

HPV Vaccine Reduced Abnormal Pap Results

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FROM THE ANNUAL MEETING OF THE
AMERICAN COLLEGE OF OBSTETRICIANS
AND GYNECOLOGISTS

SAN FRANCISCO — A vaccine for human papillomavirus decreased the risk for cytologic abnormalities over a 3-year period by 56%-68%, compared with placebo vaccine, a secondary analysis of data on 17,347 women in a phase III clinical trial found.

The analysis looked at vaccination with all three doses of Cervarix, the atropine sulfate–adjuvanted vaccine for human papillomavirus types 16 and 18 (HPV-16/18), in 8,665 young, predominantly sexually active women compared with a control group of 8,682 women who got hepatitis A vaccine.

The primary results of the Papilloma Trial Against Cancer in Young Adults (PATRICIA), reported last year, showed the vaccine was highly prophylactic against grade II cervical intraepithelial neoplasia (CIN2) associated with HPV-16/18 and against several oncogenic non-vaccine types of HPV (Lancet 2009;374:301-14).

Dr. Mark G. Martens reported on a secondary end point built into the PATRICIA trial to assess vaccine efficacy in preventing abnormal Pap smear results and

VITALS

Major Finding: Irrespective of HPV type, the vaccine reduced the risk for ASCUS by 8%, the risk for LSILs by 14%, and the risk for HSILs by 41%. The risk for CIN2 and CIN3 was 30% and 33% lower than in the control group.

Data Source: Secondary analysis of data on 17,347 women from a phase III efficacy trial in 14 countries.

Disclosures: Dr. Martens has been a consultant for and received research funds, honoraria, and conference sponsorship from Merck & Co. and from GlaxoSmithKline Biologicals, which makes the vaccine and funded the study.

subsequent reduction in colposcopy referrals and cervical excision procedures.

Cervical samples were collected every 6 months for HPV DNA genotyping, and the women underwent yearly gynecology and cytologic examinations. The rate of atypical squamous cells of undetermined significance (ASCUS) with HPV-16/18 was 57% lower in the vaccine group compared with the control group during 3 years of follow-up, said Dr. Martens, who conducted the analysis while at Oklahoma State University, Tulsa, and now practices at Jersey Shore University Medical Center, Neptune, N.J.

The rate of low-grade squamous intraepithelial lesions (LSILs) with HPV-16/18 was 68% lower than in the control group, and the rate of high-grade squamous intraepithelial lesions (HSILs) with HPV-16/18 was 56% lower than in the

control group, he said at the meeting.

Absolute rates of ASCUS with HPV-16/18 were about 2% in the vaccine group and 4% in the control group. LSILs with HPV-16/18 were detected in 2% of the vaccine group and 6% of the control group. HSILs with HPV-16/18 were present in 0.2% of the vaccine group and 0.5% of the control group.

There was a statistically significant difference between groups for HSILs with HPV-16 (0.1% in the vaccine group vs. 0.4% in the control group) but not for HSILs with HPV-18 (0.05% and 0.1%).

Irrespective of HPV type, the vaccine reduced the risk for ASCUS by 8%, the risk for LSILs by 14%, and the risk for HSILs by 41%, he added.

The risk for CIN2 and CIN3 was 30% and 33% lower than in the control group. “That means the lesions we’re going to

act upon”—HSILs, CIN2, and CIN3—“were 30%-40% lower with the vaccine,” Dr. Martens said.

HSILs were found in 0.5% of the vaccine group, irrespective of HPV type, and 0.9% of the control group. CIN2 was detected in 2.5% of the vaccine group and 3.7% of the control group. The rate of CIN3 was 0.8% in the vaccine group and 1.3% in the control group.

Compared with the control group, colposcopy referrals were reduced by 10% and cervical excision procedures were reduced by 25% in the vaccine group, he reported.

Dr. Martens said he did an extra calculation for one state—Ohio—and estimated that each physician performing Pap smears in the state would see 20 fewer cases of CIN2/3 per year if patients were vaccinated. Nationally, the vaccine could result in 5 million fewer Pap smears per year because there would be less abnormal cytology, he added.

Women were included in the analysis regardless of their HPV DNA status, HPV serostatus, or cytology at baseline. Evidence of past or current infection with HPV-16/18 was present at baseline in 26% of women, but only 98 participants (less than 1%) were DNA positive for both HPV-16 and HPV-18. ■

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