Pharmacologic Measures of PrEP Adherence among High-Risk MSM in HPTN 067

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METHODS

• HPTN 067/ADAPT was a randomized trial of intermittent and daily PrEP (PMID: 28986209, 2014/183).

• Data collection and follow-up concluded in 2014

• Participants randomly assigned to daily, time- or event-driven oral PrEP regimens

• Study visits at weeks 0, 4, 12, and 24 post randomization

• Plasma and hair samples at each visit to assess FTC and TFV concentrations; Wisepill™ and sexual behavior data collected weekly

• This analysis included 350 men who have sex with men (MSM) enrolled in Bangkok, Thailand and Harlem, United States. Estimaded Pearson correlation coefficients among measures - Linear mixed models to assess predictors of log-transformed plasma (short-term) and hair (long-term) concentrations of TFV/FTC

RESULTS

Table 1. Participant characteristics at enrollment (N=350)1

<table>
<thead>
<tr>
<th>Arm</th>
<th>Daily arm</th>
<th>Event-driven arm</th>
<th>Time-driven arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site</td>
<td>Bangkok, Thailand</td>
<td>Harlem, USA</td>
<td>176 (50.3%)</td>
</tr>
<tr>
<td>Age, years</td>
<td>31 (25.8%)</td>
<td>31 (25.8%)</td>
<td>31 (25.8%)</td>
</tr>
<tr>
<td>Secondary school or less education</td>
<td>171 (49.9%)</td>
<td>24 (69.1%)</td>
<td>1 (3.3%)</td>
</tr>
<tr>
<td>AUDIT score 29 2</td>
<td>73 (20.9%)</td>
<td>7 (20.3%)</td>
<td>66 (20.1%)</td>
</tr>
</tbody>
</table>

Number of sex partners in prior 3 months 4 (2-8)

Any HIV-positive sex partners in prior 3 months 44 (12.6%)

Any unprotected sex in prior 3 months 264 (75.4%)

1% (n) or Median (IQR). Indicative of heavy alcohol use

Methods of PrEP adherence (n=350): 5

Daily (89): 1 tablet/day; 6

Event driven (1): 1 tablet pre-sex and 1 tablet post-sex

No more than 2 tablets daily or 7 tablets/week

Figure 1. Correlations between PrEP pill-taking measures

Table 2. Pill-taking and sexual behavior during follow-up

<table>
<thead>
<tr>
<th>Event/Time-Driver</th>
<th>FTC Plasma Drug Concentrations (µg/mL)</th>
<th>TFV Plasma Drug Concentrations (µg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time-driven</td>
<td>0.95 (0.13, 0.95)</td>
<td>2.03 (0.34, 0.24)</td>
</tr>
<tr>
<td>Daily</td>
<td>0.95 (0.13, 0.95)</td>
<td>2.01 (0.34, 0.24)</td>
</tr>
<tr>
<td>72 weeks follow-up</td>
<td>0.95 (0.13, 0.95)</td>
<td>2.01 (0.34, 0.24)</td>
</tr>
<tr>
<td>FTC and TFV</td>
<td>0.45 (0.24, 0.63)</td>
<td>0.26 (0.14, 0.04)</td>
</tr>
</tbody>
</table>

1 Models included all covariates shown here. TFV and FTC concentrations are log-transformed. Significant effects (p-value <0.05) are highlighted. Measured per 10 sex acts

Table 3. Estimated multivariable associations of covariates with hair and plasma drug concentrations

CONCLUSIONS

• Among MSM in HPTN 067, plasma and hair drug concentrations and Wisepill2 data were correlated with one another.

• Site, study arm, education, age, alcohol use, and sexual risk were differentially associated with long- and short-term pill-taking behavior (e.g., age was associated with short-term but not long-term pill-taking).

• Patterns of pill-taking can be assessed by examining plasma and hair concentrations of PrEP cocktails in conjugation

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