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A Survey of ATRIPLA Use in Clinical Practice among Treatment-naïve HIV-positive Patients in Europe

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BACKGROUND AND OBJECTIVES

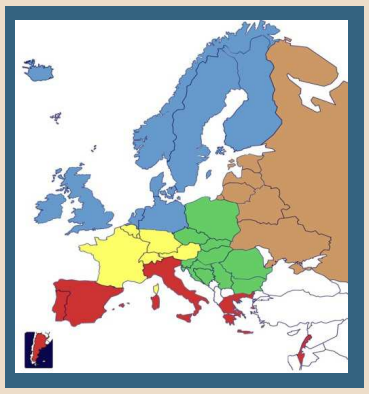
The European Medicines Agency (EMA) has licensed ATRIPLA for use only in patients whose HIV-RNA <50 cp/mL for >3 months on their current ART regimen. Reasons for the current EMA labelling are that intake of tenofovir (TDF) is normally with food while ATRIPLA is usually taken in a semi-fasting state prior to bed, and ATRIPLA has never been formally shown to provide similar viral efficacy to intake of TDF together with food.

It is important to understand the extent to which centres treating HIV-positive individuals adhere to EMA recommendations in general. The aim of this survey was to assess ATRIPLA use in daily clinical management of ART-naïve patients.

METHODS

A cross-sectional web-based survey of HIV clinics participating in EubbroSIDA in autumn 2012 using REDCapTM, in agreement with the REDCap Consortium, Vanderbilt University (available at www.chip.dk).

In descriptive analysis, EuroSIDA was divided into 4 geographical regions, as previously described – South (red, incl. Argentina – only 1 clinic participating), Central West (yellow), North (blue) and East (green /brown).



RESULTS

96/112 clinics (85.7%) completed the survey. Summary characteristics of those who completed or did not complete the survey are shown in **Table 1**.

The overall responses from the clinics and the regional differences are shown in **Figure 1**. The current ART-recommendations for naïve patients in the 96 clinics were: TDF and emtricitabine (ETC) as one tablet, with efavirenz (EFV) administered separately (N=36, 37.5%), ATRIPLA as initial therapy (N=35, 36.5%), a different 1st line regimen (N=12, 12.5%), decision up to the treating physician (N=7, 7.3%) and separate administration of the three components (N=6, 6.3% - all from Eastern Europe).

The reasons for using ATRIPLA are shown in **Figure 2** and reasons for administrating the 3 components separately are listed in the box in **Figure 1**.

For the 18 clinics where ATRIPLA was used based on local decision, reasons included feasibility (18, 100%), financial decision (1, 5.6%), and there were not any regional differences in the proportion of clinics indicating 'local decision').

Among the 15 clinics where usage of ATRIPLA was due to national guidelines, reasons included feasibility (14, 93.3%), financial considerations (4, 26.7%), and efficacy (1, 6.7%).

For the 4 clinics where ATRIPLA was used as initial therapy for other reasons, reasons included ATRIPLA being considered to be state of the art therapy (1), financial reasons (1) and patient's request (2).

A total of 30 of the 35 clinics (85.7%), where ATRIPLA was used as initial therapy, stated that ATRIPLA was used as a 1st line regimen for feasibility either as part of local or national decision making.

CONCLUSIONS

Over one third of 96 participating clinics in this survey were using ATRIPLA as 1st line ART, despite the EMA recommendations. Clinics participating in EuroSIDA may not be representative of all European HIV clinics, but initial use of ATRIPLA was highest in Northern Europe, while Eastern and Southern Europe more commonly used TRUVADA plus efavirenz.

Table 1

Comparison of summary statistics between participating and non-participating centres

	Excluded		Included		
	Median	IQR	Median	IQR	P
N, %	16	14.3	96	85.7	
Gender	74.9	65.1 – 85.5	75.0	67.2 – 81.0	0.61
White race	94.0	88.7 – 98.2	94.6	83.7 – 99.0	0.91
Homosexual	34.4	16.9 – 63.8	36.2	19.4 – 54.7	0.65
IDU	11.8	4.2 – 38.0	20.0	6.6 – 38.5	0.41
Heterosexual	26.3	17.3 – 42.0	27.5	20.0 – 36.3	0.76
Prior AIDS	23.4	14.8 – 28.1	27.5	19.2 – 33.5	0.31
Started cART	32.3	10.5 – 63.7	50.4	32.2 – 72.1	0.078
ARV naïve	31.0	20.9 – 49.9	25.3	17.1 – 35.3	0.17
VL < 400	57.0	44.0 – 67.1	59.6	46.0 – 70.8	0.44

Table 2

Comparison of summary statistics between participating and non-participating centres

	Excluded		Included		
	Median	IQR	Median	IQR	P
Region					
South	7	24.1	22	75.9	0.35
Central West	3	12.0	22	88.0	
North	3	12.5	21	87.5	
East	3	8.8	31	91.2	
Age (years)	35.6	33.8 – 38.1	36.6	33.9 – 39.3	0.40
CD4 (/mm^3)	372	224 – 465	339	257 – 400	0.55
VL (Log_{10}cp/ml)	2.4	1.7 – 2.9	2.6	1.7 – 3.0	0.57
Enrollment (month/year)	3/99	7/94 – 3/04	1/02	2/97 – 5/06	0.16

Figure 1

Current recommendation for first line cART

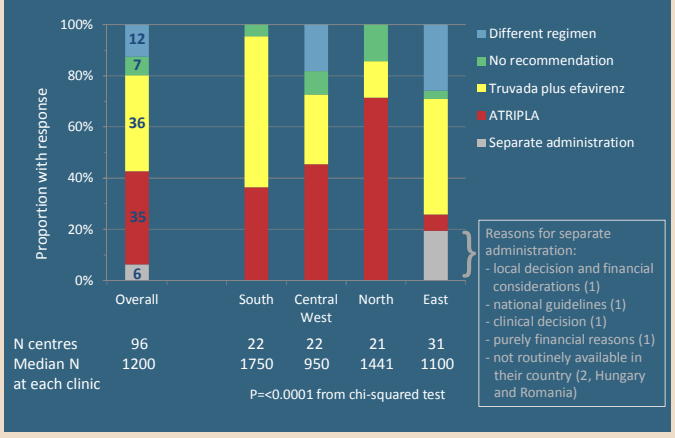
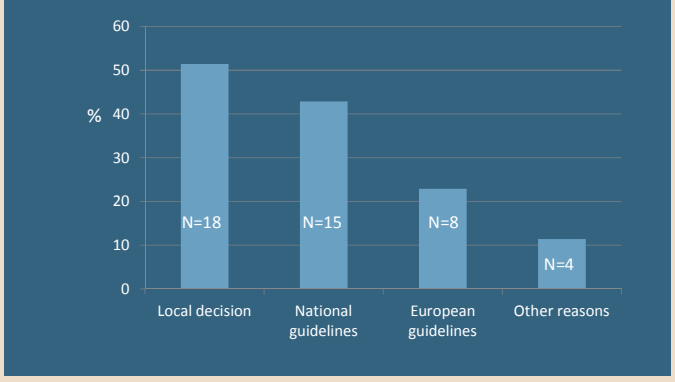


Figure 2

Reasons for using ATRIPLA as initial ART regimen (35 clinics)



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