

# <u>CP-054</u>: OFF – LABEL USE OF EMTRICITABINE / RILPIVIRINE / TENOFOVIR



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## Background

Emtricitabine / rilpivirine / tenofovir (FTC/RPV/TDF) was initially approved for the treatment of human immunodeficiency virus type 1 in treatment-naïve adult patients with a viral load ≤ 100,000 copies/mL.

## Objective

To evaluate the effectiveness and safety of off-label use of FTC/RPV/TDF after this drug was included in our hospital's drug therapy guide.

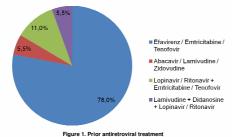
#### Methods

- > This retrospective observational study included all patients dispensed FTC/RPV/TDF from our university hospital's pharmacy department from October 2013 through March 2014.
- > We collected the following information from medical records: age, sex, pharmacologic history, prior antiretroviral treatment, reasons for treatment change, viral load, CD4 count, and atherogenic index at the start and end of the study period, adherence, side-effects, and reasons for discontinuing treatment.
- > The results were analysed using SPSS version 15.0.

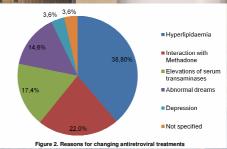
### Results

- ➤ We included 19 consecutive patients (14 men and 5 women; mean age, 44.7 years).
- > All patients were treatment-experienced; 78% were previously treated with efavirenz / emtricitabine / tenofovir (figure 1).
- The most frequent reasons for changing antiretroviral treatments were hyperlipidaemia (38.8%) and interaction with methadone (22%) (figure2).
- The viral load was <50 copies/mL in 10 patients. The mean CD4 count was 634.6/mm³ at baseline and 596.4/mm³ at end-study (normal range: 450-1400/mm³). The mean atherogenic index, recorded in 16 patients, was 4.5 (normal range: 0-5) at both the beginning and end of the study.
  - No side-effects were documented. Two patients discontinued treatment for reasons unrelated to the antiretroviral (pregnancy and death). We detected no nonadherence to medication.









#### Conclusions

In our centre, changing treatment to FTC/RPV/TDF is mostly due to side-effects and interactions in prior treatment. Although our preliminary data preclude definitive conclusions, FTC/RPV/TDF seems safe and effective.