Men

Dried blood spot (DBS) analyses of To

To assess the pattern of FTC/TDF for PrEP use

Participants

The efficacy of FTC/TDF for PrEP greatly depends on adherence, estimated at 76% reduction in HIV infection if the individual takes 2 tablets per week, and over 90% for 4 tablets per week among MSM. 2,3

Dried blood spot (DBS) analyses of tenofovir-diprophosphate (TFD, in femtomoles per punch) in red blood cells measure chronic TDF drug use, which provide an integrated, objective evaluation of adherence for individuals taking FTC/TDF for PrEP.

Objective

To assess the pattern of FTC/TDF for PrEP use in a globally diverse MSM population;

To evaluate the association between PrEP adherence, objectively measured by TFV-DP concentration in DBS, with the rate of new HIV infections in the pooled population.

Methods

Data were pooled from 8 open-label HIV prevention studies or demonstration projects. The mean TFV-DP concentration was determined for each participant based on DBS from all follow up visits of the participant.

Categories of the mean TFV-DP DBS are defined to use FTC/TDF for PrEP dosage equivalent as: <2 (less than 350 fmol/punch of TFV-DP), 2−3 (350−699 fmol/punch), 4−6 (700−1,249 fmol/punch), and ≥7 (1,250 fmol/punch) tablets of FTC/TDF per week.

Demographics, HIV-1 infection status, and DBS measures of TFV-DP were collected at baseline and during follow-up visits.

Logistic regression was used to estimate odds ratios for adherence, and Poisson regression to calculate incidence rates and incidence rate ratios of new HIV cases.

Results

A total of 3,058 participants were given FTC/TDF PrEP and had at least one measurement of TFV-DP in DBS during follow up visits up to 3.4 years.

Of the 3,058 participants, 99% were men who have sex with men (MSM), 68% were in the U.S., 25% in South America, 2% in Asia, and 1% in Africa.

In the pooled population, the median age at PrEP initiation was 30 years (interquartile range, IQR, 25–38), and the median TFV-DP exposure was 0.96 years (IQR, 0.90–1.39).

Table 1. Number of participants by level of TFV-DP in DBS and odds ratios with corresponding 95% confidence interval of adherence by age at PrEP initiation

<table>
<thead>
<tr>
<th>Age at PrEP Initiation (Years)</th>
<th>Median (IQR) TFV-DP</th>
<th>Odds ratio (95% CI) for adherence to ≤700 fmol/ml as reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;26</td>
<td>292 (240–340)</td>
<td>0.39 (0.23–0.63)</td>
</tr>
<tr>
<td>26−29</td>
<td>205 (193–217)</td>
<td>1.00 (Reference)</td>
</tr>
<tr>
<td>30−39</td>
<td>192 (121–203)</td>
<td>0.57 (0.39–0.85)</td>
</tr>
<tr>
<td>≥40</td>
<td>81 (62–107)</td>
<td>1.53 (1.18–2.00)</td>
</tr>
</tbody>
</table>

Table 2. Incidence rate per 100 person-year and incidence rate ratio of new HIV infections by DBS measured adherence

<table>
<thead>
<tr>
<th>Mean TFV-DP (fmol/punch)</th>
<th>Non-HIV Infected</th>
<th>HIV Infected</th>
<th>Incidence Rate per 100 Person-Year (95% CI)</th>
<th>Incidence Rate Ratio with &lt;700 fmol/ml as reference</th>
</tr>
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<tbody>
<tr>
<td>&lt;350</td>
<td>4.90 (4.70–5.10)</td>
<td>7.22 (6.92–7.53)</td>
<td>0.92 (Reference)</td>
<td>1.52 (0.76–3.03)</td>
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<tr>
<td>350−700</td>
<td>4.90 (4.70–5.10)</td>
<td>7.22 (6.92–7.53)</td>
<td>0.92 (Reference)</td>
<td>1.52 (0.76–3.03)</td>
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<td>700−1250</td>
<td>4.90 (4.70–5.10)</td>
<td>7.22 (6.92–7.53)</td>
<td>0.92 (Reference)</td>
<td>1.52 (0.76–3.03)</td>
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<tr>
<td>1250+</td>
<td>4.90 (4.70–5.10)</td>
<td>7.22 (6.92–7.53)</td>
<td>0.92 (Reference)</td>
<td>1.52 (0.76–3.03)</td>
</tr>
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</table>

Findings and Conclusions

In this multi-national pooled analysis of FTC/TDF PrEP use in a geographically diverse MSM population receiving PrEP, 26%, 14%, and 27% of all participants were taking <2, 2−3, and ≥4 tablets of FTC/TDF PrEP per week, respectively.

Participants under 30 years of age were less likely to remain adherent at 24 tablets/week, which is the established protective dosage of FTC/TDF PrEP. Participants 40 years of age and older were more likely to be associated with increased adherence.

A total of 41 out of the 3,058 individuals tested HIV positive (IR=1.13/100 person-years exposure, 95% confidence interval, CI, 0.82–1.54), and 38 of the 41 cases (93%) had FTC-DP consistent with taking less than 4 FTC/TDF tablets/week.

Individuals taking 24 tablets/week were protected from HIV infection at a low incidence rate of 0.14/100 person-years, compared with 3.41 and 1.59 for individuals who took <2 and 2−3 tablets/week, respectively.

References


Acknowledgments

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