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Presentation Title: Liver Toxicity is Not Related to CD4+ Cell Counts in 221 Patients Switching to Nevirapine (NVP) Due to Simplification or Substitution Strategies (Toscana Study)

Keywords: Liver toxicity, Nevirapine, CD4+ cells

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Background: In ARV-naïve patients, NVP liver toxicity is related to high CD4+ cells. It is not clear whether this it also happens in simplification or substitution strategies. **Methods:** Retrospective analysis of 221 patients treated with NVP due to simplification (n=141) or substitution for toxicity (n=43) or bad tolerability (n=37). Liver toxicity defined as increase in 5 times the upper normal level of AST or ALT. CD4+ cell counts defined as high if greater than 250/ μ L in women and 400/ μ L in men. Summary statistics for describing variables, relative risk for prevalence, and logistic regression model for liver toxicity associated factors were performed with SAS 9.1.3. **Results:** 221 patients were included (164 men, 57 women), with a follow-up of 1134.83 patient-years. Median previous time on viral suppression was 15 months (IQR 4-34), median exposure time to NVP was 36 months (IQR 12-66), median baseline CD4+ cell count was 464/ μ L (IQR 298-710) with 167 (75.6%) and 54 patients (24.4%) initiating NVP with high (H) and low (L) CD4+ cell counts, respectively. HCV and HBV co-infection were present in 45.7% and 4.5% of patients. Liver toxicity was detected in 18 patients (8.14%), with a prevalence of 6.59% in H and 12.96% in L, and a relative risk of 0.508 (95% CI: 0.207, 1.245) for H. Incidence rate was 1.58/100 patient-years (2.63 in L vs 1.26 in H). The only factor significantly associated to liver toxicity was hepatitis C co-infection (OR: 3.53; 95% CI: 1.19, 10.39). Overall, there were more cases of liver toxicity after 6 months of therapy (61%). **Conclusions:** In our cohort, incidence of liver toxicity was low and not related to high CD4+ cell counts. The only factor related to liver toxicity was hepatitis C co-infection. Liver toxicity presented mainly after six months of therapy, was mild to moderate in intensity and always reversible upon suspension of NVP.