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EFFICACY AND SAFETY OF LONG-ACTING INTRAMUSCULAR CABOTEGRAVIR AND RILPIVIRINE IN WOMEN: A SUBSTUDY OF THE RELATIVITY COHORT

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BACKGROUND

Intramuscular cabotegravir (CAB) and rilpivirine (RPV), administered every two months, can be used as a switching strategy in virologically suppressed people who live with HIV (PLWH). Women are underrepresented in clinical trials (1-3). Real-life data regarding efficacy and safety in this population are scarce. The aim of this substudy is to determine efficacy, tolerability and safety of this strategy when used to treat women who live with HIV (WLWH) in real life, out of a clinical trial context.

MATERIAL AND METHODS

The RELATIVITY cohort is a multicentre, non-controlled, ambispective study, which evaluates virologically supressed PLWH who switched to long-acting CAB+RPV from 37 hospitals in Spain (RELATIVITY Cohort). Patients were compared based on gender. Quantitative variables were contrasted using T-Student and U-Mann-Whitney tests; categorical variables were compared using Chi-Square and Fisher's Exact tests.

RESULTS

Of 1358 HIV-positive patients on CAB+RPV, 201 (14.8%) were women. Baseline characteristics compared to men are depicted in table 1.

Time on ART [13.0 (8.0, 20.0) vs. 9.0 (5.0, 13.5) years; p-value < 0.001], and length of undetectability before switching to CAB+RPV [96.0 (45.0, 147.0) months vs. 80.0 (40.0, 124.0) months; p-value = 0.058] were longer in women. Additionally, rate of virological failure (VF) prior to switching was higher compared to men (11.7% vs. 3.5%; p-value < 0.001).

	Women (N=201)	Men (N=1157)	p-value
Demographic data			
Age (years), median [IQR]	51.0 [42.0, 58.0]	44.0 [37.0, 53.4]	**<0.001**
Body Mass Index (Kg/m2), median [IQR]	23.6 [20.7, 28.0]	24.8 [22.4, 27.2]	0,226
Country of origin, n (%) **Spain**	129 (62.5)	822 (71.9)	0,067
Migrants	69 (34.8)	322 (28.1)	0,072
Latin America	37 (18.4)	262 (22.6)	0,213
Africa	12 (6.0)	13 (1.1)	**<0.001**
Transmission route			
Transmission route, n (%) **GBMSM**	0 (0.0)	814 (75.2)	-
HTX	133 (72.7)	108 (10.0)	**<0.001**
PID	23 (12.6)	68 (6.3)	**<0.001**
Comorbidities			
Comorbidities, n (%) **Hypertension**	28 (13.9)	104 (9.0)	**0,04**
Peripheral vascular disease	4 (2.0)	5 (0.4)	**0,041**
Osteopenia/osteoporosis	29 (14.4)	51 (4.4)	**<0.001**
Psychiatric disorders	25 (12.4)	94 (8.1)	**0,063**
HIV Data			
CD4 nadir (cells/mm3), median [IQR]	249.5 [115.8, 380.8]	350.0 [210.0, 500.0]	**<0.001**
CD4/CD8, median [IQR] **Baseline**	1.1 [0.7, 1.5]	0.9 [0.7, 1.3]	**0,001**
CD4/CD8, median [IQR] **End of period**	1.1 [0.8, 1.6]	0.9 [0.7, 1.3]	**<0.001**
AIDS, n (%)	35 (19.2)	128 (11.7)	**0,007**

Table 1. Comparative baseline analysis of women and men living with HIV who switched to long acting CAB+RPV in the Relativity cohort in Spain. n(%) number (percentage)
GBMSM: gays, bisexuals and other men who have sex with men; HTX: heterosexual; IQR: interquartile range; PID: people who inject drugs

	Women (N=201)	Men (N=1157)	p-value
Basal Genotype			
Basal genotype n(%) type B	41 (71.9)	270 (81.1)	0,152
type A1/A2	6 (10.5)	15 (4.5)	0,102
type F/CRF	5 (8.8)	16 (4.8)	0,211
other	5 (8.8)	32 (9.6)	1
Present mutations			
Wild type without mutations, n (%)	55 (27.4)	394 (34.1)	0,075
Mutations in IT analog resistance, n (%)	7 (3.5)	55 (4.8)	0,539
184V	4 (2.0)	9 (0.8)	0,216
Other	8 (4.0)	56 (4.8)	0,726
Mutations in IT resistance to non-analogs, n (%)	9 (4.5)	38 (3.3)	0,519
K103N	5 (2.5)	13 (1.1)	0,22
E138A	0 (0.0)	3 (0.3)	1
Other	9 (4.5)	28 (2.4)	0,156
Mutations in integrase, n (%)	0 (0.0)	5 (0.4)	0,762
L74M/I/F	0 (0.0)	1 (0.1)	1
T97A	0 (0.0)	2 (0.2)	1
Others,	2 (1.0)	5 (0.4)	0,621

