Safety and efficacy of rilpivirine-tenofovir-emtricitabine in treatment experienced patients infected with HIV-1

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Introduction

Rilpivirine (RPV) is a recently approved second generation NNRTI, launched in combination with Tenofovir (TDF) and / Emtricitabine (FTC) as a once-daily fixed dose regimen called Eviplera in Europe and Complera in the United States. RPV has shown similar efficacy to Efavirenz in clinical trials before its approval in treatment naïve patients with baseline viral loads below 100,000 copies/ml (1,2). Preliminary data from ongoing studies have demonstrated efficacy and improved tolerability by switching to RPV/TDF/FTC (3). We sought to explore the safety and efficacy of fixed-dose combination of RPV with TDF and FTC in treatment experienced patients at Chelsea and Westminster Hospital.

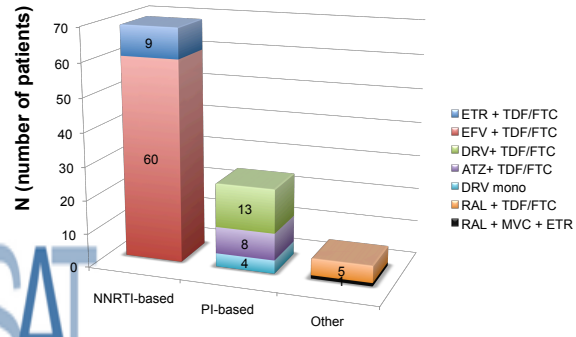
Methods

HIV-infected individuals switching to RPV/TDF/FTC were identified from the departmental database. Patient demographics were extracted from this database and biochemical, virological and immunological parameters were collated. At baseline, 1 month, 3 month and 6 month time points the following laboratory results were compared using the Kruskal-Wallis test: CD4 count, HIV viral load, amino transferase (ALT), cholesterol, triglyceride and HDL/ cholesterol ratio levels.

Results

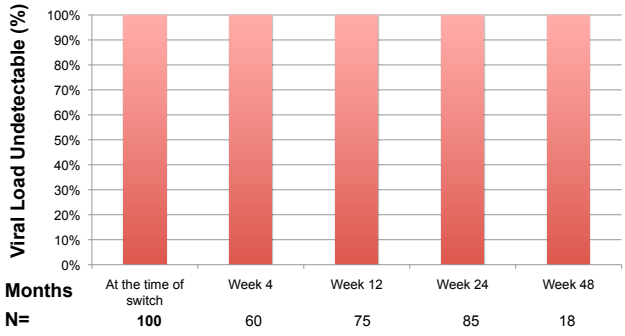
One hundred individuals (93 male, 7 female) were switched to RPV/TDF/FTC between December 2011 and December 2012. Median age was 40 years (23-74). Overall exposure to antiretroviral (ARV)s was 67 months (16-115). Sixty patients switched from EFV/TDF/FTC (once daily single tablet regimen). The reason to switch was mainly neurological side effects (53/100) and ease of compliance (21/100).

Figure 1: Pre-switch ARV profile in treatment experienced group



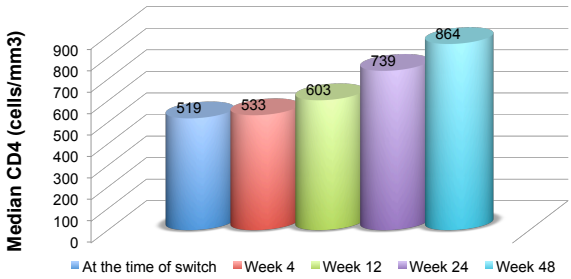
At the time of switch all patients (100/100) had HIV-RNA-1 <40 copies/mL Seventy-one patients (71/75) at week 12, sixty three (63/65) patients at week 24 and seventeen (17/18) patients at week 48 remained undetectable (Fig 2). One individual had HIV-RNA-1 of 2291 copies/mL at week 24 and one individual had 248 copies/mL at Week 48.

Figure 2: Virological suppression after switch to RPV/TDF/FTC



At the time of switch baseline median CD4 count was 536 cells/ mm3 (96-1586), which increased significantly to 739 cells/mm3 ($p<0.005$) at Week 24 and to 864 cells/mm3 at Week 48 (*Fig.3*).

Figure 3: Median CD4 count levels up to 48 weeks



Switching to RPV showed improvement in fasting lipids (Cholesterol and Triglyceride) at Week 24 and 48. Nine patients stopped using RPV/TDF/FTC due to various reasons; caloric restrictions (2/9), fatigue (2/9), nausea and vomiting (2/9), diarrhoea (1/9), nephrotoxicity (1/9) and depression (1/9).

Discussion

This small study highlights the use of RVP/TDF/FTC as a safe and efficacious switch option in treatment experienced HIV-infected individuals. In this study there was no significant reason to stop RPV/TDF/FTC in this group of patients. However more robust clinical data are needed to establish the longer term efficacy, safety and tolerability of RVP/TDF/FTC as a switch option.

References:
1- Cohen et al, AIDS, 2012, Volume 60, p 33–42
2- Molina et al, The Lancet, 2011, Volume 378, p 238- 246
3- Palella F, et al. IAC 2012; Washington, DC. Oral

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