

HPV Vaccine Cuts Abnormal Pap Smears in 4 Years

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Senior Editor

Abnormal Pap tests and cervical procedures have already declined markedly among young women who were vaccinated against the human papillomavirus in three pivotal clinical trials, according to data presented in Tampa at the annual meeting of the Society of Gynecologic Oncologists.

Comparison of 4,696 vaccinated women with 4,759 women in placebo groups showed reductions of 19% in colposcopy, 22% in cervical biopsy, and 42% in excisional therapy at an average follow-up of 3.3 years after the first dose of the quadrivalent vaccine (Gardasil/Silgard) against human papillomavirus (HPV) types 6, 11, 16, and 18.

Beyond the immediate benefit in reduced anxiety for women and costs for insurers, the results suggest the vaccine can deliver on the promise of preventing cervical cancer, investigator Dr. Warner K. Huh said in an interview. At least 20 years of follow-up are needed to see the impact of HPV prevention on cervical cancer.

"In the course of a lifetime, one in three women in the United States will have an abnormal Pap smear," said Dr. Huh of the University of Alabama, Birmingham.

He estimated the cost of screening of cervical abnormalities as more than \$2 billion a year in the United States. When the cost of treating cervical abnormalities is added, the bill comes to about \$4 billion, according to the SGO.

The end-of-study data reported came from three large efficacy trials sponsored by Merck & Co., maker of the vaccine. All told, the studies randomized 18,150 women aged 16-26 years to the vaccine or a placebo. Participants had cervicovaginal sampling and Pap smears on their first day in the studies and were followed with Pap smears every 6-12 months for up to 48 months. Median follow-up was 4 years from day 1.

The analysis of abnormal Pap results covered findings due to any HPV type and not just the targets of the vaccine. Dr. Huh said previous research suggests the vaccine provides some cross-protection though this has not been defined. The comparison of abnormal Pap results in-

cluded 4,870 vaccinated women and 4,758 women given a placebo.

The most dramatic reduction was 43% in high-grade squamous intraepithelial lesions (HSILs) seen on Pap smears. Although the drop was substantial, the numbers were small with only 41 cases in the placebo group and 24 among vaccinated women. Low-grade squamous intraepithelial lesions (LSIL) declined by 14%, occurring in 864 vaccinated women vs. 1,000 women on placebo. Other re-

ductions in abnormal Pap tests included:

- ▶ A drop of 16% in atypical squamous cells of undetermined significance that were high-risk positive (meaning positive for one of the 13 cancer-causing HPV types for which the sample was tested), LSIL, or worse (1,062 women in the vaccine group vs. 1,226 on placebo).

