Adverse events associated with nevirapine use in pregnancy: a systematic review and meta-analysis

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ABSTRACT

Introduction:
The risk of adverse drug events associated with nevirapine (NVP) is suggested to be greater in pregnant women. We conducted a systematic review and meta-analysis of severe adverse events in HIV-positive women who initiated NVP while pregnant.

Methods:
We searched six databases for studies reporting adverse events among HIV-positive pregnant women who had received NVP-based antiretroviral therapy for at least 7 days. Data were pooled by the fixed-effects method.

Results:
Twenty studies (3582 pregnant women) from 14 countries were included in the final review. The pooled proportion of patients experiencing a severe hepatotoxic event was 3.2% [95% confidence interval (CI) 2.1–4.3%], severe rash was experienced by 3.3% of patients (95% CI 2.1–4.5%) and 6.1% (95% CI 3.9–8.3%) of patients discontinued NVP due to an adverse event. These results were comparable to frequencies observed in the general adult patient population, and to frequencies reported in non-pregnant women within the same cohort. For pregnant women with a CD4 cell count above 250 cells/μl there was a non-significant tendency towards an increased likelihood of severe cutaneous adverse events (OR 1.4, 95% CI 0.8–2.4) and severe hepatotoxic events (OR 1.5, 95% CI 0.9–2.3) and consequently an increased risk of toxicity-driven regimen substitution (OR 1.7, 95% CI 1.1–2.6).

Discussion:
These results suggest that the frequency of adverse events associated with NVP use in pregnant women, although high, is no higher than reported for NVP in the general adult population. Pregnant women with a
high CD4 cell count may be at increased risk of adverse events, but evidence supporting this association is weak.