ROLE OF MATERNAL VIRAL LOAD IN HIV TRANSMISSION IN PROMISE

PROMISE TEAM

IMPAACT PREVENTION SCIENCE MEETING, JUNE, 2018
OVERALL STUDY: Randomizations Antepartum, Postpartum during Breastfeeding and at the End of Infant HIV Transmission Risk
In Antepartum Component, HIV RNA was assessed at entry, week 4 and delivery/postpartum week 1.

In Postpartum Component, HIV RNA was assessed at weeks 1 (6-14 days postpartum, entry), 6 and 14, 26 and 50 weeks postpartum.

Both components, HIV RNA assessments were performed real-time for women receiving ART and stored and batched for those not receiving ART.
There were no differences in AP baseline viral load among infants.

- Median viral load at enrollment: 3.8 log_{10} copies/ml for ZDV Alone (N=1543), 3.9 log_{10} copies/ml for ZDV-Based ART (N=1541), and 3.9 log_{10} copies/ml for Total (N=3084).
- IQR: 3.2–4.4 for both groups and Total.

Among infected infants, viral loads most often greater than 1,000 copies/ml.

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>ZDV Alone</th>
<th>ZDV-Based ART (no. of mother-infant sets/total no. (%)</th>
<th>TDF-Based ART</th>
<th>Difference, ZDV-Based ART and TDF-Based ART vs. ZDV Alone (percentage points (repeated CI))</th>
<th>P Value for Interaction</th>
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</thead>
<tbody>
<tr>
<td>Maternal viral load at trial entry</td>
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<tr>
<td>&lt;1000 copies/ml</td>
<td>0/299</td>
<td>1/253 (0.4)</td>
<td>0/57</td>
<td>0.3 (−0.4 to 1.0)</td>
<td>0.22</td>
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<tr>
<td>≥1000 copies/ml</td>
<td>25/1083 (2.3)</td>
<td>6/1129 (0.5)</td>
<td>2/268 (0.7)</td>
<td>−1.7 (−2.8 to −0.7)</td>
<td></td>
</tr>
<tr>
<td>Missing data</td>
<td>4</td>
<td>3</td>
<td>0</td>
<td></td>
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</tbody>
</table>
Maternal viral load was similar at baseline.

By week 6, more women randomized to mART had undetectable viral load compared to those randomized to infant NVP.

Similar distribution of maternal viral loads persisted at subsequent measurements.
MATERNAL VIRAL LOAD AND HIV TRANSMISSION IN PP COMPONENT

- Baseline maternal viral load was not significantly associated with infant transmission (p=0.11)
- Time-varying maternal viral load was significantly associated with infant HIV infection in the mART arm (hazard ratio (95% CI): 12.04 (2.54, 57.06)) but not in the iNVP arm (hazard ratio (95% CI): 1.04 (0.20 – 5.52))
- Of 7 postnatal infections in mART arm, 2 had maternal viral loads <40 copies/ml close to time of NAT detection in the infant
### Infant HIV Testing Result

- **Mother's age at PP entry = 40**
- **AP LPV/r+TDF/FTC arm**
- **ID = 1077BL4748**

### Graphs

1. **Log10 Maternal RNA (copies/ml)**
   - **Time from Delivery (weeks)**
   - **PP Randomization**
   - **mART Stopped**
   - **Infant HIV testing result**:
     - ** Negative**
     - ** Positive**

2. **Log10 Maternal RNA (copies/ml)**
   - **Mother's age at PP entry = 27**
   - **AP LPV/r+ZDV/3TC arm**
   - **ID = 1077BA28384**
Mother's age at PP entry = 40

Log10 Maternal RNA (copies/ml)

Time from Delivery (weeks)
DISCUSSION

- Among women receiving mART during breastfeeding, increased maternal viral load was associated with increased risk of infant HIV-1 infection.

- Analysis of viral load and ART adherence is still in progress, but we suspect there will be a correlation between viral load and medication adherence.

- iNVP should be considered in addition to mART in situations with documented poor maternal ART adherence.