

## Abstract

Background: Stavudine (d4T) and zidovudine (AZT) form the backbone of the most commonly used first-line highly active antiretroviral therapy (HAART) regimens in Kenya. In 2012, more than 60 % of patients undergoing combination antiretroviral therapy were either on AZT or d4T based regimens, mainly due to their affordability and availability in fixed dose combinations. Following the World Health Organization's recommendation in 2010 that d4T should be phased out due to safety concerns, Kenya has been steadily withdrawing d4T from HIV/AIDS treatment programmes. Despite these decisions, questions as to whether stavudine ought to be altogether abandoned in resource constrained settings continue to elicit debate among clinicians, researchers and patient groups. Objective: This study was consequently designed to compare the tolerability and efficacy of AZT with low dose d4T in treatment of HIV infected adults in urban Kenya, and to generate data on the safety of low dose stavudine. Method: The design was an analytic retrospective hospital-based cohort study that involved examination of records of patients on antiretroviral therapy. The study had two comparator arms: (i) ART-naive adult patients initiated on stavudine 30 mg based HAART, and (ii) ART-naive adult patients initiated on zidovudine based HAART. Quantitative variables were described with medians or means, and compared between groups using Wilcoxon rank sum test. Association effects were determined by use of Chi-square test. Categorical variables were summarized using proportions. The time to event analysis was estimated using the Kaplan–Meier product limit method. Cox Proportional Hazards regression was used to model the hazard rates of regimen switching. Results: The incidence rate (IR) of switching regimen was higher in patients initiated on zidovudine than in patients initiated on low dose stavudine (11.3 % and 7.0 % respectively). The most common reason for regimen switch was toxicity (79.2 %). In patients initiated on stavudine, lipodystrophy was the main reason for treatment change (53.2 %) followed by peripheral neuropathy (23.4 %). Amongst patients initiated on zidovudine, anaemia was the main reason for treatment change (33.3 %). There was no significant difference in median change in CD4 cell counts between the two treatment groups. Conclusion: The study has showed that patients initiated on a zidovudine based regimen were more likely to change their treatment compared to those on a low dose stavudine. Stavudine therefore still has its benefits, and public health programmes should not altogether abandon it.