P075

Real-Life Effectiveness, Safety, and Acceptance of Long-Acting Cabotegravir-Rilpivirine: Results from a large single center cohort

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Background

Long-acting intramuscular cabotegravir plus rilpivirine (LA-CAB/RPV) is available in Spain since January 2023. We aim to analyze effectiveness, tolerability and acceptance, including patient-reported outcomes (PROs), in a real-word scenario in the first year of follow-up.

Material and Methods

People starting LA-CAB/RPV in Hospital Clínic Barcelona were invited to participate in an observational, prospective single-center study approved by the local Ethical Committee. Clinical information was routinely collected, and PROs were self-administered though electronic questionnaires. We evaluated effectiveness, defined as HIV-RNA <50 copies/mL, [on treatment (OT), modified intention-to-treat (mITT), and intention to-treat (ITT)], tolerability, and safety in patients who reached week 28 and week 52.

Results

From 2Feb2023 to 2May2024, 554 people with HIV started LA-CAB/RPV (9% of total cohort), and 533 accepted to participate, 92% male. Of these, 318 (60%) and 99 (19%) participants reached week 28 and week 52 of follow up, respectively. Baseline characteristics of the 318 participants who reached w28 are shown in Table1 and Table 2. Eight (3%) participants underwent an oral lead-in (OLI) phase, 96% of injections were administered within the window period, and 2% of administrations were delayed (Figure 1)

Figure 1. Adherence to injection visits

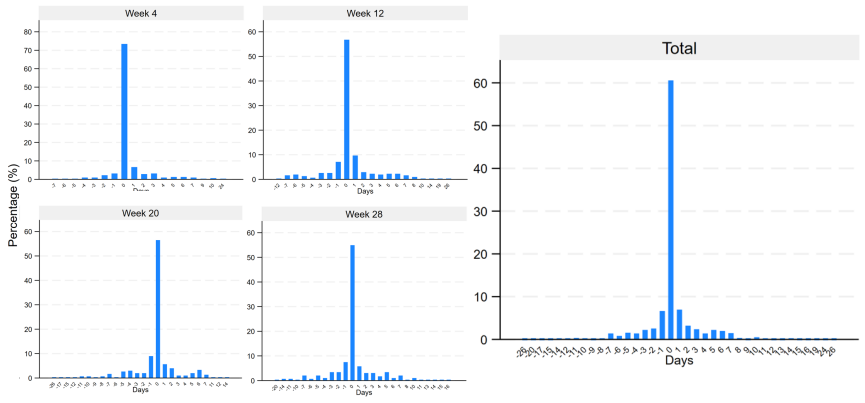


Table 1. Baseline characteristics of participants who reach week 28 (n 318)

Age, median (IQR)	45 (37 - 54)
Sex, male, n (%)	293 (92%)
Origin, n (%)	
Spanish	142 (45%)
Other European countries	43 (14%)
Latin America	104 (33%)
Other	29 (9%)
Mode of HIV acquisition, n (%)	
MSM	258 (82%)
Heterosexual	29 (9%)
IDU	21 (7%)
BMI >30 kg/m^2, n (%)	28 (11%)
Years since diagnostic, median (IQR)	12 (8 - 19)
Undetectable VL (<50cp/mL), n (%)	313 (98%)
Time with VL < 50cp/mL, median years (IQR)	8 (4 - 13)
Last CD4, cells/μL, median (IQR)	724 (563 - 938)
Nadir CD4, cells/μL, median (IQR)	335 (214 - 452)
Historic genotype available, n (%)	166 (52%)
Any non polymorphic mutation present	33 (10%)
Subtype A	4 (1%)
Years in ART, median (IQR)	9 (4 - 15)

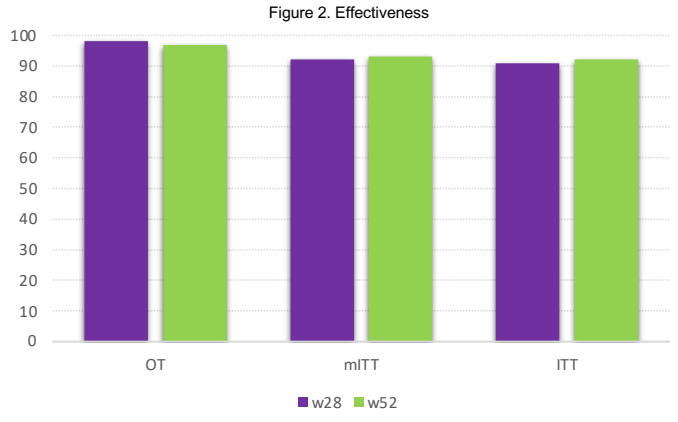
IQR: interquartile range; MSM: men who have sex with men; IDU: injection drug user; VL: viral load.

