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Adverse drug reactions in a South African HIV clinic cohort over a 5-year period; findings and future implications.

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Abstract

Background: Adverse drug reactions (ADRs) contribute to morbidity and mortality, which in many cases are preventable. Pharmacovigilance plays an important role in the detection, assessment and prevention of these ADRs.

Objective: This study aimed to ascertain the association of ADRs with antiretroviral and concomitant medicines in a country with high rates of HIV.

Methods: Retrospective cohort study using data extracted from 595 patient files enrolled on ART, ≥15 years and receiving ART at the facility from April 2013 to December 2018. Bivariate analyses were performed to test for association of factors potentially associated with ADRs. All statistical tests were two-tailed with $p < 0.05$ considered statistically significant.

Results: ADRs were reported in 58.9% (349/595) of the patients. Eighty-seven point five percent (523/595) of the patients were receiving concomitant medicines. A total of 904 ADRs were reported, of which the most common included general body pain (n = 111, 12.0%), headache (n = 82, 8.9%), and facial and oral sores (n = 78, 8.6%). No significant association was found between ADRs and concomitant medicines. A significant association was found between ADRs and $CD4^+$ counts ≤ 350 cells/mm^3 ($p<0.015$) and with different age categories ($p<0.001$) with the 10 most prominent ADRs.

Conclusion: Special attention should be given to patients with a low $CD4^+$ count and patients older than 30 years, especially in the first 6 months of treatment, as this is the period where patients are most vulnerable to ADRs.

Keywords: adverse drug reactions, antiretroviral treatment, Pharmacovigilance, primary health care, South Africa.

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