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Lipid elevations in the ARTEMIS and TITAN trials: effects of demographics, HIV disease stage, treatment arm and lipid-lowering drugs

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Background

The ARTEMIS trial (TMC114-C211) evaluated LPV/r vs. DRV/r 800/100 mg OD in treatment-naïve patients, in combination with TDF/FTC. The TITAN trial (TMC114-C214) evaluated LPV/r vs. darunavir/ritonavir 600/100 mg BID in LPV-naïve, treatment-experienced patients with HIV-1 RNA >1000 copies/mL, in combination with optimised NRTI/NNRTI combinations.

Methods

Lipid parameters included total cholesterol, LDL (calculated, for samples with triglycerides below 4.52 mmol/L), HDL, triglycerides, apolipoprotein A1, Apo B, glucose and insulin. Analysis of covariance was used to correlate changes in each lipid parameter with baseline lipid levels, age, gender, and race, baseline CD4 count, HIV-RNA, treatment arm (LPV/r vs. DRV/r), and use of NNRTI (TITAN trial only) and lipid-lowering drugs (fibrates/statins). Numbers in brackets show the size of effects of factors on lipid elevations at week 48 – these effects were all statistically significant ($p < 0.01$).

Summary of results

For both trials, baseline CD4 <200 cells/uL or HIV-RNA >100,000 copies/mL did not correlate with changes in any lipid parameter.

In ARTEMIS, older patients showed greater rises in total cholesterol, LDL, triglycerides and Apo B. Men showed greater rises in triglycerides than women (+31). LPV/r led to significantly greater rises in total cholesterol (+11 mg/dL), HDL (+3) and triglycerides (+55). Use of lipid-lowering drugs was infrequent in ARTEMIS (8% in DRV/r arm, 11% in LPV/r arm).

In TITAN, use of NNRTIs led to significantly greater rises in total cholesterol (+19 mg/dL). LPV/r led to significantly greater rises in total cholesterol (+9 mg/dL), HDL (+3) and triglycerides (+47). Men showed greater rises in triglycerides than women (+50). In TITAN, 23% of patients on DRV/r and 24% on LPV/r used lipid-lowering drugs. In both trials, adjustment for use of lipid-lowering drugs had little effect on the estimates of change in any lipid parameter for the overall treatment groups. TCHOL/HDL ratios did not differ significantly between LPV/r and DRV/r in either trial.

Conclusion

Rises in lipid parameters during the ARTEMIS and TITAN trials were influenced by several factors, including older age and use of NNRTIs. Use of DRV/r led to significantly smaller rises in total cholesterol, HDL and triglycerides than LPV/r in both trials. Some of the effects on lipids, while statistically significant, are very small and unlikely to affect 10-year cardiovascular risks.