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Determinants of use of the fixed dose combination emtricitabine/rilpivirine/tenofovir (Eviplera) in HIV-infected persons receiving care in Italy

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BACKGROUND

Emtricitabine/rilpivirine/tenofovir (Eviplera-EPA) is a fixed dose combination of antiretrovirals approved by the Food and Drug Administration in August 2011.

It was also approved by the European Medicines Agency in November 2011 and introduced in care in Italy in February 2013 for patients who have not previously been treated for HIV.

It is available as a once-a-day single tablet and In the European Union is licensed for use only in patients with a viral load less than or equal to 100,000 copies/ml as of International treatment Guidelines

OBJECTIVE

To describe the use of EPA in clinical sites in Italy and identify its determinants and pattern of prescription

PATIENTS AND METHODS

Clinical sites in Icona Foundation Study in which ≥1 patient had started EPA were selected for this analysis. From these sites we included all patients who started an EPA-based cART regimen as well as those concomitantly starting other cART regimens

All regimens selected had to be initiated after the date of first introduction of EPA at the specific site (and after February 2013 in any case) with a viral load ≤100,000 copies/ml when they were ART-naïve.

Statistical analysis

Characteristics at the time of starting cART were compared using chi-square test and unadjusted and adjusted logistic regression analysis.

Factors showing unadjusted associations with a p-value of 15% or smaller, were retained in the multivariable model.

RESULTS

We identified 183 patients starting EPA and 173 starting a concurrent control regimen from ART-naïve from 23 clinical sites participating to the Icona Foundation Study in which there was evidence of use of EPA. The number of patients starting EPA included at each site ranged from 1 to 12 and the number of those starting concurrent regimen was similar. Percentages in EPA vs. concurrent were as follows: heterosexuals (37% vs. 47%, p=0.33), University level of education (10% vs. 15%, p=0.62) and two-fold higher prevalence of students (6% vs. 3%, p=0.33). There were imbalances between the two groups in median CD4 count (390 vs. 348 cells/mm3, p=0.002) and time from HIV diagnosis to starting cART (17 vs. 3 months, p=0.001). No larger differences were observed for other factors examined (Table 1).

Table 1. Main characteristics according to regimen started

Characteristics	Regimen started			
	Eviplera	Concurrent control	p-value*	Total
	N= 183	N= 173		N= 356
Education, n(%)			0.622	
Primary school	6 (3.3%)	6 (3.5%)		12 (3.4%)
Secondary school	21 (11.5%)	20 (11.6%)		41 (11.5%)
College	46 (25.1%)	49 (28.3%)		95 (26.7%)
University	19 (10.4%)	25 (14.5%)		44 (12.4%)
Other/Unknown	91 (49.7%)	73 (42.2%)		164 (46.1%)
Employment, n(%)			0.332	
Unemployed	15 (8.2%)	22 (12.7%)		37 (10.4%)
Employed	68 (37.2%)	59 (34.1%)		127 (35.7%)
Self-employed	22 (12.0%)	27 (15.6%)		49 (13.8%)
Occasional	7 (3.8%)	6 (3.5%)		13 (3.7%)
Student	11 (6.0%)	5 (2.9%)		16 (4.5%)
Retired	2 (1.1%)	6 (3.5%)		8 (2.2%)
Invalid	2 (1.1%)	0 (0.0%)		2 (0.6%)
Housewife	1 (0.5%)	1 (0.6%)		2 (0.6%)
Other/unknown	55 (30.1%)	47 (27.2%)		102 (28.7%)
Mode of HIV Transmission, n(%)			0.223	
IDU	12 (6.6%)	7 (4.1%)		19 (5.4%)
Homosexual contacts	87 (48.1%)	72 (42.1%)		159 (45.2%)
Heterosexual contacts	67 (36.6%)	81 (46.8%)		148 (41.6%)
Other/Unknown	15 (8.3%)	11 (6.4%)		26 (7.4%)
Hepatitis co-infection, n(%)			0.705	
No	0 (0.0%)	25 (14.5%)		25 (7.0%)
Yes	6 (3.3%)	5 (2.9%)		11 (3.1%)
Not tested	85 (46.4%)	88 (50.9%)		173 (48.6%)
Calendar year of baseline			0.592	
Median (IQR)	2013 (2013, 2014)	2013 (2013, 2014)		2013 (2013, 2014)
Age, years			0.393	
Median (IQR)	35 (27, 40)	36 (27, 41)		35 (27, 40)
CD4 count, cells/mmc			0.002	
Median (IQR)	390 (312, 476)	348 (219, 459)		372 (276, 473)
Viral load, log10 copies/mL			0.498	
Median (IQR)	4.29 (3.92, 4.67)	4.38 (3.78, 4.74)		4.31 (3.86, 4.69)
Site geographical position, n(%)			0.321	
North	130 (71.0%)	123 (71.1%)		253 (71.1%)
Centre	42 (23.0%)	33 (19.1%)		75 (21.1%)
South	11 (6.0%)	17 (9.8%)		28 (7.9%)
Time from HIV diagnosis to date of starting cART, months			<.001	

