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Long-term safety and efficacy of nevirapine (NVP)-based antiretroviral therapies

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Purpose of the study

The presentation will report long-term (>4-year) data on safety and efficacy of antiretroviral regimes including NVP as a component of their antiretroviral therapy in five centers' databases, and included in a retrospective cohort study.

Methods

Data collected included lipid and liver function tests, viral load and CD4 cell counts at baseline, 2-year and >4-year timepoints. HCV co-infection, adverse events, and reason for using NVP were also recorded.

Summary of results

229 patients (pts) were included. Mean age was 37 years. Most pts (54%) were former intravenous drug users. 135 individuals were co-infected with HCV. Median time on NVP was 72.6 months. The main reasons to use NVP were: second or third-line therapy (40%), simplification (30%), first-line therapy (19%), and efavirenz intolerance (10%). Combinations of nucleosides most widely used were: ABC+3TC (25%), AZT+3TC (23%) and TDF+3TC (14%). HDL-cholesterol and GGT increased from baseline to >4-year timepoint (48 mg/dl to 62 mg/dl and 58 U/l to 145 U/l, respectively). LDL-cholesterol, triglycerides and alkaline phosphatase showed decreasing values at follow-up (135 mg/dl to 109 mg/dl, 216 to 153 mg/dl, and 177 to 92, respectively). Total cholesterol and liver function tests had no significant changes. CD4 cell counts increased from 439/mm3 at baseline to 628/mm3 at the last available visit. 172 out of 184 pts who remained on NVP-based therapy at last visit maintained viral load values below limit of detection. NVP was stopped or withdrawn in 43 patients due to virological failure (13 pts), toxicity (five pts), virological resistance (four pts), therapy interruption (three pts), death (two pts), dyslipidemia (one pt), simplification (one pt) or unknown reasons (14 pts). Adverse events were reported in 40 patients but none was directly attributed to NVP. The reported follow-up pattern of laboratory tests was also found in the subset of HCV co-infected patients by comparing men and women and stratifying patients with a CD4 cell count cut-off value of 250/mm3.

Conclusion

Results suggest that NVP-based antiretroviral therapy (either first-line, simplification, or second-line) not only provides stable immunological and virological efficacy for over 4 years, as well as a favourable safety profile with few adverse events leading to discontinuation, but also increases HDL-cholesterol, which may have a protective impact on cardiovascular risk. The same safety profile was found in the subpopulation of HCV co-infected patients and individuals with CD4 cell counts above 250/mm3.