Quality of life in asymptomatic- and symptomatic HIV infected patients in a trial of ritonavir/saquinavir therapy. The Prometheus Study Group.

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Abstract

OBJECTIVE: To compare the impact on quality of life (QoL) of treatment with ritonavir (RTV)/saquinavir (SQV) versus RTV/SQV/stavudine (d4T) in asymptomatic [Centers for Disease Control (CDC) class A] and symptomatic HIV-infected patients (CDC B and C) who did or did not receive antiretroviral therapy (ARVT) before entry into the study.

DESIGN: A multicenter randomized clinical trial.

PATIENTS: Protease inhibitor- and d4T-naive patients were allocated to RTV/SQV (n = 84) versus RTV/SQV/d4T (n = 83).

MAIN OUTCOME MEASURE: Changes from baseline in QoL assessed by the Medical Outcomes Study Health Survey for HIV (MOS-HIV) and a symptom checklist administered at baseline and after 12, 24, 36 and 48 weeks.

RESULTS: Changes in QoL were comparable in both treatments, although more neuropathy was reported in the RTV/SQV/d4T group. QoL improved significantly in both groups regarding health distress, energy/fatigue, mental health, health perceptions, physical function and overall QoL, despite an increase in reported symptoms. More favourable changes in cognitive and social function were observed in symptomatic compared with asymptomatic patients, with symptomatic patients showing an improvement and asymptomatic patients showing a decline in function after baseline. ARVT-naive patients showed more favourable changes in mental health, health distress and social function compared with patients with previous ARVT.

CONCLUSION: RTV/SQV and RTV/SQV/d4T were equally effective in improving the QoL of patients over 48 weeks, despite an increase in reported symptoms. Symptomatic patients reported more QoL benefit than asymptomatic patients, and ARVT-naive patients benefitted more than those with previous ARVT. The impact on patients' QoL should be considered in the search for the optimal management of HIV infection.