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# Hepatic steatosis and fibrosis in people with HIV aged ≥ 60 years eligible for long-acting injectable cabotegravir plus rilpivirine

## Baseline findings from the LOVER60 trial

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**CLINICAL QUESTION**

**What are the baseline prevalences of hepatic steatosis and liver fibrosis, and which factors are associated with hepatic steatosis?**

**~1 in 3**

**had hepatic steatosis**

defined as CAP ≥268 dB/m

31.1% · 32/103

**KEY FINDING**

**Hepatic steatosis was associated with greater adiposity, a higher TyG index and higher fasting glucose. No statistically significant differences were detected according to baseline ART regimen.**

**Adiposity and selected metabolic markers characterized participants with prevalent hepatic steatosis.**

*Baseline associations do not establish causality.*

## WHY THIS MATTERS

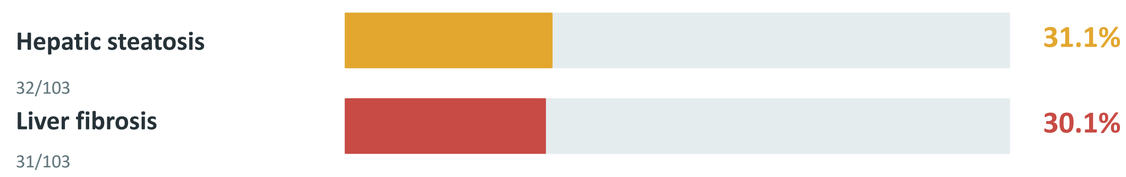
Older PWHIV are at increased risk of metabolic dysfunction-associated steatotic liver disease and liver fibrosis. Baseline hepatic phenotyping is essential for interpreting longitudinal changes after switching to long-acting injectable cabotegravir plus rilpivirine (LAI CAB+RPV).

### OBJECTIVE

**To describe baseline hepatic steatosis and liver fibrosis and explore factors associated with prevalent hepatic steatosis.**

## HEPATIC STEATOSIS AND LIVER FIBROSIS EACH AFFECTED ONE THIRD

Prevalence at baseline among 103 participants with FibroScan




*Approximately one third had steatosis grade ≥1, and a similar proportion had liver fibrosis.*

**Valid FibroScan measurements required a success rate ≥60% and a liver-stiffness IQR/median ratio <30%.**

## STUDY AT A GLANCE

| | |
|---|---|
| **103** with baseline FibroScan | **65.8 ± 5.3** mean age, years |
| **77.6%** male | **244.7** mean CAP, dB/m |

## METHODS

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

1. 120 PWHIV aged ≥60 years
2. Virologically suppressed
3. **103 baseline FibroScan**
4. Switch to LAI CAB+RPV
5. CAP for hepatic steatosis · liver stiffness ≥7 kPa for fibrosis assessment

*COMPARISON: No steatosis vs hepatic steatosis (CAP <268 vs ≥268 dB/m)*

**ANALYSIS** Continuous variables were compared using two-sided independent-samples Student's t tests, assuming equal variances. Sex was compared using Pearson's chi-square test. Analyses were based on available cases.

## STEATOSIS WAS ASSOCIATED TO ADIPOSITY AND METABOLIC MARKERS

Comparison of anthropometric and metabolic parameters between participants with steatosis grade <2 vs ≥2

| Variable | CAP <268 | ≥268 dB/m | p value |
|---|---|---|---|
| BMI, kg/m² (SD) | 25.00 (3.49) | 30.05 (3.60) | <0.001 |
| Waist circumference, cm | 94.44 (9.88) | 106.83 (9.57) | <0.001 |
| Abdominal circumference, cm | 97.80 (7.28) | 106.16 (9.49) | <0.001 |
| TyG index | 8.54 (0.54) | 8.95 (0.59) | <0.001 |
| Triglycerides, mg/dL (SD) | 111.4 (53.9) | 148.9 (67.4) | 0.003 |
| Fasting glucose, mg/dL | 104 | 119 | 0.036 |
| HOMA-IR | 6.41 (9.02) | 9.33 (12.01) | 0.17 |

*No statistically significant between-group differences were detected in ALT, LDL cholesterol, insulin, CD4 count, age, sex or the CD4/CD8 ratio.*

**31.1%**

**Hepatic steatosis defined as CAP ≥268 dB/m**

≥S2 · 32/103

## BASELINE CHARACTERISTICS

| Characteristic | Value |
|---|---|
| Participants with FibroScan | 103 / 120 |
| Mean age | 65.8 ± 5.3 years |
| Male sex | 77.6% |
| Mean CAP | 244.7 dB/m |
| Virological status | Suppressed |
| | |

*This baseline analysis included 103 participants enrolled in the liver substudy at centres with access to transient elastography and CAP measurement.*

## NO DIFFERENCES BY BASELINE ART REGIMEN

Dual vs triple therapy

| | Dual therapy n=65 | | Triple therapy n=55 | | |
|---|---|---|---|---|---|
| Mean CAP | 240.3 | vs | 250.3 | dB/m | p=0.38 |
| Steatosis prevalence | 29.8% | vs | 32.6% | | p=0.93 |

**No statistically significant differences in mean CAP or steatosis prevalence were detected between baseline dual and triple ART.**

*Dual therapy: 46 Dovato, 18 Juluca, 1 other*

*Baseline FibroScan-CAP findings before exposure to LAI CAB+RPV*

## INTERPRETATION

**PREVALENCE** **Hepatic steatosis and liver fibrosis were each identified in approximately 30% of the liver substudy population.**

**PHENOTYPE** **Participants with hepatic steatosis had a higher BMI, greater central adiposity, a higher TyG index, higher triglycerides and higher fasting glucose.**

**ART REGIMEN** **No statistically significant differences in mean CAP or steatosis prevalence were detected between participants receiving dual and triple ART at baseline.**

### Scientific caution

**These cross-sectional baseline comparisons identify unadjusted associations and cannot establish causality or determine the effect of long-acting CAB+RPV on hepatic outcomes.**

## LIMITATIONS

- Cross-sectional analysis of baseline data
- **Liver substudy restricted to 103 of the 120 LOVER60 participants**
- Selected, single-arm clinical trial population
- Exploratory comparisons using Student's t tests, with no adjusted analyses reported
- No longitudinal effect of LAI CAB+RPV assessed in this baseline analysis

### Next supported step

Longitudinal follow-up will assess changes in hepatic outcomes from this baseline during the LOVER60 study.

**TAKE-HOME MESSAGE**

**Approximately one third of the 103 virologically suppressed older PWHIV included in the liver substudy had hepatic steatosis, and a similar proportion met the study definition of liver fibrosis. Participants with hepatic steatosis had greater adiposity, a higher TyG index and higher fasting glucose. No statistically significant differences in mean CAP or steatosis prevalence were detected between participants receiving dual and triple ART at baseline. These exploratory, unadjusted cross-sectional findings do not establish independent associations, causality or treatment effects.**

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