Review of Clinical experiences: Dual Therapy and Long Acting

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Clinical Experiences and New Perspectives

Disclosure

- Advisory committees, speaking and teaching:
  - *Gilead, Janssen, GSK, Merck, SOBI, ViiV*

Introduction

- Evolution of ART
- Challenges in adherence to daily oral therapy
- Long-acting antiretrovirals (LAI) as new options

What is CAB/RPV LAI

Long-acting injectable regimen: CAB + RPV

Approved for virologically suppressed HIV-1 adults

Administered every 8 weeks (Q8W)

Our Experience

Italian single-center retrospective study

Assessment: durability, adherence, reasons for discontinuation

CAB/RPV LAI every 8 weeks (Q8W)

Population

334 (25.3% female, median age of 51 years [IQR: 42-61],)

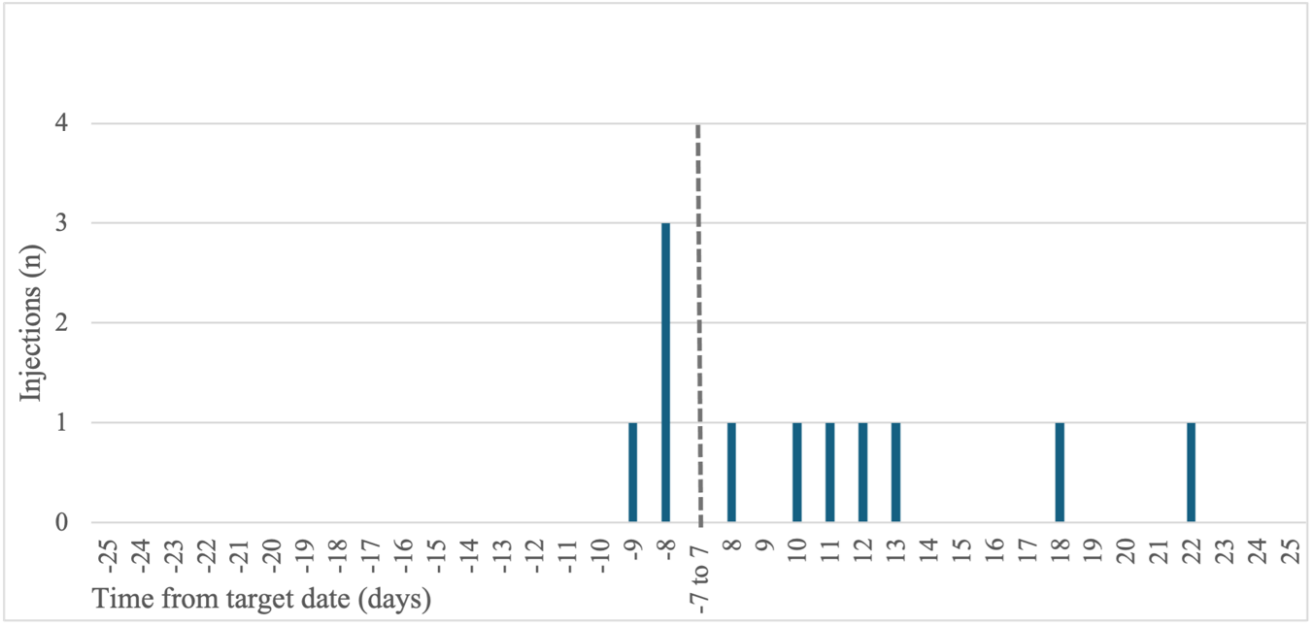
Comorbidities: 47% were taking at least one additional therapy
Previous ART exposure:
- 63.8% INSTIs
- 58.7% NNRTIs
- 43.5% Pis

Median VL <50 cp/mL before the switch: 10 years (IQR: 6–16)

Observation period: 70 weeks (IQR: 24-96)

Key Results

- 12 discontinuations (8.7%)
- No virological failure
- 92.8% of injections within schedule
- High adherence



