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Oral Communications

From naive to highly treated subjects. Efficacy of cART

N. prog: OC 62

Title: **Virological outcomes of first line regimens in women living with HIV from Icona cohort: comparison with clinical trials data**

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Abstract body
Background: Women living with HIV (WLWH) are under-represented in RCT, and few studies are specifically designed. The aim of this analysis was to verify in a real-life setting the efficacy of newer cART regimens in WLWH and to compare the virological efficacy of regimens for whom WLWH-specific RCT are available (Waves and ARIA).
Methods: All cART naïve WLWH enrolled in Icona from January 2006 starting a ATV/r-, DTG-, EVG/c-, DRV/r or DRV/c -, RAL-, RPV-based regimens regardless of backbone and having at least 1 HIV RNA after 24 weeks from cART initiation were included in the analysis. Primary endpoint was occurrence of treatment failure (TF) (first of two consecutive plasma HIV RNA>200 c/mL after 24 weeks or discontinuation for any reason apart from simplification). Secondary endpoints were: 1) rate of treatment discontinuation or change of cART for any reason; 2) rate of treatment discontinuation or change of cART for toxicity; 3) occurrence of VF (HIV RNA >50 copies/mL at week 48 [Modified FDA Snapshot Algorithm]) for regimens mimicking available WLWH-RCT (EVG/c, DTG, ATV/r).
Incidence rate of single endpoint was calculated dividing the total number of events over the person years at risk. Cox regression analysis was used to estimate the hazard risk (HR) of the outcome according to different cART regimens, after adjusting for AIDS diagnosis, nationality, CD4 cell count, plasma HIV-RNA, HCV-Ab and NRTI backbone.
Results: 1084 WLWH were included (median FU: 1.9 yrs [IQR 0.9-3.2]). 258 WLWH (26%) started ATV/r, 166 (16%) DTG, 115 (11%) EVG/c, 219 (21%) DRV/r or DRV/c, 71 (7%) RAL, 219 (21%) RPV. Study population's characteristics according to third drug are reported in table 1. At multivariable regression, women on ATV/r showed higher risk of TF, after adjusting for main confounders; the only other factor independently associated to a higher risk of TF was AIDS (HR 1.55, 95%CI 1.12-2.16, p=0.009). Hazard risk of different outcomes for each third drug of the regimen are reported in figure 1. On the subgroup of 404 WLWH starting regimens mimicking available WLWH-RCT, the proportions of HIV RNA<50 using FDA snapshot were 50.7% in ATV/r (vs 81% in Waves and 71% in ARIA), 79.2% in EVG/c (vs 87% in Waves) and 74.7% in DTG (vs 82% in ARIA).
Conclusions: In a real world cohort of WLWH starting newer cART regimens, treatment failure is still an issue, particularly in women using PI/r based regimens. Results from clinical practice are not in agreement with those seen in randomized trials. These data suggest the need for focused intervention on adherence and vulnerability support in cART treated HIV infected women.

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Table 1. General characteristics of study population

	ATV/b N=258	DGV N=166	EVG N=115	DRV/b N=219	RAL N=71	RPV N=219	p
Age, median (IQR)	36 (30-44)	45 (33-55)	39 (32-50)	39 (31-47)	44 (32-52)	38 (29-49)	<0.001
Mode of HIV infection, n(%)							
heterosexual	215 (83.3%)	139 (83.8%)	99 (86.1%)	186 (84.9%)	62 (87.3%)	184 (84.0%)	0.297
IVDU	27 (10.5%)	11 (6.6%)	10 (8.7%)	21 (9.6%)	1 (1.4%)	21 (9.6%)	
other/unknown	16 (6.2%)	16 (9.6%)	6 (5.2%)	12 (5.5%)	8 (11.3%)	14 (6.4%)	
Nationality							
Italian	132 (51.2%)	87 (52.4%)	59 (51.3%)	124 (56.6%)	40 (56.3%)	134 (61.2%)	<0.001
not Italian	125 (48.4%)	58 (34.9%)	39 (33.9%)	88 (40.2%)	24 (33.8%)	68 (31.0%)	
missing	1 (0.4%)	21 (12.7%)	17 (14.8%)	7 (3.2%)	7 (9.9%)	17 (7.8%)	
AIDS diagnosis, n(%)	26 (10.1%)	25 (15.1%)	16 (13.9%)	45 (20.6%)	9 (12.7%)	7 (3.2%)	<0.001
HCVAb, n(%)							
negative	198 (76.7%)	128 (77.1%)	91 (79.2%)	174 (79.4%)	59 (83.0%)	172 (78.5%)	0.153
positive	35 (13.6%)	9 (5.4%)	9 (7.8%)	21 (9.6%)	6 (8.5%)	22 (10.1%)	
missing	25 (9.7%)	29 (17.5%)	15 (13.0%)	24 (11.0%)	6 (8.5%)	25 (11.4%)	
HBsAg, n(%)							
negative	224 (86.8%)	131 (78.9%)	92 (80.0%)	187 (85.4%)	63 (88.7%)	182 (83.1%)	0.386
positive	9 (3.5%)	5 (3.0%)	6 (5.2%)	5 (2.3%)	2 (2.8%)	9 (4.1%)	
missing	25 (9.7%)	30 (18.1%)	17 (14.8%)	27 (12.3%)	6 (8.5%)	28 (12.8%)	
CD4, n(%)							
0-200	80 (31.0%)	64 (38.5%)	43 (37.4%)	94 (42.9%)	26 (36.6%)	17 (7.8%)	<0.001
201-350	85 (33.0%)	30 (18.1%)	24 (20.9%)	59 (26.9%)	14 (19.7%)	41 (18.7%)	
351+	88 (34.1%)	66 (39.8%)	46 (40.0%)	60 (27.4%)	29 (40.9%)	158 (72.1%)	
missing	5 (1.9%)	6 (3.6%)	2 (1.7%)	6 (2.8%)	2 (2.8%)	3 (1.4%)	
HIVRNA, n(%)							
<100.000	156 (60.5%)	103 (62.0%)	74 (64.3%)	107 (48.9%)	41 (57.8%)	209 (95.4%)	<0.001
>=100.000	96 (37.2%)	57 (34.4%)	40 (34.8%)	103 (47.0%)	27 (38.0%)	5 (2.3%)	
missing	6 (2.3%)	6 (3.6%)	1 (0.9%)	9 (4.1%)	3 (4.2%)	5 (2.3%)	
NRTI backbone							
TDF/FTC	219 (84.9%)	64 (38.6%)	95 (82.6%)	176 (80.4%)	58 (81.7%)	202 (92.3%)	<0.001
TAF/FTC	0	5 (3.0%)	20 (17.4%)	3 (1.4%)	1 (1.4%)	6 (2.7%)	
ABC/3TC	39 (15.1%)	97 (58.4%)	0	40 (18.2%)	12 (16.9%)	11 (5.0%)	
Causes of discontinuation							
failure	14 (7.6%)	4 (9.8%)	2 (14.3%)	4 (3.2%)	0	5 (14.3%)	<0.001
toxicity	64 (35.0%)	9 (22.0%)	7 (50.0%)	24 (19.4%)	3 (8.8%)	12 (34.2%)	
semplification	32 (17.5%)	4 (9.8%)	0	37 (29.8%)	15 (44.1%)	2 (5.7%)	
patient's decision	12 (6.6%)	3 (7.3%)	1 (7.1%)	4 (3.2%)	4 (11.8%)	1 (2.9%)	
other	28 (15.3%)	8 (19.5%)	2 (14.3%)	17 (13.7%)	8 (23.5%)	11 (31.5%)	
missing	33 (18.0%)	13 (31.6%)	2 (14.3%)	38 (30.7%)	4 (11.8%)	4 (11.4%)	

