IMPACT OF EARLY ART INITIATION ON PERFORMANCE OF HIV CROSS SECTIONAL INCIDENCE ASSAYS

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Background

- RV217 study is an early capture cohort designed to examine the progression of HIV from the early stages of infection.
- Individuals considered to be high risk for contracting HIV were eligible to enroll.
- Participants were screened regularly prior to and after their first positive test.
- We used longitudinal samples from the RV217 Cohort with ART initiation at different time points and evaluated the impact it had on OD-n (Avidity) and Avidity Index (BioRad-Avidity).
- Previous studies have shown that ART can impact HIV cross-sectional incidence assays, giving a false positive for recent infection.
- We sought to assess the performance of the LAg-Avidity and BioRad-Avidity assays among individuals who initiated ART at varying lengths after infection.

Methods

- We tested 320 samples that had been collected from 55 participants. Participants were from Thailand, Kenya, or Uganda.
- Each participant contributed 4-7 samples (Average: 5.5) and samples were collected 0.15 to 4.20 years post infection.
- Participants were divided into three groups: individuals who never received ART (N=34); individuals who received ART <1 year after infection (N=9); and individuals who received ART 1-3 years after infection (N=12).
- We assessed the OD-n and Avidity Index (AI) slope values in the first year post-infection among the three groups from the RV217 Cohort.
- We assessed the slope after ART initiation among the two RV217 groups that received ART.
- Data was compared to previously published data from the Johns Hopkins HIV Cohort, which included participants who did not initiate ART until an average of 10 years after infection.
- Analyzed data to test for differences in assay performance across country, age, and gender. Demographic comparisons were limited to participants not on ART.
- Analysis utilized a mixed-effects random slope, random intercept model in STATA 14.

Table 1: Participant Demographics

<table>
<thead>
<tr>
<th>Country</th>
<th>Thailand</th>
<th>Kenya</th>
<th>Uganda</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td># of Participants</td>
<td>31 (56%)</td>
<td>19 (35%)</td>
<td>5 (9%)</td>
<td>55</td>
</tr>
<tr>
<td>Median Age (y)</td>
<td>23 (18-25)</td>
<td>24 (22-24)</td>
<td>26 (25-26)</td>
<td>23 (20-26)</td>
</tr>
<tr>
<td>Cisgender Male</td>
<td>19 (100%)</td>
<td>0</td>
<td>0</td>
<td>19</td>
</tr>
<tr>
<td>Cisgender Female</td>
<td>2 (8%)</td>
<td>19 (73%)</td>
<td>5 (19%)</td>
<td>26</td>
</tr>
<tr>
<td>Transgender Female</td>
<td>10 (100%)</td>
<td>0</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>No ART</td>
<td>19 (56%)</td>
<td>11 (32%)</td>
<td>4 (12%)</td>
<td>34</td>
</tr>
<tr>
<td>ART &lt;1 Year</td>
<td>3 (33%)</td>
<td>6 (67%)</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>ART 1-3 Years</td>
<td>9 (75%)</td>
<td>2 (17%)</td>
<td>1 (8%)</td>
<td>12</td>
</tr>
</tbody>
</table>

Results

- Figure 1A: LAg-Avidity - RV217 results by duration of infection
  - ART initiation <1 year after infection resulted in a OD-n slope -2.15 units lower than in participants who did not initiate ART (95% CI -2.96, -1.33).
  - Prior to ART initiation there was no difference in OD-n slope between the group who did not receive ART and the group who received ART 1-3 years after infection (p=0.31).

- Figure 1B: LAg-Avidity - RV217 & Johns Hopkins HIV Cohort results by time on ART
  - When ART was initiated 1-3 years after infection the OD-n decreased at a slope 0.74 units/year steeper than when it was initiated <1 year after infection (95% CI 0.28, 1.20).
  - ART initiated 1-3 years after infection resulted in an OD-n decrease of 0.90 units/year quicker than when ART was initiated 10 years after infection (95% CI 0.47, 1.32).

Conclusions

- ART had a more significant impact on the LAg-Avidity assay when ART is initiated earlier in infection. This could lead to the overestimation of HIV incidence in populations where ART use is prevalent or unknown.
- ART did not have an impact on the Johns-Hopkins modified BioRad-Avidity assay. Use of this assay with this procedure could yield more accurate HIV incidence estimates in populations with where ART use is unknown.
- Statistical significance was not achieved in comparing HIV cross-sectional assay results between: country; gender; or age at study enrollment. Despite this, we observed 9/31 (29%) individuals from Thailand who had a persistently low AI. Future research should seek to explain this phenomenon.
- ART initiation <1 year after infection did not result in a significant difference in AI slope (p=0.41).

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