Very Low HIV Rate in Study of High-Risk Gays on PrEP

November 16, 2015 By Benjamin Ryan

A major, multi-site American real-world study of Truvada (tenofovir/emtricitabine) as pre-exposure prophylaxis (PrEP) among high-risk men who have sex with men (MSM) has seen a very low HIV rate despite a high rate of other sexually transmitted infections (STIs). Publishing their findings in JAMA Internal Medicine, researchers conducted a demonstration project study of 557 participants, almost all of whom were MSM while a small number were trans women, at two municipal STI clinics in San Francisco and Miami and a community health center in Washington, DC, from October 2012 through January 2014.

There was no evidence that taking PrEP led to a higher level of sexual risk-taking among the participants.

On the whole, the participants adhered very well to the daily Truvada regimen. African-Americans, participants in Miami, and those without stable housing were less likely to adhere well. Men reporting more sexual risk-taking were more likely to adhere.

The study provided free Truvada to the initially HIV-negative participants for 48 weeks, during which they were scheduled to return for clinic visits on weeks 4, 12, 24, 36 and 48—a schedule that, save the week-four visit, matched the quarterly visits required to maintain a PrEP prescription in everyday clinical practice. The participants also received regular HIV testing, brief client-centered counseling and clinical monitoring.

To qualify for the study, the participants reported any of the following during the previous year: condomless anal sex with at least two male or trans female partners; at least two occasions of anal sex with at least one HIV-positive partner; or sex with a male or trans female partner and a diagnosis of syphilis, rectal gonorrhea or chlamydia.

The investigators measured adherence to Truvada through dried blood spot samples, which were collected from the participants at all clinic visits. Levels of the tenofovir component were measured in about 100 randomly selected participants from each study site. Additionally, the researchers decided to test the drug concentrations of all the African-American and trans participants, since there were disproportionately low numbers of them in the study.

A total of 437 of the participants (78.5 percent) stayed through to the end of the 48-week study,

including 383 (68.8 percent) who made all five study visits. The group that stayed through the whole study included five trans women (71.4 percent of the trans women who started the study) and two individuals with a sex categorized as "other" (100 percent of those who started). Broken down by race, 25 African-American (62.5 percent), 139 Latino (72.4 percent) and 226 white participants (85 percent) completed the study. The study had a total follow-up of 481 person-years (person years are the cumulative years participants spend in a study follow-up period).

Two participants contracted HIV during the follow-up, for an incidence of 0.43 per 100 person-years. Both had tenofovir levels at the time indicating they were taking fewer than two tablets per week around the time they contracted the virus. The first individual contracted HIV about 19 weeks after entering the study and the second was diagnosed about four weeks after the end of the study, at which point Truvada was no longer dispensed to participants.

Because there is no comparison, or control, group in this study, it was not set up to estimate an effectiveness level of PrEP.

Adherence tests showed that the rate of participants who were taking four or more tablets of Truvada per week, which research has shown confers maximum protection against HIV, ranged between 80 and 86 percent, a much higher level than was seen in the global 2010 iPrEx study of PrEP given to MSM or its open-label extension (OLE) phase, published in 2014. In the latter trial, participants took at least four tablets per week only 33 percent of the time. (However, Americans adhered much better than the global average in iPrEx OLE.)

The participants' level of sexual risk-taking did not change as a result of receiving a Truvada prescription. This finding is in line with all of those seen in major studies of PrEP among MSM, but runs contrary to the findings in a recent study of MSM in a large PrEP program in San Francisco. At the outset of this new study, 365 participants (65.5 percent) reported having had condomless receptive anal intercourse during the previous three months. This rate remained stable through the study. A total of 147 participants (26.4 percent) had early syphilis, rectal gonorrhea or chlamydia at the beginning of the study. The STI infection rate was stable across the subsequent study visits. Half of all participants were diagnosed with at least one STI during the follow-up period.

After adjusting the data with regards to the rate of those taking four or more tablets of Truvada per week, the researchers found that participants in Miami were 68 percent less likely than those in San Francisco to adhere well; African-Americans were 72 percent less likely to adhere well than whites; those without stable housing were about half as likely to adhere well as those with stable housing; and those who reported having condomless anal sex with at least two partners during the previous month were 82 percent more likely to adhere well than those who reported zero or one such sexual encounters.

Because of the low proportion of African-American participants, the study's findings about this group are not necessarily generalizable to the broader MSM population. However, a previous study of young MSM found a very poor level of adherence among African-American participants.

The researchers of this new study concluded, “These results provide support for expanding PrEP implementation in MSM in similar clinical settings and highlight the urgent need to increase PrEP awareness and engagement and to develop effective adherence support for highly affected African American and transgender population."

To read the study abstract, click here.

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http://beta.docker.poz.com/article/PrEP-demo-28046-9866