U.S. Women Prefer a Pill Over a Vaginal Gel for Prevention

March 4, 2011 By David Evans

U.S. women involved in a study comparing the safety, blood levels and acceptability of two methods of pre-exposure prophylaxis (PrEP) to prevent HIV transmission—an oral version of the antiretroviral (ARV) drug tenofovir and a vaginal gel version—strongly preferred the pill over the gel. These data were presented Monday, February 28, at the 18th Conference on Retroviruses and Opportunistic Infections (CROI) in Boston.

Two large studies last year offered the first unambiguously positive results of a biomedical effort to prevent HIV transmission. The CAPRISA 004 study found that women who used a vaginal gel containing tenofovir—typically used to treat HIV and found in Viread, Truvada and Atripla—cut HIV transmission by 39 percent. Several months later, the first trial studying tenofovir plus emtricitabine (Truvada) taken orally every day found that it cut HIV infections in men who have sex with men (MSM) and transgender women by 44 percent.

Further oral PrEP studies, either with tenofovir alone (as Viread) or as Truvada, are ongoing in a variety of populations, and further trials of the tenofovir gel are planned—both as vaginal and rectal gels. In the meantime, researchers have been curious to learn as much as they can about both methods outside of large clinical trials. Craig Hendrix, MD, from the Johns Hopkins University in Baltimore presented data on one such study.

That study, Microbicide Trials Network 001 (MTN-001), was the first study to do a head-to-head comparison of oral versus vaginal daily PrEP with tenofovir. The study looked at three factors: the acceptability of the two methods in HIV-negative women, the level of adherence to the two methods, and the blood and vaginal drug concentrations that occurred with either dosing strategy or both oral and vaginal PrEP taken together.

Hendrix and his colleagues enrolled 144 sexually active women, ages 18 to 45 at seven sites: one in Uganda, two in South Africa and the rest in the United States. In the study, all of the women ultimately took six weeks of oral PrEP, six weeks of vaginal gel and six weeks of both methods together.

Overall, there were no differences in serious side effects with any of the methods. The only difference was an increased likelihood of mild headache and nausea with oral tenofovir compared with the vaginal gel.

In terms of drug concentrations, they fell along expected lines. Researchers have hypothesized that the prevention potential of either method will rest on the drug's ability to be taken up into the cells in the vagina more so than the cells elsewhere. This was the case with the gel, where vaginal cell concentrations of tenofovir were 100 times higher when women used the gel compared with when they took the drug orally. When the women took the drug both orally and by vaginal application, vaginal drug levels were no higher than when women used the gel alone.

Researchers have also been keen on ensuring that tenofovir won't get absorbed into the blood stream too much when the gel, rather than the pill, is used. The concern is two-fold: first, that higher blood levels could result in side effects and second, that if a person were to become infected while taking the gel, having lower blood levels might reduce the chance of the person's virus becoming resistant to tenofovir.

Given that studies have not yet determined the minimum effective concentrations of tenofovir required in vaginal cells to offer protection it is unclear what these study results will mean in the real world.

Overall, however, actual adherence was pretty lousy. By self-report, women reported taking 94 percent of their doses correctly, whether using the gel or the pill. As was noted in the iPrEx study, people often dramatically overstate their actual adherence. When blood and tissue levels of tenofovir were taken, it became clear that between 35 and 65 percent of the women did not take their doses correctly.

Overall, women indicated that they were somewhat more likely to prefer the pill over the gel (93 percent compared with 83 percent). However, geography played a huge roll in determining preference. Women in the United States preferred the pill to the gel by a fairly wide margin—with 72 percent saying they'd use the pill and only 14 percent saying they'd use the gel—whereas 99 percent of African women said they would gladly use either.

This difference could have resulted at least somewhat from differences in perception about the value of the gel. For instance, the majority of African women reported that the gel enhanced their sexual pleasure, which was not the case in the U.S. women.

Hendrix concluded that more work will be needed to determine minimum levels of adherence and blood, vaginal and rectal concentrations of tenofovir needed to achieve protection.

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