

Original Investigation

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HIV Preexposure Prophylaxis With Emtricitabine and Tenofovir Disoproxil Fumarate Among Cisgender Women

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Key Points

Question What is the HIV incidence among cisgender women with different adherence trajectories to preexposure prophylaxis (PrEP) with emtricitabine and tenofovir disoproxil fumarate?

Findings In this pooled analysis of 6296 participants from 11 postapproval studies of PrEP in cisgender women, the overall HIV incidence was 0.72 per 100 person-years. The HIV incidence rates per 100 person-years for different PrEP adherence trajectories were 0 for consistently daily (7 doses/week), 0.13 for consistently high (4-6 doses/week), 0.49 for high but declining (from a mean of 4-6 doses/week and then declining), and 1.27 for consistently low (less than 2 doses/week) adherence.

Meaning In a pooled analysis of postapproval studies, cisgender women with daily or consistently high adherence to emtricitabine and tenofovir disoproxil fumarate for PrEP experienced very low HIV incidence.

Abstract

Importance Emtricitabine and tenofovir disoproxil fumarate (F/TDF) for HIV preexposure prophylaxis (PrEP) is highly effective in cisgender men who have sex with men (MSM) when adherence is high (>4 doses/week). Real-world effectiveness and adherence with F/TDF for PrEP in cisgender women is less well characterized.

Objective To characterize the effectiveness of F/TDF for PrEP and its relationship with adherence in cisgender women.

Design, Setting, and Participants Data were pooled from 11 F/TDF PrEP postapproval studies conducted in 6 countries that included 6296 cisgender women aged 15 to 69 years conducted from 2012 to 2020. HIV incidence was

evaluated according to adherence level measured objectively (tenofovir diphosphate concentration in dried blood spots or tenofovir concentration in plasma; n = 288) and subjectively (electronic pill cap monitoring, pill counts, self-report, and study-reported adherence scale; n = 2954) using group-based trajectory modeling.

Exposures F/TDF prescribed orally once a day. HIV incidence was analyzed in subgroups based on adherence trajectory.

Main Outcomes and Measures HIV incidence.

Results Of the 6296 participants, 46% were from Kenya, 28% were from South Africa, 21% were from India, 2.9% were from Uganda, 1.6% were from Botswana, and 0.8% were from the US. The mean (SD) age at PrEP initiation across all studies was 25 (7) years, with 61% of participants being younger than 25 years. The overall HIV incidence was 0.72 per 100 person-years (95% CI, 0.51-1.01; 32 incident HIV diagnoses among 6296 participants). Four distinct groups of adherence trajectories were identified: consistently daily (7 doses/week), consistently high (4-6 doses/week), high but declining (from a mean of 4-6 doses/week and then declining), and consistently low (less than 2 doses/week). None of the 498 women with consistently daily adherence acquired HIV. Only 1 of the 658 women with consistently high adherence acquired HIV (incidence rate, 0.13/100 person-years [95% CI, 0.02-0.92]). The incidence rate was 0.49 per 100 person-years (95% CI, 0.22-1.08) in the high but declining adherence group (n = 1166) and 1.27 per 100 person-years (95% CI, 0.53-3.04) in the consistently low adherence group (n = 632).

Conclusions and Relevance In a pooled analysis of 11 postapproval studies of F/TDF for PrEP among cisgender women, overall HIV incidence was 0.72 per 100 person-years; individuals with consistently daily or consistently high adherence (4-6 doses/week) to PrEP experienced very low HIV incidence.