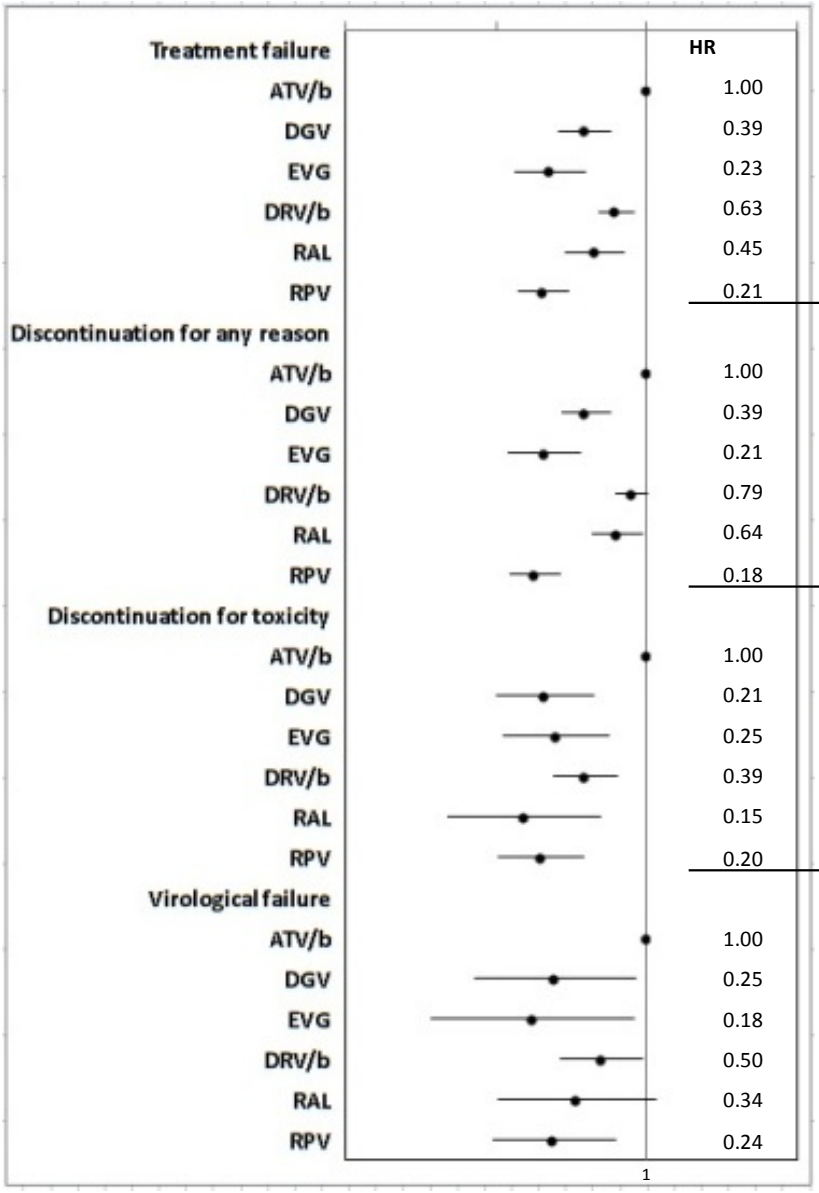

Figure 1. Adjusted hazard ratio according to third drug of the regimen from 4 separate Cox models.