Abstract

THE SAFETY AND TOLERABILITY OF LOW DOSE STAVUDINE VERSUS ZIDOVUDINE IN PATIENTS AT KENYATTA NATIONAL HOSPITAL

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Background: Stavudine (d4T) and zidovudine (AZT) form the backbone of the most commonly used first-line highly active antiretroviral therapy (HAART) regimens in Kenya.
Due to safety concerns, and in line with the World Health Organization's recommendation, Kenya is currently phasing out d4T from HIV/AIDS treatment programmes.
However, the move to abandon stavudine in resource constrained settings continues to elicit debate in Africa among clinicians, researchers and patient groups.
Objective: This study was designed to compare the tolerability and efficacy of AZT with low dose d4T (30 mg) in treatment of HIV infected adults in urban Kenya, and to generate data on the safety of low dose stavudine.

Method: The design was a 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. Safety concerns persist for stavudine despite dose lowering, however the low dose stavudine retain benefits comparable to zidovudine, and public health programmes should not abandon it completely.