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Virological and immunological response to three boosted protease inhibitor regimens

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Purpose of the study

To compare the virological, immunological and clinical response to three boosted double protease inhibitor (PI) regimens of saquinavir and ritonavir in combination with lopinavir (LOPSAQ), atazanavir (ATSAQ) or fosamprenavir (FOSAQ) without reverse transcriptase inhibitors (RTI) in HIV-positive patients with limited RTI treatment options.

Methods

Comparative cohort observation of pre-treated patients (n = 279) who had experienced therapy failure on their RTI-regimen due to resistance and/or toxicity. Patients with PI-resistance mutations or RTI toxicity underwent a structured treatment interruption until virus reverted to wild-type or resolution of toxicity symptoms.

Summary of results

In this critical patient collective, the proportion of patients still on observational regimens at week 48 was overall 187 out of 279 patients (67%) and 133/198 for LOPSAQ, 44/67 for ATSAQ and 10/14 for FOSAQ. The overall response to treatment at week 48 was 52% for LOPSAQ, 57% for ATSAQ and 64% for FOSAQ (ITT). Compared to baseline, median viral loads (log10 copies/mL, ITT-analysis) decreased through week 48 from 4.98 to 1.60 (LOPSAQ), from 4.83 to 1.60 (ATSAQ), and from 4.51 to 1.60 (FOSAQ), respectively. Median CD4 increase in cells/μL at week 48 was comparably high for LOPSAQ (+140) and ATSAQ (+141; $p = 0.919$), but lower for FOSAQ group (+14; $p < 0.01$ vs. LOPSAQ; $p = 0.013$ vs. ATSAQ), in LOCF-analysis accordingly (see Figure 1).

Conclusion

The virologic response to treatment was similar in between the three combinations of LOPSAQ, ATSAQ or FOSAQ, respectively. This RTI-sparing, PI-only antiretroviral therapy may be an effective option for treatment experienced patients after RTI-failure due to toxicity or resistance. The immunological outcome of both LOPSAQ and ATSAQ seems to be superior to FOSAQ. For extensively pre-treated patients at low CD cell counts, this historical option of a double-PI only combination regimen is today extended by new antiretroviral classes.

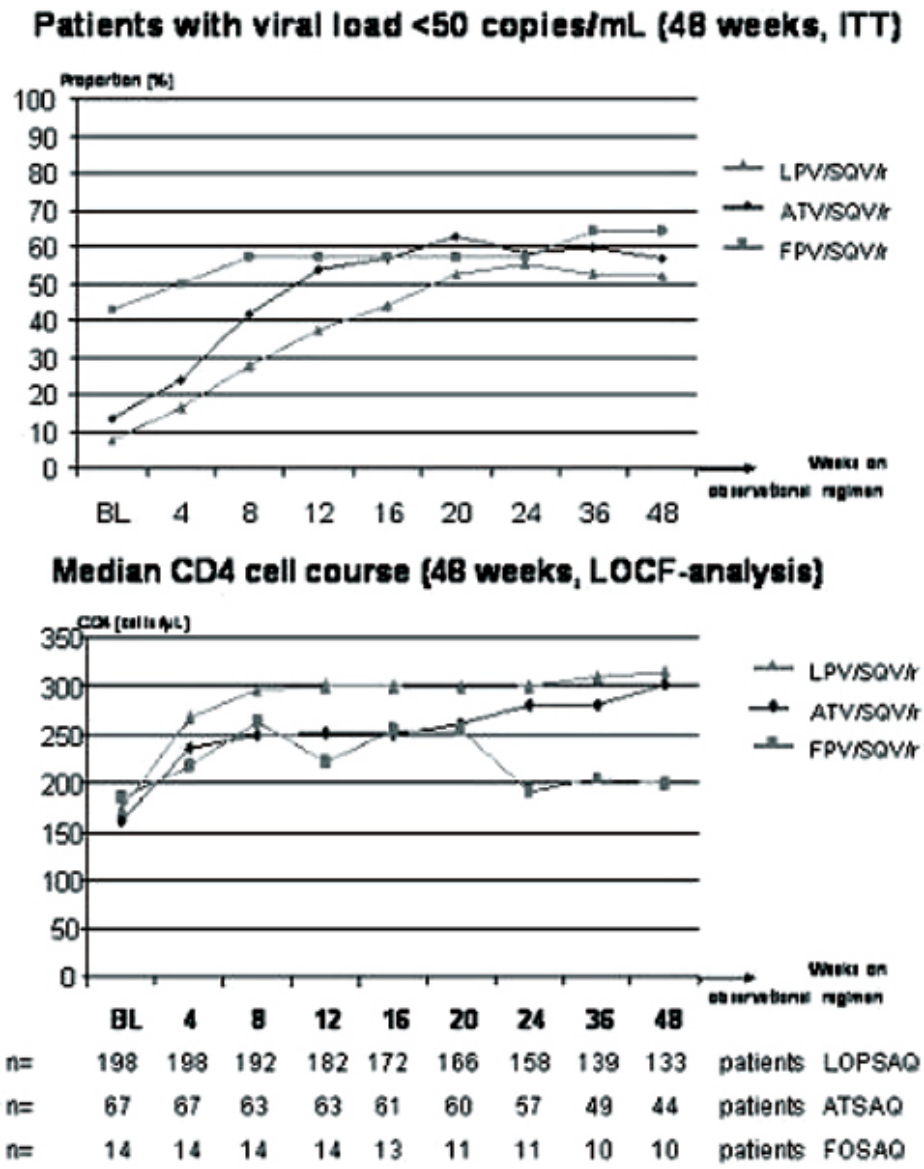

Figure 1
Proportion of patients below the detection limit (<50 copies/mL) and CD4 cell count-development during 48 weeks on three different boosted double protease inhibitor regimens – without further additional antiretrovirals.