2. METHODS

- This was a non-randomized, open-label, multi-centre phase-II study in HIV-infected pregnant women enrolled in two different centres.
- Here, we report on HIV-infected pregnant women treated with 300/100 mg ATV/r and without TDF, as part of their ART.
- Blood was collected for a 24h pharmacokinetic curve (t=0, 0.5, 1.2, 3, 4, 6, 8, 12, 24 hours after the last dose of the medication in the third trimester). At least 2 weeks post-partum, plasma samples were collected. Samples were stored frozen until analysis.
- All samples were analysed for ATV and RTV plasma concentrations by validated UPLC method.

3. RESULTS

- Data were available for 29 HIV-infected women who used 300/100 mg ATV/O in the pregnancy data are available.

Pharmacokinetics

- Paired PK approaches (3rd trimester to postpartum) were available for 25 patients.
- Non-statistical difference in pharmacokinetic parameters was found between women treated with tenofovir or not.
- None of the patients showed atazanavir concentrations >0.15 mg/L (target for treatment-naive patients). The non-parametric test was used for independent samples. No detrimental effect was observed.
- The median ratio of cord blood/placental plasma concentrations was 0.06 (0.03; 0.06).

4. CONCLUSIONS

- Despite 34% lower atazanavir exposure during pregnancy, introduction of 300/100 mg OD generates effective concentrations for protease inhibitor naïve patients, even if co-administered with tenofovir.
- The therapeutic portal of atazanavir is preserved.
- For treatment-experienced patients (with relevant PI resistance mutations) therapeutic drug monitoring of atazanavir should be considered to adapt the atazanavir/tenofovir dose on an individual basis.

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Figure 1: Mean ATV concentrations

Table 1: Demographics

Table 2: Pharmacokinetic parameters

- * Derivative mean, 90% confidence interval, except for Time to peak (max) which was determined using LOGISTIC 50 mg ATV
- ** Non-parametric analysis.