Sexually transmitted infections may play an important role in mediating the effect of microbicides in Phase III trials

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ABSTRACT TEXT

Introduction:
Sexually Transmitted Infections (STIs) are important co-factors in HIV transmission. Microbicides which are effective against STIs, in addition to HIV, may have a greater effect against HIV. During the Microbicide Development Programme feasibility study in Johannesburg, we measured the prevalence of STIs at enrolment to determine which STIs were strongly associated with HIV acquisition.

Methods:
752 HIV-negative, sexually active women consented to enrolment and follow-up over 12 months in a prospective cohort study. At enrolment, participants were interviewed regarding sexual behaviour, condom use and genital symptoms. Following pelvic examination, cervical swabs were tested by PCR for C. trachomatis (CT), and N. gonorrhoea (NG). Vaginal swabs were cultured for T. vaginalis (TV), and bacterial vaginosis was diagnosed on gram stain. Blood was collected for syphilis and herpes simplex type 2 (HSV-2) serology.

Results:
Participants contributed a total of 590 person-years of follow-up. 21 women seroconverted to HIV, resulting in an HIV incidence of 3.56/100 person years. BV, TV, CT and GC were diagnosed in 52%, 32%, 12% and 2.2% of all participants at enrolment. In addition, 2.4% RPR positive and 53% HSV-2 seropositive at enrolment. In an unadjusted analysis, NG (OR 5.93, p=0.012), HSV-2 (OR 2.86, p=0.034) and CT (OR 2.71, p=0.05) were associated with an increased risk of HIV acquisition. Results of the adjusted analysis will be presented.

Conclusions:
In an unadjusted analysis, NG, CT and HSV-2 were associated with HIV acquisition. Certain microbicides, like PRO-2000 have been shown to have activity against these STIs. During the Phase III trials of new microbicides, it will be important to measure the effectiveness of these products of HIV both directly, but also indirectly through their effect on STIs which facilitate HIV transmission.

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