Gardasil Prevents Warts, HPV Infection in Males

BY MIRIAM E. TUCKER

ATLANTA — The human papillomavirus vaccine was efficacious in preventing persistent infections and genital warts caused by HPV strains 6, 11, 16, and 18 in a Merck-sponsored study of 4,065 males aged 16-26 years.

The findings were presented by Dr. Richard M. Haupt at a meeting of the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices. Merck had previously reported immunogenicity and safety data for its HPV vaccine (Gardasil) in younger males aged 9-15 years, but these are the first data on efficacy in males and the first findings in older adolescent and adult males.

The rationale for use of Gardasil in males is twofold. There is intrinsic benefit to males themselves since HPV strain 18 causes penile, anal, and oropharyngeal cancer and HPV 6 and 11 are associated with genital warts. There is also a public health benefit to vaccinating males against HPV since coverage among girls is likely to be incomplete, transition of HPV occurs frequently between sexual partners, and “gender-neutral” vaccination would be expected to reduce overall viral transmission in the entire population, noted Dr. Haupt of Merck Research Laboratories, Whitehouse Station, N.J.

ACIP is expected to recommend the vaccine for use in males aged 11-12 at the adolescent visit, just as it is now given to girls. This should simplify implementation, Dr. Haupt said.

Safety analysis showed similar findings to those seen in females. Local site reactions were the most common adverse event, occurring in 60% of the 2,029 Gardasil recipients and 54% of the 2,029 placebo recipients. Systemic reactions, serious adverse events, and discontinuations were uncommon and were not different between the Gardasil and placebo groups, Dr. Haupt reported.

Merck has filed an application with the Food and Drug Administration for licensure of Gardasil in males aged 9-26 years.

Vaccine efficacy was 90.4% against external genital lesions and 95.6% in preventing infection.

DR. HAUPT

HPV Misunderstood, Feared In One Border Community

BY PATRICIE WENDELING

Hispanic men and women living on the United States–Mexico border have little understanding about the human papillomavirus and its role in the etiology of cervical cancer, according to a small prospective study. Not only were there very low levels of knowledge among these residents, but their misconceptions and confusion continued even after they were given some basic information about HPV and cervical cancer, Maria Fernandez, Ph.D., said in Carefree, Ariz., during a press conference sponsored by the American Association for Cancer Research. For example, participants tended to compare HPV with HIV and other sexually transmitted infections, and were confused or unaware that men could have HPV and transmit it.

She reported on 30 Hispanic women and 11 Hispanic men without a diagnosis of HPV who lived in Rio Grande Valley colonias (unincorporated border settlements) and participated in focus groups in Brownsville, Tex. The mean age was 41 years among the women (range, 20-74 years) and 39 years among the men (range, 19-76 years). The average annual income for a family of four in these semirural neighborhoods was $13,000. About 60% of participants had not completed grade school.

Analysis of the Spanish-language focus group transcripts revealed that attitudes and concerns about HPV differed by gender, said Dr. Fernandez of the division of health promotion and behavioral sciences at the University of Texas in Houston. Women in particular viewed the disease with fatalism, interpreting a diagnosis of HPV as a diagnosis of cancer. They expressed their fears of cancer and their belief that, once diagnosed, it is “essentially a death sentence.” The women said they would be reluctant to disclose their HPV status to their partners because they believed they would be accused of infidelity. Men initially expressed anger at the possibility of an HPV diagnosis, attributing it to infidelity, Dr. Fernandez said. After a brief explanation about the ambiguity of HPV transmission, they ascribed their initial reaction to cultural ideals of machismo.

Dr. Fernandez acknowledged that the border communities and colonias face unique challenges, and that the findings of this small, qualitative study should not be generalized.

“The other hand, it raises some interesting questions about what we need to do in many of the other studies about cultural norms, such as things like machismo and the way we’ve traditionally interpreted this concept,” she said. “As we saw in these focus groups, there’s sort of an initial reaction, but then people talked about standing by their partner.”

Clues about these cultural norms and beliefs are essential to the design and implementation of successful and badly needed interventions for HPV prevention.

“You have to be very cautious in terms of generalizing these findings, but many of the populations that are suffering increased incidence of HPV and cervical cancer and increased mortality are in this area,” Dr. Fernandez said.

The study was funded by the National Institutes of Health. The authors reported no conflicts of interest.

New Smallpox Vaccine Found Safer Than Existing Vaccines

BY MARY ANN MOON

The third-generation smallpox vaccin LC16m8 was found to be as immunogenic as existing smallpox vaccines but appeared to be safer in a study of over 3,000 Japanese adults.

The live, attenuated, tissue-cultured vaccine LC16m8 was found to be as immunogenic as existing smallpox vaccines and safer in a study of over 3,000 Japanese adults.

The rationale for use of LC16m8 is twofold. There is intrinsic benefit to Japanese males themselves since a study of 4,065 males aged 16-26 years showed that the vaccine was as immunogenic and safe as existing smallpox vaccines.

Dr. Tomoya Saito of the department of tropical medicine and parasitology, Keio University, Tokyo, and associates.

“Developing a vaccine that is safer than first-generation vaccines yet highly immunogenic is crucial to constructing a prevention plan in the event of a bioterrorist attack,” the investigators noted.

They assessed the LC16m8 vaccine in healthy personnel in the Japan Self-Defense Forces inoculated in 2002-2005. Nearly 99% were men, and all were Asian. A total of 1,529 had never been vaccinated, and 1,692 had previously been vaccinated against smallpox (JAMA 2009;301:1025-33).

The proportion of “takes”—the visible skin reactions to a single intraepidermal scarification—was comparable to that expected with other smallpox vaccines. The seroconversion rate was 90% in those who were never vaccinated and 60% in those who were previously vaccinated, Dr. Saito and colleagues wrote.

There were no severe adverse events such as autoinoculation/contact inoculation, eczema vaccinatum, progressive vaccinia, generalized vaccinia, encephalitis, or the myopericarditis that has been “a major concern” in the U.S. vaccination program. The researchers noted that while the total sample size in the trial limited the ability to “conclusively confirm that absence of severe adverse events,” their results support the conclusion that LC16m8 “causes minimal local manifestations and systemic adverse effects.”

Findings suggest that LC16m8 “is a viable alternative to first-, second-, and other third-generation vaccines in a smallpox preparedness program,” they added.

The lesions on this patient’s arm were caused by the smallpox virus, variola major, variola minor, and vaccinia. The lesions were large and raised, with a central scab. The patient had a history of a smallpox vaccination. The lesions were treated with topical corticosteroids and antibiotics.