Efficacy of Rilpivirine-based Regimen as Switch Therapy in HIV-infected Patients: A Randomized Controlled Trial

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Background: Nevirapine (NVP)-based antiretroviral therapy (ART) remains to be used in human immunodeficiency virus (HIV)-infected patients in resource limited countries despite its adverse effect and compliance concerns. Rilpivirine (RPV) is a newer non-nucleoside reverse transcriptase inhibitor that could be used as an alternative to NVP in virologically suppressed patients. However, there has been limited experience with switching to RPV-based regimens.

Objective: We aimed to study the efficacy and adverse events after switching ART from NVP-based to RPV-based regimens.

Methods: A randomized controlled non-inferiority trial was conducted in HIV-infected patients who received NVP-based regimens and had undetectable plasma HIV RNA for >6 months. Patients were randomized 1:1 to continuation group (continuing NVP-based regimens) or switch group (switching to RPV-based regimens). Tenofovir disoproxil fumarate (TDF) plus lamivudine (3TC) or emtricitabine (FTC) remained as backbone of the regimen. The primary endpoint was HIV RNA <40 copies/mL at 24 weeks, with a non-inferiority margin of 12%. Changes of CD4 cell counts and lipid profiles from baseline were analyzed.

Results: A number of 103 patients were enrolled, 50 in the switch group and 53 in the continuation group. Mean (SD) age was 48.8 (9.2) years and 51.5% were females. Median (interquartile range, IQR) baseline CD4 cell counts was 558 (442-709) cells/µL. Baseline characteristics including age, gender, CD4 cell counts, and ART duration were similar between the two groups (p >0.05). At 24 weeks, 49 patients (98.0%) in the switch group and 52 patients (98.1%) in the continuation group had virologic suppression. The switch group was non-inferior to the continuation group (efficacy difference 0.11%; 95% confidence interval (CI), −8.15% to +8.11%). Both regimens were generally well tolerated, despite 1 death from hematologic malignancy, occurring in the first 3 months of enrollment in the continuation group. A significant decrease in mean total cholesterol was observed in the switch group (-13.3 mg/dL, 95%CI -22.1 to -4.5, P = 0.002), but not in continuation group.

Conclusion: In HIV-infected patients virologically suppressed with NVP-based regimen, once daily RPV-based regimen, including TDF plus 3TC or FTC, is an alternative switch option. This regimen can maintain viral suppression and decrease total cholesterol. Nonetheless, further study of long-term efficacy of this switching strategy should be investigated.

Keywords: HIV, Randomized controlled trial, Rilpivirine, Switch therapy