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

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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.
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