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Abstract #: O-308

(Please note: The original number K-142 was changed as the abstract was transferred to Category O. Complications of HIV Infection and Antiretroviral Therapy)

Title: Randomized Comparison of Darunavir/r versus Atazanavir/r on Serum Lipids in HIV-infected Persons on Fully Suppressive Lopinavir/r or Fosamprenavir/r with High Serum Triglycerides

Background- Lopinavir/ritonavir (LPV/r) and fosamprenavir/ritonavir (FPV/r) are HIV protease inhibitors (PIs), which have been associated with elevation of triglyceride (TG) levels. We designed a study to determine if switching virologically suppressed patients on a regimen containing LPV/r or FPV/r to either darunavir/r (DRV/r) or atazanavir/r (ATV/r) resulted in improved TGs while maintaining virologic suppression.

Methods- Eligible patients had undetectable HIV RNA for ≥ 12 weeks, no history of PI resistance, were receiving LPV/r (n= 46) or FPV/r (n= 3) plus nucleosides, and had fasting TGs > 200 mg/dl. Patients were randomized to either once daily DRV/r (800mg/100mg) or ATV/r (300mg/100mg) while maintaining the same nucleoside backbone. The primary endpoint was the change in fasting TGs from baseline to week 24. Assessments included fasting lipids, HIV RNA, CD4 counts, adherence, quality of life assessments (QOL) and symptom assessment.

Results- 66 patients were screened, 51 enrolled and 49 completed the study. 25 patients were randomized to DRV/r and 24 patients to ATV/r. 92% of subjects were male, 73% were white, with a mean age of 47. Mean baseline CD4 cell count was 569 cell/mm³ and HIV RNA was < 50 copies/mL in 88% of subjects. Baseline characteristics were similar in both arms. Mean baseline TGs were similar: 342 mg/dl (DRV/r) and 326 mg/dl (ATV/r). The two arms combined had a decline in TGs from baseline to week 24 by 113 mg/dl (p <0.001) with a non significant difference by arm: -126 mg/dl (DRV/r) and -99 mg/dl (ATV/r). At week 24, 48% of DRV/r and 50% of ATV/r subjects had TGs < 200 mg/dl. (Difference 2%, 95% CI: -30% to 34%.) Mean decrease in TGs was -311 mg/dl if baseline TGs ≥ 400 mg/dl (n = 13) and -41 mg/dl if baseline TGs < 400 mg/dl (n = 36). Total and HDL cholesterol decreased and LDL increased (all non significantly) and were similar in both arms. QOL was high at baseline (83%), remained high at week 24 (85%), and did not differ between treatment groups. Adherence was high: 97% vs 98%, DRV/r vs ATV/r. At week 24 there were no differences between the groups in CD4 cell counts or HIV RNA levels and virologic control was maintained. Both arms were well tolerated.

Conclusions- Patients with well controlled HIV and high TGs who switched from LPV/r or FPV/r to once daily DRV/r or ATV/r had improvements in TGs, while maintaining virologic suppression and immunological control. QOL and adherence remained high.