

POSTER PRESENTATION

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# CD4 response, lipid changes and liver outcome in 506 patients receiving nevirapine-based regimens for a median of 9 years

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## Purpose of the study

To evaluate long-term outcomes in pts maintaining a NVP-based regimen.

## Methods

Retrospective cohort study. Pts received a NVP regimen for at least 5 years and continued up to present. Demographic, clinical, and analytical variables were recorded. A sample size of 506 pts was randomly selected from participating cohorts.

## Summary of results

Median follow up 8.9 (5.7-11.3) years (506 pts followed  $\geq 6$  years and 270  $\geq 9$  years). At baseline: 74% men, 47 years old, 36% drug users, 40% AIDS, 40% HCV+, 14% alcohol. 45% detectable VL, CD4 395/uL, 19% CD4 < 200/uL, 27% ALT Grade 1-2, 36% AST grade 1-2. 30% ART naïve. 84% received NVP+2 nucleosides (NRTI) during the study period, 17% PI.

Most frequent current combinations were NVP+TDF/FTC in 31%, +ABC/3TC in 24% and +ZDV/3TC in 22%. 97% reached undetectable VL. In pts receiving 2 NRTI+NVP (n=423), regardless of being HCV+ or -, a significant increase was observed in general health status markers: hemoglobin, platelets and albumin (all  $p < 0.001$ ), and +218 and +322 CD4 cells increase after 6 and 9 years ( $p < 0.001$ ). Triglyceride levels decreased 19% and total cholesterol 4% in pretreated pts vs 9% and 12% increase in naïve pts. After 6 years, the proportion of pts with lipid levels above (below in HDL) the NCEP

thresholds for recommending lipid lowering therapy was 50% for TC, 43% TG, 34% LDL and 14% HDL.

Regarding liver outcomes in the 506 pts, a significant decrease in ALT and AST levels were found in naïve ( $p = 0.02$ ,  $p < 0.001$ ) and HCV+ pts ( $p = 0.065$ ,  $p < 0.001$ ), while a strong decrease in alkaline phosphatase (AP) levels (up to -44%) was observed in naïve and pretreated pts as well as in HCV+ or - (all  $p < 0.001$ ), regardless of TDF use. GGT levels increased by 78% regardless of the patient status ( $p < 0.001$ ).

This favourable changes in liver function tests occurred despite 53% of 89 pts in whom biopsy or fibroscan was performed after a median of 7.1 years of NVP therapy, fibrosis ( $\geq F2$  and/or  $7 \geq kPa$ ) was detected. In addition, as a consequence of transaminase and platelet changes, Fib-4 index significantly decreased in ARV naïve HIV/HCV pts at 9 years ( $p = 0.01$ ).

## Conclusions

Patients receiving a long-term NVP-including regimen, show a progressive improvement in general health status and CD4 response, an acceptable lipid profile and favourable changes in liver function tests, even in those with HCV+. The marked decrease in AP levels shown in this large cohort of NVP-treated pts merits further study.

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