Table 2. Previous ART

Number of previous ART	1	60 (19%)
	2-5	183 (58%)
	6-10	59 (19%)
	>10	9 (3%)
ART combination	PI based	24 (8%)
	DRVc/FTC/TAF	19 (6%)
	NNRTI based	41 (13%)
	RIL/FTC/TAF	18 (6%)
	EFV/FTC/TDF	6 (2%)
	DOR+FTC/TAF	6 (2%)
	INSTI based	206 (66%)
	BIC/FTC/TAF	90 (29%)
	DTG/3TC	64 (21%)
	EVG/FTC/TAF	22 (7%)
	Other combinations	40 (13%)
	DTG/RPV	35 (11%)

By OT, mITT and ITT, effectiveness was 98%, 92%, and 91% at W28 and 97%, 93%, and 92% at W52 (Figure 2). There were 4 (1%) confirmed virological failures (defined as two consecutive VL >50 cp/mL) all with low level viremia (VL <200 cp/mL), 2 achieved VL<50cp/mL without changing ART and 2 did so after switching to oral ART. See more details on virological failures on poster P080.

Figure 2. Effectiveness



By week 28, 21 (7%) participants discontinued: 2 (10%) virological failure, 7 (33%) potential treatment related adverse events (TRAEs), 7 (33%) patient preference, 2 (10%) medical decision, and 3 (14%) changed location. From w28 to w52 one additional participant discontinued due to medical decision.

Pain score and ISR improved during follow up (Figures 3 and 4). Besides injection site reactions (ISR), 12 (4%) participants reported TRAE by w28, all grade 1-2. Treatment acceptance (ACCEPT questionnaire), as well as acceptance of ISR and pain significantly improved during follow up (Figure5 y 6). At week 28, 87% of participants considered injection site reactions to be very or totally acceptable (p 0.001).

Figure 3. Pain score (Visual Analogue Scale)

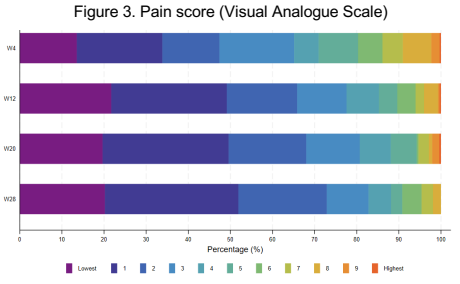


Figure 4. Perception of Injection (PIN)

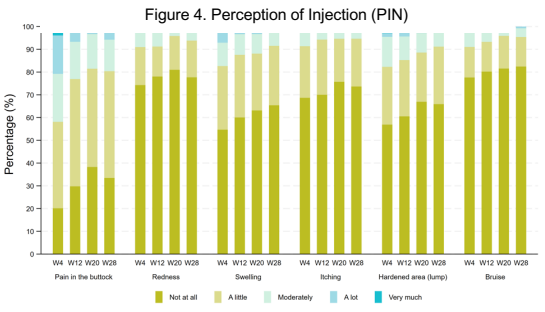


Figure 5. Treatment acceptance (ACCEPT questionnaire)

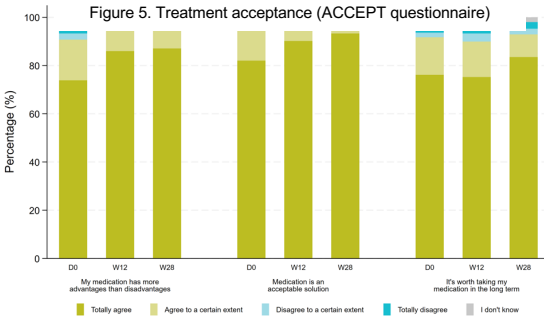
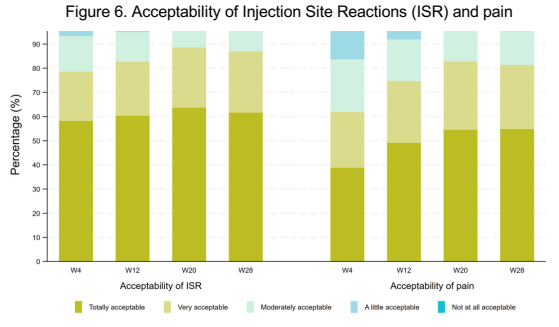


Figure 6. Acceptability of Injection Site Reactions (ISR) and pain



Conclusions

LA-CAB/RPV showed high effectiveness and tolerability in a real-life setting. Adherence to the injection visits was high and acceptance of injections site reactions improved during follow up. Ongoing additional analysis will aid to understand the impact on quality of life of people on CAB/RPV treatment.