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Poster presentation

Switching from zidovudine/lamivudine (ZDV/LMV) to tenofovir/emtricitabine (TDF/FTC) or abacavir/lamivudine (ABC/LMV) in HIV/HCV co-infection (COTKI study)

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Background

Patients with HIV/hepatitis C co-infection have glucose and lipids metabolism alterations. Both HAART and HCV contribute to lipids and glucose metabolic damage. HAART-related insulin resistance contributes to the liver steato/fibrosis evolution. Fewer data on metabolic and hepatic tolerability are available in HIV/HCV co-infected patients who switch from ZDV/LMV to TDF/FTC or ABC/LMV.

Methods

A total of 150 HIV/HCV co-infected subjects with HIV-RNA <50 copies/ml, on BID ZDV/LMV + atazanavir/ritonavir (ATV/rtv) >6 months were randomized 1:1:1 to continue this regimen or to switch to QD TDF/FTC+ATV/rtv or QD ABC/LMV +ATV/rtv. The primary end-point was change in insulin resistance, calculated with HOMA score (Homeostasis Model Assessment: fasting insulin UI/ml x glucose mmol/l/22.5) at 48 weeks. Secondary end-points included changes in absolute haemoglobin, AST, ALT, fasting lipids, CD4, and viral load. Liver fibrosis assessment by Fibroscan was planned at baseline and 96 weeks. Two sample t-test for between group comparison was used.

Summary of results

All 150 subjects were randomized: 49 to continue ZDV/LMV; 50 to switch to TDF/FTC; and 51 to switch to ABC/LMV. All patients were available for the 48-week analysis. Subjects were well matched for baseline characteristics and received a mean of 9 years prior ZDV/LMV. Median stiffness score was 7.9. Cirrhosis was in 13.5%. At 48 weeks, all randomized subjects maintained the same study therapy with VL <50 copies/ml. The change in median HOMA score was 0.2, -0.4 and -0.1 in ZDV/LMV, TDF/FTC and ABC/LMV, respectively (ZDV/LMV vs. TDF/FTC: $p < 0.001$; ZDV/LMV vs. TDF/FTC: $p > 0.001$; TDF/FTC vs. ABC/LMV: $p = 0.06$). Total cholesterol significantly decreased in subjects who switched from ZDV/LMV to TDF/FTC (-23 mg/dl; ZDV/LMV vs. TDF/FTC: p 0.005). Change in median HDL-cholesterol was -2, +2.5, +4 mg/dl in three arms, respectively (ZDV/LMV vs ABC/LMV: $p > 0.001$; ZDV/LMV vs. TDF/FTC: $p > 0.001$; TDf/FTC vs. ABC/LMV: p 0.08). T CD4 cell count increased significantly in subjects who switched from ZDV/LMV to TDF/FTC (+23 cell/mm3: p 0.01) or ABC/LMV (+87 cell/mm3: $p = 0.001$).

Conclusion

Switching from ZDV/LMV to TDF/FTC or ABC/LMV in HIV/HCV persons treated with ATV/rtv provides a simplified QD regimen which maintains virological control and improves both lipid and glucose parameters without increase in hepatic toxicities.