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Antiretroviral Preexposure Prophylaxis for Preventing HIV Infection in High-Risk Individuals

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Clinical Question

Does antiretroviral preexposure prophylaxis reduce the risk of contracting human immunodeficiency virus (HIV) infection in high-risk individuals?

Evidence-Based Answer

For some groups of patients at greater risk of HIV infection (e.g., serodiscordant partners, men who have sex with men and engage in high-risk behaviors, persons with multiple concurrent sex partners, persons who exchange sex for money), preexposure prophylaxis decreased the risk of acquiring HIV infection (number needed to treat [NNT] = 56). (Strength of Recommendation: C, based on consensus, disease-oriented evidence, usual practice, expert opinion, or case series.)

Practice Pointers

In 2011, there were 34 million persons living with HIV infection and 1.7 million AIDS-related deaths around the world.¹ The burden of disease falls disproportionately on residents of sub-Saharan Africa, who comprise approximately two-thirds of all persons who are HIV positive.² Current efforts to prevent the spread of HIV involve surveillance programs, health communications strategies, efforts to reduce the rates of unprotected sex, needle exchange services, antiretroviral treatment, and vertical transmission prophylaxis.³ A promising additional method to prevent the spread of HIV infection involves preexposure prophylaxis.

This Cochrane review investigated the effects of preexposure prophylaxis in six randomized controlled trials involving 12,945 participants from the United States, South America, Southeast Asia, and Africa. Participants were given the reverse tran-

scriptase inhibitor tenofovir (300 mg) or tenofovir/emtricitabine (Truvada; 300/200 mg), or placebo daily. At baseline, participants had to be HIV negative and fall into at least one high-risk category.

In four studies (n = 8,918) comparing tenofovir/emtricitabine with placebo, patients in the intervention arm had a risk ratio of 0.51 (95% confidence interval [CI], 0.30 to 0.85) for contracting HIV. In two studies (n = 4,027) comparing tenofovir with placebo, patients in the intervention arm had a risk ratio of 0.38 (95% CI, 0.23 to 0.63) for becoming infected. The absolute risk reduction in the tenofovir/emtricitabine arm was 1.8% (NNT to prevent one infection = 56). In the tenofovir-only arm, the absolute risk reduction was 1.6% (NNT = 61). There were no differences in preventive effectiveness between males and females, nor was there a benefit of tenofovir/emtricitabine over tenofovir alone. Although study participants in the intervention and placebo groups reported high levels of adherence, two studies demonstrated lower detectable drug levels among those in the intervention arm who contracted HIV infection. Rates of serious adverse effects were similar among all groups (risk ratio = 1.00; 95% CI, 0.83 to 1.19). Changes in viral resistance patterns, a potential concern of widespread preexposure prophylaxis use, were not assessed.

The U.S. Food and Drug Administration has approved the combination of tenofovir/emtricitabine for preexposure prophylaxis in persons at high risk of contracting HIV. Based on its own review of the evidence, the Centers for Disease Control and Prevention (CDC) has offered guidance on which individuals to consider for preexposure prophylaxis: men who have sex with men and engage in high-risk behaviors (e.g., multiple partners in an HIV-endemic area, frequent partner changes) and heterosexual individuals in a serodiscordant relationship.^{4,5} Another group to consider based on this review is heterosexual persons with

multiple partners, including those working in the sex trade. The use of HIV preexposure prophylaxis is not universally accepted because of concerns about poor medication adherence and the potential development of resistance. In its guidance, the CDC stresses that preexposure prophylaxis should be part of a comprehensive program that includes safer-sex counseling, condom distribution, education, testing, and other established strategies to reduce the risk of HIV transmission.^{4,5}

The opinions and assertions contained herein are the private views of the author and are not to be construed as official or as reflecting the views of the U.S. Army Medical Department or the U.S. Army Service at large.

SOURCE: Okwundu CI, Uthman OA, Okoromah CA. Anti-retroviral pre-exposure prophylaxis (PrEP) for preventing HIV in high-risk individuals. *Cochrane Database Syst Rev*. 2012;7:CD007189.

The practice recommendations in this activity are available at <http://summaries.cochrane.org/CD007189>.

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