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RISK OF HEPATOTOXICITY IN VIROLOGICALLY SUPPRESSED HIV PATIENTS SWITCHING TO NEVIRAPINE ACCORDING TO GENDER AND CD4 COUNT

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BACKGROUND: There is an increased risk of hepatotoxicity in antiretroviral-naive patients starting a nevirapine-containing combination antiretroviral therapy (NcART) with high CD4 counts. It is not known whether this higher risk also applies to virologically suppressed patients.

METHODS: Meta-analysis of all randomized studies in which virologically suppressed patients were switched to a NcART and have a follow-up = 3 months. CD4 was classified as high (HCD4) ($\geq 400/\text{mm}^3/250/\text{mm}^3$; male/female respectively) or low (LCD4). Main endpoint was hepatotoxicity defined as elevation of ALAT or ASAT above 200 if normal at baseline or ≥ 3 fold increase if abnormal at baseline within first 3 months. Mortality, symptomatic hepatitis and rash were also evaluated. The combined estimates were assessed by a random-effects meta-analysis.

RESULTS: Four studies with a pooled total of 410 patients were included (133 in the LCD4 and 277 in the HCD4 groups respectively). The risk of hepatotoxicity was 2% and 4% in the LCD4 and HCD4 groups, with an overall OR of 1.46 (95% CI: 0.43–4.98; $P=0.54$). The overall OR for hepatotoxicity or rash was 1.17 (95% CI: 0.56–2.42; $P=0.68$). No patients died and 2 patients (1%) in the HCD4 group developed a symptomatic hepatitis. Only a baseline elevation of transaminases was associated ($P=0.08$) with an increased risk of hepatotoxicity. The risk of hepatotoxicity at any moment during the evolution was also similar in both groups with a combined HR of 0.854 (95% CI 0.3–2.5; $P=0.80$). Differences in hepatotoxicity $\geq 8\%$ would have been detected with a power of 80% and $P<0.05$ if existed.

CONCLUSIONS: Contrary to naive patients, virologically suppressed patients do not have a higher risk of hepatotoxicity or rash when stratified by gender and CD4 count.

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