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Therapeutic drug monitoring of new formulation Kaletra in pregnancy

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Purpose of the study

The new LPV/r tablet formulation has significant patient benefits over the old LPV/r SGC, including a lack of food/fluid restrictions, no need for refrigeration and a reduced daily pill count. However, like many antiretroviral drugs, the pharmacokinetics of the new LPV/r tablet during pregnancy is poorly understood. Here we report total and unbound LPV plasma concentrations during pregnancy and at post-partum.

Methods

In this prospective, open-labelled study, pregnant HIV-positive patients received the LPV/r tablet formulation as part of their routine pre-natal care. Demographic and clinical data were collected and LPV plasma (total) and ultrafiltrate (unbound) concentrations were determined in the first (T1) and/or second (T2) and/or third (T3) trimester using HPLC-MS/MS. Post-partum (PP) sampling was performed where applicable. Ante-partum and post-partum PK parameters were compared using a one-way ANOVA (for independent data sets) and a paired t-test (for paired data).

Summary of results

From January 2007, 33 women were enrolled in the study; 31/33 received LPV/r tablet at the standard dose of 2 tablets BID. The remaining two patients were prescribed 4 tablets OD and 3 tablets BID, respectively. 30/33 women initiated LPV/r treatment during pregnancy. Median gestation at initiation was 25 weeks. 3/33 women were receiving HAART prior to pregnancy. Median baseline CD4 count was 349 (14–836). Median baseline viral load was 9,100 copies/ml (<50–267,408).

LPV/r (total and unbound) concentrations were determined in 1/33 (T1); 10/33 (T2); 29/33 (T3) and 8/33 (PP) (≤12 weeks) patients. 2/10 patients at T2 and 3/29 patients at T3 fell below the recommended LPV MEC (<1000 ng/ml), respectively. Median total LPV concentrations at T2 and T3 were 2770 ng/ml (1759–4202) and 3371 ng/ml (2331–4310), respectively; and were significantly lower relative to LPV concentrations observed at PP [5352 ng/ml (2667–7293)] (p = 0.042). Equally, in a paired analysis of eight patients (T3 vs. PP), total LPV concentrations were significantly reduced at T3 vs. PP (p = 0.021). However, no significant difference was observed in the % unbound LPV at T3 [0.93% (0.71–1.10)] vs. PP [0.96% (0.81–1.19)].

Conclusion

Standard dosage of LPV/r during pregnancy resulted in adequate therapeutic drug levels in the majority women examined. In addition, the similarities in the percentage of unbound LPV in the third trimester versus post-partum suggest that the standard dose of LPV/r is appropriate during pregnancy. Further research into this is required.