ART Adherence And Elevated Viral Load in Pregnant & Postpartum Women Initiating DTG Versus EFV

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BACKGROUND

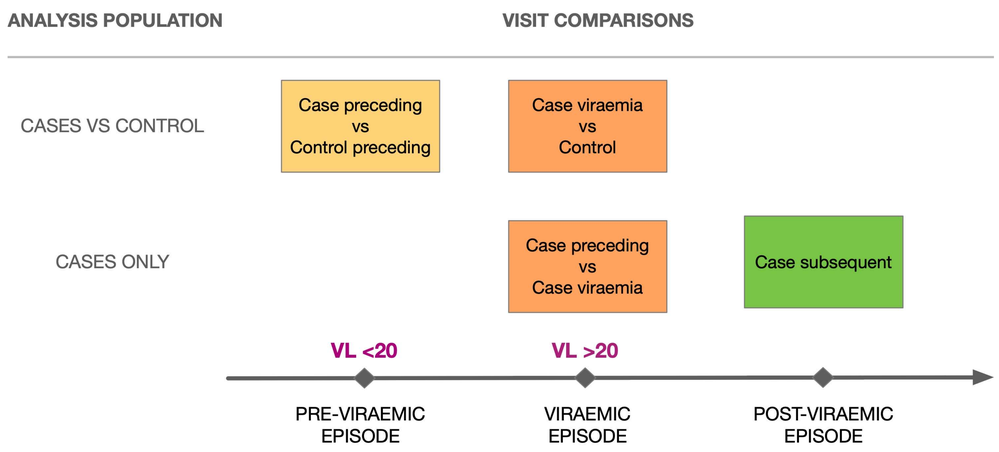
- Pregnant and postpartum women living with HIV (PPHIV) exhibit considerable non-adherence to antiretroviral therapy (ART).
- The transition from efavirenz (EFV) to dolutegravir (DTG) as first-line ART has been extensive, yet data comparing objective adherence rates between DTG and EFV in this population are scarce.
- Understanding the relationship between non-adherence and viral load (VL) elevation in PPHIV individuals on DTG versus EFV remains underexplored.
- We assessed adherence levels objectively and examined their association with VL outcomes in PPHIV women using DTG and EFV regimens.

METHODS

- The DolPHIN-2 trial (NCT03249181) randomized pregnant women initiating ART from 28 weeks gestation to DTG vs EFV with tenofovir (TDF) and lamivudine/emtricitabine.
- A nested case-control study was conducted within the trial cohort to investigate adherence to DTG vs EFV using random plasma tenofovir (TFV) levels as an objective adherence measure in both arms until 72 weeks postpartum maximum.
  - TFV levels ≥35.5ng/mL indicated effective adherence (EA).
- Eligible participants had an initial VL >1000 at enrolment and achieved viral suppression (VS, VL <20 copies/mL) during follow-up through 18 months postpartum.
- Case specimens had ≥1 VL >20 copies/mL after initial viral suppression; control specimens were incidence density sampled from PPHIV with persistent viral suppression, matched on ART duration and trial arm.
- Additional specimens were included from the suppressed visit preceding the first VL >20 copies/mL (cases) or a time-matched visit (controls) and all visits after viremia for cases (subsequent visits).
- Analysis populations and visit comparisons analysed are shown in Figure 1
- Logistic regression, with conditional models for matched data, was used to examine associations between effective adherence and elevated viral load.

While DTG shows potential for better adherence vs EFV, both regimens exhibit similar associations between adherence and VL suppression, highlighting need to address non-adherence during critical postpartum period.

Figure 1: Analysis populations and visit comparisons



RESULTS

- Overall, 357 case and 708 control specimens were included from 188 PPHIV (mean age 28y, DTG=97 women, EFV=91 women)
- At preceding visits with VS (pre-viraemic), EA was higher in DTG (56%) compared to EFV (44%).
- Self-reported missed doses (8%) and ARV-related side effects (5%) were low and similar by regimen.

RESULTS Cont.

- At viraemic visit:
  - EA was observed in 56% of viraemic cases compared to 81% of controls (VL <20 with matched ART duration).
  - Differences consistent between DTG (**OR 2.78, 95% CI 1.35 - 5.74**) and EFV (**OR 3.92, 95% CI 1.80 – 8.51**).
- Among viraemic cases at the preceding visit, 65% had EA compared with 56% at viraemic visit (**conditional OR 2.00, 95% CI 0.76 – 5.86**).
- At the subsequent visits (post-viraemia), 88% of cases with detectable TFV achieved VS again with no differences by regimen.

CONCLUSIONS

- The association between objectively measured adherence and viremia was comparable between DTG and EFV regimens.
- These findings collectively imply that DTG may be linked with improved ART adherence compared to EFV.
- However, DTG does not appear to be more tolerant of the short-term non-adherence frequently observed during the postpartum period.

ADDITIONAL KEY INFORMATION

- Funded by UNITAID
- DTG donation from ViiV Healthcare
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