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Efficacy and tolerability of long-term nevirapine plus nucleoside reverse transcriptase inhibitors for HIV-1 infection

CA Carocci*[1], MC Martinelli[1], MV Mastronardi[2], CP Corsi[1] and LF Leoncini[1]

Address: [1]Unit Infectious Diseases, Azienda Ospedaliero Universitaria Careggi, Florence, Italy and [2]Azienda Ospedaliero Universitaria Careggi, Florence, Italy

* Corresponding author

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Purpose of the study

The objective of this study is the evaluation of long-term viral efficacy, liver enzyme safety and metabolic profile during nevirapine plus nucleoside reverse transcriptase inhibitor treatment.

Methods

In this open-label observational study, 120 (75 male and 45 woman) HIV-1 infected patients received a nevirapine (NVP)-containing HAART regimen: first-line, simplification or switch due to intolerance to the prior regimen.

Summary of results

Mean duration of therapy in the patients with NVP regimen at the recruitment was 7.3 ± 1.9 years. Forty-three patients (35.9%) were antiretroviral-naïve: mean HIV-RNA level was 50,000 copies/ml (range 2,000–214,000) and mean CD4 cells count was 386 cell/mm3 (11–976). Seventy-seven patients (64.1%) switched to NVP for simplification or intolerance: mean viral load was 100,000 copies/ml (range 49–>500,000) and mean CD4 cells count was 450 cell/mm3 (30–1,600). Baseline characteristics included liver enzymes (ALT 31.6, AST 41.2 and GGT 23.4) and fasting lipid profile (total cholesterol 202.4, HDL-cholesterol 59.17, LDL-cholesterol 131.4 and triglycerides 210.7). Co-infection with hepatitis C viruses were present in 25 (20.8%) patients. The efficacy and tolerability were evaluated at three time points for analysis: baseline, at 2 years, and at 4 years after baseline.

At the last measurement, all patients had undetectable viral loads (<50 copies/ml) and the mean CD4 cells count increased from baseline values by 340 cells/mm3. In naïve patients viral loads decreased during the first 6 months (range 3–9 months).

Throughout follow-up ALT (mean value 33,8 U/l) and AST (mean value 39.1 U/l) remained within standard normal range. Mean value of GGT increased from the baseline (mean value 57.04 U/l); $p < 0,01$). Total cholesterol, HDL-cholesterol, LDL-cholesterol and triglycerides levels at the second years and at the fourth years remained in normal range in patients who switched to NVP for simplification or intolerance. Significant differences were found in total cholesterol levels in antiretroviral-naïve patients with increased value from the baseline to the last measurement ($p = 0.01$).

Conclusion

The follow-up results showed that prolonged treatment with NVP is a safe and potent antiretroviral regimen associated with viral suppression and increased CD4 cells count. In our patients the long-term exposure to NVP showed an increased total cholesterol (not requiring use of statins) and, in concordance with previous studies, an increased GGT level essentially in patients co-infected with HCV.

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