Figure 1. Drug used in the control group

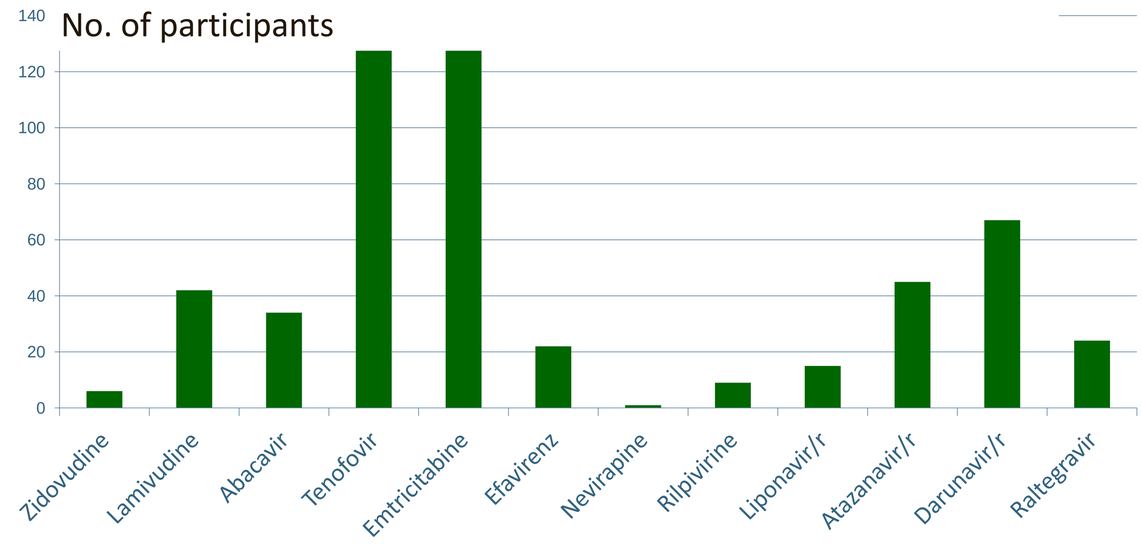

Figure 1 shows antiretroviral use in the control group. EPA was more likely to be initiated in people with high CD4 count (OR=1.17 per 100 cells/mm3 higher; 95% CI:1.04, 1.32) and those with a longer time from HIV diagnosis (OR=1.10 per year longer; 1.03, 1.18). There was also a tendency for EPA to be prescribed more frequently in students (OR=3.49 vs. employed; 0.93, 13.08) and in those with primary/secondary school as their highest level of education (OR=2.28 vs. University; 0.91, 5.72, Table 3). The association with CD4 count was also independent of viral load and the result was consistent across viral load strata (p-value for interaction =0.52)

Table 3. Odds ratios from fitting a logistic regression model

	Odds ratios of starting Eviplera			
Characteristic	Unadjusted OR (95% CI)	p-value	Adjusted OR (95% CI)	p-value
Education				
University	1.00		1.00	
Primary/Secondary school	1.37 (0.61, 3.05)	0.446	2.28 (0.91, 5.72)	0.080
College	1.24 (0.60, 2.54)	0.565	1.38 (0.64, 2.98)	0.415
Other/Unknown	1.64 (0.84, 3.21)	0.149	2.05 (0.94, 4.49)	0.072
Employment				
Unemployed	1.00		1.00	
Employed	1.69 (0.80, 3.55)	0.166	1.78 (0.79, 4.01)	0.162
Self-employed	1.20 (0.50, 2.84)	0.686	1.25 (0.50, 3.14)	0.640
Occasional	1.71 (0.48, 6.11)	0.408	2.18 (0.58, 8.27)	0.251
Student	3.23 (0.93, 11.19)	0.065	3.49 (0.93, 13.08)	0.064
Retired/Invalid/Housewife	1.05 (0.28, 3.93)	0.945	0.65 (0.15, 2.71)	0.551
Other/unknown	1.72 (0.80, 3.68)	0.165	1.85 (0.79, 4.31)	0.155
Mode of HIV Transmission				
IDU	1.00		1.00	
Homosexual contacts	0.70 (0.26, 1.88)	0.486	1.24 (0.39, 3.99)	0.714
Heterosexual contacts	0.48 (0.18, 1.29)	0.148	0.75 (0.23, 2.39)	0.626
Other/Unknown	0.80 (0.24, 2.68)	0.712	1.10 (0.28, 4.36)	0.887
CD4 count per 100 cells/mm³ higher	1.15 (1.03, 1.28)	0.014	1.17 (1.04, 1.32)	0.008
Time from HIV diagnosis to date of cART per year longer	1.11 (1.03, 1.18)	0.004	1.10 (1.03, 1.18)	0.008
Other factors investigated (showing no evidence for an association) included- gender, nationality, AIDS diagnosis, HCV-Ab status, age, CD8 count, viral load, diabetes, smoking, total cholesterol, HDL cholesterol, use of statins, use of BP lowering drugs, eGFR, blood glucose, and site geographical location				

CONCLUSIONS

In a subset of sites of our cohort with documented use of EPA, no large differences in the characteristics of patients starting EPA or concurrent regimens were observed

Although it is a selected sample of people with viral load<100,000, people with high CD4 count were more frequently treated with EPA

EPA also tended to be preferably given to people with lower education and students. This might be related to clinicians' perception of treatment adherence in these population groups

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