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Safety Profile of Anti-Retroviral Medicine in South Africa Based on Reported Adverse Drug Reactions

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Abstract : Background: Antiretroviral therapy (ART) has been effective in the reduction of mortality and resulted in an improvement in the prognosis of HIV-infected patients. However, treatment with antiretrovirals (ARVs) has led to the development of many adverse drug reactions (ADRs). It is, therefore, necessary to determine the safety profile of these medicines in a South African population in order to ensure safe and optimal medicine use. Objectives: The aim of this study was to quantify ADRs experienced with the different ARVs currently used in South Africa, to determine the safety profile of ARV medicine in South Africa based on reported ADRs, and to determine the ARVs with the lowest risk profile based on specific patient populations. Methodology: This was a quantitative study. Individual case safety reports for the period January 2010 – December 2013 were obtained from the National Pharmacovigilance Center; these reports contained information on ADRs, ARV medicine, and patient demographics. Data was analysed to find associations that may exist between ADRs experienced, ARV medicines used and patient demographics. Results: A total of 1916 patient reports were received of which 1534 met the inclusion criteria for the study. The ARV with the lowest risk of ADRs were found to be lamivudine (0.51%, n=12), followed by lopinavir/ritonavir combination (0.8%, n=19) and abacavir (0.64%, n=15). A higher incidence of ADRs was observed in females compared to males. The age group 31–50 years and the weight group 61–80 kg had the highest incidence of ADRs reported. Conclusion: This study found that the safest ARVs to be used in a South African population are lamivudine, abacavir, and the lopinavir/ritonavir combination. Gender differences play a significant role in the occurrence of ADRs and both anatomical and physiological differences account for this. An increased BMI (body mass index) in both men and women showed an increase in the incidence of ADRs associated with ARV therapy.

Keywords : adverse drug reaction, antiretrovirals, HIV/AIDS, pharmacovigilance, South Africa
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