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Saquinavir/ritonavir monotherapy as a new nucleoside-sparing maintenance strategy

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Purpose of the study

The high antiviral potency and low toxicity of saquinavir/ritonavir (SQV/r), prompted us to assess the antiviral efficacy and safety of SQV/r monotherapy as a new maintenance regimen in chronically virological suppressed HIV-infected patients.

Methods

Pilot, multicenter and randomized trial of 48 weeks follow-up. Patients with undetectable viral load (VL <50 copies/mL) under a HAART, without history of virological failure to a PI-based regimen or PI-related resistances were randomly assigned (2:1) to receive SQV 1000 mg/ritonavir 100 mg BID (SQV/r group) or to continue on the same treatment (control group). They were followed monthly until week 24 and each 3 months thereafter. Comparison were performed by the Mann-Whitney test for medians and by the $\chi 2$ or Fisher's exact test for proportions.

Summary of results

A total of 28 patients were randomized: 17 to SQV/r group and 11 to control group. Only one patient from SQV/r group experienced a virological failure at week 36. Similar mean increase in CD4+ cell counts from baseline to week 48 were seen in both groups: +31 cell/mm3 in SQV/r group and +53 cell/mm3 in control group. Three patients (10.7%), from SQV/r group, interrupted prematurely the study for reason other than virological failure (an acute hepatitis B, a 2-fold increase of transaminases in a VHC co-infected patient with high baseline levels, and a voluntary cessation of therapy). Total cholesterol did not significantly vary throughout the study in any group ($p = 0.794$); HDLc showed a significant increase at week 48 in comparison with the baseline values only in SQV/r group (from 41 ± 11 mg/dl to 56 ± 35, $p = 0.028$), while patients from control group showed a decrease in LDLc (from 129 ± 37 mg/dl to 107 ± 17, $p = 0.028$). Median (IQR) trough concentrations of SQV in plasma were 760 (379.5–1332.25). No patient had saquinavir concentrations lower than 100 ng/mL.

Conclusion

SQV/r monotherapy, administered twice daily, may be a valid and economic option as a nucleoside-sparing strategy for virologically suppressed HIV-infected patients without prior history of virologic failure to protease inhibitor-containing regimens, especially in those with intolerance or toxicities to nucleosides.