Switching Tenofovir/Emtricitabine/Efavirenz (TDF/FTC/EFV) to TDF/FTC/Rilpivirine (RPV) vs Continuing TDF/FTC/EFV in HIV-infected Patients with Complete Virological Suppression: A Randomized Controlled Trial

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Background: Tenofovir/emtricitabine/efavirenz (TDF/FTC/EFV) is currently recommended as the preferred first-line antiretroviral therapy (ART) in Thailand and other countries in resource-limited settings. However, central nervous system (CNS) side effects and dyslipidemia are commonly associated with EFV use. Rilpivirine (RPV), a newer NNRTI, has shown non-inferiority to EFV in treatment-naïve HIV-infected patients.

Objective: This study aimed to compare the efficacy and adverse effects between switching from TDF/FTC/EFV to TDF/FTC/RPV and continuing TDF/FTC/EFV in patients with complete viral suppression.

Methods: A randomized controlled non-inferiority trial was conducted in HIV-infected patients currently on TDF/FTC/EFV with undetectable HIV RNA (<50 copies/ml). Patients were randomized to switch from TDF/FTC/EFV to TDF/FTC/RPV (Group A) or continue TDF/FTC/EFV (Group B), and were followed up for 24 weeks. The primary endpoint was the proportion of patients with undetectable HIV RNA and a prespecified non-inferiority margin of 12%. Changes in CD4 cell count, lipid profiles, and adverse events were also analyzed. This study was registered with ClinicalTrials.gov, no.NCT03251690.

Results: A total of 246 patients were enrolled, with 124 in Group A and 122 in Group B. Mean age was 44.6 years and 63% were males. Mean baseline CD4 cell count was 565 cells/mm³. Baseline characteristics including age, sex, CD4 cell count, lipid profiles, duration of ART and CNS side effects between the two groups were similar (p>0.05). Mean baseline values for total cholesterol (TC), LDL, HDL, and triglycerides (TG) were 196, 117, 47, and 148 mg/dl, respectively. At 24 weeks, 95.9% of patients in Group A and 97.6% of those in Group B maintained HIV RNA <50 copies/ml (difference -1.68%; 95% CI, -7.06 to 3.35), showing non-inferiority of switching to TDF/FTC/RPV. Mean CD4 cell count was 564 and 581 cells/mm³ in Group A and B, respectively (p=0.604). Mean change in lipid profiles (Group A vs B) were: TC, -22.4 vs -1.8; HDL, -4.2 vs +0.5; LDL, -6.4 vs +3.2; and TG, -29.4 vs +0.3 mg/dl (all p<0.05). CNS side effects persisted in 6.5% and 0% of patients in group A and B, respectively (p<0.001).

Conclusions: Switching TDF/FTC/EFV to TDF/FTC/RPV is non-inferior to the continuing TDF/FTC/EFV in maintaining viral suppression at 24 weeks, with better lipid profiles and CNS side effects. Switching to TDF/FTC/RPV should be considered in HIV-infected patients with TDF/FTC/EFV for complete viral suppression.

Keywords: HIV, Rilpivirine, Efavirenz, Efficacy, Switching, Dyslipidemia