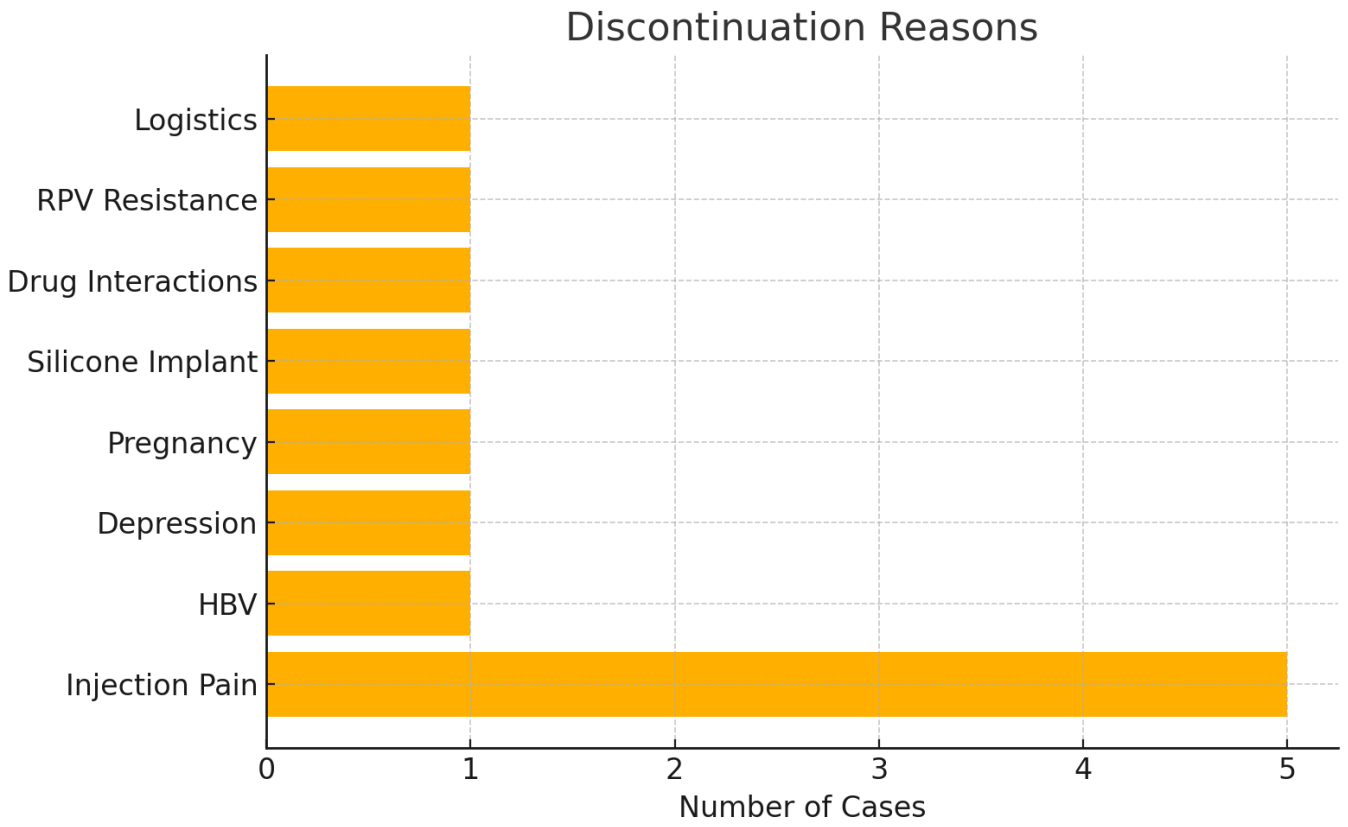
- 96.3% of injections were administered within the ±7-day window.
  Significant delays (>13 days): only 2 patients.

