Abstracts of current literature on epidemiology, diagnosis, and treatment

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A CONTROLLED TRIAL OF HUMAN PAPILLOMAVIRUS TYPE 16 VACCINE

A double-blind, multicenter, randomized clinical trial was conducted to determine whether a human papillomavirus type 16 (HPV-16) vaccine could prevent HPV-16 infection in women. Female subjects (N = 2392) age 16 to 23 years were randomly assigned to receive 3 injections of either HPV-16 vaccine or placebo at day 0, month 2, and month 6. Genital samples to test for HPV-16 DNA were obtained at enrollment, 1 month after the third vaccination, and every 6 months thereafter. Women were referred for colposcopy according to a protocol, and those with abnormal results underwent biopsy. The primary end point was persistent HPV-16 infection, defined as the detection of HPV-16 DNA in samples obtained at 2 or more visits. The primary analysis was limited to 1533 women who were negative for HPV-16 DNA and HPV-16 antibodies at enrollment and for HPV-16 DNA at month 7; women were followed for a median of 17.4 months. The incidence of persistent HPV-16 infection was 3.8 per 100 woman-years at risk in the placebo group and 0 per 100 woman-years at risk in the vaccine group ($P < 0.001$). Nine cases of HPV-16–related cervical intraepithelial neoplasia occurred among placebo recipients. The authors concluded that the administration of the HPV-16 vaccine reduced the incidence of HPV-16 infection and HPV-16–related cervical intraepithelial neoplasia and that immunizing HPV-16–negative women may eventually reduce their risk for cervical cancer.

Koutsky LA, Ault KA, Wheeler CM, et al. A controlled trial of a human papillomavirus type 16 vaccine. N Engl J Med 2002;347: 1645–51.

GLYCOPROTEIN D–ADJUVANT VACCINE AGAINST GENITAL HERPES

Two double-blind, randomized trials evaluated a herpes simplex virus type 2 (HSV-2) glycoprotein D–subunit vaccine containing aluminum hydroxide and 3-*O*-deacylated monophosphoryl lipid A in subjects whose regular sexual partners had a history of genital herpes to determine its efficacy in preventing genital herpes acquisition. In study 1, subjects were seronegative for herpes simplex virus type 1 (HSV-1) and HSV-2, and in study 2, subjects were of any HSV serologic status. The primary end point was the occurrence of genital herpes disease in all subjects in study 1 and in HSV-2–seronegative female subjects in study 2. A total of 847 subjects who were seronegative for HSV-1 and HSV-2 (study 1) and 1867 subjects who were seronegative for HSV-2 (study 2) underwent randomization and received injections. The overall efficacy of the vaccine was 38% in study 1; in study 2, efficacy in all female subjects was 42%. Further analysis showed that the vaccine was effective in women who were seronegative for both HSV-1 and HSV-2; efficacy in study 1 was 73% ($P = 0.01$), and efficacy in study 2 was 74% ($P = 0.02$). Researchers concluded that the vaccine has efficacy against genital herpes disease in women who are seronegative for both HSV-1 and HSV-2 at baseline but not in women who are seropositive for HSV-1 and seronegative for HSV-2 at baseline or in men.

Stanberry LR, Spruance SL, Cunningham AL, et al. Glycoprotein-D–adjuvant vaccine to prevent genital herpes. N Engl J Med 2002; 347:1652–61.

SEROPREVALENCE OF HUMAN PAPILLOMAVIRUS TYPE 16 INFECTION

A study investigated the US seroepidemiology of HPV-16 infection—the cause of approximately 50% of cervical cancers worldwide—using serum samples collected from 1991 through 1994 for the National Health and Nutrition Examination Survey. Of the 9629 subjects who had participated in the original survey in the 12- to 59-year-old age group, 7476 (77.6%) agreed to have their serum samples tested, and 7218 serum samples were available for HPV-16 testing. Logistic regression analysis was used to determine variables independently associated with HPV-16 antibodies in sexually active men and women. Overall, 13% of study participants had antibodies to HPV-16; seroprevalence was significantly higher in women (17.9%) than in men (7.9%). In female participants, seroprevalence increased to 24.7% at age 20 to 29 years; seroprevalence peaked (11.5%) at age 30 to 39 years in men. Besides age, HPV-16 seropositivity was associated in women with race/ethnicity, education level, alcohol and drug use, early age at first sexual intercourse, number of lifetime sex partners, oral contraceptive use, and herpes simplex virus seropositivity and in men with race/ethnicity, marital status, poverty index, residence, age at first sexual intercourse, years of sexual activity, number of lifetime sex partners, and homosexual intercourse. The authors concluded that their data have public health implications for the development of cervical cancer prevention and control strategies and that such national HPV seroprevalence data should be valuable for HPV vaccine research and implementation.

Stone KM, Karem KL, Sternberg MR, et al. Seroprevalence of human papillomavirus type 16 infection in the United States. J Infect Dis 2002; 186:1396–402.

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