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Tolerability after the first injection of long-acting cabotegravir plus rilpivirine and baseline satisfaction with previous oral antiretroviral therapy in virologically suppressed people with HIV aged ≥60 years

Baseline oral treatment satisfaction and early patient-reported acceptability in the LOVER60 trial

Salvador Valero Cifuentes[1,2,3]; Helena Albendín Iglesias[2,4]; Francisco Vera Méndez[2,5]; Joaquín Bravo Urbieta[2,3,6]; Sergio Padilla[7,8]; Sergio Reus[9]; Concepción Gil Anguita[10]; Raquel Garijo[11]; Antonia Alcaraz Garcia[1,2,3]; Antonia Castillo Navarro[2,4]; Onofre Martínez Madrid[2,5]; Isabel Carpena Martínez[2,6]; Javier Garcia Abellan[7,8]; Livia Giner Oncina[9]; Isabel Ribas Mengual[10]; Angeles Muñoz Perez[1,2,3]; Maria Angeles Fernandez Lopez[2,4]; Lorena Martinez[2,5]; Maria Dolores Hernandez Lorente[1,2,3]; Paula Mascarell[7,8]; Jimena Teran[9]; Cristina Tomas Jimenez[1,2,3]; Carlos Galera Peñaranda[2,4]; Rosa Blazquez Garrido[2,6]; Esperanza Merino[9]; Enrique Bernal Morell[1,2,3]; and LOVER60 Group.

[1] Hospital General Universitario Reina Sofía, Murcia · [2] IMIB Pascual Parrilla, Murcia · [3] Universidad de Murcia, Murcia · [4] Hospital Clínico Universitario Virgen de la Arrixaca, Murcia · [5] Hospital General Universitario Santa Lucía, Cartagena · [6] Hospital General Universitario Morales Meseguer, Murcia · [7] Hospital General Universitario de Elche, Elx · [8] CIBERINFEC, ISCIII, Madrid · [9] Hospital General Universitario Dr. Balmis / ISABIAL, Alacant · [10] Hospital General Universitario Marina Baixa, Vila Joiosa · [11] ViiV Healthcare, Madrid

CLINICAL QUESTION

Among virologically suppressed PWHIV aged ≥60 years who switched to long-acting injectable cabotegravir plus rilpivirine (LAI CAB+RPV), what was their baseline satisfaction with previous oral ART, and how tolerable and acceptable was the first injection?

84.2%

would definitely choose injectable treatment outside the clinical trial after the first injection

KEY FINDING

Early patient-reported acceptability was high, although 40.0% of participants experienced at least one injection site reaction.

High baseline treatment satisfaction, predominantly mild injection site reactions and infrequent treatment discontinuation.

Findings on injectable treatment are limited to outcomes after the first injection.

WHY THIS MATTERS

Older PWHIV have been underrepresented in pivotal trials of LAI CAB+RPV, and evidence specifically concerning those aged ≥60 years remains limited. Early tolerability and patient experience are important considerations when implementing injectable therapy in clinical practice.

OBJECTIVE

To describe the baseline clinical profile, previous ART and satisfaction with oral treatment, and to assess early tolerability and patient-reported acceptability after the first injection of LAI CAB+RPV.

METHODS

Prospective · open-label · single-arm · multicenter phase IV study · 24-month treatment period · Spain

1. PWHIV aged ≥60 years
2. Virologically suppressed
3. Switch oral ART to LAI CAB+RPV
4. Baseline HIVTSQs: satisfaction with previous oral ART (score: 0-60)
5. **injection site reactions and PIN assessment after the first LAI CAB+RPV injection**

ANALYSIS

Descriptive analysis of baseline and first-injection outcomes. Continuous variables were summarised as mean ± standard deviation, and categorical variables as frequencies and percentages.

HIVTSQs assessed satisfaction with the previous oral ART regimen at baseline; the PIN questionnaire assessed acceptability of LAI CAB+RPV after the first injection.

