THPE0179 - Risk factors for hepatotoxicity of nevirapine-containing antiretroviral drug regimens in a large antiretroviral treatment program in Rwanda

J. van Griensven1, F. Rasschaert2, E.F. Atté1, A. Asiimwe3, R. Zachariah2, T. Reid2
1Medecins Sans Frontieres, Kigali, Rwanda, 2Medecins Sans Frontieres, Brussels, Belgium, 3TRAC, Kigali, Rwanda

Background: Whereas studies from high-income countries have shown that female sex and a baseline CD4 cell count >250 cells/µL increase the risk of nevirapine-induced hepatotoxicity, data from low-income countries show conflicting results. However, given the tendency to start antiretroviral treatment (ART) at higher baseline CD4 cell counts, in particular within prevention-of-mother-to-child (PMTCT) programs, the safety of using nevirapine at CD4 counts > 250 cells/µL needs to be further assessed.

Methods: Analysis of toxicity-related drug substitutions of 2367 adults starting nevirapine-containing ART regimens in two urban government health centers in Kigali, Rwanda. Risk factors for severe nevirapine-related hepatotoxicity (grade III/IV) were assessed using multivariate Cox regression analysis.

Results: Of a total of 2367 patients, 73% were female (n=1724). The median baseline CD4 count was 162 cells/µL and 22% started ART with a baseline CD4 count > 250 cells/µL. Thirty patients (1.27%) developed severe hepatotoxicity (incidence rate 9/1000 patient-years). In multivariate analysis, abnormal baseline liver function tests (hazard ratio (HR): 5.37 (95% CI 2.04-14.14) P=0.001) and a body mass index (BMI) < 20 kg/m2 (HR: 2.27 (95% CI 1.03-5.27); P=0.037) were significantly associated with hepatotoxicity. There was no significant associated risk with baseline CD4 counts > 250 cells/µL (HR: 1.19 (95% CI 0.34-4.17); P=0.778) or female sex (HR: 1.22 (95% CI 0.42-3.58); P=0.711).

Conclusions: These data suggest that nevirapine administered to women with baseline CD4 counts > 250 cells/µL, as can occur in PMTCT programs, is not significantly associated with a higher risk of hepatotoxicity. Further evidence from other similar settings would be useful to compliment this finding.

Presenting author email: tony.reid@brussels.msf.org