ABSTRACT

INTRODUCTION: Since the advent of the Highly Active Anti-Retroviral Therapy (HAART), HIV has been reconsidered as a manageable chronic disease with a dramatic fall in HIV–related morbidity and mortality. The therapeutic goals of ART are the production of long term virological suppression, immune reconstitution leading to decreased morbidity and mortality arising from opportunistic infections and improvement in the quality of life. This can only be achieved by rational choice of effective first line regimen that will enhance good adherence while also ensuring minimal toxicity. This study therefore sets out to compare the therapeutic efficacy and adverse effects profile of Tenofovir/lamivudine and Zidovudine/lamivudine, two of the commonly used first line nucleoside reverse transcriptase inhibitor (NRTI) backbone.

METHODOLOGY: This was an open labeled, prospective, non-inferiority, randomized clinical trial carried out at the Ahmadu Bello University Teaching Hospital, Zaria between 18th June 2012 to 18 June 2013. Newly diagnosed HIV positive patients aged 18 years and above were randomly assigned in a 1:1 ratio, to standard doses of Tenofovir/lamivudine once daily or Zidovudine/lamivudine twice daily. In addition, each patient received standard doses of Nevirapine or Efavirenz according to the national guideline. History and physical examination were recorded using a pre-tested questionnaire. Venous blood samples were collected for necessary investigations during recruitment and at follow-up for six months.

RESULTS: Two hundred and forty-nine (249) HIV patients were screened and 197 were randomized to Tenofovir/lamivudine (Group A) or Zidovudine/lamivudine (Group B). The mean
and standard deviation of the age for group A was 32.0 ± 0.86 years while that of group B was 36.2 ± 0.94.0 years. Fewer patients in the group A achieved a viral suppression of < 400 copies/ml compared to group B [68% vs. 84%, difference = −16%, $\chi^2$, p = 0.04].

There was no statistically significant difference in the proportion of patients in group A with increased baseline CD4+cell ≥ 25/mm³ compared to Group B [66% vs. 78%, $\chi^2$, p = 0.10].

The incidence of hematological adverse events was higher in the Zidovudine/lamivudine group compared to Tenofovir/lamivudine [grade 1-2 anemia, 4% vs. 0%; grade 3-4 neutropenia, 8% vs. 1%]. More patients in Tenofovir/lamivudine experienced a rise in baseline serum creatinine level compared to Zidovudine/lamivudine [53.1% vs. 47.5%].

**CONCLUSION:** Through six months of follow-up, the combination of Tenofovir/lamivudine fails the criteria for noninferiority to Zidovudine/lamivudine in terms of viral suppression. While the Tenofovir/lamivudine regimen may cause renal toxicity, patients on Zidovudine/lamivudine are prone to anemia and/or neutropenia. Frequent measurement of hematologic parameters and serum creatinine is necessary in order to detect early toxicity of these regimens.