Oral Communication   Session/Topic: **Antiretroviral therapy: focus on integrase inhibitor**

N.   **Title:**

OC 5   **Patient-Reported Outcomes (PROs) evaluation among HIV-infected (HIV+) patients (pts) starting elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (E/C/F/TDF)**

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Abstract:

PRO is defined as any report of the status of a pt's health condition that comes directly from the pt. Besides the viroimmunological outcomes, PRO measurements are an important tool for long term control of HIV infection, since they represent benefits over provider-reported outcomes in terms of symptoms, quality of life (QoL) and health. To date, the impact on pts' health of E/C/F/TDF has been described in clinical trials but real-life data are lacking. We conducted a longitudinal evaluation of PROs in a cohort of HIV+ pts starting E/C/F/TDF.

All HIV+ pts enrolled in ICONA Network who started E/C/F/TDF, from either ART-naïve or when ART-experienced (exp) pts, over 2015-2017 were included. At the start of E/C/F/TDF (baseline, bl), after 3 and 6 months, pts were asked to complete previously validated self-administered questionnaires, on: QoL (EuroQol-EQ-5D-5L), self-reported adherence (visual analogue scale, VAS 0-100, not including bl evaluation for ART-naïve pts), depression (CES-D-10), health status (VAS 0-100 for general, psychological and physical health). A likert scale on 21 symptoms was also provided. Kruskall Wallis test was used to test the change over time in median values of the scores. Stepwise backward multivariable logistic regression was used to identify independent predictors of having a EQ-5D worse than the ideal score of (11111) at bl, from socio-demographic, clinical features and answers to the other PROs.

We included a total of 277 pts (160 ART-naïve and 117 exp). Main charachteristics of study population are shown in Table 1. Among ART-naïve pts, mean value of each visit questionnaire improved for all items: i) EQ-5D -0.15, -0.11, -0.08 (p=0.003); ii) CES-D-10 7.7, 6.5, 5.7 (p<0.001); iii) physical VAS 62%, 70%, 72% (p=0.001); iv) psychological VAS 60%, 67%, 70% (p=0.001); v) general VAS 61%, 68%, 72% (p<0.001). Among exp pts, only general VAS improved [63%, 70%, 71% (p=0.037)], while the others remained stable: i) EQ-5D -0.16, -0.13, -0.10 (p=0.486); ii) CES-D-10 7.8, 7, 7.1 (p=0.438); iii) physical VAS 63%, 69%, 70% (p=0.057); iv) psychological VAS 63%, 68%, 67% (p=0.322). Treatment adherence was high and stable overtime: for naïve, VAS 96%, 93% (p=0.322); for exp, VAS 95% at each visit (p=0.936). Tables 2a and 2b show factors independently associated with the risk of having a EQ-5D worse than (11111) at bl, separately in the ART-naïve and exp groups.

Our analysis showed that starting E/C/F/TDF led to an improvement in health status particularly in ART-naïve pts, suggesting that use of E/C/F/TDF may have maximum benefit at early stages of the HIV disease and those who have never used ART before. Adherence to E/C/F/TDF was persistently high through the duration of the study. Reporting symptoms related to mental health were associated with a higher risk of lower quality of life, suggesting that implementing PROs evaluation in clinical practice may be key to identify pts in greater need for tailored interventions.

Table 1.

