Monthly antibiotic chemoprophylaxis and incidence of sexually transmitted infections and HIV-1 infection in Kenyan sex workers: a randomized controlled trial.


Abstract

CONTEXT:
Sexually transmitted infections (STIs) are common in female sex workers (FSWs) and may enhance susceptibility to infection with human immunodeficiency virus type 1 (HIV-1).

OBJECTIVE:
To examine regular antibiotic prophylaxis in FSWs as a strategy for reducing the incidence of bacterial STIs and HIV-1.

DESIGN, SETTING, AND PARTICIPANTS:
Randomized, double-blind, placebo-controlled trial conducted between 1998-2002 among FSWs in an urban slum area of Nairobi, Kenya. Of 890 FSWs screened, 466 who were seronegative for HIV-1 infection were enrolled and randomly assigned to receive azithromycin (n = 230) or placebo (n = 236). Groups were well matched at baseline for sexual risk taking and STI rates.

INTERVENTION:
Monthly oral administration of 1 g of azithromycin or identical placebo, as directly observed therapy. All participants were provided with free condoms, risk-reduction counseling, and STI case management.

MAIN OUTCOME MEASURES:
The primary study end point was incidence of HIV-1 infection. Secondary end points were the incidence of STIs due to Neisseria gonorrhoeae, Chlamydia trachomatis, Trichomonas vaginalis, Treponema pallidum, and Haemophilus ducreyi, as well as bacterial vaginosis. Analysis of herpes simplex virus type 2 (HSV-2) infection was performed post hoc.

RESULTS:
Seventy-three percent of participants (n = 341) were followed up for 2 or more years or until they reached an administrative trial end point. Incidence of HIV-1 did not differ between treatment and placebo groups (4% [19 cases per 473 person-years of follow-up] vs 3.2% [16 cases per 495 person-years of follow-up] rate ratio [RR], 1.2; 95% CI, 0.6-2.5). Incident HIV-1 infection was associated with preceding infection with N gonorrhoeae (rate ratio [RR], 4.9; 95% CI, 1.7-14.3) or C trachomatis (RR, 3.0; 95% CI, 1.1-8.9). There was a reduced incidence in the treatment group of infection with N gonorrhoeae (RR, 0.46; 95% CI, 0.31-0.68), C trachomatis (RR, 0.38; 95% CI, 0.26-
0.57), and T vaginalis (RR, 0.56; 95% CI, 0.40-0.78). The seroprevalence of HSV-2 infection at enrollment was 72.7%, and HSV-2 infection at baseline was independently associated with HIV-1 acquisition (RR, 6.3; 95% CI, 1.5-27.1).

CONCLUSIONS:

Despite an association between bacterial STIs and acquisition of HIV-1 infection, the addition of monthly azithromycin prophylaxis to established HIV-1 risk reduction strategies substantially reduced the incidence of STIs but did not reduce the incidence of HIV-1. Prevalent HSV-2 infection may have been an important cofactor in acquisition of HIV-1.