Clinical and pharmacological aspects of induction-maintenance therapy in HIV-1 positive patients: the ADAM study
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Chapter 7

Quality of life in maintenance- vs prolonged induction therapy for HIV.

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To the Editor:

The feasibility of induction-maintenance therapy for human immunodeficiency virus type 1 (HIV) infection has been studied as a strategy to simplify antiretroviral regimens.\textsuperscript{1,2} In the Amsterdam Duration of Antiretroviral Medication study, maintenance dual therapy after 26 weeks of quadruple induction therapy resulted in less viral suppression than prolonged induction therapy.\textsuperscript{3} However, a prolonged quadruple regimen may have a negative impact on patients' quality of life (QOL) because of pill burden and adverse effects. We compared QOL in maintenance vs prolonged induction therapy.

Methods

Antiretroviral-naive HIV-infected patients with a CD4 cell count of at least 200 x \(10^6\) (200/\(\mu\)L) and 1000 HIV RNA copies/mL received 26 weeks of induction therapy comprising stavudine, lamivudine, saquinavir, and nelfinavir. If the plasma HIV RNA concentration at weeks 24 and 25 was less than 50 copies/mL, patients were randomly assigned to receive prolonged 4-drug induction or maintenance therapy (either stavudine and nelfinavir or saquinavir and nelfinavir). From week 26, plasma HIV RNA concentrations were assessed by an ultrasensitive assay procedure (Amplicor HIV-1 Monitor Ultrasensitive; Roche Diagnostics, Branchburg, NJ) with a variable quantification limit. Clinical results have been reported elsewhere.\textsuperscript{3}

In a subsample, QOL was assessed at weeks 24 and 48 by the Medical Outcome Study (MOS) HIV Health Survey, comprising 10 subscales.\textsuperscript{4} We calculated changes in QOL scores from week 24 to week 48. Effect sizes for between-group differences were calculated by dividing mean differences by pooled SD.\textsuperscript{5} Effect sizes equaling 0.20, 0.50 and 0.80 are considered to indicate small, moderate and large effects, respectively.\textsuperscript{5} We calculated correlation coefficients between the plasma HIV RNA concentration at week 48 and changes in QOL scores. Analysis was by intention to treat.

Results

Ten out of 16 patients assigned to receive maintenance therapy and 9 of 15 patients assigned to receive prolonged induction therapy participated in the QOL study. Both groups were comparable (\(p > .20\)) in terms of age (39 vs 44 years), sex (91\% vs 100\% men), Centers for Disease Control and Prevention HIV classification A (73\% vs 67\%), median baseline CD4 cell count (370 x \(10^6\)/L vs 420 x \(10^6\)/L), and median baseline HIV RNA log\(_{10}\) copies/mL (4.50 vs 4.58).\textsuperscript{6}
Participants were similarly comparable to those who did not participate. Patients assigned to receive maintenance therapy showed more decline in QOL scores than patients assigned to receive prolonged induction therapy on the following MOS-HIV subscales: physical function (-11 points; effect size, 0.4), role function (-18 points; effect size, 0.4), social function (-17 points; effect size, 0.5), overall QOL (-19 points; effect size, 0.7), health distress (-17 points; effect size, 0.7), health perceptions (-13 points; effect size, 0.5) and energy/fatigue (-8 points; effect size, 0.3). At week 48, plasma HIV RNA was higher in the maintenance group than in the prolonged induction group (2.3 log_{10} copies/mL vs 1.6 log_{10} copies/mL; p=.05), although concentrations in both groups were quite low. A higher plasma HIV RNA concentration was correlated with more decline in QOL scores for energy/fatigue (r = -0.51; p=.03), social function (r = -0.66; p=.003), health distress (r = -0.64; p=.005), health perceptions (r = -0.55; p=.02) and overall QOL (r = -0.58; p=.009) (Figure).

**Figure 1** HIV indicates human immunodeficiency virus type 1. Values on the y-axis that are less than 0 indicate decline in quality of life, whereas values greater than 0 indicate improvement in quality of life. Solid line is regression and regression prediction line of the mean; dashed lines, 95% confidence interval. Horizontal line indicates no change in quality of life. There were 10 patients allocated to maintenance therapy and 9 to prolonged induction therapy.
Quality-of-life scores declined more during maintenance therapy than during prolonged induction therapy. The data from this small unblinded study raise the interesting possibility that the negative effects of inferior viral suppression on QOL were greater than the added burden of a 4-drug regimen.
References


