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Women report experimental vaginal ring for HIV prevention did not negatively affect sexual experience

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Most women who used an experimental vaginal ring for HIV prevention report that the physical act of sex was largely unaffected by using the product, which is inserted monthly for continuous wear. This finding is among several insights gleaned about experiences of women who used the ring during the ASPIRE study, also known as MTN-020, announced today at the HIV Research for Prevention (HIVR4P) meeting in Chicago.

ASPIRE evaluated whether the ring, which continuously releases the anti-HIV drug dapivirine, could safely reduce HIV infection among 2,629 women aged 18-45 years living in Malawi, South Africa, Uganda and Zimbabwe. Among participants randomized to receive the dapivirine ring, risk of HIV infection fell by 27 percent. A further analysis found that the ring reduced the risk of HIV infection by at least 56 percent among women who used it with greater frequency, and up to 75 percent or higher among those who used it consistently. Further exploration of the ring's clinical potential began in July 2016 through the large-scale HOPE (HIV Open-Label Prevention Extension) study, also known as MTN-025. ASPIRE, HOPE and their ancillary studies were primarily funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The nonprofit International Partnership for Microbicides developed the dapivirine ring and supplied it for the studies.

"Women need an HIV prevention modality that offers safe, effective protection and is practical for use in their daily lives," said NIAID Director Anthony S. Fauci, M.D. "Women enrolled in the MTN-020/ASPIRE study reported that the experimental vaginal ring generally did not interfere with sexual intercourse, which is an encouraging sign that this product could appeal to a larger group of women at risk for HIV infection."

The ASPIRE study staff interviewed 214 participants who used the ring to obtain qualitative data about their sexual experiences during the trial. A team led by Nicole Laborde, Ph.D., M.P.H., of RTI International in Research Triangle Park in North Carolina, analyzed the participant responses. While most of these women found that the ring did not negatively affect the physical act of sex, some women said they were continually preoccupied with how their partners would react if they felt or discovered the ring. To address this issue, some women removed the ring before sex, a practice not recommended by study investigators. Other women limited sexual activities that they believed might heighten their partners' awareness of the ring, such as certain sexual positions and receptive oral or digital sex.

Some women reported greater sexual satisfaction partially due to perceived protection provided by the ring. Other women reported diminished sexual pleasure associated with the worry that their male partners would notice the ring during sex.

Additional analyses of the ASPIRE data revealed other patterns of experience among study participants. Because women who face intimate partner violence and other social harms more often find it difficult to adhere to the clinically proven once-daily antiretroviral drug Truvada as pre-exposure prophylaxis, or PrEP, researchers investigated the connection between consistent use of the ring and these issues. While fewer than 5 percent of all ASPIRE study participants reported incidents of intimate partner-related violence or other social harms, women who did report violence or social harm within a month of the interview were nearly 2.5 times more likely to have low adherence to the ring. Younger age at enrollment, having a new primary partner and not disclosing study participation or ring use to the primary partner were significantly associated with reporting social harms. These findings, reported by a team led by Thesla Palanee-Phillips, M.Med.Sci, Ph.D., M.Sc., at the Wits Reproductive Health and HIV Institute in Johannesburg, South Africa, indicate that more research is needed to determine strategies to mitigate low adherence in the context of intimate partner violence and other social harms in future studies of female-controlled prevention methods.

The potential for women to suffer social harm and violence by sexual partners, along with other qualitative data from HIV prevention studies, suggest that some women may prefer methods of HIV protection undetectable by sexual partners. Additional new data revealed that a majority of women--64 percent--disclosed the use of the ring to their male partners at the outset of the study, while 13 percent of study participants never revealed that they were using the ring. The investigators, led by Lulu Nair, M.B.Ch.B., M.P.H., of the Desmond Tutu HIV Centre at the University of Cape Town, found that neither disclosing nor concealing use of the ring affected women's adherence to

the product.

"Sub-Saharan African women have a broad range of sexual experiences and relationship dynamics, and we are learning more about how these diverse behaviors and circumstances influence the use of the ring," said Dr. Palanee-Phillips, director of Network trials at the Wits Reproductive Health and HIV Institute in Johannesburg, South Africa and protocol co-chair on the ASPIRE study. "While we have found that most women do disclose ring use to their primary partners, it is reassuring that adherence is not affected for the significant minority of women who choose to use it more discreetly."

Researchers led by Ariane van der Straten, Ph.D., M.P.H., of RTI International also found that women's concerns about using an experimental vaginal ring for HIV prevention decreased significantly over the course of the study. At clinical visits, women were asked, "How worried are you about having a vaginal ring inside you every day for at least a year?" While 29 percent of women reported this concern at the start of the study, only 4 percent of participants did so at their final follow-up clinic visit. Specific concerns related to use, health, hygiene, sexual enjoyment and social approval also decreased significantly between the start and the end of the study.

As research on the ring continues in the HOPE study, investigators will collect both quantitative and qualitative data from women at risk for HIV infection. All participants in HOPE will receive access to a package of HIV prevention services, including condoms, partner testing and counseling, and will be able to stay in the study regardless of whether or not they choose to accept the ring after their initial clinic visit. The study investigators believe this approach will shed light on the critical questions of whether participants like using the ring, and why.

Source:
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