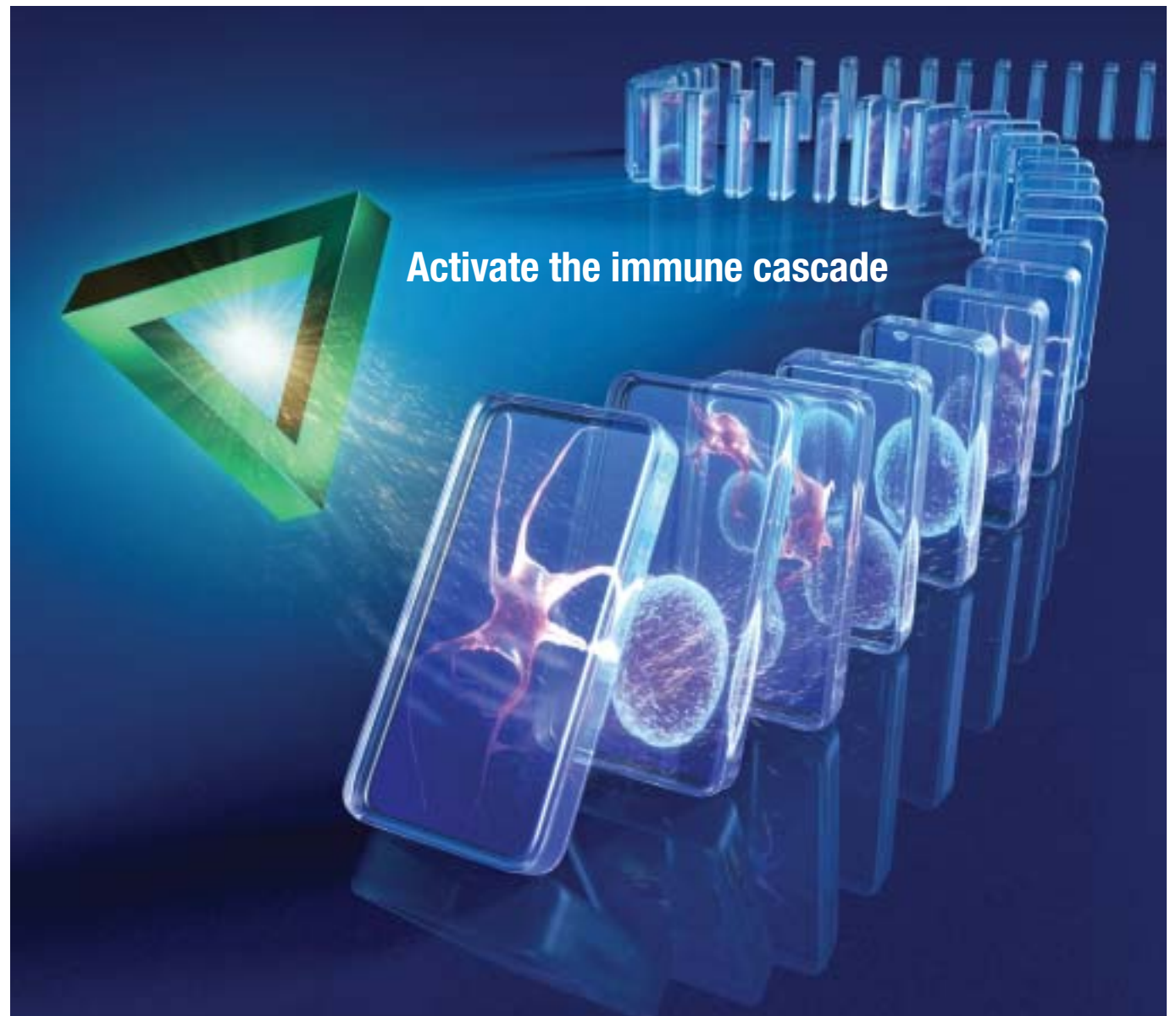
- ▶ A decrease of 23% in atypical squamous cells of undetermined significance that were high-risk positive (285 vs. 359).

- ▶ A decrease of 35% in atypical squa-

mous cells that could not exclude HSIL (59 vs. 89).

Absolute numbers in the data comparing procedures showed: colposcopy in 869 vaccinated women vs. 1,077 on placebo (a 19% reduction); biopsy in 741 vaccinated women vs. 950 on placebo (a 22% reduction), and definitive therapy in 132 vaccinated women vs. 230 on placebo (a 42% reduction).

He disclosed relationships with Merck, including being a consultant and speaker and receiving a research grant. ■



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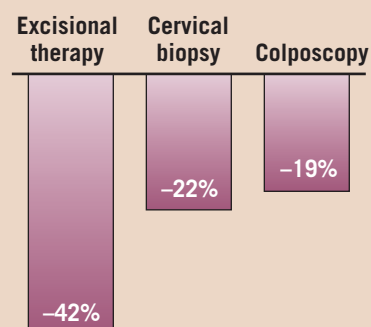
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Human Papillomavirus Vaccine Leads to Reduction In Procedures



Note: Based on an average 3.3-year follow-up of 4,696 vaccinated women, compared with 4,759 given placebo.
Source: Dr. Huh