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Long-Acting Cabotegravir-Rilpivirine in Real-Life: Sex-based Characteristics, PROs and Effectiveness

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BACKGROUND

Long-acting intramuscular cabotegravir plus rilpivirine (LA-CAB/RPV) is approved as a switch strategy for HIV treatment and is available in Spain since January 2023, administered Q2M. We aim to analyse effectiveness, tolerability and acceptance, including patient-reported outcomes (PROs), in a real-word scenario.

This sub-study focuses on sex-based characteristics, PROs and effectiveness in people with HIV switching to LA-CAB/RPV in Hospital Clínic of Barcelona, Spain.

METHODS

People starting LA-CAB/RPV were invited to participate in an observational, prospective study approved by the local Ethical Committee. Clinical information was routinely collected, PROs were self-administered through electronic questionnaires. Participant characteristics, treatment effectiveness [HIV-RNA <50 copies/mL by on treatment (OT), modified intention-to-treat (mITT), and intention to-treat (ITT)], and PROs were analyzed focusing on sex-at-birth based differences.

Proportionally less women than men switched to LA-CAB/RPV. Baseline characteristics could partially explain this difference, although we cannot exclude prescription biases or other barriers.

RESULTS

From 2Feb2023 to 2Jul2024, 611 participants of 6477 in active follow up (9%) started LA-CAB/RPV, and 587 accepted to participate, 547 (93%) men and 40 (7%) women at birth, compared to 4862 (84%) men and 909 (16%) women that continued with other ART ($p < 0.001$). Women were older, had longer time since HIV diagnosis, longer time on ART, had higher last-CD4 count but lower nadir-CD4, and were more frequently Spanish-born than men both in LA-CAB/RPV group (Tables) and in general cohort. Women had more previous virological failures but no differences in number of historical mutations.

Effectiveness by OT, mITT and ITT in the 402 participants on LA-CAB/RPV (29 women and 373 men) who reached week 28 of follow up was 100%, 93%, and 90% in women and 97%, 92%, and 90% in men without significant differences. Injections were administered on time in 96% (men) and 97% (women). There were 5 (1%) confirmed virological failures (defined as two consecutive VL >50 cp/mL), all in men, and all but one with low level viremia (VL <200 cp/mL). Two of them achieved VL<50cp/mL without changing ART and 3 did so after switching to oral ART.

RESULTS (continued)

No significant differences in reason for switching to LA-CAB/RPV nor in treatment acceptance (ACCEPT questionnaire) were observed between men and women. No differences in life satisfaction and HIV medication relationship domains of baseline HIV/AIDS-Targeted Quality of Life (HAT-QoL) questionnaire were noted, nonetheless **women expressed more frequent disclosure issues** than men ($p <0.001$). No relevant differences were observed in injection site reactions nor in Perception of Injection questionnaire.

CONCLUSIONS

Compared to our general cohort, proportionally less women than men switched to LA-CAB/RPV. Baseline characteristics could partially explain this difference, although we cannot exclude prescription biases or other barriers.

No differences in effectiveness and adherence were observed. Women expressed more frequent disclosure issues than men.

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Table 1. Baseline characteristics of participants by sex at birth

