Boston — “Genital herps is a recurrent, lifelong viral disease. This is one thing that patients and clinicians don’t like to say, but there’s no way around it,” Laury J. Mulcahy said at a conference on diagnostic technology sponsored by Contemporary Forums.

Other truths about infection with herpes simplex virus (HSV) type 2? “The overwhelming majority of people infected with the virus don’t know that they have it, and people with asymptomatic or unrecognized disease shed the virus intermittently in the genital tract,” Ms. Mulcahy continued. “When we ask patients prior to screening for HSV-2, they have a history of genital herpes... about 90% of those who ultimately test positive for HSV-2 antibodies reported having no history or symptoms of the infection,” she said. This underscores the difficulty in attributing the clinical presentation to the fact that the leading cause of HSV-2 infection is asymptomatic shedding of the virus.

“There is a misconception among clinicians and patients that the infection is spread only through HSV-2 sores. This is absolutely not true. The virus can spread even when the skin looks normal, and that’s when most infections occur,” she said. Patient education about asymptomatic disease is critical to an effective screening protocol. “When patients come in and have no symptoms, it means nothing to us,” Ms. Mulcahy stressed.

Patients who come in for STD screening are told, “from this day forward, the fact that you or your partner have no symptoms means nothing; the fact that you and your partner look fine means nothing; and the fact that you or your partner had a negative screen 6 months ago, if you had partners in the interim, means nothing,” she said.

Another factor contributing to the high rate of unrecognized disease is that many patients who have been screened for STDs believe they have been tested for genital herpes. “A complete STD screen does not include testing for herpes. Clinicians don’t always tell this to patients, so many patients believe they are being tested for everything. If their STD screen is negative, they assume that means they don’t have herpes,” said Ms. Mulcahy.

The few clinicians who don’t routinely screen for herpes [as part of an STD screening protocol] must inform patients that they are not being tested and that in the patient record so there is no confusion,” she added. If a patient asks to be screened for HSV-2, there are several points that should be addressed before testing, Ms. Mulcahy stressed:

- The absence of symptoms does not predict a negative screen.
- Herpes is an asymptomatic, lifelong illness, especially as lesions heal. As such, a negative culture does not rule out HSV-2.
- In the event of a positive HSV-2 test in an asymptomatic person, it is not possible to determine how long the virus has been present, when or whether they will have symptoms, or whether they will ever have a problem with herps.
- In the event of a positive HSV-2 test, patients in some states have a legal obligation to notify their recent or future sexual partners of their infection status before genital skin contact. “It is a misdeemeanor in New York state, for example, to knowingly pass on or put someone else at risk for a sexually transmitted disease,” she said. Ms. Mulcahy’s counseling patients on these points be aware that even uncharacteristically for HSV-2, counseling and history are insensitive and nonspecific. “Symptoms are easily confused with other conditions or may present atypically, for example, as redness rather than sores.”

Genital Herpes: What Patients Might Not Know

By Diana Mahoney

New England Bureau

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■ Experimental HPV Vaccine Shows Promise

The vaccine’s design is based on long, overlapping peptides covering the complete amino acid sequence of the HPV-16 E6 and E7 oncogenes. Patients in the study were vaccinated four times at 3- to 4-week intervals. The vaccine’s effectiveness in inducing an immune response is different in healthy patients than in infected patients, and prol-


Experimental HPV Vaccine Shows Promise

Tampa — An experimental vaccine against human papillomavirus appeared to have therapeutic potential in a study of 20 women with HPV-16 positive vulvar intraepithelial neoplasia.

The treatment with the vaccine resulted in important T-cell responses in most patients after two vaccinations in the phase II study involving 20 women with histologically proven vulvar intraepithelial neoplasia (VIN). At 3 months, clinical efficacy was apparent in most of the patients, with a complete response observed in 25%. Dr. Gemma G. Kenter reported at the annual meeting of the Society of Gynecologic Oncologists.

The vaccine’s design is based on long, overlapping peptides covering the complete amino acid sequence of the HPV-16 E6 and E7 oncogenes. Patients in the study were vaccinated four times at 3- to 4-week intervals. The vaccine’s effectiveness in inducing an immune response is different in healthy patients than in infected patients, and proliferation assays in this study showed that the “vaccine-conditioned T cells” that are induced is associated with the production of IFN-gamma and interleukin-5, similar to the cytokine profile of the HPV-16-specific memory T-cell responses observed in healthy individuals, Dr. Kenter explained.

A local immune response, namely infiltration of both the vaccination site and the VIN lesion by HPV-16-specific Th1 and Th2 cells, also was demonstrated.

The findings are encouraging, because HPV infection is common in young, sexually active individuals, and although most will clear the infection spontaneously, those in whom the disease continues and progresses into clinical disease, some people experience a failure of the immune system in controlling the virus, and in these patients, malignant disease develops. The current study followed a phase I study in which the vaccine was found to elicit a strong HPV-16-specific T-cell response in 35 patients with end-stage cervical cancer, with no toxicity greater than grade 2 occurring.

“To our surprise, even in this patient group with end-stage disease, vaccination induced a strong-type 1 immune response,” Dr. Kenter added.

The vaccine was developed by OrthoNovoTect, a collaborative research effort between Ortho Biotech and the National Institutes of Health. The vaccine is based on the HPV-16 E6 and E7 oncoproteins, which were deleted from the plasmid DNA vaccine and replaced with a strong immunostimulating adjuvant, Dr. Kenter said.

As a result, the vaccine generates a strong Th1 cytokine response in vivo, which is associated with the generation of strong HPV-specific T cells, Dr. Kenter said.

The high number of vaccine-induced T cells with HPV specificity supports the concept that this vaccine is immunogenic and may be useful in patients with VIN up to grade IV.

“The next step in the clinical trials will be to test the vaccine in a phase IIa trial in 150 patients with VIN grade III,” Dr. Kenter said.

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