Impact of Switching Virologically Suppressed, HIV-1–Infected Patients from Twice-Daily Fixed-Dose Zidovudine/Lamivudine to Once-Daily Fixed-Dose Tenofovir Disoproxil Fumarate/Emtricitabine

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Objective: Evaluate the impact of switching from twice-daily zidovudine/lamivudine (AZT/3TC) to once-daily tenofovir DF plus emtricitabine (TDF/FTC) with efavirenz (EFV). **Design:** Prospective, multicenter, single-arm 24-week trial. **Methods:** Patients on EFV + AZT/3TC for ≥8 weeks with HIV-1 RNA <400 copies/mL were switched to EFV + TDF/FTC and assessed for safety/tolerability, virologic and immunologic responses, adherence, and quality of life at 4, 12, and 24 weeks. **Results:** Of 402 patients, 2% discontinued for an adverse event (AE) and 1 patient for virologic failure. At 24 weeks, 87% had HIV RNA <400 copies/mL, and 74% versus 71% at baseline had undetectable (HIV RNA <50 copies/mL) viral load (ITT; M=F). Treatment-emergent AEs were infrequent (≤5%) with gastrointestinal complaints being the most common. At 24 weeks compared to baseline, hemoglobin (Hb) increased by a median of 0.6 g/dL ($p < .001$), and a decrease in creatinine clearance of 7.6 mL/min ($p < .001$) was observed. Fasting lipids decreased slightly ($p < .02$) in a subset of patients studied ($n = 160$). A higher percentage of patients reported being "very satisfied" with treatment and the absence of regimen side effects at 24 weeks versus baseline ($p < .001$). At 24 weeks, 86% of patients took ≥95% of doses versus 78% at baseline ($p = .002$). **Conclusion:** Patients switched to EFV + TDF/FTC maintained virologic suppression and the regimen was well tolerated. Patients reported increased satisfaction with treatment and fewer were bothered by side effects. **Key words:** *AZT/3TC, TDF/FTC, treatment simplification*