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Lipometabolic side-effects of three ritonavir-boosted double protease inhibitor regimens without reverse transcriptase inhibitors

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Purpose of the study

To compare the lipometabolic profiles of three double-boosted protease inhibitor (PI) regimens at standard dose, containing saquinavir and ritonavir in combination with lopinavir (LOPSAQ), atazanavir (ATSAQ) or fosamprenavir (FOSAQ) in HIV-positive patients, treated without reverse transcriptase inhibitors (RTI).

Methods

Comparative cohort analysis on 173 patients receiving LOPSAQ, ATSAQ or FOSAQ as only antiretroviral therapy (ART). Total cholesterol and triglycerides were measured at baseline (BL) and in the course over 48 weeks after initiation of a ritonavir-boosted double PI regimen. High-density-lipoprotein (HDL) and low-density-lipoprotein (LDL) were measured after an overnight fast.

Summary of results

Median baseline characteristics were a patient age of 42 years, male gender (n = 139; 80.4%) and 10.1 years from first HIV-positive test. 158 patients were ART-experienced and received a boosted double PI regimen due to previous RTI-resistance and/or toxicity. Among these, 68 patients previously had a structured treatment interruption and 90 patients have been treated with a PI-sparing ART regimen; 15 patients were ART-naïve. Differences for metabolic parameters between groups were not significant. Fifty-eight out of 173 patients received a lipid-lowering agent (LLA) (LOPSAQ n = 42, ATSAQ n = 11, FOSAQ n = 5) and seven (4%) were initiated on a new LLA during the study. Total cholesterol significantly increased over 48 weeks for all groups: 166 mg/dL to 213 mg/dL (LOPSAQ), 168 mg/dL to 216 mg/dL (ATSAQ) and 161 mg/dl to 235 mg/dl (FOSAQ) after 48 weeks (for all, $p < 0.01$; ITT-analysis), whereas median triglyceride levels significantly increased only for the LOPSAQ-group (195 mg/dl to 283 mg/dl; $p < 0.01$), but not for the other two groups (ATSAQ: 161 mg/dL to 202 mg/dL, $p = 0.2$; FOSAQ: 130 mg/dl to 220 mg/dl, $p = 0.6$). HDL- and LDL-cholesterol increased non-significantly in all groups. See Figure 1.

Conclusion

After 48 weeks on a double-boosted PI regimen, all three patient groups showed significant increases in total cholesterol. The increase in triglyceride levels was only significant for LOPSAQ, but not for ATSAQ or FOSAQ. Overall, <5% required a new LLA-therapy during the first 48 weeks. HDL- and LDL-cholesterol increases were not significant. The cardiovascular impact of these lipometabolic interferences requires further investigations.

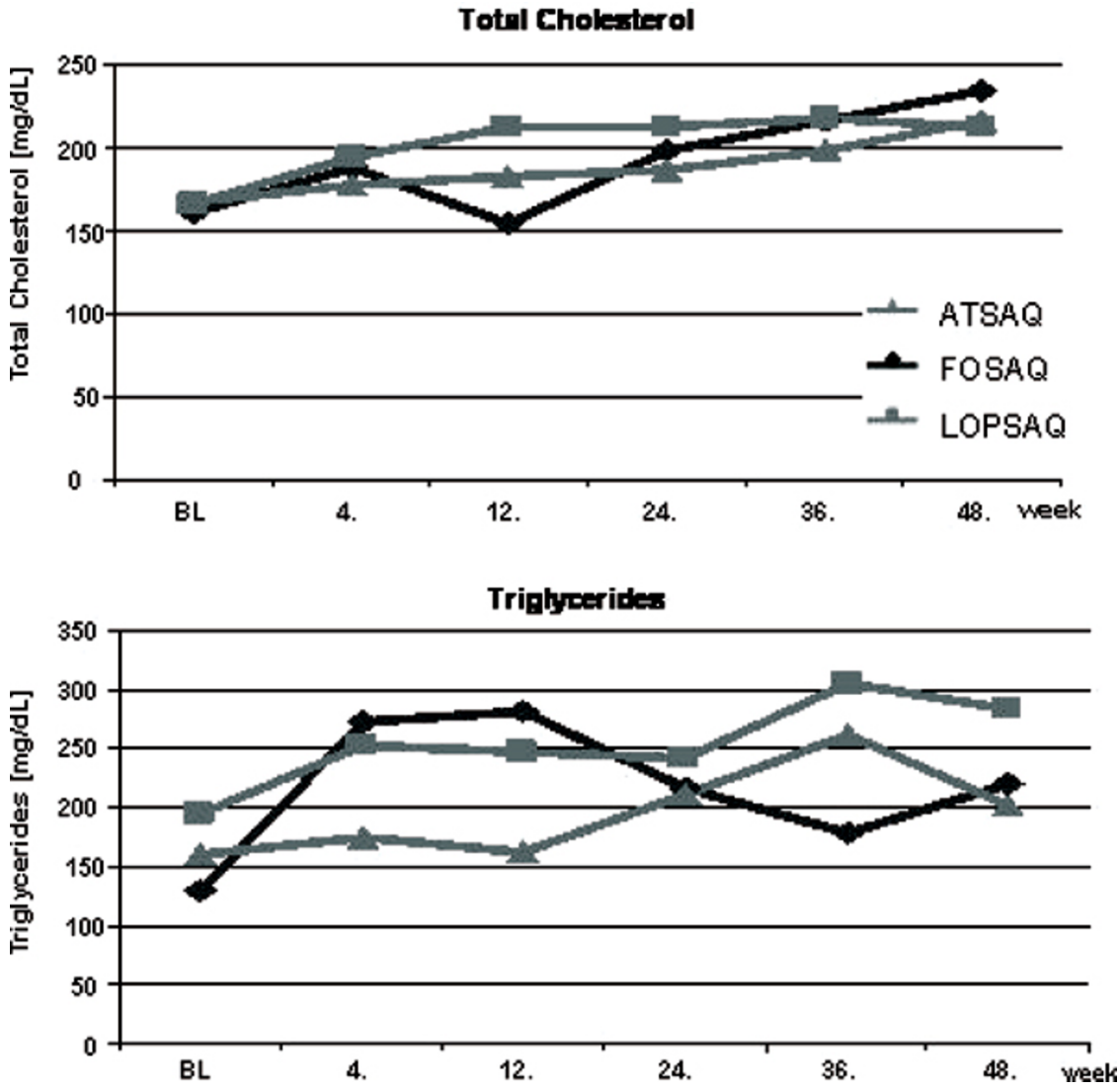

Figure 1
Serum total cholesterol and triglycerides of three double boosted protease inhibitor regimens over 48 weeks.