Adverse drug reactions in HIV-infected patients registered at four sentinel sites in South Africa

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Background: HIV and TB are common infections in sub-Saharan Africa. Due to HIV's suppression of the immune system, infected patients are prone to opportunistic infections. Co-treatment of HIV and TB places patients at risk of adverse drug reactions (ADRs) and drug interactions. This study aimed to determine the incidence and risk factors for ADRs in HIV-infected patients and those co-infected with TB. **Methods:** Data from patients (aged >15 years) enrolled on the Medunsa National Pharmacovigilance Centre's database from March 2007 to May 2017 were analysed. Censoring targeted the first incident of ADRs in HIV-TB co-infected patients and those not co-infected. A Cox-proportional hazard model was used to determine associations of dependant variables and identify predictors for developing ADRs. **Results:** 3608 HIV-infected patients were included. 12% (n=437) had HIV-TB co-infection. Overall prevalence of ADRs was 31% (n=1 131). Of these, 12% were experienced by patients with HIV and TB co-infection and 885 by patients with no co-infection. Higher rates of ADRs were found to be significantly associated with patients initiated on stavudine (aHR=9.4; 95% CI 7.4-12.1; p<0.001) and non-standardised regimens (aHR=6.6; 95% CI 4.5-9.8; p<0.001). Peripheral neuropathy and skin rash were the most common ADRs. Patients initiated on a CD4+ count <350 cells/mm^3 (aHR=1.3; 95% CI 1.1-1.4, p<0.001) and cigarette smokers (aHR=1.4; 95% CI 1.1-1.7, p=0.015) were at higher risk of developing ADRs. **Conclusion:** Overall, results suggested a modest incidence of ADRs amongst HIV- and TB co-infected, with no significant association between ADRs and TB-coinfection. A pharmacovigilance surveillance system remains essential.