

Oral Abstract Session: Track A and C Late Breaker Session

WESS304 - The diaphragm and lubricant gel for prevention of HIV acquisition in Southern African women: results of a randomized controlled trial

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Objectives: Female-controlled HIV prevention methods are an urgent priority. We evaluated the effect of providing All-flex[®] latex diaphragm, Replens[®] lubricant gel and condoms (intervention) compared to condoms-alone (control) on HIV seroincidence in women.

Methods: We conducted an open-label, randomized controlled trial among 4948 HIV-negative, sexually-active women at three sites in South Africa and Zimbabwe. Women were followed quarterly for 12 to 24 months to assess HIV-status, product use, and adverse events. HIV-seroincidence was compared between study arms by intent-to-treat (ITT), per-protocol, and direct effects analyses, controlling for study sites.

Results: Baseline characteristics were balanced between arms: almost 80% of the sample was under 35 years of age, and reported an average of 2.2 lifetime sexual partners, 67% currently lived with their partner, 59% were married, 56% earned income, and 44% graduated from high school. Only 3 women had ever used a diaphragm, 87% had ever used condoms. Retention rate was over 92%, and we observed an overall HIV incidence of 4.0% per 100 woman-years. Arm-specific incidence and relative hazard by intent-to-treat and other types of analysis will be reported at the meeting. Over the course of the study, women in the intervention arm reported diaphragm use at last sex 73% of the time. Overall, condom use at last sex was reported 69% of the time. The proportions of participants reporting adverse events (60.4% vs. 60.7%) and serious adverse events (5.1% vs. 4%) were similar between arms.

Conclusion: The trial was successfully implemented, and study product uptake was high. The effects of providing the diaphragm and lubricant gel in addition to provision of a comprehensive HIV prevention package will be discussed at the meeting.

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