Journal of the International AIDS Society

BioMed Central

Poster presentation

A 24-month follow-up of the metabolic profile of Greek HIV (+) population on lopinavir/ritonavir-based regimen: the ACA GREC trial

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Purpose of the study

Use of protease inhibitors has been associated with plasma lipids and glucose changes. Co-formulated lopinavir/ritonavir (LPV/r) is a potent antiretroviral drug. However, it has been implicated in lipid and glucose abnormalities. We evaluated changes in lipids and glucose in HAART naïve and experienced patients enrolled in a clinical trial of LPV/r-based regimen.

Methods

This prospective, 24-month, open label, phase IV, multicenter study, comprised of 131 Greek HIV+ subjects randomized into two groups according to PI and HAART history. Group A (N = 91) included antiretroviral- or PI-naïve subjects who initiated a LPV/r-based regimen, and group B (N = 40) included PI-experienced subjects who switched their regimen to include LPV/r. All subjects underwent clinical and laboratory evaluation (total cholesterol [TC], triglycerides [TG], LDL, HDL, ApoB, glucose) at baseline and at 3, 6, 12, 18 and 24 months of follow-up. Changes in laboratory parameters were compared within and between the two groups using linear mixed effects models.

Summary of results

Mean fasting glucose levels declined from baseline to 24 months value of 10.3 mg/dl (p = 0.002) in group B while remaining unchanged in group A. TG and TC levels were higher at baseline in group B compared to group A with higher baseline levels associated with higher end values for both groups. Both markers tended to increase during follow up, but never reached toxicity limits as defined by CTCAE v3.0. TG increased 0.1 log10 mg/dl (p < 0.001) from baseline in group A with no change in group B. CD4+ cell levels at baseline of 80–350 resulted in lower TG levels. A mean increase of 36.1 mg/dl (p < 0.001) and 24.9 mg/dl (p = 0.004) for group A and B, respectively, was observed for TC at 24 months. HDL showed a statistically significant mean increase of 6.2 mg/dl (p = 0.001) for group A and a 5.1 mg/dl indicative increase for group B (p = 0.071). TC/HDL ratio remained below 5 throughout the study. ApoB values showed a 31.3 mg/dl mean increase (p < 0.05) in group A.

Conclusion

Minimal differences were observed in fasting glucose and lipid profile between HAART naïve and experienced subjects receiving LPV/r in a 2-year study period. The TC and

TG increase observed never reached toxicity levels. TC/HDL, an important predictor of cardiovascular event occurrence, remained below the critical value 5 for the whole period. Severity of condition as defined by the baseline CD4+ count affects TG levels.