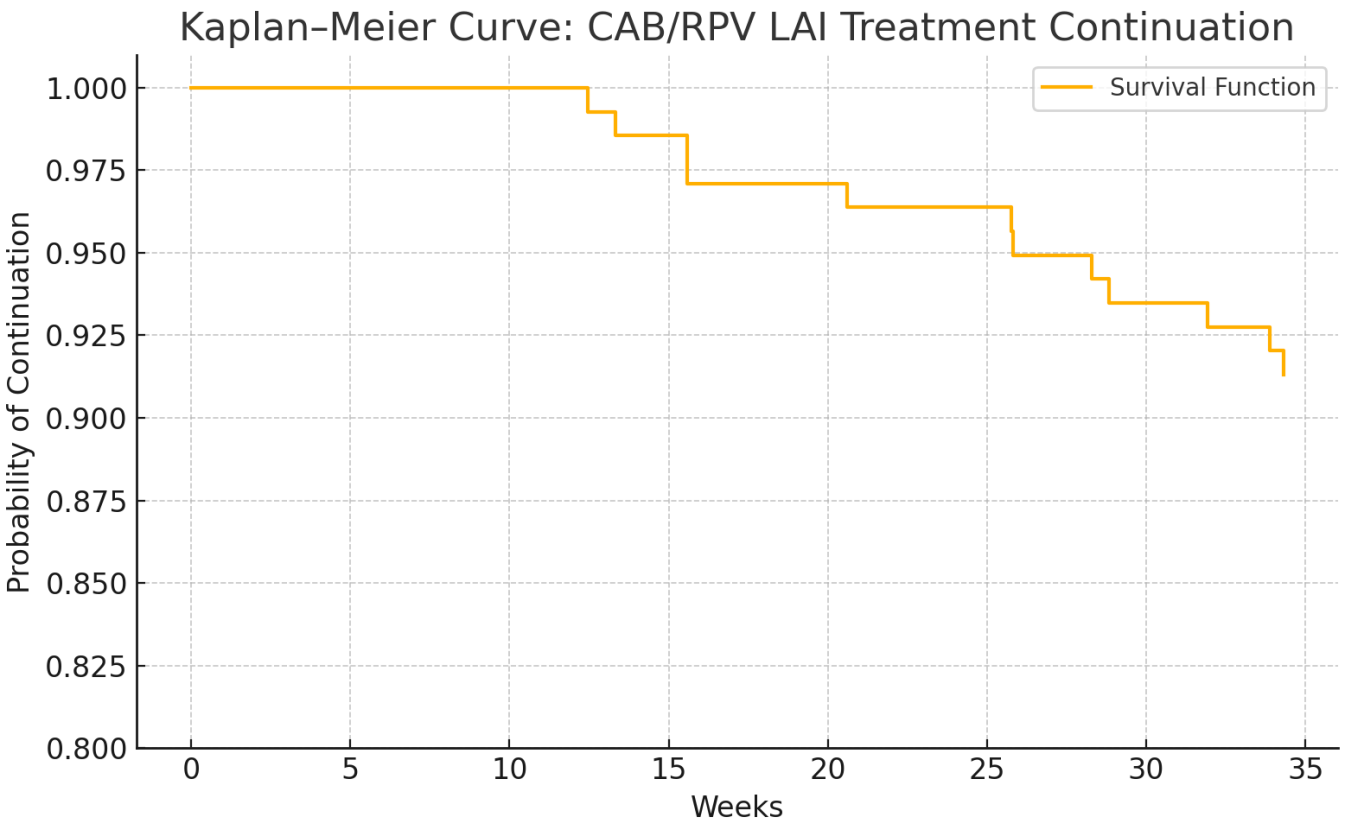
Adherence to the injection schedule

Discontinuation Factors

- Injection site pain (5/12)
- Higher in women (21.7%)
- Other causes: HBV, depression, pregnancy, interactions

Discontinuation Reasons - Chart




Kaplan–Meier Curve: CAB/RPV LAI Treatment Continuation
Survival Function
Probability of Continuation
1.000
0.975
0.950
0.925
0.900
0.875
0.850
0.825
0.800
0
5
10
15
20
25
30
35
Weeks

Organizational Approach

- Dedicated nursing clinic
- Reduced hospital visits to 6/year
- Enhanced clinical efficiency and adherence

Other site of administration ?

Clinical issue

Some patients, such as transgender individuals, have injected silicone in the gluteal or thigh areas, making standard administration impossible.

Proposed solution:

Off-label administration via the deltoid muscle.

Clinical cases analyzed:

Two transgender women with anatomical modifications due to surgery and silicone.

Deltoid Route

- 2 transgender women switched due to silicone implants
- Maintained virological suppression

Deltoide Route

Study objective:

To evaluate the pharmacokinetics and tolerability of long-acting rilpivirine and cabotegravir (LAI).

Site of administration: Deltoid muscle

Study significance:

Alternative administration options for patients with contraindications to gluteal injections (e.g., injected silicone).

Patient 1

- **Age:** 40 years
  BMI: 27.7
  HIV-RNA: < 20 copies/mL for 9 years
  Plasma concentrations (rilpivirine): 219 ng/mL → 178 ng/mL (24 weeks)
  Plasma concentrations (cabotegravir): 738 ng/mL → 699 ng/mL (24 weeks)

Patient 2

Age: 30 years
BMI: 23.6
HIV-RNA: < 20 copies/mL for 3 years
Plasma concentrations (rilpivirine): 180 ng/mL → 178 ng/mL (24 weeks)
Plasma concentrations (cabotegravir): 1,834 ng/mL → 2,047 ng/mL (24 weeks)

Pharmacokinetics via Deltoid

- CAB/RPV concentrations > 4x PA-IC90

- No side effects

- Excellent tolerability profile

Advantages of Deltoid Route

- Valid alternative to gluteal/thigh sites
- More discreet
- Useful in patients with anatomical limitations

Clinical Considerations

- Effective and well-tolerated regimen
- High real-world adherence
- Injection site choice is key

Conclusions & Future Directions

- CAB/RPV LAI simplifies HIV therapy
- Excellent adherence and patient satisfaction
- Need for longer, multicenter studies