Health-related quality of life outcomes in HIV-infected patients starting different combination regimens in a randomized multinational trial: the INITIO-QoL substudy.


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Abstract

The health-related quality of life (HRQoL) outcomes in HIV-infected, treatment-naive patients starting different HAART regimens in a 3-year, randomized, multinational trial were compared. HRQoL was measured in a subgroup of patients enrolled in the INITIO study (153/911), using a modified version of the MOS-HIV questionnaire. The regimens compared in the INITIO trial were composed by two NRTIs (didanosine + stavudine) plus either an NNRTI (efavirenz) or a PI (nelfinavir), or both (efavirenz + nelfinavir). Primary HRQoL outcomes were Physical and Mental Health Summary scores (PHS and MHS, respectively). During follow-up, an increase of PHS score was observed in all treatment arms. The MHS score remained substantially unchanged with the four-drug combination and showed with both NNRTI- and PI-based three-drug regimens a marked trend toward improvement, which became statistically significant when a multiple imputation method was used to adjust for missing data. Overall, starting all the combination regimens compared in the INITIO study was associated with a maintained or slightly improved HRQoL status, consistently with the positive immunological and virological changes observed in the main study. The observed differences in the MHS indicate a possible HRQoL benefit associated to the use of three-drug, two-class regimens and no additional benefit for the use of four-drug, three-class regimens, confirming that three-drug, two-class regimens that include two NRTIs plus either an NNRTI or a PI should be preferred as initial treatment of HIV infection.

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