

ORAL COMMUNICATION

The long-acting ART landscape in Italy

OC 46 Effectiveness and patient reported outcomes (PROs) of long-acting ART with cabotegravir/rilpivirine: the Long-Icona study

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ABSTRACT

Background: Cabotegravir (CAB) + Rilpivirine (RPV) Long Acting (LA) have been effective and tolerable in phase 3 studies. However, real-life data on the effectiveness of CAB+RPV LA and the correlation with patient reported outcomes (PROs) are scarce.

Material and Methods: People with HIV (PWH) enrolled in the ICONA cohort who agreed to participate in the prospective observational Long-Icona study initiating LA with CAB/RPV while on a stable antiretroviral therapy (ART) and virologically suppressed were included. Time to treatment discontinuation (TD), to TD for toxicity/intolerance/PWH's choice and to virological failure (VF, 2 viral loads [VLs]>50 cp/ml or 1 VL>1,000 cp/mL followed by ART-change) were estimated using the Kaplan-Meier curves. The following PROs were evaluated: HIVTSQs and HIVTSQc, HIV HIVDQoL, HIV-Stigma scale, PHQ-9 and PIN (PROs description, interpretation and timepoints in Table 1). Linear mixed models with random intercept and slope per subject were used to evaluate the mean score in the different questionnaires/domains at each timepoint. The association between the domain "Acceptance of Injecting Site Reactions" (ISR) of PIN (injection 1) and the mean HIVTSQc score (injection 2) with TD due to intolerance/toxicity/PWH choice was evaluated using Cox regression models adjusted for age, sex and mode of HIV transmission.

Results: Overall, 226 PWH switching to CAB/RPV LA with ≥1 follow-up were included: 11.9% were female, median age 45 years (interquartile range, IQR, 37-55), 88.5% Italian natives, median CD4 at BL 743 cells/mm³ (IQR 603-925). An oral lead-in was used in 24.8% of cases.

The 1-year estimated cumulative probability of TD for any cause was 11.6% (95% confidence interval, CI, 7.8-17.0%). Reasons for TD were toxicity/intolerance (7.1%, injection site reactions 3.1%), PWH's choice (1.3%), VF (1.3%) and pregnancy (0.4%). The 1-year cumulative probability of TD for toxicity/intolerance/PWH's choice was 9.7% (95%CI 6.2-15.0) while for VF was 1.6% (95% CI 0.5-4.9%).

At 1 year, improvements in 3/4 domains of HIV-Stigma scale, in HIVTSQs and in generic quality of life item of HIVDQoL were observed. Instead, no significant changes were detected in PHQ9. Acceptance of ISR domain in the PIN questionnaire significantly improved after 1 year (Figure).

Moreover, lower acceptance of ISR using the domain of PIN questionnaire at injection1 (per 1 point higher: adjusted hazard rate, aHR 1.76, 95% CI 1.29-2.41, p<0.001) and lower treatment satisfaction at injection2 (per 1 point mean HIVTSQc score lower: aHR 3.18, 95% CI 1.73-5.85, p<0.001) significantly correlated with treatment discontinuation due to toxicity/intolerance/PWH's choice.

Conclusions: This analysis shows good short-term effectiveness of CAB-RPV, with a low rate of virological failure but a 11.6% probability of TD at 1 year, mainly due to toxicity/intolerance. Small improvements were observed in stigma-related PROs, treatment satisfaction and overall quality of life.

Table 1: Description, domains, score range, timepoints and interpretation of each PRO

PRO	Description	Domains	Score Range	Timepoints	Interpretation
HSS (HIV-Stigma Scale 12-items)	Measurement of enacted, anticipated and internalised stigma in people living with HIV	4 domains: personalized stigma, negative self-image, disclosure concerns, concerns with public attitude	4-12 per domain	Inj1, Inj4, Inj7	↑ HSS score= ↑ stigma
PIN (Perception of Injection)	Assessment of PWH experience with the injections of CAB/RPV: injecting site reactions (ISR), anxiety, sleep problems, mobility	5-individual items+4 domains: Acceptance of ISR, Bother from ISR, Leg movement, Sleep	1-5 per domain	Inj1, Inj2, Inj3, Inj4, Inj5, Inj6, Inj7 (one week after)	↑ PIN score= ↓ perception of injection
PHQ-9 (Patient Health Questionnaire-9)	Assessment of the degree of depression severity	9 items contributing to the PHQ-9 score	Overall 0-25; >10 pt for severe depression	Inj1, Inj4, Inj7	↑ PHQ-9 score= ↑ depression
HIVTSQs (HIV Treatment Satisfaction Questionnaire Status)	Measurement of treatment satisfaction with the used ART	12 items, first 11 contributing to the score	Overall 0-66	Inj1, Inj3, Inj4, Inj5, Inj6, Inj7	↑ HIVTSQs score= ↑ satisfaction with the treatment
HIVTSQc (HIV Treatment Satisfaction Questionnaire Change)	Measurement of treatment satisfaction with the current ART compared to previous one	12 items contributing to the score	Overall -3/+3	Inj2	↑ HIVTSQc score= ↑ satisfaction with the ACTUAL treatment compared to previous one
HIVDQoL (HIV-dependent Quality of Life)	Measurment QoL and the impact on QoL in people living with HIV	26 domain specific items (not analyzed)+ 2 general items: Generic QoL and HIV-dependent QoL	Generic QoL:-3/+3 HIV-dependent QoL: -3/+1	Inj1, Inj4, Inj7	↑ scores= ↑ QoL



