

## High Treatment Retention and Success Rates of Tenofovir/Emtricitabine/Rilpivirine (Eviplera) in ART-naive HIV-infected Persons in Clinical Practice: A Comparative Study on Determinants of Use and Treatment Outcome

A. Cozzi-Lepri<sup>1</sup>, S. Lo Caputo<sup>2</sup>, F. Maggiolo<sup>3</sup>, A. Antinori<sup>4</sup>, A. Ammassari<sup>4</sup>, G. Marchetti<sup>5</sup>, C. Mastroianni<sup>6</sup>, A. Gori<sup>7</sup>, G. Di Perri<sup>8</sup>, G. Angarano<sup>9</sup>, A. Carbone<sup>10</sup>, A. d'Arminio Monforte<sup>5</sup>, on behalf of the IcoNa Foundation Study Cohort

<sup>1</sup>University College London, London, United Kingdom, <sup>2</sup>S. M. Annunziata Hospital, Firenze, Italy, <sup>3</sup>Ospedali Riuniti, Bergamo, Bergamo, Italy, <sup>4</sup>INMI Spallanzani, Roma, Italy, <sup>5</sup>San Paolo University Hospital, Milano, Italy, <sup>6</sup>University La Sapienza, Roma, Israel, <sup>7</sup>San Gerardo Hospital, Monza, Italy, <sup>8</sup>Amedeo di Savoia Hospital, Torino, Italy, <sup>9</sup>University of Bari, Bari, Italy, <sup>10</sup>San Raffaele Hospital, Milano, Italy

**Objectives:** To describe the use of Eviplera (EPA) in Italy, to identify patterns of prescription and response in persons starting from ART-naive.

**Methods:** We included patients from 23 sites of the IcoNa cohort who started an EPA-based cART regimen as well as those concomitantly starting other cART regimens. All regimens had to be initiated after the date of introduction of EPA at the site (>February 2013) with a viral load  $\leq 100,000$  copies/mL and from ART-naive. Characteristics at starting cART were compared using chi-square test and logistic regression analysis. We also compared EPA and control with respect to several prospective outcomes (KM and Cox regression): 1. Time to VL $\leq 50$  copies/ml 2. Time to viral failure (VF) >50 (single determination) 3. Time to stop of  $\geq 1$  drug for any reason 4. Time to stop  $\geq 1$  drug because of toxicity and 5. Time to treatment failure (VF or stop). Multivariable models included all measured common causes of exposure and outcomes.

**Results:** We identified 603 individuals (311 starting EPA-based cART, 292 control regimen). The most frequent regimens given in the control group were (all with backbone TDF/FTC): DRVr (23%), ATVr (16%), RAL (9%) and EFV (9%). Factors associated with a greater chance of starting EPA were: pre-ART CD4 count (median values in EPA and in controls 390 vs. 327, adjusted odds ratio (OR)=1.11 per 100 cells/mm<sup>3</sup> higher, 95%CI: 1.03-1.20), time from HIV diagnosis (median 15 vs. 3 months) OR=1.11 per year longer (1.05-1.17) and education below university level OR=2.40 (1.19-4.83). Table shows the comparison EPA vs. control for the prospective outcomes.

**Conclusion:** EPA was preferably given to people with lower education, high CD4 count and diagnosed with HIV for longer. Likely driven by greater tolerability, response to EPA seemed superior to that of other concomitant regimens (mainly PI/r-based) after controlling for measured confounding factors.

Outcomes	Unadjusted and adjusted relative hazards (RH)			
	Unadjusted RH (95% CI)	p-value	Adjusted* RH (95% CI)	p-value
<b>1. Success <math>\leq 50</math> copies/ml</b>				
Concurrent control regimen	1.00		1.00	
Eviplera	1.25 (1.05, 1.57)	0.014	1.23 (0.99, 1.53)	0.062
<b>2. VF Single VL &gt; 50 copies/ml</b>				
Concurrent control regimen	1.00		1.00	
Eviplera	0.26 (0.07, 0.94)	0.040	0.36 (0.13, 0.97)	0.043
<b>3. Discontinuation (all reasons)</b>				
Concurrent control regimen	1.00		1.00	
Eviplera	0.13 (0.07, 0.27)	<.001	0.13 (0.06, 0.26)	<.001
<b>4. Discontinuation due to toxicity</b>				
Concurrent control regimen	1.00		1.00	
Eviplera	0.26 (0.07, 0.94)	0.040	0.26 (0.07, 0.98)	0.047
<b>5. TF - Single VL &gt; 50 copies/ml or discontinuation (all reasons)</b>				
Concurrent control regimen	1.00		1.00	
Eviplera	0.16 (0.08, 0.30)	<.001	0.13 (0.07, 0.26)	<.001

\* Adjusted for age, gender, nation of birth, mode of HIV transmission, hepatitis co-infection status, AIDS diagnosis, baseline CD4 count and viral load and year of starting cART

[Table. Relative hazards from fitting five separate]