Editorial

Two Ounces of Prevention

Jeffrey M. Weinberg, MD

G iven the morbidity and treatment challenges posed by many disease states, prevention of those conditions clearly would be a preferable alternative. Over the past year, we have observed examples of progress in this direction, especially in the field of infectious diseases. The 2 most recent prevention strategies will have direct relevance to dermatologists.

In October 2005, Merck announced that an investigational vaccine (quadrivalent human papillomavirus [HPV] types 6, 11, 16, and 18, recombinant vaccine) prevented 100% of high-grade cervical precancers and noninvasive cervical cancers associated with HPV types 16 and 18 in a recent phase 3 study (P < .001).¹ The analysis compared the vaccine to placebo in women who were not infected with HPV types 16 and 18 at enrollment and who remained free of infection through the completion of the vaccination regimen. Women were followed for an average of 2 years after enrollment. This phase 3 study was a prospective, randomized, double-blind, placebocontrolled study with 2 vaccination groups. Women aged 16 to 26 years were randomized to receive a 3-dose regimen of either vaccine or placebo at day 1, month 2, and month 6. A total of 12,167 women were enrolled from 90 study centers worldwide. The most common vaccine-related adverse event reported was local discomfort at the injection site.¹

Of particular interest to dermatologists, this HPV vaccine demonstrated 100% efficacy in preventing genital warts, vaginal dysplasia, and vulvar dysplasia in another study (P<.001).² In this trial, 2261 sexually active women aged 16 to 23 years received one inoculation with vaccine and then received additional vaccinations at month 1 and month 6. A similar group of 2279 age-matched women received placebo vaccinations on the same schedule. The investigators determined that, of the women who were vaccinated according to the protocol, none developed genital warts or high-grade vaginal or vulvar dysplasia. Forty cases (1.8%) of genital warts or precancerous lesions occurred in the placebo group.²

Herpes zoster is another disease for which a new vaccine is in development. The incidence and severity of this condition and the associated postherpetic neuralgia increases with age, and we have an increasingly aging population. Oxman et al³ conducted a large study to determine if vaccination against varicella-zoster virus would decrease the incidence, severity, or both of herpes zoster and postherpetic neuralgia among older adults. They enrolled 38,546 subjects 60 years or older in a randomized, double-blind, placebo-controlled trial of an investigational live attenuated Oka/Merck varicella-zoster virus vaccine ("zoster vaccine"). The pain and discomfort associated with herpes zoster were measured repeatedly for 6 months. The primary end point was the burden of illness due to herpes zoster, a measure affected by the incidence, severity, and duration of the associated pain and discomfort. The secondary end point was the incidence of postherpetic neuralgia.

More than 95% of the subjects completed the study, with a median of 3.12 years of surveillance for herpes zoster.³ The use of the zoster vaccine reduced the burden of illness due to herpes zoster by 61.1% (P<.001), reduced the incidence of postherpetic neuralgia by 66.5% (P<.001), and reduced the incidence of herpes zoster by 51.3% (P<.001). Reactions at the injection site were more frequent among vaccine recipients but were generally mild.³

The application of vaccines represents a new and exciting paradigm in the treatment of dermatologic diseases. The HPV and zoster vaccines will offer us assistance in preventing 2 very challenging conditions and offer our patients the potential for improved quality of life.

REFERENCES

- 1. Edelman Public Relations. Merck investigational vaccine GARDASIL prevented 100 percent of cervical pre- & noninvasive cancers. Available at: http://www.brightsurf.com /news/headlines/view.article.php?ArticleID=21282. Accessed February 24, 2006.
- Susman E. HPV vaccine protects women from external genital lesions: presented at ICAAC. Available at: http://www.docguide.com/news/content.nsf/news/85256977 00573E18852570DC0054023E. Accessed February 24, 2006.
- 3. Oxman MN, Levin MJ, Johnson GR, et al. A vaccine to prevent herpes zoster and postherpetic neuralgia in older adults. *N Engl J Med.* 2005;352:2271-2284.

Dr. Weinberg is a member of the speakers bureau for Merck & Co, Inc.