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LONG-ACTING INTRAMUSCULAR ANTIRETROVIRALS: WHAT REAL-WORLD DATA DO WE HAVE?

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BACKGROUND & IMPORTANCE

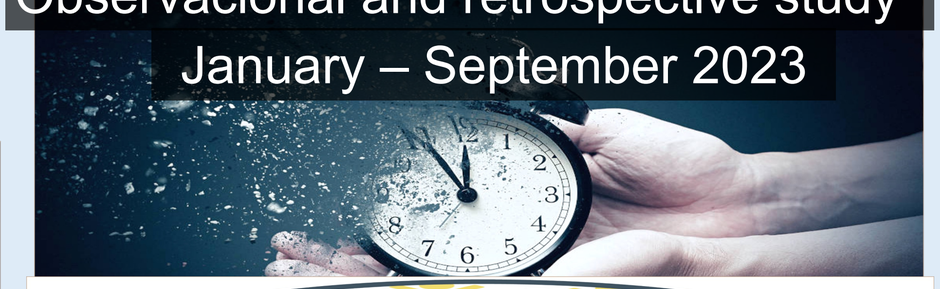
The new intramuscular antiretroviral treatments (IM-ART), cabotegravir-rilpivirine, have represented a breakthrough in reducing stigma and improving adherence among HIV patients. However, it is necessary to understand how their real-world use impacts patient outcomes.

OBJETIVES

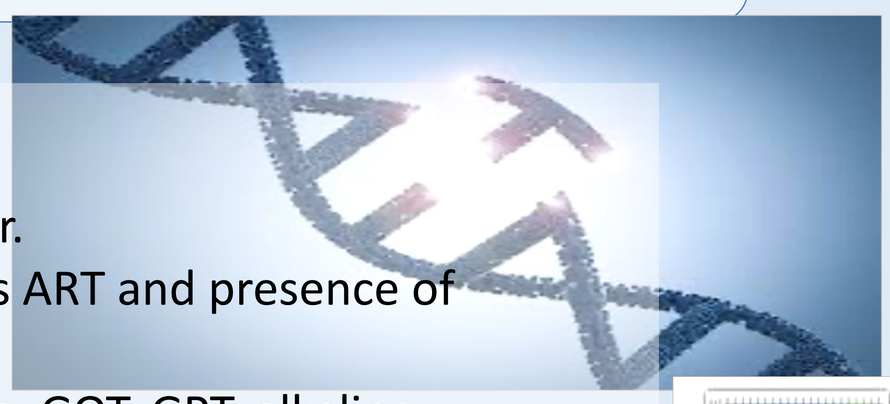
To assess the effectiveness and safety of IM-AR in real-world settings and investigate their impact on analytical parameters.

MATERIALS & METHODS

Observacional and retrospective study
January – September 2023

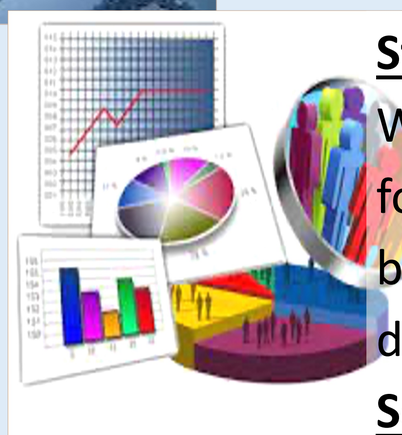


Inclusion criteria: All patients treated with LA-AR with at least 3 doses



VARIABLES:

- **Demografic**: Age and gender.
- **Treatment-related:** Previous ART and presence of resistance mutations (RM).
- **Clinical:** LDL, HDL, creatinine, GOT, GPT, alkaline phosphatase, GGT, total bilirubin, calcium, and phosphorus before and after IM-AR .
- **Effectiveness**: HIV-1 RNA copies (CV), CD4 count, and CD4/CD8 ratio before and after starting IM-ART .
- **Adverse events (AE) and pain visual analogue scale (VAS)**.



Statistics: Paired Student's t-test and Wilcoxon signed-rank test were used for statistical analysis of differences between pre and post-LA-AR variables, depending on the distribution

Software: STATA/IC v.16.1.

- **66 patients (93.9% men)**
- Median age: 42 years (IQR: 38-46).
- 55% were receiving triple therapy before the switch.
- At least one Resistance mutations: 27.6% (none affect IM-AR).
- 3 patients had CV > 30 copies/mL before starting LA-AR. All maintained CV < 30 copies/mL during the study period.
- Statistically significant differences were observed in LDL (p=0.0193) and CD4 (p=0.0035) between pre and post IM-AR values.
- All patients experienced at least one AE -- > the most frequent: injection site reactions (98.5%).
- The observed AEs included: general malaise (36.7%), asthenia (13.6%), fever (12.1%), diarrhea (9.1%), headache (7.6%), sleep disturbances (6.1%), nausea (3.0%), and others (4.5%).
- **One patient discontinued IM-ART due to AE**.
- **Differences in pain assessed on the VAS were observed** between rilpivirine vs cabotegravir administration [0.9 (95% CI: 0.3-1.5; p=0.0029)] and between the second vs. first administration: rilpivirine [1.6 (95% CI: 0.5-2.7; p=0.0042)]; cabotegravir [1.6 (95% CI: 0.6-2.6; p=0.0032)].

CONCLUSIONS & RELEVANCE

LA-AR has demonstrated effectiveness and acceptable safety in real-world data, consistent with the results of the ATLAS and FLAIR studies.
Longer-term studies are needed to evaluate the evolution of CD4 counts, LDL levels, and pain.