Recent Cancer Data Support HPV Vaccine Approval for Young Men

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Recent data linking human papillomavirus with oropharyngeal cancers, which typically occur in men, suggest a need for stepped-up efforts to gain approval for use of the HPV vaccine in young men and adolescent boys, according to Dr. Erin Sturgis and Dr. Paul M. Cinciripini, of the University of Texas M.D. Anderson Cancer Center, Houston.

Although the incidence of most types of squamous cell carcinomas of the head and neck have declined over the past 20 years, in tandem with declines in the prevalence of smoking, the incidence of oropharyngeal cancers has remained stagnant—a trend that may be attributable to the growing incidence of oncogenic HPV-associated cancers, the authors stated in the report (Cancer 2007 Oct. [doi:10.1002/cncr.22693]).

"We encourage the rapid study of the efficacy and safety of [HPV-16/18] vaccines in males and, if successful, the recommendation of vaccination in young adult and adolescent males," they wrote. They praised efforts to promote the recently approved HPV-16/18 vaccine among young women and adolescent girls to reduce the incidence of cervical cancer and dysplasia, but warned that limiting vaccination programs to women and girls would delay potential benefits of preventing the HPV-16/18 oropharyngeal cancers in males.

Dr. Cinciripini has acted as a consultant for GlaxoSmithKline, the manufacturer of Cervarix, a bivalent HPV vaccine protecting against types 16 and 18.

Primary per protocol vaccine efficacy analysis included subjects who received all three of the doses, were sero- and PCR-negative to the four HPV types at day 1 and PCR-negative through month 7, and had no major protocol deviations. Dr. Olsson reported that in the group that received the vaccine, there were 6 cases of HPV 6/11/16/18 CIN, compared with 148 cases in the placebo group, providing the vaccine efficacy of 96%.

"And for CIN [grade] 2 or worse, including adenocarcinoma in situ, there was 1 case in the vaccine group and 76 cases in the placebo arm, for an 99% efficacy rate," he said, adding that vaccine efficacy against HPV 6/11/16/18-related CIN ranged from 95.5% to 100% based on CIN grade.

The single case of CIN 3 in the vaccinated group (there were 46 in the placebo arm) was a Brazilian woman who was positive for HPV 52 at day 1 and at 12 months was shown to be positive for both 52 and 16. She subsequently underwent a loop electrosurgical excision procedure.

The lifetime risk of acquiring an HPV infection for sexually active people is 50% and approaches 75% in some settings," Dr. Olsson explained, adding that HPV causes cervical cancer in 3%-4% of unscreened women. "When we look at the screening and reduce the frequency of cervical cancer, but in doing so we create a new disease ... CIN.”

A separate analysis of data from this same cohort of women suggests that in these women, aged 16-26 years, Gardasil vaccination reduces the overall incidence of Pap abnormalities regardless of the HPV types involved.

In a poster presentation, the researchers analyzed the impact on rates of abnormal Pap tests in women who, at day 1 of the study, had a negative Pap test and were negative for HPV types 6/11/16/18 and seronegative to the four vaccine HPV types discussed above.

In this generally HPV-naïve population, Gardasil vaccination reduced the Pap abnormalities rate from 5% in high-risk HPV-positive and grade squamous intraepithelial lesions, compared with placebo. "Given these results, the impact on HPV 6/11/16/18-related Pap abnormalities is expected to be dramatic," the authors wrote.