Lack of correlation of maternal human immunodeficiency virus infection with neonatal malformations.

OBJECTIVE—To determine the efficacy of the nonoxynol 9 contraceptive sponge in preventing sexual acquisition of the human immunodeficiency virus (HIV). DESIGN—Prospective, randomized placebo-controlled trial. SETTING—Research clinic for prostitutes in Nairobi, Kenya. PATIENTS AND INTERVENTIONS—One hundred thirty-eight HIV-seronegative women were enrolled, of whom 74 were assigned to nonoxynol 9 sponge use and 64 to placebo use. These two groups did not significantly differ with respect to demographic characteristics, sexual practices, or prevalence of genital infections at enrollment, except for a lower number of sex partners per week and a higher initial prevalence of genital ulcers among women assigned to nonoxynol 9 sponge use. Among the 116 women who returned for follow-up, the mean durations of follow-up were 14 and 17 months for the two groups, respectively. MAIN OUTCOME MEASURE—HIV seroconversion. RESULTS—Nonoxynol 9 sponge use was associated with an increased frequency of genital ulcers (relative risk [RR], 3.3; P less than .0001) and vulvitis (RR, 3.3; P less than .0001) and a reduced risk of gonococcal cervicitis (RR, 0.4; P less than .0001). Twenty-seven (45%) of 60 women in the nonoxynol 9 sponge group and 20 (36%) of 56 women in the placebo group developed HIV antibodies. The hazard ratio for the association between nonoxynol 9 sponge use and HIV seroconversion was 1.7 (95% confidence interval [CI], 0.9 to 3.0). Using multivariate analysis to control for the presence of genital ulcers at enrollment, the adjusted hazard ratio for the association between nonoxynol 9 sponge use and seroconversion was 1.6 (95% CI, 0.8 to 2.8). CONCLUSIONS—Genital ulcers and vulvitis occurred with increased frequency in nonoxynol 9 sponge users. We were unable to demonstrate that nonoxynol 9 sponge use was effective in reducing the risk of HIV infection among highly exposed women.