

Prevalence of Adverse Events in Children and Adolescents on Antiretroviral Therapy: Examining the Pediatric Cohort in the Eastern Cape

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Abstract : Studies on AE of highly active antiretroviral therapy (HAART) in children and adolescents are rare. The aim of this study is to observe the frequency of treatment limiting adverse drug reactions against years on ARVs and specific ARV regimen. Methods: A retrospective cohort study was conducted in East London, South Africa. All patient files in the pediatric (0 - 18 years) ARV cohort were examined, selecting only those patients started on HAART. ARV regimen changes explicitly due to AE, age on ARV treatment onset, age of AE onset, and gender were extrapolated. Eligible subjects were obtained from patient folders, anonymized and cross-referenced with data obtained from electronic records. A total of 1120 patients [592 male (52.9%) and 528 female (47.1%)] were charted by incidence and year. Additional information was extrapolated in cases where the patient experienced lipodystrophy and lipoatrophy to include the number of years on ARVs prior to the onset of the AE. Results: Of the 1120 HIV infected children of the hospital cohort, a total of 105 (9.37%) AE (53.3% male) observed were deemed eligible for the study due to completeness of medical history and agreement between electronic records and paper files. The AE cited were as follows: lipoatrophy 62 (5.53% of all subjects), lipodystrophy 27 (2.41%), neuropathy 9 (0.8%), anemia 2 (0.17%), Steven Johnsons Syndrome 1 (0.08%), elevated LFTs 1 (0.8%), breast hypertrophy (0.08%), gastritis 1 (0.08%) and rash 1 (0.08%). The most prevalence ARV regimens associated with the onset of the AE are: D4T/3TC/EFV 72 cases (64.86% of all AE), D4T/3TC/LOPr 24 cases (21.62%). Lipoatrophy and lipodystrophy combined represent 84.76% (89 cases) of all adverse events documented in this cohort. Within the 60 cases of lipoatrophy, the average number of years on ARVs associated with an AE is 3.54, with 14 cases experiencing an AE between 0-2 years of HAART. Within the 29 cases of lipodystrophy, the average number of years on ARVs associated with an AE is 3.89, with 4 cases experiencing an AE between 0-2 years on HAART. The regimen D4T/3TC/EFV is associated with 43 cases (71.66%) of lipoatrophy and 21 cases (72.41%) of lipodystrophy. D4T/3TC/LOPr is associated with 15 cases (25%) of lipoatrophy and 7 cases (24.14%) of lipodystrophy. The frequency of AE associated with ARV regimens could be misrepresented due to prevalence of different 1st line regimens which were not captured in this study, particularly with the systematic change of 1st line drugs from D4T to ABC in 2010. Conclusion: In this descriptive study we found a 9.37% prevalence of AE were significant enough to be treatment limiting among our cohort. Lipoatrophy accounted for 59.04% of all documented AE. Overall, D4T/3TC/EFV was associated with 64.86% of all AE, 71.66% of lipoatrophy cases and 72.41% of lipodystrophy cases.

Keywords : ARV, adverse events, HAART, pediatric

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