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Evaluating Viral Decay Kinetics of Long Acting Cabotegravir/Rilpivirine in Pregnancy

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BACKGROUND

- ~3,500 pregnancies occur annually among people with HIV in the U.S.
- 35–40 cases of perinatal HIV transmission reported yearly (CDC)
- Sustained maternal viral suppression is the strongest predictor of prevention of vertical transmission
- Adherence to daily oral ART may be compromised by:
  - Late entry into prenatal care
  - Psychosocial instability
  - Pill intolerance
  - Prior disengagement from care
- Long-acting injectable cabotegravir/rilpivirine (LA CAB/RPV) offers:
  - Directly observed therapy (DOT)
  - Reduced pill burden
  - Potential adherence advantage in high-risk populations
- However:
  - Pregnancy PK data remain limited
  - Rilpivirine exposure may decline during pregnancy
  - Current guidelines advise discontinuation due to insufficient data

Clinical Question:
Can LA CAB/RPV achieve rapid viral decay when initiated during pregnancy in viremic individuals?

METHODS

- **Design:** Multi-center retrospective cohort
- **Population:** Pregnant persons initiating LA CAB/RPV while viremic
- **Data collected:**
  - Baseline viral load
  - Gestational age at initiation
  - Serial HIV RNA measurements
  - Viral decay slopes (log_{10}/week)
  - Mode of delivery
  - Neonatal outcomes
  - Vertical transmission
- Viral decay slopes calculated from paired early timepoints

PLAIN LANGUAGE SUMMARY:
This small case series describes four pregnant persons with HIV who started long-acting injectable cabotegravir and rilpivirine while their virus levels were high. All experienced rapid declines in HIV viral load, achieved suppression within four weeks, and had no cases of infant HIV transmission. This suggests that this injectable regimen may be a promising option for pregnant people who cannot reliably take daily pills.

Long-Acting Injectables may be a viable alternative for pregnant people unable to tolerate or adhere to oral ART

RESULTS

Cohort Characteristics

- N = 4 pregnant cisgender women
- Median gestational age at initiation: 25 weeks
- Median baseline HIV RNA: 89,500 copies/mL
- All initiated LA CAB/RPV due to:
  - Inability to tolerate oral ART OR
  - Poor adherence to oral therapy

KEY NUMBERS

- 4/4 achieved <1,000 copies/mL by Week 4
- Median decay: –1.6 log_{10}/week
- 0 perinatal transmissions
- 0 congenital anomalies

RESULTS II

Viral Decay Kinetics

- 3 participants with paired week 1 viral loads
- Median decay slope:
  –1.6 log10 copies/mL per week
  (Range: –1.36 to –1.83)
- Decay comparable to non-pregnant populations on LA therapy
  - Typical first–phase decay on standard integrase- based therapy ART is ~–1.0 to –2.0 log_{10}/week.
  - Observed decay here falls within expected range
- 100% achieved HIV RNA < 1,000 copies/mL within 4 weeks of starting LA CAB/RPV

Obstetric and Neonatal Outcomes

- No perinatal HIV transmission
- Majority were term deliveries
- 1 Cesarean section for elevated HIV viral load
- Median birth weight: 2,597 grams
- No congenital anomalies observed

Table 1: Cohort Characteristics

Initial Regimen	Gestational age at first prenatal visit (weeks)	HIV VL at first prenatal visit (copies/mL)	Gestational age at switch to LA CAB/RPV (weeks)	HIV VL at switch to LA CAB/RPV (copies/mL)	Gestational age at delivery (weeks)	LA CAB/RPV Dosing frequency	HIV VL at delivery (copies/mL)
FTC/TAF/BIC	20	30,000	22	30,000	34	Monthly	< 20
FTC/TAF/BIC	8	42,440	17	22,000	38	Monthly	< 20
FTC/TAF/BIC	9	150,000	28	149,000	38	Monthly	89
FTC/TAF/BIC + DRV/c + DOR	16	111,000	36	150,000	37	Monthly	2,200

CONCLUSIONS / CLINICAL IMPLICATIONS

- LA CAB/RPV demonstrates preserved antiviral potency during pregnancy
- Rapid viral decay may reduce transmission risk even when initiated late in pregnancy
- May represent a harm-reduction strategy for:
  - Late presenters
  - Individuals unable to take oral ART
  - Those with significant adherence barriers
- Supports need for prospective PK and safety studies
- Raises question of whether current guideline discontinuation should be revisited

LIMITATIONS

- Small sample size
- Retrospective design
- No pharmacokinetic measurements
- No comparator oral ART group
- Limited long-term infant follow-up

STRENGHTS

- First case series of LA CAB/RPV initiation in pregnant patients with viremia
- Direct assessment of viral decay slope
- Real-world, multi-center data

Figure 1. Viral kinetics after starting LA CAB/RPV during pregnancy