Table 2: basal genotype

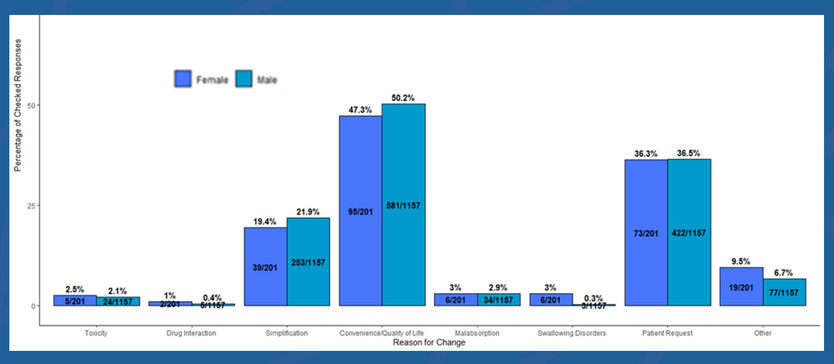

Figure 1: Reasons for switching to CAB+RPV LAI

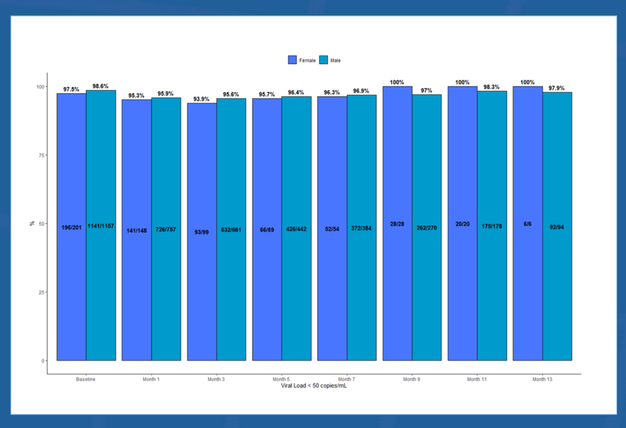

Figure 2: percentage of women and men living with HIV with VL<50 cp/ml during follow-up

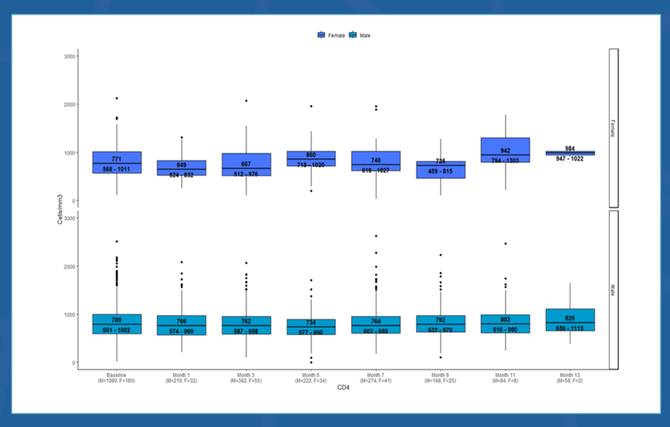

Figure 3: Evolution CD4 (cel/mcl) in men and women during the follow-up

Current follow-up period was shorter for women (7.2 [4.6, 9.6] months vs. 7.7 [5.1, 11.1] months; p-value = 0.051) and discontinuation rate (8.5% vs. 4.1%; p-value = 0.014) and rate of local adverse injection reactions were higher compared to men (3.5% vs. 1.1%; p value < 0.001). There were no differences in systemic side effects or VF development compared to men.

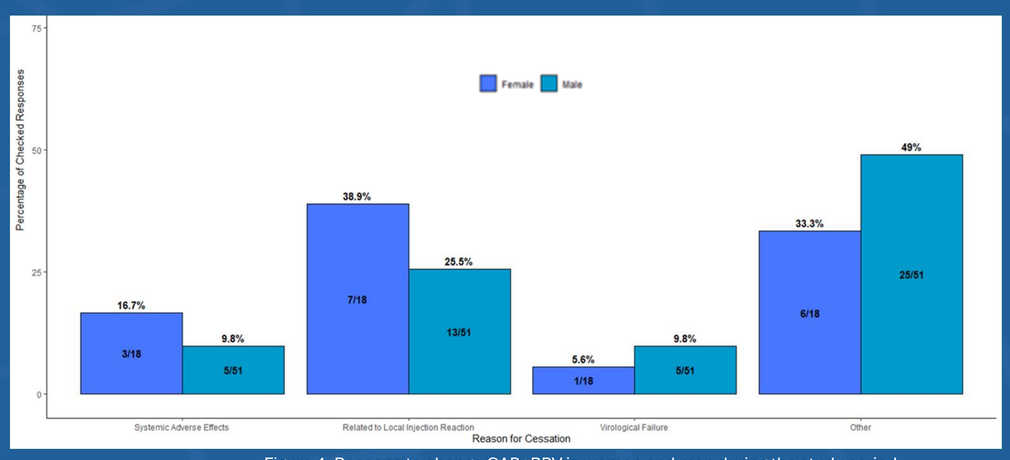

Figure 4: Reasons to change CAB+RPV in women and men during the study period

CONCLUSIONS

Although WLWH who switched to CAB+RPV had a worse profile regarding comorbidities and prevalence of AIDS, they do not seem to have a higher risk of VF compared to men, but discontinuation rate might be higher. A longer follow up is necessary to understand outcomes in this underrepresented and critical subpopulation of PLHIV treated with CAB+RPV.

References:
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RELATIVITY