The Prevalence of Nevirapine Toxicity among Pregnant Women in three Health Facilities in Johannesburg: 2004 to 2008 and 2010 to 2011

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Abstract

Introduction: Nevirapine (NVP) is used in combination antiretroviral treatment especially for pregnant HIV infected women. NVP has been shown to be inferior and more toxic than other similar drugs, but continues to be used in developing countries due to cost.

Aim: This study aimed to determine the prevalence of NVP toxicity and associated factors among 478 pregnant women from three public health facilities in inner city Johannesburg.

Materials and methods: We employed a cross-sectional retrospective record review study design to analyse the records of 478 pregnant women in the above mentioned public health facilities. Variables including demographic (age, weight, gestational age) and clinical (CD4 cell count, WHO HIV clinical stage, prior ART experience) characteristics were extracted and the association between these characteristics and the development of toxicity post NVP exposure was explored.

Results: The study found that approximately nine out of ten women (89.5%) were ART naïve at the time of NVP initiation. When compared with ART naïve women, ART experienced women had a slightly higher mean CD4 cell count, however, for both groups of women, mean CD4 cell count was less than 250 cells/mm^3. Overall, 85.1% of women had a CD4 cell count less than 250 cells/mm^3. More than half (55.3%) of the women were in the third trimester of pregnancy and the majority (82%) classified as WHO HIV clinical stage one. At least one adverse event was reported in 63 (13.2%) women. Mild skin rash was the most prevalent adverse event, occurring in 9.6% of women. Hepatotoxicity occurred in 5.3% of women and severe skin rash occurred in 1.5% of women. Almost 85% of adverse events occurred in women with CD4 cell counts <250 cells/mm^3. WHO HIV clinical stage II and IV were significantly associated with the overall development of toxicity (ρ <0.01).

Conclusions: Whilst the overall prevalence of mild and severe skin rash in this sample was less than that demonstrated in earlier studies, a higher overall prevalence of hepatotoxicity was found. When compared with ART naïve women, ART experienced women were found to have a higher prevalence of mild skin rash. Hepatotoxicity and severe skin rash only occurred in ART

naïve women. In this sample, CD4 cell count ≥250 cells/mm^3 was not associated with the development of NVP adverse events.

Recommendations: Our findings support the continued use of NVP as part of combination ART regimens in women of African descent. In contrast with previously published data, our study showed a significant association between WHO HIV clinical stage and NVP toxicity, our study also included relatively few women with higher CD4 cell counts. Further research including predominantly healthy HIV infected pregnant African women as well as women with higher CD4 cell counts is required in order to fully explore the association between these variables and the development of NVP post-exposure toxicity.