	Main Characteristics on Study Population			
	ART-naive	**ART-switch**	**p-value**	**Total**
	N= 160	N= 117		N= 277
Gender			0.444	
Male	124 (77.5%)	86 (73.5%)		210 (75.8%)
Female	36 (22.5%)	31 (26.5%)		67 (24.2%)
Mode of HIV transmission			0.091	
PWID	11 (7.0%)	12 (10.3%)		23 (8.4%)
MSM	86 (54.4%)	51 (44.0%)		137 (50.0%)
Heterosex	51 (31.9%)	50 (42.7%)		101 (36.5%)
Other/Unknown	10 (6.3%)	3 (2.6%)		13 (4.7%)
Nationality			0.085	
Italian	114 (71.3%)	94 (80.3%)		208 (75.1%)
Foreign/Unknown	46 (28.8%)	23 (19.7%)		69 (24.9%)
Education			0.001	
Elementary	6 (3.8%)	4 (3.4%)		10 (3.6%)
Secondary	25 (15.6%)	11 (9.4%)		36 (13.0%)
College	59 (36.9%)	30 (25.6%)		89 (32.1%)
University	31 (19.4%)	15 (12.8%)		46 (16.6%)
Other/Unknown	39 (24.4%)	57 (48.7%)		96 (34.7%)
CD4 count, cells/mm3			<.001	
Median (IQR)	348 (162, 526)	560 (422, 773)	<.001	404 (200, 581)
350+	70 (50.0%)	38 (84.4%)		108 (58.4%)
201-350	26 (18.6%)	4 (8.9%)		30 (16.2%)
0-200	44 (31.4%)	3 (6.7%)		47 (25.4%)
Period of enrolment			0.002	
Median (IQR)	2016 (2015, 2016)	2015 (2015, 2016)	0.002	2015 (2015, 2016)
2015	67 (41.9%)	72 (61.5%)		139 (50.2%)
2016	91 (56.9%)	42 (35.9%)		133 (48.0%)
2017	2 (1.3%)	3 (2.6%)		5 (1.8%)
Age, years			<.001	
Median (IQR)	38 (30, 47)	44 (38, 50)		41 (34, 48)
HIV-RNA, log10 copies/mL				
Median (IQR)	4.75 (4.09, 5.21)			3.97 (1.59, 5.01)
Time from HIV diagnosis, years			<.001	
Median (IQR)	0 (0, 1)	7 (3, 14)		1 (0, 7)
CD4 count nadir, cells/mm3			0.009	
Median (IQR)	347 (158, 526)	421 (246, 646)		373 (189, 569)

Table 2a.

		OR of EQ-5D worse than (11111)				
	EQ-5D<1	EQ-5D=1	Unadjusted[*] OR (95% CI)	p-value	Adjusted[*] OR (95% CI)	p-value
	N= 86	N= 74				
Nationality						
Italian	54 (62.8%)	60 (81.1%)	1.00	0.012	1.00	0.058
Foreign/Unknown	32 (37.2%)	14 (18.9%)	2.54 (1.23, 5.26)		3.02 (0.96, 9.51)	
CES-D				<.001		0.023
Mean (SD)	9.40 (3.86)	6.08 (3.98)	1.26 (1.14, 1.40)		1.21 (1.03, 1.43)	
Pshycological Wellbeing (VAS)				<.001		<.001
Mean (SD)	50.35 (22.46)	71.76 (18.01)	0.95 (0.93, 0.97)		0.94 (0.91, 0.97)	
Symptoms						
Anxiety				<.001		0.341
No	19 (22.1%)	38 (52.1%)	1.00		1.00	
Yes	67 (77.9%)	35 (47.9%)	3.83 (1.93, 7.60)		0.57 (0.18, 1.81)	
Mental Confusion				<.001		0.029
No	29 (33.7%)	55 (74.3%)	1.00		1.00	
Yes	57 (66.3%)	19 (25.7%)	5.69 (2.86, 11.31)		3.46 (1.13, 10.56)	
Sleeping Problems				0.006		0.013
No	24 (35.3%)	40 (58.8%)	1.00		1.00	
Yes	44 (64.7%)	28 (41.2%)	2.62 (1.31, 5.24)		3.76 (1.32, 10.67)	
Fat Loss				0.202		0.633
No	61 (70.9%)	59 (79.7%)	1.00		1.00	
Yes	25 (29.1%)	15 (20.3%)	1.61 (0.77, 3.36)		0.75 (0.23, 2.42)	
ART Reccomendation (VAS)				0.145		0.075
Mean (SD)	78.40 (24.99)	84.26 (22.35)	0.99 (0.98, 1.00)		1.02 (1.00, 1.05)	

[*]adjusted for all factors included in Table

Table 2b.

		OR of EQ-5D worse than (11111)				
	EQ-5D<1	EQ-5D=1	Unadjusted[*] OR (95% CI)	p-value	Adjusted[*] OR (95% CI)	p-value
	N= 57	N= 60				
Symptoms						
Anxiety				<.001		0.009
No	15 (26.8%)	39 (65.0%)	1.00		1.00	
Yes	41 (73.2%)	21 (35.0%)	5.08 (2.29, 11.24)		3.22 (1.33, 7.77)	
Mental Confusion				<.001		0.007
No	18 (31.6%)	43 (71.7%)	1.00		1.00	
Yes	39 (68.4%)	17 (28.3%)	5.48 (2.48, 12.10)		3.38 (1.40, 8.16)	
Adherence (VAS)						
100%	36 (67.9%)	51 (85.0%)	1.00	0.035	1.00	0.065
0-99%	17 (32.1%)	9 (15.0%)	2.68 (1.07, 6.67)		2.61 (0.94, 7.26)	

[*]adjusted for all factors included in Table