HIGH PATIENT-REPORTED ACCEPTABILITY OF THE INJECTABLE REGIMEN

PIN assessment of injectable-treatment acceptability after the first injection, % of participants (N=120)



STUDY AT A GLANCE

120 participants	**65.7 ± 5.3** mean age, years
77.5% male sex	**21.1** mean years since HIV diagnosis

INJECTION SITE REACTIONS WERE COMMON BUT PREDOMINANTLY MILD

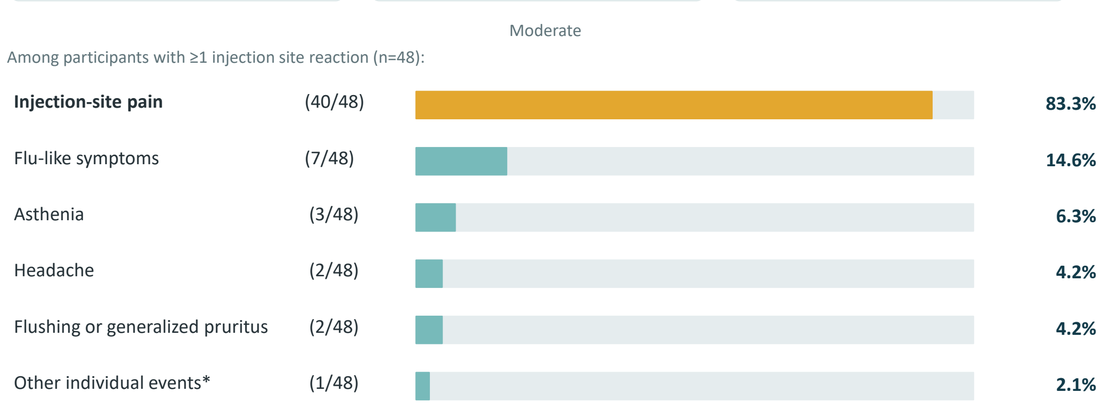
Early tolerability following the first injection

40.0% (48/120) — **experienced ≥1 injection site reaction**

Moderate **16.7%** (8/48); Severe **4.2%** (2/48) — **of participants with injection site reactions experienced these events**

4.2% (5/120) — **permanently discontinued treatment because of an AE**

Among participants with ≥1 injection site reaction (n=48):



*Insomnia, rhinoconjunctival syndrome, a hepatic AE and suicidal ideation were each reported in one participant (2.1% of those with injection site reactions).

79.2%

of participants with injection site reactions experienced mild events

(38/48)

BASELINE CLINICAL PROFILE

Characteristic	Value
Prior AIDS-defining condition	31.7%
Mean CD4 count	778 cells/µL
Mean CD4/CD8 ratio	1.12
Previous 2-drug ART	55.0%
INSTI-based previous ART	91.7%
NNRTI-based regimens	12.4%
Rilpivirine-containing regimens	8.3%
Protease inhibitor-based regimens	3.3%

BASELINE SATISFACTION WITH PREVIOUS ORAL ART

HIVTSQs assessment before switching to LAI CAB+RPV

55.5/60 — **Mean baseline HIVTSQs score**

85.8% — **HIVTSQs score ≥50 (103/120)**

HIVTSQs assessed satisfaction with the previous oral ART regimen before switching.

Previous ART

55% receiving a 2-drug regimen

45% receiving a 3-drug regimen

30% with historical resistance test results available

INTERPRETATION

SATISFACTION — **Satisfaction with previous oral ART was high at baseline.**

Baseline HIVTSQs scores reflect satisfaction with previous oral ART and should not be interpreted as satisfaction with LAI CAB+RPV.

TOLERABILITY — **Four in ten participants experienced at least one injection site reaction; most reported events were mild.**

ACCEPTABILITY — **Most participants rated local reactions and injection site reactions as totally acceptable after the first injection.**

Scientific caution

HIVTSQs results describe satisfaction with previous oral ART at baseline, whereas PIN and tolerability findings describe experience after the first LAI CAB+RPV injection only. These early findings do not establish long-term satisfaction, acceptability, treatment persistence, safety or comparative effectiveness.

LIMITATIONS

- Single-arm descriptive analysis without a comparator
- Selected population eligible for LAI CAB+RPV
- **Outcomes limited to the period after the first injection**
- No concurrent oral-ART control group after switching
- No longitudinal comparison between satisfaction with oral ART and satisfaction with injectable treatment

Next supported step

Longitudinal follow-up will assess tolerability, patient-reported acceptability and virological outcomes during the LOVER60 study.

TAKE-HOME MESSAGE

Among virologically suppressed PWHIV aged ≥60 years, baseline satisfaction with previous oral ART was high. After the first injection of LAI CAB+RPV, injection site reaction adverse events were predominantly mild, permanent treatment discontinuation was infrequent, and patient-reported acceptability of the injectable regimen was high.

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CONTACT

Enrique Bernal Morell
ebm.hgurs@gmail.com

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