
  - SA (vs Uganda): **13.00kg (95% CI 9.28 – 16.72)** difference in mean weight between sites
    - No difference in trend over time, no evidence of interaction by site

- Similar findings were observed throughout for BMI

Figure 2: Mean predicted postpartum weight by trial arm and site



CONCLUSIONS

- These randomized data show increased PP weight gain in women receiving DTG vs EFV in women initiating ART late in pregnancy
- Differences in PP weight also varied by site, pointing to potential heterogeneity across populations that requires further investigation
- Weight gain in HIV-infected women can exacerbate other comorbidities – implications for other maternal conditions
- Long term follow-up ongoing – weight assessed through 2 years postpartum

ADDITIONAL KEY INFORMATION

- Funded by UNITAID, DTG donation from ViiV Healthcare
- Author contact: thokomalaba@uct.ac.za