Vaginal Ring Shows Promise as HIV Prevention Tool Women Will Use

Poised for regulatory approval, the monthly vaginal ring appeared to lower the risk of HIV by about 39% overall in a recent study.

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Just as an antiretroviral (ARV)-infused vaginal ring stands at the threshold of regulatory approval, a new study raises hopes that women will indeed use the new HIV prevention tool. The addition of the ring to the HIV prevention armamentarium could prove vital to women compelled to keep secret from their sexual partners their efforts to avoid acquiring the virus.

Jared Baeten, MD, PhD, a professor of global health, medicine and epidemiology at the University of Washington in Seattle, presented the final findings from the Phase IIIb HIV Open-Label Extension (HOPE) study at the 10th International AIDS Society Conference on HIV Science in Mexico City (IAS 2019).

Also known as MTN-025, the study of women in southern and eastern Africa investigated a ring infused with the ARV dapivirine. It is meant to be inserted into the vagina and worn continuously for four weeks before being swapped out for a new one.

The European Medicines Agency is currently reviewing the ring for possible regulatory approval.

In 2016, two previous studies, ASPIRE and The Ring Study, indicated that the ring reduced the risk of HIV by about 30% overall among women 18 to 45 years old. The ring proved well tolerated.

The HOPE study enrolled 1,456 people—representing 59% of the former ASPIRE study participants who remained HIV negative—at 14 sites in Malawi, South Africa, Uganda and Zimbabwe. These women had remained free of HIV, were sexually active and ranged between 20 and 49 years old. They had a median age of 31 years old, and 12% were younger than 25. Forty-seven percent were married, and 43% used a condom during their last sex act. Women who were pregnant or breastfeeding were not eligible to use the ring.

In contrast to the ASPIRE trial, during which participants did not know whether they were receiving dapivirine-infused rings or placebo rings, those who continued into HOPE all knew they were receiving rings infused with active drug. For the first three months, the women made monthly visits at which they received a single new ring; thereafter, they returned quarterly and received a

set of three rings each time, just as they would in a real-world setting should the ring be approved.

Women were permitted to remain in HOPE regardless of whether they decided to use the ring, which 92% of the participants did at the outset. At each subsequent study visit, the proportion of the cohort still using the ring declined, reaching 79% at the nine-month mark.

The study authors determined the women's adherence to the monthly ring regimen by measuring the amount of dapivirine remaining in each ring the women returned at their study visits. Ninety percent of the returned rings had been depleted of the ARV to the extent that they likely had been used for at least some of the previous month. This was an improvement from the ASPIRE study, in which 77% of the returned rings had likely been used at least some of the time.

By the 12-month mark, 98% of the women remained in the study; 73% accepted use of the ring for the entire follow-up period. The most common reasons for declining the ring was having chosen another HIV prevention method. All told, the participants made 8,436 follow-up visits.

During this yearlong period, 35 (2.7%) of the women in the trial contracted HIV, for an infection rate of 2.7 cases per 100 cumulative years of follow-up. Because there was no control group, the HOPE study authors could not precisely determine the efficacy of the ring. Using the infection rate seen in the ASPIRE placebo group as a comparison, they estimated that without the ring, the women in HOPE would have contracted the virus at an annual rate of 4.4%. Consequently, they estimated that the vaginal ring reduced the risk of HIV by 39% overall.

This figure does not necessarily indicate what the ring's efficacy would be when women adhere perfectly to the regimen. Imperfect adherence or nonuse of the ring among certain women in HOPE may have dragged down the efficacy rate for the group as a whole, meaning that the ring's actual capacity to prevent HIV acquisition when used perfectly may be higher than 39%.

To read the study abstract, click here.

To read a press release about the study, click here.

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http://beta.docker.poz.com/article/vaginal-ring-shows-promise-hiv-prevention-tool-women-will-use