TUAC0203 - Oral Abstract

TITLE
High adherence and sustained impact on HIV-1 incidence: Final results of an open-label extension trial of the dapivirine vaginal ring

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Background: Phase III clinical trials (MTN-020/ASPIRE & IPM 027/The Ring Study) showed that a monthly vaginal ring containing 25 mg dapivirine was well-tolerated and reduced HIV-1 incidence by approximately 30% compared to placebo. This abstract presents the final results of MTN-025/HOPE, one of the two phase IIIb open-label extension trials of the dapivirine vaginal ring.

Methods: HOPE initiated in July 2016 and concluded in August 2018. HIV-1 uninfected women who had participated in ASPIRE were offered 12 months of access to the dapivirine vaginal ring at 14 sites in Malawi, South Africa, Uganda, and Zimbabwe. Used rings were returned at each study visit (monthly for 3 months, then quarterly) and were tested for residual levels of dapivirine. HIV-1 serologic testing was done at each visit and archived, frozen plasma samples, collected quarterly, were tested for HIV-1 RNA to more precisely define incident infection, and infections occurring after enrollment and through the Month 12 visit were considered to have occurred on study. HIV-1 incidence was compared to that expected by weighted bootstrap sampling of the placebo arm of ASPIRE, matched on trial site, age, and presence of a curable sexually transmitted infection at trial entry; a limitation is lack of a contemporaneous placebo group in this open-label trial.

Results: A total of 1456 women enrolled into HOPE. The median age was 31 years. At baseline, 1342 (92%) accepted the dapivirine vaginal ring; ring acceptance remained high: 90%, 89%, 87%, 83%, and 79% at Months 1, 2, 3, 6, and 9. 86% of returned rings had residual dapivirine levels consistent with some use during the prior month (>0.9 mg released). A total of 35 HIV-1 infections were observed (incidence 2.7 per 100 person-years, 95% CI 1.9-3.8). Expected HIV-1 incidence was 4.4 per 100 person-years (95% CI 3.2-5.8) in the absence of access to the dapivirine vaginal ring, and an incidence of 2.7 would be expected to occur in fewer than 33 in 10,000 samplings (0.33%).

Conclusions: Final results from this open-label extension trial of the dapivirine ring indicate high uptake and lower than anticipated HIV-1 incidence in this high-risk population.

More information