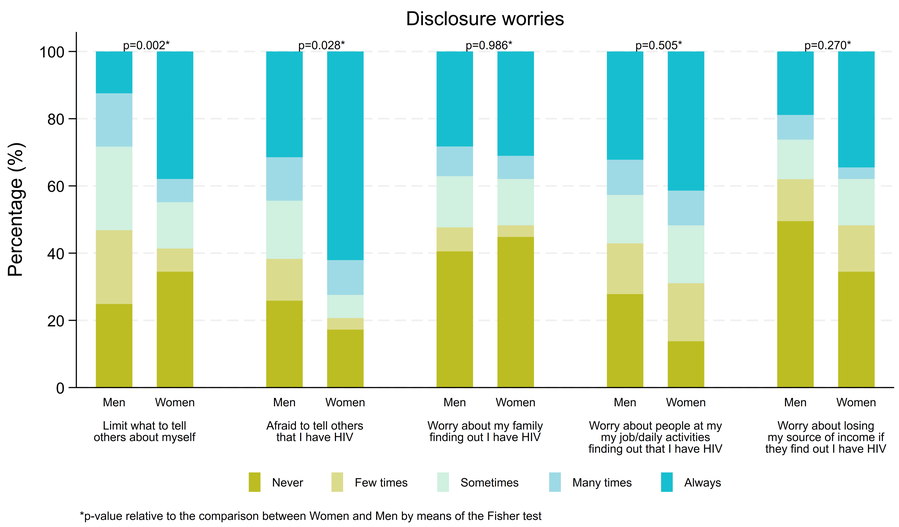
	MEN (n 547)	WOMEN (n 40)	**TOTAL (n 587)**	p
Age, median (IQR)	43 (36 – 52)	54 (46 –59)	**44 (36 – 53)**	< 0.001
Gender, male, n (%)	543 (99%)	0 (0%)	**543 (93%)**	< 0.001
Gender, female, n (%)	4 (1%)	40 (100%)	**44 (7%)**	
Origin, n (%)				
Spain	230 (42%)	29 (72%)	**259 (44%)**	< 0.001
Other European countries	67 (12%)	2 (5%)	**69 (12%)**	
Latin America	211 (39%)	6 (15%)	**217 (37%)**	
Other	39 (7%)	3 (8%)	**42 (7%)**	
Mode of HIV acquisition, n (%)				
MSM	485 (89%)	0 (0%)	**487 (84%)**	< 0.001
Heterosexual	28 (5%)	27 (68%)	**55 (9%)**	
IDU	21 (4%)	9 (22%)	**30 (5%)**	
BMI ≥ 30 kg/m², n (%)	38 (9%)	8 (30%)	**46 (10%)**	0.003
Years since diagnostic, median (IQR)	11 (7 - 17)	23 (15 – 31)	**12 (8 – 18)**	< 0.001
Undetectable VL (<50cp/mL), n (%)	538 (99%)	38 (95%)	**576 (99%)**	0.077
Years in ART, median (IQR)	8 (3 – 13)	16 (10 – 25)	8 (3 – 14)	< 0.001
Time with VL < 50cp/mL, median years (IQR)	7 (2 – 12)	12 (6 – 18)	**7 (2 – 12)**	< 0.001
Last CD4, cells/μL, median (IQR)	693 (554 - 899)	848 (666 - 1061)	**701 (555 - 917)**	0.041
Nadir CD4, cells/μL, median (IQR)	370 (244 - 503)	247 (153 - 440)	**363 (233 - 499)**	0.010

IQR: interquartile range; MSM: men who have sex with men; IDU: injection drug user; VL: viral load; BMI: body mass index.

Table 2. Baseline characteristics of participants by sex at birth

	MEN (n 547)	WOMEN (n 40)	**TOTAL (n 587)**	p
Historic genotype available, n (%)	279 (51%)	17 (42%)	296 (50%)	0.299
Subtype A	5 (3%)	0 (0%)	5 (3%)	1.000
Subtype B	153 (87%)	10 (100%)	163 (88%)	
Any mutation present	39 (14%)	2 (12%)	41 (14%)	1.000
NNRTI mutations*	20 (7%)	1 (6%)	21 (7%)	1.000
Number of previous ARTs, median (IQR)	3 (1 – 5)	6 (3 – 9)	3 (1 – 5)	< 0.001
Previous ART				0.286
II based	367 (69%)	24 (62%)	391 (69%)	
PI based	34 (6%)	5 (13%)	39 (7%)	
NNRTI based	61 (11%)	3 (8%)	64 (11%)	
Other combinations	69 (13%)	7 (18%)	7 (18%)	
Previous virological failure	57 (10%)	16 (40%)	73 (12%)	< 0.001
Oral lead-in phase (OLI)	18 (3%)	2 (5%)	20 (3%)	0.639

IQR: interquartile range; NNRTI: non-nucleoside reverse transcriptase inhibitors; ART: antiretroviral therapy; II: integrase inhibitors; PI: protease inhibitors
*NNRTI mutations (100I,103N,106A/I,108I,138A,179D,188L,236L): 20 (7%) men vs. 1 (6%) woman, p 1.000



*p-value relative to the comparison between Women and Men by means of the Fisher test